GUIDE CO-CREATION WESHARE

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1. Purpose of this Guide

The purpose of this guide is to outline the various possible steps involved in participatory research between patients and researchers. It also aims to provide recommendations and a list of tools to support the implementation of these co-creation steps through the WeShare platform.

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Please refer to the WeShare Infrastructure Operating Charter available on our website at https://weshare.unicancer.com, under the "How to Use WeShare" tab, or upon request.

4. Co-creation in Research

4.1 Objectives and advantages

Traditionally, research is often designed and planned without input from the individuals who will ultimately be affected by the intervention. Patients, stakeholders, and end users typically play a passive role [1]. By stakeholders, we refer to patients, researchers, healthcare professionals, social workers, associations, family caregivers, citizens, institutions, organizations, or other entities that influence or are influenced by the subject of the analysis. However, the literature shows that the participation and contribution of stakeholders or representatives of end users at various stages of research development and execution are crucial to achieving real-world impact and adapting best research practices—a need that has become increasingly evident in pragmatic clinical trials in recent years [2]. The involvement of patients and stakeholders is ultimately a critical step in establishing a research ecosystem that prioritizes the preferences and needs of end users, while valuing and incorporating their unique perspectives [3].

Co-creation helps reduce inequalities in knowledge (e.g., general research, clinical research, participatory research) and in power dynamics among stakeholders. This collaborative approach enables the active involvement of stakeholders from the very beginning of a study or clinical trial. Patients can contribute valuable experiential knowledge and move beyond a purely clinical perspective to help guide the setting of priorities and the planning of research activities [4].

There are three main reasons why patient participation should be encouraged throughout a study or clinical trial:

1. To address patients' needs, as they have the right to be involved in decision-making processes related to research that may affect their health conditions and healthcare issues [5];
2. To foster trust between patients and healthcare professionals as well as with the clinical trial protocol, which can contribute to better outcomes, greater adherence to the study, and opportunities for support in later phases of the project. This can also enhance the quality, relevance, and dissemination of research findings [6];
3. To improve the design and implementation of study-related activities so they better align with the needs and expectations of patients and other stakeholders.

From a research perspective, co-creation helps make research questions and the design of study materials more applicable and acceptable to end users and stakeholders [7]. It can enhance the credibility of findings and their applicability to patients [8], thereby adding value to the research process. Co-creation can also improve patient recruitment and reduce attrition rates [3], as well as minimize the waste of resources in research and development (R&D) [9–11]. Finally, it can benefit researchers by strengthening connections with the community and improving the translation of research into clinical practice.

Overall, co-creation aims to facilitate the planning and development of ideas, making an objective or outcome more practical, efficient, and cost-effective by leveraging the skills and motivation of stakeholders. It is a collaborative and iterative process that draws on participatory research. In this context, it is important to foster genuine "co-production" by adopting a stance of horizontal and balanced relationships and being open to new ideas—designing *with* rather than *for* end users. Overall, co-creation strengthens innovation, implementation, and the success of studies/clinical trials [4, 12–13].

4.2 What other stakeholders, besides patients, should be involved?

It is essential to involve a diverse range of stakeholders in the co-creation process. For example, in cancer research, it is crucial to include healthcare professionals such as oncologists, nurses, supportive care specialists, or general practitioners. These healthcare professionals are also directly affected by the intervention, innovation, or topic being developed in the research, as they may be responsible for implementing the intervention or enrolling patients in clinical trials. Their input is therefore highly valuable in the co-creation process.

Other stakeholders, such as social workers, family members, associations, citizens, institutions, organizations, or other entities concerned with the research objective, can also serve as relevant and valuable partners in co-creation. They can contribute specific knowledge and perspectives that enrich the research.

Research should enable individuals with lived experience to participate in and help guide the development of interventions aimed at improving health outcomes and experiences [14].

