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Legal, Technical and Medical Aspects of User Interfaces for Personalized Treatment Pathways in Hematology and Oncology

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by

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Wien, 22. März 2024

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Maximilian Bischof

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Disclaimer

This work does not represent or constitute Treetop Medical's opinions or views. Treetop has supported the work through feedback and expert interviews. No guidance or direction has been given on the methodology, nor have specific comments been made regarding competitors or to include or exclude certain parts.
Furthermore, the insights gained from this work do not replace the advice from a legal professional.

Kurzfassung

Ziel dieser Arbeit ist eine interdisziplinäre Auseinandersetzung mit der Visualisierung von patientenspezifischen, klinischen Behandlungspfaden, wobei die Integration von Labortestergebnissen in die jeweiligen Behandlungspfade im Fokus steht. Beleuchtet wird dieses Thema aus technischer Sicht, im Sinne der Visualisierung durch grafische Benutzerschnittstellen (GUIs), sowie aus der Perspektive der Rechtswissenschaften. Zu diesem Zweck wurden eine narrative Literaturanalyse, eine rechtswissenschaftliche Auseinandersetzung sowie eine Feldanalyse bestehender Softwarelösungen durchgeführt.
Auf der einen Seite haben wir uns mit den Perspektiven verschiedener Benutzergruppen, Datenstrukturen und domänenspezifischen Anforderungen auseinandergesetzt und konnten dadurch Prinzipien identifizieren, die eine Grundlage für die Entwicklung von Software-Artefakten für die Visualisierung von patientenspezifischen, klinischen Behandlungspfaden bilden. Diese Prinzipien wurden dann mit Hilfe einer Feldanalyse evaluiert.
Andererseits haben wir den rechtlichen Rahmen für die Entwicklung ebensolcher Software-Artefakte abgesteckt. Eine zentrale Rolle hierbei spielen die EU-Datenschutzgrundverordnung sowie die EU-Medizinprodukteverordnung.
Darüber hinaus zeigt diese Arbeit den Zusammenhang zwischen Designanforderungen und rechtlichen Anforderungen bei der Entwicklung von Software-Artefakten zur Visualisierung komplexer medizinischer Behandlungsdaten.
Es handelt sich bei dieser Arbeit um eine Überblicksarbeit, die Anknüpfungspunkte für weitere Forschung liefert.

Abstract

This work aims to examine the visualization of patient-specific clinical treatment pathways, focusing on integrating laboratory test results into the respective treatment pathways. This topic is discussed from a technical perspective regarding visualization through graphical user interfaces (GUIs) and from a legal perspective. To this end, we conducted a narrative literature analysis, a legal analysis, and a field analysis of existing software solutions.

On the one hand, we dealt with different user perspectives, data structures, and domain-specific requirements. We were thus able to identify principles that form a basis for developing software artifacts for the visualization of patient-specific clinical treatment pathways. These principles were then evaluated with the help of a field analysis.

On the other hand, we have defined the legal framework for developing such software artifacts. The EU General Data Protection Regulation (GDPR) and the EU Medical Devices Regulation (MDR) play a central role here.

In addition, this work shows the relationship between design requirements and legal requirements in developing software artifacts to visualize complex medical treatment data.

Furthermore, this work is an overview thesis that provides starting points for further research.

Contents

Chapter 1 - Introduction

The undeniable ubiquity of digitalization in many different aspects of our lives has evidently found its way into the healthcare sector, too, although the transition from analog to digital is moving slowly compared to other sectors like, for example, finance, commercial, or transportation.[1] This has various reasons, one being the sensitivity of the health sector in general and another being the number of obstacles emerging when digitizing medical processes.[2] Besides the technical requirements like usability, security, data integrity, etc., medical software needs to fulfill a lot of legal requirements, for example, those defined by the EU regulation of medical devices.[3] From a legal point of view, a lot of critical questions arise regarding, for example, general data protection, intellectual property law, or the rights of patients regarding their data.[4] But while including the medical, legal, and technical requirements when developing an artifact for the medical sector, one thing should not be overlooked: in the end, it is the users who should profit from the new solution.

The Swiss company Treetop Medical has developed a web-based platform containing structured medical treatment pathways for smarter patient care. Their next step will be designing smart digital applications that support the different healthcare stakeholders during their day-to-day tasks and add additional value for patients, clinicians, laboratories, and researchers by merging real-time patient data with their existing guideline structure. This is planned for different health departments, starting with hematology and oncology.

To contribute to this ambitious goal, the overall objective of this thesis will be to provide an interdisciplinary framework for the development of graphical user interfaces that visualize personalized treatment pathways in hematology and oncology together with patient-specific data like laboratory test results from blood tests or bone marrow biopsies. This framework consists of a legal examination and subsequently appropriate solutions for dealing with the legal issues that emerge when wanting to visualize contextualized patient data, as well as user interface implementation guidelines from a scientific literature perspective and takeaways from a field analysis.

[1] Calvino et al. 2018
[2] https://cockpit.gfsbern.ch/de/cockpit/ehealth-gesundheitsfachpersonen-2020/ last visited 2022-12-04
[3] MDR
[4] Mattsson 2019, p. 286

Chapter 2 - Preliminaries

Before elaborating on a detailed description of the problem statement, the goal of this thesis, and the methodology used, some topics and preconditions need to be outlined to get a better understanding of the actual problem this thesis tries to tackle. Firstly, a brief introduction about the company Treetop is given, which serves as a starting point and as the general context in which this work will take place. Additionally, there will be a short introduction about some medical and terminological topics that are relevant to this thesis.

2.1 Treetop Medical

The Company Treetop Medical, specializing in software solutions for the digitalization of medical processes, was founded in 2019 by Dr. Michael Roiss and is operating out of Vienna, Austria. It was born out of a clinical setting by the founder, who is a Hematologist - Oncologist and has experienced the different aspects of clinical care.[5]

2.1.1 Problem Identification

The founder's experience, combined with research and input from senior clinicians and data scientists, led to the identification of several issues within the context of digitization processes in a clinical environment:[6]

- Slow integration of new medical knowledge into medical care

  Despite growing medical knowledge, information on new treatment options and procedures can take up to several years to reach the clinical setting.

- Increasingly complex patient treatment procedures

  Personalized medicine is on the rise, and with it, treatment strategies are becoming more complex and need to be adapted even more quickly. Since new medical guidelines are not dynamically integrated into standard operating procedures (SOPs) for treatments of diseases, doctors struggle to deliver high-quality care efficiently to patients.

- Fragmented IT landscape:

  On average, clinicians rely on four or more different IT systems with information in different formats to make treatment decisions and document the results. These systems include medical guidelines/SOPs, electronic health record (EHR) systems and sources for clinical data, clinical tools (e.g., patient consent forms), medical calculators, and websites.

- Unstructured medical context information

  Structured content is a basic requirement for the development of smart digital tools to support the different stakeholders and increase the efficiency and quality of healthcare.

[5] Treetop Medical 2022
[6] Treetop Medical 2022

Medical guidelines cover the definition, diagnosis, and treatment of the most common disease types. However, less than a third of medical providers have a standard for updating and adhering to medical guidelines.[7]
Although guidelines are essential to the clinical workflow, they cannot be implemented into current IT systems as they are published in unstructured data formats.

The company's goal is to tackle the problems mentioned above by developing an interconnected, cloud-based platform solution for the different stakeholders within the healthcare ecosystem, including doctors, patients, clinics, and ancillary services (e.g., laboratories or radiology). They aim to increase the efficiency and quality of current clinical care while building structured medical context information. It is planned to develop a dynamic and flexible solution suitable for all kinds of different health departments, but for the pilot projects, the hematology and oncology department serves as a starting point, and for the time being, their focus lies on the DACH region (Germany, Austria, and Switzerland) where all trials will take place.

There are different phases when it comes to the development of Treetop's solution, which will be outlined briefly.

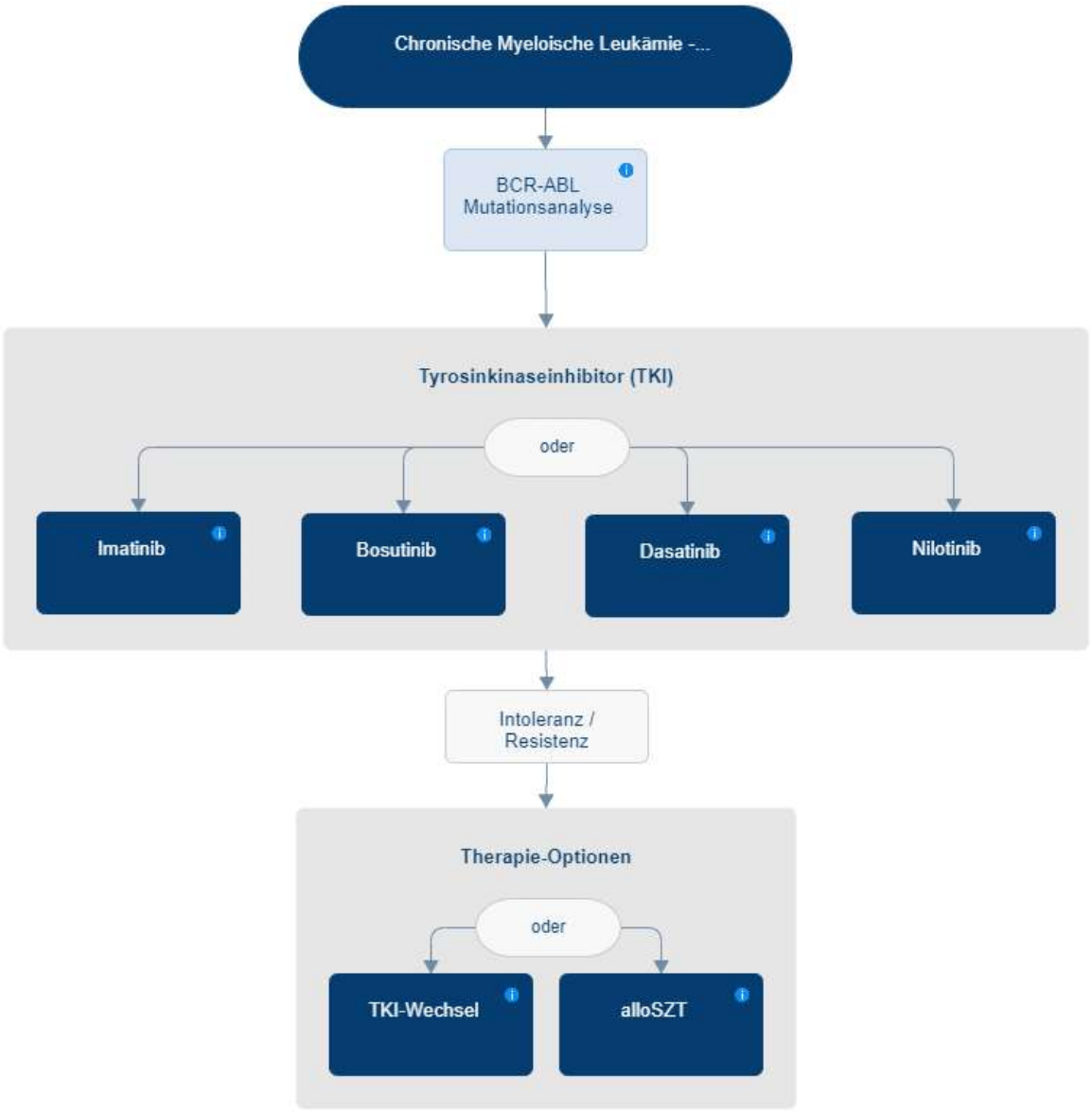
2.1.2 Phase 1 - Structured medical guidelines

The first phase consists of developing a cloud-based platform for physicians that enables the easy creation and adoption of structured medical guidelines. This kind of structured data builds the foundation for developing digital tools that support the different healthcare stakeholders and are integrated within the healthcare ecosystem. Phase 1 tackles the problem of unstructured medical context information mentioned above.

Prototype

The prototype provides access to concise state-of-the-art clinical workflows for defined disease areas. Recommended evidence-based workflows by content partners can be customized easily to reflect the local standards, new treatment options are dynamically integrated, and all the relevant local information, documents, and tools can be accessed directly from the platform. Figure 2.1 shows an example of an interactive depiction of a part of the treatment pathway for the treatment of chronic myeloid leukemia (CML). Further information on leukemia can be found in Section 2.2.1 Leukemia.

[7] Murad 2017, p. 430



(Figure 2.1: Interactive CML treatment pathway (accelerated phase) created with Treetop Medical[8])

2.1.3 Phase 2 - Patient Data

In phase two, the platform developed in the first phase will be extended by merging the existing structured guidelines with individual patient data. With the help of smart digital applications for different healthcare stakeholders, such as patients, clinicians, and laboratories, the data will be integrated into the platform. The goals are to provide the opportunity for active patient engagement, user-friendly interfaces for patient care plans and long-term treatment support, sophisticated clinical decision support and documentation based on integrated patient results, as well as a shared view of disease information and care plans between doctors and patients.

[8] Treetop Medical Application 2023

2.1.4 Phase 3 - Analytics

Based on the collection, processing, aggregation, and storage of the data obtained with the developed solutions from the first two phases, Treetop Medical wants to extend its platform with multiple advanced analytics capabilities regarding the clinical workflow and patient outcomes in order to obtain a higher efficacy of treatments and to provide an analytical tool for medical research purposes.

2.1.5 Relation to Academia

The company's project involves many different stakeholders and requires a lot of engineers, developers, experts, advisors, and many more in order to be realized. But within the development, there are also questions emerging which are relevant from an academic point of view. For that reason, Treetop launched a joint research project with TU Wien. Different questions, among others, in the fields of data law, software architecture, or user interface design are trying to be answered scientifically, which not only contributes to the company's plans but also adds scientific knowledge within the respective research fields.

Relation to this Work

Phase two of the company's project includes developing smart digital applications for different healthcare stakeholders. One of these will be an application for clinicians (and subsequently also for patients themselves) that informs them about their patients' individual care plans and shows them relevant information about the progression of the disease and other relevant parameters based on the structured medical guidelines provided by the solution from phase one. As already stated, the Department of Hematology-oncology will serve as a starting point, and therefore, the application will initially be developed for hematological-oncological diseases but should be able to be extended to other diseases as well in the future.

For the treatment of such diseases, laboratory test results for examinations like blood tests or bone marrow biopsies are essential for clinical decision-making.[9] But when these results and other individual medical parameters are merged with the respective structured medical guidelines, a rather complex dataset is created. This thesis focuses on two specific questions. Firstly, how to visualize this complex dataset consisting of medical treatment pathways together with laboratory test results in a way that there is an information gain for the user, compared to current methods. Secondly, when merging, contextualizing, and visualizing this highly sensitive patient data, what are potentially arising legal issues, and how to deal with them. The exact problem statement will be described in Chapter 3 - Problem Definition and Research Objectives.

[9] Treetop Medical 2022

2.2 Medical Background Information - Hematology-Oncology

In order to get a better understanding of the problems this thesis is trying to tackle, a short overview of diseases in the field of hematology-oncology will be given.

Hematology-Oncology refers to the combination of hematology, which is the study of the morphology of blood and blood-forming tissues,[10] and oncology, which is a medical branch that specializes in the diagnosis and treatment of cancer.[11] Therefore, this branch of medicine is characterized by diagnosing and treating cancerous blood disorders and blood cancers as well as managing symptoms of these diseases and, if present, resultant tumors. Hematologists-Oncologists treat a variety of diseases, including different types of lymphoma, multiple myeloma, hemophilia, sickle cell disease, clotting disorders, or leukemia.[12]

2.2.1 Leukaemia

Leukaemia is a type of cancer affecting circulating white blood cells. Starting in the blood-forming cells of the bone marrow, where they crowd out normal cells, they leave the bone marrow at some point and spill into the bloodstream. Once in the blood, they can spread to other organs and restrict them from functioning properly. Leukaemia is classified among two different dimensions, one of them being whether most of the proliferating abnormal cells are immature blast cells (more like stem cells) or mature cells (more like normal white blood cells. The other one is which kind of bone marrow cells are affected- lymphocytes or myeloid cells.[13]
If immature blood cells are affected, it means that the disease is rapidly progressing and is classified as acute Leukaemia. With this type, malignant cells build up in the marrow, decreasing its ability to produce healthy blood cells. If most of the affected cells are mature, the disease is classified as chronic leukemia, which is progressing more slowly but may be more difficult to treat.[14] The other dimension concerns the type of bone marrow cells affected - either cells that give rise to lymphocytes or early myeloid cells, which become white blood cells (other than lymphocytes), red blood cells, or platelet-making cells. In the former case, the disease is categorized as lymphocytic (also known as lymphoid or lymphoblastic) leukemia, and the latter is classified as myeloid (also known as myelocytic, myelogenous, or non-lymphocytic) leukemia.[15]
These two dimensions together result in the four main types of leukemia: acute myeloid leukemia (AML), chronic myeloid leukemia (CML), acute lymphocytic leukemia (ALL), and chronic lymphocytic leukemia (CLL).[16]

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[10] https://www.sysmex-europe.com/academy/knowledge-centre/haematology.html last visited 2022-02-05
[11] https://www.cancer.gov/publications/dictionaries/cancer-terms/def/oncology last visited 2022-02-05
[12] https://www.regionalcancercare.org/news/what-is-hematology-oncology/ last visited 2022-02-05
[13] Grigoropoulos et al. 2013, p. 29
[14] https://www.cancercenter.com/cancer-types/leukemia/types last visited 2022-02-05
[15] https://www.mskcc.org/cancer-care/types/leukemias/types last visited 2022-02-05; https://www.cancer.org/cancer/chronic-myeloid-leukemia/about/what-is-cml.html last visited 2022-02-05
[16] Grigoropoulos et al. 2013, p. 29; https://www.cancer.org/cancer/chronic-myeloid-leukemia/about/what-is-cml.html last visited 2022-02-05

		Type of cells	
		lymphocytic	myeloid
Maturity of cells	Immature (acute)	ALL	AML
	Mature (chronic)	CLL	CML

(Table 2.1: Types of Leukaemia)

Additionally, there are also other rare forms of leukemia, for example, prolymphocytic leukemia (PLL), large granular lymphocytic leukemia (LGL) or hairy cell leukemia (HCL) which are sometimes considered as subtypes of lymphocytic leukemia, or myelodysplastic syndromes (MDS) which is a group of closely related diseases where the bone marrow is not able to produce enough functioning blood cells.[17]

2.2.2 Chronic Myeloid Leukaemia - CML

The CML is well suited as a model disease in the context of neoplastic diseases.[18,19] Although we do not need a specific model disease in this thesis, apart from a few illustrative examples, we nevertheless devote a paragraph here to CML to explain why it is particularly suitable for further research based on our work.

The incidence rate is about 1 - 2 cases per 100.000 adults, and approximately 15% of newly diagnosed leukemia cases are classified as a CML. Central to this disease is a fusion of two specific genes which results in an oncoprotein ("*..a protein [..] that is involved in the regulation or synthesis of proteins linked to tumorigenic cell growth*")[20] termed BCR-ABL1 which is one type of a tyrosine kinase.[21] Tyrosine kinases play an important role in biological processes like growth, differentiation, metabolism, or apoptosis (A type of cell death).[22] In normal cells, the activity of tyrosine kinases is tightly regulated, but due to mutations, as in the case of BCR-ABL1, they may acquire transforming functions that lead to malignancy.[23]

The introduction of a medication called "Imatinib" revolutionized the treatment of CML. It serves as a tyrosine kinase inhibitor (TKI), which inhibits the specific malignant BCR-ABL1 protein. Later on, other TKIs followed, and therefore, the annual mortality of this disease decreased further and currently amounts to 1,7%.

The disease progresses in several phases, and the first (chronic) phase can be especially well influenced therapeutically. Also, the medical guidelines for the treatment of CML are highly structured and highly dependent on results from blood tests and bone marrow biopsies.[24] This is also the main reason why it is very well suited as a model disease.

[17] https://www.cancercenter.com/cancer-types/leukemia/types last visited 2022-02-05
[18] https://www.onkopedia.com/de/onkopedia/guidelines/chronische-myeloische-leukaemie-cml last visited 2022-02-05
[19] Neoplasm: "*An abnormal mass of tissue that forms when cells grow and divide more than they should or do not die when they should.*"
(https://www.cancer.gov/publications/dictionaries/cancer-terms/def/neoplasm last visited 2022-02-05)
[20] https://www.merriam-webster.com/medical/oncoprotein last visited 2022-02-05
[21] Jabbour and Kantarjian 2018, p. 422
[22] https://www.cancer.gov/publications/dictionaries/cancer-terms/def/apoptosis
[23] Paul and Mukhopadhyay 2004, p. 101
[24] https://www.onkopedia.com/de/onkopedia/guidelines/chronische-myeloische-leukaemie-cml last visited 2022-02-05

2.3 Terminology - Clinical Pathway

Different termini have been used so far, seemingly describing the same thing: clinical or medical (treatment) pathway, (structured) medical guideline, standard operating procedure, or clinical workflow. This rather confusing terminology emerges from the fact that there is no real consensus, neither by clinicians nor by researchers, when it comes to the definition of this concept. A study by De Bleser et al. found 84 different definitions, which all describe the same concept, namely the one of a clinical pathway.[25]
Kinsman et al. describe clinical Pathways as "*[..] tools used to guide evidence-based healthcare that have been implemented internationally since the 1980s.*"[26] De Bleser et al. define them as "*[..] a method for the patient-care management of a well-defined group of patients during a well-defined period of time.*"[27]

Kinsman et al. proposed an approach for a standard definition of what constitutes a clinical Pathway, which was later refined by Lawal et al.[28]
According to Lawal et al. `s definition, four criteria need to be met for an intervention in order to be constituted as a clinical pathway:[29]

1. It is a structured multidisciplinary plan of care
2. It is used to translate guidelines or evidence into local structures
3. It details the steps in a course of treatment or care in a plan, pathway, algorithm, guideline, protocol or other 'inventory of actions' (i.e., the intervention has time-frames or a criteria-based progression)
4. It aims to standardize care for a specific population.

Due to the heterogenic usage of these termini, it doesn't make sense to limit this work to use only one term, mainly because it could become even more confusing, especially when it comes to citations and references where different termini are being used. Instead, we try to reduce the number of different terms to a minimum and try to make every statement concerning the respective concept as clear and self-explanatory as possible.

[25] De Bleser et al. 2006, p. 555
[26] Kinsman et al. 2010, p. 1
[27] De Bleser et al. 2006, p. 553
[28] Kinsman et al. 2010 and Lawal et al. 2016
[29] Lawal et al. 2016, p. 1

Chapter 3 - Problem Definition and Research Objectives

The treatment of hematological and oncological diseases is usually a long and complex task. For example, the average medication therapy for chronic myeloid leukemia takes about three years, depending on the subtype and other prognostic factors.[30] During this time, a patient has to undergo a lot of treatments, examinations, and medical consultations. Existing clinical pathways, digitized and integrated into the platform developed by Treetop Medical, as already stated previously, build the foundation for these kinds of treatments.

3.1 Visualization

In order to provide additional support for patients as well as doctors, smart digital applications will be built for tasks like automatically receiving laboratory results of blood tests or bone marrow biopsies and integrating these results into personalized treatment pathways. When, as in the case of this thesis, focusing on the user interface design of such an application, some specific issues arise.
Essentially, there are two different types of information that somehow need to be combined in an understandable way to provide a user with additional information. On the one hand, there is the clinical pathway information of a specific disease (in our case, leukemia), often visualized as a flowchart or a decision tree. On the other hand there is a complex dataset consisting of health-related personal information of a specific patient which, among others, includes the following:

- Personal data (Age, Sex, Weight, pre-existing conditions,..)
- Disease progression/state within the treatment pathway
- Parameters and decisions which led to the current state of the pathway
- Disease specific data (e.g. disease phase, Prognosis Score,..)
- Given medication over time
- Possible side effects of given medication
- Former treatment decisions
- Alternative treatment possibilities (from the past as well as in the future)
- Individual information by the doctor in charge (e.g. explanations for certain decisions, comments, etc.)
- Epidemiological data (e.g. disease frequency, distribution according to age, sex, etc.)
- **Laboratory test results**
- **Reference intervals for laboratory test results**
- **Variation of laboratory test results over time**

The question that arises now is how to visually combine these two datasets and visualize them in a way that there is an information gain for the user, be it a patient on the one hand or a clinical professional on the other hand.
While there may be many parameters that influence the treatment decision based on a medical pathway, we limit ourselves to the results of blood tests and bone marrow biopsies (including data directly related to it, which are highlighted in the listing above), as these are

[30] Simonsson 2005, p. 1

the most decisive for most hemato-oncological diseases. Furthermore, the complexity due to the addition of further parameters would be too high for us to answer the question adequately within the scope of this work. Nevertheless, we hope that the findings from our study can be transferred to other parameters and/or diseases in future contributions.

3.2 Legal Issues

When developing software solutions for visualizing this very kind of complex data, besides the questions regarding the design itself, a lot of legal issues emerge. Due to the high sensitivity of the data that needs to be processed and due to the high demands that are placed on (software) products in the medical sector in general, we develop a legal framework where we identify potential legal issues regarding data processing and data visualization in particular. We also come up with guidelines or appropriate solutions for dealing with those issues. Since it is planned to roll out the respective applications in Austria, Germany, and Switzerland, we also take into account nation-specific legislation as well as their respective correlations.
Some of the concrete questions we are dealing with are:

- What is the general legal framework for the processing of data?
- What are the specific regulations and requirements for data concerning health?
- How and to which types of data processing does a user need to give their consent?
- How do data pseudonymization techniques affect the legal requirements for the processing of data concerning health?
- What is the legal correlation between data processing and data visualization?
- What are the specific legal requirements for the visualization of data concerning health?
- When is software legally qualified as a medical device, and what are the implications thereof?
- What should be considered when digitally facilitating doctor-patient communication using data visualizations?
- Does the user interface design of software have an effect on liability issues, and if so, how?
- Is there a necessity and also a means to legally protect innovative data visualization methods specifically?

These questions, among others, as well as their answers and other possibly arising legal issues, will be summarized under the term ‘Legal Framework.’ Developing such a framework and finding appropriate solutions for dealing with these legal issues will be the aim of this thesis.

3.3 Research Questions

The concrete research questions are specified as follows:

> **R1**: What is an appropriate means to design a graphical user interface for merging and visualizing a medical treatment pathway together with a patient's laboratory test results in the context of the treatment of a hemato-oncological disease, which increases a user's knowledge and understanding about the current disease state compared to state-of-the-art methods?
>
> **R2**: What is the legal framework in Austria, Germany, and Switzerland for processing and visualizing contextualized patient data (according to RQ1) that is being generated during the treatment process of a hemato-oncological disease, and what are the appropriate solutions for dealing with emerging legal issues?

3.4 Change of Course during the Research Process

During our research process, we encountered several problems that caused us to rethink our original plan for answering the first research question. In this section, we would like to explain what our original plan was, why it changed, what the new approach is, and why this change is an interesting finding in itself. The plan to answer the second research question, in turn, was retained as it still contributes to our overall research design. The objective of the second research question is thus also discussed in this section.

3.4.1 Original Plan - Expected Outcomes

In order to answer the first research question, we originally wanted to build a graphical user interface prototype in line with our findings from the examination of the scientific literature, which is then evaluated either through a controlled experiment with patients as potential users or through interviews with experts from the field. The whole build and evaluation process would have been conducted using the guidance of a design science research framework.
It is important to mention that whether our research question is answered adequately depends on subjective parameters. Therefore, it is quite possible that there is more than one suitable solution to our question. Furthermore, we defined certain objectives that need to be met by our solution:

- The solution must contain the medical pathway information, the respective patient's current disease state, and laboratory test results related to the respective pathway.
- The solution must be new insofar as it is not just simply a copy of an existing solution
- The solution must be designed according to principles and guidelines developed in the course of creating our knowledge base, taking into account the current state of technology

- The solution needs to provide a possible information gain for the user, compared to existing solutions (for example, in the form of better usability or a better disease overview)

While also taking into account the findings from the analysis of the question from a scientific, legal perspective, that would have been our original plan in broad outline. But as already mentioned, we encountered a few problems on our way. In the following, we want to elaborate on these problems and why they led to the decision that appropriately answering the research question according to our original plan would have been far too extensive for the typical scope of a master's thesis.

3.4.2 Reason 1 - Indications from Literature

The number of scientific papers dealing with this very problem is rather small. While there is existing research in the area of visualization of treatment pathways in general, as well as data integration into pathways, the very combination of patient-specific data, respectively laboratory test result data, and medical treatment pathways is something where several unanswered questions appear in the corresponding scientific literature.
Of particular interest to us is, on the one hand, the work of Balatsoukas et al. from 2015,[31] which will be elaborated on in section 6.4.3 Interactive Clinical Pathway Visualization. They try to find ways to match individual health records with medical treatment pathways, and while providing meaningful insights, they conclude their work with the claim that there is a need for further investigation of this topic. But when looking at all subsequent work citing this very paper, no satisfying advancements have been made from a scientific perspective. On the other hand, a PhD Thesis from 2012 by Theresia Gschwandtner[32] and subsequently published papers[33] also provide meaningful insights into the subject matter, which will also be elaborated in section 6.6.1 CareCruiser. But apart from these publications, which were written some time ago, it was hardly possible in the course of our research to find papers that adequately address our specific problem. Klucken et al. predicted in 2018 that in the future, the interactive visualization of personal disease profiles integrated into medical treatment pathways will gain more importance,[34] which is what the overall project is trying to contribute.
This, in turn, suggests that the overall problem is more extensive than originally thought. Because of the high complexity, the need to subdivide the problem into smaller parts, and the lack of specific theoretical discussion in literature, it is, therefore, also difficult to address even more specific parts of the problem in our work. This is, therefore, one of the reasons why we have adapted our research approach.

3.4.3 Reason 2 - Indications from the Field and the Problem of Comparison

During the course of our scientific investigation, we found existing commercial solutions for supporting different stakeholders during the long-term treatment of chronic diseases.[35] While

[31] Balatsoukas et al. 2015
[32] Gschwandtner 2012
[33] Gschwandtner et al. 2011
[34] Klucken et al. 2018
[35] See Chapter 8 - Field Analysis

the use of medical treatment pathways together with individual patient data is given in the respective applications, the different ways of visualizing and representing named data are quite heterogeneous and very much entangled in the overall concept of the respective application. As a result, it is very difficult to look at the methods used for data representation in isolation and even more problematic to use them as a metric to meaningfully compare our own prototype. One solution would be to extract and rebuild specific parts of existing applications for the purpose of scientifically comparing them to our own prototype. Another idea would be to build several prototypes based on the findings from our theoretical examination and compare them against each other in order to get usable results. Both of these ideas would involve an amount of work that would exceed the scope of our thesis, especially since it is only one of two research questions we need to examine. In addition, it should be noted that the Treetop Medical project is also to be understood as an integrated concept, which is why an isolated prototype would probably not provide the desired insights. In the end, our research question is also one of the core questions, the answer to which is an important part of the unique selling proposition (USP) of Treetop Medical. Therefore, an investigation of already existing applications and recommendations for development and design derived from them (which we will come to in a moment) seemed to us to be the more reasonable way to contribute to the overall understanding of the problem.

3.4.4 Reason 3 - Interdisciplinarity

As already mentioned, we took an important aspect of the overall project and tried to illuminate the subject from different perspectives. As the title of this thesis suggests, we want to outline an interdisciplinary approach, which is also the reason why we have two research questions from different research areas that are partly interconnected with each other. Nevertheless, this reduces the amount of effort and level of detail we can devote to each of those questions. Instead, we want to present the problem from a more holistic perspective, so to speak. This further supports our decision to change course during our research process.

3.5 New Plan - Expected Outcomes

Now that we have explained the reasons for the change in our plan, we would like to outline the new plan and the expected results of our work. The following can be expected:

- A comprehensive examination of the problem from different perspectives. The answer to the first research question is based on findings from the research literature and an analysis of commercially available applications with comparable functions. For the second research question, we build an extensive legal framework that can be used and consulted when implementing further software artifacts that process the described types of data. Furthermore, the two research questions are not independent of each other but rather have crossover points. So, while answering the first question, findings from the second question will be taken into account and vice versa, which leads us to interdisciplinary findings.
- The realization that the problem is more profound than originally thought. Furthermore, it will present why this is the case and where the individual difficulties lie.

- A starting point for further research. While we do not follow the entire cycle of building and evaluating a technical artifact prototype using a design science research framework, we nonetheless want to provide a profound starting point for further research insofar as we try to conduct some important steps needed for future research.
- Guidelines and recommendations for the design and build process. With our work, we want to provide guidelines that point out several aspects to consider from a design perspective as well as from a legal perspective when building the aforementioned artifacts.

Chapter 4 - Research Framework

Due to the interdisciplinary nature of this work and the aforementioned change of course during our research process, it is necessary that different methodologies will be used to answer the respective research questions. In the following, we outline our methodology for our literature review, the methodology for our analysis of examples from the field, and the methodology used for the legal part of this thesis. Furthermore, it is also important to note that our approaches are, like the research questions, interconnected at some points.

4.1 Literature Review Methodology

Already during the preparation of our research project, when we had to choose an approach for the literature review, it became apparent that (semi-)systematic approaches were not particularly well suited for our specific question(s). This is due to the fact that our work is an interdisciplinary survey, which tries to link and contextualize different fields, as well as to the enormous heterogeneity of some term definitions.[36] Instead, a narrative review approach was chosen. Narrative literature reviews "*[..] describe and discuss the state of the science of a specific topic or theme from a theoretical and contextual point of view.*"[37] While this approach, unlike systematic approaches, does not necessarily list the keywords and databases used and, therefore, does not claim to be exhaustive or reproducible, the focus is instead on critical discussion, synthesis, and contextualization of the literature consulted. A narrative approach is usually well suited for broad questions of qualitative nature.[38]
For the concrete implementation of this approach, we take guidance from a work by Ferrari.[39] While the strict documentation of the literature search process is not explicitly necessary, it is still advised to explain the procedure as it adds clarity to the overall project. Furthermore, it is important to clarify that this whole research process is rarely linear but rather a dynamic process consisting of several cycles where new knowledge and new scientific resources are gradually added to the overall review.[40]
The main principles we followed in conducting our literature review are as follows:

- Keyword search revolving around terms related to the research questions.
- Identification of term definition papers for ambiguous keywords.
- "Funneling": Start with comprehensive works about broad topics (i.e., general principles for UI Design) and get more specific after the identification of relevant concepts.
- Consultation of systematic literature reviews of certain topics in order to get an overview of sub-topics relevant to us.
- Identification of key papers, i.e., works that are particularly relevant to our project.
- Snowballing: Review the references of key papers.
- Reverse Snowballing: Review works that reference the identified key papers.

[36] cf. section 2.3 Terminology - Clinical Pathway
[37] Rother 2007, p. vii
[38] Rother 2007, p. vii, viii
[39] Ferrari 2015
[40] Ferrari 2015 p. 231-233

Figure 4.1 depicts the main principles of our literature review in a concise form.

(Figure 4.1: Main principles of our narrative literature review approach)

One particular example of the application of these principles is the following: At first, we started a keyword search about medical treatment pathways. Then, we quickly noticed that there are many different synonyms for the term, which was then confirmed by a term definition paper dealing with this issue, which led us to refine our keyword search. When searching for methods for visualizing such pathways, we tackled the problem from different perspectives. We started quite broadly with general user interface design principles and gradually got more specific from there, which again led to the refinement and addition of our keyword search. Later in the process, we identified a systematic literature review for visualizations of medical data, which served as an overview and also helped us to identify a few key papers that were very close to our specific research question. From there, we used the aforementioned snowballing techniques and synthesized the findings into a concise form.
Of course, this is only an example for a better understanding of the used approach and does not portray the entire research process.
It is also important to mention that we used a similar approach for parts of our legal research; however, in addition to the scientific literature, the legal texts and the connection thereof must also be taken into account here. For a detailed elaboration of the legal science research methodology used, see section 4.3 Legal Science Research Methodology.

4.2 Field Analysis Methodology

Due to the broad scope of our research question and the heterogeneous product landscape regarding software solutions for visualizing clinical pathway data, we could not identify an existing “go-to” methodology for analyzing commercial products in a way that suits our interest. Instead, we took inspiration from different research methodologies and adapted them to our needs.

Firstly, there are approaches such as competitor analysis.[41] While this can be useful for the identification of potential software solutions for our analysis, the focus here lies more on the assessment of a market situation and issues regarding a company's strategic management, which is not the focus of our research.
Next, we have general methods for the evaluation of user interfaces. Most of them are designated for evaluating your own software artifacts before or during release, with design improvements as a goal. One particular example would be knowledge-based user interface evaluation.[42] Since no company provided us access to a usable demo of their product, this method is also not really an option.
Jeffries et al. distinguish four different methods for user interface evaluation in the real world: software guidelines, cognitive walkthroughs, usability testing, and heuristic evaluation,[43] whereas the latter seems to be at least partly applicable to our case. With heuristic evaluation, the software artifacts to be examined (or, in our case, secondary material such as brochures or screenshots) are analyzed qualitatively, whereby the expertise and previous experience of the analysts are used to assess the respective properties.[44]
For a fraction of the identified software solutions, we could gather enough data to conduct a more detailed analysis. Therefore, we also have taken a look at the case study methodology. Again, with the caveat that we do not have the resources to carry out one or more complete case studies. Nevertheless, we followed the basic structure of case study design when developing our research approach and also gained inspiration from a comparative case study approach.[45]
Finally, we could, of course, also refer to the results of our literature review and build our field analysis on these.
The concrete approach for our analysis is as follows:

- Identification of analytes: The first step was to identify relevant software solutions through a keyword web search, a systematic review of apps related to hematological conditions, a search in the German National Directory of Health Care Applications according to DiGAV-DE,[46] as well as through the consultation of Treetop Medical, since they could already provide a list of relevant companies and other stakeholders.
- Data collection: For integrative commercial solutions, we searched for useful information on the respective websites and tried to contact all identified software manufacturers several times within the timespan of two months by contact form, if available, and additionally by email. Information about mobile solutions was gathered through the aforementioned systematic review as well as through downloading the respective app, whereby it was assessed whether they qualify as relevant for us.
- Qualitative primary assessment: The next step was assessing the gathered material and trying to find answers to the following questions: What are meaningful ways to categorize the data? Are there already interesting features glancing through upon first look? In what way does comparison make sense? And by which attributes? And what can be said about the relation to the findings from our theoretical discussion?

[41] Hatzijordanou et al. 2019
[42] Löwgren and Nordqvist 1992
[43] Jeffries et al. 1991, p. 119
[44] Jeffries et al. 1991, p. 120
[45] Baxter and Jack 2008; Bartlett and Vavrus 2017
[46] See section 7.3.3 Digitale-Versorgung-Gesetz - DVG-DE

- Arrangement and Comparison: Afterwards, we arranged the data in a more structured manner, i.e., via an overview table, and tried to compare them by previously defined attributes and features and maybe draw conclusions.
- Detailed study of selected analytes: If sufficient data was available, a more detailed examination of the respective software solutions with regard to our question and our overall concept was done.
- Synthesis and Conclusion: Finally, we brought everything together and tried to draw meaningful conclusions from the field analysis.

4.3 Legal Science Research Methodology

The second research question deals, amongst other issues, with data protection, privacy, data policies, and data ownership as well as creating legally compliant software artifacts, as already outlined before, is theoretical in nature and requires a research methodology situated in the field of legal sciences. As Chynoweth states: "*Legal researchers have always struggled to explain the nature of their activities to colleagues in other disciplines.*"[47] Many different dimensions exist amongst which legal research can be categorized. We take three common ones, briefly describe them, and examine where our research question is situated in order to outline a research methodology based on a combination of approaches that are well-suited to our problem.

4.3.1 The dimension of "Purpose"

Duncan and Hutchinson describe a division of legal research into four major categories: Doctrinal, Reform-oriented, Theoretical, and Fundamental research, depending on the purpose of the conducted research.[48] Since we do not want to suggest changes to the current law, nor to question the adequacy of existing rules or the nature of law itself but rather develop a legal framework within current and emerging rules, a doctrinal approach is well-suited for the purpose of this thesis which is described as: "'*Research which provides a systematic exposition of the rules governing a particular legal category, analyses the relationship between rules, explains areas of difficulty and, perhaps, predicts future developments.*"[49]

4.3.2 The dimension of "Tradition"

McConville and Chui[50] make a distinction between traditional (which they also refer to as 'Doctrinal Research' but which slightly differs from the definition from Hutchinson and Duncan insofar as reform-oriented, theoretical, and fundamental research can theoretically be conducted in a 'traditional', as well as in a 'non-traditional' manner) and non-traditional, interdisciplinary legal research.
The traditional methods for conducting legal research are targeted almost exclusively at 'black-letter' law, which means that the law is seen as a complex, self-sustaining set of rules and principles that can be accessed entirely by reading statutes, papers, court judgments, etc., without significant references to the 'real world'.

[47] Chynoweth 2008, p. 28
[48] Hutchinson and Duncan 2012, p. 101f
[49] Pearce et al. 1987 quoted in Hutchinson and Duncan 2012, p. 101
[50] McConville and Chui 2007

Non-traditional methods, also referred to as empirical legal scholarship or socio-legal studies, try to understand law from a more contextual, interdisciplinary perspective by doing empirical research and introducing methods from other disciplines in humanities and social sciences.
They also point out that both types of methods can be used complementary and do not exclude each other.[51]
Nevertheless, we stick to a traditional 'black-letter' approach in order to solve our problem because, on the one hand, we want to examine current and emerging legal rules concerning our specific problem, and our goal is not to question it (which can indeed be an interesting question for further research) and on the other hand an empirical legal study would go beyond the scope of this thesis.

