



**SIMSAM five first years and beyond
Umeå, 5 November 2013**

Register research in Denmark

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[Comorbid diseases interact with breast cancer to affect mortality in the first year after diagnosis-a danish nationwide matched cohort study.](#)

Ording AG, Garne JP, Nyström PM, Frøslev T, Sørensen HT, Lash TL.
PLoS One. 2013 Oct 9;8(10):e76013. doi: 10.1371/journal.pone.0076013

[Birth Defects After Early Pregnancy Use of Antithyroid Drugs: A Danish Nationwide Study.](#)

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J Clin Endocrinol Metab. 2013 Oct 22. [Epub ahead of print]

[Genetic and familial environmental effects on suicide - an adoption study of siblings.](#)

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Danish Civil Registration System (CRS)

Danish Cancer Registry

Danish National Registry of Patients (NRP)

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Danish Civil Registration System

Medical Birth Register

Prescription Register

Danish National Hospital Register (DNHR)

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Danish Adoption Register

Danish Civil Registration System (CRS)

Cause of Death Register

Psychiatric Discharge Register

[Impact of technology on cytology outcome in cervical cancer screening of young and older women.](#)

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Danish Civil Registration System (CRS)

Danish Pathology Register (Patobank)

Danish Cancer Register (DCR)



REGISTERS AND LEGISLATION

1943: Death Register,
1943: Cancer Register
1964: Employment Register
1968: Population Register, CPR
1970: Census with CPR-numbers
1973: Medical Birth Register
1977: Hospital Discharge Register
1978: Breast Cancer Register
1981: Health Insurance Register
1981: Education Register
1995: Prescription Register
1996: Pathology Register

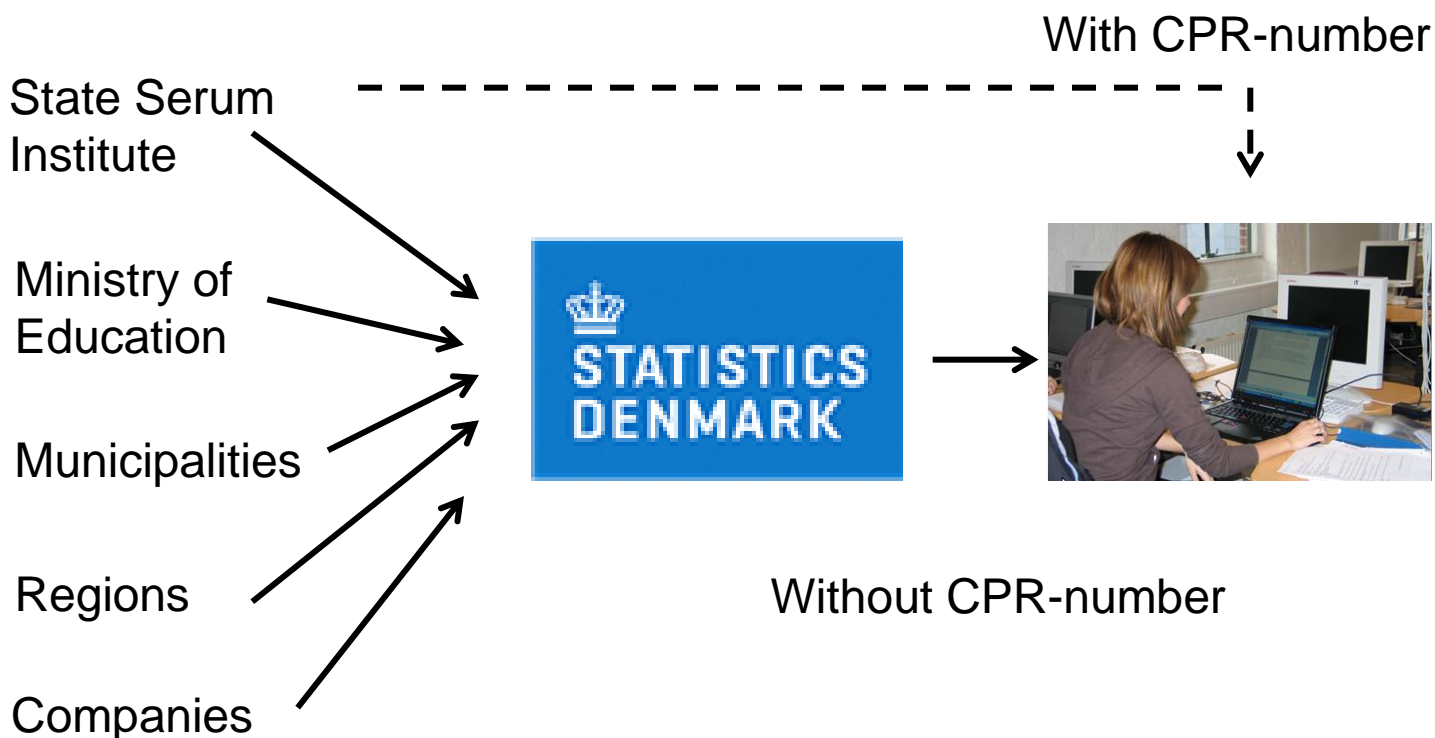
According to Danish legislation, notification to the Danish Data Inspection Agency serves as ethical approval of registry-based research projects in which no contact is made to patients, their relatives or treating physicians.



