multi-act

Deliverable D6.1

CRIF Integrated Manual for R&I Actors

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Short description of the Deliverable*:

The present Manual collects and describes all the components of the Collaborative Research Impact Framework (CRIF) which, together with its digital interface (the Toolbox) underpin all the core outputs of the project. In this sense, the Manual is a supporting tool for R&I actors (including RFPOs) that aim to innovate the research process making it a collaborative and participatory multi-stakeholder process.

***Note for the EC Reviewers:** the present description complements and expands the original one included in the DoA "*This manual is expected to be a tool to be used by brain diseases working groups in WP7 to transfer the model to other disease domain beyond MS*". Although the transferability of the CRIF to other brain disease initiatives is core to the success of the capitalization and exploitation activities of the project, the Consortium has designed the present Manual with the aim to make of it an instrument easy to consult and use for anyone is promoting, coordinating or managing a health research initiative with a multi-stakeholder approach.

REVISION HISTORY

REVISION	DATE	COMMENTS	AUTHOR (NAME AND ORGANISATION)
V0.1	23/03/2020	Governance Chapter draft	Marcin Kautsch (DiA), Natalia Matuszak (DiA), Patryk Sierpowski (DiA)
V0.2	1/04/2020	Governance Chapter draft review	Ilaria Neirotti (EY SPA), Francesca Spagnoli (EY SPA), Andrea Gavazzi (EY SPA), Luca Molinari (EY SPA), Corrado Paternò Castello (EY SPA), Danilo Devigili (FISM)
V0.3	31/03/2020	Accountability Chapter draft	Marcin Kautsch (DiA), Natalia Matuszak (DiA), Patryk Sierpowski (DiA)
V0.4	01/04/2020	Accountability Chapter draft review	Danilo Devigili (FISM), Anna Kork (TAU), Ericka Costa(UNITN), Michele Andreaus (UNITN), Caterina Pesci (UNITN), Juliette Senn (UBU), Nicolás García-Torea (UBU), Carlos Larrinaga (UBU)
V0.5	08/04/2020	Governance Chapter "chronology" draft and Materiality Analysis draft	Marcin Kautsch (DiA), Natalia Matuszak (DiA), Patryk Sierpowski (DiA)

V0.6	9/04/2020	Governance Chapter draft review	Deborah Bertorello (FISM)
V0.7	22/04/2020	Governance Chapter "chronology" draft and Materiality Analysis draft review	Ilaria Neirotti (EY SPA), Francesca Spagnoli (EY SPA), Andrea Gavazzi (EY SPA), Luca Molinari (EY SPA), Corrado Paternò Castello (EY SPA), Deborah Bertorello (FISM)
V0.8	11/05/2020	Materiality Analysis draft	Marcin Kautsch (DiA), Natalia Matuszak (DiA), Patryk Sierpowski (DiA)
V0.9	9/06/2020	Accountability Steps draft	Marcin Kautsch (DiA), Natalia Matuszak (DiA), Patryk Sierpowski (DiA)
V1.0	11/06/2020	Accountability Steps draft review	Danilo Devigili (FISM), Anna Kork (TAU), Ericka Costa (UNITN), Michele Andreaus (UNITN), Caterina Pesci (UNITN), Juliette Senn (UBU), Nicolás García-Torea (UBU), Carlos Larrinaga (UBU)
V1.1	20/07/2020	Accountability Pillars and Workflow draft	Marcin Kautsch (DiA), Natalia Matuszak (DiA), Patryk Sierpowski (DiA)
V1.2	03/11/2020	Finalization of First Draft for Consortium Review	Marcin Kautsch (DiA), Natalia Matuszak (DiA), Patryk Sierpowski (DiA)
V1.3	02/12/2020	Review by the Consortium members	Valentina Tageo (FISM), Deborah Bertorello (FISM), Paola Zaratin (FISM), Giampaolo Brichetto (FISM), Danilo Devigili (FISM), Ilaria Neirotti (EY SPA), Francesca Spagnoli (EY SPA), Andrea Gavazzi (EY SPA), Luca Molinari (EY SPA), Corrado Paternò Castello (EY SPA), George Tsakirakis (INTRA), Sofia Tsekeridou (INTRA), Juliette Senn (UBU), Mercedes Luque (UBU), Nicolás Garcia Torea (UBU), Carlos Larrinaga (UBU), Ericka Costa (UNITN), Michele Andreaus (UNITN), Caterina Pesci (UNITN), Olivia Balagna (UNITN), Anna Kork (TAU), Eija Vinnari (TAU)

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V2.0	01/03/2021	Finalisation of the second draft	Marcin Kautsch (DiA), Natalia Matuszak (DiA)
V2.1	27/03/2021	Review by the Consortium Reviewers	Valentina Tageo (FISM), Elke de Witte (EBC), Françoise Van Hemelryck (EBC)
V3.0	30/04/2021	Final edition and submission to the EC	Marcin Kautsch (DiA), Natalia Matuszak (DiA), Valentina Tageo (FISM)

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STATEMENT OF ORIGINALITY:

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

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ACRONYMS

ARSEP	Fondation Pour L'aide A La Recherche Sur La Sclerose En Plaques
CRIF	Collective Research Impact Framework
DiA	Dane-i-Analizy.pl Sp. z o.o.
EBC	European Brain Council
EU	European Union
EHMA	European Health Management Association
EY SPA	Ernst & Young Financial Business Advisors
FISM	Fondazione Italiana Sclerosi Multipla FISM Onlus
INTRA	Intrasoft International
MSCU	Multiple Sclerosis Care Unit
TAU	Tampereen Yliopisto
UBU	Universidad De Burgos
UCP	Universidade Catolica Portuguesa
UNITN	Universita Degli Studi Di Trento
WP	Working Package

EXECUTIVE SUMMARY

MULTI-ACT. Collective Research Impact Framework and multi-variate models to foster the true engagement of actors and stakeholders in Health Research and Innovation is an EU-funded project with a goal of increasing positive impact of health research on people living with brain disorders and society. It has created the Collective Research Impact Framework (CRIF). The CRIF offers a set of tools to establish participatory governance mechanisms and enable realistic evaluation of collective impact of health Research and Innovation (R&I) multi-stakeholder initiatives, namely the Baseline Analysis, Governance Criteria, Materiality Analysis, Patient Engagement Guidelines, and Master Scorecard. They are also made available and operationalised in the digital Toolbox which facilitates application of the CRIF and interaction among stakeholders. They were created and refined in work packages 1, 2, 3, 4 and 5.

The D6.1 *CRIF Integrated Manual for R&I actors* collects these tools and translates them into accessible guidelines. The deliverable is a result of co-creation process undertaken by the MULTI-ACT Consortium to integrate and refine outputs of the previous work packages. It is intended to be used by all the potential CRIF adopters, i.e., any other collaborative R&I initiatives in the field of brain diseases and health research in general, who might have an interest in learning more about the CRIF and apply it or part of it beyond the end of the project.

The Manual prioritizes ease of understanding of the CRIF. It employed an iterative structure where models and guidelines are first explained in general terms, in the context of the whole framework, and later described in full detail. D6.1 complements the material from the deliverables it is based on with easy-to-follow explanations of key concepts of the framework and compilations of the guidelines.

1 INTRODUCTION

The work package 6 is focused on gathering outputs of work packages 1, 2, 3, 4 and 5, and translating them into guidelines accessible to R&I actors and specifically Research Funding and Performing Organisations (RFPOs) who wish to embrace a more participatory approach in designing, executing and evaluating their research programmes or projects and, thus, are the ultimate CRIF's Users. *D6.1 CRIF Integrated Manual for R&I actors* is the first deliverable of the work package.

1.1 Purpose of the document

This document presents the deliverable *D6.1 CRIF Integrated Manual for R&I actors.* The Manual includes:

- Patient engagement procedures developed in WP1: Patient Engagement Guidelines, Patient Engagement Plan Toolbox functionality description and Patient-reported dimension indicators.
- Multidimensional database template for research classification and description of the Toolbox, developed in WP2.
- CRIF metrics and Master Scorecard description – developed in WP3, refined in WP4.
- Governance Model – developed in WP5, refined in WP4.
- Baseline Analysis and Materiality Analysis, developed and refined in WP4.

The purpose of the Manual is to present, in a clear way, integrated outputs of the above-mentioned work packages to facilitate implementation of the CRIF by R&I organisations. The Manual is intended to be utilized in conjunction with the Toolbox. The aim is to encourage use of the CRIF by initiatives working on diseases other than multiple sclerosis, broadening its reach. Moreover, the Manual will be used by the initiatives that do not collaborate directly with the MULTI-ACT project. It will be available, together with the digital Toolbox, for all parties interested in implementing CRIF in their health research and innovation undertakings.

For the sake of completeness and to the ease the review of its content by the EC experts, the present deliverable includes the Manual and all its Appendices in the standard deliverable template used across the project. However, the Manual has been made also available to the public in a graphically edited and enhanced version and it is possible to either consult or download it via the Toolbox.

1.2 Process of co-creation of the CRIF Manual

While DiA led the process of writing the Manual, it is in fact an output of co-creation of the whole Consortium, especially leaders of the work packages 1, 2, 3, 4 and 5 (the "source deliverables"), supported and guided by the coordinator. Much of the work done on D6.1 consisted in integrating these deliverables with the aim of presenting the User with a fully coherent and easy-to-follow instruction of CRIF implementation. Consequently, D6.1 contains full fragments of deliverables from these work packages, especially D4.3, D1.6, D1.8, D3.6.

While combining the "sources deliverables", we were vigilant about any areas that might need convergence of language, concepts or models between the work packages. We regularly brought these to the attention of the Consortium, offering various solutions and collaborating on the input. In fact, many partial drafts were commented on and discussed by the Consortium during WP6

teleconferences, when the solutions were decided upon by consensus. The Consortium took the key decisions regarding the shape of the Manual, implemented solutions and the manner of proceeding. In this sense, it was one of the most collaborative deliverables in the project so far, exemplifying the process of co-creation advocated for by the CRIF.

It is worth noting that while the Manual was being written, the CRIF was also applied in a case study, in cooperation with the Multiple Sclerosis Care Unit (MSCU) initiative promoted by the European Charcot Foundation as part of WP4. The feedback from the case study led to refinement of the CRIF. We actively contributed to developing the refined solutions presented in D4.3, suggesting areas for inter-WPs convergence. The results of the case study described in D4.3 were fully integrated into the D6.1.

The Manual itself is integrated into the Toolbox. The Toolbox includes the full text of the Manual, which the User can browse. Comments and tips accompanying all the functionalities of the Toolbox were created within T6.3; they derive from the Manual's text and also reference to it via hyperlinks. DiA closely collaborated with the WP2 Leader (INTRA) on harmonizing the text of the Manual with the Toolbox.

1.3 Structure of document

The Manual is divided into 7 chapters:

1) **The CRIF Manual chapter** presents the structure of the CRIF Manual and its purpose. The User learns who are main intended appliers of the CRIF and how to utilise the Manual in conjunction with the Toolbox for maximum benefit to the research and innovation initiative.

2) **About the MULTI-ACT project chapter** briefly introduces the MULTI-ACT and the rationale for creation of the CRIF. Basic epidemiological and economic data concerning the burden of brain diseases are presented. The chapter explains the need for increased stakeholder engagement and co-accountability in health research and innovation initiatives.

3) **Collective Research Impact Framework chapter** presents the components of the CRIF, interconnections between them, and their conceptual underpinnings. It emphasizes the importance of co-accountability, and introduces Co-accountability Pillars. Governance Criteria, Patient Engagement Guidelines and Master Scorecard are explained first. Baseline and Materiality Analyses are described as functionalities in the Toolbox. The CRIF Workflow introduces structure and gives an overview of the most important steps in CRIF implementation.

4) **Governance chapter** starts with deepening User's understanding of the Governance Model and discussion of the stakeholder typology and the governance bodies. They serve both as an explanation and as a later reference in case the User looks for concentrated information when implementing CRIF. The chapter contains the full text of the Governance Criteria. Baseline Analysis is also described.

5) **Patient Engagement Strategy and Guidelines chapter** elucidates all the concepts related to CRIF stakeholder engagement: science with and of patient input, return on engagement, experiential knowledge. It introduces Research and Innovation Path. This section contains shortened version of the Patient Engagement Guidelines

6) **Collective Impact Assessment chapter,** after defining materiality, concentrates on Materiality Analysis and the Master Scorecard as tools for establishing co-accountability. It deepens User's understanding of CRIF dimensions and prepares them for using the indicators. The section also explains Patient-Reported Outcomes.

7) **Toolbox chapter** is devoted to guiding the User through the Toolbox. Because the Toolbox is intuitive and contains enough guidelines to be easy to use, the Manual focuses only on more complicated functionalities. Special attention is given to the Materiality Analysis as it is the only tool that requires planning and relies on stakeholders' willingness to participate.

The Manual was created first and foremost with the User's comfort in mind. The CRIF combines expert knowledge from several disciplines. The Users may not be familiar with all the concepts. In order to avoid overwhelming the User, we adopted a gradual approach: we first present a model or a tool in general terms, explain its use and place within the framework, and only then describe it in detail.

Additionally, we used hyperlink references heavily throughout the text to help the User quickly find the relevant fragments and definitions.

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COLLECTIVE RESEARCH IMPACT FRAMEWORK INTEGRATED MANUAL

FOR RESEARCH & INNOVATION ACTORS

This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under the Grant Agreement No. 787570

TABLE OF CONTENT

1 THE CRIF MANUAL

This Manual collects all the key outputs of the MULTI-ACT project. which are integrated in the Collective Research Impact Framework (CRIF). The final version of the CRIF, after validation and refinements made following a case study, is presented hereafter. The case study's focus was a research and innovation multi-stakeholder initiative focused on multiple sclerosis treatment and care. The CRIF Manual consolidates all components of the framework to make it easy to use for the research and innovation organisations like yours.

1.1 Structure of the CRIF Manual

The CRIF Manual's structure is intended to first introduce you to the Collective Research Impact Framework (CRIF) and its main concepts (chapter 2: About the MULTI-ACT project), and then present more detailed information and guidelines in subsequent chapters dedicated to individual CRIF parts. The chapter 3: Collective Research Impact Framework explains the CRIF' underlying philosophy, structure, building blocks, tools and the recommended pathway of implementation. The chapter 4 presents full Governance Criteria, and chapter 5 – Patient Engagement Guidelines. In the chapter 6 Collective Impact Assessment, you will explore the Materiality Analysis and Master Scorecard. Lastly, the chapter 7 Toolbox is a brief introduction to the web-based platform, which we encourage you to use in the CRIF implementation process from the very start.

1.2 For whom the CRIF Manual is intended

This Manual is addressed mainly to the organisations and individuals who are interested in or responsible for implementation of the CRIF in responsible research and innovation (RRI) initiatives in the area of brain research and health research in general. The CRIF Manual's purpose is to guide these organisations through the process of adoption of the CRIF.

1.3 How to use the CRIF Manual

The CRIF's main goal is to **help your initiative in applying RRI principles and making a positive social impact** by creating a collaborative, participatory process among your different stakeholders.

We recommend that you go through the CRIF Manual first and familiarize yourself with the components of the CRIF, its concepts, and its terminology. Doing that will make it easier not only to implement the steps advised in the CRIF Manual itself but also to use the Toolbox more efficiently.

The Toolbox is an indispensable companion of the CRIF Manual and you will find many cross-references between them. In the CRIF Manual, there will be basic instructions on how to use the Toolbox but it is intuitive and easy to follow on its own. You can set up an account even now (https://toolbox.multiact.eu), before reading the whole Manual. It is free to use.

The Manual illustrates the rationale behind collaborative governance and stakeholder engagement methods and tools, such as the Baseline Analysis (BA) and Materiality Analysis (MA), that can only be performed via the Toolbox. The results of the Baseline Analysis will serve to profile your research multi-stakeholder initiative and suggest which parts of the Governance Chapter you should pay special attention to. With the help of the Patient Engagement Plan tool, your initiative will be able to choose the best methods for patient engagement and smoothly organise the process appropriately for every

stage of the research. Materiality Analysis will determine which impact aspects are most relevant for the stakeholder involved in your research and consequently propose you a set of indicators that your initiative can use to build its tailored impact scorecard and evaluate its impact in a co-accountable manner. In the case of Materiality Analysis, you can use the Toolbox to engage your initiative's stakeholders in such a process with a "sending invitation" function.

We developed this document on the assumption that CRIF should be flexible and customizable, so you will find out that many activities are left to your discretion: you should use them according to your specific situation, needs and your best judgement also in consideration of the stage your initiative is currently in.

2 ABOUT THE MULTI-ACT PROJECT

MULTI-ACT. Collective Research Impact Framework and multi-variate models to foster the true engagement of actors and stakeholders in Health Research and Innovation (https://www.multiact.eu/) is an EU-funded project with a goal of increasing positive impact of health research on the society by applying a Responsible Research and Innovation (RRI) approach. It has created the Collective Research Impact Framework (CRIF). The CRIF offers a participatory and realistic evaluation of impact of health Research and Innovation (R&I) multi-stakeholder initiatives through:

- Governance Criteria which facilitate cooperation of all relevant stakeholders in defining the mission and agenda for health research initiatives, while ensuring participative, patient-focused and efficient operation.
- New metrics for the evaluation of the research results to enable multi-dimensional impact assessment and thus overcome the limitation of the current focus on research excellence
- Comprehensive patient engagement guidelines to foster their effective involvement in research programmes and projects in line with the core objectives of the "Science with and for Society" (SwafS) H2020 programme and specifically its ambition to enable public engagement in RRI.

The MULTI-ACT project works with patients and patient organizations, research organizations, academics, policy makers, neurologists and other care providers, scientists and pharmaceutical industry to develop innovative tools that will help you assess the collective impact of your research, implement the best governance practices and incorporate experiential knowledge of the engaged patients and their communities.

2.1 Project rationale

179 million Europeans will be affected by a brain disorder at some point in their lives: an estimated 1 in 3. In 2017, 307,9 million brain diseases were counted in the 28 European Union member states (EU28), of which 74,5 million were newly diagnosed, including Alzheimer's disease and other dementias, epilepsy, headache (migraine and tension-type headache), multiple sclerosis, Parkinson's disease, brain cancer, motor neuron diseases, neuroinfectious diseases, and stroke (Gustavsson *et al.*, 2011; Deuschl *et al.*, 2020). The WHO stated that brain disorders account for 35% of the burden of all diseases in Europe (Wittchen *et al.*, 2011).

Patients with brain disorders had a total number of disability-adjusted life-years (DALYs) of approximately 21 million and the total number of deaths was 1,1 million. After cardiovascular diseases and cancer, neurological disorders' burden on DALYS and deaths in the member states was the third highest. The proportion of total DALYs attributable to neurological disorders was approximately 13,1% and the proportion of deaths was around 19%. In addition to the negative impact on healthy life years and the quality of life, brain disorders also have consequences beyond the healthcare system by

impacting the increasing costs of technological progress, prolonged impairment, great dependency and significant reduced productivity at work, as well as the burdens on health and social welfare systems (European Brain Council, 2017; Deuschl *et al.*, 2020).

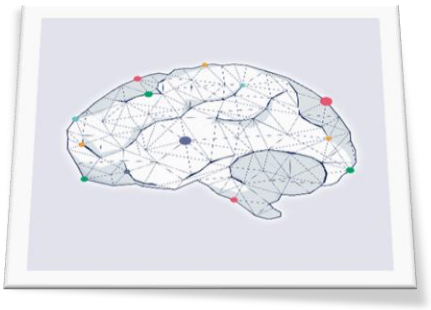
The annual direct and indirect costs for the EU economy and national health budgets of these disorders exceed 800 billion euro, of which 60% is attributable to direct healthcare and non-medical costs and 40% is from the loss of productivity in the labour market. The average yearly costs of brain disorders per person vary considerably from one disease to another based on the severity of and life expectancy with the disease. Whereas a person with chronic headaches incurs on average 285 euros per year, someone with Multiple Sclerosis incurs approximately 27.000 euros per year on average (Gustavsson *et al.*, 2011; European Brain Council, 2017).

The rise in the number of people with brain diseases (such as Alzheimer's, Parkinson's, depression, Multiple Sclerosis, addictions, and many more) and the high proportion of deaths and DALYs attributable to those diseases are due to factors such as higher life expectancy and the increasing incidence and the increasingly long duration of diseases related to ageing. There are substantial sex differences in the burden of neurological disorders within the member states. DALY rates for dementia, migraine, and multiple sclerosis were higher in women in all age groups, whereas the rates were higher for men as they relate to stroke and Parkinson's disease. The sex differences reflect the differing distribution of each clinical condition in men and women (Deuschl *et al.*, 2020).

It is of utmost importance to develop a mission-oriented research model that, in addition to producing academically excellent research, addresses societal concerns and delivers results that have a real impact on the lives of affected patients and their caregivers.

To mitigate the burden of brain disorders, research and innovation initiatives must become more collaborative and co-accountable. So far, most multi-stakeholder initiatives have lacked an impact assessment system shared among its stakeholders. A support infrastructure which would ensure alignment of efforts and accountability has been also missing (Zaratin, Battaglia and Abbracchio, 2014; Zaratin *et al.*, 2016).

In the past decade, many collaborative research initiatives were launched with the view of developing innovative treatments for brain disorders. Despite the significant progress in terms of understanding the mechanistic underpinnings of neurological diseases at the molecular, cellular and circuit levels, translation of these discoveries into therapies remains a critical challenge.



Taking patients' needs and perspectives into account through the entire research process is another challenge research initiatives encounter. Aligning differing priorities and assessment systems of the members of the research initiatives is another. Cooperation among various organizations is often identified as a key success factor in maximizing the positive impact of research and innovation initiatives in the brain disorders area. Different stakeholders need a shared language and shared metrics to be able to be accountable to one another and progress towards the mission.

Fostering Responsible Research and Innovation requires different stakeholder groups' commitment to find collective solutions to solve a specific problem (mission) and, thus, achieve a socially desirable result (von Schomberg, 2013) through the fulfilment of a number of strategic objectives (agenda). In health research and innovation, it entails collaboration of academia, government and regulatory agencies, patients' and citizens' organisation, healthcare organisations, biotechnological companies (biotech), pharmaceutical companies and others along the entire research and innovation research pathway.

In MULTI-ACT, we departed from research on multiple sclerosis as the basis to develop the proposed Collective Research Impact Framework (CRIF).

One of the key novelties it entails is its multidimensional approach to assess research impact that **integrates conventional metrics related to research excellence with new ones, relating to economic impact, efficacy (intended as adherence to the common mission), social impact and patient-reported outcomes.** We also conducted extensive consultations (e.g. surveys, interviews) with several stakeholder representatives, such as healthcare professionals, patients, policy makers and industry actors. On this basis, we formulated **recommendations on how and when to engage patients to allow them to contribute their most valuable experience and opinions**. During the project, the CRIF was tested and adapted for initiatives doing research on other brain diseases as well.

3 COLLECTIVE RESEARCH IMPACT FRAMEWORK

In the context of multi-stakeholder initiatives**, accountability is a relationship among stakeholders who are required to give account for their actions**. Traditionally, accountability was addressed to shareholders and concentrated on financial results and processes. Nowadays, multiple categories of stakeholders both need to be consulted and reported to: not only shareholders, but also other stakeholders: customers, employees, local community, NGOs etc. In response to this shift in accountability relations, and even higher complexity of multi-stakeholder initiatives, MULTI-ACT puts forward the concept of **co-accountability: it is a democratic and participatory approach to implementing accountability that incorporates plurality of stakeholders' perspectives into decision-making processes, while recognizing their competing and complementary interests around health research.** Co-accountability is the theoretical foundation of the CRIF. All CRIF tools have an objective of establishing co-accountability among stakeholders. Its model enriches and evolves the Integrated Accountability Model (IAM) (Andreaus and Costa, 2014). In order to accommodate all the impact dimensions which we deemed most relevant for a comprehensive impact assessment of health R&I, we added two more dimensions, i.e. excellence (scientific and academic quality) and patient-reported dimension, to the three dimensions proposed in the IAM (efficiency, mission fulfilment (efficacy), and social impact).

The five CRIF dimensions, and the corresponding impact aspects and indicators proposed to assess them, cover all the most relevant areas of the impact of brain research. Thanks to this, you can be sure that your initiative assesses its impact in a comprehensive, holistic way. At the same time, CRIF's impact assessment is flexible – you do not need to use all 125 indicators as long as you use a minimum number from each dimension. Your initiative's stakeholders help you choose which aspects to measure. This allows your initiative to establish priorities, monitor progress, report the results and – last but not least – talk about your achievements in a language relevant to all key stakeholders.

In addition to facilitating internal and external communication, CRIF helps your initiative's many stakeholders unite around common goals despite their competing interest. The Governance Model provides guidelines on how to engage stakeholders to formulate a common mission and agenda. Stakeholder engagement, and especially **patient engagement**, should permeate all management operations. Moving to a more open, co-creative approach, as well as changing the focus of the analysis from an organization's objectives to the social issue unifying the field, CRIF enables deeper analysis of the relationships established between different stakeholders. In summary, the CRIF gives you tools to:

- Engage stakeholders – initiative's participant organizations, patients, their families, and caregivers;
- Subsequently, involve these stakeholders in selecting the metrics that all the initiative's participants will employ for assessing their collective impact and monitoring their performance;
- Use multidimensionality in its co-accountability approach by measuring impact in five areas, i.e., efficacy in reaching the mission, efficiency in economic and financial performance, research scientific excellence, broad social impact, and – last but crucial – patient-reported perspective.
- Offer a principle-based, participatory governance model which makes it possible to implement the RRI approach.

The CRIF is intended for organizations grouped in multi-stakeholder initiatives working on or willing to start conducting their R&I in the area of brain disorders. Though, it is conceived to be flexible and

extensible to other health research domains. These organizations should be interested in adopting a multi-stakeholder, participatory approach based on co-accountability and focusing on reaching their transformational mission.

CRIF is also designed to meet requirements set for Responsible Research and Innovation (RRI), which must (Strand *et al.*, 2015; Yaghmaei, 2018):

- Include stakeholders;
- Make researchers and societal actors mutually responsive;
- Strengthen the relevance of ethical standpoints and sustainability in decision-making;
- Improve the outcomes and maximising the impact of research.

There are many reasons to adopt the CRIF. For many initiatives, the Framework will offer methods of implementing what they already had in mind and what they believed in: genuine patient engagement, participatory governance, and ability to evidence impact. Additionally, CRIF helps to ensure continuity of research initiative by promoting stakeholders' commitment, and financial sustainability. All these qualities may help to meet stringent requirements of the funding agencies, whether private or public, and make the initiatives compliant with CRIF good candidates for other projects.

Being a **flexible and customizable framework**, the CRIF **does not place an undue burden on its Appliers, allowing them to focus on what matters most to the final Beneficiary of research: patients and the society**.

3.1 Co-accountability Pillars

Health research impact is a complex phenomenon. To measure it, perspectives and values of different stakeholders engaged in the research need to be understood and integrated.

The MULTI-ACT CRIF represents a valuable step forward in this direction as it makes stakeholder engagement the backbone of the process.

Co-accountability Pillars are one of the ways to conceptualize the implementation process of the CRIF, during which the stakeholders' perspectives and values are gathered and integrated into the evaluation tools of research initiative. We created them based on the analysis of the most relevant state-of-the-art impact assessment methodologies and refined them during consultations with stakeholders. They describe the flow of the collective impact assessment process, expressing the philosophy of the CRIF.

	**Mapping of stakeholders and establishment of the scope**	Based on the mission, the research initiative will select the stakeholders, which are engaged in setting or refining the agenda that the research initiative aims to achieve. The research initiative should identify the potential stakeholders that are strategic in the fulfilment of the impact. In defining the priorities, the plurality of interests should be considered, according to the CRIF dimensions (efficacy, excellence, social, economic, patient-reported).

	Development of operative framework	Stakeholders are engaged in defining the resources, activities and desired results. The governance model should be agreed together with the stakeholders and aligned with the different perspectives related to the dimensions of CRIF.
	Co-selection of aspects	Stakeholders are engaged in identifying the most relevant aspects for mission of the initiative. In the selection, multiple aspects related to all the dimensions of CRIF should be ensured.
	Shared measurement system	Stakeholders are engaged in data collection, analysis, co-selection and customization of indicators. The measurement system should enable a multi-perspective approach: with the Master Scorecard, the impacts are assessed from the multiple perspectives considering the dimensions of CRIF.
	Reporting, monitoring and assessment	To facilitate collective decision making, the results should be reported and monitored for each dimension of CRIF. The impact assessment supports the shared mission enabling refinement of the activities to increase the impact on people and society. This pillar represents a starting point for the whole process, thus making co-accountability a dynamic and iterative process. Therefore, this pillar represents both the end point and the starting point of the process, because the iterative process allows learning and continuous improvement.

Table 1 Co-accountability Pillars description

The Co-accountability Pillars represent two key features of the CRIF:

- **Circularity**: an on-going engagement process and re-definition task within the research initiative. Circularity guarantees a dynamic and an iterative approach.
- **Strategic value**: they offer a possibility to adapt and assess research initiative through continuous monitoring.

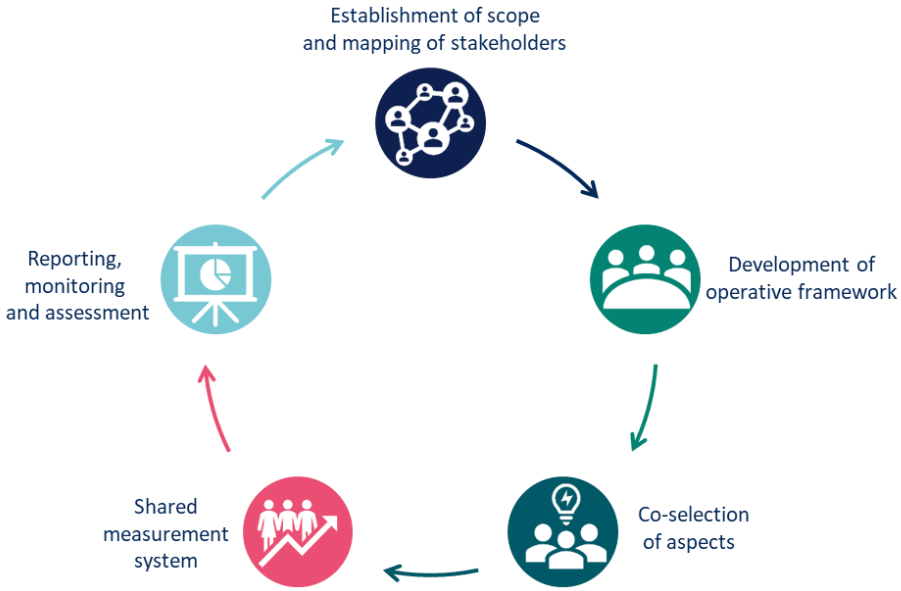


Figure 1 Co-accountability Pillars

3.2 CRIF components

The MULTI-ACT CRIF relies on three main conceptual components i.e., the Governance Criteria, the Patient Engagement Guidelines and the Master Scorecard. The first two took a form of guidelines and recommendations describing what to do and how to do it. The Master Scorecard is a set of 125 indicators intended for monitoring and reporting.

These components are accompanied by a digital Toolbox with functionalities for stakeholder engagement, analyses, and impact assessment. Namely, it allows to perform the Baseline Analysis and the Materiality Analysis and it accompanies the initiative owners in the design of their Patient Engagement Plan and their tailored Master Scorecard. This Manual provides guidelines for all other tools.

You will find that all the elements of the CRIF are intertwined: after having conducted the self-assessment exercise meant to profile your initiative (Baseline Analysis), the governance process requires conducting Materiality Analysis and implementing a common agenda and measurement system, which are in turn instrumental to enable Co-accountability. As a result, all the indicators point towards achieving the mission and agenda formulated at the early stages of the governance implementation.

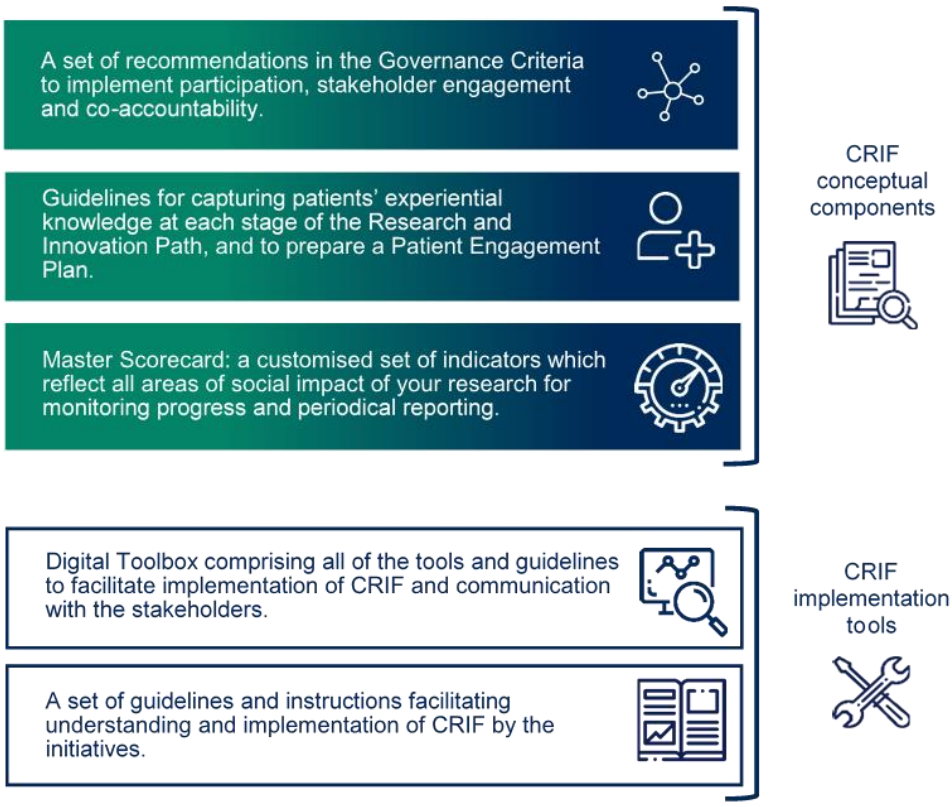


Figure 2 CRIF Concepts and Tools

3.2.1 Governance Model

The Governance Criteria are a set of recommendations on how to organize your initiative's governance bodies, define its mission and agenda, and implement a monitoring and measurement system. Thanks to the Governance Criteria, your initiative can **define its mission and shared agenda** in accordance with the MULTI-ACT principles of stakeholder engagement and co-accountability. You will also find instructions how establish a **shared and effective assessment system**, including a set of indicators of the Master Scorecard that promotes improvement and communication, and set a mechanism to receive feedback.

They facilitate collaboration among different stakeholders and improve stakeholder engagement. The model is developed according to the Responsible Research & Innovation (RRI) agenda, which aims to encourage societal actors to work together to better align research and its outcomes with the values, needs and expectations of society.

The Governance Model includes 5 Criteria and 19 sub-criteria detailed in 41 recommendations. The Criteria are not rigid steps to be followed, rather they are meant as general requirements to be met. Baseline Analysis is a web-based questionnaire, a part of the Toolbox, which you can use to assess your initiative's compliance with the Governance Criteria.

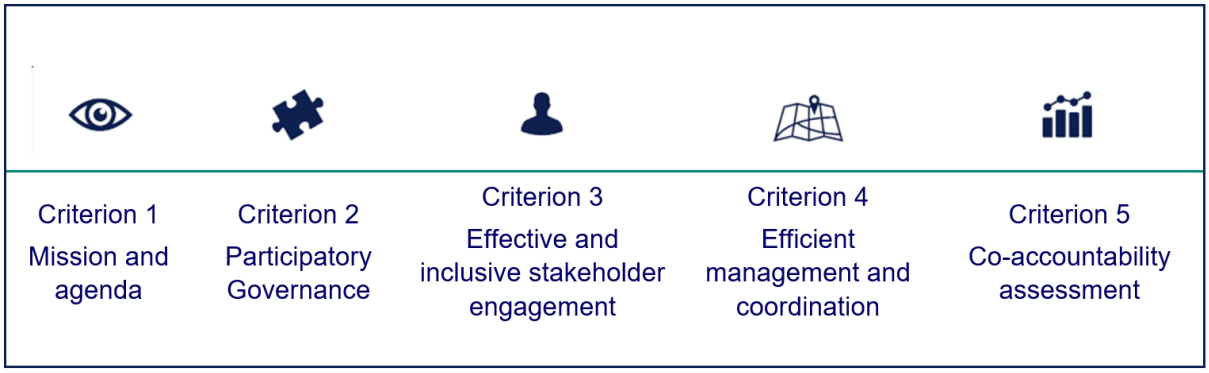


Figure 3 Governance Model: Governance Criteria

The implementation of the Governance Criteria guarantees an **inclusive** and **equitable** governance model, which allows the involvement of all interested parties under a co-design approach. It helps you put in place comprehensive, balanced and efficient stakeholder **engagement process**, ensuring also the participation of patients, their families and care givers, and patients' organizations. Finally, it promotes an effective, cooperative and efficient coordination and **alignment** of the objectives and actions required to pursue the vision and the agenda of the initiative.

While developing the Model, we considered both the practical solutions implemented by existing multi-stakeholder initiatives from various health and non-health sectors and the recommendations emerging from a context analysis, and the approach and objectives of the MULTI-ACT project itself, namely fostering the diversification of stakeholders in Health Responsible Research and Innovation processes. We looked into various collaborative multi-stakeholder initiatives and their governance systems and best practices, paying special attention to MULTI-ACT's principles i.e., developing a participatory governance model, co-designing a transformational agenda and adopting a co-accountability approach.

3.2.2 Patient Engagement Guidelines

The Patient Engagement Guidelines are an operative guide for meeting the criteria "participatory governance" and "effective stakeholder engagement" for the key and often under-represented stakeholder category "patient, their families and caregivers". The Patient Engagement Guidelines provide advice on how to engage patients and to what extent to include them in your decision-making processes depending on your situation. They will help you select the research priority and stages of research where patient engagement is instrumental to meet the initiative's mission and agenda.

The actions covered by the guidelines include:

- Establishment of **governance bodies** in charge of patient engagement (Criterion 2: Participatory Governance) and training of its members, from recruitment to cooperation with other bodies,
- Formulation of appropriate **plans for patient engagement** (Patient Engagement Plan) for each identified research priority & step,
- Choosing from a **catalogue of methods** **for stakeholder engagement** (Criterion 3: Clear, effective and inclusive methodology of stakeholder engagement) and finally
- Monitoring and assessing the impact of patient engagement.

Patient engagement strategies are directed to engage patients according to specific needs and requirements that emerge on each of the 7 stages of research, described by Research &Innovation Path. Engaging patients both in the governance of research & innovation (*Science with Patient Input*) and in the impact assessment (*Science of Patient Input*) is instrumental to meeting transformational mission's health R&I. High-standard patient engagement strengthens credibility and improves research results. Considering that the whole society is going to be "patient, family or caregiver" in some periods of the lifetime, it also makes it easier to maximize research social impact.

The guidelines also offer a set of patient-reported outcomes indicators to measure the success and effectiveness of this engagement. The **value and effectiveness of patient engagement** relies on producing outcomes that matter to patients, while being financially sustainable in achieving this goal.

Over the last decade, along with the democratization of health sciences and patients' empowerment, patient engagement has become increasingly important. Patients have been actively engaged as co-researchers and can now share their own experience of the disease, which translates into a form of knowledge that integrates with scientific and experiential knowledge. The MULTI-ACT project leverages both patient and other stakeholder experiences and increasing their ability to co-create and participate in decision-making processes in health research.

We produced the Patient Engagement Guidelines (Multi-Act Project, 2020) based on the lessons learnt from the landscape analysis of existing patient engagement procedures: literature review, web-search, interviews, surveys, and connections. They were developed into guidance, recommendations, methods and suggestions in line with existing good practice on guidelines production (WHO, 2014) and subsequently co-created with a series of actions including a public consultation, discussions, and reviews by the key stakeholders (experts, patients, researcher, clinical professional, policy makers, industries, etc.), and consolidated with two real life pilots made possible thanks to the collaboration established with existing multi-stakeholder research initiatives focusing on multiple sclerosis.

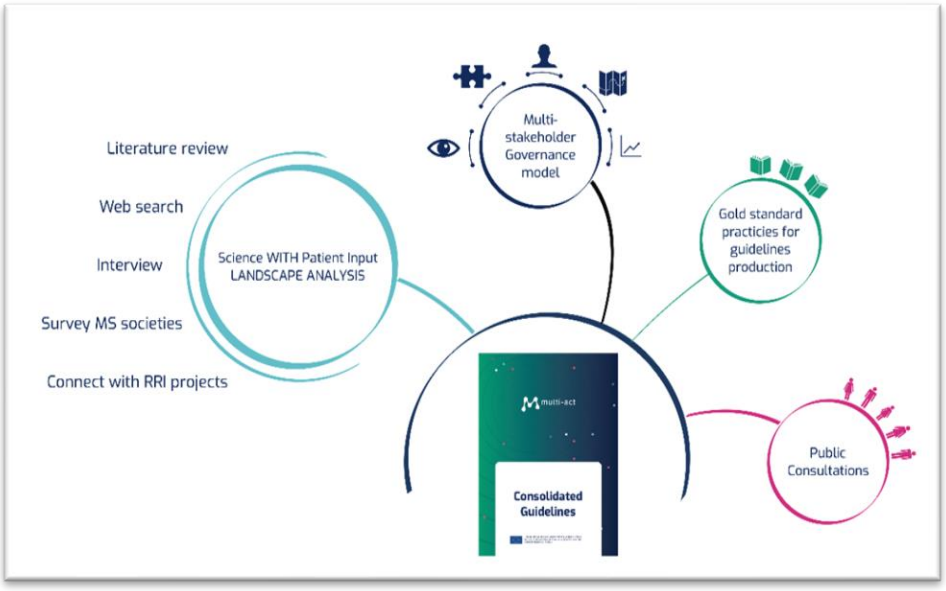


Figure 4 MULTI-ACT Patient Engagement Guidelines

3.2.3 Master Scorecard

The Master Scorecard is a component of the CRIF which helps you implement co-accountability. It is a set of 125 indicators, from which your initiative will choose the most relevant ones for, creating a customised scorecard. The indicators used in the Master Scorecard come from an extensive literature review and from a co-creation process (especially for the patient-reported dimension).

The scorecard is intended for monitoring the initiative's progress and assessing its impact. The selection is performed via the Collective Materiality Analysis, an auxiliary operative tool which allows you to engage all relevant stakeholders in your initiative in selecting the indicators. There are five dimensions of the Master Scorecard which reflect different areas of impact but also different and often competing interests of stakeholders involved in the research and innovation process as shown in the figure 5.

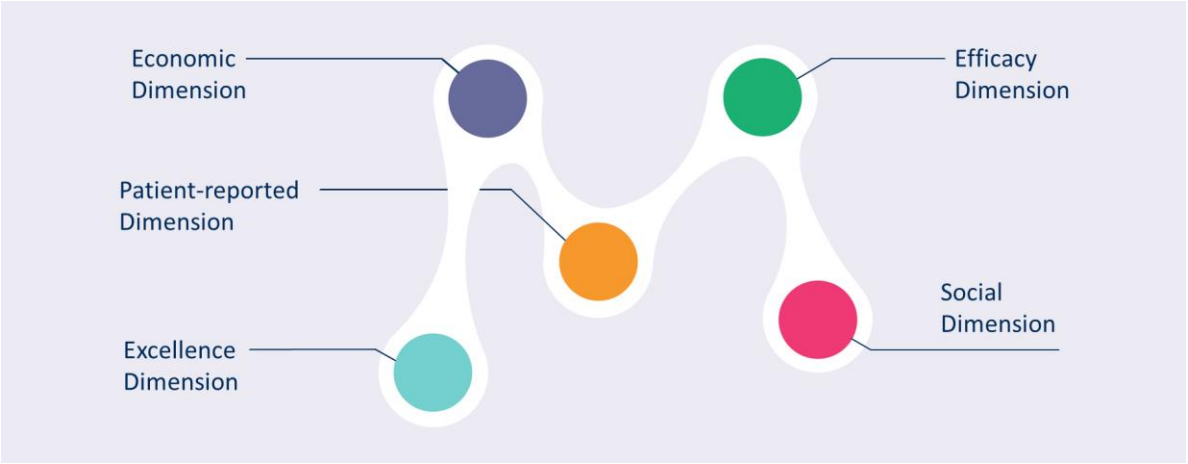


Figure 5 Five CRIF Dimensions

- **Efficacy**: refers to the capacity of a given initiative or programme to achieve its mission (strategic priorities set via the stakeholder engagement process). For more, see Efficacy dimension.
- **Excellence**: concerns the quality of research and its findings. For more, see Excellence dimension.
- **Social**: considers the direct and indirect effects of health research for the whole society, going beyond patient needs. For more, see Social dimension.
- **Economic**: refers to long-term financial sustainability of health R&I initiatives. For more, see Economic dimension.
- **Patient-reported**: concerns patients whose needs and perspectives must be understood and incorporated into health research impact evaluation. For more, see Patient-reported dimension (PRD).

The dimensions are divided into 53 aspects, which are key topic areas.

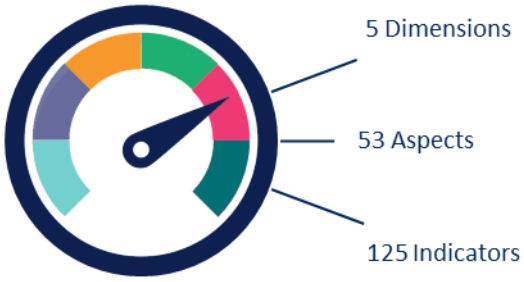


Figure 6 Master Scorecard: CRIF dimensions, aspects and indicators

The Master Scorecard translates the MULTI-ACT philosophy and your initiative's agenda into action, providing indicators to evaluate the impact of health research and innovation on all stakeholders, with a special focus on the benefits for patients and society.

During the Master Scorecard's development, we assessed a range of (health) research impact frameworks e.g., the Payback Model, the expected monetary value, the Research Impact Framework (RIF), the Research Excellence Framework (REF), logic models (Weiss, NIEHS), the Canadian Academy of Health Sciences model (CAHS), the research Impact Model (Kalucy *et al.*, 2009; Graham *et al.*, 2012; Ovseiko, Oancea and Buchan, 2012; Milat, Bauman and Redman, 2015; Raftery *et al.*, 2016; Andreaus *et al.*, 2019). Additionally, Social Return on Investment (SROI) (Jeremy Nicholls *et al.*, 2012) was considered. These research frameworks offer different indicators to evaluate health research impact. However, they have some limitations concerning their suitability for assessing research from multi-stakeholder and multi-dimensional perspectives. First, they lack public (and specifically patient) engagement and multi-stakeholder participation in defining and selecting the indicators. Second, they provide a limited picture of multidimensional impacts as they focus on what is measurable rather than on relevant long-term social impacts.

The Master Scorecard is intended to be used as a strategic management tool for monitoring the progress of your initiative and for demonstrating how your initiative produces an actual social impact.

3.3 Digital Toolbox

The digital Toolbox is available at https://toolbox.multiact.eu. It is the web-based tool through which the CRIF is made available and thus an integral part of the MULTI-ACT project outcomes. Its components are described below.

