



## Deliverable 5.2

Country specific infographics that summarize the relevant regulations for Big data technologies in the healthcare sector

## Big Data for Medical Analytics

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## Management Summary

Based on desk research and at least 20 expert interviews in each country we have developed nine infographics on the relevant European and National regulations for the collection, management and use of Big Data (technologies) in healthcare. The pilot partners can use the different infographics to develop their business model and prohibit false starts in the projects.

We developed eight country-specific infographics that are addressed towards business stakeholders and IT-developers aiming to develop Big Data technologies in Europe. We focused on the following countries: Austria, France, Germany, Ireland, the Netherlands, Spain, Sweden, and the United Kingdom. The infographics summarize core contextual factors in relation to regulation, governance, and public opinion. The infographics will help business stakeholders to decide if and how to invest in Big Data technologies in particular countries and allows them to better align their activities to the countries' specific needs and concerns. This will increase stakeholders' chances of success. The infographics offer concrete practical advices and relevant considerations to take into account.

We also developed one additional infographic aimed at policy makers at the national and European level. In this infographic we compare the eight countries on major themes: digitalization, governance, regulatory challenges, ethical debates, and social and cultural norms. This infographic will allow policy makers to learn from initiatives and approaches in other countries.

The infographics will be made publicly accessible and can be used for other Big Data initiatives.

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## 1. Introduction

In this document we present the results of work package 5.3 ('Develop infographics that summarize the relevant European and national regulations'). Based on expert interviews with 160 experts in eight countries, BMG (now known under the name ESHPM) has developed a total of nine infographics that summarize the most important rules and regulations for Big Data. A major benefit of infographics is their ability to present key messages distilled from large amounts of information in an actionable format.

The infographics have two target audiences. We developed eight country-specific infographics that are addressed towards business stakeholders and IT-developers aiming to develop Big Data technologies. We focused on the following countries: Austria, France, Germany, Ireland, the Netherlands, Spain, Sweden, and the United Kingdom. These infographics summarize core contextual factors in relation to regulation, governance, and public opinion. The infographics will help business stakeholders to decide if and how to invest in Big Data technologies in particular countries and allows them to better align their activities to the countries' specific needs and concerns. This will increase stakeholders' chances of success. The infographics offer concrete practical advices and relevant considerations to take into account.

We also developed one additional infographic aimed at policy makers at the national and European level. In this infographic we compare the eight countries on major themes: digitalization, governance, regulatory challenges, ethical debates, and social and cultural norms. This infographic will allow policy makers to learn from initiatives and approaches in other countries.

The infographics are attached in Appendix A.

## 2. Methodological appendix

Based on expert interviews with 160 experts in eight countries, ESHPM has developed a total of nine infographics that summarize the most important rules and regulations for Big Data. Eight infographics are country-specific and one additional infographic compares the countries on major themes. We focused on the following countries: Austria, France, Germany, Ireland, the Netherlands, Spain, Sweden, and the United Kingdom. This methodological appendix serves as a background document to the infographics. We outline our methodological approach, describe and substantiate the decisions that were made in the process, specify the analytical steps that were taken and highlight which quality checks were conducted in order to enhance the validity of the results.

### *Selecting respondents*

One core challenge within this project is the identification of high-level experts in the different countries in a relatively short period of time. In order to identify the relevant experts with regards to (health-related) Big Data in each country, we decided to build on the knowledge of the consortium partners. We organized a series of workshops at the consortium meeting of March 7th in which we sought to utilize the knowledge of the partners in identifying the right experts. Before the workshop, we identified the most important categories of experts: (1) healthcare professionals & management; (2) ethical experts & legal experts; (3) technology / IT developers & data scientists; (4) patient representatives & visible actors in public / societal debate; (5) policy makers & additional experts.

The goals of the interviews are to get a detailed understanding per country about the relevant rules and regulations regarding Big Data in each country. More specifically, the wide range of experts allows us to get a detailed understanding of not only the formal aspects of regulation and legislation, but also the ways in which these regulations 'play out' in organizational practice. The objective of the interviews is to provide insights that can help business stakeholders in their decision-making with regard to investments in new Big Data technologies. Given the diversity in national health systems, national and international legislation, governance structures, public opinions and regulatory approaches, it becomes difficult for business stakeholders to make informed decisions about where and how to invest in Big Data technologies, and to know what aspects to take into consideration. Via detailed interviews with a broad range of stakeholders we were able to provide insights into both similarities and differences between countries.

We use a broad, sociologically inspired definition of 'regulation' that includes informal work practices, organizational procedures, routines and habits. We also explicitly aim to include ethical and 'societal' experts to gain insights into the main debates that are being held in relation to Big Data (as these can point to potential misalignments between rules and practice, provide insight into diverse interpretations of rules, and can also lead to new forms of regulation and new work practices).

