

Presenetasjon av ECRIN

NorCRIN brukermøte, Stjørdal 23. september 2019



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ECRIN er en Europeisk infrastruktur

- Som støtter multinasjonale kliniske forskningsprosjekter
- Fasiliterer tilgang til pasienter og kompetanse
- Koordinerte tjenester i multinasjonale kliniske forskningsprosjekter

History At A Glance

Norway as Member in
the consortium
May 2016

- **2004:** ECRIN created; began 1st project (EU Framework Program 6, FP6) on strategy development involving **six countries**
- **2006:** 2nd project (FP6) on tools development with **12 countries**; listed on European Strategy Forum on Research Infrastructures (ESFRI) roadmap
- **2008:** 3rd project (FP7) with **14 countries** to develop ECRIN's business plan and legal status
- **2012:** 4th project (FP7), ECRIN Integrating Activity (ECRIN-IA), with **23 countries** to structure national scientific partners and build their capacity to manage multinational trials – **Norway inn for first time**
- **2013:** Awarded ERIC status
- **2016:** Listed as an “ESFRI Landmark” on the updated ESFRI Roadmap
- **2019:** ECRIN – ERIC, consortium between **12 countries and several more** are working on the process of becoming member of **ECRIN-ERIC**

ECRIN Members / Observers and national scientific partners

Country	National hub	National CTU Network	Host Institution (linked third party)
Czech Republic	Brno	CZECRIN	Masaryk University
Germany	Berlin	KKSN	KKSN Berlin
Spain	Barcelona	SCReN	ISCIII
France	Toulouse	F-CRIN	INSERM
Hungary	Pecs	HECRIN	University of Pecs
Ireland	Dublin	CRCI	HRB
Italy	Rome	ItaCRIN	ISS
Norway	Trondheim	NorCRIN	St. Olav Hospital
Portugal	Lisbon	PtCRIN	Nova University
Slovakia	Kosice	SlovaCRIN	Kosice University
Switzerland	Berne	SCTO	SCTO
Poland	Warszawa	MRA	Polish Medical Research Agency

Hva slags støtte tilbyr ECRIN?

- Kontakt med etikkomiteer og relevante myndigheter
- Kontrakter / budsjetter
- Oversettelse / tilbakeoversettelse av relevante dokumenter og tilpasning av protokoll og informert samtykke
- Lokal opplæring av studiepersonell
- Monitorering
- Datahåndtering
- Bivirkningshåndtering (pharmacovigilance)

ECRIN SUPPORT SERVICES

1

**PREPARATION:
ADVICE & INFORMATION**



- Trial design and methodology
- Funding sources and costs
- Investigation sites and patient recruitment
- Task distribution for multinational trial management
- Funding applications
- Regulatory, ethical and insurance requirements

2

**REVIEW:
PROTOCOL & FEASIBILITY**



- Scientific and methodological evaluation of the protocol
- Assessment of project implementation plans

