A Personalised Integrated Care Platform

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D8.6 Evaluation Framework

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1 Executive Summary

The Evaluation Framework presented here is a result of task T8.45 Trials Evaluation. It focuses specifically on trial evaluation, i.e. on the trials as demonstrating PICASO as proof-of-concept, and thus also on evaluation activities involving trial participants. The evaluation framework specifies the content (what), methodologies and methods (how), and planning (when) of the evaluation. As a framework it is not intended to be prescriptive or restrictive; it will set the boundaries for the evaluation while being flexible to accommodate to changing shape and needs of the project and its informants.

The evaluation framework is inspired by the Donabedian model that focuses on three interrelated aspects: structure (resources and administration), process (culture and professional co-operation) and outcome (competence development and goal achievement) and the framework proposed by Cornford, Doukidis and Forster (1994) that added three categories: system functions, human perspectives and organisation context. The details of the latter two are included in this deliverable while system functions will be tested and validated in the technical work packages.

The evaluation methodology will be diverse; employing the conceptual approach and data collection methods most suited to obtain the relevant data necessary to evaluate specific outcomes and selected key performance indicators of the project. Both formative and summative evaluation approach will be used and combined with a participatory evaluation approach where the actual end-users in the two trials are invited to evaluate PICASO based on their involvement in the trials. Both quantitative and qualitative research methods, often in combination, will be used to gather data from users in the clinical trials. Generally, quantitative methods are used to collect quantifiable data to assess “how many” and “how often” and obtain a numerical result. Qualitative methods, on the other hand, focus on getting a deeper and more wide-ranging understanding of something, of a phenomenon. The focus is here on “how” and “why” and the data is descriptive and in a narrative format.

The specific aims of the evaluation have been divided into three main categories; i) health outcomes, ii) efficiency gains, and iii) perceptions of usability and adaptability in integrated care settings. The methods and tools that are foreseen to be used include: questionnaires, interviews, desk research/database review, focus group, self-reports, e^3value tool, usability tests, and written comments/feedback.

The following specific issues/ aims that will be addressed under each category are:

Health Outcomes

- Reduction in hospital admissions and re-admissions
- Reduction in bed days
- Reduction in visits to General Practice
- Improvement of physical well-being/Quality of Life
- Enhanced interaction with care provides (Improved interaction paradigms)
- Patient adherence to care plan(s)

Efficiency gains

- Increased cost efficiency in workflows of health and social carers
- More active participation of the patients in the care process
- Overall positive cost-benefit analysis in trial use cases (pay-back years)

Usability and adaptability in integrated care settings (experiences/perceptions of)

- Usability in integrated care settings
- Organisational adaptability

Software usability

- Software usability – Clinician Dashboard (with Care plan manager, Data resource viewer, Clinician manager, Risk assessment)
- Software usability – Patient Dashboard.

2 Introduction

Evaluation should be an integral element in any project, service or programme; indeed in their entire lifecycle. Evaluation is a tool to help us understand what works and what doesn't and why, and it can be used to make changes to and improve existing services etc. Evaluation generally focuses on the overall efficiency, effectiveness and relevance and should do so from the perspective of the various stakeholders affected. There are of course different approaches to evaluation which have an influence on the evaluation and the analysis of the data. It is therefore crucial to carefully consider the purpose of the evaluation and the key evaluation questions, how they will be answered (methodology and data), by whom, and when.

The evaluation of PICASO will naturally focus on the aims and objective of the project overall, as well as on the evaluation aspects (KPIs) and metrics, as already identified in the Description of Action (DoA). This deliverable provides a framework for how to evaluate the aims and objectives by translating these into concrete key evaluation questions, defining intended use and users, metrics, data and data collection methods etc.; the evaluation will include both qualitative and quantitative data.

To support the evaluation, the project will run two separate and complementary trials for proof-of-concept demonstrators of integrated care. The trial run by UDUS will involve patients above the age of 18 with Rheumatoid Arthritis (RA) and Cardiovascular Disease as co-morbidity and the trial run by UTV will involve patients above the age of 65 with Parkinson Disease (PD) and Cardiovascular Disease as co-morbidity.

The trials will run in two phases of nine months each, following the release of the PICASO platform prototypes. There is, however, a fundamental design difference between the two trials. The trial run by UDUS will involve 30 patients, splitting them into two groups for each phase so that the first group will be exposed to the first PICASO prototype and the second group to the updated prototype. The UTV trial will also involve 30 patients but here 20 patients will constitute the control group and 10 patients will be exposed to PICASO, both the first and second prototype. This basic difference will of course be considered when analysing the evaluation results.

The trials are at the core of the evaluation activities that will be carried out involving patients, their informal caregivers, and formal carers (including the trial owners). The evaluation of the project will therefore include distinct evaluation activities in each of the two trials based on the trial specific endpoints.

While adding a level of complexity to the evaluation framework, planning and analysis, the obvious contextual differences between the two trial sites (national, clinical, medical, cultural, economic, structural and organisational) are still considered a strength for evaluation purposes as PICASO aims to develop a generic eHealth solution that is deployable in different EU countries.

2.1 Purpose, context and scope of this deliverable

The Evaluation Framework presented here is a result of task T8.45 Trials Evaluation. The focus here is specifically on trial evaluation, on the trials as demonstrating PICASO as proof-of-concept, and thus also on evaluation activities involving trial participants. Technical internal testing and verification activities (e.g. unit tests, integration tests and system tests) will be carried out in the technical work packages and will therefore not be considered in this framework.

The evaluation of PICASO, and the evaluation framework presented in this deliverable, focus primarily on summative evaluation.[1] However, as formative evaluation is also an integral part of the project's iterative approach and the evaluation framework will therefore also include a particular aspect of formative evaluation that directly involves trial participants (mainly clinicians but also patients), namely usability.

The evaluation framework is a tool to organise and link the key evaluation questions, outcomes, metrics (indicators), data sources, data collection methods and targets (key performance indicators). The evaluation framework thus specifies the content (what), methodologies and methods (how), and planning (when) of the evaluation.

In an earlier (confidential) deliverable, *D8.1 Trial Definition for Integrated Care Management*, the two PICASO trials identified the overall health related endpoints and aspects that will be evaluated in each trial. The use cases that will be implemented in the trials are described in *D2.1 Scenarios and Use Cases for Integrated Care*. The evaluation data from the trials will be used to evaluate each trial separately with regards to their specific patient health related endpoints and combined to present an overall evaluation of PICASO as a decision support system to help clinicians in the management of co-morbidities. The results of the evaluation

[1] See section 4.1 for a description of summative and formative evaluation.

of PICASO will be documented in *D8.11 Final Evaluation Report of Early Risk Detection and ICT-Based Intervention*.

2.2 Content and structure of this deliverable

Chapter Three describes *what* will be evaluated based on the experiences and knowledge gained in the trials. The overall purpose of the evaluation is defined and a conceptual model to ensure a holistic evaluation is presented.

The methodological approach is described in Chapter Four. The methodology describes the broad philosophical underpinning to the chosen research methods, including whether qualitative or quantitative methods, or a mixture of both, are used and why.

In Chapter Five the evaluation framework for the summative evaluation based on the trials is presented. Three specific aims of the evaluation have been identified and divided into three main categories; i) health outcome, ii) efficiency gains, and iii) perceptions of usability and adaptability in integrated care settings.

A separate framework for software usability as formative evaluation based on trial specific use and experience is presented in Chapter Six. The framework is limited to software usability tests that will involve trial participants, first of all clinicians and secondly patients.

The methodology calls for the use of various data collection tools and method which are described in Chapter 7.

A brief note of ethics in supplement to the ethical guidelines provided in D3.3 The PICASO Ethical Guidelines is presented in Chapter 8.

A conclusion in the form of a brief note of how to use this deliverable is found in Chapter 9.

3 Evaluation Subject

The first step in defining the evaluation framework is to determine *what* will be evaluated. The evaluation, and this framework, is grounded firmly in the experiences and feedback from the users in the two trials in the project. The notion of perception is integral to the evaluation in the sense that users' perceptions based on their experiences with using PICASO will be gathered and are considered as valuable input to the analysis of user acceptance, usability and usefulness.[2]

User requirement validation and internal testing and verification are out of scope of this current framework; these activities will be conducted internally in the technical work packages.

