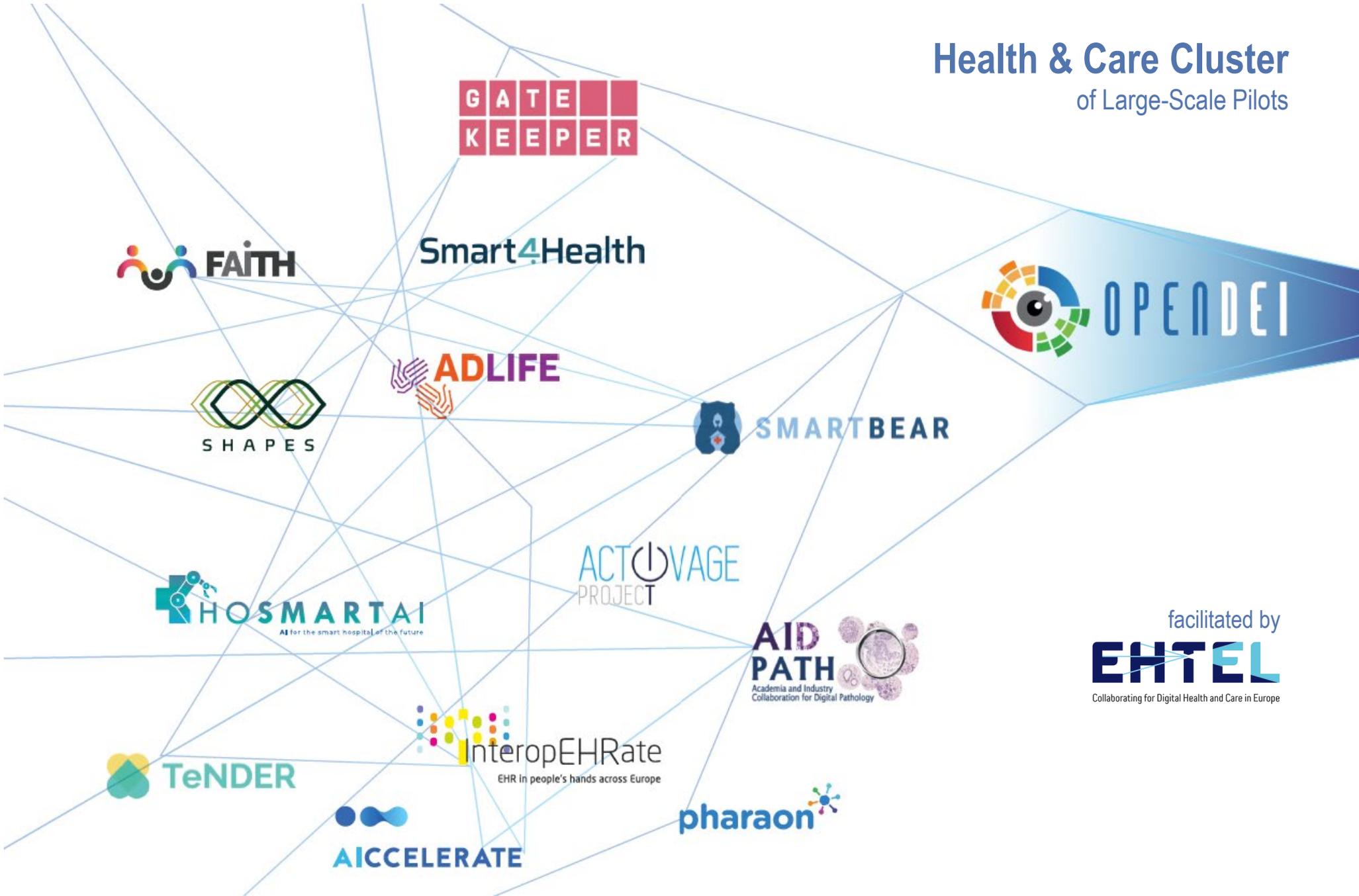


Health & Care Cluster of Large-Scale Pilots



facilitated by
EHTEL
Collaborating for Digital Health and Care in Europe

The OPEN DEI ecosystem: 35+ Ecosystem Projects (incl. 2 LSPs)

Health & Care Cluster of Large-Scale Pilots

Agri-food (7)



Energy (9)



