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1 Executive Summary

This deliverable describes how a user-centred development process in accordance to ISO 9241-2010:2010 "Ergonomics of human-system interaction" has been implemented in PICASO. This process includes thorough investigation of the users' needs targeted for in PICASO. Acknowledged methods of user-centred design (UCD) have been employed for this purpose such as field studies in form of user workshops with clinicians and therapists at UDUS and UTV and interviews with patient at UDUS. From the user workshops To-Be use cases have been developed to support system development and foster the potential of PICASO developments to be transitioned into the real world. Vision scenarios have also been derived from the outcomes of the user workshops, the To-Be use cases and the patient interviews to explore in particular the context-of-use of future PICASO services.

For requirement specification it was a major challenge to aggregate the information inherent in the above mentioned sources to a traceable set of more prescriptive system requirements. The Volere template for requirements specification proved to be useful for this step, since the results need to be documented in a way that can be communicated efficiently to the developers in the PICASO project. To ensure that specified system requirements are of high quality and valuable for system specification, a requirements specification workflow was implemented in PICASO with support of the bug tracking platform JIRA. A description of this workflow as well as the features of the Volere requirements specification template can also be found in this deliverable.

In Accordance to T2.2 Initial Requirements Specification an initial set of requirements has been created in PICASO as presented in this deliverable. However, requirements specification will continue and lead to the development of the first PICASO prototype. User evaluation of this prototype will result in the refinement of this initial set of requirements, which will be discussed in next version of this deliverable.

2 Introduction

The PICASO project focuses on the needs of patients with multi-morbidity conditions and aims to build an ICT based integrated care platform with dynamic orchestration of care services adapted to newly developed care models. It will support collaborative sharing of care plans across sectors using a unique, trust federated solution to the problem of data privacy in cloud based health systems. PICASO will further aim to stimulate the independence and empowerment of patients.

Therefore, development of PICASO services will address many different stakeholders such as physicians from different medical fields, therapists, patients and their informal carers, all in need to accomplish their assigned everyday tasks. So for the success of the project, it will be crucial to investigate users' needs and reflect those thoroughly in the definition of system requirements.

2.1 Purpose, context and scope of this deliverable

The purpose of this deliverable is to provide a systematic formalization for creation of system requirements that base on PICASO stakeholders' real needs. These requirements will guide the developments in the technical work packages.

Requirements engineering involves a process that regards discovery, analysis, validation and formalization of requirements. In PICASO the following types of requirements will be taken into consideration:

- Functional requirements
- Ethical requirements
- Security requirements
- Business requirements
- Societal requirements

The list of requirements in Appendix C of this document reflects the work performed in Task 2.2 – Initial Requirements Specification. The requirements were derived from user workshops conducted with clinicians from project partners UTV and UDUS and patient interviews accomplished at UDUS, altogether resulting in the design of To-Be use cases and vision scenarios.

2.2 Content and structure of this deliverable

The deliverable is organized as follows:

Chapter 3 – describes the methods and principles applied in user-centred development of software in general

Chapter 4 – explains how these methods and principles are implemented in PICASO

Chapter 5 – shows the current state of the initial requirements gathering process in PICASO

Chapter 6 – provides a conclusion regarding the requirements engineering process initiated in PICASO

Appendix A – includes the interview guideline for the semi-structured patient interviews

Appendix B – shows summarized protocols of the conducted interviews

Appendix C – consist of a table with requirements defined so far in accordance to the Volere requirements specification template

3 Methods and principles of user-centred development

Requirements are descriptions of how a system should behave, include application domain information, constraints on the system's operations, and provide specifications of system properties and attributes. This deliverable is the result of the process of requirements engineering that the PICASO project has started. Requirements engineering is a continuous iterative process driven by an adopted user-centred design (UCD) approach and not a stage or a phase in that way. Compromising on achieving a complete requirements analysis would mean having issues or inconsistencies later in the system development. In fact, it is difficult to identify and analyse all aspects of a problem during the initial phase of a project. This is why it is important to continuously support the user-centred design process outlined in this document. As a consequence, this document should be considered as a first initial version of the requirements that will be the basis for updated and changed requirement reports as new requirements arise or outdated disappear in the iterations of the project.

The general approach to requirements gathering involves the following activities in the PICASO project:

- Elicitation. Discovering, extracting and learning about needs of stakeholders. This includes understanding of the current clinical workflow and patients' situation in managing their disease to identify problems and deficiencies in the existing system, opportunities and general objectives. Conducting user workshops with clinicians and achieving patient interviews are part of this activity.
- Negotiation and agreement. To establish priorities and to determine the subset of requirements that will be included for the next phase.
- Specification. Requirements expressed in a more precise way, sometimes as a documentation of the external behaviour of the system.
- Verification/Validation. Determining the consistency, completeness and suitability of the requirements. It could be done by means of static testing (using regular reviews, walkthroughs or other techniques) and prototyping.
- Evolution and management. The requirements are modified to include corrections and to answer to new objectives. It is important to ensure that requirement changes do not produce a large impact on other requirements. Requirement management means to face those modifications properly, to plan requirement identification and to ensure traceability (source, requirements and design traceability).

It is important to underline that most of those activities are performed in parallel guided by the project's user-centred design approach as it is in the focus of the ISO 9241-210 standard.

3.1 The ISO 9241-210 standard

The ISO 9241-210 (ISO, 2010) "Ergonomics of human-system interaction" provides guidance on user-centred design activities throughout the life cycle of computer-based interactive systems. It shall be noted here that in ISO 9241-210 the term 'human-centred design' is used rather than 'user-centred design'. In accordance to W3C Notes on User-Centred Design Process¹ these terms can be understood as referring to the same process, so for readability of this deliverable only the term user-centred design will be used in the following.

Essential principles in the UCD process are:

- Multi-disciplinary design
- Iteration of design solutions
- Appropriate allocation of function between developer-user and technology
- Active involvement of users and a clear understanding of user needs and tasks requirements

The multi-disciplinary design is given by the expertise in PICASO, which includes psychologists, computer scientists, and usability engineers and designers. The iteration of solutions is implemented in the PICASO work plan.

¹ <https://www.w3.org/WAI/redesign/ucd>

The user-centred design approach implies an iterative life cycle in a project. Iterative cycles allow advancing from requirements specification to implemented prototypes, from experience and evaluation of these prototypes to improved specifications and improved prototypes. In PICASO two cycles are planned for the project lifetime, aiming at validating and evaluating prototype specifications, including concepts of usage.

The current design proposals are reflected in the requirements definitions and base on the investigated understanding of the context of use through user workshops with clinicians and interviews with patients. These proposals provide an idea on how to meet identified or assumed user requirements. The evaluation of the design proposals by user testing of prototypes in PICASO yield a rich understanding of the context of use and new or modified requirements and thus guide the evolutionary improvement of the design.

One of the core tasks of user-centred design is to negotiate and facilitate the communication across the well-known user-developer gap while acknowledging the different forms of expression and different requirements on each side. The literature has a lot of examples demonstrating that end users have to bridge the large gap in understanding, especially in projects that apply a waterfall model. Clark, Lobsitz & Shields, (1989) show that evolutionary or iterative approaches drastically reduce this gap.

The user-centred design process reflects an iterative process with no sharp start and end points: Eliciting the 'context of use' requires intensive user involvement continuously for the whole duration of the process, and the requirements elicitation likewise extends well into the design proposal phase. There are four essential user-centred activities recommended by the ISO standard (ISO-9241-210):

- to understand and specify the context of use
- to specify the organizational and user requirements
- to produce design solutions
- to evaluate design regarding requirements

3.2 The Volere schema

The ISO 9241-210 standard does not prescribe specific methods to achieve the above mentioned goals, they are to be chosen according to the current state of the art and what is appropriate under the respective project goals. Based on practical experiences from other R&D projects it was decided in PICASO to follow a use case and scenario driven approach based on information gathered from user workshops and patient interviews.

Specification of requirements is a recommended activity of ISO 9241-210 as mentioned above. The Volere process recommended by Robertson & Robertson (1999) provides a means to ensure consideration of all important aspects of requirements specification which have proven to be of high value in practical work. Detailed information about the applied process for requirements elicitation in PICASO is provided in the subsequent chapters as well as a description of the main aspects of requirement creation according to the Volere schema. The distinction in Volere between global constraints affecting the project, functional requirements and non-functional requirements, with a fine-grained distinction of different types has proven to be of great practical value. Experience also shows the usefulness of the categorisations of the Volere template as well as the need to define fit criteria and a rationale for each requirement whether or not the requirement is implemented. The philosophy of Robertson & Robertson is very much in line with ISO 9241-210 and allows a structured processing of the requirements assuring that they remain always applicable and testable.

3.3 Sources for the derivation of requirements

Derivation of requirements needs to be based on sound sources of information. Conducting field studies is a standard method to gain such information that comprises for example performing interviews or workshops with users representing the target user groups of an envisioned service as well as ethnographical methods like participatory observation of the domain context. From the results of these field studies typical usage scenarios and use cases of the service under development can be deduced, all of them building a detailed base for elicitation of requirements.

3.3.1 User Workshops

User workshops in general provide a suitable means of gathering information about users' needs and expectations of a service to be developed. They provide an interactive setting fostering discussion among workshop participants revealing individual opinions, attitudes and also bear the potential to compile agreed solutions. Therefore, user workshops were conducted with clinicians from various disciplines at UTV and UDUS at the beginning of the PICASO project, because it was understood crucial to gain a thorough understanding of the current patients' pathway when under treatment and how clinicians work today (i.e. the clinical workflow). However, it was just as important to discuss constraints and desirable improvements in regard to these procedures as well as what additional, not readily available, patient information about patients clinicians would need to have at hand to optimise treatment. Among those were pictures of joints affected by rheumatism over a certain time frame, an overview of vital parameter measuring or pain ratings. Documentation of the workshops was achieved by written protocols. As described in D2.1 Scenario and Use Cases for Integrated Care, To-Be use cases and vision scenarios emerged out of these workshops both used as base of requirements specification in PICASO.

3.3.2 Patient interviews

Interviews are characterized by direct communication and therefore provide a suitable method for collecting comprehensive, in-depth information about an issue under investigation particularly during an early design phase. Interviewers have the possibility to address directly a response from interviewees in case it is unclear or may inquire further to understand the entire scope of a response. Interviews can be conducted in a structured, semi-structured or unstructured way which basically refers to the level of how close an interviewer will follow a predetermined interview guideline. In order to attain a more complete understanding of broader issues, semi-structured interviews are acknowledged as most useful (see Maguire (1998)) and thus will be used in PICASO to deepen knowledge about the patients' situation in dealing with his or her disease(s).

Interviews were also understood in PICASO as a feasible approach for data collection, because revealing personal approaches in dealing with a disease presumes sharing of very personal information which one might feel most comfortable with in a one-to-one situation. However, to ensure proper documentation of interview results it was chosen in PICASO to conduct interviews not only with a lead interviewer but involve also an assistant whose main task was to take notes (four eyes principal). Videotaping of the interviews was excluded due to privacy issues.

