



Norwegian University of  
Science and Technology

EHDS – Centralization of the  
HDAB function for population-  
based health studies – what  
are the risks?

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# Agenda

- EHDS – secondary use of health data
- The HDAB role
- Norwegian population-based health studies
- The HUNT Study
- HUNT as a HDAB?
- What are the risks for HUNT not having the HDAB role?

HUNT Research Centre

Norsk

The HUNT Study - a longitudinal population health study in Norway



The Trøndelag Health Study (The HUNT Study) is one of the largest health studies ever performed. It is a unique database of questionnaire data, clinical measurements and samples from a county's inhabitants since 1984.

The HUNT Study is well-known in the county of Trøndelag, with high participation rates, providing a good base for further health surveys in the county and an excellent research environment.

Today, HUNT Research Centre has a database with information on 250,000 people, and has been certified in [conformity with NS-EN ISO 9001:2015](#) since 2011.

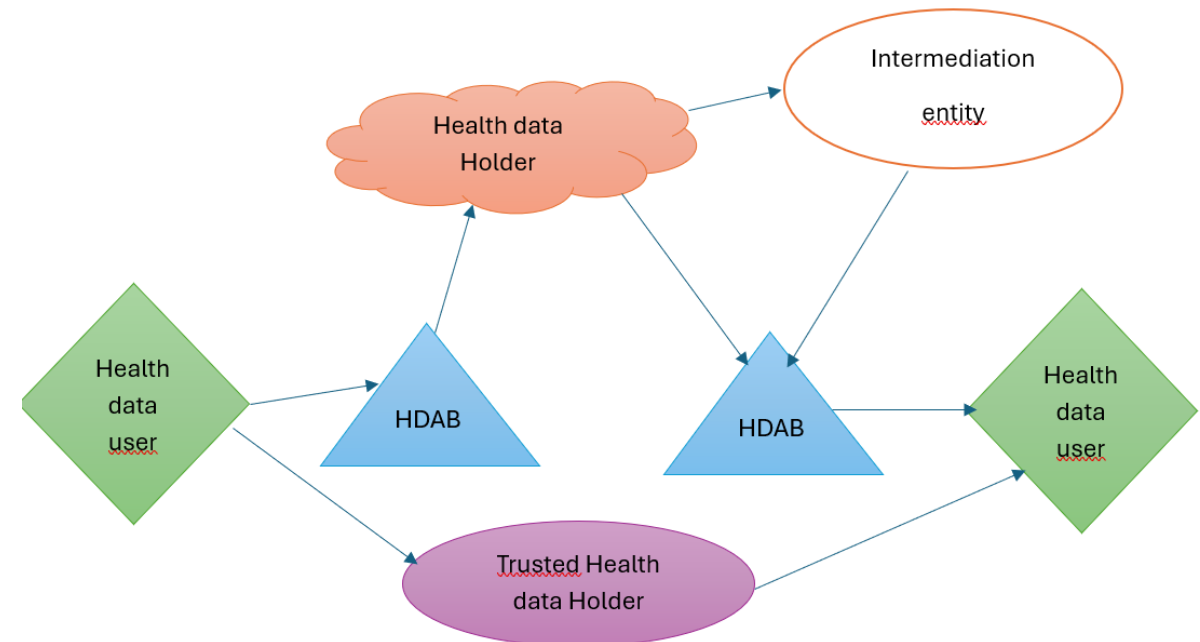
# EHDS – Secondary use of health data

## The EHDS

- Establishes a common framework and data infrastructure for sharing health data for secondary purposes such as research, innovation and policymaking within the EU/EEA.
  - Harmonized rules for easier access to health data
- And aims to:
  - Facilitate for research and innovation by making more health data available for secondary use.

