



# Stakeholder Needs

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## Overview:

This milestone summarizes research ethics and integrity stakeholder needs in times of global crisis.



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## List of abbreviations

<b>DoA</b>	Description of Action
<b>NGO</b>	Non-governmental organisation
<b>RE</b>	Research ethics
<b>REC</b>	Research ethics committee
<b>RI</b>	Research integrity
<b>RIO</b>	Research integrity organisation
<b>WP</b>	Work Package

# 1. Executive Summary

To ensure better preparedness for the next global crisis, the PREPARED project canvassed stakeholder needs in the area of research ethics and research integrity. The needs of research funders, researchers, publishers and editors, policy-makers and policy-advisors as well as research ethics and research integrity bodies were investigated in the aftermath of COVID-19.

To bolster research ethics and integrity in future crises, **research actors cited four common needs**. First, as actors found themselves operating in silos during the pandemic, they called for increased collaboration and open dialogue with other stakeholder groups and the public. RECs, for example, sought structured consultations with policymakers, researchers, and other ethics review bodies, while policymakers called for the development of a robust public engagement plan. Second, actors in the research process demanded guidelines to establish a coherent crisis response. Publishers and editors, for example, asked for uniform fast-track review procedures for crisis-related manuscripts – procedures developed during the COVID-19 pandemic were impromptu, leading to confusion and diverging expectations. NGOs noted a lack of localised guidance on remote data collection and standard operating procedures for research ethics review. Third, stakeholders agreed on the need for tailored training materials to prepare for future crises. And fourth, actors requested financial and human resource support to meet funding shortages that made coping with increasing workloads during the COVID-19 pandemic extraordinarily difficult.



## 2. Introduction

### 2.1 Background

The Pro-active Pandemic Crisis Ethics and Integrity Framework (PREPARED) project aims to develop an **operational research ethics and integrity framework that safeguards key ethical values, supports a rapid and effective research response to crises, and improves overall pandemic preparedness**. Within the project, WP2 focuses on global engagement and participatory dialogue.

To build an international network of key actors for stakeholder engagement on RE/RI challenges associated with sudden and unexpected crises, the PREPARED consortium is working with **eight engagement or stakeholder platforms** (see Table 1). These platforms will serve as fora to share information, expertise, and experiences concerning RE/RI in crises. They will also help explore synergies and complementarities and provide feedback on project activities.

Core contacts within the stakeholder groups for the eight engagement platforms were identified in the early stages of the project. Each platform corresponds with tiered groups of stakeholders affected by – or affecting – the RE/RI landscape during sudden, global crises. Each platform consists of

- 1) Relevant PREPARED advisors and consortium members
- 2) Platform owners with extensive knowledge of – or influence on – stakeholder groups
- 3) Existing networks managed by platform owners
- 4) Other relevant actors identified by platform owners.



Table 1 Stakeholder Platforms

Stakeholders	Platform owner
Research funders public	European & Developing Countries Clinical Trials Partnership (EDCTP)
Research funders private	Foundation Global Values Alliance
Researchers	University of the Witwatersrand, Johannesburg
Publishers	University of Central Lancashire UK

Stakeholders	Platform owner
Policy-makers/advisors	Co-Lead UNESCO/EDCTP
Public/citizens	VU University Medical Center Amsterdam
Research governance	Finnish National Board on Research Integrity and European Network of Research Ethics Committees.

## 2.2 Task and outline

A portfolio of stakeholder needs is required for the PREPARED project so that project outputs can be tailored to key actors, providing the stakeholders shaping the RE/RI landscape and/or those burdened by RE/RI challenges with resources to promote ethical research in crisis contexts. The public/citizens' platform was excluded from this task due to time constraints. Preliminary stakeholder needs for the remaining seven engagement platforms are mapped in the following sections.

First, we describe our approach to stakeholder needs identification, establishing a working definition for both needs and tools. Next, we summarise the tools used by platform owners in needs identification and the limitations of our approach. Then, we outline the needs identified from each platform, focusing on present and future challenges in RE/RI, observed adaptations, and support needed in the face of sudden, global crises. Finally, we draw parallels between platform findings and suggest next steps towards needs refinement.

## 2.3 Description of approach

To compile a portfolio of stakeholder needs across platforms, we asked platform owners from seven stakeholder engagement platforms to address the following research question:

**What research ethics and integrity support do stakeholders need in sudden, global crises?**

We defined stakeholder needs, following Beatty (1991), as a “discrepancy between a present state of affairs and a desired state of affairs,” cited by the “owner” or “authority” of the need. Given PREPARED’s goal of addressing a “syndemic” (Horton, 2020) rather than a pandemic, we asked platform owners to consider needs resulting from stakeholders’ past experiences, current challenges, and anticipated short- and long-term future challenges.

Platform owners elicited preliminary stakeholder needs through a two-step process (Figure 1). First, they contributed to a list of tools suited for stakeholder needs analysis. We defined tools as any *procedure, technology, or analytical technique* (Cornell Legal Information Institute, 2018) assisting in needs identification.





