



Deliverable D5.4

## MULTI-ACT Model for collaborative initiatives



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The deliverable is the outcome of T5.4 where the goal of this task is to define the MULTI-ACT Model for the implementation of multi-stakeholder engagement processes for the realization of collaborative initiatives.

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## EXECUTIVE SUMMARY

This document illustrates the activities and the results of the last task of WP5 (task 5.4), which aims to develop the MULTI-ACT Governance Model for the implementation of multi-stakeholder engagement and collaborative initiatives in brain diseases research.

Such Model represents one of the two core pillars of the MULTI-ACT Collective Research Impact Framework (CRIF) along with the Master Scorecard developed in WP3.

The process carried out in WP5 to develop the model has considered both an analysis of practical solutions implemented by already existing multi-stakeholder initiatives and recommendations emerging from a context analysis, considering also the innovative approach and objectives of MULTI-ACT project itself. The final Model presented in this deliverable is the result of a co-design process carried out by MULTI-ACT partners who have assessed and integrated possible solutions defined through the above-mentioned analysis, and presented during a dedicated workshop held in Milan on the 10<sup>th</sup> of April 2019.

The final Model is composed by 5 main criteria and 19 sub-criteria reflecting the key characteristics of the Governance Model that multi-stakeholder initiatives should consider to maximizing the impact of Research & Innovation (R&I) toward a transformational mission. According to this framework, an initiative applying MULTI-ACT Governance Model should:

- Define its vision, scope and a shared agenda, considering MULTI-ACT Governance Model recommendations;
- Guarantee an inclusive and equitable governance model, which allows the involvement of all interested parties under a co-design approach;
- Guarantee a comprehensive, balanced and efficient stakeholder engagement process, ensuring also the participation of patients, their families and care givers, and patients organizations;
- Guarantee an effective, cooperative and efficient coordination and alignment of the objectives and actions required to pursue the vision and the agenda;
- Establish a shared and effective assessment system, including a set of indicators that allows improvement and communication, and set a mechanism to receive feedbacks.

The Model contains detailed recommendations to guide the user in the application of such criteria and sub-criteria; furthermore, when possible, it also offers practical solutions for implementation applicable to the purposes of MULTI-ACT.

The Model will be further integrated with the results of WP1 (dedicated to enable the engagement of patients, their families and caregivers, thus implementing the so-called “Science with patient inputs”) and WP3 (dedicated to the definition of a Master Scorecard containing a set of indicators to evaluate the collective impact of health research initiatives). Moreover, within the WP4, the Model will be tested through a tailored case study and, during WP6, it will be integrated in a set of detailed Guidelines.

# 1 INTRODUCTION AND PURPOSE OF THE DOCUMENT

This deliverable is the final output of WP5 and illustrates the MULTI-ACT Governance Model for the implementation of multi-stakeholder engagement and collaborative initiatives in brain diseases research developed through the four tasks of the WP. The Model is the result of a co-design process carried out by MULTI-ACT partners and a discussion with the External Advisory Board<sup>1</sup>, which has assessed and integrated possible solutions presented during a dedicated workshop.

The Model is structured according to 5 main criteria and 19 sub-criteria (identified in D5.3 and refined during the dedicated workshop), which are composed by 42 recommendations comprehending both principles and practical solutions for implementation. The process carried out to define the Model is described in the following section of this document.

MULTI-ACT Governance Model is developed within the framework of Responsible Research & Innovation (RRI), which aims to encourage societal actors to work together during the whole R&I process to better align R&I and its outcomes with the values, needs and expectations of society. Early in 2014 the European Commission appointed an expert group to Monitor the evolution and benefits of Responsible Research and Innovation (MoRRI<sup>2,3</sup>) in the dimensions of **governance**, ethics, public engagement, open access and science literacy and scientific education, to identify and/or propose indicators and gaps. The MoRRI project had the aim of establishing a monitoring system that measures how, where, and to what extent RRI has become integrated within European Research practices<sup>4</sup>. The monitoring of the evolution and benefits of RRI has highlighted among others that an unmet need is the existence of formal governance structures for RRI within research funding and performing organisations (MoRRI Progress report D3.2 - Indicator GOV2). The MULTI-ACT Governance Model has been developed to address this need.

As represented in figure 1, the MULTI-ACT Governance Model is part of a broader framework - “Collective Research Impact Framework (CRIF)” that aims to meet the different (and sometimes competing) needs of all the actors involved in the R&I process, involving all interested stakeholders, in the development of the initiative that want to adopt a participatory, multi-stakeholder structure, according to MULTI-ACT recommendations.

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<sup>1</sup> MULTI-ACT External Advisory Board (EAB) includes representatives from the International Economic Policy and Sustainability Management, Polytechnic University of Milan, the European Federation of Pharmaceutical Industries and Associations EFPIA, The Italian Ministry of Health, The Neurology Sapienza University, the European Charcot Foundation, the European Connected Health Alliance ECHAlliance, the European Research Area Network ERANET NEURON and Rare Disease Europe EURORDIS and the Chair of the MULTI-ACT Patient Forum (the European Patient Forum EPF).

<sup>2</sup> Please refer to the following website: <https://morri.netlify.com/>

<sup>3</sup> Please refer to the following website: <https://ec.europa.eu/programmes/horizon2020/en/news/monitoring-evolution-and-benefits-responsible-research-and-innovation-morri>

<sup>4</sup> Please refer to the following website: <https://publications.europa.eu/en/publication-detail/-/publication/fdd7dd10-c071-11e8-9893-01aa75ed71a1/language-en/format-PDF/source-87584048>

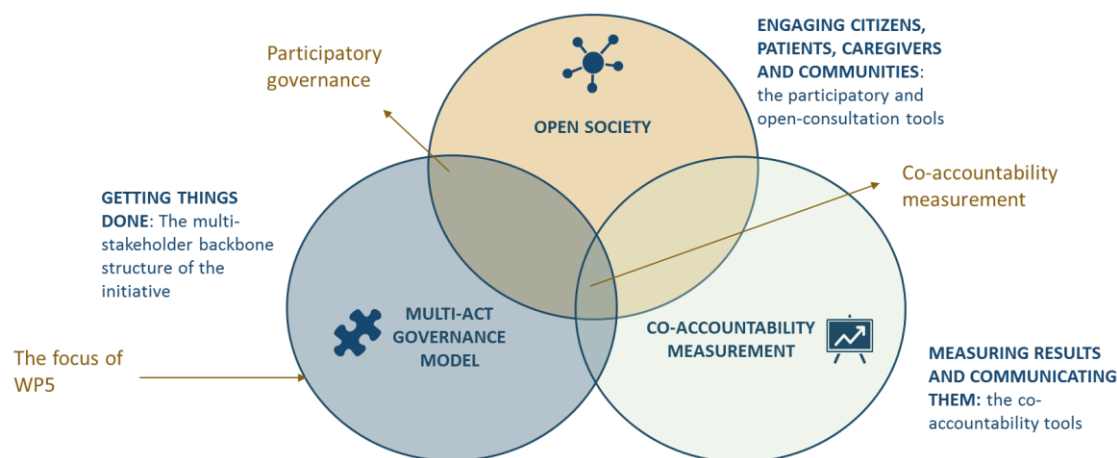


Figure 1: The participatory framework of MULTI-ACT Governance Model

The MULTI-ACT Governance Model will be integrated with the results of the other WPs that are actually in progress (WP1 and WP3) and will also represent the basis for the development of all the other Work Packages including WP2, WP4, WP6. In particular, WP4 will test the Model through a case study, which will offer empirical insights on its implementation and will pave the way for a review process of the Model itself, in order to identify critical issues and potential gaps.

WP6 will develop a set of guidelines for the application of the recommendations and solutions of the Governance Model, integrating the outputs of other WPs, in particular:

1. The Patient Engagement guidelines developed in WP1<sup>5</sup>;
2. The performance and co-accountability indicators identified in WP1<sup>6</sup> and WP3.

In this regard, it is worth mentioning that the Governance Model and the guidelines mentioned at point 1 deal with the participation of patients within the governance structure (“science with patient input”), while the indicators mentioned at point 2 regard to the patient reported dimension (“science of patient input”).

In the attempt of clarifying the relationships among WPs, figure 2 offers a view of the role of WP5 in the project and its integration with the other WPs.