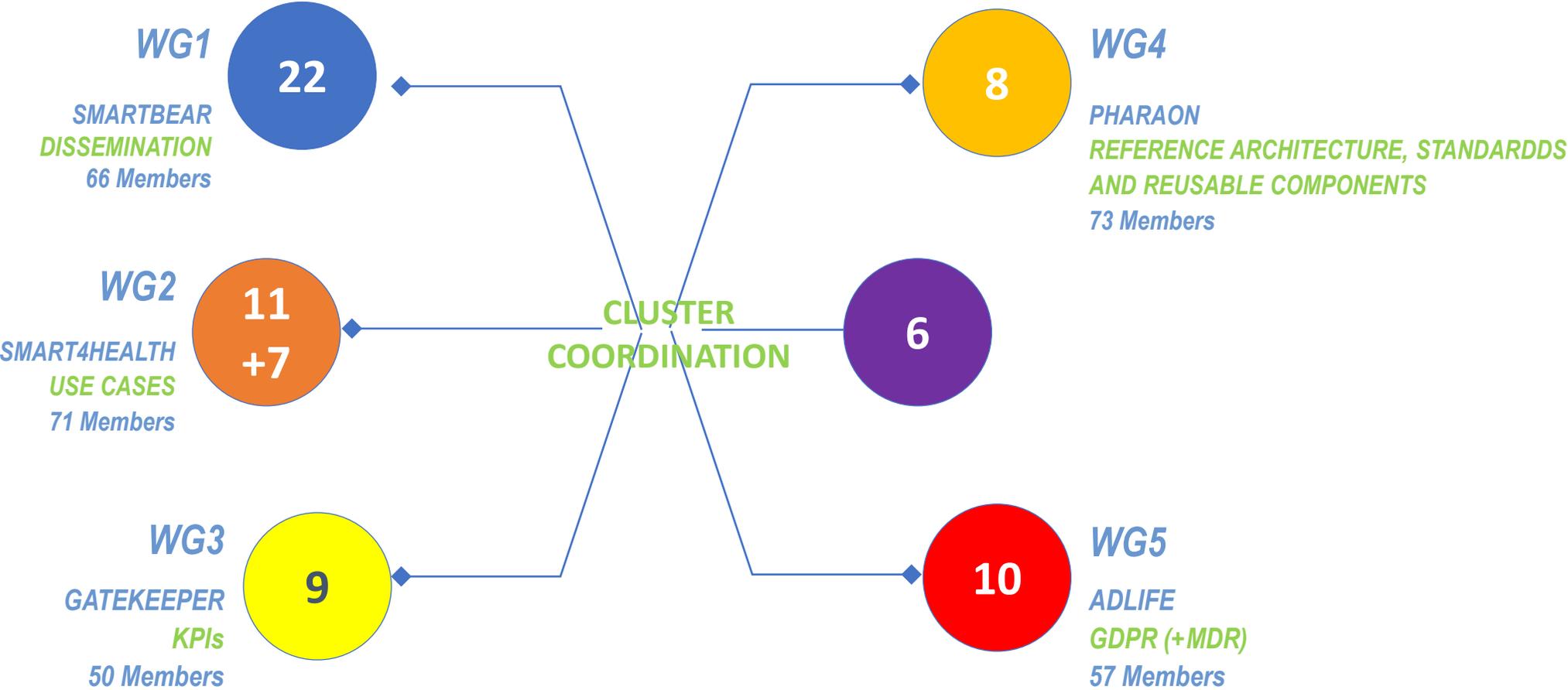
Manufacturing (7)



Health & Care (15)



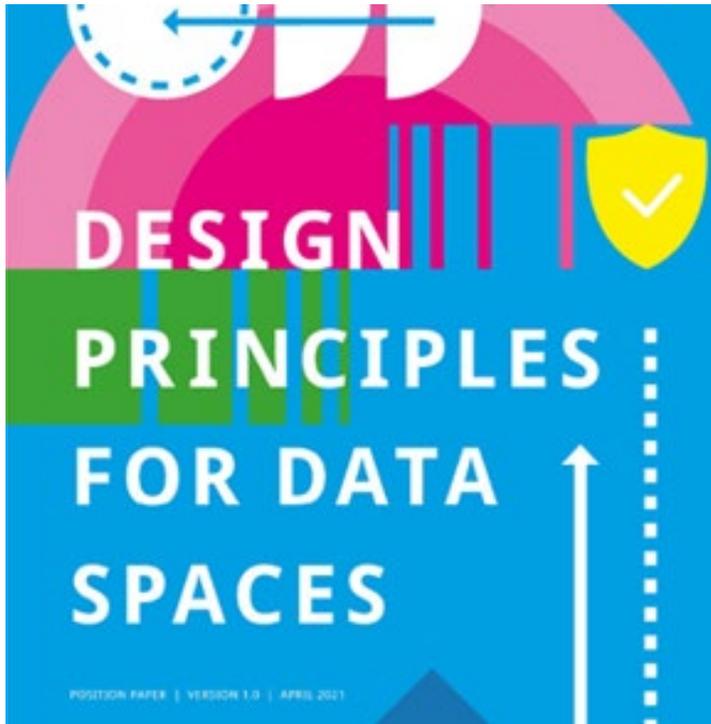
Sharing responsibility and taking the lead where experience and skills pre-exist



