

SCAN-AED summary

The aim of the Nordic multi-registry study of antiepileptic drug teratogenicity (SCAN-AED) www.SCANAED.org is to investigate effects of antiepileptic drugs in pregnancy on maternal- and child health. The study uses Nordic health and socioeconomic register data linked at the individual level. We have drawn key variables from all pregnancies in the Medical Birth Registries in Norway, Denmark, Sweden, Finland and Iceland, and linked them to medication data from the Prescribed Drugs Registers, diagnostic codes from the Patient and Cancer Registries, as well as socioeconomic data from the National Statistical Institutes (NSIs).

Organization and funding

Researchers at the University of Bergen lead The SCAN-AED in collaboration with co-PIs from partner institutions in the other Nordic countries: Aarhus University Hospital, Aarhus University, Karolinska Institutet, Finnish Institute for Health and Welfare Finland (THL) and University of Iceland. Together the PI and the co-PIs form the SCAN-AED consortium. The main funder of the study is NordForsk.

Legal and practical issues

By using the Nordic Microdata Access Network (NordMAN, www.nordman.network), it is possible to transfer NSI data to the research servers at Statistics Finland, Statistics Sweden or Statistics Denmark. However, the Danish legislation prevents transfer of Danish pharmacy data across national borders, as well as access to pharmacy data by personnel not employed by a Danish institution. As the SCAN-AED contains both NSI data and Danish pharmacy data, we have pooled our files at the Statistics Denmark server. The data manager at University of Bergen can access the server at Statistics Denmark by remote access. Only researchers employed by a Danish institution approved by the Statistics Denmark can manage procedures involving Danish medication data. These are stored at a separate server area at Statistics Denmark.

All SCAN-AED partners have signed a common Research Collaboration Agreement, which also includes a Data Protection Agreement. In addition, all partners have signed a bilateral Data Transfer Agreement with the Danish partner. The legal advisors at the universities and THL have drafted and negotiated the contracts. Each partner is a controller of their national datasets whilst the data are stored at their home institutions. However, after data transfer the Danish partner is the controller of the joint dataset. The individual partners have approved the Danish partner institution as the data processor. The Danish partner is the independent controller of all processing activities that the Danish Partner performs after receiving the data at Statistics Denmark, and the Danish partner is solely responsible for ensuring compliance with Data Protection Laws.

Each co-PI has applied locally for ethical approvals and data access. To gain data access, we needed ethical approval in Norway, Iceland and Sweden. The data inspectorate had to approve of the project in Finland and Denmark. A Data Protection Impact Assessment was required in all countries. After approvals were granted, the co-PIs submitted data access applications to the registry holders. For data from the NSIs, we used a joint Nordic application. The registry holders pseudo-anonymized the datasets and delivered them to the local applicants. We thereafter uploaded the files to the Statistics Denmark server and pooled them before statistical analyses.

Necessary legal documents and applications (2019)	Requestor/point of contact	Applicant	Countries
Common Research Collaboration Agreement	Signatures by Institutions and PIs	Draft and approval by University legal advisors	DK-NO-SE-FI-IS (joint)
Data Transfer Agreements	Signatures by Institutions and PIs	Draft and approval by University legal advisors	DK-NO, DK-SE, DK-FI, DK-IS (bilateral)
Data Protection Agreement	Local data inspectorates	National PIs	DK, FI
Data Protection Impact Assessment	Local Personal data protection officer	National PI	DK*, NO, SE, FI, IS
Ethical Approval	Local ethical committees	National PIs	NO, SE, IS
Data Access Applications			
Socio-economic data	NordMAN Network within the NSIs	Project PI	DK-NO-SE-FI-IS (joint)
Health data	National data holder(s)	National PIs	DK, NO, SE, FI, IS
Pharmacy data	National data holder	National PIs	DK, NO, SE, FI, IS

* Part of the Data Protection Agreement.

Abbreviations: Principal Investigator (PI), Denmark (DK), Norway (NO), Sweden (SE), Finland (FI), Iceland (IS)