



# Unchaining Real-World Evidence in Germany

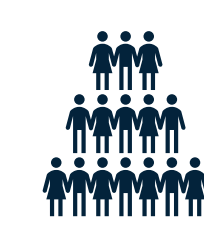
## A first look at the potential of a nationwide German Health Data Lab for outcomes research and data-driven market access strategies

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### What's on the Horizon with the German Health Data Lab?

## 90% of the German Population in One Database

- ▼ To foster the utilization of real-world data, the so-called “Forschungsdatenzentrum Gesundheit” (German Health Data Lab, HDL) is currently being set up at the Federal Institute for Drugs and Medical Devices (BfArM).
- ▼ The HDL will provide a comprehensive claims dataset of all approx. 74 million insured individuals in the German Statutory Health Insurance (SHI), representing about 90% of the German population.
- ▼ The operational launch of the HDL application portal is scheduled for early 2025.



**Representative nation-wide SHI claims dataset**



**Patient-level insights across care sectors**



**Advanced data analytics (incl. machine learning)**

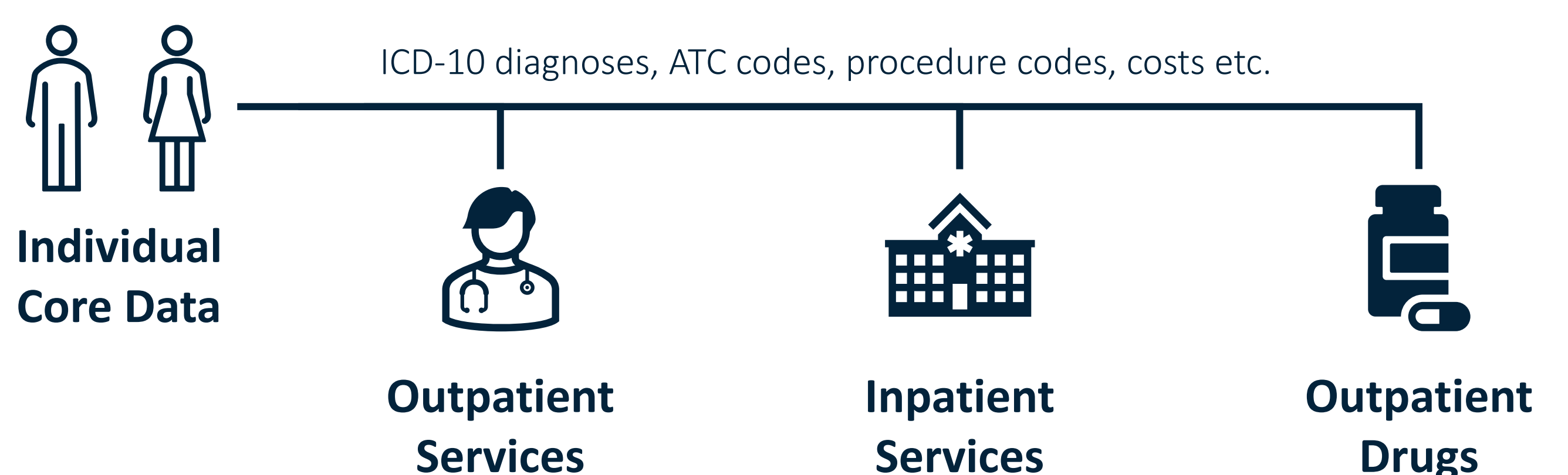


**Plannable 3-month application process**

### What's in the German Health Data Lab?

## Complete Longitudinal Patient-Level Claims Data

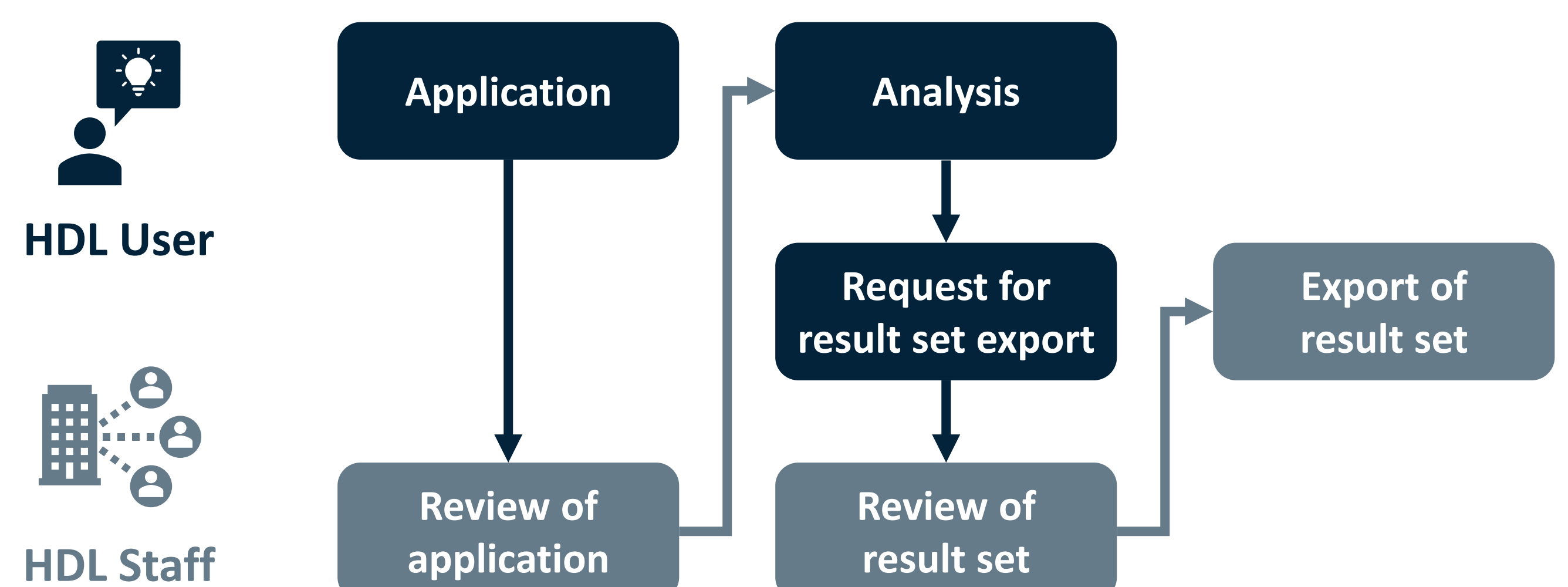
- ▼ At the start of the HDL, basic data will be available for the years 2009-2018. For more recent years, namely 2019-2022, the pseudonymized data will include detailed information on demographics of the insured persons, claimed outpatient and inpatient services (incl. diagnoses, procedures, costs) as well as outpatient prescription drugs (Data Model 3).
- ▼ The complete, legally defined dataset, including data on further care sectors such as medical devices or digital health applications, will be available beginning with the observation year 2023 (Data Model 4).
- ▼ In future, data will be enriched by a regular transfer of electronic health record data and links to other external data sources (e.g., registries).



### How to work with German Health Data Lab?

## Application Process and Working Environment

- ▼ Access to the data is governed by an application process that verifies a legitimate study purpose (e.g., epidemiological or health services research) as defined in German law. Anyone, including companies, can submit applications via the online portal.
