

A Personalised Integrated Care Platform

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D7.9 Third PICASO Integrated Care Platform

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1 Executive Summary

This deliverable D7.9 is a Demonstrator (software) deliverable and represents the integrated PICASO Care Platform including the functional components with end user tools, user interfaces and their deployment in the cloud-based run-time architecture.

The main updates compared to the previous version of this deliverable include,

- Improved network traffic and certificates management
- Reference Data Server: improved value set support
- ODS: improved performance and API support
- Clinician Dashboard user interface and performance improvements
- Patient Dashboard improved Diary interface with medication support

For details of individual components, we refer to the previous deliverables D7.6 Second Care Management and Design Tools and D7.7 Second Private and Public Cloud Integration.

The PICASO platform is currently (June 2019) used in the PICASO clinical trials, involving three different hospitals and clinics, as reported in deliverables D8.9 Third Annual Trial Progress and Ethical Report and D8.10 Second Trials Installation and Annual Updates.

2 Introduction

2.1 Purpose, context and scope of this deliverable

This report describes the third and final version of the integrated PICASO platform and it accompanies the Demonstrator deliverable D7.9 and describes the integrated PICASO platform deployed for PICASO clinical trials.

The PICASO Private Care Cloud and the Public Cloud are implemented in two deliverables,

- D7.7 Second Private and Public Cloud Integration.
- D7.9 Third PICASO Integrated Care Platform (this deliverable).

Task 7.4 "Care System Private Cloud Integration" and Task 7.5 "PICASO Integrated Care Platform" have contributed to this deliverable.

2.2 Intellectual Property (IP)

The different software components of the PICASO Integrated Care Platform are subject to open source and commercial licences, which are subject to the licences reflected in the IP repository being created for the project.

2.3 Content and structure of this deliverable

Section 3 describes different aspects related to the deployment of the PICASO integrated care platform in the two trials. In particular, the privacy and security provisions are described in this section. In Section 4 the Clinician Dashboard user interfaces are described and illustrated.

3 Integrated care platform

3.1 Cloud deployment for Trials

The PICASO platform for the trials includes one Care System Private Care Cloud per clinical partner (UTV, SLUCIA, UDUS) and a single Platform Public Cloud configured to integrate the set of Patient Private clouds of the trial patient users.

Care System Private Clouds

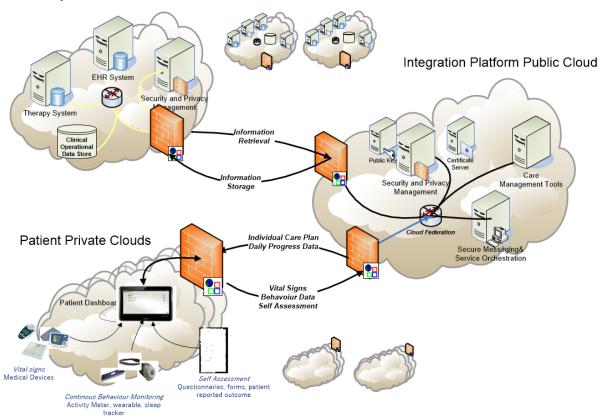
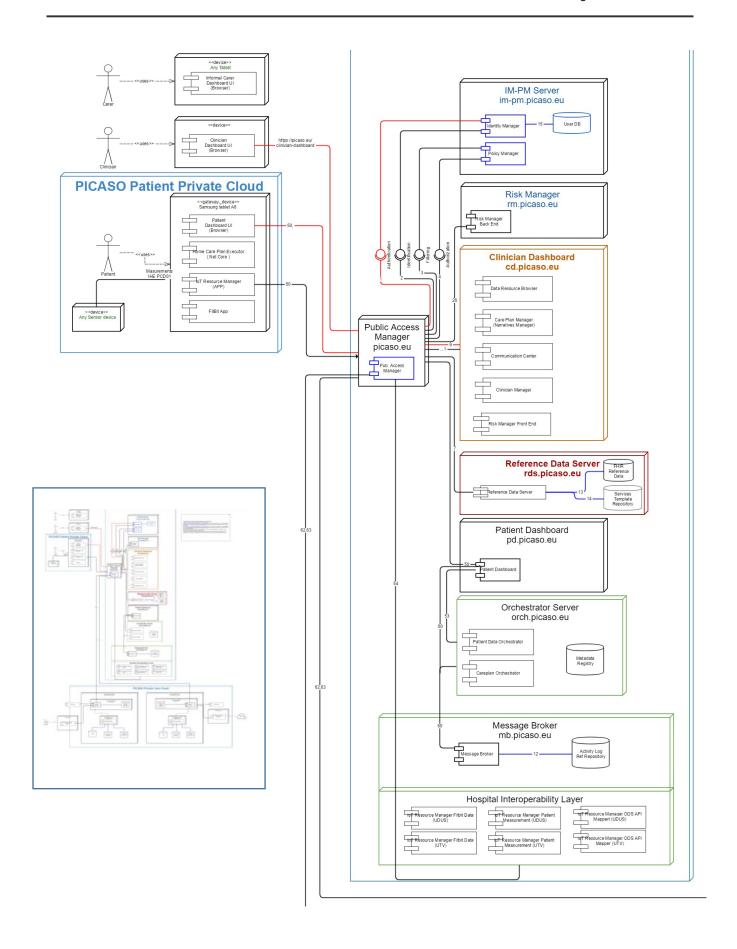


