Clinical Trials in Global Health 1

Better engagement, better evidence: working in partnership with patients, the public, and communities in clinical trials with involvement and good participatory practice

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In May 2022, member states of WHO adopted the World Health Assembly WHA75.8 resolution on strengthening clinical trials to provide high-quality evidence on health interventions and to improve research quality and coordination. The resolution recognises the central role of community stakeholders in the clinical trial ecosystem. This paper aims to take stock of the state of the field and define key actions from stakeholders across the clinical trial ecosystem for systematic engagement of patient, public, and community stakeholders in clinical trials. Upfront, sustained, inclusive, and meaningful engagement with patients, public, and community stakeholders intended to benefit from trial outcomes is crucial for several reasons. First, better engagement ensures that trials are well designed and well implemented by considering the unique perspectives and experiences of those they aim to benefit. Second, better engagement enhances the scientific, ethical, and pragmatic value of trials by improving the acceptability, feasibility, and relevance of trial design, implementation, and outcome dissemination. Lastly, improving engagement fosters trust in science and scientists, strengthens research literacy, and contributes to greater trust in research processes. This trust is particularly important in public health emergencies where the urgency for identifying effective interventions, including new vaccines and medicines, often results in limited engagement. In practice, engagement involves activities throughout the trial lifecycle, including research agenda setting, protocol development, trial conduct, and outcome dissemination. Key stakeholders, such as researchers, funders, research ethics committees, and regulators play crucial roles in enabling and implementing engagement via participatory practices. Despite some key markers of progress, challenges remain, including systemic gaps, limited engagement beyond tokenistic involvement, and structural inequities. Addressing these challenges requires action across the clinical trial ecosystem, including strengthening policies, enhancing funding mechanisms, improving regulatory oversight, advocacy, and education of all stakeholders about engagement, and promoting a strong culture of engagement. Advancing the agenda for engagement can promote trust, ethical research conduct, and improve outcomes and wider uptake of findings.

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This is the first in a **Series** of six papers about clinical trials in global health

See **Comment** page e608

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Introduction

Science plays a crucial role in responding to 21st century health challenges.[1] Clinical trials are essential research tools for this purpose, providing high-quality evidence to steer policy and practice. The primary purpose of research involving human participants is for scientific and social value; that is, the prospect of generating the knowledge and the means necessary to protect and promote people's health.[2] At the 75th World Health Assembly in May, 2022, Member States of WHO adopted resolution WHA75.8 on strengthening clinical trials to provide high-quality evidence on health interventions and to improve research quality and coordination.[3] This resolution came at a time when the world was emerging from one of the most considerable events of the 21st century, the COVID-19 pandemic. The COVID-19 pandemic led to an unprecedented investment in evidence production, including data from clinical trials.[4,5] A decade earlier, during the H1N1 strain influenza A (ie, A[H1N1]pdm09) pandemic, no evidence from randomised clinical trials was available during the event itself to inform clinical management of patients.[6] In contrast, during the COVID-19 pandemic, over 8000 randomised trials were recorded, with 80% evaluating treatments and 17% reporting results, including several high impact trials of effective treatments that informed clinical guidance and

Key messages

- The World Health Assembly WHA75.8 resolution on strengthening clinical trials to provide high-quality evidence on health interventions recognises the central role of stakeholder engagement
- Engaging patients, the public, and community stakeholders throughout the clinical trial lifecycle—from design to dissemination—improves trial relevance, feasibility, and acceptance within the community
- Guidance and tools are available to underpin engagement efforts, but structural and system-wide change is needed
- Across the clinical trial ecosystem, all stakeholders are accountable for embedding patient, public, and community engagement in clinical trial processes

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management of patients with COVID-19, saving millions of lives.[5]

The rapid expansion in clinical trial activity during the COVID-19 pandemic revealed key challenges regarding funding and capacity disparities between high-income and low-income to middle-income countries;[7] competition for resources and participant recruitment;[4] multiple underpowered studies that yielded no outputs of social or scientific value; limited engagement of patients, the public, and communities in clinical research activities;[8] and unethical research practice.[9–11] These trends underscore research inequities, undermine trust in science and scientists, and represent a substantial waste of human and financial resource. Of note is the limited evaluation of non-pharmaceutical interventions, including a range of public health and social measures, to inform policy regarding their use.[1,12,13] Evidence of effectiveness in real-world settings, including among crisis-affected populations and those living in informal settlements, is much needed, particularly in rationalising use of interventions that restrict personal choice and liberty, such as case isolation, physical distancing, and burial constraints. The singular focus on evidence production for the COVID-19 pandemic also came at a cost to research and development for other diseases and conditions.[14] To drive an agenda of research that has social value, the effect on society needs to be accounted for. Learning lessons from the COVID-19 pandemic means calling attention to these trends and considering not just what kinds of research should be done in future pandemics, but also how this research should be conducted.

The systems and processes established during non-emergency times are foundational to drive more equitable and inclusive practice across disease areas and contexts in emergencies. Collective efforts to strengthen the clinical trials ecosystem should build inclusion and equity into the fabric of its design in ways that are anticipatory rather than reactive. The WHA75.8 clinical trials resolution recognises the central role of patients, the public, and communities in the clinical trial ecosystem and calls for well-designed and well-implemented trials. In the first paper in this Series, we make the case for upfront, sustained, inclusive, and meaningful engagement with the patients, the public, and communities intended to benefit from interventions being evaluated in clinical trials. We argue that trials are neither well designed nor well implemented if they do not account for the unique experiences and perspectives of the patients they are intended to benefit. Our aim is to take stock of the state of the field and define key actions from stakeholders across the clinical trial ecosystem for systematic engagement of patients, the public, and community stakeholders in clinical trials.

Rationale for and development of the paper

During the first WHO Global Clinical Trial Forum held in Geneva (Nov 20–21, 2023), the engagement of patients, the public, and communities for clinical trials emerged as a priority area for strengthening the global ecosystem for high-quality clinical trials. WHO convened a working group to bring together expertise from across the clinical trial ecosystem, including the voices of researchers, patient advocacy, regulatory authorities, ethicists, funders, and national public health agencies, and those working with under-represented populations that include maternal health and paediatrics. The scope for this Series paper was to be a high-level overview of the state of the field with the purpose of proposing key actions needed across the clinical trial ecosystem to strengthen community stakeholder engagement for trials. We rapidly reviewed existing guidance and evidence and deliberated about key issues. Together with wider stakeholder consultations, conducted to advance WHO guidance for good practice in clinical trials, these discussions shaped key content presented in this Series paper.