The workshops provided us with a first list of expert names and contact details. The list was extended via desk research in which we sought high-profile experts per country on health-related Big Data. The additional names were verified via consortium members that served as contact person per country (typically these are the various pilot leaders). We strived towards a balance between different expert categories, yet also chose to be pragmatic and inclusive in our approach. The interviews varied between 30 minutes and 110 minutes and had an average length of 60 minutes per interview.

### *Developing a protocol*

In the first month of the project, we developed a more detailed protocol that describes the envisaged structure of the country-specific infographics. The goal of this protocol was to achieve a clear focus for the interviews, that were to be conducted by various team members in various countries, in order to allow for a systematic comparison of rules and regulations. In the protocol we also defined some of the main concepts used in the research.

The protocol also functioned as an instrument to further operationalize the broadly framed aims of the project. We envisaged that a better understanding of the different facets of Big Data (collection, analysis, integration) and their regulation requires a broader framework that takes into

account the multiple actors involved with Big Data (vendors, health care providers, payers and patients). We therefore conceptualized regulation in terms of governance, which is defined as the development and implementation of public policy by the state and societal actors. The notion of governance contrasts to the notion of public administration. The main difference between public administration and public governance is the number of actors. While public administration presumes one ruling actor (the state), public governance presumes multiple ruling actors.

In the protocol, we also further operationalized and substantiated this broader notion of regulation. Through our background as organizational, sociological and policy scholars we aimed to move beyond a summary of relevant legislation but to produce infographics with detailed attention towards how different rules and regulations relate. In addition, we aimed to know how they work out in practice, where they align and where they misalign in the perspectives of the practitioners, and how they fit (or not) with more informal norms and routines. This broadened framework recognizes three elements of regulation:

- 1) Regulation is not only about formal legislation, but is also shaped by and embedded in cultural and social practices and procedures. Legislation furthermore always needs to be interpreted in practice, where it becomes experienced as meaningful or not;
- 2) Especially in relation to a controversial topic such as Big Data, it is important to situate the formal rules within broader societal and ethical discussions;
- 3) From a sociological perspective, rules do not only refer to official organizational policy, but also to informal rules and norms, such as culturally and socially accepted ways of working and implicit routines that are taken for granted.

In order to produce useful infographics that are helpful to all stakeholders, our 'angle' for the infographics was therefore not to map every single piece of legislation, but to investigate the practices of diverse people, who are either working with Big Data and in their daily practices are confronted with rules and regulations on different levels (organizational, national, European), or who are reflecting on developments of Big Data (for instance from an ethical or legal perspective), and therefore acquired expertise about relevant cultural norms and rules.

### *Conducting the interviews*

By means of desktop research of policy documents, news articles, scientific papers, presentations and grey literature, a document analysis was conducted for each country in order to become familiar with the different health systems, the public discussions about the application of Big Data in healthcare, and policy perspectives on Big Data. This desktop research allowed us to increase our understanding of various country-specific elements, such as the organization of the health system, concrete examples of media discussions or debates about Big Data, specific legislations, etc. This resulted in draft reports per country. We conducted semi-structured interviews focusing on several core themes, but simultaneously allowing room for flexibility and adjustment. This had the advantage of enabling both a systematic comparison on themes that are addressed in each interview, and allowing for sufficient flexibility to align the questions to specific expert categories and tailor the interview towards the specificities of the individual respondents, producing better interviews and better quality of data.

Examples of the general themes that were addressed in each interview are: 1) the development and policy goals in relation to Big Data in the country; 2) the main regulations for health-related Big Data in the country; 3) the ethical questions and debates generated by Big Data in the country; 4) social and cultural influences on the practices and regulations of Big Data in the country. Examples of questions that were asked in every interview, were the following:

- How would you describe the current development of Big Data in the [name country] healthcare field? How would you describe or classify its current use?
- What do you consider to be benefits or risks for Big Data in healthcare – and why?
- What do you see as main regulatory challenges in relation to Big Data in your country? To

what extent do you feel that the most important regulatory issues have been tackled?

- Are there regulatory or legal issues that are in your perception particular to the [name country] context?
- In relation to Big Data, what would you currently consider to be the main ethical concerns? Are there specific health-related ethical concerns as well?
- To what extent do you feel these concerns are adequately addressed in current legislation?
- Are there relevant actual events or discussions (e.g. items that have appeared frequently in the news) that have an influence on the way Big Data is perceived or regulated?
- Have there been particular problems or mistakes related to the use of Big Data that received much media coverage? If so, to what extent you feel this has or might in the future influence rules and regulations regarding Big Data?
- Are in your experience more informal social or cultural norms or customs specific to [name country] that could be relevant for how Big Data is regulated or received?

Next to these more general themes and questions, the interviews were tailored to the specific expert category and the individual expertise of the respondent. Thus, for example, interviews with legal experts focused more on the legal questions that are raised by Big Data developments (such as tensions between GDPR principles and general aims of Big Data, the legal status of machine learning algorithms, or diverse interpretations of legislation in different health contexts). Interviews with data scientists focused specifically on technical rules, for instance about interoperability of databases, what kind of analyses are allowed and under which conditions, etc.).