Figure 1: Two-step process for stakeholder needs identification

In line with a value-sensitive design method (Gultekin et al, 2016), we encouraged stakeholders and task contributors to record the advantages and disadvantages of selected tools on a spreadsheet (to be updated throughout the project). In recording these advantages and disadvantages, platform owners were asked to consider three evaluation questions (see Gultekin et al, 2016):

1. What does the tool mean to the user? – *Value for the user*
2. How is the tool better than existing ones? – *Value for the market*
3. Why would stakeholders want to use the tool? – *Value for stakeholders*

Then, platform owners used selected tools to answer the questions listed in the Stakeholder Needs Identification Template (Figure 2).

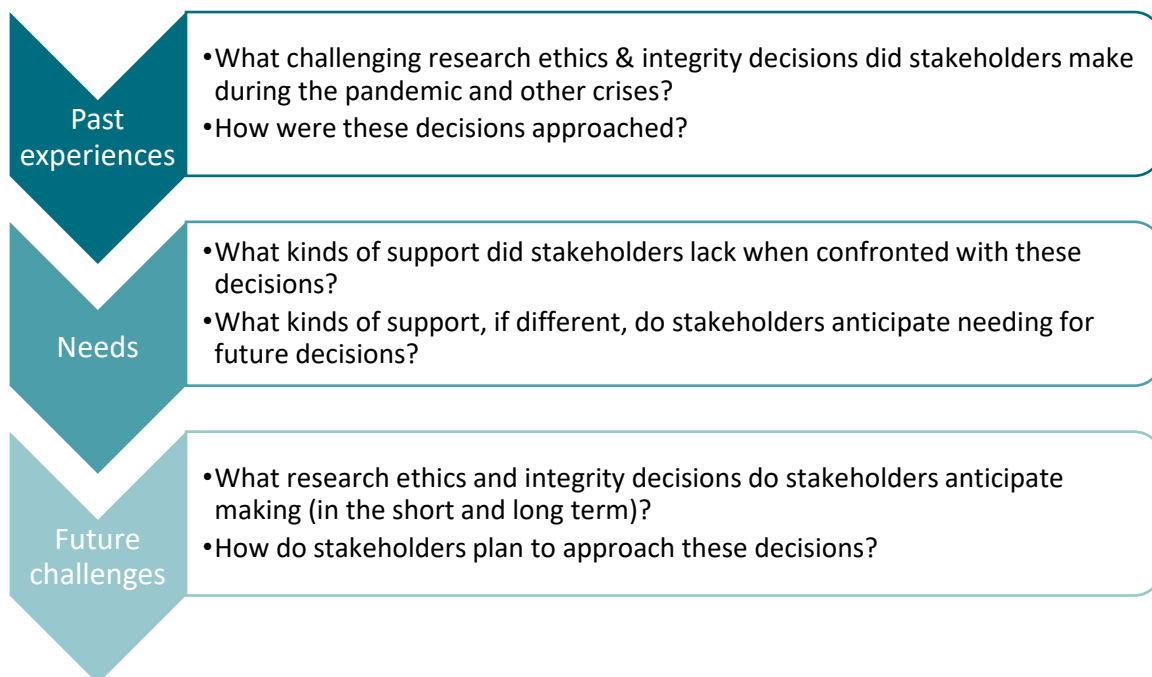



Figure 2: Questions for stakeholder needs identification



Lastly, we summarised key findings from the templates in the following sections. We organised findings from each platform into three subsections: present and future challenges in RE/RI, observed adaptations, and support needed in the face of sudden, global crises.

## 2.4 Limitations

The applicability and accuracy of our report are limited by several factors. First, as platform owners had approximately five weeks to identify stakeholder needs, many opted for tools outside of those traditionally used in primary data collection, e.g., informal conversations (Swain & King, 2022) and secondary data collection methods. While secondary data analyses and informal methods may provide preliminary answers to a research question, they often fall short in refining hypotheses (e.g., Cheng & Phillips, 2014). Thus, as a next step, results will be tested with selected stakeholders.

Across all stakeholder platforms, needs primarily centred on the implications of the COVID-19 crisis. This occurred despite the design of templates and tools that encouraged stakeholders to consider non-pandemic crisis needs. Stakeholders' tendency to focus on COVID-19 may result from cognitive biases, e.g., stakeholders may attribute greater significance to recent events, thereby neglecting other crises with RE/RI effects (Boyce, 2022). We will thus consider the possible presence of cognitive biases in subsequent needs refinement.

## 2.5 Tools used

Tools used by platform owners consisted of surveys, literature reviews, and informal conversations. Two platform owners (researchers and private funders) reviewed relevant literature focused on their stakeholder groups' needs. The research governance platform owners distributed online surveys, using Google Forms, to networks of research ethics committees (RECs) and research integrity organisations (RIOs). A mix of informal expert consultations and experiences with previous projects to identify stakeholder needs were used by the publishers' platform, the public and private funders' platform, the policy-makers' and advisors' platform, and the non-governmental organisations' (NGOs) platform.

## 3. Portfolio of stakeholder needs – preliminary results

### 3.1 Researchers

#### 3.1.1 Overview


This platform includes actors carrying out research as well as other stakeholders in research-performing organisations. It covers researchers in a wide range of disciplines and strives for geographic diversity.

