

## APPENDIX 3: MULTI-ACT Patient Engagement Plan Template

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

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

	<p><i>Action 2.2: ECT organize a Focus group with WG (and other relevant stakeholders) to revise the initiative/project according to the outcomes of the public consultation. (offline method)</i></p> <p><i>Action 2.3: ECT and WG works remotely to integrate outcomes of Action 1.1 and Action 1.2 into the development of the initiative/project.</i></p> <p><b>Level of engagement:</b> <i>Example - Consult</i></p> <p><b>Type of patients' representative:</b> <i>Patients, family members and caregivers</i></p> <p><b>Requirements:</b> <i>No specific or scientific expertise of patients is required other than their experiential knowledge</i></p>
<b>STEERING INSTITUTIONS</b>	<p><b>Expectations:</b> <i>Example - Patients are enabled to integrate their experiential knowledge in R&amp;I being part of the governance and having decision making power.</i></p> <p><b>Actions plan 3:</b> <i>Example - Action 3.1: Establish governance bodies to enable Patient Engagement in line with MULTI-ACT Governance Model (i.e. ECT, PAB)</i></p> <p><b>Level of engagement:</b> <i>Example - Co-design</i></p> <p><b>Type of patients' representative:</b> <i>Example - Patients, family member and caregivers</i></p> <p><b>Requirements:</b> <i>No specific or scientific expertise of patients is required other than their experiential knowledge</i></p>
<b>DESIGN &amp; PLAN</b>	<p><b>Expectations:</b> <i>Example - Patients help to co-design specific programs/project</i></p> <p><b>Actions plan 4:</b> <i>Example - Action 4.1: ECT engage patients as evaluators in the selection of funding or as peer-reviewers</i></p> <p><b>Level of engagement:</b> <i>Example - To be defined based on the identified actions</i></p> <p><b>Type of patients' representative:</b> <i>Example - To be defined based on the identified actions</i></p> <p><b>Requirements:</b> <i>Example - To be defined based on the identified actions</i></p>
<b>RESEARCH EXECUTION</b>	<p><b>Expectations:</b> <i>Example - Patients help the execution of R&amp;I as co-researchers providing experiential knowledge.</i></p> <p><b>Actions plan 5:</b> <i>Example - Action 5.1: ECT engage patients for helping in recruitment and data collection</i></p> <p><b>Level of engagement:</b> <i>Example - To be defined based on the identified actions</i></p>

		<p><b>Type of patients' representative:</b> <i>Example - To be defined based on the identified actions</i></p> <p><b>Requirements:</b> <i>Example - To be defined based on the identified actions</i></p>
EVALUATION		<p><b>Expectations:</b> <i>Example - Patients help the evaluation of R&amp;I on the outcomes that matter most to them.</i></p> <p><b>Actions plan 6:</b> <i>Action 6.1: ECT engage patients for data analysis and interpretation, patients asked to design PROs that matter to them.</i></p> <p><b>Level of engagement:</b> <i>To be defined based on the identified actions</i></p> <p><b>Type of patients' representative:</b> <i>To be defined based on the identified actions</i></p> <p><b>Requirements:</b> <i>To be defined based on the identified actions</i></p>
TRANSLATION COMMUNITY	TO	<p><b>Expectations:</b> <i>Example - Patients participate to advocacy campaigns that leverage on R&amp;I's results and help their translation to community as ambassadors.</i></p> <p><b>Actions plan 7:</b> <i>Example - Action 7.1: ETC engage patients in communication activities and outreach, patients co-authored publications and conduct knowledge translation.</i></p> <p><b>Level of engagement:</b> <i>Example- To be defined based on the identified actions</i></p> <p><b>Type of patients' representative:</b> <i>Example - To be defined based on the identified actions</i></p> <p><b>Requirements:</b> <i>Example - To be defined based on the identified actions</i></p> <p><b>Discussion questions:</b> <i>Example - Is the dissemination material understandable by patients? Are the papers resulting from R&amp;I relevant also from the patient's perspective?</i></p>
Wrap-up for all steps		<p>Considering all the action plans, summarize the actions, type of patients and requirements instrumental to define/implement governance boards composition (i.e. ECT and WGs).</p> <p><i>Note 1: define if it is enough a WG for all the steps or if there is the need of multiple WGs. WGs are coordinated by the ECT.</i></p> <p><i>Note 2: assure to be sustainable and to maintain an easy structure.</i></p>
<b>3) RISKS AND MITIGATION PLAN</b>		
Risks		Mitigation plan
<i>Anticipate potential risks</i>		<i>Propose mitigation plan for the risk</i>

<i>Low participation of the patient community</i>	<i>Taking advantage of the network of patient organizations and relationships establishment</i>
<b>4) PE PERFORMANCE ASSESSMENT*</b>	
<i>MULTI-ACT provide a menu of indicators</i>	
<b>Objectives</b>	<b>Means of verification</b>
<i>Define objectives for evaluating the PE Plan</i>	<i>Clearly define how you are going to verify that the objectives are met.</i>
<i>Example:</i>	<i>Example:</i>
<i>Patient engaged with mixed methods</i>	<i>Number and type of methods used and events that have taken places to grant patients the possibility to express their views/experiences</i>
<i>Vision and Agenda meet the needs of patients</i>	<i>Number of reviews/changes made by patients to the Vision and Agenda according to the gaps identified by patients</i>
<i>Outcomes of R&amp;I are co-developed and endorsed by patients</i>	<i>Number of reviews/changes of outcomes related to the 7-steps R&amp;I path produced and endorsed by patients</i>
<b>5) TRAINING FOR PATIENTS and ECT*</b>	
<i>Describe the training program related to the Patient Engagement Plan.</i>	
<i>Please note that the MULTI-ACT Training module® for the ECT is under development to address the needed skills.</i>	
<b>SCOPE:</b>	
<i>Examples:</i>	
<i>Explain the mission and vision</i>	
<i>Provide basic information on the topic, the research context and process</i>	
<i>Explain what is expected from patients and the benefit of engagement (i.e. PE Plan)</i>	
<i>Keep informed on progress (regularly update)</i>	
<b>ACTIONS:</b>	
<i>Example:</i>	
<i>Online/offline training sessions for PWGs</i>	
<i>online engagement methods duly anticipated by exhaustive Information sheet</i>	
<b>6) RECOGNITION AND REWARDS - VALUE OF COLLABORATION*</b>	
<i>Clearly state the mutual benefit of engagement and the mechanism to assure it.</i>	
<i>Financial<sup>1</sup></i>	<i>Compensation for expenses incurred when participating in research activities (e.g., travel, fuel, parking)</i>

