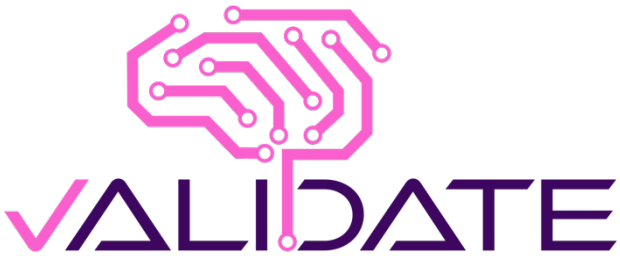

DELIVERABLE

Project Acronym: **VALIDATE**
Grant Agreement number: **101057263**
Project Title: **Validation of a Trustworthy AI-based Clinical Decision Support System for Improving Patient Outcome in Acute Stroke Treatment**

D3.2 – Integrated requirements report covering technical and user requirements

Revision: 1.0

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Project co-funded by the European Commission within **HORIZON-HLTH-2021-DISEASE-04-04**		
Dissemination Level		
PU	Public, fully open	X
CO	Confidential, restricted under conditions set out in Model Grant Agreement	
CI	Classified, information as referred to in Commission Decision 2001/844/EC	

This project has received funding from the European Union's Horizon Europe research and innovation program under grant agreement No 101057263

Revision History, Status, Abstract, Keywords, Statement of Originality

Revision History

Revision	Date	Author	Organisation	Description
0.1	05.09.2022	Ingo Werren	IBM iX	Setup of document and first draft of process / plan of user-research
0.2	5.10.2022	Ingo Werren	IBM iX	Integrated “intended use”
0.3	09.11.2022	Kilian Kugler	IBM iX	Chapters “Stakeholder Research” and Interpretation
0.4	10.11.2022	Julian Aengenheister	IBM iX	“Methods of research” and “Interpretation” of technical research
0.5	18.11.2022	Ingo Werren	IBM iX	Work on “Frameworks”, “Value driver” and “Pain point tracker”
0.6	30.11.2022	Julian Aengenheister	IBM iX	“Value driver” and “Requirement overview”
0.7	02.12.2022	Ingo Werren	IBM iX	“Value driver”, “Pain Point tracker”, “Methods and frameworks”
0.8	16.12.2022	Ingo Werren	IBM iX	Review and additions
0.9	20.12.2022	Kilian Kugler	IBM iX	Review and additions
1.0	23.12.2022	Ingo Werren	IBM iX	Review and Executive Summary

Date of delivery	Contractual:	30.12.2022	Actual:	02.01.2023
Status	final ☒ /draft ☐			

Abstract (for dissemination)	This document presents the version 1.0 of the integrated requirement report covering technical and user requirements The requirement report explains the procedure, methods and findings from the technical and user-oriented research phase for a clinical-decision-support software for stroke as it is to be researched within the VALIDATE project. The aim is to identify direct and indirect user groups and, as far as possible, to record their involvement and needs with regard to such a system. The first requirements for a later software will be derived from the procedure, collected findings and defined framework described here. However, the derivation of requirements is still a work-in-progress and a first starting point. Building on the first findings and requirements formulated here, in the next project phase of designing a prototype, further these requirements and hypotheses are either verified, refuted or new requirements are raised. These are then considered and included within the following reports.
Keywords	Design Thinking, User-centric, value-driver, pain-points, requirements

Statement of originality

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation, or both.

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Executive Summary

The "Integrated requirement report covering technical and user requirements" summarises the results of the phases "T3.2 - Technical Requirement and specification analysis" and "T3.3 Prognostic tool user requirement analysis and specifications". The focus here is on the requirements for the software, which is to be developed as a decision support system for the users.

The report describes the procedure by means of workshops, interviews, site visits and questionnaires and also explains the bases used for the evaluation and derivation of requirements.

The aim of the above-mentioned phases was to define relevant target groups for the software and to establish important initial hypotheses and requirements that will serve as a starting point for the following phase (T3.4. Design & development of demonstrator user interface prototype). The requirements and findings collected in this report do not claim to be complete, but serve as a basis and starting point for the next phase. In this phase, these requirements can and should be expanded or, under certain circumstances, revised through reviews.

An important basis for this and also the following phases is the application of methodologies of the Design Thinking Framework as well as methodologies of the "IBM Garage" framework. These are also described shortly in this report.

Three stakeholder groups have been identified as a realisation of the phases. Primary, secondary, and tertiary user groups. The primary user group includes the neurologists involved in the acute patient treatment, and the neuroradiologist who oversees the interpretation of the radiological images of the patient. Secondary users provide data that is necessary to use the CDSS. The tertiary user group does not use the tool directly but provide services to manage the CDSS tool e.g., administration, verification, data collection and ethical use.

The report describes a user journey along the treatment of an acute stroke in which the described stakeholders act.

Derived from the individual findings, the report defines three so-called "hills" as a starting point, which serve as targets for the further work in the phase "T3.4. design & development of demonstrator user interface prototype". These are:

A neurologist can view all stroke related patient data within 1 minute after patient admission.

A neurologist is provided a visualization of the likelihood distribution for the patient's mRS shift per treatment method to take an even more qualified decision for treating the patient.

A neurologist can provide feedback on the information and machine results they currently

view to continuously improve the user experience and machine learning model quality.

1 Methods of Research and Analysis

This chapter describes the methods used to collect relevant stakeholder requirements for the VALIDATE project with the purpose to develop a demonstrator-software. Most methods are part the IBM Enterprise Design Thinking Framework[1].
The findings and requirements collected and observed in the different ways form the basis for the derivation of concrete requirements for a later product.
In the following chapters, the findings are therefore listed first, then methodologies and frameworks for the interpretation and derivation of findings are named and finally the interpretations as well as first derivations of requirements for the demonstrator are listed.

1.1 Workshops

Workshops help to bring people from different organisations together to share and create a common understanding of a topic. We organise workshops following a co-creation framework[2]. Co-creation workshops serve as a platform to iterate on 'in-progress'working stages and receive feedback. The workshop host chooses the invitees and prepares the workshop guidelines in advance. The session itself consists of three stages: a general introduction of the participants and the topic, a guided discussion where each member is invited to contribute their perspectives, and finally the collection of action points for the future working process.
In our case we invited key stakeholders from all participating clinics (Heidelberg University Hospital, Heidelberg, Germany; Hadassah University Medical Center, Jerusalem, Israel; and Fundacio Hospital Universitari Vall d'Hebron, Barcelona, Spain). The session was one-to-two-hours long and took place virtually using video conferencing software and the co-creation tool Mural[3] to record and document the input from the workshop attendees.
The focus was to learn how the process of treatment in each participating hospital is conducted and learn about the used tools, guidelines and the problems and obstacles that are being faced.

Date	Participating institutions
19.09.2022	University Hospital Heidelberg, Heidelberg, Germany Hadassah University Medical Center, Jerusalem, Israel Fundacio Hospital Universitari Vall d'Hebron - Institut de Recerca, Barcelona, Spain

Table 1: Past Workshops

1.2 Interviews

"Interviewing stakeholders provides helpful information about their context, allows us to identify business goals they are concerned with, and increases their support"[4].

[1] https://www.ibm.com/design/thinking/

[2] https://www.designkit.org/methods/co-creation-session

[3] https://www.mural.co

[4] https://www.nngroup.com/articles/stakeholder-interviews/

We use interviews to determine common goals and hopes connected to VALIDATE. Together with individual stakeholders we explore their context on a shared process visualization. In addition, personal interviews help discover new correlation between project goals and the working context of our stakeholders.

Through Interviews of about one hour in length, we collected individual insights on a specific task or challenge. To document and analyse the interview findings, we used the co-creation tool Mural.

Date	Participating institutions
08.09.2022	University Hospital Heidelberg, Heidelberg, Germany • Susanne Bonekamp
23.08.2022	Charité – University Hospital Berlin • Vince Madai • Catherine McGarvey
18.08.2022	Charité – University Hospital Berlin • Dietmar Frey

Table 2: Past interviews

1.3 Site visits

Site visits help to understand the work reality of our stakeholders. They reveal new insights through chance encounters and ad-hoc interviews. During our site visit, we conducted interviews with stakeholders, observed interactions, and explored physical touchpoints. The visits followed the shadowing method known from design thinking[5]. Shadowing is a qualitative research technique in which an observer seeks to understand how stakeholders perform their daily tasks. Thereby, we learn about the daily business of people in the clinic and can better map overall research results to real situations. After the site visit, we documented all insights and challenges in Mural. The type of shadowing conducted is in the field of "controlled shadowing". In our case the researcher did not design the task, but the task was described and shown by the hosts in Universitätsklinikum Heidelberg.

