A Personalised Integrated Care Platform

(Grant Agreement No. 689209)

D5.1 Data Models & Shared Memory Objects

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Index:

1 Executive Summary

This document covers the approach PICASO has defined to date and will take to defining, presenting and sharing data across the target PICASO platform.

The scope focuses on the needs of the three hospitals involved in the PICASO clinical trials, but also explains how the data management solution might extend into a full production solution with many hospitals, clinicians and patients integrated through a “PICASO network”.

During development of the PICASO Architecture, it has been agreed to simplify the concept of “shared memory objects” as being the means by which data is made accessible. The project has adopted a more pragmatic and proven approach, whereby each participating hospital is required to present data conformed to a standard model and definition – in the form of a standardised Operational Data Store (ODS). This mirrors many production solutions such as the processing of IBAN transactions in the Banking sector. In addition to greatly simplifying and standardising the PICASO architecture, it provides for better data governance and insulation of PICASO from changes within the data landscape in participating hospitals.

The ODS solution is currently very simple in nature, highly extendable and could be either extended or cloned and adapted for other similar purposes. It adheres to existing International Healthcare standards where applicable and as such, the evidence we have from UDUS is that it can be easily integrated with systems within participating hospitals.

2 Introduction

2.1 Purpose, context and scope of this deliverable

The PICASO project is designing and implementing a range of technical solutions and innovations to support improvements in the management of age-related comorbidities. As the European population continues to age with increasing life expectancy, a growing proportion of the population are living with multiple complex long term medical conditions, many of which are interrelated and also require coordination of treatment plans to optimise the cost and effectiveness of patient outcomes.

Amongst these initiatives is the desire to share clinical data between clinicians across hospitals and clinics, with patients and with their carers. To do so involves solving technical, legal and ethical issues. This document covers the technical and legal issues around the management of Clinical data. Ethical issues are the domain of the Ethical Board and Work Packages 3 & 10.

2.1.1 In Scope

The scope of this deliverable is to describe all aspects of the data management plan for clinical data within the PICASO solution, covering:

- Clinical Data obtained from the various Hospital Clinical Systems and device observations data from LinkWatch Remote Monitoring.
- Data Privacy of clinical data.
- Data Activity Logging – auditing the creation of and access requests for clinical data.
- Sharing of data between PICASO actors across different locations.
- Standardisation of data formats and definitions across PICASO.
- Compliance with and exploitation of Healthcare data standards.
- Consideration of data governance challenges around PICASO.
- The impact of the withdrawal of patients early from clinical trials.
- Some aspects of Data Security (although Data Security is covered more thoroughly in D2.3 Initial Architecture

2.1.2 Out of Scope

This deliverable does not consider the following data used and maintained within PICASO.

- Data relating to Narratives Templates, Narratives and Service Components.
- Alerts or Events created in PICASO.
- Audit of Transactional activity, such as the above.
- PICASO policies, as maintained by the Policy Manager.
- Administration data about devices at Patients' homes. This is the responsibility of the remote monitoring/LinkWatch components of PICASO.
- Hospital data retention requirements at project closedown.

In addition, the project does not include the following:

- Consideration of potential data feeds from pharmacies or health insurers.

2.2 Content and structure of this deliverable

The content and structure of this document is as follows:

- The Common Information Model

  - Logical Data Model and Schema
  - Standards Compliance
  - ODS/ETL implementation
  - Scalability considerations
  - Principle of non-duplication of clinical data
- Data Privacy
- Data Governance
- Activity Logging of Data Creation & Access
- Data Orchestration approach

3 Common Information Model

3.1 Data Investigation & Requirements

The project has conducted a data analysis for both Tor Vergata/Santa Lucia and UDUS. The two countries took quite different approaches, but have ended with a similar result; a set of data requirements for both clinical trials.

D2.1 Initial Requirements Specification

A set of "data categories" was identified as part of the Initial Requirements work in D2.2 Initial Requirements Report. Data Investigation used these data categories as a major input.

These data categories are listed in Appendix A, mapped to the primary data entities described in the Common Information Model in Section 3.2. This spreadsheet shows the mapping of data categories to the initial Common Information Model developed as part of Task 5.1, which will become the basis of the Clinical Operational Datastore schema, as described in D2.3 Initial Architecture.

3.1.1 UDUS Data Investigation & Requirements

UDUS primarily wants PICASO to be a platform where data is shared between hospitals and clinicians, to create a more complete Electronic Patient Record - covering the key data that is required to support the management of comorbidities.

Clinical Data Sources

UDUS currently has two main clinical systems; the Hospital Information System (based on the Medico package) and a system developed specifically for the Rheumatoid Arthritis department called DocuMed.rh, based on DocuMed's Electronic Medical Records software. There are two Medico instances in UDUS. We are only accessing data from the "HIS" instance.

