

GloPID-R Clinical Trial Coordination Survey Summary

The aim of the Funders Living Roadmap for Coordination of Clinical Trials is to identify a set of principles that all funders can endorse, supported by actions for funders to achieve these. Not all funders will be able to achieve all the recommended actions, due to internal regulations and remit, but all funders should be able to implement some. The aim of this survey was to explore the feasibility of the identified principles and recommended actions from the perspective of funding agencies, to refine them to inform the first version of the GloPID-Rs Funders Living Roadmap for Coordination of Clinical Trials. The survey was developed by the GloPID-R Research and Policy Team in consultation with our Clinical trial Network and Funders (CTN&F) working group.

1. Methodology

The survey was informed by previous work, including a scoping review, high level stakeholder meetings and semi-structured interviews with clinical trial networks (CTNs) and funder representatives and associated stakeholders (regulators, ethicists) in May to June 2022. Through pre-defined, multiple choice and open ended questions the survey explored the feasibility, acceptability and appropriateness of the identified principles and actions, focused on: strengthening and sustaining outbreak trial response research capacity and capability; alignment of funding to research priorities, national and international research agendas; outbreak response plans; agile funding mechanisms; surge capacity; data sharing principles; synergistic and coordinated funding models. We asked funders if the principles and actions identified from the initial review and engagement activities were already implemented; were actively considered, or if they could be considered; or if they were not feasible.

The survey was programmed on the JISC database and piloted by the GloPID-R Research & Policy Team and by two external funding agency representatives before being finalised. The final survey was circulated to all GloPID-R funder members (n=35) via e-mail, with six reminders. The survey was opened from 8 June to 15 August 2022. Data was analysed using Microsoft excel. The results are presented in a narrative way, organised by explored topics.

2. Survey respondents

The response rate was 51% (n=18/35). Respondents represented GloPID-R funder members in 13 countries, five continents (Figure 1). Of these, 15 (83%) were public, 2 (11%) non-governmental, and 1 (0.1%) a private organisation.