3.3.3 Scenarios

The aim of scenarios is to capture and illustrate features of a system, modes of its usage and the benefits for its users. They can be used for various purposes, and at all stages of a project. Particularly in an early design phase creation of vision scenarios is an acknowledged method to make obvious user and consequently system requirements. They describe end user activities as well as application functionalities thus bridging the gap to the formulation of technical user requirements. Scenarios in general have proven their potential to communicate project goals and design solutions among consortium members and are widely used to understand users' goals and to document system requirements. There is huge amount of literature concerning scenario-based approaches (see: Carroll (2000), Sutcliffe (2003), Weidenhaupt et al (1998), Dzida et al (1998) and Dzida (1999)). In PICASO particularly vision scenarios will serve as source for a systematic formalisation of relevant user requirements and derivation of system requirements in the initial requirements specification phase.

4 User-Centred Design Process in the PICASO Project

The user-centred design approach (UCD) in PICASO pursues the goal to investigate thoroughly user needs throughout the project and feed back immediately its results into the development cycle to ensure proper usability and user experience of PICASO services. It is a challenge in PICASO to consider comprehensively the needs of all stakeholders with their much varying tasks and needs. Taking into account this situation, acknowledged UCD methods have been chosen in PICASO that promise to yield most valuable results (see Rubin et al (2008)). Figure 1 gives an overview on methods employed in PICASO and how they are processed. User workshops and patient interviews were conducted at the beginning of the project to investigate stakeholders' needs and tasks. The information gained served as base for development of To-Be use cases and vision scenarios which then built the main source for requirements specification. This work will become part of technical developments that will end in the emergence of a PICASO prototype to be evaluated by PICASO's target user groups. Results of the user evaluation will be fed back into To-Be use cases and vision scenarios which then will lead to the update or creation of new requirements. As an iterative design approach is followed in PICASO these steps will be repeated twice.

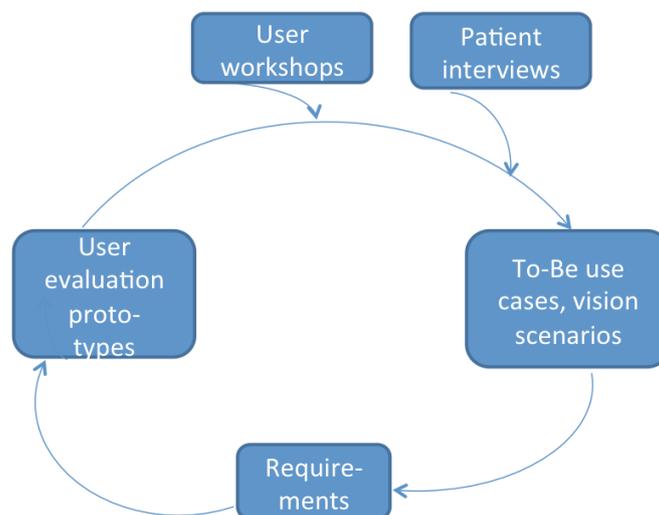


Figure 1: User-centred design process

In the following chapters methods used to ensure a UCD approach in PICASO will be explained in more detail.

4.1 User workshops

For elicitation of initial user requirements two user workshops were conducted in PICASO involving all relevant clinicians and therapists for development of PICASO services. The first workshop was held in April at UTV and the second one in May at UDUS. A detailed description of the methodology followed in these workshops as well as their outcomes is subject of D2.1 Scenarios and Use Cases for Integrated Care and will therefore not be described here further. The main objective of the workshops was to understand the mainstream clinical workflow a patient will have to follow when in need of treatment at these sites serving as representative example case for their respective country. This includes identification of all clinicians involved and their activities, the handover procedures and necessary exchange of patient data. Beyond this challenges and conflicts arising along the clinical workflow were discussed and how PICASO services could possibly serve to counteract those.

As a result of the workshops, the clinical workflows were described and mapped in a drawing. They were summarized in so-called As-Is use cases (see D3.1 Integrated Care Plans Across Sectors – Analysis and Recommendation for a detailed description). After verification of the As-Is use cases by PICASO's clinical partners, a set of To-Be use cases was developed describing how current clinical workflows could be

improved as discussed during the workshops and envisioned by PICASO. Thus, the To-Be use cases will serve as one of the main sources for requirement collection in regard to PICASO services.

In fall 2016 further workshops are planned with patients and their informal carers at UDUS as well as UTV to discuss usage scenarios of PICASO that represent consolidated and planned service developments in PICASO in order to receive feedback on usefulness and sufficient coverage of user requirements.

4.2 Patient Interviews

Patient interviews in PICASO were particularly conducted to evaluate and investigate further expert's assumptions about patients' needs as presented during the user workshops with clinicians and in the DoA. So the goal was to gain better understanding of how the organization of everyday life of patients is affected by their disease(s) and what specific tasks they need to fulfil in order to take care of it like medication intake, documentation of daily health status and being handed over among different physicians. The interviews took place from 2016-06-06 until 2016-06-15 and were conducted at the premises of UDUS' outpatient clinic in Düsseldorf, Germany. Results of these interviews serve in PICASO as valuable source for derivation of user requirements, since they provide a first hand view on problems encountered and possibly compensating solutions pointing at novel future services. Beyond this the interviews were used to introduce PICASO services foreseen to optimize patients' treatment like the home monitoring platform, to gather information about opinions and attitudes of patients towards such an environment as well as conditions precedent to user acceptance.

4.2.1 Methodology

For elicitation of user requirements it was considered most appropriate to investigate patients' contexts in dealing with their disease in form of semi-structured interviews. This is an acknowledged method for gathering valid in-depth information suitable particularly in early design stages where issues to be considered for technical development are still broad. For this purpose, 10 patients were interviewed at UDUS involving patients suffering from rheumatism and co-morbidities. They were considered representative also for patients with other diseases like patients suffering from Parkinson disease at the trial site at UTV, because their treatment plan involves similar actions such as following a strict medication plan and the necessity of being referred among different physicians.

Before starting with the interview, interviewees were provided a brief introduction to the goals of the PICASO project and the purpose of the interview. In the following interviewees were presented a letter of consent which they were asked to sign, in case they agree.

4.2.2 Interview guideline

In accordance to the goal of the interview, the interview guideline addressed basically four areas:

- personal details like year of birth and, if applicable, work situation
- IT usage and possible accessibility problems
- care organisation at home
- care organisation outside of home
- suggestions for improvement of personal care management procedures

(for the complete interview guideline please see Appendix A).

With regard to IT usage, interviewees were asked what kind of IT they are using (e.g., tablet PC, smartphone, Desktop PC, smartwatch) and, if so, what are they mainly using it for and whether they encounter any accessibility issues. The aspect care organisation at home included questions about patient's personal care plan, personal procedures to ensure proper medication intake and, if applicable, measuring, documenting and evaluating vital parameters. It also covered whether they can handle their care tasks on their own or need help with these for instance by informal carers. Questions about care outside of home aimed at investigating how patients deal with treatment by different physicians, therapists and rehabilitation facilities. Finally, interviewees were asked what they think could possibly help them ease management of their disease by utilizing IT. If feasible, some scenarios were presented to interviewees for that purpose involving usage of a medication planner, automatic monitoring of vital parameters, documentation of personal health status and the like.

4.2.3 Interviewee sample

For conducting the interviews, a sample of 10 interviewees was selected. All of them were suffering from rheumatoid arthritis (RA) since several years (from 9 up to 39 years), except for an 83-year old woman who was visiting the outpatient clinic at UDUS for the first time and was diagnosed two months ago. All of the interviewees were affected by at least one co-morbidity like hypertension, asthma and/or degenerative diseases of the skeletal system. The sample consisted of 9 women and 1 male between the age of 24 and 83 (see figure below). Five of the interviewees were working full time, whereas the other five were on (early) retirement.

Table 1: Age range of interviewee sample

Age range	20 - 30	45 - 55	65 - 75	80 - 90
Number (10)	2	3	3	2

4.2.4 Results of the interviews

Below, interview results are summarised under the headings 'Health management at home' and 'Health management out of home' in accordance to the structure of the interview guideline. A documentation of the interviews in form of protocols can be found in Appendix B. It is to note that for anonymisation the protocols are written in feminine form and the roles 'husband' and 'wife' are referred to as 'life partner'.

4.2.4.1 Health management at home

- **Automated measurement of vital parameters and data protection**

Five out of the ten interviewees did not measure any vital parameters at home. The other five did blood pressure measurements either on a regularly basis (two of them every day, one of them every other day) or from time to time, but none of them documented the measured values continuously or has instructions from a physician when and how often to do blood pressure measurements. Two of them stated that they note increased blood levels on a piece of paper respectively in a booklet to discuss them with their physicians but did not need further documentation because of their relatively stable health state. One of them using the daily measurements for self-regulations mentioned that at present the last 50 values stored in the blood measurement device are sufficient for stating her health status and she does not want to use any electronic support system. Yet, depending on her further health conditions she did not want to rule out for the future to use an app in order to get an overview about long term measured values graphically presented on her smartphone.

The five other interviewees as well did not consider it necessary to take sensor-based measurements and electronically document the values by a mobile app, due to their stable health status. Four of the older interviewees with long medical histories pointed out, that they decided not to take such a close look at their disease, as this rather harms their overall wellness. They consider it more advantageous in their every day life to focus on activities which do them good as e.g. hiking, swimming, biking, gardening, reading or meeting friends. Patients with increased risk potential because of co-morbidity, which requires regular measurements of vital parameters, might have a different opinion, because automated measurements support can relieve them in their every day lives and allow them to concentrate on other activities. To achieve this, reliable measurements and result transmissions are vital requirements as well as easy to use and non-stigmatizing devices.

Regardless of their health state, the two interviewees under 30 considered wireless measurements of vital parameters with a wrist band interesting, in order to e.g. find correlations between sleep patterns and previous behaviour such as physical activities or for weight control. Automatic measurement and documentation appeared attractive to them also because it can be done without any extra expenditure of time, however, health apps also are seen as a risk to lose self-responsibility and to rely too much on 'objective' parameters. Furthermore, they indicated that they attach major importance on data protection and privacy issues when transferring personal health data either collected automatically via sensors or by the patients themselves for individual documentation.

In total, six of the interviewees stressed that it would be important for them that misuse of personal data can be excluded. Furthermore, it has been noted that data of personal health status and everyday behaviour must not be shared with insurance companies and that health data may only be accessed by persons like

physicians, who are authorised by the patients themselves and the access must be limited to specific purposes.

- **Self monitoring, documentation and design aspects**

At present none of the ten interviewees documented regularly, e.g. on a daily base symptoms of the rheumatic disease and/or the overall well-being. Four of them noted on paper the date of rheumatism attacks with severe pain for discussions with physicians.