<sup>5</sup> MULTI-ACT Patient Engagement Guidelines to enable the engagement of patients as key stakeholder in R&I (WP1 Science with patient input, D1.6)

<sup>6</sup> Patient Reported Dimension integrated into the Master Scorecard (WP1 Science of patient input, D1.8)



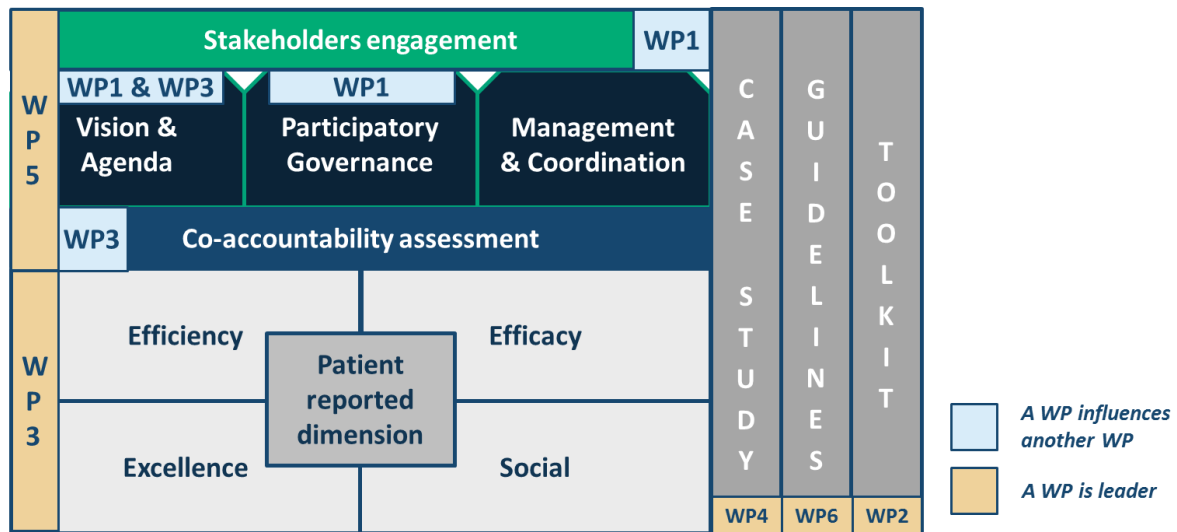


Figure 2: The role of WP5 within MULTI-ACT

The following sections illustrate the path undertaken to develop the MULTI-ACT Governance Model and the criteria, sub-criteria and recommendations that represent the specific contents of the Model. Furthermore, a specific focus is finally dedicated to the explanation of how the results of WP5 could be integrated and exploited in the next steps of the project.

## 1.1 Glossary

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

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

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

- The **Leadership Board** (referred to as “LB”) is composed by representatives from the categories of stakeholders that have a strategic importance for the initiative and represents the decision-making body;
- The **Stakeholder Advisory Board** (referred to as “SAB”) is composed by interested stakeholders and provides advices to the LB. Within the SAB, patients, their families and caregivers, one of the categories of stakeholders involved, might be asked by the LB to provide their specific contribution and advice for the most crucial decision-making processes according to the specific need of the initiative. This category of stakeholders can be defined as a sub-group within the SAB, called **Patient Advisory Board** (referred to as “PAB”).
- The **Committees and Working Groups** (referred to as “WG”) can be appointed by the LB according to the specific needs of the program/project and the activities that will be carried out in order to achieve the desired change.
- The **Engagement Coordination Team** (referred to as “ECT”) is in charge of coordinating the involvement of stakeholders, including patients, relatives and caregivers, in all the operations;
- The **Compliance Committee** (referred to as “CC”) is in charge of maintaining a balance among stakeholders’ stances and expectations and oversee the ethical issues that might arise during the implementation of the initiative.

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

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

**Possible solutions:** solutions that MULTI-ACT Governance Model might adopt and embody, that have been evaluated by partners during task 5.4

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

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

**WP5 Database:** document containing information regarding the analyzed initiatives.

## 2 THE PATH TOWARDS MULTI-ACT GOVERNANCE MODEL

### 2.1 The activities carried out in WP5 and the identification of the final criteria and sub-criteria

The MULTI-ACT project aims at fostering the participation of actors and stakeholders in Health Research and Innovation processes by developing a strategic collective framework, including a “governance model” to be applied by health research and performing organizations. The model aims at facilitating the participation of a wide variety of stakeholders, with a focus on patients affected by brain disorders using multiple sclerosis and their families and caregivers as first case study, within the governance of the research funding and performing organizations.

The process carried out in WP5 to develop the model (as shown in figure 3) has considered both an analysis of practical solutions implemented by multi-stakeholder initiatives and the recommendations emerging from a context analysis, considering the approach and objectives of the MULTI-ACT project itself, namely fostering the diversification of actors and stakeholders in Health Research and Innovation processes (for the main sources considered please refer to the References at the bottom of this document).

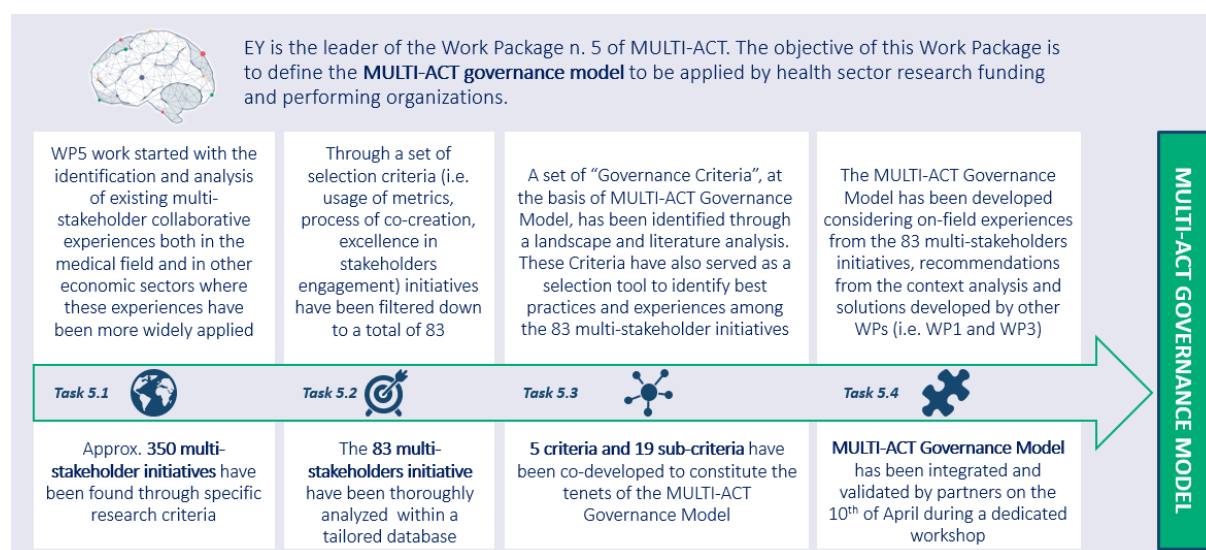


Figure 3: The path of WP5

By carrying out a context and literature analysis, WP5 identified a set of 5 criteria and 19 sub-criteria, which reflects some of the key characteristics of multi-stakeholder initiatives in line with MULTI-ACT vision and objectives in terms of responsible governance. These criteria, represented in the figure below, reflect the need of developing a participatory governance model, defining and co-designing a transformational agenda and adopting a co-accountability approach.


	1. 	2. 	3. 	4. 	5. 
CRITERIA	VISION AND AGENDA	PARTICIPATORY GOVERNANCE	CLEAR, EFFECTIVE AND INCLUSIVE METHODOLOGY OF STAKEHOLDER ENGAGEMENT	EFFECTIVE AND EFFICIENT MANAGEMENT AND COORDINATION OF THE INITIATIVE	CO-ACCOUNTABILITY ASSESSMENT
SUB-CRITERIA	<ol style="list-style-type: none"> <li>1. Define a shared vision and common agenda</li> <li>2. <u>Define clear intended beneficiaries</u></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 private intended beneficiaries</li> <li>2. Set up 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. Define and approve a methodology to engage stakeholder</li> <li>2. Engage private <u>intended beneficiaries</u></li> <li>3. Differentiate the level of engagement according to participants</li> <li>4. Ensure a balance between engagement of participants and agile management of the initiative</li> </ol>	<ol style="list-style-type: none"> <li>1. Enable cooperation and competition among participants</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. Shared assessment and monitoring system</li> <li>2. Effective feedback mechanism</li> <li>3. Continuous learning, communication and disclosure of knowledge</li> </ol>

Figure 4: The list of criteria and sub-criteria

According to this framework, an initiative applying the MULTI-ACT Governance Model should:

- Define its vision, scope and a shared agenda, considering MULTI-ACT principles;
- Guarantee an inclusive and equitable governance model, which allows the involvement of all interested parties under a co-design approach;
- Guarantee a comprehensive, balanced and efficient stakeholder engagement process, ensuring also the participation of patients, their families and caregivers;
- Guarantee an effective, cooperative and efficient coordination and alignment of the objectives and actions required to pursue the vision and the agenda;
- Establish a shared and effective assessment system, including a set of indicators, that allows improvement and communication, and establish a mechanism to receive feedbacks.

Against this backdrop, to understand and integrate the mechanisms of participatory governance and to leverage the knowledge of already existing participatory frameworks, WP5 has also analyzed existing multi-stakeholder collaborative initiatives at international level and from a multi-sector perspective, with the aim of identifying a series of best practices (“experiences”) that might be relevant for MULTI-ACT.

According to this analysis, practical solutions for the implementation of criteria and sub-criteria have been identified. When practical solutions were not available for a given sub-criterion, a detailed description has been provided to guide the user in the application of that specific recommendation of the Model.