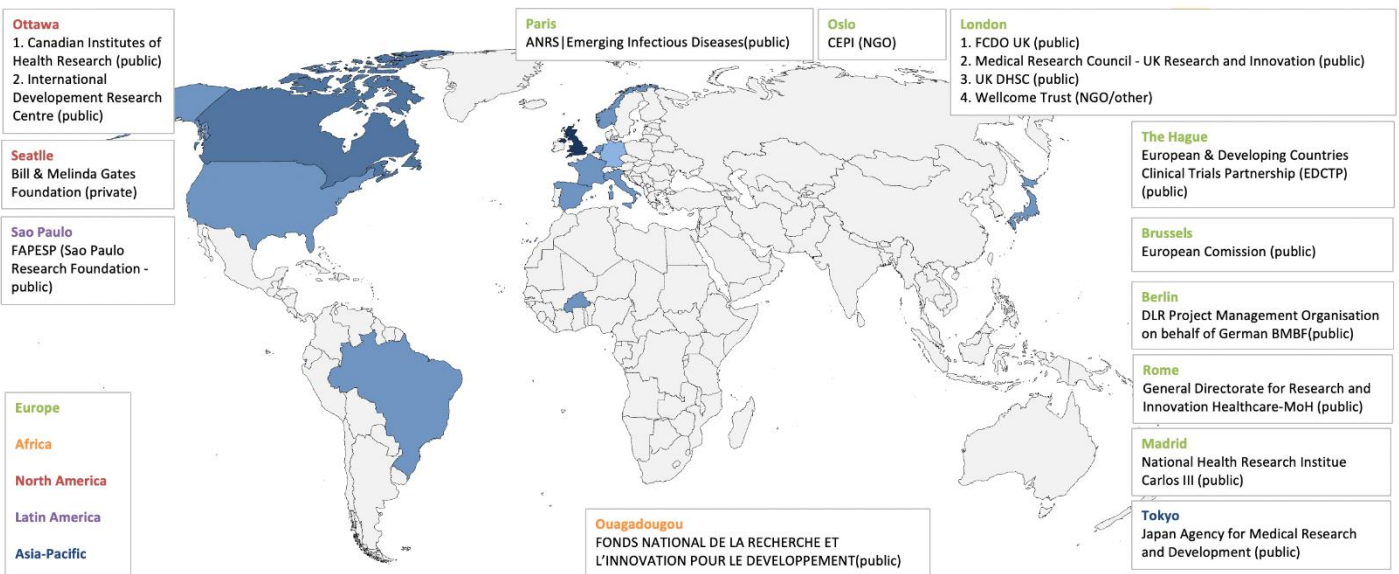


Figure 1: Funder organisation survey representation

3. Survey results by topic

International remit of the funder organisations

Survey participants were asked what their funding organisations geographical remit for infectious disease funding was from a series of pre-determined multiple-choice questions. Eight (44%) organisations reported that they are able to fund international principal investigators. Twelve (67%) can provide fund for trials outside of their country through national principal investigators with international collaborators. Five (28%) allow international infectious disease research funding through national research teams and eight (44%) have a national research remit only.

Supporting and sustaining international research funding

Sustaining clinical trial networks was a key action identified through the consultation processes. Of the survey respondents, nine (50%) organisations reported that they fund CTNs. Two (11%) funders indicated that they have plans in place to sustain CTNs; through large investments and core funding alongside project-based funding. Another four (22%) that they are actively considering putting plans in place to sustain funding for CTNs, six (33%) stated it could be considered, whereas six (33%) respondents were unsure of any plans to sustain funding.

Data sharing and data management plans

Ensuring that data from clinical trials are made accessible and disseminated for action, is essential during outbreaks for the timely translation of clinical trial results into policy and practice. Survey participants were asked to indicate if their funder organisations promote data sharing that is urgent or policy relevant among applicants/grantees through funding calls, as a criterion for review at application assessment, or as a stipulation in grant conditions. They could select multiple options. Fourteen (78%) organisations recommended data sharing as part of their funding calls, 13 (72%) as a criterion for review at the application assessment stage and nine (50%) as a stipulation in the grant conditions. Seventeen (94%) organisations require a data management plan (DMP) to be submitted with proposals, but only eight (44%) monitor compliance with data sharing requirements. Nine (50%)

provide guidance on how to develop DMPs and seven (39%) require applicants to allocate a budget for implementing their DMP.

Data sharing standards.

Survey participants were asked to indicate which data sharing practices their funder organisations require from a pre-determined list of multiple choice options. Seven (39%) organisations had requirements on preferred data repositories and/or data standards (e.g., metadata documentation). Seven (39%) reported having requirements in place for linking data to be shared to a persistent identifier and in publications about the trial to facilitate data sharing practices Four (22%) require equitable data sharing arrangements between high-income and low-and middle- income countries. These include specificities in funding calls, grant agreements and DMPs.

Strengthening capacity and capability and facilitating standardisation

A series of pre-defined grant conditions were provided to survey participants, asking them to indicate which ones they stipulate adherence to in their grant conditions to strengthen capacity and capability, and facilitate the standardisation of trials (Figure 2). Regarding strengthening capacity and capability, 14 (78%) funders reported that their organisation allow funding for research equipment for clinical trial capacity strengthening and 10 (56%) that they allow funding for training or other capability strengthening activities. Regarding standardisations, six (33%) recommended globally recognised standardised data collection forms when available, and five (28%) standardised clinical trial management systems.

