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C3-Cloud

"A Federated Collaborative Care Cure Cloud Architecture for Addressing the Needs of Multi-morbidity and Managing Poly-pharmacy"

PRIORITY Objective H2020-PHC-25-2015 - Advanced ICT systems and services for integrated care

D2.1 Data Management Plan

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ABBREVIATIONS AND ACRONYMS

Abbreviation/Acronym	Definition
CDS	Clinical Decision Support
C3DP	Coordinated Care and Cure Delivery Platform
DMP	Data Management Plan
eCCIS	eCare Client Impact Survey
eCUIS	eCare User Impact Survey
EHR	Electronic Health Record
GDPR	General Data Protection Regulation
FHIR	Fast Healthcare Interoperability Resources
MDT	Multidisciplinary team
PEP	Patient Empowerment Platform
QUIS7	Questionnaire for User Interface Satisfaction
SIS	Semantic Interoperability Suite
TIS	Technical Interoperability Suite
UTAUT	Unified Theory of Acceptance and Use of Technology

1. EXECUTIVE SUMMARY

This document is the Data Management Plan for the C3-Cloud project. Its purpose is to provide an inventory of the kinds of data that are being generated within the project. For each category, this document indicates: where and how the data are generated; their purpose; whether they are personal data or not; how they are safeguarded; and what opportunity there might be for data sharing and wider reuse of the data beyond the project.

The reason for this deliverable is to align with the EC ambition to promote wider sharing and reuse of data generated by its funded research projects, in order to grow the scale of data reuse and research potential across Europe. All of the partners support that ambition, and the consortium has examined carefully what opportunities might exist to make data assets of the project available to others downstream.

A significant amount of the data generated in the project is personal data, captured through the evaluation studies at the three demonstration sites within the consortium, in the UK, Spain and Sweden. The nature of the ethical approvals granted at the sites, and the patient consent that will be obtained, do not permit this information to be shared at subject level, even if anonymised, beyond the pilot sites. Similar constraints apply to evaluation questionnaires completed by study participants. These will be collected anonymously, online, by the lead evaluation partner.

Aggregated research results will be shared beyond the project. The interim and final evaluation results will be made available in the public deliverables D9.5 and D9.6. These results will also be included within academic publications, and in supplementary data submitted online to the journals which publish our papers. The consortium will make every effort to curate an openly shareable set of useful aggregated data results and find appropriate channels, whereby these can be discovered and accessed.

This deliverable presents a summary template for each of the eight categories of data that we have identified being generated and handled within the project, as summarised in Table 1 within the main text of the document. The templates themselves provide a high-level summary of the approach being taken. More detailed documents on information governance, information security and the evaluation methodology of the project are given in other deliverables.

2. INTRODUCTION

2.1. Open Research Data in Horizon 2020

The European Commission defines open research data as "the data underpinning scientific research results that has no restrictions on its access, enabling anyone to access it."[1]

The Commission is running a pilot on open access to research data in Horizon 2020: the Open Research Data (ORD) pilot. The pilot aims to improve and maximise access to and re-use of research data generated by Horizon 2020 projects, taking into account:

- the need to balance openness and protection of scientific information
- commercialisation and intellectual property rights
- privacy concerns
- security
- data management and preservation questions

Participating projects are required to develop a Data Management Plan, in which they must specify what data will be open.

2.2. Open Research Data in C3-Cloud

The partners of the C3-Cloud consortium are strongly supportive of open access and to the principles of open data, data sharing, reusing data resources and research transparency. The Open Research Data pilot clearly states the need to balance openness and protection. In the case of C3-Cloud, this protection relates to the protection of privacy, and not to the protection of partner interests or exploitation potential. The reason for the latter not being a concern is because C3-Cloud intends to exploit its foreground software but not any knowledge derived from data (which will be openly published).

