

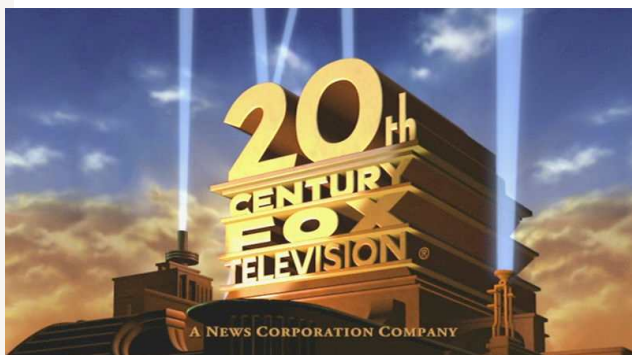


L'écosystème de recherche clinique en Europe

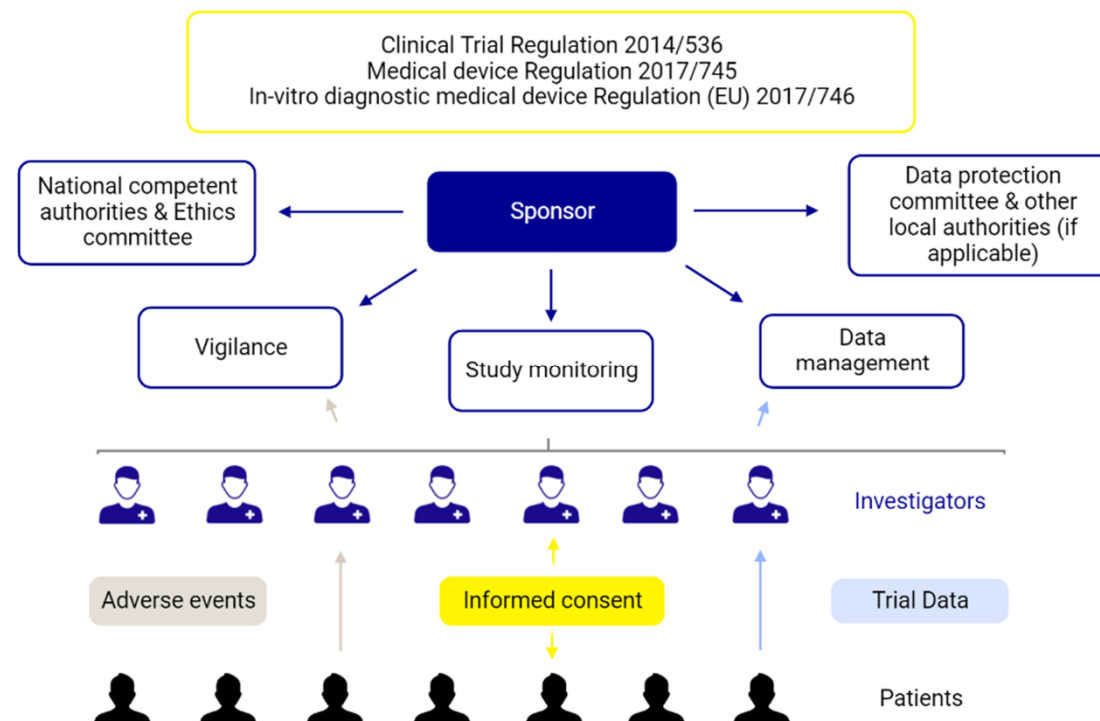
Jacques Demotes

ECRIN

Sponsor, investigator, patients



Clinical research is regulated research : Single sponsor, investigators and patients



Maturation of national clinical research ecosystems

- Support to investigation
 - Clinical research centres / facilities
 - Investigation networks
- Support to trial management / sponsors
 - Clinical trial units (CTU) -> WHA 75.8 Resolution
 - CTU networks
- Public funding for investigator-initiated clinical studies
 - Academic innovation ?
 - Repurposing ?
 - Comparative effectiveness research ?