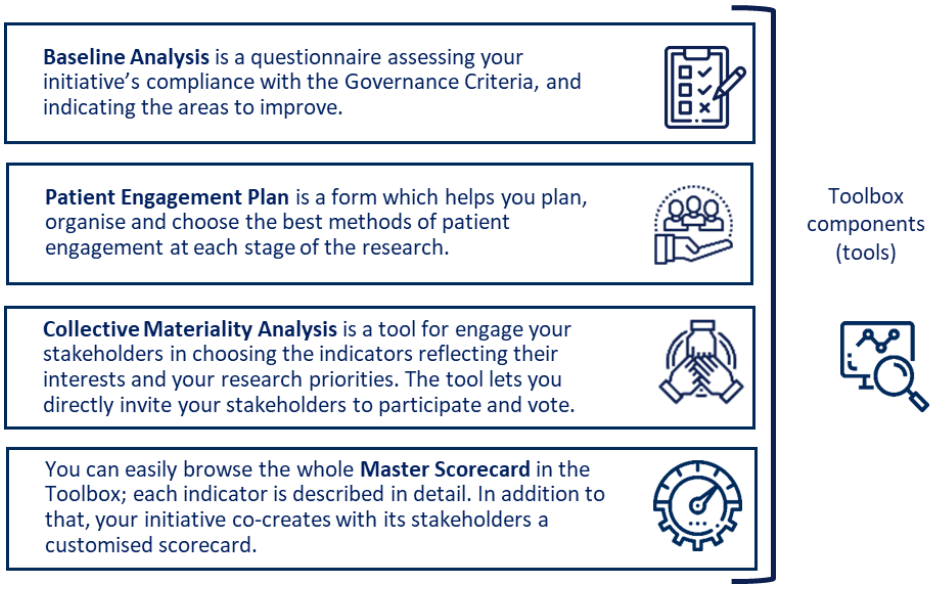


Figure 7 Components of the Toolbox

In addition to the above, the Toolbox contains guidelines, instructions and additional materials, including the full text of this Manual and the Patient Engagement Guidelines. Using the Toolbox together with the CRIF Manual is the easiest way to familiarize yourself with CRIF and implement it. The Toolbox is intuitive, so you will not need any special guidelines to use it. The Toolbox is intended for continuous use: you can store documentation and stakeholder contacts there, update them, and re-conduct Baseline Analysis, Collective Materiality Analysis and Patient Engagement Plan as needed.

3.4 CRIF Workflow

Following the evolution of the Co-accountability Pillars, a logic flow for implementation of CRIF has been defined. The CRIF Workflow will guide you through the adoption and implementation of the CRIF, emphasizing the crucial steps. It also shows how the Co-accountability Pillars and Governance Criteria work together. The CRIF Workflow described below shows the operative steps for your initiative to follow. The CRIF Workflow's backbone is **co-accountability**; it enables the cyclical evolution of the agenda over time as a result of the initiative's development or of external circumstances.

The Workflow's 9 steps are clustered into 5 phases which directly correspond to the Co-accountability Pillars. The Workflow shows how the CRIF promotes continuous improvement. Furthermore, it embeds patient engagement in both the design of the most appropriate governance structure and bodies, the definition of the stakeholder engagement methodology and the definition of a tailored impact assessment system, thus enabling the concepts of "science with and of patient inputs" which is at the root of the MULTI-ACT patient engagement approach.

First, your initiative needs to define its scope and mission (phase 1), and then implement an operating framework which makes it possible to attain the mission (phase 2). It can control its results by defining specific impact aspects that matter most to the engaged stakeholders (phase 3) which are the basis for the selection of co-accountability indicators of a measurement model shared by the stakeholders involved in your initiative (phase 4). Finally, continuous monitoring of these indicators provides the basis for corrective actions (phase 5) to be taken in order to ensure that the agenda is aligned with the

mission. For each of the phases described below, there are dedicated MULTI-ACT tools and corresponding Toolbox functionalities: Governance Criteria, Patient Engagement Guidelines, Collective Materiality Analysis and Master Scorecard. Being a flexible tool, the CRIF is not entirely chronological. However, some activities only make sense when performed before or after other activities. Below you will find a proposed sequence of activities. The Toolbox is designed in such a way that it will guide you and other users through the entire process.

If you do not find clear instructions at which stage to perform an action, it means you should act according to your best judgement.

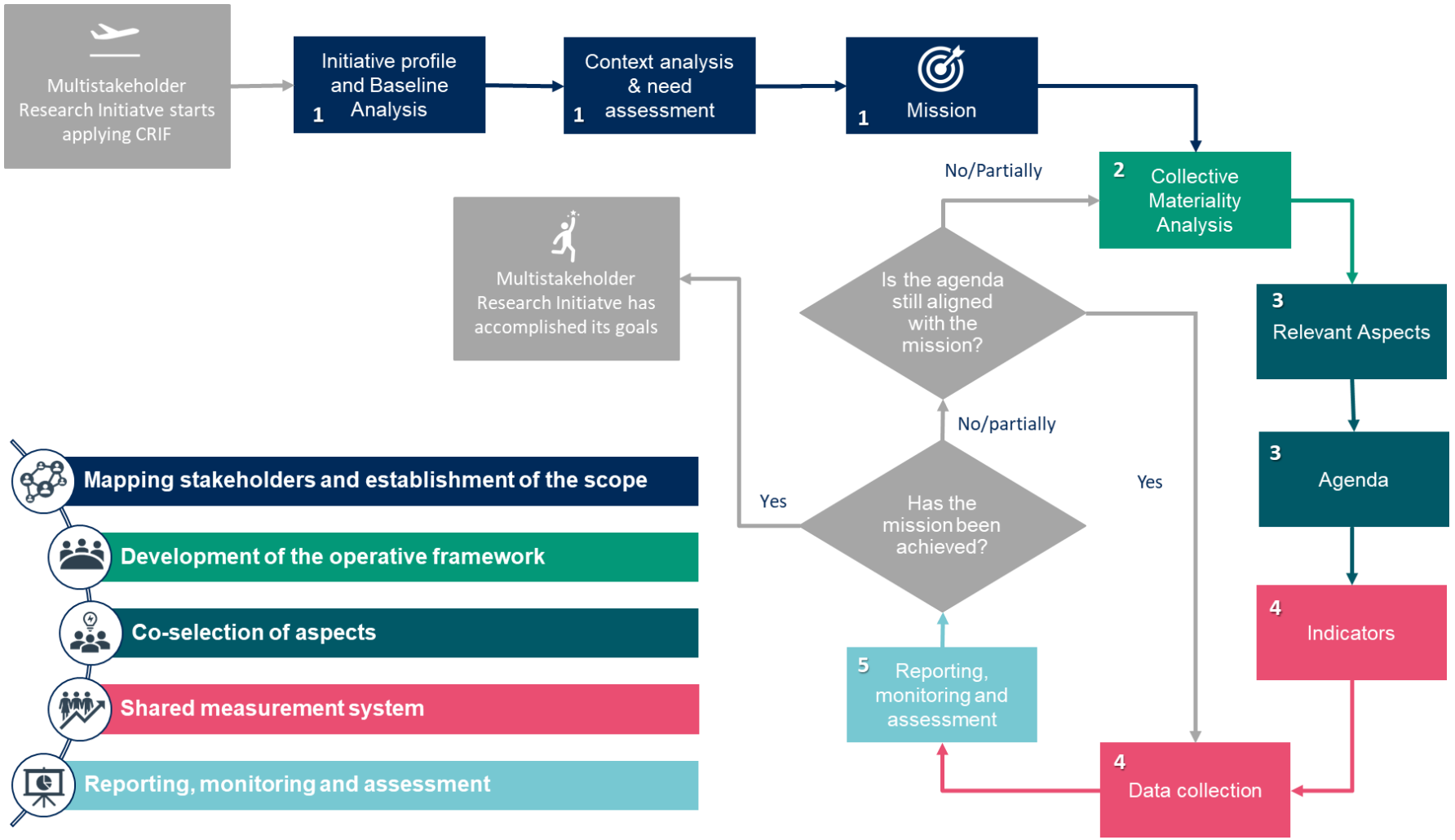


Figure 8 The MULTI-ACT CRIF Workflow and the relation with the Co-accountability

3.4.1 Phase 1

The three steps of the phase 1 lead to the definition of your initiative's mission. The mission usually remains unchanged in the long run:

- If your initiative is already set up, conduct a Baseline Analysis in order to measure its level of compliance with the Governance Model.
- Your initiative identifies its intended Beneficiaries, analyses its operating context, and learns about the needs of its stakeholders. If the "patients" stakeholder category is selected, then a patient engagement plan should be defined (see sub-criterion 2.1).
- On this basis, your initiative defines its new mission or refines an existing one.

3.4.2 Phase 2

Through the phase 2, MULTI-ACT proposes a specific methodology for defining the material topics which establish the agenda of the initiative: the Materiality Analysis. The materiality analysis is a way for your initiative to engage its stakeholders in defining which topics are significant and relevant for them. Based on that, the initiative can define next steps towards meeting their expectations.

3.4.3 Phase 3

Based on the material topics selected through the materiality analysis, your initiative can outline its agenda, identifying the transformative objectives that reflect the stakeholders' perspective.

3.4.4 Phase 4

The agenda needs be monitored through a measurement system (relevant indicators associated with the material aspects are collected in the Master Scorecard). Once the indicators associated with the relevant aspects are identified, the initiative should put in place a consistent and efficient data collection procedure, in order to gather effectively and on a regular basis, the requested information.

3.4.5 Phase 5

At this stage, your initiative and its different stakeholders co-select aspects and indicators that best reflect their claims and interests. You are strongly encouraged to use the dedicated functionality in the Toolbox for this process. Your initiative's own score card should contain 12-15 aspects chosen from a list of 53, and 12-15 indicators chosen among the 125 that the model makes available in its impact assessment scorecard. The circle closes with the publication of the periodic report of the initiative, which MULTI-ACT suggests to produce annually and which provides the basis for the analysis of the differences between what was planned and what was achieved, allowing to identify the appropriate improvements of the agenda of the initiative. While the mission is defined at the beginning of the initiative, the alignment of the agenda with the mission needs to be monitored and checked regularly, and therefore, phases 2 to 5 should be repeated accordingly (e.g. on an annual basis). Your initiative needs to base the entire process (phases 1 to 5) and application of the tools on continuous engagement with its stakeholders, especially patients. Patient Engagement Guidelines will help you do it correctly.

4 GOVERNANCE

As you can see in the, the **Governance Criteria** are constructed in a hierarchical manner. They set the main areas of governance. Each criterion is divided into several sub-areas: **sub-criteria**. The order is thematic, not chronological, so they are more like tasks to be accomplished that steps to follow. In each sub-criterion, there is at least one **recommendation**. Recommendations concisely describe the actions that an initiative needs to take to achieve the goal outlined in the sub-criterion. They are accompanied by detailed explanations of the actions and concepts behind them.

Many of the recommendations give instructions on how to structure governance bodies, how to set their areas of responsibility and rule of participation in them. For your convenience, there is a Governance bodies section which summarizes information about the governance bodies in one place.

First, check your initiative's compliance with the Governance Model (both the Criteria and the Patient Engagement) through the Baseline Analysis, and then focus on the areas identified as gaps. Your initiative then may focus on implementing these specific recommendations in order to become compliant with the Model. Below you will find the full text of the five Governance Criteria. We encourage you to read them in full at least once, so you will have an overall understanding of all the key concepts and how they relate each other. To make the implementation of the recommendations easier, the Governance Model's flexibility leaves your initiative as much discretion as possible, so that you can implement the recommendations in the most suitable way for your specific circumstances and mission.

Since the Criteria deal with stakeholder engagement and governance structures and procedures, it is worth understanding CRIF's stakeholder typology (presented below) and its approach to the governance structure before starting.

4.1 Stakeholder typology

Stakeholder is an individual or group that is affected by the outcomes of your initiatives' actions, or who can influence these outcomes or may have an interest in them(Freeman, 1984). In other words, stakeholders are people, communities, organisations and other entities that experience a change – positive, negative or neither – as a result of the activities of your initiative. Some of them will be participants of your initiative, others will not be even aware of its existence. Using a stakeholder classification is a useful way of thinking about people and organizations relevant to your initiative. While not all of them are equally relevant for your research, nor are they all going to be involved to the same degree, it is important not to overlook any group influenced by your initiative.

- **Patients** are defined as **people with a disease** (i.e. with lived experience of the disease), and **people affected by the disease** (i.e. relatives, caregivers). It is important to keep in mind that the term "patients", as used throughout this Manual, includes family, significant others, and caregivers of persons with the disease. This is in recognition of the fact that all these people may provide crucial information about influence of your initiative on lives of persons with the disease and those around them.
- **Patient organisations** are non-profit organisations which are patient-focused. Patients should constitute majority in governing bodies of these organisations. They are mostly patient associations and patient advocacy groups, but also all networks and foundations which actively

promote patient-centred approach also count. Examples: MS International Federation (MSIF), Patient Focussed Medicines Development (PFMD).

- **Society**. This broad category includes individuals, civil society organizations and civil society networks. In terms of research impact, it describes "society at large" – people you will not be able to trace or directly engage, but who are (or may be) nevertheless influenced by your initiative's research.
- **Care providers** are health and social care organizations and professionals (doctors, nurses, assistants etc.). Their focus is on networking among the professionals, helping them in continuous development and representing them. Australian Nursery and Midwifery Accreditation Council (ANMAC), European Academy of Neurology (EAN). Caregivers and care providers should not be confused. In this Manual, "caregivers" are understood not to provide care to people with a disease in a professional capacity, unlike care providers. "Caregivers" are patients.
- **Payers and purchasers** are public or private entities responsible for underwriting the costs of health care. Examples of public entities include Polish Narodowy Fundusz Zdrowia (NFZ). In some countries, regions or central government may play this role. Depending on the system adopted in a given country, health insurance companies (AXA, Cigna) and health care providers may also fall into this category.
- **Research Funding and Performing Organizations** (**RFPOs**) are universities, research hospitals, research projects, foundations, and all private and public research funders. This category encompasses organisations that conduct research and those that are in charge of grants funding to research or funds it directly. Examples: European Charcot Foundation, Mario Negri Institute, Rare Neurologic Movement Disorders, Muscular Diseases and Epilepsy Clinic in Universitätsklinikum Bonn. Most of the organizations participating in your initiative will likely fall into this category. RFPOs can differ widely one from another, so the communication between them may be challenging, not to mention different motivations and goals.
- **Policy makers**. This is a broad category, as policies are made on many levels. EU institutions like the European Commission or the European Council are obvious examples, but also national ministries of health and various regional and local authorities as long as they are empowered to make decisions concerning health programmes (vaccination, hearing loss screening, and awareness campaigns).
- **Regulators** are regulatory agencies and Health Technology Assessment (HTA) bodies, at the national and international level. Agencies for the scientific evaluation and safety monitoring of medicines: the European Medicine Agency, Agence nationale de sécurité du médicament et des produits de santé (ANSM). Polish Agency for Health Technology Assessment and Tariff System (AOTMiT) oversees medical devices and health care programmes.
- **Industry**. Companies developing and selling health products and services. Prominent members of this category are pharmaceutical companies. However, small medical products retailers also fall into it, as do e.g. health mobile apps developers. As far as services are concerned, there are health services like rehabilitation or counselling, but also those related to health care management and health research management, e.g. patient-reported outcomes measurement framework. Examples: Blackford Analysis Ltd., Sanofi Genzyme, European Federation of Pharmaceutical Industries and Associations (EFPIA).

Additionally, the CRIF Manual refers to Promoters, Appliers and Beneficiaries of the Collective Research Impact Framework, when describing how stakeholder organizations and their representatives participate in governance of your initiative.

- **Promoters** are individuals that guide the adoption of the CRIF within their organizations or initiatives. They can be either already existing multi-stakeholder organizations or initiatives, with a defined governance structure or a newly established one, willing to fully adopt MULTI-ACT governance approach. They represent various stakeholder categories, most often RFPOs, industry and Patient organizations.
- **Appliers** are Research Funding and Performing Organisations grouped in a multi-stakeholder initiative who implement the CRIF.
- **Beneficiaries** are individuals benefitting in the long-term, directly or indirectly, from a multi-stakeholder initiative. Particular focus is on Patients, Patients organizations and society.

4.2 Governance bodies

Governance bodies are groups with specific roles within a multi-stakeholder initiative that are composed of individuals participating to the initiative itself. In CRIF, it is crucial to ensure both participation and balance of power of different stakeholder categories in the bodies. The suggested governance bodies to be established are presented in the figure below.

Information about functions, composition and significance of the governance bodies are described in the Governance Criteria. In the tables below, you can find condensed summaries of the functions, composition and appointment procedures for each governance body, with references to the Governance Criteria. It may prove useful later on when you decide to set up a governance body or compare characteristics of the bodies that already exist in your initiative with those set out by the CRIF.

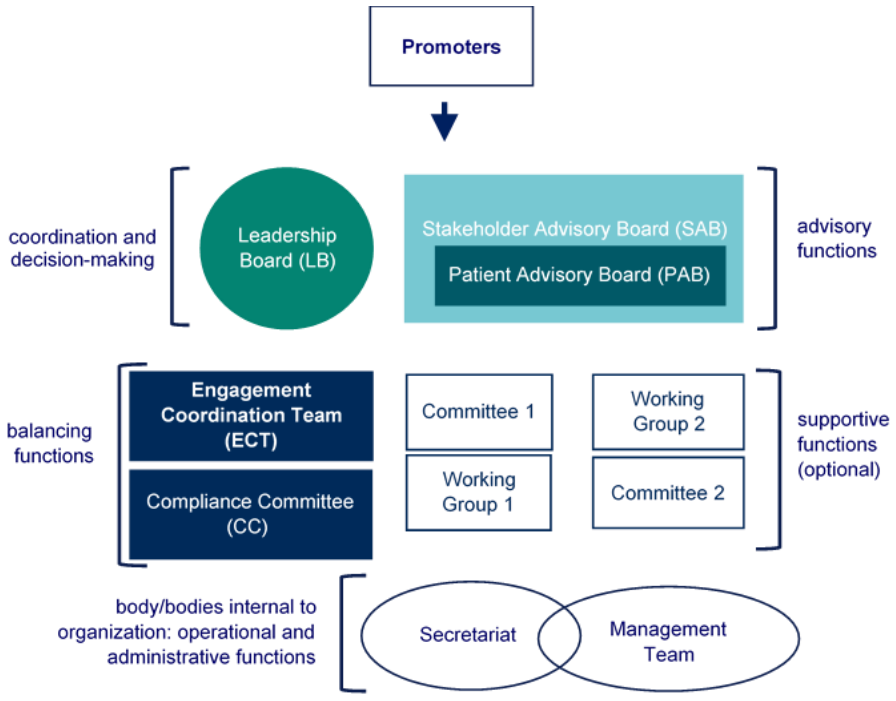


Figure 9 Governance Bodies

4.2.1 Leadership Board (LB)

FUNCTION	LB is the decision-making body within the governance structure (recommendation 2.3.1). It oversees fulfilment of the mission and agenda, and coordination and implementation of the activities of your initiative. It supervises Working Groups (WGs), Committees, and administration (recommendation 2.3.2). It enforces deadlines and improves your initiative's performance (sub-criterion 4.2), with help from the Management Team, if needed. The LB evaluates and chooses actions and tools (e.g. Progress Report, to respond to current needs of the Beneficiaries and changing circumstances) (sub-criterion 4.3). It delegates tasks to WGs or other bodies, as needed. It leads the review process (recommendation 5.1.7), with the Stakeholder Advisory Board (SAB). LB creates a procedure formalizing various aspects of how the initiative functions, from governance bodies appointment to stakeholder engagement (recommendation 2.3.3), with support of Compliance Committee and the Engagement Coordination Team. This procedure needs to be approved by the SAB. LB appoints (recommendation 2.3.2): • Chair/coordinator acting as an internal and external point of reference for the initiative; • Operational teams, such as a sub-board and the Secretariat/ Management Team – when needed; • Working Groups, Committees, and collaborative team to carry out various tasks LB is responsible for formalizing procedures and strategies: • It creates the Engagement Plan (sub-criterion 3.1, Implement phase) with ECT and Stakeholder Advisory Board (SAB). • LB has a responsibility to define the collective Action Plan and enforce its implementation (sub-criterion 4.1) through establishment of dedicated WGs, and creating accountability mechanisms. • It creates a process for collecting feedback, opinions, and grievances of internal and external stakeholders (recommendation 5.2.1), with the ECT. • It formalizes procedures on how the initiative's participants interact with each other, balancing stakeholder engagement and agile management (sub-criterion 3.4) with the ECT and the CC. The LB also determines the budget and conduct a cost analysis of the initiative, as well as identifies critical issues and gaps in your initiative's operations (sub-criterion 4.4). It may delegate these tasks to the Secretariat/Management Team. LB Identifies gaps in stakeholder engagement capacity (sub-criterion 3.1) and then monitors, evaluates and improves quality of stakeholder engagement (sub-criterion 3.1), with SAB. It ensures appropriate communication to relevant stakeholders and the general public (recommendation 5.3.1)

	The LB is responsible for constantly maintaining an alignment between the shared assessment system and the mission and agenda of the initiative (recommendations 5.1.4 and 5.1.5).
APPOINTMENT	LB is set up by the Promoters. Composition of the LB needs to be approved by the SAB and PAB (sub-criterion 2.3).
COMPOSITION	The composition of the LB reflects the categories of the stakeholders that participate in your initiative and have strategic importance. Its members act as these categories' representatives. Their number varies according to the initiative's needs. LB has to be balanced in terms of gender, sector and geographical background, language, political diversity, perspectives and experiences. The members of LB should be committed and skilled individuals, which should ensure constant participation to the initiative's development. LB members hold equal power because it guarantees equity among participant stakeholders. The composition of the LB and its members should undergo the approval of the SAB and the PAB (recommendation 2.3.2).

Table 2 Leadership Board (LB)

4.2.2 Engagement Coordination Team (ECT)

FUNCTION	The ECT coordinates the involvement of stakeholders, including patients, in all the operations. It coordinates all training and coaching activities to facilitate the stakeholders' engagement (sub-criterion 3.2), which includes providing briefing materials and organizing training sessions. Cooperation between the ECT and the Leadership Board (LB) plays a crucial role in the initiative's governance. While the LB provides agile management, the ECT should guarantee and facilitate the participation of weak and/or marginalized stakeholders as well as a balance among different points of view (sub-criterion 3.4). • The ECT works as a facilitator between the Stakeholder Advisory Board (SAB) and the LB. (recommendation 2.1.1). • It identifies gaps in stakeholder engagement capacity (sub-criterion 3.1), together with the LB. • It assesses stakeholder engagement (sub-criterion 3.1), together with the LB and the SAB. • The ECT maintains the active participation of the internal stakeholders in the LB-led process of setting up a stakeholder feedback mechanism (sub-criterion 5.2). In terms of patient engagement responsibilities, the ECT: (full description in the Composition and skills of Engagement Coordination Team): • Designs, implements and monitors the Patient Engagement Plan. • Makes sure that the experiential knowledge of the patients is used to improve patient-reported outcomes.

	• Moderates interdisciplinary dialogue. • Translates technical language into a language that patients easily understand • Mitigates issues like ethical conflicts in protocol design, tokenism, patient recruitment etc.
APPOINTMENT	Promoters establish the ECT: they recruit and appoint its members. The agreement of the LB is needed (sub-criterion 2.3, recommendation 2.1.1). You can find detailed instruction Establish the Engagement Coordination Team.
COMPOSITION	The composition of the ECT is described in detail in the Patient Engagement Guidelines. However, the composition of this team can vary depending on the specificity of individual programs and projects. All recruited experts are encouraged to undertake additional training.

Table 3 Engagement Coordination Team (ECT)

4.2.3 Stakeholder Advisory Board (SAB)

FUNCTION	The main function of the SAB is advisory – it supports the Leadership Board (LB). It may, however, evolve over time into a decision-making body, acting like a Stakeholder Assembly. The SAB leads the review process (recommendation 5.1.7) with the LB. It confirms appointment of the Compliance Committee (CC), with the LB (sub-criterion 2.4). Patients, as a specific stakeholder category included in the SAB, may be asked by the LB for their own contribution. This group may form a sub-board of SAB: the Patient Advisory Board (PAB) (recommendations 2.1.1, 2.3.1). It approves the composition of the LB, with the PAB (sub-criterion 2.3).
APPOINTMENT	Appointed by Promoters with the contribution of the Compliance Committee (CC) and the Engagement Coordination Team (ECT) (recommendation 2.3.1).
COMPOSITION	The SAB is composed of interested stakeholders. The Promoters, with the ECT, arrange an open call for participation in the SAB. The CC and the ECT establish the rules regarding selection, composition, and balance of the SAB. PAB is a sub-board of SAB (recommendation 2.3.1).

Table 4 Stakeholder Advisory Board (SAB)

4.2.4 Patient Advisory Board (PAB)

FUNCTION	PAB may be a separate body or group representing patients within the Stakeholder Advisory Board (SAB). It presents the voice and opinions of patients, including underrepresented patients (recommendation 2.1.1). It is to be consulted by the Engagement Coordination Team (ECT) and the Leadership Board (LB). It approves the composition of the LB, with the SAB (sub-criterion 2.3).

APPOINTMENT	Promoters with the Compliance Committee (CC) and ECT appoint PAB during creation of the SAB (sub-criterion 2.3).
COMPOSITION	PAB is composed of patient representative from the SAB (recommendation 2.1.1).

Table 5 Patient Advisory Board (PAB)

4.2.5 Compliance Committee (CC)

FUNCTION	CC maintains a balance among stakeholders' stances and expectations. It oversees ethical issues too (sub-criterion 2.4). The CC takes part in the decision-making process of your initiative. It contributes to the Leadership Board's (LB) activities, especially: • Guaranteeing equity (sub-criterion 2.4) • Ensuring that the self-interest of stakeholders does not prevail on collective decision-making processes (sub-criterion 2.4) • avoiding tokenism (sub-criterion 2.4) • Making sure that the decision-making process considers different views (sub-criterion 2.4) • Managing conflicts (sub-criterion 2.4) • Guaranteeing ethical acceptability and social justice of the initiatives' objectives and activities (sub-criterion 1.4); • Ensuring a balance between effective engagement of participants and agile management of the initiative (sub-criterion 3.4); • Supporting the LB in formalizing a procedure (recommendation 2.3.3). It also may support Secretariat/Management Team if needed in its duties related to financial oversight (sub-criterion 4.4).
APPOINTMENT	First appointed by the Promoters in the beginning of Governance Model implementation, later officially confirmed by the LB and the Stakeholder Advisory Board (SAB) (sub-criterion 2.4).
COMPOSITION	It can be a committee or an individual, depending on the size, level of development and resources of your initiative (sub-criterion 2.4).

Table 6 Compliance Committee (CC)

4.2.6 Committees and Working Groups (WGs)

FUNCTION	Creation of WGs is optional, and their responsibilities, role and specific tasks are assigned according to current needs of your initiative. For example, the Leadership Board (LB) may charge the bodies with research or reporting. They may also be responsible for maintaining feedback mechanism and communication (recommendation 5.3.1). WGs may carry out operative tasks, while Committees may provide insights and opinions (recommendation 2.3.1). They report to the LB and are supervised by the Management Team.

APPOINTMENT	LB appoints WGs if needed and as needed (sub-criterion 2.3).
COMPOSITION	The WGs should be composed and balanced in terms of the stakeholders' categories and needs of the initiative (recommendation 4.1.1).

Table 7 Committees and Working Groups (WGs)

4.2.7 Secretariat/Management Team

FUNTIONS	The Secretariat and Management Team may be two different bodies or one. It depends on the size and structure of the multi-stakeholder initiative. Secretariat/Management Team supervises administrative and operational tasks. The body: • Enforces the deadlines and oversees activities in your initiative (sub-criterion 4.2). • Supervises of the general performance of the initiative according to the defined mission and agenda (sub-criterion 4.2). • Helps the Leadership Board (LB) with the Progress Report (recommendation 5.1.6). • Runs administrative duties. • Ensures of financial security and legal compliance of your initiative (sub-criterion 4.4). • Oversees Working Group's (WG) activities. • Supports the LB in gathering data for Progress Reports (recommendation 5.1.6). • May support the LB and the Stakeholder Advisory Board (SAB) in the review process (recommendation 5.1.7). • Supports the LB in setting up a process for gathering stakeholders' feedback (recommendation 5.2.1). The LB may decide to delegate to the Secretariat/Management Team the tasks of determining the budget and conducting a cost analysis of the initiative, as well as identifying critical issues and gaps in your initiative's operations (sub-criterion 4.4).
APPOINTMENT	The LB appoints it/them based on the initiative's needs and tasks to be performed (sub-criterion 4.2).
COMPOSITION	The LB can decide on the composition of these bodies (or body). A multi-stakeholder approach is not required here.

Table 8 Secretariat/Management Team

4.3 Governance Criteria

In this section, you will find the full text of the Governance Criteria. You can see the structure of the Governance Criteria in the table below.

3. Clear, effective and inclusive methodology of stakeholder engagement

The Appliers of the Governance Criteria guarantee a comprehensive, balanced and efficient stakeholder engagement process, ensuring participation of patients and of other relevant stakeholders. The Criterion 3 is transversal to the other four Criteria, because stakeholder engagement permeates the governance operations.

- 3.1: Define and approve a methodology to engage stakeholders
- 3.2: Engage intended Beneficiaries
- 3.3: Differentiate the level of engagement according to involved stakeholders
- 3.4: Ensure a balance between engagement of involved stakeholders and agile management of the initiative

1. Mission and agenda	2. Participatory Governance	4. Effective and efficient management and coordination of the initiative	5. Co-accountability assessment
Appliers define a mission and a shared agenda, considering CRIF principles.	Appliers guarantee an inclusive and equitable governance model, which allows involvement of all relevant parties through a co-design approach.	Appliers guarantee an effective, cooperative and efficient coordination of the objectives and actions required to pursue the mission and the agenda.	Appliers establish a shared and effective measurement system, comprising of a set of indicators, which promotes continuous improvement and communication. They set a mechanism to receive feedbacks.
• 1.1: Identify intended Beneficiaries, analyse the operating context of the initiative and understand the needs of stakeholders • 1.2: Define a shared mission and common agenda • 1.3: Promote a movement building approach to achieve transformative changes • 1.4: Guarantee ethical acceptability and social justice	• 2.1: Allow the involvement of intended Beneficiaries • 2.2: Adopt a multi-stakeholder approach enabling co-creation • 2.3: Implement a participatory structure • 2.4: Guarantee equity and mechanisms to avoid self-interest	• 4.1: Enable involved stakeholders to coordinate their efforts and perform activities • 4.2: Set clear and transparent processes and timeline • 4.3: Maintain flexibility • 4.4: Ensure the presence of secure funding, solid organizational structure and resources management	• 5.1: Define a shared assessment system • 5.2: Set effective feedback mechanism • 5.3: Ensure continuous learning, communication and disclosure of knowledge

Table 9 Governance Criteria

4.3.1 Criterion 1: Mission and agenda

In the process of formulating a mission and a shared agenda for your initiative, it is important that Appliers:

- Identify the initiative's intended Beneficiaries and analyse the context in which it operates;
- Define a shared mission and common agenda;
- Promote a movement-building approach to achieve transformative changes;
- Guarantee ethical acceptability and social justice.

4.3.1.1 Sub-criterion 1.1: Identify intended Beneficiaries, analyse the operating context of the initiative and understand the needs of stakeholders

Recommendation 1.1.1: Be aware of who are the initiative's intended Beneficiaries and have clear strategies to facilitate their active participation

Recommendation 1.1.2: Carry out a context analysis to understand the operating context of the initiative and identify the needs of its stakeholders, with particular regard to the intended Beneficiaries

The Appliers **identify the intended Beneficiaries** and set clear strategies to engage them and enable their participation (in this regard, please refer to sub-criterion 2.1 and 3.2). In the health R&I, society and patients are the key Beneficiaries, and the ultimate goal is to improve their health and well-being. The Appliers should explicitly identify these Beneficiaries, their characteristics, and their needs. This step is necessary for the identification of the initiative's long-term goals later on.

The initiative also conducts a **context analysis**. Its purpose is to identify the main actors and trends that may be challenging for the initiative, as well as risks and assumptions that may affect its performance. Context analysis involves looking at the current state of the "issue" that your initiative seeks to influence or the problem it seeks to solve: its social, environmental, and political conditions, actors who may be able to bring change. This is why, before defining the mission and agenda (see sub-criterion 1.2), Appliers first analyse which "ecosystems" and communities are affected, what key issues and pressures are faced, and the main social, political, economic, and technological factors that together create the context.

It is recommended to carry out the context analysis in parallel with the Plan phase of sub-criterion 3.1, which describes profiling and mapping of the stakeholders.

Having identified the intended Beneficiaries, analysed its operating context, and mapped its stakeholders, your initiative is ready to deepen its understanding of the stakeholders' needs. **Needs assessment** is a fundamental process that leads to a better understanding of the challenges faced by the initiative and its stakeholders. You can use it to identify the change that your initiative wants to bring about in society. This change will be subsequently expressed through the initiative's mission and detailed through its agenda, as described in sub-criterion 1.2.

The need assessment is also related to sub-criterion 2.2, which recommends initiatives to set up an initial consultation process to understand the bottom-up needs and challenges of the potential participants of the initiative.

It is possible to integrate the context analysis and needs assessment: Appliers can identify the problem faced, its main roots, and its most relevant consequences, involving relevant stakeholders in this analysis. In the process, the stakeholders present their needs.

This exercise may facilitate the steps described in the following sub-criterion 1.2, namely the definition of the mission and the agenda.

4.3.1.2 Sub-criterion 1.2: Define a shared mission and common agenda

Recommendation 1.2.1: Define a shared mission and a common agenda involving relevant stakeholders, thus tackling the intended issue with a unifying long-term vision and a clearly defined set of objectives and actions necessary to pursue the mission.

Recommendation 1.2.2: Identify appropriate indicators in alignment with the initiative relevant aspects and objectives considering the different perspectives of the stakeholders involved.

Initiatives adopting the CRIF have in common the **vision of striving to conduct mission-oriented research.** They define their mission and agenda according to their specific vision and unique circumstances.

Mission definition

A mission statement defines your initiative's current and future role, its goals[1], and its approach to reaching them. The mission statement includes:

- Descriptive elements clearly illustrating what the initiative wants to achieve;
- Transformative elements i.e. the changes the initiative wants to create in the context in which it operates.

With regard to the descriptive elements, your initiative may want to describe:

- Its potential Beneficiaries;
- The scope of the intervention (e.g. health domain, geographical area, gender, socio-economic conditions).

With regard to the transformative elements, your initiative may need to clarify:

- The expected change intended to happen for the Beneficiary;
- A baseline against which this change could be assessed.

Example of a research initiative mission (Mazzucato, 2018)
Decreasing the burden of dementia by 2030 reducing the progression of the disease in affected patients in Europe. *Descriptive elements:* 1. Beneficiary: affected patients 2. Scope of the intervention: dementia brain disease in Europe *Transformative elements:*

[1] Goal is a description of a destination, and an objective is a measure of the progress that is needed to get to the destination.

3. Expected change for the Beneficiary: reducing the progression of the disease
4. Baseline: the current burden of dementia.

Materiality analysis and identification of aspects

Figure 10: The materiality analysis as the bridge between the initiative's mission and its outcome.

According to the criterion 5, Appliers need to **establish a shared and effective assessment system,** and a mechanism to receive feedback. The assessment system must include a set of indicators and promote continuous improvement, and communication.

Then, the Appliers enable the stakeholders to co-select measurable objectives in order to assess the progress and outcomes of the initiative. The initiative's governance bodies, on other hand, identify the aspects of measurement through a process that requires identification of measurable and achievable targets: in this way, they ensure stakeholders' engagement over time.

In order to assure coherence between the indicators used in monitoring and reporting and the interests of different stakeholder categories involved, the initiative carries out a **materiality analysis**.

Materiality analysis is a managerial tool that can facilitate the adoption of co-accountability and multidimensional impact assessment (Master Scorecard). It allows you to gather stakeholders' perspectives and to **identify the CRIF aspects** that are significant for stakeholders. From this point of view, materiality analysis can be defined as a bridge between your initiative's mission and the outcomes of the research it conducts. It links the reasons why the initiative was established with the results that matter most to the stakeholders. You will find detailed instructions on how to conduct it in the Materiality Analysis section.

Agenda definition

An agenda is a list of fundamental transformative objectives (i.e. priorities), including a description of the main outputs[2] and activities needed to achieve them. It is agreed upon by stakeholders and your initiative will aim to achieve its agenda in order to fulfil its mission. The agenda must be consistent

[2] The products, capital goods, and services that result from a development intervention.

with the aspects selected as relevant during the materiality analysis. For each priority of the agenda, the initiative formulates:

- A transformative objective, describing the type of intervention and the transformative threshold and baseline according to which the initiative considers its intervention successful
- Outputs and related activities needed to reach the transformative objective

Once they are defined, your initiative ensures proper dissemination and circulation among all involved stakeholders of the agenda, timeline, and objective that should be shared among all team members.

Example of a research initiative (Mazzucato, 2018)

Agenda of Dementia Care Initiative (timeline 2020-2030)

- Increase the percentage of dementia patients who are given personalized treatments, through the development of a customizable therapy protocol, according to specific patients' needs, to be shared with an "X" number of medical facilities.
- Increase the dementia patients' feelings of being more physically and intellectually independent through the development of a customised, free smartphone and computer IT application to be easily accessed by patients in Europe to perform daily tasks.
- Increase the percentage of early-diagnosed (within one year from the disease start) dementia patients in Europe through development of a digital application (e.g. background app linked to smartphone and computer) that is able to detect early symptoms of neurodegenerative diseases and recommend prompt treatment to users, to be available on at least on 2 operative systems (e.g. Android and IOS).

The transformative objective (priority): The number of dementia patients who are given personalized treatments in Europe is increased by * %.

Outputs: Development and adoption of a customizable therapy protocol according to specific patients' needs.

Activities: Research and development of the customizable therapy protocol.

Assumption considered:

- If patients could get personalized treatment, the progression of the disease could be slowed down up to * %.
- If patients would feel more independent in performing daily tasks, the feeling of the disease burden could be decreased. Furthermore, performing these tasks could also be a stimulating activity to slow down the progression of the disease.
- If dementia patients are diagnosed earlier, the burden of the disease is drastically decreased thanks to the specific therapies patients can adopt.

When defining the agenda, always keep in mind the relevant aspects in order to ensure the alignment between the assessment system and the mission, agenda and objectives of the initiative. In the case of initiatives at an advanced stage of development, which have already defined and tested a mature governance model, an additional internal control system can be introduced in order to measure

progress towards its agenda and the achievement of its transformative objectives. In this regard, the box below gives some further suggestions[3].

Timeline and Coherence Check

Once defined the agenda, the initiative should monitor the timeline of the intervention, namely the temporal and operation feasibility needed to achieve the objective. For instance, your initiative could answer the following questions:

1) In what timeframe is it reasonable to reach our objective?
2) Is it in line with our initiative's timeframe?
3) Is the threshold identified as our expected results realistically achievable? Can we contextualize the number? Did we make explicit the reference I am using to set up my percentage for my objective?

Having defined the priorities of the agenda, the initiative should ensure the **coherence** and the causal link among activities, outputs, objectives, agenda and mission. In this regard the activity should lead to the output, the output – completely under the responsibility of the project – should lead to the objective. For instance, the initiative could answer the following questions:

- Is the agenda contributing to the mission statement? In which way?
- Are we accountable 100% over the activity and outputs?

Are the activities contributing to the agenda? In which way?

Finally, ensure secure funding to guarantee adequate resources for the development and the correct deployment of activities, as defined in sub-criterion 4.4. In particular, implement an effective cost-management process, i.e. focus on the determination of the needed budget, cost analysis, and identification of gaps and critical issues.

The table below offers a set of additional data to be considered when defining the mission and agenda. In this last regard, please consider that the expected impact could be influenced by several factors both in and out of control of your initiative.

MULTI-ACT definition	Description	Question to answer	Timing	Sphere of control / influence
Mission	The initiative's current and future role, its goals and its approach to reach them	What is the long-term goal of the initiative?	Long term	Influence

[3] An initiative should have 100% accountability of these two elements for which it is considered accountable. Differently, the transformative objective in most cases is affected by external factors and variables – this obviously reduces the initiative's accountability over the effective achievement of the results.

Agenda	The transformative objective, describing the type of intervention and the transformative threshold and baseline (according to which the initiative considers its intervention successful)	Why/What do I want to achieve? Which change do I want to contribute to/to bring about?	Medium- to long term	Influence
	The outputs needed to reach the transformative objective	How do I want to achieve it? Which concrete actions do I need to put in place?	Short term	Control
	Activity	Which activities will I perform?	Short term	Control

Table 10 Table Mission and agenda practical questions

4.3.1.3 Sub-criterion 1.3: Promote a movement building approach to achieve transformative changes

Recommendation 1.3.1: Promote a movement building approach throughout all the initiative phases by enabling the generation of a community aspiration, becoming a platform that fosters change and innovation, engaging stakeholders in long term strategic action, enacting constant learning mechanisms and enabling authentic involvement of community

Recommendation 1.3.2 Be transformative and disruptive by promoting innovative problem-solving and critical thinking approach among involved stakeholders, in order to open new horizons for the research and go beyond the boundaries of the current research system, with the aim of achieving collective social impact

Appliers of the CRIF should embody a movement-building approach (Cabaj and Weaver, 2016) by integrating the above recommendations. In order to promote a movement-building approach and achieve transformative changes, your initiative:

- Creates a sense of aspiration shared by the stakeholders in which everyone agrees and works together toward the achievement of the related goals;
- Tries creating a “container for change” that seeks the change of the people involved in your initiative;
- Engages in long-term (strategic) actions, at all stages of the project;
- Focuses efforts on activities that result in a greater opportunity for change. This is achieved by having the agents participate and collaborate in long-term or strategic actions;
- Incorporates a shared measurement process as part of a complete sharing learning process in which participant members “hold each other accountable and learn from each other’s successes and failures” (Kania and Kramer, 2011). In this sense, the shared impact assessment serves as a resource to provide feedback to the system and serve as a constant learning mechanism;
- Ensures authentic community engagement including those negatively affected by certain measures in the process of change.

4.3.1.4 Sub-criterion 1.4: Guarantee ethical acceptability and social justice

Recommendation 1.4.1: Consider societal relevance and ethical acceptability of the initiative while minimizing potential unintended negative consequences

Recommendation 1.4.2: Aim to extend the positive impact of research to as many people as possible and ensure social justice

Appliers consider how relevant their initiative's objectives are for the society and how to maximize its positive impacts while minimizing its negative consequences and ensuring that the rules of social justice are reinforced.

This recommendation is of qualitative nature and should be considered as a guidance and a reference to be applied throughout the entire process of decision-making. The responsibility of ensuring the consideration of this recommendation throughout the entire process could be assigned to the Compliance Committee, a body described in detail within sub-criterion 2.4.

4.3.2 Criterion 2: Participatory Governance

Appliers should guarantee an inclusive and equitable governance model promoting the involvement of all interested parties through a co-designing approach. To this end, ensure that the initiative:

- Allows the involvement of private intended Beneficiaries;
- Adopts a multi-stakeholder approach enabling co-creation;
- Implements a participatory structure;
- Guarantees equity and mechanisms to avoid self-interest.

4.3.2.1 Sub-criterion 2.1: Allow the involvement of intended Beneficiaries

Recommendation 2.1.1: Involve intended Beneficiaries in the agenda design, in the decision-making process and in the initiative development, implementation and assessment. For the purpose of MULTI-ACT, patients are usually the intended Beneficiaries. With specific regard to patients, develop a roadmap to capture "experiential knowledge" of patients, to better understand how to draw on their experience and use the experience constructively for co-creation purposes and to evaluate the impact of research on the outcomes that matter to patients.

MULTI-ACT proposes a set of guidelines to support the engagement of patients which aim at leveraging patients together with the other stakeholders' experience and at raising their ability to co-create and participate to decision-making processes.

The involvement of patients – defined as the intended Beneficiaries – is pivotal in the implementation of the CRIF. In this regard, MULTI-ACT proposes a path for patient engagement to ensure that people affected by brain diseases are given an equal voice with other stakeholders. To ensure continuous engagement of patients throughout the entire initiative and give them authentic influence, Appliers:

1) Appoint an Engagement Coordination Team (ECT) that will be in charge of coordinating the involvement of stakeholders, including patients, in all the operations. Initially, you (the Promotes) appoint the ECT, and the LB later accepts your choice or suggests a different composition.
2) Create a Patient Advisory Board (PAB), a specific group of patients within the Stakeholders Advisory Board (SAB), to be involved and engaged throughout the entire development of the

initiative, providing advice, insight, and perspectives on the initiative's activities and operations.

For the details about roles, responsibilities, appointment procedures, and structure of the above bodies, please refer to the Governance Bodies section. ECT is additionally discussed in a section of the Roadmap Action 1: Establishment of an Engagement Coordination Team (ECT).

4.3.2.2 Sub-criterion 2.2: Adopt a multi-stakeholder approach enabling co-creation

Recommendation 2.2.1: Prepare the initiative to implement co-creation processes by framing/reframing the composition of the initiative according to the new multi-stakeholder nature

Recommendation 2.2.2: Set up an initial consultation process in order to understand the bottom-up needs and challenges of the potential participants of the initiative

Multi-stakeholder approach to governance is essential for co-creation to happen. Co-creation may be defined as co-operation and learning from one other to raise awareness on important issues and to build relationships between groups and individuals (Cottam and Leadbeater, 2004), with particular attention to those that normally do not interact. In order to adopt the multi-stakeholder approach, your initiative needs to build participatory governance structures and processes, which are designed to create shared ownership of among its stakeholders (i.e. you – the Promoter, patients, care providers – medical professionals, the industry, research institutions etc.). To shape the governance structure of your initiative that would be compliant with the multi-stakeholder perspective, first you need to identify the structure and tools best suited to help your initiative achieve its objectives.

To achieve this goal, the initiative first analyses its current composition and envisions a stakeholder structure that would be ideal for achieving its mission and agenda. This activity allows to map the potential gaps in terms of stakeholder composition and to ensure that the initiative involves participants from all the relevant stakeholder categories. Once the initiative defines its composition, it identifies and considers stakeholders' needs, challenges, and barriers to guarantee genuine participation.

In order to accomplish this goal, conduct the analysis described below:

1) Analyse the current structure of the initiative, its organizational model, and its current participant composition (if your initiative already exists). Envision, what would be ideal for achieving your mission and agenda.
2) Identify the stakeholders' categories that could be involved according to the context and the objectives pursued by the initiative and, therefore, that could be potential participants in the initiative.
3) Identify the potential relevant gaps in terms of stakeholder composition and, if applicable, integrate the participation of those stakeholder categories that are missing according to the above-mentioned point 2; Ensure that your initiative involves participants from all the relevant stakeholder categories.
4) Identify and consider stakeholders' main needs, challenges, and barriers to guarantee their genuine and committed participation.

Conducting this analysis is your task as a Promoter. It precedes structuring of the governance model of the initiative itself, the composition of its bodies, and the formalization of the structure, participants,

and roles, which will be explained in the Sub-criterion 2.3: Implement a participatory structure and in the Governance Bodies section.

You will integrate the results of this analysis with the activities described in the Sub-criterion 3.1: Define and approve a methodology to engage stakeholders.

4.3.2.3 Sub-criterion 2.3: Implement a participatory structure

Recommendation 2.3.1: Define a clear and agile backbone structure and define clear roles and responsibilities of all involved stakeholders, based on the mission and the agenda

The participatory structure is the system by which an organization makes and implements decisions in pursuit of its strategic objectives. Appliers will need to adapt the structure to the organizational model proposed below or, if they are new-born organizations, define their structures accordingly. The section Governance bodies describes in detail the main bodies of the MULTI-ACT Governance Model: their main functions within the structure, process of appointment, and stakeholder composition. It is crucial that you become familiar with the content of this chapter.

The roles of the other bodies are further described under specific sub-criteria and in the Governance bodies section. In particular, the Leadership Board is described in the recommendation 2.3.2, the Working Groups in recommendation 4.1.1, the Engagement Coordination Team (ECT) in sub-criterion 2.1, and the Compliance Committee in sub-criterion 2.4. You, with assistance from the ECT, are responsible for arranging an open call to interested stakeholders for participation in the Stakeholder Advisory Board (SAB). Establish rules for selection, composition, and balance of the SAB with the contribution of the Compliance Committee and the ECT.

Recommendation 2.3.2: Identify a mix of committed and skilled individuals that will be a part of the Leadership Board and balance them in terms of gender, sector background, geographical background, language, political diversity, opinion and experience

Set up the Leadership Board (LB), comprising of at least one representative from each category of stakeholder (categories of stakeholders are defined in the recommendation 2.2.2 and sub-criterion 3.3). The composition of the LB should be balanced in terms of gender, sector and geographical background, language, political diversity, perspectives, and experiences. The members of LB should be committed and skilled individuals, which should ensure constant participation in the initiative's development. The members of the LB should have equal power, in order to guarantee equity among participant stakeholders. The composition of the LB and its members should undergo the approval of the SAB and the PAB.

