Data sharing and Data regulation

Insights and experiences on the implementation of open platforms and digital technology in the AHA and AAL domains

10.03.2022 **()** 14:00 - 15:30 PM CET



Hosts:

- SYNYO GmbH
- Agency for the Promotion of European Research





Agenda

Times are only indicative



Time	Presenter
14:00 - 14:05	Alexander Nikolov SYNYO GmbH, Austria
14:05 - 14:10	Mathilde De Bonis IDIH Project
14:10 - 14:25	Mahsa Shabani (PhD), Assistant Professor in Privacy Law Metamedica, Faculty of Law and Criminology, Ghent University, Belgium
14:25 - 14:40	Konstantinos Bromis Institute of Communication and Computer Systems, Greece
14:40 - 14:55	Catherine Chronaki HL7 Europe
14:55 - 15:10	Maria Palombini Director, Emerging Communities & Opportunities Development, Healthcare & Life Sciences Practice Lead, IEEE
15:10 - 15:25	Prof. Itziar Alcorta University of the Basque Country, Spain
15:25 - 15:30 (Q&A)	Frederic Lievens Lievens-Lanckman, Belgium



All participants are kindly invited to raise questions in the chat.





Assessing the State of the Art and supporting an evidence-based Uptake and Evolution of Open Platforms in the Active and Healthy Ageing Domain





Introduction to PlatformUptake.eu

- PlatformUptake.eu: Assessing the State of the Art and supporting an evidencebased Uptake and Evolution of Open Service Platforms in the Active and Healthy Ageing Domain
- Project Type: Coordination and Support
 Action
- Project duration: 29 months (01/01/2020 – 31/05/2022)
- Partners: 12 from 10 countries



PlatformUptake.eu

Current achievements





Gaps and challenges for uptake of open platforms in AHA/AAL domains



PlatformUptake.eu

Gaps and challenges for uptake of open platforms in AHA/AAL domains



PlatformUptake.eu



IDIH project

Mathilde De Bonis

















Inclusive Design of Digital Solutions for Active and Healthy Ageing (AHA)

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 826092.



- Full Title: International Digital Health Cooperation for Preventive, Integrated, Independent and Inclusive Living
- **Duration:** May 2019 April 2022
- Aim: Promote and increase international collaboration to advance digital health in the EU and key Strategic Partner Countries to support active and healthy ageing (AHA) through innovation







PROJECT PARTNERS

9 partners – 4 from the EU and 5 from the Strategic Partner Countries: From research to industry through to governmental support organisations and networking platforms







To support the definition of common priorities to enhance strategic international cooperation in digital health.





To provide specific contributions to the international dialogue in digital health with the creation of a Digital Health Transformation Forum. To facilitate the exchanges between RTI stakeholders from the EU and the Strategic Partner Countries in digital health.



To foster international collaboration for digital solutions in health care benefitting the society.





IDIH has set-up an expert-driven **Digital Health Transformation Forum** gathering top-notch experts, executives and advocacy groups from the six regions

Experts Policy Makers Users (UCG) IDIH

consisting of **4 Expert Groups**



to work on defining **common priorities** & identifying **opportunities** of mutual benefit.

to define a Roadmap towards enhanced International Collaboration on Digital Solutions for AHA



IDIH PRODUCTS AND SERVICES (I)

1 IDIH Factsheets

Overview of the **digital health research and innovation landscape** in Strategic Partner Countries (CAN, CN, JP, KR, USA):

- Priorities within digital health and AHA
- Challenges,
- Relevant key programmes
- Key players in the field
- Strengths and weaknesses

Overview of international collaboration and

• Success stories in digital Health bw EU and Strategic Partner Countries

2 IDIH Guidebooks

Updates on opportunities for researchers and innovators

- from IDIH Strategic Partner Countries under EU Funding
- from the EU under the American, Canadian, Chinese, Japanese and South Korean Funding Programmes

<u>ttps://idih-global.eu/outcomes/</u>







IDIH PRODUCTS AND SERVICES (II)

3 IDIH Helpdesk

idih-global.eu/idih-helpdesk

Ad-hoc advice to RTI stakeholders from the EU and the Strategic Partner Countries on Funding Programmes and Calls that offer opportunities for international cooperation in the field of Digital Health and AHA

4 IDIH Long-term Matchmaking Platform

Networking among all key-stakeholders of digital solutions for AHA Register at: https://idih-week-2021.b2match.io/

• Create your online profile specifying your Area of Activity and/or expertise request/offer in the Marketplace + Schedule B2B-meetings with your potential international partners until Dec 31, 2021.

