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PERSPECTIVES

Enhancing accessibility and impact of digitally enabled clinical trials: the WeShare engagement and equity toolkit

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Digital technologies are advancing rapidly, reshaping the way we design, operate, and execute clinical trials. Digitally enabled trials are particularly well-positioned to accelerate the implementation of oncology research by streamlining key clinical trial processes such as screening, recruitment, consent, data collection, follow-up, and intervention delivery. Ensuring engagement and addressing equity concerns are critical to the success of these trials, especially if the goal is for digital health to act as an equalizer, reducing existing and persistent disparities in oncology care. This perspective emphasizes the development and implementation of a comprehensive toolkit to tackle engagement and equity challenges within digitally enabled clinical trials.

Key words: health equity, engagement, digitally enabled clinical trials, diversity and inclusion, implementation science

Inclusion of diverse populations in clinical trials improves the generalizability of scientific outcomes and enhances the capacity of research to affect policy and practice. It also contributes to health equity by giving all potential participants the same opportunity to access innovations in care and research. In oncology, and in several other health practices, it is established that clinical trial populations do not reflect the real-world population.[1] Clinical trials often exclude older adult patients, patients with comorbidities, patients living in rural areas, and patients belonging to a marginalized racial, ethnic or lower sociodemographic group, despite increasing concern about this issue among policymakers, patient advocates, medical society, and some industry leaders.[2-11]

FACILITATING A DIVERSE PARTICIPATION THROUGH DIGITALLY ENABLED CLINICAL TRIAL PROCEDURES

Digital health has the potential to overcome many of the barriers and constraints that typically affect the operation of clinical trials. As previous research has shown, many clinical trial procedures can be digitized, including eligibility screening, eConsent, randomization, teleconsultation, the collection of patient-generated data [electronic patient-reported outcomes (ePROs), biosensors] including remote monitoring of adverse events, automatic capture of clinical data from electronic health records, and delivery of research interventions.[12-17] This can enable remote participation, offering greater convenience for patients with demanding work schedules, those who live far away from cancer centers, or individuals who have difficulty traveling due to health reasons or lack of family support.[18]

While these digital tools are well-positioned to reduce inequalities and expand the reach of clinical research, structural barriers at the patient, provider, and health care system levels can still hinder full participation in research or prevent certain groups from benefiting.[18-20] For this reason, we argue that if patient engagement and equity considerations are not carefully integrated during the design and implementation of digitally enabled trials, these trials risk replicating the limitations of traditional studies— reaching only highly educated and privileged populations, and missing an opportunity to serve as a true equalizer in health care.

In this context, the WeShare consortium (https://weshare.unicancer.com/), an academic web platform for digitally enabled research, has been developing a toolkit of key components to ensure digitally enabled trials are accessible and impactful for all participants (Figure 1). This toolkit is being implemented and tested within different pilot studies at the national and international level (Table 1) and it includes the following components.

Co-designing digital tools and trial interventions with all stakeholders including patients

A key element in creating successful and engaging interventions that effectively reach real-world populations is

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Figure 1. WeShare engagement and equity toolkit for digitally enabled research.
ePROs, electronic patient-reported outcomes.

the ability to co-design them from inception with end users, including a diverse group of patients. In this context, the development and prototype testing of digital platforms should involve a wide range of stakeholders, such as patients (with a variety of digital literacy levels), family members, health care providers, researchers, technology experts, and legal and regulatory professionals.[21] This process is crucial for shaping these platforms to meet the needs of the end users while also identifying potential barriers to access and engagement at multiple levels before implementation.

Similarly, many clinical trial protocols tend to be overly provider-centric and may not fully address the needs of patients, family members, or regulators.[22,23] Digital platforms can be leveraged to engage digital communities in the co-design of research protocols.[24] This approach is exemplified by the EU-funded PragmaTIL[25] and PATH-FOR-YOUNG trials,[26] where researchers from the WeShare platform are actively involving stakeholders from protocol development and across the entire project.

Qualitative research methods[21,27-29] and frameworks from implementation science[30] can guide this process and are being used in the setting of the WeShare platform and WeShare studies.[31] Multiple rounds of virtual focus groups can be conducted throughout the entire project lifecycle—covering exploration, preparation, implementation, and sustainability phases—to achieve these objectives. A guide for co-creation will be available to WeShare researchers.