However, the validation of C3-Cloud's implementation takes place in three healthcare pilot sites that will collect and use personal data. The project will primarily respect conformance to the EU GDPR above any wish to make research data openly accessible. The consortium has considered carefully the legal basis on which pilot site data will be collected, how they will be processed and what may be retained post-project. It has concluded that it will not be possible to provide individual level data as an open access resource to the research community. Because these patients will have potentially unusual combinations of disease and other clinical characteristics, the project has concluded that anonymised patient-level data cannot be published as open access data. However, aggregate data that shows the utilisation and benefit of using C3-Cloud solutions will be published, as described further in Section 8. The majority of the data will remain locally held at each pilot site, retained for continuity of care and medico-legal purposes, and will not exist as a central project resource.

This deliverable is the C3-Cloud Data Management Plan. It outlines each of the different kinds of data that the project will generate, how each will be managed and protected, and what potential exists for the wider use of the data beyond the project. This analysis is presented as a series of tables, one per category of data.

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[1] https://ec.europa.eu/info/research-and-innovation/strategy/goals-research-and-innovation-policy/open-science/open-science-monitor/facts-and-figures-open-research-data_en

2.3. Categories of data

Table 1 below lists eight categories of data that are being generated within the C3-Cloud project. The data management plan for each of these eight is provided as a template in the following eight sections of this document.

Category	Description
1	Patient-level clinical data, fully identifiable, to be created and used within each pilot sites exclusively for patient care, and troubleshooting by technical partners.
2	Patient-level clinical data, anonymised, for use in the development of the discrete event simulation tool.
3	Anonymous, individual questionnaire responses on the C3-Cloud users' perception of the usability, satisfaction and acceptability of the C3-Cloud components.
4	Anonymous, individual data summarising various aspects of system usage statistics, shared from each pilot site with Empirica, the evaluation lead partner. The pilot sites will be supported by the technical partners in extraction of this data from the C3-Cloud platform.
5	System audit logs and other reporting information that assist technical partners with monitoring and evaluation the performance of technical components.
6	Analysed aggregated data processed by Empirica and shared with the full consortium as the study results, for inclusion in deliverables and publications. Scientific reports of the aggregated results in journals and as European Commission deliverables will be published as open data.
7	Knowledge assets created within the project to populate components (e.g. harmonised multi-condition guidelines) in human readable and computable formats and might be reusable after the project, by others.
8	Educational resources that were created during and used in the pilot study and might be reusable after the project, by others.

Table 1: Categories of C3-Cloud generated data covered by this DMP

3. IDENTIFIABLE PATIENT LEVEL DATA

The pilot sites will collect healthcare and care planning data on enrolled patients, collected by patients, informal caregivers and healthcare providers who will use C3-Cloud components to enter and review the data. Some data will have been imported directly into C3-Cloud components from existing electronic health record (EHR) systems.

Template for reporting the C3-Cloud Data Management Plan
For what category (1-8) above does this template apply
1. Patient level clinical data, fully identifiable, to be created and used within each pilot site exclusively for patient care and troubleshooting by technical partners.
What kind of data is being collected or processed (high-level description)
Patient-level demographic and clinical data, fully identifiable, to be collected and used within each pilot site exclusively for patient care, and accessed by specific agreement by technical partners for troubleshooting.
For what purposes are the data being processed in C3-Cloud
Direct patient care.
Where do the data originate (which party or which system creates the data?)
The data are taken primarily from the EHRs of the pilot sites through direct electronic interfaces or through data extracts. Data is also entered manually into the C3-Cloud system by healthcare professionals and patients.
Are the data personal or not (i.e. are they identifiable, pseudonymous, anonymous, aggregated) **- at the point of origin** **- when shared within the project**
Data are identifiable at all stages.
What is the legal basis for C3-Cloud to process the data if it is personal according to the GDPR? (e.g. is it with participant consent.) State "Not applicable" if the data are not personal.
Consent will be obtained from all patients and healthcare professionals to access their personal information prior to the start of the study, after ethical approval has been obtained.
With which parties will the data be shared within the consortium?
Only healthcare professionals who are directly involved with the care of the patient will access identifiable data about patients in the C3-Cloud system. Pilot sites will only have access to their own data, not the data of other pilot sites. With the appropriate data processing agreements in place, C3-Cloud technical partners may access identifiable data when providing support and maintenance to the system. Requirements for access will be assessed and authorised on a case by case basis, i.e. access to data in the system will not be permanently enabled.
Where and for how long data will be stored, under which partner's control?
Data will be stored by the pilot sites according to the pilot sites' own legal requirements. Secure destruction of the data will take place after this. A patient's C3-Cloud record may be extracted as a PDF file and attached to the patient's record in the appropriate EHR at the end of the study.
What downstream derived data will be created from this category of data, if any?