5 IDIH Week 2021 & 2022

- 4 days online event dedicated to researchers, innovators, care providers and user associations dealing with Digital Health for AHA.
- Information, Networking & Matchmaking, Co-creation sessions
- Materials available at: <u>https://idih-week-2021.b2match.io/page-4061</u>









IDIH PRODUCTS AND SERVICES (III)

6 IDIH Podcast

- The Future of Ageing Actively and Happily is the podcast of the EU Project IDIH - International Digital Health Cooperation for Preventive, Integrated, Independent and Inclusive Living.
- Each episode focuses on one of these **topics**, and a strategic **region** of the world: Europe, China, Canada, Japan, South Korea, and USA.
- Available on 6 platforms

7 IDIH Magazine

- IDIH MAG FORMAT: a full PDF version
- IDIH MAG FORMAT: a reduced HTML version

You can just draft your article promoting *events*, initiatives and R&I projects at national/international level or experts/stakeholders from your organization/network, dealing with Digital Health for Active and Healthy Ageing

IDIH MAG



IDIH FOCUS ON Health











TIMING PODCAST 1: March 2021 (Intro HE) PODCAST 2: July 2021

PODCAST 3: October 2021 PODCAST 4: December 2021 PODCAST 5: January 2021 PODCAST 6: March 2022

Duration: max. 25 minutes

WHERE TO LISTEN 🐠 💽 🖬 🥃 🔊

6 sections:

IDIH EXPERTS VOICE



Join the IDIH Week 2022 | March 21 – March 24



https://health-innovation-community-platform.b2match.io/



Asian slot 9.00 - 11.00 CET/16.00 - 18.00 CST/17.00 - 19.00 JST&KST Americanslot 15.00 - 17.00 CET/9.00 - 11.00 EST/6.00 - 8.00 PST



- INFO DAY (March 21, 9.00 11.00 CET)
- This Info Day is dedicated to the IDIH findings and products, as well as to IDIH progress towards sustainability. It will also *highlights* current opportunities for international cooperation in the field of Digital Health for Active and Healthy Ageing.
- US REGIONAL WORKSHOP (March 21, 17.00 19.00 CET) This workshop is dedicated to the US landscape of R&I around Digital Health for AHA. It will focus on how COVID has impacted independent and connected living of the older persons with the perspective of start-ups, investors, and the patients themselves. A session will be dedicated to O&A with the audience.
- PARTNERING DAYS (March 22, 9.00 11.00 CET/March 23, 15.00 17.00 CET)
 Partnering Days will be dedicated to the presentation through a short pitch of ongoing
 projects (for results dissemination/exploitation purposes), new project ideas and expertise
 offers/requests by the organizations working in the field of Digital Health for AHA. Sessions
 are planned for March 22, 9.00 11.00 CET and March 23, 15.00 17.00 CET and will be
 respectively dedicated to Asian and American audience. Do you wish to pitch your project
 idea or expertise?Apply <u>HERE</u>! Use <u>this template</u> to send your Flash Presentation
 to <u>idih@apre.it</u> by March 14.
- JAPAN REGIONAL WORKSHOPS (March 23, 9.00 11.00 CET)

A panel-discussion (in Japanese with English subtitles) will be held with the participation of the Ministry of Internal Affairs and Communication, in charge of HORIZON 2020 in Japan, and some key-players in the R&I landscape in Japan. A session will be dedicated to Q&A with the audience.

INNOVATION DAY (March 24, 9.00 – 11.00 CET & 15.00 – 17.00 CET)
 Starting from the findings of IDIH Experts – gathered in the IDIH Digital Health
 Transformation. Forum – this event will be the occasion to address Digital Health for Active
 and Healthy Ageing focusing on the three areas suggested by the IDIH Experts for
 enhancing international cooperation in the field: Data Governance, Digital Inclusion,
 Interoperability-by-design. Thanks to the participation of the <u>eVita project</u> and the <u>North
 American Chapter International Society for Gerontechnology</u>, 2 Panel Discussions will
 further explore these areas highlighting tech challenges and opportunities offered by
 collaborative research at international level. Co-creation sessions will follow among the
 panelists, as well as the audience through ad hoc tools for live interactions.





Thank you for your attention!

Project coordinator

Steinbeis 2i GmbH For enquiries, please contact:

IDIHglobal@steinbeis-europa.de



https://idih-global.eu/

IDIH Partners













Metamedica, Faculty of Law and Criminology, Ghent University, Belgium

Mahsa Shabani (PhD), Assistant Professor in Privacy Law









Data Protection Regulations and Data Sharing



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 826092.



- Increasing attention to the importance of data sharing in health for clinical and research purposes
- Increasing investment in developing data sharing infrastructure
- Existing regulatory framework related to data protection (the GDPR) which clarifies some aspects including definition of personal data, health data, legal grounds, and importance of adopting safeguards, among others.







