



Deliverable D4.3

Review Report on the implementation of the Framework on MS case



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This document illustrates and integrates the evidences emerged from the first implementation of MULTI-ACT framework and reviews it accordingly whereas needed.

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EXECUTIVE SUMMARY

The EU-funded MULTI-ACT project aims to increase the impact of health research on people with brain diseases. According to this scope, MULTI-ACT provides a new Collective Research Impact Framework (CRIF) and a set of governance guidelines (MULTI-ACT Governance Model) to improve the governance of Multi-Stakeholder Research Initiatives and stakeholder co-accountability in health research and innovation (R&I), with a focus on brain diseases. CRIF has been translated into an online toolbox (MULTI-ACT Toolbox) and an assessment co-accountability system (MULTI-ACT Master Scorecard). MULTI-ACT model considers patients as key stakeholders and, for this reason, developed Patient Engagement Guidelines to enable science with and of patient input.

Against this backdrop, the deliverable illustrates the activities and the results of the Task 4.3 of WP4, which aims at reviewing the MULTI-ACT CRIF after its application to an existing initiative, the Multiple Sclerosis Care Unit (MSCU), carried out under Task 4.1 and 4.2.

In this regard, through a baseline analysis that the MSCU initiative carried out, the case study highlighted the gaps between the current status of the initiative and the recommendations of MULTI-ACT Governance Model. According to the gaps identified, specific focus was dedicated to the stakeholders' representation in the initiative, the definition of a mission and agenda, the materiality analysis¹ and the identification of relevant aspects and indicators. Moreover, recommendations for the implementation of the Patient Engagement guidelines have been provided.

This document presents a refined version of the MULTI-ACT CRIF and identify several lessons learnt, insights and recommendations, emerging from a thorough reflection on the first implementation of the model to an existing initiative.

First, this analysis required the clarification of a logic flow to be followed by the initiative seeking to implement, as the first MULTI-ACT "user" - the multi-stakeholder approach proposed by MULTI-ACT. Second, it led to a comprehensive and detailed update of MULTI-ACT Governance Model's criteria, sub-criteria and recommendations taking into consideration the evidences generated from the MSCU initiative case study. Finally, the analysis shows the approach that the appliers of the guidelines could adopt when integrating the governance model within its initiative or organization.

The overall review has provided the MULTI-ACT consortium with the opportunity to test the overall framework with a potential user and finetune it in view of the finalisation and release of the Digital Toolbox (WP2) and the Manual (WP6). It is also deemed to facilitate the work to be carried out in the subsequent Work Packages of MULTI-ACT project and WP7, specifically the uptake of the MULTI-ACT CRIF by Multi-Stakeholder Research initiatives and the exploitation of the MULTI-ACT project results.

¹ Materiality is the principle that determines which relevant topics are sufficiently important that it is essential to report on them, Global Reporting Initiative, update 2020.

1 INTRODUCTION AND PURPOSE OF THE DOCUMENT

The Work Package 4 of MULTI-ACT project tested and applied the collective research impact framework (CRIF) to a real case study, the Multiple Sclerosis Care Unit (MSCU), with multiple aims:

- assessing the application of MULTI-ACT recommendations on a case study and identify potential gaps and areas of improvement;
- providing recommendations on how to use the MULTI-ACT Governance Model, including a guidance on how to apply Patient Engagement strategy;
- evaluating the functioning of the overall implementation of the MULTI-ACT CRIF.

The case study was carried out through two workshops in May 2020 and through a constant flow of communication with the MSCU.

This deliverable provides a report on the findings emerged during Tasks 4.1 and 4.2 in relation to the application of the CRIF to the case study and a refined and validated version of the MULTI-ACT framework leveraging lessons learnt from the implementation of the Model.

In this regard, evidence emerged during the workshops highlighted the need for some refinements and further specifications of the MULTI-ACT Governance Model previously described in WP5's deliverable 5.4, including the recommendations related to accountability, stakeholder engagement and governance.

1.1 Structure of the document

This document is structured as follows:

- Executive summary
- Chapter 1 introduce the contents of the document and its purpose.
- Chapter 2 describes the main features of the MSCU and the findings from Tasks 4.1 and 4.2.
- Chapter 3 explains how the accountability pillars' model evolved and guided the definition of the governance model, focusing in particular on the cyclical evolution of the agenda, as the result of the Multi-Stakeholders Initiative development or of an external unexpected change (e.g. COVID-19 pandemic).
- Chapter 4 contains the refined version of the governance model, on the basis of the case study, and MSCU's feedback to the MULTI-ACT Patient Engagement Strategy.
- Chapter 5 provides the indications regarding the order of implementation of criteria.
- Chapter 6 presents the conclusions and outlines further possible developments of the CRIF.

1.2 Glossary

Agenda: An agenda is a list of fundamental transformative objectives agreed upon by stakeholders that an initiative aims to achieve to fulfill its mission, including a description of the main outputs² and activities needed to achieve them.

MULTI-ACT CRIF (Collective Research Impact Framework): the conceptual framework that MULTI-ACT is developing to enable a new collective accountability approach to multi-stakeholder R&I initiatives in the field of brain diseases. The framework is composed of a set of governance recommendations (MULTI-ACT Governance Model), a set of Patient Engagement Guidelines and a set of co-accountability indicators (MULTI-ACT Master Scorecard).

It is composed of five dimensions:

- **Efficacy** refers to the capacity of a given initiative or programme to achieve its mission, whereas the term mission entails all the strategic priorities settled via the stakeholder engagement process.
- **Excellence** concerns the quality of research data and findings in health research. Only excellent research will have a positive impact on people and society.
- **Social** considers the evaluation of direct and indirect effects of health research on the whole society, beyond the mission-related dimension that for health R&I would typically focus on patients' needs.
- **Economic** refers to the assessment of the long-term economic and financial sustainability of health R&I.
- **Patient-reported** concerns patients as key stakeholder, whose needs, information and perspectives must be understood and incorporated into the process of health research impact evaluation. Thus, it works as an overarching dimension in which the other four dimensions should be rooted. This dimension includes indicators that are reported by patients.

Criteria and sub-criteria: the main tenets that constitute the MULTI-ACT Governance Model and their related description/specification.

Experience: a practical case study within a multi-stakeholder initiative.

Experiential knowledge: "Experiential knowledge arises when [these] experiences are converted, consciously or unconsciously, into a personal insight that enables a patient to cope with individual illness and disability. When patients share experiential knowledge, the communal body of knowledge exceeds the boundaries of individual experiences." (Caron-Flinterman et al. 2005) Thus, experiential knowledge is knowledge gained through experience, as opposed to a priori (before experience) knowledge.

Governance bodies: the bodies identified by MULTI-ACT Governance Model which are described below:

² The products, capital goods and services which result from a development intervention.

- The **Leadership Board** (referred to as “LB”) is composed by representatives from the categories of stakeholders that have a strategic importance for the initiative and represents the decision-making body;
- The **Stakeholder Advisory Board** (referred to as “SAB”) is composed by interested stakeholders and provides advices to the LB. Within the SAB, patients, their families and one of the categories of stakeholders involved (e.g. caregivers) 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** (referred to as “PAB”).
- The **Committees and Working Groups** (referred to as “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.
- The **Engagement Coordination Team** (referred to as “ECT”) is in charge of coordinating the involvement of stakeholders, including patients, relatives and caregivers, in all the operations;
- The **Compliance Committee** (referred to as “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.

MULTI-ACT Governance Model or simply referred as “Model”: the set of strategic and governance recommendations proposed by MULTI-ACT project to be applied by multi-stakeholder research and performing organizations.

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

Patient(s): In order to clarify the terminology for the potential roles of patients’ interaction presented in this and other MULTI-ACT documents, we use the term “patients” which covers the following definitions:

- **“People with the disease”:** persons with lived experience of the disease;
- **“People affected by the disease”:** persons or groups that are affected by the disease, including family members and caregivers.

Promoter(s): are the actors that decide to implement MULTI-ACT Governance Model within their existing or new organizations. After the implementation of the Model, they will be part of the governance bodies (i.e. Leadership Board)

Recommendations: detailed description of a sub-criteria, which is constituted by principles and practical solutions that guide the implementation of the MULTI-ACT Governance Model

Stakeholder: any individual or group that is affected by, can influence or may have an interest in the outcomes of an organization's actions.

1.3 Abbreviations

Acronyms	
CC	Compliance Committee
CRIF	Collective Research Impact Framework
ECF	European Charcot Foundation
ECT	Engagement Coordination Team
LB	Leadership Board
MSCU	Multiple Sclerosis Care Unit
MSRIs	Multi-stakeholder research initiatives
PAB	Patient Advisory Board
PE	Patient Engagement
PROs	Patient Reported Outcomes
PROMs	Patient Reported Outcomes Measures
R&I	Research and Innovation
RFPO	Research Funding and Performing Organization
RRI	Responsible Research & Innovation
ROI	Return on Investment
SAB	Stakeholder Advisory Board
WG	Committees and Working Groups

2 MAIN FEATURES AND ANALYSIS OF THE MS CASE STUDY

The Multiple Sclerosis Care Unit (MSCU), promoted by European Charcot Foundation (ECF), was selected as the case study to test and apply the MULTI-ACT CRIF into an existing multi-stakeholder research initiative, at an early stage of development.

As the first step, during WP4, a baseline analysis was carried out in order to evaluate the current status of the initiative with respect to the implementation of the five criteria of the MULTI-ACT Governance Model³ and to pave the way for the application of CRIF within a mission-oriented initiative. The detailed description of the activities being carried out during the case study are reported in Deliverable 4.1 Assessment report on the applicability of the MULTI-ACT framework in a Multiple Sclerosis case and Deliverable 4.2 Recommendations on the use and tailoring of the MULTI-ACT Framework. In this regard, for the purpose of Deliverable 4.3, it is worthy to recall the main results of the case study.

The initiative has defined its vision as “leading the way for personalised treatment” and has determined its mission as follows: “MS Care Unit is a patient-centred initiative that aims to provide the highest possible leading-edge interdisciplinary care model for people with and affected by MS, while advancing research to prove its cost-effectiveness for the society (sustainability).”

Based on its mission, the MSCU has identified its strategic priorities, which are:

- To define MS Care Unit **Structure**
- To define MS Care Unit **Function**
- To define MS Care Unit **Impact**
- To define MS Care Unit **Sustainability**
- **Research purposes** to fill the gaps.

A governance structure has also been defined, and it is composed of:

- The Executive Board
- The Assembly (all partners)
- ECF MS initiative Advisory Board
- A working group which defined the characteristics of a MS Care Unit, chaired by two coordinators (co-chairs)

At the current stage, MSCU has identified the following categories of relevant stakeholders: Patients, Patients organizations, Citizens and civil society organizations, Payers and purchasers, Care providers, Industry companies and services sector.

