Collaborating for Digital Health and Care in Europe

# Study on the legal and organizational frameworks for delivery of healthcare services on distance

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## Agenda

1. *Context: telemedicine & (digital) healthcare in Germany*
2. *Organizational framework for telemedicine*
3. *Legislation and regulation for telemedicine*
4. *Ethical guidelines*
5. *Legal and ethical challenges to date*



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# 1. Context: telemedicine & (digital) healthcare in Germany



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# 1. Background information about Germany


(Pixabay, 2012)

| | |
|---|---|
| Capital and largest city | Berlin |
| Official language | German |
| Area | |
| • Total | 357,022 $km^2$ (137,847 sq mi) |
| • Number of federal states | 16 |
| Population | |
| • 2021 | 83.2 million |
| • Density | 232/$km^2$ (600.9/sq mi) |
| GDP (PPP) | 2021 |
| • Total (Per capita) | $4,743 trillion ($56,956) |
| • Health expenditure in GDP | 13.1 % |
| Life expectancy | Women 83.4 years<br>Men 78.6 years |
| Health care system | Bismarck Model (≈ 10.5% PHI) |

(Destatis, n.d.; Destatis, 2021; vdek, 2022)



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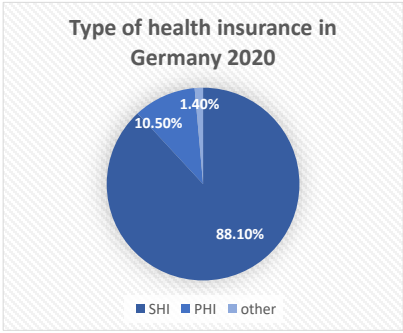
# The German healthcare insurance system largely consists of statutory health insurance based on the Bismarck model.

- **Dual health insurance system**:

| statutory health insurance (SHI) | private health insurance (PHI) |
|---|---|
| → apportionment procedure<br>→ assumption of costs | → capital cover method<br>→ reimbursement |

- **Statutory health insurance (SHI) based on the Bismarck model**
  - system: social insurance system
  - access to care: by employee & occupational status
  - financing: contributions of the insured
  - regulation: self-governance




(own representation according to: vdek, 2022)

(Gerlinger, 2017)



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# The German interpretation of the Bismarck model assumes free choice of health insurance and a regulated competition.

- **Statutory health insurance** (SHI): social health care system, based on the **Bismarck model**
- **Characteristics**: free choice of health insurance & regulated competition between health insurance

**Financing**:
- income-related contributions by employees (7,3%)
- same percentage by employers (7,3%)

→ + additional contribution (health insurance individual) → collected in the health fund

Payment of all health care services of the SHI-insured (independent of income and burden of disease)

(Bundesgesundheitsministerium, n.d. a; AOK-Bundesverband, n.d.)



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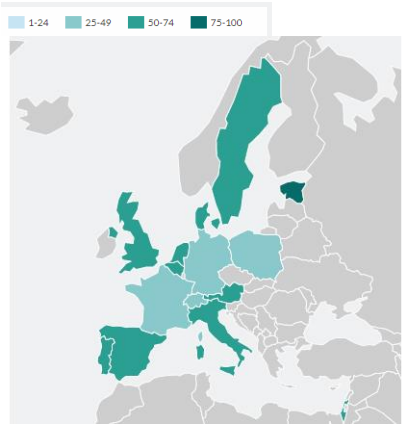
# Overall, Germany is one of the least digitalized healthcare systems in the OECD/EU.