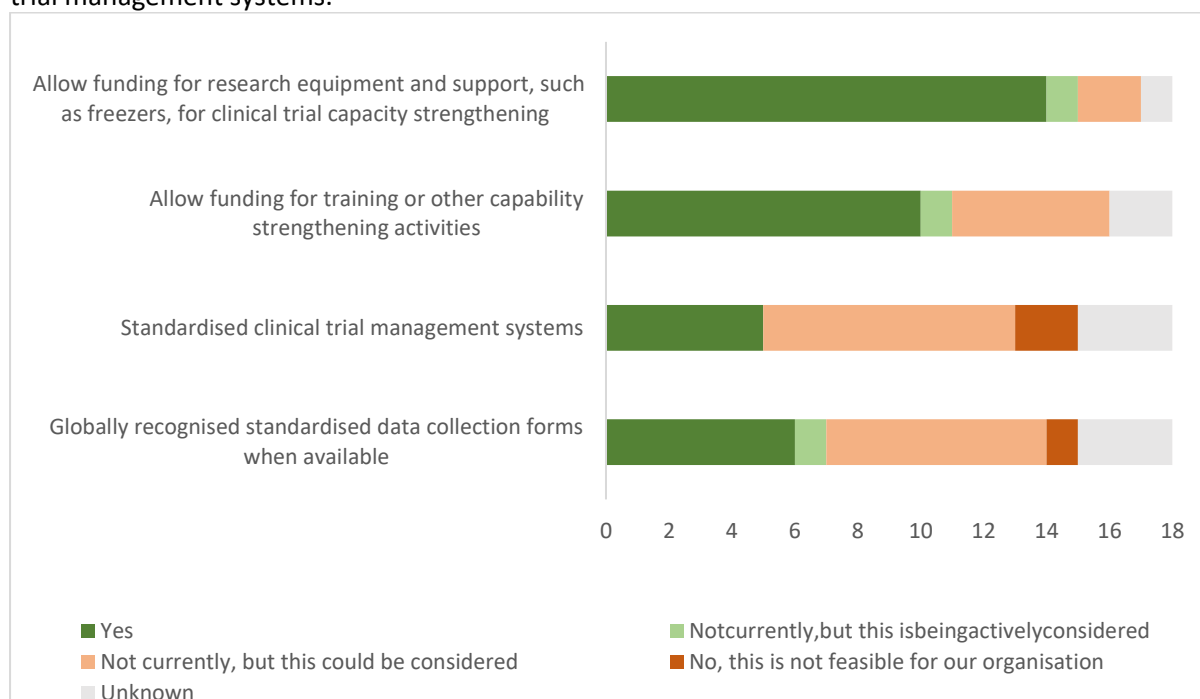


Figure 2: Stipulations in grant conditions that help to build capacity and facilitate standardisation

Some respondents emphasised in the survey that whilst many stipulations in grant conditions are recommended, they are not mandated. Others stated that these factors may not be stipulated in grant conditions, but that they are an element in the review process.

Agile policies for an efficient response to outbreaks

Outbreak response plans.

Efficiently responding to epidemics and pandemics is supported by funders having outbreak response plans and agile policies in place prior to outbreaks. Of the survey respondents, seven (39%) reported that their organisation has an outbreak response plan, five (26%) are actively considering implementing one within the next year, and six (33%) are considering implementing one in the future. Of the 12 funders with an outbreak response plan, or who are actively considering one, nine (75%) had pre-approved internal governance mechanisms for rapid funding, and eight (67%) had identified a standing review board which could be activated during outbreaks for the rapid review of applications. Additional mechanisms and plans incorporated in these outbreak response plans are presented in Figure 3.

