



## Deliverable D7.4

# Plan for self-sustainability and CRIF implementation in the other brain diseases identified



This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Grant Agreement No 787570

<b>PROJECT ACRONYM:</b>	MULTI-ACT
<b>CONTRACT NUMBER:</b>	787570
<b>DISSEMINATION LEVEL:</b>	Public
<b>NATURE OF DOCUMENT:</b>	Report

<b>TITLE OF DOCUMENT:</b>	Plan for self-sustainability and CRIF implementation in the other BRAIN diseases identified
<b>REFERENCE NUMBER:</b>	D7.4
<b>WORKPACKAGE CONTRIBUTING TO THE DOCUMENT:</b>	WP7
<b>VERSION:</b>	V0.3
<b>EXPECTED DELIVERY DATE:</b>	28/02/2021
<b>DATE:</b>	08/04/2021
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This document describes the plan of actions to continue to use the MULTI-ACT CRIF beyond the EC funding. It includes plans for the development of tailored Master Scorecards for the other BRAIN diseases identified in this WP.

#### REVISION HISTORY

REVISION	DATE	COMMENTS	AUTHOR (NAME AND ORGANISATION)
V0.1	05/01/2021	First draft	Françoise Van Hemelryck, Elke De Witte (EBC)
V0.2	25/01/2021	Second draft with inclusion from EY to align self-sustainability plan and exploitation plan	Lorenzo Ciaschi, Iacopo De Angelis (EY) Françoise Van Hemelryck, Elke De Witte, (EBC)
V0.3	24/02/2021	Third draft including comments from partners: EY SPA, FISM, UNITN, TAU, UBU, DiA, ARSEP, EHMA	Andrea Gavazzi, Luca Molinari, (EY SPA), Deborah Bertorello, Paola Zaratini (FISM), Sabri Ben Rommane (EHMA), Anna Kork (TAU), Ericka Costa, Michele Andreass (UNITN), Nicolás García-Torea, Carlos Larrinaga (UBU), Natalia Matuszak, Marcin Kautsch (DiA), Florence van Steenbrughe (ARSEP).
V0.4	08/04/2021	Final version edited and recommendations formatted as a separate document to be shared with the EPICLUSTER initiative	Valentina Tagueo (FISM)

**FILENAME:** MULTI-ACT\_D7.4\_EBC\_20210408\_v0.4

**STATEMENT OF ORIGINALITY:**

This deliverable contains original unpublished work except where clearly indicated otherwise.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

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## 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) composed of a set of governance guidelines (MULTI-ACT Governance Model) to improve the governance of Multi-Stakeholder Research Initiatives, a collective impact assessment system (MULTI-ACT Master Scorecard) and Patient Engagement Guidelines to enable science with and of patient input. The MULTI-ACT model considers patients as key stakeholders.

The MULTI-ACT CRIF was tested on a multi-stakeholder initiative in the field of Multiple Sclerosis (MS) entitled the MS Care Unit (MSCU) initiative, promoted by the European Charcot Foundation (WP4). The CRIF was revised based on the insights and lessons learned from its first implementation on the MSCU (D4.3). Clarification was provided on the logic flow to be followed by initiatives seeking to implement MULTI-ACT CRIF and the approach to adopt when integrating the governance model within initiatives or organizations. It led to a comprehensive and detailed update of MULTI-ACT Governance Model's criteria, sub-criteria and recommendations.<sup>1</sup>

The goal of WP7 is to apply the revised CRIF to another disease case study than multiple sclerosis. MULTI-ACT offers guidelines and tools for structuring a Responsible Research and Innovation governance model for collective sustainability of transformational health missions, such as those needed in brain conditions.

The CRIF approach was proposed to the existing EBRA Clusters, the multi-stakeholder networks established under the EU funded European Brain Research Area project (EBRA)<sup>2</sup>. Engagement activities took place with the EPICLUSTER, the EBRA cluster in the field of epilepsy which led to tailored recommendations on its governance and patient engagement roadmap.

This deliverable is the self-sustainability plan. It describes a plan of action for the continued use of the CRIF among end users after the end of the project. The plan includes further actions with the EBRA EPICLUSTER and other brain diseases in which key players have been grouped in EBRA clusters as well as action in the brain research community as a whole.

This self-sustainability plan seeks to promote the use of all tools and guidelines deployed by the MULTI-ACT consortium to support brain research consortiums in the development of multi-stakeholder managerial models in which each stakeholder has its return on investment aligned with the common goals of improving health and providing effective care for patients.

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<sup>1</sup> [www.multiact.eu/deliverables](http://www.multiact.eu/deliverables)

<sup>2</sup> <https://www.ebra.eu/about/the-mission/>

## 1. INTRODUCTION AND PURPOSE OF THE DOCUMENT

Brain conditions, mental and neurological alike, account for a large burden on the European population. It was estimated conservatively that every year, 27% of the total adult EU population are affected by a mental disorder, amounting to over 82.7 million affected persons.<sup>3</sup>

The future of health research sustainability requires new multi-stakeholder and multidisciplinary managerial models in line with the Responsible Research and Innovation (RRI) approach. In these models, the mission is the explicit driver where, besides being deeply coordinated, each stakeholder has its return on investment aligned with the common goals of improving health and wellbeing and developing effective care for patients.<sup>4</sup>

The RRI stipulates that that excellence, validity and relevance are connected by engaging patients in the research continuum as key stakeholder.<sup>5</sup> In this context, engaging patient as key stakeholder (science with patient input) and measuring the impact of research on outcomes that matter to them (science of patient input) are becoming instrumental to make stakeholders co-accountable for the mission and the agenda of brain conditions and to enable a unique health research and care ecosystem.<sup>6 7</sup>

MULTI-ACT CRIF offers guidelines and tools for structuring a RRI governance model enabling collective impact assessment leading to sustainable transformational health missions, as needed in the field of brain research.

Within this strategic intent, MULTI-ACT provides a new Collective Research Impact Framework (CRIF) which is translated into: new participatory governance criteria; a new system for the assessment of research impact across different dimensions; innovative guidelines for effective patient engagement across the health research and innovation pathway and a digital toolkit that integrates the MULTI-ACT model and tools.

The goal of WP7 is to apply the revised CRIF to a disease case study other than multiple sclerosis.

D7.1 described the engagement with the EBRA clusters<sup>8</sup> and the establishment of the collaboration between the selected EBRA cluster in the field of epilepsy (EPICLUSTER) and the MULTI-ACT

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<sup>3</sup> Wittchen HU, Jacobi F, Rehm J, Gustavsson A, Svensson M, Jönsson B, Olesen J, Allgulander C, Alonso J, Faravelli C, Fratiglioni L, Jennum P, Lieb R, Maercker A, van Os J, Preisig M, Salvador-Carulla L, Simon R, Steinhausen HC. The size and burden of mental disorders and other disorders of the brain in Europe 2010. Eur Neuropsychopharmacol. 2011 Sep;21(9):655-79. doi: 10.1016/j.euroneuro.2011.07.018. PMID: 21896369.

<sup>4</sup> P. Zarin et al, Nonprofit foundations spur translational research (2014) Trends Pharmacol Sci Nov;35(11):552-5. doi: 10.1016/j.tips.2014.09.003.

<sup>5</sup> <https://rri-tools.eu/public-engagement>

<sup>6</sup> Anderson M, McCleary KK. On the path to a science of patient input 2016; Sci. Transl. Med. 8, 336ps11; <https://www.fastercures.org/programs/patients-count/science-of-patientinput-resources/>.

<sup>7</sup> Brichetto G, Zarin P. Measuring\_outcomes\_that\_matter\_most\_to\_people\_with multiple sclerosis: the role of patient-reported outcomes. <https://www.multiact.eu/wp>

<sup>8</sup> <https://www.ebra.eu/about/the-mission/>

Consortium. D7.3 and D7.2 respectively reported on the set up of the working group established in the EPICLUSTER and the subsequent engagement activities.

This deliverable promotes the adoption and implementation of the CRIF beyond the end of the project. The document includes a set of actions for the extended collaboration with the EPICLUSTER and other EBRA clusters when established. This self-sustainability plan is a plan of action for the use of the CRIF in other brain diseases to support sustainable transformational health missions in the field of brain research.

## 1.1 STRUCTURE OF THE DOCUMENT

This document is structured as follows:

- Chapter 1 introduces the purpose of the document.
- Chapter 2 briefly describes the components of the revised CRIF. It outlines the tools and material available to Research Funding and Performing Organisations (RFPOs) to ease implementation of the MULTI-ACT CRIF.
- Chapter 3 describes the steps which led to the identification of brain disease areas beyond multiple sclerosis, selection and outcomes of the engagement with the EPICLUSTER initiative in the field of epilepsy. Tailored recommendations on patient engagement to the EPICLUSTER are included in appendix 2.
- Chapter 4 outlines a plan of action to pursue the full implementation of the CRIF within the EPICLUSTER initiative and to promote uptake of CRIF by RFPOs in the field of epilepsy
- Chapter 5 outlines a plan of action to promote the adoption of the CRIF in the other brain disease areas identified beyond MS and epilepsy (other EBRA clusters and networks within these clusters) and the brain community as a whole.
- Chapter 6 presents the conclusions.

## 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 outputs<sup>9</sup> 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 Research & Innovation (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).

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<sup>9</sup> The products, capital goods and services which result from a development intervention.

The Master Scorecard 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.

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

**Promoter(s):** 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:

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

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



**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** refers to “any individual or group that is affected by, who can influence or may have an interest in the outcomes of an organization’s actions”<sup>10</sup>.

**Stakeholder engagement** refers to activities that can be done with stakeholders such as consult, listen, understand, communicate, influence, negotiate, etc., with the broader objectives of satisfying their needs, gaining approval and support, or at least minimizing their opposition or obstruction.

## 1.3 ABBREVIATIONS

Acronyms	
CRIF	Collective Research Impact Framework
ECT	Engagement Coordination Team
MSCU	Multiple Sclerosis Care Unit
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

## 2. USING THE MULTI-ACT COLLECTIVE RESEARCH IMPACT FRAMEWORK

### 2.1 In a nutshell – the path for the adoption of the CRIF by Research Funding and Performing Organisations (RFPOs)

The MULTI-ACT Collective Research Impact Framework (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 in line with the RRI concept.

<sup>10</sup> Freeman, R. E. (1984). Strategic management: A stakeholder approach. Boston: Pitman.

The users of the MULTI-ACT framework could be part of existing multi-stakeholder organizations or initiatives, having already established a governance structure, or they might be part of recently launched initiatives or organizations willing to be structured with multi-stakeholder and co-accountable governance. In both cases, the different stakeholders will usually become part of the governance bodies of the organisations.

A refined version of the MULTI-ACT CRIF was produced based on the learnings and reflection on the first implementation of the model to an existing initiative, the Multiple Sclerosis Care Unit (MSCU), carried out under WP4 between June 2019 and July 2020. The refined version was detailed in D4.3<sup>11</sup>

Below is a condensed recap of its main components and characteristics.

### **MULTI-ACT Governance model**

The MULTI-ACT Governance Model is the set of 41 strategic recommendations proposed by MULTI-ACT to be applied by multi-stakeholder research and performing organizations. Recommendations are practical suggestions and solutions that guide the appliers in their implementing process. Instead of being based on a process following a chronological order, it is based on principles translated into criteria, sub-criteria and recommendations. The Model is composed of 5 criteria and 19 sub-criteria, and 41 recommendations (see Figure 1).