Image data in the Rheumatology department is held on a standalone DICOM platform with a single PC as interface to the DICOM database.

It is considered possible to transfer a selection of DICOM images and sample documents to a Document Management System, which would enable these files to be accessible to PICASO. This will be explored further during iterative development of the PICASO solution within UDUS. Most likely the location of these documents and images will be stored as URLs in the ODS and made accessible to clinicians and patients, restricted by the Authentication & Access Control Manager and the inherent security features within the hospital's DMZ.

Visualisation of Patient Health Records

The primary weakness of both these systems is that they are in effect "electronic filing cabinets" through which clinicians can view data one record at a time. There is no visualisation capability showing trends, correlations and pointing towards potential causality between changes in a patient's wellbeing, their medication and other factors.

UDUS has outlined how they would benefit from a visualisation capability – termed the Clinician Dashboard in PICASO. An illustration of how this might look is shown below. Focusing on this requirement will form the basis of how prioritise extracting data from the UDUS clinical systems to be used by PICASO in the first clinical trial.

Example data components of the dashboard include:

- Blood Pressure & Heart Rate readings
- Weight measurements
- Activity & Pain levels
- Patient hospital and GP visits
- History of medication plans

In order to facilitate prioritisation of clinical data and design of the Clinical ODS, IBM has prototyped the Clinical Dashboard using Excel. This will also provide detailed requirements for the main Clinical Dashboard to be developed by TUK.

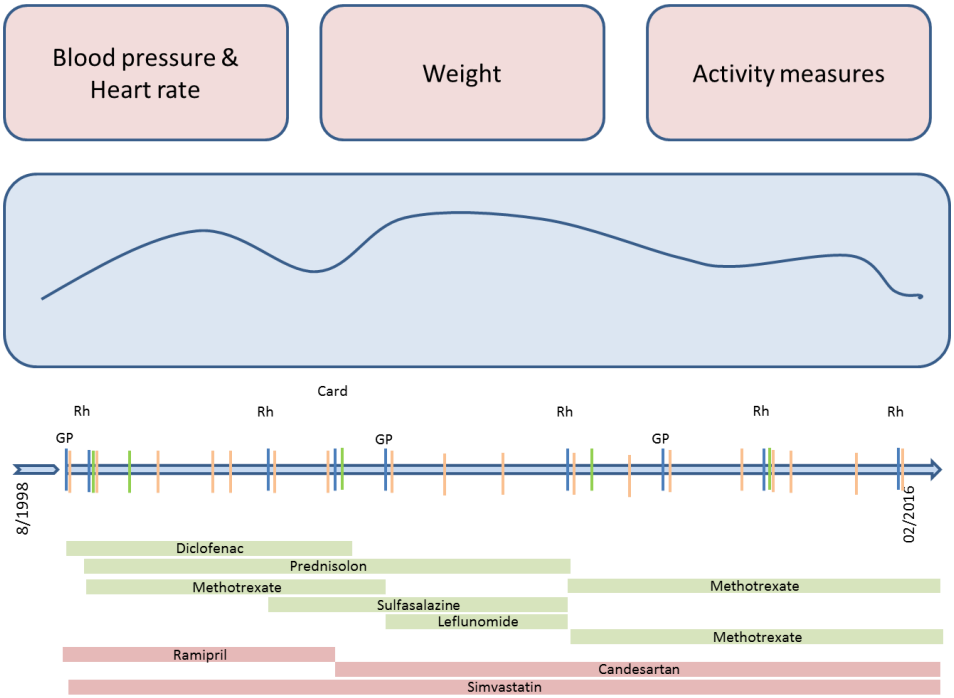

Figure 1: UDUS Clinical Dashboard Mock-up UI

Establishing a complete Electronic Patient Record for PICASO

UDUS already employs a messaging based approach to sharing data between various systems, using an enterprise service bus (ESB) solution built using a Message Broker product called Cloverleaf. PICASO will exploit this existing solution, intercept the messages it is interested in and use these to populate the UDUS ODS.

This Cloverleaf solution will work in conjunction with an open source ETL tool to process messages through creating micro-batches of HL7 messages and loading these into the ODS on a frequent basis – typically every 5 minutes. In this way, the UDUS PICASO ODS will contain almost real-time data updates from the UDUS clinical systems.

LinkWatch remote monitoring observations will most probably use a similar mechanism to load into the ODS, since LinkWatch will also be providing HL7 compliant messages into the Cloverleaf ESB.