## 2.2 Key concepts and preliminary aspects of the applicability of the Model

In order to clarify some of the most critical aspects of MULTI-ACT Governance Model, MULTI-ACT project partners have been asked to cooperate and co-define the answers to a set of preliminary questions. These answers have been further discussed during WP5 workshop, held on April 10<sup>th</sup>, 2019, in which WP5 results and a first draft of the Model have been validated. This considered, the following points summarize the key aspects discussed with Consortium partners:

- ***Who are the possible appliers of the Model?***

MULTI-ACT model is originally intended for health sector research funding and performing organizations (RFPOs) that may already have been grouped in a multi-stakeholder initiative (e.g. Alliance) or that are willing to start conducting their R&I with a multi-stakeholder and co-accountable approach<sup>7</sup> toward common goals to reach a transformational mission<sup>8</sup>.

Beyond MULTI-ACT focus on health sector, in the future the MULTI-ACT model could also be particularly applicable for those initiatives with a transformational mission that, according to an innovative approach, seek to maximize the impact of research and to explore and assess the impact of research beyond financial return, adopting a multi-stakeholder perspective. In the exploitation phase of MULTI-ACT it would be possible to see if this approach is applicable to initiatives (beyond the health sector) that:

- Have a transformational mission
- Have multiple-stakeholder structure
- Consider and intend to generate both financial and social return

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<sup>7</sup> Categories of users of MULTI-ACT model are indicated in the DoA (KPI n.1): “Innovative framework used by various R&I stakeholders for their strategic planning; Beneficiaries: RFPO, Academia, Industries (Pharma, Biotech, ICT, consultancy), Policy makers (EC, Ministries, Regions, Local Agencies, Insurers), Regulatory agencies (EMA, Medicine National Agencies), Patients organizations, Foundations.”.

Furthermore, it is worth noticing that Science with and for society H2020 programme aims at contributing to the implementation of Responsible Research and Innovation (RRI) through RPOs (Research Performing Organizations) and RFOs (Research Funding Organizations) focusing on developing new partnerships and involving patients, researchers, policy makers, citizens and industry. In this strategic orientation, RFPOs should be understood broadly as organisations developing or funding activities in the field of R&I as one of their objectives (e.g. a civil society organisation engaged in R&I could be eligible). This considered, the RFPOs are the primarily users of the MULTI-ACT framework, that fosters the funding and performing of research in a co-accountable approach, considering the participation of new constellations of actors collaborating toward a common mission are the target users of the MULTI-ACT framework that aim to govern research in a co-accountable approach. Examples are: PMSA, ERANET Consortia (e.g. NEURON, PPP; etc.). The RFPOs are the primarily users of the MULTI-ACT framework, they may already have been grouped in a multi-stakeholder initiative (e.g. Alliance) or they may be RFPOs that are willing to start conducting their R&I in a multi-stakeholder and co-accountable approach.

<sup>8</sup> Mission as transformational or transformative means 'changing forms'. Transformational health research is a term that became increasingly common within the science and health policy community in the 2000s for research that shifts or breaks existing scientific paradigms.

- **Which framework represents the «standard» research process applied by a user of the Model? Can we adapt the Patient Engagement 7-steps R&I Path presented in D1.3**

The 7-steps R&I path identified by Patient Engagement Group (PEG)<sup>9</sup> members is focused on the areas where patients can or need to be engaged in the R&I continuum in order to maximize impact toward a given mission. We can apply the 7-steps R&I path for the purpose of MULTI-ACT framework (please refer to figure 5). The 7-steps R&I path appears to cover most relevant areas of R&I, and is applicable by users of the model. It is worth noticing that in the upcoming steps of the projects, it may happen that integrating the 7-steps R&I path, Governance Criteria, patient engagement indicators and the CRIF dimensions will require some adjustments in the path described.

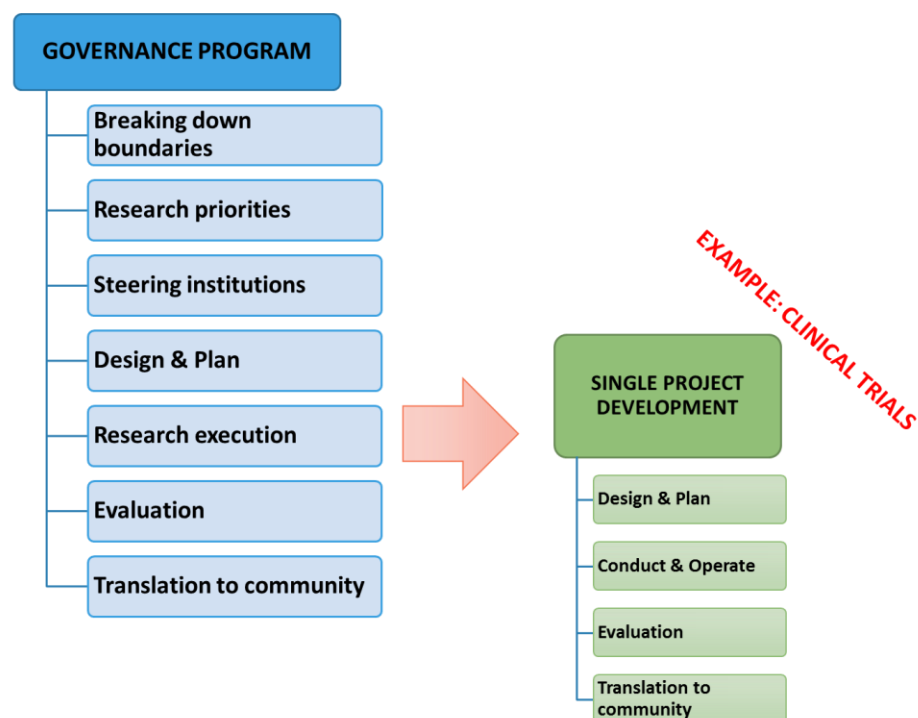


Figure 5: Patient Engagement R&I Path

- **How the Model will be developed and applied? Will it be «principle-based» (i.e. based on the criteria and sub-criteria), «operational-based» (i.e. based on the process) or something else?**

A key aspect of the governance model is the set of governance criteria developed in WP5. Those criteria involve principles (such as: define a vision and agenda; be participatory; engage stakeholders; be effective; and be transparent) that are the basis of the model, which therefore will be principles-based. However, different criteria need to be stressed more in specific phases of the research process in order to make them concrete and applicable. For example, participatory governance would need to

<sup>9</sup> MULTI-ACT Patient Engagement Group (PEG): National Multiple Sclerosis Society, Multiple Sclerosis International Federation Research Staff Network, European Multiple Sclerosis Platform, European patient Academy EUPATI, Mario Negri Institute, Danish Board of Technology Foundation, Engage2020.

be particularly stressed in the establishment of steering institutions, while co-accountability and measurement will guide actions in the evaluation stage of research (please refer to the Patient Engagement 7-steps R&I path in WP1, represented above).

In this regard, the principles-based model needs to keep flexibility, defining which principles need to be applied to each step of the research process. The flexibility needs to be defined on the basis of the different stakeholders, because the stakeholder will, for instance, select the indicators that are more applicable to their mission. One consequence is that different principles will have a different emphasis when applied to different initiatives with different stakeholders.

### 3 THE MULTI-ACT MODEL FOR COLLABORATIVE INITIATIVES

The MULTI-ACT Governance Model is composed by 5 criteria and 19 sub-criteria, detailed in 42 recommendations, which can be solutions for implementation or principles to be followed by the appliers of the Model.

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

#### 1) The distinction between principles and solutions

The following paragraphs describe in detail the MULTI-ACT Model recommendations, both in terms of principles and solutions. The first are general principles that should be considered by MULTI-ACT appliers throughout the setting up phase, the development of the initiative and the assessment of its performances; the second are operational actions that should be implemented by appliers, adapting their initiatives' structure, strategy and activities. This distinction is expressed in the following chapter by the letter "(P)", which stands for principle, and "(S)", which stands for solution.

#### 2) The Promoters

The Promoters are the actors that decide to implement MULTI-ACT Governance Model within their existing or new organization. After the implementation of the Model, they will be part of the governance bodies (i.e. Leadership Board). The Promoters of MULTI-ACT Governance Model 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 a multi-stakeholder and co-accountable governance.

In either case, the individuals that guide the adoption of MULTI-ACT are defined in this document as the "Promoters". Please note that Promoters might in turn represent different stakeholders' categories.

#### 3) The Level of detail

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

and recommendations is left to the applier, who will apply them to the specific context, objectives and organization characteristics. In this regard, WP5 results will be tested and implemented in a MS case study initiative in WP4 and further developed in WP6, which aims to develop MULTI-ACT Guidelines.



### 3.1 Criterion 1: Vision and agenda

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

To achieve this objective, the initiative should:

- Define a shared vision and common agenda;
- Define clear intended beneficiaries;
- Promote a movement-building approach to achieve transformative changes;
- Guarantee ethical acceptability and social justice.