Figure 1: Clouds over the PICASO platform

Figure 2 below illustrates the deployment of the different components to the cloud.



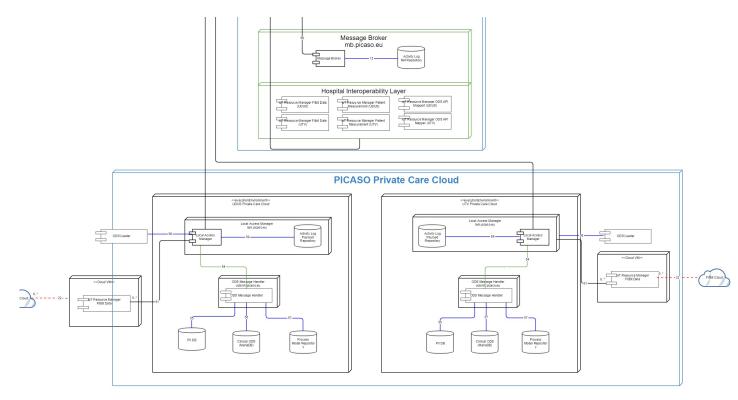


Figure 2: Deployment of components to clouds

The Private Care Cloud is designed to store sensitive patient data on the premises of the participating hospitals in a format suitable for PICASO (see the Operational Data Store (ODS) component Deliverable D5.7). Further, it provides the necessary services for data retrieval via the Public Cloud.

3.2 UTV Deployment (Roma)

Figure 3 illustrates the architecture of the PICASO Private Care Cloud deployed at the University of Rome hospital. The cloud consists of seven components, each deployed on separate Virtual Machines (VMs):

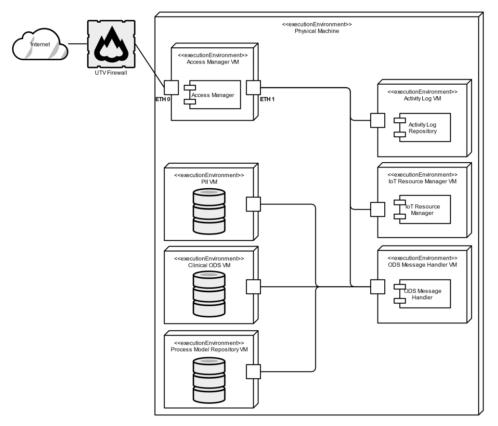


Figure 3: The Private Care Cloud at the University of Rome Hospital

Access Manager (DIVA node): a component which filters all communications by actively monitoring all connections at the application level. Access is granted only if it is allowed by specific access rules. Access rules are coordinated with the PICASO Public Cloud Access Manager Component by means of the Public Cloud Policy Manager. The Access Manager is one of several nodes of Distributed Validation Authority (DIVA) in PICASO Platform.