Definitions and scope

While engagement is fundamental for all forms of health research, our focus is on clinical trials and the engagement of the patients, the public, and communities intended to benefit from trial outcomes. There are no universally agreed terms for this body of work. Here, we use engagement as the umbrella term capturing the set activities to involve stakeholders in phase 1–4 clinical trials. The term good participatory practice (GPP) refers to a leading approach within engagement.[15,16] By engagement, we mean sustained, collaborative partnering with stakeholders to co-develop key aspects of trial design, delivery, and dissemination. This approach implies a working relationship where decision-making power is shared and the different kinds of expertise needed to deliver high quality clinical trials is valued equally.

By clinical trials, we quote WHO as a "research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes".[17] Also referred to as interventional trials, clinical trials evaluate treatments, vaccines, surgical procedures, devices, behavioural interventions, and other population or environmental interventions. Clinical trials can produce high-quality evidence for decision making regarding further development of the intervention and its use in real-world settings.

By patient, public, or community, we mean individuals or groups who represent the study population. These are the people to whom study findings will be generalised and those who are intended to benefit directly from the intervention under evaluation. Thus, there will be different groups of relevance for a phase 3 vaccine trial (ie, wide, highly varied population), a paediatric trial (ie, children based on age, parents, caregivers, or guardians), or a trial enrolling people living with a rare disease (ie, a closely defined patient group). Patient,

public, and community groups might extend to families and wider social networks of potential participants, and to patient advocacy groups and organisations.[15,16,18,19] The term community stakeholder is often used to refer to people living locally around trial sites who represent the enrolled trial participants in important ways.[15] The public comprises a wider population of patients and their carers, potential patients, people with lived experience, health and social care services users, and organisations representative of service users. When defining the study population and thus the patient, public, or community stakeholders for engagement, it is also important then to

	Focus	Audience	Terms and definitions for those to be engaged with
Good participatory practice: guidelines for biomedical HIV prevention trials (Joint UN Programme on HIV/AIDS, AIDS Vaccine Advocacy Coalition)[15]	Biomedical HIV prevention trials	Specific stakeholders: sponsors, principal investigators, and trial site engagement staff	Stakeholders referred to as "individuals or collections of individuals who can influence or be affected by the conduct or outcome" of a trial. Community stakeholders referred to as a subset of stakeholders, as individuals or groups representing the interests of participants, who might reside locally around trial sites.
Good participatory practice guidelines for TB drug trials (Critical Path to TB Drug Regimes)[19]	Tuberculosis drug trials	Specific stakeholders: sponsors, principal investigators, and trial site engagement staff	Stakeholders referred to as all "individuals, groups, organisations, government bodies, and communities who have an interest in the conduct and outcomes of a specific TB (tuberculosis) drug trial". Community stakeholders referred to as a subset of stakeholders, "individuals and groups that are either directly affected by the conduct of a drug trial or that represent the interests of parties that are directly affected".
International Ethical Guidelines for Health-related Research Involving Humans (Council for International Organizations of Medical Sciences, WHO)[2]	All health-related research in any setting	Specific stakeholders: ethical review of research protocols	Refers to communities but clarifies that this comprises "different sectors of society that have a stake in the proposed research".
Good participatory practice guidelines for trials of emerging and re-emerging pathogens that are likely to cause severe outbreaks in the near future and for which few or no medical countermeasures exist (GPP-EP; WHO)[16]	Trials of pathogens likely to cause severe outbreaks for which no known medical countermeasures exist	All stakeholders: governments, government-sponsored research networks, non-governmental organisations, organisations, academic institutions, foundations, public–private partnerships, pharmaceutical companies, other private or public sector entities, and research teams	Stakeholders referred to as "individuals or collections of individuals who can influence or are affected by the conduct or outcome of a trial, ie, all those who have a stake in an emerging pathogen prevention or treatment trial". Community stakeholders referred to as a "subset of stakeholders–who represent the interests of people who would be recruited to participate in a trial" and other local stakeholders.
Guidance for patient involvement in ethical review of clinical trials (European Patients' Academy on Therapeutic Innovation)[21]	Medicines research and development	All stakeholders: all involved in the ethical review of clinical research projects, with special emphasis on members of research ethics committees and patients or carers or patient representatives providing patient input	Refers to patients as "all age groups across conditions". Recommends "structured interaction between patients of all age groups and across conditions, their representatives and other stakeholders". Also, recommends "partnership between the various stakeholders including healthcare professionals' organisations, contract research organisations, patients' and consumers' organisations, academia, scientific and academic societies, regulatory authorities and health technology assessment (HTA) bodies and the pharmaceutical industry".
Good Participatory Practice Guidelines for TB vaccine research (AERAS)[18]	Tuberculosis vaccine research	Specific stakeholders: sponsors, principal investigators, trial site engagement staff	Stakeholder is referred to as anyone "who is directly or indirectly affected by TB (tuberculosis) vaccine research, who has an interest in the research and who can potentially influence the outcomes, whether positively or negatively". Community stakeholders include individuals and groups who are directly affected by tuberculosis and by tuberculosis vaccine research, and representatives of people who participate in the research.
UK Standards for Public Involvement (National Institute for Health and Care Research)[22]	All health research in the UK	Specific stakeholders: research funders and charities, members of the public, and all researchers conducting health or social care research	Refers to the public throughout, but clarifies that this includes patients, service users, survivors, carers, and family members.
Recommendations for Community Engagement in HIV/AIDS Research (Division of AIDS, National Institute of Allergy and Infectious Diseases, National Institutes of Health)[23]	NIH-funded HIV/AIDS clinical trials research	Specific stakeholders: sponsors, principal investigators, and trial site engagement staff	Community is defined as the population in and for which the research is being conducted—ie, might be further segmented into different communities depending on the nature of the research. Refers to community-based stakeholders, such as the media, policy makers, and faith-based organisations, and notes that community-based, service and advocacy organisations, political leaders, and decision makers, comprise part of the larger community.
Enhancing the diversity of clinical trial populations—eligibility criteria, enrolment practices and trial designs; guidance for industry (US Food and Drug Administration)[24]	Efficacy and bioequivalence trials	Specific stakeholders: industry and trial sponsors	Refers to community and recommends "fostering community engagement through medical societies, focus groups, Community Advisory Boards, disease registries, and community-based participatory research".
Clinical research in resource-limited settings (Council for International Organizations of Medical Sciences)[25]	Clinical research conducted in the Global South or resource-limited settings	Specific stakeholders: research ethics committee members, government and regulatory authorities, researchers and international funders, and organisations working in the Global South	Notes that engagement of "local stakeholders, including community members, study participants and family, is crucially important".

