



Health  
Food Chain Safety  
Environment

# Towards Coordinated Public Funding of Clinical Studies & Trials on Infectious Diseases During Outbreaks

*Introduction (Part 1)*

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## Introduction

- Rapid initiation of COVID-19 clinical studies and trials within 33 days of the WHO PHEIC declaration.
- Impactful trials like REMAP-CAP and RECOVERY informed practices and policies and saved lives.
- Fragmented clinical research landscape with a proliferation of many uncoordinated and competing clinical studies and trials that failed to generate actionable evidence.
- Lack of coordination at the European level between the Member States.
- Call for strengthening and better coordinating the clinical research response during infectious disease outbreaks.
- Role of research funders plays a crucial role in supporting a coordinated, effective and timely clinical response during infectious disease outbreaks.

# Multi-step Approach

## Towards Coordinated Public Funding of Clinical Studies & Trials



\*EU-FUTURE-ID database : European FUnders of clinical studies, Trials and Urgent REsearch for Infectious Disease outbreaks

## PLAN

### Day 1

14 May

1. Database of European Funders on Infectious Diseases
2. Survey & Interviews - Approach and Challenges
3. Funding Organisations Attending the Workshop

### Day 2

15 May

1. Funding Landscape & Policies
2. Number of Funded Studies & Trials & Budget Distribution
3. Multinational Clinical Studies & Trials on Infectious Diseases
4. Gaps & Obstacles Limiting a Coordinated Funding of Multinational Clinical Studies & Trials

# 1. Database of European Funders on Infectious Diseases

# Existing Up-to-Date Database

## Global Research Collaboration for Infectious Disease Preparedness (GloPID-R) Database

[www.pandemicpact.org](http://www.pandemicpact.org) (launched in March 2024)

Pandemic PACT tracks and analyses global funding and evidence for research on diseases with pandemic potential and broader research preparedness efforts, ready to pivot in response to outbreaks.



|  |                |
|--|----------------|
| Institut Pasteur International Network (IPIN)  | France         |
| Agence nationale de recherche sur le sida et les hépatites virales [National Agency for AIDS Research] (ANRS)                          | France         |
| Wellcome Trust   | United Kingdom |
| Bundesministerium für Bildung und Forschung [German Federal Ministry of Education and Research] (BMBF)                                 | Germany        |
| Ministry of Health - Italy   | Italy          |
| Netherlands Organisation for Health Research and Development (ZonMW)   | Netherlands    |
| Coalition for Epidemic Preparedness Innovations (CEPI)   | Norway         |
| Research Council of Norway (RCN)   | Norway         |
| Trond-Mohn Foundation  | Norway         |
| National Institute of Health Carlos III [El Instituto de Salud Carlos III] (ISCIII)  | Spain          |
| Swiss National Science Foundation (SNSF)   | Switzerland    |
| UK Research and Innovation (UKRI)  | United Kingdom |
| Department of Health and Social Care / National Institute for Health and Care Research (DHSC-NIHR)   UK Research and Innovation (UKRI) | United Kingdom |
| British Academy  | United Kingdom |
| Department for Environment, Food and Rural Affairs (DEFRA)   | United Kingdom |

- Pandemic PACT includes only few European funding organisations.
- No comprehensive and up-to-date database of European funding organisations on infectious diseases.