2.1 MS Case study: main results from task 4.1

The fulfilment of the 5 governance criteria is the entry point for a Multi-Stakeholder Research Initiative to apply the whole CRIF. The baseline analysis showed that, even if the initiative is at an early stage of development, several essential features of the MULTI-ACT Governance Model are already

³ Criterion 1 – Mission and agenda, criterion 2 – Participatory governance, criterion 3 – Effective stakeholder engagement, criterion 4 – Effective and efficient management of the initiative, criterion 5: Co-accountability assessment

implemented. Nevertheless, it should be noted that there is still room for development of governance assets. Table 1 shows the main findings from Task 4.1.

Table 1: Result of the baseline analysis of the MSCU Case Study according to the MULTI-ACT criteria

MULTI-ACT CRITERION	CURRENT STATUS	MSCU'S ROOMS FOR IMPROVEMENT
Mission and agenda	Mission and intended beneficiaries have been defined.	MSCU agenda and the related objectives/actions plan could be further defined.
Participatory governance	There is a governance structure, involving stakeholders at different levels (Patients, Patients organizations, Care Providers, Policy makers, Industry companies, Research and education organizations).	<p>Development of a procedure describing the roles and responsibilities within the governance structure.</p> <p>Definition of the different decision-power among stakeholders and the mechanisms to ensure the participation of all stakeholders.</p> <p>Definition of how to maintain commitment and ownership among the participating stakeholders as well as mechanisms to ensure that self-interest of stakeholders does not prevail.</p>
Effective stakeholder engagement	<p>Stakeholders beyond the governance structure (Payers and purchasers, stakeholders dedicated to create a culture to effect and sustain change) who may influence the initiative are partially identified.</p> <p>There is an ad-hoc training related to patient engagement.</p>	<p>Definition and differentiation of the level of engagement;</p> <p>Dedicate a function for the patient engagement strategy and plan;</p> <p>Development of indicators to measure return on patient engagement. (e.g. to develop a Patient Engagement Plan and monitor it over time).</p>
Effective and efficient management of the initiative	An internal team with solid skills is in place.	<p>Development of a mechanism ensuring flexibility;</p> <p>Development of a collective action plan;</p> <p>The cost management process could be improved (e.g. the implementation of a resource monitoring system).</p>

<p>Co-accountability assessment</p>	<p>Some medium and long-term measures of the effects of the establishment of the multidisciplinary MS care Units have been identified</p>	<p>Identified measures do not necessarily reflect collective stakeholders' perspective;</p> <p>Development of a monitoring system for the implementation of the actions and the performance of the initiative itself;</p> <p>Development of a progress report or a system to collect feedback from external stakeholders and the public.</p>
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2.2 MS Case study: main results from task 4.2

The findings of the case study were discussed during the virtual workshop held under Task 4.2 in May 2020, whose overall aim was to enable the process of co-creation within MULTI-ACT using the MSCU initiative as a case study.

During the workshop, which actively involved patient organizations and clinician MSCU stakeholders, the materiality analysis was carried out in order to define the list of relevant aspects of the initiative and to identify its related indicators.

In consideration of Task 4.2, several considerations emerged from MSCU stakeholders that can be summarised as follows:

- 1) **Purpose of materiality analysis:** a clarification is needed on the link between the materiality analysis to performance assessment. It has been stated that the assessment on the initiative impact should be based on indicators that are related, through the Master Scorecard, to the aspects that the stakeholders of an initiative consider relevant to fulfill the MSCU mission. In this regard, materiality analysis allows the identification of the relevant aspects.
- 2) **Stakeholder representation:** in the context of materiality analysis, further explanations and clarifications are needed on the minimum number of individual views required to be considered representative of a stakeholder category. Also, it would be useful to give the possibility to have additional specificities within each category. For example, in the case of a patient, different levels of psychological attitudes toward the engagement can be identified.
- 3) **Stakeholder perspective:** research initiative promoters will need to collect the perspective of multi-stakeholder categories. Guidelines and/or tools could be helpful to support promoters in this process and the stakeholders who have to fulfil the questionnaire.
- 4) The MULTI-ACT co-accountability system (MULTI-ACT Master Scorecard) include a list of **aspects and indicators**. It has emerged that potential appliers might be interested in aspects or indicators not included in the list. The opportunity to give promoters the possibility to add new aspects or indicators could be discussed

These insights are very useful to integrate the MULTI-ACT CRIF with genuine feedbacks coming from the implementation of the Framework. In this regard, the following pages illustrate how and to which extent findings and insights emerged during tasks 4.1 and 4.2 could be exploited to refine MULTI-ACT Governance Model and co-accountability system (MULTI-ACT Master Scorecard).

3 FROM THE ACCOUNTABILITY PILLARS TO THE MULTI-ACT CRIF FLOW

3.1 Co-creation and alignment activities: from accountability steps to co-accountability pillars

CO-CREATION AND LEARNING FROM MS CASE STUDY

The initial set of accountability steps were introduced in WP3 (D3.2). They were theoretically oriented on the post-normal science ideas and based on the review on existing measurement methodologies of multi-stakeholder initiatives. However, the necessity to further develop these steps to be applied to the context of health research and innovation was acknowledged. Therefore, based on the feedback received from the MSCU (WP4), the relationship between accountability steps and governance model was suggested to be improved.

STEPS VS. PILLARS: WHAT WAS IMPROVED

After considering the MSCU case-study empirical insights and in the light of the co-creation philosophy of the MULTI-ACT project, the consortium reflected further on language and terminology and decided to re-label them as “*Co-accountability pillars*” in order to align their role in expressing the philosophy of the MULTI-ACT and to reflect the circularity and flow of the process. Indeed, the co-accountability approach behind the co-accountability pillars is related to the core philosophy and strategic value proposition of whole MULTI-ACT framework. In detail, two elements are reflected in the co-accountability pillars:

- *Circularity*: The co-accountability pillars reflect an on-going engagement process and re-definition task within the research initiative. Circularity guarantees a dynamic and an iterative approach.
- *Strategic value*: Co-accountability pillars reflect the strategic value of the CRIF because pillars recognize the possibility to adapt and assess research initiative through continuous monitoring.

Table 2 describes the amendments made to the accountability steps and it presents improved descriptions of the co-accountability pillars.

Table 2: Evolution from the accountability steps in the co-accountability pillars.

Accountability steps (D3.2)	Co-accountability pillars (D4.3)	Improvements/ changes	Description
Establishment of scope and mapping of stakeholders	Mapping of stakeholders and establishment of the scope	Clarified description	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 conceptual framework	Development of operative framework	Operative model better illustrates the agenda of the initiative	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 indicators	Co-selection of aspects	Added description of core and additional indicators through the materiality analysis	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.
Measurement of indicators	Shared measurement system	Stakeholders can participate BOTH in the data collection AND analysis.	Stakeholders are engaged in 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	Reporting, monitoring and assessment	The notion of the Master Scorecard's functions	<p>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.</p> <p>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.</p>



Figure 1: The five co-accountability pillars

3.2 The MULTI-ACT CRIF workflow

Following the evolution of the CRIF pillars, a logic flow for the initiative seeking to implement a multi-stakeholder approach has been defined. The so-called MULTI-ACT CRIF workflow described in figure 2 shows the steps to be undertaken by the initiative in this stage. The backbone that underpins the model described below is **co-accountability**, that enables the cyclical evolution of the agenda over time (in coherence with the mission of the initiative) as the result of the multi-stakeholder initiative development or of an external unexpected change (e.g. COVID-19 pandemic).

The workflow is composed by 5 main phases (corresponding to the five co-accountability pillars in figure 1) divided in 9 steps (displayed in figure 2). The workflow guides the user in the adoption and implementation of MULTI-ACT CRIF, pinpointing its main contents. These contents are then described in detail within the 41 recommendations of MULTI-ACT Governance Model (see Chapter 4).

The workflow ensures a continuous improvement by the sequence of phases described in figure 2. Each research initiative must define its scope and mission (phase 1) and implement an operating framework for its realization (phase 2). The control of the results is entrusted to the definition of specific aspects (phase 3) which are the basis for the selection of indicators of a measurement model shared by the stakeholders involved in the initiative (phase 4). Finally, the continuous monitoring of these indicators provides the basis for corrective actions (phase 5) to be made in order to ensure that the agenda is monitored to meet the mission.

For each of the phases described above, MULTI-ACT has defined specific operational tools that make up the content of the three components of the model: governance, patient engagement and co-accountability/impact assessment scorecard.

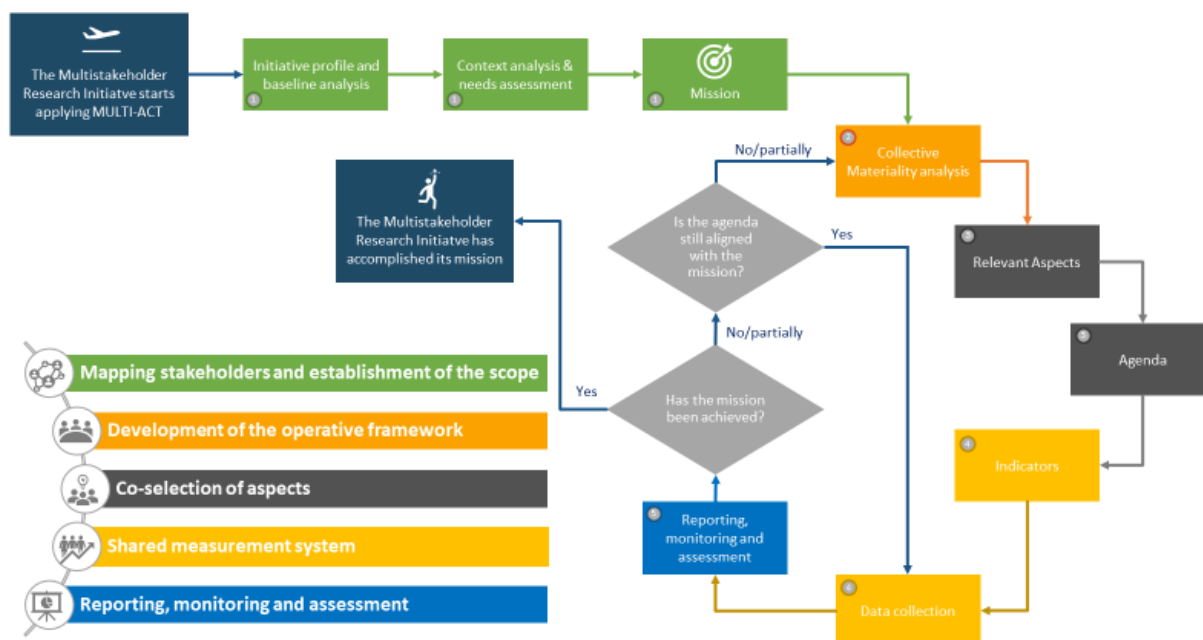


Figure 2: The MULTI-ACT CRIF Workflow and the relation with co-accountability pillars.