(Table continues on next page)

	Focus	Audience	Terms and definitions for those to be engaged with
(Continued from previous page)			
Ethics guidance for research (HIV Prevention Trials Network)[26]	HIV prevention research, including clinical trials, behavioural studies, implementation research, and community-based trials	Primary—ie, specific stakeholders: HIV Prevention Trials Network and other HIV prevention researchers; secondary—ie, all stakeholders: collaborating institutions, community representatives; government representatives and agencies, pharmaceutical companies and other industry sponsors, non-governmental organisations, HIV and AIDS activist groups, and ethics and scientific review committees	Refers to community and community stakeholder and notes the good participatory practice distinction between community stakeholder and broader stakeholder groups.
Ethical considerations in HIV prevention trials (Joint UN Programme on HIV/AIDS, WHO)[27]	HIV prevention trials, particularly new tools for primary biomedical prevention	All stakeholders: potential research participants, investigators, research staff, community members, government representatives, regulators, funders, pharmaceutical companies and other industry partners, trial sponsors, and ethical and scientific review committees involved—ie, development of HIV prevention products and interventions	Refers to community but recognises that the "the concept needs to be broadened […] to include advocates, media, human rights organisations, national institutions and governments" and refers to "communities of people affected by research".
Quality standards for adolescent participation in clinical research decision-making (Burke and Conway, 2022)[28]	Paediatric and adolescent research, including clinical trials	All stakeholders: funders, research ethics committees, trial managers, researchers, practitioners and patient and public engagement leads, and adolescent participants	Refers to adolescents and define adolescents as people aged between 10 and 19 years. Notes that children "are not a homogenous group and participation needs to provide for equality of opportunity for all, without discrimination on any grounds. Programmes also need to ensure that they are culturally sensitive to children from all communities".
Good clinical trials guidance for good randomized clinical trials (Good Clinical Trials Collaborative)[29]	Randomised clinical trials	All stakeholders: sponsors, principal investigators, trial site engagement staff, civil society, and funders	Refers to patients, participants, people, and "members of the relevant community" and "relevant members of the public".
International guidelines on good governance practice for research institutions (Council for International Organizations of Medical Sciences)[30]	Clinical research	Specific stakeholders: research institutions or principal investigators, and clinical trialists	Refers to key stakeholders of a research institution for communication as […] "research participants; patient groups; the general public and media; research ethics committees and regulatory agencies; professional scientific associations/organizations/networks; research project sponsors; funding bodies […]". Refers to collaborators, including "patients, families, caregivers, patient organizations, patient representatives and persons with lived experiences" (as well as many others).
Patient involvement in the development, regulation and safe use of medicines (Council for International Organizations of Medical Sciences)[31]	Medicines development, regulation, and safety	Specific stakeholders: clinical trialists and sponsors	Defines patients as "a wider group of people than just those taking medicines". The term can include patient organisations, patients' families, patients' carers, and patient representatives in various forums. All of these are said to make up the patient community.
Framework for engagement between EMA and patients and consumers and their organisations (European Medicines Agency)[32]	Medicines development, assessment, and safe use	Specific stakeholders: the European Medicines Agency	Defines patients' organisations as "not-for profit organisations that are patient focused, and where patients and/or carers (the latter when patients are unable to represent themselves) represent a majority of members in governing bodies". Defines relevant organisations as "general umbrella organisations (eg, representing either European disease-specific organisations and/or national umbrella organisations) and European disease specific organisations representing national organisations or individual patients on acute and/or chronic diseases". Defines consumers organisations as "not-for profit organisations that defend and promote the general interests of European consumers – citizens as purchasers or users of goods and services" and individual patients or carers as "people with experience of living with a particular condition who are interested in engaging with EMA (European Medicines Agency)".

Table: **Key guidance documents for and relevant to community engagement for clinical trials**

consider subpopulations, including, but not limited to, marginalised groups; migrant communities; people living with disabilities, mental health difficulties, or non-communicable diseases; pregnant women; children; adolescents; and older adults. Where possible, researchers should seek to engage with people representing these subpopulations for qualitative diversity in the composition of advisory mechanisms and to account for varied perspectives, preferences, and needs. In some cases, there might be groups or individuals who are excluded from or not recruited as trial participants under a specific clinical trial protocol, such as pregnant and lactating women,[20] and researchers should strive to engage such groups. We use the term inclusive to refer to an approach that seeks to proactively create opportunities for involvement of all relevant stakeholders.

The many guidance documents available to help researchers consider and implement participant

engagement approaches encourage moving past a narrow focus on the patient or participant in trials, or the community stakeholder that they represent, and recommend being mindful of a broader set of stakeholders that can influence the trial or its uptake (table).[15,16,27–29] This approach is consistent with the increasing recognition that for engagement to strengthen scientific and ethics outcomes, many stakeholders need to participate in trial planning, governance, and implementation activities (figure 1). For example, engagement with health providers at site level might inform feasibility and acceptability of trial procedures and reduce duplication and the burden on health workers involved in participant recruitment. Engagement with policy makers and programme implementers might ensure the uptake of results enhancing the social value of trials. Our focus in this paper on engagement with patient, public, and community stakeholders is not intended to deprioritise the crucial need for engagement with these other groups across the clinical trial ecosystem.

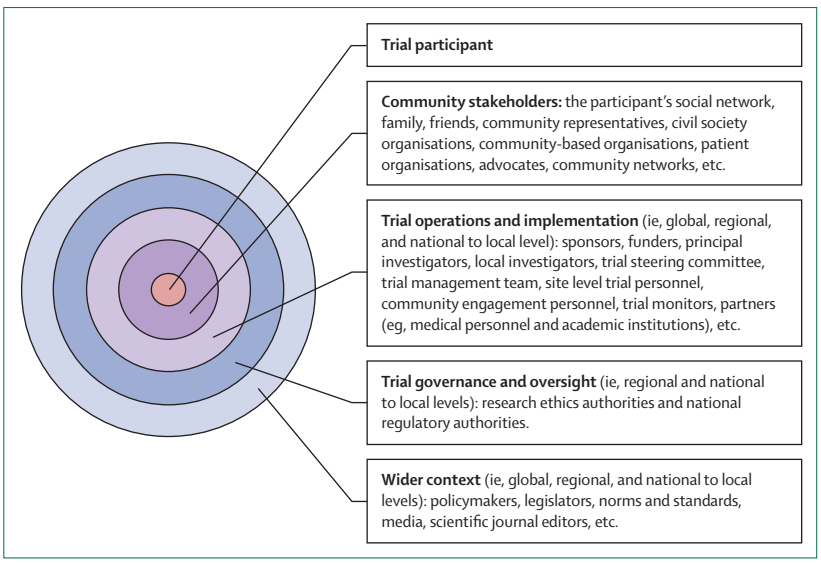

Figure 1: **Key stakeholders in the clinical trial ecosystem**
Adapted from the Joint UN Programme on HIV/AIDS good participatory practice guidelines for biomedical HIV prevention trials.[15]

