

# CLINICAL TRIAL COORDINATION MECHANISM FOR BETTER HEALTH CRISIS PREPAREDNESS AND RESPONSE

Cornelius Schmaltz, Head of Unit “Intelligence Gathering, Analysis and Innovation” European Commission, HERA

Workshop towards the Coordination of Publicly Funded Clinical Studies and Trials on Infectious Diseases during Outbreaks

14/15 May 2024

- ❖ One of the key lessons learned from the COVID-19 pandemic was the **lack of a coordinated clinical trials infrastructure at EU level** that could have been activated early on.
- ❖ **The bottlenecks that hamper a swift set up of clinical trials** during public health emergencies were well identified at the onset of the Mpox outbreak.
- ❖ **Nevertheless**, the set-up of clinical trials was significantly delayed.

**Need for improved coordination of appropriate clinical trial networks readiness and response and streamlined funding mechanisms for clinical trials**, to swiftly activate multi-national, large-scale trials that generate meaningful data.



**ESTABLISHMENT OF SUB-GROUP OF HERA BOARD TO ADVISE  
ON THE PRIORITISATION OF CLINICAL TRIALS AND THEIR FUNDING FOR PUBLIC HEALTH EMERGENCIES**

**Mission:** To strengthen crisis preparedness and response of clinical trials



IMPROVED COORDINATION ACROSS MEMBER STATES



RANKING OF  
PRODUCTS

**Identification and  
prioritisation of product  
profiles and/or investigational  
medicinal products targeting  
high-priority threat**



WARM-BASED  
NETWORKS

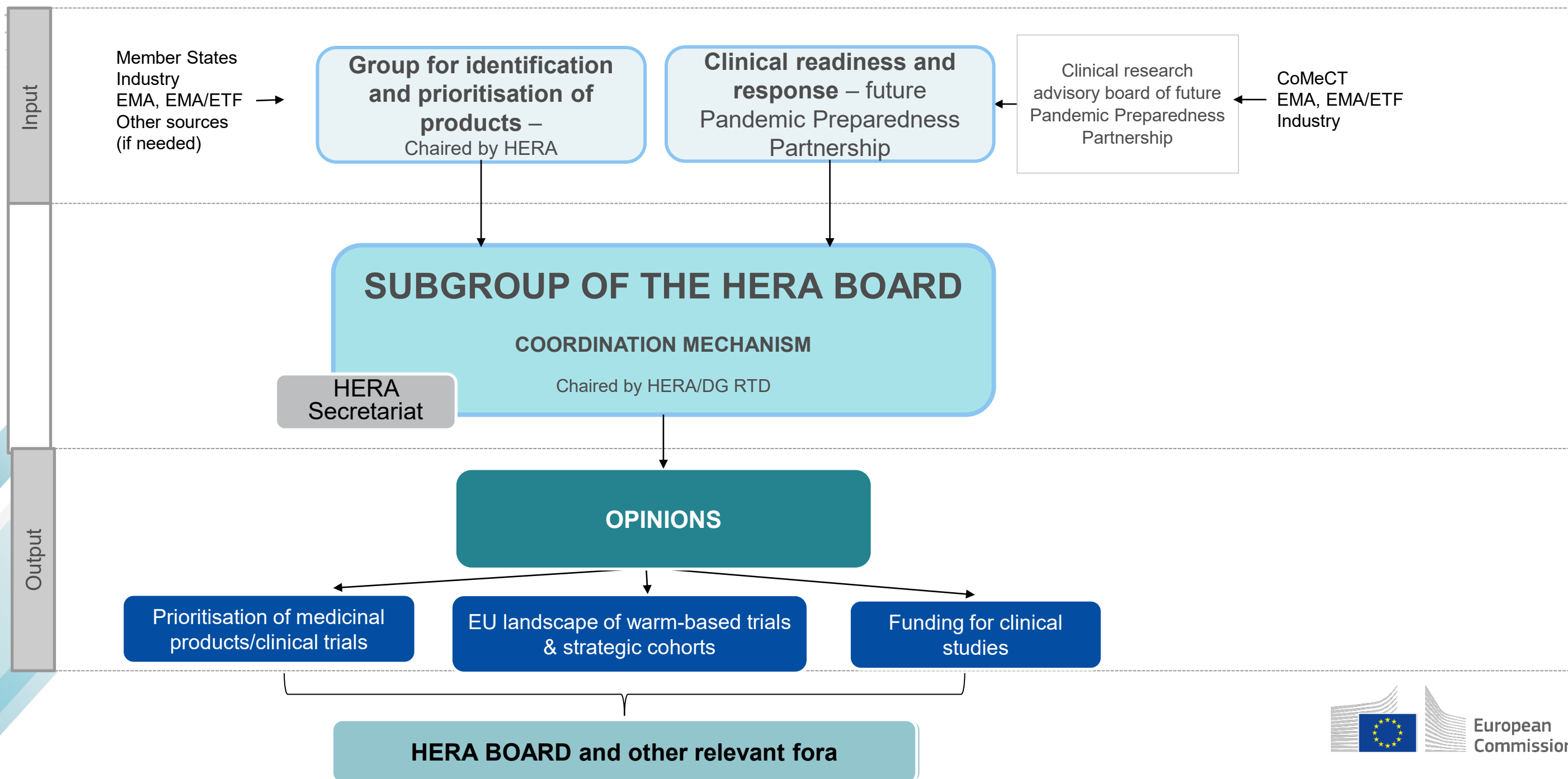
**Creation/Maintenance of an  
appropriate landscape of  
perpetual/warm-based trials  
and strategic cohorts in the  
EU**



