GloPID-R Funders Living Roadmap for Clinical Trial Coordination

March 2023

GL⬤PID-R

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Funding statement

Executive summary

This living roadmap provides a guide for funding agencies to improve the coordination of clinical trials in response to new, emerging, and re-emerging outbreaks with epidemic or pandemic potential. The roadmap was developed by the Global Research Collaboration for Infectious Disease Preparedness (GloPID-R) Clinical Trial Networks and Funders Working Group in consultation with GloPID-R's members, its Data Sharing Working Group, observers, and associated stakeholders.

In response to the COVID-19 pandemic, clinical trials were initiated within 33 days of the declaration of a public health emergency of international concern (PHEIC) (1). Some of these trials informed practices and policies and helped save lives (2-4). However, there was a proliferation of trials that were uncoordinated, at times competing for inclusion of patients, and many trials failed to generate actionable evidence (1, 5, 6). There were also few trials implemented in resource-deprived settings (7, 8). This inefficient use of resources underscores a clear need to strengthen our capacity for a globally coordinated clinical trial response to outbreaks with epidemic and pandemic potential.

Building a national, regional, and globally coordinated clinical trial ecosystem that has the capacity to mount a coordinated, effective response will require strengthening global capacity and capability to deliver well-designed clinical trials with sufficient statistical power to produce actionable results (9).

Concerted efforts must be directed toward strengthening clinical trial ecosystems globally and with an emphasis on the capacity to implement trials in resource-deprived settings (10). The World Bank's Money & Microbes report (2018) details actions for funders and other stakeholders to improve clinical trial research capacity globally, including the integration of research into clinical care (11).

Research funders have a key role to play in supporting a clinical trial ecosystem that has the capacity for a coordinated, effective, and equitable clinical trial response to generate actionable evidence to inform public health policies and improve global health security (10). The World Health Assembly (WHA) 75.8 Resolution on strengthening clinical trials calls on research funders to support coordination (12). This roadmap provides a structure for funders to operationalise these improvements.

At the core of this living roadmap are **three goals** and **a set of 11 principles** (Figure 1), **identified through consultations with GloPID-R members, clinical trial network representatives, and observers.** For each principle, a set of recommended actions were identified to support their implementation. These actions are meant as guidance for funders to help achieve the principles while recognising that not all funders will be able to implement all of them, yet all funders should be able to act on some of them.

Figure 1. The three goals and eleven accompanying principles of the roadmap
CTN: Clinical Trial Network   FAIR: Findability, Accessibility, Interoperability, and Reuse of Digital Assets

GOAL: Support epidemic-ready clinical trial networks and platforms		
Principle	1	Strengthen and sustain strategic clinical trial networks and platforms
Principle	2	Promote a culture of good clinical trial practice including FAIR[1] data practices
Principle	3	Support harmonisation of clinical trial responses

GOAL: Facilitate an agile, effective clinical trial response		
Principle	4	Ensure agile funding policies
Principle	5	Strategic allocation of funds for an effective response
Principle	6	Establish coordinated funding mechanisms
Principle	7	Exert wider influence to address challenges to trial implementation

GOAL: Promote an equitable research environment		
Principle	8	Improve equitable clinical trial practice
Principle	9	Ensure investments promote equity of access
Principle	10	Provide support for researchers and an equitable research environment

Cross-cutting principle		
Principle	11	Monitor, evaluate and integrate

[1] Findability, Accessibility, Interoperability, and Reuse of Digital Assets

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1. Introduction

1.1 Background

Previous outbreaks, epidemics and pandemics have highlighted that clinical research response efforts have often been delayed and fragmented, failing to enrol a sufficient number of patients to generate actionable evidence (13). This was evident during the Influenza A (H1N1) pandemic in 2009 when clinical trials on medical countermeasures were initiated too late, and the opportunity to generate clinical evidence during the pandemic was missed, partly due to the delays in accessing funding (13). Substantive clinical research was undertaken during the the Ebola outbreak in West Africa (2013-2016). However, the rapid, uncoordinated launch of multiple clinical trials led unintentionally to the consequence of trials competing for enrolment (14), with the result that many failed to reach their enrolment targets. In review of the Ebola response, funders were called upon to renew commitments to trial coordination and to reduce unnecessary duplication and delays (14, 15).

The COVID-19 pandemic showed unprecedented successes in terms of rapid clinical research responses, with effective therapeutics (dexamethasone) identified within 138 days (2) and vaccines in just over 300 days after the WHO declared a public health emergency of international concern (PHEIC). However, the pandemic also highlighted remaining and new challenges, including the proliferation of trials that were small and uncoordinated, and in many cases underpowered, which therefore failed to meet their aims (5). Moreover, a very limited number of trials were based in lower-resourced settings (7).

During the early stages of the COVID-19 pandemic, we witnessed how in the face of a global threat, most of the early research response efforts were initiated and conducted at the national or regional level (6). Later during the pandemic, we saw more international cooperation and coordination (8), exemplified by initiatives such as COVAX (16), the Solidarity (17) and RECOVERY (18) platform trials, and expansion of REMAP-CAP (4). Yet, there were few trials set in low-income countries (7). In the wake of the pandemic, there have been calls to action, including a renewed call for better coordination of clinical trials, e.g. in the 100 Days Mission, the G7 Therapeutics and Vaccines Clinical Trials Charter, and the World Health Assembly (WHA) 75.8 Resolution on strengthening clinical trials (19-21). From our experience, we have learnt that enacting such calls to action requires dedicated and ongoing monitoring and evaluation to support effective implementation.

Funders have a key role in promoting and facilitating coordination of clinical trial responses to epidemics and pandemics, through both what they fund, and how they fund it. GloPID-R, as a coalition of global research funders, is well placed to identify and agree upon actionable changes to harness renewed momentum for improved clinical trial coordination through collaboration across funding policies, conditions, and mechanisms.

GloPID-R is named in the G7 Clinical Trials Charter in terms of promoting collaboration and communication among research systems to avoid the proliferation of clinical trials in response to epidemics or pandemics which do not contribute to valid or actionable scientific evidence (20). In addition, the WHA 75.8 Resolution, adopted in May 2022 to strengthen the quality and coordination of clinical trials, includes key recommendations for funding agencies (Box 1).

GloPID-R has brought together globally representative funders and clinical trial networks in its **Clinical Trial Networks and Funders Working Group (CTN&F WG)** (22), as a platform to strengthen global preparedness and response to epidemics and pandemics by identifying and addressing challenges to timely, effective, inclusive, and equitable clinical research efforts. A key focus in 2022 was to build on previous work and incorporate lessons learnt from the COVID-19 pandemic to identify best practices and principles for research funders to facilitate the coordination of clinical trials.

The WHA 75.8 Resolution: Key recommendations for funders

To encourage research funding agencies to prioritise and fund clinical trials that are well-designed and well-implemented, conducted in diverse settings and include all major population groups the intervention is intended to benefit, have adequate statistical power, and relevant control groups and interventions in order to generate the scientifically robust and actionable evidence needed to inform public health policy, regulatory decisions, and medical practice while preventing underpowered, poorly-designed clinical trials and avoiding the exposure of clinical trials participants to unjustified and unnecessary risk, in normal times as well as in public health emergencies of international concern, including through:

(a) encouraging investment in well-designed clinical trials, including through clinical trials networks, that are developed in collaboration with affected communities, with a view to addressing their public health needs and with the potential for trials to contribute to clinical trial capabilities, including strengthening the core competencies of research personnel, particularly in developing countries;

(b) introducing grant conditions for funding clinical trials to encourage the use of standardized data protocols where available and appropriate and to mandate registration in a publicly available clinical trial registry within the World Health Organization's International Clinical Trials Registry Platform (ICTRP) or any other registry that meets its standards;

(c) promoting, as appropriate, measures to facilitate the timely reporting of both positive and negative interpretable clinical trial results in alignment with the WHO joint statement on public disclosure of results from clinical trials and the WHO joint statement on transparency and data integrity, including through registering the results on a publicly available clinical trial registry within the ICTRP, and encouraging timely publication of the trial results preferably in an open-access publication;