Considering readable, understandable, and multilingual clinical trial materials

Clinical trial informational materials and instruments used to collect patient-generated data should be accessible to all patients. Substantial evidence, however, shows that many patient-facing materials, including consent forms, informational notices, and patient-reported outcome measures, often fail to meet readability and understandability standards.[32-36] Moreover, considering global patterns of migration and increasingly diverse national populations, limiting clinical trial information to a single language can pose a significant barrier to the enrollment of non-native speakers in clinical trials.[37]

Table 1. Components of WeShare engagement and equity toolkit and its implementation in selected pilot studies

Selected pilot study	Pragmatic trial design	Co-design with stakeholders	Readable and understandable patient-facing trial materials	Multilingual trial materials	Embedded supportive care and self-management support	Engagement and retention feedback loop	Collection and monitoring of inclusion and sociodemographic metrics	Implicit bias training	Digital navigation support	Online eligibility screening and referrals
STEPPINGSTONE (NCT06505590)	✓		✓		✓		✓		✓	✓
PATH FOR YOUNG (EU101156800)	✓	✓	✓	✓	✓		✓	✓		✓
PRAGMATIL (NCT06630611)	✓	✓	✓	✓	✓					
CANTO ATTITUDE (NCT01993498)			✓			✓	✓		✓	

Within the WeShare consortium, we advocate for the development of digital patient-facing clinical trial tools, both for informational purposes (patient-facing animation videos explaining the clinical trial pathway) and data collection (ePROs), in multiple languages. We also emphasize the importance of considering readability and understandability metrics to ensure that research instruments and materials are as accessible and inclusive as possible.

Collecting and monitoring inclusion and sociodemographic metrics in clinical trials

A critical step in understanding health care disparities and developing effective interventions is the ability to measure the prevalence of disparities and the gaps in inclusive participation. While growing attention has been given to the role of social and environmental factors in cancer care—particularly in relation to access, treatment response, adherence to treatment plans, and participation in clinical trials—there remains a lack of standardized data collection on social determinants of health (SDOH) and health-related social risks within oncology trials.[38-40] Many clinical trials still do not systematically capture this information, thereby limiting their ability to address existing disparities.

Within the WeShare program, we have collaborated with inequality researchers to develop a standardized dataset of key SDOH indicators and health-related social risks, designed to be measurable across clinical trials. This standardized approach can facilitate more consistent and meaningful comparisons across studies.

Inclusion and diversity metrics

The use of digital research platforms provides an opportunity to collect and monitor inclusion and diversity data in real time. This capability not only enables the identification of underrepresented groups in a trial's patient population, but also facilitates timely action planning with research centers.

The WeShare platform provides real-time sociodemographic data and periodic reports to researchers to inform them of the quality of diversity and representation in the recruited sample compared with the target patient population. With these data, researchers can make informed changes to recruitment processes to include a more representative patient population, and thereby enhance the quality of their data sample and generalizability of research outcomes.

Additionally, by implementing equity-focused interventions, such platforms can also enhance recruitment among patients who are often excluded from trials and are in greatest need of targeted care.

Risk factors and health-related social needs metrics

In addition to collecting and monitoring inclusion and diversity metrics with the goal of addressing clinical trial access barriers, incorporating standardized and systematic collection of SDOH and health-related social needs can significantly enhance our understanding of disease, patient experiences, and health system interactions. Embedding these metrics into trial toolkits enables researchers to

analyze how factors such as transportation access, housing instability or financial strain impact study participation and outcomes. Including such data as covariates in analyses strengthens the validity of findings by reducing confounding and helps identify context-specific disparities. Moreover, institutionalizing the routine assessment of SDOH and health-related social needs fosters a culture of equity-driven care and research, ensuring that future trial designs are more inclusive, representative, and attuned to the real-world environments of diverse populations.

Eligibility screening and easy access to research centers

Implementing a comprehensive and effective eligibility screening and recruitment process is crucial for ensuring the inclusion of a diverse population in clinical trials. It is not uncommon, however, for clinical trials to be unavailable at the centers where clinicians practice or where patients receive treatment. The referral process often depends on the physician's knowledge of available trials or on patients' networks to learn about open studies.

