



Helse- og
omsorgsdepartementet

Norges prioriteringsprosjekt

"Nordisk samarbeid for bedre helse 2017-2019"

Nils Olav Refsdal



The Nordic Region in Transition

The Nordic Region in Europe

The Nordic Region in the World



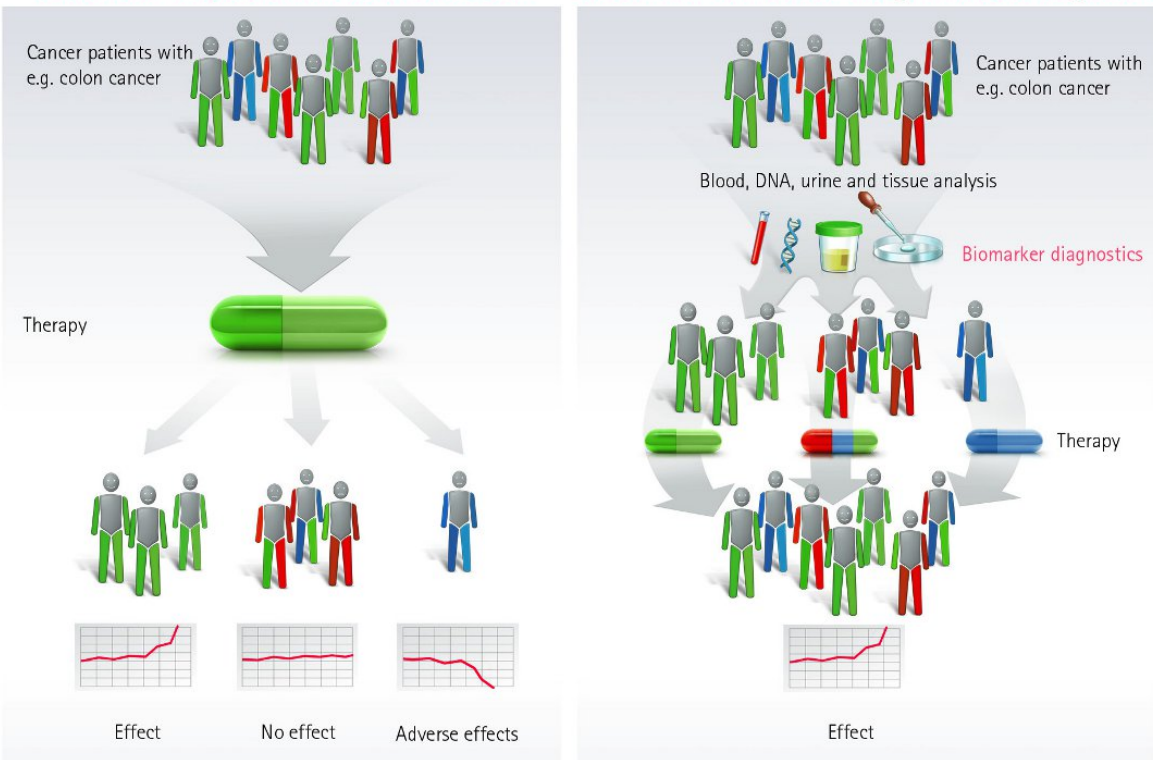
THE NORWEGIAN PRESIDENCY 2017



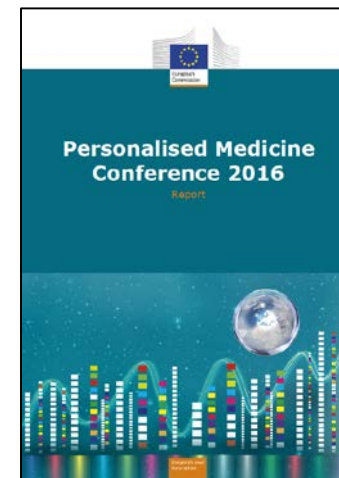
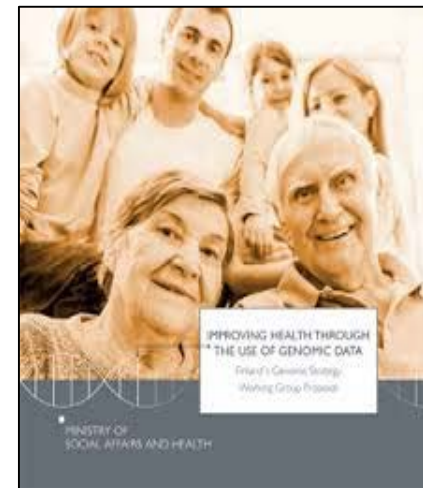
Personalized medicine: tailored treatments