4.3 Awareness and Challenges Encountered

Researchers are increasingly recognizing the value of involving stakeholders, end users, and particularly patients, in the design, implementation, and communication phases of clinical research. Furthermore, institutions such as the European Medicines Agency (EMA), the European Society for Medical Oncology (ESMO), the American Society of Clinical Oncology (ASCO), the U.S. Food and Drug Administration (FDA), and the EU Clinical Trials Regulation all advocate for greater patient inclusion in health research and consider co-creation to be an integral part of the research process [15]. Funding bodies have also begun to require patient involvement in health research [16].

However, despite this growing awareness and the recommendations found in foundational texts on health promotion—as well as in French legislation recognizing stakeholder participation—the frequency and intensity of co-creation in health research still vary widely between studies and are often limited. Effective participatory approaches and co-creation methodologies remain underdeveloped or are merely symbolic, often restricted to consultation or feedback mechanisms. It is essential that stakeholders develop both interpersonal and technical skills to lead projects under optimal conditions and to avoid tokenistic participation. This

requires a reciprocal posture among stakeholders to foster a balanced partnership, in line with the bottom-up approach typical of community-based research [37].

Otherwise, there is a risk that only relatively simple activities will be selected for patient participation, such as reviewing patient-facing materials (e.g., information sheets or informed consent forms) [4]. More intensive patient engagement throughout the R&D process can have a greater long-term strategic impact, but it may be more complex to implement (e.g., requiring cultural change within universities and industry), more time-consuming (requiring back-and-forth at each step and time dedicated to emotional responses [37]), or more costly.

These challenges stem from several factors, such as poorly defined boundaries (including vague terminology and descriptions of co-creation) [7, 8, 17], or contextual factors that impact its implementation (e.g., a lack of awareness on how to participate in co-creation, both among researchers and the individuals concerned) [18].

Thus, the lack of existing resources and concrete guidelines makes it difficult for researchers to undertake co-creation in health studies. Moreover, health research is often designed to align with the priorities of researchers rather than those of patients, healthcare providers, or other stakeholders, rendering the research or interventions less relevant to them [19, 20, 21]. In addition, the effectiveness of stakeholder co-creation is rarely evaluated.

Some organizations are now striving to promote the participation of all interested parties in co-creation within health research [8, 22, 23]. In recent years, co-creation has been increasingly used in cancer care studies. For example, co-creation has been applied in the context of nutritional care pathways [24], communication skills training [25], the development of videos or mobile applications [26, 27], pre-treatment care pathways [28], physical activity support for cancer survivors [29], and care experience research [30–32], among others. The role of co-creation in these projects reflects a growing interest in and increasing use of co-creation approaches in cancer research [33, 34].

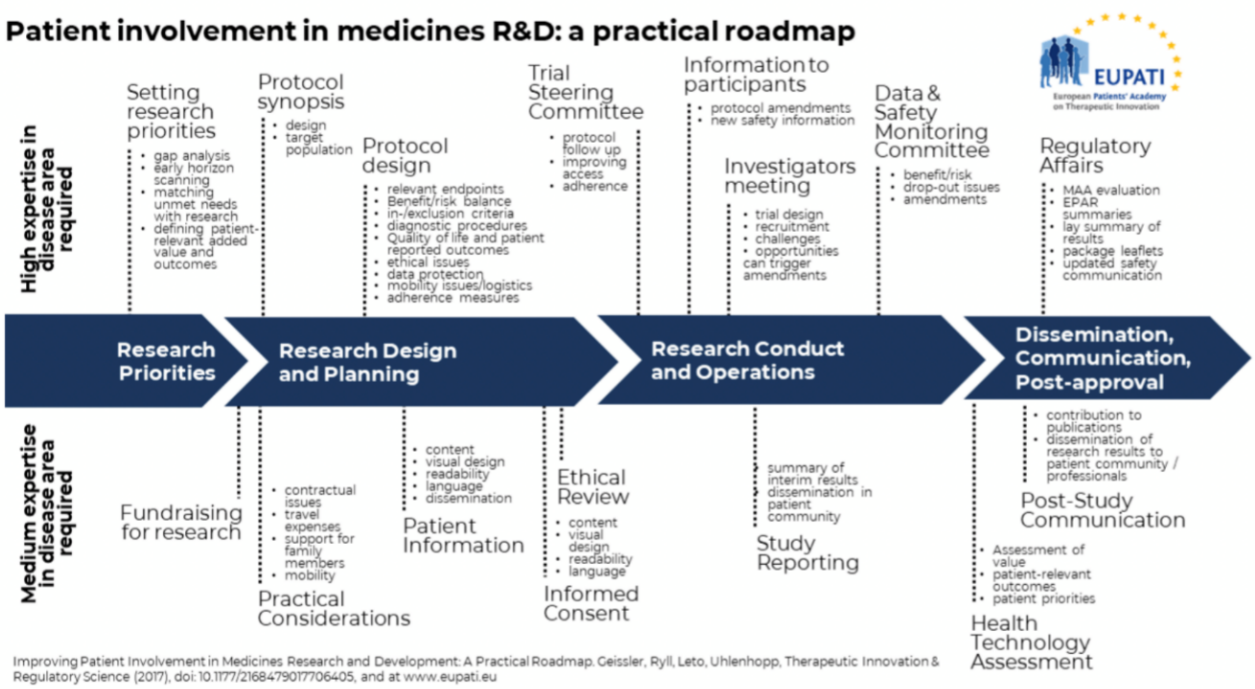
By offering a co-creation guide for research, we aim—through the WeShare program—to promote better practices in oncology research.

