

Clinical Research Initiative for Global Health (CRIGH)



CRIGH

CRIGH - muligheter for Norge

Brukermøte NORCRIN

25. september 2017

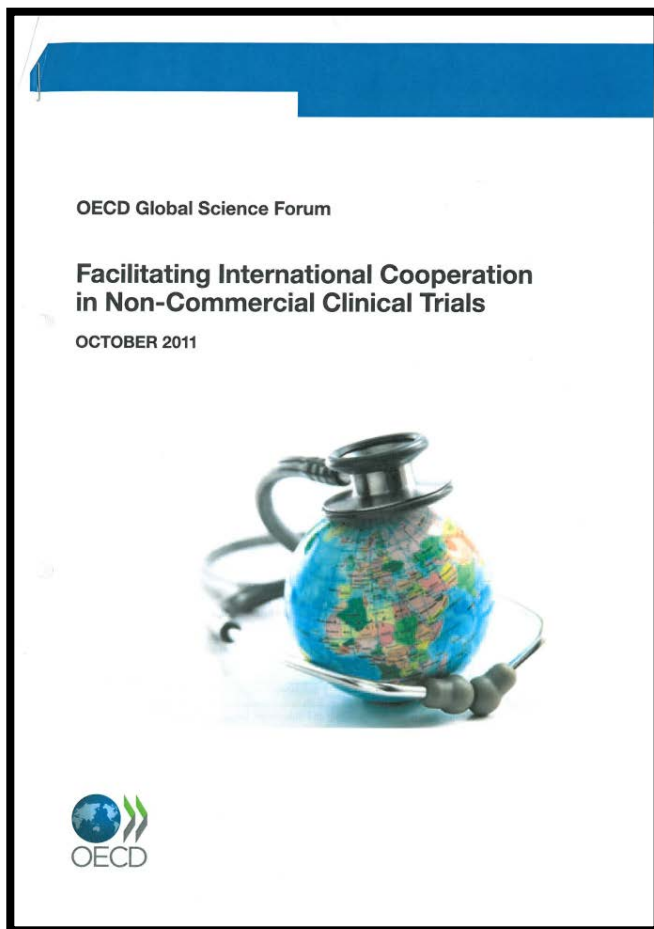
**Øyvind Melien
CRIGH Core Team**

Brukermøte NORCRIN,
Radiumhospitalet, 25-09-2017

OECD GSF initiativ « Facilitating international cooperation in non-commercial clinical trials »

- Forslag fra **Tyskland og Spania til OECD Global Science Forum (GSF) 2010**
- Behov for å styrke samarbeidet internasjonalt om ikke-kommersielle kliniske studier
- Betydning for nasjonale og internasjonale guidelines/policies
- Initiativ tilsluttet av OECD GSF og iverksatt fra 2010.
- Sekretariat OECD. Bred deltakelse fra OECD og ikke-OECD land

OECD GSF Working Group Report



Hovedanbefalinger 2011/2012:

A: Regulatorisk harmonisering

B: Risiko-basert strategi

C: Utdanning
Kompetanse
Infrastruktur
Pasientinvolvering

OECD anbefalinger - On the Governance of Clinical Trials

OECD Recommendation on the
Governance of Clinical Trials



**Tilsluttet av OECD Council
desember 2012**

Policy instrument som definerer
rammeverk for kliniske studier

Anbefalinger om å tilpasse
nasjonale regelverk til en risk-
based approach

Etablering av oppfølgingsprosjekt

- Dialog med **WHO** – prosjektdraft m/innspill fra nasjonale/internasjonale organisasjoner 2013/2014
- **OECD** – draft på høring i medlemslandene 2015
- Dialog med **EU**-kommisjonen 2015/2016
- **OECD GSF** plenary meeting oktober 2016
- **Clinical Research Initiative for Global Health (CRIGH)** – formell oppstart fra 1. januar 2017

Clinical Research Initiative for Global Health (CRIGH)