Regulatory ecosystem

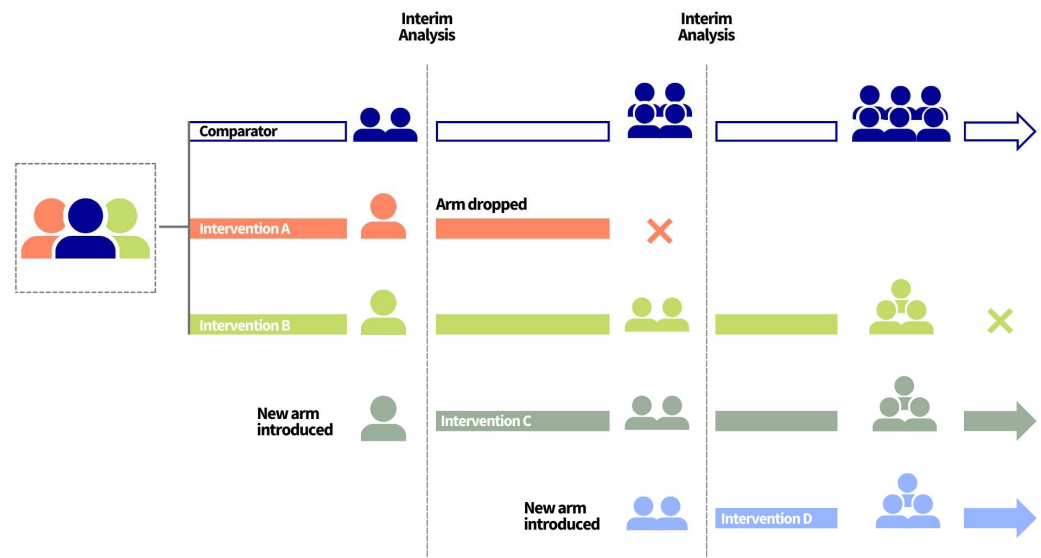
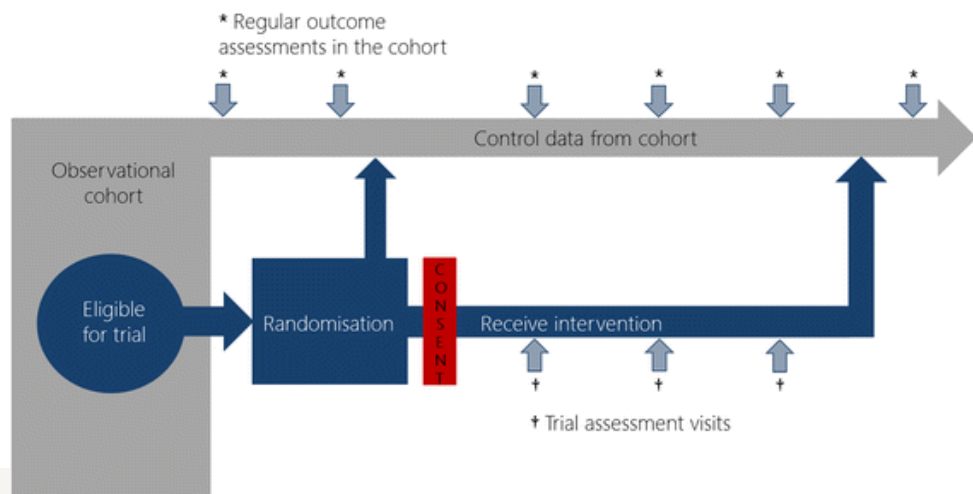
- Regulation 536/2014 (CTR)
- Regulation 2017/745 (MDR)
- Procedural intervention
- Observational
- GDPR
- EHDS Regulation
- -> Amendment CTR ?



- Low-intervention trials (?)
- Single sponsor in the EU
- Co-sponsor
- Contract between sponsor and investigation sites in different jurisdictions
- CTIS and multiple amendments

New trial designs

- Platform trials
- Trials within cohorts (TwICs)
- Decentralised trials



Adaptive Platform Trial Toolbox

The Adaptive Platform Trial Toolbox aims to collect the accumulated knowledge, experience, and resources (collectively termed as 'tools') from multiple projects and trials into a practical and guided toolbox to facilitate planning and conduct of future adaptive platform trials in any therapeutic area.

Public funding for investigator-initiated clinical studies

- Academic innovation ?
- Repurposing ?
- Comparative effectiveness research / treatment optimisation ?

Cross-border use of national funding ?

Central budget ?



ERA4Health partnership : EFFECTRIAL

<https://era4health.eu/calls/effectrial2025.php>

'virtual common pot' (70%) plus EU-COFUND (30%)



Public funding through missions and partnerships

- Cancer mission
- ERA4Health
- EP-PerMed
- ERDERA
- BeReadyNow (ever-warm networks)
 - CoMeCT, JAAM
 - HERA, CT-CM, GIP



8

Demotes et al. *Trials* (2024) 25:278
<https://doi.org/10.1186/s13063-024-08126-5>


Trials

COMMENTARY

Open Access

Coordination of COVID-19 platform trials in Europe



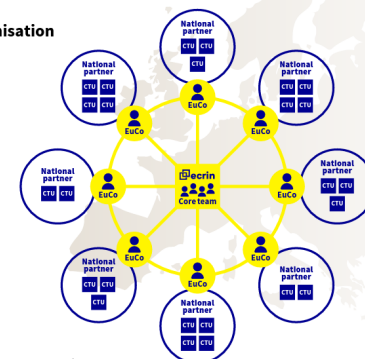
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ECRIN: Supporting clinical studies across borders

ECRIN's mission is to support the conduct of multinational clinical trials across Europe

- Distributed research infrastructure
- **13** countries | **130** Clinical Trial Units | **360** million EU citizens
- **80** clinical trials supported | **50** Infrastructure projects
- ISO 9001:2015 certified for its principal services