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

Figure 1: MULTI-ACT Governance criteria and sub-criteria

<sup>11</sup> MULTI-ACT deliverables : [www.multiact.eu/deliverables](http://www.multiact.eu/deliverables)

The stakeholder engagement is the overarching principle for the other four governance criteria. As the MULTI-ACT is a collaborative model which requires the involvement of relevant stakeholders in the governance, stakeholder engagement should be considered throughout the entire adoption of MULTI-ACT Governance Model. Therefore, it guarantees a comprehensive, balanced and efficient stakeholder engagement process, ensuring the participation of patients and care givers, and of other relevant stakeholders.

Promoters should focus on the creation of a participative governance structure, as a prerequisite to the achievement of the Mission and Agenda, that guarantees an inclusive and equitable governance model and allows the involvement of all interested stakeholders through co-creation.

### ***Patient Engagement Guidelines***

As collateral to the Governance Model, the MULTI-ACT Patient Engagement Guidelines have been developed as tools to address “Participatory Governance” and “Clear, effective and inclusive methodology of stakeholder engagement”.

The guidelines propose a roadmap to capture ‘experiential knowledge’ of patients (i.e. knowledge gained through lived experience that researchers may not have), to better understand how to draw on this experience and use it constructively for raising patients and stakeholders ability to co-create and make research responsible toward patients and society.

### ***MULTI-ACT Master Scorecard***

In order to design an assessment system coherent with stakeholders’ perspectives and the aspects that matter most to them, the promoter can use the materiality analysis. On the basis of the list of relevant aspects covered by the MULTI-ACT Master Scorecard, the promoter is offered a list of potential indicators that allow reporting the initiative’s results in relation to different dimensions (efficacy, excellence, economic, social and patient-reported dimensions).

The promoter should ensure that the list includes relevant indicators under the dimension “Patients Reported Dimensions”. These indicators are measuring the impact on patients directly reported by them without the intervention of the clinicians, such as the Patient Reported Outcomes (PROs).

## **2.2 Tools for RFPOs (Research Funding and Performing Organization) to facilitate the implementation of the CRIF**

The CRIF Manual<sup>12</sup> has been produced with the purpose to facilitate the implementation of the CRIF by all interested research & innovation initiatives and RFPOs. It employs an iterative structure where models and guidelines are first explained in general terms, in the context of the whole framework, and later on described in full detail. The Manual is intended to be utilized in conjunction with the MULTI-

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<sup>12</sup> D6.1 CRIF Integrated Manual for R&I actors

ACT Toolbox. The Toolbox is a web-based platform which facilitates implementation of the CRIF from start to finish, guiding the user on the path towards participatory governance and stakeholder co-accountability.

The Toolbox includes:

- a) Baseline Analysis - a questionnaire that assesses to what extent user's research initiative is already compliant with the governance criteria. The final report identifies gaps in the user's initiative governance and indicates which recommendations from the governance criteria are most relevant for them..
- b) Patient Engagement (PE) Plan that helps the initiative's Engagement Coordination Team to build a strategic plan for patient engagement at each stage of the research process. The PE Plan also allows the initiative to choose patient-reported outcomes indicators which it may use to monitor its progress and impact. The tool is a part of the Patient Engagement Guidelines which give conceptual basis for understanding this tool.
- c) Materiality Analysis tool allows the initiative to conduct materiality analysis in an easy way. It includes a function for inviting stakeholders to participate, while ensuring anonymity to the participants. The participants – who represent different stakeholder groups – vote for the indicators from each CRIF dimension that are most relevant from their point of view. The most chosen indicators will create the initiative's customised Master Scorecard.
- d) Master Scorecard is a set of indicators covering all five CRIF dimensions. The initiative is supposed to use them to assess the social impact of their health research. They can be used periodically to monitor progress. Each indicator is meticulously described; the user may learn the tips for implementation, expected frequency of data collection, unit of measure.
- e) Forum for discussions among initiatives' representatives.

A tutorial video will be available to the users to better understand and navigate in the Toolbox.

Factsheets are also available on the three key areas of the CRIF: the governance model, patient engagement guidelines, and the master scorecard<sup>13</sup>. In addition to the Manual and the Toolbox, Patient Engagement Guidelines are available separately, in long and short version.

### 3. BRAIN DISEASE AREAS IDENTIFIED BEYOND MULTIPLE SCLEROSIS (MS)

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<sup>13</sup> <https://www.multiact.eu/publications/>

Following the European Brain Council (EBC)'s suggestion (leader of WP7), the MULTI-ACT consortium explored possibilities to collaborate with brain research consortia established under the EU funded European Brain Research Area project (EBRA)<sup>14</sup> named as 'EBRA clusters'.

EBRA was created in 2018 as a catalysing initiative for brain research stakeholders (researchers, clinicians, patients, governments, funders and public institutions) to streamline and better co-ordinate brain research across Europe while fostering global initiatives.

EBRA Clusters are understood as "research communities that can be directed towards basic research, clinical research and/or methodological approaches under a common topic, and disease and/or thematic area". They aim to promote cooperation and exchange between brain research projects and to enable or enhance international collaboration in all areas of brain research.

The CRIF was introduced to the existing EBRA Clusters: the EPICLUSTER in the field of epilepsy and the PSMD Cluster in the field of Prevention of Severe Mental Disorders.

The EPICLUSTER expressed interest in exploring the use of MULTI-ACT tools and guidelines in particular to support the cluster building its community, identify and engage with relevant stakeholders. Patient engagement guidelines were seen as particularly valuable to the community as well as the governance criteria to define the stakeholders and possibly better define the cluster's priorities and agenda.

Interactions with the Prevention of Severe Mental Disorders (PSMD) cluster, revealed that in its early stage of development, the MULTI-ACT CRIF was not suitable in addressing their current needs and could be reconsidered at a later stage.

Therefore, the brain disease area selected to implement MULTI-ACT CRIF beyond multiple sclerosis was epilepsy. The consortium established a collaboration with the EPICLUSTER based on agreed terms of reference<sup>15</sup>.

### 3.1 Engagement with the EPICLUSTER

As per the terms of reference agreed upon, for the collaboration between MULTI-ACT and the EPICLUSTER, an EPICLUSTER working group was established on the basis of the following criteria:

- a minimum representation of 3 different stakeholder categories (incl. the patient as this was one of the main interests of the cluster)
- a maximum of 4 people in order to ensure the feasibility of meeting on a regular basis

As the EPICLUSTER is a recent initiative, the CRIF is used "ex-ante" to help to set the following:

- EPICLUSTER's governance (defining stakeholders);
- Mission, Strategic priorities and Agenda

The use of the CRIF follows the steps as per the MULTI-ACT CRIF workflow (see figure 2 below):

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<sup>14</sup> <https://www.ebra.eu/about/the-mission/>

<sup>15</sup> <https://www.multiact.eu/partnerships/>

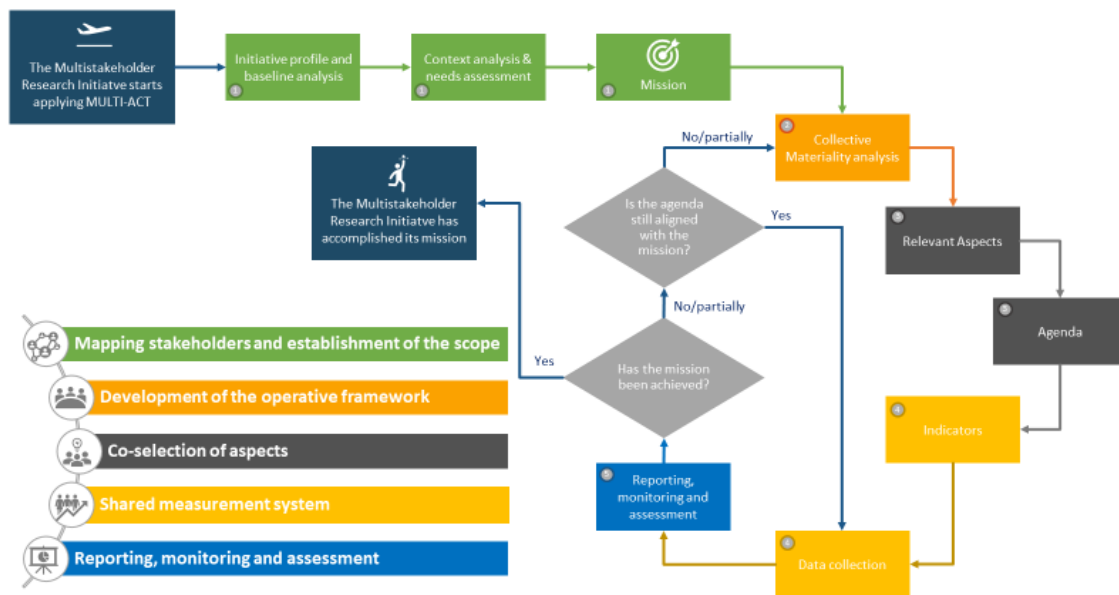


Figure 2: MULTI-ACT CRIF workflow

As per step 1 on the above figure, a baseline analysis of the EPICLUSTER was performed to identify governance strengths and potential rooms for improvement. The EPICLUSTER completed the baseline analysis questionnaire in the MULTI-ACT toolbox with the help from EBC. A meeting was dedicated to finalize the completion of the questionnaire.

According to the original action plan, EBC arranged a second EPICLUSTER working group meeting on 21 October 2020. The objective of this meeting was to share information, discuss the results of the baseline analysis and present initial recommendations. Moreover, the purpose of these discussions was to incentivize the EPICLUSTER to use the MULTI-ACT CRIF in the long term by promoting the Materiality Analysis and impact assessment model.

Four participants from the EPICLUSTER and MULTI-ACT partners attended the second working group meeting. The programme consisted of the presentations of the MULTI-ACT on the EPICLUSTER governance, MULTI-ACT Patient Engagement Guidelines with tailored priority recommendations to the EPICLUSTER and an Introduction to the Materiality Analysis and impact assessment model (Master Scorecard).

The baseline analysis questionnaire drew the attention of the EPICLUSTER to possible areas for improvement by explaining the gaps in meeting the participatory governance criteria and in engaging their stakeholders.

A table with the main drivers to strengthen the coherence of the EPICLUSTER to the MULTI-ACT model according the five criteria is available in APPENDIX 1.

The presentation of the Patient Engagement Guidelines introduced the MULTI-ACT Patient Engagement Roadmap with concrete examples for the implementation of each action of the roadmap by the EPICLUSTER.

The EPICLUSTER working group gave their initial feedback on the MULTI-ACT model. The following issues were raised.

- where to start the implementation of the MULTI-ACT framework
- Budget and resources needed to implement the framework
- Size of the ECT and balance of stakeholder representation in the governance
- Recruitment of “patient” members
- Training focus on the empowerment of engagement
- Stigma linked to Epilepsy and the fact that patients don’t stand up
- How to overcome the barriers to engagement in EPICLUSTER
- How to build on the existing network and initiative on patient engagement in Epilepsy

MULTI-ACT was invited to contribute to the EBRA EPICLUSTER leadership meeting on 1st December 2020 which focused on the EPICLUSTER governance, funding and patient engagement.

