

## WP-1 / 23rd community of expertise IDMP data : from source to final use

21 April 2023

Moderation:

Christian Hay, NICTIZ/UNICOM WP 1, ISO TC 215 WG 6, GS1  
Esther Peelen, NICTIZ/UNICOM WP 1



## SOME RULES FOR THE VIRTUAL MEETINGS

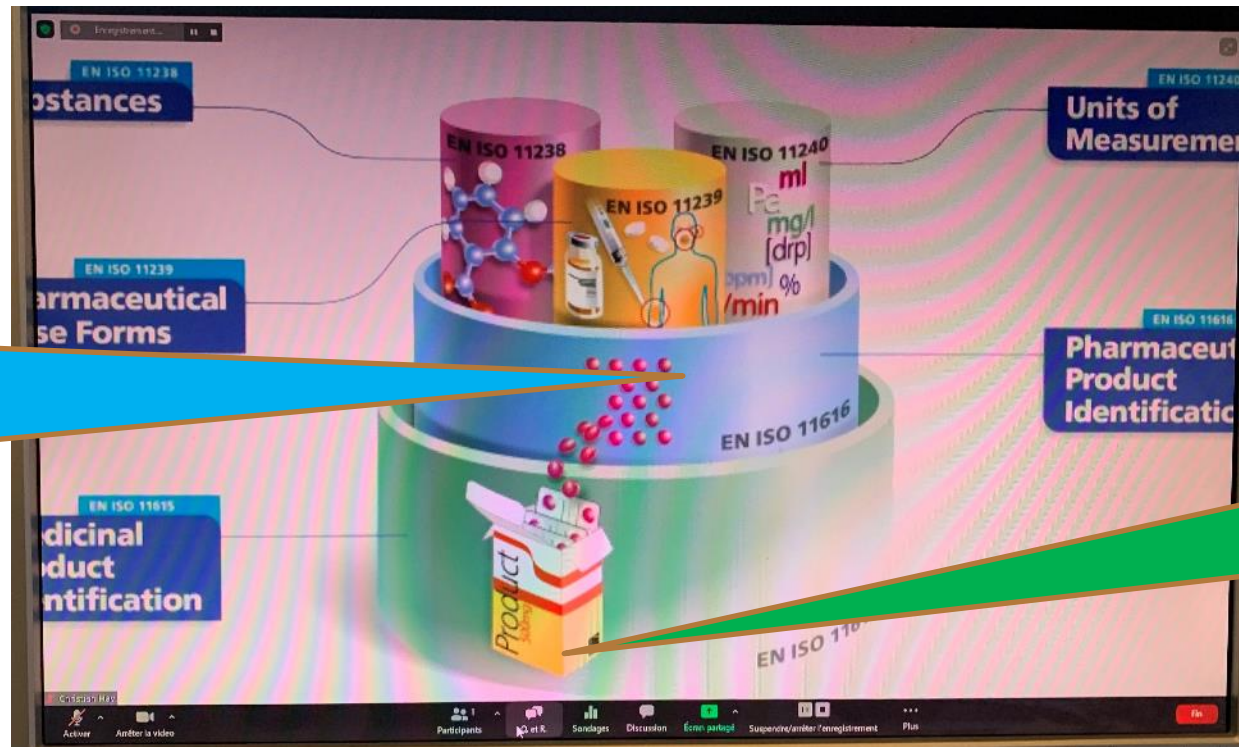
- ✓ **Everybody is on mute**
- ✓ **You post your question in the Q&A facility**
- ✓ **When you speak, please keep concise**
- ✓ **You may show your approval !**

After (and during) the introduction presentations, any UNICOM related question / comment may be shared with Q&A



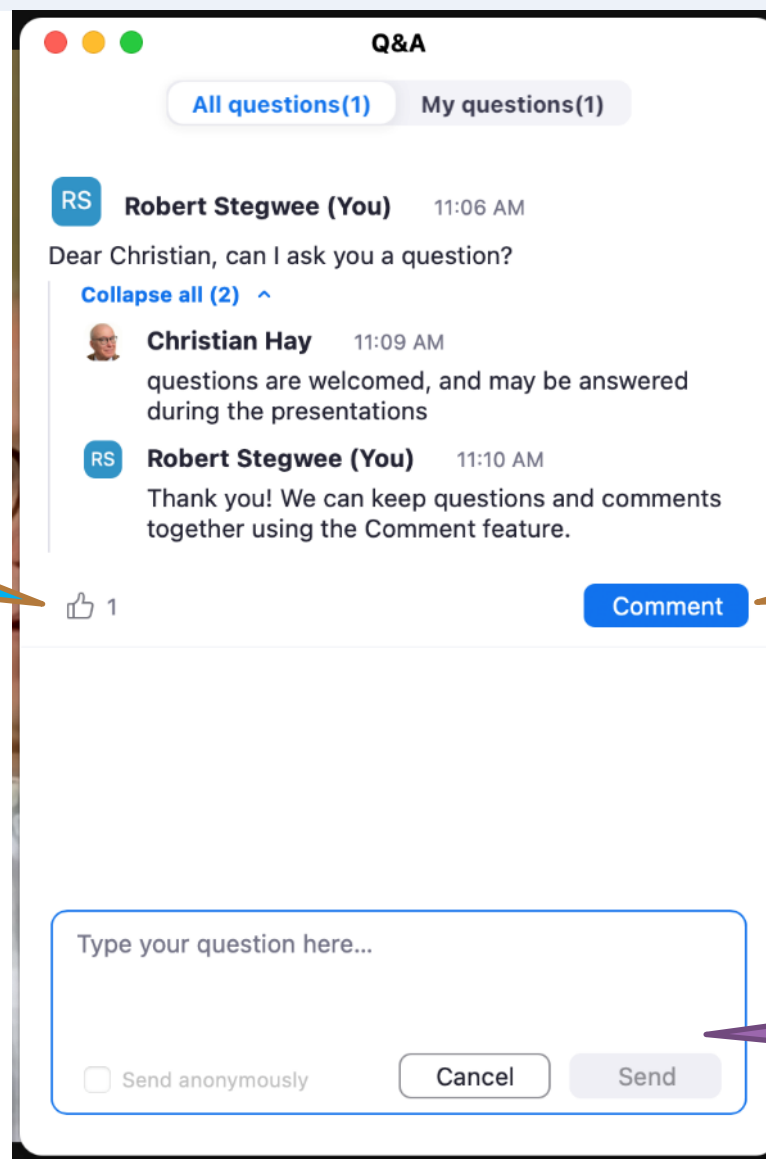
Asking a question or making a comment: please use the Q&A facility

1. Move the mouse on the screen to have the options bar appearing



2. You then select «Q&A» and write your question

You can support a question by clicking the «thumbs up» which moves it up on the list for the presenters



The screenshot shows a Q&A interface with the following elements:

- At the top, there are two tabs: "All questions(1)" and "My questions(1)".
- A question from "Robert Stegwee (You)" at 11:06 AM: "Dear Christian, can I ask you a question?".
- A "Collapse all (2)" link with an upward arrow.
- An answer from "Christian Hay" at 11:09 AM: "questions are welcomed, and may be answered during the presentations".
- A comment from "Robert Stegwee (You)" at 11:10 AM: "Thank you! We can keep questions and comments together using the Comment feature.".
- Below the comment, there is a thumbs-up icon with the number "1" and a blue "Comment" button.
- At the bottom, there is a text input field with the placeholder "Type your question here...".
- Below the input field, there is a checkbox labeled "Send anonymously", a "Cancel" button, and a "Send" button.

