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[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

Table of Contents

List of Definitions

The definitions used in the deliverable are based on the AIDAVA Glossary [ref].

List of Abbreviations

CVD - Cardiovascular Disease
DPIA - Data Protection Impact Assessment
DTS- Data Transfer Specification
ELSI - Ethical Legal and Social Issues
G1 - Generation 1 (of prototype)
G2 - Generation 2 (of prototype)
GP - General practitioner
QALY - quality-adjusted life year
HDI - Health Data Intermediary
ICF - Informed Consent Form
MDR - Medical Device Regulation
SIP - Study Information Package
SUS - System Usability Scale

Executive Summary

The AIDAVA prototype will be delivered in 2 generations: Generation 1 in Q3 2024 and Generation 2 in Q2 2026. It will be tested in 4 hospitals and 2 Health Data Intermediaries, with 45 patients respectively per therapeutic area across all sites (90 patients for the 2 therapeutic areas in scope).
This deliverable includes the description of the 4 documents developed to support the execution of this assessment study of the two generations of the AIDAVA prototype in an ELSI compliant way, with a minimum burden for the patients and the sites.

The first document - and the most important one - is the study protocol (Annexe 1); it starts with a synopsis of the study and includes a description of the objectives of the study, the specification of the primary and secondary endpoints, the study schedule with the different activities to take place during the evaluation of the prototype across the 2 generations (including the washout period between the 2 generations), the study population with eligibility criteria, the data points to be collected with associated data collection forms (in RedCap) and the statistical analysis.
Another important document, related to the protocol is the English version of the Study Information Package and Informed Consent Form (Annexe 2) to be translated by each site and provided to patients during the recruitment process.
The third document includes a training plan (Annexe 3) for the patients participating in the evaluation and for the study team. It includes a specification of the different modules and a training program for the participants of the study, based on their role.
The final document is a template Data Sharing agreement (Annexe 4), to be adapted and finalised by each site, including guidance for technical and legal provisions.

The deliverable also includes description of work that was conducted with the help of Health Data Intermediaries (HDI) who helped to identify vendors who would provide a patient app application (to collect Quality of Life information) and a blood pressure medical device to be used during the study; the collected data will be managed by the HDI and provided to AIDAVA for integration in the patient record.

We also provide an overview on the feedback provided by the patients´consultants for the different materials mentioned above, and specify the study design with the schedule of activities as well as the Study Information Package and the Informed Consent Form.

1 Introduction

The AIDAVA intelligent virtual assistant is a prototype medical device[3] that supports patients to curate and publish their personal data in a secure environment, generating an interoperable and reusable personal medical record that can be used in clinical care to improve patient outcomes and to support data driven clinical research. To verify that the resulting prototype meets the requirement, we need to perform a formal assessment study. More specifically, we want to check that the AIDAVA intelligent virtual assistant is:

1. effective in **improving data curation and publishing process** against existing practices,
2. usable and acceptable **by patients** with different levels of health, digital and data literacy **and by expert data curators** whenever their input is required,
3. **valuable for "data users"** such as cardiovascular treating physicians and breast cancer clinical researchers.

The efficacy of AIDAVA virtual assistant will be influenced by the quality of the different data curation tools (supporting automation) and by the explainability module (managing the human computer interaction). The study should help identify how these components impact the effectiveness of the device.

Task 1.4 "*Details testing scenario to assess performance/acceptance of prototypes*", in scope of this document, is responsible for describing the different steps and activities needed to formally evaluate the prototype with on-site patients using their personal data in real life settings. The assessment study includes Generation 1 and Generation 2 of the AIDAVA prototype. As it was decided to keep as much of the same patient as possible across the 2 generations of the prototype, the assessment study also must cover the period of inactivities for the patients during the two generations.

The first objective of the task was to define an end-to-end testing scenario from data sources, ingestion into the AIDAVA environement, curation and then to publishing based on the use cases defined in Deliverable D1.1 and in compliance with ELSI requirements. An important point in the study was to identify practical and measurement endpoints to measure effectiveness of the prototype and user acceptability. The scenario was developed and agreed upon with key user representatives, hospital staff and Health Data Intermediaries (HDI) representatives; it was also validated by the patient consultants to ensure its feasibility.

The second objective was to translate this testing scenario into a set of formal documents to be submitted to the different local ethical committees for approval.

