The background features a cluster of light blue gears of various sizes. 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 soccer ball, a document with a pencil, a person running, a bed, a glass, a scale, a person on a scale, a fish, a microscope, a bone, and a pill bottle.

# SHARING OF SENSITIVE HEALTH DATA

## – TWO PRACTICAL EXAMPLES –

Iris Pigeot

Leibniz Institute for Prevention Research and Epidemiology – BIPS

G20 DGI-2 Workshop on Recommendation II.20 “Promotion of Data Sharing”  
25 March 2021

# 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

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 'Achterstrasse 30' and 'BIPS'. The sky is clear and blue.

BIPS

# 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

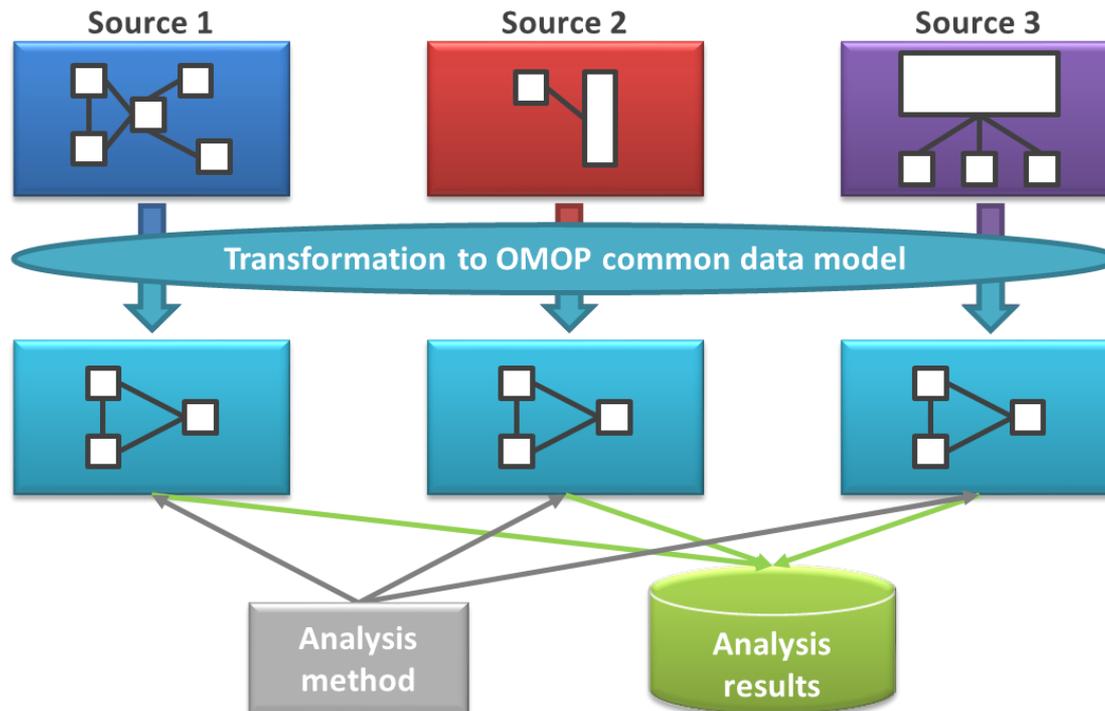
- **Claims data of ~25 million insurants**
  - 4 statutory health insurances: DAK, hkk, TK, AOK Bremen/Bremerhaven,
- Information on persons who have been insured with one of the providers since **2004** or later
- About **20% of German population**
- As of today: yearly data delivery (most recent 2018)
- **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

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## OUTLOOK

# National Research Data Infrastructure for Personal Health Data

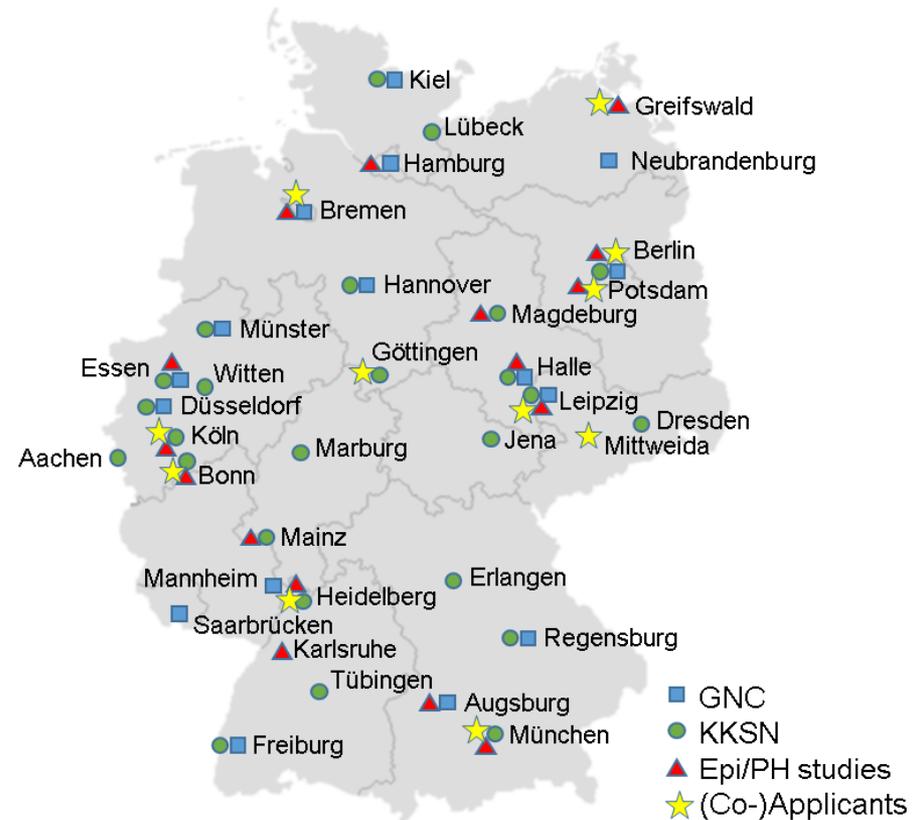


# National Research Data Infrastructure

- 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!**

[www.leibniz-bips.de/en](http://www.leibniz-bips.de/en)

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