CRANE

D5.3 Solution design concepts developed by R&D suppliers

Dissemination Level:	**PU**
Deliverable Type:	**R**
Date:	**31-07-2023**
Distribution:	**WP5**
Editors:	**EXT**
Contributors:	**VLD**

*** Dissemination Level:** *PU=Public; CO=Confidential, only for members of the Consortium (including the Commission services); EU-RES= Classified information: RESTRAINT UE (Commission Decision 2005/444/EC); EU-CON= Classified Information: CONFIDENTIEL UE (Commission Decision 2005/444/EC); EU-SEC=Classified Information: SECRET UE (Commission Decision 2005/444/EC)*

**** Deliverable Type:** *R=Document, report; DEM=Demonstrator, pilot, prototype; DEC=Websites, patent fillings, videos, etc; ETHICS=Ethics requirement; ORDP=Open Research Data Pilot; DATA=data sets, microdata, etc.; OTHER*

Document Summary

Each supplier to indicate the innovative solution (in its current form), the innovativeness of the solution, the degree of innovation, solution overview

Funded by the European Union

This project has received funding from the European Union´s Horizon 2020 research and innovation programme under grant agreement No 965277

DISCLAIMER

The work associated with this document has been carried out in accordance with the highest technical standards and CRANE partners have endeavored to achieve the appropriate degree of accuracy and reliability. However, since the partners have no control over the use to which the information contained within the document is to be put by any other party, any other such party shall be deemed to have satisfied itself as to the suitability and reliability of the information in relation to any particular use, purpose or application.

Under no circumstances will any of the partners, their servants, employees or agents accept any liability whatsoever arising out of any error or inaccuracy contained in this document (or any further consolidation, summary, publication or dissemination of the information) and/or the connected work. CRANE disclaim all liability for infringement of third-party rights and any loss, damage, expenses or claims suffered by any person using the information.

The contents of this document are the sole responsibility of the CRANE consortium and can in no way be taken to reflect the views of the European Commission.

Funded by the European Union

This project has received funding from the European Union´s Horizon 2020 research and innovation programme under grant agreement No 965277

Table of Contents

Funded by the European Union

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 965277

List of Authors

Partner	Authors
EXT	Jonathan Gomez, Carmen Galán
VLD	Sofia Moreno, Guillem Castro

Funded by the European Union

This project has received funding from the European Union´s Horizon 2020 research and innovation programme under grant agreement No 965277

Document History

Date	Version	Editors	Status
03-July-2023	0.1	Guillem Castro, Jonathan Gomez,	Table of contents
10-July-2023	0.2	Carmen Galán	Publishable information from solutions
17-July-2023	0.3	Sofia Moreno, Jonathan Gomez,	Draft version
25-July-2023	0.4	Guillem Castro	Draft version v2
16-August-2023	0.5	All	Complete version
06-September-2023	0.6	All	Reviewed version
13-September-2023	1	Guillem Castro	Final version

Funded by the European Union

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 965277

Introduction

This document describes each solution of the 5 Contractors participating in Phase 1 of CRANE PCP implementation. The description provided is based on the information collected in the Contractors' deliverables D1.4 Abstract of the main Results achieved, where they describe the publishable part of each solution defined by the Contractors.

In addition, the summary of the Monitoring Team's performance during Phase 1 and the result of each Contractor is included, following the rules defined in the Tender Documents.

Funded by the European Union

This project has received funding from the European Union´s Horizon 2020 research and innovation programme under grant agreement No 965277

Monitoring Team Organisation and Results

Monitoring Team organisation

The Monitoring Team defined by CRANE PCP is defined according to the standards established in the Call for Tenders:

1. The **Contract Implementation** will be **monitored periodically** and reviewed against the **expected outcomes** for the Phase 1;
2. **Request documents** and/or information from the contractors;
3. Each contractor will be assigned a main contact person (their **supervisor**) from the **monitoring team appointed by the procurers**;
4. There will be monthly monitoring online **meetings** between each **contractor and the supervisor**/monitoring team (Buyers can request more frequently meetings);
5. The **monitoring team** and/or **supervisor** will provide **written feedback** to contractors.

The Monitoring Team is composed of the three buyers of the project (RVB, EXT, KSK) and the assistance of the consortium experts for the technical evaluation of the solutions. The team appointed a contact person for each of the 5 contractors awarded Phase 1 (Figure 1), as defined in the tender.

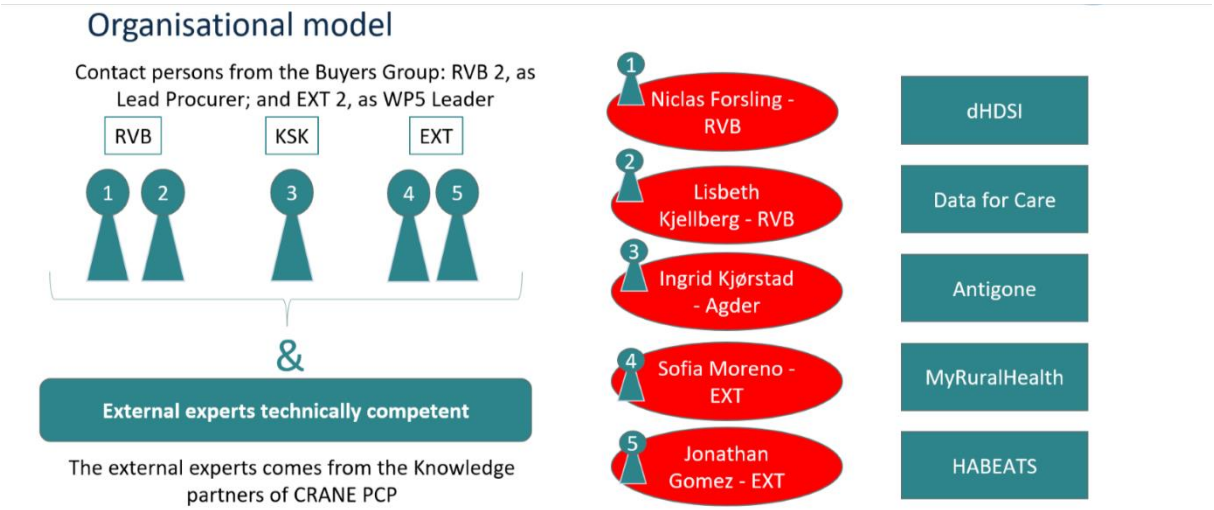

Figure 1. Organisational model for the Monitoring Team in Phase 1

Monitoring online meetings

During Phase 1, due to the short timeframe for execution, it was decided that each supervisor would meet weekly with the designated contractor. The TM also met weekly and discussed the progress of each contractor, as well as any questions and needs that arose. To avoid unequal treatment, all pertinent questions were solicited in writing from the contractors and the response was made public to all contractors. Contractors were encouraged to publish all questions in a manner that did not disclose any confidential information.

