
TaylorWessing

# Session #9

Webinar

18 September 2024

COFFEE BREAK
Life Sciences Start-ups

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# Data Protection for Life Sciences start-ups

*Unlock data treasures for better medical research and care*

18 September 2024 | Dr. Tim Schwarz | Phillip Heske

# Agenda



# A | Introduction

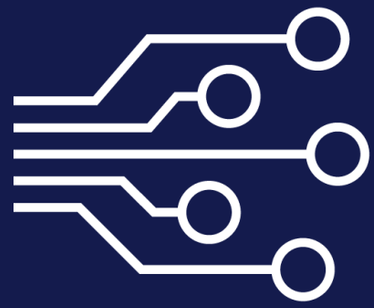
# Introduction

## Key assumption

***"Better use of health data is required** to unlock data treasures for improved medical research and care"*

## Everyone is striving to improve data usage:

- Researchers
- Patients
- Ethics committees
- Data protection authorities



# Use of health data and its challenges

**Chances:**

## Research & Development

- Unlock and access **real world evidence data** for better R&D purposes
- **Effectiveness testing** of healthcare treatment methods

## Better patient care

- **Diagnostic support** for HCP
- **AI systems** in medical care

**Major obstacles:**

**Uncertainty regarding data protection / lack of digital infrastructure**

- Data protection must find the balance between patient's right to privacy and the enormous potential of unlocking real world evidence data
- New legal framework for the sharing of health data and digitalization of healthcare

# B | Health Data and Data Protection

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# Key obstacles

## Healthcare companies struggling with

### Fragmented legal framework

(GDPR, Federal Data Protection Act (*BDSG*), federal state and hospital laws)

### German data protection authorities

- **Use** of health data is **essential** for R&D (cf. DSK, Petersberg Declaration of 24.11.2022)
- **Conservative approach** and **lack of pragmatism**; DSK is
  - Focus on patients' interests (right to self-determination)
  - High data protection requirements, especially for digital management systems for information, control and participation options

### Uncertainty as to when anonymization is sufficient

# Legal basis for processing health data

- Special data category with **sensitive information** including information about health status, medical history, and treatment
- **Prohibition** of processing health data unless an **exception** applies, such as medical treatment, consent or a statutory basisw

## Express consent

- Voluntary sharing of sensitive health data requires a **high degree of trust**
- **Shifting responsibility** to the patient
- High **administrative efforts** to obtain – specific, informed and unambiguous
- **Uncertain** for future – freely revocable at any time without giving reasons

Special form: **data donation** (mostly anonymized/pseudonymized)

## Statutory basis

- Processing in the context of **scientific research** purposes (= research privilege) **without** express consent
- **Responsibility of processor**, whether requirements are met
- **Contact** with data subject to authorize processing **not necessary**
- **Permanent** as long as requirements of statutory basis are met

# R&D privileges in GDPR

| | |
|---|---|
| **Special legal basis**<br>Art. 9 (2) lit. j) | ▪ **Opening clause** for proportionate provisions respecting data protection → § 27 BDSG<br>▪ **No express consent** required by data subject |
| **Change of purpose**<br>Art. 5 (1) lit. b) | ▪ **Restricted** purpose limitation<br>▪ Presumption of **compatibility of processing** for R&D purposes of data collected in commercial and other contexts |
| **Information obligation**<br>Art. 14 (5) lit. b) | ▪ Restricted insofar as provision of information involves **disproportionate effort**<br>▪ If data is **not collected directly** from data subject |
| **Right to erasure**<br>Art. 17 (3) lit. d) | ▪ Restricted insofar as the right is likely to render **impossible** or seriously **impair** purpose of processing<br>▪ Case-by-case consideration in context of **prediction** |
| **Right to object**<br>Art. 21 (6) | ▪ Balancing of interests does not apply in case of objection<br>▪ But restricted if relevant data is **necessary** for performance of a task in **public interest** |

# German legislation – § 27 BDSG

Note: Exceptions if special laws are applicable

*"*

*(1) […], the processing of special categories of personal data […] shall be permitted also **without consent** for scientific […] purposes, if such processing is **necessary** for these purposes and the **interests of the controller** in processing **substantially outweigh** those of the data subject in not processing the data. […]*

## Types of R&D

- Scientific research must be **interpreted broadly**
- **Transparency** of research process and results, **independence** and autonomy of researchers and goal of gaining knowledge in **public interest**
- Scientific purposes must not be **overridden by commercial purposes** or external directives