You can comment on a question or answer to engage in a conversation

Typing and sending a new question does not retain the context of your comment



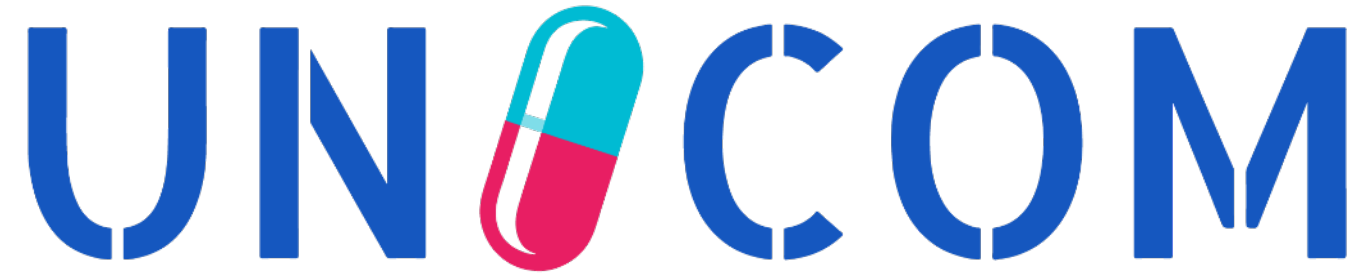
- ▶ Security is our priority
- ▶ This session is password protected



Recording of this session is made available on UNICOM's youtube channel <https://https://www.youtube.com/c/UNICOM-IDMP>

At the end of the virtual session, a questionnaire will be sent to the participants, to help us understand participant's reactions and needs





## IDMP data : from source to final use

Quentin Darrasse – Roche Pharma  
Andreas Franken – BAH, ISO TC 215, WG 6  
Stefan Peev – NNIT  
Frederic Doc, Vidal, UNICOM WP 9  
Boukje Raemaekers, WHO-UMC

Malin Fladvad, WHO-UMC, UNICOM WP 1, ISO TC 215, WG 6



Introductions to our esteemed colleagues and today's speakers...



Quentin Darrasse



Andreas Franken



Stefan Peev



Frederic Doc



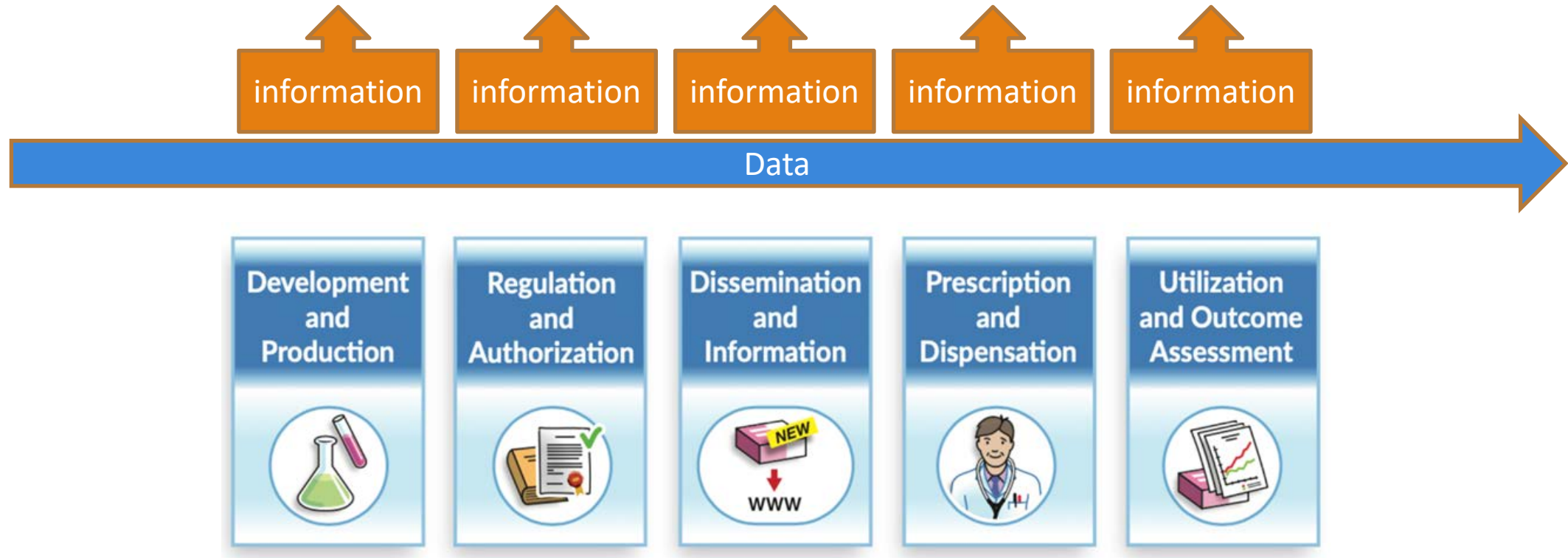
Boukje Raemaekers

...and pannelist



Malin Fladvad





Questions in the Q & A facility, please  
For feedback, please go to :

[https://docs.google.com/forms/d/e/1FAIpQLSd6Zvppbz3IQIZXYtMbeFUstSU0mpXsf1XxNV5bAD64oGHnwQ/viewform?usp=pp\\_url](https://docs.google.com/forms/d/e/1FAIpQLSd6Zvppbz3IQIZXYtMbeFUstSU0mpXsf1XxNV5bAD64oGHnwQ/viewform?usp=pp_url)

*Thanks for your time*

UN  COM



# IDMP Implementation – An Industry Position

## Disclaimer

The opinions expressed in this presentation and on the following slides are solely those of the presenter and not necessarily those of Roche.

Roche does not guarantee the accuracy or reliability of the information provided therein.

# IDMP@Roche



- 5+ years of Regulatory Transformation towards the adherence to IDMP
    - IDMP seen as an opportunity for digital transformation -
  - Some early success: Master Data Developments, integration with Technical, seamless XEVMPD, SPOR readiness...  
**BUT** IDMP still often seen as a Regulatory Compliance topic  
**AND** still challenges in reusing data across lifecycle with back traceability (shortages, counterfeits, ICSRs, etc.)
- >>> Is the big shift to FAIR Data and Digital Ways of Working still happening, and if so, when?

# The Global Challenge with Data Standards



- ISO IDMP standards are prone to interpretation as well as to jurisdictional implementation specifics
  - Diverging IDMP implementations create more silos and are a risk for standardization benefits of IDMP for Pharma
- >>> How can we prevent IDMP from making our operating models more complex, and how can we make sure that it delivers envisioned standardization benefits instead, across our organizations as well as across the whole Industry?

# IDMP-Ontology

- IDMP-Ontology provides a universal framework for the implementation of the IDMP product data model as a common language to effectively bridge the gap between people, processes, and systems
- Digital, machine-processable standard, meant to resolve the ambiguities of ISO IDMP and enrich it
- Could IDMP-Ontology be the missing link between ISO IDMP and a global, harmonized, meaningful implementation of critical data standards for Pharma, in the context of Digital Transformation?
- Project led by Pistoia Alliance, 12+ Pharma sponsors, many interested parties incl. Regulators
- <https://www.pistoiaalliance.org/projects/current-projects/idmp-ontology/>

Doing now what patients need next



# UNICOM IDMP data : from source to final use

21. April 2023

Dr. Andreas Franken

**.B.A.H**

Bundesverband der  
Arzneimittel-Hersteller e.V.

