WP-1 / community of expertise

February 2022

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

Clinical applications for IDMP

Robert Vander Stichele
Mohammad Nouri Sharikabad
Malin Fladvad

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SOME RULES FOR THE VIRTUAL MEETINGS

UNICOM

Our interactive session:

- ✓**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

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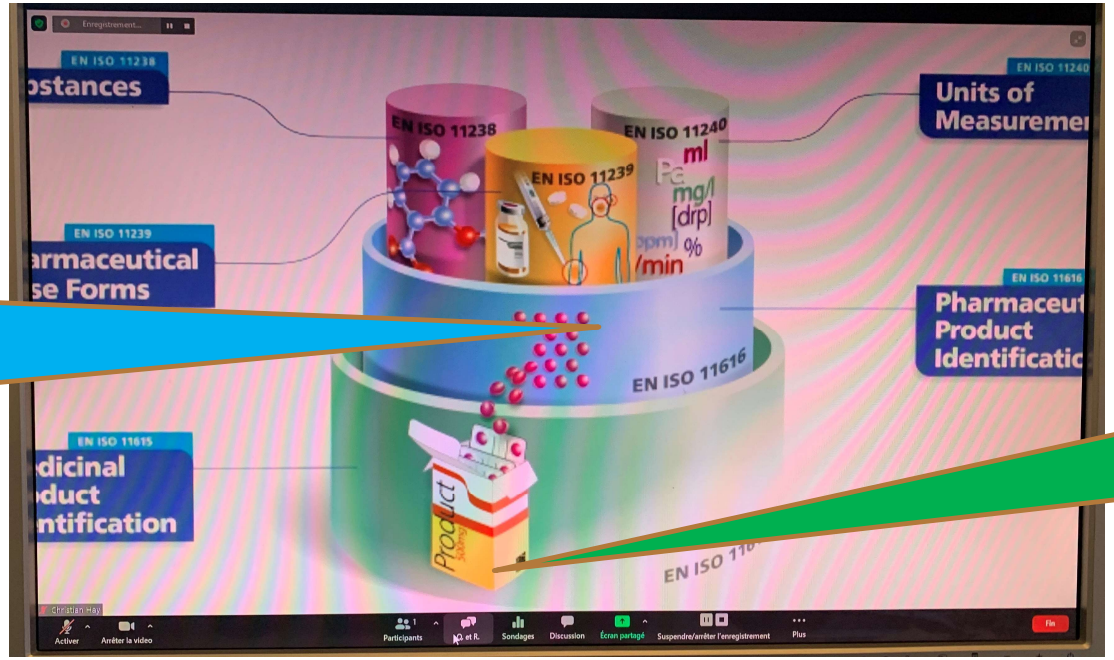
Asking a question or making a comment: please use the Q&A facility

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



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

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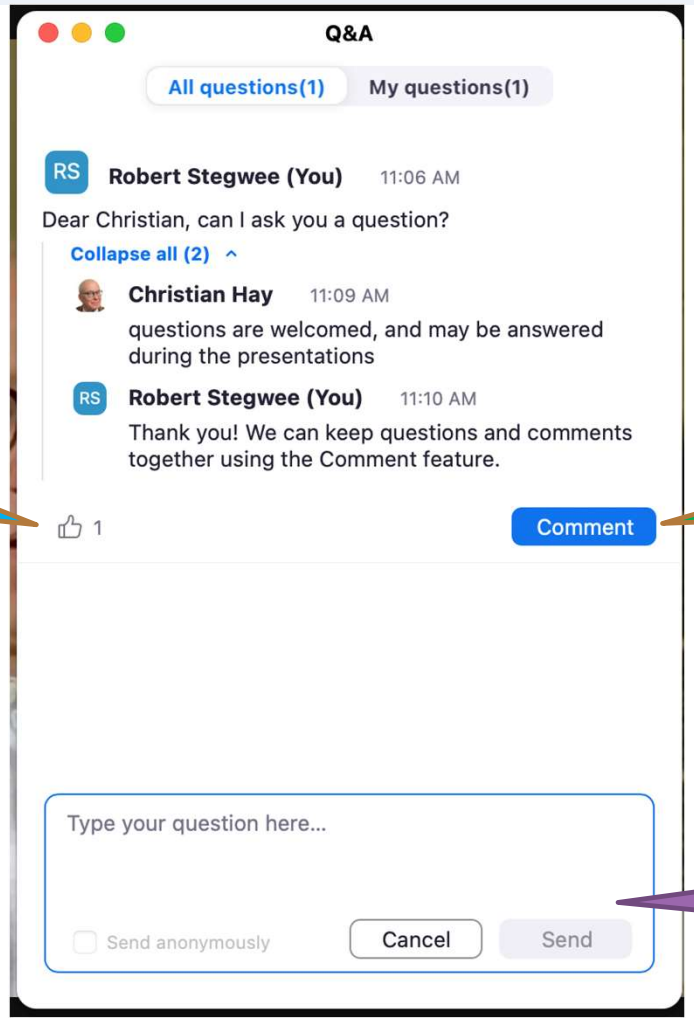
Showing support and providing a comment on a question or answer

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



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

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Security

- Security is our priority
- This session is password protected

Recording of this session is made available on UNICOM's youtube channel
https://www.youtube.com/channel/UCBsNj4B33Q7-50XTXdqAGIg

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

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Introductions to our esteemed colleagues and today's speakers

Robert Vander Stichele

Mohammad Nouri Sharikabad

Malin Fladvad

...and our panellist

Annet Rozema

Olof Lagerlund

Jean-Gonzague Fontaine

Dipak Kalra

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Questions in the Q & A facility, please

For feedback, please go to : https://forms.gle/YAq3XqvGodyNDw2p9

Thanks for your time

UNICOM

Steps to make IDMP relevant for Clinical Care : The importance of linking the Pharmaceutical Product Identifier (PhPID) to international drug Classifications

Robert Vander Stichele, I-HD

WP1 Community of Experts Webinar

February, 2022

Workpackage 8 in UNICOM

IDMP and Clinical Care

What have been achieved ?

Motivation to focus on the procedure for PhPID production

What were the breakthroughs with regard to PhPID production ?

Substance, dosage form, Strength

The role of WHO UMC and WHO Oslo

Applications in drug information applications and decision support systems

Achievements in Work Package 8

What have been achieved in Workpackage 8 ?

(half way throught the UNICOM project)

Interesting deliverables

On Clinical Care	D8.1	(Approved)
on Research	D8.2	(Approved)
on Pharmacovigilance	D8.7	(Approved)
on Pharmacogenetics	D8.9	(Approval pending)

Focus on the minimal data set for PhPID-Level IV production

Resolving issues in description of

substance
dose form
strength codes

to feed the algoritm that produces a global Pharmaceutical Product Identifier

Starting to think about concrete applications

to be developped in the second half of the UNICOM project

Motivation to focus on the production of the Pharmaceutical Product Identifier
PhPID Level IV

Motivation for the focus on PhPID production

1. **All pilots in UNICOM need sufficiently large datasets for experimenting concrete projects that demonstrate te value of IDMP.**
    1. To enable the cross border Pilots of WP5 and WP7 (minimal dataset)
    2. To feed the ambitious demonstrators in task 1 of Workpackage 8
    3. To realize concrete Patient-facing apps (more than a mock up)
    4. To support initial steps of readiness of NCAs for IDMP

2. **The fear of delay in the official channels**
    1. Delay in the EU Implemention Guide (no mentions yet of PhPID production procedure).
    2. Initiating concertation in the Global IDMP Working Group (GIDWG)
       between FDA/EMA/WHO_UMC
    3. Covid-19 burden wihtin NCAs

=➔ the possibility that before the end of the unicom project in 2023
there will be no sufficiently big data set of medicinal products
from a minimal number of coutries

Remedial actions

The UNICOM Pilot Product List

1. A list of 35 substances
2. Collection of relevant modifiers and codes for each of these 35 substances
   (with the help of WP2 and the EU Substance cleansing team SMS)

A proposal for the development of an IDMP FHIR Server solution

Full implementation of IDMP wihtin NCAs focusing on a few products,
based on evolving versions of the EU Implementation guide

A proposal (WP8 and WP1) for collaboration with WHO_UMC

taking advantage of the WHO-UMC/FDA pilot
Focusing on procedures for PhPID production

Establishement of a minimal data set for Cross border eHealth Pilots

including Substance, dose form, Strength

In this Community of Experts Meeting three parts

Initiatives within Workpage 8 (Task 8.1)

Remaining issues in PhPID-Production for substance, dose form, strength (D8.1)

as identified in the Gap Analysis in WP1

Creation of a repository of PhPIDs and minimal data (for WP6 software factory)

- starting with the 35 substances of the Unicom Pilot Product List
- for a collection of national medicinal products from a number of countries
- for the pilots of UNICOM on short notice (mid 2022)

Creation of a link from PhPID to international drug classifications

Report on the current activities of WHO_UMC

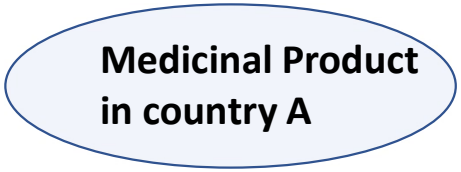
Malin Flavad, WHO_UMC

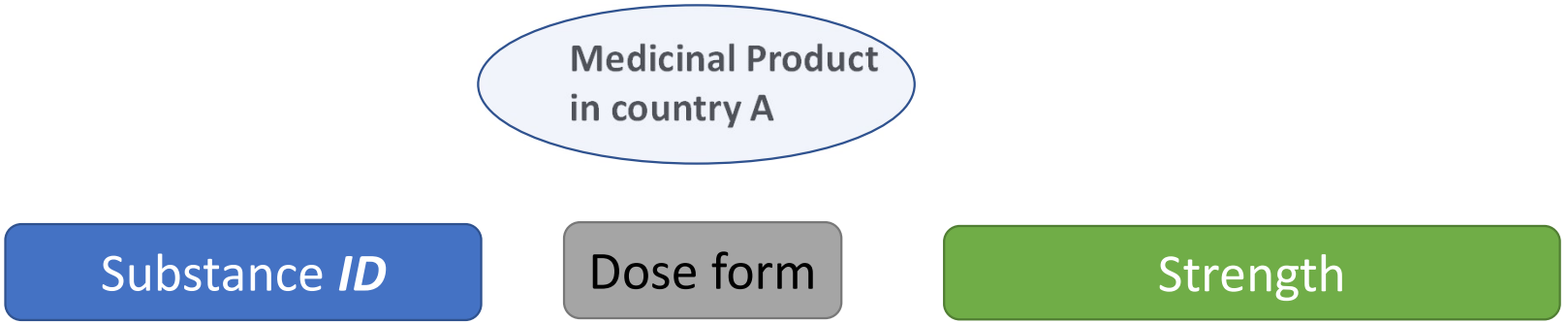
Report on efforts to create links between WHO ATC Classfication and IDMP