Activity Log: component designed to store logs which may containing sensitive data.

IoT Resource Manager: component designed to fetch information form the IoT devices of patients.

ODS Message Handler: component designed to provide a common API to access PII, Clinical ODS and Process Model Repository data bases.

PII: component which stores the personal identifiable information of PICASO users who are associated with the institution where the Carer Private Cloud is located.

Clinical ODS: component stores clinical information of PICASO users who are associated with the institution where the Private Care Cloud is located.

Process Model Repository: component stores Process Models.

3.3 Stakeholders

Fehler! Verweisquelle konnte nicht gefunden werden. presents an overview of the different stakeholders in the project. The list is constrained to the actual end-users of the system in the pilots.

Role	Description
Medical specialist	Medical doctor who is specialized in a certain field in medicine, such as General Practitioner, Rheumatologist, Cardiologist, Radiologist, Nuclear Medicine Physician, Neuropsychologist/ Psychiatrist, Clinical Neurologist, or Occupational Physician

General Practitioner (GP)	Medical doctor, who normally is the first point of contact with a patient and who works together with other medical specialists.
Patient	A person who suffers from an illness or injury and who is the recipient of health care services or treatments. In the PICASO trials patients are chosen who suffer either from rheumatoid arthritis and cardiovascular diseases or from Parkinson's disease and cardiovascular diseases.
Informal carers	Individuals (e.g., relatives, friends) assisting the patient, as a complement to the health-care professionals assigned in the care plan.
IT-Administration hospital	Group of people who are responsible for configuration, maintenance and the reliable and secure operation of the hospital information systems.

Table 1: Stakeholders in PICASO

3.4 Privacy and security

In this section we give a high-level description of the privacy and security provisions implemented in the PICASO platform. The more detailed description can be found in D5.7 Third Data Management Subset in Picaso Cloud section 5 Security and Privacy Management.

3.4.1 Clinical data

Clinical patient data is persistently stored only in the Private PICASO Cloud instances of the participating hospitals in a non-identifying – pseudonymized - way by linking it to a Unique PICASO IDs (UPIDs) for each patient. The UPID is a random, 32-character hexadecimal key. Patient data are collected, passed on, and processed - whenever possible – in this pseudonymized way. An important exception is the temporary aggregation of patient data in the public cloud for presentation to clinicians and patients via the clinician and patient dashboards.

Clinical patient data are provided to the PICASO platform by the participating hospitals via an upload from their hospital systems or via manual entry. Except for the purpose of uploading data into the Operational Data Store (ODS), the hospital systems and databases are strictly separated from the PICASO platform. Additional patient data are collected via sensors deployed in home-monitoring devices and transferred over secure SSL/TLS-connections to the ODS servers where the data are persistently stored and processed in pseudonymized form. In addition, all communication between Public PICASO Cloud and Private Cloud Instances in hospitals are achieved via Virtual Private Network (VPN).

3.4.2 Personal identifiable information

Personal identifiable information (PII - like name, address, contact information) is stored for all users (including patients, formal carers, and informal carers) in a dedicated database at the participating hospitals, and which is strictly separated from the databases holding clinical data.

3.4.3 Patient access to the PICASO platform

After giving their written informed consent to the hospitals, patients are provided with a tablet device together with a set of home-monitoring devices and their logon credentials. With the account patients get:

- Ability to login to the Patient Dashboard via the provided tablet device
- Ability to transmit home monitoring data to the hospital via the provided tablet device

3.4.4 Formal carer access to patient data

Formal carer access to patient data is granted based on the written informed consent by the patient: By default, all clinical data of a patient included in PICASO platform are accessible to all formal carers participating in each trial (across participating institutions). Patients have the option to deactivate any formal carer's access to their patient data by request to their clinicians. Formal carer access is further restricted by access limitations per the formal carers' role.