Researchers	
RE/RI challenges in crises	<ul style="list-style-type: none"><li>▷ The adaptation of research designs</li><li>▷ Funding shortages</li><li>▷ Publication timelines</li></ul>
Solutions and adaptations to crises	<ul style="list-style-type: none"><li>▷ Shift toward remote research</li><li>▷ Utilisation of pre-print servers</li></ul>
Support needed	<ul style="list-style-type: none"><li>▷ Enhancement of digital skills</li><li>▷ Increased coordination with other stakeholders</li><li>▷ The development of crisis-specific RE/RI guidelines</li></ul>

#### 3.1.2 Research ethics and integrity challenges in crises – present and future

During unexpected crises, researchers were burdened with the ethical adaptation of research projects. During the COVID-19 pandemic, physical restrictions prevented many traditional forms of data collection, and many funds were diverted towards COVID-19 vaccine and treatment research. Researchers who relied on biological data collection and the physical presence of research participants had to halt or terminate much clinical research. In addition, as governmental and research management bodies responded formally to the crisis, ever-changing guidelines and restrictions hampered researchers' ability to plan new research projects and adjust ongoing studies, especially if they were not focused on COVID-19.

When sudden crises forced researchers to move to remote spaces, researchers encountered RE/RI challenges in designing and managing remote research methods. During the COVID-19 pandemic, researchers noted a lack of digital literacy amongst research participants, leading to the exclusion of many marginalised and low-income groups from research projects (Mitchell, 2021). Before seeking approval from RECs, researchers were tasked with a self-evaluation of ethical risks within remote research designs, which they may not have piloted before. In addressing ethical challenges in remote research – which run the gamut from data management to informed consent (see, e.g., Gelas et al, 2021) – researchers lacked ethical know-how on previously unknown topics as well as additional time needed to consider ethical issues. A shift towards remote collaboration methods



also had wider disciplinary impacts on research. For example, during the COVID-19 pandemic, researchers struggled to advance interdisciplinary research projects – essential for improving outcomes in sectors like healthcare – due to their reliance on remote communication and data exchange (Sy et al., 2020).

Crises also compelled researchers to navigate shifting publication landscapes in which crisis-relevant data were shared quickly and, in many cases, utilised by policy-makers in decision-making. During the COVID-19 pandemic, the rise of pre-print servers chiefly characterised this changing landscape. Researchers grappled with the decision of whether to share their findings early considering lengthy peer review processes and publication timelines. They scrutinised other researchers' rapidly published results while, at the same time, assessing the potential benefits to society of sharing their own work on pre-print servers (Dinis-Oliveira, 2020).

### **3.1.3 Solutions and adaptation to crises**


During crises, researchers adapt their approaches to data collection and analysis to ensure their research can continue, even where adaptations are likely to create new RE/RI dilemmas. For instance, the onset of the COVID-19 pandemic marked a shift toward remote research, requiring both the digital collection of data, e.g., remote interviews and focus group discussions (Sy et al., 2020), and an increased reliance on secondary data sources (Mitchell, 2021).

When faced with the pressure to accelerate publication processes, many researchers opted to publish on pre-print servers, valuing the timeliness of their contribution to crisis-relevant scientific discourse over extended quality assurance mechanisms. In these cases, researchers often looked to research integrity standards and processes followed by their institutions (Dinis-Oliveira, 2020), rather than those required by publishers, when drafting and publishing their work.

Researchers look to government and state leaders, universities, and funding bodies for guidance when confronting RE/RI challenges during crises. At the same time, these decision-makers often use research findings to justify their choices (Lavazza and Farina, 2020), e.g., when deciding on restrictions or funding opportunities, pointing to increased interdependence between researchers and decision-makers.

### **3.1.4 Support needed during crises – present and future**

When asked what kind of support is needed during crises, researchers advocated for general skills development within the research community. This may include measures to address discrepancies in digital literacy (Kasımoğlu et al., 2022) amongst research teams and participants as well as greater capacity building to ensure “science preparedness,” i.e., the formation of a



scientific research framework to enable better preparation for sudden, global crises (Kinyanjui et al., 2020).

In addition, researchers cited the need for crisis-focused training materials (e.g., Ingrassia et al., 2014) that encourage greater awareness of RE and RI issues in crisis settings. They called for crisis-specific RE/RI guidelines to frame scientific integrity standards and set forth clear best practices for dealing with crises and change (e.g., Morens & Hammatt, 2021; Ahmed et al. 2020). Newly developed materials focused on crisis settings could be integrated into wider research integrity education programs, which should be tailored to target groups in both formal and informal formats at the institutional level (as suggested by Labib et al., 2022).

Researchers also noted that a lack of time for ethical reflection and oversight impinged on upholding RE/RI standards during crises. During the COVID-19 pandemic, healthcare experts who were previously engaged in research were increasingly diverted to mitigation efforts on the ground). This meant that researchers could no longer allocate valuable time to addressing research ethics and integrity issues, which are best assessed when researchers themselves – rather than just supervisors or ethical reviewers – can dedicate time and expertise to identifying challenges. Hence, the paring down of research teams can also reduce the quality of RE/RI in research projects in crisis contexts.