- Insufficient health data exchange negatively impacts on the provision of healthcare services (primary use of health data)
- Exercise access and control over own health data (not all citizens have access to their health data in the member states)
- Fragmentation of digital standards and limited digital interoperability between healthcare systems
- Access to and exchange of health data for scientific research remain limited in EU, as the rules for processing health data are fragmented. (secondary uses of health data/ reference to article 89 of the GDPR and article 9 (2) (j))







- Data Governance Act (upcoming)
 - Introducing new concepts: data altruism consent, general ineterst, role of data cooperatives
 - Raising questions related to interplay with the existing consent and public interest related requirements under the GDPR

- Legislative Proposal for European Health data Space
 - A number of important studies have been conducted in preparation (e.g. assessment of the member states rules regarding processing health data)
 - The joint action for European Health Data Space is conducting e-consultation with citizens
 - Difficult task ahead to navigate through the existing legal complexities in processing health data









Institute of Communication and Computer Systems, Greece

Konstantinos Bromis











Konstantinos Bromis

ICCS, Greece







UIB









Expected benefits of sharing data in the field of open platforms and digital technology for active and healthy ageing

- For the providers of open platforms
 - Extended operational capacity (more applications)
- For developers of solutions for active and healthy ageing
 - Optimised resources management
 - Insights on device usage
 - Real life user feedback using multiple devices for health monitoring
- For the care/health care organisations
 - Complex analytics on large pools of data
 - Advanced Machine Learning analytics
- For the end users (older persons, patients etc)
 - Improved service delivery in terms of efficiency and precision
 - Personalized interventions
- For the policy makers (municipalities, regional administration etc)
 - Enhanced evidence based approach on decision making



Main challenges related to data regulation that providers and developers of open PlatformUptake.eu

- Common understanding of standardization efforts
- Adoption of a common framework of standards
 - SNOMED CT
 - LOINC
 - ICD
- Providers of data and device manufacturers to adopt domain standards (such as HL7 FHIR) to enable interoperability with open platforms

Practices proven to be effective in implementing data sharing within the current regulatory framework(s) with other institutions



- Data sharing agreements in place since the beginning of the project
- Data standardisation using widely accepted ontologies
 - SNOMED CT
 - LOINC
 - ICD





- Providers of open platforms and developers of technology for active and healthy ageing should
 - Follow closely the standardization initiatives of data sharing protocols
 - Try to adopt interoperable data exchange protocols
 - Try to extend existing ontologies to cover data handling that are not covered by existing ontologies









Europe

HL7 FHIR Standard: an enabler for data sharing

Catherine Chronaki

HL7 Europe, Belgium chronaki@HL7europe.org







sion: A world in which everyone can securely access and use the right health data when and where they need it.

-eHealth

Gravitate (() Health

HL7 EUROPE NEWS

HL7 Europe HL7 the best and most widely-used

eHealth standards since 1986

- HL7 v2, Clinical Document Architecture, HL7 FHIR
- 22 National Affiliates in Europe (~35 wordwide)
- European HL7 foundation established in 2010

European Funded Research Projects

- Past: eHGI, Antilope, Semantic Healthnet, Trillium Bridge, Expand, ASSESS CT, OpenMedicine, eStandards, Trillium-II
- Current: Gatekeeper, FAIR4Health; mHealthHub, UNICOM, Gravitate Health
- Annual HL7 in Europe Newsletter
- Website: www.HL7.eu

eHealth policy & Research

- EU eHealth stakeholders; mHealth Guidelines; ENISA expert grp
- EFMI council (2012-): EFMI Board (2016-), EHSG (2012-2018)
- WHO Digital Health TAG & Roster of Experts
- HIMSS Europe PIE
- Digital Health Society TF#1
- **SDO Joint Initiative Council**





PanCare SurPass



Joint Initiative Counci

Europear

mHealth

🛛 Europe

Austria, B&H, Croatia, Czech Republic, Denmark, Finland, France, Greece, Germany, Italy, Netherlands, Norway, Poland, Portugal, Romania, Russia, Slovenia, Spain, Sweden, Switzerland, UK, Ukraine







What are the **main challenges related to data regulation** that providers of open platforms and developers for technology for active and healthy ageing (SMEs developing smart watches, wearables, sensors, mobile applications etc.) encounter **in sharing data with/from other stakeholders in the field?**
European Health Data



Dace Creation of European Health Data Space is one of the priorities of the Commission 2019-2025

- better exchange and access to health data from electronic health records, genomics, patient registries etc.
- protect citizen data and reinforce portability as in art. 20 of the General Data Protection Regulation (GDPR).

