CRANE

CRANE TD2 Challenge Brief

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Document Summary
This document is the TD2, Challenge Brief of the tender documents in CRANE.

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Acronyms

Acronym	Meaning
AES	Advanced Encryption Standard
AI	Artificial Intelligence
API	Application Program Interface
CoED	Compute on Encrypted Data
COP	CRANE Open Platform
COPD	Chronic obstructive pulmonary disease
CPS	Convertible Pseudonym System
CRANE	Comprehensive Treatment of Chronic Citizens in Rural Areas
CVD	Cardiovascular diseases
DMP	Data Management Plan
DPIA	Data Privacy Impact Assessment
EC	European Commission
EHDS	European Health Data Space
EHR	Electronic Health Record
FEV1	Forced Expiratory Volume in one second
GA	Grant Agreement
GDPR	General Data Protection Regulation
HSM	Hardware Security Modules
HTA	Health Technology Assessment
IACR	International Association for Cryptologic Research
ICT	Information and Communications Technology

CHD	Coronary Heart Disease
IMR	Identity Mixer
IoT	Internet of Things
IPR	Intellectual Property Rights
IRMA	I Reveal My Attributes
KPI	Key performance indicator
MPC	Multiparty Computation
MVP	Minimum Viable Product
NCDs	Non Communicable Diseases
OMC	Open Market Consultation
OUS	Oslo university hospital
PCP	Pre-Commercial Procurement
PDS	Personal Data Spaces
PEP	Polymorphic Encryption and Pseudonymisation
PII	Personally Identifiable Information (PII)
R&D	Research and Development
RTD	Research Technology and Development
SME	Small and Medium-sized Enterprises
SMPC	Secure Multi Party Computation
TRL	Technology Readiness Level
VBP	Value-Based Procurement

Glossary

Category	Definition
24/7 health data	Health data collected continuously (24 hours a day/7 days a week) by monitoring devices.
Analyst	An analyst can be any entity that wants to do research, analytics or insights on the CRANE data sets available.

Anonymisation and Pseudonymisation	Anonymization of personal data in the GDPR is the process of encrypting or removing personally identifiable data from data sets so that the person can no longer be identified directly or indirectly and that cannot be reversed. Pseudonymisation of data in the GDPR means replacing any information which could be used to identify an individual with a pseudonym, or, in other words, a value which does not allow the individual to be directly identified and that be reversed.
Artificial intelligence (AI)	Artificial intelligence (AI) is a wide-ranging branch of computer science concerned with building smart machines capable of performing tasks that typically require human intelligence.
Blockchain	Blockchain technology is a software; a protocol for the secure transfer of unique instances of value via the internet without requiring a third-party intermediary such as a bank or government. The blockchain is an immutable, distributed ledger that is used for recording transactions and tracking assets over a network of peers.
Computing on Encrypted Data (CoED)	Computing on encrypted data is a series of new technologies in cryptography, which enable calculations on the data without the need to decrypt them.
Data altruism	Data altruism refers to people voluntarily donating their data for the public good, e.g. for studies and research.
Data ethics	Data ethics is a branch of ethics that evaluates data practices that have the potential to adversely impact people and society. Data Ethics describe a code of behaviour, specifically what is right and wrong, encompassing the following: - Data Handling: generation, recording, curation, processing, dissemination, sharing, and use. - Algorithms: AI, artificial agents, machine learning, and robots. - Corresponding Practices: responsible innovation, programming, hacking, and professional codes.
Data Governance Act	The Data Governance Act (approved 16 May 2022) is an important component of the European strategy for data, which aims to bolster the data economy. The act creates a mechanism to enable the safe reuse of certain categories of public-sector data that are subject to the rights of others. This includes, for example, trade secrets, personal data and data protected by intellectual property rights.
Data Privacy Assessment or Data Protection Impact Assessment (DPIA)	A Data Protection Impact Assessment (DPIA) describes a process designed to identify risks arising out of the collection, storing and/or processing of personal data and to minimise these risks as far and as early as possible. DPIAs are important tools for negating risk, and for demonstrating compliance with the GDPR.
EHDS	The European Health Data Space is a health specific ecosystem comprised of rules, common standards and practices, infrastructures and a governance framework that aims at ● empowering individuals through increased digital access to and control of their electronic personal health data, at national level and EU-wide, and support to their free movement, as well as fostering a genuine single market for

	electronic health record systems, relevant medical devices and high risk AI systems (primary use of data) ● providing a consistent, trustworthy and efficient set-up for the use of health data for research, innovation, policy-making and regulatory activities (secondary use of data)
Encryption	Data encryption is a computing process that encodes plaintext/cleartext (unencrypted, human-readable data) into ciphertext (encrypted data) that is accessible only by authorised users with the right cryptographic key. Encryption converts readable data into encoded data that only people with the right password can decode and view.
ENISA recommendations	Recommendations provided by ENISA (European Union Agency for Cybersecurity) on data protection and cybersecurity.
European Digital Strategy	The EC's European Digital Strategy for the period until 2025 sets out four overarching aims: 1. Technology that works for people 2. A fair and competitive digital economy 3. An open, democratic and sustainable digital society 4. Setting Europe as a global digital player.
Personal Data Space	Personal data spaces, or PDS's, are emerging intermediary services that allow users control over the sharing and use of their data
FEV1	FEV1 is the volume of air that can forcibly be blown out in the first 1 second, after full inspiration. Values of between 80% and 120% of the average value are considered normal.
Homomorphic encryption	Homomorphic encryption is a relatively new type of encryption technology that allows computations to be done directly on encrypted data.
Interoperability	Interoperability refers to the basic ability of different computerised products or systems to readily connect and exchange information with one another, in either implementation or access, without restriction.
IoMT (Internet of Medical Things)	The Internet of Medical Things (IoMT) is the network of Internet-connected medical devices, hardware infrastructure, and software applications used to connect healthcare information technology. IoMT allows wireless and remote devices to securely communicate over the Internet to allow rapid and flexible analysis of medical data.
Lifestyle coach	A lifestyle coach is an expert on human behaviour who helps clients set and achieve their health goals.
Machine learning (ML)	A subset of artificial intelligence is machine learning, which refers to the concept that computer programs can automatically learn from and adapt to new data without being assisted by humans. The process requires a first step training that can be done with the support of humans (supervised training) or without them (unsupervised). Deep learning techniques enable this automatic learning through the absorption of huge amounts of unstructured data such as text, images, or video.
Open platform	In computing, an open platform describes a software system which is based on open standards, such as published and fully documented external application programming interfaces (API) that

	allow accessing the software functionalities. Using these interfaces, a third party could integrate with the platform to add functionality. This approach avoids any vendor lock-in by being able to replace the platform as long as the interface API continues to comply with the same standards.
Peer networks	Peer-to-peer networking is a serverless networking technology that allows several network devices to share resources and communicate directly with each other.
PEF	Peak flow measurement is a quick test to measure air flowing out of the lungs. The measurement is also called the peak expiratory flow rate (PEFR) or the peak expiratory flow (PEF).
PREMs and PROMs	Citizen reported experience measures (PREMs) are self-reporting instruments that measure a Citizens' perception of their experience whilst receiving care. Citizen reported outcome measures (PROMs) are standardised, validated self-reporting instruments which use a Citizens' views and opinions in order to assess their health status and overall well-being.
Proof of stake	Proof-of-stake protocols are a class of consensus mechanisms for blockchains that work by selecting validators in proportion to their quantity of holdings in the associated cryptocurrency. This is done to avoid the computational cost of proof-of-work schemes (which consume vast amounts of energy).
Secure Multiparty Computation	Secure multiparty computation enables a set of parties to interact and compute a joint function of their private inputs while revealing nothing but the output.
Self-care	Self care focuses more on treatment.
Self-management	Self management is about Citizens coping with their long-term health conditions, and managing the emotional and practical issues they present.
Sensitive and non-sensitive PII (Personal Identifiable Information)	Personally identifiable information (PII) is information that, when used alone or with other relevant data, can identify an individual. Sensitive personally identifiable information can include your full name, Social Security Number, driver's licence, financial information, and medical records. Non-sensitive personally identifiable information is easily accessible from public sources and can include your zip code, race, gender, and date of birth.
UI/UX design	UX (user experience) and UI (user interface) are two interdependent terms. UX design involves managing the user journey as they interact with a product or service, while UI design focuses on the actual construction of that product or service's interface. UI design is usually considered part of the UX design process.
Web3	Web3 is the third generation of the evolution of web technologies. It is still evolving and being defined so there isn't a canonical definition. What is clear is that it will have a strong emphasis on decentralised applications and make extensive use of blockchain-based technologies. Web3 will also make use of machine learning and artificial intelligence (AI) to help empower more intelligent and adaptive applications. Another aspect is the

	notion of a semantic web (with advanced means for categorising and processing data, as well as for discovering relationships within varied data sets). It includes several technologies in order to arrange and structure data on the internet to make it available and usable by programs and software thanks to a metadata system. The purpose is to make the web readable by machines and not only by humans.
Web4	Web4 is the fourth generation in the evolution of web technologies. It is also known as the "Symbiotic Web". The idea being the symbiotic web is that once the metadata are organised in Web3, humans and machines can interact in symbiosis. Meaning that we would be able to build more powerful interfaces like mind controlled interfaces for example. But Web4 is still an underground idea in progress. There is no definition of it yet.
Zero-knowledge proof	Zero-knowledge proof is a mathematical technique to verify the truth of information without revealing the information itself. Zero-knowledge proofs can be used to protect data privacy.

Reading guide

This document is intended to provide the functional requirements that should guide bidders in preparing their proposal. It intends to be specific enough in describing the problem that needs to be solved while leaving room for innovative design.

Chapter 1 in this document defines the context and the vision that motivated the development of the CRANE model for self-management of chronic conditions in rural areas through the use of personal data.

Chapter 2 describes the CRANE Open Platform Architecture and Services, this description should always be understood from a functional perspective, the proposed architecture is just as an example. Bidders are expected to propose their own approach.

Chapter 3 describes specifically the concrete expectations for development differentiated in six chapters named as common challenges. The three first sections are the core of CRANE including the development of the CRANE Open Platform Architecture and Services, and sections 4, 5 and 6 describe the services to be integrated/developed for the validation stage.

Chapter 4 includes the concrete list of requirements, associated with the common challenges, and other requirements.

Chapter 5 includes some useful information related to the pilots' sites.

Annex 1 includes a more detailed description of the participant procurers.

Annex 2 includes a use case for COPD.

Annex 3 provides useful references about the regulatory environment that is significant for CRANE.

Annex 4 includes an example of a minimum viable product for CRANE implementation.

1 CRANE MODEL

This chapter defines the context and the vision that motivated the development of the CRANE model for self-management of chronic conditions in rural areas through the use of personal data.

Setting the scene

CRANE has been developed based on the idea that the use of a broader range of data - including health data but also other personal data - will help manage, reduce the progression, and even prevent chronic conditions.

This has been expressed through the CRANE vision:

> For CITIZENS enabled through public & private data access,
> who are at risk or have a chronic condition which requires action and want to self-manage or improve the management of their health conditions,
> CRANE makes the citizens' public & personal health data automatically accessible and provides through intelligent technologies new smart and tailored insights. Unlike siloed health and social care provision, CRANE provides citizens with open & trustworthy control of their own data AND the use of it.

In the CRANE vision much personal data (e.g. the food you eat, your sleep or activity data or even the weather) is as relevant as standard clinical data; and relevant for stakeholders in patients' healthcare to be able go beyond healthcare and social care systems, and involve family/carers (e.g., the local gym, sports clubs or the municipality), especially in rural settings.

Currently all these data are dispersed in multiple silos and citizens lack mechanisms to benefit from them.

The most important challenge that CRANE faces is how to generate trust in CRANE: for sharing private data, creating a positive user experience, fostering responsibility and consciousness in users regarding their personal data management, and awareness of and management of their current health.

CRANE plans to purchase the research, development and validation of the CRANE infrastructure which will make possible for citizens to get control over their personal health data stored in public and/or private databases and to easily manage and consent the access to them to different entities, such as healthcare services, but also to analysts & researchers to be able to give back useful insights for citizens' own health management.
CRANE infrastructure will be validated with a **proof of concept** where **citizens in rural areas use their health data to improve the self-management of their chronic conditions**.

CRANE and European Health Data Space – infrastructure synergies.

CRANE aims to build the road to provide and facilitate citizens' actual and ethical control over their own health data and create a proof of concept by integrating data driven services for the self-management of three chronic conditions (COPD, Diabetes, CVDs) in rural areas.

The objectives of the European Health Data Space (EHDS) are similar to the objectives and principles behind CRANE, and have been shaping CRANE even since before the EHDS was published. For this reason, it is important that future groups of collaborators developing CRANE are aligned with EHDS:

Particularly relevant for CRANE are the following objectives of European Health Data Space[1] :

- Empower individuals through better digital access to their personal health data; support free movement by ensuring that health data follow people;
- Unleash the data economy by fostering a genuine single market for digital health services and products;
- Set up strict rules for the use of individual's non-identifiable health data for research, innovation, policy-making and regulatory activities.

The EHDS will create an opportunity for EU citizens to benefit from their own data in an ethical way, and the EHDS will set the regulatory and policy context.

We understand therefore that the CRANE infrastructure to be developed must combine as a minimum:

- An open, interoperable, and secure technological foundation based on the best of breed of current and future trust enabling technologies that safeguards the privacy and security of citizens' data while ensuring its availability for legitimate use.
- An easy-to-use service that makes it possible to substantiate informed consent management, promoting and enabling a responsible use of citizens personal data with varying levels of digital literacy.

The two pillars of CRANE

CRANE's **proof of concept for self-management of chronic conditions** is thus built on the combination of two pillars, to obtain the CRANE integrated model for self-care:

- Healthcare from home powered by a large diversity of personal data and supported by state-of-the-art technologies.
- An ecosystem for well-being to help motivate patients and engage a large community of support, creating a Garden of Care around the patient.

[1]

https://ec.europa.eu/health/latest-updates/factsheet-european-health-data-space-ehds-2022-05-03_en

Figure 1 Pillars of CRANE

Furthermore, CRANE's description and requirements have been established through a value-based model approach to secure long-term sustainability. CRANE focuses on patients and empowers them. Furthermore, CRANE can also be viewed as a Citizen2Citizen (C2C) network, for improved health through data sharing.

The CRANE Foundation

CRANE suppliers must develop an open, interoperable and secure technological infrastructure that will allow compliance with the GDPR, afford end-to-end state-of-the-art data protection, mitigate data breaches, and empower citizens as data holders to retain control and transparency. An infrastructure that will be based on user-driven design, stimulating uptake and awareness of privacy principles and data use. In CRANE, data will continue to be stored where it is generated, but CRANE will demonstrate how to unlock this data and make it available to individuals.

The CRANE infrastructure, which puts citizens in control of their data, will be the basis for a large ecosystem of developers that will create a virtuous cycle where new actionable and personalised insights will be generated through access to wider and more diverse data pools (CRANE's holistic approach), and where these insights in turn will become new valuable data sources. It will be a novel framework for interoperable data sharing enabling value-based self-management.
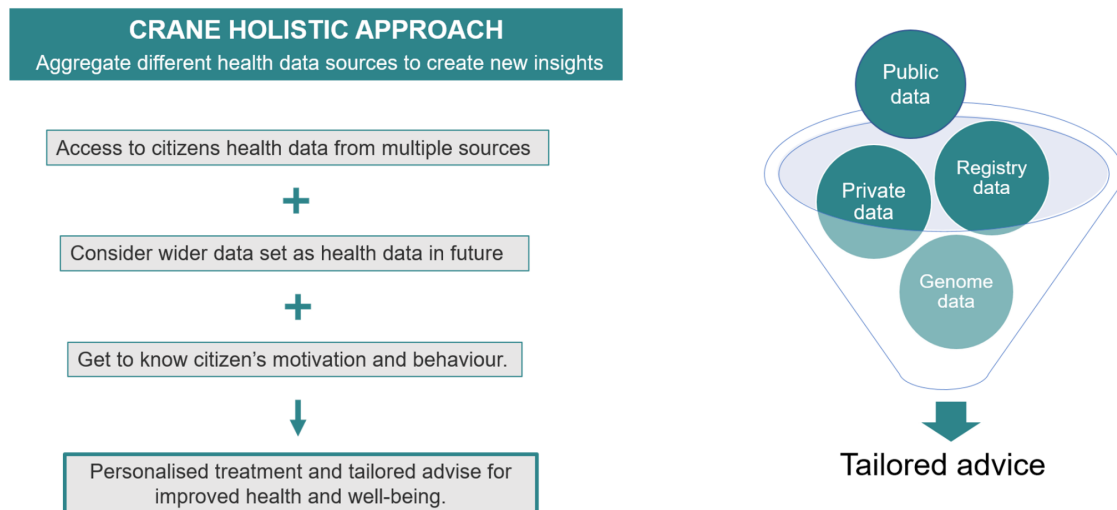
Figure 2 CRANE Foundation

The CRANE integrated model for self-management

The CRANE integrated model for self-management is, as described in Figure 3, a combination of empowering and enabling citizens with adequate health care from home, combined with an ecosystem of wellbeing. An attempt to illustrate the CRANE integrated model for self-management can be seen in Figure 3 below:
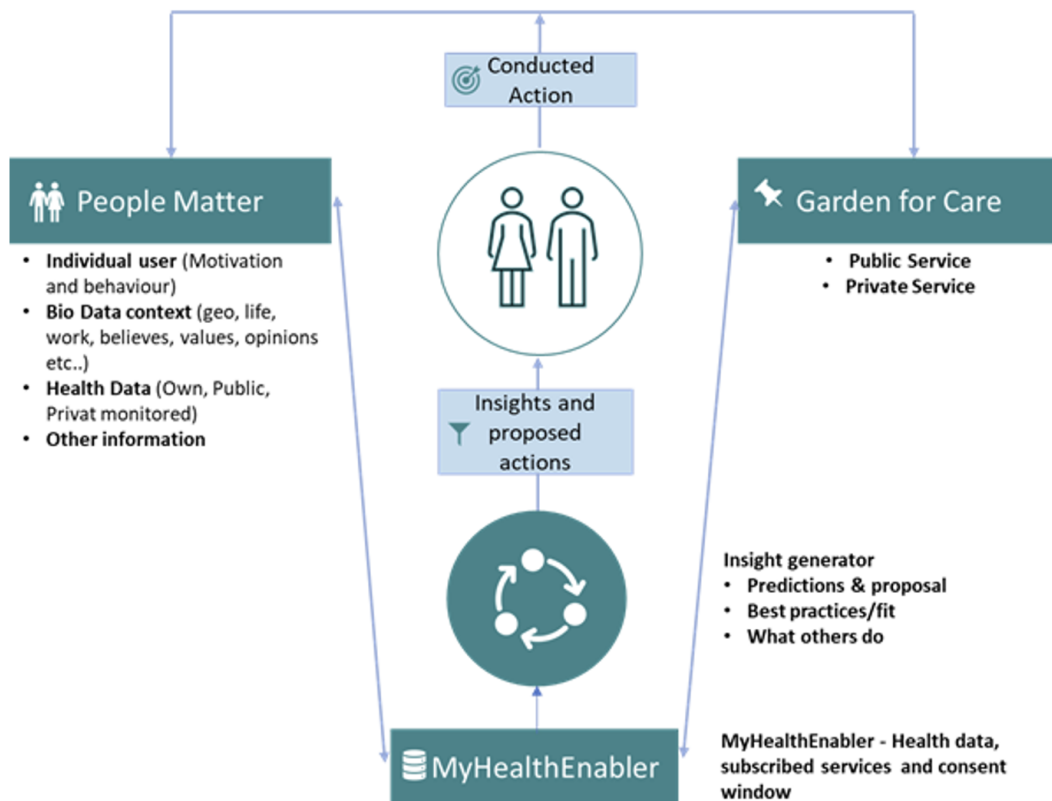
Figure 3 CRANE integrated model for self-management

CRANE will hide all the underlying complexity from citizens, providing a powerful but easy to use web-based app, *MyHealthEnabler. MyHealthEnabler* will allow citizens to access their health data at any moment, and to receive personalised content.

CRANE will also integrate third party services, and will be able to monitor vital signs, collect inputs and access personal data to provide individually tailored advice, including fostering motivation adjusted to context and behaviour.

CRANE foresees a wider ecosystem for well-being illustrated in Figure 1 (healthcare, social care, local community businesses, loved ones, innovation industry, etc) which have been grouped in Figure 3 in the **Garden of Care**.

Motivation plays a capital role in self-management, and motivation is very dependent on each individual character, circumstances, and context. The exercise to get to know the CRANE citizen user has been ascribed to **People Matter** and may be based on multiple sources of data.

It is expected that the CRANE solution will demonstrate a dynamic interplay between People Matter, Garden of Care and insights generation (e.g. Health data is changed due to increased activity level, which generates improved health data and suggest new and further tailored activities from Garden of Care).

An example of the expected services associated with CRANE can be found in Annex 4, describing how a minimum viable product of CRANE implementation could look like. These services have already been integrated in the requirements in Chapter 4.

