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Q2 Panel: Vulcan ePI/eLabeling Project, IDMP and EMA/SPOR: The Way Forward

Session Chair: Anne Moen, University of Oslo and Gravitate-Health

January 18, 2024

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Q2 Panel: Vulcan ePI/eLabeling Project, IDMP and EMA/SPOR: The Way Forward

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Panelists

1. ePI Pilot Project – Progress & Next Steps: *Elizabeth Scanlan, ePI pilot, European Medicines Agency*
2. Compendia ePI Pilot: *Bente By Jansen, Felleskatalogen AS, Norway*
3. Improving Package Leaflets: Summary of IATF Recommendations : *Kate Porch **(online)**, Global Labeling, Johnson & Johnson*
4. PhPID operating model, GIDWG: *Magnus Wallberg, Uppsala Monitoring Centre*
5. UNICOM achievements and next steps from an NCA perspective: *Farah Diehl-Fahim, empirica, Christer Backman & Pelle Persson, Swedish Medical Products Agency*
6. Health Data and the Link to ePI : *Georgos Georgiannakis **(online)**, DG SANTE - European Commission*
7. SPOR the way forward: *Isabel Chicharo **(online)**, SPOR lead, European Medicines Agency*
8. Scaling IDMP for Global use cases: *Panagiotis Telonis, European Medicines Agency*

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Q2.1 ePI Pilot Project – Progress & Next Steps

Elizabeth Scanlan, ePI pilot, European Medicines Agency

January 18, 2024

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EUROPEAN MEDICINES AGENCY

ePI Pilot Project – Progress & Next Steps

EuroVulcan 2

EuroVulcan 2 European Meeting of the Vulcan Accelerator

Presented by Elizabeth Scanlan on 18 January 2024
ePI Product Owner, Public and Stakeholders Engagement Department

An agency of the European Union

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Disclaimer

The presenter does not have any conflict of interests.

ePI Definition

ePI is authorised, statutory product information for human medicines (i.e. summary of product characteristics, package leaflet and labelling) in a semi-structured format created using the **EU ePI Common Standard**. ePI is adapted for electronic handling and allows dissemination via the web, e-platforms and print.

EU ePI common standard based on FHIR to support a harmonised ePI across the EU network

Fast
Healthcare
Interoperability
Resources

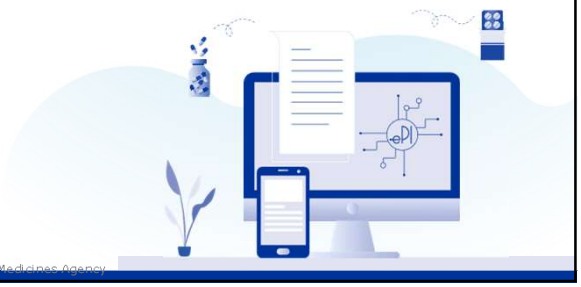
Adopted EU Common Standard for ePI
- ❖ Published on EMA GitHub
- ❖ Aligned with ePI type 1 in the Vulcan Accelerator / Gravitate ePI IG

Benefits for patients & healthcare professionals.. ..regulators & companies

- Patient apps
- Digital & Video content
- Accessibility features
- Update alerts
- Targeted searches

- Rapid updates
- Link to national language ePI
- Timely access to up-to-date information in patient's language at point of need

- Support mitigation of medicine shortages
- Optimise signal validation
- Administrative efficiencies



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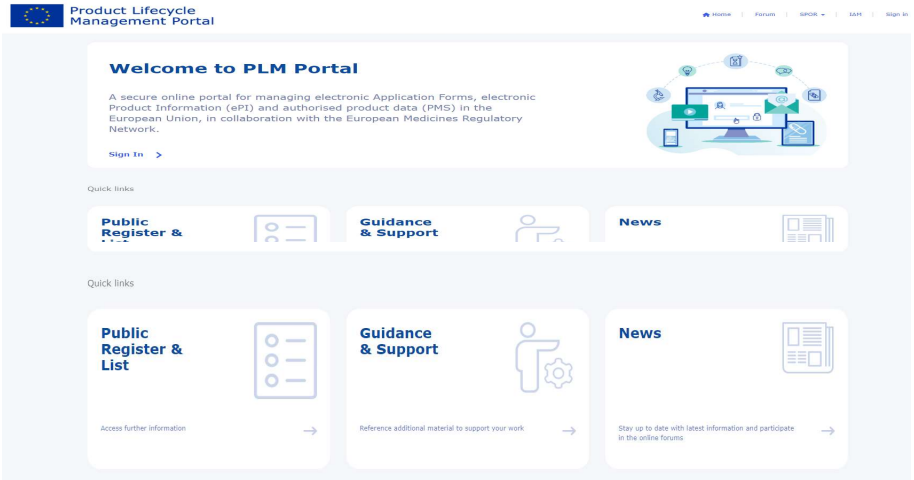
ePI at Product Lifecycle Management Portal

https://plm-portal.ema.europa.eu/



Developed with funding by the European Union

From the same portal, applicants can manage ePI, electronic application forms and product data. PLM portal ePI enables:

- ePI authoring & management
- Rich-text editing
- Repository & API

10 ePI pilot project – progress & next steps

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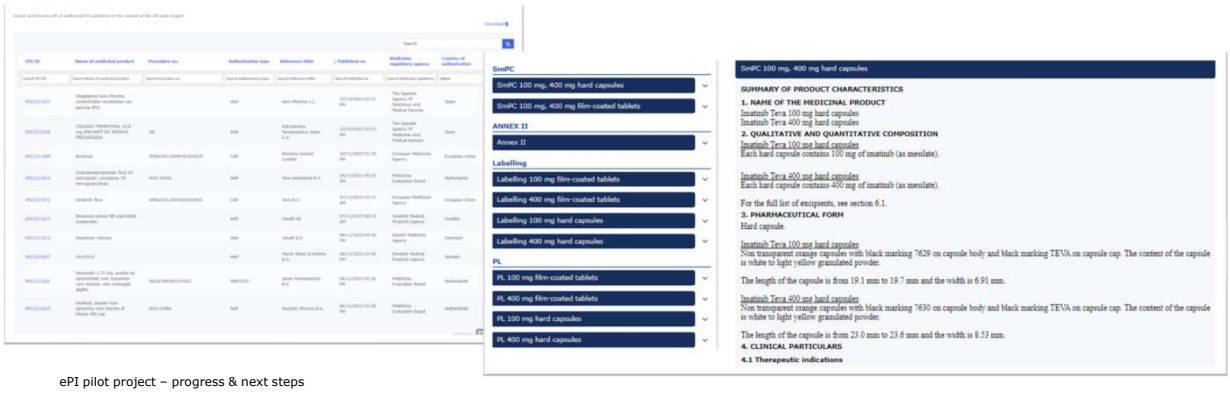
Pilot ongoing

- 25 real-time procedures
- CAP (EMA) and NAP (Denmark, Netherlands, Spain, Sweden)
- Duration: July 2023 – July 2024
- First ePIs published: https://plm-portal.ema.europa.eu/ePIAll/

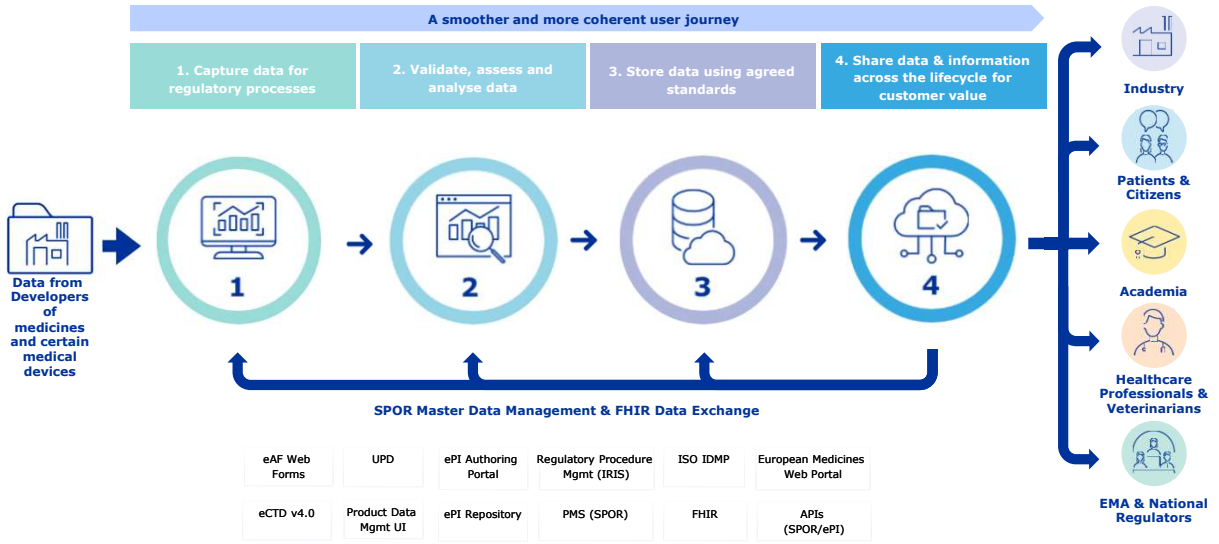


Next challenges

- ➢ Pilot outcomes on business process, guidance, and roadmap
- ➢ Essential functionalities for launch
- ➢ Coverage full suite regulatory procedures
- ➢ Translations and linguistic review
- ➢ Downstream: linking ePI to medicine package

2021	2022	2023	2024-future
• EU ePI Common Standard developed • Public consultation • EU ePI Common Standard adopted by EMRN	• MVP development • Network product owner and SMEs onboarded	• MVP development • Pilot begins	• Pilot outcomes • Roadmap to implementation • Phased implementation across network

Product Lifecycle Management – Connecting the Value Stream



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Thank you for your attention

Further information

Contact us at ePI@ema.europa.eu
Next **system demo** live on YouTube and EMA website on 26th March

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
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Q2.2 Compendia ePI Pilot

Bente By Jansen, Felleskatalogen AS, Norway

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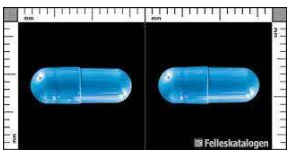
FASS

Medicin.dk

PHARMACA

FELLESKATALOGEN



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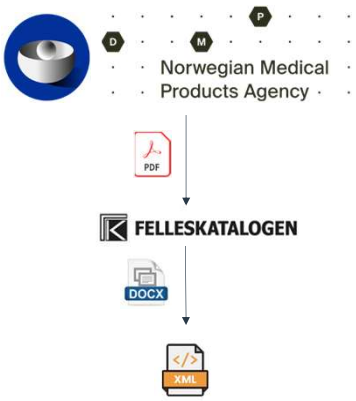
The Nordic compendia are in a unique position, providing updated and structured package leaflets for all products on the Nordic market.



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4+1 Compendia ePI Pilot

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The Nordic compendia will use their common knowledge and experience to convert package leaflets from proprietary XML formats to the FHIR ePI standard - well aligned with the ePI provided by EMA in the future.

Template header	Element from Felleskatalogen's structure
1. What X is and what it is used for	pil-indikasjon
2. What you need to know before you <take> <use> X	pil-forsiktighet
Do not <take> <use> X	pil-kontraindikasjon
Warnings and precautions	pil-advarsel
Children <and adolescents>	pil-barn-unge
Other medicines and X	pil-interaksjon

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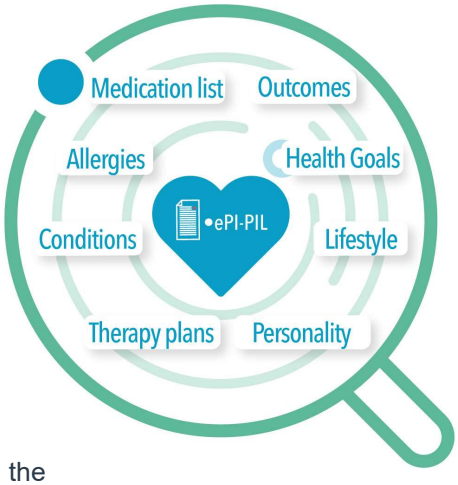
The Gravitate Lens (G-Lens) – Focusing



- International Patient summary (IPS) as window to curated information about a person's health
  - Medications, allergies, vaccinations, problems and procedures,
  - Labs, diagnostic imaging, encounters, implantable devices
  - Advance directives
- For Gravitate-Health the IPS offers personal health information the lens to focus on the contents of the ePI

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The goal of the 4+1 Compendia ePI Pilot is to..

- Support the Gravitate Health scenarios in Norway, Sweden and Denmark.
- Demonstrate cross-border functionality in a Nordic setting (+ UK) by investigating the use of a common, international identifier, like MPID or PhPID.
- Uncover potentially hurdles and needs for improvements in the FHIR ePI standard and SPOR, and by this ensure the best outcome of EMA's ePI project, a projects highly supported by the national competent authorities and the pharma companies all over Europe.
- Ensure the compendia's reediness for the FHIR ePI standard, for early adaption in the Nordic region.