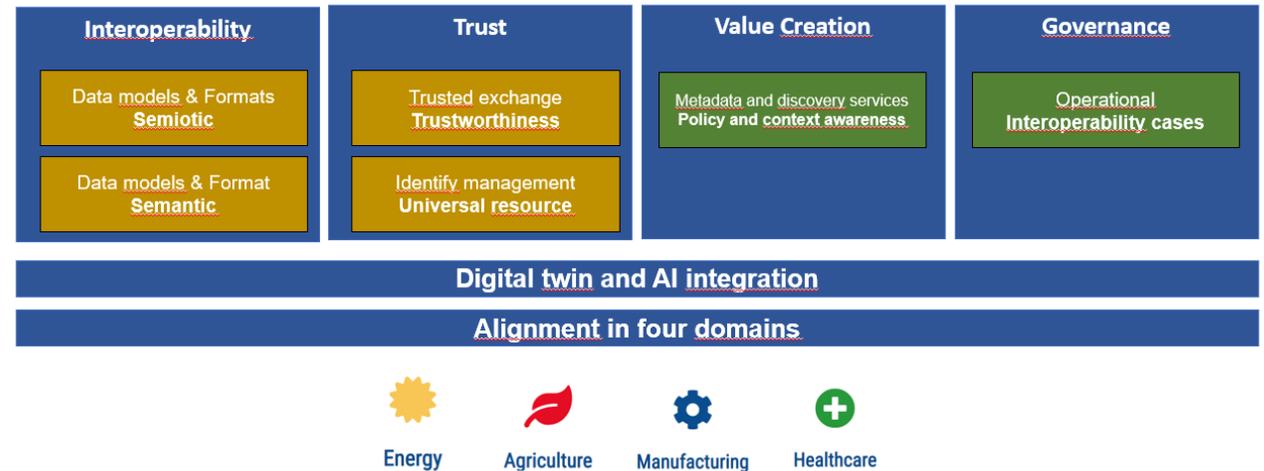
Figures = Number of meetings organized (not including preparation meetings)

Design principles for Data Spaces

- A first approach to define the design principles for data spaces, agreements on the building blocks for a soft infrastructure and governance for data spaces”



To agree and standardise associated building blocks in the design of **data spaces**



REFERENCE ARCHITECTURES AND INTEROPERABILITY IN DIGITAL PLATFORMS



SEPTEMBER 2022

REFERENCE ARCHITECTURES AND INTEROPERABILITY IN DIGITAL PLATFORMS

TABLE OF CONTENTS

1	Introduction
1.1	Structure of Position Paper.....
1.2	Acknowledgement.....
2	Aligning Digital Platforms for DEI
2.1	Context.....
2.2	Reference Architectures
2.2.1	OPEN DEI Reference architecture framework.....
2.2.2	Digital Platforms Convergence - DSBA Initiative
2.2.3	Purpose of Reference Architectures.....
2.2.4	Building an architecture.....
2.3	Interoperability Frameworks.....
2.3.1	Purpose of interoperability Frameworks.....
2.3.2	Building Interoperability
2.3.3	Hyperdimensional Interoperability.....
2.4	Topics of Interest for Federated Platforms.....
2.4.1	Trustworthiness.....
2.4.2	Universal resource management.....
2.4.3	Digital twin and AI integration
2.4.4	Semiotic approach to support cyber physical systems.....
2.4.5	Interoperability approaches.....
2.4.6	Executable policies for digital governance
2.5	Aligning with Solutions.....
	Reference Architectures and Interoperability for Digital Manufacturing Platforms
3.1	Context for Manufacturing
3.2	Reference Architectures for Manufacturing.....
3.3	Interoperability Frameworks for Manufacturing.....
3.4	Aligning the Manufacturing domain for DEI.....
	Reference Architectures and Interoperability for Digital AgriFood Platforms
4.1	Context for AgriFood.....
4.2	Reference Architectures for AgriFood.....
4.3	Interoperability Frameworks for AgriFood.....
4.4	Aligning the AgriFood Domain for DEI.....
	Reference Architectures and Interoperability for Digital Energy Platforms
5.1	Context for Energy.....
5.2	Reference Architectures for Energy.....
5.3	Interoperability Frameworks for Energy.....
5.4	Aligning the Energy Domain for DEI.....
	Reference Architectures and Interoperability for Digital Health & Care Platforms
6.1	Context for Health and Care.....
6.2	Reference Architectures for Health and Care.....
6.3	Interoperability Frameworks for Health and Care.....
6.4	Aligning the Health and Care domain for DEI.....
6.5	Example of InteropEHRate Research Project.....
7	Conclusion and Recommendations

Position Paper on Digital Platforms Uptake



Contributing organizations



Contributing Projects



- *The “distance” with the other domains was actually bigger than expected; the healthcare domain has often been viewed as being the “other voice” with its focus on the demand - and demand enabler - side, the need to integrate societal value, and its already long tradition of cooperation between companies, organisations, and public authorities*
- *The contacts with the other domains through OPEN DEI have also greatly contributed to put more emphasis on the supply side also in the healthcare domain: the Internet of Things being considered as a key cross-domains enabler and the perspective of quick progresses thanks to the use of meta-data*
- *This project was a “première” by many aspects:*
 - *This was the very first time that a formal collaboration between funded projects was established at a very early stage of their initiation.*
 - *This was also the first time that four domains very different in nature were provided with a chance to interact and identify commonalities and specificities. A new space of discussion and interactions has thus been created.*
- *To progress further, the identification of realistic use cases which would directly connect the different domains will be important*