CRANE– research hypothesis

1. Trust in privacy preserving and data access and consent management can be built using state of the art technologies – this is the biggest challenge on the road towards making CRANE a reality. Implementing CRANE (and the full potential of the ambitions of the GDPR) requires tools able to generate safe and easy consent management for personal data access, guaranteeing privacy preserving, facilitate secure and interoperable access to and analysis of personal (public and private) data, making the process secure, understandable, and credible for citizens.

2. **Relevant data for health management goes beyond health data**, as there are many kinds of personal data (grocery lists, exercise routines, social activities, …) which are relevant in building better data driven insights for the **self-management of chronic conditions**, including those generated by monitoring devices or by any other means.

3. **Self-management of chronic conditions in rural areas** should be supported by **proactive preventive care** when needed and a **supportive environment to promote the self-confidence and motivation necessary for permanent lifestyle changes.** All these imply safe and timely access and/or sharing of data between organisations. Healthcare resources should be proactively and preventively ready to be used (only) when a chronic patient is sick, while a supportive environment and data driven digital tools should create a caring and supportive environment able to preserve citizens' health and self-management.

The CRANE Buyers Group

The CRANE Buyers Group represents regions with large rural areas at risk of depopulation, where digitisation of healthcare services is at an advanced stage, data repositories between health and social services are siloed, and patients' personal data is distributed along the repositories of many service providers.

Participant procurers in CRANE are Region Västerbotten in Sweden, Extremadura in Spain, and Agder in Norway. Full description of participant procurers in CRANE can be found in Annex 1.
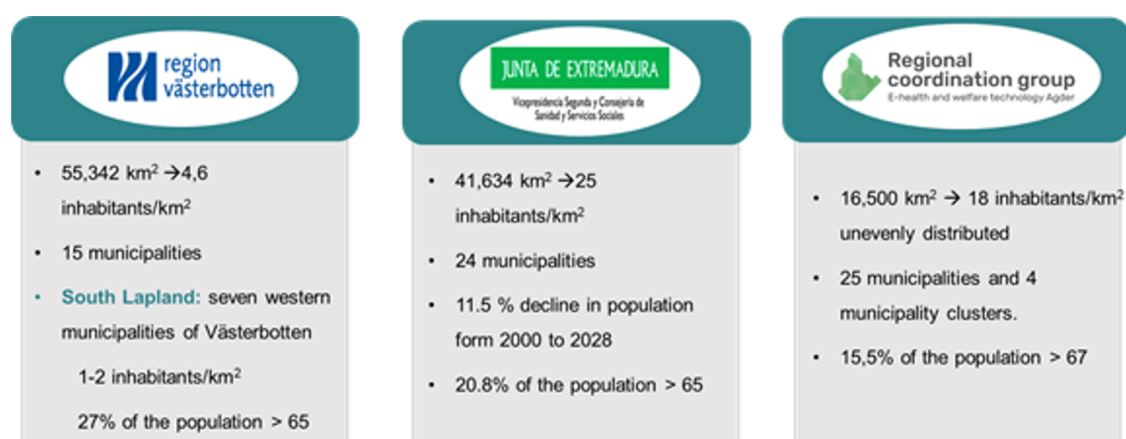

Figure 4 Procurers general description

(* for Region Agder, the age of 67 is chosen as a divider as this is the normal retirement age)

Common Needs

The present section introduces the needs identified from CRANE's users – patients and caregivers, healthcare professionals, and healthcare systems that motivates the development of CRANE. These needs have been identified and elaborated in workshops addressing the two perspectives simultaneously: on the one hand, the core CRANE data consent and access management concept, and, on the other, the proof of concept using personal data for self-management of chronic diseases in rural areas.

Patient and caregiver's perspective

Motivated patients understand that analytic use of their personal data could bring them benefits in self-managing their chronic diseases. For patients who are conscious of the need of preventing their chronic condition to evolve negatively and have the drive to improve their health status, the advantages of giving access to their personal data are worth the potential risks, although they also expect those to be minimised. Most patients would trust data sharing through CRANE if the health professionals who habitually care for them prescribe the service. Chronic patients in rural areas find visiting specialists annoying as they need to travel. At the same time, they miss support in the process of changing their lifestyle and unhealthy habits and a closer contact with other patients in their same circumstances.

Professional's perspective

Healthcare professionals are already overburdened. Most of them are aware of the possibilities offered by technologies in patients' self-management and are supportive of the idea of increased empowerment of patients in this regard. However, they are concerned about the reliability of the monitored data and about its management, fearing it may increase their workload. It is important to not burden healthcare professionals with administrative tasks that have no clinical value.
Self-management of chronic conditions entails changes in lifestyle, and this is the most difficult step for patients. Collaborating with other entities in the community that can support them in this step has been identified as a positive influence.

Healthcare system perspective

European regulations (the GDPR and the upcoming EHDS), require healthcare services to create infrastructures that handover to citizens the control over their own data, but these infrastructures do not yet exist. On the other hand, healthcare systems face an increased demand due to an ageing population; meanwhile professional resources remain limited. This is especially true in rural areas, where the fairness and balance of healthcare systems are being stressed.

Increasing efficiency in chronic conditions management could be obtained by facilitating tools to citizens to become responsible for their own health.

Also increasing the efficiency of healthcare systems requires access to decision driven knowledge of the results from the current initiatives, but the capacity is lacking in most healthcare systems due to a lack of available data to aggregate and analyse.

CRANE principles in a nutshell

CRANE recognizes citizens as the producers and owners of their own health data.

CRANE acknowledges that health data related to citizens are also generated outside the healthcare and social care system.

CRANE acknowledges the challenge for citizens to (re)view and understand their complete 24/7 health data sets.

CRANE understands the challenges in encouraging citizens to actively use their health data to improve their health condition and well-being.

CRANE acknowledges ethical and legal challenges for healthcare and social care providers to access citizens' health data.

CRANE acknowledges that self-monitoring and home healthcare are important service models to address the demographic challenge of an increasingly ageing population.

CRANE also acknowledges the increased level of complexity, caused by self-monitoring and healthcare at home due to the large amount of 24/7 health data being generated.

CRANE understands that smart data governance including efficient, effective, safe, and secure data handling becomes a key challenge when increasing the self-monitoring capacity.

CRANE understands that the future of healthcare requires a broader approach, involving entire communities.

CRANE data management

CRANE solution should facilitate:

1. The use of **GDPR and the coming Data Governance Act** including:
    - o Ethical issues.
    - o Data Management Plan.
    - o Privacy issues.
2. **Data governance for the CRANE technology and platform** including:
    - o Access to centralised and distributed platforms.
    - o Secure and privacy aware access to sharing information.
3. The **list of data sources** & enabling technologies:
    - o Use of **open, interoperable, and standards-friendly technologies** that allow to work with data from different sources that will feed the CRANE repositories, including open data, wearables, sensors, IoT devices, smartphones, medical devices, social networks, …
    - o The use of e.g. blockchain or similar technologies that can offer trust for:
        - ▪ **storing and managing informed consents**.
        - ▪ **time stamping** or time ordering in relation to any activity.
        - ▪ **smart contracting** when adding clauses or making changes.
    - o Different technologies and solutions for **managing and integrating open data**, anonymised data and pseudonymised data.
        - ▪ With a very specific requirement on **interoperability** that allows later integration of systems.
    - o Zero-proof of knowledge technologies like e.g. Secure Multiparty Computation to **share secret data (private data)**.
    - o The use of Artificial Intelligence (AI) and Machine Learning (ML) for **data exploitation**.
    - o The different **possible system architecture**, both based on centralised and distributed repositories including management, information shared and governance tools.

o   And **encryption** as an overall tool with several possibilities: for hashing in pseudonymisation, for data integrity, for confidentiality, for accountability, …

Moreover, the GDPR encourages controllers or processors to adhere to data protection certification mechanisms and/or codes of conduct. Tenderers should consider standard certified mechanisms on privacy, security, de-identification and/or anonymisation and pseudonymisation, AI and Secure Multiparty Computation. Moreover, a DPIA (Data Privacy Impact Assessment) could be necessary before authorisation to the privacy data treatment. And, for the DPIA, it will be necessary to follow the guides of the Authorities on Data Protection (DPAs) from the three CRANE countries (Norwegian Data Protection Authority Datatilsynet, Spanish Data Protection Agency AEPD, Swedish Data Protection Authority) plus the European Data Protection Board EDPB.

2. CRANE Open Platform Architecture and Services

This chapter describes the CRANE Open Platform Architecture and Services; this description should at all times be understood from a functional perspective, the proposed architecture is just an example. Bidders are expected to propose their own approach.

2.1 CRANE Technical Objectives

Objective 1: Easy compliance with the GDPR
Develop a framework which allows organisations to continue to use PII (Personal Identifiable Information) within the regulatory framework of the GDPR in a privacy-preserving manner.

Enabling technologies for this objective could be:
- Blockchain for both storing and managing informed consents.
- Tools for anonymisation and pseudonymisation.
- Secure Multiparty Computation SMC for sharing secrets (PII). [2]
- Governance tools for managing and monitoring repositories, infrastructure, access control, logs, backups, …
- Different encryption methods and algorithms for private information data processing.

Objective 2: Mitigate data breaches

Design the CRANE framework to mitigate the effect of data breaches during storage, transport or communication, and processing.

The CRANE project will therefore have a particular focus on ensuring that local data breaches have a minimal and non- escalating impact on privacy.

Enabling technologies for this objective could be:

- Blockchain for both storing and managing informed consents. But considering the ENISA[3] recommendations on access control to the stored information.
- Secure Multiparty Computation (SMC) or similar technologies for sharing secrets (PII).

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[2] ISO/IEC DIS 4922-1 - European Standards is currently under development.
[3] Distributed ledger technology and cybersecurity". January 2017

- Governance tools for managing and monitoring repositories, infrastructure, access control, logs, backups, …
- Different encryption methods and algorithms for private information data processing. For instance, Computing on Encrypted Data taking advantage of the new research activities on homomorphic encryption.

- Data Privacy Impact Assessment DPIA and security measures and security policies and guides in different items like AI and Machine Learning.

Objective 3: Control and transparency

Allow data subjects and data holders to retain control of the data and ensure transparency in its use.

Some enabling technologies for this objective could be:

- Governance tools for managing and monitoring repositories, infrastructure, access control, logs, backups, …
- Integrated proposal for all the functional and technological requirements.
- Blockchain for storing and managing informed consent.

Objective 4: UI/UX to stimulate uptake and awareness
Use the CRANE framework to raise awareness of privacy principles and solutions within academia, industries, and society in general and to support the wider uptake of the CRANE framework.

Objective 5: CRANE and standards. Compliance to relevant interoperability standards. The CRANE services should apply relevant de facto standards for interoperability, as described in chapter 2.8.

2.2 The circular CRANE model

The CRANE model is a circular framework for interoperable data sharing for value-based integrated care.

Below is the image of an overall conceptual framework for the CRANE technological model. The idea is to unlock the many individual data repositories for the CRANE user, exercising their rights as recognised in the GDPR and supporting the vision proposed by the EHDS.
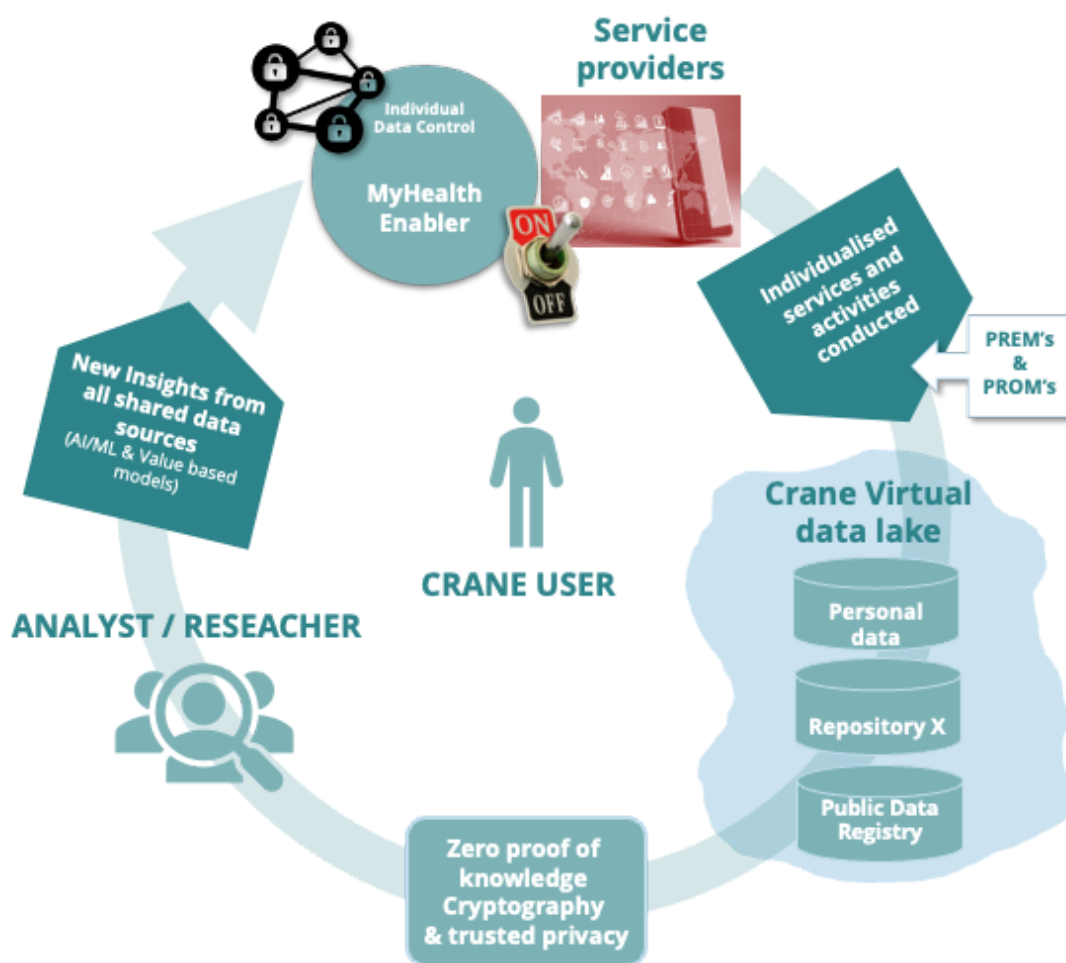
Figure 5. The circular CRANE Model

An example to illustrate the circular model in figure 5.

Lucas, a CRANE citizen user, records his diabetes data from a CGM device and other structured data measurements like weight and blood pressure from a CRANE diabetes service provider.

Lucas is exercising his right to share his data using one of the many trusted 3rd party data intermediaries, as suggested in the upcoming EHDS regulation. The data is now - via the CRANE API access - ready to be used for processing through the virtual data lake. Lucas also registers some private data (e.g. sleep data or other data) in his Personal Data Space, using MyhealthEnabler.

All these data can then be accessed for the service providers, including Municipalities/care providers and others using the CRANE insight service to compute on them.. Computing could be done anonymously or directly on the encrypted data using best of breed Zero-proof of knowledge principles and privacy measures.

Analysts/researchers from the service providers of CRANE can start build new insights and knowledge to their applications, by accessing not only their own user group data, but a range of other relevant data and even data from other diabetes service providers to be used for developing the future new AI/ML services on big data sets.

Administering advice for a diabetes patient to manage manual insulin injections can now be based on more accurate algorithms based on more contextual data, like sleep food, activity etc. That could be brought to insulin pumps thus creating new business opportunities and creating actual significant improvement in self management. These algorithms will generate data themselves that will feed into the CRANE virtual data lake enlarging the available data sources.

As the challenge is ambitious, in CRANE we aim to validate this technical infrastructure for a virtual data lake on health related data for a limited set of data. But it is vital that the ecosystem would be ready to be enlarged with more data sets and domains.

2.3 CRANE Open Platform (COP) Architecture, Roles, and Virtual Data Lake

The architecture proposed here is for inspiration, but it should not be understood as a technical specification. Bidders are expected to propose their own solution to deliver the same functionality.

The CRANE Open platform could be functionally designed in five separate layers as briefly described and shown in the figure below:
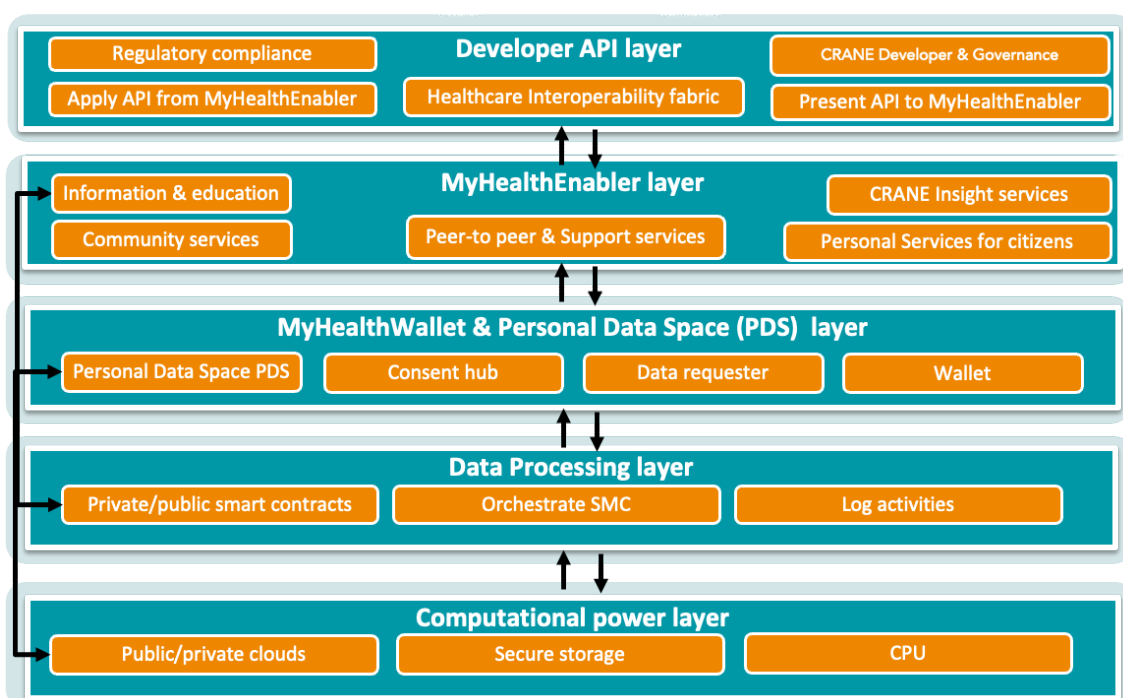
Figure 3 A proposed infrastructure for MyHealthEnabler & CRANE InfrastructurePlatform Service

CRANE Open Platform Layers

Developer API Layer that describes COP API, makes testing tools available, enforces compliance to standards, governance & regulatory framework and exposes CRANE SDK for service providers that want to use CRANE services. These service providers will be the ones delivering the CRANE use cases for COPD, CHF and Diabetes, but can be other data sources or

services. For the tendering stage, we do not require this layer to be fully developed beyond an integration API.

MyHealthEnabler layer: This layer in COP provides a bedrock for a variety of data sources and applications interacting with citizens and their peers. CRANE Insights Services is where different commercial, research or public actors can access and request data from the CRANE users either directly or anonymously (as well for primary or secondary use of citizens' data) and this request will be sent to the consent hub and stored in the wallet . Any service/platform connected to CRANE will be done through its open API from the developer layer.

MyHealthWallet and PDS layer: This layer centralises the COP services for citizens, related to consent based and privacy-preserving use of personal data potentially using Smart Contracts. It also provides a secure Personal Data Space for the storage of citizens' own data. Citizens should be able to authenticate themselves using e.g. current state-of-the-art european, national or local standards in the three buyer regions. eIDAS is a desirable additional authentication standard to be supported at the time of the tender execution.

Data Processing layerz: This layer is a two-sided distributed network that both offers transparency and privacy-preserving computation capabilities, in particular Secure MultiParty Computation (SMC)[4]. The COP should offer with reference to the Web 3.0 (web3.foundation) Tech Stack the following basic services:

- P2P Internet overlay protocols, platform-neutral execution environments e.g. containers
- Data distribution protocols, Zero/Low trust interaction platform and protocols, Transient Pub/Sub messaging all for public and private data
- Smart Contracts management for incentivised and enforced execution, secure secret management and decentralised key management, off-chain optimisations
- Developer API support

Computational Power layer: The bottom layer is the actual computing nodes running the different components of the entire system i.e.:

- The basic CRANE Open Platform Operating System
- The raw storage capabilities for the Personal Data Space (PDS) of MyHealthEnabler.
- The nodes that run the Web 3.0 Platform (SMC, P2P). Each node is intended to be operated by independent organisations, and each node consists of both a public and a private layer.

CRANE Open Platform Roles

From a user perspective, the CRANE Open Platform provides the following set of common user roles:

- **Citizens living with a chronic condition**: We expect that citizens will create an account on the CRANE Open Platform via the Personal MyHealthEnabler service and accept or reject the use of their data managing their consent via the interface. The CRANE Open Platform facilitates the use of citizens' data in exchange for insight, services or potentially other types of rewards (e.g. like tokenization).
- **Analytics**: Analysts/researchers can hold an account on the CRANE Open Platform via CRANE Insights Services and request consent to the use of citizens' data through the CRANE Insights Services interface. Analysts/researchers will explicitly describe the

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[4] SO/IEC DIS 4922-1 Information security — Secure multiparty computation

proposed use of data and the desired privacy measures applied to the outputs received from the data.