Phase 1 is composed by three linear steps that lead to the definition of the initiative's mission, which usually remains unchanged in the medium-long run:

- Already set up initiatives submit a baseline analysis in order to measure their initial level of coherence with the MULTI-ACT Governance model.
- The initiative should identify its intended beneficiaries, analyze the operating context of the initiative and understand the needs of stakeholders. If the “patients” stakeholder category is selected, then a patient engagement plan should be defined (see sub-criterion 2.1).
- On this basis, the initiative should define its mission, stating its current and future desired role and goals. This step refers both mission definition in case the initiative does not feature a mission yet and mission refinement if the initiative has to align it to the context analysis and the needs assessment.

Through phase 2, MULTI-ACT proposes a specific methodology for defining the material topics which establish the agenda of the initiative: the collective materiality analysis. This methodology allows to identify the relevant issues for the stakeholders involved in the initiative and therefore to define the operational steps to develop their expectations. Based on the material topics emerged from materiality analysis, the initiative can outline an agenda, identifying the transformative objectives that meet stakeholders' perspective (Phase 3).

The agenda should be monitored through the relevant indicators associated with the material aspects in the MULTI-ACT Master Scorecard. Once the indicators associated to 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 (Phase 4).

MULTI-ACT has developed a digital tool that allows a co-selection process of the aspects and indicators that best reflect the relevant issues for the stakeholders. By operating in this way, each initiative will have a score card of 12-15 aspects chosen from a list of 53 aspects available, and relevant 12-15 indicators chosen from 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, 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. Indeed, for a mission-oriented approach, while the mission is defined at the beginning of the initiative, the alignment of the agenda to the mission need to be monitored and checked regularly, and therefore, phases 2 to 5 should be repeated accordingly (e.g. on an annual basis).

The management approach of the entire process (phases 1 to 5) and the application of its operational tools must be based on the constant involvement of the stakeholders, in particular the patients, according to the principles and indications provided by the patient engagement and related guidelines.

The following pages illustrate the MULTI-ACT CRIF for collaborative initiatives seeking to implement a mission-oriented approach and multi-stakeholder structure, aligned with the updated findings emerged during WP4 works.

4 REFINED MULTI-ACT CRIF FOR COLLABORATIVE INITIATIVES

The MULTI-ACT Governance Model is one of the fundamental elements of MULTI-ACT CRIF. It is composed by 5 criteria and 19 sub-criteria, detailed in 41 recommendations to be followed by the appliers of the Model.


<div> <div>3</div> <div>  </div> <div>CLEAR, EFFECTIVE AND INCLUSIVE METHODOLOGY OF STAKEHOLDER ENGAGEMENT</div> </div>			
<ol style="list-style-type: none"> 1. Define and approve a methodology to engage stakeholders 2. Engage intended beneficiaries 3. Differentiate the level of engagement according to involved stakeholders 4. Ensure a balance between engagement of involved stakeholders and agile management of the initiative 			
<div> <div>1</div> <div>  </div> <div>MISSION AND AGENDA</div> </div>	<div> <div>2</div> <div>  </div> <div>PARTICIPATORY GOVERNANCE</div> </div>	<div> <div>4</div> <div>  </div> <div>EFFECTIVE AND EFFICIENT MANAGEMENT AND COORDINATION OF THE INITIATIVE</div> </div>	<div> <div>5</div> <div>  </div> <div>CO-ACCOUNTABILITY ASSESSMENT</div> </div>
<ol style="list-style-type: none"> 1. Identify intended beneficiaries, analyze the operating context of the initiative and understand the needs of stakeholders 2. Define a shared mission and common agenda 3. Promote a movement-building approach to achieve transformative changes 4. Guarantee ethical acceptability and social justice 	<ol style="list-style-type: none"> 1. Allow the involvement of intended beneficiaries 2. Adopt a multi-stakeholder approach enabling co-creation 3. Implement a participatory structure 4. Guarantee equity and mechanisms to avoid self-interest 	<ol style="list-style-type: none"> 1. Enable involved stakeholders to coordinate their efforts and perform activities 2. Set clear and transparent processes and timeline 3. Maintain flexibility 4. Ensure the presence of secure funding, solid organizational structure and resource management 	<ol style="list-style-type: none"> 1. Define a shared assessment system 2. Set effective feedback mechanism 3. Ensure continuous learning, communication and disclosure of knowledge

Figure 3: The MULTI-ACT governance criteria and sub-criteria

Before moving on to the analysis of the Model, it is worth mentioning two methodological premises:

1) The promoters

The promoters are the actors that decide to implement MULTI-ACT Governance Model within their existing or new organization. After the implementation of the Model, they could be part of the governance bodies (i.e. Leadership Board). The promoters could be part of:

- Already existing multi-stakeholder organizations or initiatives, with a governance structure, that decide to adapt it to the MULTI-ACT Governance Model;
- New-born organizations willing to be structured with multi-stakeholder and co-accountable governance.

In either case, the individuals that guide the adoption of MULTI-ACT are defined in this document as the “promoters”. Please note that promoters might represent different stakeholders’ categories.

2) The level of detail

The following recommendations have the objective to define the MULTI-ACT Governance Model and guide the promoters in its implementation. The content describes what should be done and how it should be done, at a high level, in order to achieve the implementation of responsible governance. The implementation and adaptation of the specific solutions and

recommendations are left to the applier, who will apply them to the specific context and the organization's objectives and characteristics.

As collateral to the Governance Model, the MULTI-ACT Patient Engagement Guidelines and the connected functionalities in the Digital Toolbox, has been developed as tools to address the criteria n.2 Participatory Governance and n.3 Clear, effective and inclusive methodology of stakeholder engagement.

The promoters of MSCU have been provided with recommendations on patient engagement based on the MULTI-ACT guidelines (see D4.2 – Appendix n.5).

The promoters evaluated the guidelines as **interesting, clear to understand, comprehensive, feasible/applicable, useful for actuating patient engagement activities in multi-stakeholder initiatives such as MSCU, and with potential to bring value to the research activities and its impact.** The recommendation will be used in the implementation of MSCU's research activities. The positive feedback from MSCU has consolidated the approach recommended by the MULTI-ACT Patient Engagement Guidelines (see D1.6, or short version).

As stated above, the MSCU is at an early stage of development and the case study carried out under WP4 focused on those recommendations that could have been applied in a relatively short time span, especially those related to Criterion 1 of MULTI-ACT Governance Model and the definition of the mission and the agenda. In terms of future development, it would be interesting and useful to analyze the adoption of the recommendations on patient engagement in the MSCU on a larger time span. This long-term exercise would allow to observe the robustness of the MULTI-ACT Patient Engagement Guidelines over time, to carry out a complete assessment of the implementation of the recommendations, to identify potential challenges and complexities that the Promoters and actuators (e.g. ECT) may potentially face, and propose alternative solutions to simplify the recommendations.

4.1 Criterion 1: Mission and agenda

The appliers of the MULTI-ACT Model should define a mission and a shared agenda, considering MULTI-ACT principles.

To achieve this objective, the initiative should:

- Identify the intended beneficiaries and analyze the context;
- Define a shared mission and common agenda;
- Promote a movement-building approach to achieve transformative changes;
- Guarantee ethical acceptability and social justice.

4.1.1 Sub-criterion 1.1: Identify intended beneficiaries, analyze 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 of the MULTI-ACT Governance Model should **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). For the purpose of MULTI-ACT project, the society in general and, within it, the patients are often key beneficiaries. The appliers should explicitly identify these beneficiaries, their characteristics and related needs, which are preliminary to the identification of the initiative’s long-term goals.

In this initial phase, the initiative should also focus its efforts on the **context analysis** to clarify which are the main actors and trends related to the challenges faced by the initiative. This step entails the analysis of the current state of the “issue” that the project is seeking to influence, the social, political and environmental conditions, and the actors able to influence change. Furthermore, the analysis identifies the risks and the assumptions that an initiative should consider when achieving its objectives. In this regard, before defining the mission and the agenda (see sub-criterion 1.2) appliers should analyze which ecosystems and communities are affected, what are the key issues and pressures faced and, what are the main social, political, economic and technological factors that influence the issue in this context.

It is recommended to carry out the context analysis in parallel with the “Plan” phase of **sub-criterion 3.1**, according to which initiatives applying MULTI-ACT should profile and map their stakeholders.

Having identified the intended beneficiary of the initiative, analysed its operating context and mapped its stakeholders, an initiative should deeply understand which are the needs of its stakeholders through a **needs assessment**, paying attention to the intended beneficiaries that it strives to satisfy. The needs assessment is a fundamental process that allows to better understand the challenges faced by the initiative and its stakeholders and to identify more clearly the change that it wants to bring in

society, which will then be expressed through its mission and detailed through its agenda, as described in sub-criterion 1.2.

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

In this process, the initiative could integrate its context analysis and needs assessment through the identification of the problem faced, its main roots and its most relevant consequences, involving relevant stakeholders in this analysis, which will represent their needs in the process. This exercise could facilitate the steps described in the following sub-criterion 1.2, namely the definition of the mission and the agenda.

4.1.2 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 MULTI-ACT model have in common the **vision of striving to implement mission-oriented research**. According to their specific nature and in line with this vision, initiatives should define their mission and agenda.

4.1.2.1 Mission definition

A mission statement defines the initiative’s current and future role, its goals⁴ and its approach to reach them.

This statement should include both descriptive elements clearly illustrating what the initiative wants to achieve, and transformative elements i.e. the changes the initiative wants to create in the context where it operates.

Regarding the first category, the initiative should describe:

- the potential beneficiaries
- The perimeter of intervention (e.g. health domain, geographical area, gender, socio-economic conditions)

Regarding the second category the initiative should clarify:

- The expected change aimed for the beneficiary
- The comparative baseline against which this change could be assessed

⁴ A goal is a description of a destination, and an objective is a measure of the progress that is needed to get to the destination.

