

# Epidemics: What are relevant for health practitioners / clinical researchers

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# The ICU-the canary in the coal mine



# The ICU-the canary in the coal mine



- High mortality, significant morbidity and disability in survivors
- Cost of care is significant
- Opportunity for research to improve outcomes

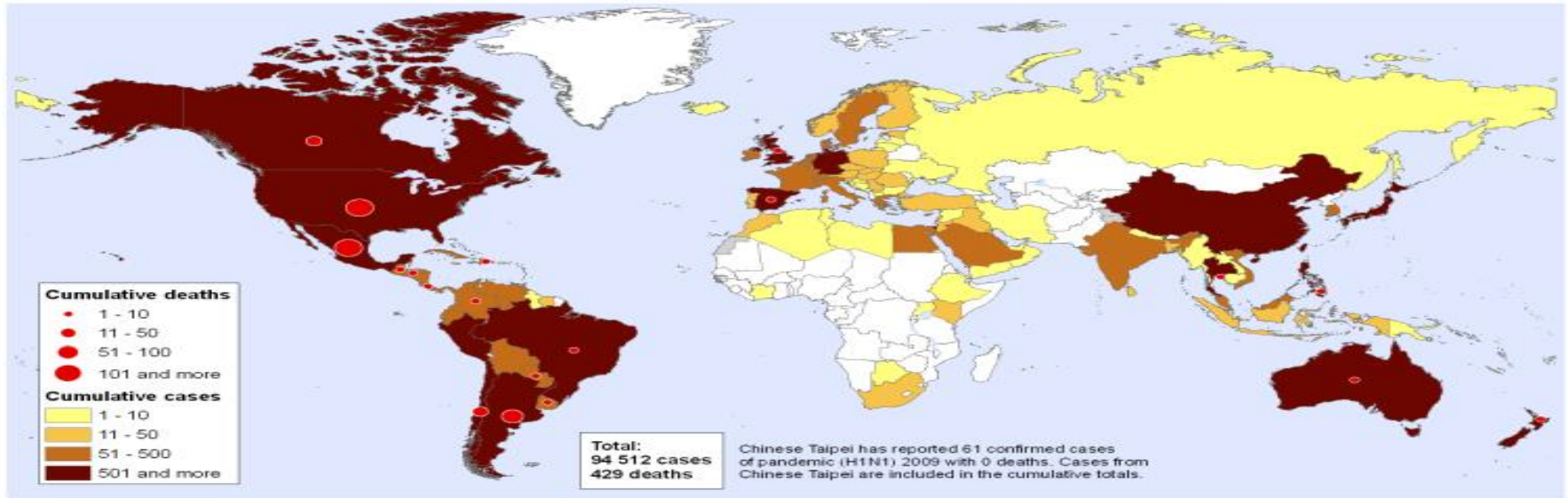
# A clinicians view of epidemic's

- Infectious diseases with epidemic potential
  - Acute respiratory tract infection,
  - Central nervous system infection,
  - Haemorrhagic fevers
  - Severe diarrhoea, and
  - Severe undifferentiated fevers.

