

HL7 FHIR Connectathon 36: Vulcan/Gravitate Health - ePI/IPS and UNICOM/GIDWG track kickoff

2024-05-09



HL7 FHIR CONNECTATHON 2024



Improve your app at the Vulcan Accelerator Gravitate Health Track – ePI



UN/COM



36th FHIR Connectathon, Dallas United States 18-19 May 2024



Agenda for 36th HL7 FHIR Connectathon, Launch Event

1. Introduction (Catherine, Joao) – 5 min
2. GIDWG (Panagiotis) 10 min
3. PhPID (Magnus) – 15 min
4. Nordic+1 (Adam and Philippe) 15 min
5. Q&A 15 min

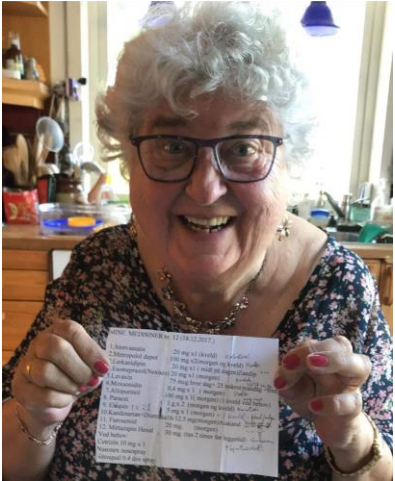
Picture from 35th HL7 FHIR Connectathon, Athens, Greece



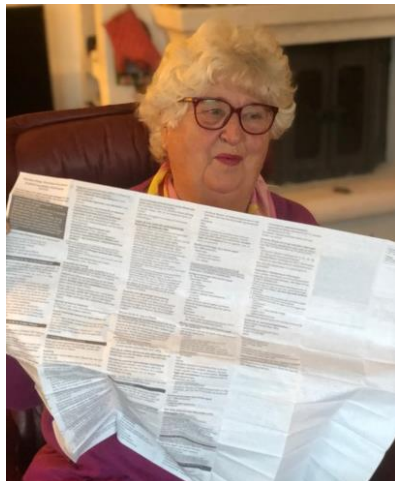
Gravitate-Health in a nutshell

An integrated digital health information project

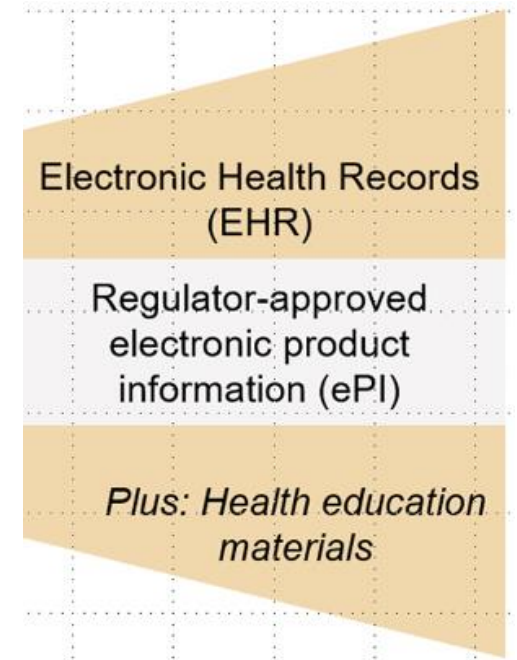
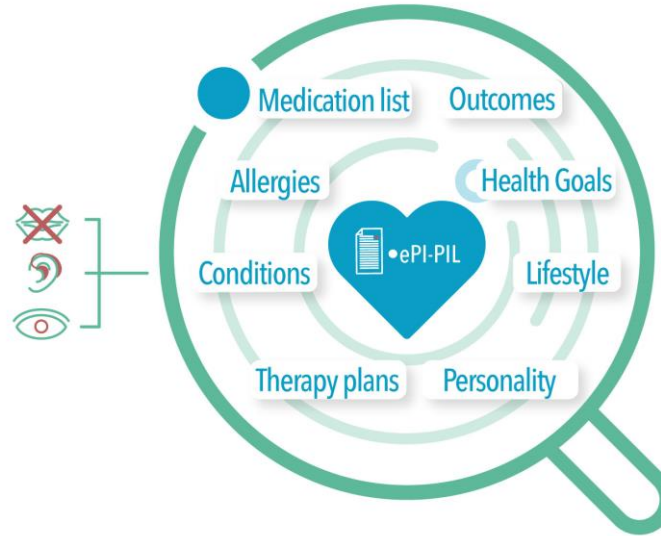
“Maria and her medicines”



Picture: Line H. Linstad, NSE



Picture: Hanne Bjertnes, UiO



Overall Research Question

How can we apply an open access digital platform with trusted Digital health Information to transform the way patients access and understand health information, and apply this in personal health for adherence to treatment, risk minimization and quality of life ?

Key deliverables

- Federated open-source platform with G-lens services
- White Paper on strategies for future use of ePI
- Pilot studies evaluation
- Sustainable impacts



Gravitate-Health Public-Private Partnership



41 partners in Europe & USA



60 months
11/20 – 10/25



19.4 mill €



European start
Global Outreach

ACADEMIA / RESEARCH INSTITUTES

Universitetet i Oslo (UiO) (Coordinator)
 Karolinska Institute (KI)
 Universidad Politécnica de Madrid (UPM)
 Empirica (empirica)
 Norwegian Center for eHealth research (NSE)
 The European Institute for Innovation through Health Data (i-HD)
 Università Cattolica del Sacro Cuore (UCSC)
 University of Copenhagen (UCPH)
 Trinity College Dublin (Trinity)
 University College Dublin (UCD)

REGULATORS & PRODUCT INFORMATION PROVIDERS

Norwegian Medicines Agency (NoMA)
 Spanish Drug Agency (AEMPS)
 Dutch Medicines Evaluation Board (CBG)

STANDARDISATION & OTHER STAKEHOLDERS

HL7 Europe
 PredictBy* (PBY)

PATIENT ORGANISATIONS & CONSUMER GROUPS
 Forum Européen des Patients (EPF)



DISSEMINATION & COMMUNICATION

European Connected Health Alliance (ECHA)
 HIMSS Europe
 MINDVIEW* (MW)
 The Synergist*

HEALTH CARE PROVIDERS & PAYERS

Akershus University Hospital (AHUS)
 Shared Services of Ministry of Health (SPMS)
 Servicio Madrileño de Salud (SERMAS)
 Beth-Israel Deaconess Medical Center (BIDMC)
 Karolinska Institute (KI)
 Oslo University Hospital (OUS)

DIGITAL TECHNICAL EXPERTISE

Datawizard* (DW)
 GuardTime*
 Norsk e-Helse* (NeH)
 Trifork

EFPIA & IMIZ Associated PARTNERS

Pfizer (Project Lead)
 AstraZeneca (AZ)
 Bayer
 Grünenthal (GRT)
 EliLilly
 Medidata
 Viartis
 Novartis
 Roche
 UCB Biopharma (UCB)
 Janssen
 Datapharm

*SME (small and medium sized enterprises)



Gravitate-Health external liaison community (2024)

<p>Academia Research</p>	
<p>Consortia</p>	
<p>Government Regulators</p>	
<p>Implementers</p>	
<p>Pharma (beyond consortium)</p>	
<p>Others</p>	

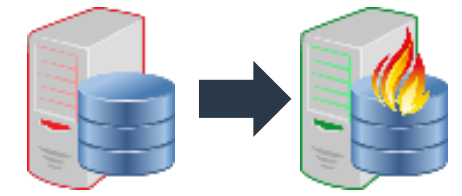


Overview of HL7's Vulcan Accelerator

- FHIR is an enabling technology for harmonising and processing data.
- Vulcan exists to help Clinical and Translational Research start using FHIR to manage the vast amount of data they have to work with.
- Vulcan also exists to bring Clinical and Translational Research and Clinical Care closer together through FHIR.