Synergies and consolidations achieved in the Healthcare Working groups

From information sharing to new knowledge: 54 resources shared - 33 collaborative ones

Related Working Group	Asset name	Type of document	Status	Origin
Coordination	Consolidated Answer to EU consultation on Data strategy	Public	Available	Collaborative effort
Coordination	Projects initial presentation (slides)	Public	Available	Single project
Coordination	Projects status as of October 2020 (slides)	Restricted	Available	Single project
Coordination	Projects strategies to cope with COVID-19 (slides)	Restricted	Available	Single project
WG1 Dissemination	Common slide deck (Logos)	Public	Available	Collaborative effort
WG1 Dissemination	Common slide deck (decscription)	Public	Available	Collaborative effort
WG1 Dissemination	Pilots description	Restricted	Available	Collaborative effort
WG1 Dissemination	Guideline to succesfull digital workshops (Shapes)	Public	Available	Single project
WG1 Dissemination	LSPs Pilots description (Excel file)	Restricted	Available	Collaborative effort
WG2: Use Cases	Use cases extensive description (Excel file)	Restricted	Available	Collaborative effort
WG2: Use Cases	Use cases consoldated (Excel file)	Restricted	Available	Collaborative effort
WG2: Use Cases	LSP Use cases reference template description	Restricted	In Process	Collaborative effort
WG3: KPIs and assess	Key Performance Indicators Framework (MAFEIP) GATEKEEPER	Public	Available	Single project
WG3: KPIs and assess	Startegic Evaluation approach (Slides) SMARTBEAR	Restricted	Available	Single project
WG3: KPIs and assess	Meta-analysis of Pilots outcomes (categories of KPIs): GATEKEEPER	Restricted	Available	Single project
WG3: KPIs and assess	Summary of LSPs reference KPIs (including Open Dei digital maturity)	Restricted	In Process	Collaborative effort
WG3: KPIs and assess	Template for designing interventions	Restricted	In Process	Collaborative effort
WG4: Reference arch	Draft Repository of technological tools useful for LSPs (PHARAON)	Restricted	In Process	Collaborative effort
WG4: Reference arch	Initial survey results on RA and reusable components (EXCEL)	Restricted	Available	Collaborative effort
WG4: Reference arch	Initial survey results on standardisation s (Word)	Restricted	Available	Collaborative effort
WG4: Reference arch	WG results and status as of November 2020 (Slides)	Restricted	Available	Collaborative effort
WG4: Reference arch	Working Paper on RA for LSP in healthcare (with also cross domain persp	Public	In Process	Collaborative effort
WG4: Reference arch	Standards adoption: Vcare experience (slides)	Public	Available	Single project
WG4: Reference arch	SMARTBEAR & PHRAON approaches to RA (slides)	Restricted	Available	Single project
WG4: Reference arch	ACTIVAGE reference Data model and ontologies for Healthy ageing	Public	Available	Single project
WG4: Reference arch	HL7 and IHE: Assets repository, testing platform and simulators	Public	Available	Single project
WG5: GDPR and othe	Projects informed consent template and approach	Restricted	Available	Single project
WG5: GDPR and othe	Guideline to infomed consent in LSPs	Public	In Process	Collaborative effort
WG5: GDPR and othe	Consolidated feed back to EU consultation on Data governance	Public	Available	Collaborative effort