5. Recommendations and Tools to Support Co-Creation

5.1 Possible Stages in Participatory Research

Existing frameworks on co-creation suggest implementing co-creation at key moments and stages throughout the research process. The roadmap produced by the European Patients' Academy (EUPATI) below [4] illustrates patient involvement at various points in the research process and has now become a reference standard. EUPATI consists of 33 organizations, including patient organizations, universities, non-profit organizations, and pharmaceutical companies.

This roadmap can serve as a model and, by extension, be applied to all stakeholders involved in a study. **For more information on the key stages in participatory research, please refer to Annex 1.**



Improving Patient Involvement in Medicines Research and Development: A Practical Roadmap. Geissler, Ryll, Leto, Uhlenhopp, Therapeutic Innovation & Regulatory Science (2017), doi: 10.1177/2168479017706405, and at www.eupati.eu

5.2 Key Elements and Methodological Tools to Support Participatory Research: Assistance and Support Offered by WeShare

A literature review based on publications from 2012 to 2023, marking the patient involvement in clinical trials, identified practical recommendations regarding patient engagement in clinical research [2]. The ten key points highlighted are as follows:

Clearly define the roles and responsibilities of patient partners as well as the expectations for their involvement
Ensure that multiple patients contribute to guarantee diversity
Include patient participation in the study budget

Provide tools and templates designed for researchers
Offer training and informational materials for patients
Involve patients from the very beginning of the trial
Enable continuous participation at all stages of the trial
Maintain regular points of contact throughout the project (meetings, newsletters, etc.)
Engage patient groups and organizations/associations
Evaluate the impact and experience of patient participation

These points are generally applicable to all stakeholders and types of studies. Ideally, stakeholder engagement should begin as early as possible and continue throughout the research process to ensure that the goals of both stakeholders and researchers are aligned, to define outcomes related to the needs and priorities of stakeholders and researchers, and to maximize the potential for dissemination and implementation of results within the scientific and public communities. Longitudinal inclusion of stakeholders can help address the major challenge of bridging the gap between research production and research utilization. Developing co-creation protocols will enable the relevant stakeholders to express themselves and make decisions within health research.

Several tools to support participatory research already exist. For example, instruments such as the Patient-Centered Outcomes Research Institute (PCORI) Engagement Rubric [35], which provides principles and methodological suggestions for co-creation, and the GRIPP2 tool [36] (tools to improve reporting of patient and public involvement in research), serve as good examples of co-creation frameworks to follow.

Three main phases can be identified in the co-creation process: the co-creation planning phase, the co-creation execution phase, and the evaluation phase of the co-creation implemented. These three phases are described below. For each phase, we offer practical recommendations based on the literature, as well as digital tools that facilitate qualitative research through the WeShare platform.

