Day 2
17 October 2023

3d Global IDMP Working Group (GIDWG) Stakeholders Meeting

AGENDA

Global IDMP Working Group (GIDWG) Stakeholders Meeting **17 October 2023**

Day 2 9:00-17:00 CET

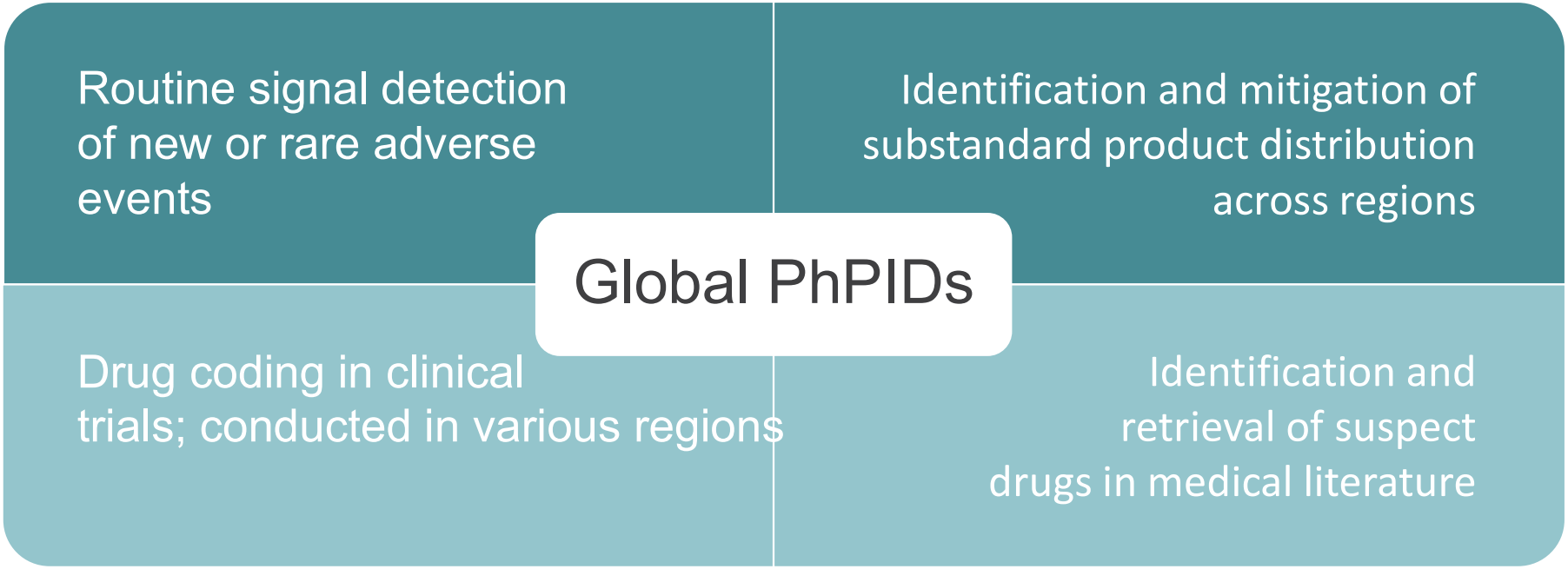
9:00	Review of Day 1 Progress / Day 2 Agenda	Malin Fladvad (UMC) / Ron Fitzmartin (FDA) / Panagiotis Telonis (EMA)
9:30	End-to-End Use Case #1 (Pharmacovigilance)	Malin Fladvad (UMC)
10:10	End-to-End Use Case #2 (Cross Border Healthcare)	Robert Stegwee (CEN/TC 251)
10:50	Break	
11:20	End-to-End Use Case #3 (Drug Shortages)	Marilina Castellano (UMC) / Sofia Zastavnik (EMA)
12:00	Lunch	
13:30	Wrap up of the break-out sessions	All
14:00	Break	
14:30	Presentations by Regulators & Industry	Bjørg Overby (NoMA) / Philipp Weyermann (SwissMedic) / Ron Fitzmartin & Ta-Jen Chen (FDA) / Vada A. Perkins (IFPMA)
16:30	Wrap Up and Review Action Items/Decisions Overview of Day 3 Public Meeting	Isabel Chicharo (EMA)/Malin Fladvad (UMC)/Ron Fitzmartin (FDA)/All

Showcase how global Pharmaceutical Product Identifiers (PhPIDs) support faster and more accurate identification of global safety issues

Enabling interoperability at global level

Malin Fladvad, UMC

Overview of use cases in pharmacovigilance where global PhPIDs would add value



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Learning objectives: understand use cases for PhPID

- Substance, dose form and strength are defined and reported differently in different countries. This limits analysis of global data and data sharing between regulators.
- The PhPID globally and uniquely identifies a pharmaceutical product's substances, dose form and strength. It is the medicinal product's "common denominator" from country to country regardless of where it is prescribed, dispensed and used.
  PhPID support faster and more effective data retrieval of ICSRs globally as well as safety alerts and follow-ups.

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Routine signal detection of rare adverse events

Muscle spasms associated with methotrexate

Methotrexate was delivered via a single-dose pre-filled pen – 15 mg once a week for the treatment of rheumatoid arthritis.

“The intensity of this ADR was described as very intense. Disabling and painful arm or leg pain, with varying frequency, 1 to 3 times a day.”

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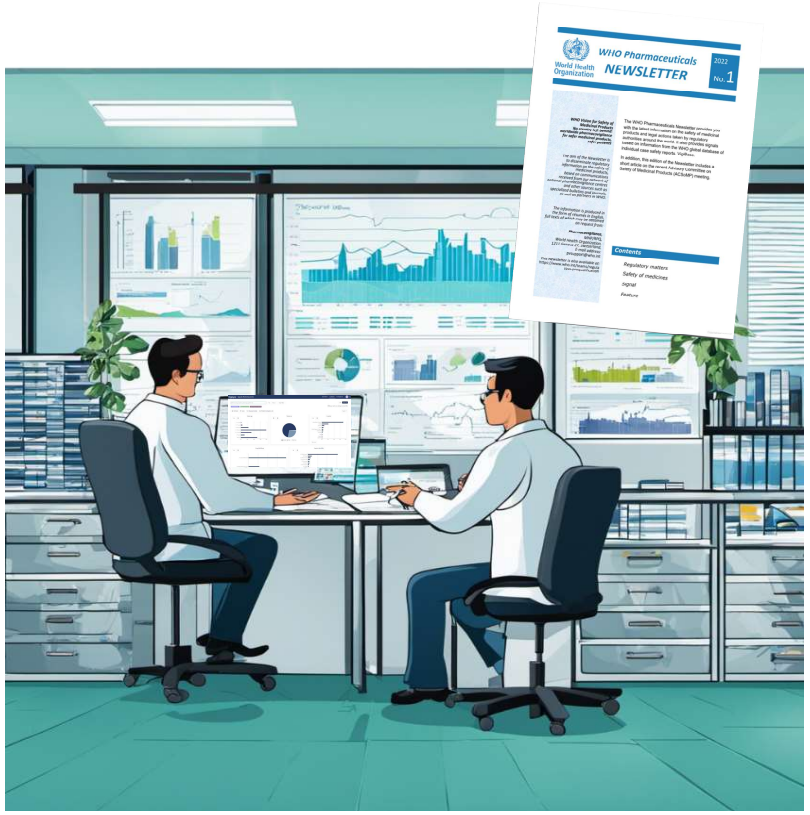
UMC's global signal review process

- 397 reports from 18 countries in the WHO PIDM* as of May 2020
- Manual assessment of case reports by doctors and pharmacists at UMC
- External peer review by clinical experts**
- MAH invited to comment
- Signal shared with the WHO PIDM via VigiLyze
- Signal published in the WHO Pharmaceuticals Newsletter***



* WHO Programme for International Drug Monitoring
**https://who-umc.org/signal-work/clinical-expert-group/
***WHO Pharmaceuticals Newsletter - N°1, 2022 www.who.int/publications/i/item/9789240042452

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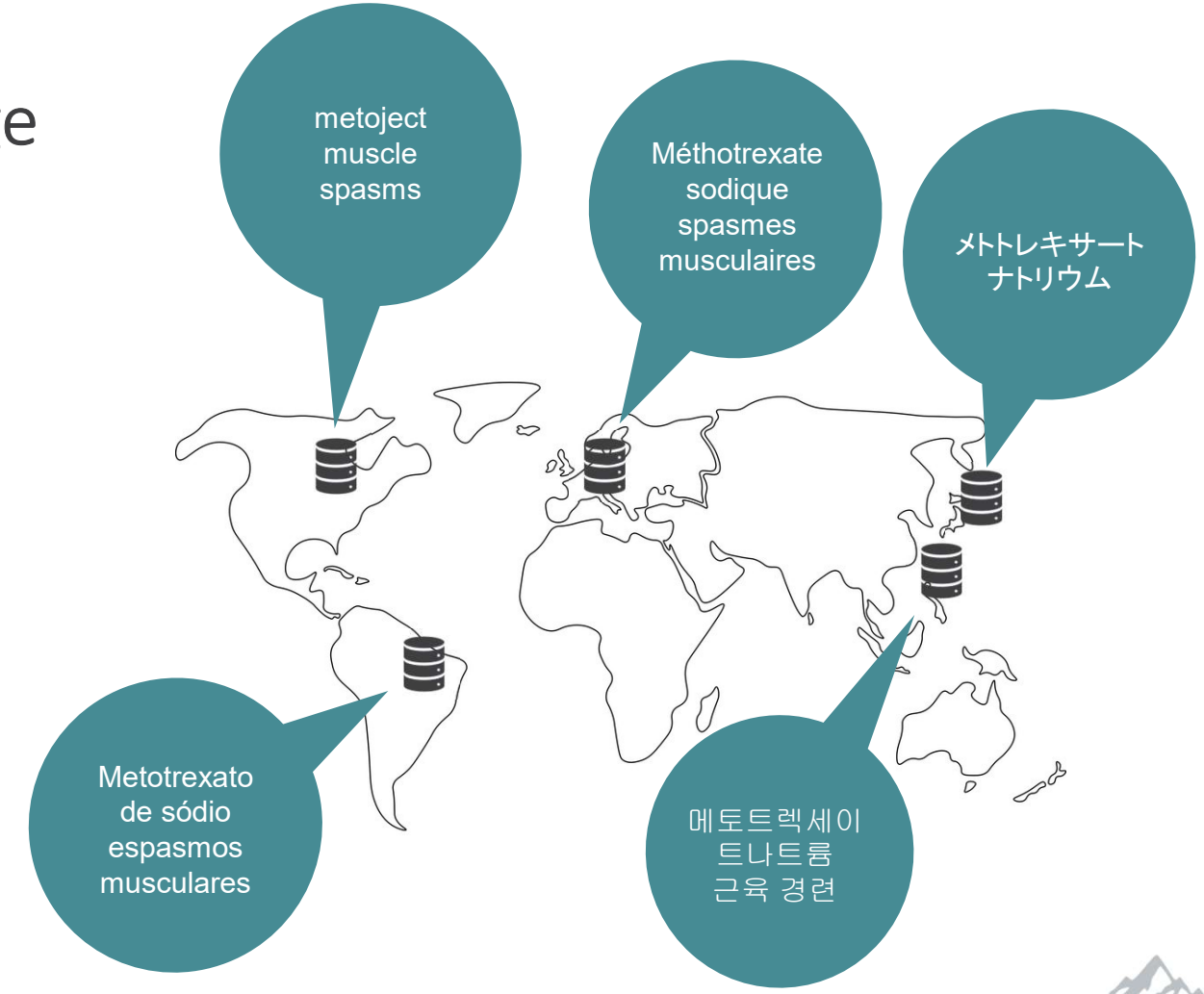
Spontaneous reports contain local language

Similar reports are received at various national centres globally, including the Netherlands, US, Canada, Brazil, and Republic of Korea. The information is received in digital format and contains local language in free text data elements.



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Different terminology used for regional analysis

ICSRs undergo standard regional coding to facilitate analysis at each respective Pharmacovigilance centre, highlighting variations in coding standards across countries (Netherlands, Brazil, Republic of Korea, Canada and US).

Recoding to global standards is time consuming

UMC receives these reports continually in VigiBase, WHO's global database of potential side effects of medicinal products.

Manually recoding at this stage to a global standard with WHODrug potentially delays analysis.

Recoding by UMC coding team

- Number of reports in VigiBase
  - 36,448,316 reports
- Coding of drug name verbatim terms in VigiBase
  - 98% automatically coded to WHODrug
  - 2% require manual coding
- Time spent on manual coding
  - 20 to 25 unique drug name verbatim terms per hour
  - 6,000 hours or 250 business days are needed to manually code 120,000 unique drug name verbatim terms; corresponding to about 300,000 reports

Data as of 2 Oct 2023

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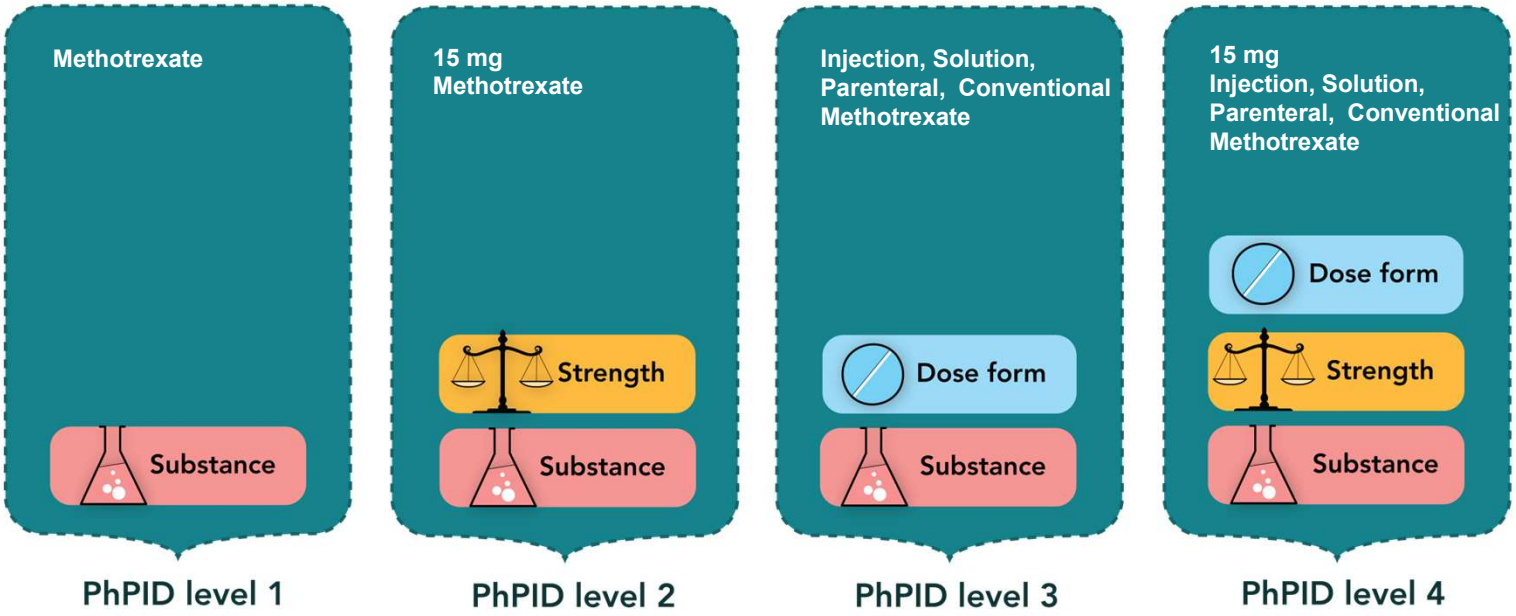
What if we had global PhPIDs?



If products were assigned to a global PhPID standards, each product name would automatically be linked to active ingredient, strength, dose form.

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ICSRs contain heterogeneous information

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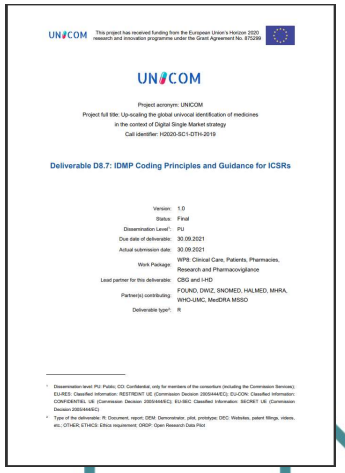

UNICOM

Project acronym: UNICOM

Project full title: Up-scaling the global univocal identification of medicines in the context of Digital Single Market strategy

Call identifier: H2020-SC1-DTH-2019

Deliverable D8.7: IDMP Coding Principles and Guidance for ICSRs

Version: 1.0
Status: Final
Dissemination Level[1]: PU
Due date of deliverable: 30.09.2021
Actual submission date: 30.09.2021
Work Package: WP8: Clinical Care, Patients, Pharmacies, Research and Pharmacovigilance
Lead partner for this deliverable: CBG and I-HD
Partner(s) contributing: FOUND, DIWZ, SNOMED, HALMED, MHRA, WHO-UMC, MedDRA MSSO
Deliverable type[2]: R

[1] Dissemination level: PU: Public, CO: Confidential, only for members of the consortium (including the Commission Services); EU-RES: Classified Information: RESTREINT UE (Commission Decision 2005/444/EC); EU-CON: Classified Information: CONFIDENTIEL UE (Commission Decision 2005/444/EC); EU-SEC: Classified Information: SECRET UE (Commission Decision 2005/444/EC)

[2] Type of the deliverable: R: Document, report; DEM: Demonstrator, pilot, prototype; DEC: Websites, patent filings, videos, etc.; OTHER; ETHICS: Ethics requirement; ORDP: Open Research Data Pilot

ICSRs with heterogeneous information are coded to PhPIDs

Metotrexato de sódio 15 mg uma vez por semana Solução injetável

PhPID Level 4

Méthotrexate sodique; AUTO-INJECTEUR PRÉREMPLI À DOSE UNIQUE, 10 mg/week

PhPID Level 4

Metotrexato de sódio

PhPID Level 1

메토트렉세이트 나트륨 ; 주 1회 15mg 주사 ; 주사액

PhPID Level 4

Methotrexate sodium, injections, 15 once a week

PhPID Level 4

methotrexate 15 once a week

PhPID Level 2

*Deliverable D8.7: IDMP Coding Principles and Guidance for ICSRs: https://unicom-project.eu/wp-content/uploads/2022/01/UNICOM_D8.7_IDMP-coding-principles-and-guidance-for-ICSRs.pdf

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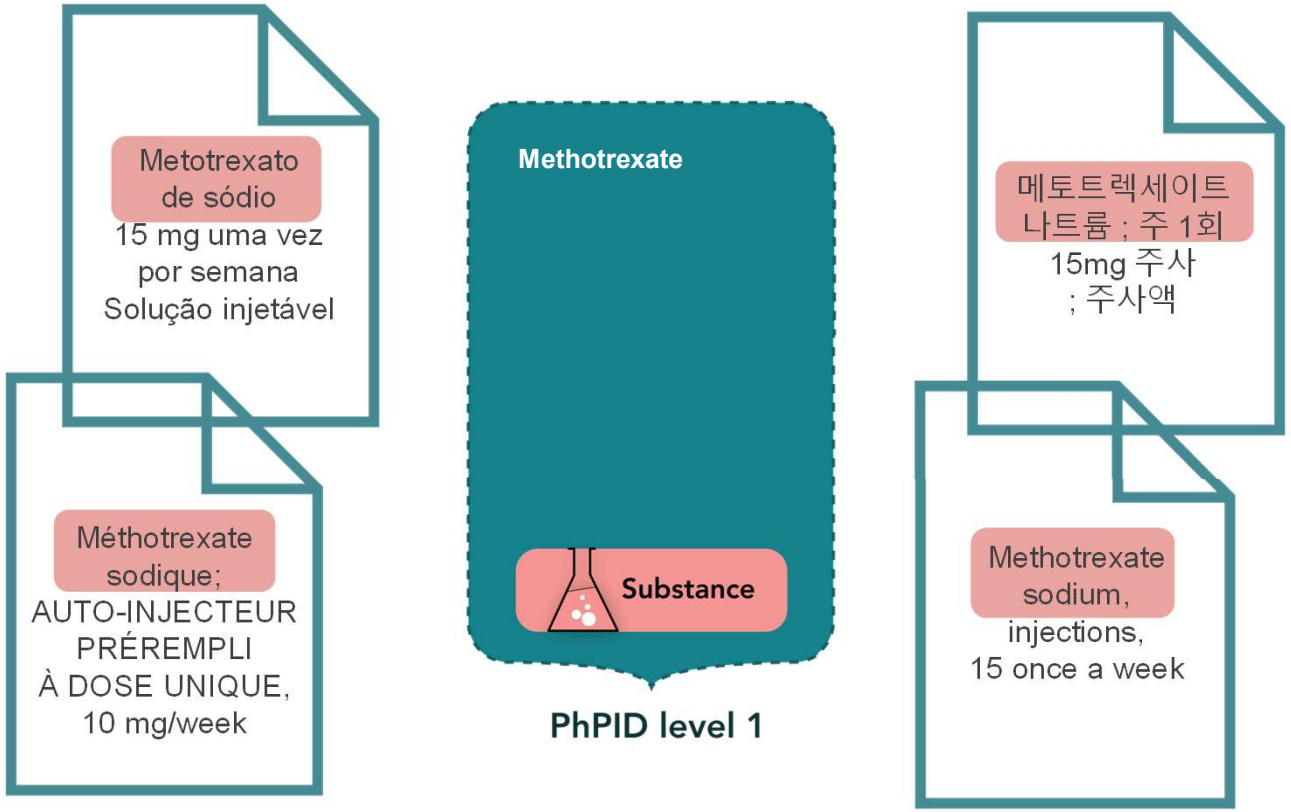
Signalling with Global PhPID level 1

Initiating national centres' coding processes using global PhPIDs will speed up analysis and data sharing between regulators.



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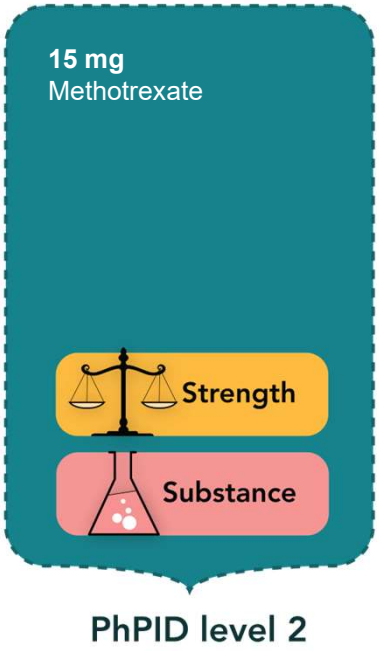
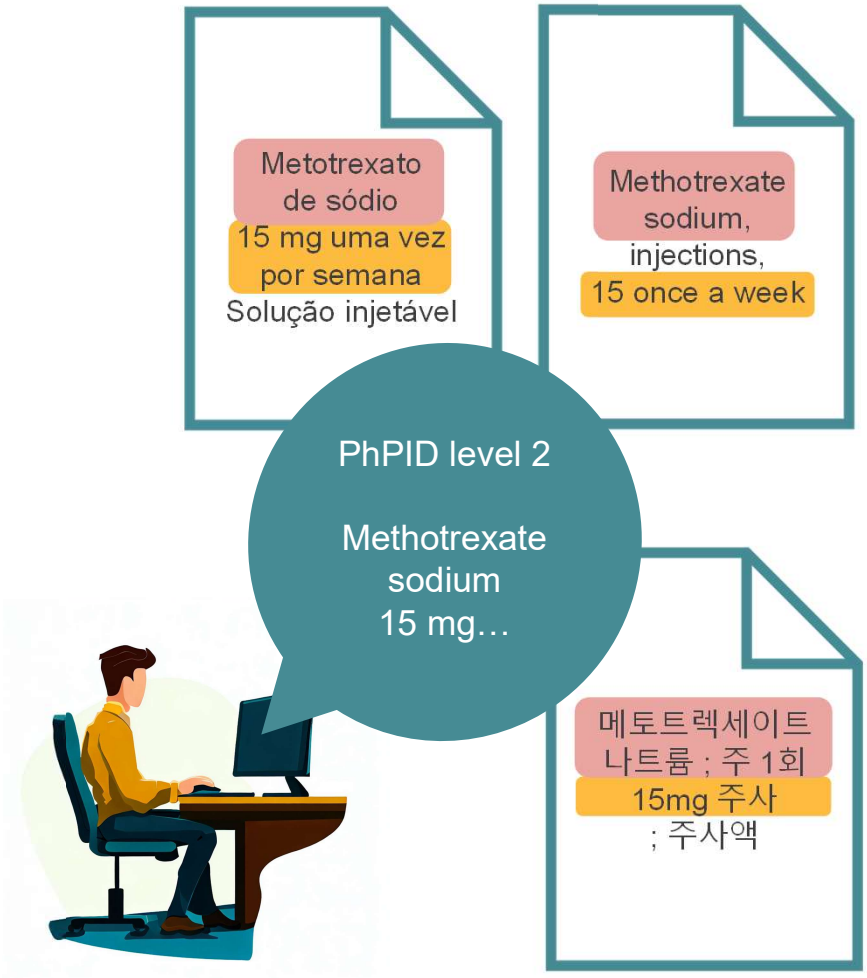
Signalling with Global PhPID level 2

Data coded to the appropriate PhPID level when reports come in facilitates more nuanced analysis, particularly regarding strength or dose form.

This enables not only faster and more granular analysis, but also limits the number of patients harmed.





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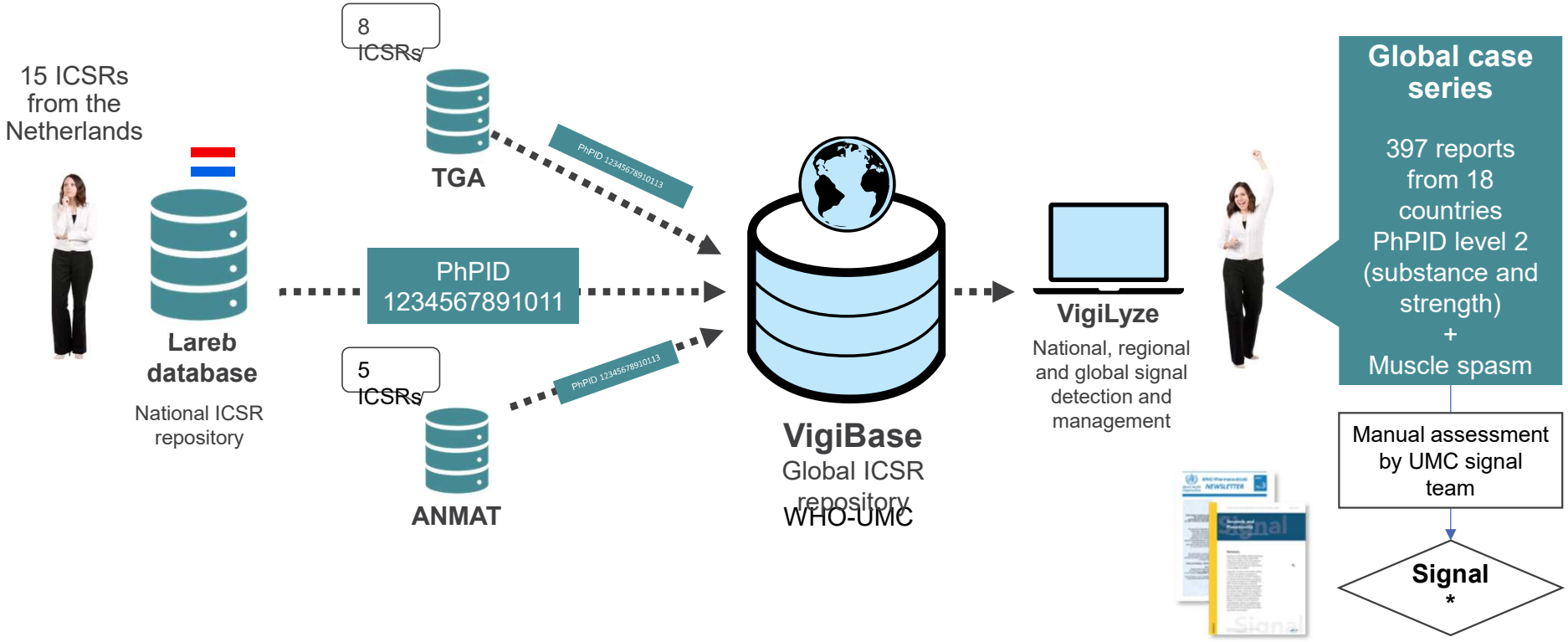
Wrap-up: If we had global PhPIDs



*Source: WHO Pharmaceuticals Newsletters

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How do global PhPIDs support routine signal detection of new or rare adverse events?

- Drug coding to global standards is initiated at national level
- VigiBase receives/validates data coded to PhPID standards
- The use of global PhPIDs allows for:
  - comprehensive data retrieval
  - analysis at different levels of granularity
  - faster and more specific signal detection

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WHO Global Surveillance and Monitoring System for substandard and falsified (SF) medical products

WHO Global Surveillance and Monitoring System for substandard and falsified (SF) medical products

Advice on reporting a suspected SF medical product

If you suspect that you have an SF medical product or have suffered an adverse reaction which you believe was caused by a medical product you should consult a pharmacist or medical doctor and report the case to your National Medicines Regulatory Authority. The WHO global surveillance and monitoring system receive reports from trained focal points in the National Drug Regulatory Authorities and International procurement agencies who if necessary will forward your report to the WHO.

In emergencies please contact: rapidalert@who.int

WHO Medical Product Alerts

When a report of an SF medical product is received, WHO will seek to validate the report. In cases where there is a significant threat to public health, a wider geographic risk or where steps have not been taken to reduce the risks to patients, WHO will consider issuing a public medical products alert.

www.who.int/who-global-surveillance-and-monitoring-system

World Health Organization

Alert

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Acute kidney injury in children

Serious unexpected adverse reactions reported after treatment with over-the-counter cough and cold medications.

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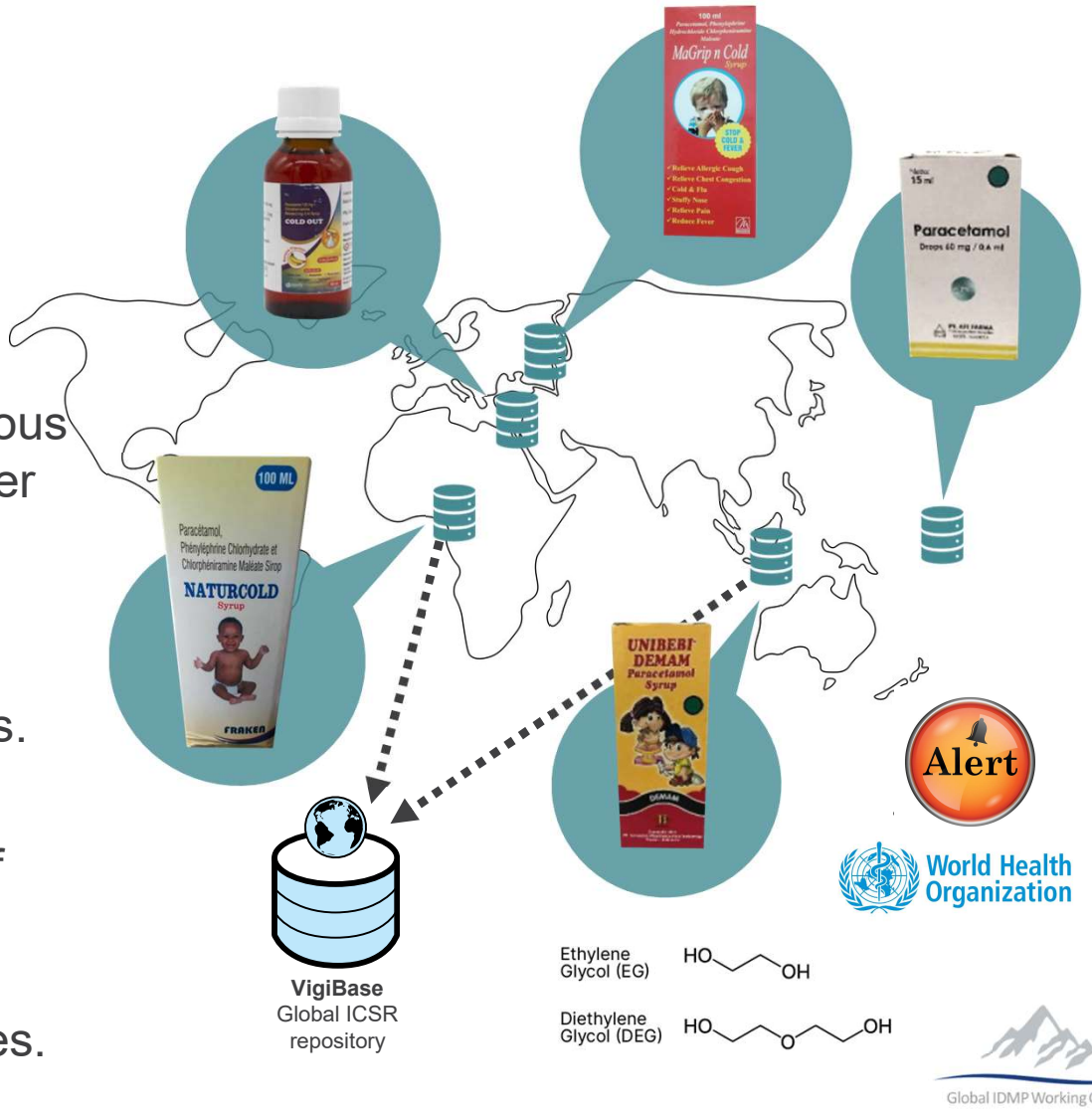
Substandard pediatric liquid dosage medicines cause fatalities

- As of January 2023, at least seven countries have reported unexpected serious incidents (adverse events) in children after treatment
  with over-the-counter cough and cold medications.
- More than 300 fatalities in three countries.
- Mostly children under the age of five.
- The investigation identified toxic levels of **diethylene glycol and ethylene glycol**, known
  to result in acute renal failure and fatalities.



