

# CoMeCT

COordination MEchanism for Cohorts and Trials

**CSA Horizon HLTH program, 2024-2027**

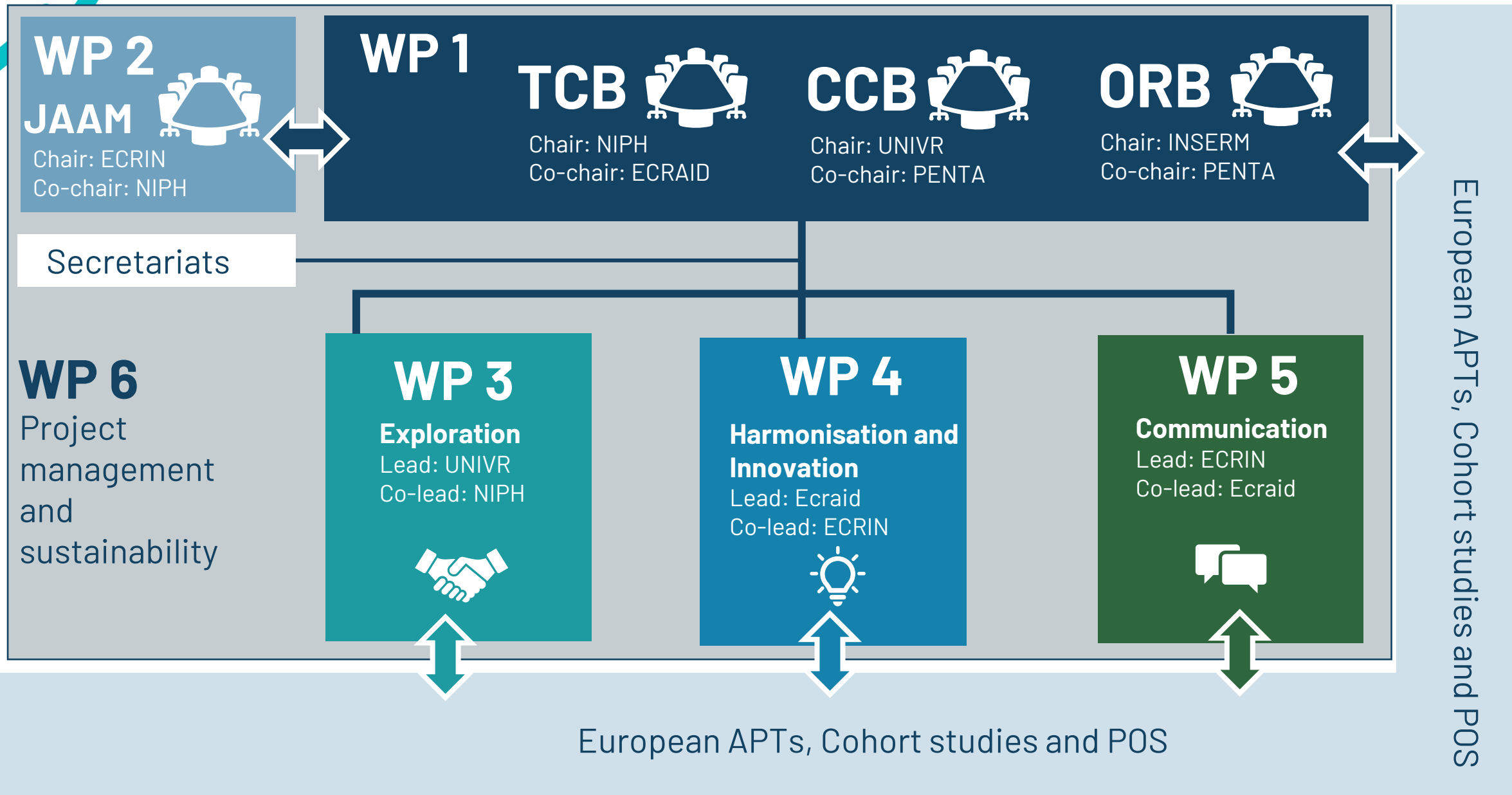
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*May 14<sup>th</sup>, 2024*



Funded by  
the European Union

# 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 cohorts**
- Coordinator: Norwegian Institute of Public Health  
Partners Ecrin, Ecraid, U Verona (CCB), INSERM, Penta, U Cologne (VACCELERATE)
- Total available funding: 3 mill Euro, GA signed Nov 10<sup>th</sup>, project start Dec 1<sup>st</sup> 2023 (-2026)
- Will expand the work of the Trial Coordination Board (TCB) and the Cohort Coordination Board (CCB) into a common Coordination Board (and include an Outbreak Response Board)
- Strengthen the Joint Access and Advisory Mechanism (assessment and selection of compounds)
- Include working groups on harmonization (of data extraction and synthesis), communication and exploration (mapping)
- Will promote synergies with stakeholders and other preparedness initiatives in Europe and beyond