As well as with documentation of vital parameters, some of the elderly long-term patients meanwhile in a stable health condition stated that daily documentation of possible symptoms would force them to occupy themselves too much with their disease whereas they were feeling better when distracting from illness and thus worry and concentrate on positive aspects of their lives. One of two eldest interviewees however added, that although she would not get 'anything new' out of regular documentation, she however regretted in retrospective not to have documented her disease progress and the medicine taken, because she often cannot tell physicians which dose of which medicine she has taken and how her health state has changed in detail over the years.

One of the other interviewees considered to be informed enough to estimate her symptoms and disease progress even without documenting it and therefore sees no need for doing that. She felt familiar with patient diaries and in general thinks them to be useful for realistic self-assessment and discussions with physicians.

Four interviewees reported on own experiences with daily documentation. One of them used a self created paper based table for daily notes for more than half a year and documented her daily level of pain, duration of pain attacks, drugs taken in and her overall physical as mental condition. Creating the table was toilsome for her, but she was highly motivated by the wish to see improvement in disease progression and to achieve drug reduction. When her health condition stabilized, she quit documenting, but she could imagine to use electronic assistance in the future. As she is not very technology-affine, the assistance has to be easy to use and show her a graphical overview of disease progress and medication on a weekly or monthly base. For privacy reasons, she would use these data only on a local device and refuse to transfer them, but would think it useful to have the analysis printed to discuss it with others.

The three others used a rheumatism test app for documentation, which they accessed via smartphone. The app was available to them in the context of a voluntary study the outpatient clinic in Düsseldorf was involved in. Whereas a 66 years old interviewee with less experience in using electronic devices dropped out very soon due to technical problems, two interviewees (50 and 24 years old and well experienced in using (mobile) electronic devices) used it for about four months. Apart from some technical problems they found it to be a "good idea" and "a useful support" that was useful for their personal perception as well as for discussions with physicians and therapists, other patients, friends and relatives. A long-term pain documentation with a disease like rheumatism is seen as useful, e.g. for discussions with new physicians.

However, it also was pointed out that they would go on using an app like this after the test phase only if the daily documentation could be done in much shorter time (less than 5 minutes). Therefore, it must not include long question lists, but has to be flexibly adaptable to patients' needs and besides default indications about pain level, affected joints, term and manifestation of joint stiffness in the morning, no further input should be mandatory. A graphical analysis of disease progress in correlation with medication was estimated as an important feature.

The GUI design should support efficient handling, that means it should focus on few meaningful symbols instead of too much text information. This also fulfils needs of less technology-affine users which might be easily stressed by learning new technologies as one of the interviewees pointed out.

Accessibility requirements like keyboard-only control particularly have to be taken into account. Navigation via wipe gestures is less suitable for this user group, because they require longer lasting pressure which conflicts with limited fine motor skills and partly severe pain sensitivity of the fingers due to the rheumatism disease.

- **Automated reminders**

Nine out of ten interviewees organized their medication intake with a conventional drug box and a paper based calendar. Because of the rare changes in medication, dose and intake times they stated not to need any automated reminders, at least as far as their memory still works as well as it does at the moment, as one of the elder interviewees noted. Yet, one interviewee admitted, that from time to time she forgets her evening drug, another one jokingly reported her children's adequate control calls. There was no further questioning, if the supporting partners, children or friends mentioned by the interviewees carried out occasional reminder tasks apart from the noted assistance.

An automated reminder function for medication intake was used only by one of the two younger interviewees under 30 years of age. Her medication changed frequently and she worried about missing the intended intake time or mixing up the permanently changing dose in her hectic daily work routine.

All of the 5 employed interviewees (all of them under 60 years) were using a smartphone, but only three of them also used a reminder function. To them an automated reminder for daily exercises, for sufficient motion, which often is avoided, especially in pain phases, or for daily documentation (to overcome lack of motivation) would be a useful feature. One interviewee suggested to design reminders based on a step counter, opposing current and target motion states in a way that motivates the user to fill the 'motion gap'.

- **Organizer and other important information**

Just three interviewees using electronic reminders also used their smartphones to organize their appointments, including visits in the clinic, at other physicians or physiotherapists. All other interviewees organized their appointments with a paper-based calendar.

As additional useful features to facilitate daily life with their disease the interviewees pointed out a constantly available medication list, a personal question list for physician visits as well as a medical dictionary to look up e.g. the meaning of lab values abbreviations.

4.2.4.2 Health management out of home

Some general problems noted by the interviewed rheumatism patients relate to framework conditions of health care policies, which are not in focus of PICASO, but should not be forgotten. This includes e.g. immense administrative effort to apply for assistive technologies like an ergonomically designed computer mouse for the office or restrictive prescribing practices caused by the budgeting system of medical practices, which leads to situations where patients are struggling for physiotherapist sessions and end up with 'pointless' prescriptions for three sessions. These prescribing practices go at the expense of patients to whom they cause stress that they actually should avoid.

Organizational constraints like restricted opening hours of doctors' offices and outpatient clinics cause a tremendous organizational effort, especially for employed people. They do not only have to take into account travelling times between their residence, workplace and doctors' offices during rush hours, but also long waits at GPs and medical specialists that occur despite fixed appointments. In addition to that, getting prescriptions or referrals usually requires appearance in person and phone contacts, e.g. to make appointments often fail because of never ending wait loops. All this is hardly compatible with work demands and working times of the interviewees and therefore leads to stress. To improve this situation, additional consultation hours in the evening, on-line date assignment and mailing of prescriptions and referrals provided with a QR-code would be a great relief to the interviewees, as they noted.

Further problems, especially missing or insufficient information exchange between GPs, different specialists, physiotherapists and patients were noted by the interviewees. In this context patients particularly criticized that medication often is not matched with the primary disease and patients with co-morbidities have to point out contraindications by themselves. It is a main issue of PICASO to meet the interests of all parties involved in the treatment process by providing better information exchange e.g. with integrated care plans.

4.3 Vision scenarios

On base of To-Be use cases as well results from patient interviews, vision scenarios were created that intended to fulfil the need to investigate and illustrate PICASO users' context of use, that is the real day to day use of PICASO services by its different stakeholders with the focus on how PICASO will support them in achieving typical daily tasks. They are intended to complement the To-Be use cases which aim more at describing new PICASO services from a system perspective. To lend the vision scenarios authenticity, personas have been created that serve as representatives of future PICASO users such as physicians of various medical specialties, therapists, patients and caring relatives. The vision scenarios describe in form of a story how these different stakeholders may interact with PICASO services while moving along a standard treatment workflow requiring exchange of patient data and continuous updates of the patient's treatment plan. The development of vision scenarios was part of the work achieved for T2.1 Scenario and Use Case Definition, so they are included in D2.1 Scenario and Use cases for Integrated Care.

Although vision scenarios are tentative and future oriented, they make user requirements obvious by examining intended developments in real life situations. Therefore, vision scenarios served in PICASO for discussion among consortium partners about goals and necessary system requirements. They also provided an important source for derivation of user requirements.

4.4 Requirements derivation

In PICASO elicitation of an initial set of requirements will be based on To-Be use cases and vision scenarios as described above, since they provide the consolidated result of user workshops and patient interviews. In course of the project they will be constantly updated and developed further according to newly emerging user requirements from, e.g., user evaluation of the first prototype.

The requirements derived from these sources will relate to various aspects of PICASO services and its use, and will be classified according to the Volere scheme (see Robertson and Robertson, 1999). In the first step requirements need to be subdivided in functional or non-functional requirements. Functional requirements provide the specification of the services' functionalities, derived from the fundamental purpose of the services, whereas non-functional requirements are the properties of the services, the qualities and characteristics that make the services attractive, usable, secure and reliable. The current set of user requirements can be found in Appendix C of this deliverable.

4.4.1 Functional requirements

As already mentioned the functional requirements created in PICASO will relate to the envisioned usage of PICASO services described in the To-Be use cases and vision scenarios. They will define how the demands of users may be implemented by PICASO services considering the project's goals. They will also serve as base for evaluation of PICASO functionalities which is part of T2.4 Requirements Re-engineering where lessons learned during usability testing of the first prototype will be reported, most likely leading to the emergence of new and/or updated requirements. So in summary, the aim of this work is to capture functional requirements in such a way that they can drive technical decisions and the architectural design. Beyond this they should be usable to validate the various sub-systems.

4.4.2 Security requirements

Since much of the data generated and transferred in PICASO are highly sensitive personal data, there is a strong need to implement high security standards to protect the whole network against, e.g., intrusion and malicious attacks, and also to undertake measures that ensure users' privacy. Therefore, acknowledged algorithms for encryption of data and protocols for transmission will be implemented in PICASO. Beyond this Privacy by Design methodologies will be considered everywhere in the design and development process. Requirements reflecting these important issues need to be gathered and documented to ensure appropriate implementation.

4.4.3 Ethical requirements

As already mentioned above PICASO deals with highly sensitive personal data, so ethical issues such as privacy and data protection will need to be considered thoroughly. According requirements will be created for PICASO services and incorporated in the early design of the Privacy by Design framework.

4.4.4 Societal requirements

Mitigation of the expected explosion of health care costs mainly due to the demographic change is posing a big societal challenge. PICASO aims at developing an ICT based integrated care platform with dynamic orchestration of care services, therefore contributing to strengthen quality of life and care efficiency gains. To align PICASO developments with these features, requirements definition will also consider societal needs particularly in regard to the design of PICASO's integrated care platforms.

4.4.5 Business requirements

In order to come up with sustainable and realistic business models, aspects of health economics and organisational implementation will be studied in PICASO in the context of migration of the integrated care platforms into real life care systems. This will provide a suitable framework for analysis of value creation and business modelling and allow for accurate and viable metrics for cost-effectiveness and organisational adaptability. Under these premises business requirements in regard to PICASO developments will become part of PICASO requirements specification.

4.4.6 Non-functional requirements

Non-functional requirements refer mainly to properties and characteristics of services. User needs and requirements such as security, ethical, societal and business requirements as described above will have most likely functional as well as non-functional aspects. However, there are further categories of non-functional requirements that are considered in PICASO and shall be mentioned in the following:

- Look and feel requirements (intended appearance for end users)
- Usability requirements (based on the intended end users)
- Performance requirements (how fast, big, accurate, reliable...)
- Operational requirements (what is the intended operating environment?)
- Maintainability and portability requirements (how changeable it must be)

4.5 Requirement description (Volere schema and template)

The workflow ensuring that all necessary input and revise processes in the Volere schema are adhered to is rather complex, therefore in PICASO it was decided to support the requirements gathering process by the web based bug tracking tool JIRA (<http://www.atlassian.com/software/jira>), since it allows to implement and track the workflow of the Volere schema and can be made easily available for all partners of the project.