Which products?

Over-the-counter cold medications with a variety of common ingredients

“Oral solution”, “syrup”, “drops”…

Paediatric strength/dosages

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What other regions could be affected?

While WHO Medical Product Alerts refer to specific batches of substandard (contaminated) products Identified in a specific country, these products may have marketing authorisations in other countries or regions, or may have been distributed through informal markets to other countries.

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The starting point for identifying what other regions could be affected

Alert

World Health Organization

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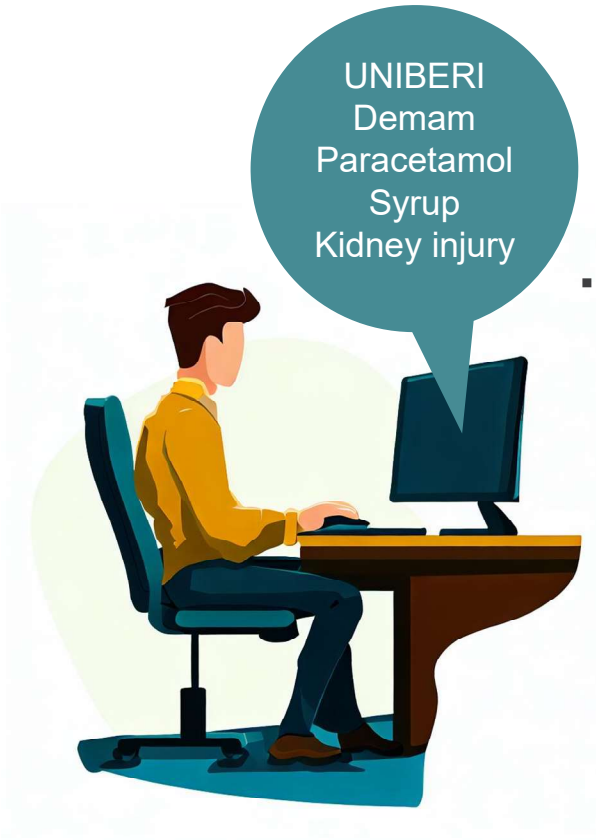
ICSR coding at national centres



VigiBase
Global ICSR repository

National centres code to regional standards

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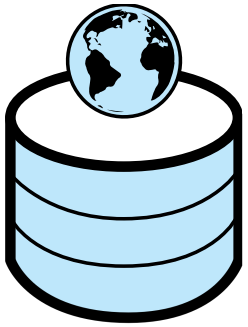
ICSR coding at national centres

WHODrug

MedDRA

Unibebi demam

Acute Kidney Injury



VigiBase
Global ICSR repository

National centres code to international standards

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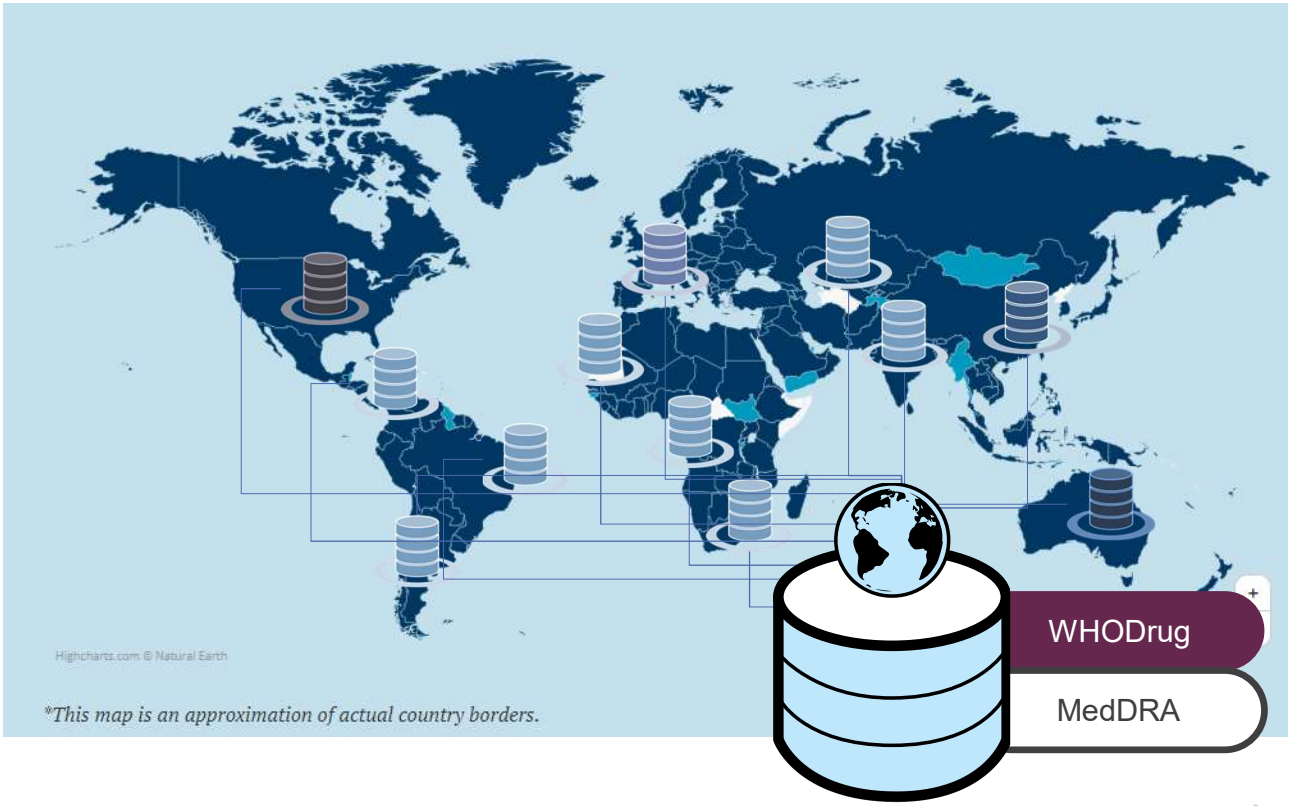
VigiBase basics

- National collection of ADRs and AEFI
- WHO PIDM collection in VigiBase is global with >36 million cases from 155 members
- National analysis, regional collaborations and global reference
- Statistical signal detection and method development
- Structure and coding
- Heterogeneity



MedDRA: Medical Dictionary for Regulatory Activities

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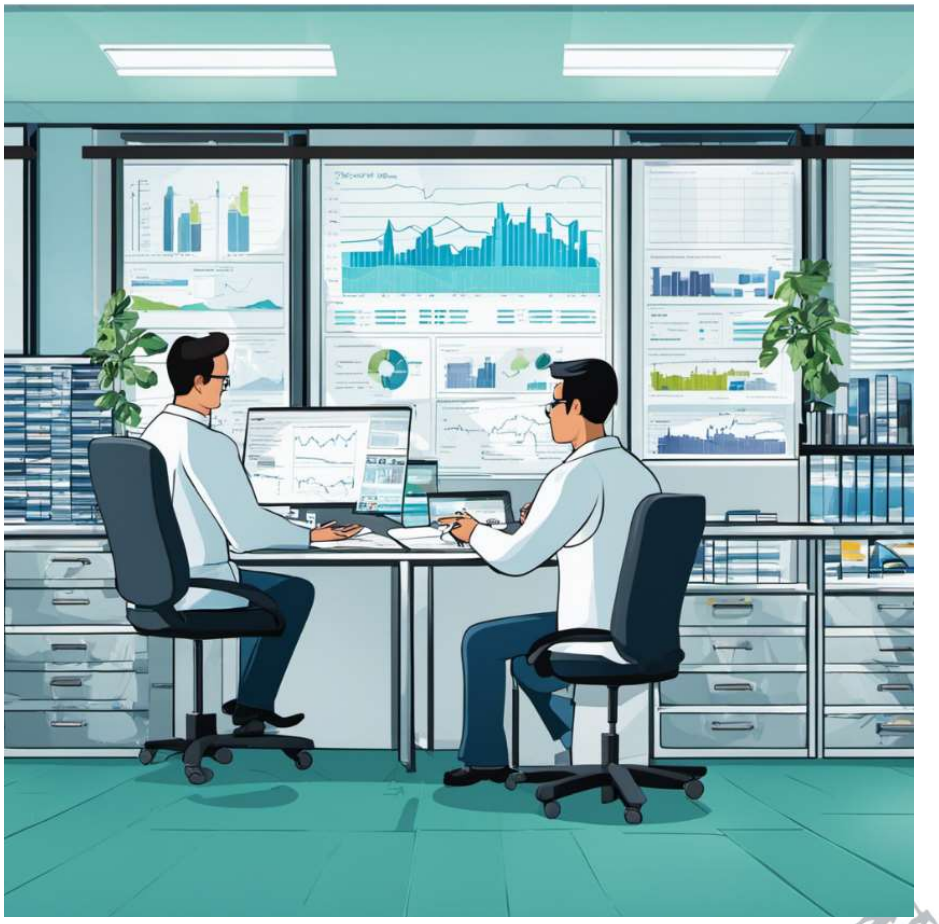
VigiBase data mining

Today, information on dose forms is not standardised in ICSRs.

Trade names are coded with WHODrug.

Retrieving relevant information is challenging and time consuming, especially in a database of over 36 million ICSRs.



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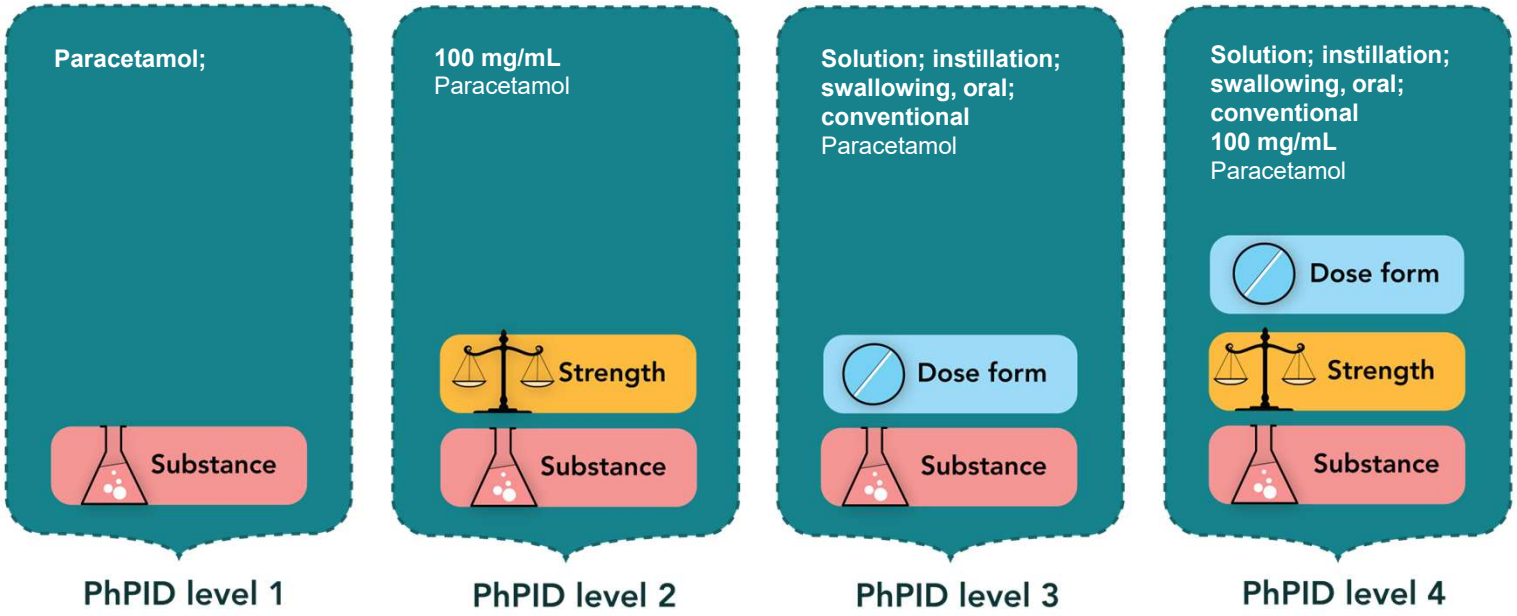
What if we had global PhPIDs?

If these products were assigned to global PhPID standards, each product name would automatically be linked to active ingredient, strength, dose form.



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Signalling with Global PhPID level 1

Alert on unexpected child fatalities after treatment with paracetamol in single and multi-ingredient products

Current alert
(without Global PhPID level 1) would likely
be weakened by different reported product names, necessitating further investigation to determine the active ingredient(s).

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Paracetamol-containing medicinal products globally

19635 rows

Export | CDG | Add Columns

Product Name B3	Drug Code	Active Ingredients	ATC	Country of Sales	MAH	Pharmaceutical Form	Strength
LITTLE FEVERS	000200 01 954	Paracetamol	**N02BE,** Anilides *official*	Puerto Rico • United States of America	Medtech • Medtech labs • Prestige brands • Vetco	LIQUIDS • LIQUIDS, DROPS	80 mg • 80 mg/ml
INFANTS LITTLE REMEDIES FOR FEVERS	000200 01 A0R	Paracetamol	**N02BE,** Anilides *official*	Canada	Prestige brands	LIQUIDS	80 mg/ml
ACETAMINOPHEN NAEWOE	000200 01 A3J	Paracetamol	**N02BE,** Anilides *official*	Korea (the Republic of)	Nae woi	TABLETS	80 mg
BUBDEL	000200 01 BK3	Paracetamol	**N02BE,** Anilides *official*	Taiwan (Province of China)	Winston	TABLETS	80 mg
CAUSALON [PARACETAMOL]	000200 01 212	Paracetamol	**N02BE,** Anilides *official*	Argentina	Phoenix	LIQUIDS • LIQUIDS, DROPS • SUPPOSITORIES, ADULT • TABLETS • TABLETS, CHEWABLE	80 mg
CHILDREN'S CHEWABLE ACETAMINOPHEN	000200 01 982	Paracetamol	**N02BE,** Anilides *official*	Canada	Vita health products inc	TABLETS, CHEWABLE	80 mg
CHILDRENS MAPAP	000200 01 AXR	Paracetamol	**N02BE,** Anilides *official*	Puerto Rico • United States of America	Major Pharmaceuticals	TABLETS, CHEWABLE	80 mg
CORIVER INFANTIL	000200 01 BBI	Paracetamol	**N02BE,** Anilides *official*	Mexico	Maver	TABLETS	80 mg

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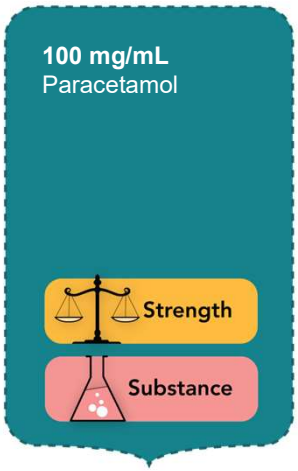
Signalling with Global PhPID level 2

Different expressions of strength from all around the world are captured in PhPID level 2



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Signalling with Global PhPID level 3

Global PhPID level 3 would enable identification of all medicinal products that share the same substance (paracetamol) and dose form (drops or syrup).

*products circled in blue: Solution; instillation; swallowing, oral; conventional
products circled in red: Suspension; swallowing, oral; conventional

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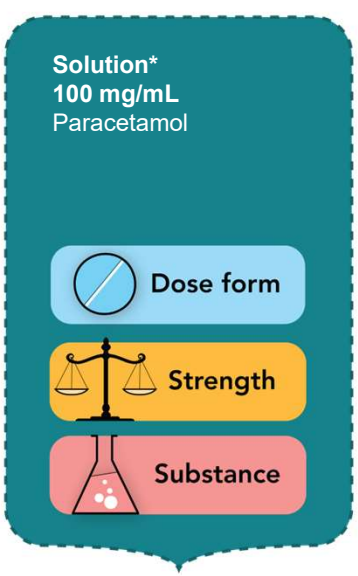
Signalling with Global PhPID level 4

Global PHPID level 4 uniquely identifies medicinal products that have the same active ingredient, dose form, and strength.



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How can global PhPIDs support the WHO Global Surveillance and Monitoring System for SF medical products?

- **Effective alert communication**
  Include global PhPID identifiers in alerts to strengthen regional pharmacovigilance. Regulators could in turn mine their databases using Global PhPID level 1, 2, 3 or 4 to retrieve relevant ICSRs.
  Similarly, the alert could be shared with healthcare professionals, such as paediatricians and pharmacists, dispensing over-the-counter products for children with the identifiers available in eDispensing and ePrescribing software systems.
- **Improved data mining**
  Aid mining of VigiBase or other pharmacovigilance databases for similar cases in regions where a contamination is not yet identified. Global PhPIDs can be used to identify similar medicinal products reported in combination with relevant adverse events such as acute kidney injury.
- **Quicker testing of suspect products**
  The use of Global PhPID level 3 or 4 would allow for more targeted testing of medicinal products if MAHs included global Identifiers in their medicinal products records.
- **Limitations**
  PhPID alone cannot identify contaminated products or be used for tracking manufacturing supply chains.

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Global PhPID take-home message

- Quicker and reliable signalling of rare adverse events
- Data analysis can be performed at different levels of granularity globally
- Real-time identification of unexpected serious adverse events/incidents in PV databases thanks to global standards
- Effective alert communication to stakeholders
- Immediate generation of accurate safety data for further investigation by regulators for evaluation and regulatory action

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Thank you

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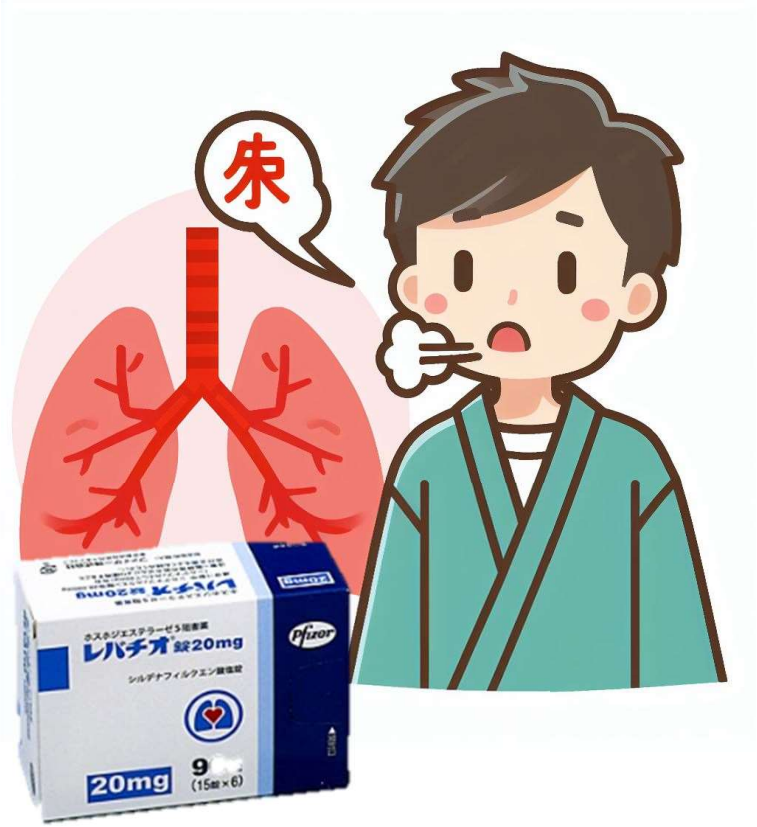
Showcase the value of global PhPID in cross-border healthcare

Therapy Compliance and Health Concerns



Please meet our Japanese friend Tanaka.

Tanaka is under a treatment regimen with レバチオ, a medication prescribed for his pulmonary arterial hypertension (PAH) condition.

His Japanese physician emphasizes the importance of **therapy compliance**.

Travel from Japan to USA

Tanaka embarks on an international journey from Japan to the United States, poised for his anticipated vacation.

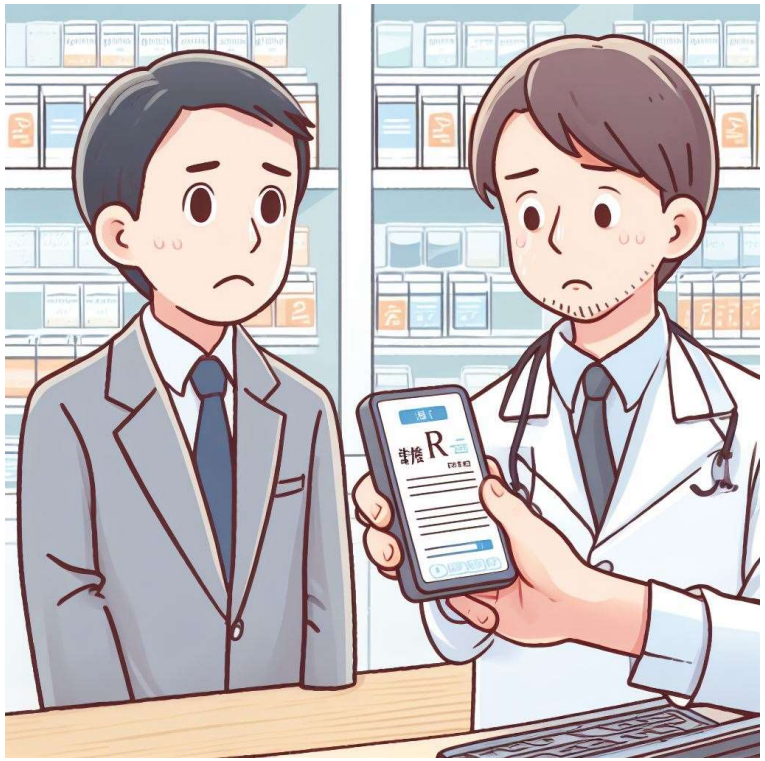
Forgotten Medication

Tanaka inadvertently forgets to carry an adequate medication supply for his three-week vacation in the United States.

Japanese ePrescription

Luckily, Tanaka can leverage a healthcare mobile app to access an electronic prescription for his medication, which he can presents to a U.S. pharmacist.

Challenge: Dispensing a foreign prescription in the US



There are only few pharmacies in the US that can dispense a foreign prescription.

The pharmacist in US cannot type the Japanese brand name in his own software system.

This provokes genuine concern over potential prescription misinterpretation and erroneous medication dispensation.

If we had a global PhPID

Global PhPID level 4 is luckily available in the Japanese prescription.

Tanaka now holds out the prescription confidently, a bridge between languages and cultures.

Therapy compliance is successfully ensured preserving patient's health.

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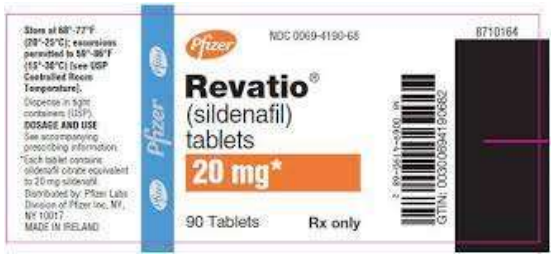
The value of PhPID in cross border healthcare

sildenafil
20mg
tablets

sildenafil
20mg
tablets



Global Phpid lvl 4

D934E701B1FF6B452828E1C6703B257E

Global PhPID level 4 is luckily available in the Japanese prescription.

This allows the American pharmacist to search in his own system for medicinal products US FDA approved in the US market that share the same PhPID level 4. Language is no longer a barrier.

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Global PhPID connecting the dots

Global PhPID level 4, connected to a global resource of medicinal products can help to identify medicinal products that are *equivalent to each other*

The PhPID becomes the medicinal product's "common denominator" from country-to-country

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End to end testing

Implementing this scenario

- The scenario has been tested as part of the HL7 FHIR Connectathon

- Our Japanese friend takes:
  - テグレトール, Tegretol 200mg, SJ214
  - Global PhPID is: FB9808F4FED210183F412F9998622287

- Get the US equivalents for テグレトール, Tegretol 200mg, SJ214
  - https://umc-ext-dev-phponfhirdemo-preview-rg01-webapp.azurewebsites.net/MedicinalProductDefinition?_has:AdminstrableProductDefinition:form-of:identifier=http://www.who-umc.org/phpid|FB9808F4FED210183F412F9998622287&name-country=USA
- Results (with NDC codes):
  - 51672-4005 Carbamazepine
  - 60505-0183 Carbamazepine

Implemented in HL7 FHIR

```
"resourceType": "Bundle",
"type": "searchset",

"entry": [
      "resourceType": "MedicinalProductDefinition",
       "identifier": [
                {
                 "system": "http://hl7.org/fhir/sid/ndc",
                 "value": "51672-4005"
                }
       "name": [
                  "productName": "CARBAMAZEPINE",
       "usage": [
              "country": {
                           "code": "USA"
```

Breaking down the API call

- https://umc-ext-dev-phponfhirdemo-preview-rg01-webapp.azurewebsites.net
- /MedicinalProductDefinition?
- _has:AdminstrableProductDefinition
- :form-of:identifier=
- http://www.who-umc.org/phpid|
- FB9808F4FED210183F412F9998622287
- &name-country=USA

What we have demonstrated

- We now have a FHIR service
- that will support the medication lookup
- based on the global PhPID of a medication
- as prescribed in a country of origin
- for equivalent medication in a particular target country
- resulting in a (list of) MPID(s)
- to be presented to the pharmacist.

Next steps

Guided by questions

In a perfect world, this would be easy

- Do we need to change the scenario?
  - “There are only few pharmacies in the US that can dispense a foreign prescription.”
  - Is a prescription the proper way forward?
  - Prescribing and dispensing are heavily regulated within each jurisdiction, with quite a few differences and incompatibilities between them
  - Bi-lateral legal agreements may be needed to enable cross-border eP/eD

- The UNICOM Demonstrator has a slightly different scenario
- The UNICOM Patient Facing Apps take yet another perspective

How do we truly test end-to-end?

- Do we engage the provider of *“a healthcare mobile app to access an electronic prescription for his medication”*
- Do we engage a provider of *“his own system for medicinal products”* that the pharmacist uses to search and dispense the medication
- Do we need to engage other system providers, like MPD providers?

Do we need visibility of the PhPID?

- Our HL7 FHIR Connectathon scenario was a bit more elaborate:
  - Submit to the PhPID maintenance organization(s) (e.g. Uppsala WHO UMC)
    - country of origin MPID, or
    - Substance, Administrable Dose form, Strength or
    - **PhPID** (covered as part of the country of origin MPID in the first sub-bullet)
    - plus the **target country** (supported by the maintenance organization) (covered in the first sub-bullet)
  - Receive a list of Medical Products (MP) for the target jurisdiction

- We also had discussions on whether to include the PhPID in:
  - The electronic Product Information (ePI/SPL)
  - The medication summary data block of the International Patient Summary

What is the best use of the ePI

- In the HL7 FHIR Connectathon we have demonstrated the link between ePI and SPL (through the MPID and global PhPID lookup).
- However, the need to access a different language ePI could be strengthened:
  - New medication prescribed for Tanaka in US, but he needs to read the information in Japanese to properly understand the details
  - This also enables the use of the G-Lens from the Gravitate Health project* in Japanese on US-prescribed medication, highlighting the relevant sections of the ePI

* The HL7 FHIR Connectathon Track was organised as part of the Vulcan Accelerator, with Gravitate Health and UNICOM projects supporting

More extensive patient safety

- Would a scenario including cross-border hospitalization make sense?
  - The country of origin medication is key in safely treating a patient in a cross-border situation
  - That is why the Medication Summary is mandatory in the International Patient Summary
  - How do we make sure that the clinicians can introduce the medication list into their Electronic Health Record Systems to guide their processes?

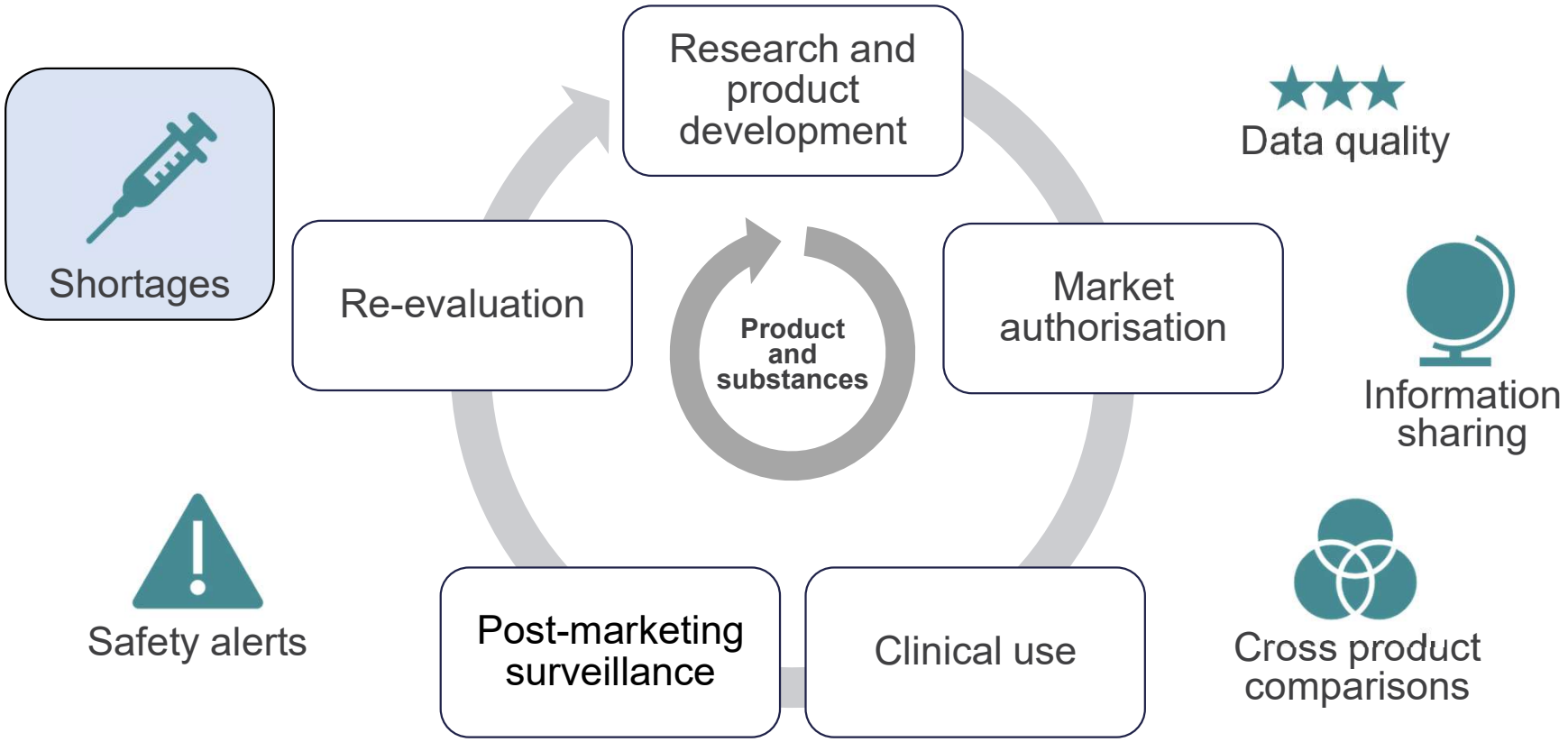
Next HL7 FHIR Connectathon

- 16-18 January 2024
  - HL7 Europe FHIR Connectathon – Athens
  - Virtual HL7 FHIR Connectation
  - Vulcan/Gravitate Health/UNICOM will continue their work

- What would GIDWG like to be tested here related to the cross-border use case?

Thank you

Benefits of IDMP in the medicinal product life cycle



Cisplatin shortage in the U.S.

Global PhPIDs increase the speed and systemisation of identification of foreign substitutes

Manufacturing demand outstrips FDA approved cisplatin suppliers

A quality-related manufacturing halt at one of the primary production facilities for cisplatin with a US FDA approval causes a ripple effect[1,2].

Other approved marketing authorisation holders (MAHs) are unable to meet the demand for this product.

Global IDMP Working Group

Regulatory agencies informed of cisplatin shortage

MAHs notify regulatory agencies of the shortage.

Regulators cannot require MAHs to increase production of a drug to meet demand.

Global IDMP Working Group

Cisplatin shortage investigated

Initial outreach to approved/pending US application holders.