# IDMP Implementation and use from a SME's viewpoint

23. April 2023

**.B.A.H**

Bundesverband der  
Arzneimittel-Hersteller e.V.

## Disclaimer

The views and opinions expressed in or with this presentation are those of the speaker and do not necessarily reflect the views or positions of the .B.A.H.



# Small and Medium Size Companies

[SME definition \(europa.eu\)](https://europa.eu)

**Small and medium-sized enterprises (SMEs) represent 99% of all businesses in the EU.**

Company category	Staff headcount	Turnover	or	Balance sheet total
Medium-sized	< 250	≤ € 50 m		≤ € 43 m
Small	< 50	≤ € 10 m		≤ € 10 m
Micro	< 10	≤ € 2 m		≤ € 2 m

Further details:

- [The revised user guide to the SME definition \(2020\)](#) (2 MB, available in all EU languages)
- The [SME self-assessment tool](#) which you can use to determine whether your organisation qualifies as a small and medium-sized enterprise

# SME ↔ Big Pharma - General

SME	Big Pharma
Single Country	Multi Country
Only a few people involved. One or two person per task.	Can switch and rotate assignments easily. Group assignments.
Will stick to the people they have	Can hire new skilled people
Follow the need and mandatory requirements	Follow technical development
Have established processes	Gain overview and quality
Implementation easier. Updates follow necessity	Implementation and update Hard- and Software difficult (everywhere the same)
Some internal recommendations	Strict policies and company rules
Narrow budget	Budget resources

# SME ↔ Big Pharma – Data&Information

SME	Big Pharma
Single Computer; small network	Internal Network
Apps and Tools	Cloud Services
Paper/ePaper focused	ePaper+Data focused
Outsourcing difficult work	Everything internal
External Manufacturer	Own production
Apps, Online UI,	In House Tools/Systems
Follow development, React&comply	Join Discussions, send experts, contribute
Pharmacovigilance	Pharmacovigilance

# Conclusions

- For a national company, it is sometimes difficult to think Europe (or even Global)
- SME will generate and use IDMP data if they have to.
- SME fulfil their duties but following and predicting data centric developments is very often difficult for them.
- Until then, it is additional workload. A lot of work is still done in paper/e-paper
- It is difficult for them to change (mentally) the established processes
- At the same time, if they decide so, it is easier for them to switch
- SME will see benefits of IDMP later, if the new processes replace the old ones
- Benefit does not come from the interoperability of their internal systems
- The situation of SME is often not seen when projects are pushed forward on a EU or global level
- The financial buffer of such companies is small, unsuspected costs might lead to the cease of business

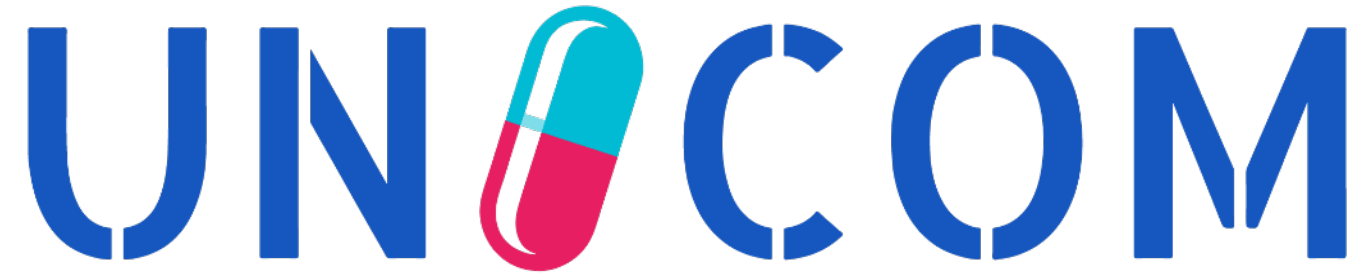


# Data standalone?

We need a door and a staircase....







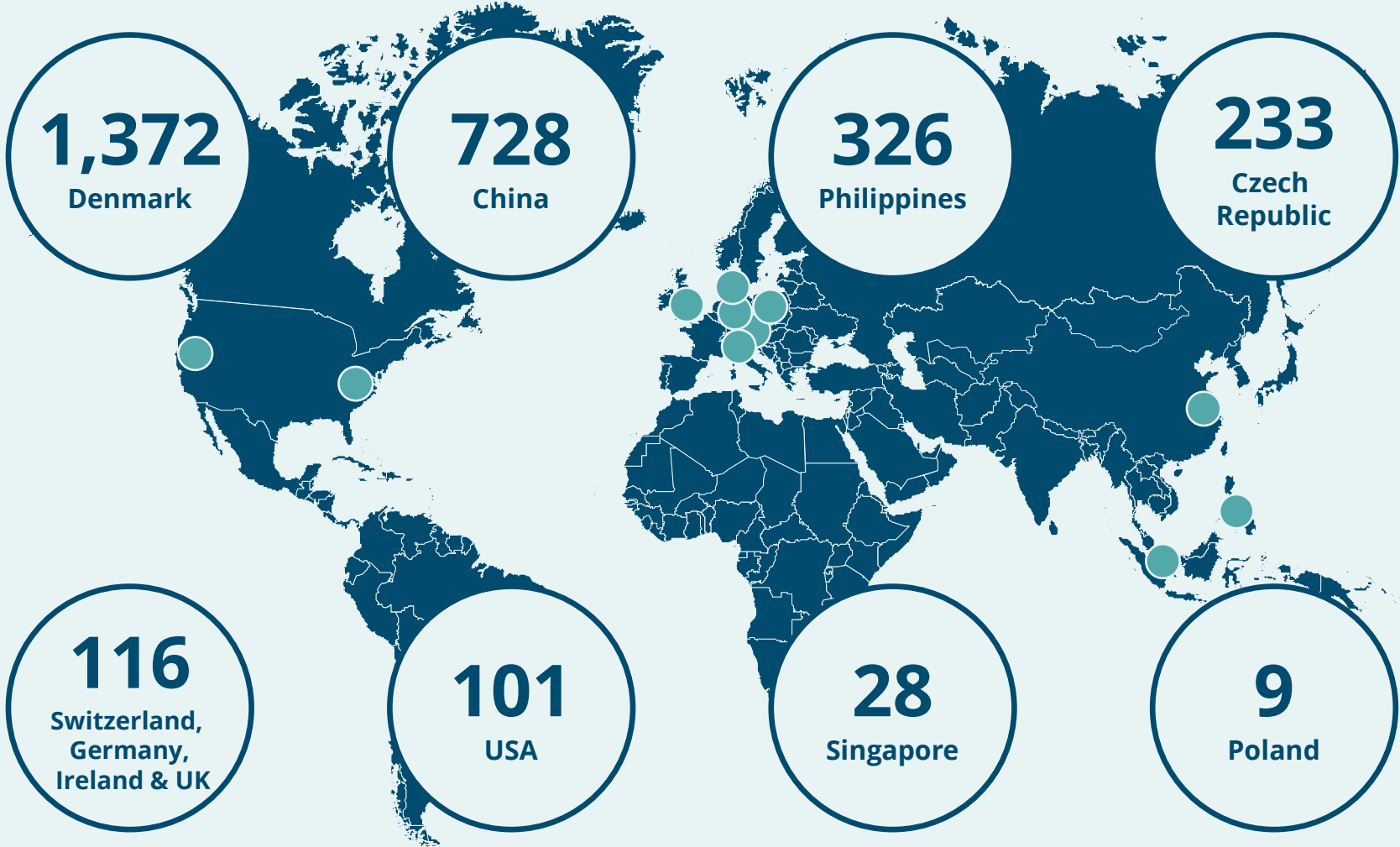
## IDMP data : from source to final use

Some considerations



# Who are we?

*NNIT is a Global Life Sciences IT Powerhouse with more than 3,300 Employees Worldwide*