(d) promoting transparent translation of results, including comparison to existing treatments and data on effectiveness, based on thorough assessment, into clinical guidelines where appropriate;
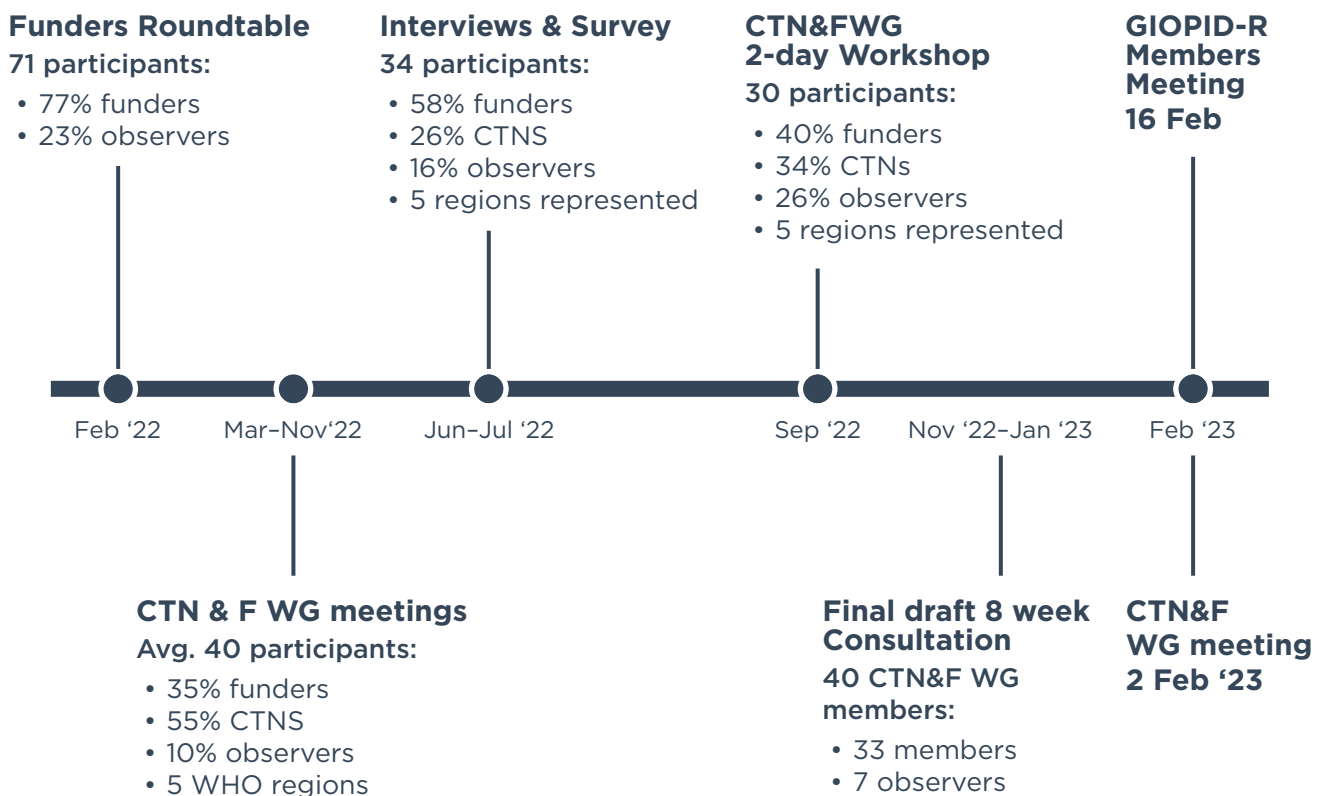
(e) exploring measures during public health emergencies of international concern to encourage researchers to rapidly and responsibly share interpretable results of clinical trials, including negative results, with national regulatory bodies or other appropriate authorities, including WHO for clinical guideline development and emergency use listing (EUL), to support rapid regulatory decision-making and emergency adaptation of clinical and public health guidelines as appropriate, including through pre-print publication;

Box 1. Extract from the WHA 75.8 Resolution to strengthen clinical trial coordination

Adopted at the 75th World Health Assembly. Strengthening clinical trials to provide high-quality evidence on health interventions and to improve research quality and coordination. 2022.

1. Introduction

1.2 Methodology

Funders Roundtable
71 participants:
- 77% funders
- 23% observers

Interviews & Survey
34 participants:
- 58% funders
- 26% CTNS
- 16% observers
- 5 regions represented

CTN&FWG
2-day Workshop
30 participants:
- 40% funders
- 34% CTNs
- 26% observers
- 5 regions represented

GIOPID-R Members Meeting 16 Feb

Feb '22   Mar–Nov'22   Jun–Jul '22   Sep '22   Nov '22–Jan '23   Feb '23

CTN & F WG meetings
Avg. 40 participants:
- 35% funders
- 55% CTNS
- 10% observers
- 5 WHO regions

Final draft 8 week Consultation
40 CTN&F WG members:
- 33 members
- 7 observers

CTN&F WG meeting 2 Feb '23

Figure 2. Roadmap engagement and consultation timeline and process

This living roadmap (2023 version) has been produced by GloPID-R's CTN&F Working Group, in consultation with GloPID-R members, its Data Sharing Working Group (23), observers and associated stakeholders, under the lead of the GloPID-R Research and Policy team of the Pandemic Sciences Institute at the University of Oxford. The principles and supporting recommended actions presented in the roadmap have been informed and refined through a series of high-level meetings (24-27), scoping reviews, and consultations with GloPID-R funder members, clinical trial network representatives, observers and associated stakeholders (Figure 2.). This roadmap is 'living' in the sense that it will be supported by a monitoring and evaluation plan to support implementation and to identify new inclusions for future updates.

This work builds on pre-pandemic work from GloPID-R (28) and others. It is supported by an initial rapid review in early 2022 of key policy guidance and publications to identify new and remaining challenges to effective clinical trial responses and solutions to address them. These results were used to inform the engagement and consultation process with GloPID-R funders, clinical trial network representatives, GloPID-R observers (including WHO & CEPI), and wider stakeholders involved in clinical trial responses, such as regulators and ethicists (Figure 2.). The engagement and consultation process included a series of meetings and workshops, together with semi-structured interviews and an online survey for broad and in-depth engagement and consultation. The interviews and survey reached 34 members of the CTN&F WG and wider GloPID-R funder members and observers in five regions (9.7% Africa, 12.9 % Asia, 52.3 % Europe, 5.7% Latin America, 19.4% North America). A summary of the survey results can be found on our GloPID-R website.

2. Goals and principles

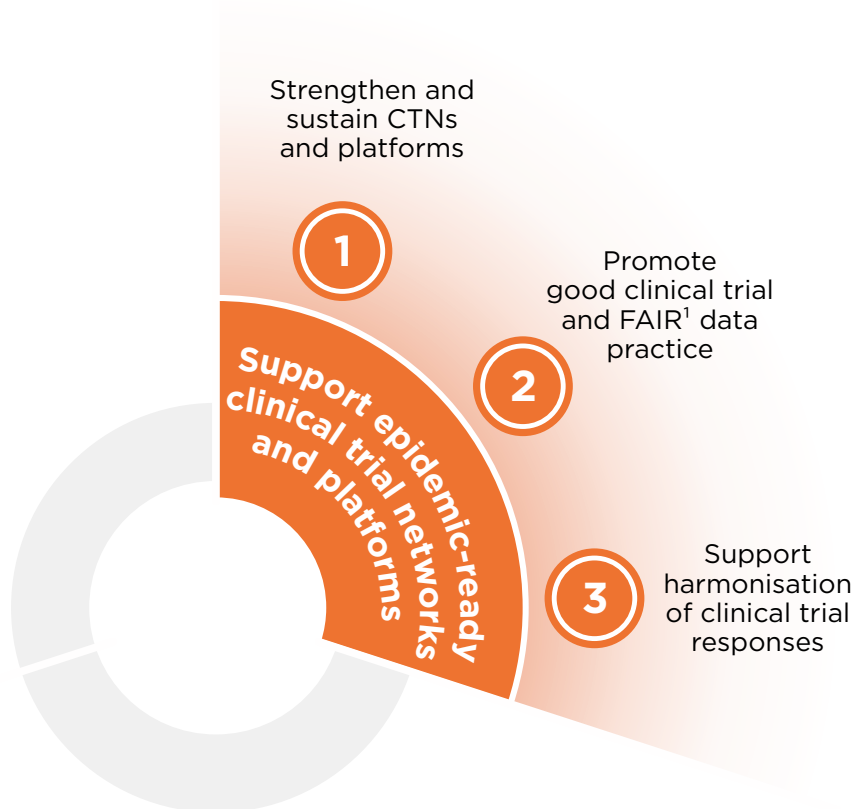**Figure 3.** The three goals and eleven accompanying principles of the roadmap

Through the engagement and consultation process, **three overarching goals** were identified, supported by **11 key principles** for funders (Figure 3). The 11 principles are structured under the key goals that they will support, while recognising that there is overlap. For each principle, a set of actions has been formulated to support their implementation, informed by solutions identified during the consultation process. These actions are meant as guidance for funders; not all funders will be able to implement all of them, yet all funders should be able to act on some of them. In chapters 3, 4 and 5, the three goals, associated core principles, and the accompanying set of actions are described.

