Future ICSR Specification and Related Files

In May 2005, a revised guideline for Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports (E2B(R3))was released for public consultation. The ICH Steering Committee has taken a key decision that technical specifications should no longer be developed solely within ICH, but should be created in collaboration with Standards Development Organisations (SDOs) to enable wider inter-operability across the regulatory and healthcare communities. The ICSR is the first topic to go through this process.

The International Organisation for Standards (ISO), Health Level 7 (HL7) and European Committee for Standardization (CEN) have collaborated to form the Joint Initiative through which a single, common standard for the ICSR could be advanced. ICH representatives have been heavily involved in this initiative in addition to other experts from beyond the ICH community. The overall standard is based upon the HL7 ICSR model that is capable of supporting a wide range of product types (e.g. human medicinal products, veterinary products, medical devices etc.) The framework is described in:

- ISO/DIS 27953-1 Health informatics -- Pharmacovigilance - Individual case safety report -- Part 1: The framework for adverse event reporting

The second part of the standard defined the details of the reporting requirements for human pharmaceuticals :

- ISO/ DIS 27953-2 Health informatics -- Pharmacovigilance - Individual case safety report -- Part 2: Human pharmaceutical reporting requirements for ICSR

It is envisaged that at some time in the future the standard would be extended by the addition of other Parts applicable to different product types.

The standards mentioned above have reached Draft International Standard level and are out for ballot through national standards bodies. The balloting period closes on 30 September 2009. It is also being balloted within the same timescales by HL7, CEN and the Clinical Data Interchange Standards Consortium (CDISC) which has latterly become a member of the Joint Initiative.

Proposed Use of the ISO ICSR Standard in ICH

ICH proposed to use this standard to meet the reporting requirements for E2B(R3). ICH will define the way that this standard should be used by the publication of an ICH Implementation Guide which covers the use of the fields defined by the E2B(R3) guideline. The ISO standard itself does contain some additional fields that are not used by ICH but may be used by specific regions for reporting of adverse reactions on specific product classes, not included within the ICH scope. Such use, where appropriate, will be defined by regional Implementation Guides.

ICH Public Awareness

During the ISO ballot of the Draft International Standard, the E2B(R3) and M2 Expert Working Groups of ICH has undertaken extensive testing of the standard. In order

to undertake this testing, it produced a set of documentation that was made available to the public to support testing by a wider group of stakeholders. ICH invited comment on the set of documentation until 22 July 2009. It is recognised that the time for commenting was limited, but at this stage it was important to offer the opportunity as significant change to the standard is unlikely to be achievable at a later stage.
Based upon the testing conducted and additional feedback received, ICH is providing consolidated comments into the ISO ballot and will also update the ICH Implementation Guide to make it more robust. The ICH Implementation Guide will then go through the usual ICH Step 3 consultation for a period more typical for ICH consultations.

Documents available for awareness

To download the package click here

The closing date for comments was 22 July 2009 but the documents will remain available on this page for awareness until they are superseded by revised versions for public consultation.

The documents comprise

- Electronic Transmission of Individual Case Safety Reports Message Specification - Implementation Guide (version 1.31)
- Recommendation for compatibility of data elements in E2B (R2) and E2B (R3)

Additional documents are provided for information

- ICH Test Plan
  Provided to allow awareness of how ICH will be testing the standard but also as a basis for others to undertake complimentary testing
- E2B(R3) guideline : v3.96
  The version of the guidance has been developed based upon feedback received during the Step 3 consultation in 2005 plus additional consideration during the development of the ISO standard
- Schemas
  These have been extracted from the ISO standard and can be used for testing purposes

The Draft International Standards themselves may be accessed on the ISO website but it is considered that there is sufficient information included in the ICH documents to allow assessment in the context of production of ICSRs compliant with E2B(R3)

- ISO/DIS 27953-1 Health informatics -- Pharmacovigilance - Individual case safety report -- Part 1: The framework for adverse event reporting
- ISO/DIS 27953-2 Health informatics -- Pharmacovigilance - Individual case safety report -- Part 2: Human pharmaceutical reporting requirements for ICSR