# EU-FUTURE-ID Database

## *Approach & Characteristic*

**EU-FUTURE-ID: European Funders of clinical studies, Trials and Urgent Research for Infectious Disease outbreaks**

### Database construction

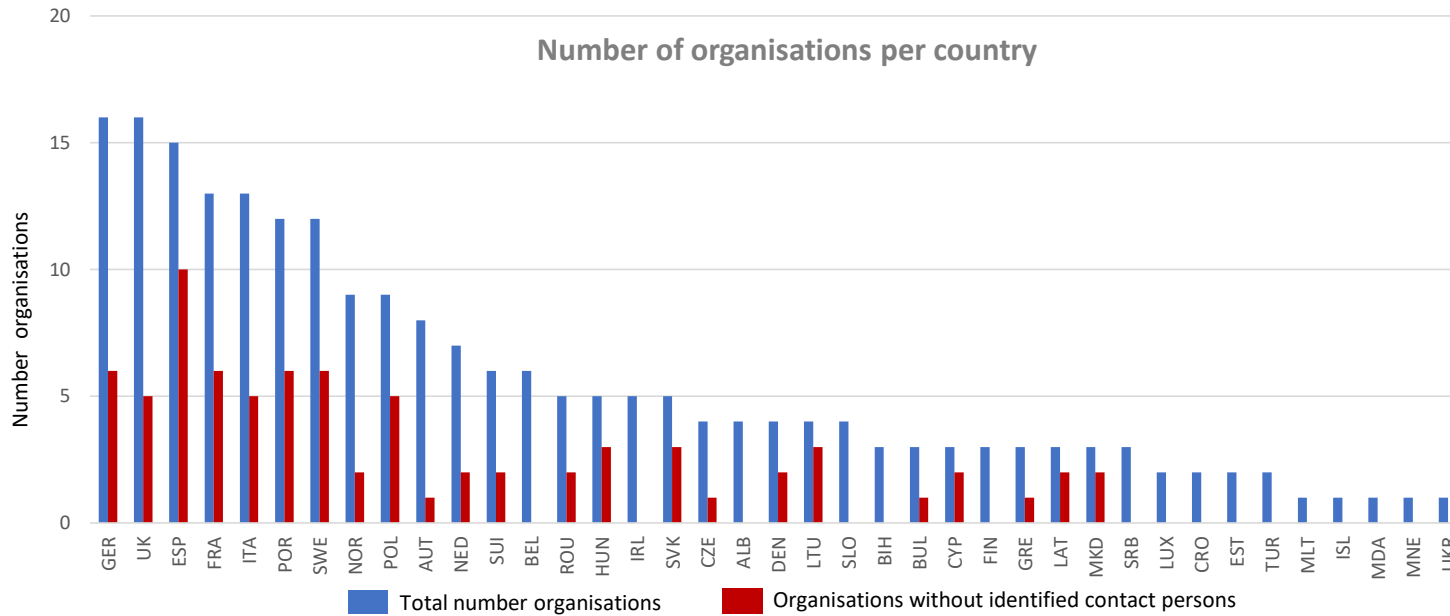
- Working group built in summer 2023 under the leadership of UAntwerpen with relevant stakeholders (Ecraid, WHO Geneva, ECRIN, INSERM, ItaCRIN, JPI-AMR, KCE Belgium, Global AMR Hub and EWI Flanders) to define scope, eligibility criteria and strategy to build a sustainable database.
- List of funders defined using pre-existing initiatives in ID field, established clinical research networks.
- List refined based on desk research and curated through phone calls.
- Organisations participating in survey/interviews invited to provide input and correct information for their country.

### Eligibility criteria to build the database

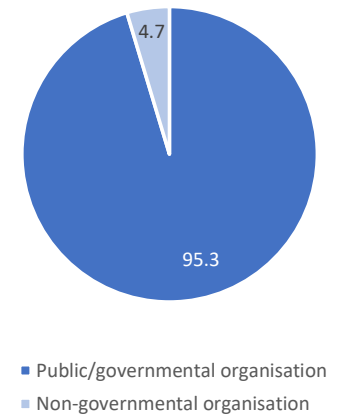
- Countries: EU27, EFTA Members, EU accession candidates, United Kingdom (40 countries in total).
- Public and charity institutions and organisations (commercial organisations excluded).
- Funding resources on clinical research and/or trials (third party funding).
- Funding resources during interepidemic, epidemic and/or pandemic times.
- Funding resources for infectious diseases only.

# EU-FUTURE-ID Database

## Identified funding Organisations



Type (%) of funding organisations



- 219 funding organisations from 39 countries listed after database curation.
- 65% listed organisations include personal email addresses.
- 35% listed organisations have only generic or no e-mail addresses and do not provide reachable telephone numbers.
- Need to continuously update the EU-FUTURE-ID database and define a strategy to ensure its sustainability.



