

Call: HORIZON-HLTH-2021-TOOL-06

Topic: HORIZON-HLTH-2021-TOOL-06-03

Funding Scheme: HORIZON Research and Innovation Actions (RIA)

Grant Agreement no: 101057062



AI powered Data Curation & Publishing Virtual Assistant

Deliverable No. 1.3

Business requirements for G1

Approval by the European Commission Pending

Contractual Submission Date: 30/06/2023

Actual Submission Date: 31/07/2023

Responsible partner: P7- MUG



**Funded by
the European Union**

Grant agreement no.	101057062
Project full title	AIDAVA - AI powered Data Curation & Publishing Virtual Assistant

Deliverable number	D1.3
Deliverable title	Business requirements for G1
Type ¹	R
Dissemination level ²	PU
Work package number	WP1
Work package leader	P8 - NEMC and P2 - b!loba
Author(s)	Petros Kalendralis (UM), Isabelle de Zegher (b!lo), Michaela Kargl, Monika Kindslehner (MUG), Kerli Norak (NEMC), Daniel Dallos, Bela Bihari (GND), Isabella Cina (EHN)
AIDAVA Reviewer(s)	GND, b!loba, EHN, MID
Keywords	Requirements, acceptance criteria

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the European Health and Digital Executive Agency (HaDEA).

Neither the European Union nor the granting authority can be held responsible for them.

Document History

Version	Date	Description
V1	31.07.2023	First submission

¹ **Type:** Use one of the following codes (in consistence with the Description of the Action):

R: Document, report (excluding the periodic and final reports)
 DEM: Demonstrator, pilot, prototype, plan designs
 DEC: Websites, patents filing, press & media actions, videos, etc.

² **Dissemination level:** Use one of the following codes (in consistence with the Description of the Action)

PU: Public, fully open, e.g. web
 SEN: Sensitive, limited under conditions of the Grant Agreement

List of Abbreviations and definitions

The abbreviations and definitions used in the deliverable are based on the [AIDAVA Glossary](#)³.

Key definitions for this document:

Terms	Description
Personal Health Knowledge Graph (PHKG)	Format for storing curated personal health data: all data sources from a patient are transformed, curated/cleaned and integrated into a single knowledge graph
Health Data Intermediary (HDI)	Organisation allowing citizens to access, manage their personal health data and control how it is shared. In AIDAVA, they are managing non-hospital data (e.g. medical device app, patient reported outcomes, GP data).
AIDAVA prototype	Software application (or tool) being developed as part of the AIDAVA project, to support ingestion, curation and publishing of personal health data; it will be deployed within the hospital. The AIDAVA prototype is the core components of the AIDAVA platform which also include the Health Data Intermediaries managing non-hospital data, as well as the patient Interional Patient Summary (IPS).
Requirements = functional + non-functional requirements	Requirements are clear, concise, and specific statements that describe what a software system should do or the qualities it must possess. Requirements can be differentiated into functional requirements and non-functional requirements
Functional requirements (FR)	Specific features or capabilities that a system or application must have in order to meet the needs of its users: what the AIDAVA health data curation and publishing virtual assistant does . These requirements describe the AIDAVA health data curation and publishing virtual assistant's behaviour, or what it must do.
Non-functional requirements (NFR)	Describe the qualities that a system or application must possess in order to be considered usable or effective. These requirements do not describe what the AIDAVA health data curation and publishing virtual assistant does, but rather how it does it .
Epics	Agile term. Group of requirements that represents a significant and complex piece of work. Epics are used to capture and describe requirements or features that are too big to be completed in a single development iteration (sprint) and require further decomposition into smaller, manageable user stories.
Product	A software product is the final, fully-developed version of a software application that is intended for release and use by end-users. It is the result of the complete software development process, which includes requirements gathering, design, coding, testing, and deployment. A software product undergoes rigorous testing and quality assurance to ensure it meets the specified requirements, is reliable, and performs well under various conditions. Once developed and released, the software product is ready for commercial use or distribution to end-users (source: ChatGPT)
Prototype	A software prototype is an early, incomplete, and simplified version of a software product. It is created to demonstrate and validate specific features, design concepts, or ideas before investing further resources in the full

³ <https://www.aidava.eu/helpdesk/glossary>

Terms	Description
	development process. Prototypes are often used in the initial stages of a project to gather feedback from stakeholders, refine requirements, and make necessary adjustments based on user input. They can be quick and low-fidelity representations of the final product, aimed at discovering potential issues and validating design decisions. (source: ChatGPT)
Software as a Medical Device (SaMD)	A Software as a Medical Device (SaMD) refers to software intended to be used for medical purposes that can function on its own or be integrated into other hardware or software systems. SaMD operates solely through software and does not have any physical components (such as medical devices). (Inspired by ChatGPT)

Table of contents

Executive Summary	6
1 Introduction.....	7
1.1 Aim of task T1.3.....	7
1.2 User groups identified for the AIDAVA virtual assistant prototype	7
1.3 Prototype versus product.....	8
2 Description of Activities.....	10
2.1 Elicitation of requirements from the users	10
2.2 Elicitation of non-functional requirements	14
2.3 Consolidation and prioritisation of requirements.....	15
2.4 Acceptance criteria.....	16
2.4.1 Acceptance criteria for functional requirements	16
2.4.2 Acceptance criteria and acceptance process for non-functional requirements	18
3 Results	19
3.1 Functional requirements	20
3.1.1 Data ingestion.....	21
3.1.2 Data curation	25
3.1.3 User interaction and multilingual use	31
3.1.4 Data publishing.....	34
3.1.5 User management	38
3.1.6 Data use.....	41
3.1.7 Quality management.....	44
3.1.8 Integration (APIs, usage in hospitals)	47
3.2 Non-functional requirements.....	50
3.2.1 Performance	50
3.2.2 Scalability.....	50
3.2.3 Availability	51
3.2.4 Reliability	51
3.2.5 Maintainability	52
3.2.6 Serviceability	53
3.2.7 Security and data privacy	54
3.2.8 Regulatory	55
3.2.9 Usability.....	56
3.2.10 General design principles	57
3.2.11 Documentation requirements.....	58
4 Conclusions.....	61
5 Next steps.....	61
6 Annexes	63
6.1 Photos of the workshops.....	63

Executive Summary

This document provides a detailed description of the business requirements – functional and non-functional requirements - of the AI-powered data curation and publishing assistant, aimed at supporting patients (and expert curators) in managing and cleaning their personal health data – in compliance with ethical and regulatory requirements.

The first objective of the AIDAVA project is to demonstrate that the prototype works in a realistic - though strictly controlled through an assessment protocol approved by the local ethical committees as described in Deliverable D1.4 - environment, considering data privacy and regulatory constraints. The second objective is to develop a solution that can be transformed into a full-fledged product, including MDR certification; to meet this second objective we decided to keep all requirements that were captured, and to indicate if they were in scope of the prototype or only in scope of the future product. While the product related requirements will not be developed during the AIDAVA project, it is expected that the technology architects will take these into account when defining the architecture of the system and ensure the prototype can smoothly evolve toward a marketable product.

The requirements were gathered through a structured approach.

- First, the **user journey** was defined. It includes the following steps: registration and logging, upload and ingestion of patient personal data from different sources, integration & curation of data from these sources, use of the resulting curated data, deletion of account (and data).
- Second, the **requirements** were gathered along the steps of this user journey for the different users - and potential customers - identified for the prototype: patient, expert curator, data users but also administrator and third-party app developers. Capture of requirements took place mainly through structured workshops and on-line meetings across the different sites.
- The requirements across the users were then consolidated and clustered in **epics**, defined in Deliverable D2.3 Solution Design; duplicate requirements across user groups were deleted.
- Each consolidated requirement was then provided with a level of **severity** (blocking/crucial, major, minor, out of scope) indicating the importance of having the requirement successfully developed. While assessing the severity, specific attention was given on data privacy, security, and regulatory process as well as on patient needs and acceptability.
- Finally, the team identified the need to have the requirement in the prototype or only in the future product.

A total of 596 requirements were gathered with the different users; after consolidation across users and prioritisation, 277 requirements were considered as needed for the prototype (46 blocking, 178 major, 53 minor) and 99 additional ones were considered in scope for a product. As the need for information and documentation came regularly while gathering requirements, the content of four different documents was drafted.

The content of the business requirements will be consolidated with the automation requirements from Task 2.1 and from quality management requirements from Task 4.2 and transformed by the development team into features-centric user stories to be further used as the basis of the development.

The content of the deliverable will be re-assessed – and potentially adapted – after the evaluation of Generation 1 of the prototype to deliver Generation 2.

1 Introduction

1.1 Aim of task T1.3

This deliverable is the result of the work conducted during Task 1.3 in Work Package 1 of the AIDAVA project. The aim of this task was to elicit business requirements for the first generation (G1) of the ‘AI-powered data curation and publishing assistant’ to be developed in the AIDAVA project. Business requirements describe from the point of view of a system’s stakeholders (i.e. users, consumers, customers) *what* functionalities the system shall provide, and *why* these functionalities are needed. Consequently, the primary goals of Task 1.3 were to:

- Identify user groups of AIDAVA and implement independent workshops to collect a list of business requirements for each user group.
- Review and consolidate all business requirements to specify requirements in scope and out of scope of the project and prioritise all requirements based on level of importance to users.

Five user groups were identified as explained in Section 1.2. Business requirements workshops were held for each user group to discuss the ‘user journey’ to ensure that the AIDAVA health data curation and publishing virtual assistant meets the expectations and needs of users, and to better understand how to provide an intuitive interaction, considering different levels of digital and health literacy. As a result of these workshops held across all users, five lists of business requirements were created for each user group and further processed as described in Section 2.1.

1.2 User groups identified for the AIDAVA virtual assistant prototype

For the AIDAVA prototype virtual assistant, the following groups of potential users were identified. As mentioned in the glossary, the overall solution includes the virtual assistant prototype deployed within hospital settings as well as the Health Data Intermediaries (HDI) solution. This document focuses on the AIDAVA prototype.

User	Roles and description of participants in the user requirements
Patient	<p>Role. They are the main user group. As expert curator, the patient ingests their personal data from the different source systems, initiates the curation process and answers questions from the AIDAVA health data curation and publishing virtual assistant whenever needed.</p> <p>As data consumers, the patients request to forward their personal data to the local Health Data Intermediary (HDI) for further visualisation.</p> <p>Participants. Patients were represented by ‘patient consultants’ from the 2 patients associations (P-EHN and P-ECPC). They are patients - sometimes with serious health conditions - who were selected by each association and agreed to participate in the project as consultants (with a daily fee recommended by the European Patient Forum). The patient consultants were introduced to the project during a special onboarding session; they contributed to the business requirements but also to the evaluation of the study assessment. They will also be asked to provide input during the prototype development and they will be requested to pre-test the AIDAVA health data curation and publishing virtual assistant - with synthetic data - before site patients.</p>

User	Roles and description of participants in the user requirements
(Data) Curator	<p>Role. Support patients in curating their data, whenever they are able to answer questions that require a level of health literacy or digital literacy that the patient does not have.</p> <p>Participants. Existing hospital staff with medical knowledge/know-how in the healthcare field and with computer/data literacy who are currently curating data in the hospital for clinical research purpose (e.g. maintain a clinical registry); they will benefit from using AIDAVA in their everyday work if AIDAVA reduces their workload when curating the patients' data.</p>
Data user	<p>Role. Access to data extract, published from AIDAVA (with patient consent) to answer a specific need in clinical care or in clinical research.</p> <p>Participants. Data stewards, health care providers, scientific staff who use these patients' data to do their everyday tasks in the field of medicine and/or research.</p> <ul style="list-style-type: none"> • Data Stewards who need to extract data to support researchers. • Breast Cancer specialist who can perform analytics on a 'Breast Cancer' registry spread across the 3 sites. • Cardiovascular specialist who has access to an automatically computed risk score (instead of having to compute it manually) and can more effectively monitor CVD risks.
Administrator (AIDAVA and SITE)	<p>Role. Responsible for configuring, integrating, and testing the solution</p> <ul style="list-style-type: none"> • with all <u>components reusable across sites</u>, before actually deploying the AIDAVA health data curation and publishing virtual assistant in local sites (AIDAVA Administrator). • at local level, to support local adaptation, local user registration and support (Site Administrator). <p>Participants. Local data scientist with support of local IT staff, development team</p>
3rd- party app developer	<p>Role. They develop applications which utilise AIDAVA's APIs (application programming interfaces)⁴ either to provide health data to AIDAVA or to extract and reuse curated health data from AIDAVA.</p> <p>Participants.</p> <ul style="list-style-type: none"> • CTO of healthcare analytics company • Professor at school of engineering and computer science • Director of institute of medical informatics • Developers of institute of medical informatics • Director of Medical and eHealth at a HDI • Management member at a different HDI

1.3 Prototype versus product

Moving from a prototype to a product may require significant refactoring to fulfil additional - product related - requirements. While validating the requirements across the different user groups, we made the difference between the requirements for the prototype in scope of AIDAVA and the requirements

⁴ In the context of the prototype to be delivered during the project, all integration will be done through existing and/or prototype APIs and/or through asynchronous data transfer based on predefined data transfer specification to minimise disruption with productive systems.

for a marketable product. To establish this, we also considered our contractual requirements to the European Commission following quotes from the Technical Annex of DoA (Part B) - see table below.

Section 1.1.3 Position in terms of R&I maturity (incl. TRL level)

Subsequent deployment models, integration and security aspects, and medical device certification requirements will be considered in the technical architecture but not developed in the prototype.

Section 1.2.7. Research data management and management of other research outputs

From an ethical point of view, the AIDAVA-curated data will NOT be presented to clinicians and patients as being reliable for decision making, but as a research prototype output to be validated before being used—if they wish—in the care process. The partners intend, provided the project demonstrates success, to obtain Medical Device Regulation (MDR) certification after the project, so that the outputs can be accepted and used. Since a number of the quality processes for certification need to be in place from the beginning, through the work packages, we will progressively build up the evidence that will later be required as part of MDR submission.

Section 2.1.2. Requirements and potential barriers

Barrier 4: The AIDAVA prototype qualifies as a medical device (software as a medical device), expected to be used in the future for health care decision making. Achieving MDR (probably Class 2a) Certification within the lifetime and resources of the project is not feasible as we want to focus on the innovative components rather than at productizing the software.

- *Mitigation. There is recognition that research prototypes can still be piloted within health care environments provided that there is full transparency of their status, and they are regarded as probationary tools to be evaluated and whose outputs cannot be relied upon for decision making. We will adopt this approach within the project, with the ambition of realising MDR Certification after the project. We will therefore put in place the necessary formative steps such as evidence traceability and robust documentation, so that we are in a sound position to apply for MDR Certification shortly after completion of the project.*
- *Time impact. None expected*

In short, our first priority in the project is to develop a prototype while keeping in mind the potential of productization.

2 Description of Activities

For the AIDAVA project, workshops with the user groups mentioned in Section 1.2 were conducted from February to April 2023 in order to identify the needs and the requirements of the user groups for the AIDAVA virtual assistant for health data curation and publishing. The primary objective of these activities was to identify the needs and requirements specific to Health Data Ingestion, Health Data Curation, Checking and Using Curated Data, and System Usage.

2.1 Elicitation of requirements from the users

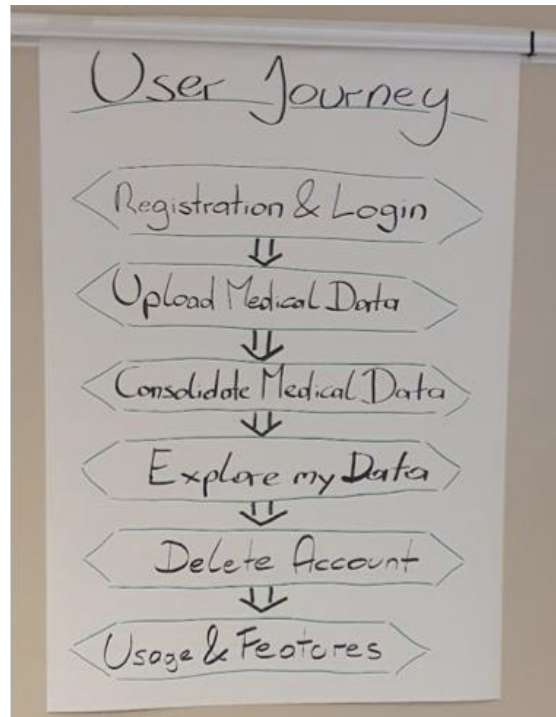
Workshops were conducted by 9 different partners, across the different user groups, as shown in the table below. During these workshops all requirements - functional and non-functional requirements - were gathered. Elicitation of non-functional requirements, through online meetings with the - AIDAVA and SITE - administrators, consolidated from input from the user workshops, is explained below.

	Patients	Expert curators	Data users	Administrators	3rd-party app developers
University of Maastricht, The Netherlands (UM)		yes	yes	yes (SITE admin)	
North Estonia Medical Centre, Estonia (NEMC)		yes	yes	yes (SITE admin)	
Medical University of Graz, Austria (MUG)	yes	yes	yes	yes (SITE admin)	
Digi.me Ltd, United Kingdom (DME)					yes
MIDATA Cooperative, Switzerland (MID)					yes
European Heart Network AISBL, Belgium (EHN)	yes				
European Cancer Patient Coalition, Belgium (ECPC)	yes				
b!loba, Belgium (b!lo)				yes (AIDAVA admin)	
Egnosis, Romania (GND)				yes (AIDAVA admin)	
TOTAL participants	8	7	7	8	10

In total, workshops were conducted with 40 participants. Different settings were chosen for different participant groups. While the patient workshop took a whole day (8 hours), the other workshops with the remaining user groups were held either online or face to face at the premises of the respective partner for 2-3 hours.

