European partnership on clinical trials initiative

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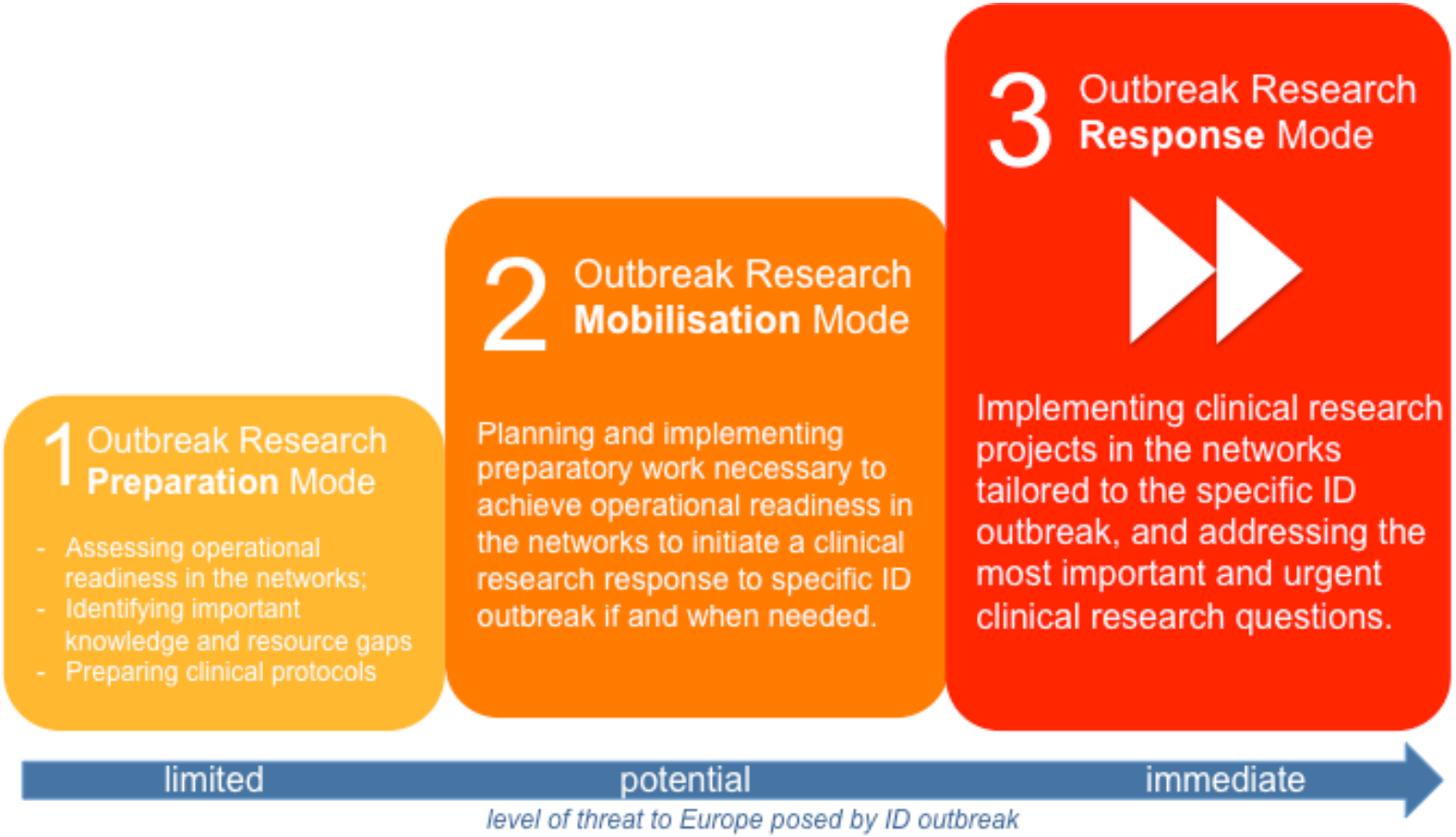
Outbreak Response Modes