- Vulcan:
- Creates a community
 - Supports projects that have a clear and practical objective and short timescale
 - Creates Implementation Guides (IGs)
 - Uses connectathons to test the Implementation Guides
 - Provides Events & Education

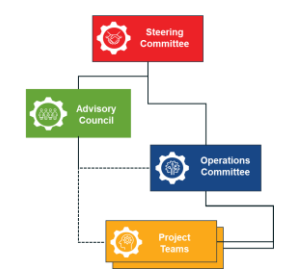
- Over 40 members drawn from Pharma, Academic, Vendors, Regulators, SDOs.
- Operations Committee formed from Members
- Supported by Project Management Office
- International scope



Schedule of Activities, RWD, Electronic Product Information (ePI), Adverse Events, FHIR to OMOP, Phenotypic Data



Current Member Organizations of Vulcan
As of July 2023





Topics for this ePI track

1. ePI Governance: Define joint profiles and governance model between EMA, Gravitare Health and Vulcan
2. ePI style sheet: Create and test a final draft of a default style sheet for ePIs
3. ePI Capability: Define basic API functionality requirements
4. Connectathon Roadmap: Define objectives for the next 4 connectathons (including IDMP testing)
5. PhPID IG: Test and clarify API capability, profiles and resources to support GIDWG (and related) end-to-end request process
6. ANVISA: Incorporate Brazilian scenarios and data into ePI and GIDWG end-to-end IDMP testing

GIDWG (1/6) Global Identification Working Group



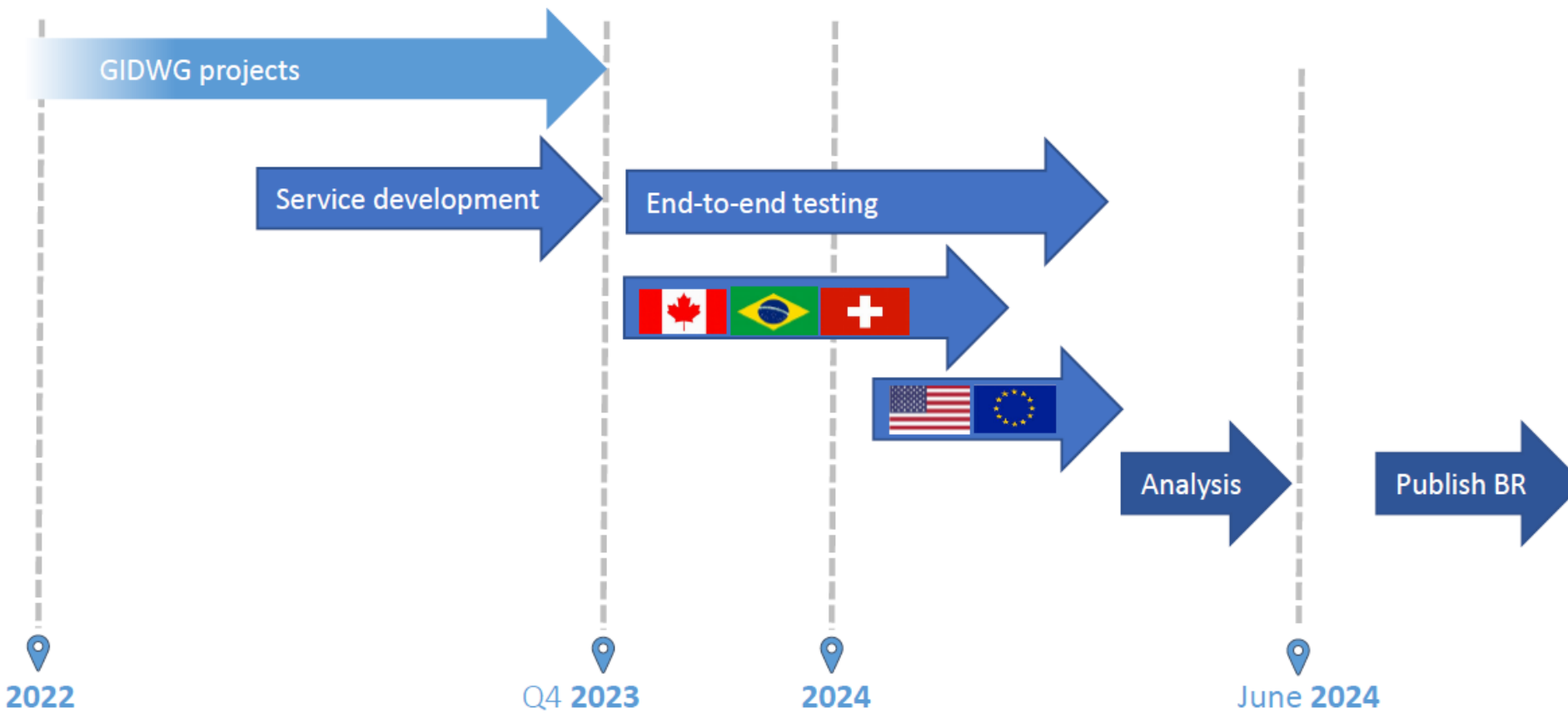
Chartered in 2021 as an outcome of a 2019 WHO IDMP Workshop in Geneva, September 2019.

- Why was GIDWG established?
 - There was no organization focused on demonstrating that the standards can be implemented globally.
- Membership
 - Founding members include EU EMA, U.S. FDA, and WHO-UMC. Additional regulatory members are Health Canada, ANVISA, Swissmedic and Saudi FDA. IFPMA has joined as an industry member
- What is its 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.