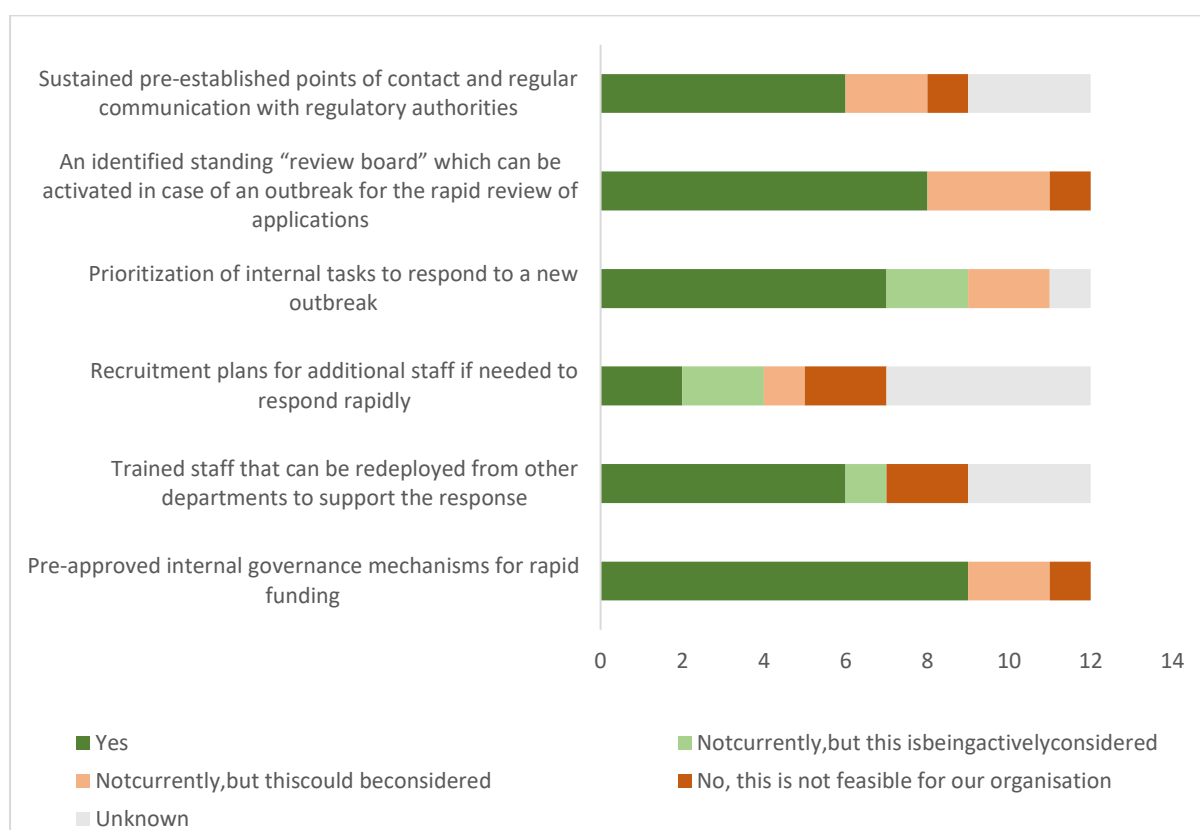


Figure 3: Key outbreak response plans mechanisms

Contingency funds.

A contingency fund that can be used during outbreaks can also strengthen preparedness for an efficient research response. Although 12 (67%) funders stated that they have a contingency fund in place, only two activated it during the COVID-19 pandemic. Of the 12 with a contingency fund, three (25%) can mobilise their funds in less than two weeks and nine (75%) in less than three months. The respondents cited different triggers for mobilising these funds, with most triggers coming from the ministry of health or government, followed by internal funding bodies and national public health emergencies.

Rapid mobilisation of funds.

To help facilitate rapid mobilisation of funds during an epidemic/pandemic, respondents indicated several policies and practices that their organisations have in place, informed by a pre-defined list provided in the survey.

These include:

- Accepting past accreditation
- Removing the external review process
- Providing supplemental grants to existing grantees allowing the pivoting of research
- Funding clinical trials indirectly through other platforms and mechanisms
- Regional research centres which can re-direct core funding during outbreaks

Respondents were asked to reflect on what key factors they believe would help facilitate the rapid mobilisation of funds. Suggestions included:

- Emergency procedures that allow the immediate launch of grants
- Pre-established implementing partners with contracts that allow for amendments
- A clearly identified need for research and funding, such as a WHO recognition of an international emergency
- Established processes at the international and national level.

Amending grant agreements.

The ability to amend grant agreements during outbreaks and accept unsolicited applications for funding can also support an agile response. The respondents indicated that during an epidemic/pandemic, 15 (83%) funders can amend their grant agreements, 11 (73%) of them stated this was only in exceptional circumstances. Seven (39%) funder organisations accept unsolicited applications, two do not (11%), and nine (50%) did not know if they could.

