Mapping Standards

Indications

MedDRA User Group
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What's in a Name?
Indication term variations across functions, systems and external vocabularies

Global Target Label

Research Scientist

Health Authority Reporting

D1 D2 PCC D4 D5 D6 D7 D8 Reg. Appr. D9
Problem Statement

Harmonisation of indication terms and codes

Indications are needed in a variety of internal and external processes, including information exchange between pharma industry and authorities. This involves:

- Internal data, systems, and documents, during development and post-approval
- External data and documents, e.g., real-world data/evidence (RWD/E) usage and Health Authority (HA) reporting
- Indications as text and codes
- Standard vocabularies: MeSH, MedDRA, SNOMED CT, ICD9/10, ATC* codes

The use of one standard vocabulary for indications is not feasible due to:

- Different HA reporting requirements
- Standard vocabularies are all fit for different purposes
- Global compatibility via standardization is needed

Mapping between vocabularies is necessary for consistency in documentation and reporting.

- Different hierarchy levels and sizes of the terminologies cause complexity in mapping:
  - 1:1 mapping is often not possible
  - Associate and link terms
  - Define characteristics and show relationships

Harmonize indication terms and codes for efficient and comprehensive reporting and a deeper and more consistent understanding of diseases.
Problem Statement

Indications @Bayer

Harmonize indication terms and codes for efficient and comprehensive reporting and a deeper and more consistent understanding of diseases

Health Authorities

RWD/E registries, databases

Healthcare Providers

Mappings

Reference Vocabularies MedDRA & Co

Documents

Internal Systems

External

Internal

Therapeutic Indications – ISO Proposal for Technical Specifications

Use Cases for standardizing our terminologies and codes

// Fulfill differing Health Authority reporting obligations
// European Medicines Agency (EMA): Indications coded in MedDRA
// Food and Drug Administration (FDA): Indications coded in MeSH, or SNOMED CT mapped to MeSH
// Support population- and value-based indications from the Health Technology Assessment (HTA) / re-imbursement perspective (e.g. ICD, ATC codes)
// Standardize definitions of indications throughout drug development and beyond (Label; Adverse Event Reporting)
// Define and describe indications in recognizable terms based on identifiable patient populations (usage of real world evidence (RWE))
// Include standardization of lay term translations
Current Activities March 2020

// Standardize Indications mappings internationally
// ISO draft proposal at plenary meeting, April

// User Interface for Bayer Indications Vocabulary with mappings as basis

// Application Programming Interface (API) / Backend service for systems

// Initiation of a concept for standardization of lay term translations in alignment with Clinical and Labelling

// Interviews with potential customers ongoing
Indication Vocabulary Requirements from Health Authorities

- **Food and Drug Administration (FDA)**
  - Indications are coded in MeSH or SNOMED CT mapped to MeSH
  - MeSH indication term: Pneumonia, pneumococcal

- **European Medicines Agency (EMA)**
  - Indications are coded in MedDRA
  - MedDRA indication term: Pneumonia, streptococcal

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Various Hierarchy Systems in the Required External Vocabularies
Mapping Complexity between MedDRA, SNOMED CT and MeSH

EMA Requirement
Medical Dictionary for Regulatory Activities

FDA Requirement
Systematized Nomenclature of Human and Veterinary Medicine – Clinical Terms

EMA and FDA Requirement / Publications
Medical Subject Headings

Bayer Indications Vocabulary – One Source for Terms and Codes
Indication terms and codes mapped for internal and external use

Provide and maintain indication terms and mappings centrally

For usage in

Data analytics

Documents, e.g.

Global Target Label (GTL), regulatory applications, HA reporting

Pharmacovigilance

Integrate usage of key indication terminology and coding standards via UMLS and mapping via unique IDs (CUI)

Enable indications to be findable, accessible, interoperable and reusable (FAIR)
Resolution Team Indication

Thank you!

Ideas, proposals and feedback are very welcome
Please address your comments to

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