5.2.1 Co-Creation Planning Phase

To ensure the success of a co-creation project, health researchers must carry out a planning phase to guarantee that the environment is adaptable, relaxed, and inclusive; that facilitators are competent; that the purpose and goals of the process are clearly understood by all participants; and that trust, empathy, and cultural appropriateness are established [9, 39].

Here are some steps, as well as suggested support and tools, offered by the WeShare consortium, along with supporting documents or recommendations:

Co-Creation Actions	**Support and Tools Offered by WeShare**	**Useful Resources and Recommendations**
Identify and recruit stakeholders (patients, researchers, healthcare professionals, social workers, associations, family caregivers, citizens, institutions, organizations, or other entities that influence or are influenced by the subject of analysis)	**=> Leverage the WeShare network and its communities of researchers and citizens.** **=> Contact the WeShare team for personalized support and guidance.**	- Depending on the study sponsor and its objectives, patients may be recruited through partners such as Seintinelles, Patient Committees of Comprehensive Cancer Centers (CLCCs), and patient representatives from the R&D department at Unicancer, patient associations, the French Cancer League, the Patients' University, or European structures such as EUPATI. - Other stakeholders should be approached based on the type and focus of the study.
Clearly define the roles and responsibilities of stakeholders, the process steps, and expectations for their involvement	**=> Contact the WeShare team for personalized support and guidance.**	You can also consult the PCORI resources available at the following link: https://research-teams.pcori.org
Co-Creation Actions	**Support and Tools Offered by WeShare**	**Useful Resources and Recommendations**
Include stakeholder participation in the study budget.	- It is important to consider from the beginning of the research whether stakeholder involvement should be factored into the study's budget. Note: The WeShare team is not responsible for determining the applicable budget.	- Example: reimbursement of travel expenses, meals, or even gift cards/compensation (depending on the study and institution). - You can consult PCORI's compensation framework for engaged research partners here: https://www.pcori.org/sites/default/files/PCORI-Compensation-Framework-for-Engaged-Research-Partners.pdf
Ensure the involvement of multiple patients to promote diversity	**=> Contact the WeShare team for personalized support and guidance.** Through the Unicancer network, the patient committee at Gustave Roussy or other Comprehensive Cancer Centers (CLCCs), representatives from the French Cancer League, the Patients'	Recommendations: - See Section 4.2 - Recommended number: generally 6 to 8 stakeholders, with at least 2 patients - Ensure diversity in characteristics such as age, gender, and socioeconomic status
Recruit stakeholders		It is preferable to include a mix of stakeholders in order to capture the perspectives of both individuals who are new to research and those who are more educated or trained in research. However, depending on the study's objectives, it

	University (Sorbonne), or online via the EUPATI network of expert patients (https://fr.eupati.eu).	may be more appropriate for the stakeholders to be either research-naïve or research-educated.
Co-Creation Actions	**Support and Tools Offered by WeShare**	**Useful Resources and Recommendations**
Provide training in participatory research and/or clinical research and/or the specific study, and supply informational materials tailored to stakeholders.	For study-specific training, we recommend a personalized program tailored to the study protocol's topic (delivered remotely and/or in person), consisting of at least two sessions of two hours each. **=> The WeShare team offers a Wiki Module to facilitate the sharing and exchange of documents, enabling you to train the stakeholders involved in your projects.**	Participatory Research Training Below is a selection of training programs available for patients (this list is not exhaustive): Patients' University: Université des Patients – Transforming patients' experience into expertise Seintinelles Training: scheduled for release in 2025 Eupati toolbox : https://toolbox.eupati.eu/guidance/
Value stakeholders	_	Plan, for example, to involve stakeholders and include them as co-authors in communications such as posters, abstracts, and articles.

