Transition plan from Article 57/XEVMPD data submission to SPOR

Organisation, referential and substance data submissions by marketing authorisation holders and sponsors of clinical trials

In the context of the implementation of the ISO IDMP standards, the European Medicines Agency (EMA) is establishing services to support the management of master data, i.e. substance, product, organisation and referential (collectively referred to as 'SPOR') data.

The European Commission, the European Union (EU) Network Data Board and the EU ISO IDMP Task Force have endorsed a phased implementation of the ISO IDMP standards. The phased implementation plan envisages the prioritisation of the 'Referentials' and the 'Organisation' management services (RMS and OMS) in 2016 with the view of making them available in 2017.

This document is a preliminary communication on the foreseen transition from the current Article 57 processes to the 'to be' SPOR processes. It is aimed at clarifying the change management plan for the provision of information related to the **referential** and **organisation** entities, currently managed via the eXtended EudraVigilance Product Report Message (XEVPRM) format, within the OMS and RMS requirements. This document also includes the process change for submissions of **approved substance** information to the Agency.

The requirements will apply to the marketing authorisation holders (MAHs) and sponsors of clinical trials currently submitting data in the eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD).

The processes and technology for the EMA and the relevant stakeholders to enable the registration and maintenance of the master data are currently being established, and will be communicated to all stakeholders once available.

Organisations

		Phase I: current process	Phase II: OMS implementation is enforced
Organisations	MAH/sponsor organisation information	MAHs/sponsors continue submitting referential data via an XEVPRM; EV Code is communicated via an XEVPRM	MAHs/sponsors submit data to OMS OMS register data and provide MAHs/sponsors with EV Code/ID to reference in their product entities

Phase I: Current process

MAH and sponsors continue inserting/maintaining organisation data (MAH and sponsor organisations) in the XEVMPD via an XEVPRM. New organisation(s) can be inserted/maintained and referenced in a product entity (authorised and/or development) within the same XEVPRM. Following a successful submission, an EV Code is generated and communicated to the sender organisation via an XEVPRM acknowledgement.

Phase II: OMS implementation is enforced

Foreseen timeline: Second half of 2017

MAHs and sponsors will request the insertion/maintenance of organisation data from the organisations management service (OMS). Following the evaluation of the request, OMS enter/update the organisational data and provide the requestor (i.e. MAH/sponsor) with the EV Code/ID to be referenced in their product entity.

Concomitantly to the registration in OMS, the organisation and its EV Code will become available in the XEVMPD database to be referenced in the product entities as applicable (i.e. the requestor will not have to submit this data in the XEVPRM format anymore).

XEVPRM messages submitted by MAH or sponsor organisations containing operation type 'Insert (1)', 'Update (2)' or 'Nullification (4)' of any organisational data will be rejected and will generate a negative XEVPRM acknowledgement. Once OMS is fully enforced, the only acceptable process to register organisation information will be via OMS.

Referentials

		Phase I: current process	Phase II: RMS implementation is enforced
Referentials	sources, proposed pharmaceutical forms, proposed routes of administrations, proposed ATC Codes	MAHs/sponsors continue submitting referential data via an XEVPRM; EV Code is communicated via an XEVPRM	MAHs/sponsors submit data to RMS RMS register data and provide MAHs/sponsors with EV Code/ID to reference in their product entities

Phase I: Current process

MAHs and sponsors continue inserting/maintaining referential data (i.e. sources, proposed pharmaceutical forms, proposed routes of administrations, proposed ATC Codes) in the XEVMPD via an XEVPRM as per current procedures.
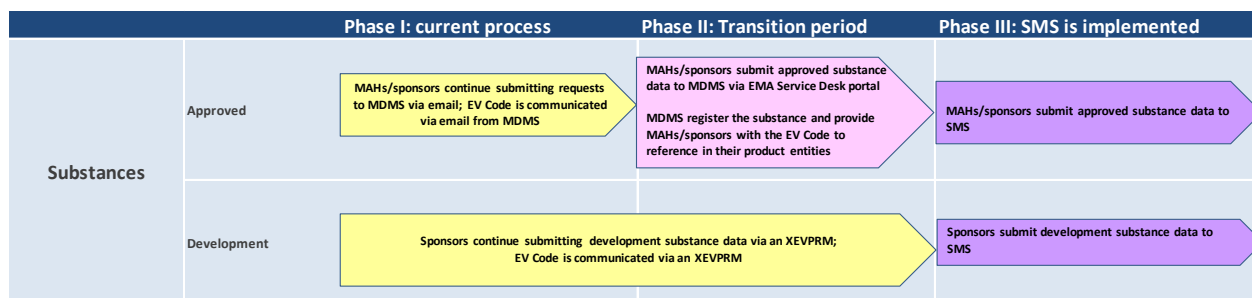
Phase II: RMS implementation is enforced

Foreseen timeline: Second half of 2017

MAHs and sponsors will request the insertion/maintenance of referential data from the referentials management service (RMS). Following the evaluation of the request, the referential data will be handled in RMS and the requestor (i.e. MAH/sponsor) will be provided with the EV Code/ID to be referenced in their product entity.

Concomitantly to the registration in RMS, the term and its EV Code will become available in the XEVMPD database to be referenced in the product entities as applicable (i.e. the requestor will not have to submit this data in the XEVPRM format anymore).

XEVPRM messages submitted by MAH or sponsor organisations containing operation type 'Insert (1)', 'Update (2)' or 'Nullification (4)' of any referential data will be rejected and will generate a negative XEVPRM acknowledgement. Once RMS is fully enforced, the only acceptable process to register referential data will be via RMS.

Substances

		Phase I: current process	Phase II: Transition period	Phase III: SMS is implemented
Substances	Approved	MAHs/sponsors continue submitting requests to MDMS via email; EV Code is communicated via email from MDMS	MAHs/sponsors submit approved substance data to MDMS via EMA Service Desk portal / MDMS register the substance and provide MAHs/sponsors with the EV Code to reference in their product entities	MAHs/sponsors submit approved substance data to SMS
	Development	Sponsors continue submitting development substance data via an XEVPRM; EV Code is communicated via an XEVPRM		Sponsors submit development substance data to SMS

Phase I: Current process

MAH and sponsors continue requesting insertion/maintenance of **approved substance data** in the XEVMPD via requests submitted to an MDMS email address. Following the evaluation of the request, MDMS enter/update the approved substance data in the XEVMPD and provide the requestor (i.e. MAH/sponsor) with the EV Code to be referenced in their product entity. XEVPRM message submitted by an MAH/sponsor containing operation type 'Insert (1)', 'Update (2)' or 'Nullification (4)' of an approved substance data is rejected and generates a negative XEVPRM acknowledgement.

Sponsors continue inserting/maintaining **development substance data** in the XEVMPD via an XEVPRM. Development substances can be inserted/maintained and referenced in a development product entity within the same XEVPRM. Following a successful submission, an EV Code is generated and communicated to the sender organisation via an XEVPRM Acknowledgement.

Phase II: Transition period

Foreseen implementation: Second half of 2017

MAHs and sponsors will request the insertion/maintenance of **approved substance data** from MDMS service via the EMA service desk portal. Following the evaluation of the request, MDMS enter/update the substance data and provide the requestor (i.e. MAH/sponsor) with the EV Code to be referenced in their product entity.

Sponsors continue inserting/maintaining **development substance data** in the XEVMPD via an XEVPRM.

Phase III: SMS is implemented

Once SMS is fully enforced the insertion/maintenance of approved and development substance data will be requested from the substance management service (SMS).