Mohammad Nouri Sharikabad, Mohammad, WHO-OSLO

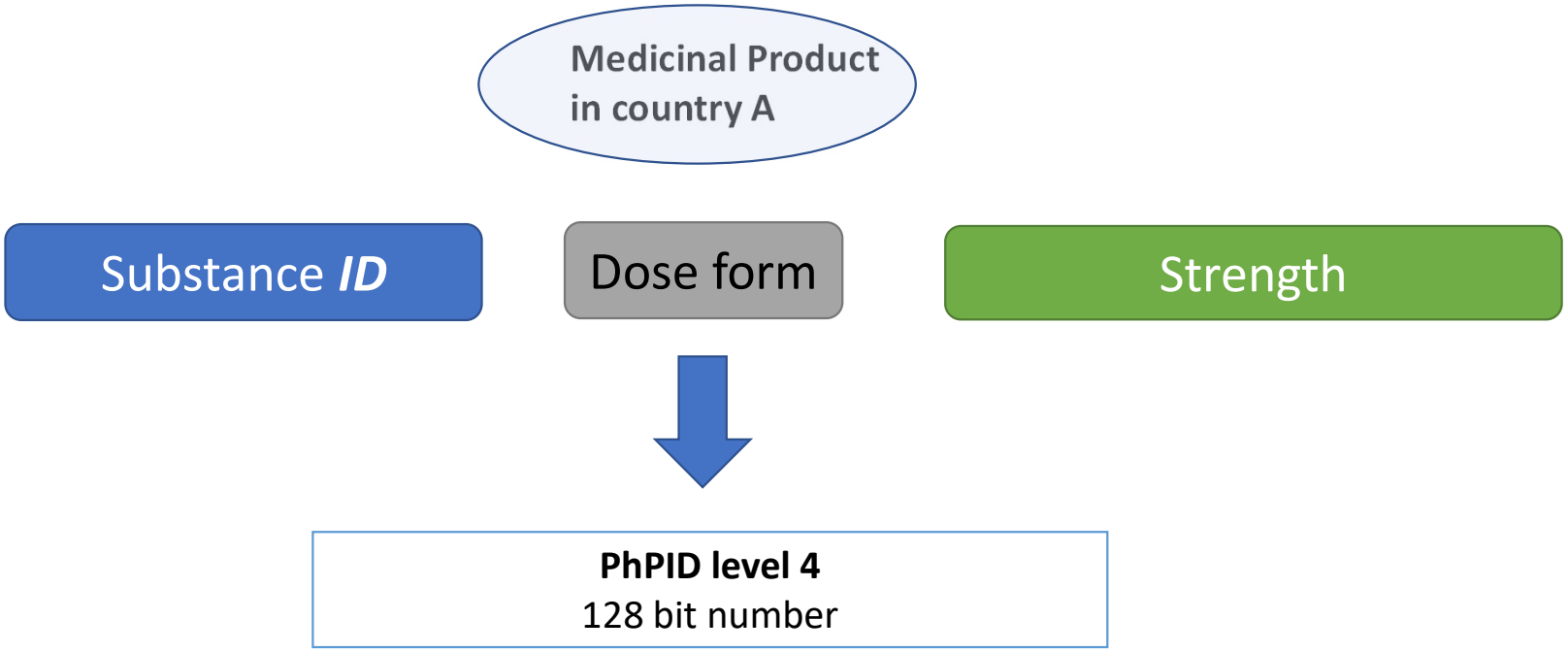
Remaining issues in PhPID-Production

Focus on PhPIDID production

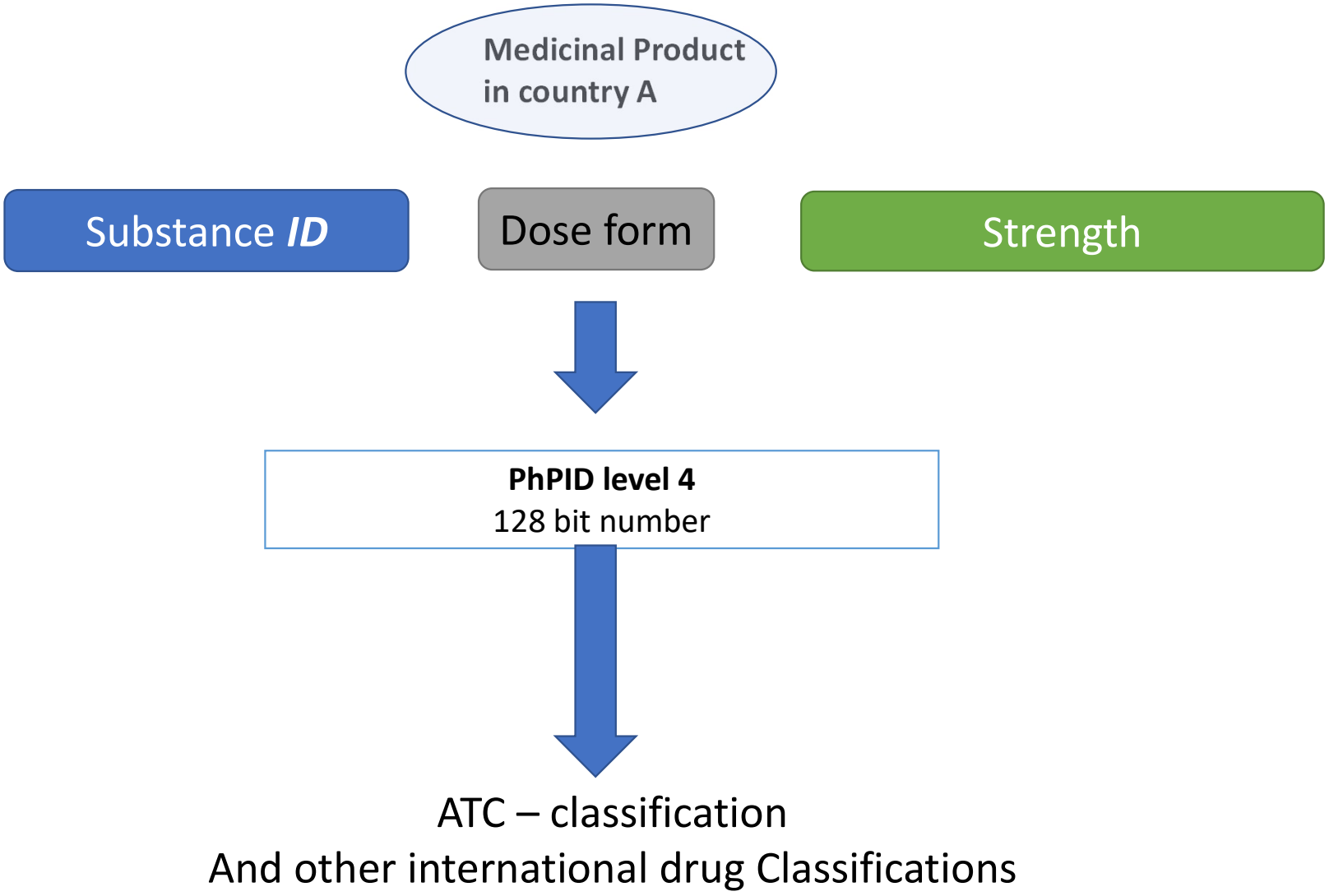



Medicinal Product
in country A
Substance *ID*
Dose form
Strength

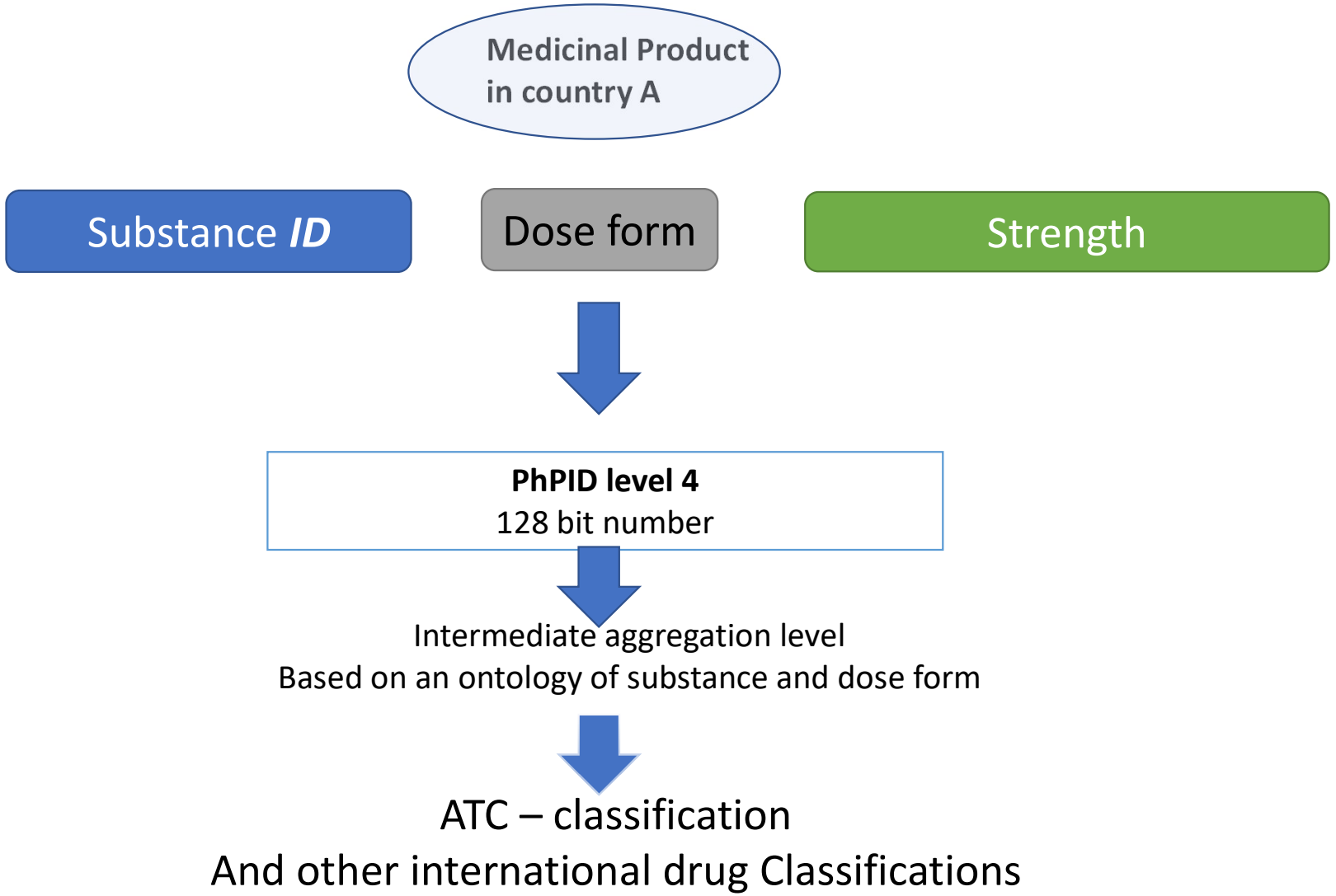
Focus on PhPIDID production

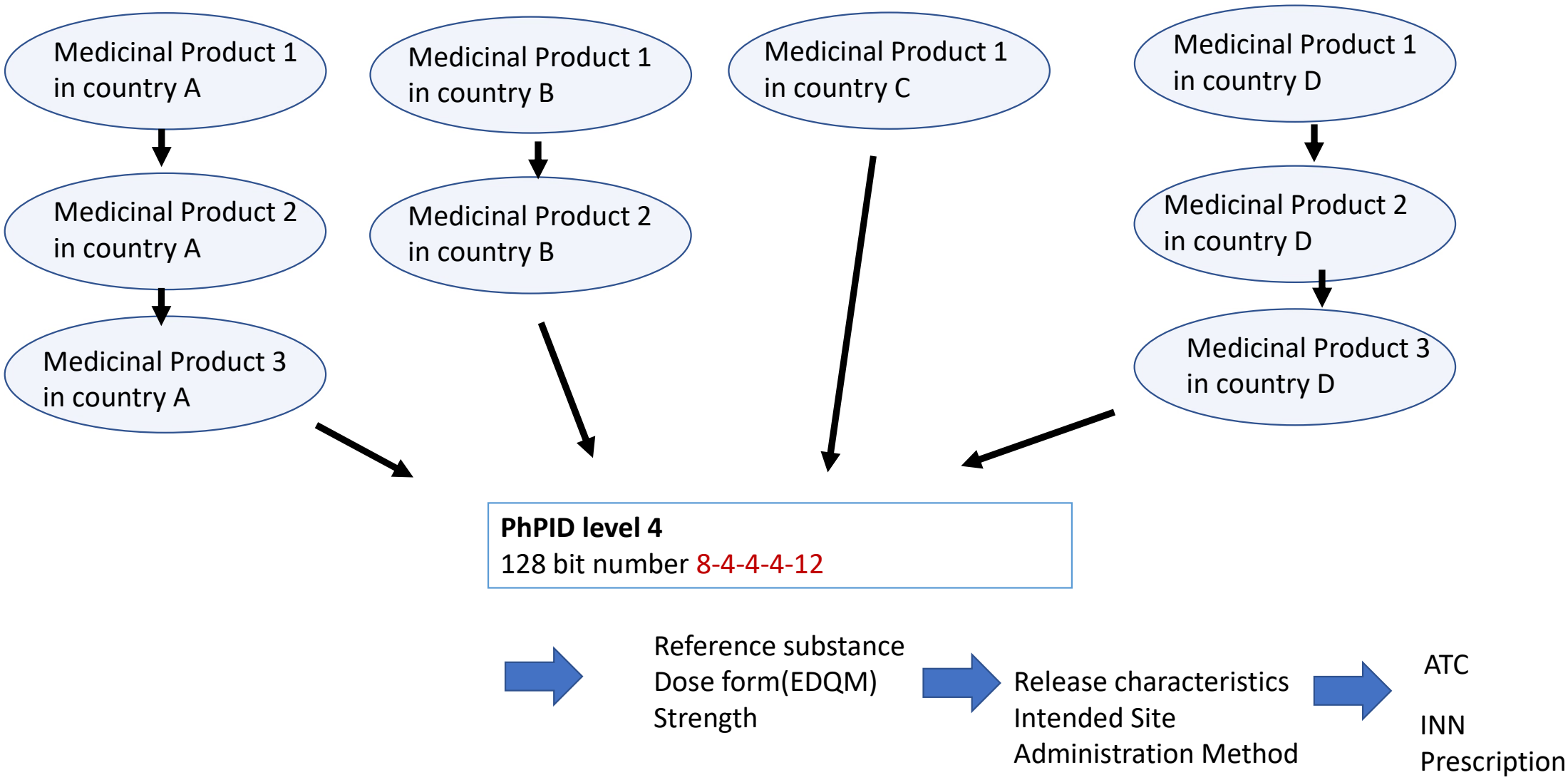


Focus on PhPIDID production



Focus on PhPIDID production




Medicinal Product 1 in country A
Medicinal Product 2 in country A
Medicinal Product 3 in country A
Medicinal Product 1 in country B
Medicinal Product 2 in country B
Medicinal Product 1 in country C
Medicinal Product 1 in country D
Medicinal Product 2 in country D
Medicinal Product 3 in country D
PhPID level 4
128 bit number 8-4-4-4-12
Reference substance
Dose form(EDQM)
Strength
Release characteristics
Intended Site
Administration Method
ATC
INN
Prescription

Information inheritent to the PhPID Level 4 number

PhPID level 4
128 bit number

Reference substance

Dose form(EDQM)

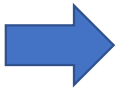
Strength

Information inheritent to the PhPID Level 4 number

PhPID level 4
128 bit number

Reference substance

Dose form(EDQM)