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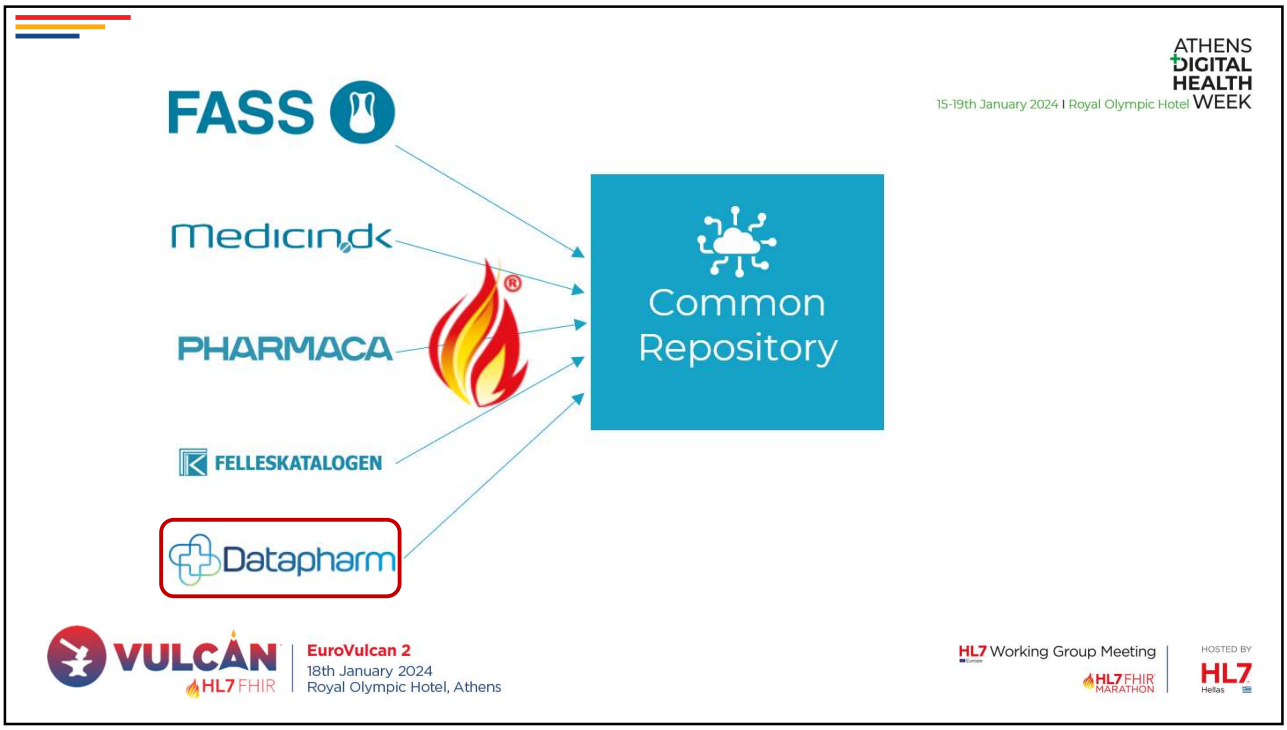
FASS
Medicindk
PHARMACA
FELLESKATALOGEN
Datapharm
Common Repository
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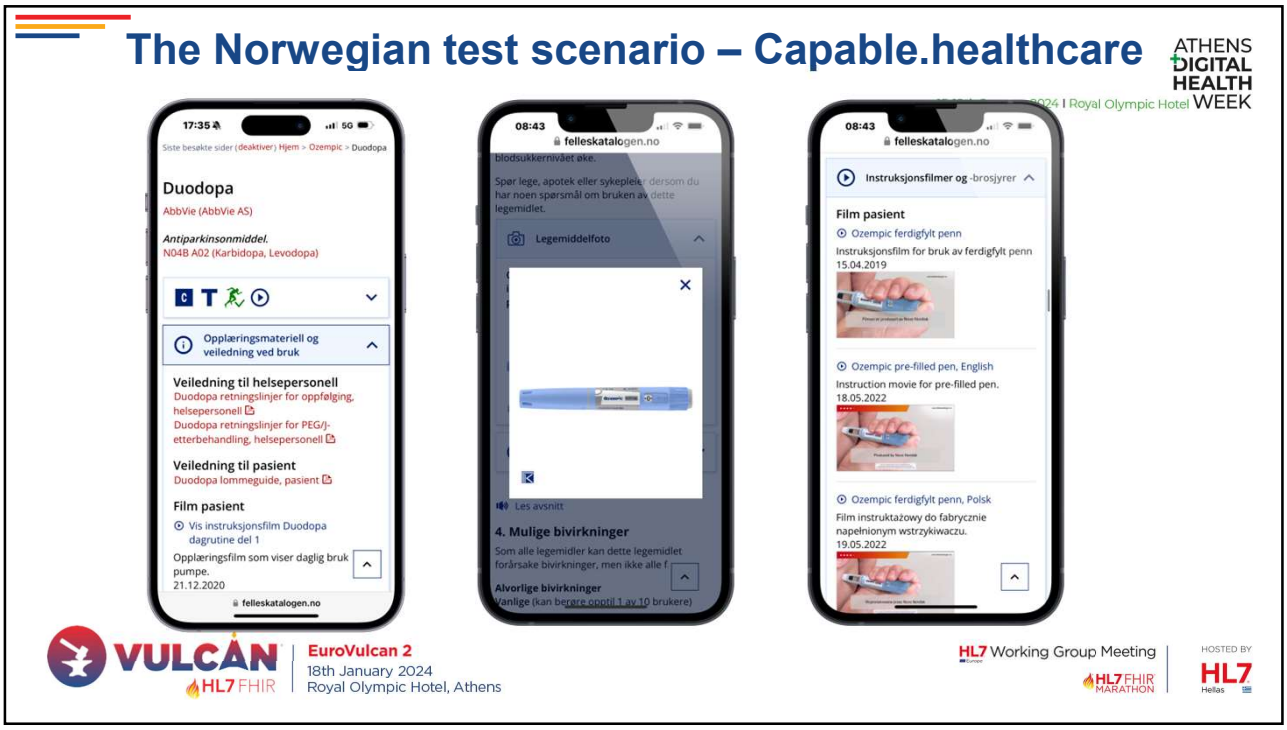
The Norwegian test scenario – Capable.healthcare
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Duodopa
AbbVie (AbbVie AS)
Antiparkinsonmiddel.
N04B A02 (Karbidopa, Levodopa)
Opplæringsmateriell og veiledning ved bruk
Veiledning til helsepersonell
Veiledning til pasient
Film pasient
felleskatalogen.no
Legemiddelfoto
4. Mulige bivirkninger
Instruksjonsfilmer og -brosjyrer
Film pasient
Ozempic ferdigfylt penn
Ozempic pre-filled pen, English
Ozempic ferdigfylt penn, Polsk
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Status of the 4+1 Compendia ePI Pilot

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- Declared common structure with a profile on Composition - Building on the Vulcan Electronic Medicinal Product IG.
- Set up of common profiles for structured medicine resources.
- Set up of Implementation Guides, separately for profiles and content - Using GitHub and the HL7 IG Publisher.

- All Nordic compendia are in progress with document conversion and mapping of medicines in-scope for the test scenarios.
- Converted ~360 package leaflets.

Main challenges identified during the pilot

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- Definition of medicines in-scope for each country. Mapping equivalent products across countries is work-intensive. Each compendium has unique identifiers for medicines, but not international identifiers such as PhPID or terminology like SNOMED (International Edition).
- Loose document structure – Package leaflets do not always conform to the section – Named/identified subsection hierarchy, according to SmPC template.

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Gravitate Health

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Information campaign for ePI in Norway

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ONLINE

Q2.3 Improving Package Leaflets: Summary of IATF Recommendations

Kate Porch, Global Labeling, Johnson & Johnson

January 18, 2024

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Improving Package Leaflets: Summary of IATF Recommendations

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Inter-Association Task Force: Who are we?

We represent the pharmaceutical industry main associations:

- EFPIA (Innovative medicines)
- Medicines for Europe (Generic medicines)
- AESGP (non-prescription medicines / self-care)

- **Dialogue with other Trade Associations too**
- **Since 2015, we've been working together on the topic of the content of the package leaflet.**

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Framework on package leaflet compilation

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- Package leaflet sections and order of content is set down in legislation
- QRD template includes standard statements for inclusion
- Requirements in the guidelines have to be followed
- User testing/consultation is required with lay people, for readability
- Updates are made to ensure the most current content

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Improving the Package Leaflet and the voice of the patient

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Package leaflets contain A LOT of information. How do patients interact with them, today and in the future? What is important to them?

- Shortcomings identified in NIVEL Reports (2015) & recommendation made by European Commission

To further explore, IATF conducted:

- 2 Workshops with patients and carers (DE and FR)
- User Testing Company interviews & Workshop ('22-'23)
- Shared proposals with a small no of patients (2023)

➢**Goal:** To co-develop proposals for improved content, format and testing methodology for patient-centric package leaflets of the future

➢**A clear, informative package leaflet that motivates people to read**

➢**Proposals:** shared with European Medicine's Agency Quality Review of Documents Group in May 2023

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Proposals for improvements to the Package Leaflet

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Shortening the Length of the Package Leaflet
Omit opening paragraph, optional sections, avoid repetition & use signposting. Data supportive.

Focus on Patient Relevant Content
Benefits, therapy goals (e.g., prevention, alleviate symptoms), mode of action if a consequence (fact based, not promotional)

Improved clarity, structure including standardisation of terms
Definition of a contraindication vs. warning/precaution, frequencies of side effects and actions to take, dictionary

Note: Proposals where it is felt further exploration is required, User Testing Company colleagues are onboard to user test.

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IATF proposals for improvements

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Benefit

- Patients want benefits included
- Therapy goals: does the medicine treat, cure or prevent the condition?
- What is the risk of not being treated?
- Not promotional

Warnings

- Separate contraindications and warnings into 2 sections to be clear on the distinction, and to ease navigation
- Move any side effects linked to warnings to the side effects section, as this is where patients look for them – reserve for “class warnings”
- Pregnancy standard statements should be implemented, as we have for the SmPC.

Side effects

- Consider how frequency is described in the template. Current definitions are not well understood and generally overestimated by lay people. E.g., order according to body part or severity.
- Consider recommended actions – see Australian CMI example.
- Aim: readable and actionable for patients.

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Proposals for Indication Section

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Information on Benefit

Patients want to see the benefits explained to them

Most leaflets are perceived as too risk based – consider recommendation that information on benefits should also include the risk of not being treated. However, the emphasis on the risks involved in taking the medicine must not unsettle the patient in such a way that they do not take the medicine and thus exposes themselves to an even greater risk of not having their condition treated.

Therapy goals should be explained in patient friendly terms only. Examples are useful e.g., is it treatment of symptoms or prevention of recurrence of an underlying disease?

It should not be promotional.

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Current side effect frequencies

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Standard language in the QRD template

Within each section mentioned above, side effects should be arranged by frequency. The following frequency convention is recommended:

Very common: may affect more than 1 in 10 people
Common: may affect up to 1 in 10 people
Uncommon: may affect up to 1 in 100 people
Rare: may affect up to 1 in 1,000 people
Very rare: may affect up to 1 in 10,000 people
Not known: frequency cannot be estimated from the available data

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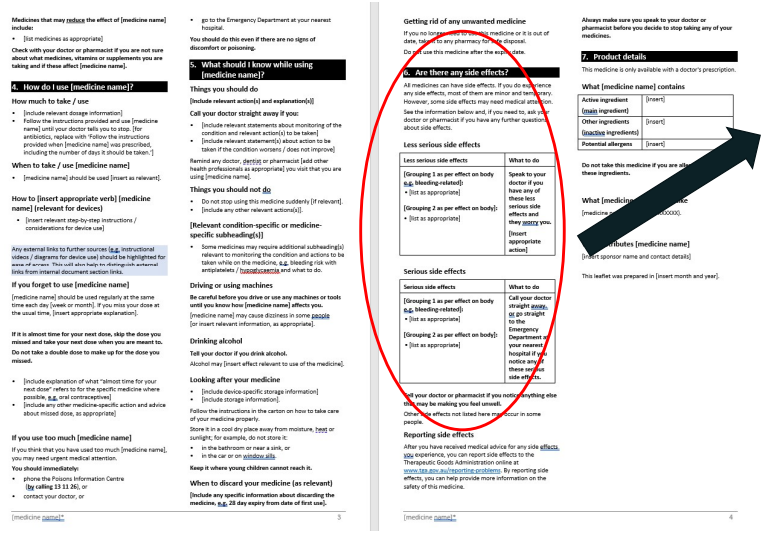
Australian CMI example of side effects presentation



Less serious side effects

Less serious side effects	What to do
Nervous system related: • headache **Stomach and intestine related:** • diarrhoea • abdominal or stomach pain • flatulence (stomach discomfort or fullness, relieved by passing wind) • nausea (feeling sick) • vomiting **Skin related:** • mild skin rash	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Nervous system related: • dizziness • numbness, tingling or weakness of the arms and legs **Blood and lymph system related:** • bruising easily, unusual bleeding (e.g. nosebleeds), signs of infection such as fever, chills, sore throat and mouth ulcers **Bone, muscle and tissue related:** • muscle aches and pains • painful or swollen joints **Stomach and intestine related:** • severe upper stomach pain, nausea and vomiting	**Call your doctor straight away, if you notice any of these serious side effects.**

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Proposals for improvements to the Package Leaflet - *Summary*

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- Shortening the length of the package leaflet will help to declutter make leaflets more attractive and easy to navigate in appearance and content
- Focus on patient relevant content – a well understood leaflet translated to the right behaviour
- Improved clarity and structure – more navigatable by section
- Based on research articles and interviews with patients and user testing companies, open to further exploration and discussion

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Q2.4 PhPID operating model, GIDWG

Magnus Wallberg, Uppsala Monitoring Centre

January 18, 2024

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IDMP and PhPID

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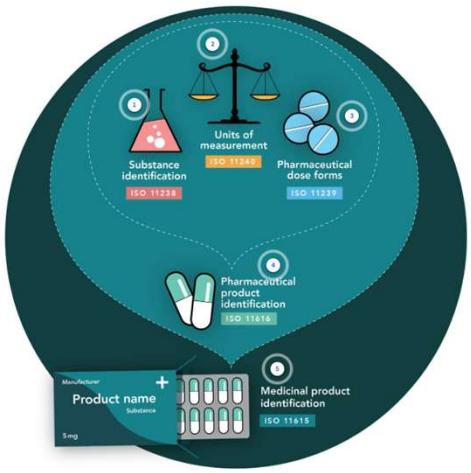