Researchers also called for enhanced coordination with other stakeholder groups. Ideally, this coordination should result in a joint response to RE/RI issues across public and private sectors (National Academies Press, 2020), support from state and university leaders in ethics approval (Sisk et al., 2022), and the standardisation of a fast-tracked peer review process (Mohanty et al., 2021). Recognising the need for greater access to information – especially in communities vulnerable to crises (World Economic Forum, 2022) – researchers cited an increased need for dialogue on data management to address equity issues in RE/RI.

## 3.2 Research governance

### 3.2.1 Overview

Research governance covers a wide range of actors. This platform primarily encompasses stakeholders from two networks: the European Network of Research Ethics Committees (EUREC) and the Finnish National Board on Research Integrity (TENK), which drew upon its connections to the European Network of Research Integrity Offices (ENRIO).

RIOs are defined here as non-profit or public entities with a demonstrated commitment to promoting and furthering research integrity at the regional or national level. They include national


research integrity offices and national research funding organisations and national science academies with their own nationally implemented RI guidelines.

Research governance		
	RECs	RIOs
RE/RI challenges in crises	<ul style="list-style-type: none"> <li>▷ Rapid turnaround time for research applications needed</li> <li>▷ Large volume of research applications for ethical review</li> <li>▷ COVID-19 outbreaks within RECs</li> <li>▷ Shift towards remote work</li> </ul>	<ul style="list-style-type: none"> <li>▷ Enhanced urgency of research and threats to basic values</li> <li>▷ Publishing without peer review, overriding quality mechanisms</li> <li>▷ Additional roles during the pandemic for RIOs (e.g., as science communicators)</li> </ul>
Solutions and adaptations to crises	<ul style="list-style-type: none"> <li>▷ New fast-track procedures</li> <li>▷ New work formats</li> <li>▷ Recruitment of additional experts</li> </ul>	<ul style="list-style-type: none"> <li>▷ Participation in public crisis discourse</li> </ul>
Support needed	<ul style="list-style-type: none"> <li>▷ Greater financial support and human resources</li> <li>▷ Increased collaboration with other stakeholders to jointly respond to RE/RI challenges</li> <li>▷ Facilitation of remote research and interaction</li> </ul>	

### 3.2.2 Research ethics and integrity challenges in crises – present and future

During crises, RECs are pushed to provide a rapid turnaround time for crisis-related research applications while maintaining a high standard of ethical review. During the pandemic, the volume of COVID-19-related research applications exploded, greatly increasing workloads for REC members. In addition, as researchers switched to remote work and were thus able to increase the time spent on desk-based projects, applications increased for review of non-COVID-related research projects (Sprumont, 2021). This pressure coincided with high turnover rates within RECs, COVID-19 outbreaks within institutions, the implementation of decentralised ethics review procedures, and funding shortages – impeding REC capacity to carefully assess emerging RE challenges. In the switch to remote work formats, many REC members, notably those located in lower- or middle-income countries, lacked internet connectivity and/or working laptops and thus could not attend meetings in full (Masiye, 2021).

The promotion of RI principles in crisis settings – amidst enhanced urgency of research and threats to basic values – constituted a main challenge of RIOs. During the COVID-19 pandemic, at the review and pre-approval stage, RIOs decided between timesaving “generalist” approaches and time-intensive consultations with topical expert reviewers when reviewing research. Some



research was published without peer review, overriding quality mechanisms and potentially endangering the reliability of results. RIOs also handled subtle RI infractions that arise during crises, such as the tendency for researchers to communicate preliminary or unsubstantiated results as clear and certain.

RECs frequently weighed the potential benefits of crisis-related research to society against the potential risks of untested treatments and unknown harms to participants. Though crisis settings like pandemics can result in increased infringements related to therapeutic misconceptions, problems with sample sizes and representativeness, privacy, consent, data management, and primacy of the person over the benefit to society, researchers argued for exceptions from core research ethics principles and norms due to the urgency of the situation.


RIOs juggle additional roles during crises. During the COVID-19 pandemic, they also functioned as science communicators: endorsing, commenting on, and/or criticising reviewed research and research processes. RIOs were called upon as key advisors for researchers and research institutions, who look to them for clarity and guidance on RI issues. RIOs also supported evidence synthesis activities that could feed into national policies and guidelines to avoid duplication of activities and research waste.

RIOs also noted that crises magnified differences between lower- and higher-income countries. They contributed to the discourse on global justice, especially in the context of the COVID-19 pandemic. This proved important not only in supporting RI in vaccine and treatment research but also when considering general representation and inclusion in research processes.

### **3.2.3 Solutions and adaptation to crises**

RECs provided direct and transparent communication on emerging ethical challenges in crisis contexts. During the COVID-19 pandemic, they developed fast-track assessment procedures, covering, for example, incomplete submissions, identification of COVID-19-relevant studies at submission, and guidance on the management of clinical trials during the pandemic. RECs in Europe sought to align new procedures with EC guidance. They also encouraged researchers to collaborate on projects to reduce the strain on RECs and avoid study duplication (Sprumont, 2021).