# EU-FUTURE-ID Database

## Example of collected information

Completed

Funding organization details

Completed

Funding organization details

Funding organization details

### 1. Funding organization details

1.1 Funding organization (full name)

1.2 Funding organization (short)

1.3 Funding organization (local name)

1.4 Public/Charity  Public  Charity

1.5 Country (NOC-code)

1.6 Only ad hoc pandemic funding?  Yes  No

1.7 General e-mail address

1.8 General telephone number

1.9 Contact information

| Name       | E-mail address | Telephone number |    |
|------------|----------------|------------------|----|
| [REDACTED] | [REDACTED]     | [REDACTED]       | ⚙️ |
| [REDACTED] | [REDACTED]     | [REDACTED]       | ⚙️ |

1.10 Contact information entered?  Yes ⚙️

1.11 Reference  ⚙️

1.12 Source  ⚙️

1.13 Remarks  ⚙️

## 2. Survey & Interviews

### *Approach & Challenges*

# EuCOfund Survey

## EuCOfund: European COordination of Clinical REsearch Funding

### Objectives

- Explore funders' experiences in funding clinical studies and trials in Europe before (2015-2019) and during the COVID-19 pandemic (30 Jan 2020 - 5 May 2023).
- Compare public funding allocated to clinical studies and trials for infectious diseases in the contexts of both pre-pandemic and pandemic times.

### Approach

- Working group created in summer 2023 to prepare the survey.
- Survey piloted by a selected group of funding organisations: Belgium (KCE); France (INSERM), Germany (DLR), Italy (FRRB), The Netherlands (ZonMW).
- Survey launched from 17 Oct 2023 to 30 Nov 2023 (initial duration).

### Key information collected

- Number and types of clinical studies funded on infectious diseases.
- Funding policies.
- Calls supported and selection processes.
- Estimated budgets dedicated to clinical studies before and during the pandemic.

# Qualitative Interviews

## Objectives

- Gain a deeper understanding of the funding policies & mechanisms (before and during the COVID-19 pandemic).
- Identify challenges and gaps in funding clinical studies and trials on ID (before and during the COVID-19 pandemic).

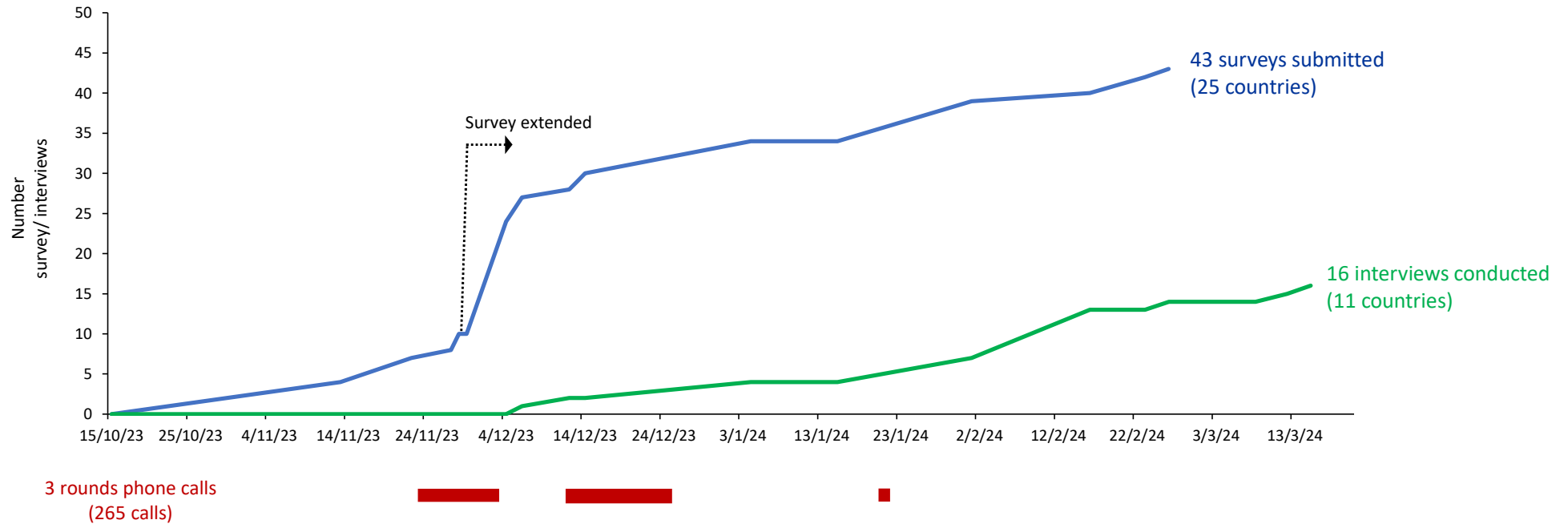
## Approach

- Questionnaire developed based on desk research and feedback from relevant stakeholders.
- Questionnaire distributed to interviewees before interview, additional information collected after interview when needed.

