A Personalised Integrated Care Platform

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D8.7 Second Trial Progress and Ethical Report

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Index:

1 Executive Summary 4
2 Introduction 5
2.1 Purpose, context and scope of this deliverable 5
2.2 Intellectual Property (IP) 5
2.3 Content and structure of this deliverable 5
3 Trial Progress at UDUS 6
3.1 Current Status 6
3.2 Trial 6
3.2.1 Protocol 6
3.3 Technical issues and data security aspects 7
3.4 Ethical aspects 7
3.4.1 UDUS Ethical Board 7
3.4.2 PICASO Ethical Board 8
3.5 Other trial relevant activities 8
4 Trial Progress at UTV 9
4.1 Current Status 9
4.2 Trial protocol 9
4.3 Data security aspects 10
4.4 Ethical aspects 10
4.5 Other trial relevant activities 10
5 Ethical Status and Progress 11
5.1 Ethical Board Meeting (IN-JET) 11
5.1.1 Trials reporting to the Ethical Board 12
6 Appendix A: PICASO Trial and User Evaluation Meeting Agenda 16 January 2018 13
7 Appendix B: PICASO Ethical Board Meeting Agenda 30 January 2018 14
8 Appendix C: UDUS patient informed consent 15
9 Appendix D: UDUS physician informed consent 34
10 List of Tables 51

1 Executive Summary

This deliverable presents the annual progress of the PICASO trials in Germany (UDUS) and Italy (UTV). The trial protocols are available from D8.2 Trial Protocol for RA and Co-morbidities Trial in Germany and D8.2 Trial Protocol for PD and CVD trials in Italy. In Germany recruitment for the trials started in February 2018. In Italy patient recruitment started in September 2016.

Furthermore, the deliverable gives a brief report of the PICASO Ethical Board's activities in relation to the trials.

2 Introduction

2.1 Purpose, context and scope of this deliverable

This deliverable presents the second annual progress of the PICASO trials in Germany (UDUS) and Italy (UTV). It covers the period from M21 to M32. The trial protocols are available from *D8.2 Trial Protocol for RA and Co-morbidities Trial in Germany* and *D8.3 Trial Protocol for PD and CVD trials in Italy*. In Italy ethical approval of the trial protocol has been achieved and patient recruitment started in September 2016. In Germany ethical approval of the trial protocol has also been achieved and the trial started in February 2018.

Furthermore, the deliverable gives a status report on local ethical issues, i.e. in relation to the trials' progress and current status. A deeper analysis of the ethical issues relevant to the trials and the project as a whole is presented in the deliverable *D3.4 Ethical Analysis of Monitoring and Privacy Impact*. In addition, adherence to the Ethical Guidelines (in D3.3) will be assessed in the internal deliverables Annual Compliance Monitoring Reports.

2.2 Intellectual Property (IP)

At UDUS new IP was identified: One of the evaluation questionnaires that will be used in in PICASO (in a modified version) previously have been used by UDUS in a different project. In conformity with the contract project permission to use the questionnaires has been obtained. UDUS aims to include this IP into the grant agreement. The project management was informed in 2017.

Furthermore, intellectual property was identified in regard to the technical component developments and have been added to an IPR list of the consortium.

No other new intellectual property was identified.

2.3 Content and structure of this deliverable

Chapters Three and Four present a progress report of the UDUS and UTV trial respectively. These chapters provide an insight into all the work involved in setting up and deploying the trials.

3 Trial Progress at UDUS

Trial 1 is carried by PICASO partner UDUS (Policlinic of Rheumatology and Hiller Research Unit Rheumatology) and will involve patients above the age of 18 years with Rheumatoid Arthritis (RA) and any Cardiovascular Disease as co-morbidity. For UDUS this deliverable intends to give an overview of the status and implementation of the trials.

UDUS meets in person on a bi-weekly basis and are co-chaired by the Head of the Department and the PICAOS Clinical Manager. During the meetings the research team discusses upcoming topics and determines the further procedures. Additionally, the team monitors the progress against project milestones and budget. Contact to UDUS IT is performed as necessary and within the above-mentioned meetings.

3.1 Current Status

The Trial protocol D8.2 *Trial Protocol for RA and Co-morbidities Trial in German* and all necessary material was submitted to the UDUS specific local committee "Kommission Klinische Studien" in October 2017, positive vote was achieved in November 2017.

The UDUS PICASO trials were registered to register of clinical trials at the Medical Faculty, Heinrich-Heine-University Duesseldorf on 5th October 2017

The UDUS PICASO trials were registered to the German Clinical Trials Register (DRKS) - www.drks.de. After initial submission on 4th January 2018 after one iteration process, final registration was achieved on 17th January 2018.

Home monitoring devices were bought from UDUS. To have devices at hand in case they get broken 20 Tablets (Samsung Galaxy Tab A 10.1 16 GB black, model number: SM-T585), 20 scales (http://www.andonline.com/medical/products/details.php?catname=&product_num=UC-351PBT-Ci), 20 blood pressure devices (http://www.andonline.com/medical/products/details.php?catname=&product_num= UA-767PBT-Ci), and 20 FITBIT2 (small and large sizes) were bought. 15 SIM Cards were contracted with Telekom Germany (6 GB, LTE standard), a comparative offer was obtained from Vodafone Germany in two face-to-face meetings at Vodafone Germany, Duesseldorf. The devices were set-up together with FIT on 18th May 2018. A mobile phone and SIM card was ordered for the UDUS PICASO clinical team to be available on request during business hours. Due

For trial recruitment regular queries to the local patient documentation system were and are performed to identify potential patients, additional hand research in patients charts for eligibility was and is performed. Trial recruitment started in February 2018. Currently n=28 RA patients agreed to participate.

3.2 Trial

3.2.1 Protocol

The trial protocol that is available from the deliverable *D8.2 Trial Protocol for RA and Co-morbidities Trial in Germany* reached ethical approval on 13th December 2017. Patients' recruitment and initial training processes were defined more closely. This included inclusion and exclusion criteria, education material as well as the monitoring protocol. In addition, the trial execution time tables were adjusted as required in collaboration with the technical PICASO partners.

Shortening of the trial length from 9 to 6 months was consented with all PICASO partners as no relevant additional information is expected from longer proof-of-concept trials:

- The main reasons for trial shortening were:
    - Delay of component and prototype development and resulting time schedule constraints
    - Impact on trial protocol, data security protection officer, submission to ethical committee at Medical Faculty and the UDUS local administrative processes
- Importance of keeping two trials running
    - Higher number of patients anticipated delivering experiences

- Higher number of UDUS external participants anticipated delivering experiences and proof-of-concept data
- Prototype optimization based on experiences from first UDUS evaluations in trial 1.

Patient information and the informed consent forms were updated according to ethical requirement, for current versions translated with DeepL see Appendix C.

The evaluation framework including was finalized and the corresponding deliverable D8.6. Evaluation framework was submitted in September 2017. On 16th January 2018 a meeting on patient empowerment (related task T3.5 Patient Empowerment) and evaluation aspects (T8.5 Trials Evaluation) took place at UTV in Rome. The workshop agenda is available from Appendix B.

According to the results of the workshop and the reviewer feedback from the review meeting in Brussels in February 2018 UDUS trial evaluation processes were aligned as much as possible to UTV trial. Developed questionnaires were shared among each other's. Thus, the performance of PICASO will be assessed by detailed questionnaires administered to patients and statistical analyses of differences of number of (re-)visits or access to hospital. Detailed questionnaires will be administered to UDUS physicians in order to evaluate the impact of PICASO.

3.3 Technical issues and data security aspects

For setting up the IT infrastructure and thus for trial implementation a close adjustment process with the UDUS IT and the IT personal of the Policlinic of Rheumatology and Hiller Research Unit Rheumatology was necessary and is still ongoing. This does not only apply to the local clinical and technical partners. Also the close interaction of the local IT partners and the PICASO technical partners was and is still necessary. The ODS solution is still developed in cooperation with the PICASO partners. The ODS will hold the data extracted from the clinical system that has been made available to the PICASO solution and will be fed by the HIS (hospital information system) at UDUS and the Rheumatology specific patient documentation system (DocuMed.rh) at UDUS. The ODS interacts with the other PICASO infrastructure.

The ODS design was developed in close collaboration of UDUS IT and IT personal of the Policlinic of Rheumatology and Hiller Research Unit Rheumatology and the technical partners predominantly CNET and INUIT.

To ensure maximum data safety, we have been in constant exchange with the responsible data security officer at UDUS.

The "Privacy and Data Protection Agreement" document was agreed upon with all PICASO consortium members in an iterative approach. This needed administrative work at UDUS legal department. To release the document the UDUS legal department needed approval from the UDUS local data protection officer. As at UDUS the local data protection officer changed with date 01.01.2018 interaction of UDUS PICASO team with the local data protection officer was necessary. According to new internal regulations a document including specific questions on data security needed to be filled in. To complete the pre-defined document collaboration was necessary with UDUS IT and the technical partners from the PICASO consortium. The document is available from UDUS PICASO team but due to the status "public" of this deliverable not available as an Appendix. After initial submission minor issues needed to be clarified and positive vote was achieved on 17th May 2018. The first version of the "Privacy and Data Protection Agreement" was released from the legal department on 29th May 2018 and signed from the UDUS chancellor on 4th June 2018. An updated version was signed from the UDUS chancellor on 2nd August 2018.

3.4 Ethical aspects

3.4.1 UDUS Ethical Board

Informed consent is an important component of PICASO project and especially of UDUS. Most of the patients that will be recruited have been treated by the UDUS over several years. This intimate care process forms a good basis for achieving informed consent.

Positive ethical approval from the ethics committee at Medical Faculty Heinrich-Heine-University Duesseldorf has been obtained by 18th December 2017.

However, during the trial phase the ethics committee gave more attention to General Data Protection Regulations (GDPR) and existing and forthcoming patients' informed consents. On 23rd May 2018 the ethics committee at Medical Faculty Heinrich-Heine-University Duesseldorf published new text modules, which must

be part of the consents. This holds true for already existing informed consents and recruited patients but had also implications on the patient information and informed consent for newly to recruit patients. Thus the existing patient and physician information as well as the corresponding informed consents needed to be updated again.

Also, the consortium identified that the patient and physician information as well as the corresponding informed consents needed updates as they did not hold the necessary data processor information of the technical partners. The text was consented between FIT and VUB in a bilateral process and then provided to the clinical partners.

After the necessary text modules had been put into place and the text modules that needed to be adapted to the PICASO requirements the various documents were submitted to the ethics committee at Medical Faculty Heinrich-Heine-University Duesseldorf on 18th July 2018, ethical approval was obtained on 20th August 2018.

In contrast to UDUS initial information from the ethics committee at Medical Faculty Heinrich-Heine-University Duesseldorf, UDUS needed to obtain insurance coverage. In collaboration with the administrative department a patient insurance and a travelling, accident insurance was taken out that covers patients and informal carers. The updated documents are provided in Appendix C.