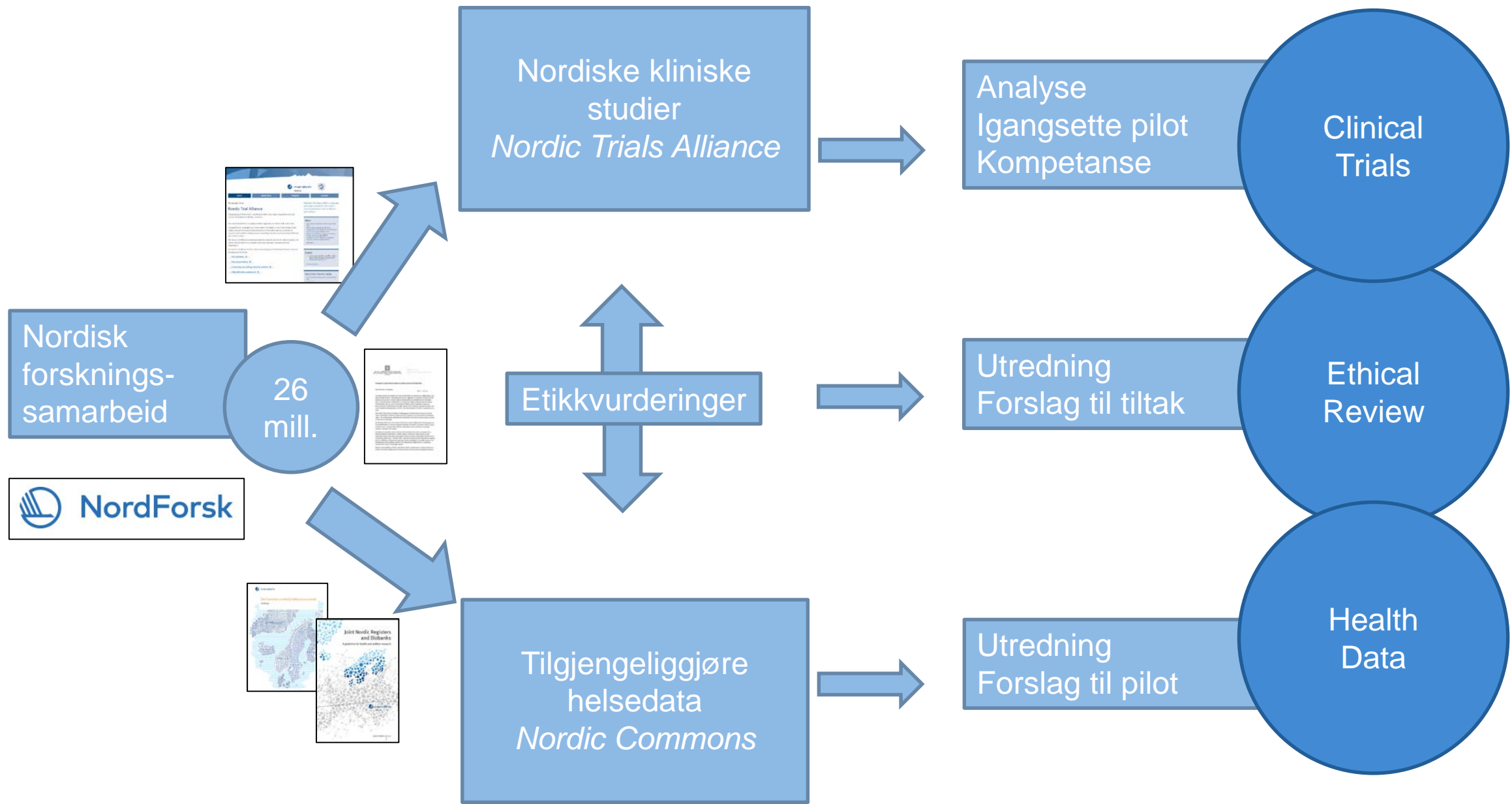
Medicine of the present: one treatment fits all