(The Analytic and Insights service are not a tool to be used by clinicians for any direct clinical decision-making towards citizens)

●	**Service and data source provider**: Data sources are integrated with the CRANE Open Platform through APIs. Each data source represents multiple citizens. Data sources can also be PDS data sources, representing a service that manages multiple PDS on behalf of individual citizens (i.e. the CRANE Open Platform PDS or third-party PDS services).

●	**System administrator**: The System administrator controls the CRANE Open Platform at IT level and provides support to the rest of the users of the CRANE Open Platform according to best practices and applicable law.

CRANE Virtual Data Lake

The CRANE infrastructure is envisioned to facilitate decentralised control on behalf of citizens. The CRANE virtual data lake will allow applications to blend data from various sources, local or remote, and it is connected or disconnected from data sources when required by the apps that use it. It is a directory of citizens' data sources (with accurate and updated data descriptions) so that applications can search for data as if it were a single data set and retrieve the needed data from its location. It guarantees control access based on user consent (managed by Smart Contracts). The users of applications/analysts/insights may only see and/or access the data they are entitled to.

Figure 4 illustrates the data flow and the involvement of: Citizens, Data sources, and Analysts.
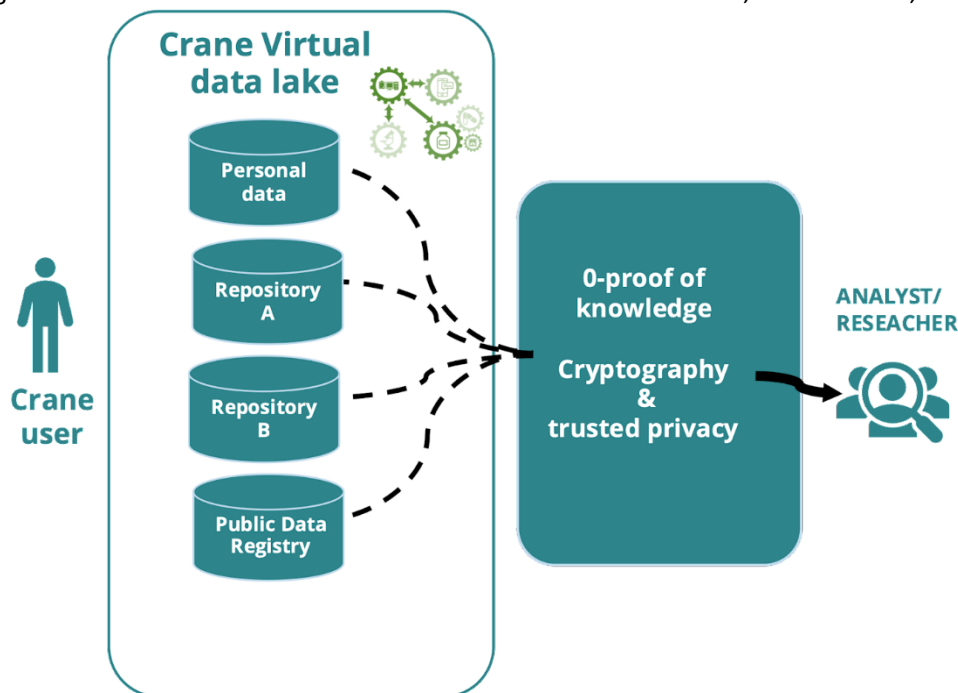

Figure 4 Data flow and SMC based processing.

The types of data sources as in the previous picture can be:

●	The CRANE Open Platform PDS or other third party PDS integrated with the CRANE Open Platform

●	Health Data Source providers (existing providers from Health Services)

- Other data sources integrated with the CRANE Open Platform

Most data is kept in external data sources, displayed and used as requested on the CRANE Open Platform.

Data according to the user consent, described in a subsequent chapter, can be transferred in different ways according to the receiver and to the type of processing as described in the following chapter.

The types of output can be:

- Direct transfer of clear data, i.e. data is not supposed to be processed by the CRANE Open Platform.
- With SMC processing the output can be any approved result e.g.:
  o Pseudonymised data
  o K-anonymity data
  o Aggregated statistics

2.4 Data Handling Types in CRANE Open Platform and Consent Management

Figure 5 pinpoints the three different types of data handling orchestrated through the CRANE Open Platform.
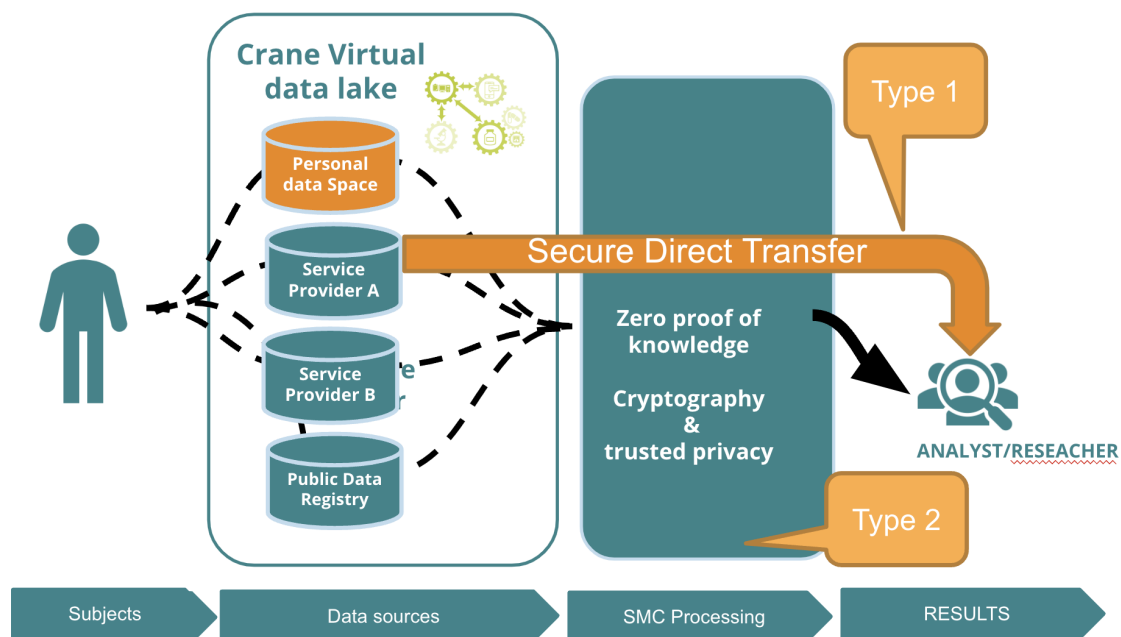
Figure 5 Types of data exchange

2.4.1 Data Handling Types

Type 1: Direct Transfer of data for Analyst elaboration

The CRANE Open Platform should allow for secure direct data transfer from a single data source to the Analyst. Direct transfer is managed by consent, could be e.g. cryptographic tokens and of course API integration. The transfer should be secured by traditional best practice encryption during transit. The CRANE MyhealthEnabler is only involved in the consent management, not the data processing.

The following steps apply for the Direct one-to-one transfer:

- Based on the citizen's consent, data should be securely transferred from a single data source to the Analyst
- The data source are encrypted
- The encrypted data is sent to the Analyst also using encryption in transit
- The Analyst decrypts the data

Type 2: Indirect Transfer through SMC processing

All data requests that are not a "Direct Transfer" are managed by the CRANE Open Platform that should be using secret sharing and technologies like e.g SMC. The data is secretly shared before it leaves the data source (an external data source or the Citizen PDS). The secretly shared information is suggested to be distributed to the three (or more) SMC nodes (servers) that constitute the SMC system. Each SMC node will then hold anonymised (i.e. secretly shared) information only. The SMC nodes collectively manage all data processing and only the result dictated by the consent should be shared with analysts. The secretly shared data should be deleted when the data request is fulfilled. Neither of the SMC nodes can access the input data at all times i.e. the CRANE Open Platform does not rely on single points of trust.

Consequently, the 3rd party data intermediary that manages the CRANE Open Platform can only access the basic data involved in managing accounts on the CRANE Open Platform, not citizens' personal data.

Breaching personal data requires the SMC nodes to collude, or multiple and simultaneous breaches and precise reconstruction of the secret shared data. The SMC protocol defines the number of simultaneous breaches required to break the security of the applied secret sharing and SMC scheme.

The following steps apply for the SMC-based many-to-one processing:

- Based on citizens' consent, data is combined and/or processed as requested using SMC orchestrated by the COP.
- The data source "secret share", encrypts data and forwards the separate shares to the independent COP node operators.
- The COP node operators receive secret shares.
- The COP nodes conduct the allowed SMC computations.
- The output from the SMC computation is constructed, encrypted and sent to the analyst. Data is erased from the COP nodes
- The analyst decrypts the output.

2.4.2 COP Approach to Consent Management

The CRANE citizen consent management and data-supported transfers play a central role in the COP. At least two types of consent management must be supported:

- **Identifiable transparent consent**, in which users grant identifiable access to selected parts (or all) of their data to an external third party. This consent is linked to Type 1 data transfers.
- **Anonymous consent** in which user data is anonymised and users' identity is kept anonymous when shared with an external third party. This consent is linked to Type 2 data transfers.

Both types of consent can also be a one-time consent, permanent consent or only for a specific period of time consent.

2.5 Transparent auditability and privacy

The CRANE Open Platform will have to find an adequate balance between transparency, auditability and privacy for it to work in fulfilling the CRANE vision. For this the COP can be regarded as a decentralised infrastructure composed of:

- A public layer that functions as a traditional distributed ledger with full transparency
- A private layer that orchestrates e.g SMC computation and other privacy-preserving computations.

The public layer should ensure a complete and transparent audit, and the private layer will ensure that data is kept encrypted while used.
The specific COP design and implementation should provide full compliance to the provisions of the GDPR. Data is kept private in all stages: at rest, in transit and in process.

2.6 COP Governance

Bidders in CRANE are expected to propose a governance model that is compliant with the current legislation, including the GDPR, the EU Data Governance Act proposal, and the upcoming European Health Data Space Regulation. This should include incorporating a trusted entity, expected to be a 3rd party data intermediary, to represent the citizens in the data sharing ecosystem of CRANE

2.7 Personal Data Spaces

PDS is a service where people store their data securely in decentralised data stores called PDS. PDS are like secure personal web servers for data. When data is stored in someone's PDS, they control the people and applications that can access it.[5]

This functionality ensures that the offering of a Personal Data Space, ideally from a 3rd party provider (PDS) can be made accessible and used through the CRANE Open Platform. The integration with the CRANE Open Platform requires that citizens represented by the PDS hold an account on the CRANE Open Platform. The CRANE Open Platform API then allows the functionality to be orchestrated by third-party applications.

The COP could consist of the following components further described below:
- Data query statistics
- Data request
- Consent
- Use of consent data

Data query statistics: This functionality ensures that data from the PDS is part of the data query statistics that analysts find on the CRANE Open Platform.

Data request: This functionality allows analysts to select the relevant data subjects and data points using data query statistics. This process should be entirely managed by the CRANE Open Platform and poses no requirements on the PDS.

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[5] Read more here: https://solidproject.org/

Consent: This functionality ensures that data from the PDS is governed by the CRANE consent. This process is entirely managed by the CRANE Open Platform (potentially through Smart Contracts) and poses no requirements on the PDS.

Use of consent data: This functionality ensures that data accessed and used through the CRANE Open Platform is secretly shared client-side at the PDS, transferred and used according to consent. This requires that the PDS integrate the CRANE API and extensions used to share secret data.

2.8 Services of the COP

The CRANE Open Platform is a three-sided platform that serves the following three primary user groups:
- Citizens
- Analysts
- Service and Data Source Providers

The three groups of users are served through the following three tailored user interfaces:
- **MyHealthEnabler**: a citizen user-centric system that provides several functionalities and services and allows a citizen to gain control and activate confidential use of personal data. The applications provide both decentralised control of personal data and orchestrate trustful privacy-preserving use of personal data.

- **CRANE Insights**: an analyst-centric application that provides several functionalities & services that allows analysts to request consent-based and confidential use of personal data.

- **CRANE SDK Developer services:** developer-centric interfaces and documentation for Service and Data Source Providers integration.

Complementing the main services described above, other basic services shall be considered, such as:

MyHealthEnabler

MyHealthEnabler will be a Web application usable by different devices that are suggested to provide the following services to the citizens:
- A dashboard exposing services that use the CRANE Open Platform where users can access their 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 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 PDS.
- Services for citizens (such as those described in chapters 3.4, 3.5, 3.6).

MyHealthWallet

The features of **MyHealthWallet** are:
- to support data sharing, consent handling and management according to the two types of consent/data handling.

● tracking the use of data and other necessary features, such as a list of consents given, withdrawals of consent, etc.

CRANE Insights

CRANE Insights should provide the following services to analysts:
● Definition of targeted citizens.
● Aggregated statistics about the data available through the CRANE Open Platform.

● Overview of data sets, together with a data dictionary wherever applicable referring to relevant standard semantic definitions, clarifying intended meaning of data, including used algorithms in the case of computed data.
● A platform/service for requesting the use of data.
● Functionalities to receive the output of the data requested.

CRANE SDK Developer services

The CRANE SDK Developer services will offer services for Service/Data Source Providers to manage the data stores and their access to them. CRANE exposed API will follow a JSON/Rest mode to import/export data from/to the data stores.
In the long term the CRANE platform could have full-fledged testing environment facilities (e.g. sandboxed docker images) to allow quality tests that, together with a standard documentation and publication process, would contribute to creating reliable and trustable services, meeting the needs of all actors.

Base Infrastructure services

The platform shall offer with reference to the Web 3.0 (web3.foundation) Tech Stack the following base services:
● Encryption services, able to provide data security encrypted with at least AES-256 or comparable algorithm;
● P2P Internet overlay protocols, platform-neutral execution environments e.g. containers;
● Data distribution protocols, Zero/Low trust interaction platform and protocols, Transient Pub/Sub messaging all for public and private data;
● Smart Contracts management for incentivised and enforced execution, secure secret management and decentralised key management, off-chain optimisations.

In addition to the above, the following will be part of the basic services:
● API Management;
● Identity & Role Management;
● Real-time logging;
● Integration management.

2.8 Healthcare Interoperability in CRANE

In ensuring successful interoperability in CRANE, it is key to support the relevant technical syntactic & semantic standards (including those of EHR). For the healthcare domain, the relevant standards will be ICD10-11 CM, LOINC, SNOMED CT, DICOM, HL7/FHIR and IEEE-073 PHD/ITU H.813.

For example, EHR data can reside in many systems. EHR data can be Patient summaries; Patient Reported Outcome Measures such as vital signs and other structured data. For the data exchange of these health-related data sets, it should be using HL7/FHIR following the semantic standards[6].

Other data sources not coming from the healthcare domain can be relevant. These are not specified here but should be added to the interoperability fabric of CRANE.

Bidders are expected to propose a governance policy for the maintenance and update of integrated data sources.

2.9 CRANE, regulation, and certification

CRANE Platform does not itself compute or deliver any medical regulated services. It provides the data and the computing capability for this to be done by external third parties (Service Providers). These parties have to comply with MDR when applicable.

The following list provides an overview of some of the identified technical standards that should be complied with when applicable (to be determined by the bidder) in all CRANE components:

- ISO 13485 - Quality Management System
- ISO IEC 27000 Standards family on Information Technology. (Security)
- ISO 14155:2020 - Clinical Evaluation Process
- ISO 14971 - Risk Management
- IEC 62304 - Software life cycle
- IEC 82304 - Software life cycle
- IEC 62366 – Usability
- ISO IEC 4922 on Security Multiparty Computation
- ITU H.8130 - Interoperability Design Guidelines for Personal Connected Health Systems

Apart from the previous regulations, CRANE solutions should also observe the following certifications and regulations if feasible:

- ISO 17523_2016 (Health info— Requirements for e-prescriptions); https://www.iso.org/obp/ui/#iso:std:iso:17523:ed-1:v1:en
- ISO 8601, Data elements and interchange formats — Information interchange — Representation of dates and times

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[6] As an example, a diabetes patient is using e.g a Roche Accuchek Guide. This device is a PCHA Continua certified product (https://www.pchalliance.org/product-showcase) that means it complies to the IEEE-073-PHD and ITU H.813 for device interoperability. That data can be used in e.g a self-monitoring service, that integrates the medical device from the device suppliers. The device supplier can also have the EHR data available in their own data repository and app, as well. This means there can be several ways to communicate the EHR data to COP.

- ISO 11238, Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on substances
- ISO 11239, Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging
- ISO 11240, Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of units of measurement
- ISO 11615, Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information
- ISO 11616, Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information
- ISO 17090-1, Health informatics — Public key infrastructure — Part 1: Overview of digital certificate services
- ISO/TS 16791, Health informatics — Requirements for international machine-readable coding of medicinal product package identifiers
- ISO/TS 22220, Health informatics — Identification of subjects of health care
- ISO/TS 27527, Health informatics — Provider identification

Other relevant to CRANE available guides are:

- "Pseudonymisation techniques and best practices. Recommendations on shaping technology according to data protection and privacy provisions". November 2019
- "Data pseudonymisation: advanced techniques and use cases. Technical analysis of cybersecurity measures in data protection and privacy". January 2021
- "Privacy and data protection in mobile applications. A study on the app development ecosystem and technical implementation of GDPR". January 2018
- "Distributed ledger technology and cybersecurity". January 2017
- "Securing Machine Learning algorithms". December 2021

3 The Common Challenges

This chapter describes the features that are expected to be delivered during the tender execution and they are classified according to six common challenges. The expected features mentioned here are further refined into requirements (chapter 4), making them more specific and providing details, such as whether they are mandatory, essential, or just desirable.

Common challenges 1, 2 and 3 are the core of the expected CRANE development, while common challenges 4, 5, and 6 are for validation and are expected to be based mostly on the integration of existing services.

3.1 Common Challenge 1: CRANE Open Platform

Rationale
To build an open, secure, interoperable infrastructure, for health-related privacy-protected data sharing and collaboration, controlled by citizens, thus creating new economic possibilities, knowledge and insights for all stakeholders for value-based healthcare.

The proposed example of infrastructure (2.3) is a possible solution to address this challenge.

Shortcomings

The components and technology pieces to build the CRANE Open Infrastructure are there, but there is not an integrated and validated existing infrastructure to be used for the purposes described. It is CRANE's vision to make it happen as close as possible to the expressed overall vision in Chapter 2 COP Architecture and Services.

Expected features and services

CRANE Guiding Concepts:

The Proposed solution for CRANE must be:
  1) Based on Open Interfaces
  2) Secure and private by design
  3) Provide support to data interoperability and integration from multiple data source providers through a Virtual Data Lake
  4) Fully comply with applicable national regulations, GDPR, applicable standards and be aligned to the upcoming EHDS Regulation.
  5) Provide citizens complete control of access to their health data through MyHealthEnabler and MyHealthWallet functionalities.

Technical Architecture Solution

We expect that COP will be built on a modular layered interoperability approach according to Open Standards components. At the conceptual level two primary layers comprise the COP:
  1. Public Layer that exposes the available services, end points, connectors, auditability, etc
  2. Private Layer that manages all the data handling privacy-preserving operations, storage, consents, etc.

From a technical approach, a layered architecture is also expected, with different functionalities exposed in each of the layers, some of them may fall into the public layer while others into the private one. The functionality provided by these layers is expected:
  1. Developers API, for learning how to work with COP.
  2. MyHealthEnabler, providing the Insights functionality and the connectors to external data sources/service providers to connect and operate within COP (and thus support the creation of the Virtual Data Lake Concept);
  3. MyHealthWallet & PDS. Its components and functionalities are covered in more detail in Challenge 2 Citizen Data Control Empowerment.
  4. Data Processing, that orchestrates access to the SMC Nodes, logs activity, and enforces smart contracts (potentially based on blockchain technology).
  5. The Computational power that provides support to the above layers ensuring they are fully secure and compliant to the utmost privacy requirements.

The proposed solution must also support different types of users in the platform, each of them with different granted permits. The minimum are: Citizen; Data Source and Service Provider; Analyst and System Administrator.

CRANE Insights Service

The proposed COP must support an analyst-centric component that provides several functionalities & services that allows a third-party external analyst to request consent-based and confidential use of personal data.

This component, part of the Data Source providers layer, is the one that will orchestrate over the Processing Layer the requested analysis and operations over the Citizen data potentially using SMC.

CRANE Virtual Data Lake Functionality

It is one of the foundation pillars of the CRANE Concept that a Virtual Data Lake built upon the available data from the different connected Data Source Providers be supported. This functionality is described in more detail in the Common Challenge 3.

CRANE Base infrastructure services

A part of the most internal, private, and lower COP layer, these services - in order to support the services of the upper layers - must include, among others, the following data encryption functionalities: P2P communication protocols; data distribution protocols and smart contracts management.

3.2 Common Challenge 2: Citizen data control empowerment

Rationale

To empower CRANE Citizens to gain technical, operational and knowledgeable control and management over its distributed data by relying on confidential, privacy-preserving and trustworthy technologies.