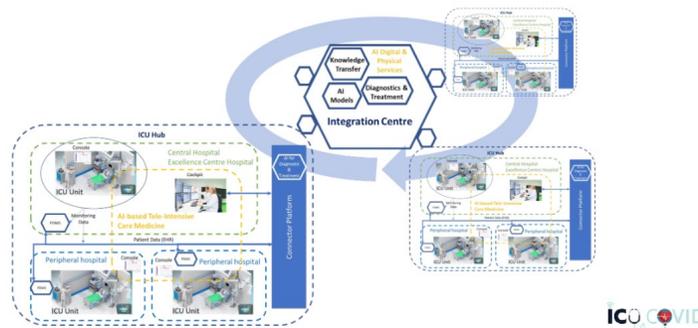
LSP Use Case Reference template

The Glue for
bilateral/multilateral
collaboration

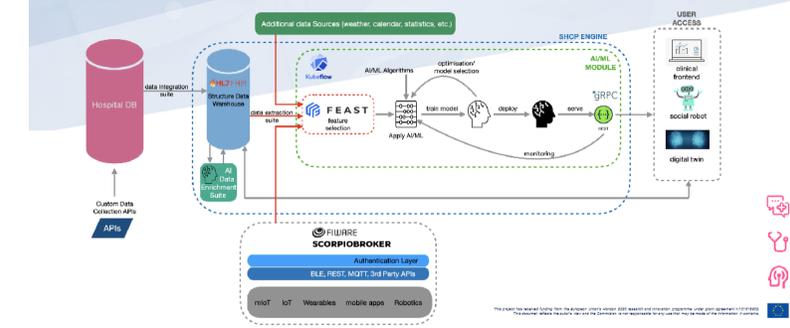
Code / Abbreviation	<The name of the Use Case>	
Use Case storyline	<A textual description of the Use Case, describing the situation AS-IS and the situation TO-BE with the usage of blueprint/assumption personas>	
Persona(s) / Target Group(s)	<The main beneficiary of the Use Case (e.g. patients with a specific condition)>	
Stakeholders	<Other Entities with interest in the Use case, that may affect it and/or interact with it (e.g. clinicians)>	
Use Case Objectives and how they contribute to the overall project objectives		
	Use Case Objective (if metrics are defined, include them) <The objectives of the Use Case (e.g. collect data on a specific condition)>	Overall Project Objective (if metrics are defined, include them) (optional) <The overall project objectives linked to the use case objectives (e.g. improve overall health data collection)>

From IoT to AI to EHDS

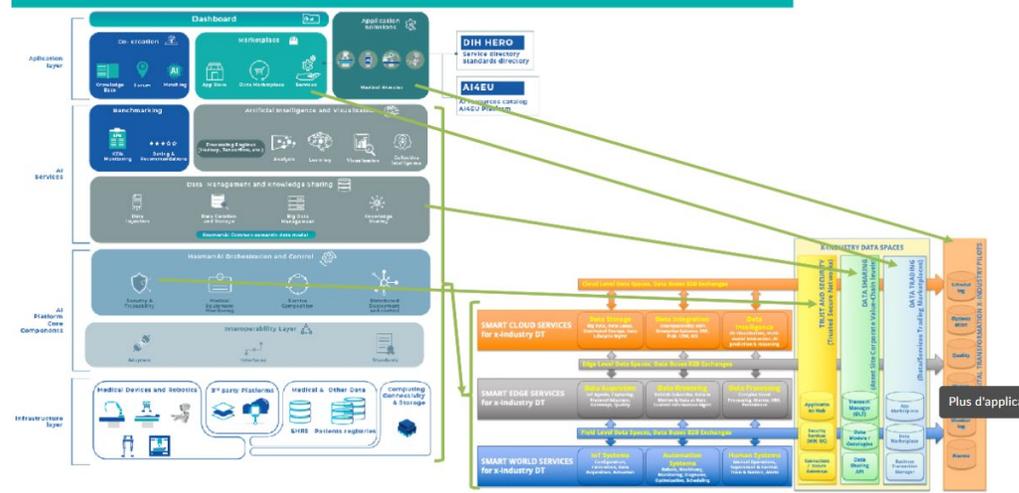
ICU4Covid Telehealth: ICU Hubs network



AICCELERATE Reference Architecture



Mapping to OPEN DEI architecture



eHSG

05/07/2023

10

Reference architectures and platforms for European Large-Scale Pilots on Smart and Healthy Living – analysis and comparison

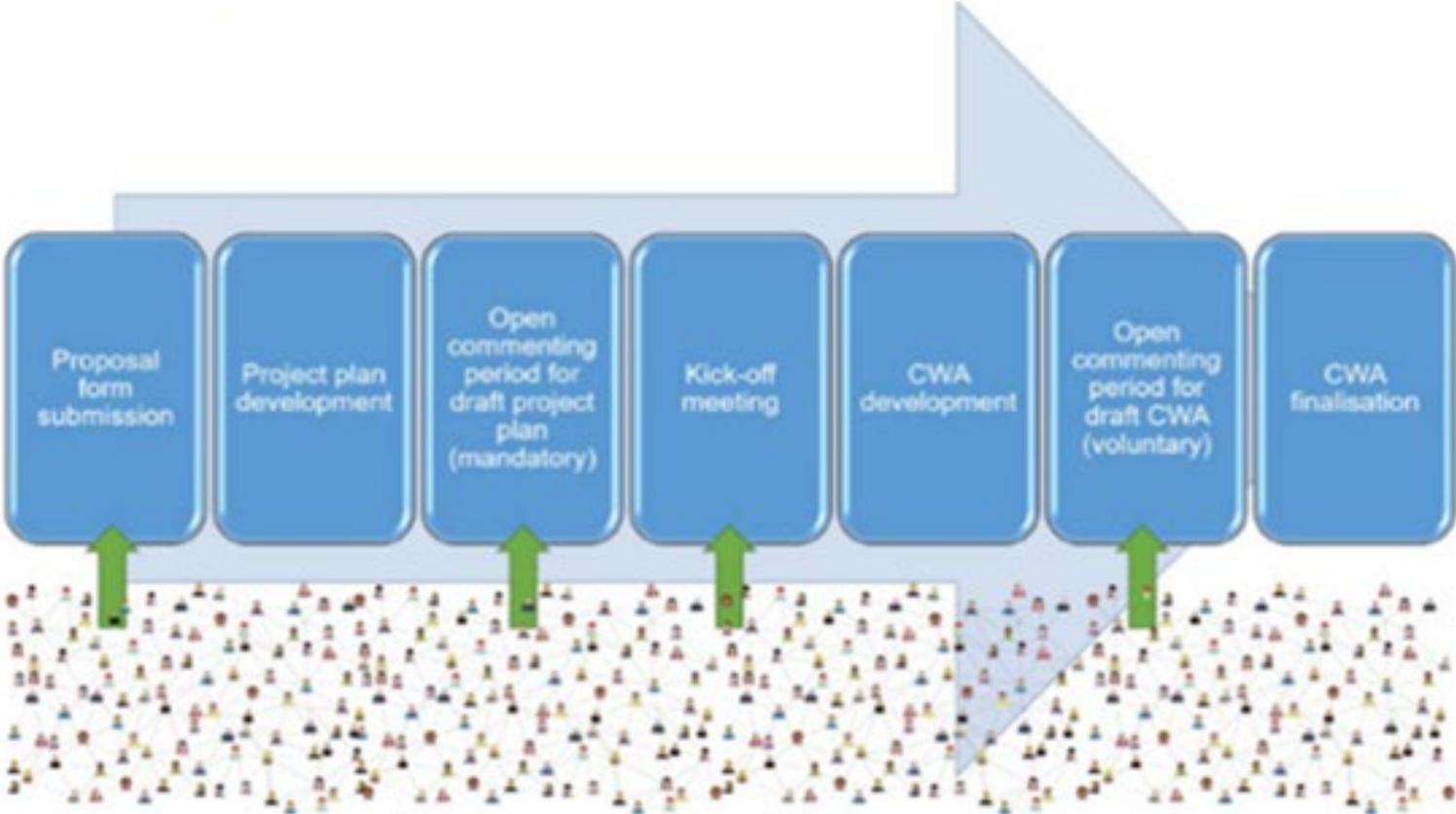
Andrej Grguric ^{1*}, **Firstname Lastname ²** and **Firstname Lastname...**