#### ***Sub-criterion 1.1: Define a shared vision and common agenda***

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***Recommendation 1.1.1:*** “Define a vision 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 vision” (S)

***Recommendation 1.1.2:*** “Select appropriate multidimensional indicators in alignment with objectives considering the different perspectives of the stakeholders involved. Establish coherent monitoring mechanisms to measure the impact of the initiative and to link closely future investment with initiative vision and objectives” (S)

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Defining a shared vision and agenda means identifying the change that the initiative wants to fulfill, and defining the priorities and related actions in order to achieve this change. On a methodological standpoint, the approach proposed by MULTI-ACT is based on the Theory of change (ToC). The ToC provides a comprehensive description and illustration of how and why the desired change is expected to happen in a particular context. It focuses on mapping out or “filling in” what has been described as the “missing middle” between what a program or change initiative makes (its activities or interventions) and how these lead to the desired goals being achieved. This approach allows to coherently identify the initiative’s short-, mid- and long-term objectives. The participatory process for developing a ToC is as critical as the final ToC output itself because it is fundamental to build a consensus on the initiative’s priority outcomes and impacts, and to define the pathways by which the initiative can achieve these outcomes through mobilizing stakeholders and resources.

In order to define the vision and agenda according to the ToC methodology, the appliers of the MULTI-ACT model should implement the following steps:

#### **1) Understanding the context for the initiative and the target beneficiaries**

This step entails the analysis of the current state of the “issue” that the project is seeking to influence, the social, political and environmental conditions, and the actors able to influence change. In this regard, appliers should analyze which ecosystems and communities are affected, what are the key issues and pressures faced and, what are the main social, political, economic and technological factors that influence the issue in this context.

Appliers should clearly identify beneficiaries, which are individuals that take advantages from the long-term direct or indirect effects of the initiative. For the purpose of RRI MULTI-ACT project, the society and within it the patients are key beneficiaries. The appliers should explicitly identify these

beneficiaries, their characteristics and related needs, which are preliminary to the identification of the initiative's long-term goals.

In this step, the analysis of the stakeholders of the initiative, which is carried out under sub-criteria 2.2 and 3.1, should be considered.

## **2) Identifying long-term goals**

This step requires MULTI-ACT Model appliers to identify the initiative's long-term objectives, by exploring issues such as: what is the desired change that the initiative aims to achieve in the target community; what is the long-term objective of the initiative; what is the scope of the initiative; when will the potential goals be achieved.

For the purpose of MULTI-ACT, the definition of long-term goals also requires the consideration of the following aspects and priorities, in accordance with WP1 and WP3 results:

- Scientific-rational priority (i.e. identify and contribute to find a given treatment, cure, response to a treatment)
- Functional priority (i.e. contribute to the quality of life of the patient and its relatives/caregivers)
- Context priority (i.e. contribute to the impact on the healthcare context and the improvement of research through the promotion of synergies, awareness, knowledge, integration of multi-stakeholder perspectives)

## **3) Backwards mapping, connecting outcomes and reality check**

This step requires the identification of the pre-conditions to achieve the desired change. This process requires the analysis of the sequence of events in the long-, medium- and short-term that are necessary to achieve the change. This means that, once the appliers have identified the desired long-term goals, they need to work back from these to identify all the conditions (outcomes) that must be in place (and how these relate to one another causally) for the goals to occur.

Appliers should then understand which are the outcomes that the initiative would directly generate and those that would be achieved by other organizations. In this regard, appliers should also reflect on what sort of partnerships and collaboration the project team needs to build on among the internal stakeholders identified. Furthermore, they should reflect on which collaborative relationships, and relationships with researchers from other disciplines, are needed in order to achieve the long-term goal of the initiative. Therefore, the initiative can then decide on which specific outcomes to focus. The result of this analysis should be summarized in an outcome framework. This document provides the basis for identifying what type of activity or intervention will lead to the outcomes identified as preconditions for achieving the long-term goal. Through this approach the precise link between activities and the achievement of the long-term goals is more fully understood. This leads to better planning, in that activities are linked to a detailed understanding of how change happens. It also leads to better evaluation, as it is possible to

measure progress towards the achievement of longer-term goals that goes beyond the identification of program outputs.<sup>10</sup>

Please note that for the purpose of MULTI-ACT appliers, operating in the health research funding, there is often a complex relationship between cause and effect, which “is explained by multiple causal factors and, therefore, remains only weakly understandable”<sup>11</sup>.

In this regard, the objective of the ToC is to understand the priorities and challenges faced by stakeholders in their operating context and clarify the relationships and connection points to other research programs and actions carried out by other initiatives and stakeholders. This analysis will help to detect the opportunities for the research funding and performing activity to play a role and influence the creation of a desired change, as part of a more complex ecosystem. In this regard, ToC analysis “encourages programs/projects to make these activities a visible and integrated part of the research programs/project and to allocate resources to ensure that this happens”.

#### **4) Identifying Assumptions**

The objective of this step is to identify those assumptions that can determine the success or failure of the achievement of the objectives identified through the ToC. This analysis should also consider those enablers that can influence the success of the initiative. For instance, appliers should analyze issues such as: what values and norms are influencing the perception of the change process, which is the most important bottom-line change which, if it is not achieved, would mean the project has failed, which trade-offs have to be considered when achieving initiative’s goals, how individual beliefs and values, professional experience, organisational values influence the definition of the initiatives objectives.

#### **5) Defining actions**

This step requires the appliers to identify the activities that need to be carried out to achieve the outcomes that the initiative has decided to target according to step 3. To achieve this, appliers have to understand which actions and partnerships are needed to produce outcomes.

This step is preliminary to the development of the Action Plan, which is carried out under sub-criterion 4.1.

#### **6) Selecting Indicators**

This step aims at assessing the change produced by the initiative on intended beneficiaries. The appliers of MULTI-ACT Governance Model can rely on the list of indicators developed under WP3<sup>12</sup>. Once appliers have defined a vision and agenda according to the ToC methodology, they should correlate the priorities of the initiative to the aspects of measurement and the related indicators.

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<sup>10</sup> For further information regarding the ToC methodology please refer to the following website <https://www.theoryofchange.org/> and the guide “Theory of Change e valutazione dell’impatto sociale per una Filantropia Strategica” published by Lang Foundation.

<sup>11</sup> Ericka Costa Caterina Pesci , (2016), "Social impact measurement: why do stakeholders matter?", Sustainability Accounting, Management and Policy Journal, Vol. 7 Iss 1 pp. 99 - 124

<sup>12</sup> The indicators developed in WP3 will be integrated with the Patient Reported Dimension to evaluate the impact of R&I on the outcomes that matter most to patients

The results will allow to eventually review the vision and agenda according to the research initiative's changing needs and will allow a coherent monitoring to assess the impact of the initiative and its alignment with its vision and objectives, as further detailed in criterion n.5.

The identification of aspects and indicators that allow to measure alignment of the carried out activities and related outcomes with the vision and agenda is strongly interrelated with the work carried out in WP3, that will offer to users a tool and a master scorecard for the selection of indicators, and will be further discussed in the next tasks of the project, such as WP4.

## 7) Diagram and narrative summary

This step requires the applier to develop a final report on the ToC of their initiative, which includes as minimum:

- The results of the context analysis;
- The targeted beneficiaries;
- A graphical and a detailed representation of the ToC, considering long-term objectives, long-medium-short term outcomes (including the reality check and the outcomes on which the initiative decided to focus), outputs and activities;
- Assumptions on which the ToC relies;
- A list of indicators, identified according to the MULTI-ACT framework as defined by WP3.

The decision-making bodies of the initiative, as defined in criterion 2, will carry out the identification of the vision and the agenda. This process will also need to involve interested stakeholders through consultation processes and open participatory tools, which will allow stakeholders to:

- Have information about the initiative, its objectives and scope of application;
- Express their opinion on the most relevant aspects that should be tackled by the initiative;
- Vote among different options, if applicable, in relation to the vision and agenda of the initiative.

The vision and agenda of the initiative will embody the perspectives and expectations of stakeholders, which will have equal power in the definition of the vision and agenda, and, eventually, will be finalized and approved by the governance bodies of the initiative once formalized. In particular, to ensure that stakeholders participate with equal powers to decision making processes, a specific body, which is the Compliance Committee, is established and part of the governance model (please refer to sub-criterion 2.4). Therefore, it should be integrated and revised in multiple steps, ensuring the integration and validation of the first "proposal" made by the promoters with the inputs and expectations of all stakeholders equally represented.

### ***Sub-criterion 1.2: Define clear intended beneficiaries***

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***Recommendation 1.2.1:*** "Be aware of who are the initiative's intended beneficiaries and have clear strategies to facilitate their active participation" (S)

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The appliers of the MULTI-ACT Governance Model should identify the intended beneficiaries and set clear strategies to engage them and enable their participation (in this regard, please refer to sub-

criterion 3.1). The identification of beneficiaries is also mentioned in recommendation 1.1.1, under the first step of the ToC implementation.

Beneficiaries are individuals that take advantages from the long-term direct or indirect effects of the initiative, which could be for example patients, their families and caregivers. The appliers should explicitly identify these beneficiaries, their characteristics and related needs, while defining the vision and agenda.

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

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

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

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

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

- Enable the generation of a community aspiration in which everyone agrees and works together toward the achievement of the related goals;
- Focus on trying to create a “container for change” that seeks the change of the people involved in a certain program/project;
- Engage in long-term (strategic) actions, at all stages from the beginning to the end of a program/project;
- Focus efforts towards activities that result in a greater change opportunity. This is achieved by having the agents participate and collaborate in long-term or strategic actions;
- Incorporate the shared measurement process as part of a complete sharing learning process in which participant members “hold each other accountable and learn from each other’s successes and failures”<sup>13</sup>. In this sense, the shared assessment should serve as a resource to provide feedback to the system and serve as a constant learning mechanism;
- Ensure authentic community engagement including those affected by certain measures in the process of change.