Aggregated data will be used to support the evaluation of outcomes (Section 8).
What post-project data reuse is expected outside of the consortium, if any?
None

4. ANONYMISED PATIENT-LEVEL DATA

Anonymised patient data from all three pilot sites will be used for discrete event simulations for predictive modelling of large-scale impact assessment. The data originates from local EHRs and from the C3-Cloud system.

Template for reporting the C3-Cloud Data Management Plan
For what category (1-8) above does this template apply
2. Patient-level clinical data, anonymised, for use in the development of the discrete event simulation tool.
What kind of data is being collected or processed (high-level description)
Anonymised, patient-level demographic and clinical data. These will be extracted from local EHR systems - the pilot sites will be supported by the technical partners in the processes how this data can be extracted from the EHRs. Data will also originate from the C3-Cloud system.
For what purposes are the data being processed in C3-Cloud
To develop, validate and run the discrete event simulation-based modelling tool.
Where do the data originate (which party or which system creates the data?)
EHR extracts from the local systems of pilot sites and C3-Cloud FHIR repository.
Are the data personal or not (i.e. are they identifiable, pseudonymous, anonymous, aggregated) - at the point of origin **- when shared within the project**
The data will be anonymous at the point of origin. The data will be anonymous when sharing within the project.
What is the legal basis for C3-Cloud to process the data if it is personal according to the GDPR? (e.g. is it with participant consent.) State "Not applicable" if the data are not personal.
Not applicable
With which parties the data will be shared within the consortium?
Aggregated data will be shared as results in several public deliverables.
Where and for how long data will be stored, under which partner's control?
Retained securely by University of Warwick for a minimum of ten years.
What downstream derived data will be created from this category of data, if any?
The results of large-scale impact modelling of the C3-Cloud application by evaluating the estimated/predicted impact of C3-Cloud application.
What post-project data reuse is expected outside of the consortium, if any?
The data will be used for the predictive modelling for the project. No re-use is planned.

The variables that will be used are detailed below:

Data item	Value
Patient age	54 or younger 55-59 60-64 65-69 70-74 75-79 80-84 85-89 90 or older Missing value
Patient sex	male female other Missing value
Patient location	Basque Country, Spain Region Jämtland Härjedalen, Sweden South Warwickshire, UK Missing value
Technology trial group	Intervention group Control group Missing answer
Has the patient an informal caregiver?	Yes No Missing value
Diabetes Melltitus Type II diagnosed?	Yes No Missing value
Heart failure in compliance with NYHA I-II diagnosed?	Yes No Missing value
Renal failure with estimated or measured Glomerular filtration rate GFR of 30-59 diagnosed?	Yes No Missing value
Mild or moderate depression diagnosed?	Yes No Missing answer
For intervention patients: Did patient drop out?	Yes No Missing value
Dropout because of death?	Yes No Missing value
Dropout date	- Insert Date - Missing value
List of all drugs prescribed or administered during C3-Cloud trial period, in relation to the four inclusion health conditions. All fields required for each drug.	Drug name ATC classification code Drug doses Number of days that the drug was prescribed Missing value