3. GOAL

Support epidemic-ready clinical trial networks and platforms

Figure 4. The three principles for achieving the goal of supporting epidemic-ready clinical trial networks and platforms

For an effective clinical trial response during an epidemic, clinical trial networks and platforms must be adequately prepared and supported in inter-epidemic times to sustain capacity and capability such that they can be pivoted or surged at the outset of an outbreak. The COVID-19 pandemic showed the success of building on specific pre-positioned capacity as well as clinical research capacity in general. However, it also showed the need to build and strengthen the same capacity for efficient implementation of clinical trials including in LMICs.

Core funding and investments in baseline science in inter-epidemic times are needed to sustain expertise and identify medical countermeasure (MCM) trial candidates to facilitate effective trial implementation.

Long-term clinical trial funding is needed to prevent loss of intellectual and infrastructural capacity; to build and sustain intellectual and physical infrastructure; and to maintain established, trusted relationships within networks.

Principle 1

Strengthen and sustain strategic clinical trial networks and platforms

✓ Invest in sustained, strategic clinical trial networks and adaptive platform trials with the capacity and capability to deliver high-quality, large-scale multi-centre trials including in LMICs to produce actionable evidence addressing local and global research priorities.

✓ Invest in baseline research in inter-epidemic times, to develop necessary diagnostic, vaccine, and therapeutic candidates ready to trial during outbreaks while sustaining research capacity and capability.

Recommended actions for strengthening and sustaining strategic clinical trial networks and platforms

Action 1.1	
Support and sustain clinical trial networks and platforms via core funding and fund research on endemic high-priority diseases in inter-epidemic periods to sustain capacity and capabilities. **Action by** **Funders**	▸ Coordination across funding organisations is needed to ensure that agile, strategic clinical trial networks and adaptive trial platforms are sustained globally through core and project funding. Core funding for clinical trial networks and platforms is essential to maintain the necessary intellectual and physical infrastructure and established, trusted relationships within and between trial networks and associated stakeholders required for a timely, effective trial response during outbreaks. ▸ Sustaining clinical trial networks' research capabilities by focusing research on endemic diseases or syndromes and/or at different levels of care can allow for a rapid pivot to emerging outbreaks. For example, ADVANCE-ID is a network set up for observational studies focusing on antimicrobial resistance in ICU settings in South-East Asia with the intent, once capacity has been established, to pivot during outbreaks to address novel research questions through clinical trials.
Action 1.2	
Support strengthening of core infrastructural components (including administrative and logistical research support) of clinical trial networks and platforms to allow for the rapid scale-up of clinical research in response to outbreaks. **Action by** **Funders**	▸ An emphasis was made on strengthening and sustaining capacity and capability for trial implementation in LMICs. One challenge noted was regional centres in LMICs often lack supporting research infrastructure to lead and implement trials. A solution identified to address this was to support strategic regional research coordination hubs or support centres, providing support for administrative, ethical, and regulatory needs, and more agile funding channels. ▸ Consensus should be reached on the knowledge and skills required to act as trial sponsors. Frameworks to establish the necessary professional requirements for conducting trials have been developed in the past and should be built upon. ▸ Supporting and promoting standardised trial management tools and systems, can facilitate implementation and management of trials, and standardise practices.

Action 1.3	▸ Establishing open-access platform trial master protocols may facilitate an efficient research response ecosystem which can be leveraged to encourage collaborations while also promoting quality standards across sites. Strategic design of master protocols with appropriate endpoints for high priority diseases can be developed in the inter-epidemic period.
Fund the development of pre-approved, standardised open-access master trial protocols for diseases with epidemic and pandemic potential.	
Action by	▸ Development of protocols should be a collaborative process with early engagement from experts in endemic regions, communities, regulators, and ethics committees.
Funders	▸ Consideration of resource availability can be incorporated into master protocols, to allow flexibility for implementation in different contexts as in the example of the EU-SolidAct study protocol (29).

Principle 2

Promote a culture of good clinical trial practice including FAIR² data practices

✓ Require and support grantees in relevant commitments to good clinical trial practice, including well-designed and ethical trials, founded in open science, incorporating FAIR (findability, accessibility, interoperability, and reuse of digital assets) data practices.

✓ Ensure local, national and international stakeholder engagement to address local needs, and facilitate translation of findings into national and international policies, to benefit the local populations participating in trials.

Recommended actions for promoting a culture of good clinical trial practice including FAIR data practices

Action 2.1	
Prioritise funding to clinical trials that are well-designed, inclusive, and with adequate statistical power to produce actionable evidence benefitting local and global health. **Action by** **Funders**	▸ Investments should be made in trials that aim to identify optimal treatment strategies, with a focus made on prioritising affordable and scalable interventions including optimal supportive care, to improve outcomes. ▸ Critical expert review is needed to ensure that funding is prioritised for high-quality clinical trials that are (i) designed to address key research questions for all at-risk populations (ii) powered to produce actionable evidence, and (iii) complementary to other trials addressing research gaps. ▸ Trials should be inclusive of diverse populations, including pregnant women, children, and people with immunosuppression by age, medication, or illness as appropriate. ▸ The Good Clinical Practice guideline is a widely accepted guidance on the good design of trials, refined by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and has been incorporated by the U.S. FDA, EMA, and other regulatory authorities. Another effort to contribute to the dialogue on trial standards has been prepared by The Good Clinical Trials Collaborative (9), which has developed guidance that can be referenced in calls for proposals.

² Findability, Accessibility, Interoperability, and Reuse of Digital Assets

Action 2.2 **Require and support applicants in submitting data management plans in applications for clinical trial funding and monitor adherence.** **Action by** **Funders**	▸ Data management plans (DMPs) detail how grantees will handle, organise, and structure research data and are an effective tool for funders and researchers to ensure that data complies with the FAIR[2] principles (30). Requiring DMPs for review at the application stage with guidance to ensure that DMPs meet requirements can support this. DMP requirements should be harmonised across funders
Action 2.3 **Allocate appropriate funds to enable engagement of community members and relevant stakeholders during trials in line with the Good Participatory Practice for Trials on (re-) emerging Pathogens guidelines.** **Action by** **Funders**	▸ Engagement of a wide range of stakeholders, including local and national topic experts, public health professionals, community groups, and policymakers, throughout clinical trial development, deployment, and dissemination can help ensure that trial implementation is "understood, acceptable, relevant, and trusted"(31). Further, this ensures results can be rapidly translated into practice, to improve outcomes during the outbreak. ▸ Community engagement in clinical trial research should be prioritised and maintained throughout outbreaks. The WHO has developed Good Participatory Practice for Trials on (re-) emerging Pathogens guidelines (GPP-EP) (31). Within the guidelines, it is recommended that trial funders ensure that sufficient funding is allocated to enable engagement. ▸ Requiring evidence of GPP with full costings for delivery can help deliver on this. Building competency in GPP among researchers ahead of outbreaks and investing in contextual GPP models and frameworks also improve preparedness.

Action 2.4

Include in grant conditions that beneficiaries of funding:

- Register trials and disclose trial results on a publicly available clinical trial registry within the WHO International Clinical Trials Registry Platform (ICTRP).

- Share positive and negative results in a timely manner with regulatory authorities and other relevant authorities such as the WHO.

- Publish peer-reviewed trial results in a timely manner, preferably with open access.

- Deposit research data in an appropriate data repository, linked with a persistent identifier such as a Digital Object Identifier (DOI)

- Include a data availability statement (DAS) and persistent identifier linking to the underlying clinical trial data in publications.

- Include a metadata record in an appropriate data repository with a persistent identifier, in cases where data cannot be made publicly available.

Action by

Funders

Action 2.5

Invest in machine readable metadata and support semantic and technical interoperability between clinical trial registries.

Action by

Funders

Action 2.6

Support the TRUST (Transparency, Responsibility, User Focus, Sustainability, and Technology) principles and FAIR certification of repositories.

