

RECOVER Closing Conference

Coordination of Adaptive Platform Trials – the JAAM and the platform trial toolbox

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Esplanade Hotel, Zagreb, Croatia



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Governance



Why a Joint Access Advisory Mechanism ?

1 – **Prioritization** of scientific questions / intervention arms

- platform trials are **infrastructures** able to address multiple scientific questions
- need for access procedure through independent scientific assessment of new intervention arms (part of the governance of any platform trial)

2 – **Coordination** of COVID-19 platform trials

- distribution of roles to optimise use of resources
- generate robust and relevant evidence
- avoid competition between platform trials

ecraid
Prime



JAAM

<https://covid19trials.eu/en/jaam>

contact : covid19trialeu@ecrin.org



- Independent prioritisation mechanism for new intervention arms, to optimise the use of EU-funded COVID19 platform trials

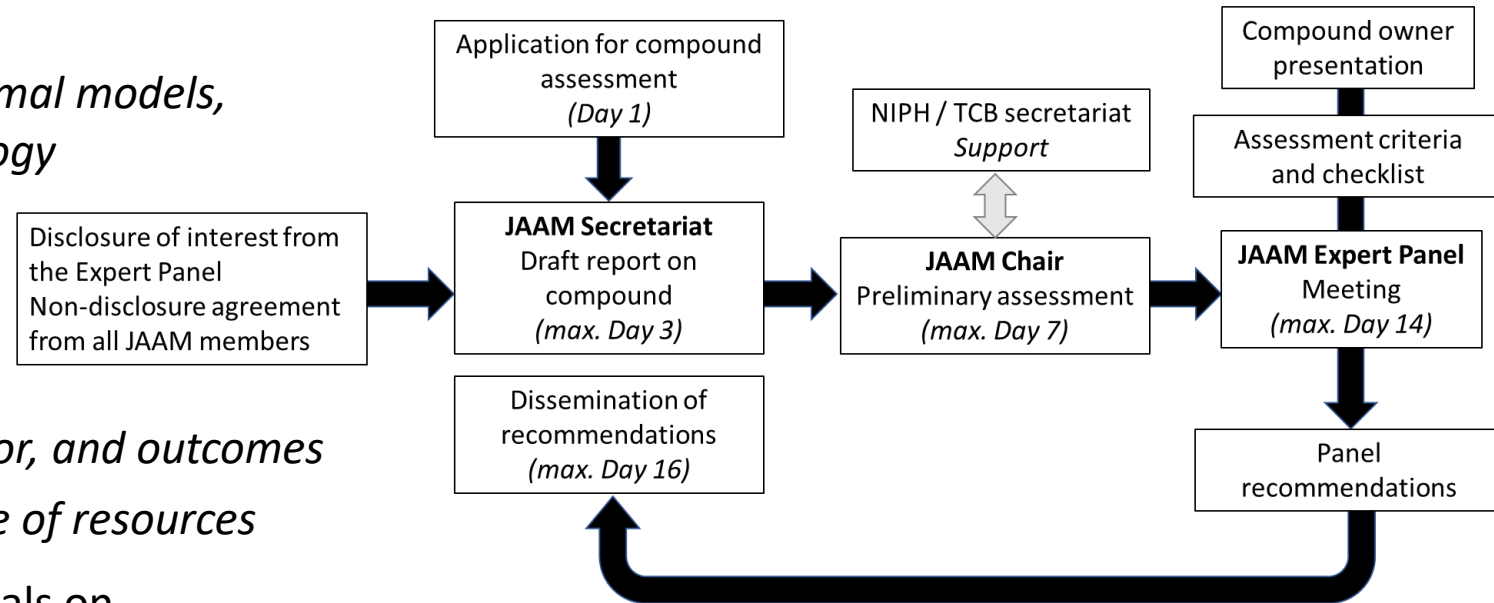
- Assessment of candidate intervention arms

- *JAAM expert panel (7): infectious diseases, animal models, immunology, pharmacology, statistics, HTA, virology*

- *Criteria*

- *Public health interest*
- *Scientific, medical, and ethical soundness*
- *Appropriate patient population, comparator, and outcomes*
- *Promotion of coordination and optimal use of resources*