GDPR gives citizens the right to have control over their data, but the practicality is that this right can hardly be exercised and guaranteed/enforced as there are almost no available tools or services for citizens to do so.

Shortcomings

Personal data are currently stored in siloed repositories and citizens can't access them easily. Similarly, they do not have an overview of all their data and what is being done with them and by whom. In fact, the current approach to most consents is not actual informed consent, but just a checkbox that the user is required to approve if they want to use the requested service.

Building trust in citizens for making use of their personal data requires ensuring that they understand what privacy is based on and how it is gained and by providing a trustworthy environment.

Expected features and services

As part of MyHealthEnabler layers several critical components are expected to be provided in order to make possible citizens' data empowerment.

They are at a minimum:

- MyHealthEnabler. It is a web portal that based on web technologies provides citizens an overview of all their health data (including their PDS), data source providers, insight results, etc., and provides access to the management of the user data access consent (in MyHealthWallet).
- A Personal Data Space. Provided by CRANE itself (or possibly by an external certified third party). This PDS will provide to citizens the capability to store inside CRANE's validated infrastructure their own health related data, from basic data such as personal private data, glucose measurements, and other data.

  This PDS must be kept in a secure location as well as make use of state of the art security and data encryption technologies.

- MyHealthWallet. It is a headless (visualisation through MyHealthEnabler) service that centralises citizen data sharing, consent handling and management, and data tracking. The consent management must allow the two types of data handling (direct and indirect transfer).

The two types of data handling (direct and indirect transfer) and consent management (identifiable transparent and anonymous consent) introduced in Chapter 2.4 are to be supported.

3.3 Common Challenge 3: Unleashing the power from sharing siloed data

Rationale
In order to obtain a full holistic vision of citizens' health condition it is required that not only their healthcare and social care records be available for access, but that there be a large plethora of data sources (such as data from supermarkets, banking, personal quantifiers, etc.) that can provide valuable insights on citizens' health status. This common challenge addresses thus the interoperability of data sharing: How to integrate siloed (health) data from different sources.

Shortcomings
Citizens' data is kept in isolated systems. It is not currently possible - or not easy - to overcome the administrative, procedural and technical barriers in order to make it possible that citizens' data be used elsewhere at citizens' will. In addition there are many potential health data sources that are not/cannot be usually integrated when trying to make an assessment of citizens' health condition, but that should be taken into account.

Expected features and services
Many companies still rely on a business model based on collecting data in vendor-lock-in mode for hospitals, with individual non-interoperable siloed data. In some cases these data are "traded" or sold. CRANE wants to enable new ways of accessing this data to carry out analytics HealthEnabler layer as proposed in the Common Challenge 1. It is also administered and managed via MyHealthWallet & PDS layer from Common Challenge 2.

Guiding principles of Common Challenge 3:
- It is key to highlight that data is NOT transferred or stored into COP, but data resides where it is born, stored, handled and being continuously updated. COP only provides the access capacity to this data under citizens' control.
- Any data source connected to COP Virtual Data lake must guarantee the adequate level of security and data encryption in its interface.
- Any data source connected to COP Virtual Data Lake must provide description of the available datasets and used formats according to established standards.
- Any data source connected to COP Virtual Data Lake must abide by the consent management control of MyHealthWallet.
- The CRANE Insights service will orchestrate the analysis of citizens' data based on the extent and type of consent provided by citizens.

The integration of the external Data Source Providers into the CRANE Virtual Data Lake will be supported via the Base Infrastructure services (as exposed in the Challenge 1) that will guarantee that any data being processed or at transit in COP is always secure and encrypted. Similarly the Base Infrastructure Services will also provide the SMC nodes for any analysis orchestrated by the CRANE Insights Service.

All the Citizen Data Sources will be managed via MyHealthWallet via its MyHealthEnabler Interface.

The final purpose of creating the COP Virtual Data Lake of citizens' data is to provide as much data as possible for the CRANE Insights service in order to execute consented to analysis of citizens' own data either in CRANE or externally.

3.4 Common Challenge 4. Self-management: Monitoring

Services for self-management: Monitoring vital signs and activity of chronic Citizens and supporting them with insights

Rationale

Monitoring vital signs and activity of chronic citizens and supporting them with actionable insights are core components of self-management.
CRANE understands health data in a broader context as already described in 3.3.
Analysing all these data has a huge potential in bringing new tailored insights to help guiding people with chronic conditions towards effectively self-managing their pathology.

Shortcomings

A broader spectrum of data needs to be integrated to make advice given to citizens more personalised and useful.
There are currently no known services that allow data analysts to access this kind of live pools of data that include citizens' control of their consent, and where citizens can appear completely anonymous if they wish to.

Expected services for validation in CRANE:

1. **Vital signs and activity monitoring**

The use of sensors and/or medical devices will facilitate capturing data - at home and on the move - about citizens' health and well-being.

It is up to the awarded consortiums to select a number of parameters to be used for self-monitoring for each chronic condition. CRANE buyers expect a minimum of 2 parameters per chronic condition but encourage more relevant data sources/types to be made available for data sharing.

These services should be integrated from the state of the art in available market apps or devices when validation is to take place.

2. **Provide feedback and actionable insight on health status to citizens.**

Citizens and/or carers should receive relevant and actionable insight on how to effectively manage their chronic conditions via their self monitoring app or device service provider. In order to validate COP, the bidders are expected to include data from commercially available service providers that offer this functionality.

Insights should be:
● based on new data consented by the CRANE users through MyHealthEnabler 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, informing CRANE 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 it is so agreed, such as a prioritised summary out of threshold parameters classified according to three categories: (green, yellow, red). Periodicity, procedure (e.g. email), and receptors are to be configured.

3.- CRANE Support Centre.
The CRANE support centre entails that all tasks with no clinical value but that are necessary for the smooth execution of the CRANE services will be carried out by the different CRANE service providers.

The CRANE support centre will be able to run the logistics for device distribution, phone support for installation, online helpdesk and maintenance; the provision of lifestyle coaching; and the triage of incoming calls from CRANE users according to predefined procedures.

3.5 Common Challenge 5: Self-management: coordinating carers.

Rationale
Coordinating health and social services, municipalities, and other community resources for care around the chronic patient.
The Garden of Care is an enlarged healthcare community including healthcare, social care, municipality services, services from NGOs, private services, family, etc.

CRANE's vision of health is focused on citizens' responsibility and control. CRANE vision for chronic citizens' health is a large concept which relates to mood, joy, and social activities and not only to clinical data. So, CRANE supports an extended vision of health data that includes a large diversity of private data with health related information and an extended vision of healthcare services, which includes many other entities, such as sport municipality departments, gyms, supermarkets, NGOs or neighbours.

The availability of social activities related to adopting healthy habits could motivate citizens to comply and adhere to therapies and programmes to improve their health condition or adapt to healthier lifestyles. Interventions promoted by members/entities of citizens' Garden of Care will be "offered" according to the health preferences of citizens. This will also secure continued insight into the progression of citizens' chronic condition(s) and will help citizens with chronic conditions remain autonomous for longer.

Furthermore, the coordination and data sharing between all involved entities would increase the effectiveness of any activity.

Shortcomings
Professional care does not use data generated by citizens; social care doesn't share information with health care providers; and follow-up of citizens living with chronic conditions is usually

reactive, triggered by demand from the citizen, and not adjusted to actual real-time citizen needs.

Available resources from municipalities, NGOs, and private entities with a potential impact on people's health status are not aligned, and their data is not shared but stored in silos, not accessible between them.

Expected services to be encompassed in CRANE:

1. **Facilitating data sharing by CRANE users with healthcare and social care services based on citizens' consent.**

Both healthcare and social care services should have access to relevant information related to citizens.

The information to be shared should be co-decided by professionals and citizens.

The format, periodicity, etc., should be decided by the professionals.

Notifications of the evolution of citizens should be available for healthcare services, according to their preferences.

Data sharing between health and social services should be facilitated.

2. **Facilitating precise, concise, and relevant information about citizens' status and/or evolution to carers, family, friends, or any other member of citizens' Garden of Care based on citizen's consent.**

Citizens' Garden of Care may include family, loved ones, the gym, catering services, the municipality, etc. Members of the Garden of Care should be able to propose activities to citizens through the MyHealthEnabler Service.

Individuals/entities included in the Garden of Care of citizens should be able to decide on the procedure, content, and time format of notifications, and citizens should be able to decide what data they consent to share.

3. **Inform citizens about the activities that promote the adoption of healthy habits advocated by the Garden of Care.**

CRANE should be able to facilitate mechanisms to engage in the activities by the organising entities and to motivate citizens to participate.

4. **Education, training, and motivation in the use of CRANE for those included in the Garden of Care of citizens.**

All members of a Garden of Care, including those from the public healthcare and social services and individuals around citizens and other included entities should receive adequate education material and training to understand the CRANE service and be able to effectively support citizens.

3.6 Common Challenge 6: Self-management- empowering citizens.

Citizen empowerment, education, and motivation to foster adherence to treatments in self-management

Rationale

Compliance and adherence to self-monitoring and self-care are essential ingredients for users to succeed in self-management of their health, as are a good understanding of their condition and making the necessary behavioural changes required for healthy habits adoption; self-management is highly dependent on motivation.

Motivation is connected to a range of factors that can be monitored, including health data but also other biodata. Equally important for compliance and adherence are psychological aspects of users, such as their personality.

There are technologies at different maturity levels which have been proven to be effective in motivation towards behavioural changes; behavioural change and psychological support are research areas which offer promising perspectives based on AI and insight data.

Shortcomings

Motivation for behavioural changes needs to be adapted to the individual characteristics of citizens; to this end, CRANE's procedures should be tailored to users' profiles. Additionally, adherence to treatment demands building trust in the healthcare system and in CRANE. This will have a big influence on individuals' engagement and willingness to share their data and will therefore also influence the quality of the services provided by CRANE; the quality of CRANE services depends not only on compliance and adherence but also on trust and safety.

Expected services to be encompassed in CRANE:

- **Digital literacy, training, and trust-building. Facilitating actual informed consent.**
  CRANE should include intuitive means to explain CRANE to users, especially what is possible and what is not possible with MyHealthEnabler and with any other service available to them. A clear understanding of what CRANE means is a cornerstone to building trust and fostering engagement, especially in regards to the elements of CRANE data sharing.
  For example, self-instruction videos, games, explainers or other multimedia content can also be considered to help citizens understand how correct self-monitoring procedures are performed. Other sources of information such as FAQ sections, chatbots, telemedicine call centres, and any other intuitive communication means that will remain fashionable within the next 5 years shall be considered.
- **Health literacy**
  Users of CRANE should understand their condition and the implications of the information provided by the system. This information should be clear and presented in an attractive format to reduce any uncertainty related to their chronic condition.
  Content used to increase the health literacy of citizens must be qualified and agreed with procurers. It could come from procurers' health information channels or from other channels such as https://www.gravitatehealth.eu
- **Motivation**
  CRANE Service providers should support users to adopt permanent lifestyle changes relevant to their self-management treatment; this means that the selected CRANE

service providers should facilitate resources such as setting goals, gamification, reminders to increase motivation and adherence.

- **Peer (Citizens) networks**
  Facilitate access to existing peer networks.
- **"Prescription" of activities proposed in the Garden of Care.**
  Entities composing the Garden of Care (healthcare services, social services, municipalities, associations, NGOs, etc.) should be able to propose activities that could be especially convenient for CRANE users, such as guided walks. This could be featured in the CRANE MyHealthEnabler Portal services.
- **Citizen evaluation of CRANE services**
  Citizens should be able to score the quality of all CRANE services provided to them, both from selected service providers and the services in MyhealthEnabler.

4 Requirements

This chapter includes the concrete list of requirements associated with the common challenges, and other requirements.

4.1 Functional requirements linked to the common challenges

Each of the features included in the challenge brief has been translated into concrete requirements. To avoid constraining innovation, requirements have been defined as openly as possible.
The requirements are classified according to the following criteria:

- Functional/Non-functional: Functional requirements explain how the system must work, while non-functional requirements explain how the system should perform.
- Mandatory/Essential/Desirable: If a mandatory requirement is not met; the bid will be disqualified. Meeting requirements qualified as "essential" and "desirable" will contribute to a higher score in the fields of Excellence, Impact, and Implementation, depending on the added value they provide to the proposal - although meeting essential requirements, which contain specific details on how the requirement is to be met, will generally contribute more to the score than meeting desirable requirements.

Tenderers must include in their proposal a description of how and when (in which phase) they plan to comply with each requirement.

COMMON CHALLENGE	ID	Requirement	Non-functional or Functional Mandatory/Essential/Desirable
CH1: CRANE Open Platform			
Services for Citizen	CH1.1	MyHealthEnabler should be an application usable by different (d)apps & devices that should provide users : - a dashboard displaying services that use the CRANE Open Platform, where users can access data from public/private service providers.	Functional Mandatory

		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 keeps track of the use of data and possible rewards. - functionalities to engage CRANE Remote Support Centre.	
	CH1.2	MyHealthEnabler should be able to incorporate any relevant service for users of the CRANE open Platform, such as information sources, dashboards, educational content, peer to peer support, etc.	Functional Mandatory
	CH1.3	The bidder is expected to provide a personal data space for the MyHealthEnabler users.	Functional Mandatory
	CH1.4	MyHealthWallet application shall provide: - Data sharing, consent handling & management. The platform will ensure that any use 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.	Functional Mandatory
	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.	Functional Mandatory
	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.	Non-Functional Mandatory
	CH1.7	https://digital-strategy.ec.europa.eu/en/library/data-act-proposal-regulation-harmonised-rules-fair-access-and-use-data	
Services for the Analyst	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.	Functional Mandatory F

		- in general, the possibility to integrate with the CRANE Open Platform through APIs or through direct queries on data from COP that is available. CRANE Insights shall provide the Analyst with: - an overview of data sets, together with a Data dictionary wherever applicable, referring to relevant standard semantic definitions. Provides intended meaning of data. - 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 application users may only see the data they are entitled to see	Functional Mandatory
Base Functionalities	CH1.9	Data sources shall be integrated with the CRANE Open 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).	Functional Mandatory
	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 associated with its architectural layers.	Functional Mandatory
CRANE Public and Private Layers	CH1.11	The platform shall support public and private data sharing layers: A public layer that functions as a traditionally distributed ledger with full transparency, and a private layer that orchestrates privacy preserving computation.	Functional Mandatory

Computational Power	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.	Non-Functional Essential
	CH1.12	Computing nodes should use the best technologies (e.g. SMC, homomorphic encryption) to ensure privacy, trust and efficient computation.	Non-functional Essential
	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.	Non-functional Essential
Sustainability	CH1.14	If any trust enabling technologies like e.g. blockchain are applied to the solution, it should be done using Proof-of stake (or better) methods to minimise energy consumption.	Non-Functional Essential
Availability	CH1.15	CRANE Open Platform services should be available 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 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).	Non-functional Mandatory
	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.	Non-functional Desirable
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	Non-functional Desirable

		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 increases in the energy demand, with sustainable energy models and cost models, and without compromising on security.	Non-functional Desirable
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.	Non-Functional Desirable
	CH1.20	Solutions 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 and authentication capability of both the server and client. 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.	Non-Functional Mandatory
	CH1.21	The solution shall track various steps carried out as 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.	Functional Mandatory
	CH1.22	Data Encryption: At least AES-256 algorithm (or similar) for data encryption should be supported in order to protect data.	Functional Mandatory
Data Protection, sharing Privacy and ethics	CH1.23	CRANE's Open Platform should implement data protection and privacy protocols in compliance with GDPR.	Non-functional Mandatory
	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 to see who has access to it. The platform should	Non-functional Mandatory

			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.	Non-functional Essential
Language	CH1.26		The services should be multi-language, with support for min: Swedish, Spanish, Norwegian & English, and other regional languages.	Non-functional Mandatory
Openness	CH1.27		CRANE's Open Platform should have proven existing EU, national and/or regional infrastructure components as the first choice.	Non-functional Essential
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).	Non-functional Essential

CH2: CRANE DEVELOPER Services				
Common challenge	**ID**		**Short Description**	**Category**
Developer Tools and Process	CH2.1		CRANE's Developer's Layer should provide service developers with APIs, and related documentation, necessary to be able to integrate to the COP.	Non-functional Mandatory
	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 the CRANE Platform).	Functional Essential
	CH2.3		CRANE's Developer's Layer should be well defined in the form of APIs, preferably using the JSON REST model.	Functional Mandatory
	CH2.4		CRANE's Developer's Layer shall provide tools to visualise the data stores together with the associated JSON view.	Functional Mandatory
	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.	Functional Mandatory
	CH2.6		CRANE's Developer's Layer shall provide API for data sharing and consent management, including Pub/Sub, to trigger downstream workflows.	Functional Mandatory

	CH2.7	CRANE's Developer's Layer shall provide an API to import/export data from/to the data stores.	Functional Mandatory
	CH2.8	CRANE's Developer's Layer shall provide an API to activate the SMC to perform analysis.	Functional Mandatory
	CH2.9	CRANE's Developer's Layer shall provide an API to manage identity, roles and audit.	Functional Mandatory
	CH2.10	CRANE's Developer's Layer should provide a Developer Community Support Channel (e.g., Developer Forum)	Non-functional Desirable

CH3: CRANE Service providers			
Common challenge	**ID**	**Short Description**	**Category**
Role of Service providers	CH3.1	Bidders are expected to work with market ready service providers (as part of their consortium) that are able to deliver part or all of the services and functionality described in Challenges 4,5, and 6 and deliver their services for the 3 pathologies in phase 3 to the Citizen users in all 3 Buyer regions.	Non-functional Mandatory
Integration	CH3.2	All participating service providers have to integrate and share citizens' data with the COP according to their consent for data sharing.	Non-functional Mandatory
	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).	Non-functional Mandatory
Data sharing	CH3.4	Service providers are expected to share as a minimum 2 or more vital sign parameters with the COP. More data is recommendable.	Non-functional Mandatory

COMMON CHALLENGE	ID	REQUIREMENT	CHARACTERISTICS Non-functional / Functional Mandatory / Essential/ Desirable
CH 4: Monitoring vital signs and activity of chronic Citizens and supporting them with insights			
Vital signs and activity monitoring.	CH4.1	The **use of sensors and/or medical devices** will facilitate capturing data at home and on	Functional Mandatory

		the move about Citizens' health and well-being. At least 2 vital sign parameters per chronic condition should be collected. Data collection should be done seamlessly or minimising Citizens' intervention in terms of time and efforts.	
	CH4.2	**Provide feedback and actionable insight on health status to Citizens.** Citizens and/or carers should receive relevant and actionable insights on how to effectively manage their chronic conditions via their self monitoring app or device service provider. In order to validate COP, the bidders are expected to include EHR data from commercially available service providers that offer this functionality. Insights should be: ● based on new data consented by the CRANE users through MyHealthEnabler 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. ● notifications of out of threshold parameters, including some kind of intuitive approach, such as three levels: green (stable), yellow (moderate), and red (severe). Feedback by CRANE's Service Providers could provide notifications: ● according to pre-defined preferences by Citizens, carers, and Garden of Care entities/members, ● including disclaimers, informing CRANE 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 of out of threshold parameters classified according to three categories:	

		(green, yellow, red). Periodicity, procedure (e.g., email), and receptors are to be configurable.	
	CH4.3	If any health advice is given to Citizens during the piloting-phase testing, it should be indicated that the advice is part of a research project and adheres to all relevant applicable laws.	Functional Essential
	CH4.5	It would desirable if the Service Providers testing CRANE Open Platform provided a service that allows for self-reported PROM's and PREMS's and made it available to the care team.	Functional Essential
	CH4.6	Services that can deliver alerts for CRANE users about anticipating impending crises, e.g exacerbation attacks, hyper- or hypoglycemia or relative fast weight increase.	Functional Desirable
	CH4.7	Make disclaimers clear and easily understood to users about the limits of CRANE functionality, which does not include dealing with emergencies. Inform CRANE users (Citizens) about their role and informal and formal routes towards obtaining further guidance.	Functional Mandatory
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 all interactions 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 Citizens with the healthcare system, or eventually with the emergency department.	Functional Essential
CH5. GARDEN OF CARE. Coordinating health and social services, municipalities, and other community resources in caring.			
Facilitate access to the appropriate information for healthcare and social care services.	CH5.1	Make possible access to and notifications about the status of Citizens to healthcare services and family	Functional Essential
	CH5.2	It would be desirable that the service provider provided a dashboard of prioritised status of Citizens classified according to at least three categories: green (good), yellow	Functional Desirable

		(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 service provider created a summary of relevant updated health information that could be shared by Citizens when visiting health professionals.	Functional Desirable
Facilitating access to relevant information to health and social services, or any other entity/people in the Citizen Garden of Care about Citizens' data.	CH5.4	It would be desirable that the selected CRANE Service providers shared important notifications and data with Citizens' circle of care, with their explicit consent.	Functional Desirable
	CH5.5	Make possible data sharing between healthcare and social services according to Citizen's preferences and consent expressed through MyHealthEnabler.	Functional Essential
Engaging Citizens in activities to promote and create behavioural changes and the adoption of healthy habits promoted by the Garden of Care.	CH5.6	The MyhealthEnabler service should make it accessible for members of Citizens' Garden of Care to propose different social and other activities that are relevant to them, according to their profile and expressed preferences.	Functional Essential
CH6. PEOPLE MATTER. Citizen empowerment, education, and motivation to foster adherence to treatments in self-management.			
Digital education and empowerment.	CH6.1	Bidders should have functionality to access educational content for both Citizens and the rest of users (carers, health services, etc.) e.g., using MyHealthEnabler service as a main 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 be made available through MyHealthEnabler	Functional Essential

Trust building	CH6.2	CRANE's potential success lies in its 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 Citizens. Bidders should provide user friendly, rigorous, and easy to understand material (e.g., self-instruction videos, explainers, or other multimedia content) for all CRANE users such as Citizens, Garden of Care members, and CRANE insight data requesters (service providers/analysts & researchers).	Non-Functional Mandatory
Health literacy	CH6.3	The selected service providers should provide functionality given access to health education to Citizens, to promote long-term management of the relevant condition, including adoption of a healthy lifestyle. Educational Content that is provided in the MyHealthEnabler service must be qualified and agreed with procurers. It could come from procurers' health information channels or from other channels such as https://www.gravitatehealth.eu	Functional Essential
Motivation	CH6.4	Include motivation functionalities such as goal settings, gamifications, and reminders for healthy habits adoption and treatment adherence.	Functional Desirable
Peer support for Citizens and family	CH6.5	MyHealthEnabler should facilitate access to existing networks of peers in social media, such as Facebook.	Functional Essential
Prescription of activities proposed in the Garden of Care.	CH6.6	MyHealthEnabler should inform and send reminders to Citizens about the activities proposed in the Garden of Care, which are defined as adequate for them.	Functional Essential

Table 6: CRANE functional and non-functional requirements.