REGISTER BASED RESEARCH

- 1986:** Statistics Denmark starts “ON-SITE” access for researchers. Researchers have direct access to all databases in Statistics Denmark, provided they use computer in Statistics Denmark (Copenhagen or Århus). Access encompasses health registers as these are provided by National Board of Health to Statistics Denmark.
- 1993-2000:** In parallel with on-site access, possibility to send programmes to Statistics Denmark and to have the output sent back.
- 2000:** Statistics Denmark starts “ON-LINE” access for researchers. Researchers have direct access to all databases in Statistics Denmark (including health registers) from own computer, provided security has been approved by Statistics Denmark.
- 2001:** Ministry of IT & Research issues “Register research, Unique Danish possibilities”.
- 2002:** Ministry of Science, Technology and Development starts supporting computer time for researchers in Statistics Denmark and update/documentation of selected data bases, which means lower prices for researchers.
- 2012:** Health registers moved from National Board of Health to State Serum Institute.
- 2013:** Ministry of Research, Innovation and Higher Education issues “Register research, New possibilities and new challenges”.

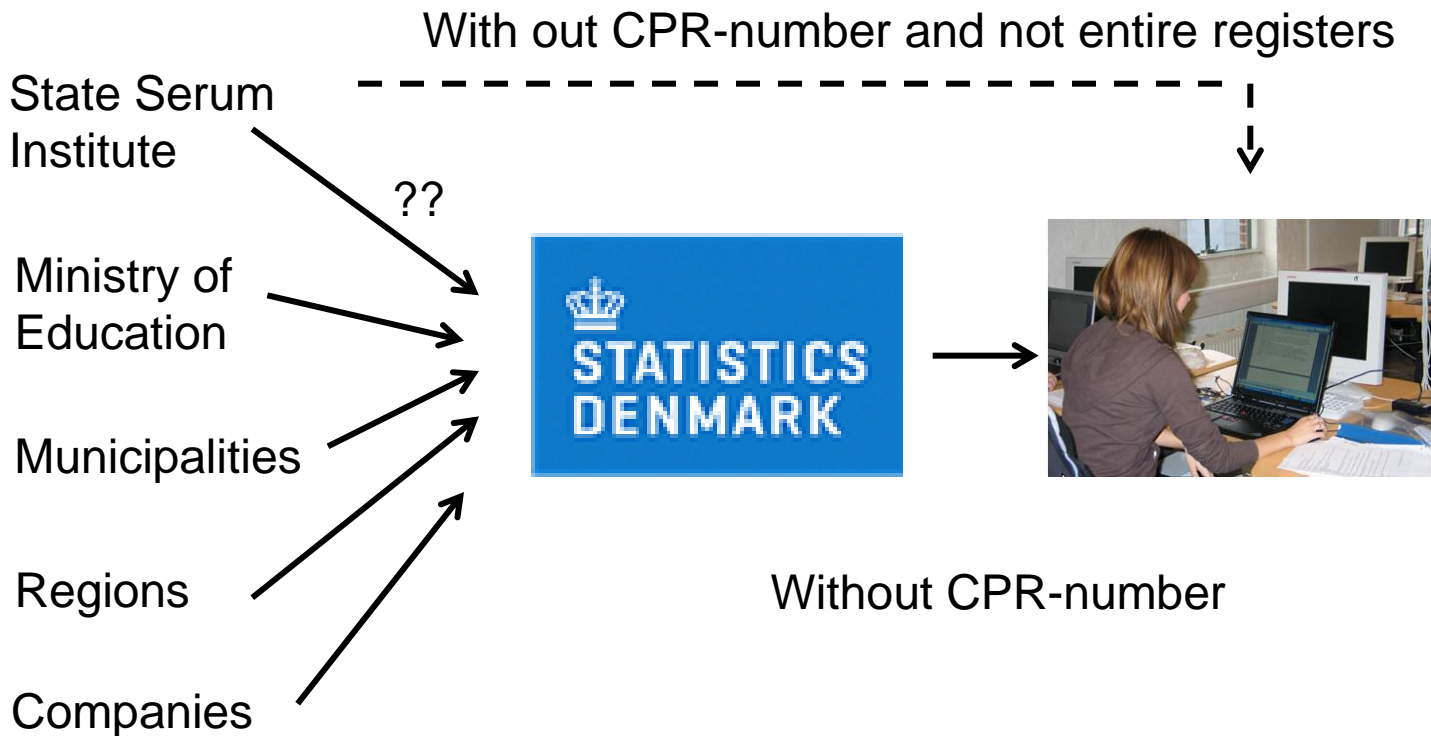
RESEARCH SERVICE AS IT HAS FUNCTIONED SO FAR



LAW ON STATISTICS DENMARK

- stk. 3. If a public authority or institute start collection and analysis of statistical data, Statistics Denmark has to be informed with the aim to negotiate on coordination
- § 6. Public authorities and institutions shall, within the frame of the working plan decided on by the Board of Statistics Denmark, when asked provide Statistics Denmark with their data
- The coordinating role of central statistical offices is expected to be strengthened in new EU regulation
- Andreas Georgiou, ELSTAT: “The situation is “surreal” he admits. “I am being accused of acting in accordance with both Greek and European law.”” NRC Handelsblad, 18 March 2013

RESEARCH SERVICE RECENT CHANGES





CONCERNS ABOUT RECENT CHANGES

- **No CPR-number:** Research on Statistics Denmark's server has been successful without access to CPR-number, but error check sometimes complicated
- **No CPR-number:** It is not possible to make small extra projects as data can not easily be linked up with other available data
- **Not entire registers:** A big problem for error check, as there can be even large errors in data retrievals. Not possible to check with previous official statistics data
- **State Serum Institute:** In contrast to Statistics Denmark and National Board of Health, the State Serum Institute is in itself an institution with a vast register-based research activity. Potential conflict of interest

21 September 2013



Registerforskning. Dansk forskning har vigtige styrkepositioner inden for analyser af registerdata. Disse positioner er i fare på grund af en yderst uheldig sammenblanding af interesser.