- Recommendation to negotiate with platform trials on mild, moderate – severe, or ICU patients



Expert panel



JAAM Expert Panel

- Sanjay Bhagani (clinical infectious diseases)
- Giota Touloumi (biostatistics)
- Roger Le Grand (animal models)
- Joaquín Sáez Peñataro (pharmacology)
- Frank Hulstaert (HTA)
- Julia Garcia Prado (Immunology)
- Javier Sanchez Cespedes (Virology)

JAAM Secretariat

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Lessons learned



JAAM candidate compounds

- Repurposed and innovative compounds
- Mostly broad spectrum antivirals and immunomodulators
- Mostly SMEs
- Mostly targeting primary care patients

JAAM review, January 12th 2023



- **More detailed “JAAM checklist”, and “instructions”** document, and guidance on when to apply to JAAM;
 - need for evidence from Phase I studies, robust evidence from animal models and PK/PD results.
 - JAAM meeting dedicated to updated presentations of the three platform trials to the expert panel.
 - Updated terms of reference for the JAAM
- **Proactive horizon scanning** of compounds in the pipeline, mapping early phase academic trials, liaise with AGILE and other initiatives, communication with industry, raise awareness among developers, IMI / IHI
- **Strengthen collaboration with EMA.** EMA can contribute to the mapping of the pipeline and JAAM could make EMA aware of its findings to ensure full visibility. Also liaise with surveillance agencies.
- **Wider scope of infectious diseases,** expand the expert panel (Public Health expert ?)
- **Model for platform governance** in other disease areas.

JAAM in COMECT application



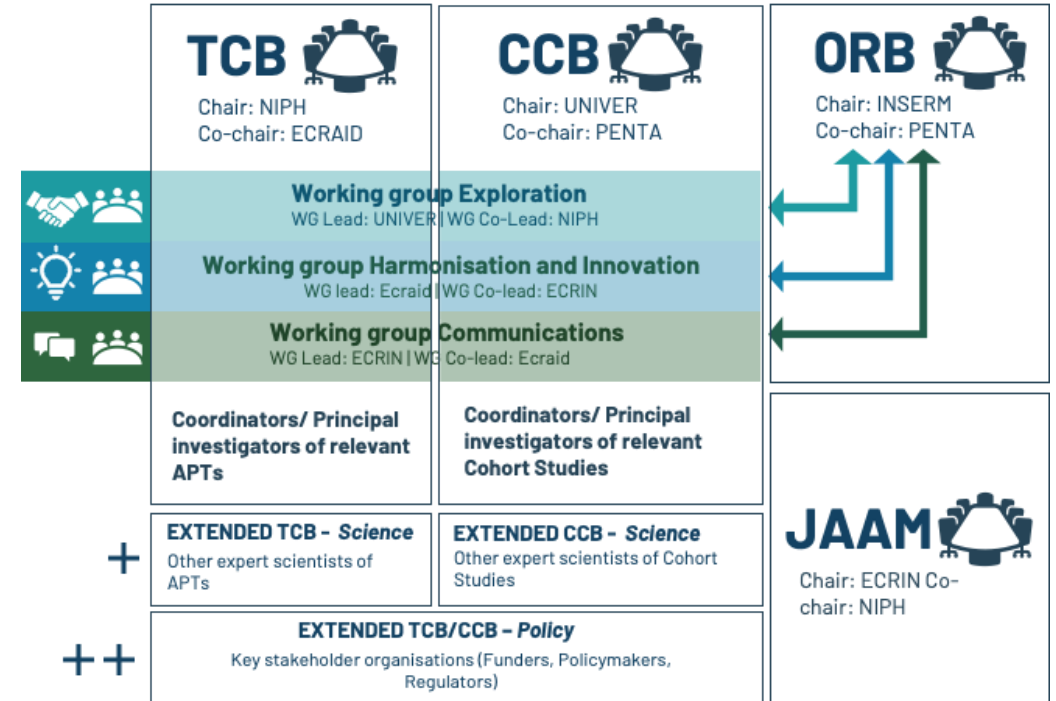
- **WP2 JAAM**

- Expand JAAM (emerging infectious diseases, vaccines ?)
- Mapping drug / vaccine development pipeline : proactive mapping early phase academic trials, reach out to EFPIA, HERA, EMA, funding bodies
- JAAM operations