Reasons for engagement and its value

The importance of engagement is widely acknowledged, and strong arguments have been made in support of the scientific, ethical, and pragmatic added value of working in a way that engages stakeholders.[33] A multitude of guidance documents,[2,15,16,18,19,21,23–31,34,35] frameworks,[33] and implementation toolkits[36] are available to steer practice at global, national, and local levels. These guidance documents vary in their aims, purpose, and intended audiences across the clinical trial ecosystem. Common across these documents is an emphasis on ethical principles, specifically of respect, fairness, integrity, transparency, accountability, and autonomy, and an emphasis on the beneficial outcomes of engagement for each principle.[15,16,31] These documents focus on a range of activities to include, involve, and collaborate with stakeholders. The documents reflect a set of values that clinical trials should be marked by equitable partnerships between researchers and key stakeholders to produce results that translate into social benefit—whether it be further research or implementation—and deliver outcomes that are responsive to patient, public, and community priorities.[37]

Beyond the moral imperative to facilitate engagement with clinical trials is the pragmatic added value that engagement with such groups brings, which improves the acceptability, feasibility, and relevance of trial design, implementation, and use of outcomes. Such groups offer valuable perspectives about the priorities, preferences, and outcomes that are relevant and meaningful to them. Contributions of these groups are key to a wide range of activities across the lifecycle of a clinical trial, including, for example, setting priorities for research or product development, optimising acceptable and feasible trial design and implementation processes; developing plain language explanations of complex trial issues;[38] and providing participant experience data for regulatory decision making. Involving under-represented groups in particular, where scientifically, ethically, and legally possible, in the planning and design stages of the trial, can support and enhance the recruitment of a more diverse set of participants, leading to better quality research that is generalisable to a wider population (ie, better in terms of scientific value) and trusted by more people (ie, better in terms of moral or social good). Clinical trials that are participant-centred in design could produce better recruitment and less drop-out.[39] Engagement of patient, public, and community stakeholders can improve consent experiences for participants, with culturally and contextually appropriate practices and plain language summaries that provide balanced descriptions of the risks and benefits of participation. These outcomes are more likely to result in participants that are better informed and empowered regarding their (sustained) choice to participate or not. Engagement might therefore enhance the ethical conduct and transparency of trial processes; strengthen research literacy; contribute to greater trust in scientists, in science, and in product development; and affect uptake and adherence. Engaging patient, public, and community stakeholders in processes for disseminating information about the outcome of clinical trials might help with explaining complex scientific outcomes in plain language, including for those trials that produce no intervention effect.[40] Communication methods and media should aim to target various audiences, including at-risk groups.

Failure to engage patient, public, and community stakeholders also comes at a cost—ie, the status quo is not cost-neutral. Rather, there are considerable negative

effects on trust in science, in scientific research processes, in research regulation, in product developers, and in the products themselves.[41] This lack of trust likely affects the uptake of interventions post-trial and future health research and implementation. There is also an effect on the scientific value of funded trials, including wasted time and financial and human resources when outcomes meaningful to community members are not delivered. This waste occurs when trials fail to recruit or retain participants or when they produce results that lack necessary participant diversity. Lastly, there is an effect on study implementation and costs via increased trial duration, for example when trial designs need to be revised due to implementation features that are unfeasible or unacceptable from the perspective of participants or other key groups, such as front-line implementation staff.

Engagement throughout the clinical trial lifecycle

This section illustrates entry points for patient, public, and community engagement across the clinical trial lifecycle, with the actions of funders, researchers, research ethics committees (RECs), regulators, health and research authorities, patient and advocacy groups and networks, and other stakeholders. We highlight activities we see as important during the design stage of trials—ie, before trial initiation, during trial delivery or implementation, and during dissemination of trial outcomes.

Research agenda setting that involves community stakeholders strengthens the social value of research by informing research questions that are relevant to these groups and might effectively address their needs.[2,42] An example is the James Lind Alliance, a non-profit organisation that brings together patients, carers, and clinicians in a priority setting partnership to identify and focus on research gaps. During protocol development, engagement might add value in defining community-relevant sub-questions, selecting inclusion and exclusion criteria, selecting trial outcomes, selecting outcome measures, feasibility, acceptability of design implementation choices (eg, participant follow-up), reviewing public facing documents (ie, including information for consent), advising on participant recruitment methods, advising on key trial procedures (eg, blood tests), and identifying community feedback mechanisms. Also, legislation governing clinical trials in the EU now requires a description of how potential participants were involved in the design of the clinical trial to be included in the study protocol (annex 1 of the application dossier, section D protocol, point 17 e of EU regulation number 536/2014).[43] Advisory mechanisms are best convened as early as possible and in a way that accounts for the diversity of the trial-specific study population. Trial governance mechanisms should include community stakeholder expertise. Research centres and clinical trial units increasingly have agreed standard operating procedures for engagement, for example designated, trained staff to lead this work as part of multidisciplinary trial teams.

For the **James Lind Alliance** see https://www.jla.nihr.ac.uk/

Funders, commissioners, regulatory and competent authorities, RECs, sponsors, and other actors involved in trial governance oversight play important roles in enabling GPP and setting norms that call for proactive, inclusive practice upfront and during clinical trial protocol development and implementation. Increasingly, funding applications require researchers to describe community engagement plans[44,45] or for them to call explicitly for community partnership models, grant review panels to include GPP experts, and evaluation of proposals to include budget and time allocation for GPP and trial team expertise for facilitating the work. However, these actions are not consistent across funders and more is needed to build this early stage embedding of community engagement into funder requirements. More efforts are needed to educate all stakeholders in the clinical trial ecosystem about GPP benefits, principles, and implementation.

International guidelines empower research ethics authorities to review engagement. RECs have an important role during their initial review of clinical trial protocols by requesting community stakeholder engagement plans and, for submissions that omit these, requesting a justification for such omissions. Capacities for this review can vary within and across RECs. However, the stakeholder can promote ethics guideline recommendations by evaluating whether broad community stakeholder engagement plans reflect key ethics recommendations—eg, that engagement is responsive to context and dynamic over time, broad and inclusive, and early and sustained across the trial lifecycle.[46] Application forms for REC review should prompt researchers to describe their broad engagement plans and how community stakeholder engagement has shaped trial protocols.[47]

Once a clinical trial is open to participant recruitment, GPP aims to strengthen day-to-day trial operations. Those leading GPP work as part of the trial management team, can identify and help troubleshoot practical challenges, such as those related to community awareness or acceptance of the research, participant information and informed consent experiences, challenges related to trial participation, participant retention, and shape communications (as part of the wider trial team) regarding managing adverse events, including serious adverse events. Proactively establishing feedback mechanisms enable trial teams to be sensitive and responsive to questions, challenges, concerns, misinformation, and rumours that might emerge throughout a trial and to be able to implement the necessary changes to the clinical trial, subject to the relevant notification or approval requirements. To avoid tokenism, mechanisms are needed to document contributions of these key groups, offering recognition of their expertise, and to share best practices.

