



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

September 2015 Ginas Meeting Highlights

European Network Data Board Meeting – 24 Sep 2015
ISO IDMP EU Taskforce – 25 Sep 2015



GINAS MEETING CONTENT

- The meeting was divided in two main sessions:
 - Public meeting
 - Subject Matter Experts(SMEs) meeting
- The public meeting slides are available at:
 - <https://tripod.nih.gov/ginas/september2015.html>
- The SMEs meeting focussed on:
 - Controlled Vocabularies
 - Blood, cell and advanced therapies
 - Messaging
 - G-SRS software
 - WHO-UMC proposal to maintain a Global substance repository

G-SRS SOFTWARE

- EMA is fully committed on using the G-SRS software, as agreed at the EUTMB on March 2015.
- NCATS is carrying a major re-development
 - Next release expected on 1 November
 - FDA deployment expected in Q1-Q2 2016
- Current software:
 - is based on Jason schema (no HL7 version 3 schema for now).
 - is available only in English
 - has “hard-coded” business rules in Java
 - Since validation rules will be regions specific or can change over time, FDA agreed in principle to implement this functionality as configurable within their own development plan
- Protocol for synchronising multiple instance of G-SRS software is still open

G-SRS DATA MODEL

- G-SRS data model is:
 - in JSON Schema
 - no UML or ER diagrams available as of now
 - planned to implement all substance classes
 - planned to implement only Group 1 Specified Substances
 - Group 2 and other left for the future, no dates set at the moment.

G-SRS DATA MIGRATION

- FDA and NCATS migrated to G-SRS several FDA data sets
 - a September 2015 snapshot of public data is published on GInAS web page
- FDA will continue to use UNII numbers for substance data registered:
 - FDA started mapping of UNII and against other coding systems, incl. EVCODEs
 - Mapping UNII vs EVCODEs: not completed, not validated
- Once the future IDMP ID will be decided, the possibility for storing old regional IDs(e.g. EVCODEs) may need to be added

G-SRS CONTROLLED VOCABULARIES(CVs)

- G-SRS is using a number of look-up lists to help populate data (at the moment 58 lists)
- Some of lists will be from external sources (EDQM, UCUM), others are local for GINAS and at the moment are populated based on data values used by FDA in current SRS systems
- Since lists can be specified for a region, EMA asked to NCATS and FDA to implement lists as a configurable parameter
- CVs maintenance processes and technicalities needs to be further discussed (e.g. creation of a Substance Advisory Board to address the scientific issues).
 - Integration with EMA RMS is necessary

GLOBAL SUBSTANCE IDENTIFICATION

- WHO-UMC proposed to globally map **publicly** available substance data from EU and US with information from other countries
- However there are aspects that needs to be clarified:
 - Scope
 - Financial model
 - Availability of Subject Matter Experts
 - Operating model
 - Difficulties of mapping IDs using only public data elements

CURRENT CHALLENGES FOR AN ADOPTION OF G-SRS IN EUROPE

- G-SRS software is based on requirements gathered from some Regulators like for instance: FDA, NL, DE, Health Canada, Swissmedic and lately also EMA.
 - Additional EU requirements need to be incorporated
 - FDA requirements need to be fully documented
 - Technical and business documentation need to be created and finalised (e.g. User acceptance testing for all substance classes and writing of the User guidance still has to be done)
- Need for a joint software maintenance model and governance between EU and US
 - Allocation of budget and human resources
 - Creation/endorsement of a development plan
 - Integration with telematics systems
 - Versions control process for the software
- No automated parsing software for HL7 Substance Messages

OTHER KEY POINTS

- FDA, EMA, WHO-UMC are planning to submit a proposal to ICH (IPRF) to create a group aiming to fostering the creation of global substance identifiers
- There were intensive scientific discussions on substance data models
- The need of a Substance Advisory Board has been raised and need to be further discussed when the detailed business process will be defined in the PMS/SMS projects

KEY PRESENTATIONS

- Overview of the Ginas Project:
<https://tripod.nih.gov/ginas/docs/sept2015/Monday/Southall.pdf>
- G-SRS Software for Substance Registration:
<https://tripod.nih.gov/ginas/docs/sept2015/Monday/Peryea.pdf>
- State of Public Seed Data and System Demo:
<https://tripod.nih.gov/ginas/docs/sept2015/Monday/Tyler.pdf>
- Controlled Vocabulary in ginas:
<https://tripod.nih.gov/ginas/docs/sept2015/Tuesday/Balzer.pdf>
- G-SRS Software Development:
<https://tripod.nih.gov/ginas/docs/sept2015/Tuesday/Sheils.pdf>

Thank you for your attention

Further information

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