Action by

Funders

▸ There is a need for better coordination to enable clinical trial data from multiple platforms, institutions, and geographies to be collated and analysed with minimal effort. Under the steer of the WHO Implementation Guide on Data Sharing (32), funders hold significant influence over data-sharing principles. Existing platforms can be leveraged to advance this.

▸ Results, both positive and negative should be shared with regulatory authorities and other appropriate organisations, such as the WHO, and as open-access data through pre-print publication during the rapid-response phase (21). This will support rapid regulatory decision-making and the development and adaptation of clinical and public health management guidelines in emergencies.

▸ Moreover, grantees should be mandated to share clinical trial results by registering them on a publicly available clinical trial registry including within the WHO International Clinical Trials Registry Platform (21, 33, 34).

▸ Funders can promote measures to facilitate the timely reporting of interpretable trial results in alignment with:

- The WHO Sharing and Reuse of Health-Related Data for Research Purposes: WHO policy and implementation guidance (35)

- The WHO joint statement on public disclosure of results from clinical trials (36)

- International Coalition of Medicines Regulatory Authorities and WHO joint statement on transparency and data integrity (37)

- The FAIR principles (30)

Principle 3

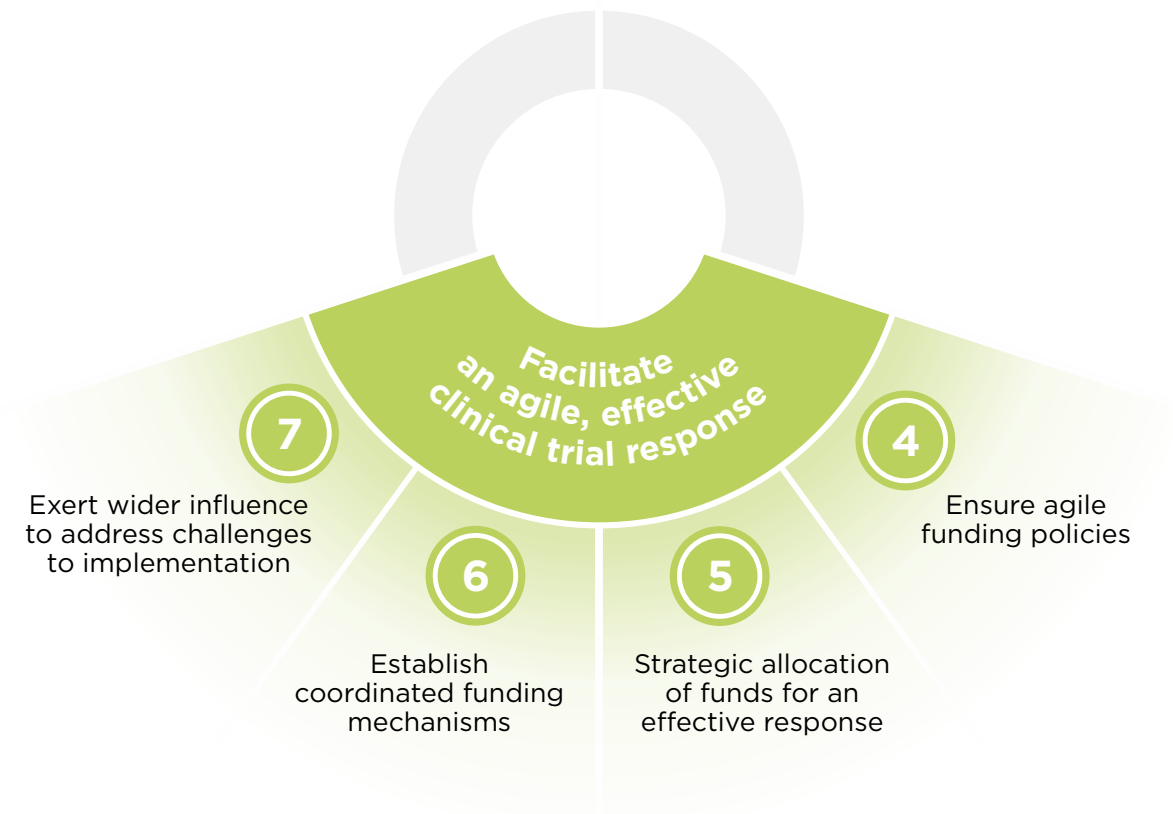## Support harmonisation of high-quality clinical trial responses

☑ Promote early collaboration across clinical trial networks and adaptive platform trials to support the use of harmonised definitions and trial endpoints and well-designed clinical trial protocols, facilitated by collaborative data-sharing platforms.

☑ Ensure trials are adequately powered to produce actionable evidence addressing local and global research priorities.

☑ Facilitate rapid collaborative, meta-analysis through standardised data collection and ensure effective sharing of actionable evidence with relevant bodies, including negative results.

Recommended actions for supporting harmonisation of clinical trial responses

Action 3.1 Include in grant conditions the requirement for harmonisation of trials through collaboration, systems, and tools to the extent possible and appropriate (e.g. trial management systems; protocols; data standards; definitions, and endpoints) and support review of protocols against industry gold standards during proposal evaluation. **Action by** Funders	▸ When individual trials cannot enrol a sufficient number of patients across clinical spectra and demographics, pooling data across clinical trials can provide robust answers, if data sampling and end points are harmonised. During the COVID-19 pandemic, a lack of infrastructure, standardisation, collaboration, and data-sharing agreements hindered the ability to share and pool data across research networks. When data was shared, a lack of standardisation made it challenging to analyse and interpret. In applications, funders can mandate that protocols are registered as open-access sources in a recognised registry. ▸ Funders can also request that applicants describe which protocols, data collection forms, core outcome measures, and data standards they will use. They are then prompted to identify whether a 'gold-standard protocol' and standardised definitions e.g. Core Outcome Set (COS), should be considered
Action 3.2 In grant conditions, require that protocols are accessible in a recognised open access register. **Action by** Funders	▸ During the review of applications, funders should include reviewers with previous knowledge of pre-existing 'gold-standard' protocols to establish (i) whether applicants understand the research landscape, (ii) whether the proposal is designed to add new information to existing studies, and (iii) whether their data will be comparable to other projects.
Action 3.3 During outbreaks, promote collaboration with other relevant research networks and consider this during proposal evaluation. **Action by** Funders & GloPID-R Secretariat	▸ GloPID-R and its members can further support researchers in harmonising trials by convening a forum similar to the EU-funded Trials Coordination Board (38). The board has facilitated coordination and helped to identify opportunities for collaboration to reduce the proliferation of small-scale competing trials, which risk oversaturating the research ecosystem in a given setting at the expense of better-powered new and existing trials.

4. GOAL

Facilitate an agile, effective clinical trial response

Figure 5. The four principles for achieving the goal of implementing agile effective clinical trial response

The goal is to facilitate an agile, effective clinical trial response to epidemics and pandemics through coordination, collaboration, and transparency in funding intentions and decisions to prevent unnecessary duplication and, proliferation of trials and unmet research needs. Investments in clinical trial capacity and capability in inter-epidemic periods are necessary to enable a timely and effective response during outbreaks. Utilising existing clinical trial infrastructures, networks, and adaptive platform trials, supported by core and agile funding policies, is required to effectively address implementation barriers including site recruitment, trial implementation training, and contractual and regulatory challenges.

Principle 4
Ensure agile funding policies

4

✓ Identify how funding agencies' policies and practices may better allow for existing research capability to more efficiently 'pivot' or 'surge' to address novel research questions in response to new and re-emerging outbreaks.

✓ Reduce administrative and resource challenges to facilitate rapid release of funds.

Recommended actions for ensuring agile funding policies

Action 4.1	
Establish emergency contingency funding mechanisms, including rapid calls for proposals, supplementary funding to (shortlisted) existing clinical trial network platforms, and rapid approval processes for rapid release of funds during outbreaks. **Action by** **Funders**	▸ During an epidemic, the speed with which clinical trial capacities can be directed to urgent research questions is, in part, dependent on the agility of funding allocation. ▸ Policies should allow for funds to be allocated to ongoing research through supplementary funding, and by launching new calls for proposals. Pre-established contracts with strategic research networks and organisations can facilitate the swift transfer of funding to enable a rapid response. ▸ Rapid response agility in funding systems should be coupled with agility in trial designs to allow nimble shifting as well as re-prioritising of funds so that clinical trial networks can pivot or surge capacity without the need to apply for amendments, for example as seen with REMAP-CAP (4). ▸ Where needed, it is important to permit amendments retrospectively to clinical networks and platforms that have already received funding. Adding simple procedures to existing grant agreements during outbreaks and accepting unsolicited researcher-driven applications for funding to address urgent needs are also important. ▸ Other policies should also be explored, for example assigning contingency funds allocated to certain grants to be able to pivot and surge research capacity. During the pandemic, funders used different indicators to mobilise emergency contingency funds, such as decision making at the ministry of health or declaration of a PHEIC.
Action 4.2	
Explore ways to expedite reviews in advance through surge review capacity, and by accepting past accreditation from own or other funder agencies. **Action by** **Funders**	▸ Internal procedures to provide surge capacity within funding organisations should be in place and activated early on during public health emergencies. These can include pre-approved internal governance mechanisms for rapid funding, a pool of trained staff, prioritisation of internal tasks, rapid review procedures, and early formal engagement of regulatory authorities facilitated by pre-established relationships.

