

## APPENDIX 2: Criteria for Patient Engagement

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

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

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

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

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

Clear, effective and inclusive methodology of stakeholder engagement

<p>Clear, effective and inclusive methodology of stakeholder engagement <i>(and Effective and efficient management and coordination of the initiative)</i></p>	<p>Mechanisms in place to recognize the value of patients' experiential knowledge</p>	<p>Establish and describe appropriate mechanism for recognition of patients' contribution. Examples from Smith et al. 2019: Financial (compensation for incurred expenses, consultant fees, remuneration, etc.); Personal (thank-you letter, public mention, etc.); Knowledge (access to publications, access to training and scientific literature); Academic (acknowledgement in knowledge transfer, co-authorship in articles, etc.); Altruistic (moral satisfaction, augmentation of self-worth and wellbeing of others, etc.). Ensure equality of treatment with respect to the other stakeholders.</p>
<p>Clear, effective and inclusive methodology of stakeholder engagement</p>	<p>Define and approve a methodology to engage patients</p>	<p>Describe the methodology that will be adopted to engage patients, and list the actions that will be undertaken for each of the fundamental steps identified in such engagement processes (i.e. 7-steps R&amp;I path)</p>
<p>Clear, effective and inclusive methodology of stakeholder engagement</p>	<p>Define the level of engagement and type of patients for each steps of the 7-steps R&amp;I path</p>	<p>Based on the steps where patients are engaged (7-steps R&amp;I path) define categories of patients and clearly define the related level of engagement; moreover, it should be formalized what the duties, rights and responsibilities are linked to each level of engagement.</p>
<p>Clear, effective and inclusive methodology of stakeholder engagement</p>	<p>Training and initiating intended beneficiaries</p>	<p>Assure that patients are duly trained for the purposes. Clearly describe and report the process of training patients 1) on the R&amp;I and engagement process, 2) on what is expected from them and 3) on how to provide their experiential knowledge</p>
<b>Effective and efficient management and coordination of the initiative</b>		
<p>Effective and efficient management and coordination of the initiative</p>	<p>Define a clear framework, such as a Patient Engagement Plan</p>	<p>Confirm that the initiative/project has defined a "Patient Engagement plan", and describe all the actions contained that should be put in place by the ECT in order to achieve its objectives, and related responsibilities. The Patient Engagement Plan must contain as minimum requirements:</p> <ul style="list-style-type: none"> <li>- Patient Engagement actions that needs to be implemented in order to achieve the Vision;</li> <li>- Definition of roles and responsibilities of the ECT that should manage and carry out the implementation of such actions;</li> <li>- Definition of clear and measurable targets;</li> <li>- Presentation of clear timeline of activities;</li> <li>- Definition of a clear review process (e.g. objectives of</li> </ul>

		<p>Patient Engagement);</p> <ul style="list-style-type: none"> <li>- Information regarding the organization "touch points meetings" (such as periodic strategic meeting with PAB or other stakeholders)</li> </ul>
<p>Effective and efficient management and coordination of the initiative</p>	<p>Maintain flexibility and put in place mechanisms to avoid tokenism</p>	<p>Assure a process that allows the incorporation of feedbacks from patients and reviews to revise/change objectives and approach of the initiative/project in a flexible manner. Assure and report oversight and overtime mechanism to avoid tokenism and value the experiential knowledge of patients.</p> <p>Report on the following information:</p> <ul style="list-style-type: none"> <li>- Number and type of methods used and events that have taken places to grant patients the possibility to express their views/experiences</li> <li>- Number of reviews/changes of the Vision and Agenda, according to the gaps identified by patients</li> <li>- Number of reviews/changes of outcomes related to the 7-steps R&amp;I path produced and endorsed by patients</li> </ul>
<p>Effective and efficient management and coordination of the initiative</p>	<p>Implement an effective cost management process</p>	<p>Describe the cost of the Patient Engagement implementation by the ECT, which should at least be composed by the following activities:</p> <ul style="list-style-type: none"> <li>- Determination of a clear budget for Patient Engagement</li> <li>- Implementation of a cost analysis and assure sustainability of the Patient Engagement plan</li> <li>- Identification of possible gaps and critical issues</li> </ul>
<p><b>Define a shared assessment and monitoring system</b></p>		
<p>Define a shared assessment and monitoring system</p>	<p>Progress Report development</p>	<p>Confirm that there is a regular publication of Progress Report (on-going, ex-post)</p>

Define a shared assessment and monitoring system	Communication channels set up and maintenance	Confirm that the initiative has created communication channels for constant communication on progress to patients involved (to constantly keep engage patients)
Define a shared assessment and monitoring system	Review process in place	<p>Describe the review process that the initiative has adopted to consider the performance and value of the Patient Engagement to make the initiative's produce outcomes that matter to patients.</p> <ul style="list-style-type: none"> <li>- Describe how objectives of Patient Engagement are met on performance and on /value, impact and return on engagement)</li> <li>- Define the value of Patient Engagement (Patient Engagement Plan/ Cost to put in place the Plan = Value)</li> </ul>
Define a shared assessment and monitoring system	Feedback mechanisms in place	Describe the mechanisms in place to gather feedback on the Patient Engagement actions and outcomes from stakeholders and the public (other than PAB).

Table 1 A list of qualitative indicators to evaluate the implementation of MULTI-ACT Governance Model with respect to Patient Engagement