Digital platforms, leveraging artificial intelligence (AI) methodologies, now offer the capability to map existing trials at both national and international levels.[41-43] These platforms allow patients to easily self-screen for eligibility and then suggest suitable clinical trials to their clinicians. Additionally, clinicians can directly refer patients to research centers, thereby democratizing access to clinical trials and improving trial recruitment.

Too stringent clinical trial eligibility criteria represent a potential limitation to this approach, as algorithms rely on inclusion/exclusion criteria that may disproportionately exclude patient populations that are underrepresented in trials.[44-48] Despite the extended reach of clinical trial recruitment facilitated by AI algorithms, narrow inclusion/exclusion criteria may further exacerbate disparities and skew the sample population by continuing to exclude patients who are disproportionately underrepresented in clinical trials and enhancing access for those patients who are already well represented. These strategies can help increase reach but must also be linked to more pragmatic and generalizable inclusion criteria to fully achieve this goal.

As part of the WeShare program, we are collaborating with such platforms within the European Union funded PATH-FOR-YOUNG trial[49] to facilitate digital recruitment for this trial, streamlining the process and making it more accessible to both patients and providers in different European Countries and simultaneously promoting the adoption of thoughtful eligibility criteria to not further exclude patients from accessing and participating in clinical trials.

Embedding supportive care planning and empowerment tools within clinical trials to address structural inequalities

As with traditional clinical trials and routine clinical care treatments, access to and retention in digitally enabled trials can be hindered by structural inequalities that affect patients' daily lives.[50] These barriers may include unmanaged physical symptoms, socioeconomic challenges, and a lack of psychosocial support.[51] Supportive care plays a critical role in comprehensive cancer care delivery, particularly in managing symptoms, enhancing quality of life, and facilitating daily living. Such supportive care interventions can also help overcome enrollment and retention barriers linked to inadequate supportive care delivery and symptom management, and thus enable patients to engage more fully in clinical trials and have a more positive experience.[52] Such interventions may include nurse navigation, social support, access to pain management, return-to-work assistance, psychological support, adaptive physical activity, nutritional counselling, and mind—body therapies.[53]

Incorporating supportive care planning and delivery into the design of clinical trials requires researchers to map the standard supportive care resources available at recruiting centers and nearby community-based associations. Additionally, digital tools can be activated to provide supportive care within clinical trials such as remote symptom monitoring apps, and patient educational and empowering portals.[54,55] These tools, employed within some of the studies being carried out in the setting of WeShare, aim to reduce the impact of structural inequalities, address disparities in supportive care delivery, improve symptom management, and ultimately foster a more positive experience both in care and research.

Engagement feedback and community building

Several clinical trials have highlighted the challenges of maintaining patient engagement in long-term follow-up procedures, particularly when it comes to quality-of-life data.[56-58] These long-term data, however, are crucial for understanding the sustained impact of our oncology practices on patients' quality of life, improving care delivery, and shaping health policies effectively.[59] Sustaining long-term engagement can also be challenging in digitally enabled trials, where in-person visits with the research team may be limited and communication with the research team less personal.[60,61]

At the same time, digital infrastructures offer an opportunity to leverage advanced communication, engagement, and community-building techniques between patients and researchers. Examples include using digital tools to provide real-time feedback to participants through personalized messages, reminders, thank-you notes, and acknowledgments related to trial procedures, as well as continuously sharing both early and long-term trial results throughout the study.[62] Additionally, online features can facilitate connections between participants and researchers, enabling the creation and management of online patient communities, launching crowdsourcing research campaigns, and organizing webinars and interactive sessions.[24]

This engagement and community feedback loop is currently being developed within WeShare and will be tested to improve long-term retention within the prospective CANTO cohort (CANTO ATTITUDE pilot study).[60]

