**Getting ready** for European Health Data Space(s): **Towards meaningful reuse of health data**

EHTEL

Collaborating for Digital Health and Care in Europe

# Towards European data spaces for medicines: Semantic interoperability for patient safety

EHTEL ELO Virtual Meeting / Webinar, **21 September 2020, 14:00 – 15:30 CET**

@ehtel_ehealth

In focus:

## Leveraging interoperability for better quality of medicine data to improve patient safety and healthcare

- Data quality principles and standards endorsed by European policies
- Interoperability frameworks for data quality and re-usable clinical documentations (medication)
- Seamless support for value chains for medicinal products through consistent and unambiguous data interoperability
- Governance and investments at national and European level (medicinal products and patient safety)

GoToMeeting ▾ REC

Talking: Tino Marti

View Everyone

7 8

ML

TM

DW

Marc Lange (FHTEL)

Tino Marti

Diane Whitehouse

PROJECT REVIEW

**5. Recommendations concerning future work, if applicable**

CR1.R04: Most of the deliverables follow a 3-iteration approach and there is no indication of what will be covered in each iteration. In that sense it is not easy to judge whether a deliverable version is complete. It is recommended that a matrix with these deliverables, iterations and expected advancements from one iteration to the next one, be delivered.

- **D8.8 Governance model – V1** [M18 – June 2020]
- **D8.9 Governance model – V2** [M36 – December 2021]

2

Mic Camera Screen Leave

Tino Marti is presenting

44%

# Towards European data spaces for medicines Semantic interoperability for patient safety

#Imagining2029

14:00 – 14:05 | **Welcome and Introduction to the third EHTEL ELO Virtual Meeting**
ELO CoChairs Andreas Grode, Gematik GmbH, Germany and (apology) Vesa Jormanainen, THL, Finland

14:05 – 14:10 | **Setting the Scene – Lessons from ELO webinars – EU preparing data re-use**
Dr Stephan Schug, EHTEL

14:10 – 14:30 | **Wide use of real world medication data: Routes for European data spaces**
Prof Dr Miriam Sturkenboom, i~HD Ghent and Utrecht UMC, Department of Epidemiology, Belgium/Netherlands

14:30 – 14:50 | **Data quality and semantic interoperability along the medicine data value chain**
Prof Dr Karl Stroetmann, UNICOM coordinator, empirica GmbH, Bonn - Germany
InteropEHRate Scenarios and data re-use for research, Stefano Dalmiani, FTGM, Pisa, Italy

14:50 – 15:10 | **Data quality for patient safety in Belgium: Ecosystems for coding and reporting medicine use**
Jos Devlies, Eurorec, Belgium, Dr Robert Vander Stichele, i~HD, Belgium and Luc Nicolas, EHTEL

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15:30 | **Closing**
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# Setting the Scene
# Lessons from two ELO EHDS webinars

Dr Stephan H Schug, MD MPH, ELO Secretary & EHTEL Chief Medical Officer

@ehtel_ehealth

# European Strategy for data and perspectives towards (Health) Data Spaces

## European Health Data Space(s) are one element of the European strategy for data

- **The European strategy for data** (released February 2020) **aims at creating a single market for data that will safeguard Europe's global competitiveness and digital sovereignty.** **Read here how EHTEL contributed to the European consultation on the data strategy**
- **European Health Data Space(s) (EHDS) are foreseen as implementing this strategy for health, for leveraging opportunities for better healthcare based on better research.**
- **EHDS implies/imply**
  - increased data sharing between all stakeholders in health and care,
  - helping citizen to better control their own data, e.g. by building new infrastructures and by establishing fair data sharing models.

# European Commission's next steps towards the EHDS

## Data governance and rules

- ✓ Measures on governance and rules for primary and secondary use of data, respecting the GDPR
- ✓ Free movement of digital health services
- ✓ Regulatory framework for AI (including safety and liability)

## Data quality and interoperability

- ✓ Increase uptake of and further development of the EEHRxF framework for interoperable EHRs)
- ✓ FAIR-ification of health data for primary and secondary use
- ✓ Measures on governance and rules for primary and secondary use of data, respecting the GDPR

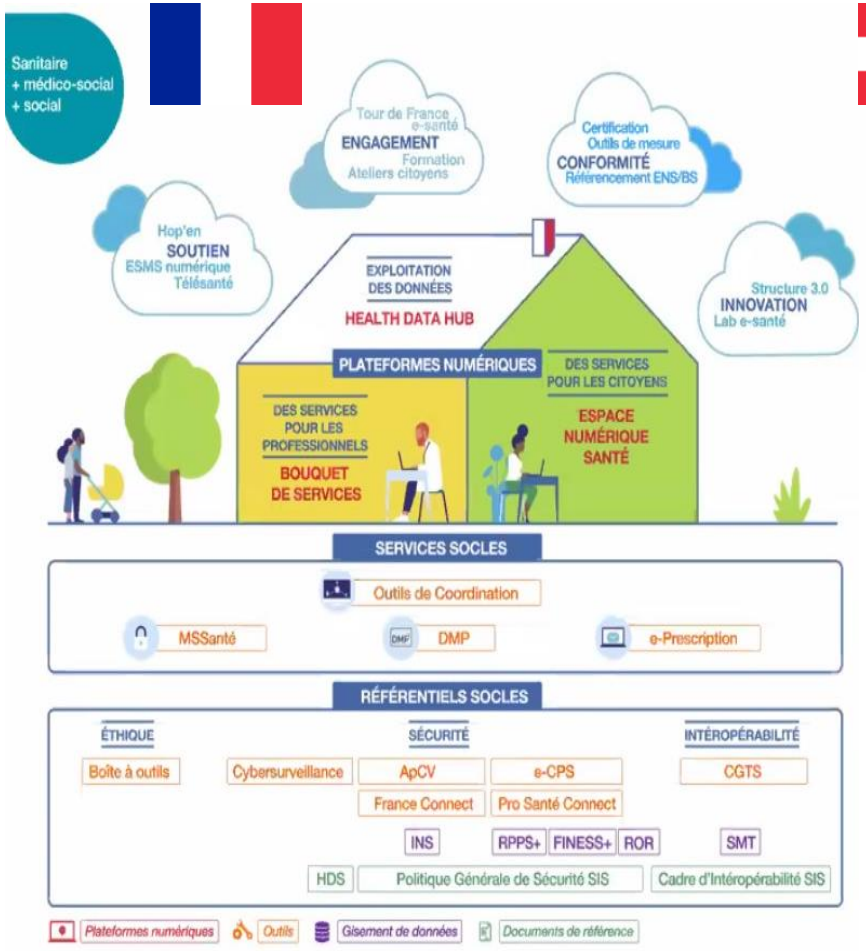
## Infrastructure and technology

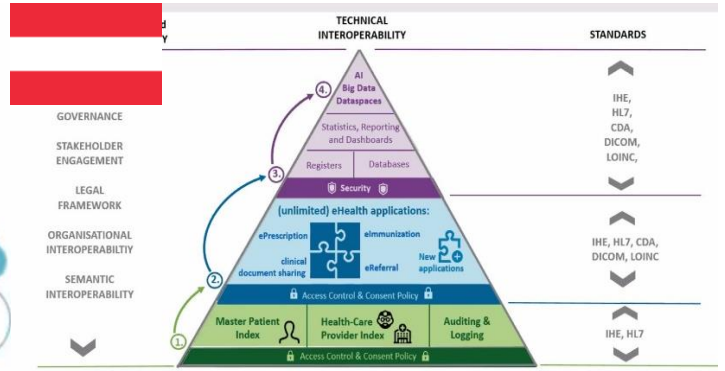
- ✓ eHealth Digital Services Infrastructure
- ✓ European Reference Networks
- ✓ Link different repositories in Europe, e.g. cancer registries, clinical reference networks, transplantation etc.
- ✓ Link the data permit authorities

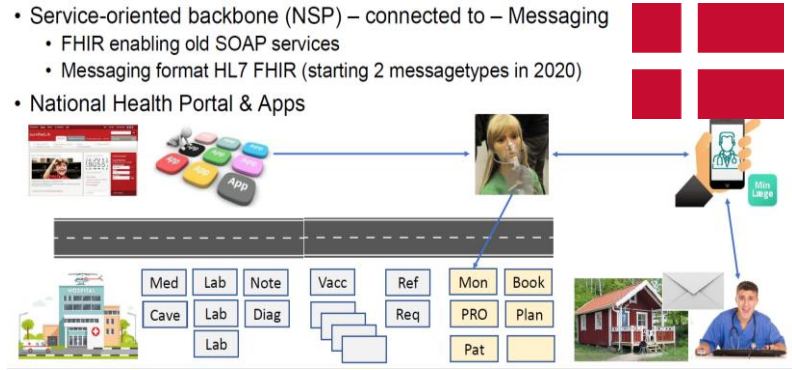
## Capacity building / Digital skills

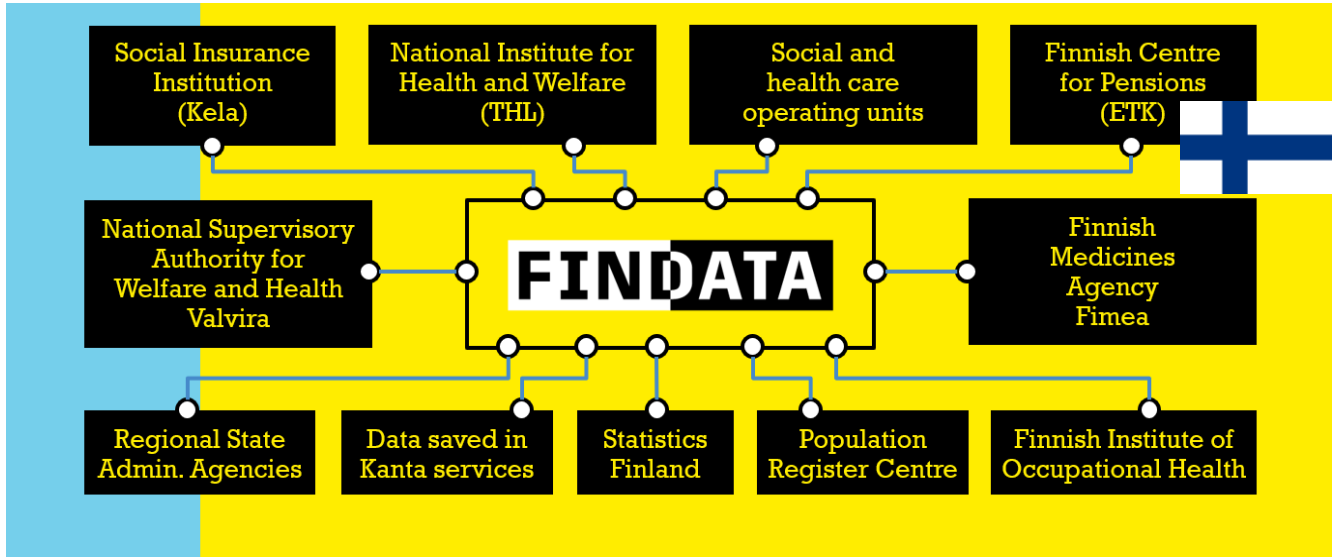
- ✓ Support for digitisation of healthcare systems
- ✓ Support for national eHealth contract points
- ✓ Foundational and advanced digital skills
- ✓ Skills for graduates, health professionals
- ✓ Training options, support mobility health professionals