Globalt initiativ for helse

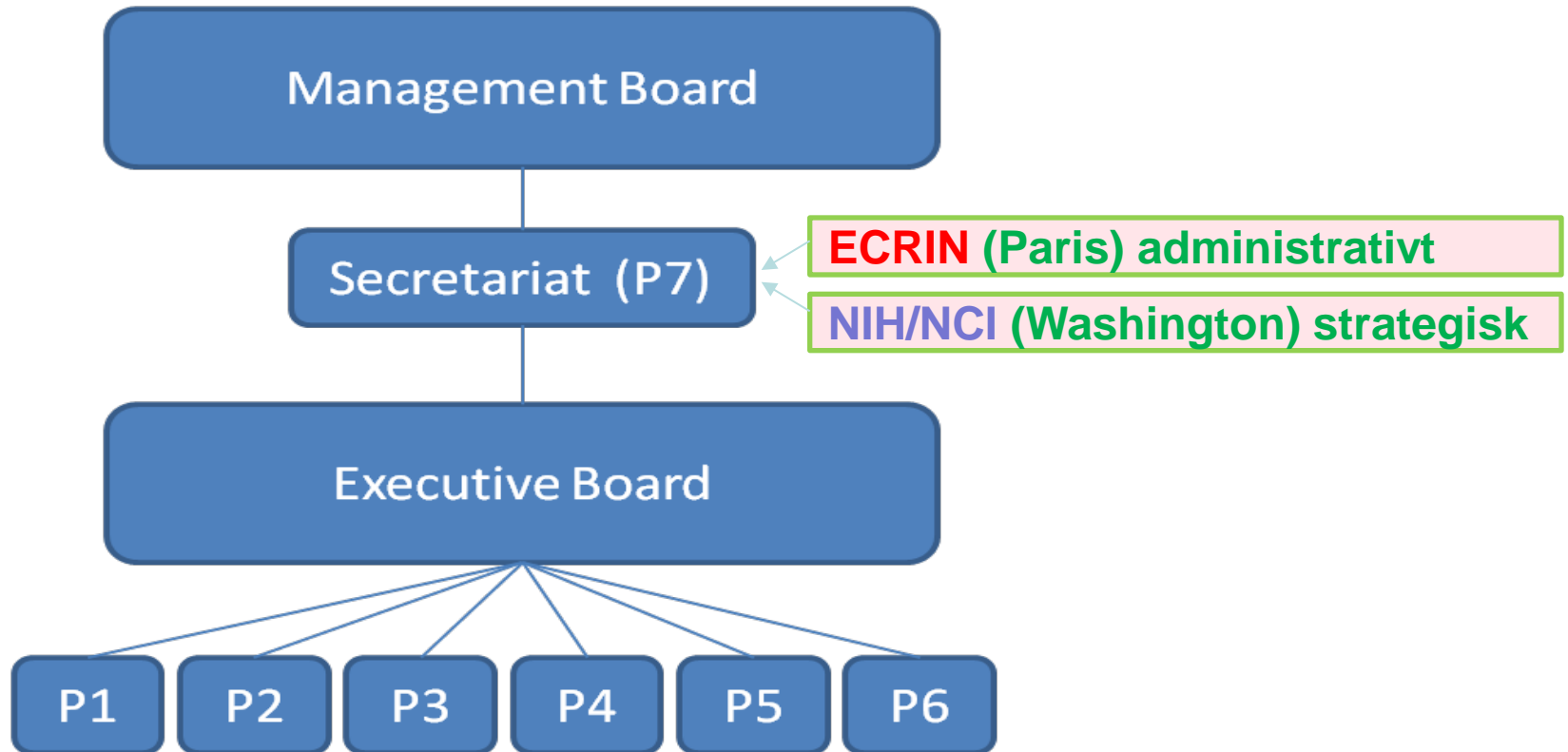
- Internasjonalt samarbeid for kliniske studier
- Bygge mer effektive infrastrukturer
- Raskere gjennomføring av studier
- Raskere tilgang for pasientene
- Impact for
 - Helse
 - Innovasjon
 - Økonomi

Fokusområder

Initiale oppstartsområder organisert i 6 prosjekter (P1-P6), koordinert av sekretariat (P7), suppleres over tid med nye prosjekter:

- **P1: Infrastructure and funding** (Sekretariat ECRIN, Paris)
- **P2: Global core competencies** (Sekretariat Australia, MRC)
- **P3: Research ethics** (Sekretariat Japan, Tokyo)
- **P4: Patient involvement** (Sekretariat National Institutes of Health, Washington DC)
- **P5: Comparative effectiveness research** (Sekretariat Folkehelseinstituttet, Oslo)
- **P6: Regulatory awareness** (tbc)
- **P7: Coordination, strategy, communication** (ECRIN og NIH-National Cancer Institute)

Governance



Medlemmer CRIGH

National Institutes of Health, Washington, USA

Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard, MRCT, USA

FIOCRUZ, Clinical Research Organization, Brazil

Medical Research Council of South Africa (MRCSA)

Academic Research Organization (ARO) Council, Japan

National Cancer Centre, NCC, Japan

Osaka University Hospital, Japan

European Clinical Research Infrastructure Network (ECRIN)

HECRIN, Hungarian branch of ECRIN

Health Research Board Clinical Research Coordination Ireland, HRB CRCI, Ireland

F-CRIN (Inserm), France

Istituto Superiore di Sanita, ISS, Italy

Istituto di Ricerche Farmacologiche Mario Negri, Milan, Italy

Medlemmer CRIGH

Department of Health and Human Services (DHHS), Australia

Association of Clinical Trials Organizations (ACTO), Russia

Luxembourg Institute of Health (LIH), Luxembourg

Norwegian Institute of Public Health

Belgian Knowledge Center, KCE

UK focal point for CRIGH; Oxford University (Global Health Research, Global Health Network)

Observatører CRIGH

World Health Organization (WHO)