- **WP6 Communication**

- **WP4 Harmonisation**

- Share best practice on platform trial management



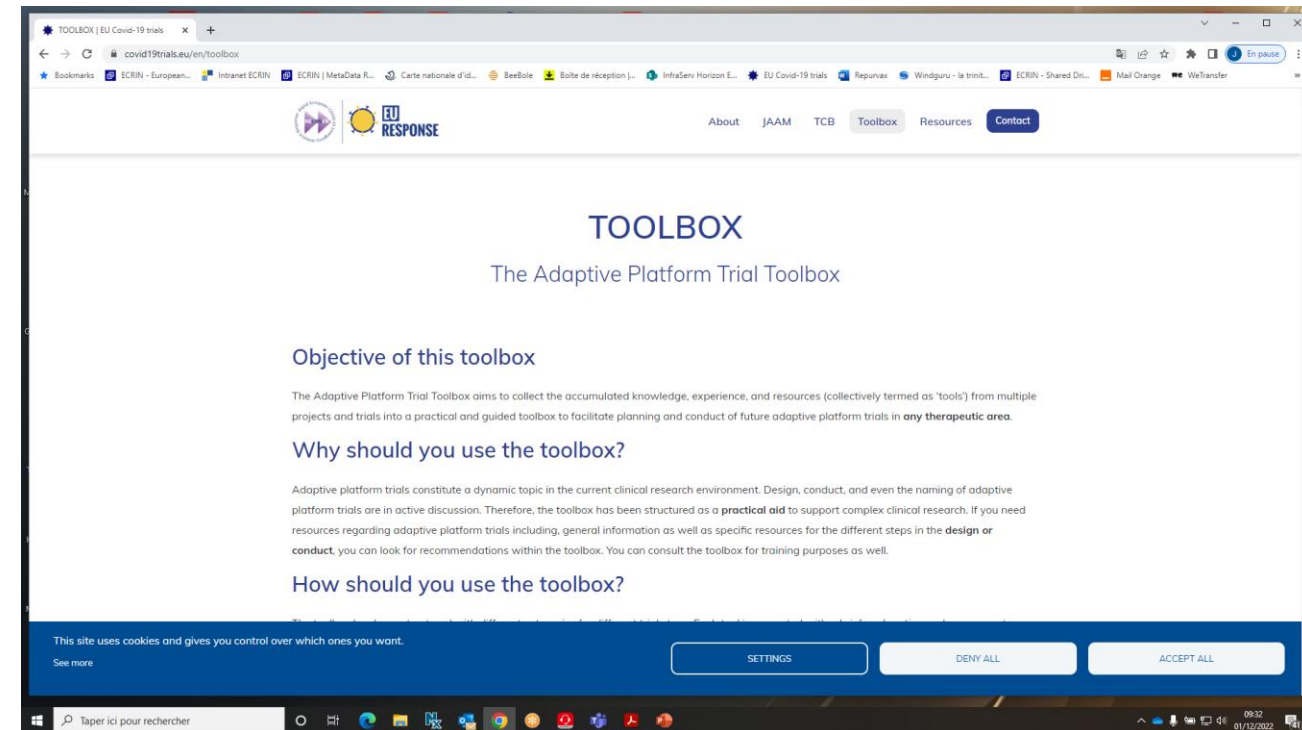
Platform trial toolbox



- Share experience and create a community of practice on platform trials
- Cross-fertilisation beyond infectious diseases
- Consider the diversity of platform trials
 - objectives ?
 - how pragmatic / data intensive ?
 - statistical model ?
- Repository of publications / guidance documents on adaptive platform trials

<https://covid19trials.eu/en/toolbox>

- Yearly updates
- Synergy with other sources : IMI EU-PEARL material



Synergy with IMI EU-PEARL material



- Sustainability of EU-PEARL material :
 - Master protocol template
 - Intervention-specific appendix template
 - Coverletter template for regulatory application
 - Clinical operation tool
- will be available from ECRIN website
- yearly updates with ad hoc working parties