No other local ethical aspects were yet identified.

3.4.2 PICASO Ethical Board

UDUS attended the PICASO ethical board meetings that included external board members in in January 2018 (Bonn). For further progress notes see Chapter 5 of this deliverable and Deliverable *D3.4 Ethical Analysis of Monitoring and Privacy Impact Assessmen*t and the internal deliverable *D3.7 Annual Compliance Monitoring Report.*

3.5 Other trial relevant activities

We collaborate with a German statutory health insurance. The established contact is still networked for the dissemination of PICASO. Further collaboration was declared.

Integration of the CHS (Centre of Health Society) at UDUS in the trials at UDUS is warranted. Personal communications with The Institute of General Medicine were performed for recruitment of collaboration CHS physicians. Relevant integration steps and prerequisites for participation need to be explored further and are planned for autumn 2018.

In addition, an information letter was developed for the general practitioners of the participating PICASO patients. It informs them on the project and is sent with the physician information and informed consent that was developed as well.

In 2018 a new collaboration was established with the Institute of General Practice and Family Medicine at Ruhr-Universität Bochum (RUB), a first meeting took place on July 4th 2018.

On 13th June 2018 PICASO project and UDUS trials were presented at the Annual Meeting of the European League against Rheumatism (EULAR) Meeting in Amsterdam (Netherlands) in a PARE (People with Arthritis and Rheumatism) Session on digital health titled “E-health for better care”.

PICASO was presented in the “Rheumahaus” (a special booth from the German Society of Rheumatology) at the Annual Meeting of the German Society for Rheumatology in Mannheim (Germany) (19th-22nd September 2018) in collaboration with FIT, CNET and IN-JET.

Further dissemination activities are available from deliverable *D1.7 Second Interim Progress Report*.

4 Trial Progress at UTV

Preparatory work for trial 2 required the conjunction of data derived from the experience of several professional figures involved in the management of patients with the Parkinson disease (PD) and co-morbidities. In particular, since the number of patients that may show the clinical characteristics mentioned in the previous paragraph is relatively high, the efforts of the clinical, medical and paramedical personnel involved in the trial was aimed to a) identify in detail the prototype of the patients to be enrolled in the study; and b) identify the main operational and technical aspects and scenarios where trial implementation could introduce the most significant benefits.

A retrospective analysis of clinical records was performed in order to identify those crucial points that may represent a good substrate for clinical implementation of Trial 2 for both patients and physicians. For example, the lack of seamless communication between physicians represents one of the major problems when the coordination of the activities between two hospitals is required, leading to inefficient and time consuming procedures for physicians and frustration for the patients who await agreements between doctors. Patients with PD and autonomic dysfunction or mood disorder represent the optimal prototype, grouping the main limitations of clinical management/aspects mentioned above.

SLUCIA and UNITOV meet in person or via teleconference on a bi-weekly basis and are chaired by the Project Manager or the Clinical Trial Coordinator. During the meetings, the two research teams also monitor progress against project milestones. An internal review for the evaluation of the progress of the trial is scheduled monthly.

Trial 2 is in progress and is being carried out in the Department of Biomedicine and Prevention, University of Rome Tor Vergata (UNITOV, PICASO Partner) in conjunction with the Department of Neurology and Psychiatry of the Santa Lucia Hospital (SLUCIA) in Rome. The trial is based on the recruitment of subjects affected by PD and at least one of the following pathologies as comorbidities: cardiovascular disease (i.e. hypertensive diseases, congestive heart failure) and/or psychiatric condition as depression or anxiety. At the time of writing, 20 subjects have been enrolled in the “standard arm” while 9 have been enrolled in the “experimental arm”. For additional details please check *D8.3 Trial Protocol for PD and CVD trials in Italy*. This chapter presented a progress report to date.

4.1 Current Status

At the time of writing, 20 subjects have been enrolled in the “standard arm” while 9 have been enrolled in the “experimental arm”. For additional details please check *D8.3 Trial Protocol for PD and CVD trials in Italy*.

Clinical data including blood tests, imaging data, clinical history, medications and other relevant medical parameters have been collected for both patients included in the experimental arm. As for standard arm, clinical data have been collected and served only for patient’s selection during the recruitment phase.

The end of recruitment phase is expected to finish in September.

4.2 Trial protocol

The trial protocol is largely presented in deliverable *D8.3 Trial Protocol for PD and CVD trials in Italy*. In brief, case studies are divided in two arms: 1) the standard arm (the patient will be followed as in current clinical practice) and 2) the experimental arm (the patient management based on electronic information sharing and monitoring vital signs with electronic devices). At the end of the recruitment 20 patients will be enrolled in the standard arm, and 10 patients in the experimental arm. Informal carers with their crucial role in supporting the patient in managing and living with their condition(s) and in caring for the patient at home are involved in the trial as well. A detailed statistical comparison of data extrapolated from both standard and experimental arm will serve for an objective assessment of Trial 2 outcomes.

The performance of PICASO on Trial 2 will be assessed a) by means of detailed questionnaires administered to both patients and their caregivers (see annex 2) and b) a statistical analysis of differences between number of re-visits or access to hospital. Lastly, a detailed questionnaire will be administered to physicians in order to evaluate the impact of PICASO on workflow.

4.3 Data security aspects

Establishing an appropriate Governance model for managing such a complex project is critical in order to comply with the requirements of the National and European Statement on Ethical Conduct in Human Research (LEGGE 6 aprile 2007, n. 46; LEGGE 6 agosto 2013, n. 96; LEGGE 6 agosto 2013, n. 97).

Moreover, the following Italian laws should be respected:

Decreto Legistativo n.196 del 30/06/2003; Linee guida per i trattamenti di dati personali nell'ambito delle sperimentazioni cliniche di medicinali adottate dal Garante per la Protezione dei dati personali in data 24/07/2008 (G.U. n.190 del 14/08/2008)

Autorizzazione n. 8/2014; Autorizzazione generale al trattamento dei dati genetici - 11 dicembre 2014

Autorizzazione n. 9/2014; Autorizzazione generale al trattamento dei dati personali effettuato per scopi di ricerca scientifica - 11 dicembre 2014.

The requirements listed above represent the background of several talks/discussions and meetings between information technologists (IT) of UTV and SLUCIA. Moreover, the main administrative representative of each hospital were informed of the decisions of each meeting both formally and informally. In collaboration and through workshops with IBM and INUIT, the Clinician Dashboard and clinical data requirements both for UTV and SLUCIA were defined. The requirements listed above represent the background of several discussions and meetings between information technologists (IT) of UTV and SLUCIA. Moreover, the main administrative representatives of each hospital were informed of the decisions of each meeting both formally and informally.

Finally, the intensive cooperation with PICASO partner INUIT led to the definition of the IT requirements mentioned above in conjunction with other technical requirements by other partners: certificates, static IPs, ssh, http, https, outgoing connections to specific IPs and specified domains, incoming connections from a specific IP and specified domains as well as connections from any IP.

4.4 Ethical aspects

Following the granting of funds in February 2016, ethics approval was sought and granted by the Local UTV Ethics Committee on July 2016 (registro sperimentazioni 158/16). After an internal meeting held in SLUCIA on September 2016, a representative of both UTV and SLUCIA in this project decided to perform a formal submission of Trial 2 to SLUCIA Ethics Committee. The Trial 2 was approved on November 2016.

UTV attended the PICASO ethical board meeting that included external board members in January 2018. Observations and comments were reported and then discussed internally between UTV and SLUCIA. Moreover, an informal meeting between UTV partner representative Dr. Agostino Chiaravalloti and ethics committee representative Dott.ssa Alessandra Nistri was held in UTV on February 2017.

The UTV informed consent form is available in Appendix C.

4.5 Other trial relevant activities

PICASO project was presented on 10th April 2018 in Rome, Italy at Rome Startup Week EU and HealthTech. Presentation was held by Agostino Chiaravalloti, University of Rome Tor Vergata. And on 2-5 March 2017 in Rimini, Italy at AIMN 13th National Congress of the Italian Association of Nuclear Medicine and Molecular Imaging.

5 Ethical Status and Progress

The PICASO Ethical Board has a special interest in the status and progress of the two trials in the project. As defined in the Ethical Board's Term of Reference (please see D3.3 The PICASO Ethical Guidelines), the board "acts as an advisor" to project partners and patients involved in the trials.

The Ethical Board met on 30th January 2018 at FIT in St. Augustin/Bonn, Germany. A summary of the discussion is provided below.

5.1 Ethical Board Meeting (IN-JET)

The PICASO Ethical Board met on 30 January 2018 at Fraunhofer Institute. The trials had not yet begun at the time and the trial owners had therefore no ethical issues directly related to the running of the trials to report. The meeting focused on perceived challenges and potential ethical problems, the implementation of the PICASO Ethical Checklist, and a demonstration of the PICASO Patient Dashboard and Clinician Dashboard.

The demonstration allowed the external board members to get a better insight into the solution, it's functionalities and user interface, and several concrete suggestions for improvement of the latter was discussed to make the user interface and design more coherent and intuitive. For example, some changes to the icons used in the Patient Dashboard were made and have since been implemented.

Security aspects were also discussed and the access and authorisation structures were described to the board. Finally, the content of the first Annual Compliance Monitoring (ID3.7) was presented to the board and the Ethical Checklist discussed. Some rephrasing or slight refinement of specific items in the checklist was suggested based on the new knowledge gained of the trials and trial design, see below.

Table 1: Refinement of selected items in the Ethical Checklist

Item	Original version	Updated version
3	Participants have had the opportunity to rethink if they want to participate or not and were given a week to decide; thus, they did not have to sign the informed consent form immediately.	Participants were offered to take some time to consider whether or not they wanted to participate before making any decision.
4	Participants have been informed that participation in the trial does not replace existing and usual treatment.	Participants have been informed that participation in the trial does not replace existing and usual treatment (usual care would still be ongoing).
5	The trial's informed consent form included all the issues that were identified in D3.3 The PICASO Ethical Guidelines (Chapter 5.5.1 and 5.5.4)	The information given to participant included points identified in *D3.3 The PICASO Ethical Guidelines*.
6	The informed consent process defined in D3.3 The PICASO Ethical Guidelines (Chapter 4.5) has been followed and copies of all participants' signed informed consent forms have been forwarded to the PICASO Ethical Manager.	The informed consent process defined in D3.3 The PICASO Ethical Guidelines (Chapter 4.5) has been followed and copies of all signed informed consent forms are stored with the trial owner.
16	Participants' needs and requirements have been defined and used to guide the selection of technologies/devices as usability is a priority.	Usability requirements have been considered in the design and development of the solution.
20	Participants have been given detailed information on all aspects related to the handling of personal data in the trial and the project.	Participants have been given detailed information on the main aspects related to the handling of personal data in the trial and the project, including

		compliance with the applicable legal framework concerning data protection and privacy.
21	Participants have been enabled to exercise flexible and granular data access.	Participants have been informed that access to their data is subject to their consent.
24	If any Clinical Incidental Findings have been discovered, the trial owner has verified the PICASO platform and data accuracy in cooperation with PICASO technical partners.	If any Clinical Incidental Findings are discovered, the trial owner will first verify the accuracy of the data collected by PICASO before taking further action.
25	If any Clinical Incidental Findings have been discovered, the trial has followed their institution's standards clinical procedures for dealing with these and for informing the patient in question.	If any Clinical Incidental Findings are discovered, the trial will follow their institution's standards clinical procedures for dealing with these and for informing the patient in question.

