







2nd European EHR Exchange Format Expert Summit

COFFEE BREAK

Starts again at 15:40

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2nd European EHR Exchange Format Expert Summit

Session 5: Next steps for collaboration and communication

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IPS and the format evolution

Robert A. Stegwee Chair, CEN/TC 251 Health Informatics

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EHRxF work started in 2008

- The epSOS project launched the cross-border Patient Summary
- HL7 and IHE helped to create the specifications and profiles
- The eHealth Network published the Guideline for the Patient Summary
- The eHealth Digital Service Infrastructure (eHDSI) was launched, including the cross-border sharing of the Patient Summary
- EC requested CEN to start a project to turn the Guideline into a standard
- Worked closely together with HL7 and IHE to incorporate the learnings from eHDSI and make sure the standard could be implemented easily
- Jointly decided to call it the International Patient Summary IPS





IPS published from 2018 onward

- HL7 CDA and FHIR Implementation Guides for the IPS are published
- CEN IPS standard EN 17269 is published
- SNOMED International publishes the IPS Free Set (and IPS Terminology)
- IHE International publishes the IPS content profile (and sIPS access profile)
- ISO adopts the IPS standard as ISO 27269 now called EN ISO 27269 in Europe
- Revision of the EN ISO 27269 is now ongoing, with input from the EU















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It's all about collaboration





Driving Digital Health Forward HL7 Europe and IHE-Europe Strengthen Their Collaboration to Enhance Interoperability



Scan to read the press release





Working together on the IPS

- The JIC IPS Coordination Committee has been established
 - Joint Initiative Council for Global Health Informatics Standardization
 - CEN, HL7, IHE, ISO and SNOMED have delegates in <u>IPSCC</u>
 - Open discussion with contributors and visitors also <u>a website</u>
 - JIC is reaching out to the global community on <u>IPS stewardship</u>
- In Europe, the PS is just one of six EHDS categories of data
 - Stewardship is different because of the link with EHDS Regulation





Working together on the format - xShare



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The EHRxF Standards and Policy Hub



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A neutral place to evolve the EHRxF



- In the Hub we co-create, but we don't "own" EHRxF
 - Specifications are maintained by partners in the Hub
 - Tools and support are made available by partners in the Hub
 - Supporting materials are maintained by partners in the Hub
- The Hub assembles references to these assets, bundles them into useful combinations for health information domains, use cases, audiences, stakeholders, etc.
- Partners in the Hub align across these assets, making sure the EHRxF is adopted and the assets mature, within a global context











We need your input!

What does it mean for you to become a partner in the Hub?

Make sure this is addressed before formally establishing the Hub mid-2025

Ensure sustainability beyond the duration of the xShare project











Next steps for collaboration and communication

Karolina Mackiewicz, Innovation Director, ECHAlliance

- Yellow Button Campaign
- European EEHRxF Standards and Policy Hub

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Yellow Button Campaign

- Campaign 1: May June 2024
- Campaign 2: May June 2025











Campaign 1

- Whole-of-consortium effort
- Events, webinars, social media, newsletter
- Patients / users, developers and data users, industry, regulators, policy makers, regional ministries of health, SMEs, academic and research institutions, standard developing organisations
- Reach: >8.000











Campaign 2

- May June 2025
- Related to the release of the industry label





Are you ready for the **Button**?

xShare envisions everyone sharing their health data in European Electronic Health Record Exchange Format (EEHRxF) with a click-of-a-button – the xShare Yellow Button!

#xShareYellowButton





EHDS comes true!

With the European Health Data Space implemented, the xShare Yellow Button offers a lot of opportunities for innovative services to people, for better managing their health conditions!





Co-funded by the European Union



Early Adopters take Action to Empower Individuals, Health Systems and Businesses in Europe

#xShare





The xShare Yellow Button

will allow our health systems to easily solve cross-border data interoperability issues.



#xShareYellowButton











Why are we establishing a Hub?