PICASO aims to:

- improve cooperation and exchange of knowledge between professional caregivers in health, rehabilitation and social care domains and actively include patients and their relatives in the integrated care settings thus supporting patient empowerment and self-care
- bring about improvements in health outcomes, daily activities, and quality of life of older persons with multimorbidities by personalising care management programmes to specific characteristics of the patients' profiles and support adherence to care plans at the point of need;
- reinforced medical knowledge and create new care models for management and treatment of patients with multimorbidity conditions;
- allow more cost-effective care management through increased skills and collaboration of care professionals and more automated and efficient workflows, which eventually will lead to better health outcome and a reduction in hospitals admissions, and thus contributing significantly to the sustainability of health and social care systems in Europe.

The aims above form the cornerstone of the decisions made in this framework with regards to the evaluation purpose, key questions, approaches and methodological choices.

3.1 Evaluation Purpose

The overall purpose of the evaluation is to 1) gain knowledge and 2) assess the impact of PICASO from different stakeholder perspectives and on various levels. Combined, the intended use of the evaluation is thus to gather evidence from the PICASO trials that can help promote a change in existing clinical practices to improve the care of chronically ill patients with multimorbidities.

With respect to the internal purpose of the evaluation, the intended use is to facilitate the future exploitation of PICASO. Evaluation results are therefore crucial to support the dissemination and exploitation strategies in the project.

The intended users of the evaluation are all affected stakeholders, but primarily clinicians (specialists and GPs), patients, health authorities and administrators, home and community carers, and health technology providers.[3]

To sum up, the purposes and intended uses of the evaluation are:

- Gain and share knowledge:
    - Document clinicians' experiences of using PICASO to support the management and care of patients with multimorbidities
    - Usability (formative)
    - User acceptance/satisfaction and barriers
    - Inform stakeholders of the functionalities and effects of PICASO
    - To build trust in the PICASO system for all stakeholders

[2] User acceptance and satisfaction are used as synonyms as done also in e.g. the MAST methodology: "The patients' acceptability is sometimes used synonymously with the patients' satisfaction of telemedicine applications in empirical studies. Here the two terms are also used as synonyms ((MedCom & NST, 2010:29). In PICASO, patient, clinician and informal carer acceptance will be evaluated.
[3] Please refer to *D9.3 Dissemination Strategy and Plan V2.0* for a detailed analysis of stakeholders.

- Inform stakeholders of the evidence-based results of PICASO for the integration of care.

- Impact assessment
  - Impact and improvement on the management of multiple care plans from a clinician and patient perspective
  - Cost-benefits of PICASO
  - Patient empowerment and how this in turn affects the patient and their informal carers, as well as their medical status
  - Innovations.

3.2 Existing Evaluation Models

In order to provide a more holistic evaluation, different interconnected aspects of the PICASO solution will be considered. This means including different stakeholder perspectives and contexts of use in the evaluation, and ensuring that focus of the evaluation is adapted to the aspect that is being evaluated. In other words, different users have different expectations and different uses of the project results, and will therefore evaluate different aspects according to their intended use of the project results.

The PICASO evaluation focus and the definition of key questions is inspired by the framework for the assessment of the quality of care proposed by Donabedian (1988), as well as by the evaluation framework for eHealth proposed by Cornford, Doukidis and Forster (1994), as they allow for a more holistic evaluation, considering various aspects, levels, and stakeholder perspectives. Moreover, the MAST model mentions several elements/topics which will also be included in PICASO.

The Donabedian model focus on three interrelated aspects: structure (resources and administration), process (culture and professional co-operation) and outcome (competence development and goal achievement) that all need to be analysed in order to assess the quality of care. Structure refers to prerequisites, such as hospital buildings, staff and equipment. Process describes how structure is put into practice, such as specific therapies. Outcome refers to results of processes, for instance, results of therapy (Kunkel et al., 2007).

The evaluation framework proposed by Comford, Doukidis and Forster (1994) uses the same three categories as the Donabedian model, applying these to three levels: system functions, human perspectives and organizational context as illustrated in Figure 1.

	System functions	Human perspectives	Organizational context
Structure	technical detail	changed work conditions and implied requirements	sustainability, opportunity costs, management needs, skill requirements
Process	information processing correct and valid	human participation in tasks; social interaction	altered delivery and practice
Outcome	relevant, applicable, reliable	quality of service and outcomes	effect in the world

Figure 1: eHealth evaluation framework proposed by Comford et al (1996)

Another well-renowned mode is the MAST model (MedCom & NST 2010). MAST should only be applied when assessing the effectiveness and contribution to quality of care of a *mature* telemedicine application in order to provide a sound basis for clinical, administrative and political decision-makers. MAST focuses primarily on the prerequisites for and the consequences of the use of a telemedicine application.

Nevertheless, the PICASO evaluation framework is inspired by the multidisciplinary assessment used in MAST, and the final evaluation of PICASO will include elements related to the 7 domains in MAST.[4] For example, several of the topics MAST recommends can be included in the assessment will also be included in the PICASO evaluation framework and KPIs have been defined for key topics. The topics from MAST included in PICASO are:

Clinical effectiveness:

- Effects on health related quality of life
- Behavioural outcomes
- Utilization of health services (e.g. number of readmissions)

Patient perspectives:

- Satisfaction and acceptance
- Understanding of information
- Ability to use the application
- Empowerment, self-efficiency

Organisational aspects:

- Process
- Structure
- Culture[5]
- Management

Socio-cultural aspects:

- Changes in the patient's role in major life areas
- Societal, political context and changes
- Changes in responsibility

Ethical aspects:

- Potential ethical problems
- Autonomy

Legal aspects:[6]

- Information governance
- Professional liability
- Patient control – consent, access

Economic evaluation:[7]

- Amount of resources used when delivering the assessed telemedicine application and its comparators in the health care sector and other sectors
- Unit costs or prices for each resource used
- Related changes in use of health care resources
- Clinical effectiveness of the telemedicine application and comparators

[4] The seven domains in MAST are: 1. health problem and characteristic of application, 2. safety, 3. clinical effectiveness, 4. patient perspectives, 5. economic aspects, 6. organisational aspects, and 7. socio-cultural, ethical and legal aspects.
[5] In MAST, "Culture" includes clinical staff's attitudes towards and experiences with the use of telemedicine applications. In PICASO, clinicians' and informal carers attitudes, acceptance and satisfaction will be assessed as part of user acceptance.
[6] Primarily related to technical validation and verification ativities in WP7
[7] Economic evaluation and business cases will be carried out in WP9.

Business case

- Expenditures per year
- Revenue per year.

3.3 PICASO Evaluation Framework

The PICASO evaluation framework is inspired by the models mentioned above which have been adapted to fit the project's key ambitions and success criteria. The PICASO evaluation framework is illustrated in Table 1 using Comford, Doukidis and Forster's model (1994).

In the horizontal categories, "system functions" refers to technical functions of the PICASO platform. This will be evaluated in the technical work packages and will therefore not be described in more detail here. The category "human perspectives"[8] distinguishes between clinicians and patients and their informal carers because their perspectives differ, and thus the evaluation focus for these two end-user groups differs. The "organisational context" includes the clinics/hospitals directly involved in the trials.[9] The interrelations between the cells are important to achieve a more holistic and contextual evaluation. The vertical categories; structure, process and outcome are used in the same meaning as proposed by Donabedian.

The PICASO evaluation model reflects the key ambitions and success criteria of the project as outlined in the beginning of this section. The cells in the model represent the high level key aspects and issues that the evaluation seeks to answer or in other words, the factors that will be evaluated. This will be used to define the specific questions that will be addressed, i.e. the method(s) that will be used to collect data, the measures of success or KPIs, and involved partner(s) (cf. Chapter 5).