COMMON CHALLENGE	ID	Requirement	CHARACTERISTICS Non-functional / Functional Mandatory/ Essential/ DesirableConvenient
CH7 Value Based Care Model			
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.	Functional Mandatory
Data analytics capabilities	R7.2	CRANE Insight service shall demonstrate the possibility to show Citizen reported outcomes for all 3 pathologies (CVD, Diabetes Type 1 and COPD) over time using secure anonymous but identifiable data - using the COP platform SMC processing.	Functional Essential

Table 7: CRANE requirements

4.2 Other requirements

Other requirements				
Requirement				**CHARACTERISTICS Mandatory/ Essential/ Desirable**
Commercialization and Business Plan	CBR1	Affordability and competitiveness: The solution itself and its elements shall be affordable and highly competitive in the market.		Essential
	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 a commercialization 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.		Essential

Table 9:Other requirements

4.3 Legal and Regulatory requirements

CRANE is expecting that the different services presented by bidders' consortium partners will have different levels of maturity. The requirements included in this list - and classified as mandatory/essential/desirable - apply to those components with TRL levels 8 or 9, when applicable. For components still in the R&D stage (TRL ≤ 7), it is compulsory to present a description on how all applicable certifications will be reached for the industrialisation and commercialisation phases.

Legal and Regulatory requirements		
COMMON CHALLENGE		**Requirement**
Data processor reliability[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 referred to in Article 40 of the GDPR or an approved certification mechanism as referred to in Article 42 of the GDPR or: ▪ Favourable compliance audit report issued by a trusted third party. ▪ Favourable security audit report issued by a trusted third party. ▪ Certification or accreditation of the training of personnel in personal data protection, confidentiality and security. ▪ Have a data protection officer or legal support in this area. ▪ Have a security officer or technical support in this area.
	LR3	Providing adequate guarantees regarding international data transfers in case of Non-EU country location.
Ensure Data Protection by design and by default	LR4	Demonstrate the ability to apply methodologies for data protection by design and by default as required by Art. 5 and 25 of the GDPR.

[7] Providing sufficient guarantees to implement appropriate technical and organisational measures in such a manner that processing will meet the requirements GDPR and ensure the protection of the rights of the data subject (art. 28 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 before determining 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, applies the measures that have been determined and checks 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	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 of Treatments	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 techniques and 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 of security 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 national legislation.[8]
	LR19	Able to cooperate with controllers in analysing risks of varying likelihood and severity to the rights and freedoms of natural persons and able to design and implement appropriate technical and organisational measures to ensure a level of security appropriate to the risk.
Risk-based design approach and Data Protection Impact Assessment (DPIA)	LR20	Able to cooperate with controllers in conducting 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	Includes measures to address risks, safeguards and mechanisms to ensure data protection.
	LR24	Reviews the DPIAs whenever necessary and whenever there is a change in the risks posed by the processing operations.

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[8] Such as National Security Framework (ENS) and The National Interoperability Framework of Spain

	LR25	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.
Compliance and Monitoring mechanisms	LR26	Adheres to a Code of Conduct as foreseen in the GDPR.
	LR27	Is certified by a Competent Certification Body 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	Is certified in other standards related to information security (ENS, ISO 27000…).
	LR30	Adequately documents and provides 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 Impact Assessment[9]	LR32	Demonstrates capabilities to develop an AI ethics impact assessment based on the High-Level Expert Trustworthy AI assessment list to operationalise Trustworthy AI.[10]
Mobile Applications	LR33	Ensures compliance with the obligations of the ePrivacy Directive on user permissions and cookies/fingerprints.
EU Data Act[11]	LR34	The Data Act is a key measure for making more data available in The proposed Regulation on harmonised rules on fair access to and use of data — also known as the Data Act — was adopted by the Commission on 23 February 2022. The Data Act is a key pillar of the European strategy for data. It will make an important contribution

[9] If applicable
[10] https://altai.insight-centre.org/

[11] Data Act: Proposal for a Regulation on harmonised rules on fair access to and use of data | Shaping Europe's digital future

CRANE	Page 56 of 97	to the digital transformation objective of the Digital Decade. This new act should be taken into account when designing the CRANE Open Platform and it's data governance model

Table 10: Legal and Regulatory requirements

5 Validation of data-driven self-management of chronic conditions in rural areas.

This chapter includes information that is relevant for the Phase 3 implementation. It provides details for the execution of the pilots.

5.1 Targeted pathologies

The criteria used in selecting the pathologies for validation have been:
- High prevalence to facilitate recruitment
- Relevance of large data sets for caring
- Evidence of positive results in self-management.
- Availability of proven technology to support self-management
- Standard care process programs should be included

Based on the above criteria the selected pathologies are:

Cardiovascular diseases

Data use can lead the transition from a passive and reactive experience (depending on the healthcare system) to a more proactive experience of self-care.

A monitoring system for citizens at risk (hypertension with high stress levels, for instance) could help prevent adverse events or anticipate them, allowing for a more efficient employment of scarce healthcare resources. For citizens that already have had an adverse event, awareness is high and a supportive service could help make lifestyle changes easier and help them adapt their changes to real outcomes.

There are a large range of CVD, for validation in CRANE during piloting the selected ones are:
- coronary heart disease (CHD), and
- hypertension (this is not a condition but a risk factor)

Diabetes
Diabetes is probably the most complex chronic condition to deal with from the point of view of patients, especially when it is in an advanced state or if it is type 1. It requires a lot of knowledge about one's own illness and about the condition's myriad interferences in lifestyle.

Respiratory Disorder
From clinicians' perspective, the COPD care pathway workload is too heavy for using all follow-up guidelines. The lack of resources may affect the proper follow-up of COPD citizens.

Citizens need to be taught about how to live with the condition and how to rehabilitate themselves reducing the needs of rehabilitation resources.

Initial selection criteria for recruitment
- Independent citizens affected by the selected chronic conditions.
- Dependent citizens with caregivers/relatives interested in using the CRANE solution as a form of support for patient care
- NO cognitive impairment

- Digital literacy at a medium-high level, where patients are easily able to manage a tablet and/or smartphone making use of advanced functionality such as downloading apps or setting their preferences.
- Self-motivation capacity for self-management and preserving autonomy: medium to high level.
- Language: high level of the native language
- Social integration: high-level of knowledge about the system where they live.

Pilot Site	Number of users in sample for evaluation				
Region Västerbotten	Diabetes Mellitus		COPD	CVD	
	Type 1	Type 2		Hypertension	CHD
Storuman Municipality	3	3	3	9	3
Vilhelmina Municipality	3	3	3	9	3
Total	12		6	24	
Agder	Diabetes Mellitus		COPD	CVD	
	Type 1	Type 2		Hypertension	CHD
Arendal	3	7	5	12	3
Kristiansand	3	7	5	12	3
Total	20		10	30	
Extremadura	Diabetes Mellitus		COPD	CVD	
	Type 1	Type 2		Hypertension	CHD
Villanueva de la Vera	2	17	5	25	3
Jarandilla de la Vera	2	17	5	25	3

Total	40	10	56
Total	72	26	110

Table 11: Distribution of the users in the pilot sites according to the pathologies

5.2 Involved entities per validation site

Each successful bidder will be requested to validate their solution **at one validation site per procurer**. Each procurer will facilitate two validation sites with similar characteristics to avoid interference during the pilot's execution for the two final competitors. The assignment of the site to bidders will be done by lottery.

Region Västerbotten

The validation sites are:

- Vilhelmina
- Storuman

And the involved entities will be:

- Local voluntary associations NGO's
- Centre for rural medicine
- National Networks / health related
- Digital Competence Centre
- Local business offers

Agder

The validation sites are (these sites could be changed):

- Arendal
- Kristiansand

And the involved entities will be:

- Primary Care
- Hospitals SSHF
- Exercise programmes
- Frisklivssentral
- Local voluntary associations NGO's
- University of Agder
- I4H / Center for e-health
- National Networks / health related?
- Digital Competence Centre (NCC)
- Town halls

Extremadura

The validation sites are:

- Jarandilla de la Vera (Cáceres)
- Villanueva de la Vera (Cáceres)

And the involved entities will be:

- Campo Arañuelo Hospital in Navalmoral de la Mata: General Hospital with 99 beds, ER services, outpatients' consultation by specialist doctors.
- Primary care centres in the municipalities of Jarandilla and Villanueva de la Vera.
- City council of Jarandilla and Villanueva de la Vera.
- Social Services provided by both the city council and the healthcare system.
- Local associations (retired people, women, etc.)
- Digital Competence Centre in Extremadura: https://www.nccextremadura.org/
- Association of Popular Universities of Extremadura (AUPEX): https://www.aupex.org/
- Red Cross in Extremadura: https://www.cruzrojaextremadura.org/
- "The Physical Exercise takes care of you" programme (Physical Exercise for the elderly people in the municipalities of Extremadura): https://elejerciciotecuida.com/

IT systems and data sets

At this stage a complete integration is not needed for validating the CRANE concept.

So, two stages must be considered:

- In validating developments during Phase 3, EHR data will be necessary and will be used; integration of data from EHRs will be expected but will be accepted in varying formats (including manual or pdf reading with no integration at all of systems). Moreover, the way in which integration is to be done should have no impact on the CRANE concept.
- For scale-up CRANE bidders should provide evidence on how they plan to move from a pilot project to a deployment at scale and how they will integrate EHRs.

Since WHO and ITU promote the use of open standards (*reference to WHO/ITU "Digital Health Platform: Building a Digital Information Infrastructure (Infostructure) for Health"*), CRANE shall be interoperable with any of open source EHRs (e.g., OpenMRS, DHIS2 products) (*reference to Fig. 5.5.1 of WHO/UNICEF "Digital Implementation investment guide"*) for both, validation and scale-up phases.

The description of the IT systems from participant procurers is done in Annex 1.

Procurers will co-decide with contractors and facilitate during phase 1 and 2 what are the possible data set accessible through and API for phase 3

Annex 1: Participant procurers

Region Västerbotten

General description (extension, population, socio-economic data, …)

The county of Västerbotten covers 55.342 km^2 which makes it the second-largest county in Sweden when it comes to geography. However, only 2,65% of all Swedes live in Västerbotten. Its total population of 274.301 people (numbers from 2021) makes it only the 14th most populated region in the country, with a population density of 4,6 inhabitants/km^2. Almost 80% of the population live in coastal municipalities. 21% of the total population is over 65 years of age.

The largest city in the county is Umeå, which holds a university and a university hospital. There are a total of 15 municipalities in the county, ranging in population size from almost 131.000 people in Umeå to 2.380 in Bjurholm.

South Lapland which is the target area in Västerboten consists of the seven western municipalities of Västerbotten. They cover more than half of the total area of the county, but its total population is only 35.458 people, making it the most sparsely populated and rural area in the county, with a population density of 1-2 inhabitants/km2. More than 27% of the population is over 65 years of age, and in some of the municipalities, the rate is more than 32%. The distances to healthcare can also be very far from the more remote villages. The two municipalities to take part in CRANE in South Lapland will be Vilhelmina and Storuman municipality

Healthcare, social care organisation. Municipalities' role.

Healthcare and social services are organised in two different ways in Västerbotten. While primary care and specialised care are provided by Region Västerbotten; nursing homes, home care and social care are provided by the different municipalities. Primary care and specialised care use the same medical- and health information system. Health information system for social services is not integrated and can differ among different municipalities. The range of integrated care also varies among different municipalities, although most have tele-alarm systems. The information transfer that is shared with the social services is upon discharge from the hospital, if the Citizen needs additional assistance from social services, for example, home care.

Region strategy related to CRANE

Related to CRANE's vision, **region Västerbotten has a newly revised strategy for digitalization, focusing on how digital transformation can support the development within healthcare and care** for the region's inhabitants. In order for new digitalization and digitization initiatives to have the desired effect, where care recipients and care providers can take advantage of the possibilities of digital solutions. The strategy shall secure that a functioning and future-proof digital infrastructure can be developed. The goal is to meet the citizen's needs for healthcare and care "in the right way, in the right place and at the right time". For this to be possible, new working methods are also required in combination with new technology that provides secure information exchange, good communication and efficient processes and flows within and between operations and principals.

The strategy does not have any separate digitalization objectives of its own but defines four key areas that are strategically important in order to gain a clearer direction and provide energy in the transition. These focus areas also constitute an important starting point for the development of digitalization in the organisation of Region Västerbotten. These **focus areas** are:

1. Improved access to care.

2. Strengthened conditions for the individual's participation in care and health.

3. Increased digitization in infrastructure and support processes for more time for care.

4. More efficient management and advanced analysis of data for better decision support.

The content of focus areas two and four is quite aligned to the scope of the CRANE project.

Examples from Guiding principles from Focus Area two:

· A framework needs to be established and used regarding how the technical infrastructure for the area of self-monitoring is to be designed. Above all, must describe architecture to be able to support services from different providers, with user-friendly interfaces on both the Citizen and caregiver side.

· Have an innovative and development-oriented perspective for progressing further, and to create more actions towards new services and solutions.

· Extra care to ensure Citizen safety in-home care. Encourage and facilitate data sharing where it creates a basis for new medical evidence.

Examples from Guiding principles from Focus Area four:

· Open up - data is a common, strategic resource that can be used for a primary purpose and reused for purposes other than what they were originally intended for.

· Have a holistic view of information/data management.

· Access to and efficient exchange of information is a prerequisite for successful digitization.

· Laws and routines for information security must be followed.

· The data quality of data must be appropriately high.

CRANE is also **aligned with other national (Swedish) reforms** like the major national primary care reform "Good quality, local health care" launched by the end of 2020, where Region Västerbotten and the local healthcare district of South Lapland is a model area. In Good quality, local health care doctors and other healthcare professionals have committed themselves, in the next few years, to work for a change and create a model area for Sweden. The objective is that access to healthcare and care will increase and move closer to the citizens. The vision with CRANE is to move healthcare and care into citizens own homes, through Remote Citizen Monitoring, which is completely in line with Västerbotten's strategies and priorities within the national primary care reform "Good quality, local health care".

This means that the highest level of management, operation managers and associated personnel in health and care will invest in making CRANE a reality and have the conditions required to make it happen. Region Västerbotten will also provide the support needed for industrial consortia through co-creation to secure the system support, so this can be aligned to other existing <u>software infrastructure</u>. The ambition is to make RPM work for the entire population that is living in Västerbotten and beyond.

Reimbursement models

In Sweden there is no specific reimbursement model for self-monitoring or self-care activities carried out by Citizens or their relatives on behalf of the Citizens within Region Västerbotten.

At the same time, this is a question that has been debated within <u>Region Västerbotten</u>. Since it can be seen as an instrument to divert Citizens with chronic conditions into self-monitoring or self-care. Currently, investments are made where there can be a clear reduction in costs, related to personnel since our healthcare region is then reducing the use of medical locums. Knowing that self-monitoring and self-care is a strategic priority within Region Västerbotten, then reimbursement models will be addressed at a given point in time.

From a <u>municipality perspective</u>, where resources for social services and home healthcare are scarce and more limited, then a reduction of the need for physical consultations would mean that more time can be devoted to those who need physical attention.

At the same time, reimbursement models in Region Västerbotten, and when reimbursement models exist in municipalities, are only an administrative construction to secure that tax funds are distributed to where the funds are most needed and make the best use.

There is no known <u>reimbursement model in Sweden</u> that takes into account both users (e.g. social services and home healthcare from a municipal lens) and Citizens (from the healthcare system point of view). Since self-monitoring and self-care are expected to benefit both organisations, then it is important that benefits are clear for personnel (e.g. provides better working conditions, by less time spent on simple tasks and more time for what is really important) and that it saves money for both municipalities as well as healthcare services. The main benefit of CRANE from a municipal and healthcare perspective has to be to free up resources, so the increasingly ageing population with their increased physical service needs can be met with a service model that allows physical attention when so is needed. CRANE will be a paradigm shift to empower the citizens so they can fully utilize their health data for the purpose they want to use this for.

All current self-monitoring and self-care options are currently carried out in a project/pilot format, no general service options exist for the citizens' use.

ICT systems, interoperability

The actual **technology and infrastructure related to CRANE in use at the Region Västerbotten** are:

1. <u>1177 Vårdguiden</u>: Web portal for Swedish residents to get information and access to several e-services related to healthcare. Inera AB, the company behind the portal is owned by the regions and municipalities in Sweden. The residents can log in and read their medical records, book appointments and communicate with their healthcare providers.

2. <u>NPÖ</u> (National Citizen Overview): This web service makes it possible for healthcare providers to share Citizens' medical records information with each other if the Citizen has given their consent. It will also be available for the Citizen through 1177 Vårdguiden.

3. <u>Digital care meetings</u>: Citizens can book digital meetings with their doctors and care providers through their smartphones or computers. This service is only available in certain health centres.

Ongoing/planned projects:

1. <u>Digital health centre</u>: The purpose of a digital health centre is for the residents to be able to easily get in touch with healthcare, describe their search reasons and gain access to support, assessment, diagnosis and treatment via digital services. If there is a need for a visit to the care providers, the resident should be able to easily book an appointment at the health centre where he or she is listed, for further assessment and treatment, either for a physical visit or a digital care meeting. The Digital health centre will be using platform24 as the platform. It consists of 5 main modules: Triage24 for automated triage and medical history presentation, Meeting24 for communication between Citizen and care provider, You24 for management of the digital care chains, Connect24 for integration with surrounding ecosystems and Manage24 for adaptation to a care provider's unique needs.

2. <u>TIQUE</u>: A neighbouring Horizon 2020 PCP project focusing on integrated care and how to bring specialist care as close as possible to Citizens with severe heart failure, and also how to reduce the number of emergency admissions for this Citizen group.

3. <u>Data as a strategic resource (POC):</u> We are conducting a POC with IBM Cloud Pak for data. The goal is to save and store unstructured and structured health data and make it available in an efficient way when needed and to make better decisions. Simplify access to data by automatically discovering and curating it to deliver actionable knowledge assets to the users, while automating policy enforcement to safeguard use. Further, accelerate insights with an integrated modern cloud data warehouse.

4. <u>Digital transformation – Good quality, local health care (RVB)</u> – Working to develop a service option, for Citizens with chronic conditions in rural areas, for 100 Citizens (in a pilot phase) that will carry out self-monitoring and self-care. In addition, municipal social services in 7 municipalities in a rural part of Västerbotten are involved to develop distance spanning social service options for two services in each municipality.

5. <u>Self-monitoring project (Telia Health Monitoring):</u> Healthcare professionals receive regular information about the Citizen's state of health. Via sensors, the Citizen can measure, for example, blood pressure, heart rate and weight from home and then communicate and discuss the results with the staff at the health centre for a possible adjustment of medication and treatment. The objectives of this project are:

   ○ Develop working methods, processes and routines for home monitoring. These should form an integral part of the existing care processes for the Citizens included in the project.

○ Reduce the need for physical visits to the health centre for the Citizens included in the project.
○ Obtain knowledge regarding appropriate selection criteria and selection processes for the selection of Citizens for home monitoring.
○ Increase the medical quality and increase the security and quality of life for the Citizens included in the project.

6. VISUS (Cosmic): Jointly procured medical records solution between nine regions in Sweden. It is a complete solution that includes basic support for care documentation, care administration and medicines, but also support for surgical planning, anaesthesia / intensive care, obstetrics, cytostatics and operational services and maintenance. The project objectives are:

○ Create value for residents, employees and decision-makers and create conditions where Citizens will become more involved in their care.

○ Have one structured medical record per Citizen.

○ Simplify the exchange of information between different care providers so that the care staff receive better support when they have to make a diagnosis and decide on treatment.

○ Support for mobile working methods.

Home devices:

· Self-monitoring sensors.