Amidst increased workloads and pressure to hasten review processes, RECs sought to adopt new work formats and expand review teams. During the pandemic, RECs recruited additional experts to help perform expedited ethics assessments. To accommodate work-from-home policies, RECs planned virtual meetings for plenary discussions and held remote discussions between secretaries, experts, and executive committee members. In response to new ethical challenges,



RECs increased the number of meetings held overall and communicated quickly with principal investigators and sponsors where clarification on ethical issues was needed. To encourage remote meeting attendance amidst video call fatigue, RECs sometimes granted sitting allowances to members present at meetings (Masiye, 2021).

RIOs participated actively in public discourses on research during crises. They highlighted the increased importance of RE/RI in a crisis, promoted RE/RI as a prerequisite for the quality and the trustworthiness of research, and cautioned against heat-of-the-moment changes to RE/RI legislation and guidelines.

### **3.2.4 Support needed during crises – present and future**

Both RECs and RIOs reported the need for greater financial support and human resources. Where available, sufficient funds enabled RIO and REC members to dedicate more time to reviewing research projects. Adequate attention to individual research projects – achievable through increased funding and human resources – is key in flagging and communicating RE/RI issues early on in crisis contexts. RECs reported a shortage of topical experts able to assist with review; such experts were often needed elsewhere (e.g., in hospitals) and thus could not meaningfully contribute to REC work.

RECs and RIOs believe in increased collaboration with other stakeholders to respond jointly to emerging RE/RI challenges. These stakeholders should include policy-makers, researchers, other research governance actors, and the public. Increased collaboration should include dialogue with European ministries to establish new guidelines for REC members during crises, the development of a national REC for future pandemics, clarification on data protection regulations, frequent consultation with academics and the broader public, and the formulation of crisis-relevant quality assurance policies for RIOs.

RECs also require additional resources to train ethics experts. They especially advocated for resources targeting young REC members. In addition, they hope to augment existing training schemes with crisis-relevant materials.

RECs and RIOs called for support in facilitating remote research and interaction. While both RECs and RIOs requested the development of didactic and technological tools for online interaction, RECs also called for the development of ethical standards on decentralised processes found in many research proposals, such as e-consent and telemedicine, at the international level.



### 3.3 Research funders – public

#### 3.3.1 Overview

This platform consists of representatives from funding agencies, funding coalitions, or networks of funders who support clinical research in low- and middle-income countries and/or contribute to science education, fellowships, clinical trials, capacity building, infrastructure, and regulatory capacity strengthening. Many funders are involved in epidemic and pandemic preparedness.

Research funders – public	
RE/RI challenges in crises	▷ Pressure to support urgently needed projects concentrating on solutions to crises
Solutions and adaptations to crises	▷ Rapid-response funding calls for crisis-relevant proposals ▷ Supplements to existing funding schemes to benefit COVID-19 research, expedited reviews, and grant awarding processes
Support needed	▷ RE/RI professionals to strengthen internal teams ▷ Increased exchange and coordination with other funders and members of the research community

#### 3.3.2 Research ethics and integrity challenges in crises – present and future

Like researchers and research governance actors, research funders faced both top-down and bottom-up pressure to support urgently needed projects concentrating on solutions to crises. At the same time, since funders provide oversight throughout the lifespan of research projects, they oversaw RE/RI review processes and had to establish ethically sound protocols for funding crisis-related research.

Knowledge of local needs was crucial to RE oversight during crises. During the pandemic, research funders struggled to identify needs at the community level and were thus limited in their capacity to fund and oversee ethical, crisis-relevant research specific to local contexts.

#### 3.3.3 Solutions and adaptation to crises

Public research funding bodies steered the adaptation of research to crises through a variety of approaches: supplementing existing funding schemes to benefit COVID-19 research, expediting scientific proposal reviews, and accelerating grant awarding processes. For example, during the COVID-19 pandemic, global funders launched rapid-response funding calls for proposals to support research relevant to COVID-19. Such approaches were an opportunity to reiterate RE/RI standards, encouraging – or even requiring – researchers to take ethical considerations into account at the conceptual phases of research.

Funding actors have the leverage to impose new regulations that ensure scientific quality and ethics and integrity in the research they fund. They communicate their quality expectations to researchers and research-performing organisations (e.g., on dissemination and data sharing) and, in some cases, mandate open-access publication and data sharing.

### 3.3.4 Support needed during crises – present and future

Public research funders sought to expand their teams to include RE/RI professionals. Specifically, they called for internal experts to assess clinical, methodological, and regulatory RE aspects of crisis-relevant research projects.

Public research funders lacked coordination with other funders and members of the research community. To fill this gap, they hope to institute a joint emergency funding mechanism for pandemic preparedness, bringing together funders and donors. They also plan to develop trackers for funders and the research community, such as the Pandemic PACT Research tracker (GLOPID-R, 2022), which informs policy through an analysis of funding data. In addition, to localise funding processes, they hope to establish regional funding hubs familiar with the local funding and research landscapes, better enabling cross-funder collaboration.

## 3.4 Research funders – private


### 3.4.1 Overview

This platform consists of industry leaders and private-sector stakeholders that fund research. The platform includes stakeholders who funded the development of COVID-19 treatments and vaccines.