4.3.3 The dimension of "Comparison"

Another aspect by which legal research can be categorized is whether the problem in mind is examined from a comparative legal perspective or not. McConville and Chui define comparative legal research as its own category,[52] but different types of categorization exist as well. Van Hoecke points out that the situation is a bit paradoxical because, on the one hand, the lack of consistent methodology in the field of comparative legal research has been widely criticized, but on the other hand, the comparison between domestic law and the implementation in other countries "*[..] has become almost compulsory in doctrinal legal research.*"[53] In his paper, he introduces a 'toolbox' of methods that can be used by themselves or in combination, namely the functional, analytical, structural, historical, and law-in-context methods.[54]
It is evident that we need some kind of comparative method in order to answer our research question, which focuses on three different countries, of which only two are in the European Union. Since we try to analyze the current legal situation and have a specific problem in mind, a functional approach is well suited. In the end, we want our legal solution to be applicable to all of the respective countries, and unifying law is one of the goals of functional comparative legal research. When using this approach, we need to have a specific problem in mind (i.e., our research question) and try to find similarities, differences, contradictions, and possibilities for unification regarding the problem, which means we are looking at law on a micro-level.[55] Looking at this problem from a broader perspective (e.g., taking a cultural or historical context into account) can be an interesting question for further research but is beyond the scope of this thesis.

4.3.4 Application to our Problem

In order to answer our research question, we used the guidelines for doctrinal research methodologies described by Duncan and Hutchinson as a foundation. They describe the basic steps that are typically executed when using a problem-based doctrinal research methodology as follows:[56]

[51] McConville and Chui 2007, p. 3f
[52] McConville and Chui 2007, p. 6
[53] Van Hoecke 2015, p. 1
[54] Van Hoecke 2015
[55] Van Hoecke 2015, p. 9f
[56] Hutchinson and Duncan 2012, p. 106

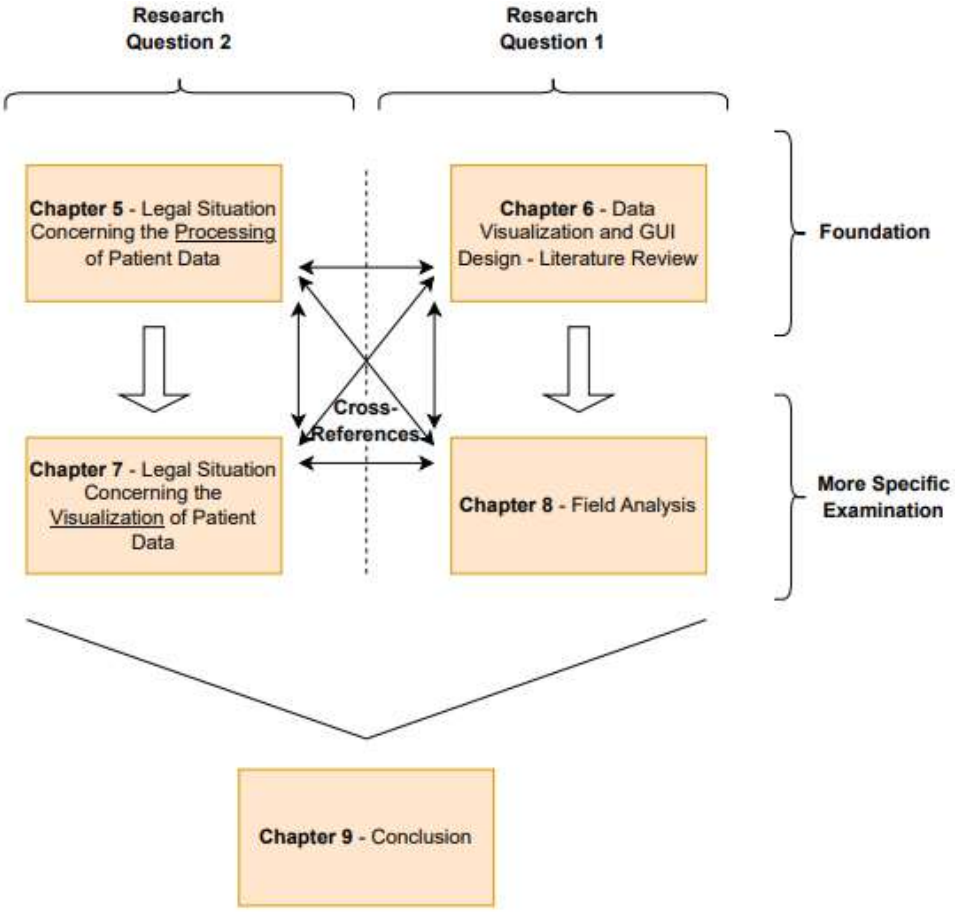
- Assembling relevant facts;
- Identifying the legal issues;
- Analyzing the issues with a view to searching for the law;
- Reading background material (including legal dictionaries, legal encyclopedias, textbooks, law reform and policy papers, loose leaf services, journal articles);
- Locating primary material (including legislation, delegated legislation and case law);
- Synthesizing all the issues in context;
- Coming to a tentative conclusion;

They also clarify that these are only the basic steps and there is a lot of room for additional steps depending on the specific problem and that one "*[..] would not need to slavishly follow research steps such as undertaking 'background' reading.*"[57] They also point out that the element of 'discovery' with which science in general is often immediately associated is not as apparent as in other scientific disciplines.[58] Nonetheless, more can be done than simply reviewing and analyzing legal documents: "*Often the most profound 'discoveries' are in fact those that give new coherence to familiar legal phenomena. For this reason, the process of ascertainment and synthesis of existing legal principles constitutes original research[..]*"[59]
Finally, while following the guidelines from above, we stuck to the suggestions for comparative legal research using functional methods by Van Hoecke. Although there are many different functional approaches, depending on the research question (comparing rules, focusing on similarities, building a legal system, etc.), the main idea is to look at the ways different legal systems try to solve conflicts of interest.[60] This is of great interest to our research problem since we wanted to develop a legal framework situated in the legal systems of different countries.

4.4 Thesis Structure

Now that we have explained the various methodologies used in the following chapters, we would also like to give a schematic overview of how the subsequent parts of the thesis are structured and interconnected. Due to the interdisciplinary nature and multifaceted research approach, it helps to provide an overview before we dive into the individual chapters. Figure 4.2 shows a schematic representation of the structure of this thesis.

[57] Hutchinson and Duncan 2012, p. 107
[58] Pendleton in: McConville and Chui 2007
[59] Pendleton in: McConville and Chui 2007, p. 161
[60] Van Hoecke 2015, p. 9f



(Figure 4.2: Schematic representation of the structure of this thesis)

Chapter 5 - Legal Situation Concerning the Processing of Patient Data

The first step when developing an application-specific legal framework is to take a look at the general legal situation concerning the processing of medical data, and more precisely, patient data in the DACH region before we dive deeper and examine the legal situation regarding data visualization. In the language of our research framework, this is the first round of assembling relevant facts before we can identify emerging legal issues that serve as a starting point for the answer to our research question. In other words, this chapter can be seen as the foundation for the development of our legal framework in Chapter 7 - Legal Situation Concerning the Visualization of Patient Data.
Since we are examining laws concerning German-speaking countries, we will cite the German version of the respective passages. If necessary, we will provide either an existing translation or our own translation. Otherwise, we will summarize or paraphrase the cited text for better understanding. Furthermore, we use the suffixes -AT, -DE, and -CH for the national laws of the respective countries (Austria, Germany, and Switzerland).

5.1 Preliminaries

Before diving deeper into the subject matter, it is necessary to clarify some basics, such as the legal relationship between the European Union, its Member States, and third countries when it comes to the law concerning the processing of personal data, as well as some terms that will be used later.

5.1.1 EU-DACH Relationship

The law of the European Union consists of primary and secondary law. The contracts, ratified by all member states, respectively the Treaty on European Union and the Treaty on the Functioning of the European Union, form the primary EU law while regulations, directives, and resolutions of the EU which are being implemented by the member states form the secondary EU law.[61]
Laws about data, more precisely about data protection, are already mentioned at the top of this hierarchical structure. The EU Charter of Fundamental Rights, which is enshrined in the Treaty of the European Union, already constitutes the significance of data protection.[62] Article 8 of the EU Charter specifically states: "*Everyone has the right to the protection of personal data concerning him or her.*"[63] In addition, the Charter enshrines the data subjects' consent to the processing, access, and right to rectify their data, as well as that compliance with these rules must be controlled by an independent authority.[64]
While still very general in primary law, secondary law provides for comprehensive treatment of data protection. The main EU legal instrument related to data protection, which used to fall

[61] Handbook on European data protection law 2018, p. 27
[62] Charter of Fundamental Rights of the European Union
[63] Charter of Fundamental Rights of the European Union Art. 8, Nr. 1.
[64] Charter of Fundamental Rights of the European Union Art. 8, Nr. 2., 3.

under the Data Protection Directive,[65] is now the General Data Protection Regulation,[66] commonly called GDPR.[67] Unlike the former Data Protection Directive, the GDPR has direct applicability since it is an EU regulation. An overview of the GDPR, in particular the aspects relevant to our project, is provided in section 5.2 EU General Data Protection Regulation (GDPR).
Switzerland is not a member of the European Union; therefore, the GDPR as well as other EU laws, is not directly applicable. Since we are following a functional comparative legal research approach, our goal is to find similarities, discrepancies, and possibilities for unification regarding the data protection law in Switzerland. However, in the case of the GDPR, the legal situation in Switzerland is quite clear. Namely, on September 1st., 2023, a total revision of the Swiss data protection law will come into force. It has already been ratified with a transition period of one year. In addition to adapting to changing technological and social conditions, one of the stated goals of the revision was to bring Swiss data protection legislation as a whole closer to the requirements of the GDPR in order to be recognized as a third country with an adequate level of data protection by the EU.[68] Nevertheless this is only the case for the GDPR which doesn't mean that there aren't any other relevant country-specific laws concerning patient data. And even though the GDPR is of great significance for us, it only marks the start of our legal research.
In the next sections, some relevant key points of the GDPR, as well as country-specific features, are explained in more detail.

5.1.2 Terminology

The first thing we need to explain is how the terms we work with are defined, especially in the GDPR as well as in national legislation concerning data protection, namely the terms "data", "personal data", and "patient data".

Data

There is no legal definition of the term "data" per se in the legal texts we examined. From a legal point of view, the term is generally very broadly defined and is always further specified or extended in the respective laws in order to define what kind of data is involved. For example, the GDPR defines the term "personal data" but not the term "data" itself.[69] In other places, too, such as the Austrian Criminal Code[70], it says for example: "*Im Sinne dieses Bundesgesetzes sind Daten sowohl personenbezogene und nicht personenbezogene Daten als auch Programme*"[71] which means that personal as well as non-personal data and programs are subsumed under the term "data". Thus, the term is defined by itself here. For now, we will leave it at the fact that the concept of data must be understood with regard to the respective legal text.

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[65] Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data
[66] GDPR
[67] Handbook on European data protection law 2018, p. 29f
[68] https://www.bj.admin.ch/bj/de/home/staat/gesetzgebung/datenschutzstaerkung.html last visited 2022-02-10
[69] GDPR, Art. 4
[70] StGB-AT
[71] StGB-AT §74 Nr. 2

Personal Data

In contrast to the term “data”, the term “personal data” has a very clear definition in the examined legal sources. The GDPR states:

“*‘personal data’ means any information relating to an identified or identifiable natural person (‘data subject’); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person;* ”[72]

The Austrian as well as the German Data Protection Laws adopt this definition[73] (The German Data Protection Law directly refers to the definitions of the GDPR therefore it is not mentioned again explicitly[74]). The term is defined in a similar way in the new Swiss data protection law,[75] as well, though not as detailed (While German and Austrian legislation uses the term "personenbezogene Daten", Swiss data protection law speaks of "Personendaten").[76]

The first thing worth mentioning is the extensive explanation of the term “identifiable”. While it is quite clear what “identified” means, namely that the data itself already contains information about the respective natural person, the latter needs some further discussion. In that case, the connection between the respective information and the corresponding natural person can be established through additional data. However, it is not easy to draw a precise line as to how far this definition extends. The GDPR suggests that in order to determine whether information counts as identifiable to an individual natural person, consideration should be given to the means that could be or are likely to be used by both the controller and other actors to identify the respective person, also including costs and time constraints determined by current technology and possible future developments. Furthermore, it explicitly states that this consideration should also be taken when dealing with pseudonymized data, which we will have a closer look at in Section 5.4.1 Pseudonymization and Anonymization.[77]

Another mentionable aspect is the fact that this Article (and subsequently the GDPR as a whole, as the title of the regulation already suggests) deals with the protection of a natural person’s data and also explicitly excludes the processing of the data of a legal person.[78] The question of to what extent data protection laws apply to legal persons is debated, especially in Austria, since former versions of the Austrian Data Protection law also included legal persons, and the most recent version, though adapted to the GDPR, still mentions a former definition as well.[79] This leads to debate and legal challenges, as seen in a recent final court decision.[80] In former versions of the Swiss Data Protection Law, legal persons also haven’t been excluded from the definition of “personal data”. While it is worth mentioning these issues, they won’t be discussed any further because elaborating on this topic would go

[72] GDPR Art. 4, Nr. 1
[73] DSG-AT §36 Nr. 1 resp. BDSG-DE §2
[74] BDSG-DE §1 Nr. 5
[75] revDSG-CH
[76] revDSG-CH, Art. 5
[77] GDPR Rec. 26
[78] GDPR Rec. 14
[79] DSG-AT §1
[80] GZ: 2020-0.191.240 https://www.ris.bka.gv.at/Dokumente/Dsk/DSBT_20200525_2020_0_191_240_00/DSBT_20200525_2020_0_191_240_00.html last visited 2022-05-08

beyond the scope of our thesis since our focus lies solely on natural persons' data, respectively on patient data, which we will discuss in the next section.

Patient Data and Data Concerning Health

So far, in developing our problem statement and research question, we have used the term "patient data". However, the GDPR provides a definition for the term "Data Concerning Health," and as Mulder explains, the terminology on this subject is quite ambiguous. "Medical Data", "personal Health Data", and "medical welfare data" are also terms that are being used in a legal context, thus making it difficult to grasp what is covered by the respective terms and what is not.[81] Additionally, the term "patient data" ("Patientendaten") is also used in Austrian law.[82] (e.g.) As Mulder suggests, for legal examinations, the term "Data Concerning Health" should be used because the legal definition provided by the GDPR is so broad that the other terms are expected to be covered by this definition.[83] The term "patient data", on the other hand, shall be used in our thesis not as a legal definition but as an umbrella term whenever we are talking about the specific types of data relevant to our research project.

According to the GDPR, "*'data concerning health' means personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status;*"[84] This implies that this type of data is a subset of "personal data" which means that personal data laws as well as the more restrictive laws about "data concerning health" apply here.

A more extensive explanation is also provided and indeed tries to cover as many circumstances as possible. It explicitly states that "*[..] information derived from the testing or examination of a body part or bodily substance, including from genetic data and biological samples;*"[85] is covered by the legal definition which is of great significance to our project since the data or at least an important fraction of the data we are working with is undoubtedly covered by this definition.

Data Processing

The term "processing" is again defined very broadly: any operation, manual or automated, performed on personal data falls under this definition according to the GDPR.[86] Again, the national Data Protection Laws of Germany, Austria, and Switzerland apply this legal definition just as broadly. Since it is part of our research question to provide a framework for the processing of our formerly defined contextualized data, the legal implications of this term are of great significance to us and will be elaborated in the following sections.

One thing worth mentioning is that the definition only includes personal data. Therefore, if we identify types of data in our project that do not fall under the category of personal data, the elaborated aspects of data processing do not apply.

[81] Mulder 2019, p. 209
[82] Example: W258 2201288-1/10E https://www.ris.bka.gv.at/JudikaturEntscheidung.wxe?Abfrage=Bvwg&Dokumentnummer=BVWGT_20190403_W258_2201288_1_00 last visited 2022-05-10
[83] Mulder 2019, p. 220
[84] GDPR Art. 4, Nr. 15
[85] GDPR Rec. 35
[86] GDPR Art. 4, Nr. 2

5.2 EU General Data Protection Regulation (GDPR)

In the following, we will take a closer look at the aspects of the legal situation relevant to our project with regard to "data concerning health" as defined by the GDPR since this is the central legal source regarding this topic.

5.2.1 Processing of personal data

The GDPR provides a general set of principles for the processing of personal data. Additionally, there are further requirements when dealing with special categories of personal data, such as data concerning health. First, we will take a look at the laws applicable to all types of personal data and get more specific from there.
Table 5.1 provides an overview of the Articles of Chapter 2 of the GDPR concerning the processing of personal data and their relationship to each other. The first Article of the Chapter, namely Article 5, introduces several principles, amongst them the term ‘lawfulness’, which is then again further defined in Article 6. Article 6 again introduces new concepts, and one of them, namely the term “consent,” is further elaborated on in Articles 7 and 8. So, these Articles are directly linked to each other. Articles 9 and 10, on the other hand, do not apply in all cases of personal data processing but rather define additional legal obligations for processing special categories of personal data, such as data concerning health. Article 11 defines the indemnity against the obligation to keep or collect additional data if the identification of a data subject is no longer required for the sole purpose of complying with the GDPR. Not all of these principles and concepts are equally relevant to our project, and not all warrant further discussion, so we will provide an overview of the various concepts and delve deeper where it seems necessary.

GDPR Chapter 2: Principles[87]	
Article 5: Principles relating to the processing of personal data	Defines several principles for personal data processing, namely 'lawfulness, fairness and transparency', 'purpose limitation', 'data minimisation', 'accuracy', 'storage limitation', 'integrity and confidentiality' and 'accountability'
Article 6: Lawfulness of processing	Provides a further definition of the term 'lawfulness' from Article 5(1)(a) including several conditions, namely Consent, Contract, Legal Obligation, Vital Interest, Public Interest, and Legitimate Interests
Article 7 & 8: Conditions for Consent	Provides a further definition of the term 'consent' from Article 6(1)(a) including Demonstration, Distinguishability, Right of Withdrawal, Assessment of Necessity and additional rules for Children's consent
Article 9 & 10: special categories of personal data	While the Articles above also apply for special categories of personal data (such as data concerning health), additional rules are defined in this chapter for these types of data.
Article 11: Processing that does not require identification.	An additional principle for the case is that the identification of a data subject is no longer necessary.

(Table 5.1: Overview of Chapter 2 of the GDPR)

Three Big Words

The first Paragraph of Article 5 of the GDPR states that: "*Personal data shall be: processed lawfully, fairly and in a transparent manner in relation to the data subject ('lawfulness, fairness and transparency');*"[88] These three principles, enshrined in a single paragraph, raise some questions and call for a more detailed discussion. What do these terms actually mean, and what are their legal implications?

While the term "lawfulness" is further defined in Article 6 of the GDPR, the principles of fairness and transparency tend to leave more room for interpretation and discussion, which is also noted by Gil González and De Hert.[89] While further remarks exist about the transparency principle within the GDPR (which is nonetheless a debated topic[90]), the principle of fairness is not further elaborated within the GDPR. As Clifford and Ausloos describe it: "*Despite the fact that this principle* [Note: the principle of fairness] *is often referred to as a key tenet of the data protection framework, a precise understanding of its role remains elusive.*"[91] In the following, we will take a closer look at each of these principles.

Big Word 1 - Lawfulness

Article 6 of the GDPR lists the conditions for processing personal data, at least one of which must be met for the processing to be considered lawful. Paragraph 1 lists the respective

[87] GDPR Chapter 2
[88] GDPR Art 5, Nr. 1(a)
[89] Gil González and De Hert 2019, p. 19
[90] cf. Spagnuelo et al. 2019
[91] Clifford and Ausloos 2018, p. 1

conditions, while paragraphs 2 and 3 open the possibility for the introduction of more specific and additional conditions by the Member States of the European Union, which we will discuss in section 5.3 State-Specific Law. Table 5.2 provides an overview of the conditions for the lawful processing of personal data as described in Article 6 of the GDPR.

LAWFULNESS OF PROCESSING		
ARTICLE	**CONDITION**	**RELEVANT EXTRACT FROM PROVISION**
Article 6(1)(a)	Consent	the data subject has given consent to the processing of his or her personal data for one or more specific purposes;
Article 6(1)(b)	Contract	processing is necessary for the performance of a contract to which the data subject is party or in order to take steps at the request of the data subject prior to entering into a contract;
Article 6(1)(c)	Legal obligation	processing is necessary for compliance with a legal obligation to which the controller is subject
Article 6(1)(d)	Vital interest	processing is necessary in order to protect the vital interests of the data subject or of another natural person;
Article 6(1)(e)	Public interest	processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller;
Article 6(1)(f)	Legitimate interests	processing is necessary for the purposes of the legitimate interests pursued by the controller or by a third party, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data, in particular where the data subject is a child.

(Table 5.2: Conditions for lawful processing of personal data by Clifford and Ausloos[92])

Ausloos claims that due to the broad scope of the GDPR, a lot of terms tend to suffer from vagueness, among them also the term “lawfulness” because when understood in an ordinary language fashion, it can easily be interpreted as “in accordance with the law”. However, with Article 6, the GDPR managed to narrow down the scope of the term, distinguishing it from concepts like legitimacy, fairness, or legality and actually giving it meaning. This, in turn, has the effect that it can be effectively used as a condition for the rights of a data subject, namely the right to erasure.[93]

Another aspect worth mentioning is that while the concept of consent and the requirements that make a data subject’s choice legitimate received a lot of attention from academia and practitioners, other concepts like the term “legitimate interest” have been discussed reasonably less.[94]

While we are discussing the concept of consent in section 5.2.1 - Consent, giving an elaborate answer to the question about the interpretation of the term “legitimate interest” and how to determine whether something justifies as such for the processing of personal data would go beyond the scope of our thesis. However, the work of Kamara and De Hert can serve as a starting point for further investigation of this topic.[95]

[92] Clifford and Ausloos 2018, p. 8
[93] Ausloos 2017; See also section 5.2.3 Rights of the Data Subject
[94] Kamara and De Hert 2018, p. 1
[95] Kamara and De Hert 2018

Big Word 2 - Fairness

As already mentioned, the principle of fairness is very broad and leaves a lot of room for interpretation and discussion. The intended purpose of the term is to cover the prohibition of unreasonable practices that are not directly precluded by any legal provision. Or as Ausloos puts it: "*Fairness constitutes a dynamic safeguard – changing over time – compelling controllers to take account of the interests and reasonable expectations of data subjects. It is connected to concepts such as reasonableness, proportionality and transparency in their broadest meaning.*"[96]

While the principle is even enshrined in the EU Charter of Fundamental Rights,[97] several academic interpretations of the term exist. Clifford and Ausloos try to further divide fairness into sub-principles, namely procedural fairness and fair balancing elements, while still claiming that they only provide the first steps for a better understanding of the concept, which are by no means exhaustive.[98] Malgieri, on the other hand, tries to elaborate a linguistic as well as a contextual interpretation of the term.[99] In his linguistic analysis of the translations of the term used by the respective EU Member States, he discovers mainly three different semantic notions of the concept, namely correctness, loyalty, and equitability. With regard to our project, it is interesting to note that the German version of the GDPR, in particular, provides for a specific legal term ("Treu und Glaube"), which is subsumed under the term loyalty in his work. In his contextual interpretation, he introduces the term "vulnerability" and overall suggests that the fairness principle should be understood as "*[..] the mitigation of data subjects' vulnerabilities through specific safeguards and measures [..]*"[100] while also taking into account the notion of procedural fairness as well as the balancing aspect between the interests of data controllers and data subjects, as also elaborated by Clifford and Ausloos.

While the concept of fairness in the context of the GDPR has received considerable attention in the academic literature, a more thorough examination of this topic is beyond the scope of our thesis, so this section can only serve as an overview. However, our main takeaway with regard to our project is that when planning to execute a specific type of data processing, although there might be no exact legal prohibition, we still need to ask ourselves whether our practices might violate the commonsensical notion of fairness.[101]

Big Word 3 - Transparency

In contrast to the fairness principle, there are some remarks and definitions regarding the principle of transparency within the GDPR; Recitals 39 and 58, in particular, provide further explanation. Additionally, the concept is elaborated again in the first section of Chapter 3 concerning the rights of the data subject, which we will take a closer look at in Section 5.2.3 Rights of the Data Subject.

In summary, transparency means that any information relating to the processing of personal data (especially information about the data controller's identity, the purpose of the processing, rules, risks, safeguards, rights, and how to exercise those rights) should be provided in a way that is linguistically clear, precise as well as easy to understand and to

[96] Ausloos 2017
[97] Charter of Fundamental Rights of the European Union Art. 8, Nr. 2
[98] Clifford and Ausloos 2018
[99] Malgieri 2020
[100] Malgieri 2020, p. 154
[101] For a few remarks on the ethical aspects of our research question see section 7.6 Remark on the Ethical Nature of our Research Question

access and, if necessary, additionally supported by visualization.[102,103] Or, simply put, the concept of transparency is to help the data subject know what happens with their data.
Nonetheless, there is a lot of ambiguity when taking a closer look. Words like "easy" and "clear" are highly subjective, and there is a lot of room for interpretation. Spagnuelo et al. state: "*Deciding whether a tool gives a presumption of compliance with a GDPR's principle is an open and hindering problem because the Regulation's provisions are broadly defined and admit several interpretations[..]*", but they also add: "*[..] one could attempt the task by leveraging on the existing literature.*"[104] Especially together with the aspect of visualization, this provides a starting point for further research within our project, which will be taken up again in Chapter 7 - Legal Situation Concerning the Visualization of Patient Data.
Another aspect worth mentioning is that the principle of transparency (in contrast to fairness and lawfulness, which are legalistic concepts) describes a socio-technical concept that should be realized as a technical feature whenever necessary.[105] This is another reason why this concept is of particular importance in the context of our work.

Purpose limitation

The GDPR states that Personal Data shall be: "*collected for specified, explicit* [106] *and legitimate purposes* [107] *and not further processed in a manner that is incompatible with those purposes;*"[108] In addition, with reference to Article 89, there are some exceptions defined, especially in the context of research, statistics or archiving in the public interest. The statistical and scientific context could be especially relevant for our project, which will be discussed in section 5.4.2 Patient data in the context of research.
Again, there is a lot of discussion regarding the technical compliance with this concept. We would like to highlight two issues in particular: First of all, from a technical perspective, it often remains challenging to precisely represent the purpose of a data processing system due to its complexity and lack of tools.[109] Secondly, this concept is strongly linked to the concepts of transparency and consent.[110] The consent of the data subject, therefore, has a major influence on the scope of the purpose limitation.[111] This, in turn, provides a challenge and begs the question of how to provide easily understandable information about the processing of their data if the processing itself remains complex and hard to represent.

Data Minimisation and Storage Limitation

Furthermore, the GDPR requires minimization of the processed data both in terms of data volume[112] and limitation of the storage period.[113] With regard to the time constraint, there is

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[102] GDPR Rec. 39 and Rec. 58
[103] Here we can already see a connection point to Chapter 7 of our work which deals with this very aspect of visualization.
[104] Spagnuelo et al. 2019, p. 114
[105] Spagnuelo et al. 2019, p. 114
[106] cf. Transparency
[107] cf. Lawfulness
[108] GDPR Art. 5, Nr. 1(a)
[109] Basin et al 2018, p. 1f
[110] (cf. section xy)
[111] Donelli and McDonagh 2019, p. 6f)
[112] GDPR Art. 5, Nr. 1(c)
[113] GDPR Art. 5, Nr. 1(e)

an exception when storing data for "*[..] archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1)*",[114] whereas Article 89 defines the requirements for such derogations.
These concepts seem especially interesting from a technical perspective. It is quite possible to determine what data minimization means from a theoretical perspective, namely that none of the input data that is semantically used by a program should be processed or stored. But in practice, some difficulties arise, as Antignac et al. explain:

> *The goal of the* data minimisation process *is to minimise the input data so only what is necessary is given to the program. Whenever the input data exactly matches what is necessary we may say that the minimisation is the* best*. Best minimisation is, however, difficult to achieve in general since it is not trivial to exactly determine what is the input needed to compute each possible output.*[115]

The implications of the technical implementation challenges that arise to comply with these concepts are discussed in section 5.2.5 Technical implications of the GDPR.

Accuracy

The role of the notion of accuracy, i.e., the need to keep personal data accurate and up to date,[116] in the context of the GDPR is probably best understood by looking at the opposite of this notion: This requirement is fulfilled by eliminating inaccurate data. Therefore, the concept of accuracy can be understood as an enabler of a data subject's right to rectify their data.[117]
While it is often assumed by legal authorities that the concept of accuracy is self-explanatory,[118] there are, as usual, ambiguities from a legal as well as from a technical perspective. One problem relating to the former occurs when looking at the relation between accuracy and other principles of personal data processing: Some scholars claim that accuracy, together with the principle of fairness, seems to be at odds with other requirements - most evidently with the principle of data minimization.[119]
Another point worth mentioning is that while the notion of accuracy is quite clear when looking at factual data, challenges arise when looking at inferences based on personal data. Predictions based on personal data, data profiling, human-generated opinions (e.g., by a medical professional) - Data such as this causes debate as to whether it is considered personal data and, if so, to what extent the concept of accuracy applies to it.[120]

Integrity and Confidentiality

"*Personal Data shall be processed in a manner that ensures appropriate security of the personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organisational measures.*"[121] While our literature review indicates that this concept gives little cause for

[114] GDPR Art. 5, Nr. 1(e)
[115] Antignac et al 2017, p. 442
[116] GDPR Art. 5, Nr. 1(d)
[117] Biasin 2021, p. 2f
[118] Biasin 2021, p. 2
[119] Biasin 2021, p. 3
[120] Biasin 2021, p. 3
[121] GDPR Art. 5, Nr. 1(f)

discussion from a legal, scientific perspective, the scientific focus here lies primarily on the implementation of this requirement, especially what "*appropriate technical or organisational measures*" means in the context of the respective field, for example in Blockchain-based solutions,[122] IoT Systems,[123] Fog-To-Cloud Environments,[124] or more general when looking at the challenges smaller businesses with fewer resources face when working towards compliance with the GDPR.[125] These guidelines also exist, of course, in the health sector, which we will discuss in more detail in section 5.2.5 Technical implications of the GDPR.

Accountability

Article 5(2) of the GDPR requires the data controller to be accountable and to demonstrate compliance with all the legal requirements and concepts mentioned above. While this requirement seems easy to understand when the data controller is a legal entity, problems arise in the area of automated data processing and algorithmic decision-making. Castets-Renard points out that while algorithms make decisions with huge impact on the individual, such as employee screenings or credit checks, they cannot be held accountable and that "[..] *the GDPR's lack of a right to individual explanation regarding these decisions poses a problem.*"[126] This could be especially interesting for future research when implementing decision support systems in the context of our project - which will, however, not be part of this thesis.

Consent

As mentioned above, consent is one of the key concepts of data processing not only in the GDPR but also in the EU Charter of Fundamental Rights. It is one of the conditions for the lawfulness of data processing, as set out in Article 6 of the GDPR, and its requirements are further defined in Article 7. The GDPR defines consent of the data subject as: "*[..] any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her;* "[127] This concise definition is supported by numerous recitals as the term is mentioned in no less than seventeen of them. First, we take a short look at the theoretical foundation of the concept within the GDPR before discussing some issues that seem to appear in practice as well as in academic discussions.
Four main conditions concerning the data subjects' consent regarding the processing of their personal data are defined:[128]

1. The ability of the data controller to demonstrate that consent regarding the respective personal data processing was given.
2. The consent form should clearly distinguish the matters to which consent is being given. It should also be easily accessible and use clear and simple language.
3. Withdrawal of consent by the data subject should always be possible.

[122] Haque et al 2021
[123] Rhahla et al 2019
[124] Crompton and Jensen 2018
[125] Freitas and Mira da Silva 2018
[126] Castets-Renard 2019, p. 91f
[127] GDPR Art. 4, Nr. 11
[128] GDPR Art. 7

4. Particular attention should be paid to whether access to services unrelated to the respective consent form is dependent on giving consent to other parts of a contract when eliciting whether consent was given freely.

These conditions are then further specified by several recitals, and the concept itself is used multiple times in the context of defining the data subjects' rights in the GDPR. The concept of consent also plays a special role when it comes to the processing of data concerning health, which will be elaborated in section 5.2.2 Processing of Data Concerning Health. In addition to that, it is also strongly linked to the concept of purpose limitation, as mentioned before. So, as you can see, the data subject's consent is quite entangled in the GDPR.

But while the theoretical definition is quite extensive, a lot of uncertainties emerge when looking at its implications. As already elaborated, terms like "clear" and "simple" remain quite ambiguous and leave a lot of room for interpretation.[129] As Kamara and De Hert state: "*Much debate has taken place over consent and the conditions for a meaningful informed choice of the data subject [..]*"[130], and we try to briefly outline some of the issues being debated.

The GDPR requires that consent dialogs on websites or apps must be designed and presented in such a way that the user has the opportunity to make a free and informed decision. But even though many of these dialogs seem consistent with this policy, there is often more to it than what meets the eye at first glance. A study by Machuletz and Boehme provides evidence supporting the hypothesis that there is a common practice of using certain design elements in consent dialogs to "*[..] deceive users into agreeing to more data processing purposes than intended.*"[131] One could argue that this problem concerns policymakers as well as data subjects and not so much data controllers. But since we are looking not only at current regulations but also at possible future developments, it is important to keep this in mind since there is a demand for better regulation regarding consent dialogs. And even if no such design patterns are used on purpose, it is important to point out that the way people interact with consent notices is substantially impacted by seemingly small implementation decisions, as, for example, Utz et al. suggest.[132]

Another issue emerges with the requirement of the data subject's ability to revoke consent and the "right to be forgotten".[133] To mention one, the common practice of creating data backups troubles some researchers' minds. As Politou et al. put it: "*Propagating the required erasure mechanisms to backups, empower users and financial institutions to manipulate data integrity according to their needs, like hiding transactions from audit controls when deemed necessary.*"[134]

To sum it up, the processing of personal data is highly dependent on consent given by the data subject. While in practice, many data controllers seek to obtain consent for as many contingencies as possible, research suggests that sometimes the opposite (i.e., differentiation and clarification) may be beneficial to all parties, particularly in the context of scientific research.[135]

[129] cf. Transparency
[130] Kamara and De Hert 2018, p. 1
[131] Machuletz and Boehme 2020, p. 494
[132] Utz et al. 2019, p. 973
[133] cf. section 5.2.3 Rights of the Data Subject
[134] Politou et al. 2018, p. 15
[135] cf. Comandè and Schneider 2021; cf section 5.4.2 Patient data in the context of research

5.2.2 Processing of Data Concerning Health

The reason for the detailed elaboration regarding the processing of personal data is that compliance with the aforementioned laws forms the prerequisite for the legal processing of data concerning health.[136] Moreover, some additional criteria need to be met as defined in Article 9 of the GDPR.
It is interesting to mention that Article 9 is (in the same way as Article 6 - Lawfulness of Processing) formulated as a prohibition with reservation of permission. This means that, as Article 9(1) states, the processing of data concerning health is generally prohibited, with exemptions defined in Article 9(2). Some of them turned out to be particularly relevant for our project. The prohibition shall not apply if:[137]

- Article 9(2)(a): explicit consent to the processing has been given
- Article 9(2)(c): consent cannot be given for legal or physical reasons and the processing is necessary for the protection of the data subject's vital interests
- Article 9(2)(h): there are medical purposes, preventive or occupational, including "[..] *medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services [..]*"
- Article 9(2)(i): there is a necessity for processing personal data in order to ensure "[..] *high standards of quality and safety of health care and of medicinal products or medical devices [..]*" within the sector of public health.

While the importance of consent, as mentioned in the first two points, has already been elaborated before, the latter two points raise the question as to what extent our project is covered by these legal definitions. In general, the GDPR opens up some possibilities in the area of scientific research, even in the absence of consent,[138] but at the same time restricts the use of personal data for interests other than those of the public or the data subject.[139] Therefore, it is important to separate the different purposes of data processing in our project and to ask the question of whether they can be separated at all. Especially when considering Olimid et al.'s statement: "*[..] the GDPR enables a new legal framework for the healthcare industry and a new interpretation of 'research'.*"[140] This, however, cannot be entirely covered by our thesis, but it will nevertheless be elaborated further in section 5.4.2 Patient data in the context of research.
Article 9(4) explicitly states that member states may introduce additional limitations or conditions regarding the processing of data concerning health, which will be a starting point for us to take a closer look at the national legislation in section 5.3 State-Specific Law.

5.2.3 Rights of the Data Subject

Chapter 3 of the GDPR defines several rights executable by the data subject. Since our thesis focuses on the processing (and, in the later run, the visualization) of data concerning health, this topic is not our main interest. Nevertheless, it will be briefly outlined since it cannot be separated entirely from the legal obligations regarding the processing. (We

[136] the definition of this term is covered in section 5.1.2 Terminology
[137] GDPR Art. 9, Nr. 2
[138] (cf. section 5.4.1 Pseudonymization and Anonymization; cf.section 5.4.2 Patient data in the context of research)
[139] Comandè and Schneider 2021, p. 4
[140] Olimid et al 2018, p. 635

already mentioned a data subject's rights when talking about the concepts of lawfulness, transparency, accuracy, and consent.) It is also interesting to point out that the GDPR does not include any additional rights for special categories of personal data, such as data concerning health. Below, we will give a brief overview of the rights granted to the data subject.

Right to access (Article 15)

The data subject has the right to know whether their personal data is being processed, and if so, access to several types of information shall be granted, like, among others, the purpose of processing, a complete copy of the data or the storage period. The right to access can be interpreted as a logical first step towards executing other rights since it is, for example, hard to demand data rectification if one doesn't have access to the respective data.[141] Interestingly, there is a lot of literature on the potential exploitation of this right,[142] but this is an entirely different topic.

Right to rectification (Article 16)

Inaccurate personal data shall be corrected, and incomplete data shall be completed by the controller at the request of the data subject. (Article 19 adds the exception that this does not need to be the case if the rectification involves disproportionate effort or proves impossible). It is important to mention that this right is directly linked to the concept of accuracy, as already elaborated before.[143]

Right to erasure - 'right to be forgotten' (Article 17)

As mentioned before, the data subject's right to erase their personal data is directly connected to the concept of consent,[144] respectively the revoking of consent as well as to the concept of lawfulness, as Ausloos describes it.[145] Also, the technical challenges that arose have been discussed. There are also other cases defined in which the controller must erase the personal data of a data subject, for example, if the data are no longer necessary for the intended purpose or if the processing was unlawful. Altorbaq et al. point out that the term "erasure" remains ambiguous, and some companies are not sure what it actually means. Sometimes, it can be sufficient to unlink the information from the subject, and sometimes, complete destruction of the data is legally necessary, depending on the platform, the data subject's request, and the reason for the necessity to erase the data.[146]

Right to restriction of processing (Article 18)

According to the GDPR, "restriction of processing" is defined as "*[..] the marking of stored personal data with the aim of limiting their processing in the future;*"[147] Recital 67 provides additional information how this restriction should be executed, namely by methods such as "*[..] temporarily moving the selected data to another processing system, making the selected personal data unavailable to users, or temporarily removing published data from a*

[141] Wolters 2018, p. 7f
[142] cf. Di Martino et al. 2019 and Bufalieri et al. 2020
[143] cf. Dimitrova 2021, p. 1; cf. Accuracy
[144] cf. Consent
[145] cf. Lawfulness; Ausloos 2017
[146] Altorbaq et al. 2017, p. 309
[147] GDPR Art. 4, Nr. 3

website."[148] Article 18(1) lists the conditions under which the data controller is obliged to restrict the processing of personal data. This restriction can act as a temporary solution, for example, if there is a conflict concerning the data's accuracy, or it can be an alternative to erasure, for example, if the data is needed by the data subject for a legal claim.[149]

Right to data portability (Article 20)

According to Article 20 of the GDPR, a data subject has the right to receive their personal data in a format that is structured, commonly used, and machine-readable so that it can be transferred to another controller either manually or directly by automated means. This way, according to Recital 68, service providers shall be encouraged to develop interoperable formats and interfaces. This right can also be interpreted as an extension of the right to access insofar as it grants the data subject additional control over their data.[150]
De Hert et al. attribute great importance to this right, as it represents an important novelty, both when it comes to ensuring data subjects' rights of control over their data and at the interface between data law and other areas of law, such as competition law or intellectual property. But at the same time, they claim that there is room for interpretation, as they elaborate on two different ways in which this law can be understood, which could prove interesting for further research.[151]

Right to object (Article 21)

If the data subject objects to the processing of their personal data, the criteria depend on the type of processing. For example, if the data is used for direct marketing purposes, the data subject can object to the processing at any time. In other cases, the controller will not immediately be obliged to stop the processing if they can provide legitimate grounds for the processing. As Wolters puts it: "[..] *the successful exercise of the right to object depends on a comparison of interests* [Note: of the data subject and the data controller]."[152]

Automated decision making (Article 22)

Strictly speaking, this "right to obtain human intervention" is not a right of the data subject but rather a data controller's obligation since it does not require any action by the data subject.[153] According to Article 22 of the GDPR, automated profiling and decision-making are generally prohibited unless one of the three exceptions can be invoked. These exceptions, on the other hand, come with several ambiguities.[154] Without going into further detail, it is important to point out that it is relevant to our project when it comes to automated decision-making that "*Special categories of data* [Note: such as data concerning health] *can never be used, unless there is consent or public interest [..]*"[155]

[148] GDPR Rec. 67
[149] Wolters 2018, p. 10
[150] Wolters 2018, p. 10
[151] De Hert et al. 2018, p. 193
[152] Wolters 2018, p. 11
[153] Wolters 2018, p. 12
[154] cf. Gil González and De Hert 2019, p. 17
[155] Gil González and De Hert 2019, p. 19

5.2.4 Other Aspects

Since it would be disproportionate to address all aspects of the GDPR to the same extent here, we will now briefly summarize a few topics that seem relevant on the periphery.