| Country | Average of Index Ratings | Policy Activity Index Rating | Digital Readiness Index Rating | Actual Use of Data Index Rating |
|---|---|---|---|---|
| Estonia | 81,93 | 88,06 | 86,05 | 71,67 |
| Canada | 74,73 | 87,34 | 71,58 | 65,28 |
| Denmark | 72,47 | 80,81 | 65,96 | 70,65 |
| **Israel** | 72,45 | 78,50 | 69,49 | 69,35 |
| Spain | 71,35 | 73,83 | 76,92 | 63,31 |
| NHS England | 69,98 | 78,14 | 72,54 | 59,26 |
| Sweden | 68,26 | 79,92 | 67,37 | 57,5 |
| Portugal | 67,19 | 72,04 | 68,63 | 60,89 |
| Netherlands | 66,05 | 85,16 | 51,79 | 61,2 |
| Austria | 59,82 | 78,82 | 60,72 | 39,91 |
| Australia | 57,31 | 60,34 | 64,39 | 47,19 |
| Italy | 55,81 | 73,57 | 56,59 | 37,28 |
| Belgium | 54,67 | 73,77 | 53,68 | 36,57 |
| Switzerland | 40,62 | 63,91 | 43,96 | 13,98 |
| **France** | 31,61 | 39,93 | 33,17 | 21,72 |
| Germany | 30,02 | 44,16 | 30,08 | 15,83 |
| Poland | 28,53 | 47,96 | 25,86 | 11,76 |

(Bertelsmann-Stiftung, 2022)



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# 2. Organizational framework for telemedicine



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# The underlying legislation for German telemedicine was kickstarted in the last legislative period (2018-2021).

| Year in effect | Shortcut | Name | Brief description |
|---|---|---|---|
| 12/2015 | E-Health-Act | Act for secure digital communication and applications in the healthcare system | • 1st foundation stone for the establishment of a secure telematics infrastructure (TI)<br>• enables introduction of digital health applications (DiGA) |
| 05/2019 | TSVG | Appointment Service and Supply Act<br>→ Act for faster appointments and better care | • obligation of health insurance companies to offer an electronic patient record (ePA) for their patients starting in 2021<br>• creates prerequisites for the electronic certificate of incapacity for work (eAU) |
| 08/2019 | GSAV | Act for more safety in the supply of medicines | • gradual introduction of the electronic prescription (e-prescription) |
| 12/2019 | DVG | Digital Supply Act | • entitlement of people with statutory health insurance to DiGAs (can be prescribed)<br>• expansion of the digital network in the healthcare system is ensured<br>• definition of IT security requirements through standards |
| 10/2020 | PDSG | Patient Data Protection Act<br>→ Act on the Protection of Electronic Patient Data in the Telematics Infrastructure | • regulations on ePA & e-prescription & Patients get a legal right to digital care<br>• pharmacies & hospitals to be connected to the TI on a mandatory basis<br>• requirements for the TI in Germany (including data protection) |
| 10/2020 | KHZG | Hospital Future Act | • promoting & improving the digital infrastructure in hospitals |
| 06/2021 | DVPMG | Digital Supply and Care Modernization Act | • expansion of telemedical applications in care & modern networking in the healthcare sector<br>• transfer of data to the ePA (e.g. electronic emergency)<br>• future financing of digital care applications (DiPAs) |

(Interoperabilitäts-Navigator (INA), n.d.; Bundesgesundheitsministerium, n.d. c)



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# The gematik has become the central national provider of telematics infrastructure.

gematik

- *The gematik was founded in 2005 by the public healthcare system in order to implement an electronic healthcard in Germany*
- *Today, the legal mandate of gematik includes*
  - the introduction, operation and further development of the telematics infrastructure,
  - the electronic health card and associated specialist services and
  - so-called other services for communication between healthcare professionals, payers and insured persons.

*Tasks in particular in accordance with § 311 SGB V :*

- Regulation of functional and technical specifications as well as a security concept,
- Defining the content and structure of the data records to be used,
- Creation of the specifications for the secure operation of the telematics infrastructure,
- Ensuring the necessary testing and certification measures
- Defining the procedures for managing legally regulated access authorizations and controlling this access
- Approval of components, services and providers

*Relevant regulations:*

- § 306 SGB V telematics infrastructure
- § 311 SGB V tasks of the Society for Telematics

(Gematik GmbH, 2022 a)