5.2.2 Co-creation phase

The co-creation phase is the stage during which the co-creation process itself takes place. Several methodologies or co-creation actions exist and can be used simultaneously or to address the same objective. Below are some strategies along with suggested tools, supporting documents, and recommendations:

Co-Creation Actions	Support and Tools Offered by WeShare	Useful Resources and Recommendations
Organization of a workshop with stakeholders	**=> The WeShare team offers a Videoconferencing and Audio Transcription Module (feature planned for 2025).**	Possibly during the study design, protocol preparation phase, operational phase, results phase, etc.Idéalement en 4 grandes étapes : - Design phase (at least 1 working workshop); - Preparation phase of study documents: protocol, information sheet and consent form, etc. (at least 2 working workshops); - Operational phase of the study (at least 1 working workshop); - Results communication phase (at least 1 working workshop). It should be conducted by a professional trained in participatory research or interview techniques (ideally with experience in conducting group interviews).
Co-Creation Actions	**Support and Tools Offered by WeShare**	**Useful Resources and Recommendations**
Distribution of questionnaires	**=>** The WeShare team offers an ePRO (electronic Patient Reported Outcomes) Module: a module managing the distribution, completion, and recording of ePRO data and non-standard questionnaires.	

Co-design	**=> Conduct qualitative research through co-design with research teams partnered with WeShare:** **=> Contact the WeShare team for guidance.**	Organization by a third party or a neutral individual (if feasible) can be beneficial for the results obtained. Each team may use different methodologies (e.g., the System Oriented Dialogue Model (SODM)).

5.2.3Co-Creation Evaluation Phase

The co-creation evaluation phase corresponds to the stage during which the implementation of co-creation is assessed. It should be planned and conducted only if it has a significant impact (e.g., evaluation of the co-creation process, improvement of co-creation for future research). An evaluation of the co-creation process and its outcomes can be performed at several levels:

1. The impact of co-creation on the study/clinical trial protocol and the implementation of the study/clinical trial. These data can be extracted from transcriptions of focus groups, study materials (protocol, cross-checking of suggestions and protocol modifications):
   - List of actions suggested by stakeholders and their implementation,
   - Changes to the original study design or outcome measures,
   - List of actions to consider in future research.

2. Experience, motivation, and satisfaction of stakeholders and researchers regarding the co-creation process.

Co-Creation Actions	**Support and Tools Offered by WeShare**	**Useful Resources and Recommendations**
Organization of focus groups with stakeholders	**=> The WeShare team offers a Videoconferencing and Audio Transcription Module (feature planned for 2025).**	It should be planned and conducted only if it has a real impact. The objective is to deepen the understanding of researchers' and stakeholders' opinions regarding the co-creation process and to examine the key determinants of effective co-creation as well as the contextual factors associated with successful implementation. This includes identifying areas for improvement, motivations, barriers, expectations regarding participation in co-creation, and overall satisfaction. Interviews will follow a predefined guide that can be adapted to meet the specific needs of each study. They will be recorded for analysis, transcribed verbatim with identifiers removed, coded, and analyzed using standard qualitative research methods, including thematic content analysis.