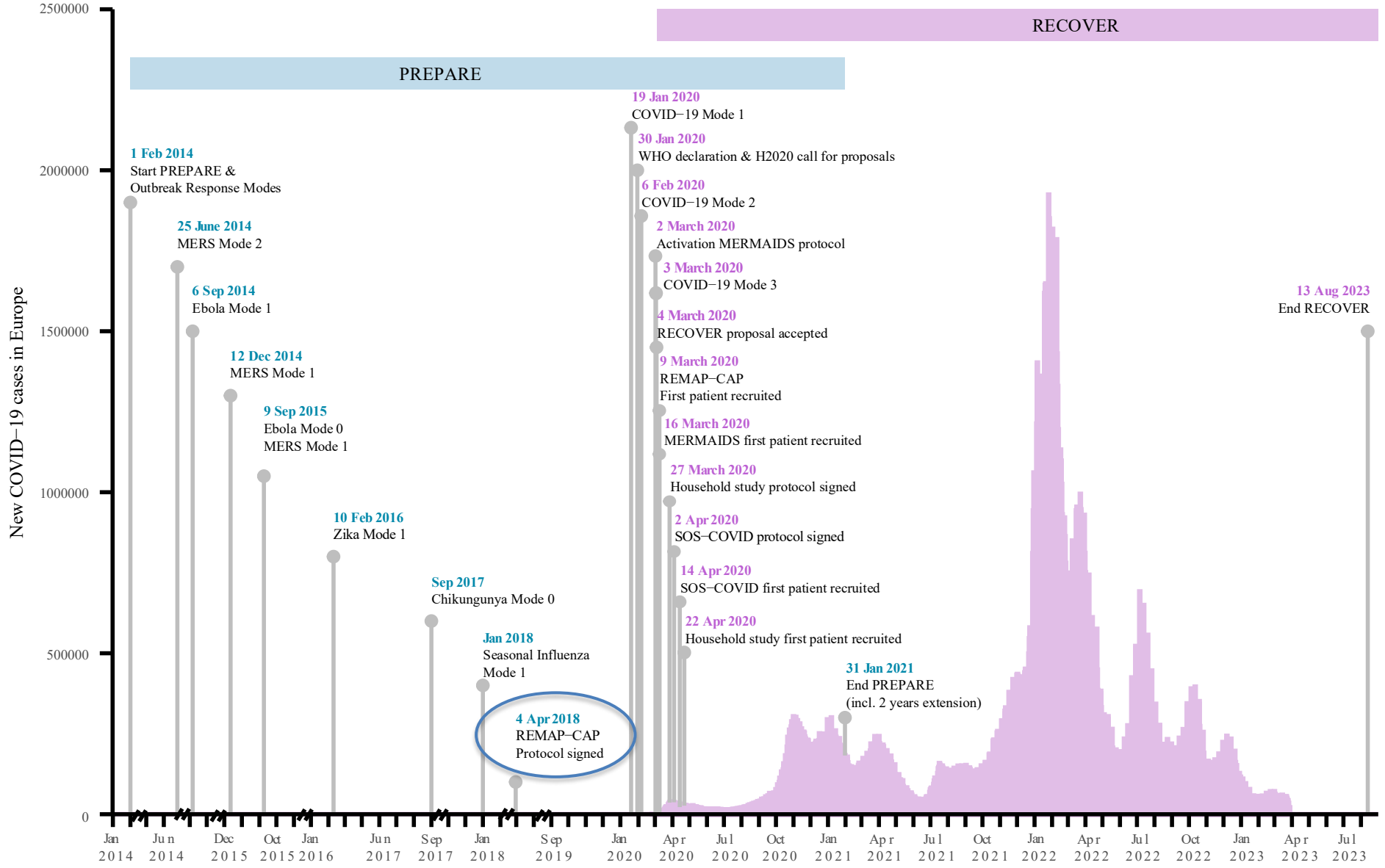


This project is funded by the European Commission's FP7 Programme under grant agreement No. 602525

The clinical research response January – April 2020: **VERY ENCOURAGING**

- In response to COVID-19 substantial research **funding** was quickly made available through competitive calls in the ongoing EU research framework programme Horizon2020 to support clinical research (but not for primary care…).
- Because we had established structures and procedures before the pandemic started to facilitate a rapid, large scale clinical research response in the event of a pandemic, we were able to **rapidly deploy** observational and interventional studies in March – April 2020 in the RECOVER project (= Mode 3).