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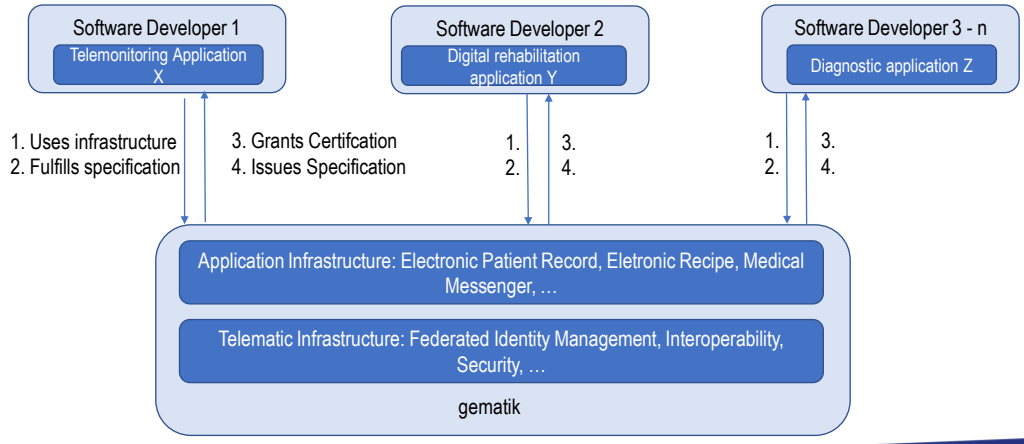
# The gematik's services act as infrastructure to telemedicine applications.



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# In Germany, there are several funding schemes that organize telemedicine projects on national and regional level.

**Public federal funding scheme: "Innovationsfonds" for healthcare**

- German Innovation Fonds supports new forms of healthcare and healthcare research in statutory health insurance
- From 2020 to 2024: yearly budget of 200.000.000€ for all projects (not limited to telemedicine)

**Public funding scheme on regional level e.g. from ministries of the states**

- Hamburg funds up to 200.000€ per project for research, development or innovation projects
- Lower Saxony funds up to 200.000€ per digital or telemedicine project in healthcare
- Saxony funds projects developing digital applications. The funding size depends on available budget.
- Bavaria funds research or development for up to 50% of the total necessary budget.
- Bavaria funds multi-partner projects (including Life Sciences) for up to 100% of the total necessary budget

**Funding through foundations, e.g.**

- Bertelsmann Stiftung: project "the digital patient" assess the influence of digitalization on health care
- Robert Bosch Stiftung: projects regarding challenges like demographic change, globalization, digitalization, biotechnologies

- Projects can be additional to standard care („Regelversorgung")
- Critics from Prognos Evaluation 2022 regarding Innovation Fonds:
  - **There is lack of systematic and focused selection** and **channeling of project funding**
  - Lack of communication and exchange among different projects → isolated solutions

(Prognos AG, n.d.; Robert Bosch Stiftung, 2022; Bertelsmann Stiftung, 2022)



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# 3. Legislation and regulation for telemedicine - framework



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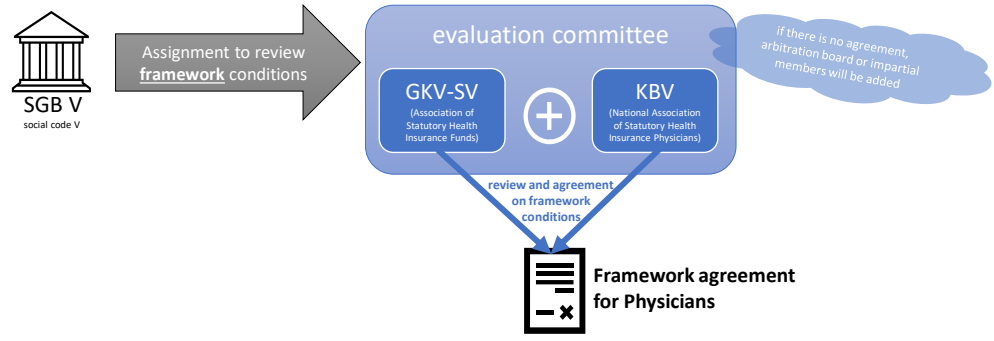
# The framework-setting for the German healthcare system is organized by shared evaluation and arbitration.