Data item	Value
List of all contact dates between the patient and the primary care doctor at the care centre.	List of dates per patient Missing value
List of all remote contact dates between the patient and the primary care doctor.	List of dates per patient Missing value
List of all home visit dates between the patient and the primary care doctor.	Date Missing value
List of all contact dates between the patient and the primary care nurses at the care centre.	List of dates per patient Missing value
List of all remote contact dates between the patient and the primary care nurses.	List of dates per patient Missing value
List of all home visit dates between the patient and the primary care nurses.	List of dates per patient Missing value
List of all contact dates between the patient and the cardiologist / cardiology department.	List of dates per patient Missing value
List of all contact dates between the patient and the endocrinologist / endocrinology department.	List of dates per patient Missing value
List of all contact dates between the patient and the nephrologist / nephrology department.	List of dates per patient Missing value
List of all contact dates between the patient and the psychiatrist / psychology department.	List of dates per patient Missing value
List of all contact dates between the patient and the internal specialist / internal medicine department.	List of dates per patient Missing value
List of all contact dates between the patient and the Accident and Emergency department (A&E services).	List of dates per patient A&E diagnosis (ICD-10) Missing value
List of all periods when a patient was hospitalized.	Admission date Discharge date Admission diagnosis (ICD-10) Missing value
List of all periods when a patient was home hospitalized.	Start date End date Main diagnosis (ICD-10) Missing value
For control patients: Did the patient leave the region (loss to follow up)?	Yes No Missing value

5. ANONYMOUS QUESTIONNAIRE RESPONSES

Pilot site patient participants, informal caregivers and healthcare professionals will all complete evaluation questionnaires during the technology trial, about their experience of using the C3-Cloud solution. These will be anonymous data at the point of capture.

Template for reporting the C3-Cloud Data Management Plan
For what category (1-8) above does this template apply
3. Anonymous, individual questionnaire responses on the C3-Cloud users' perception of the usability, satisfaction and acceptability of the C3-Cloud system.
What kind of data is being collected or processed (high-level description)
Anonymous, individual questionnaire responses on the C3-Cloud users' perception of the usability, satisfaction and acceptability of the C3-Cloud.
For what purposes are the data being processed in C3-Cloud
To evaluate usability, satisfaction and acceptability of the C3-Cloud components.
Where do the data originate (which party or which system creates the data?)
Survey responses (data) is created by patients, their informal caregivers and MDT members in all three pilot sites on an online questionnaire platform hosted on Empirica servers (called "LimeSurvey").
Are the data personal or not (i.e. are they identifiable, pseudonymous, anonymous, aggregated) **- at the point of origin** **- when shared within the project**
The data will be anonymous at the point of origin with four stratifiers: Age group (5-year ranges), sex, region, user category (MDT or patient). The data will be aggregated when sharing within the project.
What is the legal basis for C3-Cloud to process the data if it is personal according to the GDPR? (e.g. is it with participant consent.) State "Not applicable" if the data are not personal.
Not applicable
With which parties the data will be shared within the consortium?
Aggregated data will be held by Warwick for long-term storage. Aggregated data will be shared as results in several public deliverables.
Where and for how long data will be stored, under which partner's control?
Retained securely by University of Warwick for a minimum of ten years.
What downstream derived data will be created from this category of data, if any?
Questionnaire data will be aggregated and presented in several deliverables.
What post-project data reuse is expected outside of the consortium, if any?
The data is used to evaluate the usability, satisfaction and acceptability of the C3-Cloud solutions only. No re-use is planned.

The following table lists the questionnaires that will be completed by study participants. The full questionnaire questions are reported in deliverable D9.2.