Detailed design of the ODS for UDUS will be based on:

- Detailed requirements from the Clinical Dashboard prototype being developed by UDUS and IBM
- HL7 FHIR standards
- The detailed contents of the UDUS HL7 messages
- The detailed contents of the LinkWatch HL7 messages
- Detailed requirements for the Risk Management component

3.1.2 UTV / Santa Lucia Data Investigation & Requirements

Data Requirements

At the outset, UTV viewed data requirements as a transactional exchange of data between clinicians rather than a “Clinical Dashboard”.

Of particular interest was the provision of the complete set of data required to better facilitate the planning, preparation and diagnosis of Nuclear Medicine tests. At the moment all too frequently this information is not available in advance to the Nuclear Medicine clinician resulting in the following issues:

- Preparation for the tests is very lengthy since the Nuclear Medicine clinician must repeat previously taken observations to ensure the correct tests and diagnoses are carried out. The tests can take 4 hours to complete for one visit.
- The patient has not been taken off relevant medication, which can reduce the effectiveness of the tests.
- It's not always possible to plan for the most appropriate tests – for example a glucose-based test might not be suitable if the patient has Diabetes.
- Similar to UDUS, UTV and Santa Lucia want the ability to share DICOM images and clinical documents.

Since the materials have to be pre-ordered and have a limited "shelf-life" (such as radioactive materials), the tests are carried out regardless and resulting diagnosis needs to factor in adjustments for these compromises.

A very detailed spreadsheet was produced for the data investigation at UTV which shows the considerable amount of detailed data that is optimally required, frequently already collected, but rarely available to the Nuclear Medicine clinician. The output from this investigation is available in BSCW on request.

Clinical Data Sources and the ODS design

Much of the work performed in both Santa Lucia and University Hospital of Tor Vergata is only available through documents and images and only a limited amount of data is available as structured data. Indeed, much of the clinical data is available only in paper form.

This represents a significant limitation for a potential PICASO solution without complex mapping and extraction of structured data from these electronic unstructured sources, using technology such as IBM Watson. There is insufficient time and resources for such an approach on PICASO; the technique is anyway already proven elsewhere so does not represent an innovation. It could be considered as a part of a potential long term solution at these two hospitals but for the two Italian hospitals to truly be candidates for a production PICASO solution there is clearly a lot of internal work required on their clinical systems.

One structured data source has been identified at Santa Lucia Hospital; StatView, which is a statistical analysis application used by the clinical department. This is a database that contains a single, very long and growing, record for each Parkinson's Disease patient containing all available clinical data. Where data is available from StatView, this has been mapped to the data attributes defined in the above spreadsheet. The solution has been built by the clinical department in Santa Lucia.

Populating the ODS in UTV and Santa Lucia

Because of these limitations of the clinical systems in these two hospitals, it has been agreed that the hospitals will be solely responsible for populating their Clinical ODSs. IBM will provide the ODS schema, from the detailed requirements based on:

- Clinical Dashboard Requirements (to be provided by TUK and FIT)
- HL7 FHIR standards
- Detailed contents of the LinkWatch HL7 messages
- Detailed requirements for the Rick Management component

3.1.3 LinkWatch IoT Device Observations

As part of the PICASO solution, the CNET LinkWatch platform with gather observations from the various IoT devices deployed at patients' homes and pass them to the main PICASO platform as encrypted messages.

These observations will be stored in the Clinical ODS in the same way as observations taken directly by the clinicians and held in the hospitals' clinical systems.

Cloverleaf will be used as the Message Handler, both receiving the HL7 messages from LinkWatch and processing the messages into the respective ODSs.

3.2 Common Information Model

As mentioned above, the data investigation has resulted in a Common Information Model for PICASO clinical data. The structure of this data is illustrated in the data model below.

As shown in the Data Categories spreadsheet in Appendix A, the data categories identified during Initial Requirements Definition and confirmed as part of Data Investigation have been used to validate the completeness and correctness of the Common Information Model.

At this stage, the Common Information Model is a logical data model. During the design and development of the Clinical ODS, a full data dictionary will be created and this logical model will be developed into the physical model. This will cover any necessary performance improvements for the PICASO prototypes, but also fully populate the data attributes available from the hospitals' clinical systems.