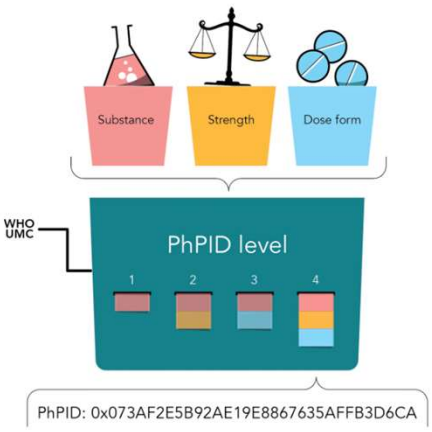

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PhPID Operating Model

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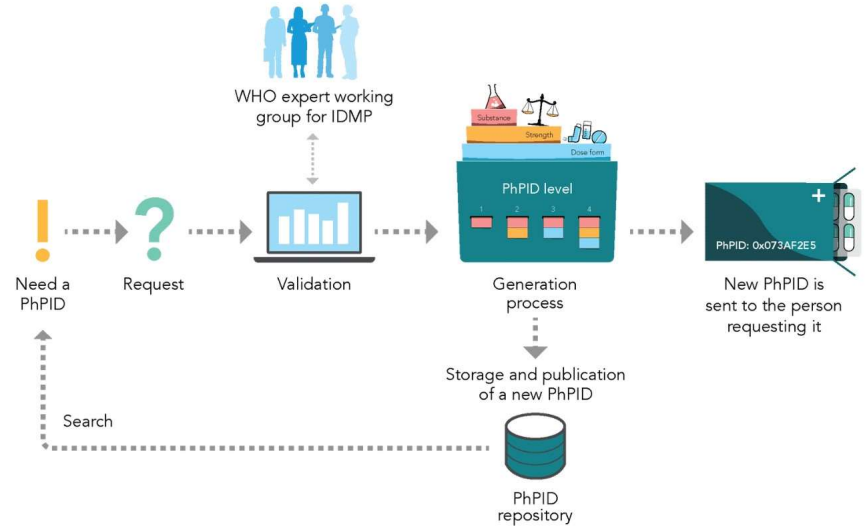

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GIDWG Project Business Rules and Validation Results

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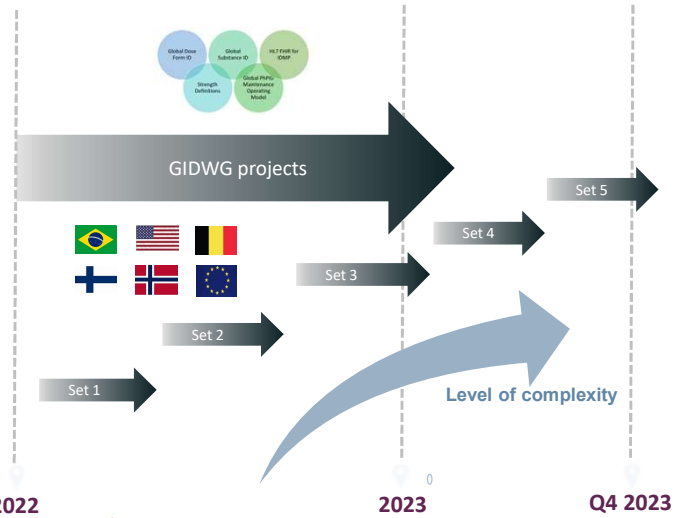

5,600 medicinal products validated
92-99% could be assigned a Global PhPID using current business rules

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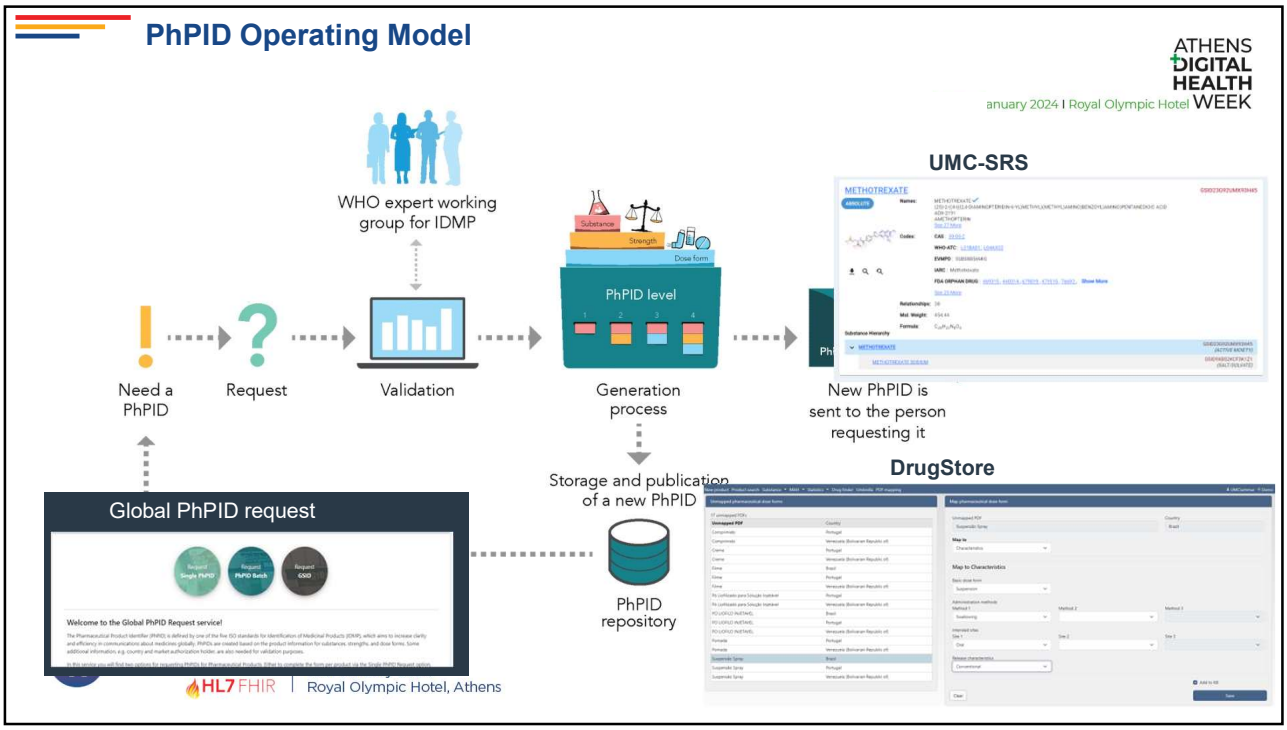
PhPID Operating Model
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WHO expert working group for IDMP
UMC-SRS
Need a PhPID
Request
Validation
PhPID level
Generation process
New PhPID is sent to the person requesting it
Storage and publication of a new PhPID
DrugStore
Global PhPID request
PhPID repository
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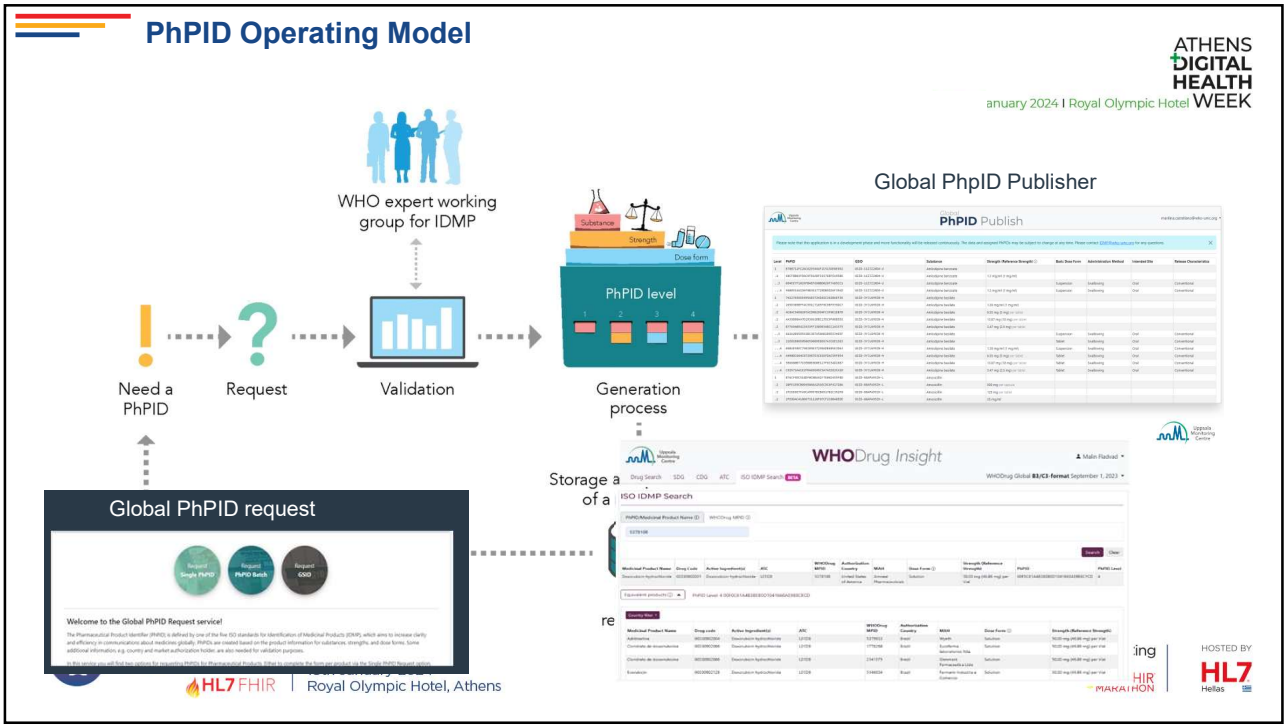
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WHO expert working group for IDMP
Global PhpID Publisher
Need a PhPID
Request
Validation
PhPID level
Generation process
Global PhPID request
WHODrug Insight
ISO IDMP Search
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ISO IDMP PhPID and WHODrug

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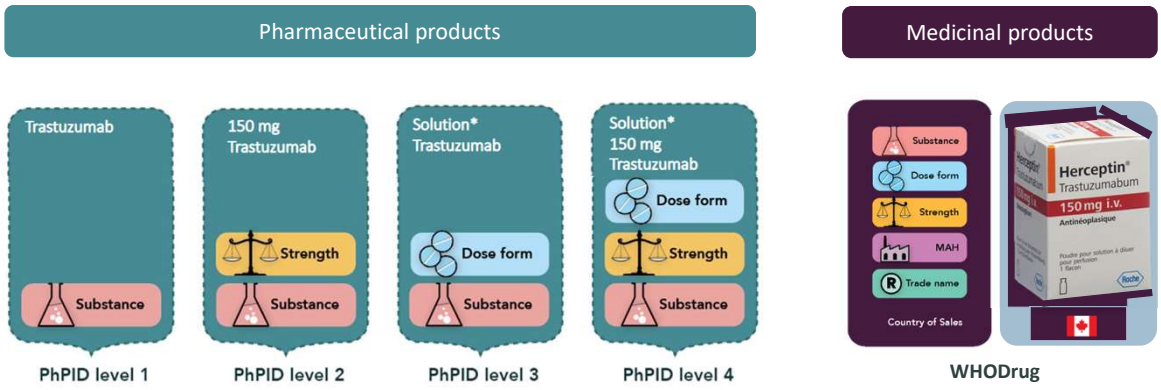

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PhPID Operating Model

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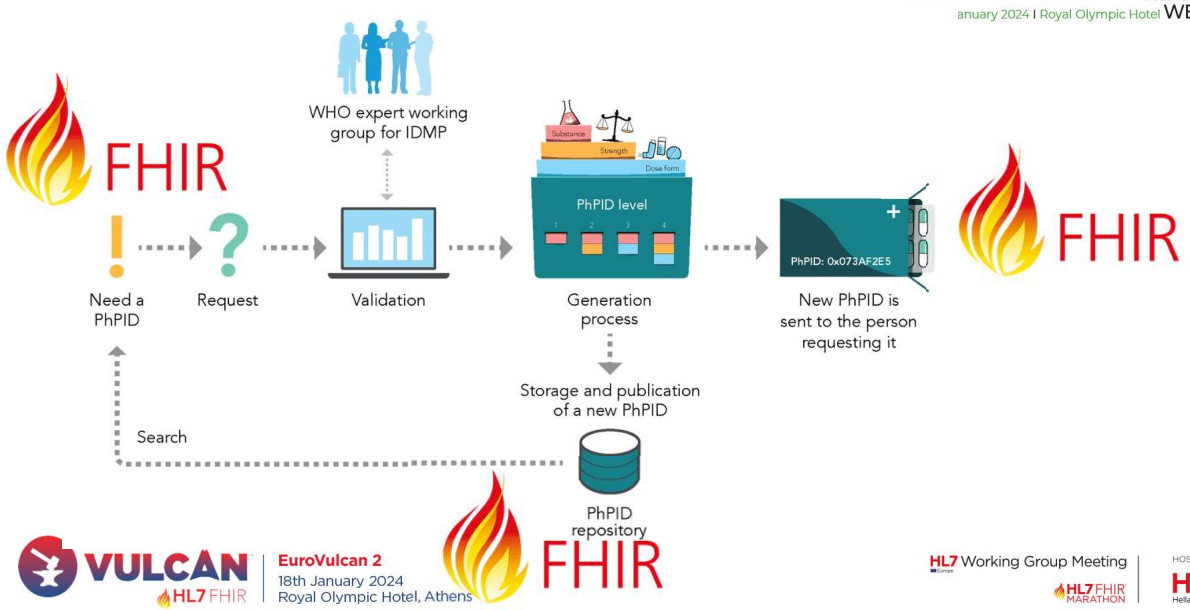

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FHIR resources used in the PhPID operating model