LÆS FLERE KRONIKKER PÅ [B.DK/DEBAT](#)

KRONIKKEN

Alvorlige hindringer for forskning

ALLAN FLYVBJERG, dekan og professor, Aarhus Universitet
PETER MUNK CHRISTIANSEN, formand for Det Frie Forskningsråd og professor, Aarhus Universitet
NIELS BORREGAARD, formand for Det Frie Forskningsråd for Sundhed og Sygdom og professor, Københavns Universitet

En registerforsker ønsker at gennemføre et simpelt studie af en psykisk lidelse. Forskeren skal for at kunne gennemføre studiet have adgang til data i sundhedsregistrene. Statens Serum Institut nægter i to omgange at give tilladelse og henviser til, at det ikke er godkendt, hvorfor man skal bruge oplysninger fra baggrundsbeholdningen, selvom det er indlysende, at man har brug for oplysninger om raske personer, hvis man skal studere risikofaktorer for sygdom. Registerforskerne har ikke tidligere mødt disse hindringer.

Andre registerforskere har af Statens Serum Institut fået afslag på en ansøgning om levering af data til et forskningsregister til hjertemedicinske undersøgelser til et projekt, som har kørt i flere år og som er godkendt af Datatilsynet ved projektets begyndelse. En sagsbehandler begrundede afslaget med, at mængden af data opfattes som en registerkopi, som af princip ikke



blev Statens Koordinerende Organ for Registerforskning (KOR) ikke hørt, og de danske universiteter blev heller ikke hørt.

Hvis forskersamfundet var blevet inddraget ville svaret nok have været en almindelig tilslutning til en samling af registrene med en betoning af vigtigheden af direkte og fleksibel adgang til data for hele den danske befolkning, men en alvorlig betænkelighed ved at overgive registerforvaltningen til en af aktørerne inden for registerforskningen.

Statens Serum Institut har selv registerforskning som et vigtigt område og konkurrerer med alle andre forskningsinstitutioner om midler til forskning fra bl.a. forskningsrådene, private fonde og udenlandske partnere. Der er hermed fare for, at konkurrencen får alvorlig slagside.

Ændringen har medført, at Statens Serum Institut nu bestemmer hvilke data, forskere for andre institutioner kan få adgang til efter, at de har indhentet Datatilsynets godkendelse.

Statens Serum Institut har som ny registerforvalter besluttet, at forskere fremover skal arbejde via instituttets forskermaskine, og at store datasæt ikke udleveres til forskere på de danske universiteter. Dette er et nyt princip i forhold til tidligere, og det har en række konsekvenser, der desværre er hæmmende for registerforskningen.

Som nævnt er der risiko for, at der opstår ulige konkurrence om forskningsmidler. Der er også en risiko for, alene ved registerforvaltningens indretning, at usaglige hensyn kan gøre sig gældende ved afgørelser om adgangen til registrene.

Noget af det vigtigste er dog, at denne måde at forvalte på hindrer danske forskere i fleksibelt at arbejde med store høj kvalitetsdatasæt til brug i udviklingen af forskningen til gavn for befolkningen. Der vil også være hindringer i retning af, at data ikke kan indgå ved deltagelse i en række internationale forskningsprojekter, hvor data skal analyseres sammen med data fra andre lande.

I processen har det været nævnt, at de opstrammede krav skulle være begrundet i hensynet til datasikkerhed. Der er dog ingen fortillende på, at danske forskere har kompromitteret datasikkerheden, og danske universiteter har noget af den højeste datasikkerhed i verden.

Forskersamfundet støtter naturligvis en sikker dataanven-

27-30 September 2013, sent out for hearing



Registerforskning

- nye muligheder og nye udfordringer



Styrelsen for Forskning
og Innovation
Ministeriet for Forskning, Innovation
og Videregående Uddannelser

Rapport fra udvalget for reorganisering
af registerforskningen

The report operates to a large extent with Statistics Denmark and the State Serum Institute as two parallel institutions for providers of service to register-based research. This is not in full accordance with the current situation, where this service is provided by Statistics Denmark.

26 September 2013



Strategisk Alliance for Register og
Sundhedsdata (STARS)

Ny strategisk alliance skal sparke gang i sundhedsforskningen

26-09-2013

PRESSEMEDDELELSE – Repræsentanter fra forskningsverdenen, patientforeningerne, erhvervslivet og sundhedsvæsenet samles i et nyt forum, der i fællesskab skal sparke gang i sundhedsforskningen og komme med anbefalinger til, hvordan Danmark bedst muligt kan bruge oplysninger i de nationale sygdomsregistre og den nationale biobank til at udvikle nye og forbedrede behandlinger til gavn for patienterne.