- The benefits foreseen by the EHDS are dependent on the specifications of the European EHRxF
 - Standards-based innovation is a key policy objective across the European Union
- Users wanting to realise interoperability for their specific use cases will never need the full breadth and complexity of the European EHRxF
 - The Hub will provide them with dedicated guidance, compliant with the EHRxF
- Industry will realise systems conformant with the European EHRxF
 - \circ $\;$ The Hub will provide industry engagement from an early stage on
- Regulators need to rely on mature specifications for legal reference
 - The Hub will provide regulatory responsiveness and alignment with (global) standards
- The Hub enables a standards-based digital health ecosystem
 - Co-creating the health data economy in Europe











Community of Excellence



- Vibrant network of experts from various fields
- Industry, government, academia and society....
- Lasting coalition of partners dedicated to enabling policies and advance EHRxF implementation











Thank you!

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Expanding the X-Nets and maturing the ecosystem

Carola Schulz (Empirica)

Stefano Dalmiani – Hospitals on FHIR Co-Chair (FTGM)

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Joint ecosystem priorities: expectationsfrom the EEHRxF~30 Stakeholder Consultation Events – both group-
specific and multi-stakeholder

- Improvements of standardisation -> better clinical efficiency and patient care: national and cross-border, smooth patient data flow, continuity of care, enhanced patient safety
- Patient empowerment: better accessibility to health data,
- Less cost: less redundant tasks, tests, imaging,
- Less administrative burden (e.g. through less data entry)
- Advanced disease comprehension (e.g. basis for new research methods)



Conflicting ecosystem priorities

• Quick economic wins, clear ROI

XpanDH

- High stakes in making data interoperable and reusable
- Expand use cases of the EEHRxF
- Broad stakeholder consultation
 especially with clinicians,
 industry, vendors, patients

- Long-term goals of the EEHRxF
- Burden on healthcare practitioners through system/ data entry changes

European Commission

- Wish for practical, immediate usability – especially for small organisations
- Efficient and agile development process











EEHRxF Ecosystem Maturation

Efficient energy and nutrient cycles:

- not there yet: many unused health data resources
- big potential for EEHRxF as instrument of energy flow here

Ecosystem resilience:

- partially established: major steps e.g. eHN guidelines, maturity models, X-Bundles, X-Bubble experiences
- Major changes still ahead: Implementing Acts, Member State level implementation

Well established relationships between organisms:

- hugely advanced by XpanDH
- solid basis for future work









HL7[°]FHIR



...set your hospital on FHIR...

Hospitals

Stefano Dalmiani

Co-Chair

The HoF what, why and how (Maturity Model)



STEFANO DALMIANI

Hospitals On FHIR Co-Chair Monasterio Foundation Hospitals



MARIA MANUEL SALAZAR

Hospitals On FHIR Co-Chair CHU Porto

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Hospitals



HL7 FI

What Hospitals-on-FHIR is not

A playground for technical geeks

• HL7 FHIR is a mean not the goal..

Just another infrastructure

• We are not selling solutions...

A consultancy program

• ...nor services...

An award system

• We promote cooperation not competition ..

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Very Digital Health through and European EHRXF-based Ecosystem Image: Comparison of the comp				
¥		Preparing	2 4	
2	Setting-Up to be On-Fhir	The hospital has performed a self assessment on conditions to establish and operate HL7 FHIR-based services.		
3	Preparing to be On-Fhir	The hospital is preparing to technically have functional HL7 FHIR-based services		
4	Testing to be On-Fhir	The hospital is engaging in internal and/or external testing also with external (e.g., HL7 affiliate/HL7 Europe) support		



SpanDH Image: Spanding Digital Health through a gan-European EHRxF-based Ecosystem					
Hospitals HL7 FHIR					
Ū		Using	6 5		
5	Living On-Fhir				
6	Responding On-Fhir				






SpanDH Image: Spanding Digital Health through a pan-European EHRxF-based Ecosystem Image: Spanding Digital Health through a pan-European EHRxF-based Ecosystem Image: Spanding Digital Health through a pan-European EHRxF-based Ecosystem			
Hospitals HL7 FHIR			
°°€	•	Collaborating	<mark>9</mark> 8
8	Networking On-Fhir	The hospital is networking with other hospitals about offered HL7 FHIR-based services. This includes also mentoring activities.	
9	Exchanging On-Fhir	•	





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Members



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SpanDH Expanding Digital Health through a pan-European EHRxF-based Ecosystem