# European Member States Initiatives towards Eur. Health Data Spaces



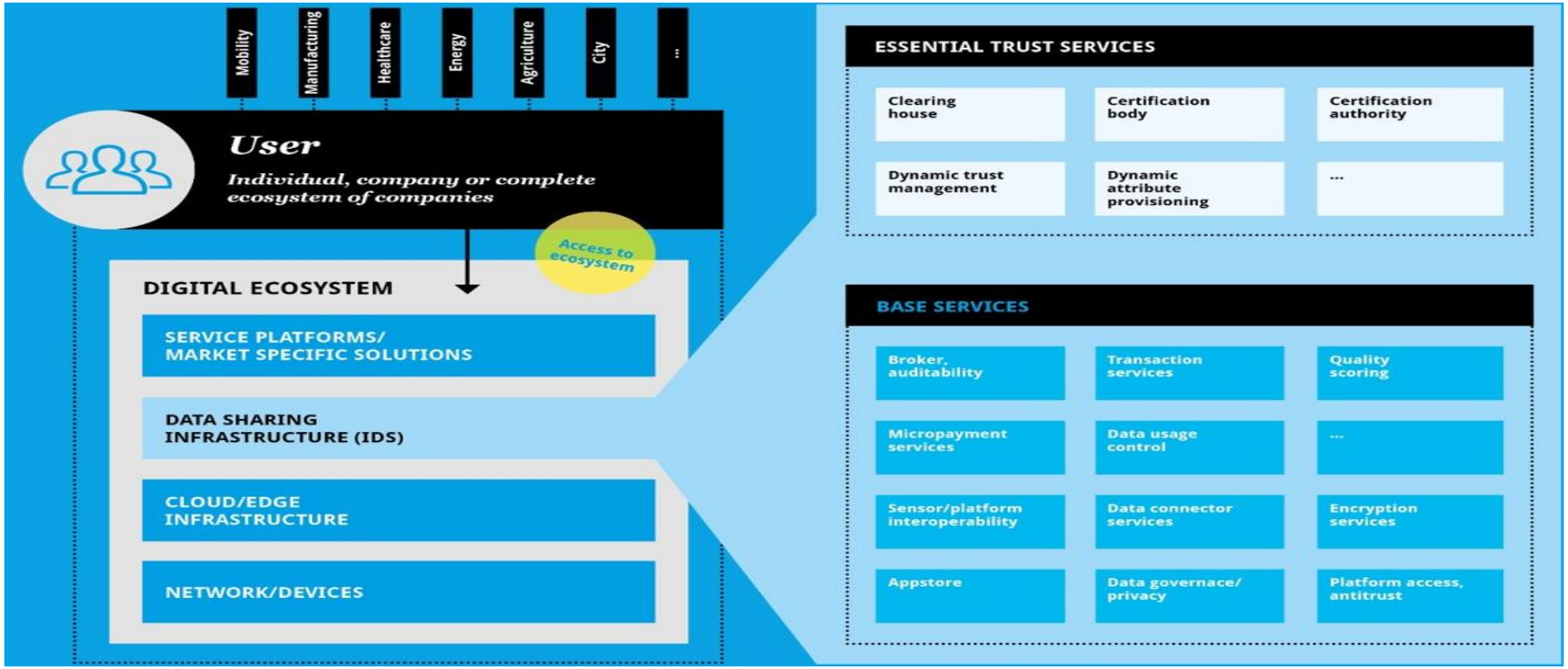



# Digital Ecosystems to enable data sovereignty of persons and organisations

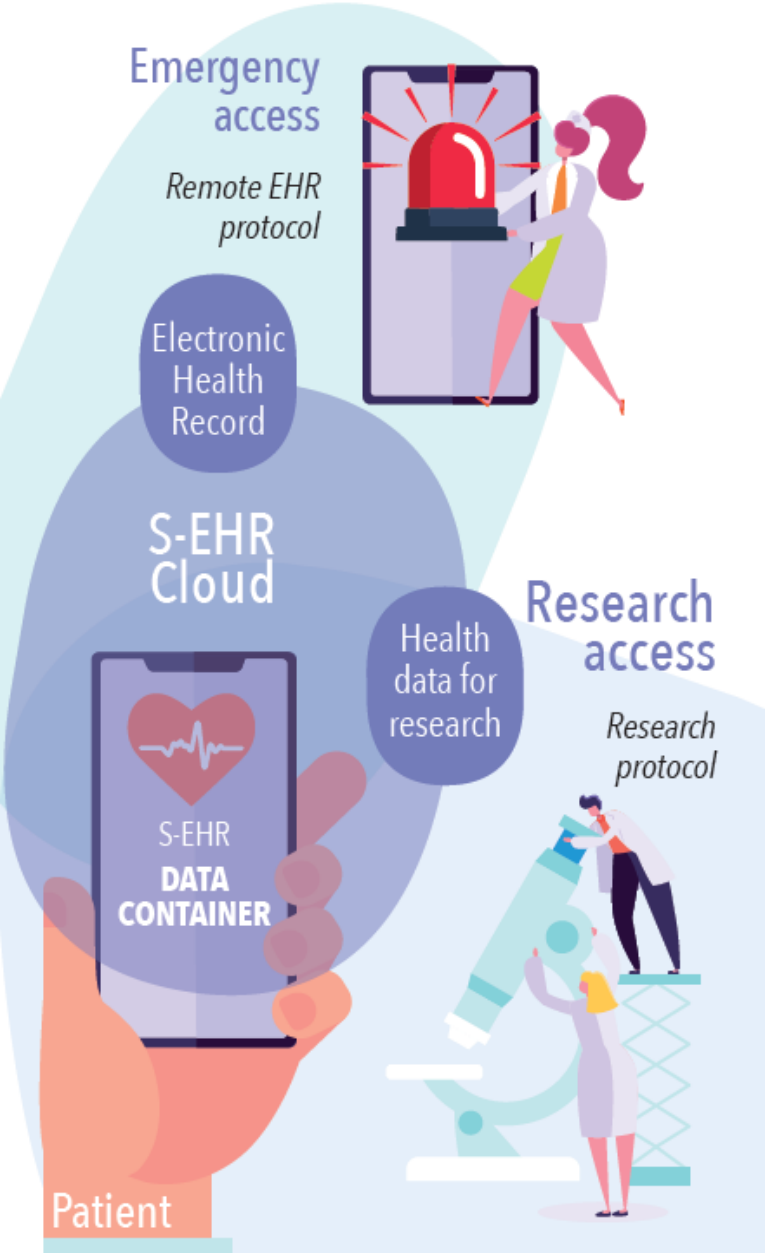
**The International Data Spaces Association (IDSA) developed approaches for maintaining data sovereignty. Wide acceptance of those approaches across sectors – incl. health - established IDSA as one player in the European GAIA-X initiative** (appearance of IDSA supported by OpenDEI project).




INTERNATIONAL DATA SPACES ASSOCIATION

OPENDEI
Aligning Reference Architectures, Open Platforms and Large-Scale Pilots in Digitising European Industry

# Architectures and processes enabling data re-use: **InteropEHRate**




**1. *D2D protocol – applied to* Medical visit abroad**

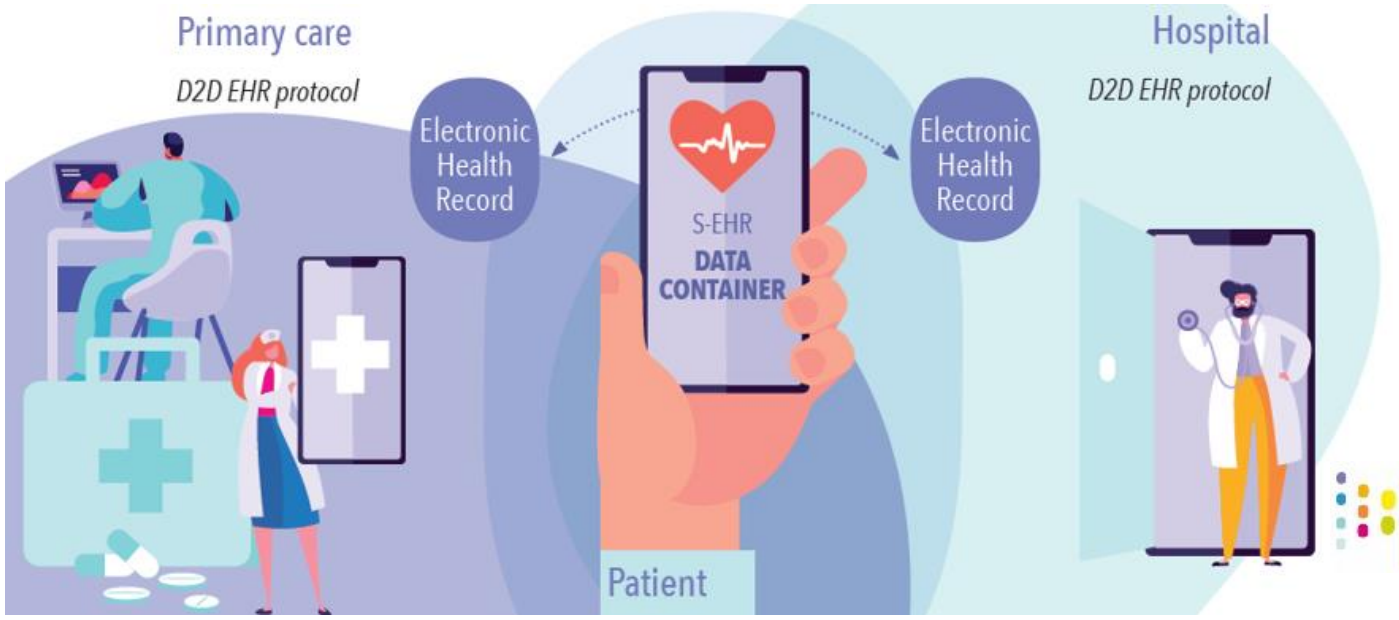
*Exchange of health data without internet connection*

**2. R2D protocol – *applied also to* Emergency access**

***Remote access to HRs sources and back-up on personal cloud***

**3. *Research protocol* – Health Research studies**

*Sharing of health data for specific research studies*




***D2D protocol***

InteropEHRate

# Learn more in factsheets and full videos of ELO Imagining 2029 webinars:


Imagining 2029 webinar series:
Moving towards for European Health Data Space(s)

**From the European Strategy for Data to Health Data Spaces**

**1st EHTEL/ELO Network Factsheet**

OPENDEI
Aligning Reference Architectures, Open Platforms and Large-Scale Pilots in Digitising European Industry

InteropEHRate

**Internal Review**


Imagining 2029 webinar series:
Moving Towards European Health Data Space(s)

**Architectures and processes enabling data re-use:**

**2nd EHTEL/ELO Network factsheet**

InteropEHRate
EHR in people's hands across Europe

This factsheet provides a contribution to the InteropEHRate project

**Published**



**Full Webinar Recordings**

# Getting ready for EHDS: Towards meaningful reuse of health data

- *Webinar ELO I:* ***European Strategy for Data: Pathways for moving towards (Health) Data Spaces***
  ***Wednesday 20 May 2020, 11:00 – 12:15 CET***
- *Webinar ELO II:* ***Making real-world data fit for EHDS: Architectures and processes enabling data re-use***
  ***Monday, 29 June 2020, 11:00 – 12:30 CET***

➡ *Webinar ELO III:* ***Towards European data spaces for medicines: Semantic interoperability for patient safety***
***Monday, 21 Sep 2020, 14:00 – 15:30 CET***

# Towards European data spaces for medicines Semantic interoperability for patient safety

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# Wide use of real world medication data in Europe & challenges

Prof. dr. Miriam Sturkenboom, i~HD, University Medical Center Utrecht

m.c.j.sturkenboom@umcutrecht.nl

See also https://www.youtube.com/watch?v=Ao-q3Y-oprM&feature=youtu.be

# Outline

- Why do we need big data and collaboration to evaluate medicines
- Explanation of issues using examples
  - SOS project (Safety of NSAIDS)
  - Vaccines
- ConcePTION CDM
- Conclusions

# Need and landscape for big data to evaluate medicines

- USA: Based on rofecoxib issues in 2004, the IOM review of pharmacovigilance concluded that the way medicines safety is evaluated should drastically change
  - Electronic health data on 100 M to be used
- Canada:
  - CNODES
- Europe:
  - EU-ADR project
  - 2009-2014 EMA requested evaluation of safety of specific drug classes, through FP7 (SOS, SAFEGUARD, ARITMO, CARING…)
  - Continuing evolution of methods/tools

# Example 1: need to evaluate traditional NSAIDS & Coxibs and rank risk of CVD and UGIB

EMA-requested study funded through FP7

SOS study (2008-2012) Grant agreement ID: 223495

BMJ. 2016 Sep 28;354:i4857. doi: 10.1136/bmj.i4857.

PLoS One. 2018 Nov 1;13(11):e0204746. doi: 10.1371/journal.pone.0204746. eCollection 2018.

PLoS One. 2018 Sep 19;13(9):e0203362. doi: 10.1371/journal.pone.0203362. eCollection 2018.

Drug Saf. 2012 Dec 1;35(12):1127-46. doi: 10.2165/11633470-000000000-00000.

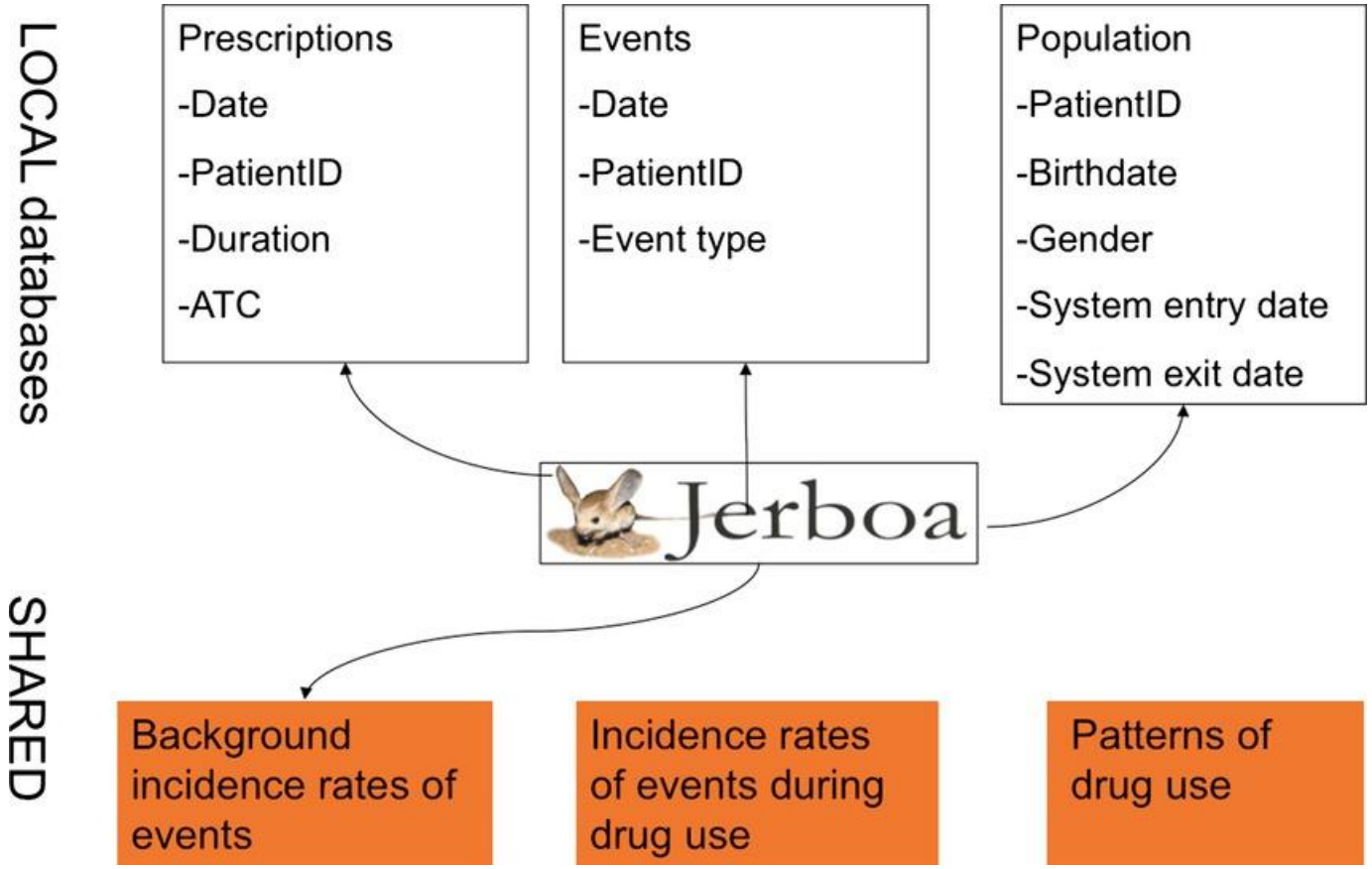
Clin Pharmacol Ther. 2011 Jun;89(6):855-66. doi: 10.1038/clpt.2011.45. Epub 2011 Apr 6.