Relevant regulations can be found in the following laws:
– 87 Abs. 2a Satz 7 SGB V
– § 378 Abs. 1 und 2 SGB V
– Anlage 31, 31a, 31b & 32 zum Bundesmantelvertrag-Ärzte (BMV-Ä)



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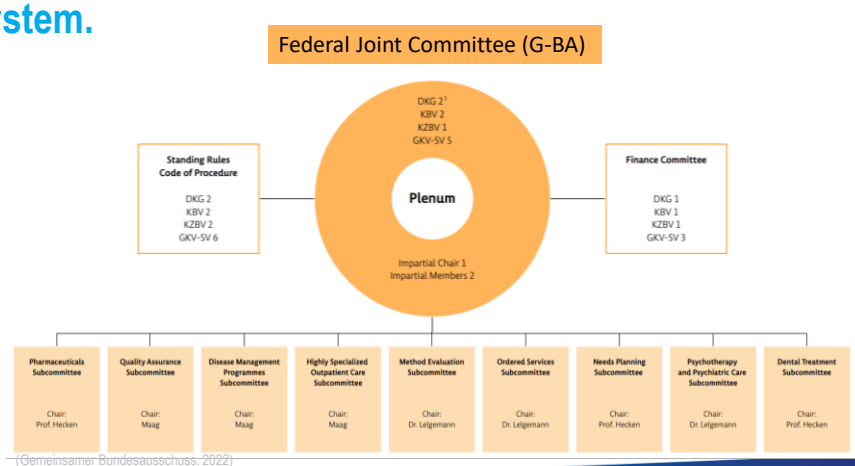
## The assessment of individual telemedicine treatments is carried out by a central federal office consisting of various players in the health care system.




(Gemeinsamer Bundesausschuss, 2022)



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## Within the digitalization of the German healthcare system, the BfArM* has recently gained a central role.

- *Central regulatory body for*
  - permission, improvement and safety evaluation of pharmaceutical products
  - Risk assessment and evaluation of medical products
- *Approximately 1.350 employees (medicine, pharmacy, chemics, biology, legal, engineering)*
- *Central gateway for the certification and permission of digital health applications to be prescribed and financed within the SHI*

*Federal Institute for Pharmaceuticals and Medical products

(BfArM, 2022)



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## There are several paths to achieve certification as a manufacturer for video consultation and TI products in Germany.

*Telemedicine Manufacturer Certification:*

- *video consultation*
  - manufacturers can choose between different certification bodies
  - the service provider (doctor/psychotherapist etc.) must submit the application/certificate to the KV (Association of Statutory Health Insurance Physicians of the state)
- *TI products*
  - gematik is the official approval body for all TI products as well as for providers of operating services and other applications. If manufacturers can prove the requirements for interoperability, security and functionality according to the profile, gematik will issue approvals and confirmations for the TI.



## Telemedical methods & terminology: The following categories are not to be understood as completely distinct - there are overlaps and connections.

| eHealth | | examples |
|---|---|---|
| eCare | health care | teleconsultation, telemonitoring/remote patient management |
| eAdministration | Administrative processes | eGK, eDoctor's card, electronic files, ePrescription |
| ePrevention | Prevention | Age-appropriate assistance systems, coaching |
| eResearch | Research | Genome research using ICT, Internet trend analyzes (e.g. Google Flu) |
| eLearning | Teaching | blended learning via platforms (e.g. ILIAS) |

*Developed by the AG-Telemedizin and decided by the board of the German Medical Association:*

"Telemedicine is a collective term for various medical care concepts have in common the basic approach that medical services of healthcare for the population in the areas of diagnostics, therapy and rehabilitation as well as in medical decision-making advice over physical distances (or time delay) can be provided. Information and communication technologies are used here."

(Bundesärztekammer, 2015)

# 3.1 General scope of services in eHealth & telemedicine

*General services*

- **eArztbrief** (electronic medical certificate of inability to work)
- **eMedikationsplan** (electronic medication plan)
- **ePA** (electronic patient file)
- **eDMP** (electronic data transfer in disease management programs)
- **eRezept** (electronic prescription)
- **eNotfalldatenmanagment** *NFDM* (electronic emergency data management)
- **Telekonsil** (teleconsultation)
- **VSDM** (master data management of insured persons)
- **Videosprechstunde** (online consultation)
- **KIM** (communication in medical field)
- **TI-Messenger** (telematic infrastructure messenger)
- **ISIK** (technical information system in the hospital)
- **DEMIS** (German electronic reporting and information system for infection protection)