Survey	**Questionnaires included in the survey**
First survey for patients – Survey for all patients	Baseline - UTAUT patients (acceptability of C3-Cloud)
Second survey for patients	Study end - UTAUT patients (acceptability of C3-Cloud)
Detailed survey for 50 patients (number 1) – survey for 150 layer 3 patients	Baseline - Patient Questionnaire (usefulness of C3-Cloud for care planning and empowerment) Baseline - QUIS7 Patients (Usability questionnaire) Baseline - Patient Material Output (Evaluation of training material) (video, information leaflet wallet card)
Detailed survey for 50 patients (number 2) – survey for 150 layer 3 patients	Study end - Patient Questionnaire (usefulness of C3-Cloud for care planning and empowerment) Study end - QUIS7 Patients (Usability questionnaire) Study end - eCCIS patient (System satisfaction questionnaire) Study end - Patient Material Outputs (Evaluation of training materials (Leaflets and web pages as well as peer support groups)
First survey for MDTs – survey for all MDTs (layer 3 and 4)	Baseline - UTAUT MDT (acceptability of C3-Cloud) Baseline - QUIS7 MDTs (Usability questionnaire)
Second survey for MDTs - survey for all MDTs (layer 3 and 4)	Study end - MDT Questionnaire (usefulness of C3-Cloud for care planning and empowerment) Study end - UTAUT MDT (acceptability of C3-Cloud) Study end - QUIS7 MDTs (Usability questionnaire) Study end - eCUIS MDT (System satisfaction questionnaire)
First survey for informal caregivers	Baseline - eCCIS informal caregivers (System satisfaction questionnaire)
Second survey for informal caregiver	Study end - eCCIS informal caregiver (System satisfaction questionnaire)
Survey about sensor device usage for patients	Study end - Device usage patients (feasibility study to show usage of data from multiple sources)
Survey about sensor device usage for MDTs	Study end - Device usage MDTs (feasibility study to show usage of data from multiple sources)

6. ANONYMOUS USAGE DATA

Since the C3-Cloud components will log the entry of new data in all modules, and have audit trails that monitor access as well as data creation, there will be data that tracks when and how each user has used the system. This will complement the evaluation questionnaire data to provide insight into the use made of C3-Cloud by different actors.

Template for reporting the C3-Cloud Data Management Plan
For what category (1-8) above does this template apply
4. Anonymous, individual data summarising various aspects of system usage statistics, shared from each pilot site with Empirica. The pilot sites may be supported by the technical partners in the processes how this data can be extracted from the C3-Cloud platform.
What kind of data is being collected or processed (high-level description)
Anonymous, individual d**ata summarising various aspects of system usage statistics**.
For what purposes are the data being processed in C3-Cloud
To evaluate frequency of use and effectiveness of C3-Cloud components.
Where do the data originate (which party or which system creates the data?)
FHIR repository extracts at the pilot sites.
Are the data personal or not (i.e. are they identifiable, pseudonymous, anonymous, aggregated) - at the point of origin **- when shared within the project**
The data will be anonymous at the point of origin with four stratifiers: Age group (5-year ranges), sex, region, user category (MDT or patient). The data will be aggregated when sharing within the project.
What is the legal basis for C3-Cloud to process the data if it is personal according to the GDPR? (e.g. is it with participant consent.) State "Not applicable" if the data are not personal.
Not applicable
With which parties the data will be shared within the consortium?
Anonymous data will be shared with Warwick for long-term storage. Aggregated data will be shared as results in several public deliverables.
Where and for how long data will be stored, under which partner's control?
Retained securely by University of Warwick for a minimum of ten years.
What downstream derived data will be created from this category of data, if any?
None anticipated, the data will be examined internally to monitor system usage and behaviour
What post-project data reuse is expected outside of the consortium, if any?
FHIR data on system usage and effectiveness will be used only for the reporting within the project. No re-use is planned.

The usage data are responses to the following questions:

- From which pilot site does the FHIR repository data originate?
- When did the technology trial start at the pilot site?
- When did the technology trial end at the pilot site?
- What is the number of CDS-detected disease-disease interactions at the pilot site over the project time?
- What is the number of CDS-detected disease-drug and drug-disease interactions at the pilot site over the project time?
- The number of CDS-detected drug-drug contraindications at the pilot site over the project time? The different types of drug-drug contraindication classifications are: "to be avoided, used with caution, requires monitoring, other considerations, contraindicated, save to use, not recommended"
- What is the number of all digital PEP communication messages between a patient and their MDT (per patient)?
- Reason for dropout
- What C3DP feedback regarding the CDS was received from clinicians through feedback function?
- List the care plan goals per patient that were defined, including its status (e.g. 'in progress'; 'achieved', 'rejected').
- List each type of care plan activity from the activities taxonomy that was prescribed on the patients' care plans and the number how often it was prescribed during the trial.
- List each care plan activity title that was prescribed on the patients' care plans manually (not from the taxonomy).
- List care plan goal title from the goals taxonomy that was defined on the patients' care plans and the number how often it was defined during the trial.
- List each care plan goals title that was defined on the patients' care plans manually (not from the taxonomy).
- What is the conformance level of prescribed and performed weight self-measurements?
    - Extract the weight measurement activity attribute and the linked measurements coming from the patient.
- What is the conformance level of prescribed and performed glucose level self-measurements?
    - Extract the glucose measurement activity attribute and the linked measurements coming from the patient.
- What is the conformance level of prescribed and performed blood pressure self-measurements?
    - Extract the blood measurement activity attribute and the linked measurements coming from the patient.
- What is the conformance level of prescribed and performed heart rate self-measurements?
    - Extract the heart rate measurement activity attribute and the linked measurements coming from the patient.
- What is the average care team member session duration per month?

7. SYSTEM AUDIT LOGS

In addition to the usage data referred to in the previous section, the audit logs will contain more detailed system and actor activity records that may serve to detect or investigate errors, and other issues with the software and networks.

Template for reporting the C3-Cloud Data Management Plan
For what category (1-8) above does this template apply
5. System audit logs and other reporting information that assists technical partners with monitoring and evaluation the performance of technical components.
What kind of data is being collected or processed (high-level description)
In C3-Cloud each Create, Read, Update or Delete (CRUD) activity performed in the C3-Cloud FHIR Repository (where patient data collected from local care systems via Technical Interoperability Layer (TIS) and Patient Empowerment Platform (PEP) and care plan being created and managed by Coordinated Care and Cure Delivery Platform (C3DP) are stored) are audited to an Audit Record Repository in conformance to IHE ATNA Profile. In addition to this, each component: TIS, SIS, C3DP and PEP has its own local system logs.
For what purposes are the data being processed in C3-Cloud
The Audit Record Repository logs are stored and processed to ensure accountability. The system logs are utilized for logging errors, and performance issues.
Where do the data originate (which party or which system creates the data?)
The audits of the CRUD activities on top of the C3Cloud FHIR repository are created by C3Cloud FHIR repository. Apart from that each component (i.e. TIS, SIS, C3DP and PEP) creates its own system logs.
Are the data personal or not (i.e. are they identifiable, pseudonymous, anonymous, aggregated) **- at the point of origin** **- when shared within the project**
The data stored in audit logs in the audit record repository may contain patient and professional identifiers. System logs kept for logging errors and performance issues do not contain identifiable data.
What is the legal basis for C3-Cloud to process the data if it is personal according to the GDPR? (e.g. is it with participant consent.) State "Not applicable" if the data are not personal.
Participant consent.
With which parties the data will be shared within the consortium?
These audit logs will be anonymised and aggregated and will be shared with evaluation team (Empirica, Osakidetza) for impact analysis studies.
Where and for how long data will be stored, under which partner's control?
The audit logs are stored in Audit Record Repository, which will be deployed at local sites. Hence it will be under the pilot site's control. It will be managed based on the data processing rules of local pilot sites.
What downstream derived data will be created from this category of data, if any?

Performance and effectiveness indicators will be derived from this data and used for the usage data in Section 6.
What post-project data reuse is expected outside of the consortium, if any?
None.

The data from the C3-Cloud FHIR repository are as follows (part of data in Section 4):

- Patient age (ranges)
- Patient sex
- Patient location (pilot site)
- Technology trial group
- Has the patient an informal caregiver?
- Diabetes Melltitus Type II diagnosed?
- Heart failure in compliance with NYHA I-II diagnosed?
- Renal failure with estimated or measured Glomerular filtration rate GFR of 30-59 diagnosed?
- Mild or moderate depression diagnosed?
- For intervention patients: Did patient drop out?
    - Dropout because of death?
    - Dropout date
- List of all drugs prescribed or administered during C3-Cloud trial period, in relation to the four inclusion health conditions. All fields required for each drug.