Date	Participating institutions
21.09.2022	University Hospital Heidelberg, Heidelberg, Germany

Table 3: Past site visits

1.4 Questionnaire for technical requirements

Open questionnaires allow us to primarily understand the IT-maturity of the target organization and verify the responsibilities of our contact persons. This qualitative questionnaire consists of not more than 20 open questions (see Appendix A). Participants asynchronously assess these questions and, in case they are unable to answer, forward the questionnaire to the respective people in their organization. By using open questions, it is intended to contact the extended list of participants in form of workshops or guided interviews again to establish a personal relationship for the continuing project.

[5] https://think.design/user-design-research/shadowing/

Before participants access the questionnaire, they are introduced to the project and the related objectives to establish trust, nurture engagement and spark interest. The questionnaire asks participants about the current IT-infrastructure, software development environments, stroke-related data accessibility, and department regulations of the organization. It will also serve as a guideline for subsequent interactions as answers are expected to be complex and require personal contact with responsible IT personnel.
The questionnaire was sent out to following institutions:

- University Hospital Heidelberg, Heidelberg, Germany
- Hadassah University Medical Center, Jerusalem, Israel
- Fundacio Hospital Universitari Vall d'Hebron - Institut de Recerca, Barcelona, Spain

2 Summary of observations based on research activities

2.1 Stakeholder research results

In this section, we present the stakeholder research results derived from the activities mentioned in the previous section. In the beginning, we list primary, secondary, and tertiary stakeholders. Primary stakeholders directly interact and benefit from the VALIDATE decision-support system. Secondary stakeholders on the other hand, help collect input data for the decision-support. The tertiary stakeholders might not be involved directly in the treatment-process but influence or are influenced by it due to their involvement in processes related to the treatment or tools used in the treatment.
The main part of this chapter describes the current activities and challenges of the stakeholders. The current, or as-is situation, is structured according to the patient journey. Starting with the patient transport to the hospital, ending shortly after potential surgery.
We conducted our customer research with the three VALIDATE partner clinics:

- Universitätsklinikum Heidelberg, Germany
- Hadassah Medical Organization Jerusalem, Israel
- Fundacio Hospital Universitari Vall d'Hebron - Institut de Recerca Barcelona, Spain

Due to different healthcare systems of the clinic location, we will highlight geographical differences where necessary.

The stakeholders

We distinguish between primary, secondary, and tertiary user groups. The primary user group includes the neurologists involved in the acute patient treatment, and the neuroradiologist who oversees the interpretation of the radiological images of the patient.

Group name	Description
Neurologist	In charge of the diagnosis and treatment of stroke patients.
Neuroradiologist	Specialized radiologist in charge of imaging and interpretation of of abnormalities of the central and peripheral nervous system, spine, head, and neck using neuroimaging techniques.

Table 4: Primary stakeholders

Secondary users provide data that is necessary to use the CDSS.

Group name	Description
Neurology Resident	Junior medical staff who often serves as first contact point for stroke patients once admitted to the hospital. Residents perform and initiate initial tests.
(Triage) Nurse	In some countries nurses are the first point of contact for stroke patients. Triage nurses determine the seriousness of the patient condition.

Patient[6]	Depending on their state of consciousness, patients provide important information about their condition and medical history.
Relative / informal caregiver	If the patient is accompanied by relatives, they provide further important information about medical history of the patient.

Table 5: Secondary stakeholders

The tertiary user group does not use the tool directly but provide services to manage the CDSS tool e.g., administration, verification, data collection and ethical use.

Group name	Description
IT-Administrators	Technical staff providing an overview of the existing IT-landscape who are also knowledgeable of institutional and departmental IT system regulations.
Financial Controlling	This could evolve managers interested in the profitability of the hospital and / or also staff involved in the procurement and controlling processes.
Ethics Committee	Group of people reviewing research project proposal
Data-Protection Officer	Data privacy and security guidelines will be discussed and agreed upon with each institution's own data-protection officer to integrate multiple perspectives.
Project Consortium	The consortium members provide functional and regulatory requirements in form of meeting notes and the proposal of the project.

Table 6: Tertiary stakeholders

Patient journey overview

This section presents the current care-pathway in place in stroke treatment observed. To ensure a decision support tool can fit into the daily routines of the stakeholders, we analysed the steps patients take from transportation until shortly after a potential surgery. All the while, we mapped current challenges and insights which are later used to define stakeholder requirements.
To better present the stakeholder challenges, we identified seven key steps in the patient journey :

1. Patient transport
2. Hospital admittance and examination
3. Imaging
4. Intravenous tissue plasminogen activator (IV.TPA) treatment
5. Interpretation of examination results and imaging
6. Surgery
7. Post surgery

[6] In the context of this stakeholder research, a patient is an acute ischemic stroke patient.

In everyday situations in hospitals, some steps happen in parallel, therefore the separation mainly serves to present stakeholder challenges along a structured timeline.

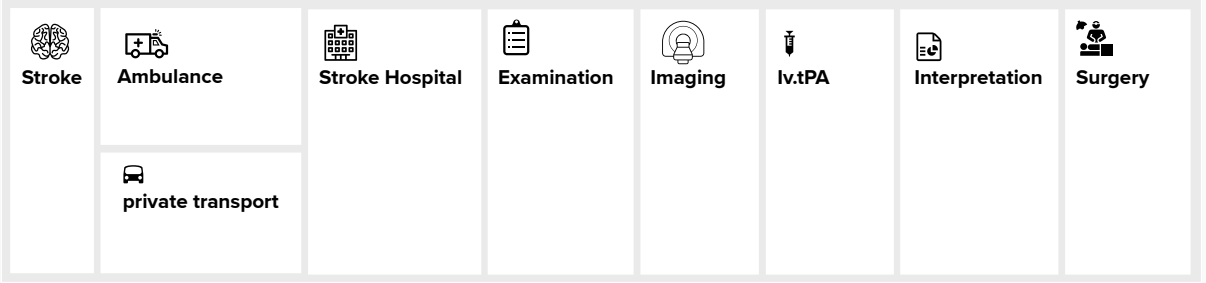

Figure 1 – User Journey of care-pathway of acute stroke

2.1.1 Patient transport

About half of the patients arrive by their own means of transport. In this scenario, the hospital admittance is the first point of contact between the patient and the clinic.
The other half of the patients, commonly more severe cases, arrive by ambulance. In this case, the ambulance staff may obtain relevant information for later diagnosis and treatment. Ambulance staff can record the time the patient was last seen well and record information about their medical history.
If the emergency staff suspects a stroke, they will inform the hospital of the arrival of a stroke patient, which helps the hospital in their preparations. In regions with an advanced digital health record, nurses or residents can us this time to collect information about the medical history of the patient before their arrival.

Hospital	Description
Hadassah University Medical Center, Jerusalem, Israel	Test to perform FAST-ED (Field Assessment Stroke Triage for Emergency Destination) through video calls between the ambulance and the hospital.
Fundacio Hospital Universitari Vall d'Hebron - Institut de Recerca, Barcelona, Spain	The hospital has a large area of influence. Difficulty to determine whether a long trip with the ambulance to the stroke clinic is beneficial.
General	Considering ICU (intensive care units) capacities and distance to next stroke unit for distributing emergency patients.
University Hospital Heidelberg, Heidelberg, Germany	Ambulance uses handwritten forms to record patient history.
University Hospital Heidelberg, Heidelberg, Germany	No access to electronic patient record.
Fundacio Hospital Universitari Vall	It takes too long to find relevant information from national patient record.

d'Hebron - Institut de Recerca, Barcelona, Spain / Hadassah University Medical Center, Jerusalem, Israel	

Table 7: Patient transport - Challenges and insights

2.1.2 Hospital admittance and examination

When a stroke patient arrives at the hospital, the stroke team will initiate the clinical examination of the patient and prepare the neurological emergency room. Commonly, a stroke patient is first seen by a neurological resident and triage nurse. Initially, the resident or nurse assess the current degree of disability and dependence of the patient through a Modified Rankin Scale (MRS)[7]. In addition, the resident or nurse try to determine the level of disability and dependence of the patient before the stroke occurred (pre stroke MRS)[8]. For this step, information obtained from accompanying relatives can be crucial.
Afterwards, the resident excludes stroke mimics caused by accidents, known tumours or past surgeries. Once stroke-mimics can be excluded, the resident records the initial NIHSS[9] (National Institutes of Health Stroke Scale) of the patient and assess the eligibility for anticoagulant treatment (intravenous tPA) and the susceptivity of the patient for contrast medium.