FUNDING

**Fostering alignment of funding  
options between EU and  
national funding to support the  
prioritised product profiles and/or  
investigational medicinal products**

# HERA BOARD SUBGROUP FUNCTIONING



# COMPOSITION OF THE SUB-GROUP

(preliminary )

**HERA**  
#HealthUnion

- **Chairs:** HERA/DG RTD
  
- **Members:** Member States will be invited to nominate **Member State representatives**
  - Balanced composition in terms of regulatory expertise for medicinal products as well as representation of national health and research authorities.
  - Envisaging the establishment of the future pandemic preparedness partnership, the Commission recommends that several of the HERA subgroup members will equally be a member of that Partnership to ensure full complementarity
  
- **Invited Experts:** Experts with specific expertise with respect to a subject matter on the agenda may be invited to participate in the work on ad hoc basis
  
- **Observers:** (i) A representatives from EMA, ECDC and HaDEA (ii) representatives from other Union decentralized and executive agencies may participate upon invitation of the chairs

# TWO WORKSTREAMS SUPPORTING THE HERA BOARD SUBGROUP

The Sub-group will develop opinions based on the input provided from **two workstreams**:

- I. A **working group on the identification and prioritisation** of relevant medicinal products
- II. The **Pandemic Preparedness Partnership** will support an optimal clinical trial readiness and response in the EU



# I. WORKING GROUP IDENTIFICATION & PRIORITISATION HERA

(Preliminary) #HealthUnion

## Composition

**Chair:** HERA

**Participants:**

- Member States
- Scientific experts
- EMA and Commission services

**Ad hoc participation upon invitation:**

- Industrial Stakeholders

## Tasks

- Develop a methodology for the identification and prioritisation of medicinal products
- Adequately map pipeline or available medicinal products starting in phase I.
- Prioritise the medicinal products applying the methodology developed under task (i)

## Working Procedures

- Regular meetings
- Ad hoc workshops with broader audience

# II. PANDEMIC PREPAREDNESS PARTNERSHIP

- **GOAL:** Enable coordination of research for pandemic preparedness and response in the EU.
- Horizon Europe Work Programme 2024 Topic: HORIZON-TH2024-DISEASE-12-01.
- Opening 25<sup>th</sup> of April - Deadline 26<sup>th</sup> of November 2024.
- Co-Fund action. Expected EU contribution 50 million Euros.

## Expected outcomes

Comprehensive Knowledge Framework to improve transnational research in pandemic preparedness and response.

Evidence-based strategies and policies on pandemic preparedness and respond for Health Authorities.

Strengthen of the EU as an internationally recognised actor in pandemic preparedness research and response contributing to global cooperation and coordination.

### Network of clinical trial sites

Coordinated large-scale multi-country clinical trials, able to transition to public health interventions under cross border health threats and respond to public health emergency.



**HERA SUBGROUP  
CLINICAL TRIAL  
COORDINATION  
MECHANISM**



# OVERVIEW OF POTENTIAL FUNDING MECHANISMS

(NON-COMPREHENSIVE)

<b>Preparedness</b>	Support for limited number of selected multi-national preparedness trials and cohorts	Horizon Europe, EU4Health, HERA Invest, industry, national funds
	Setting up and/or maintaining clinical trial networks infrastructure <ul style="list-style-type: none"><li>• Trial sites capacity</li><li>• Coordination between trials, including training to ensure the sites are up to date</li></ul>	Horizon Europe, National funds (via Pandemic Preparedness Partnership) and/or drawn from the EU cohesion funds; EU funds for coherence and harmonisation across sites
<b>Public Health Emergency</b>	Emergency trials	ESI, complemented by other national and/or EU funding sources

- **Nomination letters for HERA Board sub-group** to be sent out to Member States in the **week of 20th May**
- **Kick-off meeting of the HERA Board sub-group** end of June
- **Launch of the working group** for identification/prioritisation in **July/August**

# Thank you!

In case of questions/comments, please send an email to:  
[HERA.02@ec.europa.eu](mailto:HERA.02@ec.europa.eu)