Principle 5

Strategic allocation of funds for an effective response

5

☑ Consider alignment of global, regional, as well as local research agendas and priorities, and investigator-driven research during outbreaks.

Recommended actions for strategic allocation of funds for an effective response

Action 5.1 **Align funding with national, regional, and international clinical research prioritisation to address key research gaps.** **Action by** **Funders & GloPID-R Secretariat**	▸ During an outbreak, a top-down approach to research funding may be needed to ensure strategic prioritisation of funds into a few well-designed trials. ▸ Such a top-down prioritisation model aligned with international and national research priorities, together with an adaptive and pragmatic trial design, research staff surge capacity and resources, contributed to the successful implementation of the novel RECOVERY trial and evidence of the effectiveness of corticosteroids 138 days after the declaration of a PHEIC (2). ▸ Another example of effective national top-down prioritisation aligned with key research priorities during the pandemic includes the US National Institutes of Health Accelerating COVID-19 Therapeutic Interventions and Vaccines initiative (39).
Action 5.2 **Include early engagement and co-development of trials with local stakeholders in grant conditions and/or evaluation criteria to ensure trials are appropriate and acceptable to local needs and priorities.** **Action by** **Funders**	▸ Besides a top-down approach in prioritising calls for proposals aligned with key priorities, there also remains a key role for a bottom-up approach to inform trial design, facilitate innovation, address local research priorities, build capacity and capability, and facilitate local engagement in trials to support effective implementation and delivery. ▸ GloPID-R's regional hubs have a key role to play here in informing regional prioritisation setting and facilitating collaboration and coordination, with global actors.

Principle 6

Establish coordinated funding mechanisms

☑ Transparent sharing, and mapping of information about funding calls and decisions among funders.

☑ Explore opportunities for synergies across funding organisations, and collaboration to ensure that national, regional, and global public health needs are met.

☑ Achieve better alignment of funding by working together to develop the concepts and practices of sustained, collaborative, aligned, and when feasible jointly funded clinical trials that are equipped to answer questions of local and global relevance.

Recommended actions for establishing coordinated funding mechanisms

Action 6.1 **Establish cross-funder proposal evaluation committees.** **Action by** **Funders**	▸ Information sharing during the funding cycle is recommended to support coordination of funding and to mitigate unnecessary duplication of funded trials. It has been argued that sharing anticipated funding during outbreaks through convening funding organisations is insufficient. ▸ Having strategic members of other funding organisations participating in review committees can help avoid duplication of funding.
Action 6.2 **Establish a platform for pre-award information sharing among funders.** **Action by** **Funders & GloPID-R Secretariat**	▸ A closed funder platform for funders to share outcomes of review committees could take this a step further and centralise expert advice from external review. ▸ Formal mechanisms to facilitate funder-funder dialogue, throughout the funding cycle (from defining topics to call publication, evaluation, and selection) at national, regional, and international levels should be explored further.
Action 6.3 **Share information on funded research projects within centralised systems such as Pandemic PACT.** **Action by** **Funders & GloPID-R Secretariat**	▸ Pandemic PACT (Pandemic Preparedness: Analytical Capacity and Funding Tracking Programme) will provide a live database of funding allocation to facilitate coordination of resources. By registering allocation of funds in Pandemic PACT, it will help inform research prioritisation reviews, identify unmet research needs (based on research topic, inclusivity, and geography), and mitigate proliferation and duplication of trials. ▸ These systems should be utilised to inform research prioritisation and funding decisions to improve coordination and equity in trial responses. Further, such systems provide a useful tool for funders to identify and contact other agencies for potential joint funding opportunities to build on existing initiatives to address identified research gaps.

Action 6.4	
Explore coordinated funding models of strategic, sustained clinical trial networks, adaptive trial platforms, and outbreak response-specific trials, such as collaborative, joint, and pooled funding models.	▸ Establishing coordinated funding models was recognised as a key priority among funding organisations as a solution to reduce the proliferation of clinical research efforts and to maximise the impact of research investments.
Action by	▸ Traditional project-based funding of international trials presents challenges in terms of continuity. The success of such trials is contingent not only on the trial design but also on broad political support and long-term financial commitment. Core funding from multiple funders can bridge this gap to support capacity, capability, and sustainability (i.e. REMAP-CAP).
Funders & GloPID-R Secretariat	▸ To improve coordination of trials for a more effective global response to future outbreaks, closer collaboration between funders is necessary. Agile, rapid funding models (Box 2) are needed for a timely response to generate evidence to inform practices during outbreaks (40).

Aligned **funding:** funding bodies allocate funds in collaboration, aligning the contents and scope of the activities for which funding can be applied to one another, to avoid duplication of funding, and to address research gaps, considering the wider funding ecosystem. Such alignment can be facilitated through establishing cross-funder proposal evaluation committees, which was identified as beneficial for efficiency and transparency of funding during the COVID-19 pandemic. Another example could be the establishment of a closed platform for funders for rapid sharing of funding intentions and for facilitating funder-funder dialogue on call topics from the earliest stages of the funding cycle.

Synchronised **funding:** funding bodies not only share their funding priorities and intentions, but also follow **one funding timeline**. Following a joint panel review, individual shortlists for each funder are drawn up, identifying and exploiting potential synergies across funded projects with the funding organisations retain the final decision on which applications to support.

Joint **funding:** funding bodies share a **common portal for the submission** of applications with an agreed standard application form and a joint review process. Akin to the synchronised funding model, individual ranking lists for each funder will be drawn up, and the final decision of which applications to select still rests with individual funding organisations.

Pooled **funding,** participating funding bodies agree to **pool resources into a common budget** for a joint call on an agreed research topic. This requires a centralized management structure for the selection of applications with a common ranking list as a result, possibly operated by a third party acting on behalf of participating funding agencies.

Box 2. The four collaborative funding mechanism described can be explored and developed in a tiered structure

Principle 7

Exert wider influence to address challenges to trial implementation

☑ **Engage with wider stakeholders including private actors, ethicists and regulators in addressing contractual, ethical, and regulatory challenges to rapid trial activation.**

Recommended actions for exerting wider influence to address challenges to trial implementation

Action 7.1	▸ Trial regulatory processes are one of the key challenges to the rapid implementation of trials and must be accelerated during outbreaks. For improved clinical trial coordination, coordinated requirements and processes across regulatory agencies should be established. Funders can support grantees by facilitating communication of these requirements in advance of and during outbreaks.
Establish and sustain a point of contact and regular communication with relevant regulatory authorities.	
Action by	▸ Early engagement with regulatory agencies is important to facilitate communication on a) what regulatory authorities expect in terms of outcomes b) what researchers can provide and c) what funders can do to facilitate coordination of this kind.
Funders	
	▸ The EU-funded Trial Coordination Board (38) provides a platform for bringing clinical researchers, regulators, medicine, and vaccine agencies together to identify challenges and solutions to address these in inter-epidemic times and in real-time during epidemics. GloPID-R can provide support for the establishment of a network of regional Trial Coordination Boards, providing a platform to address regulatory challenges at regional and international levels.
	▸ Strengthening regulatory systems in low-resourced settings for outbreak response has been explored by the Wellcome Trust through its commissioned report on Strengthening Regulatory Systems in LMICs (41). Sustained investment, through a robust strategy, is needed in legal and policy reform, and addressing infrastructure issues such as digital infrastructure, and transparent performance measures.
	▸ Strengthening regulatory authorities and facilitating their involvement in strengthening the clinical trial ecosystem is needed to promote the perspective that clinical trials are a public good.

Action 7.2

Recommend implementation of standardised multi-jurisdictional contracts/ pre-agreed 'sleeping contracts'.

