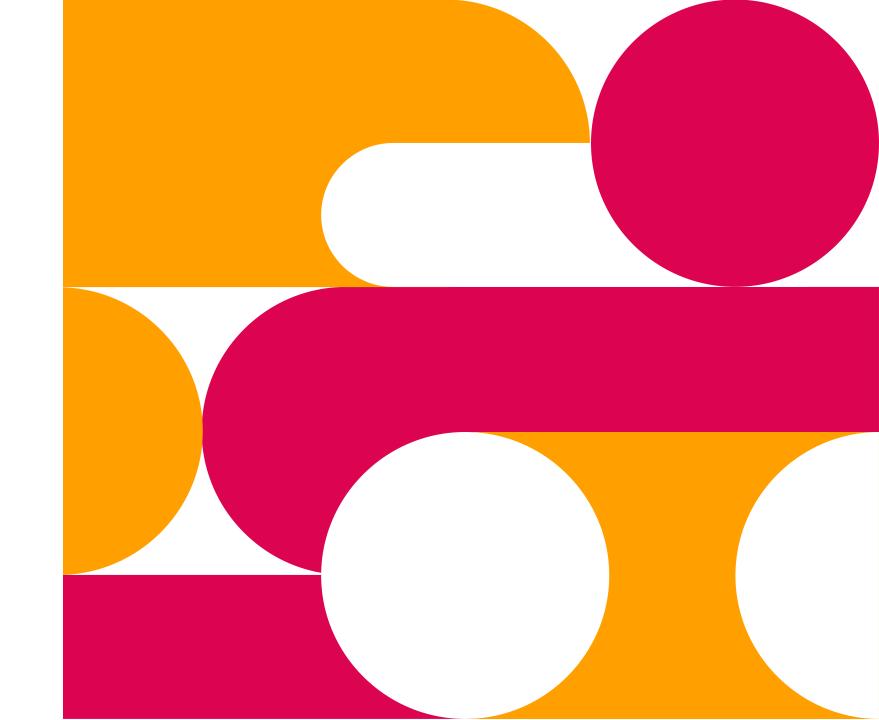


Presentation of the CSA Be Ready

Lessons-learned workshop on Clinical Trials in emergencies *EMA, Amsterdam 9th June 2023*



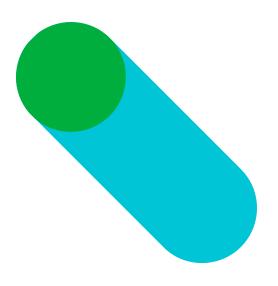




Title and Acronym:

Building a European strategic REsearch and innovation AREA in Direct sinergY with other eu-international initiatives for Pandemic Preparedness (BE READY)

- <u>TOPIC: "HORIZON-HLTH-2021-DISEASE-04-06: Building a European partnership for pandemic preparedness"</u>
- Budget: 2 Million Euros
- Instrument: Coordination and Support Action (CSA)
- 25 Partners from 15 European and Associated countries
- General coordination by ANRS | Maladies infectieuses émérgentes





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The COVID-19 pandemic illustrated how unilateral research initiatives may lead to a fragmented research landscape, with substantial room for efficiency gains in the development of the highly needed evidence to guide policy actions when facing an emergency.

The European partnership for pandemic preparedness is working to improve the EU's preparedness to predict and respond to emerging infectious health threats by better coordinating funding for research and innovation at EU, national (and regional) level towards common objectives and an agreed Strategic Research and Innovation Agenda.

The Partnership is expected to continue to build on existing pandemic preparedness networks and research infrastructures, and work in synergy with the Health Emergency Preparedness and Response Authority (HERA).

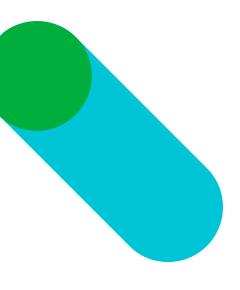


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READY CSA OBJECTIVES

- ENGAGE with all prospective partners of the expected future Partnership to support alignment on its scope, common objectives, governance and ways of working/operationalisation;
- 2. ELABORATE an innovative and visionary Strategic Research and Innovation Agenda for pandemic preparedness ensuring a cross-cutting, interdisciplinary One Health approach
- 3. **CONSOLIDATE** the future European Partnership on Pandemic Preparedness
- 4. ENSURE complementarities, coordination and collaboration with the future HERA
- **5. INVOLVE** relevant stakeholders and initiatives in the area of pandemic preparedness, ensuring collaboration and coordination, and avoiding duplication; e.g. GloPID-R, WHO R&D blueprint, ACT-Accelerator, G7/G20 Health WGs, etc.
- **6. RAISE** awareness of the importance of increased pandemic preparedness both outside and during epidemic/pandemic episodes

