This a draft description of the new Firely (https://fire.ly) "IDMP on FHIR" training course.

We would greatly appreciate your review of the outline of this training course, especially if you are part of its intended audience. Please let us have your personal suggestions and opinions, whether good or bad, by e-mailing René Spronk, Firely training coordinator, at rene@fire.ly, or by using the DM feature of chat.fhir.org.

Timeline: review phase up to September 18th, 2020. Initial delivery dates of the course: November 10-12.

Implementing IDMP and SPOR using FHIR

Number of days: Two 8-hour days (face-to-face training course), or three 5-hour sessions on 3 different days (online training courses).

Summary of course content

The European Medicines Agency (EMA) have adopted the HL7 FHIR messaging standard for their EU wide implementation of the international Identification of Medicinal Products (IDMP) standard. The EMA is implementing IDMP based on the four domains of master data in pharmaceutical regulatory processes: substance, product, organisation and referential data (SPOR).

This training course offers an overview of the IDMP standard, and solid grounding of the FHIR exchange standard, as well as a hands-on sessions focused on the implementation of IDMP using FHIR.

Who should attend

1. Regulatory bodies (NCAs), and those who maintain central registries, who will be involved with the implementation and support of SPOR/IDMP using FHIR.

2. Pharma companies involved with the design, implementation or support of medicinal products and substance information systems. For example, the submission of data to regional registries (or SPOR), or exporting data from their own systems or RIMS (Regulatory Information Management Systems) in a standard exchange format.

3. Any software workers who need to represent medicinal product or substance data using the emerging standard that is shaping the whole healthcare industry. This includes maintaining and sharing drug catalogues and knowledge bases, to support regulatory or non-regulatory healthcare processes.

Goals of the training course

Upon completion of this training course, attendees will be able to:

- Understand the core IDMP architecture and data model, and how this relates to SPOR services
- Explain the key principles underlying the FHIR exchange standard
- Describe the characteristics and contents of the core IDMP models as expressed in FHIR
- Build upon hands-on experience with FHIR gained during the training course
- Plan an effective strategy for IDMP implementation for their organization, or other (non-IDMP) product and substance data sources or flows using FHIR

Prerequisite knowledge

The attendees are assumed to be familiar with:

- The basics of medicinal product data (and its regulatory/healthcare context)
- General principles of data modelling
- Software development principles such as object orientation, databases, layered software design
- XML or JSON, as well as web-infrastructure protocols (HTTP etc)

Agenda

Note: the topics of the agenda below will be presented over the course of 2 days (face-to-face training course) or 3 days (online training course). The agenda is subject to change; there are additional exercises beyond those shown below.

Overview of IDMP, SPOR and FHIR

- Introduction
  - The regulatory context
  - Submission of Product and Substance Information and SPOR
  - The case for IDMP

- Overview of the IDMP model
  - High level tour of the model areas
  - Product and Substance models

- Details of IDMP model
  - A look at the data items of each model area (products, packages, authorisations etc.)
  - Representing full product details in IDMP (how the different areas relate)
  - **Exercise:** Representing basic product data in IDMP

- FHIR Basics
  - What is HL7 FHIR?
  - Why is FHIR needed? Why not just IDMP?
  - HL7 and interoperability
  - FHIR “resources”, data types, REST
  - How FHIR does IDMP
    - The FHIR IDMP resources
    - Versions of FHIR (R4 vs R5)

- FHIR MedicinalProductDefinition, a use case
  - How medications and packages are represented in FHIR

- **Exercise:** Mapping of product IDMP data to FHIR

- REST and CRUD
  - How the FHIR API handles data transfer
  - Facades and REST architecture
  - **Exercise:** CRUD / REST
    - Working with FHIR data and servers

- FHIR “Bundles” and simple search
  - Search parameters and modifiers
  - References - how FHIR links work

SPOR implementation of IDMP on FHIR

- SPOR v2 API - PMS (products)
  - How EMA will implement FHIR
    - The FHIR endpoints
    - Extensions, what are they and why they are needed
    - Transactions - multiple resources at once
    - FHIR “Operations”
    - Asynchronous REST
  - The SPOR IG (Implementation Guide)
  - Other parts of SPOR - OMS, RMS, SMS and UPD
    - And other international projects
  - **Exercise**: Transactions

- FHIR/SPOR Conformance Layer
  - Profiles
    - What these are, and how is EMA using them
  - **Exercise**: Validation

- Terminologies
  - How codes work in FHIR

- IDMP SPOR and Substances
  - SMS and G-SRS, EU-SRS
  - Relationship of SubstanceDefinition to Ingredients and products
  - **Exercise**:
    - Registering a substance

- Summary and recommendations for further reading and study

Registration and pricing

This course has been scheduled for initial delivery on November 10-12, 2020, 9:30-15:00 Central European Time. The registration fee for this course is EUR 1295 (exclusive of VAT).