EXAMPLE OF A RESEARCH INITIATIVE MISSION⁵

Decreasing the burden of dementia by 2030 reducing the progression of the disease in affected patients in Europe

Descriptive elements

- Beneficiary: affected patients
- Perimeter of intervention: dementia brain disease in Europe

Transformative elements

- Expected change in the beneficiary: reducing the progression of the disease
- Baseline: current burden of dementia.

4.1.2.2 Materiality analysis and identification of aspects



Figure 4: The materiality analysis as the bridge between the initiative's mission and its outcome.

According to the 5th MULTI-ACT Governance Model criterion, appliers of the MULTI-ACT Model should **establish a shared and effective assessment system**, including a set of indicators, that allows improvement and communication, and establish a mechanism to receive feedback.

The appliers of the MULTI-ACT Model should then enable the stakeholders of the initiative to co-select measurable objectives in order to measure the progress and outcomes of the initiative.

The initiative's governance bodies should identify the aspects of measurement through a process that requires the identification of measurable and achievable targets thus ensuring stakeholders' engagement over time. The initiative should carry out a **materiality analysis** in order to ensure

⁵ Inspired by Mission-Oriented Research & Innovation in the European Union. A problem-solving approach to fuel innovation-led growth – Decreasing the burden of dementia, Mariana Mazzucato.

coherence between the indicators that the initiative shall report on periodically and the interest of the different stakeholder categories involved

Materiality analysis is a managerial tool that can facilitate the adoption of co-accountability and multidimensional impact assessment (MULTI-ACT Master Scorecard). Materiality analysis allows promoters to gather stakeholders' perspective and to **identify the aspects** considered as relevant, having an impact on or influencing the decisions of stakeholders. In this perspective, materiality analysis can be defined as the managerial tool that makes the bridge walkable between the mission/agenda and the outcome of a multi-stakeholder research initiative.

Promoters will be able to carry out materiality analysis via the MULTI-ACT Toolbox. Regardless of how the materiality analysis is carried out (whether it is via questionnaire, online survey, interviews, etc.), there are some general recommendations to be followed to get a robust and reliable analysis:

- 1) Cluster the responses into different stakeholder categories. Results can be then aggregated following the suggested methodology hereby.
- 2) Ensure the anonymity of responses in order to guarantee freedom of choice for the respondent.
- 3) Define a minimum number of individual views required to be considered representative of a stakeholder category (e.g. min 5), in order to ensure balanced and veridical representation.
- 4) Try to reach a heterogeneous cluster of responses within the same category: introducing additional specificities inside each stakeholder category enables to catch potential differences among the same clusters (i.e. in the case of a patient different level of levels of psychological attitudes toward the engagement).
- 5) Provide complete guidelines and/or tools to a respondent that may not be fully aware of the initiative.
- 6) Clarify a significance threshold under which the responses can be considered under-represented and thus not material.

Once the materiality analysis is completed, relevant aspects should be defined. In the example below (table 3), the materiality analysis identified 12 relevant aspects. As can be seen from the example, the number of relevant aspects can be lower than 15. Additionally, the promoter using the Digital Toolkit can decide whether to expand or reduce the number of relevant aspects.

Table 3 Example of a list of material aspects

MISSION	EXCELLENCE	ECONOMIC	SOCIAL	PATIENT REPORTED
Patient quality of life	Informing healthcare practice decision making	Improvement of health services	Political externalities	Patient Satisfaction
Drug supply to patient	-	-	-	Anxiety & Depression
Health services and products accessibility	-	-	-	Locomotion
Stakeholder engagement	-	-	-	Fatigue
-	-	-	-	Bladder function

4.1.2.3 Agenda definition

An agenda is a list of fundamental transformative objectives agreed upon by stakeholders that an initiative aims to achieve to fulfill its mission, including a description of the main outputs⁶ and activities needed to achieve them.

Coherently with the aspects emerged as relevant in the materiality analysis, for each priority of the agenda, the initiative should point out:

- The transformative objective, describing the type of intervention and the target and baseline according to which the initiative considers its intervention successful
- The outputs and related activities needed to reach the transformative objective

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

⁶ The products, capital goods and services which result from a development intervention.

EXAMPLE OF A RESEARCH INITIATIVE AGENDA⁷

Agenda of Dementia Care Initiative (timeline 2020 – 2030)

1. Increase the percentage of dementia patients which are treated with 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.
2. Increase the feeling of dementia patients of being more physically and intellectually independent through the development of a tailored free smartphone and computer IT application to be easily accessed by patients in Europe to perform daily tasks.
3. Increase the percentage of early diagnosed dementia patients in Europe (within one year from the disease start) through the 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 which are treated with personalized treatments in Europe is increased by * %.

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

Activities: research and development of the customizable therapy protocol.

Assumption considered:

1. If patients have personalized treatment, the progression of the disease could be slowed down up to * %.
2. If patients are more independent in performing daily tasks, the feeling of the disease burden is decreased. Furthermore, performing these tasks could also be a stimulating activity to slow down the progression of the disease.
3. If dementia patients are diagnosed earlier, the burden of the disease is drastically decreased due to the specific therapies that can be adopted.

When defining the agenda, promoters should 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 in an advanced stage of development that have already defined and tested a mature governance model, a further internal control system can be introduced in order to

⁷ Inspired by Mission-Oriented Research & Innovation in the European Union. A problem-solving approach to fuel innovation-led growth – Decreasing the burden of dementia, Mariana Mazzucato.

measure the advancement of the agenda and the fulfillment of its transformative objectives. In this regard, the box below gives some further suggestions⁸.

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, the initiative could answer the following questions:

- *In which timeframe is it reasonable to reach our objective?*
- *Is it in line with our initiative's timeframe?*
- *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?⁷*
- *Are the activities contributing to the agenda? In which way?*

Finally, in this phase promoters should secure funding in order to guarantee the maintaining of adequate resources to the development and the correct deployment of activities, as defined in sub-criterion 4.4. In particular, they should implement an effective cost management process, focusing on the determination of the budget needed, the implementation of cost analysis and the identification of possible gaps and critical issues.

Table 4 offers a set of additional information that could be considered by the initiative when defining its mission and agenda. The table includes the description of mission and agenda according to MULTI-ACT framework, a practical question that an initiative should be answering when defining them, the timespan according to which the changed aimed is expected to happen, and finally the level of influence or control that the initiative could have in respect to its mission and agenda. In this last regard, please consider that the expected impact could be influenced by several factors both dependent and independent from the initiative.

⁸ An initiative should have 100% accountability of these two elements for which it is considered accountable for. 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 final results.

Table 4: Mission and agenda practical questions

MULTI- ACT definition	Description	Question to answer	Expected impacts?	Sphere of control/influence ⁹
mission	The initiative's current and future role, its goals and its approach to reach them	What is our long-term goal?	Long term	Influence
agenda	The transformative objective, describing the type of intervention and the transformative threshold and baseline (according to which the initiative considers its intervention successful)	What do we want to achieve and why? What is the change we want to bring about?	Medium-long term	Influence
	The outputs needed to reach the transformative objective	How do we want to achieve the transformative objective? Which concrete actions do we need to put in place?	Short term	Control
	Activity	Which activities will we perform?	Short term	Control

4.1.2.4 Identification of indicators

The materiality analysis leads to the identification of the indicators that the initiative should report in order to disclose its performances regarding the matters that most affect its stakeholders. The Master Scorecard links every aspect to a number of indicators to be taken into account. For instance, the initiative in the example identified *Patient quality of life* as a relevant aspect, thus it should report on the indicators shown in Table 5.

⁹ Sphere of control: refers to everything the initiative can control and is fully responsible for.

Sphere of Influence: refers to the reaction the project expects to see as a result of its activities. (Source: Hivos ToC Guidelines, Theory of change thinking in practice.)

Table 5. Indicators connected to the aspect "patient quality of life"

Aspect to be measured	Core/ Additional	Advantages
Patient quality of life	Core	The indicator measures the value of money of intervention since the quality-adjusted life year (QALY) is a generic measure of disease burden, including both the quality and the quantity of life.
Patient quality of life	Additional	The indicator measures the number of deaths.
Patient quality of life	Additional	The indicator measures the average time patient is expected to live.

The materiality analysis shows a static representation of the stakeholders' priorities that might change over time. For this reason, the analysis should be carried out periodically, on a yearly or bi-yearly basis in order to ensure the alignment with stakeholders' priorities and their commitment in the accomplishment of the initiative's mission and agenda.

4.1.3 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"

The appliers of MULTI-ACT Governance Model should embody a movement "building approach" (Cabaj M. and Weaver L., 2016) considering the integration of the above-mentioned recommendations, throughout the entire application of the model.

In particular, to promote a movement building approach to achieve transformative changes, the initiative should:

- Enable the generation of a community aspiration in which everyone agrees and works together toward the achievement of the related goals;
- Create opportunities for the people involved in a certain program/project to promote transformative changes;
- Engage in long-term (strategic) actions, at all stages from the beginning to the end of a program/project;

- Focus efforts towards activities that result in a greater change opportunity. This is achieved by having the agents participate and collaborate in long-term or strategic actions;
- Incorporate the shared assessment process as part of a complete sharing learning process in which involved stakeholders hold each other accountable and learn from each other's successes and failures"¹⁰. In this sense, the shared assessment should serve as a resource to provide feedback to the system and serve as a constant learning mechanism;
- Ensure authentic community engagement including those affected by certain measures in the process of change.

4.1.4 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"

The appliers of MULTI-ACT Governance Model should consider the relevance for society of the initiative's objectives and implementation strategy and extend the positive impacts to the largest extend, minimizing negative consequences and guaranteeing social justice.

This recommendation has a 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.

4.2 Criterion 2: Participatory Governance

The appliers of the MULTI-ACT Model should guarantee an inclusive and equitable governance model, which allows the involvement of all interested parties through a co-design approach.

To achieve this objective, the initiative should:

- Allow the involvement of intended beneficiaries;
- Adopt a multi-stakeholder approach enabling co-creation;
- Implement a participatory structure;
- Guarantee equity and mechanisms to avoid self-interest.

¹⁰ Kania, J., & Kramer, M. (2011). Collective Impact. Stanford Social Innovation Review.

4.2.1 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 knowledge¹¹’ 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 MULTI-ACT Model. In this regard, MULTI-ACT proposes a path for patient engagement, to ensure that people affected by MS have an equal voice with other stakeholders. This considered, to enable the involvement of intended beneficiaries throughout the entire governance, the appliers of MULTI-ACT Model should implement two main actions:

- 1) Appoint an Engagement Coordination Team (hereinafter also referred to as “ECT”), that will be in charge of coordinating the involvement of stakeholders, including patients, in all the operations;
- 2) Form or identify a Patient Advisory Board (hereinafter also referred to as “PAB”), a specific group of patients within the Stakeholders Advisory Board to be involved and engaged throughout the entire development of the initiative providing advice, insights and perspectives on the activities of the initiative.