# Remembering 2009

Pandemic (H1N1) 2009,  
Number of laboratory confirmed cases as reported to WHO

Status as of 06 July 2009  
09:00 GMT



The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

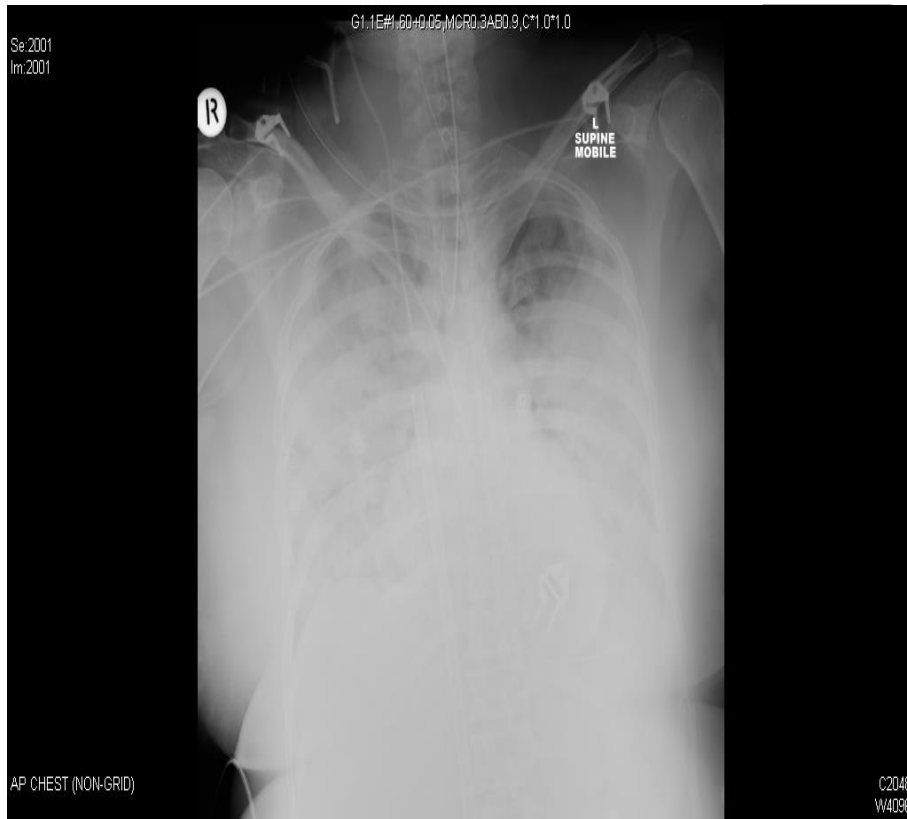
Map produced: 06 July 2009 09:00 GMT

Data Source: World Health Organization  
Map Production: Public Health Information  
and Geographic Information Systems (GIS)  
World Health Organization



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# Acute Respiratory Distress Syndrome (ARDS)





# Clinical care considerations

- Informed consent
- Vulnerable populations
- Standard of care
- Allocating access to scarce resources
- Emergency use of unproven interventions
- Procedural considerations and communication plans
- HCW rights and obligations

# Clinical research considerations

- Observational study difficult

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Critical Care Services and 2009 H1N1 Influenza  
in Australia and New Zealand

The ANZIC Influenza Investigators\*





# Clinical research considerations

- Observational study difficult
  - Clinical work load
- Interventional study impossible
  - Ethical approvals
  - IMP approvals
  - Contracts / Funding / Indemnity
  - Novel designs