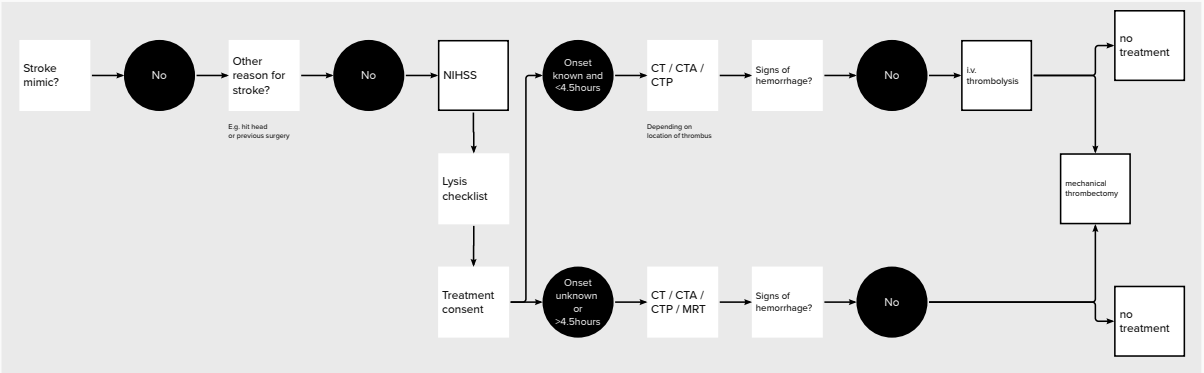

Figure 2 – Flowchart of treatment process

Hospital	Description
Hadassah University Medical Center, Jerusalem, Israel	After 5pm the staff capacity is lower. More communication between junior staff and on call neurologist is needed.
Fundacio Hospital Universitari Vall d'Hebron - Institut de	Stroke team communicates through the Join medical platform application. The App records all medical data about the patient in one place.

[7] https://www.stroke-manual.com/modified-rankin-scale-mrs/

[8] https://n.neurology.org/content/about-prestroke-mrs

[9] https://strokengine.ca/en/assessments/nihss/

Recerca, Barcelona, Spain	
Hadassah University Medical Center, Jerusalem, Israel	The current medication of the patient is recorded in the national patient record.
General	Patients with prescription medication are not necessarily taking it. This complicated the assessment for tPA treatment.
General/Hadassah University Medical Center, Jerusalem, Israel	Most information about the patient is recorded when patient sees triage nurse or resident. Usually, only little information is obtained before the patient arrives at the hospital.
University Hospital Heidelberg, Heidelberg, Germany	The Stroke unit can only access records of their own unit. Communication between different units or between hospitals is challenging and can lead to repeated examinations.
University Hospital Heidelberg, Heidelberg, Germany	tPA checklist done on paper and often lost.
University Hospital Heidelberg, Heidelberg, Germany	NIHSS done on paper. It later serves as reference for hospital reimbursement.
University Hospital Heidelberg, Heidelberg, Germany	Patients are required to sign a paper consent form before starting any treatment.
General/ Fundacio Hospital Universitari Vall d'Hebron - Institut de Recerca, Barcelona, Spain	Relatives commonly help filling missing information about the patient
University Hospital Heidelberg, Heidelberg, Germany	Difficult to establish direct phone line between hospital reception and stroke unit when relatives call to obtain and give information about the patient.

Table 8: Hospital admittance and examination - Challenges and insights

2.1.3 Imaging

After determining the NIHSS and MRS, the patient is brought to the radiology. Radiological imaging helps determine the type, severity, and location of the stroke. Depending on the hospital, different imaging technology is used:
Computed tomography imaging (CT) is the fastest and most accessible type of imaging. Therefore, CT is performed by smaller clinics as well. A basic CT image sequence is done in

every case. All participating hospitals further perform CT angiography (CTA) and CT perfusion (CTP) imaging if necessary. CTA and CTP imaging utilises contrast medium to visualise the blood circulation of the patient while a basic CT shows all tissues inside the body unfiltered. In contrast to CT, magnetic resonance tomography (MRT) has a higher resolution and improves diagnosis. Due to its downsides: higher time consumption, restriction of metallic equipment, and a more challenging supervision of the patient during the screening; MRT is not commonly used to diagnose acute ischemic strokes in the three participating hospitals. In case of their absence, radiologists get the images through mobile applications like mRay[10], RAPID[11], or JOIN[12]. These applications allow neurologists and radiologists to interpret images remotely while on call duty.

Hospital	Description
Fundacio Hospital Universitari Vall d'Hebron - Institut de Recerca, Barcelona, Spain	CTP is always done together with the regular CT imaging
University Hospital Heidelberg, Heidelberg, Germany	CTP is only used in rare cases
Fundacio Hospital Universitari Vall d'Hebron - Institut de Recerca, Barcelona, Spain	CT imaging is done before any other examination.
Fundacio Hospital Universitari Vall d'Hebron - Institut de Recerca, Barcelona, Spain	While CT imaging is in progress, staff has time to review patient record or fill in missing data.
Fundacio Hospital Universitari Vall d'Hebron - Institut de Recerca, Barcelona, Spain / Hadassah University Medical Center, Jerusalem, Israel	Uses RAPID ai for image interpretation
University Hospital Heidelberg, Heidelberg, Germany	Uses Brainomix ai for image interpretation

[10] https://mbits.info/mray

[11] https://www.rapidai.com/stroke

[12] https://g.allm.net/join/

University Hospital Heidelberg, Heidelberg, Germany	MRT and CTP mainly used for “wake-up strokes” (onset unknown)

Table 9: Imaging - Challenges and insights

2.1.4 Intravenous tPA

Without counter indication, stroke patients always receive an injection of anticoagulants (tPA) to attempt resolving the thrombus causing the stroke. Counter indication includes prior medication, signs of haemorrhages, or when the time of stroke onset is unknown. Generally, tPA is only given when the stroke onset is less than 4.5 hours in the past.

Hospital	Description
General	The time a patient spends from arrival until tPA treatment is measured in the “time to needle” value, an important indicator for the efficiency of a stroke unit.

Table 10: intravenous tPA - Challenges and insights

2.1.5 Interpretation

In addition to a manual assessment through the neurologist and neuroradiologist, all three hospitals use image recognition software to interpret CT images. These programs generate an electronic “Alberta stroke programme early CT score” (ASPECTS)[13]. The electronic ASPECTS shows the brain areas affected by the stroke. Together with the assessment of the radiologist, both the neurologist and neuroradiologist, consider the most relevant parameters to determine whether to perform a mechanical thrombectomy.

Hospital	Description
University Hospital Heidelberg, Heidelberg, Germany	If there are no strong counter indication always treat – with best intention.
Hadassah University Medical Center, Jerusalem, Israel	It takes about 10Min for the RAPID(e-ASPECTS) results
Hadassah University Medical Center, Jerusalem, Israel	Have a dashboard with all relevant parameters of the patient.
Hadassah University Medical Center, Jerusalem, Israel	Most important factors: patient history, age, pre-MRS, ASPECTS, NIHSS, risk factors (and more)
University Hospital Heidelberg, Heidelberg, Germany	Treatment decision mainly relying on angiography, vessel occlusion and ASPECTS score.

[13] https://www.stroke-manual.com/aspect-score/

University Hospital Heidelberg, Heidelberg, Germany	Uses Brainomix[14] to determine e-ASPECTS
University Hospital Heidelberg, Heidelberg, Germany	Electronic ASPECTS can lead to algorithm bias if weighted too highly in the decision making.
Fundacio Hospital Universitari Vall d'Hebron - Institut de Recerca, Barcelona	Results from RAPID and Brainomix go directly to JOIN.
Fundacio Hospital Universitari Vall d'Hebron - Institut de Recerca, Barcelona	In JOIN stroke team has access to all images and information on their mobile phone.
Fundacio Hospital Universitari Vall d'Hebron - Institut de Recerca, Barcelona	The baseline MRS is considered in the treatment decision.
University Hospital Heidelberg, Heidelberg, Germany	MRS is not a strong indication for treatment decision.
General	E-ASPECTS does not work equally well for all types of vessel occlusion.