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<sup>13</sup> Kania, J., & Kramer, M. (2011). Collective Impact. Stanford Social Innovation Review.

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

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**Recommendation 1.4.1:** “Consider societal relevance and ethical acceptability of the initiative while minimizing potential unintended negative consequences” (P)

**Recommendation 1.4.2:** “Aim to extend the positive impact of research to as many people as possible and ensure social justice” (P)

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

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

## 3.2 Criterion 2: Participatory Governance

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

To achieve this objective, the initiative should:

- Allow 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.

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

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***Recommendation 2.1.1:*** “Involve intended beneficiaries in the agenda design, in the decision-making process and in the initiative development, implementation and monitoring. Please note: for the purpose of MULTI-ACT patients are key beneficiaries” (S)

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The involvement of patients, their families and caregivers, defined as the intended beneficiaries, is pivotal in the implementation of MULTI-ACT Model. In this regard, WP1 is dedicated to creating an innovative path for patient engagement, especially for R&I phases that are lacking in terms of procedures, and ensure that representation enables people affected by MS to have an equal voice, in partnership with researchers and other actors. This considered, to enable the involvement of patients (and their families and caregivers) throughout the entire governance program, the appliers of MULTI-ACT project 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, their families and caregivers, in all the operations;
- 2) Create a Patient Advisory Board (hereinafter also referred to as “PAB”), a specific group of patients, their families and caregivers within the Stakeholders Advisory Board, to be involved and engaged throughout the entire development of the initiative, providing advices, 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 caregivers) in the agenda design, in the decision-making process, in the initiative development, and eventually in the implementation, monitoring and evaluation phases. It works as a facilitator and “floating” body between the Stakeholder Advisory Board and the Leadership Board. As guarantor and point of reference of patients’ participation in the initiative, it is in charge of the engagement processes and of all training and coaching activities that are preliminary to the patients and other stakeholders’ engagement. Furthermore, this team has not only the responsibility of patients’ engagement, but of all stakeholders, whose participation is necessary to the initiative’s development.

The 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 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 Governance Model with the agreement of the Leadership Board.

Furthermore, during the constitution of the Stakeholder Advisory Board, carried out under Recommendation 2.3.1, Promoters should create a PAB, a specific sub-group, formed by patients, their families and caregivers. 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 (thus not relying only on the governance of the constituent actors, but involving missing relevant stakeholders)” (S)

**Recommendation 2.2.2:** “Detect the functional typology of the initiative, which is the main objective that the initiative wants to achieve, and adapt the structure and participatory governance of the initiative accordingly” (S)

**Recommendation 2.2.3:** “Set up an initial consultation process in order to understand the bottom-up needs and challenges of the potential participants of the initiative” (S)

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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>14</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 vision and agenda. This activity will allow to map the potential relevant gaps in terms of stakeholder composition, and to ensure that the initiative involves participants from all the interested stakeholder categories. Once 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 participants, 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>14</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 a 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 further integrated 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 participants involved, based on the defined vision and the agenda" (S)

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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 new born 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 a 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 advices 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 need 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 and the activities that will be carried out in order to achieve the desired change.
- **Engagement Coordination Team** and **Compliance Committee** (hereinafter also referred to as "CC") are described respectively under sub-criterion 2.1 and 2.4.

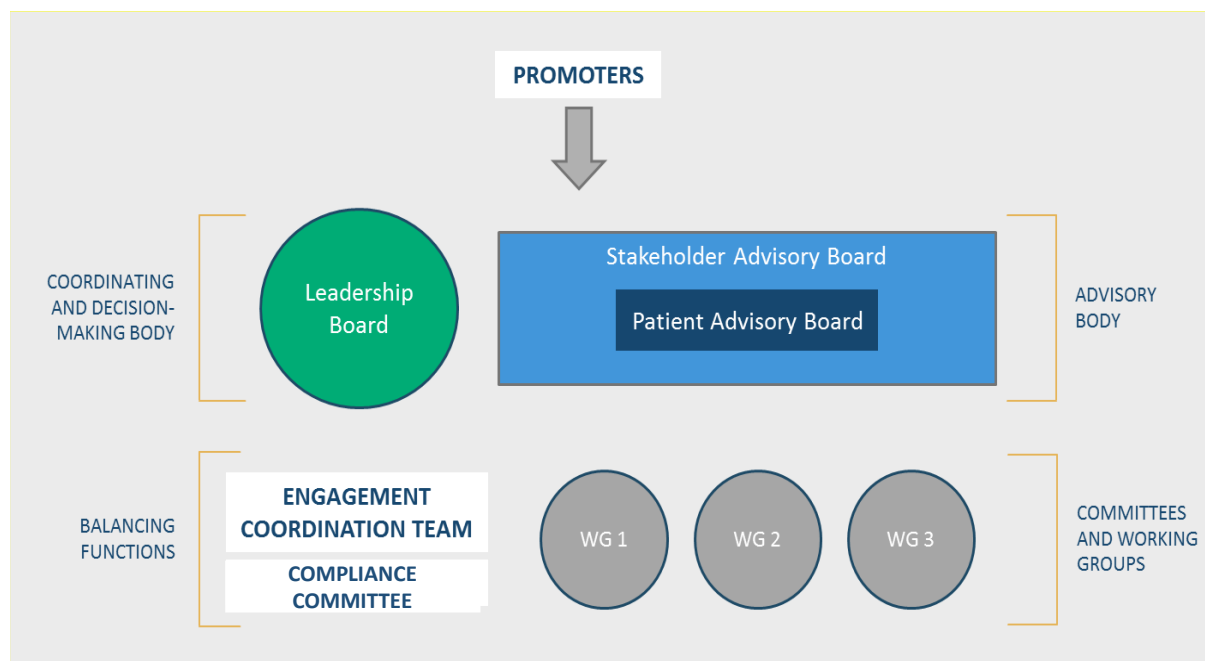


Figure 6: MULTI-ACT Governance Model

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 specific sub-criteria. 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 also 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
Leadership Board	Promoters with the contribution and approval of SAB and PAB
Stakeholder Advisory Board and Patient Advisory Board	Promoters with the contribution of the Compliance Committee and Engagement Coordination Team

Compliance Committee	Appointed by Promoters and confirmed by the LB
Engagement Coordination Team	Appointed by Promoters in consultation with LB
Working Groups	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 organizational structure and balance them in terms of gender, sector background, geographical background, language, political diversity, opinion and experience” (S)

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The LB is the body in charge of decision-making processes, it oversees the implementation of the Vision 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 composition of the LB should be balanced in terms of gender, sector and geographical background, language, political diversity, perspectives and experiences. The members of LB should be committed and skilled individuals, which should ensure constant participation to 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. 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 participant stakeholders. The composition of the LB and its members should undergo the endorsement of the SAB and the PAB.

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**Recommendation 2.3.3:** “Formalize how participants will interact with each other and cooperate within the governance structure” (S)

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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 relationships 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” (S)

***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” (S)

***Recommendation 2.4.3:*** “Implement appropriate engagement mechanisms to create and maintain commitment and ownership among the participating stakeholders” (S)

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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 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 (*“Guarantee ethical acceptability and social justice”*) and sub-criterion 3.4 (*“Ensure a balance between engagement of participants and agile management of the initiative”*).

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.

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

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

To achieve this objective, the initiative should:

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

#### ***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” (S)

***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” (S)

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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 understand 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 Vision (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, it should be assessed the different characteristics and needs that these several stakeholders might have and 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 their 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. The profiling analysis could be carried out as follows: once identified the vision (mission) of the initiative, actions to be implemented in order to achieve such change should be identified, and consequently actors that might have an interest (or might be affected) in achieving such change (please refer also to sub-criterion 2.2).
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>15</sup> that might be encountered could be, for instance: unwillingness to engage,

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<sup>15</sup> The a more detailed list of potential stakeholder risks is contained in the document: AccountAbility. (2015). *AA1000 Stakeholder Engagement Standard*.



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 and Action Plan: at the beginning of the engagement, the LB, with input from the stakeholders and the support of the established SAB, shall establish procedural and behavioral rules for the participants in the engagement, which might include for example: guarantee that the opportunities for providing inputs are evenly distributed among participants, allow all participants to express their opinion completely, stay focused on the change that the initiative aims to achieve. It is fundamental to define clear roles and responsibilities for all the participants, in order to regulate their cooperation and allow them to hold each other accountable. Moreover, based on the defined Vision, the Promoters should define a Collective Action Plan (please also refer to the sub-criterion 4.1), adopted in accordance with all the participants of the initiative, to guarantee that it fully corresponds to the expectations of all interested stakeholders.