Specific activities, roles, and responsibilities of the LB are described and formalized within a procedure as pointed out in the recommendation 2.3.3 and in the governance bodies section. The LB appoints a chair/coordinator who will become the internal and external point of reference to the initiative. It may also create an operational team, such as a sub-board (the executive team) and a secretary (supporting operations).

Recommendation 2.3.3: Formalize how the stakeholders involved in the governance will interact with each other and cooperate within the governance structure

As an initiative, adopt a formal procedure, which will be public and will transparently define:

- Which is the governance structure of your initiative,

- How the governance bodies are composed,
- How members are appointed,
- How decision-making processes are handled,
- How stakeholders and the public might participate in the initiative and/or take part in its governance bodies or in other bodies.

An example of how the procedure could be structured is reported below:

- roles and responsibilities,
- structure and membership of the governance bodies,
- operations (i.e. regular operations and meetings),
- relations between the governance bodies,
- External relations and public involvement.

The Leadership Board (LB) has the responsibility of developing this procedure, with the support and contribution of the Compliance Committee (CC) and the Engagement Coordination Team (ECT). The resulting document should be shared and approved by the Stakeholder Advisory Board (SAB).

4.3.2.4 Sub-criterion 2.4: Guarantee equity and mechanisms to avoid self-interest

Recommendation 2.4.1: Guarantee the support to and the meaningful participation of disadvantaged stakeholders (for financial, communication, language, cultural, age or mobility reasons) through appropriate mechanisms to give voice to each of them and avoid marginalization

Recommendation 2.4.2: Ensure that monitoring measures are put in place to protect the integrity and multi-stakeholder nature of the initiative and manage potential conflicts, considering that different views have to be accommodated in the decision-making process

Recommendation 2.4.3: Implement appropriate engagement mechanisms to create and maintain commitment and ownership among the participating stakeholders

To guarantee equity and implement mechanisms preventing self-interested actions of stakeholders, a specialized body is needed. To this end, you appoint the Compliance Committee (CC); this decision needs to be later confirmed by the Leadership Board (LB) and the Stakeholder Advisory Board (SAB). It will be in charge of maintaining a balance among stakeholders' influences and expectations and overseeing the ethical issues that may arise during the implementation of the initiative. More on the composition, appointment, and functions of the CC in the Governance bodies section.

The CC represents the point of reference for the implementation of recommendations 2.4.1, 2.4.2, 2.4.3, and with regard to those included in sub-criterion 1.4 and sub-criterion 3.4.

4.3.3 Criterion 3: Clear, effective and inclusive methodology of stakeholder engagement

Appliers of the CRIF are able to guarantee a comprehensive, balanced, and efficient stakeholder engagement process, ensuring the participation of patients and caregivers, and of other relevant stakeholders, by:

- Defining and approve a stakeholder engagement methodology;
- Engaging private intended Beneficiaries;
- Differentiating the level of engagement according to participants;

- Ensuring a balance between the engagement of participants and agile management of the initiative.

Since CRIF is a collaborative tool, which requires the involvement of stakeholders in the entire governance process, this criterion works as an overarching principle for the other four governance criteria. In addition, Patient Engagement Guidelines provide a methodology to engage the stakeholder "patient" and facilitate development of a roadmap to capture patients' voices and help them to co-create with the other stakeholders' experience.

4.3.3.1 Sub-criterion 3.1: Define and approve a methodology to engage stakeholders

Recommendation 3.1.1: Define a methodology to engage stakeholders, create and maintain an open dialogue with them and manage the engagement processes of participants throughout the entire design and implementation of the health research initiative

Recommendation 3.1.2: Provide clear information regarding why the initiative is engaging (the purpose), what issues to engage on (the scope), and who needs to be involved in the engagement

This fundamental process relates to the engagement of stakeholders who cooperate towards the achievement of the objectives of the initiative. The Appliers define and implement a structured and detailed methodology to effectively engage those stakeholders who are of strategic importance, so they can cooperate towards the achievement of the objectives of the initiative.

Successful engagement depends on deep understanding why an organization is engaging (the purpose), what issues to engage on (the scope), and who needs to be involved in the engagement (the stakeholders). An engagement process should clearly describe:

- How to establish commitment;
- How to determine the purpose, scope, and stakeholders of the engagement;
- How to integrate stakeholder engagement within the governance;
- How to carry out the processes that will deliver quality and inclusive engagement practices, and valuable outcomes.

The methodology of stakeholder engagement should comprise at least some key phases, which can be summarized as follows:

a) **Plan –** identify which stakeholders should be engaged in your initiative due to their strategic importance to achieve your mission. Cluster them into different categories that reflect different levels of engagement. Determine the rights, duties, and responsibilities for each category of stakeholders.
b) **Prepare –** when you identify the stakeholders and determined the levels of engagement, assess:
    i) the different characteristics and needs that these stakeholders may have;
    ii) barriers concerning their effective engagement;
    iii) risks related to the involvement of such a diverse group of actors.
c) **Implement –** define activities that will allow the participation of stakeholders in your initiative through formalized procedures that define in detail the interaction and cooperation between the different actors.
d) **Review and improve –** put in place mechanisms that would guarantee the monitoring and evaluation of the stakeholders' engagement in order to improve it.

In the *Plan* phase:

- Profile and map your stakeholders: To design the stakeholder engagement process, you need a clear understanding of who the relevant stakeholders are, and how and why they may want to engage with your initiative. Profiling and mapping shall be reviewed and revised throughout the process and for this reason, it should be formalized. It is recommended to carry out the stakeholder profiling analysis in parallel with the context analysis as described in sub-criterion 1.1.
- Determine their levels of engagement: Map and cluster stakeholders into different categories to determine which groups and individuals are most important to be engaged from the point of view of the engagement process's purpose and scope (please refer also to sub-criterion 3.4). Define different levels of engagement, which determine the different rights, duties, and responsibilities of the interested stakeholders. Defined levels are also used to establish the composition of the SAB (please also refer to sub-criterion 2.3).

In the *Prepare* phase:

- Build capacity: Different actors have different levels of expertise, confidence, and experience. Some individuals and groups may find it difficult to take up your invitation to engage, or their circumstances may hinder them from fully contributing to the process. This may be due to language, literacy, disability, or cultural barriers, problems of geographical distance, or lack of time, or gaps in their knowledge about a specific issue. The Leadership Board (LB), with the help of the Engagement Coordination Team (ECT), should timely identify where engagement capacity needs to be built , in order to avoid exclusion of these stakeholders, or to prevent them from disengaging (please also refer to the sub-criterion 3.2).
- Identify and prepare for engagement risks: In order to formally identify, assess, and address engagement risks, Promoters you need to perform a risk assessment. The potential stakeholder risks could be, for instance: unwillingness to engage, participation fatigue, creating expectations of change that the organization is unwilling or unable to fulfil, a conflict between participating stakeholders, etc.

In the *Implement* phase:

- Invite and properly brief stakeholders: The Leadership Board (LB) ensures that stakeholders are invited to participate in the engagement activities in advance and that communications are appropriate for each stakeholder category. In order to mitigate the risks identified in the previous phase, Engagement Coordination Team (ECT) develops and provides the participants with the briefing materials and coaching needed to ensure the success of the engagement (please also refer to the sub-criterion 3.2).
- Develop an Engagement and Action Plan: The LB, with input from the stakeholders and the support of the Stakeholder Advisory Board (SAB), establishes procedural and behavioural rules for the participants, which may include for example: guaranteeing that the opportunities for providing inputs are evenly distributed among participants, allowing all participants to express their opinion, staying focused on the transformational change that your initiative aims to achieve. Roles and responsibilities for all the participants have to be clearly defined, to regulate their cooperation and allow them to hold each other accountable. Based on the defined mission, create a collective Action Plan (please refer to the sub-criterion 4.1), adopted after consultation with all the

participants of your initiative, to guarantee that it corresponds with the expectations of all relevant stakeholders.

In the *Review and Improve* phase:

- Monitor and review the engagement: The Leadership Board (LB), in cooperation with the Stakeholder Advisory Board (SAB), systematically monitors and evaluates the overall quality of the stakeholder engagement, including the evaluation of (please also refer to the recommendation 5.1.7):
  - Commitment and integration;
  - Purpose, scope, and stakeholder participation;
  - Process (planning, preparing, engaging, acting, reviewing, and improving);
  - Outputs and outcomes;
  - Reporting.
- Learn and improve: The LB, in cooperation with the SAB and with direct inputs from stakeholders, if needed, continuously assesses the value of the engagement and improves its stakeholder engagement activities for stakeholders' engagement. These processes need to be formalized to strengthen and optimize future activities.

The stakeholder engagement process is meant to be customized by each initiative which adopts the CRIF, so feel free to adapt and develop it so that it fits your initiative's specific needs. However, the above-mentioned phases represent the minimum requirements that you have to take into account to implement an effective stakeholder engagement process.

The above-described phases are supposed to be carried out by the Promoters and the LB supported by the Engagement Coordination Team (ECT). This is due to the fact that the first phase (Plan) is expected to be carried out when your initiative is being set-up, while the other activities occur when the Governance Criteria are being implemented, once the LB has been identified.

However, the appointment of the LB itself is carried out through a multi-stakeholder methodology. For this reason, you should follow the recommendations included in this sub-criterion when setting up the LB.

The ECT should support you, as the Promoter, first, and the LB, later, during the entire process that will culminate in the definition of the stakeholder engagement process. This body will also be directly in charge of the implementation of the engagement methodology throughout the development of the initiative.

4.3.3.2 Sub-criterion 3.2: Engage intended Beneficiaries

Recommendation 3.2.1: Guarantee the availability of customized training for lay participants (patients), who might not be trained to participate in complex research initiatives

Stakeholders such as patients are often involved in a research project as data providers (clinical trials, drug development) or users testing innovative technologies (biotechnological R&I), rather than engaged in the governance of R&I with decision making role. Each initiative adopting the CRIF needs to involve this category of stakeholders to understand their needs and expectations and translate them into practice throughout the entire R&I process. You provide the right tools to all the stakeholders involved, so they are able to equally participate in all the steps of the process.

To successfully engage private intended Beneficiaries, several activities need to be performed. These should be coordinated by the Engagement Coordination Team (ECT), the body that will manage the process of involving several categories of stakeholders including patients, identified in sub-criterion 2.1.1. The main activities are described below:

- Setting in place the engagement process and providing the participants with the necessary briefing materials. These materials should contain a clear explanation of the initiative's expectations concerning stakeholders' engagement and facilitate communication between experts and lay participants; the materials should be made available in a timely manner. Make sure that aspects such as linguistic proficiency, disability, and literacy issues of stakeholders are addressed;
- Organizing training sessions in which private Beneficiaries are transparently informed on the process and the role they play within it;
- Guaranteeing the involvement of private intended Beneficiaries that may have experiences in multi-stakeholder initiatives to become the point of reference between the initiative and the stakeholder group.

The ECT focuses not only on the engagement of patients but trains all categories of stakeholders to ensure their fruitful engagement.

Recommendation 3.2.2: Guarantee a fair and equitable process that takes into account the limitations that participants might encounter (e.g. cognitive impairment, behavioural issues, fatigue)

Science with patient input approach requires the active participation of patients in the governance, priority setting, and conducting of research, as well as in summarizing, distributing, sharing, and applying research results. A multi-stakeholder initiative can potentially engage a variety of stakeholders with different levels of expertise, confidence, and experiential knowledge. As explained in the recommendation 3.1.1, it is important to appreciate that some of the stakeholders may face obstacles to becoming engaged by your initiative or contributing to the process to the best of their abilities. Reasons range from lack of knowledge to life-limiting disabilities.

Another essential aspect to be considered is the fact that a research program/project within the health sector can be imagined as a path, namely a sequence of processes and activities in the R&I continuum where patients can be engaged in order to maximize the impact of R&I. R&I Path conceptualizes research as a sequence of processes and activities in the R&I continuum where patients can be engaged in order to maximize the impact of R&I. Consequently, after identifying the possible limitations that might be encountered in the engagement of patients, the Appliers define if these limitations are the same for all patients involved across the R&I Path, or if there are some steps of the R&I Path which are more complicated and for this reason should be considered with more attention.

Following that, the actions to overcome these barriers and limitations need to be envisioned and, if not possible, alternative forms of engagement need to be discussed (i.e. engaging parents for children; relatives of people with cognitive impairments).

The ECT coordinates the participation of patients in the agenda design, in the decision-making process, in the initiative development, and finally in the implementation, monitoring and evaluation phases. Its facilitator role should guarantee that all possible limitations that might affect the effectiveness of patients' engagement are taken into consideration and that mechanisms to avoid these situations are put in place. Indeed, it is extremely important that the R&I is carefully analysed so that the ECT can be

well informed and prepared on the possible limitations that this specific category of stakeholders might encounter in the several R&I steps, and carefully address them to guarantee an efficient and effective stakeholder engagement process. This activity also relates to the Prepare phase of the Stakeholder Engagement Methodology.

4.3.3.3 Sub-criterion 3.3: Differentiate the level of engagement according to involved stakeholders

Recommendation 3.3.1: Differentiate the level of engagement of involved stakeholders, considering:

- Their skills, capabilities and characteristics;
- The stages and processes of the initiative;
- The relationship with the involved stakeholders and their strategic importance to the initiative;
- The resources available and the organizational constraints

Stakeholders engaged in multi-stakeholder health research initiatives have different skills, expertise, and interests. Once you mapped which stakeholders should take part in the initiative (refer to the sub-criterion 3.1), cluster them into different categories. Engage stakeholders according to their identified Levels of Engagement. In determining the Levels of Engagement, define the nature of the relationship you will develop with their stakeholders.

Cluster the stakeholders selected by your initiative according to their strategic importance, which could be based on their skills and resources to achieve the initiative's mission and be accountable.

Stakeholders' strategic importance for your initiative would then determine the Level of Engagement to be selected to best meet the needs, capacity, and expectations of the relevant stakeholders. Revise the level of engagement periodically, as they may change it over time as relationships deepen and mature. An example of levels of engagement is the following:

- Co-design: stakeholders are engaged since the very beginning of the steps of the R&I Path with a decision-making role (i.e. they are part of the Leadership Board (LB));
- Involve: stakeholders are engaged in research project activities with an active role (i.e. they could be part of the Stakeholder Advisory Board (SAB) with specific roles and/or working groups according to their specific relevance);
- Consult: stakeholders can provide feedbacks to decision-makers on their analysis and/or decisions, and they participate by being asked for advice and opinion (i.e. they could be part of the SAB and/or specific committees);
- Inform: stakeholders are informed about research priorities, activities, outcomes and impact of the initiative.

This prioritization effort will facilitate processes such as the election of representatives of each stakeholder's category to be part of the LB, advisory bodies, or Working Groups (WGs). It will also be useful during the materiality analysis, when you engage the stakeholders based on the category and strategic importance, among others.

4.3.3.4 Sub-criterion 3.4: Ensure a balance between engagement of involved stakeholders and agile management of the initiative

Recommendation 3.4.1: Ensure that there is a right balance between an agile management process and the opportunities for engaging a wide range of participants. In particular, set in place processes to mitigate the challenges faced by collaborative groups, such as competition, conflict, cultural and behavioural differences, equity, resource sharing, communication, confidentiality concerns, and geographical dispersion

Identification of appropriate stakeholders to be involved in your initiative is essential to guarantee that there is a balance of different characteristics and backgrounds among participants, which is needed to achieve the transformational change. Moreover, it is fundamental that an initiative prepares appropriate mechanisms to deal with possible challenges that might arise due to the diverse background and characteristics of the stakeholders involved.

To mitigate the challenges that may be encountered by a collaborating group, the Leadership Board (LB), with the support of the Engagement Coordination Team (ECT) and the Compliance Committee (CC):

1. Achieves a balance of interests in the subject matter and in the geographic scope among the participants within the governance bodies;
2. Strives for consensus on decisions that might define the milestones for the initiative;
3. Defines criteria in advance to determine when alternative decision-making procedures should come into effect, in case consensus cannot be achieved. Criteria for determining when to consider voting could include those decision-makers who are not in the agreement. The initiative may want to provide alternative solutions and, if these are not accepted by the majority and a compromise is not reached, then alternative decision-making procedures could be implemented;
4. Defines a decision-making threshold (in relation to the voting process) to ensure that no stakeholder group or type can control the decision-making process.

The ECT guarantees and facilitates the participation of stakeholders with obstacles to engagement, encouraging and maintaining commitment, and ensuring a balance among different points of view. On the other hand, the LB should support the implementation of an agile management process.

These two principles might sometimes be in contrast: in this case, the cooperation between the ECT and the LB, with the support of the CC is fundamental to ensure a balance between the engagement of participants and the adaptive management of the initiative.

4.3.4 Criterion 4: Effective and efficient management and coordination of the initiative

Guarantee an effective, cooperative, and efficient coordination of the objectives and actions required to pursue the mission and the agenda. To achieve this goal, the initiative:

- Enables cooperation and competition among participants;
- Sets clear and transparent processes and timeline;
- Maintains flexibility;
- Ensures the presence of secure funding, solid organizational structure, and resource management.

4.3.4.1 Sub-criterion 4.1: Enable involved stakeholders to coordinate their efforts and perform activities

Recommendation 4.1.1: Put in place processes that allow involved stakeholders to perform mutually reinforcing activities and coordinate collective efforts to maximize results and create opportunities for change

One of the objectives of your initiative is to create accessible and innovative mechanisms to facilitate interaction and bridge the gap between stakeholders to collaborate. Consequently, the Appliers also put in place processes that allow participants to perform mutually reinforcing activities and hold each other accountable through a clear definition of roles and responsibilities.

To allow participants to carry out mutually reinforcing activities, the Leadership Board (LB) should implement the following activities:

- Definition of a collective Action Plan in line with the mission and agenda and specifies the strategies and actions that the different partners commit to implement to achieve such change;
- Implementation of these strategies by all the participants to advance the shared Action Plan;
- Establishment of the Committees and Working Groups (WGs) and other collaborative structures with the role to coordinate activities aligned with the Action Plan;
- Setting up accountability mechanisms to hold partners accountable for implementing activities as planned;
- Organization of Touchpoint Meetings to create opportunities for change, such as:
  - Holding periodic events in order to discuss potential challenges, foster innovative thinking, and identify practical solutions;
  - Hosting webinars to support stakeholders in the implementation of actions.

The LB is in charge of the implementation of the above actions. It defines the collective Action Plan and oversees that the defined actions are implemented by all the participants. The WGs are composed and balanced according to the stakeholders' categories and the needs of your initiative. They are in charge of specific tasks (e.g. research or reporting activities, as described in criterion 5). WGs report to the LB. Both cooperation and competition within these bodies should be promoted: participants with different backgrounds, experiences, and interests should be involved in the implementation of a given task/activity to provide multi-disciplinary inputs while pursuing a common goal. This could provide an added value to the initiative itself since multi-stakeholder interactions are considered at all steps of the Research & Innovation Path.

4.3.4.2 Sub-criterion 4.2: Set clear and transparent processes and timeline

Recommendation 4.2.1: Identify and negotiate with stakeholders a consistent program/project timeline and schedule, in order to assure that the progress is soundly implemented

Recommendation 4.2.2: Commit to transparent, evidence-based decision making, in order to reach the objectives established in the mission and agenda

Recommendation 4.2.3: Guarantee a mechanism of review and evaluation, which allows to learn and improve the collaboration among stakeholders

The Appliers define a timeline to assure that progress is soundly implemented and that the organizational process is transparent. Moreover, they should define clear roles and responsibilities

among participants to guarantee that each actor clearly knows their role, exercises their rights, and fulfils their duties. To implement an effective process, the collective Action Plan should also contain:

- Clear and measurable targets to be achieved by the initiative;
- A clear program/project timeline with achievable deadlines to allow participants to hold each other accountable and evaluate the progress achieved by the initiative over time;
- A clear review process which will have to be carried out on a periodical basis to keep track of the achieved targets.

The definition of these rules and deadlines should be discussed and defined by the Leadership Board (LB), because their implementation will be pivotal to guide the initiative in the achievement of its defined mission and agenda.

The implementation of the above activities is strictly related to the previous sub-criterion because WGs are the bodies responsible for carrying out the activities through which the targets can be measured and achieved. To facilitate this process, the LB can appoint a Secretariat or Management Team (please consult Governance bodies section) which will help to enforce deadlines, supervise activities, and improve your initiative's performance as defined by mission and agenda.

4.3.4.3 Sub-criterion 4.3: Maintain flexibility

Recommendation 4.3.1: Maintain flexibility, adjusting the goals and implementation actions to the changing reality and needs

It is the task of the Appliers to stay up to date on the current needs of the Beneficiaries. In the implementation phase of the research initiative, they should consider adjusting the goals of the initiative and which stakeholders it engages due to changing needs and reality. When adopting this recommendation, the initiative needs to adapt it to its specific needs and context. Several practices could be evaluated by the Leadership Board (LB) of your initiative to respond to current needs, such as:

1) Prepare a Progress Report (for example on a yearly basis) as it is a useful tool to collect all the achievements but also the concerns raised throughout the process by stakeholders and possible recommendations for the future (sub-criterion 5.1.6);
2) Organize a consultation event on a periodical basis where stakeholders can express their views and confirm their alignment with the defined agenda (sub-criterion 5.2.1);
3) Consider the review by external actors to identify possible gaps and areas for improvements;
4) Periodically review the mission and agenda according to the above-mentioned activities (sub-criterion 1.2).

These activities could be carried out by specific WGs or other bodies working under the supervision of the governance bodies. We recommend that they adopt **flexible risk management**. The structure of the initiative and the organization of the activities should be flexible enough to:

- Allow for managing major changes that may arise within and outside the project;
- Guarantee that the initiative is able to pursue the same transformative objective through a different strategy.

It is better to structure the initiative focusing on the objectives, rather than the activities, that may be reviewed following a potential external or internal change and according to the changing scenarios.

4.3.4.4 Sub-criterion 4.4: Ensure the presence of secure funding, solid organizational structure and resources management

Recommendation 4.4.1: Provide and maintain adequate resources (including financing, staff and technical expertise, and in-kind contribution)

Recommendation 4.4.2: Ensure that the internal team has solid skills to carry out the activities and cooperate with involved stakeholders

Recommendation 4.4.3: Adopt a cost management process and an efficient management to avoid inefficiencies

Recommendation 4.4.4: Maintain accountability over time keeping track of expenses and revenues

For an organization to accomplish its mission and carry out its operations, it is necessary to ensure that it is financially secure. To do so, the organization has to secure funding, create a solid organizational structure with technical expertise, and solid resources management. To implement an effective cost management process, the Leadership Board (LB) may:

- Determine a budget: establish the amount of funding that your initiative has at its disposal;
- Conduct a cost analysis of the project: based on the timeline included in the collective Action Plan, understand the real costs that will be sustained by your initiative throughout the timeline of the project (including research funding, staff, and technical expertise, organization of meetings, other general expenditure);
- Identify possible gaps and critical issues in financial and resource management: identify potential critical issues and develop possible adjustments that would guarantee efficient management of the budget. Identify possible gaps and critical issues based on cost analysis. The analysis should also propose some possible refinements that would guarantee efficient management of the budgeting to avoid inefficiencies.

The LB may choose to appoint a Secretariat/Management Team (sub-criterion 2.2) which will ensure financial security. Depending on the size of your initiative, it could also be supported by other bodies such as the CC and/or others. This process is conducted to ensure that your initiative is financially secure, running public accounting for expenditures and income, and ensuring that it operates in a legally compliant manner in relevant jurisdictions.

4.3.5 Criterion 5: Co-accountability assessment

Appliers establish a shared and effective measurement system, including a set of indicators that promotes the improvement of operations and communication, and set a mechanism to receive feedback. This Criterion is connected to the Materiality Analysis and Master Scorecard (detailed in the respective chapters). To achieve this, the initiative will:

- Develop a shared measurement and monitoring system;
- Establish effective feedback mechanisms;
- Guarantee continuous learning, communication, and disclosure of knowledge.

In this regard, a key step is materiality analysis (sub-criterion 1.2) that enable the initiative to align its activities in coherence with its mission and stakeholders' perspective.

4.3.5.1 Sub-criterion 5.1: Define a shared assessment system

Recommendation 5.1.1: Enable the co-selection of relevant aspects, according to the different impact dimensions, in order to identify the topics that matter the most to the initiative and its stakeholders

Recommendation 5.1.2: Select appropriate indicators from the list of relevant aspects according to different impact dimensions and stakeholder perspectives in order to comprehensively assess the impact of health research

Recommendation 5.1.3: Ensure that the list of selected indicators consider the impact on patients

In order to define an assessment system that would be coherent with stakeholders' perspective and would include the aspects that matter most to them, Appliers consider the aspects chosen via the materiality analysis (recommendation 1.2.1).

In the customised Master Scorecard, the Appliers are able to identify a list of indicators that allow reporting the initiative's results in relation to different dimensions (efficacy, excellence, economic, social, and patient-reported dimensions). It is important to ensure that the list includes relevant indicators under the dimension Patients Reported Dimensions, indicators that are related to impact on patients directly reported by them without the intervention of the clinicians, such as the Patient Reported Outcome (PRO).

The LB is responsible for the definition of a shared assessment system, however it could nominate a committee to carry out the related activities.

Recommendation 5.1.4: Establish a shared assessment system consisting of a set of indicators consistently tracked over time and a shared data collection process

Recommendation 5.1.5: Ensure that the shared assessment system (Master Scorecard) is coherent to the mission and the agenda of the initiative over time, guaranteeing its alignment to stakeholder perspective

To establish a shared assessment system, the initiative defines a data collection process based on the indicators selected during the Materiality Analysis, which includes all the relevant stakeholders. The indicators need to be consistently tracked over time.

The Leadership Board (LB) ensures that there is constant alignment between the shared assessment system and the mission and agenda of the initiative. Periodically, when the agenda is updated, the shared assessment system needs to be updated as well.

Recommendation 5.1.6: Transparently report and communicate the initiative's results and progresses to the public

Your initiative communicates its results and progress to the public in a transparent manner, through two complementary solutions:

- **A Progress Report published on a regular basis.** The Progress Report is a document made available to the public that discloses information regarding the achievement (or non-achievement) of your initiative's objectives and key performance indicators. In particular, the Progress Report discloses

information regarding the indicators identified by the initiative in the sub-criterion 5.1.2, according to the aspects of measurement identified in the sub-criterion 1.2.2. The Progress Report contains general information regarding the management and implementation of the CRIF aspects and other relevant information regarding the achievement of the initiative's mission and agenda. The Progress Report should be published on a regular basis, every one or two years, according to the specific circumstances of your initiative, and should be published online and made available to relevant stakeholders.

- **An open platform, which includes a visualization of the performance of the initiative according to the identified indicators.** An open platform is an online tool offering a visualization of the performance of the initiative according to the indicators identified by your initiative (in the sub-criterion 5.1.2, according to the aspects of measurement identified in the sub-criterion 1.2.2). The open platform offers access to key performance indicators regarding the initiative's implementation. The platform contains general information regarding the management and implementation of the key aspects measured and other relevant information regarding the achievement of the initiative's mission and agenda.

The Leadership Board (LB) is in charge of gathering information that will constitute the basis for the Progress Report, to create the open platform and to make these tools available to stakeholders and to the public. The LB may appoint a Working Group or a Committee for this purpose or use the help of the Secretariat or Management Team.

Recommendation 5.1.7: Constantly review the initiative according to the results of the assessment

Leveraging the performance assessment requires your initiative to establish a review process that will use its results. The assessment helps in improving performance and practices. To achieve this, the initiative will conduct a periodic review that includes at least the following activities:

- Perform an analysis of the indicators on the initiative's performance and results, emerging from the shared assessment process;
- Set up an improvement plan identifying counteractions and improvement actions for the initiative;
- If necessary, refine the agenda according to the results of the review.

A third-party actor could be involved in the process to ensure transparency and external oversight. The process should be open to the public to allow external stakeholders to provide suggestions and feedback. It should be implemented on a periodic basis (i.e. every 2 years), according to the needs and the characteristics of your initiative.

The review process should be led by the Leadership Board (LB) and the Stakeholder Advisory Board (SAB), which might appoint a specific committee to carry out the operational activities linked to this process, or depending on the size of the initiative, the Secretariat or Management Team could be as well in charge of developing such activities.

4.3.5.2 Sub-criterion 5.2: Set effective feedback mechanism

Recommendation 5.2.1: Implement structures and processes allowing to inform, engage, and seek feedback from internal and external stakeholders, including concerns about the initiative and its development

The CRIF attaches great importance to the initiative's ability and willingness to receive constant feedback from internal and external stakeholders. Both are crucial to improving the efficacy and efficiency of the initiative, not to mention its responsiveness to the ever-evolving needs of stakeholders. For this reason, it is necessary that your initiative establishes a process that allows stakeholders to raise concerns and express their opinions. It is Leadership Board's (LB) task to:

- Identify the most suitable and appropriate channels through which stakeholders can communicate and raise their concerns (e.g. email, website, letter);
- Set up the activities necessary to gather stakeholders' feedback;
- Elaborate stakeholders' feedback;
- Ensure that the feedback is appropriately managed and considered within the review process, under recommendation 5.1.7.

The initiative encourages stakeholders to provide feedback on the implementation of the initiative and keep them informed about the process in place to consider their concerns and integrate their feedback. Channels for feedback may be individual-based (e.g. anonymous hotline, web-format to be filled in) or participative (e.g. working groups, stakeholder consultation processes).

The initiative reports formally on how your initiative analyses, manages, and integrates stakeholders' feedback. The implementation of this sub-criterion should foster the review process carried out under recommendation 5.1.7.

The LB, supported by the Secretariat or Management Team, is in charge of setting up a process to collect concerns and opinions from stakeholders. The Engagement Coordination Team (ECT) participates in this process and is in charge of maintaining the active participation of internal stakeholders.

4.3.5.3 Sub-criterion 5.3: Ensure continuous learning, communication and disclosure of knowledge

Recommendation 5.3.1: Establish processes for continuous learning to improve the research evaluation framework and engage the public and the community, building trust among all involved stakeholders through constant communication. Ensure the existence of mechanisms for transparency and prioritize clear, accessible internal and external communication

The Appliers need to build a trustful and continuous relationship with the public and the communities with which your initiative interacts. This can be achieved through a constant, clear, and useful flow of information. To implement this recommendation, the Leadership Board (LB) ensures that:

- Communication on the most salient activities of the project is made public;
- Communication is clear, accessible, and useful. It is made available to stakeholders according to their specific needs.

The initiative can use "unilateral" tools, such as newsletter, website, blogs, reports, but also "interactive" tools, such as training courses, thematic events, peer learning processes, practical guides for users, in-person meetings, events, and others.

The LB is to ensure a constant communication process with other health initiatives that may benefit from (or contribute to) your initiative itself. The LB is in charge of identifying opportunities for information exchange and cooperation and developing the most appropriate means to ensure these relationships in collaboration with the Stakeholder Advisory Board (SAB).

The LB might appoint a specific committee to carry out these activities.

4.4 Baseline Analysis

The Baseline Analysis is a questionnaire that measures the level of compliance of your initiative's governance and patient engagement with the CRIF. It is recommended that you conduct the Baseline Analysis as soon as you decide to implement the CRIF within your initiative. Performing such self-assessment and learning the results of the Analysis has benefits regardless how advanced the initiative is.

You can conduct the Baseline Analysis via the Toolbox. It contains two sets of questions which evaluate your initiative's compliance with:

- The five Governance Criteria.
- Existing practices and techniques used in patient engagement (science with patient input, covered in Patient Engagement Guidelines)

The Baseline Analysis tool will automatically provide customized governance recommendations based on the Governance Model Guidelines and Patient Engagement Guidelines, indicating gaps to be addressed. After learning the results, you will know which aspects of your initiative's governance and patient engagement systems need further development and/or correction. Before starting, take a look at the respective chapter in this Manual with practical tips on how to prepare for maximum efficiency.

5 PATIENT ENGAGEMENT STRATEGY AND GUIDELINES

According to the concept of Responsible Research Innovation (RRI) (European Commission, no date), for research to achieve excellence, validity and relevance, it needs to engage patients and broader society as key stakeholders with decision-making roles. Over the last decade, as health sciences democratize, patient engagement has become more important. Patients started to be engaged not only in a passive role, but also as co-researchers.

Our research concluded that many of the current guidelines for Patient Engagement focus on involving expert patients in the Medicines Lifecycle (i.e. the drug production sequence, from scientific discovery to evaluation).

5.1 Experiential Knowledge

MULTI-ACT proposes a complementary strategy that expands the scope of engagement: **a roadmap to capture experiential knowledge of patients** (Multi-Act Project, 2020). Experiential knowledge is knowledge gained through experience, as opposed to a priori (before experience) knowledge. It arises when patients' experiences are converted – consciously or unconsciously – into personal insights that help the patient to cope with the illness. When patients share their experiential knowledge, the collective experiential knowledge exceeds the sum of individual experiences. The notion that patients' life experience complements researchers' expertise gains wider recognition nowadays. Patients' experiential knowledge provides different, yet equally relevant, insights into the R&I. They have a potential of increasing R&I's impact and producing outcomes that matter most to patients. The experiential knowledge can be harnessed at all stages of the R&I process – from planning to reporting the results.

While collecting patient data has always been important in health research, engaging patients at all relevant stages of your project can enrich the research, enhance its relevance, and ensure that it achieves its goals and brings about outcomes that matter most to people affected by brain diseases.

Patient Engagement Guidelines address the Criterion 2 Participatory Governance and Criterion 3: Clear, effective and inclusive methodology of stakeholder engagement by providing a strategy to empower the stakeholders-patients to be engaged in research & innovation at the same level of the other stakeholders and to empower all the stakeholders to collaborate and co-create with the patients. Compliance with the Governance Criteria is essential for effective patient engagement, and for ensuring return on the engagement for all stakeholders.

5.2 Key assets

The innovativeness of the Patient Engagement strategy relies on three key assets. The first ones are the Governance Criteria and the Engagement Coordination Team. The second – providing training in empowering patients and stakeholders to cooperate and to bring their experiential knowledge into the R&I. It complements currently existing training to make patients "experts". The final asset is emphasis on the importance of understanding and measuring the impact of R&I. It makes it possible to produce outcomes that matter to patients.

5.3 Science of/with patient input

Science of patient input is about using data provided by people with a disease through passive or active contribution to evaluate impact of R&I. You may think of it as more "traditional" way of doing research, where patients "are studied". For example, in the context of the CRIF, data about patients' experiences (Schneeman, Barton and Huneycutt, 2019) outside the clinic are critical to evaluate impact of mission-oriented health research on outcomes that matter most to patients. **Science with patient input** occurs when patients actively collaborate in the governance, setting priorities, research performance assessment etc. of R&I. It aims to maximize impact of R&I. The concept is relevant to the recommendation 3.2.2.

The figure below illustrates how patient engagement relates to transformational mission and governance bodies. It is important to always ground the engagement process in the mission of your initiative. Governance bodies are responsible for conducting engagement at all stages of the Research & Innovation Path. The Patient Engagement Guidelines are ultimately about raising the return on engagement for your initiative.

5.4 Return on Engagement (RoE)

You can think about return of engagement as akin to return on investment, but your investment is not purely monetary: it is investment in engaging patients in R&I and building relationship with them. The return is considered in broader sense – it is about various impacts and benefits resulting from performing patient engagement in your R&I initiative. RoE is discussed at length in Measuring the performance and effectiveness of patient engagement section of these guidelines, where metrics developed to evaluate whether engagement adds value for different stakeholder groups are described.

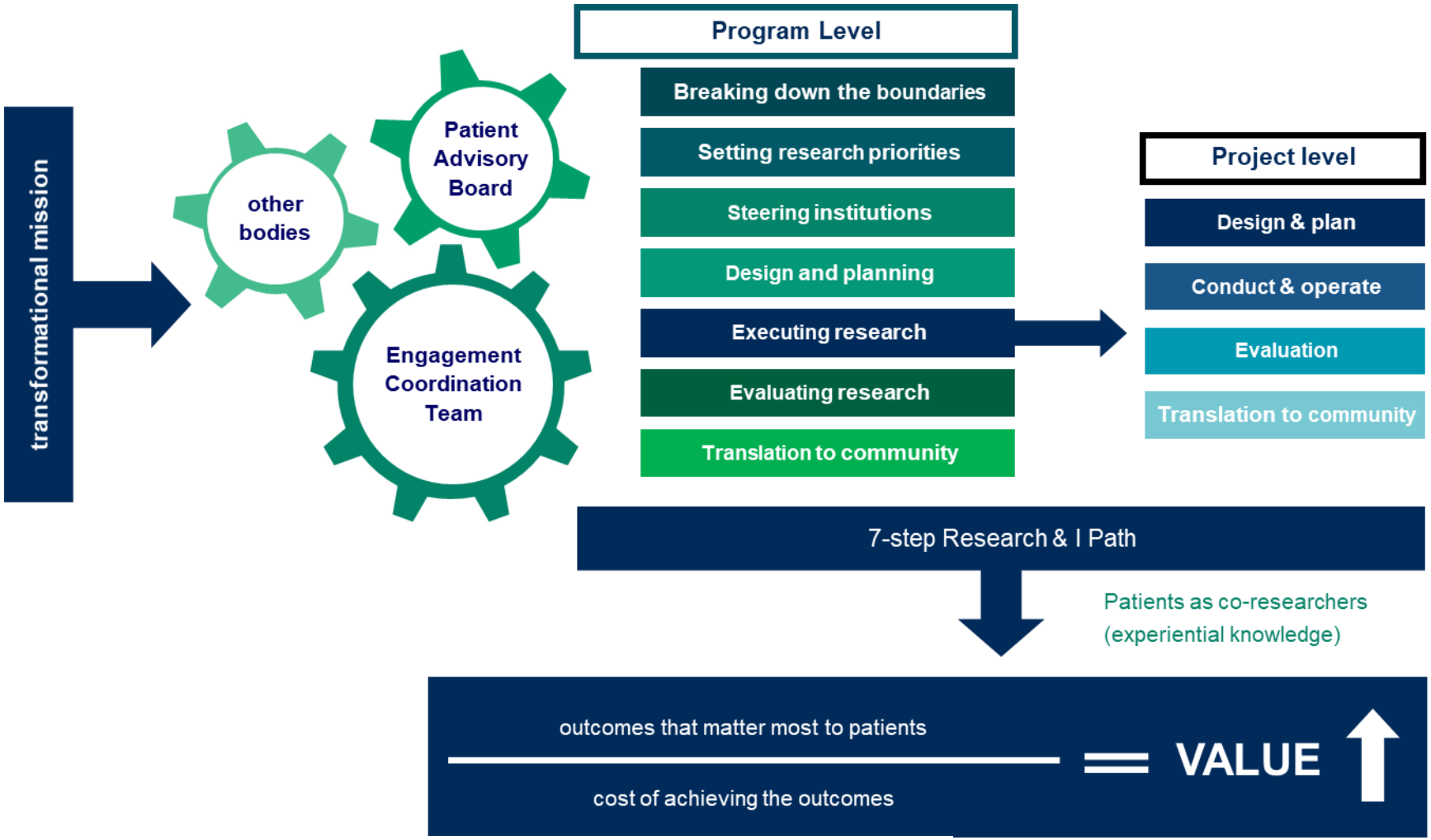


Figure 11 Patient Engagement: from transformational mission to the raised value

5.5 Patient Engagement Roadmap

The Patient Engagement Guidelines provide a Patient Engagement Roadmap for your initiative to capture, understand and draw on patients' experiential knowledge. You implement the Patient Engagement Guidelines by following this roadmap. We strongly advise you to use the digital Patient Engagement Tool available online in the MULTI-ACT Toolbox (described in the corresponding chapter). The tool will guide you through the following steps:

1) As the Promoter, you are responsible for establishing an Engagement Coordination Team (ECT), the body in charge of management of stakeholder engagement and organize the training modules for the ECT.
2) The ECT defines the phases of R&I Path in which Patient Engagement is instrumental in achieving the mission and agenda of the initiative (see: Research & Innovation Path).
3) The ECT develops Patient Engagement Plans for the steps of the R&I Path identified in the previous action.
4) The ECT identifies indicators to monitor and assess the value and effectiveness of the initiative (Return on Patient Engagement), to verify if it has reached the expected impact on the initiatives.

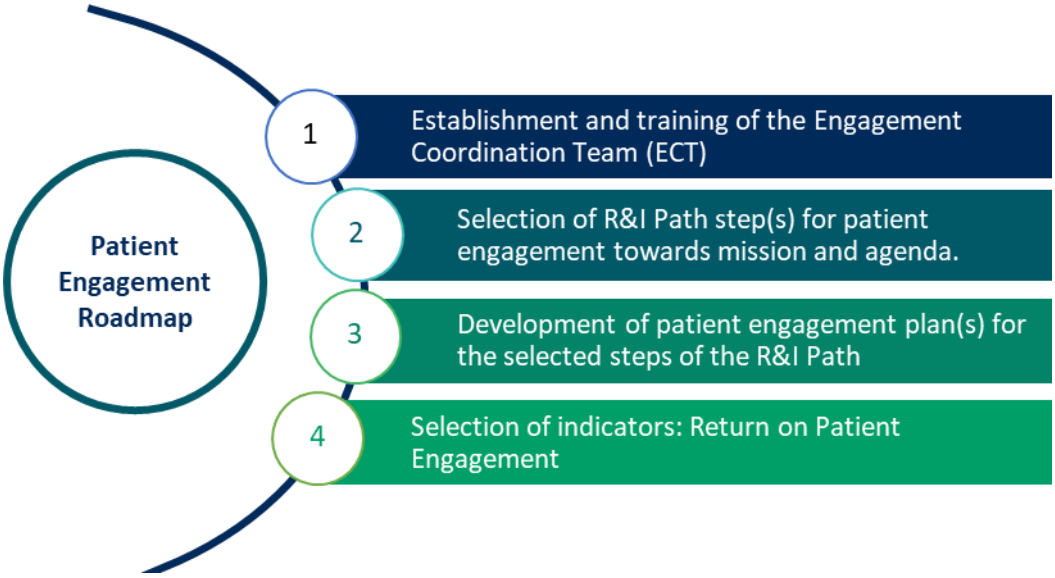


Figure 12 Patient Engagement Roadmap

5.5.1 Roadmap Action 1: Establishment of an Engagement Coordination Team (ECT)

The establishment and training of an Engagement Coordination Team (ECT) is mandatory. This crucial body embeds patient engagement in your initiative's governance structure.

Establishing the Engagement Coordination Team is a pre-requisite for effective use of the Patient Engagement Guidelines. As a Promoter:

- Ensure that the governance structure, boards and processes of the initiative enable effective patient engagement. Ask yourself: *Does the governance structure and process in charge of the Patient Engagement meet the Governance Criteria?*
- Define the requirements for appointment of the ECT. It needs to be an open and inclusive process, emphasizing expertise needed from the members to do their jobs. Ask yourself: *What is the role and expertise required for the ECT? What training does the ECT needs?*

5.5.1.1 Role of Engagement Coordination Team

The ECT assures that patients feel valued by **facilitating their interactions** with research teams and creating an inclusive research environment. The team harnesses patients' experiential knowledge and ensures representativeness of the patients' community. It gathers **patients' feedback**. To this end, it needs to be able to translate technical terminology into lay language that patients understand.

The ECT is also responsible for **creating commitment** among the members and their community. It is therefore its role to facilitate and moderate **dialogue** between interdisciplinary and different (and sometimes competing) voices and experiences. The ECT sets up your initiative' **dispute resolution** system.

Consequently, it also mitigates challenges such as **ethical conflicts** in protocol design, tokenism, power struggles, difficulties in recruiting different patients, need for additional time, cost.

5.5.1.2 Skills of Engagement Coordination Team

The following skills as essential to engaging patients effectively:

- Empathy and active listening compassion,
- Communication skills,
- Expertise in engagement strategies & methods (online and offline).

Other preferred abilities and characteristics are:

- scientific knowledge of the disease in question,
- personal experience of the disease as a patient,
- family member or caregiver,
- team work abilities,
- motivational and coaching abilities,
- socio-psychological knowledge/background,
- ethical management knowledge/background,
- understanding of group dynamics,
- project management knowledge/background.

5.5.1.3 Composition of the Engagement Coordination Team

Below is an example composition of the ECT. It can be modified to fit your initiative's situation. The important thing is to ensure that all key stakeholders and represented and that

- Co-Chair, patient (1 person),
- Co-Chair, MULTI-ACT trained representative (1 person): this individual has to complete the training (see Training of Engagement Coordination Team members),
- Initiative's board representative (1 person),
- Initiative's staff representative (1 person),

- Patients (with consideration to the balance of gender, geography, disease progression, age, socioeconomic background) (3-6 persons),
- Expert(s) on the mission and priorities of the initiative, e.g. Working Group representative, industry forum representative.

5.5.1.4 Training of Engagement Coordination Team members

The ECT is expected to be a unique board of experts with innovative functions, knowledge and expertise. If they are a new team, they will require innovative training. In order to allow the ECT to integrate patient experiential knowledge in research of your initiative, you should design and provide to the ECT a training module. Make sure that it includes:

- Adequate information about the project's mission and strategy;
- Explanation of what is expected from patients and other stakeholders;
- Explanation of what are the expected outcomes of the multi-stakeholder initiative;
- Explanation of how these outcomes relate to the patients' needs in the given disease area;
- Basic knowledge about innovative communication, learning and co-working techniques, and evidencing the value of patient and stakeholder engagement.

Information on methods for patients' engagement should be integrated with examples of application in real cases for each method. The training should focus on the ability to elicit and capture patients' stories and translate them into experiential knowledge. Use **plain language** and keep the content simple. Respect for human rights and dignity of the patient should always be considered.

5.5.2 Roadmap Action 2: Selection of research priorities and steps where patient engagement is instrumental to meet the Mission

Although patient involvement is crucial at every stage of the research, it is advisable to verify in which steps of the Research &Innovation Path (R&I Path) it is best to engage patients to maximize the impact of your research.

As described in the Plan phase in the sub-criterion 3.1 and in the recommendation 3.2.2, it is equally important for your initiative to identify obstacles that the patients may face in becoming fully engaged and contributing. The Criterion 3: Clear, effective and inclusive methodology of stakeholder engagement of the Governance Criteria looks at involving stakeholders (including patients) from a broader, governance a perspective. We advise that you look into the engagement-related governance recommendations alongside the Patient Engagement Guidelines.

5.5.2.1 Research & Innovation Path

Research & Innovation Path (R&I Path) is a sequence of processes and activities in the R&I, in which patients can be engaged in order to maximize the impact of the research initiatives. The steps of the R&I Path represent stages in research and management of funding and performing research within initiatives or in projects conducted by Research Funding and Performing Organisations (RFPOs). The steps of the R&I Path differ slightly for the Governance Program Level, which concerns often complex research programs comprising of multiple projects, and for Project Development Level, which concerns single research projects. Although patient involvement is considered crucial at every stage of the

research, it is advisable to verify in which steps of the R&I Path it is best to engage patients to maximize the impact of your research.