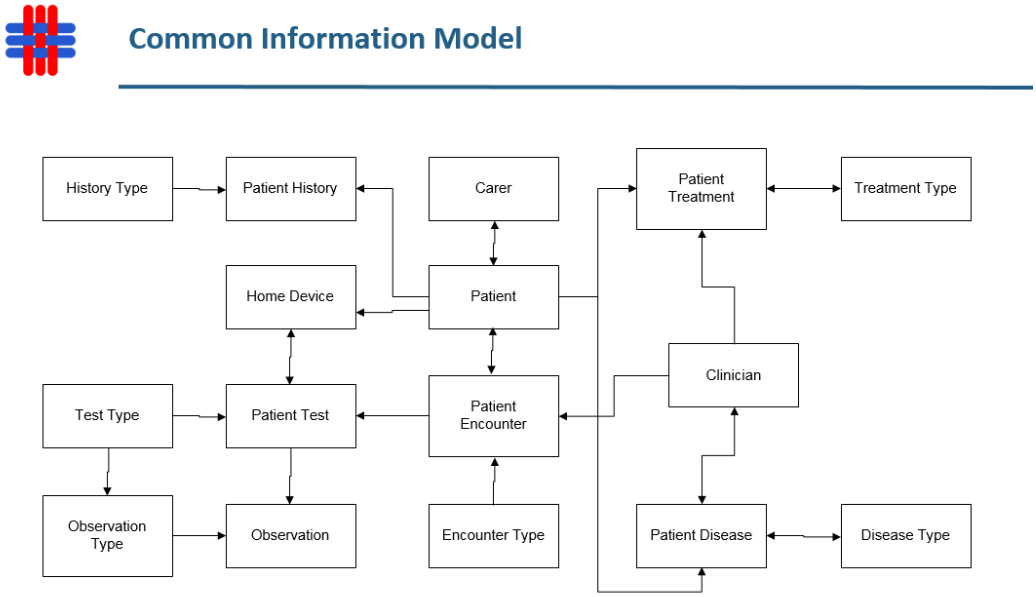

Figure 2: PICASO Common Information Model

3.3 Standards Compliance

Data Investigation has not identified any fully implementable Common Information Models from across the organisations creating European Healthcare Systems standards. Where conceptual models such as the HL7 Reference Information Model overlap with PICASO we have aligned with these standards; such as naming entities such as "Observation" & "Encounter".

Various commercially available models (such as from IBM) are available, but tend to be unsuited to the specific requirements of PICASO and are typically much more complex than PICASO's immediate requirements.

Within the Common Information Model developed for PICASO there is however strong opportunity to comply with the HL7 FHIR standard (http://www.hl7.org/fhir/). This defines the data attributes within an Electronic Patient Record. These attributes, together with any additional ones specifically identified in Data Investigation and missing from the standard will be applied during the design and build phase.

3.3.1 Exchange of Documents using IHE XDS Cross-Enterprise Document Sharing

Cross-Enterprise Document Sharing (XDS) is focused on providing a standards-based specification for managing the sharing of documents between any healthcare enterprise, ranging from a private physician office to a clinic to an acute care in-patient facility and personal health record systems. This is managed through federated document repositories and a document registry to create a longitudinal record of information about a patient within a given clinical affinity domain. These are distinct entities with separate responsibilities.

As XDS is document content neutral, any type of clinical information without regard to content and representation is supported. This makes the XDS IHE Integration Profile equally able to handle documents containing simple text, formatted text (e.g., HL7 CDA Release 1), images (e.g., DICOM) or structured and vocabulary coded clinical information (e.g., CDA Release 2, CCR, CEN ENV 13606, DICOM SR). To ensure the necessary interoperability between the document sources and the document consumers, the XDS Affinity Domain must adopt policies concerning document format, structure and content.

XDS is document exchange protocol to allow 2 different clinical systems to exchange documents. To use XDS an Affinity Domain has to be maintained and it intended to operate as a two way document exchange. PICASO has no need for a two-way document exchange. We are building an ODS which will hold the actual data fed from an ETL tool or we are holding the URL of a document in a document management system. Therefore, we currently have no documents to exchange. This will be revisited later if such requirements emerge.

3.3.2 Data from Devices using IHE PCD Patient Care Device used for Continua Compliant communications

As referenced in the D2.3 PICASO Architecture IHE PCD 01 standard will be used for messages from the patient home devices connected to the LinkWatch when they are sent to the PICASO Message Handler. Details of the message content of the IHE PCD01 are fully specified by the LinkWatch remote monitoring platform and can be mapped to PICASO ODS CIM entities.

As a result of the above, IHE PCD is suitable for PICASO for the input of Linkwatch messages to the Message handler.

3.3.3 Personal Healthcare Monitoring Report (PHMR) using HL7-CDA release 2.0

The HL7 Version 3 Clinical Document Architecture (CDA®) is a document markup standard that specifies the structure and semantics of "clinical documents" for the purpose of exchange between healthcare providers and patients. It defines a clinical document as having the following six characteristics: 1) Persistence, 2) Stewardship, 3) Potential for authentication, 4) Context, 5) Wholeness and 6) Human readability.