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

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

Each multi-stakeholder initiative adopting the MULTI-ACT Model could define a customized stakeholder engagement process; however, the above-mentioned aspects represent the minimum requirements that should be taken into account 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



setting-up phase 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 private intended beneficiaries***

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

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According to D1.4, stakeholders such as patients are often involved in research project and mainly focused on clinical trials and drug development as data providers (or in biotechnological R&I as users to test innovative technologies) rather than engaged in the governance of R&I with decision making role. According to MULTI-ACT objectives, 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 process. To achieve this objective, the Promoters 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.

To achieve the engagement of the private 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 and caregivers’ 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 private 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 he/she is part of.

Please note that such suggestions will be further integrated in WP1, which aims to explore innovative path of patients and caregivers’ engagement action in R&I and develop innovative guidelines to put in place effective and impactful engagement strategies.

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)” (P)

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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 appliers of MULTI-ACT Governance Model should define if these limitations are the same for all the patients involved in the entire R&I process, or if there are some phases of the R&I process which are more complicated and for this reason should be considered with more attention. This been done, actions to overcome these barriers and limitations should be envisioned and, when not possible, an alternative solution for the engagement should be discussed (i.e. engaging parents for children; relatives for people with cognitive impairments).

The ECT coordinates the participation of patients in the agenda design, in the decision-making process, in the initiative development, and finally in the implementation, monitoring and evaluation phases. Its facilitator role should guarantee that all possible limitations that might affect the effectiveness of patients’ engagement are taken into consideration and that mechanisms to avoid these situations are put in place. Indeed, it is extremely important that the R&I is carefully analyzed so that this team can be well informed and prepared on the possible limitations that this specific category of stakeholders might encounter in the several R&I phases, and carefully address them to guarantee a smooth 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 participants**

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**Recommendation 3.3.1:** “Differentiate the level of engagement of participants, considering:

- their skills, capabilities and characteristics;
  - the stages and processes of the initiative;
  - the relationship with the participants and their strategic importance to the initiative;
  - the resources available and the organizational constraints” (S)
-

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, once mapped which stakeholders should take part to the initiative (refer to 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 vision 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.

To quote one example, the levels of engagement through which patients will be engaged (please indicated the related WP1 deliverable) are represented by the following approaches:

- Co-design, which means they are engaged since the very beginning of the steps of the R&I Path with a decision-making role (i.e. they could be part of the LB);
- Involve, which means they are engaged in research project activities with an active role (i.e. they could be part of the LB and/or WGs according to their specific relevance);
- Consult, which means they 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);
- Inform, stakeholders are informed about research priorities, activities, outcomes and impact, but passively participate.

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.

#### ***Sub-criterion 3.4: Ensure a balance between engagement of participants 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” (P)

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The identification of the appropriate stakeholders to be included in the initiative is essential to guarantee that there is balance among those that participate in relation to their different

characteristics and backgrounds needed to achieve the expected change. Moreover, it is fundamental that an initiative prepares appropriate mechanisms to deal with possible challenges that might arise due to the diverse background and characteristics of the stakeholders involved.

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 among the participants 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 that 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 participants and the agile management of the initiative.

### 3.4 Criterion 4: Effective and efficient management and coordination of the initiative

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

#### ***Sub-criterion 4.1: Enable cooperation and competition among participants***

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***Recommendation 4.1.1:*** “Put in place processes allowing participants to perform mutually reinforcing activities and coordinate collective efforts to maximize results and create opportunities for change” (S)

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

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

- Definition of a Collective Action Plan in line with the Vision and Agenda and specifies the strategies and actions that the different partners commit to implement in order to achieve such change;
- Implementation by all the participants of these strategies in order to advance the shared Action Plan;
- Establishment of WGs and other collaborative structures with the role to coordinate activities aligned with the Action Plan;
- Setting up accountability mechanisms to hold partners accountable for implementing activities as planned;
- Organization of “touch points meetings” in order to create opportunities for change, such as:  
a) holding periodic events in order to discuss potential challenges, foster innovative thinking, and identify practical solutions; b) hosting webinars to support stakeholders in the implementation of actions.

The implementation of such activities should be led by the LB, which should have the responsibility to define the Collective Action Plan and oversee that the defined activities are implemented by all the

participants so that they can hold each other accountable. The WGs could be bodies composed and balanced according to the stakeholders' categories and the needs of the initiative and could be in charge of specific tasks (such as for example specific research activities or reporting activities, as described under criterion 5). These bodies should report to the LB. Within these bodies, both cooperation and competition should be promoted, which means that participants with different backgrounds, instances and interests should be involved in the implementation of a given task/activity, in order to offer various and multi-disciplinary inputs, while pursuing a common goal. This could provide an added value to the initiative itself since multi-stakeholder instances are considered at all levels of the R&I process.

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

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

***Recommendation 4.2.2:*** "Commit to transparent, evidence-based decision making, in order to reach the objectives established in the vision and agenda" (S)

***Recommendation 4.2.3:*** "Guarantee a mechanism of review and evaluation, which allows to learn and improve the engagement with stakeholders" (S)

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

To implement an effective process, the "Collective Action Plan" should also contain:

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

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

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

***Sub-criterion 4.3: Maintain flexibility***

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

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The appliers of MULTI-ACT Governance Model should stay up-to-date on the current needs of the beneficiaries they are trying to tackle. In order to be able to achieve this, from the implementation of the research program/project they should take into consideration the possibility of adjusting the goals of the initiative and possible involved stakeholders due to changing needs and reality. The initiative applying the Model should consider adopting this recommendation according to its specific needs, context and specificities.

Several practices could be evaluated by the LB of the initiative to guarantee that the initiative actually responds on correct and current needs, such as for example:

- Prepare a Progress Report (for example on a yearly basis) is as a useful tool to collect all the achievements, but also the concerns raised throughout the process by stakeholders and possible recommendations for the future (please also refer to the sub-criterion 5.1.7);
- Consider organizing a consultation event on a periodical basis where stakeholders can express their views and confirm their alignment with the defined Agenda (please also refer to the sub-criterion 5.2.1);
- Consider the review by external actors, in order to identify possible gaps and areas for improvements;
- Periodically review the Vision and Agenda according to the activities above-mentioned.

These activities could be carried out by specific working groups or bodies working under the supervision of the Governance bodies of the organization.

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

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***Recommendation 4.4.1:*** “Provide and maintain adequate resources (including financing, staff and technical expertise, and in-kind contribution)” (P)***Recommendation 4.4.2:*** “Ensure that the internal team has solid skills to carry out the activities and cooperate with participants” (P)***Recommendation 4.4.3:*** “Adopt a cost management process and an efficient management to avoid inefficiencies” (P)***Recommendation 4.4.4:*** “Maintain accountability over time keeping track of expenses and revenues” (P)

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For an organization to deliver its mission and carry out its activities, it is necessary to ensure that it is financially secure. In order to do so, it is fundamental to have secure funding, a solid organizational structure with technical expertise and solid resources management.

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



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

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



### 3.5 Criterion 5: Co-accountability assessment

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

To achieve this objective, the initiative should:

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

#### 3.5.1 Sub-criterion 5.1: Define a shared assessment and monitoring system

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**Recommendation 5.1.1:** “Enable the co-selection of measurable and achievable targets in order to measure progress and outcomes through the involvement of participants” (P)

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

The governance bodies should define the vision and agenda of the initiative (recommendation 1.1.1) and identify the “aspects” of measurement (recommendation 1.1.2). This process requires then the identification of measurable and achievable targets (sub-criterion 4.2) and the development of a multi-stakeholder assessment tool to monitor their achievement.

The implementation of this recommendation will be further detailed through the integration of the results of WP1, WP2 and WP3. In particular, these will enable the classification of research in relation to different dimensions (mission, excellence, economic, social and patient reported dimensions) making it easier to assess the impact of research in a comprehensive approach.

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**Recommendation 5.1.2:** “Co-define appropriate indicators to measure impact according to the different dimensions and stakeholder perspectives to enable a more comprehensive assessment of the social impact of health research, allowing all participants to hold each other accountable” (P)

**Recommendation 5.1.3:** “Establish a shared assessment system, which consists of a set of indicators, tracked consistently over time, and a common data collection tool” (P)

**Recommendation 5.1.4:** “Develop indicators for impact assessment with a specific focus on the impact on patients (i.e. Patient Reported Outcomes measures or patient prioritized outcome)” (P)

**Recommendation 5.1.5:** “Develop indicators that allow to assess the initiative’s long-term impact” (P)

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Please note that the implementation of these recommendations depends on the results of WP1, WP2 and WP3. WP3 will define a list of indicators to measure impact according to the different dimensions and stakeholder perspectives to enable a more comprehensive assessment of the social impact of the health research and will develop indicators that allow to assess the initiative’s long-term impact. WP1 will integrate the indicators identified in WP3 with PROs metrics (Patient Reported Dimension) to evaluate the impact of R&I on the outcomes that matter to patients. Stakeholders of the initiative will be able to select the most relevant aspects of measurement linked to the initiative’s agenda (please also refer to the sub-criterion 1.1.2) and therefore identify the related indicators. Once the aspects to assess are defined, the initiative should select the specific indicators to be measured. A committee could be appointed by the LB to carry out these activities.

For the reasons expressed above, the implementation of this recommendation will be further detailed integrating the results of WP1, WP2 and WP3.