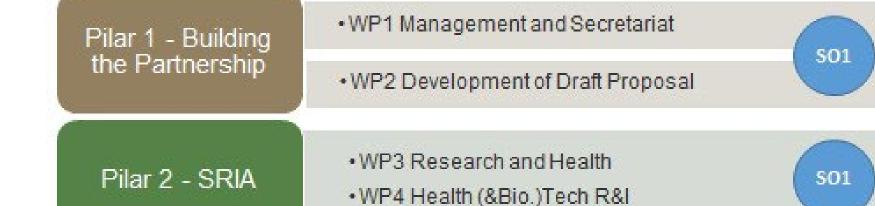




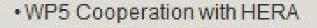


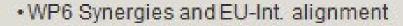


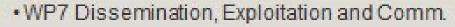
WORK PACKAGE STRUCTURE

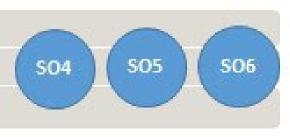












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SO2



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SO6

BE APPROACH TOWARDS THE DEVELOPMENT READY OF THE SRIA

- ☐ It has to be a guideline for research on preparedness
- ☐ The main articulation is around:
 - Prepare and understand
 - Prevent and anticipate
 - Respond and control
- ☐ 2 timeframes:
 - Basic science and applied research in between epidemics: prepare a response to future crises, and to analyse the determining factors of the development and spread of emerging events.
 - Response during the acute crisis phase;







V. RESEARCH AND INNOVATION PRIORITIES AND ACTIONS Identified through lessons learned and a gap analysis

PRIORITY 1: ACCELERATE KNOWLEDGE IN A COORDINATED AND

INTEGRATIVE MANNER

PRIORITY 2: BOOST HEALTH INNOVATION OR EARLY DEVELOPMENT OF

INNOVATION POSSIBLY UP TO HUMAN PROOF OF PRINCIPLE

PRIORITY 3: PREPARE FOR THE MANAGEMENT OF RESEARCH DURING A

CRISIS

PRIORITY 4: REINFORCE INFRASTRUCTURES AND NETWORKS

PRIORITY 5: TRAIN, EDUCATE AND COMMUNICATE ON EMERGING

INFECTIOUS DISEASES





Focus on clinical trial issues

PRIORITY 1: ACCELERATE KNOWLEDGE IN A COORDINATED AND

INTEGRATIVE MANNER

PRIORITY 2: BOOST HEALTH INNOVATION OR EARLY DEVELOPMENT OF

INNOVATION POSSIBLY UP TO HUMAN PROOF OF PRINCIPLE

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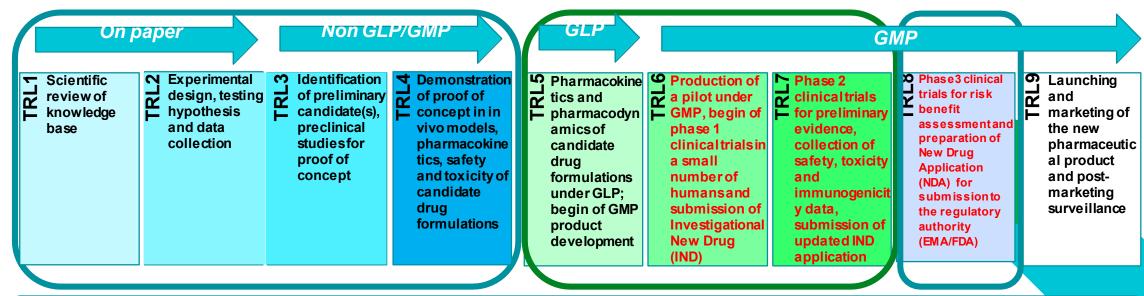




1 - Accelerate knowledge in a coordinated and integrated manner

2 – Boost health innovation

3 - Prepare for the management of research during crisis



4 - Reinforce infrastructure, platforms and networks

5 – Train, educate and communicate and EID





Priority 3: Prepare for the management of research during a crisis

- ☐ Develop standard protocols and procedures easily adaptable at the time of a crisis
- ☐ Participate in the development of harmonized & central regulatory and ethical approval procedures
- □ Participate in the development of flexible framework (can be adapted to an evolving understanding about a disease for which there is poor pre-existing knowledge)
- □ Participate in the development of standardized EUendorsed contract templates

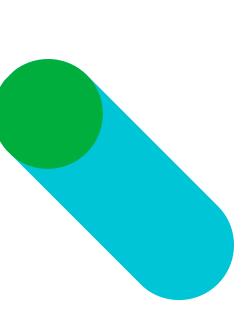






Priority 4: Reinforce infrastructure, platforms and networks

- ☐ Cohorts and clinical platforms can be considered in these categories
- ☐ For an efficient response at the time of a crisis, they have to be created and maintained operational during peaceful time:
 - ☐ First through national funds in the frame of clinical trials
 - ☐ With participation to EU/Int clinical trials
 - ☐ With integration to EU/Int networks
 - □ Over time through support from the partnership on preparedness







AGENDA



- First draft partnership proposal submitted for review
- •Start developing Strategic R&I Agenda

Q1 2023

mid 2023

- Partnership proposal finalised and published
- Draft Strategic R&I agenda presented

• Strategic R&I agenda finalised and adopted including consultation process

mid 2024

2024-2025

 Adoption of the work programme including the calls related to the partnership

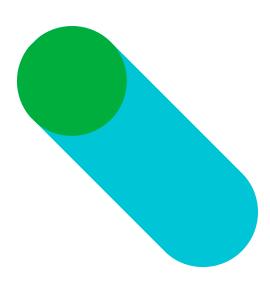






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