The most important fields of the Volere template for requirements specification (see also Figure 2) will be described in the following:

The *summary* of a requirement contains a one-sentence description of the requirement. The description is the intent of the requirement and should be clear and brief (see first line in the screenshot: PICASO provides a patient diary for self-recording of symptoms).

In the 'Details' section of the template the following information needs to be provided:

The *priority* of a requirement has to be determined as this defines the relevance of this requirement in relation to other requirements. It allows classification of the specified requirement in three categories: "Critical", "Major", "Minor". The rating needs to be carefully assigned. The *priority* of a requirement is based on several important aspects included in the Volere schema:

- The source defining where this requirement was derived from, e.g., To-Be use cases, patient interviews, DoA.
- The estimation, if the requirement is within the scope of the project.
- The component that the requirement is associated to.

The *component* this requirement will belong to is important to define, because this will help to structure requirements and to get a clearer picture of the technical developments to achieve by whom and how. A requirement might affect several components which will then be listed here. In PICASO the following

components were considered for assignment in accordance to the initial architectural components agreed among consortium members:

- Message Handler
- Metadata Registry
- Transaction Audit Log
- Privacy Manager
- Policy Manager
- Data Orchestration
- Supplementary Datastore
- LinkWatch
- Sub Care Plan Execution
- Risk Manager
- Care Plan Orchestration
- Process Model Repository
- Service Catalogue
- Situational Awareness and Next Steps
- Data Browser
- Dashboard
- Goal Optimizer
- Narratives Manager
- Narratives Template Repository

Selection of a *requirement type* of a requirement classifies a requirement as either functional or non-functional.

The *rationale* of a requirement expresses the reason behind the requirement’s existence. The rationale provides the reason why the requirement is important and the contribution it makes to the services’ purpose. The rationale contributes to the understanding of the requirement.

The *source* of a requirement provides information about where this requirement was derived from to ensure validity.

The *Fit Criterion* field is one of the most important fields. Fit criteria are the quantified goals that the solution (i.e. the realization of the requirement) has to meet. This field describes how to determine if a requirement is met. It should be written in a precise quantified manner. The fit criterion sets the standards to which the developer constructs the service.

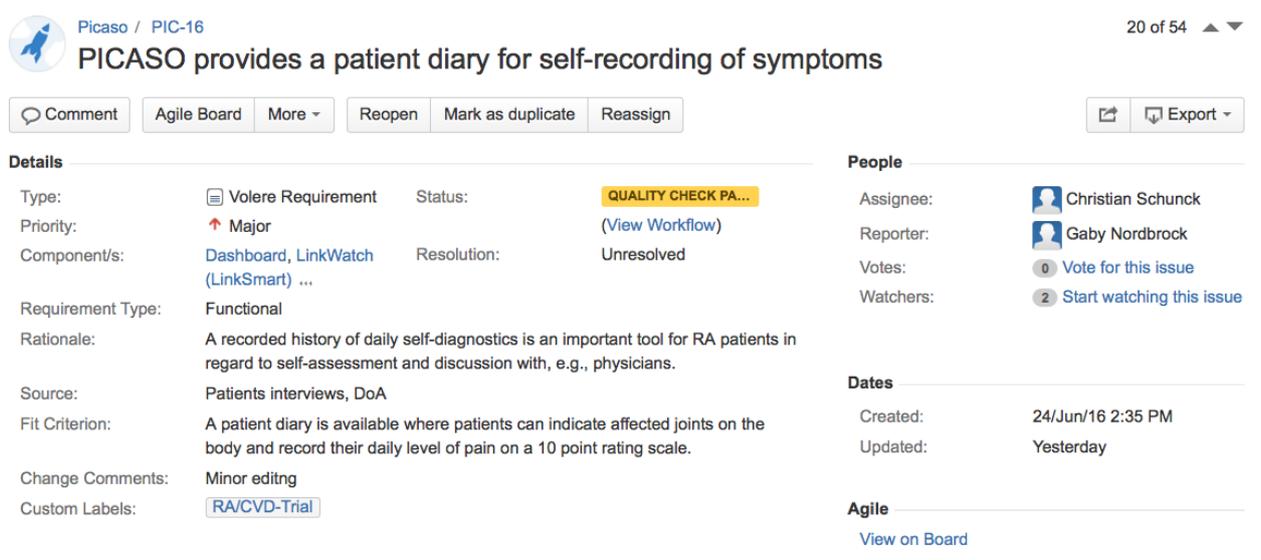


Figure 2: Screenshot of JIRA with input fields for a requirement

PICASO requirements are entered in JIRA by different so-called requirement ‘reporters’ (see section ‘People’). Each requirement is then quality checked by another beforehand assigned consortium member,

which ensures that there are always two consortium members controlling the quality of a requirement. In case a requirement has passed the quality check, it is moved on through the quality gateway and in PICASO assigned to the component leader to decide whether or not it should become part of specification.

4.6 The requirements workflow

The workflow for requirements gathering in PICASO is that in general all project partners are able to create requirements derived from different sources like To-Be use cases, the DoA etc. The requirement will then be quality checked by FIT or IN-JET and if successful, it will be assigned to the component leader where this requirement is dedicated to. The component leader can then decide whether a requirement will become part of the specification or should be revised. In the latter case, feedback to the reporter of that requirement is necessary. The quality control in JIRA is realised by processing requirements along the steps of a workflow. Each requirement has a status that changes depending on the current workflow step. Figure 3 displays the possible status and the main transitions between them.

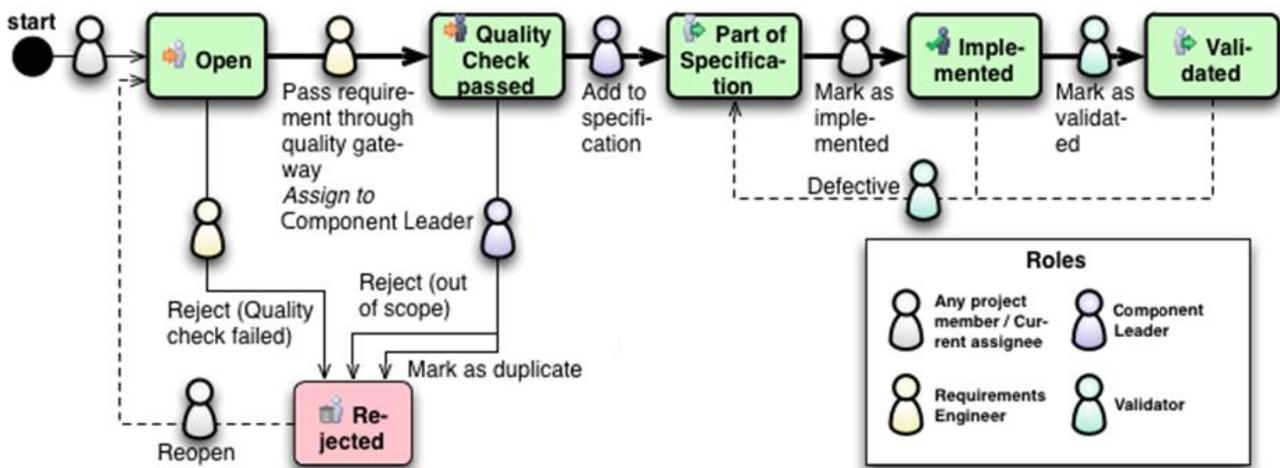


Figure 3: Structure of the requirement specification workflow

When a requirement is entered, it is assigned with the status 'open'. If it is complete and unambiguous, it passes the quality check. In this case it is important, that not only the text fields are filled in sensibly, but also appropriate values are chosen from the drop-down lists. The priority must be selected to make it possible to rank requirements among each other.

A requirement can fail to pass the quality gateway for three reasons:

- A requirement can be incomplete. Some fields may have meaningless entries like '?'
- A requirement can be ambiguous; certain terms are not clearly specified
- A requirement is completely senseless. This can happen for example when a requirement is entered into the system for testing.

If a requirement fails the quality check, it gets one of the following statuses 'Requirement is incomplete', 'Requirement is ambiguous' or 'Requirement does not make sense'. Once the requirement is updated properly, its status is changed to 'reopened'. This status equals exactly the initial status 'open' and the quality check process restarts. The status 'reopened' is used to indicate that a requirement has gone through the quality control at least once. This helps to detect requirements that are yet untouched.

Eventually, all requirements will pass the quality gateway. That means that they are complete and all fields are filled in sensibly. A requirement that passed the quality gateway cannot be edited any more. The last step is to decide whether a requirement becomes part of the specification, or whether it should not be considered any longer. This can happen for two reasons:

- *A requirement can be a duplicate of another requirement*
- *A requirement can be rejected, e.g., because it is out of the project's scope.*

If its status is either 'Part of specification', 'Rejected' or 'Duplicate', a requirement is said to be resolved.

5 Status overview of requirements specification

As shown in Figure 3 requirements can be in six different stages in the PICASO workflow: 'Open', 'Quality check passed', 'Rejected', 'Part of specification', 'Implemented and 'Validated'. Requirements specification in PICASO is in its beginning stage, so most requirements created so far are in an 'Open' stage (see Table 2). However, the process of quality checking has begun and a small number could be processed already through the quality gateway and assigned to component leaders.

Table 2: Status of requirements

Status	Count
Open	30
Quality Check passed	13
Part of specification	0
Rejected	0

In accordance to the Volere requirements specification template requirements have been subdivided in functional and non-functional requirements. As it can be seen in the following table, most of the requirements created so far describe functional requirements and therefore will have mainly impact on technical developments.

Table 3: Requirements types

Type	Count
Functional	19
Non-Functional	2
Non-Functional – operational	5
Non-Functional – maintainability	2
Non-Functional – performance	3
Non-Functional – legal	1
Non-Functional – security	7
Non-Functional – usability	3
Non-Functional – look & Feel	1

The vast majority of defined requirements is prioritised as major (see Table 4) which is most likely due the fact that in this early stage the focus is on specifying functional and non-functional requirements of high impact for technical development.

Table 4: Priority distribution of requirements

Priority	Issues	Percentage
Critical	1	2 %
Major	42	98 %
Minor	0	0 %

An initial set of requirements has been created in regard to most components foreseen for development in PICASO (see Table 5). There are requirements that are assumed to affect more than one component that is why the number of requirements (issues) in Table 5 exceeds the total number of requirements listed in Table 2. In such cases the requirement will be assigned to the leader of the component named first. The process of

requirements specification is still ongoing, however, discussion among consortium members arising from this process could already be initiated.

Table 5: Distribution of requirements across components

Unresolved: By Component

Component	Issues
📦 All	4
📦 Care plan orchestration	1
📦 Dashboard	6
📦 Data browser	4
📦 Data Orchestration	2
📦 Goal optimizer	1
📦 LinkWatch (LinkSmart)	19
📦 Many	3
📦 Metadata registry	1
📦 Narratives manager	3
📦 Policy manager	1
📦 Privacy manager	5
📦 Risk manager	1
📦 Transaction audit Log	1

6 Conclusion

The PICASO project has implemented a user-centred development process in accordance to ISO 9241-210. The specific challenges in developing an ICT based integrated care platform with dynamic orchestration of care services that will support collaborative sharing of care plans across sectors using a unique, trust federated solution raised the need to choose appropriate methods and implement the development process in an adequate way.