The ECT is part of the staff of the initiative and coordinates the participation of patients in the agenda design, in the decision-making process, in the initiative development, and eventually in the implementation and assessment phases. The ECT works as a facilitator and “floating” body between the Stakeholder Advisory Board and the Leadership Board. The ECT acts as guarantor and point of reference of patients’ participation in the initiative, it is in charge of the engagement processes and of all training and coaching activities that are preliminary to the patients and other stakeholders’ engagement. Furthermore, this team has not only the responsibility of patients’ engagement, but of all stakeholders whose participation is necessary to the initiative’s development.

The Initiative, according to its mission, might consider appointing a PAB. PAB is the body within the governance structure that presents the voice and opinions of patients, including underrepresented patients. It should be consulted and involved by the Leadership Board and the

¹¹ “Experiential knowledge arise when [these] experiences are converted, consciously or unconsciously, into a personal insight that enables a patient to cope with individual illness and disability. When patients share experiential knowledge, the communal body of knowledge exceeds the boundaries of individual experiences.” (Caron-Flinterman et al. 2005). Thus, experiential knowledge is knowledge gained through experience, as opposed to a priori (before experience) knowledge.

ECT during the key phases of the development of the initiative and when changes of any kind need to be implemented. It is part of a larger body, the Stakeholder Advisory Board.

The promoters of the initiative should appoint the ECT in the setting-up phase of the adoption of MULTI-ACT Model with the agreement of the Leadership Board. During the constitution of the Stakeholder Advisory Board, carried out under recommendation 2.3.1, promoters should create the PAB, a specific sub-group, formed by patients. This structure is deemed to facilitate the involvement of patients and to give relevance to their stances and contribution to the development of the initiative.

4.2.2 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”

The adoption of a multi-stakeholder approach is essential to enable co-creation processes. To allow this development, the initiative should build up participatory structures and processes, which aim to create shared ownership of a program/project between different stakeholders (i.e. initiative promoters, patients, corporations and institutions, and many others). Co-creation requires indeed professionals to co-operate with and learn from each other to raise awareness on important issues and to build relationships between groups and individuals¹², with particular attention to those that normally do not interact. To allow the implementation of co-creation processes, it is necessary to shape the governance structure of the initiative under a multi-stakeholder perspective and to identify the most suitable structure and tools that enable participation according to the objectives that the initiative wants to achieve.

To achieve this goal, the initiative should first analyze its current composition and should envision the ideal stakeholder structure in order to achieve its mission and agenda. This activity will allow to map the potential gaps in terms of stakeholder composition and to ensure that the initiative involves participants from all the interested stakeholder categories. Once the composition has been defined, the initiative should also identify and consider stakeholders’ main needs, challenges and barriers to guarantee genuine participation.

In order to adopt a co-creation approach and pave the way for tangible cooperation among involved stakeholders, the promoters should:

- 1) Analyze the current structure of the initiative, its organizational model and the composition of its current participants (if it is an already existing initiative);
- 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 gaps and, if applicable, integrate the participation of those stakeholder categories that are missing according to point 2);

¹² Cottam, H., Leadbeater, C., 2004. RED PAPER 01 HEALTH: Co-creating Services. London: Design Council

- 4) Identify and consider stakeholders' main needs, challenges and barriers to guarantee genuine and committed participation.

This analysis should be carried out by the promoters and is preliminary to the 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 performed in the sub-criterion 2.3 "Implement a participatory structure".

This analysis should be implemented coherently with the activities described under sub-criterion 3.1 "Define and approve a methodology to engage stakeholders".

4.2.3 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 the pursuit of its strategic objectives. Appliers of MULTI-ACT should adapt their structure to the organizational model proposed or, if they are newborn organizations, they should define their structure accordingly.

The following bodies, as illustrated in the picture below, compose the main bodies of the MULTI-ACT Governance Model:

- The **Leadership Board** (hereinafter also referred to as "LB"), composed by representatives from the categories of stakeholders that have strategic importance for the initiative, represents the decision-making body.
- The **Stakeholder Advisory Board** (hereinafter also referred to as "SAB"), composed by interested stakeholders, provides advice to the LB. Within the SAB, patients - as 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 needs of the initiative. This category of stakeholders can be defined as a sub-group within the SAB, called **Patient Advisory Board**.
- **Committees and Working Groups** (hereinafter also referred to as "WG") can be appointed by the LB according to the specific needs of the program/project. In particular, the WG could be appointed by the LB to carry out specific operative tasks, while the Committee could be appointed to provide insights and opinions on specific issues.
- **Engagement Coordination Team** and **Compliance Committee** (hereinafter also referred to as "CC") are described respectively under sub-criterion 2.1 and 2.4.

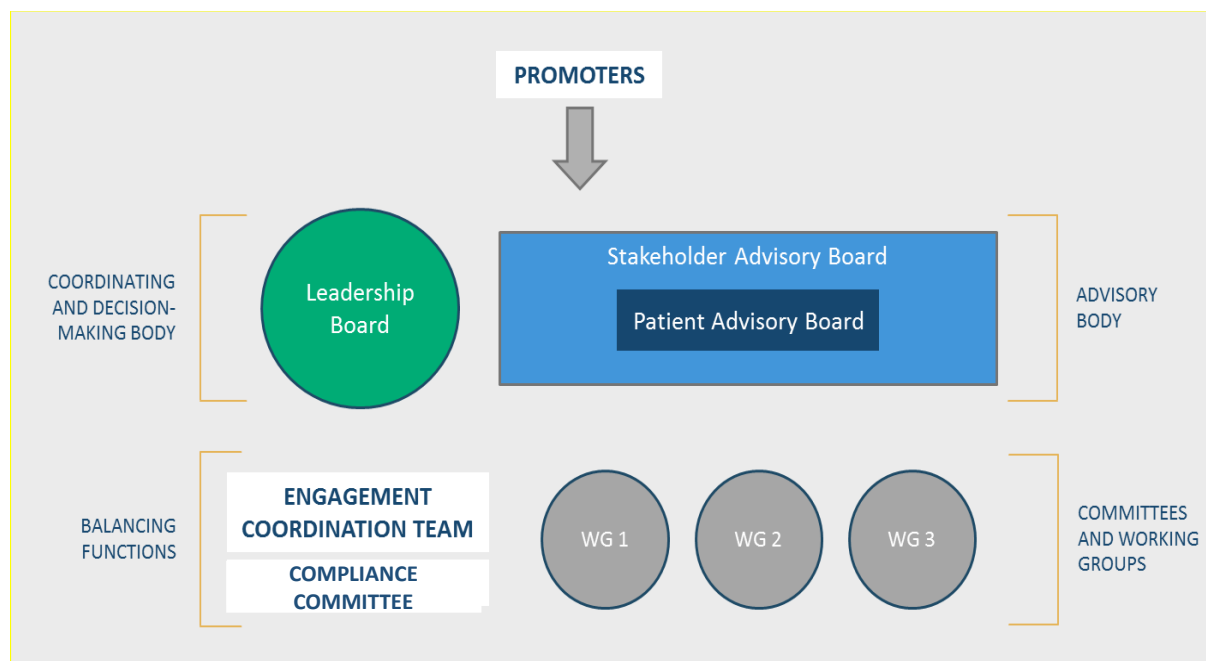


Figure 5: The MULTI-ACT Governance Model

Within MULTI-ACT Governance Model, the SAB has an advisory function; however, it could potentially also play a decision-making role. In this last case, the SAB works like a Stakeholder Assembly, and is called to express its vote and exercise decision-making powers. The evolution from advisory to a decision-making function can be implemented over time, according to the need, the characteristics and the status of development of the initiative.

The role of the other bodies of MULTI-ACT Governance Model are further described under the next recommendations. In particular, the LB is described under recommendation 2.3.2, the Working Groups under recommendation 4.1.1, the Engagement Coordination Team under sub-criterion 2.1 and the Compliance Committee under sub-criterion 2.4.

During the first phases of the implementation of the Model, the promoters should work together with the ECT and organize an open call to interested stakeholders for participation in the SAB. Rules for selection, composition and balance of the SAB should be established with the contribution of the CC and the ECT. SAB will include the PAB, as described in recommendation 2.1.1. promoters should also set up the LB, as described under recommendation 2.3.2.

In this regard, Table 6 aims at clarifying the process of appointment of the governance bodies:

Table 6. Process of appointment of the members governance bodies

Governance body	Process of appointment
Engagement Coordination Team	Appointed by promoters
Compliance Committee	Appointed by promoters and, afterwards, confirmed by the SAB and the LB
Stakeholder Advisory Board and Patient Advisory Board	Promoters with the contribution of the Compliance Committee and Engagement Coordination Team
Leadership Board	Promoters with the contribution and approval of SAB and PAB
Working Groups and Committees	Appointed, if necessary, by the Leadership Board

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”

The LB is the body in charge of decision-making processes, it oversees the implementation of the mission and agenda, the coordination and implementation of the activities carried out by the initiative, and operations of the working groups, committees and administration.

The composition of the LB should reflect the stakeholders’ categories that participate in the initiative, which should have equal decision-making powers. The number of members could vary according to the initiative’s nature and its participants.

The members of LB should be committed and skilled individuals, which should ensure constant participation in the initiative’s development.

The LB has many responsibilities, which are described in the recommendations of the MULTI-ACT Governance Model. Specific activities, roles and responsibilities of the LB are described and formalized within a procedure as pointed out in recommendation 2.3.3. The LB should in any case appoint a chair/ coordinator who will become the internal and external point of reference of the initiative. If useful, the LB could also appoint an operational team, such as a sub-board (which is the executive management team) and a secretary (which supports operations).

Promoters should set up the LB, which is the decision-making body of the initiative, identifying at least one representative from each category of stakeholder (please note that categories of stakeholders are defined under recommendation 2.2 and sub-criterion 3.3). The members of the LB should have equal power, in order to guarantee equity among involved stakeholders. The composition of the LB and its members should be endorsed by the SAB and the PAB.

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

The initiative should adopt a formal procedure, which includes the description of the chosen governance structure, the roles and responsibilities of all participants, how they will cooperate, how decision-making processes will be carried out, and the relationship structures, both among the several bodies of the initiative and between the governance bodies and the public.

The procedure should be public and should transparently define which is the governance structure of the initiative, how the governance bodies are composed, how members are appointed, how decision making-processes are handled, and how stakeholders and the public might participate in the initiative and/or take part to 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 Governance Bodies
- External Relations and public involvement

The LB has the responsibility of developing such procedure, with the support and contribution of the CC and the ECT. This document should be shared and approved by the SAB.