Basic dose form
State of matter
Release characteristics
Intended Site
Administration Method

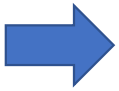
Strength

Information inheritent to the PhPID Level 4 number

PhPID level 4
128 bit number

Reference substance

Dose form(EDQM)



Basic dose form
State of matter
Release characteristics
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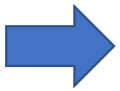
Administration Method

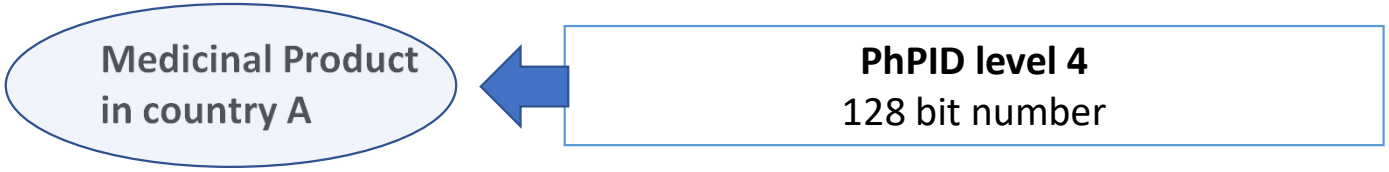
Strength



INN prescription instruction

ATC – Code

Information inheritent to the PhPID Level 4 number



Reference substance

Dose form(EDQM)

Basic dose form
State of matter
Release characteristics
Intended Site
Administration Method

Strength

INN prescription instruction

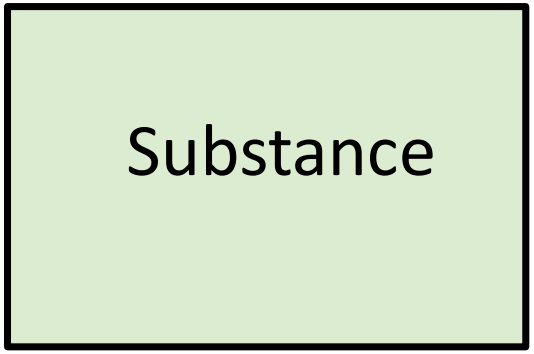
ATC – Code

Remaining Issues regarding PhPID production

Substance

Dose form

Strength


Substance

The great work in the European Substance Management System cleansing team

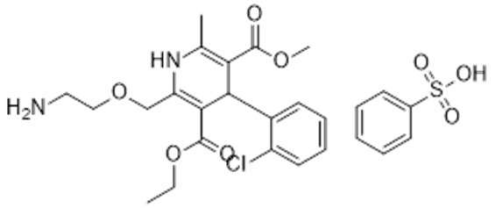
Terminology of substance : synonyms, spelling differences

Differentiating between Substance and Reference substance, when needed (moiety with or without a modifier)

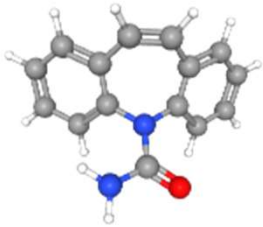
Identify all relevant modifiers of a substance, if appropriate

Based on a practice reality check for number of occurences in adverse event reports

The distinction between 2 kinds of precise active ingredients

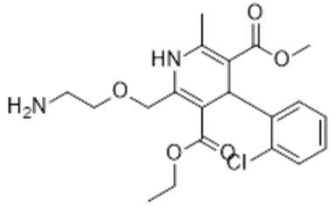


modified substance
amlodpine besilate



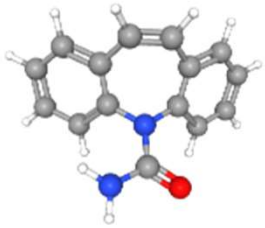
moiety without modifier
carbamazepine

The distinction between 2 kinds of moieties



(+)

the ionized moiety
amlodpine



moeity without modifier
carbamazepine

The distinction between meanings of the same term representing different concepts

Three meanings of a substance term		
	Amlodipine (1)	
		Term for the physical reality of chemical molecule, which consitutes the active part of an ingredient with therapeutic role. This molecule has a chemical structure, molecular mass, a code in the CAS-system, and a mechanism of action.
	Amlodipine (2)	
		Term for the collection of modified substances (amlodipine besilate, mesilate and maleate), which all contain amlodipine (1)
	Amlodipine (3)	
		Term for the collection of medicinal products that contain any one of the 3 modified substances (named with amlodipine (2), and no other ingredients with an active role. A medicinal product can be entered in the collection even is the modifier is unknown.
Two meanings of a modified substance term		
	Amlodipine besilate (1)	
		Term for the physical reality of a chemical molecule, consisting of the active part and the salt. This molecule has a chemical structure, molecular mass, a code in the CAS-system, and a mechanism of action
	Amlodipine besilate (2)	
		Term for the collection of medicinal products containing this specific modified substance

Three ways of dealing with combinations of medicinal product

1. Single X and combinations with x
   in separate classes

2. Single X as a subset of
   all combinations containing x

3. Single and combinations in one
   class, linked to a database of
   substanced with the role of
   precice ative ingredients

Three ways of dealing with aggregation of medicinal product combinations

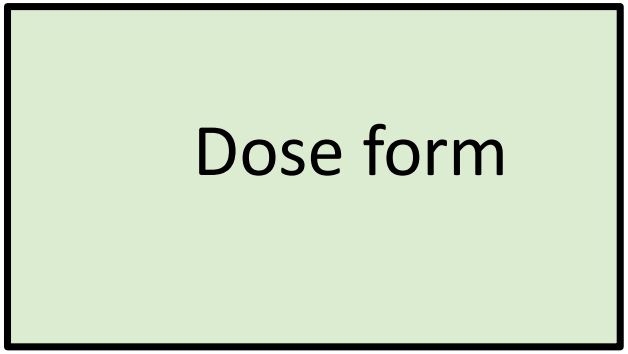
1. Single X and combinations with x in separate classes

2. Single X as a subset of all combinations containing x

3. Single and combinations in one class, linked to a database of substanced with the role of precice ative ingredients

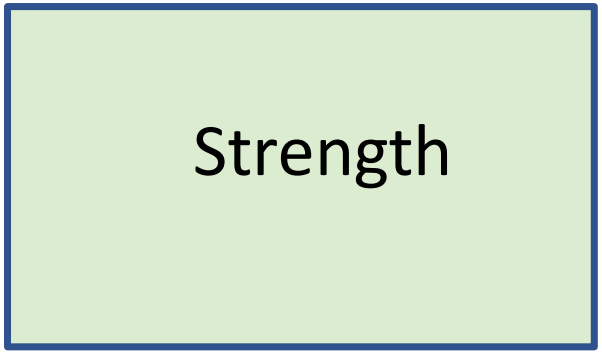
Different solutions are tested for the use case of PhPID production.

Different solutions can fit different use case

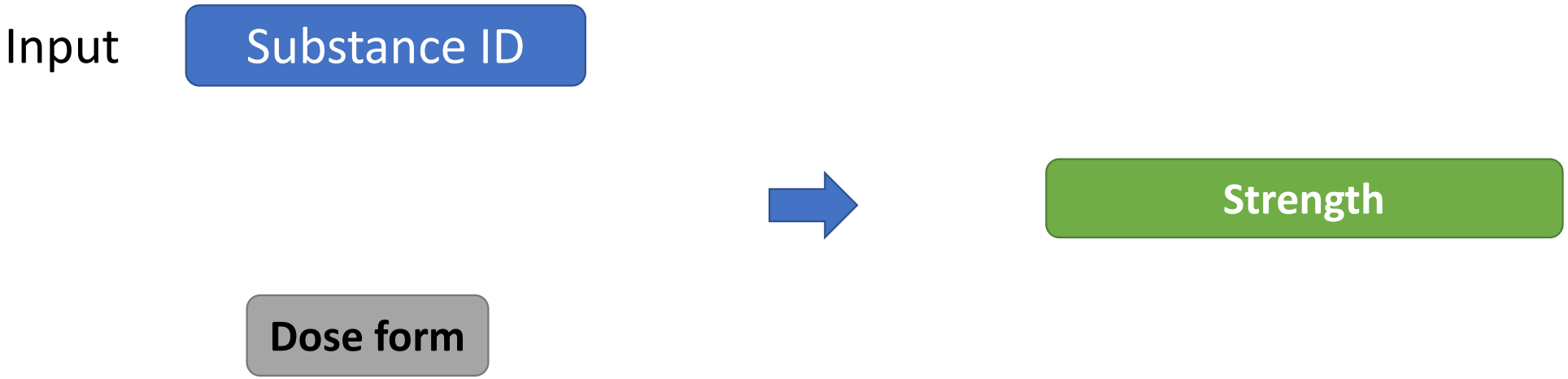

Dose form

Progress with regard to Dose form

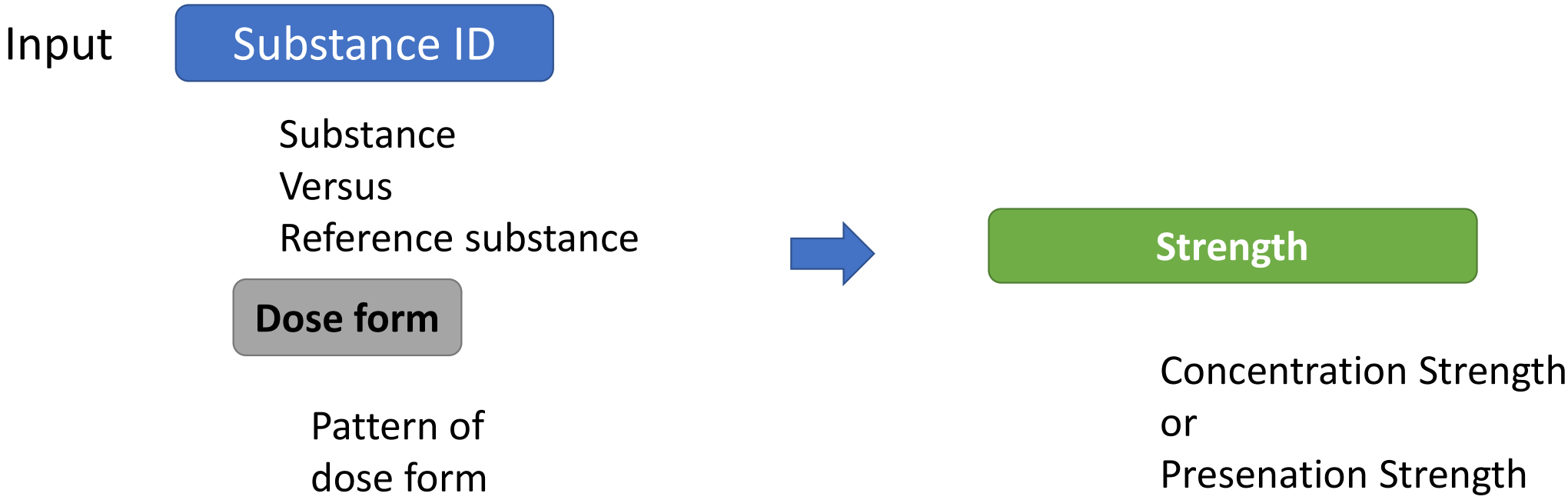
- The choice between Manufactured dose form vs Administrable dose form
- The choice of granularity of dose form
  - Full EDQM ?
  - Combination of Characteristics (as in the FDA/WHO_UMC pilot) ?
- The choice of the coding system
- European EDQM and/or a Global coding system ?
- The creation of an ontology of dose forms based on EDQM
- The acknowledgement of the need for training of industry and regulatory experts to standardize the dose forms in national MPDs to EDQM


Strength

Harnessing the intricate relationship between expression of strength, on the one hand, and substance and dose form, on the other hand