5.1.1 Trials reporting to the Ethical Board

The PICASO trial owners have not reported any ethical problems specifically related to the running of the trials, nor problems reported by patients, informal carer or formal carers, to the PICASO Ethical board to date. The first Annual Compliance Monitoring Report (ID3.7) reported a compliance with the project ethical guidelines (the checklist shows confirmation of compliance) and the report was approved by the PICASO Ethical Board with comments.

6 Appendix A: PICASO Trial and User Evaluation Meeting Agenda 16 January 2018

Meeting Subject:	Trial and User Evaluation
Venue:	Sala Riunioni, Presidenza Facoltà di Medicina e Chirurgia, Università Tor Vergata Via Montpellier 1, 00133, Roma, Italy
Date:	16th January 2018
Chair:	Agostino Chiaravallotti
Distribution:	UTV. UDUS, INUIT, FIT, IN-JET

Time	Subject	Topics to be covered	Time (mins)	Participants
8:45-9:00	**Welcome**	Arrival and coffee	15	ALL
9:009:00		**Evaluation of PICASO Health Outcome and Efficiency gains** • Reduction of admissions, bed days, visits to General Practice; enhanced interactions with care providers: which type of data should be provided? • QoL and improvement of physical well-beings; patient adherence to care plans: collective evaluation of the data collection modalities	4 h	UTV INUIT FIT IN-JET UDUS
13:009	**Lunch**		60	
14:0011:00		**User evaluation of PICASO platform** • Evaluation of Clinician Dashboard: clinician perspective • Evaluation of Patient Dashboard: patient and informal carer perspective • Usability Tests for Patient and Clinician Dashboard • Publication Requirements (see * section for additional details)	2.30h	UTV INUIT FIT IN-JET UDUS
16:30-17:00	**Other issues - Close of meeting**			

7 Appendix B: PICASO Ethical Board Meeting Agenda 30 January 2018

Meeting Subject:	PICASO Ethical Board Meeting
Venue:	Fraunhofer Institute for Applied Information Technology (FIT), Schloss Birlinghoven, 53754 Sankt Augustin (close to Bonn)
Room:	C5-033
Date:	30 January 2018
Chair:	Trine F. Sørensen (IN-JET)
Distribution:	The PICASO Ethical Board. CC to consortium partners

Time	Subject	Topics to be covered	Time (mins)	Lead participant
13:00	**Welcome & Status update**	**Progress and current status** • Objectives of today • Overview of project status • Results from the review	15	Trine F. Sørensen (IN-JET)
13:15	**Trial 1: Cardio Vascular Disease (CVD) with Rheumatoid Arthritis (RA)**	**Trial 1 status update** • Trial definition and implementation plan • Recruitment & informed consent issues • Ethics committee approval status.	15	Jutta Richter (UDUS)
13:30	**Trial 2: Parkinson's Disease (PD) with Cardio Vascular Disease (CVD)**	**Trial 2 update** • Trial definition and implementation plan • Recruitment & informed consent issues • Ethics committee approval status.	15	Agostino Chiaravalloti (UTV)
13:45	**Discussion**	**Discussion** • Ethical issues to be investigated / resolved.	60	All
14:45	**Coffee break**		15	
15:00	**Discussion**	**Discussion** • Ethical issues to be investigated / resolved	45	All
15:45	**Concluding remarks**	**Next Steps** • Upcoming deliverable: D8.5 First Annual Trial Progress and Ethical Report (due 31 January 2017)	15	Trine F. Sørensen (IN-JET)
16:00	**Close of meeting**			

8 Appendix C: UDUS patient informed consent

Policlinic, Functional Unit & Hiller Research Center for Rheumatology
University Clinic Duesseldorf, Medical Faculty, Heinrich-Heine-University Duesseldorf
Director Professor Dr. med. M. Schneider, MD

Patient information and consent to the project

-PICASO-[1]

An individualized, patient-oriented platform for improved care of patients with

rheumatoid arthritis

Version 1.3 – Status 16.07.2018

Dear Patient,

Because of your rheumatoid arthritis (RA), you receive continuous care at the Policlinic for Rheumatology. In the following we present a project of the clinic, which should offer you and everyone involved in your treatment an improved individual care in the long run. We look forward to your participation in our project.

As a patient of the Rheumatology Outpatient Clinic at the University Clinic Duesseldorf, you are already familiar with our DocuMed.rh patient documentation system, which has been in use for many years. With the help of this system and with the help of our hospital information system, we record important medical data in our routine care with your support. It enables us to assess your state of health during the outpatient visits in our clinic. Now we would like to know more about your well being during the time between the performances at our clinic. This knowledge should help us to assess your state of health better and to be able to intervene at an early stage if it deteriorates.

Therefore, the University Clinic Duesseldorf, the Fraunhofer Institute for Applied Information Technology (FIT) in Bonn and other international partners are working together within the framework of an EU-funded project called PICASO (A Personalised Integrated Care Approach for Service Organisations and Care Models for Patients with Multi-Morbidity and Chronic Conditions).

As part of this project, we have developed a platform, the so-called PICASO platform. It enables us to merge data collected from you or your treating physicians. Then this data can be made available to all responsible parties involved. You grant the authorizations for this. This way the platform is intended to support more efficient cooperation between all those involved in your treatment. We would like to test and advance the PICASO platform together with you and your treating physicians.

[1] A Personalised Integrated Care Approach for Service Organisations and Care Models for Patients with Multi-Morbidity and Chronic Conditions, www.picaso-project.eu

The following text explains the goals and the course of our project. Please read it carefully. We will then have an informative discussion with you. Please do not hesitate to address all points that are unclear to you. You will then be given enough time to think about your participation.

1. Why is this project being carried out?

As you know, rheumatoid arthritis (RA) is a chronic inflammatory systemic disease that affects approximately 800,000 people just in Germany. The therapy and management of RA represents a great challenge for your treating rheumatologists as well as for you as a patient. Above all, cooperation and communication between doctors and patients are essential for efficient care and successful treatment. We therefore want to further optimize your medical care by obtaining information about your state of health between your regular outpatient appointments, providing you with an up-to-date treatment plan and sharing it with all persons authorized by you.

In the course of RA, co-morbidities often occur, making treatment even more complex and demanding. In your case, this is a disease of the cardiovascular system. Since RA and cardiovascular disease and their therapies can influence each other, it is crucial to adequately adjust the therapy and monitor both diseases. Rheumatologists, general practitioners, cardiologists, physiotherapists and many others are involved in the treatment of RA and its accompanying cardiovascular disease. The information transfer between these actors of the health care system is often incomplete, so that overlaps in diagnostics and failures in therapy can occur. The PICASO platform is intended to facilitate and thus improve this information transfer.

In addition, we want to find out how the collection of health data in your home environment and the use of the PICASO platform can contribute to assessing your state of health, registering deteriorations and optimizing your care. Through the collection of relevant data and the always up-to-date provision of your treatment plan, you will be actively involved in your treatment process and receive direct feedback via the PICASO platform on your physical activity, your disease activity and the tasks you have to perform for your illnesses (e.g. taking your medication, information on necessary doctor appointments, etc.).

The information and communication technologies used in the course of the PICASO project should enable you and your attending physicians to work together efficiently in order to maintain and improve your health and quality of life despite your chronic illness. One of the aims of the project is to adapt the information and communication technologies used to your requirements and needs and to evaluate their manageability in everyday life with the help of questionnaires. Therefore, we would like to test the usability and feasibility of the PICASO platform together with you, your family doctors and, if necessary, other doctors treating you.

What does the PICASO platform offer you?

You receive:

- a personal, secure profile on the PICASO platform.
- Your always up-to-date medication plan including a reminder function in case you missed your medication.
- Your always up-to-date further treatment plan (upcoming and to be arranged doctor appointments, physiotherapy, etc.).
- The possibility of regular documentation
    - Your weight,

- Your blood pressure,
- Your physical activity (with the help of an activity meter),
- your disease activity and functional limitations (with the help of questionnaires).

- A clear presentation of the documented health data in tables and slides (description of the devices see 2. "How is the project run and what do I have to consider when participating?").
- Setting individual goals for your physical activity.
- Feedback to help you achieve your individual goals.
- A reminder function for upcoming visits to the doctor.
- A list of health services provided.
- A list of the check-ups you consider necessary.

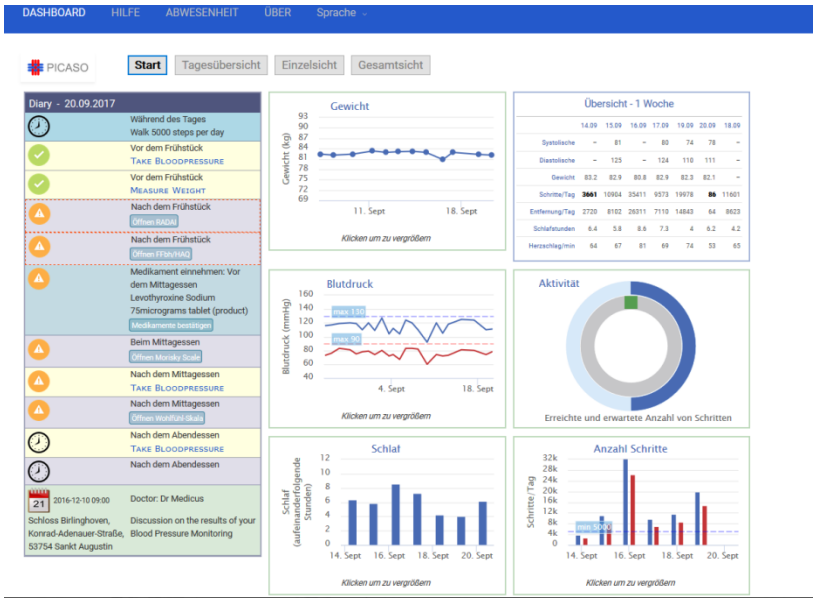

Figure 1: My PICASO

Figure 1 shows an example of what your personal PICASO platform can look like. Your health data is clearly presented in the form of tables and diagrams.

2. How is the project run and what do I have to consider when participating?

30 patients with rheumatoid arthritis and an accompanying cardiovascular disease will be invited to participate in the PICASO project over a period of six months and share their experiences with us. Each participating patient receives a project-specific patient number under which all health data and questionnaires collected during the project are combined (see paragraph 12 "What happens to my data" p. 8).