While defining the assessment, we needed to ensure that any risks involved with the transfer, storage and disposal of data during the study were properly managed. The third objective was therefore to ensure that the infrastructure supporting the testing of the prototype which is to be deployed at the different sites, would meet local security and data privacy requirements (security, qualification, environment) at each organisation. A thorough overview with details on data streams and

[3] A prototype does not need to go through MDR certification ; at the end of the project the idea is to develop a product medical device that will require MDR.

responsibilities was created, and a template sharing agreement between parties exchanging data was defined.

The task resulted in 4 documents:

1. Study Protocol following best practices for digital device evaluation
2. Study Information Package (SIP) and Informed Consent Form (ICF); the SIP will be provided to the patients as part of the recruitment process, before they are asked to sign the ICF
3. Training modules and training program for the different participants of the evaluation
4. Data Sharing agreement with legal and technical provision to support data sharing across the different sites

The different activities that took place to develop these documents are presented in Section 2, while Section 3 provides a brief overview of these documents which are attached in full as annexes.

2 Description of Activities

Across the task, the project followed a co-creation approach amongst the different participants: we organised bi-weekly meetings of 2 hours between February and November 2023, held multiple meetings with clinicians and specialists to discuss the specifics of the both use cases (breast cancer and cardiovascular disease (CVD)) and more particularly the secondary endpoints related to medical aspects of the use cases. We also organised one face-to-face workshop with clinicians as a part of the General Assembly meeting on 25-26 October 2023 in Graz to specify details of the study protocol. Finally, we had several meetings with the patient consultants to check the feasibility of the activities to be done by the patients and to verify if the material was acceptable and understandable.

The following table provides an overview of the activities performed during the task.
A more detailed description of the activities related to the different document is provided in the remainder of this section.

Activity	End Date	Lead	Partners involved
Scientific aspects			
Draft Assessment Study Protocol	Apr. 23	NEMC, b!lo	NEMC, UM, MUG, b!lo
Test the protocol with patient consultants	Jun-Aug 23	ECPC, EHN	ECPC, EHN, b!lo
Detailed review of schedule of activities and simulation of testing (see Figure 2)	Sept 23	NEMC	NEMC, MUG, b!lo
Finalise Assessment Study Protocol (with local requirements/translations)	Oct. 23	NEMC	NEMC, UM, MUG, ECPC, EHN, b!lo
Draft Study Information Package (SIP) & ICF	May 23	b!lo	b!llo, NEMC, UM, MUG, EHN, ECPC
Finalise SIP (test with patient consultants)	Aug. 23	NEMC	ECPC, EHN, b!lo
Translate SIP and ICF	Oct. 23	NEMC	NEMC, UM, MUG
HDI agreement	Nov. 23	NEMC	NEMC, UM, MUG, MIDATA, DME, b!lo
Create data collection forms in RedCap	Sep. 23	MUG	NEMC, MUG, b!lo
Create translations for all needed forms in all sites	Oct. 23	MUG	NEMC, MUG, UM
Draft training for patient & other users (non technology aspects)	Nov.23	B!lo, NEMC	
Get Local Ethical Committee´s approval of Assessment Study protocol (by each site)	Nov.23	NEMC	NEMC, MUG, UM
Data Privacy aspects			
Review Assessment protocol + ICF + SIP with Data Protection Officer (IHD)	Sept.23	IHD	IHD, NEMC, other

Activity	End Date	Lead	Partners involved
Template Checklist ready (Information Governance)	Aug.23	IHD	IHD, b!Lo
Information Governance checklist review and Data Privacy Impact Assessment (DPIA) - see Task 4.1 - executed and approved (by each site)	Sept.23	IHD	NEMC, UM, MUG
Data Management/ handling			
Data Transfer Specification (DTS)	Nov.23	b!lo	NEMC, UM, MUG, MIDATA, DME
Definition of data transfer specification (DTS) template; creation of the local DTS for each evaluation site	ongoing and continues in Task 1.5.	NEMC	NEMC, UM, MUG, MIDATA, DME
Draft Sharing Agreement (legal provision and technical provision) - HDI ⇔ AIDAVA	Oct. 23	NEMC, IHD	NEMC, MUG, UM, MIDATA, DME
Selection of blood pressure medical device	Sept 23	NEMC	NEMC, MUG, UM
Third parties app (QALY) s - selection with doctors, introduction, agreement with HDI	Oct. 23	MIDATA	NEMC, UM, MUG, MIDATA, DME
GP data from MUG/UM/NEMC	Oct. 23	MIDATA, DME	NEMC, UM, MUG, MIDATA, DME

