

# Coordination of Adaptive Platform Trials – the TCB

Coordination in crisis 2020-2023

09.06.2023



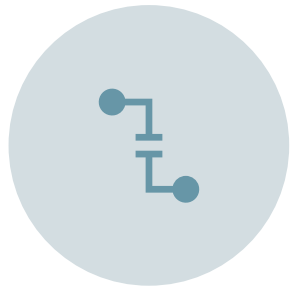
# Research challenges during the pandemic



The Covid-19 crisis unmasked vulnerabilities in many aspects of society, including health systems and the clinical trial landscape



Evident that more knowledge was required to understand virus properties, transmissibility, and the interventions needed to counteract the virus



Hundreds of clinical trials were started, efforts often underpowered, duplicating and fragmented



The momentum promoted transition in the research landscape by enforcing collaboration and harmonization through coordination



SOLID-ACT (WP2)

DISCOVERY  
(WP1)

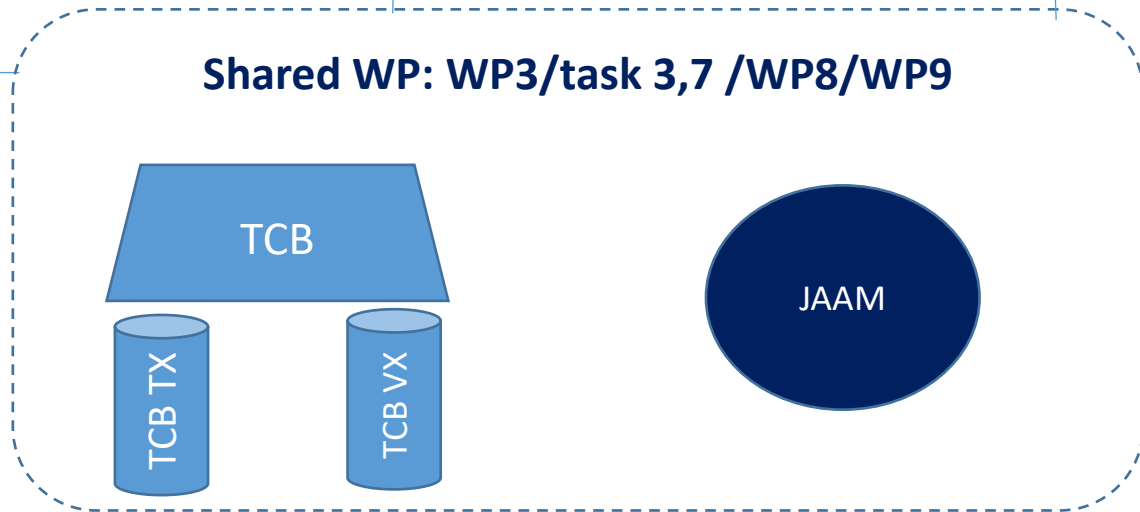
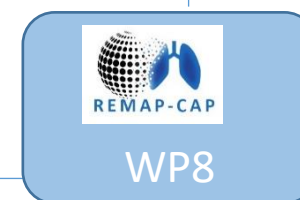
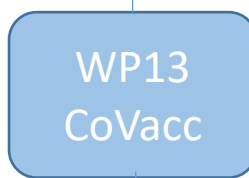
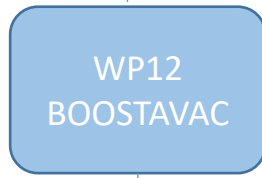
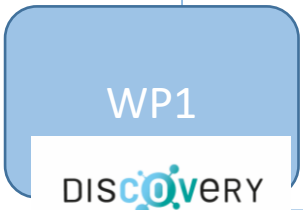
REMAP-CAP  
(WP8)

WP1-WP7

VWG

WP3/WP9  
Trial Coordination Board  
JAAM





# Composition TCB- Core

CORE TCB		
NIPH		<b>John-Arne Røttingen (chair)</b>
NIPH		Victoria C. Simensen
NIPH		Øyvind Melien
ECRIN		<b>Jacques Demotes (co-chair)</b>
ECRIN		Sareema Javaid
EU Commission		Evelyn Depoortere, Stefanie Sowinski
EU Commission HERA		Ulla Narhi, Corinna Hartung
EU-RESPONSE		Yazdan Yazdanpanah
RECOVER		
ECRAID-Prime		Chris Butler
VACCELERATE		
MPX- RESPONSE		Yazdan Yazdanpanah

# Composition TCB - Tx









## EU FUNDED PARTNERS

Discovery/SolidAct		Dominique Costagliola
SolidAct		Marius Trøseid, Inge C. Olsen
REMAP-CAP		M.J.M. Bonten
REMAP-CAP		Lennie Derde
ECRAID-PRIME		Chris Butler