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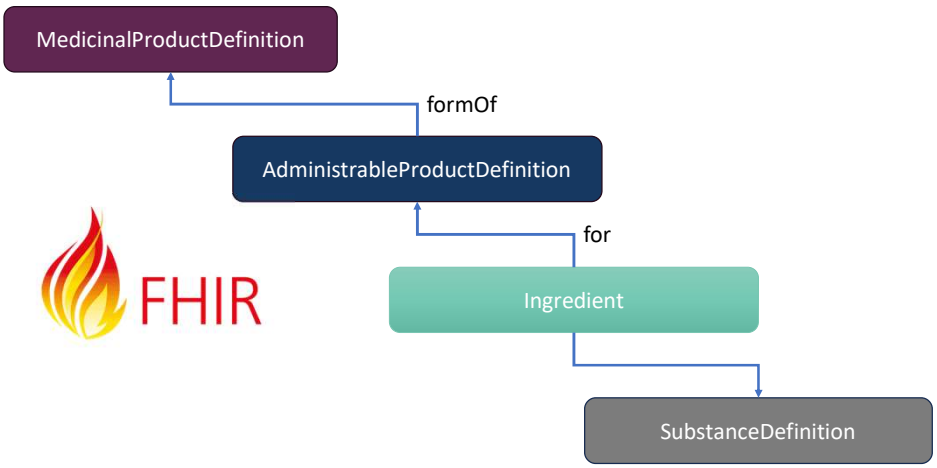

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Request and publishing using FHIR

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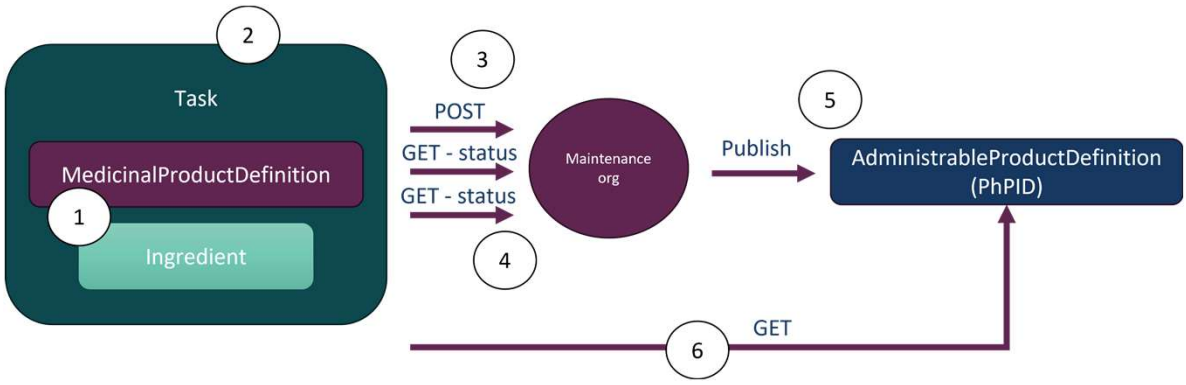

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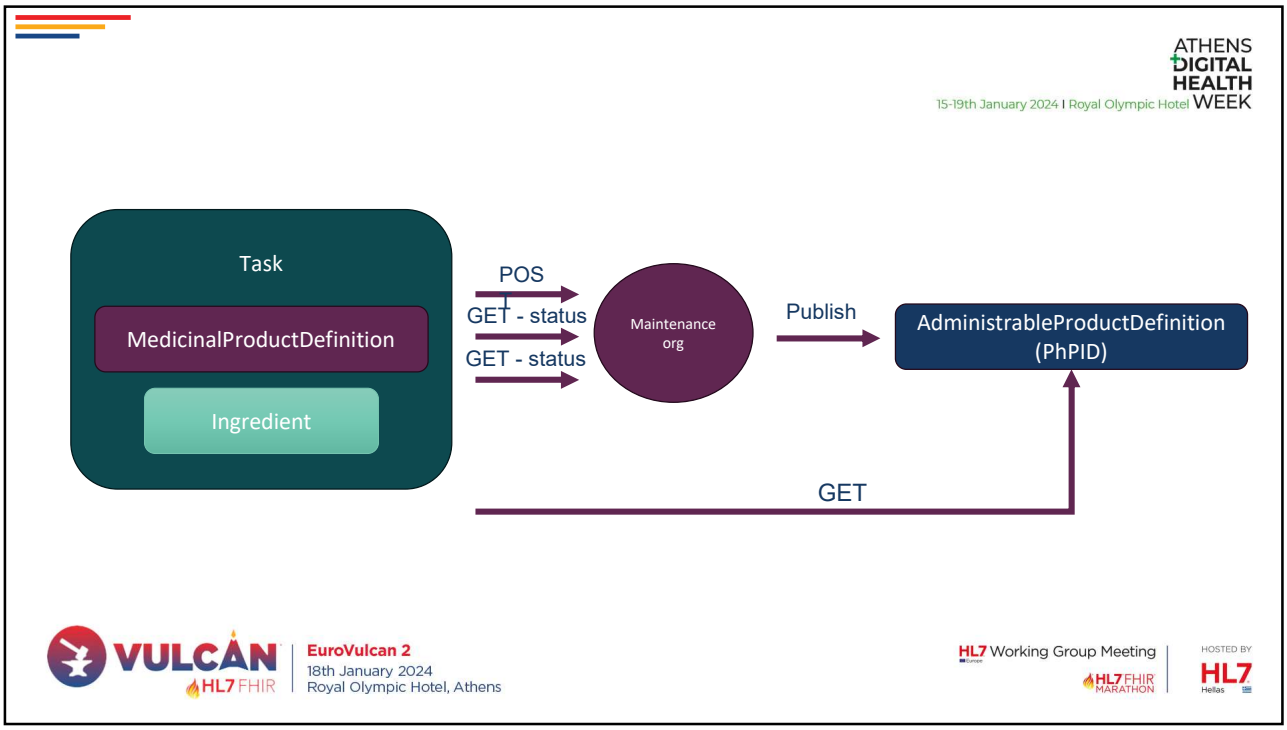
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Task
MedicinalProductDefinition
Ingredient
POS
GET - status
GET - status
Maintenance org
Publish
AdministrableProductDefinition (PhPID)
GET
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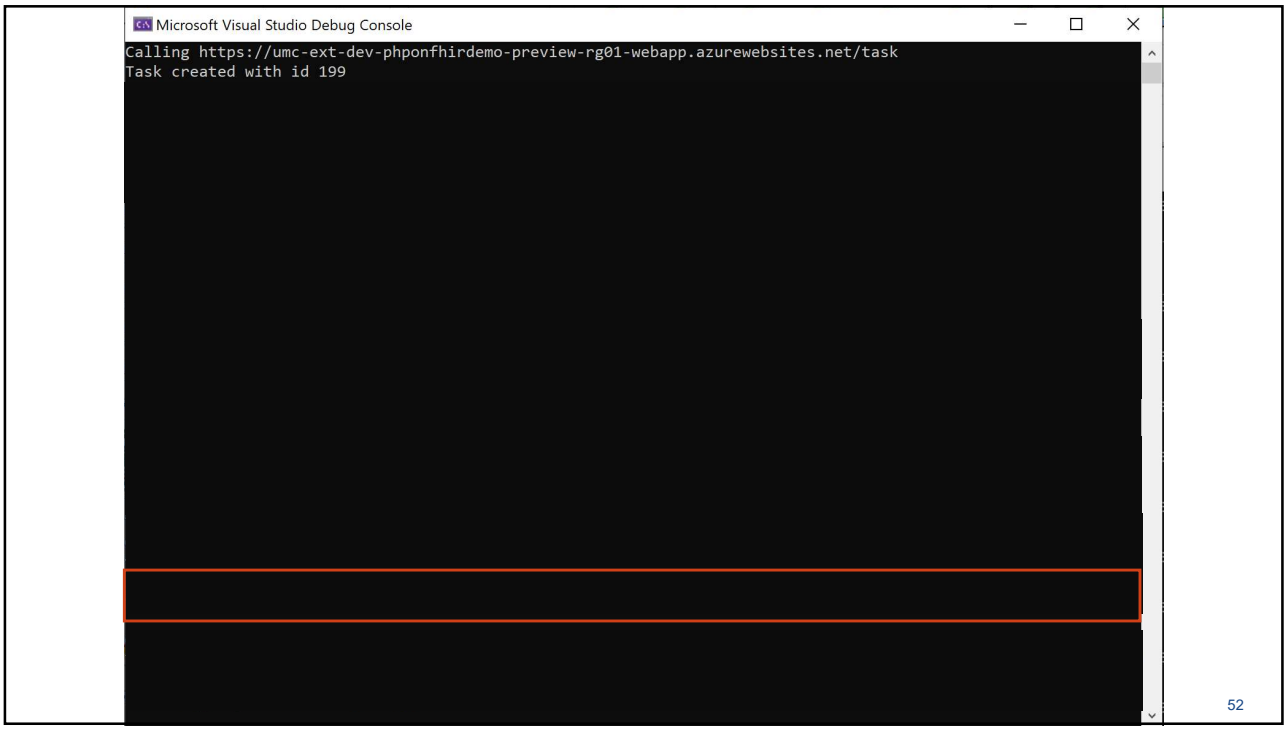
Microsoft Visual Studio Debug Console
Calling https://umc-ext-dev-phponfhirdemo-preview-rg01-webapp.azurewebsites.net/task
Task created with id 199
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Implementation guide

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PhP on Fhir demo API
0.1.0 - CI Build

HL7 FHIR

IG Home | Background | Table of Contents | Specifications | Artifact Index | Support

Table of Contents > Home Page

PhP on Fhir demo API, published by WHO UMC. This guide is not an authorized publication; it is the continuous build for version 0.1.0 built by the FHIR (HL7® FHIR® Standard) CI Build. This version is based on the current content of https://github.com/gcangioli/who-umc-poc/ and changes regularly. See the Directory of published versions

1 Home Page

Official URL: http://who-umc.org/fhir/php/ImplementationGuide/who-umc.fhir.poc-php	*Version*: 0.1.0
Active as of 2024-01-10	*Computable Name*: WhoUmcPhPProofOfConcept

Note
The specification herewith documented is for the time being a proof of concept specification, and may not be used for any implementation purposes. No liability can be inferred from the use or misuse of this specification, or its consequences.

- Scope
- Introduction
- Dependencies
- Cross Version Analysis
- Global Profiles
- IP statements
- Authors and Contributors

1.1 Scope
Document the WHO-UMC IDMP FHIR server.

1.2 Introduction
This implementation guide describes how the global PhPIDs and GSIDs are delivered through FHIR and how new global PhPIDs and GSIDs can be requested using asynchronous FHIR requests.

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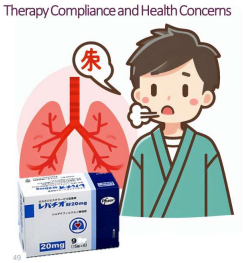
Cross-border healthcare Use Case

Therapy Compliance and Health Concerns

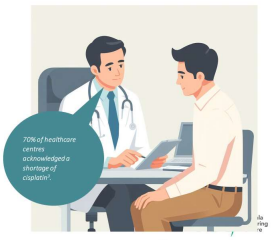


Travel from Japan to USA

Drug Shortage Use case for Cisplatin

Healthcare demand outstrips MAH's cisplatin supply

Cancer patient unable to start therapy



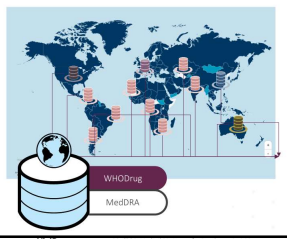
PV Use case for routine signal detection of rare adverse events

Recoding to global standards is time consuming

Different terminology used for regional analysis

PV Use Case: WHO Global Surveillance and Monitoring System for substandard & falsified (SF) medical products

VigiBase basics



VigiBase data mining

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Q2.5 UNICOM achievements and next steps from an NCA perspective

Farah Diehl-Fahim, empirica, Christer Backman & Pelle Persson, Swedish Medical Products Agency

January 18, 2024

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UNICOM: Up-scaling the global univocal identification of medicines / implementing ISO IDMP
Main Achievements of UNICOM

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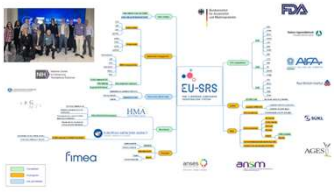
Impact on Processes

- Gap Analysis of Existing and Need for New Standards and Profiles
- EU-SRS Implementation and going live
- DADI – Electronic application forms
- IDMP implementation on National level
- Contributions in eHDSI Waves 6 and 7 (2022-2024)
- IDMP Coding Principles and Guidance for ICSRs
- Implementation guidelines for use of IDMP within MPD



Resources and Assets

- IDMP in a capsule
- Minimum Attribute List and Pilot Product List (PPL)
- UNICOM FHIR IDMP server, UNICOM FHIR IG, and IDMP product browser for test and reuse
- Smart Substitution Component and Patient Facing App

Knowledge exchange

- Community of Expertise
- Trans-Atlantic exchange and workshops
- NCA Best Practice exchanges
- Contribution to Research papers

Country participating in UNICOM / eHDSI	NCA	eHealth Agency	eHDSI operation (Wave(s))			
			ePI eD A	ePI eD B	PS A	PS B
Austria	AGES	ELGA	7	7	-	-
Belgium	AFMPS	-	-	-	7	7
Croatia	HALMED	HZZO	2	1	3	2
Estonia	EESAM	TEHIK	1	1	5	5
Finland	FIMEA	KELA	1	1	6	7
Germany	BFARM	-	-	-	-	-
Greece	-	IDIKA	6	6	6	6
Ireland	HPRA	IEDoH	5	6	5	6
Region of Lombardia, Italy	-	ARIA / REGLOMB	6	6	6	6
Netherlands	-	NICTIZ	-	-	-	5
Norway	NOMA	-	7/8	7/8	7/8	7/8
Portugal	INFARMED	SPMS	2	2	2	2
Spain	AEMPS	SAS	6	6	5	5
Sweden	SE-MPA	SEHA	6	6	-	-

In Operation
Next waves (5-6-7-8)

UNICOM – who are we?