## Roles:

- Health data access Body
- Health data holder
- Trusted Health data Holder
- Health data Intermediation entities



# The HDAB role

- Art. 55 nr. 1 – member states shall designate one or more health data access bodies responsible for carrying out the tasks set out in Articles 57,58 and 59.
  - Main responsibilities:
    - Decision-making authority - decide to give access and permits to applicants
    - Ensure that data is made available anonymized or pseudonymised within 3 months of application
    - Publish dataset catalogues and provide public transparency by informing natural persons.
    - Liaise with health data holders, request data and support them.
    - Avoid conflicts of interest and have the necessary qualifications, experience and skills.
- Centralization of the HDAB role or not?
  - Upsides?
    - One professional institution that handles all the requests, equal treatment and professionalized system with standards and technological requirements – could be easier to fulfill EHDS requirement of standard common process for issue of permits?
  - Downsides?
    - Do not have the same needed knowledge of the datasets or the geographical closeness
    - Access could take more time
- Could you partially centralize?
  - Depending on the type of data and the existing infrastructure?

# Norwegian population-based health studies



- Norwegian law differentiates between consent-based and non-consent-based health data registries.
  - One type of consent-based-registry are population-based health studies.
  - Regulation of population-based health studies
- During the period of 1974 till today, there have been several large population-based health studies carried out.
  - The data collected are available for researchers through application and have been used in large amounts of research projects both nationally and internationally.
  - SAMINOR, The Tromsø Study, The HUNT Study



SAMINOR - The Population-based Study on Health and Living Conditions in Regions with Sami and Norwegian Populations



The HUNT Study

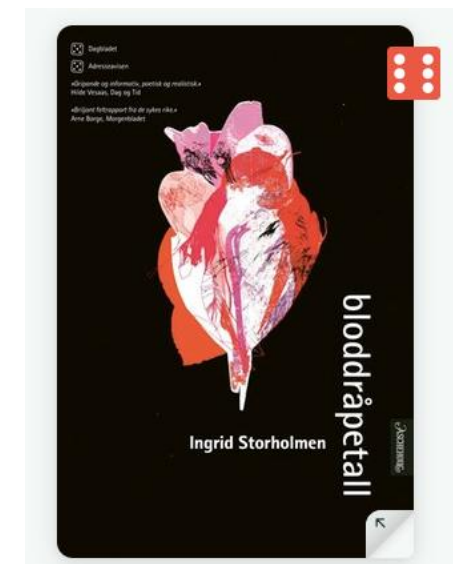
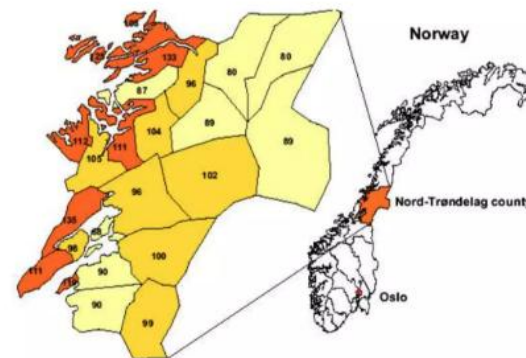


# The HUNT Study

- Since the mid 1980's the HUNT study has collected both health data and biological samples from more than 250 000 participants that come from the local areas of North-Trøndelag.
- The study has gained enormous popularity among the locals and enjoys great trust, which has contributed to high participation.
- Today, HUNT consists of a databank and a biobank
  - With data of enormous value to researchers both in Norway and abroad.