Medicine of the future: more personalized diagnostics

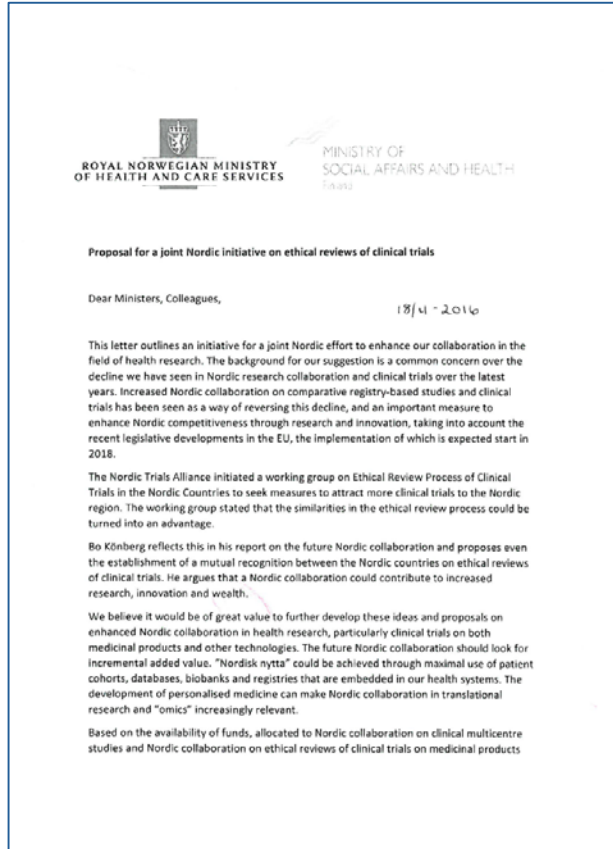


Different people respond differently to the same therapy: while one treatment brings about the desired success in one group of patients with e.g. colon cancer, it does not change the condition of other groups at all, or even leads to adverse effects (left). The reason: the genetic makeup and metabolic profile of each individual patient influences the effect of a drug. Personalized medicine takes these individual patterns of cellular and metabolic products into account in the diagnostic phase: **biomarker diagnostics** separates patients into groups with similar characteristics, and provides information on the best individual treatment. This should enable all patients to benefit from their own, "personal" therapy.





Project 1: Explore models for more efficient ethical reviews



Felles verdigrunnlag – ulik organisering



WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964
and amended by the:

29th WMA General Assembly, Tokyo, Japan, October 1975

35th WMA General Assembly, Venice, Italy, October 1983

41st WMA General Assembly, Hong Kong, September 1989

48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996

52nd WMA General Assembly, Edinburgh, Scotland, October 2000

53rd WMA General Assembly, Washington DC, USA, October 2002 (Note of Clarification added)

55th WMA General Assembly, Tokyo, Japan, October 2004 (Note of Clarification added)

59th WMA General Assembly, Seoul, Republic of Korea, October 2008

64th WMA General Assembly, Fortaleza, Brazil, October 2013

Preamble

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.

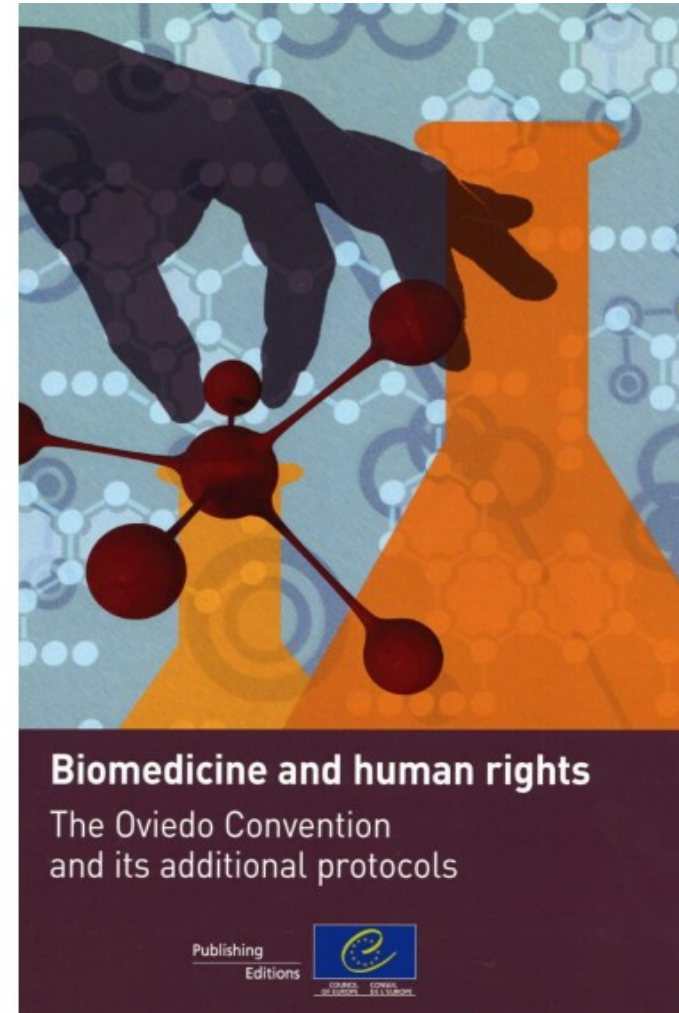
The Declaration is intended to be read as a whole and each of its constituent paragraphs should be applied with consideration of all other relevant paragraphs.