## Key information collected

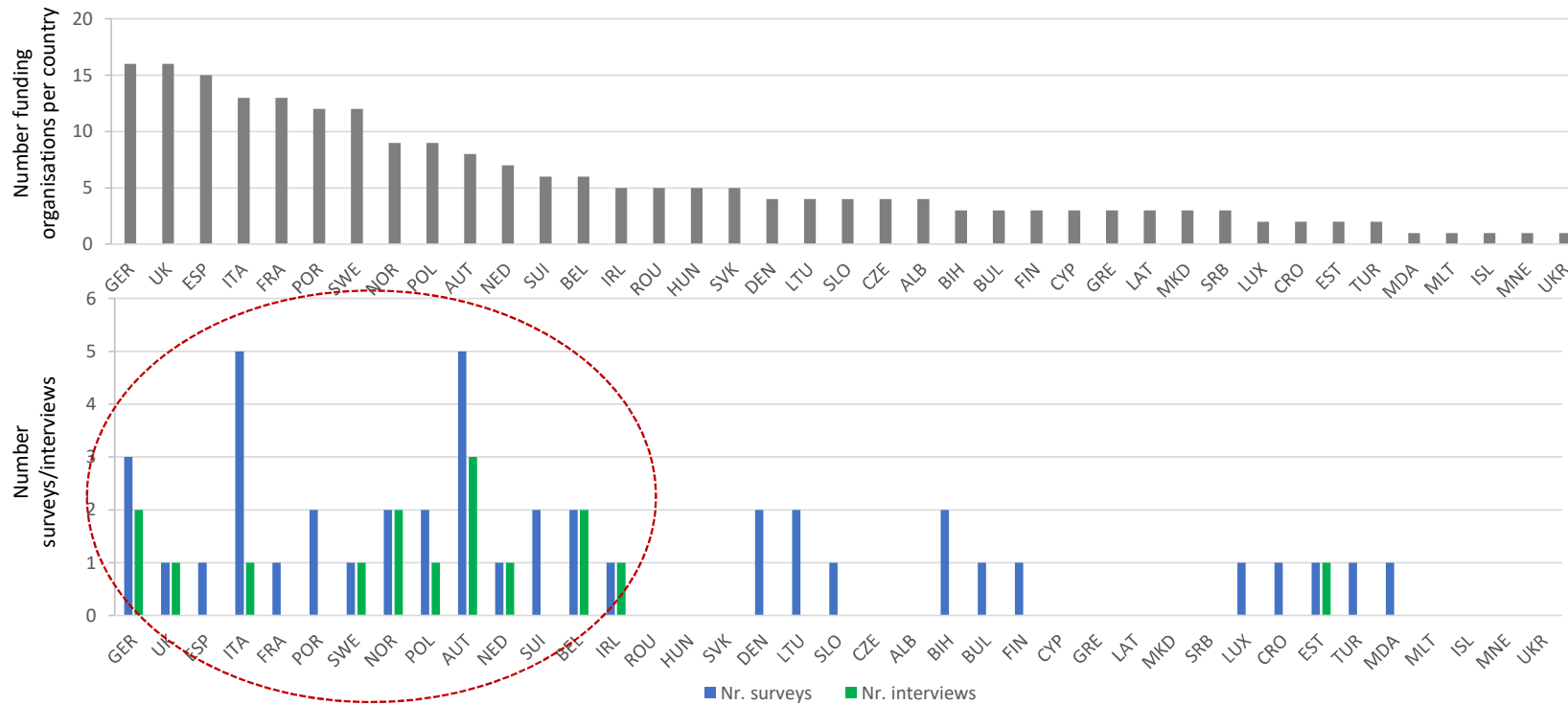
- General information on funding clinical studies and trials on ID.
- Funding mechanisms on ID (before and during the pandemic).
- Budget distribution and flexibility to fund clinical studies and trials on ID (before and during the pandemic).
- Experience in multinational clinical research.
- Future plan to prepare to future disease outbreaks.
- Vision to facilitate coordination of multi-countries clinical studies and trials.

## Response to EUCoReFund Survey and Interview (1)



- 20% funding organisations from the database submitted the survey.
- 47% funding organisations who submitted the survey accepted to be interviewed (several reminders by email and/or phone calls).
- Four case studies selected based on conducted interviews (Belgium, Germany, Nordic countries, UK).