A CDA can contain any type of clinical content -- typical CDA documents would be a Discharge Summary, Imaging Report, Admission & Physical, Pathology Report and more. The most popular use is for inter-enterprise information exchange; such as is envisioned for a US Health Information Exchange (HIE).

There are currently no requirements for PICASO to create clinical documents, so this requirement will not be used for now. This will be revisited if such requirements emerge later.

3.4 ODS/ETL implementation

As a result of the Data Investigation carried out at both hospitals, the PICASO project has elected to implement an Operational Datastore approach to the modelling and sharing of Clinical Data.

The Clinical Operational Datastore (described more fully in D2.3 Initial Architecture) is a relational database with a standardised schema and data dictionary, to be used by every hospital using PICASO. The approach is similar to that used in many industries where a central capability links multiple organisations; each with unique IT systems – such as the IBAN system used by the Banking industry.

This approach:

- Standardises the structure of Clinical Data shared through PICASO at all participating hospitals, thereby allowing PICASO to build a common solution for all hospitals without worrying about the specific ways in which each hospital stores and models its own data.
- This in turn standardises the interfaces PICASO has with the Clinical Data, thereby greatly reducing the complexity of the metadata required to make PICASO work, which in turn reduces the risk of exposure of patient data outside the hospitals.
- It also insulates any future central PICASO organisation from changes to a hospital's clinical system, by making it the responsibility of each hospital to present data.
- It insulates the hospitals' systems from PICASO (as required by the Grant Agreement), thereby ensuring both Data Security and Performance of the hospitals' systems can be better protected.

- Provides better scalability; meaning that there does not need to be a potentially vast central PICASO team to manage the interfaces with and changes to each hospital's clinical data sources.
- Supports better Data Governance (as described further in Section 5), wherein the central PICASO team only has to define the standard data dictionary, thereby ensuring that the data presented by each hospital shares a similar meaning and definition across all hospitals. Each hospital will have the responsibility to correctly implement this data dictionary.
- Mean that the role and structure of the Metadata Registry is greatly simplified and removes the need for complex metadata that might allow a hacker to "infer" a patient's identity and medical details, even if they cannot see the actual data.
- Provides a permanent, accessible Datastore after completion of the project for the retention of Linkwatch IoT Device observations and all hospital clinical data used within PICASO. A requirement exists in Germany to retain these observations for 10 years after the completion of PICASO. The requirement needs to be detailed further by the Ethical Committee, including whether there are similar requirements in Italy. This requirement will therefore be addressed at a later stage in the project.
- Taking an ODS approach also brings a secondary benefit for the hospitals since it provides a single physical source of Electronic Patient Data, joined from the multiple and disparate systems typically in use within a large hospital. This becomes a more accessible source for data visualisation and analytics purposes within the hospital – privacy constraints permitting.

Taking this approach, each hospital would have responsibility for developing the ETL code to extract data from their existing systems, transform it into the common format and meaning used by PICASO and then loading it to the ODS. Again, these techniques are common standards in many industries and is part of the intention of the HL7 standards.

4 Data Security & Privacy

4.1 Data Security

4.1.1 Principle of non-duplication of clinical data

The PICASO Grant Agreement has a stated underlying principle to store clinical data in one place and share it wherever it is needed and permitted by patient consent. In addition, the Grant Agreement states that direct access to the hospitals' clinical systems is not permitted, for the reasons described in Section 3.4 above.

As described in D2.3 Initial Architecture, clinical data will only persist in the Clinical ODSs at each hospital. For practical operational reasons, LinkWatch IoT Device observations will reside on the LinkWatch Home Hub until such time as they are confirmed to have been successfully stored in the Clinical ODS.

Note that as per task 5.1 of the Grant Agreement, where multiple clinicians all request the same types of observations from a patient via the LinkWatch IoT devices, each clinician/hospital will receive and store these same readings in their ODS. This apparent conflict in the non-duplication of data still needs to be resolved by the project.

4.1.2 Actor Tokenisation

The project is adopting a tokenisation approach for all actors using PICASO. This means that:

- Where Patient-related data; such as Patient Pathways and LinkWatch IoT Device observations can only be related to an actual patient inside the hospital when accessing the data through a PICASO application
- Similarly, all Alerts and Events generated by PICASO can only be related to the Clinician, Patient or Carer through PICASO applications. In this case, Patients and Carers will access the PICASO Patient Dashboard through an https web interface. Any translation of actor tokens will still need to happen within the hospital environment that is processing the actor's request.
- As defined in the Open EHR Architecture standard, actor tokens will be stored by each hospital in a separate database and server from the Clinical ODS, thereby further protecting actors' identities and data were one of the servers' security is breached.