BMC Pediatr. 2013 Nov 19;13:192. doi: 10.1186/1471-2431-13-192

# 7 Data sources participating in SOS

| | | | | |
|---|---|---|---|---|
|  | SISR | 9,000,000 | general population | ICD-9 |
|  | OSSIFF | 3,000,000 | general population | ICD-9 |
|  | Pedianet | 160,000 | children, general population | ICD-9, free text |
|  | IPCI | 1,000,000 | general population | ICPC, free text |
|  | PHARMO | 3,000,000 | general population | ICD-9 |
|  | BIPS | 13,600,000 | general population | ICD-10-GM |
|  | THIN<br>QRESEARCH | 3,600,000<br>6,000,000 | general population | READ, free text |

# Combining multiple healthcare databases for postmarketing drug and vaccine safety surveillance: simple CDM?




In many of the initial projects most resources and problems happened with harmonization of events

Medicines were harmonized at ATC, various approaches were used to calculate duration: DDD based, PDD based



Journal of Internal Medicine, Volume: 275, Issue: 6, Pages: 551-561, First published: 17 March 2014, DOI: (10.1111/joim.12159)

# Initial hurdles for medicines evaluation were how to deal with heterogeneity in diagnosis recording

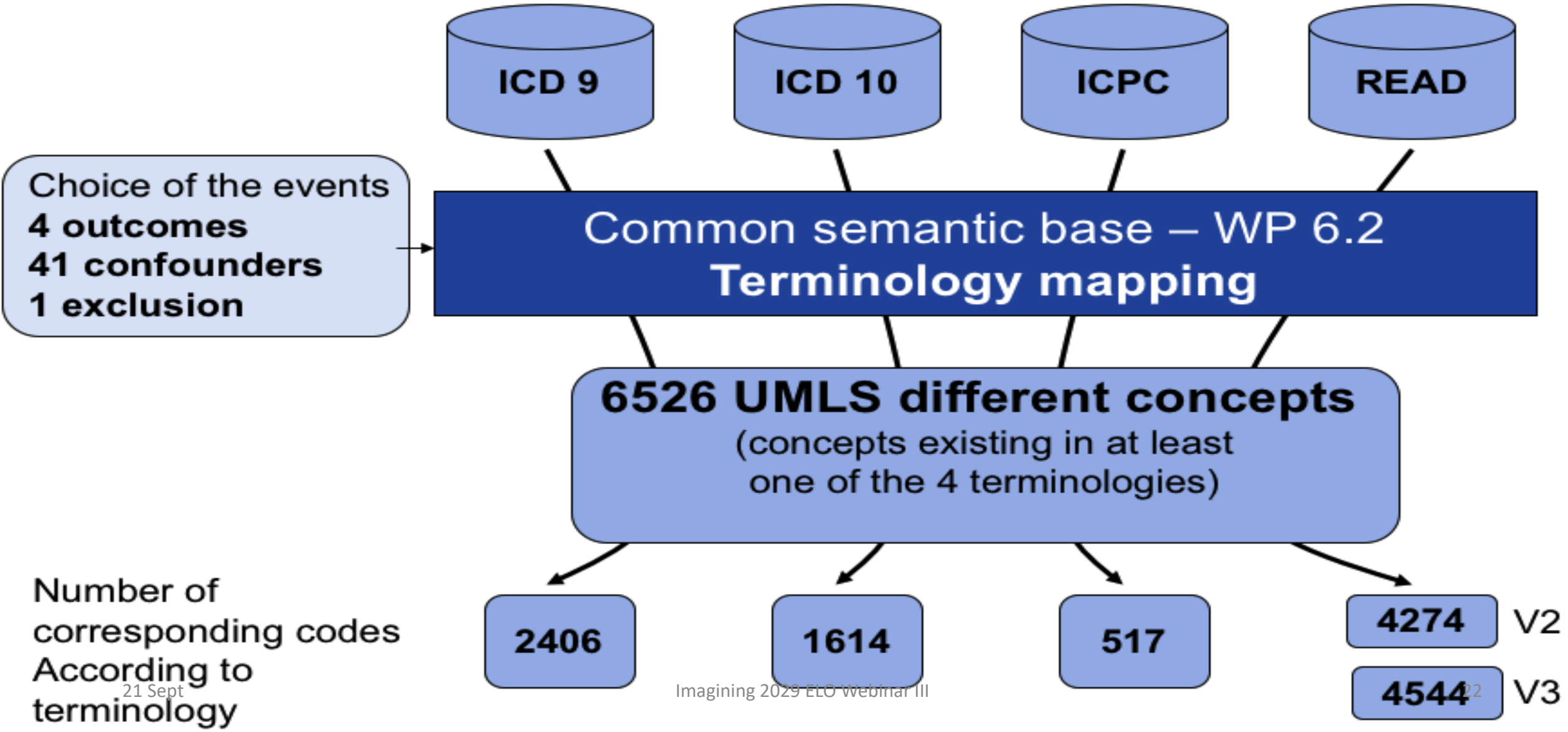
# Approach to harmonization of events

> J Am Med Inform Assoc. 2013 Jan 1;20(1):184-92. doi: 10.1136/amiajnl-2012-000933. Epub 2012 Sep 6.

## Harmonization process for the identification of medical events in eight European healthcare databases: the experience from the EU-ADR project

Paul Avillach [1], Preciosa M Coloma, Rosa Gini, Martijn Schuemie, Fleur Mougin, Jean-Charles Dufour, Giampiero Mazzaglia, Carlo Giaquinto, Carla Fornari, Ron Herings, Mariam Molokhia, Lars Pedersen, Annie Fourrier-Réglat, Marius Fieschi, Miriam Sturkenboom, Johan van der Lei, Antoine Pariente, Gianluca Trifirò, EU-ADR consortium

# Terminology Mapping



# Codemapping process of events has been optimized

> Pharmacoepidemiol Drug Saf. 2017 Aug;26(8):998-1005. doi: 10.1002/pds.4245.
Epub 2017 Jun 28.

## CodeMapper: semiautomatic coding of case definitions. A contribution from the ADVANCE project

Benedikt F H Becker [1], Paul Avillach [1 2], Silvana Romio [1 3], Erik M van Mulligen [1], Daniel Weibel [1], Miriam C J M Sturkenboom [1 4], Jan A Kors [1], ADVANCE consortium

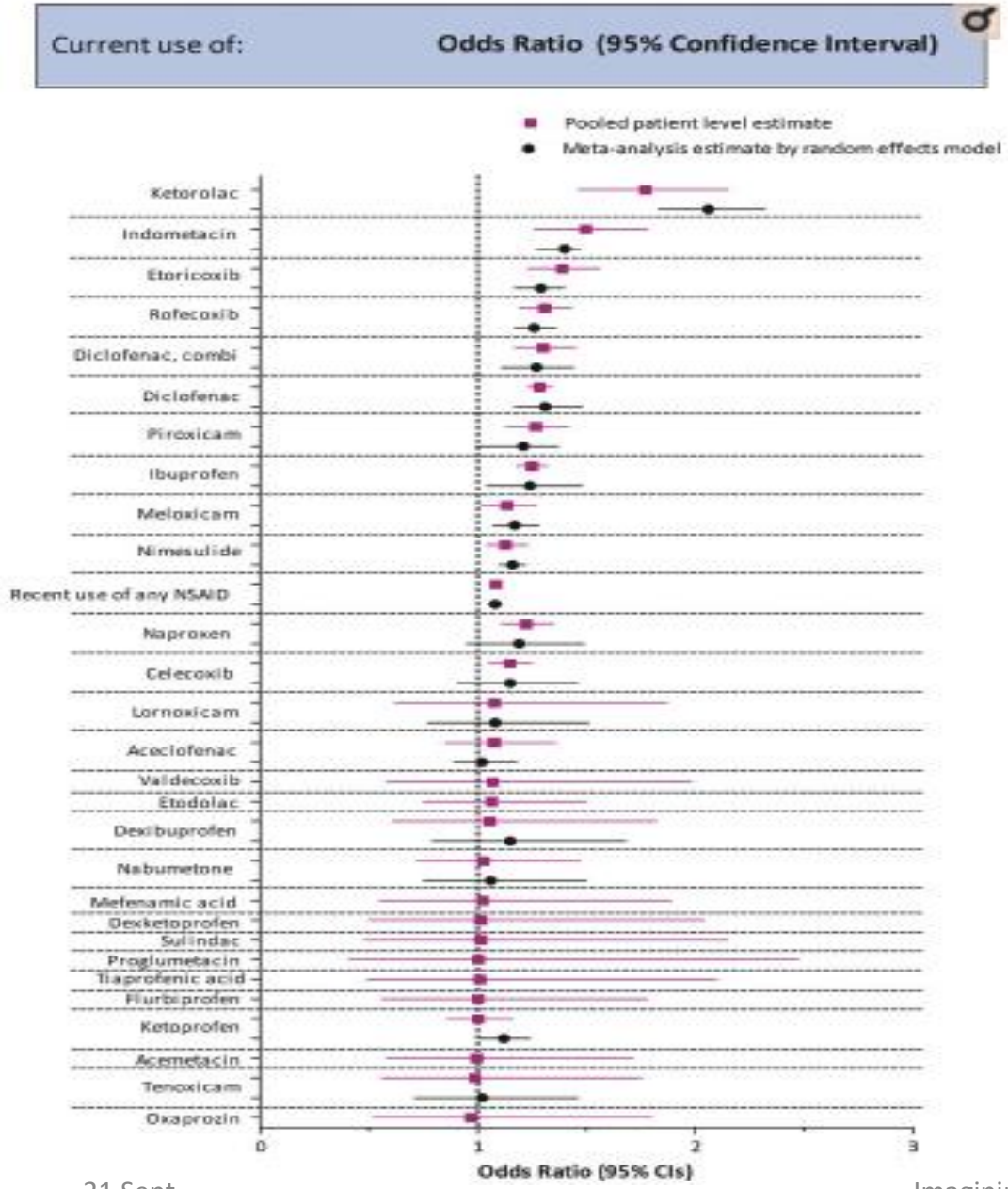
Affiliations + expand

PMID: 28657162 PMCID: PMC5575526 DOI: 10.1002/pds.4245

Free PMC article

https://vac4eu.org/codemapper/

## Risk of AMI

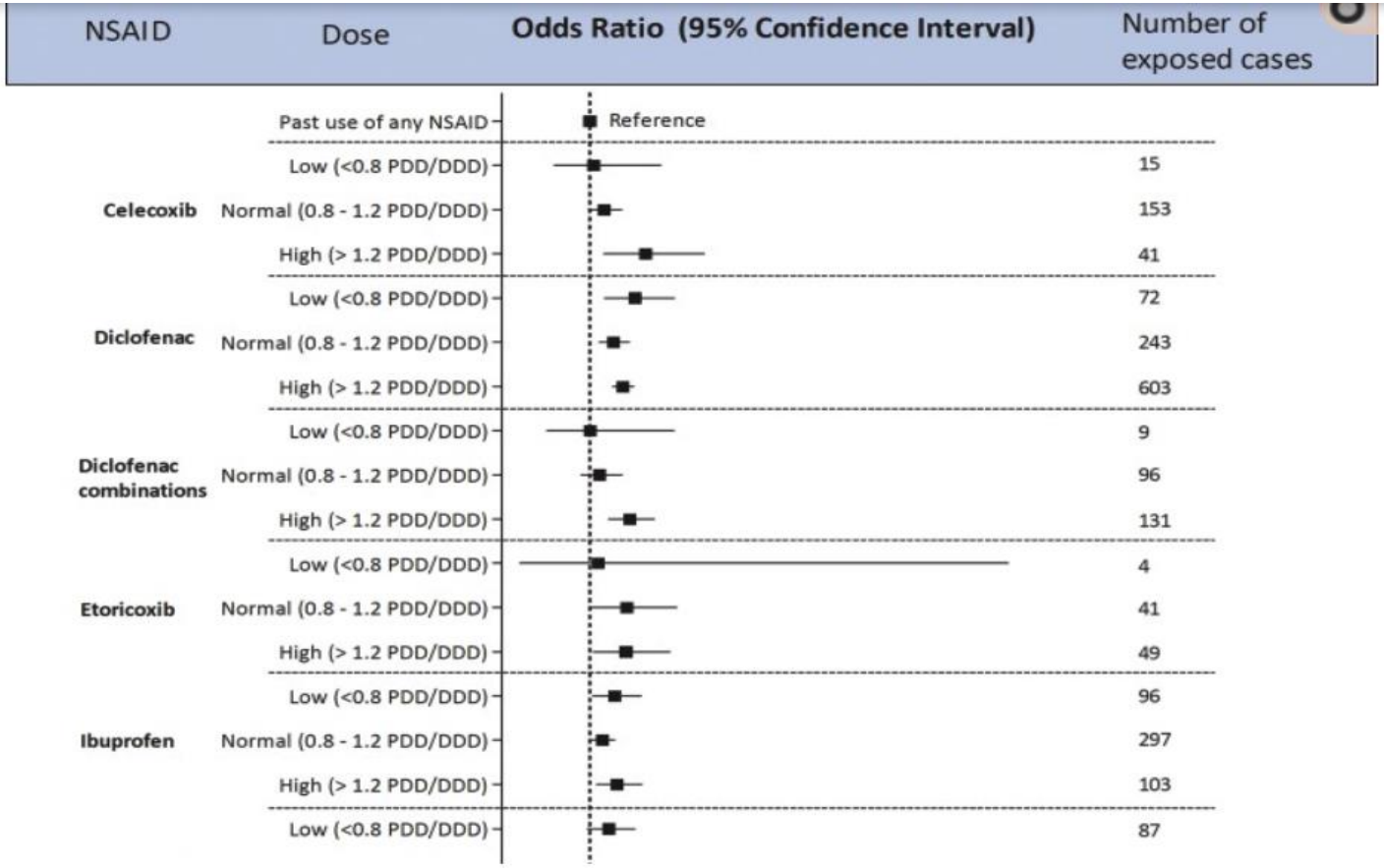



## Risk of Heart failure

| NSAID | No/percent Case patients | No/percent Controls | Odds ratio (95% CI) |
|---|---|---|---|
| Ketorolac | 449/0.49 | 17 459/0.21 | 1.83 (1.66 to 2.02) |
| Etoricoxib | 835/0.91 | 50 039/0.61 | 1.51 (1.41 to 1.62) |
| Indomethacin | 267/0.29 | 13 556/0.16 | 1.51 (1.33 to 1.71) |
| Rofecoxib | 1213/1.32 | 78 930/0.96 | 1.36 (1.28 to 1.44) |
| Sulindac | 16/0.02 | 639/0.01 | 1.32 (0.79 to 2.21) |
| Piroxicam | 974/1.06 | 74 422/0.90 | 1.27 (1.19 to 1.35) |
| Acemethacin | 16/0.02 | 979/0.01 | 1.21 (0.73 to 2.02) |
| Diclofenac | 3228/3.50 | 241 792/2.93 | 1.19 (1.15 to 1.24) |
| Dexibuprofen | 47/0.05 | 3668/0.04 | 1.19 (0.89 to 1.59) |
| Nimesulide | 2717/2.95 | 197 387/2.39 | 1.18 (1.14 to 1.23) |
| Ibuprofen | 2012/2.18 | 135 945/1.65 | 1.18 (1.12 to 1.23) |
| Naproxen | 590/0.64 | 42 397/0.51 | 1.16 (1.07 to 1.27) |
| Valdecoxib | 38/0.04 | 2801/0.03 | 1.14 (0.82 to 1.59) |
| Nabumetone | 66/0.07 | 5298/0.06 | 1.13 (0.88 to 1.45) |
| Tiaprofenic acid | 9/0.01 | 834/0.01 | 1.07 (0.55 to 2.09) |
| Lornoxicam | 50/0.05 | 4324/0.05 | 1.06 (0.80 to 1.41) |
| Tenoxicam | 51/0.06 | 4716/0.06 | 1.06 (0.80 to 1.41) |
| Ketoprofen | 749/0.81 | 66 950/0.81 | 1.03 (0.96 to 1.11) |
| Aceclofenac | 296/0.32 | 28 758/0.35 | 1.03 (0.91 to 1.15) |
| Meloxicam | 629/0.68 | 54 491/0.66 | 1.02 (0.94 to 1.11) |
| Diclofenac, combination | 453/0.49 | 37 292/0.45 | 1.02 (0.93 to 1.12) |
| Proglumethacin | 16/0.02 | 1401/0.02 | 1.01 (0.61 to 1.67) |
| Flurbiprofen | 30/0.03 | 2781/0.03 | 0.97 (0.68 to 1.40) |
| Celecoxib | 1253/1.36 | 118 925/1.44 | 0.96 (0.90 to 1.02) |
| Etodolac | 40/0.04 | 3578/0.04 | 0.87 (0.63 to 1.19) |
| Dexketoprofen | 8/0.01 | 528/0.01 | 0.86 (0.41 to 1.81) |
| Oxaprozin | 29/0.03 | 3647/0.04 | 0.82 (0.57 to 1.19) |