The large majority of interview was conducted face to face. Face to face interviews are generally preferable as they allow the interviewer to pick up subtle cues, non-verbal communication, to get a better understanding of a person's context, and to establish a relation of trust in which the respondent feels comfortable in expressing her/his thoughts on a topic. The other interviews were conducted via Skype (or a similar medium) and via phone. At the start of each interview, we asked permission to record the interview. We emphasized that no direct quotes would be used in the infographics. In all cases, permission was obtained and the interviews were recorded and consecutively transcribed. In a couple of cases, interviews could not be recorded due to technical malfunctioning of equipment. In those situations, the interviewer took extensive notes during the interview and made a summary of the answers. All interview files and transcripts were stored via a secure server (Workspace).

### *Analyzing the material*

In the analysis of the material we used a method of constant comparison (Corbin & Strauss 1990) to facilitate peer review between team members, increase mutual understanding and facilitate in-depth comparison. We organized several full-day meetings to present our initial analysis and reflect on similarities and differences between countries. To facilitate this joint reflection, we were inspired by the work of Deville, Guggenheim & Hrdličková (2016), who show that comparison is facilitated through conducting small assignments that trigger the joint analysis (such as 'select an image that captures the most important regulatory tension in your country'). This process of constant comparison resulted in the selection of five general themes: ethical framing, digitalization, regulatory challenges, governance of Big Data, and social and cultural norms. The interview material and data gathered via the desk-top research were subsequently coded along these five themes. Each team member developed a '5-pager' in which a summary of main results was presented. The 5-pagers were discussed and fine-tuned in a day-long meeting, resulting in 1-page storylines capturing and organizing the main themes for each country. These served as the basis for the resulting infographics. Given the nature of the infographics, which aim to summarize and make accessible the core aspects for each country, we focused on the most common themes. The infographics do not contain idiosyncratic experiences, but only information that has been triangulated via other interviews and/or document analysis. All interpretive information reflecting the perspectives of stakeholders has been mentioned multiple times and can therefore be seen as reflecting a more widely shared belief or concern.

### *Quality checks and ethical requirements*

During the project we have maintained various quality checks in order to increase the validity, reliability and generalizability of our results. The large majority of the interviews are recorded and transcribed. We have conducted most interviews face to face. We have used the expert network of the Big Medilytics consortium to gain access to high-level respondents and have used the personal networks of respondents to further supplement our list of experts (snowballing-method). We have kept an 'audit trail' that serves as a working document in which we reflect on the decisions we have made and the steps we have taken in the project. This increases transparency and replicability. Triangulation of sources has furthermore increased the validity of the results. Through continuous peer review we were able to enhance consistency in the approach. This increases the validity of the comparison.

In terms of research ethics, we have handled all data with the utmost confidentiality. We have informed respondents about the purpose of the interview and how the material would be used and asked for consent to record the interviews. We have worked with student assistants who transcribed the interviews. They have signed confidentiality statements and only had access to the interviews that were attributed to them. After transcribing they have deleted all materials. All interviews are stored on secure servers, accessible only via a Workspace-account. We have not used identifiable quotes in the infographics in order to enhance anonymity.

### *References*

Corbin, J. M., & Strauss, A. (1990). Grounded theory research: Procedures, canons, and evaluative criteria. *Qualitative sociology*, 13(1), 3-21.

Deville, J., Guggenheim, M., & Hrdličková, Z. (2016). Same, same but different: Provoking relations, assembling the comparator. In: Deville, J., Guggenheim, M., & Hrdličková, Z. (2016) Practising comparison: Logics, relations, collaborations (pp. 99-129).

## Appendix A infographics



## REGULATORY CHALLENGES AND OPPORTUNITIES FOR BIG DATA IN



## SPAIN

## Regional differences as a variety of Spanish tapas



## VARIOUS FLAVORS OF HEALTHCARE DIGITALIZATION

There are considerable differences between the autonomous communities with regards to the digitalization of healthcare and the development of big data initiatives. Some communities have developed extensive systems to share and analyze healthcare data. Other communities are lagging behind. For example, some communities have hospitals that still work with paper-based medical records.



## LACK OF STANDARDIZATION

In most communities, data is collected and stored on an individual basis in organizations. Spanish medical professionals work independently and systems are not equipped for data exchange, leading to interoperability issues. In addition, there is a lack of national and regional guidelines. All these reasons make exchange of data between organizations difficult.



## FUNDING CHALLENGES

Spain is still struggling with the lasting results of the financial crisis. As a consequence, big data projects often struggle with a lack of continuous funding. Initiatives are mostly financed through external funds and it is hard to obtain funds from the government and governmental agencies. This leads to continuity problems for promising initiatives.



## PUBLIC SUPPORT

In general, big data is seen as a positive development and there is great willingness among patients and the general public to help others and improve healthcare. Sharing data is seen as a public duty as it helps to improve our knowledge about diseases.