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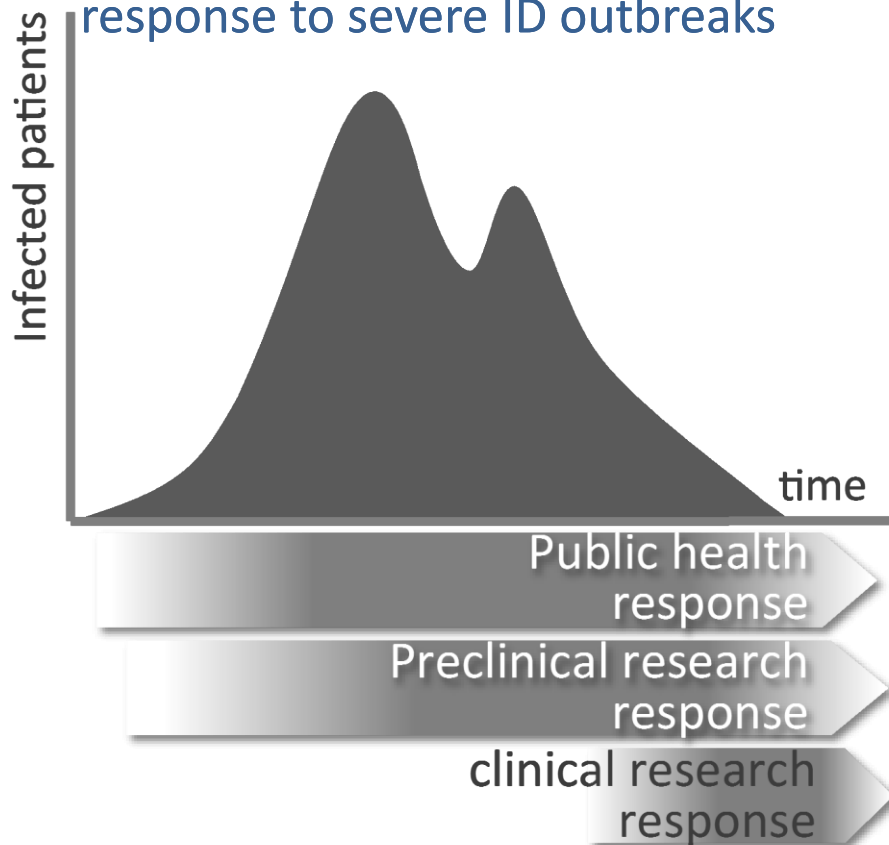
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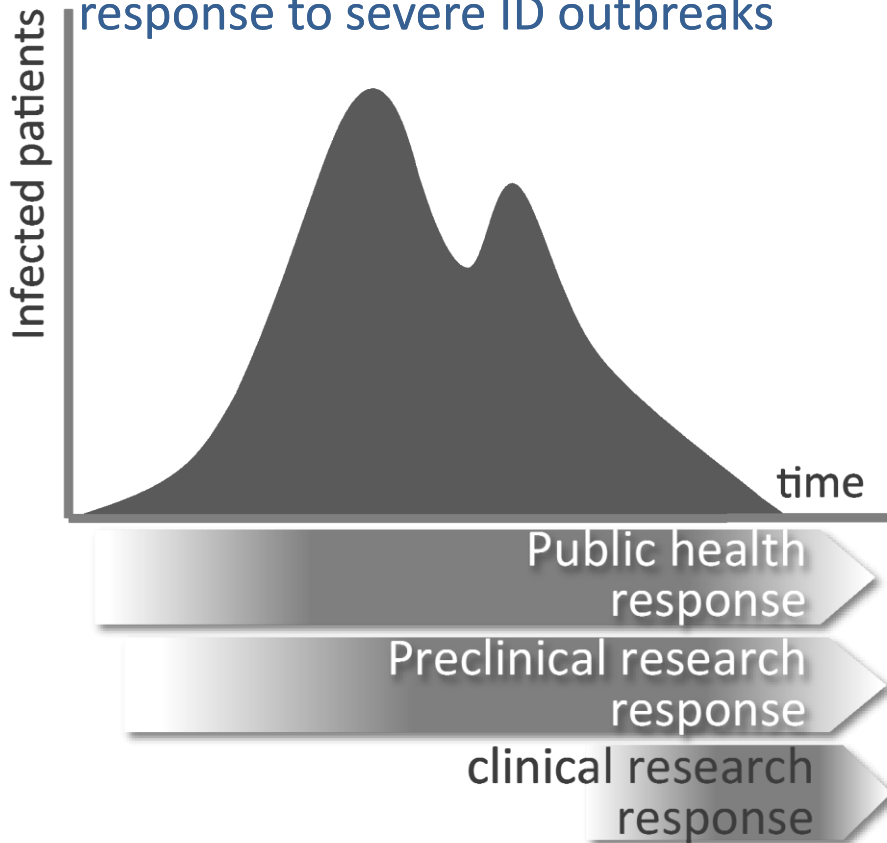
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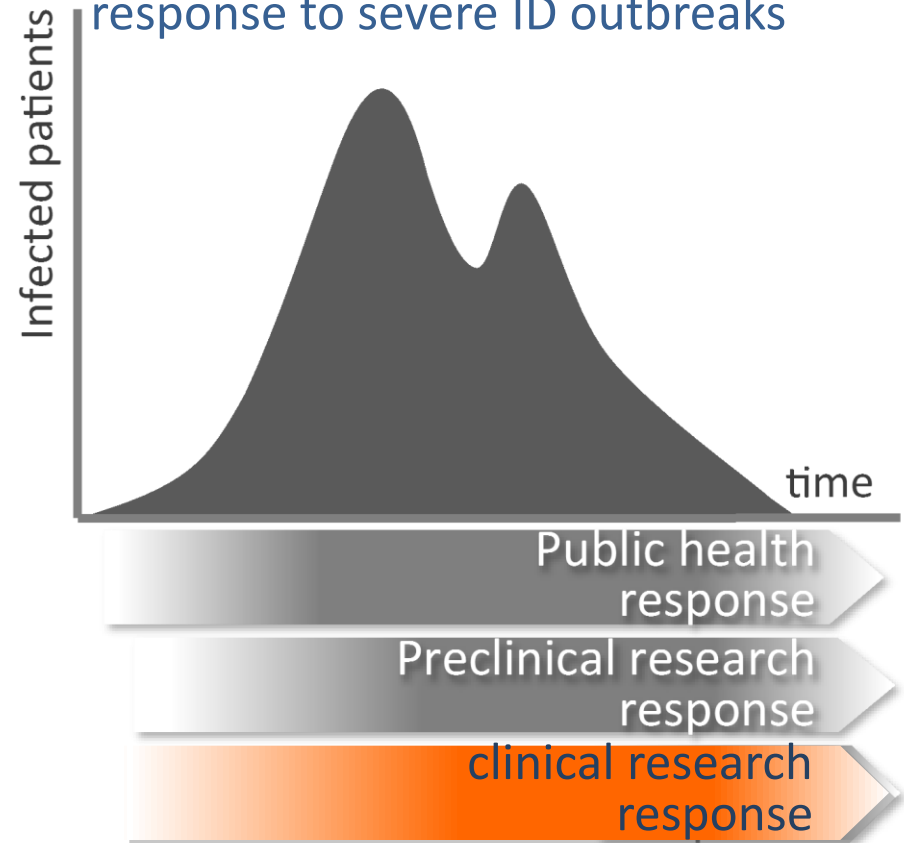
**Current situation:** delayed, isolated and fragmented clinical research response to severe ID outbreaks



