WeShare user guide for improving inclusion, diversity, and respect in Quality of life and social and human sciences focused Research

WeShare believes in the critical importance of improving diversity, equity and inclusion in research. The importance of principles are outlined in recent guidelines emphasizing that clinical trials must be more relevant to the populations most likely to benefit from their outcomes *(Bagley et al., 2016)*. To enhance both the effectiveness of clinical trials and patient participation, researchers can take several strategic actions. The points below serve as an initial guidance for researchers using the WeShare platform. Several projects are ongoing within our WeShare Research Group with the aim of generating evidence and tools to continuously update and feed this guidance – Learn more about it at the end of the page.

PLANNING OF A CLINICAL TRIAL

1. **Prioritize co-creation with end-users.** To ensure that research trials are as relevant, convenient, and effective as possible, the active involvement of patient representatives and other stakeholders has increasingly been encouraged. The concept of engaging end-users—those who may ultimately benefit from research outcomes—in the development process is now widely recognized as a critical and normative aspect of clinical research. This shift is reflected in the growing emphasis placed on patient and citizen engagement by regulators and funders. WeShare has supported several trials that adopt this participatory approach and actively encourages researchers to integrate co-creation into the design of new studies.

   Establishing a Co-Creation Board—comprising diverse individuals who represent the target population affected by the project's outcomes—can provide valuable perspectives often overlooked by researchers throughout the duration of the project. This includes insights on understandability of electronic patient-reported outcomes (ePROs) and other trial documents, feedback on interventions, trial design, and necessary adjustments during follow-up. Patient input can be gathered through collaborative, iterative workshops between patients and study researchers, conducted in a living-lab setting. In these sessions, patients with prior trial experience can share their testimonies, offer insights, and suggest improvements for future studies. Co-creation is encouraged throughout all phases of a clinical trial, fostering stronger connections and building trust between the scientific community and end-users, and ensuring research is more aligned with patient needs and perspectives.

2. **Leverage pragmatic trial design.** Pragmatic trials are specifically designed to evaluate the effectiveness of interventions within the context of routine clinical practice. Unlike traditional trials conducted in highly controlled settings, pragmatic trials aim to reflect real-world conditions by adapting interventions for everyday use. By employing broader inclusion and exclusion criteria, pragmatic trials make participation more accessible, resulting in a study population that better represents the real-world patient population. This approach addresses a key limitation of conventional trials—limited external validity. WeShare actively supports pragmatic trials as a way to bridge the gap between clinical research and the clinical care pathways that characterize everyday healthcare delivery.

RECRUITMENT

3. **Build an inclusive recruitment and inclusion strategy**. Propose and explain the study to a potential candidate regardless of socioeconomic status, gender or age. Make sure patients understand what is at stake in your research:

i. Take the time to give participants explanations before inclusion: sometimes, patients decline or drop out of a study due to secondary misunderstandings. Before the inclusion, be sure to explain to the patient about: (a) study design (randomization, placebo, blinding, anonymization), (b) expected benefits and risks related to the study, (c) what is expected from the participant in the study including periodicity of answering PROs (d) reasons to stay enrolled, and the possibility to leave at any time, and (e) expected time to access the first results of the study.

ii. Create patient centered support information to allow agile communication with patients and enhance their understanding of your study and the role they may play in it. Use different methods to deliver information about the research planned to boost inclusion and diversity in your recruitment: the use of various communication channels (direct contact with the physician, multidisciplinary team, patient community and associations, paper and virtual flyers, social media campaign, e-mail) could reach a more extensive and diverse research participation.

iii. Make sure to include underrepresented populations in clinical trials. Individuals from lower-income backgrounds often face structural challenges that hinder their involvement in research. Many have jobs with limited access to paid leave or flexible scheduling and may shoulder caregiving responsibilities for children, elderly family members, or both. These obligations make it difficult to comply with rigid clinical trial visit schedules. The challenge is even greater for those living in rural or remote areas, who may need to overcome logistical and financial obstacles to access trial sites. Addressing these barriers is essential for fostering equitable participation. Increasing the diversity of patients in clinical trials enhances the generalizability and relevance of study findings. When minority populations are underrepresented, it can lead to biased conclusions and potentially harmful outcomes.

iv. Offer healthcare providers training on implicit bias. WeShare participates in trials in which investigators received access to an online course on real-world examples of implicit bias drawn from community-based cancer programs and that offers practical strategies for reducing disparities in cancer research settings. By completing this training, participants will be better prepared to foster diversity, equity, and inclusion in their clinical trials.