Research funders – private	
RE/RI challenges in crises	<ul style="list-style-type: none"> <li>▷ Fast-tracked vaccine development requiring expedited ethics approval</li> <li>▷ Loss of public trust</li> </ul>
Solutions and adaptations to crises	<ul style="list-style-type: none"> <li>▷ Changes to clinical trial format (e.g., virtual trials)</li> </ul>
Support needed	<ul style="list-style-type: none"> <li>▷ Increased data sharing</li> <li>▷ Knowledge about RECs</li> <li>▷ Established crisis protocols</li> </ul>

### 3.4.2 Research ethics and integrity challenges in crises – present and future

Under pressure to produce solutions, private research funders, like public funders, sought rapid REC approval during sudden, global crises. At the same time, though, they carried the primary



responsibility of maintaining RE safeguards. In the context of clinical trials in the pharmaceutical sector, private research funders reported ethical tension between fast results and optimal safety. In the later stages of COVID-19 clinical trials, research funders also faced the ethical dilemma of withholding treatments and vaccines whose efficacy and short-term safety were proven from participants who received a placebo.

In the case of pandemics, private research funders were often the target of public scrutiny of research. For example, funders suffered from the loss of public trust following discussions of a possible link between the AstraZeneca vaccine and a rare clotting disorder (Kupferschmidt & Vogel, 2021).

Research funders sometimes lacked information on RECs necessary to oversee both fast and ethical research. For example, during the COVID-19 pandemic, a research team at the *Institut Pasteur de Lille*<sup>1</sup> (Arte, 2022) tried to drop phases from clinical development because the compound they wanted to use in the development of COVID-19 medication had been approved in other medical contexts. They failed to advance in the development of a COVID-19 treatment due to delays in the ethics approval process, which may have resulted from a lack of insight into the functioning of RECs.

### 3.4.3 Solutions and adaptation to crises

During crises, private research funders facilitated successful drug development through close collaboration with RE reviewers to expedite research. This occurred during the pandemic in the case of the BioNTech vaccine, in which research teams maintained close ties with RECs, promptly communicating changes to research plans (Miller et al., 2022).

Private funders assembled crisis leadership teams to make RE/RI decisions. In the case of the BioNTech vaccine, most decisions were made by a rapidly convened leadership team (Miller et al., 2022). Private funders sought consensus amongst experts, including social scientists and ethicists, particularly on the following question: who must compensate whom for what if assumed risks result in real damage? The decision to address RE/RI issues was ultimately made at the highest hierarchical level of a company.

Private funders supported adaptations to research formats where possible. During the COVID-19 pandemic, they encouraged the use of virtual trials. This approach involved remote recruitment and monitoring, lowering risks to participants of contracting the virus and allowing for the continuation of large-scale trials (Sokol, 2020).

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<sup>1</sup> It is not entirely clear whether this is a private or a publicly funded institute. However, this is irrelevant to our collection of stakeholder needs.

### 3.4.4 Support needed during crises – present and future

Private research funders call for clear protocols to guide RE/RI decision-making during crises. Established protocols should provide guidance on working with RECs. They should, above all, emphasise the protection of clinical trial participants from serious harm.

Private research funders also call for greater collaboration and sound information flows. Funders aim to assemble networks of international experts across institutional settings with the capacity to consult in crisis contexts. Such networks should outline data-sharing processes and must exist before an actual crisis, as mutual trust, established during “normal” work routines, is key in high-stakes crisis decision-making. More frequent and transparent communication with the public may result in enhanced acknowledgement and praise, motivating private funders to uphold RE/RI in future crises.

## 3.5 Publishers and editors

### 3.5.1 Overview

This platform covers academic publishing staff and editors of academic journals. Leading publishing company Nature Springer is represented here, together with contributions from editors at SAGE and RIS (Research Information System for Developing Countries), the Indian partner on PREPARED who is associated with the Indian Ministry of External Affairs and publishes academic journals.

Publishers and editors	
RE/RI challenges in crises	<ul style="list-style-type: none"> <li>▷ Overstretched editorial teams and constrained reviewer pool</li> <li>▷ Duplicate submissions</li> <li>▷ Concerns about trustworthiness of evidence base</li> </ul>
Solutions and adaptations to crises	<ul style="list-style-type: none"> <li>▷ Tasking junior reviewers and/or people lacking relevant expertise with assessing submitted manuscripts</li> <li>▷ Fast-track procedures that prioritised crisis-relevant research</li> </ul>
Support needed	<ul style="list-style-type: none"> <li>▷ Common editorial standards on peer review and common quality standards on reporting and data</li> <li>▷ Clear processes for manuscripts published on pre-print servers</li> <li>▷ Framework for rapid rejection of manuscripts</li> <li>▷ Amended guidelines for authors and reviewers, e.g., on fast-tracking and pre-prints</li> <li>▷ Guidelines for publishers and editors on facilitation of fast-track review and publication</li> </ul>



### **3.5.2 Research ethics and integrity challenges in crises – present and future**

During crises, publishers struggled to cope with a demand for fair fast-track review processes that safeguarded the scientific integrity of manuscripts. Following the start of the COVID-19 pandemic, for example, publishers did not know how to respond to authors who submitted their research to multiple platforms or who published via pre-print servers. Though they recognised the potential importance of research findings, publishers also questioned the quality of the evidence base of many fast-tracked papers submitted, expressing data and methodology concerns.