In addition, the MT organized meetings with each contractor's team. At these meetings, information was provided to the contractors based on the presentations and documentation provided in advance.

Funded by the European Union

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 965277

The participation of the entire MT in each of the meetings facilitated equal treatment. Any findings that were not confidential but relevant to the other contractors were included in the Q&A log.

Request Documents from Contractors

As defined in the contracts with the contractors, all contractors were obliged to deliver deliverables throughout the course of the phase. To this end, a delivery and consultation mailing was provided for Phase 1. The different deliverables and deadlines are described below:

Deliverables	Deadline	How
D1.1) Phase 1 project abstract	One month after starting Phase 1	Report
D1.2) Interim Progress Report	Mid Phase 1	Report + presentation
D1.3) Solution Design – End of Phase 1 Report	End of phase 1 (Half a month before ending of Phase 1)	Report + presentation
D1.4) Abstract of the main Results achieved	End of Phase 1	Report

Table 1 Deliverables Phase 1

All deliverables submitted by the contractors were evaluated as defined in the Challenge brief of the Call for Tender. The requirements answered by the contractors were to be scored according to the criteria described in the table below. In addition, the Monitoring Team had to provide recommendations for each requirement that did not receive a rating of Excellent. To score the different deliverables (specifically D1.2) Interim Progress Report and D1.3) Solution Design - End of Phase 1 Report), the Monitoring Team created the Monitoring Outcome Report (MOR) template where all the requirements and relevant points to be evaluated were reflected (see Annex 1 MOR Template).

In the event that a requirement was not described by the contractor, but the Monitoring Team felt it needed to be described, the Monitoring Team member was to indicate it in this table for the contractors to review.

Assessment	Description
Fail	Fails to address the Requirement under examination or cannot be judged due to missing or incomplete information
Poor	The Requirement is addressed in an inadequate manner, or there are serious inherent weaknesses
Fair	While the Requirement is broadly addressed, there are some weaknesses
Good	The Requirement is addressed well, although improvements would have been necessary

Funded by the European Union

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 965277

Very Good	The Requirement is addressed well, although certain improvements are still possible
Excellent	All relevant aspects of the Requirement are successfully addressed; any shortcomings are minor

Table 2 Assessment MOR template

The last two chapters (**Use case and Implementation of recommendations**) had a different format, but should be evaluated in the same way as in the other cases, there are specific instructions in the section.

Completion status procedure and Monitoring Team findings

The Monitoring Team met in person in Copenhagen to define the final results for Phase 1, they evaluate each Contractor as defined in the Tender Documents: Satisfactory completion of the Phase and Satisfactory Completion of the Phase. Results are shown below:

The 5 Contractors completed Phase 1 satisfactory, and the results are below in the Table 4.

Satisfactory completion of a Phase* (Requirement for payment)	Antigone	Data for Care	dHDSI	HABEATS	MyRural Health
1. If the work corresponding to all milestones / deliverables has been carried out	**YES**	**YES**	**YES**	**YES**	**YES**
2. If a reasonable minimum quality has been delivered	**YES**	**YES**	**YES**	**YES**	**YES**
3. If the reports have been submitted on time	**YES**	**YES**	**YES**	**YES**	**YES**
4. If the spending has been allocated to the planned objectives	**YES**	**YES**	**YES**	**YES**	**YES**
5. If the spending has been allocated and the work has been carried out according to the on/off criteria (place of performance, public funding and R&D definition criteria)	**YES**	**YES**	**YES**	**YES**	**YES**
6. If the work has been carried out in compliance with the provisions of the contract (including in particular verification if the contractor has duly protected and managed IPRs generated in the respective Phase)	**YES**	**YES**	**YES**	**YES**	**YES**

Funded by the European Union

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 965277

7. If the feedback provided by the monitoring team has been addressed properly by the contractor making required changes or improvements or giving a sufficient justification for not having made them.	**YES**	**YES**	**YES**	**YES**	**YES**

Table 3 Satisfactory Completion results

(*Satisfactory completion in each of the Phases does not mean successful completion)

The 5 Contractors completed Phase 1 successfully, and the results are below in Table 5.

Successful completion of Phase 1 (Prerequisite for passing from one Phase to the next)	**Antigone**	**Data for Care**	**dHDSI**	**HABEATS**	**MyRural Health**
1. If all milestones have been successfully completed	**YES**	**YES**	**YES**	**YES**	**YES**
2. If the R&D results meet the minimum functionality/performance requirements of the challenge description (i.e. the minimum quality/efficiency improvements which the procurers set forth for the innovative solutions to achieve)	**YES**	**YES**	**YES**	**YES**	**YES**
3. If the results of the R&D are considered to be promising (Promising means that the feasibility is convincing).	**YES**	**YES**	**YES**	**YES**	**YES**

Table 4 Successful completion result

Solution design concept per R&D suppliers

Antigone project

The consortium consists of 4 companies and is led by Egde:

- **Egde** is a leading Norwegian IT services company with a strong position nationally within e-Health. Egde has developed a gateway for health data sharing with integrations with journal

Funded by the European Union

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 965277

vendors and common public health services and networks. Egde's expertise in e-health standards combined with the company's interdisciplinary nature means that we can deliver a product that is supported by European standards and at the same time is of high technical quality.

- **Siemens Healthineers** is one of the world's leading companies in medical technology with over 66,000 employees in 70 countries working to ensure that more and more people have access to good, sustainable and cost-effective health services.
- **Zyberia** is a Norwegian health tech company that has launched a personal health platform called HealthB. HealthB is a personal health platform and app that allows users to collect their health data in one place. HealthB is designed to empower users to collect, understand and communicate their health, and achieve self-care and help people own their health and improve their quality of life.
- **Defendable** is a security team with unique technical, operational, and strategic experience from, among others, National Security Authority, the police, the armed forces, and health. Defendable has deep domain knowledge of the primary care space, health literacy and health technology assessment.

The innovative solution

The consortium's proposed solution is to design, build and test a reference architecture that (no change from TD6 C1.1.1):

- Evolves around the patient, maximising the patient's benefits, and safeguarding the patient's rights.
- Enables an open ecosystem of services, where the core services are established by the consortium's members.
- Maximises the use of adopted standards (HL7 FHIR, IHE, ISO 27002, CIS Controls Framework, NIST SP 800-207 Zero Trust, GDPR) – relevant framework for each layer of the architecture.
- Builds on emerging technologies and frameworks developed under EU funding.
- Showcases the partner's current solutions across the CRANE use-cases.
- Establishes an improved mechanism for sharing health data supporting self-care.
- Provides for future enhancements through research and AI.
- Can scale across all countries while allowing those communities to include best-of-breed applications beyond Phase 3

The innovativeness in the solution

The proposed solution is a collection of mature and proven concepts, configured and adapted to serve the goals of the delivery. However, concepts and technology related to Personal Data Space, Consent Management and Virtual Data Lakes have been researched and evaluated and hold results that can be innovative in the form as guidance for future application within the respective domains.