At the start of the workshops, the participants were introduced to the AIDAVA project for the first 15 minutes of the workshop and then they were asked to participate in several small brainstorming sessions for elicitation of requirements. The photos of the workshops can be found in the Annex of this document.

The requirements for each user group were collected following the user journey of the respective user groups described below. For each step in the user journey, the participants were asked questions and then given time to brainstorm to find out all the specific requirements for the AIDAVA prototype and product.



The questions were already prepared in a way that first, the participants were asked a general question, e.g. "What is important for me when the AIDAVA health data curation and publishing virtual assistant asks me for help with data curation?". After that, there were several more specific follow-up questions that were asked to the participants in case the answers had not come up in the discussion already, e.g. "Which context information do I need for manual data curation?".

Every requirement was written on an index card and continuously collected and put up on the pin-board or laid out on the table so they could be seen by every participant.

3. Check the data (QA, data quality checks)
4. System usage (Potential integration of the AIDAVA health data curation and publishing virtual assistant within the hospital environment)

Expert curators' workshop: The requirements were categorised in four different steps:

1. Medical data input (Important aspects regarding the ingestion or upload of medical data to AIDAVA)
2. Medical data curation (Automatic data curation, identify the cases where the AIDAVA health data curation and publishing virtual assistant asks for help)
3. Checks of curated data (QA of the data curation process)
4. System usage (Interaction between the expert curators and the AIDAVA health data curation and publishing virtual assistant, functionalities)

3rd-party app developers' workshop: The requirements were categorised in four different steps:

1. Upfront information (Important information before uploading data from AIDAVA to the third-party app and the other way around)
2. Retrieve medical data (data format, interfaces, documentation, versioning)
3. Upload medical data (data format, interfaces, documentation, versioning)
4. System usage (Important aspects during the daily use of AIDAVA, stability, functionality)

The workshop was held electronically. The 10 participants were equally distributed to two discussion rooms, with each room going through all topics. During the workshop, an electronic flip chart/post-it note system was used to collect input from the participants. Participants provided several inputs per topic. Subsequently, participants elaborated on their inputs and the inputs were discussed. After the workshop, the collected participant input was formulated into requirements. The formulated requirements were sent to the participants for review.

SITE (hospital) administrators' workshop: The requirements were categorised in four different steps:

1. Installation and set-up of the AIDAVA health data curation and publishing virtual assistant (Security, data privacy, installation process)
2. Integration with the hospital information system and HDI (Data access, interfaces, system infrastructure, data privacy)
3. User management (Definition and management of default user/profiles, user account creation, maintenance, deletion)
4. Maintenance (Updates, licence, documentation)

Following the initial workshops, the administrators - in alignment with the senior developer - expressed the need to have an in-depth description of the "admin" requirements as non-functional requirements. A set of additional dedicated workshops were held under the coordination of b!loba and Egnosis - responsible for development and being the AIDAVA administrators - to elicit these requirements, as described in Section 2.2 below.

After the workshops, each of the needs and expectations stated by the workshop participants and collected on the index cards or in the workshop notes were formulated into requirements. For this, a template was provided in the following form:

As a [user group], [doing step of the user journey], I want [needed functionality stated by the WS participants], so that [reason/expected benefit stated by WS participants].

When formulating the requirements, it was made sure that each requirement

- has a need,
- is verifiable and
- is clear and cannot be misunderstood.

ID	Actor "As a ..."	Epic "...doing/ situation." .."	Description "...I want..."	Rationale "...so that..."	Source of this Requirement
BR-P052	patient	helping with data curation	I want the system to provide me with suggestions of how to address the issue, which is raised by the system, and in addition give me the option to make my own fix, if I find the suggestions provided by the system are not appropriate/good	so that I can help the system with clarifying ambiguities found in my data	WS with patients consultants, Brussels, 20230228

After formulating the requirements, each partner had a requirement list for each workshop they held. As several workshops were held for data users and expert curators at the different premises, those lists were consolidated into one requirement list per user group.

The steps mentioned above, delivered a group of user stories that were then aligned with the epics identified for D2.3 Solution Design.

The (site) administrator requirements were incorporated into the non-functional requirements as described in Section 2.2.

2.2 Elicitation of non-functional requirements

The non-functional requirements were established with the hospital (SITE) administrator and the AIDAVA administrator (senior developers) through a series of 5 online meetings coordinated by b!loba and Egnosis (GND). Requirements were divided into different typical categories (Performance, Scalability, Availability, Reliability, Maintainability, Serviceability, Security & Data privacy, Regulatory, Usability, General Design Principles and Documentation). A draft description of the requirements was established based on input from ChatGPT, validated and - whenever needed - modified by the team during the on-line meetings.

In a second step, non-functional requirements issued by the users through the different workshops (e.g. need for HelpDesk or documentation) were included in the list.

While defining and validating the non-functional requirements, the team considered the following aspects:

- AIDAVA is not generating any new data - except for clarification purposes, when the AIDAVA health data curation and publishing virtual assistant is asking a question (e.g. clarification on the timing of an event).
- The curation and publishing tasks of AIDAVA are not time critical; it is a transformation of data to increase their interoperability and reuse.
- While it is hoped that most of the curation and publishing process can be automated, we can still expect that input from the users (patient or expert curator) will be needed. Reproducibility of the Personal Health Knowledge Graph (PHKG) - storing the curated personal data - from

the different data sources can therefore not be guaranteed without keeping a strict audit trail specifying what information was entered by the time by whom, at which part of the process to answer which query from the AIDAVA health data curation and publishing virtual assistant.

- Any transaction in the AIDAVA health data curation and publishing virtual assistant must have an audit trail.

2.3 Consolidation and prioritisation of requirements

Following the requirement workshops across user groups, the requirements with duplicate meaning were combined into a single one and consolidated into one table per user group, as described in section 2.1. The prioritisation of the consolidated requirements was discussed and agreed upon during online meetings for 2 hours at a time (in total 13 meetings). The meeting participants included the project's clinical coordinator, as well as representatives from the Health Data Intermediaries (HDI), the clinical sites, the development team and the patient organisations.

While the focus on AIDAVA is on the development of a prototype, the expectation from the consortium partners is that - if the prototype is successful - a product (software as a medical device) should be developed. While developing the requirements, we realised that many of the requests of the workshop participants were rather aimed for a finished product than a prototype. In addition, several partners expressed the wish that the prototype should not be a "throw away" prototype, but rather would constitute a reusable basis, therefore a starting point for a marketable product.

Moving from a prototype to a product may however require significant refactoring to fulfil new requirements if not thought out properly from the onset in the system architecture. While this deliverable is focusing on the first generation (G1) of the prototype⁵, we decided to keep all requirements for G1 and G2 as well as product requirements, but indicated whenever a requirement was considered needed for the product but not relevant for the prototype. The requirements which were considered for the product only were not further treated in Task 1.3, and are out of scope of the development.

It is expected that this will allow the technology architects to include - as much as possible - the critical requirements for an end product in the technology architecture of the prototype. It is also expected that the requirements collected now will need to be adapted for G2 in Deliverable D1.9.

All requirements were categorised as

- in scope of the prototype and/or the product with the following level of severity in terms of acceptance
 - blocking: critical, if not present the AIDAVA health data curation and publishing virtual assistant is not acceptable
 - major: must be present
 - minor: nice to have

⁵ G1 = first generation with basic functionalities; G2 = bug fixes + improved Human Computer Interface (explainability) + additional automated tools which should improve performance versus G1 (measure following certain parameters).

- out of scope (i.e. belonging to a complete solution based on AIDAVA but including aspects such as digital wallet, dynamic consent,...).

Original Requirement ID	Actor "As a ..."	Situation "...doing/ situation ..."	Description "...I want..."	Rationale "...so that..."	Severity	Prototype	Product
BR-P052	patient	helping with data curation,	I want the system to provide me with suggestions of how to address the issue, which is raised by the system, and in addition give me the option to make my own fix, if I find the suggestions provided by the system	so that I can help the system with clarifying ambiguities found in my data	major	Yes	Yes

After reviewing the initial requirements to ensure we did not miss any aspect to support the use cases - described in Deliverable D1.1, and endpoints described in the Study Protocol developed as part of Task 1.4 - the partners reviewed these initial requirements and completed them whenever needed (e.g. computation of study protocol endpoints such as quality score and CVD SMART risk score).

After collecting all the requirements and reviews from the responsible parties, all business requirements were compiled into one large consolidated table. Each requirement was grouped in epics defined in the solution design in D2.3, comments cleaned and remaining duplicates as well as out of scope requirements deleted. The consolidated requirement was provided with a new identification number, linked with the original requirements, to ensure traceability from - potentially multiple - requirements from different users. The list was reviewed by all three sites.

2.4 Acceptance criteria

Acceptance criteria are the criteria used to evaluate whether the prototype and later the product fulfil the requirements from the different user groups.

2.4.1 Acceptance criteria for functional requirements

For every functional requirement that was defined relevant for the prototype in the clarification sessions, user acceptance criteria were defined and then reviewed.

User group	Partners responsible for definition of acceptance criteria	Partners reviewing the acceptance criteria
Patients	MUG	EHN, GND, b!lo
expert curators	NEMC	UM, MUG, GND
Data users	UM	NEMC, MUG, GND
3rd-party app developers	MUG + GND	MID

The rules for defining acceptance criteria were:

1. Every acceptance criterion by itself needs to be very specific and measurable. It must be evident if a criterion is reached or not. If needed, you will have to add useful measures, e.g. once a day, minimum 90% of xxx, or similar.
2. One row of acceptance criteria cannot hold more than one criterion – be very mindful of using the word “and” or commas or second sentences, they can indicate the need to split the criterion into several criteria.
3. All of the acceptance criteria of one requirement together should cover every aspect of the respective requirement including the rationale.

The acceptance criteria were added to the requirements in the existing requirements tables.

Epic	Original Requirement ID	Actor "As a ..."	Situation "...doing/ situation ..."	Description "...I want..."	Rationale "...so that..."	Acceptance Criterium ID	Acceptance Criterium	Severity	Prototype	Product
02_ Curation	BR-P052	patient	helping with data curation,	I want the system to provide me with suggestions of how to address the issue, which is raised by the system, and in addition give me the option to make my own fix, if I find the suggestions provided by the system are not appropriate/good	so that I can help the system with clarifying ambiguities found in my data	AC0064.1	The system provides options for solving the raised data curation issue when asking the user for help	major	Yes	Yes
02_ Curation						AC0064.2	The user can either select one of the provided answer options or enter a user-specified answer to the system's question	major	Yes	Yes

Acceptance of the prototype will be based on the following metrics:

Epics	Weight	Minimum required (% of "pass")		
		Blocking	Major	Minor
Data Ingestion	10%	100%	80%	As much as possible (to be confirmed after delivery of user stories in D3.2)
Data Curation	15%		90%	
User Interaction	15%		80%	
Data Publishing	10%			
User Management	15%			
Data Use	10%			
Quality Management	15%			
Integration	10%			
TOTAL - formula	Sum	Sum all Weight * % pass		
TOTAL - value	100%	100%	80%	NA

2.4.2 Acceptance criteria and acceptance process for non-functional requirements

Each category in the non-functional requirements' list was provided with a weight, clarifying its importance, as displayed in the table below. This will be used in the acceptance process of the prototype⁶ in the following way:

- In each category, each criterion will be assessed with a "pass/fail" following testing **in each site**. The % of "pass" will be measured against the total.
- The minimum required for each epic, as well as the minimum total required across all epics for accepting the AIDAVA health data curation and publishing virtual assistant is provided in the table below.

Epics	Weight	Minimum required (% of "pass")		
		Blocking	Major	Minor
Performance	5%	100%	80%	As much as possible (to be confirmed after delivery of user stories in D3.2)
Scalability	Not applicable	Not applicable	Not applicable	
Availability	5%	80%	80%	
Reliability	10%	100%	80%	
Maintainability	5%	80%	80%	
Serviceability	15%	80%	80%	
Security & Data privacy	15%	100%	80%	
Regulatory	10%	100%	80%	
Usability	15%	100%	80%	
Automation	15%	100%	80%	
General Principles	5%	80%	80%	
TOTAL - formula	Sum all Weights	Sum all (Weight * % of pass)		
TOTAL - value	100%	90%	80%	

These parameters will be measured at the following time for each generation:

1. Central evaluation - before deployment - within the development environment in P-GND. This will be done in collaboration with the patient consultants.
2. Local evaluation in each site where the site is deployed, before being used by the patients. The local test will be done by the site administrator and the local expert curator.

⁶ It is expected that the weight will need to be adapted for the product

3 Results

The tables below provide an overview of all requirements that were gathered during Task 1.3 as explained previously. The first table displays the distribution of the requirements according to user groups; the second table displays the distribution of the requirements in functional requirements (FRs) and non-functional requirements (NFRs) after consolidation and grouping per type (FR and NFR), per epics and per severity. Functional requirements are further detailed in Section 3.1, while non-functional requirements are described in Section 3.2.

In total, 596 requirements were captured across the different user groups.

	Total
patient	124
expert curator	112
data user	170
3rd-party app developer	125
administrator	65
Total Requirements	596

After consolidation, 113 (19%) requirements were identified as duplicates across user groups and 107 (18%) as out of scope; 376 (63%) requirements were elicited for the AIDAVA virtual assistant. Out of these 376 requirements, 277 were considered as in scope of the prototype and 99 were identified as additional requirements needed to deliver a full-fledged product.

Among the duplicates and out of scope requirements, the majority (84 or 48% of the total FRs) are related to Data Publishing for further use and visualisation of curated data in clinical care or in the context of sharing with consent, demonstrating the high interest across the user groups on having high quality data for further use. The NFRs have much less duplicates and out of scope elements as they were captured directly with the AIDAVA and the SITES administrators, in joint meetings across sites, building on a predefined list specified from best practices for NFRs in software development.

A part of the 376 in scope requirements, 81 (52% of the NFRs or 22% of the total requirements) are related to documentation on the prototype and the product to be. As a result, we identified 4 different manuals to be developed together with the prototype.

	duplicates	out of scope	Total	blocking	major	minor	Total	% of FR or NFR	% Total
Data Ingestion	9	7	16	6	23	8	37	17%	10%
Data Curation	11	3	14	5	21	9	35	16%	9%
User Interaction	8	8	16	2	9	12	23	11%	6%
Data Publishing	35	49	84	4	27	10	41	19%	11%
User Management	2	0	2	2	11	8	21	10%	6%
Data Use	11	12	23	3	15	7	25	11%	7%
Quality Mgt	11	2	13	0	9	2	11	5%	3%
Integration	2	6	8	9	13	4	26	12%	7%
Total FR	89	87	176	31	128	60	219	100%	58%

	duplicates	out of scope	Total	blocking	major	minor	Total	% of FR or NFR	% Total
Performance	2	-	2	2	4	1	7	4%	2%
Scalability	-	-	0	-	-	3	3	2%	1%
Availability	3	-	3	-	3	1	4	3%	1%
Reliability	-	-	0	1	2	1	4	3%	1%
Maintainability	-	-	0	1	5	1	7	4%	2%
Serviceability	7	-	7	2	9	3	14	9%	4%
Security & Data Privacy	2	-	2	7	4	-	11	7%	3%
Regulatory	1		1	4	2	1	7	4%	2%
Usability	-	-	0	-	4	2	6	4%	2%
General Design	-	12	12	4	8	1	13	8%	3%
Documentation	9	8	17	1	54	26	81	52%	22%
Total NFR	24	20	44	22	95	40	157	100%	42%
Total FR + NFR	113	107	220	53	223	100	376		
% Total	19%	18%	37%	9%	38%	17%	63%		
Prototype				46	178	53	277		
Product (addition)				7	45	47	99		

3.1 Functional requirements

This section describes the functional requirements of the prototype, grouped following the epics identified in Deliverable D2.3 - Solution Design, with the severity level and acceptance criteria.

Acceptance criteria from the perspective of the users have been defined for those functional requirements, which are relevant for the prototype to be developed within the AIDAVA project. In total, out of the 277 requirements in scope of the prototype, 144 functional requirements have been assessed to be relevant for the prototype, which will be developed for G1 in the course of the AIDAVA project.

3.1.1 Data ingestion

26 functional requirements concerning data ingestion to AIDAVA have been assessed to be relevant for the prototype to be implemented within the AIDAVA project. For these 26 functional requirements in total 44 acceptance criteria have been defined.

Requirement ID	Requirement	Severity	Accept. Criterium ID	Acceptance Criterium
C0005	As an expert curator ingesting medical data into AIDAVA, I want to be able to manually upload data to AIDAVA. There should be on the desktop an "Add File / Scan" or "Upload" button to manually enter data so that I can enter the results of medical examinations from other hospitals, medical records, ICU charts, nursing medical records, and medications.	blocking	AC0005.1	The system provides the possibility to manually upload data as specified in the DTS for the prototype.
			AC0005.2	The system provides the possibility to manually scan and upload data (limited to what is provided to DTS), which are only available in paper format.
C0004	As an expert curator ingesting medical data into AIDAVA, I want the application to upload data from the Health Information System, the Hospital Information System, the EMO card, the Laboratory Information System, the Cancer Registry and the patient's own data so that these data do not have to be searched for manually in separate systems.	blocking	AC0004.1	All data sources described in DTS are ingested (for the prototype via asynchronous data transfer).
C0011	As an expert curator ingesting data, I want all data to be automatically ingested into the AIDAVA health data curation and publishing virtual assistant without my input so that I can only focus on curating.	blocking	AC0011.1	Data (according to the DTS) is automatically ingested by the AIDAVA health data curation and publishing virtual assistant. No input is required from expert curators for that data ingestion.
C0013	As a data user when considering to access medical data through AIDAVA, I expect AIDAVA to be compatible with diverse nomenclature/data models such as FHIR, SNOMED CT, and OMOP CDM, so that data from diverse sources are made usable and interoperable.	blocking	AC0013.1	AIDAVA is compatible with diverse nomenclatures and data models, such as FHIR, SNOMED CT.
C0040	As a 3rd-party app developer ingesting medical data into AIDAVA, I want to be able to uniquely identify a single record (patient) so that it's easy to understand.	blocking	AC0040.1	The system provides the functionality to uniquely identify a single patient record.