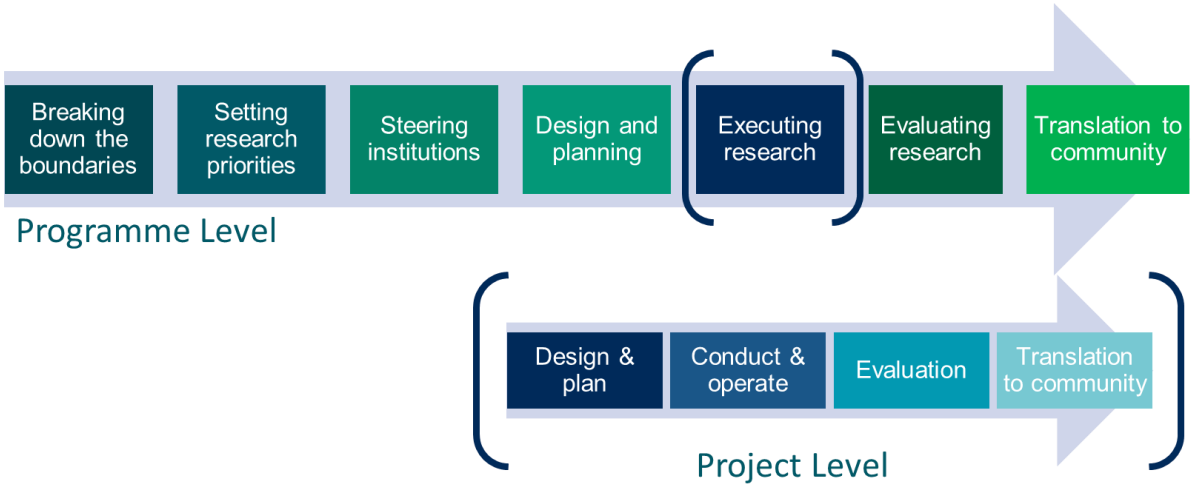


Figure 13 Research and Innovation Path

Detailed descriptions of the steps for each level are presented in the tables below.

Governance Program	
Breaking down the boundaries	Conditions that should be set in RFPOs in order to facilitate patient engagement as standard practice, e.g. patients help to review patient engagement policies and guidelines.
Setting research priorities	Actions to raise interest in a specific research domain, its importance, priority or rank. E.g., patients advance their interests in a specific research area.
Steering institutions	Actions performed to establish governance bodies. E.g. patients are invited to be member of committees and boards.
Design and planning	Design and planning of all the activities that lead to implementation of a concept or idea, and which help to achieve initiative's designated objective. Patients are engaged in the development and monitoring of research programs
Executing research	Activities to perform the research program or a specific research project for the purpose of achieving the initiative's designated objectives. **Project Development** (see below) level takes places at this stage.
Evaluating research	Activities to determine the value created by a research program or project, establishing their outputs and outcomes, the degree to which their pre-established goals were achieved, and their impact. Patients are engaged to working with other stakeholders on research reports.

Translation to community	Activities to foster and facilitate the uptake of results of research programs or projects within wider society. Patients are engaged in the development of guidelines and advocacy activities.

Table 11 R&I Path's steps (Governance Program)

Project Development	
Design & plan	Design and planning of all the activities that lead to implementation of a concept or idea, and which help to achieve initiative's designated objective. Patients are engaged in the development and monitoring of research programs.
Conduct & operate	Conducting & monitoring project (e.g. ICT device development).
Evaluation	Activities to determine the value created by a research program or project, establishing their outputs and outcomes, the degree to which their pre-established goals were achieved, and their impact. Patients are engaged to working with other stakeholders on research reports.
Translation to community	Activities to foster and facilitate the uptake of results of research programs or projects within wider society. Patients are engaged in the development of guidelines and advocacy activities.

Table 12 R&I Path's steps (Project Development)

5.5.2.2 Levels of Engagement

Stakeholders can contribute to the health research and innovation simply by getting informed or by participating in your initiative with various levels of decision-making power. Levels of Engagement presented below are a useful way of describing the varying depth of patient engagement with research and innovation (R&I) process. The same stakeholder may be engaged at different levels depending on the phase of the initiative, their role, or other factors. Levels of Engagement are relevant to sub-criterion 3.3 of the Governance Criteria.

CO-DESIGN	Stakeholders are engaged since the very beginning of the R&I initiative with a decision-making role. Examples: Patients are asked to co-define the share agenda and co-design research governance. Stakeholders are members of the Leadership Board.
INVOLVE	Patients are engaged in the research initiative and given an active role: they provide their perspective and/or data on a specific topic. However, the initiative is designed and initiated by professionals and researchers. Examples: Gathering patients' views on the topics that are important for them.

	Co-creation of the patient-reported outcome measurements for clinical trials development. Stakeholders act as members of the Leadership Board or Working Groups.
CONSULT	Stakeholders are asked to provide feedback for decision-makers about their analysis or decisions. Stakeholders participate by being asked for advice and opinion, by expressing their views and having discussions. It does not usually include any share in decision-making. Examples: Consulting activities, survey, interviews, establishing and maintaining relationship with stakeholders. Stakeholders act as members of the Stakeholder Advisory Board.
INFORM	Stakeholders are informed about research priorities, activities, outcomes and impact. Patients receive information from researchers in a passive way.

Table 13 Levels of Engagement

5.5.3 Roadmap Action 3: Design and implement a Patient Engagement Plan for each identified research priority and step

Once defined and agreed, the R&I Path steps where patient engagement is instrumental to achieving the mission, the Engagement Coordination Team designs and implements a Patient Engagement Plan for each identified research priority and define Patient Engagement Actions for each step. The Plan should include:

- Selected actions of patient engagement that needs to be implemented in order to achieve the vision of the project;
- Roles and responsibilities of the team that should manage and carry out the implementation of such Patient Engagement actions;
- Methods to value and acknowledge the experiential knowledge of patients, including the establishment of appropriate recognition of patient contribution, and avoid tokenism;
- Measurable targets (measuring the performance and Return on Engagement);
- Timeline of activities and sustainable budget;
- Review process (e.g. report on the performance and Return on Patient Engagement).

Below you will find the **Menu of Patient Engagement Activities**: these are suggestions of patient engagement activities suitable for each of the R&I Path steps. You are encouraged to create your own activities.

7-steps R&I Path	**Menu of Patient Engagement Activities**
BREAKING DOWN BOUNDARIES	Patients help to define what are the boundary condition for patient engagement in your multi-stakeholder initiative. Patients help to provide an overview on the facilities and infrastructure they need to be engaged in the R&I.

	Patients help to review patient engagement policies and guidelines.
RESEARCH PRIORITIES	Patients are engaged to co-design research agenda. Patients are engaged in advancing their interests in a specific research area. Patients are engaged to prioritize research objectives.
STEERING INSTITUTIONS	Patients are invited to be members of committees and boards; they provide guidance on key issues such as company's policy and objectives, budgetary control, marketing strategy, resource allocation, and decisions involving large expenditures. Patients are invited to advise the steering and advisory committees. Patients are engaged in defining ethical issues, anticipating risks and barriers for patient engagement in governance bodies.
DESIGN & PLAN	Patients are engaged to suggest endpoints and outcomes of research. Patients are engaged to propose specific objectives of research. Patients are engaged to define the relevance and acceptability of proposed research to patient community.
RESEARCH EXECUTION	Patients are engaged in the development and monitoring of research projects (e.g. collaborating for ICT device development, for the enrolment to increase participation and decrease drop-out rate, to increase compliance with protocols and facilitate data collection, for writing and review of publications. Patients are engaged in development and monitoring of research programs (e.g. release of calls for proposals, selection of projects to be funded, monitoring of funded projects).
EVALUATION	Patients are engaged in discussions in multi-stakeholder teams about new methods to measure the impact of research. Patients are engaged in assessment of new approach and products arising from research. Patients are engaged to working with other stakeholders on research reports.
TRANSLATION TO COMMUNITY	Patients are engaged in shaping the 'translation strategy' of research results into easy-to-use and easy-to-understand (lay) material and in communication activities to disseminate the research results. Patients are engaged in the development of guidelines and advocacy activities Patients are engaged in advocacy to leverage uptake of the research results.

Table 14 the Menu of Patient Engagement Activities along the Research and Innovation Path

5.5.3.1 Patient Engagement Plan

The Patient Engagement Plan is a framework that allows your initiative to plan patient engagement in a systematic manner consistent with progress towards fulfilling the mission. The MULTI-ACT Guidelines offers a practical template to support design of the Patient Engagement Plan: you can find it in the

Appendix 3: Patient Engagement Plan Template and/or a digitally function to develop Patient Engagement Plan in the Toolbox. Its purpose is to provide you with a tool to facilitate the design of operative patient engagement plans that are compliant with the MULTI-ACT guidelines. The Plan is structured to integrate patients' experiential knowledge into your R&I initiative, bringing expertise and knowledge complementary to the ones of other stakeholders. Patients, as members of the ECT and key stakeholders, develop the Patient Engagement Plan with the other stakeholders, ensuring representativeness of their community.

The assessment of the implementation of the Patient Engagement Plan is aligned with the Plan phase in the sub-criterion 3.1.

The indication included in the template found in the Appendix 3: Patient Engagement Plan Template is not necessarily the norm or a common practice, but rather a first attempt to provide practical guidance to RFPOs on how to plan, launch and monitor their Patient Engagement actions. Each mission is unique and requires *ad-hoc* interventions.

We recommend using the Patient Engagement Plan tool in the digital Toolbox that facilitates you with drop-down options and suggestions for compiling each field.

5.5.3.2 Methods to engage patients

The following paragraphs contain recommendations on methods of patient engagement. They align with the *Prepare* phase of the sub-criterion 3.1.

5.5.3.3 Creating right conditions

It is important that the ECT establishes a **supportive research environment** which leverages patient engagement (communication channels, resources, infrastructures, organizational/institutional). The ECT needs to assure that **patients understand and agree** on the research agendas, and to assure that they feel comfortable and recognize that their perspective is unique. The ECT also has to strengthen the **team spirit** by creating a supportive environment that promotes **partnership** and **open dialogue**.

You can find more tips and principles to follow when engaging this special stakeholder category in the recommendations 3.1.1 and 3.2.2 and in the Patient Engagement Guidelines.

5.5.3.4 Using the right methods

In practical terms, the best way to engage patients is to use mixed methods: offline (face-to-face) methods (engagement without using computers, smartphones, tablets, or other internet-connected device/digital systems) and online methods (engagement through computers, smart phones, tablets, or other internet-connected device/digital systems).

Online methods make it possible to gather patients' perspectives on a global scale while **offline methods** are useful to facilitate patients in providing their experiential knowledge as they may feel more comfortable to express their feelings face-to-face and they may be supported by a professional skilled managerial team (i.e. the ECT). Moreover, offline methods allow stakeholders to discuss more in-depth and to establish and to maintain a good partnership with patients. In particular, the ECT works mainly offline and they may use online methods to reach their community and a large consensus.

IT tools are useful for joining and recording conversations, proactively resolving complaints, promoting transparency, and enhancing patient experiences. It also requires organizations to comply with

meaningful use criteria, such as engaging patients and families in their care, improving quality and care coordination, and reducing disparities (Thielst, 2011). Use of social media may affect patient engagement and satisfaction in healthcare and research. Integration of social media into clinical practice and research can empower surgeons to synthesize effectively a patient support community that increases patient engagement and satisfaction (Dhar *et al.*, 2018). The same may apply as well to the R&I domain and environment.

Social media may play a role in identifying patient insights and engaging them in R&I for the purpose of capturing their experiential knowledge. Evidence related to the efficacy and effectiveness of social media in this function is currently limited. Various challenges related to privacy and security concerns, usability, the manipulation of identity, and misinformation have also been identified (Househ, Borycki and Kushniruk, 2014). You have to exercise caution in their use and investigate, whether the way to envision employing them for patient engagement has a scientific basis. Use of social media and social networks for science and research as a method to capture patients' voice is worth investigating for a start (Musso *et al.*, 2018; Fontaine *et al.*, 2019), even though it has not been scientifically validated.

5.5.3.5 Review and ranking of the most appropriate methods for the engagement of patients and other stakeholders

Below you will find descriptions of the methods selected by MULTI-ACT as appropriate for the engagement of the public in decision-making processes in the R&I, and in particular of patients. These methods are the following: Focus Group, Democs Card Games, World Café, Consensus Conference, Community Advisory Board, Delphi Method, Citizens Hearing, Serious Gaming. Many of the methods have a versatility to be used both online and offline.

The list is by no means exhaustive; your choice of the method depends on:

- the goal of the specific engagement event – what you want to get out of it,
- the stakeholders being engaged: how much time and effort they can contribute, what obstacles they may face,
- what resources you have assigned for the occasion (monetary, human, time etc.),
- how familiar you are with the technologies to be used.

Focus Group and Democs Card Games are useful for capturing experiential knowledge and give voice to Patients. In line with the CRIF, these two methods are considered "good methods" that the ECT could apply to engage patients and stakeholders in R&I.

Focus Group	Focus Group is a qualitative method which is used to determine the preferences of people or to evaluate strategies and concepts. The method has originally been designed for market research. Focus group is undoubtedly the most widespread technique of engagement. It is rooted in qualitative studies, where it is a standard way of gathering patients' input and learning about their views and experiences. Its scope of application has widened in recent years, with the method being used for decision-making and guidelines formulation (Doria *et al.*, 2018), not without some criticism regarding insufficient separation of these two functions. Participants are selected according to certain common characteristics that relate to the research topic and are grouped into 8-10 people.

	It can be conducted face to face or in virtual digital space. The method is often used to generate or evaluate hypotheses and ideas in conjunction with a quantitative method, or as a primary data-collection method. Example: Selected patients and stakeholders are invited to a meeting to discuss about a topic.
Democs	It is both a card game and a policy-exploration tool that enables small groups of people to engage with complex public policy issues. It aims to help people find out about a topic, express their views, seek common ground with other participants, and state their preferred policy position. There are already a number of Democs kits on different issues which can be bought or downloaded for free from New Economics Foundation (NEF) and Play Decide. Example**:** Patients are provided with discussion cards that help them to express their views on a topic, to seek common ground with the other participants, and to express their preferences.

Table 15 Engagement methods: Focus Group and Democs

In the Appendix 5: Patient Engagement Methods, there is a brief presentation of other suggested methods, based on the descriptions from the Engage2020 – Action Catalogue.

5.5.4 Roadmap Action 4: Selection of the indicators to be used to measure the success and effectiveness of this engagement

5.5.4.1 Measuring the performance and effectiveness of patient engagement

To maximize the impact of patient engagement, the ECT identifies indicators suitable for performance measurement and assessment of the effectiveness of patient engagement in your initiative's R&I processes. The assessment should combine quantitative and qualitative evaluation. The assessment of the implementation of the Patient Engagement Plan is a part of the Review and improve phase in the sub-criterion 3.1: Define and approve a methodology to engage stakeholders.

For patients, the most important benefit from the engagement in the R&I is its influence on the outcomes that matter most to them, such as their care, treatment, quality of life, and how they feel about their symptoms and/or functions.

Performance of patient engagement is about the **success of your initiative in terms of participation.** The associated indicators are to be selected ex-ante (before), included in the Patient Engagement Plan and verified ex-post (after) the development of the plan. The additional indicators should be considered examples only.

Core indicators	• Number of different phases of the research process (Patient engagement in the Research & Innovation Path) patients were engaged in. • Number of patients engaged across different socio-economic statuses, education backgrounds, genders, etc., to assess the capacity to engage diverse groups, including the most vulnerable ones. • Number of engagement actions (online and offline) that took place, in which patients had an opportunity to express their views.

Additional quantitative indicators	• Number of KPIs selected to assess the impact of patient engagement. • Number of conducted training. • Extent into which the patient involvement at the end is implemented in the research path. • Number of interviews about patients' experience in the engagement process. • Number of co-created tools the engagement measurement. • Number of reality test made by the patients. • Number of patient 'intervention' directly, or indirectly.
Additional qualitative indicators	• Analysis of the patients' expectation with respect to the patient engagement are met. • Analysis of whether the patients have felt engaged, listened and valued. • Analysis of how meaningful the engagement was to the patients as well as to the research team. • Analysis of how patients have been engaged (e.g. collecting comments, surveys, feedback, etc.)

Table 16 Patient Engagement Performance Assessment indicators

Effectiveness of patient engagement is about success of your initiative in term of **real impact of the participation on the research process**: whether the actions performed have effectively produced impact and change in the R&I process. The indicators of effectiveness are included in the Digital Toolbox as a sub-set of the Patient Reported Dimension. You can also find the in the Appendix 4: Master Scorecard.

Core indicators	*Quantitative* • Number of changes in the research process (e.g. policies, composition of boards, objectives and priorities, strategic plan, evaluation of results, dissemination actions, etc.) according to the review made by patients. • Number of research initiatives, programs and/or projects that include and show an effect on Patient Reported Outcomes (i.e. questionnaire reporting how they feel about symptoms and functions). • Number of research initiatives, programs and/or projects involving patients in research activities, according to the needs of the mission. *Qualitative* • Analysis of whether patients' expectation with respect to the research and mission of the initiative are met. • Evidence of the satisfaction and endorsements given by patients to research outcomes and results. • Evidence on patients' satisfaction with their engagement in the research in terms of expectation and influence on research outcomes, including identification of benefits and critical issues (pros and cons), and need for implementation. • Analysis of the achievement in terms of new knowledge produced, from the perspective of all the stakeholders.

Additional quantitative indicators	• Number of patients engaged in research activities, according to mission's requirements. • The degree of representativeness: the number of the underrepresented population and of the disadvantaged patients involved in the research. • Number of dissemination actions carried out by patients (e.g. events where patients presented and endorsed research results). • Number of scientific articles in which patients are co-authors and/or reviewers. • Number of endorsements given by patients to research activities and results. • Number of endorsements given by patient organisations.
Additional qualitative indicators	• Analysis of how patients' lives may be or have been improved by the research. • Analysis of the long-term improvement in health indicators. • Analysis of whether the value of patient contribution is the same as other stakeholders. • Evaluation of the research initiative, program and/or project plan, of all single research phases and of the results, by patients and if and how their suggestions has been integrated into the research activities.

Table 17 Effectiveness and value assessment indicators

6 COLLECTIVE IMPACT ASSESSMENT

Co-accountability lies at the centre of the CRIF: stakeholders agree on a common mission and a shared agenda. Subsequently, they co-create a common impact assessment system for measuring their progress towards the agenda. By "**impact**" we understand changes in the world (e.g. for the society, for patients) that happened because of an initiative's activities. MULTI-ACT defines impact as long-term (over 5 years) socio-economic changes the intervention brings about, as opposed to "outcomes" which are more short-term. Impact assessment is a mean to measure the effects/changes/results that the initiative brings about. It includes conceptualization of the causal relationships between what inputs and impact, i.e. the research and other activities of an initiative and changes in the society (health improvement, higher well-being etc.). Additionally, some measure of both the activities and changes is needed. In the co-accountability framework, the indicators are not static but subject to change across time in order to properly respond to the changing environment and to the changing stakeholders needs.

This chapter discusses the MULTI-ACT tools your initiative can use to establish the common impact assessment system and the system itself:

- Through the Materiality Analysis, you engage all categories of stakeholders in selecting indicators for a customised assessment system based on their materiality
- The Master Scorecard provides the indicators to choose from, at the same time covering all relevant aspects of impact
- Additionally, Patient-reported Outcomes allow you to measure the impact of your research on the patients.

6.1 Materiality Analysis

Not all changes brought about by an intervention or research initiative can be taken into account, and not all are equally relevant and significant. Choices have to be made about which data is tracked and reported, and when monitoring is optional: that is how impact indicators are chosen and created. Generally speaking, a piece of data is **material** if its omission or misrepresentation may affect stakeholders' decisions or their ability to draw reasonable conclusions about the impact. It may be useful to think about **materiality** as a threshold above which missing or misrepresented information is considered to have an impact on the decision making.

Naturally, organizations and individuals differ in their decisions on what is material, depending on their sector, mission, vision, values, strategy, dominant stakeholders and background.

In order to achieve **co-accountability**, stakeholders in your initiative participate in selecting of the indicators. The process is called **materiality analysis**. CRIF makes it easy to conduct the Materiality Analysis via the Toolbox.

Within the CRIF, the materiality analysis is a process through which your initiative's stakeholders will determine which indicators the initiative will use for assessing its impact. Materiality analysis is a step towards co-accountability, as representatives of all stakeholders categories within your initiative will be engaged in selecting the indicators. The representatives will be collectively held responsible for

monitoring and reporting these parameters. They will give their judgements on which aspects and indicators of the Master Scorecard are both:

- **Relevant** to your initiative's mission and agenda and
- **Significant** enough to be considered material, i.e. their inclusion or omission may influence decision-making

Therefore, it is a prerequisite to creating your customised Master Scorecard and to conducting impact assessment. The materiality analysis is a "bridge" leading from the Governance to the Impact Assessment part of the CRIF.

In the Materiality Analysis, you make use of information that you have already provided in the Baseline Analysis: mission and agenda and stakeholder engagement. If your initiative has not yet formulated mission and priorities, you need to conduct the Baseline Analysis before starting the Materiality Analysis. Governance guidelines in the Criterion 1 will help you to do this. In the Criterion 2, you will find guidelines for effective stakeholder engagement.

It is your task, as the Promoter, to start the process of materiality analysis in the Toolbox. These are some general recommendations to be followed to get a robust and reliable analysis:

1) Cluster the responses by different stakeholder categories. Results can be then aggregated following the suggested methodology presented in the box below
2) Ensure anonymity of the responses.
3) Define a minimum number of individual views required to be considered representative of a stakeholder category (e.g. minimum 4), in order to ensure a balanced and veridical representation.
4) Try to reach a heterogeneous cluster of responses within the same category: introducing additional specificities inside each stakeholder category helps catching potential differences within the same cluster (i.e. perspective of patients who are under treatment and not under treatment).
5) Provide complete guidelines and/or tools to respondents that may not be fully aware of the initiative and the CRIF.
6) Clarify the threshold under which the responses are considered non-representative and thus inadmissible.

6.2 Master Scorecard

The Master Scorecard is an adaptive tool for assessing health research & innovation initiatives and projects. It applies a multi-stakeholder perspective to provide a list of indicators for the assessment of research impact, considering the five CRIF dimensions (excellence, efficacy, social, economic and patient-reported). The scorecard provides the indicators to evaluate the impact of health research and innovation, paying special attention to the benefits to patients, healthcare and society in line with the multi-stakeholder initiative's mission. More specifically, its purpose is to offer an innovative and multi-perspective approach for the organization to gather information on the achievement of its objectives concerning its impact.

It provides a catalogue of 125 indicators grouped into five CRIF dimensions. For each indicator, the scorecard offers its description, example, qualitative or quantitative measurement, and methods and data sources, among other details.

6.2.1 CRIF Dimensions

Conventional metrics of academic excellence in research were integrated with indicators of economic impact, financial balance, social influence and – last but not least – measures of capacity to accomplish one's pre-defined mission. Patient-reported dimension overarches the other four dimensions, introducing the perspective of patient as the key stakeholder to impact assessment as a whole.

CRIF impact assessment comprises five dimensions that reflect different accountability perspectives: efficacy, excellence, economic, social and patient-reported that are described below.

6.2.1.1 Efficacy dimension

Efficacy dimension looks at your initiative's capacity to accomplish the mission it defined for itself. This dimension is the main driver for co-accountability within CRIF, because it assesses to what extent the initiative brings value for its stakeholders as pre-defined in the mission. In the context of brain research, the mission focuses on the improvement of the life conditions of patients affected by brain diseases, while balancing the conflicting perspectives of the different stakeholders involved. This dimension has the strongest links to Governance Criteria.

6.2.1.2 Excellence dimension

This dimension focuses on the quality of scientific research that is conducted as part of you initiative. While it contains traditional bibliometric indicators used to measure academic performance, it goes beyond them, allowing for appraise contribution to knowledge and impact on society. The indicators reflect MULTI-ACT conviction that research should positively influence people's lives to be deemed "excellent".

6.2.1.3 Economic dimension

The economic dimension contains a set of economic and financial indicators. Monitoring your initiative's internal financial balance is crucial to make it sustainable in the long run. Estimating its influence on the economy, e.g. through keeping patients in the workforce, is important for demonstrating its social impact in holistic manner.

6.2.1.4 Social dimension

In implementing social dimensions indicators, you are encouraged to look at the long-term direct and indirect effects of your initiative on the society as a whole, beyond primary stakeholders and Beneficiaries. It also includes communication with the society (e.g. external reporting) and community engagement.

6.2.1.5 Patient-reported dimension (PRD)

Patient-reported dimension is the transversal one, in which the other four are rooted. It places patient at the centre of health research as the key stakeholder, whose needs and perspectives must be understood and incorporated into the research process. It is a tool enabling the Science of Patient Input since it includes indicators that are reported by patients. PRD comprises two groups of indicators:

- Patient Reported Outcomes (PROs) and Patient Reported Outcomes Measures (PROMs),
- Qualitative indicators to assess the Return on Engagement (RoE).

6.2.2 CRIF Aspects

Indicators within each dimension are grouped in order to make them more manageable, both at the stage of selection (Materiality Analysis) and later on, when the initiative implements them and uses them in monitoring its impact. They reflect assessment perspective.

Aspects are broader categories, and groups – more specific, narrower categories of indicators. In each aspect, there is at least one core indicator.

6.2.3 CRIF Indicators

The Master Scorecard provides a catalogue of 125 indicators, grouped into 5 dimensions.

Dimensions	Aspects	Indicators
Patient-reported	9	11
Economic	9	20
Efficacy	9	22
Social	6	15
Excellence	20	57
Total	**53**	**125**

Table 18 CRIF dimensions, aspects and indicators

6.2.4 Core and additional indicators

Not all indicators are equally important for each initiative. Core indicators are obligatory to use. There is at least one core indicator per CRIF aspect.

Dimension	Core indicators	Additional indicators
Patient-reported	9	2
Economic	9	11
Efficacy	9	13
Social	7	8
Excellence	20	37
Total	**54**	**71**

Table 19 Core and additional indicators

The CRIF recommends your initiative to select additional indicators that will increase its co-accountability in an aspect that you consider material, or in situations when your initiative is not able to apply a related core indicator, e.g. due to lack of required data. Indicators were selected and divided into these categories based on extensive literature review.

6.2.5 Qualitative and quantitative indicators

Indicators in the Master Scorecard, irrespective of their core or additional status, are of either qualitative or quantitative nature. This distinction will help you to figure out what kind of input is expected from you when you fill in each particular indicator in the Toolbox. For qualitative indicators, you are expected to provide a narrative description and/or mark your answer to a qualitative question. When it comes to quantitative indicator, some kind of numerical input is required.

6.2.6 Using the Master Scorecard

The indicator can be applied for impact assessment at the beginning or during the development of a research initiative to select the indicators through the approach described in the Materiality Analysis. Depending on the stage of the project life cycle, the Master Scorecard can serve different purposes:

Initiation	Planning: The CRIF dimension (and the potential indicators) developed with the Master Scorecard allows the research initiative to (ex-ante) strategically design and evaluate the expected impact of a research project, according to its vision and agenda.
Execution	Monitoring: the Master Scorecard can serve to implement the mission selected by the initiative, in line with its vision and agenda. It can be used as a monitoring tool to assess the research and innovation activities delineated by CRIF dimensions. It could be used iteratively during the execution of the initiatives with the appropriate frequency.
Closure	Assessment: the Master Scorecard can be applied at the end of the initiative in order to assess how the desired results were reached. If the Master Scorecard is applied from the beginning of the project, the impacts can be compared with the initial evaluation output. This can help to strategically orient also future initiatives.

Table 20 Master Scorecard use at different stages of the initiative

The Master Scorecard enables strategic management of multi-stakeholder research initiatives. It assists initiatives in the evaluation of the multiple dimensions and impacts of their health research and innovation activities. It can be used as a strategic management tool as it helps to monitor the progress of research and innovation projects and to demonstrate whether and how the initiatives are producing actual outcomes and impacts. However, the user must be aware that the computation of the indicators selected by an initiative from the scorecard will not provide an overall “score” or “ranking”.

The Master Scorecard can be used in managing initiatives’ operations, identifying outcomes of the research, or for controlling and improving the initiative's performance.

The Master Scorecard is useful for initiatives aiming to increase the impact of research on people and society. The multi-stakeholder nature of MULTI-ACT allows the engagement of a broad range of users, which can be engaged in customizing and applying the Master Scorecard.

The Master Scorecard can be adapted to many individual needs:

- It allows flexibility and can be tailored to diverse multi-stakeholder projects, so it should not be used as a fixed set of indicators. It offers a starting point to be applied and tested in different contexts and settings, especially to multiple sclerosis or other brain diseases.
- It is dynamic as you can select indicators for different purposes and specific needs of many stakeholders through Materiality Analysis.

It is constructed in a way that it can be used, customized and applied by a broad range of users. It is an indicator catalogue that covers a wide range of relevant aspects that can be used in assessing the multiple impacts of health research. Therefore, initiative can select indicators among different topics and possibilities according to their own needs.

Your initiative can adopt Master Scorecard to build co-accountability by linking the research outputs with the mission and priorities of the initiative. It can be done regardless of the stage of R&I initiative, although early adoption renders best results.

6.3 Patient Reported Outcomes (PROs) and Patient Reported Outcomes Measures (PROMs)

PRO is any report about patient's health status coming directly from the patient. This report cannot be used or interpreted by anyone else (FDA, 2009). PROs are strictly about patient's perception of disease and treatment (European Medicines Agency, 2014), so they hold a special place within CRIF, where the patient is the key stakeholder, contributing their experiential knowledge to the research.

PROMs are standardized, validated questionnaires (which are also called instruments) completed by patients to measure their perception of their functional well-being and health status (Department of Health, 2009). PROMs are questionnaires measuring the patients' views of their health status. PROMs are used to assess a patient's health status at a particular point in time. PROMs tools can be completed either during an illness or while treating a health condition. In some cases, using pre- and post-event PROMs can help measure the impact of an intervention. PROMs are tools used to measure patient-reported outcomes (PROs). PROMs are offered in the Toolbox.

7 DIGITAL TOOLBOX

The digital MULTI-ACT Toolbox is an online platform that will assist you in implementing CRIF. While it is possible to implement CRIF without using it, it is much easier to use it, and this Manual is based on the assumption that you do. Using the Toolbox is free. It is available at: https://toolbox.multiact.eu

The Toolbox is designed to be intuitive in use and it contains a wealth of tips and explanations at each step. It will often refer you to relevant parts of the CRIF Manual. Therefore, in this chapter you will find only general introductions to the Toolbox functionalities. The main tools in the Toolbox are:

- Baseline Analysis
- Patient Engagement Plan
- Materiality Analysis
- Master Scorecard
- Patient-reported Outcomes

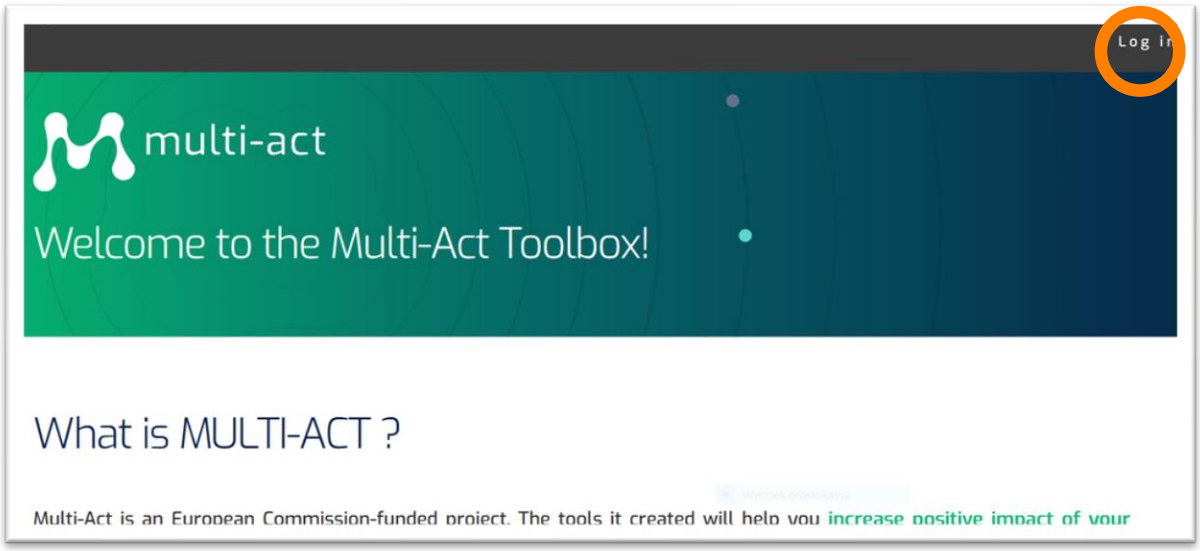


Figure 14 Logging in to the Toolbox

7.1 Creating an account

If you have not yet set up an account, go to “log in” in the right upper corner of the page. You will be taken to a page where you can log in, create an account and reset your password.

7.2 Your user account

Once you create your account and log in, you get access to all the functionalities.

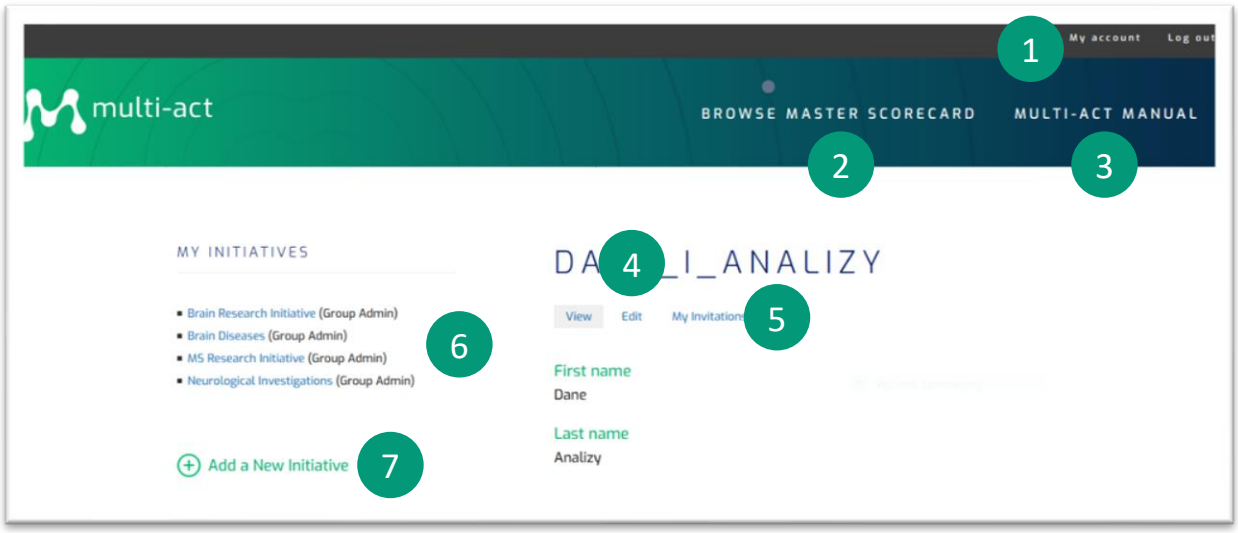


Figure 15 Toolbox: user account

Below you will find explanations of the functionalities marked with numbers

1. Wherever you are in the Toolbox, you can always go back to your account.

2. At any time, you can go to the Master Scorecard browser. Therein, you can read detailed information about each indicator from the Master Scorecard: related literature, examples, expected data collection frequency, expected reporting frequency, limitations, unit, method of measurement, and many more.

3. This Manual is available both as a .pdf document and as a sub-page on the Toolbox website. The Toolbox will often refer you to a relevant section of the CRIF Manual when explanations are needed. Feel free to use the format you prefer.

4. This is the place where you can change your password, your e-mail and other registration data.

5. In here, you can see invitations to become a member. To invite others to be members of your initiative, you have to create an initiative and enter the “invitations” functionality from there.

6. Once you create initiatives, they will be listed here. You can enter each of them by clicking on its name.

7. To start the process of creating a new initiative, click here.

7.3 Creating an initiative

Once you name your initiative, you will be asked to add basic information about it. You will be asked to provide basic information about your undertaking, and you will be given a chance to upload documents that will be useful later on. After you do it, you will get access to the initiative overview page.

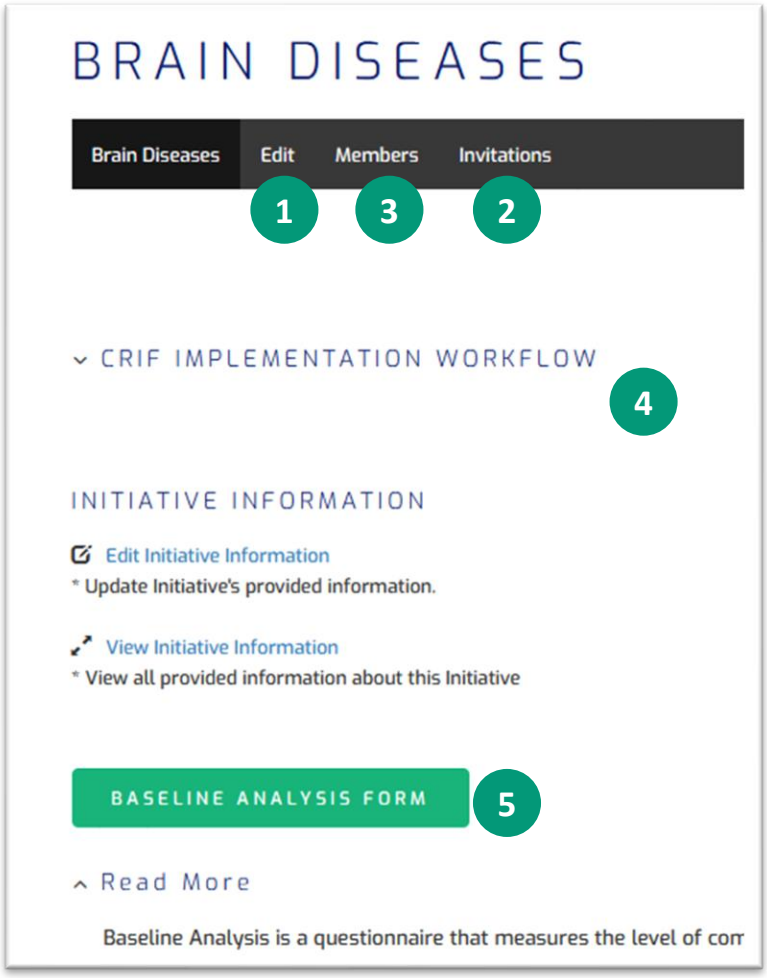


Figure 16 Initiative overview page

As with the user account, get to know the functionalities of the account.

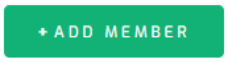
1 You can change the name of your initiative here.

2 This functionality allows you to send invitations to other members of the governance bodies who will manage the implementation of CRIF alongside you. Members of the Engagement Coordination Team (ECT) are especially important, since it is they who are responsible for the preparation of the Patient Engagement Plan. Be sure to invite them early on and encourage them to read the CRIF Manual.

Invite one member by introducing their e-mail.

Invite multiple members by introducing their e-mails in bulk.

3 In the "members" section, you can see the invitees who have accepted your request.



Appoint members to specific roles in the initiative.

4 Throughout the CRIF Manual, you will see the roll-down texts which can assist you at each step. It is worth it to read them.

5 The next step after filling the initiative information is to conduct the Baseline Analysis. The Patient Engagement Plan tool will appear only after you will have finished the Baseline Analysis. Similarly – the Materiality Analysis appears only after accomplished Patient Engagement Plan.

7.4 Baseline Analysis

During the process of filling in the Baseline Analysis questionnaire, you will be asked to upload various documents: financial reports, yearly reports, sustainability reports, internal policies on patient engagement, mission and vision, ethical compliance, monitoring and evaluation, social and environmental impact assessment, governance bodies and management procedures, academic achievement etc. While it may require effort to collect the documents, it will pay off as the Baseline Analysis results will help you identify gaps in governance of your initiative and align different procedures with the mission. The Toolbox will ask you to categorize the documents you will upload and sources you will refer to. You may find Appendix 1: Documents classification helpful.

When you fill in the questionnaire, you will receive your score and accompanying recommendations.

You can learn your compliance status for each criterion. You will see excerpts from the Governance Criteria relating to the areas where the Baseline Analysis identified gaps. It will be beneficial to read the Governance Criteria in their entirety first to understand interconnections, concepts etc. At the same time, data and self-reflection produced for the Baseline Analysis will also be useful later on, during the Materiality Analysis. Keep in mind that the feedback from the Baseline Analysis is a crucial input for the process of creating the Patient Engagement Plan.

You can re-take the Baseline Analysis questionnaire at any time. This will, naturally, result in re-scoring and an update of the recommendations.

7.5 Patient Engagement Plan

This tool is essentially a digital and interactive version of the Appendix 3: Patient Engagement Plan Template.

The prerequisite for preparing the Plan is establishing the Engagement Coordination Team (ECT) as this governance body is responsible for preparing the Plan. You need to invite the ECT's chair and other members to the Toolbox and assign them roles, so they have access and rights to the fill in the tool. It is important that the ECT's members undergo training as outlined in the Patient Engagement Guidelines and are given enough time to reflect on this task and contact the patients if needed.

After the ECT fills in the Plan, you can download it in the .pdf format. It is also possible for members of you initiative to discuss in the comment section under the Plan.

Accomplishing the Patient Engagement Plan allows you to proceed to the Materiality Analysis.

7.6 Materiality Analysis

1.1.1 *Identification of stakeholders*

For each stakeholder category, which your initiative identified in the Baseline Analysis, your initiative needs to engage at least five representatives. This is important for ensuring a balanced voting process. At least **16 participants must take part** in the survey before the tool produces final results. They do not have to register in the Toolbox to participate. For those unregistered, you need to add their **e-mail addresses** under corresponding stakeholder category to allow them to participate.

7.6.1 Creating the invitation list

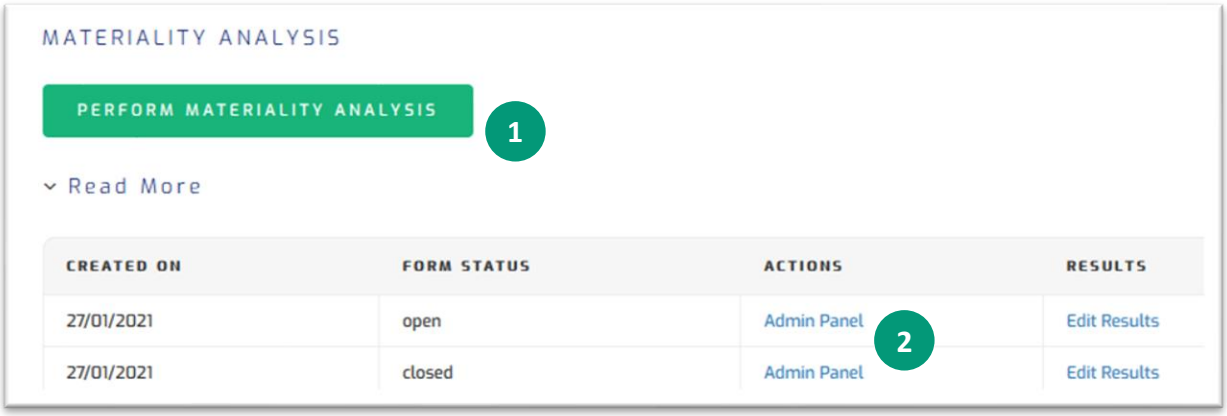


Figure 17 Materiality Analysis: Initialization and Invitation List

After clicking the "Perform Materiality Analysis" button (1) and saving, you go the Admin Panel (2).

In the Admin Panel, click the „Edit invitation list" button. In the invitation list, write (or paste) the text of the invitation e-mail and reminder e-mail. The Toolbox will send them for you. Using "Add member" button, add e-mail addresses of your stakeholders and select their stakeholder category. Once you finish – save your work.

It is practical to **prepare texts of two e-mails** before launching the tool: one inviting the stakeholders to take part in the materiality analysis and one reminding them to do so. You may want to explain what materiality analysis is, why they are invited, and what is expected of them, as well as assure them of anonymity. It may be prudent to give deadlines for response. Consequently, reflect on how much time the whole process of the materiality analysis can take within your initiative's unique timeline, and plan accordingly.

7.6.2 Initiation

By clicking „Email Invitation" button, you initiate the materiality analysis: an email is sent to all the participants you listed in the previous step. In addition to the text you provided, it contains a secure link to the Materiality Analysis interface in the Toolbox. Tokenization of the link guarantees:

- Anonymity of the participants.
- Association of every entry with its respective stakeholder category.
- One-vote-per-participant rule.

7.6.3 Selection of aspects

The participants are requested to select CRIF aspects that are relevant and significant from their perspective. They can read concise descriptions of aspects and are provided with concise instructions and links to additional material explaining CRIF and materiality analysis. Each participant must select minimum one aspect from each of the five CRIF dimensions and prioritize the aspects they selected by grading them from 0 (non-relevant) to 6 (most relevant), separately for each dimension. At least two aspects in every dimension must be graded above 0 before participant may submit their form.

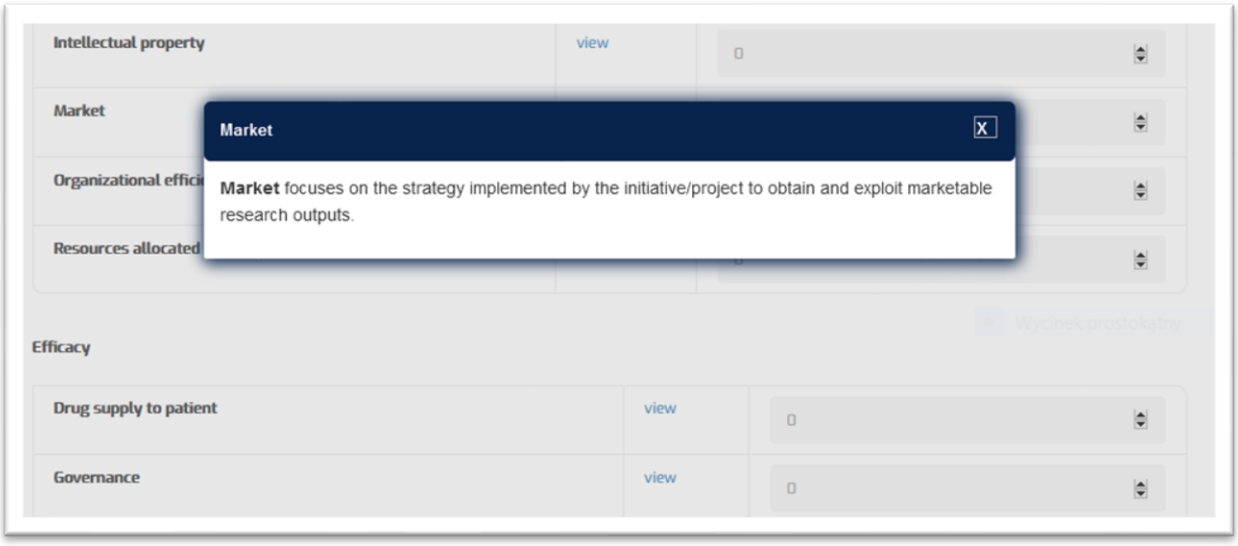


Figure 18 Materiality Analysis: aspect selection

The Toolbox ensures that nobody, including you will know how any individual participant voted, or whether they voted at all. You will be able to monitor how many participants from each stakeholder category voted, and track frequency of responses on a timeline. Only Promoters can initially see

intermediate results and monitor level of participation. When the analysis is complete, all participants are able to see the results as.

7.6.4 Selection of indicators

You can see the selected aspects by clicking on “Edit Results” in the initiative overview page.

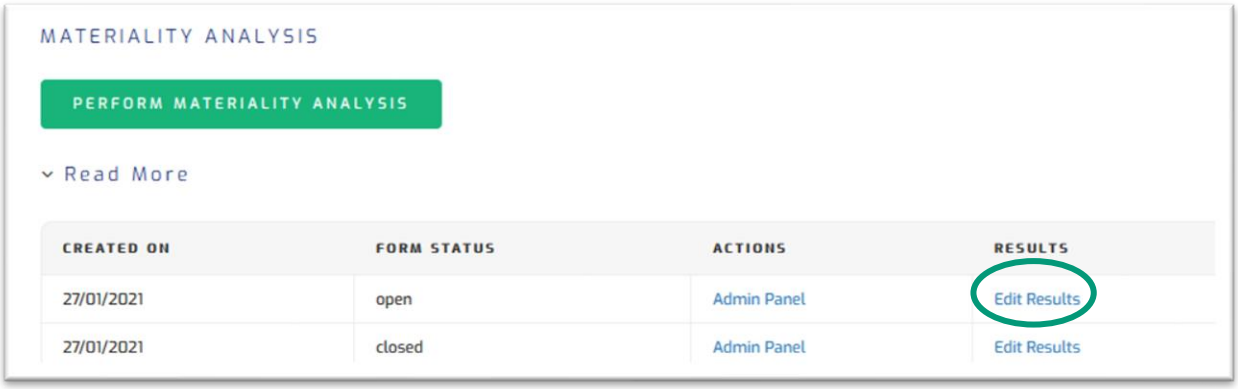


Figure 19 Materiality Analysis: monitoring the results

You will see a list of aspects selected by the participants along with their average score. Your initiative decides on the number of the aspects it wants to implement. It is advised that the final selection of indicators is limited to a manageable number: you can decide to limit the list to less than 15 aspects. The final set of selected indicators will constitute the customised Master Scorecard that your initiative will use to assess its impact and monitor its progress. Remember that submission of the final results is possible after the minimum number of participants have voted.