For the use of the PICASO platform you will receive individual access data at the beginning of the project in order to access your data within your personal platform. An Internet connection is required to use the platform. We will make this available to you free of charge as part of the project. We will hand-over a tablet (Samsung Galaxy Tab A 10.1" (2016) LTE (16 GB)) with integrated SIM card (see paragraph 13 "Notes on using

the tablet and the Internet connection" p. 10), which you must return to us at the end of your project participation (i.e. after approx. 6 months).

To record your health data, we provide you with an activity meter for recording your step count, your heart rate and your sleeping habits, a scale and a blood pressure monitor, which you will confirm to us:

- Activity meter (Fitbit, Fitbit Charge 2)
- Balance (A&D, UC-352 BLE 200kg)
- Blood pressure monitor (A&D, UA-651 BLE)

We want you to

- always carry the activity meter with you,
- record your weight once a day, at best soberly in the morning,
- measure your blood pressure three times a day sitting and at rest, e.g. in the morning, at noon and in the evening.

Together with your attending physician, you can agree on different individual measurement frequencies.
The data transfer from scale and blood pressure monitor to the tablet is wireless via a Bluetooth connection, so that the measured health data is automatically sent to the tablet. You can then decide individually whether the measurement you have just taken should be repeated or released for dispatch to the PICASO database at University Clinic Duesseldorf. If you release the measured health data, they will become visible in the graphics and tables on your PICASO platform. If you are near the tablet and the tablet is switched on, the health data of the activity meter are also continuously synchronised via Bluetooth with the Fitbit app on your tablet and in the so-called Fitbit database, then also forwarded to the PICASO database at the University Clinic Duesseldorf and made accessible via the platform (see paragraph 12 "What happens to my data" p. 8).

In order to ensure that everything works at your home, we offer the installation of the required devices at your site. After installing the platform and handing over the devices, you will receive verbal instruction on the correct use of the devices and the platform on a device at the University Clinic Duesseldorf, as well as written documentation and instructions for use of the devices in German.

The devices made available to you are commercially available devices. However, please read the instructions for use carefully before using the devices. We do not assume any warranty for the devices. However, if a device shows improper behavior, please contact us (see paragraph 14 "Who should I contact if I have further questions?" p. 10). It will then be replaced as quickly as possible by members of the PICASO project team.

The PICASO platform offers you the possibility to fill out the already known functional questionnaire Hannover (FFbH), the Rheumatoid Arthritis Disease Activity Index (RADAI), and the Morisky Questionnaire. We ask you to complete the FFbH and the RADAI once a week, if possible on the same day of the week, as part of the project. The Morisky questionnaire (a questionnaire on how easy it is for you to take your medication regularly) is completed three times (at the beginning, after three and six months). An appropriate reminder function for when you should complete the questionnaires is integrated into the platform.

The information you provide is visible in a doctor-specific view of the PICASO platform. Only persons, such as the medical staff of Policlinic of Rheumatology and Hiller Research Unit Rheumatology
University Clinic Duesseldorf, Medical Faculty, Heinrich-Heine-University Duesseldorf, who you have authorised to access your data, have access to it. In the next project step this can be your general practitioner

and/or your cardiologist. In order to be allowed to contact them and include them in the project, we need your consent. If your general practitioner does not agree, you can still participate in the project.

Your personal treatment plan as well as your medication plan are visible to you in your patient view and can be modified by your attending physicians via the physician-specific view. Once you have measured the health data and taken your medication, you can confirm this on the PICASO platform. If this confirmation does not take place, reminder functions will be activated to inform you about measuring health data or taking medication.

You will receive your routine appointments in our outpatient clinic 3 and 6 months after the start of your participation. During these visits, the normal routine medical examination takes place, which is documented as before by our DocuMed.rh system and the HIS. You will fill in the FFbH, the RADAI and the pain scales as usual. At this appointment your doctor will view the data collected in the meantime on the PICASO platform and include it in his overall assessment.

In order to assess the usability and manageability of the platform, you will receive standardized, paper-based questionnaires at the appointments in our outpatient clinic, which you return to us directly on the day of the presentation. To enable us to better classify these data, you will be asked about your previous knowledge of information technology at the beginning of the project by means of a paper questionnaire. We may also make some questionnaires available to you online; your personal data will then also be secure. Furthermore, at the end of the project we ask you to personally exchange your experiences with the international PICASO team and other participants.

If you contact us outside of the scheduled outpatient visits, the PICASO project team will document this contact using your project-specific patient number in order to be able to evaluate questions and problems of all patients around the platform in a standardized way.

If you have any questions or technical problems, PICASO team members can be contacted by telephone on weekdays (see paragraph 14 "Who should I contact if I have further questions?" p. 10).

3. What commitments do I agree to when I participate?

If you accompany us within this project, that means for you:

- To participate in this project for six months.
- To install the PICASO platform at your home before the start of the project, possibly with the support of members of the PICASO project team.
- Weigh yourself every day, measure your blood pressure three times a day and wear an activity meter every day to determine your physical activity.
- Regularly use the PICASO platform with your integrated questionnaires on disease activity and functional limitations as intended.
- Perform your normal routine appointments in the rheumatology outpatient clinic.
- Fill in a questionnaire about your experience with information technologies.
- To evaluate the PICASO platform by means of questionnaires at different times.
- To exchange your experiences with the platform in personal discussions with national and international PICASO employees.

- If you are not able to interact independently with the platform, you can assign a trusted person to take over the function.

4. What personal benefit do I have from participating in the project?

In the following six months, you will receive more intensive care compared to our routine care. If the consolidation of your treatment data and the determination of health data in your home environment make it possible to better assess your state of health and register deteriorations, your care could be more individual and more contemporary in the future.

With the help of the health data collected between your regular outpatient appointments, you may be able to anticipate questions from your rheumatologist and answer the extent of functional limitations more precisely. If you have not taken a drug once, the PICASO platform may support you to explain why you did not take it.

In addition, on the basis of your data available in the PICASO database, the platform calculates a standardized, but so far little used value that gives us information about your personal cardiovascular risk, which may change during the six-month project phase. Based on this value, further cardiological diagnostics may be useful. This diagnosis represents a medical standard and should protect you from undesired events. The calculated value is displayed to the attending physician in the physician view and stored in the PICASO database. Your medical data needed for this calculation of your personal cardiovascular risk is only pseudonymized and temporarily transmitted to a special functional unit in the PICASO platform. If they are no longer needed for the calculation of your risk value, these data are deleted there.

The experiences resulting from the project will lead to improvements in the interaction and exchange of data between patients and different physicians. You and later other patients, practices/clinics and the health care system in Germany will benefit from these developments. They will have at their disposal a modern opportunity for interaction with their physicians.

5. What are the risks associated with participating in the project?

One risk could be an incorrect recording and/or summary of your health data, which could lead to incorrect information for doctors. In addition, the use of the platform can lead not only to misinformation of the physicians but also to their own misinformation. If you notice any differences between the medications communicated during the outpatient visit and the medications listed in the Patient Dashboard, please contact us by telephone. In addition, malfunctions within the PICASO platform can lead to incorrect documentation of your health data. It is precisely these malfunctions that we hope to be able to detect with your help. In order to minimize these risks, we collect your data as usual at the time of the outpatient presentation.

The significance of high or low blood pressure values can unsettle you. A person's blood pressure fluctuates significantly on a daily and seasonal basis. Depending on the condition, it can fluctuate by up to 30 to 50 mmHg during the day. In people with a tendency to high blood pressure, the fluctuations can be even greater. Normally, blood pressure rises during work or leisure activities and drops to its lowest level during sleep. Therefore, do not let the results of a single measurement worry you. Take measurements at the same time each day to get your normal blood pressure. Regular readings give a more complete picture of the blood pressure situation. Contact your family doctor to assess your blood pressure data.

Beyond that there are no risks with the participation.

6. What should I do in an emergency?

Outside normal practice opening hours, you can contact the medical emergency service or an emergency outpatient clinic of a hospital as usual in the event of complaints. Visits to the doctor, presentations in the emergency practice as well as emergency doctor assignments are billed as usual by your health insurance company. The University Clinic Duesseldorf does not bear any costs for this.

7. Who is not allowed to participate in this project?

You are not allowed to participate in this project if you simultaneously participate in clinical trials, i.e. drug studies.

There are no other special exclusion criteria.

8. Will I receive an expense allowance?

You will not receive an expense allowance for participating in this project.

9. Am I insured during the PICASO project?

Please note that the equipment you use (activity meter, balance, blood pressure monitor, tablet) is either approved as a medical device and/or freely available on the market. Damage occurring through no fault of your own is therefore not covered by the University Clinic Duesseldorf. Please contact us (see section 14) if the PICASO devices do not work.

In consultation with the Ethics Commission of the Medical Faculty of the Heinrich-Heine-University we have taken out a travel and residence insurance as well as a patient insurance for your participation in the project. This insurance covers, among other things, your way to and your stay with us in case you should come to us for an unforeseeable reason due to the PICASO project.

The commuting accident insurance was taken out by us with the following insurance company:

Name and address of the insurance company:	HDI Global SE
Phone:	+49 211 7482246
Fax:	+49 511645-1153794
Insurance number:	65958420035943901002018 (test person insurance) 50071724172 (travel and residence insurance)

10. Will I be informed of new findings during the project?

You will be informed about new findings which become known in relation to this project and which may be essential for your willingness to participate further. On this basis you can then reconsider your decision to continue participating in the project.

In addition, findings from the project will be made available to the EU, which finances the project, and will also be made available to the interested public via the EU and PICASO websites. Data will only be transmitted in a summarized form, which does not allow conclusions to be drawn about individual patients.

11. Cancellation possibility / Who decides if I want to leave the project?

You can withdraw your consent to this project and terminate your participation at any time without stating reasons, without this resulting in any disadvantages for your further medical treatment.

Under certain circumstances, however, it is also possible for the project physician to decide to terminate your participation in the research project prematurely without you having any influence on the decision. The reasons for this may be, for example, that your further participation in the project is no longer medically justifiable or the entire project is discontinued.

If you wish to revoke your consent, please contact us:

Policlinic, Functional Unit & Hiller Research Center for Rheumatology
University Clinic Düsseldorf,
Heinrich-Heine-University Duesseldorf
Moorenstrasse 5
40225 Düsseldorf
Phone 0211 81-17817
Fax 0211 81-16455
Email: picaso@rheumanet.org

Contact person:
PD Dr. med. Jutta Richter, MD
Dr. Gamal Chehab, MD
Monika Tomczak, MD
Cand. med. Elisabeth Ricken
Cand. med. Catarina Schwartz
Thilo Kluß
Prof. Dr. med. Matthias Schneider, MD

12. What happens to my data?

The storage and safekeeping of your data is subject to German and European data protection guidelines.