During clinical trial implementation, other stakeholders in the clinical trial ecosystem have important roles to play in driving accountability for GPP. For example, when reviewing renewals for clinical trials, RECs can request updates on engagement from the previous year. RECs should use norms in international ethics guidance to adjudicate stated progress, craft insightful queries to probe progress, and work towards a sound collaborative relationship where engagement approaches can be constructively discussed.[47] REC renewal forms should accommodate descriptions of engagement.[47] Study funders and sponsors can include monitoring of GPP activities as part of the contract and scope of appropriately trained clinical trial monitors. Contract Research Organisations can update their site monitoring tools to capture relevant information, such as whether a GPP plan exists and how it is being implemented.

Once clinical trials are completed, results should be reported directly back to those that participated in the trial and their communities using appropriate language and communication mechanisms. This communication is an important and often neglected step, even when dedicated GPP staff are well embedded as part of clinical trial teams. Researchers need to plan this feedback at the outset of the trial and budget time and resources. Reporting trial outcomes to community stakeholders shows accountability, respect, builds trust, and can strengthen engagement for future research participation or demand creation, policy, and programming for proven interventions. RECs and regulatory or competent authorities can strengthen researcher accountability to this process by requesting descriptions of engagement in close-out reports and constructive self-reflection on engagement processes and outcomes. Journal editors and trial reporting guidelines should, at a minimum, require feedback on how key trial outcomes were communicated back to participants.[48] Funders should include descriptions of engagement outcomes in final reporting requirements.

Public health emergency and pandemic considerations

Driven by global trends, such as climate change, globalisation, deforestation, conflict, and population mobility, health emergencies are increasing in size, scale, and complexity. For clinical trials delivered in health emergencies, engagement of key stakeholders is as important as ever. During these events there is an urgent need to produce high-quality evidence regarding both pharmaceutical and non-pharmaceutical measures under accelerated timelines to inform practice and policy decisions.[49] This need for high-quality evidence has spurred innovations in methods and novel clinical trial designs that are fit-for-purpose to these challenging contexts.[4,50,51] To be sufficiently powered, these trials need to recruit large numbers of participants during peak outbreak waves, which is optimised with multisite and multi-country trials using master protocols and novel, adaptive trial design features.[51] Alongside these technological developments is the need for transparency and trust.[52–55] Frameworks that guide health emergency management emphasise the crucial importance of community-centred practices that draw from and strengthen local community and health systems and engage those affected as partners in response activity.[17,56,57] If the interventions evaluated in these trials are to be used, the people intended to use them should have trust and confidence in the process by which they are developed.[54,58]

Engagement for clinical trials delivered in public health emergencies needs to be responsive to these realities.[59] Specific challenges arise because of the accelerated timelines of trial activity.[8] Rapid engagement is needed to assess acceptability and social value of research agendas, to inform master protocol design, to steer contextual adaptations to trial procedures delivered under master protocols, and to respond to new needs and priorities that inevitably arise in a dynamic and unpredictable context.[4,49,58,59] In a public health emergency, the extent to which meaningful engagement of patients, the public, and communities can be achieved depends on the agility and resilience of pre-existing research infrastructure and systems, including that of engagement mechanisms.[8,51] For research readiness, these systems should be primed and ready to rapidly transition their activity to the specifics of the emergency event.[51] For engagement, this means having engagement specialists as part of trial teams and having patient, public, and community advisory mechanisms that are informed about the specifics of epidemic or pandemic research that have well developed, user-tested plain language explanations (including using visual materials) of complex study design features. Furthermore, there is a need for well developed, pre-prepared communications that can be rapidly adapted to support participant decision making based on the risks or benefits of participating in a trial, providing clear explanations of the difference between trial participation and receiving interventions under usual care or compassionate use, and having site-level community feedback mechanisms established to follow and respond to community questions and concerns. This community-centred research engagement work is a core part of readiness for effective responses to public health emergencies. For greater effect, research readiness for enabling engagement in clincal trials can and should be built in ways that strengthen research, health, and wider community systems.

State of the field

Important advances have been made in integrating engagement into standard clinical trial practice. The revised draft guidance for the International Council for Harmonisation (ICH E6 R3) Good Clinical Practice now

refers to the added value of participant involvement.[60] The EU Clinical Trials Regulation includes several provisions that enable community engagement, such as inclusion of a layperson to review trial protocols and the requirement for a publicly accessible simplified summary of all clinical trials registered in the EU database.[38] There is a raft of guidance documents, implementation tools,[36,61,62] and resource hubs[22,63–68] to steer policy and practice, and many models and examples of good practice. These documents are important to illustrate the diverse ways in which the principles, norms, and standards for engagement steer contextually sensitised implementation of involvement activities.[67,68] Increasingly, shifting norms are raising expectations around engagement in clinical trials. For example, journal editors and funders are raising the bar on expectations of what constitutes adequate engagement of communities in all stages of the clinical trial lifecycle. For some time now, research reviews have required partnerships with local communities to help reduce the burden of research that is not relevant to a target country or context.[37] Communities expect greater engagement to enhance relevance and responsiveness of research to their needs and priorities and to ensure respectful practices.[69,70] For example, the UN Declaration on the Rights of Indigenous Peoples acknowledges the right to self-determination of Indigenous peoples in research[70] and funding bodies have recognised the significance of this expectation. Many funding bodies now require applicants to describe how engagement with community stakeholders shaped their application and show meaningful partnerships that respect local research capacities. Journal editors are encouraging more equitable inclusion with more accurate reporting criteria.[71] Across disciplines, academic institutions and researchers are beginning to acknowledge engagement activities as valuable aspects of research and are including them as part of the broader range of impact metrics in careers and institution evaluations.[72]

Despite these advances, there remain many systemic and structural gaps and challenges that hinder progress. Meaningful engagement requires establishing working relationships that navigate complex power structures and challenge dominant research frameworks.[40,73] Many trials continue to be delivered with no, restricted, or tokenistic involvement of stakeholders, for example with engagement limited to a narrowly representative group, such as community gatekeepers, engagement restricted to Community Advisory Boards alone, or one-off engagement activities.[74] Engagement is often restricted to trial implementation and to aid in instrumental goals (eg, recruitment or retention). Rarely does engagement move beyond the baseline to agenda setting, trial design, governance, or outlook-shaping. For example, in clinical trial publications in scientific journals, accounts of engagement are highly variable from having some description to nothing at all.[59] Engagement practitioners and participant representatives, particularly those at local levels, are frequently overlooked in authorship lists.