Action by

Funders

Action 7.3

Engage with clinical trial networks to explore how funding agencies may be able to resolve well-recognised obstacles to trial implementation, including negotiations with private vaccine and pharmaceutical companies for access to approved products.

Action by

Funders & GloPID-R Secretariat

▸ Researchers need less-complex contracts to facilitate country participation and reduce time delays. As presented earlier, sustaining clinical trial networks and trial platforms was identified as a key priority to address this key challenge.

▸ Further, an agreed legal framework and a standing emergency contract between funders and implementers are recommended.

▸ It is recommended to explore the feasibility of implementation of pre-positioned 'sleeping contracts', authorised in advance of outbreaks in strategic settings among funders and identified institutions. These contracts also need to be flexible to allow rapid amendments to support pivoting in response to outbreaks.

▸ GloPID-R could explore creating a database of successful 'simple' standardised contracts using de-identified templates from funders and networks, that can be adapted by end-users to accelerate new agreements. Funders could also take an approach whereby conditions of funding are contingent on research institutes participating in a multi-jurisdictional standardised contracting agreement, such as a multi-model clinical trials agreement. In addition, having agreements to protect and share intellectual property in place ahead of outbreaks can facilitate the timely sharing of data and MCMs.

Promote an equitable research environment

Figure 6. The three principles for achieving the goal of promoting an equitable research environment

Enhanced coordination of clinical trials requires promotion of mutually supportive partnerships and equitable trial governance. During the COVID-19 pandemic, there was a mismatch between funding allocation and needs of diverse populations. Research questions of relevance to LMICs remained unaddressed, and there was an imbalance in access to research outputs. Furthermore, some grant conditions may place unsurmountable administrative burdens on researchers during an emergency which may particularly affect those in resource-deprived settings, and clinical sites without access to administrative research support, making participation in clinical research inequitable. During outbreaks, this restricts capacity to produce actionable evidence.

Principle 8

Improve equitable clinical trial practice

8

✅ Promote and maintain mutually supportive and equitable partnerships and governance of national and international multi-centre clinical trials.

✅ Promote and support equitable trial leadership and facilitate effective implementation of multi-centre clinical trials in affected regions worldwide.

✅ Prioritise trials benefitting diverse local as well as global populations.

✅ Encourage community engagement for improved patient recruitment, and ensure trials are designed to address and benefit local needs and the whole population.

Recommended actions for improving equitable trial practice

Action 8.1	
Promote more diverse and equitable governance of clinical trials, clinical trial networks, and platforms.	▸ In grant conditions, evaluation criteria, and policies, funders can promote diversity in trial governance and leadership, and ensure that research outputs benefit the populations included in trials.
Action by	▸ There is a need to shift the balance, to actively engage and support researchers in lower-resourced settings so they can sponsor, design, and lead trials.
Funders	▸ One challenge is a lack of supporting research infrastructure, including administrative support, and in some settings a lack of political support for research. Funders can play an important role in addressing this challenge by supporting research capacity strengthening in LMICs to lead on trials including local administrative trial support (action 1.2).
	▸ While capacity to sponsor trials is being strengthened in resource-deprived settings, some clinicians in LMICs still welcomed the opportunity to co-lead trials with researchers from higher-income countries, as they currently lack the required infrastructure, administrative and operational resources to lead. Other experienced clinical researchers in LMICs, who have the capacity to lead, are faced with a lack of funds.
	▸ For effective implementation of trials, trials led by and co-developed with local communities at the heart of the outbreak are recommended. This ensures that trials are well-designed for implementation in local healthcare practices and address local needs, benefitting local populations. For new and emerging infections, prioritising investments in trials that are not dependent on lengthy and expensive drug pipelines can ensure they can benefit populations at the highest risk of severe disease during outbreaks to improve survival rates.

Action 8.2	▸ Incentivisation for collaboration is recommended at all levels of the clinical research ecosystem (from academic institutions to publishers) to mitigate the current motivational bias toward acting as principal investigator, even of small studies that provide little benefit.
Include dissemination of research outputs beyond scientific publications in grant evaluation criteria, in line with The Declaration on Research Assessment (DORA) recommendations.	▸ Collaboration should come to have a higher or equal value to leading trials, so researchers in higher-income countries are better motivated to support and contribute to trials led by scientists in under-researched regions.
Action by	▸ Supporting the DORA[3] (42) can be a first step toward ensuring that collaboration is incentivised, both during and in between outbreaks. Funders as well as publishers bear a responsibility to leverage research governance equity through policies and action.
Funders	

[3] In the San Francisco Declaration on Research Assessment funding agencies are called upon to adapt policies to (a) be explicit regarding criteria used to evaluate the scientific productivity of grant applications and (b) in addition to research publications, consider the value and impact of all research outputs, including those which promote collaboration (42).

Principle 9

Ensure investments promote equity of access

9

✓ Agree on equitable standards and distribution of products derived from research.

Recommended actions for ensuring investments that promote equity of access

Action 9.1 **Explore establishing framework contract agreement access terms with industrial partners ahead of an outbreak concerning diseases of epidemic and pandemic potential in areas such as post-trial product access, and price.** **Action by** **Funders**	▸ While researchers are limited in their capacity to negotiate the cost of drugs, funders have the leverage to establish contracting agreements with industry partners. ▸ Negotiations during outbreaks can cause significant delays in initiating trials. For known high-consequence infectious diseases, there is usually a limited number of industry partners. Funders are recommended to engage with these partners on predictable areas of negotiation such as post-trial drug pricing and supply, cost of goods, and legal issues, ahead of an outbreak.
Action 9.2 **Monitor equity in access to products being tested, by including key indicators in progress reporting requirements.** **Action by** **Funders** **Action 9.3** **In the circumstance of a pandemic response with large product demand, promote making products available at time of first authorization to serve as a comparator in support of trialling product development efforts.** **Action by** **Funders**	▸ Research funding organisations should include conditions in their funding arrangements to ensure access to medical countermeasures in clinical trial settings at any resource level is delivered at affordable prices and the scale required, in an emergency. ▸ Equitable access considerations in business-as-usual investments should be mirrored by similar equitable access efforts during a pandemic. ▸ In grant agreements, affordable access to products that come from research is often included, but monitoring of implementation needs to be undertaken by funders or their commissioned independent organisations (19).

Principle 10

Provide support for researchers and equitable research environments

10

☑ **Support equitable access to research funding, research infrastructure, and operational support to deliver high-quality trials in both high- and low-resource settings**

Recommended actions for providing support for researchers and an equitable research environment

Action 10.1	
Reduce administrative burdens on clinical researchers e.g. by exploring harmonised funding and monitoring systems. **Action by** Funders	‣ Funders have a responsibility for scientific stewardship, and as such, should ensure equity throughout the research process. ‣ Grant applications are a challenging and resource-intensive exercise favouring researchers in higher-resourced settings and large academic institutions with access to logistical support and resources. ‣ Standardising grant proposal forms and systems between funders will decrease some of the administrative burden and challenges faced by applicants in low-resource settings and diversify the trial ecosystem.
Action 10.2	
Ensure researchers are supported with the necessary resources to implement trials effectively in different resource settings to meet grant requirements. **Action by** Funders	‣ Many grant conditions place heavy burdens on trialists, especially impacting those in resource-deprived settings and clinicians without access to research support centres, making participation in clinical research inequitable. ‣ Where changes in grant conditions are made with resource implications, additional funding must also be granted. This is particularly relevant for researchers based in resource-limited settings. ‣ Adaptations to reduce reporting requirements during outbreaks are also recommended, particularly given that resources are stretched during the response effort and an often rapidly evolving situation.

6. Cross-cutting principle

The three goals and associated principles are supported by a cross-cutting principle focused on monitoring and evaluation to support implementation of the roadmap and to identify specific challenges, solutions, and good practice examples to integrate into future updates.

Principle 11

Monitor, evaluate, and integrate

⊘ Embed monitoring and evaluation of progress against the three goals and principles to identify and address specific challenges, to support implementation and knowledge dissemination across the GloPID-R membership and wider funding bodies.