One way to achieve this was seen in conducting field studies including user workshops with clinicians and patient interviews. This has proven to be a valuable approach to keeping a user-centred focus throughout the system specification process, and to allow early user involvement. From the user workshops To-Be use cases have been developed to support system development and foster the potential of PICASO developments to be transitioned into the real world. Vision scenarios have also been derived from the outcomes of the user workshops, the To-Be use cases and the patient interviews to investigate particularly the context-of-use. Therefore, user requirements in PICASO are based on empirical data, i.e. on real users' statements about expectations of PICASO services. For requirement specification it was a major challenge to aggregate the information inherent in the beforehand described sources to a traceable set of more prescriptive system requirements. The Volere template proved to be useful for this step, since the results need to be documented in a way that can be communicated efficiently to the developers in the PICASO project.

The next major step within the user-centred development process in PICASO is to determine the impact of the requirements on each PICASO component respectively work package. In order to achieve this, all created requirements need to be quality checked and moved on to component leaders who decide whether they should either become part of specification or be rejected. However, since requirement gathering in PICASO is in its initial stage more requirements will need to be created and in the next step condensed and improved in regard to accuracy. This will involve reformulations of the original requirements to clarify their scope and to ensure that the Fit Criterion is measurable. As a result of the requirements specification process implemented in Volere, the total number of requirements will be reduced to a set of requirements within the scope of the PICASO project, i.e. not all the requirements from the initial set will be addressed and implemented. The determined impact of the selected requirements on the components will initiate the creation of a software architecture specification draft and the technical work in the work packages.

As we are following an iterative approach the set of requirements will constantly be updated and refined for instance by user evaluation of the first PICASO prototype. This will be documented in the next version of the deliverable.

7 Appendix A: Interview guideline for patient interviews at UDUS

Interview Guideline

for patient interviews at UDUS June 6/06/2016. 13/06/2016, 15/06/2016

ID no.: DÜ-00 , Datum: . . 2016

1. Personal information

1.1 Sex:

1.2 Born in which year?

1.3 Working? If yes, in which professional area

1.3 Are you using any of the following electronic devices?

- Smartphone
- Mobile phone
- Smartwatch
- Tablet PC
- Laptop
- Desktop PC
- Fitness gadgets
- Other ICT-Devices:

1.5 Do you have any problems with using device(s) X

(X refers to the device(s) the patient has said that they are using. Possible problems to address could be control of the mouse, select menus by finger tap, wiping on a smartphone/tablet.

1.6 What are you mainly doing with X?

(In case the patient has said that she/he uses a smartphone/tablet, then the interview will focus on what apps they are using, what are there favourite ones and why, which are the ones they think are difficult to use and why. In case they are using the MiDEAR app offered by UDUS, patients will be asked what they do/do not like about it, find useful/not useful)

2. Care organisation at home

2.1 Do you need help with household activities or any other activities?

2.2 Who is helping you? (informal vs. professional carer)

2.3 When and how often do you have to take in medication?

2.4 How do you manage medication intake?

- Tablet box
- Calendar
- Alarm
- Telephone
- Reminder:
- Others / particularities:

2.5 Are you measuring vital parameters at home like blood pressure, blood sugar, Quick test (INR value)?

If yes: Which ones, how often, at what time?

2.6 Are there any constraints in regard to taking these measurements like do it only before having a meal?

2.7 Do you encounter problems when using any one of the devices?

2.8 How are you documenting your measurements (paper, electronically ...)?

2.9 How do you know when to take a measurement?

3. Care organisation outside of home

3.1 You are probably seeing different physicians. Which physicians are involved in your treatment? (How often do you see them? Who refers you to whom?)

3.2 Do you have other treatment appointments like physiotherapy or ergotherapy?

3.3 Are you pursuing any other activities for your fitness such as rehabilitation sport, sport for patients with heart diseases?

3.4 Do you have to take along documents when seeing a physician or therapist?

3.5 In case you would like to ask your physician(s) questions about your treatment or your disease, do you record those before (after) seeing your physician(s)?

3.6 Would it be helpful for you, if you could get in contact with your physician(s) outside of regular appointments, e.g. via email?

If yes: How and in what situations?

3.7 Has there ever been a situation where you were surprised, because you got for instance another drug as you thought you should or an information that did not match with information provided by another physician or therapist?

If yes: What did you do then (asked somebody, changed medication...?)

3.8 Are you making your doctor's appointment yourself, e.g. by calling in? How do you keep track of your appointments, e.g. an electronic organizer?

4. Suggestions for improvement of personal care management

What do you think could be made easier for you in managing your disease by utilizing information technology such as a smartphone or a computer?

(If applicable, some visions are presented to patients such as

- support in monitoring proper medication intake, running out of medicine etc. by a medication planner
- usage of wireless sensors for automatic monitoring of vital parameters for the convenience of patients as well as information of physicians to e.g. adjust medication more precisely, provide alerts and recommendations in critical situations
- documentation of personal health status in a diary, e.g. about daily pain level, to have a sound basis for communication with physicians
- having themselves access to medical information such as content of a referral letter

8 Appendix B: Protocols of patient interviews at UDUS

Summary of interviews with 10 patients of UDUS' outpatient clinic

DÜ-001 Patient
<p>Personal information She is using desktop PC in the daily work and privately she is using a smartphone only for phone calls and text messages. She neither has problems using a standard computer mouse nor the onscreen keyboard of her smartphone. She strictly refuses to use any electronic support like a health app.</p>
<p>Care organisation at home She is managing the rheumatism treatment at home on her own:</p> <ul style="list-style-type: none"> - she takes different drugs, some of them daily, some every two days and in addition painkiller when required. She manages the medication with a pill box and a paper-based calendar. - She does not measure any vital parameters. <p>She does not need support in documentation, although she knows things like a patient diary and thinks it to be very useful for self-assessment as well as for consultations with physicians in order to get a realistic view of the current state. She herself does not need documentation because she is working in the health sector and can state symptoms and the history of her disease very well. She feels well informed about symptoms and therapy of rheumatism and besides the medication she does a lot for her health like vegan (and alkaline) nutrition and engagement in sports. She does rehabilitation sports once a week and regularly goes hiking, swimming and does yoga.</p>
<p>Care organisation out of home She visits the outpatient clinic 2 times a year. After each visit in the clinic her GP gets the referral letter, but the GP is not really involved in the therapy. She can organize the appointments at the clinic and with other physicians and the ergo therapist on her own.</p>
<p>Problems mentioned</p> <ul style="list-style-type: none"> - Extended opening hours in the evening would reduce stress caused by the morning rush hour (she has to reach the clinic in time as well as her place of work afterwards). - Direct contact for e.g., rescheduling an appointment via phone (without endless wait loops) or via email (that reaches the person in charge promptly) would also reduce stress.
DÜ-002 Patient
<p>Personal information She uses a desktop PC in her daily work and privately she uses a smartphone for phone calls and text messages only. During periods of severe pain, she has problems with typing. She feels not technique-affine and does not want to deal with a computer or the internet after work. At the moment she does not want to use something like a health app because to learn how to handle this would cause additional stress for her. She needs her strength to manage her everyday life.</p>
<p>Care organisation at home The treatment at home is managed by herself:</p> <ul style="list-style-type: none"> - she takes different drugs 5 times a day and in addition medicine from her alternative practitioner as well as painkiller when required. She manages the medication with a pill-box and a paper based calendar and does not need further support. <p>She used to document the history of her disease in the past (for more than half a year) on paper. For this purpose, she created a table for filling in the following parameters on a daily base:</p> <ul style="list-style-type: none"> - her overall condition (physical and mental), - the level of pain, - the duration of pain attacks,

<p>- drugs taken (dose, taking time and duration). Her aim and motivation doing this was to reduce the drugs due to less attacks of rheumatism. It worked, but to create the table was toilsome. Now with a stable health condition the continuous notes are no longer necessary. She feels well informed about her disease and uses the drug database at her working place in case of questions. At the moment she decided not to document the process continuously but for the future she does not rule out restarting a documentation supported by an electronic device.</p> <p>- she measures blood pressure daily but not always at fixed times (there are no instructions for measurement of vital parameters). The measurement serves mainly as a means of self-regulation. The blood pressure meter records the last 50 measurements. This gives a sufficient overview and she does need further documentations even not for the physician. Twice a week she visits a physiotherapist and twice a week she does a special strength training to promote muscle building. She manages appointments with a paper-based calendar and does not need reminders.</p>
<p>Care organisation out of home She visits the outpatient clinic 3 to 4 times a year. Afterwards her GP gets the referral letter. She visits the GP only in case of an "emergency" e.g. when she runs out of drugs, 95 % of the treatment is covered by the clinic. Sometimes she has to bring results of other examinations e.g. an X-ray image. She prefers to contact the clinic via phone. She likes it more than communicate via email (although she also has got an email address). She calls her treating physician e.g., in case she wants to reduce a medicine. The physician calls her back promptly and this she mentioned to be very helpful.</p>
<p>Problems mentioned</p> <ul style="list-style-type: none"> - "Begging" for prescription of physiotherapy is stressful and should be avoided. Often she gets prescriptions only for 6 units, or even for 3 units from her GP. - More agreements/communication between different physicians and clinics would be helpful. Many things go wrong with prescriptions e.g., allergies or gastrointestinal disturbances often are not taken into account. Physicians often do not consider the basic drugs when prescribing further medicine. She herself has already found contraindications of prescribed drugs and obtained a medication change.

<p>DÜ-003 Patient</p>
<p>Personal information She gets help in her everyday life from her life partner, because she cannot carry heavy things, open glasses or do demanding cleanings at home. She uses a mobile phone with bigger keys for phone calls and text messages via WhatsApp. She used a smartphone before and took part in the MiDEAR app tests for a short time. She dropped out soon due to technical problems (she could not see the results she had typed in). Sometimes she has problems with typing.</p>
<p>Care organisation at home The treatment at home is managed by herself:</p> <ul style="list-style-type: none"> - she takes 4 different drugs 3 times a day and 1 injection per week. She manages the medication with a pill-box and a paper based calendar without any problems and does not need further support. However, it may (rarely) happen that she forgets about taking a pill. She does no documentation and has no need for further support. - she measures blood pressure and blood sugar once in a while but not regularly and does not document this. <p>She regularly does exercises with a thera-band. She visits a physiotherapist weekly and does aqua gymnastic. From time to time she uses a home trainer. She knows about her medication that most of the time stays the same. If necessary, she gets support by her pharmacy. There they take care about possible conflicts between ingredients of different drugs.</p>

<p>Care organisation out of home</p> <p>She visits the outpatient clinic 2 times a year. Afterwards her CP gets the referral letter. She visits the GP approx. every 8 weeks mainly for blood tests. Furthermore, she visits a lung specialist, an urologist and more rarely an orthopaedist.</p> <p>She calls the clinic and they send prescriptions per mail. Further contact is not necessary.</p> <p>She can call her treating physician e.g., in case she wants to reduce a drug and the physician calls her back promptly.</p>
<p>Problems mentioned</p> <ul style="list-style-type: none"> - Asking for physiotherapy prescription is stressful and should be avoided. Often she only gets prescriptions for 4 units. Even after an operation she did not get a hint that she can visit a physiotherapist. - The clinic can be reached by phone only until noon and often she has to wait in the line.