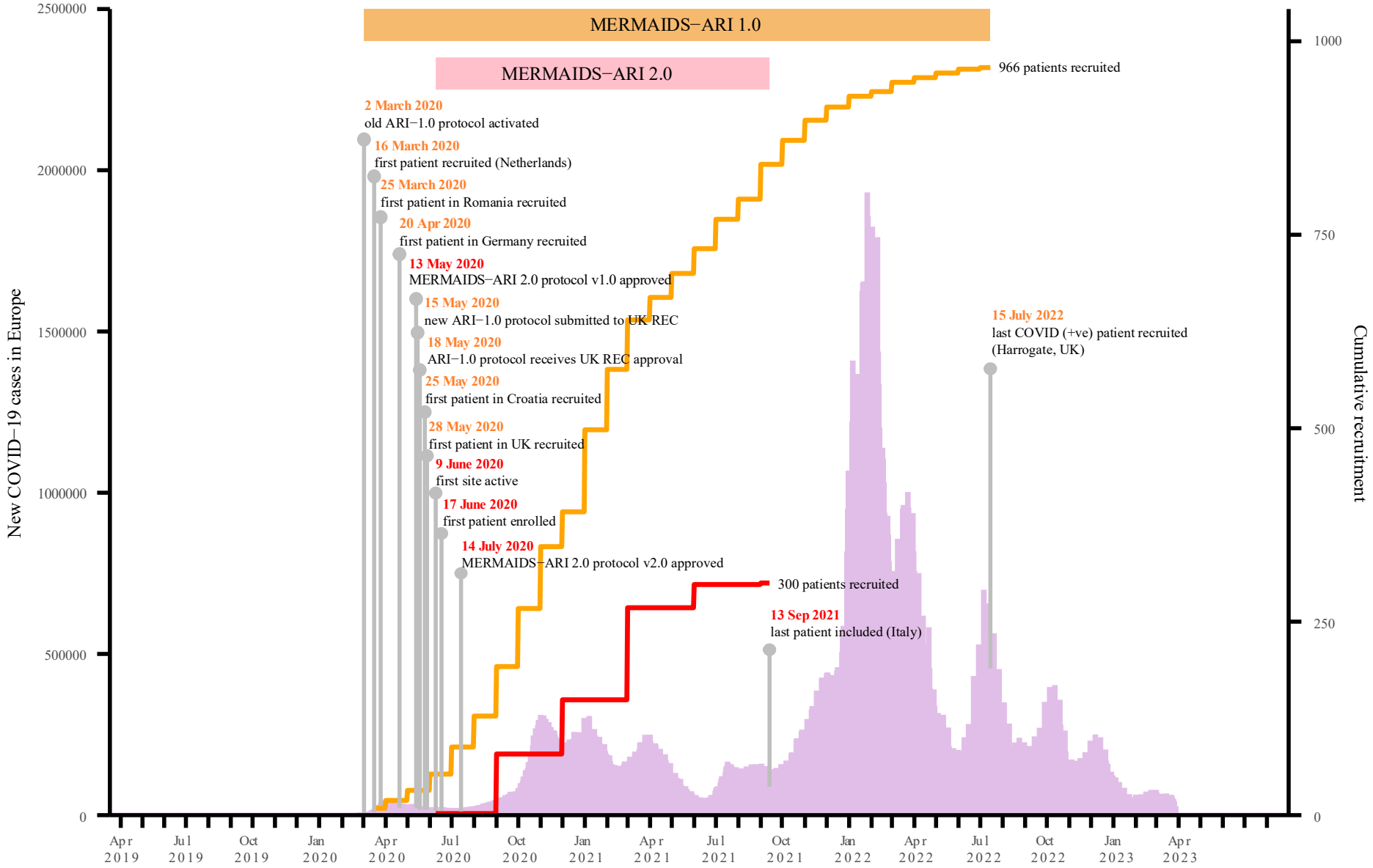
PREPARE Outbreak Response Modes activation