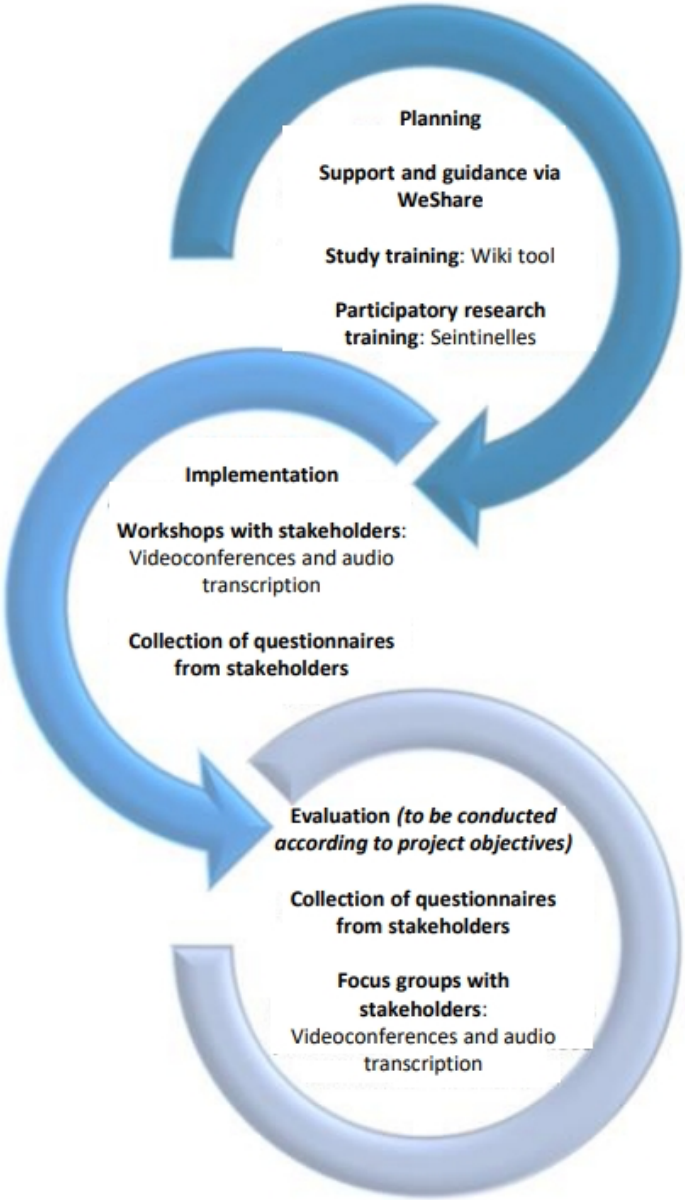
Distribution of questionnaires	**=> The WeShare team offers an ePRO (electronic Patient Reported Outcomes) Module: a module that manages the distribution, completion, and recording of ePRO data and non-standard questionnaires.** Stakeholders' and researchers' satisfaction with the co-creation process can be evaluated using an ad hoc questionnaire included in the WeShare ePRO library. This questionnaire aims to assess participants' and researchers' experiences, their engagement, and the level of collaboration. A 5-point Likert scale (strongly disagree, disagree, neutral, agree, strongly agree) can be used to measure the experience of the co-creation process.	For stakeholders, the aspects evaluated may include: their understanding of their role in the co-creation process (clarity and effectiveness of communication), comfort and sense of safety during focus groups, the opportunity to express themselves and be heard during discussions, the use of their contributions in the research, their level of satisfaction with the co-creation process, recommendations to others, and willingness to participate in co-creation again. For researchers, the aspects evaluated may include: the perceived usefulness of co-creation focus groups for their research, the added complexity from stakeholders' suggestions, the perceived improvement of the protocol following the co-creation process, their level of satisfaction with the co-creation process, recommendations to others, and willingness to participate in co-creation again.

3. Engagement in the Co-Creation Process:

- Researcher interest: Number of focus groups organized
- Participation: Number of participants in each focus group
- Retention: Number of stakeholders who remained engaged throughout the entire co-creation process

5.2.4 Services Offered by WeShare

This diagram summarizes the different possible stages of co-creation, as well as the services offered by WeShare.


Planning
Support and guidance via WeShare
Study training: Wiki tool
Participatory research training: Seintinelles
Implementation
Workshops with stakeholders: Videoconferences and audio transcription
Collection of questionnaires from stakeholders
Evaluation (to be conducted according to project objectives)
Collection of questionnaires from stakeholders
Focus groups with stakeholders: Videoconferences and audio transcription

6. Ethical and Regulatory Considerations: Stakeholder Information

As with any clinical study or trial, stakeholders must be informed about the proposed co-creation process. The information sheet or non-opposition letter must specify:

4. The context of the co-creation process
5. The objectives and structure of the co-creation process: organization of workshops or focus groups, video/audio recordings, data collected, etc.
6. The different stages of the co-creation process
7. The protection of personal data
8. Stakeholders' rights and how to exercise them

⇨ **The WeShare team provides you with a template.**

Use the WeShare eConsent module: this is a digital consent tool offering an efficient, paperless solution for presenting information sheets or non-opposition forms (text/video) and for capturing consent signatures (simple or advanced electronic signatures).