14 October 2013

Example of hearing response:

**Danmarks Forskningspolitiske Råds høringsbrev over rapporten
Registerforskning - nye muligheder og nye udfordringer**

Det er DFRs vurdering, at der ikke er behov for at opbygge en udvidet Forskerservice ved Statens Serum Institut, da den forskningsmæssige adgang til og kobling med Statens Serum Instituts register kan sikres ved, at Statens Serum Instituts registre leveres i kopi til Danmarks Statistik.

So, this is where we are for now in Denmark

It is the opinion of DFR that there is no need for an extended Research Service at the State Serum Institute, as researchers' access to and linkage with registers from the State Serum Institute can be ensured by provision of copies of the State Serum Institute registers to Statistics Denmark

INTERNATIONAL COLLABORATION

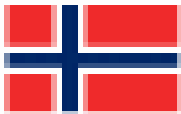
[Autoimmune, neurological, and venous thromboembolic adverse events after immunisation of adolescent girls with quadrivalent human papillomavirus vaccine in Denmark and Sweden: cohort study.](#)

Arnheim-Dahlström L, Pasternak B, Svanström H, Sparén P, Hviid A.
BMJ. 2013 Oct 9;347:f5906. doi: 10.1136/bmj.f5906

Denmark: Childhood Vaccination Database
Drug Prescription Register
National Patient Register

Sweden: Svevac
Drug Prescription Register
National Patient Register

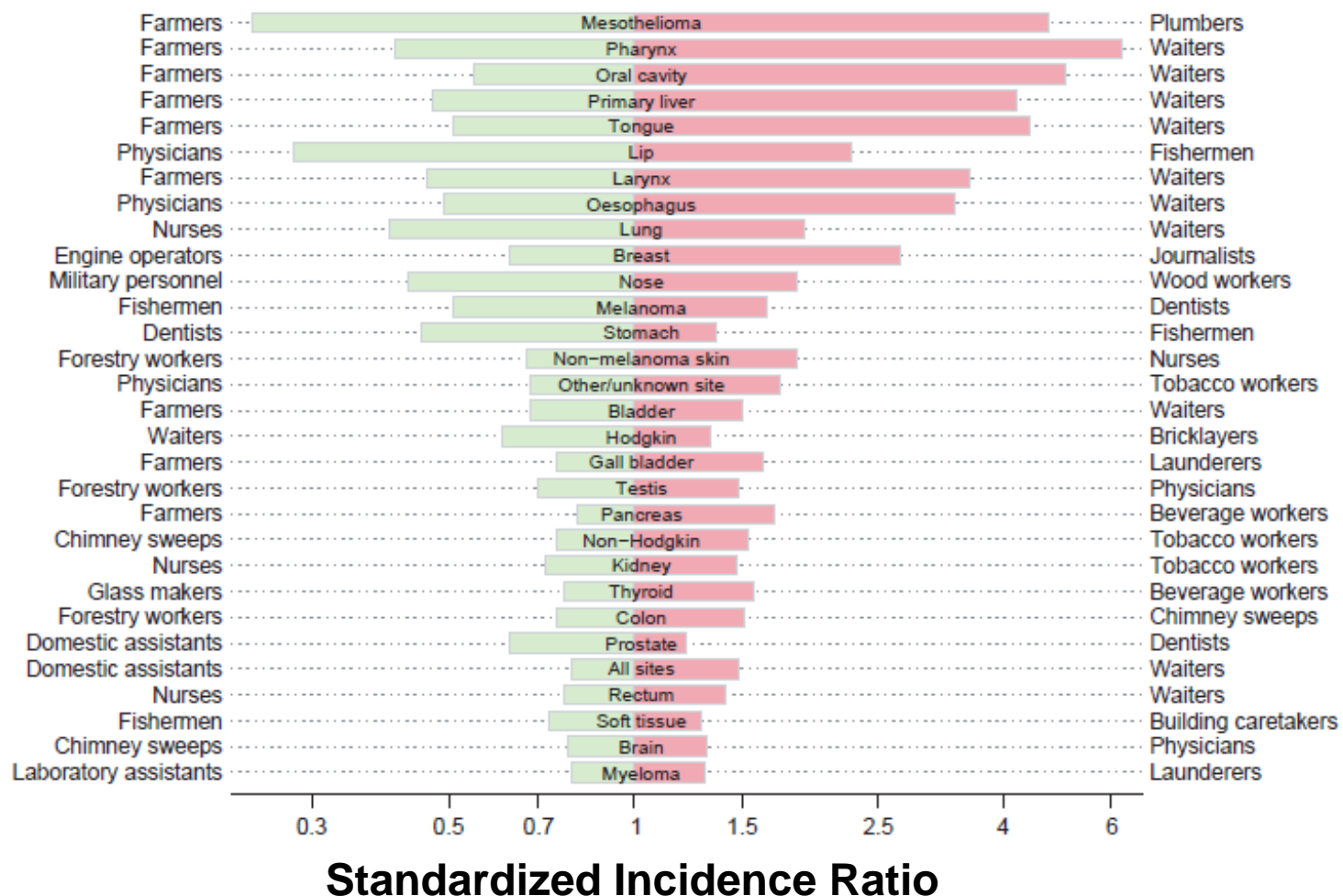
} Swedish data sent to Danish State Serum Institute. All data sent to Statistics Denmark for linkage with Danish socio-economic data and analysis.
[Hviid, personal communication, October 2013]