Fig 1 Distribution of current use of individual NSAIDs among cases and controls and pooled associations between current use of

# Areas of improvement: Not all datasource could analyse dose/strength (not enough detail)

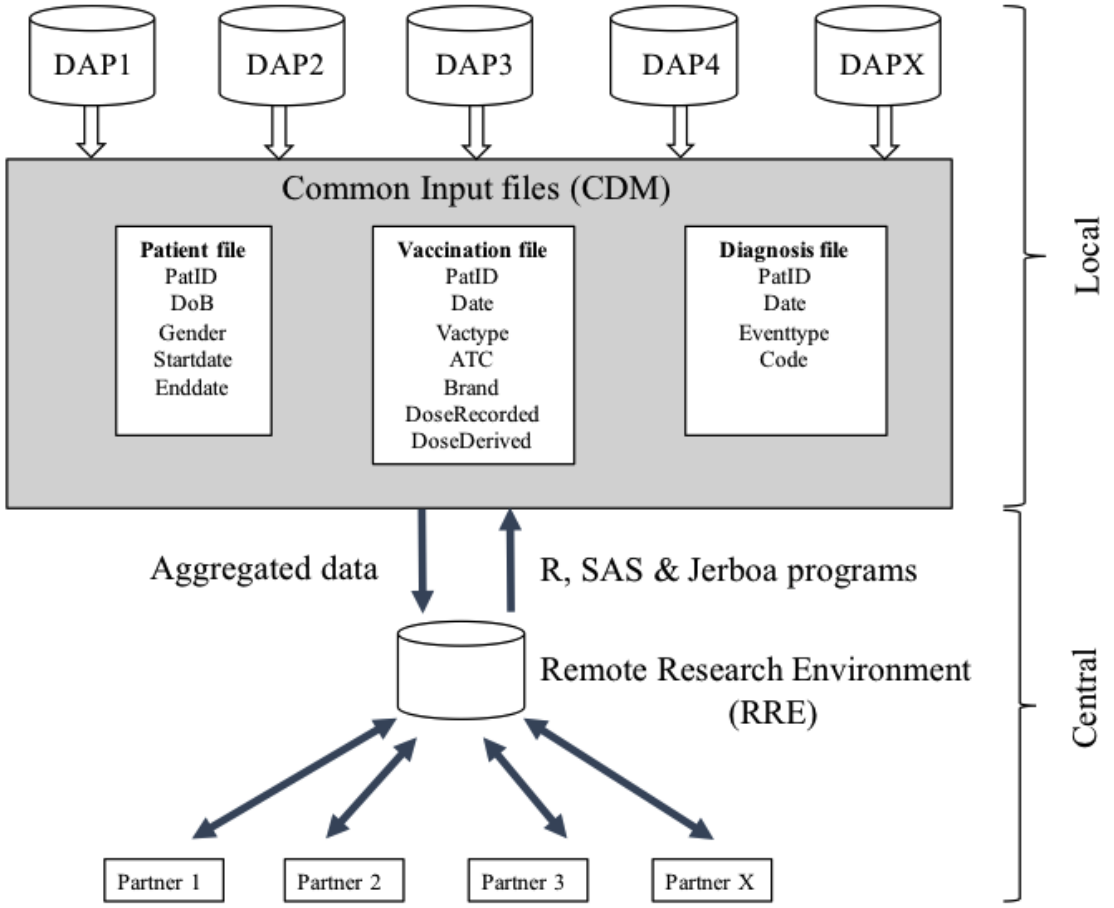



**Adjusted risk estimates for AMI in current users for dose of use of individual NSAIDs in three databases pooled (THIN, IPCI, PHARMO), using past use of any NSAID as common reference group.**

PDD, prescribed daily dose; DDD, defined daily dose. Number of exposed cases do not add up to all current users of that particular NSAID in all three databases pooled as dose information could have been missing.

# Example 2: building an ecosystem to monitor vaccines (IMI-ADVANCE)

# Distributed analytics model ADVANCE: 10 datasources




*DAP: data access providers*

**Figure 1: ADVANCE data management workflow** [9]

# Example 2: Vaccine safety monitoring (IMI-ADVANCE): identification even more difficult

**Coding systems used in regular dictionaries do not allow for proper identification and datasources cannot even code to ATC**

| Property category | SNOMED-CT | Read-2 | MeSH | ATC | BNF | AHD |
|---|---|---|---|---|---|---|
| Pathogen | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Disorder | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Vaccine strategy | ✓ | ✓ | ✓ | ✓ | | ✓ |
| Ingredient | | ✓ | ✓ | | ✓ | ✓ |
| Route | | ✓ | ✓ | ✓ | | ✓ |
| Valence | | ✓ | ✓ | ✓ | | |

Will pose difficulties to monitor COVID-19 vaccines if IDMP cannot be recorded

# Recording of vaccines (HPV) in datasources

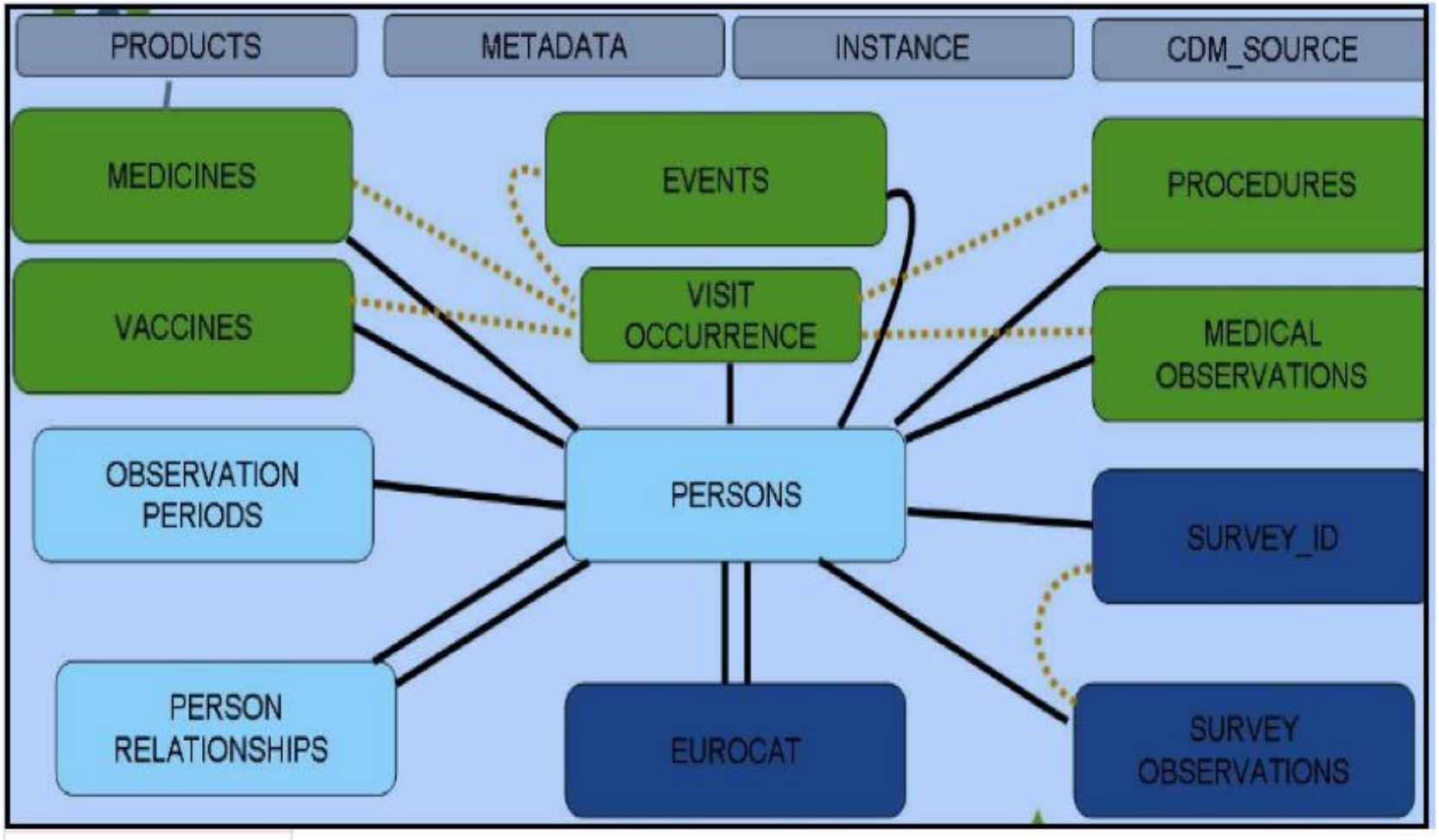
| | Denmark | | Spain | | | Italy | | United Kingdom | Netherlands |
|---|---|---|---|---|---|---|---|---|---|
| | **AUH** | **SSI** | **BIFAP** | **SIDIAP** | **PEDIANET** | **Val Padana** | **Tuscany** | **RCGP** | **RIVM** |
| Birthyears included | 1990-2015 | 1990-2019 | 1995-2017 | 1990-2017 | 2006-2007 | 2000-2017 | 1990-2018 | 1990-2018 | 2000-2017 |
| Total persons | 499,195 | 2,198,545 | 1,613,125 | 1,840,037 | 9708 | 64,990 | 1,042,368 | 1,692,040 | 3,550,933 |
| **Brands during follow-up** | | | | | | | | | |
| Cervarix (HPV 16-18) | | 60143 | | | | 15159 | 122913 | | |
| Gardasil (HPV9) | | 203423 | | | | 6824 | 37363 | | |
| No brand known | 240550 | 737822 | 531578 | 473667 | | | | | |
| **Total** | **240,550** | **1,001,388** | **531,578** | **473,667** | **not extracted** | **21,983** | **160,276** | **not extracted** | **not extracted** |

# Evolution and current recording of medicines in common data models

# EU: novel CDM in IMI-funded Conception

Concept is:

1. Syntactic harmonization by DAP
2. Semantic harmonization done centrally/study based



# Medicines & products table ConcePTION CDM

**Target table: MEDICINES**

**Origin table: ...**

| Target column | Origin column | Rule | Notes |
|---|---|---|---|
| person_id | | | |
| date_dispensing | | | |
| date_prescription | | | |
| disp_amount_drug | | | |
| disp_amount_drug_unit | | | |
| presc_units_per_day | | | |
| presc_duration | | | |
| product_lot_number | | | |
| product_code | | | |
| product_ATCcode | | | |
| code_indication | | | |
| code_indication_vocabulary | | | |
| meaning_of_drug_record | | | |
| origin_of_drug_record | | | |
| prescriber_type | | | |
| visit_occurrence_id | | | |

**Target table: PRODUCTS**

**Origin table: ...**

| Target column | Origin column | Rule | Notes |
|---|---|---|---|
| product_code | | | |
| full_product_name | | | |
| box_size | | | |
| box_size_unit | | | |
| drug_form | | | |
| route_of_administration | | | |
| product_ATCcode | | | |
| ingredient1_ATCcode | | | |
| ingredient2_ATCcode | | | |
| ingredient3_ATCcode | | | |
| amount_ingredient1 | | | |
| amount_ingredient2 | | | |
| amount_ingredient3 | | | |
| amount_ingredient1_unit | | | |
| amount_ingredient2_unit | | | |
| amount_ingredient3_unit | | | |
| product_manufacturer | | | |

**Can this be mapped to IDMP?**

# Conclusion

- Medicines evaluation needs big data and access to multiple data sources across countries
- Data sources are very heterogeneous
- There has been a lot of focus on harmonization of events and less on medicines

- Medicines often harmonized on ATC code
- Vaccines very difficult to harmonize even at ATC level
- Next steps towards harmonization at more specific levels is needed

# Thank you

m.c.j.Sturkenboom@umcutrecht.nl

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UNICOM

Up-scaling the global univocal identification of medicines

# Data Quality and Semantic Interoperability along the Medicine Data Value Chain

**Prof. Dr. Karl A. Stroetmann**

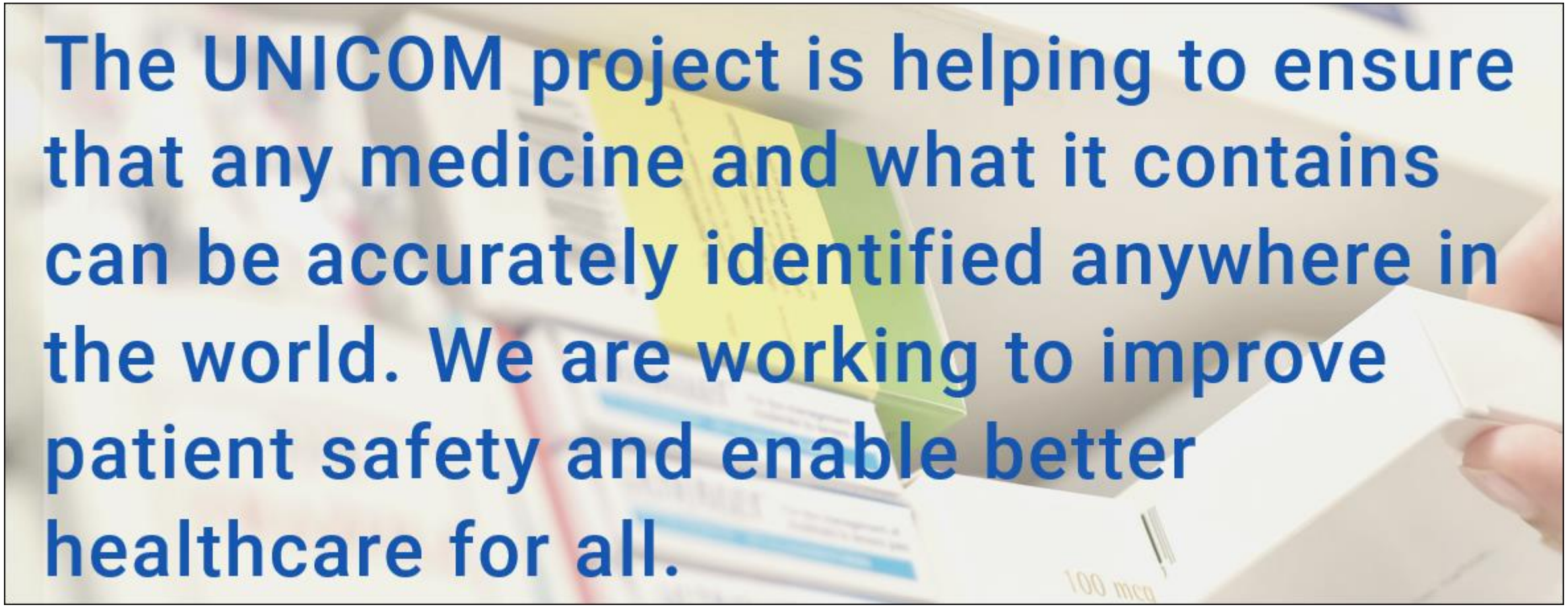
**UNICOM coordinator, empirica GmbH, Bonn, Germany**