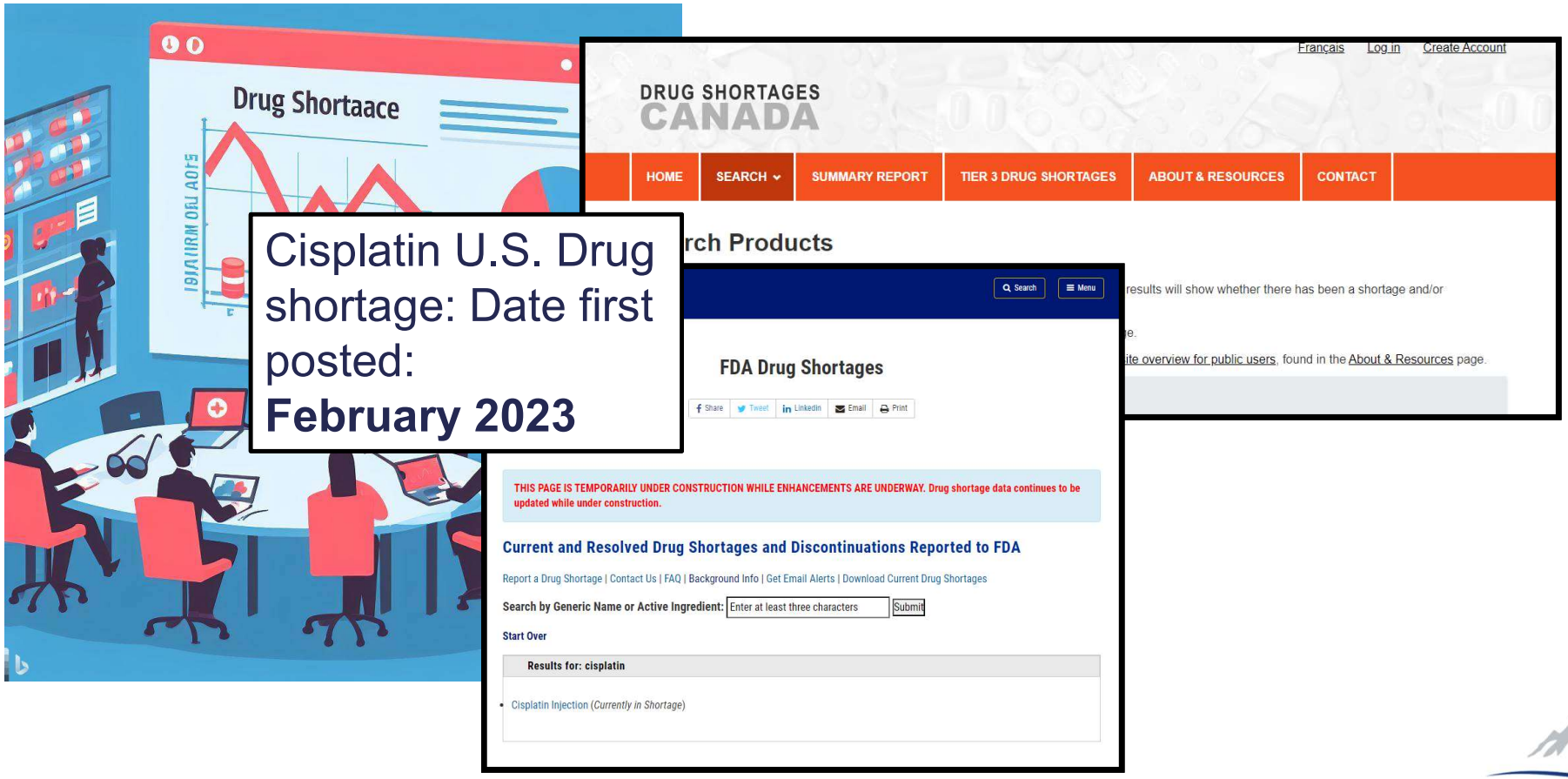
Outreach to other international jurisdictions.

3 potential non-US sources identified.

Challenges:

- ✓Quantity available
- ✓Different strength
- ✓Lack of prospective US distributors
- ✓Time for proposal submission

Shortage communicated to stakeholders



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Cancer patient unable to start therapy

Stage 3 cancer patient informed by his doctor that he will not be able to commence treatment with cisplatin due to an ongoing shortage.

70% of healthcare centres acknowledged a shortage of cisplatin[3].

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Impact of cisplatin shortage

The cisplatin shortage potentially affects **100,000-500,000 patients** annually[2].

Consequences may include treatment delays, dose adjustments, and transitions to alternative therapies. Such alterations increase the risk of medication errors and adverse events[4].

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Challenges and time delay in finding an alternative

Regulatory action is prompt.

However, identification of foreign substitutes is challenging and **time** consuming.

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Lack of a global resource

A comprehensive evaluation of available cisplatin products proves challenging due to the lack of a global resource containing information about equivalent medicinal products harmonised with global identifiers.

Drug alternatives and foreign labelling/packaging

The announcement of the temporary importation of non-US labelled Cisplatin Injection, occurring four months later in **May 2023**, offers a potential solution[5].

The medicinal product, Cisplatin Injection (50mg/50ml), is manufactured by Qilu Pharmaceutical Co Ltd in China[6].

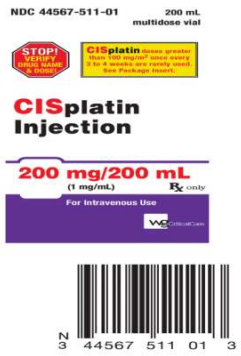
IMPORTANT PRESCRIBING INFORMATION

May 24, 2023

Subject: Temporary Importation of CISplatin Injection with non-U.S. Labeling to Address Drug Shortage

Dear Healthcare Professional,

Due to the critical shortage of CISplatin Injection in the United States (U.S.), Qilu

	U.S. FDA Approved Product	Imported Product
Carton Labeling		

Healthcare professionals notified

A Dear Healthcare letter is sent out to relevant stakeholders, explaining labelling and packaging distinctions[5].

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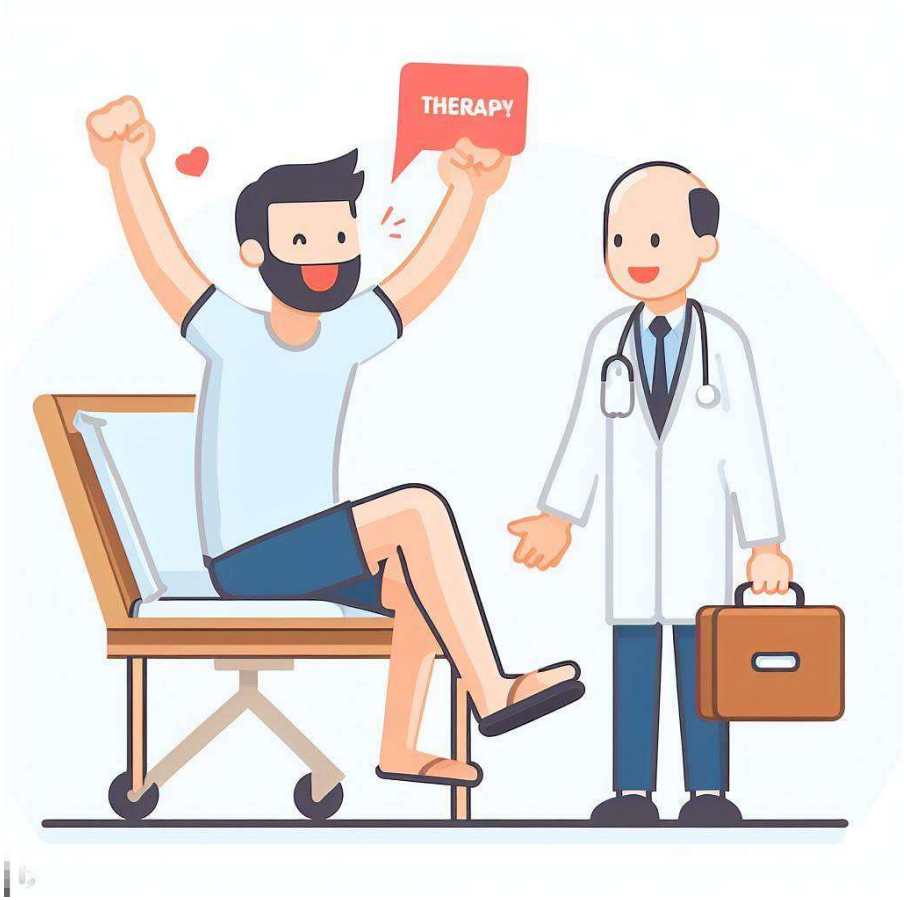

Start of patient therapy

Following these developments, patients, doctors, pharmacists, and healthcare centres are now equipped to access the necessary medication.

The cancer patient can finally begin therapy.

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What if we had global PhPID?

Connected to a global resource of medicinal products, global PhPID level 4 can help to identify medicinal products that are *equivalent to each other.*

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The value of global PhPID in drug shortages

USA Shortage

Cisplatin
1 mg/ml
Concentrate for
Solution for
infusion

China

顺铂注射液
50ml:50mg

Global PhPID level 4

D934E701B1FF6B452828E1C6703B257E

Substance	Strength	Basic Dose Form	Administration method	Intended site	Release characteristics
Cisplatin	1mg/ml	Solution	Injection	Parenteral	Conventional

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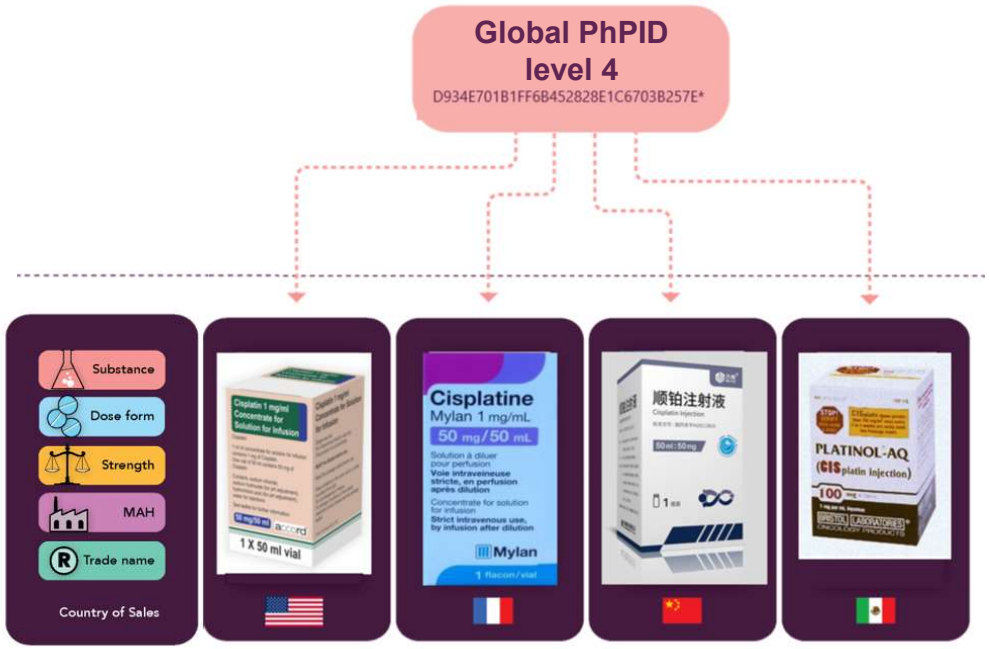

The added value of global PhPID

Initial identification stages.

Drug shortages staff need to know who is **currently marketing** a medicinal product.

Global PhPID can be useful in identifying non-US product sources to assist with drug shortages.

The added value of global PhPID cont.

Save days to weeks finding a substitute

Unbiased and instant identification of equivalent medicinal products allows drug shortages staff to invest their time more efficiently for patient's benefit.

Prevent harm to patients

100,000 patients annually would potentially benefit from uninterrupted access to life-saving medicine[2]. By eliminating the need for alternative regimens, the risk of medication errors and patient harm stemming from less familiar or less safe treatments can be mitigated.

Better use of resources

Staff hours allocated to managing oncology drug shortages at healthcare facilities can be reduced or used elsewhere.

Limitations

Global PhPIDs must be connected to medicinal product information and related marketing status.

References

1. Cisplatin U.S. Drug shortage. Date first posted: 02/10/2023 https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Cisplatin%20Injection&st=c
2. Julie R. Gralow, Chief Medical Officer & Executive Vice President, Association for Clinical Oncology testimony to congress. https://cancerletter.com/the-cancer-letter/20230526_2/ https://d1dth6e84htgma.cloudfront.net/Julie_Gralow_Witness_Testimony_06_13_23_7d56adc776.pdf?updated_at=2023-06-12T15:59:08.173Z
3. Survey by the National Comprehensive Cancer Network: https://www.nccn.org/docs/default-source/oncology-policy-program/NCCN-Drug-Shortage-Survey.pdf
4. National survey on the effect of oncology drug shortages on cancer care, McBride et all, 2013 https://academic.oup.com/ajhp/article-abstract/70/7/609/5112445?redirectedFrom=fulltext&login=false
5. Temporary Importation of CISplatin Injection with non-U.S. Labeling to Address Drug Shortage: https://www.fda.gov/media/168657/download
6. Qilu Pharmaceutical cisplatin product: https://www.qilu-pharma.com/products_details/9758137247175393 28.html

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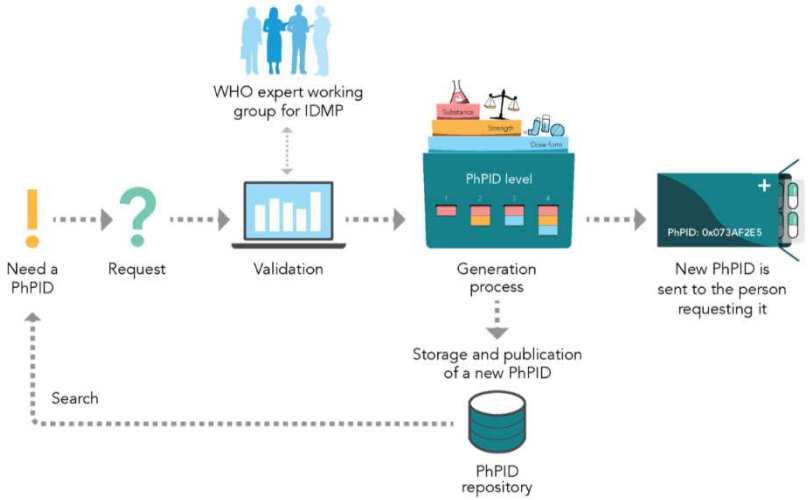
End-to-End Demonstration Q4 2023

Testing to demonstrate the use cases for GSID/PhPID operating model

SCOPE:

- Validate and generate PhPIDs for products based on the GIDWG/EWG business rules
- EDQM + non-EDQM countries
- Similar products from different countries
- Larger batches & smaller **data sets** for regulators
- Validated Data Sets based on **150 substances** including Chemicals, Biosimilars, Polymers, Nucleic Acids, Structure Divers, 'Mixtures'



Proposed candidate countries:

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Special interest to Drug Shortage Staff, examples

- Amoxicillin Powder, For Suspension
- Carboplatin Injection, Solution
- Methotrexate Sodium Injection, Solution
- Methotrexate Sodium Tablet
- Vinblastine Sulfate Injection
- nitroglycerin spray

Next steps

- Test value of global PhPID in drug shortages:
  - Medicinal products data sets from different regions are key for the test
  - Data sets are based on substances of special interest for drug shortages staff from different countries (included in substance list in E2E);
  - Identify similar medicinal products based on PhPID level 4 nationally and across regions.
  - Locate country of sales and MAHs information for identified similar medicinal products

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Medicine shortages management at EMA

Presented by Sofia Zastavnik, ESMP Product Owner
Supply and Availability of Medicines and Devices, EMA

How does the EU manage shortages?

EUROPEAN MEDICINES AGENCY

Improving the availability of medicines authorised in the EU is a key priority for the **European Medicines Regulatory Agencies**

Regulatory authorities - within and outside Europe - are increasingly **working together** to prevent shortages and to limit their impact whenever they occur

In December 2016, a joint **HMA/EMA Task Force on the Availability of Authorised Medicines for Human and Veterinary Use (TF-AAM)** was established to:

- provide **strategic support** and advice to tackle disruptions in supply of human and veterinary medicines and ensure their continued availability

Monitoring and mitigating shortages of medicines and management of public health emergencies/major events

EUROPEAN MEDICINES AGENCY

Regulation (EU) 2022/123

Provides a framework for activities established by the European Medicines Agency to monitor and **mitigate potential and actual shortages of medicines**

Sets **processes/tools for shortages reporting** and coordinates **responses** of EU countries to shortages of critical medicines (during a crisis) and for monitoring of events, including medicine shortages, which might lead to a crisis situation

Establishes "**Medicines Shortages Steering Group**" (MSSG) supported by the **SPOC Working Party** and a Network of contact points from pharmaceutical companies (i-SPOCs)

Foresees the development of the **European Shortages Monitoring Platform** (ESMP) by Feb 2025

KEY BENEFIT

More coordination in preventing and mitigating medicines shortages in the EU

The European Shortages Monitoring Platform (ESMP)

EUROPEAN MEDICINES AGENCY

Implementation date: **2 February 2025 ***

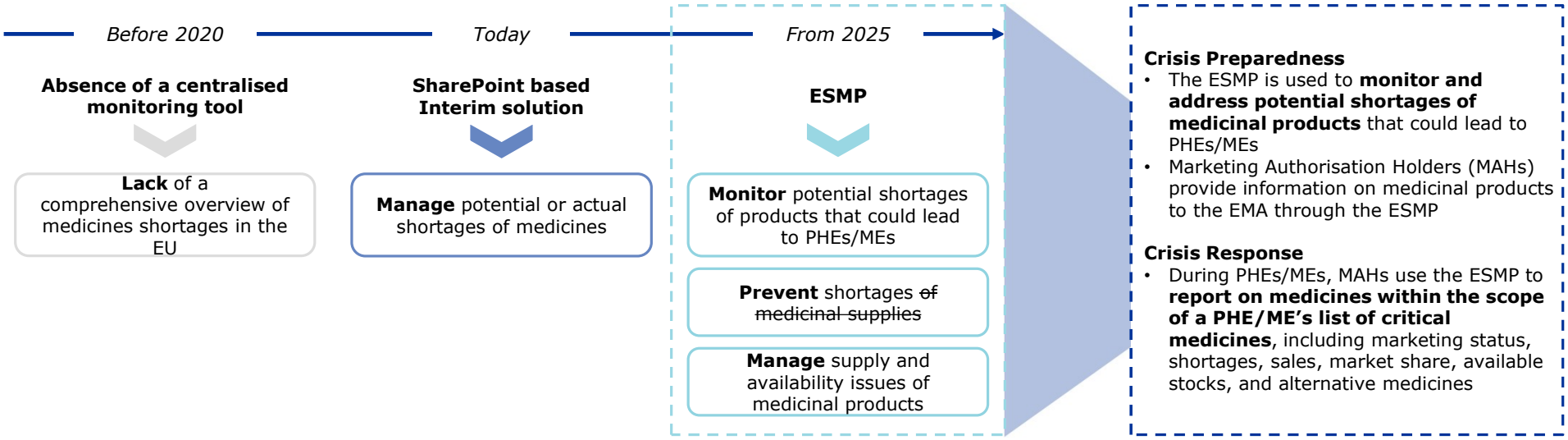
Article 13 of Regulation 2022/123 foresees the development of an **IT platform** to facilitate collection of information on **shortages**, **supply** and **demand** for medicinal products, including information on marketing status and marketing cessations, from both Industry's and Member States' SPOCs

Scope: monitoring, prevention and management

- Crisis: Shortages of medicinal products (within the scope of the relevant list of **critical** medicines) during a **PHE or a major event**
- Preparedness: Actual and/or potential medicines shortages (in a given Member State), that **can lead to** a Major event or a PHE

KEY BENEFIT

Providing a centralised EU platform to report, monitor, prevent and manage medicine shortages



**Reporting obligations for MAHs/NCAs apply immediately (day 31) and according to Art 9 the Agency needs to develop IT streamlined tools to address the requirements of Articles 4, 7, 8 and 9 swiftly and earlier than Feb 2025*

Discussion

Thank you

Global IDMP Working Group

Wrap up of the break-out sessions.

Presentations by Regulators & Industry

Substances at NoMA

Present and future

Bjørg Overby, Senior adviser and pharmacist

Norwegian Medicines Agency

Present solution for Substance database

- Someone at NoMA enters a temporary term
  - English term
  - Norwegian term – often same as English
  - Active substance and/or excipient
- Three experts can complete the substance, verify and set valid for use
  - Valid in SPOR if found in SMS (by IRIS) and/or GSRS
  - Valid internally if found OK in any other database or SPC
  - Valid only for unauthorised products
  - Valid NLS (Ph. Eur.) when there is a mongraph in Ph. Eur..

  - https://iris.ema.europa.eu/substances/
  - https://gsrs.ncats.nih.gov/ginas/app/beta/

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How to gather all information (so far)

- The public view of substances in IRIS, provided be EMA
  - Correct English term and SMS ID
  - Substance type
- GSRS
  - UNII
  - MW
  - Verify substance type
  - Verify substance name according to structure – if chemical
- Translation rules at NoMA
  - Procedure on how to translate as standardised «Norsk språk»

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How to gather all information – New

- The public view of substances in IRIS, provided be EMA
  - Correct English term and SI[illegible]
  - Substance type
- GSRS
  - UNII
  - MW
  - Verify substance type
  - Verify substance name according to structure – if chemical
- Translation rules at NoMA

EU-SRS

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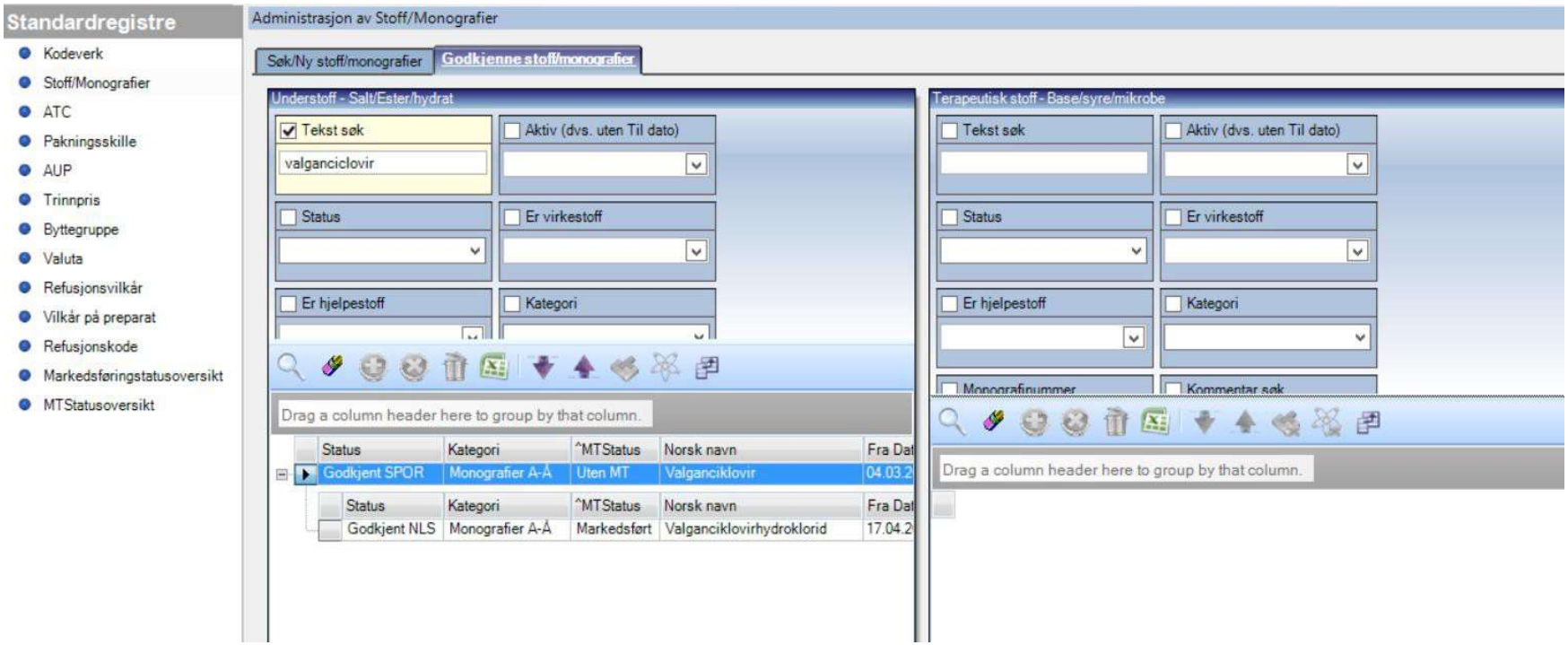
Athene; substance validation entry



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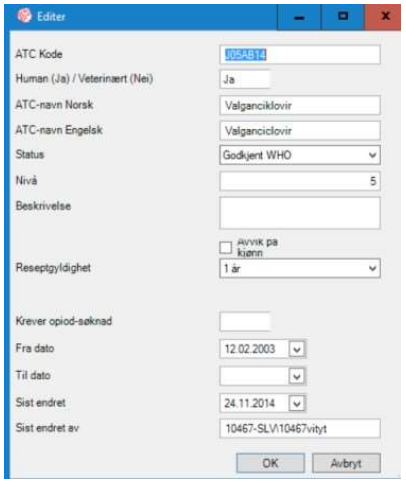
Present solution for ATC codes

- Manually copied from the web sites at WHOCC
  - https://www.whocc.no/lists_of___temporary_atc_ddds_and_alterations/new_atc_5th_levels/
- Translated in accordance with substances
- Temporarily during the year
- Verified by the end of the year and manually changed to Valid.

Status	ATC kode	Nivå	Huma	ATC navn norsk	ATC navn engelsk	Fra dato	Til dato
Godkjent WHO	J05	2	Hum	Antivirale midler til syste..	Antivirals for systemic u..	08.02.2002	
Godkjent WHO	J05A	3	Hum	Direktevirkende antiviral..	Direct acting antivirals	08.02.2002	
Godkjent WHO	J05AA	4	Hum	Tiosemikarbazoner	Thiosemicarbazones	08.02.2002	
Godkjent WHO	J05AA01	5	Hum	Metisazon	Metisazone	08.02.2002	
Godkjent WHO	J05AB	4	Hum	Nukleosider og nukleoti..	Nucleosides and nucleo..	08.02.2002	
Godkjent WHO	J05AB01	5	Hum	Aciklovir	Aciclovir	08.02.2002	
Godkjent WHO	J05AB02	5	Hum	Idoksuridin	Idoxuridine	08.02.2002	
Godkjent WHO	J05AB03	5	Hum	Vidarabin	Vidarabine	08.02.2002	
Godkjent WHO	J05AB06	5	Hum	Ganciklovir	Ganciclovir	08.02.2002	
Godkjent WHO	J05AB09	5	Hum	Famciklovir	Famciclovir	08.02.2002	
Godkjent WHO	J05AB11	5	Hum	Valaciklovir	Valaciclovir	08.02.2002	
Godkjent WHO	J05AB12	5	Hum	Cidofovir	Cidofovir	08.02.2002	
Godkjent WHO	J05AB13	5	Hum	Penciklovir	Penciclovir	08.02.2002	
Godkjent WHO	J05AB14	5	Hum	Valganciklovir	Valganciclovir	12.02.2003	
Godkjent WHO	J05AB15	5	Hum	Brivudin	Brivudine	04.03.2007	
Godkjent WHO	J05AB16	5	Hum	Remdesivir	Remdesivir	22.07.2020	



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Solution in SAFEST – in Dynamics

- Pt – need to gather same information into Athene,
  - both substances and ATC codes
  - updated to Dynamics each night
- Regular relationship, no need for actions
- Relationships Prodrug vs active moiety
- Contrast media – substance wher iodine is incorporated in structure
- Relationships between ATC code and substances
  - Only single codes, not combinations
- Substances – SAFEST

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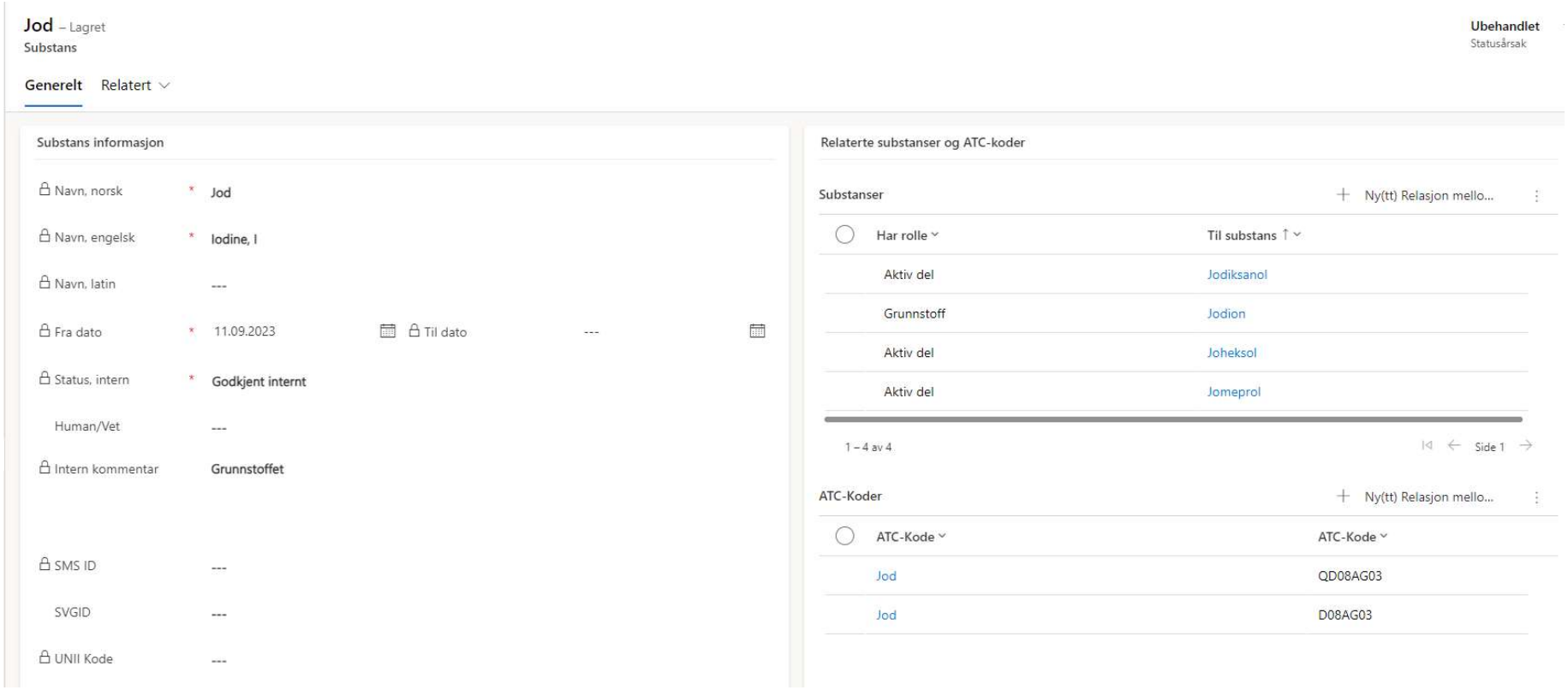
Iodine for contrast media



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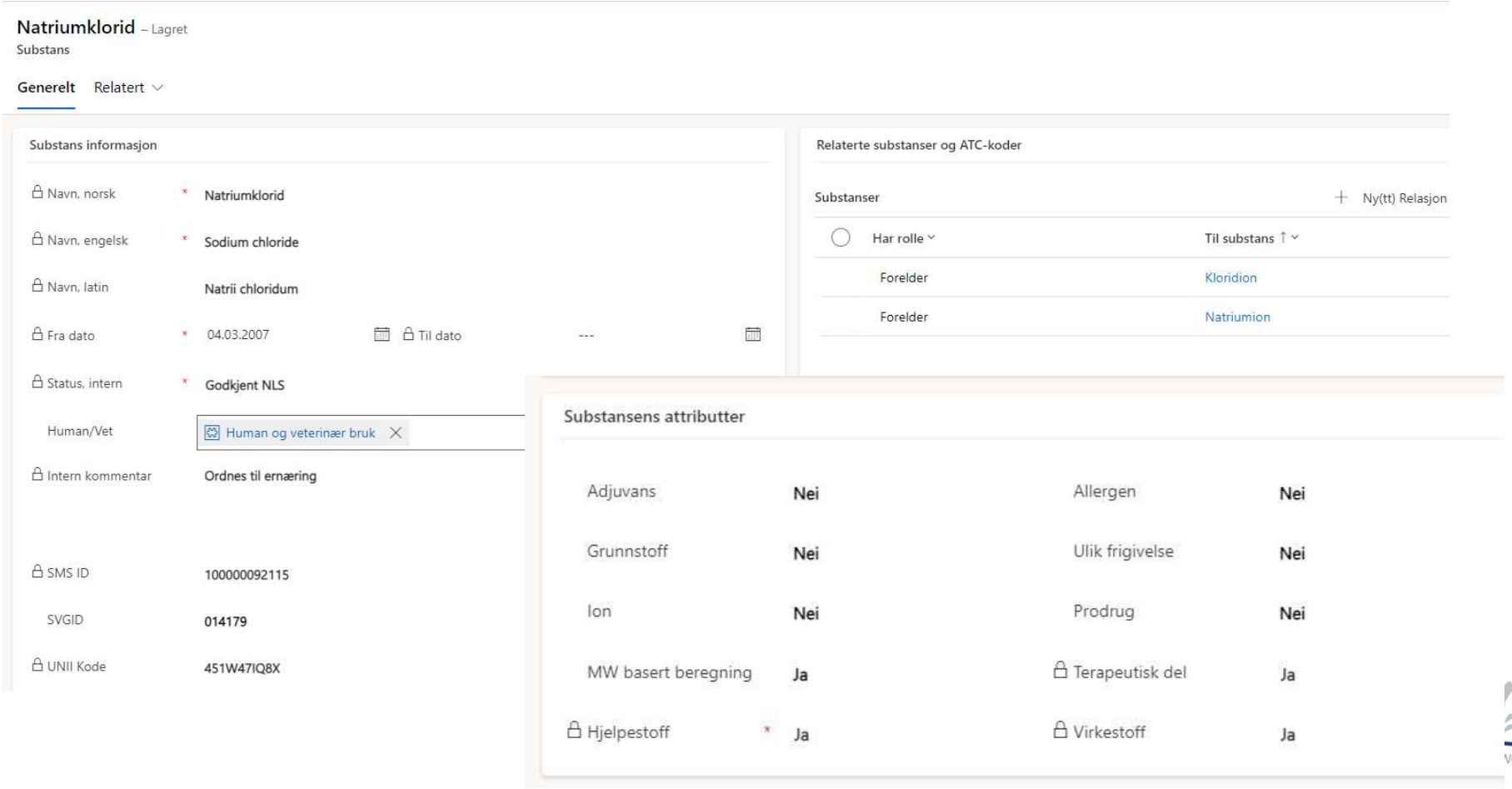
Sodium chloride & use of ions



New features

- New attributes which we missed previous
  - Complex
  - To be used for e.g., Sacubitril valsartan sodium hydrate
- New roles for relationships
  - Complex
  - Biosimilar
  - Infraspecific (forgotten previously)
  - SSG1

Synonyms vs Alias

- We use Synonym as the Norwegian term for Alias in SRS.
- No duplicats when comes to terms
- Need for different names for ions used in Nutrition, would be same as chemical elements.
- Solution is to publish two different fields to be used externally.
- Sodium – Sodium ion = Sodium as alias in new field, **Automatically generated.**

noma.no

Norwegian
Medicines Agency

swissmedic

GIDWG Stakeholder Meeting

Philipp Weyermann

17.10.2023

Schweizerisches Heilmittelinstitut
Institut suisse des produits thérapeutiques
Istituto svizzero per gli agenti terapeutici
Swiss Agency for Therapeutic Products

Hallerstrasse 7, 3012 Bern
www.swissmedic.ch

Overview

Digital Transformation and IDMP

Swissmedic's approach to IDMP implementation

Current status

Digital Transformation at Swissmedic

Excerpt strategic objectives 2023 – 2026 Swissmedic

- «Swissmedic uses state-of-the-art digital technologies»
  - Swissmedic has the technological capabilities required to **collaborate** with the therapeutic products industry, other authorities and other countries **on a data-focused basis**. It operates a modern enterprise information management system. The working infrastructure consists of a sensible combination of private and public clouds. The open data architecture and structure are **compatible with national and international standards**. Artificial intelligence in the form of machine learning or natural-language processing is deployed wherever this is sensible. The implemented data protection and information security measures and business continuity management ensure the integrity, legal conformity and availability of data.