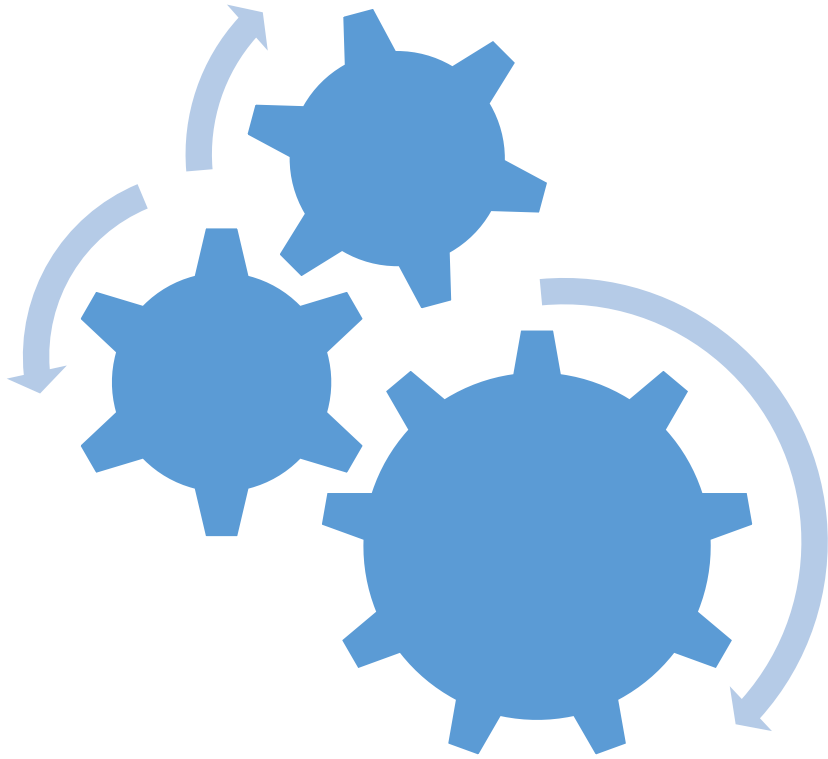
3

**IMPLEMENTATION:
TRIAL MANAGEMENT**



- Project management and trial coordination
- Clinical study authorisations (regulatory, ethical) and follow-up
- Monitoring
- Vigilance
- Data management
- Health product and biosample management

I praksis betyr dette...



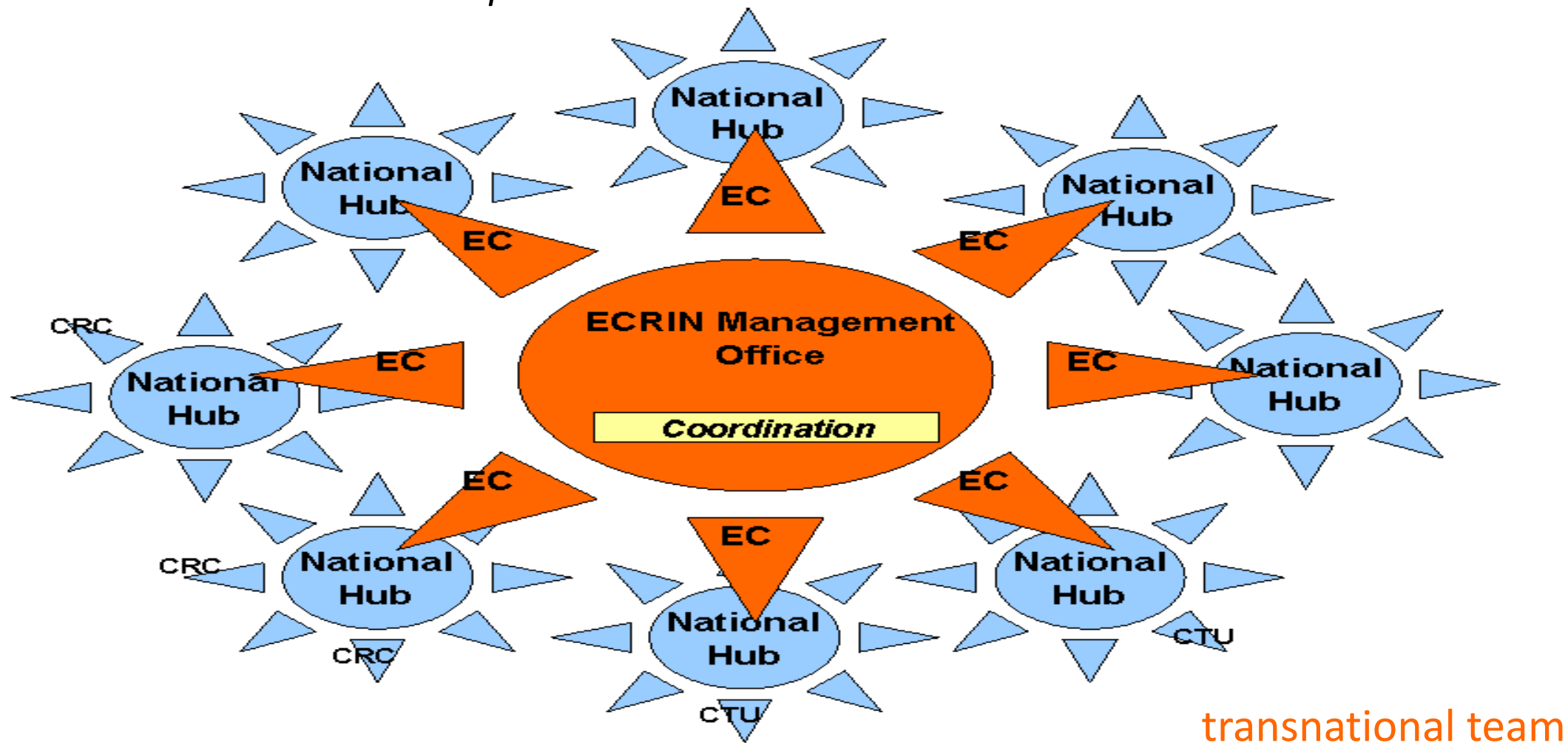
Hovedutprøver (PI) leverer et prosjektsammendrag til den europeiske korrespondenten i sitt land