Aligning priorities and funding

Alignment to research funding priorities.

One identified recommendation for facilitating a coordinated clinical trial and wider research response, is to align funding priorities. Survey participants were asked to select all that applied to them during the COVID-19 pandemic regarding funding alignment to priorities from a list of pre-defined options. Several respondents reported alignment with multiple prioritisation processes. Twelve (67%) of the agencies aligned their funding to internally identified research priorities, 11 (61%) to the WHO Research Roadmap, 10 (56%) to national priorities and 8 (44%) to regional priorities. Five (28%) funders reported alignment to others, such as the Access to COVID-19 Tools (ACT) Accelerator, WHO broader identified needs, the African Centres for Disease Control and African Academy of Science prioritisation.

Alignment with other funder organisations.

Aligning funding with other organisations during epidemics/pandemics was identified as another method for facilitating improved coordination of trial responses. Funder-funder dialogue throughout the grant cycle can facilitate this (i.e., from intention to release a call through to allocation of funds). Thirteen (72%) organisations reported that they share information about calls or proposals confidentially with other funding organisations, 11 (61%) share information at the point at which they intend to develop a call. Survey participants were asked if they include employees of other funding agencies on external review panels, when reviewing grant applications for research funding calls. Ten (56%) reported that they did and five (28%) that it could be considered.

Synchronised funding

Funder mechanisms for joint funding.

Joint or collaborative funding mechanisms have been identified as a key action for facilitating a coordinated funding response during an outbreak. Survey participants were asked if they engaged in one or more of the following joint funding mechanisms:

- Pooled funding whereby organisations pool resources into a common budget for a joint call
- Coordinated funding whereby organisations agree to a common portal for the submission of applications with an agreed standards application and a joint review process
- Synchronised funding whereby organisations attempt to adhere to a basic timeline whilst maintaining their established procedures to receive and review applications

Fifteen (83%) organisations have previously engaged in pooled funding, whereas two (11%) stated that pooled funding was not feasible for their organisation. Fourteen (78%) engaged in coordinated funding, three (17%) stated this was not feasible. Ten (56%) engaged in synchronised funding, three (17%) stated this was not feasible. From respondents who indicated they had engaged in one or more of the above funding mechanisms, 16 (94.1%) stated that they had done so with funding agencies outside their country.

Addressing local need.

We explored if funder organisations emphasised that proposals should address local as well as international public health needs during outbreaks, and for trials to produce evidence to inform local decision making. We asked survey participants to indicate if their organisations promote this through a stipulation in grant conditions, a criterion for review at assessment, or as a recommendation in the funding call text. Fourteen (78%) promote this as a recommendation in the funding call text, 13 (72%) as a criterion for review at assessment, and 5 (28%) as a stipulation in grant conditions (Figure 4).

