Public consultation for the WHO guidance for best practices for clinical trials

Consent

Consent and provide feedback
Yes ✔

Personal information

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General comments (optional)

Please provide general comments on addressing context-specific issues, considerations, and implications for adapting and implementing the guidance, as well as identifying gaps in the evidence that should be addressed through future research. Please also provide any comments about the strengths of the draft guidance. Feedback to specific content to enhance clarity, address technical errors, and provide any missing information will be in the suggested amendments.

Involvement is mentioned five times throughout the document. However, while we (in the patient community) are well versed on what involvement is, why is it important, who should be doing it, and when it should happen – many on the implementation side of the clinical trial ecosystem are not.

It is our hope that this WHO guidance can help the many actors involved in clinical trials understand more about how they can partner with patients in their work. To this end, we suggest that the guidance consider providing:

- A definition of patient and public involvement in clinical trials, or failing that, a framework on what good patient & public involvement (PPI) looks like in a clinical trial environment;
- A categorisation of the different types of PPI partners in clinical trials, outlining the distinction between these and trial participants. Indeed, it is often not appropriate for trial participants to be involved in certain aspects of trial design, implementation, and evaluation, hence the need for such a distinction;
- A list of principles underpinning the practice of PPI during clinical trials (for example, quality, trust, respect, empathy, shared responsibility, partnership, knowledge transfer etc.);
- A sample of best practice in relation to PPI in clinical trials from different jurisdictions.

NOTE: PPI is distinct from, albeit indirectly related to, the participation of individuals on clinical trials. It relates more specifically to the broader involvement of patient organization representatives, individual patient advocates, family members, carers and supporters. A review of international definitions of patient and public involvement may be helpful in standardizing language and identifying audiences for engagement.

Please provide general comments for *Section A: Key scientific and ethical considerations for good clinical trials.*

• Clinical trial data without Patient Experience Data (PED) is incomplete for meaningful decision-making.
• Generating and using PED without patient involvement can lead to inaccurate insights, uninformed decision-making, and missed opportunities for improvement and innovation.
• Not providing feedback on how patients' input or data was used results in patients questioning the value of their engagement and subsequently a lack of commitment to future opportunities.

Please provide general comments for *Section B: Guidance on strengthening the clinical trial ecosystem.*

The clinical trial ecosystem does not make it easy for patients and the public to access relevant, easy to understand and accurate clinical trial information. Also, effectively matching patients with appropriate clinical trials is a well-known challenge due to the lack of standard structured data and patient-accessible language for registration with a Clinical Trial.

The resulting burden of inaccessibility and inoperability makes it unnecessarily difficult for patients and healthcare profesionnals to identify and understand options for clinical trials and extends the time-frame and cost of drug development. While there are significant efforts to develop solutions, such as search tools and matching services that leverage AI or custom data mapping on existing unstructured data, these services are proprietary, fragmented and unable to independently establish the standard structured data and plain language summaries which would broadly improve search, match, and enrichment of clinical trial information. They also build data silos and inequities as opposed to feeding and enriching an open, accessible and equitable global distribution system.

To strengthen the ecosystem from a patient perspective, we need:

o Promotion of the use of open standards to improve efficiency and innovation in Clinical Trial matching, which will also promote health equity and inclusion.
o Collective action bringing beneficiaries and data feeders together to address this issue.
o Investment in an optimized data distribution model that leverages standardized structured data and plain language summaries.
o Promote multi-stakeholder collaboration to address data source and distribution network issues and challenges.

Please provide general comments for *Section C: Addressing under-represented subpopulations.*

The recommendation above will increase patients' access to novel treatments and promote health equity and inclusion by breaking accessibility barriers, especially for those communities that traditionally do not get access to clinical trials.

Please provide general comments for *ANNEX 1: Provisions for rapid funding and approval of good randomized evidence generation in emergencies.*

Please provide general comments for *ANNEX 2: Recommendations for Member States, research funders and researchers.*

Do you have specific amendments to suggest? If yes, please click "Yes" to continue. If not, please click "No" and "Submit".

Yes ✔

Suggested amendment 1 (maximum 30 amendments to be suggested)

Please indicate the line number where the suggested amendment starts
687

Amendments

‘Good clinical trials involve patients and interested members of the public from beginning to end, promoting collaboration and transparency’.

Please provide the rationale for the suggested amendments

The focus on patient involvement in this section needs strengthening, and the best way to do this is to make it the focus of the section title.

There has been much discussion about patient involvement in the clinical trial ecosystem, but there is much less action. Involvement in general remains too little, and too late.

Ensuring early and continuous patient & public involvement is crucial for anchoring research to actual unmet needs. Designing clinical trials without input from patients and caregivers leads to endpoints and outcomes that are not clear, meaningful, or relevant to them.

Do you have another amendment to suggest? If yes, please click "Yes" to continue. If not, please click "No" and "Submit".