· Telecare through smartphone, tablet or computer.

Currently in the region we can find the following systems:

RVB is soon launching a new EMR/HIS system for the more specialised care with Cambio as a vendor called VISUS (Cosmic). This is a jointly procured medical records solution between nine regions in Sweden that includes basic assistance for care documentation, care administration and medicines, but also support for surgical planning, anaesthesia / intensive care, obstetrics, cytostatics and operational services and maintenance. It uses an open architecture through open API.

Both municipalities taking part in this project are using the following systems for social care/elderly Care: Priserva system in Vilhelmina and Lifecare from Tieto in Storuman. However, the 7 municipalities connected to the healthcare district of South Lapland in Region Västerbotten are currently conducting a joint tender to purchase new EMR/HIS systems.

Regarding chronic care services, RVB is just about to launch a test for 100 Citizens related to self-monitoring and plan a trial for Telia Health Monitoring. Telia Health Monitoring sensors will be connected with the app through Bluetooth protocol and the Citizen will be able to measure heart rate, blood pressure, weight, oxygen saturation, rose, calprotectin, blood sugar, bA1c, blood status, albumin and lung function.

RVB accounts with *Registercentrum Norr*, a support organisation that works for the development of existing and new quality registers. Their task is to create synergy effects in the collaboration between registers, offer technical operation, perform statistical analyzes, provide

support for clinical improvement work with the help of register data and contribute to register data becoming useful for different users. Among their registries, we can find VHU (*Västerbottens hälsoundersökningar*), an initiative to promote the health of the population. Primarily focus on preventing cardiovascular disease and diabetes. RVB can ask for information, and they usually provide it in 1-2 weeks.

In relation to National data registries, health data is often stored in different ways at different care providers and in several different regions, which creates shortcomings in, for example, information management and situation overviews. A more cohesive infrastructure for the national quality register can contribute to raising the quality of care, improving care results, streamlining the use of resources in health care and stimulating research, development and contributing to more data-driven health care. This, however, requires a common digital infrastructure that reduces the administrative burden that currently exists for national quality registers. Therefore, has the government commissioned the e-health authority to carry out a feasibility study on the creation of a common digital infrastructure for so-called national quality registers used in healthcare. A nationally cohesive system is judged to increase the quality of care when caregivers have access to the same data. Information about the commission study on the national quality register by the Swedish government can be found here: https://www.regeringen.se/pressmeddelanden/2021/09/nationell-digital-infrastruktur-for-nationella-kvalitetsregister-ska-utredas/

Most biobanks are stored and hosted by the regions and the universities. The co-operation Biobank Sweden prepares, documents and coordinates common routines within the biobank area so that all regions apply the law in a uniform manner. In addition to representatives of biobank operations within the regions and Sweden's municipalities and regions (SKR), Biobank Sweden also includes representatives from universities, the pharmaceutical and medical technology industry and the Citizen organization. Information about Biobank Sweden and the regions' joint documents in the biobank area can be found at www.biobanksverige.se.

Biobank Sweden is a national infrastructure for biobanking that is regionally accessible and is established through collaboration between health care, academia, business and Citizen organisations. The infrastructure aims to provide Sweden with the best conditions for care and research in the biobank area, both nationally and internationally. Biobank Sweden also works to facilitate the application of the Biobanks Act. The work is carried out on assignment and with the support of regions and universities with medical faculties. The work is also supported by SKR. Data from the biobanks are easily accessible contacting their head.

Extremadura

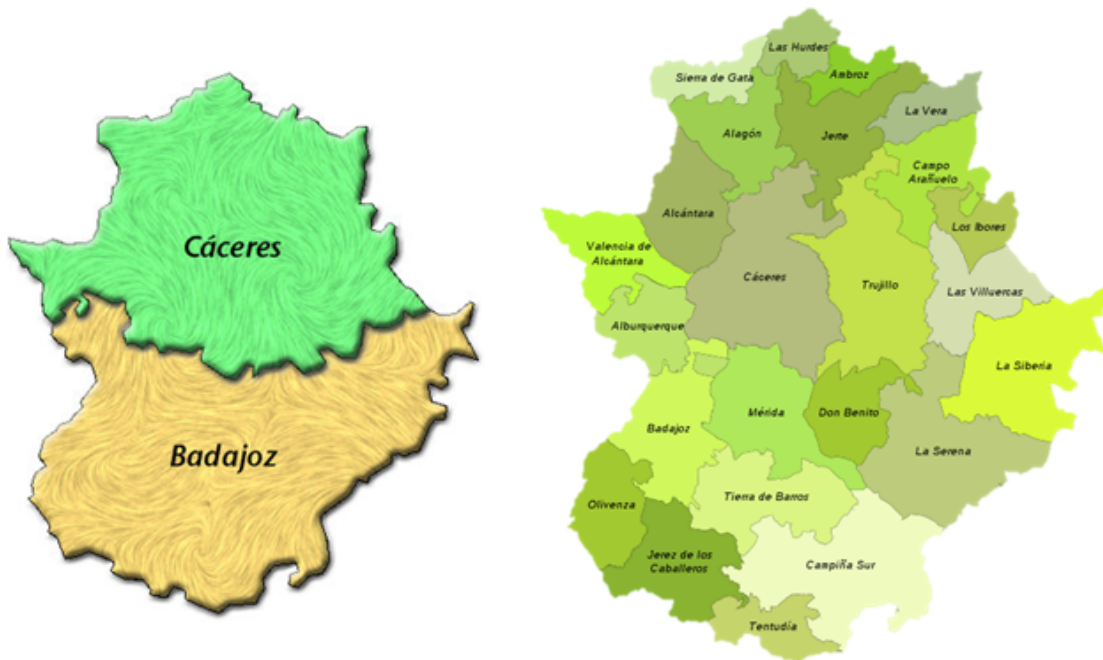## General description (extension, population, socio-economic data, …)

Figure 15 Extremadura provinces (left) and municipalities (right)

Extremadura is a Spanish region with an area of 41.634 km^2 and 1.059.501 inhabitants (25 inhabitants/km^2). It has one of the lowest population densities in Spain and at the same time, the highest percentage (>50%) of the rural population in the country. In Extremadura, half a million people leave in municipalities with less than 5.000 inhabitants in its 2 provinces Badajoz and Cáceres (Figure 18).

Current coverage of internet broadband of non-satellite technologies in the region is 85% of the population and 75% of the territory, with satellite coverage close to 100% (99.5%). There is a national Strategic plan for broadband access that aims to increase it (https://digital-strategy.ec.europa.eu/en/policies/desi-spain)

The main challenges that the region faces are:

· Ageing and chronic diseases management: Population over 65 years old represents 20.75 %. According to the Spanish national institute of statistics the ageing index (proportion of those over 65 years of age compared to those under 16 years of age) in Extremadura was 147.2% in 2021, well above the national average (129,1%)[1]. Ageing intensity (proportion of those over 80 years of age compared to those over 65 years of age): was 35.30% in 2016. 63.4% of those over 15 years of age declared that they perceive a chronic disease.

· Depopulation: The population in Extremadura has declined 11,5% between 2000 and 2018.

Competitiveness of regional companies: incorporate the digital transformation of traditional businesses.

Healthcare, social care organization. Municipalities' role.

Health and care policies are designed, promoted and managed by the Regional Ministry of Health and Social services at the Government of Extremadura. The executives partners implementing the health and care policies are Extremadura public Healthcare system (SES; "Servicio Extremeño de Salud") and Public social system (SEPAD; "Servicio Extremeño de Promoción de la Autonomía y Atención a la Dependencia"), respectively (see Fig 19). Additionally, Research and Innovation porgrammes are promoted, coordinated and managed by FUNDESALUD, bringing new product and services, as well as capabilities and new skills to the health and care system in Extremadura.

Municipalities implement care programs funded and coordinated by SEPAD. They provide a more local support to citizens, promoting healthy life styles and autonomy (healthy and active aging) through different porgrammes (although health programmes are not under their responsibility).
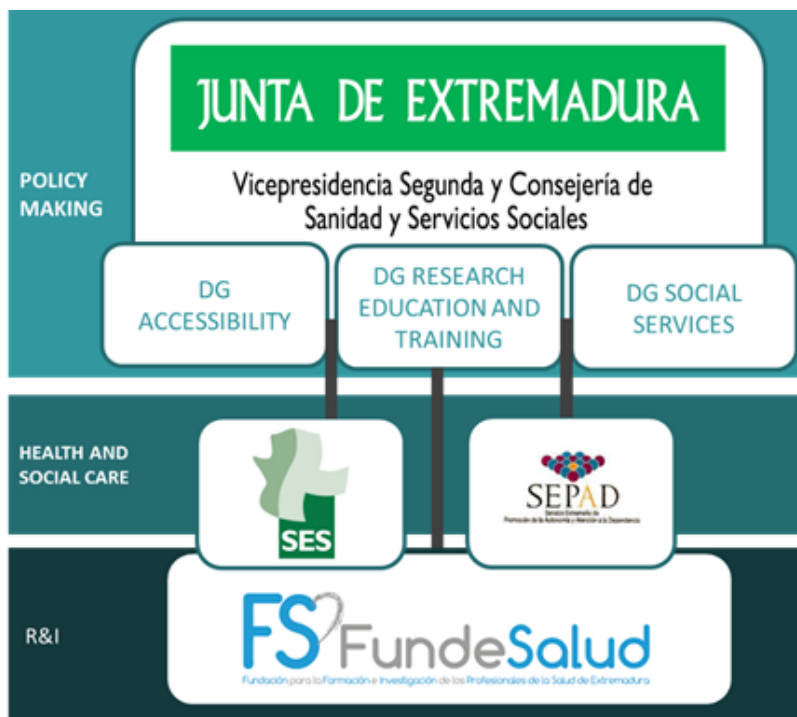

Figure 16 Public Health and care sector organization in Extremadura

Region strategy related to CRANE,

In line with CRANE vision, the region of Extremadura has on its **action lines** for the next 5 years the incorporation of digital channels in healthcare provision that allow remote monitoring and assistance to the Citizen, specifically for those in situations of high vulnerability like chronic or complex chronic Citizens. This strategy is already in place and has nearly 5M€ of governmental

funds allocated by the ministry of "*Asuntos Económicos y Transformación Digital*" [2]. Based on this infrastructure, the health and care system of Extremadura is involved in this project on the promotion of digital public services, digital literacy, e-learning, e-inclusion and e-health »includes, among the expenditure categories that can be co-financed by the Funds, the actions aimed at promoting the use of ICT in management chronic pathologies as well as telemedicine and telecare projects; the promotion of innovation in the application of ICTs for the prevention of chronic conditions and dependency; the development of content and mobile applications to promote information to Citizens, their participation and collaboration in decision-making and the integration of health information systems and social services. More info: https://www.boe.es/diario_boe/txt.php?id=BOE-A-2021-510

The current health and care system in the region already account with different digital systems:

· The regional Electronic Health Record (JARA) was implemented in 100% of primary care centres, hospitals and specialized care centres.

· Interoperability with other regions for exchanging clinical information, with an issuing and receiving profile for seven of the nine types of reports (Summary Medical Record, Emergency Clinical Report, Discharge Clinical Report, Consultation Clinical Report, Laboratory Test Results Report, Imaging Test Results Report, and Nursing Care Report). The service is activated for both citizens and professionals, having, as of April 1, 2020, 98.82% of citizens who have references to a clinical document shared in the National Healthcare System, out of the total number of citizens with a health card individual as of the reference date.

· The electronic Prescription solution is 100% implemented in health centres, doctor's offices, hospitals, and pharmacy offices. As of December 2019, it is 84.45% of the prescriptions dispensed were electronic prescriptions.

· Electronic Prescription in the National Health System since July 2015 with an issuing profile, and July 2016 with a receiving profile.

· Communication tools such as e-consultation, e-dialogue, and the availability of collaborative and multidisciplinary clinical documents are being incorporated. Video consultation between professionals of various healthcare levels and the Citizen is also available through the Online Health Center (CSOnline), a platform available in web and app modality that facilitates the relationship between citizens of Extremadura and the SES and that incorporates the health (user) folder, appointment request, treatment monitoring, information and recommendations.

Nowadays, all data is collected and stored at different entities responsible for measuring the data, under the legislation, however, few examples of distributed data approaches exist. It would be possible, through the integrated healthcare and care approach proposed in CRANE, to use the health data generated on one occasion for several purposes and multiple interventions. Health data will be gathered at citizens' own health wallet for their overview and preferred secondary use. So, **Extremadura is fully aligned with the following topics**:

· Integrate data from social care & healthcare services

· Develop innovations to improve citizens' well-being using CRANE.

· Offer to citizens a safe harbour to safely store, export and share health data through consent when so is requested.

· Offer secure, anonymous, sophisticated data processing systems to create new services which provide a foundation for improved well-being among the citizens.

· Help to tailor the appropriate combination of healthcare and social care services around the citizens, services that are easily accessible.

· Enlighten the citizens and offers increased independence including possibilities to make independent choices. CRANE empowers the citizens and allow citizens to share the data they wish with healthcare, social care providers, private service providers, data lakes, and other bodies.

Reimbursement models

In the region of Extremadura (Spain), the buyer is the Regional Ministry of Health in Extremadura and the treatments offered are part of its portfolio of social and health services. Treatment is fully covered, including monitoring devices, but some drug prescriptions may be paid or co-paid by the user.

ICT systems, interoperability

It is planned in the region for the near future:

· Launch Mobile health services through content and application development as part of the Online Health Center, to promote information and training for Citizens and caregivers.

· Implement the technology and devices necessary for the registration of Citizen care by the professional in places other than health establishments, thus ensuring a higher quality of care and security in decision-making.

To implement CRANE's approach, the region highlights the **need for a unique social history and the interconnection of medical and social history**. At the same time, **the main barriers** identified for CRANE <u>implementation include the lack of a clear definition in the tele surveillance and telecare service, the programming language of the health information system and the absence of valid information systems in social services</u>.

In the region, they have implemented an SAP-based and customised EMR system developed by IBM (JARA system-<u>https://www.fundacionsigno.com/archivos/publicaciones/PPB02.pdf</u>) that integrates specialised and primary care. Health and medical data, but also images, lab tests, prescription, human resources, finances, procurements and contracts are available at the JARA system EMR. Access is available by log-in only being authenticated as a healthcare professional. Citizens can check the history in accessing (logging) their health data (who and when). Additionally, a data management office takes care of GDPR and potential non-justified and authorized access to health profiles. However, no data for research is available (no structured data for secondary use). It is also in use an <u>app</u> for online healthcare in the region .

For data exist a national registry of the electronic health record of Citizens with interoperability and data sharing between regions, but there is no registry or datasets. Similarly, a national Biobank network exists but without a registry (<u>https://redbiobancos.es/en/about-us/</u>). In

Extremadura, regional Biobank facilities are available but only accessible locally and without integration of data and samples.

Municipalities for piloting

· Jarandilla de la Vera (Cáceres)

· Villanueva de la Vera (Cáceres)

Agder

General description (extension, population, socio-economic data, …)

Norway consists of 11 regions (counties) and has an area of 323.779 km^2 with 5.415.166 inhabitants. Agder is the southernmost region (county) in Norway and consists of 25 municipalities and 4 municipality clusters. It has an area of 16.500 km^2 and 309.000 inhabitants.

The two largest cities in the region of Agder are the county capital Kristiansand and Arendal with 113.000 and 45.000 inhabitants, respectively. The majority of the region's population and businesses are concentrated along the coastline. The population growth in Agder is unevenly distributed. The growth is highest in the "capital" Kristiansand region, while several inland municipalities experiencing weak growth.
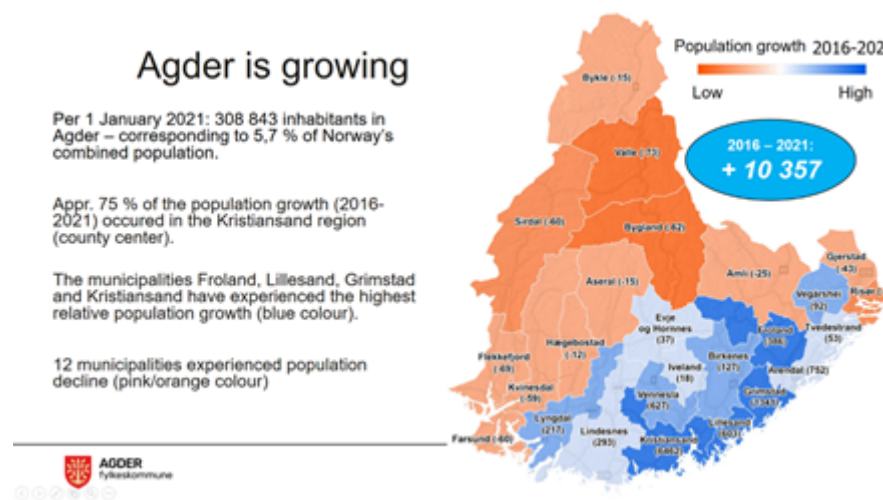

Figure 17 Population growth in Agder

It is a trend that more people choose to live in cities and rural centres, along the coast. The Centrality Index is a methodology to classify municipalities and basic (underlying) units according to the access of the population to jobs and services. Connecting statistics to centrality it becomes easier to highlight disparities and commonalities when discussing "urban-rural" issues, and one gets some objective criteria for the definition of centrality and district.
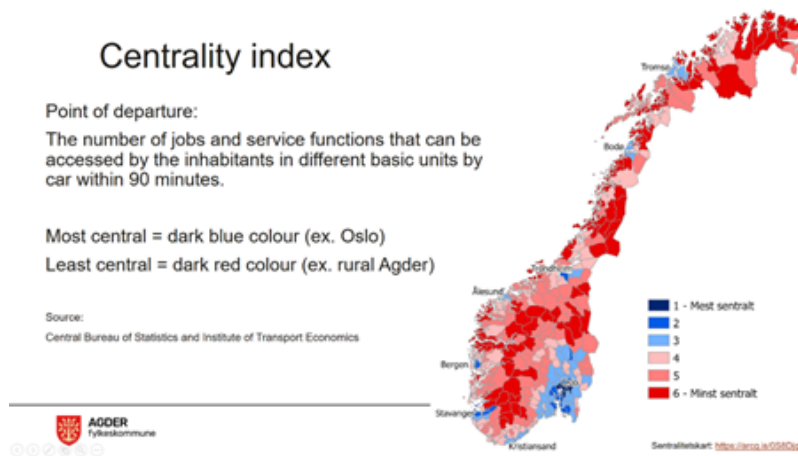
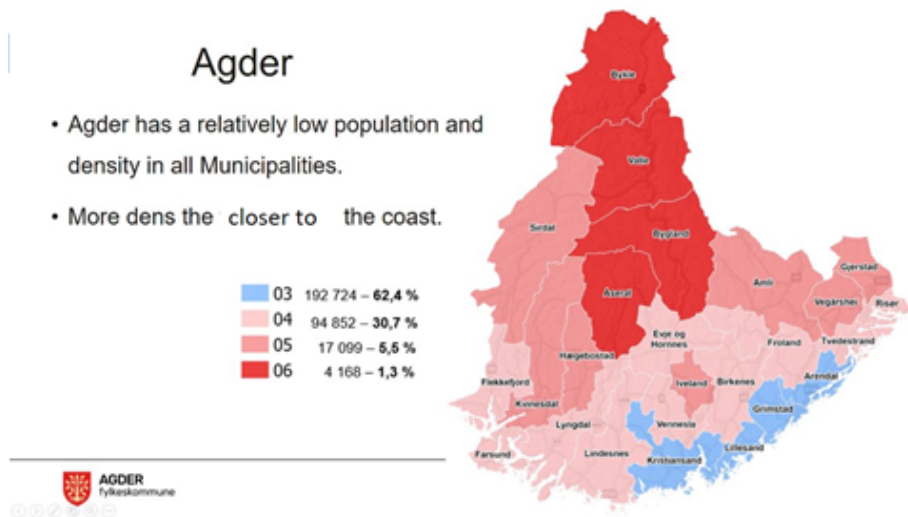Figure 18 Centrality index diagram

Figure 19 Density Population in Agder

Population projections indicate a weaker growth and increased ageing for Norway and Agder, due to expected lower immigration and continued fertility reduction. Population forecast is picturing radical changes in the age sustainability in Agder by 2020-2040- here defined as the number of people aged 20-66 per 67+. Assuming that the (low) employment rate will continue, the estimated age sustainability will become even lower.