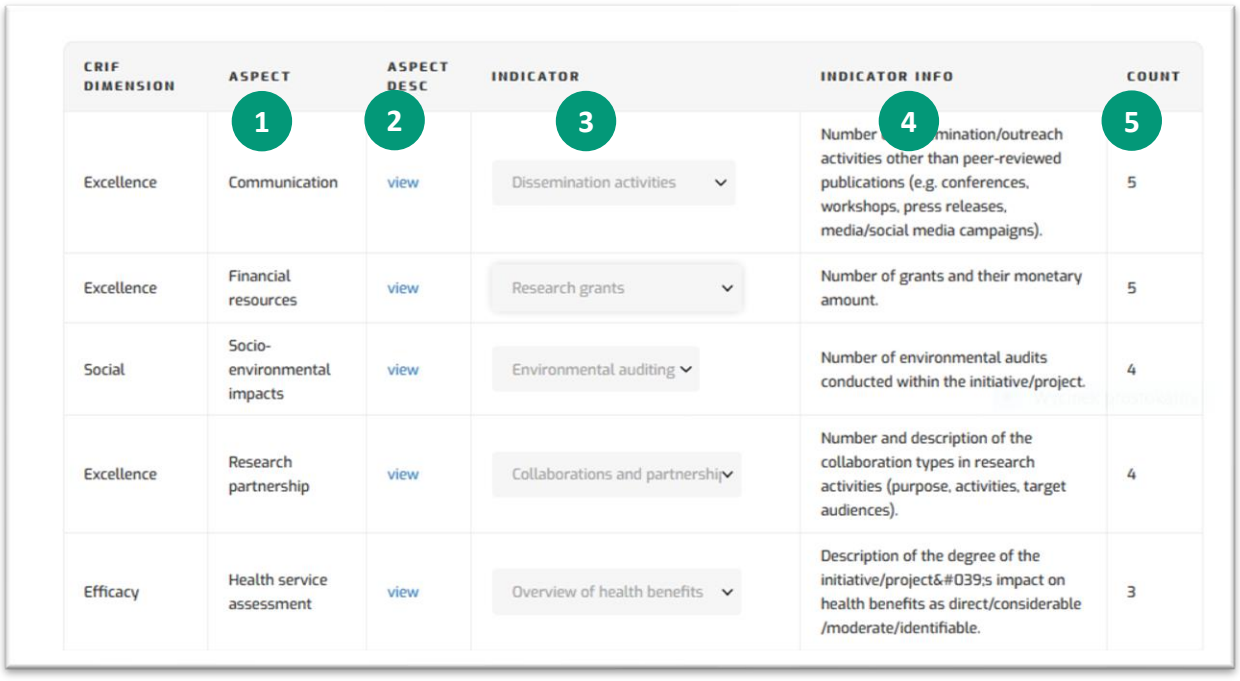


Figure 20 Materiality Analysis: partial results

The aspects are selected by the participants, the initiative controls how many will to be used.

1	Aspect selected by the materiality analysis participants.
2	Description of the aspect.
3	Indicator related to the aspect. The initiative can select which indicators related to the selected aspects it wants to use. Detailed descriptions of the indicators found in the Master Scorecard browser may help in the process.
4	Description of the selected indicator (it will change when you change the indicator).
5	Average score based on participants' prioritisation scores.

7.6.5 Final results

The Materiality analysis shows a snapshot in time of the stakeholders' priorities; however, they may change over time. For this reason, a materiality analysis should be carried out periodically, on a yearly or biyearly basis, in order to ensure its alignment with stakeholders' priorities and their commitment to accomplishment of the initiative's mission and agenda. Past materiality analysis results are stored in the initiative's database which enables comparison.

7.7 Impact Assessment Dashboard: the Master Scorecard

After you submit the final results of the materiality analysis, Assessment Dashboard section will appear in the Toolbox. Both the members of the initiative and the participants of the materiality analysis can see the initiative's scorecard by clicking on the *Final Results* link. The scorecard can be downloaded as a .pdf.

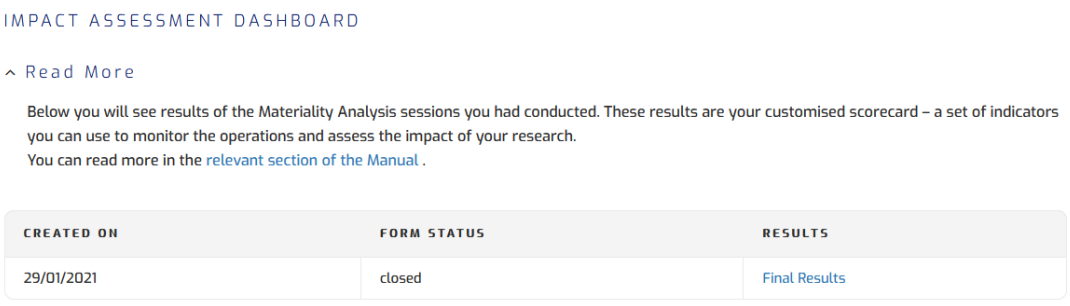


Figure 21 Impact Assessment Dashboard

FINAL RESULTS

CRIF DIMENSION	ASPECT	ASPECT DESC	INDICATOR	INDICATOR INFO	COUNT
Social	Corporate reputation	view	Social reputation	view	4
Patient Reported	Anxiety and depression	view	HADS - Hospital Anxiety and Depression Scale	view	4
Efficacy	Health service assessment	view	Overview of health benefits	view	3
Efficacy	Patient quality of life	view	Quality-adjusted life year	view	2
Social	Stakeholder engagement	view	Community engagement activities	view	1
Patient Reported	Upper-limb dexterity	view	Abilhand - Manual ability for adults with upper limb impairment	view	1
Excellence	Academic production	view	Publications	view	1
Excellence	Bibliometric	view	Academic citations	view	1

Figure 22 Materiality Analysis Final Results: the Master Scorecard

7.8 Impact Assessment (PRO)

The impact assessment includes additional tool for assessing an initiative's impact using Patient Reported Outcomes (PRO) data. The link to this tool is always available at the bottom of the initiative overview page. You can download an example file containing anonymized patient data of their periodical Hospital Anxiety and Depression Scale assessment, and upload it back to the Toolbox to see how the tool works. The Toolbox produces graphs to portray the progress of the collective number of patients or of individual ones from the uploaded data. Furthermore, you can add individual patient's data "by hand".

PARTNERS OF THE MULTI-ACT CONSORTIUM

The MULTI-ACT consortium brings together European societies, patients, patient organizations, research and academic institutions, and private consultancies.

Coordinator	
SCLEROSI MULTIPLA fondazione italiana un mondo libero dalla SM	The **Italian Multiple Sclerosis Society Foundation** (FISM) is the leading funding agency of research in the field of multiple sclerosis (MS) in Italy and the third worldwide (after MS Societies in the USA and Canada). FISM is member of the International MS Federation and collaborates with other MS societies to improve the quality of life of people with MS ("PwMS") and to provide better treatments toward a definitive cure for a MS. The overall goal of FISM is to make the bridge walkable between PwMS and governmental healthcare and research agencies, and thus to support people with MS in making decisions for their treatments and quality of life. As Coordinator of the project, FISM act as boundary organization between research and patients and society.
Partners	
UNIVERSITAS ATHESINA STUDIORUM	**Università degli Studi di Trento, UNITN** is responsible for the coordination among academic partners. The Department of Economics and Management (DEM) of the University of Trento features a multidisciplinary research environment where researchers apply a vast array of different approaches to describe the choice of economic agents, investigate their determinants and analyse their effect at the individual, sectoral and aggregate level.
EY	**ERNST & YOUNG Italy, EY**, is the partner responsible for the design and implementation of the health collaborative initiatives' approach and policies. EY is a global leader in advisory, assurance, tax, and transaction services. The insights and quality services EY delivers help build trust and confidence in the capital markets and in economies all over the world.
UNIVERSIDAD DE BURGOS	**Universidad de Burgos, UBU**, contributes to the MULTI-ACT Project with theoretical insights and empirical evidence about accountability, indicator measurement and impact assessment of research across different dimensions.
Tampere University	**Tampere University** is a higher education institution with the social mission of educating visionaries who understand the world and can change it towards the better. The new multidisciplinary Tampere University brings together research and education focusing on technology, health and society.

EBC European Brain Council	The **European Brain Council (EBC)** is a non-profit organization aiming to promote brain research in Europe, improve treatment, care and quality of life of people living with brain disorders. EBC stimulates dialogue between scientists, society and all interested parties by promoting collaboration of member organizations with the European Commission, the European Parliament and other relevant EU and international institutions.
INTRASOFT INTERNATIONAL	**INTRASOFT International S.A., INTRA** is a leading European IT Solutions and Services Group with strong international presence, offering innovative and added-value solutions of the highest quality to a wide range of international and national public and private organizations. It has proven expertise in conceptual system architecture and system design, advanced application development and integration services, information portal management and communication services and project management.
EHMA European Health Management Association	**European Health Management Association, EHMA**, is a Belgium-based non-profit membership organisation that focuses on enhancing the capacity and capability of health management in order to deliver high quality healthcare. EHMA operates at an international, European and national level, with a membership of over 80 organisations and individuals and a broader network in excess of 5,000. Its activities revolve around three key work streams: membership-focused actions and network engagement; research and EU project work focused on dissemination and stakeholder engagement; and events and workshops.
arsep fondation	**Fondation pour l'Aide à la recherche sur la Sclérose en plaques, ARSEP** is the leading funding agency of research in the Multiple Sclerosis (MS) field in France. ARSEP, taking advantage of its international network, including the International MS Federation (MSIF) and the Progressive MS Alliance (PMSA), has a leading role in enabling patient-reporting and in communication and /dissemination of scientific results to people with Multiple Sclerosis, families, friends, and caregivers.
Dane i analizy www.dane-i-analizy.pl	**Dane-i-Analizy.pl Sp. z o.o., DiA**, is a company developed by Jagiellonian University academics. It focuses mainly on the health care sector, dealing with data analysis, producing analysis and reports on data presentation and innovation and providing modern solutions for public administration.
UNIVERSIDADE CATÓLICA PORTUGUESA	**Universidade Catolica Portuguesa, UCP**, is an autonomous higher research and education institution in Portugal. The Católica Lisbon School of Business & Economics at UCP is an internationally recognized centre of research excellence in management and economics and the leading business school in Portugal since 2008.

ACRONYMS

ARSEP	Fondation Pour L'aide A La Recherche Sur La Sclérose En Plaques
BA	Baseline Analysis
CC	Compliance Committee
CRIF	Collective Research Impact Framework
DiA	Dane-i-Analizy.pl sp. z o.o.
EBC	European Brain Council
EC	European Commission
ECT	Engagement Coordination Team
EHMA	European Health Management Association
EU	European Union
EY SPA	Ernst & Young Financial Business Advisors
FISM	Fondazione Italiana Sclerosi Multipla FISM Onlus
INTRA	Intrasoft International
LB	Leadership Board
MA	Materiality Analysis
MSC	Master Scorecard
MSCU	Multiple Sclerosis Care Unit
PAB	Patient Advisory Board
PE	Patient Engagement
PRD	Patient-reported dimension
PROMs	Patient Reported Outcomes Measures
PROs	Patient Reported Outcomes

PwMS	People with multiple sclerosis
R&I	Research and Innovation
RFPO	Research Funding and Performing Organization
ROE	Return on Engagement
ROI	Return on Investment
RRI	Responsible Research & Innovation
SAB	Stakeholder Advisory Board
TAU	Tampereen Yliopisto
UBU	Universidad De Burgos
UCP	Universidade Catolica Portuguesa
UNITN	Università Degli Studi Di Trento
WG	Committees and Working Groups

GLOSSARY

Agenda: fundamental transformative objectives agreed upon by stakeholders that an initiative aims to achieve to fulfil its mission.

Appliers: RFPOs grouped in a multi-stakeholder initiative (e.g. Alliance) who implement the CRIF.

Beneficiaries: individuals that benefit from the long-term direct or indirect effects of the initiative, which could be for example patients, their families and caregivers.

Breaking down the boundaries: see Research & Innovation Path.

Care providers: see Stakeholder.

Co-design: see Levels of Engagement.

Compliance Committee, CC: see Governance bodies.

Conduct & operate: see Research & Innovation Path.

Consult: see Levels of Engagement.

Collective Research Impact Framework, CRIF is a conceptual framework developed by MULTI-ACT enabling a new collective accountability approach to managing and assessment multi-stakeholder R&I initiatives.

CRIF Dimensions are a set of grouped indicators from Master Scorecard for assessing the impact of an initiative. For more, see CRIF Dimensions. There are five CRIF Dimensions defined below:

- **Efficacy**: refers to the capacity of a given initiative or programme to achieve its mission (strategic priorities set via the stakeholder engagement process). For more, see Efficacy dimension.
- **Excellence**: concerns the quality of research and its findings. For more, see Excellence dimension.
- **Social**: considers the direct and indirect effects of health research for the whole society, going beyond patient needs. For more, see Social dimension.
- **Economic**: refers to long-term financial sustainability of health R&I initiatives. For more, see Economic dimension.
- **Patient-reported**: concerns patients whose needs and perspectives must be understood and incorporated into health research impact evaluation. For more, see Patient-reported dimension (PRD).

Criteria and sub-criteria: a set of guiding principles that constitute the MULTI-ACT Governance Model and are intended to be followed by the Model's user.

Design & plan: see Research & Innovation Path.

Design and planning: see Research & Innovation Path.

Economic: see CRIF Dimensions.

Engagement Coordination Team, ECT: see Governance bodies.

Efficacy: see CRIF Dimensions.

Evaluating research: see Research & Innovation Path.

Excellence: see CRIF Dimensions.

Executing research: see Research & Innovation Path.

Experiential knowledge: knowledge gained through experience, as opposed to a priori (before experience) knowledge.

Framework: see Multi-stakeholder framework.

Governance bodies: groups with specific roles within a multi-stakeholder initiative that are composed by individuals participating to the initiative itself. For more, see Governance bodies.

- **Engagement Coordination Team** (ECT) is in charge of coordinating the engagement of stakeholders, including patients, relatives and caregivers, in all the operations. For more, see Engagement Coordination Team (ECT).
- **Committees and Working Groups** (WG) can be appointed by the LB according to the specific needs of the program/project and the activities that will be carried out in order to achieve the desired change. For more, see Committees and Working Groups (WGs).
- **Compliance Committee** (CC) is in charge of maintaining a balance among stakeholders' stances and expectations and oversee the ethical issues that might arise during the implementation of the initiative. For more, see Compliance Committee (CC).
- **Leadership Board**, LB: is composed by representatives from the categories of stakeholders that have a strategic importance for the initiative and represents the decision-making body. For more, see Leadership Board (LB).
- **Patient Advisory Board**, PAB: may be a separate body or group representing patients within the Stakeholder Advisory Board (SAB). It is composed of patient representatives from the SAB. For more, see Patient Advisory Board (PAB).
- **Secretariat/Management Team** may be two different bodies or one. It depends on the size and structure of the multi-stakeholder initiative. It supervises administrative and operational tasks. For more, see Secretariat/Management Team.
- **Stakeholder Advisory Board**, SAB: a governance body composed by interested stakeholders and provides advices to the LB. Within this board, patients, their families and caregivers (one of the categories of stakeholders involved) might be asked by the LB to provide their specific contribution and advice for the most crucial decision-making processes according to the specific need of the initiative. This category of stakeholders can be defined as a sub-group within the SAB, called Patient Advisory Board (PAB). For more, see Stakeholder Advisory Board (SAB).

Governance Initiative: is a stage in multi-stakeholder initiative (including RFPOs) implementation process concerned with governance and management of a programme or a project, see Research & Innovation Path.

Health Research & Innovation, Health R&I: refers to "activities of research, technological development, demonstration and innovation, including the promotion of cooperation with non-EU countries and international organisations, the dissemination and optimisation of results and mobility of researchers in the Union (Eur-lex, no date) within the healthcare domain.

Impact: is the long-term socio-economic changes the intervention brings about (e.g. over 5 years).

Impact Indicator: is a "quantitative or qualitative factor or variable that provides a simple and reliable means to measure achievement, to reflect the changes connected to an intervention, or to help assess the performance of a development actor" (OECD, 2010).

Industry: see Stakeholder.

Inform: see Levels of Engagement.

Initiative: see Multi-stakeholder initiative.

Input: the contributions made or required by each stakeholder/organization. It can include financial, human, technical and relational resources.

Involve: see Levels of Engagement.

Leadership Board, LB: see Governance bodies.

Levels of Engagement: a way of describing the varying depth of patients' involvement and agency in the research and innovation (R&I) process. For more, see Levels of Engagement.

- **Co-design**: Stakeholders are engaged with a decision-making role. For more, see Levels of Engagement.
- **Involve**: Stakeholders participate in research design and development as co-researchers and are engaged by providing their perspective and data. They are not involved in co-designing of the project as decision-makers. For more, see Levels of Engagement.
- **Consult**: Stakeholders provide feedback for decision-making, give advice and opinions, but do not participate in decision-making. For more, see Levels of Engagement.
- **Inform**: Stakeholders are informed about research in a passive role. For more, see Levels of Engagement.

Management Team: see Governance bodies.

Mission: initiative's current and future role, what it wants to achieve, and how it wants to achieve it.

Monitoring and evaluation framework a logical sequence that explains causal relations between inputs, processes, outputs, outcomes and impacts. It offers indicators of each of this stages and serves organizations in monitoring and evaluating their progress towards the goals and their impact.

Multi-stakeholder framework: is a conceptual structure applicable by/to a variety of stakeholders. Framework examples include (but are not limited to) guidelines, standards, certifications, normative schemes, etc.

Multi-stakeholder initiative: is a governance structure that seeks to bring different stakeholders together to participate in the dialogue, decision-making and implementation of solutions to the shared problems or goals.

Outcome: is the intermediate results and effects of the intervention (e.g. within 5 years), and is less tangible than outputs.

Output: is the activity in relation to each stakeholder's inputs in quantitative terms. Alternatively, it can be defined as the tangible and intangible products resulting from research and innovation.

Patient Advisory Board, PAB: see Governance bodies.

Patient-Provided Information: a range of input or data that is collected from patients.

Patient-Reported Outcomes, PROs: "any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else" (FDA, 2009).

Patient-Reported Outcomes Measures, PROMs: standardized, validated questionnaires (which are also called instruments) completed by patients to measure their perception of their functional well-being and health status.

Patient-Reported Dimension, PRD: see CRIF Dimensions.

Patients' organizations: see Stakeholder.

Patients see Stakeholder.

Payers and purchasers: see Stakeholder.

Policy makers: see Stakeholder.

Process: "includes all the activities that enable the research to happen (i.e. reviewing of evidence, data collection, analysis, reporting and so forth)" (Hinrichs-Krapels and Grant, 2016).

Program Level: see Research & Innovation Path.

Project Level: see Research & Innovation Path.

Patient Engagement: is the action of engaging patients and their communities in R&I as key stakeholders with a decision-making role, "occurring when people with and affected by the disease meaningfully and actively collaborate in the governance, priority setting, and conduct of research, as well as in summarizing, distributing, sharing, and applying its resulting knowledge" (de Wit *et al.*, 2013).

R&I Path: see Research & Innovation Path.

R&I: see Health Research & Innovation.

Research Funding and Performing Organizations: see Stakeholder.

Research & Innovation Path (R&I Path): refers to sequence of processes and activities in the R&I where patients can be engaged in order to maximize the impact of R&I. For more, see Research & Innovation Path. Governance program level and project development levels are distinguished (also see Governance Initiative):

- **Program level**: steps in multi-stakeholder initiative process concerned with the governance and management of research funding & performing programs:
  - **Breaking down the boundaries**: conditions that should be set in RFPOs in order to facilitate patient engagement as standard practice.
  - **Setting research priorities**: actions to establish justified interest in a specific research domain to a certain higher degree, importance, precedence, or rank over others.
  - **Steering institutions**: actions performed to establish steering and advisory committees and bodies.
  - **Design and planning**: the design and planning of all the activities that lead to the realization of a concept or idea and which helps achieve the item's designated objective(s).

  - **Executing research**: activities to actualize the research program or a specific research project for the purpose of achieving the item's designated objectives. Project level takes places at this stage.
  - **Evaluating research**: activities to determine the value created by a research program or project, establishing the outputs and outcomes, the degree to which the pre-established goals were achieved, and their impact.
  - **Translation to community**: activities to foster and facilitate the uptake of results of research programs or projects.
- **Project level**: steps in multi-stakeholder initiative process concerned with performing single research projects. In this case, patient is a co-researcher. Project development pertains to research execution stage of the governance program level.
  - **Conduct & operate**: project conduct & monitoring (e.g. ICT device development).
  - **Design & plan**: the design and planning of all the activities that lead to the realization of a concept or idea and which helps achieve the designated objective(s).
  - **Evaluation** activities to determine the value created by a research project, establishing the outputs and outcomes, the degree to which the pre-established goals were achieved, and the impact.
  - **Translation to community:** activities to foster and facilitate the utilization/uptake of results of research projects.

Responsible Research and Innovation, RRI: research and innovation process in which societal actors work together in order to better align its outcomes with the values, needs and expectations of society (European Commission, no date).

Return on Engagement, RoE: the benefit, impact and value resulting from performing engagement in R&I. For more, see Return on Engagement (RoE).

Return on Investment, ROI: is a measure of the efficiency of an investment as a percentage of return relative to the investment's cost.

RRI: see Responsible Research and Innovation.

Science of patient input: scientific research which uses data provided by people with a disease through passive or active contribution to evaluate its impact. For more, see Science of/with patient input.

Science with patient input: scientific research where patients actively collaborate in governance, setting priorities, performance assessment etc. For more, see Science of/with patient input.

Setting research priorities: see Research & Innovation Path.

Social Return on Investment, SROI: a method of measuring and accounting for extra-financial value (such as environmental or social value) for the stakeholders.

Social Dimension: see CRIF Dimensions.

Society: see Stakeholder.

Stakeholder: refers to "any individual or group that is affected by, who can influence or may have an interest in the outcomes of an organization's actions" (Freeman, 1984).

- **Patients**: people with the disease (persons with lived experience of the disease); and people affected by the disease (persons or groups that are affected by the disease, including family members and caregivers).
- **Patients' organizations**: not-for profit organisations which are patient focused, where patients and/or their carers constitute majority in governing bodies, e.g. patient associations, advocacy organizations.
- **Society**: individual citizens, civil society organizations and networks.
- **Payers and purchasers**: public or private entities responsible for underwriting the costs of health care.
- **Care providers**: health and social care organizations and professionals (doctors, nurses, etc.).
- **Policy makers**: EU institutions; national, regional and local policy makers of different levels.
- **Regulators**: regulatory agencies and Health Technology Assessment (HTA) bodies, e.g. agencies for the scientific evaluation and safety monitoring of medicines, i.e. the European Medicine Agency.
- **Industry**: companies developing and selling health products and services.
- **Research Funding and Performing Organizations**, RFPO: universities, research hospitals, research projects, foundations, and all private and public research funders.

Promoter: individuals that guide the adoption of the CRIF within their organizations or initiatives, and are members of their governance bodies.

Stakeholder Advisory Board, SAB: see Governance bodies.

Steering institutions: see Research & Innovation Path.

Sub-criterion: see Criteria.

Transformational mission: mission of research initiative that shifts or breaks existing scientific paradigms.

Translation to community: see Research & Innovation Path.

BIBLIOGRAPHY

Andreaus, M. *et al.* (2019) 'Deliverable 3.6 Multi-Act Master Scorecard'. Available at: https://www.multiact.eu/wp-content/uploads/2020/02/D3.6.pdf.

Andreaus, M. and Costa, E. (2014) 'Toward an Integrated Accountability Model for Nonprofit Organizations', in, pp. 153–176. doi: 10.1108/S1041-706020140000017006.

Cabaj, M. and Weaver, L. (2016) *Collective Impact 3.0: An evolving framework for community change.* Available at: https://www.tamarackcommunity.ca/library/collective-impact-3.0-an-evolving-framework-for-community-change.

Cottam, H. and Leadbeater, C. (2004) *Red Paper 01 Health: Co-creatingServices*. Available at: https://www.designcouncil.org.uk/sites/default/files/asset/document/red-paper-health.pdf.

Department of Health (2009) 'Guidance on the routine collection of Patient Reported Outcome Measures (PROMs)', (April 2008), pp. 1–28. Available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_092625.pdf.

Deuschl, G. *et al.* (2020) 'The burden of neurological diseases in Europe: an analysis for the Global Burden of Disease Study 2017', *The Lancet Public Health*, 5(10), pp. e551–e567. doi: 10.1016/S2468-2667(20)30190-0.

Dhar, V. K. *et al.* (2018) 'Benefit of social media on patient engagement and satisfaction: Results of a 9-month, qualitative pilot study using Facebook', *Surgery*, 163(3), pp. 565–570. doi: 10.1016/j.surg.2017.09.056.

Doria, N. *et al.* (2018) 'Sharpening the focus: differentiating between focus groups for patient engagement vs. qualitative research', *Research Involvement and Engagement*, 4(1), p. 19. doi: 10.1186/s40900-018-0102-6.

Eur-lex (no date) *Glossary of summaries*. Available at: https://eur-lex.europa.eu/summary/glossary/research_and_development.html.

European Brain Council (2017) *Early Intervention: Bridging the Early Diagnosis and Treatment Gap*. doi: 10.13140/RG.2.2.20145.07520.

European Commission (no date) *Horizon 2020*. Available at: https://ec.europa.eu/programmes/horizon2020/en/h2020-section/responsible-research-innovation.

European Medicines Agency (2014) *EMEA Appendix 2 to the guideline on the evaluation of anticancer medicinal products in man*.

FDA, H. (2009) 'Guidance for Industry Patient-reported Outcome measures: Use in Medical Product Development to Support Labeling Claims', *Clinical/Medical Federal Register*, (December), pp. 1–39. doi: 10.1111/j.1524-4733.2009.00609.x.

Fontaine, G. *et al.* (2019) 'Communicating Science in the Digital and Social Media Ecosystem: Scoping Review and Typology of Strategies Used by Health Scientists', *JMIR Public Health and Surveillance*, 5(3), p. e14447. doi: 10.2196/14447.

Freeman, E. R. (1984) *Strategic management : a stakeholder approach*. Latest edi. Boston, MA.

Graham, K. E. R. *et al.* (2012) 'Evaluating health research impact: Development and implementation of the Alberta innovates-health solutions impact framework', *Research Evaluation*, 21(5), pp. 354–367.

doi: 10.1093/reseval/rvs027.

Gustavsson, A. *et al.* (2011) 'Cost of disorders of the brain in Europe 2010', *European Neuropsychopharmacology*, 21(10), pp. 718–779. doi: 10.1016/j.euroneuro.2011.08.008.

Hinrichs-Krapels, S. and Grant, J. (2016) 'Exploring the effectiveness, efficiency and equity (3e's) of research and research impact assessment', *Palgrave Communications*, 2(1), p. 16090. doi: 10.1057/palcomms.2016.90.

Househ, M., Borycki, E. and Kushniruk, A. (2014) 'Empowering patients through social media: The benefits and challenges', *Health Informatics Journal*, 20(1), pp. 50–58. doi: 10.1177/1460458213476969.

Jeremy Nicholls *et al.* (2012) 'Social Return A guide to on Investment Social Return on Investment', *Update*, (January), p. 108. Available at: http://www.thesroinetwork.org/publications/doc_details/241-a-guide-to-social-return-on-investment-2012.

Kalucy, E. C. *et al.* (2009) 'The feasibility of determining the impact of primary health care research projects using the Payback Framework', *Health Research Policy and Systems*, 7, pp. 1–10. doi: 10.1186/1478-4505-7-11.

Kania, J. and Kramer, M. (2011) 'Collective Impact', *Stanford Social Innovation Review*, Winter. Available at: https://ssir.org/images/articles/2011_WI_Feature_Kania.pdf.

Mazzucato, M. (2018) *Mission-Oriented Research & Innovation in the European Union. A problem-solving approach to fuel innovation-led grow*. doi: 10.2777/36032.

Milat, A. J., Bauman, A. E. and Redman, S. (2015) 'A narrative review of research impact assessment models and methods', *Health Research Policy and Systems*, 13(1), pp. 1–7. doi: 10.1186/s12961-015-0003-1.

Multi-Act Project (2020) *Guidelines for Patient Engagement in Health Research & Innovation. Short version Version 0.1 – World Multiple Sclerosis Day 2020, May 30th*. Available at: https://www.multiact.eu/wp-content/uploads/2020/06/MULTI-ACT-Patient-Engagement-Guidelines-Short-v0.1_compressed.pdf.

Musso, M. *et al.* (2018) 'How Social Media Platform can Support Value Cocreation Activities in Healthcare', in *Excellence in Services*, pp. 535–555.

OECD (2010) 'Glossary of Evaluation and Results Based Management (RBM) Terms'. Available at: https://www.oecd.org/dac/evaluation/dcdndep/31950400.pdf.

Ovseiko, P. V., Oancea, A. and Buchan, A. M. (2012) 'Assessing research impact in academic clinical medicine: A study using Research Excellence Framework pilot impact indicators', *BMC Health Services Research*, 12(1). doi: 10.1186/1472-6963-12-478.

Raftery, J. *et al.* (2016) 'Models and applications for measuring the impact of health research: Update of a systematic review for the health technology assessment programme', *Health Technology Assessment*, 20(76). doi: 10.3310/hta20760.

Schneeman, K., Barton, V. and Huneycutt, B. (2019) *Advancing Models of Patient Engagement: Patient Organizations as Research and Data Partners*. Available at: https://milkeninstitute.org/sites/default/files/reports-pdf/Full Series_Advancing Models of Patient Engagement- Patient Organizations as Research and Data Partners copy.pdf.

von Schomberg, R. (2013) 'A Vision of Responsible Research and Innovation', in *Responsible Innovation*. Chichester, UK: John Wiley & Sons, Ltd, pp. 51–74. doi: 10.1002/9781118551424.ch3.

Strand, R. *et al.* (2015) *Indicators for Promoting and monitoring responsible research and innovation*. doi: 10.2777/9742.

Thielst, C. B. (2011) 'Social media: ubiquitous community and patient engagement.', *Frontiers of health services management*, 28(2), pp. 3–14. Available at: http://www.ncbi.nlm.nih.gov/pubmed/22256506.

WHO (2014) *Handbook for Guideline Development. 2nd edition.* Available at: https://www.who.int/publications/guidelines/handbook_2nd_ed.pdf?ua=1.

de Wit, M. P. T. *et al.* (2013) 'What Has Been the Effect on Trial Outcome Assessments of a Decade of Patient Participation in OMERACT?', *The Journal of Rheumatology*, 41(1), pp. 177–184. doi: 10.3899/jrheum.130816.

Wittchen, H. U. *et al.* (2011) 'The size and burden of mental disorders and other disorders of the brain in Europe 2010', *European Neuropsychopharmacology*, 21(9), pp. 655–679. doi: 10.1016/j.euroneuro.2011.07.018.

Yaghmaei, E. (2018) 'Responsible research and innovation key performance indicators in industry: A case study in the ICT domain', *Journal of Information, Communication and Ethics in Society*, 16(2), pp. 214–234. doi: 10.1108/JICES-11-2017-0066.

Zaratin, P. *et al.* (2016) 'Progressive MS Alliance Industry Forum: Maximizing Collective Impact To Enable Drug Development', *Trends in Pharmacological Sciences*, 37(10), pp. 808–810. doi: 10.1016/j.tips.2016.07.005.

Zaratin, P., Battaglia, M. A. and Abbracchio, M. P. (2014) 'Nonprofit foundations spur translational research', *Trends in Pharmacological Sciences*, 35(11), pp. 552–555. doi: 10.1016/j.tips.2014.09.003.

APPENDIX 1: DOCUMENTS CLASSIFICATION

The below table may help you orderly classify the documents you upload and sources you refer to during filling in Baseline Analysis and Master Scorecard.

Bibliometric	Academic search databases
	Bibliometric data sources
	Classification of journals with open access options, such as DOAJ list (Directory of Open Access Journals), PMC (PubMed Central), the ROAD list (Directory of Open Access scholarly Resources), CrossRef, and OpenAIRE
	Google analytics or similar web engines.
	Google scholar
	Rankings of journals (e.g., JCR, SJR)
	Scopus
	Web of Science (WoS)
	World Intellectual Property Organization Database
Codes and Guidelines	Code of conduct
	Code of ethics
	Community development plans
	Guidelines
	Official document containing evaluative criteria in the research proposal evaluation
	Stakeholder engagement plans
	Strategy documents
	Treatment guidelines
Codes and Guidelines	Code of conduct
	Code of ethics

	Community development plans
	Guidelines
	Official document containing evaluative criteria in the research proposal evaluation
	Stakeholder engagement plans
	Strategy documents
	Treatment guidelines
Health Records	Clinical data
	Clinical information system
	Electronic health record system
	Electronic medical records
	Health care providers, clinics records
	Hospital data
	Hospital record information systems
	Medical costs
	Patient records
Interviews and Surveys	Database and interviews
	Dedicated survey
	Expert survey
	Health surveys
	Interviews
	Interviews and/or surveys with practitioners/experts
	Interviews with practitioners/clinicians
	Market surveys

	Patient surveys and interviews
	Preference surveys
	Public consultation
	Questionnaires used in trials
	Questionnaires
	Surveys
Reports	Annual reports
	Expected duration of life and degree of disability
	Financial statement, balance sheet and internal management control systems
	Human resource management report
	Initiative financial report
	Initiative scientific report
	Internal report
	Internal reports by press office
	Local data registries
	Local statistics
	Meeting reports of works councils
	Mission statement
	National statistics
	Policy report
	Records of service delivery
	Regional data registries
	Regional statistics

	Research report
	Scientific report
Other	Administrative data
	Billing and accounting systems, procurement or supply management department
	National registries
	Production and research sites of the company
	Professional association

APPENDIX 2: CRITERIA FOR PATIENT ENGAGEMENT

Criteria for Patient Engagement use MULTI-ACT Governance Model Criteria as a basis for defining qualitative indicators to evaluate the implementation of Patient Engagement strategies in line with the MULTI-ACT multi-stakeholder and co-accountable strategy. The criteria for Patient Engagement constitute a part of MULTI-ACT Governance Model, being an attempt to provide good practices and recommendations under the MULTI-ACT Governance Model.

Each Governance criterion was qualitatively analysed in view of empowering patients to become a stakeholder with an "equal decision power". Moreover, the special needs of patients as stakeholder with special needs were considered.

Customized/ad hoc criteria and indicators for engaging patients are presented in the table below.

Governance Criteria	Specific criteria for Patient Engagement	Check-list and indicators
Vision and Agenda		
Vision and Agenda	Vision and agenda Patient Engagement adherence	Describe if and how Patient Engagement (focus on gathering patient experiential knowledge) can enable alignment with the vision and with the desired change (i.e. transformational mission) and facilitate the achievement of defined objectives.
Vision and Agenda	Vision and agenda Patient Engagement adherence	Rely on the identified intended beneficiaries (patients), covering different aspects, such as (not exhaustive); state of the disease, gender, sector, geographical background, culture, language, and background etc.
Participatory Governance		
Participatory Governance	Governance structure	Describe the governance boards in charge of Patient Engagement and, in particular, the structure and composition of the following bodies: • **Engagement Coordination Team** in charge of coordinating the patient and stakeholders' engagement, ensuring the representativeness of their communities. A MULTI-ACT Patients' Recruitment Plan relevant to the target mission should be developed based on the Governance (D5.4) and Patient Engagement Criteria. • **Patient Advisory Board**

		• **Compliance Committee** (describe how the board meets requirements to ensure ethical approaches to Patient Engagement)
Participatory Governance	Boards composition	Describe the composition of the Boards in terms of patients (gender, sector, geographical background, language, and background)
Participatory Governance	Procedure development	Confirm that the initiative/project has formalized a procedure that describes the governance structure (i.e. interaction between the boards) dedicated to implement Patient Engagement strategies, the roles and responsibilities of all participants and the decision-making processes
Participatory Governance	Mechanisms in place to ensure multi-stakeholder participation	Describe mechanisms in place to: 1) ensure that disadvantaged patients are represented; 2) protect the integrity and multi-stakeholder nature of the initiative; 3) maintain commitment and ownership among the participating patients; 4) assure that the perspective of underrepresented population is duly considered (and that individual perspective is turned into a population one); 5) support patients to express themselves avoiding the sense of self-deprecation; 6) maintain attitudes of respect, trust, reciprocity and co-learning; 7) ensure equality of treatment for all the stakeholders
Participatory Governance *(and Clear, effective and inclusive methodology of stakeholder engagement)*	Identify and cluster patients	List the patients, categories relevant for the MISSION, that should be involved according to the 7-steps R&I path in line with the objectives to be pursued by the initiative/project. It must be mandatory to include those affected by a certain measure in the process of change.
Participatory Governance *(and Clear, effective and inclusive methodology of stakeholder engagement)*	Identification of patients' need, challenges and barriers	Describe the analysis carried out to identify patients' main needs, challenges and barriers to guarantee genuine participation considering their goals and perceptions of impacts (since the beginning) and identify limitations that some specific category of patients might encounter in their participation within the initiative/project, in the 7-steps R&I path.
Clear, effective and inclusive methodology of stakeholder engagement		

Clear, effective and inclusive methodology of stakeholder engagement *(and Effective and efficient management and coordination of the initiative)*	Mechanisms in place to recognize the value of patients' experiential knowledge	Establish and describe appropriate mechanism for recognition of patients' contribution. Examples from Smith et al. 2019: Financial (compensation for incurred expenses, consultant fees, remuneration, etc.); Personal (thank-you letter, public mention, etc.); Knowledge (access to publications, access to training and scientific literature); Academic (acknowledgement in knowledge transfer, co-authorship in articles, etc.); Altruistic (moral satisfaction, augmentation of self-worth and wellbeing of others, etc.). Ensure equality of treatment with respect to the other stakeholders.
Clear, effective and inclusive methodology of stakeholder engagement	Define and approve a methodology to engage patients	Describe the methodology that will be adopted to engage patients, and list the actions that will be undertaken for each of the fundamental steps identified in such engagement processes (i.e. 7-steps R&I path)
Clear, effective and inclusive methodology of stakeholder engagement	Define the level of engagement and type of patients for each steps of the 7-steps R&I path	Based on the steps where patients are engaged (7-steps R&I path) define categories of patients and clearly define the related level of engagement; moreover, it should be formalized what the duties, rights and responsibilities are linked to each level of engagement.
Clear, effective and inclusive methodology of stakeholder engagement	Training and initiating intended beneficiaries	Assure that patients are duly trained for the purposes. Clearly describe and report the process of training patients 1) on the R&I and engagement process, 2) on what is expected from them and 3) on how to provide their experiential knowledge
Effective and efficient management and coordination of the initiative		
Effective and efficient management and coordination of the initiative	Define a clear framework, such as a Patient Engagement Plan	Confirm that the initiative/project has defined a "Patient Engagement plan", and describe all the actions contained that should be put in place by the ECT in order to achieve its objectives, and related responsibilities. The Patient Engagement Plan must contain as minimum requirements: • Patient Engagement actions that needs to be implemented in order to achieve the Vision; • Definition of roles and responsibilities of the ECT that should manage and carry out the implementation of such actions; • Definition of clear and measurable targets; • Presentation of clear timeline of activities;

		• Definition of a clear review process (e.g. objectives of Patient Engagement); • Information regarding the organization "touch points meetings" (such as periodic strategic meeting with PAB or other stakeholders).
Effective and efficient management and coordination of the initiative	Maintain flexibility and put in place mechanisms to avoid tokenism	Assure a process that allows the incorporation of feedbacks from patients and reviews to revise/change objectives and approach of the initiative/project in a flexible manner. Assure and report oversight and overtime mechanism to avoid tokenism and value the experiential knowledge of patients. Report on the following information: • Number and type of methods used and events that have taken places to grant patients the possibility to express their views/experiences. • Number of reviews/changes of the Vision and Agenda, according to the gaps identified by patients. • Number of reviews/changes of outcomes related to the 7-steps R&I path produced and endorsed by patients
Effective and efficient management and coordination of the initiative	Implement an effective cost management process	Describe the cost of the Patient Engagement implementation by the ECT, which should at least be composed by the following activities: • Determination of a clear budget for Patient Engagement. • Implementation of a cost analysis and assure sustainability of the Patient Engagement plan. • Identification of possible gaps and critical issues.
Define a shared assessment and monitoring system		
Define a shared assessment and monitoring system	Progress Report development	Confirm that there is a regular publication of Progress Report (on-going, ex-post).
Define a shared assessment and monitoring system	Communication channels set up and maintenance	Confirm that the initiative has created communication channels for constant communication on progress to patients involved (to constantly keep engage patients).
Define a shared assessment and	Review process in place	Describe the review process that the initiative has adopted to consider the performance and value of the Patient

monitoring system		Engagement to make the initiative's produce outcomes that matter to patients. • Describe how objectives of Patient Engagement are met on performance and on /value, impact and return on engagement). • Define the value of Patient Engagement (Patient Engagement Plan/ Cost to put in place the Plan = Value).
Define a shared assessment and monitoring system	Feedback mechanisms in place	Describe the mechanisms in place to gather feedback on the Patient Engagement actions and outcomes from stakeholders and the public (other than PAB).

Table 21 A list of qualitative indicators to evaluate the implementation of MULTI-ACT Governance Model with respect to Patient Engagement

APPENDIX 3: MULTI-ACT PATIENT ENGAGEMENT PLAN TEMPLATE

Please note that fields with asterisks (*) in the Patient Engagement Plan are mandatory fields to enable Patient Engagement.

<table>
<tr><td colspan="2">INITIATIVE/PROJECT TITLE:</td></tr>
<tr><td colspan="2">MISSION/SCOPE:
Briefly describe the mission and vision and its specific objectives in a language that is clear and understandable by multi-variate stakeholders.</td></tr>
<tr><td colspan="2">1) PURPOSE OF Patient Engagement *
Considering the mission, how can patients and stakeholders help to meet the challenge?</td></tr>
<tr><td>PE goals and challenges
List the goals and challenges</td><td>How patients can help to meet the goals and overcome barriers
Describe how patients can help to meet the goals/overcome barriers.</td></tr>
<tr><td colspan="2">2) PATIENT ENGAGEMENT EXPECTATIONS IN RELATION TO THE 7-STEPS R&I PATH*
What we expect from patients? What type of patients we need to engage? What expertise we need to engage? What are discussion questions to capture patients' experiential knowledge? (Note: Given the expectation from LB, the ECT identify level of engagement, type of patients and requirements. An initiative/project does not necessarily have to act on all the steps).</td></tr>
<tr><td>BREAKING DOWN BOUNDARIES</td><td>Expectations: Example – Patients help to identify requirements, roles and skills of boards in charge of Patient Engagement in order to integrate the patients' experiential knowledge into the R&I process.
Actions plan 1: Example – Define a method to asks patients to provide an overview on the facilities, infrastructures, tools they need to be engaged in research.
Level of engagement: Example – Co-design
Type of patients' representative: Example – people with and affected by the disease, including family members and caregivers
Requirements: Example – No specific or scientific expertise of patients is required other than their experiential knowledge</td></tr>
<tr><td>RESEARCH PRIORITIES</td><td>Expectations: Example – Patients help to identify and prioritize the unmet needs of Patients
Actions plan 2: Examples – Action 2.1: ETC and WG design and launch a "Public consultation" to identify patients' needs, relevance of initiative/project approach and confirm compliance with the initiative/project direction. (online method)
Action 2.2: ECT organize a Focus group with WG (and other relevant stakeholders) to revise the initiative/project according to the outcomes of the public consultation. (offline method)
Action 2.3: ECT and WG works remotely to integrate outcomes of Action 1.1 and Action 1.2 into the development of the initiative/project.
Level of engagement: Example – Consult
Type of patients' representative: Patients, family members and caregivers</td></tr>
</table>

	Requirements: *No specific or scientific expertise of patients is required other than their experiential knowledge*
STEERING INSTITUTIONS	Expectations: *Example – Patients are enabled to integrate their experiential knowledge in R&I being part of the governance and having decision making power.* Actions plan 3: *Example – Action 3.1: Establish governance bodies to enable Patient Engagement in line with MULTI-ACT Governance Model (i.e. ECT, PAB)* Level of engagement: *Example – Co-design* Type of patients' representative: *Example – Patients, family member and caregivers* Requirements: *No specific or scientific expertise of patients is required other than their experiential knowledge*
DESIGN & PLAN	Expectations: *Example – Patients help to co-design specific programs/project* Actions plan 4: *Example – Action 4.1: ECT engage patients as evaluators in the selection of funding or as peer-reviewers* Level of engagement: *Example – To be defined based on the identified actions* Type of patients' representative: *Example – To be defined based on the identified actions* Requirements: *Example – To be defined based on the identified actions*
RESEARCH EXECUTION	Expectations: *Example – Patients help the execution of R&I as co-researchers providing experiential knowledge.* Actions plan 5: *Example – Action 5.1: ECT engage patients for helping in recruitment and data collection* Level of engagement: *Example – To be defined based on the identified actions* Type of patients' representative: *Example – To be defined based on the identified actions* Requirements: *Example – To be defined based on the identified actions*
EVALUATION	Expectations: *Example – Patients help the evaluation of R&I on the outcomes that matter most to them.* Actions plan 6: *Action 6.1: ECT engage patients for data analysis and interpretation, patients asked to design PROs that matter to them.* Level of engagement: *To be defined based on the identified actions* Type of patients' representative: *To be defined based on the identified actions* Requirements: *To be defined based on the identified actions*
TRANSLATION TO COMMUNITY	Expectations: *Example – Patients participate to advocacy campaigns that leverage on R&I's results and help their translation to community as ambassadors.*

	Actions plan 7: *Example – Action 7.1: ETC engage patients in communication activities and outreach, patients co-authored publications and conduct knowledge translation.* Level of engagement: *Example – To be defined based on the identified actions* Type of patients' representative: *Example – To be defined based on the identified actions* Requirements: *Example – To be defined based on the identified actions* Discussion questions: *Example – Is the dissemination material understandable by patients? Are the papers resulting from R&I relevant also from the patient's perspective?*
Wrap-up for all steps	Considering all the action plans, summarize the actions, type of patients and requirements instrumental to define/implement governance boards composition (i.e. ECT and WGs). *Note 1: define if it is enough a WG for all the steps or if there is the need of multiple WGs. WGs are coordinated by the ECT.* *Note 2: assure to be sustainable and to maintain an easy structure.*
3) RISKS AND MITIGATION PLAN	
Risks *Anticipate potential risks*	Mitigation plan *Propose mitigation plan for the risk*
Low participation of the patient community	*Taking advantage of the network of patient organizations and relationships establishment*
4) PE PERFORMANCE ASSESSMENT* *MULTI-ACT provide a menu of indicators*	
Objectives *Define objectives for evaluating the PE Plan*	Means of verification *Clearly define how you are going to verify that the objectives are met.*
Example: *Patient engaged with mixed methods*	*Example:* *Number and type of methods used and events that have taken places to grant patients the possibility to express their views/experiences*
Vision and Agenda meet the needs of patients	*Number of reviews/changes made by patients to the Vision and Agenda according to the gaps identified by patients*
Outcomes of R&I are co-developed and endorsed by patients	*Number of reviews/changes of outcomes related to the 7-steps R&I path produced and endorsed by patients*
5) TRAINING FOR PATIENTS and ECT* *Describe the training program related to the Patient Engagement Plan.*	
Please note that the MULTI-ACT Training module® for the ECT is under development to address the needed skills. *SCOPE:* *Examples:* *Explain the mission and vision* *Provide basic information on the topic, the research context and process* *Explain what is expected from patients and the benefit of engagement (i.e. PE Plan)* *Keep informed on progress (regularly update)*	

ACTIONs: *Example:* *Online/offline training sessions for PWGs* *online engagement methods duly anticipated by exhaustive Information sheet*	
6) RECOGNITION AND REWARDS – VALUE OF COLLABORATION* Clearly state the mutual benefit of engagement and the mechanism to assure it.	
Financial[4]	*Compensation for expenses incurred when participating in research activities (e.g., travel, fuel, parking)*
Personal	*Thank-you letter* *Public mention and acknowledgment (e.g., in social events, on social media)* *Certificate of participation*
Knowledge	*Access to publications resulting from the research to which they contributed* *Access to training* *Access to scientific literature (or other types of knowledge)* *Opportunities to exchange with researchers and other PPRs after completion of the project*
Academic	*Acknowledgement in knowledge transfer communications* *Acknowledgement in articles* *Invitations as speakers at scientific conferences* *Co-authorship in articles*
Altruistic	*Moral satisfaction* *Augmentation of self-worth* *Augmenting wellbeing of others*
Other	
7) PRELIMINARY BUDGET FOR THE PLAN* Define the cost and person months (PM) for the actions resulting from this Plan	
The 7-steps R&I path	Expected costs
BREAKING DOWN BOUNDARIES	*Cost and PM for needed infrastructure set-up* *Cost and PM for ECT establishment and training*
RESEARCH PRIORITIES	*Cost of Public consultation* *Cost for Focus Group (if other representatives beyond ECT and PWGs)* *Cost for ECT (PM needed to develop the actions)* *Cost for PWG (if remuneration is foreseen)*
STEERING INSTITUTIONS	*Cost and PM for the actions defined in step "Steering institution"…*
DESIGN & PLAN	*Cost and PM for the actions defined in step "Design & plan"…*
RESEARCH EXECUTION	*Cost and PM for the actions defined in step "Research execution"…*
EVALUATION	*Cost and PM for the actions defined in step "Evaluation"…*
TRANSLATION TO COMMUNITY	*Cost and PM for the actions defined in step "Translation to community"…*
SUSTAINABILITY	
FUNDIGN SOURCES[5]	*What % of budget may be dedicated to the actualization of PE Plan?*
8) Reporting, meetings & communication channels	
Channels	Use

[4] Please note that the template presents the rewarding model of Smith et Al. 2019 as example. A general description of recognition mechanism is sufficient.