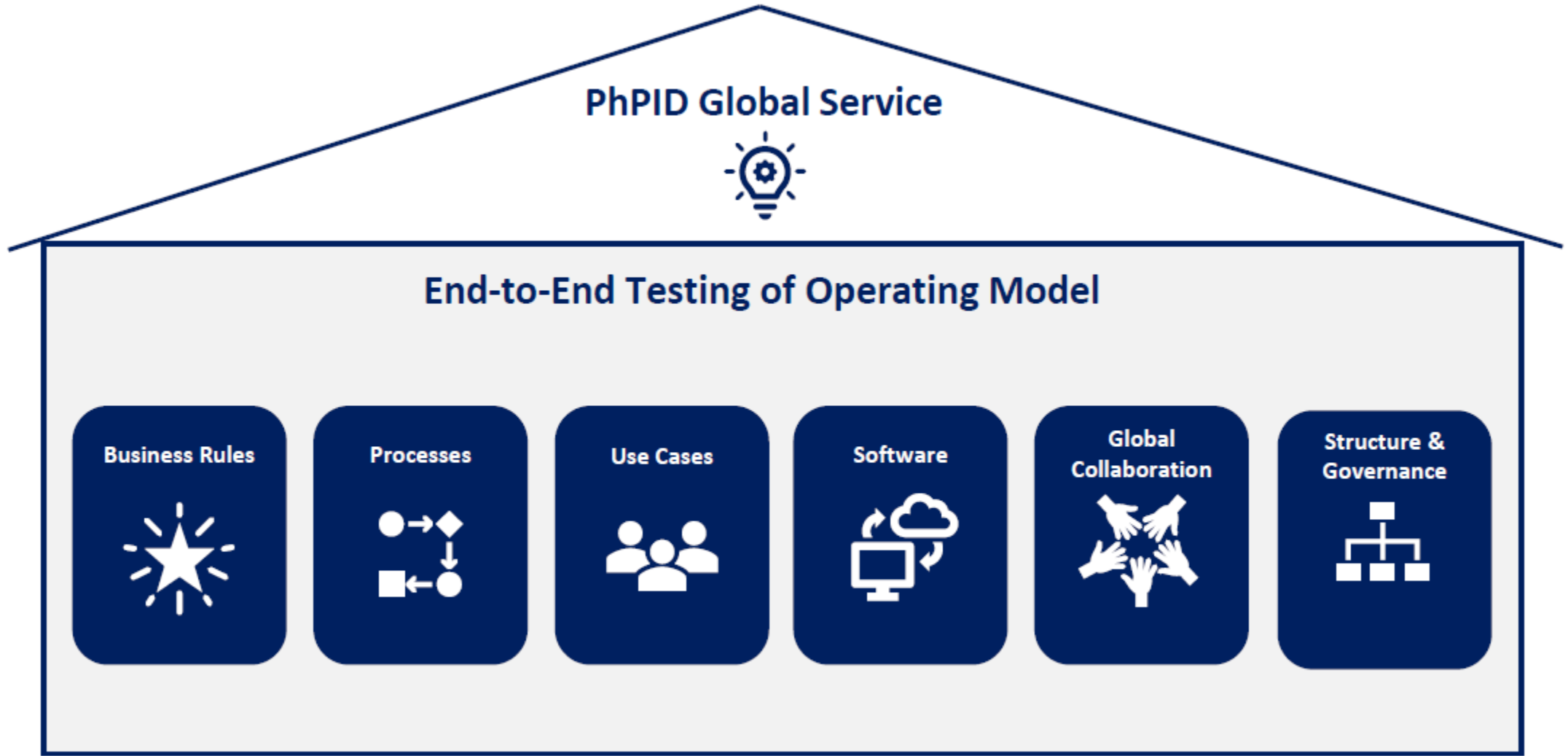
<https://gidwg.org/>



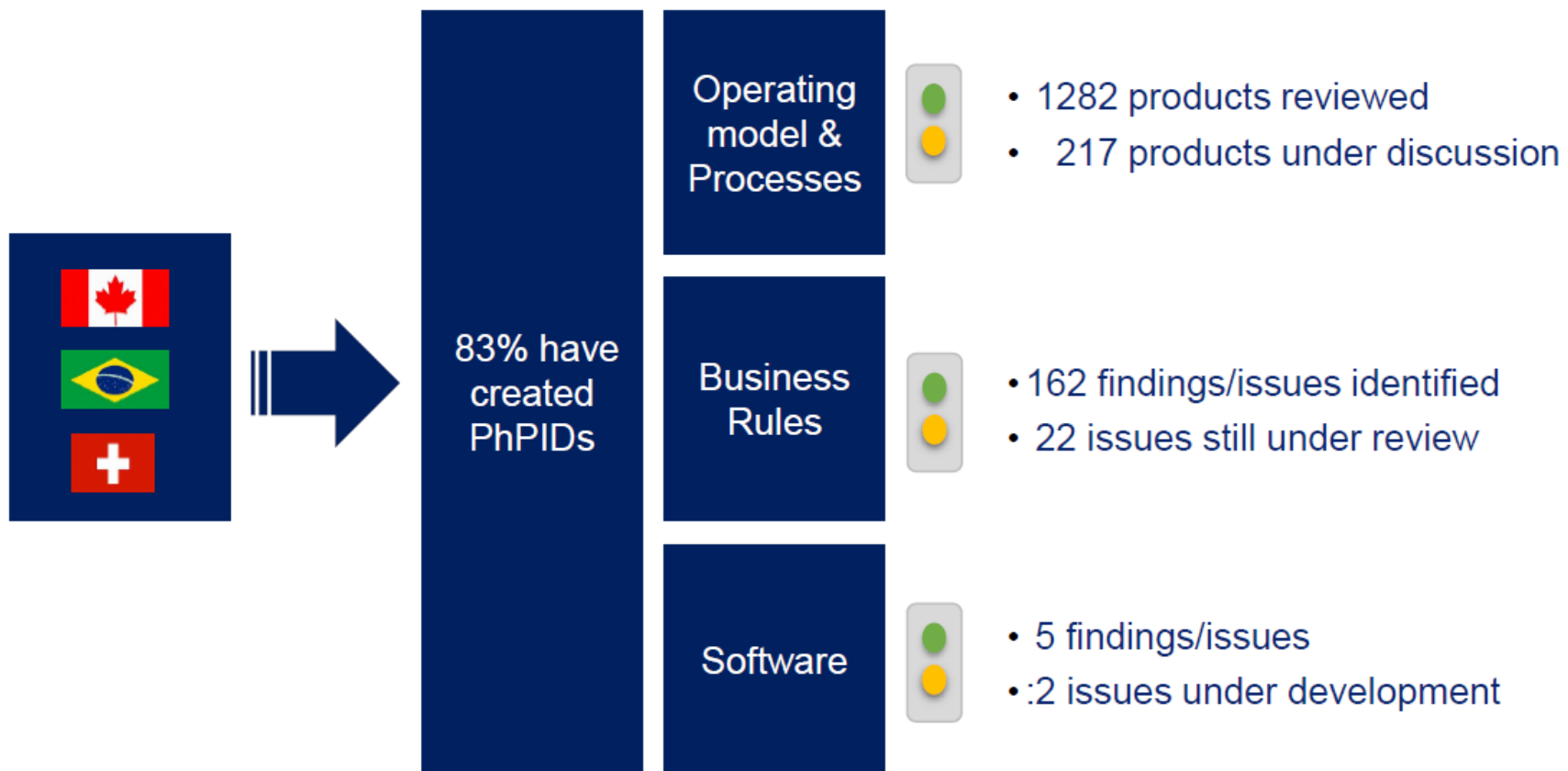
GIDWG project end to end testing for Global PhPID



GIDWG (3/6) - End-to-End Testing /Scope



GIDWG (4/6) - End-to-End Testing /results so far



GIDWG (5/6) - Proposed change management of PhPID (high level)



Regulatory authorities are responsible to publish updates/changes to Medicinal products



WHO-UMC is responsible for displaying updated PhPID data (Deprecated/Merged/Split) in Global PhPID service



Updates communicated through APIs and publish service



Daily updates and biannual release service

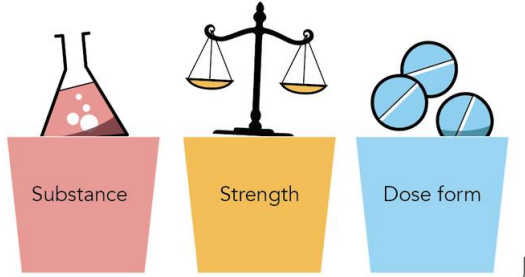


GIDWG (6/6) - Annual Stakeholders' meeting

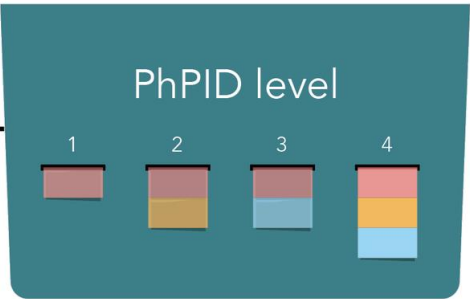
Sao Paulo, Brazil, September 9-12

- **September 9-10, Technical meeting for GIDWG members**
- **September 11, Regulatory and Industry forum**
- **September 12, Open meeting (hybrid)**

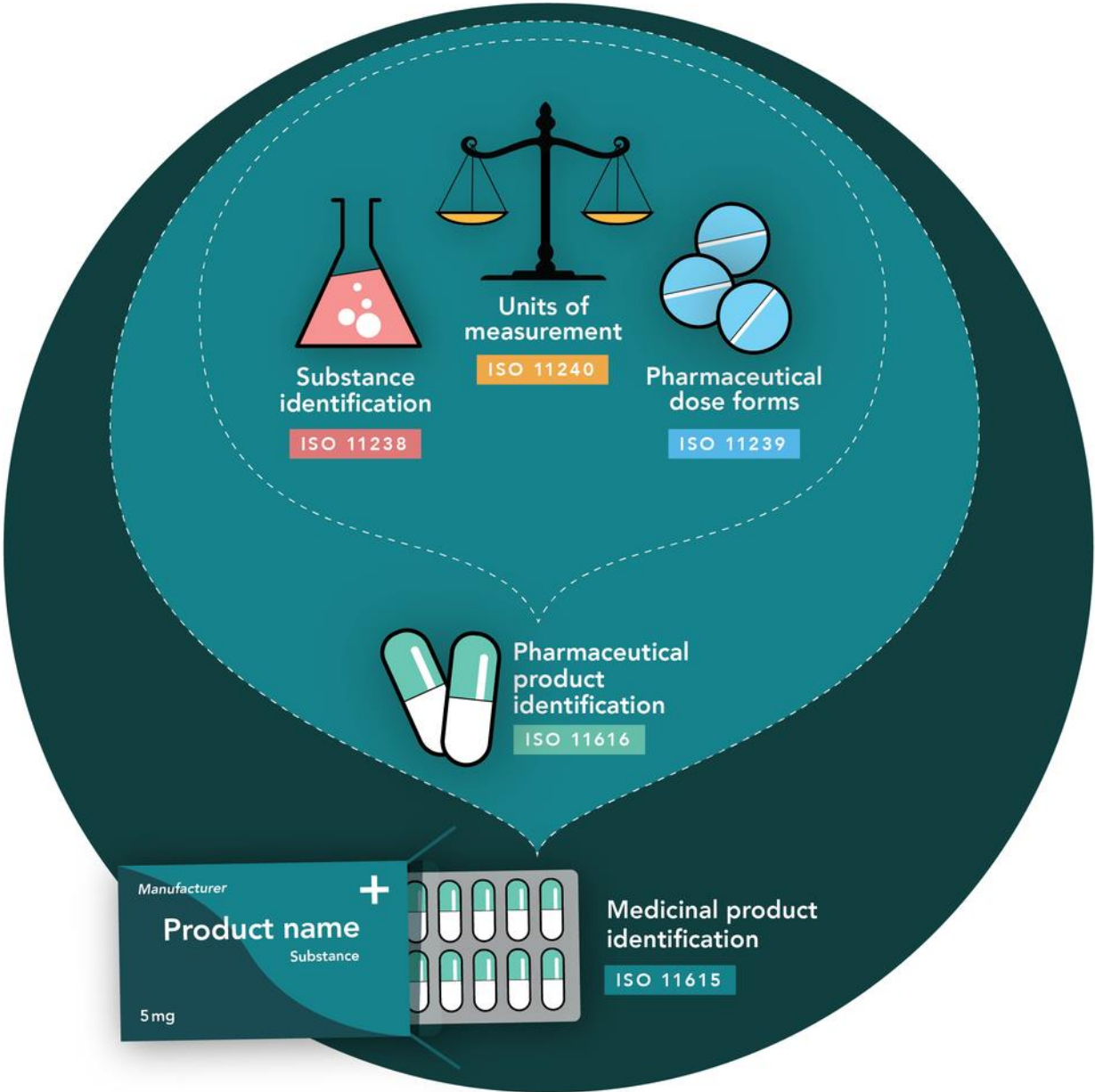
Global PhPID and Substance ID (GSID)