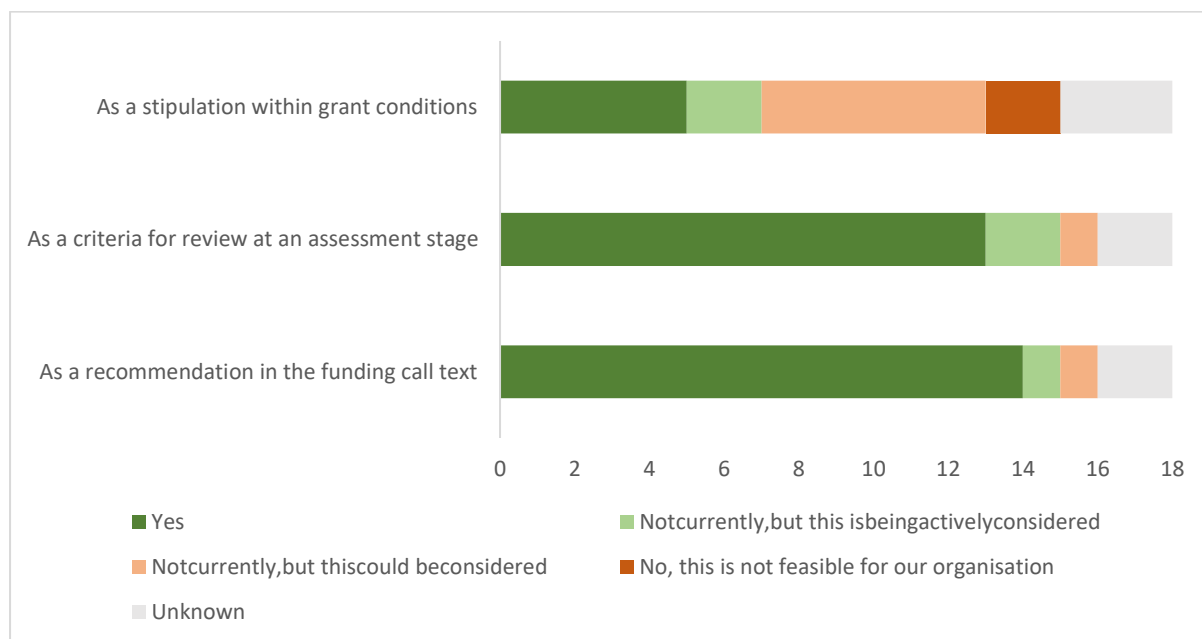


Figure 4: Promotion of research outputs that inform local decision making

Perceptions about funders’ wider role in facilitating a coordinated response

Funders may also be able to play an important role in influencing wider, well recognised challenges to timely, effective trial responses globally, such as regulations, contracts, and insurance. Recommendations provided by the respondents on how funders may be able to influence wider challenges include:

- Leveraging collective action by public and private funders to address these barriers
- Providing clear guidance/resources to manage wider challenges
- Supporting global universal processes e.g., harmonized study designs

- Joint initiatives and sharing of information and best practises

Promoting collaboration

Respondents were asked if their organisations promote collaboration with other research activities and networks when funding clinical trials during epidemics and pandemics. Fourteen (78%) reported that they promote collaboration as a recommendation in the funding call, 13 (72%) as a criterion for review at the assessment stage, and four (22%) as a stipulation within grant conditions (Figure 5).

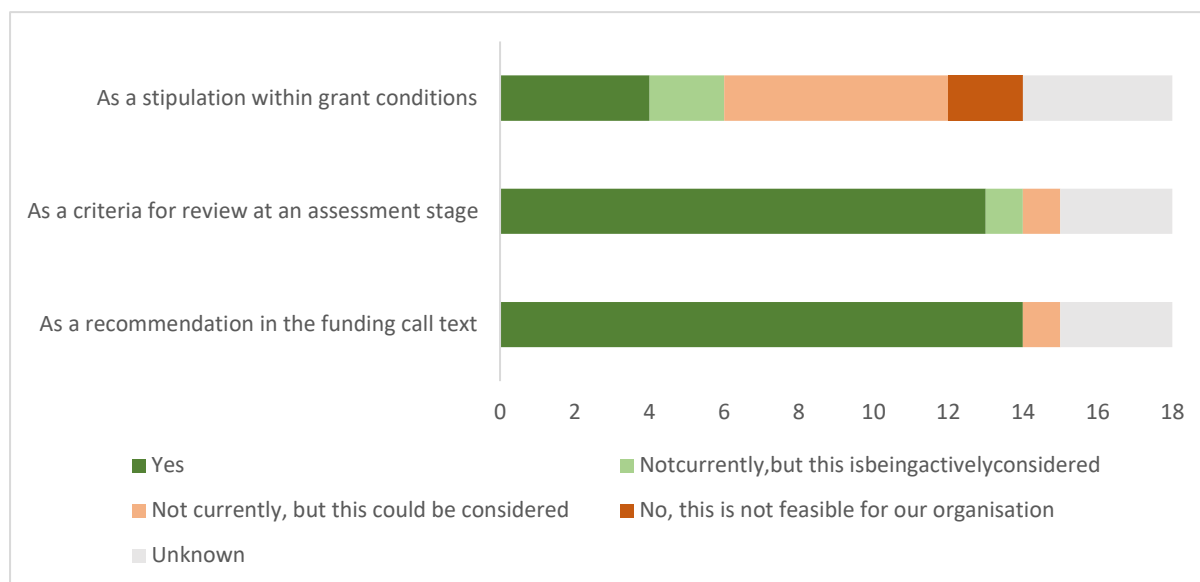


Figure 5: How funders promote collaboration with other relevant research activities