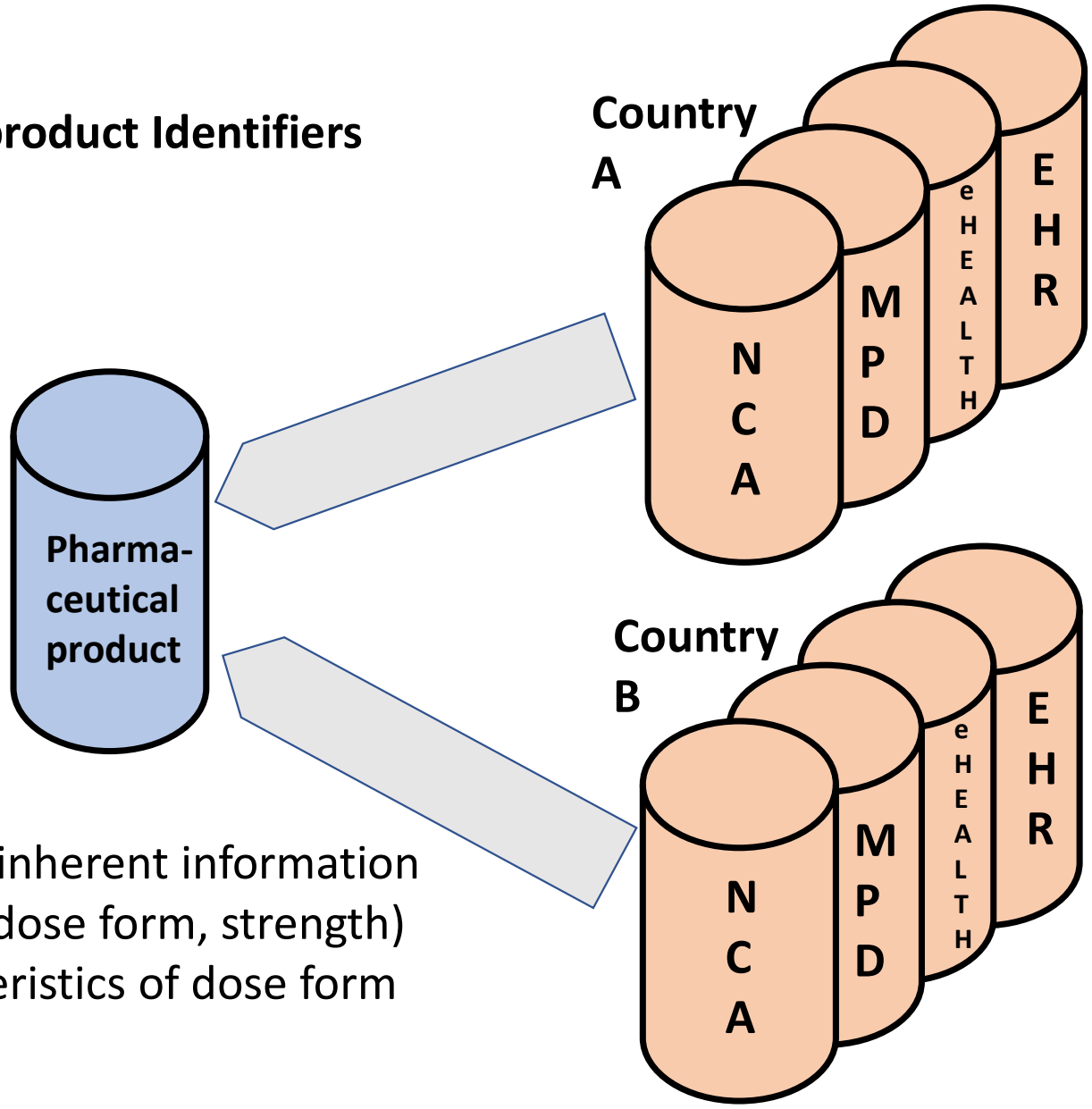


Harnessing the intricate relationship between expression of strength, on the one hand, and substance and dose form, on the other hand



Creation of a repository of PhPIDs and minimal data (for WP6 software factory)

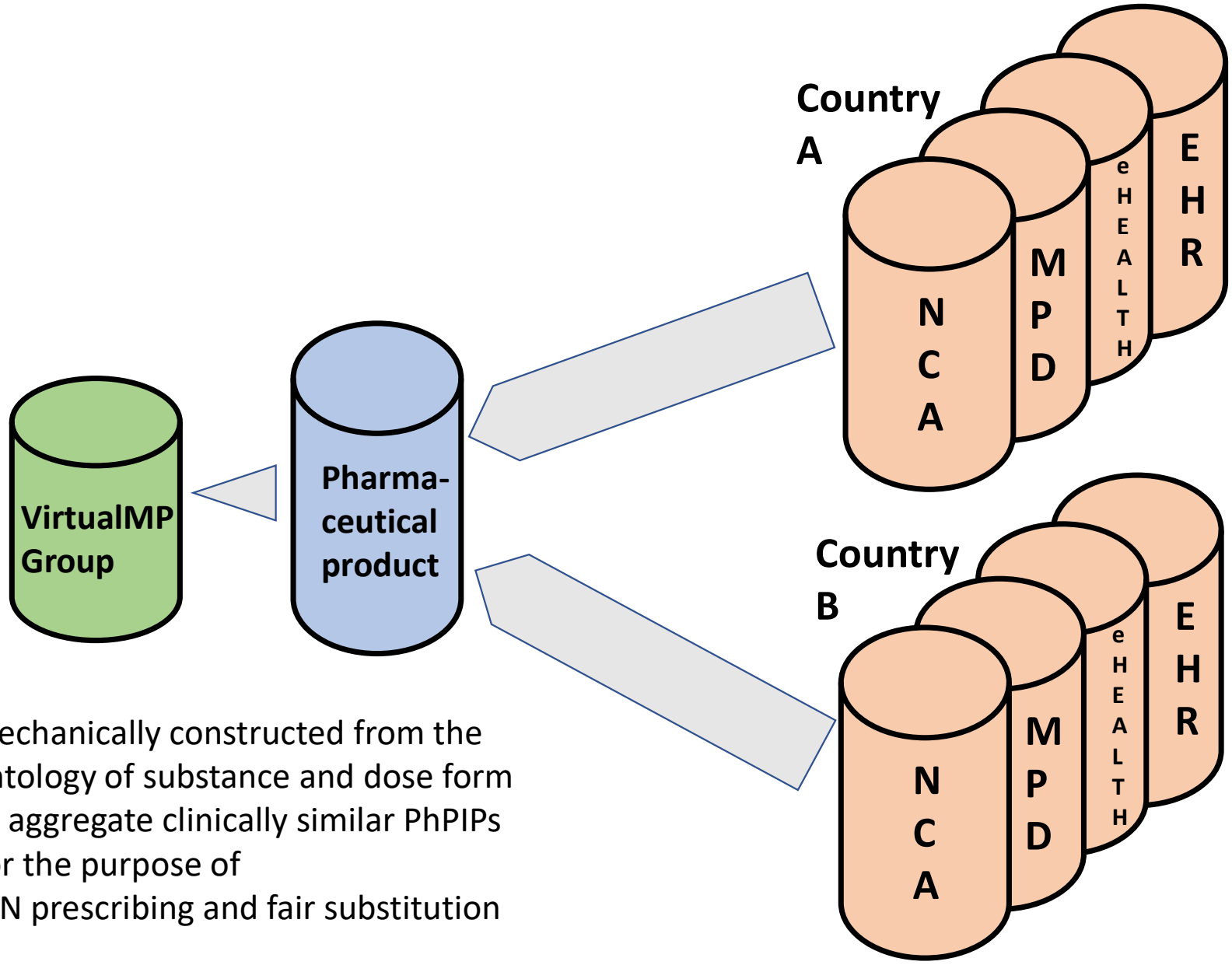
Build a repository of Pharmaceutical product Identifiers



With all the inherent information (substance, dose form, strength) and characteristics of dose form

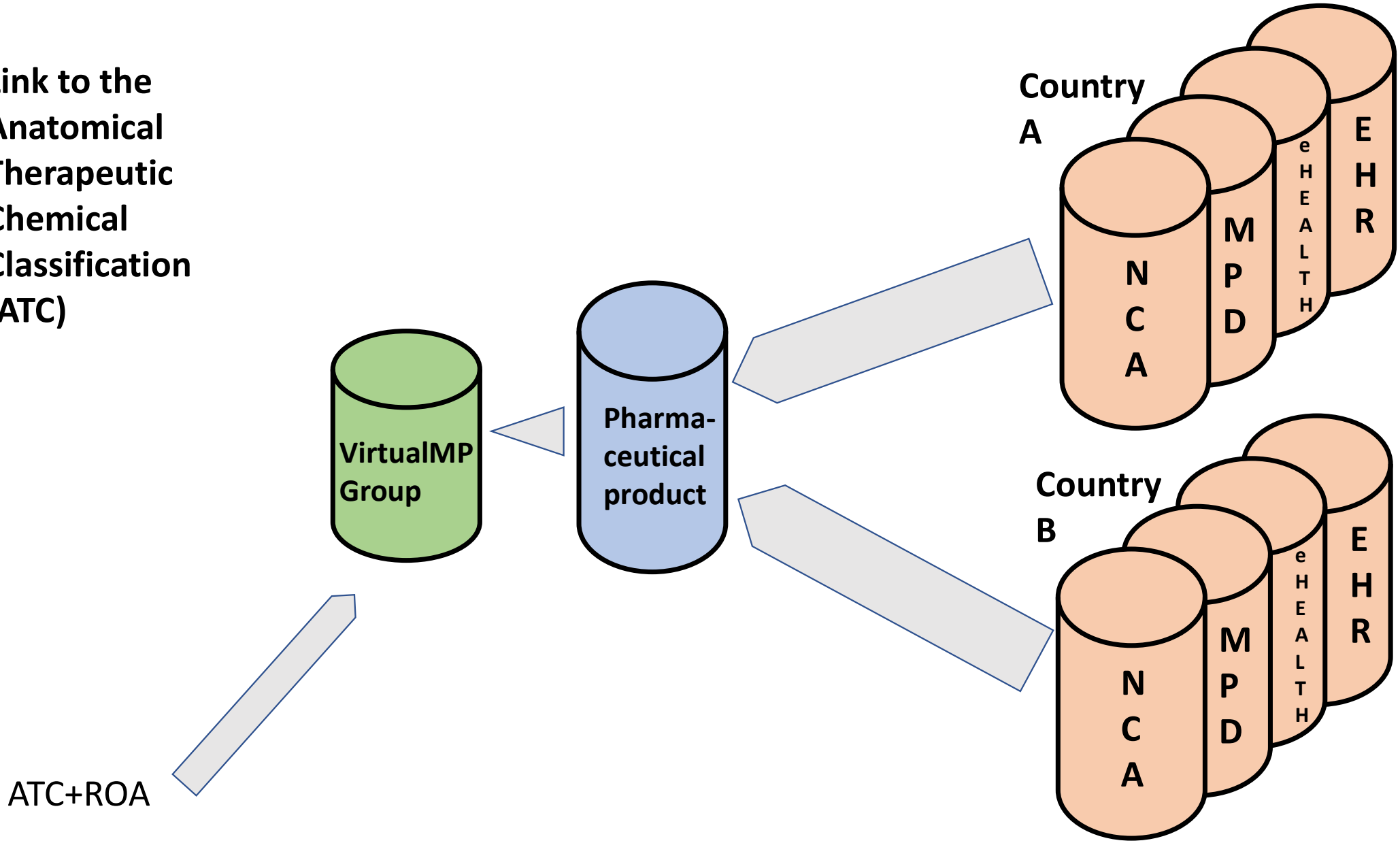
Creation of a repository of PhPIDs and minimal data (for WP6 software factory)

Add
an ontological Layer

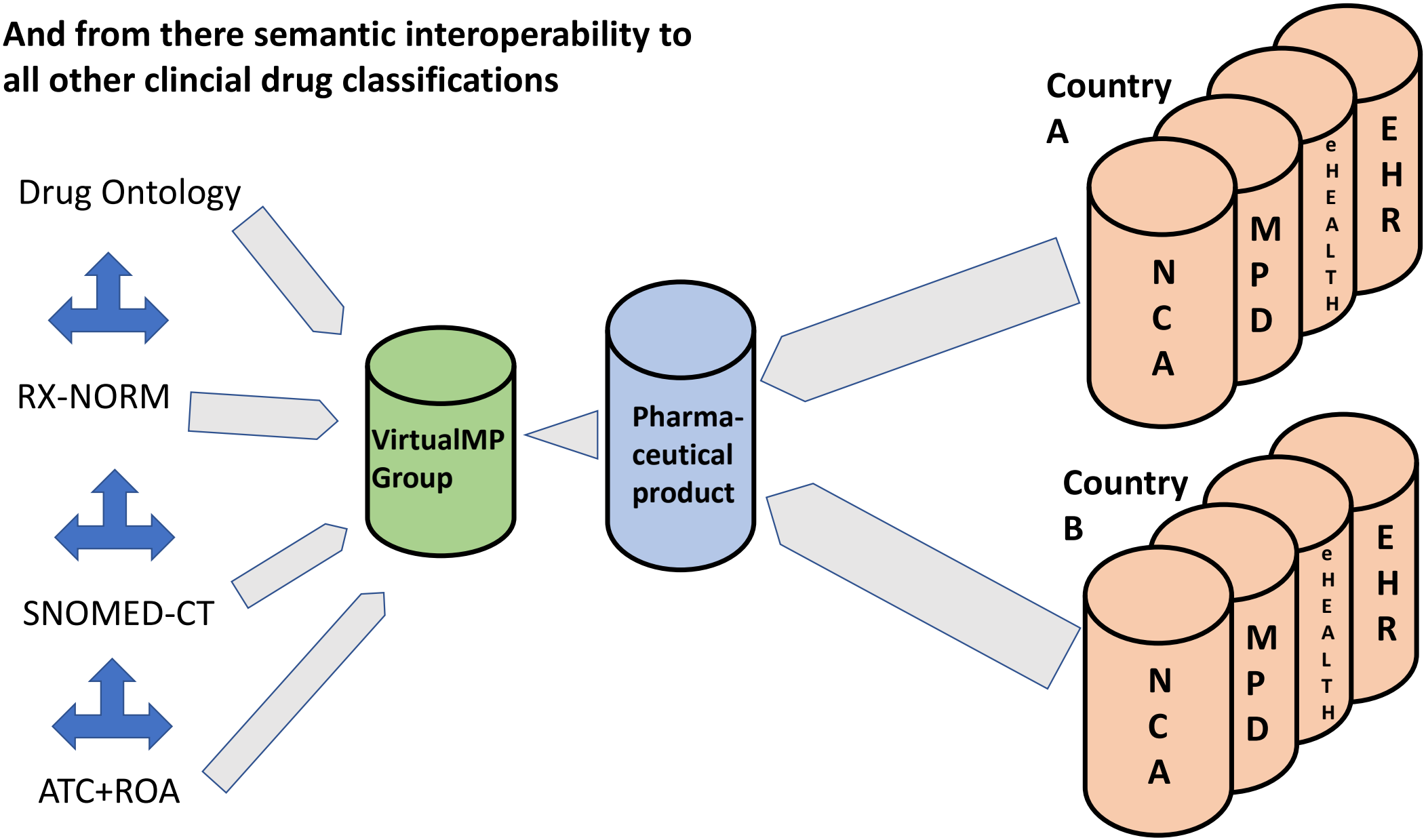


Mechanically constructed from the
ontology of substance and dose form
To aggregate clinically similar PhPIPs
For the purpose of
INN prescribing and fair substitution