[5] Consider and define the funding sources to cover budget for the Plan.

Meetings (F2F, virtual)	*Meetings among the ECT*
Emails	*Formal and informal communication*
Reporting format	*The Report is expected at M12, M24 describing:* • *the review process in relation to the performance and value of the Patient Engagement;* • *how the objectives of Patient Engagement are met (both on performance and on return on engagement),* • *the value for Patient Engagement (Patient Engagement Plan's outcomes/ Cost to put in place the Plan = Value).*

9) ETHICAL ASSESSMENT/ ETHICAL COMPLIANCE OF THE PLAN*

Describe any ethical aspects to be considered in the plan and propose compensative actions in case of gaps

Actions	Ethical aspects	Tools, mean of verification
Action 1.1: Establish governance bodies and team dedicated to the engagement (i.e. ECT)	*Agreement with the boards' members (i.e. ECT)*	*Term of Reference for boards (i.e. ECT)*
Action 2.1: "Public consultation": Data collection and management	*Develop/check a Data Management Plan (DMP) and integration of patient perspective into its development*	*Informed sheet, Informed consent. Possibility to edit and review DMP with a simple sharing tool (e.g. google drive doc, etc.)*
Action 2.2: Focus group with PWG including people with high disability (e.g. in wheelchair)	*Check accessibility of venue, agenda and timing not stressful. Possibility of web-streaming and recording in case the person cannot participate in person the day of the meeting.*	*Accessible location, light agenda. Recording and web-streaming of the meeting, possibility to give late contribution*
Action 2.3: ECT and PWG works remotely to integrate outcomes	*Compliance with respect of time*	*Appropriate technologies to connect and facilitate the people involved in activities*

10) COMPLIANCE OF THE PE PLAN TO THE MULTI-ACT CRITERIA

Check the criteria for Patient Engagement and list the criteria that are NOT met and if those may affect the performance or the value of the engagement.

Check file MULTI-ACT PATIENT ENGAGEMENT CRITERIA – see D1.6 – Appendix 5

11) TECHNICALITIES, OPERATIONAL ASPECTS

List material and document to be prepared and other technicalities

Timeline for Patient Engagement Plan (GANTT) – PLAN ANNEX 1

Description of rationale for deciding methods to be used – PLAN ANNEX 2 (See D1.6 for suggested methods), etc.

APPENDIX 4: MASTER SCORECARD

Below you will find the full Master Scorecard. Please keep in mind that there are other versions available for your convenience:

- a version in the .xlsx format available in the Digital Toolbox
- a Master Scorecard browser page in the Digital Toolbox

Economic Dimension

Indicator code	Name	Dimension	Topic - Dissagregated – Aspect to be measured	Level 3 – Group of indicators (inductive classification)	Description	Rationale	Core/ Additional	Data Type Representation
Numeric code assinged to the indicator	Short name of the indicator.	PBM/CRIF dimension to which the indicator relates to: - Excellence - Social - Efficacy - Economic	Indicate the overall aspecy that the indicator evaluates within each dimension.	Indicate the category to in which similar indicators can be grouped	Description of the indicator.	Relevance of the indicator and advantages for its use.	Type of indicator within each aspect. Core indicators are key to evaluate each aspect. Additional indicators evaluate some areas which are not covered by the core indicators but that are relevant to provide a more in depth evaluation of the aspect. Additional indicators can also be provided when computing the core indicator is not feasible.	Type of inidicator: Qualitative/Quantitative
1	Anti-competitive behaviour	Economic	Anti-competitive behaviour	Anti-competitive behaviour	The initiative/project applies an intellectual property strategy that is conducive to facilitating access to medicine, operating in accordance with the international consensus on intellectual property standards as it pertains to public health, confirmed by the Doha Declaration.	The indicator evaluates if intellectual property strategies are employed to contribute to access to medicine (e.g. companies pressure governments not to adopt TRIPS flexibilities), at least in developing countries.	Core	Qualitative
2	Projects deviation	Economic	Control	Control process	Deviations related to the schedule or costs of health research processes.	The analysis of deviation allows identifying their causes, as well as reformulate programs and implement corrective actions.	Core	Quantitative
3	Number of audits	Economic	Control	Control process	Number of observations/audits carried out during a specific period of time to monitor the results expected of health research processes.	Audits produce preventive effects in control. The indicator is easy to obtain. Certifications could be used as a proxy.	Additional	Quantitative
4	Economic impacts from commercial development	Economic	Economic externalities	Indirect economic impact	Description and measurement of the impacts of commercializing the outputs of research (e.g. drugs, treatments) on the economy.	The indicator assesses the effect that research findings may have on the overall economy when been commercialized.	Core	Quantitative/Qualitative
5	Economic impact on workforce	Economic	Economic externalities	Indirect economic impact	Description of the economic impact on workforce related to the improvement of employees' health and wellbeing as a consequence of the initiative/project's research findings.	The indicator informs about the contribution to a healthy workforce i.e., work-life balance.	Additional	Qualitative
6	Economic impact on communities	Economic	Economic externalities	Indirect economic impact	Description of the economic effects of the initiative/project's research findings on communities.	The indicator informs about how research findings affect the economic conditions of communities.	Additional	Qualitative

7	Direct economic value generated and distributed	Economic	Economic externalities	Indirect economic impact	Direct economic value generated by the initiative/project, i.e. revenues as well as economic value distributed (operating costs, employee wages and benefits, payments to providers of capital, payments to government by country, and community investments).	This indicator evaluates how the financial resources of the of the initiative/project are distributed among stakeholders.	Additional	Quantitative
8	Return On Investment (ROI)	Economic	Financial Performance	Profitability	Return on investment (ROI) for the research initiative/project. Comparison between the net income obtained or expected to be obtained relative to the cost of investments (value of the assets devoted to their obtention).	The indicator evaluates the capacity of the initiative/project to generate economic profits. It measures its economic efficiency. The calculation of the indicator is simple and enables a high level of comparability.	Core	Quantitative
9	Debt-to-revenue ratio	Economic	Financial Performance	Financial stability	Percentage of the level of debt incurred by an initiative/project compared to the income generated by its research activity.	The indicator evaluates the capacity of an initiative/project to pay back their debt through the profit generated by its research activity. The indicator is standard, easy to calculate and enables comparison with other initiatives.	Additional	Quantitative
10	Return on intellectual property	Economic	Financial Performance	Revenue	Percentage that the revenues obtained from research patents and other intellectual property rights represent with respect to their book value.	The indicator assesses the generation of income of the initiative through the exploitation of their research findings compared to the cost or value of obtaining the right to exploit them. The indicator is easy to calculate, and the information required for its computation is accessible.	Additional	Quantitative
11	Benefit-Cost Ratio (BCR)	Economic	Improvement of health services	Effectiveness in healthcare practice	Cost-benefit ratio of healthcare practice	The indicator measures the overall economic value generated by the initiative/project.	Core	Quantitative
12	Revenue from intellectual property	Economic	Intellectual property	Patents	Value of the revenues obtained from the exploitation of patents and other intellectual property rights.	The indicator assesses the initiative/project's capacity to generate economic revenues from the exploitation of their patents and intellectual property rights. The indicator is easy to calculate, and the information required for its computation is accessible.	Core	Quantitative
13	Achievement of milestones	Economic	Market	Strategy	Number and percentage of achieved health research initiative/project's milestones.	The indicator is clear and applicable to every initiative/project.	Core	Quantitative
14	Market presence	Economic	Market	Market presence	Number of past/potential products and treatments resulting from the outcomes of the research initiative/project.	The indicator is clear and related to efficacy. It also allows evaluating the scope of the treatment/product audience.	Additional	Quantitative
15	Long-term stakeholders loyalty	Economic	Market	Perspective of long term relationships	Describe the perception of and relationships to the different stakeholders related to the research initiative/project.	The indicator evaluates the capacity of the initiative/project to develop a multi-stakeholder and the long term perspective, which is key for RR&I.	Additional	Quantitative/Qualitative
16	Cost per unit	Economic	Organizational efficiency	Cost	Cost per unit of product/service/contracted process provides an accepted measure of economic efficiency.	Cost per unit of product/service/contracted process provides an accepted measure of economic efficiency.	Core	Quantitative
17	Cost control	Economic	Organizational efficiency	Cost savings	Analysis of the influence of the research carried out by the initiative/project on the cost-containment and cost-effectiveness of health services.	The indicator assesses the influence of research on reducing the cost of health systems and health care delivery.	Additional	Quantitative/Qualitative
18	Drug recall system	Economic	Organizational efficiency	Quality	Number and description of drug recalls of products produced by the initiative/project.	The indicator provides details on the effectiveness of drug recall systems.	Additional	Quantitative/Qualitative
19	Job creation	Economic	Resources allocated	Employment	Number of jobs created / expected, disaggregated by gender.	The indicator informs about the capacity of the initiative/project to contribute to employment.	Core	Quantitative
20	Job movement by categories	Economic	Resources allocated	Employment	Total number and percentage of employees of the initiative/project by age group, gender and region.	The indicator offers a description of the employees of the initiative/project.	Additional	Quantitative

Associated terms	Preferred data sources	Method of measurement and estimation	Type of information to be reported by the initiative	Monitoring & Evaluation Framework	Unit of measure	Expected frequency of data dissemination	Expected frequency of data collection

Definition of associated terms that are relevant for understanding the definition of the indicator.	Datasources preferred for gathering the data required for elaborating the indicator. The initiative should provide information that indicate the accurateness of the data	Description of method and/or process to elaborate and report the indicator. (In some cases there is information on this in the last column).	Indicate the type of information that the initiative must provide to disclose the indicator to determine the input areas that the users will need to feed into the Toolbox. - Average - Categorical options list - Free text - Link - Number in monetary units - Number in physical units - Ordinal options list - Percentage, with numerator and denominator - Proportion/Ratio, with numerator and denominator - Table with percentage disaggregated per categories - Table with monetary units disaggregated per categories - Table with absolute numbers disaggregated per categories- Table with absolute numbers and ratios disaggregated per categories – Yes/No	Levels of the results chain framework. Thus, indicate the stage of research process to which the indicator relates: – Input (resources used), - Process (actions carried) – Output (goods and services directly produced) - Outcome (initial results and effects) - Impact (long-term changes)	Indication of the unit in which the indicator is measured Only in those cases where it is applicable.	Indication of how periodic should be the dissemination of the data.	Indication of how periodic should be the collection of the data.
Doha Declaration: World Trade Organization adopted the TRIPS Agreement in 2001 in Doha. The Doha Declaration acknowledges the role of patents in the development of new medicines, but affirms that "the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health". It supports the "principles WHO has publicly advocated and advanced over the years, namely the re-affirmation of the right of WTO Members to make full use of the safeguard provisions of the TRIPS Agreement in order to protect public health and enhance access to medicines for poor countries" (WHO, https://www.who.int/medicines/areas/policy/doha_declaration/en/) TRIPS: Agreement on Trade Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods (https://www.wto.org/english/docs_e/legal_e/27-trips_03_e.htm) TRIPS flexibilities (paragraph 6 of the Preamble of the TRIPS Agreement): "[...] the special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base."	Initiative/project's internal data	Provide a narrative description of the policy of the initiative/project regarding its intelectual property strategy. The initiative/project can provide a link to a document where it is disclosed.	Free text	Process	N/A	Annually	Annually
Project deviation: Any non-conformity between the plan of a project and actual work.	Initiative/project's internal data	Compute a percentage that accounts for the deviations identified. There are different alternatives: - Number of projects with cost overrun issues / total number of projects - Number of projects with schedule overrun issues / total number of projects – Total cost overrun by all the project / expected cost by all the projects This information should ideally compared with the previous year or with targets.	Percentage, with numerator and denominator	Process	Percentage	Annually	Annually
Audit: An internal (conducted by the own organization)/external (conducted by third independent parties) examination of a process to add credibility to its reliability and integrity. Certification: Tool that adds credibility to a process, product or service, demonstrating that it meets certain characteristics. There are numerous certifications available in the market for different products, processes, services and characteristics.	Initiative/project's internal data	Provide the number of observations/audits performed during the reporting period. This information should ideally be compared with the two previous years or with targets.	Number in physical units	Process	Absolute number Table with absolute numbers disaggregate d per categories	Annually	Annually
Drug supply: The distribution, provision and/or sale of health care products.	Information compiled internally by the organization with the input of other stakeholders (if needed)	Provide a narrative description of the economic impact for society of commercializing research outputs, for example, creation of employment, import substitution and drug cost. When possible, provide the monetary value of those impacts (e.g. reduced drug cost).	Free text Number in monetary units	Impact	Local currency	Annually	Annually

Healthy workforce: Status of health of the employees that comprise a specific work systems at the organizational, local, regional, national or supranational level.	Initiative/project's internal data National/regional/local registries	Provide a narrative description of the economic impact on workforce related to the improvement of employees' health and wellbeing resulting from the initiative/project's research.	Free text	Impact	N/A	Annually	Annually
Community benefit: The enhancement of community health outcomes as a result of research outputs (Sarli et al., 2010).	Information compliled by the initiative	Provide a narrative description of how the initiative/project's research findings lead to the enhancement of well-being and economic conditions among community members.	Free text	Impact	N/A	Annually	Annually
Economic value: Wealth that an organization creates for stakeholders. Revenues: Net sales plus income from financial investments and sales of assets.	Annual report Financial statement Initiative/project's internal data	Provide a table dissagregating the total direct economic value generated (Financial resources obtained – financial resources produced) for each stakeholder type to which the initiative/project relates.	Table with monetary units disaggregated per categories	Outcome	Local currency	Annually	Annually
Return on investment: Percentage of the net profit of an investment compared to the cost of the investment/assets. Income: Revenue minus expenses. Assets: Elements owned by or belonging to an organization, which can be monetarily valued. An asset can be (1) something physical, such as cash, machinery, inventory, land and building, (2) an enforceable claim against others, such as accounts receivable, (3) right, such as copyright, patent, trademark, or (4) an assumption, such as goodwill.	Financial report	There are two alternative methods. The initiative/project can decide to provide one or both. 1) Specific for health research initiatives: Calculate the percentage that health gains and wider economics gain represent relative to the investment in medical research, with a lag between expenditure and outcomes, adjusting for inflation and discounting at a rate of 5% (More detailed information on how to calculate the ratio is provided in KPMG, Economic Impact of Medical Research in Australia (2018)). 2) General ROI: Calculate the percentage that the income generated by the initiative represents respect to the value of its assets.	Percentage, with numerator and denominator	Output	Percentage	Annually	Annually
Debt: Amount owed for funds borrowed. Income: Revenue minus expenses.	Initiative/project financial report	Divide the total debt registered in the balance sheet of the initiative/project by the operating income registered in the profit and loss statement that can be directly attributed to research result exploitation, and multiple the result times 100.	Percentage, with numerator and denominator	Output	Percentage	Annually	Annually
Patent/intellectual property: The official legal right to make or sell an invention for a particular number of years (Cambridge Dictionary). Book value of the patent/intellectual property: Value that a patent has in the balance sheet of the initiative.	Initiative financial report	Divide the revenues obtained from the exploitation of patents and other intellectual property rights during the reporting period by the total value of the patents and intellectual property registered in the balance sheet of the initiative, and multiply the result times 100.	Percentage, with numerator and denominator	Output	Percentage	Annually	Annually
Cost-benefit analysis: Process by which organizations can analyze/identify the benefits of an action as well as the associated costs. The ratio is obtained by dividing the total benefits by the total costs. Health outcomes: Changes in health that result from specific health care interventions/programs. Return on investment: Percentage of the net profit of an investment compared to the cost of the investment/assets.	Annual report	Divide the (discounted) benefits of a project expressed in monetary terms by the (discounted) incremental costs. Monetary benefits can be assessed, for instance, through willingness to pay techniques.	Percentage, with numerator and denominator	Outcome	Percentage	Annually	Monthly/Annually
Patent/intellectual property: The official legal right to make or sell an invention for a particular number of years (Cambridge Dictionary). Revenue from intellectual property: Income obtained from exploiting intellectual property rights.	Scientific report Financial report	Provide the total amount of income (in euros or the domestic currency of the initiative/project) that the initiative obtained from the exploitation of their patents and other intellectual property rights. For the sake of comparison, the initiative shall report the same figure for the two prior periods.	Number in monetary units	Output	Local currency	Annually	Annually
N/A	Initiative/project's internal data.	Provide the number (#) and percentage (%) of strategic/plans completed and milestones met.	Number in physical units Percentage, with numerator and denominator	Process	Project/Milestone Percentage	Annually	Annually
N/A	Information compiled internally by the organization.	Count the number of past/potential products and treatments developed by the initiative/project.	Number in physical units	Output	Products and treatments	Annually	Annually

Stakeholder engagement: Activities that can be done with stakeholders: consult, listen, understand, communicate, influence, negotiate, etc., with the broader objectives of satisfying their needs, gaining approval and support, or at least minimising their opposition or obstruction (D9.1)	Surveys	Description of the relationships with stakeholders related to the research initiative/project. Quantitative scores given by stakeholders in surveys disaggregated by stakeholder type.	Free text Table with absolute numbers and ratios disaggregated per categories	Outcome	N/A	Triennial	Triennial
Cost per unit: The production cost for each unit. Equal to total cost of production divided by the quantity of units produced.	Financial statements Internal management control systems	Calculate the overall costs per unit divided by the number of units (please note that the unit can vary from products to services and processes).	Number in monetary units	Input	Local currency	Annually	Annually
Cost-effectiveness: Comparison between the relative costs and outcomes (effects) of health services.	National/Regional/Local health systems' records and financial statements Expert consultation	Provide a narrative description of costcontainment strategies as well as monetary information describing the effectiveness of those strategies. Cost-effectiveness can be studied by analyzing research-related changes in health systems in terms of both expenditure and related health outcomes.	Free text Number in monetary units	Outcome	Local currency	Annually	Annually
Drug recalls: Removal of a defective drug product from the market.	Annual report	Narrative description and numbers of products tracked and whether this information is publicly disclosed (where, when and why a drug recall has taken place).	Free text Number in physical units	Process	Product recall	Annually	Annually
Job creation: Process by which the number of jobs increases.	Annual report Initiative/project's internal data	Count the total number of job created and expected to be created (i.e. the total number of employees) disaggregated by gender.	Number in physical units	Input	Number of new employees	Annually	Annually
N/A	Initiative/project's internal data	Calculate the total number and percentage of employee by age group, gender and region.	Table with absolute numbers disaggregated per categories Table with percentage disaggregated per categories	Input	Employees Percentage	Annually	Annually

Limitations	Indicator in use	Example	Links	Comments	Feasability of elaborating the indicator
Main problems that could emerge when elaborating the indicators and potential disadvantages and/or shortcoming when using the indicators.	Indication of whether the indicator is currently being used: Yes/No	Example of a report, webpage, etc that provides an example on how to report the indicator.	Links of interest to either understand or compute the indicator.	Additional comments.	The initiative shall indicate whether it considers that it has access to the data needed to compute the indicator considering the data sources and additional information provided in the scorecard. To be filled by the initiative: Yes/No.
The information and data required to produce this indicator could not be easy to find, particularly if there is no formal policy regarding intellectual property.	Yes	See Sanofi CSR report 2011, p. 463			
Comprehensiveness might come at the expense of producing overburdening information.	Yes	McKinsey & Company 2012, p. 4 more specifically: it shows an example of deviation projects' causes.		Although this information is available, research organizations might not be prone to disclosing it as it might indicate the existence of inefficiencies.	
The indicator does not provide information on the quality of the audit conducted.	Yes	Bayer Annual Report 2017, p. 105		Certifications could be used as a proxy.	
Comprehensiveness might come at the expense of overburdening information.	Yes	Example of financial impact evaluation included in the section on "financial, environmental and social impact valuation": Novartis Corporate Responsibility Report 2017 (p. 15)			
Providing a thorough description might require a large amount of information.	No				
Providing a thorough description might require a large amount of information.	No				
Accurately disaggregating the economic value and attributing it to stakeholders might be difficult and time-consuming.	Yes	Rovi Annual Report 2017 (p .9)			

Although the ROI specific for health research can provide valuable economic and financial information, its calculation might be difficult for some initiatives/projects.	Yes	For the ROI specific for health research: KPMG, Economic Impact of Medical Research in Australia (2018) (p. 42, Table 7). For the general ROI: Bayer Annual Report 2018 (p. 103, named as ROCE).		Ideally, an initiative/project should provide the ROI specific for health research. Given the complexity of its calculation, it can opt for the general ROI if the first option is too demanding.	
Estimating the direct operating income directly attributed to the exploitation of research findings might be difficult due to the complexity of allocating the operating expenses that are directly related to their obtention. If the initiative/project cannot estimate them, it can use the overall operating income as proxy if its main activity is performing research.	No			Process to calculate it considering the information provided in financial statements. For instance, in the Burnet Institute 2018 Financial Report, divide "total liabilities" (p. 10) by "results from operating activity" (p. 9) times 100. The Burnet Institute 2018 Financial Report is available at: https://www.burnet.edu.au/system/annual_report/file/25/Financial_Report_2018_-_digital.pdf	
The indicator only evaluates the economic return of patents, but it does not capture the actual effect that the application of patents has on patients.	No			Example on how to calculate it: Sanofi 2018 Annual report: divide "other intangible assets" (see note D.35.3 – page F111) by "carrying amount of products, trademarks and other rights" (see note D.4 – page F44) If the indicator is difficult to calculate to some initiatives, it could be simplified by dividing the revenues obtained from the exploitation of patents and intellectual property rights by the total number of patents/intellectual property rights owned by the initiative.	
The indicator requires that all costs and benefits can be identified and appropriately quantified. Assessing monetary values of health outcomes can be difficult.	Yes	For the Benefit to cost ratio specific for health research: "Exceptional returns: the value of investing in health R&D in Australia II" (pp. 34-35).		The data can be provided in a graphic like in the example.	
The indicator only evaluates the economic return of patents, but it does not capture their actual application.	Yes	Fraunhofer Institutes Annual Report 2017 (p. 33)		This indicator can be used to compute the indicator "return on intellectual property".	
The indicator does not reflect the quality or impact of projects. It needs to be complemented with that information.	Yes	Australia and New Zealand CRC for Spatial Information Annual Report 2016-17, p. 9			
The indicator does not account for the products/treatments' efficacy or impact on patients nor society. It needs to be complemented.	Yes	Sanofi Integrated Report 2018 (p. 6).		The example only provide the number of new products developed during the reporting period.	
Difficulties in performing the survey and reaching the proper stakeholders.	No				
There might be difficulties in attribution issues regarding costs included in the calculation and indirect costs involved in the production process.	No			The indicator must be tested and adjusted through a regular, double-feedback-loop process (Kaplan & Norton, 2006), which analyses the differences between what was foreseen and the actual results and accordingly changes the model and the strategic assumptions at the basis of its construction.	
The uncertainty of estimations and the differences in choices of measurement of costs and benefits significantly impact the interpretation of the information. Difficulty of attributing the specific contribution to cost saving of the initiative/project.	No				
The indicator does not inform about the effects on the initiative/project (possibility of wrong judgements). The indicator is particularly relevant for pharma industry.	No				
The indicator does not inform about the quality and long-term horizon of the jobs created.	Yes	PhRMA web page: https://www.phrma.org/ media/industry-economic impact		The example does not disaggregate the number of jobs created by gender.	
	Yes	Bayer Annual Report 2018, pp. 53-54			

Social Dimension

Indicator code	Name	Dimension	Topic - Dissagregated – Aspect to be measured	Level 3 – Group of indicators (inductive classification)	Description	Rationale	Core/ Additional	Data Type Representation

Numeric code assinged to the indicator	Short name of the indicator.	PBM/CRIF dimension to which the indicator relates to: - Excellence - Social - Efficacy - Economic	Indicate the overall aspecy that the indicator evaluates within each dimension.	Indicate the category to in which similar indicators can be grouped	Description of the indicator.	Relevance of the indicator and advantages for its use.	Type of indicator within each aspect. Core indicators are key to evaluate each aspect. Additional indicators evaluate some areas which are not covered by the core indicators but that are relevant to provide a more in depth evaluation of the aspect. Additional indicators can also be provided when computing the core indicator is not feasible.	Type of inidicator: Qualitative/Quantitative
101	Social reputation	Social	Corporate reputation	Reputation	Description of the social reputation of the research project/initiative.	The indicator allows evaluating how research is perceived by society.	Core	Qualitative
102	Ethical marketing & anti-corruption	Social	Ethical marketing	Ethical marketing	Indication of whether the initiative/project has clearly defined enforcement procedures and, if there have been misconducts, evidence of taking disciplinary action against employees or third parties who have violated its code of conduct for ethical marketing or anti-corruption. The initiative/project provides evidence of follow-up actions taken to mitigate the risk of future breaches.	The indicator is feasible for research funding and performing organizations. The existence of enforcement procedures for the compliance with the code of ethical marketing and anticorruption denotes the existence of such code.	Core	Qualitative
103	Safety & security policy	Social	Labour	Safety and security	Number of employee accidents and infections in laboratory facilities.	The indicator evaluates the effectiveness of health, safety and security policy.	Core	Quantitative
104	Labor practices	Social	Labour	Labour rights	Significant actual and potential impacts for labour practices driven by the research initiative/project.	The indicator describes the impact on labour at the national/regional/local levels driven by the effect of research findings.	Additional	Qualitative
105	Employee turnover	Social	Labour	Labour rights	Employee turnover during the reporting period, by age group and gender at the local/regional/national levels.	The comparison of this indicator contributes to evaluate the influence of the initiative/project on the overall labour condition by comparing its trend to the ones of the initiative/project.	Additional	Quantitative
106	Training for researchers	Social	Labour	Training and education	Average hours of training programs for research employees, disaggregated by gender group, in the reporting period relative to the average number of research employees.	The indicator evaluates the contribution of the initiative to improve the human capital and education of its research employees.	Additional	Quantitative
107	Knowledge-driven changes in policy	Social	Political externalities	Political influence	Description and number of policies and guidelines informed by the research initiative/project.	The indicator provides an overview of the influence of the research initiative/project in the development of health policies and guidelines.	Core	Quantitative/Qualitative
108	Improved research governance	Social	Political externalities	Improved governance	Description and number of adopted measures to improve the governance and organization of the project/initiative's research activities.	The indicator allows the initiative/project to self-evaluate the governance and organization its research activities and identify best practices and measures that could help to improve them.	Additional	Qualitative
109	Interaction with relevant external actors	Social	Political externalities	Political contributions	Description of the interaction between the research initiative/project and external relevant actors (e.g. government agencies).	The indicator allows identifying new/closer external relevant actors (e.g. government agencies). The lack of relationships can be a weak point of a research initiative/project. Importance to enhance the possibility of research results to influence policy and practice.	Additional	Qualitative
110	Environmental auditing	Social	Socio-environmental impacts	Audits and certification	Number of environmental audits conducted within the initiative/project.	The indicator allows stakeholders to evaluate the commitment regarding the management of environmental impacts resulting from research.	Core	Quantitative
111	Material intensity	Social	Socio-environmental impacts	Sustainable consumption	Quantity of raw materials needed for manufacturing purposes (during the research and production processes).	The indicator can be computed by applying clear guidelines. Considering the characteristics of research funding and performing organizations, it could be advisable to consider a relative measure of material intensity.	Core	Quantitative
112	Transparency in sustainability reporting	Social	Socio-environmental impacts	Scope and parameters of information	Public reports about the economic, social and environmental impacts resulting from the research and how they are being managed.	The indicator demonstrates the accountability and transparency of research by providing information for stakeholders to evaluate it.	Additional	Qualitative
113	Volume of GHG emissions	Social	Socio-environmental impacts	Pollution	Amount of greenhouse gas (GHG) emissions from activities carried out by the initiative or project. The main gases to be considered are carbon dioxide (CO_2), methane (CH_4), nitrous oxide (N_2O) and hydrofluorocarbons (HFCs), among others.	The indicator informs about the effect of the initiative/project on climate change through their GHG emissions. By providing data of the current and prior reporting periods, stakeholders can evaluate the evolution (reduction or increase) of emissions. Emissions can be computed using clear available guidelines.	Additional	Quantitative

114	Successful operations aimed to engage the local community	Social	Socio-environmental impacts	Impact on communities	Implemented actions for enhancing local community engagement, impact assessments, and development programs based on local needs.	The indicator seeks to identify the scope of community engagement efforts applied by the initiative/project.	Additional	Quantitative
115	Community engagement activities	Social	Stakeholder engagement	Stakeholder engagement	Description of the activities organized by the initiative/project to promote the engagement with community members.	The indicator provides information on the actions taken by the initiative/project to foster and increase the collaboration with communities.	Core	Qualitative

Associated terms	Preferred data sources	Method of measurement and estimation	Type of information to be reported by the initiative	Monitoring & Evaluation Framework	Unit of Measure	Expected frequency of data dissemination	Expected frequency of data collection
Definition of associated terms that are relevant for understanding the definition of the indicator.	Data sources preferred for gathering the data required for elaborating the indicator. The initiative should provide information that indicate the accurateness of the data	Description of method and/or process to elaborate and report the indicator. (In some cases there is information on this in the last column).	Indicate the type of information that the initiative must provide to disclose the indicator to determine the input areas that the users will need to feed into the Toolbox. - Average - Categorical options list - Free text - Link - Number in monetary units - Number in physical units - Ordinal options list - Percentage, with numerator and denominator - Proportion/Ratio, with numerator and denominator - Table with percentage disaggregated per categories - Table with monetary units disaggregated per categories - Table with absolute numbers disaggregated per categories- Table with absolute numbers and ratios disaggregated per categories – Yes/No	Levels of the results chain framework. Thus, indicate the stage of research process to which the indicator relates: – Input (resources used), - Process (actions carried) – Output (goods and services directly produced) - Outcome (initial results and effects) - Impact (long-term changes)	Indication of the unit in which the indicator is measured Only in those cases where it is applicable.	Indication of how periodic should be the dissemination of the data.	Indication of how periodic should be the collection of the data.
N/A	Surveys Interviews	Provide a narrative description of the social reputation of the research project/initiative.	Free text	Outcome	N/A	Annually	Annually
Ethical marketing: The systematic study of how moral standards are applied to marketing decisions, behaviours and institutions (Murphy et al., 2005, p. 17). Corruption: The abuse of entrusted power for private gain (Transparency International). Code of ethics/Code of conduct: A statement setting down corporate principles, ethics, rules of conduct, codes of practice or company philosophy concerning responsibility to employees, shareholders, consumers, the environment, or any other aspects of society external to the company (Langlois and Schlegelmilch, 1990, p. 522). Enforcement procedures: Mechanisms and sanctions established to guarantee the effective application of the code of ethics and deal with potential violations. Risk: Future uncertainty about deviation from expected outcome.	Initiative Code of Ethics/Conduct. The initiative should provide a link to the public documents where the code of ethics/conduct is provided.	Indicate Yes/No depending on whether the initiative/project has clearly defined enforcement procedures and (where there has been misconduct) provide evidence of taking disciplinary action against employees or third parties who have violated its code of conduct for ethical marketing or anti-corruption. Provide a description of evidence of follow-up actions taken to mitigate the risk of future breaches.	Yes/No Free text	Process	N/A	Annually	Annually

Working conditions: Conditions in which employees work, including degree of safety or danger.	Annual report Sustainability report Internal report	Calculate the frequency rate of accidents as the number of accidents suffered during the period, divided by the total hours worked in the same period and multiplied by 1,000,000.	Number in physical units	Impact	Frequency rate	Annually	Annually
N/A	Sustainability report	Provide a narrative description of the impact on labour at the national/regional/local levels driven by the effect of research findings.	Free text	Impact	N/A	Annually	Annually
Employee turnover: Percentage of workers who leave an organization and are replaced by new employees.	Initiative/project's internal data National/regional/local data registries	Calculate the employee turnover during the reporting period by age group and gender at the local/regional/national levels. Employee turnover is the percentage of employees leaving the organization in a period, relative to the average number of employees during this period.	Percentage, with numerator and denominator	Input	Percentage	Annually	Annually
Training program: Set of activities that contribute to improving health care research and practice by the means of courses, workshops and mentoring.	Sustainability report	Divide the hours of training programs for research employees disaggregated by gender group in the reporting period by the average number of research employees during this period.	Number in physical units	Input	Hour/employee	Annually	Annually
Expected / targeted changes: Milat et al. (2013) follow Banzi et al. (2011) to differentiate five broad categories of research impacts: i) advancing knowledge; ii) capacity building; iii) informing decisionmaking; iv) health benefits; and, v) broad socio-economic benefits. Milat et al. (2013) found that knowledge generated through research projects can inform practice and lead to changes through: informing organizational development, leading to new intervention tool and resources, informing professional development, health promotion and programs.	Initiative/project's internal data	Provide the number and description of policies and guidelines informed by the research initiative/project. The initiative can provide a link to a document where it is disclosed.	Free text Number in physical units	Impact	N/A	Annually	Annually
Governance: Internal structure and decision-making scheme of a research initiative, which will enable the appropriate management of project activities in the long run (D5.1)	Initiative/project's internal data.	Provide a narrative description of the measures adopted by the project/initiative to improve the governance and organization of its research activities. The initiative/project can provide a link to a document where the description is disclosed.	Free text	Process	N/A	Annually	Annually
External stakeholder: Individuals or groups that are outside the organization's environment, have some interest in the initiative's aims and might influence to different extents its execution and the accomplishment of its expected results. Government agencies are a type of external stakeholders.	Own organization	Narrative description of the interaction between the research initiative/project and external relevant actors (e.g. government agencies). The initiative can provide a link to a document where it is disclosed.	Free text	Outcome	N/A	Annually	Annually
Environmental audit: External (conducted by third independent parties) examination of a process to add credibility to its reliability and integrity. Environmental management/compliance: Conforming to environmental laws, regulations and standards.	Environmental management system documentary Annual report Sustainability report	Provide the number of internal and/or external environmental audits conducted.	Number in physical units	Process	Physical units	Annually	Annually
Sustainable product manufacturing: Creation of healthcare products through economically-sound processes (i.e. with few negative environmental impacts). Raw material: Materials or substances used in the primary production or manufacturing of products (e.g. the excipients or the components).	Production and research sites of the company Sustainably report Billing and accounting systems, procurement or supply management department	Identify the total materials used (raw materials, natural resources, materials needed for the manufacturing process, parts, components and materials for packaging purposes). Report the total weight or volume of all raw material needed for developing, producing and packaging the primary products (or services): i. non-renewable materials used; ii. renewable materials used.	Number in physical units	Input	Physical units	Annually	Monthly/Annually
N/A	Sustainability report Strategy documents Annual report	Indicate whether there is a publicly available information on the social and environmental impacts resulting from the research and/or how they are being managed. Provide a reference or link to access the information.	Yes/No Free text	Process	N/A	Annually	Annually
Greenhouse gas (GHG): Any of various gaseous compounds (carbon dioxide for example) that trap heat or longwave radiation in the atmosphere and contribute to the greenhouse effect.	Initiative/project management control systems	Calculate direct GHG emissions using relevant global warming potential (GWP) rates to translate the amount of emissions of a GHG into CO2 equivalents. Considering the characteristics of research funding and performing initiatives/projects, it could be advisable to consider the change in emissions to demonstrate reduction, rather than the absolute amount of GHG emissions. Following GRI and the Greenhouse Gas Protocol, GHG emissions are measured according to three scopes: • Direct (Scope 1) • Energy indirect (Scope 2) • Other indirect (Scope 3) emissions.	Number in physical units	Output	Tons	Annually	Monthly/Annually
Community involvement/engagement: The inclusion and consideration of communities as a key stakeholder in the decisionmaking process to plan, manage and carry out research.	Initiative/project's internal data Social/gender/health/environmental impact assessments Stakeholder engagement / community development plans	Identify the total number of actions aimed to improve community development and calculate the percentage of actions that have been executed in practice respect to the planned actions (local community engagement, impact assessment, or development programs).	Number in physical units Percentage, with numerator and denominator	Outcome	Physical units	Annually	Annually

Public/community involvement/engagement: The inclusion and consideration of communities as a key stakeholder in the decisionmaking process to plan, manage and carry out research. Stakeholders engagement: Activities that can be done with stakeholders: consult, listen, understand, communicate, influence, negotiate, etc., with the broader objectives of satisfying their needs, gaining approval and support, or at least minimizing their opposition or obstruction (D9.1).	Own organization	Provide a narrative description of the activities organized by the initiative/project to promote the engagement with community members. The initiative can provide a link to a document where it is disclosed. Patient Engagement model elaborated by MultiAct provides information about engagement activities.	Free text	Outcome	N/A	Annually	Annually

Limitations	Indicator in use	Example	Links	Comments	Feasibility of elaborating the indicator
Main problems that could emerge when elaborating the indicators and potential disadvantages and/or shortcoming when using the indicators.	Indication of whether the indicator is currently being used: Yes/No	Example of a report, webpage, etc that provides an example on how to report the indicator.	Links of interest to either understand or compute the indicator.	Additional comments.	The initiative shall indicate whether it considers that it has access to the data needed to compute the indicator considering the data sources and additional information provided in the scorecard. To be filled by the initiative: Yes/No.
Computing the indicator requires the use of surveys and interviews to identify the social perception of research.	Yes	Corporate Reputation of Pharma in 2018 – the Global Patient Perspective			
This indicator measures procedures but not performance (results).	Yes	See the "Code of pratices for the pharmaceutical industry 2016" (see Sections 21 and 22 p. 34) and the GSK Annual Report 2018 (p. 244).			
This indicator can suffer for the unclear definition of "infection". The idea is to keep this indicator broad and it would consider all sort of accidents.	Yes	Sanofi CSR report 2013, p. 105	Injury frequency rate: http://www.hse.gov.uk/statistics/adhoc-analysis/index.htm		
The information is mainly qualitative, which can be difficult to compare between initiatives/projects.	No				
Employee turnover could be misleading in this sector, as mobility could be a problem, but excellence in research also requires the mobility of talent.	Yes	Novartis – Corporate Responsibility Report 2017, p. 47			
	Yes	See Sanofi Turkey Sustainability Report 2017 (p. 89)			
It can be challenging to distinguish how specific research informs a particular policy.	No			In research organizations, this information is often implicit. Indicators 66 & 107 provide complementary perspectives.	
Identifying best practices to adopt improving measures can be time consuming. It requires the establishment of effective identification methodologies.	No			MoRRI – Monitoring the Evolution and Benefits of Responsible Research and Innovation (pp. 86-92)	
The breath of the information that might be included under this indicator may be general information about stakeholder engagement.	Yes	GSK Annual Report 2018, p. 11		This information is often embedded in the general section about stakeholder engagement (see example). If that is the case, the initiative can refer to that section.	
Informing about the results of environmental audits can be compromising.	Yes	Sanofi CSR report 2013, p. 51	ISO 14001 provides the guidance for use an environmental management system https://www.iso.org/standard/60857.html		
This is a rough indicator to measure eco-efficiency. Difficulty in obtaining all the information necessary.	Yes	Takeda Sustainable Value Report 2018, p. 61	See GRI standards (GRI 301) for more information on how to calculate the indicator: https://www.globalreporting.org/standards/		

The indicator might be negative in many case which does not necessarily imply lack of interest in being transparent. Producing external information could be costly and some research initiatives might not be able to do it.	Yes	FISM sustainability reports 2018			
Difficulty in obtaining all the information necessary to calculate GHG emissions for research	Yes	Novartis Health, Safety and Environment (HSE) Data 2018 https://www.novartis.com /our-company/corporateresponsibility/environmen tal-sustainability			
The indicator does not reveal the effectiveness or content of the community development and the engagement actions taken.	No				
The indicator does not provide information on the quality of actions.	Yes	Ottawa Public Health Strategic Direction A Background Document September 2016 (p. 14).			