Hospitals







Regno Unito Regno Unito Danimarca Ho Poloni Va Parigi Parigi

Competitive advantages for Hospitals and Healthcare Organizations joining HoF

- Join a top-notch Community of Practice
- Reduce costs and effort to implement HL7 FHIR by benefiting of learning exchanges and decrease time to scale
- Place your hospital in a privileged position to participate in large scale pilots and projects once reached level 6 or more





Hospitals







Competitive advantages for Companies helping use HL7 FHIR and grow HoF



- Understand how hospitals and other healthcare providers evolve in interoperability desires, needs and capabilities, moving toward the acquisition of interoperable services and systems.
- Serve as a networking space for future business opportunities.
- Evolve business models, intercompany partnerships around the provision of combined IT services based on FHIR while knowing which clients are ready for them.

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National Ambassadors



Active:

- France •
- Portugal •
- Belgium •
- Germany •
- In activation
 - Spain •
 - Italy •
 - Cyprus •
 - Greece •



MARIE-ALEXANDRA LAMBOT



KARLIEN ERAUW





EUGENIA RINALDI

Germany Ambassador Charitè



GIUEPPE FICO



SYLVIA THUN



VICTOR COSTA Portugal Ambassador

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Hospital on FHIR users days



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Thank You

More information and joining Hospitals-on-FHIR: https://www.hospitalsonfhir.eu info@hospitalsonfhir.eu

- Let's build people interoperability around technical interoperability
- Beyond a technical standard to higher standards of Care



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Recommendations for future use cases from the Community of Doers (3C3P)

George Kapetanakis (ELLOK)

Mariam Shokralla (HIMSS)

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3C-3P (community of doers)

Co-Creation Community of Patients, Professionals and Programmers To bring together implementers and end-users of new and existing solutions IT developers and vendors/suppliers; patients and healthcare professionals.



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1 Community, 4 focus points



The Community of Doers comprises a large group of doers who may rejoin in plenary sessions, and smaller, focused teams developing specific topics (4) who meet periodically and aim to produce practical recommendations for developing new service evolutions.















Community of Doers

Purpose: Development of a functional proposal to the E.U. for the proper planning of MTDs using the EEHRxF

Stakeholders involved:

- Healthcare professionals
- Healthcare administrators
- Cancer patients
- Policy makers
- Regulatory authorities
- IT developers

Duration: 6 months (July – December 2024) Participants: 55 5 meetings up to now (2 meetings remaining)

HELLENIC CANCER FEDERATIO ΥΠΟΥΡΓΕΙΟ ΥΓΕΙΑΣ **ΚΟΙΝΩΝΙΚΗΣ**^ΔΑΛΑΗΛΕΓΓΥΗΣ 🛢 Κέντρο Τεκμηρίωσης & Κοστολόγησης Νοσοκομειακών Υπηρεσιών ΗΔΙΚΑ Ελληνικό Ινστιτούτο DRG EEAO HELLENIC SOCIETY OF MEDICAL NOBEPAREYTIKH ΕΣΝΕ

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Subjects of discussion

- Functional model of the MDTs in Greece
- Clinical Documents: types of documents required & their format
- Need to digitize documents
- Review flow charts
- Present the "AS-IS" status
- ✓ Suggestions for the "TO-BE" status
- Technical issues (IT infrastructure, systems integration etc)
- Patient involvement
- Legal aspects of MTDs in Greece and comparison with the EHDS











Interactive sessions using Mentimeter tool



Ποιος θα ήταν ο καλύτερος τρόπος σύστασης ογκολογικών συμβουλίων;



Για μια ισότιμη σχέση γιατρού/ασθενή, και εφόσον ο γιατρός μπορεί να βρεθεί υπόλογος για τις συμβουλές του, πρέπει να γνωρίζει ονομαστικά τον ασθενή;



Έχοντας ως παράδειγμα τις ενότητες του IPS, ποιες θα προτεραιοποιούσατε ως περιεχόμενα αναφοράς των ογκολογικών συμβουλίων;



Θεωρείτε ότι η υφιστάμενη νομοθεσία και ειδικότερα το άρ.135 ν.4052/2012 καλύπτει τις προϋποθέσεις για την ορθή εφαρμογή του κανονισμού EHDS;