<p>DÜ-004 Patient</p>
<p>Personal information</p> <p>In her everyday life she gets support from her daughter.</p> <p>She uses a mobile phone for phone calls and text messages only.</p>
<p>Care organisation at home</p> <p>The treatment at home is managed by herself:</p> <ul style="list-style-type: none"> - she takes different drugs (7-8 pills a day) and manages the medication with a pill box. She does not forget to take medicine, she knows by heart when to take which drug. She does not document that. - she measures blood pressure from time to time and notes the values in a booklet. <p>Once a week she visits a physiotherapist if she has got a prescription.</p>
<p>Care organisation out of home</p> <p>She visits the outpatient clinic for the first time and she does not know yet how often she has to come in the future. Furthermore, she regularly visits a neurologist to check her serotonin level. Only rarely she visits her GP.</p> <p>When visiting a physician, she takes notes with her in order to remember all questions that occurred in the meantime.</p>
<p>Problems mentioned</p> <ul style="list-style-type: none"> - To set up the first appointment was difficult because of the waiting loop. - Putting on weight due to cortisone intake

<p>DÜ-005 Patient</p>
<p>Personal information</p> <p>Normally she does not need any help in her everyday life.</p> <p>She is using desktop PC in her daily work. For private purpose she has got a tablet PC that she does not really use. She is using a smartphone for phone calls, text messages, communication in social networks, appointment management and for reminders.</p> <p>Normally she has no problems with typing, nevertheless she would like to use an ergonomic computer mouse, but could not find useful information about that so far.</p>
<p>Care organisation at home</p> <p>The treatment at home is managed by herself:</p> <ul style="list-style-type: none"> - once a week she needs a subcutaneous injection which she can manage on her own. To use the reminder function of her smart phone is very important for her, because there are often changes in the medication and without an electronic reminder she sometimes would not be sure whether she has already taken the injection with the right dose. - She does no measurements at home.

Appointments with doctors etc. she also manages via her smartphone. Once a week she visits a physiotherapist next to her working place. Furthermore, she trains in a fitness studio and everyday she takes the bike to get to her working place.

She took part in the tests with the MiDEAR App for ca. 4 month. Apart from some technical problems (sending information and choosing the last option of some lists did not work), she considered it to be useful. She would like to use it:

- as a reminder on taking medicines
- as an organizer for appointments
- for a list of medication and questions for visits at the physicians
- for documenting her health state, e.g. when visiting a doctor for the first time and not remembering her whole treatment history.

Her requirements for electronic documentation: less time consuming, easy to handle and adaptable to the patients' needs in regard to the input sequence of data and as little mandatory fields as possible, saving the entries at any point even if not all fields have been filled in.

The patient's documentation should be integrated into the clinical data collection in order to avoid double efforts, which demotivates the patients. It therefore should be possible to transfer the patient's data to the clinic.

To avoid that patients document their health status only when they get problems and feel bad but also in good times, fixed hours should be defined for documentation. That would help to overcome your „weaker self“ (self-assessment, avoid self deception).

An interesting feature would be the logging of vital parameters e.g. by wearing a wristband which documents sportive activities and actively requests how the user feels after having done sports.

Care organisation out of home

She visits the outpatient clinic 3-4 times a year. She sees a gastroenterologist outside the clinic (when she was under the age of 18 she could go to the paediatric gastroenterologist division within the clinic). Normally she takes the last referral letter when she visits a physician. Only when she sees a doctor for the first time she takes her complete folder with all copies of referral letters, findings etc. Mostly she takes questions on a piece of paper to be sure that she will not forget asking anything important.

In case of acute health complaints she calls her physician in the clinic or writes an email e.g., if she needs quickly an appointment for a colonoscopy because she noticed blood in stools. The physician always calls her back within 2 hours e.g. with an appointment suggestion. The communication with her treating physician at the outpatient clinic and within the clinic works very well.

Problems mentioned

- Coordination of her working hours (8 am to 6 pm) with physician appointments, collection of prescriptions, referrals or sick certificates are difficult to manage, because she has to pick them up personally.
- To save time, she visits a GP close to her residence, when she has to stay at home due to illness, whereas otherwise she visits a GP close to her working place.

Criteria for choosing a physician are online appointment allocations, opening hours and easy reach.

Suggestion: QR-code for transferring referrals or prescriptions to save time.

- Problems with health insurances: to get assistive devices like ergonomic chairs or computer mice requires a lot of administrative effort, admission to a specialist in a clinic like a radiologist needs special referrals which a GP often is not willing to make out.

DU-006 Patient

She can manage everyday life and gets support from her life partner if necessary, e.g. when she is not able to drive due to pain, he will bring her to the doctor.

She uses a mobile phone only for urgent phone calls e.g., to inform her waiting life partner in case of traffic jam.

Care organisation at home

<p>The treatment at home is managed by herself:</p> <ul style="list-style-type: none"> - she takes different drugs twice a day on Monday and Wednesday and manages the medication with a pill box. - she measures blood pressure every day, but notes the value only when it is very high (more than 170) and then calls her GP. <p>She is not documenting anything. Looking back, she regrets this, because it would have been helpful for her communication with physicians, as she had not been able to remember details of her disease history. Nowadays she is not willing to start a daily documenting because forgetting about her disease in daily life makes her feeling better.</p> <p>She is doing walks, goes swimming regularly and does a lot of gardening. Unfortunately, because of physicians' small budgets, she does not get any more prescriptions for physiotherapy.</p>
<p>Care organisation out of home</p> <p>She visits the outpatient 2 to 3 times a year and then she gets the date for the next visit in the clinic. In case of urgent problems (e.g. swollen hands) she calls her GP or the clinic to ask whether she should take a higher dose of cortisone.</p>
<p>Problems mentioned</p> <ul style="list-style-type: none"> - Longer waiting times in the clinic lead to problems e.g., in case someone wants to pick her up at a fixed time. Furthermore, the parking fees are very high and lead to extra costs. - 2 years ago she had got a prescription for back exercises from her orthopaedist, it had not been prolonged – she thinks due to budgeting physicians. A fixed date for doing guided exercises would be good, because at home she often misses practising due to daily housework.

DÜ-007 Patient
<p>Personal information</p> <p>She is using a desktop PC in the daily work as well as a smartphone. She often uses the Internet, writes text messages and - following customers' requests - she uses apps for contacting them although she personally does not like it due to missing privacy protection.</p> <p>When she has pain in her fingers she prefers typing on the enlarged online keyboard of her smart phone instead of using swipe gestures because this requires continuous pressure. A pen is not useful then because the required pinch grip generally should be avoided.</p>
<p>Care organisation at home</p> <p>The treatment at home is managed by herself:</p> <ul style="list-style-type: none"> - The medication stays the same for a longer time. She manages the daily take (3 pills) in the evening with a pill box. At the beginning she had to take further medication in the morning, that she sometimes forgot. - She does no measurements at home. <p>Appointments with doctors etc. she also manages on her own. She notes long time appointments in her smartphone as well as in a paper-based calendar at home, where she also notes all short time appointments. From time to time she makes a photo of the calendar.</p> <p>She does not need physiotherapy any more, but does exercises at home (Qi Gong) as it suits her working day. A reminder for that would be useful.</p> <p>She took part in the tests with the MiDEAR App for ca. 4 months. Apart from some technical problems (the reminder function does not work reliably), to her opinion the general structure was designed well and she thinks it is to be a useful support.</p> <p>An electronic support system should:</p> <ul style="list-style-type: none"> - Use symbols instead of too much text information - Document the daily health status to support self-assessment and prepare visits to physicians The documentation process should be flexible and adaptable to the patient's needs in order to be time efficient (as little mandatory fields as possible, flexible input sequence) - Visualise the results via time based curve diagrams to get an overview - The input should not be transferred to a physician because of lacking data protection. In no case an insurance company should get access to her personal health data.

<p>Additional useful features would be:</p> <ul style="list-style-type: none"> - medication list because she often cannot remember all names when requested. - reminder for daily exercises would help to do them. - abbreviation list to better understand e.g. measurement values - Sleep monitoring to relate evening activities like sports or bed time - pedometer to compare target state with actual moving activity (moving activity tends to decrease when having pain) - nutrition hints - weight control - too much monitoring can be dangerous, because it may lead to less self-responsibility
<p>Care organisation out of home</p> <p>She visits the outpatient clinic 2-3 times a year. She emphasizes the fact, that physicians can be reached easily via email in case of problems and explain things comprehensively.</p> <p>Furthermore, she sees an eye specialist and has to visit an outpatient clinic for hepatitis within the outpatient clinic doing blood tests in regular intervals.</p> <p>For the blood tests she has to make an extra appointment. This is time consuming and she has to balance it with her job.</p> <p>Referral letters are sent to her GP and she gets a copy as well. She thinks it is good that the patient also is informed that way and can have a look e.g., at results of blood tests.</p> <p>It is important for her, that physicians' offices are well organized and that she can order prescriptions or referrals by phone at night and get them the morning after. She also finds it disburdening that her GP in urgent cases makes appointments at specialists for her.</p>
<p>Problems mentioned</p> <ul style="list-style-type: none"> - Reachability by phone to make or reschedule appointments without waiting loops. - Managing job demands and appointments at the clinic and with specialists is not easy.