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9. Supplementary Material

1. Key Steps in Participatory Research During the Course of a Clinical Study/Trial

In practical terms, co-creation involving patients—as well as all relevant stakeholders—can be implemented at multiple stages of a clinical study, as outlined below:

1) **Definition of Research Priorities:** Stakeholders can participate in defining and evaluating research priorities, playing a critical role in developing, refining, and prioritizing research questions or strategies. Several approaches may be used to identify research priorities, including gap analyses, early horizon scanning, assessments of unmet research needs, and defining added value or outcomes that are meaningful to patients. To identify unmet needs, stakeholders can participate in focus groups or discussion panels.
2) **Funding :** Stakeholders may support research funding efforts by contributing to grant applications, forming partnerships with pharmaceutical companies, organizing fundraising initiatives, or identifying new sources of funding through the proposal of novel research topics.
3) **Protocol Synopsis**: Stakeholders can contribute to drafting the study synopsis (e.g., indication, primary and secondary objectives, study design, inclusion and exclusion criteria, methodology, primary and secondary endpoints, sample size, study duration). They can help identify acceptable comparators (e.g., best standard of care versus placebo, or pharmaceutical versus non-pharmaceutical interventions), relevant outcome measures (e.g., treatment-free survival, progression-free survival, or overall survival), appropriate target populations, acceptable levels of risk relative to potential benefit, and the clarity of patient-facing documents (e.g., information leaflets and informed consent forms).
4) **Protocol Design**: Stakeholders can assist in defining outcome measures that are meaningful to end users, balancing benefit-risk profiles (and minimizing risks), setting inclusion/exclusion criteria, and ensuring these do not exclude those most in need or most likely to benefit. They may promote inclusion of patients who reflect the broader, unselected population, ensure the integration of patient-reported outcomes (PROs), and address ethical considerations such as the handling of sensitive patient information. Ethical review boards increasingly require evidence of stakeholder involvement in the development of patient materials. Stakeholders can also assess whether the study aligns with the proposed target population's needs, its potential to generate meaningful outcomes, and the feasibility of participation based on patient needs, logistical considerations (e.g., visit frequency, remote monitoring availability), and treatment adherence.

5) Patient Information and Informed Consent: Stakeholders can contribute to the clarity and effectiveness of informational materials by advising on content, structure, and visual presentation. They can help ensure readability and comprehension for all participants by choosing appropriate language levels and avoiding ambiguous or overly technical language.

6) Ethics Committee Submission: Stakeholders can assist in preparing documentation for ethics committee approval (e.g., IRBs, CPPs, or data protection authorities such as the CNIL in France), ensuring all documents are appropriate and accessible to study participants.

7) Trial Steering Committee: Stakeholders may support protocol oversight by contributing to protocol updates, addressing accessibility issues, and improving adherence to study procedures.

8) Participant Communication: Stakeholders can assist in drafting amendments to correct errors or add important safety information, ensuring participants are kept fully informed throughout the study.

9) Investigator Meetings: Stakeholders can review study design, provide input on recruitment strategies (e.g., offering insights into recruitment challenges), and raise concerns that may prompt protocol adjustments.

10) Study Report: Stakeholders can assist in drafting a more meaningful and comprehensible summary of interim results (e.g., by helping to communicate the findings and their relevance to the broader patient community, thereby enhancing understanding and supporting continued participation in studies); dissemination within the patient community and to other stakeholders.

11) Post-Study Communication: In recognition of their contribution to the study, stakeholders may be involved in publications (including writing and being listed as co-authors) and in the dissemination of research results to the patient community, professionals, end users, and other stakeholders. This may include developing updates, feedback materials, and thank-you letters for participants, as well as preparing plain-language summaries of the results with clear explanations of the potential benefits and risks for patients.

12) Regulatory Affairs: Patient representatives may be involved in advisory groups of the European Medicines Agency (EMA) and certain national competent authorities across Europe. When applicable, they may also participate in the evaluation of marketing authorization applications (MAAs), the review of European Public Assessment Report (EPAR) summaries, updates to patient information leaflets, and the development of safety communications that clearly describe and contextualize any new safety issues identified during clinical trials from the patient perspective.

9. Stakeholder communication

Participant Information Sheet and Non-Opposition Letter Template
Information Sheet and Informed Consent Form Template

=> Please contact the WeShare team to obtain the templates available through the eConsent module.