C0006	As an expert curator ingesting medical data into AIDAVA, I want the application to notify me of the correct upload of data so that a corresponding message appears on the screen.	major	AC0006.1	The system notifies the user of successful data (as specified in DTS) upload (e.g. via respective message on the screen).
C0010	As an expert curator using the AIDAVA prototype, I want AIDAVA to include medication information so that every doctor can see what medication is being taken for what issue.	major	AC0010.1	The system is able to provide the list of prescription medicines for a patient (as specified in the DTS).
C0002	As an expert curator ingesting medical data into AIDAVA, I want mandatory fields for data input so that I can ensure the data is complete.	major	AC0002.1	The system indicates mandatory fields (for data ingestion).
			AC0002.2	The system notifies the user if mandatory fields (for data-ingestion) are not filled, and prompts the user to fill these fields.
C0003	As an expert curator ingesting medical data into AIDAVA, I want the AIDAVA health data curation and publishing virtual assistant to decide which of the ingested information is relevant for updating or completing the patient data set and discard outdated or duplicate information so that I don't need to find/filter the relevant data myself.	major	AC0003.1	The AIDAVA prototype checks duplicate information in the PHKG (for ingestion in general).
			AC0003.2	AIDAVA will mark outdated/old data when a newer/corrected version has been added.
C0009	As an expert curator onboarding data sources, I want to know if the data are located in different data sources in order to know whether I should communicate with the data stewards of the hospital.	major	AC0009.1	The PHKG identifies whether a specific data node can be found in different data sources (e.g. tumour site comes in a structured field and in free text as well).
			AC0009.2	The system notifies the user if a specific data node can be found in different data sources (e.g. tumour site comes in a structured field and in free text as well).
C0012	As a data user using the AIDAVA prototype, I want the AIDAVA health data curation and publishing virtual assistant to automatically collect data in the background for registries in scope of AIDAVA so that we can use the data for research.	major	AC0012.1	The system automatically collects data in the background for registries related to AIDAVA, enabling its utilisation for research purposes.
C0017	As a patient ingesting medical data into AIDAVA, I want to be able to get all formats of data into AIDAVA (e.g. pictures/scans of paper documents, x-rays, pdf, lab results, etc.) so that I can upload all my health-related data to the AIDAVA health data curation and publishing virtual assistant.	major	AC0017.1	The system allows to ingest at least pictures, scans of paper documents, pdf and structured data (eg. Lab results).

C0020	As a patient ingesting medical data into AIDAVA, I want to connect AIDAVA with third party apps (e.g. fitness app) so that data from these third-party apps can automatically be ingested into AIDAVA.	major	AC0020.1	The system allows to ingest data from a QLY questionnaire from selected a PROMS application (in local language).
C0021	As a patient ingesting medical data into AIDAVA, I want to include medication information in AIDAVA so that my doctor can see all relevant information at a glance.	major	AC0021.1	The system allows to ingest medication information.
C0025	As a patient ingesting medical data into AIDAVA, I want the AIDAVA health data curation and publishing virtual assistant to check and handle duplicates automatically so that I do not need to bother.	major	AC0025.1	The system informs the user that these data are already in the AIDAVA health data curation and publishing virtual assistant if the user tries to ingest duplicates.
			AC0025.2	The system keeps only one copy of the duplicate data - but keeps a trace of the provenance of the different sources.
			AC0025.3	If the AIDAVA health data curation and publishing virtual assistant is not 100% sure about the duplicate, it provides the user the option to specify: a) this is a duplicate; b) this is not a duplicate, keep both.
			AC0025.4	The system recognises duplicate data automatically.
C0026	As a patient having my data in AIDAVA, I want the AIDAVA health data curation and publishing virtual assistant to notify where data/information is missing in a structured field so that I am aware of missing data/information.	major	AC0026.1	The system checks if there is information missing in a structured field.
			AC0026.2	The system notifies the user if there is information missing in a structured field.
C0038	As a 3rd-party app developer ingesting medical data into AIDAVA, I want to check that the uploaded data is valid, i.e. the whole data was uploaded and not just part of it so that I can trust AIDAVA.	major	AC0038.1	The system will provide HTTP status when the upload is completed.
C0041	As a 3rd-party app developer using the AIDAVA prototype, I want to be able to send new data if I get them (for instance longitudinal wearable data) so that I can enhance my data.	major	AC0041.1	The system allows the patient to ingest new data at any time.
C0007	As an expert curator ingesting medical data into AIDAVA, I want the application to notify me of an error in the data sources which should be automatically uploaded (case one: document missing, case two: wrong document) so that I can immediately	major	AC0007.1	The system fires/activates the relevant quality rule if an error in automatic data ingestion (according to the DTS) occurs.
			AC0007.2	The system notifies the user (site admin) if an error in automatic data ingestion (according to the DTS) occurs.

	go to correct the error (case 1: error message to local support, case 2: delete the document + message to local support).		AC0007.3	The quality rule is requesting for human input to correct the error and check that the input is ok.
			AC0007.4	The user (site admin) has the option to delete the ingested document that caused the error of the AIDAVA health data curation and publishing virtual assistant.
C0001	As an expert curator ingesting medical data into AIDAVA, I want a structured, well-arranged interface so that I can work in a structured way.	minor	AC0001.1	The AIDAVA platform provides a well-structured interface for the curator.
			AC0001.2	The system provides the curator with the opportunity to hide parts of the user interface, which they do not need at the moment.
C0008	As an expert curator ingesting medical data into AIDAVA, I want the application to save and store all the data I enter so that I can go at any time and search/view and if necessary change the already curated data.	minor	AC0008.1	The system saves and stores all the ingested data.
C0016	As a patient contemplating registering to AIDAVA, I expect AIDAVA to automatically ingest any relevant data sources to keep my medical information accurate and up to date so that I always have my medical information "at the tip of my fingers" but the burden of responsibility for my data is taken from me.	minor	AC0016.1	The user is able to change the definition of relevant data sources anytime.
			AC0016.2	If there are changes in the relevant data sources, these are automatically ingested into AIDAVA (assuming that the Data Holder agreed to send the changes to AIDAVA through the agreed transfer mechanism).
			AC0016.3	The data sources defined by the patient are automatically ingested by AIDAVA.
			AC0016.4	The patient can define in AIDAVA which data sources are relevant to be automatically ingested into AIDAVA.
C0022	As a patient ingesting medical data into AIDAVA, I want to include information about my allergies in AIDAVA so that my doctor can see all relevant information at a glance.	minor	AC0022.1	The system allows to ingest information about the user's allergies.
C0024	As a patient ingesting medical data into AIDAVA, I want to see a checkmark within the AIDAVA health data curation and publishing virtual assistant (no separate email and no messaging!) signalling the data was well received by the AIDAVA	minor	AC0024.1	The system provides explicit and clear-to-understand error messages including advice on how to overcome the error.
			AC0024.2	The system provides a visual indication when data was NOT ingested successfully, e.g. an error occurred.

	health data curation and publishing virtual assistant so that I know ingestion of the data to AIDAVA was successful.		AC0024.3	The system provides a visual indication of when data was ingested successfully.
C0328	As a 3rd-party app developer and as a patient ingesting medical data into AIDAVA, I want to have more information of what is the level of reliability that the medical data should have in order to be uploaded so that (in the case of a high level of reliability) the requirements regardless of the checks of the issued documents are appropriate.	minor	AC0328.1	The system checks the level of reliability of the ingested document during onboarding.
			AC0328.2	The system gives feedback to the user on whether the level of reliability is appropriate.
C0329	As a 3rd-party app developer ingesting medical data into AIDAVA, I want to have a versioning of files so that I can see what changes were applied to it.	major	AC0329.1	This information is included in the documentation.

3.1.2 Data curation

28 functional requirements concerning data curation have been assessed to be relevant for the prototype to be implemented within the AIDAVA project. For these 28 functional requirements in total 52 acceptance criteria have been defined.

Requirement ID	Requirement	Severity	Acceptance Criterion ID	Acceptance Criterion
C0047	As an expert curator helping AIDAVA with manual data curation, I want AIDAVA to log who answered the questions or who made changes so that it is traceable where a certain piece of information comes from.	blocking	AC0047.1	AIDAVA logs user activity regarding who has made changes.
			AC0047.2	The system offers a user access management to organise who can see which logs.
C0051	As an expert curator using the AIDAVA prototype, I want to have as few manual steps as possible in order to decrease the possibility of an erroneous data curation process.	blocking	AC0051.1	The user perceives that the amount of help requests is adequate.
C0056	As an expert curator using automatic data curation in AIDAVA, I want to have an automatic notification when there is an erroneous parameter during the data curation in order to avoid errors.	blocking	AC0056.1	The system automatically runs quality checks according to the defined quality rules.
			AC0056.2	When the AIDAVA health data curation and publishing virtual assistant recognises a breach of any quality rule applicable, the AIDAVA health data curation and

				publishing virtual assistant fires an alert and asks the user to correct the error.
			AC0056.3	In G1 - the question to the user is clear/straightforward (without domain-specific terminology). (In G2 - the AIDAVA health data curation and publishing virtual assistant provides more contextual information to support the user.)
C0070	As a patient using AIDAVA, I want to always see clearly which account I am in so that I can be sure I am adding/curating data for the right person.	blocking	AC0070.1	The system displays the account holders name clearly visible during the whole usage session.
C0049	As an expert curator using AIDAVA, I want to get a notification if new data gets added to a patient in AIDAVA, where AIDAVA needs help for data curation, so that I can check the urgency and either curate it right away or do it in the monthly curation cycle.	major	AC0049.1	The system provides the user the possibility to decide the frequency of notifications for curation requests.
			AC0049.2	The system provides the user the possibility to work on the data curation requests (i.e. curate data) at any time.
C0042	As an expert curator helping AIDAVA with manual data curation, I want AIDAVA to offer me the option to answer the questions of the AIDAVA health data curation and publishing virtual assistant all together at a specific point in time (daily preferably) so that the rest of the time I can still proceed with my usual work.	major	AC0042.1	The system sends notifications to the curator's AIDAVA account if there are open curation questions to answer.
			AC0042.2	The system provides on the dashboard of the curator's AIDAVA account a button/link to display the open questions (which still need answers from the curator) on the screen.
			AC0042.3	The system displays a list of all open questions needing curation on the screen.
C0043	As an expert curator helping AIDAVA with manual data curation, I want AIDAVA to offer me the option to answer the questions of the AIDAVA virtual assistant for health data curation and publishing, sorted by patient so that I don't need to read up about the patient for each question.	major	AC0043.1	The system displays a list of patients whose data need to be curated, and the curator can select a patient from this list.
			AC0043.2	When the curator selects to curate a patient's data, the AIDAVA health data curation and publishing virtual assistant displays a list of all curation requests for that patient's data.
			AC0043.3	The curator can pick any curation request (from the list of all curation requests for a patient's data) to work on.

C0044	As an expert curator helping AIDAVA with manual data curation, I want the AIDAVA health data curation and publishing virtual assistant to give me answer options/suggestions so that I can quickly answer the AIDAVA health data curation and publishing virtual assistant's question.	major	AC0044.1	The system provides the curator answer options for the AIDAVA health data curation and publishing virtual assistant's request for curation help.
			AC0044.2	The system allows the curator to select one of the provided answer options (e.g via check-boxes).
C0045	As an expert curator helping AIDAVA with manual data curation, I want the AIDAVA health data curation and publishing virtual assistant to allow me to put in my own answer if the answer options provided by the AIDAVA health data curation and publishing virtual assistant do not cover the right answer so that I am not getting restricted by the AIDAVA health data curation and publishing virtual assistant.	major	AC0045.1	The system provides the curator the option to enter a curator-specified answer to the AIDAVA health data curation and publishing virtual assistant's request for curation help.
			AC0045.2	The system confirms to the user that an answer has been received.
C0046	As an expert curator helping AIDAVA with manual data curation, if I don't know the answer to a question of the AIDAVA health data curation and publishing virtual assistant, I want to have the option to extract the question including the respective medical report(s) in an email so I can forward it to the doctor/expert of the respective field so that I don't have to write all the information by myself (e.g. which patient, which medical report of which date, in which line, what is the question, ...).	major	AC0046.1	The AIDAVA health data curation and publishing virtual assistant provides the curator the option to forward or mark a question to ask an expert to help with the curation task (in G2).
C0050	As an expert curator using AIDAVA, I want the app to have a bookmark so that it knows where the work is stopped and can continue.	major	AC0050.1	The system provides the possibility to bookmark unfinished tasks (e.g. patient only partly curated).
			AC0050.2	The system provides the possibility to continue work in progress (for example, there would be a bar on the screen to show which entries are done and which ones are not done).
C0052	As an expert curator using automatic data curation in AIDAVA, I want the AIDAVA health data curation and publishing virtual assistant to proactively ask for help, if medical reports are not clear or the information from different medical reports are contradicting so that I don't need to check for unclear medical reports by myself.	major	AC0052.1	The system checks if the information ingested from every medical report is clear and fits with the information about the patient that is already in the AIDAVA health data curation and publishing virtual assistant (not contradicting).

			AC0052.2	The system fires/activates the relevant quality rule if contradicting information is found, and asks for human help with clarifying this issue.
C0054	As an expert curator using automatic data curation in AIDAVA, I want the application to ask for help when it doesn't understand abbreviations, certain words, when there are similar diagnoses, double loaded files, confusing dates, or when a cell is empty so that I can open a separate view with the data for review.	major	AC0054.1	The system asks for human help when it doesn't understand abbreviations or certain words, when there are contradicting diagnoses, double loaded files, confusing dates, or when a cell is empty.
			AC0054.2	The system opens a separate window/section to curate data.
C0057	As a data user retrieving medical data from AIDAVA, I want the AIDAVA health data curation and publishing virtual assistant to recognize medical abbreviations in the right context* and put them in a consistent form so that the right records end up in the results. [*e.g. the German abbreviation HWI means Harnwegsinfekt (urogenital context) and Hinterwandinfarkt (cardiovascular context)].	major	AC0057.1	The system accurately recognizes medical abbreviations in their appropriate context and ensures consistent formatting/coding.
C0058	As a data user retrieving medical data from AIDAVA, I want the AIDAVA health data curation and publishing virtual assistant to correctly recognize negations so that no information is misrepresented.	major	AC0058.1	The system accurately identifies negations within the medical data and ensures the representation of information is correct.
C0059	As a data user retrieving medical data from AIDAVA, I want the AIDAVA health data curation and publishing virtual assistant to take into account whether a finding/X-ray/lab-result was taken before or after a treatment so that I know whether a patient is suitable for a study or not.	major	AC0059.1	The system incorporates the timing of findings, X-rays, and lab results to determine if they were taken before or after a treatment.
C0062	As a patient helping with data curation, I expect the AIDAVA health data curation and publishing virtual assistant to make almost all curation work automatically so that I receive only very few questions / help requests from the AIDAVA health data curation and publishing virtual assistant.	major	AC0062.1	The user perceives that the amount of help requests is adequate and they do not feel overwhelmed from the AIDAVA health data curation and publishing virtual assistant.
			AC0062.2	The system performs at least 70% to 90 % of the curation processes automatically.