Governance and Business models have been researched and designed and hold innovative aspects for structures to govern the solution and how to frame the business model in practice.

Funded by the European Union

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 965277

A set of mock-ups for MyHealthEnabler have been designed and are an innovative part of the solution. The main part of the planned activities for co-creation for phase 2 are intended to verify and build MyHealthEnabler.

The degree of innovation

The proposed solution is based on a combination of existing products and services. It holds an aspect of "new product" where MyHealthEnabler will be the patience's interface towards the configuration of the existing products and services. The Business model proposed is a tentative new service if implemented.

Data for Care project

The consortium of this project is led by DATA for GOOD FOUNDATION, with the collaboration of TECH4CARE S.R.L., Cardiolyse Oy, METEDA SRL and the subcontracting SME Partisia.

The innovative solution

The **Data For Care** solution is a new technological solution which aspires to revolutionize the way that today personal data are generated, stored, accessed and elaborated within the health care domain. The solution will pave the way for a sustainable data- driven society with a new balance between protecting and using data. Data For Care will provide a platform to facilitate citizens control over their own data, thereby facilitating their ethical use for promoting the single market of digital health services and products and leveraging data value for care provision, health and social care policy making. The solution is currently built on the existing **Data For Good platform**, which is already highly innovative both in terms of technologies adopted (**cutting edge blockchain** and **Secure Multiparty Computation** – MPC – solutions) and governance (Data For Good Foundation is a not-for-profit organization inspired by the highest ethical and transparency standards).
The **Data For Care** solution will consist of following three components:

(A) The **application for citizens**, developed by Meteda and Partisia, including the following features:

(A1) the **MyHealthWallet** interfaces and related functions for authentication, PDS and most importantly the management of informed consents by the citizens (*Lead developer: Partisia*);

(A2) the **MyHealthEnabler** interfaces and related functions, such as dashboards, tools for data entry (PREM and PROMs), educational contents, peer to peer support, etc (*Lead developer: Meteda*);

(A3) **Intelligent services** for diabetes, COPD and CVD care (*Lead developer: Cardiolyse*).

(B) The **application for Garden-of-Care (GoC) actors**, i.e. analysts/researchers, caregivers, healthcare professionals, and policy makers, jointly developed by Data For Good, Partisia, Meteda and Tech4Care. The so-called "GoC application" will include features according to the role, i.e.

(B1) The "**DfC insights for policy makers and analysts**": a tool for visualization of anonymous and aggregated health data (e.g. those related to the geographical area of interest).

(B2) The **"DfC insights for care professionals"**: a tool for management of the EHR including visualization of health data, prioritization of citizens gravity, prescription of therapies, setting of therapeutic target, remote patient monitoring;

(B3) The **"DfC insights for caregivers"**: a tool for visualization of selected health care data of the cared person, especially those related to the therapeutic adherence;

(B4) The "**DfC Virtual Data Lake"**: a feature through which external (third party) applications

Funded by the European Union

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 965277

might required access to data sets for which consent has been granted.

(C) The **Data For Care Open Platform**, developed by Data For Good and Partisia, orchestrating all the services offered to the citizens and to the GoC actors, including the following layers:

(C1) a developer API layers;
(C2) a MyHealthEnabler layer;
(C3) a MyHealthWallet & Personal Data Space (PDS) layers;
(C4) a data processing layer;
(C5) a computational power layer.

The innovativeness in the solution

Data For Care will provide valuable insights compared to conventional "siloed" monitoring of chronic patients by using complete private and public health data sets, thus improving healthcare and care.

Our intention is to validate our infrastructure in rural areas in a pilot involving citizens who will have the possibility to test the prototype with the aim of improving the self-management of their chronic conditions. The Data For care project addresses very well the ambitious challenges launched by the CRANE call for tender, especially as:

- It leverages existing background knowledge, know-how and technologies of Data For Good Foundation. The experience of DfG in the creation, management, and evolution of innovative architecture for data security will become the backbone of the R&D activities that will be performed during the PCP. This will give the possibility not to start from scratches but to promptly focus the R&D activities on the most innovative and promising developments.
- It incorporates in the value proposition the clinical and technological expertise of two leading SMEs in the field of telemedicine and digital health, namely METEDA and Cardiolyse. The two companies together cover all the required clinical and technological expertise required to address the need of integrating in the CRANE prototype advanced and smart services for self-management. The MyHealthEnabler app will be designed by METEDA and will offer to the citizens' access to a wide range of services, including:
    - Virtual Coach to appropriate recommendations for diabetes, COPD and CVD treatment, exercises and healthy lifestyle (In collaboration with Cardiolyse)
    - Shared Care Plan to set up and track goals, schedule events, manage alerts and notifications, medication and dosage, as well as view, generate and export reports
    - Education with validated questionnaires to capture patients' knowledge and capabilities

The degree of innovation

Data For Care is a totally new product with related method.

DHDSI project

The consortium of this project is led by Combitech AB, with the collaboration of iGrant.io.

The innovativeness in the solution

The dHDSI proposal, aims to establish a Health Data Space enabling an open, secure and auditable health data ecosystem for patients, Caregivers and researchers, focussing on improved self-management and integrated care for patients with chronic disease. The fundamental problem these

Funded by the European Union
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 965277

stakeholders face is not a lack of data but access to relevant data, often locked in organisational silos due to legal, technical or cultural challenges. The dHDSI solution addresses these issues and brings in the following benefits:

- For patients, it provides a self-management solution and empowers them to control and share their primary and secondary data. Treatments can be personalised by collecting data from multiple sources and sharing insights with the caregiver without compromising privacy and digital rights concerns.
- For organisations, the CRANE data space makes endpoints and services discoverable via the data marketplace, powered by data intermediaries as per the EU Data Governance Act, while addressing critical data regulations in a scalable manner. Once discovered, they can dynamically enter into data-sharing agreements to share and reuse personal data across organisational boundaries. It uses well-defined technologies and open standards supporting centralised legacy systems and decentralised architectures, ledger and non-ledger based.

The degree of innovation

The solution is based on existing and emerging standards in Europe and is based on a couple of basic principles such as that the individual should have control over their data and that the concept is open and stimulates collaboration and interoperability. The key innovations for services for the CRANE Open Platform (COP) include the following:

1. The use of **data intermediary services** with digital wallet technologies enables the scalable exchange of data and decentralised apps (dApps) for citizen-empowered, secure, privacy enabled data sharing as part of the COP.

2. **Solid pods** were added as a backup and restore function for digital wallets, an industry first. Users can save data and share with consent to any application using the solid protocol[1].