Table 1: The PICASO Evaluation Model

	System Functions	Human Perspectives		Organisational context
		Clinicians	Patients and informal carers	
Structure	Integration and interoperability of system components Requirement assessment and validation	Access to and sharing of patient data and medical knowledge	Ease of providing personal health information to clinicians Demands/efforts of using home-monitoring system	Sustainability Cost-efficiency User acceptance and satisfaction Adaptability
Process	Transfer and sharing of patient data / data processing	Changes in work flows and conditions Changes in interactions with other specialist and/or social carers Changes in interaction with patients/informal carers	Changes in behaviour & self-management Changes in interaction with clinicians and social carers	Changes to care plan management for multimorbidities Effect on integration of care Adaptability
Outcome	Usability Applicability Reliability	Management of multimorbidities Integration of care plans	Quality of life Health outcome	Health outcome More active participation of the

[8] It is important to note that the phrasing "human perspective" does not mean that the two end-user groups named here will only participate in evaluating the points listed in this column; they will also be involved in e.g. usability evaluation under "system functions". In other words, note that it is their perspective described, not their activity,

[9] The work in WP9, particularly T9.4 Healthcare Economics and Business Models and T9.5 Business and Exploitation Planning will contribute to the evaluation from the organisational perspective.

	Security (data security) Accurateness Transferability	Sharing of data Care efficiency (effectiveness and usefulness)	Adherence support to care plans Care efficiency (effectiveness and usefulness)	patients in the care process Care efficiency (effectiveness and usefulness) Adaptability

4 The Methodological Approach

The overall methodological approach in PICASO is to use the proof-of-concept method for evaluating the clinical feasibility of PICASO based on its implementation in the two trials involving real patients and clinicians. The two trials will test PICASO as a proof-of-concept and are therefore the primary sources of empirical data for the evaluation of the project. This proof-of-concept methodology is particularly useful for collecting primary data on the clinical applicability of the PICASO system, its usability and usefulness (including perceived usefulness and usability), and issues regarding the physical and organisation deployment of the system (see Bardram 2008).

Diverse evaluation methodologies will be used in order to employ the conceptual approach and data collection methods most suited to collect the relevant data necessary to evaluate specific outcomes and selected key performance indicators of the project.

The specific trial definitions, endpoints, and trial protocols have been described elsewhere; in this section we will focus on describing *how* the evaluation of PICASO will be carried out.

4.1 Formative and Summative Evaluation Approaches

The purpose of the evaluation and the object under evaluation must be considered when determining the conceptual approach to the evaluation. Two main types of evaluation exist: formative evaluation and summative evaluation. As the names suggests, the former focuses on e.g. needs assessment, implementation and processes, whereas the latter focuses on e.g. outcomes, impact and cost-effectiveness.

> "*Formative evaluation is an on-going process that allows for feedback to be implemented during a program cycle."*
>
> "*Summative evaluation occurs at the end of a program cycle and provides an overall description of program effectiveness.*"[10]

The main difference between how formative and summative evaluation approaches are used is illustrated in the figure below:

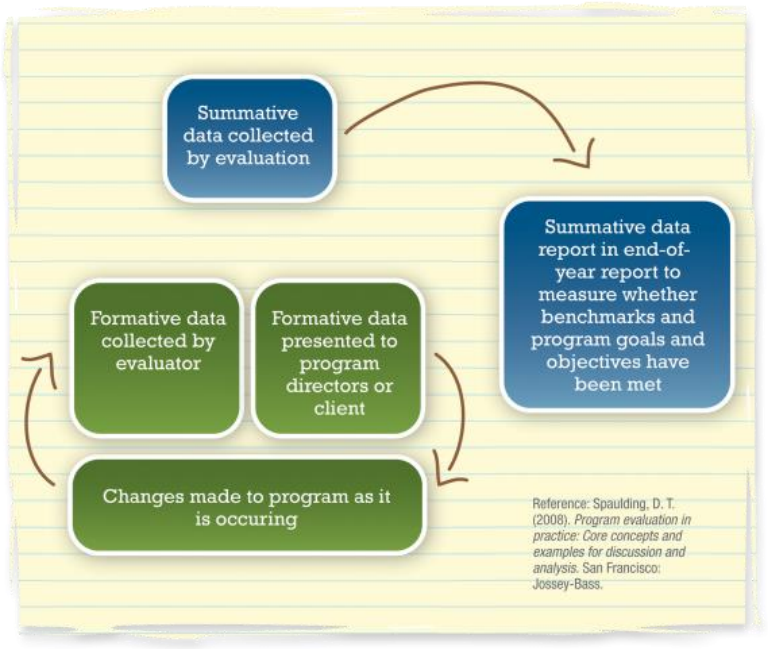

Figure 2: The application of formative and summative evaluation approaches[11]

[10] Reference: http://toolkit.pellinstitute.org/evaluation-101/evaluation-approaches-types/
[11] Ibid.

In PICASO, both formative and summative evaluation approach will be used and combined with a participatory evaluation approach where the actual end-users in the two trials are invited to evaluate PICASO based on their involvement in the trials.

However, as noted in the introduction, the evaluation activities in WP8 are focused on a summative evaluation based on the trials and the framework presented in this deliverable thus focuses on summative evaluation. Nevertheless, formative evaluation underpins the iterative approach adopted in the project and as elements of it will involve trial users, the related activities and methodology will therefore be briefly described below.

4.1.1 Formative Evaluation in PICASO

In PICASO, the formative evaluation is primarily for internal use in the project and is mainly carried out in the technical work packages. It includes user validation of requirements, internal testing and verification activities, focusing on technical testing of the reliability, accuracy, security and usability of the platform. Formative evaluation is used to provide timely input and feedback to partner responsible for developing and implementing the PICASO platform. Feedback from end-users, tests, and lessons learned will be used iteratively to improve the final PICASO prototype.

As mentioned above, usability testing is part of the formative evaluation in the project and as end-user feedback is very important here, trial clinicians and patients (their informal carers may also be involved) will be asked to participate in usability tests and the results used to update the usability of the Clinician Dashboard, Patient Dashboard and PICASO App.

Efforts will be made to collect input from all end-users in the trials, however, some limitations are expected with regards to patients' (and their informal carers') participation in usability tests and the tests will thus be designed to fit patient's availabilities and needs in the best way possible.[12] These limitations (i.e. patient availability and needs) are considered as acceptable as the Patient Dashboard and the PICASO App are technically less complex and have fewer functions than Clinician Dashboard. Even if usability tests can only be made with few patients and informal carers, the results will still be valuable for improvement and further development of the Patient Dashboard and the PICASO App.

It is important to note, that usability is used in two meanings in the DoA: 1) software usability testing as part of formative evaluation used to collect valuable input to software development (technical improvements of the prototype)[13], and 2) usability of PICASO in the integrated care setting to support and facility integrated personalised care.[14] The former will collect data such as concrete suggestions for improvements of e.g. content, presentation, navigation etc., as part of the formative evaluation activities, whereas the latter will collect data on subjective experiences and impressions as part of the summative evaluation activities.

Formative evaluation is carried out in two phases: pre-trial and continuously during the trials. Pre-trial formative evaluation is not part of the current deliverable as it has been carried out prior to the submission of this deliverable and as it, in relation to the technical testing activities, occurs in the technical work packages, notably WP4-7.[15]

However, to briefly sum up here, pre-trial *user* evaluation activities focus on system structures and processes and on processes from a human perspective (cf. Figure 1). It is concerned with testing the functionalities in a controlled environment up against the user requirements to ensure that the first released prototype is mature enough for implementation and testing in the trials.

The pre-trial formative evaluation have only involved PICASO partners, including clinicians and other non-developer partners, who have tested the PICASO home-monitoring solution "as patients" and "as clinicians" from a user acceptance and satisfaction perspective. Patients have not been involved in the pre-trial formative evaluation as it would potentially be very confusing, stressful and de-motivating for patients to use a pre-mature prototype of the solution. The pre-trial formative evaluation precisely aims at ensuring that the prototype solution released to the patients and implemented in the trial is robust enough for patient use.

Partners from IN-JET and CNET have carried out user acceptance tests in form of acting as patients taking the prescribed home measurements (blood pressure and weight) and using the Fitbit activity tracker on a daily basis for 6-8 weeks, noting errors and making comments to the Patient Dashboard's user interface design;

[12] See also section 6.1
[13] See also section 6.1
[14] See aslo section 5.3
[15] Results will be reported in D8.11 Final Evaluation Report of Early Risk Detection and ICT-Based Intervention

issues that would affect user acceptance and satisfaction. This period allowed for a correction of main errors and improvements to the design, presentation and navigation of the Patient Dashboard before the solution was released to the clinical partner, UDUS, for further testing and feedback. These activities allowed for functionality and user acceptance tests from a user perspective (albeit users who are quite IT literate) before the solution is released to real patients and deployed in the trials.