## Balancing interests

- **Increased requirements** in fulfilment of Art. 9 (2) lit. j) GDPR
- Interests of processing health company has to **substantially outweigh** interests of data subject
- **No lower or higher value** to certain research areas or projects per se

**Legal uncertainty is to detriment of healthcare companies → High fines if data is not processed lawfully**

# Appropriate safeguards

**Both GDPR and BDSG require appropriate safeguards for privileges**

Art. 89 (1) GDPR / § 27 (1) BDSG

Safeguards should be based on the state of the art, implementation costs, nature, scope, circumstances and purposes of processing, as well as the probability of occurrence and severity of the risks to the rights and freedoms of the data subject.

- **Technical and organizational measures** and related assessment procedure
- **Awareness** among those involved in processing operations
- **Restricting access** to personal data within the controller and processors
- Principle of **data minimization**
- **Pseudonymization** of personal data
- **Encryption** of personal data

# Outlook

**Pragmatic interpretation**

Data protection law is required to **promote innovation** and data protection authorities have to facilitate with their interpretation

**Legislative initiatives**

EU and national legislative acts have clear aim of **promoting innovative progress** in medical research and healthcare

**Momentum must be used for a paradigm shift in healthcare data protection**

# C | Health Data Spaces

# Overview

**A harmonized legal framework for the use and exchange of health data is required**

## EU examples:

- Denmark
- Finland
- France

## National examples:

- Data Integration Center (MII)
- RACOON

## EU Framework :

- European Health Data Space (EHDS)

# German Digitalization Strategy

## In 2023, BMG has published a comprehensive digitalization strategy

*// **Germany's healthcare system is decades behind** in terms of digitalization. We can no longer be responsible for this. That's why we're making a fresh start - **opening up electronic patient records for everyone**, ... and **facilitating research based on health data**. Modern medicine is based on **digitalization and data**. Using their advantages makes treatment better. //*

Federal Minister of Health, Prof. Karl Lauterbach

## Key cornerstones

**Digital Act**

Introduction of the electronic patient file „ePA“ for all, starting 2025 (§ 342 SGB V)

**Health Data Usage Act („GDNG“)**

Introduction of a data infrastructure for the use and exchange of health data for secondary purpuses

# German Health Data Usage Act

## Key facts

*"Act on the Use of Health Data for Research in the Public Interest and for the Data-Based Further Developments of the Healthcare System"* (*Gesundheitsdatennutzungsgesetz* – "GDNG")

- **Objective:** GDNG will **make health data available for public interest purposes**, such as research and digitization, including AI development
- GDNG provides a new harmonized framework for:
  - An infrastructure for the exchange of health data
  - Linking health data with cancer registries
  - Processing of health data for quality assurance, research and statistical purposes by HCPs
  - Evaluation of health data to identify health risks by health insurance funds

# German Health Data Usage Act

## Key facts

- GDNG anticipates and prepares for the **EHDS**
  - GDNG is similar to the **EHDS** - but is limited to Germany
  - GDNG will enable **connectivity** of the German healthcare system to the EHDS

# German Health Data Usage Act

**New infrastructure for the exchange of health data**

- § 3 GDNG creates a decentralized **health data infrastructure** with a central **Data Access and Coordination Office** at the BfArM acting as an **intermediary** between data holders and data applicants
- Data Access and Coordination Office maintains a **public metadata catalog** in which information on the health data available in the German healthcare system and the respective holders of this data are collected (§ 3 (2) no. 1 GDNG)
- **Billing and health data from the ePA** are transfered in pseudonymized and encrypted form by the German health insurance funds to the **Research Data Center** and made accessible (§§ 295b, 303b SGB V, 363 SGB V)
- For cancer research, the health data stored in the Research Data Centre can be **linked** with **data from clinical cancer registries** in pseudonymized form and made accessible (§ 4 GDNG)
- Patients can **opt-out** from the ePA data transfer to the Research Center

# German Health Data Usage Act

**Data access** can be requested by **anyone in the EU** for **permitted purposes** via the **Data Access and Coordination Office** (§ 303e SGB V)

**Permitted uses** include:

- **Quality improvement/ resource planning**
- **Scientific analysis/ research/ development**
- **Monitoring drug safety**
- **AI training and validation**

Requirements for **linking data** with cancer registries of the federal states:

- **Linking is necessary for the objectives of the research project**
- **Access authorization already granted**
- **Weighing of interests and risk assessment**

**Note:** According to the FDZ website, applications will be possible from fall/winter 2024.

The data is made available to the applicant as a pseudonymized (possibly anonymized) **individual data set**
Disclosure to third parties is **not permitted**

# German Health Data Usage Act

**Further processing by healthcare providers (§ 6 GDNG)**

- **Scope:** Use of legally stored health data by the healthcare provider for the permitted purposes of quality assurance, research and statistical purposes
- **Safety measures:** Pseudonymization / anonymization, data access and storage concept
- **Restriction on the disclosure of data:** Disclosure of health data to third parties only with consent, legal obligation or anonymization (legal basis for anonymization)
- **Transparency**
  - General privacy policy and
  - Specific privacy policy upon request of patient
- **No right of objection for patients**

# German Health Data Usage Act

**Data-based evaluation of health data by health insurance funds, § 25b SGB V**

- **Health insurance funds** can process health data they hold for the evaluation of specific health risks, such as
  - detection of rare diseases
  - detection of cancer
  - detection of serious health risks from drug therapies
- If a specific health risk is identified, the patient **must be informed**, §25b (4) SGB V.
- Patients have the **right to object**.

# German Health Data Usage Act

**Confidentiality obligations (§ 7 GDNG) and criminal law sanctions (§ 9 GDNG)**

- GDNG provides for statutory **confidentiality obligations**
  - Health data may only be used for permitted purposes and may not be passed on to third parties without authorization
  - Prohibition to establish a personal reference or for the purpose of identifying herlthcare providers
- GDNG provides for criminal law sanctions in the event of a breach of the aforementioned obligations

**New registrations and publication obligations (§ 8 GDNG)**

- Research projects with health data based on the GDNG without data subject's consent must be registered for clinical studies at the WHO
- Research results must be published within 24 months of the completion of the research project in anonymized form and in a manner accessible to the general public

# Questions and discussion

# Your Taylor Wessing Team

Tim Schwarz is a member of the Technology, Media & Telecommunications practice at Taylor Wessing and specialises in technology transactions and data protection law.

Tim focuses in particular on transactions driven by the use, licensing and exploitation of technology and intellectual property rights. In this context, he advises clients on the structuring and negotiation of a variety of complex technology transactions, including technology and asset acquisition, license, outsourcing, research, development, manufacture and supply, promotion, marketing, distribution, and services agreements.

Another focus of Tim’s consulting activities lies in the area of data protection law, where he advises on all aspects that may arise in the context of data security and privacy, with a strong focus on the healthcare, life science as well as the financial services industries.

Tim's clients include national and international technology, healthcare, financial services and Fintech companies at all stages of growth, from promising start-ups to industry-leading multinational public companies.

He has studied law at the Humboldt-University in Berlin and has acquired his doctorate in copyright law at the University of Freiburg.

Tim is a member of Deutsche Gesellschaft für Recht und Informatik (German Association of Law and Informatics).

**Languages**

- German, English

Recommended lawyer for IT-Transactions and Outsourcing, The Legal 500 2024
Especially highlighted for Data Protection law, Kanzleimonitor (diruj) 2019/2020 and 2020/2021


**Dr. Tim Jonathan Schwarz**

**Salary Partner**
**Munich**

**+49 89 21038-0**
**t.schwarz@taylorwessing.com**


Key areas of expertise

- IT & Telecoms
- Data Protection
- Copyright & Media Law
- Litigation & Dispute Resolution

# Your Taylor Wessing Team

Tim Schwarz is a member of the Technology, Media & Telecommunications practice at Taylor Wessing.

Phillip advises in the fields of AI, data, and software with a focus on transactions involving digital technologies. He represents clients at all stages of growth, from start-ups to industry-leading multinationals, in technology related disputes in and out of court, the development, use and licensing of proprietary and open source software as well as on the governance of complex technology transactions.

Phillip's clients include domestic and international companies from the technology and media industry, as well as in the life sciences sector.

He has studied law at the Georg-August University in Göttingen.

Languages

- German, English

**Phillip Heske**

**Associate**
**Munich**

**+49 89 21038-0**
**p.heske@taylorwessing.com**

Key areas of expertise

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- Data Protection
- Copyright & Media Law
- Litigation & Dispute Resolution

Europa > Mittlerer Osten > Asien

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