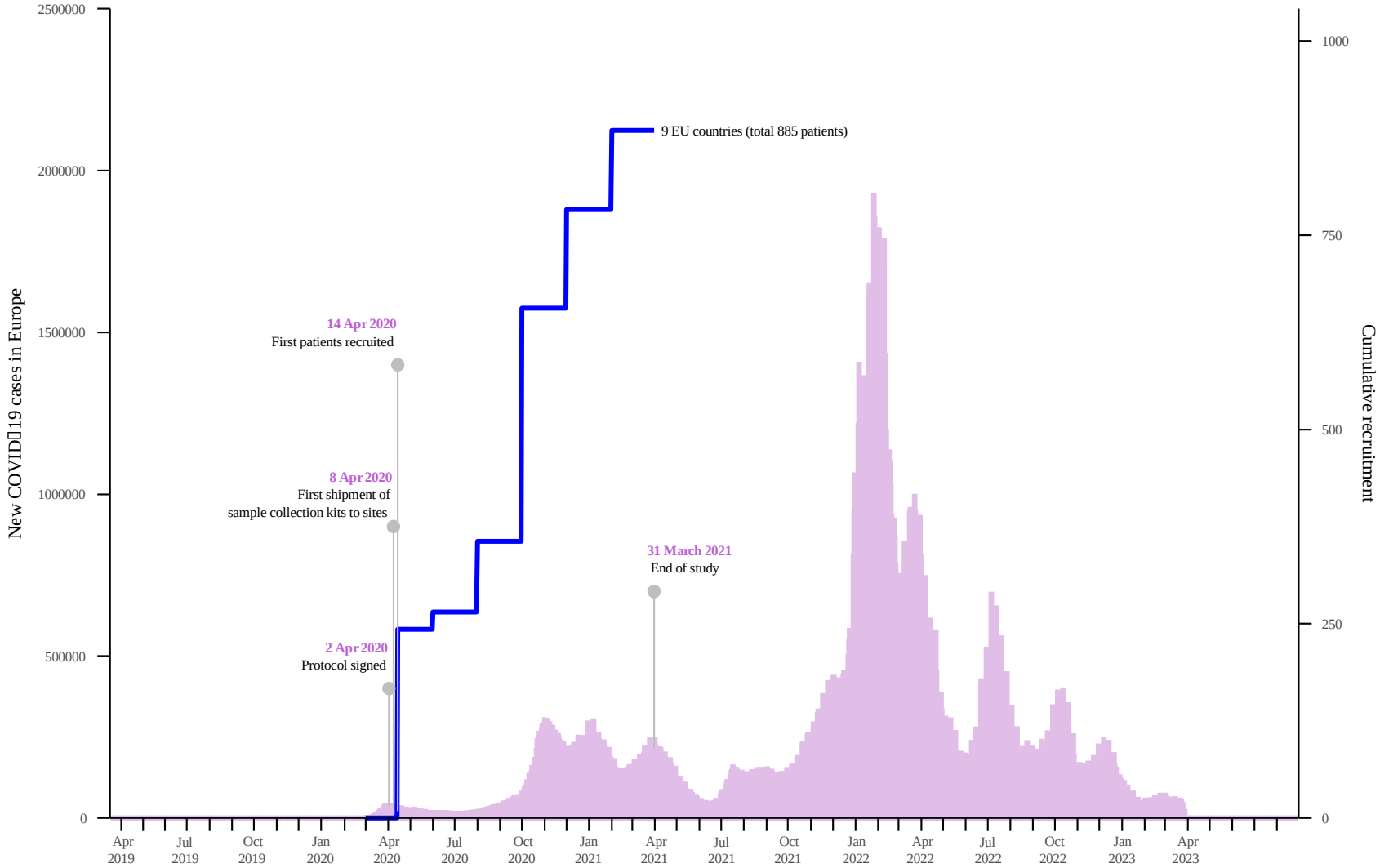
Can we start clinical trials in 15 days? Yes!