# Background

.....Shared WP model



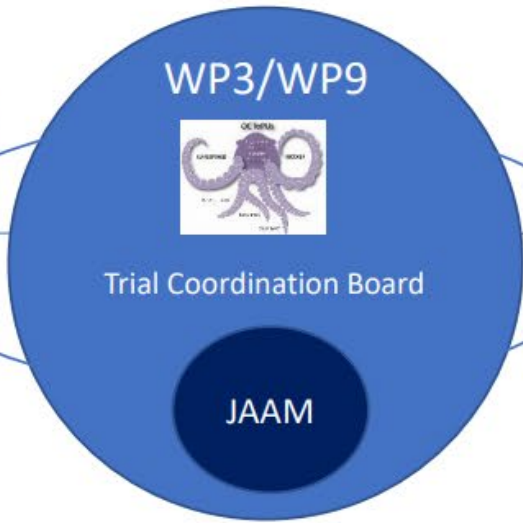
SOLID-ACT (WP2)

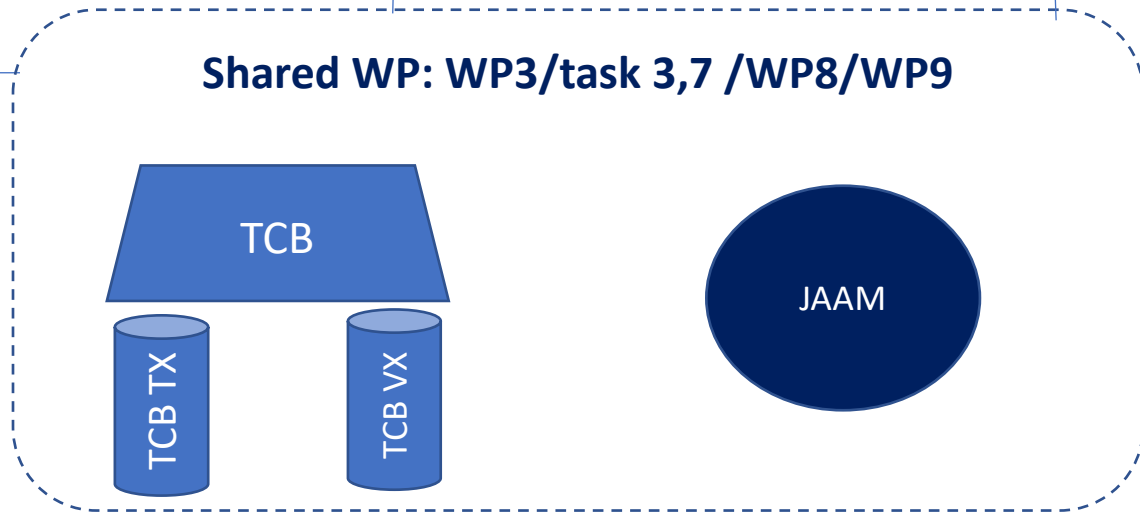
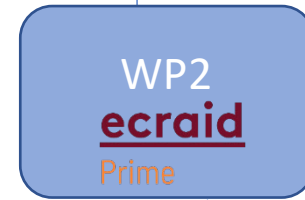
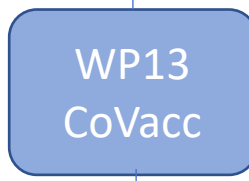
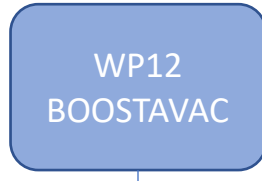
DISCOVERY  
(WP1)

REMAP-CAP  
(WP8)