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**Recommendation 5.1.6:** “Ensure that the shared assessment and monitoring system provides a consistent and systematic structure of indicators that allows a tailored monitoring against objectives by each participant involved in the co-accountability process (also through "self-reporting")” (P)

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The appliers of MULTI-ACT Model should ensure that the assessment system is effective and that measures the achievement of objectives through a fair co-accountability process.

To achieve this objective, the LB is in charge of ensuring that:

- There is alignment between the measurement system and the vision, agenda and objectives of the initiative;
- There is a fair co-accountability process in place.

If needed according to the specific characteristics of the initiative, the LB could appoint a specific working group in charge of these tasks.

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**Recommendation 5.1.7:** “Report and communicate on progress, results and impact thus making it possible for external stakeholders to judge the initiatives’ results” (S)

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The initiative’s results and progresses should be transparently communicated to the public, through two complementary solutions:

- *A Progress Report* published on a regular basis

The Progress Report is a document made available to the public that discloses information regarding the achievement (or no achievement) of initiative’s objectives and key performance indicators. In particular, the Progress Report should disclose the information regarding the indicators identified by the initiative at sub-criterion 5.1.2, according to the aspects of measurement identified at sub-criterion 1.1.2. Furthermore, the Progress Report should contain general information regarding the management and implementation of the aspects of measurement and other relevant information regarding the achievement of the initiative’s vision and agenda. The Progress Report should be published on a regular basis, every one or two years, according to the specificities of the initiative, and should be published online and made available to interested stakeholders.

- *An Open Platform*, which includes a visualization of the performance of the initiative according to the identified indicators

The open platform is an online tool offering a visualization of the performance of the initiative according to the identified indicators (identified by the initiative at sub-criterion 5.1.2, according to the aspects of measurement identified at sub-criterion 1.1.2). It offers access on periodic key performance indicators regarding the initiative’s implementation to all stakeholders. The open platform should also contain general information regarding the management and implementation of the key aspects measured and other relevant information regarding the achievement of the initiative’s vision and agenda. The open platform might contain other functionalities and features that will be discussed in the next steps and WPs of MULTI-ACT project. The MULTI-ACT toolbox,

under development in WP2, will serve as open platform for those initiatives which decides to adopt the MULTI-ACT Collective Research Impact Framework. However, complementarily, research initiatives can in some cases also possess their own portals and platforms and disclose relevant information about their collective impact and participatory governance structures and rules via them.

The LB, which might appoint a working group or a committee for this purpose and through the help of the Secretariat or Management Team, is in charge of gathering information that will constitute the basis for the Progress Report, to create the Open Platform and to make these tools available to stakeholders and to the public.

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**Recommendation 5.1.8:** “Adapt and improve the initiative, as well as the shared assessment and monitoring, according to the results of the assessment” (S)

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MULTI-ACT Model considers the importance of leveraging the results of the assessment to improve the initiative’s performances and practices. For this reason, the initiative should establish a review process, which aims at exploiting the results of the evaluation of its performances. This process could also include improvement objectives and actions for the initiative.

To achieve this goal, it is necessary to conduct a periodic review that includes at least the following activities:

- 1) Perform an analysis of the indicators and the information on the initiative’s performances, emerging from the shared assessment process;
- 2) Identify counter-actions and improvement actions for the most crucial activities;
- 3) Set up an improvement plan and new objectives to be achieved by the initiative.

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

The review process should be led by the LB and the SAB, which might appoint a specific committee to carry out the operational activities linked to this process, or depending on the size of the initiative, the “Secretary or Management Team” could be in charge of developing such activities.

### **3.5.2 Sub-criterion 5.2: Set effective feedback mechanism**

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

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

In order to do so, the LB should:

- 1) Identify the most suitable and appropriate channels through which stakeholders can communicate and raise their concerns (e.g. email, website, letter);
- 2) Set up the activities necessary to gather stakeholders' feedback;
- 3) Elaborate stakeholders' feedback;
- 4) Ensure that the feedback is appropriately managed and considered within the review process, under sub-criterion 5.1.8.

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

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

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

### ***3.5.3 Sub-criterion 5.3: Ensure continuous learning, communication and disclosure of knowledge***

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

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

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

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

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

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

## 4 CONCLUSION AND NEXT STEPS

The activities performed in WP5 have led to the identification of best practices in the governance of multi-stakeholder initiatives and the development of principles and practical solutions to govern and manage a research funding and performing organization. These recommendations, which are thoroughly described in Section 3 of this deliverable, have been co-created and evaluated by MULTI-ACT consortium partners and constitute the Governance Model of MULTI-ACT, the main output of WP5.

As shown in the previous Section, the Governance Model consists of 42 recommendations, clustered according to 5 criteria and 19 sub-criteria, which are not in chronological order of implementation. For this reason, and for the sake of clarity, in the next steps of the project the implementation of the possible solutions of MULTI-ACT Governance Model could also be reframed in temporal order, considering the ownership (i.e. Promoters, LB) of the steps that would allow a given initiative to be in accordance with the MULTI-ACT Governance Model. In this regard, the implementation can be divided into evolutionary steps, such as those identified in WP1 by the 7 steps R&I Path, considering the phases in which an initiative could adapt its structure to MULTI-ACT Governance Model (from the moment in which Promoters set up the scene, lay the foundation of the governance bodies, which then will define the vision and the agenda, run the initiative, and assess, communicate and improve the work done).

The implementation of the Model by an applier multi-stakeholder organization/initiative will also be assessed through a questionnaire including qualitative indicators (a draft of the possible criteria and indicators is available at Annex I of this document).

Furthermore, it is worth considering that the Model will undergo a series of revisions during the upcoming tasks of MULTI-ACT project. It will be tested through the implementation of a case study during WP4, and will be further refined considering the results of the case study itself and the outputs of WP3 and WP1. This work will be further revised and finalized during WP6, where the Guidelines of the Model will be developed.

## ANNEX I: A first list of qualitative indicators to evaluate the implementation of MULTI-ACT Governance Model

Criteria	Specification	Description
Vision and Agenda	Vision and agenda definition	Describe if and how the initiative has defined its vision and objectives
Vision and Agenda	Long term goal and outcomes identification	Describe what is the vision and what are the objectives of the initiative and how and why a desired change is expected to happen in the context in which the initiative operates (considering the necessary outcomes to be achieved)
Vision and Agenda/ Define a shared assessment and monitoring system	linkage between objectives and impact aspects and indicators	Describe how the objectives of the initiative are connected to the aspect of measurement and the related indicators
Vision and Agenda	Stakeholder participation to vision and agenda definition	List which stakeholders took part in defining the vision and agenda of the initiative
Vision and Agenda	Intended beneficiaries	List which are the intended beneficiaries of the initiative
Participatory Governance	Governance structure	Describe the governance model of the initiative and, in particular, if applicable, the structure and composition of the following bodies: - Leadership Board - Stakeholder Advisory Board and Patient Advisory Board - Compliance Committee - Engagement Coordination Team - Working groups/committees
Participatory Governance	Leadership Board composition	Describe the composition of the Leadership Board in terms of gender, sector, geographical background, language, and background
Participatory Governance/Clear, effective and inclusive methodology of stakeholder engagement	Identify and cluster stakeholders	List the stakeholder categories identified by the initiative, that should be involved according to the context and the objectives pursued by the initiative



Participatory Governance/Clear, effective and inclusive methodology of stakeholder engagement	Identification of stakeholders' need, challenges and barriers	Describe the analysis carried out to identify stakeholders' main needs, challenges and barriers to guarantee genuine participation and identify limitations that some specific category of stakeholders might encounter in their participation within the initiative, also according to the several phases of the R&I process
Participatory Governance	Procedure development	Confirm that the initiative has formalized a procedure that describes the governance structure, the roles and responsibilities of all participants and regulates the decision-making processes and relationships structures
Participatory Governance	Mechanisms in place to ensure multi-stakeholder participation	Describe mechanisms in place to: 1) ensure the participation of disadvantaged stakeholders; 2) protect the integrity and multi-stakeholder nature of the initiative; 3) maintain commitment and ownership among the participating stakeholders
Clear, effective and inclusive methodology of stakeholder engagement	Define and approve a methodology to engage stakeholders	Describe the methodology that will be adopted in order to put in place a process of stakeholder engagement, and list the actions that will be undertaken for each of the fundamental steps identified in such engagement processes which are: Plan, Prepare, Implement, Review and Improve
Clear, effective and inclusive methodology of stakeholder engagement	Engage private intended beneficiaries	Clearly describe the process of training stakeholders; in particular, report on the total amount of average hours per participant that the initiative dedicated to informing and training its stakeholders
Clear, effective and inclusive methodology of stakeholder engagement	Define the level of engagement for each stakeholder	Based on the categories of stakeholders identified, clearly define the related level of engagement. It should be clearly stated the link between category of stakeholder - level of engagement; moreover, it should be formalized what the duties, rights and responsibilities are linked to each level of engagement in order to hold each other co-accountable.
Effective and efficient management and coordination of the initiative	Define a clear framework, such as a Collective Action Plan	<p>Confirm that the initiative has defined a "Collective action plan", and describe all the actions contained that should be put in place by the initiative in order to achieve its objectives, and related responsibilities.</p> <p>The Collective Action Plan must contain as minimum requirements:</p> <ul style="list-style-type: none"> <li>- Actions that different partners commit to implement in order to achieve the Vision;</li> <li>- Definition and composition of Working Groups, which might practically deal with the implementation of such actions;</li> <li>- Definition of clear and measurable targets;</li> <li>- Presentation of clear project timeline;</li> <li>- Definition of a clear review process;</li> </ul>