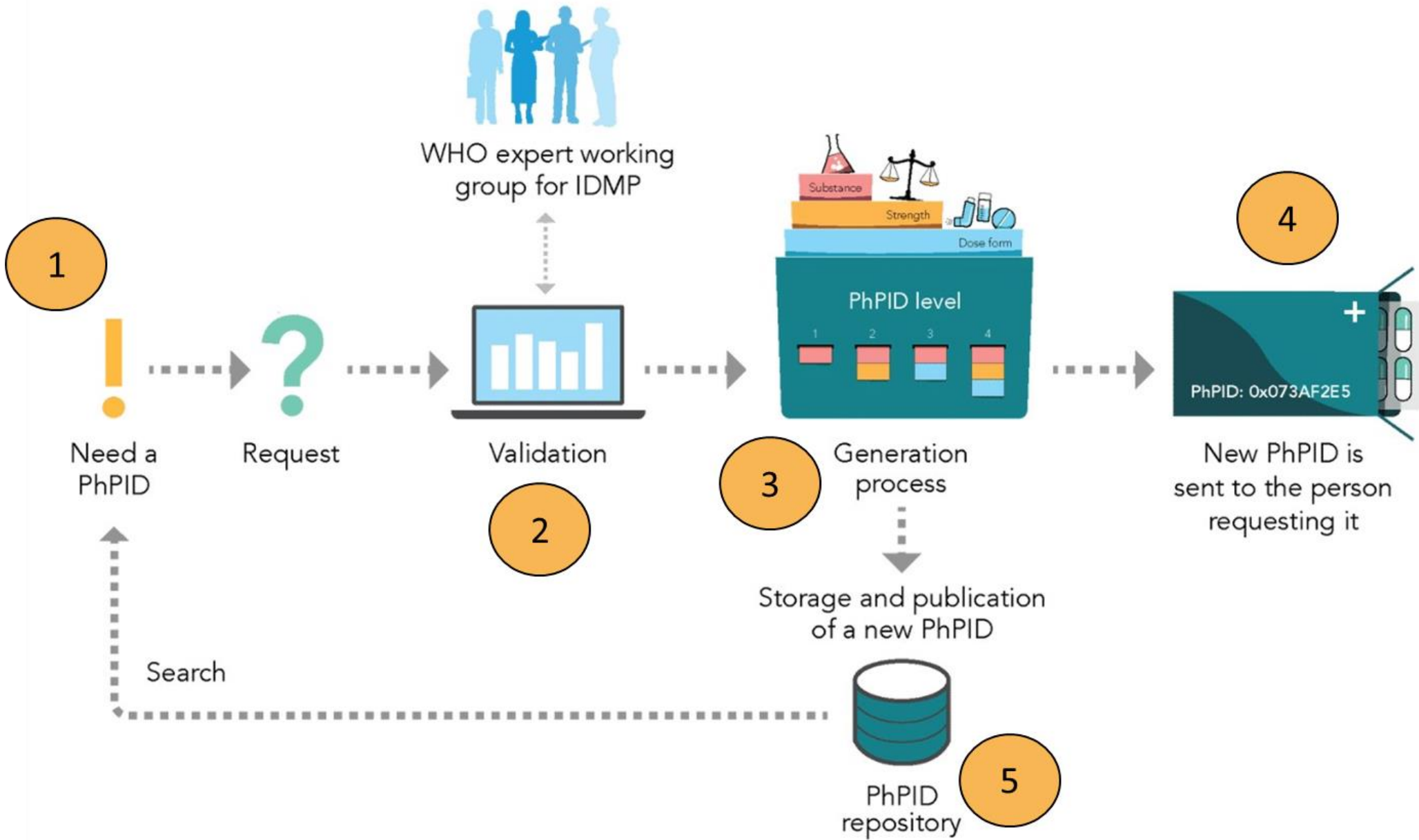


WHO UMC

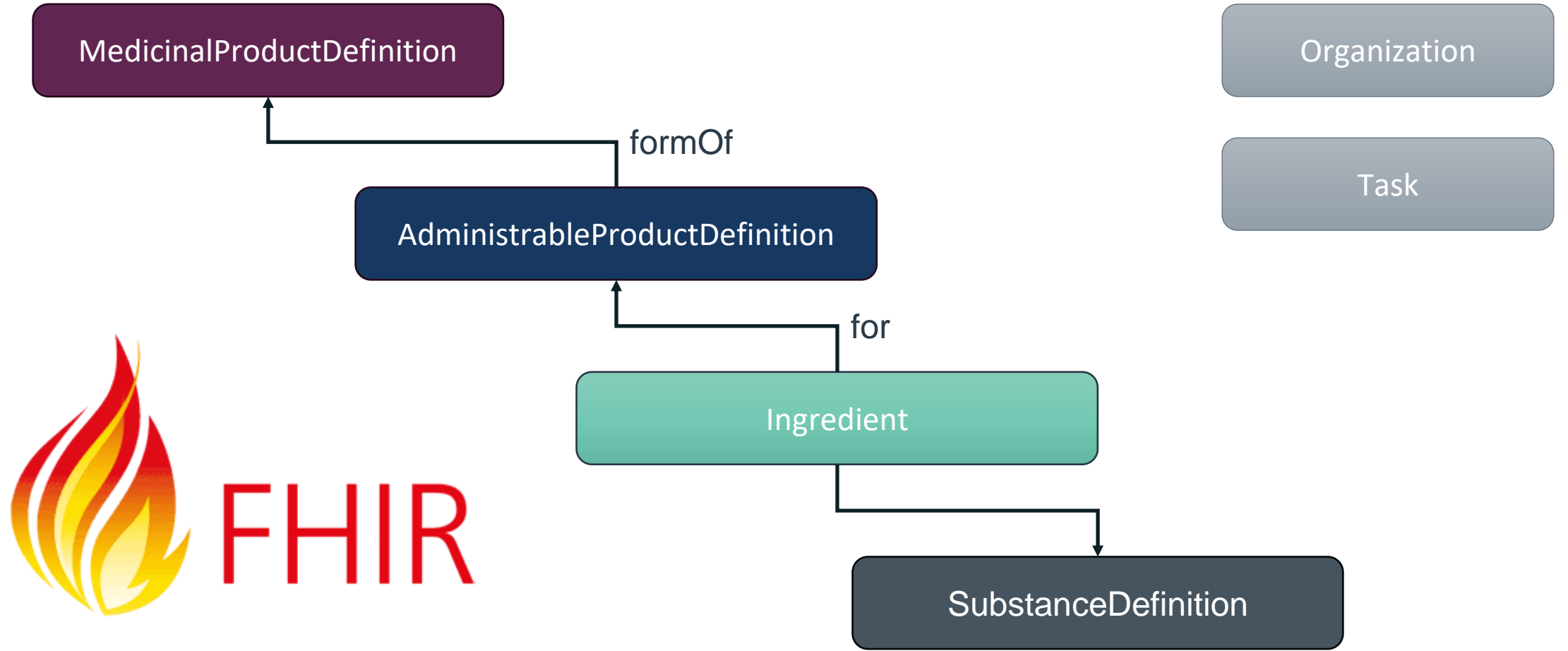


PhPID: 0x073AF2E5B92AE19E8867635AFFB3D6CA

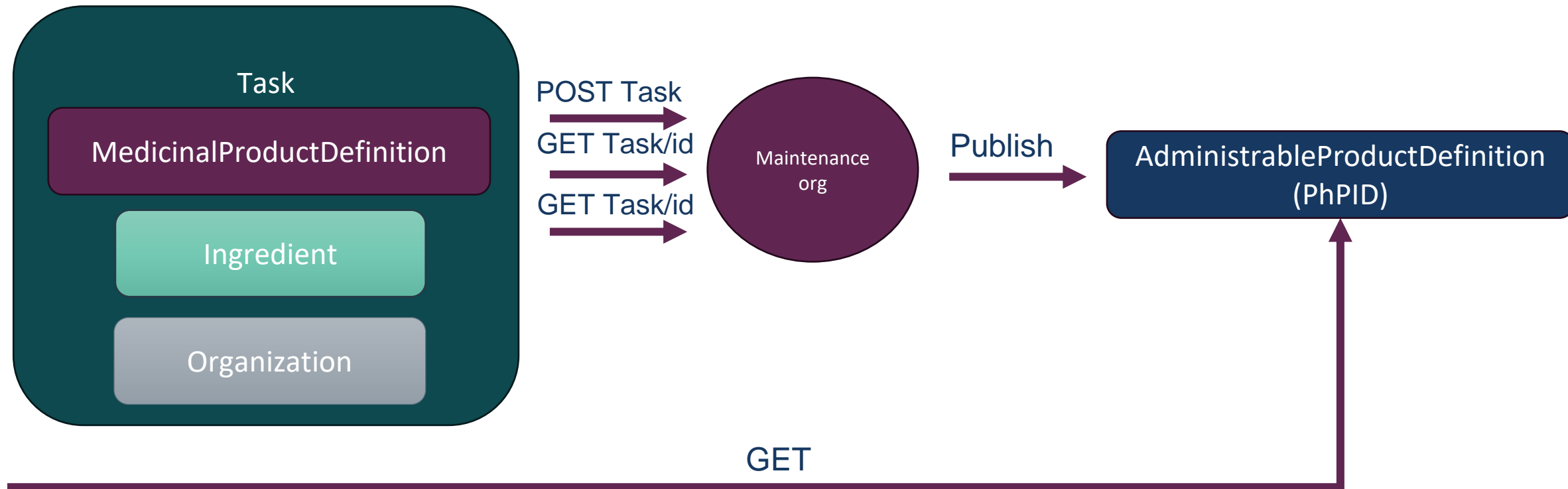




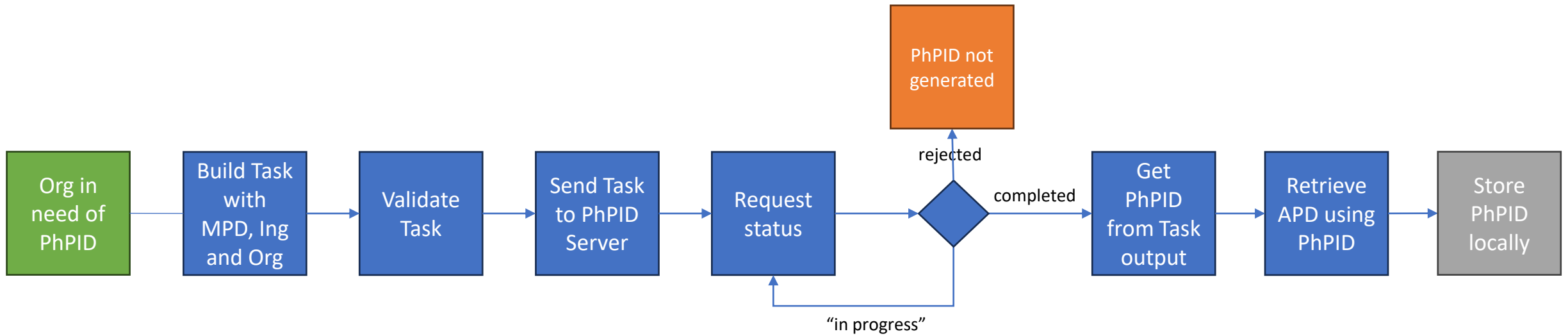
IDMP on FHIR

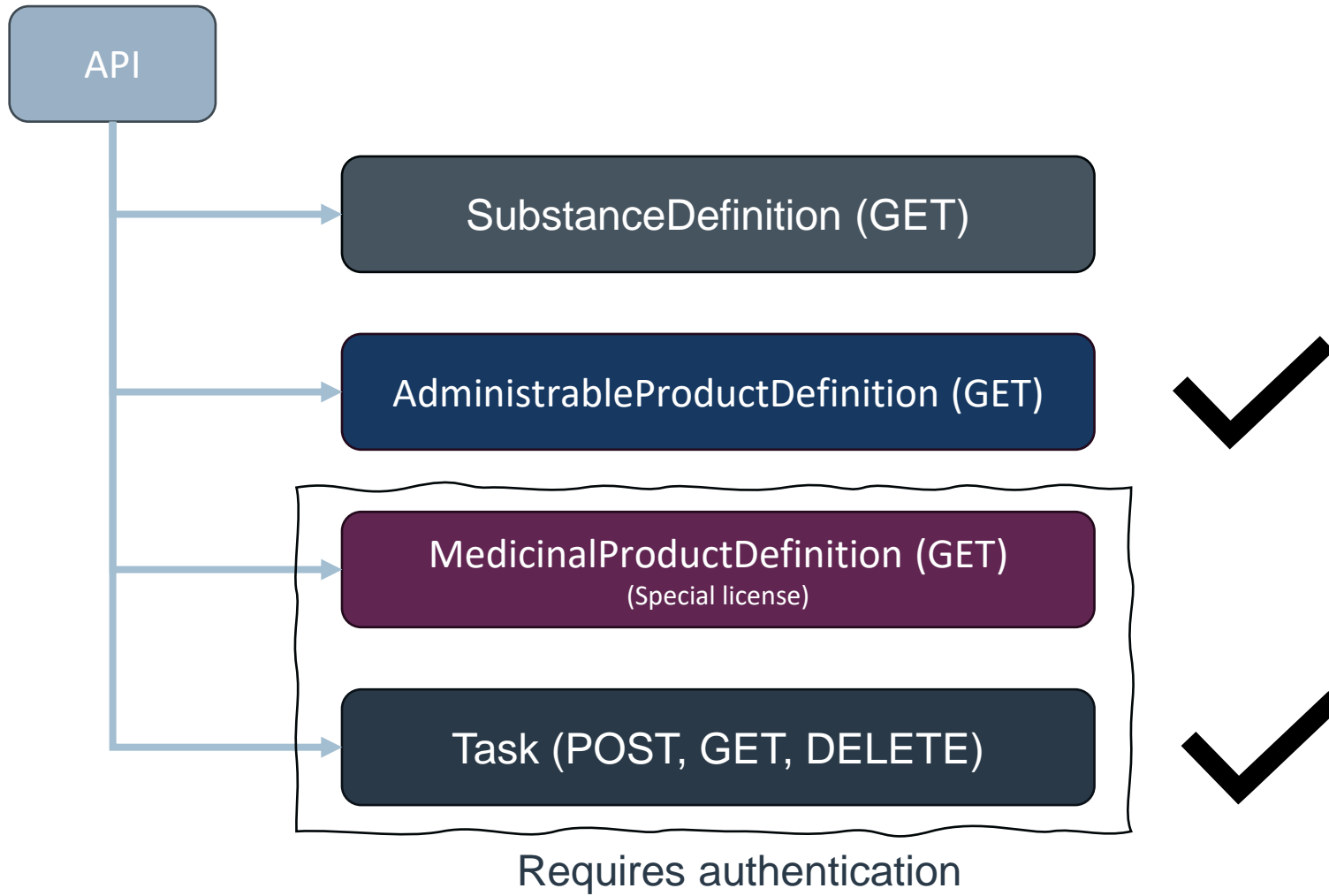


Request PhPID



Request Process







Overview of Task APIs

- POST Task
 - Sends a request, responds with an [OperationOutcome](#) if failure and a [Task](#) with a status if successful
- POST Task/\$validate
 - Validates a Task (should always be used before POSTing the task “for real”, responds with an [OperationOutcome](#))
- GET Task/[taskId]
 - Retrieves a specific Task (as a single [Task](#) resource)
- GET Task
 - retrieves all “my” Tasks in a [Bundle](#)