The meeting gathered existing networks of epilepsy at European level. Three consortium partners contributed to the meeting. MULTI-ACT presentations highlighted the strengths in the EPICLUSTER governance and rooms for improvement towards a stronger participatory governance and stakeholder engagement as per the results of the baseline analysis. Building from the feedback received during the 21st October meeting, as described above, concrete suggestions for the development of an EPICLUSTER Patient Engagement Roadmap were provided underlining the stepwise approach of the Roadmap.

The EPICLUSTER leadership welcomed the MULTI-ACT approach which it considered as relevant for the entire epilepsy community and future projects. The leadership expressed a strong wish to move into the direction of a more participatory governance and stakeholder engagement which it believes will be critical to their success in future EU Horizon2020 project applications. The Chair of the EPICLUSTER saw in the MULTI-ACT governance criteria, the “solution to their problem” but also saw the challenges to put all the pieces together.

Participants representing the patient community expressed some concerns on the increased demand that is put on the patient community to contribute with their expertise in research initiatives. MULTI-ACT explained the attempt of its framework to mitigate this aspect in making sure that the patient perspective is used as and when needed in the most efficient way.

A consolidated document with tailored recommendations on Governance and Patient Engagement (including the EPICLUSTER Patient Engagement Roadmap) and addressing the issues raised, has been sent to the Chair of the EPICLUSTER subsequently to the meetings held in October and December 2020. See APPENDIX 2 <sup>16</sup>

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<sup>16</sup> See appendix 2

## **4. NEXT STEPS TO PURSUE THE FULL IMPLEMENTATION OF THE CRIF WITH THE EPICLUSTER**

The plan below outlines proposed actions to pursue the full implementation of the CRIF on the EPICLUSTER initiative and how to promote the CRIF further in the field of epilepsy.

### **4.1 Development of tailored patient engagement roadmap**

According to EPICLUSTER's feedback on the consolidated document with recommendations on EPICLUSTER Governance and PE Engagement, the MULTI-ACT consortium will seek to assist the EPICLUSTER in the management of its roadmap that may include training of relevant team members on the topic.

### **4.2 Contribution and attendance at MULTI-ACT final conference**

The EPICLUSTER community will be invited to attend the MULTI-ACT final conference that will include a dedicated educational session for research organisations to implement the CRIF. This will provide an opportunity for the epilepsy community to learn about the material and tools available for project consortiums willing to make their research more collaborative and impactful across multiple dimensions. The EPICLUSTER will also be invited to contribute to the actual programme of the final conference with a testimonial on their engagement and learning from MULTI-ACT as a way to provide a concrete example to all participants to the final conference.

### **4.3 Invitation to perform materiality analysis for epilepsy research initiatives**

EBC as coordinator of the EBRA project will seek to continuously invite the EPICLUSTER community to use the MULTI-ACT offerings as and when appropriate. In particular, they will be invited to perform a materiality analysis which include the use of the current Master Scorecard established for the purpose of multiple sclerosis. They will be invited to provide feedback on the Master Scorecard including the relevance of the indicators for their field of research, in particular those related to the patient reported dimension which are seen as most likely to potentially differ depending on the disease area.

All of these activities as and when performed will make use of the digital toolbox and manual that will be available to the community in the short term. The Digital Toolbox functionalities guide the users step by step in the implementation of the CRIF. These functionalities will support users in the design of a Patient Engagement Plan and will enable the research promoters to invite stakeholders of their research initiative to directly engage in the process of choosing which aspects are most relevant and



should be assessed in terms of impact along five dimensions: efficacy, excellence, economic, social, and patient-reported dimensions.

## 5. PLAN OF ACTION TO PROMOTE THE ADOPTION OF THE CRIF IN THE OTHER BRAIN DISEASE AREAS IDENTIFIED BEYOND MS AND EPILEPSY

### 5.1 Promotion of MULTI-ACT CRIF in other existing EBRA clusters

The CRIF will be promoted with the other existing EBRA Clusters <sup>17</sup>. EBRA clusters are currently established in the following areas.

- Brainfood
- Trisomy 21
- Prevention of Severe Mental Disorders

Two additional clusters were selected based on a call for applications and established in February 2021:

The PREDICTIVE MODEL SYSTEMS (PREMOS). The primary objective of the PREMOS cluster is to enhance the alignment of EU disease model development resources and preclinical research expertise with clinical and brain research community needs across academia and industry

The second cluster is due to be officially announced in the course of March 2021. It will be announced on the EBRA website<sup>18</sup>.

In contrast with the previous clusters, these clusters cover overarching themes and are of relevance for many brain disease areas.

The following actions will be performed with existing and new clusters established.

- 1) Personal invitation to attend MULTI-ACT Final conference including session on presentation of CRIF to RFPOs will be sent to each cluster.
- 2) The MULTI-ACT factsheets and promotional material (e.g. videos) will be used as much as possible in clusters activities/meetings. EBC as coordinator of the EBRA clusters will be in a privileged position to ensure the material is promoted at best as and when appropriate, in particular when the cluster's plans of activities address the topics of participatory governance, multi stakeholder engagement and/or Impact assessment, outcomes measures.

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<sup>17</sup> <https://www.ebra.eu/existing-clusters/>

<sup>18</sup> <https://www.ebra.eu/existing-clusters/>

- 3) Invitation to perform materiality analysis and provide feedback including the relevance of the indicators for their field of research, in particular those related to the patient reported dimension which are seen as most likely to potentially differ according to the disease area.
- 4) Invitation to build on the training module on patient engagement that will be developed after the project and provide feedback for the development of potential additional disease-specific modules.

## 5.2 Promotion of MULTI-ACT CRIF to brain research community

There will be regular dissemination of MULTI-ACT outputs to EBC membership and partners through regular updates at strategic and Board meetings. EBC will look for potential synergies with EBC policy roadmap (eg. improving access and outcomes pillar) under development.

An exploitation plan is being designed with a strategy to exploit the identified MULTI-ACT exploitable results towards RFPOs.

The MULTI-ACT exploitable results are:

- **Governance model:** to support the management and collective evaluation of multi stakeholder initiatives.
- **Master Scorecard:** a new model for the assessment of the research impact across different dimensions.
- **Patient Engagement Guidelines:** for capturing “patient experiential knowledge” across the health research and innovation path, as well as to assist multi-stakeholder health research promoters in the use of the integrated collective research impact framework.
- **Toolbox:** for using the MULTI-ACT framework.

## 6. CONCLUSIONS

The prevention, treatment and care of brain diseases can only be attained through well-supported and well-coordinated research efforts involving all stakeholders.

MULTI-ACT offers guidelines and tools for structuring a Responsible Research and Innovation governance model for collective sustainability of transformational health missions, such as those needed in brain conditions.

The MULTI-ACT Collective Research Impact Framework (CRIF) is comprised of new participatory governance criteria; a new system for the assessment of research impact across different dimensions; innovative guidelines for effective patient engagement across the health research pathway. All of these are integrated in the MULTI-ACT digital toolbox.

These have been developed in co-creation with end users starting with a case study in the field of multiple sclerosis, followed by a collaboration with a large network of researchers in the field of

epilepsy. Research consortiums in all brain conditions can potentially benefit from the services offered by MULTI-ACT.

The digital Toolbox has been identified as the key instrument to exploit MULTI-ACT model by sharing and delivering content online to end-users in the short term.

Feedback from the MULTI-ACT Patient Forum and External Advisory Board members during a dedicated meeting held on 29/01/2021 highlighted the value of the toolbox as a way to rapidly take advantage of the CRIF to document the characteristics of a RFPO and be more data driven to decide on the way to pursue its mission and develop its activities.

The CRIF has the ambition to help RFPOs to deliver value and contribute to their sustainability. The circularity of the CRIF's workflow enables RFPOs to continuously refine and adapt their agenda based on feedback and stakeholders perceived returned on investment. It can be of value both to new RFPOs willing to align the expectations of their stakeholders or existing RFPOs willing to add new categories of stakeholders in their governance and/or activities.

The Toolbox will be more than an organized database on research in relation to different layers, but rather a consultancy tool that will include decision-support elements that will make it possible to introduce advanced search functions, logical links, and different scenarios able to accommodate the diversity of different research dimensions (mission, excellence, economic and social dimensions – transversal dimension: patient reported dimension). Specifically, the MULTI-ACT digital Toolbox will be a web-based tool with an advanced search function enabling smart navigations throughout the knowledge base, by using filters and different weights.

Longer investments are still needed to improve RRI principles policy integration strategy and implementation. The MULTI-ACT deliverables represent a timely opportunity and a reference for structuring an RRI participatory governance model for collective sustainability of transformational health missions.

## APPENDIX 1: EPICLUSTER baseline analysis - the main drivers to strengthen the coherence of the EPICLUSTER to the MULTI-ACT Governance model

Strengths	Suggestions for areas of improvement	Relevant MULTI-ACT recommendations
<b>1. Mission and agenda</b>		
<p>The initiative has defined a mission shared with relevant stakeholders and a related agenda setting short, mid and long-term objectives, involving some of the relevant stakeholders.</p> <p>The initiative has identified intended beneficiaries.</p>	<p>There are not significant weaknesses for this criterion, however it could be strengthened the set of stakeholder categories involved.</p>	<p>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.</p>
<b>2. Participatory governance</b>		
<p>The initiative has defined a governance structure.</p>	<p>The initiative should implement a participatory governance guaranteeing an inclusive and equitable governance model, which allows the involvement of all interested parties through a co-design approach-</p> <p>The initiative should guarantee equity and mechanisms to avoid self-interest.</p>	<p>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.</p> <p>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.</p> <p>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.</p>
<b>3. Stakeholder engagement</b>		

Strengths	Suggestions for areas of improvement	Relevant MULTI-ACT recommendations
<p>The initiative has identified and mapped the stakeholders that might be influenced by or might influence the initiative, with a different level of engagement:</p> <p>Academics/researchers: basic and translational science, Clinicians/caregivers, Infrastructure/data, Patient, Industry.</p> <p>The initiative performs a consultation process in order to understand the needs, expectations and challenges of the stakeholders involved in the initiative.</p>	<p>The initiative should define and approve a methodology to engage stakeholders.</p> <p>The initiative should define and implement a Patient Engagement Strategy, as patients are foreseen as a key stakeholder in the Health Research &amp; Innovation process</p>	<p>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.</p> <p>Within this context, specific attention should be addressed to the Patient Engagement Strategy</p>
<b>4. Effective management</b>		
<p>The initiative features an action plan in order to achieve its objective.</p> <p>In addition, it has a cost management process in place and maintains accountability over time keeping track of expenses and revenues.</p> <p>Moreover, the internal team has solid skills, consistent with the activities.</p>	<p>To enhance the overall coherence to the model, further aspects should be defined in order to achieve clear and transparent processes and timeline:</p> <p>Processes to ensure the balance between management and opportunities for engaging a wide range of participants.</p> <p>Contingency plan/risk management approach.</p>	<p>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.</p> <p>4.2.3) Guarantee a mechanism of review and evaluation, which allows to learn and improve the collaboration among stakeholders.</p> <p>4.3.1) Maintain flexibility, adjusting the goals and implementation actions to the changing reality and needs.</p>
<b>5. Co-accountability assessment</b>		
<p>The initiative has a monitoring system for the</p>	<p>To enhance the overall coherence to the model,</p>	<p>5.1.2) Select appropriate indicators from the list of relevant aspects according to different impact</p>

Strengths	Suggestions for areas of improvement	Relevant MULTI-ACT recommendations
<p>implementation of the actions of the initiative and the performance of the initiative itself.</p> <p>It also publishes a progress report and communicates with stakeholders about the progress of the initiative.</p> <p>Finally, there is a review process in place to improve the initiative's performance and practices and a process to gather feedback from external stakeholders and the public.</p>	<p>further aspects should be defined in order to achieve a shared and effective management system:</p> <p>Define an assessment system that allow to measure the initiative's "long-term impact" (ex-post).</p>	<p>dimensions and stakeholder perspectives in order to comprehensively assess the impact of health research.</p> <p>5.1.3) Ensure that the list of selected indicators consider the impact on patients.</p> <p>5.1.4) Establish a shared assessment system consisting of a set of indicators consistently tracked over time and a shared data collection process.</p>

## **APPENDIX 2: Tailored recommendations to EPICLUSTER**

The next pages present the dedicated document prepared to share the recommendations to the EPICLUSTER initiative.