Strategic objectives (swissmedic.ch)

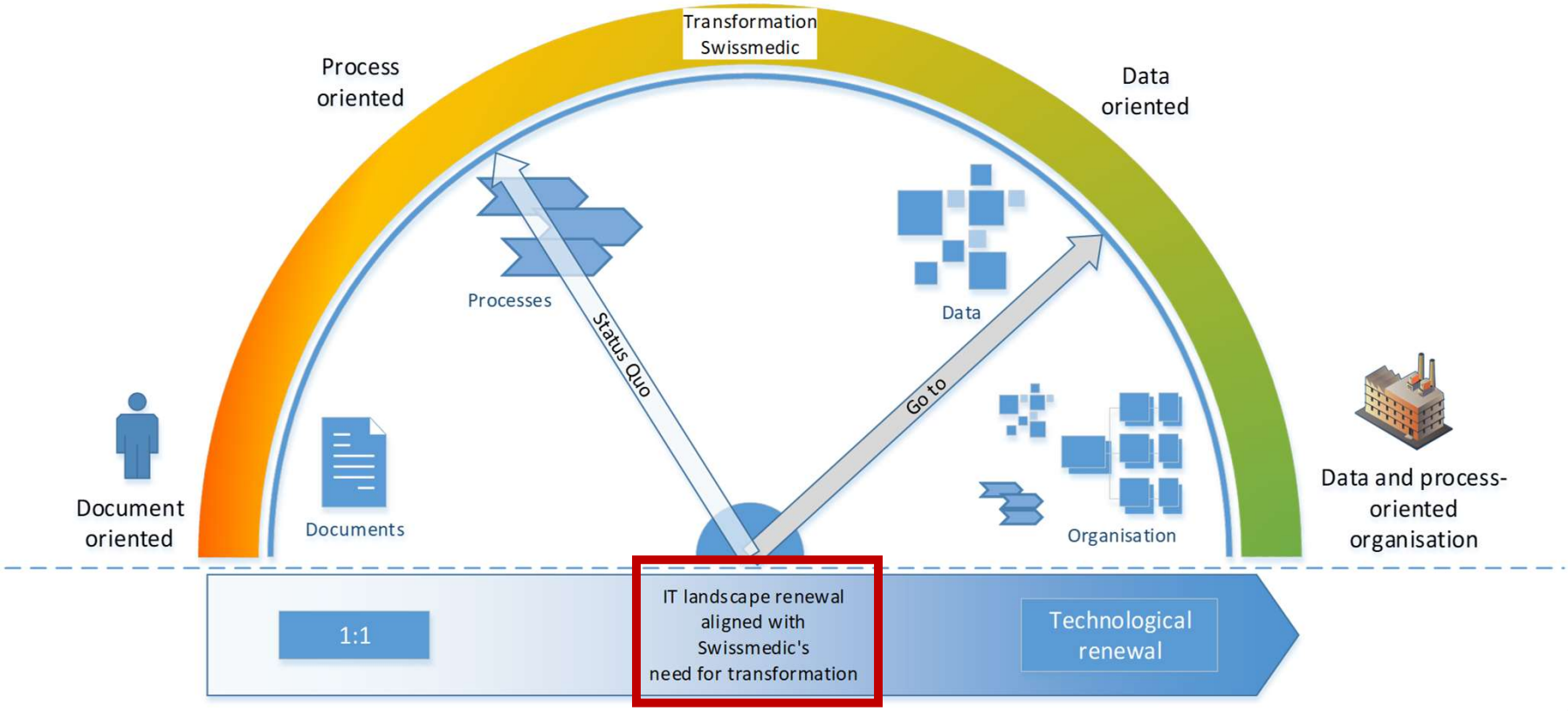
Digital Transformation at Swissmedic

Excerpt strategic objectives 2023 – 2026 Swissmedic

- «Swissmedic is an agile and data-focused authority»
  - Swissmedic is a knowledge-based organisation well-versed in the wide variety of scientific and regulatory disciplines found in the therapeutic products sector. A continuous exchange and processing of analogue and digital information form the basis of and are the precondition for Swissmedic's ability to perform. The use of new digital technologies means that far more data from a variety of sources are available and can be networked. Swissmedic supports the **interoperability of data and standards** in the Swiss healthcare system and in international collaboration with authorities and organisations. Work processes are digitally transformed and data-driven. Swissmedic promotes its employees' digital skills and assists them in working with innovative new business models and ways of thinking.

Strategic objectives (swissmedic.ch)

Digital Transformation of the Swissmedic Platforms



Digital Transformation of the Swissmedic Platforms

From an automated organisation…

Data Center

Silos

Process-Driven

Project-Driven Technology Decisions

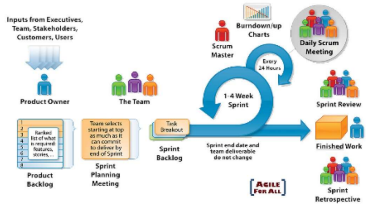
IT Organisation Focused on Operations

IT Target Operating Model and Technology Change

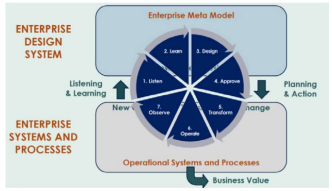
Competence Building

Cultural Change

…towards a digital organisation



Agile Product Development



Continuous Change

Cloud Computing

Platform Economy

Data-Driven

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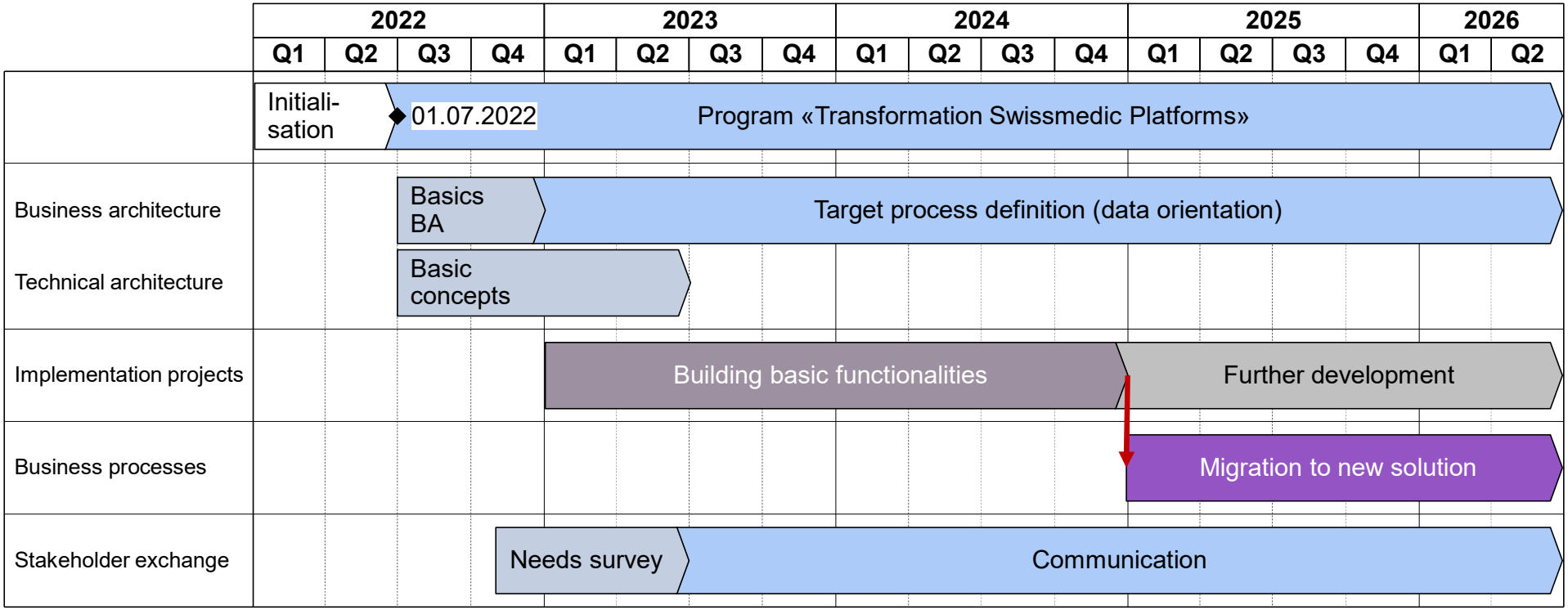
Digital Transformation of the Swissmedic Platforms

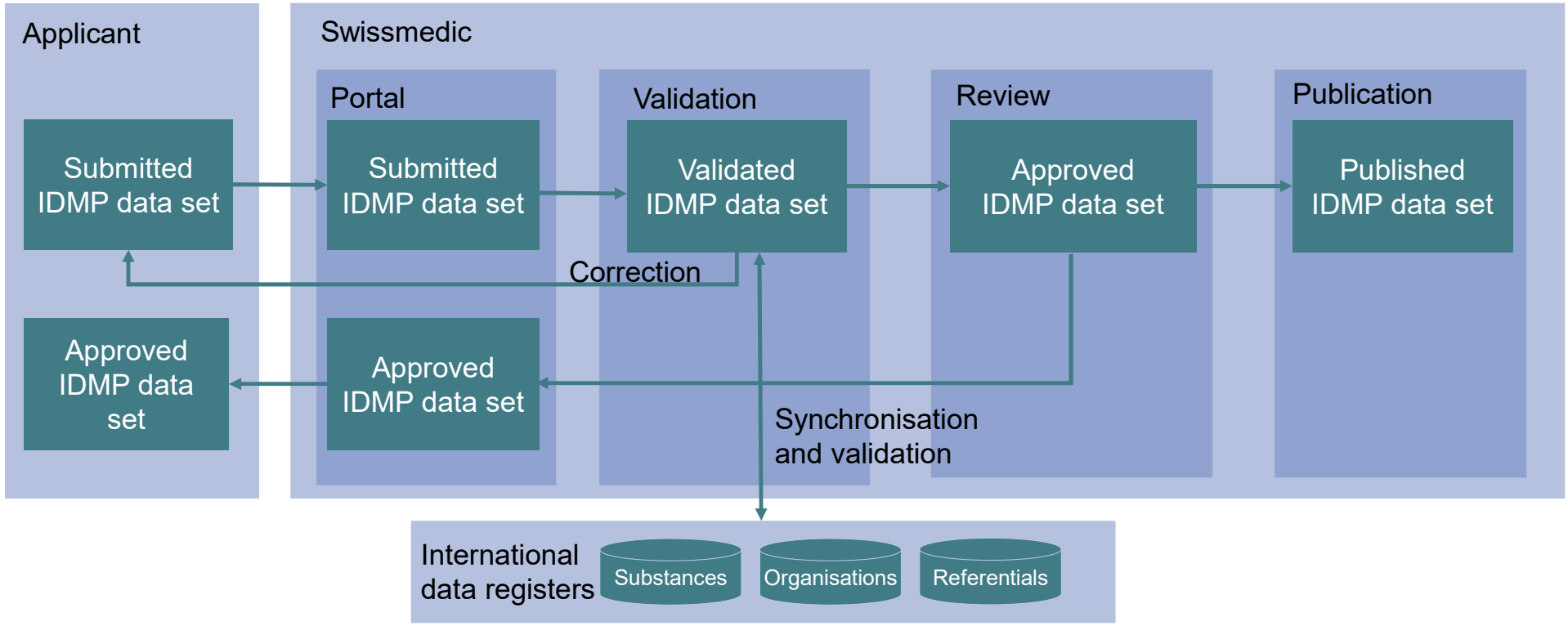


IDMP as part of the digital transformation of Swissmedic

- Implications of the IDMP implementation at Swissmedic
  - External and internal interface for medicinal product data
  - Marketing authorisation holders will be able to view their data in the future
  - Exchange/synchronisation with international databases (e.g. for substances, referentials)

- No “isolated” implementation of IDMP at Swissmedic
  - Exchange of data via portal as part of the application process
  - Electronic application forms for capturing IDMP data
  - Electronic patient and professional information as a later use case

Structured Data with IDMP (Product Data)



Overview

Digital Transformation and IDMP

Swissmedic's approach to IDMP implementation

Current status

Swissmedic's approach to IDMP implementation

- There is no IDMP legislation in Switzerland.
  But: (electronic) Application forms will require IDMP-compliant data somewhen in the future

- Only data used in day-to-day business will be required
- Introduction of the 1st iteration in coordination with an eAF
- The current scope of data is based on CH Module 1

- Intention to be close to the EU implementation
- Swiss IDMP Implementation Guide will be necessary

Networking & Collaboration

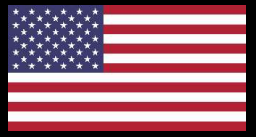
- Swissmedic is active in both international and national bodies

- Our intentions:
  - High compatibility, harmonised implementation
  - Connection to international databases
  - Building our solution on existing experience

→ Representation and contribution in specific bodies

→ Formation of a dedicated IDMP body for the specific needs of Swissmedic and its stakeholders

Overview of IDMP-related Organisations

				
Standardisation Organisations	**SNV NK 165** HL7 Switzerland	**CEN TC 251** HL7 Europe	ANSI HL7	**ISO TC 215** HL7 International
Implementation Groups	**SMC IDMP Advisory Group** **Refdata IDMP User Group**	**EU IDMP Task Force** EU IDMP Key User Group UNICOM HMA SVG	FDA SRS **NCATS GSRS**	**IPRP IDMP WG** **GIDWG** Pistoia Alliance **CTADHL** **IRISS Forum**

Overview

Digital Transformation and IDMP

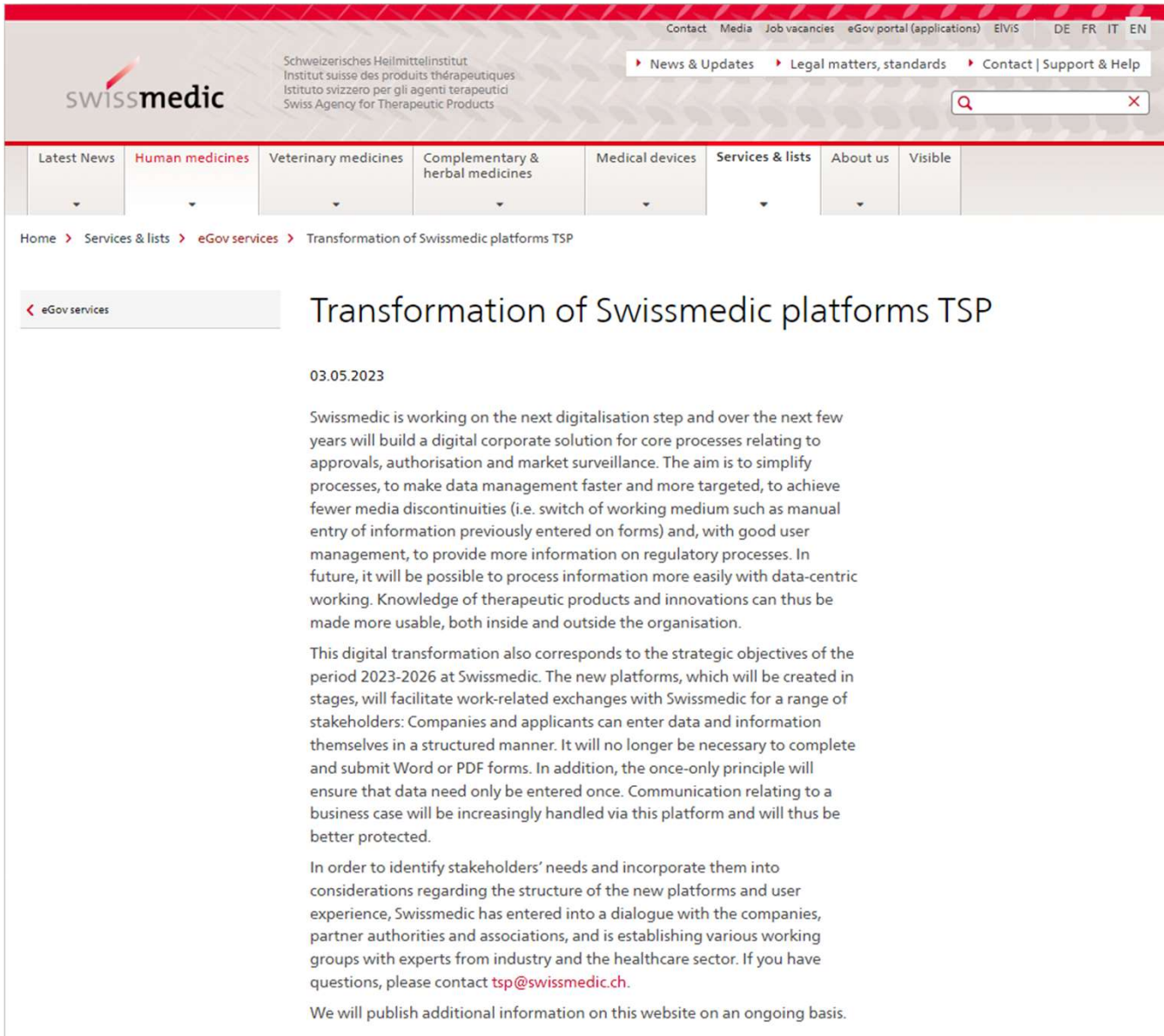
Swissmedic's approach to IDMP implementation

Current status

Current Status

[Homepage TSP]

First project started in 2023 (but that does not involve medicinal products and does not deal with IDMP yet)



Efforts towards implementation IDMP

- Dose forms – migrated to EDQM Standard Terms in 2013 (still ongoing)
- Substances – mapping to UNII since 2014 (ongoing, ca. 70% are mapped)

- OMS-ID's for Swiss organizations with an establishment license – since 2022 (ongoing)

- Website on IDMP @ Swissmedic should go live soon

FDA Regional Standards and the approach to harmonize with Global IDMP Implementation

Ron Fitzmartin, PhD, MBA
Center for Biologics Evaluation and Research

Ta-Jen Chen
Center for Drug Evaluation and Research

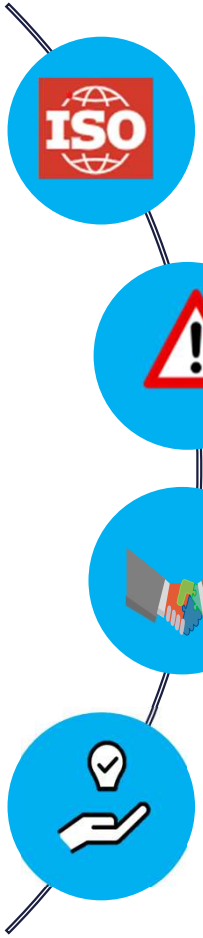
Oct 17, 2023

Topics

- FDA IDMP Roadmap to IDMP Implementation
- FDA Guidance: IDMP – Implementation and Use
- Current/existing standards used by FDA & in US
- FDA approach to Global IDMP Implementation

Global IDMP Working Group

Topics



FDA IDMP Roadmap to IDMP Implementation

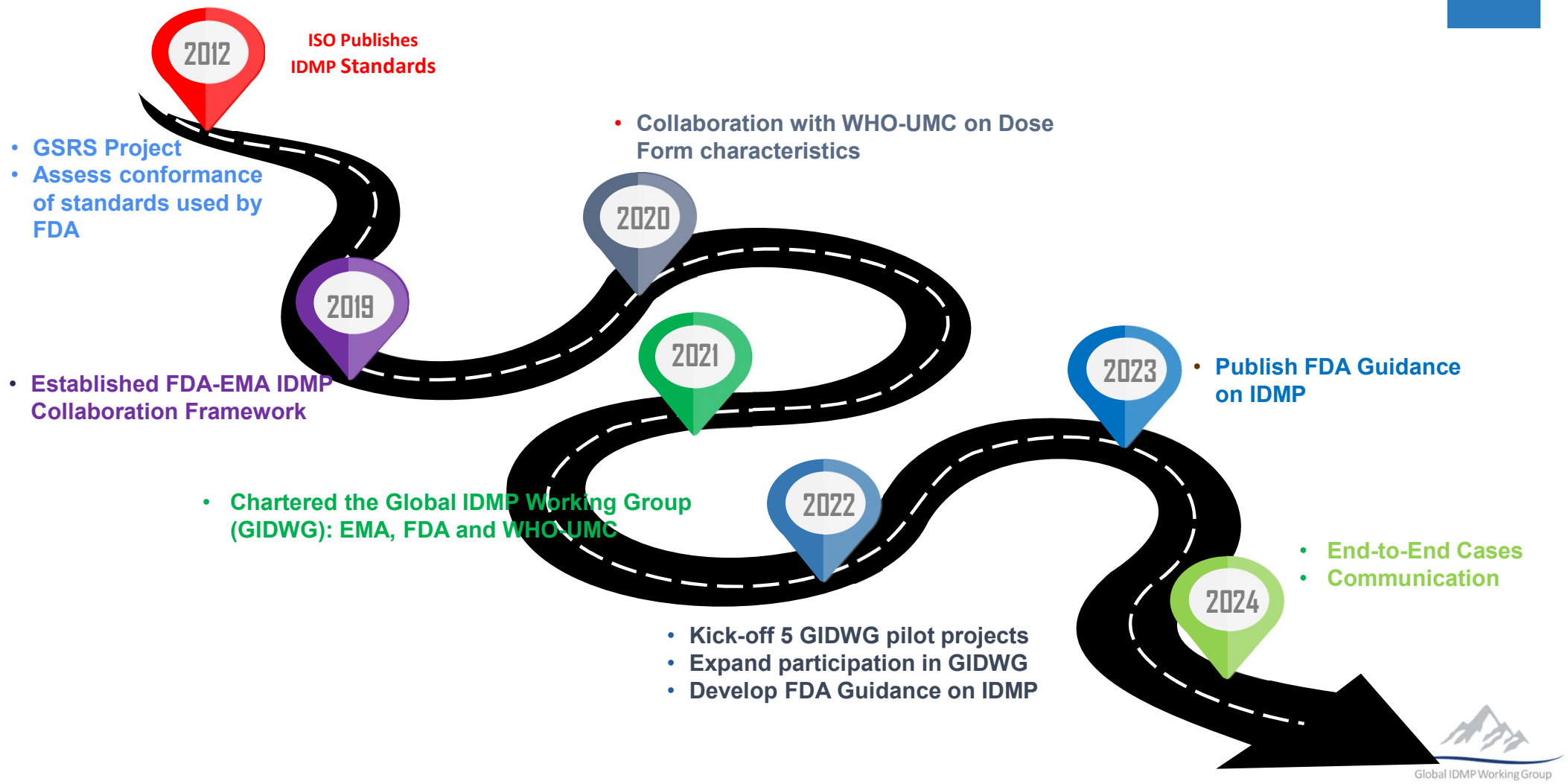
FDA Guidance: IDMP – Implementation and Use

Current/existing standards used by FDA & in US

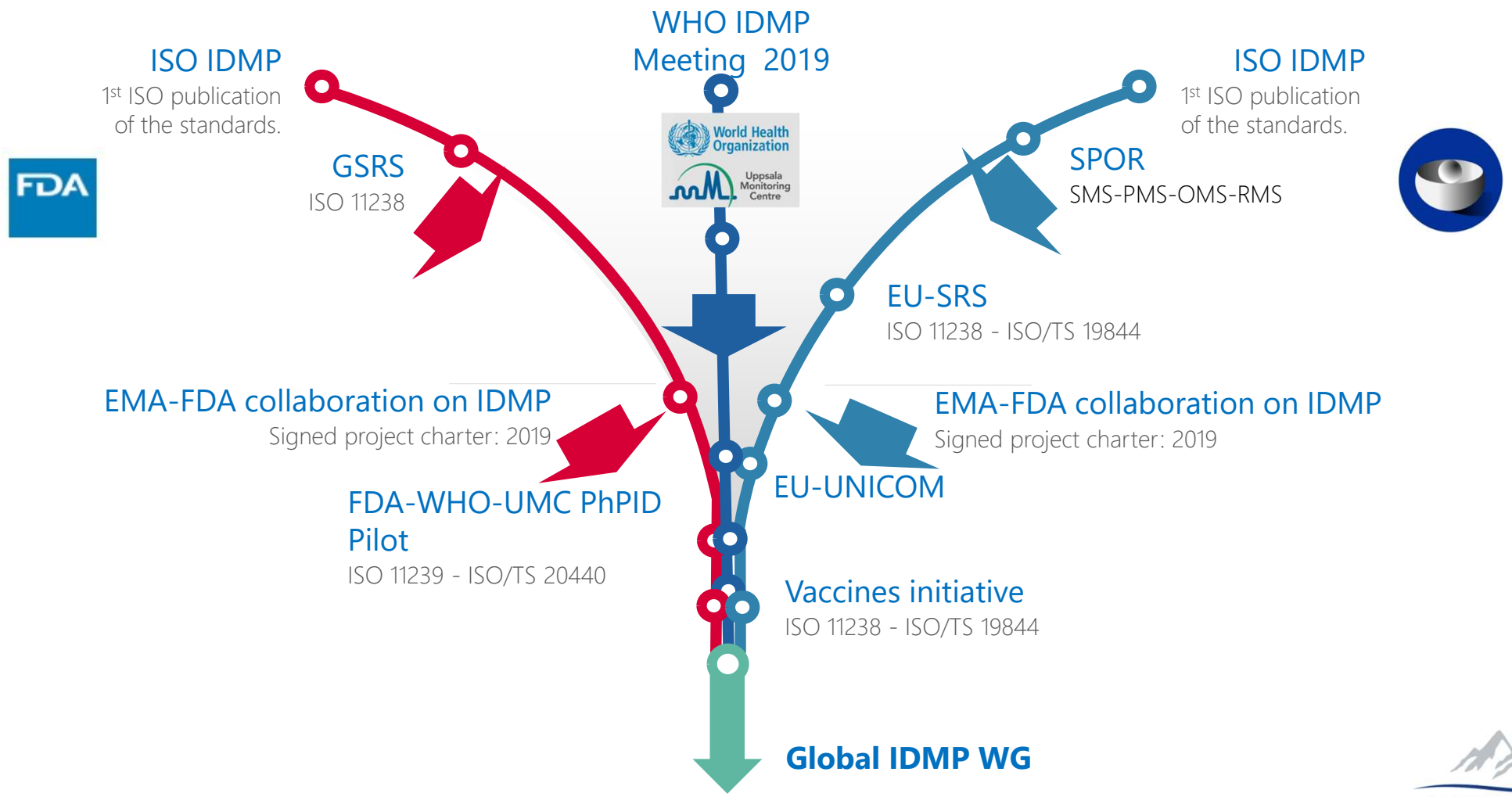
FDA approach to Global IDMP Implementation

Global IDMP Working Group

FDA IDMP Roadmap to Implementation - 2012-2024



Convergence in Cross Region Collaboration



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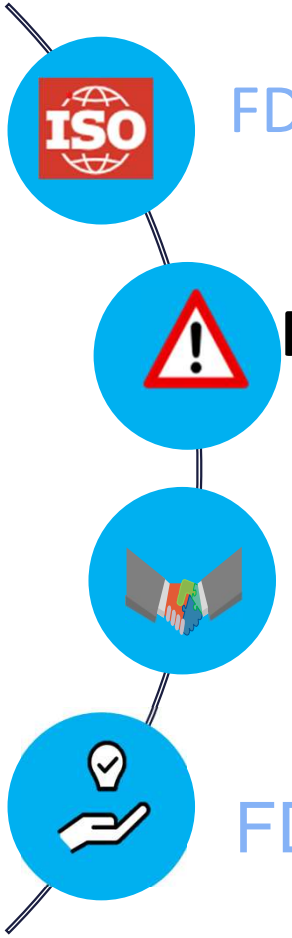
Topics



FDA IDMP Roadmap to IDMP Implementation

FDA Guidance: IDMP – Implementation and Use

Current/existing standards used by FDA in US

FDA approach to Global IDMP Implementation

Global IDMP Working Group

Purpose of the Guidance

- Until this guidance, FDA had no formal policy on the implementation and use of the IDMP standards.

- Provides FDA's position and progress on aligning the Agency's standards to Identification of Medicinal Products (IDMP) standards

- FDA's goal is the harmonization of the standards for the international exchange of medicinal product data.

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Objectives of the Guidance

To inform sponsors, applicants and registrants:

1. FDA has used, for many years, standards that are in conformance to IDMP.
   - *National Drug Code (Medicinal Product ID)*
   - *Unique Ingredient Identifier (Substance ID)*
   - *Unified Code for Units of Measure (Strength)*

2. FDA sees that there are 3 key benefits to global IDMP
   - *Drug Safety & Pharmacovigilance*
   - *Medicinal Product Traceability and Supply Chain Integrity*
   - *Exchange of Medicinal Product Information*

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Objectives of the Guidance

3. FDA will continue to work with international stakeholders (e.g., WHO-UMC, HL7, ISO, GIDWG, ICH) to ensure the standards can be implemented for the key use cases above.