3. Decentralised apps are powered by the **CRANE dataspace**. In the data space, data sources make their endpoints and services discoverable. Once discovered, they can dynamically enter into data-sharing agreements to share and reuse personal data across organisational boundaries.

4. Data spaces, served by the data intermediation layer, facilitate both the primary and secondary use of data enabling a new level of scalability and interoperability between a data source and a data-using service. The data can be repurposed or reused.

5. The **data management and governance** use the DEXA (Data Exchange Agreement) protocol. The DEXA protocol SW is also recognised as a DPG (Digital public good) by the UN body DPGA and is led by iGrant.io, the data intermediary in consortia.

6. The dataspace is governed via a governance framework that ensures only **trustworthy** parties are involved in the data exchange ecosystem. This includes the validator nodes that

[1] Data Pod by iGrant.io, listed as a SOLID pod provider: https://solidproject.org/users/get-a-pod

Funded by the European Union

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 965277

operate the trust anchor (DLT) network, ensuring that all data (for its authenticity and data integrity) and data transactions are trustworthy.

HABEATS project

The consortium of this project is led by Wiring Technologies SLU, with the collaboration of Worldline Iberia SA, Consorci Sanitari de Terrassa and Entrepreneur Capital SL (Opinno).

The innovative solution, innovativeness and degree of innovation

The The **HABEATS** consortium has designed an innovative and technologically advanced solution that empowers citizens to self-manage their personal and health data based on user-centric trust while ensuring compliance with GDPR. Accordingly, we're pushing to make healthcare more personal and inclusive, where citizens can stay informed and engaged in their own care by obtaining added-value insights. As a collaborative and no-code digital health solution, the platform also provides access to personalised content and community services through Garden of Care geolocated offerings. This can greatly improve the overall health-related quality of life (HRQoL) of patients living with chronic conditions, especially those in areas with low population density, using a boarder range of data.

The **HABEATS** platform leverages a user-friendly Personal Data Space linked to a consent model mechanism (MyHealthWallet), allowing patients to share their own data with 3rd entities for research purposes and with clinicians interested in monitor citizens health status. This approach enables researchers and analysts to generate new insights for **HABEATS** users using anonymized and aggregated data, both personal and public data from multiple sources such as wearables and allow clinicians to detect decompensation prematurely.

The Virtual Data Lake architecture proposed for the platform adheres to **European Data Space (EDS)** standards, based on a decentralized design that will become a secure and federated data sharing infrastructure. In the future, **HABEATS** aims to become a new execution node of the European Health Data Spaces (EHDS) framework, enabling access to benefits such as scalability, efficient data exchange, secure interoperability, and new market opportunities. The platform is designed to enhance privacy and security mechanisms for citizens' data, guaranteeing that user data remains stored in its original source, while ensuring its availability for healthcare purposes through features like encryption services and smart contract management, facilitating compliance with the GDPR.

Citizens can access the **HABEATS App** (MyHealthEnabler) to upload their personal data and view data history or generate reports automatically in the same place. Additionally, the app provides access to the Garden of Care services catalogue, including hospital educational sessions, physician contacts, city council agendas, as well as personalized content like exercises, coaching, and diets based on the patient's condition. We will promote a campaign to maximize the number of affiliated entities, understanding these as a fundamental part for the success of HABEATS implementation.

HABEATS value-based model focuses on delivering user-centric care that considers the unique needs, preferences, and circumstances of chronic citizens living in remote areas. By sharing their data, citizens gain a better understanding of their health conditions, treatment options, and potential risks. This empowers citizens to make informed decisions about their care and actively engage in their treatment plans.

Finally, we want to highlight we obtained some new findings in regard the technology and the innovations adopted to design the HABEATS system. In this regard, we'd been researching on European

Funded by the European Union

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 965277

Data Spaces (EDS) identifying best practices (e.g., https://www.health-x.org/en/home Health-X project) to ensuring data protection, privacy, and security for platform's users and studying how HABEATS will be implemented into and meet EDS standards compliance. In the near future, we consider feasible to become an EDS execution node towards federated data exchange and also provides a robust governance framework.

MyRuralHealth project

The consortium of this project is led by TELEVES SAU, with the collaboration of ETHNIKO KENTRO EREVNAS KAI TECHNOLOGIKIS ANAPTYXIS (CERTH) and Universidad Politécnica de Valencia.

The innovative solution

MyRuralHealth aims to provide a comprehensive solution that enables the monitoring and follow-up of patients with diabetes, CVD and COPD between regular visits by medical staff, as well as the empowerment and self-management of patients and their caregivers, in rural areas.

It is a solution focused on generating a data space with access for citizens to share their data freely, under a consolidated framework specifically designed and evaluated to apply evidence-based knowledge and innovations, enabling citizens to take care of themselves.

Through it, services and tools are incorporated to empower citizens for their own self-management and care. This will enable data-driven self-management of three chronic diseases (diabetes, CVD and COPD), with the common thread of personalised care plan monitoring and ubiquitous use of personal data, communication and data sharing with health and social care services and other relevant entities, feedback and recommendations on health status, and motivation for behavioural change.

The innovativeness in the solution

The most relevant innovations incorporated in MyRuralHealth are:

Technical innovation

- ✓ A Shared SocioHealth Data Space (CRANE Virtual Data Lake -CVDL-) as a key enabler, which allows the creation of a private Personal Health Record (PHR) that includes a data repository for each individual person through the aggregation of various data sources, including both controlled data space (generated by trusted procedures and certified by health systems) and uncontrolled data space (generated by the user and non-certified third-party systems and providers), i.e. an open and trusted control over their own data and its use.
- ✓ The MyRuralHealth platform will have different modules for decision support, prediction and prevention and generation of public and private PHR data, based on the amount of data from multiple sources and the use of Artificial Intelligence (AI) and Machine Learning (ML) around Interactive Process Mining (IPM). As an innovation from an interoperability perspective, through the CRANE SDK + CRANE Insight, the platform will allow approved external developers and third-party services to have specific access to data for personalised services to users, always ensuring GDPR and user preferences.
- ✓ Distributed ledger technologies and smart contracts will be used as a security layer for data access management. The conjunction of DLT and data lake will enable private data storage and decentralised access management. In addition, the layered architecture can manage privacy issues and comply with regulations such as GDPR by offering an audit trail, decentralised and

Funded by the European Union

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 965277

fair code execution, and future scalability with the inclusion of nodes as network needs change.

- ✓ Today, interoperability is mostly conceived from the point of view of usability of several systems (separated by devices, middlewares, applications, etc.). In MyRuralHealth, interoperability is approached from the minimum data expression phase (bridging protocols and data formats) orbiting around the concept of data spaces.
- ✓ MyRuralHealth's integrated innovation process is not only about creating or validating innovation, but also about adopting it in a long-term approach.