Obligations of the Data Controller

Chapter 4 of the GDPR lists several obligations of the data controller when processing personal data. Among them are:[156]

- Data protection by design and by default (Article 25):
  This obligation aims to ensure that systems are already designed and equipped with the technical means to meet and fulfill the data protection requirements of the GDPR. We will come back to this Article when talking about the technical implications of the GDPR.[157]
- Maintaining records of processing activities (Article 30):
  Whenever applicable, records of processing activities shall be maintained by the data controller, containing information, inter alia, about the processing purposes, metadata, such as categories of data subjects and categories of personal data, or applied security measures.
- Security of processing (Article 32):
  While taking into account several prerequisites, the data controller is obliged to implement measures to ensure an appropriate level of security, considering the involved risks. How these means could look will then be further elaborated. We will come back to this Article when talking about the concept of pseudonymisation.[158]
- Notification of a personal data breach (Article 33 & 34):
  In the event of a personal data breach, the controller is obliged to notify the supervisory authority and to inform the data subject of the breach without undue delay (Some exceptions are defined when a delay may occur).
- Data Protection Officer (Article 37, 38 & 39):
  The data controller is obliged to designate a data protection officer in certain circumstances, e.g., if special categories of data are processed on a large scale. Article 39 then defines the tasks that shall be carried out by the designated officer, such as informing and advising the controller about their obligations, monitoring compliance with the GDPR, or cooperating with the supervisory authority.

Please note that this list is not complete and is intended only as an overview. In addition, it may give ideas for a more profound engagement with this topic.

Transfers of personal data to third countries

This part of the GDPR, namely Chapter 5, represents an aspect worth mentioning in relation to our project since one part deals with the relationship between EU member states and third countries (Switzerland in this case) regarding the processing and transfer of personal data, respectively data concerning health.

[156] GDPR Art. 25 - Art. 39
[157] cf . section 5.2.5 Technical implications of the GDPR
[158] cf. section 5.4.1 Pseudonymization and Anonymization

The main goal is to ensure and safeguard a data subject's rights and freedoms on the same level as the GDPR. Hereby, the key aspect is a so-called "adequacy decision".[159] The criteria for the assessment of the level of data protection provided by a third country's legislation are defined in Article 45. Wagner claims that it is possible to identify and separate these criteria into substantive requirements on the one hand and supporting procedural and enforcement requirements on the other hand. While the former, which includes key principles such as the principle of purpose limitation as well as GDPR-specific demands like the "right to be forgotten", build a solid legal foundation, the latter seems to be more difficult to generalize since "*The comparative analysis of different data protection regimes reveals considerable differences in relation to their procedural and enforcement mechanisms and therefore, one cannot identify a definite list of requirements common to all of them.*"[160]
Furthermore, he claims that while the Working Party provided guidelines to the European Court of Justice and published several opinions concerning the adequacy of specific countries' data protection regimes (among others, also Switzerland), it still remains challenging to exactly identify and standardize the process of an adequacy decision.[161] However, how these decisions are made shall not be our concern. What is important, though, is that there is a general agreement on the sufficient adequacy of the Swiss data protection law, which we will discuss in section 5.3.3 Implementation in Switzerland.

5.2.5 Technical implications of the GDPR

As we have seen, although many concepts are comprehensively defined from a theoretical point of view in the GDPR (while still causing a lot of debate, as can be observed when looking at the principle of fairness, for example[162]), many questions arise when it comes to the actual technical implementation of a data processing system. May it be the challenge to provide easily understandable information about the processing, if processing itself is rather complex,[163] the challenge that it is often a non-trivial task to exactly determine the input that is needed for a pacific processing operation[164] or the challenges that arise when combining backup mechanisms with the data subject's right to be forgotten.[165] The GDPR provides little technical guidance for the actual implementation in order to comply with the regulation. Jasmontaite et al. suggest that "*[..] the entire weight of the GDPR rests on the 'shoulders' of Article 25 [..]* " and that the key to GDPR compliance is complying with this Article.[166] As already mentioned, guidance on compliance with the GDPR already exists in several areas, one of which Georgiou and Lambrinoudakis suggest may prove helpful in the context of our research.[167]
We could find no better words to summarize the issue with GDPR compliance from a technical perspective than those used by Politou et al.:

> "*Despite the long lasting heavy discussions, negotiations and revisions on the final GDPR text and the ample time given to organisations to apply the corresponding changes to their processes,*

[159] Furramani and Ozpozan 2023, p. 1
[160] Wagner 2018, p. 318
[161] Wagner 2018, p. 324f
[162] cf. Fairness
[163] cf. Purpose limitation; cf. Consent
[164] cf. Data Minimisation
[165] cf. Right to be Forgotten
[166] Jasmontaite et al 2018, p. 1
[167] Georgiou and Lambrinoudakis 2020

products and services, few organisations are yet able to prove actual GDPR compliance. One of the main reasons for this is that GDPR is mostly a legal document, providing little if any technical guidance to the entities that are obliged to implement it. Although this was an intentional choice as the EU did not want to bind GDPR to explicit technologies that would favour specific platforms and solutions, this technology agnostic approach may cause unforeseen complications to organisations attempting to adapt their internal processes to the GDPR's provisions."[168]

5.3 State-Specific Law

The GDPR explicitly states that Member States may introduce additional conditions, may it be further limitations or requirements regarding the processing of special categories of personal data,[169] or the introduction of data processing prohibitions which cannot be lifted by the data subject's consent,[170] only to name a few. Therefore, we will examine the peculiarities of Austria, Germany, and Switzerland (where the situation is evidently different) when it comes to data protection law, in particular to the processing of data concerning health. It should also be mentioned that these are subtleties compared to the discussion of the entire GDPR, as all three countries essentially adhere to the GDPR, as we will see in the following.

5.3.1 Implementation in Austria

One of the central Austrian laws when it comes to data protection law is the "Datenschutzgesetz" (DSG-AT),[171] which has already been mentioned before, as it directly implements and concretizes the GDPR and also introduces opening clauses in some cases.[172] In addition, other laws prove relevant in relation to the processing of personal data, among them the "Gesundheitstelematikgesetz" (GTelG-AT),[173] whose provisions form the core of automation-supported data processing in Austria.[174] When it comes to the context of scientific research, the "Forschungsorganisationsgesetz" (FOG-AT),[175] needs to be consulted.[176] Furthermore, the "Ärztegesetz" (ÄrzteG-AT),[177] the "Bundesgesetz über die Dokumentation im Gesundheitswesen" (DokGG-AT),[178] and the "Medizinproduktegesetz" (MPG-AT),[179] each contain passages that are relevant in the context of our project.[180] The MPG-AT, however, which is a national implementation of the MDR,[181] will be discussed extensively in section 7.2.2 EU Medical Devices Regulation (MDR) and is therefore intentionally not further discussed here. In the following, we will address the aspects of each of these laws that are relevant to data processing with regard to our research question.

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[168] Politou et al 2018, p. 15
[169] GDPR Art. 9, Nr. 4
[170] GDPR Art. 9, Nr. 2(a)
[171] DSG-AT
[172] Schreiter 2020, p. 5
[173] GTelG-AT
[174] Degelsegger-Márquez 2021, p. 2
[175] FOG-AT
[176] cf. Oberhofer et al. 2019
[177] ÄrzteG-AT
[178] DokGG-AT
[179] MPG-AT
[180] cf. Degelsegger-Márquez 2021
[181] MDR

Datenschutzgesetz (DSG-AT)

In essence, the DSG-AT adopts the provisions of the GDPR and expands or specifies some of them. In accordance with Article 9(2)(j) of the GDPR, DSG-AT §7 further specifies the processing of personal data as well as special categories of personal data for scientific purposes by explicitly excluding purposes that have person-related results as a goal. Additionally, the processing of special categories of personal data is further specified within the DSG-AT in §39, where the processing is further restricted by stating that these types of data shall only be processed if absolutely necessary and if effective measures are taken to protect the rights and freedoms of data subjects. Along with this, DSG-AT §54, which introduces additional data security measures, once again explicitly refers to the processing of special categories of personal data.
It is also worth mentioning that when looking at the judicial practice of the Austrian courts and authorities, the assessment of whether consent to data processing was given freely is handled very strictly. For example, in a case where the accuser was proven right, their consent was not freely given since it was linked to additional conditions.[182]

Gesundheitstelematikgesetz (GTelG-AT)

The GTelG-AT regulates, in generalized terms, the basis for technical implementation with regard to the processing of data concerning health by healthcare providers and is to be applied lex specialis to the DSG-AT.[183] This law refers directly to the GDPR both in the definitions of terms and in the concrete implementation of legal requirements. Whether this law is applicable to our project depends on the definition of a healthcare provider ("Gesundheitsdiensteanbieter" - GDA) and if it falls under that category. When looking at the Definition of the term, GDAs are controllers and processors (as defined in GDPR Article 4) that process data concerning health for the purpose of, among others, medical treatment or care.[184] When referring to Burgstaller and Kolmhofer, the short answer is that our project does fall under that category,[185] but we cannot answer this question in its entirety here.
Since we have already discussed Article 9 of the GDPR in great detail and §3 GTelG-AT directly refers to it as well as extends it with additional requirements, it is worth mentioning them. The additional requirements for processing data concerning health are the verification of the identity of the involved GDAs as well as of the data subject, the roles of the involved GDAs, and the guarantee of confidentiality and integrity.[186] These concepts are defined afterwards in §4 to §7 of the GTelG-AT.

Forschungsorganisationsgesetz (FOG-AT)

This law defines the legal framework for scientific research activities in Austria. It also directly refers to the GDPR. The implementation, as well as supplementary regulations, are defined in section 2 of the FOG-AT. In accordance with GDPR Article 89 and Article 9(2)(j), it grants the collection of personal data (also in particular data concerning health) by 'scientific institutions' for the purpose of 'scientific research', in §2(f) FOG-AT, whereas these terms are also legally defined. §2(d)(1) prescribes the measures to be taken when processing such

[182] cf. GZ: 6Ob140/18h https://www.ris.bka.gv.at/Dokument.wxe?Abfrage=Justiz&Dokumentnummer=JJT_20180831_OGH0002_0060OB00140_18H0000_000 last visited 2022-06-13
[183] Schreiter 2020, p. 15
[184] GTelG-AT §2, Nr. 2(a)
[185] Burgstaller and Kolmhofer 2017, p. 261
[186] GTelG-AT §3, Nr. 4

data. These include the obligation to maintain an access protocol, the reference to data secrecy, the data controller's duty of confidentiality, and the requirement that the data subject must not be disadvantaged in any way.
Perhaps one of the most important novelties within the FOG-AT is the concept of “broad consent” as defined in §2(d)(3), which means that a data subject can give consent regarding the processing of their data for one or more research areas or projects collectively. It further extends GDPR Rec. 33, and due to the fact that it contains elements of a conventional declaration of consent as well as elements of a statutory exception, it raises some questions, for example, how the data subject can prevent certain types of data processing.[187] While the concept of broad consent itself is not new, it remains a debated topic in the field of ethics as well as within the legal sciences.[188]
Another aspect worth mentioning is that processing for scientific purposes is greatly facilitated if additional measures are taken, such as pseudonymization or anonymization of the data,[189] which we will address in section 5.4.1 Pseudonymization and Anonymization.

Others

In addition to the aforementioned laws, several other laws were also adapted to the GDPR in the course of the second Data Protection Amendment Act (“2. Materien-Datenschutz-Anpassungsgesetz”), among them, the Austrian “Ärztegesetz" (ÄrzteG-AT). While both the GDPR and the DSG-AT are directly applicable, some extensions are concretized here, which essentially concern the data processing executed by medical practitioners, such as the clinician's obligation concerning the documentation and archiving of a patient’s data in connection with the preservation of patients' rights of inspection.[190] Detailed provisions on how this documentation is to be carried out can, in turn, be found in the “Bundesgesetz über die Dokumentation im Gesundheitswesen" (DokGG-AT), which can be translated to “Federal Law on Documentation in Healthcare".[191]
While it is not irrelevant to know that these laws exist, they concern our project only peripherally and will therefore not be further elaborated for now.

5.3.2 Implementation in Germany

In Germany, data protection is governed by the “Bundesdatenschutzgesetz” (BDSG-DE),[192] which, like the DSG-AT, directly implements and expands the GDPR. In principle, the two laws differ only slightly from each other, so the BDSG-DE will not be discussed in detail here.[193] One detail that is mentioned more often is that the BDSG-DE, in contrast to the GDPR and the DSG-AT, differentiates between public and non-public entities in terms of processing, with the former being granted extended rights.[194] Furthermore, it should be mentioned that the BDSG-DE is understood as a catch-all law, and the applicability of the

[187] Haimberger 2021, p. 26
[188] cf. Hallinan 2020 and Sheehan 2011
[189] FOG-AT §2, d(2)
[190] Keplinger 2019, p. 31
[191] Degelsegger-Márquez 2021, p. 4; DokGG-AT
[192] BDSG-DE
[193] Mühlich 2016
[194] Kapfer 2018 p. 6; https://www.activemind.legal/de/law/ last visited 2022-07-24

law depends on whether further, area-specific laws exist for the respective application case, such as the Telecommunications Act (TKG-DE[195]) or the Telemedia Act (TMG-DE[196]).[197]
Another aspect worth mentioning is that, unlike in Austria, there is no additional law for the processing of health data. Instead, the GDPR and the BDSG-DE are referred to. This is also evident when looking at the official orientation guide on health data protection ("Orientierungshilfe zum Gesundheitsdatenschutz "), published by the German Federal Ministry for Economic Affairs and Climate Action, since here, as far as data protection is concerned, reference is also made to these two laws.[198]

5.3.3 Implementation in Switzerland

In principle, Switzerland is not obliged to comply with the GDPR of the European Union, as it is not a member state. Nevertheless, it is in the interest of both countries, especially due to the bilateral economic proximity, to legally recognize each other's level of data protection.
To give a brief historical overview of the development of Swiss data protection law, it should be said that at the beginning of 2018, the Swiss Parliament decided to carry out a total revision of the outdated Data Protection Act in two stages. In the first stage, mainly parts related to criminal law in the context of data protection were adapted because these are part of the so-called acquis to the Schengen Association Convention. This Schengen Data Protection Act (SDSG-CH[199]) entered into force at the beginning of 2019. At the end of 2020, a total revision of the law was then adopted, implementing the remaining parts regarding data protection, which entered into force on September 1, 2023 (revDSG-CH[200]). This law is designed to be in compliance with the GDPR, and it has to be said that large parts of the Swiss economy already apply the GDPR. Differences compared to the GDPR are mainly found in the brevity of the Swiss law and the partly different definitions of terms.[201]
And also from the EU's side, cooperation regarding data protection should not pose many problems. The EU Commission had already recognized the old data protection law in 2000. An adequacy decision on the revDSG-CH is still pending, but it is assumed that the Swiss data protection law will continue to be recognized by the EU.[202]
However, the most important takeaway for us is the following: *"Allgemein wird davon ausgegangen, dass die Schweiz und die EU nach der Erneuerung ihrer Datenschutzgesetzgebungen gegenseitig die Gleichwertigkeit ihrer Datenschutzniveaus anerkennen werden, so dass der formlose Austausch von Personendaten über die Landesgrenzen weiterhin möglich bleibt."*[203] (Translation: "It is generally assumed that Switzerland and the EU, after the renewal of their data protection legislation, will mutually recognize the equivalence of their data protection levels so that the informal exchange of personal data across national borders will continue to be possible.")

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[195] TKG-DE
[196] TMG-DE
[197] Langhanke 2018, p. 29
[198] https://www.bmwk.de/Redaktion/DE/Downloads/M-O/orientierungshilfe-gesundheitsdatenschutz.pdf last visited 2022-08-26
[199] SDSG-CH
[200] revDSG-CH
[201] EDÖB 2022, p. 2f
[202] EDÖB 2022, p. 3; https://commission.europa.eu/law/law-topic/data-protection/international-dimension-data-protection/adequacy-decisions_en last visited 2022-08-13
[203] EDÖB 2022, p. 3

5.4 Additional Remarks

Before reaching a preliminary conclusion, some topics already mentioned, such as the aspect of pseudonymization and anonymization in the context of personal data processing, processing of data concerning health in the context of scientific research, and some other minor additional remarks, are discussed here in more detail.

5.4.1 Pseudonymization and Anonymization

Since we have already referred to the term pseudonymization several times in the course of this analysis, be it in the context of scientific research or when we talked about security measurements, it makes sense to take a closer look at the meaning of the term and its implications for our project.
While the term is defined in various ways, it makes sense to stick to the definition of the GDPR in our case. The GDPR defines pseudonymization as:

> *"[..]the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person"*[204]

While the question of the technical implementation of this concept cannot be answered within the scope of this work, the question still arises for us as to how pseudonymization legally affects the processing of personal data.
A study by Hintze and El Emam, examining the concept within the context of the GDPR, helps us to answer this question. According to them, pseudonymization and anonymization are so-called de-identification techniques, which means that identifiers referring to the respective data subject are removed from the data. This can be achieved in several ways, from only removing direct identifiers such as IDs and names to data perturbation or even complete anonymization where re-identification is technically not possible.[205] While de-identification can be viewed as a spectrum, they identify four main categories: identified data (not pseudonymized at all), pseudonymous data, strongly pseudonymous data, and anonymous data.[206] Depending on which of these categories applies, there are different legal implications, which are summarized in Table 5.3.

[204] GDPR Article 4, Nr. 5
[205] Hintze and El Emam 2018, p. 146
[206] Hintze and El Emam 2018, p. 147

GDPR obligation	Type of data			
	Identified	Pseudonymised (basic)	Strongly pseudonymised	Anonymised
1. Provide notice to data subject	Required	Required	Required	Not required
2. Legal basis for processing (legitimate interests, consent)	Required	Stronger case for legitimate interests	Much stronger case	Not required
3. Data subject rights (access, portability, rectification)	Required	Required	Not required	Not required
4. Give right to erasure/right to be forgotten	Required	Required	May not be required	Not required
5. Basis for cross-border transfers	Required	Required	Required	Not required
6. Data protection by design	Required	Partially met	Strengthens the ability to meet this obligation	Not required
7. Data security	Required	Partially met	Strengthens the ability to meet this obligation	Not required
8. Data breach notification	Likely to be required	Less likely to be required	Strengthens the case that notification is not required	Not required
9. Data retention limitations	Required	Required	Required	Not required
10. Documentation/recordkeeping obligations	Required	Required	Required	Not required
11. Vendor/sub-processor management	Required	Required	Required	Not required

(Table 5.3: GDPR obligations for different types of pseudonymized and anonymized data by Hintze and El Emam[207])

To conclude these findings, it has to be mentioned that when it comes to obligations introduced by the GDPR, pseudonymous data is more similar to identified data than to anonymous data, which means that while pseudonymization provides some benefits regarding GDPR compliance, it does not completely relieve companies from GDPR obligations. Therefore, even when processing pseudonymized data, the GDPR and other legal provisions cannot be ignored.[208]

5.4.2 Patient Data in the Context of Research

As we have already seen at various points in this elaboration, the context of scientific research plays a major role in assessing the lawfulness of the processing of personal data, especially data concerning health. Different concepts such as Data Minimisation, Storage Limitation, or Consent introduce several adjustments or exemptions when it comes to scientific research. Austrian legislation even deals with data processing for the purpose of scientific research in a separate law.[209] Therefore, it appears reasonable to us to briefly address this topic again at this point.

Although this topic is very complex and extensive, when looking at primarily legal material and academic papers, it can be said that there seems to be a general agreement that the GDPR promotes and enables scientific research. At the same time, however, it also imposes additional obligations (e.g., additional requirements regarding confidentiality or security measures such as pseudonymization) on the data controller.[210] Or as Donelli and McDonagh

[207] Hintze and El Emam 2018, p. 148
[208] Hintze and El Emam 2018, p. 157
[209] cf. FOG-AT
[210] Olimid et al. 2018, p. 635; Chico 2018, p. 118; Chassang 2017, p. 12

put it: "*For health researchers, the General Data Protection Regulation [..] is a mixed blessing*."[211]
Furthermore, there is criticism that the GDPR leaves too many freedoms for member states in this regard, which can lead to an inconsistent environment for the scientific community.[212]
While there is a wealth of discussion, open issues, and emerging questions on this topic, the question of whether and to what extent the legal exemptions and obligations regarding the processing of personal data in the context of scientific research are applicable to our project remain unanswered for now.

5.4.3 Other Legal Issues Regarding Patient Data

At this point, we would like to briefly point out that, so far, we have dealt in detail with the legal requirements concerning the protection of personal data, specifically the rights of data subjects and the obligations of data controllers. While this is perhaps the first topic that comes to one's mind and also the aspect that receives the most attention from legislators as well as academics, it is not the only perspective that one can take. For example, are there types of personal data that may not be shown to the data subject without restriction or prior supervision? Or are there specific legal requirements for the design of the user interface of an application that processes data concerning health, in addition to the principles we have already explained, such as data security or precise and clear consent forms? These questions, as well as those that have already arisen in this section, will be addressed in Chapter 7 - Legal Situation Concerning the Visualization of Patient Data, where we will look at application-specific legal requirements and issues concerning the visualization of data concerning health.

5.5 Results

When sticking to the language of our research framework, we tried to assemble relevant facts, identified legal issues, analyzed them, and examined primary as well as background material, and now we are trying to synthesize the issues in context and come to a tentative conclusion regarding the first part of our legal research question.
As we can see, while there are extensive legal requirements when it comes to the processing of personal data, respectively data concerning health, there is a lot of ambiguity, uncertainty, and discussion about many of the defined terms as well as when it comes to the practical implementation of data processing systems. There is indeed some wiggle room when trying to partially circumvent certain legal obligations (e.g., the possibility to nudge data subjects into giving consent to more than what is actually necessary), and also one can argue that many companies do not have complete GDPR compliance today while not facing any legal consequences. But from our perspective, due to the very broad scope of some terms within the GDPR, especially the concept of fairness, there is a clear emphasis on the data controller's intent when building a system. If, when building a system, the question is: "How can we provide transparency to the user, and how can we include and inform the user?" one is on the right track to GDPR compliance. If, on the other hand, one tries to find and abuse loopholes within the legislation, this may work in the short run, but in the long run, there is a lot of risk involved.

[211] Donelli and McDonagh 2019, p. 1
[212] Chico 2018, p. 110; Donelli and McDonagh 2019, p. 18f

The same is true for national legislation, which we also examined. When in doubt, it is recommended to stick to the most restrictive requirements. Since Austria, Germany, and Switzerland mostly adhere to the GDPR, this only applies to marginal cases. With this regard, it is worth taking another look at the Austrian “Gesundheitstelematikgesetz” (GTelG-AT) since it contains some specific regulations.
To sum up the most important points when it comes to the processing of data concerning health, the following should be mentioned:

Consent is Key: It is generally possible to process sensitive data if the data subject has given their free, informed, and explicit consent. These adjectives should be understood very strictly, though.

Pseudonymization and Anonymization: The former provides some liberties, but they are often overestimated. In case of doubt, anonymizing your data is the safer option.

The GDPR as a Research Enabler: If data is processed for research purposes, there is more freedom for the data controller as well as additional obligations. The question of to what extent software artifacts planned by Treetop qualify for this research definition remains unanswered, though.

Emphasis on Technical Requirements: One of the foundations when building a system that processes data concerning health is meeting the technical requirements defined by legislation. Among them are the concepts of data protection by design and by default or implementing appropriate security measures. Nevertheless, while there are strict requirements defined, the legislation does not provide technical implementation guidance.

Emphasis on Intent: There is a lot of ambiguity and discussion about used terms and concepts within the law. While it may be possible to circumvent certain legal restrictions, this might be counterproductive in the long run, as there is a high risk of a potential backlash due to the broad scope of the used termini. In other words, the data controller's intent plays a big role in the GDPR.

Legal Harmonization: We could observe that when it comes to data protection law, member states, as well as Switzerland, are making a great effort towards harmonizing their laws. This makes perfect sense. Both for economic reasons (especially for Switzerland) and because legal harmonization plays an important role in the digital sector, mutual recognition of the respective national laws is being sought.

This Chapter can be seen as a general legal framework for processing data concerning health and builds the foundation for our legal framework specific to our research project, where we will look in more detail at the questions that have not yet been answered as well as new ones that have arisen. We will deal with the legal aspects of data visualization in detail in Chapter 7 - Legal Situation Concerning the Visualization of Patient Data.

Chapter 6 - Data Visualization and GUI Design - Literature Review

As explained in Section 4.1 Literature Review Methodology, we stick to a narrative literature review approach where we start quite broadly with general UI design and data visualization principles and gradually get more specific regarding our problem. We try to examine how to visualize the different parts of the needed data and, furthermore, how to merge them together. We also point out some issues specific to user interface design in the medical sector. Finally, we will draw conclusions from the gathered knowledge. These findings will later on serve as a foundation for analyzing several existing applications with regard to our problem.

6.1 General UI Design Principles

User Interface design is an enormously huge field in academia as well as in the commercial sector, split into numerous sub-areas with an unmanageable amount of publications, books, guidelines, and principles available. So, the emerging question is now how to narrow it down and find a consistent path of principles one can stick to when developing the respective software artifacts.

Ruiz et al. conducted a systematic literature review where they tried to analyze and unify the fragmented landscape of functional user interface design principles and extracted a core selection of principles that should provide UI designers with a distinct path for learning, evaluating, and improving functional UI design.[213] This work, therefore, serves as our starting point. However, while providing a helpful overview to us, the principles and concepts mentioned in their work remain rather abstract and theoretical in nature. Therefore, while we also include other theoretical discourses in our work, practical guidelines for actually designing software artifacts are needed as well. For this purpose we decided to use "*Designing with the Mind in Mind - Simple Guide to Understanding User Interface Design Guidelines*"[214] by Jeff Johnson and "*Designing the User Interface - Strategies for Effective Human-Computer Interaction*"[215] by Shneiderman et al. as our primary sources since they are among the most recent works in this field, are well acknowledged within the scientific community due to their numerous citations and also when looking at Ruiz et al.'s work, the authors play a central role in the network of user interface design principle citations.[216] Both of them offer a slightly different perspective on the topic since the latter tries to give a more comprehensive overview while the former focuses on the psychological aspects and implications of user interface design.

We also want to mention that while it is important to have an underlying theoretical foundation and guidelines to consult, it is our work to put them into the right context and select what seems appropriate to our problem. Quite often, conflicting or even contradicting principles are applicable to a certain problem, which requires the designers to find trade-offs and the right balance between competing rules.[217] To use Johnson's words: "*User-interface*

[213] Ruiz et al. 2021
[214] Johnson 2020
[215] Shneiderman et al 2016
[216] Ruiz et al. 2021, p. 54
[217] Johnson 2020, p. 18f

design rules and guidelines are more like laws *than like* rote recipes. *Just as a set of laws is best applied and interpreted by lawyers and judges well versed in the laws, a set of user-interface design guidelines is best applied and interpreted by people who understand the basis for the guidelines and have learned from experience in applying them.*"[218] (As a side note, this also turns out to be quite an interesting link to our legal research question) So, let's take a look at some of the most important principles.
Shneiderman et al. introduce what they call "The Eight Golden Rules of Interface Design". Interestingly, when looking at Ruiz et al.'s work, the rules with the highest degree of centrality in their analysis correspond more or less to these eight rules. We give a brief overview of the most important principles according to these sources and add some additional remarks from other sources where necessary. Please note that this list and the elaboration of these principles is by no means exhaustive since that would go way beyond the scope of our thesis. It should rather serve as a first glance before we get more specific regarding our problem.

6.1.1 Offer informative Feedback

According to Ruiz et al., the design principle of offering informative feedback to the user is by far the one with the highest degree of centrality and the most citations and, thus, of the utmost importance for user interface design.[219] There are several reasons why this principle is so prominent. First of all, it is very broad and can thus be applied in many circumstances. Secondly, it is also embedded within other principles, e.g., when looking at dialog design[220] or as a prerequisite for applying the principle of giving the user control.[221] And thirdly, it is also one of the eight golden rules defined by Shneiderman et al.,[222] which also partly explains the high citation count.
In short, every interaction by a user should result in feedback from the interface, while the type of response should match the significance of the action (The more severe the action, the more substantial the response should be). Visual presentation of feedback is perhaps the most obvious, but there are also other ways of providing (additional) feedback for each action, like a haptic or auditory response.[223]
When it comes to offering feedback to the user, one specific issue turns out to be especially important when looking at the subject matter from a psychological perspective: a user's time constraints regarding perception and behavior. Johnson introduces the concept of responsiveness, for that matter. When a responsive system is not able to fulfill a user's request within a specific timeframe, it still keeps the user informed about what is happening and adheres to the behavioral deadlines set by the human body and mind.[224] While we cannot go into great detail about time constraints regarding human perception for our project, it is still good to keep in mind the general concept of responsiveness.
Even when looking at a very specific type of information that needs to be provided visually, it makes a great difference concerning the user's perception of *how* the respective information is presented. Chen and Li conducted an experiment where they provided different types of visual indicators to inform the user about waiting times. (bar-, pie- and cartoon-style wait

[218] Johnson 2020, p. 19
[219] Ruiz et al. 2021, p. 55f
[220] cf. section 6.1.3 Dialog Design
[221] cf. section 6.1.6 User Centricity
[222] Shneiderman et al 2016, p. 96
[223] Shneiderman et al 2016, p. 96
[224] Johnson 2020, p. 365ff

time indicators) Depending on the type of indicator, the waiting times are perceived differently.[225] This suggests that even small details can have a great impact on a user's perception and overall satisfaction with the user interface.

6.1.2 Strive for Consistency

This is also one of the most commonly cited principles for user interface design, and at first glance, it may seem obvious and simple to make design decisions for a consistent user interface, but there are actually many different perspectives that can be taken when considering the concept of consistency.

First of all, we can look at consistency within an application: Using consistent terminology, color schemes, and layouts, as well as the positioning of elements, fonts, icons, etc., throughout the whole application can provide orientation to the user. Inconsistency can manifest itself either by a complete lack of consistency or by consistent design with a single or a few exceptions, which is even more disruptive to the user. On the other hand, a consistency violation can also be used on purpose, for example, when all of the attention needs to be drawn to a specific interface element. It can also be the case that there are competing forms of consistency within an application, which forces the designers to make tough choices or come up with new strategies. Furthermore, it is not only about consistent design within an application but also about making design choices that are consistent with what users are being used to. For example, when designing a mobile application, it is important to stick to common patterns used by the respective operating system as well as other applications in order to make the user interaction more familiar and, therefore, easier for the user.[226]

Johnson elaborates on the importance of consistency by explaining that it is a prerequisite for the predictability of an application and consistently designed user interfaces can be learned more quickly. With inconsistent systems, on the other hand, a high cognitive load is placed on the user.[227] Furthermore, he distinguishes between consistency on a conceptual and a keystroke level. The former defines how many concepts a user has to learn. In other words, conceptual consistency means that the same actions can be applied to different objects within an application. Keystroke consistency (which he claims to be at least as important) refers to standardizing physical actions for all activities of a certain type. The explanation for that lies in the fact that muscle memory plays a big role when trying to use an application efficiently, and keystroke consistency favors that. He recommends taking a look at so-called "look-and-feel standards" during the implementation process.

While this turns out to be an important guideline, Grundin points out that consistency alone is an insufficient measurement of good user interface design. While it is important to think about the concept during the design process, strictly adhering to this guideline can sometimes even be counterproductive, and putting more focus on the user's working environments can sometimes be the better option.[228] With our project in mind, especially being consistent with regard to established patterns seems to be fairly important to us.

[225] Chen and Li 2020
[226] Shneiderman et al 2016, p. 110f
[227] cf. section 6.1.4 Minimize User's Memory Load
[228] Grudin 1989, p. 1170f

6.1.3 Dialog Design

When it comes to UI design, dialogs play an important role in the overall application. Ruiz et al. summarize different concepts for dialog design in the scientific literature under the term "simple and natural dialog".[229] This raises the question of what the terms “simple” and “natural” actually mean. While Bakaev and Razumnikova have introduced a metric to measure the simplicity of a user interface, they also claim that this is only one way to answer the question of what makes a user interface simple.[230] But there are many other points of view to that question as well.[231] The term “natural” remains even more vague in this context. Wigdor and Wixon devote an entire chapter in their book explaining this concept, in simplified terms being a design philosophy.[232] Since our two main reference works treat dialogs similarly to other design elements and don’t explicitly state the mentioned concepts, we decided to leave it like that and not go into further detail here. Instead, we emphasize a different concept related to UI dialogs mentioned by Shneiderman et al.: Designing dialogs to yield closure. As they state: “*Sequences of actions should be organized into groups with a beginning, middle, and end. Informative feedback at the completion of a group of actions gives users the satisfaction of accomplishment, a sense of relief, a signal to drop contingency plans from their minds, and an indicator to prepare for the next group of actions.*”[233] So, it is not so much about the design of a certain dialog element itself but rather about the whole process a user goes through when performing a specific set of actions leading to the desired result. This is something that needs to be considered and is applicable to our problem and, therefore, important to keep in mind.

6.1.4 Minimize User’s Memory Load

Shneiderman et al. have included this concept in their eight golden rules. They point out that the human capacity for processing information is quite limited and that one should avoid designing user interfaces where it is necessary that the user remembers information over the course of different displays. However, they don’t go into much more detail regarding this topic.[234] Johnson, on the other hand, devotes two whole chapters to human’s limited attention and memory and how this shapes our thoughts and actions. While we will not go into great detail regarding the elaborated underlying cognitive mechanisms, we will briefly discuss the most important takeaways and practical implications from those chapters instead.

In psychological terms, the type of memory most important to us is the so-called “working memory”. One must not imagine this as a separate memory store but rather as everything that one is paying attention to at a specific time. This capacity is severely limited, and the number of simultaneously attendable concepts or ideas is five (plus or minus one). Attention is also an important keyword in this context since *what* we are paying attention to has, in turn, a great influence on our working memory. Therefore, while trying to minimize the number of calls to action on an interface and providing memory aids and tools instead of

[229] Ruiz et al. 2021, p. 54f
[230] Bakaev and Razumnikova 2021, p. 16
[231] cf. Maeda 2006
[232] Wigdor and Wixon 2011, p. 9f
[233] Shneiderman et al 2016, p. 96
[234] Shneiderman et al. 2016, p. 96f

expecting the user to remember information over a longer period, it is also advantageous to purposely attract attention where needed in order to minimize the user's memory load.[235]
But not only does the targeted use of attracting attention lead to a memory load minimization, but the overall reduction of attention that is needed to interact with an interface also has a positive impact on the needed memory capacities. Hence, Johnson also provides some guidelines for this purpose. Amongst others:[236]

- Don't let a user calculate stuff. A Computer is way better at that.
- Aim for familiarity and consistency.[237]
- Give the user the information they need as precisely as possible.
- Guide the user towards their goals.
- Aim for low complexity when designing settings. Users are usually bad at optimizing a vast amount of combinations of adjustable parameters.

As a side note, if you want to dive deeper into the subject matter, Bakaev and Razumnikova used a specific term for the purpose of their investigation (which we mentioned earlier), namely "visual-spatial working memory", which is commonly needed when interacting with two-dimensional graphical user interfaces.[238] It is "*[..] the ability to temporarily store and mentally manipulate visual information.*"[239]
In our project, we want to merge a large number of data fields and present them visually. In doing so, we want to try to keep the complexity low in order to provide the user with the required information as advantageously as possible. Therefore, it is of enormous importance to include this design principle in our development process.

6.1.5 Error Handling

Another golden rule, which is also listed by Ruiz et al. among the most significant principles, is called "Prevent Errors". First of all, it is important to point out that this is not about system errors but rather about errors made by the user. While entirely preventing system errors is an impossible task, the measurements to be taken in those cases fall under the category of offering informative feedback.[240]
Shneiderman et al. summarize that, firstly, the aim is to design user interfaces in such a way that it is not possible for users to make severe errors. Secondly, there should be options for recovery in case the user makes an error.[241]

Error Prevention

When talking about the first key element of error handling, namely error prevention, it is important to make a distinction between mistakes and slips. A Mistake, being an error of conscious decision, is made when you make a considerate choice and it turns out to be the wrong one. This happens either because the user's understanding of the choices is incorrect or the user's information is inaccurate or incomplete. A Slip, on the other hand, is

[235] Johnson 2020, p. 203f
[236] Johnson 2020, p. 276f
[237] cf section 6.1.2 Strive for Consistency
[238] Bakaev and Razumnikova 2021, p. 1
[239] McAfoose and Baune 2009, p. 130
[240] cf. section 6.1.1 Offer informative Feedback
[241] Shneiderman et al. 2016, p. 96

unintentional. The user does something they didn't mean to, for example, wanting to click on the "OK"-Button but clicking on "Cancel" instead. While the same action can be a mistake or a slip, depending on the context, different measures regarding user interface design can be taken in order to prevent either one of them.[242]
The key element for helping the user to prevent making mistakes is to provide accurate and easily understandable information. When answering the question of how to ensure that in practice, Johnson refers to following the design guidelines and principles discussed in other sections instead of introducing new ones since providing clear information should be good for more than just error prevention.[243]
In order to help people prevent making slips, Johnson provides several design guidelines for each different type of slip, which we will not go into more detail here. What has to be said, though, is that a mistake by the designer increases the likelihood of a user making a slip.[244]
But even when making the best design choices and thoughtfully considering extensive theoretical foundations for the design of a user interface, the possibility of a user making an error can never be reduced to zero. That is why we need the second pillar of error handling: the possibility of recovery.

Error Recovery

To provide the ability to recover from errors in a user interface, Johnson introduces the concept of reversibility. (Shneiderman et al. and Ruiz et al. present the concept of reversibility as its own guideline, but we decided to include it here since it is so strongly linked together with the concept of error handling) Reversibility can be achieved through providing two-way actions (a prominent example would be the "trash bin" folder on a computer) or through providing an UNDO action (e.g., the famous Ctrl-Z key combination on Windows).[245]
Mortenson and Boring add another interesting perspective to the topic of error recovery, namely the distinction between Forward and Backward recovery. The two formerly mentioned examples are cases of Backward recovery. This means that the system is being set back to the initial state before the error has happened, without the user having to take additional actions. But sometimes this is not possible. Think of a situation where you took a wrong turn with your car. In that case, the route has to be adjusted in order to recover from that error because you can't just teleport yourself to the last intersection. Recalculating the route and guiding the user through the steps that need to be taken for error recovery is an example of Forward recovery. In some cases of user interface design (especially when the system is strongly linked to the outside world), the possibility of forward recovery needs to be considered.[246]

As a final remark, we want to mention that the measures explained before should be considered in any case, but especially in the case of risky and error-prone operations, the execution should be hard to do and only be possible by performing multiple steps.[247] Also, it

[242] Johnson 2020, p. 399f
[243] Johnson 2020, p. 408f
[244] Johnson 2020, p. 409f
[245] Johnson 2020, p. 413f
[246] Mortenson and Boring 2020
[247] Johnson 2020, p. 416f

is interesting to mention that sufficient error handling plays a role when examining the overall research topic from a legal perspective.[248]

6.1.6 User Centricity

"Know the User", "Speak the User's language",[249] "Seek universal usability";[250] These concepts can be subsumed under what we define as User Centricity. It means recognizing the different needs of different users and user groups, depending on several factors such as their expertise, their age, or their demographics. A simple example would be adding tools and hints for helping novices and adding the possibility of shortcutting for expert users.[251]
User-centered design is its own research field with a vast amount of available literature, and systematically adding the whole design philosophy into our project would go way beyond the scope of this thesis. Nevertheless, there are a few beneficial takeaways from this approach we can include in our process. According to Lanter and Essinger, using a user-centered design approach can be seen as a spectrum of possibilities. Obviously, when designing something for a user, the designer usually has the user in mind - at least to some extent. However, the amount to which personal-based or role-based design techniques are used varies.[252]
One hint regarding this approach is to use mockups in the design process since it enables iterative prototyping and convenient but still meaningful evaluation with target users.[253] Another important takeaway is that while we research development guidelines concerning specific user groups, our results should subsequently be able to be extended to other user groups as well. Therefore, while some findings may be applicable to any user group, we still have to keep an eye on possible differences. In this work, we especially focus on patients and clinicians as our two main, distinct user groups.

6.1.7 Additional Remarks

Numerous other design guidelines and principles can be found in the literature. We tried to provide a short overview of the most important, and most cited ones. A lot of the found principles can be subsumed under the ones we elaborated above, for example, to provide shortcuts and clearly marked exits or to make sure that error messages are informative. Another mentionable guideline is that it is beneficial to design a user interface in a way that the user feels like being in control of the system, especially for experienced users.[254] But, as mentioned earlier, these principles only serve as a general orientation. It may be necessary to adapt them or emphasize one over the other when applying them to our specific problem.

6.2 Data Visualization

In the following, we will discuss general aspects of data visualization, which provides an additional foundation for our specific task in mind. Since Schneiderman et al. devote a whole chapter to this topic, in which the general approach to the visualization of data is excellently

[248] see section 7.4.1 Liability for Software - Software Deficiencies
[249] Ruiz et al. 2021
[250] Shneiderman et al. 2016
[251] Shneiderman et al. 2016, p. 95f
[252] Lanter and Essinger 2017, p. 2
[253] Lanter and Essinger 2017, p. 3
[254] Shneiderman et al 2016, p. 96

presented, we will follow their example in the following and briefly summarize the most important points.[255]

6.2.1 Task-Centricity

They provide two perspectives on the topic. First of all, there is the task perspective. Why do users want to interact with data? What tasks do they want to perform? For this, they provide a (non-exhaustive) list of task types, divided into three main categories:

- Data view and specification: This represents the core functionality of almost every visual data representation tool like viewing, sorting, and filtering of the data as well as deriving values from the source data, like calculations or aggregations.
- View Manipulation: These tasks include operations that adapt and change the visual representation in order to explore the data. Examples would be selecting, highlighting, navigation possibilities, or personalization/re-organization of the screen.
- Process and provenance: This category includes meta-tasks, so to speak. While the other two categories deal with direct interaction with the data, here, it is all about things like documenting and interpreting the exploration process, being able to annotate data with remarks, the possibility of sharing insights with others and enabling collaboration.