H2020 Funded Project

11.2020 – 05.2024 (54 months)

21M € Total Budget

90 Deliverables (135 incl. versions)

41 partners, 19 countries

- 9 Standard Development Organisations
- 11 National Competent Authorities for Medicinal Products
- 10 National eHealth Competence Centers / National eHealth Contact Points
- 4 Industry partners (Health IT)
- 2 Research Organisations
- 2 Medicinal Database Providers
- 3 Non-profit organisations

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WP2 and WP3 achievements

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WP2 – Implement EU-SRS

- Develop and deliver a scientific substance database EU- SRS
- Fill it with cleansed substance data
- System is live since Jan 24th, 2023 at EMA
- A great international achievement based on collaboration of UNICOM, HMA, EMA , FDA

WP3 - Introducing IDMP compliant application forms

- IDMP from the source!
- Adaptation of the application forms and required tools towards the ISO-IDMP / FHIR standards and to increase the usage of EMA's SPOR.
- Web-based application forms compatible with IDMP standards and relevant European Guidance (EMA IDMP EU IG)
- First Variation Application Form released in production April 11th, 2022 for centralised procedures

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WP4: IDMP implementation at National Drug Agencies

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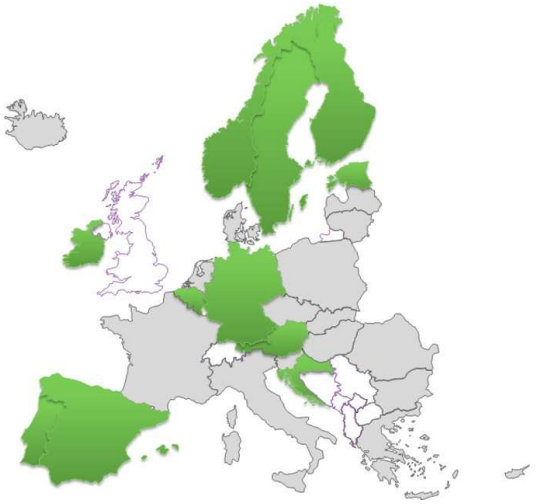
11 national implementation projects

Refactoring or building new databases/systems:

- Analysis and modelling
- Data mapping and transformation
- EMA SPOR* connection
- Prototype data feeds



*EMA SPOR - data management services

Delivering quality data management services for substances, products, organisations and referentials (SPOR) to power EU regulatory activities

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Achievements national implementation IDMP

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WP4 progress report period: Q3 2023	Spain AEMPS	Belgium AFMPS	Austria AGES	Germany BfArM	Estonia EESAM	Finland FIMEA	Croatia HALMED	Ireland HPRA	Portugal INFARMED	Norway NoMA	Sweden SE MPA
1. Analysis and modelling											
GAP-analysis between current data model and IDMP											
Datamodelling based on GAP-analysis											
2. Mapping and transformation											
Data-mapping to RMS dictionary											
Data-mapping to OMS dictionary											
Data-mapping to SMS dictionary											
Data-transformation											
3. SPOR-connection											
Referentials RMS-connection											
Organisations OMS-connection											
Products PMS-connection											
Substances SMS-connection											
4. Prototype data feeds											
Prototyping and piloting of data feeds											

Not started, as planned
In progress
Done
Risk to be mitigated
Progress in danger
Not applicable

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It's all about knowledge sharing!

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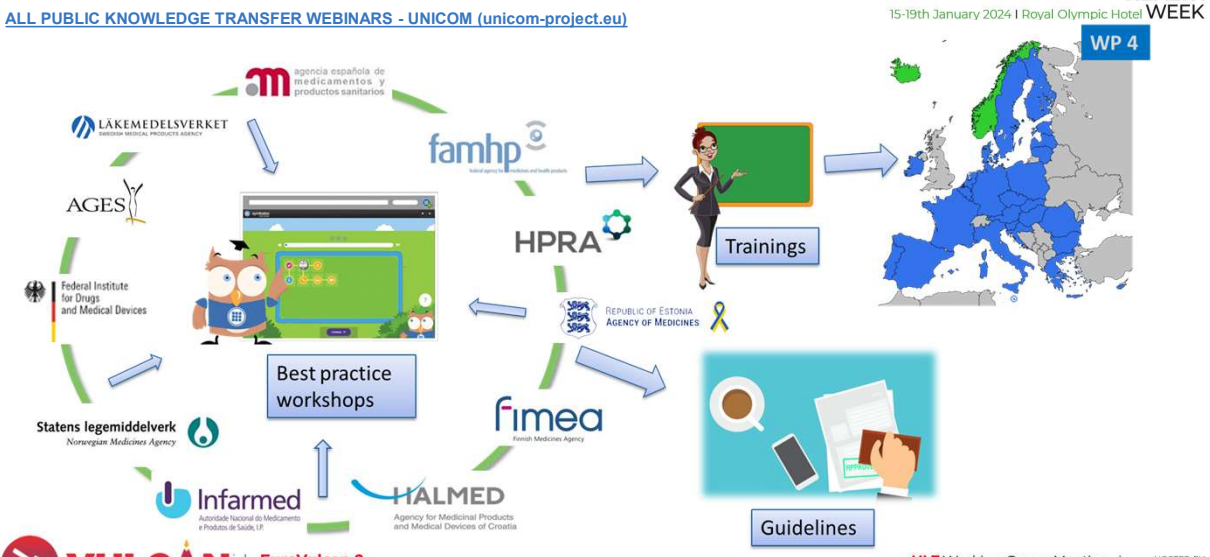
ALL PUBLIC KNOWLEDGE TRANSFER WEBINARS - UNICOM (unicom-project.eu)



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Moving forward

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- Legislation in place
- Progress in NCAs
- 11 MSs out of 30 (EEA) in UNICOM
- Project ends 31 May 2024

- Next steps from a NCA perspective

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Moving forward

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UNICOM presented at the HMA meeting during the Swedish EU Presidency 2023

Non UNICOM NCAs were invited to the Ghent consortium meeting Nov 2023
- Total of 19 National Competent Authorities attended + EMA

Final consortium meeting in Brussels 25-26 April 2024
- All NCAs invited!

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Moving forward

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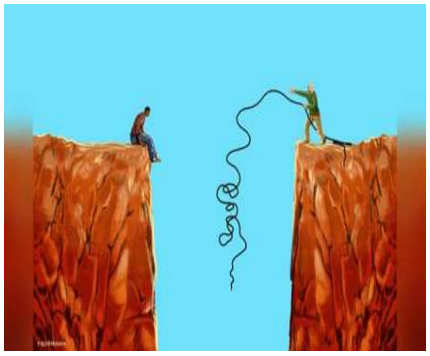
Build on experience in implementation

Strenghten connection between NCAs for medicines and e-Health

New project needed to onboard other NCAs

Close the gap until next initiative



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Q2.6 Health Data and the Link to ePI

Giorgos Georgiannakis, DG SANTE – European Commission

January 18, 2024

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Overview

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- **ePI**
- **Health data and the Health Data Space**
  - Overview
  - myHealth of EU
  - healthData@EU
- **Interoperability**

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Introduction to ePI

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ePI : electronic Product Information

- authorised,
- statutory
- product information for human medicines (including summary of product characteristics, package leaflet and labelling
- in electronic format using:
  - in a semi-structured format created using the EU ePI Common Standard.
  - adapted for electronic handling and allows dissemination via the web, e-platforms and print

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Features

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ePI complements the paper package leaflet and offers advantages:

- greater accessibility to healthcare professionals and patients;
- fits into the EU's multilingual environment;
- support wider availability of medicines across Member States;
- can have positive effects on shortages, updating product information, translations;
- creates efficiency gains for regulatory systems

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State of play

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Most recent deliverable:

The creation and testing of ePIs in real regulatory procedures is being explored through a one-year pilot initiative by HMA, EMA and the EC to enable the transition to the electronic system for medicines evaluated both nationally and at European level.

The pilot started in July 2023.

Participating countries: Denmark, the Netherlands, Spain and Sweden.

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Health data challenges

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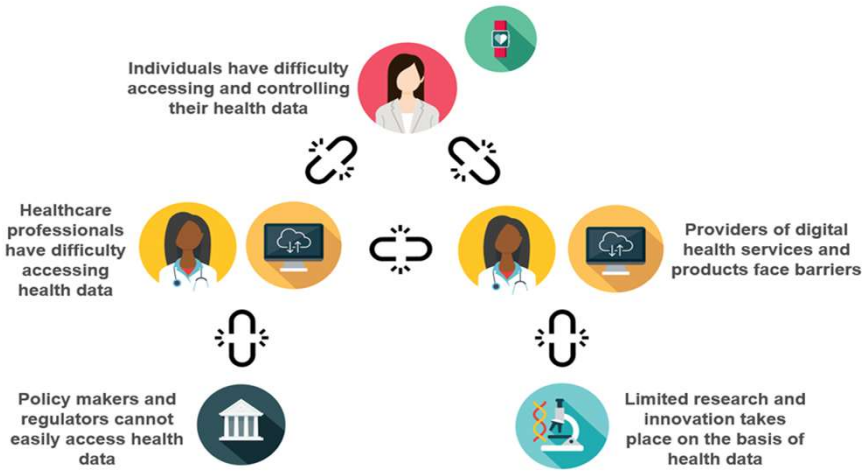

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User perspectives

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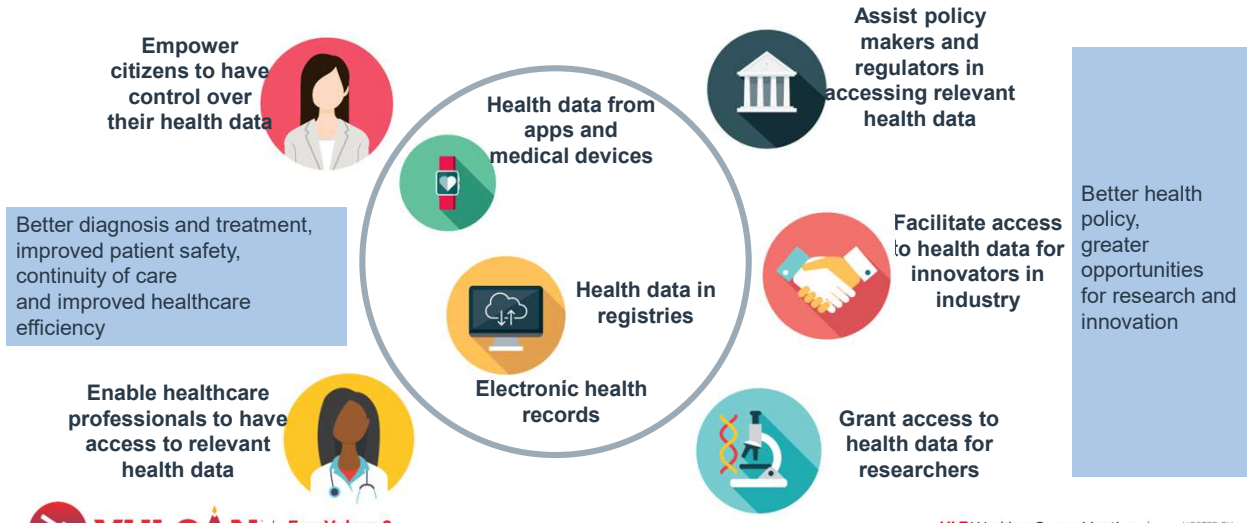

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European Health Data Space (EHDS)

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Objectives

Effective use of health data

Commission IT SYSTEMS composing EHDS

Primary use of data	MyHealth@EU
	EU database for Electronic Health Record (EHR) systems and wellness applications
Secondary use of health data	HealthData@EU Central platform and infrastructure

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eHealth Digital Services infrastructure (myHealth@EU)

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What is the eHealth DSI?

Services and Infrastructure using ICTs that enable cross border Healthcare services.

Use Cases:

Patient Summary, provides access to health professional to verified key health data of a patient during an unplanned care encounter while abroad

ePrescription, enables patients to receive equivalent medication treatment while abroad to what they would receive in their home country

FHIR Laboratory results report: enables electronic exchange of laboratory exams

Hospital discharge report: enables electronic exchange of laboratory exams

Use of FHIR model where relevant and possible: interoperability

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HealthData@EU
Central platform and infrastructure

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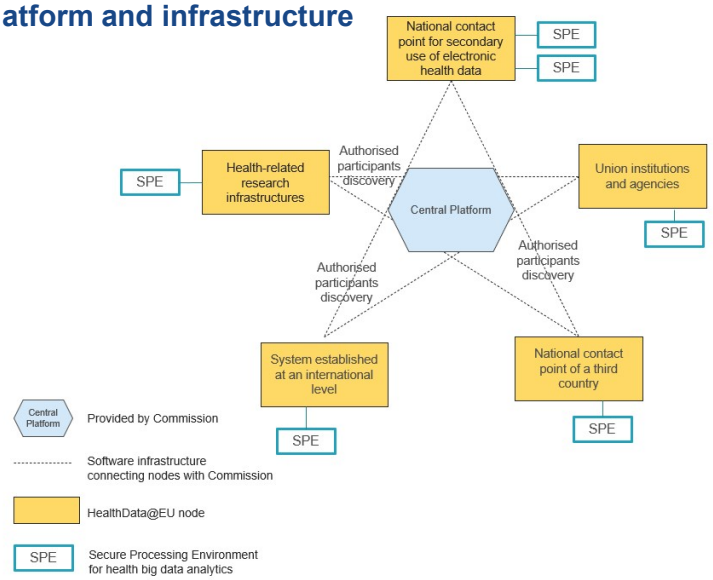

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Interoperability

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SANTE supports and funds ePI work as an enabler for transparency, availability and electronic exchange on key information for human medicinal products

Key SANTE systems that benefit from ePI

Directly: MyHealth@EU / HealthData@EU

Indirectly : eHR (future) / EUDAMED (?)