TEHDAS: Joint Action for the European Health Data Space

- help Members States and EC facilitate health data sharing in public health, treatment, research and innovation
- Pillars of the European Health Data Space
 - Governance and rules for data exchange and sharing of health data
 - mapping of how the GDPR is implemented, legal and technical modalities
 - recommendations for legislative and non-legislative actions, at EU level
 - Infrastructure and technology
 - ♦ eHealth Digital Infrastructure, European Reference Networks, GenomicsProject
 - Data quality, semantic and technical interoperability
 - ensure health data quality and that health datasources
 e.g. electronic health records, registries, digital tools, "talk" to each other.
 - FAIR health findable, accessible, interoperable and reusable. "FAIR-ification" of existing health data registries and other data sources to establish common data sets for health research and policy making.



My health @ EU eHealth Digital Service Infrastructure A service provideଙ୍କି by the European Union

SKILLS

BUSINESS

INFRASTRUCTURES

European Health

PUBLIC SERVICES

Data Space

4

GATEKEEPER: Vision and Technical Approach HL7

VISION

Build a trust and secure platform to foster large-scale deployment of integrated digital solution for early detection and intervention in different regions across Europe and worldwide enabling novel businessmodels

Howwe build it?

Europe





6 Europe

GATEKEEPER Partners





RESEARCH INSTITUTIONS & ACADEMY

ECOSYSTEM ENLARGEMENT STANDARDIZATION & IMPACT

HEALTHCARE PROVIDERS (PILOTS) LARGE AND SMALL INDUSTRIES (SUPPLIERS)



Where HL7 FHIR is used





GATE KEEPEI	GateKeeper FHIR Implementation Guide 0.0.1 - CI Build R	€ ØHL7 FH
Table of Conte	ents > Artifacts Summary > Observation Living Environment (Gatekeeper)	
GateKeeper FHIR	Implementation Guide - Local Development build (v0.0.1). See the Directory of published versions 🗗	
Content De	etailed Descriptions Mappings XML JSON TTL	
.38.1 Reso	ource Profile: Observation Living Environment (Gatekeeper)	
	ource Profile: Observation Living Environment (Gatekeeper)	
Defining URL:		
Defining URL:	http://hl7.eu/fhir/ig/gk/StructureDefinition/Observation-livingEnvironment-gk	
Verining URL: Version: Content 7.44.1 Re	http://hl7.eu/fhir/lg/gk/StructureDefinition/Observation-livingEnvironment-gk 0.0.1 Detailed Descriptions Mappings XML JSON TTL esource Profile: Observation Phonation vs Silence measurements (Al	b.Acus Gatekeeper)
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Verining URL: Version: Content 7.44.1 Re	http://hl7.eu/fhir/lg/gk/StructureDefinition/Observation-livingEnvironment-gk 0.0.1 Detailed Descriptions Mappings XML JSON TTL esource Profile: Observation Phonation vs Silence measurements (Al	b.Acus Gatekeeper)

7.46.1 Resource Profile: Sleep Duration (Gatekeeper)

Defining URL:	http://h17.cu/fhir/ig/gk/StructureDefinition/observation sleepDuration gk	
Version:	0.0.1	
Name:	SleepDurationGK	
mate.		

7.31.1 Resource Profile: Observation Exercise tracking panel (Gatekeeper)

Defining URL:	http://hl7.eu/fhir/ig/gk/StructureDefinition/observation-exercisePanel-gk
Version:	0.0.1
Name:	ObservationExercisePanel
mate.	

7.42.1 Resource Profile: Oxygen Saturation (Gatekeeper)

Defining URL:	http://hl7.eu/fhir/ig/gk/StructureDefinition/observation-oxygensat-gk	
Version:	0.0.1	
Name:	OxygenSatGK	







What **practices have proven to be effective** in implementing data sharing within the current regulatory framework(s) with other institutions, on a national and international level?

European Electronic Health Record

Format Commission Recommendation on a European Electronic Health Record exchange format (C(2019)800) of 6 February 2019.

UN/COM

- Lab observations and results
- Diagnostic Imaging observations and results
- Hospital Discharge reports
- Patient Summaries Rare diseases
- ePrescription/eDispensation
- European Health Data Space
 - Effective use of high-quality data sets

Digital Health Services, Sustainable Health Systems

RT

SurPa

- Citizen Empowerment and Engagement
- Neighborhoods and communities that are safe

survivorship

PASSP

Support of AI and decision aids



S	EUROPEA	N ION	1	
		Brussels, 6.2.2019 C(2019) 800 final		
EUROPEAN COMMISSIO	PN Brussels, 6.2.2019 C(2019) 800 final ANNEX	COMMENDATION 2019 alth Record exchange format A relevance)	Exch	
	ANNEX to the ion Recommendation is: Health Record exchange format			
afe	GE			