Link to the Anatomical Therapeutic Chemical Classification (ATC)



And from there semantic interoperability to all other clincial drug classifications



Planned applications

in the clinical field

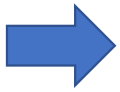
Planned applications for IDMP in Clinical Care during UNICOM (pilots)

- Connecting European Decision Support systems
  to the medicinal drug dictionaries of Europe

- Connecting European Drug Information Services to the healthcare
  providers, care givers, and patients of the member states

- Connecting European digital platforms for teaching prescribing and
  medication management to physicians to pharmacists and nurses
  of the member states

- Making the cross border projects work in relatively short term
  (ePrescription, eDispensing, International Patient Summary)



Making evidence, clinical information, prescriptions, and patients cross the borders

THANK YOU

WHO Collaborating Centre for
Drug Statistics Methodology

FHI
Folkehelseinstituttet

The ATC/DDD classification - aligning ATC with IDMP

Mohammad Nouri Sharikabad, Dr. Philos. M. Pharm.
Department director, Department of Drug Statistics and
WHO Collaborating Centre for Drug Statistics Methodology

Norwegian Institute of Public Health

4 February 2022

Aim of this presentation

- The ATC/DDD system; what, why and how
- Use of the ATC/DDD system
- How and where is ATC incorporated in different systems in Norway
- Summary and some concluding remarks

The Anatomical Therapeutic Chemical (ATC) /Defined Daily Dose (DDD) ; what, why and how

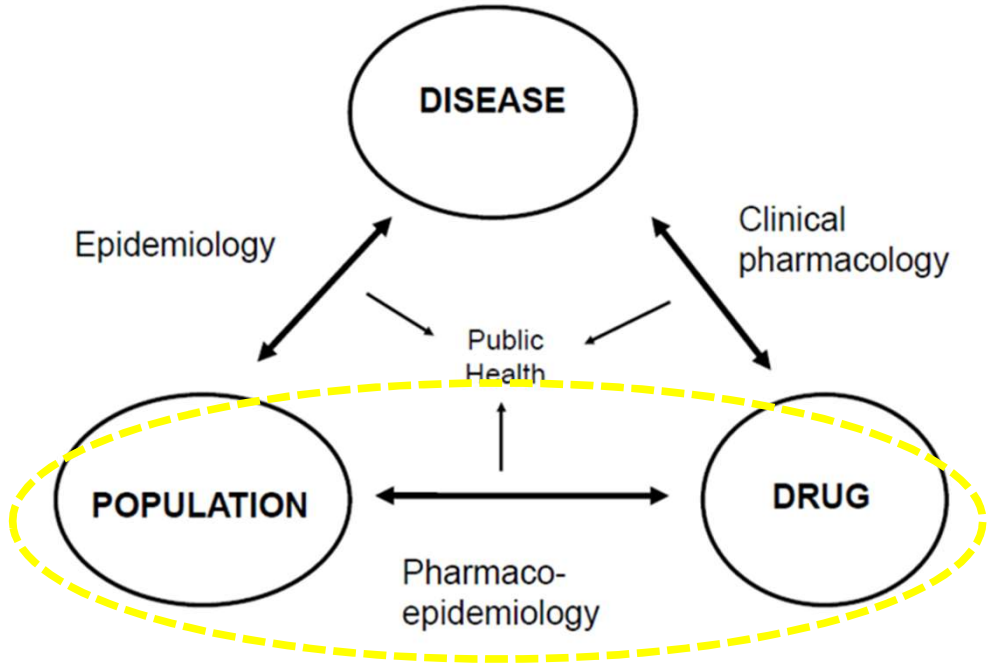
- A WHO recommended standard with hierarchic drug classes (5 levels)
- A central methodological tool for drug utilization and pharmacoepidemiology
- DDD is a unit of measurement and quantifies drug consumption
- Globally used and accepted, maintained by the ATC/DDD Centre under the guidance of WHO appointed experts
- New ATC codes and DDDs are assigned on request by pharmaceutical companies, health authorities and other users of the ATC classification system

DDD and its use

The DDD is the assumed average maintenance dose per day for a drug used for its main indication in adults

- Unit of measurement independent of strength, package, price
- International comparisons and comparisons over time
- Indicators for use of medicines

Role of the ATC/DDD system



The purpose of the ATC/DDD-system is to collect and improve drug use.

It is with this purpose in mind that all decisions about ATC/DDD assignment and alterations are made

Visions and ambitions of the ATC/DDD system

"International language for drug utilization monitoring and research" *almost for five decades*

How and where is ATC is incorporated in different systems in Norway

Examples

- Norwegian Product Register (Farmalogg) a coop. between many stakeholders
- Prescribing support system (FEST) administered by the Norwegian Medicines Agency
- National Health registries and data bases
- Electronic Patient Records in primary and secondary health care
- Medicine catalogue (Felleskatalogen)
- Norwegian medicine handbook (NLH)

(And internationally: Medicinal dictionaries e.g., WHODrug Global
and international drug textbooks such as Martindale)

Norwegian product register / The- Article- Number-Register

The Norwegian Pharmacy Association and the three (main) drug wholesaler in Norway established the Norwegian product register (Famalogg). There is further collaboration with:

- Norwegian Medicines Agency,
- The Norwegian Health Economics Administration
- WHO Collaborating Centre for Drug Statistics Methodology

This is how the Norwegian product register is maintained, updated and administered. Updated register is distributed twice monthly to pharmacies, pharmaceutical wholesalers and other subscribers

https://www.farmalogg.no/en/The-Article-Number-Register/

Example of a quality assured file for updating of the Norwegian Product Register

MPPI[1]	Article name	Quantity	Unit	Strength	ATC code	Substance	DDD	UM[2]	ROA[3]	Content[4]	Dose form	OK/NOK	Comment
315044	Klacid gran til mikst 50mg/ml	100	ML	50mg/ml	J01FA09	clarithromycin	0,5	g	O	5	Granulat til m	OK	
294159	Ciproxin gran t miks 250mg/5ml	100	MLSETT	250mg/5ml	J01MA02	ciprofloxacin	1	g	O	5	Granulat og v	OK	
446438	Mektovi 2care4 tab 15mg	84	ENPAC	15mg	L01EE03	binimetinib	0,09	g	O	1,26	Tablett	OK	
31172	Kesimpta inj 20mg/penn	0,4	MLPEN	20mg/penn	L04AA52	ofatumumab					Injeksjonsvæs	NOK	Changed to ATC 5. level code/substance name
188556	Zoledronsyre sun inf 5mg/100ml	100	MLHGL	5mg/100ml	M05BA08	zoledronic acid	4	mg	P	5	Infusjonsvæsk	OK	
523148	Levopidon miks 5mg/10ml endos	7x10	ML	5mg/10ml	N07BC05	levomethadone	0,015	g	O	0,035	Mikstur	OK	
553488	Fampridine accord depotab 10mg	28x1	ENDOS	10mg	N07XX07	fampridine	0,02	g	O	0,28	Depottablett	OK	

1: Medicinal Product Pack Identifier, 2: Unit of Measurement, 3: Route of Administration, 4: Content of active substance with same unit of measurement as for DDD

ATC – simplification

Facilitating retrieval of medicines

ATC together with DDD

DDD unit of measurement

Unit (U), abbreviations		
g	=	gram
mg	=	milligram
mcg	=	microgram
U	=	unit
TU	=	thousand units
MU	=	million units
mmol	=	millimole
ml	=	milliliter (e.g. eyedrops)

DDD route of administration

Route of administration (Adm.R), abbreviations		
Implant	=	implant
Inhal	=	inhalation
Instill	=	instillation
N	=	nasal
O	=	oral
P	=	parenteral
R	=	rectal
SL	=	sublingual/buccal/oromucosal
TD	=	transdermal
V	=	vaginal

ATC/DDD Index 2022

A searchable version of the complete ATC index with DDDs is available below. The search options enable you to find ATC codes and DDDs for substance name and/or ATC levels. In your search result you may choose to show or hide the text from the Guidelines for ATC classification and DDD assignment linked to the ATC level. The text in the Guidelines will give information related to the background for the ATC and DDD assignment.

Search query

ATC code or name Search

containing query

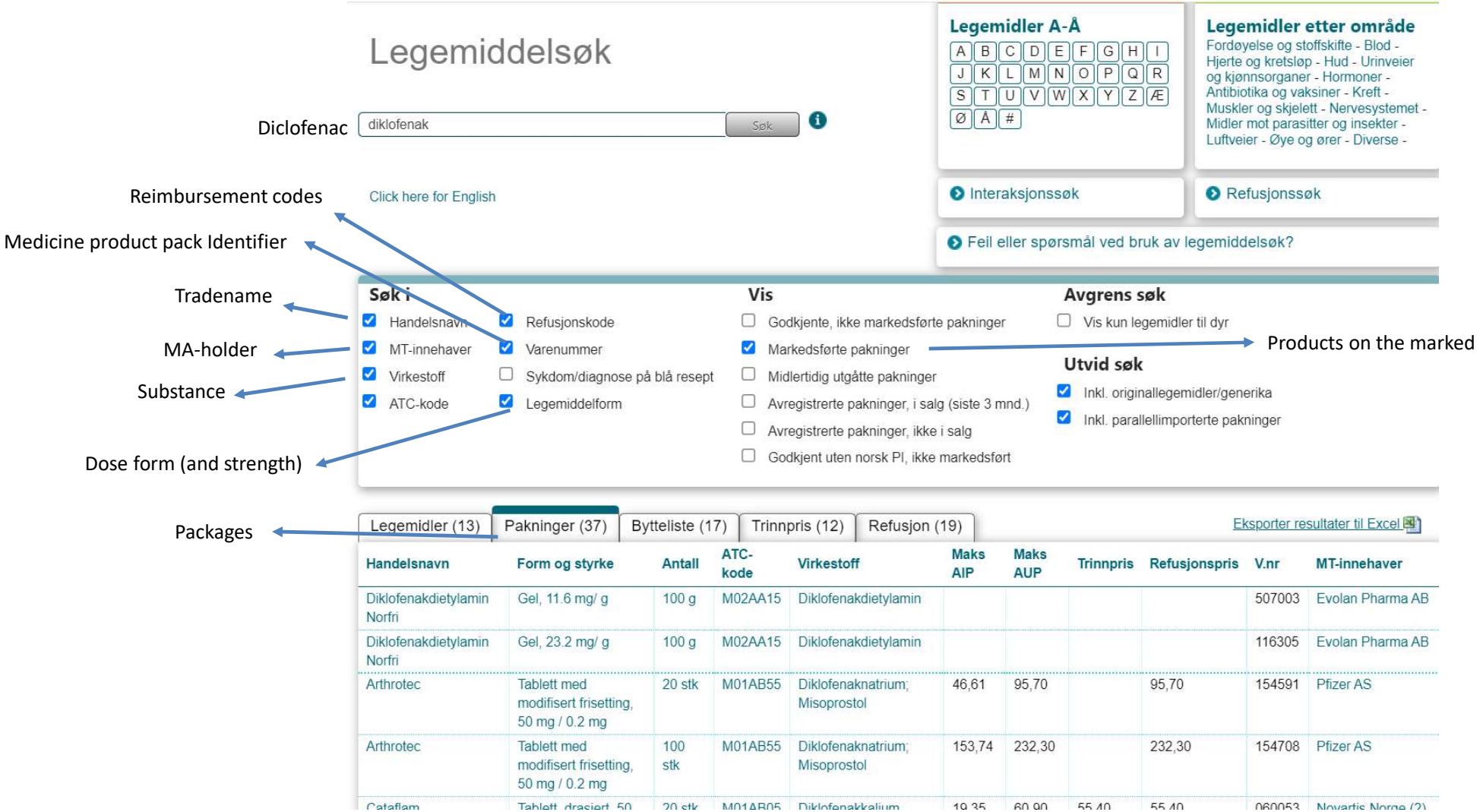
6 ATC 5th levels in 3 different ATC 1st levels

1	D11AX18	diclofenac
2	M01AB05	diclofenac
	M01AB05	diclofenac
	M01AB05	diclofenac
3	M02AA15	diclofenac
4	S01BC03	diclofenac
5	S01CC01	diclofenac and antiinfectives
6	M01AB55	diclofenac, combinations