When it comes to our project, the focus lies especially on the first category, in particular the selection of the visual encoding of the data, since it is stated to be the most fundamental operation. After that, other functionalities from the first two categories will be gradually added to our field of interest. The third category is entirely out of scope for this thesis but nevertheless provides an interesting connection point for further research.

6.2.2 Visualization Depending on the Data Type

The second major question in data visualization is how to choose a visualization technique for the given data set and the tasks to be performed. Currently, there is no unified theory for choosing the appropriate technique. Ultimately, it comes down to being a design question for each individual problem again. (This is also part of the reason why we elaborated on design principles before) Nevertheless, they outlined seven common data types and corresponding visualization examples, which can be seen in Table 6.1.

[255] Shneiderman et al. 2016, p551ff

Data Type	Visualization Techniques and Systems
1-D linear	Tag clouds, Wordle, PhraseNets, parallel tag clouds
2-D space	Geographic information systems (GIS), self-organizing maps
3-D volume	Volume rendering, medical visualization, molecule visualization
Multidimensional	Tableau, parallel coordinates, scatterplot matrices
Temporal	Google Finance, EventFlow, LifeLines, TimeSearcher
Tree	Treemaps, degree of interest trees, space trees
Network	Node-link diagrams, adjacency matrices, NodeXL, Cytoscape

(Table 6.1: Summary of data types and example visualization techniques associated with each. Table from Shneiderman et al.[256])

They also point out that this is again a non-exhaustive list. It is interesting to observe that the data to be visualized, relevant to our project, does not fall entirely into any of the above categories, especially when thinking about the integration between the pathway data and the medical detail information. Nevertheless, with this chapter, Shneiderman et al. provide an interesting perspective on how to tackle our specific problem.

6.3 UI Design in a Medical Environment

Since the medical field is particularly sensitive in terms of software, data protection, and product quality, it is important to pay attention to a number of special requirements when developing medical software products.

6.3.1 Legal Requirements and Standards for UI Design

First of all, it should be mentioned that the development and operation of medical devices, which also includes or can include software, is regulated in the EU Medical Device Regulation,[257] which will be discussed in more detail in Chapter 7 - Legal Situation Concerning the Visualization of Patient Data when elaborating our legal research question.
In order to demonstrate conformity with the technical and legal requirements set out in the Regulation, several harmonized standards should be adhered to.[258] While the application of these standards is voluntary in most cases, it facilitates mandatory conformity assessments enormously since the presumption of legal compliance can already be assumed.[259] Besides standards for software engineering in general,[260] the standards IEC 62304 (medical device software - software life cycle processes) and IEC 82304 (Health Software - Health and Wellness Apps) are of particular importance to us, whereas the former is included within the

[256] Shneiderman et al. 2016, p. 562
[257] MDR
[258] MDR Rec. 22
[259] https://health.ec.europa.eu/medical-devices-sector/directives_de last visited 2023-01-05
[260] I.e. ISO/IEC 25010:2011 Systems and software engineering - Systems and software Quality Requirements and Evaluation (SQuaRE) - System and software quality models

latter. Among other things, these standards regulate the development and maintenance process, the quality requirements, and the assessment of medical software and software in the healthcare sector. Since our project only relates to a small part of the overall development process, it would be excessive to elaborate on all the standards in detail. Instead, we list here a few relevant points. With regard to user interface design, the section about usability in the IEC 82304 standard turns out to be relevant for us. The following questions should be used in evaluating compliance with this standard:[261]

- Is the health app design based on an explicit understanding of users, tasks, and environment?
- Are intended users involved throughout the design and development of the health app?
- Is the design of the health app driven and refined by user-centered evaluation?
- Are measures in place to avoid use errors and reasonably foreseeable misuse of the health app?

Since, as mentioned above, we only accompany a small part of the application development process and deal with it scientifically, it is not our task to ensure that the application complies with the mentioned standards. Nevertheless, it is important to keep these requirements in mind during development. Due to the scientific approach to our design process, it is already in the nature of things that the mentioned requirements are met to a certain extent.
For further interest in these standards and their practical implications for software design and development, we would like to refer to two papers in particular. Firstly "*Creation of an IEC 62304 compliant software development plan*"[262] by Rust et al. and secondly "*DevOps in Regulated Software Development: Case Medical Devices*"[263] by Laukkarinen et al.

6.3.2 Legal Design

At this point, we would like to say a few words about a paper by Corrales Compagnucci et al., as it fits neatly into the intersection of UI design in the medical domain and the corresponding legal requirements that we are investigating. They introduce a concept they call "UI Layer" - Privacy-by-Design, which they claim to be especially important in the medical sector, and examine how Legal Design as an emerging research field can be beneficial to the data protection and privacy of users.[264] To cite them: "*Legal Design is an interdisciplinary approach to apply human-centred design principles to prevent or address legal problems. It prioritizes the point of view of ordinary people as the 'users' of law, i.e., citizens, consumers, business people, rather than legal professionals.*"[265] One way to approach this is to introduce UI-focused measures and corresponding design patterns, which allow the user to have a better understanding and transparency about what happens with their sensitive data.
It's an interesting perspective to bring legal issues closer to the user by including the legal perspective in the process of UI design. While the specific measures relate primarily to the

[261] IEC 82304 2021, p. 26f
[262] Rust et al. 2015
[263] Laukkarinen et al. 2017
[264] Corrales Compagnucci et al. 2021, p. 2
[265] Corrales Compagnucci et al. 2021, p. 3

design of electronic consent forms and their comprehensibility, which is not directly part of our design process, our elaboration would be incomplete without mentioning this concept.

6.3.3 Benefits of applying Design Principles - A Motivation

Alnanih and Ormandjieva examined the impact of several HCI Principles on the Quality of mobile user Interfaces in Healthcare Apps. For their examination, they conducted a controlled experiment with healthcare professionals, which supports their hypothesis that sticking to those design principles leads to an increased quality-in-use for the respective users (which is also one of the user groups we are examining in our project) in terms of reducing cognitive load, increasing productivity and efficiency and reducing human error.[266] This proves yet to be another motivation for us to acknowledge the importance of examining all of the elaborated background information.

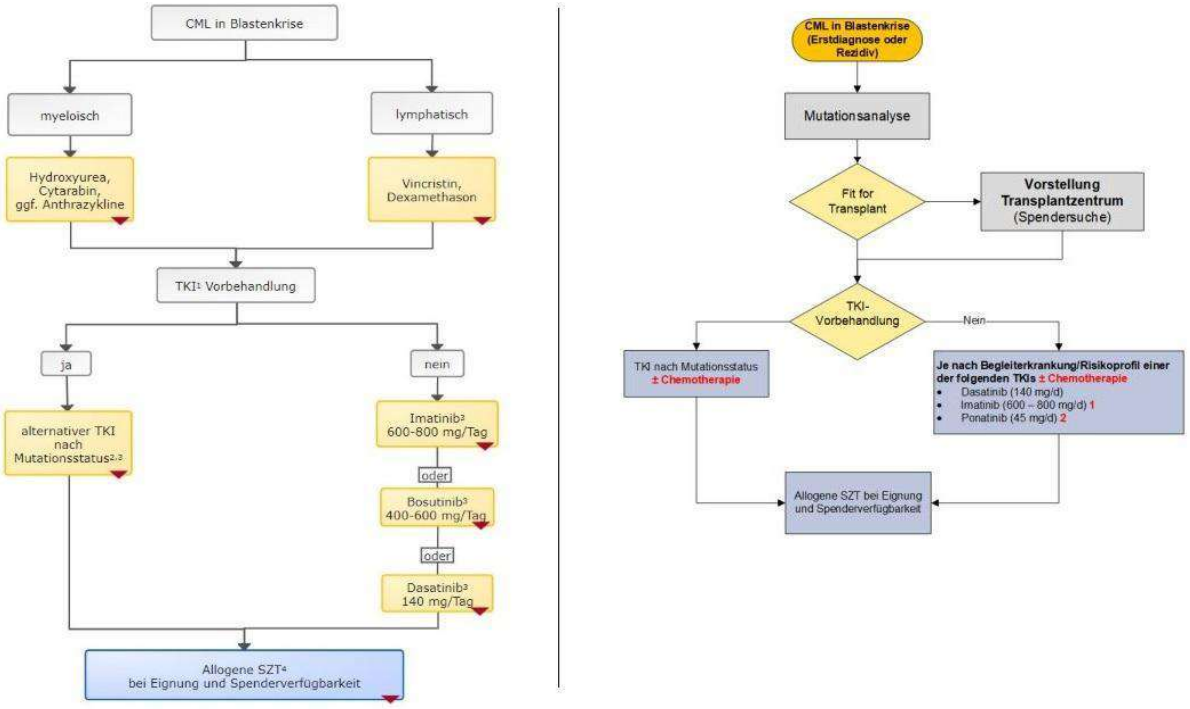
6.4 Visualization of Clinical Pathways

Now we are examining how Clinical Pathways are typically depicted, which possibilities already exist for visualizing pathway structures in user interfaces, what we can learn from visualizing pathways and similar structures in other fields, and which other solutions regarding clinical pathway visualization are being discussed in the literature. We have already seen an example of how Treetop Medical displays pathway data in section 2.1.2 Phase 1 - Structured medical guidelines. Now, we want to take a look at different approaches within the literature.
We would like to point out again the problem of heterogeneity of the term "clinical pathway", as many other terms are used synonymously for the same concept.[267]

6.4.1 Typical depiction of clinical pathways

Before we examine the visualization of clinical pathways in user interfaces, we first take a look at how they are typically graphically depicted in medical documents. Figure 6.1 shows two examples of how medical pathway information can be depicted in the case of CML in the phase of a blast crisis.

[266] Alnanih and Ormandjieva 2016, p. 81f
[267] See section 2.3 Terminology - Clinical Pathway



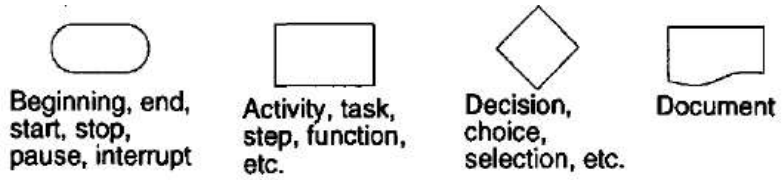
(Figure 6.1: Two depictions of a clinical pathway for blast crisis CML[268])

As we can see, the way different elements of the diagram are depicted doesn't follow a specific standard. For example, on the left, a decision is modeled as a splitting arrow pointing to the respective conditions, whereas on the right, it is modeled as a diamond-shaped element with the conditions noted at the outgoing arrows, more similar to a UML Activity Diagram.

Nevertheless, they both have the general structure of a flow chart in common, which is the usual way to depict this kind of information. To cite Harris: "*A flow chart is a diagram that visually displays interrelated information such as events, steps in a process, functions, etc., in an organized fashion, such as sequentially or chronologically.*"[269] (Please note that we are sticking to this definition since the term flow chart is also often used as a specific format in programming and software development) This definition is very broad, and there are many variations for different use cases. Additionally, the appearance of a flow chart varies significantly due to the versatility and lack of commonly accepted standards.[270] Nevertheless, there are a few common patterns that are often applied when drawing flow charts. Usually, several elements whose shapes have certain meanings are connected by arrows to indicate the direction of the process, flow, etc. (See Figure 6.2; these are just some of the most common shapes. Various other shapes and variations are often introduced to depict specific information, like color schemes, different sizes, different outlines, etc. Sometimes organizational standards are established) This type of chart is also typically not hierarchical

[268] Left: https://www.onkopedia.com/de/onkopedia/guidelines/chronische-myeloische-leukaemie-cml/@@guideline/html/index.html last visited 2023-02-11
Right: https://www.tumorzentrum.at/fileadmin/user_upload/Leitlinien/20230508_Leitlinie_CML.pdf last visited 2023-02-11
[269] Harris 1999, p. 153
[270] Harris 1999, p. 155

and not plotted against a time scale. Especially for larger flow charts, it is more advisable to plot them horizontally due to space considerations.[271]



(Figure 6.2: Typical flow chart elements and their meanings by Harris[272])

This heterogeneity and lack of standardization is challenging for us on the one hand, but on the other hand, it provides a lot of freedom to come up with several design ideas and also encourages us to examine other fields that use similar graphical structures and look at our problem from different perspectives.

6.4.2 Tools and Examples for Creating Interactive Flow Chart Structures

Having looked at typical representations of clinical pathways in the form of flow charts, the next step is to incorporate the dimension of graphical user interfaces. The key component to be added here is interactivity. Without the possibility to interact with graphical structures, it would not make such a big difference whether it is shown in a document or in a user interface. We now examine different structures and examples from other research areas for visualizing pathway-like data in user interfaces and digital tools for creating and interacting with these structures.

PRISMA2020 - Flow Charts for SLR reporting

Firstly, we look at a case where the visualization of flow charts adheres to specific standards and is therefore predefined to a certain extent. When conducting a systematic literature review and trying to comply with reporting standards such as PRISMA, it is advised to document the methods and results of the research process with the help of flow diagrams. Research suggests that there is often room for improvement in the quality and clarity of the diagrams used in literature reviews. Therefore, Haddaway et al. developed a tool for creating interactive flow charts serving this specific purpose.[273]
Their main finding when adding the element of interactivity to the visualization of flow charts is that it provides the benefit of integrating more information into the graphical structure than what would be possible with static representation alone. By layering information into different levels of detail (for example, by hyperlinking additional information to elements of the chart), users have the possibility to choose which amount and detail of information to view. This, in turn, increases the understandability of the visualized information.[274]

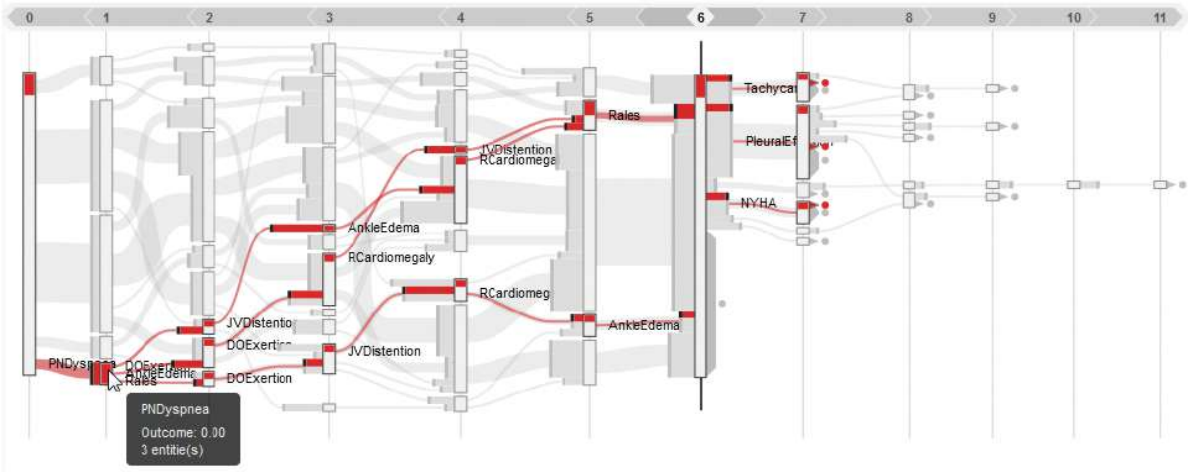
Outflow - Visualizing Event Sequences

A different way of visualizing sequences of actions or process flows has been explored by Wongsuphasawat and Gotz. They developed “Outflow”, which is “*[..] a visualization that enables interactive analysis of event sequence collections. Outflow aggregates multiple*

[271] Harris 1999, p. 153f
[272] Harris 1999, p. 154
[273] Haddaway et al. 2022
[274] Haddaway et al. 2022, p5

event sequences and displays aggregate event pathway information including timing and cardinality. It uses color-coding to depict the outcomes associated with each pathway."[275] Their solution, which is applicable for a wide variety of application areas, consists of much more than what a previously examined "ordinary" flow chart could provide. Features like timing or cardinality go beyond the classical definition of flow charts. What drew our attention to this work was the provision of an example where an event pathway concerning electronic health records had been visualized, consisting of taken and alternative routes as well as additional information that can be interactively shown for a respective node within the path. (see Figure 6.3)

[275] Wongsuphasawat and Gotz 2012, p. 2667



(Figure 6.3: Example for visualizing progression paths and their alternatives with Outflow by Wongsuphasawat and Gotz[276])

As they mention in their conclusion, while their work can be used for a variety of applications, one issue that needs to be explored further is the simplification of the visualization. The example shown represents only a fraction of what is possible with their work, which leads to the fact that their visualization quickly turns quite complex and is usually aimed at scientists and professionals who are used to working with highly complex data. Nevertheless, it is worth taking a look at their work and maybe taking parts of it as inspiration for our own solution.

Cytoscape.js and G6 - Visualization of Graph Structures

From a more abstract perspective, the previously examined clinical pathway structures can be viewed as graphs. (We are referring to graphs in the context of graph theory here, consisting of nodes and edges.[277]) Since graphs have practical applications in a huge variety of domains, many tools and guidelines exist for interactively visualizing them which may help us with the design of our own solution. Hereafter, we want to introduce two libraries for creating interactive, web-based graph structures.

Firstly, a library that is used for scientific purposes in many domains as well as for creating visually appealing applications for private users called Cytoscape.js. With features like freely designable and animate elements, layouting algorithms, gesture support for touch screens and mouses, and options for extensibility, it provides a rich toolbox for the implementation of a possible prototype. It is developed as an open-source project and is free to use. Examples, extensive documentation, and the source code can be found online.[278]

Another important contribution to the topic comes from Wang et al. They developed a graph visualization library called G6. They referred to established graph libraries like Cytoscape.js for their design and development process, coming up with the conclusion that while these libraries are well suited for use cases in the field of graph theory, there is room for improvement when it comes to expressiveness and convenient customizability. This was the motivation for developing their solution, which, according to their evaluation, provides

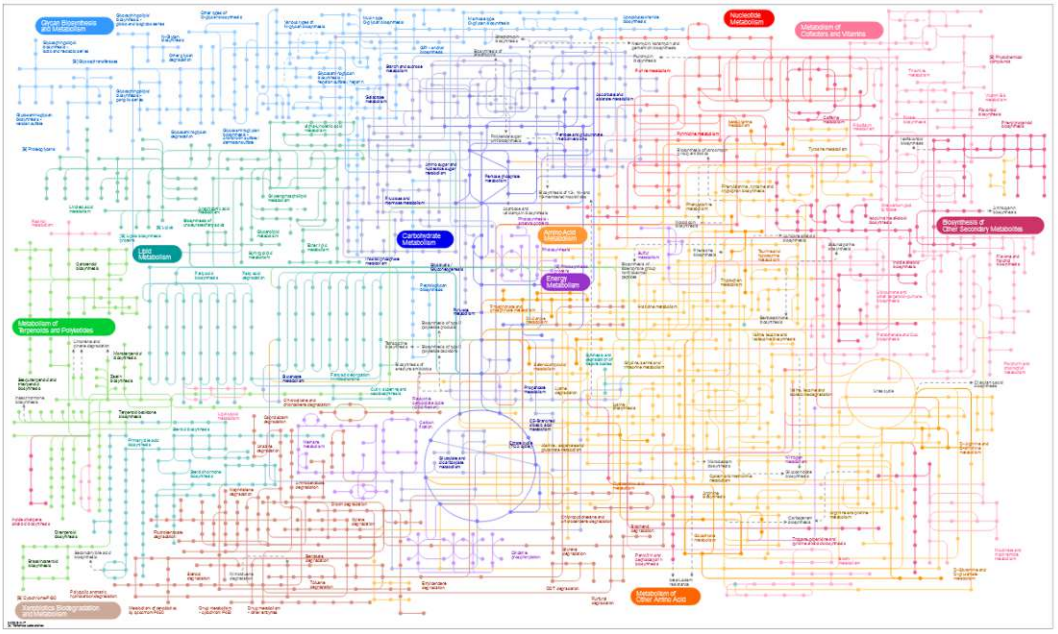
[276] Wongsuphasawat and Gotz 2012, p. 2664
[277] Harris 1999, p. 179
[278] https://js.cytoscape.org/ last visited 2023-02-23; Franz et al. 2016

several benefits over the compared libraries. It is also developed as an open-source project and can also be found online.[279]
Nevertheless, it can't be said which tool or visualization technique is better per se; rather, it depends on the specific context and problem to solve. As Huang et al. put it, while many researched predefined quality metrics regarding aesthetics and comprehensibility exist when visualizing graphs, what is often missing is the involvement of users and the recognition of their needs in the development process, which is what we strive to contribute to with our project.[280]

Takeaways from Interactive Pathway Visualization in Molecular Biology

As already mentioned, there are a vast number of domains where the visualization of graph structures plays an important role. One particular field where many interesting and insightful techniques and tools exist is molecular biology. Pathway visualization of cellular processes is a highly researched field, and although our definition of a pathway differs, there are nevertheless some useful insights for our project.
It would go beyond the scope of this thesis to go into much detail on this topic. Nevertheless, we examined three different tools for interactively visualizing molecular pathways: Pathview Web,[281] iPath3.0,[282] and Reactome.[283] What all three of them have in common is that they actively embrace the fact that they are dealing with highly complex data and the problem of finding the right granularity of detail for different presentation layers. Therefore, all three of them more or less come to the same conclusion: that there is no one-size-fits-all solution but rather that one needs to include the users' needs in the development and thought process. Figure 6.4 shows an example of a visualization with iPath3.0 to illustrate the complexity of the data they are dealing with. The fully interactive graph can be viewed online.[284]

[279] https://github.com/antvis/G6/blob/master/README.en-US.md last visited 2023-02-23; Wang et al. 2021
[280] Huang et al. 2018, p. 1
[281] Luo et al. 2017
[282] Darzi et al. 2018
[283] Sidiropoulos et al. 2017
[284] https://pathways.embl.de/ipath3.cgi?map=metabolic last visited 2023-02-26



(Figure 6.4: Overview of the complete metabolism in biological systems visualized with iPath3.0[285])

6.4.3 Interactive Clinical Pathway Visualization - Back to the Initial Question

Now, we come back to our initial question. Our goal was to examine the topic from the point of view of different areas, to get an overview, and also to get inspiration from other disciplines. Now we turn again to that literature which deals with the interactive visualization of clinical treatment pathways.

We start with a citation from Balatsoukas et al.: "*Although research on the computerisation of ICP* [Note: Integrated Care Pathway; What we have defined as a Clinical Pathway] *progresses, there is still little knowledge on what are the requirements for designing user-friendly and usable electronic care pathways, or how users (normally health care professionals) interact with interfaces that support design, analysis and visualisation of ICPs.*"[286]

Although this statement dates back to 2015, it still holds true today, as research on this particular topic is still sparse. There are a few contributions that we will get to in a moment, but the fact alone that this paper is only referenced by a few is an indication of the need for more contributions regarding this topic.

COCPIT - an Online Care Pathway Investigation Tool

The paper that statement has been cited from is actually one of the most important references for our thesis. (We will also include it again in our empirical evaluation) Balatsoukas et al. developed COCPIT (Collaborative Online Care Pathway Investigation Tool), a software tool tailored to healthcare professionals for interactively visualizing, analyzing, and developing clinical pathways. It provides the possibility of visualizing a patient's progression through the pathway as well as their health state(s) using a customized health state model. For their evaluation, they used a heuristic evaluation method and a

[285] https://pathways.embl.de/ipath3.cgi?map=metabolic last visited 2023-02-26
[286] Balatsoukas et al. 2015, p. 1

mixed-method usability test with healthcare professionals as participants.[287] Unfortunately, their tool is not publicly available anymore, but nevertheless, we can take a lot from their work. Figure 6.5 shows an example screenshot of their application with the interactive pathway in the top left corner, the health state indication in the bottom left corner, and additional statistical data on the right. As you can see, they used a modular approach, showing different components on the same screen while also providing a customizable layout. (Additionally, there is the possibility for the indication of a patient's progression within the pathway, which is not directly visible in this example)

(Figure 6.5: COCPIT User Interface Example by Balatsoukas et al.[288])

[287] Balatsoukas et al. 2015, p. 1ff
[288] Balatsoukas et al. 2015, p. 3

The main features that have been well received by the participants of their empirical usability evaluation, which are relevant to our solution are:[289]

- Full interactivity of all graph elements
- Different layers of information regarding the level of detail
- Layout customizability
- Clear visual indication of the (work)flow and the respective health states
- Reusable and modular elements
- Validity indication to provide visual feedback regarding the correctness of the process and the data

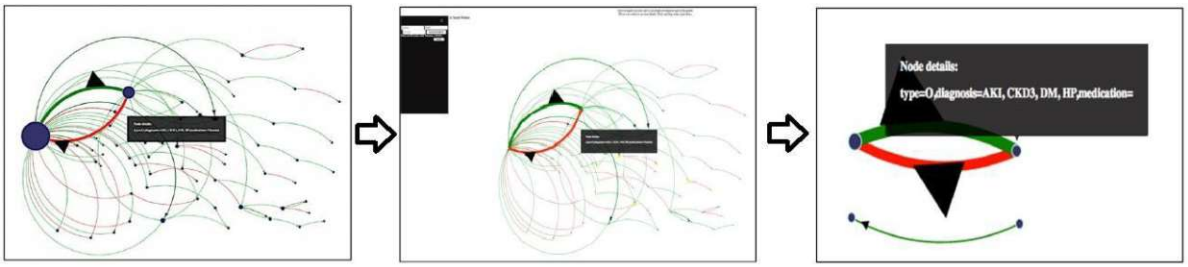
When talking about the limitations of their work, they mention that some characteristics specific to this type of technology need to be explored further. One of them is "*[..] the design and documentation of an electronic care pathway and the representation of integrated linked data from patient health records [..]*",[290] which provides excellent motivation and a connecting point for our work.

Data-Driven Approach

Until now, we have taken the structure of the treatment pathways to be visualized as given. An interesting contribution in this regard comes from Zhang, Yiye, et al. In their initial paper, they developed a data-driven approach to derive treatment pathways from a large number of medical records.[291] Subsequently, they developed a system to graphically display these using an interactive user interface. In our work, while the structures of the pathways are assumed to be given, it is nevertheless beneficial to look at their combined approach and insights.

Due to the heterogeneity and the large variety of generated path data, a versatile solution that is suitable for both highly complex and simpler structures had to be found. To tackle this problem, they have developed a solution where it is possible to filter and search directly within the path structure. This makes it easy for the user to display or highlight only information or substructures that are relevant to them. This functionality is an important addition to the layered visualization of information of varying levels of detail discussed earlier.[292] Figure 6.6 shows (from left to right) the visualization of a complete pathway graph, the highlighted partial structure due to an applied search function, and the pathway after a filter has been applied.

[289] Balatsoukas et al. 2015, p. 11f
[290] Balatsoukas et al. 2015, p. 13
[291] Zhang, Yiye, et al. 2015
[292] Zhang, Yiye and Padman 2017



(Figure 6.6: From left to right: A complete pathway graph; the highlighted partial structure after applying a search function; the Structure after applying a filter by Zhang, Yiye, and Padman[293])

While the introduction of filtering and searching is an important takeaway for us, the user interface from their work, unfortunately, remains a scientific setup without a corresponding real-world application and has not been further explored ever since. In general, it has to be said that there are few contributions regarding this specific topic, which additionally supports the statement quoted at the beginning of this section.
Another important work by Gschwandtner will be discussed in section 6.6 Visualization of Patient Data in Combination with Clinical Pathways. Additionally, non-scientific examples from the field will be analyzed,[294] and furthermore, there are a few papers that are peripherally relevant but still worth mentioning, which we will come to in the following.

6.5 Visualization of Laboratory Test Results

In this section, we are discussing the characteristics of laboratory test result data, the possibilities of how to present and interactively visualize them, and how they are being used and perceived by different stakeholders. Once again, this is a very broad field, so in the context of this thesis, we can only give a brief overview and look at some fundamentals and key points that are relevant to us.

6.5.1 Components of a Test Result

Before visualizing and integrating blood test data into our prototype, we first need to analyze the data structure itself. A single laboratory test result consists of several data points:[295]

- Type of specimen (e.g., blood, urine, bone marrow)
- Analyte (What is being tested. E.g., Leucocyte count, detection of a pathogen)
- Quantitative or binary value
- Unit of measurement
- Date and time
- Test Subject (The Person to be tested)
- Reference interval

Usually, more than one analyte is tested for a given sample (e.g. when conducting a hemogram). By now, laboratories offer around three thousand different analytes that can be

[293] Zhang, Yiye and Padman 2017, p. 674f
[294] see Chapter 8 - Field Analysis
[295] Wians 2009, p. 105ff

tested, with an upward tendency.[296] While this possibility offers great opportunities for clinicians, it also opens up a lot of issues, which we will take a look at.

6.5.2 Reference Intervals and Context

As Katayev et al. put it: "*A test result by itself is of little value unless it is reported with the appropriate information for its interpretation. Typically, this information is provided in the form of a reference interval [..]*"[297] Although there is a lot of discussion and controversy regarding the calculation of these intervals, it can be said that they generally serve as a guide to determine whether a test result lies within a "normal" range, compared to a "healthy" reference group (Usually a "normal" value lies within the range of the central 95 percent of the reference population). But quite often, a tested analyte being outside of that range does not necessarily mean that there is something wrong with the patient.[298] So, as soon as there is a contact point with the context around a test result, things start getting more complex.
Charney and Dourmashkin point out that these reference intervals differ depending on several factors like age, gender, special hormonal states such as pregnancies, interdependent analytes, etc. They introduce the concept of contextual laboratory tests whose results cannot be interpreted at all by simply comparing them to reference intervals. They also claim that, while there are existing analytes for which the context does not play a significant role, more analytes than assumed fall under the category of contextual results, and therefore, there may be a big amount of unrealized utility regarding laboratory tests.[299]
After all, the main purpose of laboratory tests is to support the process of diagnostic decision-making, where they play a significant role.

The reasons for ordering laboratory tests are:[300]

- Diagnosis (Testing in order to exclude or confirm a diagnosis)
- Monitoring (e.g., whether a drug therapy has the desired effect)
- Screening (Testing to potentially find conditions not known until then)
- Research (e.g. to scientifically examine the process of a specific disease)

When coming back to our initial problem, especially when the purpose of a laboratory test is to monitor the disease progression, a reference interval alone cannot be sufficient for providing a proper context since we already assume that the patient has a special condition. We couldn't have said it better than how Torsvik et al. put it:

[296] Wians 2009, p. 105ff
[297] Katayev et al. 2010, p. 180
[298] Katayev et al. 2010, p. 180f
[299] Charney and Dourmashkin 2021
[300] Wians 2009, p. 106f

> *"As chronic patients may have laboratory test results that are permanently outside standardized reference ranges, informants* [Note: clinicians] *would often look for significant change, rather than exact values. What constituted significant change depended on contextual information (e.g., the results of other investigations, intercurrent diseases, and medical interventions) spread across multiple locations in the electronic health record. For chronic patients, the temporal relations between data could often be of special interest. Informants struggled with finding and synthesizing fragmented information into meaningful overviews."*[301]

While it is impossible to visualize all interdependencies and contextual elements regarding a specific laboratory test result, the question can still be asked which level of granularity proves to be beneficial for the user. Maybe visualizing standard intervals still provides some benefits. And maybe the integration of the laboratory test data with the clinical pathway information alone provides sufficient context.

6.5.3 Visualization Possibilities

Now that we have discussed the components of a lab test result as well as the topic of reference intervals and context, it is time to take a look at how these results are typically presented and what some of the possible options for presentation are. We'll start by working out the most basic forms of presentation and gradually add more layers, thus increasing complexity.

Basic Representation

While the simplest form of presenting laboratory test results is in a tabular format, there is evidence that supports the claim that the preferred and also most commonly used form of depiction is via a horizontal bar graph. This form of presentation requires less time and experience for understanding, especially when more than one result is presented at a time.[302]
Various information can now be added to said bar chart. Tao et al. examined how different types of meta-information affected patients' subjective perception of test results, among others, in terms of understandability, perceived health risk, or perceived usefulness. They depicted a horizontal bar chart in black and white with markings for the normal/abnormal range according to a reference interval, the name of the test, the test value, and the unit of measurement. To this 'baseline', they incrementally added additional features:[303]

- Color: Green/Red for indicating the Normal/Abnormal range, respectively
- Color/Text: Adding text to describe what the colors and ranges mean
- Personalization: Adding personalized information to show whether the result is in a normal range compared to similar patients in terms of age and sex.

The study found that in terms of comprehension, satisfaction, and confidence regarding the understanding of the results, the presentation via color and text and personalization had a positive impact on the participants, especially. On the other hand, the perceived risk for their health status also increased when using those formats of display. Therefore, the researchers

[301] Torsvik et al. 2018, p. 203
[302] Brewer et al. 2012
[303] Tao et al. 2018

cannot give recommendations for an optimal visualization format but rather point out the importance of being aware of the fact that different presentation formats of laboratory test results have a significant impact on the recipients' perception, each with its own advantages and disadvantages.[304]

Adding more Color

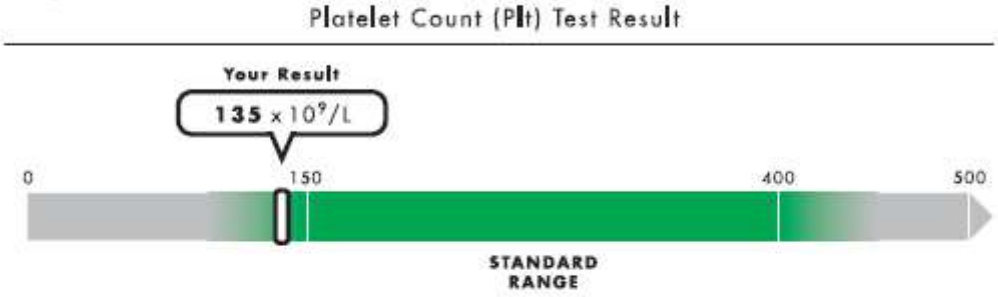
To stay with color schemes as a way of representing reference intervals and adding additional information to the presentation of a laboratory test result, we want to take a look at Zikmund-Fisher et al.'s work. They also examined the effects of using horizontal bar lines for test result representation instead of tables and suggest using the former when developing patient-facing displays. Furthermore, they examined the use of colors more closely in terms of how the visual, colorized depiction of reference value ranges has an impact on whether a deviation from the norm is perceived as urgent or non-urgent. They either partitioned the intervals into different blocks or used a gradient color scheme, as can be seen in Figure 6.7. They found that compared to tables, even the simplest form of bar graphs could greatly improve a patient's ability to distinguish between test result values that are almost normal and non-urgent and those that are more medically concerning. The differences between the different color schemes regarding this issue, however, were rather small.[305] One major takeaway from their study is that: "*The most powerful visual cue that our number line displays provide patients is the concrete placement of test results in a visual space of possible values.*"[306]

[304] Tao et al. 2018
[305] Zikmund-Fisher et al. 2017
[306] Zikmund-Fisher et al. 2017, p525

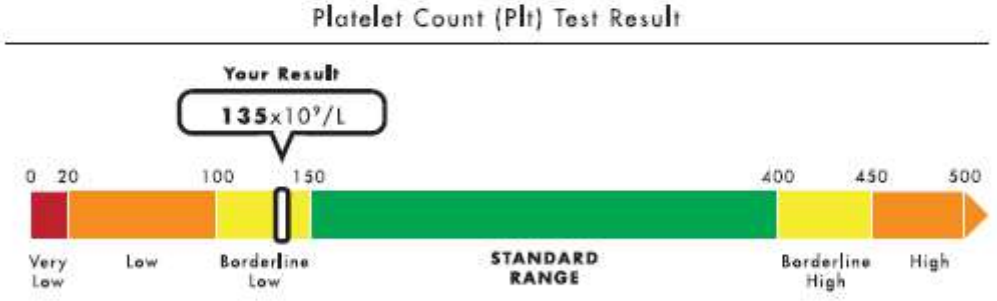
Table:

Test	Your Result	Standard Range	Units
Platelet Count (PLT)	135	150-400	$x10^9/L$

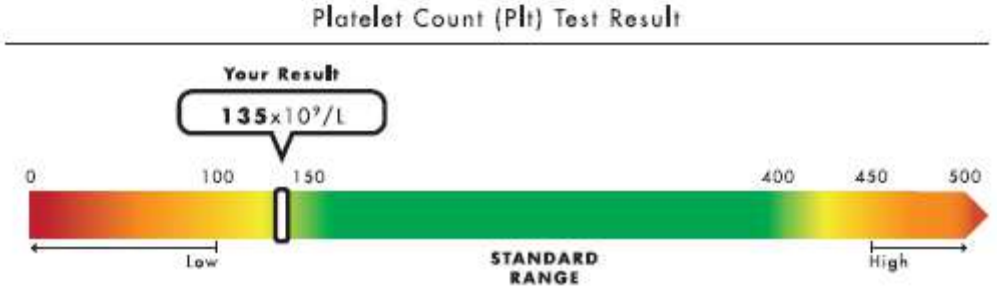
Simple Line:



Block Line:



Gradient Line:



(Figure 6.7: Different possibilities for presenting laboratory test results according to Zikmund-Fisher et al.[307])

Adding Interactivity

To further improve the presentation of laboratory test results, one could take advantage of the use of digital technologies. Although the previously described representations were shown to participants on a screen, they could theoretically be represented in the same way

[307] Zikmund-Fisher et al. 2017, p. 522

on a sheet of paper. This is when adding the layer of interactivity comes into play. Zhang, Zhan et al. developed a patient-centered user interface prototype for presenting laboratory test results, adding several novel, interactive features that were then evaluated qualitatively. The interactive features included:[308]

- The possibility to annotate the presented laboratory test results
- Hyperlinking of medical terms which linked to a detailed description of the respective term
- The possibility to interact with medical terms (favoriting, saving, or sorting)
- Adding tailored, personalized information at the click of a button.

Here, too, use was made of the concept of being able to display information in different layers or degrees of detail, which we have already mentioned a few times before. According to their evaluation, the responses of their study participants had been uniformly positive insofar as all of them acknowledged that the comprehension of the laboratory test results significantly improved compared to existing patient portals.
Nevertheless, these findings have to be taken with a grain of salt. The authors claim that since they investigated one specific scenario, which is relatively easy to understand (in their case, a cholesterol test), and manually added and hard-coded additional information, the generalizability of the results could not be ensured. From a development perspective, implementing their suggested improvements could cause issues when dealing with more complex and diverse situations. Also, from a patient's perspective, the amount of additional information given could also result in a mental overload when dealing with increasingly complex scenarios.[309] But nevertheless, their insights are a valuable contribution to investigating our problem.

Adding the Dimension of Time

Although the last study already included a feature for showing previous test results and visualizing a trend, they did not further elaborate or analyze this feature. Nevertheless, they gave a hint about another layer of information that can be added to the visualization of laboratory test results: The change of a tested value over time. If we recall part of the quote from the beginning of this section again: "*For chronic patients, the temporal relations between data could often be of special interest.*",[310] we immediately see that this type of information is important for the further course of our research.
Another work from Torsvik et al. deals with different visualization methods for time series of laboratory test results and how they are received by users in several scenarios for answering different types of questions. What is shown very clearly in this study is the fact that the introduction of a temporal component results in an exponential increase in complexity. They had to look at different visualization techniques for different patient categories (simple, emergency, chronic, and complex) for answering different questions (e.g., trend analysis or covariation of test results), which led to a large number of combinations to be investigated. For our project, however, the results concerning chronic patients are mainly relevant. According to their results, the vast majority of participants (medical students) preferred so-called sparklines and relative multigraphs for conducting diagnosis tasks. For a smaller

[308] Zhang, Zhan et al. 2021
[309] Zhang, Zhan et al. 2021
[310] Torsvik et al. 2018, p. 203

amount of tested analytes in a chronic patient, participants preferred relative multigraphs, while a larger amount of tested analytes led to the preference of sparklines due to the fact that relative multigraphs tend to become messy when there are too many analytes shown at the same time.[311] This is perhaps the most important finding for us from this study. For a better understanding, Figure 6.8 shows different types of visualizations for time series of laboratory test results.

(Figure 6.8: Four different visualizations of the same data - a chronic patient case with four tested analytes by Torsvik et al.[312])

Recognizing Different Needs for Different User Groups

Another aspect that has only been implicitly mentioned so far is the inclusion of the needs of different users when it comes to the question of the visual representation of laboratory test results. For basic representation styles as well as the aforementioned layer of interactivity, research was conducted with patients as users in mind. When adding the dimension of time, the aforementioned study participants had been from the medical field. A quite obvious pattern is already emerging in this, namely that the needs of patients and medical professionals differ and that the latter can be expected to understand a higher degree of complexity due to their greater knowledge in the field. While it may seem obvious, it is still very important to know for what kind of user you want to visually present the lab test results, and it is also worth taking another look at.

[311] Torsvik et al. 2013
[312] Torsvik et al. 2013, p. 326

Zhang, Zhan, et al. studied the needs of patients when it comes to their laboratory test results by conducting a content analysis of a major medical Q&A website. They identified several needs, which can be categorized into four groups:[313]

- Understanding the meaning of their test results.
- Interpreting their doctor's diagnosis and seeking a second opinion.
- Learning about Lab tests in general.
- Consulting the next steps before their next doctor's appointment.

