Lessons learned workshop on Clinical Trials in Public Health Emergencies

A funder's perspective

Irene Norstedt, Director, DG R&I
9 June, EMA, Amsterdam

Capitalize on lessons learnt from previous epidemics

The Commission's R&I investments during the COVID-19 pandemic built on lessons learnt from Ebola and Zika outbreaks:
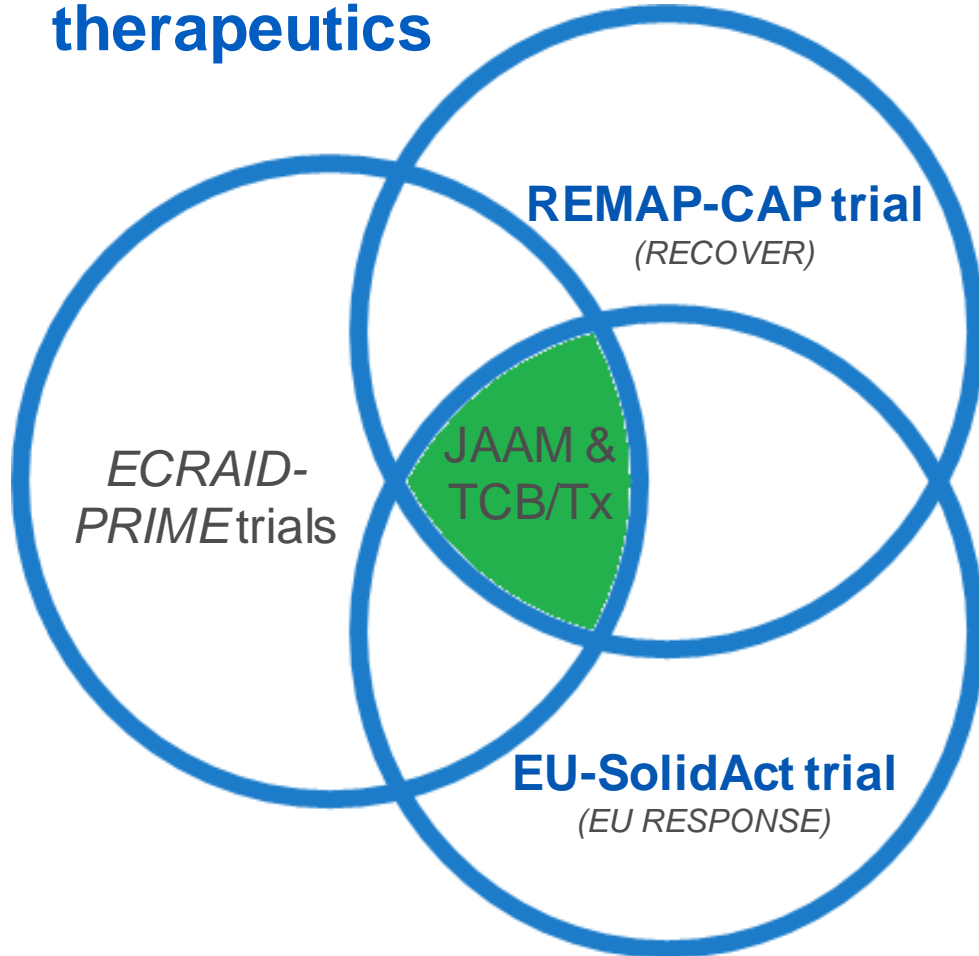
- ERAvsCORONA action plan (April 2020)
- EU Strategy on COVID-19 vaccines (June 2020) & therapeutics (May 2021)
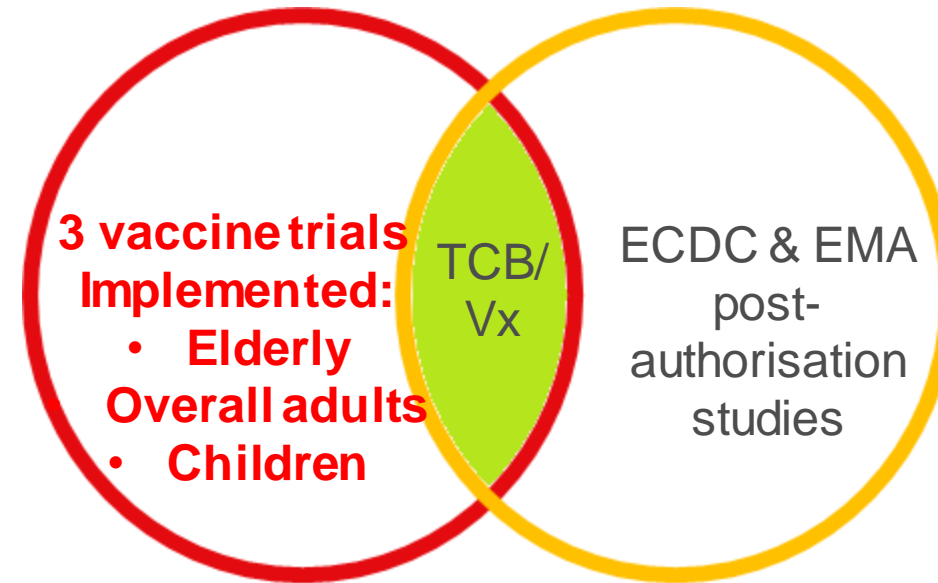
The COVID-19 pandemic:

- confirmed importance of **planning and investing in R&I** before crisis occurs
- displayed the need for **financing tools that can be mobilised rapidly**
- demonstrated the **importance of large-scale multi-centre multi-national clinical trials** to generate robust evidence
- showed the importance of **dialogue and collaboration**

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European networks for clinical trials and coordination mechanisms set up for COVID-19

Network for therapeutics

Network for vaccines « VACCELERATE »

ECRAID-PRIME trials

REMAP-CAP trial
(RECOVER)

JAAM & TCB/Tx

EU-SolidAct trial
(EU RESPONSE)

3 vaccine trials Implemented:
- **Elderly**

Overall adults
- **Children**

TCB/ Vx

ECDC & EMA post-authorisation studies

ecraid

* Trial Coordination Board (TCB) & Joint Access Advisory Mechanism (JAAM)

BE READY CSA

Partnership on Pandemic Preparedness

#ClinicalTrials

Need for EU-wide clinical trial networks within overall trial landscape

Non-preparedness &
non-crisis response related

Preparedness

Crisis Response

Preparedness

- Readiness

Response

- Speed

- Scale

- Funding

- Effective decision making

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Our vision for the future

Pre- and early clinical research

Industry   SME   Academia

**Use of
European Clinical Trial Networks**

**Regulatory authorisation for
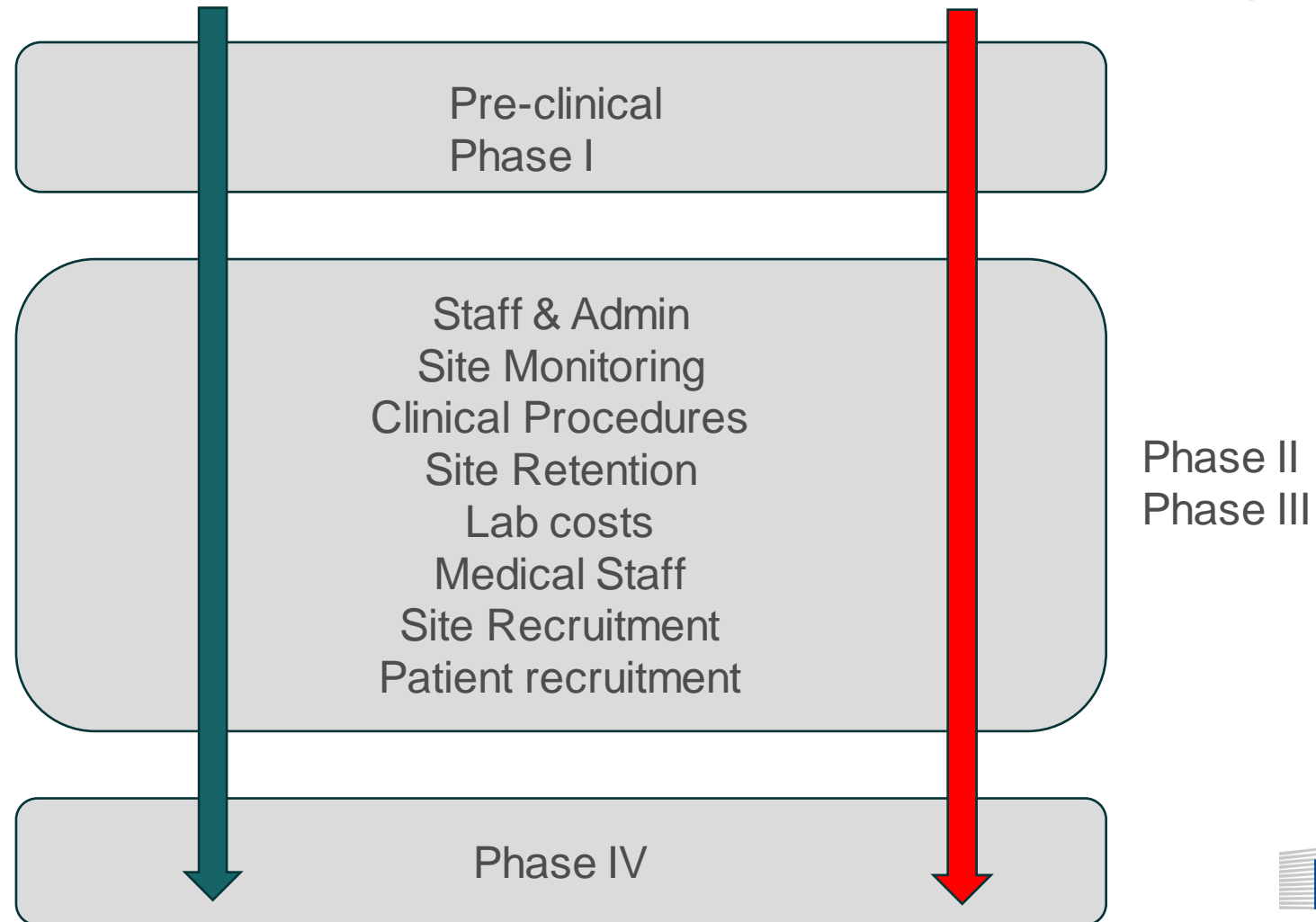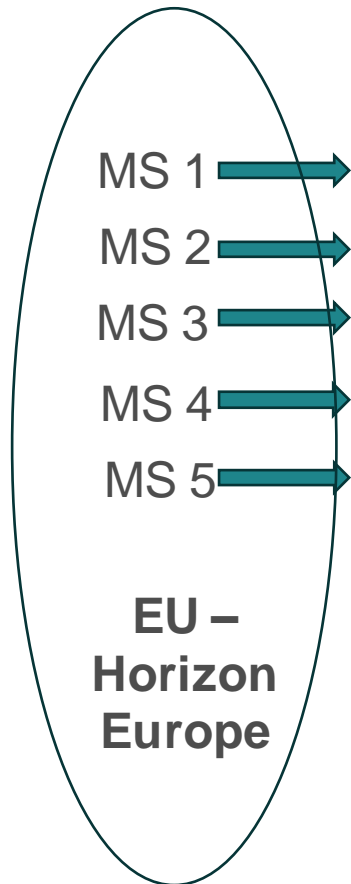diagnostics, treatments and vaccines**

Inform Public Health Policy

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Financing of clinical trial networks – in Preparedness vs Epi/Pandemic times

Preparedness financing

Compound

Emergency financing / ESI

MS 1
MS 2
MS 3
MS 4
MS 5

EU – Horizon Europe

Pre-clinical
Phase I

Staff & Admin
Site Monitoring
Clinical Procedures
Site Retention
Lab costs
Medical Staff
Site Recruitment
Patient recruitment

Phase II
Phase III

Phase IV

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Conclusion

- Commitment to build and sustain strong regional clinical trial networks with benefits beyond public health emergencies

    - Sustain the trial network infrastructure during peace time, effectively coordinate funding from multiple sources (MS, EU, industry)

        ➢ Implement Pandemic Preparedness Partnership

    - Have a quick, effective, and <u>coordinated</u> funding mechanism in place when the pandemic hits (ESI)

- Include science closely in the priority setting and decision making for the response

- Use existing instruments for funding where feasible – and open for new ideas (FP10)

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Thank you

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