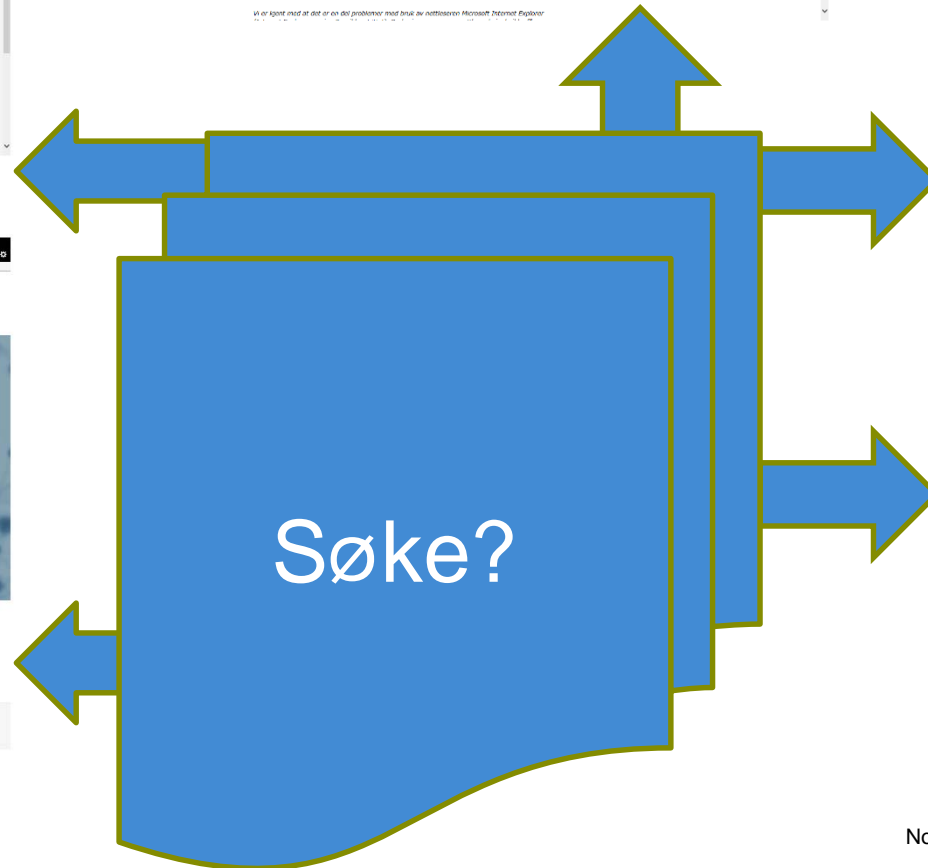
2. Consistent with the mandate of the WMA, the Declaration is addressed primarily to physicians. The WMA encourages others who are involved in medical research involving human subjects to adopt these principles.