# NNIT Regulatory Affairs

## We guide our customers through the digital business transformation

With knowledge, experience, dedication, and trust, we help our customers **impact patients' lives.**

The NNIT Group provides a **wide range of IT and consulting services** to the **global life science industry** and has been a **trusted partner** to life science companies for **+25 years.**

We are a **leading global RA advisory and consultancy** unit committed to **digitally transform** Regulatory Affairs into an **influential strategic and data driven business unit.**

We leverage **thought leadership knowledge** and the **newest technology**, with **implementation excellence** and successive **maintenance service.**

Advisory

Implementation



Continuous  
improvement

NNIT  
rated as  
**Leading RA  
consultancy**  
*GENS & ASSOCIATES*



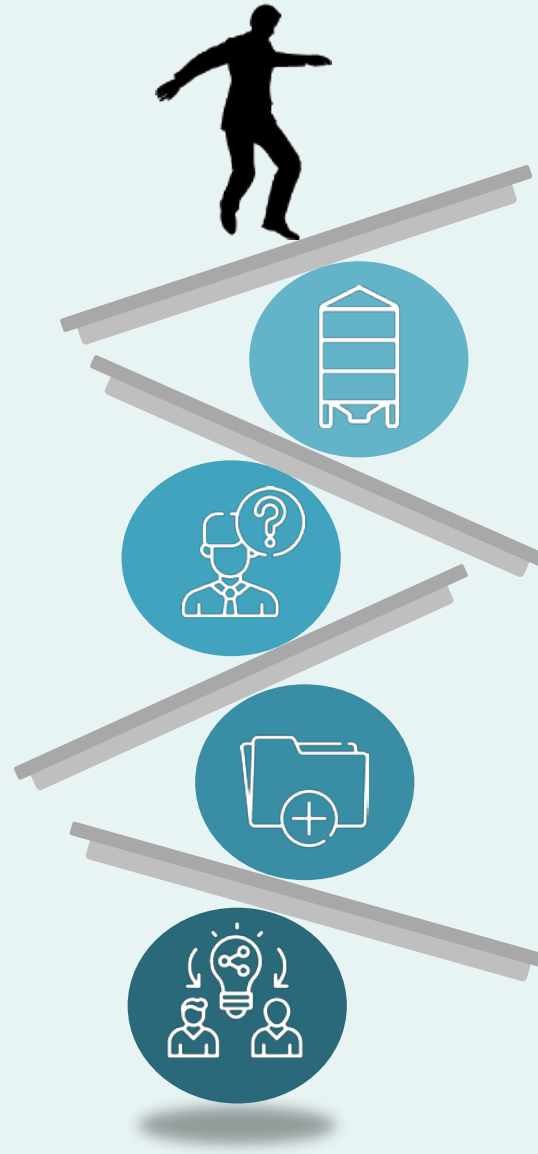
IDMP  
framework,  
leading IDMP  
mapping tool

**100+**  
RA dedicated  
consultants  
in DK, CH, DE,  
CN, US

**3000+**  
Employees in  
NNIT globally

**30+**  
Current RA  
clients, incl.  
several tier 1  
pharma clients

# IDMP data ~~challenges~~ opportunities



## DATA MANAGEMENT

We are forced to think about data and what to do with it – we are not used to data management.

## REGULATION SILOS

Every function has been looking at data and compliance in their own remit, but that has been due to fragmented authority regulation.

## KNOWLEDGE

Even though we have a lot of expertise on IDMP, there is not enough knowledge in the industry.

## DATA REPOSITORIES

We have to store data we've never had to store before – we have no place for it.

# Industry's commitment to data

## Q46

What is your Regulatory Organization's estimated investment effort (budget/ people time) for the following technology areas for the next 2 years?

(Significant + Moderate investment shown in table below, Green = >50% , Red <10%)



- Most of the listed technologies are being invested in by > 50% of the large companies
- MDM is the most common investment across large, mid and small companies

Highest per Tier

Advanced Technology Area	All Responses (n=74)	Large (n=15)	Mid Tier (n=23)	Small (n=18)	Very Small (n=18)
Master Data Management (MDM)	51%	67%	74%	50%	11%
Data Visualization	42%	60%	61%	33%	11%
Data Hub / Lake / Warehouse	39%	80%	48%	17%	17%
Reference Data Management	38%	67%	61%	11%	11%
Robotic Process Automation (RPA)	38%	73%	48%	22%	11%
Structured Content Authoring (SCA)	35%	73%	39%	17%	17%
Business Intelligence	35%	60%	39%	11%	33%
Collaborative Submission Platforms	32%	67%	30%	22%	17%
AI / Machine Learning Algorithms	24%	73%	26%	6%	0%
Low Code Application Platforms	22%	53%	22%	11%	6%
Knowledge Maps (data relationships / ontologies)	18%	40%	22%	0%	11%
Data Mining	18%	53%	22%	0%	0%
Advanced Search	16%	27%	13%	11%	17%
Natural Language Processing (NLP)	15%	53%	13%	0%	0%
Predictive Analytics Tools	11%	33%	9%	6%	0%
Natural Language Generation (NLG)	8%	27%	9%	0%	0%
Voice Recognition	1%	0%	4%	0%	0%



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Source: 2022 Gens & Associates World Class RIM study (n = 76) <sup>29</sup>



# Community of Expertise

Frederic DOC  
VIDAL France

# VIDAL Group



## Key figures

- **350+ staff in 7 companies**
- A successful digital transformation: **98%** of revenues in 2022
- **165.000** physicians use our solutions in France, **500.000** at Group level
- Revenues 2022 : **72 M€**
  - +13% in 2022; close to +100% over 5 years