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Full High Level Creating and MDT Indicative flow charts **Diagnostics / Screening** Referral Diagnosis Schedule MDT Complete Incomplete Treatment plan Preparation Progression Remission Complete Incomplete MDT Meeting Follow-up Recurrence Chemotherapy / Radiotherapy / Immunotherapy / Surgery / ... Palliative











Current outcomes (to be finalized until December 2024)

Legal & Regulatory

- ✓Patient Consent & privacy
- ✓ Duty of care & physician responsibility
- ✓ Differing opinions on treatment
- ✓ Data interoperability & security (EHDS)
- ✓ Participation of oncology patients

Policy

- ✓ Collaboration between organisations:
- · Health care providers
- Healthcare professional societies
- Research and academic institutions
- Patient advocacy organisations
- Government and regulatory bodies
- Technology providers
- Pharmaceutical companies

Care process

- ✓ Integrated care pathways
- ✓ Multidisciplinary care plans
- ✓ Role definition and accountability
- ✓ Workflow design and mapping
- ✓ Information flow and documentation
- ✓ Decision points and evidence-based guidelines
- ✓Quality controls











Current outcomes (to be finalized until December 2024)

Information

- ✓ Functional description
- ✓ Data elements
- ✓ Linking of data elements to terminologies
- ✓ Recommendations for implementation

Applications

- ✓ Adoption of FHIR
- ✓ Use of HL7 messaging standard
- ✓ Data security and privacy protocols
- Technical specifications
- ✓ Integration of Exchanged Information in user-friendly applications
- ✓ Data visualization, intuitive UI and UX, seamless integration with existing systems
- ✓ User-centered design approach, pilot testing, continuous updates

IT infrastructure

- ✓ Communication and Network protocols
- ✓ Data storage and backup solutions
- ✓ Compliance with interoperability standards
- ✓ Scalability and Flexibility
- ✓ Data Privacy and Security Measures
- ✓ Network Redundancy and Load Balancing







Standardised Medical Document Format & Record-Keeping Practices for MDT Meetings

- To establish a consistent and standardised approach for documenting patient information, treatment decisions, and care plans during MDT meetings
- Integration with Electronic Health Records (EHR)
- Finalisation by next month





Recommendations For Future Use Cases from the Community of Doers eD/eP/ePI working group

Core group : Anne Moen-Lapo Bertini-Henrique Martins-Remko Schats-Presented by Mariam Shokralla **2nd European EHR Exchange Format Expert Summit**

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What was the task ?What we did?

What: To enable cross border eP/ eD/ ePI

Why: People move across MSs, Cross border service care directive, Minimize medication errors.

How: Exploration, ideation, discussions and recommendations for the evolution of the next generation of the existing $eP/eD \rightarrow$ to eP/eD/ePI augmented services aligned with the goals of EHDS

To Build on previous EU projects: epSOS, myHealth@EU, UNICOM, Gravitate-Health, xShare, Xt-EHR

Who: The core group met weekly, collaborated on a working document to be finalized end of November.

The **Plenary group** met twice to inject further thoughts, ideas and topics to further consider.













Background













eD/ eP/ePI Augmented services – Assumptions and status oup?

- All EU countries establish eP and eD services.
- International Patient Summary (IPS), patient identification and healthcare professional (prescriber) identification are in place.
- This cross-border eP/eD applicable in temporary presence in MSs only for short periods of time (tourism –Cross border worker)-Chronic disease medication ?
- Excludes online pharmacies and non-physical dispensations
- More in depth analysis of Status quo of national eP/eD is needed

Status ePrescription/eDispensation service

9 Member States in operation

- Croatia (A&B)
- Cyprus (A&B)
- Czechia (A&B)
- Estonia (A&B)
- Finland (A&B)
- Greece (A&B)
- Poland (A&B)
- Portugal (A&B)
- Spain (A&B)



In 2026 most Member States in the EU + Norway and Iceland will be operational with the cross-border ePrescription/eDispensation service



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Concepts of cross border eD/eP/ePI services













Topics and ideas discussed ?