X-eHealth Project ultimate goal: Build a strong community around EHRxF

- X. eHealth project aims for a collaborative spirit of:
 - Joint studies driven by a global community of innovation for better use of novel technologies such as AI.
 - use of common models, standards and ICT assets to help avert the defragmentation of Digital Health services and tools.
 - Share experience on what works and what doesn't
- By recognizing the central role of collaboration in the following areas:
 - standardisation and harmonisation, computer literacy and digital indusion
 - to furnish citizens, Healthcare Professionals with the required eSkills
 - enhancing the medical response to urgent & planned care with high quality data

Rare Diseases



Laboratory Results



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant. Agreement N° 951938

Discharge Letters

eHealth art-decor.org/art-decor/decor-templates--eehrxf-Apps 2021-proposals china PCSP kuleuven 🛜 Philips X-eHealth - Templates Datasets Project Templates CDA Document CDA Document Level Template XeH Clinical Document XeH Diagnostic Imaging Report (0.1) XeH Hospital Discharge Report (0.1) XeH Laboratory Result Report (0.1) XeH RD Patient Summary (0.1) CDA Header Level Template CDA Section Level Template CDA Entry Level Template Template type not specified Medical Imaging



X-eHealth INNOVATION DAY EHRxF innovation online!



X-eHealtl

• Communities of Practice Page

https://www.x-ehealth.eu/communities-of-practice/

Here you can have a more comprehensive view of this initiative and see which are the current Engaged collaborative partners and Communities of Practice.



HL7 Croatia Assembly

X-eHealth INNOVATION DAY EHRxF innovative products online!

List of Products and Services Supporting the European EHRxF Page

https://www.x-ehealth.eu/list-of-products-and-services-supportingthe-european-ehrxf/

This page represents a registry of products and services that intent to support the European EHRxF. In the end of the page, you can find a button to submit the product or service that you want to be involved in the innovation program of X-eHealth. <u>https://mkt.egoi.page/5Be6BePFS/productsandservices</u>



List of Products and Services Supporting the European EHRxF

01/10/2021



This is a registry of products and services that intent to support the European EHRxF. They companies and developers involved are associated with x-eHealth project and upon signature of the collaboration agreement receive a copy of the specification and are involved in their validation.

If you are interested to participate in the innovation according to the innovation about your product member of the x-eHealth innovation team will contain

Click here to submit your product or service





Co-funded by the Europear Union's Health Programme



Deliverables V Communication

X-eHealth INNOVATION DAY BHRxF innovation projects and initiatives online!

Co-funded by the European Union's Health Programme (2014-2020)





National Initiatives & European Commission co-Funded Projects supporting the European EHRxF Page

https://www.x-ehealth.eu/national-initiatives-european-commission-co-funded-projects-supporting-the-european-ehrxf/

This page represents a registry the list of national initiatives & European Comission co-Funded Projects supporting the European EHRxF. If your project is not list on that page, you can fill the form for to be added.





Global IPS Community of Practice Use of IPS through a personal lens

- Listening to the patient and the family
 - Quality assurance: medication reconciliation by the family
 - Health goals: tracking progress and identifying health trends
 - Early warnings: frailty in the elderly
- Navigating digital health data: portability, trust, and flow
 - Tracking hypertension: Chronic disease management
 - Rare Disease Passport: patient summaries for patients with rare diseases
 - European Vaccination Card: Vaccination of children in communities and refugee camps
 - Survivor passport: Survivors of childhood cancer
 - Mother / Child Summary: fertility, pregnancy, child birth, infant home records
 - Engage mobile Health companies & app developers Competitions and Prizes!!!
- Tracking the health needs in communities
 - Disaster and emergency management
 - My Healthy neighborhood







FAIR4Health project

To facilitate and encourage the EU Health Research community to FAIRify, share and reuse their datasets derived from publicly funded research initiatives through the demonstration of the potential impact that such strategy will have on health outcomes and health research.

- Coordinated by Virgen del Rocío University Hospital, Andalusian Health Service (SAS)
- 17 partners from 11 EU and non-EU countries
 - 6 health research organisations
 - 2 universities experts in data management
 - 4 academic partners with strong background on medical informatics

FAIRplus

EUROPEAN OPEN

SCIENCE CLOUD

• 5 business actors

F/IR

RESEARCH DATA ALLIANCE

Collaboration



Specific Objectives

- 1 To design and implement an effective outreach strategy at EU level
- 2 To produce a set of guidelines to set the foundations for a FAIR data certification roadmap
- 3 To develop and validate an intuitive, user-centered FAIR4Health platform and FAIR4Health agents
- 4. 4. To demonstrate the potential impact in health research and health outcomes through the validation of 2 pathfinder case studies



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 824666

EOSC-Life



Raw

Data versioning

Indexing

The "FAIR4Health" FAIRification process



G F A I R

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 824666







What are the (expected) benefits of sharing data in the field of open platforms and digital technology for active and healthy ageing?