OECD

EDCTP

National Research Institution for Public Health, Russia

Observatører CRIGH

Medical Research Council Australia

Karolinska Institute, Sweden

University of Vienna

University of Aberdeen

EURORDIS – Rare disease patient organization

COHRED – Council on Health Research for Development

CEIC – National Ethic Committee for Clinical Research, Portugal

PT-CRIN, Portuguese branch of ECRIN

Instituto de Salud Carlos III (ISCIII) Spain

Korea National Enterprise for Clinical Trials (KoNECT)

Singapore Clinical Research Institute

Swiss Clinical Trial Organisation (SCTO), Switzerland

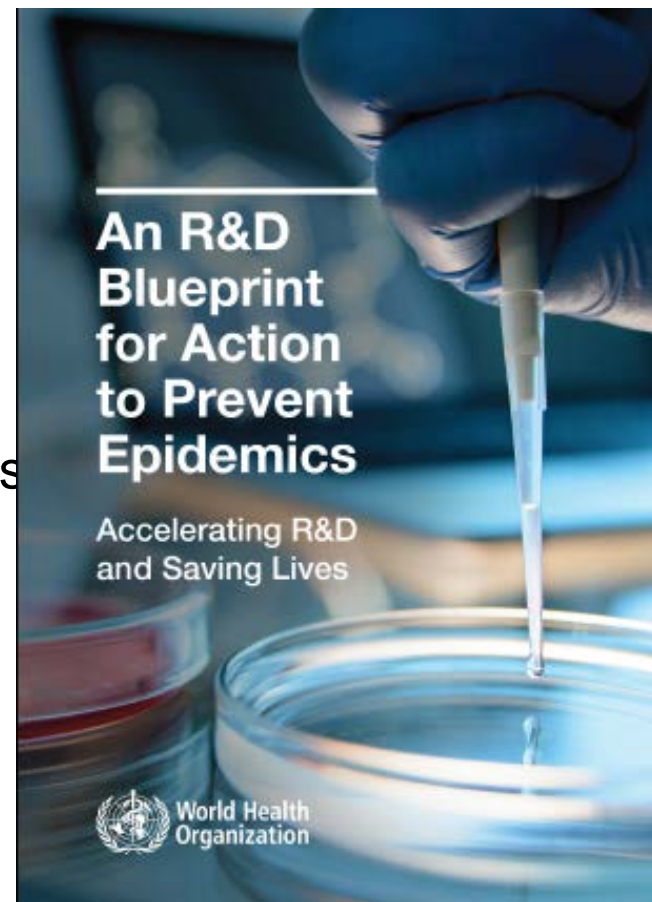
The Netherlands Organisation for Health Research and Development (ZonMW)

WHO's bidrag

- **Støtte CRIGH-prosjektene** hvor relevant fra HQ, regionalkontorer, nasjonale kontorer, Collaborating Centres
- **Utvikle synergier med WHO's satsninger**
Eksempel: WHO Blueprint 2015:
- An R&D Blueprint for action to prevent epidemics
- **Prioritise global infectious disease threats**

- **Støtte implementering på sikt**

- **Foreslå resolusjon for World Health Assembly.** Vil gi mandat for WHO's bidrag til implementering på lang sikt



Muligheter for Norge

- **Deltakelse i CRIGH**

- Medlem/observatør
- Institusjoner/organisasjoner

- I tråd med NORCRINs konsept

NORCRIN (nasjonalt) → ECRIN (europeisk) → CRIGH (globalt)

- Gå inn i prosjekter oppstartet/under etablering
- Ev. foreslå nye prosjekter

Clinical Research Initiative for Global Health

www.crich.org

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Clinical Research
Initiative for Global Health

OVERVIEW

A follow-up to the Organisation for Economic Co-operation and Development (OECD) Global Science Forum (GSF) initiative, the Clinical Research Initiative for Global Health (CRIGH) aims to support international collaboration on clinical research for the benefit of patients, healthcare professionals, and health systems.

Launched in October 2016, CRIGH will optimise clinical research programmes in participating countries, develop global standards on clinical research, promote the take-up of innovative methodology and technologies, and encourage international cooperation to rapidly and efficiently respond to global health challenges (e.g. Ebola and Zika).

The CRIGH consortium is composed of Members and Observers (research institutions, organisations, or consortia of research institutions). The secretariat is shared between the National Institutes of Health (NIH) and ECRIN.

A unique initiative to address obstacles to global collaboration

Various initiatives have already been established to address specific bottlenecks to global collaboration in clinical trials. Yet, to date, no global initiative has strove to address the wide range of obstacles to global cooperation in clinical research. Moreover, while some bilateral cooperation agreements have been signed by national partners to support the conduct of multi-country trials, no multilateral cooperation framework has been created to promote collaboration across all geographic areas, including in developing countries. With its broad international mandate, CRIGH aims to fill these significant gaps.

CRIGH

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[Mission](#)

[Why CRIGH?](#)

[Members & Observers](#)

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