In crisis contexts, resource shortages amplified the challenges faced by publishers. Namely, during the pandemic, a constrained expert reviewer pool and editorial staff stalled the review process. Editor and reviewer responsibilities to attend to more urgent matters during the pandemic worsened human resource constraints. Amidst inadequate human resources, high workloads, and expertise shortages amongst reviewers, publishers are sometimes forced to unwillingly compromise their RI standards.

### **3.5.3 Solutions and adaptation to crises**

With editorial teams stretched and under pressure, stakeholders adapted by tasking junior reviewers and/or staff and consultants without relevant expertise with assessing submitted manuscripts. These reviewers, in some cases, lacked the experience necessary to scrutinise manuscripts sufficiently or uphold established RI review standards.

Publishers and editors implemented fast-track procedures that prioritised COVID-19-related research. In addition, they outlined criteria for fast-tracked papers. However, these procedures were not tried and tested, and they were not uniform across publications. Additionally, they slowed review rates for other papers in the publication pipeline.

During crises, publishers must reinforce their quality standards to the public, contributing to discussions on misinformation. This would reassure the public about the scientific rigour of submitted research despite expedited publication processes.

### **3.5.4 Support needed during crises – present and future**

Publishers and editors call for the continuous improvement of fast-track procedures in crisis contexts. This should include the development of a framework for the rapid rejection of manuscripts that do not meet required quality standards and guidelines for authors and reviewers on fast-track processes. Common editorial standards on peer review, quality standards, and reporting would also ensure rigour throughout the publishing process. In addition, publishers need processes for handling manuscripts that are published on multiple platforms as well as

procedures for labelling to emphasise corrections for cases in which pre-print research is later published in peer-reviewed journals.

### 3.6 NGOs

#### 3.6.1 Overview

This platform includes stakeholders overseeing research on poorer and/or vulnerable populations in crises, such as sex workers and HIV+ populations. It is led by an NGO based in Kenya, and most of the experiences described here are from a Kenyan NGO (which runs research clinics and conducts clinical trials) and might not apply to smaller NGOs.

NGOs	
RE/RI challenges in crises	<ul style="list-style-type: none"> <li>▷ Protection of vulnerable research participants</li> <li>▷ Upholding RE standards amidst new challenges</li> </ul>
Solutions and adaptations to crises	<ul style="list-style-type: none"> <li>▷ Discussions with stakeholders on crisis-relevant research</li> <li>▷ Participatory approaches</li> <li>▷ Innovative methods to protect vulnerable research participants</li> </ul>
Support needed	<ul style="list-style-type: none"> <li>▷ Guidelines for ethical research during sudden, global crises</li> <li>▷ Greater consultation and collaboration with policy-makers, research governance actors, and the public</li> </ul>

#### 3.6.2 Research ethics and integrity challenges in crises – present and future

NGO challenges largely mirror those of researchers and research-performing organisations; however, their focus on marginalised populations necessitates a nuanced understanding of research participant protection and local needs. In addition, they were tasked with facilitating close collaboration with RECs, community leaders, and funders during crises, all of whom might be changing procedures to adapt to crises.

NGOs who support clinical trials (like PREPARED partner PHDA in Kenya) struggled to adapt research practices to crisis contexts. Where ongoing studies had been conducted in clinics prior to the pandemic, NGOs weighed the decision to re-open sites for enrolment and follow-up against the risk of contracting COVID-19. Where researchers were forced to halt the collection of biological samples and began collecting data remotely, NGOs noted potential consequences for research participants, some of whom obtained medical care through ongoing clinical studies.



### 3.6.3 Solutions and adaptation to crises

NGOs facilitated discussions on crisis-relevant research. During the COVID-19 pandemic, NGO actors created social media posts and hosted community engagement activities aiming to galvanise interest in ongoing studies. These discussions solidified the inclusion of marginalised populations in research, thereby contributing positively to RE/RI.

Participatory approaches aided NGOs in making RE/RI-related decisions during crises. For example, during the COVID-19 pandemic, researchers who collaborated with NGOs met with community leaders to decide upon a path forward for a research project three months after halting data collection. Consultations between research team and community members – including local as well as international partners – helped NGOs in RE/RI decision-making. NGOs who supported researchers also sought input from RECs and ministries of health when deciding how to safely proceed with research and reopen NGO-led research clinics.

NGOs employed innovative methods to protect vulnerable research participants. During the pandemic, while collecting data remotely, NGO researchers, who conducted interviews and surveys via phone, WhatsApp, Skype, and Zoom, provided participants at risk of domestic violence with “safe words” to end an interview or survey in case they felt unsafe (e.g., Peterman et al., 2021). Some NGO actors also implemented telemedicine and remote counselling schemes to support research participants affected by crises.

NGOs also mitigated risks to research teams and participants during unexpected crises through sound financial oversight. During the COVID-19 pandemic, they reallocated research funds to establish consultation forums and to purchase personal protective equipment for research teams as well as participants.