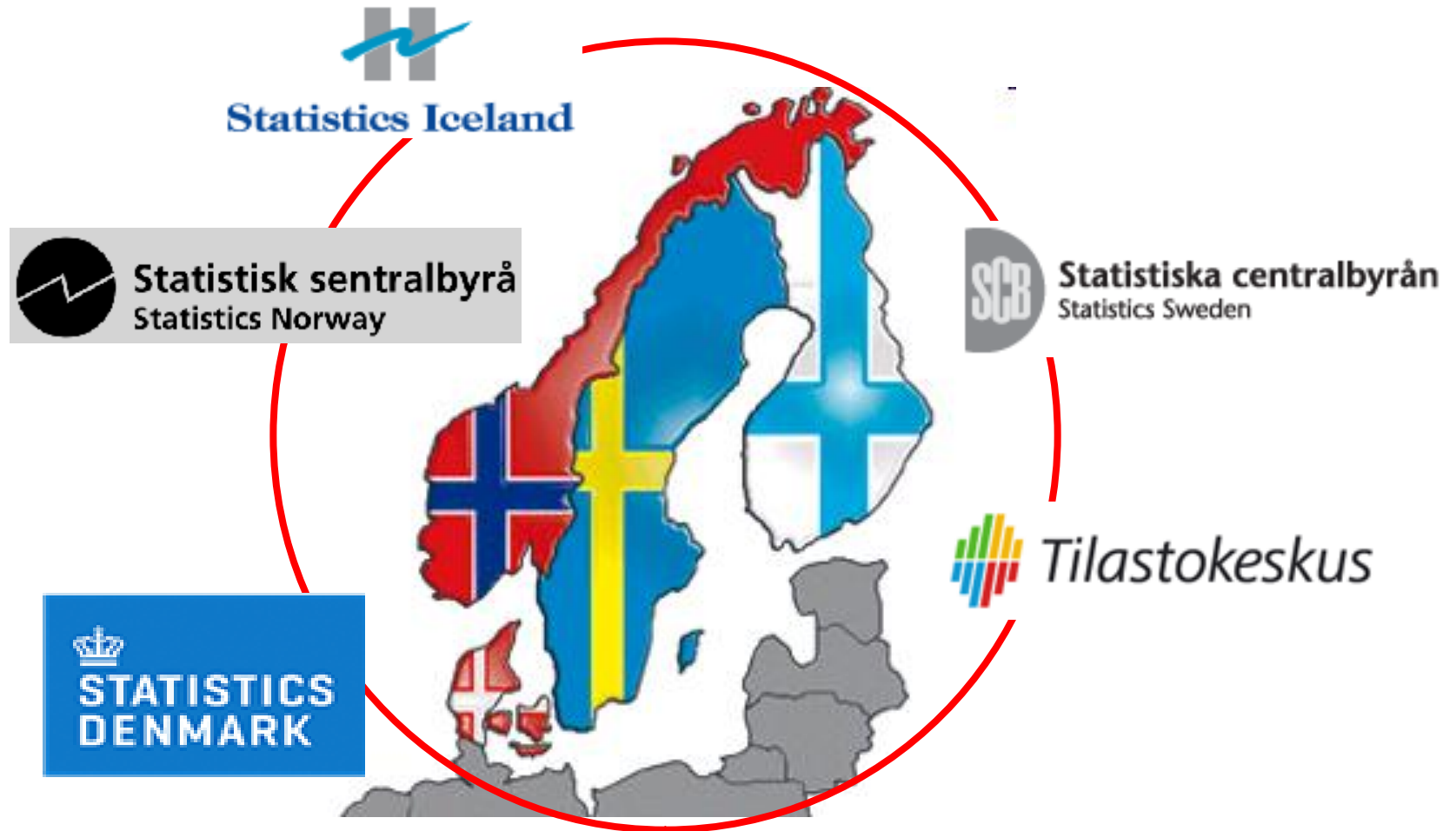
NOCCA

- Nordic Occupational Cancer Study (NOCCA)
- **NOCCA** includes up to 45 years of cancer incidence data by occupational category for the Nordic populations. The study covers the 15 million people aged 30-64 years in the 1960, 1970, 1980/1981 and/or 1990 censuses in Denmark, Finland, Iceland, Norway and Sweden, and the 2.8 million incident cancer cases diagnosed in these people in a follow-up until about 2005.
- **Norway, Sweden, and Iceland:** Individual, anonymized records provided to Norwegian Cancer Registry.
- **Finland:** Individual, anonymized records for all cancer patients and for 20% of population provided to Norwegian Cancer Registry.
- **Denmark:** Tables on person years and cancer cases provided by Statistics Denmark to Norwegian Cancer Registry.

NOCCA: socially discriminating cancers, men



NORDIC COLLABORATION - VISION





EU LEGISLATION

The Albrecht committee has got the acceptance from the EU Parliament on a text to be negotiated with the EU Council. To be finalised by April 2014

http://www.europarl.europa.eu/meetdocs/2009_2014/documents/libe/dv/comp_am_art_01-29/comp_am_art_01-29en.pdf

http://www.europarl.europa.eu/meetdocs/2009_2014/documents/libe/dv/comp_am_art_30-91/comp_am_art_30-91en.pdf

"Exemptions in the text will permit Member States to establish national rules for use of collected data (collected with consent) for other purposes than the one for which they were originally collected, provided that certain security measures are taken" DES Nyt Oct 2013

"This regulation does not regulate the work of intelligence services," said Albrecht. "Of course, national security is a huge loophole and we need to close it. But we can't close it with this regulation." Guardian, 17 Oct 2013



CONCLUSION

Register-based research has been **facilitated** in Denmark by:

- Liberal interpretation of EU directive (no ethical approval needed)
- Access to identifiable health records
- Access to entire registers
- Coordination in Statistics Denmark
- High discipline in research environment

Register-based research in Denmark are now **jeopardized** by:

- New EU regulation
- No access to identifiable health records
- No access to entire health registers
- Attempts to create parallel coordination in State Serum Institute

Thank you for your attention



Copenhagen Old Municipality Hospital, now part of University of Copenhagen