Additionally, according to their findings, there is a great variation in medical literacy between users, which is also something to keep in mind.
The needs of clinicians are more diverse since they depend on the specific situation, the task at hand, and the purpose for which the laboratory test has been ordered.[314] Since the treatment process of chronic diseases is of special interest, we look at the needs of clinicians for these very cases. A study by Torsvik et al. deals, among others, with this very question. They identified three main topics when reviewing test results as a clinician in the context of treating chronic diseases using an integrated software solution:[315]

- Initial orientation: Getting an overview of the situation.
- Sensing change: Examining the evolution of test results over time and identifying relevant changes.
- Making sense of change: The researchers identified a great need for comprehensive contextual information about a patient in order for the clinician to find out what a certain change actually means or implies.

As we can see, the needs of patients and clinicians turn out to be quite different. Nevertheless, viewing these user perspectives as completely disjunct would not be sufficient. When examining a patient-centered design approach for visualizing laboratory test results in a study already mentioned earlier, Zhang, Zhan, et al. pointed out a third category besides patient-centric and clinician-centric design: an integrated design perspective in order to encourage discussion and communication between patients and clinicians. In particular, an approach that helps patients be better prepared for their next clinical consultation might be beneficial for both parties.[316]

6.5.4 Takeaways from Integrated Solutions for Clinicians

As we can already see, there are many occasions where it is necessary to provide laboratory test results together with a certain context in order to gain meaningful knowledge about a patient's condition. This becomes especially apparent when looking at integrated solutions for diagnostic purposes. For example, when looking at a decision support tool for pediatric medicine, where standard reference intervals cause even more problems because they are, among other factors, highly dependent on a patient's age.[317] Also, the way in which laboratory test results are visualized could not only make understanding easier or harder but

[313] Zhang, Zhan et al. 2019, p. 4ff
[314] See section 6.5.2 Reference Intervals and Context
[315] Torsvik et al. 2018, p. 406f
[316] Zhang, Zhan et al. 2021, p. 10f
[317] Hirschmann et al. 2017

could also even have an impact on a clinician's decision, which is a very important thing to keep in mind during the design process of such applications.[318]
The perhaps most important takeaway from examining those integrated solutions is that all of them require domain-specific knowledge, and the methods for visualizing laboratory test results are adjusted to their environment of user groups, medical domains, and use cases. Therefore, all of these factors have to be kept in mind during the design process.

6.6 Visualization of Patient Data in Combination with Clinical Pathways

Now it is time to put everything back together. We examined the different building blocks, namely the visualization of clinical pathways on the one hand and the visualization of patient data, respectively laboratory test results on the other hand. Now, we're taking a look at the combination of those and hence come back to our research question. Since the individual parts alone open up a lot of research possibilities, their combination is clearly not something where a one-fits-all solution can be an adequate answer. Or as Aigner et al. put it: "*Visualizing clinical guidelines in combination with patients' data is a challenging task, because heterogeneous and time-oriented data and information need to be visualized in an intuitive way.*"[319]
For getting a comprehensive overview of this topic, besides our literature review, we also consulted an SLR from 2022 about state-of-the-art interactive EHR visualization.[320] When looking at the research landscape, it is interesting to see that there is a trend towards the visualization of aggregated patient data for the purpose of comparison and data analytics. The publications dealing with the visualization of individual patient data make up only a fraction of the total amount of examined papers. We identified two major contributions: CareCruiser by Gschwandtner et al.[321] and a more recent study, falling in the same category as Gschwandtner et al.'s work: A project called IDMVis by Zhang, Yixuan, et al.,[322] which we will both examine hereafter.

6.6.1 CareCruiser

The first major contribution dealing with this very question is by Gschwandtner et al. They extracted the following requirements necessary for the visual data integration of these two interconnected datasets:[323]

1. *Visualizing hierarchical data: the nesting of treatment plans and sub-plans*
2. *Visualizing temporal data: the execution sequence of treatment plans as well as the patient's condition and its evolution over time*
3. *Visualizing qualitative data: relevant characteristics of treatment plans, such as intentions of the plan, abort- and complete conditions etc.*
4. *Providing interactive means to allow for an active investigation of the course of the patient's condition and the detection of effects of applied treatments, and*

[318] Fischer et al. 2020
[319] Aigner et al. 2008, p. 8
[320] Wang and Laramee 2022
[321] Gschwandtner et al. 2011
[322] Zhang, Yixuan et al. 2019
[323] Gschwandtner et al. 2011, p. 44

~~*5. Providing means to compare multiple patients.*~~

While the fifth requirement is beyond the scope of our thesis, it is interesting to see that besides the different types of data that need to be visualized and integrated, interactivity plays an important role in their project, which is something we also discussed before.[324]
In order to tackle this problem, they introduced several features into their software solution called “CareCruiser”:[325]

- Flexible layouting and the possibility to view clinical pathway information, clinical actions, individual patient data, and interconnected events on the same screen using separate window views.
- Using color-coded highlighting for events of special interest, like significant changes in a patient’s parameter values.
- Providing the ability to filter, search, and manually highlight data points.
- Providing the ability to adjust the temporal view interval while at the same time maintaining contextual and overview information.

To evaluate and demonstrate their proposed solution, they chose a treatment plan for the ventilation of a newborn as an exemplary use case. In their example, the actions to be taken mostly rely on specific parameters such as a patient’s oxygen saturation and carbon dioxide pressure, as well as oxygen supply and ventilation frequency.[326] Due to this strong dependency between a patient’s specific parameters (laboratory test results in our case) and the individual treatment path(s) to be taken, their insights are of great value to our project.
Nevertheless, there are some pitfalls. As mentioned above, laboratory test results are not being discussed in more detail, as these have no particular relevance to their project. Secondly, the entire project was developed only from a physician's perspective and, therefore, gives us little insight into possible implications for a user-centered perspective.

6.6.2 IDMVis

Another major contribution is a project called IDMVis by Zhang, Yixuan et al.[327] This project’s major focus is on the aspect of visualizing the temporal component of the respective data, and also building upon the findings from Gschwandtner et al.’s work. Their medical use case is diabetes treatment support. To provide a better understanding, Figure 6.9 shows a screenshot of their solution, using separate windows for visualizing different layers of data, marked by A., B., and C.

[324] See section 6.4.3 Interactive Clinical Pathway Visualization - Back to the Initial Question and 6.5.3 Visualization Possibilities
[325] Gschwandtner et al. 2011, p. 43; p. 49f
[326] Gschwandtner et al. 2011, p. 44
[327] Zhang, Yixuan et al. 2019

(Figure 6.9: IDMVis multi-window view by Zhang, Yixuan et al.[328])

In order to connect the different windows with each other, several interactive features have been introduced, like additional information being shown or highlighted by hovering over data points or filtering for specific events.
One mentionable feature is what the authors call event alignment. This feature makes it possible to align the scaling of the time axis not according to equal time periods but according to one or more defined events (in their case, for example, the intake of a certain meal). Since meal intake plays an important role in diabetes, this allows a better comparison of observed effects on different days.[329] Of course, this is a very domain-specific feature for diabetes treatment, but nevertheless, it is worth mentioning as an interesting design feature to represent and compare temporal dependencies of certain events, which could maybe also be applicable to our problem.

We want to note here once again that while there are few contributions explicitly dealing with the very problem of the visual data integration of clinical pathways and individual patient data, we already examined a few resources where this problem has been implicitly tackled.[330]

6.7 Oncology-specific Issues

Last but not least, we would like to highlight a few aspects specific to hemato-oncological diseases in the context of our research question.

- As already mentioned, laboratory test results are one of the key factors in hemato-oncological diseases for treatment decision-making and the course of the

[328] Zhang, Yixuan et al. 2019, p. 512
[329] Zhang, Yixuan et al. 2019, p. 517
[330] E.g. section 6.4.3 Interactive Clinical Pathway Visualization - Back to the Initial Question - COCPIT

individual treatment pathway. Since the sources we have studied use other examples of diseases where other parameters are crucial, their results have to be adapted accordingly for our problem.

- Another important point is the long duration of treatment. For example, if we refer to the IDMVis project,[331] we see that a period of 14 days is visualized there for overview purposes since daily changes are relevant in their example disease. Accordingly, it must also be noted that the representation of much longer periods may involve new challenges.
- Lastly, especially when it comes to developing applications for patients, a particularly "gentle" approach is advantageous in the context of oncological diseases. While there is evidence that patients generally have a need for information about their own disease, the amount and type of information they want is quite ambiguous and varies widely from person to person.[332] One way of dealing with this issue would be the introduction of empathy-driven design.

6.7.1 Empathy-driven Design

When discussing interactive visualization methods for a patient's laboratory test results, one of the examined works by Zhang, Zhan et al.[333] already pointed out the importance of including empathy-driven design and adding sympathetic empathy with the patient's perspective into the design process.[334] Another important contribution in this context by Choe et al. deals with this very problem, namely that the continuous increase in digital technology gives patients more and more comprehensive and faster access to their own health data, but often overlooks the fact that this unfiltered and all-encompassing data access can be counterproductive for the well-being of patients, especially in the case of "bad news". To address this, they have developed a set of guidelines that developers and designers can follow. These guidelines include:[335]

- Prepare for the patients' visit
- Anticipate patients' feelings
- Build a partnership of trust with patients
- Acknowledge patients' physical and emotional discomfort
- Set up a scene where patients can process the information
- Help patients build resilience and give hope
- Match the level of information to the patient's level of understanding
- Communicate face-to-face, if possible
- Use nonverbal means

They also emphasize on their claim that there is no general solution since every situation and every patient is different and therefore has different needs. Nevertheless, these guidelines could help improve patient's well-being while needing to communicate "bad news".[336]

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[331] Section 6.6.2 IDMVis
[332] Friis et al. 2003
[333] See section 6.5.3 Visualization Possibilities
[334] Zhang, Zhan et al. 2021, p. 11f
[335] Choe et al. 2019, p. 1
[336] Choe et al. 2019, p. 16

6.8 Results

The original problem was to integrate clinical treatment pathways on the one hand and individual patient data, in particular laboratory test results, on the other, and to display them visually so that relevant information can be recognized as easily and efficiently as possible. For this purpose, we conducted a state-of-the-art narrative literature review,[337] and looked at the problem from different perspectives. Firstly, we looked at general UI design and data visualization principles, which serve as a foundation. Then we found out that the problem involves several relevant perspectives or dimensions:

> **User Perspective**: When visually representing this kind of data, it is crucial to make a distinction for which kind of user it will be represented. Although there are some overlapping points, patients and clinicians have different needs and a different level of expertise. Also, an integrated perspective to facilitate the interaction between doctors and patients is one that should not be forgotten.
>
> **Data Perspective**: The types of data to be visualized can be separated into hierarchical or structural data, qualitative data, a temporal data component, and the question of how to integrate them with each other.
>
> **Domain Perspective**: It is also important to take a look at domain-specific requirements and peculiarities. What are the things to pay attention to when it comes to the medical sector, to chronic diseases, to hemato-oncological diseases?

When analyzing the available literature and the different projects dealing with one or more parts of the problem, we could identify and extract some common themes or guidelines that can help develop the respective software artifacts.

> **Level of Information Detail**: The amount of provided information is a spectrum ranging from none to everything available. Now, the main task is to find a level of detail that shows everything a user wants to know without overwhelming them. This is highly dependent on the type of user but also on other perspectives. When looking at our foundation, the concept of user-centricity comes into play here.
>
> **Multi Window View**: Especially when looking at the data perspective, one question that arises is how to fit all the different types of data on a single screen. One commonly identified theme is the use of multiple windows for each kind of data on a screen while providing flexible layouting of the windows. This also corresponds to the principle of minimizing the user's

[337] See section 4.1 Literature Review Methodology

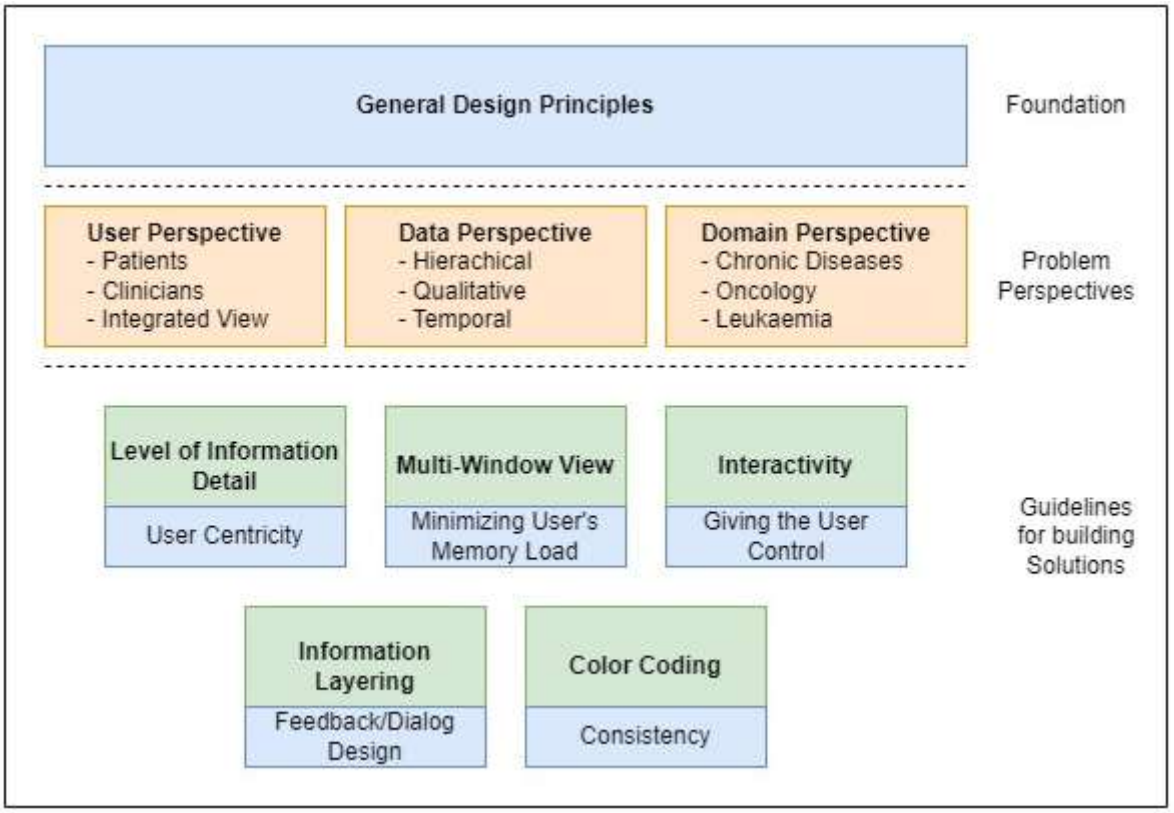
memory load since, this way, an overview of different types of information is provided without needing to switch between views. This was especially noticeable when examining desktop solutions for clinicians since the amount of data that needs to be shown in those cases tends to be higher.

Interactivity: We identified much use of interactive visualization techniques like hyperlinking, providing additional information when hovering over certain elements, or visually connecting marked data points with corresponding data from other windows. This is an appropriate means to visually indicate the connection between different data types. This corresponds to the user-centric principle of giving a user control.

Information Layering: This aspect is related to the two previously mentioned points. Literature indicates that besides the questions of how much information should be provided at all and how information is visually connected, it is beneficial to provide different layers of information. Initially, a smaller amount is used for overview purposes while providing additional details on demand. One example of achieving this could be to make use of well-designed dialogs, which can serve as informative feedback when interacting with the system.

Color Coding: Although the use of color in UI design is a commonly used method and a widely researched topic, we could observe that the majority of projects from the reviewed literature put a special emphasis on color coding since, especially in the medical sector, it can have a huge impact on a user's perception and also on decision making. When looking again at the fundamentals, this very much corresponds to the design principle of striving for consistency, both within the application and when using domain-specific color coding.

Figure 6.10 summarizes the results once again in compact form.



(Figure 6.10: Summary of this chapter's findings and the covered topics)

We want to end this chapter with the following quote: "*Care pathways are complex interventions in complex systems[..]*" and therefore, "*Care pathway implementation is characterized by a dual complexity*"[338] In this chapter, we have tried to approach our complex problem from different perspectives, using our previously elaborated literature review methodology and have been able to identify certain guidelines for the development of appropriate software artifacts. Finally, the following should be said: "*The best visualization for decision-making is still unknown, but we can continue to work toward the best representation of the data we have for both providers and patients.*"[339]
In Chapter 8 - Field Analysis, we will use guidelines we developed for our field analysis and the evaluation of different software solutions that already exist.

[338] Seys et al. 2019, p. 5
[339] Fischer et al. 2020, p. 42

Chapter 7 - Legal Situation Concerning the Visualization of Patient Data

First of all, let us recall the purpose of this legal analysis. In order to contribute to treatment support in hemato-oncological diseases, software artifacts are to be developed that visually prepare corresponding data (patient data and medical pathway data) for different user groups (patients, clinicians), as well as to facilitate communication between them. Now the question arises, which legal requirements have to be met by such artifacts during development as well as during operation, and which laws have to be adhered to in order to protect operators as well as users from possible risks.
In Chapter 5 - Legal Situation Concerning the Processing of Patient Data, we have already dealt with the legal aspects of processing data concerning health, which forms the basis for our project since data visualization is also a type of data processing.[340] The main focus here was on data privacy and protection. Now, we want to look at the legal specifics of our project. First, we will examine how and whether the term data visualization is legally defined. Then, we will turn our attention to the EU Medical Devices Regulation and its national implementations, as well as to the resulting requirements. After that, we will focus on the communication between physicians and patients and examine relevant aspects of the medical disclosure obligation, as well as the area of digital health and telemedicine. Subsequently, various liability issues in the operation of such software will be discussed, as well as possibilities to protect innovative visualization methods under intellectual property law. Finally, we try to synthesize and conclude our findings from this chapter.

7.1 Visualization in a Legal Sense - An Attempt at Definition

The first question is whether and how the term (data) visualization is defined and used in legal texts. In order to answer this question, a distinction must be made depending on the context as to what kind of legal question is actually being answered. On the one hand, there are the requirements that are placed on visualization in the sense of our research question, be it to fulfill data protection regulations or as a part of the development process of legally compliant (medical) software. On the other hand, there is the question of whether and how newly developed visualization methods can be legally protected from copying and reusing.

7.1.1 Requirements Perspective

As we have already seen in part before, high demands are placed on software in the healthcare sector, in particular with regard to security and data protection. However, the GDPR does not provide technical implementation guidance. This, therefore, also applies to the visualization of data within software. The only reference that can be found in this regard relates to the transparency principle: "*The principle of transparency requires that any information addressed to the public or to the data subject be concise, easily accessible and easy to understand, and that clear and plain language and, additionally, where appropriate, visualisation be used.*"[341] What this visualization should look like in concrete terms is not defined in more detail.

[340] See section 5.1.2 Terminology
[341] GDPR Rec. 58; cf. section 5.2.1 Processing of personal data - Transparency

Also, if we take a look at the EU Regulation on Medical Devices,[342] commonly referred to as MDR (which is discussed in detail in section 7.2.2 EU Medical Devices Regulation (MDR)), we see that possible requirements for visualizations are very broad. For example, even for devices that emit energy or substances (i.e., may have increased hazard potential), it states that if the operating or adjustment parameters are visually indicated that: "*[..] such information shall be understandable to the user and, as appropriate, the patient.*"[343]
Actually, it is also quite obvious that the law does not regulate how data should be visualized, apart from the rather abstract requirement of comprehensibility.[344] Due to the heterogeneity and complexity of such applications, this would be neither possible nor expedient. As we have seen, even the comparatively simple requirements for what a consent form should look like give rise to a number of complications.[345]
A research paper by Muchagata and Ferreira looks at the impact of the GDPR on the visual interactions between the patient and mobile health apps and how the app design can be adjusted to provide a more objective and clear view. But also here, the authors claim that they "*[..] could not find research about the impact of the new GDPR on the development of mHealth apps as well as guidelines for implementation and use.*"[346]
Another definition in this context can be found in the EU Regulation on General Product Safety,[347] commonly referred to as GPSR. It mentions the term "online interface", which is defined as follows: "*[..] any software, including a website, part of a website or an application, including mobile applications;* "[348] This term is used here primarily in connection with the requirements for so-called "online marketplaces" and is also very broadly defined. Nevertheless, it is worth taking a closer look at.
Even though there are few legal texts that explicitly mention data visualization as such, it is nevertheless important to also deal with requirements that affect the development and operation of (medical) software since implicit requirements for data visualization can also arise from these. All of this will be addressed in section 7.2 Developing Legally Compliant Medical Software.

7.1.2 Intellectual Property Perspective

Since innovative solutions for the interactive visualization of data form an important part of our project, the question arises not only as to which requirements must be met but also as to how these solutions can be legally protected.
Central here is the copyright law and its national implementations. The example of Austria shows that even a definition of the term software was intentionally left out for the sake of technology neutrality. The term computer program is used, but it is not defined either.[349] For our definition attempt, it is important that the visualization of data, in our case, is implemented in the context of a graphical user interface (GUI). In case law regarding copyright, a distinction is made between GUI as an abstract interface and software that implements the interface, which has, in turn, an impact on the protection by copyright.[350] We

[342] MDR
[343] MDR Appendix I, Nr. 21.3
[344] cf. section 5.2.1 Processing of personal data - Transparency
[345] cf. section 5.2.1 Processing of personal data - Consent
[346] Muchagata and Ferreira 2018, p. 5
[347] GPSR
[348] GPSR Art. 3, Nr. 15
[349] Tretzmüller 2023, p. 3f
[350] Tretzmüller 2023, p. 10; cf. also Zankl 2021, p. 26

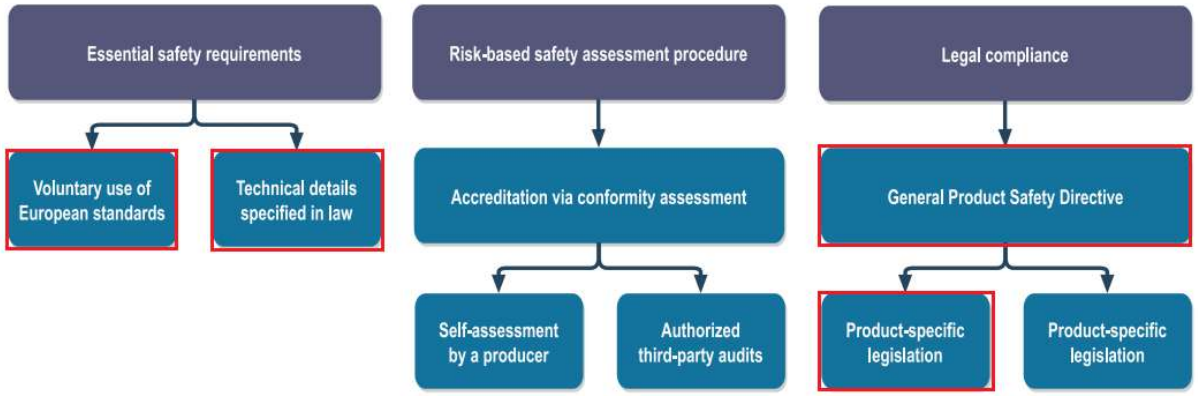
will deal with copyright law and other related topics for legally protecting data visualization solutions in section 7.5 Legal Protection of GUIs.

As we have already seen, the term is contextual, depending on the legal perspective from which it is viewed. This insight from different perspectives will now be attempted in the following sections.

7.2 Developing Legally Compliant Medical Software

We have already examined the concept of Data Protection by Design and Default in Chapter 5 - Legal Situation Concerning the Processing of Patient Data. This can now be extended to a general concept of legal compliance by design. In contrast to the compliance by detection approach, in which the software is only adapted to the legal requirements after implementation or in the event of a problem, the requirements are already included in the development process.[351] While we cannot cover the entire development process within this work, as this would go way beyond the scope, we instead focus on the aspects that are relevant for developing data visualization mechanisms.
In order to include legal aspects in a development process, it is first necessary to examine which laws are relevant and which requirements are defined. As already indicated, the MDR and the GPSR are particularly relevant in this sense, with the GPSR serving primarily to intervene where specific legislation is incomplete or non-existent. Due to this fact, and because it is not clear to what extent software is covered by the GPSR at all since it is not explicitly defined as a product there, we focus primarily on the MDR. Here, too, it must first be clarified to what extent our project is covered by this regulation. In order to integrate all this information, we will take a closer look at the concept of legal design.
It is also important to point out that there is a difference between a product complying with European standards, which is voluntary, and complying with mandatory European safety legislation. As already mentioned in section 6.3 UI Design in a Medical Environment, while the application of those standards is often voluntary (as we see later on, the MDR actually obligates manufacturers to adhere to standards), it nevertheless provides benefits for subsequent conformity assessments. Figure 7.1 illustrates the different building blocks of general product safety. The areas we focus on are marked in red.

[351] Purtova et al. 2015, p. 61f



(Figure 7.1: General Logic of Product Safety Policy in the EU by Ruohonen[352] with additional markings)

Elaborating on the risk-based safety assessment procedure is left out here, as it would go beyond the scope of this work. Also note that this figure refers to the General Product Safety Directive,[353] called 'GPSD' from now on, which will be replaced by the GPSR from 13 December 2024.[354] This, however, does not change the general logic depicted in the Figure.

7.2.1 EU General Product Safety Regulation (GPSR)

At the time of writing, the GPSR had just been published and had not yet replaced the GPSD. Therefore, no scientific contributions can yet be found that deal with the effects of the GPSR on software as a product. So, we will briefly discuss the situation up to now with the GPSD in force and, in addition, deal with the newly published primary legal text of the GPSR.

First of all, it should be noted that in the GPSD, the term software and related terms, such as interface or visualization, do not occur at all. Therefore, it is only marginally relevant to our specific question. What is interesting to see, however, is that when the GPSD came into force, great importance was already attributed to the legal harmonization of the implementations of the member states since this is of particular importance for trade within the EU.[355] For the same reason, Switzerland was committed to voluntarily implementing this directive.[356] Therefore, it can be assumed that with the enactment of the GPSR, harmonization is again being aimed at within the entire DACH region, which is why it is sufficient for us to look at the legislation at the EU level here.

In contrast to the previous directive, the new regulation, adapted to new technical conditions, does explicitly mention software-related terms. However, if we consider the legal document in its entirety, we can see that its importance for us remains marginal. Software is still not mentioned as an independent product but only as part of a product, whether as an embedded system or in the context of repair, whereby software is equated with a

[352] Ruohonen 2022, p. 353
[353] GPSD
[354] https://commission.europa.eu/business-economy-euro/product-safety-and-requirements/product-safety/general-product-safety-regulation_en#:~:text=Documents-,What%20is%20the%20General%20Product%20Safety%20Regulation%20%3F,the%20Food%20Imitating%20Product%20Directive%20 last visited 2023-05-02
[355] Ruohonen 2022, p. 353f
[356] https://www.seco.admin.ch/seco/de/home/Arbeit/Arbeitsbedingungen/Produktsicherheit.html last visited 2023-05-02

replacement part.[357] Furthermore, as already mentioned, the term appears in the definition of an 'online interface'. On closer inspection, however, it becomes clear that this term is intended here solely to describe the interface through which online retailers distribute their products so that if a dangerous or deficient product is offered, authorities have the option of having it removed from the respective platform. However, no further requirements are placed on the appearance of the online interface itself.[358] Therefore, in the following, we have to deal with the product-specific legislation in order to get sufficient insight into the legal requirements regarding our question.

7.2.2 EU Medical Devices Regulation (MDR)

Building on the legislation for general product safety, we now turn to product-specific legislation. Of central importance here, as already mentioned, is the EU Regulation on Medical Devices - MDR.[359] First, we look at the relationship between the EU Regulation and the national implementations of the respective countries in order to stay true to our comparative research approach. Then, we address the question of how a medical device is defined and whether and to what extent our project should be classified as such. Finally, we will take a closer look at practical implications as well as passages that are relevant to us and explain how they are to be interpreted from a scientific, legal point of view.

EU-DACH Relationship

Looking at the specifics of the national implementations of the MDR, we could observe a great ambition towards harmonization, as was also the case for the GDPR. This is not surprising, as the medical device sector is of enormous economic importance for both the EU and Switzerland and also plays an important role in medical supply security.[360] Switzerland, for example, exports and imports about half of all medical devices to and from the EU.[361] Nevertheless, there have been some novelties and adjustments in recent years.

In Austria, the "Medizinproduktegesetz" (MPG-AT)[362] implements the MDR from 2021. In addition, the EU Directive on in vitro diagnostic medical devices (IVDR)[363] is also implemented by the MPG-AT from 2022.[364]
The national amendments mainly concern the regulation of the bodies towards which notification obligations must be carried out, register management and measures for market surveillance.[365] None of this is of particular relevance to our specific question.

The situation in Germany is similar. Here, EU law is even more clearly implemented directly. In 2021, the German "Medizinproduktegesetz" (MPG-DE) was replaced by the MDR and the

[357] GPSR Rec. 25; Art. 15, Nr. 3(a); Art. 37, Nr. 3
[358] GPSR Rec. 49, 53, 54, 55, 56, 59; Art. 3, Nr. 15; Art. 22
[359] MDR
[360] https://health.ec.europa.eu/medical-devices-sector/overview_de last visited 2023-05-05
[361] https://germany.representation.ec.europa.eu/news/eu-schweiz-gegenseitige-anerkennung-von-medizinprodukten-nicht-mehr-gultig-2021-05-27_de last visited 2023-05-05
[362] MPG-AT
[363] IVDR
[364] https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20011580 last visited 2023-05-05
[365] Degelsegger-Márquez 2021, p. 9f

"Medizinprodukterecht-Durchführungsgesetz" (MPDG-DE[366]), whereby the latter is not defined as an independent set of regulations, but only as a national supplement to the MDR, and since 2022 also to the IVDR.[367]

Switzerland is also striving to align its laws with those of the EU to enable legal harmonization and thus facilitate trade and commerce in this industry. However, the situation is somewhat complicated at the moment since the EU considers Switzerland to be a third country in this respect since the MDR is in force due to the lack of progress on institutional issues between Switzerland and the EU. This means that some trade facilitations are no longer available. However, Switzerland is eager to take measures to ensure trade with the EU, as well as the security of supply, as this plays an enormous economic role, as already mentioned.[368]
Central in Swiss law are the "Bundesgesetz über Arzneimittel und Medizinprodukte" - (HMG-CH[369]), as well as the "Medizinprodukteverordnung" (MepV-CH[370]).

While we are focussing on EU legislation from now on, one important peculiarity to note here is that both the Austrian and German implementations have requirements for the language in which information intended for the users is provided. While information intended exclusively for professionals may suffice in English, in all other cases, it must be provided in German or a language understandable to the user.[371]
In Switzerland, the language requirements are even higher. Under most circumstances, the information provided to the user must be available in the official languages of German, French, and Italian.[372]
Thus, since we are guided by the most restrictive law in answering our research question, one of the requirements for developing an artifact that visualizes medical data is that the provided information needs to be available in German, French, Italian, and preferably English, especially when the information is also available to the patient.

Software as a Medical Device

While not defined in the GPSR, the MDR explicitly states that software in itself can indeed fall under the definition of a medical device. Recital 19 states:

> *It is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, qualifies as a medical device, while software for general purposes, even when used in a healthcare setting, or software intended for life-style and well-being purposes is not a medical device. The qualification of software, either as a device or an accessory, is independent of the software's location or the type of interconnection between the software and a device.*[373]

[366] MPDG-DE
[367] https://www.bundesgesundheitsministerium.de/themen/gesundheitswesen/medizinprodukte/definition-und-wirtschaftliche-bedeutung.html last visited 2023-05-10
[368] https://www.bag.admin.ch/bag/de/home/medizin-und-forschung/heilmittel/revision-med-prod-verord-mepv.html last visited 2023-05-10
[369] HMG-CH
[370] MepV-CH
[371] MPG-AT §7; MPDG-DE §8
[372] MepV-CH Art. 16
[373] MDR Rec. 19

Whereas the defined medical purposes are:[374]

- *"diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,*
- *diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,*
- *investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,*
- *providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations"*

Furthermore, software is also explicitly defined as an 'active device', which means that for its operation an energy source other than the human body or gravity is necessary.[375] This, in turn, has implications for the requirements placed on software as a medical device, especially when it comes to risk classification, which we will get to in a moment.

Qualification of our Project as a Medical Device

Now, the question arises whether our project should be classified as a medical device. It must be said here that we are focusing on the visualization, and no definitive statement can be made about this alone without the appropriate context. Central in this regard is the intention with which the visualization or the entire application is developed, whereby this is determined by the manufacturer.[376] For example, if a visualization tool is developed for depicting a patient's disease progression within a treatment pathway, without this software having a direct impact on clinical decisions but only contributing to patient education, there is a chance that it will not be considered a medical device. However, if this visualization is used for decision-support purposes, then it is highly likely to be a medical device as defined by the MDR.

For the general classification of software as a medical device, an official document (MDCG[377]) can be consulted. Of particular importance for us is "*Rule 11 - Software for decisions with diagnosis or therapeutic purposes or software intended to monitor physiological processes*",[378] as well as "*Annex I: Illustrative examples of qualification of software* [Note: as a Medical Device] *used in the healthcare environment*",[379] whereby examples b), c), and d) are particularly important for the latter. Especially example b): "*In general, these* [Note: Decision Support Software] *are computer based tools which combine general medical information databases and algorithms with patient-specific data. They are intended to provide healthcare professionals and/or users with recommendations for diagnosis, prognosis, monitoring and treatment of individual patients.*"[380] This more or less describes one of the intentions of the overall project of which our examined data visualization methods are a part of.

[374] MDR Art. 2, Nr. 1
[375] MDR Art. 2, Nr. 4
[376] Ludvigsen et al. 2022, p. 87f
[377] MDCG 2019
[378] MDCG 2019, p. 13
[379] MDCG 2019, p. 18f
[380] MDCG 2019, p. 19

While the classification of our project as a medical device seems obvious at first glance, we nevertheless reserve the right to make a final assessment at this point. Whether software is to be subsumed under the MDR is extremely complex and difficult to assess in practice but has far-reaching consequences for development and operation.[381] A final assessment would go beyond the scope of this work.

Practical Implications for Development and Operation

In case the classification of our project as a medical device in the sense of the MDR takes place, the most important practical implications are now outlined here. However, this section does not claim to be exhaustive but is merely intended to provide an overview.

The MDR defines various risk classes for medical devices. This classification then determines which additional rules apply to the respective product. Classes I, IIa, IIb, and III are available, with class III representing the one with the highest risk.[382] As already mentioned, software is defined as an active device according to the MDR. As a result, medical software is, in most cases, classified as class IIa to III, which implies that it receives an increased risk assessment.[383] According to the MDR, software can only be classified as class I if it is neither used for any kind of decision support nor can it monitor physiological processes.[384]
The manufacturer's obligations for software classified as a medical device include the following:[385]

- Establishment of a quality management system for planning, development, production, and operation during the entire life cycle.
- Creation and updating of technical documentation
- The obligation to demonstrate compliance with legal regulations through a conformity assessment procedure
- Performing a clinical evaluation (including a risk assessment and the demonstration of a clinical benefit)
- A special focus on safety and performance requirements, as well as data protection and interoperability[386] in compliance with the MDR

Turning now back to our original focus of data visualization, there are a few points within the MDR which are particularly interesting to us.

- When it comes to the requirements for the technical documentation, respectively a general description of functional elements, the MDR actually facilitates the use of graphical visualizations for better understanding. It states: "*Where appropriate, this* [Note: the description] *shall include labelled pictorial representations (e.g. diagrams, photographs, and drawings), clearly indicating key parts/components, including sufficient explanation to understand the drawings and diagrams.*"[387] The interesting

[381] Tretzmüller 2023, p. 297
[382] MDR Annex VIII
[383] Becker, Kurt et al. 2019, p. 211
[384] MDR Annex VIII Rule 11
[385] Tretzmüller 2023, p. 296f
[386] cf. MDR Art 2, Nr. 26
[387] MDR Annex II, Nr. 1.1.(j)

thing here is that, especially when looking at our specific case, this paragraph actually facilitates the design of self-explanatory UI since the data visualization here in itself could also be interpreted as part of the documentation.

- In general, medical devices are obliged to be assigned a Unique Device Identifier (UDI) consisting of a UDI-Device Identifier (UDI-DI) and a UDI-Production Identifier (UDI-PI).[388] We want to point out here that the MDR explicitly regulates how the assignment of a UDI for software is to be handled since software is usually continuously changed and updated. The introduction of new user interfaces or changes that have an influence on the interpretation of data are explicitly mentioned as reasons for assigning a new UDI-DI to software. While minor changes according to the regulation normally only affect the UDI-PI, comparatively small changes in the data visualization can, according to our interpretation, already result in the obligation to assign a new UDI-DI.[389]
- Also important for UI design and data visualization is the following rule, which explicitly addresses presentation on different screens and in different environments: "*Software referred to in this Section that is intended to be used in combination with mobile computing platforms shall be designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards level of light or noise).*"[390]
- Also to be noted is an additional rule for medical devices used by lay persons. It is pointed out that the user's capabilities should be included in the design and development process. This is, therefore, particularly important for us when the intended users are patients and is also a reference to the concept of user-centered design.[391]

While the whole process of developing and operating medical software compliant with the MDR is a highly complex task, and the legal aspects of used data visualization and UI design methods can often not be separated from those of the software product as a whole, we could still identify some issues specific to our research question.

7.2.3 Design Standards and Norms

At this point, we would like to refer once again to section 6.3 UI Design in a Medical Environment, as it is thematically congruent here. Harmonized standards are of great importance when it comes to legal compliance with regard to the MDR. These also form a point of overlap between the jurisprudential and the technical part of our work. We have decided to elaborate on this topic in more detail, not here, but in the referred section.

[388] MDR Art. 27, Nr. 1(a)
[389] MDR Annex VI, Part C 6.5
[390] MDR Annex I, Nr. 17.3.
[391] MDR Annex I, Nr. 22; cf. section 6.1.6 User Centricity

7.3 Legal Aspects Concerning the Digitalization of the Patient-Doctor Relationship

When examining legal requirements, in addition to taking into account the perspectives of the respective user group for which a software product is intended, it is also interesting to deal with the legal basis of digital communication between the user groups, in particular between physicians and patients and how this possibly relates to data visualization. Especially since several applications for the various stakeholders are to be developed within the context of our superordinate project, which is to actively promote this type of communication.

The technical requirements for communication, i.e., data security, encryption, privacy, etc., are already largely covered by the GDPR and the MDR. Beyond that, however, further questions arise. In the following, we will deal with the physician's medical disclosure obligation in connection with digital communication. Furthermore, the legal aspects of telemedicine, in particular telemonitoring, will be discussed. After that, we will also take a look at the German Digital Care Act (Digitale-Versorgung-Gesetz - DVG-DE[392]), which is a special legal case within the DACH region.

7.3.1 Medical Disclosure Obligation and the Patient's Right to Information

A fundamental question that arises in digital clinician-patient communication (e.g., via data visualization techniques) is what information may/should/must (not) be shown to the user, especially the patient. From a legal perspective, the medical disclosure obligation and the patient's right to information are relevant here.

In Austria, this is regulated by the "Ärztegesetz" (ÄrzteG-AT[393]), which states that physicians are obligated to grant patients access to their patient documentation and to provide all requested information regarding their treatment.[394] In Germany, this is additionally governed by patient law, which is set out in the "Bürgerliches Gesetzbuch" (BGB-DE[395]). It is interesting to note that substantial therapeutic reasons generally permit a physician to refuse access to the patient's records.[396] In practice, this is particularly relevant in psychotherapy or psychiatric treatment, as direct access to the patient's file can have a negative impact on the success of the treatment or in cases where the patient is considered to be at risk of suicide.[397] Switzerland is taking a middle course here. The attending physician can demand that the patient's file be inspected only in the presence of themselves or another healthcare professional if inspection of the patient's file could have serious consequences for the patient.[398]

It is clear that a patient will, in most cases, receive all of their relevant health and treatment information if they request it. However, it is not regulated whether this must also be done proactively. In fact, case law indicates rather the opposite here. For example, an Austrian

[392] DVG-DE
[393] ÄrzteG-AT
[394] ÄrzteG-AT §51, Nr. 1
[395] BGB-DE
[396] BGB-DE §630 g(1)
[397] Buchner 2020, p. 60f
[398] https://www.bag.admin.ch/bag/de/home/medizin-und-forschung/patientenrechte/rechte-arzt-spital/6-recht-einsicht-patientendossier.html last visited 2023-05-25

Supreme Court ruling states that: "*Nach der Rechtsprechung ist die Aufklärung nämlich bei besonders ängstlichen Menschen auf ein Minimum zu beschränken, damit solche Patienten vor psychischen Pressionen bewahrt werden.*",[399] which translates to: "According to case law, the information is to be limited to a minimum in the case of particularly anxious people, so that such patients are protected from psychological pressures."
This results in an area of tension that has existed for a long time and is also particularly important in cancer therapy. It is the "*[..] dilemma between the physician's paternalistic concern for the patient and the patient's right to know as much as possible.*"[400] While this question is, in addition to the legal aspect, relevant primarily from an ethical perspective, it has gained further relevance with the rise of digital doctor-patient communication.
A work dealing with the emerging issues when making EHRs accessible to patients points out that the unrestricted insight into their data could cause problems regarding their comprehension and response to the data before consulting a clinician, as well as the assessment of the relevance of certain data due to their lack of expertise.[401] If we now combine this with the fact that misinterpreted information can lead to considerable psychological stress, especially with cancer, this also has some implications for our project.
Data visualization is a particularly efficient but also particularly complex way of providing information. While at first glance it seems sensible and correct to provide the patient with as much information as possible and as clearly as possible,[402] the literature here suggests now that from a legal and, above all, ethical point of view, it should be carefully considered and examined for each individual case what type of information and how it should be provided. While we cannot elaborate on this in detail for our project, as this would go beyond the scope of this work, the principle that "more is not always better" is already an important finding for us.