**Current situation:** delayed, isolated and fragmented clinical research response to severe ID outbreaks



**Future situation:** rapid, integrated and harmonized clinical research response to severe ID outbreaks



# ISARIC /PREPARE





# WP 1 EARL

Ethical, Administrative,  
Regulatory and  
Logistical aspects of

**PREPARE**  
Alistair Nichol  
Chris Butler  
Steve Webb



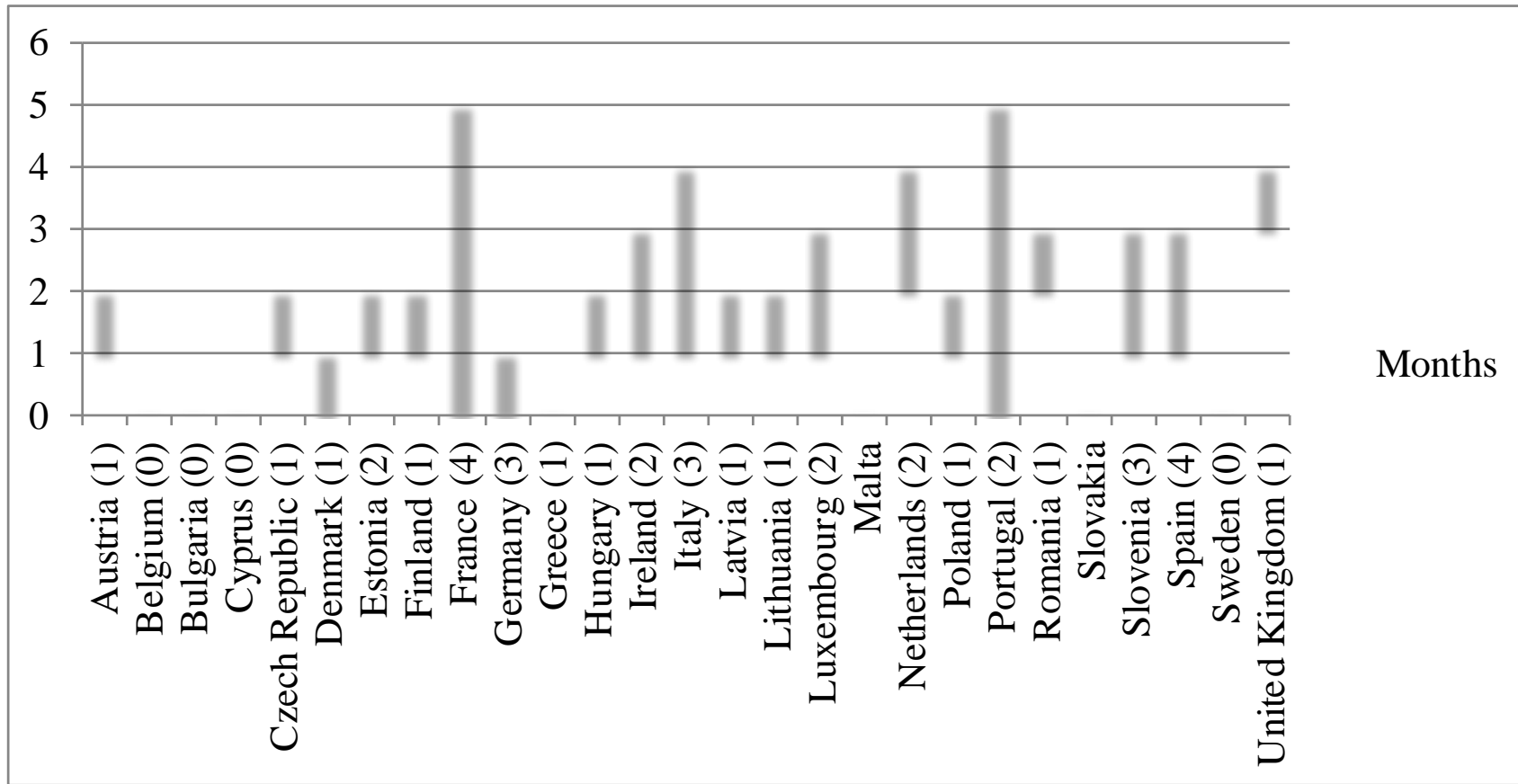


# Overarching aim of WP 1

- To **identify** and **provide solutions** to key **structural** (ethical, administrative, regulatory and logistical) bottlenecks as well as **behavioural and cultural barriers** to the rapid implementation of large multi-site clinical studies in Europe in response to severe ID outbreaks