DATA COLLECTION

4. **Conduct live inclusion tracking.** Collecting a minimum set of sociodemographic data in your study can give you a better understanding of the real-time representation of different patient groups and

the diversity of your participants. It can also help to flag a lack of diversity or an underrepresented population. This allows researchers to take targeted action to improve their recruitment strategies, as needed. Depending on your research objectives it can also provide insights on how social determinants of health and social disparities impact outcomes in oncology. WeShare proposes a minimum set of sociodemographic variables to be collected longitudinally and in real-time during your study.

5. **Use validated questionnaires.** Whenever possible, opt for a validation questionnaire when selecting the patient reported outcomes (PROs) to be included in your study. Questionnaires should ideally be validated in the scope of your research, the language, and the study population. WeShare proposes a library of validated ePROs tested and regularly implemented by the WeShare user committee.

6. **Choose questionnaires wisely.** It is important to adequately consider the amount and frequency of PROs that you will ask study participants to complete. A study with a high number or very long questionnaires could reduce the patient's interest in participating and consequently reduce adherence and retention in the study over time. Respect participants' time devoted to the study by not asking them to complete repetitive or overly long questionnaires. If you have doubts of the acceptability of your proposed questionnaire administration, the WeShare patient and participant community can help you to select and test the set of questionnaires that you would like to include in your study *(Chiodi, C. et al., 2024).*

   Study materials and questionnaires should be adapted to participants' literacy and should be easy to read and understand. A key strategy for promoting participant comprehension is the use of plain language (ideally at the sixth grade level or below, but acceptable until the 8th grade level). In addition, the WeShare ePRO library will offer you a readability and understandability index for each questionnaire, to facilitate your understanding of which questionnaires are most or least accessible and what educational level should be expected for a study participant to have a clear understanding of questionnaire content. The ePRO platform should also be easy to understand and navigate, so it is important to prioritize digital platforms that have been developed with specific accessibility considerations in mind.

STUDY CONDUCT

7. **Integrate digital technology.** Digital health technologies in clinical trials represent a shift away from traditional, centralized, often urban research centers toward more participant-centric models, often bringing trial activities directly to individuals' homes or nearby locations. Advancements in digital tools now allow for seamless virtual interactions between trial teams and participants, which can significantly enhance accessibility to participation in a clinical trial. Nevertheless, it is important to proceed carefully with the integration of digital tools.
   A digital navigator or digital navigation services may be offered to patients with reduced technology access or who are not comfortable with the use and navigation of digital devices. In-person support

with tablets or computers in the research centers may ease this transition process and aid in the uptake of digital technologies in the clinical research setting. A dedicated support phone call may also help patients navigate the ePRO system, especially during their first decentralized connection and completion of ePROs. You may also provide the option for participants to complete paper questionnaires at the research center or at home and then posted by mail, to not exclude patients who do not have digital devices such as a personal computer or smartphone available to them.

8. **Be flexible.** Offer a flexible schedule and adequate time to research participation, including questionnaire answering, key informative interviews, and focus groups. Providing a flexible schedule on different days makes participation possible for participants with different availabilities. Offer digital navigation if using technology devices for patients with lower digital literacy.

9. **Think multilingual.** Consider providing study information material, ePROs, focus groups and key informative interviews in different languages. This allows the inclusion of foreigners or refugees that don't speak the official country language.

10. **Say thank you.** Acknowledge the participant's effort. Thank you messages or thank you gifts can be a form of valuing participation and may also improve study retention.

11. **Communicate study developments and results.** Don't forget to share the results of your study with the participants. You may prepare specific informative material for study participants that is written in lay language. Different communication channels can be used (social media, press, education days, etc). It is an opportunity to thank the participant and show how their participation accelerated research and contributing to a scientific develop in the field.

Learn more about ongoing WeShare initiatives:

1. The participant in the center:

i. A WeShare user's committee has been formed with patient and citizens representatives. This group meets periodically with WeShare's research team, scientific coordinators and the technical infra-structure team in a living lab hosted by WeShare to co-create the platform. Weshare also boosts co-creation among the studies that use the platform.