## Diversified

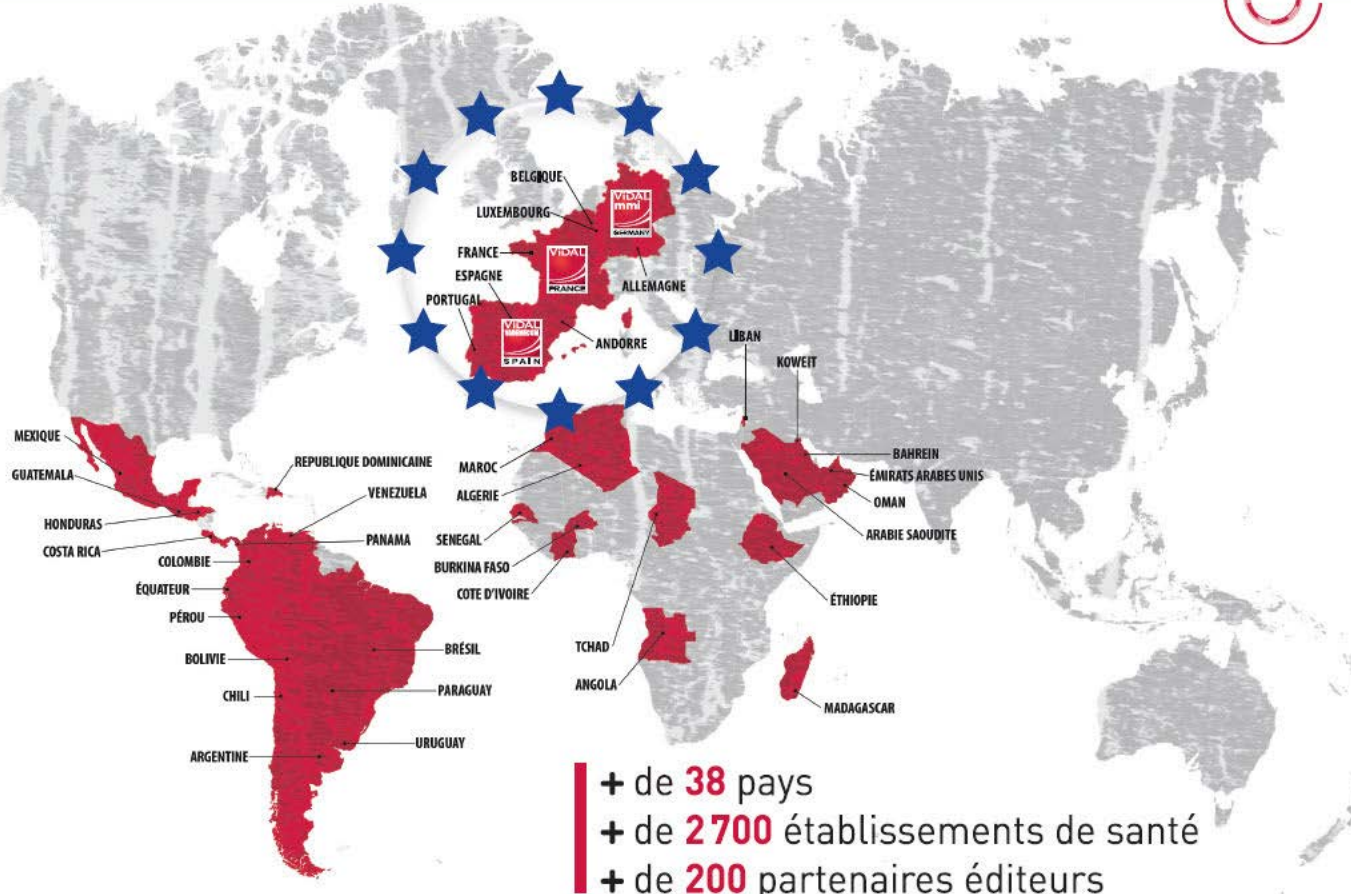
- **European leader in drug databases and Clinical Decision Support**
- Presence in other fields:
  - Continuous medical education (Eron Santé) since 2021
  - Medical communication (M-Eden) since 2020
  - Medical software (Weda, MonEcho) since 2019

## International

- Branches in **3 countries**:
  - France (VIDAL France), Germany (VIDAL MMI) and Spain (VIDAL Vademecum)
- Sales in **38 countries** (Europe, Middle-East, Latin America)
- Partnerships with over **200 medical software vendors**
- Accreditations by the French and German health authorities: **HAS & KBV**



# VIDAL Group

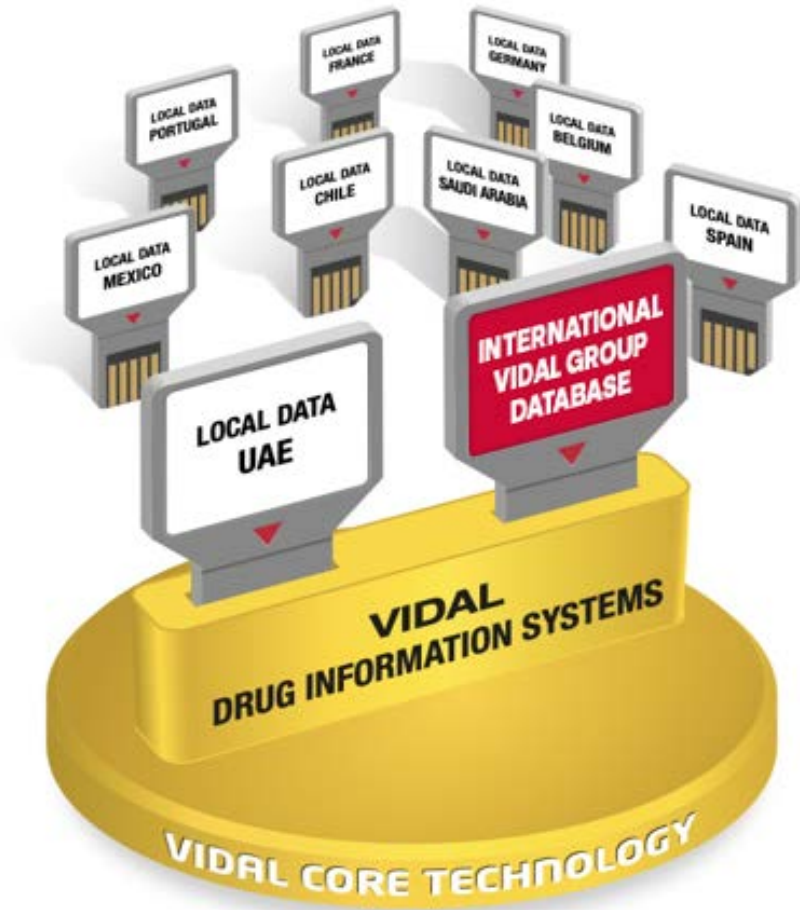


- 38 countries are using a Vidal based MPD over the world
- ...such as in Europe :
  - Andorra
  - Belgium
  - France
  - Germany
  - Luxemburg
  - Portugal
  - Spain



Our vision:

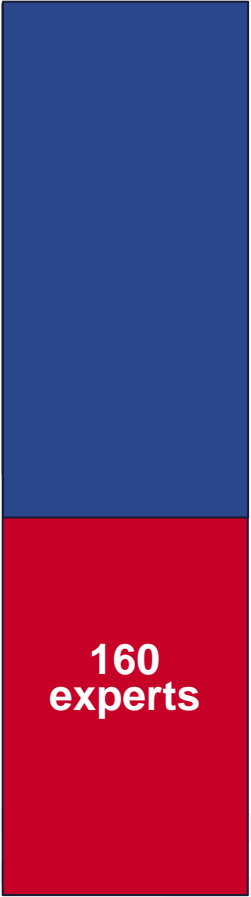
# Medical knowledge is global, data on health products is local



- Centralized management of:
  - scientific and medical knowledge
  - international terminologies
- Decentralized management of country-level data
- Unified technological backbone across the group (infrastructure, back-office, API)