4.2.4 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”

In order to guarantee equity and mechanisms to avoid self-interest, the appliers of the MULTI-ACT Model should appoint a specific body, the Compliance Committee (CC) within the Governance Model in charge of maintaining a balance among stakeholders’ influences and expectations and oversee the ethical issues that might arise during the implementation of the initiative.

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.

The CC should take part in the decision-making process of the initiative and contribute to the LB activities, especially when it comes to:

- Guaranteeing equity and ensuring that self-interest of stakeholders does not prevail on collective decision-making processes, avoiding tokenism;
- Ensuring that in the decision-making process different views are accommodated;

- Managing conflict;
- Guaranteeing ethical acceptability of the initiatives' objectives and activities and social justice;
- Ensuring a balance between effective engagement of participants and agile management of the initiative.

Considering its balancing role, the CC is firstly appointed by the promoters at the beginning of the implementation of MULTI-ACT Governance Model, then officially confirmed by the SAB and the LB. An individual or a committee, depending on the size, level of development and resources of the initiative, could cover this function.

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

The appliers of the MULTI-ACT Model should guarantee a comprehensive, balanced and efficient stakeholder engagement process, ensuring the participation of patients, and of other relevant stakeholders.

To achieve this objective, the initiative should:

- Define and approve a stakeholder engagement methodology;
- Engage private intended beneficiaries;
- Differentiate the level of engagement according to participants;
- Ensure a balance between engagement of participants and agile management of the initiative.

Since MULTI-ACT 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, the MULTI-ACT Patient Engagement Guidelines provides a methodology to engage the stakeholder "patient" and facilitate the development of a roadmap to capture patients' voices and help them to co-create with the other stakeholders' experience.

4.3.1 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"

A fundamental process that a multi-stakeholder initiative should define relates to the engagement of stakeholders that will cooperate towards the achievement of the objectives of the initiative. For this reason, any initiative applying the MULTI-ACT model should define and implement a structured and detailed methodology to effectively engage those stakeholders that are of any strategic importance for the pursuing of the desired change.

Successful engagement depends on deeply 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). In order to be successful, 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.

In order to be effective, the methodology to engage stakeholders that multi-stakeholder initiatives applying MULTI-ACT should develop should at least comprise some key phases, which can be summarized as follows:

- 1) **Plan** – identify which are the stakeholders that should be involved and engaged within the initiative because strategically important for the achievement of the mission. After the identification of the stakeholders that should take part in the initiative, they should be clustered into different categories to which different levels of engagement correspond and determine the rights, duties and responsibilities for each category of stakeholders.
- 2) **Prepare** - after having identified the appropriate stakeholders, and determined the related levels of engagement, the different characteristics and needs that these several stakeholders might have should be assessed along with relative barriers concerning their effective engagement, assessing also the risks connected to the involvement of such diverse group of actors.
- 3) **Implement** – define activities that will allow the participation of stakeholders within the initiative, also through formalized procedures that define in detail the interaction and cooperation among the different actors.
- 4) **Review and improve** – put in place mechanisms that would guarantee the monitoring and evaluation of the overall quality and value of the stakeholder engagement process in order to continuously improve it.

In the “Plan” phase, the promoters should:

1. Profile and map the stakeholders: in order to design stakeholder engagement processes that work, the promoters need a clear understanding of who the relevant stakeholders are and how and why they may want to engage with the initiative. This effort of profiling and mapping shall be reviewed and revised, as appropriate, throughout the process, and for this reason it should be clearly formalized. It is recommended to carry out the stakeholder profiling analysis in parallel with the context analysis as described in sub-criterion 1.1.
2. Determine the levels of engagement: having profiled the stakeholders, the promoters of the engagement should map and cluster them into different categories in order to determine which groups and individual representatives are most important to engage with in relation to the purpose and scope of the engagement (please refer also to sub-criterion 3.4). Based on that, the different levels of engagement can be defined, which determine the different rights,

duties and responsibilities of the interested stakeholders, and are also used to establish the composition of the SAB (please also refer to sub-criterion 2.3).

In the “*Prepare*” phase, the Leadership Board should:

1. Build capacity: engagement processes usually involve a variety of actors with different levels of expertise, confidence and experience. It is important to consider that some individuals and groups may find it difficult to take up an invitation to engage, or that circumstances may hinder them in fully contributing to the engagement. This might, for example, be due to language, literacy, disability or cultural barriers, problems of distance or lack of time, or gaps in their knowledge about a specific issue. Consequently, the LB, with the help of the ECT, should timely identify where capacity to engage needs to be built, in order to avoid their exclusion or to prevent them from disengaging (please also refer to sub-criterion 3.2).
2. Identify and prepare for engagement risks: promoters shall formally identify, assess and address engagement risks, through a robust framework for risk assessment. The potential stakeholder risks¹³ that might be encountered could be, for instance: unwillingness to engage, participation fatigue, creating expectations of change that the organization is unwilling or unable to fulfil, conflict between participating stakeholders, etc.

In the “*Implement*” phase, the Leadership Board should:

1. Invite and properly brief stakeholders: the LB should ensure that stakeholders are invited to participate reasonably well in advance and that communications are appropriate for each category of stakeholders identified. In order to properly participate and limit the risks identified in the previous phase, the ECT should develop and provide 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).
2. Develop an Engagement Plan and Action Plan: at the beginning of the engagement, the LB, with input from the ECT and the support of the established SAB, shall establish procedural and behavioral rules for the participants in the engagement, which might include for example: guarantee that the opportunities for providing inputs are evenly distributed among participants, allow all participants to express their opinion completely, stay focused on the change that the initiative aims to achieve. It is fundamental to define clear roles and responsibilities for all the participants, in order to regulate their cooperation and allow them to hold each other accountable. Moreover, based on the defined mission, the promoters should define a collective Action Plan (please also refer to the sub-criterion 4.1), adopted in accordance with all the participants of the initiative, to guarantee that it fully corresponds to the expectations of all interested stakeholders.

In the “*Review and Improve*” phase, the Leadership Board should:

¹³ The a more detailed list of potential stakeholder risks is contained in the document: AccountAbility. (2015). *AA1000 Stakeholder Engagement Standard*.

1. Monitor and review the engagement: the LB, supported by the ECT and in accordance with the SAB, should systematically monitor and evaluate the overall quality of the stakeholder engagement, including the evaluation of (please also refer to the sub-criterion 5.1.7):
 - Commitment and integration;
 - Purpose, scope and stakeholder participation;
 - Process (planning, preparing, engaging, acting, reviewing and improving);
 - Outputs and outcomes;
 - Reporting.
2. Learn and improve: The LB, supported by the ECT and in accordance with the SAB, and with direct inputs from stakeholders if needed, shall strive to continuously assess the value of the engagement and improve its stakeholder engagement activities. Stakeholder engagement is a process and for this reason it is important that organizations formalize the learning and improvement process from engagement activities and experiences to strengthen and optimize future activities.

Each multi-stakeholder initiative adopting the MULTI-ACT Model could define a customized stakeholder engagement process; however, the above-mentioned aspects represent the minimum requirements that should be considered to implement an effective stakeholder engagement process.

As noted, the phases represented above could be carried out by the promoters and the LB supported by the ECT. This is due to the fact that the first phase (“Plan”) is expected to be carried out during the development of the initiative, while the other activities would be implemented during its development, once the LB has been identified. However, also the creation of the LB should be carried out through a multi-stakeholder methodology: for this reason, promoters should follow the recommendations included in this sub-criterion when setting up the LB.

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

4.3.2 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 research project and mainly focused on clinical trials and drug development as data providers (or in biotechnological R&I as users to test innovative technologies) rather than engaged in the governance of R&I with decision making role. Differently, the appliers of the MULTI-ACT Governance Model should involve such category of stakeholders in other steps of the R&I process, to understand and embody their needs and expectations throughout the entire flow. To achieve this objective, the initiative should provide the right tools to all the stakeholders involved in order to be able to equally participate in all the steps of the process.

MULTI-ACT will exploit a training module to support the use of the MULTI-ACT Governance model in the management of multi-stakeholder research initiatives, including Patient Engagement: the MULTI-ACT Academy on Multi-Stakeholder Research Initiatives and Patient Engagement management (MULTI-ACT Training module®).

To achieve the engagement of the intended beneficiaries, there are several activities that should be put in place by the initiative. These should be coordinated by the ECT, the body that will manage the process of involving several categories of stakeholders also with regards to patients identified under sub-criterion 2.1.1. The main activities are described below:

- 1) Set in place the engagement process to develop and provide the participants with the necessary briefing materials, that provide the basis for building robust and responsive stakeholder engagement processes. These materials should be comprehensive and include a clear explanation of the expectations of the initiative in patients' engagement also to facilitate interdisciplinary communication; they should be made available in a timely manner and should consider relevant aspects such as linguistic proficiency, disability and literacy issues;
- 2) Organize training sessions in which private beneficiaries are transparently informed on the process and the role they play within the process;
- 3) Guarantee the involvement of intended beneficiaries that might have previous experiences on such type of participatory role within multi-stakeholder initiatives, in order to become the point of reference between the initiative and the stakeholder group she/he is part of.

Furthermore, it is important to notice that the ECT should not only focus on the engagement of patients but should consider the preparation and training of all categories of stakeholders to ensure a fruitful engagement among all participants.

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

Science with patient input entails the active collaboration of patients in the governance, priority setting, and conducting of research, as well as in summarizing, distributing, sharing, and applying its results. A multi-stakeholder initiative can potentially engage a variety of actors with different levels of expertise, confidence and experiential knowledge. It is important to appreciate that some individuals and groups may find it difficult to take up an invitation to engage, or that circumstances may hinder them in fully contributing to the engagement, in consideration of potential limitations that might be encountered due to language, literacy, disability or cultural barriers, problems of distance or lack of time, or gaps in their knowledge about a specific issue.

Another essential aspect to be considered is the fact that a research program/project within the health sector can be considered 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. Consequently, after identifying the possible limitations that might be encountered in the engagement of patients, the appliers of MULTI-ACT Governance Model should define if these limitations are the same for all the patients involved in the entire R&I process, or if there are some phases of the R&I process which are more complicated and for this reason should be considered with more attention. This been done, actions to overcome these barriers and limitations should be envisioned and, when not possible, an alternative solution for the engagement should be discussed (i.e. engaging parents for children; relatives for 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 analyzed so that this team can be well informed and prepared on the possible limitations that this specific category of stakeholders might encounter in the several R&I phases, 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 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"
-

Several stakeholders might be engaged in multi-stakeholder initiatives in the medical research field, with different skills, expertise, and interests. For this reason, the promoters, after mapping which stakeholders should take part to the initiative (refer to sub-criterion 3.1), should also cluster them into different categories. Based on the categories identified, it will then be possible to engage stakeholders according to several levels of engagement, such as: Co-design, Involve, Consult and Inform (see below). In this regard, in determining the levels of engagement, the promoters should define the nature of the relationship they will develop with their stakeholders.