C0063	As a patient helping with data curation, I want to be able to see my different types of data, which I shall curate, in tabs (e.g. oncology, cardio, general health, etc.) so that I am not overwhelmed by a huge list of data to curate.	major	AC0063.1	The system displays the help requests in categories related to the patient's main health issues, e.g.: oncology/general health for cancer patients; cardiovascular / general health for cardiovascular patients.
			AC0063.2	The system lets the user select in what order to work through the help requests.
			AC0063.3	If there is more than one help request by the AIDAVA health data curation and publishing virtual assistant: the AIDAVA health data curation and publishing virtual assistant gives an overview of the help requests.
C0064	As a patient helping with data curation, I want the AIDAVA health data curation and publishing virtual assistant to provide me with suggestions of how to address the issue, which is raised by the AIDAVA health data curation and publishing virtual assistant, and in addition give me the option to make my own fix, if I find the suggestions provided by the AIDAVA health data curation and publishing virtual assistant are not appropriate/good, so that I can help the AIDAVA health data curation and publishing virtual assistant with clarifying ambiguities found in my data.	major	AC0064.1	The system provides options for solving the raised data curation issue when asking the user for help.
			AC0064.2	The user can either select one of the provided answer options or enter a user-specified answer to the AIDAVA health data curation and publishing virtual assistant's question.
C0065	As a patient helping with data curation, I want the AIDAVA health data curation and publishing virtual assistant to enable me to delegate the AIDAVA health data curation and publishing virtual assistant's request to help with clarification of an issue to the expert curator, if I cannot answer the AIDAVA health data curation and publishing virtual assistant's question, so that my data can be curated even if I do not know the answer to the AIDAVA health data curation and publishing virtual assistant's question.	major	AC0065.1	The system provides the option for the user to select "I do not know the answer".
			AC0065.2	When the user selects the option "I do not know the answer", the AIDAVA health data curation and publishing virtual assistant automatically addresses the help request to the expert curator and informs the user about it.
C0068	As a patient helping with data curation, I want the AIDAVA health data curation and publishing virtual assistant to show me which review requests are still open (the AIDAVA health data curation and publishing virtual assistant stores all the issues if I am away and	major	AC0068.1	The system shows the user on demand all the open help requests.
			AC0068.2	When there are open help requests, the AIDAVA health data curation and publishing virtual assistant gives a visual indication to the user that there are open help requests.

	shows them to me all at once) so that I know which data I still need to review/curate.		AC0068.3	The system gives the option to select specific help requests to review and issue a change request to the helpdesk if needed.
C0069	As a patient helping with data curation, I want the AIDAVA health data curation and publishing virtual assistant to show me which data have been reviewed by me so that I can see which data I have already viewed and check that they are correct.	major	AC0069.1	The system shows the user on demand all help requests previously handled by the user up to 30 days in the past.
C0048	As an expert curator using AIDAVA, I want to be able to mark patients or questions from the AIDAVA health data curation and publishing virtual assistant with a colour scheme so that I know what my current status on the question is, (e.g. I want to mark a question where I have to ask the doctor to be able to answer it).	minor	AC0048.1	The system provides the curator the possibility to mark curation requests/questions with colour-codes.
			AC0048.2	The system provides the possibility to forward/send a colour-coded question to an expert.
C0053	As an expert curator using automatic data curation in AIDAVA, I want the AIDAVA health data curation and publishing virtual assistant to show me using colours and symbols (e.g. green tick = all good, red x = incomplete/error) if the curation of the data worked so that I know at a glance if the data was well received.	minor	AC0053.1	The system gives visual feedback to the user whether the curation of the data was ok.
			AC0053.2	The visual feedback is in the form of coloured symbols, so that the user can recognize the status of the curation process at a glance (for example green tick = curation finished successfully; red X = incomplete / error, ...) Note: visual feedback must not be communicated using colour as the only cue.
C0055	As an expert curator using automatic data curation in AIDAVA, I want to have a list of patients, whose data has been collected on one side of the screen so that I can curate them one by one.	minor	AC0055.1	The system shows a list of patients, for whom data needs to be curated.
			AC0055.2	The system provides the curator with the possibility to select one patient data at a time to be curated.
C0060	As a data user retrieving medical data from AIDAVA, I want the PHKG to be linked with medical images (including histopathological whole slide images) of the patient so that I know which medical images (including histopathological whole slide images) have been taken and can request access.	minor	AC0060.1	The system establishes a link between the PHKG and patient images, specifically whole slide images, for identification and access request purposes.
C0061	As a data user willing to check the data delivered from AIDAVA, I want the possibility to do a detailed check of any of the patient records included in the results delivered by the AIDAVA health data	minor	AC0061.1	The system provides the option to perform a detailed check of any patient record included in the AIDAVA health data curation and publishing virtual assistant results,

	curation and publishing virtual assistant, so that I can find out due to which parameters this record ended up in the result.			allowing the user to identify the parameters due to which the record was included in the AIDAVA results.
C0066	As a patient helping with data curation, I expect the AIDAVA health data curation and publishing virtual assistant to learn from my curation input (e.g. if I use specific units when curating lab results the AIDAVA health data curation and publishing virtual assistant will use as a default for all lab results I will curate, unless I indicate otherwise) so that I do not need to answer the same type of questions over and over again.	minor	AC0066.1	The system suggests an answer based on the user's previous answers to similar help requests.
			AC0066.2	The system provides the ability for the user to overrule the AIDAVA health data curation and publishing virtual assistant's suggestions and give a different answer.

3.1.3 User interaction and multilingual use

User interaction

9 functional requirements concerning user interaction have been assessed to be relevant for the prototype to be implemented within the AIDAVA project. For these 9 functional requirements in total 15 acceptance criteria have been defined.

Requirement ID	Requirement	Severity	Acceptance Criterion ID	Acceptance Criterion
C0090	As a patient helping with data curation, I want the AIDAVA health data curation and publishing virtual assistant to make it clear to me where and why my help is needed, if the AIDAVA health data curation and publishing virtual assistant found conflicting information, so that I can support the AIDAVA health data curation and publishing virtual assistant with improving my personal health data.	blocking	AC0090.1	The system explains the issue and why the user's help is needed for each question / help request.
			AC0090.2	The system states explicit and clear-to-understand questions/help requests for the user.
C0080	As an expert curator helping AIDAVA with manual data curation, I expect the AIDAVA health data curation and publishing virtual	major	AC0080.1	The AIDAVA platform will show one type of layout which will be agreed during the UI/UX evaluation.

	assistant to provide clear questions and supporting information to help answer this question based on the context provided so that I do not have to check for additional information.		AC0080.2	The system displays context information (e.g. provenance of the data) related to the question on the screen (in the same window).
C0081	As a data user using AIDAVA, I want to have an UI that works on PC and mobile phone so that I am not restricted to a specific terminal.	major	AC0081.1	The system's user interface is compatible with a PC / laptop.
			AC0081.2	The system's user interface is compatible with mobile platforms (smartphones and tablet computers).
C0085	As a data user using AIDAVA, I want the AIDAVA health data curation and publishing virtual assistant to have a graphic user interface so that I can save time on typing (tiresome processes).	major	AC0085.1	The system offers a graphic user interface (GUI) to users, enabling them to interact with the AIDAVA health data curation and publishing virtual assistant and perform tasks without the need for extensive typing.
C0091	As a patient helping with data curation, I want the AIDAVA health data curation and publishing virtual assistant to provide me with the context of the issue raised by the AIDAVA health data curation and publishing virtual assistant and show me which (parts of) the original documents/data are concerned and by whom and when these documents/data have been issued and uploaded to the AIDAVA health data curation and publishing virtual assistant so that I can better understand the context of the AIDAVA health data curation and publishing virtual assistant's question and more easily fix the issue.	major	AC0091.1	When requesting the users help, the AIDAVA health data curation and publishing virtual assistant provides the information, by whom and when the source of the curation issue has been ingested.
			AC0091.2	When requesting the users help, the AIDAVA health data curation and publishing virtual assistant provides the context by showing the user the source (respective part of original data/document) of the curation issue.
C0093	As a patient using AIDAVA, I want to have the option to access AIDAVA on my smartphone, tablet and computer so that I can choose the device according to my preferences and situation (e.g. at home, in the hospital...).	major	AC0093.1	The system can be used on a smartphone on the following operating systems with the respective browsers: Android - Chrome, IOS - Safari.
			AC0093.2	The system can be used on a tablet on the following operating systems with the respective browsers: Android - Chrome, IOS - Safari, Android - Android.
			AC0093.3	The system can be used on a computer on the following operational systems with the respective browsers: Windows 10 - Chrome & Edge, Mac - Safari & Chrome.

C0094	As a patient using AIDAVA, I want to be able to communicate with AIDAVA in a conversational manner (e.g. via a chatbot/live chat/hotline/e-mail address) so that the AIDAVA health data curation and publishing virtual assistant can be used on a smartphone on the browsers above 8% market share per platform (Android - Chrome, IOS - Safari).	major	AC0094.1	The system offers the option to communicate with AIDAVA via Chatbot.
C0089	As a data user retrieving medical data from AIDAVA, I want to have a user-friendly UI so that I will not spend a lot of time retrieving the data.	minor	AC0089.1	The system has a user-friendly and intuitive user interface (UI) that simplifies the process of retrieving medical data.
C0097	As a patient using AIDAVA, I want to be able to communicate with a human support via chat so that I can use my usual fast communication channels.	minor	AC0097.1	The system offers the option to communicate with a human support via chat.

Multilingual usage

2 functional requirements concerning multilingual usage of AIDAVA have been assessed to be relevant for the prototype to be implemented within the AIDAVA project. For these 2 functional requirements in total 5 acceptance criteria have been defined.

Requirement ID	Requirement	Severity	Acceptance Criterium ID	Acceptance Criterium
C0234	As a data user using AIDAVA, I want the AIDAVA health data curation and publishing virtual assistant to provide different language options to communicate with the AIDAVA health data curation and publishing virtual assistant so that everyone can choose their mother language (Estonian, Russian, ...) while working and search the literature in English.	blocking	AC0234.1	The user interface is available in Estonian.
			AC0234.2	The user interface is available in Dutch.
			AC0234.3	The user interface is available in German.
			AC0234.4	The user can select one from the available language options.
C0232	As a patient and as a 3rd-party app developer (company) using AIDAVA, I want to communicate with AIDAVA in my language / I want UI (for patients) for different languages so that patients can easily ask questions	major	AC0232.1	The AIDAVA health data curation and publishing virtual assistant prompts the user to select their preferred language and offers multiple options.

	and understand the AIDAVA health data curation and publishing virtual assistant's answers			
--	---	--	--	--

3.1.4 Data publishing

25 functional requirements concerning data publishing have been assessed to be relevant for the prototype to be implemented within the AIDAVA project. For these 25 functional requirements in total 35 acceptance criteria have been defined.

Requirement ID	Requirement	Severity	Acceptance Criterium ID	Acceptance Criterium
C0131	As a data user assessing AIDAVA/evaluating results/filling in questionnaires, I want AIDAVA to automatically calculate the SMART Risk Score (based on its data) and the time the AIDAVA health data curation and publishing virtual assistant took to calculate it so that I have the data I need to compare with manual work.	blocking	AC0131.1	The system checks if the needed information for calculating the SMART risk score is available.
			AC0131.2	If all needed data are available, the AIDAVA health data curation and publishing virtual assistant calculates the SMART risk score automatically.
			AC0131.3	When the AIDAVA health data curation and publishing virtual assistant calculates the SMART risk score, it also calculates the time needed for calculation of the SMART risk score.
C0162	As a patient wanting to get out my data from AIDAVA, I want to get my curated data from the AIDAVA health data curation and publishing virtual assistant in MACHINE-readable electronic format so that I can have all my data back, e.g. before I delete my account.	blocking	AC0162.1	The system allows the user to download all the curated information, which is in the personal health knowledge graph, in machine-readable electronic format (for the product other formats could be envisioned).
C0173	As a data user and 3rd-party app developer retrieving medical data from AIDAVA, I want to retrieve consistent structured data (that was originally unstructured) so that I can use the structured data.	blocking	AC0173.1	The system provides consistent, structured data.
C0111	As a data user retrieving medical data from AIDAVA, I want to see personal information of the patient (in scope of the use cases of	major	AC0111.1	The system displays personal information of the patient to the treating physician.

	AIDAVA) when I am the treating physician of the patient so that I can do my job more efficiently.		AC0111.2	The system provides the possibility to assign a patient to a treating physician.
C0112	As a data user when considering to access medical data through AIDAVA, I want to have the level of the data structure details so that I can have access to data at a patient specific level.	major	AC0112.1	The system provides the ability to access medical data at different levels of data structure details, enabling patient-specific data retrieval.
C0113	As a data user/clinician when retrieving medical data from AIDAVA, I want to have the option to select to see and retrieve anonymized data so that I can make reports, data analytics and research without having to take responsibility for identifiable patient data.	major	AC0113.1	The system offers the option to extract a predefined list of data elements to generate the local breast cancer clinical registry, and allows access to predefined reports/queries (per study protocol) for analytics; this enables the user to conduct research without accessing identifiable patient data.
C0114	As a data user retrieving medical data from AIDAVA, I want to retrieve data from several patients at once so that I have access to a large-scale dataset that can be used for several purposes including research.	major	AC0114.1	The system supports the retrieval of data from multiple patients records simultaneously.
C0115	As a data user retrieving medical data from AIDAVA, I want to have API-based options to programmatically retrieve data so that I can rapidly retrieve the data.	major	AC0115.1	The system provides API-based options that allow programmatically retrieving data.
C0116	As a data user/clinician retrieving medical data from AIDAVA, I want to see the name and ID number/code of the patient, whose data I am about to see, so that I can make sure I have the right patient whose data I am about to see.	major	AC0116.1	The system displays the name and ID number/code of the patient whose data is being accessed.
C0124	As a data user retrieving medical data from AIDAVA, I want to retrieve structured data as much as possible so that the data I retrieve are easy and handy to use.	major	AC0124.1	The system prioritises the retrieval of structured data, ensuring that the data provided to data users are easily accessible and convenient to use.
C0130	As a data user retrieving medical data from AIDAVA, I want the AIDAVA health data curation and publishing virtual assistant to ask the user in what form they want to get the result and offer several options so that I can choose from the suggestions.	major	AC0130.1	The AIDAVA system provides several predefined formats for retrieving results: extract for BC registry, personalised CVD score and IPS - and prompts the user to specify the desired format for retrieving the result.
C0132	As a data user assessing AIDAVA/evaluating results/filling in questionnaires, I want AIDAVA to display me the results of the SMART Risk Score and the time it took to calculate that score so that I can	major	AC0132.1	The system provides the user the possibility to request automatic calculation of the smart risk score.
			AC0132.2	If the user requests automatic calculation of the SMART risk score while any of the needed data is

	enter this information to my data user/consumer spreadsheet/assessment survey (study protocol 10.6.3) in AIDAVA.			missing, the system informs the user about the missing data.
			AC0132.3	On request of the user, the system calculates the smart risk score and presents it to the user.
			AC0132.4	On request of the user the system presents the time it had needed to calculate the smart risk score to the user.
C0133	As a data user retrieving medical data from AIDAVA, I want to extract data in agreed format from the PHKG in order to visualise the content of the PHKG.	major	AC0133.1	The system allows data users to extract data from the PHKG in a format agreed for the BC use case.
C0134	As a data user retrieving medical data from AIDAVA, I want to use a federated query across all the participating sites in order to extract data from the breast cancer registry in order for AIDAVA to automatically calculate the metrics described on page 9 of the study protocol.	major	AC0134.1	The system supports federated queries across all participating sites in order to extract data from the breast cancer registry as described in the T1.4 Study protocol.
			AC0134.2	The extracted data are used by AIDAVA to automatically calculate the metrics described in the T1.4 study protocol.
C0135	As a patient contemplating registering to AIDAVA, I want AIDAVA to enable me to give doctors and emergency responders a clear, up-to-date summary of my personal health data in digital format so that they can make accurate diagnoses and choose correct treatment options and the appropriate help in case of emergency (in case I cannot communicate myself).	major	AC0135.1	Treating physicians can access the up to date IPS of a patient's personal health data (Note: for the product, it should be more than IPS)
			AC0135.2	A clear up to date IPS of a patient's personal health data is available in/from AIDAVA (Note: for the product, it should be more than IPS).
C0146	As a patient having my data in AIDAVA, I want the AIDAVA health data curation and publishing virtual assistant to extract my IPS (International Patient Summary) for further use so that the project fulfils its goals. (D1.4).	major	AC0146.1	The system extracts the users IPS on their demand.
C0175	As a 3rd-party app developer retrieving medical data from AIDAVA for my app, I want to have access to the International Patient Summary (IPS) data in FHIR, so that my program can work in another environment.	major	AC0175.1	The system's output respects the standard FHIR.

C0176	As a 3rd-party app developer (HDI) retrieving medical data from AIDAVA, I want my account holders to be able to have a copy of the PHKG in their HDI personal health account, in addition to the structured IPS data so that the account holders can put the PHKG to secondary use, in the sense of patient empowerment, sovereignty, and informational self-determination.	major	AC0176.1	Patients receive a copy of PHKG (IPS) into their personal HDI account.
C0121	As a data user using AIDAVA, I want to be able to create data reusable for other purposes so that I can inquire and convert the data to RedCap, download an Excel format and process data in more ways than the AIDAVA health data curation and publishing virtual assistant may offer.	minor	AC0121.1	The system allows the creation of reusable data, which can be used for other purposes.
			AC0121.2	The system allows data inquiry (in context of the use case).
			AC0121.3	The system allows the conversion to REDCap format.
C0127	As a data user/clinician retrieving medical data from AIDAVA, I want to automatically see a basic overview of the patient (diagnosis, ambulance card, appointments, links to lab results) so that I have a good overview of the patient.	minor	AC0127.1	The system automatically provides (to the treating physician) a basic overview of the patient (IPS).
C0128	As a data user/clinician retrieving medical data from AIDAVA, I want the name of the patient and date of the results being presented always be visible so that I am always sure that I am looking at the right data/results and therefore I trust the information	minor	AC0128.1	The system always displays the name/ID of the patient and date of the presented results to the user.
C0163	As a patient wanting to get out my data from AIDAVA, I want to get out my curated data from the AIDAVA health data curation and publishing virtual assistant in HUMAN-readable electronic format (e.g. pdf) so that I can have all my curated data back, e.g. before I delete my account.	minor	AC0163.1	The system allows the user to download all the curated information in human readable electronic format e.g. pdf.
C0174	As a 3rd-party app developer retrieving medical data from AIDAVA for my app, I want the data from AIDAVA to be in a well-structured form, using harmonised value sets so that I can display it in a fitting way to my user (also internationalisation/translations).	minor	AC0174.1	AIDAVA holds data in a well-structured form using harmonised value sets.
C0185	As a data user willing to check the data delivered from AIDAVA, I want to access AIDAVA from my phone app so that I have a user-friendly and handy way to access my data.	minor	AC0185.1	The system provides access to AIDAVA through a mobile app, allowing users to conveniently access their data using a user-friendly and handy interface on their mobile devices.

C0363	As a 3rd-party app developer retrieving medical data from AIDAVA for my app, I want a very clear definition of the data we get and the semantic of the data must be clear.	major	AC0363.1	The semantic and structure of the data that can be retrieved from AIDAVA is clearly defined and documented.
-------	--	-------	----------	---

3.1.5 User management

12 functional requirements concerning user management (user profile set up, access management, user account deletion) have been assessed to be relevant for the prototype to be implemented within the AIDAVA project. For these 12 functional requirements in total 26 acceptance criteria have been defined.