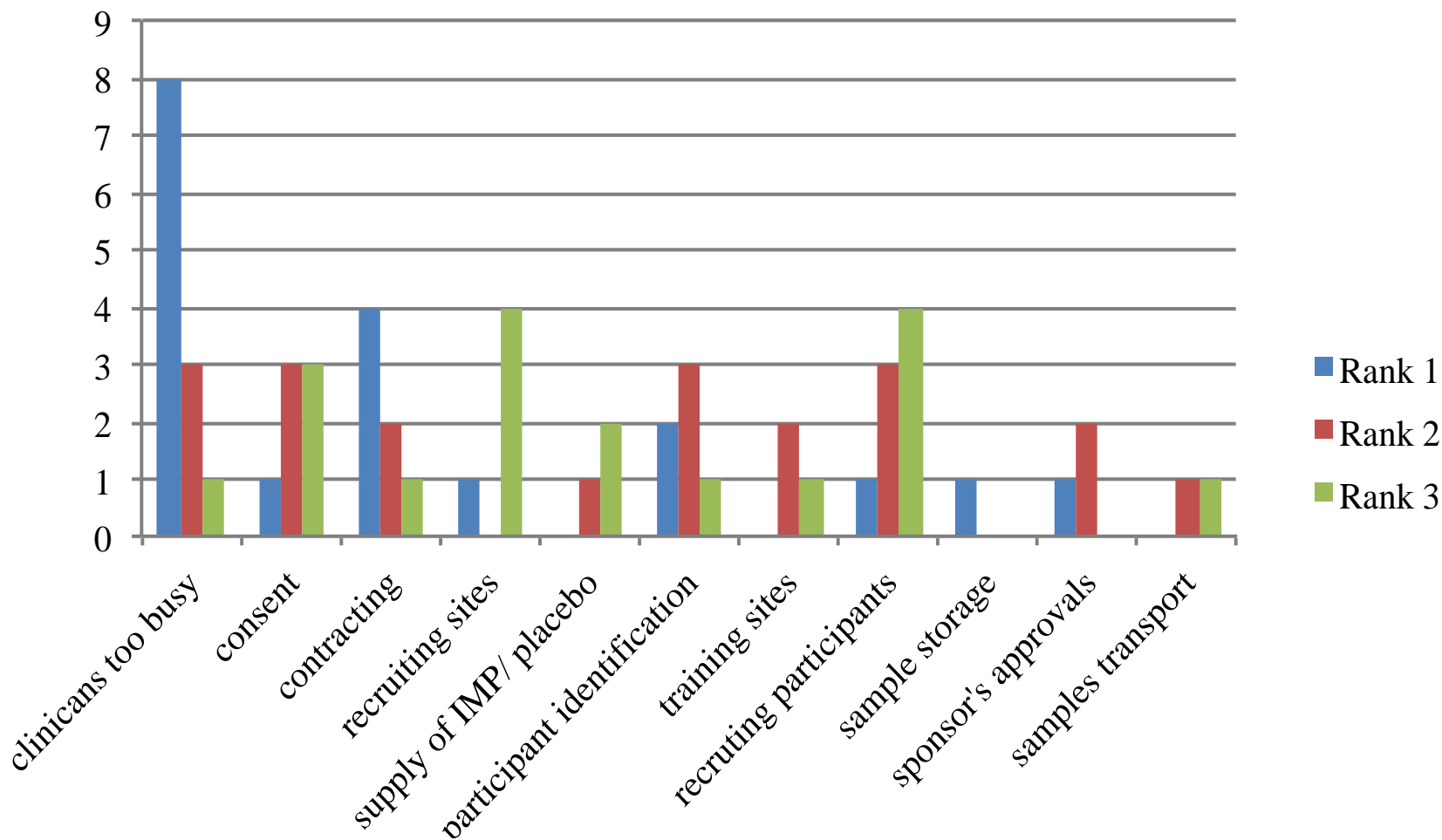


# Time for ethical approvals





# Barriers to research during epidemic





# PREPARE

## EARL: WP1

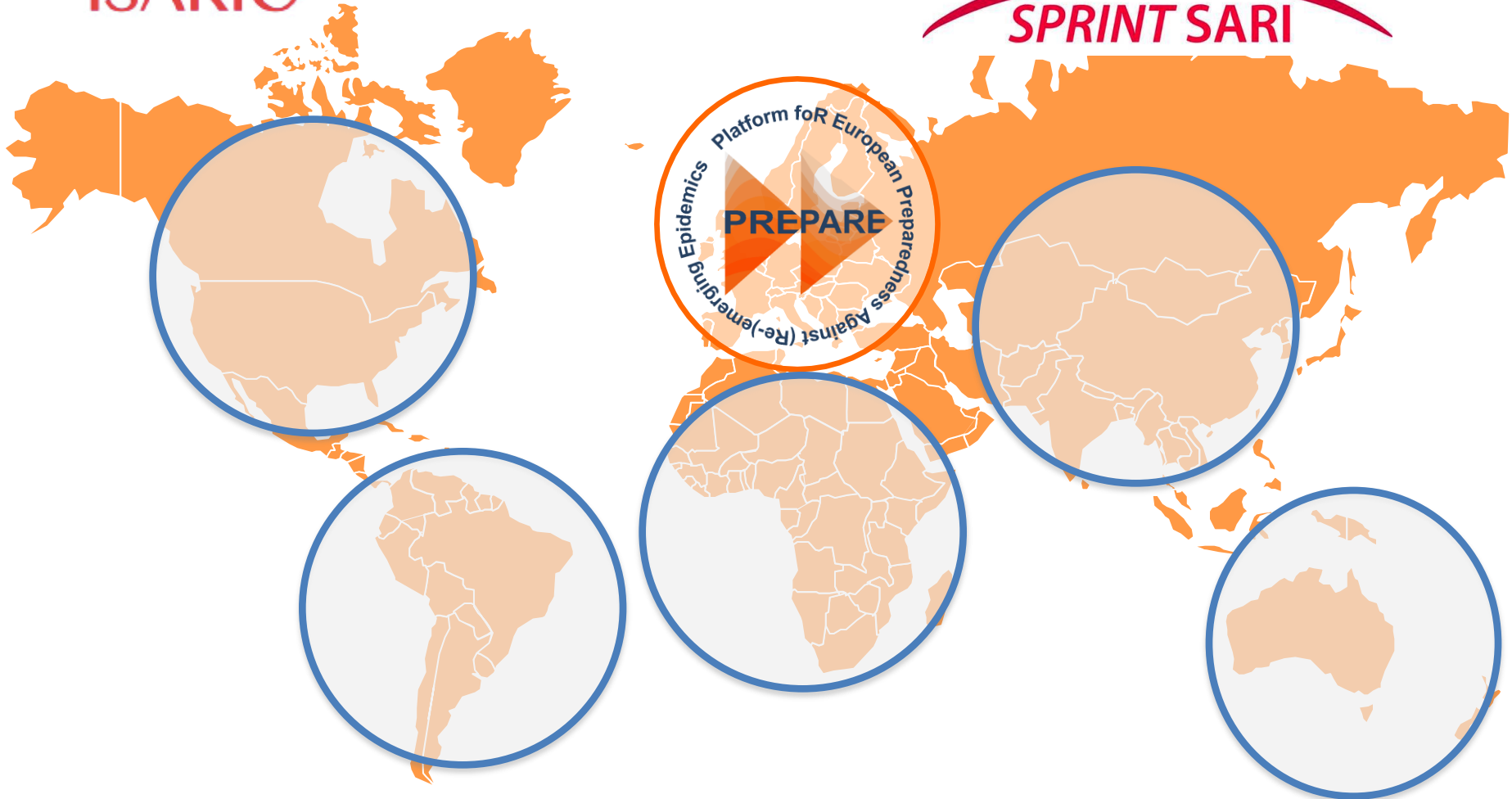
*Ethical, Administrative,  
Regulatory and Logistical  
solutions*

# Short term solutions First Report

# EARL

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# International embeddina



THOUGHTS?



Funded by the  
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