# Our asset: A team of international experts

350 staff



**10 pers.**  
Integration support  
for vendors

**70 pers.**  
Software  
development

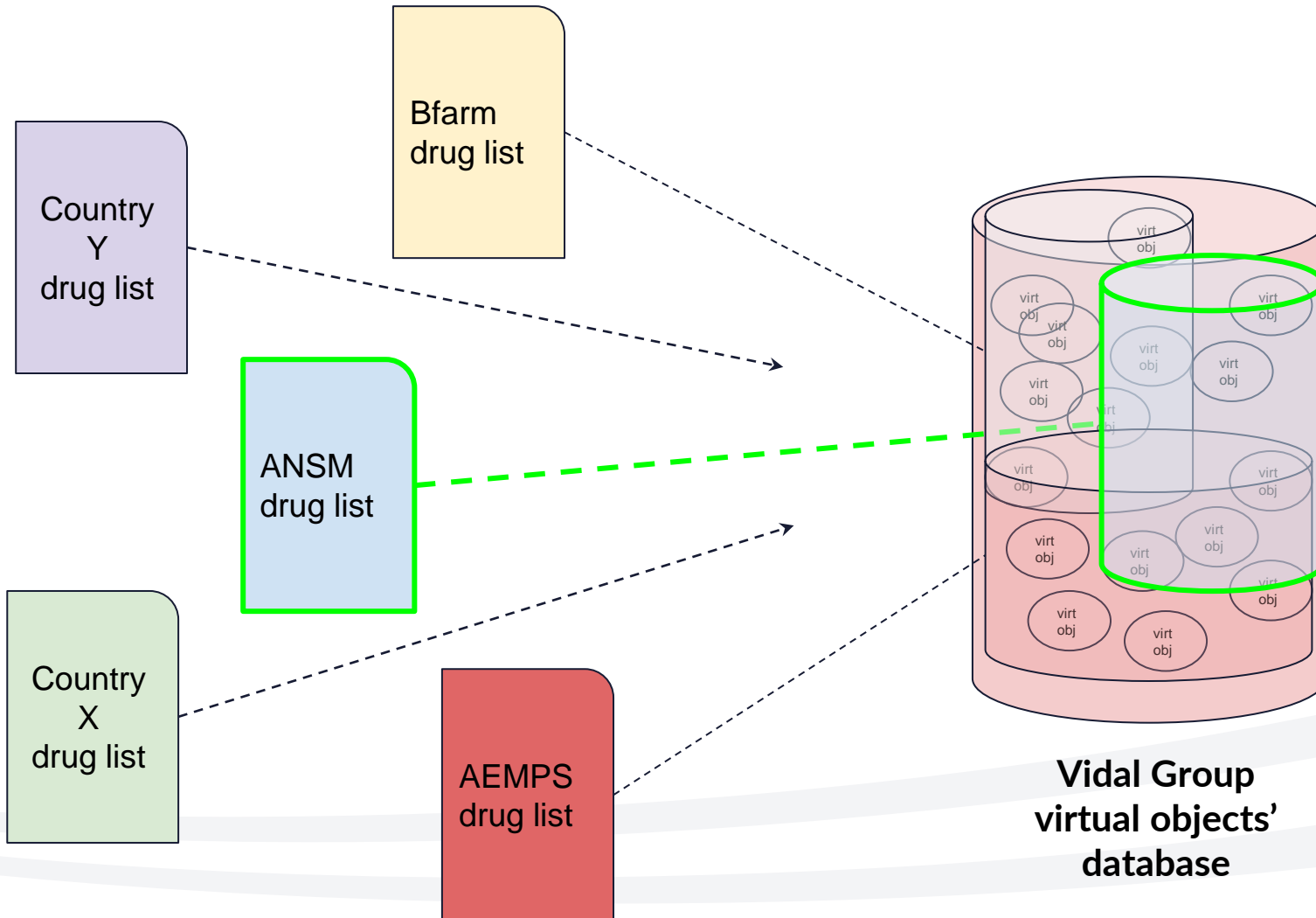


**20 pers.**  
NLP,  
terminologies, R&D

**60 pers.**  
Medical and  
scientific

# How does it work ?

## At Vidal Group level

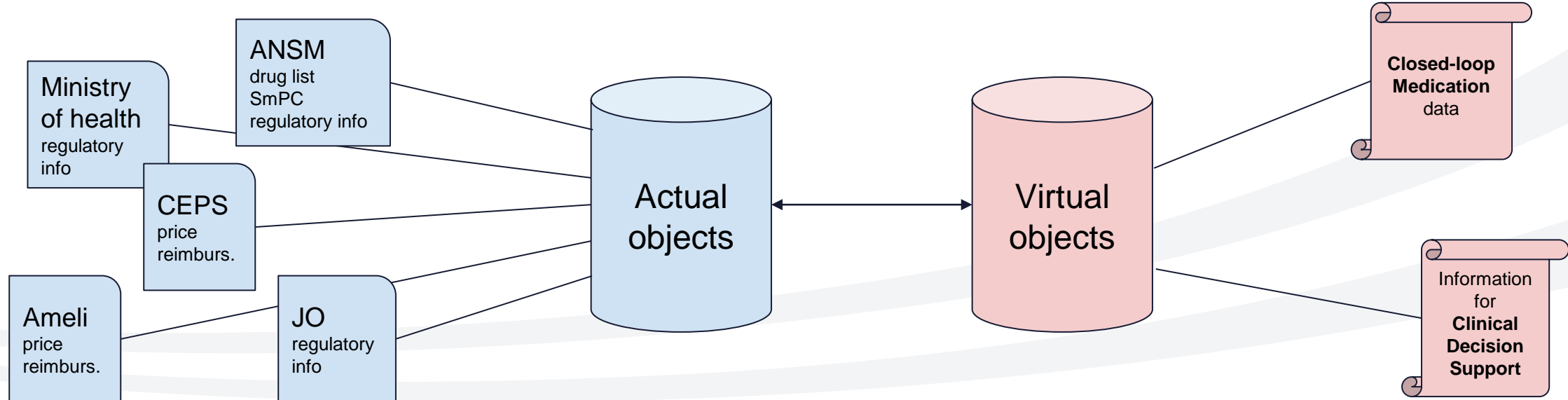


**IMPORTANT**  
Vidal Group's virtual objects are designed for patient care and clinical use cases. In this they should not be seen as PhPID but they share some characteristics with IDMP virtual objects.

# How does it work ?

## Focus on the process for Vidal France MPD

- ACTUAL LAYER
  - Authorised Medicinal products/packages/unit doses are referenced (CIS, CIP, UCD, name)  
Product description is made : full composition, strength, dose form, etc.
  - Local information is added (economics : price, VAT, reimbursement conditions / regulatory : prescription conditions / etc.)
  - Additional documents are attached : SmPC, Protocols for Temporary Use, Risk management plan, etc.
- VIRTUAL LAYER
  - Virtual product description : composition in active ingredients, strength, dose form, etc.
  - Closed-loop Medication data (CLM)
  - Therapeutic information for Clinical Decision Support (CDS)



# How does it work ?

## Focus on the process for Vidal France MPD

- Multiple data sources
  - ANSM provides a list of Medicinal products with their respective SmPC and many info like compassionate use, etc.
  - CEPS supplies pricing information including reimbursement rate, etc.
  - JO (Official Journal) publishes prescription and reimbursement conditions, etc.
  - Ameli (National Insurance system) publishes prices and reimbursement rates
  - Ministry of Health makes available the list of compassionate Medicinal product with their indications for reimbursement, etc.
  - etc.
- VIDAL takes those sources into account, creates new entries (Medicinal product, package, etc.) in the MPD, imports some data from computable sources and creates other pieces of information using non-computable sources.
- VIDAL creates virtual objects corresponding to those products (i.e. virtual twins)
- VIDAL adds value by adding scientific data to the virtual objects
  - Closed-loop Medication data (CLM)
  - Therapeutic information for Clinical Decision Support (CDS)

IDMP data :

# What are MPD provider's expectations ?

- To access unambiguous data (describing drug products) in an *easy-to-handle* structured way
  - aims at reducing data management and duplication ...and therefore reducing the risk of mistake in “re-copy”
  - saves time to focus on value-adding activities
- To be sure to deal with **validated data** that
  - are generated by pharma companies/manufacturers
  - follow **editorial rules\***
  - are validated by NCA (EMA, local drug agencies...)
- To benefit from an harmonisation of Medicinal product descriptions (at least) in the EU environment

=> Automation of data collection and processing to focus on value-adding services

\*for example : a rule could be “a semi-solid must have a strength in mg/g”. If pharma companies do not follow this kind of rule and NCA validate this data no value will be found by MPD providers.