7.3.2 Digital Health and Telemedicine

Another important topic that came up several times when examining digital communication between physicians and patients is telemedicine, which we will now examine in the context of our research question. We provide an overview of relevant termini to frame the concept of telemedicine thematically and try to elaborate on which of them and to what extent are relevant to us.

Digital Health

The umbrella term "Digital Health", which is often used for all types of combinations between healthcare and digital technologies, has no agreed-upon definition in the literature. Since it is so broad, many different concepts fall under that category, such as eHealth (electronic Health), mHealth (mobile Health), telemedicine, personalized medicine, and so on. Nevertheless, especially in recent years, scientific interest in mHealth seems to have increased.[403] Since there is no comprehensive and precise definition in the scientific literature, it can also not be expected that a meaningful legal definition of the term is available. Therefore, we have to narrow down our area of investigation

[399] OGH 4 Ob 256/16z https://www.ogh.gv.at/entscheidungen/entscheidungen-ogh/zur-aerztlichen-aufklaerungspflicht-bei-einer-seltenen-komplikation/ last visited 2023-05-25
[400] Goldberg 1984, p. 948
[401] Beard et al. 2012, p. 117f
[402] cf. Chapter 6 - Data Visualization and GUI Design - Literature Review
[403] Fatehi et al. 2020

Telemedicine

Telemedicine can be defined as "*[..] the remote delivery of clinical care services through audiovisual conferencing technology*."[404] However, different definitions exist as well. The German "Bundesärztekammer" puts an emphasis on replacing a patient's physical presence during treatment with the help of information and communication technologies in their definition but leaves out the need for using audiovisual conferencing technology. The WHO definition, in turn, has a much broader scope. It includes not only treatment but also other forms of digital communication of health-related data between different stakeholders where distance is a critical factor, for example, for diagnosis and prevention of diseases, as well as for research and evaluation purposes.[405] Furthermore, the term telemedicine is also not legally defined.[406] In practice, the categorization of telemedicine has been divided into the following three areas: Telecooperation, Teletherapy, and Telemonitoring.[407]

Telemedicine in Hematology and Oncology

Especially in the field of hematology and oncology, there are many potential use cases for telemedicine applications. Particularly due to the long treatment duration and treatment complexity of such diseases, it can be advantageous for both patients and healthcare providers to handle certain treatment steps telemedically. The goal cannot and should not be to carry out as many treatment steps as possible digitally but to utilize them where it makes sense to do so. Examples of this are additional interactions with doctors, nursing staff, or psycho-oncologists with the help of a telemedical platform or app-supported self-management. Especially in recent years, efforts are being made to extend the use of telemedical technologies in hematology and oncology further, especially (but not only) in rural areas where the density of medical care facilities is lower.[408]

Mobile Health

The aforementioned term mHealth is particularly interesting in the context of our project. It covers a wide range of health-related mobile applications. Especially in the case of app-supported self-management for patients, but also with applications that serve to strengthen patients' health literacy or those for analysis and insight purposes, it is important not to view these applications in isolation but as part of an integrated platform that includes the perspective of the treating physicians in addition to the patient's perspective.[409]
The principal framework conditions for the development of mHealth solutions are:[410]

- Quality (whereby it must be checked here above all whether the respective solution is to be classified as a medical device),
- Interoperability in accordance with established standards in the healthcare sector
- Data protection and data security.

[404] Becker, Christian et al. 2019, p. 1
[405] Beckers and Marx 2021, p. 4f
[406] Fehn 2020, p. 11
[407] Beckers and Marx 2021, p. 6
[408] Koschmieder and Brümmendorf 2021
[409] Haas et al. 2021
[410] Juffernbruch 2020, p. 447

Legal Implications for our Project

After this brief excursion, we would now like to return to the actual subject of our investigation. In the course of our research, we repeatedly came across the terms discussed earlier, which is why our work would feel incomplete without an explanation of them. However, telemedicine is such a large subject area that we can only scratch the surface here. Moreover, we are primarily interested in the legal aspects of this topic, and we were able to determine that there is no separate, legal set of rules, if only because of the difficulty of defining the term. Instead, different laws are relevant depending on the subarea (data protection, security, product requirements, liability, etc.),[411] which we will examine in more detail in the course of our elaboration anyway. Nevertheless, there is a relatively new feature in German law in the context of mHealth: the DVG-DE, which came into force at the end of 2019 and which we will turn to in the next section.

7.3.3 Digitale-Versorgung-Gesetz - DVG-DE

In order to advance digitization in the healthcare sector, legislators in Germany have amended or initiated several laws in recent years. These include, among others, the DVG-DE.[412] In addition to changes concerning the handling of EHR data, the amendment to §33a of the SGB(5)-DE,[413] which creates an entitlement to the prescription of digital health applications as part of a treatment, is of particular relevance to us. In other words, there is now a possibility that under certain circumstances, doctors can prescribe certain apps in a similar way as they prescribe medications.[414] This includes applications with a low-risk class (classes I or IIa). Here, the DVG-DE refers directly to the European MDR.[415] This, in turn, places considerable demands on the manufacturers of such applications. The legal framework for the requirements is provided by the MDR and GDPR and their national implementations, which we have already discussed. In addition, the "Digitale-Gesundheitsanwendungen-Verordnung" (Digital Health Applications Regulation - DiGAV-DE[416]) must also be complied with.[417]

The requirements specified in the DiGAV-DE concern safety, functional capability, data protection, security, quality, interoperability, and proof of positive treatment effects. They also refer in many places to the previously mentioned laws. If, in the course of a review process, a healthcare application is found to meet the requirements set forth in the DiGAV-DE, it may be added to the National Directory of Health Care Applications.[418] While we haven't found any direct reference to requirements concerning the visual appearance of a graphical user interface within the DiGAV-DE, it is worth taking a look at this directory.

As of 10 October 2023, there are 49 digital health applications listed.[419] Most of them are concerning psychological diseases like depression, anxiety, several addictions, or different phobias or provide psychological support during the treatment of another chronic disease. In our opinion, the reason for that could be that psychological support applications usually have little to no impact on medical decisions, nor do they fall into the category of applications for

[411] Fehn 2020
[412] cf. Schinnenburg 2023, p. 886
[413] SGB(5)-DE
[414] Fehn 2020, p. 14f
[415] DVG §33a Para. 2; cf. section 7.2.2 EU Medical Devices Regulation (MDR)
[416] DiGAV-DE
[417] Jukic and Rahn 2020, p. 750
[418] Knigge and Ruckdäschel 2022, p. 861
[419] https://diga.bfarm.de/de/verzeichnis last visited 2023-09-15

monitoring health parameters and are, therefore, in a lower risk class according to legislation and thus easier to certify. Unfortunately, we could not find oncology-related applications for further analysis regarding our research topic. There are two applications concerning breast cancer, but both of them primarily deal with the relief of psychological complaints. For long-term treatment support, self-management, and health parameter monitoring, there are some applications regarding the treatment of diabetes mellitus that could provide some interesting insights upon further investigation.
In Austria, similar considerations are already being discussed for the creation of the possibility of prescribing digital health applications on prescription. However, the corresponding draft legislation is not yet available at the time of writing.[420] Switzerland is even more reserved in this respect, and contributions can be found from a medical perspective in particular, which criticizes the high costs in relation to the benefits of such prescriptions.[421] So further developments remain to be seen.

7.4 Liability Issues

Our research question deals with the legal framework for the visualization of patient data. First of all, it must be said that liability issues in this context are an extremely complex subject area, and in the following, we will also explain why this is the case. Various topics overlap here, so at this point, we can only give an overview of legal contexts, scratch the surface, and try to explain different aspects using an example case relevant to our project. A case that could occur in the context of our project is the following:

> **Example case:** A physician uses a software product for monitoring and decision support in the treatment of one of their patients. Subsequently, a drug is administered incorrectly, which leads to a serious deterioration of the patient's health. In the course of the question of liability, however, the attending physician refers to the software, in particular to the visualization, in which information was presented ambivalently, and the treatment error came about as a result.

On the one hand, the general legal conditions in connection with liability and warranty for software apply here, which in themselves already form a complex subject area. On the other hand, the legal area of physicians' liability is also relevant, which is also enormous in scope. Finally, one still faces the challenge of combining these areas. In addition, MDR also plays a role here. And if all this were not enough, it would actually also be necessary to examine and compare the respective national legislations in line with our research question.
We are, of course, aware that the example we have chosen lacks a great deal of additional information that would be necessary to draw concrete legal conclusions from it. However, this is not our aim; the example is merely intended to serve as a point of reference for illuminating the various aspects of this situation.

[420] https://www.wien.gv.at/spezial/ehealth-strategie/ziele-und-handlungsfelder-der-ehealth-strategie-der-stadt-wien/diga-und-dipa-app-auf-rezept-digitaler-gesundheitspfad/ last visited 2023-09-15
[421] https://www.medinside.ch/gesundheits-apps-auf-rezept-bislang-ein-flop-20230106 last visited 2023-09-15; https://www.penso.ch/rubriken/digital/app-auf-rezept/ last visited 2023-09-15

7.4.1 Liability for Software

Now, we outline the basics of software liability. First of all, it must be said that a certain degree of legal uncertainty is inherent in software law problems. Due to the enormous dynamics, scalability, and fast-moving nature of software, the legislator simply cannot cover all eventualities here and must deliberately keep things very general.[422] In principle, liability for software deficiencies can be divided into contractual and non-contractual liability.[423] Especially in the case of non-contractual liability, there are hardly any special provisions defined for software within the applicable product liability laws of the respective countries. In Austrian law, for example, due to the media neutrality of the law, applicable regulations are not tailored to the requirements of modern information and communication technologies.[424] This is already evident in definitions of terms; for example, software is only subject to product liability law if it is part of a movable object, i.e., embedded in a physical object. This is also the case in Germany and Switzerland.[425] When looking at the foundations, one can already see that one encounters some problems when looking at legal texts only. Nevertheless, there is a great variety of specialized literature available that can be used as a guide.
The following section is largely based on Chapter 3.7. in "Handbuch Softwarerecht".[426]

Legal Nature of Software

One property inherent in software is the fact that, above a certain size and complexity, errors are (almost) unavoidable and therefore, error-free software cannot even be expected. German case law, for example, also recognizes this fact. Nevertheless, the mantra "software is not error-free", often repeated by manufacturers, cannot be used to evade any responsibility. Established measures such as extensive software tests, quality assurance, or code guidelines ensure that a certain degree of freedom from errors can be expected in principle. In the event of a legal dispute, however, an expert must almost always be consulted to assess the individual case in question, and even expert opinions must be critically evaluated due to their complexity.[427]
In principle, the manufacturer is liable for objectively required properties of software. What these properties are, however, again depends on the individual case and the circumstances. Usually, these include compliance with current security and data protection standards (according to the GDPR), proper functioning of the contractually agreed features of the software, and often a quality standard based on the international standards provided for this purpose.[428]
Another important term in this context is the "state of the art". This is particularly relevant where no concrete quality standards have been agreed since it is then used as a basis for assessing liability issues. This term is also relatively undefined in legal terms and must be evaluated dynamically for each individual case.[429]

[422] Tretzmüller 2023, p. 194
[423] Düwert 2010, p. 73
[424] Zankl 2021, p. 82
[425] Sury 2021, p127; PHG-AT §4; ProdHaftG-DE §2
[426] Tretzmüller 2023, p. 194ff
[427] Tretzmüller 2023, p. 194ff
[428] Tretzmüller 2023, p. 197f; cf. section 6.3 UI Design in a Medical Environment
[429] Tretzmüller 2023, p. 199f

Software Deficiencies

We continue with the question of how a deficiency is actually to be defined. First of all, it should be said that the technical definition is not necessarily the same as the legal definition of a deficiency. Not every bug qualifies as a deficiency in legal terms. As a general rule, software deficiencies are only legally relevant if they impair the use of the software.[430] Beyond that, one encounters, particularly in German-speaking countries, the problem that the software-technically relevant terms "error", "fault", and "failure" can all be translated with "Fehler". However, in order to focus primarily on the legal aspect here, we will use the term software deficiency, or “Mangel” in national legislation.

Typical software deficiencies can be divided into the following categories:[431]

- Functional Deficiencies (The lack of necessary or agreed upon functions or features, or a discrepancy between the expected and the actual result of a software solution)
- Lack of interoperability
- Low operating speed
- Security gaps
- Insufficient documentation
- Legal deficiencies (e.g. unauthorized use of third-party software parts integrated into the own software product without the owner's consent)
- Deficient usability

Especially the last point - deficient usability - is relevant for our example. This deficiency is more difficult to determine than, for example, the mere absence of an agreed function, but it can certainly have consequences under liability law. Such a deficiency exists if it is not possible for the user to perform a function properly due to a lack of clarity of the user interface or a lack of support possibilities. This also includes the absence of help menus, no corresponding messages in the event of an error, the absence of a user manual, or, especially in the case of more complex user software, inadequate or no offered training possibilities. Although the user is, generally speaking, not free from responsibility regarding operating errors, poor protection against operating errors (or, in our specific case, interpretation errors) can also be a reason for the manufacturer’s liability.[432] (cf. section 6.1.5 Error Handling; It is clear here that design guidelines are not only relevant from a software engineering point of view but can also have legal implications). This point is particularly important for software that represents complex data and whose use can have far-reaching consequences.
Another point worth mentioning in connection with deficiencies is that in most legal disputes in this area, the central question is whether software is actually deficient. If this is the case, warranty claims come into effect regardless of the manufacturer’s fault. For any liability claims for damages, the manufacturer's culpability for the deficiency must also be proven.[433]

[430] Tretzmüller 2023, p. 196
[431] Tretzmüller 2023, p. 200ff
[432] Tretzmüller 2023, p. 203f
[433] Tretzmüller 2023, p. 195

Limitation of Contractual Liability

We have already mentioned contractual and non-contractual liability before. Now, a few words on contractual liability. An important role in the drafting of contracts in connection with software deficiencies is the limitation of liability. It is generally accepted that a limitation of liability or even an exclusion of liability can be agreed upon in the case of damage caused by slight negligence, at least in the case of mutually business-related transactions. Another case where transactions go beyond being mutually business-related (because there is a patient involved) will be discussed later.[434]
The amount of liability can also be limited and is usually based on the amount of the liability insurance provided for it. However, it is important to carefully examine not only the contract between the manufacturer and the buyer from this point of view but also that between the manufacturer and the insurer.
It is also important to note that obligations arising from general product liability cannot be waived.[435] Furthermore, there is also a so-called immorality corrective, on the basis of which liability limitations can nevertheless be declared null and void in individual cases. The probability of this is higher, the lower the liability limitation is.[436]

Further Obligations of the Individual Parties

There are further obligations of the individual parties, the (non-)compliance of which may be of significance regarding liability issues. The manufacturer, for example, is subject to a product monitoring obligation. This means that products must continue to be monitored after they have been placed on the market, and appropriate action must be taken if a risk is identified. This is usually done, for example, by providing updates or additional training. In addition, a manufacturer may also have to recall its product due to safety risks. In general, the greater the potential for damage, the greater the weighting given to product monitoring.[437]
On the other hand, the user also has certain duties to cooperate. Thus, in the case of liability issues, it must also be evaluated whether there is contributory negligence on the part of the user. The user does not have to have acted unlawfully; carelessness with regard to the user's own goods is sufficient.[438] The user must, therefore, act conscientiously according to his own abilities. This is particularly relevant in our example since the user of the software (a doctor) must have the appropriate expertise or can be expected to act in a particularly responsible manner.
It can, therefore, be seen how many facets of general liability issues in the software area are involved and that these usually have to be considered for each individual case. This becomes even more complex for our example, which we will show in the following.

7.4.2 Medical Liability in the Context of Digital Health

To tie in with the user's duty to cooperate, it should be mentioned that our example is a special case. The user is a medical professional from whom certain knowledge and special care can be assumed. In addition, other laws regarding medical liability and medical malpractice apply here. It must, therefore, be evaluated not only whether there is a

[434] See section 7.4.2 Medical Liability in the Context of Digital Health
[435] Sury 2021, p. 129; PHG-AT §9; ProdHaftG-DE §14
[436] Tretzmüller 2023, p. 207f
[437] Tretzmüller 2023, p. 205f
[438] Tretzmüller 2023, p. 209f

deficiency in the software in question but also whether and to what extent this deficiency was then decisive for the damage to the patient treated. The situation is further complicated by the fact that there is usually a contract between the software manufacturer and the user but not between the manufacturer and the damaged person (patient).[439] It can therefore be seen that aspects of liability law depend on many different parameters here: The type of deficiency, the type of damage, contractual and non-contractual liability provisions between the involved parties (manufacturer, physician, possibly hospital, i.e., software operator, patient), medical law provisions, as well as national legislations of the respective countries. At this point, we would like to refer to a paper by Düwert, which deals with the liability law aspects of EHRs in Austria and Germany and tries to classify this complex issue legally.[440] While the work is no longer quite up to date, as some of the laws cited have since been amended, the legal context is still relevant, in part because one of his case studies is very similar to ours.[441] This work also shows the enormous scope of the topic; after all, it is a dissertation for obtaining an academic doctorate degree in law. This also means that a more detailed treatment, especially with regard to the liability of physicians, would go beyond the scope of this paper.
Furthermore, we would like to quote here a paragraph from the paper "Medical Malpractice Liability in the Age of Electronic Health Records",[442] which, we think, summarizes our problem very appropriately:

> *It is also unknown how the law may evolve to allocate liability fairly among individual clinicians, EHR developers, and provider organizations that select and implement EHR systems. Liability that arises primarily because of poorly designed EHR systems arguably should rest with those in control of system architecture and implementation, not end users. However, in many cases, suboptimal design may set the stage for user errors, complicating the assignment of fault. In addition, some contracts between provider organizations and EHR developers reportedly include provisions protecting the developer from liability arising from the use of the EHR system.*[443]

Furthermore, Nittari et al. also claim in their literature review about current legal challenges of telemedical practice that physicians' malpractice and liability are fields where there is a lot of ambiguity and a general lack of comprehensive insight regarding legal issues. There is also no consensus on whether telemedical practice introduces a new form of malpractice or not.[444] In this respect, we will leave it at this brief outline.

7.4.3 Liability in the MDR

Now, we take another look at the MDR and examine which legal specifications can be found with regard to liability issues. The first central term is that of "device deficiency".[445] The MDR defines this term very broadly. What is striking, however, is that this definition refers to "investigational devices". In all places where this term is used, it is in the context of clinical

[439] Düwert 2010, p. 73
[440] Düwert 2010
[441] Düwert 2010, p. 71
[442] Mangalmurti et al. 2010
[443] Mangalmurti et al. 2010, p. 2065
[444] Nittari et al. 2020, p. 1435
[445] MDR Art. 2, Nr. 59

investigations and not, as was the case in our previous elaboration regarding software deficiencies,[446] in the context of liability issues.[447]
Another important term in this regard is that of "incident", which means "*[..] any malfunction or deterioration in the characteristics or performance of a device*".[448] This concerns devices that are already available on the market. When looking at the numerous occurrences of the term, it is noteworthy that the MDR is primarily concerned with regulations regarding the reporting of such incidents, the actions that need to be taken in order to correct them as efficiently as possible, the measurements for avoiding these incidents in the future, as well as regulations concerning product recalls and withdrawals.[449]
Furthermore, all different stakeholders are being encouraged or obligated to take certain actions regarding incident reporting. Manufacturers, importers, as well as distributors[450] need to comply with incident reporting obligations. Additionally, member states should take measures to encourage medical professionals and even patients to participate in incident reporting regarding medical devices.[451]
Regarding compensation for damages caused by defective devices, the MDR refers nonspecifically to "*[..] applicable Union and national law*"[452] and additionally points out that manufacturers are obliged to take appropriate measures in order to be able to financially compensate for potentially incurred damages.[453]
From our point of view, the MDR is primarily concerned with how to eliminate risks and deficiencies in the first place, how to implement comprehensive error-reporting measures, and how to correct occurring incidents as fast as possible. So the main question of the MDR is "How to minimize risks for damages caused by a medical device before a patient even touches it?" and not so much "Who's fault is it, and who should pay?". In our opinion, this is very appropriate, since it is, in any case, questionable to what extent physical damage can be compensated by monetary means. But we will go into this again in section 7.6 Remark on the Ethical Nature of our Research Question.

7.4.4 Conclusion regarding Liability Issues

In general, it can be said that in the area of software liability, due to the high complexity, it is advisable for all parties involved to try to avoid court proceedings. (Tretzmüller 2023, p195) If the area of tension between software liability and medical liability is added to this, this advice should be followed all the more. A closer look at the MDR also makes this implicitly clear, since this law places enormous hurdles in the way of manufacturers of medical software until their product may be brought to market. This is necessary, however, in order to avoid damage to patients and, subsequently, associated legal disputes as far as possible. Of course, a possible legal dispute cannot be completely ruled out, but the MDR even stipulates that appropriate measures (e.g., contracts, and insurance policies) must be taken to prepare for this eventuality.

[446] Cf. section 7.4.1 Liability for Software - Software Deficiencies
[447] MDR Rec. 46, 69, 79; Art. 73 Nr. 1(e); Art. 80 Nr. 1(c), 2(b), 4; Art 81 (e),(f); Art. 120 Nr. 11.; Annex XV Chapter II, Nr. 3.14; Annex XV Chapter III, Nr. 7
[448] MDR Art. 2, Nr. 64
[449] MDR Chapter VII, Section 2 - Vigilance
[450] MDR Art. 10, 13, 14
[451] MDR Rec. 76
[452] MDR Art. 10, Nr. 16
[453] MDR Rec. 31

To come back to our example: Since the software clearly falls under the MDR, as it is a product for medical decision support, it can be assumed that gross errors in the graphical user interface should have already been discovered in the course of the mandatory clinical evaluation. Also, due to the extensive documentation requirements and quality standards to be met, it will probably be difficult to accuse the manufacturer of gross negligence if the product in question has already been launched on the market in compliance with the MDR. Nevertheless, we want to emphasize again the importance of appropriate (insurance) measurements for such cases.

Additional Remark

As the attentive reader may have noticed, various terms have been referenced in this section when including scientific sources to support our arguments, such as EHR systems, telemedicine, decision support tools, or digital health systems. At this point, we would like to point out that this was done deliberately, and in all cases, we also paid close attention to ensuring that what was said in the sources also applied to our specific case.

7.5 Legal Protection of GUIs

Now we deal with the question of the possibilities to legally protect software in general and innovative data visualizations and GUI designs in particular. Koukal divides the legal protection of GUIs into two main parts, namely, the legal regulations for copyright protection and those for the protection of community designs. Each of them has advantages and disadvantages, and they can also overlap. Therefore, "*The optimal form of legal protection may then depend on the combination and overlap of the specific systems of protection.*"[454] This, in turn, depends on the individual case.

7.5.1 Protection by Copyright

First of all, it should be said that the differences between the Austrian, German, and Swiss legal norms in the area of copyright are limited to details since all three countries largely follow the EU Directive on the legal protection of computer programs,[455] intended for this purpose.[456] These details concern, for example, the individual rights of the author in the creation of a work during an employment relationship[457] or also definitions of legal-theoretical nature. While in Switzerland, copyright law is part of intellectual property law, and therefore, software is not considered a legal object ("Sache"),[458] in Austria, for example, copyright is not considered an intellectual property right ("Immaterialgüterrecht")[459] and there is a lively debate about the extent to which software qualifies as a legal object, especially since there is an additional distinction between corporeal and incorporeal objects.[460] However, as in the search for a definition of the concept of data,[461] we can, in good conscience, resign

[454] Koukal 2018, p. 155
[455] CPPD
[456] Niedermayer 2014, p. 44
[457] Niedermayer 2014, p. 44
[458] Sury 2021, p. 166
[459] Zankl 2021, p. 188
[460] Tretzmüller 2023, p. 1f
[461] cf. section 5.1.2 Terminology

ourselves to the lack of an explicit legal definition of software and instead turn back to our concrete question.
In general, it can be said that the source code is particularly relevant in copyright issues relating to software. It is automatically protected upon creation, provided that it meets certain criteria of individuality and novelty (whereas the interpretation of these terms can indeed lead to disputes). Thus, no entry in a patent register or the like is required. Copyright law thus treats the source code like a piece of literature.[462]
The fact that the source code is central in the assessment of copyright thus leaves the question of copyright protection of data visualization within a GUI open for the time being. In our previous attempt at a definition,[463] the contextual approach to GUIs in this regard was already pointed out. While the CJEU has denied copyright protection to interfaces (including GUIs) as computer programs, the software implementing the interfaces may indeed be protected by copyright law.[464]
In this respect, surprisingly, a legal case in one of the EU states, namely the Czech Republic, and the associated court decision of the CJEU are significant. In this case, which was actually about whether the collective management of computer programs is reasonable and effective and, subsequently, whether the television broadcasting of a GUI is covered by copyright law, the general legal situation regarding GUIs first had to be clarified. Although the CJEU decision about the original question was controversially received and discussed, interesting points can be identified for our question.[465] Again, the decision was that GUIs are not protected by copyright as computer programs, but nevertheless, it came out that GUIs "*[..] could be protected by copyright under the Information Society Directive 2001/29 if the interface is the author's own intellectual creation and also that a national court may need to consider the specific arrangement or configuration of all the components which form part of the interface, in order to determine which meet the criterion of originality.*"[466]

7.5.2 Community Design Protection

Besides copyright, however, there is another way to legally protect GUIs, namely by the protection of community designs. At the EU level, the Regulation on Community Designs (CDR[467]) applies here, which distinguishes between unregistered and registered community designs.[468] This is therefore applicable in Austria and Germany, but Swiss law does not recognize unregistered community designs. For registered community designs, however, Switzerland largely follows EU law.[469]
A design is constituted as "*[..] the appearance of the whole or a part of a product resulting from the features of, in particular, the lines, contours, colours, shape, texture and/or materials of the product itself and/or its ornamentation;*"[470] In classifying whether a design is worthy of protection in this regard, the concepts of novelty and individual character are

[462] Tretzmüller 2023, p. 6f
[463] See section 7.1 Visualization in a Legal Sense - An Attempt at Definition
[464] Tretzmüller 2023, p. 10
[465] Koukal 2016; Also consult this paper or further information regarding this case and an in-depth legal discussion
[466] Neophytou 2011, p. 437
[467] CDR
[468] CDR Art. 1
[469] Carani 2022, p. 566
[470] CDR Art. 3(a)

central, which were already important in copyright law.[471] It is interesting to mention that computer programs are explicitly excluded by the CDR, but GUIs as output results of computer programs can very well be considered designs in the sense of CDR.[472]
Similar to copyright, protection for unregistered community designs automatically applies from the time of publication, provided it meets the required criteria and a similar design has not previously existed. However, in contrast to copyright law, this then only applies for the next three years from the time of publication.[473]
Registered community designs are, as the name suggests, subject to registration with the relevant authority. This is done on a national level at the respective institutions designated for this purpose, for EU-wide registrations at the European Union Intellectual Property Office (EUIPO) or, in the case of international registrations at the World Intellectual Property Organization (WIPO).[474] While the effort here is greater, extended and prolonged protection (up to 25 years) can be obtained in this way.[475]

7.5.3 Our Opinion

When looking at the possible outcomes of our project regarding novel solutions for data visualization within GUIs, we don't see a lot of danger regarding copyright infringements and the need for a lot of additional measures to legally protect these solutions. The reasons for that are the following: first of all, such complex solutions can't really be logically separated from the underlying data, algorithms, and other parts of the software anyway, so even if there are doubts as to whether the GUI is to be considered as an object in its own right subject to copyright, the underlying parts of the solution are undoubtedly protected by copyright. Secondly, although it is possible to register innovative graphical user interfaces and, at least in the EU, there is Community design protection for unregistered designs as well, the design, or more precisely, the external appearance as well as the recognition value, are most likely not what ultimately makes the product unique.
There are also other laws that may apply, including trademark and patent laws, as well as laws concerning unfair competition,[476] but ultimately, we agree with the conclusion of Barnitzke et al.: It has been shown that GUI-specific protection, going beyond the code protection of a computer program, exists in copyright law only in individual cases with rather marginal implications. In general, however, it would be difficult to justify protecting only a graphical user interface but not the software in its entirety. Furthermore, extending protection to the functionality of screen interfaces would be particularly inhibiting to innovation and ultimately to investment in the software market. Also, mere code protection has proven sufficient in recent years. Finally, it should not be forgotten that a certain degree of standardization (through imitation) in the design of user interfaces themselves ensures greater user-friendliness because users simply expect certain functions at certain positions on the screen,[477] as we have already discussed in section 6.1.2 Strive for Consistency

[471] CDR Art. 4; Carani 2022, p. 566
[472] Barnitzke et al. 2011, p. 281
[473] Kapeller-Hirsch 2021
[474] https://www.dpma.de/english/designs/abroad/index.html last visited 2023-10-02
[475] CDR Art. 12
[476] Barnitzke et al. 2011, p. 281f
[477] Barnitzke et al. 2011, p. 283f

7.6 Remark on the Ethical Nature of our Research Question

During our research work, we repeatedly encountered ethical topics at various points. This is not surprising, as the connection between ethics and law, as well as ethics and medicine, is self-explanatory. It inevitably follows that medical software must deal with not only legal but also ethical issues. Already, when examining the GDPR, one can see that the law is repeatedly oriented towards ethical principles, for example, in the case of fairness or broad consent.[478] Ethical considerations should also be taken into account when looking at the digital extension of a doctor-patient relationship,[479] or when considering software design for applications in this area.[480] But also in MDR, this is clearly shown. For example, the convening of an ethics committee is mandatory in the context of the clinical evaluation of a medical device.[481] However, since this topic is not within the focus of our work, we would like to refer to a contribution by Jumelle and Ispas, who deal extensively with the ethical issues of digital health.[482]

7.7 Results

Building on the first part of our legal examination, in which we looked at the legal framework of data processing, we have now looked in the second part at the specific legal issues of data visualization in the context of our project. We again stuck to our research framework as we tried to assemble relevant facts, identify legal issues, analyze them, and examine primary as well as background material, and now we are synthesizing the issues in context, providing our own justified opinions, and coming to a conclusion. Furthermore, we included the perspectives of the respective national legislations and their Relationship to EU law.
To sum up the most important findings of this chapter:

The Central Role of the MDR: Depending on the type of application that is developed and subsequently whether it is classified as a medical device, the MDR plays a central role when it comes to the requirements that are put on the development and operation of such an application. Concerning data visualization methods within a GUI, the following specific requirements are to be considered:

- Language: All information needs to be provided in all official languages of the respective countries, therefore at least in German, French, Italian, and also preferably in English.
- Encouragement for developing self-explanatory GUIs: Since there are also high demands placed on the documentation of many different aspects of software, the MDR actually encourages to develop GUIs as self-explanatory as possible since that can partly cover those requirements.

[478] See section 5.2.1 Processing of personal data
[479] See section 7.3 Legal Aspects concerning the Digitalization of the Patient-Doctor Relationship
[480] See section 6.7.1 Empathy-driven Design
[481] MDR Art. 62
[482] Jumelle and Ispas 2015

- Awareness of UDI requirements: If a GUI design changes due to an update, this can mean that some part of a UDI (Unique Device Identifier) needs to be changed as well. Developers and designers need to be aware of that fact.
- Taking into account different screens and environments: The MDR also requires the developers to take into account the environment in which the respective applications are being used. This applies to screen sizes as well as different lighting.
- User Centricity: The MDR generally requires a user-centered, especially a patient-centered approach when developing medical devices.

The Right Amount of Information: Not only from a GUI design perspective, it is a very relevant question, how much information should be provided to the user. In this chapter, we have seen that it can also be of relevance from legal and ethical perspectives.

GUI Design and Liability: It is also important to point out that the GUI design can actually have a legal impact on liability issues. Poor design choices or ambiguously interpretable data visualization can indeed be classified as a product deficiency from a legal perspective. However, the MDR already provides for appropriate measures to be taken for such cases, such as arranging appropriate insurance.

Legal Protection of GUIs: While there are specific cases where GUIs can be legally protected separately from the rest of the software, additional measures most likely won't be necessary in our specific case since the software itself is automatically protected by copyright law and when developing innovative visualization solutions for complex data, the GUI and the underlying programs are usually not really be separable in a way that could make the whole project be vulnerable to be easily reproducible.

Finally, we again want to emphasize the way we understood and interpreted the respective law, especially the MDR. At first glance, it seems like a lot of barriers and stones are in the way for companies who want to develop and publish software solutions for medical purposes. While this may seem tedious from a developer's perspective, it clearly puts the patient into focus, which is a good thing, in our opinion. As we already said at the very beginning, ultimately, it is primarily the patient who should benefit from the new solution.
In Chapter 9 - Conclusion, we will synthesize all of our findings from the various chapters and put them into a proper overall context in order to answer our research questions appropriately.

Chapter 8 - Field Analysis

In this chapter, we leave the realm of scientific literature analysis and investigate which software solutions already exist for merging and visualizing medical treatment pathways together with patient data in the context of treating a hemato-oncological disease, how they address the previously identified problems and issues and which interesting techniques they implement, which we can, in turn, integrate into answering our own research question. An explanation of the methodology used can be found in section 4.2 Field Analysis Methodology.

8.1 Identification of Relevant Software Solutions

First, it is necessary to investigate the commercial landscape, search for existing software solutions, and determine whether they are relevant to our research question. In addition to our own search process, we also received help from Treetop Medical since they obviously already had an overview of similar solutions, i.e., about potential competitors as well as potential cooperative partners and other stakeholders in their market segment.
After reconciling our own results with those of Treetop Medical, we felt it made sense to divide the identified solutions into two categories. On the one hand, there are integrative solutions that, like Treetop Medical, involve different user groups and allow them to interact with each other. On the other hand, there are also mobile apps that are intended for patients and are designed to support treatment. While the first category is more relevant for us from a higher-level perspective, the second category could also give us interesting insights into the basic principles of GUI design in practice, as freely available apps are easier to investigate in this regard. At least, that was our initial idea. Nevertheless, it turned out that the analysis of such apps is not particularly useful for our research purpose. In section 8.1.2 Mobile Applications for Patients, we will explain why this is the case. So, instead, we focus on the analysis of integrative solutions.
An important note is that the list of software providers we are looking at is not exhaustive. Instead, the aim is to analyze some important solutions in order to gain additional insights for our research question. It is quite possible that other providers exist that are potentially relevant, but the question arises as to how important they really are for a field analysis if neither we nor Treetop have been able to identify them.

8.1.1 Integrative Solutions

We included the following 13 providers of integrative software solutions in our analysis:

Provider	**Product Description (from Website)**
Remecare	"*Remecare Oncology is care pathway management and remote monitoring software that helps oncology teams better understand the patient experience beyond the hospital walls and use reported data to further improve care decisions.*"[483]
Amadeus by Orion Health	"*Amadeus Care Pathways provides the clinical, administration and*

[483] https://www.remecare.eu/oncology, last visited 2023-11-08

	patient-focused tools that are required to manage and optimise the care of patients. The scope of possible solutions ranges from simple, local clinical workflows to the management of chronic care patients being treated across multiple providers. Care Pathways can manage patients as part of basic clinical workflows through to chronic condition patients with complex care requirements."[484]
ZEDOC by The Clinician	"*Digital care pathways transform inefficient and fragmented processes into streamlined, patient-centric and cost-efficient healthcare journeys.* *Enabling remote digital interactions with patients in the comfort and privacy of their own homes, digital care pathways allow care teams to capture the right health data at the right time, while also engaging patients through the delivery of messages and rich media content.* *As one of the industry's most sophisticated and flexible platforms for developing digital care pathways, ZEDOC helps healthcare providers to merge their physical processes with digital encounters that improve outcomes and convenience for patients while lowering costs.*"[485]
Qpathways by TriarQ	"*Pathways Care Management Platform:* *Advanced care management platform and patient engagement technology to provide better quality care - A unique combination of instant communication, data management, and clinical and financial reporting tools. [..] Automated Care Plans: [..]* *Activate specific, evidence-based Care Plans based on assessments and test results. Each step is automatically scheduled into the patient's overall care plan, including convenient alerts to help the designated Care Managers keep the patient's care on track.*"[486]
Graphnet Health	"*CareCentric pathways solutions have been designed to support pathways of care and workflow management across multi-disciplinary teams and care settings, as well as supporting clinical correspondence if required. Used as part of the CareCentric solution as a whole, the system supports clinicians and care professionals in their decision making by giving them access to a wealth of integrated care data, presented in meaningful views applicable to their role, complemented by an easy and intuitive e-form capability, which allows for true multi-disciplinary working in real-time. CareCentric's solutions also help support virtual care pathways or remote patient care pathways by providing a system for secure clinical communications and integrating healthcare data from various teams, wearables, and the patients themselves.*"[487]
MedTronic	"*Care Pathway Innovations:* *Helping you build robust, resilient care pathways that accelerate patient access to evidence-based care, reduce variability, minimize length of stay, and support patients as they return home.* *A comprehensive solution for an array of disease states and procedures:*

[484] https://orionhealth.com/global/product/care-pathways, last visited 2023-11-08
[485] https://theclinician.com/digital-care-pathways, last visited 2023-11-08
[486] https://triarqhealth.com/value-services/qpathways-technology/, last visited 2023-11-08
[487] https://www.graphnethealth.com/solutions/care-modules/integrated-care-support-plans/, last visited 2023-11-08

	We work directly with your leaders and care teams to assess challenges and needs along the care pathway and design, prioritize and implement sustainable solutions for equitable and patient-centric care"[488]
Civica	"*Providing comprehensive, real-time information to support clinical decision making and patient care. Civica Clinical Pathways (formerly InfoFlex) combines data recorded via clinical solutions or patient portals with information from existing hospital systems.* *Designed to meet clinical needs by reflecting patient care pathways, Civica Clinical Pathways supports over 65 clinical specialties throughout the healthcare community.*"[489]
Decisios	"*Clinical Pathway Management:* *Patient journey management and tracking system.* *Decisios is a workflow modelling software for including patients in "Clinical Routes".* *These clinical pathways are defined by the user within the framework of an analysis of standardised patient treatments and analysed in advance in order to determine the precise stages of such a clinical pathway, or care pathway.*"[490]
medicalvalues	"*Diagnostic Pathway Management and Data Enrichment* *Gain a deep understanding of your diagnostic data sets and enrich them for higher quality diagnostic algorithms* *[..]* *Diagnostic Pathway optimization* *Leverage historic, clinical datasets to uncover areas for improvement in diagnostic procedures. Discover medical sub-groups and explore risk factors. Combine medical and economical datasets for optimal healthcare outcomes and efficient diagnostic pathway management.*"[491]
Lumeon	"*Lumeon's care orchestration platform automates the tasks, workflow, activities, and events that overburden care teams today. With real-time, bi-directional data/system integration and the dynamic application of clinical intelligence and automation, Lumeon helps care teams deliver on their potential and ensure that every patient is getting the care they need.*"[492]
Philips	"*Evidence-based oncology pathways:* *Empowering oncologists in their treatment decision journeys.* *Driving healthcare technology through Philips Oncology Pathways powered by Dana-Farber, physicians are empowered to provide personalized and scientifically advanced cancer care for their patients*

[488] https://www.medtronic.com/ca-en/e/ihs/integrated-health-solutions/accelerating-care-pathways.html, last visited 2023-11-08

[489] https://www.civica.com/en-gb/product-pages/clinical-pathways-software/, last visited 2023-11-08

[490] https://www.decisios.be/index-en.html, last visited 2023-11-08

[491] https://medicalvalues.de/diagnostic-pathway-management-and-data-enrichment/, last visited 2023-11-08

[492] https://lumeon.com/the-care-orchestration-platform/, last visited 2023-11-08

	through a standardized and automated process."[493]
Nano Health Suite	"*Regularize care for whole population cohorts while fostering a personalized strategy to personal patient care.* *NANO Health Care Pathways enables predictable and optimized workflows to sustain the management and track the delivery of care programs.[..]* *Care Pathways endows considerable task demands, from easy risk assessments to highly urbane predictive workflows that pursue individual patients via their care programs.*"[494]
PathMD by Bioconnetix	"PathMD f*or connected care across disciplines and healthcare systems.* *Manage care consistently and efficiently through connected delivery.* *Collaborate across disciplines with ease and the assurance that data and health records auto-populate into existing provider systems.* *Reduce patient risk through remote utilization review and analytic medicine support.* *Lower the cost of care through thoughtful shared standards.* *Pilot, optimize, and scale new clinical pathways with affordable customization and real-time outcomes reporting.*"[495]

(Table 8.1: Overview of the identified software providers and the descriptions of their products)

8.1.2 Mobile Applications for Patients

During our research process, we encountered a very useful contribution by Narrillos-Moraza et al., conducting a systematic review of mobile apps for hematological conditions.[496] They identified 2100 apps, 88 of which met their inclusion criteria. They categorized the apps as either informative, preventive, or diagnostic. According to their description, only apps categorized as preventive are interesting to us, as they include the tracking of laboratory values. Nevertheless, only 23 apps have been categorized this way. Furthermore, they included a systematic rating for the investigated apps (Mobile App Rating Scale - MARS). Of the 23 preventive apps, 20 received a MARS rating over 3.0 (acceptable quality).
We took a closer look at these 20 apps (either by downloading them if possible or by reading descriptions and instruction manuals and investigating provided screenshots in the app stores) and came to the conclusion that with these kinds of apps, there is not as much information gain for our research question as originally thought, as none of them contained sophisticated visualization methods for merging individual patient data with medical treatment pathways.
In our opinion, the reasons for this are that these apps are freely available and intentionally designed so that they cannot be classified as medical devices and are, therefore, not subject to the MDR.[497] However, this, in turn, implies that no connection between doctors and patients, respectively, the exchange of data between them can be established and that these apps are therefore limited to self-monitoring. However, this would be necessary to enable more complex forms of data presentation.