Citation: Lastname, F.; Lastname, F.; Lastname, F. Title. Information 2021, 11, x. <https://doi.org/10.3390/xxxxx>

¹ Ericsson Nikola Tesla d.d., Krapinska 45, 10002 Zagreb, Croatia; andrej.grguric@ericsson.com
² Affiliation 2; e-mail@e-mail.com
^{*} Correspondence: andrej.grguric@ericsson.com; Tel.: +38513653092

Abstract:
 Much effort is being invested in implementing ICT-enabled systems for providing a better quality of life and supporting the independent living of older people. They are often labeled as eHealth and/or AAL (Ambient/Active Assisted Living). In the process of creating such systems, that often serve various needs, different architectures emerge. However, the conceptual work of considering the Reference Architectures (RA) in the field is often missing. A standardized way of representing architecture descriptions does not exist, making the process of comparing and analyzing the work difficult and corresponding results scarce. This work focuses on presenting, analyzing and comparing the early work on architectures in several ongoing EU-funded healthcare projects. After establishing the theoretical foundation by making the definitions of core concepts explicit, we give surveys of architectures in eHealth and AAL systems. After shortly presenting the Pilots, we elaborate on the analysis method and present a comparative analysis of architectures for large-scale European pilots on smart and healthy living. [Main findings/conclusions TBD](#)

The CWA process



Source: CEN-CENELEC Guide 29 « CEN/CENELEC Workshop Agreements – A rapide way to standardization »

Contents		Page
European foreword.....		4
Introduction.....		6
1 Scope.....		8
2 Normative references.....		8
3 Terms and definitions.....		8
4 Abbreviated terms.....		12
5 Consent and legal bases.....		13
5.1 Ethical, legal and regulatory bases for consent		13
5.1.1 General.....		13
5.1.2 Ethical bases for consent.....		14
5.1.3 Legal and regulatory bases for consent		15
5.2 Consent as the basis for processing personal data within research		15
5.3 Alternative legal bases for processing personal data.....		17
5.3.1 General.....		17
5.3.2 Scientific research and presumption of compatibility		18
5.3.3 Clinical Trials Regulation and the General Data Protection Regulation.....		19
5.3.4 Clinical trials and clinical investigations		21
5.3.5 Member states' legislation regarding research with genetic data.....		21
5.4 Broad consent and data altruism.....		22
5.4.1 Broad consent.....		22
5.4.2 Data Governance Act.....		23
6 Consent and novel digital health innovations		25
6.1 General.....		25
6.2 Consent requirements when introducing a novel digital health tool		25
6.2.1 Establish the data protection roles and responsibilities.....		25
6.2.2 How to satisfy the conditions for consent.....		27
6.3 Consent for data reuse and data sharing.....		29
7 Obtaining consent.....		30
7.1 What would digital health innovators seek consent for?.....		30
7.2 When is explicit consent required?.....		31
7.3 What are the additional requirements for valid consent?.....		32
7.4 What not to seek consent for		33
7.5 The process of collecting consent – good practices.....		33
7.6 Information security safeguards.....		36
7.7 Consent from vulnerable patients		37
7.7.1 General.....		37
7.7.2 Preventing prejudice against vulnerable populations.....		38
7.8 Avoiding coercion.....		38
8 Withdrawal of consent.....		38
9 Informed Consent Form.....		39
9.1 General.....		39
9.2 Points to include in a GDPR transparency notice.....		39