Table 11: Interpretation - Challenges and insights

2.1.6 Surgery

If the diagnosis supports further treatment, the patient is brought to the endosuite for mechanical thrombectomy. During the surgery the patient is constantly screened through CT angiography.

Hospital	Description
University Hospital Heidelberg, Heidelberg, Germany	Mechanical thrombectomy is a highly cost intensive intervention for hospitals.
University Hospital Heidelberg, Heidelberg, Germany / Fundacio Hospital Universitari Vall	Recordings from the surgery are not immediately available in the patient record.

[14] https://www.brainomix.com

d'Hebron - Institut de Recerca, Barcelona	
General	The time a patient spends from arrival until the surgery is measured in the “time to puncture” value, an important indicator for the efficiency of a stroke unit.

Table 12: Surgery - Challenges and insights

2.1.7 After the surgery

24 hours after the surgery the patient is screened through CT imaging and reassessed using the NIHSS and MRS. The treatment is successful if the NIHSS score reduced significantly, and the CT images don’t show signs of further damage compared to previous images.

Hospital	Description
General	Residual contrast agent may still be visible in the CT scan. This can lead to overevaluation of the patient condition.

Table 13: After surgery - Challenges and insights

2.2 Technical research results

The two-step approach of questionnaire first and guided interview second, to engage with the IT-staff of the three hospitals, produced a variety of technical insights and opportunities. The questionnaire quickly showed it is not sufficient as a research method for technical details. As expected, the canonical response was to directly discuss IT infrastructure und development landscapes in the planned guided interview format, the questionnaire allowed us to initiate the discussion, find the responsible technical stakeholders at the clinical sites, and contact them to schedule interviews.
The first guided interview with Universitätsklinikum Heidelberg produced a traditional high-level context diagram:

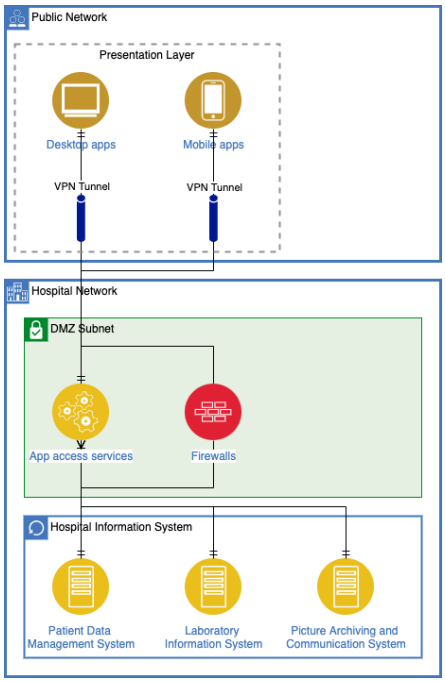

Figure 3 – High level technical context diagram of IT-infrastructure at Universitätsklinikum Heidelberg

As depicted in the context diagram (Figure 3), the technical research revealed that the application must allow deployment in a traditional DMZ pattern and as containers, as well as connect to the three main systems of record concerning stroke treatment - Patient Data Management System (PDMS), Laboratory Information System (LIS), Picture Archiving and Communication System (PACS).
There is neither an established software development environment that can be reused nor architectural guidelines provided by the IT department, though UNIX servers can be reused for deployment.
Apart from individual requirements of the clinical sites, industry standards and regulatory requirements are explicitly provided in the proposal of the project. These include but are not limited to:

- IEC 62304 (medical device software – software life cycle processes)
- Health Level Seven HL7 v2/3 (interoperability specification for health and medical transactions)
- Fast Healthcare Interoperability Resources FHIR
- Systematized Nomenclature of Medicine SNOMED International
- Clinical Data Interchange Standards Consortium CDISC
- Integrating the Healthcare Enterprise IHE
- General Data Protection Regulation GDPR

3 Interpretation

To derive relevant requirements for the software to be created from the observations of the research phase, these must be interpreted using relevant criteria and methodologies. This chapter explains the frameworks, methodologies and criteria that were considered to interpret the observations and thus to derive requirements. Furthermore, it contains the respective interpretations derived by applying them regarding the observations or the topic area.

3.1 About requirements

To meet the requirements of the Medical Device Regulation (MDR) for the approval of medical devices, it is necessary to record the stakeholder requirements for the software development and the technical documentation.
The stakeholder requirements in terms of the medical device consist of the following

- Usage requirements
- Regulatory requirements
- Technical requirements
- Organisational requirements
- Key tasks

The requirements compiled in this document are based on these areas. In detail, we will often summarise them under the collective term of stakeholder requirements. This document does not claim to have completely covered all possible requirements from all areas at this stage. In the upcoming phases ("T3.3: Prognostic tool user requirement analysis and specification" and "T3.4 – Design & development of demonstrator user interface prototype") these will be collected and recorded continuously. An updated list of requirements will then be included in the deliverable "D3.5 - Final report on usability and quality of service of clinical demonstrator".

These stakeholder requirements are the basis for deriving software requirement specifications in the subsequent steps of software development. Software requirement specifications must then be created for all stakeholder requirements that are considered relevant for the implementation of the later product, which then address and implement them accordingly.

3.1.1 Definition of requirements

A requirement is defined as an understanding to solve a problem or to achieve an objective. Requirements can be written in various levels of detail. At this stage of the project, we are defining requirements on a high-level and will add more detailed requirements during the project.
Eliciting requirements is an important part of software engineering as the purpose is not only to create an overview of what is needed but also to create a common understanding between the involved parties, users, stakeholders, analysts, and developers.

To be aware of the unknown we classify different types of requirements.

Explicit requirements are *expressed* by the client, usually stakeholders and users. To record these, open interviewing techniques and workshop formats can be performed, and they directly feed into the requirements reports.
Implicit requirements are *expected* by the client but not expressed by stakeholders and users. Eliciting implicit requirements demands the analyst to have profound domain knowledge and additional verification before they are added or denied as requirements.
Unknown requirements are *hidden* and usually discovered during the project. It is expected that an initial requirements report will be expanded through the course of the project and priorities will have to be adjusted.

3.1.2 Managing technical requirements

The following process is derived from guidelines applied at IBM iX in the technical requirement engineering process. The general technical requirements engineering process will run through the following steps and key activities to finally materialize into the Technical Requirements Report:

1. Planning
    - Form team with right skills
        - Domain knowledge
        - Facilitation skills
        - Technical skills
    - Identify source of information and get access
    - Identify relevant stakeholders
    - Get high level understanding of scope
    - Identify requirement types to use
    - Schedule requirement gathering sessions
    - Identify how to store requirements
    - Define change management process with stakeholders
2. Gathering
    - Individual Techniques
        - Document Analysis
        - Interviewing[15]
    - Group Technique
        - Brainstorming
        - Solution workshops
3. Analysis
    - Parameters of good requirement
        - Unique
        - Complete – in terms of who, what, when, why
        - Consistent – consistent in time and definition across groups
        - Implementation free – discuss what need to be done instead of how
        - Technically feasible – possible to implement with available technology
        - Unambiguous – possible to interpret in only one way
4. Verification

[15] Davis A, Dieste O, Hickey A, Juristo N, Moreno AM (2006) Effectiveness of requirements elicitation techniques: empirical results derived from a systematic review. In: Proceedings 14th IEEE international symposium on requirements engineering (RE'06). IEEE Computer Society Press, Los Alamitos, pp 176–185

- Reaching agreement with stakeholders on how to deal with them
- Agreement forms basis for estimating, planning, performing, and tracing project activities
- Store the gathered requirements along with other supporting artifacts
- Update risk register to reflect risks due to poor requirements
- Baseline and get approval from appropriate stakeholders

5. Storage (Technical Requirements Report)
   - *Store* requirements keeping the following in mind:
   - *Ensure* each requirement states only one need.
   - *Classify* requirements into different types.
   - *Identify* each requirement uniquely, reflecting parent-child relationship.
   - *Mention* the owner of each requirement.
   - *Use* version-control tools to track changes.
   - *Ensure* traceability.
   - *Reveal not* details concerning security.