- GET Task?status=rejected|completed|...
 - Retrieves all “my” Tasks with a specific status as a [Bundle](#)
- DELETE Task/[taskId] - *do we need this*



Overview of APD (AdministrableProductDefinition) API

- GET APD/[PhPID]
 - Retrieves the APD corresponding to the PhPID
- GET APD?_has:Ingredient:for:substance-code=GSID23G92UMX93H45
 - Search by substance-code
- GET APD?parent-php=8195D4AF1287CCE3442C2F308F61DBBC
 - Search all APDs with a “parent” with the specified PhPIDs
- GET APD?form-of.identifier=4C34BE81784
 - Find the APD for a specified MPID (from WHO-Drug)

Note that an APD represents a PhPID in this API

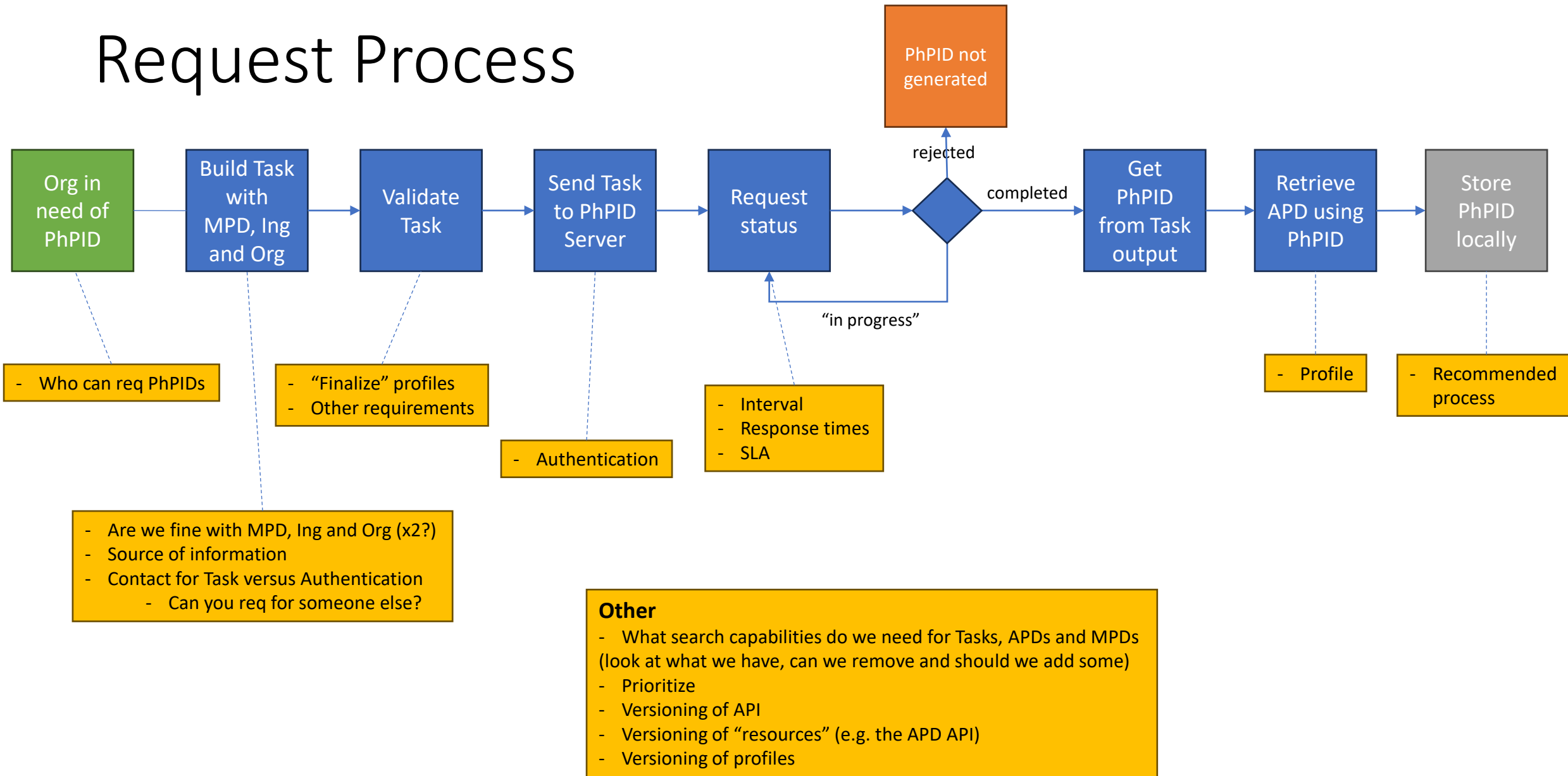
APD = AdministrableProductDefinition, shortened for clarity