Providing guidance to future projects:
 CEN WA on PATIENT CONSENT (Published in June 2023)

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

1 PROJECT OPEN CALL PROCEDURE AND METHODOLOGY

1.1 PHASE 1. AWARENESS

1.1.1 Documentation

1.1.2 Announcement

1.2 PHASE 2. IMPLEMENTATION

1.2.1 Reviewers' selection

1.2.2 Proposal evaluation

1.2.3 Conflict resolution

1.2.4 Project selection

1.3 PHASE 3. EXECUTION

1.3.1 Results' announcement

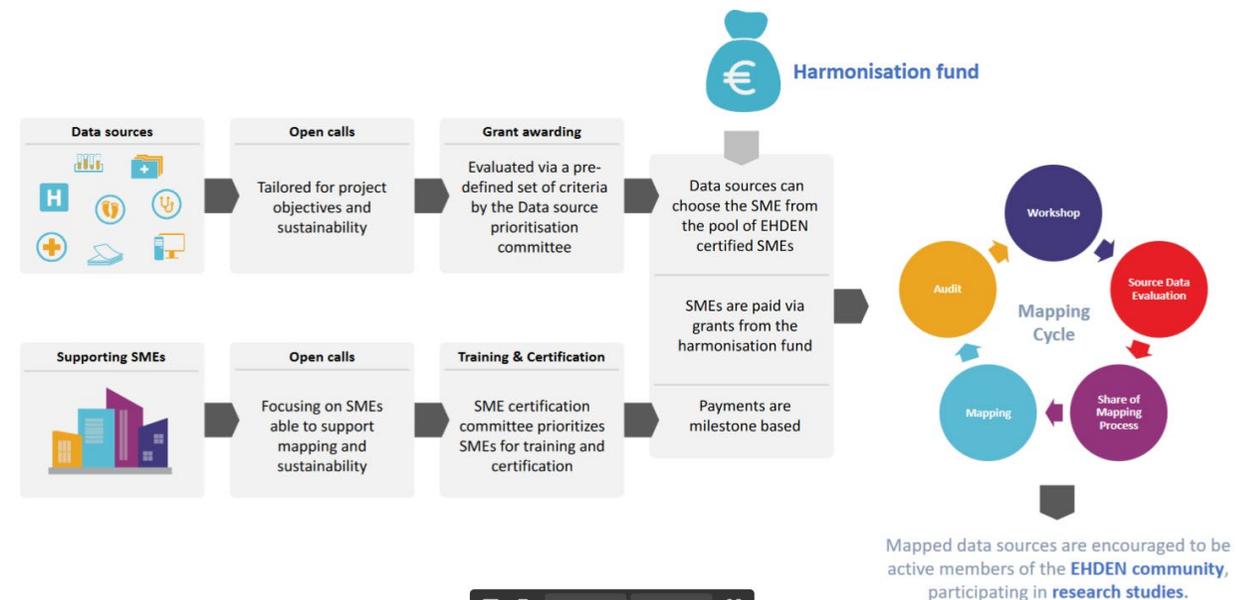
1.3.2 Contract's negotiation

1.4 PHASE 4. SUPPORT

1.4.1 Training workshops

5
6
7
8
9
9
10
11
11
11
11
13
13
13
13
14
16
16

CALL PROCESS OVERVIEW



Joint dissemination for higher impact

Health & Care Cluster of Large-Scale Pilots

Active and Healthy Living (AHL) Community @Digital4AHL · May 2 ...
 Join @ehel_health and the Health & Care Cluster at @RadicalHealthF for two sessions on:

Active and #HealthyLiving policies
 #AI in hospitals

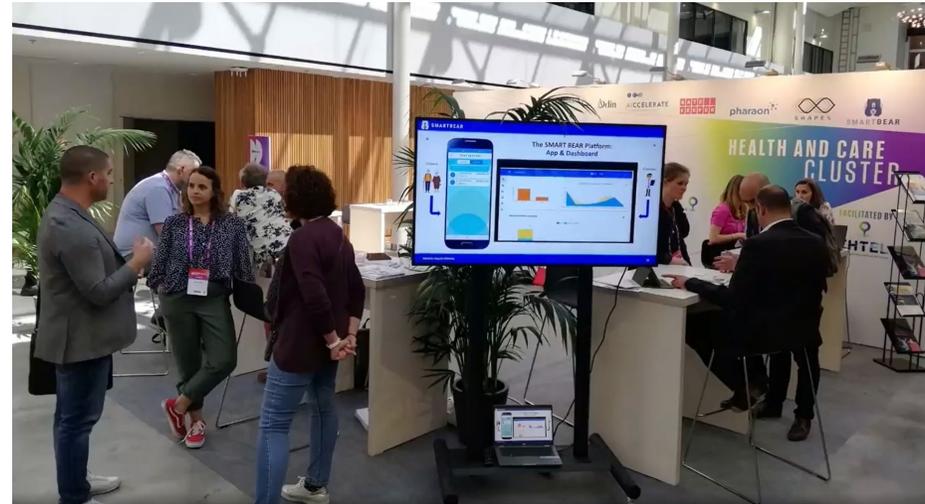
+ and an EHEL Master Class on redesigning #HybridCare