All relevant formal carer roles (like cardiologist, physical therapist, nuclear medicine physician) have been defined by the participating hospitals and for each role the accessible/non-accessible data categories have been designated by the clinical partners.

3.4.5 Informal Carer access to patient data

Patients may grant informal carers access to their patient dashboard:

- Patients must request in writing the enrolment of the informal carer
- The informal carer must agree to her/his personal data stored and processed in the PICASO platform.

A PICASO account for the informal carer is created by INUIT after the hospitals inform INUIT that steps 1 and 2 have been completed. The hospitals provide the UPID of the patient to which the account of the informal carers must be associated to. Informal carers receive browser-based access via a dedicated tablet device that will be provided to the informal carers.

3.4.6 Patient status (active/inactive)

After a patient signs the informed written consent his/her status in PICASO is "active". If the patient decides to leave the trial, her/his status becomes "inactive" and access to his patient data will be revoked for all users (the patient itself, the informal carers, formal carers). No further home-monitoring data for the patient will be uploaded to the PICASO platform.

3.4.7 Access protections

In general, access to all accounts is protected by username and password A second factor access authentication is achieved by using device specific digital certificates. Using these certificates, the PICASO Platform recognizes and authenticates the device from which the platform is being accessed.

3.5 Third-party service integration - FitBit

The PICASO platform interfaces one external third-party cloud service to get data from the FitBit activity bracelets worn by patients.

The integration of server to server communication between the PICASO Private Cloud and the FitBit activity service uses a pre-made component called OMH Shimmer, an open source JAVA project that supports multiple third-party APIs and normalizes the API calls and data. The OMH Shimmer also takes care of the OAuth 2.0 authorization and the authentication needed to be able to do the API calls. The choice to use the OMH Shimmer, was to speed up the data collection from the FitBit and other third-party APIs, providing health data.

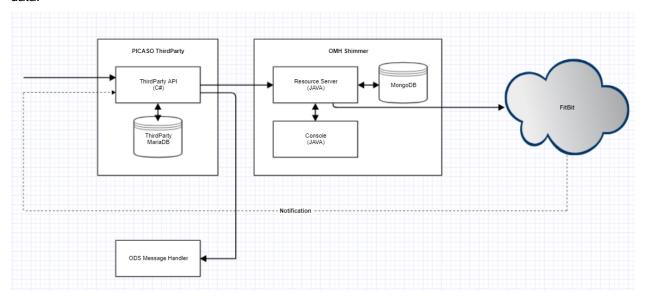


Figure 4: PICASO integration with the FItBit cloud

Additional features were needed to be able to receive the data, including using subscriptions and notifications from the FitBit server. The server will notify the PICASO platform that new data is available, rather than PICASO constantly polling the FitBit server. In order to have this feature, a third-party API wrapper (C#) was built on top of the OMH Shimmer. The API wrapper stores additional data into a separate PICASO database with a lookup table for subscription IDs and patient IDs (UPID), notification logs, and data hashes.

3.6 Data models and Structures

3.6.1 FHIR data models and extensions

The FHIR data models and the extensions relevant for PICASO are described in detail in 7.6, section 4. The key component of the system is the CarePlan,¹ together with its key components:

- ProcedureRequest²
- MedicationRequest³
- CommunicationRequest⁴
- DeviceRequest⁵

and the associated FHIR Resources, value sets and code systems. Additionally, the project has defined extensions that cope with the needs and requirements of our pilots (documented in the same deliverable).

3.6.2 ODS - Operational Data Store

The ODS and related schemas are described in Deliverable D5.7.