The region holds strong competency environments - both in the business community and at the University of Agder (13.000 students). These competency environments are world-leading within the process industry, equipment to the offshore industry and use of e-health and welfare technologies. The strongest sectors are particular process and mechanical industries (https://www.eydecluster.com/en/), and supply industries for oil and gas (https://gcenode.no/). In addition, tourism is an industry that has great potential. Agder has strong clusters and networks within these sectors. Significant digitalisation, automation and robotisation are taking place within several of these industries – something that is expected to have an impact on the use of resources, and on how
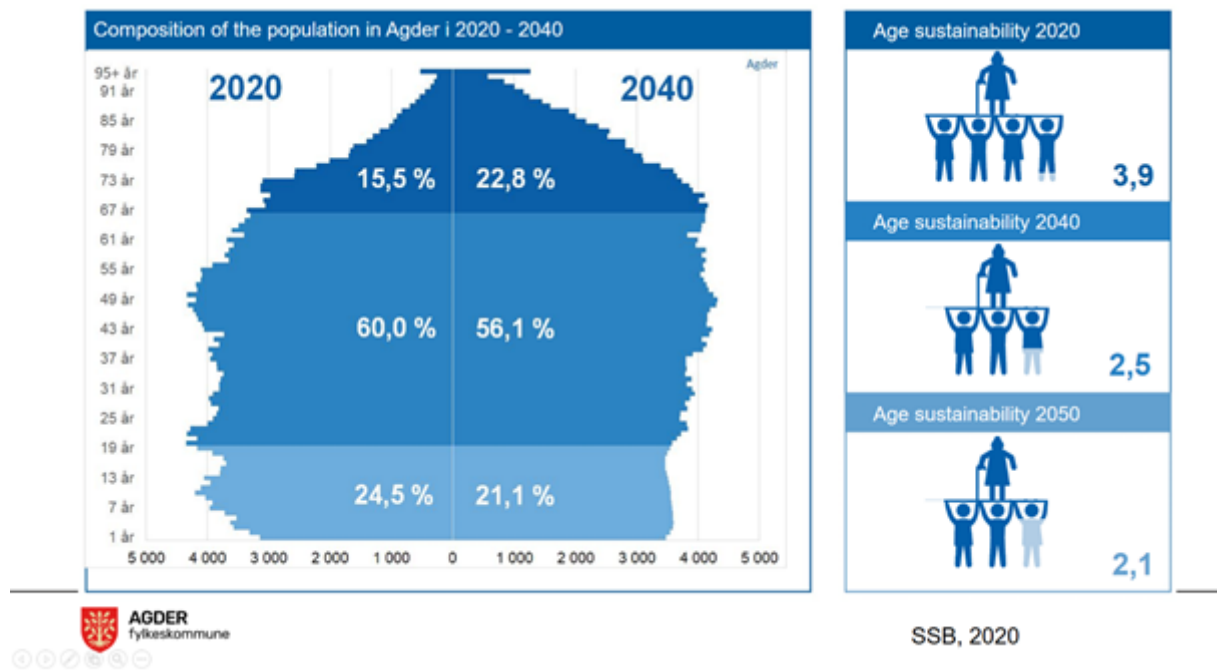
Figure 20 Population prospects in Agder

services are provided and received. There is a great potential for sustainable growth by combining the region's strong technology competencies and surplus of renewable energy (mostly hydropower). The wood industry, fishery and aquaculture have big development potential and could contribute to new jobs. Agder is among the regions in Norway with the lowest employment rates, where especially the share of young disability pensioners and recipients of allowance during the work ability assessment period is high. To maintain the current level of public welfare, the employment rate and value creation per employee must increase. It is also a priority for Agder to start using new technological solutions and new models for interaction and service development.
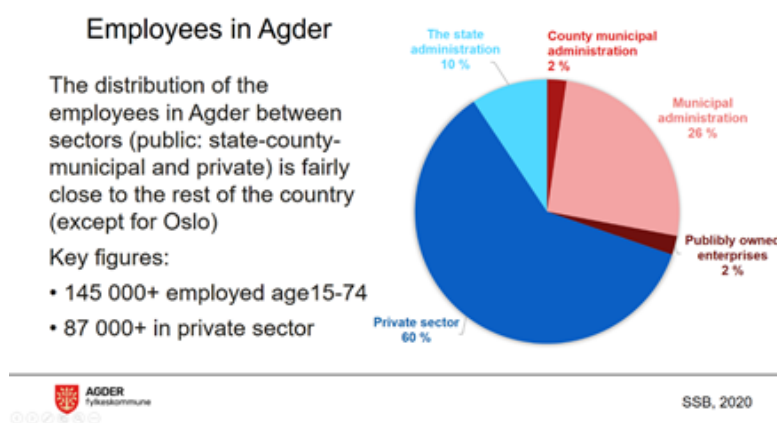

Figure 21 Distribution of the working population

More information on the Region of Agder can be found at: https://agderfk.no/_f/p1/i65e0ebe5-972d-430d-9d02-7a28e99b96d5/regional-development-plan-agder-2030_long_digital.pdf.

Healthcare, social care organization. Municipalities' role.

The Norwegian welfare state system ensures all inhabitants welfare and a certain standard of living. Everyone is entitled to a great number of universal social benefits, as well as health and care services. **In Norway, the responsibility for the provision of healthcare services is divided among different governing levels:**

1. Hospitals and specialist health services are ensured by the state.

2. The public dental health services are provided by the county municipalities.

3. The many different primary health and social care services are provided locally within each municipality.

The hospitals offer the population specialized treatment. In addition, the hospitals have tasks within research, education and training of Citizens and relatives. The Ministry of Health and Care Services has overall responsibility for all hospitals in Norway, and the state owns the public hospitals. The hospitals are organized into four regional health trusts.

The Municipal health and care services are responsible for providing good and sound health and social services to everyone who needs it, regardless of age or diagnosis. The state is responsible for ensuring equal framework conditions through regulations and financial frameworks. The state is also responsible for supervising and controlling.

Collaboration is common between the levels and between the actors at each level.

The rights to health and care services are stated by various national laws and guidelines – most importantly:

· *The Citizen and User Rights Act* – Secure users right to equal access to health and care services, regardless of individual differences (https://lovdata.no/dokument/NL/lov/1999-07-02-63).

· *The Health Personnel Act* – Outlines the responsibility of health personnel to contribute to safety and quality in the health and care services (https://lovdata.no/dokument/NL/lov/1999-07-02-64).

· *Act on municipal health and care services* – States the municipalities responsibility to ensure necessary health and care services to inhabitants (https://lovdata.no/dokument/NL/lov/2011-06-24-30).

· *Act on specialist health services* – Outline the state's responsibility to ensure necessary specialist health services to the population (https://lovdata.no/dokument/NL/lov/1999-07-02-61?q=Spesialisthelsetjenesten).

The Norwegian welfare state system is **mainly financed through state funding and taxes**-hence all inhabitants are in title to free/cheap health and care services. It is possible to buy extra private health insurance, and to some degree buy services from commercial providers. However, this system is under pressure due to the Growing elderly populations and a correspondingly decrease in workforce.

Despite all health and care services being a significant public good, the integration and flow of health data between the different providing levels are not seamless. They are both

time-consuming tools for employees and hard to familiarize with and benefit from for the Citizen/user.

The different levels of service providers use different systems, which does not offer integration between them. Even within the same level of health and care services, the systems often can't communicate.

The project *Digital home follow-up* has undertaken an interesting analysis of data flow and challenges of integration. In recent reporting, it's evident that there is no integration between solutions and systems in use at the level of hospital and that of primary health care – where Digital home follow-up usually is implemented.

- Integration between both providers at various levels and the solutions would save time and increase quality in a seamless service.

- I.e. Double entry: Alarms that trigger a measure and further record-keeping of the measures.

- No message to/from hospitals when a Citizen is hospitalized/discharged. The shortcoming of useful information to/from other services.

The Directorate of e-health Norway regarding Digital home follow-up (may 2021:14) identified National digitization needs but a common framework for harvesting and sharing data from medical equipment in the user/Citizens home is still needed.

The identified needs for integration include the following:

- Share data between actors along the course of treatment.

- Use the same equipment across actors.

- Establish a common framework for storing and using data.

- Establish common requirements for the supplier market.

- Ensure predictable functional content in joint collaboration services.

To meet these needs, a new solution must include legal elements, standardization of coding and terminology, common components and architecture.

Region strategy related to CRANE

This region has in place several strategies related to CRANE's concept with dedicated budgets from different funding sources (Municipals budgets, regional budgets and state administrator funds, National programs and allocations from the directorates, EU and other international funding and joint efforts):

1. Region plan Agder 2030

Regional plan Agder 2030's main goal is to develop Agder into an environmentally, socially and economically sustainable region by 2030 - an attractive low-emission society with good living conditions. This means to use the whole of Agder and ensure that the development benefits all parts of Agder, work together to achieve the UN's sustainability goals at a regional and local

level, work knowledge-based and purposefully to improve living conditions through a long-term and comprehensive living conditions initiative, reduce greenhouse gas emissions in Agder by at least 45 per cent by 2030, take advantage of the opportunities that digitalization provides.

2. <u>Program E-health Agder 2030, with a common regional steering group</u>

The municipalities in Agder are at the forefront and have a great influence nationally, and the solutions are based on the municipalities' needs. The Regional Coordination Group e-health (RKG) has established E-health Agder 2030, including the establishment of a regional steering group. This steering group consists of representatives at the management level from both the primary and specialist health services. In the next few years, 4 areas specifically require joint coordination and a joint program E-health Agder 2030 are established, with the following vision: "The inhabitants of Agder have access to simple, secure, comprehensive digital health and care services".

3. <u>Regional coordination group e-health and welfare technology Agder (RKG)</u>

The Regional coordination group e-health and welfare technology Agder (RKG) is the anchoring structure of 25 municipalities and it was established by the municipal directors' group (Rådmannsgruppen - regional plan Agder) in January 2016, with the following purposes:

○ The goal is for the region to be a leader in welfare technology in Norway.

○ The work will stimulate research, development, and business development in the region.

○ The purpose is to increase regional municipal coordination and anchoring in Agder.

RKG e-health works to achieve the UN's sustainability goals especially in three areas: Good health, Innovation and infrastructure and Collaborate to achieve the goals.

Reimbursement models

In Norway necessary health care is free, so the municipality/hospitals are obliged to provide the service. Regarding security technology is deductible if not necessary health care. There is no national standard for which payment solution is to be used as a basis. Therefore, today many solutions coexist and it is difficult to add or remove payment in case of change in need. Attempts to create a joint payment solution in Agder are not in place, complicated by different municipality sizes and degrees of implementation. Moreover, different technologies get different status (private purchasing vs. municipal procurement) and payment solution depends on health needs and allocation.4.2.3.5 ICT systems, interoperability.

ICT systems, interoperability

The actual technology related to CRANE implemented or planned to be in place in the region comprise:

1. Central infrastructure:

● <u>Response Center</u>, technical routing of alarms from various user devices (telecare).

In use and continuously under development:

- HelseNorge.no is the public health portal for residents in Norway. The Norwegian Health Network is responsible for the operation and development of the website.

  - Make it easier to find and choose a therapist.

  - Provide information and advice on health and lifestyle, symptoms, illness, treatment and rights.

  - Provide access to your core health journal.

  - Allow you to change GP.

  - Provide an overview of your medicines.

  - Provide an overview of your vaccines.

  - Give insights to Citizen records from the specialist health service.

  - Facilitate digital dialogue with health contacts such as GPs and municipal health services.

  - Norwegian Health Network operates national e-health solutions like Helsenorge.no, E-prescription or Core journal.

· Norwegian Health Network SF (NHN) is a Norwegian state-owned enterprise established and owned by the Ministry of Health and Care Services. NHN's mission is to deliver and further develop national ICT infrastructure for collaboration between the actors in the health and care sector. Norwegian Health Network should:

· Welfare Technology Hub (VKP) is a service that handles data flow between welfare technology solutions and electronic Citizen records. The goal is to facilitate the spread of welfare technology so that it can become a natural and integrated part of health and care services.

- Electronic Health Record (EHR) In Agder all 25 municipals, more than 300 General Practitioner and 3 Hospitals use an EPJ.
  - The municipalities use many different EPJ systems. Most common within health and care are: Gerica fra Tieto/Evry, Profil fra Visma og CosDoc/DIPS Front.
  - The specialist health service use DIPS.
  - The GP's use CGM, InfoDoc og PriDok.

Under development and planned:

· Joint Medical Record Solution (Felles kommunal journal, FKJ) are digital joint solutions that will meet the future requirements for collaboration across health treatment levels, between institutions and within the municipalities in the health and care sector. Open platform approach with a clear distinction between the data and the functionality of applications. It aims to:

  - Link municipal health and care services better together.

  - Provide Safer and better health services for the inhabitants.

o Facilitate workdays for healthcare professionals, with easy and secure access to Citizen information.

o Favour citizens access to simple and secure digital services, as well as to their own health information, logs of who has accessed their information, and opportunity to share/retain information.

o Keep data available for quality improvement, health monitoring, management and research.

- Innovation partnership
    - Procurement project, innovating a platform for follow-up services of welfare technology solutions.
    - Developing a flexible platform and an open ecosystem that handles signals from both safety and welfare technology, and medical measurements in one place. Single sign-in. The users of the platform are health personnel across the municipality, GPs and hospitals, personnel in the response services, logistics managers and technicians.

2. Home devices and sensors:
- Self-monitoring.
- Bring your own device.
- Digital home follow-up and Tele-medical Central.
- Digital telecare and Response Center Services.

Some of these are actually integrated with the health care system in the region (private tablets etc. within digital home follow-up), and are in some way part of a future implementation plan. The use of home devices and sensors are a process continuously under development, depending both on structured implementation plans and curious and knowledgeable personnel and users finding useful new ways of working together. There is a limited overview over which *Bring your own devices* that are in use.

The backend systems used for treating chronic care Citizens currently in Agder:

In the specialist health service, DIPS is used (https://www.dips.com/uk), Helse-Midt is now working towards launching the health platform provided by Epic.

To ensure that electronic messages can be sent and received in a standardized format between actors in the health and care sector, suppliers at the *Norwegian Health Network* have established a test and approval scheme. When choosing a supplier, the procurer should check whether the format has been tested and approved. The message exchanges have standard sets of messages and runs between the municipality, General practitioners (GPs) and specialist health   services.
https://www.nhn.no/samhandlingsplattform/veileder-for-elektronisk-meldingsutveksling.
Standards are available at https://www.ehelse.no/standardisering/standarder. As previously mentioned, we have a core medical record that all residents have access to at HelseNorge.no. Here data is shared from various registers, such as documents from the specialist health service, population register, GP register, SYSVAK and others. More info available at: Kjernejournal - helsenorge.no

The welfare technology hub (VKP) is used for transferring data between the welfare technology and the EHR, by means of APIs. VKP is a cloud-based collaboration solution for exchanging

synchronous and asynchronous data between healthcare applications in a secure and consistent way. The communication between the health applications runs through the Health Network Helsenettet. The systems are integrated through VKP, which in turn performs adaptations of protocols and ensures the necessary transformation of various data formats. There are open standardized interfaces between VKP and the various welfare technology solutions, but supplier-specific interfaces between VKP and the Electronic Citizen Journal (EHR). At the following site more details can be found.

Regarding chronic care service providers or Remote Citizen monitoring services, at the telemedicine centre in Arendal, *Open Tele Health* (Danish solution with Siemens Healthineers as the Norwegian supplier) is used. *The Digital Hands* (Siemens) app is downloaded from the Appstore / Google Play. Some solutions are delivered to Citizens for home use, an example is a project between the hospital (heart day centre), *NOKLUS* and Citizens on self-monitoring of anticoagulation treatment (INR and self-administer of Marevan / Warfarin). The device is called *MicroINR* and is supplied by Aidian Norway AS. Unfortunately, there is no electronic transfer of data between the instrument and the hospital or GP's medical record system. The values are hence noted on paper and coordinated orally between the Citizen and the NOKLUS consultant, who also provides the Citizen with the necessary training. Efforts are made to share data with EHR via a welfare technology hub. See more info about the APIs here: APIs: Details - VKP utviklingsportal (azure-api.net) .Reimbursement methods for medical devices to the target pathologies are uncertain, possibly different solutions dependent on status as a pilot or implemented service. Finally, Bluetooth technology is commonly used in the "devices" used at the telemedicine exchange, for example in the pulse oximeter.

In the region, there are two main actions to collect data services/registries that you can access contacting the *National Service Environment for Medical Quality Registers* in your own region for advice and guidance on how the registers can be built up (variables) and how these can be extracted. (https://www.kvalitetsregistre.no/).

> · *The health analysis platform* aims to provide more and better health research. The platform will simplify access to health data, facilitate analyzes across different data sources and strengthen privacy. It is still under development, but already open for limited use. Data is found in a number of different registers that are not linked together. Obtaining data from multiple sources takes several months, and in some cases years. This means that research takes too long, and that important hypothesis about connections between diseases are never explored. The health analysis platform responds to these challenges by linking a large number of health registers and other related data sources. Privacy and information security are key requirements for the solution. Privacy shall be strengthened, for example, by the opportunity for access to what is registered about each individual register, better opportunities to give and withdraw consent and better tracking of the use of the information. More information: Helseanalyseplattformen - ehelse.

> · *The medical quality register* is used in specialist health services to gather information on assessment, treatment and follow-up of Citizens within defined disease groups. The national service environment for medical quality registers offers assistance and operation of medical quality registers. (https://www.kvalitetsregistre.no/)

Relevant data registries for statistical, research or population health management issues that you can apply for data from KPR (Søk om data fra KPR - Helsedirektoratet) include:

> · National health analysis data platform: Helseanalyseplattformen - ehelse.

· Municipal Citizen and user register (CPR): Kommunalt pasient- og brukerregister (KPR) - Helsedirektoratet.KOSTRA mean Municipal-State-Reporting and provides management information on resource efforts, priorities and goal achievement in municipalities, districts and county municipalities. There are figures on, among other things, health and care services, and one can compare municipalities with each other, with regional divisions and with the national average. KOSTRA and much more statistics on Norway, population, health, work and many other welfare-related topics at: https://www.ssb.no/.

Norway also has an electronic tool for retrieving information from its national biobank, *eBiobank* (https://forskerstotte.no/home/biobanker/eBiobank/18889). It provides an overview and documentation of all samples (tracking). Provides access to clinical data (data warehouse) and data is structured (registry tool). Sensitive information is encrypted and unidentified donor numbers are dealt with. Ebiobank is used at OUS HF, Ahus HF and SSHF.

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[1] https://www.ine.es/jaxiT3/Datos.htm?t=1452#!tabs-grafico

[2] https://www.boe.es/diario_boe/txt.php?id=BOE-A-2021-510

Annex 2 Use case COPD

Initial input

Chronic obstructive pulmonary disease (COPD) is a chronic inflammatory lung disease that obstructs airflow from the lungs. Symptoms include breathing difficulty, cough, mucus (sputum) production, and wheezing. It's typically caused by long-term exposure to irritating gases or particulate matter, most often cigarette smoke. People with COPD are at increased risk of developing heart disease, lung cancer and a variety of other conditions.

Existing data on COPD prevalence are in general incomplete; in many regions of Europe, there is a striking scarcity of epidemiological information about this important health issue. Despite this, recent estimations suggest a prevalence of 7.7% in Europe, which means around 60 million people.

COPD has no cure, but the disease's evolution can be controlled with medication, adapted exercise, oxygen therapies, and by giving up smoking. Self-management is key; drug adherence and lifestyle changes can reduce and even avoid exacerbations and hospital admissions altogether.[12]

Citizen persona

Carmen is 66 years old, lives in Jarandilla de la Vera, a rural village in the province of Cáceres, in Extremadura, and is married to Alberto (68) and has three children, María (35), Ana (32) and Alfonso (28). Carmen was diagnosed with the condition at the age of 52, while working in the banking sector, having reached the position of deputy director of a bank branch. The diagnosis ended her professional life. Now she lives on a disability pension.

COPD appearance

Carmen was a heavy smoker for many years and not very active physically. In her mid-forties, Carmen started to develop morning coughs that gradually deepened. She also started to get increasingly tired when shopping or climbing stairs. As a result of tiredness, she steadily reduced her mobility. Her physical condition worsened, and so did her social life. As a result of her confinement at home and reduced contact with family and friends, Carmen became depressed.

Eventually, Carmen had to be interned in the emergency room due to a heavy respiratory crisis. In the hospital, the pneumology team diagnosed her with COPD, a condition Carmen and her family had never heard of. Carmen and her family never suspected she could have a pulmonary disease. They thought that she merely suffered from a smoker's cough. They also confused her symptoms with those of a heavy flu.

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[12] The Danish *Telecare North* cluster-randomised trial to assess the effect of telehealth compared with usual practice in Citizens with COPD, conducted in 2017, finds that there are no statistically significant differences in QoL between telehealthcare and usual practice (except for a concrete subgroup - gold standard 3 Citizen subgroup – where Citizen QoL is slightly lower in telehealthcare). Since 2017, nonetheless, there have been advances in telehealthcare. For instance, there are now algorithms for COPD self-management that can alert in advance of exacerbation attacks. See: Lilholt PH, Witt Udsen F, Ehlers L, et al. Telehealthcare for Citizens suffering from the chronic obstructive pulmonary disease: effects on health-related quality of life: results from the Danish 'TeleCare North' cluster-randomised trial. BMJ Open 2017;7:e014587. doi:10.1136/bmjopen-2016-014587

Therapy

The pulmonologist ordered regular respiratory medication in the form of inhalators. Carmen was prescribed home oxygen therapy - this means her lungs were deteriorated. The doctor also strongly recommended quitting smoking. The diagnosis at first did not mean much to Carmen, because COPD was not a concept used by her or her family. It took some time for them to realise that Carmen would be dependent on oxygen for the rest of her life, that her mobility would be seriously limited, that she would never work again, and that she might end up needing a wheelchair if her prognosis did not improve.

