

Global IDMP Working Group

GIDWG Global IDMP Identifiers

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Agenda

- Global IDMP identifiers in the GIDWG End-to-end
 - PhPID
 - GSID
 - Strength
 - Dose Form
- Outcomes of the GIDWG end-to-end





Pharmaceutical product ID



PhPID Dose Substance Strength form PhPID level PhPID: 0x073AF2E5B92AE19E8867635AFFB3D6CA

Units of measurement Pharmaceutical dose forms Substance identification ISO 11238 ISO 11239 Pharmaceutical product identification ISO 11616 Manufacturer Medicinal product identification **Product name** Substance ISO 11615 5 mg

ISO IDMP suits of standards ISO 11615, 11616, 11238, 11239 and 11240

E2E: Data Validation Working Process





Harmonization

Medicinal product information when assigning global identifiers.







Consultation with experts

Finding The extent of medicinal product information harmonization was evaluated across three use-cases: 1. Pharmacovigilance

- 2. Drug shortage
- 3. Cross-border healthcare

Recommendation Ensure involvement of SMEs with competence within the different use-cases for global PhPID.

Five-regions verification

Finding

Analyzing substances and products across five key regions to understand how specific substances or products are described globally.

Recommendation

Pro: Valuable method when validating additional products with the same substance variant and pharmaceutical form.

Con: time consuming, should only be applied when relevant.

Harmonization

Reduce variations on medicinal product information when assigning global identifiers.





Global substances



Several different naming (including definition) organisations

• INN

• USAN

- Ph. Eur.
- JAN

Alignment to ISO IDMP standards 11238 and TS 19844

- For the majority of substances there are no issues
- Business Rules
- Case by case mitigation



GSID assignment



Selection of GSID for PhPID Hydrates

Finding

Comparable products are often described differently when it comes to hydrates, therefore, hydrates were excluded to ensure aggregation of comparable products to the same PhPID.

Decision

After the end-to-end and considering the use cases, the recommendation is to continue to use the corresponding anhydrous substance.

Global Strength Definitions



No common approach to strength and unit

- Different unit expression
 - IU, %, mg/mL, or mg/g
- Different precision of strength
 - 18 mg vs 18.06 mg
- Concentration strength vs presentation strength for liquids
 - 500 mg or 500 mg/ml

Mitigation

- Business Rules
- Patterns
- Conversion tables
- UCUM units

Strength Unit Conversion

Finding The absence of a globally approved unit conversion framework presents challenges in handling unit conversions (e.g., mg to IU).

Strength Unit Conversion



Some examples of Unit Conversions During End-to-End Testing							
Substance	From unit	To PhPID unit	Conversion factor (Source)				
Alteplase	IU	mg	10 mg = 5.8 MIU (SPCs)				
Lenograstim	IU	mcg	150 mcg = 19.2 MIU (Martindale)				
Somatropin	IU/units	mg	3 units = 1 mg (Martindale)				

Strength Unit Conversion

Finding

The absence of a globally approved unit conversion framework presents challenges in handling unit conversions (e.g., mg to IU).

Recommendation

To minimize the number of unit conversions, a fiveregion verification has been performed to identify the most common unit which is used for PhPID generation.

Dose Form Attributes



No centralized/common terminology for Dose Form

- Different granularity
 - Capsule vs Soft or Hard Capsule
 - Tablet, Coated Tablet, Film coated Tablet
- Regulators approve different terms
 - Pellet vs granule

Mitigation

- Dose Form Attributes
- Business Rules



Dose Form Attributes Release characteristics (RCA)

Finding

The dose form are differently labeled, for example "delayed release tablet" in one country and a "modified-release tablet" in another.

Information about how the active substance is released is not always available in SPCs.

Terms such as ´controlled release´ and ´modified release´ indicate some special form of release, but not exactly which RCA.

Dose form attributes Release characteristics (RCA)



Example of advanced formulations of Mesalazine

Formulations	Proprietary names	Mode of delivery	Site of drug release	Corresponding RCA for PhPID
	Asacol [®] ; Mesren [®]	Eudragit-S coating (dissolves at pH ≥ 7)	Terminal ileum, colon	Delayed
pH dependent	Salofalk [®] ; Mesasal [®] ; Claversal [®]	Eudragit-L coating (dissolves at pH ≥ 6)	Mid ileum to color	Delayed
	Salofalk Granules [®]	Eudragit-L coating and matrix core	Mid ileum to color	Delayed + Prolonged → Prolonged
Time dependent	Pentasa [®] , Pentasa [®] granules	Microspheres encapsulated within an ethycellulose semi- permeable membrane	Duodenum to colon	Prolonged
MMX	Lialda [®] ; Mezavant XL [®] ; Mezavant [®]	Enteric coating (dissolves at pH ≥ 7). MMX of lipophilic and hydrophilic excipients	Terminal ileum and entire colon	Delayed + Prolonged → Prolonged

Dose form attributes Release characteristics (RCA)

Finding

The dose form are differently labeled, for example "delayed release tablet" in one country and a "modifiedrelease tablet" in another.

Information about how the active substance is released is not always available in SPCs.

Terms such as ´controlled release´ and ´modified release´ indicate some special form of release, but not exactly which RCA.

Recommendation

Only one RCA is used for one PhPID.

Formulations combining different release characteristics will be assigned one RCA.



Outcome of the End-to- End

Operating model for Global PhPID

Global PhPID Publishing

Medicinal Product Information

Global PhPID Requesting





GSID and PhIPD assignment in end-to-end

The 4% not assigned was due to lack of or conflicting information 96% of the substances where successfully

assigned a GSID

90% of Medicinal Products have PhPID assigned **10% of Medicinal Products are part of E2E Findings and are under evaluation**

Business rules for PhPID generation



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Technical readiness





SYSTEM TESTING: ALL FUNCTIONAL, INTEGRATION, USER ACCEPTANCE, AND REGRESSION TESTING HAVE BEEN COMPLETED.



BACKUP AND RECOVERY: BACKUP AND DISASTER RECOVERY PROCESSES ARE IN PLACE.



AND RY: AND ER RY: S ARE CE. HARDWARE, NETWORKING, AND OTHER INFRASTRUCTURE COMPONENTS ARE CORRECTLY CONFIGURED.



SECURITY AND MONITORING:

SECURITY ASSESSMENTS, AND TESTING COMPLETED. MONITORING IN PLACE



<u>.</u>



INTEGRATION READINESS: INTERFACES WITH THIRD-PARTY SYSTEMS, APIS, AND OTHER OPTIONS ARE STILL UNDER DEVELOPMENT.

Operational Readiness



User Training and documentation



Help Desk/Customer Support



SLA Agreements



Change Management



Communication Plan



Process readiness

Global PhPID linked to Medicinal product dictionaries



*Dose form characteristics: Solution, Injection, Parenteral, Conventional

Stable Local IDs

(MPID, local dose form, local strength expression, units)

Finding

End-to-end testing identified the need to collect and provide local IDs with global PhPID to facilitate interpretation of the data

Recommendation

Stable local IDs would be recommended to be included in the request both through API and PhPID Request Tool

Overarching PhPID



Overarching PhPID

Finding

There is a need to group related chemical substances, such as bases and their corresponding salts, to improve aggregation and search functionalities

Recommendation

Development of an overarching PhPID

Recommendations for non-normative amendments to ISO 11616/TS 20451

Key message Global Identifiers

The assignment of Global Identifiers and selection for PhPID are based on the ISO IDMP suite of standards and GIDWG business rules.

All of the work with the GIDWG end-to-end has provided confidence of the establishment of the global PhPID framework.

Thank you!