These challenges prompt reflection on the notion of partnership with patients, the public, and communities. There are many guidance documents that recommend meaningful engagement, which call for full participation of patients, the public, and communities (table). In practice, partnerships and participation vary in terms of the extent by which power is truly shared. At its lowest end is a partnership based on transactional exchange, such as providing information or soliciting one-way feedback. At the higher end is a more balanced power-sharing relationship, where dialogue and deliberation shape actions. At its highest end, power is truly shared and research plans are co-designed, co-developed, and co-delivered (panel 1). There are, however, some unique features of clinical trials which place constraints on the nature of partnerships.[76] For example, in developing clinical trial study protocols, decisions are often taken for methodological reasons that relate to scientific integrity of a study (eg, approach to randomisation). These decisions are not open to adjustment, even if by including patient, public, or community engagement, alternatives are preferred. In addition, decisions about how trials are designed and implemented are constrained by resource considerations, institutional policies, and other structures or established norms. In practice, navigating these realities needs trust, transparency, and pragmatism for shared decision making.

Availability of well-developed guidance has not always translated to consistent guidance implementation. There is a need to invest in and strengthen policies, systems, and structures that compel practice change and provide ongoing monitoring to ensure sustainable change. Initiatives to strengthen capacities of major actors in the clinical trial ecosystem with continuous learning and development should include practice or skills-based training to enable these actors to gain confidence in discerning meaningful engagement practices and expertise. At the same time, there is indeed specialist skill that is needed to deliver on this area of work, similar to the specialist skill of data managers, logisticians, or statisticians. Trial teams will invariably need a dedicated specialist with knowledge, skills, and expertise to contribute at key junctures in the design and delivery of clinical trials and dissemination of trial outcomes. There is also a need for tools and common indicators of success to quantify or qualify engagement outputs and outcomes, and evaluate its effects.[77] Initiatives are underway to establish standards, define pathways by which engagement results in change, agree common impact metrics, and to collate evidence and resources for this rapidly growing field.[65,78] This evidence helps to inform engagement strategies that are most effective at achieving beneficial outcomes, such as enhanced understanding, increased trust, more informed contributions, and other benefits.[79] This evidence can also point to particular risks and

***Panel 1*: Perspective from the BRILLIANT Consortium Community Engagement and Advocacy Leadership**

From guidelines to guardrails: the case for stronger regulations in clinical research to secure equitable access to research benefits, for all

When a group of African countries entered into a collaboration with the US Government in 2023 to advance HIV vaccine discovery work, a grouping of community engagement activists who had been part of the core leadership of the proposal development team knew that an opportunity to meaningfully contribute to an evolution in clinical trial research had arisen. The 5-year consortium, called BRILLIANT—Bringing Innovation to Clinical and Laboratory Research to end HIV In Africa through New Vaccine Technology—centred meaningful community engagement as a foundational pillar of its scientific strategy. Part of this strategy was for communities to take the lead in developing a blueprint that intends to reshape how community engagement in clinical trials happens and how a justice-centred approach could meaningfully advance post-trial access to the benefits of research by communities that enable the research to happen, and countries that bear a disproportionate burden of disease under investigation. A foundational step in this 5-year process was to think deeply about how the current systems, frameworks, and guidelines shaping engagement and access have either accelerated, halted, or hindered ethical research, with a particular focus on post-trial access.

There is no doubt that the publication of the Good Participatory Practice Guidelines in 2011[15] (adapted for emerging and reemerging pathogens in 2016) have been one of many important contributions that protect clinical trial participants in HIV prevention trials from ethical omissions and violations and provide greater opportunity for post-trial access to safe and efficacious products for participants and the communities where trials were conducted. The guidelines coalesced after the Cambodian government shut down a HIV prevention trial in 2005 testing the use of tenofovir to prevent HIV infection in sex workers when sex workers and advocates argued that the post-study care provisions seemed designed to increase the likelihood of infections during the trial. The guidelines' rapid development and steady evolution since testifies to the transformative powers of the HIV advocacy network, and to the value of collaboration, not just between scientists from the minority world and majority world, but also early engagement with potential beneficiaries of the proposed research. The term majority world refers to most of the world's population that live in parts traditionally referred to as developing. The term minority world is similarly used to refer to those countries traditionally referred to as developed, where a minority of the world's population resides.

17 years into good participatory practice-informed clinical research for HIV and AIDS, the new WHO Guidance for Best Practices for Clinical Trials (2024)[75] presents an opportunity to critically consider the current context of epidemics and pandemics (and the centrality of trial participants and their communities) in the evaluation of novel products. Trial participants, communities, and countries with a high disease burden, which enable clinical trials to be undertaken efficiently should be centred on the product development pathway to ensure that the advantages from and access to the benefits of that research reach them. There is an urgent need to move beyond non-binding guidelines to a regulatory and policy environment that defends the dignity of clinical trial participants and communities, especially in the majority world. Guidelines alone are not strong enough to ensure equity or distributive justice, and sponsors and clinical trialists from across the globe need to prioritise commitments that are more binding and have a clear local regulation and policy environment.

We call on researchers and trial sponsors to move beyond academic endeavours and to truly make central the rights and wellbeing of trial participants and communities. This refocusing should expand to product rationale, early evidence-building, protocol design, post-trial access, and equitable implementation. We should continue to demand that when products roll out, the product developer honours commitments made to align access on the ground to what was committed to in the early product rationale. We then need to make sure our governments take the lead in financing scale-up, meaning leadership—ie, leadership on intellectual property, voluntary licensing, and meaningful access.

For community engagement and patient advocacy groups, we should continue to keep science honest, continue with hard discussions about post-trial access, and ensure that we, as a research collective, transition from advocating for community buy-in to true co-ownership and co-production of knowledge.

potential harms that can arise from poorly planned and delivered engagement—eg, practices that might inadvertently reinforce power imbalances at local levels, put pressure on people to participate, exacerbate stigma, or fuel misinformation.[74]

Integrating engagement as a normative approach to clinical trials has practice, logistical, financial, and human resource implications. Ensuring that sites are staffed with well-trained engagement practitioners has financial implications by adding to the budget of clinical trials. Engagement activities need to be properly costed, including to cover activities for the dissemination of findings. These budget lines need to be realistic and proportional, and also need to be protected so that research teams are accountable for these costs. A return on this investment is anticipated in the form of enhanced literacy, trust, and contributions that enhance the scientific and ethical quality of the research. However, practically, in a resource-constrained environment, budgets for engagement are often among the first to be cut. Stakeholders, including funders, trial teams, and RECs should assess whether engagement is adequately budgeted