Table 1. Overview of activities

2.1 Development of the Study Protocol

B!lo and NEMC created a first draft of study protocol using the Transcelerate eProtocol template ("Common Protocol Template Now Available" 2016) as a basis; this helped the team to follow best practice in study design and ensure that no critical aspects are missed in the conduct of the study. Most specifically we paid attention to the following components:

- Patient data privacy and ELSI, while we are managing fully identifiable data of the patients with their full consent
- Identification of primary and secondary endpoints meaningful to demonstrate the effectiveness of the prototype, and provide measurable outcomes
- Consistency of the different activities
- Effective collection of all data needed during the evaluation, supporting the proposed statistical analysis
- Acceptability of the set of activities by the patients

After the creation of the first draft, clarification discussions with clinicians were held to review, edit and confirm the schedule of activities, eligibility criterias and secondary endpoints of the study.

2.1.1 Patient data privacy and ELSI compliance

The AIDAVA prototype will manage fully identifiable patient data, as we need to link and integrate patients across data sources. To ensure there is no error, it is critical to check the patient's identification before integrating a data source.

Following discussion with the AIDAVA Data Privacy Officer (from IHD), it was considered compliant with data privacy as long as the patient was properly informed of the fact that their data will be fully identifiable and that the prototype will provide appropriate security mechanisms. These aspects were respectively managed in Annex 2 (SIP and ICF) and in Annexe 4 (Data Sharing Agreement including technical description on local solution).

2.1.2 Identification of primary and secondary endpoints

As in any study, the endpoints constitute the cornerstone of the AIDAVA study protocol. The primary endpoints relats to assessing the effectiveness and acceptability of the prototype, while the secondary endpoints check on the validity of the expected output for the 2 use cases. We specifically paid attention to the aspects related to acceptability - as described below.

Assessing usability

The System Usability Scale (SUS) provides a "quick and dirty", reliable tool for measuring the usability. It consists of a 10-item questionnaire with five response options for respondents; from Strongly agree to Strongly disagree. Originally created by John Brooke in 1986, it allows you to evaluate a wide variety of products and services, including hardware, software, mobile devices, websites and applications.

Benefits of using a SUS

SUS has become an industry standard, with references in over 1300 articles and publications. The noted benefits of using SUS include that it:

- Is a very easy scale to administer to participants
- Can be used on small sample sizes with reliable results
- Is valid – it can effectively differentiate between usable and unusable systems

The System Usability Scale

When a SUS is used, participants are asked to score the following 10 items with one of five responses that range from Strongly agree to Strongly disagree:

1. I think that I would like to use this system frequently.
2. I found the system unnecessarily complex.
3. I thought the system was easy to use.
4. I think that I would need the support of a technical person to be able to use this system.
5. I found the various functions in this system were well integrated.
6. I thought there was too much inconsistency in this system.
7. I would imagine that most people would learn to use this system very quickly.
8. I found the system very cumbersome to use.
9. I felt very confident using the system.
10. I needed to learn a lot of things before I could get going with this system.

The questionnaire and scoring are outlined in the System Usability Scale template. ("System Usability Scale (SUS)" 2013)

Interpreting Scores

Interpreting SUS scoring can be complex. The participant's scores for each question are converted to a new number, added together and then multiplied by 2.5 to convert the original scores of 0-40 to 0-

100. Though the scores are 0-100, these are not percentages and should be considered only in terms of their percentile ranking.

Based on research, a SUS score above 68 would be considered above average and anything below 68 is below average, however, the best way to interpret your results involves "normalising" the scores to produce a percentile ranking.

2.1.3 Critical activities and consistency of the different activities

Screening

Screening is the process of active evaluation of potential participants for enrollment in a trial. Screening occurs during the enrollment period to see if they meet the inclusion and exclusion criteria. If they meet the criteria, the subject is eligible to be enrolled in the trial.

In AIDAVA, screening takes place during a regular hospital visit where the physician checks the inclusion/exclusion criteria and briefly introduces the project. If the patient meets the criteria and is interested in participating in the project, the research associate will then:

- share details of the project with patients ;
- introduce the Study Information Package, including use of EQ-5D Quality of Life questionnaire
- introduce Health Data Intermediary (HDI) and answers to questions regarding ownership and future use of the data through HDI
- ask to sign an Informed Consent Form including HDI agreement
- teach CVD patients how to use the medical device to measure blood pressure and send data.