Part of the PICASO project is the collection of health data. According to the valid data protection regulations, health data is only collected, processed, passed on and stored pseudonymized on a server at the University Clinic Duesseldorf. The pseudonym is a project-specific patient number which is automatically assigned to each patient at the beginning of the project by the PICASO staff of the University Clinic Duesseldorf. The patient data is pseudonymized with a random code (a randomly generated 32-digit hexadecimal key). The information about which project-specific patient number is assigned to which patient is therefore stored exclusively in the PICASO database at the University Clinic Duesseldorf. They are not visible to third parties. Only the PICASO project team and authorized employees are thus able to assign the project-specific patient

number to the respective patient. All personal patient data is only accessible to the persons involved in your treatment.

For the project, we will transfer some of your data from our clinic's own systems to the PICASO database. These clinic-owned systems include the Hospital Information System (HIS) and the DocuMed.rh which you are already familiar with. Thus, all health-relevant data for your attending physicians and you will be available in the PICASO database. Data provided by your general practitioner, for example, will remain in the practice of your general practitioner and will only be temporarily be displayed in the medical view (clinician dashboard) of the PICASO platform if they are used by other doctors such as your treating rheumatologist.

Part of the PICASO platform is the so-called PICASO cloud. This is provided by CNET SVENSKA AB (Stockholm, Sweden). This cloud manages your pseudonymised data in the PICASO database and in the entire IT infrastructure: For example, you can log in to your personal platform using your individual access data, the authorization for which has first been checked in the PICASO platform. The same applies to the authorization of your attending physicians (e.g. family doctor) before they can view your data.

The data from the scale and the blood pressure monitor are initially stored anonymously on the devices. If you release the measurements via the tablet for the PICASO platform and thus for storage in the PICASO database at University Clinic Duesseldorf, your health data will be merged with your project-specific patient number and the data will be stored in the PICASO database University Clinic Duesseldorf.

The situation is different with the activity meter. The activity meter comes from the company Fitbit Inc. This product stores the data on the device itself, but also in a cloud with data management in the United States of America (USA). Therefore, these data are not subject to the German data protection regulations. In order to protect your data as much as possible, the Fibit is not registered under your name, nor under your project-specific patient number, but with another Pseudonym, under which the data is stored in the American cloud. We collect the data there and merge it with your project-specific patient number at the University Clinic Duesseldorf in Germany. The Fitbit account will be deleted at the end of your project participation.

The allocation of the tablet and the SIM card to your person also takes place exclusively at the University Clinic Duesseldorf. The tablet for setting up the mobile Internet and the devices for determining your health data will be returned to the PICASO project team at the end of the six-month project phase. The data stored on the tablet will be deleted.

Your paper data generated during your six-month participation will be retained for 10 years. They will be entered into a database and stored in accordance with the valid data protection regulations in the Policlinic for rheumatology of the University Clinic Duesseldorf and later evaluated with the help of a statistics program.

If you contact the PICASO project team by phone outside of the scheduled outpatient appointments, the employee will ask your name as your contact may require medical recalls and access to your patient file. Once the medical or technical questions have been clarified, the PICASO project team will document the contact using your project-specific patient number in order to be able to evaluate questions and problems of all patients around the platform in a standardized manner.

In order to assess the success of the project, we will use data that is already available to us from your medical file. In particular, this includes data on the number and length of inpatient stays in the last year before your PICASO participation.

The project has already been submitted by us to the Health Data Protection Officer of the University Clinic Duesseldorf and was accepted.

The project was also submitted to the Ethics Commission of the University Clinic Duesseldorf of the Heinrich-Heine-University Düsseldorf and received a positive ethics vote with the internal study number 6139R.

13. Notes on the use of the tablet and the internet connection

The tablet provided to you and the SIM card with the resulting Internet connection serve exclusively to record your health data, make it available to the PICASO platform and give you the opportunity to interact with the PICASO platform free of charge. If you use the tablet, e.g. to download paid apps, music and/or films, you must bear these costs yourself. The University Clinic Duesseldorf does not bear such costs and will charge you for them in case of misuse.

The tablet can be connected to a WLAN (Wireless LAN). The University Clinic Duesseldorf does not assume any costs for your private WLAN access or costs that may arise when using public WLAN connections.

14. Who should I contact if I have any further questions?

If you have any medical or technical questions or problems, members of the PICASO project team can be reached on weekdays between 8:00 and 16:00 at the telephone number 0211 81-17817 or mobile (0151 25036721). Questions concerning your rights and duties as a patient and participant in the project will also be gladly answered.

Policlinic, Functional Unit & Hiller Research Center for Rheumatology
University Clinic Düsseldorf,
Heinrich-Heine-University Duesseldorf
Moorenstrasse 5
40225 Düsseldorf
Phone 0211 81-17817
Fax 0211 81-16455
Email: picaso@rheumanet.org

Contact persons:

PD Dr. med. Jutta Richter, MD
Dr. Gamal Chehab, MD
Monika Tomczak, MD
Cand. med. Elisabeth Ricken
Cand. med. Catarina Schwartz
Thilo Kluß
Prof. Dr. med. Matthias Schneider, MD

15. Information on the European General Data Protection Regulation (GDPR)

Due to the entry into force of the European General Data Protection Regulation (GDPR) on 25 May 2018, data protection regulations in Europe have changed. Also for medical research projects (in the following referred to as "studies") new requirements for the processing of personal data result from this.

In addition, we would therefore like to inform you about the rights laid down in the GDPR (Article 12 et seq. GDPR):

Legal basis

The legal basis for the processing of your personal data in studies is your voluntary written consent according to the GDPR, the Declaration of Helsinki (Declaration of the World Medical Association on Ethical Principles for Medical Research on Human Beings) and the Guideline for Good Clinical Practice. The revised Federal Data Protection Act (BDSG-neu) will enter into force in Germany at the same time as the GDPR.

Person responsible for data processing

Director of Studies:
Prof. Dr. med. Matthias Schneider, MD
Policlinic, Functional Unit & Hiller Research Center for Rheumatology
University Clinic Düsseldorf
Moorenstraße 5
40225 Düsseldorf
Phone 0211 81-17817
Fax 0211 81-16455
Email: schneiderm@med.uni-duesseldorf.de

Regarding your data you have the following rights (Article 13 ff GDPR, §§ 32 ff BDSG-new):

Right for information

You have the right to be informed about the personal data concerning you which is collected, processed or, if necessary, transferred to third parties within the scope of the study (handing over of a free copy) (Article 15 GDPR, §§ 34 and 57 BDSG-neu).

Right to rectification

You have the right to have incorrect personal data concerning you corrected (Articles 16 and 19 GDPR, § 58 BDSG-new).

Right to deletion

You have the right to delete personal data concerning you, e.g. if these data are no longer necessary for the purpose for which they were collected (Articles 17 and 19 GDPR, §§ 35 and 58 BDSG-new).

Right to limitation of processing

Under certain circumstances, you have the right to request that processing be restricted, i.e. the data may only be stored but not processed. You must apply for this. For this purpose, please contact your study director or the data protection officer of the test center (Articles 18 and 19 GDPR, § 58 BDSG-new).

Right to data transferability

You have the right to obtain the personal data concerning you that you have provided to the person responsible for the study. This will enable you to request that this data be transmitted either to you or, as far as technically possible, to another body designated by you (Article 20 GDPR).

Right of objection

You have the right to object at any time to concrete decisions or measures concerning the processing of your personal data (Art 21 GDPR, § 36 BDSG-new). Such processing will then generally no longer take place.

Consent to the processing of personal data and right to revoke this consent
The processing of your personal data is only lawful with your consent (Article 6 GDPR, § 51 BDSG-new).

You have the right to revoke your consent to the processing of personal data at any time. In the event of revocation, your personal data must always be deleted (Article 7, paragraph 3 GDPR, § 51, paragraph 3 BDSG-new). However, there are exceptions according to which the data collected up to the time of revocation may be further processed, e.g. if further data processing is necessary to fulfil a legal obligation (GDPR Art. 17 para. 3 b).
If you wish to exercise any of these rights, please first contact your study director or the data protection coordinator at your test center. If this is not successful, please contact the other offices listed below.
You also have the **right to lodge a complaint with the supervisory authority(ies)** if you have the opinion that the processing of your personal data violates the GDPR.

Contact details:

Data Protection Coordinator of the Testing Centre

PD Dr. med. Jutta Richter, MD
Policlinic, Functional Unit & Hiller Research Center for Rheumatology
University Clinic Düsseldorf
40225 Düsseldorf
Phone 0211 81-17817
Fax 0211 81-16455
Email: jutta.richter@med.uni-duesseldorf.de

Data Protection Officer of the UKD
Moorenstr. 5, 40225 Düsseldorf, Germany
datenschutz@med.uni-duesseldorf.de

Data protection supervisory authority
State Data Protection Commissioner
and Freedom of Information North Rhine-Westphalia
PO Box 20 04 44, 40102 Düsseldorf, Germany
poststelle@ldi.nrw.de

The list of the Consortium's data processors and the related Data Protection Officers of the Institutions with their contact details is as follows:

Partner	Contact-person	Function	E-mail	Contact data
Fraunhofer	Dr. Carlos A Velasco	Wissenschaftlicher Koordinator	carlos.velasco@ fit.fraunhofer.de	Fraunhofer Institute for Applied Information Technology FIT Schloss Birlinghoven 53757 Sankt Augustin Deutschland
	Ralph Harter	Fraunhofer-Gesellschaft Datenschutz-beauftragter	ralph.harter@ zv.fraunhofer.de	Zentrale der Fraunhofer-Gesellschaft Hansastraße 27c 80686 München Deutschland
INUIT	Daniela Di Gravio	Fondazione INUIT Datenschutz-beauftragter	d.digravio@ fondazioneinuit.it	Fondazione Universitaria' INUIT "Tor Vergata" Via Cracovia SNC 00133 Rome Italien
TUK	Róbert Polyácsko	Datenschutz-beauftragter	zodpovedna.osoba@ tuke.sk	Technical University of Košice Letná 9, 042 00, Košice Slowakei
	Marek Skokan, PhD	Wissenschaftlicher Koordinator	marek.skokan@ tuke.sk	Faculty of Economics Technical University of Kosice Němcovej 32 040 01 Košice S Slowakei
CNET	Peter Rosengren	Datenschutz-beauftragter	peter.rosengren@ cnet.se	CNet Svenska AB Svärdvägen 3B 182 33 Danderyd Schweden
IN-JET	Trine F. Sørensen	Datenschutz-beauftragter	tfs@in-jet.dk	In-JeT ApS Jeppe Aakjærs Vej 15 3460 Birkerød Dänemark

Policlinic, Functional Unit & Hiller Research Center for Rheumatology
University Clinic Duesseldorf, Medical Faculty, Heinrich-Heine-University Duesseldorf
Director Professor Dr. med. M. Schneider, MD

Patient information and consent to the project

-PICASO-

An individualized, patient-oriented platform for improved care of patients with

rheumatoid arthritis

Declaration of consent for participation Copy for participants

.....
Name of patient in block letters

Patient ID .....