¹ https://www.hl7.org/fhir/careplan.html

² https://www.hl7.org/fhir/procedurerequest.html

³ https://www.hl7.org/fhir/medicationrequest.html

⁴ https://www.hl7.org/fhir/communicationrequest.html

⁵ https://www.hI7.org/fhir/devicerequest.html

4 Functional view

4.1 Reference Data Server

The functionalities of the Reference Data Server are fully described in deliverable D7.6, section 4.7. Within this update, the main improvement was the incorporation of further datasets, according to the needs of the pilots and the recommendations of the clinicians. These additions increased the amount of data to be exchanged and therefore demanded an improvement of the performance to be able to deliver timely to the different applications the requested data.

Therefore, a new server-side caching mechanism has been added and tested to the system. With that, the response time of the server improved more than 70%. This caching mechanism has been added through a proxy component that interacts with the back-end application and the NoSQL database.

4.2 Clinician Dashboard

The clinicians window onto PICASO is via the Clinician Dashboard which provides an integrated user interface to the main clinical functions and tools.

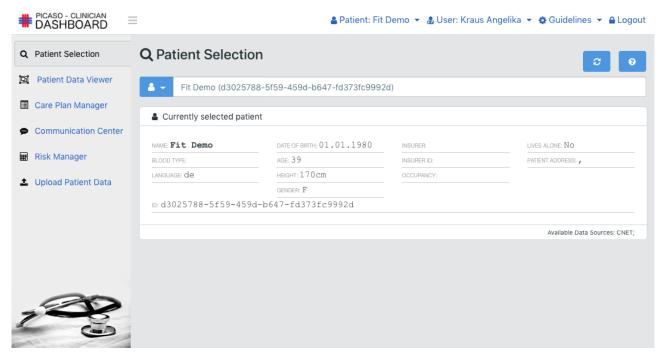


Figure 5: Clinicians patient selection window in PICASO

Clinicians select patients and their related data from one or more connected Private Care clouds of affiliated carers (subject to proper authorization). The entry web page (Figure 5) then provides access to the different PICASO tools.

4.2.1 Data Resource Browser

The Data Resource Browser (DRB) GUI is usable on PCs and Tablets and its purpose is to display any Patient's data based on the Metadata Registry that the specific end user (clinician) has permission to access (see Deliverable D2.3). The DRB displays the integrated heterogeneous patient's data in a structural interactive form. It gives (to clinicians) an intuitive and quick way to browse and check the integrated information in form of a "mind map", having in the very centre the patient. The mind map (graph) is interactive, thus by clicking on one node, a new sub-graph is shown. Finally, when clinician clicks on a certain specific data type, history of all relevant performed measurements or narratives are displayed (the content is presented by Clinician Manager or Narrative Manager).

Different care professionals would need to follow different pathways in order to obtain a good overview of what data are available for a patient (see Deliverable D5.3). Also, the DRB is capable of adaptation of mind map

based on user preferences, so only information relevant to the specialist can be presented. DRB together with Patient Data Viewer and Narrative Manager enable clinicians to grasp an overall (holistic) picture of the patient from data perspective.

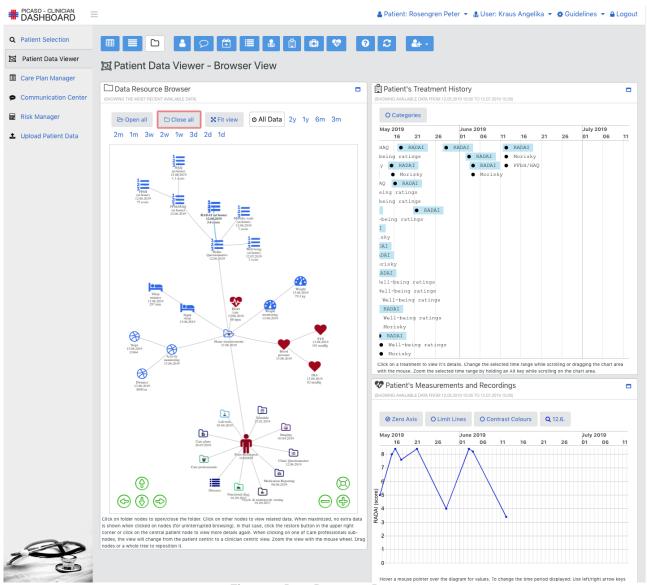


Figure 6: Data Resource Browser

Figure 6 shows the DRB with expanded home measurements and recordings and the corresponding selected node details shown on the right.