Washout Period

The washout period is the period between development and testing of the two generations (G1 and G2) of the AIDAVA prototypes. This is the period when patients are not expected to use AIDAVA and curate their data (except CVD patients who measure their blood pressure during the washout period and send their data) but during this period it is important to communicate with patients so that they do not withdraw from the study.

Communication every 2 months:

- **Objective**: provide regular information on the project to maintain the patients' interest to decrease dropout during the G2 development/ improvement phase.
- **Medium**: Regular newsletters (send through emails; additional online meetings after 9 months will be explored).
- **Expected planning and content:** n each communication across all newsletters, to include a message highlighting the advantages of using AIDAVA, key milestones and achievements in the project, the value of patients' participation in the evaluation, and the important steps the patients can take to improve the quality of care by using it.

Checking consistency across the activities

Since the important information and schedule related to the study were in several different tables and files, it was important to ensure consistency across the different parts of the Study protocol and align the activities to be performed during the study:

- Overall Schema of the assessment study, (p 11)
- Schedule of Activities (SoA), (p 12-13)
- Study visits overview, (p 30-36) and
- Data collection & entry forms in REDCap.

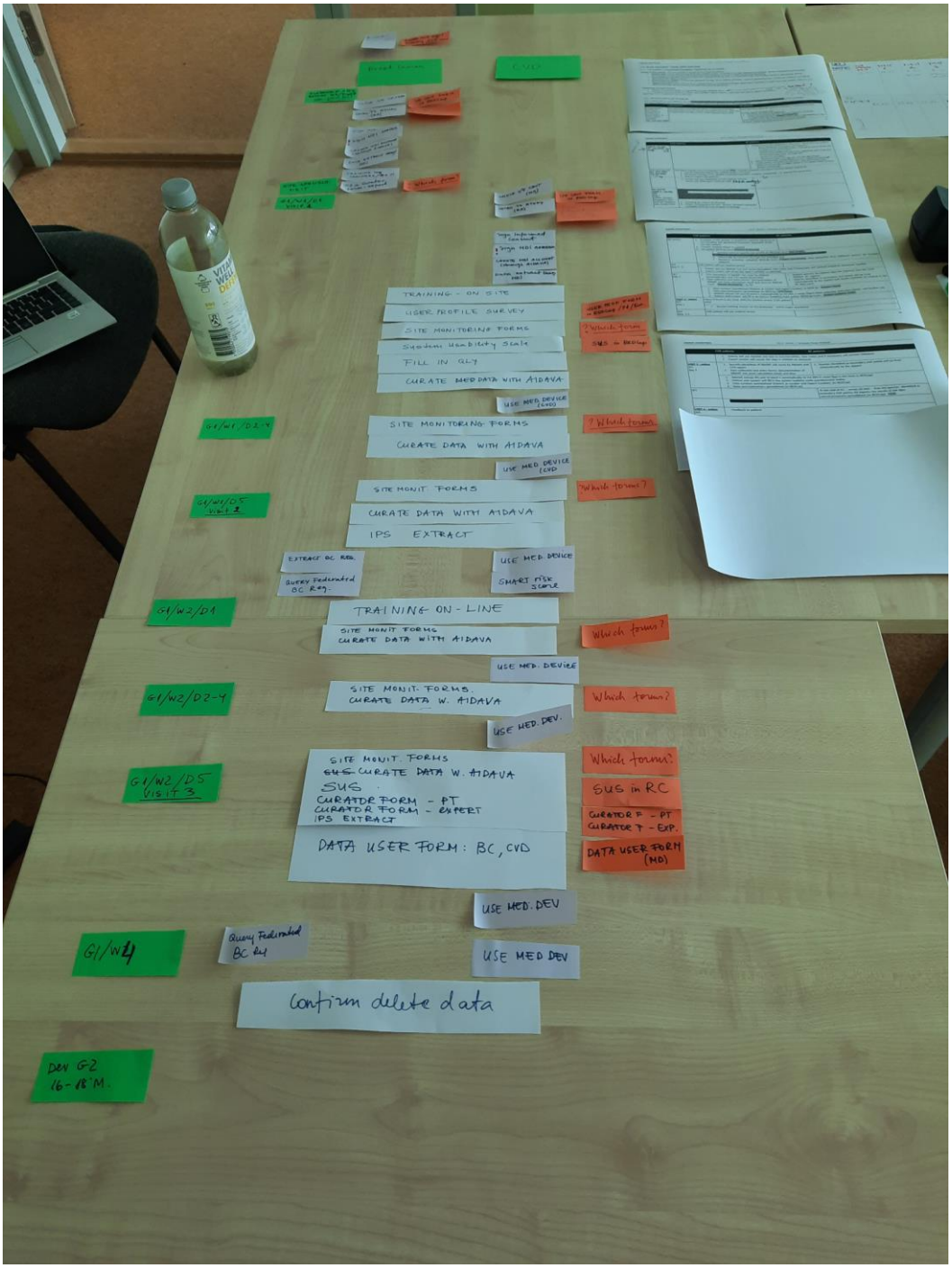

Figure 2. Checking the consistency of the different parts of the protocol

2.2.3 Effective data collection: development data collection and entry forms in REDCap

All the data needed to compute the endpoint must be captured during the study in a similar way across the three evaluation site. We decided therefore to use a formal data collection system, widely used across clinical sites for clinical trials called, REDCap.

REDCap is a secure online platform for building and managing online databases and surveys. It offers a wide range of tools that can be adapted to a wide variety of data collection strategies and allows you to export survey data to Excel and standard statistical packages (SPSS, SAS, Stata, R) and prepare various reports from the collected data in the REDCap environment.