493 https://www.usa.philips.com/healthcare/solutions/diagnostic-informatics/oncology-informatics/pathways, last visited 2023-11-08
494 https://nanohealthsuite.com/our-products/all-products/clinical-pathways, last visited 2023-11-08
495 https://www.bioconnetix.com/pathway-and-data-management, last visited 2023-11-08
496 Narrillos-Moraza et al. 2022
497 See section 7.2.2 EU Medical Devices Regulation (MDR)

As already explained,[498] there are some apps in the German National Directory of Health Care Applications that are indeed classified as medical devices according to the MDR. Nevertheless, there are no apps that are particularly suitable for our analysis either. Therefore, we decided to focus entirely on the analysis of integrative solutions instead.

8.2 Data Collection

To obtain the data required for our analysis, we first checked what information was publicly available on the respective providers' websites. The amount of available information relevant to us varies greatly. On the websites of some providers, screenshots and detailed descriptions of the products offered are available (also, for example, in the form of downloadable product information brochures). For others, however, the information available is very sparse.

In the second step, we tried to contact all providers, both via a contact form on the respective website (if available) and via email. The request included an outline of our research question and whether additional information (e.g., in the form of screenshots, examples, or product demos) could be provided for us. It also included a note that if they had concerns about publication, their actual information could be excluded from our work.

If there was no response to our request, we repeated it several times within a period of 2 months (September 14 to November 14, 2023). Here, too, the responses varied widely. Of the 13 providers, only five responded at all. One of the responses was a generic one, in which our concerns were not addressed after repeated requests. One was a straight-up rejection, and another one agreed to a video call but ultimately rejected our request as well. Two of the requested companies provided us with additional information. These two providers are discussed in more detail in section 8.5 Detailed Study of Selected Analytes. In general, it can be said that the companies we contacted were not particularly interested in providing us with information (with a few exceptions). This is not surprising, as this does not give them any direct advantages, and publishing information involves both work and risks for them. Nevertheless, we obtained some data that we can work with. Table 8.2 shows if and how the different providers responded to our inquiry.

[498] See section 7.3.3 Digitale-Versorgung-Gesetz - DVG-DE

Provider	Response
Remecare	They responded but rejected our request.
Amadeus by Orion Health	No response
ZEDOC by The Clinician	They responded and provided additional data.
Qpathways by TriarQ	No response
Graphnet Health	No response
MedTronic	No response
Civica	They agreed to a video call but ultimately turned down our request
Decisios	Generic response. No response after repeated requests.
medicalvalues	They responded and provided additional data.
Lumeon	No response
Philips	No response
Nano Health Suite	No response
PathMD by Bioconnetix	No response

(Table 8.2: Overview of the analyzed providers and their responses to our data collection request)

8.3 Qualitative Primary Assessment

When we took a closer look at the data collected, the following points caught our eye:

- In general, most providers disclose very little detailed information on their websites, especially when it comes to the design of user interfaces. But even beyond that, although there are many buzzwords such as "improving efficiency of care", "standardization of processes", or "support clinical decision making", there is hardly any insight into exactly what these solutions look like. This is hardly surprising, as these are complex and sometimes customized solutions and most providers are also not interested in disclosing too much information. Nevertheless, this makes our analysis process more difficult.
- As we have already seen in the definition of clinical pathways,[499] this term is used quite inconsistently. As a result, the solutions we analyzed are rather diverse. This diversity can be divided into two dimensions: a horizontal and a vertical dimension.
- The horizontal dimension refers to the different sub-areas or problems in the course of a treatment. Some software solutions concentrate more on data analysis processes, others on care orchestration and management, and still others focus on decision support. Or it is a mixture of all of these.
- The vertical dimension refers to the "granularity" of the respective solution. The highest level includes solutions that represent treatment paths along the respective medical facilities, i.e., pursuing an inter-facility approach. (For example, an initial examination by a general practitioner, followed by a referral to a specialist and then the admission to a hospital). At the lowest level, there are solutions that map a specific process within a treatment, for example, the administration of medication over a certain period of time.
- It is also interesting to note that all the solutions examined fall within the spectrum of these respective dimensions. Therefore, they are not necessarily always to be seen as competing products, as they cover different sub-areas. Ultimately, however, they all represent part of a clinical treatment pathway.
- With regard to legal aspects, we found that some providers make direct reference to compliance with standards or conformity with legal regulations and also advertise this.

When we now turn to the results of our literature review,[500] we have decided to first examine all software solutions with regard to the problem perspectives we have developed and then verify the guidelines we have developed using only selected examples, as this would not be possible for all solutions due to a lack of data.

8.4 Arrangement and Comparison

Our next goal is to create a structured comparison of the solutions we have examined. It should be noted that this is not a comparison in the sense of competition. It is not about showing which solution has the "best" or most features but rather about establishing an overall context, finding common patterns, and gaining an overview of the field. For this

[499] See section 2.3 Terminology - Clinical Pathway
[500] See section 6.8 Results

comparison, we refer to the problem perspectives we developed in Chapter 6 - Data Visualization and GUI Design - Literature Review. If a solution meets more of our predefined criteria, it does not necessarily mean that it is a better or more comprehensive solution, just that it has a different scope. We compare according to the following criteria:

1. User Perspective:
   - 1.1. Does the solution explicitly offer decision support functionalities for clinicians?
   - 1.2. Does the solution offer care management functionalities for additional healthcare stakeholders (i.e., hospital staff, nurses, etc.) along the pathway?
   - 1.3. Does the solution offer a connected mobile application for patients?
2. Data Perspective:
   - 2.1. Is there a possibility to automatically import or use existing pathway data (i.e., from a pathway library?)
   - 2.2. Is there a possibility of visualizing temporal patient data and the change thereof?
3. Domain Perspective:
   - 3.1. Does the provider offer specific solutions for long-term treatment support?
   - 3.2. Does the provider explicitly mention oncology-specific solutions?

Table 8.3 provides an overview of the analyzed providers regarding these criteria.

Provider	1. User Perspective			2. Data Perspective		3. Domain Perspective	
	1.1.	1.2.	1.3.	2.1.	2.2.	3.1.	3.2.
Remecare	Yes	Yes	Yes	No	Yes	Yes	Yes
Amadeus by Orion Health	No	Yes	Yes	No	Yes	Yes	No
ZEDOC by The Clinician	No	Yes	Yes	Yes	Yes	Yes	Yes
Qpathways by TriarQ	No	Yes	?	No	Yes	?	No
Graphnet Health	Yes	Yes	Yes	No	?	Yes	No
MedTronic	No	Yes	?	?	?	No	No
Civica	Yes	No	?	No	Yes	Yes	Yes
Decisios	No	Yes	?	Yes	?	?	No
medicalvalues	Yes	No	No	Yes	Yes	Yes	Yes
Lumeon	Yes	Yes	Yes	No	?	Yes	No
Philips	Yes	Yes	No	?	Yes	Yes	Yes
Nano Health Suite	No	Yes	?	?	?	Yes	No
PathMD by Bioconnetix	Yes	Yes	No	?	?	?	No

(Table 8.3: Comparison of analyzed solutions according to predefined attributes)

First of all, it must be said that this table has only been created on the basis of the information available to us. Especially when a criterion is not met, we have sometimes made this assumption based on the general nature of the solution in question. Therefore, unfortunately, we cannot guarantee the unreserved accuracy of this table. Nevertheless, a few interesting characteristics can be outlined:

- Once again, we can see that a certain heterogeneity is inherent in the solutions examined. No two solutions are completely alike in terms of the criteria we have introduced. This demonstrates the variety of this field of investigation.
- The majority of the solutions examined focus either on decision support or on care management and administration. Only a small number integrate both areas.
- Especially when looking at the data perspective, there is a lack of available information. Since we can only work with publicly available information in almost all cases, it was especially hard for us to evaluate these kinds of criteria.
- Less than half of the examined solutions explicitly mention oncology-specific topics.
- Almost all Solutions include several different healthcare stakeholders and not only doctors and/or patients.

Let us now turn to two examples in particular where more data is available.

8.5 Detailed Study of Selected Analytes

We are now examining the materials that were kindly made available to us. Firstly, the provider "medicalvalues", whose solutions focus on diagnostic pathway management as well as data enrichment and analysis. Secondly, the provider "The Clinician" with its product "ZEDOC", an integrative multi-platform solution, optimizing patient-centric healthcare journeys.

8.5.1 Medicalvalues

"*Diagnostic Pathway Management and Data Enrichment - Gain a deep understanding of your diagnostic data sets and enrich them for higher quality diagnostic algorithms.*"[501] This is the concise product description that you encounter upon visiting the website of the company "medicalvalues". The product pursues a research-driven approach. The aim is to optimize clinical diagnoses based on existing data, especially laboratory test results, and to manage, analyze, and adapt clinical pathways. This software solution is, therefore, very close to our research question, as it attempts to integrate these two types of data precisely. The company kindly provided us with additional information on request,[502] allowing us to address our research question in more detail using this practical example and compare it with the results of our literature analysis.
One thing that is immediately apparent is that this is software for clinical experts. Although it is not unlikely that mobile solutions for patients linked to this software also exist, this is not clear from the information available to us. We are therefore concentrating on a physician-centered user perspective.

[501] https://medicalvalues.de/diagnostic-pathway-management-and-data-enrichment/, last visited 2023-11-08
[502] Medicalvalues 2023

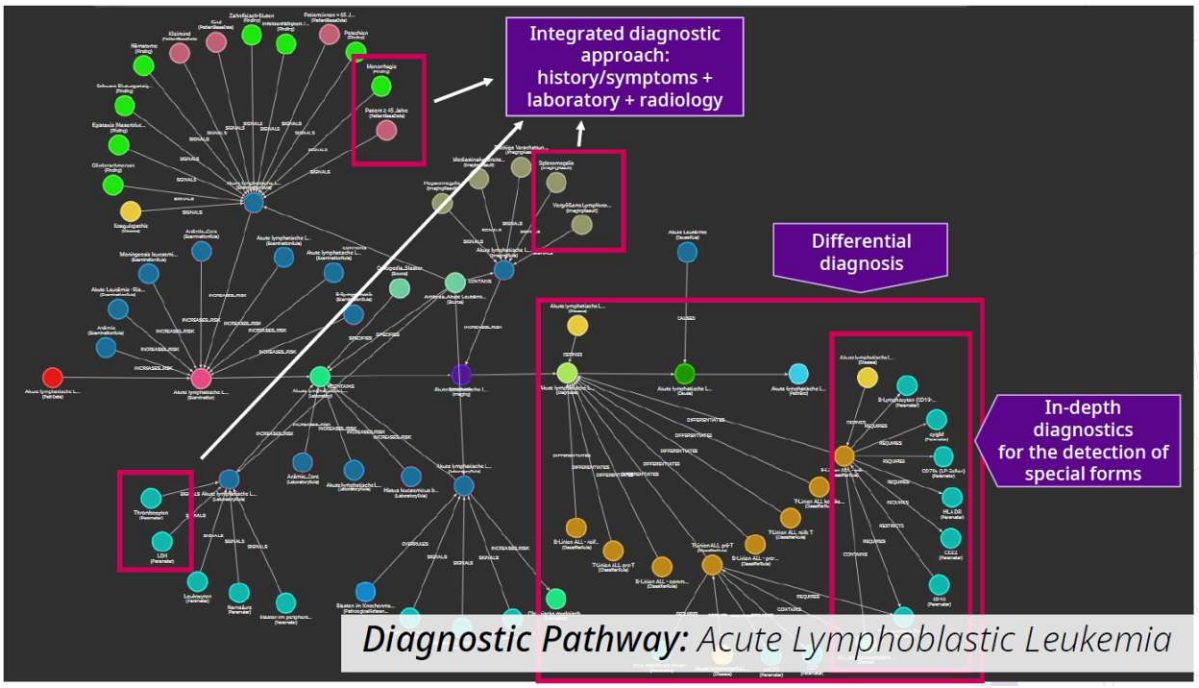
First, we look at the functions available for laboratory test results, then at the presentation of clinical treatment pathways, followed by the integration of the two data sets. In addition, we have also been provided with scientific articles that have been written in connection with this software solution, which we will also briefly discuss. Finally, we try to sum up our findings, and additionally, the question arises as to what we can specifically take away from this analysis for our research question.

Making Use of Laboratory Test Results

Before turning to the actual visual representation of integrated laboratory test result data, it is interesting to point out what can actually be achieved with this software using this data. On the one hand, existing laboratory test results can be used to generate diagnostic recommendations and targeted information for possible next steps. On the other hand, existing diagnosis data can be used by the system to suggest further diagnostic analysis, i.e., conducting additional laboratory tests. This interaction between diagnosis data and laboratory test result data, complementing each other, is an interesting and novel approach.

Turning Pathway Data into Knowledge Graphs

The way in which the clinical pathway data is composed here and how it is then visualized is also insightful. The Pathway data is derived from existing clinical guidelines, real-world data, and expert knowledge. In their approach, they use a knowledge graph to represent this complex agglomeration of data, as can be seen in Figure 8.1.



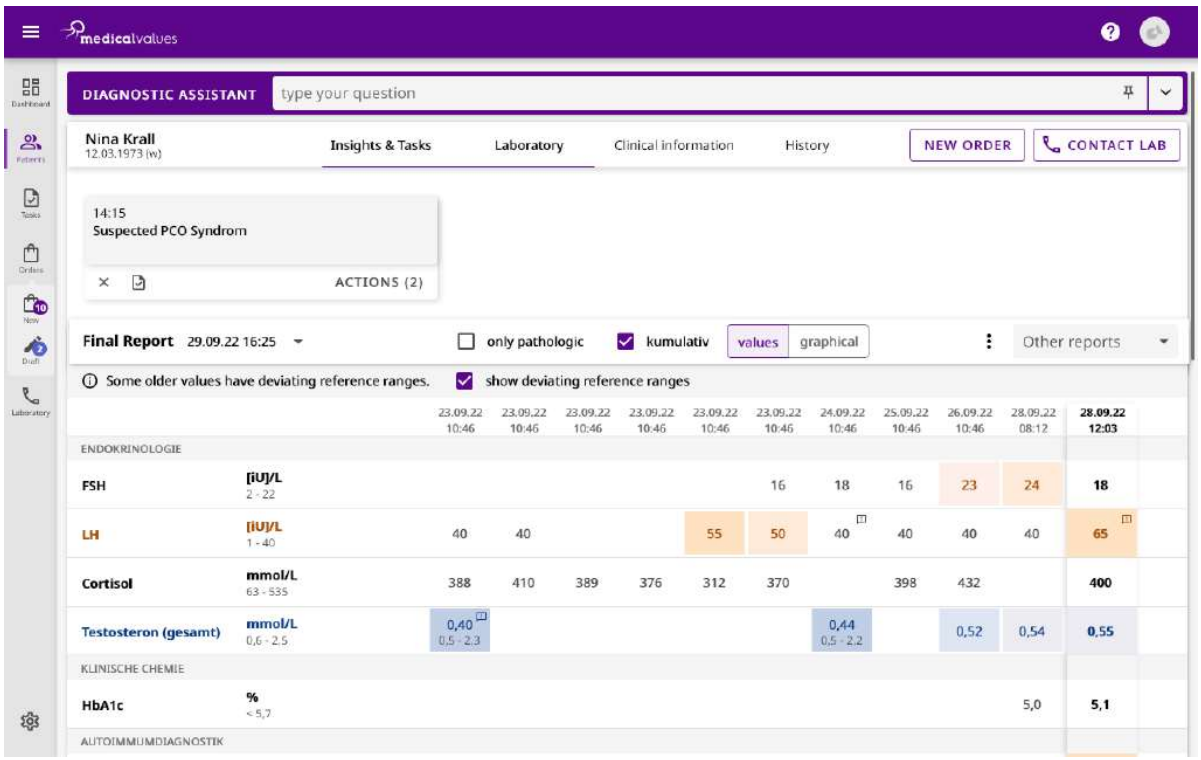
(Figure 8.1: Visualization of clinical pathway data in the form of a knowledge graph by medicalvalues[503])

The example disease (Acute Lymphoblastic Leukemia) depicted here is actually very fitting for our research question. The different colors of the data points represent different types of data, such as diseases, findings, test and imaging results, procedures, and parameters. Also, the data points can be grouped into different sub-areas, and there is also the possibility to link several pathways together with this approach. One thing that becomes immediately apparent is that this kind of view is designed for clinical experts as the focus here lies clearly on the comprehensive depiction of complex interrelationships.

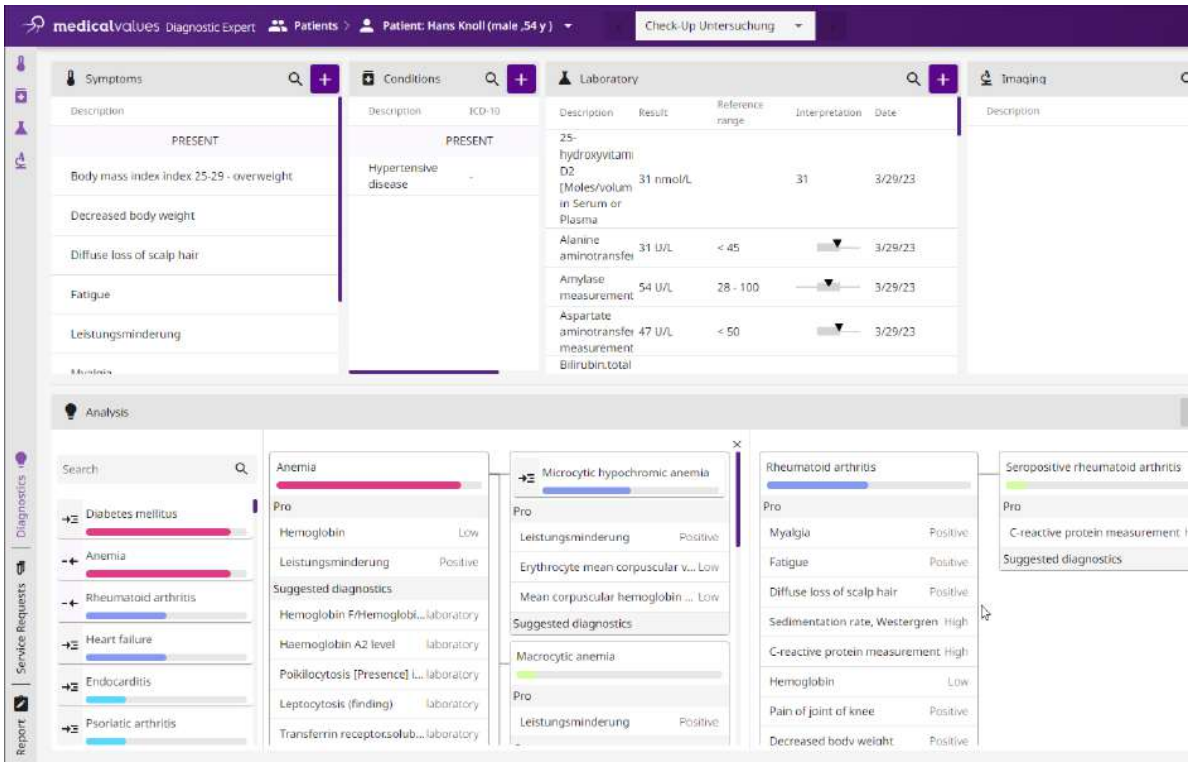
Visual Integration of Patient Data and Pathway Data

The software solution offers various views based on the knowledge graph. In addition to views for diagnostic support and laboratory test suggestions, we are particularly interested in the patient overview and the "expert view" because these depict laboratory test results together with other types of data. Figure 8.2 shows the patient overview perspective, while Figure 8.3 depicts the “expert view” for the display of patient data together with patient individual diagnostic support.

[503] Medicalvalues 2023



(Figure 8.2: Patient overview perspective by medicalvalues[504])



(Figure 8.3: “expert view” perspective by medicalvalues[505])

[504] Medicalvalues 2023
[505] Medicalvalues 2023

If we now analyze these views according to the guidelines we developed from our literature review, we can observe a certain consistency. To bring those back into memory:[506]

- Level of information detail: On the spectrum of the amount of information displayed, this solution clearly tends towards the most complete display possible. The intended user group is clinical experts. Although we have seen that even with this user group, too much information can sometimes be perceived as distracting, in this specific use case, it makes perfect sense to display available information as completely as possible.
- Multi-window view: This point is also clearly visible in the screenshots provided to us. The software offers the option of displaying related data simultaneously in several windows, and there are also options for customizing the screen layout.
- Interactivity: We are hesitant to comment on this point, as we do not have access to actual software and can only refer to an internal document and screenshots. However, based solely on the information available to us, it can be said that a certain degree of interactivity is required for the available functions. For example, the ability to highlight certain data or switch between different views can be derived from the patient overview screenshot.
- Information layering: As we could observe, the solution definitely meets this criterion. Due to the different views, it is possible to display the data in several layers, from overview data to going into more detail further on.
- Color coding: What is interesting to see here is the unexpected use of color coding. When we examined the possibilities for the visualization of laboratory test results (see chapter xy), there was a tendency to use the “classic” traffic light colors - green, yellow/orange, and red. Here, light blue and light orange are used to indicate conspicuous values in the patient overview, and also blue tones and a slightly less striking red in the expert view. This indicates that an attempt is being made here to indicate anomalies without implicitly linking them to a good/bad rating.

Scientific Approach

The product is supported and developed with the help of scientific research. In this regard, we would like to refer to two publications in particular that were produced in relation to this software solution. On the one hand, there is a paper by Berns et al. explaining the development and implementation of AI-based diagnostic assistance, predictions, and detailed suggestions, as well as overall system and pathway optimizations within the software solution of medicalvalues.[507]
On the other hand, there is also a publication by Heilig et al. explaining in great detail how the aforementioned knowledge graphs for medical diagnosis were developed and how they work.[508]
However, a detailed discussion of these papers would go beyond the scope of this work. Therefore, we leave this as a remark for the interested reader.

[506] See section 6.8 Results
[507] Berns et al. 2023, p. 171
[508] Heilig et al. 2022

Takeaways

As a summary, the following are some important and novel aspects of the analyzed software solution that are relevant to our research question:

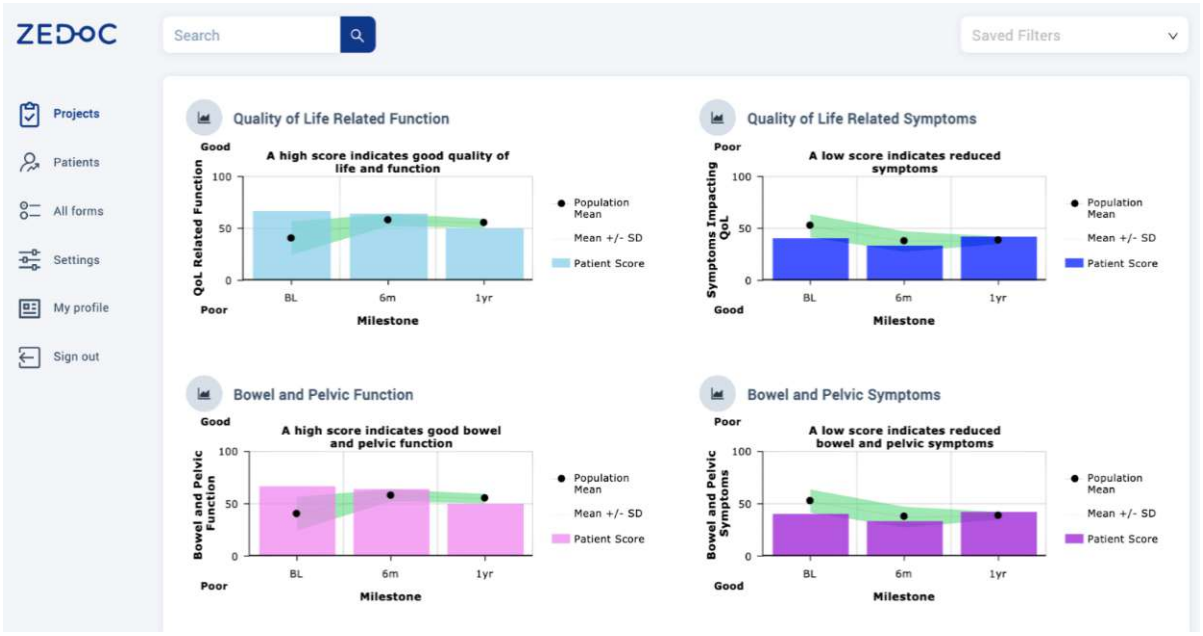
- The novel approach toward the relationship between laboratory test results, clinical treatment pathways, and diagnostic data
- The composition of pathway data based on existing guidelines, real-world data and expert knowledge
- The representation and processing in the form of a knowledge graph
- The different views associated with this knowledge graph
- Interesting aspects regarding the use of color coding

It can also be seen that when visualizing treatment pathways in combination with individual patient data, the focus of the view is either on one or the other type of data, depending on requirements. In other words, the aim is not to display all the data in as much detail as possible at once but instead to make it as intuitive and easy as possible to switch back and forth between the views.

8.5.2 ZEDOC by The Clinician

The company The Clinician provides a different approach with its software product ZEDOC. The focus here is on the patient, or more precisely, on the integration of self-reported patient data (Patient-Reported Outcome Measures - PROM) into clinical pathways. Data about a patient's quality of life (QoL) is the main interest of their kind of data collection. The reason for that is, as explained in an example about colorectal cancer: "*As surgical and oncological therapies for colorectal cancer have improved, so has patient survivorship, but studies show that survivorship does NOT equate to improved Quality of Life (QoL). To improve the outcomes of colorectal cancer patients, healthcare providers must consider the effects that treatment have on patients' QoL, physical abilities, social functions and psychological states.*"[509] The data collected and entered by the patient via the mobile app is then visually processed and made available to the attending physicians and nursing staff. So, while both patients and clinicians have their own user interfaces, data visualization only takes place on the clinicians' side. Figure 8.4 shows an example of how this self-reported data is presented to the clinician.

[509] https://theclinician.com/care-pathways/colorectal-cancer-digital-care-pathway, last visited 2023-11-08



(Figure 8.4: Overview of cumulative, self-reported patient data by The Clinician[510])

We also kindly received a document explaining and illustrating the visualization in more detail. However, we were asked not to publish it, but you can already see the basic functionality from this publicly available example.

[510] https://theclinician.com/care-pathways/colorectal-cancer-digital-care-pathway, last visited 2023-11-08

Although the patient data presented are not laboratory test results, the following points can nevertheless be noted that are relevant to our research question:

- The individual patient data can be categorized within a reference interval.
- Both the data and the respective reference intervals can be displayed over time.
- Several measured parameters can be displayed simultaneously on one screen.
- It is also interesting to note that there is no special color coding for data outside the reference interval.
- According to the internal document, it is also possible to display detailed information and correlations between the data interactively (e.g., with a mouse hover).[511]

Due to the lower complexity and the lower relevance for our research question (patient data is displayed but not visually integrated with the respective clinical pathways) compared to the previous software solution, we will leave it at this brief examination.

8.6 Results

In this chapter, we conducted a field analysis for software solutions dealing with clinical pathways as well as individual patient data according to our research question. The methodology used can be found in section 4.2 Field Analysis Methodology, which is a mixture of different methodological areas adapted to our problem. Unfortunately, the willingness to provide us with information for our research was lower than expected, so we had to adapt our approach accordingly and work with the available material. For an in-depth investigation of different user interface designs and data visualizations in this area, we would need to have access to demos of the respective applications. Originally, we also wanted to examine the various software solutions with regard to our legal research question, but there was even less willingness to provide additional information, which is why we soon abandoned this plan. Nevertheless, we were able to get an overview of the field and gain some insights, which are briefly summarized below.

[511] The Clinician 2023

Heterogeneity: As we have already seen in the definition of the term clinical pathway, it is used in a wide variety of ways. This was also evident in the software solutions examined, as different concepts were labeled as clinical pathways.

Horizontal vs. Vertical Dimension: In order to tackle this definition problem, we suggest a classification of the available solutions based on a horizontal and a vertical dimension. The former refers to the different sub-areas or problems in the course of treatment (data analysis, care management, decision support), while the latter refers to the "granularity" of the respective solution (inter-facility approaches at the highest level vs. specific process within treatment at the lowest level)

Decision Support and Care Management: We could identify two big sub-areas along the horizontal dimension: Decision support tools for clinicians and care management solutions for a wider variety of stakeholders. This does not mean that they are mutually exclusive or that all solutions clearly fall into one of those categories, but the majority of the analyzed solutions use clinical pathway data and individual patient data for one of those means.

Medicalvalues as a Promising Source for Relevant Information: This company develops its products in a very science-based way, it was willing to provide us with additional information, and its software solution is highly relevant to our research question. Therefore, their data visualization methods are of great importance to us. However, these largely coincide with the guidelines from our literature analysis anyway.

Now that we have examined our problem from the perspective of the literature and through a field analysis, it is time to synthesize the results and come to an overall conclusion.

Chapter 9 - Conclusion

In this final chapter, we will summarize the results of the individual chapters and relate them once again to our research questions and expected results. Furthermore, we point out the limitations of this work. Finally, we conclude with an outlook on what further research following this work might look like and what may be expected in the years to come.

9.1 Summary of the Results

In this thesis, we embarked on a comprehensive exploration of merging medical treatment pathways with individual patient data, respectively laboratory test results, and the legal considerations surrounding the processing and visualization of this contextualized patient data in the treatment of hemato-oncological diseases. We used a variety of research methodologies for answering the respective questions from different perspectives. The research questions guided our inquiry into both the design of a graphical user interface (GUI) and the legal frameworks in Austria, Germany, and Switzerland. We conducted a narrative literature review, a field analysis, and an in-depth legal exploration of the topic.

9.1.1 Research Question 1 (R1): Visualization of Pathway and Patient Data

> ***R1:*** *What is an appropriate means to design a graphical user interface for merging and visualizing a medical treatment pathway together with a patient's laboratory test results in the context of the treatment of a hemato-oncological disease, which increases a user's knowledge and understanding about the current disease state compared to state-of-the-art methods?*

In Chapter 6 - Data Visualization and GUI Design - Literature Review, we conducted a narrative literature review that uncovered essential principles for designing a GUI that effectively merges clinical treatment pathways and individual patient data. Understanding the nuances of user perspectives, data structures, and domain-specific requirements became pivotal. The synthesis of findings emphasizes the need for a user-centric approach, tailored information detail, multi-window views, interactivity, information layering, and strategic color coding. These design principles provide a foundation for developing software artifacts that enhance user knowledge and understanding in the context of hemato-oncological diseases.
In Chapter 8 - Field Analysis, we built on the findings from our literature research and conducted a field analysis that supports and enriches the common themes identified in the literature. Furthermore, it provides real-world examples and practical insights. The convergence of evidence from both literature and field analysis contributes to a comprehensive understanding of GUI design challenges in the context of hemato-oncological diseases, directly addressing our first research question. The identified patterns and challenges can further inform guidelines and recommendations for designing effective GUIs that enhance user knowledge and understanding of the medical treatment process.
Nevertheless, it has to be said that there was a limitation in evaluating the appropriate means for GUI design compared to state-of-the-art methods. There are various reasons for

this, as already explained in section 3.4 Change of Course during the Research Process. In short, the reasons for this were the limited access to comparable solutions, the high complexity and heterogeneity of the solutions examined, and the resulting increased workload, which would not have corresponded to an appropriate scope due to the interdisciplinary nature and the broad scope of the work.

9.1.2 Research Question 2 (R2): Legal Framework

> ***R2**: What is the legal framework in Austria, Germany, and Switzerland for processing and visualizing contextualized patient data (according to RQ1) that is being generated during the treatment process of a hemato-oncological disease and what are appropriate solutions for dealing with emerging legal issues?*

In Chapter 5 - Legal Situation Concerning the Processing of Patient Data, our legal analysis delved into the complexities of data processing within the framework of the GDPR and other regional regulations. Consent emerged as a crucial aspect, emphasizing the importance of explicit and informed agreement for processing sensitive data. Pseudonymization and anonymization were explored, highlighting the significance of safeguarding patient information. The GDPR's role as a research enabler and the emphasis on technical requirements underscored the need for a holistic approach to data protection. Legal harmonization efforts were observed, reflecting the ongoing evolution of data protection laws in the studied regions.
In Chapter 7 - Legal Situation Concerning the Visualization of Patient Data, we emphasized the legal framework for visualization of contextualized patient data and the issues involved with building respective software solutions. In summary, the second part of the legal analysis builds upon and extends the legal considerations introduced in the first part. It provides a specialized focus on the MDR, offering specific requirements and guidelines for GUI design in the medical context. Together, these legal insights contribute to addressing the second research question (R2) regarding the legal framework for processing and visualizing contextualized patient data.

9.1.3 Interdisciplinary Insights:

The interdisciplinary insights gained from this thesis offer a comprehensive understanding of the nuanced relationship between graphical user interface (GUI) design and legal considerations in the context of hemato-oncological diseases. At the core of these insights is a consistent emphasis on a user-centric approach, recognizing the diverse needs and perspectives of both patients and clinicians. This focus underscores the interconnected challenges that arise when merging medical treatment pathways with patient data, where legal implications influence design choices and vice versa.
A holistic compliance approach emerges, where the study considers multiple legal frameworks, including the General Data Protection Regulation (GDPR) and the Medical Device Regulation (MDR). This integrated perspective ensures that software artifacts not only meet design objectives, such as user-centered interfaces and effective data integration but also adhere to the legal requirements governing data processing and visualization. The impact of the data controller's intent is recognized as a crucial factor influencing both legal

compliance and GUI design choices, highlighting the need for a clear understanding of and alignment with legal definitions and requirements.

9.2 Limitations

In exploring various aspects, the thesis faced limits due to its broad scope. We often had to stop diving into more detail as it would have gone beyond the scope of our work. However, new ideas and thoughts emerged from this broad perspective, especially in combining legal and visualization elements. The altered plan and, therefore, the absence of a concrete prototype made a direct comparison to the latest technology unfeasible, as previously explained.

The field analysis encountered limitations due to data availability, and the diverse research landscape posed challenges with inconsistent definitions, especially regarding the concept of clinical pathways. Unanswered questions about concrete consent mechanisms and implementations, as well as the project's categorization as scientific research or a medical device, point to areas needing further exploration and clarification.

The depiction of clinical pathways also lacked standardization, presenting challenges but also offering room for creative solutions. While these limitations are evident, they highlight opportunities for future research and improvements in both the legal and design realms. The interplay of constraints and possibilities sets the stage for ongoing exploration at the intersection of healthcare, law, and technology.

It is also crucial to note that the insights shared in this thesis don't replace advice from legal professionals. The complex legal frameworks require tailored guidance for accurate interpretation depending, among others, on the actual implementation of a respective software solution.

9.3 Outlook

The most obvious way in which further research can follow from this work is through the execution of our original plan. We have provided the theoretical basis, both from a GUI design perspective and from a legal perspective. Now, it can, for example, be followed up by developing and evaluating different GUI prototypes. This can be done for a variety of possible scenarios, for example, for different user groups (patients or doctors). But there are also different possibilities for evaluation, which can be done by comparing several prototypes with each other, or there may be the possibility of further company cooperation in order to obtain comparative data. As already explained in section 2.2 Medical Background Information - Hematology-Oncology, we would recommend using CML as a model disease for building and evaluating prototype solutions.

As the law in this area, in particular, must constantly change and adapt due to rapid technological development, there is also a constant need for further research. While we have created a general legal framework as part of our problem definition, legal research for specific software implementations is still required. The European Health Data Space (EHDS) is an already announced legislative amendment that is particularly interesting to observe in this context; a regulation proposal already exists, and the drafting of the law is already in

development.[512] Therefore, it remains to be seen what impact this will have in general and on our question in particular.

[512] https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_en last visited 2023-11-20

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List of Acronyms

AI	Artificial Intelligence
CJEU	Court of Justice of the European Union
CML	Chronic Myeloid Leukemia
DACH	Germany (D) Austria (A) Switzerland (CH)
EHDS	European Health Data Space
eHealth	Electronic Health
EHR	Electronic Health Record
EU	European Union
EUIPO	European Union Intellectual Property Office
GDA	Gesundheitsdiensteanbieter (Health Service Provider)
GUI	Graphical User Interface
HCI	Human-Computer Interaction
ICP	Integrated Care Pathway
IT	Information Technology
mHealth	Mobile Health
PROM	Patient-Reported Outcome Measure
QoL	Quality of Life
SLR	Systematic Literature Review
SOP	Standard Operating Procedure
UDI	Unique Device Identifier
UDI-DI	UDI - Device Identifier
UDI-PI	UDI - Production Identifier
UI	User Interface
USP	Unique Selling Proposition
WHO	World Health Organization
WIPO	World Intellectual Property Organization

Legal Sources

ÄrzteG-AT. Bundesgesetz über die Ausübung des ärztlichen Berufes und die Standesvertretung der Ärzte (Ärztegesetz 1998 – ÄrzteG 1998) BGBl. I 169/1998 idF I 65/2022 (2022).

BDSG-DE. Bundesdatenschutzgesetz vom 30. Juni 2017 (BGBl. I S. 2097), das zuletzt durch Artikel 10 des Gesetzes vom 23. Juni 2021 (BGBl. I S. 1858; 2022 I 1045) geändert worden ist (2017). https://www.gesetze-im-internet.de/bdsg_2018/BDSG.pdf.

BGB-DE. Bürgerliches Gesetzbuch in der Fassung der Bekanntmachung vom 2. Januar 2002 (BGBl. I S. 42, 2909; 2003 I S. 738), das zuletzt durch Artikel 4 des Gesetzes vom 25. Oktober 2023 (BGBl. 2023 I Nr. 294) geändert worden ist (2002).

CDR. Council Regulation (EC) No 6/2002 of 12 December 2001 on Community designs, 3 OJ L § (2002).

Charter of Fundamental Rights of the European Union, 326 OJ C § (2012). http://data.europa.eu/eli/treaty/char_2012/oj/eng.

CPPD. Directive 2009/24/EC of the European Parliament and of the Council of 23 April 2009 on the legal protection of computer programs (Codified version), 111 OJ L § (o. J.).

DiGAV-DE. Digitale Gesundheitsanwendungen-Verordnung vom 8. April 2020 (BGBl. I S. 768), die zuletzt durch Artikel 3 des Gesetzes vom 20. Dezember 2022 (BGBl. I S. 2793) geändert worden ist (2020).

DokGG-AT. Bundesgesetz über die Dokumentation im Gesundheitswesen BGBl. 745/1996 idF I 100/2018 (2018).

DSG-AT. Bundesgesetz zum Schutz natürlicher Personen bei der Verarbeitung personenbezogener Daten (Datenschutzgesetz – DSG) BGBl. I 165/1999 idF I 148/2021 (2021).

DVG-DE. Gesetz für eine bessere Versorgung durch Digitalisierung und Innovation (Digitale-Versorgung-Gesetz – DVG) Vom 9. Dezember 2019 (2019).

FOG-AT. Bundesgesetz über allgemeine Angelegenheiten gemäß Art. 89 DSGVO und die Forschungsorganisation (Forschungsorganisationsgesetz – FOG) BGBl. Nr. 341/1981 idF I 116/2022 (2022).

GDPR. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), 119 OJ L § (2016). https://eur-lex.europa.eu/eli/reg/2016/679/oj.

GPSD. Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety, 11 OJ L § (2001).

GPSR. Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety, amending Regulation (EU) No 1025/2012 of

the European Parliament and of the Council and Directive (EU) 2020/1828 of the European Parliament and the Council, and repealing Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC (Text with EEA relevance), 135 OJ L § (2023). http://data.europa.eu/eli/reg/2023/988/oj/eng.

GTelG-AT. Bundesgesetz betreffend Datensicherheitsmaßnahmen bei der Verarbeitung elektronischer Gesundheitsdaten und genetischer Daten (Gesundheitstelematikgesetz 2012 – GTelG 2012) BGBl. I 111/2012 idF I 206/2022 (2022).

HMG-CH. 812.21 Bundesgesetz über Arzneimittel und Medizinprodukte (Heilmittelgesetz, HMG) vom 15. Dezember 2000 (Stand am 1. September 2023) (2000).

IVDR. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, 117 OJ L § (2017).

MDR. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance.), 117 OJ L § (2017). http://data.europa.eu/eli/reg/2017/745/oj/eng.

MepV-CH. 812.213 Medizinprodukteverordnung (MepV) vom 1. Juli 2020 (Stand am 1. November 2023) (2020).

MPDG-DE. Medizinprodukterecht-Durchführungsgesetz vom 28. April 2020 (BGBl. I S. 960), das zuletzt durch Artikel 3f des Gesetzes vom 28. Juni 2022 (BGBl. I S. 938) geändert worden ist (2020).

MPG-AT. Bundesgesetz betreffend Medizinprodukte 2021 (Medizinproduktegesetz 2021 – MPG 2021) BGBl. I 122/2021 idF I 192/2021 (2021).

PHG-AT. Bundesgesetz vom 21. Jänner 1988 über die Haftung für ein fehlerhaftes Produkt (Produkthaftungsgesetz) BGBl. Nr. 99/1988 idF I 98/2001 (1988).

ProdHaftG-DE. Produkthaftungsgesetz vom 15. Dezember 1989 (BGBl. I S. 2198), das zuletzt durch Artikel 5 des Gesetzes vom 17. Juli 2017 (BGBl. I S. 2421) geändert worden ist (1989).

revDSG-CH. BBl 2020 7639 Bundesgesetz über den Datenschutz (Datenschutzgesetz, DSG) (2020).