<sup>1</sup> Please note that the template presents the rewarding model of Smith et Al. 2019 as example. A general description of recognition mechanism is sufficient.

Personal	<i>Thank-you letter</i> <i>Public mention and acknowledgment (e.g., in social events, on social media)</i> <i>Certificate of participation</i>
Knowledge	<i>Access to publications resulting from the research to which they contributed</i> <i>Access to training</i> <i>Access to scientific literature (or other types of knowledge)</i> <i>Opportunities to exchange with researchers and other PPRs after completion of the project</i>
Academic	<i>Acknowledgement in knowledge transfer communications</i> <i>Acknowledgement in articles</i> <i>Invitations as speakers at scientific conferences</i> <i>Co-authorship in articles</i>
Altruistic	<i>Moral satisfaction</i> <i>Augmentation of self-worth</i> <i>Augmenting wellbeing of others</i>
Other	
<b>7) PRELIMINARY BUDGET FOR THE PLAN*</b>	
Define the cost and person months (PM) for the actions resulting from this Plan	
<b>The 7-steps R&amp;I path</b>	<b>Expected costs</b>
<b>BREAKING DOWN BOUNDARIES</b>	<i>Cost and PM for needed infrastructure set-up</i> <i>Cost and PM for ECT establishment and training</i>
<b>RESEARCH PRIORITIES</b>	<i>Cost of Public consultation</i> <i>Cost for Focus Group (if other representatives beyond ECT and PWGs)</i> <i>Cost for ECT (PM needed to develop the actions)</i> <i>Cost for PWG (if remuneration is foreseen)</i>
<b>STEERING INSTITUTIONS</b>	<i>Cost and PM for the actions defined in step "Steering institution"...</i>
<b>DESIGN &amp; PLAN</b>	<i>Cost and PM for the actions defined in step "Design &amp; plan"...</i>
<b>RESEARCH EXECUTION</b>	<i>Cost and PM for the actions defined in step "Research execution"...</i>
<b>EVALUATION</b>	<i>Cost and PM for the actions defined in step "Evaluation"...</i>
<b>TRANSLATION TO COMMUNITY</b>	<i>Cost and PM for the actions defined in step "Translation to community"...</i>
<b>SUSTAINABILITY</b>	

<b>FUNDIGN SOURCES<sup>2</sup></b>	<i>What % of budget may be dedicated to the actualization of PE Plan?</i>	
<b>8) Reporting, meetings &amp; communication channels</b>		
<b>Channels</b>	<b>Use</b>	
<i>Meetings (F2F, virtual)</i>	<i>Meetings among the ECT</i>	
<i>emails</i>	<i>Formal and informal communication</i>	
<i>Reporting format</i>	<i>The Report is expected at M12, M24 describing:</i> <ul style="list-style-type: none"> <li>- <i>the review process in relation to the performance and value of the Patient Engagement;</i></li> <li>- <i>how the objectives of Patient Engagement are met (both on performance and on return on engagement),</i></li> <li>- <i>the value for Patient Engagement (Patient Engagement Plan's outcomes/ Cost to put in place the Plan = Value).</i></li> </ul>	
<b>9) ETHICAL ASSESSMENT/ ETHICAL COMPLIANCE OF THE PLAN*</b>		
<i>Describe any ethical aspects to be considered in the plan and propose compensative actions in case of gaps</i>		
<b>Actions</b>	<b>Ethical aspects</b>	<b>Tools, mean of verification</b>
<i>Action 1.1: Establish governance bodies and team dedicated to the engagement (i.e. ECT)</i>	<i>Agreement with the boards' members (i.e. ECT)</i>	<i>Term of Reference for boards (i.e. ECT)</i>
<i>Action 2.1: "Public consultation": Data collection and management</i>	<i>Develop/check a Data Management Plan (DMP) and integration of patient perspective into its development</i>	<i>Informed sheet, Informed consent. Possibility to edit and review DMP with a simple sharing tool (e.g. google drive doc, etc.)</i>
<i>Action 2.2: Focus group with PWG including people with high disability (e.g. in wheelchair)</i>	<i>Check accessibility of venue, agenda and timing not stressful.</i>  <i>Possibility of web-streaming and recording in case the person cannot participate in person the day of the meeting.</i>	<i>Accessible location, light agenda. Recording and web-streaming of the meeting, possibility to give late contribution</i>
<i>Action 2.3: ECT and PWG works remotely to integrate outcomes</i>	<i>Compliance with respect of time</i>	<i>Appropriate technologies to connect and facilitate the people involved in activities</i>
<b>10) COMPLIANCE OF THE PE PLAN TO THE MULTI-ACT CRITERIA</b>		

<sup>2</sup> Consider and define the funding sources to cover budget for the Plan.

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

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

### **11) TECHNICALITIES, OPERATIONAL ASPECTS**

*List material and document to be prepared and other technicalities*

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

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