8. ANALYSED AGGREGATED DATA

Evaluation questionnaires, activity audit logs and other information will be analysed for evaluating the solution and its acceptance, usability and utility at the pilot sites. The aggregated and statistically analysed data are new (derived) forms of data that will be used for academic publications and in deliverables.

Template for reporting the C3-Cloud Data Management Plan
For what category (1-8) above does this template apply
6. Analysed aggregated data processed by Empirica and shared with the full consortium as the study results, for inclusion in deliverables and publications.
What kind of data is being collected or processed (high-level description)
Analysed aggregated data, described in Sections 4, 5, 6 and 7.
For what purposes are the data being processed in C3-Cloud
No new collection is done. Data collected under category 2, 3 and 4 will be reported in an aggregated format
Where do the data originate (which party or which system creates the data?)
No new data is created. See data categories 2, 3 and 4.
Are the data personal or not (i.e. are they identifiable, pseudonymous, anonymous, aggregated) - at the point of origin **- when shared within the project**
The data will be anonymous and aggregated at the point of reporting with four stratifiers: Age group, sex, region, user category (MDT or patient).
What is the legal basis for C3-Cloud to process the data if it is personal according to the GDPR? (e.g. is it with participant consent.) State "Not applicable" if the data are not personal.
Not applicable
With which parties the data will be shared within the consortium?
Aggregated data will be shared as results in several public deliverables.
Where and for how long data will be stored, under which partner's control?
Stored by University of Warwick for a minimum of ten years.
What downstream derived data will be created from this category of data, if any?
Aggregated data will largely be published in deliverables and papers. Further derived visualisations (e.g. charts) might be included in slide presentations and other communications materials.
What post-project data reuse is expected outside of the consortium, if any?

The aggregated data and respective analysis that will be made public in the deliverables D9.5 and D9.6 and D4.3, and publications:

- from MDT members: acceptance, usability and usefulness, impact on the clinical care process, any safety implications, impact on multidisciplinary team cooperation;
- from patients and caregivers: acceptance, usability and usefulness, perspectives on communicating with the MDT, use made of the care plan, the training materials, use of the PEP software, relevance and utility of the advice given, impact on adherence to goals.

9. KNOWLEDGE ASSETS

Harmonised clinical guidelines will be represented in computable form for operation within the C3-Cloud components, mapped to clinical terminology. The consortium has agreed that these will be published later in the project (after the pilot studies are completed).

Template for reporting the C3-Cloud Data Management Plan
For what category (1-8) above does this template apply
7. Knowledge assets created within the project to populate components
What kind of data is being collected or processed (high-level description)
Knowledge assets created within the project to populate components (e.g. harmonised multi-condition guidelines) in human readable and computable formats and might be reusable after the project, by others.
For what purposes are the data being processed in C3-Cloud
For C3-Cloud solution to be able to present relevant care plans based on clinical knowledge.
Where do the data originate (which party or which system creates the data?)
NICE guidelines and the pilot sites' clinical representatives.
Are the data personal or not (i.e. are they identifiable, pseudonymous, anonymous, aggregated) **- at the point of origin** **- when shared within the project**
These are not personal data.
What is the legal basis for C3-Cloud to process the data if it is personal according to the GDPR? (e.g. is it with participant consent.) State "Not applicable" if the data are not personal.
Not applicable.
With which parties the data will be shared within the consortium?
All parties.
Where and for how long data will be stored, under which partner's control?
Within each customer site using the C3-Cloud solution, under each pilot site clinician's control.
What downstream derived data will be created from this category of data, if any?
None.
What post-project data reuse is expected outside of the consortium, if any?
These will be published in order to promote reuse of these knowledge assets, and also serve as inspiration templates for harmonized guidelines of other clinical conditions outside of the C3-Cloud scope. However, the publication of knowledge assets derived from third-party resources will be conditional on the third-party licenses.