4.2 Data Privacy

The Data Privacy approach is based on the following principles:

- It is assumed that authentication and access control is at the professional carer / informal carer / data type / hospital level for a given patient, which means that it's not necessary to create a new privacy entry when new data records are added to the ODS. However, new privacy entries will be required as new data types / carers / hospitals are added to the system.
- Consent for the above can be provided once by the patient for each clinician, data type or hospital. The details depend on the granularity of the authentication and access controls which are being implemented by Task 5.4 based on the requirements obtained in subtask 2.2.2. The Ethical Board still needs to confirm this approach, but it is the working assumption for now.
- The approach will be compliant with current German & Italian privacy laws as well as GDPR. PICASO will provide a summary of how we have interpreted these laws.
- All requests to access clinical data will be controlled by a tokenised actor id; be it a clinician, patient or carer accessing the data.
- Patients will determine which professional carers can see which of their data types. This can be implemented through the informed consent. In a final implementation, it will be desirable to enable the patient to give and revoke consent electronically (if and as permitted by applicable laws).
- Informal carer access is managed by the patient itself through the patient portal. The patient dashboard integrates a functionality which allows patients to grant and revoke access of informal carers, and to specify which informal carers shall have access to what data types (e.g. appointments, medication

plan, LinkWatch data). The Activity Logs can be used to provide a patient – upon request and within a reasonable time– with the information about “who has viewed my data”. The data will be collected from the different activity logs, when the patient requests it..

- PICASO provides data from various sources which means that various levels of confidence or trust can be placed in the accuracy of data. In particular, LinkWatch activity data will be shared between hospitals “as is”. Therefore, the source of this data (and of any derived data e.g. a risk scores) must be marked clearly when this data is displayed to clinicians e.g. “based/based in part on patient home monitoring data”.
- The clinicians are informed wherever PICASO has additional patient data, access to which the patient has not provided consent. The PICASO ethics committee will need to suggest what solutions can be acceptable to avoid that a patient feels pressured to make data available against his will.
- PICASO will ensure that trial patients can *revoke access* to their data partially and/or completely. PICASO will *delete* trial patient data from the PICASO system *only* upon request by the hospitals which must ensure that their requests are compliant with all applicable trial and/or clinical data retention policies.

5 Data Governance

Data Governance for solutions such as PICASO involve several dimensions, each of which can lead to misinterpretation of data by an unsuspecting user.

5.1 Key Challenges

5.1.1 Standardised Data Definition

Data of apparently similar meaning can in fact mean subtly and sometimes profoundly different meanings. Without a common, understood definition, such misinterpretations could have drastic consequences, lead to lack of trust in the data and laborious checking and double checking before the data is believed.

5.1.2 Data Quality and Trust

Data Quality will vary between hospitals, departments and even between clinicians. The introduction of LinkWatch IoT observations may further challenge Data Quality, since clinicians will not be directly supervising the use of the IoT devices.

Currently clinicians instinctively know how or use their judgement to factor in the risk that the data they are looking at is wrong. The more widely available data sources are through PICASO, the lower their confidence can become, ultimately risking that PICASO becomes untrusted and useless.

5.1.3 Different Coding Systems

The use of different data coding systems such as SNOMED and ICD10, together with varying nomenclatures for Medications across hospitals may lead to confusion and mistakes.

UDUS already experiences challenges with pharmacies and insurance companies issuing different medication to patients than that prescribed. This problem is augmented by the use of different coding systems in these organisations, thereby complicating the assessment of the impact of these issues.

5.2 Impact on the Clinical Trials and Assessment

While the PICASO project will start the process of standardising data definitions through the implementation of a Common Information ,Model and ODS schema at all three hospitals, the limited number of hospitals involved in PICASO will hide many of the true challenges associated with trying to address these challenges.

As part of the assessment of the clinical trials, similar experience across the Healthcare and other industries will be considered to extrapolate the likely impact on a production PICASO solution with many participating hospitals and clinics.

6 Activity Logging of Data Creation & Access

As part of the design of the PICASO solution, a key requirement is the logging of critical data creation and access events.

PICASO will:

- Log all LinkWatch IoT device observations sent by LinkWatch to PICASO and stored in the respective hospital's ODS.
- Log all data access requests and receipts between the PICASO platform instances and the Clinical ODSs, including whether or not the request was fulfilled or rejected based on Privacy or Policy constraints.
- Log changes to Patient consent for authentication & access control of data
- Log all activity managed through the Narratives Manager component

The primary purpose of the Activity Logs is to provide the means to analyse situations where perhaps the clinical treatment has gone wrong, or conversely has gone very well. The activity logs together with the Resource Data Browser will provide the means to review precisely what data was seen by different actors at different times, thereby providing the means to in effect recreate PICASO events.

