

The background features a cluster of interlocking gears in various shades of blue and grey. Each gear contains a white icon representing a different aspect of health or medicine, such as a heart with an ECG line, a microscope, a person running, a bed, a glass, a scale, a person on a scale, a fish, a soccer ball, a document, a bone, and a pill.

SHARING OF SENSITIVE HEALTH DATA

– TWO PRACTICAL EXAMPLES –

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G20 DGI-2 Workshop on Recommendation II.20 “Promotion of Data Sharing”
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Personal Health Data

- Highly **sensitive** and specially **protected**
 - Creation of **absolute anonymity** not possible
 - Deeply phenotyped
 - **Living data sets** with need for continuous maintenance and update
 - Data usage based on **informed consent** of participants
- **Data protection and ethical issues essential**



Motivation for Data Sharing

- Not possible to **fully exploit potential** of research data obtained for projects with narrow focus and limited duration
 - Opportunity to investigate research questions that may not have been foreseen at time of project inception
 - Investigation of health risks and protective factors highly benefit from **large sample sizes**
 - Rare diseases
 - Small effect sizes (e.g., genetic risks)
 - Heterogeneous populations
 - Season effects (e.g., dietary and physical activity behavior)
 - **Record linkage** of special interest and with particular challenges
 - Use of secondary data to reduce burden of participants and recall bias
- **A matter of efficient use of resources**



IDEFICS – I.Family Cohort



Ahrens W, [...], Pigeot I, on behalf of the I.Family consortium. Cohort profile: The transition from childhood to adolescence in European children - How I.Family extends the IDEFICS cohort. *Int J Epidemiol.* 2017;46(5):1394-5j.



- **Multi-centre cohort study**
- **8 European countries**
- **Baseline 2007/2008:**
 - 16,228 children, 2-9.9 years
- **1st follow-up 2009/2010:**
 - 13,596 children, 2-12 years
- **2nd follow-up 2013/2014:**
 - 9,617 children, 5-17 years



Ahrens W, [...], Pigeot I, on behalf of the I.Family consortium. Cohort profile: The transition from childhood to adolescence in European children - How I.Family extends the IDEFICS cohort. *Int J Epidemiol.* 2017;46(5):1394-5j.



➤ IDEFICS study

- Enhance knowledge of health effects of changing diet & altered social environment & lifestyle of children, 2-9 years, in Europe
- Develop, implement & evaluate specific intervention approaches to reduce prevalence of diet- & lifestyle-related diseases & disorders

➤ I.Family study

- Make significant contribution to reduce burden of nutrition-related diseases
- Focus on individual and his/ her family
- Assess dynamic nature of causal factors over time and during transition into adolescence



- **Based on individual cooperation agreements**
 - Check whether intended usage in line with informed consent
 - Final decision by steering committee

- **Tailored analysis data set**
 - Constrained to variables needed for specific analysis (principle of data minimization)
 - Access via **Central Data Server** hosted by BIPS
 - Remote access (VPN, firewall-protected)
 - Individual password-protected user accounts
 - Access restricted to analysis data set
 - Download restricted to analysis results (summary statistics)



➤ Huge international pooling studies

- Example: NCD Risk Factor Collaboration (NCD-RisC)
- Usually based on **summary statistics**
 - Unified inclusion and exclusion criteria
 - Unified calculations



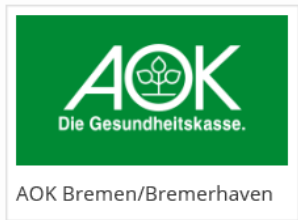
German Pharmacoepidemiological Research Database



Haug U, Schink T. German Pharmacoepidemiological Research Database (GePaRD). In: Sturkenboom MCJM, Schink T (eds). Databases for pharmacoepidemiological research. Cham: Springer. 2021. p. 119-124

Pigeot I, Ahrens W. Establishment of a pharmacoepidemiological database in Germany: Methodological potential, scientific value and practical limitations. Pharmacoepidemiol Drug Saf. 2008;17:215-23

