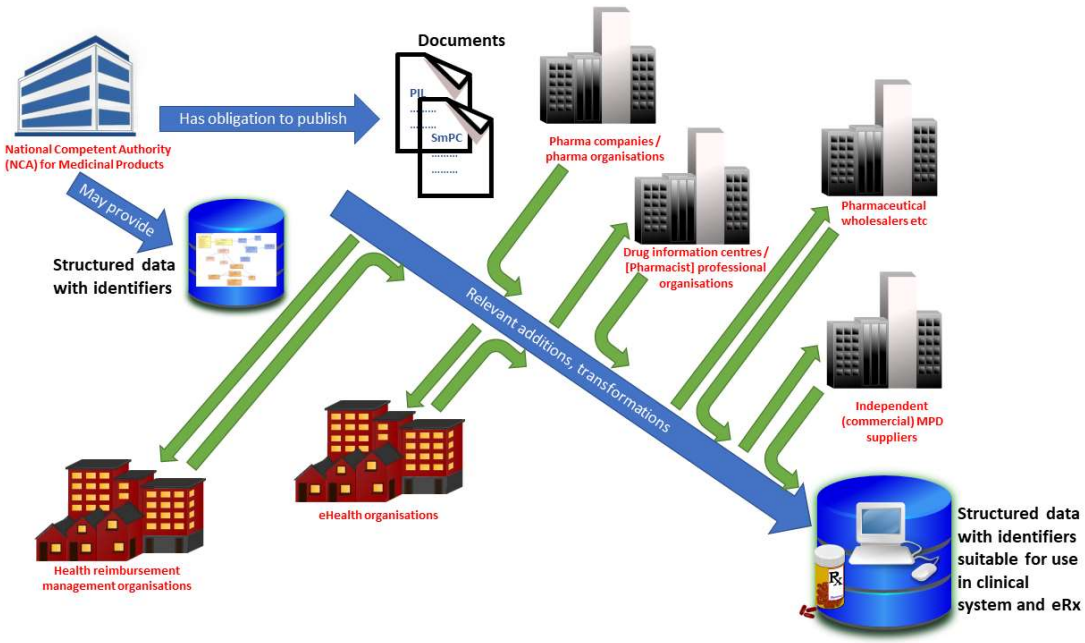
The UNICOM Project Pilot Product List

Presentation to the HL7 BR&R Workgroup
January (Virtual) WGM 2021

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

Introducing UNICOM



UNICOM is a European Commission supported Innovation Action that focuses on improving patient safety and healthcare by facilitating the flow of standardised "trusted data" about medicines from our regulatory agencies through to clinicians' desktops and to patients via apps etc.

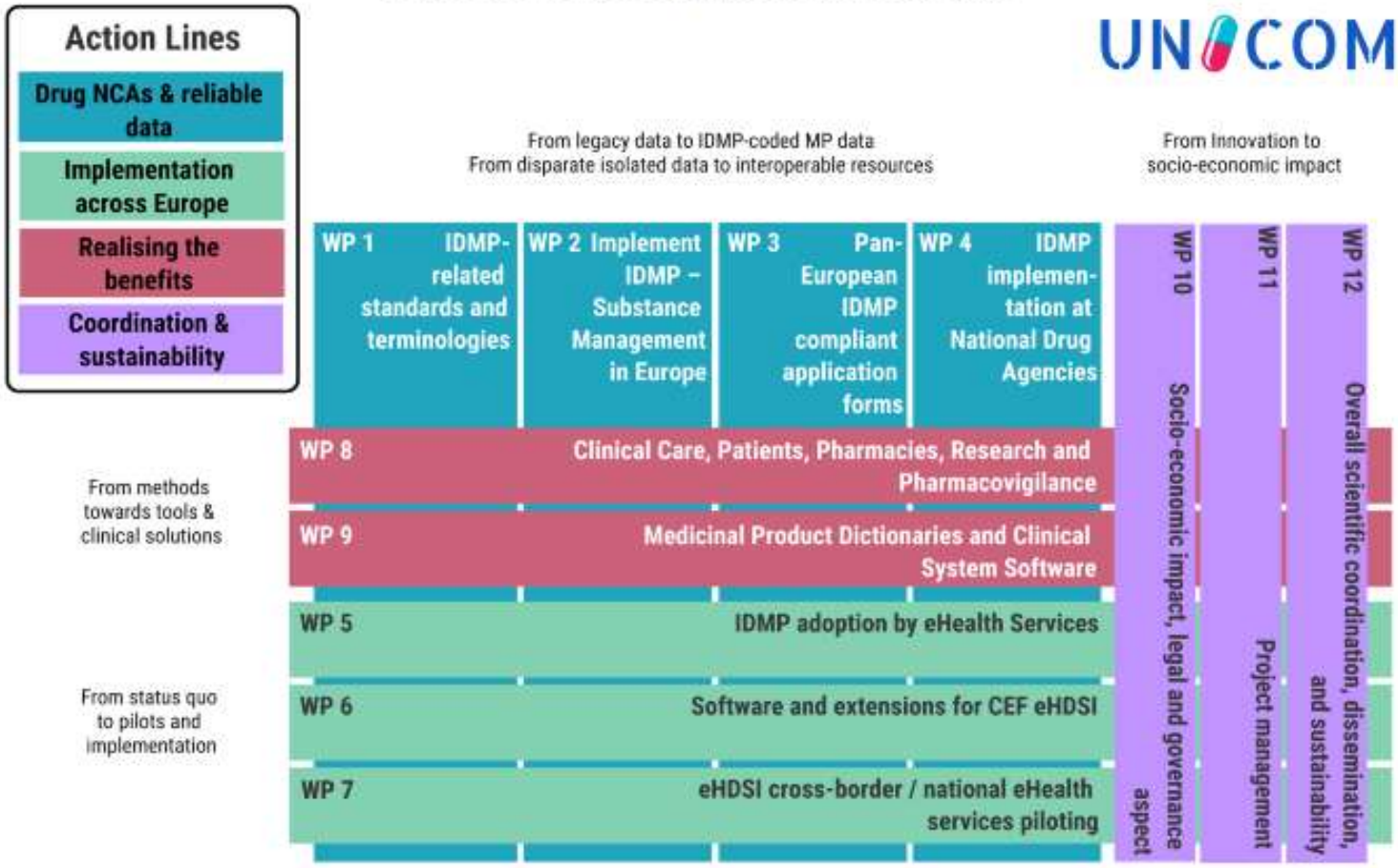
It does this by focusing on the implementation International Organization for Standardization (ISO) suite of IDMP (Identification of Medicinal Products) standards in national competent authorities and then use of that data in patient care.