4. FDA's focus is on a global phased approach to IDMP implementation when the standards are "fit for purpose."

5. FDA supports the establishment of a framework for the maintenance of the global IDMP identifiers.

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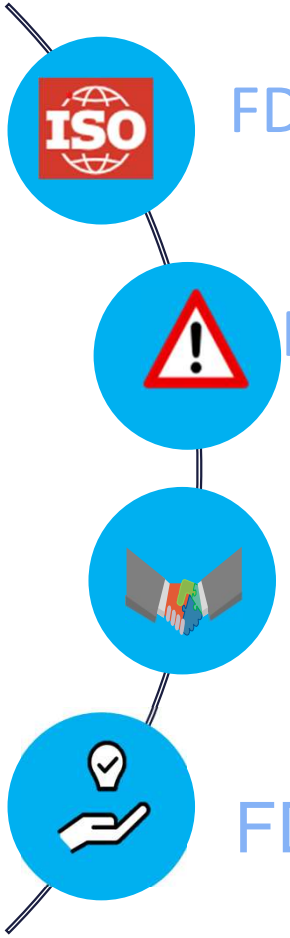
Topics



FDA IDMP Roadmap to IDMP Implementation

FDA Guidance: IDMP – Implementation and Use

Current/existing standards used by FDA & in US

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FDA Global Substance Registration System (GSRS)

- FDA created a Substance Registration System (SRS) to assign a unique ingredient identifiers (UNIIs) to substance during regulatory life cycle.
- Based on ISO 11238/TS 19844, FDA, NIH's National Center for Advancing Translational Sciences (NCATS), and the European Medicines Agency (EMA) have collaborated to create a Global Substance Registration System (GSRS) to enable the efficient and accurate exchange of substance information.
- UNIIs are used in electronic listing as seen in DailyMed and other regulatory activities throughout product life cycles.
- Public UNII sources include:
  - A flat file (spreadsheet)
  - precisionFDA
  - and a public GSRS hosted by the NCATS

https://www.fda.gov/industry/fda-data-standards-advisory-board/fdas-global-substance-registration-system

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FDA GSRS - precisionFDA

FDA's global Substance Registration System enables an efficient and accurate exchange of information on substances through their Unique Ingredient Identifiers (UNIIs) which can be generated at any time in the regulatory life cycle.

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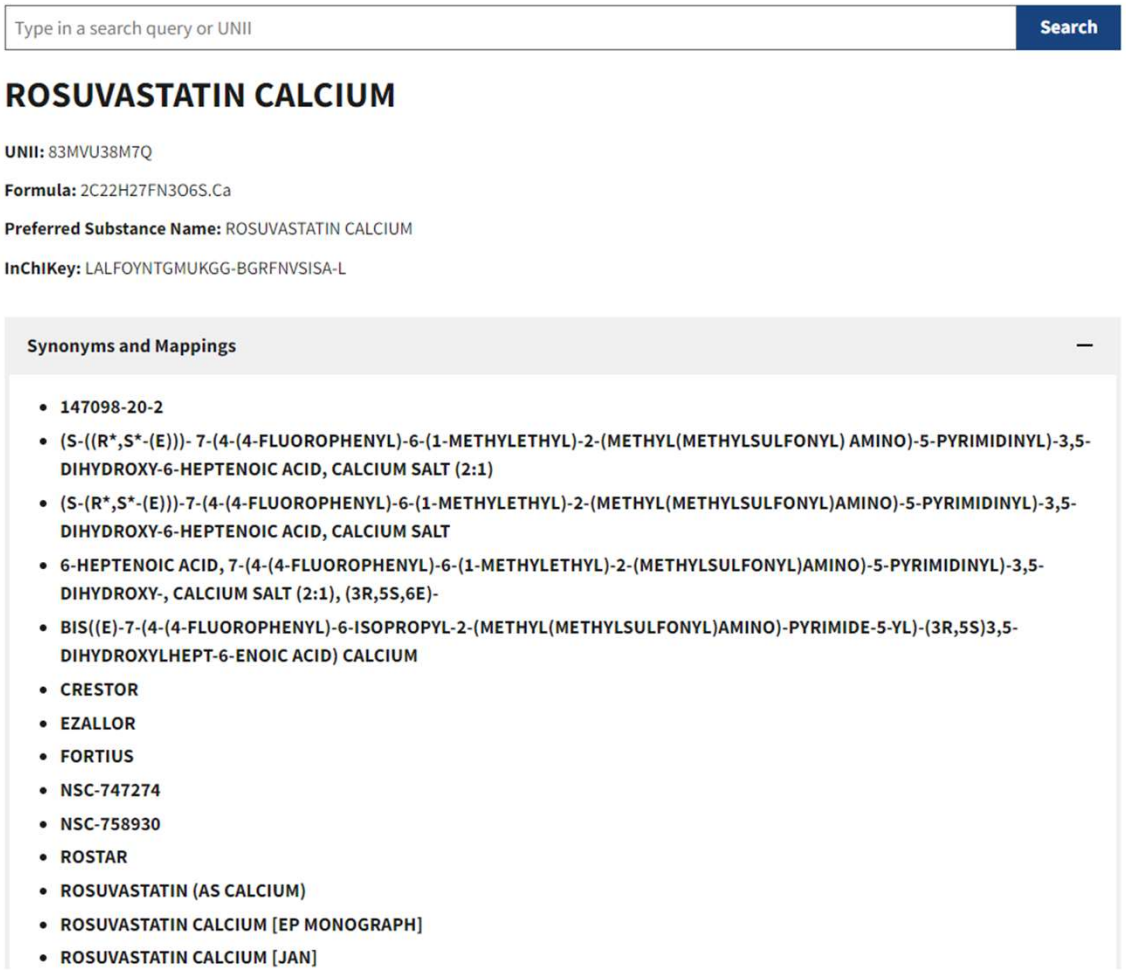
FDA GSRS - precisionFDA



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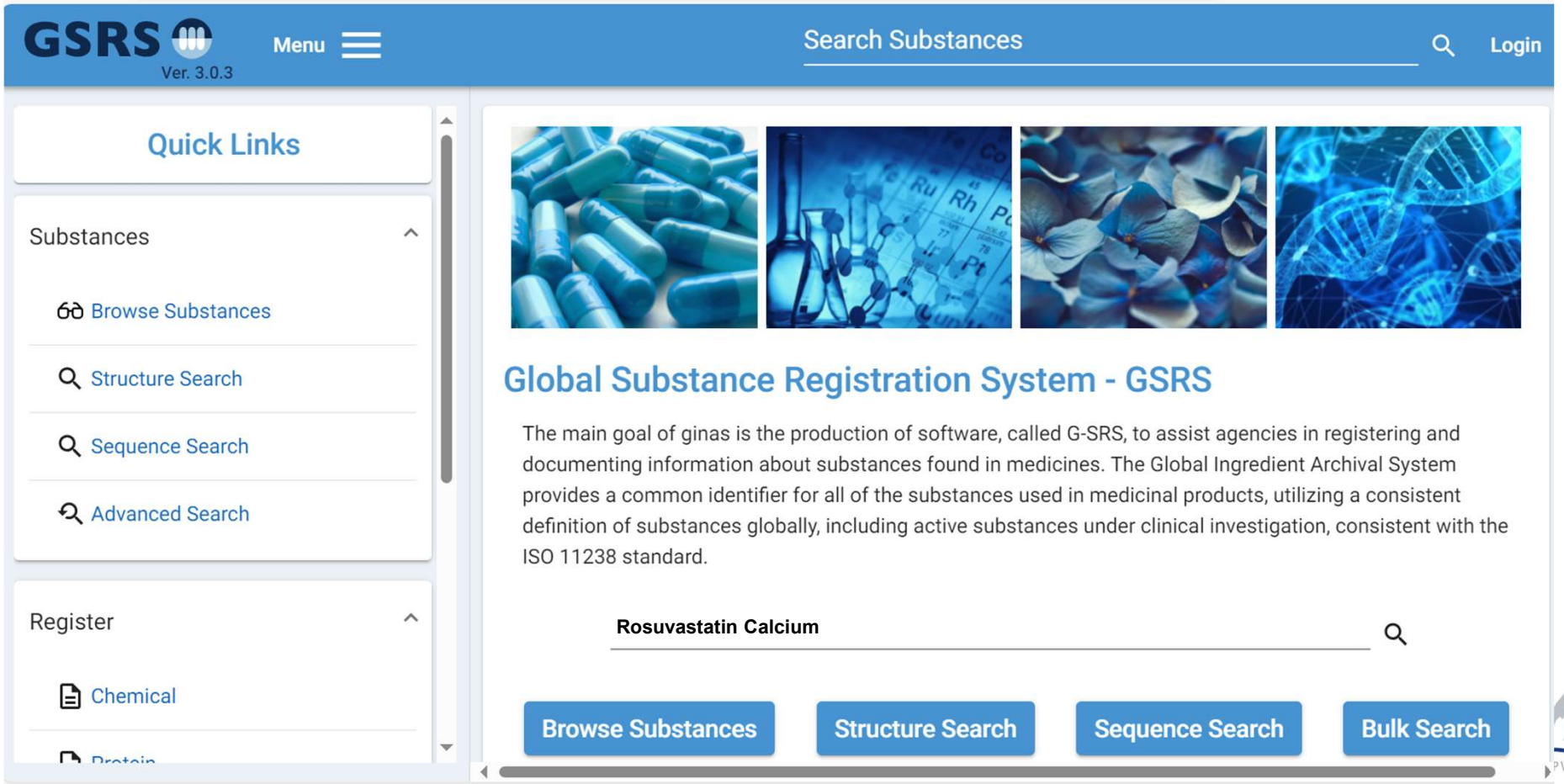
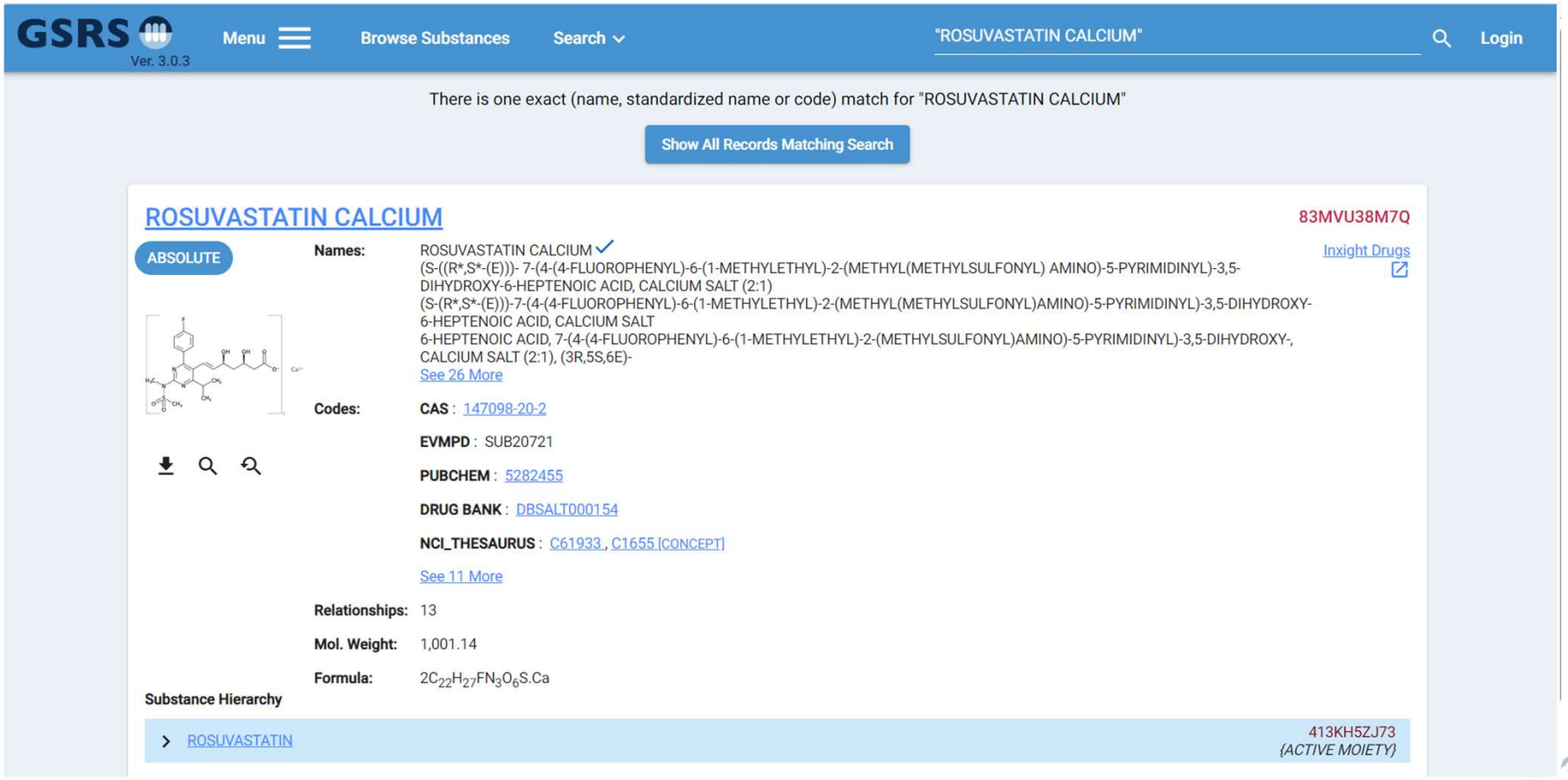
NCATS GSRS


GSRS
Ver. 3.0.3
Menu
Search Substances
Login
Quick Links
Substances
Browse Substances
Structure Search
Sequence Search
Advanced Search
Register
Chemical
Global Substance Registration System - GSRS
The main goal of ginas is the production of software, called G-SRS, to assist agencies in registering and documenting information about substances found in medicines. The Global Ingredient Archival System provides a common identifier for all of the substances used in medicinal products, utilizing a consistent definition of substances globally, including active substances under clinical investigation, consistent with the ISO 11238 standard.
Rosuvastatin Calcium
Browse Substances
Structure Search
Sequence Search
Bulk Search

NCATS GSRS



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Structured Product Labeling (SPL)

- The Structured Product Labeling (SPL) is a document markup standard approved by Health Level Seven (HL7) and adopted by FDA as a mechanism for exchanging **product** and facility information.
- FDALabel: FDA's web-based application designed to perform customizable searches of over 140,000 labeling for human prescription drug; nonprescription drugs; and labeling for other products (e.g., animal nonprescription and animal prescription drugs, cosmetics, dietary supplements, medical devices, medical foods). FDALabel and DailyMed have the same database but have different search functions and different displays of search results.
- FDA Online Label Repository

https://www.fda.gov/industry/fda-data-standards-advisory-board/structured-product-labeling-resources

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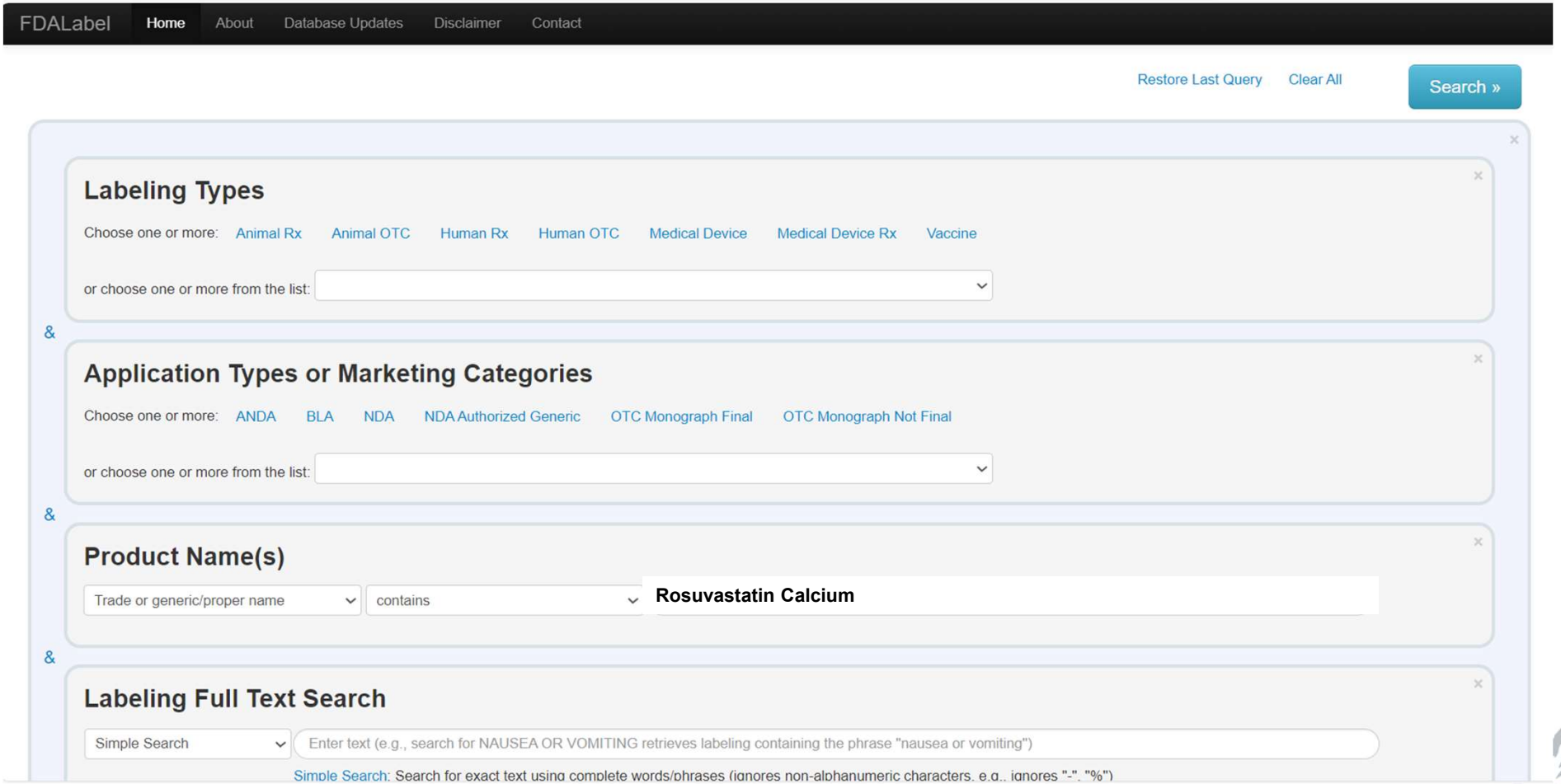
FDALabel



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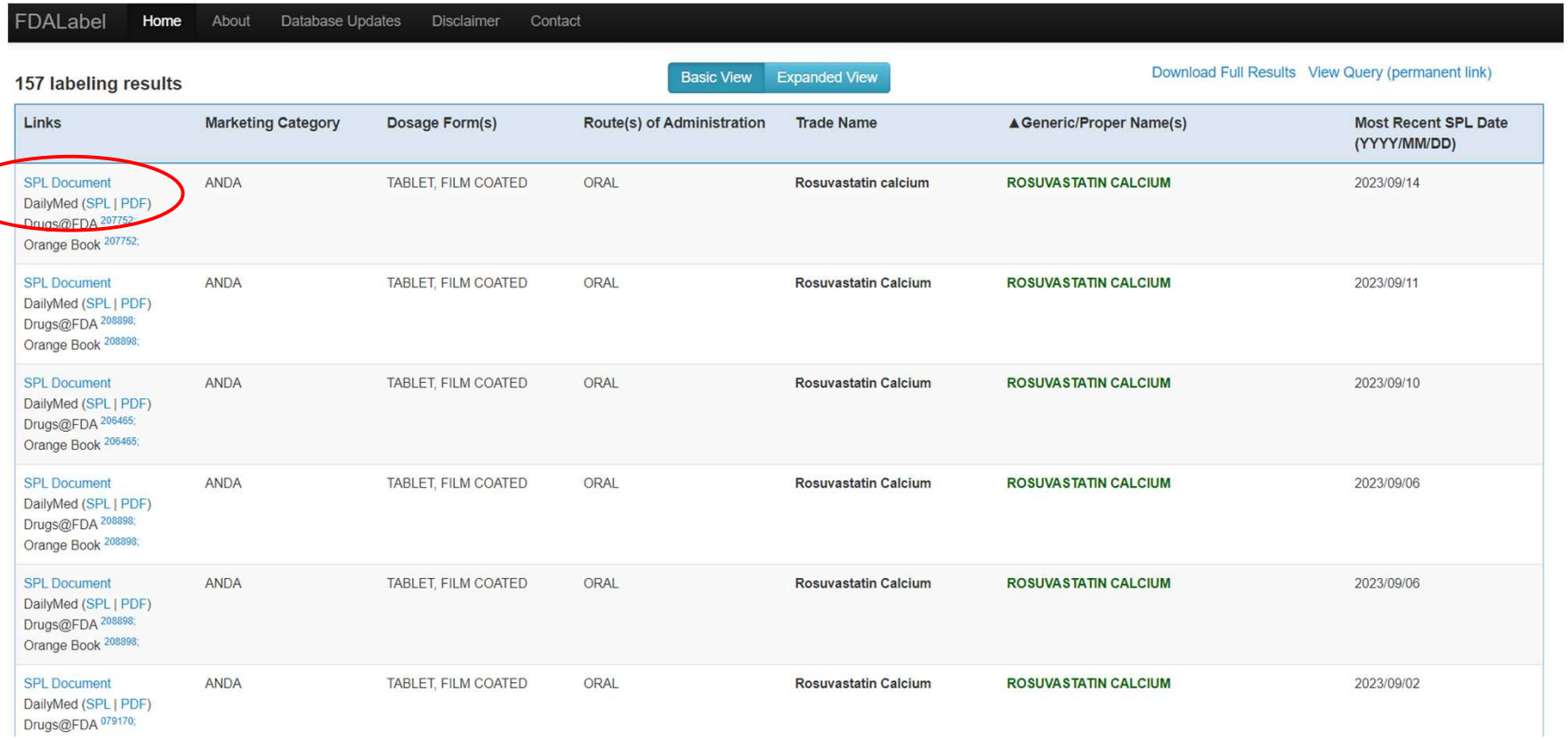
FDALabel



FDALabel | Home | About | Database Updates | Disclaimer | Contact

157 labeling results

Basic View | Expanded View

Download Full Results | View Query (permanent link)

Links	Marketing Category	Dosage Form(s)	Route(s) of Administration	Trade Name	▲Generic/Proper Name(s)	Most Recent SPL Date (YYYY/MM/DD)
SPL Document DailyMed (SPL | PDF) Drugs@FDA 207752; Orange Book 207752;	ANDA	TABLET, FILM COATED	ORAL	**Rosuvastatin calcium**	**ROSUVASTATIN CALCIUM**	2023/09/14
SPL Document DailyMed (SPL | PDF) Drugs@FDA 208898; Orange Book 208898;	ANDA	TABLET, FILM COATED	ORAL	**Rosuvastatin Calcium**	**ROSUVASTATIN CALCIUM**	2023/09/11
SPL Document DailyMed (SPL | PDF) Drugs@FDA 206465; Orange Book 206465;	ANDA	TABLET, FILM COATED	ORAL	**Rosuvastatin Calcium**	**ROSUVASTATIN CALCIUM**	2023/09/10
SPL Document DailyMed (SPL | PDF) Drugs@FDA 208898; Orange Book 208898;	ANDA	TABLET, FILM COATED	ORAL	**Rosuvastatin Calcium**	**ROSUVASTATIN CALCIUM**	2023/09/06
SPL Document DailyMed (SPL | PDF) Drugs@FDA 208898; Orange Book 208898;	ANDA	TABLET, FILM COATED	ORAL	**Rosuvastatin Calcium**	**ROSUVASTATIN CALCIUM**	2023/09/06
SPL Document DailyMed (SPL | PDF) Drugs@FDA 079170;	ANDA	TABLET, FILM COATED	ORAL	**Rosuvastatin Calcium**	**ROSUVASTATIN CALCIUM**	2023/09/02

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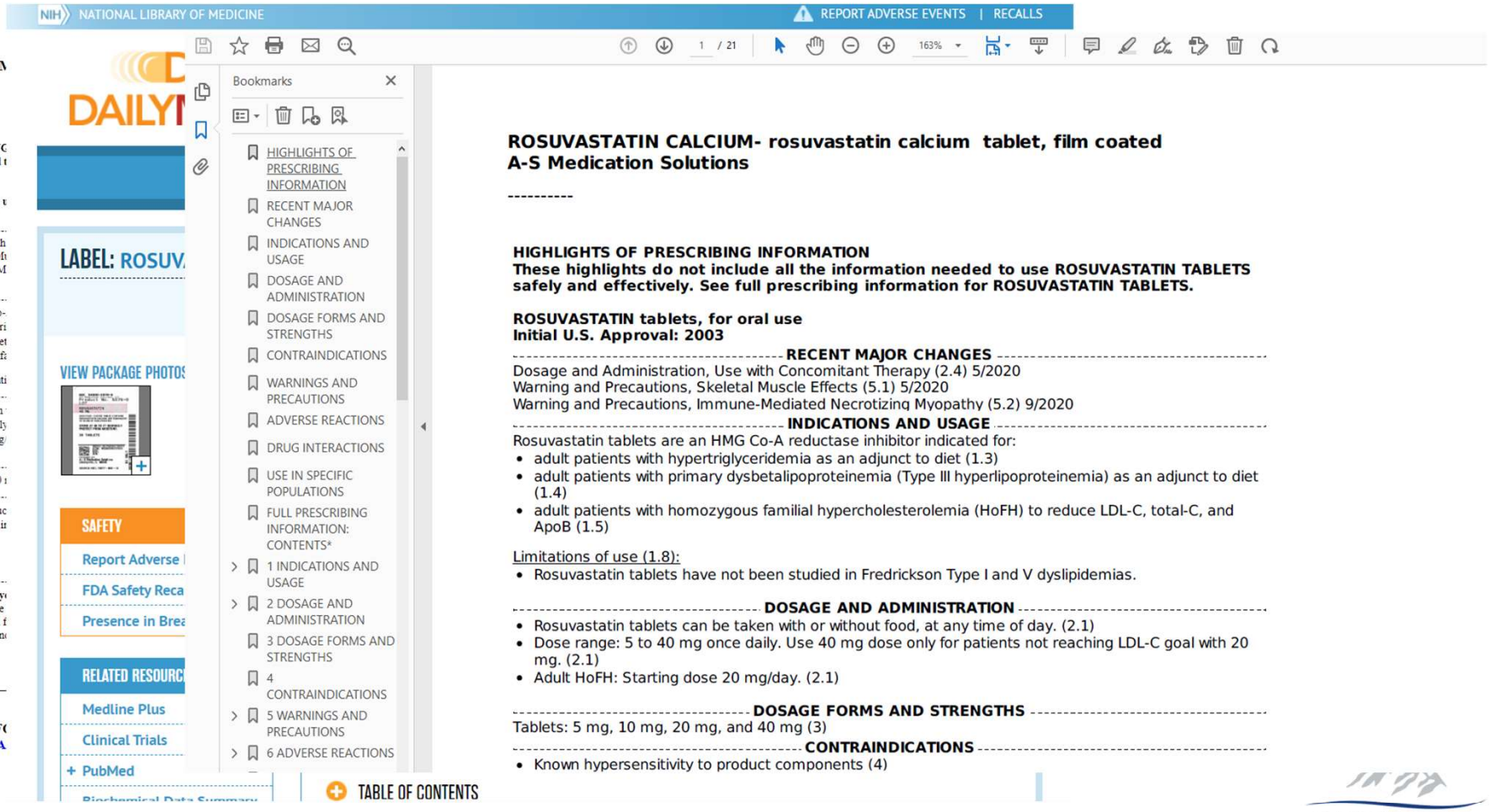
FDALabel



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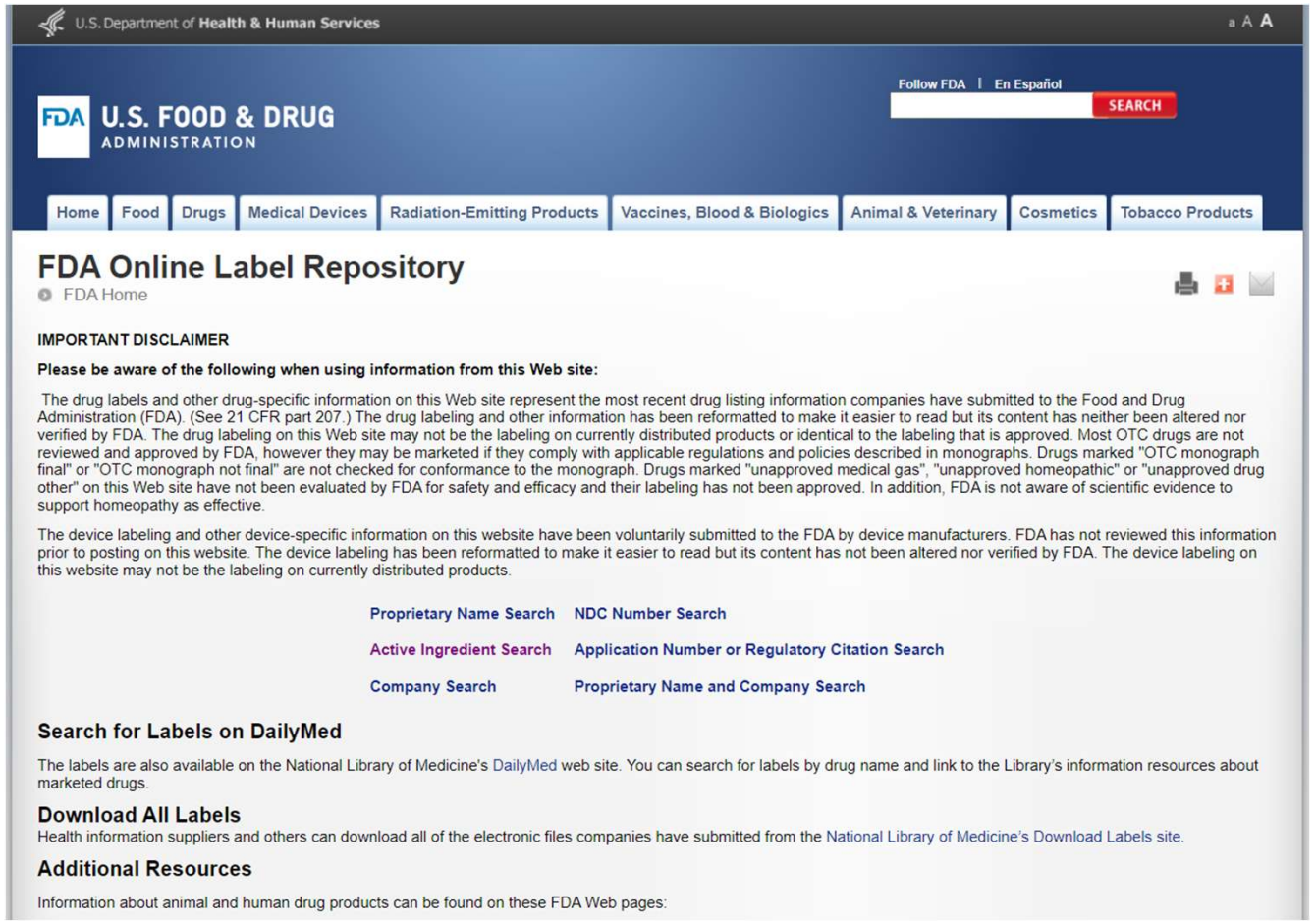
FDA Online Label Repository



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FDA Online Label Repository

FDA Home

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Please be aware of the following when using information from this Web site:

The drug labels and other drug-specific information on this Web site represent the most recent drug listing information companies have submitted to the Food and Drug Administration (FDA). (See 21 CFR part 207.) The drug labeling and other information has been reformatted to make it easier to read but its content has neither been altered nor verified by FDA. The drug labeling on this Web site may not be the labeling on currently distributed products or identical to the labeling that is approved. Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies described in monographs. Drugs marked "OTC monograph final" or "OTC monograph not final" are not checked for conformance to the monograph. Drugs marked "unapproved medical gas", "unapproved homeopathic" or "unapproved drug other" on this Web site have not been evaluated by FDA for safety and efficacy and their labeling has not been approved. In addition, FDA is not aware of scientific evidence to support homeopathy as effective.

The device labeling and other device-specific information on this website have been voluntarily submitted to the FDA by device manufacturers. FDA has not reviewed this information prior to posting on this website. The device labeling has been reformatted to make it easier to read but its content has not been altered nor verified by FDA. The device labeling on this website may not be the labeling on currently distributed products.

Proprietary Name Search | NDC Number Search

Active Ingredient Search | Application Number or Regulatory Citation Search

Company Search | Proprietary Name and Company Search

Search for Labels on DailyMed

The labels are also available on the National Library of Medicine's DailyMed web site. You can search for labels by drug name and link to the Library's information resources about marketed drugs.

Download All Labels

Health information suppliers and others can download all of the electronic files companies have submitted from the National Library of Medicine's Download Labels site.