- for the providers of open platforms
- for developers of solutions for active and healthy
- for the care/health care organisations
- for the end users (older persons, patients etc.)
- for the policy makers (municipalities, regional administration etc.)



PlatformUptake.eu

Exchanging EHR in a common format for trust and flow of data to accelerate the transformation of health and care.

What are the benefits of sharing data in the field of open platforms and digital technology for AHA?



Authorities. for the providers of open platforms: **well-identified interface** ۲

Citizens

- for developers of solutions for active and healthy ageing (SMEs developing smart watches, wearables, sensors, mobile ٠ applications etc.): learn how to work with the data, less effort, faster integration.
- for the care/health care organisations: know what to expect; plug'n play integration, sharing of patient data ٠
- for the end users (older persons, patients etc.): **empowerment and understanding** •
- for the policy makers (municipalities, regional administration etc.): know their community; plan services; understand ٠ and quantify problems, procure systems. 20







advance directives

For Gravitate Health it offers the lens to focus on the contents of the medication leaflet





What organizational/technological etc. capacities should be developed by providers of open platforms/ developers of technology for active and healthy ageing to implement successfully (inter-institutional) data sharing?



https://tinyurl.com/INNO-EHRxF

Capacity building for data sharing organizational capabilities

- Regulations, Policies, Security, Privacy
- Synthetic Data and Workflows

Technical capabilities

- Tools and standards
- HL7 FHIR Implementation Guides



HL7 FHIR Accelerator Program



VULCÁN

New Vulcan Projects: Electronic Product Information (ePI or e-Labeling)

Topic (Proposed)

Notes / Discussion

Gravitate-Health Consortium, part of the Innovative Medicines Initiative (IMI



Use Case	 Structured format for authorized product and prescribing information Enables/relates to: International Patient Summary (IPS); ePrescribing; Product identification (IDMP); pharmacovigilance; patient compliance and empowerment; clinical trial eligibility and enrolment
Rationale for Use Case	 Topic of interest in many geographical regions; growing need for a harmonized global approach Following Vulcan guiding principles to strategically connect and maximize resources to develop a single pathway for interoperable exchange of data
Initial Plans	 Connectathon in September and subsequent connectathons Partnership with EMA Roundtable in October
🚨	



HL7 Project: FAIRness for HL7

FAIR Health



- FHRAGAIR (Findable Accessible Interoperable Reusable) principles are an established best practice in the generation of health datasets for open science, research, and innovation.
 - Research Data Alliance (RDA) is a research community organization started in 2013 by the European Commission, the American National Science Foundation and National Institute of Standards and Technology, and the Australian Department of Innovation to:
 - build the social and technical infrastructure to enable open sharing and re-use of data
 - develop a recommendation for FAIR data maturity model
 - FAIR4Health (fair4health.eu) is a European Commission funded project aiming to encourage FAIRification and reuse of research data generated by publicly funded research projects
 - defines a FAIRification workflow to FAIRfy health datasets within healthcare institutions
 - created and currently validates a multicenter platform for the FAIRification and reuse of health data by PPDM algorithms
 - develops a FAIR certification roadmap

FAIR4Health and RDA joined forces in the development of the HL7 FAIRness for FHIR IG

Check: <u>https://confluence.hl7.org/pages/viewpage.action?pageId=91991234</u>

Looking forward to Connectathon 30: Why don't you join?

- Streamline the creation of ePIs
- Test Rules for G-lens rules
- Dive into accessibility and digital health literacy















Emerging Communities & Opportunities Development, Healthcare & Life Sciences Practice Lead, IEEE

This project has received funding from the European

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Maria Palombini









Data Sharing for Patient-Centered, Personalized Support for the Ageing

MARIA PALOMBINI Director, Healthcare and Life Sciences Practice Lead IEEE Standards Association





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ANNUAL CONFERENCES



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ABOUT IEEE

- Inspiring a global community of innovation
- Where forward-thinking professional collaborate
- Discover what's next in tech innovation
- Build technical communities
- Shape and share research
- Create global standards
- Engage in Humanitarian activities





HEALTHCARE AND LIFE SCIENCES

To improve the global standard quality of life at every step through affordable healthcare and access to medicines; support innovation to improve overall wellness and improve societal outcomes; and to enable innovation through open and standardized means. Three Major Branches of Focus

- 1. Pharma/Biotech
- 2. Clinical Health
- 3. Global Wellness

https://ieeesa.io/hls



PORTFOLIO OF PROGRAMS & SERVICES



Conformity Assessment

Providing confidence & assurance & accelerating market adoption



EALTHCARE &

STANDARDS ASSOCIATION

Key Numbers & Concepts- Ageing and Health

BY 2050

- 1 in 6 people in the world will be over age 65 (16%), up from 1 in 11 in 2019 (9%).
- 1 in 4 persons living in Europe and Northern America could be aged 65 or over.
- The number of persons aged 80 years or over is projected to triple, from 143 million in 2019 to 426 million in 2050.