- **Targets:**
  - Observational studies: < 5 days without sampling; < 10 days with sampling
  - Interventional trials: < 30 days
- **Two observational studies:**
  - MERMAIDS: 13 days after Mode 3 activation (reactivation of protocol)
  - SOS-COVID: 42 after Mode 3 activation (new protocol)
- **One adaptive platform trial:**
  - Six days after Mode 3 activation (existing protocol)

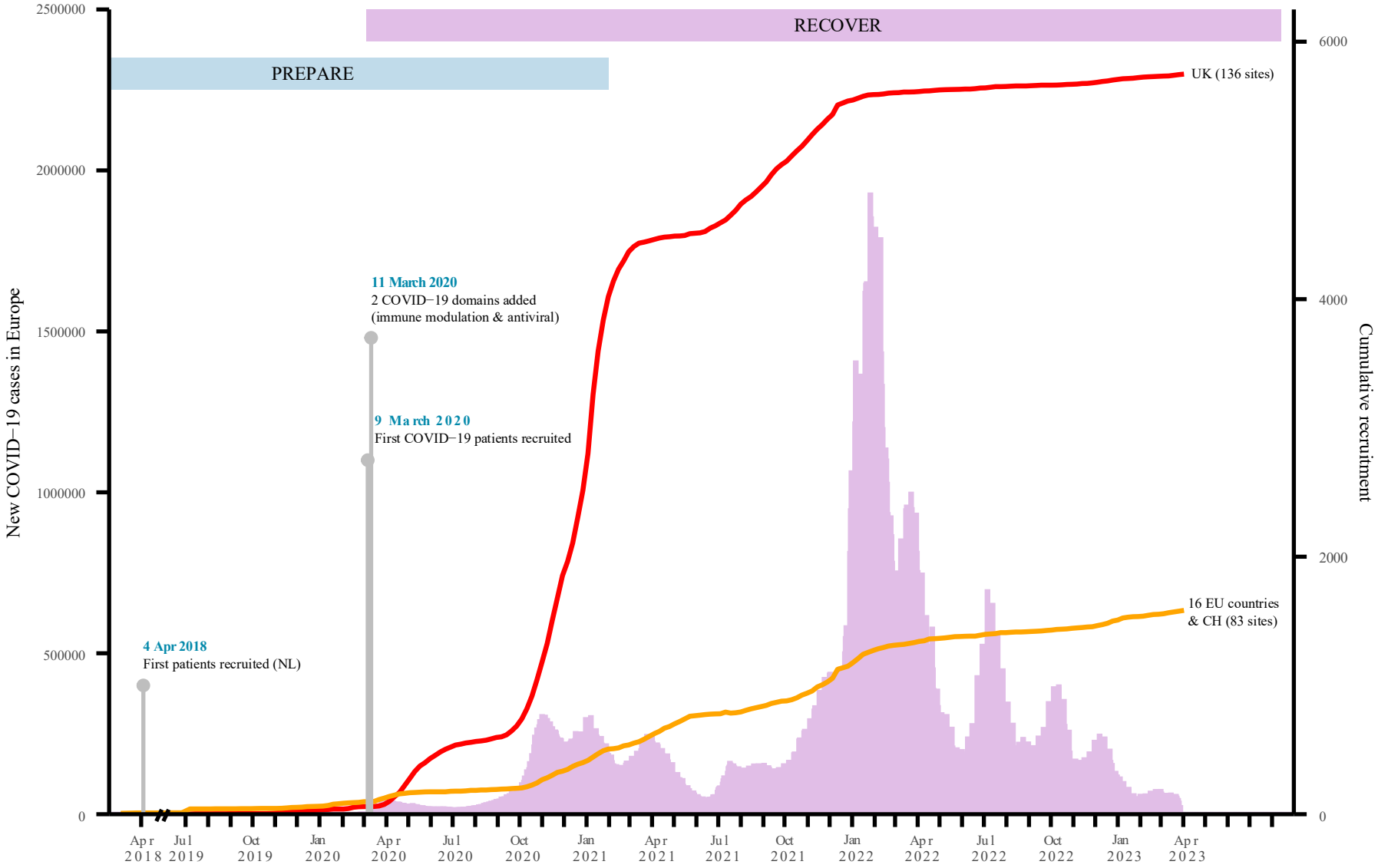
MERMAIDS−ARI 1.0 and 2.0



SOS COVID study



REMAP−CAP study



The clinical research response after April 2020: **FRUSTRATING!**

- Shortage of clinical workforce for conducting clinical studies and therefore many sites not interested to participate in clinical studies.
- Huge competition with many national studies, some of them supported by national research funding, and international studies (e.g. WHO).
- EU research programmes were disconnected from clinical research funding of Member States.
- Lack of consensus across Member States on clinical research priorities.
- Massive concentration of clinical research efforts and funding for drugs that received a lot of media attention.
- Large differences in approval times of Institutional Review Boards (IRB) and site contracts between EU countries.
- Fundamental issues inherent to the clinical research ecosystem resurfaced during the pandemic (e.g. public health and clinical research are siloed)
- Hence, most of these clinical trials failed to deliver solid conclusions.