Agenda and registrations bit.ly/3VgzfsB

#rhfh #radicalhealth



You and 9 others
 16 16 601



Pharaon Project
 @PharaonProject

We had an incredible three days at the @RadicalHealthF Festival in Helsinki, showcasing the Pharaon project! 🎉 Watch the video for the top highlights 📺📺📺

Thanks to the Health and Care Cluster and all participants for making this event so valuable!
 @ehel_health

Radical Health Festival Helsinki @RadicalHealthF · Jun 15

Thank you all for making #RadicalHealth Festival Helsinki a memorable event! Until we meet again, stay healthy and keep embracing your inner radical! 🍷
 #RadicalHealthFestival #SeeYouSoon



This is a cooperative model, in the sense that it is not possible for a single actor in the whole value chain to put a service into the market without the cooperation of the rest of the involved actors.

- ***Active cooperation mechanisms between companies and between companies and organisations not anymore based on a B2B or B2C but rather on a more inclusive B2B2C approach.***

**Robustness, Cooperation and circularity become more important than
« performance » only.**

*Platforms created have been instrumental in demonstrating the conditions for the creation of a (semi) open ecosystem but given the fact that they are not rooted in the reality of healthcare organisations **operating in a given health system**, they have very few chances to survive their project.*

*In the future, it will thus be of **key importance to work with existing already operational platforms** (managed by organisations or companies) and reorient a substantial part of the resources to the evolution of this platforms and their **capacity to integrate solutions operating on agreed standards with a work on exploitation and innovative business models initiated much earlier in the project cycle.***

Upcoming priority topics



New CEN WA to be started: Guidelines on Action Research for Large Scale Piloting



Responses to constraints related to MDR and ethics approval regulation for pilot implementation



User acceptance: Technology (pre)selection, user interface and patient stratification



Lessons learnt from project Procurement and OPEN Calls (selection of products). (aspects of COSTS of devices in relationship to prevention will also be reflected upon)



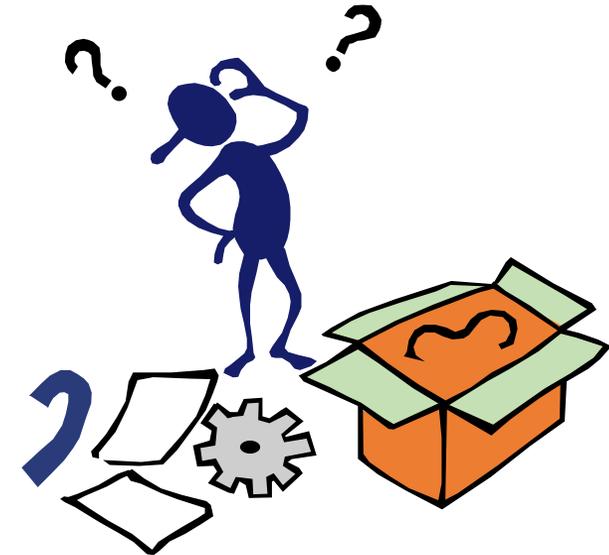
Exploitation strategy: linking innovation and implementation- in search of New business model strategies

“Architectural choices, and resulting architectures, are most often made considering functional and non-functional requirements, while **technical and business constraints are in most cases only implicit**”.

Conclusions – Domain Collaboration

- *Sharing resources between projects at an early stage has an important added value and is achievable but should be supported by an adapted infrastructure and easy to use processes.*
- *Consolidation work has also a lot of possible added value but is time consuming and requires a direct engagement from projects: it should be connected to concrete outcomes*
- *Some scarce competences needed by all projects are not equally present in all projects (e.g., MDR impact) and should be identified as early as possible.*
- *Isolating and disseminating COMMON messages rather than project-based messages remains challenging.*
- *Exploitation of developed platforms remains an important open issue for many projects.*
- *There is a clear need to document better reusable building blocks and architecture and organise better evidence collected around common use cases.*
- *Projects should be able to rely on existing common resources repositories and avoid consuming resources to reinvent the wheel (e.g., GDPR and ethical impact) but rather contribute to their evolutive maintenance.*
- *The common documentation of use cases – and related personas – is an important entry point to organise focused and in-depth collaboration between projects.*
- *Use of data collected by projects become an important issue.*

спасибо 谢谢
GRACIAS 谢谢
THANK YOU
ありがとうございました MERCI
DANKE धन्यवाद
شُكراً OBRIGADO



<https://www.ehtel.eu/health-care-cluster.html>