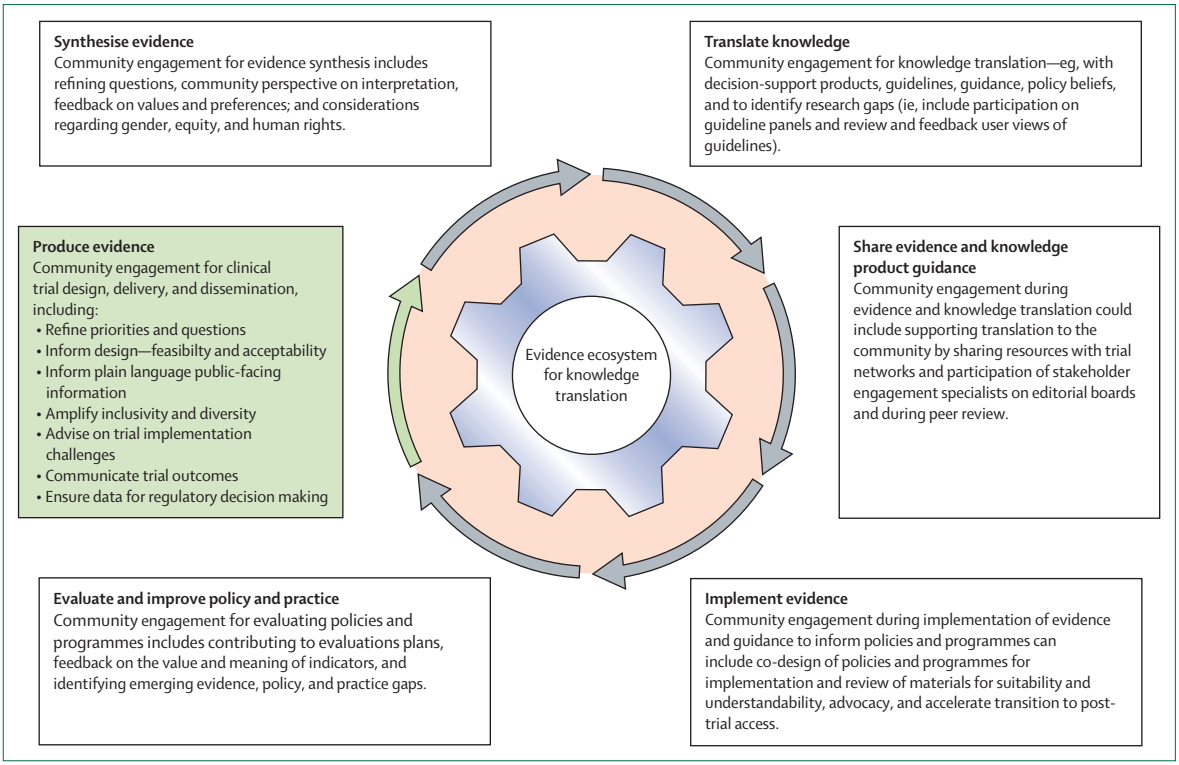

Figure 2: **Community stakeholder engagement across the evidence ecosystem for knowledge translation**
Adapted from the MAGIC efficient evidence ecosystem.[80]

when reviewing protocols and research plans.[2] However, other experts working in this field (eg, academics who are critical of this lower funding over time and advocate for greater power sharing and a need to tackle systemic inequities more forcefully) have argued that many key actions for building capacities and systems for engagement are necessary but insufficient to drive real change. More complex and challenging is tackling the fundamental inequities in wealth, power, and culture that underpin dominant health research frameworks.[71] Critiques of the patient, public, and community engagement agendas have called attention to these longstanding, structural inequities and the risks associated with community engagement efforts that fail to account for them.[71,73,74]

Action across the ecosystem for better engagement

Patients, public, and community stakeholders make important contributions throughout the evidence ecosystem at various stages of research production, translation, and implementation (figure 2), which highlights the need to strengthen research systems in ways that nurture and sustain ongoing trusting and collaborative working relationships between researchers and these stakeholders. An enabling policy and funding environment is key to establish the structures and mechanisms for this work. Examples include the UK Shared Commitment to Public Involvement, which was launched to provide system-wide visible leadership to show that public involvement is important, expected, and possible throughout all stages of research;[81] establishment of long-term mechanisms for engagement, such as Community Advisory Boards,[82] including Youth Trials Boards;[83] and a model of youth engagement co-created by adolescents living with HIV from Zimbabwe, Uganda, South Africa, and the UK to ensure their community can be part of decision making in global paediatric HIV clinical trials. To date, expectation of community engagement is supported to varying degrees by different funding bodies, with some setting clear expectations for engagement in clinical trial applications, while others not explicitly citing it as a priority. Beyond clinical trials, there are models for funding collaborative relationships between researchers and communities that include community-led research. Examples of these models include the Ideas Fund, which provides grants directly to communities to develop research ideas;[84] the National Institutes of Health Research Ready Communities programme, which aims to strengthen long-term engagement with underserved communities;[85] the National Institutes of Health Community Partnerships to Advance Science for Society, which is an innovative initiative to address health inequities in research with community-empowered research; and the Wellcome Trust's Global Centres for Exchange programme, which advances models of practice for

For **Global Centres for Exchange** see https://www.centresforexchange.org/

community-led health research. These programmes have the potential to foster an enabling environment for clinical trials by building and strengthening research literacy and trust in science among the wider public, and strengthening partnerships between researchers and the lay public to inform relevant and meaningful research.

***Panel 2*: Recommended actions for stakeholders across the clinical trials ecosystem to drive good participatory practices for clinical trials**

Funders[22,45]

- Require participant engagement planning as part of funding applications and budget templates
- Review adequate time, budget, and trial team expertise included in planning for meaningful engagement throughout the trial lifecycle (ie, trial or protocol design, trial conduct, and results dissemination)
- Include engagement experts or specialists on review and funding decision committees
- Build flexibility in grant funding to enable applicants to be responsive to community priorities, inputs, and needs
- Include requirements and resources for participant engagement and feedback in clinical research funding contracts and reporting
- Consider funding mechanisms to strengthen research systems—eg, for formative research that develops a shared understanding of true cost (budget and time) of meaningful engagement; financing for sustained community stakeholder engagement capacity at clinical research sites—eg, specialist staffing; robust training (internal and external); tools or support for planning, implementation, and relationship building; and ongoing engagement mechanisms (ie, change advisory boards)
- Create funding mechanisms to support external civil society-led engagement throughout the clinical trial process
- Harmonise minimal stakeholder engagement requirements across funders, including agreed monitoring metrics, mechanisms, and practices, to promote consensus around the role of engagement in clinical trial conduct

Principal investigators or institution leadership[87–89]

- Provide leadership: make sure there is a participant engagement technical lead in strategic and operational trial structures and processes
- Ensure adequate time, budget, and trial team expertise is allocated for meaningful engagement throughout trial lifecycle
- Ensure resources to operationalise meaningful engagement by establishing standard operating procedures, providing training, and developing and implementing an internal evaluation strategy
- Ensure mechanisms are in place and used to bring a diversity of stakeholder voices to shape trial design and implementation throughout clinical research, including those who will be affected but lack the power to influence
- Support fundraising for stakeholder engagement activities, including capacity building around seeking grants and applying for and obtaining grants, provide grant and manuscript writing support to community partners and staff with community expertise to seek grants for formative research and ongoing engagement
- Strengthen the research system, plan, and budget for stakeholder engagement as part of core funding for the research institution rather than have protocol-specific budgets
- Incentivise researchers who show good participatory practices and drive innovation in the field
- Work with local community-based organisations to provide investigators training on good community engagement programmes in clinical research
- Include community engagement methodology in all publications and presentations reporting clinical trial results; include stakeholder engagement professionals, involving community partners, in authorship