Requirement ID	Requirement	Severity	Acceptance Criterium ID	Acceptance Criterium
C0200	As a patient willing to delete my AIDAVA account, I want to have the option to delete all my data so that no one can use this data anymore from this point forward.	blocking	AC0200.1	The system allows the user at any time to delete all their data made available by the different data holder who agreed to provide data to AIDAVA (in an active account).
C0186	As a data user using AIDAVA, I want to fill my user profile questionnaire in AIDAVA so that the AIDAVA health data curation and publishing virtual assistant is configured according to my profile.	major	AC0186.1	The AIDAVA health data curation and publishing virtual assistant presents users with a questionnaire (or a link to it) during their initial use, offering several options for setting up their profile. (Note: options needed from the point of view of the use case still needs to be specified).
			AC0186.2	The AIDAVA health data curation and publishing virtual assistant ensures the correctness of user-profiles.
			AC0186.3	AIDAVA allows users to set up their profile before logging into the AIDAVA health data curation and publishing virtual assistant.
			AC0186.4	The AIDAVA health data curation and publishing virtual assistant creates a user profile based on the answers of the user profile questionnaire.

C0187	As a patient logging into AIDAVA, I want to have an easy-to-use, state-of-the-art login option (e.g. fingerprint) so that I can access my account quickly at any time.	major	AC0187.1	The system guides the user through the login procedure.
			AC0187.2	The system provides a state of the art (2-factor) login option.
C0188	As a patient logging into AIDAVA, I want to have a secure verification system in place so that there is only authorised access to my account/data.	major	AC0188.1	The system provides a state-of-the-art verification procedure for access authorisation.
			AC0188.2	The system allows only authorised access to a user's account and data.
C0189	As a patient/curator using AIDAVA, I want to fill my user profile questionnaire in AIDAVA so that the AIDAVA health data curation and publishing virtual assistant is configured according to my profile.	major	AC0189.1	The system asks the user profile questionnaire when the user first logs into AIDAVA.
			AC0189.2	The system creates a user profile based on the answers of the user profile questionnaire.
			AC0189.3	The system takes into account the configuration of the user profile of the user when asking help requests.
C0193	As a patient setting up my AIDAVA account, I want to specify what shall happen with my data in case of my death or in case I do not have the capacity to manage my account anymore so that I can be sure that my data are handled according to my will.	major	AC0193.1	This information is included in the FAQs and in the training and documentation.
C0196	As a patient setting up my AIDAVA account, I want to be able to re-access my account after I lost my access credentials so that I can access my account.	major	AC0196.1	The system provides a recovery procedure for lost access credentials.
			AC0196.2	The system has security protocols in place to prevent misuse of the recovery procedure for lost access credentials.
C0194	As a patient setting up my AIDAVA account, I want to specify when the AIDAVA health data curation and publishing virtual assistant shall ask me for automatic data curation (for every data upload or at specified intervals) so that it fits my preferences.	minor	AC0194.1	The user is able to specify when they want to receive the AIDAVA health data curation and publishing virtual assistant's request for automatic data curation.
			AC0194.2	(for the product only) The system provides at least the options "immediately after every data upload ask

				for automatic data curation" or "ask me for automatic data curation at my user-specified times".
			AC0194.3	The user is able to change the setting for automatic data curation requests of the AIDAVA health data curation and publishing virtual assistant anytime.
C0195	As a patient setting up my AIDAVA account, I want to specify when the automatic data curation shall happen (e.g. automatically each time when data are uploaded, or only after I've pressed a "start curation" button or at specified intervals) so that it fits my preferences.	minor	AC0195.1	The user is able to specify how to start the automatic data curation.
			AC0195.2	The system provides at least the options (for selection by the user): "start the automatic data curation manually", "start the automatic data curation automatically after ingestion of new data" or "start the automatic data curation at user specified intervals/time".
			AC0195.3	The user is able to change the setting for automatic data curation anytime.
C0190	As an expert curator ingesting medical data into AIDAVA, I want the app to receive the following information about the patient: name, address, age, gender, social security code, diagnosis, reason for arrival at the hospital, examination data, procedure data, anthropometric data (weight, height, etc.) so that it can be used for making treatment decisions, participating in studies, research and preparing statistical reports.	minor	AC0190.1	The system includes the patient's name, age and gender as part of the user profile, and the other information is included if it is part of the ingested information.
C0198	As a patient willing to delete my AIDAVA account, I expect the AIDAVA health data curation and publishing virtual assistant to make it clear (while I am using the AIDAVA health data curation and publishing virtual assistant) that deleting my account is not reversible so that I can make an informed decision.	minor	AC0198.1	When the user is about to delete their account, the AIDAVA health data curation and publishing virtual assistant informs the user that deleting their account is not reversible and asks if the user wants to proceed anyhow or to cancel the deletion request.
			AC0198.2	The system allows the user to delete their account.
			AC0198.3	The system points the user to the relevant point in the FAQs, where it is clearly described what happens when an account is deleted.

C0199	As a patient willing to delete my AIDAVA account, I want to have the option to get a copy of all my data (in a machine-readable format) when I delete my account so that I can use these data offline.	minor	AC0199.1	When the user is about to delete their account, the AIDAVA health data curation and publishing virtual assistant provides the option to export a machine-readable copy of the user's curated data which is in the personal health knowledge graph.
-------	--	-------	----------	--

3.1.6 Data use

13 functional requirements concerning data use including provenance information and audit trail have been assessed to be relevant for the prototype to be implemented within the AIDAVA project. For these 13 functional requirements in total 23 acceptance criteria have been defined.

Requirement ID	Requirement	Severity	Acceptance Criterion ID	Acceptance Criterion
C0210	As a 3rd-party app developer (retriever of medical information) considering using AIDAVA, I want the provenance of the medical data documented (original sources, who entered or modified what, depending on the type of use case) so that I can know if data can be used.	blocking	AC0210.1	The system provides provenance information for the data elements in the knowledge graph.
			AC0210.2	The system shows in the sensitive logging (event sourcing) who created and modified the data.
			AC0210.3	The system provides an API endpoint where each event from event sourcing can be viewed.
C0216	As a data user when considering to access medical data through AIDAVA, I want to have an overview of the different timepoints that the data were collected so that I can check the changes in a patient's medical history over time.	blocking	AC0216.1	The system provides a clear display of all time points when the data was collected for a patient (Note: here the time and date of the original data collection, not the timestamp of the ingestion to AIDAVA is meant).
C0244	As a 3rd-party app developer and patient using AIDAVA, I want to be able to access AIDAVA in several countries so that I respect national regulatory requirements because regulatory demands and hospital rules in some countries require health data to never leave the country.	blocking	AC0244.1	AIDAVA is available in Austria.
			AC0244.2	AIDAVA is available in Estonia.
			AC0244.3	AIDAVA is available in the Netherlands.

C0212	As an expert curator using automatic data curation in AIDAVA, I want the application to open the referral letters, the digital history of the emergency card and the entries of the family doctor about the patient so that I can get the necessary additional information about the patient.	major	AC0212.1	The system shows where the data come from (location as in from hospital information system or patient app) and the source data document to the curator when they request it (e.g. clicking on a button or link).
			AC0212.2	The system provides the curator the possibility to ask for the source document of a data item.
C0214	As a patient and as a curator helping AIDAVA with manual data curation, I want to get information where the data, regarding which the AIDAVA health data curation and publishing virtual assistant is asking me for curation help, comes from so that I know the provenance of the data item.	major	AC0214.1	The KG stores provenance information for each data item in the KG. (Provenance information includes source of the data item, type of the source document, legal entity issuing the source document, issuing date/time of the source document, by whom was the source document validated, ...).
			AC0214.2	The system provides the patient and the expert curator the option to ask for the provenance of a data item. (e.g. by clicking on a "provenance information"-button).
			AC0214.3	The provenance information for a data item in the KG is displayed to the patient and the expert curator on demand (by default, in IPS format or component of IPS).
			AC0214.4	The system provides the patient and the expert curator the option to see a human readable form of the source, from which a data item was extracted. Note: in case the source was a document, the document shown to the user must be the document, which was ingested. It must be human readable and showing the complete context.
			AC0214.5	In case the source was a document: The pdf/immutable rendered version of the source document of a data item in the KG, which was extracted from a document, is displayed to the patient and the expert curator on demand.
C0217	As a data user retrieving medical data from AIDAVA, I want information on the date when diagnoses/imaging/lab results have been created (note: this is usually different from when they have been entered into the AIDAVA health data curation and publishing	major	AC0217.1	The system displays the actual creation date of diagnoses, imaging, lab results and treatments, which may differ from the entry date of these data into the AIDAVA health data curation and publishing virtual assistant.

	virtual assistant!) so that I can track whether they are pre or post treatment.			
C0219	As a data user when making sure that the AIDAVA health data curation and publishing virtual assistant delivers the right data, I want to see who is the author of the document (uploaded when, changed it when) so I can verify the source of data and feel I can trust it.	major	AC0219.1	The system displays the authorship details of the document (from which data in the PHKG were retrieved from), including information about the document's upload and modification timestamps.
C0220	As a data user when making sure that the AIDAVA health data curation and publishing virtual assistant delivers the right data, I want to see the source of data so that I can adequately assess the information I see.	major	AC0220.1	The system displays the source document of the data, providing users with information about where the data originated.
C0221	As a data user when making sure that the AIDAVA health data curation and publishing virtual assistant delivers the right data, I want to see which institution the data originates from (medical facility or other, name of physician) so that I can assess the medical relevance/trustworthiness of data.	major	AC0221.1	The system displays the name of the institution/device from which the data originates (e.g., medical facility or other) and the name of the physician associated with the data.
C0222	As a data user when considering to access medical data through AIDAVA, I want to know what has been done in the previous stages and where the data in the AIDAVA health data curation and publishing virtual assistant is coming from (data from the hospital, data from other clinics or GP, or self-measured data from patients) in order to protect patient privacy.	major	AC0222.1	The system provides information about the sources of data, including whether it is from hospitals, clinics, general practitioners, or self-measured data from patients.
			AC0222.2	The data source information is easily accessible to the user.
C0225	As a patient having my data in AIDAVA, I want to ensure that in IPS the AIDAVA health data curation and publishing virtual assistant is providing the data sources/document from where it is coming from so that I can find out why the AIDAVA health data curation and publishing virtual assistant comes up with that specific curated information.	major	AC0225.1	For the extracted IPS, the AIDAVA health data curation and publishing virtual assistant provides the source for each data item.
C0230	As a 3rd-party app developer and as a patient ingesting medical data into AIDAVA, I want to be able to supply metadata along with the provided input data (such as who entered it, a patient or a professional) so that the interpretation of that data can be steered.	major	AC0230.1	The system provides the possibility to upload metadata concerning the source data, together with uploading the source data.

C0213	As an expert curator using automatic data curation in AIDAVA, I want to know what the changes to the KG were so that I have a better overview of the KG.	minor	AC0213.1	The system shows on demand the changes done in the KG due to the user's curation work.
-------	--	-------	----------	--

3.1.7 Quality management

11 functional requirements concerning quality management have been assessed to be relevant for the prototype to be implemented within the AIDAVA project. For these 11 functional requirements in total 24 acceptance criteria have been defined.

Requirement ID	Requirement	Severity	Acceptance Criterium ID	Acceptance Criterium
C0289	As an expert curator willing to check the curated data in AIDAVA, I want to be able to see how the AIDAVA health data curation and publishing virtual assistant came up with certain information or where it found certain information (e.g. size of the tumour or TNM-staging) so that I can understand exactly what was going on every step of the way and I can trust the AIDAVA health data curation and publishing virtual assistant.	major	AC0289.1	The system provides the curator the option to see where the date/information originates from.
			AC0289.2	On demand of the curator, the AIDAVA health data curation and publishing virtual assistant displays where an information/datum comes from (database or system or device or app etc).
C0292	As an expert curator using automatic data curation in AIDAVA, I want to change my response in case of an error / a mistake so that I can have support from the AIDAVA health data curation and publishing virtual assistant to guide with a more correct answer; the changes I made must be logged.	major	AC0292.1	The system automatically runs quality checks - during the curation process - according to the defined quality rules.
			AC0292.2	When the system recognises a breach of any quality rule applicable, the system fires an alert and asks the user to correct the error. Then the system stores the answer with traceability in the PHKG.
			AC0292.3	In G1 - the question to the user is predefined. (In G2 - the system provides more contextual information to support the user.)
C0293	As a data user willing to check the data delivered from AIDAVA, I want to have access to some agreed parameters (anonymised statistics) computed out of the log files so that I can have details for the validation process.	major	AC0293.1	The system computes statistical parameters from the log files. (Note: predefined parameters is to be defined)

			AC0293.2	The user has access to those statistics computed by the AIDAVA tool in a predefined table.
C0294	As a data user when considering to access medical data through AIDAVA, I want to know what kind of quality checks have been done so that I will have access to high quality data.	major	AC0294.1	The system provides information about the quality checks performed on the accessed medical data.
C0295	As a data user when making sure that I can trust the data, I want the AIDAVA health data curation and publishing virtual assistant to measure the quality of the data so that I see that it has been validated according to certain standard criteria when data have been entered to the AIDAVA health data curation and publishing virtual assistant and no errors in future treatment plans will be made based on the available data.	major	AC0295.1	The system incorporates mechanisms to measure and assess the quality of data upon entry into the AIDAVA health data curation and publishing virtual assistant.
			AC0295.2	(Upon request by the data user) the AIDAVA health data curation and publishing virtual assistant provides information about how data has been validated according to established criteria upon entry into the AIDAVA health data curation and publishing virtual assistant.
C0296	As a data user when making sure that the AIDAVA health data curation and publishing virtual assistant delivers the right data, I want the AIDAVA health data curation and publishing virtual assistant to automatically measure the quality of the data based on certain standards so that I can make the right decisions and the next physician who will see the patient can make correct decisions as well.	major	AC0296.1	The system automatically measures the quality of the data based on predefined standards.
C0297	As a patient ingesting medical data into AIDAVA, I want to have safeguarding checks in place to recognize whether the data/information was input correctly, and the AIDAVA health data curation and publishing virtual assistant shall tell me to review this information when there are obvious mistakes (e.g. when mistakenly uploaded a health document from another person) so that I can review and correct the mistake.	major	AC0297.1	The system recognises automatically if the ingested data by a user belongs to a different person.
		major	AC0297.2	The system alerts the user and asks for review of the ingested data when it recognises data ingested belongs to a different person.
C0298	As a patient using automatic data curation in AIDAVA, I want to check (on demand) what the AIDAVA health data curation and publishing virtual assistant has done when automatically curating my data and the quality of the curated data and who has accessed it so that I can be sure that data curation is working correctly and the data are of high quality.	major	AC0298.1	When showing a data quality score, the AIDAVA health data curation and publishing virtual assistant provides an easy to understand description of the criteria of the data quality score, including the validation rules, and what AIDAVA has done to improve the quality.

			AC0298.2	The system shows on user's demand the quality score of the source data and the respective curated data.
			AC0298.3	The system shows on user's demand the source data and the respective curated data.
C0290	As an expert curator willing to check the curated data in AIDAVA, I want to be able to do random checks on the curated data (e.g. check difference between source data and curated data) so that I can see if the AIDAVA health data curation and publishing virtual assistant has problems to curate certain kind of data or information.	minor	AC0290.1	The system provides the curator the option to see the original source (document) of the data (to compare (e.g. side by side) the source data and the curated data).
			AC0290.2	On demand of the curator, the AIDAVA health data curation and publishing virtual assistant display the original source (document) of the data.
C0291	As an expert curator using automatic data curation in AIDAVA, I want the AIDAVA health data curation and publishing virtual assistant to check for when a report on a comparison between radiologic images is made in the ingested data and throw an alert if the compared images were not taken within a month from each other and are actually not comparable so that images that have been taken too far apart are not wrongly compared with each other.	minor	AC0291.1	The system realises if the radiology report includes a comparison of 2 images of a tumour in the context of breast cancer.
			AC0291.2	The system identifies if there is a period of more than 30 days between the 2 images compared.
			AC0291.3	The system notifies the user that there was an issue comparing radiologic images (=more than 30 days in between the images' dates).
C0215	As a patient and as a curator helping AIDAVA with manual data curation, I want to get information on how confident the data XY is in the knowledge graph so that I can trust the AIDAVA health data curation and publishing virtual assistant.	major	AC0215.1	For data items, which were retrieved/curated by AI tools, the KG stores confidence information as well as the source of this confidence information.
			AC0215.2	The system provides the patient and the expert curator the option to ask for the confidence of a data item in the KG. (e.g. by clicking a "confidence information" button).
			AC0215.3	The confidence information for a data item in the KG is displayed to the patient and the expert curator on demand.

3.1.8 Integration (APIs, usage in hospitals)

API and data transfer

13 functional requirements concerning AIDAVA's APIs have been assessed to be relevant for the prototype to be implemented within the AIDAVA project. For these 13 functional requirements in total 16 acceptance criteria have been defined.

Requirement ID	Requirement	Severity	Acceptance Criterium ID	Acceptance Criterium
C0307	As a 3rd-party app developer considering using AIDAVA, I want to have access to an API documentation including technologies used and versions so that I may know if my team has the required knowledge, and also speed up the development.	blocking	AC0307.1	AIDAVA provides OpenAPI specification.
C0362	As a 3rd-party app developer retrieving medical data from AIDAVA for my app, I want to know if the AIDAVA API will build upon an official standard so that I can be sure it will be maintained in the future.	blocking	AC0362.1	AIDAVA provides OpenAPI specification.
C0375	As a 3rd-party app developer ingesting medical data into AIDAVA, I want documentation of the push API to upload data and sample data set	blocking	AC0375.1	AIDAVA provides OpenAPI specification.
C0309	As a 3rd-party app developer considering using AIDAVA, I want a test instance of the AIDAVA health data curation and publishing virtual assistant so that I can test my application before connecting it to the productive system.	blocking	AC0309.1	A test instance of the AIDAVA health data curation and publishing virtual assistant is hosted by the hospital.
			AC0309.2	The solution (to be hosted by the hospital) is provided by GND.
C0312	As a 3rd-party app developer retrieving medical data from AIDAVA for my app, I want future versions of the API to be backward compatible so that my tool stays compatible.	blocking	AC0312.1	The API uses API versioning.
C0313	As a 3rd-party app developer retrieving medical data from AIDAVA for my app, I want the endpoints to give descriptive error messages so that we are able to develop in a productive way.	blocking	AC0313.1	OpenAPI specification describes error messages and error statuses on endpoints.