***Sept. 21th, 2020***

This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

# European Innovation Action – Objectives, Action Lines

# Vision & Mission

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# Application Domains and Objectives

**By accelerating the diffusion of ISO IDMP (ID of *Medicinal Products*) standards, UNICOM supports**

- **regulatory processes of National Medicines Authorities (NMAs) & the European Medicines Agency (EMA)**
- **cross-border digital health services (ePrescription, Patient Summary)**
- **global pharmacovigilance**
- **better healthcare, Public Health, medical research (e.g. Big Data Analytics, Artificial Intelligence applications)**

**Core objectives focus on:**

- **Support for and Implementation of IDMP at NMA/EU levels**
- **Adaptation of Member States' cross-border digital health services (ePrescription; Patient Summary…)**
- **Exploration and implementation of IDMP for pharmacovigilance reporting, Medicinal Product Dictionaries (MPDs), digital health services, patient empowerment**

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# Semantic Interoperability and Data Users

# Health system interoperability

***facilitates the recording, sharing, understanding and acting on patient and other health information among linguistically disparate medical professionals, patients and other actors within and across health systems in a collaborative manner***

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# Barriers to the Free Flow of Drug Information

- National markets for medicinal products
- Marketing strategies of pharmaceutical industry
- Data quality/legacy data for (older) medicines
- Absence of ‘fit-for purpose’, globally agreed standards (concepts, data models, resources), coding systems, and implementation guidelines to ensure high quality data at all levels of use

***Data on medicines are probably the most widely used ones of any type of patient and health data, with the largest number of actors involved***

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# Towards a seamless MP Data Value Chain

**Semantic interoperability will facilitate data sharing**

- **across the full life cycle of medicines and**
- **all actors involved in handling MP information:**
  - **Pharmaceutical companies**
  - **National Medicinal Products Regulatory Authorities (NMAs)**
  - **Pharmacovigilance Systems (patient safety)**
  - **Providers of medicinal product dictionaries**
  - **Clinical software producers (EHR, Hospital Information, CDS, CPOE, PS, ePrescribing systems**
  - **Healthcare professionals using these systems**
  - **Pharmacy Systems (Order Systems, Supply Chain/Logistics/Stock Management Systems)**
  - **eProduct Information/Patients/Intelligent apps for patient empowerment**
  - **National ePrecription Systems**
  - **xBorder digital health services**
  - **Clinical trials/medical research**
  - **Health systems & Public Health**

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# ISO IDMP & Medicinal Products Data Model

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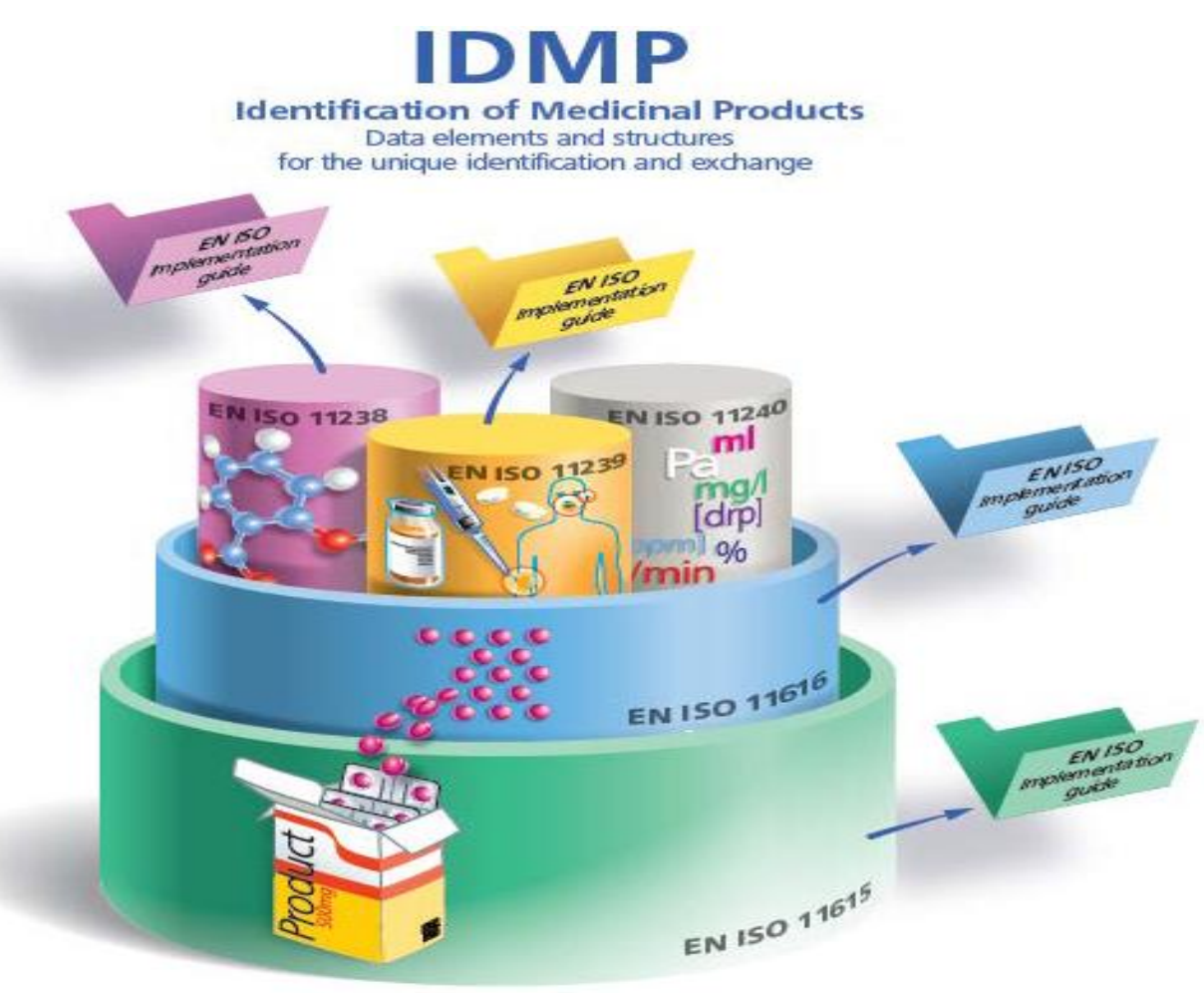
# ISO IDMP Suite of Standards




© Christian Hay

**The ISO IDMP standards establish definitions and concepts and describe data elements and their structural relationships that are required for the unique identification of:**

- ***Medicinal* products** (MPID) and **packages** (PCID) - ISO 11615
- ***Pharmaceutical* products** (PhPID) - ISO 11616
- **Substances** (Substance ID) - ISO 11238
- **Pharmaceutical** dose forms, units of presentation, routes of administration and packaging - ISO 11239
- **Units of measurement** (UCUM) - ISO 11240

**ISO IDMP standards apply to both authorised and developmental medicinal products for *human* use**

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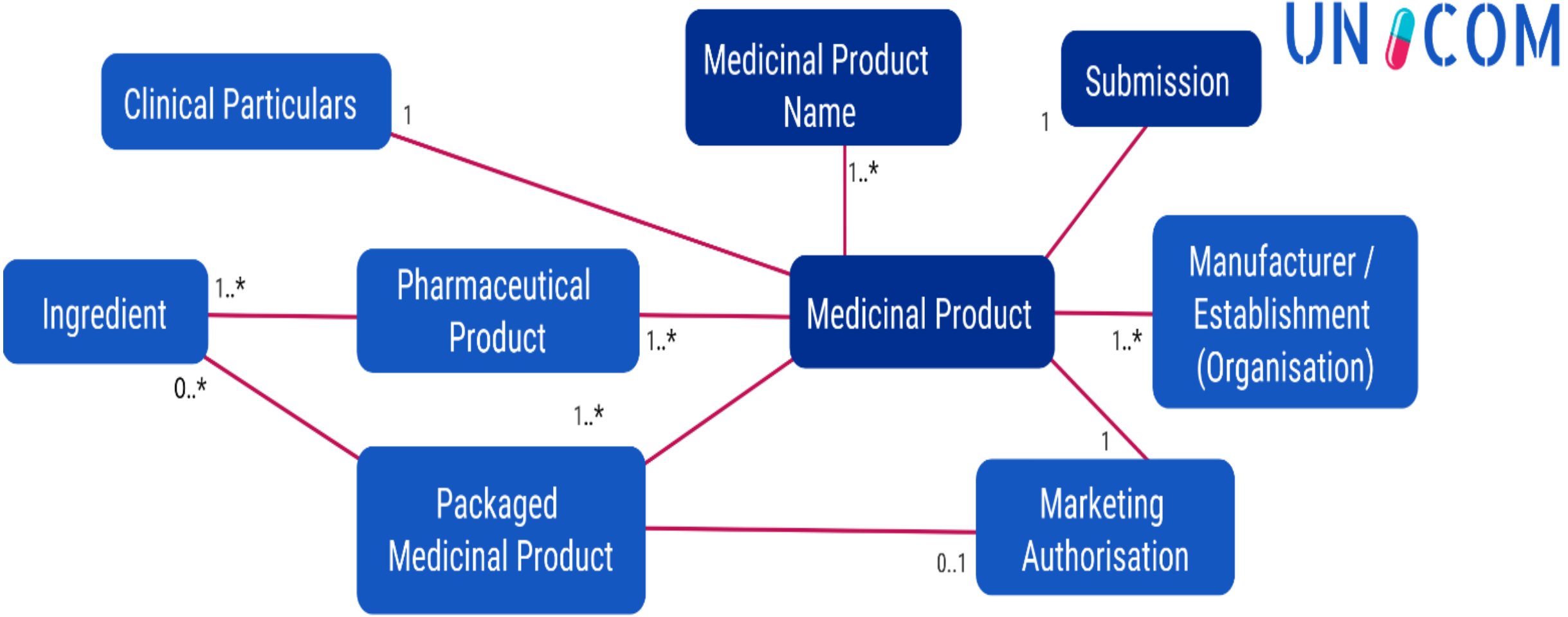
# Overarching conceptual data model for MPs

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# Defining Medicinal & Pharmaceutical Products

- **Medicinal Product (MP):**
  **"Any substance or combination of substances that may be administered to human beings (or animals) for treating or preventing disease, with the view to making a medical diagnosis or to restore, correct or modify physiological functions"**
- **Pharmaceutical Product (PhP):**
  **"The qualitative and quantitative composition of a Medicinal Product in the dose form approved for administration in line with the regulated product information. ... A Medicinal Product can contain one or more pharmaceutical products"**
- **Notes:**
  - **A prescription usually specifies a specific *package* or the quantity of a *medicinal* product**
  - **Different medicinal products with distinct (brand) names (generics) may all contain the same pharmaceutical product**
  - **If a single package contains, e.g., two types of tablets with different active ingredients, this single medicinal product contains two different pharmaceutical products**

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# Core MP and PhP Attributes

- **Active Substance(s)**
  **Codes for active substance(s)/specified substance(s) ID(s) will be based on the EU-Substance Registration System (EU-SRS), from which the European Medicines Agency will provide a Substance Management System (SMS) replacing for certain usages, e.g., INN or ATC terms/codes**
- **Strength(s) and reference strength**
  **Strength unit (unit of measurement and/or unit of presentation) codes will be based on UCUM codes (Unified Code for Units of Measure - Regenstrief Institute, USA)**
- **Administrable dose form**
  **is the "general method by which a pharmaceutical product is intended to be administered to the patient." Codes are provided by the European Directorate for the Quality of Medicines & HealthCare (EDQM) of the Council of Europe**

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# Outlook (I)

## Semantic Interoperability along the medicine data value chain will require

- close cooperation across various health Standards Developing Organisations
- the full commitment of National Medicines Authorities and other governmental actors, as well as of the European Medicines Agency (EMA)
- considerable investments by many actor groups
- involvement, exchange and cooperation across the full data value chain
- The long-term maintenance of standards, coding systems, implementation support

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# Outlook (II)

## Semantic Interoperability along the medicine data value chain will

- enable the seamless exchange and sharing of health data related to medicines across all actors and stakeholders involved in handling or consuming such data
- facilitate faster and better pharmacovigilance reporting
- create economic efficiency gains for industry and service providers
- facilitate the use case of ePrescription/eDispensation in a cross-border setting
- improve patient safety and healthcare
- improve reliable recording of medicinal product information in clinical documents (e.g. Patient Summary)
- enable better communication towards patients
- improve reuse of medication related data for Public Health and medical research
- create synergies across regulatory, healthcare, public health and scientific domains

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## Further Information on UNICOM

**unicom-project.eu**
**Twitter: @ unicom_idmp**
**www.linkedin.com/company/unicom-idmp**

# Acknowledgements


- The information presented is derived from the UNICOM Innovation Action, which receives funding from the European Commission Directorate General for Communications Networks, Content and Technology, in the context of the European Horizon 2020 research and innovation programme under grant agreement No 875299 - support which is gratefully acknowledged.
- Neither the European Commission nor any person acting on behalf of the Commission is responsible for the use which might be made of the information presented. The views expressed are solely those of the author(s) and do not necessarily reflect those of the European Commission or any other organisation.
- We are most grateful to colleagues at the participating organisations as well as external experts who contribute and critically review project work.