Services

- ✓ A value-based shared virtual care assistant that will include AI technology for the detection, management and prevention of complications for patients with diabetes, CVD and COPD.
- ✓ Self-management solution, enabling improved social healthcare and care through insights from a wider collection of data, and sharing data with third parties
- ✓ We will provide an innovative home monitoring kit to enhance existing home monitoring systems for patients with diabetes, CVD and COPD. Through this remote monitoring, we will facilitate early identification of acute episodes, improve patient experience and clinical outcomes, and avoid unnecessary emergency room visits and hospitalisations. In addition, it will be designed following an open approach that will allow the incorporation of future improved devices for diabetes, CVD and COPD monitoring, as well as, for example, other devices that enable the detection, management and prevention of frailty, such as a gait speed sensor or squats.

Organisational innovation

- ✓ Improvement of existing processes through new interaction models for citizens living in rural areas with different characteristics than those living close to the hospital.
- ✓ A new organisational model supported by a solution that addresses comprehensive and holistic self-care, enabling the management of a range of different signs and symptoms adjusted on a personalised basis per citizen.

The degree of innovation

The diabetes, CVD and COPD self-care monitoring kit, which together with other sources generates insights that enable citizens to take care of themselves, is a totally new product that provides a totally new service.

The model of self-care through citizens freely sharing their data is a totally new process.

The generation of insights that support citizen decisions for better self-care are improvements to existing processes.

Funded by the European Union

This project has received funding from the European Union´s Horizon 2020 research and innovation programme under grant agreement No 965277

Annexes

Annex 1: MOR Template

Funded by the European Union

This project has received funding from the European Union´s Horizon 2020 research and innovation programme under grant agreement No 965277

Assessment Instructions

All Requirements answered by contractors must be scored against the criteria described in the table below. In addition, you should give recommendations for each requirement that is not rated Excellent.

In case a Requirement is not described by the Contractor, but the Monitoring Team considers necessary to describe it, you should indicate it in this table for the Contractors review.

The last two chapters (**Use case and Implementation of recommendations**) have a different format, but should be evaluated in the same way as in the other cases, you will find specific instructions in the section.

Assessment	Description
Fail	Fails to address the Requirement under examination or cannot be judged due to missing or incomplete information
Poor	The Requirement is addressed in an inadequate manner, or there are serious inherent weaknesses
Fair	While the Requirement is broadly addressed, there are some weaknesses
Good	The Requirement is addressed well, although improvements would have been necessary
Very Good	The Requirement is addressed well, although certain improvements are still possible
Excellent	All relevant aspects of the Requirement are successfully addressed; any shortcomings are minor

Concept	Monitoring Team Review	
	PROGRESS EVALUATION **Fail, Poor, Fair, Good, Very Good, Excellent**	**RECOMMENDATION**
2 Solution design and approach to development.		
2.1 Progress achieved during the period		
2.2 Architecture and components		
2.3 Changes to the original plan submitted in the offer.		
2.4 Risk management.		
2.5 Value based Healthcare model.		
2.6 Update on Implementation approach.		
2.7 Plans until the end of Phase 1.		
3Interim Progress Report: expected outcomes for Phase 1.		
3.1 Description of the data sources that are to be provided and integrated in the solution for Phase 2 and 3.		
3.2 The planned approach for scalability and sustainability of the energy intensive algorithms/protocols/processing.		
3.3 Governance model for CRANE Open Platform		
3.4 Business model description		

3.5 Approach to the provision of patient self-management, education, and support to different layers and groups of users		
3.6 Mock-up of the user interface		

C.CHALLENGE	Requirement	Description (Describe how you plan to demonstrate the accomplishment of this requirement, if it has been previously described in this document define where, precisely. If it makes use of a previous background makes it explicit including the TRL. If it is expected to go beyond state of the art make it explicit).	Progress Assessment (Fail, Poor, Fair, Good, Very Good, Excellent)	Recommendations
Services for Citizen	CH1.1 MyHealthEnabler should be an application usable by different (d)apps & devices that should provide to the users: a dashboard exposing services that use the CRANE Open Platform where users can access data from public/private service providers. Visualisation can be done using the portal approach (composition of widgets) to cope with the specific user needs; - a platform for privacy preserving the use of data that can be provided by CRANE or by third parties; an overview of available data sources about the CRANE Citizen, including the Personal Data Space (PDS); an account, and a wallet (MyHealthWallet) that manages consent, access to data and keepstrack of			

	the use of data and possible rewards; functionalities to engage CRANE Remote Support Centre			
	CH1.2 MyHealthEnabler should be able to incorporateany relevant service for citizens users of the CRANE open Platform, such as informationsources, dashboards, educational content, peer to peer support etc			
	CH1.3 The bidder is expected to provide a personaldata space for the MyHealthEnabler users			

	CH1.4 MyHealthWallet application shall provide: Data sharing, consent handling & management. The platform will ensure that anyuse of data is based on consent. API service to integrate 3rd party applications. Manage requests to user data access , distributed with Direct transfer for sharing with identifiable data with 3rd party (e.g. weight, steps sleep) or Anonymous			
	CH1.5 The individual user of the MyHealthEnabler needs to be able to see a list of given Consents in a list in the consent dashboard.			
	CH1.6 All relevant user-facing services in MyhealthEnabler should be available through a service delivery channel with a mobile responsive web-enabled interface, through the portal.			

Services for theAnalyst	CH1.7 CRANE Insights should provide the following services to the Analyst: - definition/segmentation of user groups; the activation of computation either with identified Citizen data or with anonymous data in general, the possibility to integrate with theCRANE Open Platform through APIs or through direct queries on data from COP that is available. CRANE Insights shall provide the Analyst with: overview of data sets, together with a Data dictionary wherever applicable referring to relevant standard semantic definitions. Provides intended meaning of data, be able to have access to GDPR consented data and user data in ANONYMOUS form so that the user is not in any way exposed; aggregated statistics about the data available through the CRANE Open Platform; a platform/service for requesting privacy-preserving use of data; functionalities to receive the output of the data request;			

	CH1.8 CRANE shall offer a Virtual data lake to allow applications to blend data from various sources,local or remote and is connected or disconnected from data sources when required by the apps that use it. It contains a data directory so that applications can search for data like a single data set and retrieve the needed data. It enforces access control based on specific permissions based on user consent so that the application users may only see or the data they are entitled to see			
Base Functionalities	CH1.9 Data sources shall be integrated with the CRANEOpen Platform through APIs. Each data source can represent multiple citizens. Data sources, including PDS data source, represent a service which manages multiple PDS on behalf of individual Citizens (i.e. the CRANE Open Platform PDS or third-party PDS services)			
	CH1.10 CRANE's API should implement an interoperability strategy encompassing technical, software and semantic interoperability relevant standards (ie. HL-7/CDA, FHIR, ICD-11, LOINC, DICOM, IHE) to ensure data handling and transparency between the devices and benefits associatedwith its architectural layers.			