Date of birth .....

In a personal conversation with the project physician

.....

Name of the physician

I have been informed in detail and comprehensibly about the project, its significance, risks and implications. In addition, I have read and understood the text of the patient information as well as the data protection declaration printed below. I had the opportunity to talk to the project physician about the implementation of the project. All my questions were answered satisfactorily.

Questions from the patient or other aspects of the consultation:

I had enough time to make up my mind. I am aware that I can withdraw my consent to participate in the project (verbally or in writing) at any time and without giving reasons, without this resulting in any disadvantages for my medical treatment.

Data security

I am aware that in this project personal data, in particular medical findings, are to be collected, stored, exchanged and evaluated about me. The use of information about my health takes place according to legal regulations and requires the following voluntary declaration of consent before participating in the project, i.e. I cannot participate in the project without the following consent.

Declaration of consent to data protection (please tick which statements apply to you)

 I agree that data collected within the scope of this project, in particular information about my health, may be recorded and stored in paper form or on electronic data carriers **in the Policlinic, Functional Unit & Hiller Research Center for Rheumatology and in the computer center of the University Clinic Duesseldorf**. The collected data may be stored under a pseudonym and used **for statistical evaluation**. All scientific evaluations are carried out as summarized (aggregated and anonymized) analyses and are only published on this basis. Individual analyses (with reference to my person) do not take place.

 I have been informed that I can revoke my consent to the recording, storage and use of my data at any time. My data will be deleted immediately in the event of revocation. I have taken note of the information on the GDPR.

 I agree that my data may be stored for 10 years after completion or termination of the project. My personal data will then be deleted unless this conflicts with legal, statutory or contractual retention

 I agree with the fact that you can contact my

 Family doctor Mr / Mrs _____(please enter name and address here)

_____

 Cardiologists Mr / Mrs _____(please enter name and address here)

_____

 _____ Mr / Dr _____(please enter name and address here)

_____

so that they can access my data in the PICASO Cloud, and/or can provide data from me.

……

Name of patient in block letters

…… ……

Date Patient´s Signature

I agree to be involved in the project

-PICASO-

An individualized, patient-oriented platform for improved care of patients with rheumatoid arthritis

To participate voluntarily.

I have received a copy of the patient information and consent. One copy remains in the Policlinic, Functional Unit & Hiller Research Center for Rheumatology, University Clinic Duesseldorf, Medical Faculty, Heinrich-Heine-University Duesseldorf.

……..

Patient´s name

……. ……

Date Patient´s signature

I conducted the recon talk and obtained the patient's written consent.

……..

Name of the project physician in block capitals

…….. ……

Date Signature of the project physician responsible for clarification

Policlinic, Functional Unit & Hiller Research Center for Rheumatology
University Clinic Duesseldorf, Medical Faculty, Heinrich-Heine-University Duesseldorf
Director Professor Dr. med. M. Schneider, MD

Patient information and consent to the project

-PICASO-

An individualized, patient-oriented platform for improved care of patients with

rheumatoid arthritis

Declaration of consent for participation Copy for PICASO file

.....
Name of patient in block letters

Patient ID .....

Date of birth .....

In a personal conversation with the project physician

.....

Name of the physician

I have been informed in detail and comprehensibly about the project, its significance, risks and implications. In addition, I have read and understood the text of the patient information as well as the data protection declaration printed below. I had the opportunity to talk to the project physician about the implementation of the project. All my questions were answered satisfactorily.

Questions from the patient or other aspects of the consultation:

I had enough time to make up my mind. I am aware that I can withdraw my consent to participate in the project (verbally or in writing) at any time and without giving reasons, without this resulting in any disadvantages for my medical treatment.

Data security

I am aware that in this project personal data, in particular medical findings, are to be collected, stored, exchanged and evaluated about me. The use of information about my health takes place according to legal regulations and requires the following voluntary declaration of consent before participating in the project, i.e. I cannot participate in the project without the following consent.

Declaration of consent to data protection (please tick which statements apply to you)

☐ I agree that data collected within the scope of this project, in particular information about my health, may be recorded and stored in paper form or on electronic data carriers **in the Policlinic, Functional Unit & Hiller Research Center for Rheumatology and in the computer center of the University Clinic Duesseldorf**. The collected data may be stored under a pseudonym and used **for statistical evaluation**. All scientific evaluations are carried out as summarized (aggregated and anonymized) analyses and are only published on this basis. Individual analyses (with reference to my person) do not take place.

☐ I have been informed that I can revoke my consent to the recording, storage and use of my data at any time. My data will be deleted immediately in the event of revocation. I have taken note of the information on the GDPR.

☐ I agree that my data may be stored for 10 years after completion or termination of the project. My personal data will then be deleted unless this conflicts with legal, statutory or contractual retention

☐ I agree with the fact that you can contact my

☐ Family doctor Mr / Mrs _____(please enter name and address here)

_____

☐ Cardiologists Mr / Mrs _____(please enter name and address here)

_____

☐ _____ Mr / Dr _____(please enter name and address here)

_____

so that they can access my data in the PICASO Cloud, and/or can provide data from me.

……

Name of patient in block letters

…… ……

Date Patient´s Signature

I agree to be involved in the project

-PICASO-

An individualized, patient-oriented platform for improved care of patients with rheumatoid arthritis

To participate voluntarily.

I have received a copy of the patient information and consent. One copy remains in the Policlinic, Functional Unit & Hiller Research Center for Rheumatology, University Clinic Duesseldorf, Medical Faculty, Heinrich-Heine-University Duesseldorf.

……..

Patient´s name

……. ……

Date Patient´s signature

I conducted the recon talk and obtained the patient's written consent.

……..

Name of the project physician in block capitals

…….. ……

Date Signature of the project physician responsible for clarification

Translated with www.DeepL.com/Translator

9 Appendix D: UDUS physician informed consent

Policlinic of Rheumatology and Hiller Research Unit Rheumatology
University Clinic Duesseldorf, Medical Faculty, Heinrich-Heine-University Duesseldorf
Director Professor Dr. med. M. Schneider

Clinician information and consent to the project

-PICASO-[2]

An individualized, patient-oriented platform for improved care of patients with

rheumatoid arthritis and cardiovascular comorbidity/risk factors

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Version 1.3 – Stand 16.07.2018

Dear colleague,

we are pleased that you are interested in our EU project. Below we would like to give you a brief overview of the goals of the project.

More and more people suffer from chronic diseases, which are often associated with comorbidities. The care of patients with multimorbidity is becoming increasingly complex, as different medical and non-medical caregivers are often involved in the treatment and the success is significantly influenced by the communication between doctor and patient as well as the adherence of the patient.

In order to meet this increasing demand on the healthcare system, we are working together with the Fraunhofer Institute for Applied Information Technology (FIT) in Bonn and other international partners within the framework of an EU-funded technology project called PICASO (A Personalised Integrated Care Approach for Service Organisations and Care Models for Patients with Multi-Morbidity and Chronic Conditions).

[2] A Personalised Integrated Care Approach for Service Organisations and Care Models for Patients with Multi-Morbidity and Chronic Conditions, www.picaso-project.eu

The aim of the project is the development of a platform, the so-called PICASO platform, which makes it possible to bring together health-relevant data of a patient from different sources in a compact way and under consideration of the legal and data protection conditions. This includes existing patient data as well as data reported by patients or their attending physicians as part of the project. This data can then be made available to all authorised persons. The platform is intended to facilitate the transfer of information between all participants and enable more efficient cooperation in order to optimise patient management. This could also save work and costs by reducing the number of duplicate examinations or even hospital stays.

We would like to benefit from your expertise. We want to test and further develop the PICASO platform together with you and selected patients. We focus on the treatment of patients with rheumatoid arthritis and accompanying cardiovascular disease.

The following text explains the background and procedure of our project. Please read it carefully. Afterwards we will also have an informative discussion with you. Please do not hesitate to address all points that are unclear to you. You will then be given enough time to think about your participation.

1. Background

About 800,000 people in Germany suffer from rheumatoid arthritis (RA). The therapy and management of RA present a major challenge for doctors and patients alike. Among other things, drug adherence and a healthy lifestyle play an essential role in the success of treatment, especially in patients with cardiovascular comorbidity. Therefore, the PICASO project aims to further optimize the medical care of these patients by collecting additional health data from the patients between the regular three-monthly outpatient visits at the University Clinic Duesseldorf. The additional health data include physical activity, weight and blood pressure values as well as answers to already established questionnaires on disease activity and functional impairment. Patients will be able to access their treatment plan with the help of the PICASO platform, which is kept up-to-date by the medically trained participants of the PICASO project.

Cardiovascular comorbidities often occur in the course of RA. Since RA and the accompanying cardiovascular disease as well as their therapies can influence each other, an adequate adjustment of the therapies and monitoring of both diseases is crucial. Communication between the numerous persons involved in the treatment of RA and its comorbidities (e.g. general practitioners, rheumatologists, cardiologists, physiotherapists) should be improved by the platform.

2. What happens during the PICASO Project?

30 patients with rheumatoid arthritis and an accompanying cardiovascular disease are invited to participate in the PICASO project over a period of six months and share their experiences with us. The 30 patients will be divided into two equal groups and cared for in two successive project phases, each lasting six months.

The PICASO platform includes the *PICASO Patient Dashboard* for patients and the *PICASO Clinician Dashboard* for physicians. For the use of the PICASO platform, a tablet (Samsung Galaxy Tab A 10.1" (2016) LTE (16 GB)) with integrated SIM card (see paragraph 10 "Notes on using the tablet and the Internet connection" p. 7) will be made available to doctors and patients free of charge for the duration of the project. At the beginning of the project, PICASO employees assign a pseudonym to you, which is also assigned to your tablet and your SIM card. The information about which pseudonym is assigned to which doctor is stored exclusively in the so-called PICASO database at the University Clinic Duesseldorf, so that third parties have no access to it (see paragraph 5 "What happens to my data" p. 6).

In order to guarantee data exchange, source references to all available information are stored in the central PICASO database for each patient, whereas the actual data remains unchanged at its source (with the exception of the additional health data reported by the patient, see below). When a patient is selected for viewing, data from the designated sources is retrieved only for visualization in the PICASO Dashboard.

Part of the PICASO platform is also the so-called PICASO cloud, which is provided by CNET SVENSKA AB (Stockholm, Schweden). This cloud manages the data transfer between the PICASO database and the entire IT infrastructure: If you log on to your personal *PICASO Clinician Dashboard* using your individual access data, for example, to access certain patient data, your authorization is first checked by the PICASO cloud.