Overall:

- Standards are key for interoperability, data sharing and future systems. They provide efficiencies and cost savings and increase quality, availability of information and time to address needs
- Alignment with common vocabularies / reference data is beneficial for policy making, academia and research and industry and practitioners
- SANTE embarks for interoperability and standards in SANTE systems and eHEALTH domain

Useful links

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ePI

https://ec.europa.eu/newsroom/sante/newsletter-archives/48809

https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/product-information-requirements/electronic-product-information-epi#pilot-project-to-test-epi-section

EHDS

Regulation on EHDS EUR-Lex - 52022PC0197 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52022PC0197

Commission website on the European Health Data Space https://ec.europa.eu/health/ehealth-digital-health-and-care/european-health-data-space_en

Have Your Say entry on the European Health Data Space https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12663-Digital-health-data-and-services-the-European-health-data-space_en

European Health Data Space 2 Pilot Home - EHDS2 Pilot - Official website

https://ehds2pilot.eu/

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Thank You …

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Q2.7 SPOR the way forward

Isabel Chicharo, SPOR lead, European Medicines Agency

January 18, 2024

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SCIENCE MEDICINES HEALTH

SPOR the way forward

EuroVulcan 2 European Meeting of the Vulcan Accelerator

EuroVulcan 2

Presented by Isabel Chicharo on 18 January 2024
Head of Regulatory Data Management Service, EMA

An agency of the European Union

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ISO IDMP, FHIR and SPOR

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ISO IDMP standards

EMA is implementing the standards developed by the International Organization for Standardization (**ISO**) for the **identification of medicinal products** (**IDMP**).

HL7 FHIR

The Fast Healthcare Interoperability Resources (**FHIR)** was endorsed as the basis for the **application programming interface (API)** for PMS.

FHIR will be the **data standard** that supports the **exchange of information** about medicinal products in the European Medicines Regulatory Network (EMRN).

SPOR

ORGANISATION REFERENTIALS

SPOR API V1 Specification

SUBSTANCE PRODUCT

EMA is implementing the ISO IDMP standards based on four domains of **master data** : substance, product, organisation and referential (SPOR) master data.

SPOR API V2 Specification
EU IDMP Implementation Guide

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Interoperability and Product Lifecycle Management

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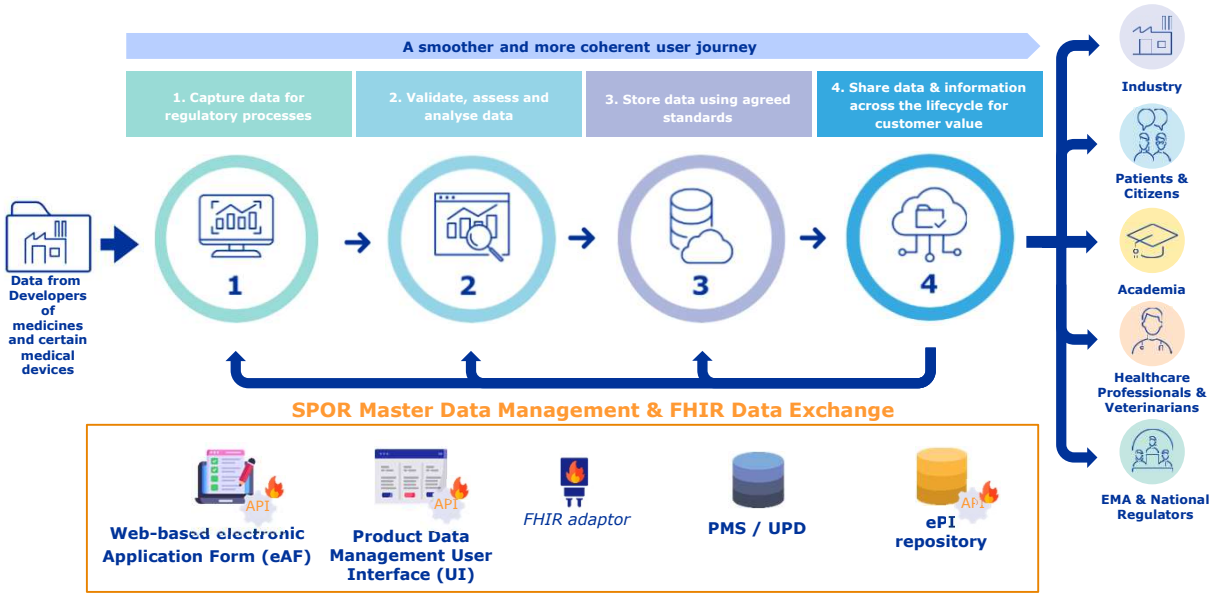

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FHIR in European Medicines Regulatory Network (EMRN)

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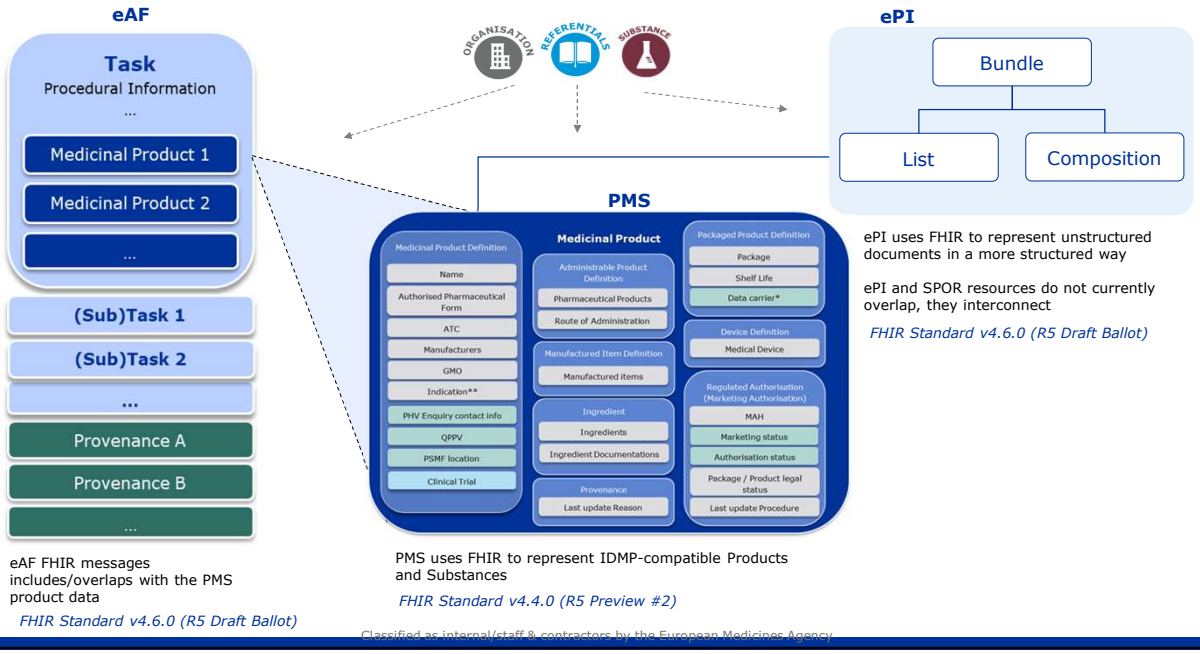

eAF FHIR messages includes/overlaps with the PMS product data

FHIR Standard v4.6.0 (R5 Draft Ballot)

PMS uses FHIR to represent IDMP-compatible Products and Substances

FHIR Standard v4.4.0 (R5 Preview #2)

ePI uses FHIR to represent unstructured documents in a more structured way

ePI and SPOR resources do not currently overlap, they interconnect

FHIR Standard v4.6.0 (R5 Draft Ballot)

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Way forward – OMS, RMS and SMS

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	Work completed	Ongoing work	Future work *(What's next?)*	Future work *(What's later?)*
OMS	Performance & stability improvements	SPOR v1.1: extending OMS v1	**Support Org/Loc needs in FHIR**	
RMS			SPOR v1.2: extending RMS v1	**Support RMS term needs in FHIR**
SMS	**SMS API (Read, EMA use only)**	**Roll out SMS API (Read, NCAs & Ind/Public use)**	**Expand Subst resources in FHIR (Min. data fields)** EU-SRS & SMS integration	**SMS API (FHIR R5 Major)**

IMPORTANT: this slide **DOES NOT represent timelines or sequencing of release** but pieces of work or events to be delivered

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Way forward – PMS and other use cases

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	Work completed	Ongoing work	Future work *(What's next?)*	Future work *(What's later?)*
PMS	CAPs migration to PMS **PMS API (Read, EMA use only)**	PMS & XEVMPD Synch **Roll out PMS API (Read, Ind/NCA use)** Product UI (view) **FHIR adaptor** Product UI- PMS API Connection Product UI (write/ edit)	**PMS API (Write, Ind/NCA use)** **PMS API (Read, Public use)** Product data verification process	**PMS API (FHIR R5 Major)** PMS direct submission PMS data validation strategy Decommissioning of XEVMPD submissions
eAF	H. Var. eAF (CAPs)	H. Var. eAF (CAPs + NAPs)	MAA eAFs **eAF API**	Renewals eAF V. Var. eAF
ePI	**ePI MVP** (Authoring Tool + publishing/consuming)	Pilot for CAPs, NAPs, MRP and DCP	ePI pre-implementation	**ePI implementation**

IMPORTANT: this slide **DOES NOT represent timelines or sequencing of release** but pieces of work or events to be delivered

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Use Cases and opportunities

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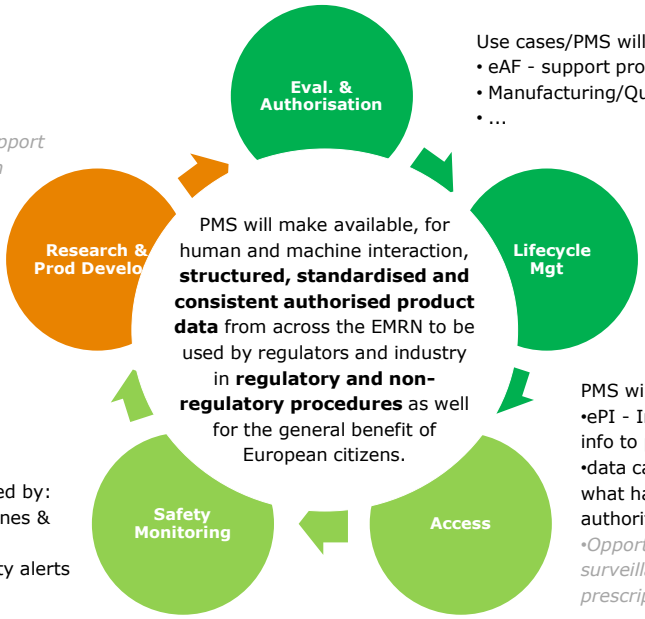
PMS may in the future support full Product lifecycle, from Research & Product Development to PharmacoVigilance



Use cases/PMS will be used by:
- eAF - support processing of regulatory applications.:
- Manufacturing/Quality/PQKMS
- ...

Use cases/PMS will be used by:
- Monitoring critical medicines & shortages (ESMP)
- Pharmacovigilance; Safety alerts

PMS will contain/link relevant info:
- ePI - Information sharing, search/targeting of info to patients
- data carrier - connects what is on the box vs what has been approved by Regulatory authorities,
- *Opportunities: EMVS & falsified medicines surveillance; Cross border comparison & prescription*

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Thank you for your attention

Further information

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Q2.8 Scaling IDMP for Global use cases

