

# Lessons-learned workshop on Clinical Trials in Public Health Emergencies EMA, Amsterdam, June 9<sup>th</sup> 2023



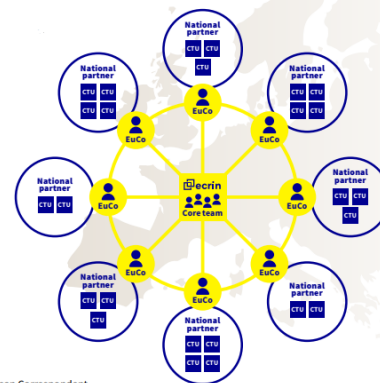
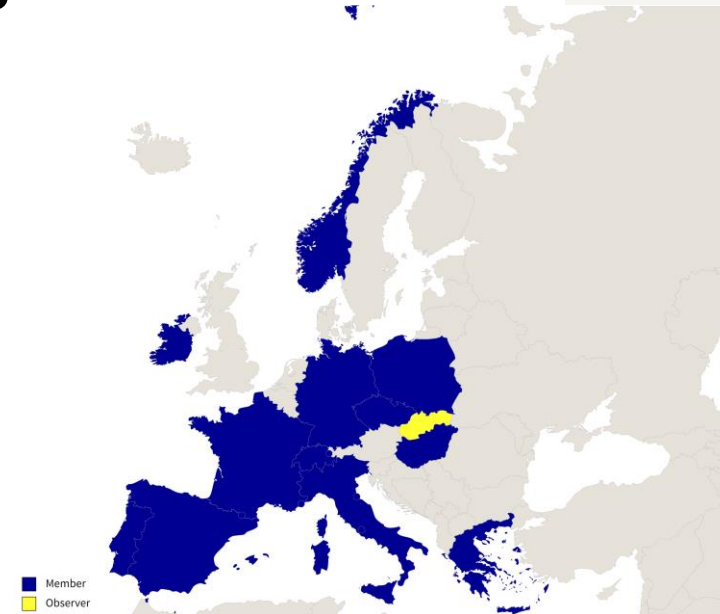
Coordinated trial management  
Coordinated access to platform trials - JAAM  
Coordinated funding – ERA4Health

Jacques Demotes

# ECRIN, a distributed infrastructure supporting multinational clinical research in Europe

**1 - Support multinational trials** in Europe (investigator-initiated and SME-sponsored trials) through **operational services to trial management** tasks: regulatory, ethics, monitoring, vigilance, data management, data sharing

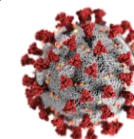
**2 - Develop tools, methods and partnerships** for multinational trials (ethical/regulatory database, data centre certification, data sharing tools, personalised medicine, platform trials)



o: European Correspondent  
i: Clinical Trial Unit



# 1 – Coordinated trial management : challenges raised by trials in public health emergencies



- **Single sponsor in multiple jurisdictions : contracting with sites ?**
  - Template contracts and financial annex (cost items and rates)
  - Co-sponsorship ?
- **Is a real fast-track approval compatible with coordinated approval ?**
  - Mutual recognition ? Central approval ?

2001/20/EC

536/2014 CTR

xxx/ 202X ?

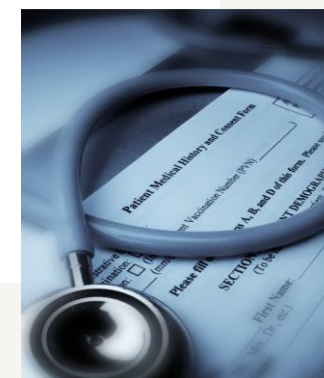
harmonised approvals

-> coordinated approval

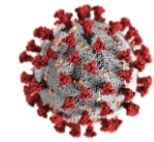
-> central approval ?

- **Risk-based provisions** : “low-intervention trials” under-used in COVID trials
  - Review the two categories and corresponding requirements in EU CTR ?
  - OECD recommendation : innovative, repurposing, comparative effectiveness
  - Notification for trials on approved products within licensed indication ?

OECD Recommendation on the Governance of Clinical Trials



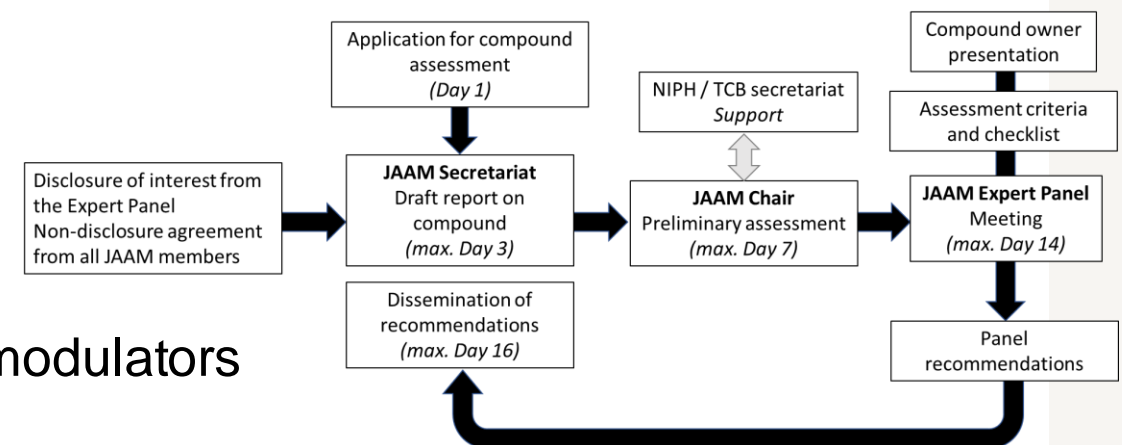
## 2 – Coordinated access to platform trials : the JAAM



- Platform trials are infrastructures -> access to new intervention arm through independent scientific assessment  
JAAM independent expert panel and selection criteria
- Coordinate and optimise the use of EU-funded COVID19 platform trials  
Recommendation to negotiate with platform trials on mild, moderate – severe, or ICU patients



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



### 3 – Coordinated funding : ERA4Health partnership

Pillar 2B: design a funding mechanism for multinational investigator-initiated clinical studies based on national funding bodies and EU-COFUND (30%)

- Inventory bottlenecks, funding instruments and support mechanisms
  - Agree on objective of supported trials, eligibility criteria
  - Agree on priorities (involvement of HTA, patients, etc)
  - Agree on selection criteria and procedure
  - Define funding mechanism, duration, flexibility, use of cofund
  - Propose funding mechanism for public health emergencies
    - *which trials should be multinational ?*
  - Coordinate with other initiatives / partnerships
- first call : end 2024 ?