WP1-WP7

VWG








































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# TCB Composition

CORE TCB	TCB – Tx pillar	TCB – Vx pillar	EXTENDED TCB
NIPH 	<b>EU FUNDED PARTNERS</b>	<b>EU (FUNDED) PARTNERS</b>	<b>POLICYMAKERS</b>
ECRIN 	Discovery/SolidAct  	EU-COVAT-1_AGED	WHO HQ (Science Division) 
ECRAID 	REMAP-CAP 	EU-COVAT-2 BOOSTAVAC 	ECDC 
EU Commission (obs)	ECRAID-PRIME 	EU-COVPT-1 COVACC	CEPI 
EU Commission HERA 	<b>EUROPEAN AND GLOBAL PARTNERS</b>	<b>EUROPEAN and GLOBAL PARTNERS</b>	COVID-19 Therapeutics Accelerator 
EU-RESPONSE/MPX RESPONSE 	Recovery 	COMCOV, COMCOV-2	<b>REGULATORS / ETHICS REPRESENTATIVES</b>
RECOVER (closed)	Principle 	COMCOV-3 	HTA 
ECRAID-Prime 	PANORAMIC 	PregCoV	EMA 
VACCELERATE/U Cologne 	AMMURAVID→MANTICO-2	COVERALL 	CTFG 
UNIVR/CCB 	ACTIV-3, TICO→STRIVE 	MVA-SARS2-ST 	EUREC 
PENTA	ANTICOV (DnDI) 	CAR-CF 	<b>INDUSTRY</b>
		Recovac 	EFPIA/VACCINES EUROPE 
		MonkeyVax 	<b>OTHER INITIATIVES</b>
			Trial Forge 
			Be Ready 



**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 ECRAID-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

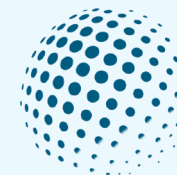


# CCB Composition

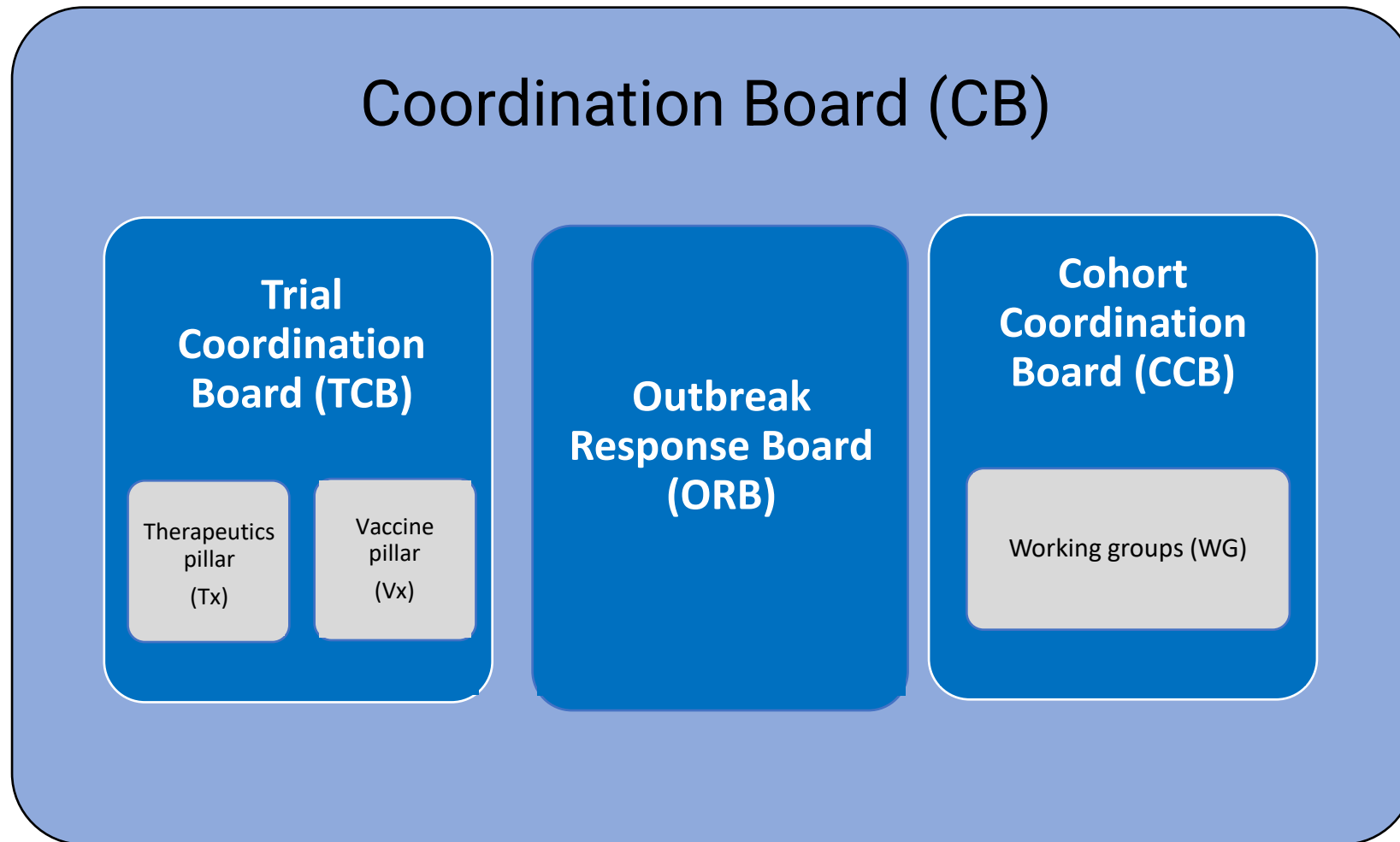
The CCB is organised on **two levels**:

- **a core group** (EC + EU funded projects)
- **an extended group** (Policymakers, Scientific Experts and experts from Industry), who are invited to participate as the need arises and according to the topic of discussion

CORE CCB		
<b>Projects</b>		<b>European Commission</b>
<b>CoMeCT</b> Victoria C Simensen	<b>NICB</b> Patrick Mitchell	<b>DG R&amp;I</b> Patricia Urban Lopez Evelyn Depoortere
<b>CONTAGIO</b> Thomas Jaenisch Lauren Maxwell	<b>NMCB</b> Jos Bosch	<b>HADEA</b> Romina Escobar Carina Pereira Serena Battaglia
<b>COVICIS</b> Giuseppe Pantaleo Song Ding Milo Puhan Agostino Riva Hester Kuipers	<b>ORCHESTRA</b> Evelina Tacconelli Lorenzo Maria Canziani Alessandro Visentin	<b>DG SANTE</b> Marta Valenciano Sigrid Weiland
<b>ECRAID</b> Marc Shamier Ankur Krishnan	<b>REACT</b> Pilar Caro Chinchilla	<b>EXTENDED CCB</b>
<b>END-VOC</b> Ibrahim Abubakar Gemma Castaño-Vinyals Patricia de Llobet Alexei Yavlinsky	<b>RIVM Long COVID</b> Kees van den Wijngaard Sophie van Wingerden Merlin van Loenen	<b>ECDC</b> Howard Needham Ajibola Omokanye
<b>EUCARE</b> Francesca Incardona Chiara Mommo Iuri Fanti Maurizio Zazzi Sara Gandini Sara De Benedittis Pontus Nauc�ler	<b>SYNCHROS</b> Josep Maria Haro Abad Ellen Vorstenbosch	<b>EMA</b> Eugenia Di Meco Marco Cavaleri
<b>EMBL-EBI/RECODID</b> Gabi Rinck Guy Cochrane	<b>unCoVer</b> Jose Luis Pe�alvo Gloria Soriano	<b>EFPIA</b> Magda Chlebus
<b>LONG COVID</b> Mari Kanerva Gunther Meinschmidt	<b>VACCELERATE</b> Zoi Pana	
	<b>VERDI</b> Ali Judd Carlo Giaquinto Deenan Pillay Gabija Morkunaite Daniela Paolotti Moira Spyer Charlotte Jackson	



# ORB addition-



*\*Work in progress: develop criteria for research response, evidence synthesis&transmission*

# Coordination lessons

- Feedback has emphasized that the current coordination structures are trusted entities that have prevailed recent crisis, showcased a model of collaboration, but lacked optimal impact
- Prospective coordination - requires authority, funding and sustained infrastructure
- Agility to stay relevant beyond Covid-19,- discuss and respond to new outbreaks
- Ability to select countries/sites and scope/questions when reacting to outbreak/ crisis
- Authority to advice the set-up of new cohorts, trials and trial arms- may achieve this by operating in conjunction/synergy with other initiatives

# Coordination advances in CoMeCT

- Strengthen, expand and align the work in the Coordination Board
- Synergies between the TCB and CCB – bridging knowledge gaps- cohorts informing trials
- Systematic mapping of relevant networks, compounds and collaborators/initiatives
- Sustained and continuous communication and visualization, information exchange on tools for data harmonization, data- reuse, adoption of data standards, etc.
- Support and visualize currently operational networks and include new ones
- Structured feedback and scientific recommendations to mechanisms at EU level (Partnership and the HERA subgroup)

# Examples of exchange

- PIs reach out in early stages of trial set up asking for opportunities to harmonize and collaborate with other networks
- Researchers making contact to be connected «common arms, data aggregation, metaanalysis, scientific exchange»
- Information exchange on relevant policy initiatives and the plans for the Partnership-established links to CoMeCT in BeReady
- New results shared in the Coordination Board early

# Value and impact

- A key objective of this project is to facilitate for continuous information exchange between researchers and stakeholders, between research domains, and between countries and regions.
- The experiences of CCB and TCB show that research quality, impact and innovation can be strengthened and harmonized through regular discussion
- An established route of communication is needed to effectuate collaborative responses in a crisis (as well as interepidemic times).

# Thank you for your attention

## CoMeCT

COordination MEchanism for Cohorts and Trials

[CoMeCT | The Coordination Mechanism for Cohorts and Trials \(comectproject.org\)](https://comectproject.org)



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