

European clinical trial networks for COVID-19

STARS Global Conference: Excellence in Regulatory Science

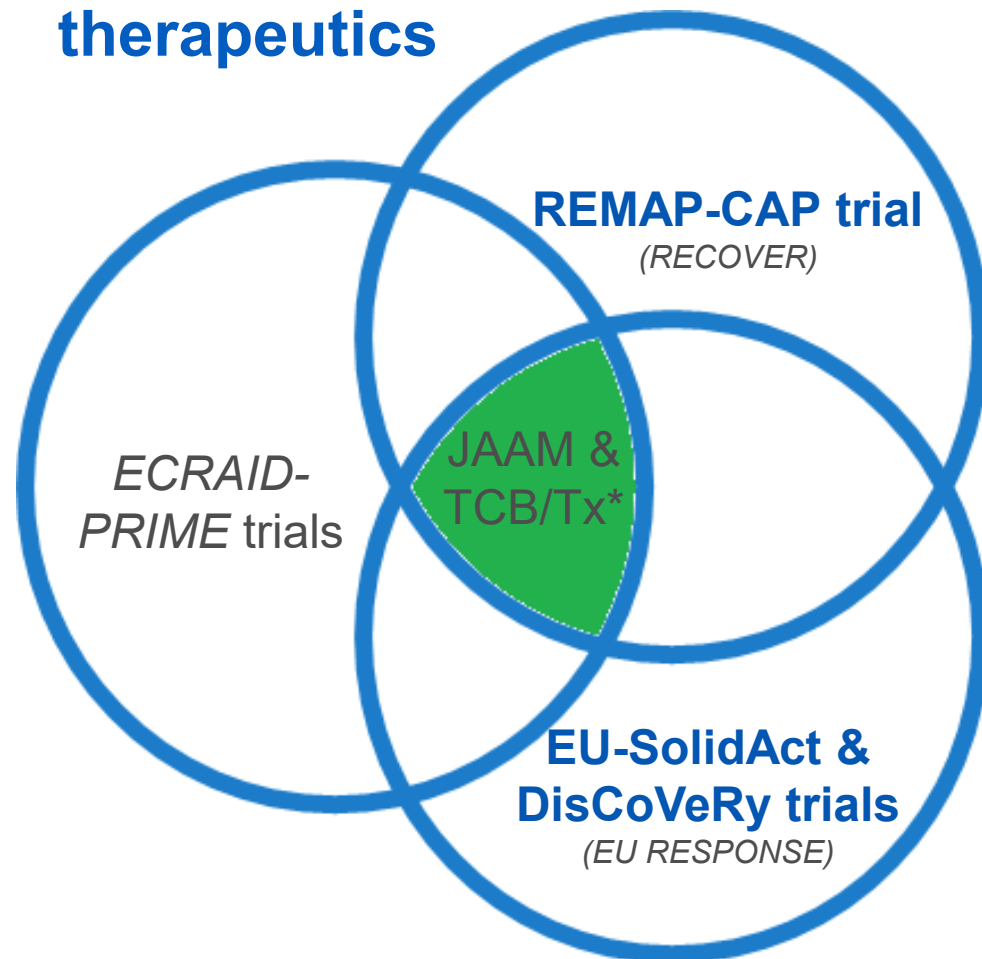
19 May 2022, Evelyn Depoortere, DG R&I/D.1

Background

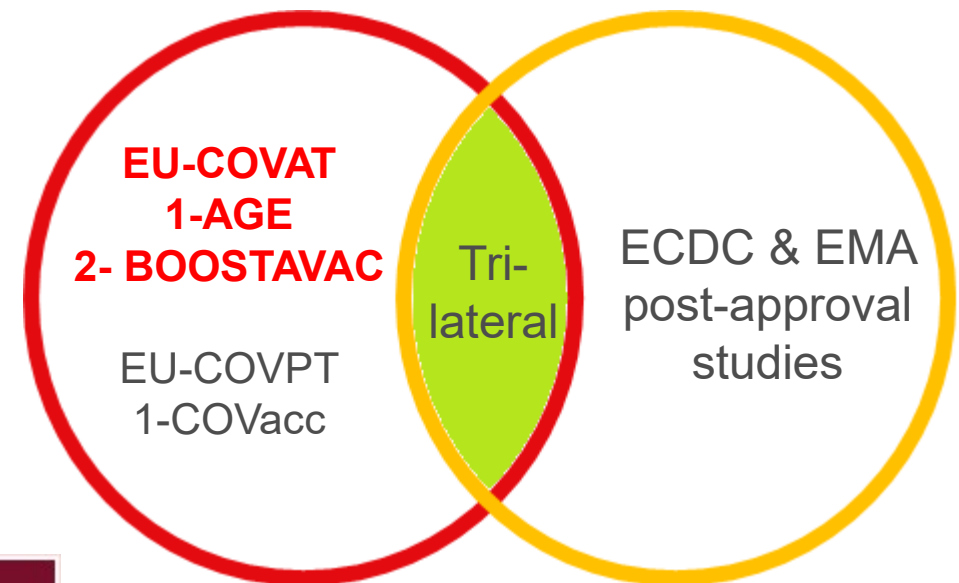
- Observed fragmentation of study initiatives
 - Call by EMA/CHMP to pool resources for large-scale multi-centre, multi-arm clinical trials
- Observed use of potential therapeutics outside of study/trial context
 - No contribution to evidence generation
- [ERAvsCORONA action plan](#)
- EU Strategy on COVID-19 therapeutics
- 2 EU-wide networks for COVID-19 clinical trials: Therapeutics & Vaccines
- Multiple large-scale multi-country cohort studies
- Open Science & FAIR data