The following REDCap forms were created to enter the data collected during the survey:

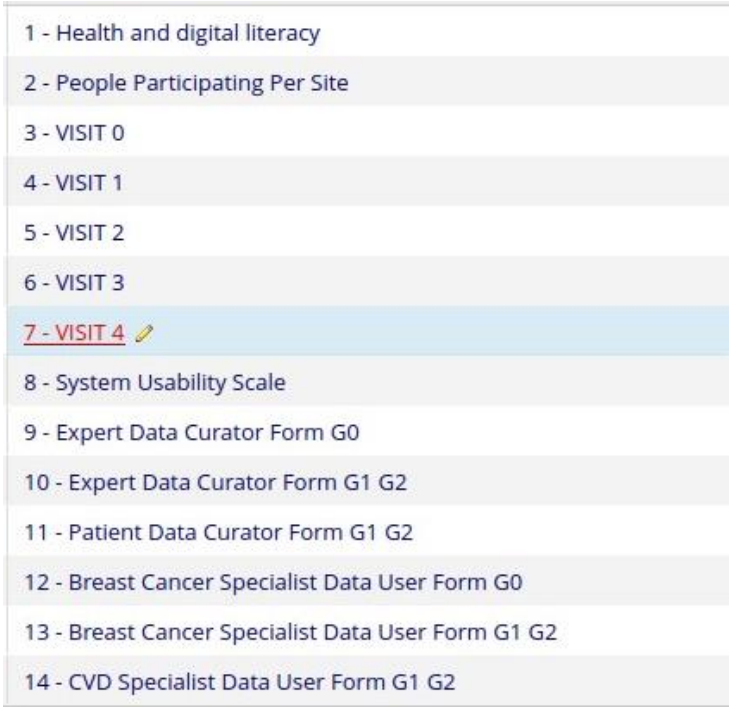

Figure 4. REDCap forms

2.2.4 Acceptability of the set of activities by the patients: Patient consultants´ feedback

After the initial draft of the study protocol, an introduction to materials was given to patient consultants who provided their feedback listed below:

Screening

- Process is generally clear, however recommendations include:
  - Provide a live demo to explain what the medical device and app are and how to use them,
  - Before patients start using the app, an appropriate explanation of its scientific importance should be provided,
  - Use plain language (i.e. no acronyms), repeat information, and explain verbally and in writing,
  - Provide enough time for patients to digest information and ask questions (ensure

staff support at screening).

Washout Period

- Most suggested a recurring newsletter by email (i.e. bi-monthly):
    - Highlighting the progress in the project, how AIDAVA can support patients and thank the participants for their contributions

Study Schedule and study activities

- Overall, the schedule is clear
- Recommendations:
    - not to use any abbreviations, acronyms, complex language,
    - explain the schedule orally and visually to site patients
    - For most, 2 weeks seems like a realistic and fair timeframe for site patients to curate data (some considered it too short)

Onsite vs. Online training

- Most consider the distribution of online vs. onsite OK - some prefer onsite, others stressed the time and effort of onsite visits
    - Suggestion to provide the option of both at each stage for participants who cannot make onsite visits

Usability questionnaire

- Overall, the usability questionnaire is clear and easy to answer
- Recommendations:
    - To change the scale (1-5) so that participants cannot answer neutrally and must consider a more positive or negative response
    - To include a free text box where site patients can elaborate on possible areas of improvements or issues encountered
- It is not possible to change the format of the SUS questionnaire as it is an official form.