Authentication

- To request a new Task and to handle existing Tasks the client needs to authenticate itself
- In the current “demo” API *any* guid on the form ‘XXXXXXXXXX-XXXX-XXXX-XXXX-XXXXXXXXXXXX’ works
- Always use the same guid for all subsequent calls for the same “user”

Request Process



Implementation Guide



WHO-UMC IDMP Management and Publish API
0.1.0 - CI Build

Uppsala Monitoring Centre logo | HL7 FHIR logo

IG Home | Background | Requesting PhP and GSIDs | Authentication | Versioning | Table of Contents | Artifact Index | Support

Table of Contents > WHO-UMC IDMP Management and Publish API

WHO-UMC IDMP Management and Publish API, published by Uppsala Monitoring Centre. 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/Uppsala-Monitoring-Centre/WHO-UMC-IDMP-Service/> and changes regularly. See the [Directory of published versions](#).

1 WHO-UMC IDMP Management and Publish API

Official URL: http://idmp.who-umc.org/fhir/ImplementationGuide/idmp.who-umc.org.fhir	Version: 0.1.0
Active as of 2024-05-08	Computable Name: whoUmcIDMPManagement

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

The scope of this Implementation Guide is to document the WHO-UMC IDMP API FHIR service, by describing the context in which the API can be used as well as the technical overview for using the API.

1.2 Introduction

This Implementation Guide has a target audience of system integrators to the WHO-UMC IDMP API. The API is based on the HL7 FHIR standard and this guide describes supported FHIR resources.

The Implementation Guide describes how FHIR standard is used to exchange data for ISO IDMP standards for global PhPIDs and GSIDs. For information about ISO IDMP, see the [Background](#) section in this guide.

The main resources maintained by the service are the Pharmaceutical Product IDs, PhPIDs, (manifested through the `AdministrableProductDefinition` resource) and the Global Substance IDs, GSIDs, (manifested through the `SubstanceDefinition` resource). However, the `MedicinalProductDefinition` resource is also vital since it serves as input for PhPID generation. The Implementation Guide describes how new global PhPIDs and GSIDs are requested using asynchronous FHIR requests, and how they are delivered through FHIR.

1.2.1 Access to the WHO-UMC IDMP FHIR server

The (preview) FHIR server with tutorials and examples can be reached at <https://idmp.who-umc.org/fhir>.



The API

WHO-UMC IDMP Management and Publish API (preview)

Resources and tutorials

[PhP related resources](#)

[Requesting a new PhPID \(AdministrableProductDefinition\) using a Task](#)

[Requesting a new GSID \(SubstanceDefinition\) using a Task](#)

[Code systems, value sets and extensions](#)

Experimental

[WHODrug code system](#)

FHIR Server

[FHIR Capability Statement resource](#)

[Implementation Guide](#)

[Open API yaml file](#)

-

[About](#)

Connectathon 36

Connectathon Manager: HL7 May 2024 Magnus Wallberg supported by **InterSystems**
Creative data technology

Home Page Track details & testing **50** Implementation Guides **76** People **444** Clients **46** **Servers 146** Test Results

Participation report

Event Activity

List all Servers Servers by track Search for supported resource Queries across Terminology servers Download Servers Json

who Only show Terminology [New Server](#)

Name	Url	FHIR Version	Description	Tracks / IGs	Notes
WHO-UMC IDMP Management and Publish API	Server root: https://idmp.who-umc.org/fhir/ Check availability UI: https://idmp.who-umc.org/ Connection type:	5.0.0	A demo server to test PhPid (and GSID) generation and lookup	Vulcan/Gravitate health - ePI/IPS (Phase 7) WHO-UMC IDMP Management and Publish API	Implementation guide found at: https://build.fhir.org/ig/Uppsala-Monitoring-Centre/WHO-UMC-IDMP-Service/

Substances to use

- METHOTREXATE SODIUM, [GSID9XBS2KCF3K1Z1](#)
- BUDESONIDE, [GSID5F15DZZ28F08D](#)
- ENALAPRIL MALEATE, [GSID1GFE68EBH236M](#)
- TRASTUZUMAB DERUXTECAN, [GSID48TV4HSX2SA6K](#)
- LEVOTHYROXINE SODIUM, [GSID74BGL0NXH45F4](#)
- AMPICILLIN, [GSID1NPK9P0LZ2Z9Z](#)
- ALBUTREPENONACOG ALFA, [GSID6LMD175ERE8YS](#)
- IMATINIB MESYLATE, [GSID73M8XV2G7PU5T](#)
- METHOTREXATE, [GSID23G92UMX93H45](#)
- NALOXONE, [GSID7FB73MCT1HS3G](#)
- BUPRENORPHINE, [GSID3ZYX232V0MC35](#)
- AMLODIPINE, [GSID9XAC86LEH7EZA](#)
- AMLODIPINE BESYLATE, [GSID429V16KLE32R6](#)
- CISPLATIN, [GSID99L1CUB38GD6S](#)

Links

- Implementation Guide
 - <https://build.fhir.org/ig/Uppsala-Monitoring-Centre/WHO-UMC-IDMP-Service/>
- FHIR API
 - <https://idmp.who-umc.org/fhir> (api)
 - <https://idmp.who-umc.org/> (tutorial)
- Connectathon
 - <http://conman.clinfhir.com/connectathon.html?event=con36>
- IG GitHub Repo (where to report issues with the IG)
 - <https://github.com/Uppsala-Monitoring-Centre/WHO-UMC-IDMP-Service>



NORDIC+UK – Project goals and participants

- Cooperation of the Nordic pharmaceutical product compendia: Medicin.dk (Denmark), Pharmaca (Finland), Felleskatalogen (Norway), and FASS (Sweden)
- Supply FHIR format package leaflets for the testing scenarios of Gravitare Health
- Joined by Datapharm (UK) to deliver package leaflets in English
- Technical teams from the compendia, using as source existing structured electronic package leaflets in proprietary formats



NORDIC+UK – Project outcomes

- Conversion of up to ~300 package leaflets for each language (depending on product availability in the country)
- Common FHIR implementation guide describing the ePI structures and code systems that are used (used internally for coordination and validation)
- Testing the Vulcan ePI IG and samples from the EMA ePI pilot



NORDIC+UK – Connectathon participation

- Test the ePI IG through an implementation
- Demonstrate regional adaptation of the global IG
- Recommend updates for version 1.1 based on experience
- Test case for API capabilities, both fetching from regulators and distributing to end users
- Use case demonstrating the need for cross-country ID like the PhPID
- Testing stylesheet and content harmonization

Default ePI stylesheet – Today's situation

- Each compendia have package leaflets, styled differently
- The content is converted from Word/PDF
- The HTML code and the view is customized to the website

Pakningsvedlegg: Informasjon til brukeren

ABASAGLAR 100 enheter/ml KwikPen injeksjonsvæske, oppløsning i ferdig penn
insulin glargin

Les nøye gjennom dette pakningsvedlegget før du begynner å bruke ABASAGLAR KwikPen. Det inneholder informasjon som er viktig for deg.

- Ta vare på dette pakningsvedlegget. Du kan få behov for å lese det igjen.
- Spør lege, apotek eller sykepleier hvis du har flere spørsmål eller trenger mer informasjon.
- Dette legemidlet er skrevet ut kun til deg. Ikke gi det videre til andre. Det kan skade dem om de har symptomer på sykdom som ligner dine.
- Kontakt lege, apotek eller sykepleier dersom du opplever bivirkninger som ikke er nevnt i dette pakningsvedlegget. Se avsnitt 4.

Symbicort Turbuhaler forte inhalaatiojauhe
budesonidi, formoterolifumaraattidihydraatti

Indlægsseddel: Information til brugeren

Baclofen Medical Valley 10 mg tabletter
Baclofen Medical Valley 25 mg tabletter
baclofen

Læs denne indlægsseddel grundigt, inden du begynder at tage dette lægemiddel, da den indeholder vigtige oplysninger.