Excellence Dimension

Indicator code	Name	Dimension	Topic - Dissagregated – Aspect to be measured	Level 3 – Group of indicators (inductive classification)	Description	Rationale	Core/ Additional	Data Type Representation
Numeric code assinged to the indicator	Short name of the indicator.	PBM/CRIF dimension to which the indicator relates to: - Excellence - Social - Efficacy - Economic	Indicate the overall aspecy that the indicator evaluates within each dimension.	Indicate the category to in which similar indicators can be grouped	Description of the indicator.	Relevance of the indicator and advantages for its use.	Type of indicator within each aspect. Core indicators are key to evaluate each aspect. Additional indicators evaluate some areas which are not covered by the core indicators but that are relevant to provide a more in depth evaluation of the aspect. Additional indicators can also be provided when computing the core indicator is not feasible.	Type of inidicator: Qualitative/Quantitative
44	Publications	Excellence	Academic production	Publications	Number of publications produced by the initiative/project, differentiating the key subject under study and whether or not they are peer-reviewed, and percentage of those articles published in high-impact journals.	The indicator evaluates the extent and level of the academic production of the initiative/project.	Core	Quantitative/Qualitative
45	Collaborative publications	Excellence	Academic production	Publications	Number of publications with co-authors affiliated to organizations in different countries and sectors.	The indicator measures the collaboration in publications as a proxy for the quality and broadness of the initiative/project's research capacity.	Additional	Quantitative
46	Open access publication	Excellence	Academic production	Publications	Number and percentage of open access publications (differentiating between green and gold open access when possible).	The indicator informs about the committment of the initiative towards transparency by faciliting the transference and openess of their research results and making them accesible to the general public.	Additional	Quantitative
47	Anticipatory health research design	Excellence	Anticipatory design	Anticipatory design	Degree of anticipatory design in health research processes.	The indicator evaluates foresight techniques. Moreover, this indicator has been identified as "key" for experts in the field through the interviews carried out in D3.5.	Core	Qualitative
48	Academic citations	Excellence	Bibliometric	Citations	Number of citations in academic publications.	The indicator shows the number of times the article has been cited as proxy for the academic relevance of research outputs.	Core	Quantitative
49	Diffusion score of academic citations	Excellence	Bibliometric	Citations	Diffusion score of the applicability of new knowledge: balance and distribution of citations from various fields.	The indicator measures the applicability of research findings across subject areas, represents the robustness of the findings, incorporates features of traditional measures of diversity in assessing the balance and distribution of citations arising from different topic/subject categories. For example, if an article A is cited by Physics and Chemistry and an article B by Math, Music and Forestry the diffusion score would be greater for article B since there is greater heterogeneity among its citing subject categories.	Additional	Quantitative
50	Research impact on practice guidelines	Excellence	Bibliometric	Citations	Number of studies produced by the initiative/project that have been cited in guidelines issued by a government agency, an organization related to the field of study, or a non-governmental organization.	The indicator shows how the findings are disseminating and cumulating knowledge. It measures the diffusion of research outputs into knowledge transfer, clinical implementation, or community benefit outcomes resulting from research studies.	Additional	Quantitative

51	Dissemination activities	Excellence	Communication	Dissemination	Number of dissemination/outreach activities other than peer-reviewed publications (e.g. conferences, workshops, press releases, media/social media campaigns).	The indicators report on the dissemination activities to promote and communicate research outcomes.	Core	Quantitative
52	Media coverage	Excellence	Communication	Media coverage	Number of media hits and press articles raising awareness on the initiative/project research activities.	The indicator measures the results of public relationship efforts.	Additional	Quantitative
53	Online content management	Excellence	Communication	Dissemination	Assessment of the reach and accessibility of the webpage of the initiative/project.	The indicator shows the activity of the webpage of the initiative/project.	Additional	Quantitative
54	Acknowledgment of Responsible Research and Innovation (RRI) standards and regulations	Excellence	Compliance	Compliance	Description of the extent to which standards and regulations regarding RRI are acknowledged, complied with and embedded in the research process of the initiative/project.	The indicator informs about the consideration of RRI standards when performing research. In so doing, it provides stakeholders with information to assess the responsibility and ethics of the initiative/project's research process.	Core	Qualitative
55	Compliance and adherence to clinical guidelines	Excellence	Compliance	Clinical guidelines	Description of the extent to the initiative/project complies with clinical guidelines.	The indicator provides a starting point to analyze whether the research process is being responsible by fulfilling the basic requirement of complying with clinical guidelines to guarantee the adequate treatment of patients.	Additional	Qualitative
56	Risk identification & management	Excellence	Compliance	Risk	Description of the processes that the initiative/project follows to identify potential risks related to the research process and how these risks are managed.	The indicator promotes accountability as it allows stakeholders to evaluate the potential risks that could emerge as a result of the research process. Additionally, it also provides benefits to the initiative/project because it helps it to make a self-assessment of its research process.	Additional	Qualitative
57	Research ethics committee	Excellence	Ethics and integrity	Ethics	Indication of the existence of an ethical committee to manage research, and description of its structure (indicating its composition and gender distribution) and functions.	The indicator provides information that allows evaluating the consideration of ethical issues in research.	Core	Qualitative
58	Principles and values	Excellence	Ethics and integrity	Ethics	Overview of the initiative/project's values, principles and standards, specifying how they have been approved, developed, and implemented in the health research process.	The indicator describes in detail the values, principles, standards and norms of behavior of the initiative/project.	Additional	Qualitative
59	Ethical assessment in funding decisions	Excellence	Ethics and integrity	Ethics	Describe whether and how the health research initiative/project integrated any type of ethical assessment/review in its funding decisions.	The indicator is based on the dedicated survey of the funding organizations and its question 'Has your organization integrated any type of ethics assessment/review in its funding decisions?' (MORRI, 2017).	Additional	Qualitative
60	Research grants	Excellence	Financial resources	Research funding	Number of grants and their monetary amount.	The indicator measures the research funding obtained from grant applications.	Core	Quantitative
61	Collaborative research and funding	Excellence	Financial resources	Research funding	Collaborative research projects funded through joint calls that address the scientific priorities identified by the initiative.	The indicator shows the success of the initiative/project in aligning its research agenda with other partners.	Additional	Quantitative
62	Public engagement in funding decisions	Excellence	Financial resources	Research funding	Indication of whether and how the initiative/project takes public engagement elements into account for the development or evaluation of R&I projects.	The indicator shows how the public engagement elements are taken into account as evaluative criteria in research proposal evaluations and developments.	Additional	Qualitative
63	Innovation in taxonomies of diseases and stratifications	Excellence	Impact evaluation	Overall impact evaluation	Number of the new taxonomies of diseases and new stratifications developed, published or implemented.	The indicator shows the development in defining the diagnosis, treatment, and mechanisms of diseases.	Core	Quantitative
64	Impact on patients	Excellence	Impact evaluation	Overall impact evaluation	Description of the overall impacts for patients generated by the initiative/project.	The indicator describes the positive and negative impacts for patients driven by the research and activities carried out by the initiative/project.	Additional	Qualitative
65	Impact on society	Excellence	Impact evaluation	Overall impact evaluation	Description of the overall impacts for society generated by the initiative/project.	The indicator describes the positive and negative impacts for society driven by the research and activities carried out by the initiative/project.	Additional	Qualitative
66	Knowledge-driven changes in practice	Excellence	Influence on public behaviour	Knowledge & Behaviour	Description of the expected or targeted changes in knowledge, attitudes and behavior as a result of research dissemination and implementation strategies.	The indicator evaluates whether the excellence of knowledge generated by health research goes together with practice changes in the application of the knowledge generated.	Core	Qualitative
67	Research targeting	Excellence	Influence on subsequent research	Influence on and improvements for future research	Level of contributions to follow-on research (e.g. pilot studies, implementation projects, methodological frameworks)	The indicator measures targeting of future research (followon projects)	Core	Qualitative

68	Influence on R&D agenda	Excellence	Influence on subsequent research	Influence on and improvements for future research	Description of the influence of the initiative/project on shaping the R&D agenda.	The indicator informs about impact on future research.	Additional	Qualitative
69	Research priorities	Excellence	Influence on subsequent research	Influence on and improvements for future research	Description of the changes in national research priorities (new or updated) so that the initiative/project can align their own to these changes.	The indicator informs about the adopted research priorities or strategies that mirror the impact of the initiative/project.	Additional	Qualitative
70	Project results applied in policy and practice	Excellence	Informing healthcare practice decision making	Influence on healthcare practice	Number and type of applicable project outputs (e.g. clinical guidelines, protocol standards, care practices or healthcare training) in policy development or in practice settings.	The indicator informs about the practical/clinical outcomes of projects	Core	Quantitative/Qualitative
71	Use of science in policymaking	Excellence	Informing healthcare practice decision making	Influence on policymaking	Description of the utilization of evidencebased knowledge/advice developed by the initiative/project in policy-making processes.	The indicator informs about the extent to which knowledge generated by the initiative/project is effectively used in policymaking.	Additional	Qualitative
72	Scientific evidence used on clinical decision-making	Excellence	Informing healthcare practice decision making	Science awareness	Description of the use of research outcomes of the initiative/project by clinical decisionmakers.	The indicator informs about how key clinical decision makers are aware of scientific evidence which is important for closing the gap between science and clinical care.	Additional	Qualitative
73	Exploitation of intellectual property	Excellence	Intellectual property	Patents	Percentage of patents and other intellectual property rights owned by the research initiative that are being or have been exploited by the pharma industry.	The indicator evaluates the extent to which the initiative/project develops research outputs that are actually being exploited.	Core	Quantitative
74	Sharing of intellectual property and research findings	Excellence	Intellectual property	Intellectual property	Number of research institutions with which the initiative/project shares their intellectual property rights and research findings to develop new drugs or treatments.	The indicator assesses the willingness of the initiative/project to collaborate and share intellectual property with other research institutions to generate more advanced and improved research outputs with the capacity to generate an impact on patients' wellbeing. Sharing intellectual property can accelerate the development of new products and treatments to maximize their potential.	Additional	Quantitative
75	Intellectual property rights	Excellence	Intellectual property	Licenses	Number of patents and other property rights owned by the initiative and awarded during the reporting period. When possible, the initiative should break down the patents and other intellectual property rights considering the time horizon for its exploitation, the country where it was awarded, and whether they are produced, commercialized or provisional.	This indicator evaluates the capacity of the initiative to generate research findings with applicable and economic exploitable potential. The indicator is clear and easy to calculate.	Additional	Quantitative
76	Advanced phase clinical trials	Excellence	Patient engagement & involvement	Clinical trials	Number of advanced phase clinical/pragmatic trials and/or Public Health research project where patient have been engaged.	The clinical trial in human beings is a significant indicator for research assessment. Research projects can be assessed on the basis of whether they have progressed to clinical trials.	Core	Quantitative
77	Potential users involvement	Excellence	Patient engagement & involvement	Potential users involvement	Description of how the initiative/project involves potential users in the research process.	The indicator describes how potential users were taken into account by the research initiative/project.	Additional	Qualitative
78	Clinicians and patients involvement	Excellence	Patient engagement & involvement	Potential users involvement	Description of the engagement with clinicians and patient on implementing strategies.	The indicator describes how patients and practitioners were taken into account to implement research finginds in health care practice.	Additional	Qualitative
79	New products	Excellence	Products generated	Products and drugs development	Number of new drugs and products developed by the initiative. Indicate the products and drugs in the pipeline, indicating their stage.	The indicator evaluates the generation of drugs and other products that will be administered to patients as part of their treatment.	Core	Quantitative/Qualitative
80	Therapeutic advances	Excellence	Products generated	Product and drug development	Number of novel therapeutic advances developed by the initiative/project during the reporting period, such as biomarkers, medical treatments, devices etc.	The indicator evaluates the capacity of the initiative to produce treatments and medical interventions that will improve the health and care of patients.	Additional	Quantitative
81	Spin-offs	Excellence	Products generated	Product and drug development	Spin-offs resulting from the development of research results.	The indicator evaluates spinoffs as a result of the initiative/project.	Additional	Quantitative/Qualitative

82	Expected (or potential) effects of new products on wellbeing	Excellence	Products generated	Product and drug development	Description of the potential effects of new products and developments of the initiative/project (e.g. novel or improved drugs, therapeutic advances or other medical interventions) on patients' wellbeing.	The indicator evaluates the potential effect that the new developments of the initiative/project might have on patients.	Additional	Qualitative
83	Collaborations and partnerships	Excellence	Research partnership	Collaboration	Number and description of the collaboration types in research activities (purpose, activities, target audiences).	The indicator evaluates the capacity of the initiative/project to collaborate with external partners.	Core	Quantitative/Qualitative
84	Patient organizations engagement	Excellence	Research partnership	Collaboration	Share of projects involving patient organizations and healthcare professionals' associations as partners/members of advisory boards.	The indicator shows the collaboration with potential users.	Additional	Quantitative
85	Translational funding level	Excellence	Research partnership	Collaboration	Number of consortia that applied for traslational funding with the initiative/project.	The indicator informs about the capacity to fund the commercialization of research findings.	Additional	Quantitative
86	Impact of research leadership	Excellence	Research recognition	Reputation	Research leadership in terms of impact of the research awareness considering: (i) number and type of public recognitions, (ii) number of editorial board served, (iii) number of research bodies.	The indicator is clear and easy to calculate.	Core	Quantitative
87	Reputation	Excellence	Research recognition	Prizes	Number and type of research awards given to initiative/project's researchers and/or programmes.	This indicator evaluates the social recognition and prestige of the research initiative. The indicator is clear and easy to calculate.	Additional	Quantitative
88	Capacity building	Excellence	Researchers' human capital	Researchers' capacity and career	Number and type of highly skilled people supported, disaggregated by gender.	The indicator evaluates the composition of the human capital of the initiative/project.	Core	Quantitative
89	Staff overview	Excellence	Researchers' human capital	Researchers' capacity and career	Description of the technical and scientific competency of staff	The indicator describes skills, knowledge and experience of the staff, takes into account the needed equipment and technology to complete their work.	Additional	Qualitative
90	Gender equality in committees	Excellence	Researchers' human capital	Gender equality	Number of women on the committees of the initiative/project and share of females over the total number of committee members.	The indicator monitors female participation in decisionmaking and the overall gender balance of the decision-making process.	Additional	Quantitative
91	Gender equality within researchers	Excellence	Researchers' human capital	Gender equality	Share of female researchers over the total number of researchers.	The indicator evaluates the representation of women across the whole initiative/project's researchers.	Additional	Quantitative
92	Financial R&D investments	Excellence	Resources allocated	Tangible and intangible resources	Total amount of financial R&D investments.	The indicator allows identifying the R&D expenses.	Core	Quantitative
93	Research organisational structure	Excellence	Resources allocated	Organisational structure	Description of the overall organizational structure specific to conduct research of the initiative/project.	This indicator provides a comprehensive picture of the research organizational structure and its contribution to achieving the research strategy of the initiative/project.	Additional	Qualitative
94	Level of knowledge work	Excellence	Resources allocated	Supporting projects	Percentage of projects with a significant impact of "knowledge work".	The indicator allows to monitor the performance of research activities in the upstream research effort (e.g. computerassited drug design)	Additional	Quantitative
95	Governance structures	Excellence	Scientific input	Research management	Description of the governance structures of the initiative/project (specifying their composition and gender distribution) and procedures that have been established to manage and monitor the research process.	The indicator provides information to evaluate the governance model and allows stakeholders to evaluate its participatory approch to engage them in the research process.	Core	Qualitative
96	Outreach activities	Excellence	Scientific input	Outreach visits	Number of outreach visits by researchers and number of attendees at outreach visits.	The indicator evaluates the direct engagement between researchers and practitioners to foster the implementation of research findings in clinical practice. By informing on the number of people that attend outreach visits, it assesses the level at which research findings are considered relevant by practitioners.	Additional	Quantitative
97	Innovation in research methodologies	Excellence	Scientific input	Research methodologies	Number of and description of research methodologies that have been developed or improved.	The indicator describes the long-term contribution of an initiative/project to improving future research, thereby leading to further knowledge that could lead to creating positive impacts.	Additional	Quantitative/Qualitative
98	Stakeholder engagement reach	Excellence	Stakeholder engagement	Participation	Number and type of target groups attending organized events.	The indicator shows the success and extent of participation. According to Graham et al. (2012) 'reach' covers an aspect of stakeholder engagement that provides a measure of the 'who' and the 'interactions' of stakeholder engagement.	Core	Quantitative
99	External stakeholder engagement mechanisms	Excellence	Stakeholder engagement	External stakeholder engagement	Number and description of mechanisms applied to interact with citizens and societal stakeholders.	D5.4 recommends (Recommendation 5.2.1) to "Implement structures and processes allowing to inform, engage, and seek feedback from internal and external stakeholders, including concerns about the initiative and its development". Further, D5.4 recommends to report on the number of consultation events with stakeholders.	Additional	Quantitative/Qualitative

100	Stakeholder participation	Excellence	Stakeholder engagement	Participation	Number of stakeholders consulted by the research initiative/project.	The indicator provides a simple measure to evaluate the stakeholder engagement of the research initiative/project,	Additional	Quantitative

Associated terms	Preferred data sources	Method of measurement and estimation	Type of information to be reported by the initiative	Monitoring & Evaluation Framework	Unit of measure	Expected frequency of data dissemination	Expected frequency of data collection
Definition of associated terms that are relevant for understanding the definition of the indicator.	Datasources preferred for gathering the data required for elaborating the indicator. The initiative should provide information that indicate the accurateness of the data	Description of method and/or process to elaborate and report the indicator. (In some cases there is information on this in the last column).	Indicate the type of information that the initiative must provide to disclose the indicator to determine the input areas that the users will need to feed into the Toolbox. - Average - Categorical options list - Free text - Link - Number in monetary units - Number in physical units - Ordinal options list - Percentage, with numerator and denominator - Proportion/Ratio, with numerator and denominator - Table with percentage disaggregated per categories - Table with monetary units disaggregated per categories - Table with absolute numbers disaggregated per categories- Table with absolute numbers and ratios disaggregated per categories – Yes/No	Levels of the results chain framework. Thus, indicate the stage of research process to which the indicator relates: – Input (resources used), - rocess (actions carried) – Output (goods and services directly produced) - utcome (initial results and effects) - mpact (long-term changes)	Indication of the unit in which the indicator is measured Only in those cases where it is applicable.	Indication of how periodic should be the dissemination of the data.	Indication of how periodic should be the collection of the data.
Peer-reviewed publications: Academic articles that have been peerreviewed for their publications. High-impact journals: Journal that are listed in the top quartile of a journal ranking. As a rule of thumb, high-impact journal are those in the top 10% of a ranking.	Initiative scientific report Rankings of journals (e.g. JCR, SJR)	Count the number of scientific articles published during the period. For the sake of comparison, the initiative shall report the same figure for the two prior periods. Provide a list of the complete references of the publications. Indicate the percentage of publications in highimpact journal by dividing the number of articles in those journals by the total number of publications during the period. The initiative can provide a link to a document where the list of publications is disclosed.	Number in physical units Percentage, with numerator and denominator Free text	Output	Number of articles Percentage	Annually	Annually
N/A	Initiative/project scientific report Bibliometric datasources Academic search databases	Count the number of scientific articles published during the reporting period resulting from the collaboration with researchers from organizations located in different countries or operating in different sectors. Indicate the number of organizations with which members of the initiative/project have published articles. For the sake of comparison, the initiative/project shall report the same figure for the two prior reporting periods.	Number in physical units	Output	Number of articles Number of collaborating organizations ons	Annually	Annually
Open access: Idea of making research results freely available to anyone who wants to access and re-use them (e.g. for full text mining) (MoRRI). Gold open access: Publications in OA journals (MoRRI). Green open access: Publications in OA self-archiving databases (MoRRI).	Initiative/project scientific report Classification of journals with open access options, such as	For the number of open access articles: Count the number of open access scientific articles (total/gold/green) published during the reporting period by the initiative/project. For the sake of comparison, the initiative/project shall report the same figure for the two prior reporting periods. For the percentage of open access articles: divide the total number of open access scientific	Number in physical units Percentage, with numerator and denominator	Output	Number of articles Percentage	Annually	Annually

	DOAJ list (Directory of Open Access Journals), PMC (PubMed Central), the ROAD list (Directory of Open Access scholarly Resources), CrossRef, and OpenAIRE	articles (total/gold/green) by the total number of publications during the reporting period, and multiply the result times 100.					
Anticipatory design: The design of products and services by using foresight techniques. Foresight techniques are coming and that is why the impact of anticipatory design needs to be thoroughly understood (Yaghmaei, 2018).	Surveys/ Questionnaires Sustainability report	Describe the extent to which anticipatory design policies and actions are considered in health research processes.	Free text	Process	N/A	Annually	Annually
N/A	Google Scholar Web of Science (WoS) Scopus	Count the number of citations of publications resulting from the the initiative/project's research since they were published.	Number in physical units	Outcome	Citations	Annually	Annually
N/A	Google scholar Web of Science (WoS) Scopus	Number and disparateness of the fields from citing publications, summarized in a diffusion score developed by Carley and Porter. Score ranges from 0 to 1.c For more information, see Carley S, & Porter A (2012).	Table with percentage disaggregated per categories	Outcome	Percentage	Annually	It will be automatically managed by specific services. The information is timely
N/A	Guidelines	Count the number of times that a publications/research output is cited in guidelines	Number in physical units	Outcome	Number of research studies that have been cited in guidelines	Annually	Annually
Outreach activities: Activities by research institutions that seek to increase public awareness and understanding of scientific knowledge and contribute to informal science education. Refereed publications: Academic articles that have been peerreviewed for their publications.	Scientific report Initiative/project's internal data	Provide the number of dissemination activities carried out during the period.	Number in physical units	Output	Number of dissemination activities	Annually	Annually
Media: Mediums of massive information dissemination (e.g., press releases, contacts, articles).	Internal reports by press office	Count the number of times that the initiative/project has been mentioned in the media as a consequence of the relevance of their research findings.	Number in physical units	Output	Number of mentions	Annually	Annually
N/A	Google analytics or similar web engines.	Provide the number of page views, unique visitors, and/or requests from the public/health care providers/researchers for more information.	Number in physical units	Output	Number of page views Number of visitors Number of requests	Monthly	Continuous
RRI: Responsible research and innovation is an approach that anticipates and assesses potential implications and societal expectations with regard to research and innovation, with the aim to foster the design of inclusive and sustainable research and innovation (EU-Horizon 2020).	Initiative/project's internal data	Provide a narrative description of the extent to which standards and regulations regarding RRI are acknowledged, complied with and embedded in the research process.	Free text	Process	N/A	Annually	Annually
Clinical guidelines: Statements that include recommendations, intended to optimize patient care, that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options (Institute of Medicine, 1990).	Initiative/project's internal data Desk analysis, database and interviews Case studies	Provide a narrative description of the extent to the initiative/project complies with clinical guidelines.	Free text	Process	N/A	Annually	Annually

Risk: Future uncertainty about deviation from expected outcomes.	Initiative/project's internal data Desk analysis, database and interviews Case studies	Provide a narrative description of the processes that the initiative/project follows to identify potential risks related to the research process and how these risks are managed.. The initiative can provide a link to a document where it is disclosed.	Free text	Outcome	N/A	Annually	Annually
Code of ethics/Code of conduct: A statement setting down corporate principles, ethics, rules of conduct, codes of practice or company philosophy concerning responsibility to employees, shareholders, consumers, the environment, or any other aspects of society external to the company (Langlois and Schlegelmilch, 1990, p. 522).	Code of ethics/conduct	Indicate Yes/No depending on the existence of an ethical committee to manage research. If yes, provide a description of f its structure (indicating its composition and gender distribution) and functions.	Yes/No Free text	Process	N/A	Annually	Annually
Code of ethics/Code of conduct: A statement setting down corporate principles, ethics, rules of conduct, codes of practice or company philosophy concerning responsibility to employees, shareholders, consumers, the environment, or any other aspects of society external to the company (Langlois and Schlegelmilch, 1990, p. 522).	Code of ethics/conduct Mission statement Initiative/project's internal data	Provide a narrative description of the initiative/project's values, principles and standards. Provide a detail description of how they have been approved, developed, and implemented in the health research process .	Free text	Process	N/A	Annually	Annually
N/A	Initiative/project's internal data	Provide a description of whether and how the health research initiative/project integrated any type of ethical assessment/review in its funding decisions.	Yes/No Free text	Process	N/A	Annually	Annually
Research grants: Non-repayable funds obtained from funding organizations to carry out research studies.	Annual report Scientific report	Count the total number of grants that the initiative/project has received to carry out research. For each grant, indicate the funding organization, amount and duration.	Table with absolute numbers disaggregated per categories	Input	Local currency per grants category	Annually	Annually
Collaborative research: Research developed by a partnership between two or more members who are pursuing mutually interesting research. Collaborative research represents the core of EU R&I funding under Horizon 2020 with a multitude of funding options, thematic priorities with a variable degree of specification, regular collaboration of science and industry/society, different governance models for funding, (https://www.kowi.de/en/kowi/collaborative-research/collaborativeresearch.aspx).	Information compiled internally	Count the number and the monetary amount of collaborative research projects funded through joint calls.	Number in physical units Number in monetary units	Outcome	Number of projects Local currency	Annually	Annually
Public involvement/engagement: The inclusion and consideration of the general public as a key stakeholder in the decision-making process to plan, manage and carry out research.	Official documents specifying the criteria to evaluate research proposals	Indicate Yes/No depending on whether the initiative/project takes public engagement elements into account for the development or evaluation of R&I projects. Provide a narrative description of how public engagement is taken into account.	Yes/No Free text	Process	N/A	Annually	Annually
Taxonomy: System for naming and organizing diseases. Disease: Any harmful deviation from the normal structural or functional state of an organism.	Scientific report Initiative/project's internal data	Provide the number of new taxonomies of diseases and new stratifications (such as the definition of patient subpopulations, development, validation and use of new diagnostics) developed, expressed as net figure.	Number in physical units	Impact	Number of taxonomies	Annually	Annually
The science of patient input: Scientific discipline aimed at understanding and incorporating patient needs and perspectives into the processes of governing and sustaining health research, developing, regulating, and delivering new therapies as well as improving care (see D1.1).	Dedicated survey	Provide a narrative description of the overall impacts for patients (considering both positive and negative impacts) driven by the research and activities carried out by the initiative/project.	Free text	Impact	N/A	Annually	Annually
Social impact: The effect on the well being of the society.	Dedicated survey	Provide a narrative description of the overall impacts for society (considering both positive and negative impacts) drien by the research and activities carried out by the initiative/project.	Free text	Impact	N/A	Annually	Annually
Expected / targeted changes: Milat et al. (2013) follow Banzi et al. (2011) to differentiate five broad categories of research impacts: i) advancing knowledge; ii) capacity building; iii) informing decisionmaking; iv) health benefits; and, v) broad socio-economic benefits. Milat et al. (2013) found that knowledge generated through research projects can inform practice and lead to changes through: Informing organizational development, leading to	Initiative/project's internal data	Provide a narrative description of the expected or targeted changes in knowledge, attitudes and behavior as a result of research dissemination and implementation strategies. The initiative can provide a link to a document where it is disclosed.	Free text	Impact	N/A	Annually	Annually

new intervention tool and resources, informing professional development, health promotion and programs.							
N/A	Initiative/project's internal data External expert (if needed)	Use the following scoring scale and justify the score given: 10 – The initiative/project made a considerable contribution to more than 1 follow-on project by the team and/or by others. 8 – The initiative/project made a contribution to more than 1 follow-on project, considerable in at least one case. 6 – The initiative/project made a contribution to more than 1 follow-on project, moderate in at least one case. 4 – The initiative/project made a moderate contribution to 1 follow-on project, or any contribution to more than one follow-on project. 2 – The initiative/project made a contribution to at least 1 follow-on project. 0 – The initiative/project made no contribution to targeting of future research.	Ordinal option list Free text	Impact	Scale	Annually	Annually
N/A	Initiative/project's internal data	Provide a narrative description of the influence on shaping the R&D agenda.	Free text	Impact	N/A	Annually	Annually
N/A	Initiative/project's internal data	Narrative description of the adopted research priorities or strategies that mirror the impact of the initiative/project. A questionnaire can be used to collect data.	Free text	Impact	N/A	Annually	Annually
Knowledge translation: The exchange and application of knowledge within interactions between different actors. It allows the development of research through improved health and a strengthened health care system. Informing practice: Provide practioners with facts or information that is useful for developing their tasks.	Research report	Count the number of potential outcomes that can be applied in practice or in policy development. When possible, classify and describe the outcomes per type.	Number in physical units Free text	Impact	Number of potential outcomes	Annually	Semi-annually
N/A	Research report	Describe the country specific activities and opportunities related to the use of science in decision-making: one dimension concerns the extent of formalized procedures feeding knowledge in decision-making (e.g. institutional sites dealing with these processes), the other dimension concerns the extent to which knowledge and advice have a real impact on decisions.	Free text	Impact	N/A	Annually	Semi-annually
N/A	Interviews with practitioners/clinicians Market surveys Case studies	Describe the use of science in clinical context (e.g. trials, treatment recommendations, algorithms). For example, surveys or "market research" type methods can be useful in assessing the clinical awareness of published research results. The tracking can vary from small scale (e.g. conference posters) to large scale (e.g. international/national reports).	Free text	Impact	N/A	Annually	Semi-annually
Patent/intellectual property: The official legal right to make or sell an invention for a particular number of years (Cambridge Dictionary).	Initiative scientific report World Intellectual Property Organization Database	Divide the number of patents or other intellectual property rights owned by the initiative that are or have been exploited by the pharma industry by the total number of patents and other intellectual property rights owned by the initiative. For the sake of comparison, the initiative shall report the same figure for the two prior reporting periods.	Percentage, with numerator and denominator	Output	Percentage	Annually	Annually
Patent/intellectual property: The official legal right to make or sell an invention for a particular number of years (Cambridge Dictionary).	Initiative scientific report Initiative internal information system	Count the research institutions with which the initiative/project has shared intellectual property or research findings during the reporting period to collaborate in and advance the development of R&D. For the sake of comparison, the initiative/project shall report the figure for the two prior reporting periods.	Number in physical units	Output	Number of research institutions	Annually	Annually
Patent/intellectual property: The official legal right to make or sell an invention for a particular number of years (Cambridge Dictionary). Produced patents: Patents that the initiatives produced. They can be commercialized or not. Commercialized patents: Patents that the research initiative manages or exploites to make a profit.	Initiative scientific report World Intellectual Property Organization Database	Count the total number of patents that the initiative owns and was awarded during the reporting period. When breaking down the patents considering the options listed in the description, provide a table that summarizes the figures (see examples). For the sake of comparison, the initiative shall report the same figure for the two prior reporting periods.	Number in physical units Table with absolute numbers disaggregated per categories	Output	Number of patents	Annually	Annually

Clinical trials phases: Phase I (pharmacology studies); phase II (therapeutic exploratory investigations); phase III (assessments of the effectiveness of the new intervention); and phase IV (investigations into uncommon adverse effects of the new intervention).	Information compiled internally by the organization with the input of other stakeholders as patients (if needed)	Provide the total number of advanced phase clinical/pragmatic trials and/or Public Health research project where patient have been engaged. When possible, classify them based on their phase.	Table with absolute numbers disaggregated per categories	Process	Number of clinical trials	Annually	Annually
Public involvement/engagement: The inclusion and consideration of the general public as a key stakeholder in the decision-making process to plan, manage and carry out research.	Information compiled internally by the organization	Provide a narrative description of how potential users are engaged in the research process. Consider the Patient Engagement model developed by MultiAct.	Free text	Process	N/A	Annually	Annually
Patients engagement: Action to engage patients in R&I processes for make them responsible (as sub-group of stakeholder). In line with RRI defintion, patient engagement implies that patients work together to other stakeholders (researchers, citizens, policy makers, business, third sector organisations, etc.) during the whole R&I process in order to better align both the process and its outcomes with the values, needs and expectations of patients.	Information compiled internally by the organization.	Provide a narrative description of the engagement with clinicians and patient on implementing strategies. Consider the Patient Engagement model developed by MultiAct	Free text	Process	N/A	Annually	Annually
Drug: Natural or synthetic substance which (when taken into a living body) affects its functioning or structure, and is used in the diagnosis, mitigation, treatment, or prevention of a disease or relief of discomfort (www.businessdictionary.com).	Initiative's scientific report	Count the total number of new drugs and other products that the initiative developed during the reporting period. For the sake of comparison, the initiative shall report the same figure for the two prior reporting periods. Provide a list of the products and drugs developed and being developed, indicating their stage.	Number in physical units Free text	Output	Number of new drugs and other products developed	Annually	Annually
Therapeutic advance: Treatment and care of a patient for the purpose of both preventing and combating disease or alleviating pain or injury (Encyclopedia Britannica).	Initiative scientific report	Count the total number of new therapeutic advances that the initiative/project developed during the reporting period. For the sake of comparison, the initiative/project shall report the same figure for the two prior reporting periods.	Number in physical units	Output	Number of new therapeutic advances developed	Annually	Annually
Spin-off: New business created by separating part of a company (Cambridge Dictionary).	Initiative scientific report Initiative financial report	Count the total number of spinoffs created during the reporting period. For the sake of comparison, the initiative/project shall report the same figure for the two prior reporting periods. Provide the main information about the spinoffs (e.g. main timeline of the spin-off, description of its business, debt ratios, detailed information of the new listed company etc.).	Number in physical units Free text	Output	Number of spinoffs	Annually	Annually
Drug: Natural or synthetic substance which (when taken into a living body) affects its functioning or structure, and is used in the diagnosis, mitigation, treatment, or prevention of a disease or relief of discomfort (www.businessdictionary.com). Therapeutic advance: Treatment and care of a patient for the purpose of both preventing and combating disease or alleviating pain or injury (Encyclopedia Britannica.	Initiative scientific report Research report Researchers' expertise	Provide a narrative description of the new developments generated by the initiative/project (drugs, products, therapeutic treatments, medical interventions, etcetera) and explain their effect on the wellbeing of patients and how they can contribute to solving, mitigating or paliating diseases.	Free text	Output	Free text	Annually	Annually
Partnerships: Relationship formed by the agreement between two or more organizations to carry on research and development of new products and services together.	Initiative/project's internal data	Number and description of the collaborations and partnerships.	Free text Number in physical units	Input	Collaboration	Annually	Annually
Patient engagement: Action to engage patients in R&I processes for make them responsible (as sub-group of stakeholder). In line with RRI definition, patient engagement implies that patients work together to other stakeholders (researchers, citizens, policy makers, business, third sector organizations, etc.) during the whole R&I process in order to better align both the process and its outcomes with the values, needs and expectations of patients. Stakeholder engagement: Activities that can be done with stakeholders: consult, listen, understand, communicate, influence, negotiate, etc., with the broader objectives of satisfying their needs, gaining approval and support, or at least minimizing their opposition or obstruction (D9.1).	Initiative/project's internal data	Divide the number of projects of the initiative that involve patient organizations in their advisory board by the total number of projects of the initiative. Consider the Patient Engagement model developed by MultiAct.	Percentage, with numerator and denominator	Input	Percentage	Annually	Annually
Funding applications: The process of elaborating, writing and proposing a request for the financing of a project.	Initiative/project's internal data.	Number of consortia applying for traslational funding. Differentiate between total number of submissions and total number of successfull projects.	Number in physical units	Input	Number of consortia	Annually	Annually

Translational funding: Funding used to 'bridge the gap' in development between early stage technology resulting from research and its commercialization.							
Leadership: The influence and impact of the research awareness (e.g. number and type of public recognitions, number of editorial board served and number of research bodies).	Information compiled internally by the organization, with the engagement of the researchers that have been involved in the specific research programme	Calculate: • Number of public recognition of leadership: (i) number and type of prestigious fellowships, (ii) number and type of awards that mark significant achievement in research, (iii) number and type of membership in honorary scientific societies. • (i) Number and type of membership of regional, national or international research bodies; (ii) number and type of review boards; (iii) number and type of funding bodies. • (i) Number and type of editorship of journals, (ii) number and type of membership on journal editorial boards and (iii) number and type of advisory committees.	Table with absolute numbers disaggregated per categories	Output	Number of recognitions, awards, memberships, editorships, and advisory committees	Annually	Annually
N/A	Initiative/project's internal data.	Provide the number of prizes and awards that were given to researchers or research programs of the initiative/project during the reporting period.	Number in physical units	Outcome	Awards/prizes	Annually	Annually
Capacity development: Improvement of skills, knowledge and resources required to do research. Training program: Set of activities that contribute to improving health care research and practice by means of courses, workshops and mentoring.	Annual report Scientific report	Count the number of each type of researcher depending on their academic level (e.g. Senior research, Postdoc, Predoc) and gender.	Table with absolute numbers disaggregated per categories and gender	Input	Absolute number	Annually	Annually
Human capital: The knowledge, skills and experience of an organization's employees.	Sustainability report Annual report	Provide a narrative description of the skills, knowledge and experience of the staff, considering also the equipment and technology required to complete their work.	Free text	Input	N/A	Annually	Annually
Gender issues: Concerns related to reaching the equal value and treatment between women and men.	Annual report Sustainability report	Count the number of women on committees. Calculate the percentage of females respect to the total number of committee members.	Number in physical units Percentage, with numerator and denominator	Process	Number of women Percentage	Annually	Annually
Gender issues: Concerns related to reaching the equal value and treatment between women and men.	Annual report Sustainability report	Divide the number of females by the total number of researchers.	Percentage, with numerator and denominator	Input	Percentage	Annually	Annually
R&D investments: Innovative and financial investments devoted to research. Disease: Any harmful deviation from the normal structural or functional state of an organism. Resource allocation: Assignment of available resources to various uses.	Information compiled internally by the organization	Provide the total amount of money (R&D expenses) invested in each project	Number in monetary units	Input	Local currency	Annually	Annually
Research strategy: Definition of the actions that should be carried out to achieve the research objectives that have been defined.	Information compiled internally by the organization	Provide a narrative description of the components and strategies of the research organizational structure. Consider the Corporate Governance model developed by MultiAct.	Free text	Process	N/A	Annually	Annually
Knowledge work: Work performed by someone with specific domain knowledge who specializes in separating relevant information from irrelevant information	Information compiled internally by the project/initiative with the input of other stakeholders as experienced workers.	Total number of projects with significant impact of knowldege work over total projects. The identification of knowldege work is based on different criteria (for example, criteria established by experts in the field).	Percentage, with numerator and denominator	Outcome	Percentage	Annually	Every threemonth
Gorvernance: Internal structure and decision-making scheme of a research initiative, which will enable the appropriate management of project activities in the long run (D5.1)	Annual report Policy report	Provide a narrative description of the governance structures (indicating their composition and gender distribution) and procedures that have been established to manage and monitor the research process.	Free text	Process	N/A	Annually	Annually
Stakeholder engagement: Activities that can be done with stakeholders: consult, listen, understand, communicate, influence, negotiate, etc., with the broader objectives of satisfying their needs, gaining approval and support, or at least minimising their opposition or obstruction (D9.1).	Scientific report Initiative/project's internal Data	Count the number of outreach visits and people attending them.	Number in physical units	Output	Number of visits and number of people	Annually	Annually
Research methodology: Specific techniques adopted in research processes to collect, assemble and evaluate data.	Scientific report Initiative/project's internal data	Count the number of methodologies advanced or developed by the initiative/project. Provide a narrative description of those advances and developments	Number in physical units Free text	Input	Number of methodologies	Annually	Annually

Stakeholder engagement: Activities that can be done with stakeholders: consult, listen, understand, communicate, influence, negotiate, etc., with the broader objectives of satisfying their needs, gaining approval and support, or at least minimizing their opposition or obstruction (D9.1)	Initiative/project's internal data	Provide the number of target groups that attend events organized to engage stakeholders and distribute them according to the different categories of stakeholders identified. This information should ideally be presented in a table and compared with the previous year data or with targets.	Table with absolute numbers disaggregated per categories	Outcome	Number of attendees per stakeholder category	Annually	Annually
External stakeholder: Individuals or groups that are outside the initiative/project's environment, have some interest in the initiative/project's aims and might influence to different extents its execution and the accomplishment of its expected results.	Own organization	Provide the number of mechanisms applied to interact with citizens and societal stakeholders. Provide a narrative description of the mechanisms and instruments used to engage these stakeholders.	Number in physical units Free text	Process	Number of stakeholder engagement mechanisms	Annually	Annually
Stakeholder engagement: Activities that can be done with stakeholders: consult, listen, understand, communicate, influence, negotiate, etc., with the broader objectives of satisfying their needs, gaining approval and support, or at least minimising their opposition or obstruction (D9.1)	Initiative/project's internal data	Provide the number of stakeholders consulted by the initiative/project in a given period. This information should ideally be compared with previous year or with expected targets.	Number in physical units	Process	Number of stakeholders	Annually	Annually

Limitations	Indicator in use	Example	Links	Comments	Feasability of elaborating the indicator
Main problems that could emerge when elaborating the indicators and potential disadvantages and/or shortcoming when using the indicators.	Indication of whether the indicator is currently being used: Yes/No	Example of a report, webpage, etc that provides an example on how to report the indicator.	Links of interest to either understand or compute the indicator.	Additional comments.	The initiative shall indicate whether it considers that it has access to the data needed to compute the indicator considering the data sources and additional information provided in the scorecard. To be filled by the initiative: Yes/No.
The indicator can be used for academic gaming, encouraging researchers to publish papers in high-impact journals and to ignore national channels (valuable for community/society). If the initiative publishes interdisciplinary research across different research areas, the indicator could be difficult to compare (differences of publication cultures/subject areas/research feeds, language used).	Yes	For the classified list of articles: Cancer Research UK Manchester Institute Scientific Report 2018 (p. 62-69). For the percentage of articles in high-impact journals: University of Limerick Health Research Institute Annual Report 2017 (p. 20)		Use the Journal Citation Report Impact Factor as benchmark to categorize journal as high-impact. Otherwise, the initiative should clearly indicate if a different ranking is used for the sake of comparability.	
The indicator does not account for the long-term relationship of collaborations and whether they have been stable over time.	Yes	For the number of international collaborating organizations: University of Limerick Health Research Institute Annual Report 2017 (p. 21)			
When interpreting this indicator, users need to consider that publication fees may prevent publishing in open access journals. The possibilities of publishing in open access varies across research topics (number of OA journals). Therefore, some initiatives/projects might have low or null values in this indicator due to the difficulties mentioned above. The data can be provided in a graphic (see example).	Yes	For the share of OA publications in Europe: The evolution of Responsible Research and Innovation in Europe: MoRRI – The Evolution and Benefits of Responsible Research and Innovation (p. 64)		The example provided is not specific of health research initiatives, but it can be adapted to their scope.	
Although the indicator informs about the level of use of anticipatory design it does not inform the impact of these techniques for patients. It needs to be complemented with additional information.	No				
Citations is just one dimension of the quality of publications. Not all citations are necessarily recorded since not all publications are indexed.	Yes	Google scholar	Using Google Scholar to Estimate the Impact of Journal Articles in Education Author(s): Jan van Aalst Source: Educational Researcher, Vol. 39, No. 5 (JUNE/JULY	Adopt Google Scholar as a reference for academic citations to make the indicator more comparable among different initiatives	

			2010), pp. 387-400 Published by: American Educational		
Calculation requires a complex formula and additional citation searching.	No			Carley S, & Porter A (2012). A forward diversity index. Scientometrics, 90:407-427. Available at: https://link.springer.com/article/10.1007/s11192-011-0528-1 See a bibliometric analysis of citations of papers in differentes disciplines by Innovative Medicines Initiative Joint Undertaking (IMI) (p. 25). This data can be used to compute the indicator. Available at: https://www.imi.europa.eu/sites/default/files/uploads/documents/reference-documents/IMI%20JU%20Bibliometric%20Report%201_FINAL.pdf	
Citations may not reflect what is considered valuable in academic terms (basic research)	No				
The indicator does no inform about the quality or intensity of activities. This limitation can be solved considering the quality and the number of participants in the activities.	Yes	See, for example, the MaxPlanck-Gesellschaft newsroom: https://www.mpg.de/rese arch. It indicates news, events, articles, podcasts, and videos by categories as well as latest science magazines.			
The indicator does not capture the scope of communication (e.g., how many people have been reached).	No				
The selection of adequate analytic tool/competence needed and the time spent for analysis.	No				
Although the indicator informs about the consideration of RRI standards, it does not offers assurance of whether or not the consideration is being effective.	No				
Although the indicator informs about the compliance with clinical guidelines, it does not offer assurance of compliance level. Other limitations are the difficulty and cost of data collection.	No				
The information disclosed in this indicator might be difficult to interpret for layperson stakeholders. To overcome this issue, the description should be clear and try to avoid complicated technical jargon to simplify its understading.	No				
This indicator measures procedures and performance. If burocracy timings of the ethical committee are slow this indicator can become too time consuming	Yes	For a description of the structure and functions of ethical committees: see "Research ethics committees" (World Health Organization, pp. 11-15) and the "Guide for Research Ethics Committee Members" (Council of Europe, pp. 1525)			
This indicator is descriptive. It might be limited by the fact that it does not include measures of deviation from values, principles, standards and norms of behavior.	No				
Comprehensiveness might come at the expense of producing overburdening information.	No				
The indicator does not account for the success of the research funded with the grants.	Yes	University of Limerick Health Research Institute Annual Report 2017 (p. 24)			
The indicator does not inform about the quality or intensity of the collaboration.	Yes	ERA-Net for Research Programmes on Rare Diseases ; European Research Projects on External Insults to the Nervous System: http://www.erare.eu/jointcall/1st-joint-calleuropean-jointprogramme-rare-diseasesjtc-2019			
The indicator does not inform about the quality or intensity of the public engagement.	Yes	PHW Research Strategy 2015-2018 (p. 4)			

The indicator requires a large amount of information.	Yes	FIND Annual Report 2013 (pp. 5, 10)			
Comprehensiveness might come at the expense of producing overburdening information.	No				
Comprehensiveness might come at the expense of producing overburdening information.	No				
Comprehensiveness in describing the changes might come at the expense of producing overburdening information.	Yes	Breast International Group – Annual Report 2016, p. 6. Changes in clinical practice derived from research and development.		Changes in clinical practice derived from excellent research seems obvious. However, institutional and economic obstacles need to be considered. Indicators 66 & 107 are two sides of the same coin	
The indicator does not inform about the quality of research.	No				
Comprehensiveness might come at the expense of producing overburdening information.	No				
	Yes	PHW Research Strategy 2015-2018 (p. 11)		Those initiatives/project that have not a a shared strategy yet can develop one, and those that already have one should update its strategy so that it is aligned with the scientific priorities as defined in the project/initiative's Research Strategy.	
The indicator may not reflect the same level of outcomes compared to academic results.	No				
Comprehensiveness might come at the expense of detailed information. It is difficult to evaluate the accuracy and update of information.	No			For more information, see MoRRI – The Evolution and Benefits of Responsible Research and Innovation (p. 78). Available at: https://op.europa.eu/en/publication-detail/-/publication/2c5a0fb6-c070-11e8-9893-01aa75ed71a1	
The successful implementation of new clinical practices resulting from research outcomes is time consuming and it may take several years before the impact of research is perceived.	No				
In some cases, it might be difficult for the initiative to calculate the actual number of patents that are being applied by the pharma industry. In these situations, the initiative/project should only consider those with evidence proving its actual application.	No			This indicator provides additional information to the indicator "Revenue from intellectual property".	
This indicator evaluates intellectual property sharing, but it does not assess whether the sharing actually leads to new significant discoveries.	No				
This indicator does not evaluate whether or not the patents are being actually applied.	Yes	For the number of patens owned and awarded: Fraunhofer Institutes Annual Report 2017 (p. 32) For the classification of patens based on their expiration date and country: Bayer Annual Report 2018 (p. 40). For the classification of patents base don whether they are provisonally filled or awarded: Australia's Medical Research Institute Snapshot 2018 (p. 20)		Link to the World Intellectual Property Organization Database: https://www.wipo.int/branddb/en/. The tabulated data can also be presented as a graphic. This indicator can be used to compute the indicator "return on intellectual property".	
This indicator can give insufficient credit to basic science. This indicator could be invalid for research projects not involving clinical trials (rehabilitation, eHealth ICT development, etc.).	Yes	Projects that are in Phase III clinical trials: Novartis Annual Report 2018, p. 65			Alternative definition: number of projects that have reached an advanced phase in clinical trials
Comprehensiveness might come at the expense of detailed information. It is difficult to evaluate the accuracy and update of information.	Yes	European Medicines Agency Stakeholder Engagement report 2017 (pp. 5-7).			
The indicator does not tell much about the quality or intensity of the involvement.	Yes	Progressive MS Alliance Report Progress 2019 (p. 5)			

The indicator does not tell about the usefulness of the products for users or their actual influence on patients and their recovery.	Yes	For the full list of products and drugs, see GSK Annual Report 2018 (p. 235-240).			
The indicator does not inform about the usefulness of the therapeutic advances or their actual influence on patients and their recovery.	No				
Commercial perspective on measurement, does not take into account the differences of disciplins/subject areas	Yes	Association of Australian Medical Research Institutes Snapshot 2018 (p. 20)			
The indicator describes the potential effect of new development,s but it does not offer information on their actual effect on patients.	No			This indicator complement the information provided by indicators "New products" and "Therapeutic advances".	
The indicator does not inform about the quality or intensity of collaboration.	No				
The indicator does not tell much about the quality or intensivity of involvement.	No			The information should be complemented by the number and budget of grant agreements that delivered them.	
The indicator does not tell much about the success of the application efforts	Yes	Era-net Neuron impact report (pp. 17)		The example provides additional information on consortia members and not the number of members.	
It needs to be calculated at the individual level (single researchers) and then aggregated at organizational level.	No				
The indicator needs to be calculated at individual level (single researchers or specific programes) and then aggregated at initiative/project level.	Yes	For a list of awards, but not the total number, see Fraunhofer Institutes Annual Report 2017 (pp. 101-103)		See AIHS health research to impact framework (Graham et al., 2012)	
The indicator assimilates the contribution to human capital of all people within the same category.	Yes	Vall d'Hebron Institute of Research Strategic Plan 2011-15 "Five years committed to people's health", p. 34		The example does not disaggregate the number by gender.	
Comprehensiveness might come at the expense of producing overburdening information.	Yes	Fraunhofer Institutes Annual Report 2017 (pp. 104-115)			
The indicator does not consider the existence of policies to enhance women representation.	Yes	Fraunhofer Institutes Annual Report 2017 (p. 37).			
The indicator does not consider the existence of policies to enhance women representation.	Yes	Fraunhofer Institutes Annual Report 2017 (p. 37).			
The company needs to clearly allocate costs to each research project.	Yes	U.S. Department of Health & Human Services: https://report.nih.gov/cat egorical_spending_project _listing.aspx?FY=2015&AR RA=N&DCat=Multiple%20 Sclerosis			
	Yes	Vall d'Hebron Institue of Research Strategic Plan 2011-15 "The organizational basis of success", pp. 51-57			
The indicator is hard to define, with a lot of possible variation and its outputs are so intangible that it is not possible to come up with a single universal assessment system.	No				
This indicator might require the disclosure of large amounts of information. Additionally, the governance model might be different among research bodies, which could hinder their comparison. To overcome this obstacles, the governance model established by MULTI-ACT might work as a benchmark when producing this indicator.	Yes	Vall d'Hebron Institue of Research Strategic Plan 2011-15 "Five years committed to people's health" (pp. 52-55).		Consider the relationship with the Governance Model established in Multi-Act. Normally this information is available on the website of the organization/project and in its statutes.	
This indicator provides one way to analyze the relevance of research findings to clinical practice. Stakeholders should be aware about the fact that few or none outreach visits have been paid does not necessarily imply that the practical relevance of research findings is low.	No				
The development of new methodologies might not always be related to future impacts. Therefore, the quality of the methodological improvements needs to be assessed.	Yes	Sustainability of evidencebased healthcare: see methodological advances pp. 8-10			

The indicator does not tell much about the quality or intensity of collaboration. The perspective/experience of target groups is missing.	Yes	European Medicines Agency – Stakeholder Engagement Report 2017 (see, for example, Table 2 p. 21): presents different analyses of the individuals and the events related to the different stakeholder engagement activities.		The example is overwhelming; usually the indicator could just consist in one table. Also, it does not present stakeholders per category.	
The indicator does not provide information on the quality or intensity of the engagement.	Yes	European Medicines Agency – Stakeholder Engagement Report 2017: see, for example, Table 1 p. 18			
The indicator does not provide information on the quality of the engagement.	No				

Efficacy Dimension

Indicator code	Name	Dimension	Topic - Dissagregated – Aspect to be measured	Level 3 – Group of indicators (inductive classification)	Description	Rationale	Core/ Additional	Data Type Representation
Numeric code assinged to the indicator	Short name of the indicator.	PBM/CRIF dimension to which the indicator relates to: - Excellence - Social - Efficacy - Economic	Indicate the overall aspecy that the indicator evaluates within each dimension.	Indicate the category to in which similar indicators can be grouped	Description of the indicator.	Relevance of the indicator and advantages for its use.	Type of indicator within each aspect. Core indicators are key to evaluate each aspect. Additional indicators evaluate some areas which are not covered by the core indicators but that are relevant to provide a more in depth evaluation of the aspect. Additional indicators can also be provided when computing the core indicator is not feasible.	Type of inidicator: Qualitative/Quantitative
21	Increase in medication use	Efficacy	Drug supply to patient	Increase in drug supply	Average and increase/decrease of the number of medications used to treat a certain disease.	The indicator allows monitoring the increase or decrease in the number and use of drugs for treating a certain disease.	Core	Quantitative
22	Patients lacking medication	Efficacy	Drug supply to patient	Improvement in drug supply	Patients treated without drugs for the disease on which the research of the initiative/project focuses over the target screened population. The indicator measures the degree to which primary care prescribers treat patients seeking curative care with nonpharmaceutical therapies.	The indicator measures the proportion of patients who are counseled and/or treated without being prescribed with drugs. This indicator can be very revealing for the initiative/project as it allows to identify and foster new research projects.	Additional	Quantitative
23	HSO governance improvements resulting from research	Efficacy	Governance	Governance	Description of the governance structures to manage and monitor HSO that result from the implementation of research results.	The indicator provides information to evaluate the impact of the initiative/project's research to foster more responsible governance structures that monitor and supervise the management of health service organizations.	Core	Qualitative
24	Overview of health benefits	Efficacy	Health service assessment	Overall health service	Description of the degree of the initiative/project's impact on health benefits as direct/considerable/moderate/identifiable.	The indicator allows an overview of the impact on health benefits. It is strategic to assess the level of achievement of a certain mission.	Core	Quantitative/Qualitative