Find us at https://unicom-project.eu/

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

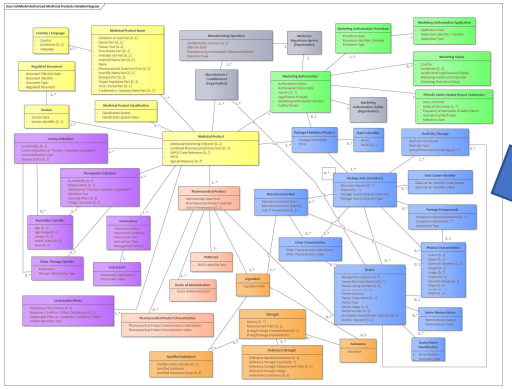
The UNICOM Project Organisation

Figure 11: Overall organisation and work plan



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

The Pilot Product List: Examples….making things “real”



1. NAME OF THE MEDICINAL PRODUCT

Bortezomib Hospira 1 mg powder for solution for injection
Bortezomib Hospira 2.5 mg powder for solution for injection
Bortezomib Hospira 3 mg powder for solution for injection
Bortezomib Hospira 3.5 mg powder for solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Bortezomib Hospira 1 mg powder for solution for injection

Each vial contains 1 mg bortezomib (as a mannitol boronic ester).

Bortezomib Hospira 2.5 mg powder for solution for injection

Each vial contains 2.5 mg bortezomib (as a mannitol boronic ester).

Bortezomib Hospira 3 mg powder for solution for injection

Each vial contains 3 mg bortezomib (as a mannitol boronic ester).

Bortezomib Hospira 3.5 mg powder for solution for injection

Each vial contains 3.5 mg bortezomib (as a mannitol boronic ester).

After reconstitution, 1 ml of solution for subcutaneous injection contains 2.5 mg bortezomib.

After reconstitution, 1 ml of solution for intravenous injection contains 1 mg bortezomib.

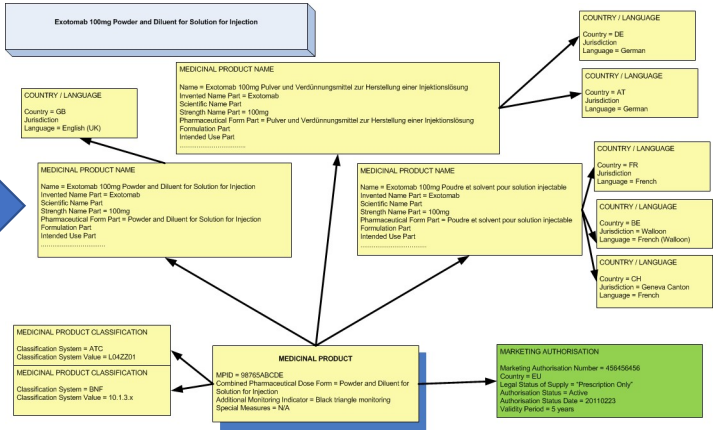
For the full list of excipients, see section 6.1.

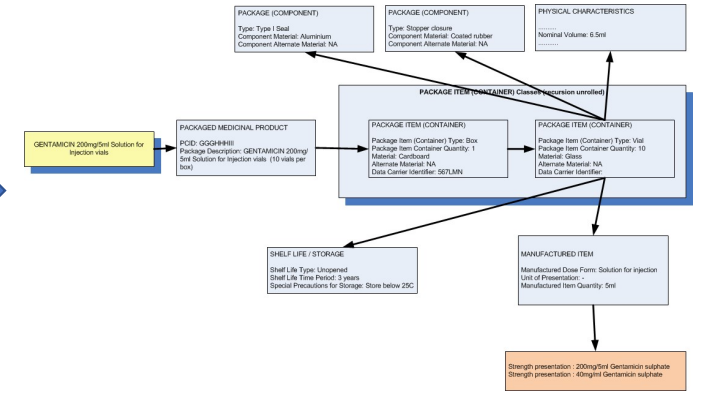
3. PHARMACEUTICAL FORM

Powder for solution for injection.

White to off-white cake or powder.