To record the additional health data, we provide patients with an activity meter (Fitbit Charge 2) for recording their daily step count, heart rate and sleep pattern, as well as a scale and a blood pressure monitor. The activity meter should always be worn on the patient's wrist. The patients record their weight once a day and their blood pressures are determined three times a day. These health data are forwarded to the PICASO database at the University Clinic Duesseldorf, where they are stored and displayed in graphs and tables for doctors and patients via the PICASO platform.

The *PICASO Patient Dashboard* enables patients to fill in questionnaires on functional limitations and disease activity. These include the Hannover Functional Questionnaire (FFbH), the Rheumatoid Arthritis Disease Activity Index (RADAI), and the Morisky Questionnaire (a questionnaire on drug adherence). The FFbH and the RADAI are to be used once a week within the framework of the project. The Morisky questionnaire will be completed three times by the patients in the project (at the beginning, after three, and six months). The *PICASO Patient Dashboard* includes a reminder function to remind patients when to complete the questionnaires.

The *PICASO Clinician Dashboard* provides you, the physician, with access to all treatment-relevant information of your patients participating in the project. The 'Data Resource Browser' function gives you access to patient data such as laboratory values and clinical findings. The 'Clinician Manager' shows you, among other things, the additional health data of the patient. In the 'Care Plan Manager' you can create and edit individual medication plans as well as advise patients to visit other doctors or physiotherapists and define the necessary time periods. The communication function enables you to easily and securely contact other doctors of the patient.

In order to assess the usability and manageability of the *PICASO Clinician Dashboard*, you will receive three questionnaires per six-month project phase (after three and six months). To enable us to better classify these data, you will be asked about your previous knowledge of information technology at the beginning of the project by means of a questionnaire. Furthermore, at the end of the project we ask you to exchange your experiences with the international PICASO team and other participants.

If you have any questions or technical problems, PICASO team members may be contacted by telephone on weekdays (see paragraph 14 "Whom should I contact if I have further questions?" p. 8).

What does the *PICASO Clinician Dashboard* offer you?

With the currently available prototype of the platform, information from your patients is available to you about

- Diagnoses, course of treatment and medication,
- Laboratory values and clinical findings of other physicians,
- Contact details of other attending physicians,
- The patient's current treatment plan under multidisciplinary control,

- Health data from the patient's home environment, such as
  - Blood pressure values,
  - Heart rate,
  - Weight,
  - Number of steps,
  - Walking distance,
  - Night sleep,
  - Well-being ratings",
  - Questionnaire on the activity of rheumatoid arthritis,
  - Questionnaire on functional impairment caused by rheumatoid arthritis,
  - Questionnaire on medication adherence

The platform offers you possibilities of interaction:

- Recommendations to the patients for a certain behaviour.
- Definition of measurement intervals for measurements of additional health data.
- Recommendation for a consultation.
- Communication with medical colleagues.

3. What should you be willing to do?

If you decided to participate in the project y should be ready to::

- Participate in this project for six months (vacation is possible!).
- Participate in outpatient appointments of the patients involved in the PICASO project, in addition to their routine care, and to use the *PICASO Clinician Dashboard* via a tablet provided by us free of charge:
  - To view and evaluate the additional health data recorded by the patients and the completed questionnaires on disease activity and functional impairment.
  - To check the medication plan and to change/complete it if necessary.
  - To collect vital parameters and store them in your own documentation system.
  - To check existing comorbidities and to record newly occurring comorbidities in your documentation system.

- Answer questionnaires at the time T0, T3 and T6 (at the beginning, after three and six months) on previous knowledge on information technology, usability and manageability of the *PICASO Clinician Dashboard*.

When participating in the project, please note:

- That the information and communication platform used in the course of the PICASO project is a prototype and not an approved medical device. Therefore, no treatment or therapy decisions should be made based on the information provided.

4. What advantages do you have?

Using the *PICASO Clinician Dashboard* gives you a clear, holistic picture of your patient.

Communication between you, the patient and other physicians is extended by one level using the *PICASO Clinician Dashboard*. During the PICASO project, you will be provided with valuable information on the patient's medical history, diagnosis and therapy recommendations in a timely manner, which will make it easier for you to treat and manage your patients.

In addition, the *PICASO Clinician Dashboard* uses the so-called Risk Manager to calculate a standardized value, the so-called SCORE score[3], based on the data available in the PICASO database. This score gives you information about the individual cardiovascular risk of the patient. The longitudinal visualization of the health data from the domestic environment can contribute to an improved evaluation of the individual cardiovascular risk.

By using the *PICASO Patient Dashboard* and collecting additional health data, patients may be able to more accurately assess the extent of functional impairment and reasons for lacking medication adherence. The active involvement of the patient in the management of his disease shall increase adherence in the long term.

The experiences resulting from the project will lead to new knowledge and improvements in the interaction and exchange of data between patients and different physicians. Patients, private practices/clinics and the healthcare system in Germany will later benefit from these developments.

You become a partner of the Polyclinic, Functional Unit & Hiller Research Center for Rheumatology University Hospital Düsseldorf and receive your direct contact person easily via a telephone project hotline.

5. What happens to my data?

The storage of your data is subject to German and European data protection guidelines.

The PICASO project and in particular the data handling procedures has been agreed with the Health Data Protection Officer of the University Clinic Duesseldorf, Mr. Dr. Haaz/O. Schmidt, UIMC, Wuppertal.

Your personal data will only be used by the staff of the University Clinic Duesseldorf to ensure the progress of the project. The international European PICASO Consortium is provided with your data exclusively under a pseudonym. The pseudonym is a project-specific physician number which is automatically assigned to each

[3] Agca R, Heslinga SC, Rollefstad S, et al. EULAR recommendations for cardiovascular disease risk management in patients with rheumatoid arthritis and other forms of inflammatory joint disorders: 2015/2016 update. Ann Rheum Dis. 2017 Jan;76(1):17-28.

physician at the beginning of the project by the PICASO staff of the University Clinic Duesseldorf. The doctor and patient data are pseudonymised with a random code (a randomly generated 32-digit hexadecimal key). Third party access to your data is excluded. Evaluations of the evaluation questionnaires are presented exclusively in aggregated form.

The data stored on your tablet will be deleted after the tablet has been returned to the PICASO team. Your data collected on paper and resulting from your participation will be stored for 10 years in accordance with the law. They are entered into a database and stored at the University Clinic Duesseldorf in accordance with the valid data protection regulations and later evaluated with the aid of a statistics program.

If you contact the PICASO team by telephone, the employee will ask for your name, your contact data and, if applicable, identification data of the respective patient, since your contact either requiresrecalls and inspection of the patient's medical file or requires advice from the technical team. Once the medical or technical questions have been clarified, the PICASO project team will document the contact using your pseudonym in order to be able to evaluate questions and problems related to the platform in a standardised manner.

6. Ethics vote

The study protocol of the PICASO project was submitted to the Ethics Commission of the University Clinic Duesseldorf of the Heinrich-Heine-University Duesseldorf. A positive vote has been received. It is listed with the internal study number 6139R.

7. Study registration

The PICASO project is registered in the HHUD study registry and in the German Clinical Trials Registry (DRKS) (https://www.germanctr.de).

8. Will I be informed of new findings during the project?

You will be informed about new findings that become known in relation to this project and that may be essential for your willingness to continue participating. On this basis, you may then reconsider your decision to continue participating in the project.

In addition, findings from the project will be made available to the EU, which finances the project, and will also be made available to the interested public via the EU and PICASO websites. Data will only be transmitted in summarised form, which does not allow conclusions to be drawn about individual physicians.

9. Right of revocation/Who decides if I leave the project?

You may withdraw your consent to this project and terminate your participation at any time, even without stating reasons, without this resulting in any disadvantages for your further cooperation with the University Clinic Duesseldorf.

Under certain circumstances, however, it is also possible that the PICASO team of the University Clinic Duesseldorf decides to terminate your participation in the research project prematurely without you having any influence on the decision. The reasons for this may be, for example, that the entire project is terminated.

If you wish to revoke your consent, please contact us:

Policlinic, Functional Unit & Hiller Research Center for Rheumatology
University Clinic Düsseldorf,
Heinrich-Heine-University Duesseldorf
Moorenstrasse 5
40225 Düsseldorf
Phone 0211 81-17817
Fax 0211 81-16455
Email: picaso@rheumanet.org

Contact person:

PD. Dr. med. Jutta Richter, MD
Dr. Gamal Chehab, MD
Monika Tomczak, MD
Cand. med. Elisabeth Ricken
Cand. med. Catarina Schwartz
Thilo Kluß
Prof. Dr. med. Matthias Schneider, MD

10. How to use the Tablet and the Internet Connection

The tablet provided to you and the SIM card which enables you to use an Internet connection serve exclusively to view and process the patient data provided in the PICASO platform and to give you the opportunity to interact with the PICASO platform free of charge. If you use the tablet, e.g. to download paid apps, music and/or films, you must bear the costs yourself. The University Clinic Duesseldorf does not bear such costs and will charge you for them in case of misuse.

The tablet can be connected to WLAN (Wireless LAN). The University Clinic Duesseldorf does not assume any costs for your private WLAN access or costs that may arise when using public WLAN connections. After the six-month project phase the tablet will be returned to us, the PICASO Project team.

11. What are the risks of participating in the project?

One risk could be an incorrect recording and/or summary of the health data of the patients, which could lead to your misinformation. In addition, malfunctions within the PICASO platform can lead to incorrect documentation of your health data collected by doctors. It is precisely these malfunctions that we hope to uncover with your help. In order to minimize these risks, you and we collect the patient data as usual at the regular outpatient visits.

The patient was informed that the use of the platform can lead not only to misinformation of the physicians but also to their own misinformation. If there are any differences between the medications communicated during the outpatient visit and the medications listed in the *PIASO Patient Dashboard*, we have asked them to contact us by telephone.

12. Am I insured during the PICASO project?

We would like to point out that the tablet you are using is freely available in stores. In consultation with the the Ethics Commission of the University Clinic Duesseldorf of the Heinrich-Heine-University Duesseldorf, we have

therefore not taken out insurance for your participation in the project. Damages occurring without personal fault are therefore not insured by the University Clinic Duesseldorf.

Please contact us (see section 14) if your PICASO device does not work properly.

13. Do I receive an expense allowance?

You will not receive an expense allowance for participating in this project.

14. Whom should I contact if I have any further questions?

If you have any medical or technical questions or problems, members of the PICASO project team can be reached on weekdays between 8:00 and 16:00 at the telephone number 0211 81-17817 or mobile (0151 25036721). Questions concerning your rights and duties as a participant in the project will also be answered.