IDMP data :

# What are MPD provider's expectations ? More in detail...

- Unambiguous data
  - “Pivot” identifier mapped to national codes : Spanish, German and French code systems for Medicinal product lead to a unique identifier in IDMP enabling the “re-use” of a large part of the product information in different countries (= only local information is populated for each market).
- Virtual description of product with PhPID and their alignment to MPD virtual objects will
  - facilitate the generic prescription process
  - guarantee the harmonisation of the Medicinal product representation across countries
    - allow cross-border prescriptions/dispensations
    - make interchangeability easier in prescription/dispensation/administration of Medicinal product
    - give solutions to patients travelling abroad to find equivalents of their chronic treatments in different countries
  - enhance the development of a common vocabulary between healthcare professionals and patients

IDMP data :

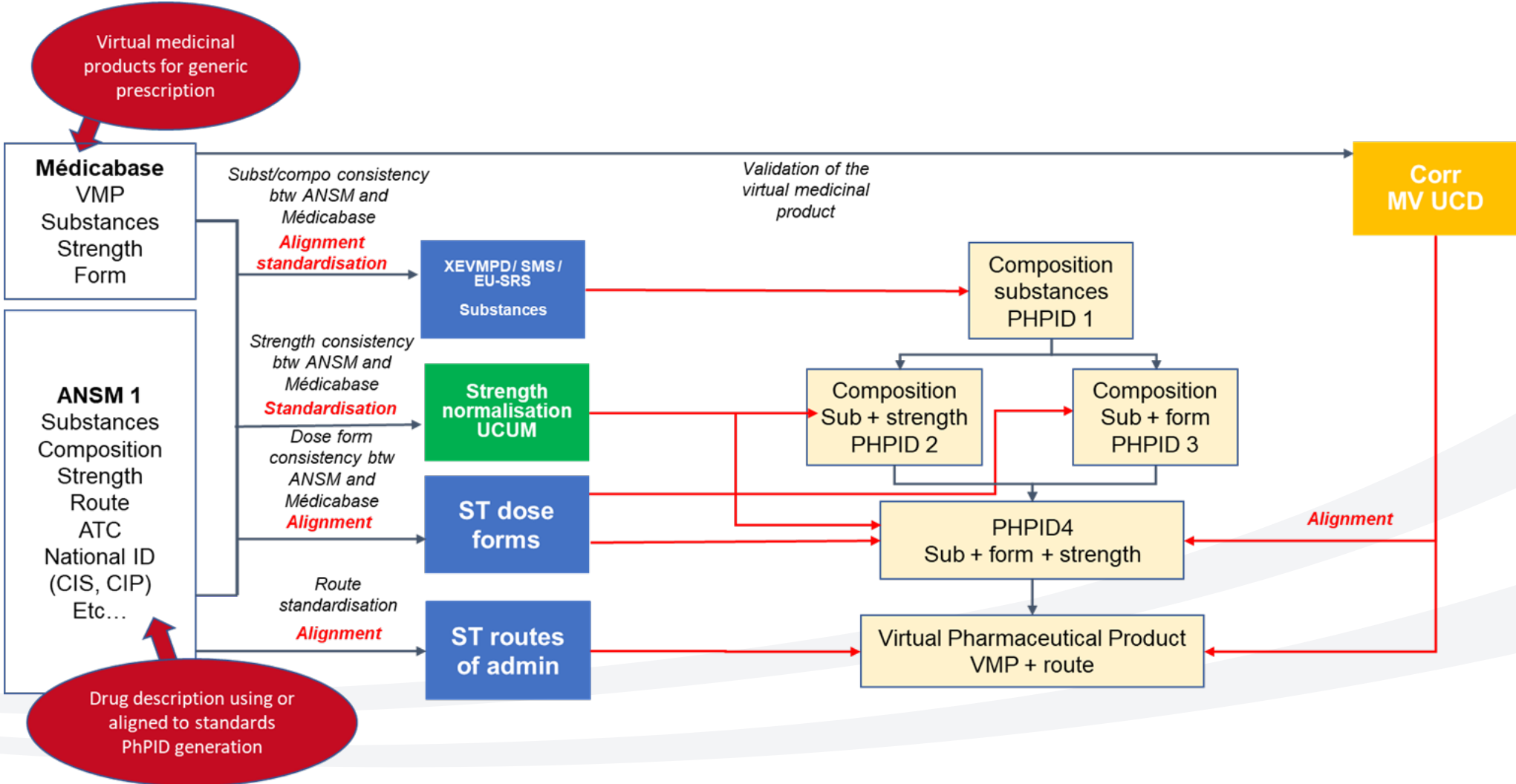
# What are MPD provider's expectations ? More in detail...

- Depending on the kind of information provided by IDMP data
  - the “substance only” (qualitative composition) would allow a first level of services : allergy check, basic level of drug-drug interactions, etc.
  - quantitative composition including roles of substances (PAI, BoSS) would help making calculations in the domain of equivalents, posology and so on...

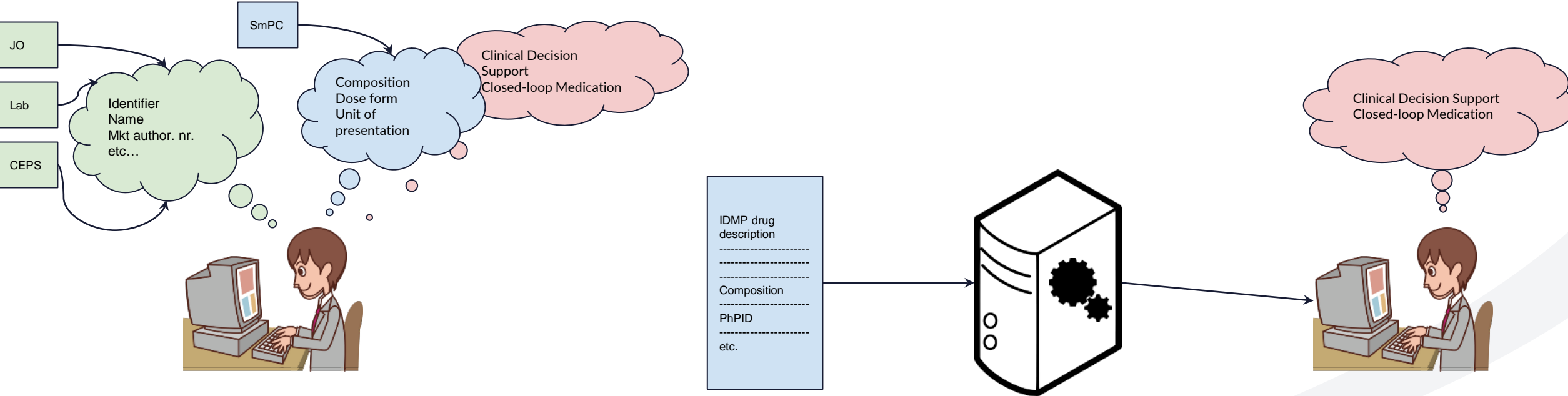


IDMP data :

# What are MPD provider's expectations ? More in detail...



# Conclusion of this presentation



### Without IDMP

- Multiple sources
- Almost non-structured information
- Manual processing
- Low speed
- Risk of mistake enhanced

### With IDMP

- 1 major & structured source
- Automated processing
- High speed
- Risk of mistake reduced

# Many thanks for your attention

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## Any question ...now or later ?

