The UNICOM Project Pilot Product List

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

From legacy data to IDMP-coded MP data
From disparate isolated data to interoperable resources
From innovation to socio-economic impact

WP 1 IDMP-related standards and terminologies
WP 2 Implement IDMP – Substance Management in Europe
WP 3 Pan-European IDMP compliant application forms
WP 4 IDMP implementation at National Drug Agencies
WP 8 Clinical Care, Patients, Pharmacies, Research and Pharmacovigilance
WP 9 Medicinal Product Dictionaries and Clinical System Software
WP 5 IDMP adoption by eHealth Services
WP 6 Software and extensions for CEF eHDSI
WP 7 eHDSI cross-border / national eHealth services piloting

Action Lines
- Drug NCAs & reliable data
- Implementation across Europe
- Realising the benefits
- Coordination & sustainability

From methods towards tools & clinical solutions
From status quo to pilots and implementation

26/01/2021
This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 875299
1. **NAME OF THE MEDICINAL PRODUCT**
   - Bortezomib (1.0 mg powder for solution for injection)  
   - Bortezomib (2.5 mg powder for solution for injection)  
   - Bortezomib (3.5 mg powder for solution for injection)  

2. **QUALITATIVE AND QUANTITATIVE COMPOSITION**
   - Bortezomib 1.0 mg powder for solution for injection
     - Each vial contains 1 mg bortezomib (as a mannitol benzenetricarboxylate).  
   - Bortezomib 2.5 mg powder for solution for injection
     - Each vial contains 2.5 mg bortezomib (as a mannitol benzenetricarboxylate).  
   - Bortezomib 3.5 mg powder for solution for injection
     - Each vial contains 3.5 mg bortezomib (as a mannitol benzenetricarboxylate).  
     - After reconstitution, 1 ml of solution for subcutaneous injection contains 2.2 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 colour 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”
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
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
We can put aside most of the regulatory document information...keeping, of course, the Medicinal Product and Medicinal Product Name.
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.
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
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
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 of 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.”
| Substance list.... |

<table>
<thead>
<tr>
<th>Substance</th>
<th>CAS Registry Number</th>
<th>EC Number</th>
<th>MP</th>
<th>Purity</th>
<th>Other Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Substance 1</td>
<td>12345-67-8</td>
<td>987-12-3</td>
<td>99.9</td>
<td>99.9</td>
<td></td>
</tr>
<tr>
<td>Substance 2</td>
<td>890-12-3</td>
<td>456-78-9</td>
<td>99.5</td>
<td>99.5</td>
<td></td>
</tr>
<tr>
<td>Substance 3</td>
<td>456-78-9</td>
<td>123-45-6</td>
<td>99.0</td>
<td>99.0</td>
<td></td>
</tr>
</tbody>
</table>

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 875299.
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 12.5 mg film coated tablet
- diclofenac potassium 12.5 mg tablet
- diclofenac sodium 1.5 % cutaneous solution
- diclofenac sodium 100 mg suppository
- diclofenac sodium 100 mg modified-release tablet
- diclofenac sodium 100 mg 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 50 mg dispersible tablet
- diclofenac sodium 75 mg prolonged-release oral tablet
- diclofenac sodium 75 mg modified-release tablet
- diclofenac sodium 75 mg gastro-resistant modified-release capsule

MPIDs – just three
countries – 230
PCIDs – maybe 500?
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 **from MAH to NCA**.
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
Questions?

Thank you