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# Towards European data spaces for medicines Semantic interoperability for patient safety

#Imagining2029

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# Data quality for patient safety in Belgium: Ecosystems for coding and reporting medicine use

Jos Devlies (Eurorec)

Robert Vander Stichele (*i*~HD )

Luc Nicolas (EHTEL)

# SAM is an Authentic validated source

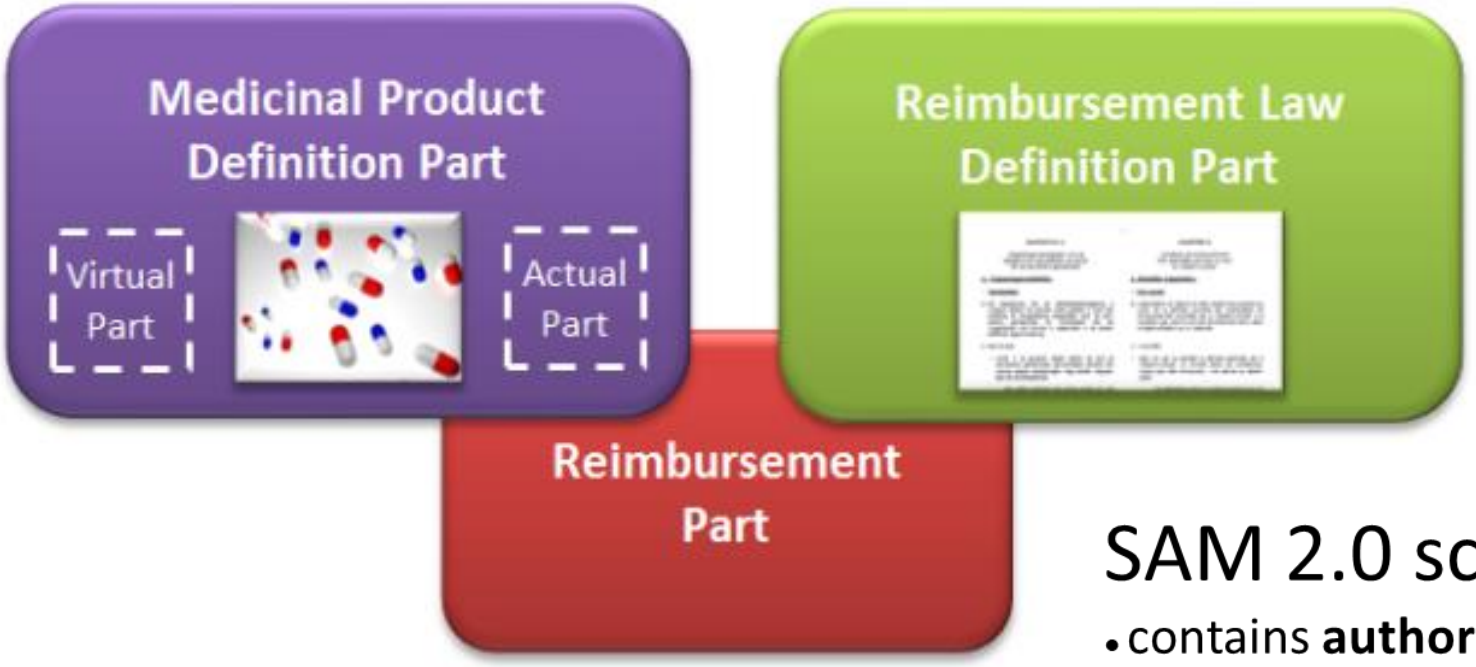
- An authentic source is a database in which the data stored are authentic: It contains **unique and original data** concerning persons, concepts, or facts of law.
- An authentic source is the gold standard within a national IT organization for obtaining specific data. It offers specific guarantees in terms of **the accuracy, completeness and availability** of this data.
- SAM stands for **Authentic Source of Medicines** within the Belgian eHealth IT organization

# BELGIAN SAM ECOSYSTEM


| | | | | | | |
|---|---|---|---|---|---|---|
| Reimbursement and specific rules | Market authorisation and pharmaco-vigilance | Scientific validated information + clustering | Medicines price | ICT development | eHealth Services orchestration and standards | Pharmacists: Raw materials, formulae, other products |

| | | | | | | |
|---|---|---|---|---|---|---|
| **Doctors** | **Pharmacists** | **Patients** | **Hospitals** | **EBM** | **Industry** | **Research centers ….** |

# IN SCOPE



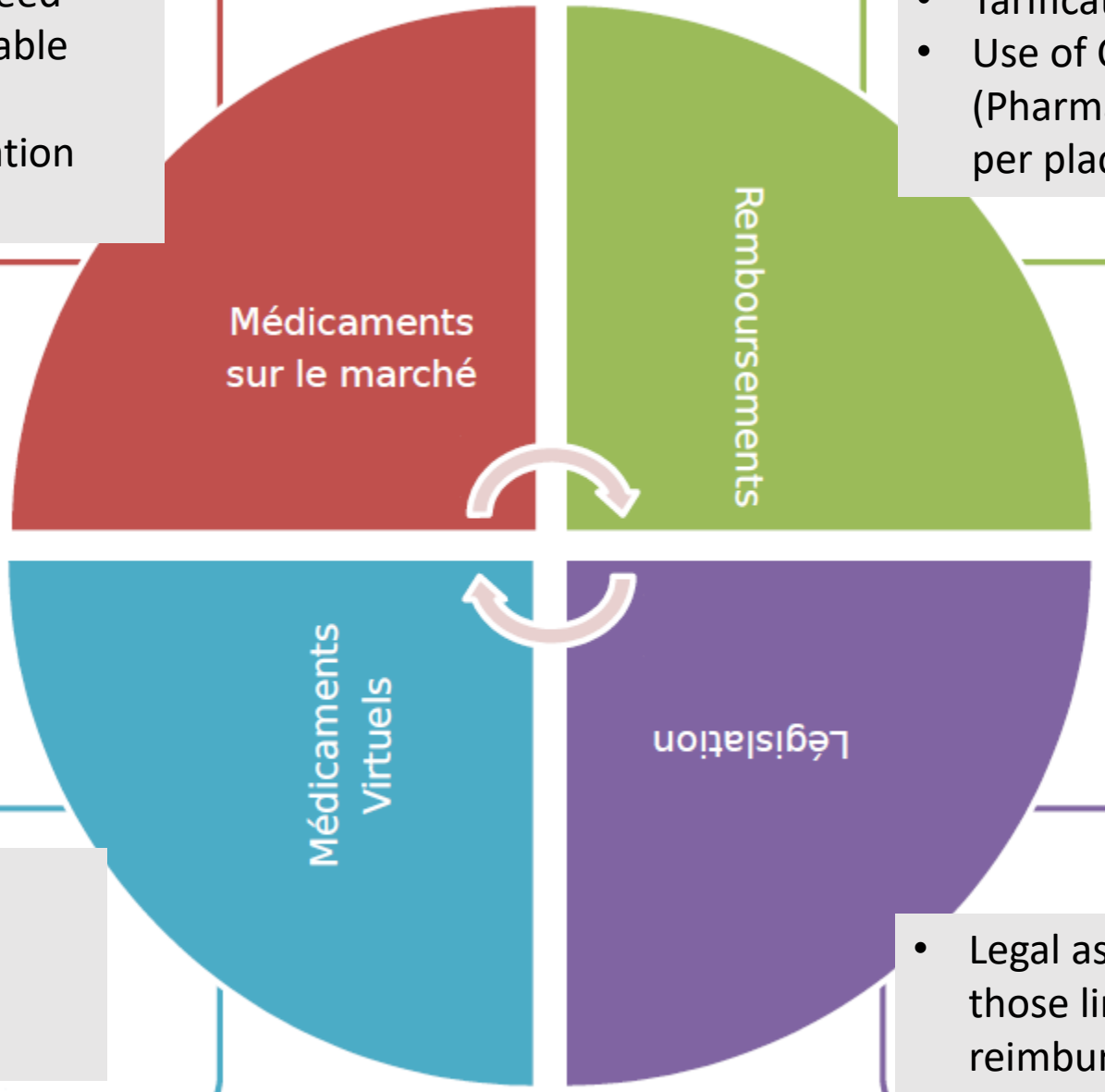

**FIRST INITIAL GOAL**: **Support Eprescription**

## SAM 2.0 scope

- contains **authorized medicines** in Belgium
  – if not on the market: only limited subset of information present
- 3 main data suppliers
  – **fagg/afmps**: e.g. official authorization info
  – **RIZIV/INAMI**: e.g. legal and reimbursement info
  – **BCFI/CBIP**: e.g. clinical info and VOS/DCI groups

- Unmet medical need
- Foreign reimbursable medicines
- Magistral preparation
- Use CNKUD

- Tarification per unit
- Use of CNK code (Pharmacy association) per place of delivery




- Prescription INN
- Allergies and intolerances
- Substitution list

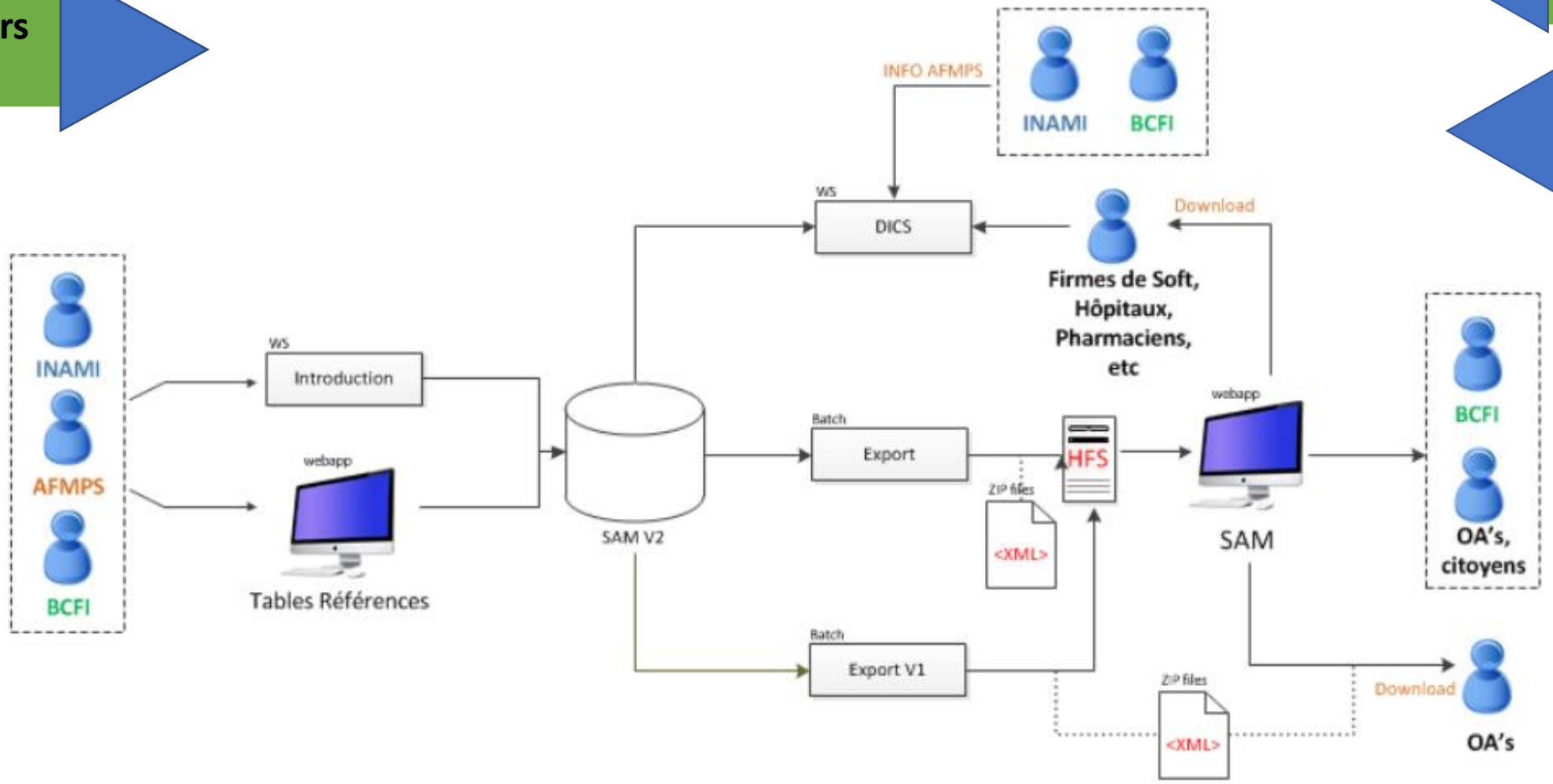
- Legal aspects (others than those linked to reimbursement)

# Architecture SAM V2

**Users and suppliers independence**

Performance Optimization

Flexibility and scalability



# SAM data model

## Medicinal product definition part

**Actual part**: describes drugs

- that are **brand name** drugs
- that are **authorized** (only complete when on the market)
- ***Flemoxin oplosb. tabl. (deelb.) Solutab 500 mg***

**Virtual part**: describes drugs

- in a generic, **brand-independent**, way
- in a **clinically** oriented way
- that are on the market (= subset of authorized drugs)
- ***amoxicilline 500 mg capsule (or.)***