Formative evaluation during the trials will focus on software usability with the intent to assess the usability of the PICASO solution and to collect feedback and suggestions from users on how to improve usability, user interaction and ease of use. Due to the crucial participation of end-users in usability testing based on their use of PICASO in the trial, this deliverable will include the framework for software usability in more detail (see Chapter 8).[16]

As explained above, formative evaluation data is a key source for input to the iterative technical development in the project. WP8 and this deliverable is, however, concerned with trial evaluation i.e. the overall evaluation of the project based on the trials as demonstrators of PICASO as proof-of-concept and as sources for evidence-based data that will be used to assess the project outcome. This type of evaluation is known as summative evaluation.

4.1.2 Summative Evaluation in PICASO

Summative evaluation looks at the impact of an intervention on the target group, in other words it is outcome-focused. There is a clear advantage of using both quantitative and qualitative methods in summative evaluation as the combination provides a deeper understanding of what was achieved, how and why.

The summative evaluation of PICASO is primarily intended for external use and focuses on providing stakeholders with an evidence-based generic knowledge of the project's results and how these can be utilised in the future in line with the formal aims and visions of the project. Baseline data is useful in most summative evaluation and will be included when relevant and feasible (some baseline data may not be available as PICASO is new solution).

The summative evaluation will provide knowledge of the strengths and weaknesses of PICASO – as a concept and technical solution - based on empirical data from the two trials used to test PICASO. The summative evaluation will (ideally) support and facilitate the future exploitation of the project's results. Suggestions for further research and development are also likely to result from a summative evaluation.

A number of key performance indicators (KPIs) were identified in the project proposal. In relation to the summative evaluation of the project the following will be assessed based on empirical data (quantitative and qualitative data) from the trials and pre-existing data (quantitative only) such as health statistics..

4.2 Data samples/Informants

The trial data sample consists of users involved in the trials and who have used PICASO

Patients will be involved in two different ways: 1) evaluating PICASO as an end-user based on their user experience and 2) as data samples on which the effect/impact of PICASO on health status and patient empowerment will be measured and assessed.

The following describes informants that may be included in the evaluation by each trial site.

Trial 1 UDUS

The following sample will be invited to evaluate PICASO, with the aim of all provide some feedback:

- 30 patients with rheumatoid arthritis as primary morbidity and a cardiovascular disease as co-morbidity (trial participants)
- When applicable, the patients' informal carers
- Rheumatologists involved
- GPs
- Cardiologists
- Nurses
- Other hospital/clinic personnel involved in the care of the patients[17]

[16] Other technical validation and evaluation activities are out of scope here.
[17] Includes nurses.

- Hospital/clinic administrative personnel[18]
- Hospital/clinic IT personnel.

Trial 2 UTV

- 30 patients with Parkinson Disease who have CVD or psychiatric comorbidities and older than 65 years
    - 10 patients participate in the experimental arm, i.e. the patient management is based on PICASO and patient use the PICASO home-monitoring solution
    - 20 patients participate in the standard arm (control group), i.e. the patient will be followed as in current clinical practice
- When applicable, the patients' informal carers
- Clinical neurologists
- Nuclear medicine physician/radiologist
- Cardiologists
- Psychiatrist / Neuropsychologist
- Patients' GPs
- Other hospital/clinic personnel involved in the care of the patients[19]
- Hospital/clinic administrative personnel[20]
- Hospital/clinic IT personnel.

[18] Includes medical documentation officers
[19] Includes nurses
[20] Includes medical documentation officers.

5 Summative Trial Evaluation Framework & Plan

Based on the chosen evaluation model and methodologies, the specific aims of the evaluation have been divided into three main categories; i) health outcomes, ii) efficiency gains, and iii) perceptions of usability and adaptability in integrated care settings. Key Performance Indicators (KPIs) have been identified and will, in relation to quantitative data, be used to measure success. Qualitative data do not have KPIs but will be used to provide context to quantitative data and – importantly – also to allow end-users to relate their personal experiences, assessments and outcomes from participating in the PICASO trials. Where trial specific baseline data and control group data are available, it will be compared to that trial's own evaluation data to indicate success/changes. If such baseline and/or control group data is unavailable, existing local and national databases will be resourced. The following tables give an overview of the different elements in the evaluation framework.

Table 2: Evaluation Framework and Plan for Health Outcome

Health outcome						
Specific aim/question to address	**KPI**	**Methodology/Data Type**	**Data collection tool/method**	**Partners involved**	**Timeframe[21]**	**Location/setting**
Reduction in admissions and re-admissions	20%	Quantitative data • Clinical records/statistics • Registration of data (PICASO Patient Dashboard	Analysis of register data	UDUS UTV	M28-29/M38-39	Clinic/Telephone/Online[22]
Reduction in bed days	10%	Quantitative data • Clinical records/statistics • Registration of data (PICASO Patient Dashboard	Analysis of register data	UDUS UTV	M28-29/M38-39	Clinic/Telephone/Online
Reduction in visits to General Practice	25%	Quantitative data • Clinical records/statistics	Analysis of register data	UDUS UTV	M28-29/M38-39	Clinic/Telephone/Online

[21] Certain quantitative will be collected continously throughout the trial periods. The timeframe here indicates when the concrete evaluation activities will be conducted, e.g. interviews, administration of questionnaires etc. The timeframe will be used for more specific evalaution planning by involved partners.
[22] "Online" includes cases where patients fill out online questionnaires, paper questionnaires outside the clinic at their own convenience (e.g. at home), use email, and/or the Patient Dashboard to submit answers and feedback.

		• Registration of data (PICASO Patient Dashboard				
Improvement physical well-being/Quality of Life	15% (~7-8 points)	Quantitative data • Scores (questionnaires) Qualitative data • Patient perception /experience	Analysis of register data Questionnaire(s) Patient interviews	UDUS UTV	Every 3 months during trial M28-29/M38-39 (qualitative)	Clinic/Telephone/Online
Enhanced interaction with care provides (Improved interaction paradigms)	> 90% satisfaction rate	Quantitative data • Scores Qualitative data • Patient perception /experience • Informal carer perception/experience	Questionnaire(s) Patient interviews Focus group (patient/informal carer)	UDUS UTV FIT IN-JET	M28-29/M38-39 (qualitative)	Online Telephone Clinic External venue (focus group)[23]
Patient adherence to care plan(s)	>80% of patients report improvement	Quantitative data • Registration of data (PICASO Patient Dashboard) Qualitative data • Patient perception /experience • Informal carer perception/experience	Analysis of register data Patient interviews Self-reports (patients) • Morisky Medication Adherence Scale	UDUS UTV FIT IN-JET	M28-29/M38-39	Clinic Telephone Online Lab[24]

[23] "External venue" refers to meeting rooms provided by/hosted by project partners. Could in reality be at the clinic's location, but the setting will be a meeting room rather than a consultation room.
[24] "Lab" refers to partner(s) internal testbeds and offices, i.e. when collection of data occurs as desk researchfrom a partner's base/location.

Table 3: Evaluation Framework and Plan for Efficiency Gains

Efficiency gains						
Specific aim/question to address	**KPI**	**Methodology/Data Type**	**Data collection tool/method**	**Partners involved**	**Timeframe[25]**	**Location/setting**
Increased cost efficiency in workflows of health and social carers	20% lower costs	Quantitative data • Existing statistical data • Existing health economics data	Analysis of data register	UDUS UTV FIT INUIT IN-JET	M29/M39	Lab
More active participation of the patients in the care process	>25% reduction of unforeseen events >80% completion rate	Quantitative data • Clinical records/statistics) • Registration of data/ User activity logs (PICASO Patient Dashboard) •	Analysis of data register	UDUS UTV CNET	M27-29/M37-39	Clinic Online Telephone Lab
Overall positive cost-benefit analysis in trial use cases, pay-back in years	≤2.5 years	Quantitative data • Existing statistical data • Existing health economics data • PICASO trial data	Analysis of data register (e^3value tool/business case analysis)	UDUS UTV FIT INUIT IN-JET	M27-29/M37-39	Lab

[25] Certain quantitative will be collected continously throughout the trial periods. The timeframe here indicates when the concrete evaluation activities will be conducted, e.g. interviews, administration of questionnaires etc. The timeframe will be used for more specific evalaution planning by involved partners.