Other recommendation include:

- Clearly indicate how long some task will take (i.e. task should take approx. x-minutes)
- Consider that some patients may find tasks harder than others and may not be comfortable expressing their issues
    - Suggested solution: Complete exercises/quizzes at the end of the training to check that the patient understands the training and are confident in using the system
- Confirmation of 3rd party app
    - Application to enter Quality of life questionnaire
    - Application to manage medical device
- Check Data Governance aspects with AIDAVA Data Protection Officer (IHD) and ensure alignment with data management plan and with form to perform local DPIA [reference from AIDAVA]
- Develop assessment questionnaires with REDCap
- Translate as needed for Ethical Committee approval

2.2 Development of Study Information Package and Informed Consent

The Study Information Package (SIP) and Informed Consent Form (ICF) form the basic material to be used when recruiting patients into our AIDAVA prototype assessment study.
The first draft of the SIP and ICF was completed in May 2023 and then sent for review by our patient consultants. It was also reviewed by our project´s data privacy officer from partner IHD.

Initial feedback on SIP based on questionnaire from patient consultants highlighted the following:

- "It is very important that words that are rare or hard to understand should be written more simply and more understandable.
  For example *CVD*, some people know what it is but also those kinds of acronyms should be written in full or explained.
  Also the words *curate* and *ingest* are hard to understand. "
- "Good that there is a list of what it is expected from the patients. This is important to be short and clear.
  How much time will it take in these 2 periods to participate in the study? 20 minutes- 8 hours/ day? Please try to specify. "
- "Good to have benefits and risks. It is important to be as clear as possible to the patients so they know what risk also can be so they are not afraid to be in this. The only area of concern was that risks are laid out in a negative format making it sound very risky; rather than saying any questions or complaints it was suggested to rephrase to lighter more positive wording such as any questions or concerns."
- "The text is really on many pages, and it can be hard to read everything for a patient. But all the text is so important that it should be there, and nothing can be taken away …Suggestion was to add in the end of the document also "most important to know" points as a summary ? It could help the patient to summarise everything they read.
  Also text was considered beautifully written but not simple to read in English. This complex writing style could be off putting to participants. It was suggested to make the first paragraph of the section on intro to AIDAVA simpler and easier to read English to get the key points across. "

The consolidated SIP and ICF will be translated into local languages by the sites, as part of the submission to the local ethical committees for approval (if required). It was agreed that a short overview summary of the SIP will be given (in a face-to-face conversation) to the patients by the treating physician during the recruitment phase when introducing the project. The longer version of the SIP will be available on paper for home reading and will be given to the patient if they would like additional information.
Amendments to the document might be made according to the feedback from local ethical committees.

2.3 Development of Training program

To ensure a proper evaluation, it is important to train the different participants: all the participants (including the patient if they are interested) must understand the purpose of the project and the assessment study, the user of the system must be trained to use the system, the research associated must be specifically trained to the different steps to be followed during the assessment, and the IT

supporting team must be trained to provide technical support. This requires a few training sessions that must be developed.
A training plan was therefore drafted; it includes an overview of the different training modules with the objective and content of each module, the estimated time to give the training, what media types are preferred, the target audience as well as the planning for developing the training module (and related materials).

2.4 Development of Data Sharing agreement

The patient data managed within AIDAVA and deployed within each hospital include data coming from the hospital itself as well as data coming from an HDI. It is therefore important to define a data sharing agreement between each hospital and the related HDI, including technical and legal provision. For transferring the data from the hospital to AIDAVA, a technical specification is sufficient.

2.4.1 Work with HDIs

In order to comply with data protection rules for data sharing health data, bilateral agreements were drawn up between HDIs (MIDATA and Digi.me) and hospitals hosting AIDAVA. These contracts specify the roles and responsibilities of parties and data handling to ensure security and compliance to regulations. This process was overseen by our project partner The European Institute for Innovation through Health Data (IHD) responsible for data protection and impact assessment.