Administration Pharmacies

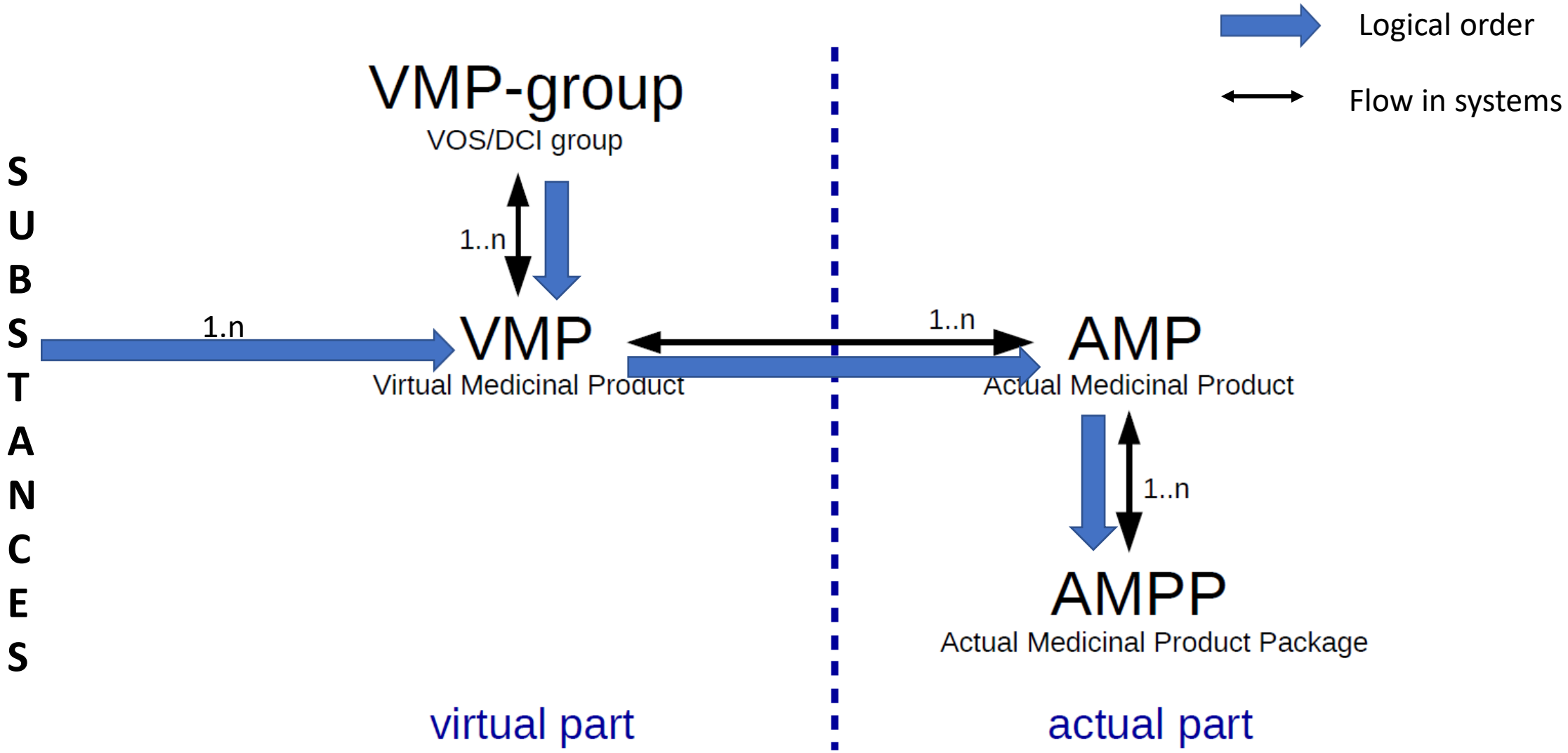
Clinical domain

## Reimbursement (law) definition part

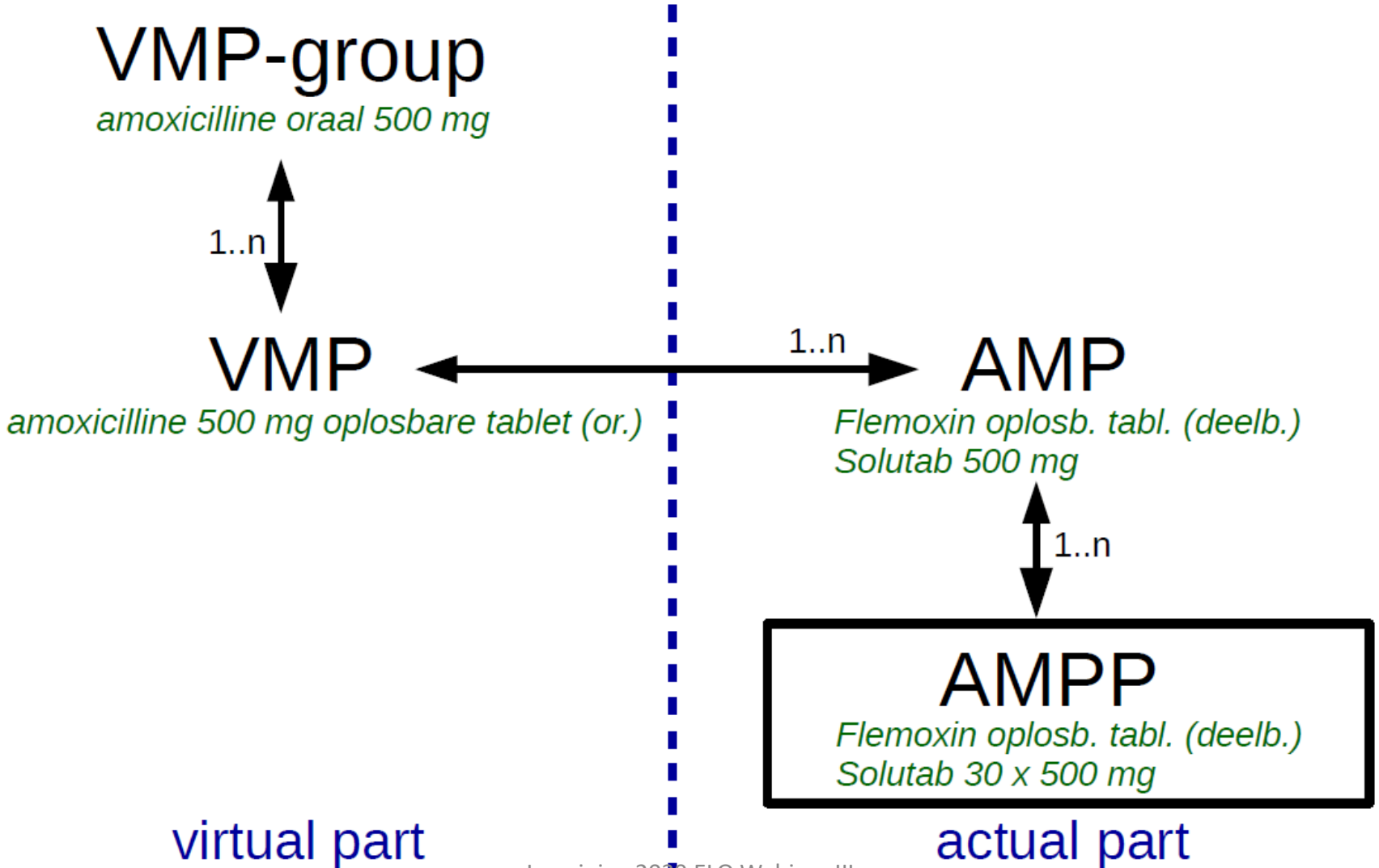
- English reference model
- **Clustering and INN**
- Extended Legislation (Contraception youth, Radio-istop etc..)
- **All medicines** on Belgian market
- **Unique Belgian identifier** (package)
- Introduction of **semantics** (SNOMED, EDQM) and initial alignment to IDMP

| | |
|---|---|
| **CTI-extended** AFMPS | 127005-02 |
| **numéro d'autorisation** AFMPS | BE127005 |
| **taille du conditionnement** AFMPS | 30 |
| **nom de prescription** CBIP | Flemoxin compr. sol. (séc.) Solutab 30x 500mg |
| **commercialisé** AFMPS | ☑ cliquer pour plus d'infos |
| **statut** AFMPS | AUTHORIZED |
| **temporairement indisponible** AFMPS | ☐ |
| **matériau du conditionnement** AFMPS | HDPE |
| **type de conditionnement** AFMPS | Plaquette |
| **nom VMP** CBIP | amoxicilline 500 mg comprimé soluble (or.) |
| **code du groupe VMP** CBIP | 1925 |
| **nom du groupe VMP** CBIP | amoxicilline oral 500 mg [CAVE séc., solide/liq.] |
| **groupe VMP prescriptible en DCI ?** CBIP | ☑ |
| **SAM-id** AFMPS | SAM127005-00 |
| **nom officiel** AFMPS | Flemoxin Solutab 500 mg |
| **titulaire d'autorisation** AFMPS | Astellas Pharma |
| **forme pharmaceutique** AFMPS | Comprimé pour solution buvable |
| **voie d'administration** AFMPS | Voie orale |
| **code** AFMPS/INAMI | 0707273 (CNK hospitalier) cliquer pour plus d'infos |
| **code** AFMPS/INAMI | 0707273 (CNK ambulatoire) cliquer pour plus d'infos |
| **code** AFMPS/INAMI | 0707273 (CNK MRS) cliquer pour plus d'infos |
| **code** AFMPS/INAMI | 2055010 (CNK public) cliquer pour plus d'infos |
| | **remboursé** ☑ |
| | **bon marché** ☑ |
| | **le moins cher** ☑ |

# Hierarchy medicinal part



# Hierarchy medicinal part



# Actual part –
# A(ctual)M(edicinal)P(roduct)P(ackage)

**Flemoxin oplosb. tabl. (deelb.) Solutab 30 x 500 mg**

## Represents a **physical package**

- Has a **unique id** (CTI-extended): 127005-02 and a CNK code
- Has a BCFI/CBIP **prescription name** (if on the market): Flemoxin oplosb. tabl. (deelb.) Solutab 30x 500mg
- Contains brand name, pharmaceutical form, proprietary suffix, pack size and strenght(s) and important information for health care providers( secability, container, parralel import company name, ...)
- Has a commercialization date
- Includes supply problem (start date + supply problem expected endate + derogation status)
- Has a **delivery modus, packaging type,** link to the **leaflet** and **SPC** (PDFs) link to the **RMA** (Risk Minimizing Activities) and link to the **BCFI / CBIP Medicinal Product Dictionary.**

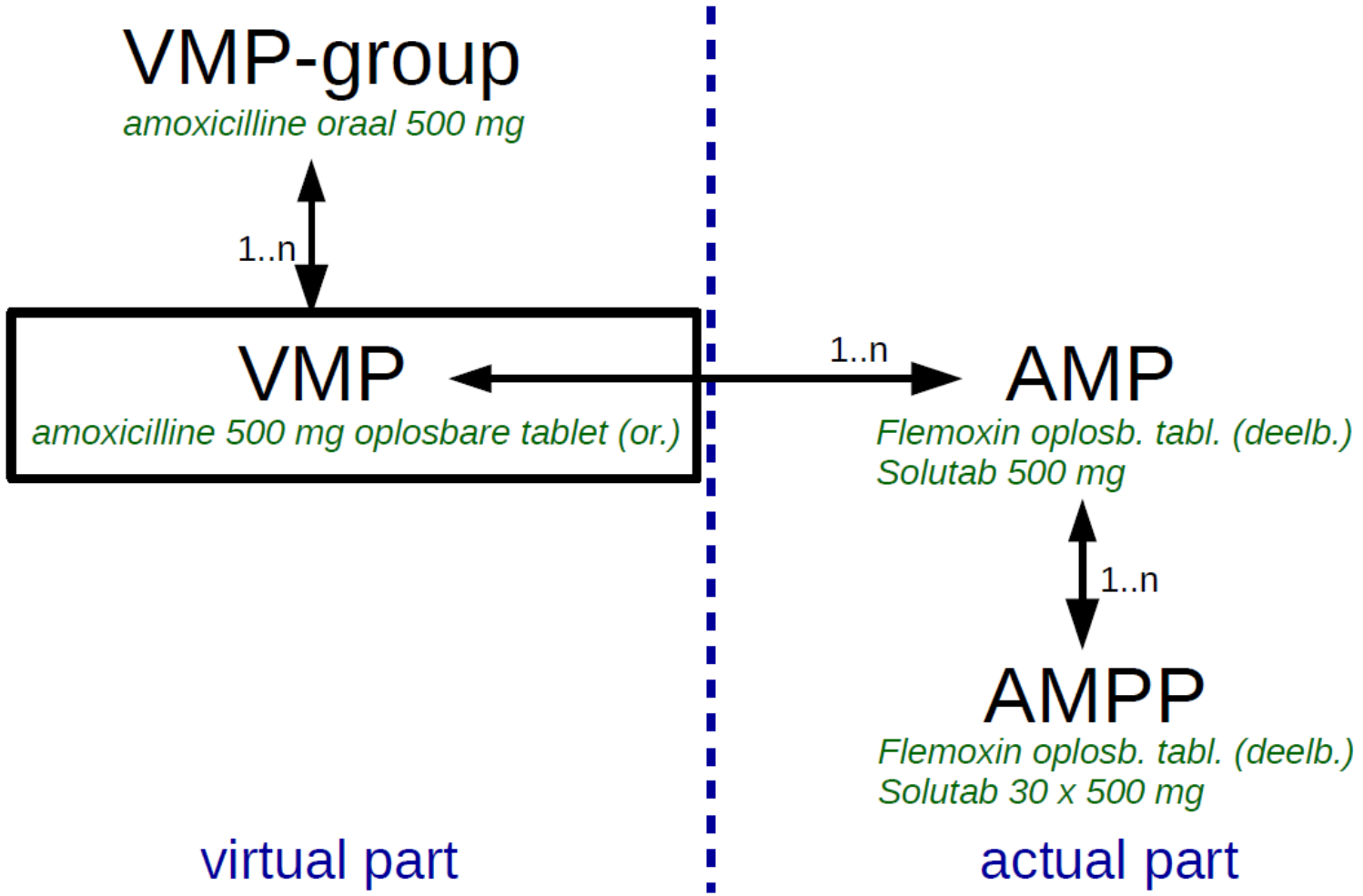
# Actual part
# A(ctual) M(edicinal) P(roduct)

**Flemoxin oplosb. tabl. (deelb.) Solutab 500 mg**

## Represents a **unidose of a branded product**

- Is linked to one ore more AMPPs (packages)
- Has a unique **id**: *SAM127005-00*
- Has an official **fagg/afmps name**: *Flemoxin Solutab 500 mg*
- **H**as a **license holder**: *Astellas*
- Has a **pharmaceutical form**: *soluble tablet*
- Has (a) **route(s) of administration**: *oral use*
- has (an) **actual ingredient(s)**:*Amoxicillinetrihydraat eq. Amoxicilline – 500 mg*
- Contains brand name, pharmaceutical form, proprietary suffix, strenght(s) and important information for health care providers( secability, container, parrallel import company name, ...)

# Hierarchy medicinal part



# Virtual part
# V(irtual)M(edicinal)P(roduct)

Amoxicilline 500 mg oplosbare tabl. (or.)

Represents a generic, **brand-independent**, product/

- Is an entity representing **clinically equivalent branded products**
- Linked to one or more **clinically interchangeable AMPs** on the market
- **Shared properties** between AMPs: active **substance**(s) and its/their **strength**(s), **route**(s) of administration generalized pharmaceutical **form**
- Has a unique **id** and an **abbreviated name**
- Contains virtual ingredient & virtual pharmaceutical form (less specific than AMP), standardized strenght and a granular description of route(s) of administration.

# Virtual part
# V(irtual)M(edicinal)P(roduct) (Continued..)

**Generic but specific enough for**

- ✓Retrieving generic prescription history in medical health record
- ✓Suggesting alternative products in case of supply problems
- ✓Informing of problem or commercialization stop of an AMP
- ✓Enhancing Medical health records analysis and decision support
- ✓Checking intolerance checking (except excipients)
- ✓Supporting main element of an international prescription in future
  - SNOMED CT
  - Evolution towards IDMP ISO

# Virtual part

# V(Irtual)M(edicinal)P(roduct) **Group**

## Amoxicilline oral 500 mg

Represents a group of VMPs for **Generic INN prescription & price comparison** of similar VMPs:

- Is linked to one or more **VMPs**
- Has a unique **id** and **Name**
- Shared properties: group of substance(s) sharing the same moiety, standardized strenght(s) and more abstract form of method of administration (or intended site of use)
- Has a **generic prescription** status (INN OK or not OK + reason & Switch after selection ok or not ok)
- Minor differences between products (e.g. solid/liquid..) but can be important in some contexts: Warning is then shown.