[frederic.doc@vidal.fr](mailto:frederic.doc@vidal.fr)

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# UNICOM Community of Expertise – IDMP data: from source to final use

Boukje Raemaekers, Uppsala Monitoring Centre

2023-04-21

# Uppsala Monitoring Centre (UMC)

- Independent, non-profit foundation established in 1978 to coordinate a **global collaboration for safer medicines**
- Organisationally and scientifically **independent from WHO**
- As a WHO Collaborating Centre, we:
  - Developed **WHODrug Global**
  - Oversee the technical and scientific operations of the **WHO Programme for International Drug Monitoring**
  - Manage **VigiBase**, WHO's global database of suspected adverse drug reactions





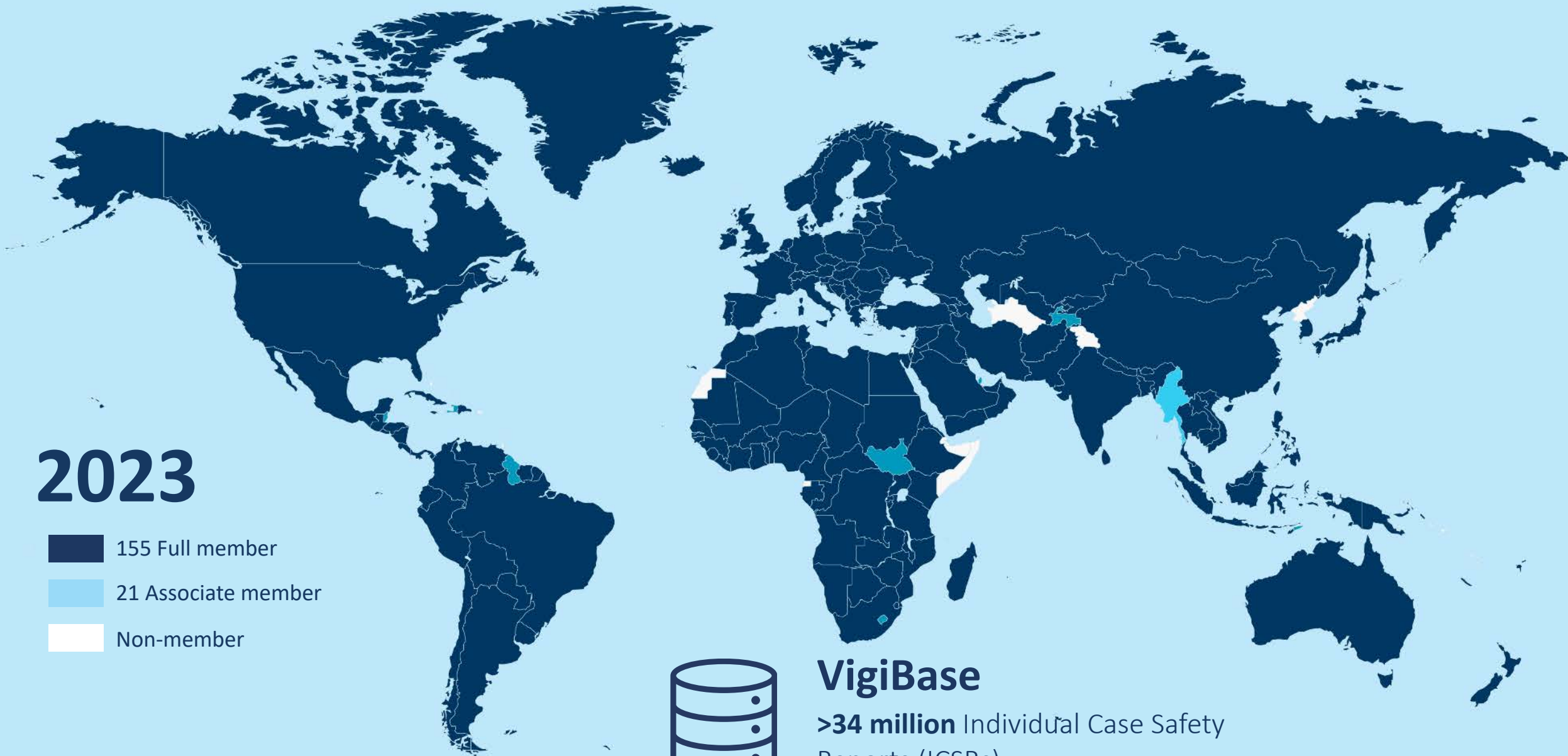
# 2023

- 155 Full member
- 21 Associate member
- Non-member



## VigiBase

**>34 million** Individual Case Safety Reports (ICSRs)



# Signal detection

- VigiBase is screened to identify **drug-ADR combinations** that are:
  - Unknown
  - Known, but incompletely documented
    - At-risk populations
    - Dose-response relationship
    - Pharmaceutical group effect
    - Interactions
    - Outcome
    - Mechanism
    - Etc

# ICSRs – Missing information

- Unknown patient age: >9 million ICSRs
- Unknown patient sex: >2 million ICSRs
- Unknown reaction start date: >15 million ICSRs
- Missing narrative: >19 million ICSRs
- Unknown drug start date: >11 million ICSRs
- Unknown route of administration: >15 million ICSRs
- **Uncoded substance: >0.5 million ICSRs**
- **Unknown drug strength: >20 million ICSRs**
- **Unknown drug dosage form: >20 million ICSRs**
- **Unknown holder/applicant: >31 million ICSRs**





# Drug dosage form

- Drug X with multiple dosage forms:
  - Capsules
  - Suppositories
  - Ampoules for intramuscular injection
  - Ophthalmic drops
- **Drug X – Connective tissue inflammation**
- Hypothesis: related to intramuscular injection?
- Of the 54 ICSRs, only 6 have a known dosage form!
- If drug dosage form is unknown:
  - Dosage regimen
  - Route of administration
  - Indication
  - Narrative



# Substance

- Medical product alert:
  - Advisory Committee on Safety of Medicinal Products (ACSoMP):  
Measures to minimize the risk of ocular adverse events with miltefosine
  - <https://www.who.int/news/item/12-04-2023-acsomp-miltefosine>
- **Miltefosine – Ocular adverse events**
- Confounding by indication? Post-Kala-Azar Dermal Leishmaniasis (PKDL)
- Query: all ICSRs with PKDL listed as the indication
- Found a ICSR with uncoded substance: Miltefosina

# Drug strength

- Drug Z is available as tablets with different strengths:
  - 25 mg
  - 100 mg
  - 400 mg
- Two manufacturers: brand A and B
  - Brand A: all tablets are white
  - Brand B: a different colour for each strength
- **Drug Z - Hypersensitivity reactions**
  - Mostly reported for 100 mg of Brand B
  - Blue colouring agent: indigo carmine



# Advancing medicine safety *together*

Uppsala Monitoring Centre (UMC)  
Box 1051, SE-751 40 Uppsala, Sweden  
Email: [info@who-umc.org](mailto:info@who-umc.org), [www.who-umc.org](http://www.who-umc.org)





Questions in the Q & A facility, please  
For feedback, please go to :

[https://docs.google.com/forms/d/e/1FAIpQLSd6Zvppbz3IQIZXYtMbeFUstSU0mpXsf1XxNV5bAD64oGHnwQ/viewform?usp=pp\\_url](https://docs.google.com/forms/d/e/1FAIpQLSd6Zvppbz3IQIZXYtMbeFUstSU0mpXsf1XxNV5bAD64oGHnwQ/viewform?usp=pp_url)

*Thanks for your time*

UN  COM