4.2.1.1 Technologies employed

The protocols employed by DRB are HTTPS/REST. The technologies include Web technologies, vis.js, AngularJS, NodeJS3.

4.2.1.2 Interfaces

The preconditions for DRB to display the integrated data are services that provide such data in a suitable (for DRB) form. The ODS provides services over the stored data. These data come from HISes, Patient's home monitoring as well as from Narrative Manager. So, patient's data are already integrated in ODS. However more ODSes can contain data about the patient (as there is one ODS per hospital in the private cloud). The Patient Data Orchestrator compose such services of ODSes including the privacy restrictions and wrap particular services as one service suited for DRB. The DRB, as part of the Clinician Dashboard, delegates the call of the

service to this wrapping component (Patient Id used in the call has been chosen there). The signature of this service is following:

API name	Parameter (I/O)	Туре	Description
patient/forDRB	patientId (I)	string	The patient identifier (obtained after user has chosen it in Clinician Dashboard)
	startDate (I)	date-time	The start date
	endDate (I)	date-time	The end date
	X-PICASO- RequesterUPI (I)	string	Non-standard header for Requester UPID (obtained after user hes logged in into Clinician Dashboard)
	resultForDRB (O)	resultForDRBtype	Structured data response that suit to the structure of the predefined DRB mind map

Table 2: Patient DRB service

The JSON schema used for data response (Output) as well as JSON sample of such response of such service are provided in the accompanying deliverable D7.4.

Once the mind map is presented and the clinician chooses concrete data to be shown in detail (e.g. from the list below the mind map or by double-clicking on the leaf node) the navigation towards the Patient Data Viewer (Clinician Manager before) or Care Plan Manager is done. Clinician Manager provides the following specific interface for DRB supporting such navigation in case of data belonging to "Home measurements and observations":

API name	Parameter (I/O)	Туре	Description
/clinician- manager/observations/ <homemonitoringsubca tegory>?startdate=<st artDate>endDate=<e ndDate></e </st </homemonitoringsubca 	homeMonitoringSubcat egory (I) startDate (I) EndDate (I)	string date-time date-time	Name of the subcategory of "Home measurements and observations" together with the start date and end date gives appropriate visualisation (type of chart or timeline) and time context - one month into past and one month into future (where applicable)
clinician- manager/treatments/ all?startenddate= <sta< td=""><td>startDate (I) EndDate (I)</td><td>date-time date-time</td><td>start date and end date gives time context - one month into past and one month into future (where applicable)</td></sta<>	startDate (I) EndDate (I)	date-time date-time	start date and end date gives time context - one month into past and one month into future (where applicable)

Table 3: Observations DRB service

In case of data belonging to data category Care plan, the navigation follows the general link: /narratives-manager. Thus, Care Plan Manager is opened with the patient selected in Clinician Dashboard.

4.2.2 Patient Data Viewer

The Patient Data Viewer (previously Clinician Manager) provides a graphical and tabular overview of patient's clinical data. This component is a subcomponent of the Clinician Dashboard web interface.