# MULTI-ACT Governance and Patient Engagement: Recommendations to EPICLUSTER

February 2021



This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Grant Agreement No 787570



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## Introduction to the MULTI-ACT Governance

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) to improve the governance of research initiatives and stakeholder co-accountability, with a focus on brain diseases.

MULTI-ACT CRIF is specifically intended for health sector research funding and performing organizations (RFPOs) grouped in a multi-stakeholder initiative or willing to start conducting their R&I with a multi-stakeholder and co-accountable approach toward common goals to reach a transformational mission.

The Model supports those initiatives with a transformational mission that seek to maximize, explore and assess the impact of research beyond financial return, adopting a multi-stakeholder perspective.

The MULTI-ACT Governance Model is one of the fundamental elements of MULTI-ACT CRIF. It is a “principle-based” model: this means that instead of being based on the process according to a chronological order, it is based on principles, represented with criteria, sub-criteria and recommendations. In particular, the Model is composed by 5 criteria and 19 sub-criteria, detailed in 41 recommendations, which can be solutions for implementation or principles to be followed by the appliers of the Model.






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

Figure 1: The MULTI-ACT governance criteria and sub-criteria

### The main contents of the 5 criteria

#### 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.

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

## **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.

## **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 participants;
- Set clear and transparent processes and timeline;
- Maintain flexibility;
- Ensure the presence of secure funding, solid organizational structure and resource management.

## **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.

## A path to the adoption of CRIF for collaborative initiatives

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.

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;
- 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.
- 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.

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.

The MULTI-ACT Digital Toolbox will be available from February 2021. To facilitate the adoption of the MULTI-ACT Governance model as well as of the other components of the framework, such as Patient Engagement and Impact assessment.

## The results from EPICLUSTER baseline analysis

As the first step, EPI-Cluster carried out a **baseline analysis** in order to evaluate the current status of the initiative with respect to the implementation of the five criteria of the MULTI-ACT governance model and to pave the way for the application of CRIF within a mission-oriented initiative.

The baseline analysis led to an evaluation on the applicability of the MULTI-ACT model to the EPI-Cluster initiative in relation to the 5 key criteria.

For each criterion, there are 4 evaluation levels:

1. Fully coherent
2. Coherent
3. To be improved
4. Lacking

The score of every criterion ranges from 0 to 20: the overall maximum score is thus 100.

	SCORE	COMMENT
Criterion 1 - Mission and agenda	17,2	Fully coherent: the initiative is fully coherent with MULTI-ACT recommendations.
Criterion 2 - Participatory governance	3,3	Lacking: the initiative is not in line with MULTI-ACT recommendations.
Criterion 3 - Stakeholder engagement	4,3	Lacking: the initiative is not in line with MULTI-ACT recommendations.
Criterion 4 - Effective management	12,4	Coherent: the initiative is overall coherent with MULTI-ACT recommendations.
Criterion 5 - Co-accountability assessment	11,1	Coherent: the initiative is overall coherent with MULTI-ACT recommendations.
<b>Total</b>	<b>48,3</b>	

Figure 2: The results of the EPICLUSTER initiative baseline analysis

The EPI-Cluster initiative baseline analysis shows a total score of 48,3/100, featuring a high degree of coherence in **criterion 1** (17,2/20) and **criteria 4 and 5** (respectively 12,4 and 11,1/20), while rooms for further development regards criterion 3 “Effective stakeholder engagement” and criterion 2 “Participatory governance” to which is dedicated a specific focus in the following pages.

## Insights from criteria 1, 4 and 5 (fully or partially coherent)

The analysis of results highlighted the coherence of EPI-Cluster to the criteria 1, 4 and 5 and led to the identification of specific areas of aspects that can be strengthened in order to align to MULTI-ACT governance model.

### Criterion 1: Mission and Agenda

The initiative has defined a mission shared with relevant stakeholder and a related agenda setting short, mid and long-term objectives, involving some of the relevant stakeholders. The initiative has identified intended beneficiaries as well. Under this criterion, the main suggestion is to enlarge and better define the set of stakeholder categories involved, thus tackling the intended mission with a unifying long-term vision and a clearly defined set of objectives and actions.

### Criterion 4: Effective management

The initiative features an action plan in order to achieve its objective. In addition, it has a cost management process in place and maintains accountability over time keeping track of expenses and revenues. Moreover, its internal team has solid skills, consistent with the activities.

The suggestion is to define further aspects in order to achieve clear and transparent processes and timeline, for instance:

- Processes to ensure balance between management and opportunities for engaging a wide range of participants
- Contingency plan/risk management approach

Relevant recommendations from Criterion 4 are the following:

- 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.
- 4.2.3) Guarantee a mechanism of review and evaluation, which allows to learn and improve the collaboration among stakeholders.
- 4.3.1) Maintain flexibility, adjusting the goals and implementation actions to the changing reality and needs.

#### **Criterion 5: Co-accountability assessment**

The initiative has a monitoring system for the implementation of the actions of the initiative and the performance of the initiative itself. It also publishes a progress report and communicates with stakeholders about the progress of the initiative. Finally, there is a review process in place to improve the initiative's performance and practices and a process to gather feedback from external stakeholders and the public.

One relevant missing element under this criterion is the definition of an assessment system that allow to measure initiative's "long-term impact" (ex-post).

Relevant recommendations from Criterion 5 are the following:

- 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.
- 5.1.3) Ensure that the list of selected indicators consider the impact on patients.
- 5.1.4) Establish a shared assessment system consisting of a set of indicators consistently tracked over time and a shared data collection process.

### **Main recommendations to EPICLUSTER from MULTIACT Governance Model**

Apart from the considerations exposed above, regarding criteria in which EPI-Cluster already proved to be in line with MULTI-ACT recommendations, a deeper focus should be placed on criteria 2 and 3. The following part of this paragraph is extracted from MULTI-ACT Deliverable 4.3 *"Review Report on the implementation of the Framework on MS case"* which will be soon publicly available.

#### **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.

## Sub-criterion 2.1: Allow the involvement of intended beneficiaries

**Recommendation 2.1.1:** “Involve intended beneficiaries in the agenda design, in the decision-making process and in the initiative development, implementation and assessment. For the purpose of MULTI-ACT, patients are usually the intended beneficiaries”.

With specific regard to patients, develop a roadmap to capture ‘experiential knowledge<sup>1</sup>’ of **patients<sup>2</sup>**, 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 roadmap for patient engagement, to ensure that people affected by MS have an equal voice with other stakeholders. Recommendations on how to apply the MULTI-ACT Patient Engagement Roadmap are available in Chapter “Recommendations for patient engagement in the relevant research steps of EPICLUSTER.”.

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 and other stakeholders’ 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.

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<sup>1</sup> “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.

<sup>2</sup> The term “patients” refers both to the people with the disease and the peoples affected by the disease such as family members and caregivers.



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 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.

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

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**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”

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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 individuals<sup>3</sup>, 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);

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<sup>3</sup> Cottam, H., Leadbeater, C., 2004. RED PAPER 01 HEALTH: Co-creating Services. London: Design Council

- 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);
- 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".

### **Sub-criterion 2.3: Implement a participatory structure**

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**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"

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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.

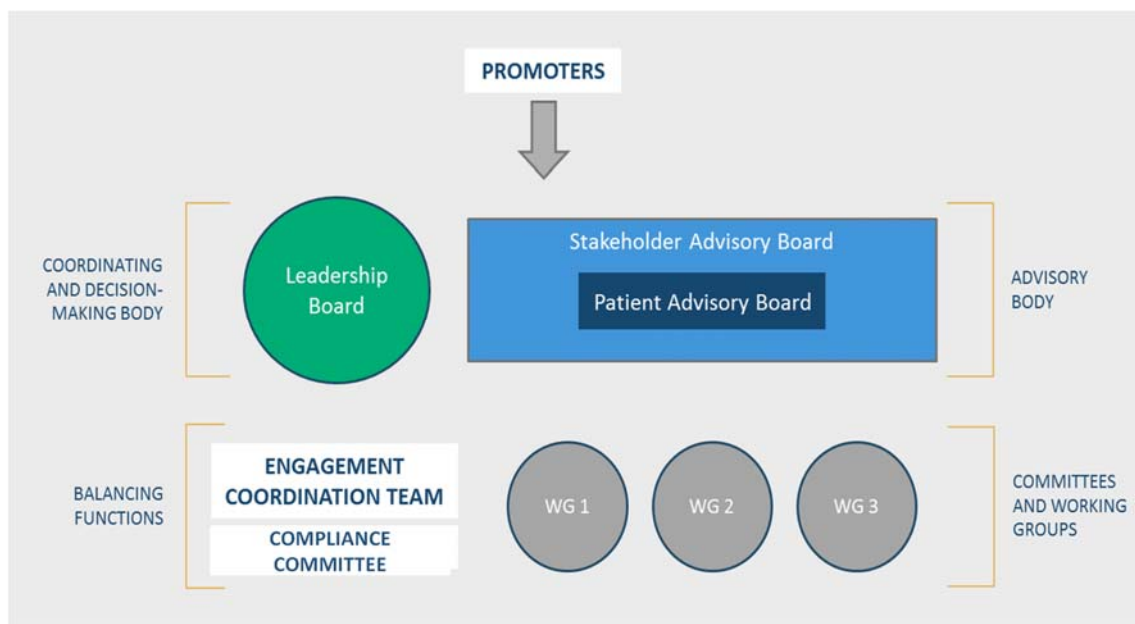


Figure 3: The MULTI-ACT Governance Model

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, the following chart aims at clarifying the process of appointment of the 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

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**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”

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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.

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

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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.

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

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**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”

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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.

### **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.

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.

Recommendations on how to apply the MULTI-ACT Patient Engagement Roadmap are available in Chapter ["Recommendations for patient engagement in the relevant research steps of EPICLUSTER."](#)

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

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**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"

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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.
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 risks<sup>4</sup> 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.

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

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:
  - 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

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<sup>4</sup> The a more detailed list of potential stakeholder risks is contained in the document: AccountAbility. (2015). AA1000 Stakeholder Engagement Standard.