CRANE Public And PrivateLayers	CH1.11 The platform shall support public and private data sharing layers. A public layer that functions as a traditional distributed ledger with full transparency, a private layer that orchestrates privacy preserving computation			
ComputationalPower	CH1.12 The solution should be built as an open cloud-native using proven and open source components as much as possible. The cloud is expected to be commercially available and approved by the sponsor country or region for healthcare use.			
	CH1.12 Computing nodes should use the best technologies (e.g. SMC, homomorphic encryption) to ensure privacy, trust and efficientcomputation.			

	CH1.13 The platform should provide a highly reliable user-centric trust model. Please describe the architecture that will be used and If a decentralised model is used: please describe how the computing nodes network will be constructed If feasible and using a blockchain, please describe what is the expected block creation time and how fast the finalisation is done if a blockchain is applied, please describe what Consensus model is being used If any blockchain is applied in the solution design, please inform what fee structure might be implied If feasible please describe how the Proof-of-Verification will be done			
Sustainability	CH1.14 If any trust enabling technologies like e.g. blockchain is applied to the solution, it should be using Proof-of stake (or better) method to minimise energy consumption			
Availability	CH1.15 CRANE Open Platform services should beavailable to its users at any time, and in any channel of their choice of the most used operating system distributions (specify: Window / MacOS/ Linux OS's); Services and Apps running on the browser should be compatible with of the most used browsers (specify: Chrome, Firefox, Opera); Services and Apps running on mobile OS's should be compatible with of the			

	most used mobile OS's (Android, iOS, Huawei).			
	CH1.16 CRANE Open Platform will be expected to be available in some capacity 95 % of the time. Down-time should be expected and planned. The solution will employ industry best practice standards to ensure appropriate availability.			
Scalability	CH1.17 CRANE's Open Platform shall be designed in all possible dimensions (e.g., number of data objects, transaction per second TPS, data storage, nodes used, ...) to respond automatically to workload variations (e.g. using elastic computing, automatic storage scaling...). Evidence should be provided on the possibility of scaling horizontally and vertically; a theoretical calculation on the upper limits, especially of TPS, should be provided			
	CH1.18 The proposed solution should be able to reach high scalability levels without or with limited increase of the energy demand, with sustainable energy models and cost models, without compromising on security.			
Architecture &Security	CH1.19 The platform must adhere to the latest security certification requirements and standards in compliance with the NIS Directive (EU) 2016/1148, and the upcoming NIS 2, and ensure that it can quickly upgrade its security levels in the case			

	vulnerabilities are identified.			
	CH1.20 Solution must use Certificate Pinning or HTTPS Public Key Pinning (HPKP) to prevent man-in-the-middle attacks and two-way authentication to gain non-repudiation andauthentication capability of both the server andclient. Make sure that all connections to your servers are encrypted (if applicable) using best practice configurations (i.e. currently TLS 1.2 or TLS 1.3), do not accept user-accepted certificates as authorities, and make sure certificates are up-to-date and signed by a trusted CA.			
	CH1.21 The solution shall track various steps carried outas part of The CRANE Open Platform's processes and must provide for system auditing and ensure user anonymity is achieved and guaranteed (where appropriate) in auditing processes.			
	CH1.22 Data Encryption: At least AES-256 algorithm (or similar) for data encryption should be supported in order to protect data			

Data Protection,sharing Privacy and ethics	CH1.23 CRANE's Open Platform should implement data protection and privacy protocols in compliance with GDPR.			
	CH1.24 CRANE's Open Platform should be designed with privacy and ethics in mind, so that the user can exercise individual data control, and decide with whom they share their data and be able tosee who has access to it. The platform should use technologies and services that create and communicate trust to users.			
Governance	CH1.25 CRANE's Open Platform should implement a governance model that facilitates cooperation with all stakeholders and that describes procedures for education, maintenance and if feasible also handover			
Language	CH1.26 The services should be multi-language, with support for min: Swedish, Spanish, Norwegian& English, and other regional languages.			
Openness	CH1.27 CRANE's Open Platform should have proven existing EU, national and/or regional infrastructure components as the first choice.			

Usability &Accessibility	CH1.28 The CRANE Open Platform shall conform to the UAAG 2.0. and WCAG 2.0 at a minimum level 2 (AA).			
C.CHALLENGE	**Requirement**	**Description** (Describe how you plan to demonstrate the accomplishment of this requirement, if it has been previously described in this document define where, precisely. If it makes use of a previous background makes it explicit including the TRL. If it is expected to go beyond state of the art make it explicit).	**Progress Assessment** **(Fail, Poor, Fair, Good, Very Good, Excellent)**	**Recommendations**
Developer Toolsand process	CH2.1 CRANE's Developer's Layer should provide Service providers developers with APIs, and related documentation, necessary to be able to integrate to the COP			
	CH2.2 CRANE's Developer's layer should provide resources to fast-track the first stages of development (E.g: Tutorials for setting up services in the CRANE platform, reusable and customisable code snippets for key standard functionalities, providing a base service code example functioning as a "Hello World" on theCRANE Platform)			

	CH2.3 CRANE's Developer's layer should be well defined in the form of APIs, preferably using the JSON REST model.			
	CH2.4 CRANE's Developer's layer shall provide tools to visualise the data stores together with the associated JSON view			
	CH2.5 CRANE's Developer's layer shall provide data dictionary definition and management. Data definition wherever applicable refers to relevant standards semantic definitions, including algorithms used and data lineage.			
	CH2.6 CRANE's Developer's layer shall provide API for data sharing and consent management, including Pub/Sub, to trigger downstream workflows.			
	CH2.7 CRANE's Developer's layer shall provide API to import/export data from/to the data stores.			
	CH2.8 CRANE's Developer's layer shall provide API to activate the SMC to perform analysis.			
	CH2.9 CRANE's Developer's layer shall provide API to manage identity, roles and audit.			

	CH2.10 CRANE's Developer's layer should provide a Developer Community Support Channel (E.g. : Developer Forum)			
C.CHALLENGE	**Requirement**	**Description** (Describe how you plan to demonstrate the accomplishment of this requirement, if it has been previously described in this document define where, precisely. If it makes use of a previous background makes it explicit including the TRL. If it is expected to go beyond state of the art make it explicit).	**Progress Assessment** **(Fail, Poor, Fair, Good, Very Good, Excellent)**	**Recommendations**
Role of Serviceproviders	CH3.1 The bidders are expected to work with market ready service providers as part of the consortium, that is able to deliver part or all of the services and functionality described inChallenge 4,5,6 and deliver their services for the3 pathologies in phase 3 to the Citizen users in all 3 Buyer regions			
Integration	CH3.2 All participating service providers have to integrate and share the citizens data to the COPaccording to their consent for data sharing.			