# A substantial, sustained but essential public investment within an all inclusive Stakeholders Governance

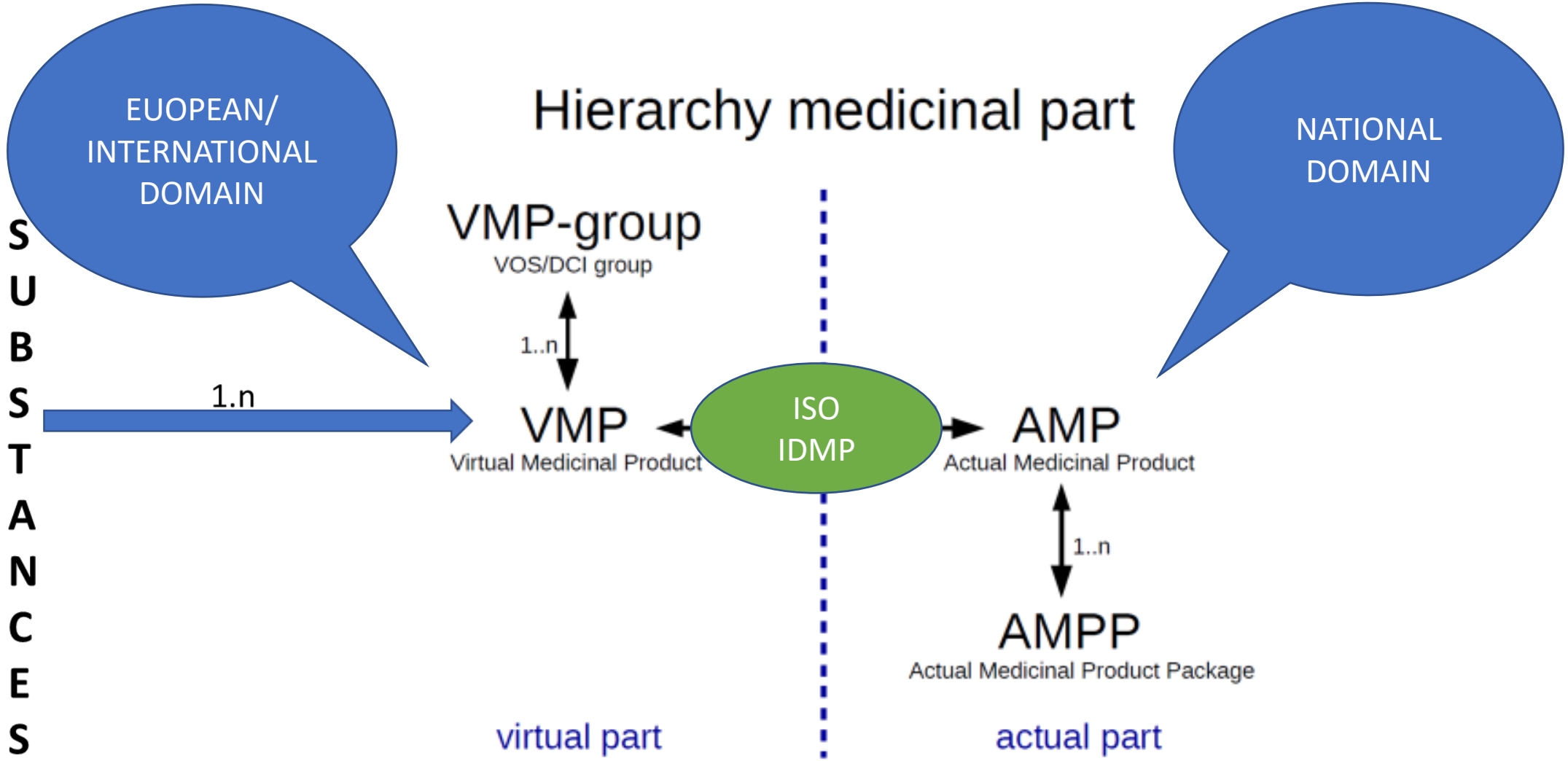
## This is done!

- Data representation is **easily understood** by end users
- Control over **the consistency of the data** that is entered into the SAM by the suppliers via a consistent object domain
- **Scalable physical model** in relation to future needs without impact for end users.
- **Independence** between the structure of business entities and the physical implementation
- **Use of a standard data exchange protocol** with openness to other suppliers
- Orchestration between suppliers via SAM ensuring data integrity
- Export based on business layer business entities and also used in Web Services
- ISO IDMP compatible

## Constraints and challenges…

- Implementation of **the physical model specific to each end user** based on the business entities received.
- Semantic standards are not yet travelling over the whole value chain (eg. Pharmacoviligance)
- Access to **complete** content of Medicines Products enabling allergies management and issue warnings: eg: No sugar.
- **Individualized dosage** management
- Operationalising ISO IDMP: Resistance to change and backward compatibility.
- Integrate Pharmaceutical Product ID (PhPID) (VMP ID) into the Clinical Record together with its concrete description.

# Going beyond across silos but also across borders



# Thank you!

http://www.samportal.be/fr/sam (French)
http://www.samportal.be/nl/sam (Dutch)

## More info on INN Prescription

https://www.afmps.be/fr/items-HOME/prescription_en_dci (Fr)

https://www.fagg-afmps.be/nl/items-HOME/voorschrijven_op_stofnaam (Nl)

E. Van Bever, et al., Operational rules for the implementation of INN prescribing, Int. J. Med. Inform.(2013),http://dx.doi.org/10.1016/j.ijmedinf.2013.09.004

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UNICOM

Up-scaling the global univocal identification of medicines

# Questions and Answers: Use cases and lessons learned

**Robert Vander Stichele, i-HD**

**UNICOM Workpackage 8**

***Sept. 21th, 2020***

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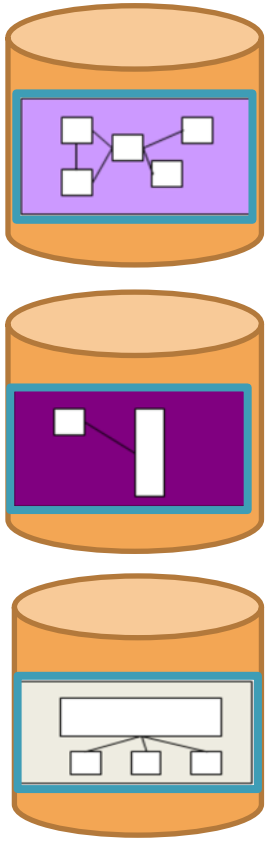
# National Drug Dictionaries
# each With their data model



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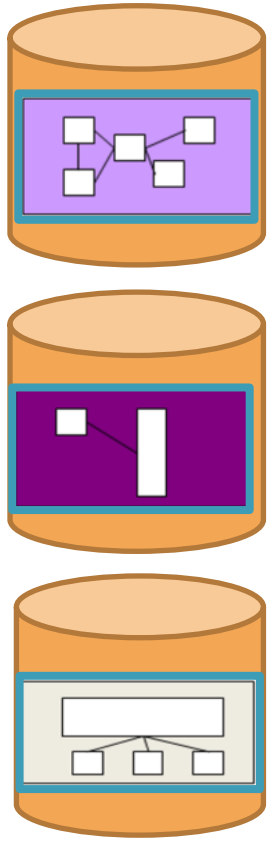
# National Drug Dictionaries each With their data model




**Connecting with a global univocal identification system**

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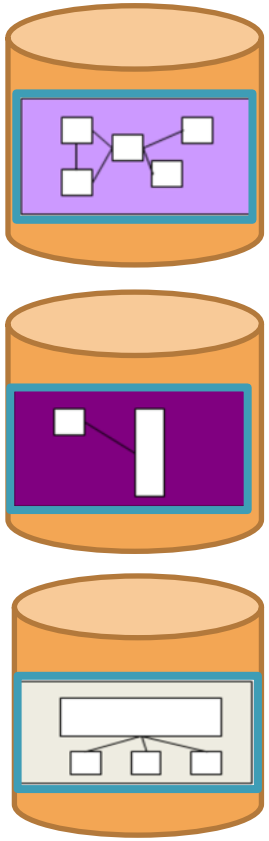
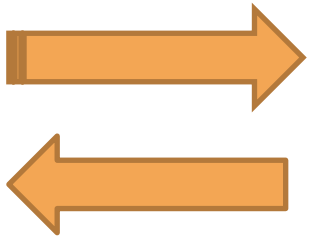
# National Drug Dictionaries each With their data model






**Harmonizing the national Medicinal product drug models**

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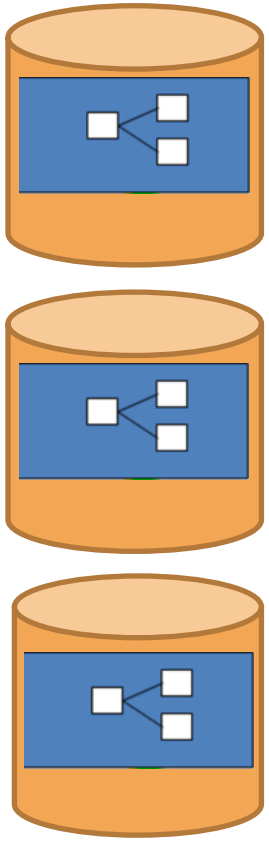
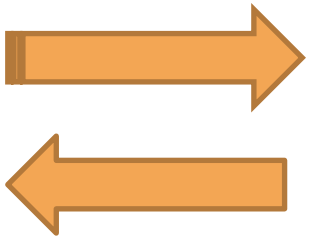
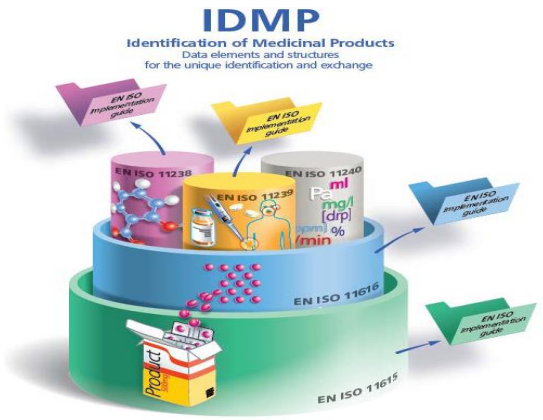
Horizon 2020 research and innovation programme under grant agreement No 875299

# National Drug Dictionaries each With their data model








**Harmonizing the national Medicinal product drug models**

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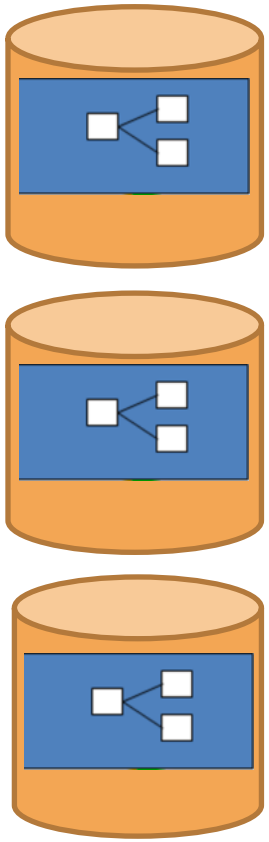

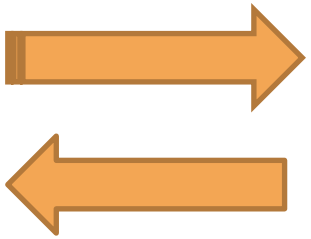


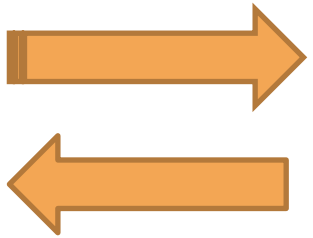

**Integration with international drug classifications in knowledge bases on pharmacotherapy**

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# Advantages of univocal identification of medicinal products

**Cross Border Migration**

of ePrescriptions

of Knowledge databases on Drug information and Decision Support

**Cross National Comparison**

**of  the national therapeutic arsenals**

**of Drug Utilisation**

**of the quality of prescribing and dispensing**

**Cross National Cooperation**

**Creating a European Data Space**

**Facilitation multi-centre multi national pharmaco-epidemiology**

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# Save the date – Next steps

#Imagining2029

- 1 Oct 2020, 15:00 – 16:30 **Digitally integrated care task force**
  **Deep diving into health data ecosystems for integrated care: sustainability and governance**
- 2 Oct 2020, 15:00 – 16:30 **UNICOM Community of Expertise**
  **Gap Analysis about existing and new standards and profiles**
  Registration: https://us02web.zoom.us/webinar/register/WN_QuVtjX60TTO33IwZw5-82A
- 2/3 Dec 2020: **EHTEL 2020 Thought Leadership Symposium**
  **Digital Services in the move towards healthy and resilient communities**

Workstreams and Events: https://www.ehtel.eu/imagining-2029.html
Webinar Documentation and Recording: https://www.ehtel.eu/activities/webinars.html

# Towards European data spaces for medicines Semantic interoperability for patient safety

#Imagining2029

14:00 – 14:05 | **Welcome and Introduction to the third EHTEL ELO Virtual Meeting**
ELO CoChairs Andreas Grode, Gematik GmbH, Germany and Dr Vesa Jormanainen, THL, Finland

14:05 – 14:10 | **Setting the Scene – Lessons from ELO webinars – EU preparing data re-use**
Dr Stephan Schug, EHTEL

14:10 – 14:30 | **Wide use of real world medication data: Routes for European data spaces**
Prof Dr Miriam Sturkenboom, i~HD Ghent and Utrecht UMC, Department of Epidemiology, Belgium/Netherlands

14:30 – 14:50 | **Data quality and semantic interoperability along the medicine data value chain**
Prof Dr Karl Stroetmann, UNICOM coordinator, empirica GmbH, Bonn – Germany

14:50 – 15:10 | **Data quality for patient safety in Belgium: Ecosystems for coding and reporting medicine use**
Jos Devlies, Eurorec, Belgium, Dr Robert Vander Stichele, i~HD, Belgium and Luc Nicolas, EHTEL

15:10 – 15:30 | **Q&A and Interactive Round Table: Use cases and lessons learned**
Facilitator: Dr Robert Vander Stichele, i~HD, Belgium

15:30 | **Closing**
ELO CoChair Andreas Grode, Gematik GmbH, Germany

# Learn more in factsheets and full videos of ELO Imagining 2029 webinars:


Imagining 2029 webinar series:
Moving towards for European Health Data Space(s)

**From the European Strategy for Data to Health Data Spaces**

**1st EHTEL/ELO Network Factsheet**

OPENDEI
Aligning Reference Architectures, Open Platforms and Large-Scale Pilots in Digitising European Industry

InteropEHRate

**Internal Review**


Imagining 2029 webinar series:
Moving Towards European Health Data Space(s)

**Architectures and processes enabling data re-use:**

**2nd EHTEL/ELO Network factsheet**

InteropEHRate
EHR in people's hands across Europe

This factsheet provides a contribution to the InteropEHRate project

**Published**



**Full Webinar Recordings**