- Gem indlægssedlen. Du kan få brug for at læse den igen.
- Spørg lægen eller apotekspersonalet, hvis der er mere, du vil vide.
- Lægen har ordineret dette lægemiddel til dig personligt. Lad derfor være med at give

Yleisiä ohjeita

Lue tämä pakkauseloste huolellisesti, ennen kuin aloitat tämän lääkkeen käyttämisen, sillä se sisältää sinulle tärkeitä tietoja.

- Säilytä tämä pakkauseloste. Voit tarvita sitä myöhemmin.
- Jos sinulla on kysyttävää, käänny lääkärin tai apteekkihenkilökunnan puoleen.
- Tämä lääke on määrätty vain sinulle eikä sitä pidä antaa muiden käyttöön. Se voi aiheuttaa haittaa muille, vaikka heillä olisikin samantyyppiset oireet kuin sinulla.
- Jos havaitset haittavaikutuksia, kerro niistä lääkärille tai apteekkihenkilökunnalle. Tämä koskee myös sellaisia mahdollisia haittavaikutuksia, joita ei ole mainittu tässä pakkauselosteessa. Ks. kohta Mahdolliset haittavaikutukset.

Bipacksedel: Information till användaren

Cabazitaxel Accord

20 mg/ml koncentrat till infusionsvätska, lösning
cabazitaxel

Läs noga igenom denna bipacksedel innan du börjar använda detta läkemedel. Den innehåller information som är viktig för dig.

du kan behöva läsa den igen.
or vänd dig till läkare, apotekspersonal eller

la med läkare, apotekspersonal eller sjuksköterska.
la **biverkningar** som inte nämns i denna information. Se



Default ePI stylesheet – Future needs

- Applications for cross-border use cases might need to display package leaflets from diverse sources
- To ensure efficient processing and a consistent display for optimal user experience, the package leaflet structures should be harmonized
- The package leaflets should now function together in the same application context

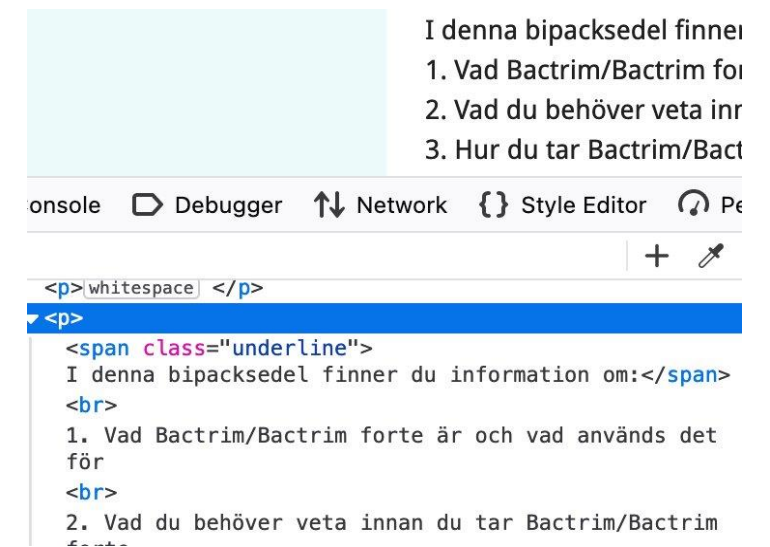
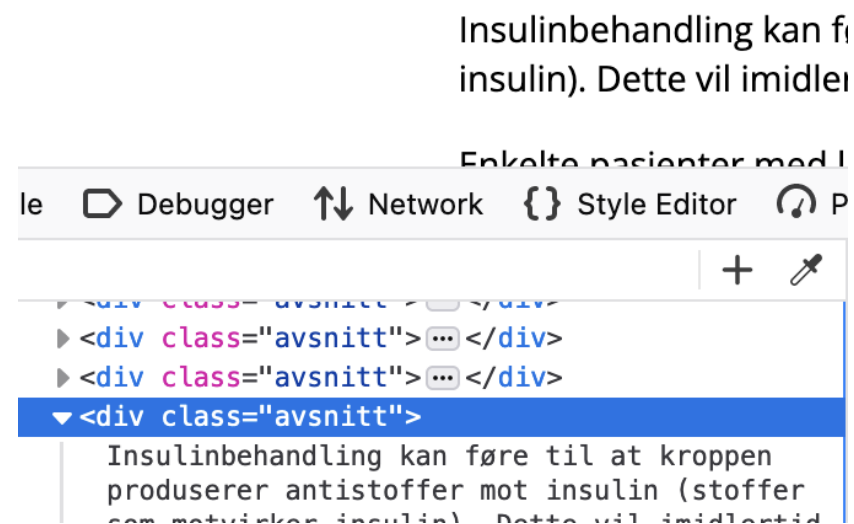


Content guidelines – Basis of a default ePI stylesheet

- FHIR profiles define the structured content of the package leaflets within the ePI, down to the section codes and section hierarchy in the Composition
- The central part of the package leaflet resource is narrative HTML
- Baseline rules (similar to profiles) should be defined for the narrative HTML
- Conforming to and building on the guidelines in the FHIR specification

ePI stylesheet Topic Working Group

- Define baseline recommendations for the HTML
- Example conversion stylesheet from FHIR ePI to HTML (including section structure, metadata, and possibly the structured resources)
- Example CSS stylesheet for visual design of the ePI