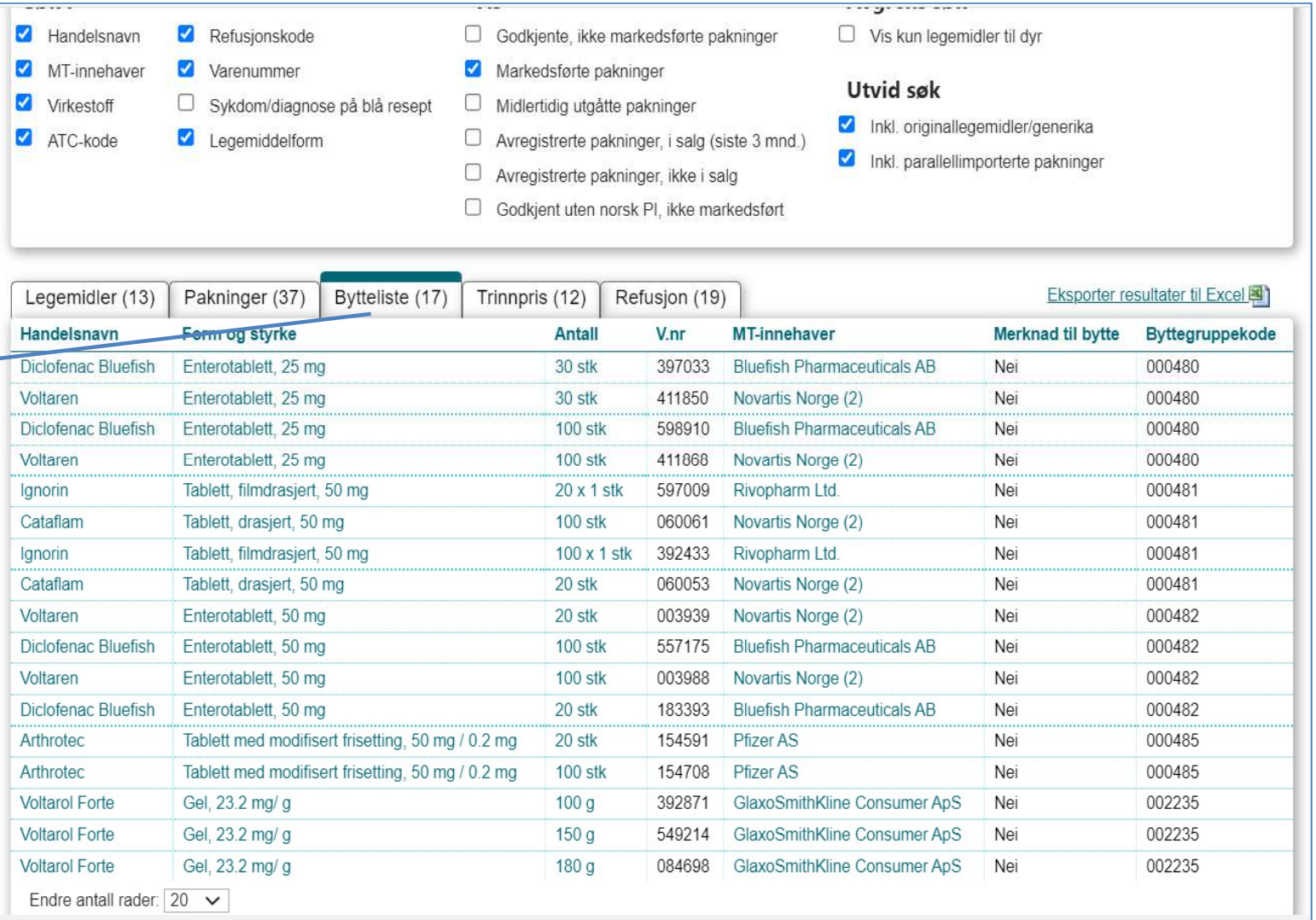
31 ATC 5th levels in one ATC 1st levels

C09XA53	aliskiren and amlodipine
C09XA54	aliskiren, amlodipine and hydrochlorothiazide
C08CA01	amlodipine
C08CA51	amlodipine and celecoxib
C08GA02	amlodipine and diuretics
C10BX03	atorvastatin and amlodipine
C10BX11	atorvastatin, amlodipine and perindopril
C10BX18	atorvastatin, amlodipine and ramipril
C07FB07	bisoprolol and amlodipine
C09DB07	candesartan and amlodipine
C09DX06	candesartan, amlodipine and hydrochlorothiazide
C09DB09	fimasartan and amlodipine
C09DB05	irbesartan and amlodipine
C09DX07	irbesartan, amlodipine and hydrochlorothiazide
C08CA17	levamlodipine
C09BB03	lisinopril and amlodipine
C09DB06	losartan and amlodipine
C07FB13	metoprolol and amlodipine
C07FB12	nebivolol and amlodipine
C09DB02	olmesartan medoxomil and amlodipine
C09DX03	olmesartan medoxomil, amlodipine and hydrochlorothiazid
C09BB04	perindopril and amlodipine
C09BX01	perindopril, amlodipine and indapamide
C09BX04	perindopril, bisoprolol and amlodipine
C09BB07	ramipril and amlodipine
C09BX03	ramipril, amlodipine and hydrochlorothiazide
C10BX09	rosuvastatin and amlodipine
C10BX07	rosuvastatin, amlodipine and lisinopril
C10BX14	rosuvastatin, amlodipine and perindopril

Medicine search at the Norwegian Medicines Agency (https://www.legemiddelsok.no)



Exchangeable packages (generic substitution) for doctors and pharmacies



- [x] Handelsnavn
- [x] MT-innehaver
- [x] Virkestoff
- [x] ATC-kode
- [x] Refusjonskode
- [x] Varenummer
- [ ] Sykdom/diagnose på blå resept
- [x] Legemiddelform
- [ ] Godkjente, ikke markedsførte pakninger
- [x] Markedsførte pakninger
- [ ] Midlertidig utgåtte pakninger
- [ ] Avregistrerte pakninger, i salg (siste 3 mnd.)
- [ ] Avregistrerte pakninger, ikke i salg
- [ ] Godkjent uten norsk PI, ikke markedsført
- [ ] Vis kun legemidler til dyr

Utvid søk

- [x] Inkl. originallegemidler/generika
- [x] Inkl. parallellimporterte pakninger

Legemidler (13) | Pakninger (37) | Bytteliste (17) | Trinnpris (12) | Refusjon (19)

Eksporter resultater til Excel

Handelsnavn	Form og styrke	Antall	V.nr	MT-innehaver	Merknad til bytte	Byttegruppekode
Diclofenac Bluefish	Enterotablett, 25 mg	30 stk	397033	Bluefish Pharmaceuticals AB	Nei	000480
Voltaren	Enterotablett, 25 mg	30 stk	411850	Novartis Norge (2)	Nei	000480
Diclofenac Bluefish	Enterotablett, 25 mg	100 stk	598910	Bluefish Pharmaceuticals AB	Nei	000480
Voltaren	Enterotablett, 25 mg	100 stk	411868	Novartis Norge (2)	Nei	000480
Ignorin	Tablett, filmdrasjert, 50 mg	20 x 1 stk	597009	Rivopharm Ltd.	Nei	000481
Cataflam	Tablett, drasjert, 50 mg	100 stk	060061	Novartis Norge (2)	Nei	000481
Ignorin	Tablett, filmdrasjert, 50 mg	100 x 1 stk	392433	Rivopharm Ltd.	Nei	000481
Cataflam	Tablett, drasjert, 50 mg	20 stk	060053	Novartis Norge (2)	Nei	000481
Voltaren	Enterotablett, 50 mg	20 stk	003939	Novartis Norge (2)	Nei	000482
Diclofenac Bluefish	Enterotablett, 50 mg	100 stk	557175	Bluefish Pharmaceuticals AB	Nei	000482
Voltaren	Enterotablett, 50 mg	100 stk	003988	Novartis Norge (2)	Nei	000482
Diclofenac Bluefish	Enterotablett, 50 mg	20 stk	183393	Bluefish Pharmaceuticals AB	Nei	000482
Arthrotec	Tablett med modifisert frisetting, 50 mg / 0.2 mg	20 stk	154591	Pfizer AS	Nei	000485
Arthrotec	Tablett med modifisert frisetting, 50 mg / 0.2 mg	100 stk	154708	Pfizer AS	Nei	000485
Voltarol Forte	Gel, 23.2 mg/ g	100 g	392871	GlaxoSmithKline Consumer ApS	Nei	002235
Voltarol Forte	Gel, 23.2 mg/ g	150 g	549214	GlaxoSmithKline Consumer ApS	Nei	002235
Voltarol Forte	Gel, 23.2 mg/ g	180 g	084698	GlaxoSmithKline Consumer ApS	Nei	002235

Endre antall rader: 20

Challenges - ATC/DDD

- Combinations, especially «old» and «national» (e.g. cough and cold preparations, vitamins and minerals)?
  - Latest 10 to 15 years – all substances listed, less of a challenge.

- Assigning ATC codes without INN or USAN

- Also challenges in the assignment of IDMPs!

ATC/DDD system alongside IDMP

- ATC/DDD system not made for the purpose of identifying medicine packages as IDMP/PhPID does
- ATC/DDD has been a cornerstone for reliable drug data for research and decision-making in Nordic countries alongside the unique medical product pack identifier (“IDMP light”).
- DDD is independent of strength, package and price. The number of DDDs in each package should be defined for those products where DDDs are assigned. This is to study and compare consumption over time in different countries.

Alignment of ATC 5th level /ROA with IDMP (PhPID level 4)

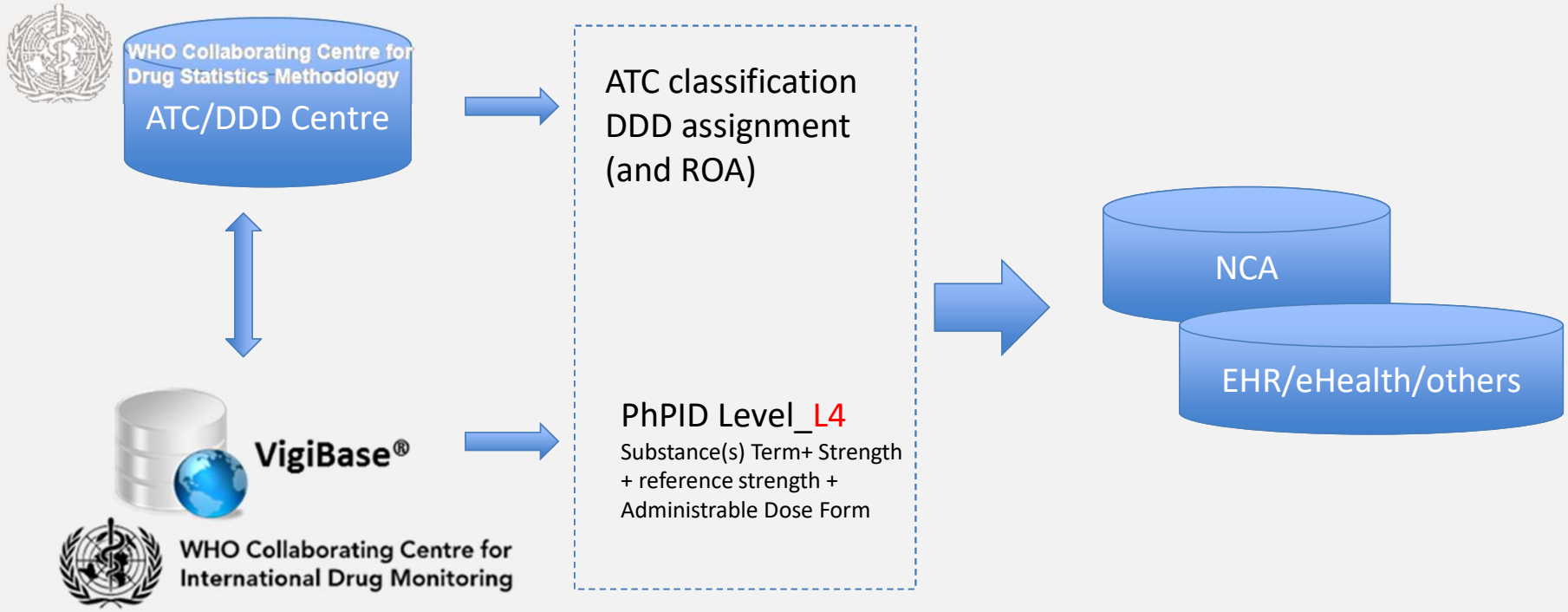
"Take home message"

ATC/DDD should be an integrated part of the long-term development of IDMPs and other e-health systems such as electronic patient journals, registries.