25	Population screened	Efficacy	Health service assessment	Overall health service	Percentage of the population screened for the disease on which the initiative/project focuses per year over the target screened population. When possible, provide the percentage of population screened disaggregated by gender.	The indicator allows an overview of the population that the initiative/project can help by improving health management through research.	Additional	Quantitative
26	Availability of digital technologies	Efficacy	Health service assessment	Overall health service	Description of the digital eHealth/eServices technologies available and used by the initiative/project, such as Unique patient ID, linked records, or scale teleservices.	The indicator provides information on the use of technologies to improve health care.	Additional	Qualitative
27	Coverage of essential health services	Efficacy	Health services and products accessibility	Health service accessibility	Coverage of essential services related to reproductive, maternal, newborn and child health, infectious diseases, non-communicable diseases and service capacity and access, among the whole population of PwMS.	The indicator gives a comprehensive overview of health service coverage because it is a composite indicator.	Core	Quantitative
28	Public reporting on access-to-medicine	Efficacy	Health services and products accessibility	Transparency	The initiative/project, particularly those developed by pharma companies, publicly reports information on access to medicine.	The indicator helps to assess whether the initiative/project is transparent about its activities regarding access to medicine.	Additional	Qualitative
29	Access to healthcare	Efficacy	Health services and products accessibility	Health service accessibility	Equity of access to healthcare on a gender or ethnic basis (or other marginalized groups).	The indicator takes into consideration that equity of access to healthcare often depends on gender and/or ethnicity.	Additional	Quantitative
30	Multidisciplinary teams	Efficacy	Healthcare practitioners human capital	Healthcare practitioners ability	Health interventions undertaken by using a multidisciplinary team over the whole interventions of the population of PwMS.	The indicator measures the proportion of health interventions that have engaged diverse stakeholders among the target group to ensure a comprehensive approach.	Core	Quantitative
31	Professional training	Efficacy	Healthcare practitioners human capital	Healthcare practitioners ability	Number of training courses available for health professionals, both of the initiative/project or of other organizations.	The indicator allows to identify the level of training of health professionals and possible gaps to be fulfilled.	Additional	Quantitative
32	Clinical academics	Efficacy	Healthcare practitioners human capital	Healthcare practitioners ability	Number of university-employed clinical academics, disagreggated by gender, that participate in the initiative/project.	The indicator provides an overview of the level of human capital of healthcare practitioners within the initiative/project.	Additional	Quantitative
33	Improvement efforts of quality of care	Efficacy	Improvement of health services	Health service quality	Description of the qualitative improvements produced by health research in the health care service delivery process applied to the whole population of PwMS.	The indicator allows evaluating the impact that research has on the day-to-day health care delivery.	Core	Qualitative
34	Risk stratification index	Efficacy	Improvement of health services	Public health	Risk stratification index (RSI) helps to assess risks and to make comparisons of the outcomes, for instance, in terms of duration of stay and mortality.	The indicator identifies the patients likely to be at high risk and prioritizing actions needed for improving management of their care.	Additional	Quantitative
35	Potentially preventable hospitalisations (PPH)	Efficacy	Improvement of health services	Hospitalization	Number of hospital admissions that could be prevented by means of preventative health interventions and/or early detecion and disease management prior to hospital admission.	The indicator provides a measure to evaluate health care delivery effectiveness.	Additional	Quantitative
36	Health and safety plan (HSP) developed	Efficacy	Influence on patient behaviour	Safety and security	A safety plan documents the process for identifying and managing the possible physical and health hazards as well as the specific safety goals related to the work environment.	The indicator allows identifying how the initiative/project manages health and safety risks.	Core	Qualitative
37	Guidelines for patients	Efficacy	Influence on patient behaviour	Patient guidelines and tools	Number and type of guidelines/tools developed for patients.	The indicator allows to screen the capability of research activities in supporting patients through guidelines and tools.	Additional	Quantitative
38	Quality-adjusted life year (QALY)	Efficacy	Patient quality of life	Patient wellbeing	Quality Adjusted Life Year is a method to evaluate the health outcomes of interventions (combined with the costs) including both the quality and the quantity of life.	The indicator helps to evaluate the health outcomes of interventions/programs and to allocate healthcare resources (health benefits and value for money).	Core	Quantitative

39	Mortality rate	Efficacy	Patient quality of life	Mortality	Mortality rate of patients in which the initiative/project's research focuses on and description of the contribution to reduce that rate.	The indicator evaluates how the initiative/project contributes to reducing the mortality rate of the disease on which its research focuses.	Additional	Quantitative/Qualitative
40	Actions expected to increase life expectancy	Efficacy	Patient quality of life	Life expectancy	Description of the expected contributions of the initiative/project to increase overall life expectancy.	The indicator describes actions carried out by the initiative/project that are expected to increase the average life expectancy of patients.	Additional	Qualitative
42	Stakeholder engagement in health promotion	Efficacy	Stakeholder engagement	Stakeholder engagement	Description of the collaboration with other societal stakeholders in health promotion.	The indicator describes how the actors collaborate in promoting health.	Core	Qualitative
43	Patient engagement	Efficacy	Stakeholder engagement	Patient engagement	Description of the engagement activities with relevant patient groups.	The indicator describes how the patient groups are taken into account.	Additional	Qualitative

Associated terms	Preferred data sources	Method of measurement and estimation	Type of information to be reported by the initiative	Monitoring & Evaluation Framework	Unit of measure	Expected frequency of data dissemination	Expected frequency of data collection
Definition of associated terms that are relevant for understanding the definition of the indicator.	Datasources preferred for gathering the data required for elaborating the indicator. The initiative should provide information that indicate the accurateness of the data	Description of method and/or process to elaborate and report the indicator. (In some cases there is information on this in the last column).	Indicate the type of information that the initiative must provide to disclose the indicator to determine the input areas that the users will need to feed into the Toolbox. - Average - Categorical options list - Free text - Link - Number in monetary units - Number in physical units - Ordinal options list - Percentage, with numerator and denominator - Proportion/Ratio, with numerator and denominator - Table with percentage disaggregated per categories - Table with monetary units disaggregated per categories - Table with absolute numbers disaggregated per categories- Table with absolute numbers and ratios disaggregated per categories – Yes/No	Levels of the results chain framework. Thus, indicate the stage of research process to which the indicator relates: – Input (resources used), - Process (actions carried) – Output (goods and services directly produced) - Outcome (initial results and effects) - Impact (long-term changes)	Indication of the unit in which the indicator is measured Only in those cases where it is applicable.	Indication of how periodic should be the dissemination of the data.	Indication of how periodic should be the collection of the data.
Disease: Any harmful deviation from the normal structural or functional state of an organism. Drug supply: The distribution, provision and/or sale of health care products.	Electronic medical records Patient records	Calculate the average number of medications used for a certain disease. Provide the change (increase/decrease) in the average number of medications used.	Number in physical units	Outcome	Number of medications	Annually	Annually
Drug supply: The distribution, provision and/or sale of health care products. Counsel: Advice, especially that given formally.	Electronic medical records Patient records	Divide the number of consultations in which no drug is prescribed by the number of consultations surveyed.	Percentage, with numerator and denominator	Outcome	Percentage	Annually	Annually
Responsible governance: Participatory governance model based on defining and co-designing a transformational agenda and adopting a co-accountability approach. Monitoring system: Set of mechanisms to measure how, where, and to what extent RRI has become integrated within European Research practices (D5.4).	Initiative/project's internal data	Provide a narrative description of the responsible governance structures and monitoring systems that result from the implementation of research results. The initiative can provide a link to a document where it is disclosed. Consider the Governance Model elaborated by MULTI-ACT.	Free text	Process	N/A	Annually	Annually

Health benefits/impact: The positive effect of the initiative/project on health (gains, improved cost-efficiency/accessibility, qualitative improvements).	Review of research documents Expert survey	Assess the degree of the project impact on health benefits using a five-point Likert scale (direct-considerable-moderate-identifiablenon). Describe the broader (societal) impact on health benefits (health gains, improved costefficiency/accessibility, qualitative improvements etc.) justifying the selection of the score. Degree of impact on health benefits can be described as free text or classified/quantified as: 10 – At least one of the health benefits was almost solely based on the project's evidence in a direct instrumental way. 8 – The project made a considerable impact on the health benefits. 6 – The project made a moderate impact on the health benefits. 4 – The project made some identifiable impact on the health benefits. 2 – A claim for impact made but no details given, or details given of a claim for expected future impacts. 0 – No impact on health benefits.	Ordinal option list Free text	Impact	Scale	Annually	Annually
Health management: Identification of best practices to improve care delivery and making it affordable Population screening: The presumptive identification of unrecognized disease in an apparently healthy, asymptomatic population by means of tests, examinations or other procedures that can be applied rapidly and easily to the target population (WHO).	Health care providers' records Clinical information systems Electronic health record system Patient records, surveys and interviews	Divide the number of population screened for the disease in which the research of the initiative/project focuses on by the number of the total population. When possible, compute this percentage disaggregated by women and men.	Percentage, with numerator and denominator	Output	Percentage	Annually	Annually
Digital technologies: All types of electronic equipment and applications that use information in the form of numeric coding including telemedicine, web-based analysis and clinic or remote monitoring sensors.	Initiative/project management control systems	Provide a narrative description of the eHealth/eServices used by the initiative/project.	Free text	Process	N/A	Annually	Annually
Service capacity: Resources and inputs in order to deal with the variety of the patient. Disease: Any harmful deviation from the normal structural or functional state of an organism.	Surveys Records of service delivery Administrative data	Calculate the percentage of PwMS receiving treatments in respect to the total number of PwMS in a given area.	Percentage, with numerator and denominator	Outcome	Percentage	Annually	Annually
Reporting: Official organization's report about its accounts or activities (societal activities for example). Information transparency: Openly available and comprehensive information.	Annual report Sustainability report	Indicate whether or not the initiative/project reports on access to medicine issues (Yes/No).	Yes/No	Process	N/A	Annually	Annually
Gender issues: Concerns related to reaching the equal value and treatment between women and men.	Local, regional and national statistics	Divide the number of people belonging to marginalized groups (e.g. gender/ethnic) without access to healthcare with the total number of the population. Percentage of men/women/other with access to health services.	Percentage, with numerator and denominator	Impact	Percentage	Annually	Annually
Multi-disciplinary approach: Process by which an issue is analyzed and studied by combining expertise of individual from different areas and backgrounds, such as scientists, biologists, patients, governmental agencies, etc.	Administrative/clinical/hospital data Surveys	Divide the number of interventions using multidisciplinary approaches by the number of total interventions.	Percentage, with numerator and denominator	Process	Percentage	Annually	Annually
Professional training: The improvement of performance and methods that could be used to analyse and improve health care quality by the means of courses, workshops and training related to specific projects. Human capital: Organizations' employees and all of the knowledge, skills, experience.	Professional associations	Calculate number of training courses available for health professionals. Contributions to research degrees (PhD) or to training of specific tasks related to research capacity building.	Number in physical units	Outcome	Number of courses	Annually	Annually
Clinical academic: Doctors who also combine research/teaching responsibilities. Human capital: The knowledge, skills and experience of an organization's employees.	Initiative/project's internal data Healthcare providers Clinical academics	Calculate the number of university employed academics who also work as practitioners that participate in the initiative/project. Provide the share of men/women respect to the total number of employed academics.	Number in physical units Percentage, with numerator and denominator	Input	People Percentage	Annually	Annually
Health care service: Any furnishing of treatment or health services. Quality improvement: Increase of the level at which care is delivered to patients.	Research reports Clinical information system Surveys and interviews	Describe how the process was improved (what was done for the patients and how effective) and/or describe the possible outcomes of the improved health care delivery process (impacts on patients health). Improvement efforts of quality of health care may address the perspectives of efficacy, availability and accessibility, responsiveness to population health needs, utilization or coverage of health services etc. After the data collection, evaluate the efforts at national, regional, local level or at hospital/clinical units. These can be specific interventions or processes aiming to improve quality of care.	Free text	Outcome	N/A	Semi-annually	Monthly/Annually

Risk stratification: Identification and prediction of patients that are at high risks (or likely to be at high risks) and to prioritize the management of their care in order to prevent worse outcomes.	Hospital record information systems	Describe the risk stratification model applied and the results of its application. A level of risk can be calculated by using diagnosis/procedures codes, for mortality and length-of-stay by using logistic regression/Cox proportional hazards modeling, together these generates an RSI.	Free text Number in physical units Table with absolute numbers and ratios disaggregated per categories	Outcome	Ratio; physical units	Annually	Annually
Hospital admission: Two types of admissions can be differentiated: (1) emergent admission happens when a patient is subsequently admitted to the hospital; and (2) elective admissions happens when a a patient is admitted on a specific day. Disease management: A set of healthcare interventions and communications to manage a specific disease.	Hospital record information systems Health surveys	Calculate the percentage of potentially preventable hospitalisations (PPH) by dividing hospital admissions (number of visits and people admitted) relative to the patient diagnoses codes in hospital admissions data. PPH is reported using the broad categories of chronic, acute and vaccine preventable conditions and using age-standardized hospitalisation rates (the number of potentially preventable hospitalisations per 1 000 or 100 000 population or the number of hospital bed days per patients admitted for a potentially preventable hospitalization).	Percentage, with numerator and denominator	Outcome	Percentage	Annually	Monthly/Annually
Safety plan: Document describing the health and safety matters in the work environment i.e, the measures to be taken as well as any other prerequisite to be applied to improve working conditions and to avoid work accidents and diseases. Physical and health hazards: (1) physical hazard is an agent, factor or circumstance that can cause harm with or without contact and (2) health hazard includes chemicals or toxic agents.	Annual report Human resource management report	Describe how health and safety issues are controlled in practice and identify preventive actions needed.	Free text	Process	N/A	Annually	Annually
Clinical guidelines: Statements that include recommendations, intended to optimize patient care, that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options (Institute of Medicine, 1990).	Clinical/treatment guidelines	Count the number of each type of guidelines and tools developed/customized for patient care.	Number of guidelines	Outcome	Physical units	Annually	Annually
Quality-adjusted life method: Method to calculate an economic indicator estimating the value of life. Health outcomes: Changes in health that result from specific health care interventions/programs.	Medical costs Questionnaires used in trials Preference surveys Expected duration of life and degree of dyability	There are several ways to estimate QALY. For instance, calculate the years of life remaining for a patient and weight each year with a quality-of-life score (on a 0 to 1 scale). "The basic idea underlying the QALY is simple: it assumes that a year of life lived in perfect health is worth 1 QALY (1 Year of Life × 1 Utility = 1 QALY) and that a year of life lived in a state of less than this perfect health is worth less than 1. In order to determine the exact QALY value, it is sufficient to multiply the utility value associated with a given state of health by the years lived in that state." (Prieto & Sacristán, 2003, p. 2).	Number in physical units Proportion/Ratio, with numerator and denominator	Impact	Years Scale Quality score (0 to 1)	Monthly	Monthly
Mortality rate: The number of deaths in a given area or period respect to the whole population.	Electronic medical records Administrative/clinical/hospita l data	Calculate the number of deaths for the specific population (disease in which the initiative research focuses on) in a given period of time and area and divide it by the number of death in the total population. Describe how the research findings of the initiative project contribute to reducing the mortality rate.	Percentage, with numerator and denominator Free text	Outcome	Percentage	Annually	Annually
Life expectancy: Average period that patients may be expected to live.	Interviews and/or surveys with practitioners/experts	Provide a narrative description of the potential influence on life expectancy of the actions and research outcomes of the initiative/project.	Free text	Impact	N/A	Annually	Annually
Health promotion: Process that enables actors to increase control over their own health including action to address social determinants and health inequity (see Ottawa Charter for Health Promotion and http://chrodis.eu/) Stakeholder engagement: Activities that can be done with stakeholders: consult, listen, understand, communicate, influence, negotiate, etc., with the broader objectives of satisfying their needs, gaining approval and support, or at least minimising their opposition or obstruction (D9.1)	Initiative/project's internal data	Provide a narrative description of the collaboration with other societal stakeholders in health promotion . The initiative can provide a link to a document where it is disclosed.	Free text	Process	N/A	Annually	Annually
Patient engagement: Action to engage patients in R&I processes for make them responsible (as a sub-group of stakeholders). In line with RRI definition, patient engagement implies that patients work together to other stakeholders (researchers, citizens, policy makers, business, third sector organizations, etc.) during the whole R&I process in order to better align both the process and its outcomes with the values, needs and expectations of patients.	Initiative/project's internal data	Provide a narrative description of the engagement activities with relevant patient groups. The initiative can provide a link to a document where it is disclosed.	Free text	Process	N/A	Annually	Annually

Limitations	Indicator in use	Example	Links	Comments	Feasability of elaborating the indicator
Main problems that could emerge when elaborating the indicators and potential disadvantages and/or shortcoming when using the indicators.	Indication of whether the indicator is currently being used: Yes/No	Example of a report, webpage, etc that provides an example on how to report the indicator.	Links of interest to either understand or compute the indicator.	Additional comments.	The initiative shall indicate whether it considers that it has access to the data needed to compute the indicator considering the data sources and additional information provided in the scorecard. To be filled by the initiative: Yes/No.
Combining the data from different sources could be difficult.	Yes	For patients with MS: Frahm et al. (2018, Figure 2, p. 6)		The indicator can also be provided in a graphic, like in the example.	
Failure to prescribe drugs can also indicate lack of availability in some settings, and this need for local interpretation requires that this be a complementary indicator.	Yes	Drug utilization in South Indian pediatrics (Thiruthopu et al. 2014): see p. 180 "complementary indicators" for the method and p. 182, table 3, for the indicator.			
This indicator requires the direct engagement of the research initiative/project and health administrative bodies to identify the development and/or improvement of governance models.	No				
It is hard to estimate and collect data. It needs precise clarification of which impacts are going to be assessed.	No				
Not all individuals participate in screening, so the sample may be biased towards those who care about their health.	Yes	See the National Comprehensive Cancer Control Program (NCCCP), Colorectal Cancer Screening Rates: https://www.cdc.gov/canc er/ncccp/screening-rates/			
The availability of digital technologies may vary depending on the scale and relevance of the initiative/project.	Yes	Finland: Healthcare system and eHealth strategy			
Estimating the denominator and numerator of the indicator might be complicated and time consuming.	Yes	Tracking universal health coverage WHO	Additional information: Hogan, D. R., Stevens, G. A., Hosseinpoor, A. R., & Boerma, T. (2018). Monitoring universal health coverage within the Sustainable Development Goals: development and baseline data for an index of essential health services. The Lancet Global Health, 6(2), e152e168. Available at: https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(17)30472-2/fulltext		
Data disclosed by company needs to be verified by an independent third party.	Yes	ESG Performance Summary 2018, pp. 2-3		Companies should track progress in access-to-medicine https://apps.who.int/medicinedocs/do outcomes against defined goals, conduct impact assessments cuments/s23336en/s23336en.pdf of access activities and make results publicly available	
Quality of data might vary across regions.	Yes	Inequalities in access to healthcare – A study of national policies (p. 37)		The example lists the training courses. It is possible to compute the number by counting the training courses provided.	
Data availability might prove problematic. Percentage does not tell much about the multidisciplinary interventions or their effectiveness.	No				
The indicator requires gathering data from several training providers.	Yes	"Understanding the development needs of the primary care and community health workforces with regard to sexual health in NHSScotland to enable the successful implementation of 'The Sexual Health and Blood Borne Virus Framework 20112015': a scoping study". Report for NHS Scotland (pp. 19-29 show examples of existing training).			
	Yes	Vall D'Hebron Strategic Plan 2011-15 (p. 34)		The example provide the information as a percentage. The number can be calculate by applying the percentage to the total number of	

				employees reported in the same page. The indicator does not disaggregate the number of employed academics by gender.	
Quality indicators are not a direct measure of quality, because quality is multidimensional requiring many different indicators.	No				
Requires large amount of information on long timescale. Risk is assessed at population level not an individual patient level.	Yes	"Validation of a Risk Stratification Index and Risk Quantification Index for Predicting Patient Outcomess"		For how to develop a predictive risk model, see the guide "A risk stratification tool for hospitalisation in Australia using primary care data". Available at: https://www.nature.com/articles/s41598-019-41383-y For how to compute the indicator, see Sigakis et al. (2013): "Validation of a Risk Stratification Index and Risk Quantification Index for Predicting Patient Outcomes". Available at: https://anesthesiology.pubs.asahq.org/article.aspx?articleid=1918181 Data can also be provided graphically (see example).	
It might be difficult to identify all potentially preventable hospitalisations. Some hospitalisations may not be avoidable. The term "preventable" might be understood at different levels for different stakeholders.	Yes	See the guide "A risk stratification tool for hospitalisation in Australia using primary care data" (Table 2) (Extract from "Khanna et al. (2019) (p. 8)).			
Health and safety are relative concepts. The plans developed describe only the risks detected under certain circumstances. Reporting might be timeconsuming requiring large amount of data collection.	No				
The indicator has a limmited enduser perspective. It does not considere how useful guidelines are for patients.	Yes	NCCN Guidelines for Patients: it provides research activities in supporting patients through guidelines and tools			
Calculating QALY or cost effectiveness thresholds is particularly complex. The calculation methodology may need refinement to realize the financial advantages and opportunity costs.	Yes	Prieto & Sacristán (2013) (Table 3, p. 7)		Full paper of Prieto & Sacristán on computing QALYs is available at: https://hqlo.biomedcentral.com/articles/10.1186/1477-75251-80	
Assessing if a given intervention has contributed to reducing mortality rates among PwMS might be difficult.	Yes	See article "Mortality in patients with multiple sclerosis" (Scalfari et al., 2013): see figure 2 for percentages of deaths due to MS			
Qualitative information is difficult to express in a uniform, comparable fashion.	No				
The breath of the information that might be included under this indicator makes it difficult to encapsulate it in a particular format.	Yes	"Fostering Mental Health in Our Community. Ottawa Public Health Strategic Direction A Background Document" (2016, p. 15)			
Comprehensiveness might come at the expense of producing overburdening information.	Yes	Sanofi CSR report 2013, p. 30			

Patient-reported Dimension

Indicator code	Name	Dimension	Topic - Dissagregated – Aspect to be measured	Level 3 – Group of indicators (inductive classification)	Description	Rationale	Core/ Additional	Data Type Representation

Numeric code assinged to the indicator	Short name of the indicator.	PBM/CRIF dimension to which the indicator relates to: - Excellence - Social - Efficacy - Economic	Indicate the overall aspecy that the indicator evaluates within each dimension.	Indicate the category to in which similar indicators can be grouped	Description of the indicator.	Relevance of the indicator and advantages for its use.	Type of indicator within each aspect. Core indicators are key to evaluate each aspect. Additional indicators evaluate some areas which are not covered by the core indicators but that are relevant to provide a more in depth evaluation of the aspect. Additional indicators can also be provided when computing the core indicator is not feasible.	Type of inidicator: Qualitative/Quantitative
41	Patient satisfaction score	Patient Reported Dimension	Patient satisfaction	Patient Reported Outcomes	Percentage change in how patients are satisfied with the care received	The indicator facilitates comparisons and scoring. The measurement of the percentage change of patients' satisfaction with the care received provides a standardized measure. It reports the patients experience. The range of interactions of patients with the health care system.	Additional	Quantitative
116	Life Satisfaction Index	Patient Reported Dimension	Patient satisfaction	Patient Reported Outcomes	Percentage change in how patients' quality of life have been improved after the care received (self reported)	The indicator facilitates comparisons. The measurement of the percentage change of patients' satisfaction with their life provides a standardized measure.	Additional	Quantitative
117	Abilhand – Manual ability for adults with upper limb impairment	Patient Reported Dimension	Upper limb dexterity	Patient Reported Outcomes	Percentage change in how patients are satisfied with their level of upper-limb dexterity after the care received (self reported)	The indicator facilitates comparisons. The measurement of the percentage change of patients' satisfaction with their level of upper-limb dexterity provides a standardized measure.	Core	Quantitative
118	HADS – Hospital Anxiety and Depression Scale	Patient Reported Dimension	Anxiety and Depression	Patient Reported Outcomes	Percentage change in how patients are satisfied with their level of Anxiety and Depression after the care received (self reported)	The indicator facilitates comparisons. The measurement of the percentage change of patients' satisfaction with their level of Anxiety and Depression provides a standardized measure.	Core	Quantitative
119	Neuro-QoL – Quality of Life in Neurological Disorders	Patient Reported Dimension	Patient satisfaction	Patient Reported Outcomes	Percentage change in how patients are satisfied with their quality of life, considering the functional domains evaluated by the scale, after the care received (self reported)	The indicator facilitates comparisons. The measurement of the percentage change of patients' satisfaction with their quality of life provides a standardized measure.	Core	Quantitative
120	OAB-Q – Overactive Bladder Questionnaire	Patient Reported Dimension	Bladder function	Patient Reported Outcomes	Percentage change in how patients are satisfied with their level of bladder functions after the care received (self reported)	The indicator facilitates comparisons. Considering that the measurement of patients' satisfaction with their level of bladder function is disease-specific (MS), the measurement of the percentage change provides a standardized measure of patient satisfaction.	Core	Quantitative
121	M-FIS – Modified-Fatigue-Impact-Scale	Patient Reported Dimension	Fatigue	Patient Reported Outcomes	Percentage change in how patients are satisfied with their level of motor, cognitive, psyco-social fatigue after the care received (self reported)	The indicator facilitates comparisons. Considering that the measurement of patients' satisfaction with the level of motor, cognitive, psyco-social fatigue is disease-specific (MS), the measurement of the percentage change provides a standardized measure of patient satisfaction.	Core	Quantitative
122	Walking Scale – 12	Patient Reported Dimension	Locomotion	Patient Reported Outcomes	Percentage change in how patients are satisfied with their level of locomotion after the care received (self reported)	The indicator facilitates comparisons. Considering that the measurement of patients' satisfaction with the level of locomotion is disease-specific (MS), the measurement of the percentage change provides a standardized measure of patient satisfaction.	Core	Quantitative
123	Mission/agenda aligned to patients' needs.	Patient Reported Dimension	Research's relevance to patients	Return on Engagement	Qualitative analysis of patients' satisfaction with the mission and agenda of the research after their engagement and influence.	The indicator provides an analysis of whether patients' expectation with respect to the research and mission of the initiative are met. A questionnaire developed ad hoc for assessing if the mission of the initiative/research meet the need of patients is submitted to patients.	Core	Qualitative
124	Endorsement of patients	Patient Reported Dimension	Patients' endorsement	Return on Engagement	Qualitative analysis of patients' satisfaction with the research outcomes due to the engagement and their endorsement of results.	The indicator provides evidence on the endorsements given by patients to research activities and results after their engagement and their influence in the process. A questionnaire developed ad hoc for assessing if the patients endorse the research results is submitted to patients.	Core	Qualitative
125	Patient engagement: expectation and satisfaction	Patient Reported Dimension	Patients' expectation and satisfaction for and with their engagement in research	Return on Engagement	Qualitative analysis of patients' expectation and satisfaction for and with their engagement in the research.	The indicator provides evidence on the expectation and satisfaction of patients for/with their engagement in the research, including identification of benefits and critical issues (pros and cons). A questionnaire developed ad hoc for assessing if the patients satisfaction with the engagement is submitted to patients.	Core	Qualitative

Associated terms	Preferred data sources	Method of measurement and estimation	Type of information to be reported by the initiative	Monitoring & Evaluation Framework	Unit of measure	Expected frequency of data disseminati on	Expected frequency of data collection

Definition of associated terms that are relevant for understanding the definition of the indicator.	Datasources preferred for gathering the data required for elaborating the indicator. The initiative should provide information that indicate the accurateness of the data	Description of method and/or process to elaborate and report the indicator. (In some cases there is information on this in the last column).	Indicate the type of information that the initiative must provide to disclose the indicator to determine the input areas that the users will need to feed into the Toolbox. - Average - Categorical options list - Free text - Link - Number in monetary units - Number in physical units - Ordinal options list - Percentage, with numerator and denominator - Proportion/Ratio, with numerator and denominator - Table with percentage disaggregated per categories - Table with monetary units disaggregated per categories - Table with absolute numbers disaggregated per categories- Table with absolute numbers and ratios disaggregated per categories – Yes/No	Levels of the results chain framework. Thus, indicate the stage of research process to which the indicator relates: – Input (resources used), - Process (actions carried) – Output (goods and services directly produced) - Outcome (initial results and effects) - Impact (long-term changes)	Indication of the unit in which the indicator is measured Only in those cases where it is applicable.	Indication of how periodic should be the dissemination of the data.	Indication of how periodic should be the collection of the data.
Patient Reported Outcomes: Report on how patient experience.	Surveys	Change in the percentage of patients satisfaction respect to the previous survey. Questions included in the scales should be distinctive to capture the disease-specific issues. The indicator is normalized by measuring the change in patient satisfaction.	Percentage, with numerator and denominator	Outcome	Percentage	Annually	Annually
Patient Reported Outcomes: Report on how patients feel or function	Questionnaires (also in the form of digital data collection)	Change in the percentage of patients satisfaction with respect to the previous questionnaire. Questions included in the scales are distinctive to capture the disease-specific issues. The indicator is normalized by measuring the change in patient satisfaction.	Percentage, with numerator and denominator	Outcome	Percentage	At the end of overall data collection and analysis	It depends on the assessment (usually at every assessment point)
Patient Reported Outcomes: Report on how patients feel or function	Questionnaires (also in the form of digital data collection)	Change in the percentage of patients satisfaction with respect to the previous questionnaire. Questions included in the scales are distinctive to capture the disease-specific issues. The indicator is normalized by measuring the change in patient satisfaction.	Percentage, with numerator and denominator	Outcome	Percentage	At the end of overall data collection and analysis	It depends on the assessment (usually at every assessment point)
Patient Reported Outcomes: Report on how patients feel or function	Questionnaires (also in the form of digital data collection)	Change in the percentage of patients satisfaction with respect to the previous questionnaire. Questions included in the scales are distinctive to capture the disease-specific issues. The indicator is normalized by measuring the change in patient satisfaction.	Percentage, with numerator and denominator	Outcome	Percentage	At the end of overall data collection and analysis	It depends on the assessment (usually at every assessment point)
Patient Reported Outcomes: Report on how patients feel or function	Questionnaires (also in the form of digital data collection)	Change in the percentage of patients satisfaction with respect to the previous questionnaire. Questions included in the scales are distinctive to capture the disease-specific issues. The indicator is normalized by measuring the change in patient satisfaction.	Percentage, with numerator and denominator	Outcome	Percentage	At the end of overall data collection and analysis	It depends on the assessment (usually at every assessment point)
Patient Reported Outcomes: Report on how patients feel or function	Questionnaires (also in the form of digital data collection)	Change in the percentage of patients satisfaction with respect to the previous questionnaire. Questions included in the scales are distinctive to capture the disease-specific issues. The indicator is normalized by measuring the change in patient satisfaction.	Percentage, with numerator and denominator	Outcome	Percentage	At the end of overall data collection and analysis	It depends on the assessment (usually at every assessment point)
Patient Reported Outcomes: Report on how patients feel or function	Questionnaires (also in the form of digital data collection)	Change in the percentage of patients satisfaction with respect to the previous questionnaire. Questions included in the scales are distinctive to capture the disease-specific issues. The indicator is normalized by measuring the change in patient satisfaction.	Percentage, with numerator and denominator	Outcome	Percentage	At the end of overall data collection and analysis	It depends on the assessment (usually at every assessment point)
Patient Reported Outcomes: Report on how patients feel or function	Questionnaires (also in the form of digital data collection)	Change in the percentage of patients satisfaction with respect to the previous questionnaire. Questions included in the scales are distinctive to capture the disease-specific issues. The indicator is normalized by measuring the change in patient satisfaction.	Percentage, with numerator and denominator	Outcome	Percentage	At the end of overall data collection and analysis	It depends on the assessment (usually at every assessment point)

Return on Engagement: Report on how patients are satisfied with how the missio/research respond to their needs and how they have influence it.	Questionnaires	Qualitative assessment of patients satisfaction with the reviewed mission/agenda and how they have influenced them, based on their answers to the questionnaire.	Qualitative report based on answers to the questionnaire	Outcome	N/A	After the data collection	It depends on the assessment (usually at every assessment point and at the end of the research to allow comparison)
Return on Engagement: Report on how patients are satisfied with how their engagement have influenced the research process and results, and how/if the research outcomes respond to their needs	Questionnaires	Qualitative assessment of patients satisfaction with the research final outcomes and their influence on the outcomes, based on their answers to the questionnaire.	Qualitative report based on answers to the questionnaire	Outcome	N/A	After the data collection	It depends on the assessment (usually at every assessment point and at the end of the research to allow comparison)
Return on Engagement: Report on what patients expect from their engagement in research (ex-ante) and how they are satisfied with their engagement in research (ex-post), including benefits and critical issues (pros and cons).	Questionnaires	Qualitative assessment of patients' expectation and satisfaction for/with their engagement in the research – including benefits and critical issues (pros and cons), based on their answers to the questionnaire.	Qualitative report based on answers to the questionnaire	Outcome	N/A	After the data collection	It depends on the assessment (usually at every assessment point and at the end of the research to allow comparison)

Limitations	Indicator in use	Example	Links	Comments	Feasability of elaborating the indicator
Main problems that could emerge when elaborating the indicators and potential disadvantages and/or shortcoming when using the indicators.	Indication of whether the indicator is currently being used: Yes/No	Example of a report, webpage, etc that provides an example on how to report the indicator.	Links of interest to either understand or compute the indicator.	Additional comments.	The initiative shall indicate whether it considers that it has access to the data needed to compute the indicator considering the data sources and additional information provided in the scorecard. To be filled by the initiative: Yes/No.
The measurement of patient satisfaction is diagnosis-specific.	Yes	WSHFT Quality Report 2016-17 – Western Sussex Hostipals NHS (pp. 152154)		This indicator resulted from WP3 literature review and was included in the D3.6 MSC (n.41). It has been moved to PRD as it is reported directly by the patients.	
The measurement of patient satisfaction is diagnosis-specific.	Yes	Brichetto G, Monti Bragadin M, Fiorini S, et al. The hidden information in patient-reported outcomes and clinicianassessed outcomes: multiple sclerosis as a proof of concept of a machine learning approach [published online ahead of print, 2019 Oct 28]. Neurol Sci. 2019;10.1007/s10072-01904093-x. doi:10.1007/s10072-01904093-x	https://pubmed.ncbi.nlm.nih.gov/31659583/		The PRO is already validated and can not be modified otherwise it will lose its validity.
The measurement of patient satisfaction is diagnosis-specific.	Yes	Brichetto G, Monti Bragadin M, Fiorini S, et al. The hidden information in patient-reported outcomes and clinicianassessed outcomes: multiple sclerosis as a proof of concept of a machine learning approach [published online ahead of print, 2019 Oct 28]. Neurol Sci. 2019;10.1007/s10072-01904093-x. doi:10.1007/s10072-01904093-x	https://pubmed.ncbi.nlm.nih.gov/31659583/		The PRO is already validated and can not be modified otherwise it will lose its validity.
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The measurement of patient satisfaction is diagnosis-specific.	Yes	Brichetto G, Monti Bragadin M, Fiorini S, et al. The hidden information in patient-reported outcomes and clinicianassessed outcomes: multiple sclerosis as a proof of concept of a machine learning approach [published online ahead of print, 2019 Oct 28]. Neurol Sci. 2019;10.1007/s10072-01904093-x. doi:10.1007/s10072-01904093-x	https://pubmed.ncbi.nlm.nih.gov/31659583/		The PRO is already validated and can not be modified otherwise it will lose its validity.
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The measurement of patient satisfaction is diagnosis-specific.	Yes	Brichetto G, Monti Bragadin M, Fiorini S, et al. The hidden information in patient-reported outcomes and clinicianassessed outcomes: multiple sclerosis as a proof of concept of a machine learning approach [published	https://pubmed.ncbi.nlm.nih.gov/31659583/	Indicators disease-specific (MS)	The PRO is already validated and can not be modified otherwise it will lose its validity.

		online ahead of print, 2019 Oct 28]. Neurol Sci. 2019;10.1007/s10072-01904093-x. doi:10.1007/s10072-01904093-x			
The measurement of patient satisfaction is diagnosis-specific.	Yes	Solaro C, Trabucco E, Signori A, Cella M, Messmer Uccelli M, Brichetto G, Cavalla P, Gironi M, Patti F, Prosperini L. Italian validation of the 12-item multiple sclerosis walking scale. Mult Scler Int. 2015;2015:540828. doi: 10.1155/2015/540828. Epub 2015 Mar 26. PubMed PMID: 25883806; PubMed Central PMCID: PMC4391321.	https://www.ncbi.nlm.nih.gov/pubmed/25883806?report=docsum&format=text	Indicators disease-specific (MS)	The PRO is already validated and can not be modified otherwise it will lose its validity.
Need of human's interaction for the qualitative analysis of the answers to the questionnaires, resulting in a report.	No	MULTI-ACT Patient Engagement Guidelines, short version v0.1 May 30th 2020, https://www.multiact.eu/ project-deliverables/	https://www.multiact.eu/project-deliverables/	Indicator elaborated from the results of the Public Consultation performed by MULTI-ACT in WP1, T1.3 (D1.6).	This qualitative indicator can be further elaborated, ad hoc questionnaires and a correspondent quantitative indicator can be developed. FISM individual exploitatio activities could be directed to develop and validate a specific PRO on this topic.
Need of human's interaction for the qualitative analysis of the answers to the questionnaires, resulting in a report.	No	MULTI-ACT Patient Engagement Guidelines, short version v0.1 May 30th 2020, https://www.multiact.eu/ project-deliverables/	https://www.multiact.eu/project-deliverables/	Indicator elaborated from the results of the Public Consultation performed by MULTI-ACT in WP1, T1.3 (D1.6).	This qualitative indicator can be further elaborated, ad hoc questionnaires and a correspondent quantitative indicator can be developed. FISM individual exploitatio activities could be directed to develop and validate a specific PRO on this topic.
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APPENDIX 5: MULTI-ACT PATIENT ENGAGEMENT METHODS

Below are listed and briefly described engagement methods recommended by the Multi-Act.

Focus Group	Focus Group is a qualitative method which is used to determine the preferences of people or to evaluate strategies and concepts. The method has originally been designed for market research. Focus group is undoubtedly the most widespread technique of engagement. It is rooted in qualitative studies, where it is a standard way of gathering patients' input and learning about their views and experiences. Its scope of application has widened in recent years, with the method being used for decision-making and guidelines formulation(Doria *et al.*, 2018), not without some criticism regarding insufficient separation of these two functions. Participants are selected according to certain common characteristics that relate to the research topic and are grouped into 8-10 people. It can be conducted face to face or in virtual digital space. The method is often used to generate or evaluate hypotheses and ideas in conjunction with a quantitative method, or as a primary data-collection method. Example: Selected patients and stakeholders are invited to a meeting to discuss about a topic.
Democs	It is both a card game and a policy-exploration tool that enables small groups of people to engage with complex public policy issues. It aims to help people find out about a topic, express their views, seek common ground with other participants, and state their preferred policy position. There are already a number of Democs kits on different issues which can be bought or downloaded for free from New Economics Foundation (NEF) and Play Decide. Example**:** Patients are provided with discussion cards that help them to express their views on a topic, to seek common ground with the other participants, and to express their preferences.

World Café	It is a method for engaging groups, both within organisations and in the public sphere. World Cafés are based on seven design principles and a simple method. World Cafés should offer an antidote to the fast-paced fragmentation and lack of connection in today's world. It is founded on the assumption that people have the capacity to work together, no matter who they are. Research indicated that World Café was not a popular method of engaging patients in the healthcare context, although some examples emerged. This may be in part due to the open-ended feature of the method. It is suitable for generating and sharing ideas, but does not guarantee a structured result, and does not support structured decision-making. (Engage2020, 2015) Example: A selected group of patients and stakeholders are invited to share their vision and position about a topic in a friendly space, and are encouraged to provide contribution to the debate.
Community Advisory Board	The Community Advisory Board (CAB) is a working group where patient advocates leaders from all world regions, work together to improve outcomes of patients covering patient information, research priorities, access to treatment and capacity building in the patients' community (CML Advocates Network, 2018). The CAB method is used in leukaemia communities and by the HIV movement. Example: Patient advocate leaders are invited as member of the working Group to work on a topics.
Delphi	The Delphi method is a multiple iteration survey method that enables anonymous, systematic refinement of expert opinion with the aim of arriving at a combined or consensual position. Its purpose is to generate discussion and enable a judgement on a specified topic to be made so that policy decisions can be taken which can claim to represent a given group's wants and views. Along with modified Delphi Method, it emerged as the second most popular patient engagement technique after Focus Group. Initially designed for panels of experts to arrive at decisions without influencing one another, it is increasingly used for including patients, either forming their own panel, or together with experts and other stakeholders (e.g. community, healthcare professionals) (Hall *et al.*, 2018). Delphi can be applied online and it often is. Delphi Method appears to be a popular tool for prioritisation of core-outcomes in patient-centred guidelines (Humphrey-Murto and de Wit, 2019), often in multi-stakeholder initiatives. Example: anonymous patients answer to multiple surveys to express their opinion about an approach defined by experts.

Consensus Conference	The purpose of this method is to enrich and expand a debate on a socially controversial topic. A group of citizens gather, set the agenda and the basis for assessment within a problem area. In the medical field, consensus conferences gathered practitioners and experts to build a consensus on either health knowledge (e.g. diagnostic criteria) or practices (e.g. best practices, treatment protocols). The format of these consensus conferences differs from event to event and cannot always be equated with the Consensus Conference engagement method, which has wider application. This literature review found papers describing engagement of patients using the consensus conference method in the course of research with the view of formulating guidelines or core outcomes. Example: A series of public events are organized to gather patients' opinions about a topic and may result in a position paper.
Citizens Hearing	"The purpose of a citizens hearing is to inform and create discussion among citizens. The method uses brainstorming, dialogue, prioritization, reasoning and voting. Through dialogue and without interference of either experts or politicians, the citizens formulate their own suggestions and ideas (as to how a political (technological) problem can be dealt with) and present them to politicians" (Engage2020, 2015). Some examples show how citizen hearing has been used to investigate the preferences of patients with respect to specific issues such as for example the use of health data and the status of health rights. This method enhanced the understanding and awareness of the barriers and achieving positive solutions to help overcome them; and seek commitment on a joint plan for monitoring and acting on the topics. Example: Patients brainstorming, dialogue, reason and voting about a topic, without interference from any experts.
Serious Gaming	"The primary objective of 'serious games' or 'applied games' is to train and/or educate the user. These games serve as tools for acquiring complex knowledge in fields such as health care, education, engineering, city planning, emergency management, etc. Some serious games simulate real-life events and/or processes, thus providing the user with a problem-solving training environment. Furthermore, 'serious games' can be used in order to develop innovative products and services." (Engage2020, 2015) Example: Patients are trained with an ICT game that presents the problem in a simple and fashionable way. The game is structured to provide patients with a training environment for problem-solving.

Research Studios Method	This method allows researchers to work closely with community members as they design studies. In 2009, the Meharry-Vanderbilt Community-Engaged Research Core began testing new approaches for community engagement (Cunningham-Erves *et al.*, 2020), which led to the development of the Community Engagement Studio (CE Studio). This structured program facilitates project-specific input from community and patient stakeholders to enhance research design, implementation, and dissemination. Developers used a team approach to recruit and train stakeholders, prepare researchers to engage with stakeholders, and facilitate an in-person meeting with both. Literature reported that input from stakeholders was valuable and that the CE Studio helped determine project feasibility and enhanced research design and implementation (Joosten *et al.*, 2015).
Scenario Workshops	An instrument for participatory planning, it is based on dialogue and collaboration between local citizens, stakeholders, experts and policy makers. The method aims to stir dialogue, provide the opportunity for exchanging experience and knowledge, and facilitate consensus on proposed solutions among. It is a "two-days meeting involving 25-30 local multi-stakeholder representatives to assess different solutions to a specific problem. Before the workshop, a set of scenarios is developed and used as visions and inspiration at the scenario workshop." (Engage2020, 2015) Example: A Scenario Workshop is organized to discuss in a multi-stakeholder group on a specific R&I problem. The assessment of the different solutions proposed by patients and stakeholders results in defined and agreed actions to solve the problem. Patients comments on the scenario based on their experiential knowledge.
World Wide Views	The method is designed to closing the gap between citizens and policy makers in the context of global policy-making. Citizens at multiple sites debate the same questions on the same day. They are given materials before and during the day and then vote to choose pre-defined questions. "The votes are collected and reported online for comparison. It is possible to compare the votes across countries, continents, gender, age and other criteria. The results are analysed and presented to policy-makers." (Engage2020, 2015) Example: A World-Wide Views is organized to gather patients' votes on a set of predefined research questions and policy-makers to design R&I and healthcare policies use results.
Voting Conference	Used in small settings and with diverse target groups, it is an approach similar to World-Wide Views. E-conference (temporary online forum on a specific topic) can be used as tool (Engage2020, 2015). Example: A Voting Conference is organized to collect patients' votes on a set of predefined research questions and results are integrated in R&I activities.

Deliberative Polling®	Developed by James Fishkin, the public consultation method which combines deliberation in small group with scientific random sampling. It informs public policy. (Engage2020, 2015)
Deliberative online forum	Web-based (in online forums) discussions between informed individuals about issues which concern them, leading to some form of consensus and collective decision (Engage2020, 2015).
Deliberative Mapping	Involving both specialists and members of the public, it combines varied approaches to assess how participants rate different policy options against a set of defined criteria. The method allows substantial involvement of public participants (Engage2020, 2015).
Deliberative Workshops	Events with a focus on in-depth informed discussions on complex or controversial issues to inform policy and regulation, exchange opinions or raise awareness. This method has also been used to develop research agendas and objectives (Engage2020, 2015). Example: Patients are engaged in deliberative surveys, small group discussions, online forums, dialogue events, etc. to express their opinions on specific R&I's questions and issues and the results are used for deliberating on specific R&I policies. Patients can also rate different policy options against a set of defined criteria.

Literature

CML Advocates Network (2018) Community Advisory Board, CML Advocates Network For Chronic Myeloid Leukemia Patient Group Advocates. Available at: https://www.cmladvocates.net/cml-cab.

Cunningham-Erves, J. et al. (2020) 'Engagement of community stakeholders to develop a framework to guide research dissemination to communities', Health Expectations, 23(4), pp. 958–968. doi: 10.1111/hex.13076.

Doria, N. et al. (2018) 'Sharpening the focus: differentiating between focus groups for patient engagement vs. qualitative research', Research Involvement and Engagement, 4(1), p. 19. doi: 10.1186/s40900-018-0102-6.

Engage2020 (2015) Engage2020 Action Catalogue. Available at: http://actioncatalogue.eu/.

Hall, D. A. et al. (2018) 'Recruiting and retaining participants in e-Delphi surveys for core outcome set development: Evaluating the COMiT'ID study', PLOS ONE. Edited by B. Young, 13(7), p. e0201378. doi: 10.1371/journal.pone.0201378.

Humphrey-Murto, S. and de Wit, M. (2019) 'The Delphi method—more research please', Journal of Clinical Epidemiology, 106, pp. 136–139. doi: 10.1016/j.jclinepi.2018.10.011.

Joosten, Y. A. et al. (2015) 'Community Engagement Studios', Academic Medicine, 90(12), pp. 1646–1650. doi: 10.1097/ACM.0000000000000794.