The promoters should cluster the initiative's stakeholders according to their strategic importance, which could be based on the skills and the resources they might have at their disposal in order to achieve the mission of the initiative and to be accountable.

Their strategic importance for the initiative would then determine the level of engagement to be selected to best meet the needs, capacity and expectations of the relevant stakeholders. The level of engagement should be revised periodically and may also change 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 LB);
- Involve: stakeholders are engaged in research project activities with an active role (i.e. they could be part of the 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 clustering and prioritization effort will facilitate processes such as the election of representatives of each category of stakeholders to be part of the leadership board, advisory bodies, or working groups. The initiative can decide the levels of engagement according to its specific characteristics and needs.

4.3.4 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 behavioral differences, equity, resource sharing, communication, confidentiality concerns, and geographical dispersion”

The identification of the appropriate stakeholders to be included in the initiative is essential to guarantee that there is a balance among those that participate in relation to their different characteristics and backgrounds needed to achieve the expected change. However, 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.

In order to mitigate the challenges that might be encountered by a collaborative group, with the support of ECT and CC the LB should:

- Achieve a balance of interests in the subject matter and in the geographic scope (or other relevant diversity criteria) among the involved stakeholders within the governance bodies;
- Strive for consensus on decisions that might define milestones for the initiative;
- Define criteria in advance to determine when alternative decision-making procedures should come into effect, in case consensus cannot be achieved. Indeed, criteria for determining when to consider voting could include those decision-makers who are not in agreement provide alternative solutions and, if these are not accepted by the majority and a compromise is not reached, then alternative decision-making procedures could come into effect;
- Define a decision-making threshold (in relation to the voting process) to ensure that no stakeholder group or type can control the decision-making process.

On one hand, the ECT should guarantee and facilitate the participation of weak and/or marginalized stakeholders, encouraging and maintaining commitment and ensuring a balance among different points of views; 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 involved stakeholders and the agile management of the initiative.

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

The appliers of the MULTI-ACT Model should guarantee effective, cooperative and efficient coordination of the objectives and actions required to pursue the mission and the agenda.

To achieve this goal, the initiative should:

- Enable cooperation and competition among involved stakeholders;
- Set clear and transparent processes and timeline;
- Maintain flexibility;
- Ensure the presence of secure funding, solid organizational structure and resource management.

4.4.1 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 a multi-stakeholder initiative in the health research sector is to create accessible and innovative mechanisms to facilitate interaction and bridge the gap between patients, the public community, policymakers and researchers and all the other stakeholders in order to implement shared actions. Consequently, the appliers of the MULTI-ACT Governance Model should put in place processes that allow involved stakeholders to perform mutually reinforcing activities and hold each other accountable through a clear definition of roles and responsibilities.

To allow involved stakeholders to carry out mutually reinforcing activities, the 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 in order to achieve such change;
- Implementation by all the involved stakeholders of these strategies in order to advance the shared Action Plan;
- Establishment of 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 “touch points meetings” in order to create opportunities for change, such as:
a) holding periodic events in order to discuss potential challenges, foster innovative thinking, and identify practical solutions; b) hosting webinars to support stakeholders in the implementation of actions.

The implementation of such activities should be led by the LB, which should have the responsibility to define the collective Action Plan and oversee that the defined activities are implemented by all the involved stakeholders so that they can hold each other accountable. The WGs could be bodies composed and balanced according to the stakeholders' categories and the needs of the initiative and could be in charge of specific tasks (such as, for example, specific reporting activities, as described under criterion 5). These bodies should report to the LB.

Within these bodies, both cooperation and competition should be promoted, which means that involved stakeholders with different backgrounds, instances and interests should be involved in the implementation of a given task/activity, in order to offer various and multi-disciplinary inputs, while pursuing a common goal. This could provide an added value to the initiative itself since multi-stakeholder instances are considered at all levels of the R&I process.

4.4.2 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"

To achieve a transparent organizational process, the appliers of the MULTI-ACT Governance Model should define a timeline, in order to assure that progress is soundly implemented. Moreover, they should define clear roles and responsibilities among involved stakeholders, to guarantee that each actor clearly knows his role and plays according to its rights and 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 in order to allow involved stakeholders 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 in order to keep track of the achieved targets.

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

The implementation of these activities is strictly related to the previous sub-criterion, because WGs are the bodies within the organization that will operationally carry out the activities through which the targets can be measured and achieved. For this reason, to facilitate this process, the LB could appoint a Secretariat or Management Team that would help in overseeing the respect of the several deadlines and activities, and the general performance of the initiative according to the defined mission and agenda.

4.4.3 Sub-criterion 4.3: Maintain flexibility

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

The appliers of MULTI-ACT Governance Model should stay up-to-date on the current needs of the beneficiaries they are trying to tackle and on stakeholders’ expectations and needs. For this reason, they should consider the possibility of adjusting the goals of the initiative. Several practices could be evaluated by the LB of the initiative to guarantee that the initiative actually responds to correct and current needs, such as for example:

- Prepare a Progress Report (for example every year) as a useful tool to collect all the achievements, but also the concerns raised throughout the process by stakeholders and possible recommendations for the future (please also refer to the sub-criterion 5.1.6);
- Consider organizing a consultation event on a periodical basis where stakeholders can express their views and confirm their alignment with the defined agenda (please also refer to the sub-criterion 5.2.1);
- Consider the review by external actors, in order to identify possible gaps and areas for improvements;
- Periodically review the mission and agenda according to the activities above-mentioned (see sub-criterion 1.2).

In the definition of the activities, it is recommended to adopt a flexible **risk management approach**. The structure of the initiative and the organization of the activities should be flexible enough to allow to manage possible major changes that may arise within and outside the project, in order to guarantee the ability to pursue the same transformative objective also through a different strategy. In this regard, the initiative should 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.

4.4.4 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 achieve its mission, deliver its agenda and carry out its activities, it is necessary to ensure that it is financially secure and well-functioning. In order to do so, it is fundamental to have secure funding, a solid organizational structure with technical expertise and good resources management.

In order to implement an effective cost management process, there are three main activities that the LB could put in place, which are:

1. Determine a budget: understand which is the amount of funding that the initiative has at its disposal;
2. Implement a cost analysis of the project: based on the timeline that the LB has agreed upon and included in the collective Action Plan, understand the real costs that will be sustained by the initiative throughout the timeline of the project (including research funding, staff and technical expertise, organization of meetings, other general expenditure);
3. Identify possible gaps and critical issues: the analysis carried out would allow identifying some potential critical issues and possible refinements that would guarantee efficient management of the budgeting to avoid inefficiencies.

To carry out such activity, the LB could appoint a “Secretariat” or “Management Team” (please also refer to the sub-criterion 2.2) that will manage all the issues related to ensuring that the initiative is financially secure or, depending on the size of the multi-stakeholder initiative, it could also be supported by other figures within the initiative, such as the CC and/or other functions. This process has the objective of ensuring that the initiative is financially secure, running public accounting for expenditures and income, and ensuring that it operates in a legally compliant manner in relevant jurisdictions.

4.5 Criterion 5: Co-accountability assessment

The appliers of the MULTI-ACT Model should establish a shared and effective measurement system, including a set of indicators, that allows improvement and communication, and set a mechanism to receive feedback.

To achieve this objective, the initiative should:

- Define a shared assessment system;
- Establish effective feedback mechanisms;
- Guarantee continuous learning, communication and disclosure of knowledge.

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

4.5.1 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 coherent with stakeholders’ perspective and effectively including the aspects the matter most to them, the initiative should consider the material aspects emerged from the materiality analysis (recommendation 1.2.1).

On the basis of the list of relevant aspects, through the MULTI-ACT Master Scorecard, the user is 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).

The initiative should 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 Outcomes (PROs)**¹⁴.

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 should define a data collection process including all the relevant stakeholders according to the selected list of indicators. The initiative should also ensure that indicators are consistently tracked over time.

The initiative, through its LB, should ensure that there is constant alignment between the shared assessment system and the mission and agenda of the initiative, by reviewing the materiality analysis and eventually adapting to possible internal or external changes that may occur. Periodically, if the agenda is updated, the initiative should also update the shared assessment system.

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

The initiative's results and progress should be transparently communicated to the public, 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 no achievement) of the initiative's objectives and key performance indicators. In particular, the Progress Report should disclose the information regarding the indicators identified by the initiative at sub-criterion 5.1.2, and the ability of the initiative to achieve its mission and agenda. The Progress Report should be published on a regular basis, every one or two years, according to the specificities of the initiative, it should be published online and made available to interested stakeholders.

- An open platform, which includes a visualization of the performance of the initiative according to the identified indicators

¹⁴ **Patient Reported Outcomes (PROs):** "any outcome evaluated directly by the patient him/herself and based on patient's perception of a disease and its treatment(s)" (European Medicines Agency, 2014).

The open platform is an online tool offering a visualization of the performance of the initiative according to the identified indicators. The open platform offers access to periodic key performance indicators regarding the initiative's implementation to all stakeholders. The open platform should also contain 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 LB, which might appoint a working group or a committee for this purpose and through the help of the Secretariat or Management Team, 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.

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

The initiative should leverage the results of the assessment to improve its performances and practices. In this regard, it is recommended to conduct a periodic review that includes at least the following activities:

- 1) Perform an analysis of the indicators on the initiative's performances and results, emerging from the shared assessment process;
- 2) Set up an improvement plan identifying improvement actions for the initiative;
- 3) 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, in order to allow external stakeholders to provide suggestions and feedback through the consultation processes. It should be implemented on a periodic basis (i.e. every 2 years), according to the needs and the characteristics of the initiative.

The review process should be led by the LB and the 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 in charge of developing such activities.

4.5.2 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"

MULTI-ACT considers the importance of receiving constant feedback from internal and external stakeholders, in order to improve the efficacy and the efficiency of the initiative and its ability to answer to the needs of evolving stakeholders. To achieve this goal, it is necessary that multi-stakeholder initiatives adopting the MULTI-ACT Governance Model establish a process that allows stakeholders to raise concerns and express their opinion.