Valentina Cabral Iversen
European Correspondent, Norway

ECRIN komitèen vil først gå gjennom studien og etterpå tar beslutning om samarbeid

Nettverk av europeiske korrespondenter



CRC= Clinical research centre
CTU= Clinical trial unit

EC= European Correspondent

Distributed infrastructure, providing distributed services



H2020 studier gjennom ECRIN til Norge -11 studier

- MENAC
- POPART
- PRECIOUS
- R-LINK
- TENSION
- WE-STUDY
- NECESSITY
- IDEA-FAST
- EXTRIM
- MIOLET
- TREOCAPA 4c4

Senter i Norge involvert i studien

Alle universitetssykehus er involvert som partner

- Oslo universitetssykehus
- ST Olavs HF Universitetssykehus i Trondheim
- Haukeland universitetssykehuset
- Stavanger universitetssykehuset
- Universitetssykehuset Nord-Norge

ECRIN er partner i søknader som ikke er typiske kliniske intervensjonsstudier (H2020 søknader)

- PERMIT (PERsonalised Medicine Trials): project on standardized methods in personalized medicine. **FUNDED**
- EOSC-Life: Providing an open collaborative space for digital biology in Europe **FUNDED**
- ECRIN-SEQUoIA: Sustainable sErVICES for QUality and InternAtionalisation **NOT FUNDED**

H2020-INFRAEOSC-2018-2020

Implementing the European Open Science Cloud(EOSC)

- EOSC-Life **WP4** – (ECRIN,BBMRI, EATRIS, EMBRC, ERINHA, UNITO MU)
- Norge, gjennom NorCRIN er med i WP4
- **WP4** vil jobbe med retningslinjer, spesifikasjoner og verktøy for styring av data for biologisk og medisinsk forskning. Deling og gjenbruk av human data inkludert GDPR i Europa.
- Prosjektets varighet - 4 år

ECRIN Data Certification

The following centres have received ECRIN Data Certification

- [Oslo Universitetssykehus](#), Oslo Norway – certified until July 2023
- Medical Faculty of the Philipps-University Marburg, Marburg IZKS, Germany - certified until November 2020
- Faculty of Medicine Carl Gustav Carus of the Technische Universität: certified until March 2022
- University Heidelberg, Germany, Heidelberg KKS - certified until March 2022
- [AIBILI Data Centre](#), Coimbra, Portugal – certified until 2020
- [Clinical Pharmacology and Therapeutic Trials Service HCL](#), Lyon, France – certified until 2020
- [Clinical Trials Unit Freiburg](#), Freiburg, Germany – certified until 2019
- [EUropean CLInical trials & Development \(EUCLID\)](#), Bordeaux, France – certified until 2019
- [Group for Adult Hematologic Diseases \(GIMEMA\)](#), Rome, Italy – certified until 2019
- [Institute of Pharmacological Research "Mario Negri" \(IRCCS\)](#), Milan, Italy – certified until 2019
- [Interdisciplinary Centre for Clinical Trials \(IZKS\)](#), Mainz, Germany – certified until 2020