"In 2018, for the first time in history, persons aged 65 or above outnumbered children under 5 years of age globally."

- There is no typical older person
- Older people with the greatest healthcare needs have the least economic and social resources
- Only a small portion are dependent on others for care
- Intrinsic capacity (mental and physical health) is a better predictor of wellbeing versus the absence of disease
- Families alone cannot meet the needs of older people.
- Long term care= basic needs + preserving their rights (incl health), fundamental freedoms and human DIGNITY

United Nations (UN) World Population Prospects: the 2019 Revision, https://www.un.org/en/global-issues/ageing



Population pyramids, EU-27, 2019 and 2050

(% share of total population)



Note: all data as of 1 January. 2019: estimates and provisional. 2050: population according to the 2019 projections, baseline variant (EUROPOP2019).

Source: Eurostat (online data codes: demo_pjangroup and proj_19np)




DYNAMICS IN PLAY





Did you know? Growing use of commercial virtual assistants such as Google Home, Apple Home, Alexa, etc) are being utilized to helping the aging although that was not their intended use case!

*Longevity Technology, 28 October 2019 https://www.longevity.technology/agetech-marketslated-to-double-from-1-to-2-trillion/





AHA/AAL: Uses, Tools and Where We Need Technology to Be



IFFF

Robotics

STANDARDS ASSOCIATION

Data Sharing for AA: Where, Why, Who and How

- WHERE
 - Collection of data from multiple tools, wider socio-demographic of elder population, and different geographic locations
- WHY
 - Realize the potential of patient-centered and personalized assistance
 - Allowing tools and algorithms to better anticipate risk and issues in the home and the immediate surrounding
 - Avoid bias in the data collection and use for development of solutions
- WHO
 - Researchers for development of technologies and tools
 - Caregivers and clinical staff
- HOW
 - Balance between open data sharing and sharing of open insights
 - Protect the privacy and dignity of the of the patient













Data SHARING vs Data PRIVACY

Real World Research Example

Use of patient data for precision oncology research study

Using anonymized data presented a challenge for reporting back new findings to clinicians.

The interesting question...why would you just not notify the patient of the issue?

Where do the lines intersect in the pursuit of absolute privacy yet maintaining the ability to protect the patient's health?



Related IEEE Global Standards/Working Projects (Snapshot)



IEEE HEALTHCARE & LIFE SCIENCES OPEN PARTICIPATION PROGRAMS

- Tech & Data Harmonization for Decentralized Clinical Trials
- Dignity, Inclusion, Identity Trust and Agency (DIITA)
- Connectivity Harmonization of the Digital Citizen/ (WAMIII)
- Neuro Tech for Brain-Machine Interfacing
- Transforming the Telehealth Paradigm
- Responsible Innovation of AI in Life Sciences
- Global Initiative on Blockchain-based Omnidirectional Pandemic
- Transforming Digital Personalized Medicine
- Ethical Assurance of Data-Driven Technologies for Mental Healthcare
- IoT Ecosystem Security
- IEEE Global Initiative On Ethics Of Autonomous And Intelligent Systems

https://standards.ieee.org/industry-connections/activities.html



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THANK YOU



GET INVOLVED:

Write about it, talk about it, develop solutions...make an impact.

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DATA SHARING AND DATA REGULATION IN SIGHTS AND EXPERIENCES ON THE IMPLEMENTATION OF OPEN PLATFORMS AND DIGITAL TECHNOLOGY IN THE AHA AND AAL DOMAINS. HEALTH DATA FOR RESEARCH

ITZIAR ALKORTA AND IDOIA LANDA

UPV/EHU-SMART BEAR

10.03.2022

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- Public and private research projects
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Co-operation is crucial for research

- European healthcare systems can make best possible use of data for the three interlinked purposes of primary use for direct patient care, secondary use to support the safe and efficient functioning of healthcare systems, and secondary use to drive health research and innovation.
- GDPR is a much appreciated piece of legislation, variation in application of the law and national level legislation linked to its implementation have led to a fragmentation of the law which makes cross-border cooperation for care provision, healthcare system administration or research difficult.
- The COVID-19 pandemic has clearly demonstrated the need for such cooperation and provided many examples and new models that can bring rapid, responsive and impactful action that should be further developed in the future.

GDPR regulation providing legal basis for processing for research

- Article 5(1)(b) indicates that further processing of data for scientific or historical research purposes is not to be considered incompatible with the purpose limitation principle if processing is undertaken with suitable safeguards in accordance with Article 89(1).
- In addition to appropriate safeguards for secondary processing health data, researchers must also ensure processing is carried out pursuant to an Article 9(2) GDPR lawful justification.
- A number of options for processing are available under Article 9(2) GDPR. Some must be implemented by EU or Member State law, which should be proportionate and provide for appropriate safeguards to protect the fundamental rights and the interests of data subjects.
- The Articles requiring such legislation relevant to the area of health and research are Articles 9 (2) (h), (i) and (j) while Articles 9 (2) (a), (c) and (e) are available without the necessity of further law.
- Further guidance is given in Recitals 156-163.