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.

### **Sub-criterion 3.2: Engage intended beneficiaries**

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**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”

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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 and implementation 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, and to capture and integrate their “experiential knowledge” into the R&I steps. 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.

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**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)”

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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 applicators 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.

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

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**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.

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

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**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”

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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.

## Introduction to the MULTI-ACT Patient Engagement Strategy & Guidelines

The notion of Responsible Research Innovation (RRI)<sup>5</sup> argues that excellence, validity and relevance are connected by engaging patients and society in the research continuum as key stakeholder with decision making role.

Over the last decade, patient engagement has become more important along with the democratization of health sciences. Patients started to be engaged not only in a passive role, but also as co-researchers.

MULTI-ACT performed a landscape analysis<sup>6</sup> in order to assess existing experiences of patient engagement in research and found out that much of the current guidelines for Patient Engagement focus on enable “expert patients” in “Medicines Lifecycle”.

MULTI-ACT aims to fill the gaps by proposing a complementary strategy: **a roadmap to capture ‘experiential knowledge’ of patients**<sup>7</sup>. A knowledge that complement the expertise of researchers and that should be acknowledged and used as a valuable asset for research. It is now more widely recognized that the life experience of patients leads to knowledge that complements the expertise of researchers by providing relevant and different insights on R&I which can potentially increase the impact of R&I on the outcomes that matter most to patients. This unique personal knowledge and experience, what we call experiential knowledge, can be applied to many stages of research and innovation, from planning research to reporting its results. While collecting patient data has always been important in MS research, more fully engaging patients and caregivers in all relevant decision-making stages of a project can enrich the research, enhance its relevance, and ensure that a research initiative reflects the goals, or outcomes, that matter most to people affected by MS.

### The Strategy

The innovation of the MULTI-ACT Patient Engagement strategy relies mainly on three key assets:

- i) the innovative MULTI-ACT Governance Model for collaborative initiatives and the Engagement Coordination Team;
- ii) training focused on how to empower patients and stakeholder to cooperate and to bring their experiential knowledge into the R&I continuum, complementing existing training to make patients “experts”; and
- iii) the importance of understanding and measuring the impact of R&I on outcomes that matter to patients.

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<sup>5</sup> <https://ec.europa.eu/programmes/horizon2020/en/h2020-section/responsible-research-innovation>

<sup>6</sup> “D1.4: Consolidated mapping of existing patient engagement initiatives and analysis of gaps and barriers to patient engagement in current health R&I processes”: <https://www.multiact.eu/project-deliverables/>

<sup>7</sup> For MULTI-ACT the term “patients” refer both to the people with the diagnosis of the disease and to the people affected by the disease, such as family members and caregivers.

## The Guidelines

MULTI-ACT has developed guidelines<sup>8</sup> for effective patient engagement across the health research and innovation path. The guidelines have been produced following a co-creation and evidence-based process which entails several steps. They include translation of the lessons learnt from the landscape analysis of existing patient engagement procedures resulting into guidance, recommendations, methods and suggestions on how to fill gaps identified with the analysis. In line with existing good practices on guidelines production, the guidelines were designed and validated with a series of actions including a literature review, a web-search, a public consultation and interviews, surveys, and reviews by key stakeholders (MULTI-ACT Patient Engagement Group, External Advisory Board, Patient Forum).

Figure 4 MULTI-ACT Patient Engagement Guidelines



## The Roadmap

The guidelines propose a **Patient Engagement Roadmap** that consists of four fundamental activities:

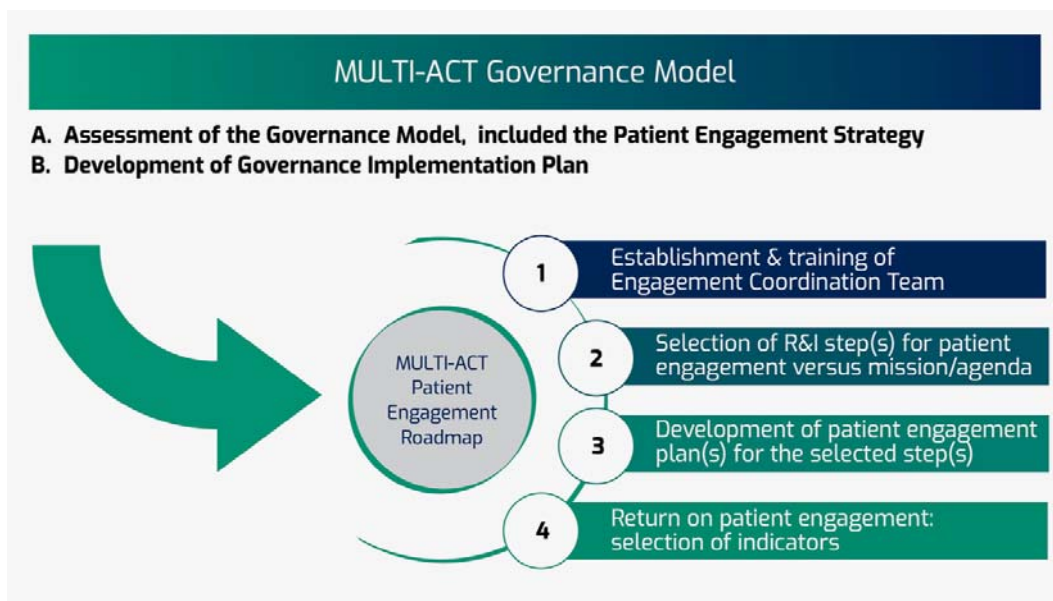
1. setting up an Engagement Coordination Team with trained figures;
2. selecting the research priority and steps<sup>9</sup> where patients engagement is instrumental to meet the project's objectives and the initiative's mission;
3. developing an engagement plan for each identified research priority & steps; and
4. selecting the indicators to be used to measure the success and effectiveness of this engagement.

<sup>8</sup> MULTI-ACT Patient Engagement Guidelines <https://www.multiact.eu/project-deliverables/>

<sup>9</sup> MULTI-ACT defined the 7-steps R&I path. The steps are: Breaking down boundaries, Research priorities, Steering committee, Design & plan, Research execution, Research Evaluation, Translation to community.

Projects applying to use the MULTI-ACT guidelines should self-assess the coherence to the MULTI-ACT governance model and criteria that includes **“Guarantee an inclusive and equitable governance model and a comprehensive, balanced and efficient stakeholder engagement process, ensuring the participation of patients, their families and caregivers”<sup>10</sup>**. In fact, multi-stakeholder governance is essential to ensure effective patient engagement and return on engagement for all the stakeholder involved in a certain research.

Figure 5 MULTI-ACT Patient Engagement Roadmap



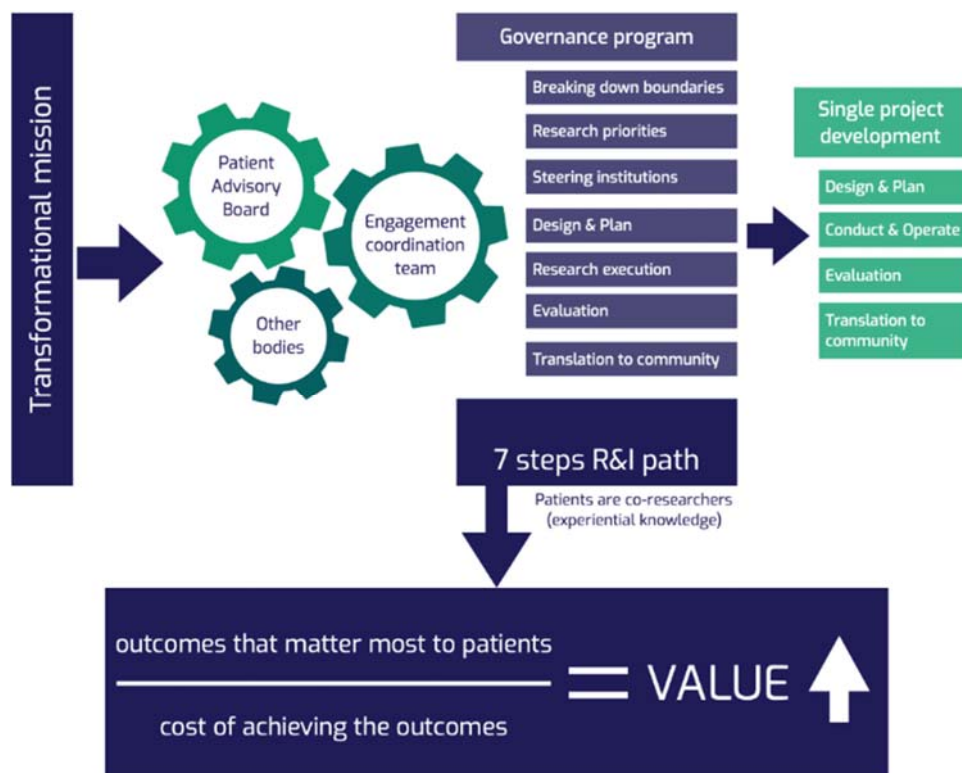
## The Value of Patient Engagement

The **value and effectiveness of MULTI-ACT Patient Engagement** relies on impacting outcomes that matter to patients while being sustainable in achieving this goal. Patient Engagement strategies directed to engage patients through the 7-steps R&I path, both in the governance of R&I (*Science with Patient Input*) and in its impact assessment (*Science of Patient Input*), are instrumental to meet transformational mission’s health R&I.

Figure 6 The value of MULTI-ACT Patient Engagement

<sup>10</sup> “D5.4 A new governance criterion allowing effective cooperation of all relevant stakeholders in multi-stakeholder research initiatives and transformative governance”. <https://www.multiact.eu/project-deliverables/>







## Recommendations for patient engagement in the relevant research steps of EPICLUSTER.

The present recommendations report relies on the **MULTI-ACT Patient Engagement Roadmap** and provides a follow up to the questions related to patient engagement include in the **baseline analysis**.

The “core” recommendation is to “design with the end in mind” and in particular, to apply the MULTI-ACT Patient Engagement Roadmap to the activities of **EPICLUSTER**, considering its Mission and Agenda (Mission-driven approach).