3.1.3 Semantics of Requirements

To formulate stakeholder requirements as succinctly and accurately as possible, we use a uniform structure and semantics. The basis for this is the adoption of a methodology from IBM's "Enterprise Design Thinking". This is based on the common methodologies of the Design Thinking Framework.

We orientate ourselves here on the formulation used for "Hills". An equivalent and more common term in agile software development is "Epic".

A Hill or Epic begins with the user that shall be served. Next, the desired outcome that we want to enable them to achieve, and the differentiator that will make the solution worth their while is described. We refer to these elements as the “Who”, the “What”, and the “Wow”.
A good Hill / Epic is implementation-agnostic. It should specify what users are trying to accomplish, not a tool they’ll use to do it. The structure is as follows[16]:

Who
Who are your users? Clear statement who we aim to serve—and who we do not serve.
What
What is the need they are trying to meet?
Wow
How will it differentiate from other solutions? How could success be measured?

3.2 Framework / Methods

The following methodologies and frameworks served as orientation points and support for the evaluation of the research results and for the derivation of requirements. Furthermore, they can and should be used in further steps of software development as a support and basis for decisions on which requirements are to be addressed in the context of this project. They can and should also be used for this purpose in the creation and evaluation

[16] https://www.ibm.com/design/thinking/page/framework/keys/hills

of the software requirements specifications derived from the requirements.

3.2.1 Intended Purpose of the Medical Product

The Medical Device Regulation requires the determination of a clear "intended purpose" or intended use. This is set out in Article 2 of REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL[17].
It is defined as follows:

> *'Medical device' means any instrument, apparatus, appliance, software, implant, reagent, material, or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:*
> *—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,*
> *and which does not achieve its principal intended action by pharmacological, immunological, or metabolic means, in or on the human body, but which may be assisted in its function by such means.'*

The aim of this project is to develop the demonstrator for VALIDATE in close alignment with the Medical Device Regulation.
For this reason, an "intended purpose" was set up for the software along the guidelines of the Medical Device Regulations. The derived purpose is listed in the chapter Intended Use.
The "intended purpose" can be read in the document "D3.2 – Integrated Requirement Report – Appendix "intended purpose". This appendix is a work-in-progress document which gives an overview over the structure of a medical intended purpose documentation following the MDR guidelines.
The medical intended purpose is an important orientation point for deriving requirements for the software. It will therefore be used for comparison when deriving requirements later.

3.2.2 IT Architecture board

The IT architecture board's goal is to govern and agree on integrated software development processes and architectural decisions affecting multiple work package components. It will regularly review the overall architecture and ensure processes are followed. With each work package providing one member to the board, it is possible to have a view on how architectural principles and development practices are being followed in the project.

[17] https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX:32017R0745

3.2.3 Data board

The data board streamlines communication and discussion on stroke related data availability, usability, relevance, access, and processing amongst the individual consortium members, especially clinics and AI development. It meets on demand with each work package providing one member.

3.2.4 Designing for "AI"

In line, in sync and in exchange with the SOP guidelines on trustworthy AI development which is being developed in work package 1 of this Grant, it is important to also consider principles and guidelines when designing the software in which the AI will then be integrated.
As a method and framework for the work on and with the requirements to create the software, we will generally follow principles and frameworks developed by IBM.
IBM has three guiding principles to approach AI Ethics

1. The purpose of AI is to augment human intelligence
2. Date and insights belong to their creator
3. Technology must be transparent and explainable

Building upon these guiding principles there are five pillars of trust that help to put these principles into action:

- Explainability
- Fairness
- Robustness
- Transparency
- Privacy

When designing for AI[18] and applying the design thinking approach - which shall be our guiding framework when designing the software - IBM has created an AI Essential Framework[19] with five focal areas.

The framework is a set of activities, tools, and principles that enable teams to design thoughtful, human-centred artificial intelligence solutions using Enterprise Design Thinking.
The AI Essentials Framework is a specific grouping of activities to work through to align the team on strategy for an AI experience. There five focal areas in the framework are:

- **Intent**: Align on the business and user intent(s) for your solution.
- **Data**: Document the data you could use to make your idea a reality.
- **Understanding**: Determine what you will need to teach your AI.
- **Reasoning**: Bring your ideas down to earth.
- **Knowledge**: Brainstorm the direct and indirect effects of your AI.

[18] https://www.ibm.com/design/ai/

[19] https://www.ibm.com/design/ai/team-essentials

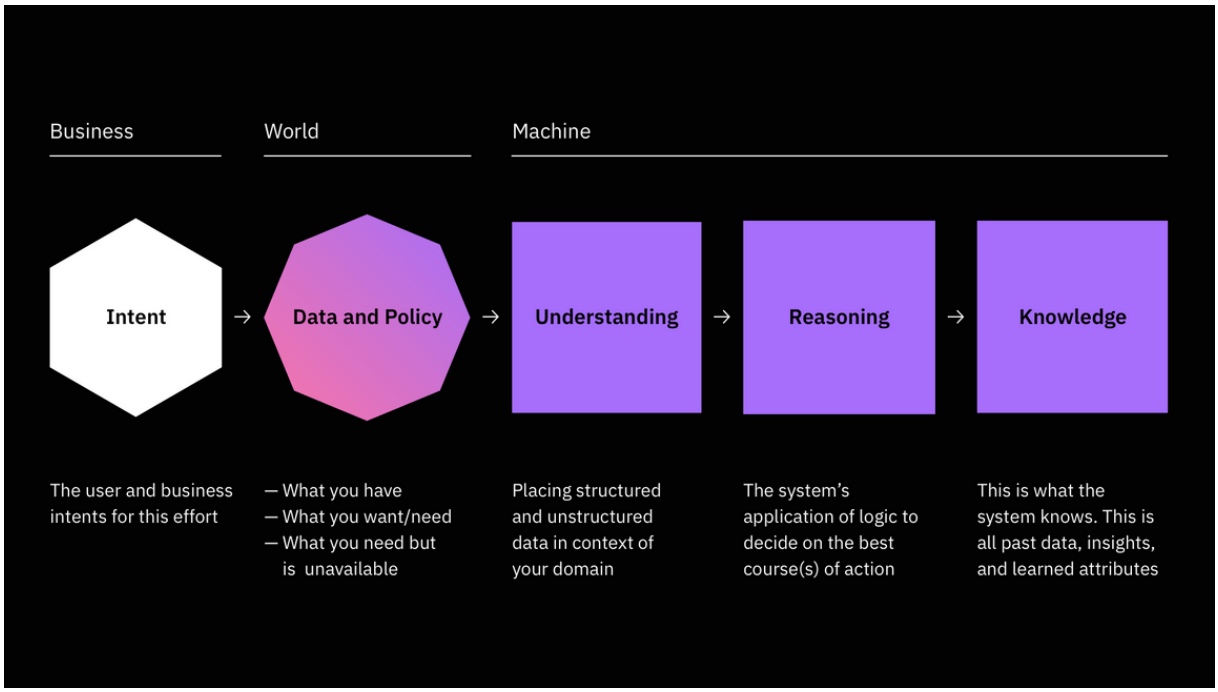

Figure 4 – Focal areas of the "IBM AI Essential Framework"

3.2.5 Value driver of the software

The goal when developing a software should always be to create a "value". IBM has taken this goal and incorporated it into a framework or operating model on how innovative software solutions are being developed for and foremost with the stakeholders. This operating model is called "IBM GARAGE[20]".

Within the tools of this framework "value driver" for a business (in our case hospital) will be identified. They are then structured in a so-called "value tree" that can relate to the task or the problem area or the targeted innovation / software.

A „value tree" is a flow diagram that maps a business' strategic goals firstly to specific value drivers (Key performance indicators - KPIs), secondly to measurable metrics and thirdly (optionally) to business initiatives or in our case "requirements".

The value-tree approach is derived from the standards described in the "value driver model" by the UN Global Compact LEAD[21]. It therefore aims for not only taking business value drivers into consideration, but also supporting a seamless and holistic integration of sustainability aspects.