C0314	As a 3rd-party app developer retrieving medical data from AIDAVA for my app, I want to be able to rely on the API from a security perspective so that the data presented to a logged-in user is actually in the scope of what the user is allowed to see.	blocking	AC0314.1	Authorisation is used within the AIDAVA platform.
			AC0314.2	The system only allows access to authorised users for specific data.
C0317	As a 3rd-party app developer ingesting medical data into AIDAVA, I want the Input API for AIDAVA to be FHIR compatible so that I do not have to rewrite my data which are FHIR.	major	AC0317.1	The input API is compatible with FHIR.
C0319	As a 3rd-party app developer and patient using AIDAVA, I want the AIDAVA health data curation and publishing virtual assistant to confirm to comply with general standard in use of IT for healthcare (FHIR, SNOMED, LOINC) so that it will be easier to insert AIDAVA into my workflows.	major	AC0319.1	The system provides APIs compatible to FHIR.
			AC0319.2	The curated data is coded according to SNOMED, a standard ontology.
C0321	As a 3rd-party app developer and as a patient retrieving medical data from AIDAVA for my app, I want to be able to specify if I want the output format to be FHIR or native knowledge graph format so that I can fulfil the regulations and satisfy my use cases.	major	AC0321.1	The system offers different endpoints for different formats, including FHIR and native knowledge graph format.
C0320	As a 3rd-party app developer retrieving medical data from AIDAVA for my app, I want to be able to access data using a programming interface (API), so that my program can work in another environment.	major	AC0320.1	The system provides access to the data for 3rd-party app developers via API.
C0349	As a 3rd-party app developer (company) considering using AIDAVA, I want to know if we need different API's to pull and push data so that we can transfer data to AIDAVA and back from AIDAVA.	major	AC0349.1	AIDAVA platform provides OpenAPI specification.
C0318	As a 3rd-party app developer ingesting medical data into AIDAVA, I want an upload API that is based on technological standards so that I can use available libraries for my application.	minor	AC0318.1	AIDAVA platform provides OpenAPI specification.

Usage in hospitals

3 functional requirements concerning topics which are related to AIDAVA's usage in hospitals (e.g. data-source onboarding, compliance to data protection rules, security, integration with hospital information system...) have been assessed to be relevant for the prototype to be implemented within the AIDAVA project. For these 3 functional requirements in total 4 acceptance criteria have been defined.

Requirement ID	Requirement	Severity	Acceptance Criterium ID	Acceptance Criterium
C0299	As an expert curator using AIDAVA, I want AIDAVA to be integrated into the hospital information system so that AIDAVA can automatically have the data the hospital information system has.	blocking	AC0299.1	All data sources from the hospital system, which are specified in the DTS, are automatically ingested into the AIDAVA health data curation and publishing virtual assistant.
C0301	As a data user using AIDAVA, I want it to be a separate application so that our already slow hospital information system would not become even slower due to another added feature.	major	AC0301.1	AIDAVA is a standalone application separate from the hospital information system.
C0325	As a data user when considering to access medical data through AIDAVA, I want AIDAVA to include diverse data sources such as e.g. data from general practitioners, data from paid healthcare, and data from smart devices so that research projects can take into account a wider variety of information, since the data from the clinic is only a snapshot and longitudinal observations will become more and more important in the future (e.g. in ageing studies).	major	AC0325.1	AIDAVA incorporates diverse data sources, such as data from general practitioners, paid healthcare providers, and smart devices.
			AC0325.2	The system enables researchers to access and utilise a wide range of data, particularly for longitudinal studies and research projects.

3.2 Non-functional requirements

3.2.1 Performance

These requirements define the overall qualities that the AIDAVA health data curation and publishing virtual assistant must possess in order to meet performance-related goals and objectives, typically speed, throughput, capacity, and other performance-related factors.

Name	Description	Severity	Value (min-max)	
			G1 & G2	Product
Response Time (RT) - Loading data	Maximum amount of time the AIDAVA health data curation and publishing virtual assistant should take to respond to a user request.	major	Less than 3 seconds	Less than 3 seconds
RT- Workflow execution		blocking	Based on document (.txt, (image) - communicate estimate to user	
RT- User dialogue		major	Less than 3 seconds	Less than 3 seconds
Throughput	Maximum number of requests or transactions the system should be able to handle per second, minute, or hour. <i>Example:</i> Number of documents processed at the same time	minor	1 data source per user, in sequence	?
Concurrent users	Ability to handle multiple users or requests at the same time, without slowing down or crashing. <i>Example:</i> Number of users who can simultaneously access and use the system without compromising its performance.	major	20	100?
Volume of data	Ability to handle the volume of data representing the longitudinal record of the patients - including multiples data sources - except imaging and omics type of data Estimates <ul style="list-style-type: none"> one patient PHKG/year = 80 MB [ref] 10 years for 30 patients = 24 GB 	blocking	50 GB	Several TB

3.2.2 Scalability

Ability to expand or reduce its capabilities in response to changing demands (increased loads or usage as the system grows). Scalability describes the expected behaviour of the system when there is an increase or decrease in the amount of data, users, or transactions it needs to handle.

A common way to measure scalability is to look at how the system performs as the workload increases and specify the expected performance characteristics of the system under various conditions. Overall, scalability of non-functional requirements is important to ensure that the system can handle increased demands without a significant decrease in performance or stability.

Name	Description	Severity	Value (min-max)	
			G1 & G2	Product
Vertical Scalability	Ability of the system to add more resources, such as memory or processing power, to a single server to handle increased demand.	minor	NA	YES

Name	Description	Severity	Value (min-max)	
			G1 & G2	Product
	<i>Example.</i> System must be able to handle a doubling of the number of users without any degradation in performance.			
Elasticity	Ability of the system to automatically scale up or down in response to changing demand. <i>Example.</i> System must be able to automatically provision additional resources when traffic spikes and release them when traffic decreases.	minor	NA	YES
Load Balancing	Ability of the system to distribute the workload evenly across multiple servers or nodes. <i>Example:</i> System must be able to evenly distribute incoming requests across all available servers.	minor	NA	YES

3.2.3 Availability

Expected uptime of the system and the level of service that the system should provide to its users; typically expressed as a percentage of time, such as ‘the system should be available 99.9% of the time’. This is important because they ensure that the system is reliable and dependable, and that users can access the system when they need to.

Name	Description	Severity	Value (min-max)	
			G1 & G2	Product
Availability	Accessibility of the system by the end user to perform the tasks.	major	8/5	24/7
Disaster Recovery	Ability to recover from a catastrophic event, such as a power outage or a natural disaster. <i>Example:</i> System must be able to recover within a certain amount of time, such as 24 hours.	major	24 hours	24 hours
Redundancy	Ability to continue functioning even if one or more components fail. <i>Example:</i> System must have redundant components, such as servers or data centres, to ensure that the system remains available even if one component fails.	major	NA	YES
Maintenance Downtime	Amount of time the system will be unavailable due to scheduled maintenance or upgrades. <i>Example:</i> System must be available at least 99% of the time, even during scheduled maintenance windows.	minor	> 90% (no maintenance foreseen during working hours)	90% (with planned maintenance)

3.2.4 Reliability

Ability to consistently deliver the expected results - i.e. perform its intended functions - over a period of time without any unexpected or unplanned downtime. This is important because it ensures that the system can be trusted to perform its intended functions without any errors or failures.

Note: AIDAVA does not include time critical transactions.

Name	Description	Severity	Value (min-max)	
			G1 & G2	Product
Mean Time Between Failures (MTBF)	Average time between system failures. <i>Example:</i> at least 10,000 hours, meaning that the system should be able to operate continuously for at least 10,000 hours without failing.	minor	90% (or 9 hours in a day of 10 working hours)	90%
Mean Time To Repair (MTTR)	Average time it takes to repair the application after a failure (show stopper) occurs. <i>Example:</i> no more than 4 hours, meaning that the system should be repaired and back to normal operation within 4 hours of a failure.	blocking	48 hours (unless failure due to data issue - e.g. difference between actual data and data transfer specifications)	24 hours
Fault Tolerance	Ability to continue functioning even if one or more components (e.g. curation tool) fail. <i>Example:</i> System must have redundant components, such as servers or data centres, to ensure that the system remains available even if one component fails.	major	YES Min = 48 hours Max = 1 week	YES

3.2.5 Maintainability

Ease with which a system or application can be maintained and updated over its lifetime, i.e. ability to be modified, updated, or repaired without affecting its overall functionality or performance. It is important because they ensure that the system can be easily maintained and updated, which can reduce the cost and time associated with system maintenance and updates.

Name	Description	Severity	Value (min-max)	
			G1 & G2	Product
Modularity	Extent to which the system is composed of individual modules or components that can be modified or updated independently without affecting the rest of the system in production. <i>Example:</i> System should be composed of independent modules or components that can be updated or modified without affecting the rest of the system.	minor	NO	TBD
<i>Documentation</i>	Extent to which the system is documented, including the code, user manuals, and technical documentation. <i>Example:</i> The system should have clear and detailed documentation that can be easily understood and updated by future developers or maintainers (see Section 3.2.10 with more details on content).	major	YES	YES
Testability	Extent to which the system can be tested and validated to ensure that it continues to function correctly after updates or modifications. <i>Examples:</i> <ul style="list-style-type: none"> Unit testing, Integration testing, Performance testing Automated test cases that can be run after updates or modifications 	major	ALL except automated test cases (NTH) Using CI/CD we will verify at each commit that tests are	ALL

Name	Description	Severity	Value (min-max)	
			G1 & G2	Product
	<ul style="list-style-type: none"> Availability of testing data sets and testing scenarios. Test coverage percentage (e.g. unit testing / code coverage = 80% in an hospital system)		still running and application is functioning properly	
Code Maintainability	Extent to which the system's code is well-organised and well-structured, making it easy to modify or update. <i>Example:</i> system's code should follow coding standards, be well-documented, and be structured in a way that makes it easy to understand and modify.	major	Nice to Have (NTH)	YES
Issue Tracking	Storing and monitoring of the issues - including priorities and status - in a centralised manner (e.g. Atlassian or Montis).	major	YES	YES
Release Management (version control)	The following components must have strict version/release management <ul style="list-style-type: none"> Centrally (and synchronised with the site instances): the library of curation tools, the Reference Ontology In each site where AIDAVA is deployed: the User Directory, the Catalogue of Data Sources, the Master Data repository 	blocking	YES	YES

3.2.6 Serviceability

Refers to the ease with which a system or application can be serviced or repaired in the event of a failure or malfunction. This is important because they ensure that the system can be quickly and easily repaired or serviced, which can reduce downtime and minimise the impact of failures or malfunctions.

These requirements were established by the administrators and further enriched with requirements concerning a helpdesk for user support by the different users.

Name	Description	Severity	Value (min-max)	
			G1 & G2	Product
Serviceability Documentation	Extent to which the system is documented for service and maintenance purposes. <i>Example:</i> System should have clear and detailed documentation for service and maintenance purposes.	major	MIN for set-up (see deployment)	YES
Remote Serviceability	Extent to which the system can be serviced or repaired remotely (assuming full access on local sites). <i>Example:</i> System should be designed to allow remote servicing or repairs to be carried out quickly and easily.	blocking	YES	YES
Tooling Requirements	Extent to which specialised tools or equipment are required to service or repair the system. <i>Example:</i> System should be designed to minimise the need for specialised tools or equipment to service or repair the system.	minor	TBC after architecture	YES
System support	24/7 "helpdesk" chat box so that I can have answers to my AIDAVA data curation questions.	major	8/5	24/7

Name	Description	Severity	Value (min-max)	
			G1 & G2	Product
HelpDesk	Access to organised support <ul style="list-style-type: none"> ● in the case of system breaks down, to be secure in terms of data privacy ● for users who <ul style="list-style-type: none"> ○ do not understand a question raised by the system and want to provide feedback to improve the system ○ want to report errors in the data and correct information in the system ○ want to report bug/mistakes in the system, so that they can be fixed 	major	Yes - See Customer support (Solution Design)	yes
Error Handling	Ability to handle errors and exceptions gracefully without affecting the overall system functionality. <i>Example:</i> System is able to handle errors without crashing or losing data, and provide notification to the users.	blocking	(After customer support agreed)	

3.2.7 Security and data privacy

System's ability to protect itself from threats and attacks such as unauthorised access, use, disclosure, disruption, modification, or destruction. It is important because this ensures that the system and its data are protected from unauthorised access, theft, or other malicious activities.

This is particularly important in the context of AIDAVA as we manage personal identifiable data which are considered as sensitive data per GDPR.

Name	Description	Severity	Value (min-max)	
			G1 & G2	Product
User Profile	The AIDAVA admin (across all sites/ product level) should be able to define templates user profiles, based on roles, with access rights and permission.	major	YES	YES
User Management	The local Site admin of the system should have the possibility to create, update, delete user accounts - based on the user profile template (see as well user management).	major	NTH (manual?)	YES
Authentication and Authorization	Extent to which the system requires users to authenticate themselves and the level of access they have to the system's resources. (Need to clarify if this is done independently or as SSO to ensure integration with HDI and national authentication systems ⁷). <i>Example:</i> The system should require strong passwords or multifactor authentication, and limit user access based on their roles and responsibilities.	blocking	Standalone system (no SSO)	SSO
Data Protection	Extent to which the system protects sensitive data from unauthorised access, use, or modification.	blocking	YES	YES

⁷ Check usability of google authentication to facilitate integration across different systems

Name	Description	Severity	Value (min-max)	
			G1 & G2	Product
	<i>Example:</i> System should encrypt sensitive data, protect it from unauthorised access, and ensure data integrity.			
Security Monitoring	Extent to which the system monitors for and responds to security threats or attacks. <i>Example:</i> The system should have intrusion detection systems, log analysis, and incident response procedures in place.	major	YES	YES
Storage and Privacy by Design	<ul style="list-style-type: none"> Ensure that PHKG are stored in patient specific data stores (e.g. HDI personal health data storage, Patient vault or SOLID Pod) to avoid a central DB with all patient data. Ensure that fundamental design choices for the prototype architecture do not preclude such future decentralised storage modes in the final product 	major	NTH	YES
Data store	<ul style="list-style-type: none"> Ensure secure data storage and transfer Type of data store (C03353), cloud or local (C0367) Permanent data storage or other – for ingested data and for PHKG (C0365, C0354) 	blocking	YES	YES

3.2.8 Regulatory

System's ability to comply/adhere with/to applicable laws, regulations, standards, and guidelines related to its operation and use. It is important because this ensures that the system operates within the boundaries set by regulatory authorities, and avoids legal or regulatory penalties or other consequences.

Name	Description	Severity	Value (min-max)	
			G1 & G2	Product
Compliance	Extent to which the system complies with applicable laws, regulations, and industry standards related to security. <i>Example:</i> System should comply with standards such as PCI-DSS, HIPAA, or GDPR, MDR, ISO27001	blocking	GDPR (DPIA)	HIPAA, GDPR, MDR
Compliance with Standards	System complies with industry standards, such as ISO or IEEE standards that are relevant to its operation. <i>Example:</i> System should comply with a specific standard or set of standards. <i>Note:</i> Following architecture principle 2, the prototype proposed for MDR certification but it should include all aspects content that will support certification for the product to come.	major	See Reference ontology (D2.1)	
Compliance with Laws and Regulations	System complies with applicable laws, regulations, and guidelines. <i>Example:</i> System should comply with specific regulations, such as data protection laws or safety regulations as well as quality/ safety requirements.	blocking	See compliance above	TBD (based on countries)
Certification and Accreditation	System has been certified or accredited by regulatory bodies or industry associations.	minor	NTH	YES

Name	Description	Severity	Value (min-max)	
			G1 & G2	Product
	<i>Example:</i> System should be certified or accredited by a specific organisation or agency.			
Auditability	The system can be audited or reviewed to ensure compliance with regulatory requirements. <i>Example:</i> System should have built-in audit trails (who, what, when, why) or other features that allow for auditing or review.	blocking	YES	YES
PWD	Periodically check, recall and/or revise issuance of Identification code and password (e.g. Password expiration after 90 days).	major	NTH	YES

3.2.9 Usability

System's ability to be easy to use and intuitive for its intended users, i.e. to provide an effective and efficient user experience, and to be easy to learn and use. It is important because this ensures that the system is user-friendly and meets the needs and expectations of its intended users.

In the case of AIDAVA, this is very important, since often patients may be elderly people (even if in our case we could select only young patients).