## ETHICAL DEBATE

The (ethical) consequences of big data are not discussed in the media, as other topics dominate the public debate. Ethical issues are also unfamiliar to many medical professionals and patients. Discussions on such ethical aspects as privacy are concentrated in specific societal groups, such as medical ethics scholars.

## PRACTICAL ADVICE



The Data Protection Agency (AEPD) publishes documents and white papers about the General Data Protection Regulation (GDPR) and its Spanish predecessor LOPD. There is still a lack of clarity about how these relate, but the AEPD aims to work constructively with the field and can be reached for advice.

Involve medical professionals in the development of projects. Medical professionals are trusted and not only important in promoting the initiative, but can also help create an awareness of big data among their peers.



Involve the general public and patients in the development of projects. There is a large willingness to share data and innovate. However, public opinion can quickly change. Invest in communication, explain the benefits and invest in the involvement of patient boards.

## THINGS TO CONSIDER



Much time is necessary to enhance database interoperability. Therefore, it is important to reserve time and the means to arrange the combination of data from different communities or hospitals.

The structures, methods and ways of working can differ substantially. Learn from best practices in the country. The large variation between regions and hospitals means that there is also a lot of opportunity to learn from other (successful) initiatives.



Be careful with involving commercial partners, as they face strong public distrust. There is especially a strong prejudice against "selling" and "profiting" from data.



## REGULATORY CHALLENGES AND OPPORTUNITIES FOR BIG DATA IN



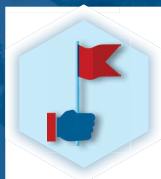
### AUSTRIA

#### Climbing the Austrian big data mountain with endurance and caution



##### NAVIGATING THE REGULATIONS

Regulation of big data in Austria is still shaped by uncertainty regarding the interpretation of newly implemented laws (GDPR and national amendment laws, such as the Research Organisation Law). There are key potential misalignments between broad forms of consent versus the right to withdraw consent and the right to be forgotten versus the duty to document.



##### GUIDANCE AND GOVERNANCE

There is no explicit vision for big data in healthcare. Public infrastructure is lacking. Multiple actors are involved but they are often unaware of each other. There is also no overview of actors, tasks and responsibilities or a generally accepted agenda. Ethics committees provide the general framework for big data research and act as guides in this 'nebulous' landscape.



##### DIGITAL ACCLIMATIZATION

Supported by strong political will, Austria developed an ambitious digitalization strategy (yet without specifically addressing big data in this context). In healthcare, this strategy includes the implemented electronic health record ELGA and a range of other services (such as e-medication and an e-vaccination pass). Due to international standards, interoperability is considered to be good in Austria.



##### A MATTER OF TRUST

The ethical debate is characterised by concerns about data ownership, privacy and data security of health-related data in general. So far there is no thorough public discussion about the specific ethical dimensions of big data in healthcare. Public opinion of big data and health-related data is biased by myths and fear. It is characterized by a lack of trust due to miscommunication and opposition.



##### SAFETY FIRST

The aversion to embracing technological innovation is characteristic for the current attitude to big data in Austria. Fear of change combined with risk aversion slows innovative processes down, but also ensures safety and allows for careful preparation of the implementation of big data.

#### PRACTICAL ADVICE



Ethical debates in Austria are mostly framed in terms of data privacy, security and trust. Honest and transparent communication is key to avoid mistrust and opposition by stakeholders.

Be aware that health data is stored where data is collected. There is no central national data repository in place. If you want to work with data, cooperation with the respective institutions - and appropriate stakeholder management - is crucial.



Pseudonymization of data is key in Austria. Be aware that data sharing across institutions can be difficult. Think carefully about the organizations you want to cooperate with and plan in advance how data sharing can be done in compliance with data protection.

#### THINGS TO CONSIDER



Be aware of negative sentiments about big data and fear of change among medical professionals and the general public. Invest in communication and explain the benefits of big data analysis for better healthcare.

There is uncertainty about the legal implications of the GDPR, MDR (Medical Device Regulation), and the newly implemented Research Organisation Law in Austria. It is advisable to wait until these implications have become visible before developing big data pilots in order to avoid unwanted consequences.



Be aware of potential differences in data quality and data availability as there are different standards for collecting inpatient and ambulatory outpatient care data.



## REGULATORY CHALLENGES AND OPPORTUNITIES FOR BIG DATA IN



### FRANCE

#### France's ambition to become the future AI-hub of the world



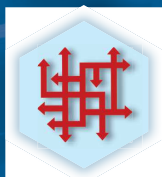
#### DIGITALIZATION

France recently established a national healthcare big data system (SNDS) that allows access to health data collected from hospitals, national medical insurance and other public organizations. Public entities, research organizations and companies can carry out statistical analyses on one of the biggest healthcare databases in the world. Currently the government invests heavily in Artificial Intelligence. The main aims are to drive innovation, catch up with the US and China, and reverse the "brain drain". Health is one of the priority sectors for this.