General Principles

3. The Declaration of Geneva of the WMA binds the physician with the words,

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Forslag i rapporten

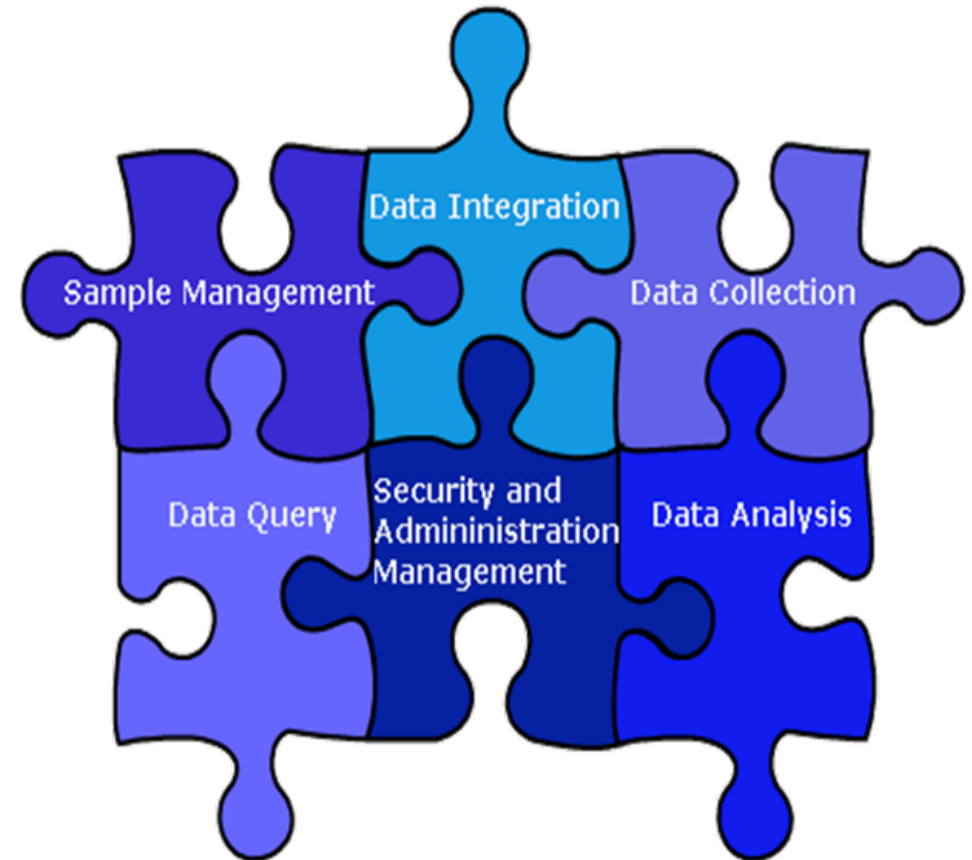
1. Nordisk informasjonsportal
2. Godta søknader på engelsk
3. Standardisering av søknader, protokoller mv
4. Single entry point – en komite koordinerer for alle
5. Koordinering av søknadsportalene
6. Felles søknadssystem

Project 2: Virtual Nordic centre for health registries



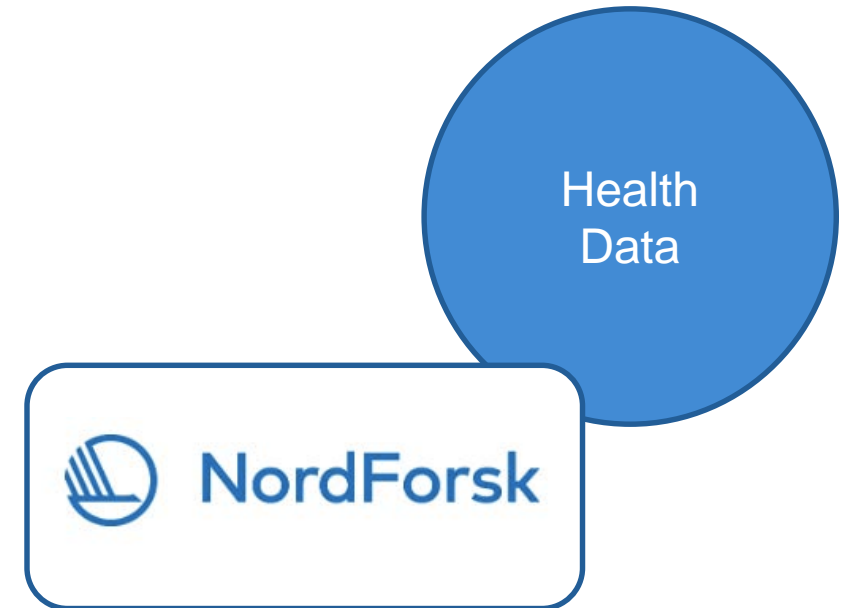
Hindre for integrasjon og bruk av datakilder på tvers

- Mange dataeiere
- Ulik regulering og praktisering av regelverket
- Varierende dokumentasjon og metadata, ulike standarder og begrepsbruk.