Table 4: Evaluation Framework and Plan for Usability and Adaptability

Usability and adaptability in integrated care settings (experiences/perceptions of)						
Specific aim/question to address	**KPI**	**Methodology/Data Type**	**Data collection tool/method**	**Partners involved**	**Timeframe[26]**	**Location/setting**
Usability in integrated care settings	>85% satisfaction rate	Quantitative data • Scores (clinician/patient/informal carer)	Specially designed questionnaire	UDUS UTV IN-JET	M28-29/M38-39	Online
Organisational adaptability	>75% satisfaction rate	Quantitative data • Questionnaire scores Qualitative data • Clinician perception /experience	UEQ questionnaire Questionnaire Clinician interviews	UDUS UTV FIT IN-JET	M28-29/M38-39 (qualitative)	Lab Online Clinic

The following sections will describe the above evaluation aims and methodologies/data types for collecting data. The methods and tools are described in Chapter 7.

[26] Certain quantitative will be collected continously throughout the trial periods. The timeframe here indicates when the concrete evaluation activities will be conducted, e.g. interviews, administration of questionnaires etc. The timeframe will be used for more specific evalaution planning by involved partners.

5.1 Health outcome

The evaluation of health outcomes will be assessed from the patient, clinician and organisational perspective. Due to the very different patient groups in the two trials, trial specific data will be collected and analysed in their clinical context. The following subsections describe in more detail the data that will be collected to evaluate PICASO's impact on patients' health outcome.

Reduction in bed days, number of hospitalisations and visits to GPs will also be used to assess efficiency gains as described in 5.2 below.

5.1.1 Reduction in admissions and re-admissions

PICASO aims to demonstrate that a 20% reduction in admissions and re-admissions for patients with multimorbidities can be achieved by PICASO-enabled integrated care for this patient group. A distinction will be made between admissions (first admission related to chronic condition) and re-admissions. Due to the small sample of patients in the trials and the relatively short trial period, the evaluation can merely indicate an effect.

The number of admissions and re-admissions for the trial patients will be recorded mainly based on direct notification by the patient (the patient dashboard could include a functionality that allow patients to record admission/re-admission) and end-of-trial/follow-up interviews with patients.

5.1.1.1 Baseline data

The baseline will have some limitations as it will out of the project's scope to collect baseline data for patients with *identical* disease stage and progression. Baseline data will be collected from clinical records and official statistics, as well as from the control group (UTV trial only) which will be used to calculate an average baseline for RA and PD patients respectively. Only admissions/re-admission related to their chronic condition and multimorbidities will be included.

Two sets of baseline data may be collected subject to possible constraints and limit of access: 1) for the patients participating in the trial the number of admissions and re-admissions during the 9 months prior to their trial start will be collected, and 2) clinical records and general statistics for the average annual admissions and re-admissions for patients suffering from the same chronic conditions at the trial patients. The UTV trial will be able to use data from the control group as baseline data; data on the number of admissions/re-admissions for the UTV control group will thus be collected for the duration of the trial and compared at trial end. The analysis will consider the progression level of the disease for each patient, keeping in mind that disease progression and hospitalisation needs will be highly subjective.

5.1.2 Reduction in bed days

The KPIs for reduction in bed days is 10% and as above the small sample of patients and relatively short trial period, the data collected from trial patients will be used to indicate a trend and effect.

The number of bed days (in hospital) for the trial patients will be recorded mainly based on direct notification by the patient (the patient dashboard could include a functionality that allow patients to record the number bed days), specified question(s) on questionnaire, and end-of-trial/follow-up interviews with patients.

5.1.2.1 Baseline data

Similar to the above, the baseline will have some limitations as it will be out of the project's scope to collect baseline data for patients with identical disease status and progression. Baseline data will be collected from clinical records and official statistics, which will be used to calculate an average baseline for a similar patient group. Only bed days related to their chronic condition and multimorbidities will be included.

Two sets of baseline data may be collected as described above in 5.1.1.1.

5.1.3 Reduction in visits to general practice

PICASO aims to reduce the patients' visits to general practice by 25%. This is believed to be achieved via a combination of home-monitoring and the improved integration of care. The impact will be measured at the end of the individual's trial participation.

Patients will be asked to record their visit(s) to the general practitioner if it is related to their chronic condition and multimorbidities. Unrelated visits will not be included in the data set. Patients will be able to record this in

the 2nd prototype of the Patient Dashboard (cf. requirement PIC-197 and PIC-198, see *D2.4 First Updated Requirements Report*), i.e. during trial 2 (M30-M39).

5.1.3.1 Baseline data

Baseline data will be collected from trial participants for the 9 months prior to enrolment in the trial. The UTV trial will also use data from the control group collected during the trial period as comparative data to data collected from trial participants. The analysis will consider the progression level of the disease for each patient, keeping in mind that disease progression and necessary number of bed days per hospital admission will be highly subjective.

5.1.4 Improvement of physical well-being/Quality of Life

The primary and most significant impact of the project on the outcomes for patients will be its decisive impact on improved health. PICASO aims to show a 15% improvement patients' assessment of their physical well-being and quality of life by the end of the trials.

Data will be collected through validated questionnaires filled in by patients. As physical well-being and quality of life can be very fluctuating for chronic patients, data will be collected every 3 months during the trials. This also allows clinicians to continuously evaluate the patient's own perception of their health status and correlate this with other data from the home-monitoring system.

In addition, the singular question "how do you feel today" will be asked in the Patient Dashboard every day and the response by the patients will be considered in the analysis (UTV only).

5.1.4.1 Baseline data

Baseline data will be collected at the start of the trials using the same questionnaire(s).

5.1.5 Enhanced interaction with care providers

Enhanced interaction with care provides here refers to the interaction paradigms between patients, informal cares and their care providers. It is related to the project's aim to improve patients' interaction with care providers making it more personalised, timely, friendly and helpful in an unobtrusive manner. The personalisation of services also aims to support each patient with a tailored care approach adjusted to his/her preferences. Enhanced interaction between patients and carers are expected to support and facilitate more active participation of patients and their informal carers in the care process. It is thus an essential element in supporting patient empowerment. The aim is to reach a >90% satisfaction rate on how well PICASO supports interaction between patients, informal carers and care providers.

The data that will be used to assess this aspect relies primarily on feedback from patients and their informal carers on their personal perceptions and experience of how the improved interaction paradigms have been manifested. The feedback will also be used to assess patients' and informal carers' attitudes and acceptance of ICT solutions to support personalised care. Clinicians will also provide feedback on their experiences of interacting with patient and their informal carers

A questionnaire will be developed to collect data on user experiences and satisfaction. Interviews and focus groups will be used to collect qualitative data to contextualise and provide a deeper understanding of the results.

5.1.5.1 Baseline data

The questionnaire used to assess this aspect will be distributed to patients, the informal carers and care givers at trial start and trial end to assess any change after having used PICASO during the trial.

5.1.6 Patient adherence

The Patient Dashboard has a reminder function asking patients to confirm that they have remembered to the take their medication today. The reminder asks patients to indicate if the correct dosage has been taken, if alternative medication has been taken, and if the prescribed timings have been upheld. This self-reported data will be logged and used to assess if PICASO supports medication plan adherence. Data will also include feedback from patient on the utility of this function.

5.1.6.1 Baseline data

As no baseline data is available, the evaluation will here simply be used to indicate if such a function is useful and helpful for patients, and for their informal carers who would like to know if patients remember to take their medication. The functionality is likely to exist in conjunction with other traditional means to keep track of medication intake such as a pill dispenser.

5.2 Efficiency gains

As described in DoA, PICASO aims to contribute to the sustainability of health care systems by facilitating a reduction in admissions and days spent in care institutions for chronic patients with multimorbidities. The evaluation of this goal will be based on data related to cost efficiency, patient activity levels and the cost-benefits of PICASO.

The metrics for measuring the efficiency impact will be based in activity based cost measurements (time, direct costs) for a set of relevant, standardised care pathways before and after the use of the PICASO platform. Improved interactions will be measured indirectly in terms of the number of unforeseen events reported during the pilot phase compared to the average for the past three years.