Choosing legal basis

- The literature shows that identifying the correct legal bases for use in the context of research is in practice difficult.
- There is uncertainty to which extent existing national laws apply. For example, the processing of special categories of data repeatedly references 'on the basis of Union or Member State law.'
- Some processing activities may fall under different legal bases simultaneously

Sectoral legislation further specifying the application of article 9(2)(j) in the context of health research

- Estonia Personal Data Protection Act
- Germany- Federal Data Protection Act BDSG- Section 22 § 2 sentence 2 in conjunction with Section 27 § 1, sentence 2 - special categories of data
- Spain Additional Provision 17^a.2 of the Organic Law 3/2018, of 5 December 2018 of Protection of Personal Data and guarantee of digital rights
- Denmark Act no. 502 of 23/05/18 In Denmark, Articles 9(2)(j) and 89 GDPR have been 'activated' in section 10 of the Act no. 502 of 23/05/18 on supplementary provisions to the regulation on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (the Data Protection Act)
- Greece Article 84 (4) (4c) of Law 4600/2019
- Italy -Decreto Legislativo núm. 101 de 10 de agosto de 2018 para la adaptación de la legislación nacional al RGPD.
- Netherlands Dutch GDPR Implementation Act, 2019
- Ireland Data Protection Act 2018
- UK Data Protection Act 2018

Comparative on diversification of bases

	REGULATION	LEGAL BASIS	COVID-19
SPAIN	Additional provision 17ª.2 of the Organic Law (LOPDGDD)	 Situation of exceptional relevance and seriousness for publich health 	The AEPD (spanish control authority) has not made any guide for the application of the legal basis in the context of Covid. Wide options for researchers.
ITALY	Articles 110 and 110 bis of the Code	The consent is the rule but multiples exceptions are identified	Partial derogation of the art 110 of the Code. Possibility to carry out the research without the need to present the research project, the impact assessment and prior consultation with the Guarantor (italian control authority)
IRELAND	Specific regulation	The explicit consent. Only exception: the declaration of consent by the Health Research Consent Declaration Committe (HRCDC)	Explicit consent

When is consent the appropriate legal basis?

- Power imbalance?
- Complementary safeguard?
- Requirement?
- Other requirements:
 - Information & Transparency
 - Confidentiality

Public and private research projects

- Variation between Member States in how they distinguish between public and non-public sector researchers.
- This is relevant as the definition can influence the selection of lawful basis: in addition to relying on the provision for scientific research in Article 9(2)(j) certain categories of researchers may also be able to rely on Article 9 (2)(i) where research is in the public interest.
- What type of data is available for researchers? Data may be stored by private companies, in anonymised databases (set up by private organisations or professional associations) or data can be collected in a clinical trial, done by private companies.

Harmonization is needed in other relevant subjects

- Anonymisation and pseudonymisation
- Security
- Interoperability
- RECs

Code of Conduct

- Code of Conduct as part of this legal framework, it was noted that there are several organisations and projects (WHO, EMBL, BBMRI, 1MGP) and national initiatives that could be a starting point.
- Key concepts in the GDPR, such as legal basis, controllership, definition of personal data, pseudonymisation versus anonymisation, as a first step, and then build on that understanding with further specific legal guidance.
- Shared interpretation of provisions in the GDPR which are valid without national implementation such as 5.1b or 17.3d GDPR.

Views of future legislation: Data Governance Act

- The proposal for a Data Governance Act, adopted based on article 114 TFEU, sets out a minimum common denominator that may be further enriched with sectoral legislation, for instance in the area of health to reply to the needs of the EU healthcare systems.
- Mindful of the rules of subsidiarity one of the country correspondents argued that EU legislation under Art. 9(2)(i) or (j) GDPR could be developed to guide the setting up of the (preferably) federated infrastructure for EU level data sharing, defining the governance of such an infrastructure including the roles of EU and Member State bodies.
- Addressing the practical needs of a European Health Data Space: infrastructure to create a single entry point to give researchers a facility for gaining trusted access to the data sets held in other EU countries.
- As a final word, it is important to note that sound health data governance will be one of the pillars
 of trust that support the European Health Data Space, but it can only be successful if it is truly
 supportive of the other pillars of trust which demand assurance of data quality, transparency, and
 the full support to patients to act as active agents in their own health and care, with full capacity
 to exercise their health data related rights.









Questions & Answers



Upcoming project activities

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