**Mission: Establish a collaborative framework for the coordinated actions of epilepsy research in Europe**

### R&I Priorities:

1. Disease-modifying and personalised medicines for epilepsy and their delivery systems
2. Target-led biomarker and diagnostics discovery and validation
3. Innovative models for diagnostics and target development
4. Digitalisation and personal monitoring for independent living in epilepsy
5. Coordination of research infrastructures and the Epilepsy data ecosystem
6. Funding initiatives and integration to society, industry and regulatory space

### Strategic priorities:

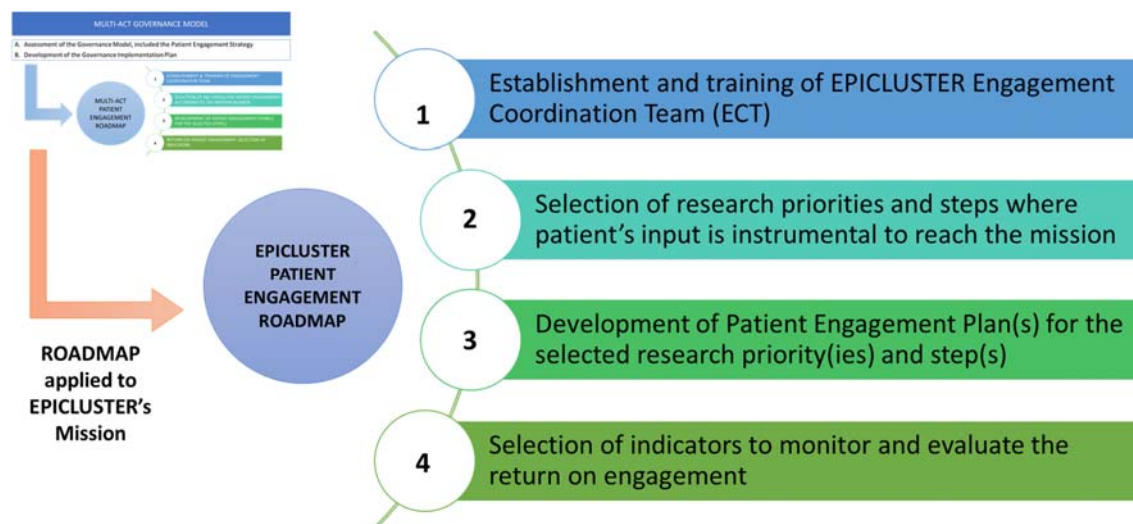
- Advance the existing collaboration
- Expand the network
- Advance research on core topics
- Enhance resource-sharing
- Develop a preclinical trial network and enhance clinical trial structures
- Develop researcher exchange mechanisms
- Increase engagement of persons with epilepsy and their representatives
- Develop a global funding initiative on epilepsy research across agencies

### Tactic/operational sub-groups:

- (1) **Synthesis:** Planning meetings and support the development of the programme for a European Forum on Epilepsy.
- (2) **Policy & sustainability:** Agreeing key research challenges, potential funding opportunities for EPI-Cluster community.
- (3) **Innovation & industry:** Responsible for contacting and engaging with SMEs and Pharma.
- (4) **Data and research infrastructure:** Coordinating interactions with partners such as HBP and supporting collaborations using our existing resources (e.g. biosamples).

The **MULTI-ACT Patient Engagement Roadmap** recommend to perform four fundamental actions:

1. setting up an Engagement Coordination Team with trained figures;
2. selecting the EPICLUSTER research priorities & steps<sup>11</sup> where patients engagement is instrumental to meet the EPICLUSTER's Mission;
3. developing a Patient Engagement Plan for each identified research priority & steps;
4. selecting the indicators to be used to measure the success and effectiveness of this engagement.



<sup>11</sup> MULTI-ACT defined the 7-steps R&I path. The steps are: Breaking down boundaries, Research priorities, Steering committee, Design & plan, Research execution, Research Evaluation, Translation to community.

## Action 1: “Establishment of an Engagement Coordination Team”

MULTI-ACT recommends<sup>12</sup> to establish and train an Engagement Coordination Team responsible for:

- ♦ creating commitment among the members and their community;
- ♦ moderating the dialogue between interdisciplinary and different (and sometimes competing) voices and experiences and settling a dispute resolution system;
- ♦ mitigating challenges such as ethical conflicts in protocol design, tokenism, power struggles, difficulties in recruiting different patients, additional time, cost;
- ♦ assuring that patients “feels valued” by facilitating team interaction and setting up an inclusive research environment.

The team should reflect the ability to empower the experiential knowledge of patients and ensure representativeness of the patients' community.

### Terms of reference for the Engagement Coordination Team

- ♦ design and put in place actions to engage patients in the steps of the initiative and constantly monitor and review the patient engagement performance and Return on Engagement;
- ♦ direct and moderate the patient’s experiential knowledge so that it is transformed into outcomes that matter to patients and to the other stakeholders and are “scientifically” validated;
- ♦ translate into a lay language eventual technical information that patients need in order to provide their feedback;
- ♦ motivate patients to stay engaged along the initiative by applying indicators to measure their Return on Engagement;
- ♦ assure the sustainability of the Patient Engagement Plan, monitoring risks and proposing mitigation actions.

### 1.1 Skills of the Engagement Coordination Team

MULTI-ACT suggest the following skills as essential to enable effective patient engagement:

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

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<sup>12</sup> The first action recommended by the MULTI-ACT Patient Engagement Roadmap refers in particular to question n.8 of the Baseline Analysis “Do you have a team/manager dedicated to coordinate the patient engagement?”.

Other preferred abilities are: Scientific knowledge of the disease; Personal experience of the disease as a patient, family member or caregiver; Team working abilities; Motivational and coaching abilities; Socio-psychological knowledge/background; Ethical management knowledge/background; Understanding of group dynamics; Project management knowledge/background.

### Composition of the team

The composition of this team depends on the specificity of individual programs and/or projects, mission and goals to be achieved. However, it is considered that the essential figures of this team are as follows:

- ✦ Co-Chair (1);
- ✦ Co-Chair, patient (1);
- ✦ MULTI-ACT trained representative (1);
- ✦ EPICLUSTER board(s) representative (1);
- ✦ EPICLUSTER group(s) representative (1);
- ✦ Patients (with consideration to balance of gender, geography, disease progression, age, socio-economic background) (3-6);
- ✦ Expert(s) on the mission/priorities topic(s): e.g. Working Group chair/representative.

## 1.2 Training of the Engagement Coordination Team

The Engagement Coordination Team members should receive adequate information about the **EPICLUSTER**'s mission and strategy<sup>13</sup>. An explanation of what is expected from patients and other stakeholders, of what are the expected outcomes of **EPICLUSTER** and how do those outcomes relate to the needs of **people affected by Epilepsy** should also be include in the training modules. The training should provide basic knowledge about innovative communication, learning and co-working techniques, and provide evidence of the value of patient and stakeholder engagement. In addition, plain language should be used and the content should be kept simple and respect for the human rights and the dignity of the patient should always be considered.

MULTI-ACT Patient Engagement Academy will provide training on how to capture and integrate patients' experiential knowledge in R&I (1Q - 2021).

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<sup>13</sup> The recommendation on the training refers to the question n.8 of the Baseline Analysis “Do you plan ad-hoc training programs related to the patient engagement, including scope and actions?”.

### Example of Roadmap Action 1:

The promoters of EPICLUSTER, in line with the recommendation of the MULTI-ACT Governance Model<sup>14</sup>, establish an Engagement Coordination Team in charge of designing and implementing a Patient Engagement Plan in the EPICLUSTER activities. The Team is a multi-stakeholder body with heterogeneous backgrounds and relevant skills such as **empathy, active listening, communication skills**, and **expertise in engagement strategies & methods (online and offline)**. After the signature of the Term of Reference (ToR), the Team is provided with a **training**<sup>15</sup> to empower the ability of patients and stakeholders to **co-created and collaborate**, to capture and integrate their experiential knowledge in the research activities of EPICLUSTER, and to **ensure the representativeness of the patients' community**.

#### *Descriptive elements*

- Beneficiary: EPICLUSTER and people with Epilepsy
- Intervention: Governance and activities

#### *Transformative elements*

- Expected change in EPICLUSTER: increasing effectiveness of patient engagement
- Baseline: current patient engagement strategy

#### Example:

ECT is added to the 4 subgroups of EPICLUSTER. The ECT will coordinate the engagement of people affected by Epilepsy in the EBRA activities of the EPICLUSTER:

#### EPI-Cluster subgroups

- (1) Synthesis: Planning meetings and support the development of the programme for a European Forum on Epilepsy.
- (2) Policy & sustainability: Agreeing key research challenges, potential funding opportunities for EPI-Cluster community.
- (3) Innovation & industry: Responsible for contacting and engaging with SMEs and Pharma.
- (4) Data and research infrastructure: Coordinating interactions with partners such as HBP and supporting collaborations using our existing resources (e.g. biosamples ).
- (5) Engagement of people with Epilepsy: Design and implement a Patient Engagement Plan along the priorities and activities of the EPICLUSTER.**

<sup>14</sup> More information on the meaning of MULTI-ACT Governance criteria are reported in deliverable D5.4. <https://www.multiact.eu/project-deliverables/>

<sup>15</sup> MULTI-ACT Patient Engagement Academy could serve for the scope. It should be ready by Q1 2021

## Action 2: “Selection of research priorities and steps where patient engagement is instrumental to meet the Mission”

MULTI-ACT recommends<sup>16</sup> to select the research priorities and steps where patient engagement is instrumental to meet the EPICLUSTER's mission/agenda and develop an engagement plan for each identified priority(ies) and step(s).

Figure 7 The MULTI-ACT 7-steps R&I path



The 7-steps R&I path is a sequence of processes and activities in R&I where patients can be engaged in order to maximize the impact of R&I. The path refers to the Governance of R&I program (Program Level) and could be applied to the project development (Project Level).

**Program Level:** Governance Program stages in Multi-stakeholder initiative (e.g. EPICLUSTER) process concerned with the governance and management of research funding & performing programs:

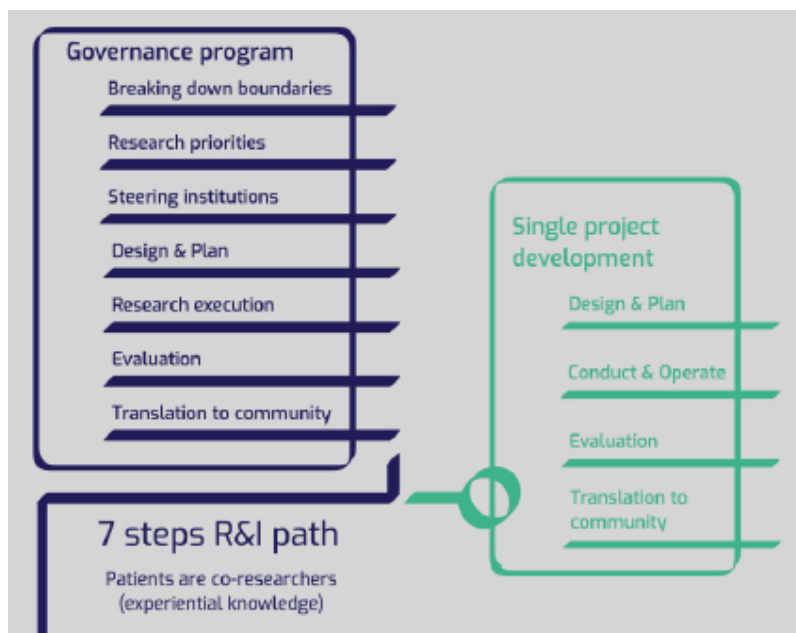
- **Breaking down the boundaries** conditions that should be set in Research Funding and Performing Organization (RFPOs) in order to facilitate patient engagement as standard practice.
- **Setting research priorities** actions to establish justified interest in a specific research domain to a certain higher degree, importance, precedence, or rank over others.
- **Steering institutions** actions performed to establish steering and advisory committees and bodies.
- **Design and planning** the design and planning of all the activities that lead to the realization of a concept or idea and which helps achieve the item's designated objective(s).
- **Executing research** activities to actualize the research program or a specific research project for the purpose of achieving the item's designated objectives. Project Development Level takes places at this stage.
- **Evaluating research** activities to determine the value created by a research program or project, establishing their outputs and outcomes, the degree to which their pre-established goals were achieved, and their impact.
- **Translation to community** activities to foster and facilitate the uptake of results of research programs or projects.