In order to allow the possibility for patient to include data from different data sources to be added to AIDAVA, the HDIs and project partners helped to identify suitable candidates for a third party application for patients to fill questionnaires - EQ-5D quality of life questionnaire was selected for the project (“EQ-5D” n.d.). The HDIs helped to negotiate with possible partners, confirm that suitable candidates could be integrated within their system and to hold contractual discussions including technical details.

To provide patients’ the ability to include data available in different formats from other healthcare providers (other than the hospital partners in the project) , the HDIs will include the possibility for patients to upload pdf-s or get data directly from a national health data centre. Different options and solutions were considered and a variety of solutions were chosen to investigate different formats being integrated to the patients data in AIDAVA.

In the cardiovascular use case, the patients will have the opportunity to collect and add their data via a blood pressure monitoring device. The HDIs helped to oversee and confirm which physician approved and CE marked devices (which indicate that a product has been assessed by the manufacturer and deemed to meet EU safety, health and environmental protection requirements) are compatible with their system or which further developments are required to achieve this.

Lastly, it was agreed that after the curation process the HDIs would provide the patient the option to view or own the curated Personal Health Knowledge Graph and display the International Patient Summary of the patient to show a value of AIDAVA from the patient point of view.

All the solutions were also introduced to and reviewed by the patient consultants in the project who then provided their feedback (E.g. on HDI agreement for patients, overview of options that will be

included) and recommendations (E.g. to be more clear in SIP materials on the role of the HDI-s and why they are separate than AIDAVA, etc.) throughout the process.

The work on integrations will continue in Task 1.5 where the HDIs will test all these added features within their systems.

2.4.1 Requirements (security, environment) for testing the prototype in each organisation.

In order to cover all data processing security concerns and legal requirements, separate meetings were held with participating sites and HDIs and the results were compiled into the template Data Sharing Agreement which covers the scope of the data exchange, legal and data privacy provisions and technical provisions. This includes an overview of the data transfer specification principles, processing and security aspects for patient data during testing and initial technical architecture.

3 Results & Discussion

This task delivered 4 documents needed to execute the assessment study and provided in Annex.

- **Annex 1. Study Protocol.**
  The complete overview on how to assess the AIDAVA prototype is provided in the form of a study protocol (Annex 1 of the current document). It gives detailed descriptions of actions and supporting materials from preparation stages to evaluation. The study protocol was developed with project partners together with the clinical sites and their clinical staff, Health Data intermediaries and reviewed by patient consultants. The work on the protocol lasted from February to November 2023 and took multiple iterations to be complete. Changes can still be implemented to the protocol in case local ethical committees request it.
- **Annex 2. Study information package and Informed Consent Form ICF**
  This includes the basic information leaflet to be translated in local language and to be provided to the patient being recruited, before asking them to sign the ICF. The ICF is a one page document with check points.
- **Annex 3. Training plan**
  This document include the different training modules to be developed and provided to the patient and the study team ; it also includes a training program based on user profile
- **Annex 4. Data Sharing agreement**
  This document was developed in collaboration with D4.4; it includes the identification of the different data flows (to and out of the hospitals), link to legal provisions to be agreed across the different partners as well as the description of the data transfer. The detailed Data Transfer Specification are still being finalised by each site and will be completed for insertion in the Data Source Catalogue (D3.5).

4 Conclusion

This deliverable clarifies the development of study protocol, describes the study process and how health data curation and data visualisation will take place. The development included all the parties that take part in the study (clinical sites, HDI-s, Patient consultants, developer of AIDAVA, IHD for data security). The results of this deliverable and its Annexes form the basis for Ethical approval forms in each site to start preparing for testing.

5 Next steps

This deliverable - and the associated material gathered during Task 1.4. - is the basis of the assessment study for generations 1 and 2 of the prototype of the project, as part of Task 1.5, to be executed after approval by the respective Ethical Committees.

We expect that the Ethical Committees will have comments; these comments will be captured across sites, discussed with the project team and adaptation will be made to the common documents provided in attachment with a change log containing the questions of Ethical Committees across site and the answer to these questions. Each site will then be responsible to adapt their local material and resubmit to the local Ethical Committees.

6 Annexes

Annex 1. Study Protocol

Annex 2. Study information package for the patients with ICF

Annex 3. Training modules and training program based on user profile

Annex 4. Data Sharing agreement (developed in collaboration with D4.4) and Data Transfer Specification

7 References

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