5.2.1 Increased cost efficiency in workflows of health and social carers

PICASO aims to facilitate more automated and efficient workflows in the handling and monitoring of patients. The automated workflows will work across the traditional silos of care, thereby supporting better handover procedures between different medical specialists and health and social care professionals. PICASO will allow carers access to the relevant patient information at the right place and time, thereby supporting personalised care based on the patient's current situation and context. This improvement of the workflows will lead to better health outcome and a reduction of unforeseen events related to the chronic conditions of the patient, namely hospital admissions, bed days and (related) visits to GP. The aim is to show an increased cost efficiency in workflows of health and social carers is 20% lower costs.

The costs related to unforeseen hospital admission, bed days, and related visits to the GP will be collected and calculated for each trial and compared to the baseline data.

5.2.1.1 Baseline data

The average number of unforeseen events (bed admissions and days spent in care) for the past three years will be used as baseline data. It will be compared to the number of unforeseen events reported during the two trials.

5.2.2 More active participation of the patients in the care process

The PICASO home-monitoring solutions which will be deployed with trial patients will facilitate patient activity in their own care process. They will actively be involved in measuring basic health parameters that help to monitor their chronic condition and multimorbidities.

Activity levels can be measured by the logs documenting when and how often patients send home measurement data to the clinic via the PICASO App and the Patient Dashboard. The data will indicate patient activity levels and adherence to care plan(s), e.g. confirming medicine intake, taking measurements as prescribed, and achieving recommended activity goals. The increase in active participation of the patients will also be measured indirectly in terms of the number of unforeseen events reported during the pilot phase compared to the average for the past three years. These two sets of data will be combined to reach a quantitative indication of how active patients were involved in the care process during the trial and the effect it would have had on unforeseen events.

5.2.2.1 Baseline data

Baseline data will not be available and the assessment here is therefore focused on measuring *how* active patients are during the trial.

5.2.3 Overall positive cost-benefit analysis in trial use cases pay-back

A survey of health economics in Europe and a cost-benefit analysis of the PICASO platform will be conducted in task T9.4 Healthcare Economics and Business Models. The survey will concentrate on the European

countries represented in the project consortium. The analysis will help to develop sustainable business models illustrating the economic foundation for PICASO in Europe. The KPI for overall positive cost-benefit analysis in pilot use cases pay-back has been set as ≤ 2.5 years.

Calculations will be made to determine the initial investment and annual costs of running PICASO for each trial site in order to estimate the pay-back in years. Actual data on savings and cost-reductions from the trial will be collected, however due to the relative short time frame and the limited number of participating patients, the assessment will essentially be based on estimations and forecasts.

5.2.3.1 Baseline data

The survey on health economics in Europe will serve as baseline data. The survey will include statistical and demographic data.

5.3 Usability and adaptability in integrated care settings

Usability in this context is related to users' concrete experiences and perceptions of how PICASO has supported and facilitated the interaction paradigms. Efforts will be made to collect feedback from all the involved users in a patient's care during the trial.

Similarly, adaptability will be evaluated from the perspective of the users in the clinical domain, assessing how well PICASO can be adapted into the workflow and procedures to provide personalised integrated care for patients.

5.3.1 Usability in integrated care settings

PICASO will provide novel interfaces that are expected to enhance the interaction with care providers. This is expected to significantly enhance the good impressions that patients will have from interacting with care providers in a personalised, timely, friendly, helpful, and unobtrusively manner. A specially designed user experience questionnaire will be developed to assess patients, informal carers and clinicians' experiences of how well PICASO meets these goals and has improved the interaction paradigms. The questionnaire will be distributed to users at end of the trial period.

5.3.1.1 Baseline data

No baseline data exist as there is not a current solution/system for integrated care.

5.3.2 Organisational adaptability

Organisational adaptability refers to the PICASO system's adaptability to the patient's status and need. It is implemented through narratives across care providers, and service orchestration of care plans with personalised feedback and routine interventions towards the patient. Organisational adaptability will be evaluated from the clinician's perspective by means of a questionnaire enquiring into the improvements enabled by PICASO. Interviews with clinicians will be conducted to collect supplement qualitative data on their concrete experiences.

5.3.2.1 Baseline data

No baseline data exist or will be necessary to assess the organisational adaptability of PICASO.

6 Formative Evaluation Framework and Plan

As described in Chapter 4, software usability testing is an important element of formative evaluation and of the user-centric approach used in the project. Usability testing will therefore be performed in conjunction with planned updates of the PICASO prototype. The usability evaluation will be used to identify where there is room for improvement based on end-user perspectives and experiences. An overview of the framework for usability testing involving end-users is presented below:

Table 5: Evaluation Framework and Plan for Software Usability

Software usability						
Specific aim/question to address	**KPIs**	**Methodology/Data Type**	**Data collection tool/method**	**Partners involved**	**Timeframe[27]**	**Location/setting**
Software usability – Clinician Dashboard (with Care plan manager, Data resource viewer, Clinician manager, Risk assessment) • Attractiveness • Use quality • Design Quality • Suitability for the task • Information presentation • User interaction • Overall ease of use/learnability	Concrete suggestions for improvement/changes Satisfaction rate: >90% (UEQ)	Quantitative data • Scores Qualitative data • Clinician experiences	Usability test(s) • Observation • Thinking Aloud • Post-test interviews • UEQ Written comments/feedback	FIT INUIT UDUS UTV IN-JET	M22-M24 M32-M33	Clinic Online
Software usability – Patient Dashboard • Attractiveness	Concrete suggestions for improvement/changes	Quantitative data • Scores Qualitative data	UQE Written comments/feedback	FIT INUIT UDUS	M22-M24 M32-M33	Online Clinic Telephone

[27] Certain quantitative will be collected continously throughout the trial periods. The timeframe here indicates when the concrete evaluation activities will be conducted, e.g. interviews, administration of questionnaires etc. The timeframe will be used for more specific evalaution planning by involved partners.

• Use quality • Design Quality	Satisfaction rate: >90% (UEQ)	• Patient experiences	Interviews	UTV IN-JET		

6.1 Software Usability

Software usability tests of the Clinician Dashboard will be prioritised as it is far more complex than the Patient Dashboard and the PICASO App for patient home-monitoring. The Clinician Dashboard is composed of a number of components that allow clinicians to perform various tasks; usability testing involves setting a specific relevant task for the clinician who then uses the particular component, or feature, of the dashboard to complete the task, such as creating a care plan, retrieving risk analysis etc.

The primary end-users involved in usability testing will therefore be clinicians in line with the overall objective of PICASO to provide a platform to support clinicians in the integrated care of chronic patients with multimorbidities.

Software usability testing involving patients (and informal carers if relevant), i.e. testing of the Patient Dashboard and the PICASO App, will be conducted but availability constraints are expected which may limit the extent, number of involved patients/informal carers and detail of the usability testing activities. If "standard" usability tests (see section 7.1 below) can only be done with few patients or none at all, it will be necessary to assess the if the efforts to set this up may be too great compared to the results that can be expected, especially considering the simplicity of the Patient Dashboard (i.e. not consisting of innovative components). An alternative would be to ask patients/informal carers to fill in a User Experience Questionnaire (UEQ) at home/online. A field for additional comments and suggestions can then be added to the UEQ inviting participants to make concrete suggestions for improvements and changes to enhance usability. Where feasible, interviews could also be used to collect feedback on usability, potentially by telephone interviews as these are more flexible than face-to-face interviews. Observation and Thinking Aloud, however, would be out of scope in this "alternative" usability testing methodology.

Patients will also be asked to provide feedback on the PICASO App and the home-monitoring devices. However, the PICASO App has very limited user interaction; basically only the function "send data" is available obviously limiting the type of suggestions for better usability. Also, as the home-monitoring devices are off-the-shelf products, it is obviously out of scope of the project to improve the usability of the devices.[28] Suggestions related to usability will rather be used to (re-)assess the type and brand of devices to select for home-monitoring in the future and to collect data on connectivity issues between the PICASO App and the devices. Patients' feedback on the PICASO App and the home-monitoring devices will be collected in connection with the evaluation of the Patient Dashboard by including a specific comment field for this on the questionnaire and/or asking specific question during interviews.