		<ul style="list-style-type: none"> <li>- Information regarding the organization "touch points meetings" (such as periodic events or webinars)</li> </ul>
Effective and efficient management and coordination of the initiative	Maintain flexibility	<p>Report on the following information:</p> <ul style="list-style-type: none"> <li>- Number of consultation events that have taken places in which stakeholders have had the possibility to express their views,</li> <li>- Number of reviews by external actors,</li> <li>- Number of reviews of the Vision and Agenda, according to the gaps identified</li> </ul> <p>Describe if there is a process that then allows the incorporation of feedbacks from consultations and reviews to revise/change objectives of the initiative in a flexible manner</p>
Effective and efficient management and coordination of the initiative	Implement an effective cost management process	<p>Describe the cost management process implemented by the initiative, which should at least be composed by the following activities:</p> <ul style="list-style-type: none"> <li>- Determination of a clear budget</li> <li>- Implementation of a cost analysis of the project</li> <li>- Identification of possible gaps and critical issues</li> </ul>
Define a shared assessment and monitoring system	Progress Report development	Confirm that the initiative has published a Progress Report
Define a shared assessment and monitoring system	Open Platform creation and maintenance	Confirm that the initiative has created an Open Platform for constant communication on progress to stakeholders
Define a shared assessment and monitoring system	Review process in place	Describe the review process that the initiative has adopted to consider the results of the measurement to improve the initiative's performances and practices
Define a shared assessment and monitoring system	Feedback mechanism in place	Describe the mechanism in place to gather feedback on the initiative from stakeholders and the public



## ANNEX II: The validation process of MULTI-ACT Governance Model

The recommendations and, when possible, the implementation solutions that will constitute the content of Governance Model of MULTI-ACT, have been discussed and validated by WP5 partners during a dedicated workshop carried out on 10<sup>th</sup> April 2019 and by External Advisory Board members on 9<sup>th</sup> April 2019. The main feedback of EAB members and WP5 partners, which are reported below in the following paragraphs, have been integrated in the recommendations and solutions represented in this document. Furthermore, together with the deliverable, a Power Point presentation with the contents discussed during the workshop will be uploaded. It also includes experiences and case studies from the multi-stakeholder initiatives analysed during WP5.

### The inputs of the EAB

The main comments from EAB members are reported below:

- The agenda should be integrated and revised in multiple steps, ensuring the integration and validation of the first “proposal” from the promoters with the inputs and expectations of all stakeholders equally represented;
- All stakeholders should have equal power in the definition of the vision and agenda;
- The patient engagement coordinator can be a team composed by one stakeholder per stakeholder category;
- The patient engagement team/coordinator works as a facilitator and “floating” body between the patient board and the leadership board;
- The patient board could include a member per each of the 7 RR&I phases;
- Patients’ involvement in decision making should be made through their representative member in the leadership board and the Patient board should be an advisory body;
- The two options of the participatory structure presented (light and heavy) could be a potential evolution across time (if needed according to the needs of the initiative);
- It is important to distinguish between direct participation and indirect participation tools.

### The evaluation of WP5 partners

The results of the voting process carried out during WP5 workshop are reported below:

Sub-criteria	Solution voted
1.1.1 Define a shared vision and common agenda	Theory of change
2.3.1 Implementation of the participatory structure	Light structure

3.1 Stakeholders engagement methodology	High-level approach
5.1 Shared measurement and monitoring system	Progress report and open platform

The main comments from WP5 partners are reported below:

- It is important to consider the fact that the Theory of Change (ToC) for the purposes of MULTI-ACT has to be applied with a “non-linear” complex approach.
- Partners agreed that the coordination activity should be carried out by a team (whose composition should be tailored according to the resources of the initiative), which should be part of the backbone structure of the initiative. This body can be called “Engagement Coordination Team”. The “Patient board” should be called “Patient Advisory Board” and – in line with EAB’s advices - it should have an advisory function and not a decision-making function (since there are already patients’ representatives within the leadership board). The Patient Advisory Board could be considered part of the broader Stakeholder Advisory Board in order to do not make the governance structure too complex and fragmented.
- Partners agreed to use the terminology “Leadership Board” and “Stakeholder Advisory Board”. Partners agreed that the Leadership Board could appoint a management team, such as a sub-board and a secretariat to support operations.
- Partners agreed that the light structure should be proposed as the preferred option. If the initiative is structured enough, after having implemented the light structure, they could opt to evolve to a heavier structure where the Stakeholder Advisory Board evolves from an advisory body to a decision-making body. Regarding the Patient Board, Partners affirmed – in line with EAB – that this should be part of the Stakeholder Advisory Board and that there is no need to create two separate bodies. Patients are indeed already represented in the Leadership Board.
- Partners agreed that, according to the resources of the organization, the Ethics Manager could be a team/committee. This function should also participate in the Leadership Board’s activities.
- According to the partners, it is necessary to start from a high-level approach (i.e., telling the applier what should be done, but to not define how it should be done operatively, in order to guarantee flexibility). However, this approach should be detailed enough to guarantee the possibility to assess that an organization has effectively engaged stakeholders.
- The level of engagement of stakeholders should be based on the strategic importance of stakeholders to achieve the vision and agenda. This requires a categorization of stakeholders and then a prioritization activity linked to their level of engagement.
- Partners decided to adopt both the Progress Report and Open Platform option. Therefore, appliers should both define a progress report and offer stakeholders access to a front-end version of the platform, where performances could be measured and disclosed over time.

## BIBLIOGRAPHY

- AccountAbility. (2015). *AA1000 Stakeholder Engagement Standard*.
- Australia Government, Department of Health. (n.d.). *Stakeholder Engagement Framework*.
- Brown, P. (2007). *Principles that make for effective governance of multistakeholder*. UN.
- Cabaj, M. and Weaver, L., "Collective Impact 3.0: An Evolving Framework for Community Change" (Waterloo, ON: Tamarack Institute, 2016). Retrieved from <https://www.collectiveimpactforum.org/sites/default/files/Collective%20Impact%203.0.pdf>.
- Gase, S. S. (2018). Does Collective Impact Really Make an Impact? *Stanford Social Innovation Review*.
- Global Development Incubator. (2015). *More than the sum of its parts: Making Multi-Stakeholders Initiatives Work*. Mountain View, CA: Omidyar Network and USAID.
- Huijstee, M. v. (2012). *Multi-stakeholder initiatives. A strategic guide for civil society organizations*. SOMO.
- ICNL - The International Center for Not-for-Profit Law. (2015). *Multi-stakeholder initiatives – theories, concepts and typologies*.
- ISEAL Alliance. (2014). *Setting Social and Environmental Standards. ISEAL Code of Good Practice*.
- ISO . (2010). *Engaging stakeholders and building consensus*. Geneve.
- Kania, J., & Kramer, M. (2011). Collective Impact. *Stanford Social Innovation Review*.
- Leading Inside Out & Collective Impact Forum (2017). *Community Engagement Forum*.
- Partners for Each and Every Child. (2016). *A handbook for Meaningful Stakeholder Engagement*. .
- Porter, E. M. et al. (2011). *Measuring Shared Value. How to unlock Value by Linking Social and Business Results*. FSG. Cambridge.
- RRI Tools. (2019, February 2). *Gender Equality in RRI terms?* Retrieved from RRI Tools: <https://www.rri-tools.eu/gender-equality>
- RRI Tools, R. (2019, February 2). *What does Public Engagement in RRI mean?* Retrieved from RRI Tools: <https://www.rri-tools.eu/public-engagement>
- RRI Tools, R. (2019, February 2). *How to put Ethics into practice* Retrieved from RRI Tools: <https://www.rri-tools.eu/ethics>
- RRI Tools, R. (2019, February 2). *How to put Governance into practice* Retrieved from RRI Tools: <https://www.rri-tools.eu/governance>
- RRI Tools, R. (2019, February 2). *What does Open Access in RRI mean?* Retrieved from RRI Tools: <https://www.rri-tools.eu/open-access>
- RRI Tools, R. (2019, February 2). *How to put Science Education into practice* Retrieved from RRI Tools: <https://www.rri-tools.eu/science-education>
- Social Value UK. (n.d.). *Supplementary Guidance on Stakeholder Involvement*. Liverpool.

Spark Policy Institute & ORSImpact. (2018). *When collective impact has an impact. A cross-site study of 25 collective impact initiatives*. Denver.

Strand, R. et al. (2015). Indicators for promoting and monitoring Responsible Research and Innovation. European Commission. Brussels.

Verhulst, S. G. (2016). *The practice and craft of Multistakeholder Governance: The case of global internet policymaking*. London.

Weaver, M. C. (2016). *Collective Impact 3.0*. Tamarack Institute.

Winter, Bujker, & Carson (2017). Multi-stakeholder Initiatives: Lessons from agriculture. CR Initiative at the Harvard Kennedy School