[20] https://www.ibm.com/garage

[21] https://www.unglobalcompact.org/library/811

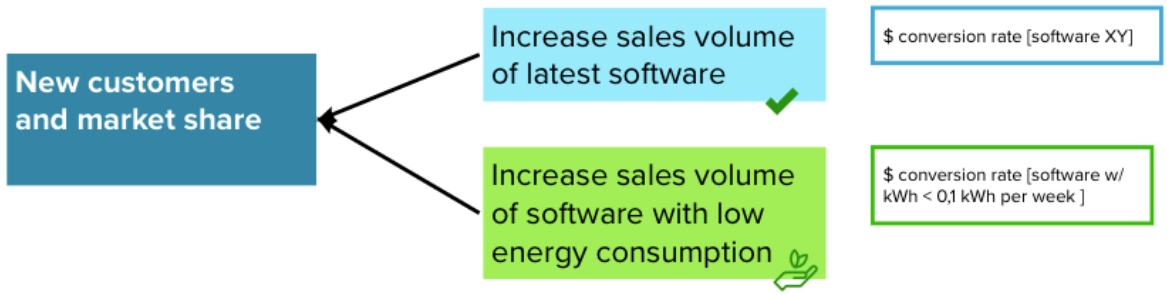

Figure 5 – Example of a "value driver tree"

The goal when setting up a value tree is to follow the **MECE principle** [22] (mutually exclusive and collectively exhaustive). MECE is a business mapping process wherein the optimum arrangement of information is exhaustive and does not double count at any level of the hierarchy.
For the Value Tree that means, that one sub-value-driver can only be associated to on single top-level item. The main branches of the value tree we set up for our project are:

- Business Growth
- Productivity Gains
- Risk Management

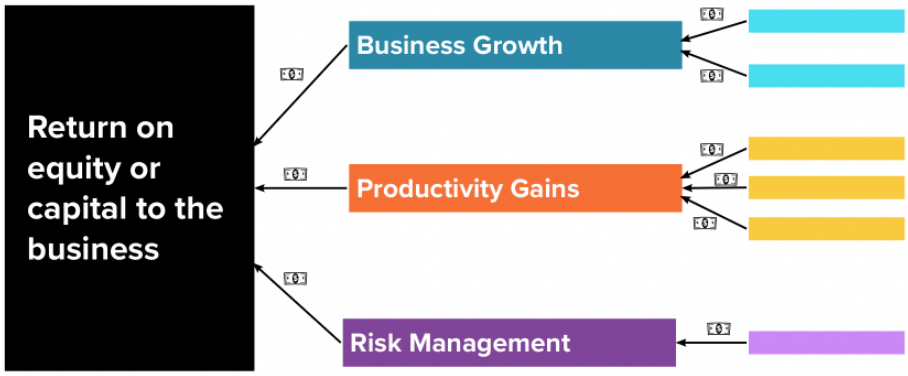

Figure 6 – Branches of a "value driver tree"

Each branch can have further ramifications like following for possible values for business growth:

- **New markets and geographies** ("Generate sales by expanding to other business areas, new customer segments or new geographical areas")
- **New customers and markets share** ("Generate sales by increasing transaction frequency or volume within existing business areas, customer segments or geographical areas")
- **Product and services innovation** ("Develop new or improve existing solutions to better meet customer needs.")

[22] https://en.wikipedia.org/wiki/MECE_principle

- **Long term strategy** (“Invest in and reach goals of a long-term strategy.”)

These can range from very general values to very specific ones. A value tree of that kind with specific value drivers and Key-performance-indicator descriptions (KPI) can then help to connect pain points / problems observed in the research to them. This contributes to the process of deriving or mapping requirements that by solving them with the software contributes to the specific values and therefore an overall business / project goal.

3.2.6 Pain Point / Hope Point Tracker

A Pain Point is any condition that adds difficulty to a job a person wants to get done.
A Pain Point tracker is therefore a document in which we strive to track everything that makes it more difficult for people to get their jobs done – and that in best case can be linked to an affected value driver of a business (see chapter 3.2.5 “Value driver of the software”).
It can be thought of a database of all the difficulties people encounter within a given system. It is an evolving work product that is used to continuously add, organize, and track findings from multiple design research activities (e.g., interviews, workplace observations, user testing, support tickets or social media feedback and ratings).
The Pain Point Tracker helps to collect and structure the pain points found. It also offers the possibility of prioritisation and, as mentioned above, assignment to the predefined value drivers. The structured collection of pain points facilitates the derivation of requirements. The Pain Point Tracker can also serve as a decision support system when deciding which features to implement in the product.

The structure is divided into five main areas:

1. Affected business area
2. Pain Point description
3. Business impact
4. Mitigation
5. Source

In each of these headings, further data are recorded for the observed pain points. These are as follows. The upper point represents the structuring point and below are the possible values for the point. This list makes no claim to completeness and can be continuously adapted.
Affected business areas

- „What offering is affected?“
    - Treatment: iv.tpa
    - Treatment: thrombectomy
    - Diagnosis: Imaging (MRT)
    - Diagnosis: Imaging (CRT)
    - All Treatments
- „What process step / journey stage is affected?”
    - Ambulance
    - Privat Transport

  - Emergency Room
  - Examination
  - Imaging
  - IV.tPA
  - Interpretation
  - Surgery
  - Stroke
  - Follow-up examination

Pain Point description

- Affected user / job role
  - Neurologist
  - Neuroradiologist
  - Neurology Resident
  - (triage) nurse
  - Patient
  - Relative
  - IT-Administrator
  - Financial Controlling

- Affected task
  - Data collection
  - Decision making
  - Feedback
  - Admission

- What is painful about this task (unstructured data).
  The description follows in best case following semantic:
  We believe that [target person]
  Feel [emotion]
  when [activity]
  we know this is true when [measurable goal / key metric] is achieved

- Supporting quote (unstructured data)
- Severity for affected person
  - Critical
  - Moderate
  - Minor
  - Suggestion or Positive
- Complexity causing the Pain Point
  - Integration complexity
  - Information complexity
  - Intention complexity
  - Environmental complexity
  - Institutional complexity

Business Impact

- Affected value driver
    - Business growth
        - From new markets and geographics
        - from new customers and market share
        - from product and services innovation
        - from long-term strategy
    - Productivity gains
        - from operational efficiency
        - from human capital management
        - from reputation pricing power
    - Risk mitigation
        - operational or regulatory risks
        - Reputational risks
        - Supply chain risks
        - Leadership and adaptability
- Affected KPI
    - Number of calls to senior Staff (e.g., neurologists)
    - Time to treatment
    - Precision of prediction
    - Length of admission time
    - Time to puncture
    - Overevaluation of patient condition
- Effect on “capital return” if resolved
    - Minor affect
    - Moderate affect
    - Major affect

Mitigation

- Mitigation Status
    - Ignore
    - Further research required
    - Mitigation required
    - Already mitigated
- Backlog item resolving the Pain Point

Source

- How did we learn about this Pain Point?
    - Primary research
        - interviews with target audience Date of research
        - survey of target audience
        - observation of target audience

        - testing with target audience
        - analytics or log file data
        - ratings, comments, tickets, forums, etc.
    - Secondary research
        - stakeholder assumption or analysis, word-of-mouth
        - industry or analyst reports, benchmarks, etc.
        - previous research with different research question and/or target audience
- Who added the Pain Point?
    - Jerusalem (Hadassah University Medical Center, Jerusalem, Israel)
    - Barcelona (Fundacio Hospital Universitari Vall d'Hebron - Institut de Recerca, Barcelona, Spain)
    - General
    - Heidelberg (University Hospital Heidelberg, Heidelberg, Germany)
    - Barcelona / Jerusalem
    - Charité (Charité – University Hospital Berlin)
- Where can I find the raw data?

3.3 Interpretation of research results within these Frameworks

3.3.1 Intended Purpose

Following intended purpose was defined for VALIDATE by the Consortium:

The medical intended purpose of the VALIDATE software is to provide a tool to enable a prediction about the individual treatment outcome in the treatment of acute ischemic stroke. This is based on the patient's individual initial health status and is geared towards the best treatment outcome applying the Modified Rankin Scale (MRS). It supports the diagnosis as well as the initiation of the appropriate therapy.

3.3.2 Trustworthy AI

At this stage, no interpretations or deductions have been made regarding possible requirements for the software. This will be done in the further course of the project in comparison with the work results of work package 1.

3.3.3 Value Drivers

The following list gives an overview of the possible "value drivers" for software in the field of clinical decision support systems for stroke that have been collected so far. The list does not claim to be complete. It is part of a continuous exchange among the consortium partners and will be adapted and updated as the project progresses.