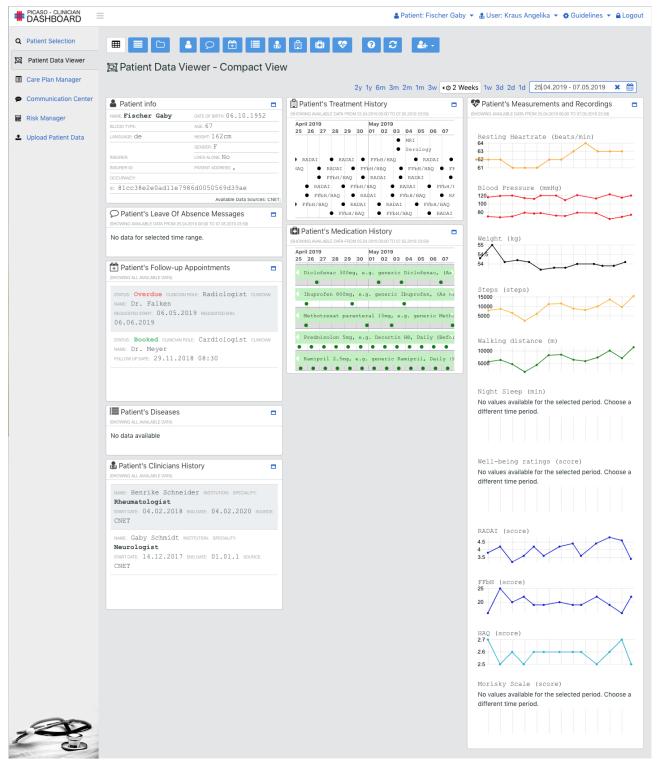


Figure 7: Presentation styles provided by the Patient Data Viewer

More detailed information is provided in the deliverable D6.7.

4.2.3 Risk Manager

The Risk Manager is a subcomponent of the Clinician Manager. It provides personalized risk scores forecasting based on two Risk Score calculators SCORE and CUORE. Whenever Risk Score Manager is opened it automatically transfers all necessary data form the relevant ODS's and performs calculations.

Clinician can provide additional data, load historic data or modify existing data and calculate predictive risk score. UI of the tools was created closely collaborating with clinicians.

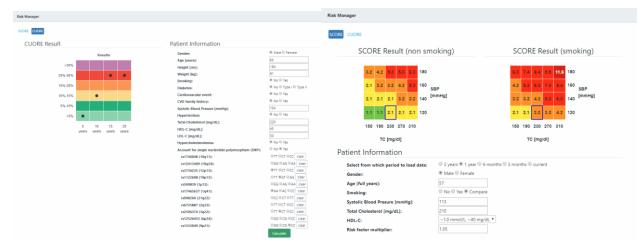


Figure 8: CUORE (left) and SCORE (right) Risk score calculators that are available directly in clinician dashboard.

This component is running in the public cloud. More detailed information is available in the deliverable D6.4. Second Risk Manager.

4.2.4 Care Plan Manager

The aim of this tool is to allow the creation, integration and effective sharing of a Patient pathway between all involved professional carers. Every organisation/physician uses a number of standard care plans for various diseases management actions. These care plans are expressed in a narrative form and are stored as care plan templates in the Process Model repository through the Care Plan Orchestrator component. A care plan template uses in a specific arrangement standard services stored in the service catalogue with open data fields for specific service parameters. In order to develop a Patient Pathway, a physician or an assistant instantiates one of the existing templates and fills the missing services' data with specific patient data.

When defining a care plan, physicians will be provided with clinical guidelines according to the patient's known disease(s). In case a patient is suffering from rheumatoid arthritis and a cardiovascular disease guidelines are provided to be accessible for physicians.

Medication table is provided for the physicians to have a quick overview of all the medications prescribed for the patient describing the medication, dosage and time of intake. Physicians can suspend a medication for scanning to take place. This can be informed to Radiologists by sending a message.

Where a physician prescribes an immunosuppressant for a patient affected by rheumatoid arthritis. In this case, a pop-up will appear notifying the physician to ensure that the patient is informed about the requirement of strict contraception. The physician will be advised to include this information also in the handover comment for the colleague who will see the patient for follow-up treatment with the advice to remind the patient in regular time intervals about this requirement.