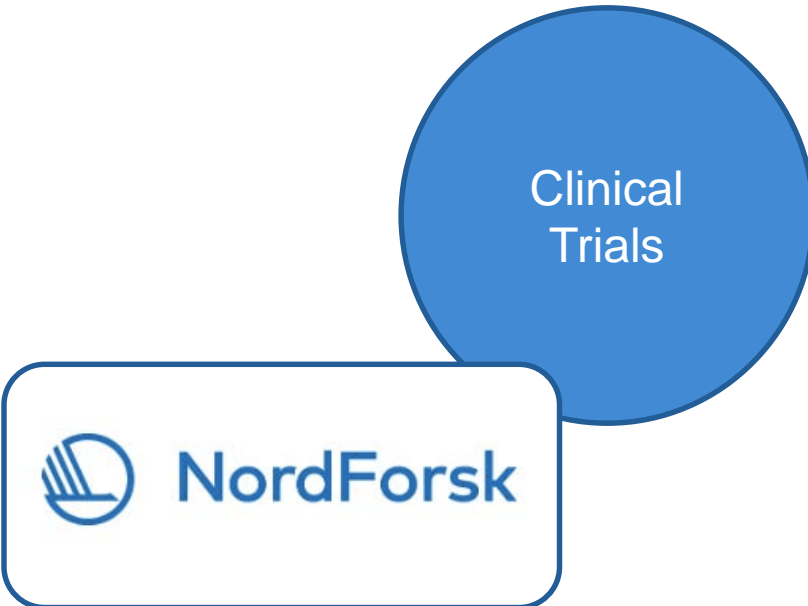


Leveranser delprosjekt 2

- Status for hvert av de nordiske landene
- Vurdering av mulige fellesløsninger
- Forslag til teknisk pilot, inkludert budsjett
- Konkret handlingsplan for gjennomføring



Project 3: Further Develop Nordic collaboration on clinical trials through Nordic Trial Alliance



Le



Løfter persontilpasset barnekreftbehandling

24.11.2017

NordForsk og Kreftforeningen går sammen om en utlysning innen persontilpasset kreftbehandling for barn. Utlysningens budsjett er på minst 19 millioner norske kroner og blir gjort tilgjengelig i løpet av mars 2018.

r innenfor

lier i

Clinical
Trials



NordForsk



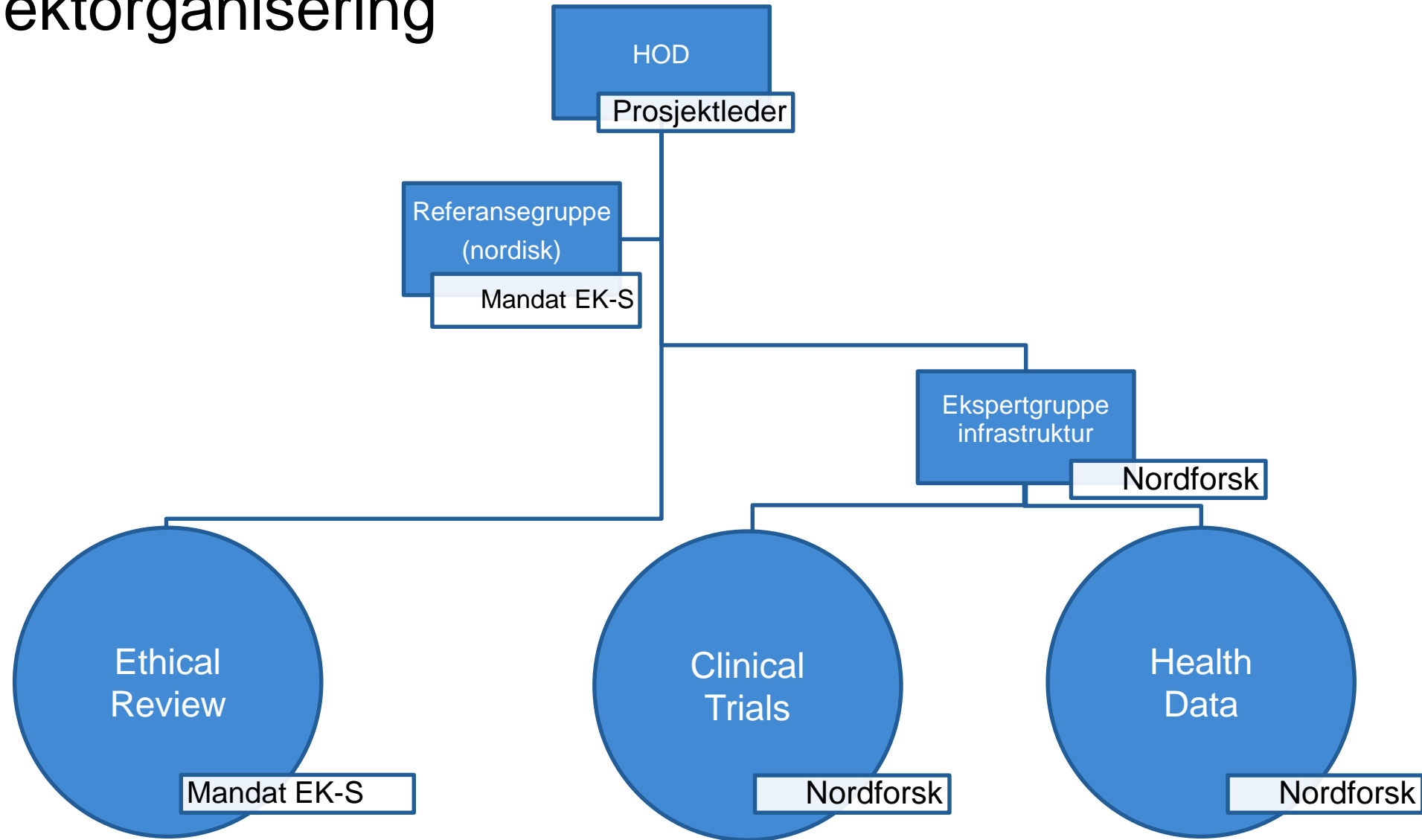
Project 3: Further Develop Nordic collaboration on clinical trials through Nordic Trial Alliance