Policlinic, Functional Unit & Hiller Research Center for Rheumatology
University Clinic Düsseldorf,
Heinrich-Heine-University Duesseldorf
Moorenstrasse 5
40225 Düsseldorf
Phone 0211 81-17817
Fax 0211 81-16455
Email: picaso@rheumanet.org

Contact persons:

PD Dr. med. Jutta Richter, MD
Dr. Gamal Chehab, MD
Monika Tomczak, MD
Cand. med. Elisabeth Ricken
Cand. med. Catarina Schwartz
Thilo Kluß
Prof. Dr. med. Matthias Schneider, MD

15. Information on the European General Data Protection Regulation (GDPR)

Due to the entry into force of the European General Data Protection Regulation (GDPR) on 25 May 2018, data protection regulations in Europe have changed. Also for medical research projects (in the following referred to as "studies") new requirements for the processing of personal data result from this.

In addition, we would therefore like to inform you about the rights laid down in the GDPR (Article 12 et seq. GDPR):

Legal basis

The legal basis for the processing of your personal data in studies is your voluntary written consent according to the GDPR, the Declaration of Helsinki (Declaration of the World Medical Association on Ethical Principles for Medical Research on Human Beings) and the Guideline for Good Clinical Practice. The revised Federal Data Protection Act (BDSG-neu) will enter into force in Germany at the same time as the GDPR.

Person responsible for data processing

Director of Studies:
Prof. Dr. med. Matthias Schneider, MD
Policlinic, Functional Unit & Hiller Research Center for Rheumatology
University Clinic Düsseldorf
Moorenstraße 5
40225 Düsseldorf
Phone 0211 81-17817
Fax 0211 81-16455
Email: schneiderm@med.uni-duesseldorf.de

Regarding your data you have the following rights (Article 13 ff GDPR, §§ 32 ff BDSG-new):

Right for information

You have the right to be informed about the personal data concerning you which is collected, processed or, if necessary, transferred to third parties within the scope of the study (handing over of a free copy) (Article 15 GDPR, §§ 34 and 57 BDSG-neu).

Right to rectification

You have the right to have incorrect personal data concerning you corrected (Articles 16 and 19 GDPR, § 58 BDSG-new).

Right to deletion

You have the right to delete personal data concerning you, e.g. if these data are no longer necessary for the purpose for which they were collected (Articles 17 and 19 GDPR, §§ 35 and 58 BDSG-new).

Right to limitation of processing

Under certain circumstances, you have the right to request that processing be restricted, i.e. the data may only be stored but not processed. You must apply for this. For this purpose, please contact your study director or the data protection officer of the test center (Articles 18 and 19 GDPR, § 58 BDSG-new).

Right to data transferability

You have the right to obtain the personal data concerning you that you have provided to the person responsible for the study. This will enable you to request that this data be transmitted either to you or, as far as technically possible, to another body designated by you (Article 20 GDPR).

Right of objection

You have the right to object at any time to concrete decisions or measures concerning the processing of your personal data (Art 21 GDPR, § 36 BDSG-new). Such processing will then generally no longer take place.

Consent to the processing of personal data and right to revoke this consent
The processing of your personal data is only lawful with your consent (Article 6 GDPR, § 51 BDSG-new).
You have the right to revoke your consent to the processing of personal data at any time. In the event of revocation, your personal data must always be deleted (Article 7, paragraph 3 GDPR, § 51, paragraph 3 BDSG-new). However, there are exceptions according to which the data collected up to the time of revocation may be further processed, e.g. if further data processing is necessary to fulfil a legal obligation (GDPR Art. 17 para. 3 b).
If you wish to exercise any of these rights, please first contact your study director or the data protection coordinator at your test center. If this is not successful, please contact the other offices listed below.
You also have the **right to lodge a complaint with the supervisory authority(ies)** if you have the opinion that the processing of your personal data violates the GDPR.

Contact details:

Data Protection Coordinator of the Testing Centre

PD Dr. med. Jutta Richter, MD
Policlinic, Functional Unit & Hiller Research Center for Rheumatology
University Clinic Düsseldorf
40225 Düsseldorf
Phone 0211 81-17817
Fax 0211 81-16455
Email: jutta.richter@med.uni-duesseldorf.de

Data Protection Officer of the UKD
Moorenstr. 5, 40225 Düsseldorf, Germany
datenschutz@med.uni-duesseldorf.de

Data protection supervisory authority
State Data Protection Commissioner
and Freedom of Information North Rhine-Westphalia
PO Box 20 04 44, 40102 Düsseldorf, Germany
poststelle@ldi.nrw.de

The list of the Consortium's data processors and the related Data Protection Officers of the Institutions with their contact details is as follows:

Partner	Contact-person	Function	E-mail	Contact data
Fraunhofer	Dr. Carlos A Velasco	Wissenschaftlicher Koordinator	carlos.velasco@ fit.fraunhofer.de	Fraunhofer Institute for Applied Information Technology FIT Schloss Birlinghoven 53757 Sankt Augustin Deutschland
	Ralph Harter	Fraunhofer-Gesellschaft Datenschutz-beauftragter	ralph.harter@ zv.fraunhofer.de	Zentrale der Fraunhofer-Gesellschaft Hansastraße 27c 80686 München Deutschland
INUIT	Daniela Di Gravio	Fondazione INUIT Datenschutz-beauftragter	d.digravio@ fondazioneinuit.it	Fondazione Universitaria' INUIT "Tor Vergata" Via Cracovia SNC 00133 Rome Italien
TUK	Róbert Polyácsko	Datenschutz-beauftragter	zodpovedna.osoba@tuke.sk	Technical University of Košice Letná 9, 042 00, Košice Slowakei
	Marek Skokan, PhD	Wissenschaftlicher Koordinator	marek.skokan@ tuke.sk	Faculty of Economics Technical University of Kosice Němcovej 32 040 01 Košice S Slowakei
CNET	Peter Rosengren	Datenschutz-beauftragter	peter.rosengren@ cnet.se	CNet Svenska AB Svärdvägen 3B 182 33 Danderyd Schweden
IN-JET	Trine F. Sørensen	Datenschutz-beauftragter	tfs@in-jet.dk	In-JeT ApS Jeppe Aakjærs Vej 15 3460 Birkerød Dänemark

Policlinic, Functional Unit & Hiller Research Center for Rheumatology
University Clinic Duesseldorf, Medical Faculty, Heinrich-Heine-University Duesseldorf
Director Professor Dr. med. M. Schneider, MD

Patient information and consent to the project

-PICASO-

An individualized, patient-oriented platform for improved care of patients with

rheumatoid arthritis and cardiovascular comorbidity/risk factors

Declaration of consent for participation – Copy for PICASO records

.....
Name of participating physician in block letters

Date of birth ..... Participant no. .....

In a personal conversation with the project physician

.....
Name of the project physician in block letters

I have been informed in detail and comprehensibly about the project, its significance, risks and implications. In addition, I have read and understood the text of the clinician information as well as the data protection declaration printed below. I had the opportunity to talk to the project physician about the implementation of the project. All my questions were answered satisfactorily.

Questions from the clinician or other aspects of the consultation:

I had enough time to make up my mind. I am aware that I can withdraw my consent to participate in the project (verbally or in writing) at any time and without giving reasons, without this resulting in any disadvantages for my medical treatment.

Data security:

I am aware that in this project personal data, in particular medical findings, are to be collected, stored, exchanged and evaluated about me. The use of information about my health takes place according to legal regulations and requires the following voluntary declaration of consent before participating in the project, i.e. I cannot participate in the project without the following consent.

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 I agree that data collected within the scope of this project, in particular information about my health, may be recorded and stored in paper form or on electronic data carriers **in the Policlinic, Functional Unit & Hiller Research Center for Rheumatology and in the computer center of the University Clinic Duesseldorf**. The collected data may be stored under a pseudonym and used **for statistical evaluation**. All scientific evaluations are carried out as summarized (aggregated and anonymized) analyses and are only published on this basis. Individual analyses (with reference to my person) do not take place.

 I have been informed that I can revoke my consent to the recording, storage and use of my data at any time. My data will be deleted immediately in the event of revocation. I have taken note of the information on the GDPR.

 I agree that my data may be stored for 10 years after completion or termination of the project. My personal data will then be deleted unless this conflicts with legal, statutory or contractual retention

……

Name of participating physician in block letters

…… ……..

Date Signature of the participating physician

I agree to be voluntarily involved in the Project

-PICASO-

An individualized, patient-oriented platform for improved care of patients with

rheumatoid arthritis and cardiovascular comorbidity/risk factors

I have received a copy of the clinician information and consent. One copy remains in the Policlinic, Functional Unit & Hiller Research Center for Rheumatology, University Clinic Duesseldorf, Medical Faculty, Heinrich-Heine-University Duesseldorf.

……..
Name of participating physician in block letters

……. ……
Date Signature of the participating physician

I conducted the recon talk and obtained the clinician's written consent.

……
Name of the project physician in block letters

…….. ……
Date Signature of the project physician

Policlinic, Functional Unit & Hiller Research Center for Rheumatology
University Clinic Duesseldorf, Medical Faculty, Heinrich-Heine-University Duesseldorf
Director Professor Dr. med. M. Schneider, MD

Patient information and consent to the project

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rheumatoid arthritis and cardiovascular comorbidity/risk factors

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Name of participating physician in block letters

Date of birth ..... Participant no. .....

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Data security:

Mir I am aware that in this project personal data, in particular medical findings, are to be collected, stored, exchanged and evaluated about me. The use of information about my health takes place according to legal regulations and requires the following voluntary declaration of consent before participating in the project, i.e. I cannot participate in the project without the following consent.

Declaration of consent to data protection (please tick which statements apply to you)

 I agree that data collected within the scope of this project, in particular information about my health, may be recorded and stored in paper form or on electronic data carriers **in the Policlinic, Functional Unit & Hiller Research Center for Rheumatology and in the computer center of the University Clinic Duesseldorf**. The collected data may be stored under a pseudonym and used **for statistical evaluation**. All scientific evaluations are carried out as summarized (aggregated and anonymized) analyses and are only published on this basis. Individual analyses (with reference to my person) do not take place.

 I have been informed that I can revoke my consent to the recording, storage and use of my data at any time. My data will be deleted immediately in the event of revocation. I have taken note of the information on the GDPR.

 I agree that my data may be stored for 10 years after completion or termination of the project. My personal data will then be deleted unless this conflicts with legal, statutory or contractual retention.

……
Name of participating physician in block letters

…… ……..
Date Signature of the participating physician

I agree to be voluntarily involved in the Project

-PICASO-

An individualized, patient-oriented platform for improved care of patients with

rheumatoid arthritis and cardiovascular comorbidity/risk factors

I have received a copy of the clinician information and consent. One copy remains in the Policlinic, Functional Unit & Hiller Research Center for Rheumatology, University Clinic Duesseldorf, Medical Faculty, Heinrich-Heine-University Duesseldorf.

……..
Name of participating physician in block letters

……. ……
Date Signature of the participating physician

I conducted the recon talk and obtained the clinician's written consent.

……
Name of the project physician in block letters

…….. ……
Date Signature of the project physician

10 List of Tables

Table 1: Refinement of selected items in the Ethical Checklist.....11