Additional Resources

Information about animal and human drug products can be found on these FDA Web pages:

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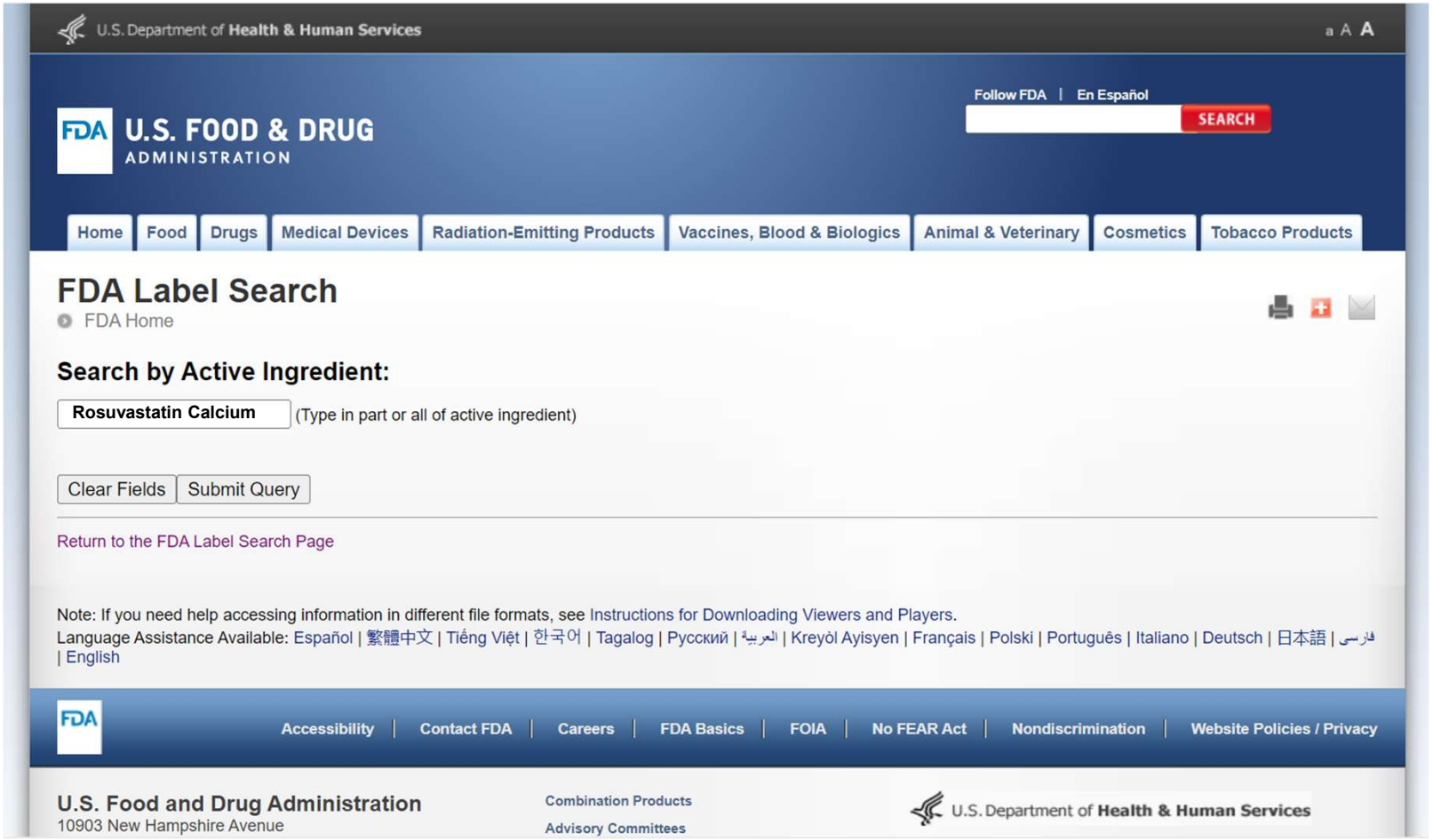
FDA Online Label Repository



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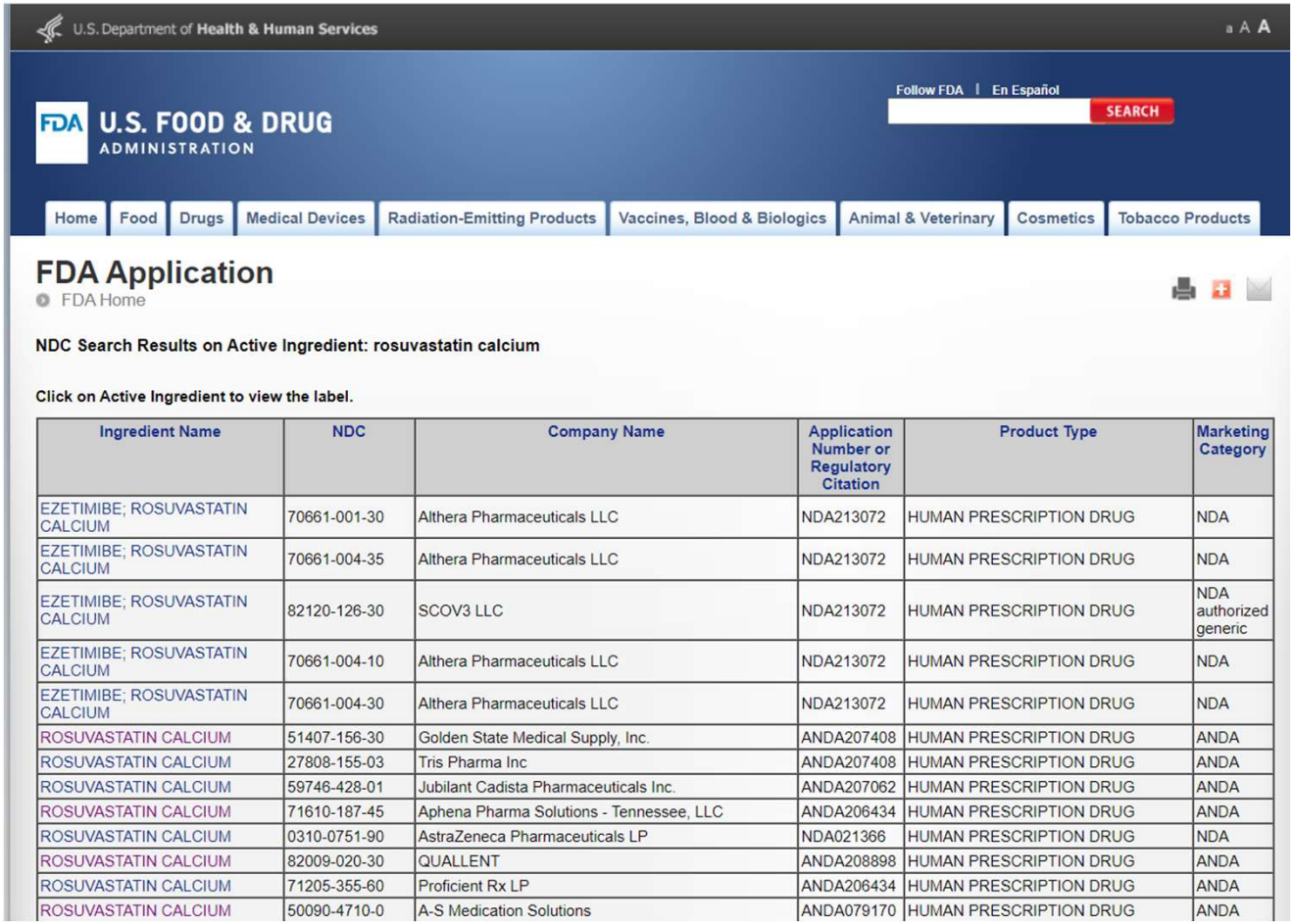
FDA Online Label Repository



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FDA Application

FDA Home

NDC Search Results on Active Ingredient: rosuvastatin calcium

Click on Active Ingredient to view the label.

Ingredient Name	NDC	Company Name	Application Number or Regulatory Citation	Product Type	Marketing Category
EZETIMIBE; ROSUVASTATIN CALCIUM	70661-001-30	Althera Pharmaceuticals LLC	NDA213072	HUMAN PRESCRIPTION DRUG	NDA
EZETIMIBE; ROSUVASTATIN CALCIUM	70661-004-35	Althera Pharmaceuticals LLC	NDA213072	HUMAN PRESCRIPTION DRUG	NDA
EZETIMIBE; ROSUVASTATIN CALCIUM	82120-126-30	SCOV3 LLC	NDA213072	HUMAN PRESCRIPTION DRUG	NDA authorized generic
EZETIMIBE; ROSUVASTATIN CALCIUM	70661-004-10	Althera Pharmaceuticals LLC	NDA213072	HUMAN PRESCRIPTION DRUG	NDA
EZETIMIBE; ROSUVASTATIN CALCIUM	70661-004-30	Althera Pharmaceuticals LLC	NDA213072	HUMAN PRESCRIPTION DRUG	NDA
ROSUVASTATIN CALCIUM	51407-156-30	Golden State Medical Supply, Inc.	ANDA207408	HUMAN PRESCRIPTION DRUG	ANDA
ROSUVASTATIN CALCIUM	27808-155-03	Tris Pharma Inc	ANDA207408	HUMAN PRESCRIPTION DRUG	ANDA
ROSUVASTATIN CALCIUM	59746-428-01	Jubilant Cadista Pharmaceuticals Inc.	ANDA207062	HUMAN PRESCRIPTION DRUG	ANDA
ROSUVASTATIN CALCIUM	71610-187-45	Aphena Pharma Solutions - Tennessee, LLC	ANDA206434	HUMAN PRESCRIPTION DRUG	ANDA
ROSUVASTATIN CALCIUM	0310-0751-90	AstraZeneca Pharmaceuticals LP	NDA021366	HUMAN PRESCRIPTION DRUG	NDA
ROSUVASTATIN CALCIUM	82009-020-30	QUALLENT	ANDA208898	HUMAN PRESCRIPTION DRUG	ANDA
ROSUVASTATIN CALCIUM	71205-355-60	Proficient Rx LP	ANDA206434	HUMAN PRESCRIPTION DRUG	ANDA
ROSUVASTATIN CALCIUM	50090-4710-0	A-S Medication Solutions	ANDA079170	HUMAN PRESCRIPTION DRUG	ANDA

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Orange Book

- The publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the Orange Book) identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (the Act) and related patent and exclusivity information.

https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book

Orange Book

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

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Additional information and resources for the Orange Book

We've updated our mobile app!
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Find Approved Drugs

- Search by Proprietary Name, Active Ingredient or Application Number

  Rosuvastatin Calcium [Search]

- Search by Applicant (Company)
- Search by Dosage Form (for example: *TABLET*)
- Search by Route of Administration (for example: *ORAL*)

Find Patent Information

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Orange Book

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

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Search Results for Proprietary Name, Active Ingredient or Application Number: *ROSUVASTATIN*

RX OTC DISCN

CSV | Excel | Print

Display 50 records per page

Showing 1 to 50 of 120 entries

20MG

Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
RX	ROSUVASTATIN CALCIUM	EZALLOR SPRINKLE	N208647	CAPSULE	ORAL	EQ 5MG BASE		RLD		SUN PHARMACEUTICAL INDUSTRIES LTD
RX	ROSUVASTATIN CALCIUM	EZALLOR SPRINKLE	N208647	CAPSULE	ORAL	EQ 10MG BASE		RLD		SUN PHARMACEUTICAL INDUSTRIES LTD
RX	ROSUVASTATIN CALCIUM	EZALLOR SPRINKLE	N208647	CAPSULE	ORAL	EQ 20MG BASE		RLD		SUN PHARMACEUTICAL INDUSTRIES LTD
RX	ROSUVASTATIN CALCIUM	EZALLOR SPRINKLE	N208647	CAPSULE	ORAL	EQ 40MG BASE		RLD	RS	SUN PHARMACEUTICAL INDUSTRIES LTD
RX	ROSUVASTATIN CALCIUM	CRESTOR	N021366	TABLET	ORAL	EQ 5MG BASE	AB	RLD		IPR PHARMACEUTICALS INC
RX	ROSUVASTATIN CALCIUM	CRESTOR	N021366	TABLET	ORAL	EQ 10MG BASE	AB	RLD		IPR PHARMACEUTICALS INC
RX	ROSUVASTATIN CALCIUM	CRESTOR	N021366	TABLET	ORAL	EQ 20MG BASE	AB	RLD		IPR PHARMACEUTICALS INC
RX	ROSUVASTATIN CALCIUM	CRESTOR	N021366	TABLET	ORAL	EQ 40MG BASE	AB	RLD	RS	IPR PHARMACEUTICALS INC
RX	ROSUVASTATIN CALCIUM	ROSUVASTATIN CALCIUM	A206434	TABLET	ORAL	EQ 5MG BASE	AB			ACCORD HEALTHCARE INC
RX	ROSUVASTATIN CALCIUM	ROSUVASTATIN CALCIUM	A206465	TABLET	ORAL	EQ 5MG BASE	AB			ALKEM LABORATORIES LTD

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Orange Book

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

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Search Results for Proprietary Name, Active Ingredient or Application Number: *ROSUVASTATIN*

RX OTC DISCN

CSV | Excel | Print

Display 50 records per page

Showing 1 to 30 of 30 entries (filtered from 120 total records)

20MG

Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
RX	ROSUVASTATIN CALCIUM	EZALLOR SPRINKLE	N208647	CAPSULE	ORAL	EQ 20MG BASE		RLD		SUN PHARMACEUTICAL INDUSTRIES LTD
RX	ROSUVASTATIN CALCIUM	CRESTOR	N021366	TABLET	ORAL	EQ 20MG BASE	AB	RLD		IPR PHARMACEUTICALS INC
RX	ROSUVASTATIN CALCIUM	ROSUVASTATIN CALCIUM	A206434	TABLET	ORAL	EQ 20MG BASE	AB			ACCORD HEALTHCARE INC
RX	ROSUVASTATIN CALCIUM	ROSUVASTATIN CALCIUM	A206465	TABLET	ORAL	EQ 20MG BASE	AB			ALKEM LABORATORIES LTD
RX	ROSUVASTATIN CALCIUM	ROSUVASTATIN CALCIUM	A079170	TABLET	ORAL	EQ 20MG BASE	AB			AUROBINDO PHARMA LTD
RX	ROSUVASTATIN CALCIUM	ROSUVASTATIN CALCIUM	A207752	TABLET	ORAL	EQ 20MG BASE	AB			BIOCON PHARMA LTD
RX	ROSUVASTATIN CALCIUM	ROSUVASTATIN CALCIUM	A207453	TABLET	ORAL	EQ 20MG BASE	AB			CADILA PHARMACEUTICALS LTD
RX	ROSUVASTATIN CALCIUM	ROSUVASTATIN	A207408	TABLET	ORAL	EQ 20MG BASE	AB			CHANGZHOU PHARMACEUTICAL FACTORY

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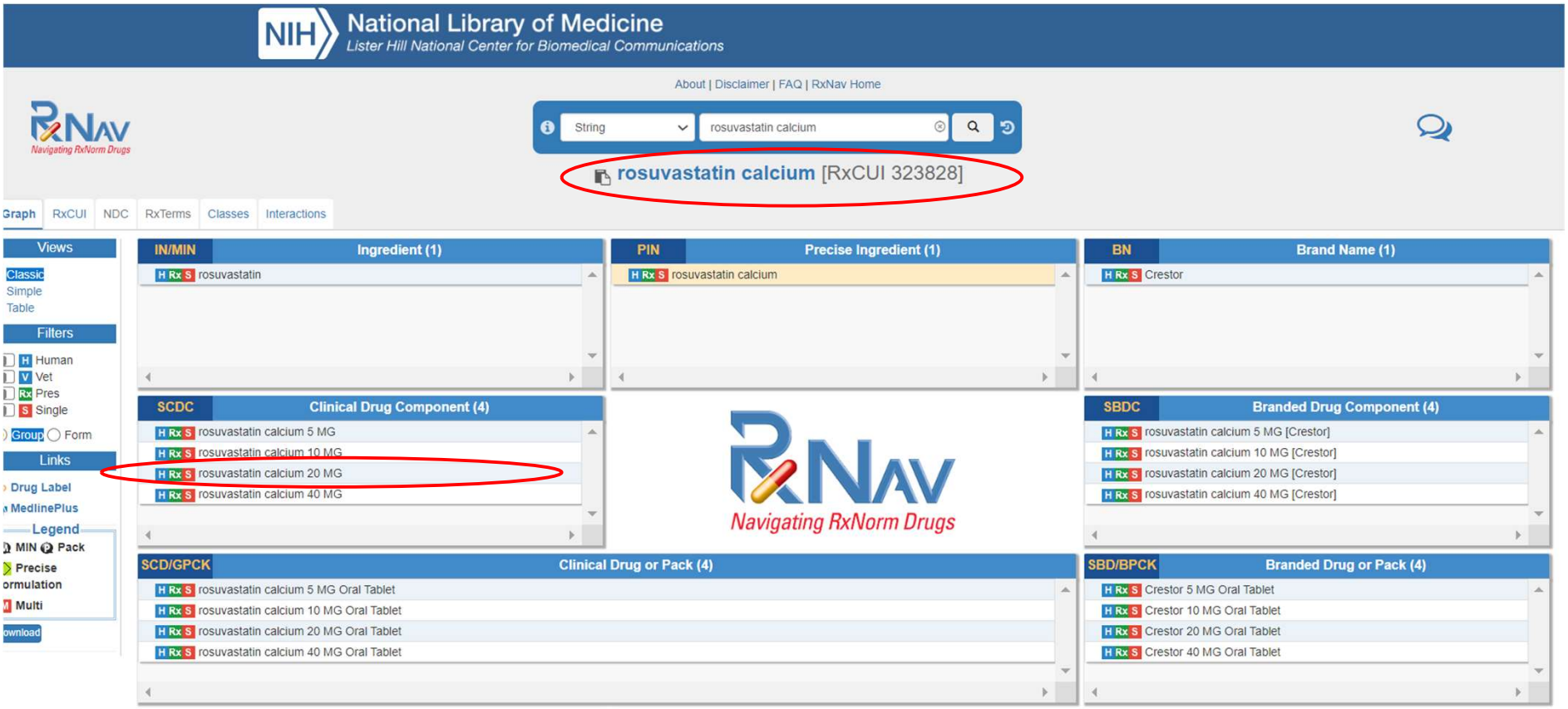
RxNorm

- RxNorm is a national initiative created by the National Library of Medicine (NLM) to provide a single system for unambiguously identifying brand-name and generic drugs.
- RxNorm enables medications information to be exchanged across electronic health records (EHRs).
- The Office of the National Coordinator (ONC) designated use of RxNorm as a criterion for EHR certification of interoperability and Stage 2 Meaningful Use.
- Concept Unique Identifier (RxCUI) is a unique, unambiguous identifier that is assigned to an individual drug entity in RxNorm and used to relate to all things associated with that drug.
- https://www.nlm.nih.gov/research/umls/rxnorm/index.html
- RxNav (nih.gov)

RxNorm - RxNorm Browser (RxNav)



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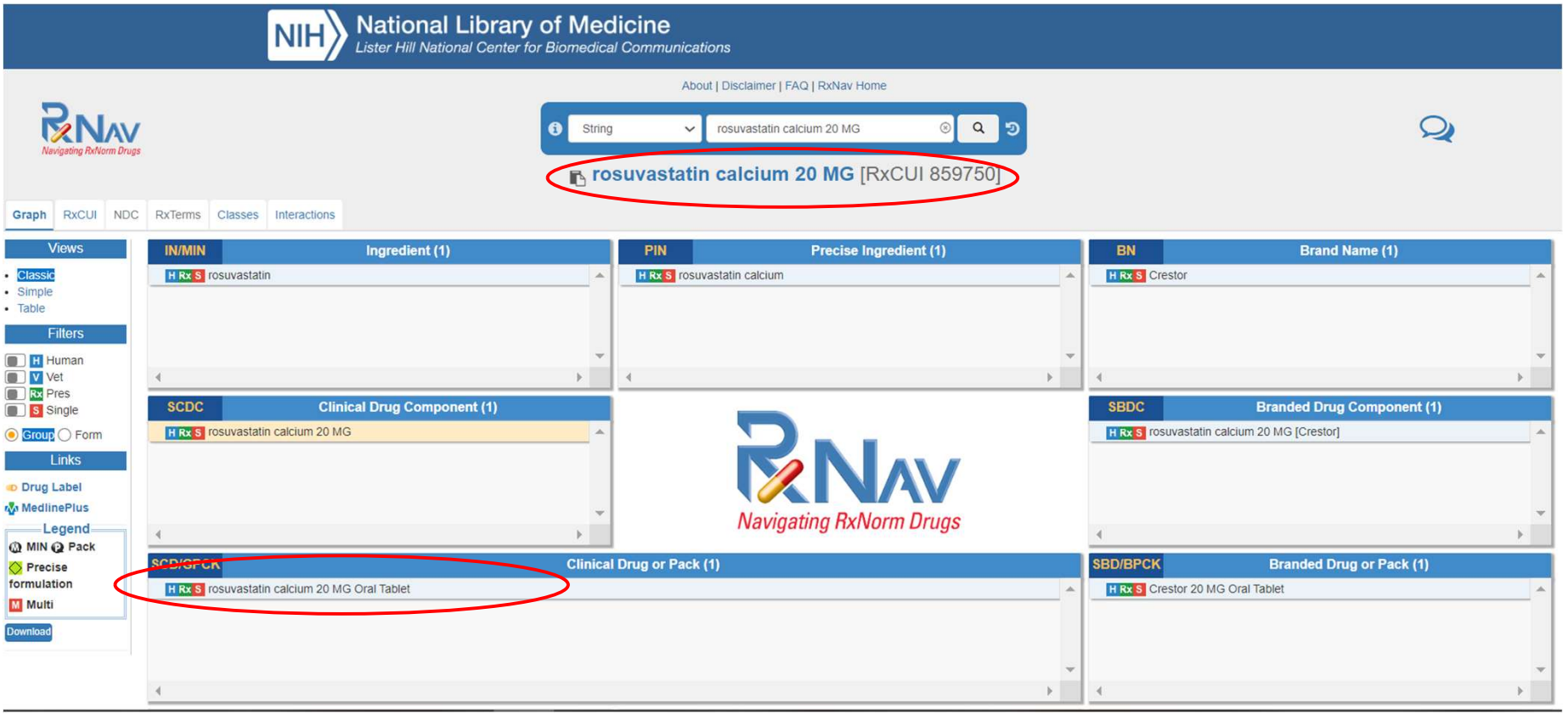
RxNorm - RxNorm Browser (RxNav)



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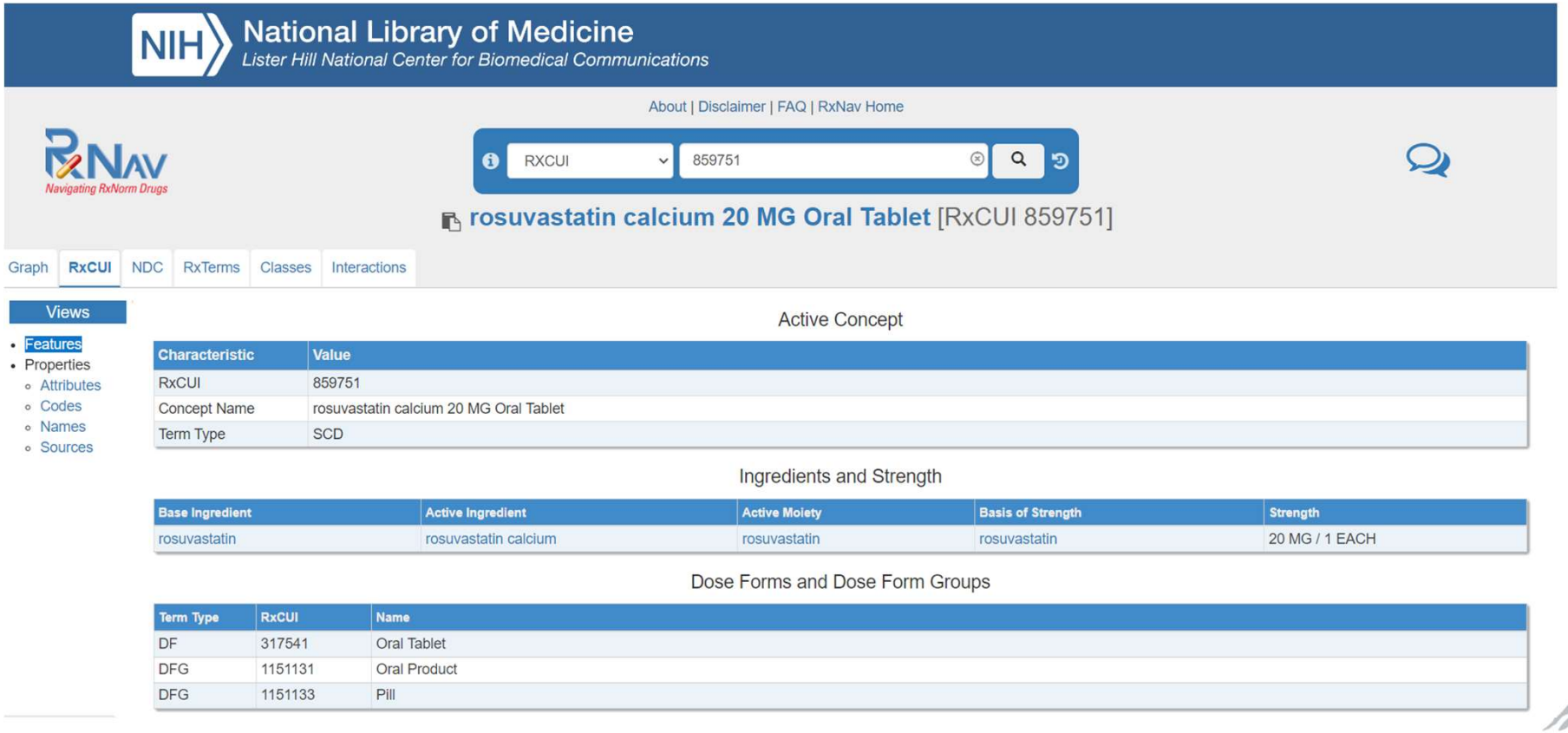
RxNorm - RxNorm Browser (RxNav)



National Library of Medicine
Lister Hill National Center for Biomedical Communications

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RxNav
Navigating RxNorm Drugs

RXCUI 859751

rosuvastatin calcium 20 MG Oral Tablet [RxCUI 859751]

Graph | RxCUI | NDC | RxTerms | Classes | Interactions

Views
- Features
- Properties
  - Attributes
  - Codes
  - Names
  - Sources

Active Concept

Characteristic	Value
RxCUI	859751
Concept Name	rosuvastatin calcium 20 MG Oral Tablet
Term Type	SCD

Ingredients and Strength

Base Ingredient	Active Ingredient	Active Moiety	Basis of Strength	Strength
rosuvastatin	rosuvastatin calcium	rosuvastatin	rosuvastatin	20 MG / 1 EACH

Dose Forms and Dose Form Groups

Term Type	RxCUI	Name
DF	317541	Oral Tablet
DFG	1151131	Oral Product
DFG	1151133	Pill

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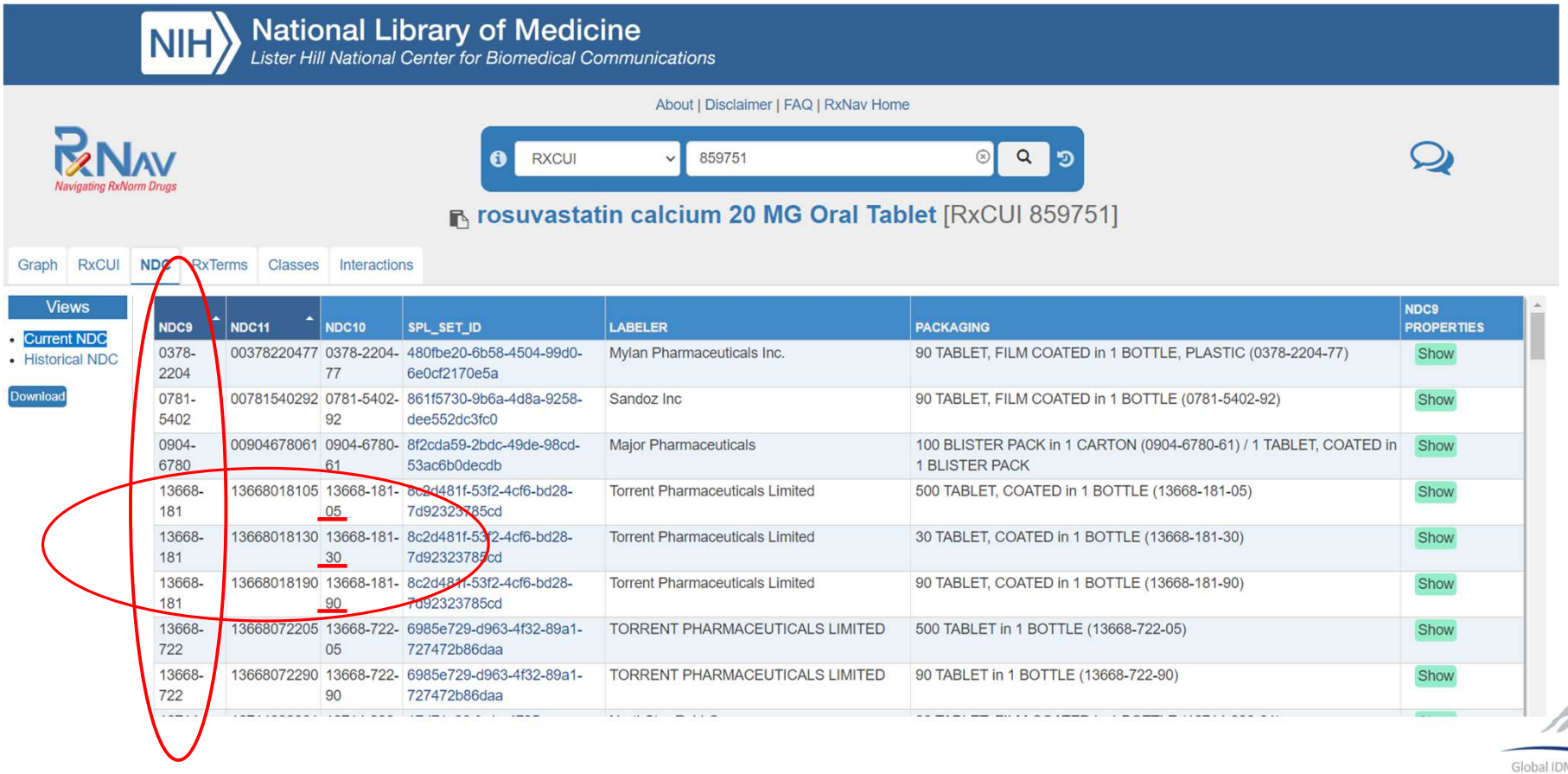
RxNorm - RxNorm Browser (RxNav)



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RXCUI 859751

rosuvastatin calcium 20 MG Oral Tablet [RxCUI 859751]

Graph | RxCUI | NDC | RxTerms | Classes | Interactions

Views
- Current NDC
- Historical NDC

Download

NDC9	NDC11	NDC10	SPL_SET_ID	LABELER	PACKAGING	NDC9 PROPERTIES
0378-2204	00378220477	0378-2204-77	480fbe20-6b58-4504-99d0-6e0cf2170e5a	Mylan Pharmaceuticals Inc.	90 TABLET, FILM COATED in 1 BOTTLE, PLASTIC (0378-2204-77)	Show
0781-5402	00781540292	0781-5402-92	861f5730-9b6a-4d8a-9258-dee552dc3fc0	Sandoz Inc	90 TABLET, FILM COATED in 1 BOTTLE (0781-5402-92)	Show
0904-6780	00904678061	0904-6780-61	8f2cda59-2bdc-49de-98cd-53ac6b0decdb	Major Pharmaceuticals	100 BLISTER PACK in 1 CARTON (0904-6780-61) / 1 TABLET, COATED in 1 BLISTER PACK	Show
13668-181	13668018105	13668-181-05	8c2d481f-53f2-4cf6-bd28-7d92323785cd	Torrent Pharmaceuticals Limited	500 TABLET, COATED in 1 BOTTLE (13668-181-05)	Show
13668-181	13668018130	13668-181-30	8c2d481f-53f2-4cf6-bd28-7d92323785cd	Torrent Pharmaceuticals Limited	30 TABLET, COATED in 1 BOTTLE (13668-181-30)	Show
13668-181	13668018190	13668-181-90	8c2d481f-53f2-4cf6-bd28-7d92323785cd	Torrent Pharmaceuticals Limited	90 TABLET, COATED in 1 BOTTLE (13668-181-90)	Show
13668-722	13668072205	13668-722-05	6985e729-d963-4f32-89a1-727472b86daa	TORRENT PHARMACEUTICALS LIMITED	500 TABLET in 1 BOTTLE (13668-722-05)	Show
13668-722	13668072290	13668-722-90	6985e729-d963-4f32-89a1-727472b86daa	TORRENT PHARMACEUTICALS LIMITED	90 TABLET in 1 BOTTLE (13668-722-90)	Show

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DailyMed

- The National Library of Medicine (NLM)'s DailyMed searchable database provides the most recent labeling submitted to the Food and Drug Administration (FDA) by companies and currently in use (i.e., "in use" labeling).
- The labeling on DailyMed is typically reformatted to make them easier to read.