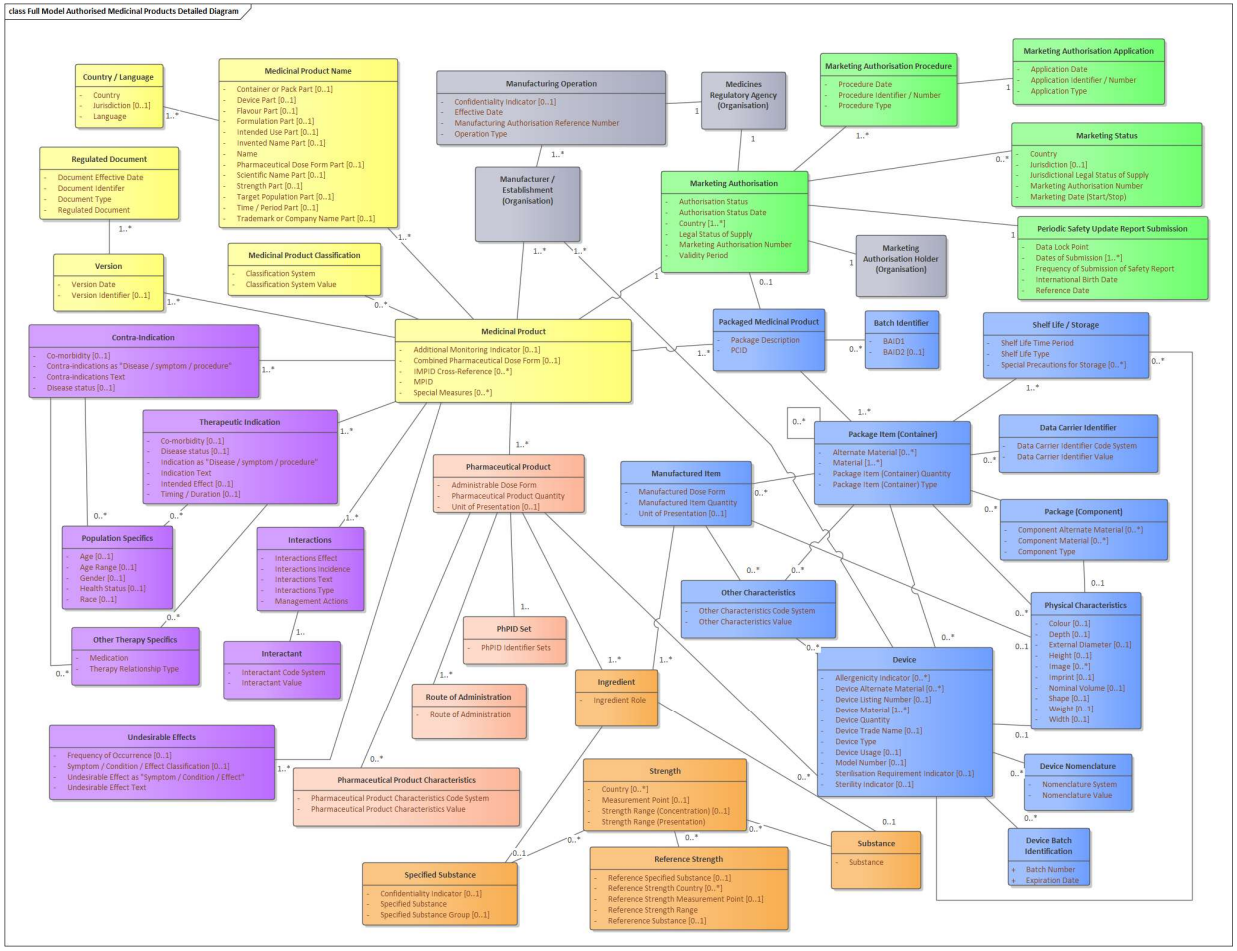
4. CLINICAL PARTICULARS





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

The full IDMP model is quite complex, and goes a long way beyond data needed just for “product identification”