#### ETHICAL FRAMING

Ethical debates in France do not treat big data as a separate theme. The ethics of algorithms and AI are gaining the most attention. The national data protection authority (CNIL) led reflection on the ethical and societal matters raised by rapid development of digital technologies. They organized public debates which led to the articulation of two founding ethical principles: a principle of loyalty and a principle of continued attention and vigilance.



#### REGULATORY CHALLENGES

Many users experience the large number of procedures and prior checks for access to (anonymized) health data for research as cumbersome as it slows down innovation and start-up initiatives. Procedures are especially challenging when it comes to linking diverse data sources. Clinical data sets from hospitals and claims from the national insurance system have their own rules and access conditions. The process has smoothened since the creation of the SNDS.



#### GOVERNANCE OF DATA

Data governance is strongly institutionalized in France. The Law for the Modernization of the Health System has provided a new framework for obtaining authorization and consent requirements to process health data. It applies to all health data processing purposes. Several public organizations have permanent access to SNDS data. In all other cases, data is available on request. Authorization is required from several actors, who assess different aspects of the proposal.



#### SOCIAL AND CULTURAL NORMS

There is a cultural fear that information collected by government and companies will be used against individuals. Such misuse clashes with the deeply held principle of *égalité*, an important cultural value that is embedded in the national motto. French society is profoundly social, which explains the strict regulation and attention for clear procedures.

#### PRACTICAL ADVICE



Consider working with French data scientists to build on their national expertise and increase funding opportunities.

Include clinical data only and claim data only when strictly necessary as gaining access will double your workload.



Consider collaborating with organizations that have a public service mission as they have permanent access to data.

#### THINGS TO CONSIDER



Consider the potential of the national healthcare big data system, but realise also that authorization is required from several actors and this process takes up to six months.

Be aware of the importance of the distinction between consumers and citizens in France. The rules and procedures (which might seem strict) are shaped by the deeply entrenched egalitarian principle.



Consider the importance given to artificial intelligence above big data in France.



## REGULATORY CHALLENGES AND OPPORTUNITIES FOR BIG DATA IN



## GERMANY

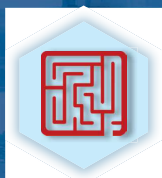
## Building a strong foundation for considerate use of data

**DIGITALIZATION**

Decentralized approaches (e.g. various electronic healthcare systems from multiple providers) resulting in interoperability issues (e.g. different data standards, interfaces) are challenges for the development and implementation of a big data strategy. Creating a linked system of health records should overcome these barriers. This system should enable data sharing and prevent misuse; the aim is not to create a national big data framework.

**RULES ARE KEY**

Governance in Germany primarily takes place through formal regulations (e.g. laws) at the national and regional level. As a result, implementation of the GDPR was relatively straightforward due to the already strong regulatory data protection framework. The effect of governance by regulations is that stakeholders demand that legislative authorities provide the necessary structure and guidance in the context of big data in healthcare.

**NAVIGATING THE RULES**

Various rules are in place alongside the well-implemented national legislative framework. The regions ('Bundesländer') can have additional (data protection) laws and the interpretation of national legislation can differ across regional borders. Besides that, organisational rules (e.g. regarding authentication or ethics) need to be considered, which may complicate cooperation across regions and between healthcare organizations.

**CONSIDERATE ACCURACY**

"German thoroughness" substantially shapes the big data discussion: the data protection law and processes in place must be followed. Paying attention to detail and "doing it right" from the start is considered important. Experiments must be planned strictly. Germany is currently not a frontrunner in the field of big data. However, many stakeholders (industry, technology, research) value the opportunities of big data and stress the (economic) benefits.

**SELF-DETERMINATION**

Data sovereignty (or information self-determination) is the underlying ethical notion in Germany as citizens have ownership and are therefore in control of their data. Furthermore, citizens overall are willing to share their data for the greater good. However, data sovereignty and the willingness to share may be limited: the state acts as a protector in this context by not allowing voluntary data donation to avoid unforeseen negative consequences for its citizens.

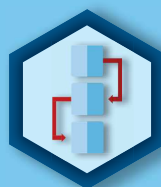
**PRACTICAL ADVICE**

Gather information about all relevant regulations before starting the initiative. Data protection agencies and organizational protection officers can provide valuable information.

Be aware of varying data protection regulations and interpretations, particularly when working across regions and between organisations.



Data may only be collected for specific purposes and strict standards for consent are in place.

**THINGS TO CONSIDER**

Note that the German big data framework does not appreciate improvisation but values considerate planning and rule-based implementation.

The German Data Protection Law argues for a reduction of the amount of data collected. This principle can conflict with the concept of big data.



Due to the sensitive historical background, dealing with personal health-related data is a matter of trust. While the state has regained the public's trust, citizens are now more sceptical about the intentions of private industry.