In further phases of the project and inclusion of "value drivers" in the decisions of the software implementation, it is necessary to expand the overview to include the metrics with which the individual value drivers can be measured accordingly.

Value driver category	Sub-category	Value driver
Business Growth	New customers and market share	Expand Sales to European Hospitals with Stroke Units
		Expand Sales to European Hospitals who refer patients to specialized stroke hospitals
	Product and Services Innovation	Provide a new image evaluation service
		Develop solution to integrate AI aided clinical decision support machine learning models quickly.
		Develop an HL7 standardised interface library to interact with all relevant systems of record more quickly.
		Develop a tool to key in Data points for NIHSS documentation, display of data and combination of this data into the further clinical decision support
		Develop a tool to predict individual success of available stroke-treatments and MRS score after 3 months based on regular available patient data
	Long term strategy	Become a holistic treatment companion from first acute stroke treatment throughout all the stages of the Post-Stroke-Therapy
Productivity gains	Operational efficiency	Improve workforce efficiency in senior neurologist team
		Reduce days in hospital for patient after treatment Decrease time spent on treatment documentation
	Human capital management	Increase worker satisfaction of senior staff
		Increase worker satisfaction of residents
		Improve skills of residents in diagnosis
		Improve skills of residents for parameters influencing improved treatment outcomes

Risk management	Operational and regulatory risks	Decrease risk of a higher number on the Modified Rankin Scale after 3 months
		Decrease risk of penalties for data protection infringements
		Decrease risk of violating treatment guidelines
	Reputational risks	Decrease risk of low rating in public or insurance intern rating portals
		Decrease risk of lawsuits against doctors for treatment errors

Table 14: Value drivers

3.3.4 Pain Points derived from the research

The following list gives an overview of currently extracted “pain points” in the field of research that could be subject of review to possibly be addressed by the VALIDATE software. The list does not claim to be complete and is just at the beginning of being compiled.
It is part of a continuous exchange and observation of pain points will be part of the ongoing process of development. The list will be adapted and updated as the project progresses. The current status is included as Appendix B: Pain Point Tracker.

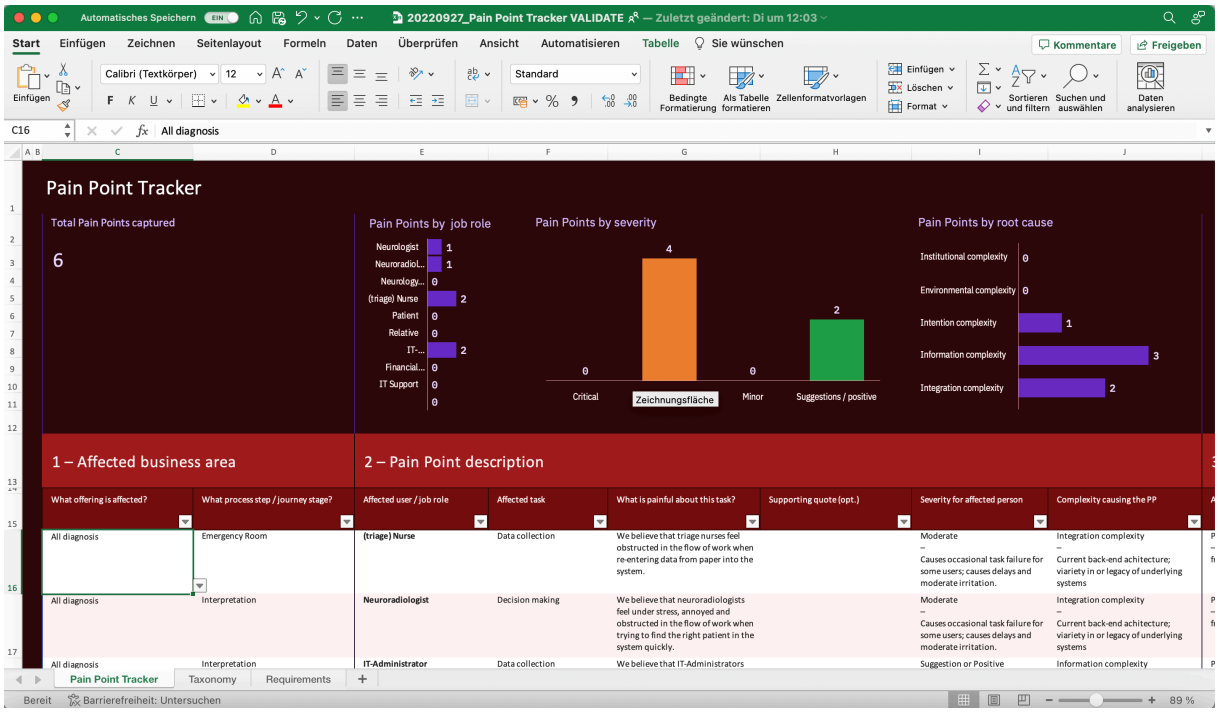

Figure 7 – Pain-Point-Tracker-Document (Excel-Spreadsheet)

4 Requirements overview

Based on our research and interpretation of the results, we derived three main categories to cluster both technical and user requirements.

The first category lists requirements for the software application and user interface of VALIDATE.

The second category contains requirements for artificial intelligence software to be applied in the clinic environment, especially considering the scalability of the application.

The third category enumerates additional benefits for hospitals. While not the primary focus of VALIDATE, these requirements can support the acceptance of a later application in the clinics.

For further planning and according to hill writing best-practices, the overview is concluded with the first three hills that the product team will focus on.

Technical and stakeholder requirements for the VALIDATE demonstrator

To support and improve decision making for ischemic stroke treatment, the VALIDATE application collects health parameters and images to predict potential treatment outcomes for a specific patient.
To guide the development of the application, we define the following requirements focusing on technical and stakeholder needs.

We follow the semantic of:

- **WHO**
- **WHAT**
- **WOW (or a little less: the goal that shall be achieved)**

No.	Task	User requirement	Type
R.001	Data collection	In addition to automatic data collection, residents and nurses can manually insert patient parameters to complete all necessary entries.	Explicit
R.002	Decision making	Neurologists and radiologists must be enabled to trace the decision support result to individual parameters, to retrace decision making.	Explicit
R.003		Neurologists and radiologists must see if/which parameters are missing and thus not included in the decision support, to assess the thoroughness of the result.	Explicit
R.004		Neurologists and radiologists can view the patient's data as well as the machine interpretation of the imaging results to support the decision-making process.	Explicit

R.005	Feedback	Neurologists and radiologists should have the option to give feedback on the algorithmic result to ensure the decision support stays beneficial for treating physicians.	Explicit
R.006		Neurologists and radiologists should be able to share and communicate edge cases in which they see limited reliability of the decision support system to improve the machine learning model's quality.	Explicit

Table 15: User requirements

No.	Task	Technical requirement	Type
R.007	Data collection	All stakeholders require the system to have secure access to and integration of systems of record to trust the CDSS.	Implicit
R.008		The consortium requires the system to adhere to HL7 and IEC62304 regulations to be able to pass the medical device regulation certification.	Explicit
R.009	Decision making	Physicians require the type of AI framework to be explainable to understand processing of the ML model.	Implicit
R.010		Physicians require the application to be available 24/7 to have access whenever a patient arrives.	Implicit
R.011		Data scientists require the ML model inference to be calculated on a central server to avoid ML framework version mismatches.	Explicit
R.012	Feedback	Software developers require management of in-app feedback to improve their application.	Implicit
R.013		Data scientists require ability and allowance of securely receiving edge cases from users to improve the ML model.	Implicit

Table 16: Technical requirements

Ai applications in the clinic environment – future application and scalability

Apart from image recognition to determine e-ASPECTS (CE-marked decision support tool for assessing stroke signs on plain CT brain scans by 'brainomix')[23], the use of artificial intelligence software in stroke treatment, and in the clinical context in general, is at an early stage. Therefore, VALIDATE serves as a scalable example for an Ai decision support tool for clinics.
To ensure the acceptance of a new tool, the needs and worries of stakeholders need to be considered. Especially, technical capabilities need to be communicated transparently to avoid

[23] https://www.brainomix.com/stroke/e-aspects/

overevaluation of predicted treatment results. To ensure technical scalability, the application must be robust, in case of errors or system failures and adaptable for diverse clinic infrastructures.