Yes ✔

Suggested amendment 2

Please indicate the line number where the suggested amendment starts
694

Amendments

Exact text is not being proposed, but the guidance should work up specific suggestions/indicators to share what ‘early involvement’ might look like.

Please provide the rationale for the suggested amendments

Early involvement’ is mentioned on line 696 without an indication of what ‘early’ means, and what ‘involvement’ looks like. An aspiration for greater early involvement is unlikely to change current and future practices. There needs to be specific indicators included in the guidance of what is ‘early involvement’. For example, Patients and their representatives (not participants on a trial) should be invited to join committees with responsibility for deciding on the final research questions.

Do you have another amendment to suggest? If yes, please click "Yes" to continue. If not, please click "No" and "Submit".

Yes ✔

Suggested amendment 3

Please indicate the line number where the suggested amendment starts
927

Amendments

Patient representatives (advocates, organisations, family members, carers, and supporters) should be listed as an audience for education and training

Please provide the rationale for the suggested amendments

Patient partners interested in getting involvement in clinical trial research priority setting, outcome identification, protocol design, trial monitoring, and trial evaluation also need education and training.

NOTE: Patient partners are not the same as trial participants, partners are patients living with one or more conditions which is a focus of the trial.

Do you have another amendment to suggest? If yes, please click "Yes" to continue. If not, please click "No" and "Submit".

Yes ✔

Suggested amendment 4

Please indicate the line number where the suggested amendment starts
976

Amendments

Patient involvement should be listed as a focus for research funders, and the guidance should suggest that research funders require that funding call documents include a section asking applicants to detail how they have involved patients and members of the public in the the trial design, and how they will continue to involve them if successful in securing funding. Successful bids should be required to report on their patient involvement activities at key points along the trial lifecycle.

Please provide the rationale for the suggested amendments

Patient involvement needs to become part of the ‘business-as-usual’ design, delivery and dissemination of clinical trials. To change the culture and move to a more partnership model of clinical trials, involvement will need to be mandated for some years at the international and national levels. The easiest way to do this is to make it a requirement for funding as well as for regulatory approval.

Do you have another amendment to suggest? If yes, please click "Yes" to continue. If not, please click "No" and "Submit".

Yes ✔

Suggested amendment 5

Please indicate the line number where the suggested amendment starts
1138

Amendments

Consideration should be given to the management and sharing of clinical trial data for additional secondary use purposes. Dialogue with patient partners, and with the participants of the trial, should identify consent preferences. In particular, consideration should be given to how data from the trials can be anonymised and shared with public research facilities through trusted research environments (TREs).

Please provide the rationale for the suggested amendments

Consideration should be given to the management and sharing of clinical trial data for additional secondary use purposes. Dialogue with patient partners, and with the participants of the trial, should identify consent preferences. In particular, consideration should be given to how data from the trials can be anonymised and shared with public research facilities through trusted research environments (TREs).

Do you have another amendment to suggest? If yes, please click "Yes" to continue. If not, please click "No" and "Submit".

Yes ✔

Suggested amendment 6

Please indicate the line number where the suggested amendment starts
1380

Amendments

Co-design and deliver information and education programmes for patients and members of the public with an interest in clinical trials and health data.

Please provide the rationale for the suggested amendments

In this section, one of the recommendations for Member States should highlight the importance of providing public education and training to patients and members of the public with an interest in clinical trials. Non-research-focused communities should be able to understand the clinical trial environment, they should be familiar with the terminology used, with the key challenges, and with the potential solutions. In this way, they can meaningfully contribute to processes which aim to strengthen, expand, and grow the clinical trial environment.

Do you have another amendment to suggest? If yes, please click "Yes" to continue. If not, please click "No" and "Submit".

Yes ✔

Suggested amendment 7

Please indicate the line number where the suggested amendment starts
1380

Amendments

Co-design and deliver information and education programmes for researchers, clinicians, and health care professionals to encourage the signposting of more patients to clinical trials.

Please provide the rationale for the suggested amendments

Another recommendation for Member States should be to also provide education and training for researchers, clinicians and other health care professionals. Doctors, consultants and nurses should be familiar with the clinicial trial environment in their speciality area, and they should be able to recognise opportunities for their patients, to explain to patients the merits (and risks) of their participation, and to complete the necessary processes and procedures to register their patients on suitable trials.

Do you have another amendment to suggest? If yes, please click "Yes" to continue. If not, please click "No" and "Submit".

Yes ✔

Suggested amendment 8

Please indicate the line number where the suggested amendment starts
1537

Amendments

…, based upon an assessment of the literacy needs of the audiences.

Lay summaries of trial results should be prepared.

All documents should be free of jargon and acronyms.

Please provide the rationale for the suggested amendments

These are the basis requirements for literacy.

Do you have another amendment to suggest? If yes, please click "Yes" to continue. If not, please click "No" and "Submit".

No ✖
