IHIC Genova 2016 OPENMEDICINE Workshop

Does IDMP fit for the purpose of bridging Clinical Practice with Regulatory Oversight?

Villa Giustiniani Cambiaso, University of Genoa, June 14th 17:00-18:30

Scope

Learn from several stakeholders what are the current gaps and the bridging opportunities between the regulatory and the clinical worlds. Reflect on IDMP standards and openMedicine proposals.

openMEDICINE (www.open-medicine.eu) is a European Project funded by Horizon 2020 research and innovation programme aiming to advance unique identification of medicinal products and thereby patient safety in cross-border settings. It addresses drug identification and substitution challenges of safely dispensing prescriptions to people no matter where these prescriptions are issued, bridging national, European, transatlantic, and global borders. Main elements of the openMedicine approach, are:

- common data models for identification and description of medicinal products, based on the ISO IDMP suite of standards
- a common vocabulary for unambiguous description of medicinal products
- rules to guarantee safe identification of medicinal products:
    - in prescriptions for cross-border dispensing
    - in case that substitution is required
    - in patient summaries as well as adverse event reporting for pharmacovigilance
- a global roadmap for post-project actions and implementation

The work of openMedicine aims to validate of the ISO IDMP suite of standards and their implementation guides for Identification of medicinal products in use cases extending beyond regulatory purposes in Europe and beyond. Meanwhile, each member state has a medicinal product database that is released regularly. openMedicine reaches out to EU member states, their health ministries, national agencies and stakeholders to raise awareness and discuss steps needed to roll out IDMP implementation and benefit from the database of medicinal products that the European Medicines Agency (EMA) is currently developing in collaboration with member states for 2018.

Multi-stakeholder experts from Regulatory agencies, HL7 affiliates, Standards leadership, academia, and national / regional healthcare organizations will present and discuss perceived and experienced gaps between the regulatory and the clinical purposes. Participants will propose and debate bridging opportunities suggesting how the openMedicine project recommendations on implementation of IDMP may help bridge these gaps.

The implications and potential impact for ePrescription/ eDispensation at the national and regional level of implementing IDMP at the European level, will be addressed. The expected added value for public health, clinical record keeping and decision support, pharmacovigilance, industry will be discussed. The opportunities, challenges, and costs of the pending roll-out of IDMP components will be identified along with further steps and activities necessary to fully engage HL7

Affiliates in the process of realizing the benefits of IDMP rollout in a coherent and consistent way across Europe.

Agenda

Introduction / Set up the scene

The aim is to introduce the workshop scope, objectives, and agenda, and present background on the openMedicine project. The role and engagement of the audience will also be clarified.

Speaker: Giorgio Cangioli

The regulatory vision

The scope is to provide the regulatory perspective, form the National and - possibly - from the European point of view, including the IDMP implementation roadmaps.

Speaker: Giovanni Ferretti, AIFA.

The SDO vision

The scope of this session is to provide the SDO perspective. Ed will provide the view of a standard development organization (HL7) that covers both the domains with its standards and whose standards (Common Product Models, SPL, etc) will be likely used for the implementation of IDMP.

Speaker: Ed Hammond, Chair Emeritus, HL7 International

How IDMP can bridge the clinical with regulatory worlds in Healthcare Delivery: national/regional perspectives and openMedicine proposals (Panel)

Jos Devlies will introduce the proposed draft recommendations of openMedicine. Then, the panelists will provide an overview of the current and future state from a national/regional perspective reflecting on the openMedicine recommendations and the role of HL7 affiliates. In view of these proposals, the panelists will address the state of play with drug lists in their country, the underlying processes and added-value services available. They will reflect on supporting EMA requirements and relevant standards for adverse drug reporting and pharmacovigilance.

Moderators: Jos Devlies, openMedicine Roadmap, Custodix, Catherine Chronaki, HL7 Foundation
Panelists:

- Germany: Christof Gessner, Gematik, Immediate past Chair HL7 Germany
- Netherlands: Bert Kabbes, D&A medical group BV; Chair HL7 the Netherlands
- Austria: Stefan Sabutsch, ELGA, Chair HL7 Austria
- Czech Republic: Libor Seidl, MoH, Chair HL7 Czech Republic
- Italy: Stefano Dalmiani, FTGM CNR / Regione Toscana

Wrap Up

Catherine Chronaki