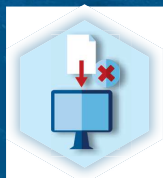


## REGULATORY CHALLENGES AND OPPORTUNITIES FOR BIG DATA IN



### IRELAND

#### Gap between policy ideals and medical practice



#### DIGITALIZATION CHALLENGES

Ireland faces challenges with regard to digitalization. While some hospitals experiment with digital health records, most hospital records are paper-based. Medical professionals experience a lack of interoperability and perceive that the proper 'groundwork' is not yet in place.



#### IMPLICATIONS OF GDPR

Professionals experience a lack of direction on legislation about health data. There are no clear guidelines on the implications of GDPR for health research. This lack of clarity about the 'rules of the game' has led to inertia among medical professionals.



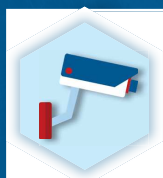
#### LACK OF TRUST IN THE HEALTH SYSTEM

There is a lack of public trust in the health system, although trust in individual professionals is high. The health system struggles with a historical legacy of controversies. Furthermore there is little public trust in the system's ability to manage health data safely and appropriately.



#### AWARENESS OF RULES

Rules and regulations for data protection are far removed from the daily work of health professionals. Policy documents on guidelines and regulations are mostly perceived as 'paper tigers'. This has changed with the introduction of the GDPR.



#### SOCIAL CONCERNS ABOUT PRIVACY

The ethical debate in Ireland is mostly focused on privacy. The general public is mostly skeptical and concerned. This concern is further strengthened by a one-sided, negative media focus on risks and data breaches.

#### PRACTICAL ADVICE



Ethical debates are primarily framed in terms of security and privacy. Invest in technologies that allow anonymization and secure data sharing and make sure that data subjects are properly informed.

Fragmentation of ethical procedures and standards between hospital research ethics committees leads to challenges for big data studies combining data from multiple sites. Allow sufficient time and resources to obtain the ethical permissions.



While trust in the health system in Ireland is generally low, trust in individual practitioners is high. In order to increase the legitimacy of big data projects it is advisable to incorporate key medical representatives who can explain and 'sell' the project to a wider audience.

#### THINGS TO CONSIDER



Be aware of negative sentiments and concerns about big data among the general public and a substantial part of the medical profession. Invest in communication to explain the benefits of big data projects.

Note that despite high policy ambitions the digital hospital infrastructure is still underdeveloped, making data extraction a very labour-intensive process.



There is currently much uncertainty about the legal implications of the GDPR for health research. It is advisable to wait until the implications are crystalized and scenarios or 'use cases' become available that provide signposts about how health data is allowed to be used.

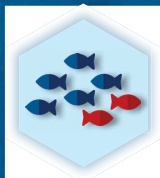


## REGULATORY CHALLENGES AND OPPORTUNITIES FOR BIG DATA IN



## SWEDEN

## Digital forerunners in need of maintenance work

**AUTONOMY OF COUNTY COUNCILS**

The lack of a national decision-maker leads to persistent legal challenges. These are most notable in relation to negotiations between councils and IT suppliers for the procurement of technologies and in relation to the implementation of systems that can facilitate patient information flow across databases. Attempts to coordinate across counties have proven difficult.

**HIGH PUBLIC TRUST IN INSTITUTIONS**

Sweden is characterized by a great deal of public trust in the system and its institutions, making Sweden open toward data sharing. In general the public perceives no problems with data sharing to enhance healthcare.

**PATIENT RIGHTS STRONGLY ESTABLISHED**

Patients can use a national patient portal ('1177.se') to access their information and there is a national law specifying the right of patients to request information at all governmental levels.

**DIGITAL FORERUNNERS NEEDING MAINTENANCE**

Sweden prides itself on its early adoption of digitalized health and its history of data sharing via comprehensive national databases and professionally driven Quality Registers. Although it is recognized that the infrastructures in place are in need of maintenance, they are difficult to change due to the historical legacy.

**STRONG TRADITION OF ETHICS**

Sweden has a strong tradition of ethics boards. Ethical questions around big data are well-recognized. Ethical debates are primarily framed as a balance between principles of (personal) integrity and (collective) patient safety, but become reframed towards ethics of sharing data ('data donation').

**PRACTICAL ADVICE**

Think carefully about the county council you want to work with. There are major differences between county councils. Try to avoid projects which require data from multiple county councils.

Sweden has a strong history of disease-specific registries. There are benefits to be gained in terms of data availability by connecting future big data projects to such registries.

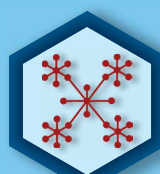


The right to access for patients has been legally entrenched in the Swedish system. Make sure that future big data projects are transparent and that opportunities for patient access are facilitated through the project's set-up.

**THINGS TO CONSIDER**

Public trust in Sweden is high and people are generally open to sharing their data. It is therefore advisable to enhance public awareness of and involvement in new big data projects.

Be aware that the positive social perception of the public ('naïveté') may also backfire when trust is abused.



Be aware that the decentralized organization of healthcare has led to an abundance of IT systems and low interoperability.