Panagiotis Telonis, European Medicines Agency

January 18, 2024

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SCIENCE MEDICINES HEALTH

Scaling IDMP for Global use cases

EuroVulcan 2

EuroVulcan 2
18th January 2024
Royal Olympic Hotel, Athens

Panagiotis Telonis
Scientific Administrator, Chief Information Office

An agency of the European Union

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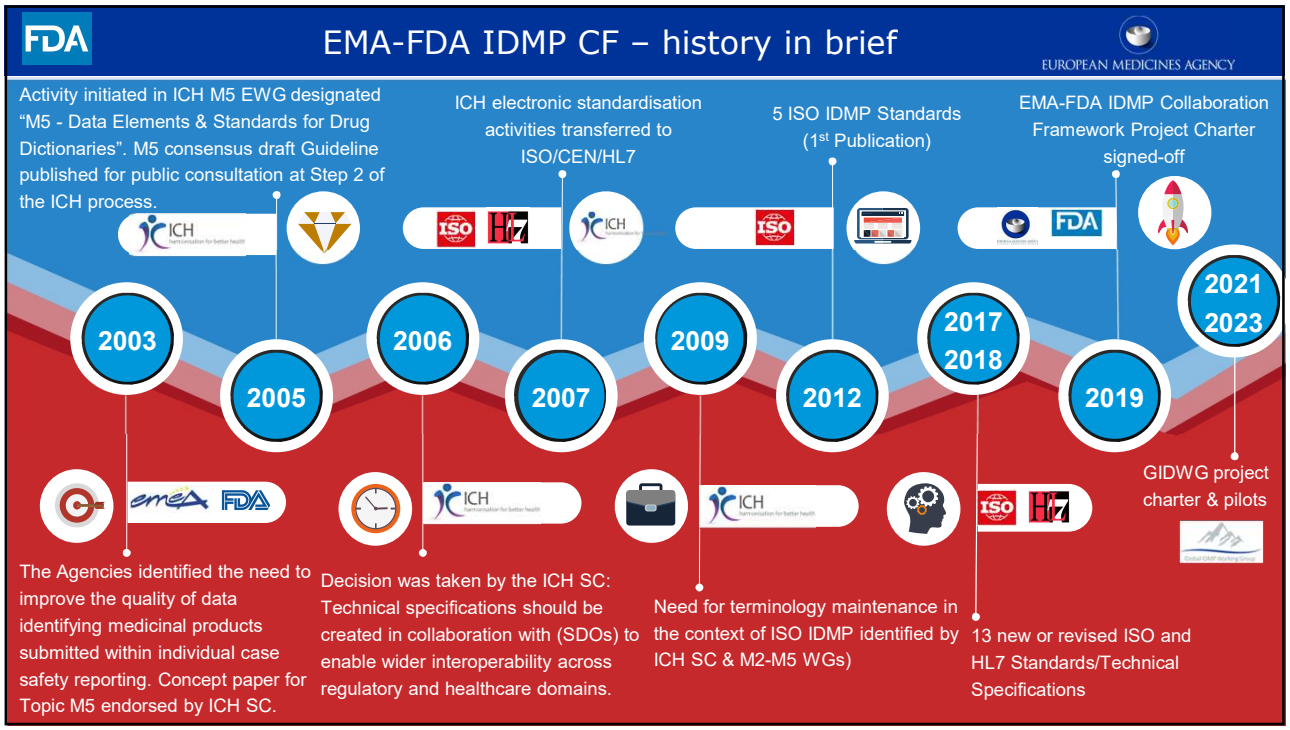
EMA-FDA IDMP CF – history in brief
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Activity initiated in ICH M5 EWG designated "M5 - Data Elements & Standards for Drug Dictionaries". M5 consensus draft Guideline published for public consultation at Step 2 of the ICH process.
ICH electronic standardisation activities transferred to ISO/CEN/HL7
5 ISO IDMP Standards (1st Publication)
EMA-FDA IDMP Collaboration Framework Project Charter signed-off
2003
2005
2006
2007
2009
2012
2017
2018
2019
2021
2023
GIDWG project charter & pilots
The Agencies identified the need to improve the quality of data identifying medicinal products submitted within individual case safety reporting. Concept paper for Topic M5 endorsed by ICH SC.
Decision was taken by the ICH SC: Technical specifications should be created in collaboration with (SDOs) to enable wider interoperability across regulatory and healthcare domains.
Need for terminology maintenance in the context of ISO IDMP identified by ICH SC & M2-M5 WGs)
13 new or revised ISO and HL7 Standards/Technical Specifications

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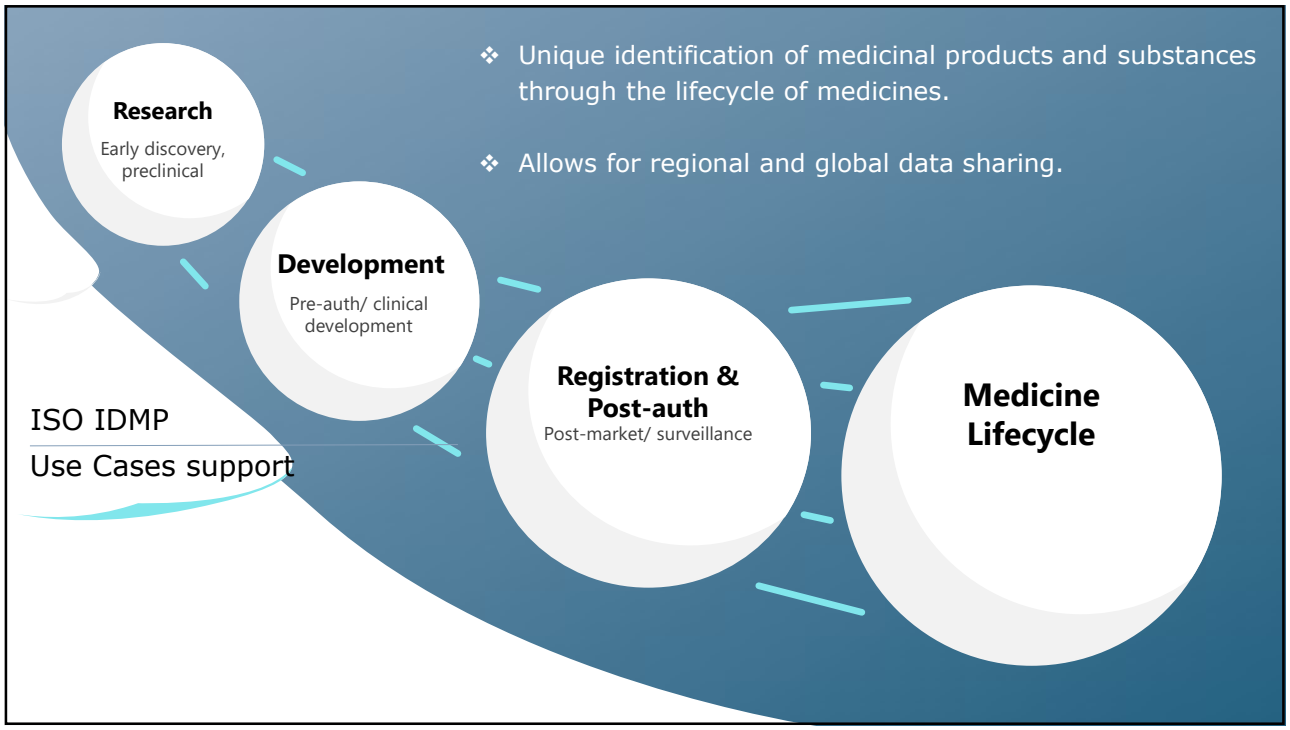
Unique identification of medicinal products and substances through the lifecycle of medicines.
Allows for regional and global data sharing.
Research
Early discovery, preclinical
Development
Pre-auth/ clinical development
Registration & Post-auth
Post-market/ surveillance
Medicine Lifecycle
ISO IDMP
Use Cases support

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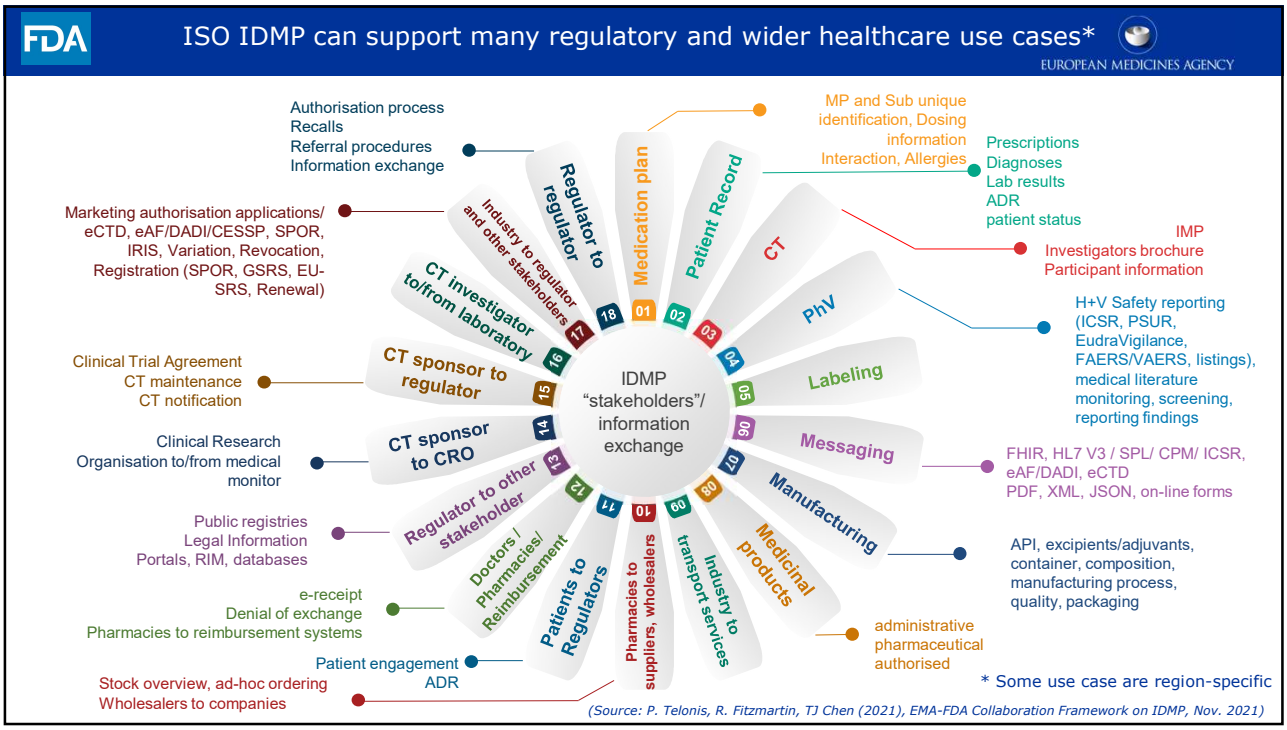
FDA
ISO IDMP can support many regulatory and wider healthcare use cases*
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Authorisation process
Recalls
Referral procedures
Information exchange
Marketing authorisation applications/ eCTD, eAF/DADI/CESSP, SPOR, IRIS, Variation, Revocation, Registration (SPOR, GSRS, EU-SRS, Renewal)
Clinical Trial Agreement
CT maintenance
CT notification
Clinical Research Organisation to/from medical monitor
Public registries
Legal Information
Portals, RIM, databases
e-receipt
Denial of exchange
Pharmacies to reimbursement systems
Patient engagement
ADR
Stock overview, ad-hoc ordering
Wholesalers to companies
MP and Sub unique identification, Dosing information
Interaction, Allergies
Prescriptions
Diagnoses
Lab results
ADR
patient status
IMP
Investigators brochure
Participant information
H+V Safety reporting (ICSR, PSUR, EudraVigilance, FAERS/VAERS, listings), medical literature monitoring, screening, reporting findings
FHIR, HL7 V3 / SPL/ CPM/ ICSR, eAF/DADI, eCTD
PDF, XML, JSON, on-line forms
API, excipients/adjuvants, container, composition, manufacturing process, quality, packaging
administrative
pharmaceutical
authorised
IDMP "stakeholders"/ information exchange
Medication plan
Patient Record
CT
PhV
Labeling
Messaging
Manufacturing
Medicinal products
Industry to transport services
Pharmacies to suppliers, wholesalers
Patients to Regulators
Doctors / Pharmacies/ Reimbursement
Regulator to other stakeholder
CT sponsor to CRO
CT sponsor to regulator
CT investigator to/from laboratory
Industry to regulator and other stakeholders
Regulator to regulator
* Some use case are region-specific
(Source: P. Telonis, R. Fitzmartin, TJ Chen (2021), EMA-FDA Collaboration Framework on IDMP, Nov. 2021)

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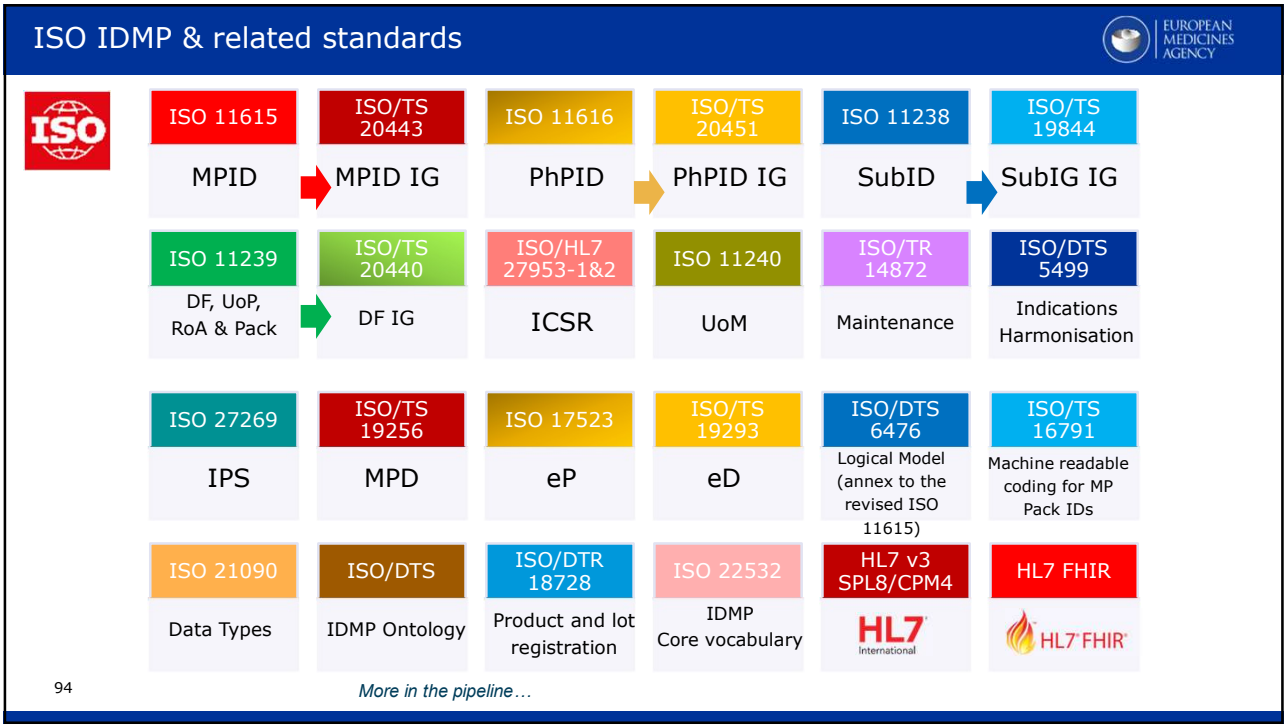
ISO IDMP & related standards
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ISO 11615
MPID
ISO/TS 20443
MPID IG
ISO 11616
PhPID
ISO/TS 20451
PhPID IG
ISO 11238
SubID
ISO/TS 19844
SubIG IG
ISO 11239
DF, UoP, RoA & Pack
ISO/TS 20440
DF IG
ISO/HL7 27953-1&2
ICSR
ISO 11240
UoM
ISO/TR 14872
Maintenance
ISO/DTS 5499
Indications Harmonisation
ISO 27269
IPS
ISO/TS 19256
MPD
ISO 17523
eP
ISO/TS 19293
eD
ISO/DTS 6476
Logical Model (annex to the revised ISO 11615)
ISO/TS 16791
Machine readable coding for MP Pack IDs
ISO 21090
Data Types
ISO/DTS
IDMP Ontology
ISO/DTR 18728
Product and lot registration
ISO 22532
IDMP Core vocabulary
HL7 v3 SPL8/CPM4
HL7 International
HL7 FHIR
HL7 FHIR
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More in the pipeline…

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Global Identification Working Group (GIDWG) in brief

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- **GIDWG was chartered in 2021:**
  - as an outcome of the WHO IDMP Workshop in Geneva, Sep 2019
  - supported by the EMA-FDA IDMP collaboration framework.
- **Why was GIDWG established?**
  - There was no organization focused on demonstrating that the standards can be implemented globally.
- **Membership**
  - Founding members include **EMA**, **FDA**, and WHO/**UMC**; other regulators, e.g., Health Canada and Brazil ANVISA, SwissMedic, as well as, IFPMA has joined as an industry observer.
- **What is GIDWG focus?**
  - Develop and execute projects to demonstrate that the IDMP standards are "fit" for global implementation.
  - Develop a framework, including business rules, best practices and operating model, for the global IDMP implementation and maintenance of global identifiers for marketed products.