Clinical trial staff, units, or managers[88]

- Provide ongoing training on engagement support tailored to different internal stakeholders without engagement expertise
- Develop and implement a stakeholder engagement plan that includes monitoring and evaluation strategies and minimum expected standards of engagement, and key activities for trial closure, such as disseminating results to community stakeholders
- Connect and share best practices across trial sites, regionally, and so on, to ensure that engagement approaches reflect community needs and innovative approaches
- Develop capacity-building initiatives that empower community members with the knowledge and skills necessary for meaningful engagement
- Implement, listen, and include strategies for feeding back how engagement affected the study
- Establish organisational culture to drive engagement—eg, with expertise in strategic and operational structure of trials units; ensure that stakeholder engagement programmes are cohesive with research programmes; and ensure engagement staff are an integral part of the study team and well informed and updated about the research content

Sponsors[90]

- Provide training on stakeholder engagement as part of compliance training
- If sponsorship is delegated to contract research organisations, inform them of stakeholder engagement planning and requirements for follow-up and monitoring
- Support global and regional advisory mechanisms that add to trial and site level mechanisms

(Continues on next page)

(Panel 2 continued from previous page)

Research ethics committee (RECs)[45–47,83,91,92]

- Develop REC forms (eg, application forms and renewal forms) that prompt trialists to describe their engagement plans
- Review for high-quality, meaningful engagement using norms in international ethics guidance for engagement (eg, early and sustained, responsive and dynamic, or adequately resourced)
- Ensure that participant representatives are involved and empowered in the review process
- Ask insightful questions about engagement, including about resources
- Have strategies for addressing research submissions with inadequate engagement
- Differentiate between engagement activities to achieve pragmatic goals (eg, recruitment) versus ensuring partnerships
- Use training opportunities that focus on how engagement can be supported during the ethics review process[91]
- Develop REC capacity and systems to facilitate participant-oriented trials with engagement

Regulators[86,93–96]

- Adapt regulatory processes for incorporating stakeholder views as early as possible
- Ensure adequate language is included on community engagement in regulatory guidance, which is currently missing from International Council for Harmonisation Good Clinical Practice
- Ensure that internal training on evaluating engagement is required for all committees reviewing clinical research protocols
- Provide training and financial support to enable participation of stakeholders during drug development and regulatory evaluation

National research authorities[72,97]

- Provide investigators training on good stakeholder engagement programmes in clinical research
- Create a culture that supports broad and robust stakeholder engagement programmes throughout the entire trial process with incentives, such as career reviews and awards
- Review national research guidelines for stakeholder engagement minimum standards

Scientific journal editors

- Require all papers reporting clinical trial outcomes to describe participant engagement activities and ways that they effected trial delivery
- Review authorship lists for inclusion of participant engagement staff; update procedures for co-authors who do not have institutional affiliation but contribute as authors or are engagement staff
- Solicit articles or issues that feature innovative engagement approaches or offer field notes or other publishing formats to allow best practices in stakeholder engagement to be peer-reviewed
- Include stakeholder engagement specialists on editorial boards and as part of the peer review process

Patient organisations or civil society advocates[98] **(Equality, Diversity and Inclusion in Science and Health, Intersectional health, and Vocal)**

- Ensure that community and broader stakeholder education should be a consistent part of all research programmes
- Advocate to improve trial conduct and increase diversity of participants, community groups, and advocates engaged in decisions around the research
- Monitor engagement best practices, provide feedback to trial sites and trialists, and hold them accountable for strong engagement performance
- Work with stakeholders to prepare for trial results and accelerate the transition from clinical research to post-trial access
- Consider and advocate for priorities regarding how a research project fits into participants' lives and other aspects of the real-world context (eg, structural issues, stigma, and complementary interventions)

Community advisory boards[83]

- Provide input to stakeholder engagement staff and researchers on the overall direction of the engagement and clinical research programme
- Support translation into the community by sharing resources with the network

For the **Equality, Diversity and Inclusion in Science and Health group** see https://edisgroup.org/

For **Intersectional health** see https://intersectionalhealth.org

For **Vocal** see https://wearevocal.org/

Enabling meaningful engagement that achieves scientific and ethical outcomes requires action from key stakeholders across the clinical trial ecosystem, including principal investigators, sponsors, RECs, regulators, journal editors, academics and health professionals, civil society organisations, advocates, health and research authorities, the media, and the public at large. These levers include a strengthened policy environment to enable involvement and engagement in clinical trials; grant mechanisms for pre-application funds for researchers to proactively engage underserved and underrepresented population groups, who often cannot afford to get involved without financial support; a funding culture that requires evidence of the engagement with patients, the public, and communities in planning together with realistic budget requests; a regulatory environment that calls for evidence on patients' experience to inform their decision making;[86] RECs and ethics review authorities that ask crucial questions during review; scientific journals that call for demonstration of engagement focal points in trial authorship; and a peer-review publishing culture that requires reporting of

engagement, particularly regarding ways in which GPP has shaped trial practice and evidence of how trial outcomes have been shared with community and other stakeholders. These, and further proposed actions to drive change, are summarised in panel 2. Engagement with a broad set of stakeholders, including formal engagement with community stakeholders, would be of value to further develop these actions and to consider their relevance and feasibility to various kinds of trials and those conducted in different settings and among varied populations.

Conclusion

This paper makes a call for engagement of patients, public, and community stakeholders in clinical trials, and with the GPP approach as a core part of delivering the promise of the WHA75.8 clinical trials resolution.[3] We highlight the large range of existing ethics guidance and tools and propose actions for key stakeholders across the clinical trials ecosystem to build on progress by driving accountability and best practice in this area. Advancing this agenda for the meaningful engagement of such groups can promote trust, drive ethical research conduct, improve scientific outcomes, and facilitate uptake of findings. Ongoing commitment and collective effort is needed for success.

Contributors

NG led and convened working meetings of the authorship group and developed the manuscript. All authors contributed to the manuscript and to updated iterations. CS, SH, and JS developed the table. NG, CS, SH, JS, GB, JGB, BP, BM-O, NS, MC, DK, AD, NLM, SMa, LS, and LR developed the panel. TJ, MT, and SMu developed the statement on the BRILLIANT consortium activities. NG developed figure 1 and NS developed figure 2. All authors reviewed the final manuscript.

Declaration of interests

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