Why I was extremely frustrated in April 2020

- I had been naive.
- Ignored the role of WHO.
- Forgot to reach out to Member States.
- Realised that this can only work with top-down (e.g. political) support.

Recommendations towards building a European clinical trial ecosystem to respond to health emergencies

- Create **top-down** structures and partnership that facilitate prioritization of clinical research.
- This partnership requires a comprehensive strategy, dedicated leadership, and **political commitment** of ministers of health and research.
- The pharmaceutical and biotechnology **industry** should be connected to this partnership.
- Develop a **mechanism** to rapidly leverage pandemic funding and to liaise EU funding with national funding.
- **Invest during "peace-time"** in clinical trial networks, platform trials and master protocols.
- The European clinical research response should be **harmonized** with the global response.

Goossens et al, Lancet Infect Dis, December 2021

Developing a partnership to improve coordination of funding and prioritisation of publicly funded clinical research and trials for infectious diseases in Europe.

A collaboration between ECRAID-Base, BE READY and ERA4Health

Supported by the Belgian EU Presidency, Ecraid Foundation, ECRIN, EWI, Global AMR Hub, GLoPID-R, INSERM, ItaCRIN, JPIAMR/OHAMR, Belgian Healthcare Knowledge Centre

Goals

- Building and maintaining a **database** of all clinical research institutions and organisations funding clinical research and trials for infectious diseases in Europe.
- Conducting a **survey** of publicly funded clinical trials in Europe during the COVID-19 pandemic.
- Developing a **mechanism** to improve coordination of funding across national and European public funding institutions and organisations of clinical research and trials for infectious diseases, embedded in global funding, and prioritization of clinical research as new health problems emerge.

Timing

- **May – June 2023**: Agreeing on the role of partners and projects in the Steering Group and the two ad hoc supporting Groups (building database and survey).
- **June or July 2023**: Kick-off meeting of the Steering Group.
- **July – September 2023**: Preparation and piloting of the questionnaire; identification of the funding institutions and organisations.
- **October – December 2023**: Survey (document analysis and interviews).
- **January – April 2024**: Analysis, developing one or several options for a mechanism for coordination of funding and prioritisation of clinical research and trials for infectious diseases.
- **14 and 15 May 2024**: Belgian EU Presidency event.
- **June 2024:** Reporting; Publication in a leading medical journal.
- **Next steps**: Website; Update the database; Rehearse and operationalize the mechanism by organizing workshops with hypothetical pandemics scenarios; Develop an implementation tool of the WHA Resolution on "Strengthening clinical trials to provide high-quality evidence and to improve research quality and coordination" (WHA75.8)

Next steps

- **Align** our initiative with the initiatives and vision of the EC.
- Bring **patient representatives** on board and discuss the role of the **private sector**.
- **Finalise** the proposal and role of the partners.
- Plan a **first meeting** with the Steering group (agenda: approval of the proposal; agree on frequency and dates of meetings; establish ad hoc groups; ...).

Conclusion

- The European clinical research response during the initial phase of the pandemic **failed.**
- The European clinical trial ecosystem is as **fragmented** as before the pandemic (or even more…).
- We will **fail** again with the next pandemic.
- Now, it is the **time to learn** and build a stronger Europe.
- Now it is the **time to forge** a partnership among countries, research institutions and organisations.
- **Political will** is required to facilitate change in the culture of clinical research and building these partnerships.

If we don’t collaborate, we will fail and stand accused of having turned our back on the prospect of tackling pandemic infectious diseases, and effective investigations and treatments of infections for our citizens.

“You may say I’m a dreamer, but I’m not the only one
I hope someday you’ll join us”

Imagine, John Lennon.