Monitoring and evaluation during the COVID-19 pandemic

Seven (39%) organisations have undertaken an evaluation of their research funding response during the COVID-19 pandemic; four (22%) have made them publicly available. Two (11%) indicated that they could consider doing this within the next six months, five (28%) in the next seven to 18 months.

Respondents’ overall suggestions for improving the coordination of clinical trials

Finally, we asked respondents to reflect on the COVID-19 pandemic, we asked the respondents to provide recommendations for how to improve the coordination of clinical trial research responses to future outbreaks, nationally and internationally. Recommendations include:

- Having national and international contact points across funding organisations to facilitate rapid coordination.
- Being transparent on planned clinical trials through an agreed mechanism that highlights duplication
- Closer coordination between health, research, and regulatory authorities
- Joint funding mechanisms and priority setting
- Having transparent and accessible standardised trial databases
- Leveraging existing platforms such as GloPID-R

Suggestions for improving coordination of clinical trials.

Survey participants were asked to provide up to five suggestions for ways to improve coordination of trials from a funders’ perspective. Table 1 illustrates the themes that emerged from these free text survey responses and the number of times a theme was mentioned.

Theme	No. of mentions
Strengthen coordination between funders, stakeholders i.e. Africa CDC, national science granting councils, policy bodies and CTNs	7
Contribute to joint funding mechanisms e.g., pooled funding	5
Invest in core funding of trials, clinical trial infrastructure and capacity building	5
Provide or support development of clear guidance/standards	3
Actively work to remove barriers to rapidly initiating research	3
Develop core protocols and methodologies at an international level for therapeutics and vaccines of pathogens of concern	3
Agree and strengthen data sharing practices	2
Maintain relations/partnership with government	2
Ensure LMIC engagement in research prioritisation, including through convening regional meetings for priority setting	2
Promote standardised grant policies	1
Strengthen monitoring and evaluation of funded research projects	1
Share national health research agendas	1
Direct funds toward large scale multi-national trials	1
Actively engage with global research roadmaps	1

Table 1: Actions for funders to strengthen coordination of clinical trial responses globally

The role of GloPID-R in facilitating coordination of clinical trial responses.

To better understand how our members perceive GloPID-R's role in this field, the survey asked participants to provide suggestions for how GloPID-R can improve and facilitate the coordination of clinical trial responses to future outbreaks. Table 2 illustrates the themes that emerged from these free text survey responses and the number of times a theme was mentioned.

Theme	No. of mentions
Facilitate funder exchange and transparency	6
Actively support good clinical trial practice; strengthen clinical trial network capacity through a coordination hub; and by identifying opportunity gaps	5
Identify and promote best practices including best practices on emergency funding, coordinated funding mechanisms, and developing emergency procedures	4
Encourage joint funding mechanisms that can overcome barriers, including managing and diversifying a pool of funders and support this with guidelines	4
Work in coordination with the WHO	4
Encourage and provide collaboration opportunities for funders	3
Enhance funder networks including national and regional networks	3
Have increased discussions with funders to understand their needs, constraints e.g. a PEARL working group, ability to provide support, and intentions	3
Encourage regional hubs and LMIC participation	3
Fundraise for emergency responses	1
Use member meetings and working groups strategically	1
Funding tracking and analysis	1
Develop a tool to aid timely decision making	1
Take an active role as a source of information for researchers seeking funding	1
Have a communication and dissemination strategy	1

Table 2: GloPID-Rs role in clinical trial response coordination