Recommended actions for monitoring, evaluation of progress and integration

Action 11.1 **Map funders current policies and procedures against recommendations and actions to identify gaps, establish a baseline and identify leading funder practices.** **Action by** **GloPID-R Secretariat & Funders** **Action 11.2** **Prioritise actions according to baseline assessment and feasibility.** **Action by** **Funders**	‣ Funders' existing commitments to the recommended principles and actions described above can be established with a baseline self-assessment, followed by the development of an implementation guide to support funders in their implementation.
Action 11.3 **Monitor the implementation of actions.** **Action by** **GloPID-R Secretariat**	‣ Implementation of putting into action the principles in this roadmap will be monitored by GloPID-R to inform further policy development and support, as well as the updating of this living roadmap. We aim to promote reflective practices in funding organisations to promote the objectives of the roadmap.
Action 11.4 **Update roadmap as best practices evolve.** **Action by** **GloPID-R Secretariat**	‣ Given that the roadmap is 'living', it will be adapted accordingly as new guidelines or best practices emerge. As such, GloPID-R will commit to effectively communicating with and supporting funding organisations in improving policies and practices, according to relevant best practices.

Annex 1: Overview of the roadmap actions

GOAL
Support epidemic-ready clinical trial networks and platforms

1 **Recommended actions for strengthening and sustaining strategic clinical trial networks and platforms**

1.1 Support and sustain clinical trial networks and platforms via core funding and fund research on endemic high-priority diseases in inter-epidemic periods to sustain capacity and capabilities.		**Funders**
1.2 Support strengthening of core infrastructural components (including administrative and logistical research support) of clinical trial networks and platforms to allow for the rapid scale-up of clinical research in response to outbreaks.		**Funders**
1.3 Fund the development of pre-approved, standardised open-access master trial protocols for diseases with epidemic and pandemic potential.		**Funders**

2 **Recommended actions for promoting a culture of good clinical trial practice including FAIR (Findability, Accessibility, Interoperability, and Reuse of Digital Assets) data practices**

2.1 Prioritise funding to clinical trials that are well-designed, inclusive, and with adequate statistical power to produce actionable evidence benefitting local and global health.		**Funders**
2.2 Require and support applicants in submitting data management plans in applications for clinical trial funding and monitor adherence.		**Funders**
2.3 Allocate appropriate funds to enable engagement of community members and relevant stakeholders during trials in line with the Good Participatory Practice for Trials on (re-) emerging Pathogens guidelines.		**Funders**
2.4 Include in grant conditions that beneficiaries of funding: - Register trials and disclose trial results on a publicly available clinical trial registry within the WHO International Clinical Trials Registry Platform (ICTRP). - Share positive and negative results in a timely manner with regulatory authorities and other relevant authorities such as the WHO. - Publish peer-reviewed trial results in a timely manner, preferably with open access. - Deposit research data in an appropriate data repository, linked with a persistent identifier such as a Digital Object Identifier (DOI). - Include a data availability statement (DAS) and persistent identifier linking to the underlying clinical trial data in publications. - Include a metadata record in an appropriate data repository with a persistent identifier, in cases where data cannot be made publicly available.		**Funders**
2.5 Invest in machine readable metadata and support semantic and technical interoperability between clinical trial registries.		**Funders**
2.6 Support the TRUST (Transparency, Responsibility, User Focus, Sustainability, and Technology) principles and FAIR certification of repositories.		**Funders**

3 **Recommended actions for supporting harmonisation of high-quality clinical trial responses**

3.1 Include in grant conditions the requirement for harmonisation of trials through collaboration, systems and tools to the extent possible and appropriate (e.g. trial management systems; protocols; data standards; definitions and endpoints) and support review of protocols against industry gold standard during proposal evaluation.		**Funders**
3.2 In grant conditions, require that protocols are accessible in a recognised open access register.		**Funders**
3.3 During outbreaks, promote collaboration with other relevant research networks and consider this during proposal evaluation.	**GloPID-R Secretariat**	**Funders**

GOAL
Facilitate a coordinated, effective clinical trial response

4 **Recommended actions for ensuring agile funding policies**

4.1	Establish emergency contingency funding mechanisms, including rapid calls for proposals, supplementary funding to (shortlisted) existing clinical trial network platforms, and rapid approval processes for rapid release of funds during outbreaks.		**Funders**
4.2	Explore ways to expedite reviews in advance through surge review capacity, and by accepting past accreditation from own or other funder agencies.		**Funders**

5 **Recommended actions for strategic allocation of funds in coordination with other organisations**

5.1	Align funding with national, regional, and international clinical research prioritisation to address key research gaps.	**GloPID-R Secretariat**	**Funders**
5.2	Include early engagement and co-development of trials with local stakeholders in grant conditions and/or evaluation criteria to ensure trials are appropriate and acceptable to local needs and priorities.		**Funders**

6 **Recommended actions for establishing coordinated funding mechanisms**

6.1	Establish cross-funder proposal evaluation committees.		**Funders**
6.2	Establish a platform for pre-award information sharing among funders.	**GloPID-R Secretariat**	**Funders**
6.3	Share information on funded research projects within centralised systems such as PACT (Pandemic Preparedness: Analytical Capacity and Fund Tracking).	**GloPID-R Secretariat**	**Funders**
6.4	Explore coordinated funding models of strategic, sustained clinical trial networks, adaptive trial platforms and outbreak response specific trials, such as collaborative, joint and pooled funding models.	**GloPID-R Secretariat**	**Funders**

7 **Recommended actions for exerting wider influence to address challenges to trial implementation**

7.1	Establish and sustain a point of contact and regular communication with relevant regulatory authorities.		**Funders**
7.2	Recommend implementation of standardised multi-jurisdictional contracts/ pre-agreed 'sleeping contracts'.		**Funders**
7.3	Engage with clinical trial networks to explore how funding agencies may be able to resolve well-recognised obstacles to trial implementation, including negotiations with private vaccine and pharmaceutical companies for access to approved products.	**GloPID-R Secretariat**	**Funders**

GOAL
Ensure an equitable research environment

8 **Recommended actions for improving equitable clinical trial practice**

8.1 Promote more diverse and equitable governance of clinical trials, clinical trial networks and platforms.		Funders
8.2 Include dissemination of research outputs beyond scientific publications in grant evaluation criteria, in line with The Declaration on Research Assessment (DORA) recommendations.		Funders

9 **Recommended actions for ensuring investments that promote equity of access**

9.1 Explore establishing framework contract agreement access terms with industrial partners ahead of an outbreak concerning diseases of epidemic and pandemic potential in areas such as post-trial product access and price.		Funders
9.2 Monitor equity in access to products being tested, by including key indicators in progress reporting requirements.		Funders
9.3 In the circumstance of a pandemic response with large product demand, promote making products available at time of first authorization to serve as a comparator in support of trialing product development efforts.		Funders

10 **Recommended actions for providing support for researchers and an equitable research environment**

10.1 Reduce administrative burdens on clinical researchers e.g. by exploring harmonised funding and monitoring systems.		Funders
10.2 Ensure researchers are supported with the necessary resources to implement trials effectively in differently resource settings to meet grant requirements.		Funders

Cross-cutting Principle

11 **Recommended actions for monitoring and evaluation of roadmap implementation**

11.1 Map funders current policies and procedures against recommendations and actions to identify gaps, establish a baseline and identify leading funder practices.	GloPID-R Secretariat	Funders
11.2 Prioritise action plans tailored to both individual funding organisations and collective action according to baseline assessment and remit.		Funders
11.3 Monitor the implementation of actions.	GloPID-R Secretariat	Funders
11.4 Update roadmap as best practices evolve.	GloPID-R Secretariat	Funders

Acknowledgements

References

1. Goossens H, Derde L, Horby P, Bonten M. The European clinical research response to optimise treatment of patients with COVID-19: lessons learned, future perspective, and recommendations. The Lancet Infectious Diseases. 2021.

2. The RECOVERY Collaborative Group. Dexamethasone in hospitalized patients with Covid-19—preliminary report. The New England Journal of Medicine. 2020.

3. WHO Solidarity Trial Consortium. Repurposed antiviral drugs for Covid-19—interim WHO solidarity trial results. New England journal of medicine. 2021;384(6):497-511.

4. REMAP-CAP. REMAP-CAP response to the COVID-19 pandemic [Internet] unknown: REMAP-CAP; 2020 [cited 2022 Nov 1]. Available from: https://www.remapcap.org/coronavirus

5. Bugin K, Woodcock J. Trends in COVID-19 therapeutic clinical trials. Nature Reviews Drug Discovery. 2021;20(4):254-6.

6. Angus DC. Optimizing the trade-off between learning and doing in a pandemic. Jama. 2020;323(19):1895-6.

7. McLean AR, Rashan S, Tran L, Arena L, Lawal A, Maguire BJ, et al. The fragmented COVID-19 therapeutics research landscape: a living systematic review of clinical trial registrations evaluating priority pharmacological interventions. Wellcome Open Research. 2022;7(24).