Challenges

- Technical disparities among countries in implementing the European eHealth Digital Service Infrastructure (eHDSI) have slowed interoperability, indicating that a similar challenge could arise with cross-border e-dispensation.
- Each country has unique pharmaceutical regulations, such as rules for prescription validity, dosage restrictions, and specific dispensing laws. Harmonizing these regulations across the EU would be necessary to ensure a seamless eDispensation experience.
- Implementing and maintaining a cross-border eDispensation system demands considerable financial and logistical resources.

Would the real benefit be: "Standardization on national Level" driven by EU standardization.













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- Šending and Retrieving e-Prescriptions across Europe: Lessons Learned













2nd European EHR Exchange Format Expert Summit

Session 6: Closing

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(Pre)Meeting messages



Veli Stroetmann

Director, Empirica Technology Research XpanDH

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How do you see the importance of the upcoming Implementing Acts to further define the EEHRxF (the Format) within the European Health Data Space?

Responses: 111 (out of 115 respondents), Average: 9



- 53 responses already in 2025
- 39 mid-end 2026
- 8 2027, 2 2029, 3 2030





What should EU projects and national initiatives <u>focus</u> on to advance the Format <u>until then</u>?

- Ensure broad understanding of the importance of using common standards as a foundation
- Focus on pragmatic use cases limited complexity but perfection in usability and usefulness
- Clear roadmap regarding use cases and information models
- Pilots + training and education. Test, pilot, and demonstrate. IHE connectathons that type of thing. Run cross-border pilot projects to test real-world usability
- Prioritise active involvement of health professionals from the very beginning
- Industry and national/local regulatory support, engage vendors
- Create multidisciplinary working groups with different expertise (clinicians, engineers, statisticians, patients, project managers)





What should EU projects and national initiatives <u>focus</u> on to advance the Format <u>until then</u>?

- Implementation guides, clear specifications, definitions, example demonstrators
- Gather information on the status quo in MS to enable a smooth and synergetic transition for systems
- Assessment of readiness level of national infrastructures for sharing of information, especially privacy and security, potential gaps among Member States
- Member States should build **capacity** and evolve their digital health architecture accordingly
- Focus on improving data collection infrastructure and data access
- Semantic interoperability, data catalogue, alignment of different MS rules





What should EU projects and national initiatives <u>focus</u> on to advance the Format <u>until then</u>?

- Define more precisely the **impact of the Format on national** eHealth systems /specifications
- Focus on interoperability then on a Format precise enough without room for interpretation
- Data Quality, terminology, concepts, data models, minimal/common data sets
- Support new domains like careplan and telemedicine





How do you think collaboration with/between industry partners can be further strengthened?

- Vendors are major target audience for most EHDS-related activities, their products will need to be ready for the Format
- Coordination and alignment of expectations with the industry will facilitate roll out of EHDS.
 transparent collaboration platforms, broad sector involvement
- Focused workshops, focus groups every quarter, focus on changes needed to meet EHDS requirements
- Show the added value of the Format and the EHDS in terms of competitive markets Single European EHR market. Prepare new promising data flow scenarios between EU countries, will attract vendors
- Use cases that demonstrate how it helps hospitals or doctors with problems they have today





How do you think collaboration with/between industry partners can be further strengthened?

- Vendors cannot participate in all different projects/groups, build one group of vendors, where experts from projects and other groups can come and ask for consultation (done in X-Net industry and xShare)
- Offer 24/7 online reference testing environment where all end-users and industry partners can validate and test independently against specifications, or one-by-one, one vs many.
 Provide testing support
- Support through national interoperability hubs and SDO affiliates
- US model clear financial incentives for healthcare providers who support the format among the first ones procuring the required functionalities. Financial sanctions for leggards

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Please indicate any significant outcomes/milestones achieved since last year's Summit

- Progress within TEHDAS2, EHDS2, Xt-EHR, xShare, XpanDH, as well as the advancement in implementing HL7 FHIR standards
- Increased awareness of EEHRxF, international standards and interoperability, many more stakeholders are involved now
- Xt-EHR XpanDH HL7 Europe IHE collaboration for EEHRxF FHIR IGs (Implementation Guides). FHIR profile for Lab Reports available. Work has started on the FHIR IG for HDR (Hospital Discharge Reports)
- The Format is more mature, business use cases defined











Do you think we can go faster? How would you suggest we do it together?