### 3.6.4 Support needed during crises – present and future

NGO actors call for guidelines for ethical research during sudden, global crises. These guidelines should cover remote data collection, standard operating procedures for RECs, and the adaptation of existing guidelines and standard operating procedures to local contexts.

NGO community members also report the need for greater consultation and collaboration with stakeholders, including policy-makers, research governance actors, and the public. They cite participatory approaches as key to ensuring RE and RI in future crises.

## 3.7 Policy-makers/advisors

### 3.7.1 Overview

Policy-makers include actors with the primary responsibility of formulating or amending national health policy. This platform specifically invited individuals who have led, or are leading, their country's response to crises like pandemics and epidemics, including experts in RE/RI.

Policy-makers/advisors	
RE/RI challenges in crises	<ul style="list-style-type: none"><li>▷ Misinformation during crises</li><li>▷ Decision-making based on limited research findings</li></ul>
Solutions and adaptations to crises	<ul style="list-style-type: none"><li>▷ Communication via multiple platforms to counter misinformation</li><li>▷ Supporting think tanks</li></ul>
Support needed	<ul style="list-style-type: none"><li>▷ Developing public engagement plans</li><li>▷ Guidelines to manage responses against corruption</li><li>▷ Increased cooperation with RE/RI actors</li></ul>

### 3.7.2 Research ethics and integrity challenges in crises – present and future

Policy-makers and advisors battled misinformation during the COVID-19 crisis and were tasked with decision-making based on limited – and often controversial – research findings. During the pandemic, misinformation and the publication of low-quality research, shared through social media as well as conventional news outlets, affected the public's trust in research as well as their interest in participating in research. Policy-makers are under pressure to heed public opinion while also basing their decisions on scientific findings. At the same time, policy-makers ensure the flow of scientific information to all social strata, including marginalised and/or vulnerable communities.

### 3.7.3 Solutions and adaptation to crises

To facilitate the flow of high-quality information, policy-makers utilised communication fora. During the pandemic, they set up national hotlines and mobile health apps and held frequent press briefings led by ministries of health and expert panels to counter misinformation. To reach marginalised and/or vulnerable communities, they translated public messages into multiple languages, designed colourful posters and advertorials, and shared information via multiple media streams. Finally, they received support from think tanks, which provided expertise in scientific communication and could better translate scientific results into policy.



### 3.7.4 Support needed during crises – present and future

Policy-makers call for the development of a robust public engagement plan to encourage cooperation. This plan would establish platforms for wider public debate, enhancing information flow and transparency. Policy-makers hope to boost early and ongoing information sharing with research experts, e.g., via social media, webinars, or mainstream media outlets, allowing them to partner with researchers directly to dispel myths, counter misinformation, and rebuild trust in research and science.

Policy-makers need guidelines to counter corruption in research funding during crises (e.g., regarding tenders and procurement). Guidelines could also delineate a set of common values amongst policy-makers to uphold RE/RI. These should aim to translate RE/RI into policy at the national and community levels.

Policy-makers call for increased cooperation with RE/RI actors. They hope to assemble a cohort of ethicists to be placed at the frontline of policy discussions during unexpected crises. RE/RI experts may help policy-makers assess the urgency of RE/RI topics in crisis contexts and could assist in RE/RI outreach.

## 4. Core stakeholder needs

Stakeholders face a wide range of challenges during sudden, global crises. Following the COVID-19 pandemic, stakeholders adapted their approaches to research and research oversight to uphold RE/RI standards. Stakeholders primarily lacked support in four key areas:

- *Collaboration.* Stakeholders call for joint responses to emerging RE/RI challenges. They hope to assemble and/or enhance platforms for dialogue on RE/RI issues amongst multiple stakeholder groups. They aim to sensitise the public to RE/RI issues through open discussion.
- *Guidelines.* RE/RI challenges should be met through a clear set of RE/RI standards and their translation into practice. Stakeholders seek guidelines specific to RE/RI challenges in crisis contexts.
- *Training.* Stakeholders believe it is not enough to simply agree upon best practices from the COVID-19 pandemic: new and existing RE/RI actors should be trained to adapt effectively to future crises. Materials should target specific actors.

- *Funding.* Across all platforms, stakeholders cited the need for additional support to meet funding shortages. This took the form of human resources, as many platforms lacked the people power to solve RE/RI challenges.



Figure 3: Core stakeholder needs

## 5. Conclusion

Though PREPARED addresses stakeholder needs at a platform level, its outputs should speak to four common needs on upholding RE/RI during unexpected crises. Namely, outputs should accomplish the following.

- Enhance collaboration between stakeholder groups
- Draft guidelines to clarify and operationalise RE/RI standards
- Train new actors to adapt to future crises
- Advocate for increased funding for stakeholders

In the first half of 2023, platform leaders will continue to develop their platforms and engage stakeholders through project activities. The stakeholder needs assessment process is ongoing: numerous workshops and other stakeholder engagement activities are planned within the scope of the PREPARED project to refine stakeholder needs. Additionally, the list of tools developed will continue to help platform leaders identify the needs of RE/RI stakeholders.


Overall, our analysis has shown that different stakeholders experience common challenges and, as a result, report similar needs. Accordingly, platform leaders must continue to exchange ideas and develop joint solutions.

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