DÜ-008 Patient
<p>Personal information</p> <p>She leads an active life and does not need any help in her everyday life.</p> <p>She uses a mobile phone (SWISSON) with relatively large buttons. She uses it for phone calls and writing text messages and has no problems handling the hardware keyboard. She uses no other electronic devices.</p>
<p>Care organisation at home</p> <p>The treatment at home is managed by herself:</p> <ul style="list-style-type: none"> - in biweekly intervals she takes different pills or an injection and additionally painkiller 3 times a day. She manages the medication with a pill box and a paper based calendar. - She does not measure any vital parameters. <p>She does not want to document anything because she will not get anything new out of it and does not want to spend much time dealing with her sickness. She prefers just to accept every day, make the best of it and focus on activities like gardening and meeting friends or her children and grandchildren.</p> <p>Appointments with doctors she can also manage using her paper based calendar.</p> <p>She often rides her bike, goes for a hike every weekend and works in her garden nearly every day.</p> <p>She had had physiotherapy at the beginning of the rheumatism treatment, but by now she does not want to visit a physiotherapist because it is too time consuming to get there for about 10 minutes of exercising. She knows how to do exercises and does it on her own.</p>
<p>Care organisation out of home</p> <p>She visits the outpatient clinic twice a year. Sometimes she has to bring an X-ray image or an ultrasound picture.</p> <p>After a visit in the clinic her CP gets the referral letter. She visits her GP about once a year for a check up including a blood count. The GP considers rheumatism drugs in her treatment.</p> <p>She prefers to contact the clinic via phone. She can call for a prescription and gets it per mail. If she has a problem (e.g., a question concerning reduction of a drug prior to an operation or withdraw from a medication for side effects) her treating physician calls her back mostly within one hour. She is very</p>

glad about this service.
<p>Problems mentioned</p> <ul style="list-style-type: none"> - Very short physiotherapeutic sessions that cost a lot
DÜ-009 Patient
<p>Personal information</p> <p>She uses a tablet PC as well as a laptop with a standard mouse. She is left-hander but uses the mouse with her right hand. Having regular breaks that works well. She is using a smartphone for phone calls, text messages, WhatsApp and Internet e.g., search for health issues.</p>
<p>Care organisation at home</p> <p>The treatment at home is managed by herself:</p> <ul style="list-style-type: none"> - Currently she takes 2 different pills, one on Saturday, the other one on Sunday. This is part of her everyday life for many years. Therefore, she does not need any support on this. On request she takes pain killers, but this is practically not necessary since many years. - She does not document her pain and health status regularly, but only notes on a piece of paper the day pain starts for the next appointment at her physician. - She organizes appointments in a paper-based calendar. - She does no measurements at home. <p>Documentation and data protection:</p> <p>Long-term pain documentation is useful. It has to be adaptable to individual needs due to personal symptoms like heat or swellings.</p> <p>Monthly overviews of pain status and drug intake are useful for self-assessment and for discussions with new or known physicians, especially relations with newly prescribed or discontinued medicine. Documentation data should not be transferred automatically because of lacking data protection and possible misuse, but printed for discussions with physicians, other patients or friends</p> <p>In case of data exchange, it has to be ensured, that every data access is password protected and authorized by the patient with regard to whom and for which purpose data access is granted (appropriation).</p> <p>Other useful features:</p> <ul style="list-style-type: none"> - reminders for taking medicine could be interesting especially for newly affected patients, where medication often changes or for patients with limited memory skills, e.g. dementia - dictionary of medical terms e.g. blood values like CAP - information about disease symptoms and therapies - nutrition counselling - platform for exchanging experiences between patients - medication list
<p>Care organisation out of home</p> <p>She visits the outpatient clinic 4 times a year. Mostly she gets an infusion.</p> <p>Once in a while she has to see the orthopaedist and every 6 months she goes to her GP for a checkup. He knows about her RA disease and considers it for other medication.</p> <p>She prefers contacts by phone rather than by email. At urgent problems she calls the clinic, which often is very time consuming, e.g. it takes half a day to reach someone. In case of pain attacks she gets near-term appointments.</p> <p>All data are collected in the clinic, so there is no need for bringing extra documents besides the GP's referral letter, where she gets a copy of. She checks the values and can ask her GP in case something is unclear to her.</p> <p>She does not need physiotherapy, but does a lot of sports (Samba twice a week and Piloxi once a week, swimming and dancing).</p>
<p>Problems mentioned</p> <ul style="list-style-type: none"> - Waiting loops when trying to contact the clinic by phone

DÜ-010 Patient
<p>Personal information</p> <p>She uses a smartphone with larger keys for phone calls, text messages via WhatsApp and for taking pictures. At home she uses a tablet PC with a standard computer mouse without any major problems but in the past it was much worst when she had an attack of rheumatism.</p> <p>She has no major problems in managing his everyday life. Due to limits of her fine motor skills she sometimes needs help from her life partner e.g., to put on socks.</p>
<p>Care organisation at home</p> <p>The treatment at home is managed by himself:</p> <ul style="list-style-type: none"> - she takes different drugs daily, weekly and every 3 weeks he gets a injection. She manages the medication with a hand-made pill box and a paper based calendar (where she sticks the labels of the different drugs). Mostly she knows it by heart, when to take which drug because she is doing that for a long time. Varying doses of medications she notes on a piece of paper that she always has with her. - Twice a week she measures her blood pressure. She does not need any instruction, she knows what the values stand for. The blood pressure values are mostly stable and in case not she knows when she has to take in antihypertensive drugs or call her GP or an emergency physician. <p>She does not need reminders for medication intake. Maybe he might use this in the future when he realises increasing forgetfulness.</p> <p>Doing documentation on her health status is not necessary. She is not interested in history of blood pressure, weight or pain status any more. Sometimes she does a Google search for symptoms but furthermore she does not want to know any more details. She enjoys her stable health status and focuses on an active life with healthy nutrition (little of meat, more fish and mainly fresh vegetables and fruits) and physical activity in her everyday life (taking the stair instead of the lift, biking, going for a walk, doing gymnastic exercises that she knows from a cure).</p>
<p>Care organisation out of home</p> <p>She visits the outpatient clinic twice a year. Other physicians she visits are an eye specialist, a lung specialist and an urologist, rather rarely an orthopaedist and a radiologist. She visits her GP if required.</p> <p>The prescription for the rheumatism drugs she gets in the outpatient clinic. If she has any question (rather rarely) she prefers calling instead of mailing, because it is easier to explain what she wants to say.</p>
<p>Problems mentioned</p> <p>No problems were mentioned</p>

9 Appendix C: Current list of PICASO requirements

The following table of requirements reflects the status of 2016-07-15

Key	Summary	Status	Prio.	Component	Fit Criterion	Source	Rationale	Req. Type
PIC-54	Policy manager to set overall use policies for PICASO platform implementations	Open	Major	Policy manager, Privacy manager, Transaction audit Log	The policy manager provides the appropriate configuration files to be executed by the relevant PICASO components. An agile validation authority monitors compliance to the security and privacy policies and the associated workflows.	DoA	Implementations of the PICASO platform by different operators and/or in different jurisdictions in the EU could require the application of different policies regarding the use of the platform. Such policies may outline various security and privacy requirements and associated workflows e.g. how transactions are documented (e.g. what parameters are documented for a certain type of transactions) or consent policies regarding data access.	Functional
PIC-53	Privacy Manager controls access to patient data	Open	Major	Privacy manager	The privacy manager allows access to patient data for the various actors in the PICASO platform only when access has been authorized by all parties that are required to give consent.	DoA	The privacy manager ensures that patient data are visible and accessible only to authorized participants in the PICASO platform.	Functional
PIC-52	Risk manager	Open	Major	Risk manager	Integration of risk assessment and decision support as a component of the clinical dashboard into clinical workflows. Automated integration and processing of new relevant patient information including changes to treatment plans and home monitoring data. An advanced version provides	DoA	The risk manager supports the decision making process of clinicians by predicting the development of a patient's health status in the medium term. Automated updates of risk profiles as new patient data become available and/or care plan and medication changes are implemented support the situational awareness of clinicians.	Functional

Key	Summary	Status	Prio.	Component	Fit Criterion	Source	Rationale	Req. Type
					experimental tools that support clinicians in determining for example the most sensitive handles that can be used to improve patient outcomes in view of all relevant comorbidities.			
PIC-51	Attractive dashboard for clinicians	Open	Major	Dashboard	A comprehensive and configurable overview of relevant patient data with integrated decision support tools is provided to the satisfaction of the clinician.	DoA	The dashboard provides a comprehensive overview of a patient's current situation. It facilitates a rapid intake of relevant patient information and supports decision making by the clinicians for example through the integration of the risk manager.	Functional
PIC-50	All data retrieved based on metadata	Open	Major	Data Orchestration	All data well described are retrieved from original sources if still available.	DoA	All data meeting requirements should be retrieved.	Functional
PIC-49	Data available in supported format	Open	Major	Data Orchestration	If original source is accessible, data has to be translated into a common formal language and available during narrative execution.	DoA	Data from original sources are available if original source is still available.	Functional
PIC-48	Data source description	Open	Major	Metadata registry	Original data can be retrieved with provided metadata description.	DoA	Metadata registry has to contain all information required to access original data.	Functional
PIC-47	The Goal Optimizer meets all hard constraints.	Open	Critical	Goal optimizer	All hard constraints are met. Alerts are raised for.	DoA	The component focuses on meeting all hard constraints. If these are not met, narrative can not continue as planned.	Functional
PIC-46	PICASO provides a patient diary for self-recording	Quality Check passed	Major	Dashboard, LinkWatch (LinkSmart)	A patient diary is available where patients can record their daily well-being on a scale from 1 to 6. The recorded rating is presented to the user relative to the schedule for medication intake.	Workshop at UTV	A recorded history of daily self-diagnostics is an important tool for PD patients in regard to self-assessment and discussion with, e.g., physicians.	Functional

Key	Summary	Status	Prio.	Component	Fit Criterion	Source	Rationale	Req. Type
PIC-45	PICASO provides a graphical presentation of the patient's self-recordings in combination with the automatically measured vital parameters.	Open	Major	Dashboard, LinkWatch (LinkSmart)	A graphical presentation giving an overall view of self-recordings and automatically measurements is available and allows adaption in regard to the time frame presented (daily, weekly or monthly).	UDUS patient interviews	Graphical presentation is an effective way to get an overview of the on-going process of the disease including the comorbidities for patients as well as for physicians.	Functional
PIC-44	Data Browser should provide a graphical interface	Quality Check passed	Major	Data browser	At least one use case can be demonstrated using the Data Browser GUI	DoA	The Data Browser should provide a GUI for its Use Cases	Functional
PIC-43	The Narrative Manager (NaM) shall provide a UI	Open	Major	Narratives manager	The health care staff was able to define workflow by herself (this may include previous training).	DoA	The NaM is a tool made for the medical staff to develop narratives for patients. Medical staff must be able to use the software by themselves with enough documentation to define workflows.	Non-Functional
PIC-42	Narrative Manager (NaM) shall access patient information and context as well as possible treatment offers.	Open	Major	Narratives manager	Through the NaM it is possible to personalize workflows based on patient information, workflow templates and general treatment plans.	DoA	The NaM allows the development of workflows based on three aspects: patient information (by monitoring or clinical history), workflow templates, and services (e.g. treatment description from the Service Catalogue).	Functional
PIC-41	Narrative Manager shall provide access to existing templates	Open	Major	Narratives manager	It is possible to add/update narratives or sub-parts of it and load them in the NaM.	DoA	The NaM (Narrative Manager) needs to bootstrap narrative templates. Without this the NaM cannot be updated, or changed without a recompilation.	Functional
PIC-40	Unique digital ID for data from home monitoring	Open	Major	LinkWatch (LinkSmart)	All patients have a digital ID. The gateway, device and sensor have a digital hardware ID	DoA	Each patient has a digital ID, each gateway and each device or sensor has a digital hardware ID. When sending or receiving data from the	Non-Functional - security