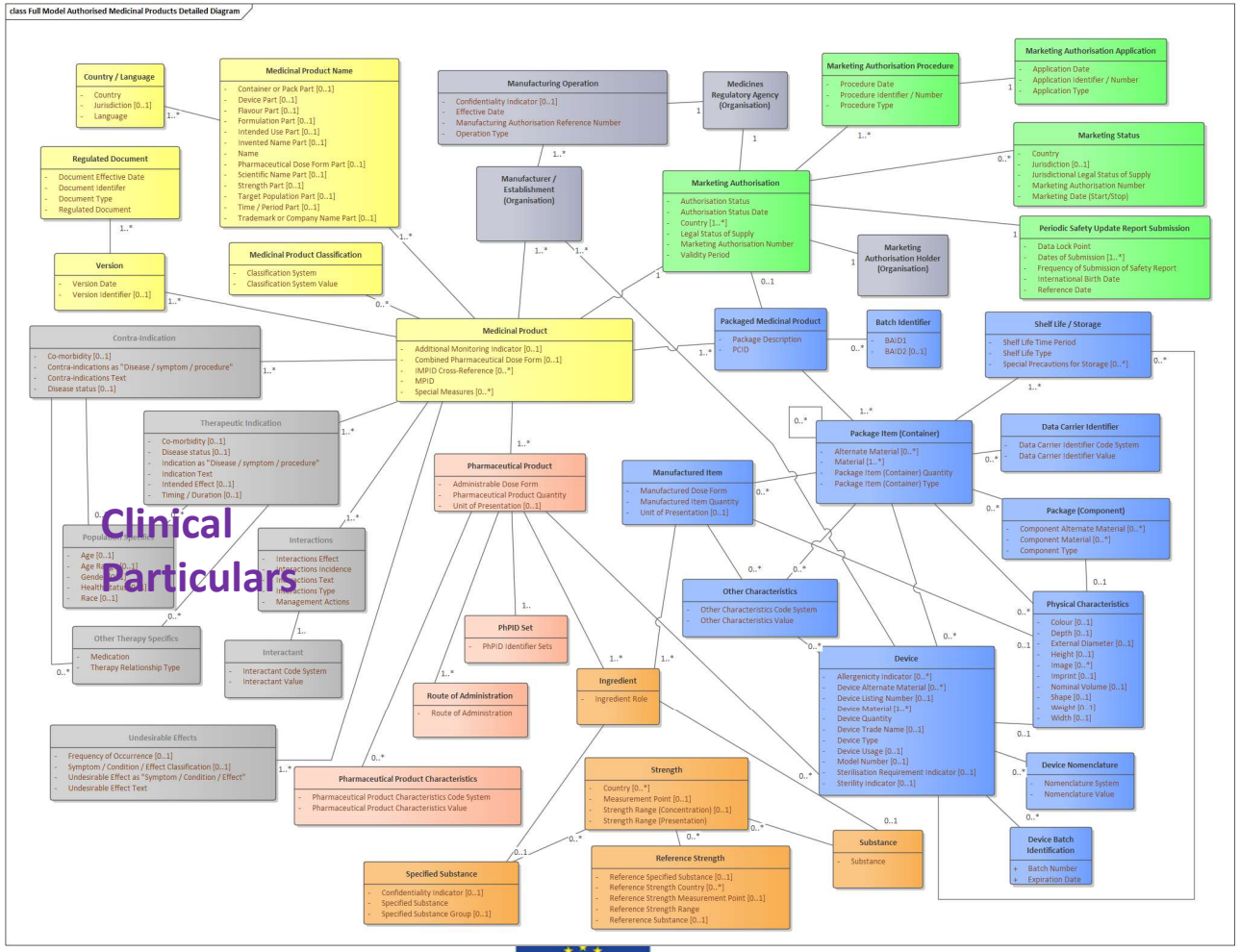
- In the full model, there are 43 classes and a couple of hundred “attributes”
- Some classes and attributes are “reused” in more than one context (e.g. “Ingredient” and all the classes linked below it). This would be elucidated more clearly in a “logical model”
- Several types of attribute have multiple parts (for example, a strength has 4 parts – numerator value + units and denominator value + units)

*We (thankfully) do not need all of these for “**product identification**”*

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

IDMP product identification data for the UNICOM pilot

So, based on our analysis of what we know MPD currently use for “product identification”, there are parts we can put aside ….. Such as the **Clinical Particulars**, which probably won’t be present early on anyway



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

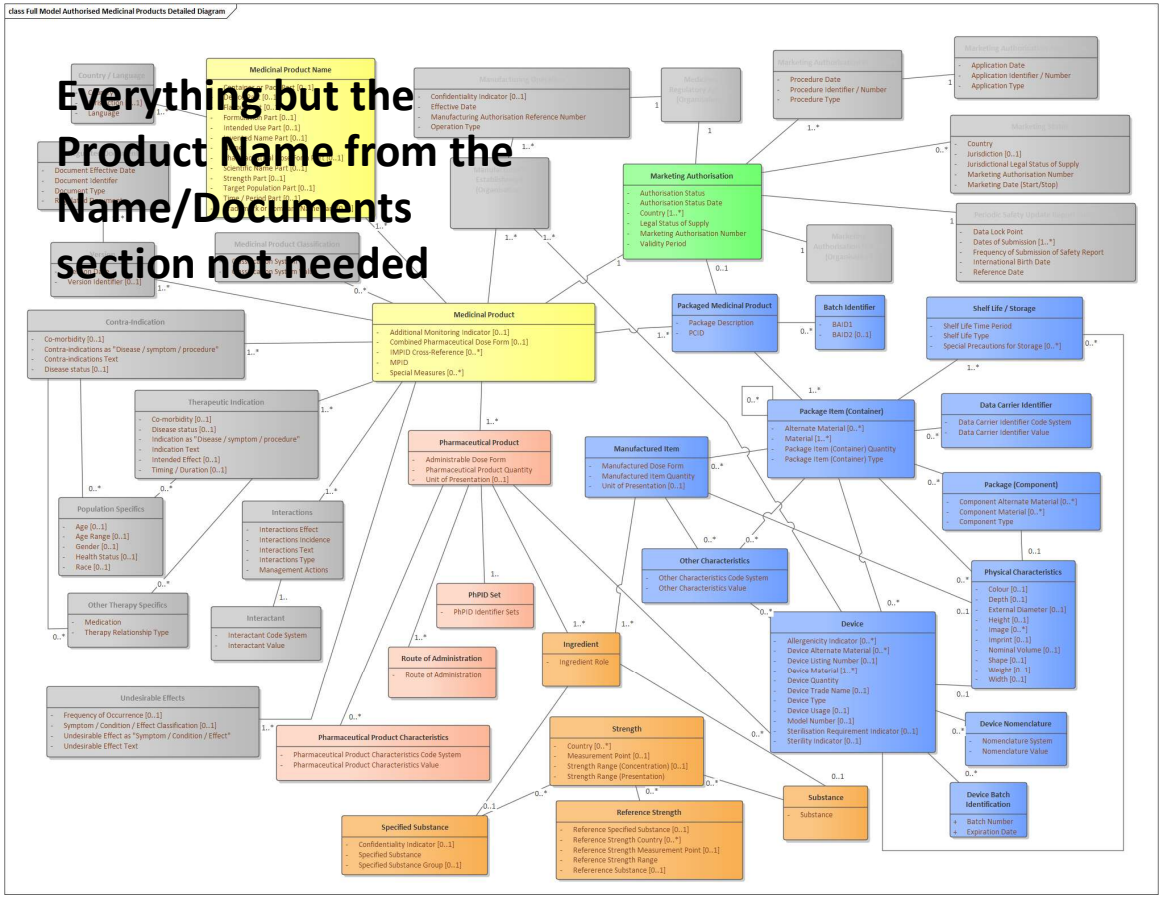
IDMP product identification data for the UNICOM pilot