<sup>16</sup> The second action recommended by the MULTI-ACT Patient Engagement Roadmap refers in particular to question n.7 of the Baseline Analysis “Do you engage patients in your Research & Innovation (R&I), in one or more of the following steps: - Breaking down boundaries - Research priorities - Steering institutions - Design & plan - Research execution - Evaluation - Translation to community? Please the steps in which you engage patients”.

**Project Level:** Project Development stages in Multi-stakeholder initiative (e.g. EPICLUSTER) process concerned with performing single research projects (e.g. single project for the development of an ICT Health monitoring device or clinical trials). In this case, patient collaborate in the phases of the project development.

- **Design & plan** the design and planning of all the activities that lead to the realization of a concept or idea and which helps achieve the item's designated objective(s).
- **Conduct & operate** project conduct & monitoring (e.g. ICT device development).
- **Evaluation** activities to determine the value created by a research project, establishing their outputs and outcomes, the degree to which their pre-established goals were achieved, and their impact.
- **Translation to community** activities to foster and facilitate the uptake of results of research projects.

Figure 8 The MULTI-ACT 7-steps R&I path: Program & Project Levels



### Example of Roadmap Action 2:

The promoters of the EPICLUSTER and the Engagement Coordination Team analyses the EPICLUSTER's Mission/Agenda and the 7-steps R&I path and define the EPICLUSTER research's priorities and steps where patient engagement is instrumental to reach the EPICLUSTER's Mission/Agenda. A consultation with internal governance boards and stakeholders produced the final selection of EPICLUSTER research's priorities, steps and associated expected outcomes.

The relevant R&I step(s) for patient engagement associated to the priority will be further discussed by the Engagement Coordination Team when designing the Patient Engagement Plan in Roadmap Action n.3.

*Descriptive elements*

- Beneficiary: EPICLUSTER
- Intervention: priority setting for patient engagement

*Transformative elements*

- Expected change in the EPICLUSTER: selection of priority and R&I's steps for patient engagement endorsed by stakeholders
- Baseline: current priority for patient engagement activities

Example:

- Selected EPICLUSTER's R&I Priorities:
  - **Digitalisation and personal monitoring for independent living in epilepsy**
    - Selected R&I step: **Execution**

Expected outcome: Capture and integrate the needs of people with Epilepsy in the activities of EPICLUSTER, starting from the mission and priorities

**NOTE:** Patient engagement might also inform the strategy of EPICLUSTER, it might be important to engage patients in defining what are the facilities, policy and infrastructure they need to be engaged, example:

- Selected EPICLUSTER's Strategic Priorities: **Increase and integrate the engagement of persons with epilepsy and their representatives in the design and execution of research activities.**
  - Selected R&I step: **Breaking down boundaries**



### **Action 3: “Design and implement a Patient Engagement Plan for each identified research priority and step”**

Once defined and agreed the R&I priorities and steps where patient engagement is instrumental to reach the EPICLUSTER mission, the Engagement Coordination Team should design and implement a Patient Engagement Plan for each identified research priority and define Patient Engagement Actions for each step<sup>17</sup>. The Plan should include:

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

MULTI-ACT provides a Patient Engagement Plan template<sup>18</sup> and a menu of patient engagement activities along the 7 steps R&I path (see Table n.1).

MULTI-ACT Digital Toolbox foreseen the functionality to digitally develop Patient Engagement Plan (v0.2 January 2021).

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<sup>17</sup> The third action recommended by the MULTI-ACT Patient Engagement Roadmap refers in general to the Baseline Analysis' questions n.6, including question n.6.3 *“Do you have a stakeholder engagement strategy in place?”*.

<sup>18</sup> The Plan template include fields that aim to reply to the Baseline Analysis' questions n.11, n.12, n.13, including questions on mechanism to reward patients, resources, and ethical assessment.

Table 1 Menu of Patient Engagement activities along the 7-steps R&I path.

7-steps R&I path	MENU of Patient Engagement Activities
<b>BREAKING DOWN BOUNDARIES</b>	<ul style="list-style-type: none"> <li>• Patients help to define what are the boundary condition for patient engagement in multi-stakeholders initiatives</li> <li>• Patients help to provide an overview on the facilities and infrastructures they need to be engaged in R&amp;I</li> <li>• Patients help to review the policies and guidelines on how to engage patients in R&amp;I activities</li> </ul>
<b>RESEARCH PRIORITIES</b>	<ul style="list-style-type: none"> <li>• Patients are engaged to co-design research agenda.</li> <li>• Patients are engaged in advancing their interests in a specific research domain.</li> <li>• Patients are engaged to exercise prioritization.</li> </ul>
<b>STEERING INSTITUTIONS</b>	<ul style="list-style-type: none"> <li>• Patients are invited to be a member of committees and boards to provide guidance on key issues such as a company's policy and objectives, budgetary control, marketing strategy, resource allocation, and decisions involving large expenditures</li> <li>• Patients are invited to advise steering and advisory committees.</li> <li>• Patients are engaged in defining ethical issues, anticipating risks and barriers for patient engagement in committee.</li> </ul>
<b>DESIGN &amp; PLAN</b>	<ul style="list-style-type: none"> <li>• Patients are engaged to suggest endpoints and outcomes of research.</li> <li>• Patients are engaged to propose specific objectives of research.</li> <li>• Patients are engaged to define the relevance and acceptability of proposed research to patient community.</li> </ul>
<b>RESEARCH EXECUTION</b>	<ul style="list-style-type: none"> <li>• Patients are engaged in the development and monitoring of research at Program Level (e.g. release of call for proposals, selection of projects to be funded, monitoring of funded projects)</li> <li>• Patients are engaged in the development and monitoring of research at Project Level (e.g. collaborating for ICT device development, for the enrolment to increase participation and decrease drop-down, to increase compliance with protocols and facilitate data collection, for writing and review of papers)</li> </ul>
<b>EVALUATION</b>	<ul style="list-style-type: none"> <li>• Patients are engaged in discussing in the multi-stakeholder team about new methods to measure the impact of research and align results to the mission/agenda.</li> <li>• Patients are engaged in the assessment of new approaches and products arising from research.</li> <li>• Patients are engaged in working with other stakeholders on research reports.</li> </ul>
<b>TRANSLATION TO COMMUNITY</b>	<ul style="list-style-type: none"> <li>• Patients are engaged in in shaping the "translation strategy" of research results to easy-to-use and easy-to-understand (lay) material and in communication activities to disseminate the research results</li> <li>• Patients are engaged in the development of guidelines and advocacy activities.</li> <li>• Patients are engaged in advocacy to leverage uptake of research results.</li> </ul>

**Example of Roadmap Action 3:**

The promoters of the EPICLUSTER finalize the R&I priorities and steps where patient engagement is instrumental to reach the EPICLUSTER's mission/agenda, and the Engagement Coordination Team design the Patient Engagement Plan for the identified priorities and R&I's steps. The Plan is designed by using the MULTI-ACT Digital Toolbox and a PDF report is produced. Promoters and stakeholders revise the Plan, resulting in a co-creation process to ensure representativeness. Once approved the final Patient Engagement Plan, the Engagement Coordination Team is in charge for the implementation of the Plan. The design of a Patient Engagement Plan is a pre-requisite to access to the MULTI-ACT Materiality Analysis.

*Descriptive elements*

- Beneficiary: EPICLUSTER
- Intervention: planning, implementing & monitoring of patient engagement

*Transformative elements*

- Expected change in the EPICLUSTER: tools for implementation and monitoring of different aspects related to patient engagement activities
- Baseline: current patient engagement implementation and monitoring

**Example:**

Selected R&I priority:

- Digitalisation and personal monitoring for independent living in epilepsy

Selected R&I step: Execution

Selected activities:

- Patients are engaged in the development and monitoring of Epilepsy research at **Program Level** (e.g. release of call for proposals targeted Epilepsy, selection of projects to be funded, monitoring of funded projects)
- Patients are engaged in the development and monitoring of research at **Project Level** (e.g. collaborating for ICT device development, for the enrolment to increase participation and decrease drop-down, to increase compliance with protocols and facilitate data collection, for writing and review of papers)

Selected strategic priority: Increase and integrate the engagement of persons with epilepsy and their representatives in the design and execution of research activities.

Selected step: Breaking down boundaries

Selected activities:

- Patients help to define what are the boundary condition for patient engagement in the activities of EPICLUSTER
- Patients help to provide an overview on the facilities and infrastructures they need to be engaged in Epilepsy Research
- Patients help to review the policies and guidelines on how to engage patients with Epilepsy in R&I activities

## Action 4: “Selection of the indicators to be used to measure the success and effectiveness of this engagement”

MULTI-ACT recommends<sup>19</sup> to define indicators to evaluate the *return on patient engagement* for each stakeholder involved, and thus its effectiveness and value. The selected indicators should be included in the Patient Engagement Plan and monitored along its implementation.

MULTI-ACT provide a list of quantitative and qualitative indicators to evaluate the “**return on patient engagement**” for patients and the other stakeholders.

### QUANTITATIVE:

- ◆ The number of changes in the research process (e.g. policies, composition of boards, objectives and priorities, strategic plan, evaluation of results, dissemination actions, etc.) according to the review made by patients.
- ◆ The number of research initiatives, programs and projects that include and show an effect on Patient Reported Outcomes (i.e. questionnaire reporting how they feel about symptoms and functions).
- ◆ The number of research initiatives, programs and projects involving patients in research activities, according to the needs of the mission.

### QUALITATIVE:

- ◆ The analysis of whether patients’ expectation with respect to the research and mission of the initiative are met.
- ◆ The analysis of the achievement in terms of new knowledge produced, from the perspective of all the stakeholders.

Please note that the indicators to evaluate the effectiveness and value of patient engagement are included in the MULTI-ACT Collective Research Impact Assessment model. In this model, conventional indicators related to the **excellence dimension** are integrated with new measures related to the **mission-related dimension** (one explicit driver), the **economic and financial dimension** (efficiency), and to the **social dimension**. The **patient-reported dimension** is applied in a transversal modality throughout the four dimensions of the co-accountability model (mission/efficiency, excellence, efficacy, and social). The indicators to evaluate the effectiveness of patient engagement on outcomes that matter to patients are included in the MULTI-ACT Digital Toolbox as a sub-set of the Patient Reported Dimension. **Measuring impact of health research on Patient Reported Dimension will maintain patients engaged as key stakeholder.**

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<sup>19</sup> The forth action recommended by the MULTI-ACT Patient Engagement Roadmap refers in particular to question n.9 of the Baseline Analysis “Do you have indicators to measure the “return on patient engagement” for each stakeholder involved in your initiative?”.

#### Example of Roadmap Action 4:

A specific exercise for defining indicators to evaluate the Return on Patient Engagement (RoE) is performed while designing the Patient Engagement Plan. The indicators are used to monitor and evaluate the Plan during and after its implementation. In addition, in line with the adoption of the MULTI-ACT Governance Model, the promoters of EPICLUSTER invite stakeholders to performed the Materiality Analysis and select aspects that are relevant to finalize the agenda of EPICLUSTER and meet its Mission. If indicators related to Return on Patient Engagement result in the final selection of indicators of the Master Scorecard, the Engagement Coordination Team will include those indicators in the Patient Engagement Plan, if similar indicators are not already included when designing the Plan (i.e. selection of RoE indicators in the drop-down menu of the Digital Patient Engagement Plan).