	CH3.3 Participating service providers are expected to use the available data from CRANE Insights service and be able to deliver new data from other sources (e.g private data) to the citizen in form of new insights or potential new algorithms (Please see Figure 9 The circular CRANE Model)			
Data sharing	CH3.4 Service providers are expected to share as a minimum 2 or more vital signs parameters to the COP. More data is recommendable			
C.CHALLENGE	**Requirement**	**Description** (Describe how you plan to demonstrate the accomplishment of this requirement, if it has been previously described in this document define where, precisely. If it makes use of a previous background makes it explicit including the TRL. If it is expected to go beyond state of the art make it explicit).	**Progress Assessment** **(Fail, Poor, Fair, Good, Very Good, Excellent)**	**Recommendations**

Vital signs and activitymonitoring.	CH4.1 The **use of sensors and/or medical devices** will facilitate capturing data at home and onthe move about Citizens' health and well-being. At least 2 vital signs parameters per chronic condition should be collected. Data collection should be done seamlessly or minimising the Citizen intervention in terms of time and efforts.			

	CH4.2 **Provide feedback and actionable insight onhealth status to Citizens.** Citizens and/or carers should receive relevant and actionable insight on how to effectively manage their chronic conditionsvia their self monitoring app or deviceservice provider. In order to validate COP,the bidders are expected to include EHRdata from commercially available serviceproviders that offer this functionality: Insights should be: • based on new data consented by the CRANE users throughMyHealthEnabler from different sources and service providers, analysing relations between e.g sleep, food and change in vital signs, • based on health data analysis algorithms, Insights could inform CRANE users via their service provider about: • current health status/well-being status, • notification of out of threshold parameters, including some intuitive approach such as three levels: green (stable), yellow (moderate), and red (severe) CRANE Service providers feedback could provide notifications: • according to pre-defined preferences by Citizens, carers, and garden of care entities/member, • including disclaimers, informingCRANE users (Citizens) about their role and informal and			

	formal routes for further guidance, • to healthcare services or other members of the garden of care where so is agreed, such as a prioritised summary out of threshold parameters classified according to three categories: (green, yellow, red). Periodicity, procedure (e.g. email), and receptorare to be configured.			

	CH4.3 If any health advice is given during the piloting phase testing by the CRANE , it should be indicated to the Citizen that the advice is part of a research project and adheres to all relevant applicable laws.			
	CH4.5 It would desirable if the service providers testing CRANE Open Platform can provide a service that allows for self-reported PROM's and PREMS's and made available for the care team			
	CH4.6 Services that can deliver alerts for CRANE users about anticipating impending crises, e.g exercabation attacks, hyper- or hypoglycemia or relative fast weight increase.			
	CH4.7 Make disclaimers clear and easily understood to users about the limits of CRANE functionality, not valid to deal with emergencies. Inform CRANE users (Citizens) about their role and informal and formal routes for further guidance.			
CRANE support centre(CSC).	CH4.8 The CRANE support centre (CSC) acts as front-end with the Citizen/carers in any interaction. The CSC should manage allinteractions with no or low clinical value. The CRANE support centre will run the logistics for device distribution, installation, online helpdesk, and maintenance; the provision of lifestyle			

	coaching; and the triage of incoming calls from CRANE users according to predefined rules on when and how to facilitate the interaction of the Citizen with the healthcare system, or eventually with the emergency department.			
Facilitate access tothe appropriate information forhealthcare and social care services.	CH5.1 Make possible access and notifications about the status of the Citizens to healthcare services and family			
	CH5.2 It would be desirable that the service provider can provide a dashboard of prioritised status of Citizens classified according to at least three categories: green (good), yellow (moderate out of threshold), red (severe out of threshold) or others e.g. due to lack of compliance to provide PREMS& PROMs			
	CH5.3 It would be desirable that the CRANE serviceprovider can create a summary of relevant updated health information that could be shared by the Citizen when visiting health professionals			
Facilitating access to relevant informationto health and social services, or any other entity/people in	CH5.4 It would be desirable that the selected CRANE Service providers can share important notifications and data to the Citizens circle of care, with their explicit consent			

the Citizen garden of careabout Citizens' data.	CH5.5 Make possible data sharing between healthcare and social services according to their preferences and Citizen consent through MyHealthEnabler.			
Engaging Citizens inactivities to promoteand create behavioural changes and the adoption of healthy habitspromoted by the garden of care.	CH5.6 The MyhealthEnabler service should make it accessible for the members of the garden ofcare to propose different social and other activities for Citizens/citizens that is relevantto them, according to their profile and preferences.			
Digital education andempowerment.	CH6.1 The bidders should have functionality to access educational content for both Citizensand the rest of users (carers, health services, etc.) e.g. using MyHealthEnabler service as amain channel, but also directly via the CRANE Service providers own channels. Elaborate and provide educational material for all CRANE users (not only Citizens) about CRANE data consent management and tools. The MyHealthEnabler service should be able to facilitate and support digital literacy for Citizens, by providing training, mentoring and support for Citizens and their caregivers in the use of the digital tools necessary to make use of CRANE, including troubleshooting management. It could include interactive educational materials, manuals, videos, demonstrations, games, personal support, etc. that should bemade available through MyHealthEnabler			

Trust building	CH6.2 CRANE success is the ability to explain the data sharing process effectively and simply to its data donors and its trust enabling technologies to the different users of the CRANE Open platform, especially to the citizen. The bidders should provide user friendly, rigorous, and easy to understand material (eg. Self-instruction videos, explainers, or other multimedia content) forall CRANE users such as Citizens, garden of care members, and CRANE insight Data requesters (Service providers/analysts & researchers).			
Health literacy	CH6.3 The selected service providers should provide functionality to access healtheducation: its Citizens to promote long-termmanagement of the relevant condition, including promoting a healthy lifestyle. Educational Content that is provided in the MyHealthEnabler service y must be qualified and agreed with procurers. It couldcome from procurers' health information channels or from other channels such as https://www.gravitatehealth.eu			
Motivation	CH6.4 Include motivation functionalities such as goal settings, gamifications, and remainders,for healthy habits adoption and treatment adherence.			

Peer support forCitizens and family	CH6.5 MyHealthEnabler should facilitate access to existing networks of peers in social media, such as Facebook.			
Prescription ofactivities proposed in the garden of care.	CH6.6 MyHealthEnabler should inform and sendreminders to Citizens about the activities proposed in the garden of care which are defined as adequate for them			
C.CHALLENGE	**Requirement**	**Description** (Describe how you plan to demonstrate the accomplishment of this requirement, if it has been previously described in this document define where, precisely. If it makes use of a previous background makes it explicit including the TRL. If it is expected to go beyond state of the art make it explicit).	**Progress Assessment** **(Fail, Poor, Fair, Good, Very Good, Excellent)**	**Recommendations**
Provision of data for value-based models	R7.1 CRANE Insights service should be able to demonstrate data types that can be used for performing value-based healthcare analytics.			