We can put aside **most of the regulatory process information**…although the information in the **Marketing Authorisation class** and **the MAH name** is needed… but at least that is really just one class + the MAH name

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

IDMP product identification data for the UNICOM pilot

We can put aside **most of the regulatory document information**…keeping, of course the **Medicinal Product and Medicinal Product Name**



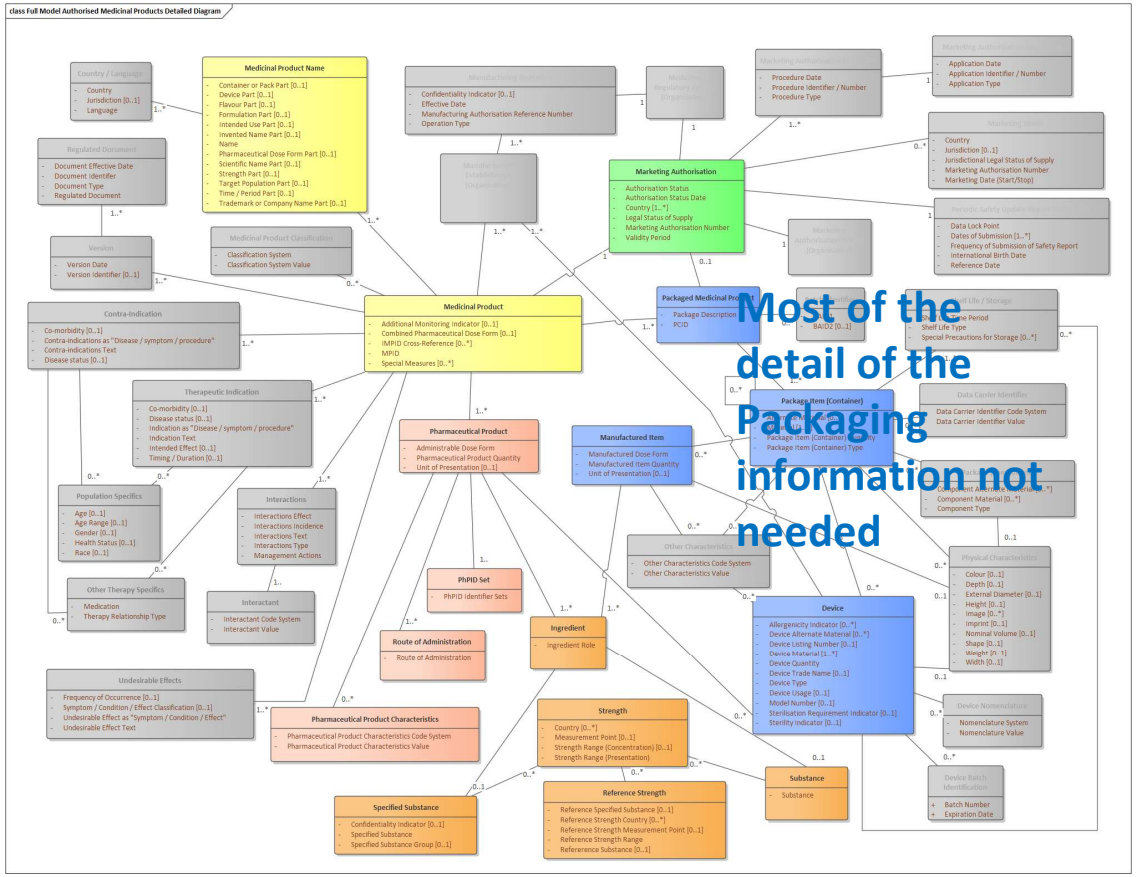
26.01.2021

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

IDMP product identification data for the UNICOM pilot

Little of the detail of the **Packaging** section is needed; maybe just one or two attributes from the Device class might be useful for some products, but not a priority for the UNICOM pilot; but the **PCID, Package Item (Container) and Manufactured Item are necessary**

The **Ingredient** information supporting both the **Manufactured Item** **AND** the **Pharmaceutical Product** is needed



