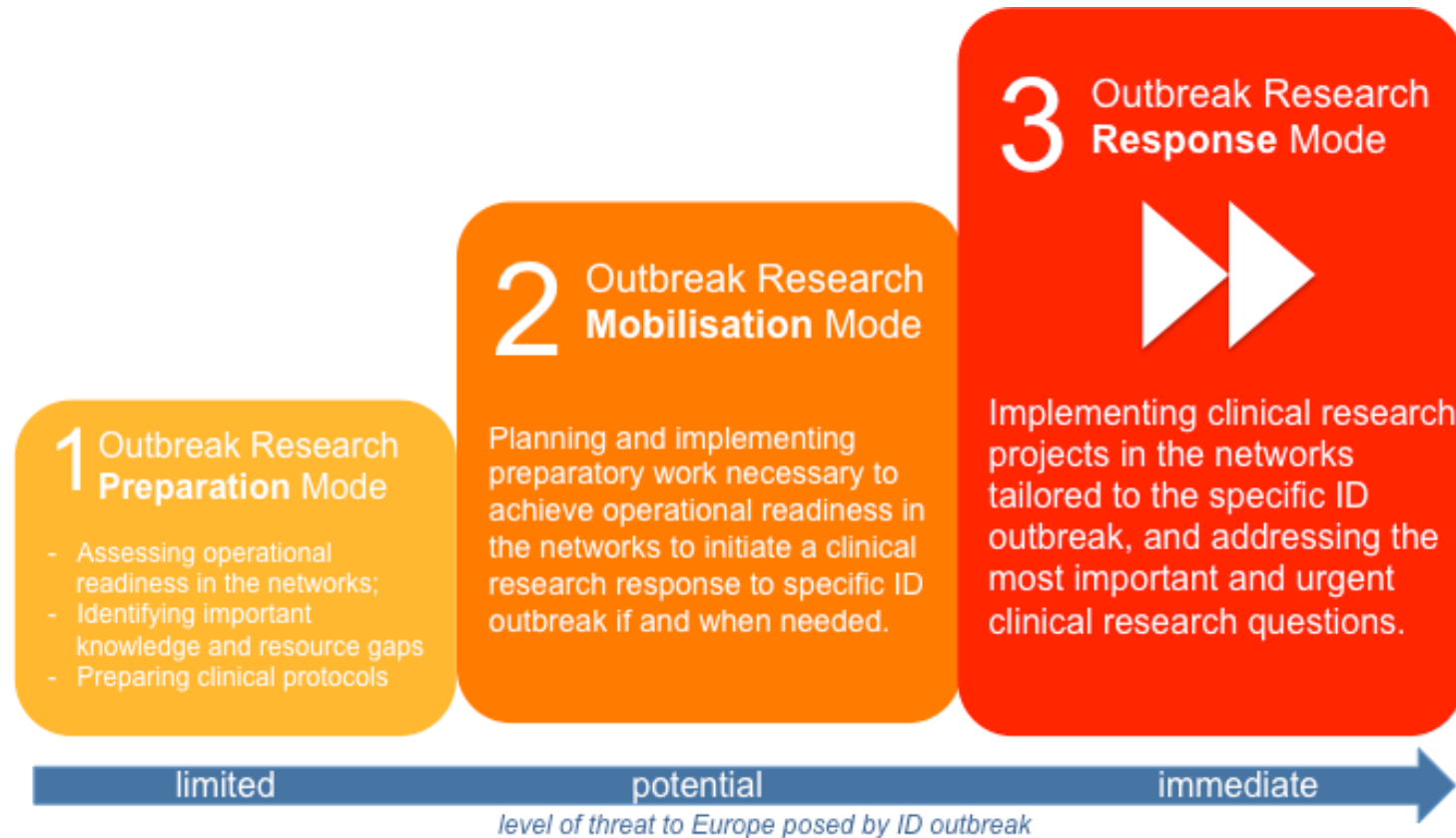




Health
Food Chain Safety
Environment

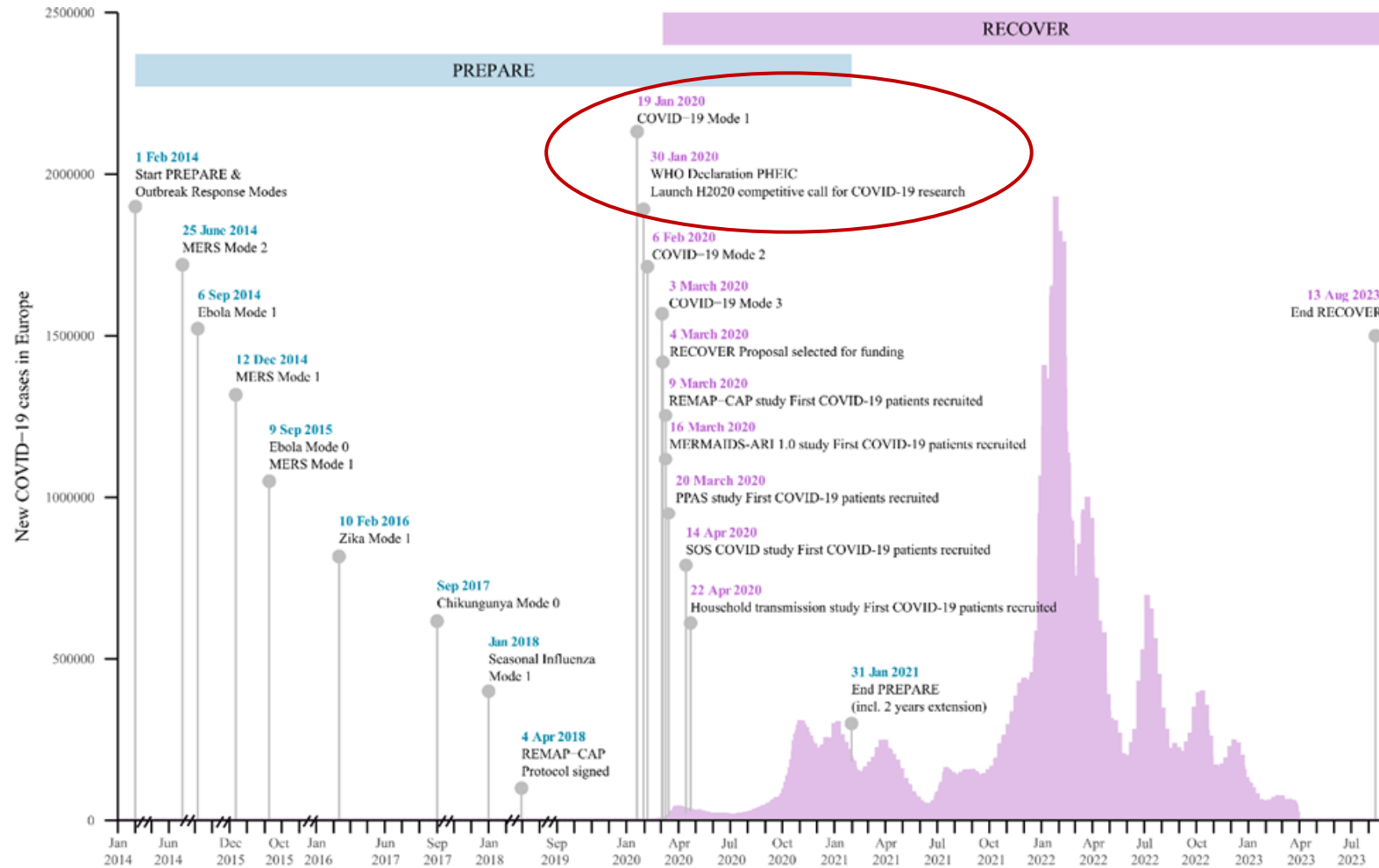
**Outbreak Response Mechanism:
what did and what did not work in the PREPARE and
RECOVER projects?**

PREPARE Outbreak Response Mechanism and Modes, tested in three Table-Top exercises