- ATC is available in the SPCs (Point 5.1) and in national drug databases and e-health systems
- IDMP/PhPID defines package according to 5 ISO standards in a very detailed manner
- ATC/DDD facilitates aggregation in therapeutic, pharmacological and chemical groups needed for retrieval of information and statistical purposes such as drug utilisation monitoring
- ATC/DDD for drug statistics- and consumption-purposes together with PhPID for detailed identification of pharmaceutical products will give a synergy in the field drug related e-health

Conclusion:

ATC and DDD for drug statistics- and consumption- purposes and PhPID for detailed identification of pharmaceutical products will give a synergy in the field drug related e-health



Thank you for your attention

WHO Collaborating Centre for
Drug Statistics Methodology

E-mail: whocc@fhi.no

Procedures for PhPID generation

Malin Fladvad, Uppsala Monitoring centre

Uppsala Monitoring Centre

Implementation of Global PhPID – achievements & plans

2019

UNICOM and FDA/UMC pilots for global PHPID generation

2021

WHO-UMC endorsed as future maintenance organization for Global PhPID

2021

FIRST PHASE CONCLUDED

Global vaccines initiative

2021

Formation of GIDWG Phase 1: FDA/EMA/ WHO-UMC

ONGOING

GIDWG pilots: Best practices for PhPID generation

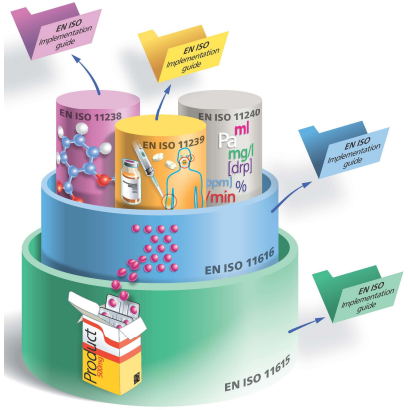
Global PHPID available for all stakeholders

Harmonisation of data using the ISO IDMP suite of standards

PhPID	Substance ID	Strength	Dose form
ISO 11616	ISO 11238	ISO 11240	ISO 11239

PhPID Set

- PhPID Level_L1 → Substance(s) Term
- PhPID Level_L2 → Substance Term(s) +Strength+ reference strength
- PhPID Level_L3 → Substance Term(s) + *Administrable Dose Form*
- PhPID Level_L4 → Substance(s) Term+ Strength + reference strength + *Administrable Dose Form*



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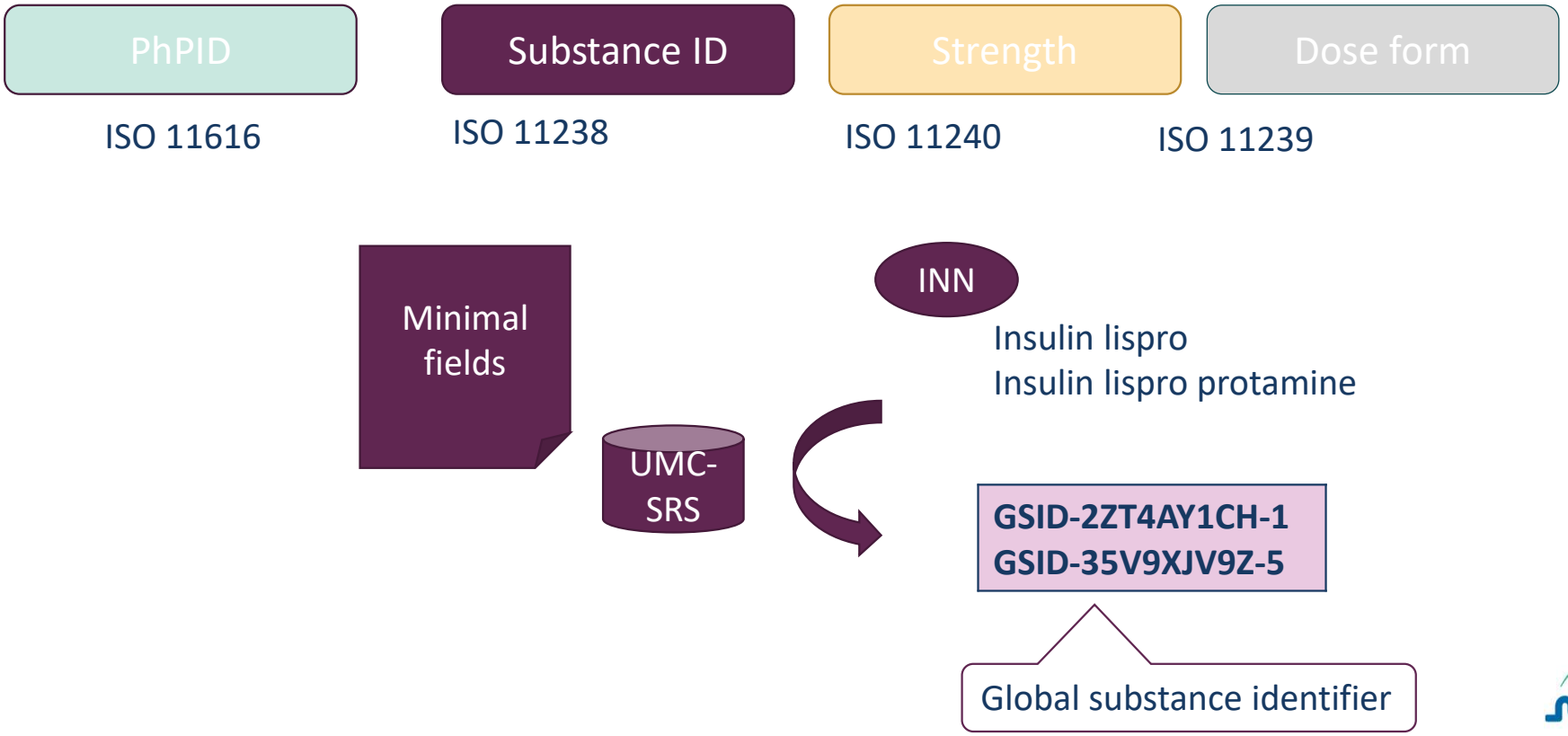
Generation of Global substance ID



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Proposed process for expression of Strength

PhPID

ISO 11616

Substance ID

ISO 11238

Strength

ISO 11240

Dose form

ISO 11239

Pattern	Type of product
A	
B	
C	
D	

Strength expression based on pattern framework

50 units/ml

50.00	37	1.00	20

Code for unit

Code for ml

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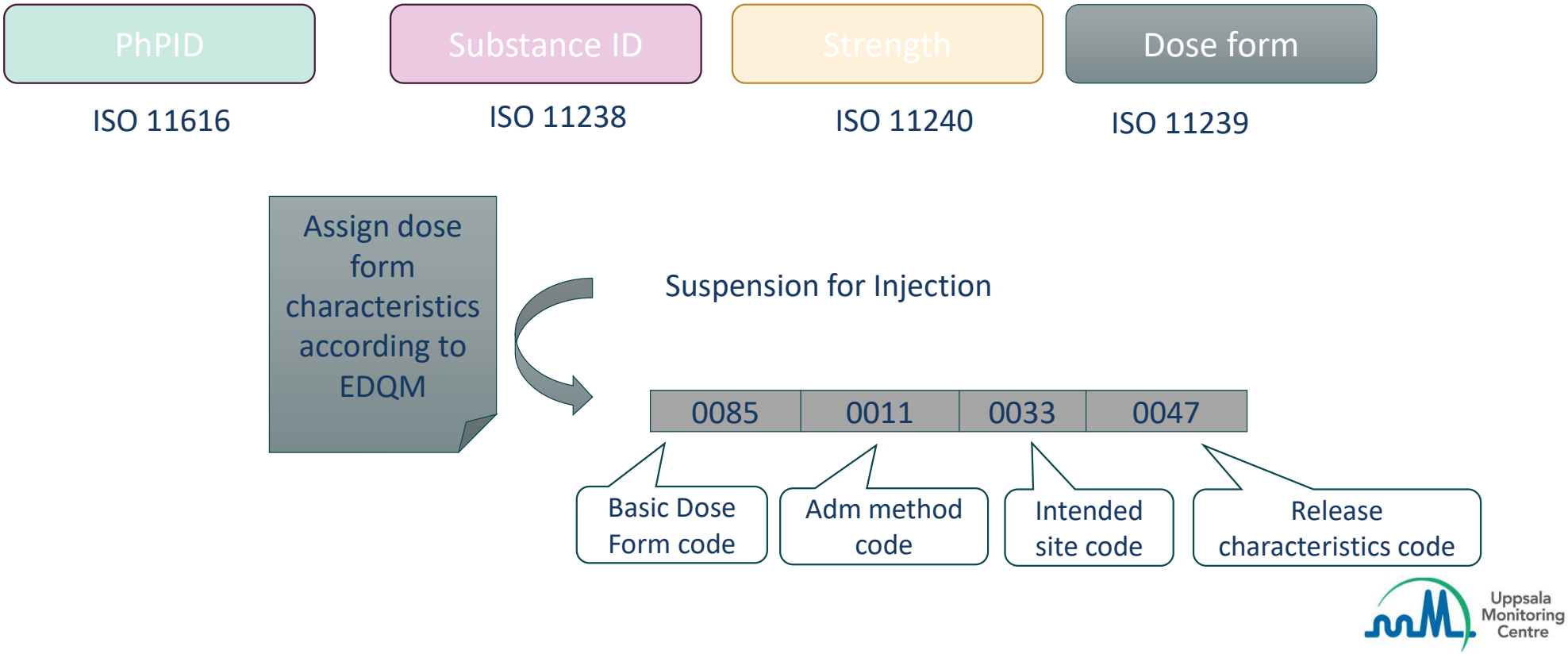
Proposed process for expression of Dose form



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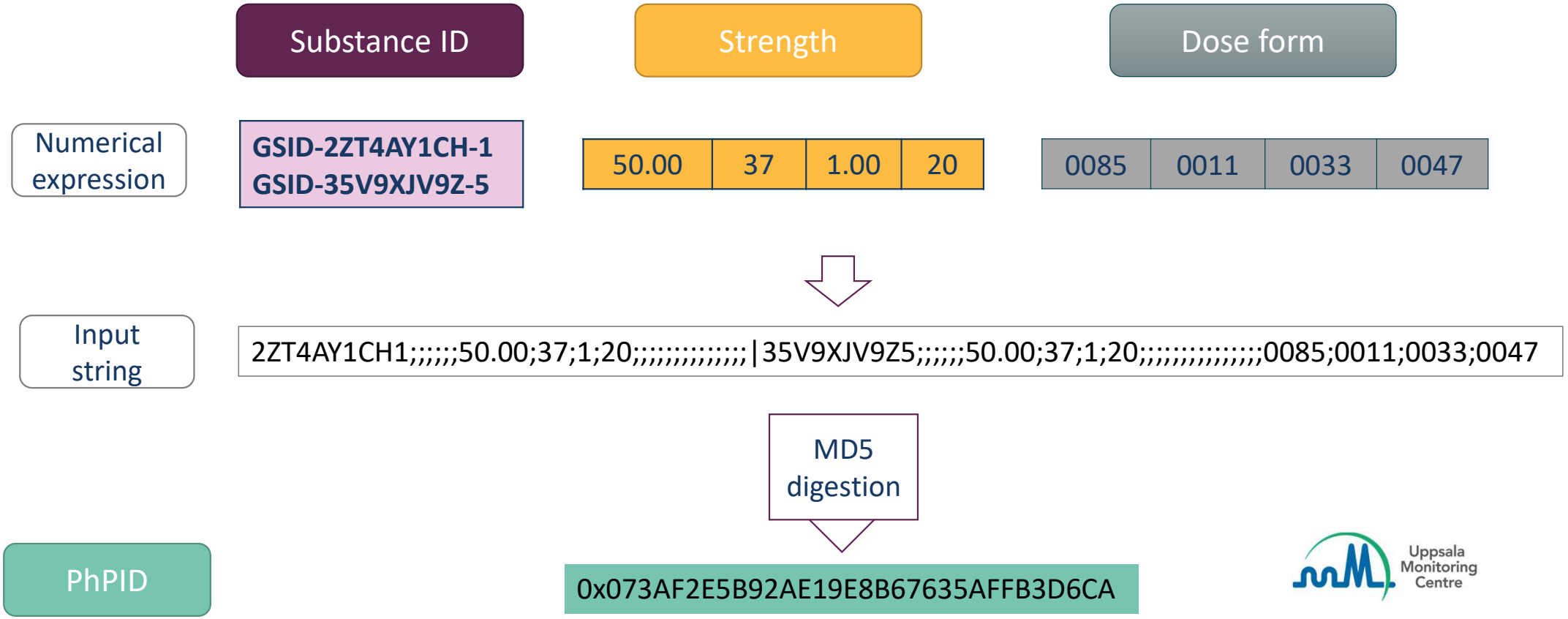
PhPID generation for Humalog Mix50 KwikPen

50 mg/ml of Insulin lispro/Insulin lispro protamine suspension, solution for injection



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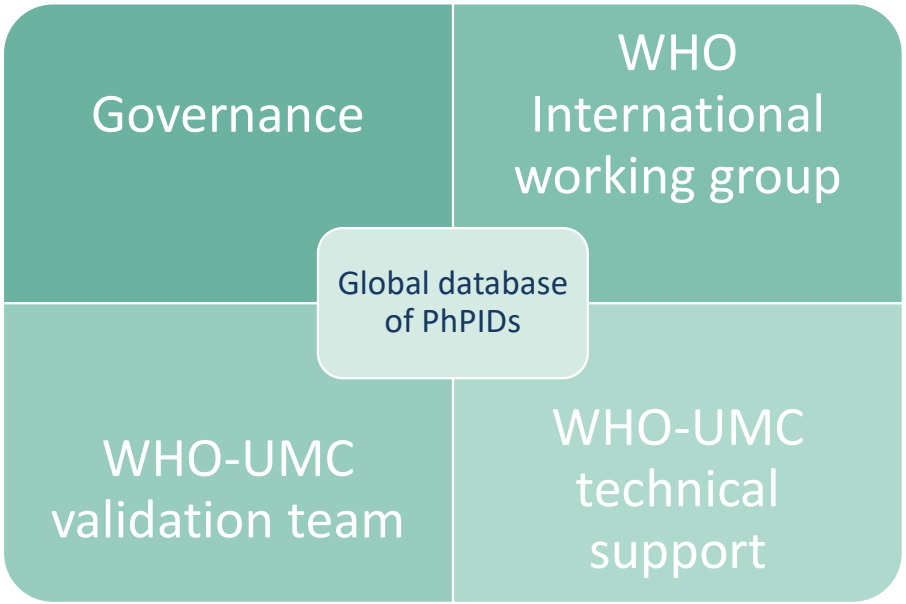
Proposed Global PhPID service responsibilities