8. Park JJ, Grais RF, Taljaard M, Nakimuli-Mpungu E, Jehan F, Nachega JB, et al. Urgently seeking efficiency and sustainability of clinical trials in global health. The Lancet Global Health. 2021;9(5): e681-e90.

9. Good Clinical Trials Collaborative. Guidance for Good Randomized Clinical Trials [Internet] London, UK: Good Clinical Trials; 2022 May [updated 01 May 2022; cited 2022 Nov 1]. Available from: https://www.goodtrials.org/guidance.

10. WHO. Supplementary report on implementing WHA resolution 75.8 on strengthening clinical trials to provide high-quality evidence on health interventions and to improve research quality and coordination 2023. Available from: https://www.who.int/publications/m/item/supplementary-report-on-implementing-wha-resolution-75.8-on-strengthening-clinical-trials-to-provide-high-quality-evidence-on-health-interventions-and-to-improve-research-quality-and-coordination

11. World Bank. Money and microbes: strengthening clinical research capacity to prevent epidemics. 2018. Available from: https://documents.worldbank.org/curated/en/120551526675250202/

12. WHO. Strengthening clinical trials1 to provide high-quality evidence on health interventions and to improve research quality and coordination. 2022. Available from: https://apps.who.int/gb/ebwha/pdf_files/WHA75/A75_R8-en.pdf

13. Lurie N, Manolio T, Patterson AP, Collins F, Frieden T. Research as a part of public health emergency response. Mass Medical Soc; 2013. p. 1251-5.

14. Rojek AM, Horby PW. Offering patients more: how the West Africa Ebola outbreak can shape innovation in therapeutic research for emerging and epidemic infections. Philosophical Transactions of the Royal Society B: Biological Sciences. 2017;372(1721):20160294.

15. National Academies of Sciences Engineering & Medicine. Integrating clinical research into epidemic response: the Ebola experience. 2017.

16. WHO. COVAX. Working for global equitable access to COVID-19 vaccines [Internet] Geneva, Switzerland: World Health Organisation; 2020 [cited 2022 Nov 1]. Available from: https://www.who.int/initiatives/act-accelerator/covax.

17. WHO. "Solidarity" clinical trial for COVID-19 treatments [Internet] Geneva, Switzerland: World Health Organisation; 2020 [cited 2022 Nov 1]. Available from: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/solidarity-clinical-trial-for-covid-19-treatments.

18. RECOVERY. International Sites [Internet] Oxford, UK: University of Oxford; 2023 [cited 2022 Nov 1]. Available from: https://www.recoverytrial.net/international.

19. Pandemic Preparedness Partnership. 100 Days Mission to Respond to Future Pandemic Threats. London, UK; 2021 12 June 2021.

20. Department of Health and Social Care. G7 Therapeutics and Vaccines Clinical Trials Charter. 2021.

21. WHO. Strengthening clinical trials to provide high-quality evidence on health interventions and to improve research quality and coordination [Internet]. Geneva, Switzerland; 2022 May 24. Avaliable from: https://apps.who.int/gb/ebwha/pdf_files/WHA75/A75_R8-en.pdf

22. GloPID-R. Clinical Trial Networks & Funders (CTN&F) [Internet] Paris, France: GloPID-R; 2022 Jun [cited 2022 Nov 1]. Available from: https://www.glopid-r.org/our-work/clinical-trials-networks-funders/.

References continued

23. GloPID-R. Data Sharing Working Group Paris, France: GloPID-R; 2022 Jun [cited 2022 Nov 1]. Available from: https://www.glopid-r.org/our-work/data-sharing/.

24. GloPID-R. GloPID-R Frontiers Meeting, London Paris, France: GloPID-R; 2019 Dec [cited 2022 Nov 1]. Available from: https://www.glopid-r.org/articles-newsletter/glopid-r-frontiers-meeting-london/.

25. GloPID-R & PREPARE. Reaching out: a meeting to advance clinical research preparedness for infectious disease outbreaks. Meeting Summary. 2018.

26. GloPID-R & UK DHSC. Funders' Roundtable: Improving clinical trials coordination. 2022.

27. GloPID-R. Successful CTN&F workshop in Annecy makes progress on GloPID-R Funders Roadmap [Internet] Paris, France: GloPID-R; 2022 Sep [cited 2022 Nov 1]. Available from: https://www.glopid-r.org/articles-newsletter/successful-ctnf-workshop-in-annecy-makes-progress-on-glopid-r-funders-roadmap/.

28. Norton A, Sigfrid L, Aderoba A, Nasir N, Bannister PG, Collinson S, et al. Preparing for a pandemic: highlighting themes for research funding and practice—perspectives from the Global Research Collaboration for Infectious Disease Preparedness (GloPID-R). BMC medicine. 2020;18(1):1-4.

29. EU-SolidAct. Protocol Title: European DisCoVeRy for Solidarity: An Adaptive Pandemic and Emerging Infection Platform Trial [Internet] Bethesda, Maryland7: US National Library of Medicine. National Institutes of Health; 2021 May 18 [updated 2023 Feb 6; cited 2023 Feb 7]. Available from: https://clinicaltrials.gov/ct2/show/NCT04891133.

30. Collins S, Genova F, Harrower N, Hodson S, Jones S, Laaksonen L, et al. Turning FAIR into reality: Final report and action plan from the European Commission expert group on FAIR data. 2018.

31. WHO. Good Participatory Practice for trials of (re-)emerging pathogens (GPP-EP): Guidelines [Internet] Geneva, Switzerland: World Health Organisation 2016 [cited 2022 Nov 1]. Available from: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/solidarity-trial-of-covid-19-vaccines/good-participatory-practices.

32. WHO. Sharing and reuse of health-related data for research purposes: WHO policy and implementation guidance. 2022.

33. WHO. Partner registries [Internet] Geneva, Switzerland: World Health Organisation; [cited 2022 Nov 1]. Available from: https://www.who.int/clinical-trials-registry-platform/network/partner-registries.

34. WHO. Primary registries in the WHO registry network [Internet] Geneva, Switzerland: World Health Organisation; [cited 2022 Nov 1]. Available from: https://www.who.int/clinical-trials-registry-platform/network/primary-registries.

35. WHO. Sharing and reuse of health-related data for research purposes: WHO policy and implementation guidance. Geneva, Switzerland: World Health Organization; 2022.

36. WHO. Joint statement on public disclosure of results from clinical trials [Internet] Geneva, Switzerland: World Health Organisation; 2017 May 18 [updated 2017 May 18; cited 2022 Nov 1]. Available from: https://www.who.int/news/item/18-05-2017-joint-statement-on-registration.

37. Joint Statement on transparency and data integrity International Coalition of Medicines Regulatory Authorities (ICMRA) and WHO [press release]. 7 May 2021. Available from: https://www.icmra.info/drupal/en/covid-19/who_icmra_statement

38. RECOVER & EU-RESPONSE. Trial Coordination Board [Internet] Unknown: EU; 2020 [cited 2022 Nov 1]. Available from: https://covid19trials.eu/en/tcb.

39. Buchman TG, Draghia-Akli R, Adam SJ, Aggarwal NR, Fessel JP, Higgs ES, et al. Accelerating Coronavirus Disease 2019 Therapeutic Interventions and Vaccines—Selecting Compounds for Clinical Evaluation in Coronavirus Disease 2019 Clinical Trials. Critical care medicine. 2021;49(11):1963.

40. Diallo A, Trøseid M, Simensen VC, Boston A, Demotes J, Olsen IC, et al. Accelerating clinical trial implementation in the context of the COVID-19 pandemic: Challenges, lessons learned and recommendations from DisCoVeRy and the EU-SolidAct EU response group. Clinical Microbiology and Infection. 2022;28(1):1.

41. Harris Rachelle LR, Poon Charlotte, Raj Nimisha and Barron Anthony. Strengthening Regulatory Systems in LMICs. London, England; 2022 Jun. Available from: https://cms.wellcome.org/sites/default/files/2022-07/strengthening-regulatory-systems-in-low-and-middle-income-countries-improving-the-sustainability-of-the-vaccine-innovation-ecosystem-in-africa.pdf

42. American Society for Cell Biology. San Francisco declaration on research assessment (DORA) [Internet] unknown: American Society for Cell Biology; 2012 [cited 2022 Nov 1]. Available from: https://sfdora.org/read/