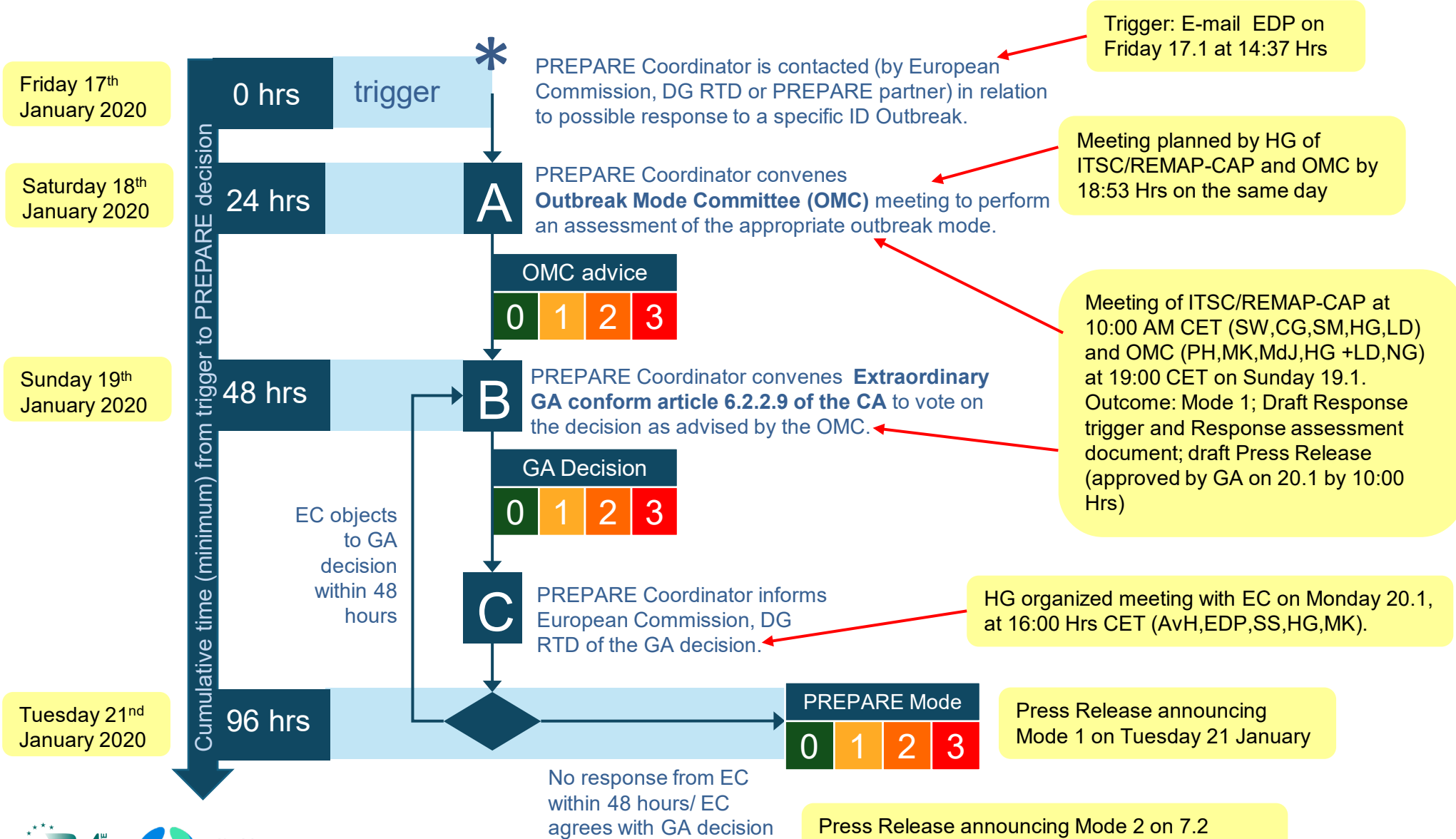


Overview of the PREPARE Outbreak Response Mode activation during disease outbreaks.

The COVID-19 pandemic led to the activation of the highest Outbreak Response Mode (Mode 3) and the funding of RECOVER



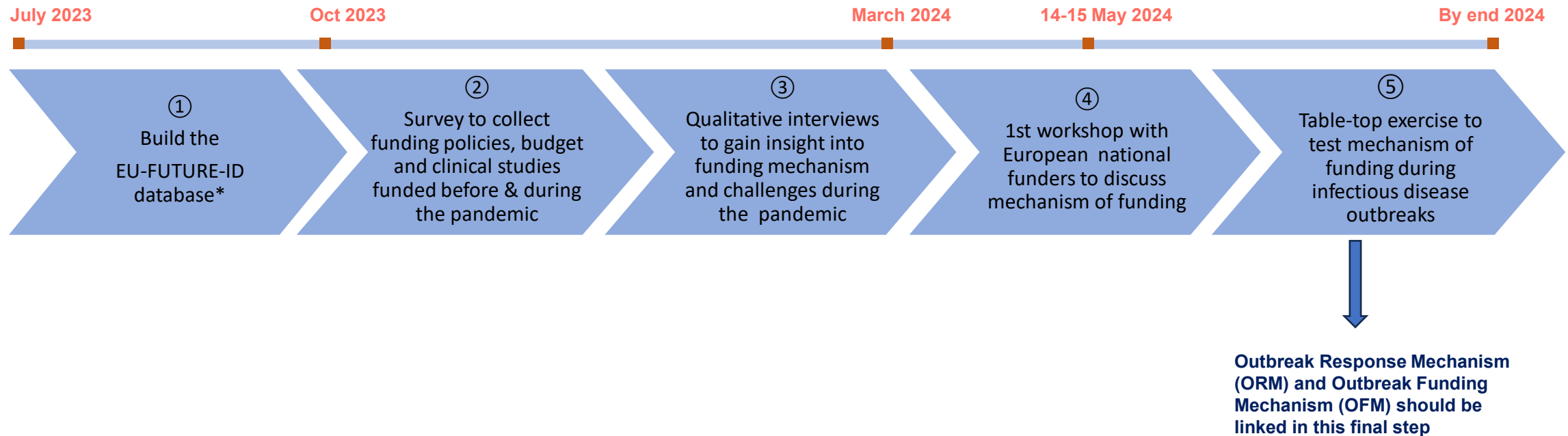
Decision making process in PREPARE and response to SARS-CoV-2 outbreak



Summary

- The PREPARE outbreak research modes constitute an important mechanism to coordinate the clinical research activities and ensure a timely response. It worked!
- However, these modes did not take sufficiently into account the inherent characteristics and limitations of the European and global clinical research ecosystem.
- The multiplication of clinical studies at national level, coupled with the lack of research prioritization strategies increased the competition for sites and has been detrimental to the rapid implementation of European clinical studies.
- Fundamental issues inherent to the clinical research ecosystem resurfaced during the pandemic (clinical research not sufficiently embedded in practice; public health and clinical research are siloed).
- Criteria of public funding of clinical research not sufficiently aligned with the concept of preparedness; this requires an understanding of publicly funding of clinical trials at the level of the Member States (Belgian EU Presidency).

Multi-step approach for developing an Outbreak Funding Mechanism (OFM)



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

Questions

Question of the plenary session on funding mechanism(s)

- **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 in 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?