Name	Description	Severity	Value (min-max)	
			G1 & G2	Product
Ease of Use	System is easy to use and navigate for the patients and the expert curator (based on System Usability Scale defined in the Study Protocol) for its intended users (to be measured through system usability scale during evaluation). Note: this does not apply to the AIDAVA admin and the Site Admin.	major	YES	YES
Learnability	System is easy to learn and use for its intended users, measured by filling the System Usability Scale questionnaire used for assessing the prototype (first primary end point in the study protocol #1. <i>Maximise acceptance by end users and potential involvement of citizens in curating health data</i>).	major	YES (see study protocol)	YES
Efficiency	System is efficient and effective in performing its intended tasks - measured by checking the following primary endpoints in the study protocol: #2. <i>Measure impact on workload for quality enhancement of data</i> #3. <i>Measure quality of data resulting from the data curation and publishing - in terms of their interoperability and reusability</i> #4. <i>Assess percentage of reuse of content of clinical narratives</i>	major	YES (see study protocol)	YES
Accessibility	System is accessible to users with disabilities or other special needs. <i>Example:</i> System should provide features such as screen reader compatibility or keyboard shortcuts. <i>Note for the product: Need to be aware of regulations related to discrimination.</i>	minor	NO (exclusion criteria)	NTH

Name	Description	Severity	Value (min-max)	
			G1 & G2	Product
Help/ training	System documented – online manuals (in English). Training material (translated in 3 languages - German, Dutch, Estonian) available for patients and expert curators, not for Administrators.	major	YES	YES
Usability	Possibility to have a copy of entity records in both human readable and electronic form, where the meaning has been preserved (CFR2).	minor	NTH	YES

3.2.10 General design principles

Name	Description	Severity	Value (min-max)	
			G1 & G2	Product
Language	System must support at least Estonian, German and Dutch as well as English (as common language).	blocking	YES	YES
Platform	Maximise usage of smartphones (Android and iPhone) versus web app. When a user works on their smartphone and goes to the web application (and vice versa, whenever possible as web functions will be richer than smartphone ones), the system should remember what was done (i.e. when the user last stopped).	blocking	YES	YES
Integration - Bot	Ensure that the Chat/type BOT interface can integrate with the existing environment of a customer mobile app.	major	YES	YES
Integration - Web	Ensure that the WEB Interface can integrate smoothly with the existing environment of a customer mobile app.	major	YES	YES
Release management	Regular release of the product with release notes. Note: In the context of AIDAVA there will be at least 2 releases: G1 and G2.	minor	NTH	YES
Metrics	Metrics to measure success and value (min-max) of the product including <ul style="list-style-type: none"> User parameters Time to perform actions Note: This relates to the end point defined in the study protocol.	major	YES	YES
Informational Self- Determination	Allow as granular as possible control - and consent - of patients over the personal data within the PHKG, i.e. its use by third parties and its long-term storage. Ensure that fundamental design choices for the prototype architecture do not preclude such future granular control modes in the final product.	blocking	NO (constrained by protocol)	YES
Parsimony and Modularity	Determine to what extent the curation assistant needs to possess the functionality of a (personal) health data storage platform (user management, data sharing, etc.) respectively, to what extent <u>it is supposed to exist as a module within such platforms</u> (hospital data systems, health data intermediaries, others), using the respective existing functionalities of the respective platforms.	major	NO	YES
Liability	As part of deployment confirm that the system cannot be liable with respect to the data output of the AI algorithm.	blocking	NO	YES

Name	Description	Severity	Value (min-max)	
			G1 & G2	Product
	In the study evaluation protocol, it is clearly specified that <i>"As the system is a prototype, no part of it (including any AI algorithm included in the system) will neither be used for clinical decision making nor be used as a decision support system for clinicians. "</i> <i>Note: AIDAVA is a Software as a Medical Device - therefore subject to Medical Device Regulation before it can be considered as a usable product.</i>			
Quality	Ensure that output (i.e. curated) data is of high quality i.e. they are a correct transformation from the original data. In case 100% certainty cannot be ensured during transformation, provide a quality score. This will be measured by checking the following primary end point #3 of the study protocol. <i>Measure quality of data resulting from the data curation and publishing - in terms of their interoperability and reusability.</i>	major	YES	TBD
Open Access	Publish results on ZENODO (EOSC) or on GitHub, using appropriate licence <ul style="list-style-type: none"> ● User requirements (D1.2 and D1.3) ● User stories with performance criteria ● Executable code 	major	YES	NO
Pricing	Ability to price AIDAVA related services based on fair cost (taking into account licensing for supporting tools as well as AIDAVA licence fee).	major	NO	YES

3.2.11 Documentation requirements

81 requirements concerning training, documentation, information, and FAQs for AIDAVA have been assessed to be relevant within the AIDAVA project, either for the use of the prototype or for a description of the "to be" product. In addition, the administrators identified a minimum set of guidelines/manuals that would be required to support their work while setting the system locally, as well as the users.

These different requirements for documentation were structured into 4 documents described below.

System Manual

Objective: Guideline for Installation, Configuration, Maintenance

Target Audience: Site Administrators, Developers

Expected Content

Installation - prerequisite <ul style="list-style-type: none"> ● Licensing ● System architecture and interfaces ● System requirements <ul style="list-style-type: none"> ○ software and hardware (docker, VMware?) ○ storage (DB type, size) -

<ul style="list-style-type: none"> ○ CPU/GPU ● Data Sources metadata ● Imaging metadata management ● Instructions for set-up/installation and data ingestion ● How to upload and download data in / from AIDAVA using the API (and Data Transfer Specification): API (endpoint / formats / version / semantics) for retrieving medical data and test <p>Configuration - How to perform curation tool onboarding Not applicable - done centrally before the tool is deployed in each site</p> <p>Configuration - How to perform data sources onboarding How to enter information into Data Source catalogue</p> <p>Configuration - How to manage users</p> <ul style="list-style-type: none"> ● Description of roles and access rights of each role: who has access to which data, ● How to manage user information into the User Directory (how to enter; how to adapt information such as role, PWD, personal info...) <p>Support</p> <ul style="list-style-type: none"> ● Contact person ● How to restore solution in case of problem ● Support process (who is responsible of support for the system including contact name) <p>Maintenance</p> <ul style="list-style-type: none"> ● What does it include - how often - what is needed? ● What interfaces need to be updated ● What access do I need for maintenance

User Manual

Objective: Information for the users (as part of the training)

Target Audience: all potential users (patients, curators, data users)

Expected Content

<p>General information</p> <ul style="list-style-type: none"> ● Goals of the AIDAVA health data curation and publishing virtual assistant and main functionalities ● Purpose of the usage of health data in AIDAVA in a detailed way ● How the tool is supposed to interact with the local hospital information system and subsystems ● Define tasks expected from patients and for expert curators, and level of literacy needed ● Standards supported (for ingestion and publishing) <p>Ensure system can be trusted</p> <ul style="list-style-type: none"> ● Legal foundation on which AIDAVA is based ● How does AIDAVA comply with data protection regulation and is secure; <ul style="list-style-type: none"> ○ are data pseudonymized; ○ what happen to my data when deleting my account ● How AIDAVA protects the data that have been ingested ● How data are curated and how does AIDAVA ensure that curated data are of quality ● Confirm that AIDAVA is not a medical product ● Confirm that AIDAVA does not make diagnoses ● How data in the AIDAVA app (smartphone of a patient) is accessible <p>Support</p> <ul style="list-style-type: none"> ● Clear definition of responsibilities for AIDAVA ● How often there will be updates and security patches

- Need to know if back-ups are necessary and if yes, how
- How to report bugs/issues

FAQ

Objective: Provide information to users on critical aspects of the systems

Target Audience: all potential users (patients, curators, data users) as well as site administrators

Expected Content

- How data protection is ensured - are data pseudonymized; is it possible to delete my data
- What about security
- Which error can be identified and how?
- Main functionalities of AIDAVA
- How to use the system
- Certification by manufacturer
- Access to online help/documentation
- How to report bugs and issues to improve the system

Product Manual

Objective: Information on the product "to be" that can be used as a basis for potential customers - like third party app developers - of this future product to assess the benefit and value

Target Audience: developers/potential customers, site administrators, patients and other users with advanced knowledge and interest in the product

Expected Content

- **Benefits** of using AIDAVA and curated data
- **Standards in use:**
 - supported formats & version for data ingestion, storage and data use
 - licensing of used standards
 - quality standards supported (e.g. ISO 27001)
 - compliance with guidelines Medical Device Regulations (MDR) and AI
- **Data privacy aspects**
 - liability,
 - data linkage,
 - consent management
- **Data ingestion:** batch or on demand - based on Create, Read, Update, Delete (CRUD)
- **Data use**
 - Standard ways to display and retrieve data
 - Allowed purpose of data use
 - Expected quality of data
- **Storage**
 - Size restrictions
 - Type of data store, cloud or local
 - Permanent data storage or other – for ingested data and for PHKG
- **Pricing & business model**

4 Conclusions

Gathering of business requirements can be a difficult task - certainly for highly innovative products like the AIDAVA virtual assistant, as it may be difficult for the end user to figure out what the system could and should do.

Thanks to the highly structured approach, starting through the user journey across the different users to collect a maximum of requirements and then going through a consolidation and prioritising exercise, allowed the team to capture what is deemed as a quite complete list of business requirements. In total, 596 requirements were found, of which 113 were duplicates and 107 are out of scope. The remaining 376 requirements are divided into 218 functional requirements and 156 non-functional requirements. 83 of the requirements in scope are patient requirements, 64 are expert curator requirements, 70 are data user requirements, 100 are third party app developers' requirements and 58 are administrator requirements. The epics for which the most requirements were identified were documentation and data publishing. This shows the extensive need for documenting the AIDAVA prototype, and also the desire of the users to use the finished product.

For the functional requirements, in total, 144 requirements are relevant for the prototype. For those 144 requirements, 246 performance criteria were formulated. These will be used further in Task 3.2, as described in Section 5.

All the requirements will be revisited and reviewed again for G2 in the Deliverable D1.9 in the year 3 of the AIDAVA project.

5 Next steps

The business requirements elaborated in Task 1.3 describe from the point of view of the stakeholders (i.e. users, consumers, customers) *what* functionalities the AIDAVA virtual assistant shall provide, and *why* these functionalities are needed. This deliverable - and the associated material created during Task 1.3. - is the basis for the elaboration of the formal specifications to be used by the development team; the acceptance criteria are specifically important as they will allow to check if the AIDAVA developed prototype fulfils the business requirements.

As the next step in the project, GND will review all the requirements provided, integrate this with interoperability and automation requirements (from Deliverable D2.1 and D2.2) as well as additional quality management requirements (from Deliverable D4.6) and identify the features of the system.

To visualise the user interface and propose UX solutions, GND will prepare wireframes, expanding on the personas identified in Deliverable D1.2 and on the concept wireframes introduced in Deliverable D2.3. These wireframes will help present possible design solutions and interactions. Then, GND will validate these solutions with stakeholders and gather their feedback, with a specific focus on the patients through the group of patient consultants. Based on the feedback received, they will continuously improve and iterate on the solutions.

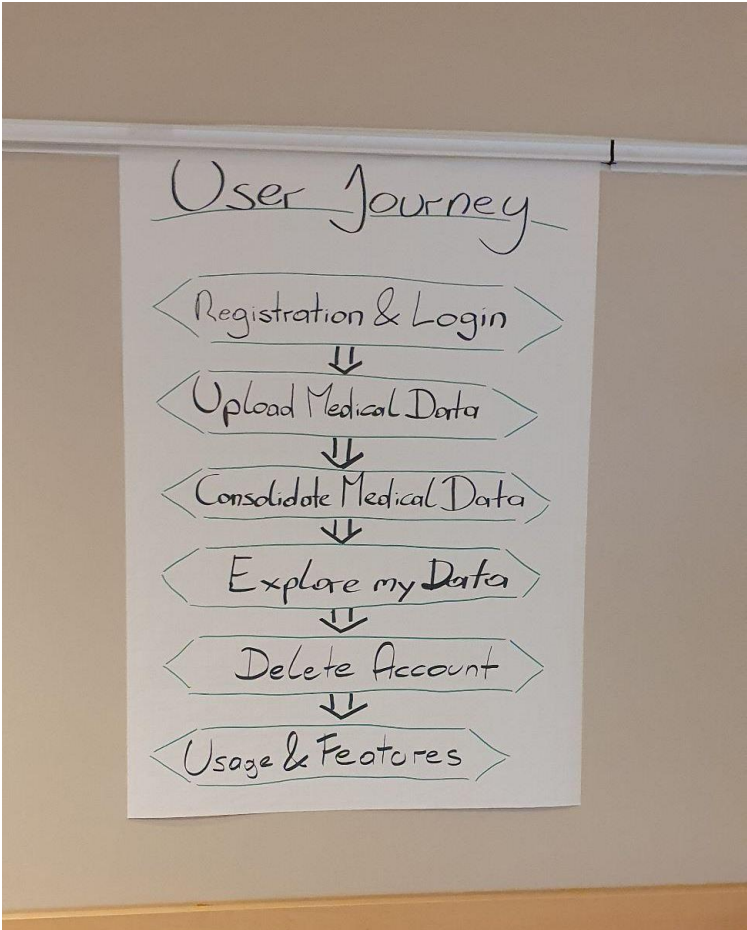
Next, they will align the system architecture with the solution design and the identified business requirements. This will involve selecting the appropriate tools, technologies, and frameworks required to fulfil the business requirements.

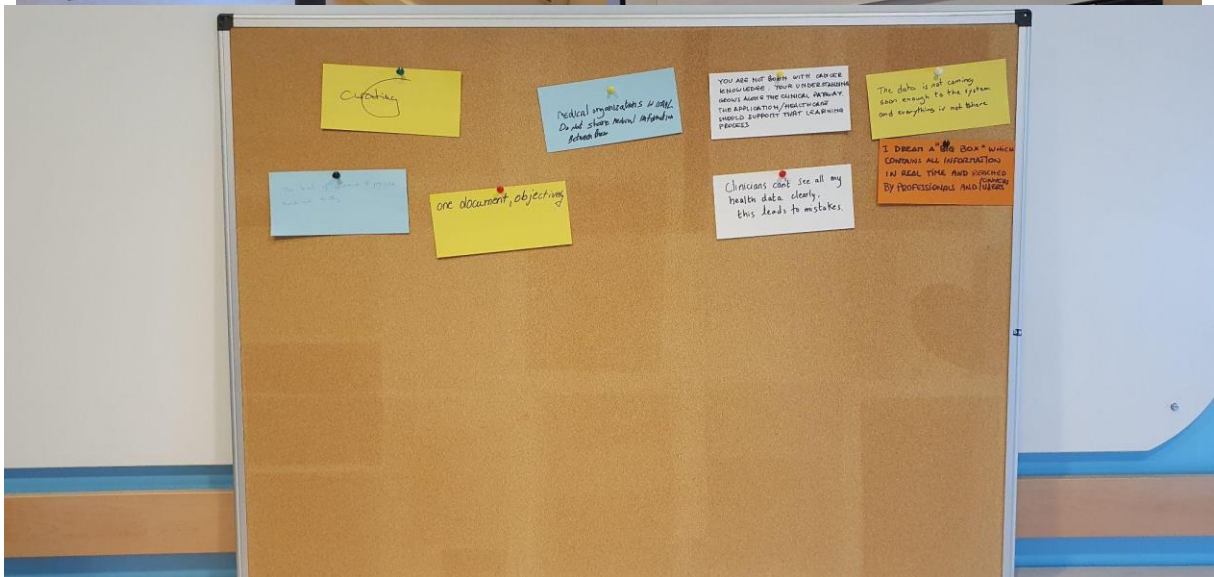
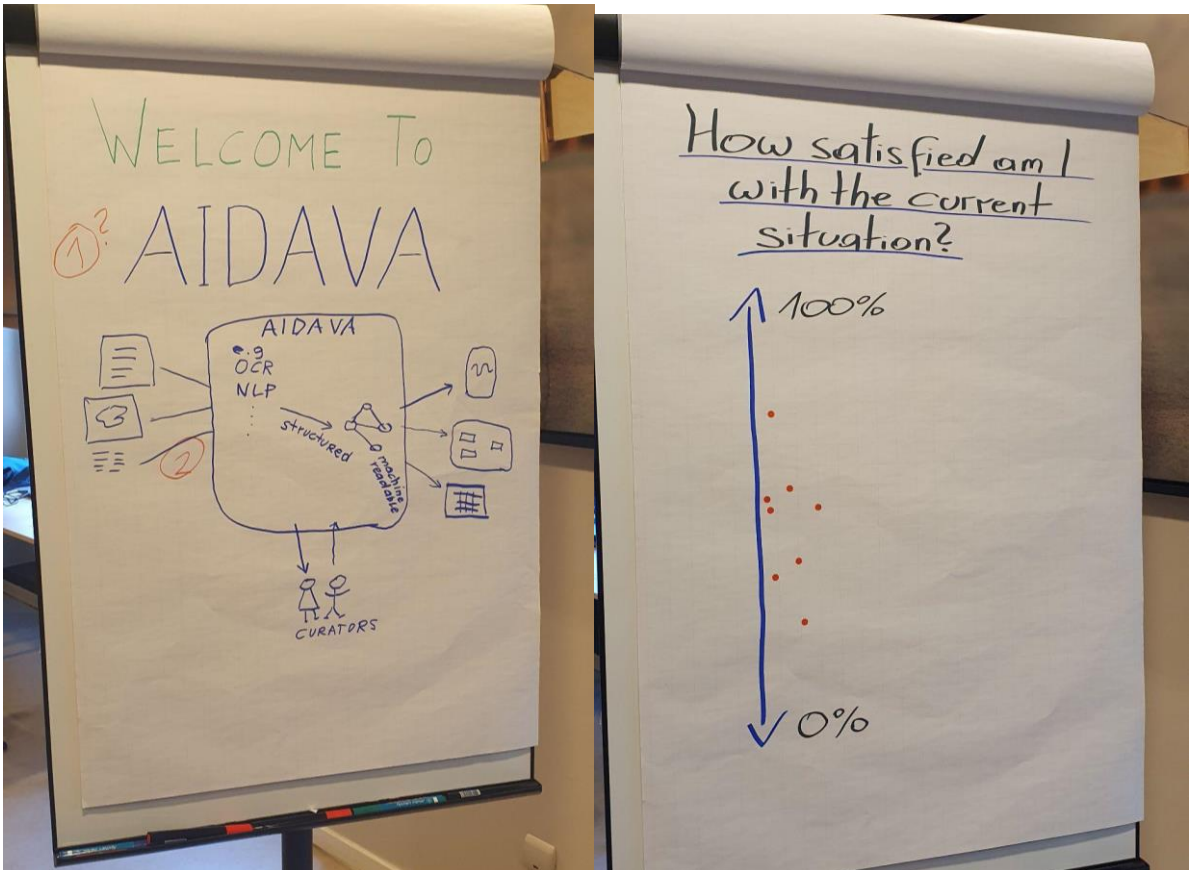
Finally, GND will write user stories - organised in epics and initiatives per the AGILE methodology - based on the finalised UX solutions and business requirements (FRs and NFRs). Epics will capture larger functionalities or features, while user stories will focus on specific user interactions or tasks. By breaking down the epics into multiple user stories, they ensure that each story addresses a particular feature.