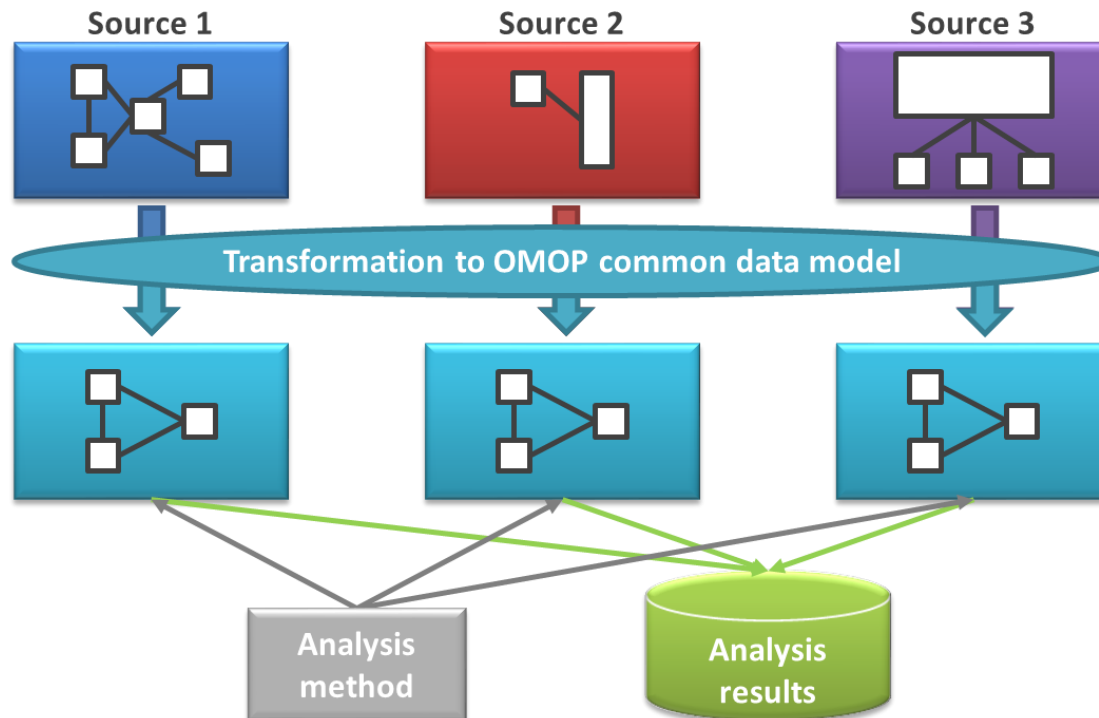
- **Claims data of ~25 million insurants**
 - 4 statutory health insurances: DAK, hkk, TK, AOK Bremen/Bremerhaven,
- Information on persons who have been insured with one of the providers since **2004** or later
- About **20% of German population**
- As of today: yearly data delivery (most recent 2018)
- **Coverage:** all geographical regions of Germany
- Contains **demographic information**, information on **hospital stays**, **outpatient visits** and **drug prescriptions**
- **National reference** for Germany



- Monitoring of drugs and vaccines after approval
- Analysis of
 - Drug and vaccine utilization, misuse in pharmaceutical therapy of certain indications
 - (Rare) drug/ vaccine risks
 - Drug/ vaccine risks with long latency periods
 - Drug-drug interactions
- Often only be possible in cooperation with international consortia
- Specific challenges in international projects
 - Social data particularly protected in Germany (Social Code Book X)
 - Data may not at all be analyzed outside BIPS (no remote access)

■ Concept:

- Transform data from different databases into common format and representation (terminologies, vocabularies, coding schemes)
- Perform systematic analyses using library of standard analytic routines based on the common format



- EU-project “Safety of non-steroidal anti-inflammatory drugs (NSAIDs)” (SOS)
 - Coordination: Erasmus University Medical Centre, Rotterdam, NL
 - 7th EU Framework Programme
- **Five population-based healthcare databases** from four European countries (Netherlands, Italy, Germany, UK)
- Revealed more **serious cardiovascular side effects** for Diclofenac than for other traditional NSAIDs

- **New safety warning by the European Medicines Agency (EMA)**
 - Diclofenac subject to the same safety precautions as selective COX-2-inhibitors

A photograph of a modern, multi-story white building with large glass windows and balconies. The word "BIPS" is mounted on the upper facade in large, blue, sans-serif letters. A blue sign on the left side of the building reads "Acherstrasse 30" and "BIPS". The sky is clear and blue.

BIPS

OUTLOOK

National Research Data Infrastructure for Personal Health Data



National Research Data Infrastructure

- Initiative of German Federal and *Länder* governments (German Joint Science Conference)
 - Based on recommendations of German Council for Scientific Information Infrastructures (RfII)
- Aims
 - Sustainable **securing, indexing and utilization** of research data via regional and networked knowledge repositories
 - Establishment of research data management according to **FAIR principles**
 - Connection and networking to international initiatives such as **European Open Science Cloud (EOSC)**
- **Budget**: 90 m€ per year (final stage)
- Up to **30 consortia** shall cover science landscape
- **First nine consortia** started in October 2020

NFDI4Health – Consortium

- Lead: ZB MED – Information Centre Life Sciences
- Co-lead: Leibniz Institute for Prevention Research and Epidemiology – BIPS
- Target data: Health data from registries, cohort studies, clinical trials, administrative health databases, epidemiological and public health studies
- 17 partners and 48 further participants
- **Vision:** To boost the scientific exploitation of personal health data



NFDI4Health – Aims

- To enable **findability** of and **access** to structured health data
- To maintain **federated framework** of data holding organisations
- To enable **privacy preserving exchange and linkage** of personal health data
- To develop **automated services** (e.g., use and access, analysis tools)
- To enhance **interoperability and reusability**
- To promote **use case oriented cooperation** between research communities

There is a strong argument to be made that leaving data unshared is an impediment to the scientists of the future.

Nature Communications Editorial



**Thank you very much for your
attention!**

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