2. Language matters for us:

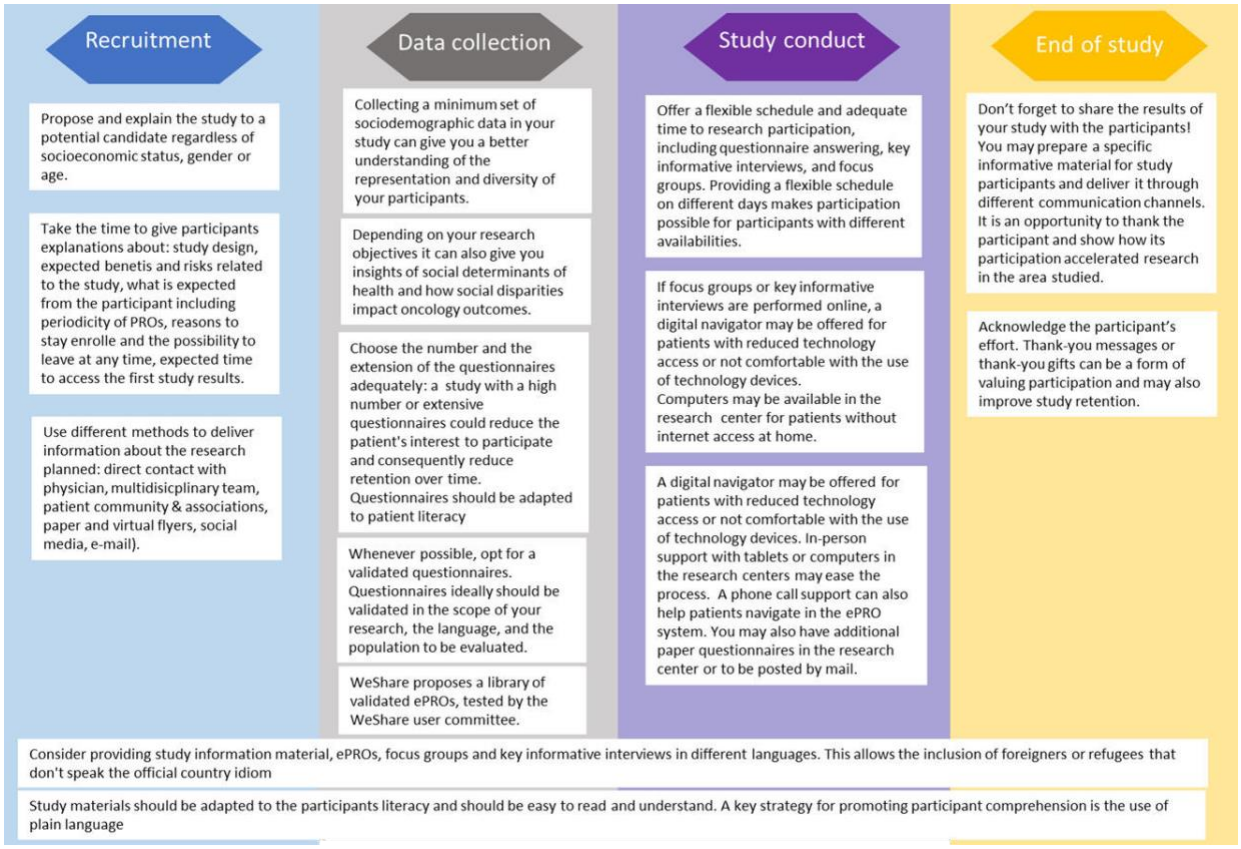
i. Understandability and readability scores help researchers assess how difficult a questionnaire may be for study participants to comprehend and engage with. National and international authorities recommend that public materials have a readability level no higher than the sixth to eighth grade level. WeShare is currently assessing the readability and understandability scores of our PRO library so that researchers can have this information when choosing a questionnaire.

ii. Using a participant-friendly language may impact study retention and make questionnaires more pleasant for study participants. We are assessing participants' perspectives and experiences regarding the introductory questionnaire language used in our PRO library.

iii. WeShare is working to have the PRO library available in several languages as well as multi-language translation modules for study materials.

3. We want to understand and reduce barriers to study participation:

i. Participants with lower economic income or educational level are frequently underrepresented in QoL research. WeShare will participate in qualitative and quantitative studies in partnership with ONGs dedicated to help vulnerable patients with cancer to understand potential barriers and facilitators of study participation. **Initial WeShare User Guide for Inclusion, Diversity, and Respect in PRO research:**



WeShare will continuously feed the initial user guide through its ongoing research projects and co-creation with We Share's user committee.