Other possible uses include statistical analysis of PICASO activities such as patient adherence to taking home measurements or medication.

PICASO will not:

- Maintain a log of changes/additions to the clinical data inside the hospitals' own clinical systems, nor the sharing of that data to PICASO from the Clinical ODS.

7 Data Orchestration Approach

The sharing of data between different actors (and in particular between different hospitals) will happen at runtime, as part of the execution of the PICASO applications.

Duplicated data will at no time persist in any location other than the datastores of the "owning" hospital or institution. Furthermore, in order to ensure correct activity logging (as described in Section 6), data shared by one hospital with another will not be cached in any part of PICASO. These rules are defined in more detail in D2.3 Initial Architecture.

The logical approach agreed for how data requests and sharing will work in PICASO are illustrated in the following diagram.

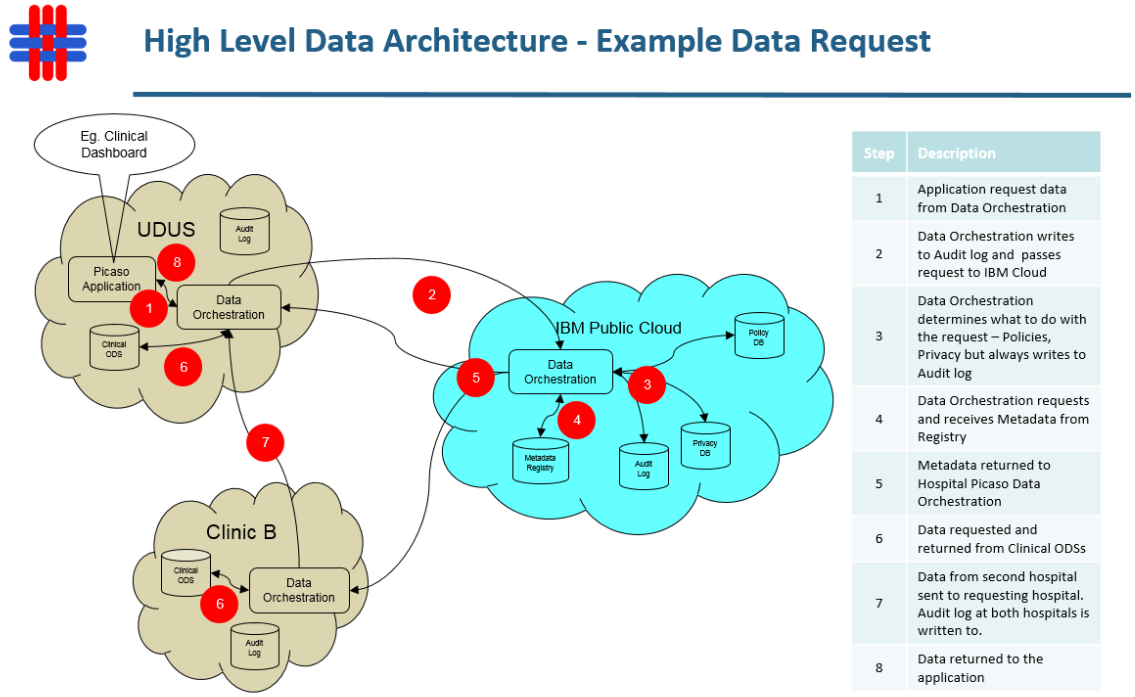

Figure 3: Example Data Requesting Processing Flow

This diagram was used in the Data Protection discussions between the project team and UDUS and UTV IT and Data Protection teams. The approach has in principle been agreed as providing adequate data protection for the hospitals' data.

8 List of Figures and Tables

8.1 Figures

9 Appendix A – Data Categories

Note that references to Picaso in the CIM Entity column refer to data categories that are created within PICASO and not stored in the Common Information Model.