In order to do so, the LB should:

- 1) Identify the most suitable and appropriate channels through which stakeholders can communicate and raise their concerns (e.g. email, website, letter);

- 2) Set up the activities necessary to gather stakeholders' feedback;
- 3) Elaborate stakeholders' feedback;
- 4) Ensure that the feedback is appropriately managed and considered within the review process, under sub-criterion 5.1.8.

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

The initiative should also formally report on how it analyzes, manages and integrates stakeholders' feedback. The implementation of this sub-criterion should foster the review process carried out under sub-criterion 5.1.8.

The LB, supported by the "Secretariat or Management Team", is in charge of setting up a process to collect concerns and opinions from stakeholders, while the ECT should participate in this process and be in charge of maintaining active participation of internal stakeholders.

4.5.3 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 of MULTI-ACT Model should build a trustful and continuous relationship with the public and the communities with which they interact. This can be achieved through a constant, clear and useful flow of information. To implement this recommendation, the LB should ensure that:

- 1) Communication on the most salient activities of the project is made public;
- 2) The communication is clear, accessible and useful and it is made available to stakeholders according to their specific needs.

To achieve these goals, 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.

Furthermore, it is pivotal for the LB to ensure a constant communication process with other health initiatives that might take advantage of (or contribute to) the initiative itself. The LB is in charge of identifying opportunities for information exchange and cooperation and develop the most appropriate means to ensure these relationships, in collaboration with the SAB.

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

5 A PATH TO THE ADOPTION OF CRIF FOR COLLABORATIVE INITIATIVES

MULTI-ACT CRIF is dedicated to health sector research funding and performing organizations (RFPOs) willing to start conducting their R&I with a multi-stakeholder and co-accountable approach towards common goals to reach a transformational mission.

The framework supports these initiatives that have a transformational mission and seek to maximize the impact of research beyond mere financial return, adopting a multi-stakeholder perspective.

The promoter of MULTI-ACT framework could be part of already existing multi-stakeholder organizations or initiatives that decides to adopt it, having already established a governance structure, or they might be part of a new-born initiatives or organizations willing to be structured with multi-stakeholder and co-accountable governance. In both cases, they will usually become part of the governance bodies.

MULTI-ACT Governance Model is a “principle-based” model. This means that instead of being based on the process according to chronological order, it is based on principles, represented by criteria, sub-criteria and recommendations. In particular, the Model is composed of 5 criteria and 19 sub-criteria, and 41 recommendations (see Figure 5). However, within each criterion and sub-criterion, there are recommendations that could be applied in different evolution phases of a given initiative. For this reason, when approaching to MULTI-ACT Model, promoters might ask themselves: “What should we do first?”.

Promoters should first focus on criterion 3 “Clear, effective and inclusive methodology of stakeholder engagement” as the overarching principle for the other four governance criteria. MULTI-ACT is a collaborative tool which requires the involvement of stakeholders in the governance process: this means that promoters should first of all start to consider the involvement of relevant stakeholders in the process. Considering this, criterion 3 should be considered by the user throughout the entire adoption of MULTI-ACT Model, guaranteeing a comprehensive, balanced and efficient stakeholder engagement process, ensuring the participation of patients and care givers, and of other relevant stakeholders (see criterion 3).

This considered, when starting to implement MULTI-ACT framework, promoters should:

- Carry out a context analysis, understanding the context for the initiative and the target beneficiaries (see recommendation 1.1.1 and recommendation 1.2.1).
- Profile and map stakeholders that should be involved and engaged within the initiative (see recommendation 3.1.1, “Plan”).
- Ensure that, even if in a preliminary step, the initiative:
 - Has a multi-stakeholder balance (see recommendation 3.1.1, “Plan”) and adopts a co-creation approach paving the way for tangible cooperation among participants, analyzing and balancing the current governance compositions of promoters (see Sub-criterion 2.2);
 - Appoints the Engagement Coordination Team (“ECT”), which will be in charge of coordinating the involvement of stakeholders, including patients, in all the operations

(see recommendation 2.1.1), and other relevant stakeholder bodies as described in recommendation 2.3.1.

- Prioritize the most relevant aspects for stakeholders (materiality analysis) and accordingly select appropriate indicators considering the different perspectives of the stakeholders involved (see recommendation 1.2.2).
- Considering the steps above, define the agenda involving relevant stakeholders, identifying the long-term transformative goal of the initiative and its fundamental transformative objectives necessary to pursue it (see recommendation 1.2.1).

At this point, promoters should focus on the creation of a participative governance structure, propaedeutic to the achievement of the Mission and Agenda, that guarantees an inclusive and equitable governance model and allows the involvement of all interested parties through a co-design approach.

This process will lead to the adoption of a governance structure in coherence to MULTI-ACT Model according to the recommendations included in criterion 2. From this moment on, promoters could be referred as the initiative's "Governance" or simply "the initiative".

6 FURTHER POTENTIAL DEVELOPMENTS OF MULTI-ACT CRIF

The activities performed in WP4 led to a refined version of the MULTI-ACT Framework and the identification of several lessons learnt, insights and recommendations, as well as consolidation and endorsement, emerging from a thorough reflection on the first implementation of the model to an existing initiative. However, further case studies and multi-stakeholder exercises could help to further improve and develop the framework developed by the project.

As stated above, the case study carried out under WP4 focused on those recommendations that could have been applied in a relatively short time span, especially those related to Criterion 1 of MULTI-ACT Governance Model and the definition of the mission and the agenda. In this regard, in terms of future development, it would be interesting and useful to analyze the application of MULTI-ACT Model to new case studies considering a long-term application of the Model. This exercise would allow observing the results of the implementation of Criteria that requires time to be put in place, namely those related to the governance structure, the engagement of stakeholder, the management of the initiative and its assessment. In this regard, a further review of the Model is recommended in order to integrate on-the-field experiences and insights emerging from the application of the Model.

In particular, the robustness of the model will depend also on the width and the completeness of the tests on real cases. Further analysis and experiences on a larger time span would be of help in order to allow:

- To carry out a complete assessment of the implementation of all the five criteria;
- To address potential challenges and complexities that the Promoters may potentially face, and propose alternative solutions to simplify the recommendations;
- To verify and tackle further specific difficulties that could arise in some research areas.

A further development of MULTI-ACT Governance Model could be its application to case studies beyond the MS domain, including for instance different brain diseases and health-related research projects. This application would be extremely interesting to test the suitability of MULTI-ACT recommendations to other fields of application and to understand the dynamics governing multi-stakeholder initiatives involving patients as fundamental stakeholders. In this regard, a first step forward will be taken under WP7, that aims to foster the application of the MULTI-ACT CRIF in Multi-stakeholder Research Initiatives focused on other brain disease areas in comparison to MSCU. This exercise has the purpose to explore the applicability of the MULTI-ACT framework to other brain disease areas and includes the elaboration of tailored sets of aspects for co-accountability assessment (i.e. tailored scorecards).

An additional level of analysis of the Model could focus on the complexity of the recommendations to understand if potential applicers are actually able to implement them or find difficulties that impede them to adopt the Model. It would be useful to test the framework both with a new-born organization

and an existing one to identify the main differences in terms of application and refine the Model accordingly to match both user categories' needs and challenges.

Finally, MULTI-ACT CRIF was co-created with a multi-stakeholder approach by MULTI-ACT project consortium. After few years from the presentation and application of the CRIF, it could be relevant to open a public consultation process to collect feedback on the framework recommendations and structure, inviting external stakeholders to participate to a public review of the framework.

APPENDIX 1: OVERVIEW OF THE UPDATES ON MULTI-ACT CRIF FRAMEWORK FOLLOWING THE MS CASE STUDY

During the case study, the two workshops carried out highlighted the need for some refinements and further specifications of the MULTI-ACT Governance Model.

In this regard, deliverable 4.3 addresses each potential revision and provides a revised version of the Model. In particular, the following table displays the major change areas that deliverable 4.3 reports for each recommendation as included in Chapter 4.

Table 7. Changes in Governance criteria in comparison to the model described in the deliverable 5.4

CRITERION		CHANGES in 4.3
1	Mission and agenda	1.1.1
		1.1.2
		1.2.1
		1.3.1
		1.3.2
		1.4.1
		1.4.2
2	Participatory Governance	2.1.1
		2.2.1
		2.2.2
		2.2.3
		2.3.1
		2.3.2
		2.3.3
		2.4.1
		2.4.2
3	Clear, effective and inclusive methodology of stakeholder engagement	3.1.1
		3.1.2
		3.2.1
		3.2.2
		3.3.1
		3.4.1
4	Effective and efficient management and coordination of the initiative	4.1.1
		4.2.1
		4.2.2
		4.2.3
		4.3.1
		4.4.1
		4.4.2
5	Co-accountability assessment	4.4.3
		4.4.4
		5.1.1
		5.1.2
		5.1.3
		5.1.4
		5.1.5
		5.1.6
		5.1.7
		5.1.8
		5.2.1
		5.3.1

	Relevant restructuring of the recommendation after the case study and the development emerged from other WPs
	Few changes to the text of the recommendation to improve clearness and quality of the work
	No intervention or simple alignment of the wording of the recommendation or of the internal references

The main changes emerging from the case study are concentrated on the first criterion. This is mainly due to the fact that the mission and agenda have been some of the main topics of the MSCU case study, considering the time span of the case study implementation and the preliminary role played by this criterion. Consequently, the recommendations included under criterion 5 have been revised in order to be coherent with the refined criterion 1. Few changes also were made in criterion 2, 3 and 4.

APPENDIX 2: SUGGESTED METHODOLOGY FOR ELABORATING THE RESULTS FROM THE MATERIALITY ANALYSIS

The following methodology was used during the MS Care Unit Workshop in order to aggregate and elaborate the results from the materiality analysis.

Premise

1. Group all the results by category of stakeholder

Focus on a single category of stakeholder (e.g. Care providers)

2. Calculate the average among the results of different stakeholders of the same category for each aspect

Replicate step 2 for each category of stakeholder.

MATERIALITY: focus on the aggregation of results of different stakeholder categories

3. For each aspect calculate the average taking into consideration the result that the aspect obtained in every stakeholder category creating an “average of the averages”. (I.e. You should be calculating the average from the results that each category of stakeholder obtained in step 2)
4. List the aspects taking into consideration their average and sort them from the highest to the lowest
5. For each dimension, choose the top two aspects (i.e. for each dimension, the aspects featuring the highest and the second-highest average). Therefore, in this step, you should select 10 aspects.
6. Excluding the 10 aspects selected in step 5, choose additional 5 aspects with the highest average.
7. Combine results of step 5 and 6 to get to the 15 material aspects list.
8. In the case of the 15th aspect having the same average of 16th or following, then extend the selection to those.