*Defined MIOs*

- **eImpfass** (electronic vaccination passport)
- **eMutterpass** (electronic Maternity log)
- **Zahnärztliches Bonusheft** (dental bonus booklet)
- **U-Heft 1.0.1**. (medical checkup booklet for children)

*MIOs in progress*

- **Überleitungsbogen** (transfer sheet)
- **KH-Entlassbrief** (hospital discharge report)
- **DigA toolkit** (app on prescription)
- **Patientenkurzakte** (patient summaries)

*Background information: MIOs (Medical information objects)*
To ensure that medical data can be understood interoperably by any system in the healthcare system, it is documented in a defined format based on international standards and terminologies. In technical jargon, this is referred to as Medical Information Objects, or MIOs for short.


(ina.gematik, 2022)



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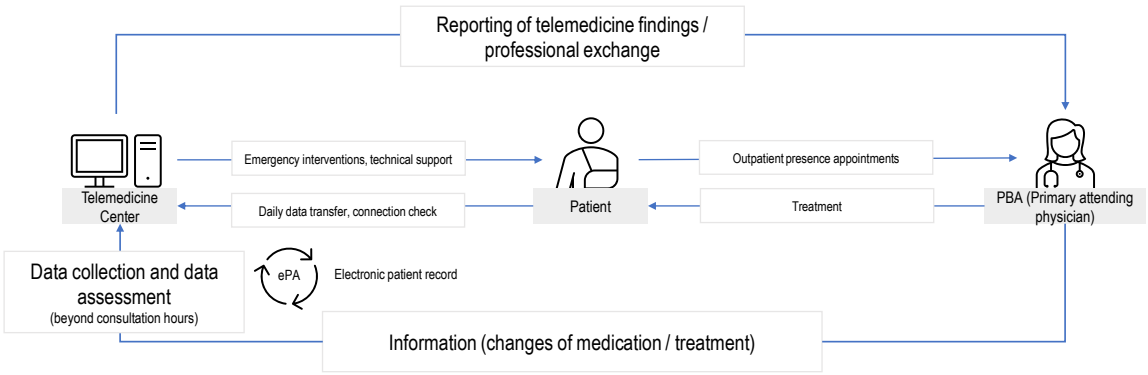
# The public program for telemonitoring of heart insufficiency always encompasses the cooperation of a telemedicine center and the PBA (Primary attending physician).




(Spethmann and Köhler, 2022)



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## Eligibility of professionals, healthcare organizations to provide telemedical services.

- *The video consultation is also possible if the patient has not previously been treated by the doctor.*
- *The doctors get fully paid if personal contact with the patient takes place in the same quarter. If this is not the case and the contact is made exclusively via video, they will be shortened (deduction of 20, 25 or 30 percent depending on the specialist group).*
- *The number of video-only treatment cases is limited to 30 percent of all treatment cases by the doctor/psychotherapist.*
- *Doctors can use the video consultation flexibly in all cases in which they consider it therapeutically useful. There is no restriction to specific indications. A sick note is also possible.*
- *All groups of doctors can use the video consultation – the only exceptions are laboratory doctors, nuclear medicine specialists, pathologists and radiologists.*

(Kassenärztliche Bundesvereinigung, 2022 a & b)



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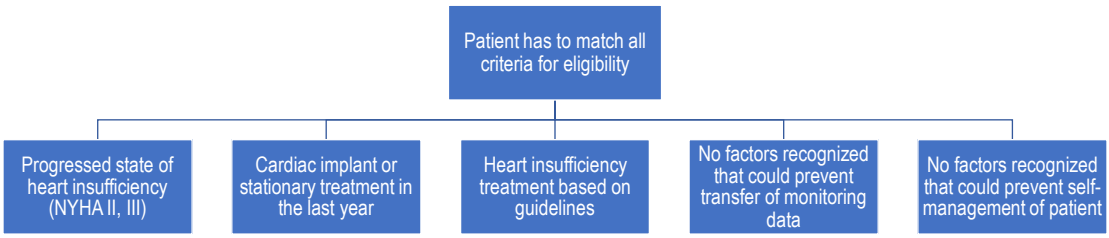
## For patients to be eligible for the publicly funded telemonitoring for heart insufficiency program, several criteria must be met.