- ▼ Applications must adequately explain the study objectives, the planned analyses (incl. schemes of results tables), and the data needed for the study. Processing of the application by the HDL will take approx. 3 months.
- ▼ After acceptance, the analyses can be performed by up to two users in a secure digital environment using either R or Python. Data outputs will be limited to 5 tables (max. 10 columns x 480 rows). A point-and-click tool for standardized analyses (e.g., disease prevalence) will be introduced in the future.



### How to benefit from the German Health Data Lab?

## Perspectives for HEOR and Data-Driven Market Access

- ▼ The HDL creates a unique source of representative real-world data from the German SHI system that is available to all public and private stakeholders given a legitimate study purpose.
- ▼ The data will include all relevant healthcare resource utilization, diagnoses, and costs. Patient-centered analyses will be possible across care sectors and over time, which allows for epidemiological, patient pathways, and comparative (e.g., matched cohorts) research on a nation-wide scale.
- ▼ Thus, for organizations that can handle the administrative and operational challenges, the HDL will bring health economics and outcomes research to a new level, enabling the development of data-driven strategies — in all phases of market access — in the most important pharmaceutical launch market in Europe

### Points to Consider



#### Timeframe

Application processing takes approx. 3 months.

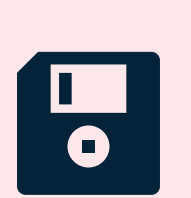
**Preparation and analysis time are in your own hands!**



#### Transparency

Application register publicly displays all HDL projects.

**Consider strategic implications!**



#### Resource Efficiency

Extent of HDL output is limited.

**Efficient analysis planning is key for effectively addressing research questions!**

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**Abbreviations:** ATC: Anatomical Therapeutic Chemical Classification, BfArM: Federal Institute for Drugs and Medical Devices, HDL: (German) Health Data Lab, ICD-10: International Classification of Diseases (Tenth Revision), OPS: Operation and Procedure Classification System, SHI: Statutory Health Insurance