- Setting the service offer, maintenance framework & validation process
- Regular reviews

- Validation according to agreed process
- Responding to questions and escalating issues
- Data updates including cross-references needed for pharmacovigilance



- Oversee assignments and solving issues
- Identify needs for updates of business rules
- Escalates to ISO for updates of the standard

- Ensure the availability of the service from a technical perspective
- User/API administration

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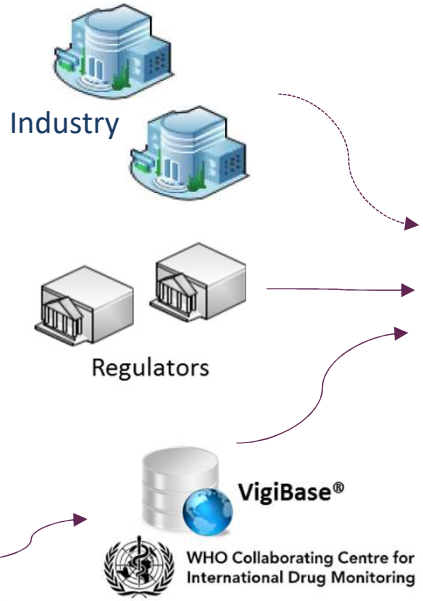
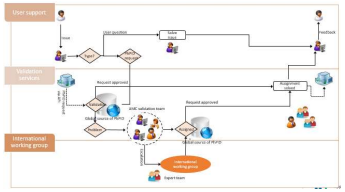
Proposed Global PHPID operations

Request | Validation | Global PHPID





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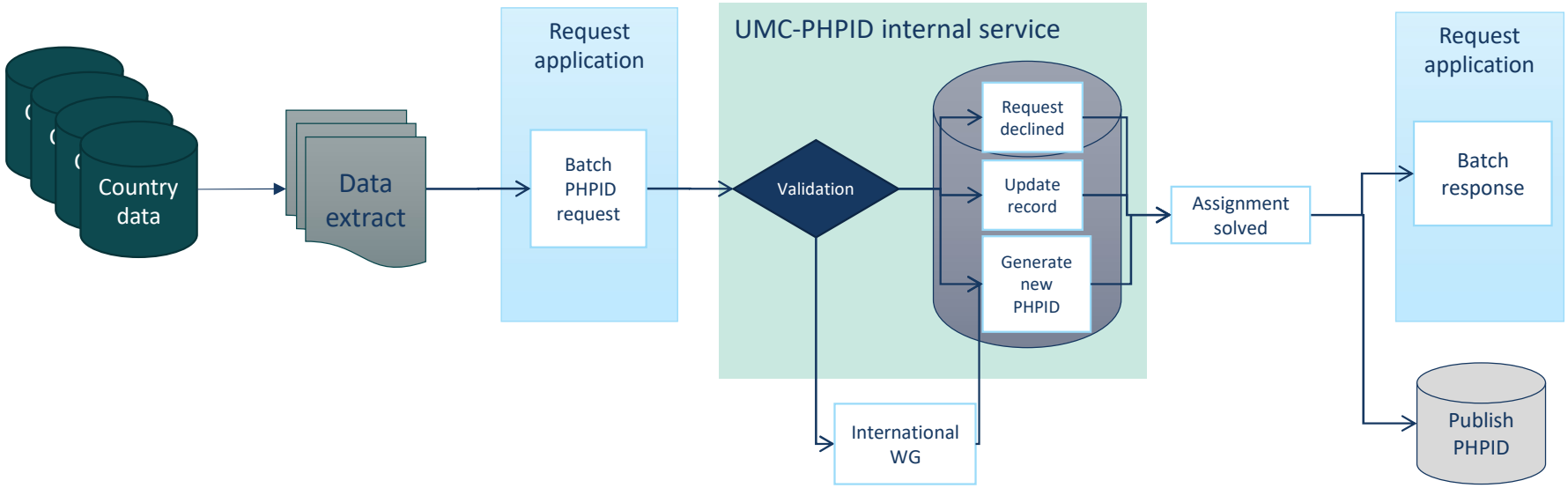
Scaling up the PhPID production

- organizing data streams of structured drug information from volunteer countries



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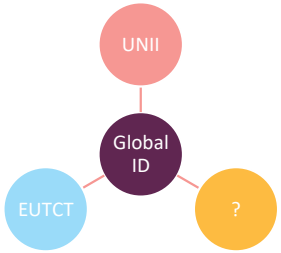
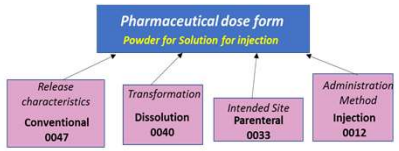
GIDWG projects to conduct in 2022

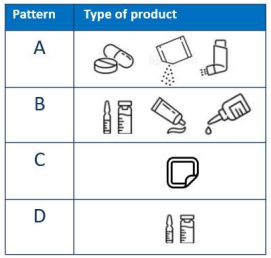
1. Global Substance ID



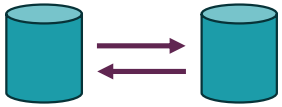
2. Global Dose Form Identifier



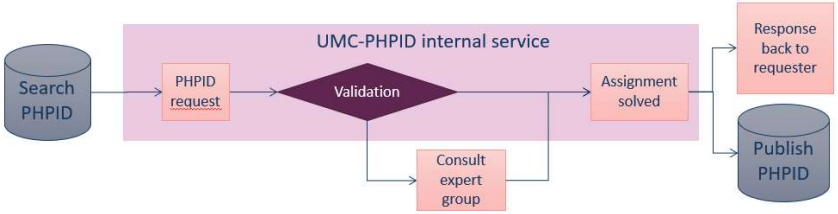
3. Strength Definitions Identifier



4. HL7 FHIR for IDMP



5. **Operating model**



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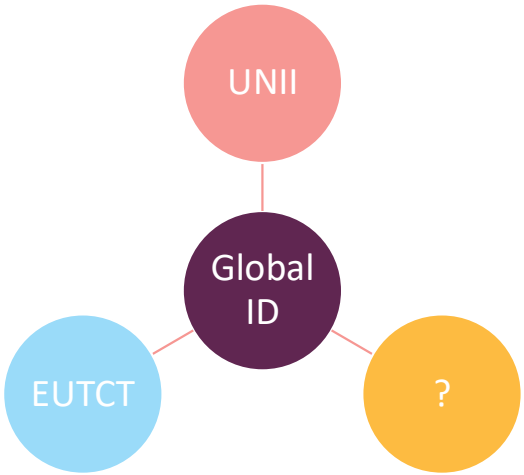
Planned Pilots to Conduct in 2022

1. Global Substance ID
   - Scope
     - Mapping EU-SRS EUTCT, FDA UNII, and one additional region (if possible) to Global identifier for a set of selected Chemicals in WHO Model List of Essential Medicines
     - Review all substance classes including more complex scenarios like certain biologics
   - Success Criteria
     - Meet requirements for unique substance identification
     - Identify and address issues and challenges
     - Identify and address regional legacy substance definition/identification
     - Propose a feasible, scalable, and most efficient operation model to maintain global substance identifiers (and definition and identification)



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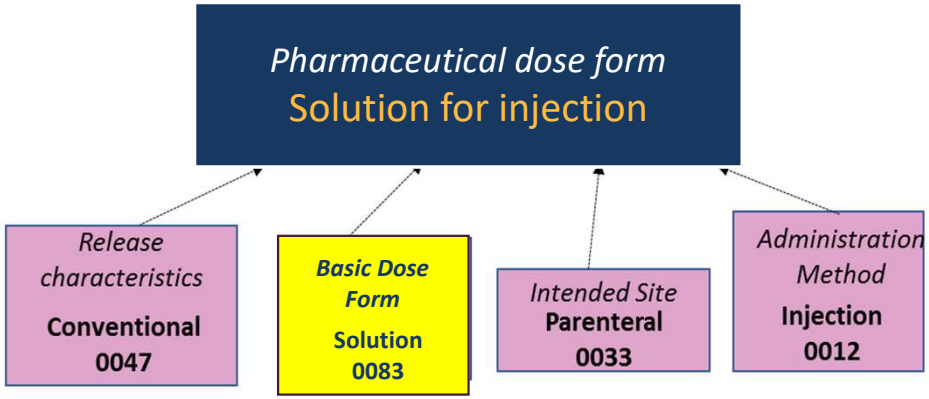
Planned Pilots to Conduct in 2022

2. Global Dose Form Identifier

- Rationale
  - To ensure consistent mapping to EDQM characteristics for products with less granular dose form expressions
- Scope
  - Map DF to another region using the DF characteristic approach
  - Further investigate DF characteristic combination and EDQM DF characteristic with multiple values
- Success Criteria
  - Identify and address issues and challenges
  - Documented rules to apply proper DF characteristics, for the generation of global PhPID, regardless regional DF variations



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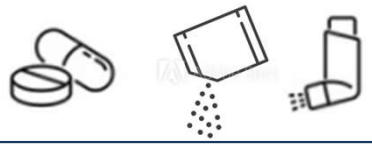
Planned Pilots to Conduct in 2022

3. Strength Definitions Identifier

- Rationale
  - To build on the FDA/ WHO-UMC pilot developed concepts the use of strength presentation versus strength concentration for different products
- Scope
  - Identify and address different representation of strength for products in different regions
  - Work with ISO, clarify the use of presentation strength and concentration strength

Pattern	Type of product
A	
B	
C	
D	

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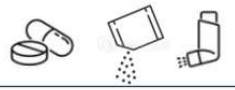
Strength considerations

All EDQM dose forms have been mapped to the suggested pattern Framework

- A,B,C patterns are well-defined
  - Range concentration to be investigated more

A number of challenges will be further identified:

- D pattern: more investigation needed
- May be a need for additional pattern(s) when strength is expressed as ´cells/´, TCMs, ´animal live´

Pattern	Type of product
A	
B	
C	
D	
TBC	

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Planned Pilots to Conduct in 2022

4. HL7 FHIR for IDMP

- Scope
  - Participate in the development, verification, and ballot of HL7 FHIR resources related to IDMP
- Success Criteria
  - Successful exchange of medicinal product and substance information between EU-SRS/SMS, FDA-SRS and UMC-SRS using HL7 FHIR as the underlining message technology for ISO IDMP standards
  - Demonstrate in HL7 FHIR connectathons and other stakeholder events
- Dependencies
  - ISO 11615 and ISO/TS 20443
  - ISO 11238 and ISO/TS 19844

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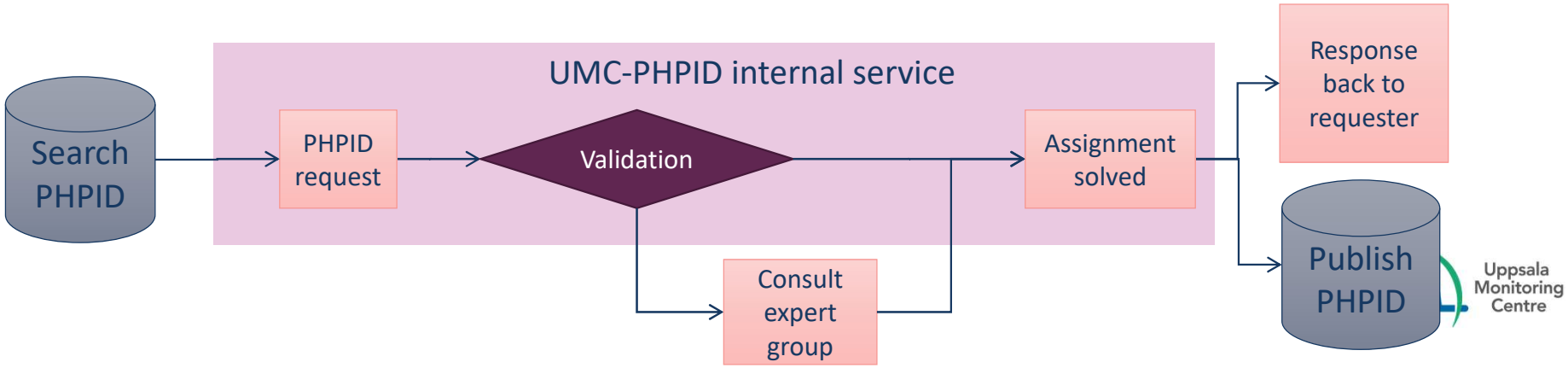
Planned Pilots to Conduct in 2022

5. Operating model

- Scope
  - Demonstration of the consensus-based operating model for WHO-UMC as the international maintenance organization as an end-to-end pilot
- Success Criteria
  - Successful process from request to publication of global PhPID for a set of selected cases



Questions in the Q & A facility, please

For feedback, please go to : https://forms.gle/YAq3XqvGodyNDw2p9

Thanks for your time

UNICOM

Questions, comments

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