IDMP Advisory Group Meeting - Questions and Answers

13.03.2024

Category	Question	Answer
Global Initiatives	Could this update include a short overview of related topics, how Swissmedic is planning to build on their output and how far they are connected to IDMP project in Swissmedic perspective? (eCTD 4.0, ePI, Accumulus, CTIS)	*eCTD:* connection via eAF, reduction of M1 considered *ePI:* Monitoring of EU developments, legal introduction still to be clarified *Accumulus:* IDMP not yet in focus *CTIS:* No participation. National data standard
Strategy/Roadmap	What are the Swissmedic's strategic roadmap & high level timelines, including duration of the transition phase(s)?	Please refer to the roadmap in the presentation. Transition phases not yet defined.
Strategy/Roadmap	What is Swissmedic's IDMP systems landscape going to look like, and how to they expect that industry will interact with it?	See the high level architecture overview.
Strategy/Roadmap	What about a first iteration in coordination with eAF (re- meeting note 2023)?	The IDMP data will be included in the eAF. However this will be done in steps or iterations and within the TSP implementation packages.
Strategy/Roadmap	Communication Plan: How (and how often) does Swissmedic plan to communicate with the external community about its progress, next steps, Q&As, demos… (Are they planning to follow the EMA approach, or do they have another plan which they could share)?	Swissmedic plans to increase stakeholder involvement with the upcoming TSP implementation packages. The details are part of the discussion with the stakeholders.
IDMP Pilot	Will the external pilot project be extended more broadly to the industry? EFPIA ERAO IDMP WG is welcoming any request for support for pilot project from Swissmedic.	Swissmedic is interested in building up a data repository and gaining experience with FHIR messages from different sponsors. However, we will consider this after the results of the first pilot.
IDMP Pilot	When are the upcoming tests rounds involving testing the data flow using FHIR messages ?	The scope and plans for the data exchange pilot are presented at the meeting.
IDMP Pilot	Outcome of 2023 data pilot	The pilot is still to come.
Strategy/Roadmap	Is Swissmedic going to prepare a comparison between EUIG and what Swissmedic is looking for (to understand Swiss specific definition/understanding of some data element, and avoid assumption of equivalence)? Would Swissmedic welcome a co-authoring of the IG with industry, following EMA model?	We will look at is likely to be on Chapter 2. We are planning to discuss this with the industry. How the exchange will be implemented in practice is part of the discussion (see discussion about stakeholder involvement).
Administration	Does Swissmedic has a list of Industry Stakeholders beyond the IDMP Advisory Board? If yes, may the list of stakeholders to be involved be shared? How Swissmedic is planning to select industry stakeholder to participate to future activities (Swissmedic IG and Pilots)?	Stakeholder involvement will be coordinated with the different stakeholder groups. They are mostly organised in round tables (see website). The round tables usually coordinate members for specific user groups (see also the discussion about stakeholder involvement).
Strategy/Roadmap	Does Swissmedic has plans to set-up a Swissmedic-SRS (leveraging on FDA developed tool)?	We don't intend to use an own G-SRS instance. We plan to create an SMS (without scientific description of the substances) that we will build up step by step.
Data/Processes	Which data will be migrated to the new Swissmedic portal (source of truth) and is the plan still not to have MAH to review/validate migrated data? (ref notes 2023)	PMS: The migration steps have not yet been defined. We still don't plan to do the validation by the MAHs because Swissmedic has the data actually.
Data/Processes	How far alignment with SPOR data can be expected (data point perspective) and what will be the process for handling specific CVs (referentials) not in SPOR?	Not defined yet. For specific CVs please see data exchange pilot.
Data/Processes	What will be the IDMP identifiers used by Swissmedic similarly to PMS, MPID, PCID, etc.?	We will use the identifiers described in the ISO IDMP standards.
Data/Processes	What would looks like a future high-level Process and R&Rs, covering the product life cycle aspects?	The high level process is similar to the high level data flow (see last meeting).
Data/Processes	What documents/attachments will be required to support Swiss IDMP data set and in which language? (in perspective of the legacy mandate on document)	We don't know this in detail. We still expect some documents in Module 1 eCTD.
Data/Processes	How far is Swissmedic on data-only submissions for purely administrative changes (e.g. Name/address Organisation change, deletion of pack size) to avoid dossier submissions? (ref notes 2023)	This would only concern changes that don't affect modules 2 to 5. Ideally this would be a data-only submission without any attachments. Examples to be discussed.
Data/Processes	What would be the overall data governance, including product / substance data ownership and assignment of identifiers?	Under discussion.
Data/Processes	What are the priority use cases leveraging on IDMP for Swissmedic? eAF has been mentioned in 2023 meeting.	The business use cases we will implement as a first priority are for marketing authorisation. This includes new applications and variations using the eAF.
System	Has/will Swissmedic pilot FHIR data exchange? Will there be a specific API for system to system data exchange ?	Intended but no plan yet.
Global Harmonization	What are the expected Synergies & Divergences between Swissmedic and FDA/EMA? US PQ/CMC/ICH SPQS?	Swissmedic participates in ICH and will adapt its guidelines and standards.
Global Harmonization	How Swissmedic incorporate GIDWG outcomes into its own plans? Links with WHO UMC? (Global Substance ID, PhPID for AE reporting, etc.)	Swissmedic participates in GIDWG. Global Substance ID and Global PHPID are relevant for Swissmedic. Timelines and use cases will depend on the progress made in GIDWG and in TSP.
Global Harmonization	How Swissmedic prepare possible extension of ISO IDMP series, toward Quality (PQ/CMC elements in 11615 MI, 11238 SSG4), following review agreed in Arlington based on Systematic Reviews?	We don't yet have specific plans for the structure of Module 3. As an ICH member we will implement any changes in the standards (e.g. M4Q).