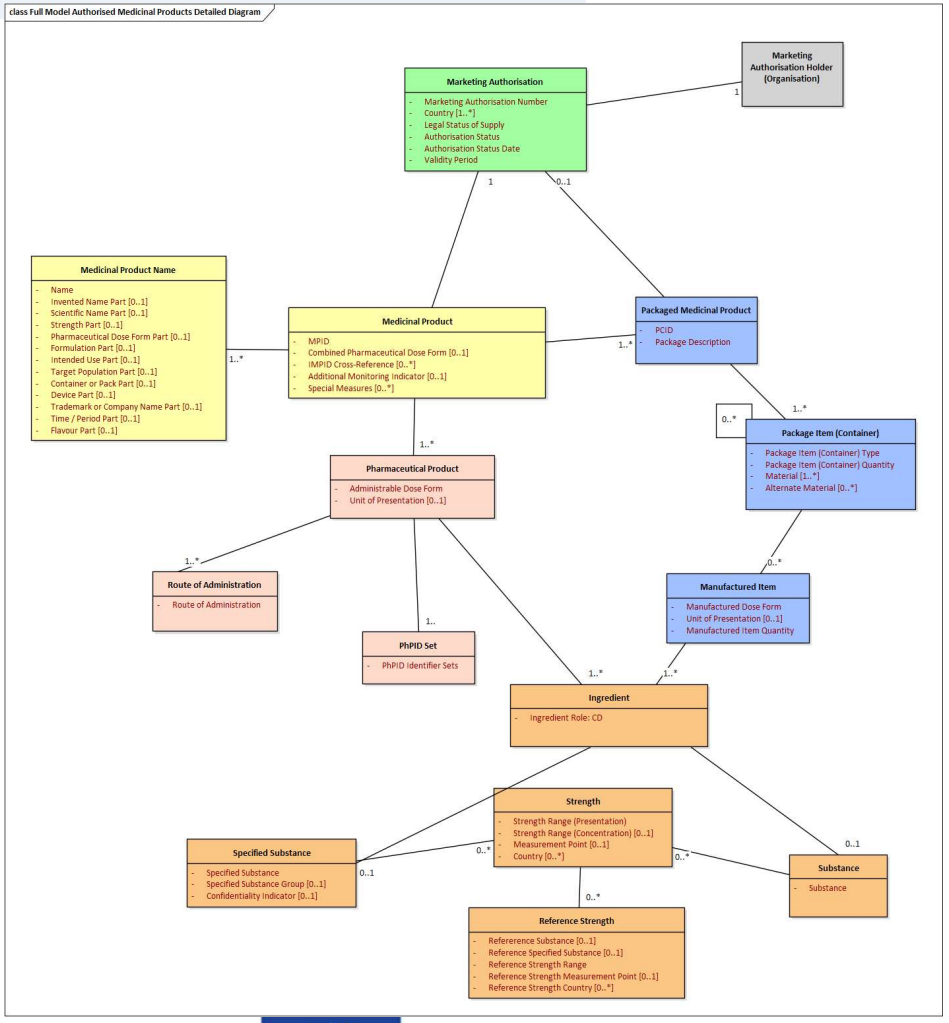
Most of the detail of the Packaging information not needed

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

IDMP product identification data for the UNICOM pilot

This leaves us with something much, much simpler to concentrate on for UNICOM for “product identification”
These are the data elements that we can populate for the PPL

For the Ingredient Role we are only interested in **ACTIVE substances**
And if we decide we do not need to include Specified Substances for the PPL, this will be even more manageable



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

So, what have we done and what are we doing

- Which substances?
- Which data elements?

- Which patterns?
  - At the logical level
  - At the implementation level

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

Substances in the PPL

- Identifying (therapeutically active) substances is one of the cornerstones of identifying medicinal products
- The “list” has been chosen on the basis of
  - The principles of ISO 11238
  - Substances that are very commonly used in patient care (e.g. a statin)
  - Substances that experience has shown are “challenging” (e.g. substances available with a variety modified release dose forms (e.g. an opioid), substances modifications that affect potency – a corticosteroid)
  - Substances that will provide a range of products for the PPL
- Provides identifiers from EU-SRS, EU-TCT, SNOMED CT, UNII, CAS
- Substances have been “cleaned” by the WP2 Substances experts in UNICOM/EU
- Will be worked on in three “batches”

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

Substance list….

UNICOM PILOT PRO Batch1 substances (all derivates and combinations)
version 2.0 BoSS = Basis of Strength Substance
May 5, 2020 PAI = Precise ingredient substance