- Ole Alexander Opdalshei, Norwegian Cancer Society (Chair)
- Marika Hellqvist Greberg, Clinical Studies Sweden
- Mia Bengtström, Pharma Industry Finland
- Pierre Lafolie, Karolinska Institutet and NTA 1.0

- Additional members are being invited and will be appointed
- Legal support

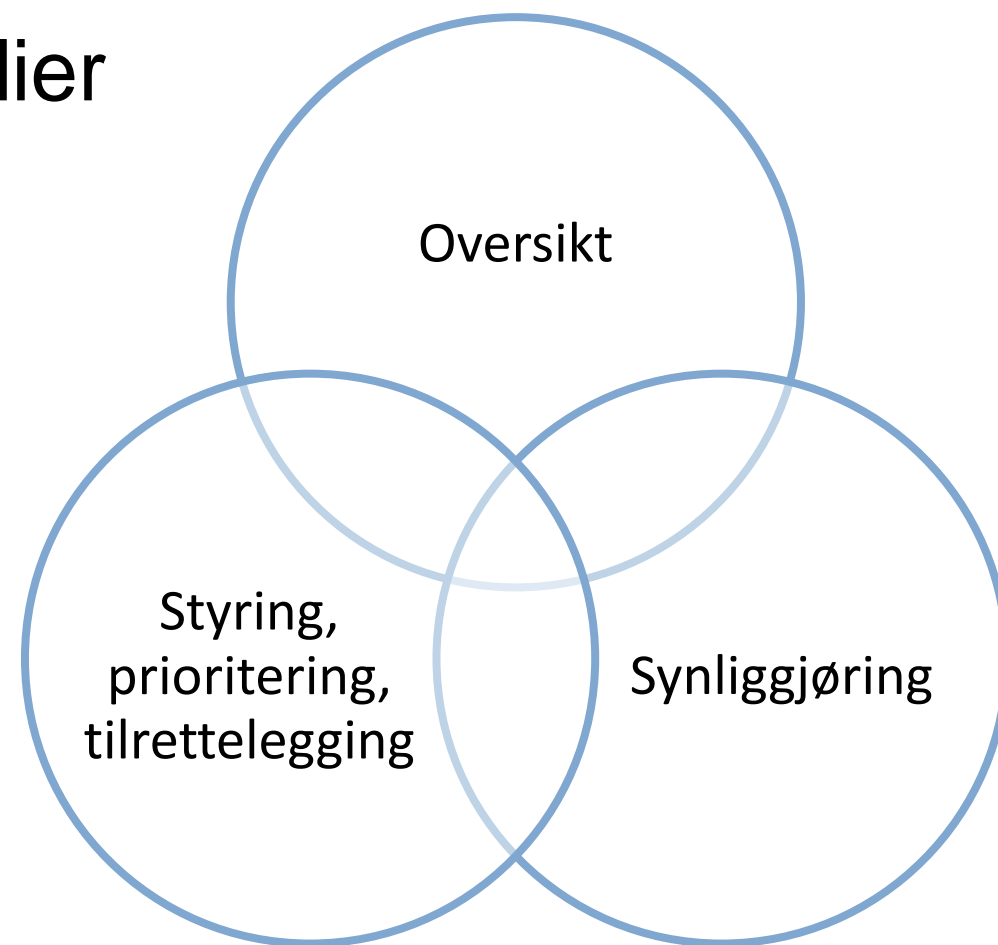


Prosjektorganisering



Indikator for kliniske behandlingsstudier og pasienter som deltar

- Alle kliniske behandlingsstudier
 - Legemiddelstudier fase I – IV
 - Andre kliniske studier
- Indiktatoren består av:
 - Faktor for oppstart av studie og koordineringsansvar
 - Faktor for antall pasienter (log)