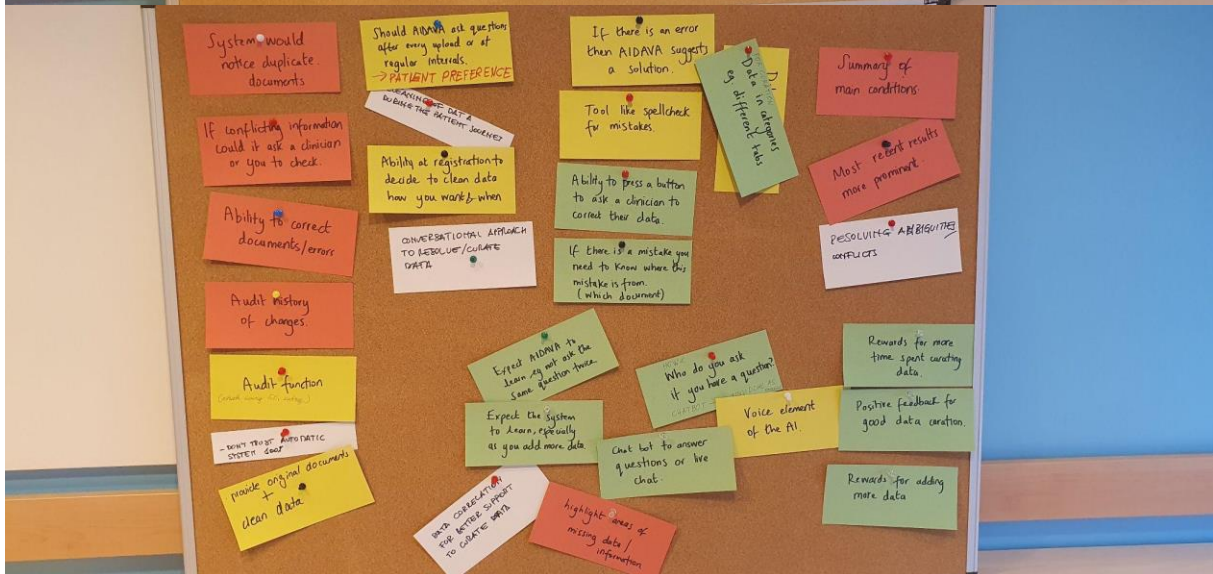
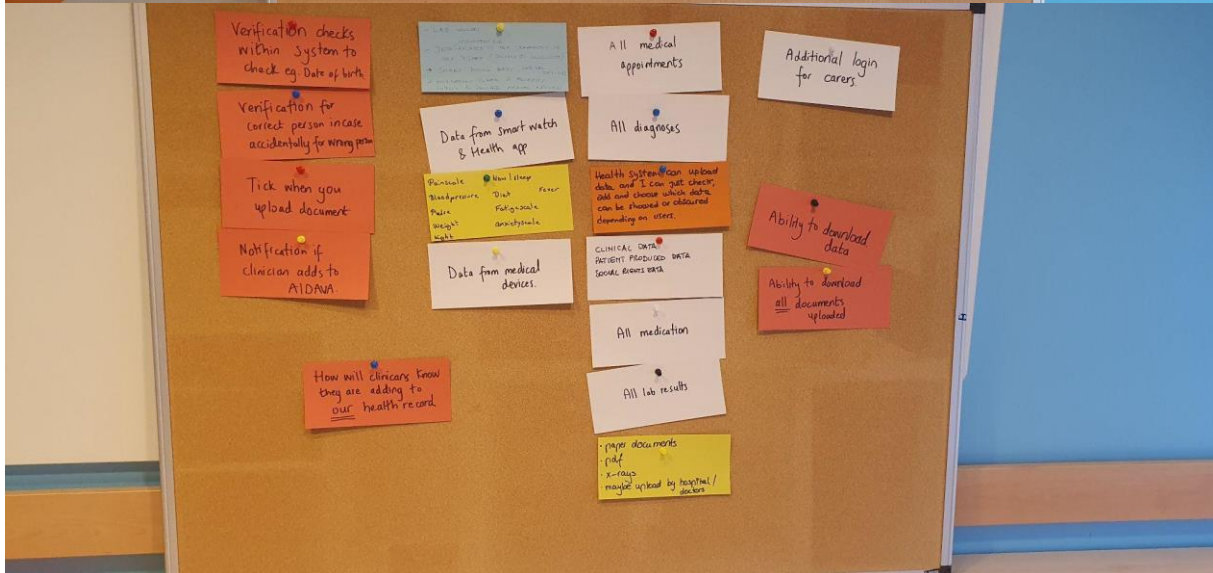
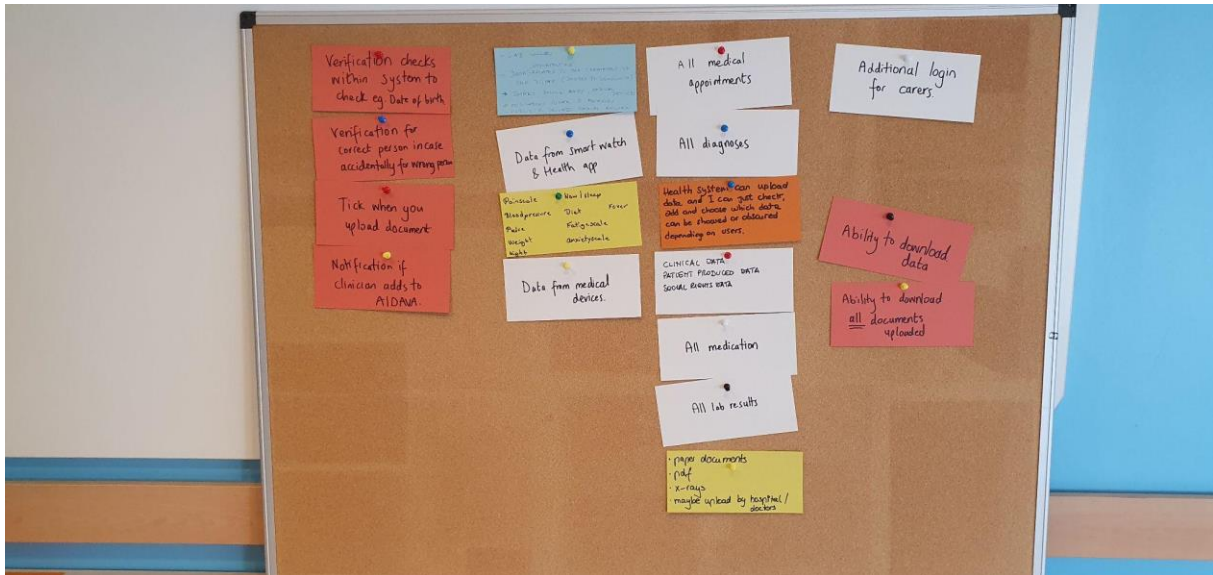
By following this approach, the development will ensure a structured and efficient progression of the project, leading to the delivery of the desired outcome as per the specified requirements.

6 Annexes

6.1 Photos of the workshops







CHECK THE DATA

Einmalige C

- Rückmeldung bei dem Ergebnis, das aus dem Analyseplan folgt
- Analyse des Datenmaterials

Problemlösung

- > Primärlösung!
- > Sekundärlösung, wenn Primärlösung nicht möglich ist

Problemlösung

- > Sekundärlösung, wenn Primärlösung nicht möglich ist
- > Tertiärlösung, wenn Sekundärlösung nicht möglich ist

Problemlösung

- > Quartärlösung, wenn Tertiärlösung nicht möglich ist
- > Quintärlösung, wenn Quartärlösung nicht möglich ist

Problemlösung

- > Sextärlösung, wenn Quintärlösung nicht möglich ist
- > Septärlösung, wenn Sextärlösung nicht möglich ist

Problemlösung

- > Oktärlösung, wenn Septärlösung nicht möglich ist
- > Nonärlösung, wenn Oktärlösung nicht möglich ist

ACCESS MEDICAL DATA

II.1.1

- > Welche Daten können abgefragt werden?
- > Wie werden diese Daten abgefragt?

II.1.2

- > Welche Daten können abgefragt werden?
- > Wie werden diese Daten abgefragt?

II.1.3

- > Welche Daten können abgefragt werden?
- > Wie werden diese Daten abgefragt?

II.1.4

- > Welche Daten können abgefragt werden?
- > Wie werden diese Daten abgefragt?

II.1.5

- > Welche Daten können abgefragt werden?
- > Wie werden diese Daten abgefragt?

II.1.6

- > Welche Daten können abgefragt werden?
- > Wie werden diese Daten abgefragt?

RETRIEVE MEDICAL DATA

R1

- > Welche Daten können abgefragt werden?
- > Wie werden diese Daten abgefragt?

R2

- > Welche Daten können abgefragt werden?
- > Wie werden diese Daten abgefragt?

R3

- > Welche Daten können abgefragt werden?
- > Wie werden diese Daten abgefragt?

R4

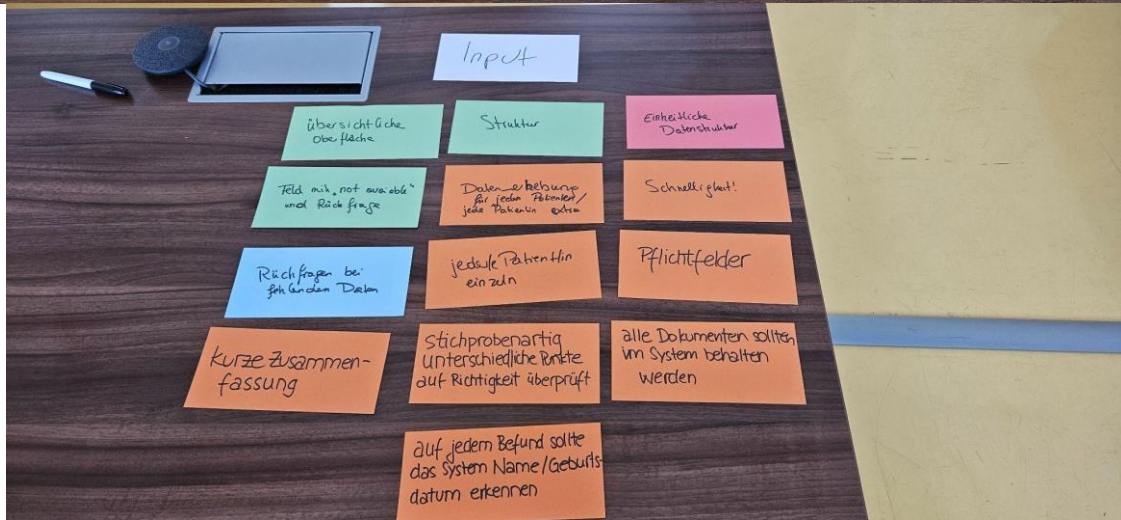
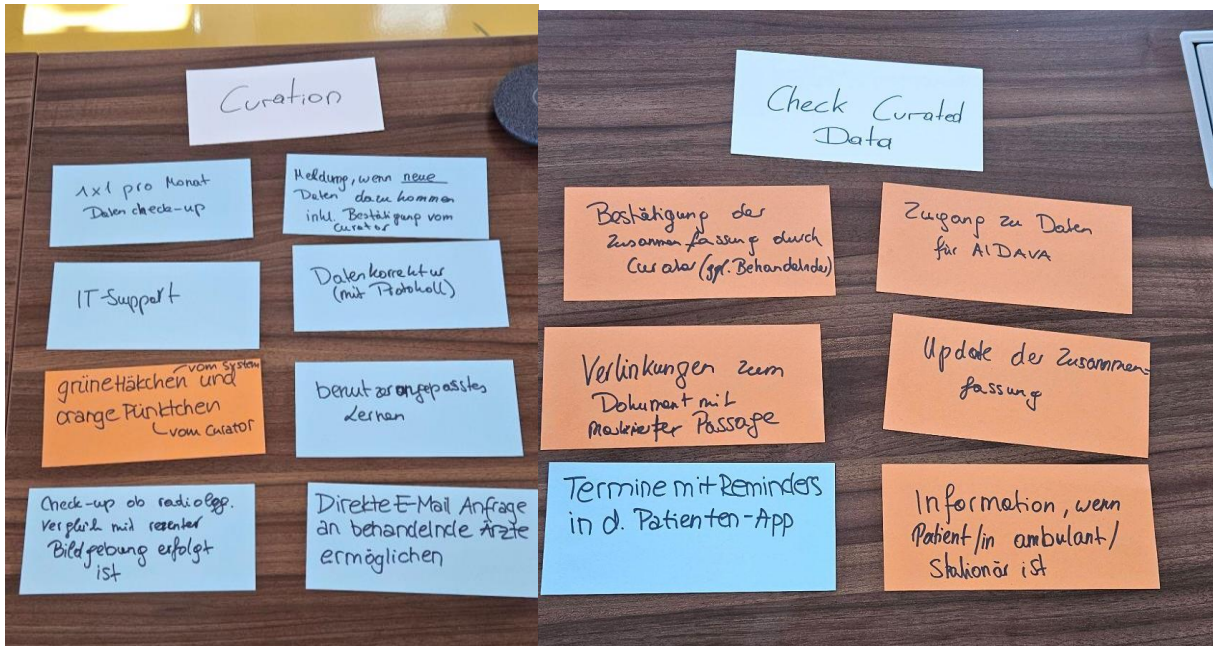
- > Welche Daten können abgefragt werden?
- > Wie werden diese Daten abgefragt?

R5

- > Welche Daten können abgefragt werden?
- > Wie werden diese Daten abgefragt?

R6

- > Welche Daten können abgefragt werden?
- > Wie werden diese Daten abgefragt?



ANDMEKURAA TOR

1. Meditsiiniliste andmete sisestamine

1.1. *QWERTZ*

1.2.

1.3.

1.4.

1.5.

1.6. ANDMETE SAÄLITAMINE

Nordic OFFICE

ANDMEKURAA TOR

2. Meditsiiniliste andmete kureerimine

2.1.

2.2.

2.3.

2.4.

2.5.

2.6.

2.7.

2.8.

2.9.

Nordic OFFICE

ANDMEKURAA TOR

3. Kureeritud andmete kontrollimine

3.1. REERIMINE OIFE

3.2. *REERIMINE*

SÜSTEEMI VIGA

Nordic OFFICE

ANDMEKURAA TOR

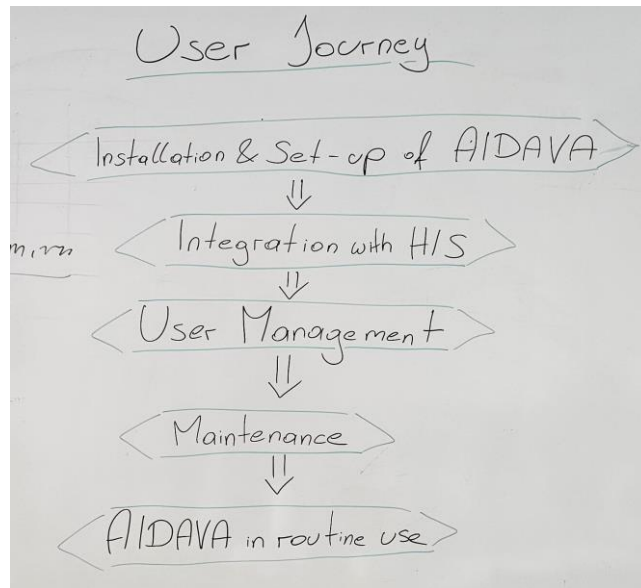
4. Süsteemi kasutamine

4.1. REERIMINE

4.2.

4.3. *REERIMINE*

Nordic OFFICE



MAINTENANCE

- TRUST
- DOCUMENTATION
- HANDBUCH
- REMOTE SUPPORT
- KOSTEN?
- 24/7
- BENÖTIGTE KRITIKER
- WENIG AUFWAND
- KOMMUNIKATIONSKANÄLE
- UPDATES
- SECURITY PATCHES
- ZUVERLÄSSIGKEIT
- PERFORMANCE
- UPDATES/WARTUNG DER SICHSTELLER
- MONITORING
- TOOLS ZUR FEHLERBEWÄHRUNG

Installation / Integration

- KLARE ANFORDERUNGEN AN DATEN, ADMINSTRATION
- ANWENDER SUPPORT FIRST-CALL-CENTRE
- INITIATION/ADMIN-PROZESSE
- SYSTEM ANFORDERUNGEN
- DATEN SAUPE
- DATEN SICHERHEIT
- ZUFÜHRUNG RECHTE
- DATENWARE-HOSTING
- INTERFACEN WENN KEIN PROBLEME
- SYSTEM ANFORDERUNGEN
- ARCHITEKTUR-CONCEPT
- RECHNERSPRACHLICHE BEWEIS-VERFAHREN
- HW/SW ANFORDERUNGEN (SPECIFICATIONS)
- SUPPORT
- BENÖTIGTE BEHÄNDLUNGSWEISEN
- KEINE CLOUD LÖSUNG
- DATENBEWAHRUNGSPROZESSE

User Management

- RECHTE MANAGEMENT
- USER SAUPE
- INTEGRATION IN BESTEHENDE LADA-SYSTEME
- SICHERHEIT
- WER IST ADMIN VON SYSTEM 3
- USER MANAGEMENT INTEGRIEREN
- SUPPORT
- WER IST ANSPRECHPARTNER?
- SECURITY MONITORING DES USER
- KONFIGURIERBARE AUTHENTIZIERUNGSRESSOURCEN