- https://dailymed.nlm.nih.gov/dailymed/index.cfm

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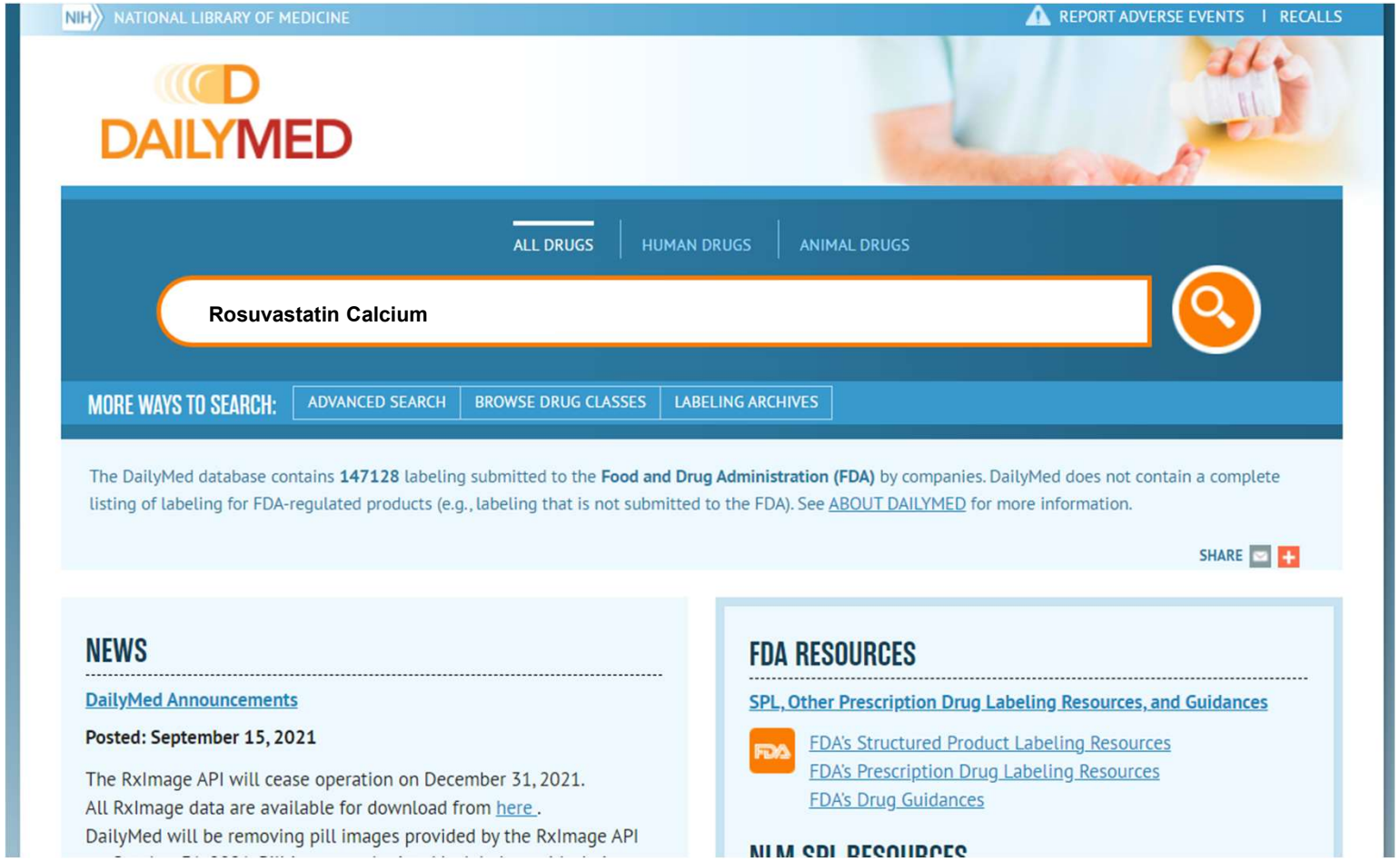
DailyMed



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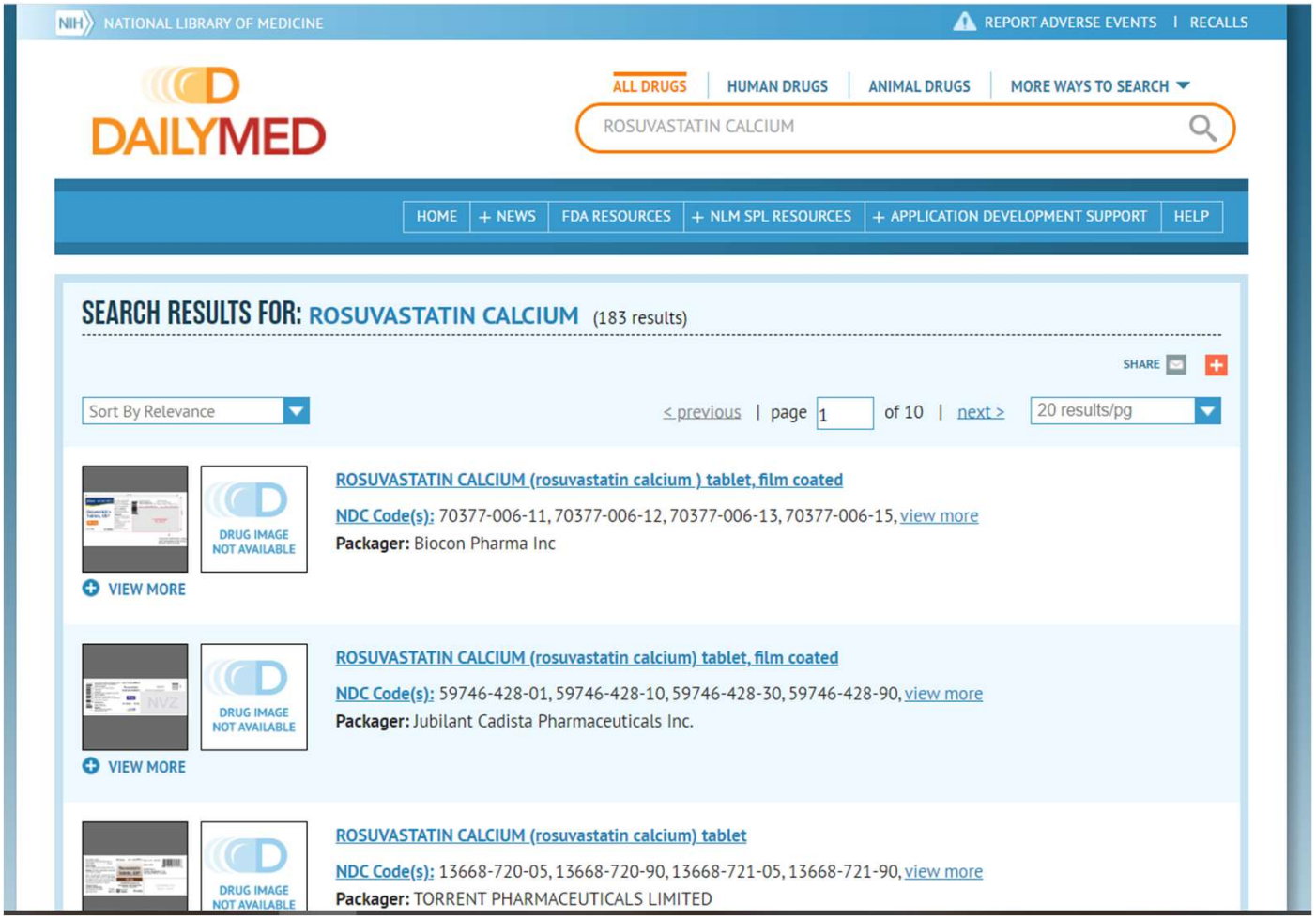
DailyMed



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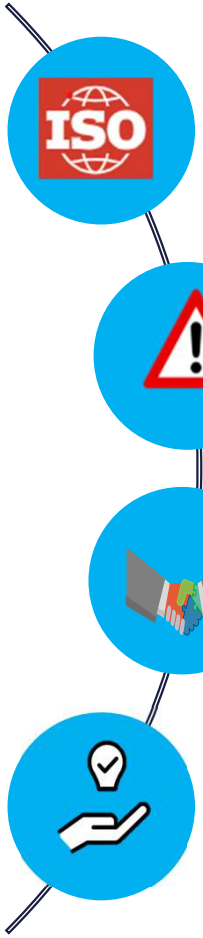
Topics



FDA IDMP Roadmap to IDMP Implementation

FDA Guidance: IDMP – Implementation and Use

Current/existing standards used by FDA & in US

FDA approach to Global IDMP Implementation

Global IDMP Working Group

FDA approach to Global IDMP Implementation

Goal – Maximize the benefits of Global IDMP Implementation and enable cross-region exchange of medicinal product information without impacts to current regulatory and business practices.

- Include UMC GSID in FDA GSRS - map UNII with UMC GSID
- Include PhPID in CDER Integrity Product Domain
- Include PhPID in FDA Orange Book
- Exploring further harmonize SPL on PHIR with EU ePI, additional data elements to further align with ISO 11615
  - Including data element for PhPID

Global IDMP Working Group

Thank You

Global IDMP Working Group

GIDWG-IFPMA

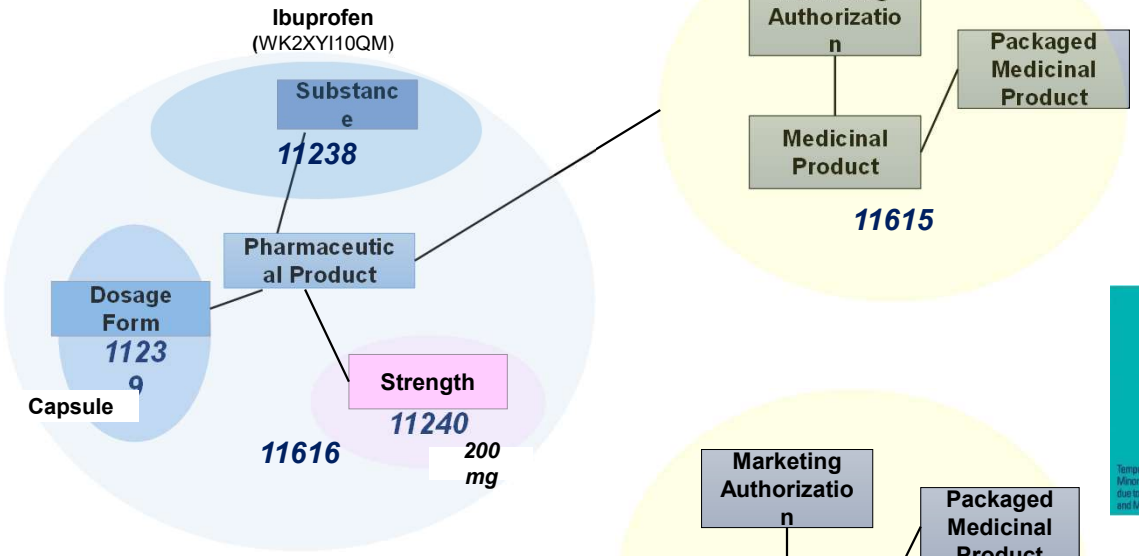
Vada A. Perkins

Executive Director, Regulatory Policy & Innovation

Co-Author: ISO IDMP 11615 & ISO IDMP 11616

10/17/2023

IDMP- Drugs


Ibuprofen
(WK2XYI10QM)
Substanc e
11238
Pharmaceutic al Product
Dosage Form
1123 9
Capsule
Strength
11240
200 mg
11616
Marketing Authorizatio n
Packaged Medicinal Product
Medicinal Product
11615
Marketing Authorizatio n
Packaged Medicinal Product
Medicinal Product
11615


Easy Open ARTHRITIS CAP
Advil
LIQUI-GELS
Solubilized Ibuprofen Capsules, 200 mg
Pain Reliever/Fever Reducer (NSAID)
160 Liquid Filled Capsules
Drug Facts
FPO


Bayer HealthCare
Midol
Liquid Gels
IBUPROFEN 200mg (NSAID)
PAIN RELIEVER/ FEVER REDUCER
LIQUID FILLED CAPSULES

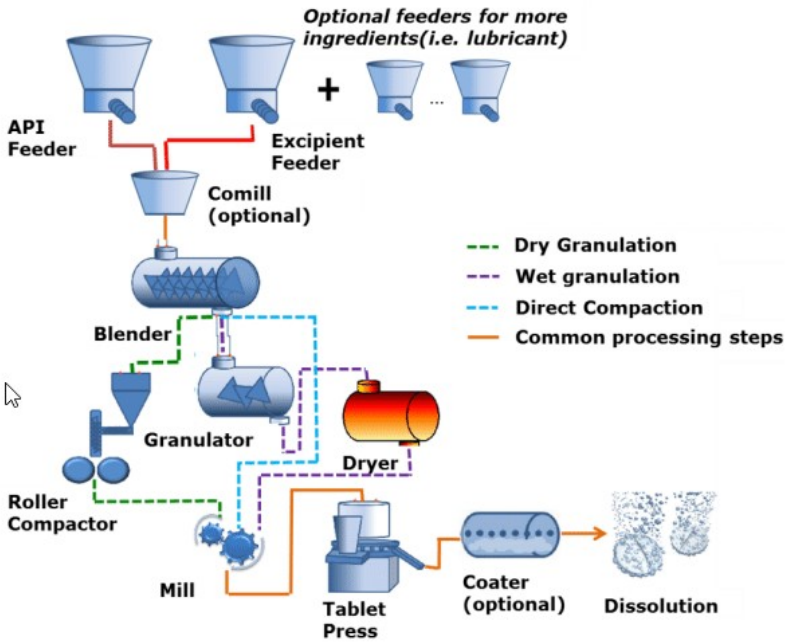

NUROFEN
8HR
PAIN RELIEF
200mg Soft Capsules
Ibuprofen
Lasts Up To 8 Hours
16 Soft Capsules

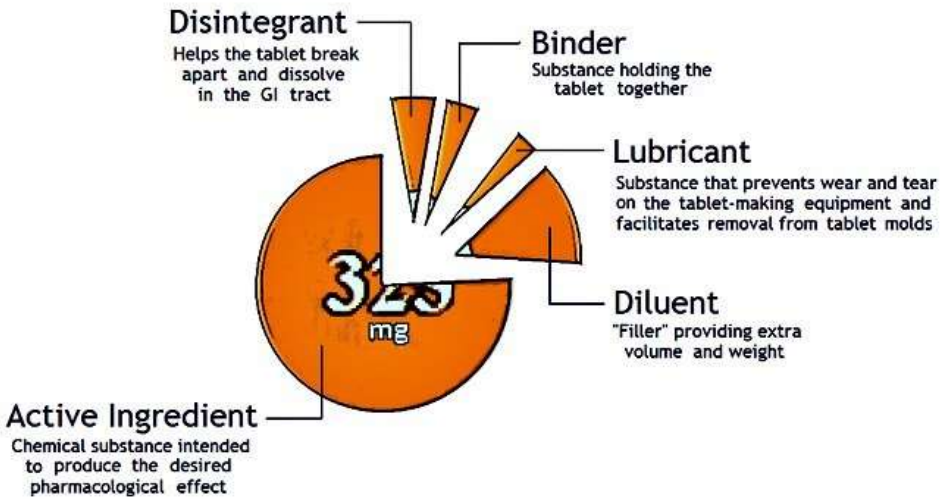

Walgreens
Ibuprofen
IBUPROFEN CAPSULES, 200 mg / PAIN RELIEVER / FEVER REDUCER (NSAID)
SOFTGELS
40 SOFTGELS
SEE NEW WARNINGS INFORMATION


VALUE SIZE
CVS Health
Ibuprofen
500 COATED CAPLETS


sato
頭痛・歯痛・発熱
生理痛・咽喉痛によく効く
Ringl
リングルアイビー
200
イブプロフェン
1回200mg
液体in カプセル
24カプセル
24回分

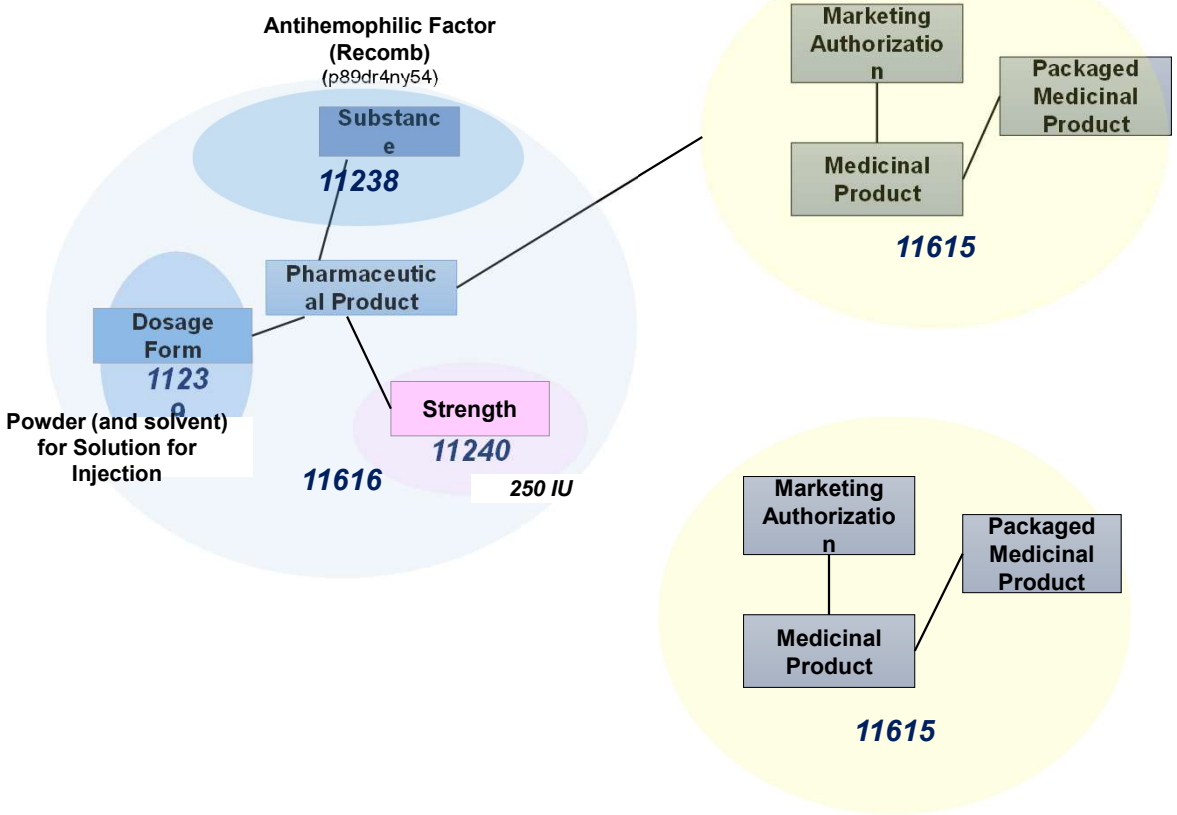
Tablet Manufacturing



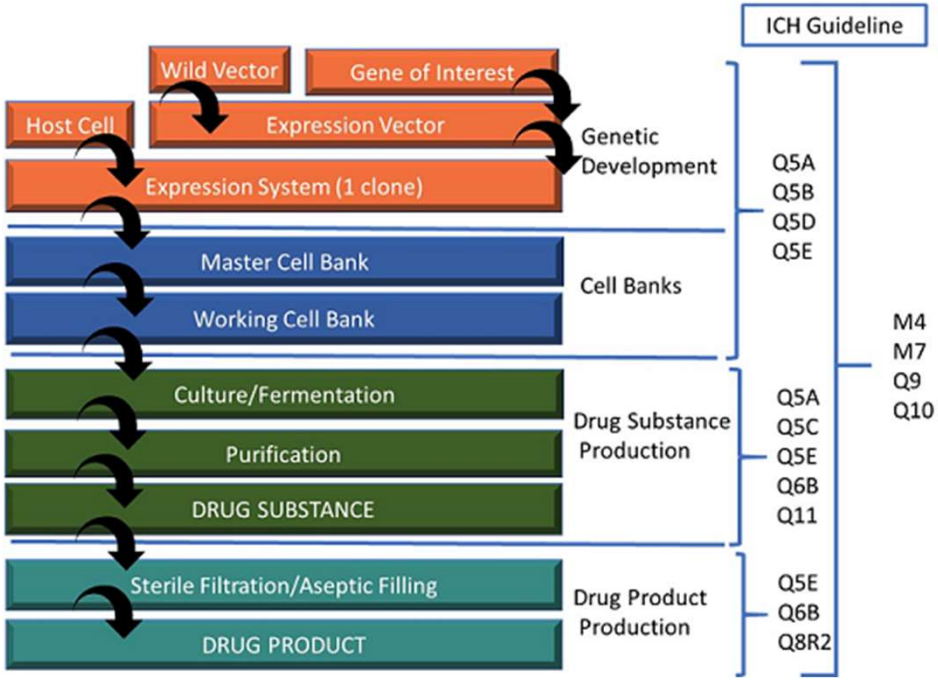


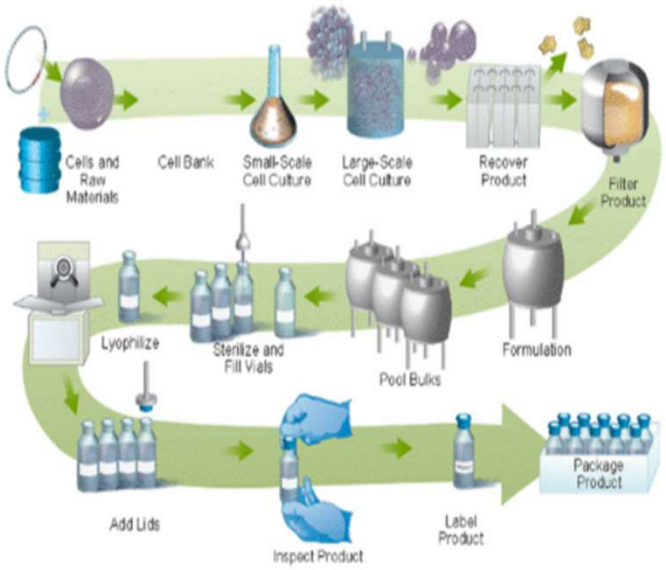
Source: saintytec

IDMP- Biologics



Biologics Manufacturing



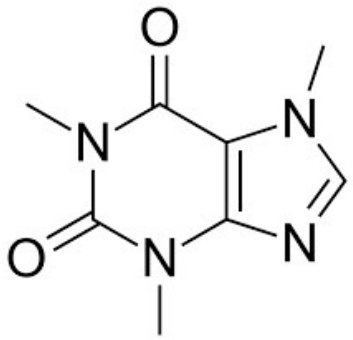


Source: outsourcedpharma

IDMP: Substance Groups and Defining Elements

IFPMA

- Chemicals
  - Defined primarily by molecular structure (connectivity and stereochemistry)



- Proteins
  - Amino Acid Sequence, type of glycosylation, modifications

- Nucleic Acids
  - Sequence, type of sugar and linkage, modifications

- **Polymers** (Synthetic or biopolymers)
  - Structural repeating units, type, geometry, type of copolymer (block or random), ratio of monomers, modifications, **molecular weight** or properties related to molecular weight, **biological source** for many biopolymers

- **Structurally Diverse Substances** (viruses, cells, tissues, complex materials)
  - **Taxonomic, anatomical, fractionation, physical properties, modifications**

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Unique Identification (Biologics): SARS-CoV-2 (mRNA)

ELASOMERAN

- **UNII:** EPK39PL4R4
- **Preferred Substance Name:** ELASOMERAN
- **2430046-03-8**
- **CX-024414**
- **ELASOMERAN [INN]**
- **ELASOMERAN [WHO-DD]**
- **M-1273**

MODERNA COVID-19 VACCINE RNA

- **MRNA-1273**
- **MRNA-BASED VACCINE**
- **TAK-919**

TOZINAMERAN

- **UNII:** 5085ZFP6SJ
- **Preferred Substance Name:** TOZINAMERAN
- **2417899-77-3**
- **BNT162B2**
- **BNT-162B2**
- **COMIRNATY**

PFIZER COVID-19 VACCINE

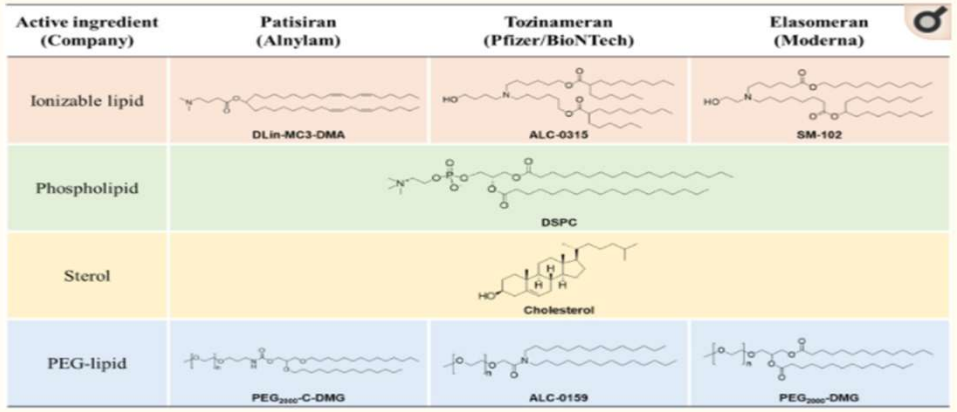
- **RNA INGREDIENT BNT-162B2**
- **TOZINAMERAN [INN]**
- **TOZINAMERAN [WHO-DD]**

GIDWG

3. Difference in formulation

Go to:

The three LNP-based drugs share multiple similarities in their formulation, and hence, behave similarly as nanoparticles in vivo. Importantly, all LNPs are composed of four types of lipids; ionizable lipid, phospholipid, cholesterol, and PEG-lipid (Fig. 3). All 3 ionizable lipids have tertiary amine group with pKa 6.0–6.7. These lipids switch its charge from neutral to cationic based on the neutral pH in the blood and the acidic pH in endosomes. The 3 PEG-lipids have dialkyl chains 14-carbon long, which are important for the rapid dissociation from the surface of LNPs once inside the body [43]. The biodegradable design of ALC-0315 [44] and SM-102 [11] is described later.



Open in a separate window

Fig. 3

Chemical structure of lipids in lipid nanoparticles. ALC-0159 has PEG_{2000}. All 3 ionizable lipids have tertiary amine groups, namely Dlin-MC3-DMA (MC3), pKa 6.44 [12] or pKa 6.35 [11]; ALC-0315, pKa 6.09 [44]; and SM-102, pKa 6.68 [11]. The related patents are as follows: Dlin-MC3-DMA, WO/2010/144740; ALC-0315, WO/2017/075531 (Lipid No. 3); and SM-102, WO/2017/049245 (Compound 25).

Drug Metab Pharmacokinet. 2021 Dec; 41: 100424.
Published online 2021 Oct 10. doi: 10.1016/j.dmpk.2021.100424

Global IDMP Working Group

TOZINAMERAN LIPID NANOPARTICLE

FZ4BV6MFB6

GROUP 1 SPECIFIED SUBSTANCE

Names: TOZINAMERAN LIPID NANOPARTICLE ✓
BNT162B2 LIPID NANOPARTICLE

Codes: **BDNUM** : 0137566AB

FDA UNII : FZ4BV6MFB6

Relationships: 1

Constituents: 5

Inxight Drugs

Created: 2/22/21

Created By: CALLAHANL

Status: Validated (UNII)

Validated By: DAMMIKA.AMUGODA-KANK

Validated Date: 2/23/21, 7:20 AM

Last Modified: 3/31/21

Last Modified By: CALLAHANL

Version: 5

Substance Hierarchy

TOZINAMERAN	5085ZFP6SJ *{ACTIVE MOIETY}*
((4-HYDROXYBUTYL)AZANEDIYL)BIS(HEXANE-6,1-DIYL)BIS(2-HEXYLDECANOATE)	AVX8DX713V
CHOLESTEROL	97C5T2UQ7J
1,2-DISTEAROYL-SN-GLYCERO-3-PHOSPHOCHOLINE	043IPI2M0K
2-(MPEG 2000)-N,N-DITETRADECYLACETAMIDE	PJH39UMU6H

Application Count:
0

Product Count:
Active: 0
Inactive: 0

Clinical Trial Count:
0

Adverse Event Count:
0

CX-024414 LIPID NANOPARTICLE

9NFK69RL7T

GROUP 1 SPECIFIED SUBSTANCE

Names: CX-024414 LIPID NANOPARTICLE ✓
ELASOMERAN LIPID NANOPARTICLE
MRNA-1273 LIPID NANOPARTICLE

Codes: **BDNUM** : 0137125AB

FDA UNII : 9NFK69RL7T

Relationships: 1

Constituents: 5

Created: 1/6/21

Created By: CALLAHANL

Status: Validated (UNII)

Validated By: DAMMIKA.AMUGODA-KANK

Validated Date: 5/5/21, 10:18 AM

Last Modified: 1/19/22

Last Modified By: CALLAHANL

Version: 8

Substance Hierarchy

ELASOMERAN	EPK39PL4R4 *{ACTIVE MOIETY}*
SM-102	T7OBQ65G2I
CHOLESTEROL	97C5T2UQ7J
1,2-DIMYRISTOYL-RAC-GLYCERO-3-METHOXYPOLYETHYLENE GLYCOL 2000	9X2596CIE0
1,2-DISTEAROYL-SN-GLYCERO-3-PHOSPHOCHOLINE	043IPI2M0K

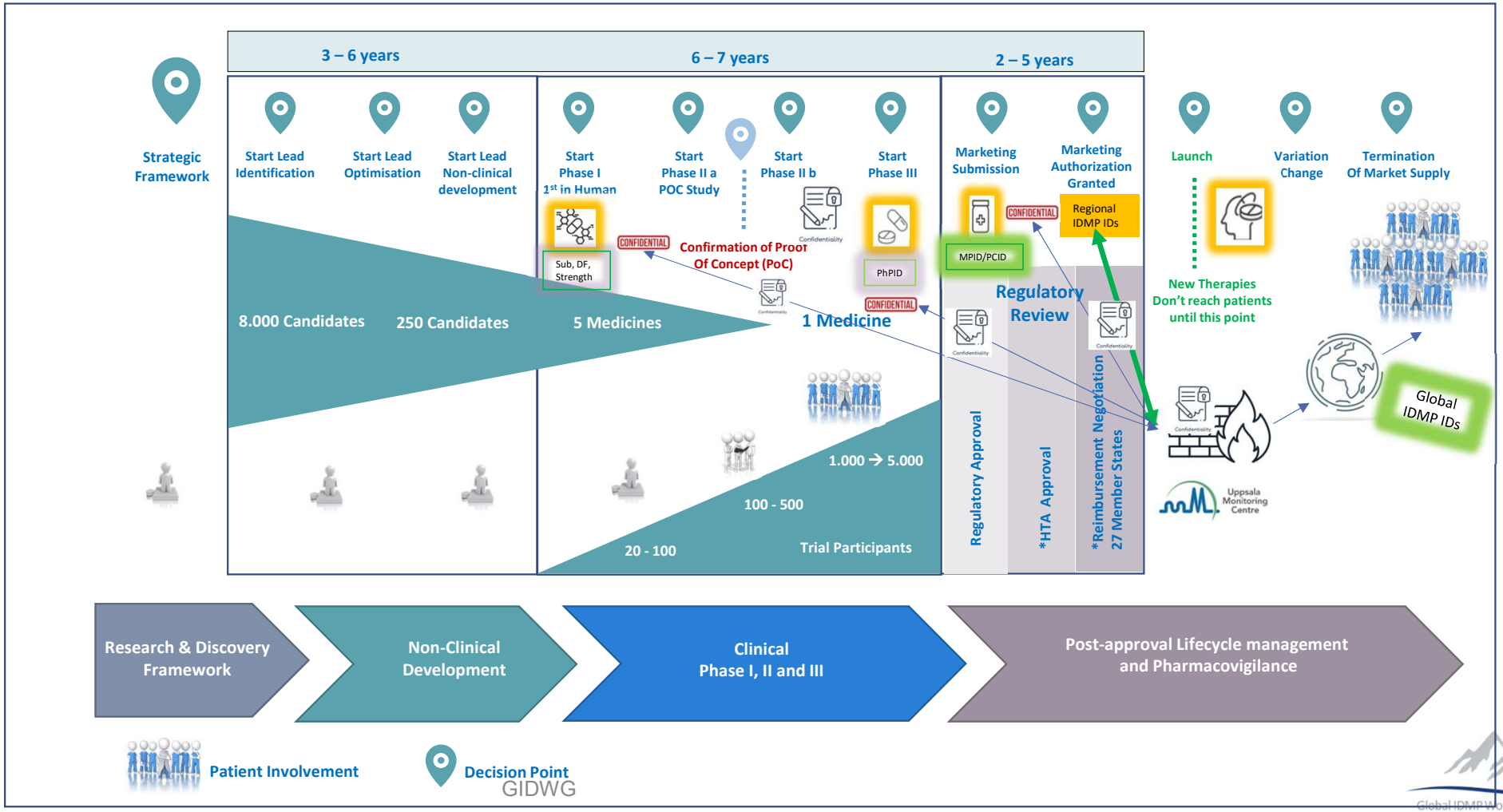
Global Substance Registration Public Resources (G-SRS)-FDA/NCATS Collaboration

- Software (open source), data and info on GSRS from NCATS
  - https://tripod.nih.gov/ginas