- RHFene gitt oppdrag om prøverapportering i 2018



<https://www.regjeringen.no/no/tema/helse-og-omsorg/innsikt/helseforskning/innsikt/forskning-i-helseforetakene--organiserin/id585593/>



Stortingsmelding om helsenæring

 **Helse- og omsorgsdep** @helse_og_omsorg Following

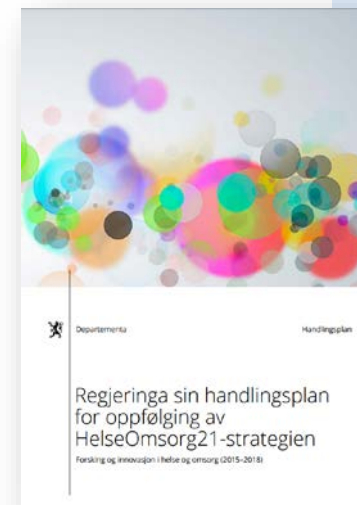
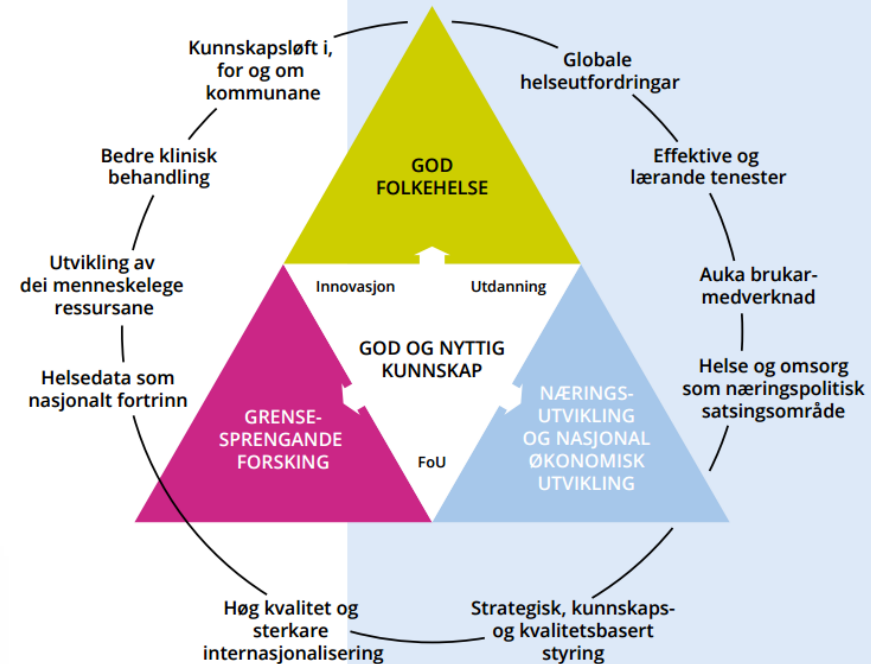
Bent Høie og Monica Mæland ber om innspill til stortingsmelding om #helsenæring 11.08. Strømmes direkte fra 9: regjeringen.no/no/aktuelt/pre ...

[Translate from Norwegian](#)



10:24 AM - 9 Aug 2017

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Takk!

Bildekreditering: slide 3: Bayer