##### *Descriptive elements*

- Beneficiary: EPICLUSTER
- Intervention: assessment of patient engagement effectiveness

##### *Transformative elements*

- Expected change in the EPICLUSTER: tools for assessment of patient engagement activities
- Baseline: current tools for assessment of patient engagement activities

#### Example:

##### Indicators:

- ◆ The number of changes in the EPICLUSTER activities and processes (e.g. policies, composition of boards, objectives and priorities, strategic plan, evaluation of results, dissemination actions, etc.) according to the review made by patients.
- ◆ The number of EPICLUSTER research initiatives, including associated programs and projects, that include and show an effect on Patient Reported Outcomes (i.e. questionnaire reporting how they feel about symptoms and functions).
- ◆ The analysis of whether patients' expectation with respect to the research and mission of the EPICLUSTER are met. *Example: A questionnaire developed ad hoc for assessing if the mission of EPICLUSTER meets the need of patients is submitted to patients.*
- ◆ The analysis of patients' satisfaction with the EPICLUSTER outcomes and their endorsement of results. *Example: A questionnaire developed ad hoc for assessing if the patients endorse the research results is submitted to patients.*
- ◆ The analysis of expectation and satisfaction of patients for/with their engagement in EPICLUSTER, including identification of benefits and critical issues (pros and cons).

## The value of the Patient Engagement for EPICLUSTER

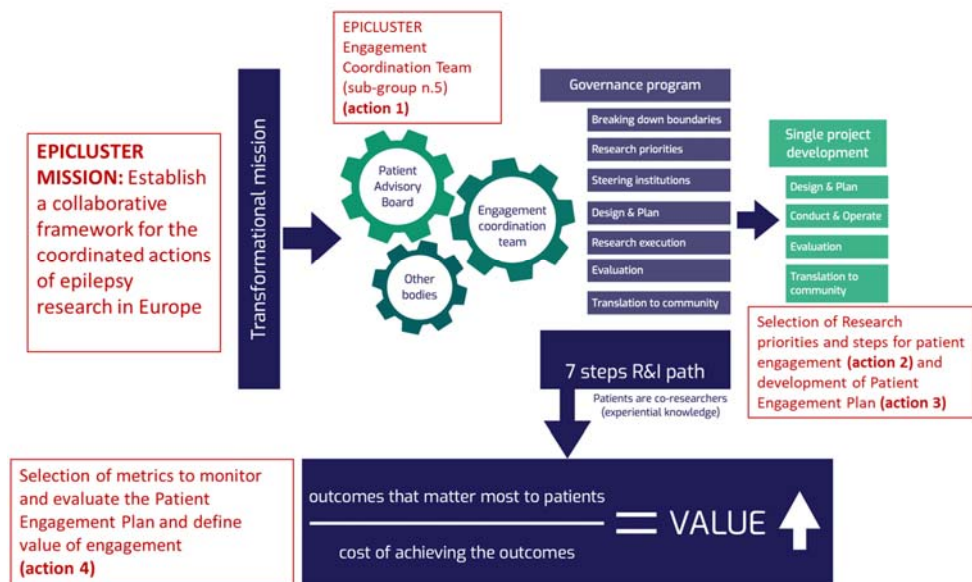


Figure 6 The value of Patient Engagement for EPICLUSTER

The **value and effectiveness of Patient Engagement** for EPICLUSTER relies on impacting on outcomes that matter to patients while being sustainable in achieving this goal. Patient Engagement strategies directed to engage patients through the 7-steps R&I path, both in the governance of R&I (*Science with Patient Input*) (i.e. sub-group n.5 ECT) and in its impact assessment (*Science of Patient Input*) (i.e. indicators to assess the return on patient engagement), are instrumental to meet the transformational mission of EPICLUSTER to “Establish a collaborative framework for the coordinated actions of epilepsy research in Europe”.

## MULTI-ACT Workshop October 21<sup>st</sup>: Follow-up and Discussion

MULTI-ACT captured and elaborated the main points raised during the workshop.

A discussion is presented for the aspects raised during the workshop (Patient Engagement Session):

1. Overwhelming feeling, where to start?
2. Do we need additional funding? What if we don't have budget and resources?
3. What is the size of the ECT and how to recruit the "patient" members?
4. Training, where to find training focus on the empowerment of engagement?
5. How to consider the stigma linked to Epilepsy and the fact that patients don't stand up?
6. How to overcome the barriers to engagement in EPICLUSTER?
7. How to build on the existing network and initiative on patient engagement in Epilepsy?

### 1. Overwhelming feeling, where to start?

MULTI-ACT Roadmap aims to facilitate the operative application of the patient engagement. We suggest to start with the first action (establishment of the ECT) and to plan their activities based on the following actions (3 to 4).

MULTI-ACT provides directions and supports with various means, such as:

- Tailored Patient Engagement recommendations to EPICLUSTER
- Landscape analysis of patient engagement experiences in R&I
- MULTI-ACT Patient Engagement Guidelines, including examples such as the Term of reference and composition of the ECT
- Video on MULTI-ACT Patient Engagement strategy
- Menu of Patient Engagement activities along the 7-steps R&I Path
- Digital Toolbox functionality to design a Patient Engagement Plan, [that that direct the user step to step](#)
- MULTI-ACT Patient Engagement Academy® (2021)

We are in a co-creation process where we aim to support you in the adoption and tailoring of the MULTI-ACT patient engagement roadmap (that build on Multiples Sclerosis as first case study) and scale up the MULTI-ACT model also in other brain diseases such as Epilepsy.

### 2. Do we need additional funding? What if we don't have budget and resources?



MULTI-ACT recommends to identify resources and a budget, it can be found among existing resources, such as “internal” personnel working on patient engagement.

The ECT should reflect the skills recommended in the guidelines (empathy, active listening, communication skills, and expertise in engagement strategies & methods) and some skills could be available in the EPICLUSTER network.

For other direct costs, it might be saved budget from other activities or in-kind contribution could be provided by partners (e.g. using available online survey platform, GoToWebinar licence, etc.).

Compensation to patients? MULTI-ACT proposed the rewarding model of *Smith et al. 2019* which includes many means of rewarding, patients might be interested in means different from monetary compensation (e.g. Public mention, acknowledgment in scientific articles, Public mention and acknowledgment, access to publications or to training, moral satisfaction, etc..) and thus this cost might be mitigated.

### 3. What is the size of the ECT and how to recruit the “patient” members?

The aim of the ECT is to identify and apply mechanisms to engage the **patient community**, the number of patients to engage depends on the engagement methods (to be define in roadmap action n.3).

Thus, the number is not fixed, an example of ECT multi-stakeholder composition is included in the Guidelines, it includes representatives of internal staff and board.

Figure 7 Extract from the MULTI-ACT Patient Engagement Guidelines

#### Composition of the team

The composition of this team depends on the specificity of individual programs and/or projects. However, it is considered that the essential figures of this team are as follows:

- ◆ Co-Chair, patient (1);
- ◆ Co-Chair, MULTI-ACT trained representative<sup>6</sup> (1);
- ◆ Initiative's board(s) representative (1);
- ◆ Initiative's staff representative (1);
- ◆ Patients (with consideration to balance of gender, geography, disease progression, age, socio-economic background) (3-6);
- ◆ Expert(s) on the mission/priorities topic(s): e.g. Working Group chair/representative.

To recruit “patient” members, we suggest to engage with European and/or National Epilepsy societies that can be the bridge to link ad recruit patients at international and national level.

Indeed, the proposed MULTI-ACT ECT is intended to be a neutral team dedicated to enable the R&I paradigm shift by enabling the transition from the individual to the collective patients’ experiential knowledge. Patient organizations might play a pivotal role in enabling the empowering of ‘collective patients’ experiential knowledge’. This role is derived from the patient organization’s role as a trusted stakeholder in the R&I ecosystem. Patient organizations can readily create linkages between patients and individual components of the R&I pathway and conversely can serve as an important translator of the interests/needs of the R&I stakeholders to patients. Indeed, by proactive engagement, patient groups can enable a robust collaboration between the stakeholders. However, there remains

considerable variability in patient organizations engagement of patients in the R&I continuum. As such, the MULTI-ACT aims to provide guidance and tools to fill knowledge gaps and enhancing the ability of patient organizations to realize the full potential of patient engagement in the R&I continuum (See MULTI-ACT Deliverable D1.6 “Final version of the MULTI-ACT Patient Engagement in Health R&I guidelines”, page n.20, <https://www.multiact.eu/project-deliverables/>).

For instance, to engage patients in the Materiality Analysis we published a Facebook page via our partner ARSEP, the national Multiple Sclerosis society in France. And this process might be replicated in other countries with the support of other MS societies, or managed directly by the international organization.

Please note that MULTI-ACT exploitation activities includes the development of a “recruiting process and template” (see MULTI-ACT Guidelines for Patient Engagement in Health Research & Innovation - Short-version 30 May 2020, page n.6).

#### **4. Training, where to find training focus on the empowerment of engagement?**

In the context of Multiple Sclerosis, the majority of trainings focus on the medicine development process, on how to make patients experts and co-researchers.

MULTI-ACT proposes a complementary approach, to capture the experiential knowledge of patients and co-create with the other stakeholders. The training should be for all the stakeholders (ECT = multi-stakeholder team), not only for patients, to empower the ability of patients and stakeholders to co-created and collaborate, and to ensure the representativeness of the patients' community.

The MULTI-ACT training (MULTI-ACT Patient Engagement Academy®) is not a scientific training, it's directed to empower the ECT to capture the experiential knowledge of patients and integrate it into the research process.

The training intends to provide strategies and methods to engage the patient community and to reach the under-represented patients, including communication tips.

#### **5. How to consider the stigma linked to Epilepsy and the fact that patients don't stand up?**

MULTI-ACT training provides methods to analyze the psycho-sociological attitude toward the engagement and how to value and manage the respective levels of engagement in an engagement process, and this will empower the ECT to understand, address and mitigate the STIGMA.

#### **6. How to overcome the barriers to engagement in EPICLUSTER?**

The scope of the MULTI-ACT module and training is to empower the ability of patients and stakeholders to co-created and collaborate.

As anticipated in slide n.7, it might be important to engage patients in defining what are the facilities, policy and infrastructure they need to be engaged.

- **Strategic priority:** Increase and integrate the engagement of persons with epilepsy and their representatives in the design and execution of research activities.
- **R&I (Research and Innovation) step:** Breaking down boundaries (e.g. policy, facilities, infrastructures, etc.)

Some examples are also mentioned in the MULTI-ACT guidelines.

## 7. How to build on the existing network and initiative on patient engagement in Epilepsy?

MULTI-ACT built on and engaged with relevant patient engagement experiences toward co-creation of its outcomes.

The MULTI-ACT landscape analysis (D1.4) provides an overview of patient engagement experiences toward mutual learning and synergies.

EPICLUSTER might rely on the landscape analysis to have an overview on the experiences non Multiple Sclerosis-specific.