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


# ACT-EU multi-stakeholder platform annual meeting Session 2 - The current landscape for clinical trials in Europe – ACT-EU and beyond

*Amsterdam, October 22nd, 2024*

**Jacques Demotes, ECRIN General Director**

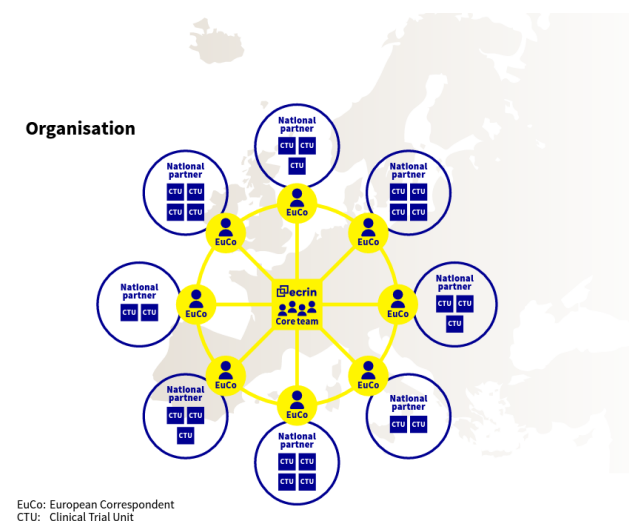
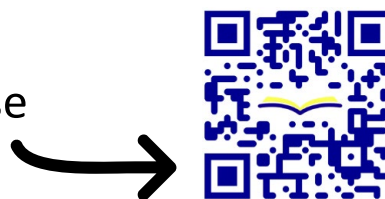
# Regulatory and administrative initiatives

- CTIS application
  - Processing simultaneous amendments for complex / platform trials
  - Fast track approval in public health emergency 
- Low-intervention trials: under-used
  - Investigator-initiated trials mostly “lower risk”: repurposing, or comparative effectiveness, optimisation / combination
- Contracting between sponsor and sites
  - Template contract
  - Enforcement ? role of funders ?



# Enabling multinational investigator-initiated studies

- Public funding for investigator-initiated clinical studies
  - Central budget
  - Cross border funding
  - Charity funding
  - ERA4Health Partnership : national funds + EU Cofund
- Bolster infrastructure for multinational studies:
  - ECRIN a distributed CTU network
  - Operational services to single sponsor in multinational studies
  - Tools, methods, partnerships
    - Including Regulatory and Ethical Database





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