HUNT Databank



# HUNT as a HDAB?

- What does HUNT do today?
  - That the decision-making authority is granted to the local administrator.
    - 70 applications per year and 400 applications for changes to existing projects.
    - 30 application for health data for student essays
  - A tight connection between the databank and the biobank
    - Over 20% of all applications include use of biological material.
  - Over 40 years of knowledge and expertise on administration of health data
    - Built up a solid infrastructure that makes sure HUNT is compliant with necessary legal basis.
    - Built up strong and specialized professional research environments
    - Proximity between the collection of data and the decision-making authority
    - Median time of one week to process an application, and median time of one day to release data. 90% of all applications are processed completely within 2 weeks.
    - Pseudonymisation of Health data.
  - Tight connection to both clinical and research environments at the local hospitals and within the university.
    - Strong focus on the reuse of all data and high quality and continuity

# HUNT as a HDAB

- Complete list of all data variables and databases available
- Availability given through secure spaces such as HUNT Cloud (SPE)
- Information on web-pages and also news letters showing the participants which research their data is a part of.
  - The feeling of participating in something important
- The opportunity to opt out by withdrawing their consent
  - The feeling of being in charge of their data
- Close connection between Health Data Holders and HDAB
  - Projects return datasets back to the databank for further use
  - Intermediation entity for other health data holders within the university sector?



# What are the risks of centralization?

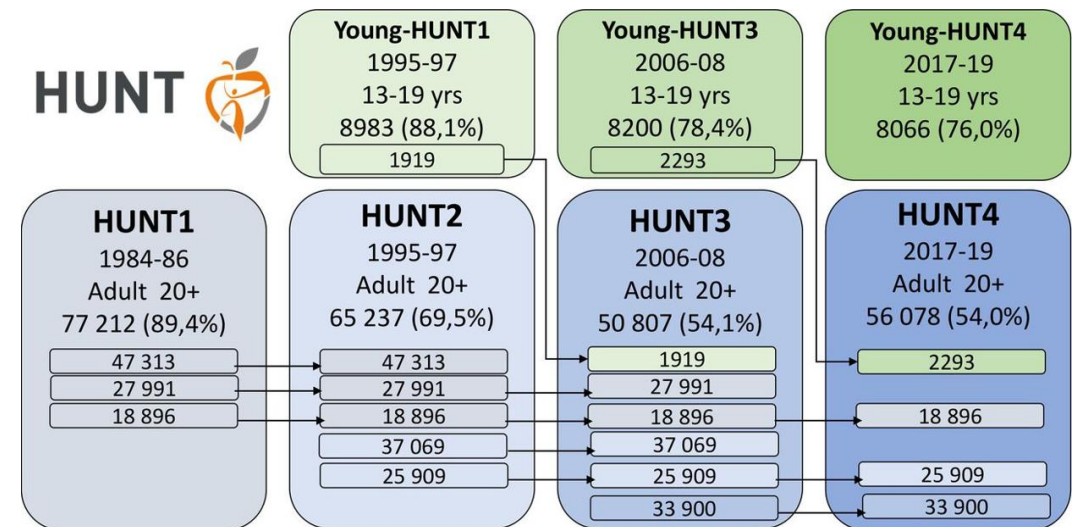
If a centralized HDAB function is chosen?

- HUNT will lose their local decision-making authority which could lead to:
  - Loosing the participants trust, more opting out and making it more difficult to recruit participants in the future as you lose the closeness and local connection between the participants and the study
  - The making of an unrealistic division between the biobank and the databank as one falls within the scope, and one falls out.
    - Difficulty handling the opt-out reservation right as consent is connected to both data and biological material.
  - The socio-economic costs could be large as you will have to destruct the existing infrastructure and build a new one somewhere else.
    - The expertise and knowledge from 40 years of building the infrastructure
  - It taking longer time to get access to data.
  - Needing to get new consents from all the participants which could lead to loosing them
    - Also, the consent is part of the legal basis for access, the knowledge and the possibility to make the necessary changes and information could be lost.

# The risks

- These risks indicate that a population-based health study such as HUNT must have the role of HDAB and be maintained as it is today.
- As the main purpose of the HUNT Study is to make health data available in a secure manner for socially beneficial research, they are already within the overall goal of the EHDS.

- They already fulfill the main responsibilities
- And the cost of building down the expertise and infrastructure is higher than the cost of making HUNT a HDAB



- Worst case – lose some of the most valuable Health data we have!