[28] At the time of writing the following devices will be usedi n the trials: FitBit Charge 2, A&D Digital Blood Pressure Monitor UA-651BLE, A&D Precision Health Scale UC-352BLE, and Samsung Galaxy Tab A (used as gateway)

6.1.1 Software usability – Clinician Dashboard

Software usability will be evaluated by setting up tasks for clinical end-users that reflect the intended and standard use of PICASO. The concrete tasks will be determined based on the development status of the prototype at the time of testing. The focus in trial phase 1 (1st PICASO prototype) will be on the creation of care plans, accessing and sharing patient data using the Clinician Dashboard and its underlying components. In trial phase 2 (2nd PICASO prototype), the focus will move towards the decision support and risk management features. Upon completion of the tasks, participants will evaluate the specific PICASO components that were used to complete the task. Standard methods will be used for the usability evaluation (see 7.7 below). The results will be fed back to the development team who will use the input to modify and improve the prototype.

6.1.2 Software usability – Patient Dashboard

Patients will also be invited to participate in usability tests where they too will be given a set of tasks related to the PICASO home-monitoring solution. Efforts will be made to have a large group of patients participating; however, patient's availability (particularly in the UDUS trial many patients will be actively working) may be a restrictive factor. Patients who are unavailable for laboratory usability tests will still be asked to complete the UEQ at home and provide comments on negative scores on the questionnaire. Thus, a comment field will be added to all statements on UEQ.

6.1.2.1 Baseline data

Baseline data for all of the above will be represented by the results of the initial usability evaluation. The results will be used as a benchmark on which to assess improvements of the updated solution resulting from the final usability tests and evaluation made towards the end of the project/trials.

7 Methods of Data Collection

As evident in the evaluation framework above, a number of different evaluation methods will be used to collect quantitative and qualitative data. The choice of method will very much depend on the focus and purpose of the evaluation activity (what and why). As the main approach is participatory evaluation, the different stakeholder and participants in the PICASO trials will be directly involved in several different evaluation activities. They must be clearly instructed in the method used, the purpose and use of the evaluation and informed consent must be obtained (cf. D3.3 PICASO Ethical Guidelines).

Both quantitative and qualitative research methods, often in combination, will be used to gather data from users in the clinical trials. Generally, quantitative methods are used to collect quantifiable data to assess "how many" and "how often" and it allows you to calculate a score and it gives us a numerical result. Qualitative methods, on the other hand, focus on getting a deeper and more wide-ranging understanding of something, of a phenomenon. The focus is here on "how" and "why" and the data is descriptive and in a narrative format. Using two or more methods to collect data on the same topic, i.e. using different data collection methods and include different types of data samples is in social sciences referred to as triangulation. The main advantage of triangulation is that it can be used to different dimensions of the same phenomenon (Kielmann et al, 2012).

For example, user activity will be measured using a quantitative method logging all user activity on the patient dashboard, including time spent per activity. This type of quantitative data can be used to assess not only how often patients were active but also if they followed the given care plan, e.g. measuring their blood pressure three times a day. But it will not tell us anything about why they either took their blood pressure more than 3 times a day or why they only took it once or not at all (on certain days). Here using a qualitative method such as interviewing the patient can provide a deeper understanding of why.

Different tools will be used to collect data taking into consideration feasibility within the project scope, access to existing data, as well as user needs and availabilities. The latter is particularly important and user involvement in evaluation activities will adhere to the project's ethical principles and ethical guidelines for end-user participation. Ethics will be described in more detail in chapter 8.

The methods and tools are suggestions and could be changed and arranged based on time and resources. They should be decided on in detail by the specific partners involved in the evaluation.

The following will briefly describe the methods that are anticipated.

7.1 Database review

Database review includes a review and statistical analysis of available data and records from local and national clinical and health records, on e.g. number bed admissions for the target patient groups. As such it is a simple extraction of data, some of which, however, will require manual recording for the duration of the PICASO trials. This type of data will have some limitations (as described in section 4) which will be considered in the analysis.

7.2 Questionnaires

The questionnaires that will be used include both recognised standard questionnaires (some may be adapted to fit the context) and specially designed questionnaires. The same questionnaires will be used in both trials (disease specific questionnaires excluded).

Questionnaires will be distributed on paper or as online versions, and in a laboratory (e.g. controlled environment such as the clinic in a PICASO context) or non-laboratory setting as appropriate (subject also to feasibility). For example, due to limitations and consideration of patients' availabilities, it may not always be possible to conduct usability tests in a laboratory setting and this test may therefore also be taken at home, preferably online as this allows for easy distribution and return. In some cases, it may be considered to perform the questionnaire in the form of a telephone interview.

Questionnaires will include precise instructions and the length must be carefully considered; a lengthy questionnaire is a likely deterrent. Specially designed questionnaires will be focused, asking essential questions (to limit length), and the wording, the order, and type of questions will be carefully considered and determined based on specific purpose of the questionnaire.

Tools such as Survey Monkey (https://en.surveymonkey.com/) will be used for online questionnaires.

7.2.1 Disease specific questionnaires

In order to support the evaluation of the health outcome for patients, specific disease related and clinical questionnaires will be used (some filled in by patients at home) such as:

- RADAI[29]
- DAS28[30]
- Well-being ratings[31]

The results from these questionnaires will allow for unique health outcome evaluation for each individual patient in the specific trial. The overall results can be generalised to indicate a common result for all patients in the specific trial.

7.3 Interviews

Interviews will be used to collect qualitative data from trial participants. Interview is a useful method to gain a better understanding of the subject's (interviewee) perspective and experiences, and to support results from other evaluation activities, e.g. observation and monitoring and questionnaires. Interviews are particularly useful to support quantitative evaluation data, adding a contextual and a subjective understanding to the analysis.

The interviews will primarily be semi-structured based on open-ended questions. Semi-structured interviews are characterised by allowing the interviewer to explore the interviewee's answers as these raise new issues, thereby broadening the scope of the interview based specifically on the interviewee's answers. The semi-structured interview has a theme and a set of open interview questions (interview guide) that ideally should invite the interviewee to answer in their own words based on their own experiences and ideas. The interview guides will be developed with a clearly defined evaluation object and purpose, but as a guide the interviewer must be prepared to ask for further information and ask questions (e.g. follow-up questions, probing questions, interpreting questions and specifying questions) that are tailored to the context and issues raised by the interviewees.

Interviews will be conducted face-to-face or by telephone, and the obvious advantages and disadvantage of both forms will be considered in the analysis. The main advantages of face-to-face interviews are that it is much easier to establish rapport with the interviewee, perceive how the interview is going, and gain an overall impression of the interviewee (do they feel comfortable during the interview, are they interested and willing to answer in depth, etc.). Face-to-face interviews are suited for semi-structured interviews. The main disadvantages are related to resources (travel and scheduling appointments) and note-taking or recording can be a disturbing element.

The main advantages of telephone interviews are that it can take place in the comfort of the interviewees home, scheduling is more flexible (no regard for travel time or costs), and note-taking or recording is less disturbing for the interviewee. On the down-side, it is harder to establish rapport and read the situation, and it is more impersonal (more distance could mean less depth of information), making the semi-structured approach more restrained.

Special consideration will be given to the power structures and relations between interviewer and interviewee, particularly in cases where patients are interviewed by clinicians (or clinical representatives). This is likely to be stronger in face-to-face interviews. It is important that the interviewee feels comfortable to relate their honest and real opinions and experiences, and interviews should therefore occur in a relaxed and comfortable environment/context (i.e. should be consistent with the guidelines for obtaining informed consent as described in *D3.3 PICASO Ethical Guidelines*). Interviewees will be provided with a copy of the transcript notes and/analysis for their approval; this helps to ensure that the subject's experiences and perspective have been understood correctly thereby also strengthening the validity of the evaluation data.

[29] Only UDUS trial
[30] Only UDUS trial
[31] Well-being ratings will consist of a single question asked every day (via the Patient Dashboard) throughout the duration of the trial. Applies only to UTV trial.

7.4 Focus group

Focus groups will be used to collect qualitative data in combination with quantitative data (e.g. from questionnaires). Focus groups will have a moderator who will lead the discussion, asking follow-up questions and ensure that the topic(s) at hand are explored from different perspectives. A detailed guide with themes to be explored and trigger questions to spark the discussion will be developed prior to the focus group meeting.