## REGULATORY CHALLENGES AND OPPORTUNITIES FOR BIG DATA IN

## THE NETHERLANDS

In the Dutch marketplace you find actors and negotiate

**THE DUTCH MARKET-BASED SYSTEM**

The Netherlands has a market-based healthcare system with private healthcare organizations and health insurance companies. Therefore, data is collected and stored by individual organizations. The Ministry of Health tried to connect all the data through the National Connection Point project. This project was heavily debated and eventually remained unsuccessful. Currently, the government lets the different parties involved decide on systems for data storage and connection.

**PRIVACY CONCERNS**

Privacy is an important theme in The Netherlands, especially when organizations use personal medical information for other purposes (such as driving licenses, job applications or mortgages). This concern was illustrated recently by a scandal about the violation of a celebrity's privacy by healthcare professionals accessing her Electronic Patient Record.

**GDPR AND ADDITIONAL LEGISLATION**

The GDPR is currently the most important legislation. Additionally, The Netherlands has developed legislation for the medical ethical assessment of the collection and re-use of medical information for research purposes. The Dutch data protection agency controls the compliance of personal data only and is authorised to levy fines in the case of non-compliance.

**DIGITALIZATION**

Most healthcare providers have their own Electronic Patient Record. In the Dutch market-based system, owning patient data is a way to retain the patient. There is no legislation forcing healthcare providers to share data. The government is pushing patient health portals by providing funds for IT companies and healthcare providers to develop these.

**STANDARDIZATION-ATTEMPTS**

There is an attempt to standardize data collection by using 'building blocks' to register health and care data once only. Such standardization aims to improve the exchange of data. Using these 'building blocks' is not mandatory and IT companies don't use them yet.

**PRACTICAL ADVICE**

The Netherlands has an opt-in system for big data. Approval is needed to re-use data collected for other purposes. People are likely to give approval if data is re-used for quality improvement, medical research on diseases, or the development of new treatments.

You need the approval of an Ethical Committee for Medical Research (located in hospitals) or the Central Committee on Research Involving Human Subjects to perform big data research using medical information. Make sure to formulate a broad scope to avoid having to ask for additional approval if the original research plan is expanded.



The Dutch center of expertise for standardization and eHealth (NICTIZ) provides information of digitalization. The national digital two-way authentication system (DIGID) of the government can be used.

**THINGS TO CONSIDER**

Pseudonymization and anonymization of data are key in The Netherlands. This has historic reasons. During the Second World War, The Netherlands had a good administrative system, which facilitated the deportation of many people. This still influences public opinion of data collection and storage.

Accreditation of big data collection, storage and re-use is currently being developed. According to both policy makers and experts, a key aspect of this accreditation is developing a system that allows independent evaluation of the reliability of algorithms. This system will be set up in the next couple of years.



Data science is a relatively new topic in the Netherlands. Both researchers and consultancy companies are offering services. Everyone is free to offer and hire.

## REGULATORY CHALLENGES AND OPPORTUNITIES FOR BIG DATA IN



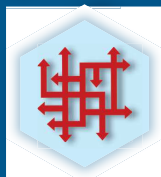
## THE UK

Citizens do not want to be surprised by how data is used



## LESSONS LEARNED THROUGH PUBLIC DEBATE

NHS England has had an open data policy that aimed to establish a central database ('care data'), which linked data from all NHS hospitals and all general practices. Policy makers gave all concerned the room for technological innovation. This backfired as citizens protested against not having a say in how their data is used.



## MORASS OF RULES

The open data policy and subsequent debate resulted in the establishment of many organizations and rules for data sharing. Permission to use data often needs to be asked from several organisations.



## NO SURPRISES AS KEY ETHICAL PRINCIPLE

A core ethical principle in the UK is that citizens may never be surprised by the way their data is shared with others. In doubtful cases when the rules for (re-)use of data are unclear, professionals are encouraged to ask advice from colleagues.



## CONFIDENTIALITY VERSUS SHARING: A SHIFTING BALANCE

The balance between confidentiality and data sharing for research and innovation has shifted towards confidentiality due to diminished trust.



## THE VALUE OF COMMON LAW

Common law (law made by judges based upon cases) proved to be valuable in response to rapid technology developments. In the UK common law is as important as the GDPR with regard to big data in healthcare.

## PRACTICAL ADVICE



There are national surveys of citizen's attitudes towards big data. These are useful to check what UK citizens expect.

If a big data project involves a commercial partner it is important to be explicit about how UK citizens get a return on their investment.



Every organisation can file a request to analyse NHS data. 'NHS Digital' prepares the data set and monitors the use of data.

## THINGS TO CONSIDER



Confidentiality is the key ethical concept, rather than privacy. Confidentiality is defined as trust that personal data will not be disclosed without control over timing and the amount of data shared.

Important policy goals are to generate wealth from big data. NHS data plays a key role in the development of big data in the UK.