Data analyticscapabilities	R7.2 CRANE Insight service shall demonstrate the possibility to show Citizen reportedoutcomes for all 3 pathologies (CVD, Diabetes Type 1 and COPD) over time using secure anonymous but identifiable datausing the COP platform SMC processing.			

4.2 Other requirements

Requirement		**Description** (Describe how you plan to demonstrate the accomplishment of this requirement, if it has been previously described in this document define where, precisely. If it makes use of a previous background makes it explicit including the TRL. If it is expected to go beyond state of the art make it explicit).	**Progress Assessment** **(Fail, Poor, Fair, Good, Very Good, Excellent)**	**Recommendations**
Commercialization and Business Plan	CBR1 Affordability and competitiveness: The solution itself and its elements shall be affordable and highly competitive in the market.			
	CBR2 Cost of ownership: The solution developers shall provide the solution at low total costs of ownership.			

	CBR3 Business plan and strategy: The CRANE solution developers shall provide a business plan strategy describing the approach for commercialising the solution (including market expansion plans,business models, etc.)			
	CBR4 Commercialization plan: The solution developers shall provide acommercialization plan including the market analysis, risk management, principles for licensing, pricing, distribution, etc.)			
Change management	CM1 Bidders should provide a change management plan, describing the proposed approach to facilitate the deployment of the pilot operation phase and the acceptance by all participants			

4.3 Legal and Regulatory requirements

Requirement	**Description** (Describe how you plan to demonstrate the accomplishment of this requirement, if it has been previously described in this document	**Progress Assessment** **(Fail, Poor, Fair, Good, Very Good,**	**Recommendations**

		define where, precisely. If it makes use of a previous background makes it explicit including the TRL. If it is expected to go beyond state of the art make it explicit).	**Excellent)**	
Data processorreliability[7]	LR1 Adequate description of the nature of the provision of its services where they involve the processing of personal data.			
	LR2 Adherence of a processor to an approved code of conduct as referredto in Article 40 GDPR or an approved certification mechanism as referred to in Article 42 GDPR or: ▪ Favourable compliance audit reportissued by a trusted third party. ▪ Favourable security audit report issued by a trusted third party. ▪ Certification or accreditation of thetraining of its personnel in personal data protection, confidentiality and security. ▪ Have a data protection officer or legalsupport in this area. ▪ Have a security officer or technicalsupport in this area.			

	LR3 Providing adequate guarantees regarding international data transfers in case of Non-EU country location			
Ensure Data Protectionby design and by default	LR4 Demonstrate the ability to applymethodologies for data protection by design and by default as required byArt. 5 and 25 GDPR			
	LR5 Demonstrate that applied methodologies of data protection by design and by default are in line with the Guidelines of the European Data Protection Board and the specific Guidelines of the national data protection authorities of the procurers' countries.			
	LR6 Analyses appropriate technical and organisational measures beforedetermining the means of processing			

	LR7 During the design of the processing, it takes into account appropriate technical and organisational measures to comply with the GDPR.			
	LR8 During treatment, apply the measures that have been determined and check the effectiveness of the measures applied.			
	LR9 Applies appropriate technical and organisational measures to ensure that,by default, only data necessary for each of the purposes are processed			
	LR10 It applies technical and organisational measures considering the amount of personal data collected, the extent of the processing, the storage period and the accessibility of the data.			

Security of Information Processing, Safety ofTreatments	LR11 Applies a risk-based analysis methodology that meets the standards required by the GDPR to quantify and map acceptable levels of risk in a processing operation.			
	LR12 Applies pseudonymisation techniquesand encryption of personal data			
	LR13 Applies measures to ensure the continued confidentiality, integrity, availability and resilience of processing systems and services			
	LR14 Implements measures to ensure the ability to restore availability and access to personal data quickly in the event of a physical or technical incident.			

	LR15 Takes into account the risks presented by the processing as a result of the accidental or unlawful destruction, loss or alteration of data that are transmitted, stored or processed, or the unauthorised disclosure of or access to such data in order to assess the level ofsecurity applied			
	LR16 Implements measures to ensure that persons authorised to access data only process them in accordance with the instructions provided			
	LR17 Knows and is able to implement the security requirements or security standards specifically set out in nationallegislation[8]			
	LR19 Be able to cooperate with controllers in analysing risks of varying likelihood andseverity to the rights and freedoms of natural persons and to design			

	and implement appropriate technical and organizational measures to ensure a level of security appropriate to the risk			
Risk-based design approach and Data Protection Impact Assessment (DPIA)	LR20 Be able to cooperate with controllers inconducting a DPIA prior to processing where it is likely to result in a high risk to the rights and freedoms of individuals			
	LR21 The DPIA includes a systematic description of the envisaged processing operations and the purposes of the processing, an assessment of the necessity and proportionality of these operations in relation to their purposes and an assessment of the risks to the rights and freedoms of natural persons.			
	LR22 Includes measures envisaged to demonstrate compliance with the GDPR, taking into account the rights and legitimate interests of data subjects and			

	other affected persons.			
	LR23 It includes measures to address risks, safeguards and mechanisms to ensure data protection.			
	LR24 Review the DPIAs whenever necessary and whenever there is a change in the risks posed by the processing operations.			
	LR25 It implements an action plan with additional control measures to reduce the level of risk exposure to an acceptable level as well as follow-up actions to ensure their effectiveness.			
	LR26 It adheres to a Code of Conduct asforeseen in the GDPR.			
	LR27			

Compliance andMonitoring mechanisms	Is certified by a Competent CertificationBody as provided for in the GDPR			
	LR28 Conducts audits to verify, evaluate and assess the degree of implementation and effectiveness of the technical and organisational measures established to ensure compliance with the GDPR and the security of processing.			
	LR29 It is certified in other standards related to information security (ENS, ISO 27000…).			
	LR30 Adequately document and provide evidence of: - Compliance with the objectives of Article 5 of the GDPR. - Proper documentation of application design decisions in relation to GDPR including checklists and evidence			

Artificial Intelligence Ethics ImpactAssessment[9]	LR32 Capabilities to develop an AI ethics impact assessment based on the "The High-Level Expert Trustworthy AI assessment list to operationalise Trustworthy AI[10]"			
Mobile Applications	LR33 Ensure compliance with the obligations of the ePrivacy Directive on user permissions and cookies/fingerprints			

4.3 Use case.

Illustrate the implementation of the use case included in the Challenge Brief:

Comments from the Monitoring Team:

Add your recommendations in relation with the approach done for the Use cases and a Progress Assessment qualification (Fail, Poor, Fair, Good, Very Good, Excellent).

4.4 Implementation of recommendations

Contractors		**Monitoring Team**	
Recommendation	**How it has been addressed**	**Progress Assessment (Fail, Poor, Fair, Good, Very Good, Excellent)**	**Recommendations**