Data Category	CIM Entity
Alerts for potential conflicts with the existing medication	Picaso
Anamnesis (health/medical history)	Patient History
Appointment details	Patient Encounter
Approval of change in prescription	Patient Treatment
Blood test results	Observation
Care plan	Patient Treatment
Clinical conference conclusions	Patient Encounter
Clinical notes/suspected diagnosis	Patient Encounter
data handling in PICASO	Picaso
data is outside the thresholds defined by the GP/Specialists	Picaso
definition of access rights.	Picaso
Descriptions of events, their cause context and time	Patient Encounter
Diagnosis	Patient Encounter / Patient Disease
Education plan	Patient Treatment
Educational material	Patient Treatment
Ergo-therapy data (what the patient has done for treatment frequency and the results)	Observation
Ergo-therapy Report	Patient Encounter
Exercise plan	Patient Treatment
Image data X-rays photographs PET ECG MRI DAS28 DEXA Ultra-sound scans	Observation
Image instructions (type of scanning and what to look for)	Patient Encounter
Images reports	Patient Encounter / Observation
Instructions advice recommendations (e.g. diet etc.)	Patient Treatment
journal entering	Picaso
Lab results	Observation
Level and Activity of RA	Observation
Medical events: physical parameters well being pains are not as expected side effects of medication is seen / detected	Patient Encounter / Patient Observation
Medication instructions	Patient Treatment
Medication list	Patient Treatment
Medication Plan	Patient Treatment
Medication Plan history	Patient Treatment
Medication review notes	Patient Encounter
Medication withdrawal (necessary for the scan)	Patient Treatment
Medicine plan	Patient Treatment
Medicine prescription	Patient Treatment
Narratives for execution interventions either manually or automatic.	Picaso
Narratives for execution of the event monitor service.	Picaso

Narratives for how to handling the event when it is raised	Picaso
Occupational physician report (workability assessment)	Patient Encounter
Patient behavioural data	Observation
Patient generated data Perform drug intake	LinkWatch
Patient Health data and compliance reporting	Patient Encounter / Observation
Patient pathway definition	Picaso
Patient pathway instructions	Picaso
Patient: Additional patient information (e.g. patient profile/personality social situation)	Patient
Patient: Environmental data from home monitoring (temperature light levels)	LinkWatch
Patient: Event data from home monitoring (falls non-compliance changes exercise water)	LinkWatch Patient Encounter / Observation
Patient: Informal carer generated Data Remind patient about drug intake	LinkWatch Patient Treatment
Patient: Informal carer generated Data Setup thresholds for drugs intake deviations	LinkWatch
Patient: Informal carer health data measurement and compliance reporting	LinkWatch Patient Encounter / Observation
Patient: no data is collected	Picaso
Patient: Physiological data from home monitoring (pulse weight ECG)	LinkWatch Patient Encounter / Observation
Patient: Physiological scalar measurements (weight blood pressure heart rate)	LinkWatch Patient Encounter / Observation
Patient: PICASO Home Network generated data Drug intake by patient	LinkWatch Patient Encounter / Patient Observation
Patient: PICASO Home Network generated data Drug intake reminder	LinkWatch
Patient: PICASO Home Network generated data Missing drug intake	LinkWatch
Patient: Raise issues with the home monitoring platform	LinkWatch
Patient: Remote Monitoring Health motion activity and behavioural data from the patient's home	LinkWatch Patient Encounter / Observation
Patient: Test scores patient-reported questionnaires and their scores	LinkWatch Patient Encounter / Observation
Pension claims.	-
Photo of joints	LinkWatch Patient Encounter / Observation

Physician generated data Contact informal carer regarding missing or unstable drug intake	Picaso
Physician generated data Contact patient regarding missing or unstable drug intake	Picaso
Physician generated data Setup thresholds for drugs intake deviations	Picaso
PICASO support log	Picaso
PICASO support log feedback	Picaso
Prescription for PD medication	Patient Treatment
Prescription of CVD medication	Patient Treatment
Prescriptions	Patient Treatment
RA progression report	Patient Encounter
Referral to the cardiologist (type of PD what to look for)	Patient Encounter
Referral to the nuclear medicine physician (type of scan what to look for)	Patient Encounter
Referral to Neuropsychologist	Patient Encounter
Reimbursement claim (to Insurance company)	-
Rejection of request for change in prescription	Picaso
Report from the neuropsychologist/psychiatrist	Patient Encounter
Report on patient's workability	Patient Encounter
Report regarding problem reported by users e.g. patients informal cares and professional carers	Picaso
Report/referral from GP	Patient Encounter
Request for change in prescription (Physician ? Physician)	Picaso
Resource events: persons (carers patients relatives and resources) are not in place or at times as expected. Resource persons shall be easily re-assignable during service execution in case of illness and vacation.	Picaso
Result and report of the complete CVD examination to the clinical neurologist	Patient Encounter
Result reports (initial and follow-ups)	Patient Encounter
Scheduled appointments (location date time information on what to bring)	Patient Encounter
Support to users e.g. patients informal cares and professional carers	Picaso
Symptoms description	Patient Encounter
Time resolved measurements (ECG exercise)	LinkWatch
Time schedules	LinkWatch
Treatment plan	Patient Treatment
Trial information	Picaso
trial informed consent form	Picaso
Verbal data (Contextual symptoms examination objectives and conclusions)	Patient Encounter