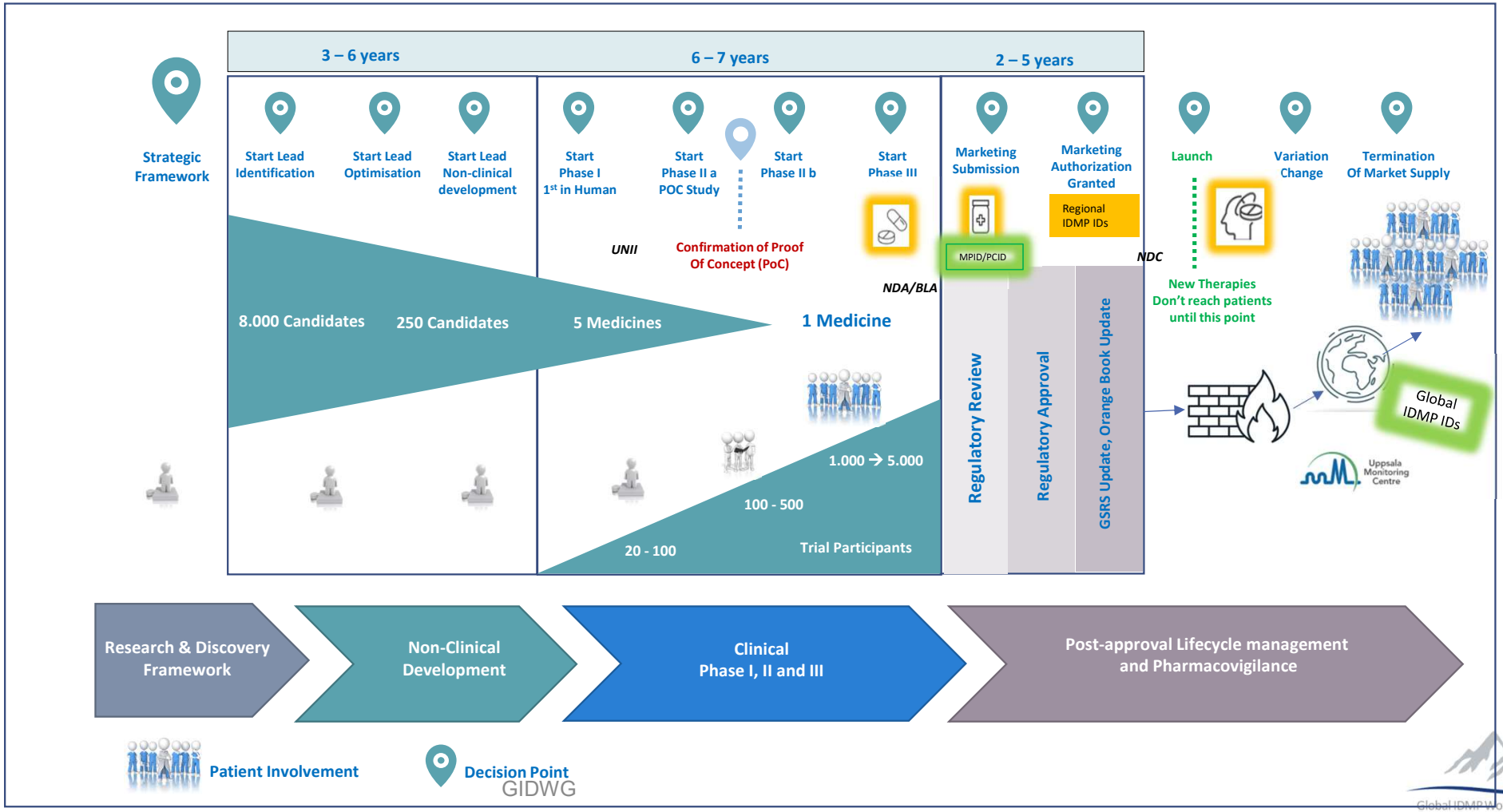
- Global Ingredient Archival System (GInAS)
  - GInAS Notification List
  - https://tripod.nih.gov/ginas

G-SRS (FDA) Expert and Point of Contact:
Dr. Lawrence Callahan/Dr. Frank Switzer

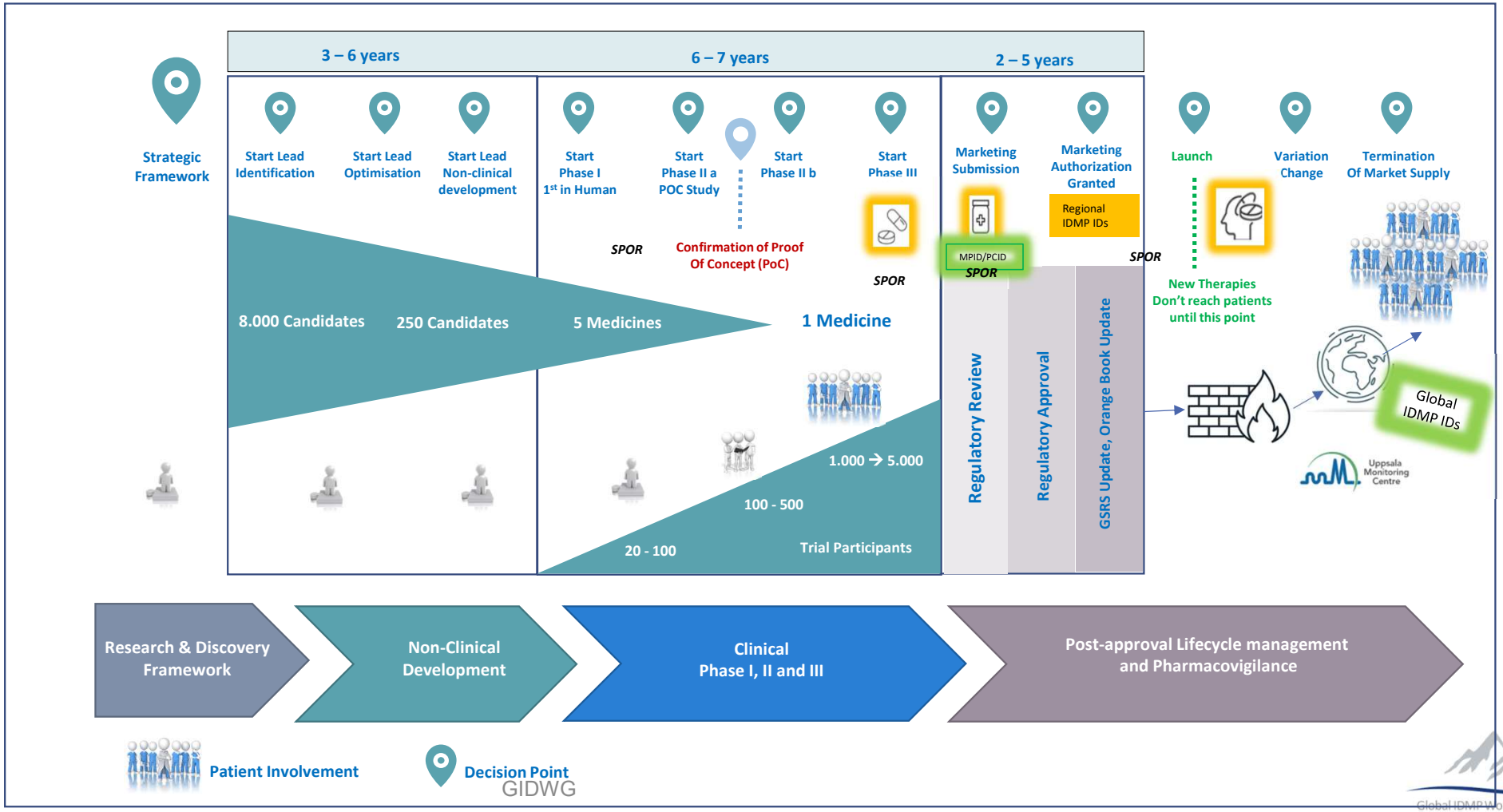
Industry and IDMP Identifiers (v0.1)



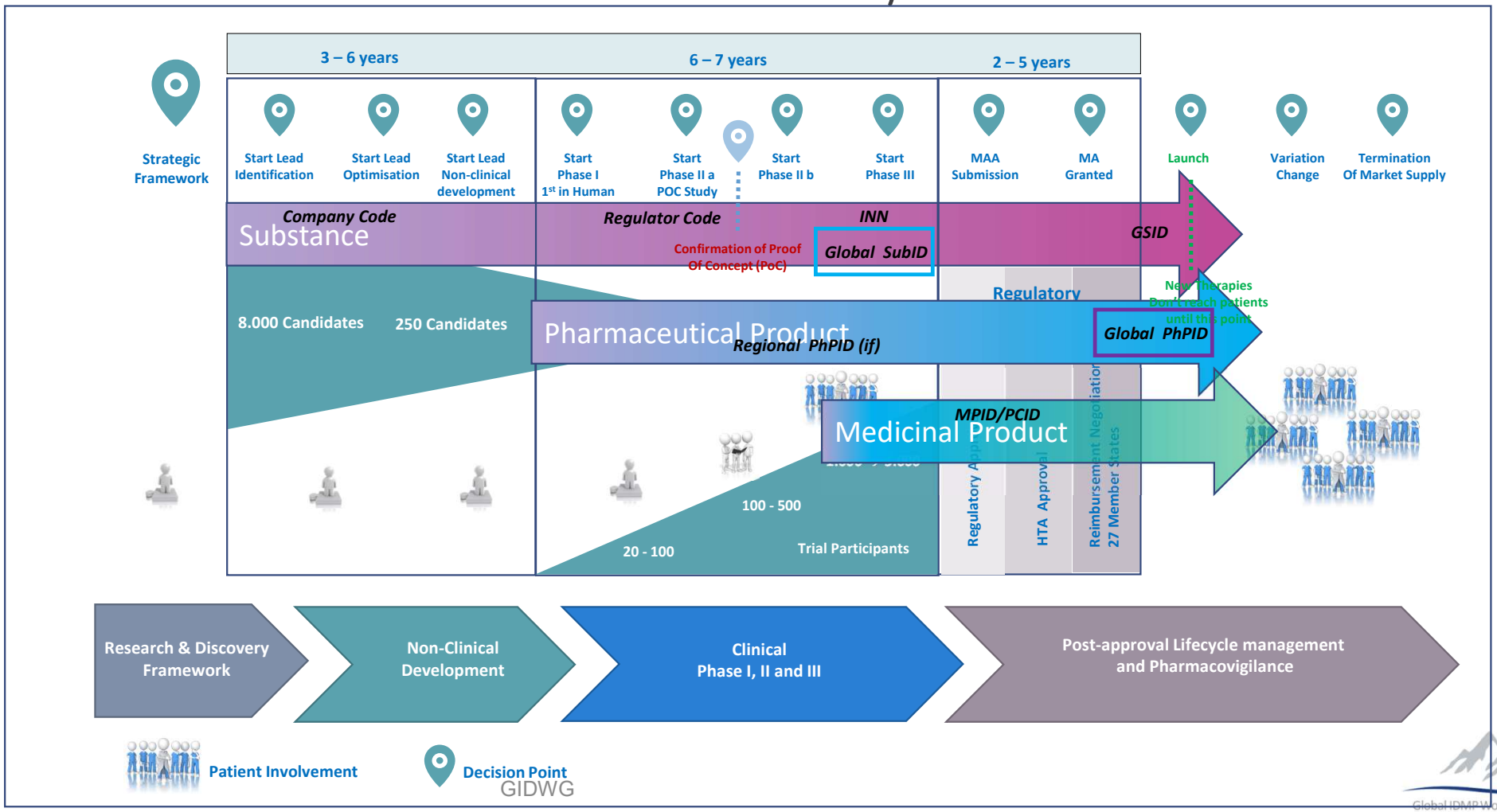
Industry and FDA IDMP Identifiers (v0.2)



Industry and EMA IDMP Identifiers (v0.2)



Recommendation: WHO-UMC MO Assignment: “Global” Substance/PhPID



Global Pharmaceutical Market: Shortages

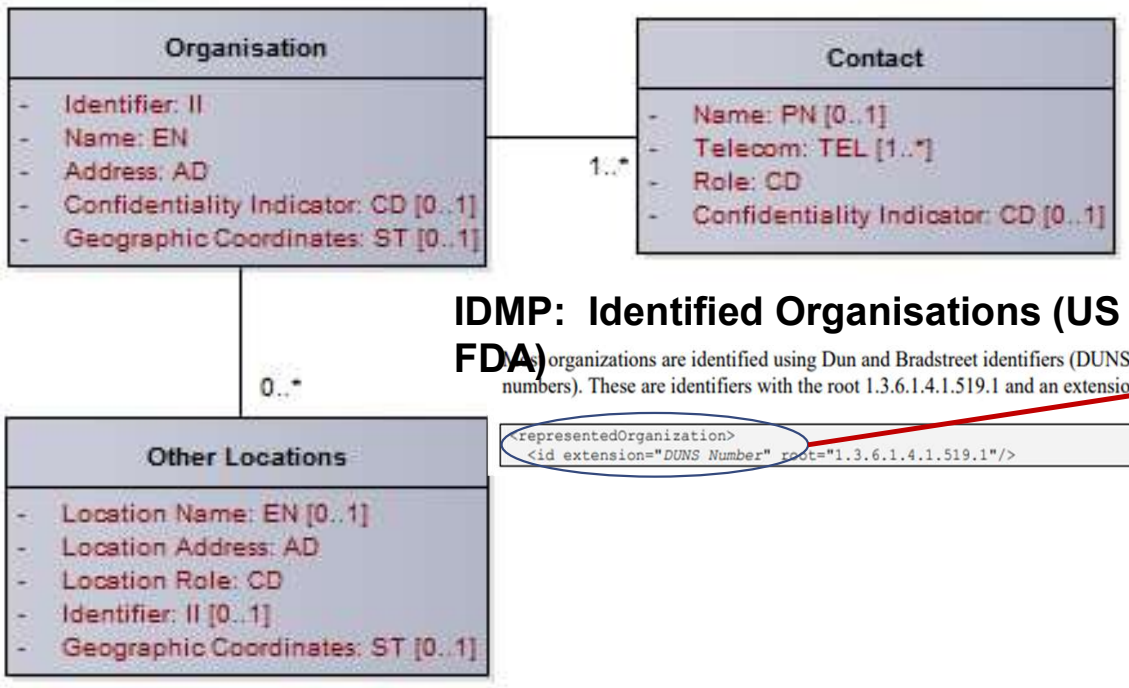
- China makes “nearly all” supplies of penicillin G and about 80% of the world’s supply of many antibiotics.
- Indian drug makers rely heavily (about 70%) on China for key starting materials
- Italy was the EU’s largest producer of antibiotics in 2018, accounting for 34% of the total EU consumption. Italy, however, was hit early and hard by COVID-19 cases
- In the US 186 new drug shortages, 82% of which were classified as due to “unknown” reasons largely because of the intentional opacity and secrecy of the upstream supply chain.
- FDA official reported to Congress in 2019 that FDA doesn’t “know whether Chinese facilities are actually producing APIs, how much they are producing, or where the APIs they are producing are being distributed worldwide, including in the United States”
- USP analyzed the labels of 40,178 prescription drug products and found that only 3% reported the API manufacturer, 30% reported the finished product manufacturer, 45% reported only the labeler or packer, and 25% reported no information on the upstream supply chain
- In 2019 vincristine—a pediatric cancer drug—was in severe short supply the drug simply was not available at any price. One of only two US manufacturers of vincristine exited the market, and the second experienced production delays and quality problems.

CIDRAP
Center for Infectious Disease Research and Policy
University of Minnesota

Global IDMP Working Group

https://www.cidrap.umn.edu/sites/default/files/public/downloads/cidrap-covid19-viewpoint-

IDMP: Unique Organisation (Facility) ID



IDMP: Identified Organisations (US FDA)

organizations are identified using Dun and Bradstreet identifiers (DUNS numbers). These are identifiers with the root 1.3.6.1.4.1.519.1 and an extension

```
<representedOrganization>
  <id extension="DUNS Number" root="1.3.6.1.4.1.519.1"/>
```

IDMP: Establishment Information (US FDA)

```
<document>
  <author>
    <assignedEntity>
      <representedOrganization> <!-- Labeler -->
        <assignedEntity>
          <assignedOrganization> <!-- Registrant -->

<assignedEntity>
  <confidentialityCode code="B" codeSystem="2.16.840.1.113883.5.25"/>

  <assignedOrganization>  <!-- Establishment -->
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    <name>Middleton Manufacturing company</name>
  </assignedOrganization>

  <performance>
    <actDefinition>
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             codeSystem="2.16.840.1.113883.3.26.1.1"
             displayName="manufacture"/>
```
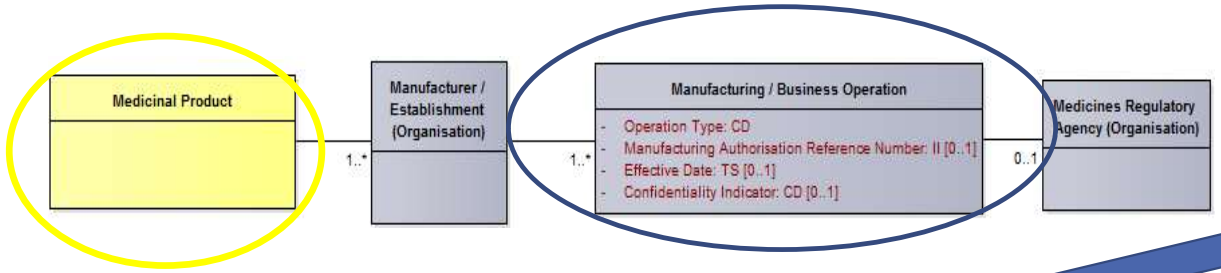

IDMP: Manufacturer/Establishment (organisation)

This subclause specifies characteristics about the manufacturing and other associated operations and their authorisations as issued by a Medicines Regulatory Agency, which grants permission to a manufacturer/establishment (organisation) to undertake manufacturing and other associated operations related to an Investigational Medicinal Product in a specific jurisdiction.



IDMP: Business Operation Qualifier

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IDMP: Business Operation Product

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    <assignedEntity><assignedOrganization>       <!-- Registrant -->
      <assignedEntity><assignedOrganization/>    <!-- Establishment -->
<performance><actDefinition>
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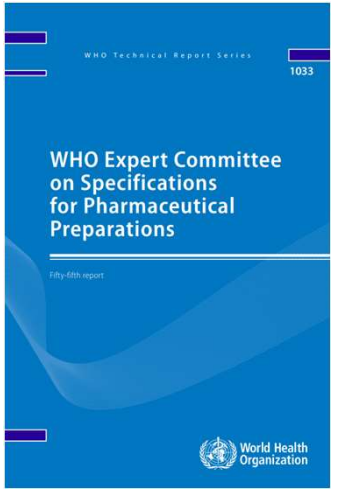
Business Operation Qualifier Examples:

- "Intent to compound 506e (drug shortage) drugs (C112087)
- "unapproved drug for use in drug shortage"(C101533)
- API manufacture (C82401)

WHO Expert Committee on Specifications for Pharmaceutical Preparations: Sameness of a Product

- Two products have identical essential characteristics (i.e. the product being submitted to the relying authority and the product approved by the reference regulatory authority should be essentially the same).
- All relevant aspects of drugs, medical devices and in vitro diagnostics, including those related to the quality of the product and its components, should be considered to confirm that the product is the same or sufficiently similar
  - Same qualitative and quantitative composition
  - Same strength
  - Same pharmaceutical form
  - Same intended use
  - Same manufacturing process
  - Same suppliers of active pharmaceutical ingredients (APIs),
  - Same quality of all excipients).
  - Additionally, the results of supporting studies of safety, efficacy and quality, indications and conditions of use should be the same



IDMP and Unique Medicinal Product Identification

IFPMA

Defining Elements

- purity or grade;
- manufacturer data including information on the manufacturer and processes in manufacturing;
- analytical data in view of the tests and specifications;
- analytical methods used for potency determination;
- constituent substances, including amounts and role when known and relevant;
- specifications for identity, impurities, degradants, related substance limits would be captured using
- constituent substances and potency;
- unitage;
- reference material

To meet the needs of medicinal product identification, the elements of the specified substance shall be divided into four groups and a specified substance identifier shall be associated with each group of elements.

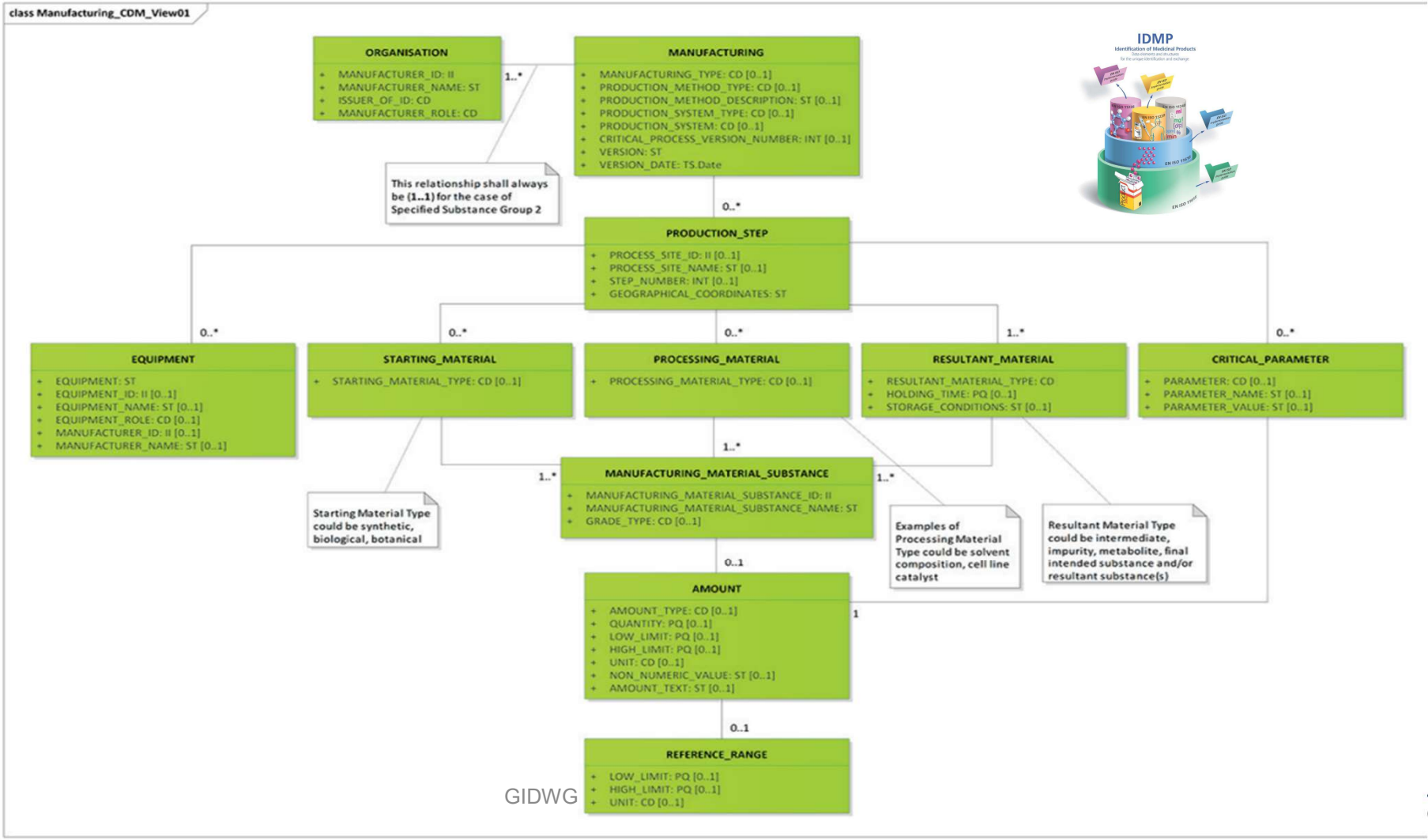
ISO IDMP and Manufacturing: Specified Substance Group 4

IFPMA

- The 'Manufacturing' element group shall capture information on the manufacturer and critical manufacturing processes that are necessary to distinguish specified substances.
  - Starting materials,
  - Processing materials,
  - Critical process parameters,
  - Equipment used and the resultant material from the manufacturing process

NOTE: The manufacturing group is not intended to capture all the details of manufacturing but only the critical processes that could impact the quality, safety or efficacy of a specified substance used in a medicinal product.

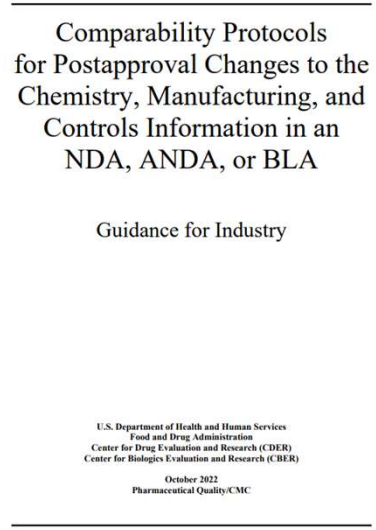
IDMP Manufacturing Information Model



Comparability Protocol for the Proposed CMC Change(s)

- The CP for the proposed CMC change(s) should describe the specific tests and studies to be performed, including analytical procedures to be used, and acceptance criteria to be achieved to demonstrate the lack of adverse effect on product quality.

- The level of detail that should be provided in the CP depends on the following (not all-inclusive):
  - Complexity of the product
  - Manufacturing process
  - Comparative assessment of relevant product quality attributes before and after the change(s)
  - Material(s) that may be affected by the proposed CMC change(s) (e.g., in-process material, drug)
  - Substance, intermediate, reagent, product component, drug product, container closure system
  - Raw material or a combination of these, as appropriate
  - Projected number of batches, batch size or scale,
  - Site of manufacture

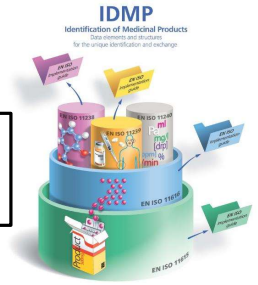

Comparability Protocols for Postapproval Changes to the Chemistry, Manufacturing, and Controls Information in an NDA, ANDA, or BLA

Guidance for Industry

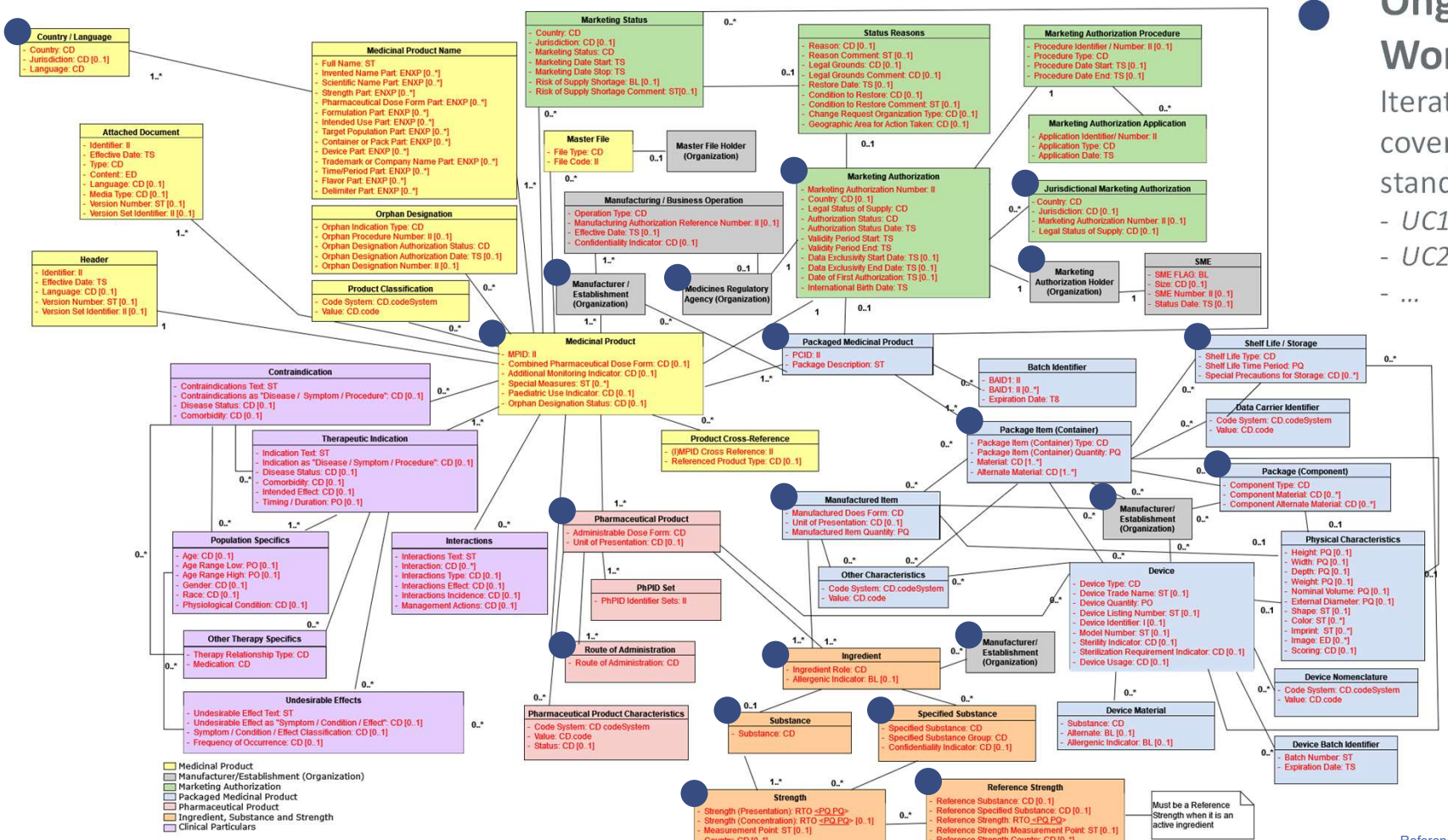
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

October 2022
Pharmaceutical Quality/CMC

ISO IDMP Specified Substance(s)



IDMP-Ontology Coverage of the ISO IDMP Model



Ongoing Work

Iteratively covering the ISO standards

- *UC1: Substance*
- *UC2: Reg-Manuf.*
- ...

Reference: Bayer

Acknowledgments

Industry

Sheila Elz, Bayer

Ciby Abraham, AstraZeneca

Elisabeth Godet, Sanofi

Jean-Gonzague Fontaine, GSK

Christian Hay, GS1

Rodrigo Palacios, Roche

IFPMA

Janis Bernat

Ginny Beakes-Read, J&J

Mumum Gencoglu

GIDWG

Lawrence Callahan, FDA

TJ Chen, FDA

Ron Fitzmartin, FDA

Malin Flavdad, WHO-UMC

Panagiotis Telonis, EMA

IFPMA

Thank you

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PhPID Global operating model
EU Lines to take for Oct GIDWG meeting

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Oct GIDWG meeting – 1/2

- EU sees value in the work of GIDWG around Global PHPID
  - This work will help regulators to **implement the PHPID in a similar way** and enable future interoperability.
  - There could be **synergies** between EU and other regions activities

- EU plans and implementation are in early stages -> **In the short term (2-3 years)**
  - Work is still ongoing in PMS (ISO IDMP 11615) and product data is **not yet fully ISO IDMP compliant and standardised**.
  - Priority will be given to support the Network in standardizing/harmonising product data (including harmonisation of substances, dose forms, strengths).
  - PHPID implementation can only start when **Product data is stable**/correct to support PhPID generation in EU and/or be exchanged with WHO i.e. **>2025**
  - EMA **plans** to implement the Pharmaceutical product (i.e. the PhPIDs as described in the ISO 11616) **in EU** to support EU PhV processes

EU engagement

- **EU will continue to be involved in GIDWG** to
  - acquire knowledge and to be aware of the global developments
  - gain practical experience and confirmation through Pilots
  - to strive that EU and global views are aligned/harmonised
- Due to other competing priorities our **capacity to lead/support pilots and any practical work will still be reduced**
- While we continue to engage, this does not predetermine our formal participation later on in any future implementation.

Oct GIDWG meeting – 2/2

- Proposals to GIDWG:
  - For any Global implementation underlying code systems need to be mapped, ideally harmonised altogether, to enable calculation of global PHPID in automated way.
  - All outcomes of the GIDWG exploratory work need to be further discussed/decided. EU believes recommendations and decisions on process/implementation/governance need to happen at the level of ICH.
  - At the moment there is **no decision taken that this is what EU will do.** If we were to go ahead with UMC proposed process the following **considerations apply**
    - Use **FHIR** for exchange of **product/PHPID** information as well as **substance** information
    - **explore the possibility to have EU & Global PHPID** i.e. sending EU PhPID to UMC, mapping/aligning PHPIDs
    - Avoid a (manual/paper) PHPID request process and **look for more automated options** and ensure it will it not create burden for other stakeholders (NCAs/Industry?)
    - Further **elaborate on process, change mgt** and particularly impact of nullified/invalid PHPID.
    - Provide further clarity on **funding** and if/how this funding ensures **sustainability.**
    - Confirm that EMA/EU is free to further **publish and distribute the PHPIDs for EU products**

Thank you

Global IDMP Working Group

Wrap Up and
Review Action Items/Decisions

Thank you for your work on IDMP!