## Response to EUCoReFund Survey and Interview (2)



- In general, countries that responded to the survey and interview have more than 5 organisations/country.
- At least one major funder per country participated in the survey/interview.
- For some countries, major funders only participated in the survey and declined the interview.

## EUCoReFund Survey & Interviews - Challenges (1)

1. Identification of contacts within organisations (partially resolved through phone calls and follow-up emails)
2. Difficulty in engaging EU national funders to participate in survey/interviews
3. Survey/interview participation complicated by organisational hierarchy that required multi-step internal approval process
4. Difficulties to collect data that led to survey extension

- *Data collection required exchange with different departments*

*“I wanted an inventory when I started ..., and I found that at least half of the studies on infectious disease were funded outside the infectious disease department. So that's why it's difficult to bring it together. And it's been said, we are working on to improve our database system, so in future we can answer these questions easier”.*

- *Different database structure & classification system*

*“Our database is not structured exactly the right way to enable answering your questions precisely. We cannot differentiate between interventional or observational studies as we do not collect this information”.*

*“It emerges from our discussion that no tool simply provides answers to the questions asked”.*

- *Lack of personnel and time to collect data*

*The survey would require a significant volume of work, given the very long period concerned and the need to return to the projects themselves. Such an investment is not currently possible [...] Our future tools will help answer to these questions”.*

## EUCoReFund Survey & Interviews - Challenges (2)

### 5. European partnership not compatible with funder's policy

*"The [organisation name] focusses on funding projects developed by the academic community in the area of knowledge-driven research. Within this mission, clinical trials funded by the organisation follow the same bottom-up principles. In this role, the organisation cannot be considered a stakeholder in initiatives towards European Partnerships". [Email]*

### 6. Data to be collected considered as sensitive

*"After thoughtful consideration, we believe that the data requested are sensitive for our institution. Hope we can collaborate in the future". [Email]*



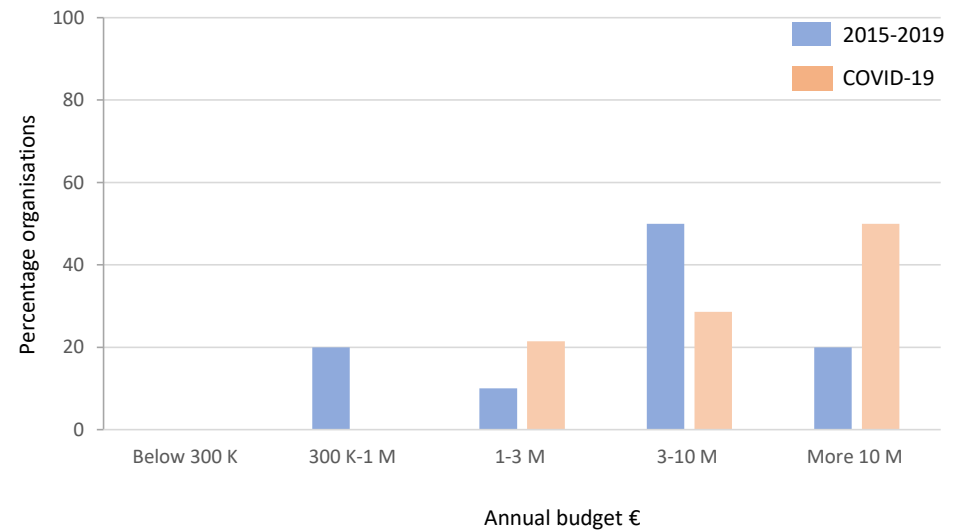
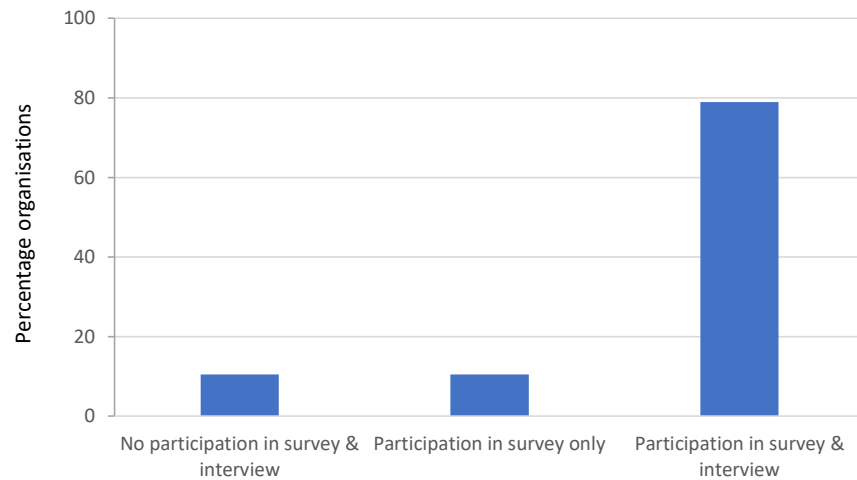
### 3. Funding Organisations Attending the Workshop