- Yes (only 3)
 - Expanding pilot programs to more EU regions and enabling fast-track testing for interoperable solutions to provide real-world insights and scalability
 - Open source reference implementation
- No
 - **"Alone you can go faster but together we can go further"**. Take more time but do it right and be sure to not leave anyone on the side
 - We should not, important to continue the process with clear sustainable milestones
 - Going faster could increase the resistance to change. Have to respect comitology process, different levels of maturity, additional national implementation tasks
 - It goes too fast already. More support needed to help the countries fit all that within their own eHealth space
 - Attention to supporting change, the transition period, the broader effects of such policies





Do you think we can go faster? How would you suggest we do it together?

- Leverage industry and user cooperation, standards and methods that already have uptake
- Open source collaboration Focus on exchange of code / libraries / ... between industry partners (open source components)
- Cooperation between eHMSEG (primary data) with HDAB (secondary data) data standards and archetypes
- More dialogue between EHDS1 and EHDS2 stakeholders to achieve better alignment
- An industry pilot in each MS to ensure that vendors in all MSs get better understanding
- Launch pilot test across hospitals and/or primary healthcare in different countries
- Attract more experts from Member States
- EU should continue supporting coordination and support actions to ensure further mobilisation of people and resources and foster adoption and uptake of the Format

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2nd European EHR Exchange Format Expert Summit

Coordinators' closing address: Xt-EHR, xShare, XpanDH

Christos N. Schizas, Mie Matthiesen, Henrique Martins

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Xt-EHR in numbers

In 12 months of Xt-EHR...

Consortium

57 partners from 27 countries

11 Leadership Committee/Steering Committee/Governmental Board meetings

Ecosystem building

Community of Doers:

3 Working groups and focuses

60+ active individuals

300+ informed individuals

Note: some numbers are approximates

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EEHRxF Awareness raising

40+ hours of workshops

3 projects engaged

Present in **10+ events**, of which 3 were (co)organised by Xt-EHR.









xShare in numbers

In almost 12 months of xShare...

Consortium

40 partners from 15 countries, ~160 participants

2 consortium meetings, 5 project forums, 4 X-Bundle retreats, 14 deliverables, 11 executive committee meetings, >100 meetings

Ecosystem building

Preparing for the

Standards and policy hub

- Workplan and draft website
- Industry Forum
- Regulator Forum
- Community of Excellence

Note: some numbers are approximates

Spreading the word:

Yellow button campaign Event attendance and speeches "Under the Hub" newsletter

- 250 Post cards
- 200 pens, 100 buttons, 100 pins
- 9 Roll-ups IHE Connectathon
- 28 visuals created
- 1 paper, 20+ presentations

EEHRxF Awareness raising

10 **events**;

6+ videos - 138 views ytube Social media: 1077 followers Website: 5967 visits Total reach achieved - **19,287**;

Experimentation

- 9 adoption sites
- 1 xShare button showcase (6 countries, 1 region, 3 hospitals, 3 digital health companies)













💠 XpanDH



In 22 months of XpanDH...

Consortium

35 partners from 13 countries

27 Leadership Committee/Steering Committee meetings

Ecosystem building

<u>10 X-Nets:</u>

150 active individuals1000+ informed individuals3 Multi-stakeholder meetings

Note: some numbers are approximates

Experimentation

11 X-Bubbles from **6 countries**, of which 7 "in-silico" Bubbles

3 available online survey tools

Community of Doers:

4 Working groups and focuses60+ active individuals200+ informed individuals

EEHRxF Awareness raising

10+ hours of public webinars

400+ hours of workshops

81 projects engaged

Present in **31 events**, of which 13 were (co)organised by XpanDH and 14 were in-person.

1,840+ Youtube views

2,000+ followers on social media













Past and future...

1st EEHRxF Expert Summit (2023):100 Participants on-site, 200 Participants online

2nd EEHRxF Expert Summit (2024):

120 Participants on-site, 500 Participants online



Coming up...XpanDH handover:

16-19 December in Lisbon, Portugal

















2nd European EHR Exchange Format Expert Summit

EC closing address

Konstantin Hypponen, Kyriakos Hatzaras

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