	Moiety	Salt/ester/modification (and notes, synonyms)	UNII	CAS	SNOMED CT	Product Notes
1	simvastatin		AGG2FN16EV	79902-63-9	387584000 | Simvastatin (substance) |	All MPs use moiety as BoSS and PAI
2	enalapril		69PN84IO1A	75847-73-3	372658000 | Enalapril (substance) |	MPs may use either as PAI - BoSS is usually the maleate - is an odd one!
		enalapril sodium	94A7UFL2SI	149404-21-7	not present	Some authorities do not consider enalaprilat related substance but completely separate
		enalapril maleate	9O25354EPJ	76095-16-4	387165009 | Enalapril maleate (substance) |	
		enalaprilat	GV0O7ES0R3	84680-54-6	48052001 | Enalaprilat (substance) |	
3	omeprazole		KG60484QX9	73590-58-6	387137007 | Omeprazole (substance) |	
		omeprazole sodium	KV03YZ6QLW	95510-70-6	441570004 | Omeprazole sodium (substance) |	
		omeprazole magnesium	426QFE7XLK	95382-33-5	384973006 | Omeprazole magnesium (substance) |	MPs may use either as PAI - BoSS is the moiety
4	diclofenac		144O8QL0L1	15307-86-5	7034005 | Diclofenac (substance) |	
		diclofenac sodium	QTG126297Q	15307-79-6	62039007 | Diclofenac sodium (substance) |	
		diclofenac potassium	L4D5UA6CB4	15307-81-0	108515008 | Diclofenac potassium (substance) |	
		diclofenac diethylamine (synonym: diclofenac diethylammor	6TGQ35Z71K	78213-16-8	426714006 | Diclofenac diethylammonium (substance) |	
		diclofenac epolamine	X5F8EKL9ZG	119623-66-4	425650004 | Diclofenac epolamine (substance) |	MPs usually use modifier as BoSS
5	cefuroxime		O1R9FJ93ED	55268-75-2	372833007 | Cefuroxime (substance) |	
		cefuroxime sodium	R8A7M9MY61	56238-63-2	48753004 | Cefuroxime sodium (substance) |	
		cefuroxime axetil	Z49QDT0J8Z	64544-07-6	89678001 | Cefuroxime axetil (substance) |	MPs use modifier as PAI and moiety as BoSS
6	salbutamol		QF8SVZ843E	18559-94-9	372897005 | Salbutamol (substance) |	
		salbutamol sulfate	021SEF3731	51022-70-9	48474002 | Salbutamol sulfate (substance) |	MPs use modifier as PAI and moiety as BoSS
7	amoxicill	amoxicillin (anhydrous, explicitly)	9EM05410Q9	26787-78-0	785686003 | Amoxicillin anhydrous (substance) |	
		amoxicillin (unspecified)	not present	not present	372687004 | Amoxicillin (substance) |	
		clavulanic acid	23521W1S24	58001-44-8	395939008 | Clavulanic acid (substance) |	
		amoxicillin sodium	544Y3D6MYH	34642-77-8	427483001 | Amoxicillin sodium (substance) |	
		amoxicillin trihydrate	804826J2HU	61336-70-7	96068000 | Amoxicillin trihydrate (substance) |	
		potassium clavulanate	Q42OMW3AT8	61177-45-5	395938000 | Clavulanate potassium (substance) |	MPs use modifier as PAI and moiety as BoSS
8	insulin glargine		2ZM8CX04RZ	160337-95-1	411529005 | Insulin glargine (substance) |	All MPs use moiety as BoSS and PAI
			10T9CSU89I	52232-67-4	425438001 | Teriparatide (substance) |	
9	teriparatide		9959P4V12N	99294-94-7	109198008 | Teriparatide acetate (substance) |	All MPs use moiety as BoSS and PAI

Sheet1

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

“Diclofenac”

List of potential pharmaceutical products Level 4

(products with single active ingredient substance only)

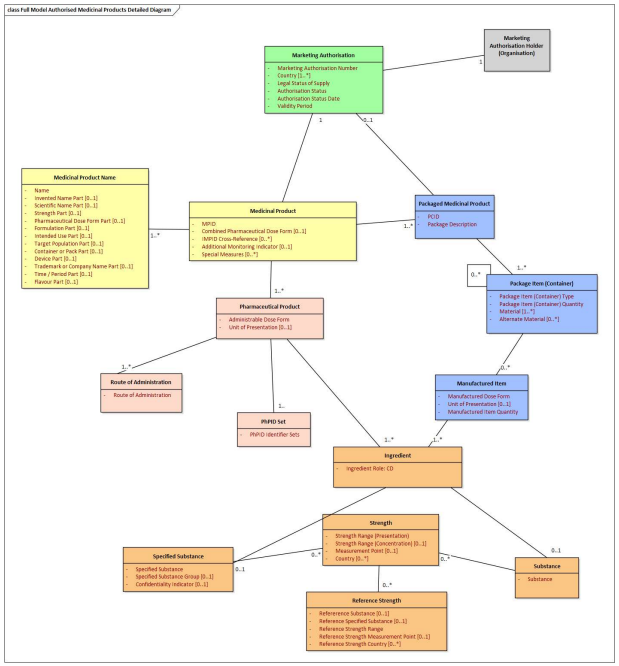
- diclofenac sodium 0.1 % ophthalmic drops
- diclofenac diethylamine 1.16 % cutaneous gel
- diclofenac sodium 12.5mg film coated tablet
- diclofenac potassium 12.5 mg tablet
- diclofenac sodium 1.5 % cutaneous solution
- diclofenac sodium 100 mg suppository
- diclofenac sodium 100mg modified-release tablet
- diclofenac sodium 100mg modified-release tablet
- diclofenac sodium 100 mg prolonged-release oral tablet
- diclofenac diethylamine 2.32 % cutaneous gel
- diclofenac sodium 25 mg gastro-resistant tablet
- diclofenac potassium 25 mg tablet
- diclofenac sodium (diclofenac epolamine) 25 mg per sachet granules for oral solution
- diclofenac potassium 50 mg oral tablet
- diclofenac sodium 50 mg suppository
- diclofenac sodium 50 mg gastro-resistant tablet
- diclofenac potassium 50 mg per pck powder for oral solution
- diclofenac sodium (diclofenac epolamine) 50 mg tablet
- diclofenac sodium (diclofenac epolamine) 50 mg per sachet granules for oral solution
- diclofenac sodium (diclofenac epolamine) 50 mg per sachet granules for oral solution
- diclofenac sodium 50mg dispersible tablet
- diclofenac sodium 75 mg prolonged-release oral tablet
- diclofenac sodium 75mg modified-release tablet
- diclofenac sodium 75mg gastro-resistant modified-release capsule

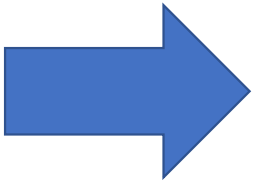
MPIDs – just three
countries – 230
PCIDs – maybe 500?