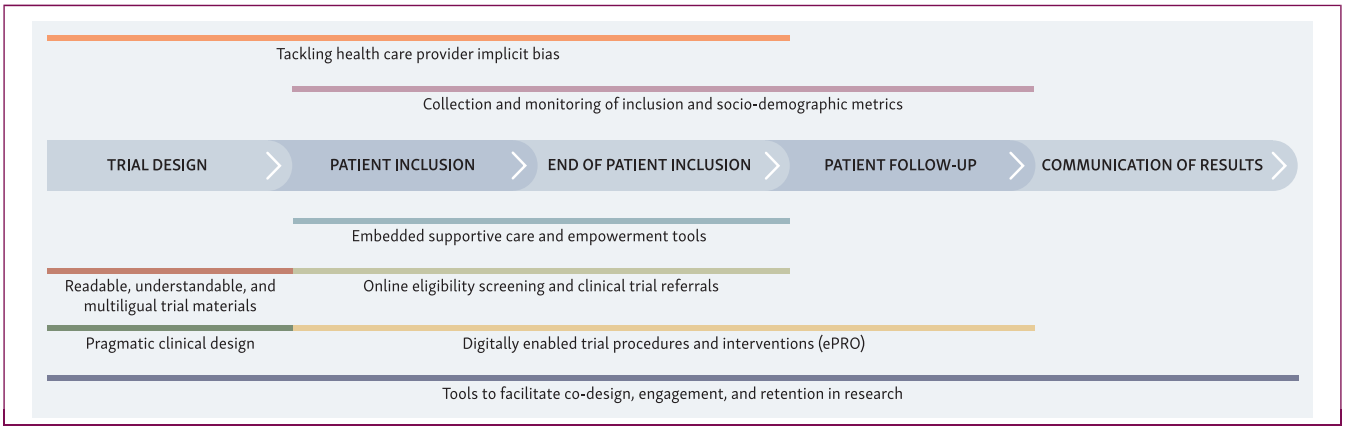

Figure 2. WeShare engagement and equity toolkit—path for young.
ePROs, electronic patient-reported outcome.

Tackling implicit bias

In addition to numerous barriers at the patient and health care system levels, evidence shows that communication and the relationship between patients and health care providers are key factors influencing a patient's decision to enroll in a clinical trial or adopt innovations in care and research.[61,62] Research has demonstrated that implicit bias at the health care provider level can prevent clinicians from proposing clinical trials and digital innovations to all eligible patients throughout their care.[63]

Training on implicit bias, equity, inclusion, and diversity—as well as on practical equity-based interventions—could be beneficial in addressing these challenges. Such training strategies have shown promise in a pilot study conducted across oncology centers in the USA.[64] Within the WeShare consortium, we aim to adapt a digital training program on implicit bias designed to help mitigate health care providers' biases when including patients in clinical trials, particularly in the setting of digitally enabled trials within the European context. Strategies such as incorporating behavioral nudges or best practice alerts to prompt trial discussions could also be considered for future development within this or similar platforms.

Providing digital navigation support

While the shift toward digitally enabled research has the potential to positively impact vulnerable populations, including those with lower digital health literacy, it has been observed that patients with limited digital literacy may be less likely to engage with digital tools.[65-67] Furthermore, digital literacy is not uniformly distributed among health care providers, which may also hinder the adoption of these tools.[68]

Digital navigation support, combined with user-centered tutorials, could potentially help address these barriers.[69] By offering individualized counselling at research centers, patients and clinical staff can receive guidance on 'why', 'when', and 'how' to use digital tools, providing a more personalized and human-centric transition to digital health care. This may also be a particularly important step to engage patients and providers who, regardless of digital literacy level, are less engaged with digital devices and would benefit from a human-in-a-loop resource. This approach is currently being piloted by WeShare partners and will be tested in the context of digitally enabled clinical trials such as the CANTO cohort and a randomized clinical trial testing a digital self-management support intervention for cancer-related fatigue (NCT06505590).

Advocating for more pragmatic clinical trials

Although sophisticated clinical trials are essential for answering a wide range of research questions—ranging from translational to biological inquiries—it is equally important to conduct pragmatic trials that address real-world questions and have a direct impact on routine care.[70,71] These trials should feature simple inclusion and exclusion criteria that reflect real-world populations, minimal data collection, and streamlined research interventions that closely mimic routine clinical practice in order to be adaptable and generalizable to various health care settings worldwide.

We believe that pragmatic trials offer an ideal platform for incorporating digitally enabled tools into trial procedures.[18] These tools can make the process more inclusive and impactful for patients, clinicians, and researchers globally.

In conclusion, addressing the many barriers related to the lack of real-world representation in clinical trials requires a multifaceted approach that encompasses diverse strategies aimed at improving accessibility, inclusivity, and equity. Through initiatives like the WeShare consortium, an engagement and equity toolkit is being tested and refined in the setting of pilot studies (Table 1 and Figure 2), with the aim of transforming participation in digitally enabled clinical trials into a more inclusive and patient-centered experience for everyone involved.

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