## Funders Participating in the Workshop (1)

*12 countries are represented*

| Organisation   | Country         |
|--|-----------------|
| Austrian Federal Ministry of Education, Science and Research (BMBWF) | Austria         |
| Austrian Research Promotion Agency (FFG)                             | Austria         |
| Ludwig Boltzmann Gesellschaft (LBG)                                  | Austria         |
| Belgian Health Care Knowledge Centre (KCE)                           | Belgium         |
| Fund for Scientific Research (FNRS)                                  | Belgium         |
| Estonian Research Council (ETAG)                                     | Estonia         |
| French National Institute of Health and Medical Research (INSERM)    | France          |
| National Institute for Care and Health Research (NIHR)               | United Kingdom  |
| Department of Health and Social Care (DHSC)                          | United Kingdom  |
| Federal Ministry of Education and Research (BMBF)                    | Germany         |
| Network of University Medicine (NUM)                                 | Germany         |
| Health Research Board (HRB)  | Ireland         |
| Italian National Institute of Health                                 | Italy           |
| National Institute for Public Health and the Environment (RIVM)      | The Netherlands |
| Netherlands Organisation for Health Research and Development (ZonMW) | The Netherlands |
| NordForsk  | Norway          |
| Research Council Norway (RCN)  | Norway          |
| Swedish Research Council (VR)  | Sweden          |
| Scientific and Technological Research Council of Turkey (Tübitak)    | Turkey          |

## Funders Participating in the Workshop (2)



- 79% funders present at the workshop participated in survey and interview.
- 50% funders present at the workshop allocated more than 10 M annual budget to clinical studies on infectious diseases during the pandemic.

## Diverse Preparedness Mindsets

*“On a national level, we do not have kind of formalized processes in place in case of a crisis. I'm not sure how to improve this type of situation. And my good guess is that if the next pandemic hits, there will be again a lot of ad hoc requests that would come in and we would react to those ad hoc.... With us, I haven't observed any formalistic processes being put in place in preparation of a new pandemic.”*

*“I believe the crucial aspect is being more prepared. When an event like this occurs, many decisions, including the funding calls [...] were made during the acute phase of COVID. This is not an ideal way to work [...] thus, having such mechanisms available, not just the concept of research calls, but also the systems to help deliver very rapid calls and unusual mechanisms to get these things through, are the truly critical elements that we should have in place for future occurrences.”*

## Case Study Session

### 15 May (9:15 am – 10:30 am)

|          |                             |   |                         |
|----------|-----------------------------|---|-------------------------|
| <b>1</b> | Frank Hulstaert             | Federal Healthcare Knowledge Center (KCE)   | <b>Belgium</b>          |
| <b>2</b> | Arne Flåøyen                | NordForsk   | <b>Nordic countries</b> |
| <b>3</b> | Mike Rogers<br>Kate Gerrand | National Institute for Care and Health Research (NIHR)<br>Department of Health and Social Care (DHSC) | <b>United Kingdom</b>   |
| <b>4</b> | Ralf Heyder                 | Netzwerk Universitätsmedizin (NUM)  | <b>Germany</b>          |

### Question

What lessons can we draw from these 4 case studies to define a European funding mechanism for clinical studies and trials during infectious disease outbreaks?

# Plenary Discussion

## 15 May (11:15 am – 12:20 pm)

### Question 1

Do you have suggestions on how to coordinate effectively and timely at the European level the funding of multinational clinical studies and trials during infectious disease outbreaks? What factors influence your preference(s)?

### Question 2

Which key elements should be considered and integrated in your organisation (and your procedures) to facilitate at the European level the timely coordination of funding multinational clinical studies and trials during infectious disease outbreaks ?

### Question 3

Which approaches do you propose for coordinating the monitoring and evaluation of clinical studies & trials being funded through a coordinated funding mechanism during infectious disease outbreaks? What are the main challenges?

# THANK YOU