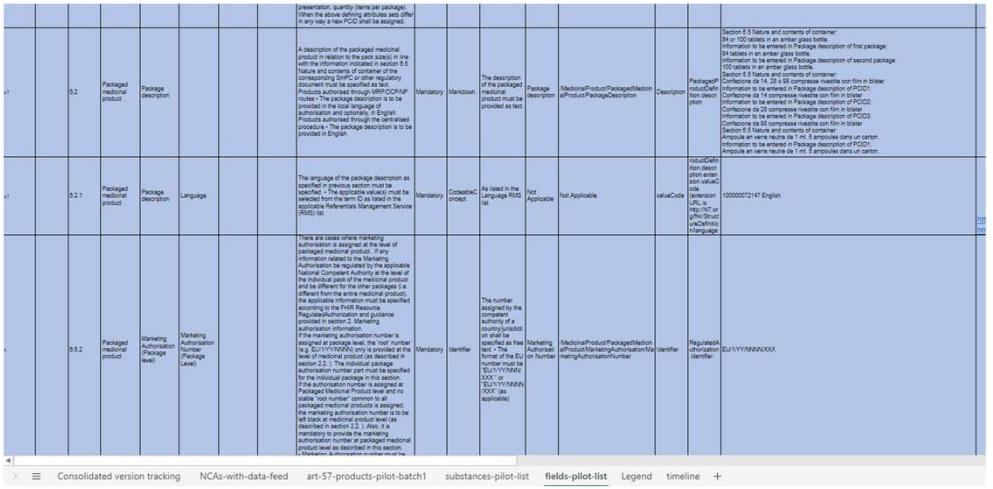
This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

Data elements for the PPL

In their “conceptual form” and through to their (various) implementation forms
Particularly here, looking at the PMS IG, as this is what the NCAs in the project will be working towards using for communication **<u>from MAH to NCA</u>**





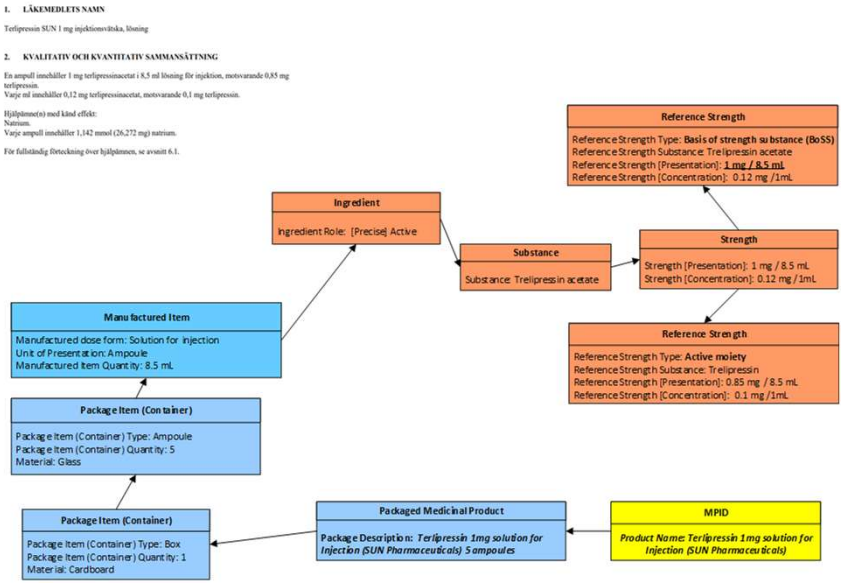


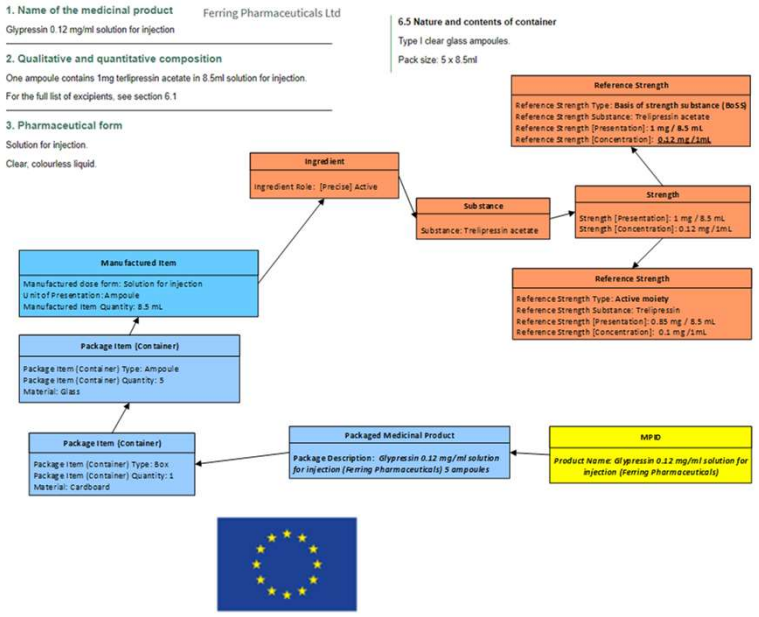
This project has received funding from the European Union's
Horizon 2020 research and innovation programme under grant agreement No 875299

Other areas to develop…for the data elements

- A technology independent (but NOT use case independent) logical model
  - Starting point….MPID or PCID (for example)

- Implementation patterns for various product types using logic from various key attributes





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

Questions?

Thank you

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