German Pharmacoepidemiological Research Database (GePaRD)

Pharmacoepidemiological research is predominantly conducted on the basis of large routine databases (secondary data). These databases facilitate the investigation of the utilization and safety of drugs, including vaccines, in real-world healthcare settings and the investigation of rare or delayed adverse events. In so-called PAS studies (Post-Approval Safety Studies), these databases are used to investigate the utilization and safety of newly approved drugs. They also provide important data for research on other healthcare services.

Since 2004, the Leibniz Institute for Prevention Research and Epidemiology – BIPS has been working on the establishment and maintenance of the project-based German Pharmacoepidemiological Research Database (short GePaRD). GePaRD is based on claims data from statutory health insurance (SHI) providers and currently includes information on about 25 million persons who have been insured with one of the participating providers since 2004 or later. Per data year, there is information on approximately 20% of the general population and all geographical regions of Germany are represented.

In addition to demographic data, GePaRD contains information on drug dispensations as well as outpatient (i.e., from general practitioners and specialists) and inpatient services and diagnoses. starting with the year 2004. New data are added on an annual basis. Before data are entered into the GePaRD database they are pseudonymized and validated through numerous plausibility checks. The entire process from data delivery to availability for studies can take up to two years, i.e., data from the year 2020 cannot be used before the end of 2022.

Data Subsets and Variables

GePaRD is linked via the central pharmaceutical number (PZN) to information from a central pharmaceutical reference database (CPR) established at BIPS. The structure of GePaRD and of the CPR is displayed in Table 1.

Table 1: Structure and content of GePaRD and of the CPR

GePaRD				CPR
Core data	**Hospital data[$]**	**Outpatient data[$$]**	**Outpatient prescription data[$$$]**	**Pharmaceutical information**
– Entry/exit date – Sex – Year of birth – Marital status – Regional district – Nationality (German / not German) – Occupation – Insurance status (principal member/co-insured person) – Co-insured member (wife/child) – Family ID – Participation in disease management program – Reason for exit (e.g., death)	– Hospital ID – Date of admission/ discharge – Admission diagnosis/ discharge diagnoses* (ICD-10) – OPS codes (surgery, diagnostic procedures, non-surgical therapeutic procedures[#]) – Birth weight (infants < 1 year) – Reason for discharge (e.g., death)	– Physician ID – Physician specialty – Date of consultation – Diagnosis* (ICD-10) (on quarterly basis**) – Diagnostic certainty – Treatments[##] (claims code with date)	– Physician/pharmacy ID – Date of prescription/ dispensation – Central pharmaceutical number (PZN) – Dispensed quantity	– Central pharmaceutical number (PZN) – Generic name – Brand – Manufacturer – Packaging size – Strength – Defined daily dose (DDD) – Pharmaceutical formulation – ATC GM code[###]

** Hospital and outpatient diagnoses are coded using the International Classification of Diseases, version 10 - German Modification (ICD-10-GM) with at least four digits*

*** Outpatient diagnoses refer to a period of three months, as physicians' services are settled quarterly*

[#] Diagnostic and surgical/medical procedures are coded using the Operations and Procedures Coding System (OPS)

[##] Outpatient treatment / diagnostic procedures are coded using claim codes for outpatient services and procedures [Einheitlicher Bewertungsmaßstab, EBM]

[###] Anatomical Therapeutic Chemical Classification System, German Modification

[$] Provided to SHIs by hospitals

[$$] Provided to SHIs by regional associations of statutory health insurance physicians [Kassenärztliche Vereinigungen]

[$$$] Provided to SHIs by pharmacies' electronic data processing centers [Apothekenrechenzentren]

Legal Restrictions

Access to the database is granted only to BIPS employees within the framework of officially approved research projects. It is only permitted to give third parties access to the data in cooperation with BIPS and after signing an agreement for visiting scientists. Project approval is based on the authorization by the SHI providers and the respective governing authorities (e.g., the Federal Office for Social Security for national SHI providers). For this purpose, BIPS applies for project-specific permits from the SHI providers. Upon approval, the SHI provider requests official project approval from the governing authority. This may be issued in accordance with Section 75 of the German Social Code (SGB) X if the interest warranting protection of the person concerned is not affected or if the public interest in the research or planning significantly outweighs the interest in personal privacy. The process of approval by the SHI providers and the respective governing authorities may take several months.

Information obligations

When asking for approval of a study, BIPS is required to send a short study outline (the so-called ‘study proposal’) to the SHIs and the governing authorities. The study proposal includes a short background, the research questions, the study methods, the variables, the data years, the scheduled operational time of the study, and the sponsor of the study. On request, the authorities may also receive a copy of the service agreement between BIPS and the sponsor of the study.

As a prerequisite to use the data from SHI providers for research purposes, BIPS is obliged to regularly inform the SHIs and the regulatory authorities about the progress of the study and to provide them with the final study report. Upon demand and after informing the sponsor of the study, SHI providers whose data are analyzed as well as the authorities may also receive the study protocol. Furthermore, BIPS has the obligation to regularly inform its Scientific Advisory Board about the progress of the study.

BIPS performs its studies according to applicable regulations and guidelines, such as the guidelines for Good Pharmacoepidemiology Practices (GPP) and for Good Epidemiological Practice (GEP). According to these guidelines and the standards of the Leibniz Association, BIPS is obliged to disseminate all results of its research in literature and at relevant scientific congresses.

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