No.	Task	Stakeholder requirement	Type
R.014	Acceptance of decision support	Treating physicians and residents of non-specialised stoke clinics or university hospitals must be able to use and understand the decision support tool to improve its application in remote settings or smaller clinics.	Explicit
R.015		Physicians of varying seniority must be able to interpret the results of the decision support correctly and understand its limitations to improve their decision-making process.	Explicit
R.016		All stakeholders using the decision support tool must have a basic understanding of the underlying decision-making process to correctly assess the implications of the results.	Explicit
R.017		Stakeholders using the tool must be able to change the language of the interface to ensure the application can be understood.	Implicit
R.018	Use case scalability	Radiologists should be able to use the decision support alongside other mobile applications, remotely on their mobile device to ensure optimal assessment in remote situations or support cases.	Explicit

Table 17: AI stakeholder requirements

No.	Task	Technical requirement	Type
R.019	Acceptance of decision support	Data scientists require continuous monitoring of the evolution and learning cycles of the Ai to ensure the physicians are not presented an unreasonable response.	Implicit
R.020		Physicians require the application to be available 24/7 to have access whenever a patient arrives.	Implicit
R.021		Software developers require the system to manage application content in multiple languages to roll out the application in multiple languages.	Implicit
R.022		Physicians require a highly responsive application to not wait in an acute case.	Implicit
R.023	Use case scalability	IT administrators require the backend application to be deployed on-premises and/or on cloud environments to reuse their existing infrastructure.	Explicit

R.024		IT administrators require the backend application to use container technology to reuse their current infrastructure.	Explicit
R.025		Software developers require the integration pattern to be extensible to connect to all current and future relevant systems of record to avoid technical debt.	Implicit
R.026		IT administrators require the system to allow for deployment in classic dual homed DMZ pattern to support their current infrastructure.	Explicit

Table 18: AI technical requirements

Improve planning of hospital capacities

During our research, we discovered several hopes and challenges a decision support tool could address in the clinic. Due to staff shortages and demographic change, artificial intelligence could in the future help to assess treatment decisions faster and thereby more efficiently. The discovery of new correlations through the analysis of more parameters, could further help to improve the planning of hospital capacities and shape decision making in the future.
Following, we list these hopes and challenges as stakeholder and technical requirements.

No.	Task	Stakeholder requirement	Type
R.027	Improve hospital processes	More junior neurologists and residents, must be aided to become more secure in their decision making through the decision support too, to reduce communication with senior staff after-hours.	Explicit
R.028		Non-specialised clinics must be assisted in their initial decision-making through the decision support system to have a better idea if the patient shall be transported to the stroke centre.	Explicit
R.029		Physicians or referring clinics should be able to assess the development of the results given by the decision support, to better assess whether to have a patient transported to a stroke clinic.	Explicit

Hills

Following the formal semantic of describing a hill, these first three hills are written to meet a specific, clearly defined user problem and are informed by user research.

No.	Hill description
H.001	A neurologist can view all stroke related patient data within 1 minute after patient admission.

H.002	A neurologist is provided a visualization of the likelihood distribution for the patient's mRS shift per treatment method to take an even more qualified decision for treating the patient.
H.003	A neurologist can provide feedback on the information and machine results they currently view to continuously improve the user experience and machine learning model quality.

Table 19: Hills

5 References

Number	Type	Source	Chapter	Date
1	IBM Enterprise Design Thinking	https://www.ibm.com/design/thinking/	1. Methods of Research and Analysis	16.12.2022
2	Article on Co-Creation Sessions on Website designkit.org	https://www.designkit.org/methods/co-creation-session	1.1 Workshops	16.12.2022
3	Mural Website	https://www.mural.co	1.1 Workshops	16.12.2022
4	Article on Stakeholder-Interviews from the Nielsen Group (23.10.2022)	https://www.nngroup.com/articles/stakeholder-interviews/	1.2 Interviews	16.12.2022
5	Article on "Shadowing" in Design Thinking on Website of Think Design	https://think.design/user-design-research/shadowing/	1.3 Site visits	16.12.2022
7	Article on "Modified Rankin Scale" on Stroke-manual.com (22.02.2022)	https://www.stroke-manual.com/modified-rankin-scale-mrs/	2.1.2 Hospital admittance	16.12.2022
8	Article about the prestroke mRS	https://n.neurology.org/content/about-prestroke-mrs	2.1.2 Hospital admittance	16.12.2022
9	Article on National Institute of Health Stroke Scale (19.08.2008)	https://strokengine.ca/en/assessments/nihss/	2.1.2 Hospital admittance	16.12.2022
10	Company Website for the App mRay	https://mbits.info/mray	2.1.3 Imaging	16.12.2022
11	Company Website of RAPID AI	https://www.rapidai.com/stroke	2.1.3 Imaging	16.12.2022
12	Company Website of the App Join	https://g.allm.net/join/	2.1.3 Imaging	16.12.2022
13	Article on "Alberta Stroke Program Early CT Score" (22.03.2021)	https://www.stroke-manual.com/aspect-score/	2.1.5 Interpretation	16.12.2022
14	Company Website of Brainomix	https://www.brainomix.com	2.1.5 Interpretation	16.12.2022
15	Effectiveness of requirements elicitation techniques: empirical results derived from a systematic review	Davis A, Dieste O, Hickey A, Juristo N, Moreno AM (2006) Effectiveness of requirements elicitation techniques: empirical results derived from a systematic review. In: Proceedings 14th IEEE international symposium on requirements engineering (RE'06). IEEE Computer	3.1.2 Managing technical requirement	2006

		Society Press, Los Alamitos, pp 176–185		
16	Article on “Hills” in the Enterprise Design Thinking Framework of IBM	https://www.ibm.com/design/thinking/page/framework/keys/hills	3.1.3 Semantics of requirement	16.12.2022
17	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices	https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX:32017R0745	3.2.1 Intended purpose of the medical product	16.12.2022
18	Website about the “Design for AI” Practice at IBM	https://www.ibm.com/design/ai/	3.2.4 Designing for AI	16.12.2022
19	Essential guidance for designer following the “Design for AI” principles of IBM	https://www.ibm.com/design/ai/team-essentials	3.2.4 Designing for AI	16.12.2022
20	Website about the “IBM Garage” Framework	https://www.ibm.com/garage	3.2.5 Value driver of the software	16.12.2022
21	Website on the “Value driver model” of the UN Global Impact	https://www.unglobalcompact.org/library/811	3.2.5 Value driver of the software	16.12.2022
22	Wikipedia Article on “MECE Principle”	https://en.wikipedia.org/wiki/MECE_principle	3.2.5 Value driver of the software	16.12.2022
23	Product Website of the decision support tool e-aspects of Brainomix	https://www.brainomix.com/stroke/e-aspects/	4. Requirements overview	16.12.2022

6 Appendix A: Technical Questionnaire

Category	Data and Development Assessment Questions
Data	What is the data collected and used for treating an ischemic stroke patient? (Patient, lab, imaging, other)
	Where is this data stored? (Applications, servers, on-premise/cloud, etc.)
	How are data sets linked?
	As part of testing strategy, do you restore production data into non-prod environment to do testing?
	What are the ways of accessing this data? (Database access, APIs, data lake/access layer, protocols)
	What are restrictions accessing the data? (Encryption at rest/in transit, access, consent, AuthN/AuthZ, standards, protocols)
Development	Can we reuse (parts of) your development/deployment environment(s)?
	If yes, is there an onboarding documentation?
	Can we develop applications on a public/private/distributed cloud to create a hybrid cloud infrastructure?
	Do you already have a cloud platform we can reuse?
	Do you already have a Kubernetes cluster or a server, running Docker containers, we can reuse to deploy docker containers?
	If not, what is the infrastructure we can use to deploy an application?
	What firewall hardware/software is currently in use and what rules have been implemented?
	Are there existing computational resources for Machine Learning training?
	If yes, does it contain GPUs? Is it possible to access your data storage (medical records, image archive) from the environment of these resources?
Artifacts	Can you provide an infrastructure architecture diagram?
	Can you provide a network topology diagram?
	Can you provide a data catalogue for the respective data?
	Is your IT landscape certified (i.e., ISO/IEC 27001)?

Table 20: Technical questionaire

7 Appendix B: Pain Point Tracker