European networks for COVID-19 clinical trials

Network for therapeutics



Network for vaccines « VACCELERATE »



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

1. European network for therapeutic trials

- DisCoVeRy trial: <https://eu-response.eu/>

- 50 centres open in 10 countries
- Long-acting antibody combination AZD7442 (AstraZeneca)
- Results on use of Hydroxychloroquine, Lopinavir, Interferon, and Remdesivir



- EU SolidAct trial: <https://eu-response.eu/>

- 55 sites open in 12 countries
- Baricitinib
- Collaboration agreement to study BerGenBio's AXL inhibitor, bemcentinib, signed



- REMAP-CAP trial: <https://www.remapcap.eu>

- 31 interventions in 11 domains
- >6600 COVID-19 patients, 215 active sites in Europe
- Important conclusion for treatment options, e.g. Tocilizumab, therapeutic anticoagulation



2. European network for vaccine trials

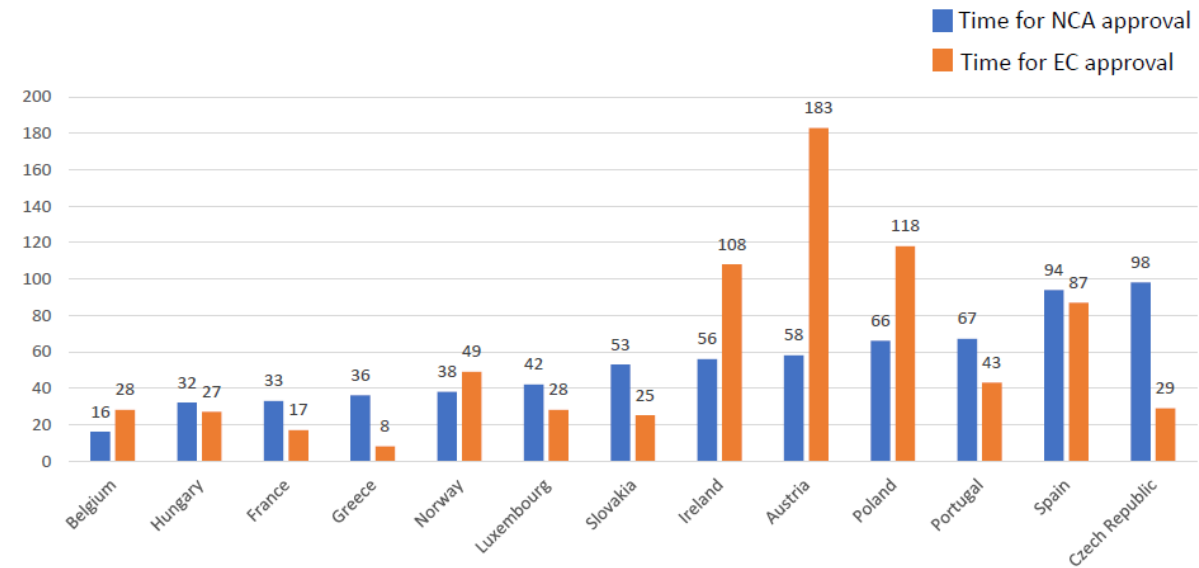


- EU-COVAT-1 AGE trial
 - Ph II, immunogenicity and reactogenicity of 2nd booster (homo- & heterologous) in >75y
 - Started Nov 2021, in DE – Aim for 20 sites in 7 countries
- EU-COVAT-2 BOOSTAVAC trial
 - Ph II, need and optimal timing of 4th homologous mRNA vaccination dose, adults
 - Started Mar 2022, in IE – Aim for 26 sites in 8 countries
- EU-COVPT-1 COVacc trial
 - Ph II, impact of reduced vaccination regimen in pediatric population with prior immunity

Challenges

- Regulatory & ethics
 - Long review cycles
 - Complex trial design
 - Quality of proposals, regulatory compliance, completeness

→ Importance of early engagement with regulatory bodies !
- Legal & administrative
 - Clinical site contracts
- Financial
 - Academic trial infrastructures



Challenges (Ctd.)

Perspectives from research community

- Accelerating clinical trial implementation in the context of the COVID-19 pandemic: challenges, lessons learned and recommendations from DisCoVeRy and the EU-SolidAct EU response group. <https://doi.org/10.1016/j.cmi.2021.10.011>
 - EC reply: <https://doi.org/10.1016/j.cmi.2021.12.027>
- The European clinical research response to optimise treatment of patients with COVID-19: lessons learned, future perspective and recommendations. [https://doi.org/10.1016/S1473-3099\(21\)00705-2](https://doi.org/10.1016/S1473-3099(21)00705-2)
 - EC reply (1): [10.1016/S1473-3099\(22\)00059-7](https://doi.org/10.1016/S1473-3099(22)00059-7)
 - EC reply (2): [10.1016/S1473-3099\(22\)00061-5](https://doi.org/10.1016/S1473-3099(22)00061-5)

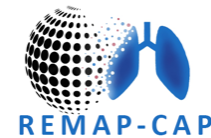
Thank you



REMAP-CAP trial: [Homepage - REMAPCAP](#)

EU-SolidAct and DisCoVeRy trial: <https://eu-response.eu/>

VACCELERATE: [Vaccelerate.EU](#)



VACCELERATE