Key	Summary	Status	Prio.	Component	Fit Criterion	Source	Rationale	Req. Type
	system						gateway, a digital token containing all three IDs is attached to the dataset.	
PIC-39	All Users have a unique digital ID	Open	Major	All	All users have a digital ID	DoA	All Users have a digital ID. When sending or receiving data from the platform, a digital token containing IDs from both sender and receiver is attached to the dataset. The digital ID is thus used to log all activities by all users in the entire PICASO platform.	Non-Functional - security
PIC-38	Unique digital ID for every transaction	Open	Major	All	Digital ID is implemented for all transactions	DoA	To identify all resources in the PICASO platform, the security model is based on exchange and comparisons of a unique digital ID. The digital ID is generated for each transaction. It is used for granting role-based access rights to information, for identifying the many transactions in an anonymous way, and for maintaining traceability throughout the system. The digital ID shall be used to log all activities by the patient or carer in the entire PICASO platform.	Non-Functional - security
PIC-37	The gateway must be able to handle both wireless and wired sensors	Open	Major	LinkWatch (LinkSmart)	Both wireless and wired devices are supported	DoA	Wireless sensors are preferred, but if not available wired sensors must be supported as well. Continuously data streams from unobtrusive behavioral and environmental sensors will be supported. Sensors supporting the IEEE Std 11073-20601™ are preferred, but if not available also support for the protocol available on the device.	Non-Functional - operational
PIC-36	Change of shared medication plan	Open	Major	Care plan orchestration	The function is implemented	Workshop at UDUS	Physicians share the patient's medication plan. A physician can only change medication prescribed by himself. If a Physician wants to change medication prescribed by another Physician, he must first request a	Functional

Key	Summary	Status	Prio.	Component	Fit Criterion	Source	Rationale	Req. Type
							change in the prescription via PICASO. The request is sent to the prescribing Physician, who must approve the change before it can be implemented	
PIC-35	Patient App	Open	Major	Data browser, LinkWatch (LinkSmart)	The App with the above functions exists	Workshop at UTV and UDUS	The patient will be provided with an App for manual input of lifestyle data, e.g., food intake, nutrition, exercise and mood data	Non-Functional - operational
PIC-34	Prioritized sensor events	Open	Major	LinkWatch (LinkSmart)	High priority sensors are registered by the gateway and data/events from these are sent before lower prioritized sensors.	DoA	Some events, measured by sensors, must be prioritized. All data from the sensors are assigned a priority. Fall sensors have high priority, contrary to temperature sensors with low priority. If a fall sensor registers a patients falling, the event must be sent to the PICASO platform immediately.	Non-Functional - security
PIC-33	No delay in continuous data from gateway	Open	Major	LinkWatch (LinkSmart)	When the data are received by the gateway, the data are immediately sent to the PICASO server.	DoA	Continuous data streams from unobtrusive behavioural and environmental sensors should be sent to the PICASO platform without noticeable delay	Non-Functional - performance
PIC-32	Measured patient data are identified with a patient Id	Open	Major	LinkWatch (LinkSmart)	All data from the gateway are marked with a Unique PID in the HL7 data record.	DoA	All measurements transmitted from the gateway must be provided with a unique patient identification to identify the patient generating the data	Non-Functional - security
PIC-31	Patient approval of data	Open	Major	Data browser, LinkWatch (LinkSmart)	Measured data are displayed on the patient's App for approval before they are transmitted to the PICASO platform	DoA	The patient shall approve all manual measurements before they are sent to the platform When the patient makes a manual a measurement, the measurement is displayed on the App for approval before transmission.	Functional
PIC-30	Remote and local maintenance and support of	Open	Major	LinkWatch (LinkSmart)	Remote configuration and maintenance of the gateway is established.	DoA	It must be possible for an administrator to connect to the gateway remotely over the Internet or to connect a PC to the gateway via a USB interface and	Non-Functional - maintainability

Key	Summary	Status	Prio.	Component	Fit Criterion	Source	Rationale	Req. Type
	the gateway						run a terminal session for upload/download of files and software updates. Software updates and gateway status information are important for maintenance and support.	
PIC-29	The gateway can store and retransmit data	Open	Major	LinkWatch (LinkSmart)	The readings are stored in the gateway if it is not connected to the PICASO platform. When the connection is reestablished, the stored readings are retransmitted.	DoA	To ensure that all data from the gateway are transmitted to the PICASO platform, the gateway must be able to store readings received from devices if the connection to the PICASO server is temporarily lost. When connection is reestablished, gateway must transmit stored data.	Functional
PIC-28	The gateway has a unique identifier	Open	Major	LinkWatch (LinkSmart)	The gateway identifier is implemented and recording in the PICASO platform implemented	DoA	The gateway must have a unique identifier in the PICASO platform. Together with the identifier PICASO must record additional information regarding location of gateway and other information of interest. (TBD)	Non-Functional - maintainability
PIC-27	Off-site configuration and testing of the gateway and devices	Open	Major	LinkWatch (LinkSmart)	Procedure for off-site configuration, testing and approval is implemented	DoA	The patient gateways and corresponding devices will be configured off-site by the consortium in such a way that they can be distributed directly from storage to patients - without further technical involvement. To be sure that the system components work together, an additional final Factory Acceptance Test and approval must be conducted before the system is installed.	Non-Functional - operational
PIC-26	The gateway acts as a bridge	Open	Major	LinkWatch (LinkSmart)	The bridge functionality is implemented	DoA	The gateway acts as a bridge between the wireless devices and wired sensor network based on IEEE11073 message protocols and the Wide Area Network based on HL7 v2.6 messages.	Non-Functional - performance
PIC-25	The gateway supports IEEE	Open	Major	LinkWatch (LinkSmart)	Selection of the IEEE 11073 Personal Health	DoA	The gateway must support IEEE 11073 Personal Health Device	Non-Functional

Key	Summary	Status	Prio.	Component	Fit Criterion	Source	Rationale	Req. Type
	11073				Device standards family is implemented.		standards family, based on the IEEE Std 11073-20601™. If a device does not support the standard, the gateway must be able to communicate using the protocol available on the device.	- usability
PIC-24	The patient gateway complies with Continua Health Alliance AHD	Open	Major	LinkWatch (LinkSmart)	The Application Hosting Device (AHD) is implemented on the gateway.	DoA	The Continua Health Alliance implementation framework, Application Hosting Device (AHD) makes it possible to receive health measurements from Personal Health Devices using PAN interface and share them with the PICASO server. It provides end-to-end interoperability of personal connected health devices and systems for health data acquisition, transmission and processing.	Non-Functional - performance
PIC-23	Legal and ethical issues of ICT surveillance in PICASO	Open	Major	All	Legal and ethical issues of ICT surveillance have been identified and addressed	DoA	Relevant legal and ethical issues of ICT surveillance must be considered, including participants' fear of surveillance	Non-Functional - legal
PIC-22	Participants can control devices and technologies used in home monitoring	Open	Major	Privacy manager	Participants can switch off equipment or choose not to send data	PICASO Ethical Guidelines	Participants must feel in control of what goes on in their home even if they have agreed to home monitoring	Non-Functional - operational
PIC-21	Participation is voluntary with option for withdrawal	Open	Major	All	Patient can opt to withdraw from trial	PICASO Ethical Guidelines	For patient autonomy they must not feel obliged to participate. They must be able to withdraw from the trial at any time without explanation or repercussions	Non-Functional
PIC-20	Minimally intrusive devices and technologies must be used	Open	Major	Many	Participants do not feel stigmatised when using PICASO	PICASO Ethical Guidelines	To avoid stigmatisation it is important that the least intrusive devices and technologies are used in the trials.	Non-Functional - look and feel
PIC-	PICASO has a	Quality	Major	Privacy	A log of who has accessed	UC-15	Only authorised users should have	Non-

Key	Summary	Status	Prio.	Component	Fit Criterion	Source	Rationale	Req. Type
19	log of who has accessed a patient's data	Check passed		manager	a patient's data and when is available in PICASO		access to a patient's data in PICASO and patients should be able to see who has accessed their data and when. A complete log can be used to verify to users that PICASO meets the requirements for the protection of personal data.	Functional - security
PIC-18	PICASO must contain a log of persons who have been granted data access by the patient	Quality Check passed	Major	Privacy manager	A log is available in PICASO for all patients in the trials	UC-15	Access to patient data requires prior authorisation from the patient and as this may change over time, a log should be kept. The log must show who has been granted access and also who have had their access withdrawn.	Non-Functional - security
PIC-17	The patient diary provides a graphical presentation of the patient's recordings	Quality Check passed	Major	Dashboard, LinkWatch (LinkSmart)	A graphical presentation of recordings is available that allows selection of the time frame presented (daily, weekly or monthly).	Patient interviews	Graphical presentation is an effective way to get an overview of the progression of the disease for patients as well as for physicians.	Functional
PIC-16	PICASO provides a patient diary for self-recording of symptoms	Quality Check passed	Major	Dashboard, LinkWatch (LinkSmart)	A patient diary is available where patients can indicate affected joints on the body and record their daily level of pain on a 10 point rating scale.	Patients interviews, DoA	A recorded history of daily self-diagnostics is an important tool for RA patients in regard to self-assessment and discussion with, e.g., physicians.	Functional
PIC-15	PICASO provides an adaptable reminder system for patients and/or carers	Open	Major	Dashboard, LinkWatch (LinkSmart)	Reminders can be presented for PICASO services medication plan, exercise plan, patient diary as defined by physicians, therapists and/or patients in regard to: date, time and mode of presentation (text, image, sound).	Patient interviews, DoA	Patients should have the option to receive reminders for proper medication intake, doing exercises and/or self-recording of symptoms.	Functional
PIC-3	It must be possible for users to browse for	Open	Major	Data browser	Users can browse for relevant data	Workshop at UTV	To avoid duplication of tests users must be able to browse for relevant information	Non-Functional - operational

Key	Summary	Status	Prio.	Component	Fit Criterion	Source	Rationale	Req. Type
	relevant data							
PIC-2	All user interfaces shall consider requirements of responsive design	Quality Check passed	Major	Many	All user interfaces are implemented in a device independent manner.	Patient interviews, DoA	Users will access PICASO services with different devices like desktops, smartphones or tablets.	Non-Functional - usability
PIC-1	All user interfaces shall consider accessibility requirements	Quality Check passed	Major	Many	PICASO components are implemented based on well known accessibility guidelines, e.g., WCAG 2.0.	Patient interviews, DoA	All PICASO services have to consider accessibility issues of the different users like operability by keyboard only.	Non-Functional - usability

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