Living with COPD

Carmen's light depression worsened because everything that was meaningful to her was falling apart. Her role in the family was rapidly changing from a central one as the mother to a dependent one.
Gradually, as the medication and oxygen started to show their effect, Carmen regained mobility and with it, her familial and social life. She has not recovered her central role in the family, but she is not so dependent any longer; she is able to find meaning in her new roles and this has a positive effect on her mental health.
Yet, the most difficult change for Carmen has been giving up smoking. She followed a program run by primary care, which helped her quit, but she sometimes still feels tempted to start smoking again.
Living with COPD requires compliance with medication and oxygen therapy, exercise, mobility, and caring about mental health. Compliance with medication is not always easy. Inhalators, for instance, are not always simple to use and doses are easy to forget. There are also cases of "false adherence", where Citizens reduce medication doses partially or totally when they feel better.
Thanks to medication and oxygen, her condition has improved, although from time to time she suffers from exacerbations (which are expected to increase in the future). Each time she suffers an exacerbation, Carmen needs to be hospitalised, her functional capacity declines and she won't fully regain the ground she loses.

Data sources and management

Carmen's pulmonologist thinks Carmen would improve if she could monitor her own health because it would mean becoming aware of her adherence levels, her body's responses, and about her physical and emotional well-being. For this reason, he talks to Carmen about CRANE, a new technological solution that can help her self-manage her condition.

As a user of CRANE, Carmen would be given a CRANE COPD kit, consisting of:

- MyHealthEnabler app, to manage and access Citizens' health data. The app also offers a lot of educational content, and access to peer networks.
- CRANE COPD app, to manage her COPD and receive insights for COPD self-management including educational videos, training videos on the use of inhaler and nebuliser, rehabilitation videos, activity diary, inhaler diary, reports and trends in lung function, and weather and pollution forecasts, among others.
- Smart spirometer, measuring PEF, FEV1.

- Smartwatch, registering heart rate, blood oxygen, and physical activity (measuring METs[13] and using an app capable of discriminating between types and intensity of exercise - i.e. whether the person is running or walking, fast or slow).

With the CRANE COPD kit, the health data sources available to Carmen are:

- Medical records with data on disease evolution, medical tests, spirometry tests, exacerbations, psychology and quality of life scales, medication prescription, and number of hospitalisations.
- Data gathered by the home respiratory therapies (oxygen) provider: oxygen consumption and adherence patterns, plus PROM and PREM results.
- Smartwatch registering heart rate, blood oxygen, and physical activity.
- Information about her participation in health activities organised by the municipality.
- Weather, including forecast and pollen.
- Smart spirometer measures
-

The actors involved in Carmen's case in CRANE are:

Actor	Role
COPD Citizen	Main user
COPD Citizen relative and/or caregiver	Secondary user
Primary care nurse	Before CRANE the nurse was the professional who knew the needs related to the disease, provided knowledge and skills to maintain adherence to the healthcare plan and who could verify if out-of-range telemetry data indicated disease decompensation. In CRANE, the nurse is the one receiving a notification from the CRANE support centre when the risk associated with a Citizen increases and decides if any action is required.
Pulmonologist	Before CRANE, the pulmonologist carried out regular follow-up of Citizens. In CRANE, the pulmonologist is exclusively dedicated to Citizens suffering a crisis or that have been detected to be at risk of exacerbation.
Lifestyle coach	Online service to motivate and maintain lifestyle changes, healthy habits, and therapeutic adherence. If necessary, the coach may also provide advice and solutions in managing the devices and apps.
Municipality sport services	The council's sports department organises easy walks for citizens who are out of shape and need to be physically active.

Table 12: CRANE actors for COPD

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[13] Metabolic Equivalent of Task (MET). METs are calculated knowing the VO_2 Max (maximum amount of oxygen a Citizen can use during exercise).

Carmen's pulmonologist has enrolled Carmen in the CRANE COPD self-management service as she is a perfect match for the programme and has shown interest in it.

She receives the basic CRANE COPD kit and basic training from the CRANE service provider in using the MyHealthEnabler app, the CRANE COPD app, the devices connected to the app, as well as her mobile device.

Silvia, Carmen's primary care nurse, informs Carmen that the MyhealthEnabler service gives her the option to share her health data using a trusted third-party data intermediary service. The option grants her the possibility of taking control of her public and private data, deciding who to share access with. She decides to activate the MyHealthEnabler data-share as she wants to help companies improve their services and research by donating her data to them and because she trusts Silvia. Carmen is informed that her data will be encrypted (using methods like those in cryptocurrencies) and anonymised so that it is not possible to relate it to her identity. She is informed that third party access always depends on her consent and that she can withdraw it at any time. She knows very little about the underlying technology, but she is explained it works the same way as when people send digital money; she has heard about this, and she is convinced that her data must be safe.

Carmen reports she likes the organisation behind the data-sharing service; she has carefully read about who's behind it and what their purpose is. She has decided to trust them to handle her data-shares and has given them consent to access all her available data; she can even consent to share data from her bank and social media; although she is a bit reluctant to do this, she likes that the CRANE technology ensures her data would be anonymised, unless she withdraws her consent.

To her surprise, she has already gathered a lot of useful data, and has received requests for access, not only from her CRANE COPD service provider, but also from two research teams, one analyst firm, and from the pharmaceutical company that produces her medicine.

One project is working to improve the prediction of health crises; this is her CRANE COPD service provider, so she consents to share her data with that project, and with all the other projects too. Some of the projects offer perks in the form of tokens she can use or donate to good causes. She likes this and donates her tokens towards helping supply educational and medical equipment and medicines to less privileged type 1 diabetes kids in Asia.

Every Thursday, Carmen receives a notification from her MyHealthEnabler app that she is expected in the Exercise Cares for You program organised by the municipality to go on a light group walk with others on her same physical level. This Thursday, though, the COPD app also notifies Carmen that there is a high level of pollen in the air, and she decides that she'd better stay home. Carmen's neighbour María, who has been diagnosed with diabetes type 2, knocks on Carmen´s door in time to attend the Exercise Cares for You walk; María also attends these walks, and this motivates Carmen, because she finds María funny and irreverent. Carmen explains to María that because she's been notified that there's a lot of pollen in the air, she has decided to stay home. María understands and proposes to meet Saturday for a walk just the two of them, to which Carmen happily agrees.

The following day, seeing that Carmen's activity levels are decreasing, the CRANE COPD app sends her a notification asking her if she feels alright and suggesting a rehabilitation exercise video for her to follow. She is also informed that it will rain in the afternoon, so she'd better get her outdoors activity done in the morning. Carmen feels tired, though, and is breathing with difficulty. By late morning, the CRANE COPD app notifies Carmen that there is a severe reduction of oxygen in her blood, suggesting she do some oxygen therapy. The app also notifies

Carmen's daughter about this, who visits her mother at lunchtime, helping her with oxygen therapy until she ascertains that her mother is breathing better. Like Carmen, her daughter has been receiving sporadic alerts when Carmen's adherence to her spirometer use guidelines is dwindling. Her daughter reminds Carmen how important it is to adhere to these routines, and Carmen acknowledges this and promises to be more careful in the future. They also look up together a training video on Carmen's CANE COPD app on the use of the new inhaler model Carmen has been prescribed, to ensure she is using it right. Carmen's daughter also convinces Carmen to watch a rehabilitation video from the CRANE COPD app with her and they do the exercise together.

When Carmen was diagnosed with COPD, she often panicked, thinking she was about to suffer an exacerbation attack and frequently contacted her primary care centre. The frequency of these calls has decreased gradually and considerably since Carmen has become a user of CRANE. Because her trust in the service is growing, she knows she will be receiving warnings in her apps if she is at risk. The CRANE COPD app includes a crisis prediction service; it was not very accurate at first, as it needed more data to help improve it, but it has gradually become reliable. The prediction service sends Carmen, Carmen's informal caregivers, and Silvia - the primary care nurse - notifications including early warnings of upcoming exacerbation attacks based on her past data and on the anonymised data of thousands of other Citizens like Carmen - users of CRANE COPD app and other apps. Carmen has chosen to give her daughter and Silvia access to this information.

CRANE assigns a risk level daily to every Citizen in the CRANE service (green, yellow, red) and every morning Silvia, the primary care nurse, receives a prioritised list of the status of Citizens in CRANE. The process doesn't take time from her daily routine, only if a Citizen moves to yellow or red, in which case Silvia can ask for more information and decide whether it's important to intervene. CRANE is not an emergency system, and Carmen knows that for immediate interventions she should call emergency services. Her MyHealthEnabler app does allow her to send the emergency services her CRANE summary automatically, including the latest relevant data.

The CRANE COPD app keeps Carmen up to date with daily and weekly health status reports on the achievement of her goals, and sometimes requests some feedback to collect Citizen Reported Outcome Measures (PROMs). CRANE COPD includes motivation modules that support Carmen in following her goals.

Carmen especially enjoys Javier, her lifestyle coach. Javier is the lifestyle coach from the CRANE service provider and Carmen has given him consent to access her health data. He pays attention to her developments, her adherence and motivation, and where there is an increase in the risk of exacerbation, he follows the procedure defined and established for Carmen. In the case of this Friday, when Carmen is having increased difficulty breathing, because the alert level has moved from green to yellow for the first time in the last few months, the protocol indicates sending Silvia, the primary care nurse, an extraordinary report including the information used by CRANE to increase the risk status, as well as the health summary of Carmen from the last three days (including information from the call he has made to Carmen today to check up on her). Javier makes sure he receives a confirmation of reception from Silvia.

Digital and Health literacy

The use of MyHealthEnabler is simple but giving informed consent for sharing data requires providing training to Carmen to build her awareness and trust. MyHealthEnabler includes an interactive tutorial for this purpose. The app also offers health educational content and games

to educate Carmen about her condition, as well as information on Citizen groups and other useful and relevant material.

What to do with the data

Carmen has agreed to share her anonymized adherence patterns with a pharma company that is working on a trial for a new therapy. Also, her data feeds the new national epidemiological study on COPD. She also shares her data with the CRANE COPD service provider, which also uses the CRANE analytics service.

Annex 3. Legal Framework

This chapter includes the legal framework in force and the technical framework, including guidelines, recommendations and results achieved by past and present EU projects in the field, in case it may be helpful to bidders.

This list is not exhaustive and it is the responsibility of the bidder to be compliance with all necessary legal requirements.

The legal framework in force.
Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of Citizens' rights in cross-border healthcare https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2011.088.01.0045.01.ENG&toc=OJ%3AL%3A2011%3A088%3ATOC
Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardization https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016L2102&from=EN
Directive (EU) 2016/2102 of the European Parliament and of the Council of 26 October 2016 on the accessibility of the websites and mobile applications of public sector bodies https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016L2102&from=EN
Commission Decision (EU) 2015/1302 of 28 July 2015 on the identification of 'Integrating the Healthcare Enterprise' profiles for referencing in public procurement https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32015D1302

Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0679&from=EN
Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745&from=EN
Guidelines from EU projects about the legal framework
EHealth Network. GUIDELINE on the electronic exchange of health data under Cross-Border Directive 2011/24/EU. ePrescription and eDispensation of Authorised Medicinal Products https://health.ec.europa.eu/system/files/2022-06/ehealth_health-data_electronic-exchange_eprescriptions-guidelines_en.pdf
E-X-EHEALTH CSA. D4.2.1 – Information paper on the current challenges in legal aspects of cross-border exchange of personal data. https://www.x-ehealth.eu/wp-content/uploads/2022/01/D4.2.1-%E2%80%93-Information-paper-on-the-current-challenges-in-legal-aspects-of-cross-border-exchange-of-personal-data.pdf
Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. Guidance on standardisation for medical devices https://health.ec.europa.eu/system/files/2021-04/md_mdcg_2021_5_en_0.pdf
The technical framework, including guidelines, recommendations and results achieved by past and present EU projects in the field:

E-Health Network_Refined eHealth European Interoperability Framework https://ec.europa.eu/research/participants/documents/downloadPublic/YWlSdDFxempSdmFMRml4NlhPcFg5ZnJOZ0xjeDZVTVUzTjNKY29ZblZ6QXJCTisxZ3pZK3ZRPT0=/attachment/VFEyQTQ4M3ptUWYyenFZY2dsUzJkaDN0NDJ0cU50YU8=
E-Health Network_Guideline on the electronic exchange of health data under Cross-Border Directive 2011/24/EU. EPrescription and eDispensation of Authorised Medicinal Products https://health.ec.europa.eu/system/files/2022-06/ehealth_health-data_electronic-exchange_eprescriptions-guidelines_en.pdf
E-Health Network_Guideline on the electronic exchange of health data under Cross-Border Directive 2011/24/EU Citizen Summary https://health.ec.europa.eu/system/files/2021-07/ehn_guidelines_Citizensummary_en_0.pdf
Other useful references
Regulation of the European Parliament and of the Council on the European Health Data Space https://ec.europa.eu/health/publications/proposal-regulation-european-health-data-space_en#description
Annexes to the Regulation of the European Parliament and of the Council on the European Health Data Space https://health.ec.europa.eu/system/files/2022-05/com_2022-197_annex_en.pdf
HL7 International International Fast Healthcare Interoperability Resources (FHIR Release 4B ; v4.3.0) http://hl7.org/fhir/

HL7 International Citizen Summary Implementation Guide

https://build.fhir.org/ig/HL7/fhir-ips/ ;

Guideline on the electronic exchange of health data under Cross-Border Directive 2011/24/EU Citizen Summary. Release 3, June 2021

https://health.ec.europa.eu/system/files/2021-07/ehn_guidelines_Citizensummary_en_0.pdf ;

Ethically Aligned Design. A vision for prioritizing human well-being with autonomous and intelligent systems

IEEE. Ethically Aligned Design

ISO 17523_2016 (Health info— Requirements for e-prescriptions); https://www.iso.org/obp/ui/#iso:std:iso:17523:ed-1:v1:en

ISO 8601, Data elements and interchange formats — Information interchange — Representation of dates and times

ISO 11238, Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on substances

ISO 11239, Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging

ISO 11240, Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of units of measurement

ISO 11615, Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information
ISO 11616, Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information
ISO 17090-1, Health informatics — Public key infrastructure — Part 1: Overview of digital certificate services
ISO/TS 16791, Health informatics — Requirements for international machine-readable coding of medicinal product package identifiers
ISO/TS 22220, Health informatics — Identification of subjects of health care
ISO/TS 27527, Health informatics — Provider identification
European Commission. DG Health and Food Safety. Assessment of the EU Member States' rules on health data in the light of GDPR. On behalf of the EUHealthSupport Consortium https://health.ec.europa.eu/system/files/2021-02/ms_rules_health-data_en_0.pdf
Country fiches for all EU MS https://health.ec.europa.eu/system/files/2021-02/ms_rules_health-data_annex_en_0.pdf
Independent high-level Expert Group on Artificial Intelligence set up by the European Commission https://www.aepd.es/sites/default/files/2019-12/ai-ethics-guidelines.pdf

Independent high-level Expert Group on Artificial Intelligence set up by the European Commission. The assessment list for trustworthy artificial intelligence (ALTAI) for self assessment https://op.europa.eu/en/publication-detail/-/publication/73552fcd-f7c2-11ea-991b-01a a75ed71a1
The European Interoperability Framework https://joinup.ec.europa.eu/collection/nifo-national-interoperability-framework-observa tory/european-interoperability-framework-detail
Horizon 2020 MyHealthMyData (MHMD) project http://www.myhealthmydata.eu/ ; http://www.myhealthmydata.eu/publicdeliverables/
mHEALTH HUB .WHO - ITU mHealth Hub in EU. Document contributing to the Policy Framework for EU on Cross-Border Adoption and Assessment of Innovation https://mhealth-hub.org/download/wp5-policy-and-innovation-policy-framework-docu ment-contributing-to-the-policy-framework-for-eu-on-cross-border-adoption-and-asse ssment-of-innovation?wpdmdl=25346&refresh=62bf40dbba88a1656701147
eHealth Network (2020). Mobile applications to support contact tracing in the EU's fight against COVID-19. Common EU Toolbox for Member States. Version 1.0. [pdf] https://ec.europa.eu/health/sites/health/files/ehealth/docs/covid-19_apps_en.pdf
eHealth Network (2020). Interoperability guidelines for approved contact tracing mobile applications in the EU. [pdf] https://ec.europa.eu/health/sites/health/files/ehealth/docs/contacttracing_mobileapps _guidelines_en.pdf

Annex 4. The Minimal Viable Product of CRANE

The Minimal Viable Product (MVP) is assessed to include services that are beneficial for healthcare and social care services and provide sufficient insights to CRANE users (patients) to improve their ability of self-management. The design of the MVP is expected to secure traction among CRANE users (patients) as well as the wider ecosystem for well-being (Garden of Care) including healthcare and social care providers. A successful MVP will create inspiration for CRANE users (patients) and the wider Garden of Care to spur innovative thinking which will be demonstrated in new business opportunities etc.

The MVP derived out of analysis of workshop results in Agder, Region Västerbotten and Extremadura when establishing Bottlenecks and Shortcomings of Self-management + Bottlenecks and Shortcomings of Data management and from the 2 workshops connected Value Based Modelling in each healthcare region. Through three following workshops in each buyer region, with strategic decision makers and strategists, a tentative list of functions for CRANE emerged, see table below.

Figure 6 – Tentative functions for CRANE service solution based on workshops in procurement regions.

Functions to support prolonged autonomy of citizens with chronic conditions

Learn to know the CRANE user (citizen) – People Matter

Service for identifying/predicting the behaviour and motivation of CRANE users, 5 main questions which require attention:

1. What is health to you?
2. What constitutes a healthy life to you?
3. What does being well mean to you?
4. What is a healthy individual able to do?
5. How does a healthy individual life look like?

- *Secure a dynamic framework to be revisited to capture changes in CRANE users' behaviour.*
    - *Co-creation professionals and citizens with chronic conditions, consider for example:*
        - o *split into sections depending on diagnosis*
        - o *apply filters*
        - o *multiple choice vs open questions*

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Possible solution for health data management - MyHealthEnabler:

A solution that helps citizens to collect their health data, both qualitative and health data parameters, according to a format and a standard from private and public sources, initial sources:

- · Healthcare providers (Public/Private)
- · Social care providers (Public/Private)
- · Self-monitoring equipment measuring parameters connected to different chronic conditions (minimum 2 parameters per chronic)
- · Smart devices and sensors, measuring health data such as Apple watch, Samsung watch etc

Further we welcome developers to include other sources of data connected to people's health and wellbeing, this could include purchase data from grocery stores and more.

- - SECURE to use API standard already in practice in buyer regions
- - Open API, for any vendor to use that wish to align to CRANE

The function of making health data accessible for CRANE users, can be described similar to a subscription of information.

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CRANE services, functions and features:

1. Subscription service on health data, what data CRANE users wants to have available in MyHealthEnabler (consider opt in/opt out)
2. Dashboard, filter out what information CRANE users want to see (possible widgets)
3. Seamless data sharing by CRANE user, based on consent:
   · CRANE user selects data to be shared
      - Qualitative information and health data parameters
   · To and between healthcare, social care, wider local community organisation, (possibly) business (local and multinational companies incl. innovation industry), loved ones and legal guardians.
   · Guiding users to make active and informed consent

4. Insight service, based on health data, for CRANE users:
   · Select health data to be used for insights (consider opt in/opt out)
   · Insights through health analysis based on algorithms
   · Insights shall indicate CRANE users on:
      - Current health status / well-being status
      - Trends of the CRANE users health status
      - Suggest appropriate actions/activities
         o Rating system of activities,
            - Possible to form peer to peer networks
            - Discussion forums
         o Social activities centred around joint activities
         o Prescription service on activities
            - Citizens have trust in healthcare professionals, likely to support compliance and adherence to preventive measures.

5. Pro-active actions, for CRANE users through relevant notification system
   · Notification system based on CRANE algorithms for CRANE users
      - Select appropriate condition for notification (silence, absence, out of range value, combination of values indicating pre stage disease, not following healthcare/care advise, who has attended the CRANE user – log book etc)
      - Disclaimers, informing CRANE users (citizen) about their role and responsibility
   · Of priory, notification system shall apply a filter (human & digital) to avoid unnecessary referrals, consider:
      - Decision trees for triage
      - Chat boot

- Support centres (outside existing health and social services, similar to telemedicine centres)

6. "What to say' form, to be used in contacts with healthcare, social care and telemedicine centres
   · A document generated where aggregated data sets, analysis (through algorithms) and progression/trend on CRANE users health are gathered.
     - Data included in what to say form is suggested by CRANE, and finally selected/confirmed by CRANE users (opt out, if not all data to be used)
     - Specific condition of concern, which may require healthcare

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Horizontal action (for all functions and features above, 1-6):

Training to foster support for self-management:

- · Digital literacy
  - Instructions for self-monitoring and use of MyHealthEnabler
    o Manual, printed and online
    o Quick guide, printed and online & FAQ (online)
    o Videos
    o Other intuitive ways to promote learning, appropriate for use in 5 years from now.
- · Health literacy
  - Refer to trusted official channels such as 1177 in Sweden, NHI.no in Norway and in Spain through the web app: https://saludextremadura.ses.es/csonline/

CRANE

Comprehensive treatment of chronic
Citizens in rural areas

Regional coordination group
E-health and welfare technology Agder