Focus group participants will mainly represent a homogenous group, i.e. clinicians or patients and their informal carers, as the object of evaluation will be related to their specific user experiences. The focus group interviews should have at least five and at most fifteen participants (fifteen would allow for all trial patients in the UDUS trial to participate).

The interaction in the group can be a useful way to collect data on different perspectives on the issue at hand, i.e. participant may express agreement or disagreement of another participant's experiences or opinions thereby either supporting the finding or highlight differences; the basis of such differences could then be explored providing valuable contextual information. The interaction in focus groups may also be particularly suited for collecting qualitative data from vulnerable groups, empowering them by giving them a voice (Kulavuz-Onal 2011).

7.5 Self-reports

Self-reporting is of course highly subjective and builds on trust; trust that the participant reports the truth. Self-reporting will primarily be used to collect data from patients on their adherence to their care plan/medication plan, e.g. patients are asked to confirm via the Patient Dashboard that they have taken their medication as prescribed. It is important to note that self-reporting will not be used to judge or otherwise exercise power over patients, but rather to collect data to see if PICASO can help support adherence and how this may progress over time.

7.5.1 Morisky Medication Adherence Scale

The 8-item Morisky Medication Adherence Scale (MMAS) rank the degree of adherence. The first seven items are Yes/No responses while the last item is a 5-point Likert response. The additional items focus on medication-taking behaviours, especially related to underuse, such as forgetfulness, so barriers to adherence can be identified more clearly. It is one of the most accepted self-report measure for adherence to medication (Lam & Fresco 2015).

7.6 e^{3}value tool

The e^{3}value modelling methodology and tool was developed by Jaap Gordijn (Gordijn, 2002). It is a modelling tool that focuses on value creation; how value is created, by whom and for whom. The e^{3}value ontology is organised in viewpoints where actors exchange objects of value. The value exchange can be analysed in terms of value proposition and profitability.

It is thus foremost a strategic tool with the aim of identifying new business opportunities and how a firm can position itself strategically to derive maximum benefits from new and emerging opportunities, which may or may not require substantial redefinition of the enterprise infrastructure. The methodology will be explained in detail in *D9.7 Integrated Care Economics and Cost-Benefit Analysis*.

7.7 Usability tests

Usability testing will be conducted in order to understand how real users experience PICASO. The usability tests will take place in a controlled environment, i.e. so not part of a normal consultation with a patient or involving real patients. They will be based on a realistic scenario, or situation, wherein the person performs a list of tasks that represent the most common user goals using PICASO while observers watch and take notes. The tests will primarily be done at the participant's location. The methods that will be used to evaluate usability are described below. Usability tests will primarily involve clinicians using the Clinician Dashboard but also patients and informal carer(s) using the Patient Dashboard to the degree it is feasible and deemed useful for formative evaluation. See also section 6.1 above.

7.7.1 Observation

When evaluating usability, it is useful to observe how participants use the system and handle the tasks that have been set. Observation may include observing body language, attitude, skills, errors made, and interest etc. Observation should be as un-intrusive as possible so as not to be a disturbing or discomforting element for participants. The purpose of observation must be made clear to participants, i.e. that it is the system, and not themselves, which is under observation and evaluation.

7.7.2 Thinking Aloud

This methodology is used in usability studies. During the testing session as described above, the test participant is asked to continuously think aloud (verbalize his or her thoughts and keep up a running monologue) as they complete the set tasks. The aim is to understand better why and what obstacles they encounter during achieving these tasks.

This method allows the observer to discover what users really think about the application and its design, learn why users guess wrong about some parts of the User Interface and why they find others easy to use. It is particularly useful in an iterative approach as voiced misconceptions can be turned into actionable redesign recommendations: when users misinterpret design elements, you need to change them.[32] This activity will involve mainly clinicians but also patients and informal carer(s) to the degree that it is feasible.

7.7.3 Post-test interviews

This type of interview will be conducted immediately after the participant has completed a usability test and/or questionnaire. The main purpose is to gain insight and feedback into the participant's immediate experience with using the system, thereby gaining a deeper understanding for the particular scoring given on a questionnaire. This activity nvolve mainly clinicians but also patients and informal carer(s) to the degree it is feasible.

7.7.4 User Experience Questionnaire (UEQ)

The validated UEQ questionnaire is useful for assessing user's experiences of using the product itself. The UEQ consists of 26 items that are associated with 6 distinct quality aspects. It uses the Likert scale for scoring, i.e. respondents must answer to which degree they agree/disagree with each statement.

The UEQ comes with a unique scoring system which allows for an automatic calculation of the scoring by using the provided Excel scoring sheet. It is possible to compare the results with a standard benchmark that allows for conclusions about the relative quality of the evaluated product compared to other products.

7.8 Written comments/feedback

Specially designed comments field added to a questionnaire will allow for qualitative data to be collected. It can be used to determine where and how follow-up would be useful, e.g. during interviews, and/or gather concrete suggestions for improvements/changes related to usability.

[32] https://www.nngroup.com/articles/thinking-aloud-the-1-usability-tool/

8 Ethics

The evaluation in PICASO will follow the ethical guidelines provided in *D3.3 The PICASO Ethical Guidelines* and the protocols in *D8.2 Trial Protocol for RA and Comorbidities Trial in Germany* and *D8.3 Trial Protocol for PD and CVD trials in Italy*.

Patients, their informal carers, and clinicians (see Data Sample in 4.2) represent a valuable group of informants for the evaluation activities planned. Their feedback will be treated confidentially and with respect, and will only be used to evaluate the PICASO project. Personal data will be anonymised in all project evaluation deliverables and external publications, and the handling of personal data will be in compliance with the applicable data protection directives.

The overall PICASO ethical principles (in D3.3) must of course be honoured. More specifically, in the context of evaluation activities with informants, the principles of informed consent, trust, honesty, and reciprocity must be respected.

8.1 Informed Consent

In accordance with the PICASO Ethical Guidelines documented in deliverable D3.3, all patients must have signed an informed consent form prior to their enrolment in the trial. Here they agree to the collection, storage and use of their personal data in connection with the evaluation activities. Patients will be informed of how their data will be used, and they can request access to their personal data collected, stored and used in the project.

All other informants participating in concrete evaluation activities must sign an informed consent form agreeing that their feedback and answers can be used by the project. The informed consent process and form must comply with the guidelines described in D3.3.

8.2 Trust

The gathering of data from informants, particularly qualitative data, is based on a relation of trust between the informant and researcher. Informants' willingness to contribute to the evaluation is largely based on a trust in and assumption of that their contribution will be reflected as accurately as possible, and that they are indeed expected to give their honest opinion which will be respected.

8.3 Honesty

In extension of trust, data must not be manipulated or left out in order to fit a desired result. The analysis of evaluation data must be honest and reflect all relevant perspectives. Sources of data must be clearly stated while keeping informants' identity anonymous.

8.4 Reciprocity

All informants participating in the evaluation activities will be given access to the evaluation results. Formal translation of the entire evaluation analysis and results into the local language is unfortunately out of scope of the project. Informants may instead receive a summary of the main results in local language.

Efforts will be made to accommodate informants' requirements and limitations with respect to their participation in the evaluation activities.

9 Conclusion

Evaluation in WP8 is concerned with trial evaluation; the two PICASO trials will be implemented to test PICASO and provide feedback to the project consortium of the applied technologies in order to evaluate the benefits of integrated care. The PICASO Evaluation Framework set out in this document is concerned with those evaluation activities that involve trial participants/stakeholders, notably clinicians, patients and their informal carers. In fact, as a framework the focus is on setting the overall boundaries for the evaluation while being sufficiently flexible to accommodate and meet the changing shape and needs of the project and the informants who will contribute to the evaluation.

The evaluation framework has identified a planned timeframe of the different activities. The exact timing (month) may shift; the crucial issue is to plan concrete evaluation activities ahead of time and allow for sufficient data to have been generated or sufficient user experience and usage to have been gained before gathering information.

The data analysis will be carried out by UDUS, UTV, INUIT, FIT, and IN-JET and presented in *D8.11 Final Evaluation Report of Early Risk Detection and ICT Based Intervention*.

10 List of Figures and Tables

10.1 Figures

10.2 Tables

11 References

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