## EUROPEAN AND GLOBAL PARTNERS

Recovery		 Randomised Evaluation of COVID-19 Therapy	Peter Horby
Principle		 Platform Randomised trial of Interventions against COVID-19 in older people	Chris Butler
PANORAMIC		 Platform Adaptive trial of NOvel antivirals for eArly treatment of COVID-19 in the Community	Paul Little
AMMURAVID→MANTICO-2			Evelina Tacconelli
ACTIV-3, TICO→STRIVE		 ACTIV INSIGHT018	Jens Lundgren
ANTICOV (DnDI)			Nathalie Strub-Wourgaft

# COMPOSITION TCB- Vx

CORE TCB		
EU (FUNDED) PARTNERS		
EU-COVAT-1_AGED		Oliver Cornely
EU-COVAT-2 BOOSTAVAC		Patrick Mallon
EU-COVPT-1 COVACC		Patricia Bruijning-Verhagen
EUROPEAN and GLOBAL PARTNERS		
COMCOV, COMCOV-2		Mahesi Ramasay
COMCOV-3		Angela Minsassian
COV-BOOST		Saul Faust
COVERALL		Heiner Bucher
MVA-SARS2-ST		Marylyn de Addo
COVIMMUNAGE		Elisabeth Botelho-Nevers
CAR-CF		Silke van Koningsbruggen-Rietschel
Recovac		Jan-Stephan Sanders
MonkeyVax		Liem Binh Luong

# Trial Coordination Board



EXTENDED TCB		
POLICYMAKERS		
WHO HQ (Science Division)		Vasee Morthy
ECDC		Howard Needham
CEPI		Bola Jones/Jakob Cramer/Christof Vinnemeier
Therapeutics Accelerator (Wellcome/Gates)		Nick Cammack
REGULATORS / ETHICS REPRESENTATIVES		
EUnetHTA		Claudia Wild
EMA		Marco Cavaleri/Eugenia Di Meo
CTFG		Ann Marie Janson Lang
EUREC		Jacob Hølen/Elin Westerheim
INDUSTRY		
EFPIA/VACCINES EUROPE		Magda Chlebus
OTHER INITIATIVES		
Trial Forge		Shaun Treewek
EU Pearl		Cecile Spiertz





**Design** (EU RESPONSE, EMA, EU-Pearl dialogue, harmonizing severity scales, MPX consortium dialogue and collaboration)



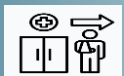
**Conduct** (seeking timely multicounty regulatory and ethical approval in crisis- VHP+ and CTIS)



**Results** (inspire meta-analysis, discuss specifics such as antigen status when receiving immunomodulating drugs)



**Subpopulations** (pregnant, children, immunocompromised)



**Outpatient trials** (e.g Ecrad-Prime, network and capacity building, logistics and funding)



**Standardization** (data collection and laboratory measurements)



**Guidelines** (alignment with the guideline landscape - harmonise with WHO etc)



**Follow-up** (long-Covid, system complications vaccine immunogenicity and safety effects)

2020

2021

2022

2023

# TCB's facilitator role (2023)

- The TCB works to increase Europe's attractiveness as a research base, and to promote partnership with other continents
- Introduce synergistic initiatives in Europe; (GloPiD-R, EU-Pearl, TrialForge, WHO working group on community engagement, EMA stakeholder working group, Pandemic Sciences Institute, ANRS-MIE); how can these initiatives be exploited by trial networks
- Harness the sustained engagement between the trial networks and priorities of the Commission (incl. RTD, SANTE, HERA)
- Expand on dialogue with WHO science division has taken an interest in the TCB- explore feasibility of global collaboration, can similar coordination efforts be of interest in other regions and for other diseases?
- Work in synergy with a strained health system, and facilitate for better access for all patients

# SWOT analysis for the TCB

## STRENGTHS

- **A relevant and trusted forum** during the Covid-19 pandemic
- Endorsed by investigators and stakeholders
- Succeeded in lifting the notion that **the research community is stronger together**

## WEAKNESSES

- Declining attendance
- Vx pillar established after results from Covid-19 vaccine (industry based) trials had emerged
- Absence of firm power for proactive coordination

SWOT

## OPPORTUNITIES

- To **explore the boundaries of coordination**- what can be steered as compared to «nudged»?
- Decision power?
- How can **prospective coordination** be elevated?
- Include and involve **Eastern Europe**
- Facilitate **public-private initiatives**

## THREATS

- Low interest outside of pandemics
- "Nationalism" in research
- Lack of funding
- Lack of sustainability