If a physician has defined a service potentially conflicting with an already existing one of same type that is active during the same or an overlapping time period, the potential conflict(s) are brought to the attention of the physician in form of a list with a clear indication of which services are affected. For services where there are further specifications available, e.g., medication services are always further specified by a drug name, these are considered as well for detecting potential conflicts.

All the services are grouped according to their types so that clinicians have a very good overview of all the services prescribed for the patient. Each service can be cloned in the care plan, which helps to quickly create a similar service for the patient. Services can also be saved as a template to access the service in other care plans. Services that are on status 'active' but have an expired end date will be highlighted to physicians when accessing a patient's care plan.

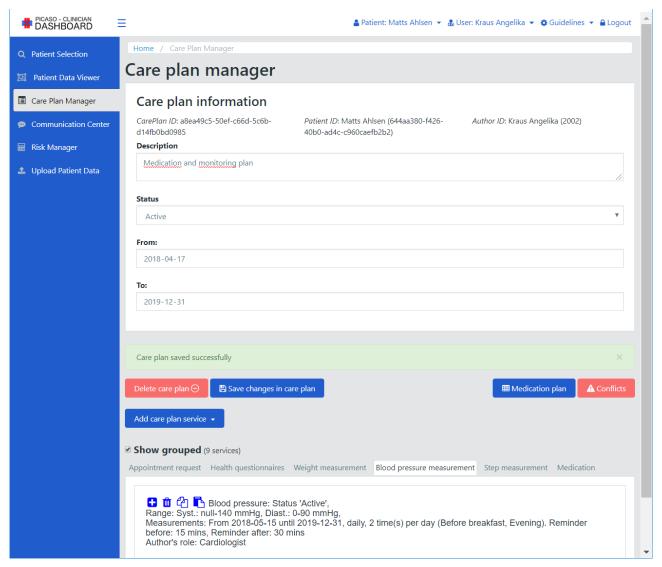


Figure 9. Care plan manager start page after loading a fictitious care plan.

The full functionality of the Care Plan Manager is described in more detail in deliverable D7.6.

4.3 Patients and informal carers views

For the PICASO Trials the Patient Dashboard (PD) is deployed on a tablet PC, with the user interface adapted to each PICASO trial (UDUS and UTV) patient group.

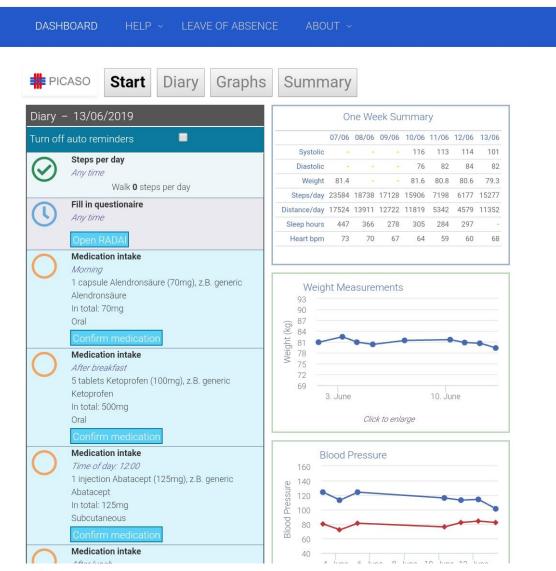


Figure 10: Patients and informal carers view of PICASO (UDUS trial format, test data)

The Patient Dashboard user interface and functionality is described in Deliverable D4.6 Third version of the Patient Private Cloud. In the Trials, the informal carers and the patients used the same patient dashboard interface.

5 Summary and Conclusions

The third (final) version of the integrated PICASO platform has now been deployed for the two clinical trial settings. A separate test environment was also set up for software component tests and cloud integration.

Potential extensions (beyond the project) include support for user administration, configuration and commissioning of equipment and, for the adaptation of the Clinician and Patient Dashboard user interfaces. The overall conclusion is that the integrated cloud platform has well met the requirements from the PICASO applications and the clinical trials.

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