Data Standardisation Strategy: Top Themes and Use Cases

Kelly H. Zou, PhD, PStat®, FASA
Head of Medical Analytics and Real World Evidence
Medicines for Europe

Data Standardisation Strategy stakeholder Workshop
European Medicines Agency
18 May 2021

Outline

1. Stakeholder Overview
2. Data Standardisation Strategy
3. Concluding Remarks

1. Stakeholder Overview: Pharma Industry – Medicines for Europe

- Medicines for Europe represents the pharmaceutical companies supplying the largest share of medicines across Europe and is the voice of the generic, biosimilar and value added industries

- As a leading partner for better healthcare, we aim to increase the health and wellbeing of all Europeans through better access to high quality medicines

- Medicines for Europe members' portfolio cover 80% of therapy areas, and in so doing, safeguards the sustainability of Europe's healthcare systems for future generations

https://www.medicinesforeurope.com/medicines-for-europe

2. Data Standardisation Strategy: Top Themes and Use Cases

- Theme #1: Product Information (PI)
- Use Cases

1) Enable structured information and text
2) Support the move to online repositories of the latest PI and linkages to this data through use of 2D barcodes on packaging
3) Support translations of PI into other languages
4) Support methods for data exchange such as FHIR messaging which would allow a more agile way of working applicable to all electronic submissions including ePI

2. Data Standardisation Strategy: Top Themes and Use Cases

- Theme #2: Data Quality
- Use Cases

1) Develop metadata catalog for data access, quality control and common data models, along with use cases and user interface

2) Access the evidence on products in order to better understand the data used and analyses that led to the results and conclusions

3) Develop algorithms to analyse disease burden, medicinal product uses, medication adherence, and healthcare resource utilisation

https://www.ema.europa.eu/en/events/technical-workshop-real-world-metadata-regulatory-purposes

2. Data Standardisation Strategy: Top Themes and Use Cases

- Theme #3: Artificial Intelligence (AI)

- Use Cases

1) Develop a framework to assess and validate AI, which can be used in randomized controlled trials, such as those using digital endpoints, but also in pragmatic clinical studies, post-approval safety studies, and non-interventional observation studies to harness real-world data

2) Make regulatory data open to search for fit-for-purpose open regulatory datasets, have international standards, and visualize and validate results using data sources, while protecting patient privacy and data security

3) Foster international collaborations while following AI regulations, guidance and standards

https://ec.europa.eu/commission/presscorner/detail/en/IP_21_1682
https://www.ema.europa.eu/en/events/joint-hmaema-workshop-artificial-intelligence-medicines-regulation

Concluding Remarks

1. All themes can be relevant but with some degree of overlap
2. Evidence-generation is important for value-added medicines
3. Top themes depend on specific goals and are fit for purpose