SDSG-CH. 235.3 Bundesgesetz über den Datenschutz im Rahmen der Anwendung des Schengen-Besitzstands in Strafsachen (Schengen-Datenschutzgesetz, SDSG) vom 28. September 2018 (Stand am 1. März 2019) (2019).

SGB(5)-DE. Das Fünfte Buch Sozialgesetzbuch – Gesetzliche Krankenversicherung – (Artikel 1 des Gesetzes vom 20. Dezember 1988, BGBl. I S. 2477, 2482), das zuletzt durch Artikel 9 des Gesetzes vom 16. August 2023 (BGBl. 2023 I Nr. 217) geändert worden ist (1988).

StGB-AT. Bundesgesetz vom 23. Jänner 1974 über die mit gerichtlicher Strafe bedrohten Handlungen (Strafgesetzbuch – StGB) (1974). https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10002296.

TKG-DE. Telekommunikationsgesetz vom 23. Juni 2021 (BGBl. I S. 1858), das zuletzt durch Artikel 5 des Gesetzes vom 14. März 2023 (BGBl. 2023 I Nr. 71) geändert worden ist (2022).

TMG-DE. Telemediengesetz vom 26. Februar 2007 (BGBl. I S. 179, 251; 2021 I S. 1380), das zuletzt durch Artikel 3 des Gesetzes vom 12. August 2021 (BGBl. I S. 3544) geändert worden ist (2021).

Bibliography

Aigner, Wolfgang, Katharina Kaiser, and Silvia Miksch. “Visualization Methods to Support Guideline-Based Care Management.” *Studies in Health Technology and Informatics* 139 (2008): 140.

Alnanih, Reem, and Olga Ormandjieva. “Mapping HCI Principles to Design Quality of Mobile User Interfaces in Healthcare Applications.” *Procedia Computer Science* 94 (2016): 75–82.

Altorbaq, Alaa, Fredrik Blix, and Stina Sörman. “Data Subject Rights in the Cloud: A Grounded Study on Data Protection Assurance in the Light of GDPR.” In *2017 12th International Conference for Internet Technology and Secured Transactions (ICITST)*, 305–10, 2017. https://doi.org/10.23919/ICITST.2017.8356406.

Antignac, Thibaud, David Sands, and Gerardo Schneider. “Data Minimisation: A Language-Based Approach.” In *ICT Systems Security and Privacy Protection*, edited by Sabrina De Capitani di Vimercati and Fabio Martinelli, 502:442–56. IFIP Advances in Information and Communication Technology. Cham: Springer International Publishing, 2017. https://doi.org/10.1007/978-3-319-58469-0_30.

Ausloos, Jef. “Giving Meaning to Lawfulness under the GDPR.” CITIP blog, May 2, 2017. https://www.law.kuleuven.be/citip/blog/2761-2/.

Bakaev, Maxim, and Olga Razumnikova. “What Makes a UI Simple? Difficulty and Complexity in Tasks Engaging Visual-Spatial Working Memory.” *Future Internet* 13, no. 1 (2021): 21.

Balatsoukas, Panos, Richard Williams, Colin Davies, John Ainsworth, and Iain Buchan. “User Interface Requirements for Web-Based Integrated Care Pathways: Evidence from the Evaluation of an Online Care Pathway Investigation Tool.” *Journal of Medical Systems* 39 (2015): 1–15.

Barnitzke, Benno, Philipp Möller, and Arne Nordmeyer. “Die Schutzfähigkeit Graphischer Benutzeroberflächen Nach Europäischem Und Deutschem Recht.” *Computer Und Recht* 27, no. 5 (January 2011). https://doi.org/10.9785/ovs-cr-2011-277.

Bartlett, Lesley, and Frances Vavrus. “Comparative Case Studies: An Innovative Approach.” *Nordic Journal of Comparative and International Education (NJCIE)* 1, no. 1 (2017). https://journals.oslomet.no/index.php/nordiccie/article/view/1929.

Basin, David, Søren Debois, and Thomas Hildebrandt. “On Purpose and by Necessity: Compliance Under the GDPR.” In *Financial Cryptography and Data Security*, edited by Sarah Meiklejohn and Kazue Sako, 10957:20–37. Lecture Notes in Computer Science. Berlin, Heidelberg: Springer Berlin Heidelberg, 2018. https://doi.org/10.1007/978-3-662-58387-6_2.

Baxter, Pamela, and Susan Jack. “Qualitative Case Study Methodology: Study Design and Implementation for Novice Researchers.” *The Qualitative Report* 13, no. 4 (2008): 544–59.

Beard, Leslie, Rebecca Schein, Dante Morra, Kumanan Wilson, and Jennifer Keelan. “The Challenges in Making Electronic Health Records Accessible to Patients.” *Journal of the American Medical Informatics Association* 19, no. 1 (2012): 116–20.

Becker, Christian D., Katherine Dandy, Max Gaujean, Mario Fusaro, and Corey Scurlock. “Legal Perspectives on Telemedicine Part 1: Legal and Regulatory Issues.” *The Permanente Journal* 23 (2019).

Becker, Kurt, Myriam Lipprandt, Rainer Röhrig, and Thomas Neumuth. “Digital Health–Software as a Medical Device in Focus of the Medical Device Regulation (MDR).” *It-Information Technology* 61, no. 5–6 (2019): 211–18.

Beckers, Rainer, and Gernot Marx. “Telekooperation–Telemonitoring–Teletherapie: Begriffserklärungen.” *Telemedizin: Grundlagen Und Praktische Anwendung in Stationären Und Ambulanten Einrichtungen*, 2021, 3–8.

Berns, Fabian, Niclas Heilig, Florian Stumpe, and Jan Kirchhoff. “Medical Operational AI: Artificial Intelligence in Routine Medical Operations.” *Journal of Laboratory Medicine* 47, no. 4 (August 28, 2023): 171–79. https://doi.org/10.1515/labmed-2023-0011.

Biasin, Elisabetta. “Why Accuracy Needs Further Exploration in Data Protection.” In *CAIP 2021: Proceedings of the 1st International Conference on AI for People: Towards Sustainable AI, CAIP 2021, 20-24 November 2021, Bologna, Italy*, 1–8. European Alliance for Innovation, 2021.

Brewer, Noel T., Melissa B. Gilkey, Sarah E. Lillie, Bradford W. Hesse, and Stacey L. Sheridan. “Tables or Bar Graphs? Presenting Test Results in Electronic Medical Records.” *Medical Decision Making* 32, no. 4 (2012): 545–53.

Buchner, Benedikt. *Die Vertraulichkeit Der Arzt-Patienten-Beziehung–Doppelt Geschützt Hält Besser?* Springer, 2020.

Bufalieri, Luca, Massimo La Morgia, Alessandro Mei, and Julinda Stefa. “GDPR: When the Right to Access Personal Data Becomes a Threat.” In *2020 IEEE International Conference on Web Services (ICWS)*, 75–83. IEEE, 2020.

Burgstaller, Peter, and Robert Kolmhofer. “Die Anwendbarkeit der Vertraulichkeitsvorgaben aus dem GTelG: Elektronische Weitergabe von Gesundheitsdaten.” *ZIR - Zeitschrift Für Informationsrecht* 2017, no. 3 (2017): 261–64.

Calvino, Flavio, Chiara Criscuolo, Luca Marcolin, and Mariagrazia Squicciarini. “A Taxonomy of Digital Intensive Sectors.” OECD Science, Technology and Industry Working Papers. Vol. 2018/14. OECD Science, Technology and Industry Working Papers, June 15, 2018. https://doi.org/10.1787/f404736a-en.

Carani, Christopher V. “Design Rights.” *Design Rights*, 2022, 1–816.

Castets-Renard, Céline. “Accountability of Algorithms in the GDPR and beyond: A European Legal Framework on Automated Decision-Making.” *SSRN Electronic Journal*, 2019, 91–137. https://doi.org/10.2139/ssrn.3391266.

Charney, Alan N., and Jordan T. Dourmashkin. “Interpreting Clinical and Laboratory Tests: Importance and Implications of Context.” *Diagnosis* 8, no. 1 (2021): 33–36.

Chassang, Gauthier. “The Impact of the EU General Data Protection Regulation on Scientific Research.” *Ecancermedicalscience* 11, no. 709 (2017).

Chen, Chien-Hsiung, and Shasha Li. “The Effect of Visual Feedback Types on the Wait Indicator Interface of a Mobile Application.” *Displays* 61 (2020): 1–10.

Chico, Victoria. “The Impact of the General Data Protection Regulation on Health Research.” *British Medical Bulletin* 128, no. 1 (2018): 109–18.

Choe, Eun Kyoung, Marisa E. Duarte, Hyewon Suh, Wanda Pratt, and Julie A. Kientz. “Communicating Bad News: Insights for the Design of Consumer Health Technologies.” *JMIR Human Factors* 6, no. 2 (2019): e8885.

Chui, Wing Hong, and Mike McConville. *Research Methods for Law*. Vol. 104. Edinburgh University Press Edinburgh, 2007.

Chynoweth, Paul. “Legal Research.” *Advanced Research Methods in the Built Environment* 1 (2008).

Clifford, Damian, and Jef Ausloos. “Data Protection and the Role of Fairness.” *Yearbook of European Law* 37 (January 1, 2018): 1–58. https://doi.org/10.1093/yel/yey004.

Comandè, Giovanni, and Giulia Schneider. “Can the GDPR Make Data Flow for Research Easier? Yes It Can, by Differentiating! A Careful Reading of the GDPR Shows How EU Data Protection Law Leaves Open Some Significant Flexibilities for Data Protection-Sound Research Activities.” *Computer Law & Security Review* 41 (July 1, 2021). https://doi.org/10.1016/j.clsr.2021.105539.

Corrales Compagnucci, Marcelo, Mark Fenwick, Helena Haapio, Timo Minssen, and Erik PM Vermeulen. “Technology-Driven Disruption of Healthcare &’UI Layer’Privacy-by-Design.” *Cambridge Bioethics and the Law Series, Cambridge University Press, Forthcoming*, 2020.

Crompton, Shirley, and Jens Jensen. “Towards a Secure and GDPR-Compliant Fog-to-Cloud Platform.” In *2018 IEEE/ACM International Conference on Utility and Cloud Computing Companion (UCC Companion)*, 296–301, 2018. https://doi.org/10.1109/UCC-Companion.2018.00071.

Darzi, Youssef, Ivica Letunic, Peer Bork, and Takuji Yamada. “iPath3. 0: Interactive Pathways Explorer V3.” *Nucleic Acids Research* 46, no. W1 (2018): W510–13.

De Bleser, Leentje, Roeland Depreitere, Katrijn De Waele, Kris Vanhaecht, Joan Vlayen, and Walter Sermeus. “Defining Pathways.” *Journal of Nursing Management* 14, no. 7 (October 2006): 553–63. https://doi.org/10.1111/j.1365-2934.2006.00702.x.

De Hert, Paul, Vagelis Papakonstantinou, Gianclaudio Malgieri, Laurent Beslay, and Ignacio Sanchez. “The Right to Data Portability in the GDPR: Towards User-Centric Interoperability of Digital Services.” *Computer Law & Security Review* 34, no. 2 (2018): 193–203.

Degelsegger-Márquez, Alexander. “Gesundheitsdaten in Österreich – Ein Überblick.” *Ergebnisbericht Im Auftrag Des Bundesministeriums Für Soziales, Gesundheit, Pflege Und Konsumentenschutz*, 2021.

Di Martino, Mariano, Pieter Robyns, Winnie Weyts, Peter Quax, Wim Lamotte, and Ken Andries. “Personal Information Leakage by Abusing the {GDPR}’Right of Access’.” In *Fifteenth Symposium on Usable Privacy and Security (SOUPS 2019)*, 371–85, 2019.

Dimitrova, Diana. “The Rise of the Personal Data Quality Principle. Is It Legal and Does It Have an Impact on the Right to Rectification?” *European Journal of Law and Technology* 12, no. 3 (2021): 1–31.

Donnelly, Mary, and Maeve McDonagh. “Health Research, Consent and the GDPR Exemption.” *European Journal of Health Law* 26, no. 2 (April 24, 2019): 97–119. https://doi.org/10.1163/15718093-12262427.

Düwert, Henning. “Haftungsrechtliche Aspekte der Einführung elektronischer Gesundheitskarten in Deutschland und Österreich.” 2010. https://utheses.univie.ac.at/detail/11377.

EDÖB. “Das Neue Datenschutzgesetz Aus Sicht Des EDÖB.” Eidgenössischer Datenschutz- und Öffentlichkeitsbeauftragter (EDÖB), October 7, 2022. https://www.edoeb.admin.ch/dam/edoeb/de/Dokumente/datenschutz/Leitfaden%20Das%20neue%20Datenschutzgesetz%20aus%20Sicht%20des%20ED%C3%96B_20221009.pdf.download.pdf/Leitfaden%20Das%20neue%20Datenschutzgesetz%20aus%20Sicht%20des%20ED%C3%96B_20221009.pdf.

Fatehi, Farhad, Mahnaz Samadbeik, and Azar Kazemi. “What Is Digital Health? Review of Definitions.” In *Integrated Citizen Centered Digital Health and Social Care*, 67–71. IOS Press, 2020.

Fehn, Karsten. “Rechtliche Aspekte Der Telemedizin.” In *Telemedizin: Grundlagen Und Praktische Anwendung in Stationären Und Ambulanten Einrichtungen*, 9–52. Springer, 2020.

Ferrari, Rossella. “Writing Narrative Style Literature Reviews.” *Medical Writing* 24, no. 4 (December 2015): 230–35. https://doi.org/10.1179/2047480615Z.000000000329.

Fischer, Shira H., Charles Safran, Krzysztof Z. Gajos, and Adam Wright. “Visualization of Electronic Health Record Data for Decision-Making in Diabetes and Congestive Heart Failure.” *ACI Open* 4, no. 01 (2020): e35–43.

Franz, Max, Christian T. Lopes, Gerardo Huck, Yue Dong, Onur Sumer, and Gary D. Bader. “Cytoscape. Js: A Graph Theory Library for Visualisation and Analysis.” *Bioinformatics* 32, no. 2 (2016): 309–11.

Freitas, Maria da Conceição, and Miguel Mira da Silva. “GDPR Compliance in SMEs: There Is Much to Be Done.” *Journal of Information Systems Engineering & Management* 3, no. 4 (November 10, 2018). https://doi.org/10.20897/jisem/3941.

Friis, Lone S., Beth Elverdam, and Kai G. Schmidt. “The Patient’s Perspective: A Qualitative Study of Acute Myeloid Leukaemia Patients’ Need for Information and

Their Information-Seeking Behaviour." *Supportive Care in Cancer* 11 (2003): 162–70.

Furramani, Emanuela, and Nilgun Kalaycıoglu Ozpozan. "Transfer of Personal Data to Third Countries and the 'Equivalent Level' of Protection According to the European Court of Justice." *European Journal of Formal Sciences and Engineering* 6, no. 1 (2023): 1–12.

Georgiou, Dimitra, and Costas Lambrinoudakis. "GDPR Compliance: Proposed Guidelines for Cloud-Based Health Organizations." In *Computer Security*, 156–69. Springer, 2020.

Gil González, Elena, and Paul De Hert. "Understanding the Legal Provisions That Allow Processing and Profiling of Personal Data—an Analysis of GDPR Provisions and Principles." *ERA Forum*, February 5, 2019. https://doi.org/10.1007/s12027-018-0546-z.

Goldberg, Richard J. "Disclosure of Information to Adult Cancer Patients: Issues and Update." *Journal of Clinical Oncology* 2, no. 8 (1984): 948–55.

Grigoropoulos, N. F., R. Petter, M. B. Van 't Veer, M. A. Scott, and G. A. Follows. "Leukaemia Update. Part 1: Diagnosis and Management." *BMJ* 346, no. mar28 4 (March 28, 2013): f1660–f1660. https://doi.org/10.1136/bmj.f1660.

Grudin, Jonathan. "The Case against User Interface Consistency." *Communications of the ACM* 32, no. 10 (1989): 1164–73.

Gschwandtner, Theresia. "Interactive Visualization of Effects of Medical Treatment on a Patients Condition," 2012. https://repositum.tuwien.at/handle/20.500.12708/10994.

Gschwandtner, Theresia, Wolfgang Aigner, Katharina Kaiser, Silvia Miksch, and Andreas Seyfang. "CareCruiser: Exploring and Visualizing Plans, Events, and Effects Interactively." In *2011 IEEE Pacific Visualization Symposium*, 43–50. IEEE, 2011.

Haas, Peter, Bernd Leicher, and Tim Terlohr. "App-Gestütztes Multidimensionales Selbstmanagement: Ein Neuer Baustein in Der Gesundheitsversorgung." *Telemedizin: Grundlagen Und Praktische Anwendung in Stationären Und Ambulanten Einrichtungen*, 2021, 411–22.

Haddaway, Neal R., Matthew J. Page, Chris C. Pritchard, and Luke A. McGuinness. "PRISMA2020: An R Package and Shiny App for Producing PRISMA 2020-Compliant Flow Diagrams, with Interactivity for Optimised Digital Transparency and Open Synthesis." *Campbell Systematic Reviews* 18, no. 2 (2022): e1230.

Haimberger, Klara. "Widerruf oder Widerspruch? Verhinderung einer Datenverarbeitung auf Grundlage des broad consent." *Journal für Medizin- und Gesundheitsrecht* 2021, no. 1 (2021): 26–30. https://doi.org/10.37942/jmg202101002601.

Hallinan, Dara. "Broad Consent under the GDPR: An Optimistic Perspective on a Bright Future." *Life Sciences, Society and Policy* 16, no. 1 (2020): 1–18.

Handbook on European Data Protection Law - 2018 Edition. European Union Agency for Fundamental Rights, 2018. https://fra.europa.eu/en/publication/2018/handbook-european-data-protection-law-2018-edition.

Haque, Akm Bahalul, A. K. M. Najmul Islam, Sami Hyrynsalmi, Bilal Naqvi, and Kari Smolander. "GDPR Compliant Blockchains–A Systematic Literature Review." *IEEE Access* 9 (2021): 50593–606. https://doi.org/10.1109/ACCESS.2021.3069877.

Harris, Robert L. *Information Graphics: A Comprehensive Illustrated Reference*. Oxford University Press, USA, 1999.

Hatzijordanou, Nadja, Nicolai Bohn, and Orestis Terzidis. "A Systematic Literature Review on Competitor Analysis: Status Quo and Start-up Specifics." *Management Review Quarterly* 69, no. 4 (2019): 415–58.

Heilig, Niclas, Jan Kirchhoff, Florian Stumpe, Joan Plepi, Lucie Flek, and Heiko Paulheim. "Refining Diagnosis Paths for Medical Diagnosis Based on an Augmented Knowledge Graph." *arXiv E-Prints*, 2022, arXiv-2204.

Hevner, Alan, and Samir Chatterjee. *Design Science Research in Information Systems*. Springer, 2010.

Hevner, Alan R. "A Three Cycle View of Design Science Research." *Scandinavian Journal of Information Systems* 19, no. 2 (2007): 87–92.

Hintze, Mike, and Khaled El Emam. "Comparing the Benefits of Pseudonymisation and Anonymisation under the GDPR." *Journal of Data Protection & Privacy* 2, no. 2 (2018): 145–58.

Hirschmann, Johannes, Brita Sedlmayr, Jakob Zierk, Manfred Rauh, Markus Metzler, Hans-Ulrich Prokosch, and Dennis Toddenroth. "Evaluation of an Interactive Visualization Tool for the Interpretation of Pediatric Laboratory Test Results." In *German Medical Data Sciences: Visions and Bridges*, 207–11. IOS Press, 2017.

Huang, Weidong, Jing Luo, Tomasz Bednarz, and Henry Duh. "Making Graph Visualization a User-Centered Process." *Journal of Visual Languages & Computing* 48 (2018): 1–8.

Hutchinson, Terry, and Nigel Duncan. "Defining and Describing What We Do: Doctrinal Legal Research." *Deakin L. Rev.* 17 (2012): 83.

Jabbour, Elias, and Hagop Kantarjian. "Chronic Myeloid Leukemia: 2018 Update on Diagnosis, Therapy and Monitoring." *American Journal of Hematology* 93, no. 3 (2018): 442–59. https://doi.org/10.1002/ajh.25011.

Jasmontaite, Lina, Irene Kamara, Gabriela Zanfir-Fortuna, and Stefano Leucci. "Data Protection by Design and by Default: Framing Guiding Principles into Legal Obligations in the GDPR." *Eur. Data Prot. L. Rev.* 4 (2018): 1–22.

Jeffries, Robin, James R. Miller, Cathleen Wharton, and Kathy Uyeda. "User Interface Evaluation in the Real World: A Comparison of Four Techniques." In *Proceedings of the SIGCHI Conference on Human Factors in Computing Systems Reaching*

through Technology - CHI '91, 119–24. New Orleans, Louisiana, United States: ACM Press, 1991. https://doi.org/10.1145/108844.108862.

Johnson, Jeff. *Designing with the Mind in Mind: Simple Guide to Understanding User Interface Design Guidelines*. Morgan Kaufmann, 2020.

Juffernbruch, Klaus. "Mobile Interaktion." In *Telemedizin: Grundlagen Und Praktische Anwendung in Stationären Und Ambulanten Einrichtungen*, 445–50. Springer, 2020.

Jukić, Anton, and Christian Rahn. "Digitale Gesundheitsanwendungen: Zulassungsfragen Und Datenschutz." *GesundheitsRecht* 19, no. 12 (2020): 749–56.

Jumelle, Ai Keow Lim, and Ioana Ispas. "Ethical Issues in Digital Health." In *Requirements Engineering for Digital Health*, edited by Samuel A. Fricker, Christoph Thümmler, and Anastasius Gavras, 75–93. Cham: Springer International Publishing, 2015. https://doi.org/10.1007/978-3-319-09798-5_4.

Kamara, Irene, and Paul De Hert. "Understanding the Balancing Act Behind the Legitimate Interest of the Controller Ground: A Pragmatic Approach." *SSRN Electronic Journal*, 2018. https://doi.org/10.2139/ssrn.3228369.

Kapeller-Hirsch, Birgit. "Unregistered Community Designs: A Secret Weapon in Design Protection?," 2021. https://www.schoenherr.eu/content/unregistered-community-designs-a-secret-weapon-in-design-protection/.

Kapfer, Marcel. "Das Bundesdatenschutzgesetz Im Vergleich Mit Der Datenschutz-Grundverordnung." Seminar Paper, Institut fur Verteilte Systeme, Universität Ulm, n.d.

Katayev, Alex, Claudiu Balciza, and David W. Seccombe. "Establishing Reference Intervals for Clinical Laboratory Test Results: Is There a Better Way?" *American Journal of Clinical Pathology* 133, no. 2 (2010): 180–86.

Keplinger, Elisabeth. "Die DSGVO Im Bereich Des Gesundheitswesens." PhD Thesis, Universität Linz, 2019.

Kinsman, Leigh, Thomas Rotter, Erica James, Pamela Snow, and Jon Willis. "What Is a Clinical Pathway? Development of a Definition to Inform the Debate," 2010, 3.

Klucken, Jochen, Rejko Krüger, Peter Schmidt, and Bastiaan R. Bloem. "Management of Parkinson's Disease 20 Years from Now: Towards Digital Health Pathways." *Journal of Parkinson's Disease* 8, no. s1 (2018): S85–94.

Knigge, Amélie, and Iris Ruckdäschel. "„Apps Auf Rezept ": Die Digitale-Gesundheitsanwendungen-Verordnung Und Das Fast-Track-Verfahren Für Die Zulassung von Medical Apps in Die Regelversorgung." *Die Urologie* 61, no. 8 (2022): 860–65.

Koschmieder, Steffen, and Tim H. Brümmendorf. "Telemedizin in Der Hämatologie Und Onkologie." *Telemedizin: Grundlagen Und Praktische Anwendung in Stationären Und Ambulanten Einrichtungen*, 2021, 203–8.

Koukal, Pavel. “Collective Administration of Graphical User Interfaces (GUI) in the Light of the BSA Decision.” *Masaryk University Journal of Law and Technology* 10, no. 2 (2016): 128–47.

———. “Graphical User Interfaces and Their Protection in the European Union.” *Horizons in Computer Science Research, Nova Science Publishers*, 2018. https://www.researchgate.net/profile/Pavel-Koukal/publication/330452786_GRAPHICAL_USER_INTERFACES_AND_THEIR_PROTECTION_IN_THE_EUROPEAN_UNION/links/5c41167392851c22a37d5963/GRAPHICAL-USER-INTERFACES-AND-THEIR-PROTECTION-IN-THE-EUROPEAN-UNION.pdf.

Langhanke, Carmen. *Daten als Leistung: Eine rechtsvergleichende Untersuchung zu Deutschland, Österreich und der Schweiz*. Mohr Siebeck, 2018.

Lanter, David, and Rupert Essinger. “User-Centered Design.” *International Encyclopedia of Geography: People, the Earth, Environment and Technology*, 2017, 1–4.

Laukkarinen, Teemu, Kati Kuusinen, and Tommi Mikkonen. “DevOps in Regulated Software Development: Case Medical Devices.” In *2017 IEEE/ACM 39th International Conference on Software Engineering: New Ideas and Emerging Technologies Results Track (ICSE-NIER)*, 15–18. IEEE, 2017.

Lawal, Adegboyega K., Thomas Rotter, Leigh Kinsman, Andreas Machotta, Ulrich Ronellenfitsch, Shannon D. Scott, Donna Goodridge, Christopher Plishka, and Gary Groot. “What Is a Clinical Pathway? Refinement of an Operational Definition to Identify Clinical Pathway Studies for a Cochrane Systematic Review.” *BMC Medicine* 14, no. 1 (December 2016): 35, s12916-016-0580-z. https://doi.org/10.1186/s12916-016-0580-z.

Livari, Juhani. “A Paradigmatic Analysis of Information Systems As a Design Science.” *Scandinavian Journal of Information Systems* 19 (2007): 39–64.

Löwgren, Jonas, and Tommy Nordqvist. “Knowledge-Based Evaluation as Design Support for Graphical User Interfaces.” In *Proceedings of the SIGCHI Conference on Human Factors in Computing Systems - CHI ’92*, 181–88. Monterey, California, United States: ACM Press, 1992. https://doi.org/10.1145/142750.142786.

Ludvigsen, Kaspar, Shishir Nagaraja, and DALY Angela. “When Is Software a Medical Device? Understanding and Determining the ‘Intention’ and Requirements for Software as a Medical Device in European Union Law.” *European Journal of Risk Regulation* 13, no. 1 (2022): 78–93.

Luo, Weijun, Gaurav Pant, Yeshvant K. Bhavnasi, Steven G. Blanchard Jr, and Cory Brouwer. “Pathview Web: User Friendly Pathway Visualization and Data Integration.” *Nucleic Acids Research* 45, no. W1 (2017): W501–8.

Machuletz, Dominique, and Rainer Böhme. “Multiple Purposes, Multiple Problems: A User Study of Consent Dialogs after GDPR.” *Proceedings on Privacy Enhancing Technologies* 2020, no. 2 (April 1, 2020): 481–98. https://doi.org/10.2478/popets-2020-0037.

Maeda, John. *The Laws of Simplicity*. MIT press, 2006.

Malgieri, Gianclaudio. “The Concept of Fairness in the GDPR: A Linguistic and Contextual Interpretation.” In *Proceedings of the 2020 Conference on Fairness, Accountability, and Transparency*, 154–66. Barcelona Spain: ACM, 2020. https://doi.org/10.1145/3351095.3372868.

Mangalmurti, Sandeep S., Lindsey Murtagh, and Michelle M. Mello. “Medical Malpractice Liability in the Age of Electronic Health Records.” *New England Journal of Medicine* 363, no. 21 (2010): 2060–67. https://doi.org/10.1056/NEJMhle1005210.

March, Salvatore T., and Veda C. Storey. “Design Science in the Information Systems Discipline: An Introduction to the Special Issue on Design Science Research.” *MIS Quarterly*, 2008, 725–30.

Mattsson, Titti. “Editorial: Digitalisation and Artificial Intelligence in European Healthcare.” *European Journal of Health Law* 26, no. 4 (October 4, 2019): 285–88. https://doi.org/10.1163/15718093-12264001.

McAfoose, J., and B. T. Baune. “Exploring Visual–Spatial Working Memory: A Critical Review of Concepts and Models.” *Neuropsychology Review* 19 (2009): 130–42.

MDCG. “MDCG 2019-11 Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR,” 2019.

Mortenson, Torrey, and Ronald L. Boring. “Forward and Backward Error Recovery Factors in Digital Human-System Interface Design.” In *Advances in Safety Management and Human Performance: Proceedings of the AHFE 2020 Virtual Conferences on Safety Management and Human Factors, and Human Error, Reliability, Resilience, and Performance, July 16-20, 2020, USA*, 267–73. Springer, 2020.

Muchagata, Joana, and Ana Ferreira. “Translating GDPR into the mHealth Practice.” In *2018 International Carnahan Conference on Security Technology (ICCST)*, 1–5. IEEE, 2018.

Mühlich, Regina. “Deutschland BDSG vs. Österreich DSG 200 - großer Unterschied?” *AdOrga Solutions GmbH* (blog), August 16, 2016. https://www.adorgasolutions.de/datenschutz-deutschland-vs-oesterreich/.

Mulder, Trix. “The Protection of Data Concerning Health in Europe.” *Eur. Data Prot. L. Rev.* 5 (2019): 209–20.

Murad, M. Hassan. “Clinical Practice Guidelines: A Primer on Development and Dissemination.” In *Mayo Clinic Proceedings*, 92:423–33. Elsevier, 2017. https://www.sciencedirect.com/science/article/pii/S0025619617300253.

Narrillos-Moraza, Álvaro, Patricia Gómez-Martínez-Sagrera, Miguel Ángel Amor-García, Vicente Escudero-Vilaplana, Roberto Collado-Borrell, Cristina Villanueva-Bueno, Ignacio Gómez-Centurión, Ana Herranz-Alonso, and María Sanjurjo-Sáez. “Mobile Apps for Hematological Conditions: Review and Content Analysis Using the Mobile App Rating Scale.” *JMIR mHealth and uHealth* 10, no. 2 (February 16, 2022): e32826. https://doi.org/10.2196/32826.

Neophytou, John Peter. “Copyright for Graphical User Interfaces.” *Journal of Intellectual Property Law & Practice* 6, no. 7 (2011): 436–37.

Niedermayer, Bernhard. “Der Urheberrechtliche Schutz von Computerprogrammen Im Internationalen Vergleich.” Master Thesis, Linz, 2014. https://epub.jku.at/obvulihs/content/titleinfo/376270/full.pdf.

Nittari, Giulio, Ravjyot Khuman, Simone Baldoni, Graziano Pallotta, Gopi Battineni, Ascanio Sirignano, Francesco Amenta, and Giovanna Ricci. “Telemedicine Practice: Review of the Current Ethical and Legal Challenges.” *Telemedicine and E-Health* 26, no. 12 (2020): 1427–37. https://doi.org/10.1089/tmj.2019.0158.

Oberhofer, Harald, Gerhard Schwarz, and Michael Strassnig. “Registerforschung: Verwaltungs-Und Statistikdaten Für Die Wissenschaft.” *Mitteilungen Der Vereinigung Österreichischer Bibliothekarinnen Und Bibliothekare* 72, no. 2 (2019).

Olimid, Anca Parmena, Liliana Marcela Rogozea, and Daniel-Alin Olimid. “Ethical Approach to the Genetic, Biometric and Health Data Protection and Processing in the New EU General Data Protection Regulation (2018).” *Romanian Journal of Morphology and Embryology* 59.2 (January 1, 2018): 631–36.

Paul, Manash K., and Anup K. Mukhopadhyay. “Tyrosine Kinase – Role and Significance in Cancer.” *International Journal of Medical Sciences* 1, no. 2 (June 1, 2004): 101–15.

Pearce, Dennis Charles, Enid Campbell, and Don E. Harding. *Australian Law Schools: A Discipline Assessment for the Commonwealth Tertiary Education Commission: A Summary*. Australian Government Pub. Service, 1987.

Pfeffers, K., Tuure Tuunanen, Charles E. Gengler, Matti Rossi, Wendy Hui, Ville Virtanen, and Johanna Bragge. “The Design Science Research Process: A Model for Producing and Presenting Information Systems Research.” In *Proceedings of the First International Conference on Design Science Research in Information Systems and Technology (DESRIST 2006), Claremont, CA, USA*, 83–106, 2006.

Politou, Eugenia, Efthimios Alepis, and Constantinos Patsakis. “Forgetting Personal Data and Revoking Consent under the GDPR: Challenges and Proposed Solutions.” *Journal of Cybersecurity* 4, no. 1 (January 1, 2018): 1–20. https://doi.org/10.1093/cybsec/tyy001.

Purtova, Nadezhda, Eleni Kosta, and Bert-Jaap Koops. “Laws and Regulations for Digital Health.” *Requirements Engineering for Digital Health*, 2015, 47–74.

Rhahla, Mouna, Takoua Abdellatif, Rabah Attia, and Wassel Berrayana. “A GDPR Controller for IoT Systems: Application to e-Health.” In *2019 IEEE 28th International Conference on Enabling Technologies: Infrastructure for Collaborative Enterprises (WETICE)*, 170–73, 2019. https://doi.org/10.1109/WETICE.2019.00044.

Rother, Edna Terezinha. “Systematic Literature Review X Narrative Review.” *Acta Paulista de Enfermagem* 20 (2007): v–vi.

Ruiz, Jenny, Estefanía Serral, and Monique Snoeck. “Unifying Functional User Interface Design Principles.” *International Journal of Human–Computer Interaction* 37, no. 1 (2021): 47–67.

Ruohonen, Jukka. “A Review of Product Safety Regulations in the European Union.” *International Cybersecurity Law Review* 3, no. 2 (2022): 345–66.

Rust, Peter, Derek Flood, and Fergal McCaffery. “Creation of an IEC 62304 Compliant Software Development Plan.” *Journal of Software: Evolution and Process* 28, no. 11 (2016): 1005–10.

Schinnenburg, Wieland. “Ärztliche Fernbehandlungen–Die Rechtlichen Und Tatsächlichen Rahmenbedingungen.” *Monatsschrift Für Deutsches Recht* 77, no. 14 (2023): 886–90.

Schreiter, Michaela. “Elektronische Übermittlung von Patientendaten: Datenschutzrechtliche Rahmenbedingungen Und Grundsätze Der Datensicherheit.” PhD Thesis, Universität Linz, 2020.

Seys, Deborah, Massimiliano Panella, R. VanZelm, W. Sermeus, D. Aeyels, L. Bruyneel, E. Coeckelberghs, and K. Vanhaecht. “Care Pathways Are Complex Interventions in Complex Systems: New European Pathway Association Framework.” *International Journal of Care Coordination* 22, no. 1 (2019): 5–9.

Sheehan, Mark. “Can Broad Consent Be Informed Consent?” *Public Health Ethics* 4, no. 3 (2011): 226–35.

Shneiderman, Ben, Catherine Plaisant, Maxine S. Cohen, Steven Jacobs, Niklas Elmqvist, and Nicholas Diakopoulos. *Designing the User Interface: Strategies for Effective Human-Computer Interaction*. Pearson, 2016.

Sidiropoulos, Konstantinos, Guilherme Viteri, Cristoffer Sevilla, Steve Jupe, Marissa Webber, Marija Orlic-Milacic, Bijay Jassal, Bruce May, Veronica Shamovsky, and Corina Duenas. “Reactome Enhanced Pathway Visualization.” *Bioinformatics* 33, no. 21 (2017): 3461–67.

Simonsson, Bengt and On Behalf of the IRIS (International Randomized IFN vs STI571) Study Group. “Beneficial Effects of Cytogenetic and Molecular Response on Long-Term Outcome in Patients with Newly Diagnosed Chronic Myeloid Leukemia in Chronic Phase (CML-CP) Treated with Imatinib (IM): Update from the IRIS Study.” *Blood* 106, no. 11 (November 16, 2005): 166–166. https://doi.org/10.1182/blood.V106.11.166.166.

Spagnuelo, Dayana, Ana Ferreira, and Gabriele Lenzini. “Accomplishing Transparency within the General Data Protection Regulation:” In *Proceedings of the 5th International Conference on Information Systems Security and Privacy*, 114–25. Prague, Czech Republic: SCITEPRESS - Science and Technology Publications, 2019. https://doi.org/10.5220/0007366501140125.

Sury, Ursula. *Digital in Law: Informatikrecht*. Stmpfli, 2021.

Tao, Da, Juan Yuan, Xingda Qu, Tieyan Wang, and Xingyu Chen. “Presentation of Personal Health Information for Consumers: An Experimental Comparison of Four

Visualization Formats." In *Engineering Psychology and Cognitive Ergonomics: 15th International Conference, EPCE 2018, Held as Part of HCI International 2018, Las Vegas, NV, USA, July 15-20, 2018, Proceedings 15*, 490–500. Springer, 2018.

Torsvik, Torbjørn, Børge Lillebo, and Morten Hertzum. "How Do Experienced Physicians Access and Evaluate Laboratory Test Results for the Chronic Patient? A Qualitative Analysis." *Applied Clinical Informatics* 9, no. 02 (2018): 403–10.

Torsvik, Torbjørn, Børge Lillebo, and Gustav Mikkelsen. "Presentation of Clinical Laboratory Results: An Experimental Comparison of Four Visualization Techniques." *Journal of the American Medical Informatics Association* 20, no. 2 (2013): 325–31.

Tretzmüller, Tobias. *Handbuch Softwarerecht: Software rechtssicher entwickeln, vertreiben und nutzen*. Wien: Linde, 2023.

Utz, Christine, Martin Degeling, Sascha Fahl, Florian Schaub, and Thorsten Holz. "(Un)Informed Consent: Studying GDPR Consent Notices in the Field." In *Proceedings of the 2019 ACM SIGSAC Conference on Computer and Communications Security*, 973–90. London United Kingdom: ACM, 2019. https://doi.org/10.1145/3319535.3354212.

Van Hoecke, Mark. "Methodology of Comparative Legal Research." *Law and Method*, 2015, 1–35.

Wagner, Julian. "The Transfer of Personal Data to Third Countries under the GDPR: When Does a Recipient Country Provide an Adequate Level of Protection?" *International Data Privacy Law* 8, no. 4 (2018): 318–37.

Wang, Qiru, and Robert S. Laramee. "EHR STAR: The State-of-the-Art in Interactive EHR Visualization." In *Computer Graphics Forum*, 41:69–105. Wiley Online Library, 2022.

Wang, Yanyan, Zhanning Bai, Zhifeng Lin, Xiaoqing Dong, Yingchaojie Feng, Jiacheng Pan, and Wei Chen. "G6: A Web-Based Library for Graph Visualization." *Visual Informatics* 5, no. 4 (2021): 49–55.

Wians, Frank H. "Clinical Laboratory Tests: Which, Why, and What Do the Results Mean?" *Laboratory Medicine* 40, no. 2 (2009): 105–13.

Wigdor, Daniel, and Dennis Wixon. *Brave NUI World: Designing Natural User Interfaces for Touch and Gesture*. Elsevier, 2011.

Wolters, P. T. J. "The Control by and Rights of the Data Subject under the GDPR." *Journal of Internet Law* 22, no. 1 (2018): 6–18.

Wongsuphasawat, Krist, and David Gotz. "Exploring Flow, Factors, and Outcomes of Temporal Event Sequences with the Outflow Visualization." *IEEE Transactions on Visualization and Computer Graphics* 18, no. 12 (2012): 2659–68.

Zankl, Wolfgang. *Rechtshandbuch Der Digitalisierung*. MANZ'sche Verlags-und Universitätsbuchhandlung, 2021.

Zhang, Yixuan, Kartik Chanana, and Cody Dunne. “IDMVis: Temporal Event Sequence Visualization for Type 1 Diabetes Treatment Decision Support.” *IEEE Transactions on Visualization and Computer Graphics* 25, no. 1 (2018): 512–22.

Zhang, Yiye, and Rema Padman. “An Interactive Platform to Visualize Data-Driven Clinical Pathways for the Management of Multiple Chronic Conditions.” In *MEDINFO 2017: Precision Healthcare through Informatics*, 672–76. IOS Press, 2017.

Zhang, Yiye, Rema Padman, and Nirav Patel. “Paving the COWpath: Learning and Visualizing Clinical Pathways from Electronic Health Record Data.” *Journal of Biomedical Informatics* 58 (2015): 186–97.

Zhang, Zhan, Lukas Kmoth, Xiao Luo, and Zhe He. “User-Centered System Design for Communicating Clinical Laboratory Test Results: Design and Evaluation Study.” *JMIR Human Factors* 8, no. 4 (2021): e26017.

Zhang, Zhan, Yu Lu, Yubo Kou, Danny TY Wu, Jina Huh-Yoo, and Zhe He. “Understanding Patient Information Needs about Their Clinical Laboratory Results: A Study of Social Q&A Site.” *Studies in Health Technology and Informatics* 264 (2019): 1403.

Zikmund-Fisher, Brian J., Aaron M. Scherer, Holly O. Witteman, Jacob B. Solomon, Nicole L. Exe, Beth A. Tarini, and Angela Fagerlin. “Graphics Help Patients Distinguish between Urgent and Non-Urgent Deviations in Laboratory Test Results.” *Journal of the American Medical Informatics Association* 24, no. 3 (2017): 520–28.

Undisclosed Sources

Medicalvalues. Undisclosed Product Presentation Brochure (2023)

The Clinician. Undisclosed custom-made information document for the purpose of our research project. (2023)

Treetop Medical. Undisclosed Internal Strategy Paper (2022)

Treetop Medical Application. Non-Public Access to Treetop Medical Software Prototype (2023)