Global IDMP implementation is a collaborative project

- **GIDWG End-2-End Use cases (2024)**
  - Pharmacovigilance
  - Shortages
  - Cross-border healthcare
  - HL7 FHIR

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IDMP Groups Internationally

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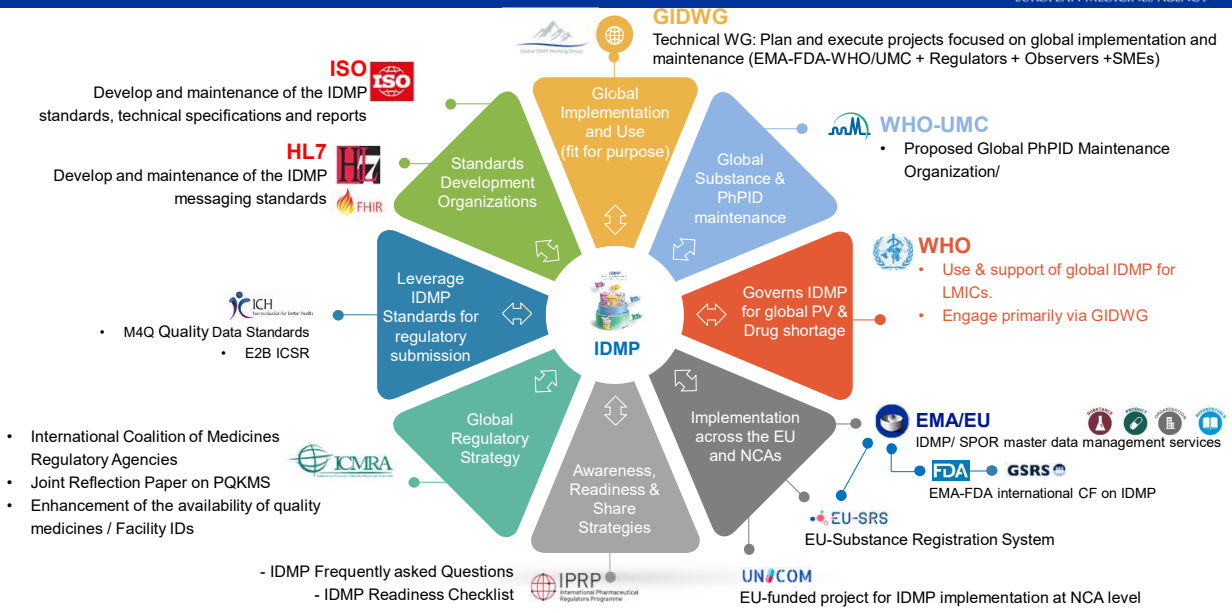

Source: EMA-FDA-WHO/UMC IDMP Collaboration Framework. Adapted from: Ron Fitzmartin (2022), IPRP IDMP report to ICH MC, Incheon, South Korea, Nov. 2022

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GIDWG use cases in FHIR Connectathons

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- Connectathon 34, Track: 2023 - 09 Vulcan/Gravitate Health - ePI/IPS and SPL-FHIR
  - FHIR demonstrated publicly that:
  - MP information can be exchanged to central Maintenance Organisation (MO).
  - PhPID can be generated centrally by Central MO using business rules and patterns defined by 4 GIDWG pilot projects (GSID, DFID, SDID, Operating Model)
  - PHPID can be distributed – as well as MP information
- Connectathon 35, Track: 2024 - 01 Vulcan/Gravitate Health - ePI/IPS and UNICOM/GIDWG

  Still on-going work today, early results will be presented during EuroVulcan 2, Panel 3 discussion

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IDMP/Substances (public info) for supporting Global use cases

Approaching Target Operating Models starting with min. data fields

- Infrastructure, processes, and SLAs (as required) related to EU SMS/EU-SRS, FDA/ GSRS, WHO/UMC-SMS operational environments.
- EMA/EU, FDA and WHO/UMC "share one" global identifier according to ISO 11238 and ISO/TS 19844 definitions and agreed business rules for supporting global use cases).
- Complete the Medication Definition FHIR resources to include the complete ISO 11238/19844 tree and the latest substance developments. National/jurisdictional FHIR profiles/IGs - Connectathons
- Public substance data sharing and Global Substance IDs support.

Secure substance info and public data sharing (national and jurisdictional instances)

HL7 FHIR

EMA/EU, FDA, WHO/UMC, CBG-MEB, BfARM, NCATS, USP, HC, SwissMedic, …

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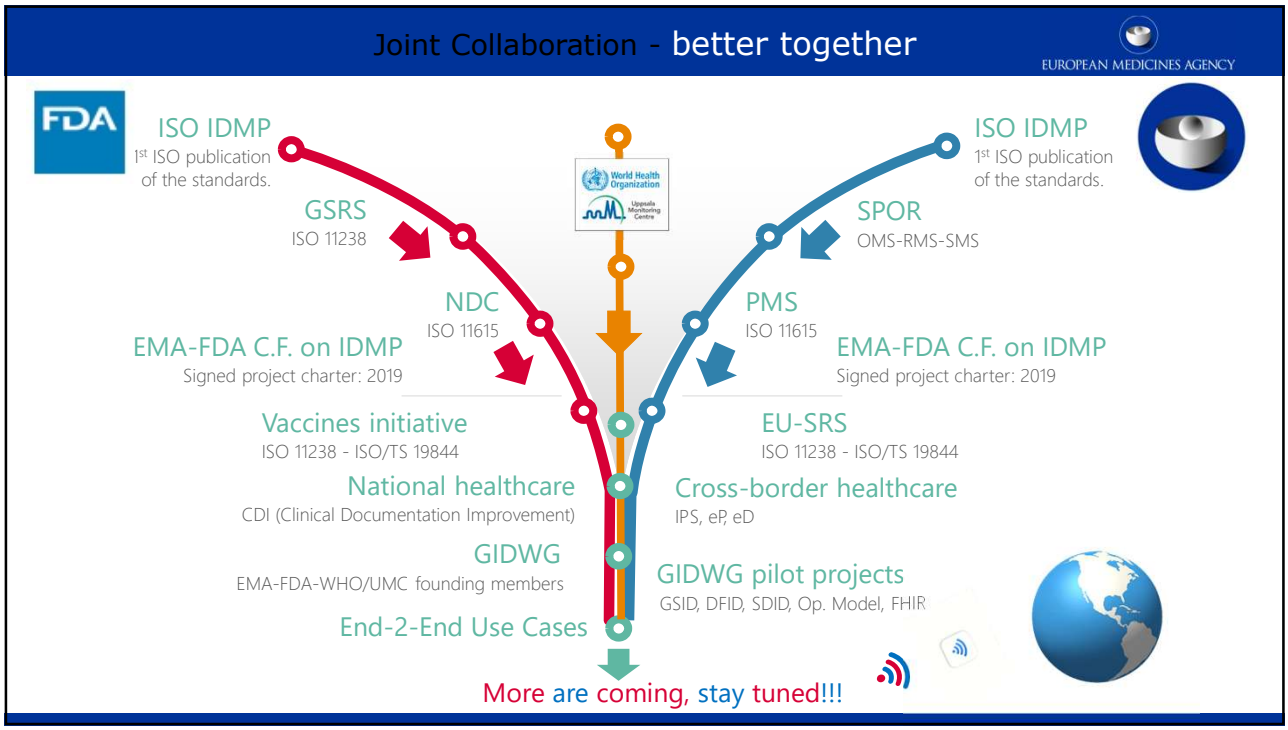

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15-19th January 2024 | Royal Olympic Hotel

Thank You …

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HL7 Working Group Meeting | HL7 FHIR MARATHON | HOSTED BY HL7 Hellas

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Gravitate-Health ePI Technology Community

Gravitate Health

Accelerating the Vision

Develop a path to achieve critical mass (i.e., 80% of ePIs converted to FHIR) within two years.

Diverse attendance

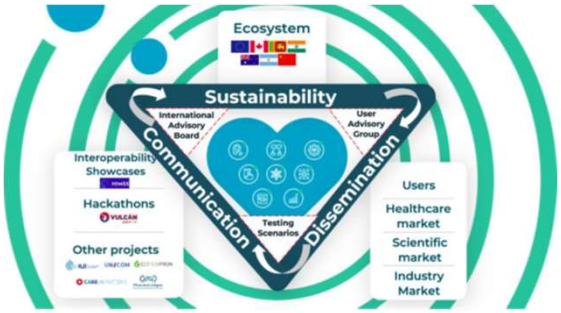
- ❑ Structured Content Authoring (SCA) Providers
- ❑ Regulatory Information Management (RIM) Providers
- ❑ Software developers
- ❑ Medicinal Product Information Compendia
- ❑ Health Authorities

Topics

- ❑ ePI vision / FHIR
- ❑ Perspectives; Health Authority, Industry, Compendia
- ❑ EMA ePI Tool
- ❑ How SCA can support Product Information vision (vendor demos)
- ❑ Focusing

Opportunities and collaboration

- ❑ Disseminating the vision
- ❑ Creating ePI
- ❑ Developing the marketplace



VULCAN HL7 FHIR

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GU0

Gravitate-Health ePI Technology Community - join us !

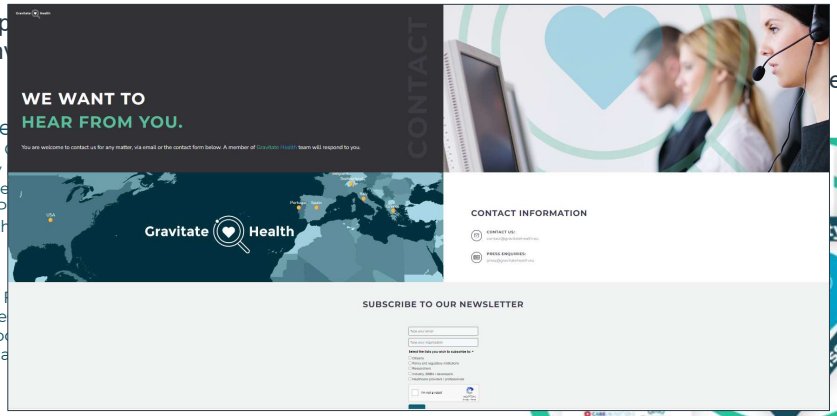
Gravitate Health

JOIN THE COMMUNITY VIA 'CONTACT US': Contact - Gravitate Health

Develop a p
of ePIs conv

Diverse atte
- ❑ Structured
- ❑ Regulatory
- ❑ Software de
- ❑ Medicinal P
- ❑ Health Auth

Topics
- ❑ ePI vision /
- ❑ Perspective
- ❑ EMA ePI To
- ❑ How SCA ca
  demos)
- ❑ Focusing



VULCAN HL7 FHIR

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Slide 102

GU0 @michael - can you change the background for the box from black to something else ? there is text hidden
Guest User, 2024-01-18T05:43:15.057

Q2 Panel: Vulcan ePI/eLabeling Project, IDMP and EMA/SPOR: The Way Forward

ATHENS DIGITAL HEALTH WEEK
15-19th January 2024 I Royal Olympic Hotel

Panelists

1. ePI Pilot Project – Progress & Next Steps: *Elizabeth Scanlan, ePI pilot, European Medicines Agency*
2. Compendia ePI Pilot: *Bente By Jansen, Felleskatalogen AS, Norway*
3. Improving Package Leaflets: Summary of IATF Recommendations : *Kate Porch (online), Global Labeling, Johnson & Johnson*
4. PhPID operating model, GIDWG: *Magnus Wallberg, Uppsala Monitoring Centre*
5. UNICOM achievements and next steps from an NCA perspective: *Farah Diehl-Fahim, empirica, Christer Backman & Pelle Persson, Swedish Medical Products Agency*
6. Health Data and the Link to ePI : *Georgos Georgiannakis (online), DG SANTE - European Commission*
7. SPOR the way forward: *Isabel Chicharo (online), SPOR lead, European Medicines Agency*
8. Scaling IDMP for Global use cases: *Panagiotis Telonis, European Medicines Agency*

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18th January 2024
Royal Olympic Hotel, Athens

HL7 Working Group Meeting | HL7 FHIR MARATHON | HOSTED BY HL7 Hellas

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VULCAN HL7 FHIR

Lunch

12:30 – 13:45

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