# Expanding Coordination

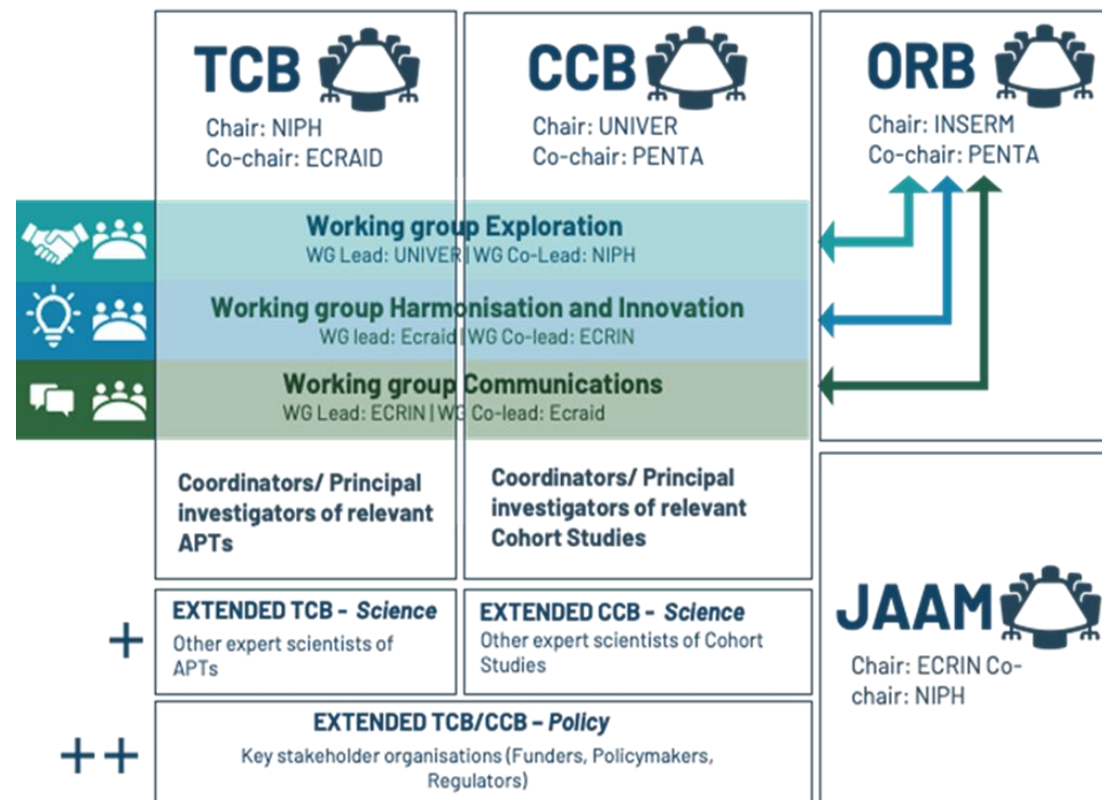
What we have vs what we need – defining the ideal

- *Established coordination (the TCB/JAAM)*
- Trust, dialogue, recognition, flexibility, neutrality
- Served a purpose during the Covid-19 pandemic gathering researchers across countries
- Showcased importance of living coordination and involving stakeholders
- Access to an independent expert panel (JAAM)
- Exploiting soft power

- *Accelerated coordination*
- *Prospective coordination - requires available prioritization and funding mechanism for Europe and sustained infrastructure for inter-pandemic phase*
- *Requires ability to select countries/sites and scope/questions when reacting to outbreak/crisis*
- *Have the authority to advice the set-up of new trials and trial arms*
- *Structured decision-making models and feedback loops*
- *Sustained and sufficient funding for mapping, visualization, data harmonization etc.*

# CoMeCT- Coordination Mechanism for Cohorts and Trials

- **HORIZON-HLTH-2023-DISEASE-03-05: Pandemic preparedness and response: Sustaining established coordination mechanisms for European adaptive platform trials and/or for cohort n**
- Coordinator: NIPH, Partners Ecrin, Ecraid, U Verona (CCB), INSERM, Penta, U Cologne
- Total available funding: 3 mill Euro
- Will expand the work of the TCB and CCB into a common Coordination Board (and include an Outbreak Response Board)
- Strengthen the JAAM
- Include working groups on harmonization, communication and exploration
- Will promote synergies with other preparedness initiatives in Europe and beyond
- Could provide input and support to a formal EC and MS led Coordinating and Financing mechanism





Thank you!

The TCB is established as part of a shared work package between the EU funded projects **EU-RESPONSE** (GA n° 101015736), **RECOVER** (GA n° 101003589), **ECRAID-Prime** (GA n° 101046109) and **VACCELERATE** (GA n° 101037867), and is a beneficiary in the **MPX RESPONSE** project (GA n° 101115188). All projects have received funding from the European Union's Horizon research and innovation programme.