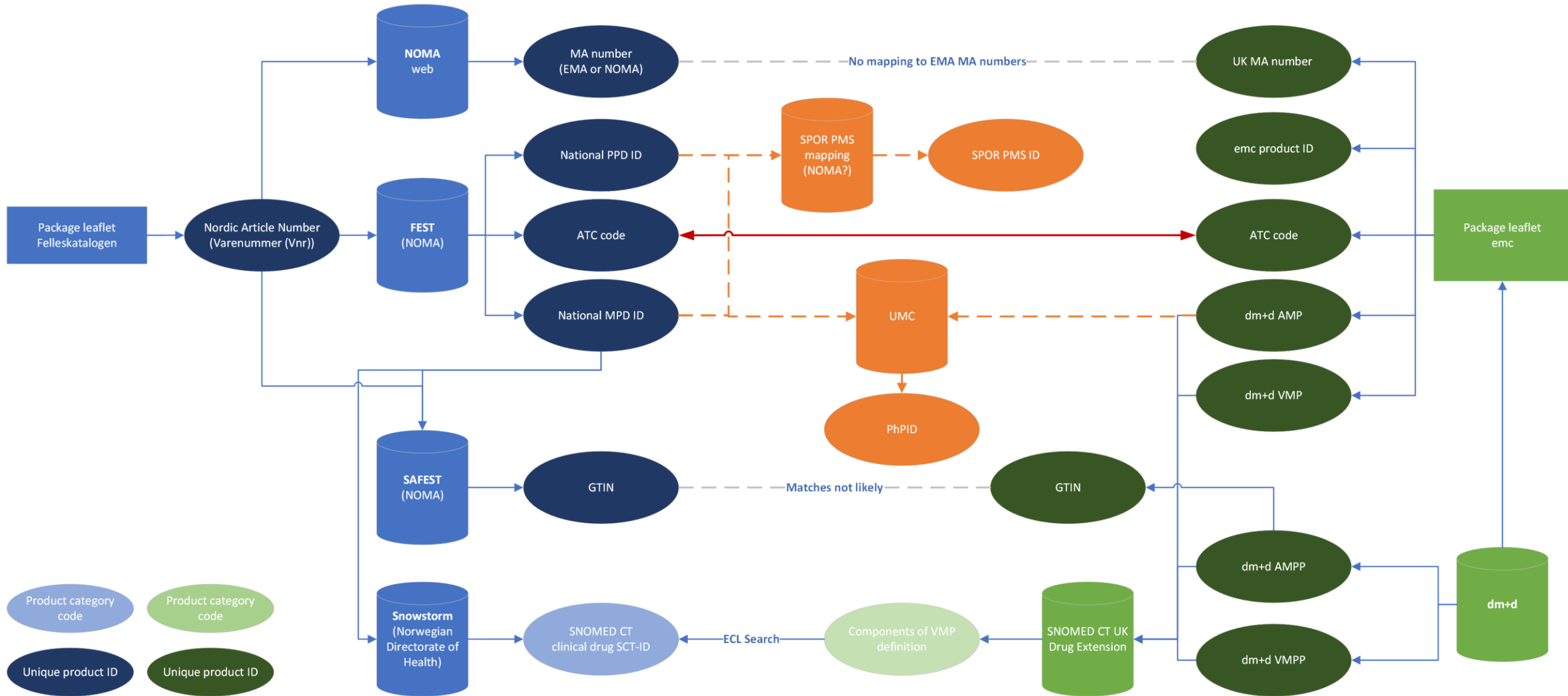


UK compendium english language ePI

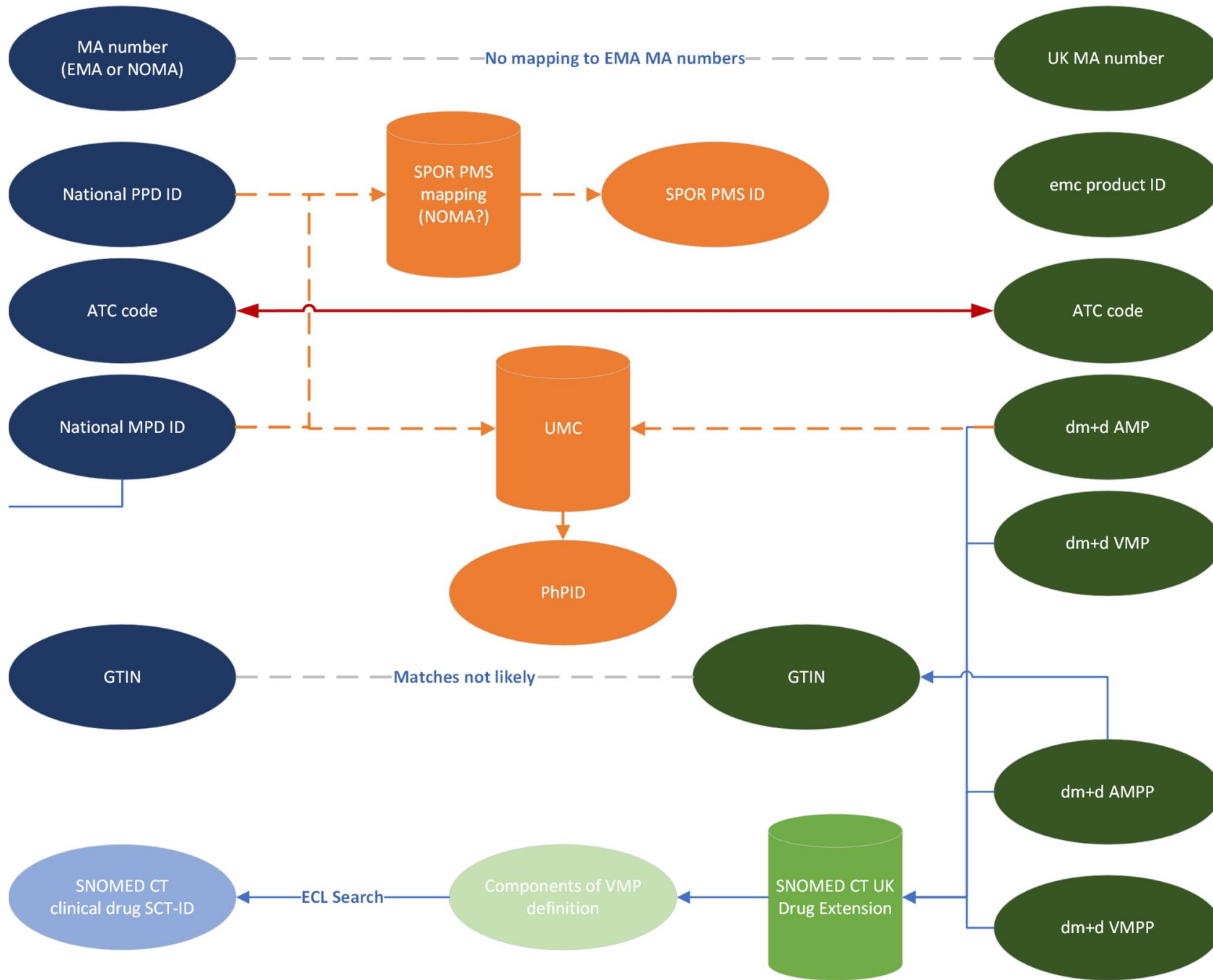
- Datapharm supporting with ePI content from emc (medicines.org.uk) for Gravitare Health test scenarios
- Connectathon to discuss suitable identifiers to correlate equivalent UK medicines.
- Candidate identifiers that could assist in the process: (ATC, dm+d AMP ID, PhP ID)
- Review of ePI preview API. Example ePIs available by API in FHIR JSON and XML formats. Feedback on API functionality.



Norway & UK linked data



Norway & UK linked data





Key topics 36th FHIR Connectathon for the Vulcan Gravitare-Health/ePI track in collaboration with UNICOM

1. ePI Governance: Define joint profiles and governance model between EMA, Gravitare Health and Vulcan
2. ePI style sheet: Create and test a final draft of a default style sheet for ePIs
3. ePI Capability: Define basic API functionality requirements
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6. ANVISA: Incorporate Brazilian scenarios and data into ePI and GIDWG end-to-end IDMP testing

Browser tabs: European Canc, RE: FHIR Conn, i2X_Prelimin, RE: FHIR Conn, 2024-05-09, Google Calend, Mail - Catherin, Home - OneDr, QUANTI FINAL, QUANTI FINAL, Toledo Portal, 2024 - 05 Com

Address bar: confluence.hl7.org/display/FHIR/2024+-+05+Connectathon+36

Navigation: Home, Search, Log in

Confluence Spaces: Glossaries

Pages / FHIR Product Family / Connectathons

2024 - 05 Connectathon 36

Created by Sandy Vance. last modified yesterday at 3:26 PM

Confluence Spaces: Glossaries

2024 - 05 Connectathon 36

- 2024 - 05 Bulk Match
- 2024 - 05 C-CDA to FHIR map
- 2024 - (Dropped) 05 CDS Hoo
- 2024 - 05 Clinical Reasoning
- 2024 - 05 Da Vinci Burden Red
- 2024 - 05 Da Vinci Clinical Dat
- 2024 - 05 Da Vinci Member At
- 2024 - 05 Da Vinci Patient Cos
- 2024 - 05 Da Vinci Payer Data
- 2024 - 05 Da Vinci Risk Adjust
- 2024 - 05 Da Vinci Value-Basev
- 2024 - 05 Enhancing Oncology
- 2024 - 05 Evidence Based Mec
- 2024 - 05 FAST Infrastructure (
- 2024 - 05 Feature Capability SI
- 2024 - 05 FHIR Clinical Docum
- 2024 - 05 Goal-Directed Care I
- 2024 - 05 Helios Query and Re
- 2024 - 05 Imaging
- 2024 - 05 International Patient
- 2024 - 05 Laboratory Report
- 2024 - 05 NHSN dQM Reportii
- 2024 - 05 Ophthalmology trac
- 2024 - 05 PACIO Advance Dire
- 2024 - 05 PACIO Transitions of
- 2024 - 05 Physical Activity - W
- 2024 - 05 Questionnaires and
- 2024 - 05 Standard Personal H
- 2024 - 05 Terminology Change
- 2024 - 05 Testing - Measure th
- 2024 - 05 Vulcan/Gravitate**
- 2024 - 05 Vulcan - UDP (Utilizi
- 2024 - 05 Mental Health Care

Space tools

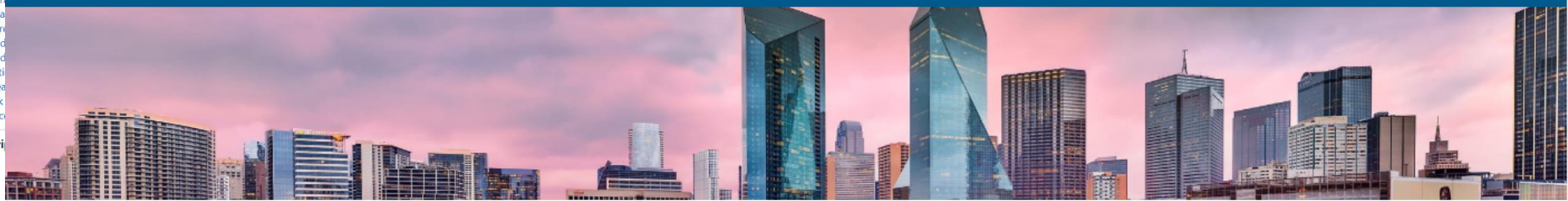
hl7.my.site.com/LightningMemberPortal/s/lt-event?id=a1YVM000001B8Xz2AK#/FHIR-Connectathon

2024 May HL7 FHIR Connectathon and Working Group Meeting

May 18-24, 2024 • Dallas, Texas

Overview FHIR Connectathon Meeting Agenda Venue

Register



HL7® FHIR® Connectathon

An HL7 Fast Healthcare Interoperability Resources (FHIR®) Connectathon features hands-on FHIR development and testing. This is a chance to get your hands dirty and learn by helping evolve the FHIR specification (lectures and presentations are not included)!

Whether the format is virtual or in-person, implementers and developers can gain experience developing FHIR-based solutions and exchange data with other FHIR interfaces.

Participants select one of several tracks based on level of readiness and area of interest, and can engage in hands-on, heads down development and testing. There is an opportunity to work directly with other FHIR developers and senior members of the FHIR standards development team. Participants are expected to write some software intended to demonstrate FHIR connectivity.

First-Time Attendee Mandatory Prerequisite Orientation

If you are a first-time Connectathon participant, please view the mandatory [FHIR Training for Beginners Newcomer Orientation](#)

Items covered are:

- HL7 FHIR 101, Viet Nguyen
- How to read an IG, Linda Michaelson
- US Core Profiles, Brett Marquard
- HL7 FHIR Testing, Tools & Heading to a Connectathon, Richard Ettema

More information about FHIR Connectathons

Find details about previous HL7 FHIR Connectathons online at <https://confluence.hl7.org/display/FHIR/Connectathons> or check out the [HL7 FHIR Connectathon FAQs](#)

