Final Concept Paper

ICH E2B(R3) IWG
Electronic Transmission of Individual Case Safety Reports

Dated 25 June 2013

Endorsed by the Steering Committee: 10 July 2013

Type of Action Proposed

Implementation Working Group (IWG) on E2B(R3) Q&A Document, Maintenance of E2B(R3) Technical Documents and Code Lists and adoption of ISO IDMP (International Organization for Standardization, Identification of Medicinal Products) standards for E2B(R3) use.

Statement of the Perceived Problem

The E2B(R3) message and technical documents are complex and, technically very different from the current E2B(R2) format. E2B(R3) implementation will require conceptual changes to business processes and due to differences in regional legislation, questions are expected regarding implementation across the ICH regions. Additionally, the use of constrained ISO IDMP terminologies in Individual Case Safety Reports (ICSRs) will require additional guidance and support activities. Due to this increased complexity, a large volume of queries from stakeholders is anticipated. Therefore, there is a strong need for the establishment of an E2B(R3) IWG and a sub-group to progress implementation activities and ensure transition from E2B(R2) to E2B(R3).

E2B(R3) IWG

Priorities for IWG Activities

The following activities have been identified:

- Establishment of an ICH mailbox to receive implementation queries for which the ICH E2B(R3) IWG will prepare responses;
- Finalisation of a Change Control Process for documents in the Implementation Guide (IG) package;
- Maintenance of technical documents related to E2B(R3);
- Monitoring of regional implementations and the need to address potential inconsistencies in messages;
- Definition of E2B(R3) codes as needed;
- Obtain term and identifier lists from Maintenance Organizations (MOs), apply, and maintain any necessary constraints consistent with E2B(R3) requirements;
- Create initial documentation for use of IDs/terms referenced in E2B(R3) IG.

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E2B(R3) IWG Deliverables

ICH Implementation Package Components	Publication Format	Responsible Maintenance Body	ICH Approval Level	Outcome of Approval
Q&A	PDF	IWG	SC sign-off	Publication of updated document
ICH Implementation Guide	PDF	IWG	SC Approval	(Technical update) Publication of updated document
				(Business update) Establishment of new EWG
BFC document	PDF	IWG	SC Approval	Publication of updated document
BFC conversion rules	XSLX	IWG	SC Approval	Publication of updated document
Schema files	XSD	ISO/HL7	N/A*	N/A*
Reference Instances	XML	IWG	IWG sign-off SC Informed	Publication of updated document
Example Instances	XML	IWG	IWG sign-off SC Informed	Publication of updated document
Values in Example Instance	XSLX	IWG	IWG sign-off SC Informed	Publication of updated document
E2B Code list version file	XML	M2	N/A*	N/A*
E2B Code lists	XML	M2	IWG sign-off SC Informed	Publication of updated document
XML snippets	In PDF document	IWG	IWG sign-off SC Informed	Publication of updated document
Xpath	In PDF document	IWG	IWG sign-off SC Informed	Publication of updated document
BFC conversion style sheets	XSL/XML	Regional	N/A*	N/A*

* Not Applicable

E2B(R3) IWG Sub-Group

Priorities for Sub-Group Activities

The sub-group uses the necessary part of the ISO IDMP standard for the purpose of ICH ICSR transmission. This work requires the following activities, which are included in the scope provided by the E2B(R3) informal IWG:

- Along with the ICH M2 Expert Working Group (EWG), obtain technical documentation, review MO processes and activities in relation to terms and IDs required for ICH ICSR transmissions to determine ICH subscription service requirements;
- Along with the ICH M2 EWG, ensure that agreements with MOs are in place;
- Along with the ICH M2 EWG, monitor and liaise with MOs after agreements are formalized;
- Review and evaluate samples of mapping of terms/definitions for Substance, Dosage form, Route of administration and Units of presentation from the regions;

- Harmonise only format and data elements of the Medicinal Product Identifier (MPID) list based on ISO IDMP 11615, and decide way of implementation by each region;
- Prepare test plan and participate in ICH beta testing of algorithm for Pharmaceutical Product Identifier (PhPID) generation.

Sub-Group Deliverables

- Agreement with each MO for ICH subscription services;
- Harmonised formats and data elements of the MPID list;
- PhPID algorithm validated for ICH E2B(R3) purposes;
- A constrained ICH document for E2B(R3) use of ISO IDMP standards.

Type of IWG Work-process and Resources

Meetings for the E2B(R3) IWG and the sub-group are expected to be held by teleconference and email. The need for face-to-face meetings will be based upon workload, progress and the need to address topics that are not well suited for resolution via TC or email. If face-to-face meetings are required, request for these meeting will be handled by the normal ICH process.
The E2B(R3) IWG should be comprised of the six ICH Parties (2 experts per Party) and ICH Observers (1 expert per Party). The E2B(R3) IWG sub-group should also reflect the composition of the IWG.