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## The security of the central federal telemedicine infrastructure – by gematik - is governed by law (SGB V).

- Identity and access security by electronic health card
- Medical data storage in electronic card or electronic health record
- Medical access only for medical professionals and purposes
- Only temporary use of medical data in digital applications if consented
- gematik provides infrastructure but has no access to data
- Insured persons have access to data log for transparency
- Certification of all components, services and providers by gematik and Federal security agency



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## The liability of physicians prescribing telemonitoring of heart insufficiency to a patient is structured by several requirements.

- Did the physician perform an individual case evaluation: Is telemonitoring appropriate for the medical status of the patient?
- Did the physician maintain medical accuracy in his/her treatment to a level, which is defined by the current medical scientific standard of the relevant medical field?
- Did the physician sufficiently inform the patient about the special nature of the telemedical treatment?
- Did the physician document that these requirements were fulfilled?



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## Reimbursment for video consultation

- *Payment*
  - The doctors get fully paid if personal contact with the patient takes place in the same quarter. If this is not the case and the contact is made exclusively via video, they will be shortened (deduction of 20, 25 or 30 percent depending on the specialist group).
  - The number of video-only treatment cases is limited to 30 percent of all treatment cases by the doctor/psychotherapist.
- *Additional billable services*
- *Surcharge for authentication of new patients*
- *Technology and funding surcharge*

(Kassenärztliche Bundesvereinigung, n.d. a)



## 4. Ethical guidelines

## The German Ethics Council issued a central opinion for ethical guidelines, which should govern "data and healthcare" that show the interconnectedness of privacy, consent and equity.

| | | | | |
|---|---|---|---|---|
| Data agents should manage „dynamic consent" in data processing systems | Reversible and transferable consent between data processing systems | Regular opt-in case-based consent | Privacy by design / Privacy by default in privacy guaranteeing systems | Education for children and adults regarding data & healthcare |
| Publicly facilitated regular discourse on data & healthcare | As Easy as Possible Frontends for all user groups for privacy, consent and equity | Regular check of data processing systems for discrimination of user groups | Possible non-consent to automatic decision making outcomes in data processing systems | Very strict regulation of chatbos to increase privacy of user groups with limited capabilities |
| | Increased support of data protection officials | Establish independent data protection inspectors | Establish data trust models between user groups and data processing systems | |



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## 5. Legal and ethical challenges to date



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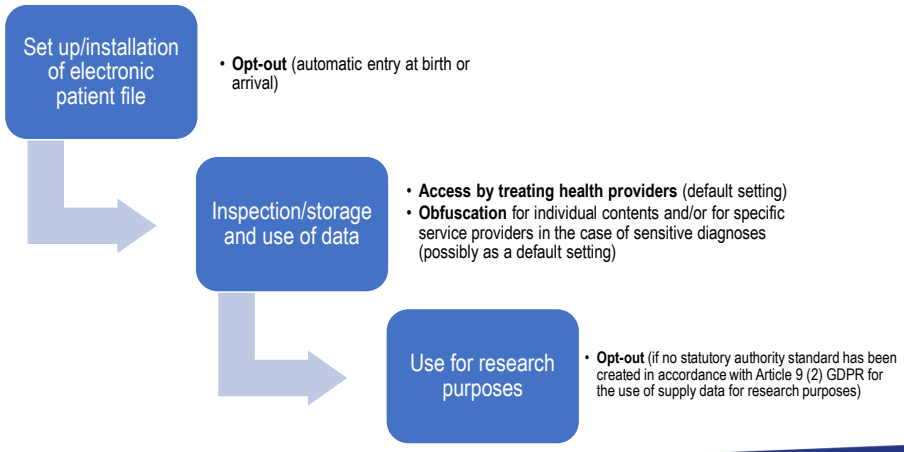
## To account for the immense cost of not using data, new proposals are moving towards opt-out processes of data use.




(Gerlach, 2022)



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