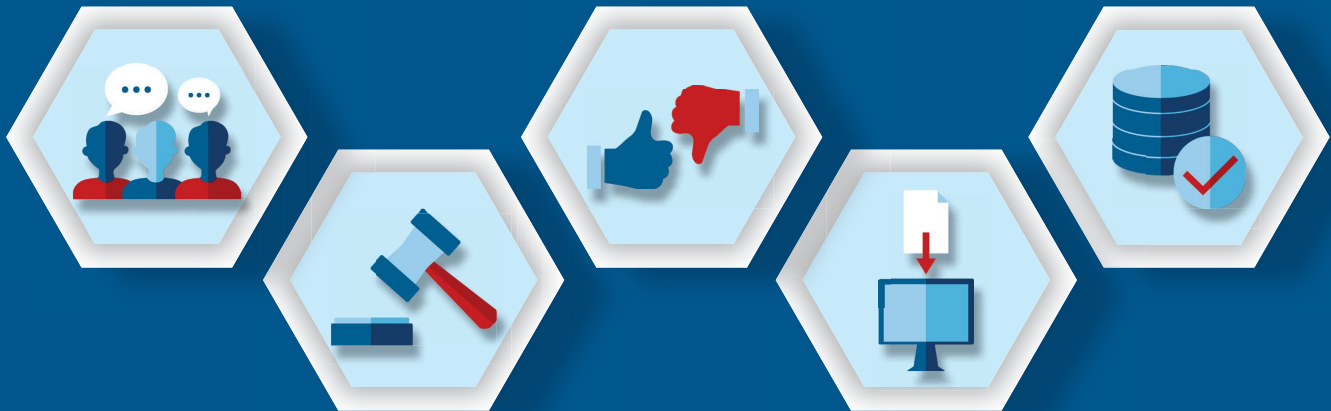


NHS Scotland and NHS Wales do not have a national repository and national rules for data access, but do have strong local networks between the NHS and health researchers.



# COMPARISON OF BIG DATA DIMENSIONS IN EU COUNTRIES:

Austria, France, Germany, Ireland, Spain, Sweden, The Netherlands, and The UK.



## ETHICAL DEBATE

Privacy issues dominate the ethical debate on big data, overshadowing other relevant ethical issues. However, when looking at the ethical debates more closely, they point to several different values that matter. In addition to privacy, other relevant values are: ownership, confidentiality, safety, security, informed consent, the common good, and trust. In some countries, the ethical debate primarily takes place behind closed doors, while in other countries the discussion is more public. Also, in some countries, academics and policymakers contribute to the debate, while in other countries the media opens up the debate on ethics. Media coverage can be fueled by recent scandals and can trigger fear of the use of big data among the general public.

## SOCIAL AND CULTURAL NORMS

Norms differ across countries according to the prioritization of values. Some countries place the emphasis on individual autonomy, while other countries place a strong emphasis on collective responsibilities with regards to big data. When prioritizing the individual's right, protection and access to personal data are seen as key values. Meanwhile, when prioritizing collective responsibility, altruistic sharing is the underlying principle. Social and cultural norms are essential to enable trust. Citizens trust medical professionals, healthcare organizations, research institutions and the government. However, the level of trust in healthcare systems, in governmental, healthcare, and research institutions differs across countries. Overall, individual medical professionals are trusted the most, and private sector companies the least.

## GOVERNANCE OF DATA

Governance of big data in healthcare is arranged on various levels that can be more or less centralized. Countries differ with regards to the involvement of public and private actors. In all countries many actors are involved in governing data: medical professionals, healthcare organizations, patients, private

companies and public organizations. Therefore, governance is always layered and complex. In response to the regulatory challenges, different kinds of governance strategies have been developed. First, there are technical strategies, such as standardization and security measures. Second, there are legal strategies, such as the introduction of new laws and regulations. Third, there are institutional strategies, such as the establishment of new organizations or councils. And finally, there are ethical strategies, with a strong guiding role for ethical committees.

## REGULATORY CHALLENGES

In the countries concerned, the big data landscape is characterized by little awareness of the large variety of rules and regulations. First, the EU General Data Protection Regulation (GDPR) has to be embedded and implemented in national regulatory frameworks. In some countries, however, the GDPR is the basis of data protection, while in others, it adds to or replaces an already existing data protection framework. Second, a variety of additional (healthcare) laws needs to be considered in all countries, for example, with regards to patient rights. This makes the regulatory framework often not clear or straightforward. And third, different actors are involved in regulating big data at national, regional and local levels, potentially leading to heterogeneous outcomes.

## DIGITALIZATION OF HEALTHCARE

Between and within countries, there are differences regarding the infrastructure for health data: paper-based health records, hospital-based electronic health records, linked electronic health records, regional datasets and national databases. These variations should not be interpreted as sole differences between pioneers or laggards. Some hospital-based electronic health records are considered very advanced and some national databases have to deal with outdated infrastructures. Moreover, the difference between central storage of data versus linking data can best be seen as different paradigms of digitalization that lead to different notions, rules and infrastructures. Some countries aim to store data in one place or multiple places while others link data from various sources by technical solutions.