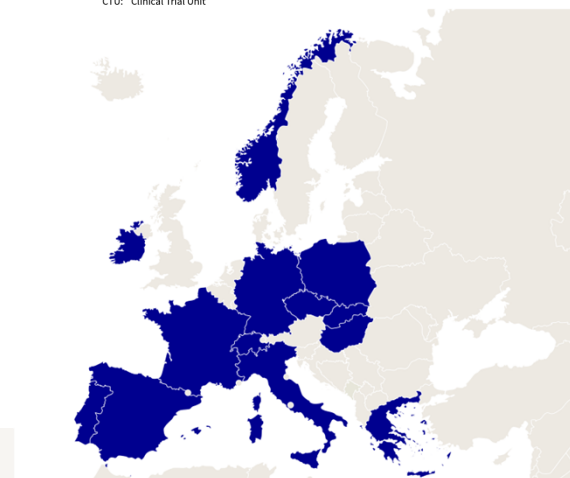
Organisation



EuCo: European Correspondent
CTU: Clinical Trial Unit

ECRIN activities

- **Coordinated support to multinational study management**
(any disease area/any type of study):
 - Collaboration on study planning and design
 - Operational study management services
- **Development of tools, methods, and partnerships**
- **Data Centre Certification**



CZECRIN
CENTRO ZŁOZOWY
REKURSYWNEJ INFRASTRUKTURY

ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK

GRECRIN
Greek Clinical Research Infrastructure

HNHRA
Hungarian National Health Research Agency

KKS Netzwerk
Klinische Krebsforschung

NCTO
National Clinical Trial Organisation

ItaCRIN
Italian Clinical Research Infrastructure Network

NorCRIN
Norwegian Clinical Research Infrastructure Network

Polish Clinical Trials Network

PtCRIN
Portuguese Clinical Research Infrastructure Network

SCReN
Spanish Clinical Research Network

swiss clinical trial organisation

SLOVACRIN
Slovak Clinical Research Infrastructure Network



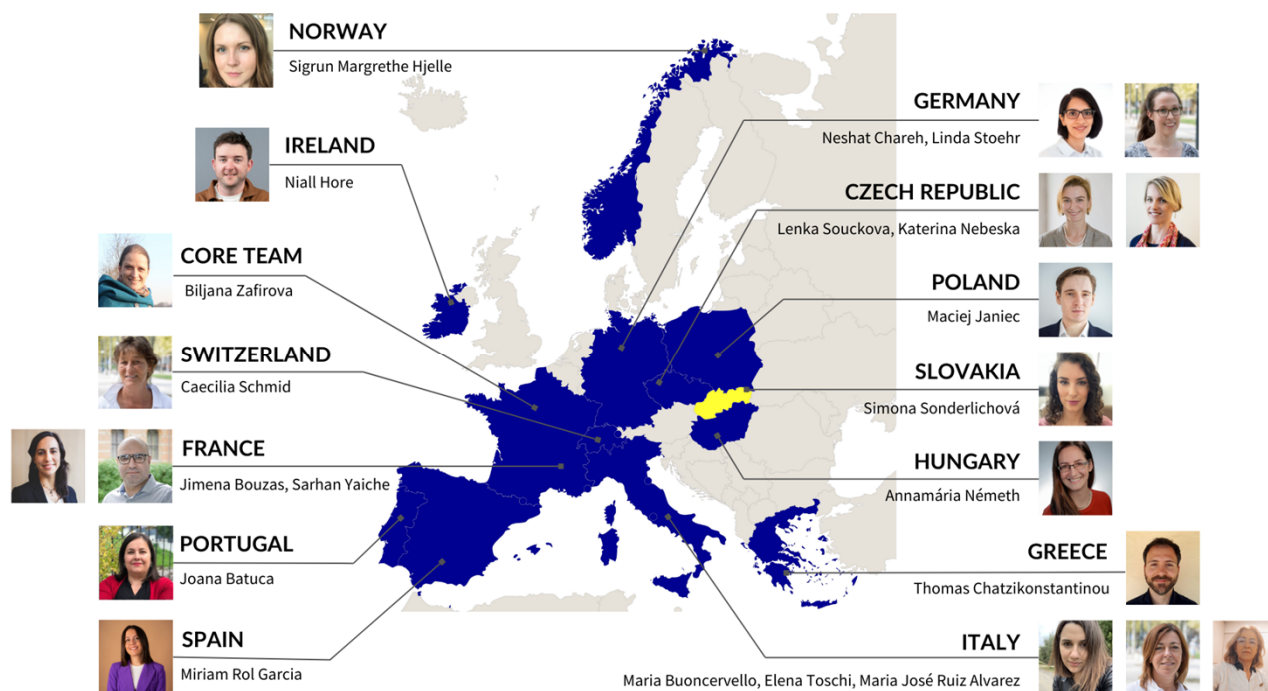
Staff involved in ClinOps

European Correspondents

Contact for investigators & sponsors

Hosted in each national partner's node

Coordinate operational service provision for multi-country trials





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