10. EDUCATIONAL RESOURCES

A series of educational materials will be produced by each pilot site, in different printed and electronic formats, to explain multi-morbidity, the C3-Cloud project and how to use the C3-Cloud applications. Some of these will be reusable by others tackling multimorbidity issues across Europe, such as explaining what multi-morbidity is.

Template for reporting the C3-Cloud Data Management Plan
For what category (1-8) above does this template apply
8. Educational resources that were created during and used in the pilot study and might be reusable after the project, by others.
What kind of data is being collected or processed (high-level description)
Educational resources created during the project. • *Introductory training video* on the impact and complexity of long-term disease and multi-morbidity, stressing the importance of self-management and treatment compliance (versions in English, Swedish and Spanish). • *Leaflet* which provides an overview of the training materials that are available in C3-Cloud, the purpose of these materials and how they can be used (versions in English, Swedish and Spanish). • *Wallet sized project card* which provides basic information about the project, including the location of the system (URL) and where to get help if needed (versions in English, Swedish and Spanish).
For what purposes are the data being processed in C3-Cloud
In C3-Cloud, patients and their informal care givers will be given access to educational materials at the relevant points in their care plan to support and educate them at the appropriate time. • Video: to help to prepare and empower patients for their educational journey, to help patients to better appreciate the complexity of co-morbidity and chronic disease and to explain the purpose of the training materials. • Leaflet: this is not strictly an educational material but will encourage and allow patients to use the training materials more effectively. • The wallet card will provide an ongoing reminder of a patient's involvement in the study, to ensure that they have details of how to access the system to hand at all times, and know who to contact for further information or for assistance with emergency medical situations.
Where do the data originate (which party or which system creates the data?)
• Video, although it was inspired by an existing animated video which is used in Basque Country, it was created from scratch by Task 5.1 team. Once completed, the storyboard was submitted to a professional audio-visual (AV) company, 'Old Port Films'. • The leaflet was developed iteratively in conjunction with the Task 5.1 team. The current version, in English, has to be updated once the system is in a sufficiently developed state, in the framework of Task 9.4. • The wallet-sized card provides basic details of the project, e.g. the C3-CLOUD logo, title of the trial, how to find the system (PEP URL), contact details for the trial and for emergencies etc. The current version is in English. It has been developed by the Task 5.1 team. It will be updated once the system is in a sufficiently developed state, in the framework of Task 9.4.

Are the data personal or not (i.e. are they identifiable, pseudonymous, anonymous, aggregated) **- at the point of origin** **- when shared within the project**
None of the three educational materials mentioned above (video, leaflet and wallet card) are personal data.
What is the legal basis for C3-Cloud to process the data if it is personal according to the GDPR? (e.g. is it with participant consent.) State "Not applicable" if the data are not personal.
Not applicable
With which parties the data will be shared within the consortium?
With all parties
Where and for how long data will be stored, under which partner's control?
Each pilot site will store the corresponding educational materials translated in their own language. The materials will be stored during the trial under each pilot site's control. The YouTube videos will be retained on the C3-Cloud web site, after the end of the project.
What downstream derived data will be created from this category of data, if any?
The data will be evaluated on user satisfaction and usage as part of the evaluation layer 3 in T9.3.
What post-project data reuse is expected outside of the consortium, if any?
The video could be edited to extract a generic educational resource about multi-morbidity for patients, which can be shared with others after the project.

11. CONCLUSION

This Data Management Plan has been updated at the end of year three of the project, since the range of different categories of foreground data has become clear, and consultation has been possible within the pilot sites where most of the data will originate.

C3-Cloud has the goal of designing and implementing novel ICT solutions to support the care of patients with multi-morbidity. The data it collects therefore serves the purpose of supporting the designs and evaluating the implementations. The project has not sought to undertake clinical research and therefore does not have the primary intention of generating new research data sets. Partly for this reason, and party in order to comply with the GDPR, only limited amounts of aggregated evaluation data are expected to be shareable beyond the project.