VICH/10/057
~~25 June~~4 October 2010
FINAL REVISED

CONCEPT PAPER

Proposal for the Establishment of an Electronic Standards Implementation of Adverse Event Reports Expert Working Group

It is proposed that a new VICH Expert Working Group (EWG), the Electronic Standards Implementation of Adverse Event Reports EWG (ESI EWG), be formed to implement the pharmacovigilance standards and procedures described in the guidelines developed by the existing VICH Pharmacovigilance EWG. Specifically, implementation of electronic submissions of adverse event reports (AERs) will require integration of the following VICH Guidelines;

GL24	Management of Adverse Event Reports
GL29	Management of Periodic Summary Update Reports
GL42	Data Elements for Submission of Adverse Event Reports
GL30	Controlled Lists of Terms
GL35	Electronic Standards for Transfer of Data

- GL24 defines many of the terms used in GL42, as well as the flow of information in the pharmacovigilance process.
- GL42 describes the specific data elements to be used for the submission and exchange of spontaneous AERs between marketing authorisation holders and regulatory authorities.
- GL29 defines all items submitted in the Periodic Summary Update concerning AERs. All data elements for the AERs submitted in the PSU are described in GL42. Until electronic submission (GL35) has been implemented, a subset of GL42 may be submitted as a line listing of AERs.
- GL30 provides guidance on the controlled lists of terms required to complete the data elements as identified in GL42, as well as the maintenance procedure for updating the lists of terms.
- GL35 provides recommendations to ensure secure transmission and definition of the electronic message structure. It also defines the cardinality among the data elements and contains additional technical vocabularies necessary for the valid transmission of the message.
- The objective of creating, delivering, and receiving a standardized AER is met by implementing GL35, using the vocabularies from GL30 to complete the data elements of GL42, allowing information to flow between the parties and pathways as defined in GL24.

The current situation among members and observers is:

US ~~FDA CVM~~ (Member) FDA CVM USDA CVB	Implementing electronic submission of AERs: HL7 ICSR standard (directly through electronic gateway and also web-based) Adopting HL7 ICSR standard for electronic submission of AERs
~~US USDA CVB (Member)~~	~~Adopting HL7 ICSR standard for electronic submission of AERs~~
EU~~MA~~ (Member)	~~Accepting~~ Mandatory electronic submission of AERs since November 2005: modified E2B standard ~~(~~(directly through electronic gateway and also web-based)
Japan (Member)	No known electronic submission standard
Canada (Observer)	No known electronic submission standard
Australia/NZ (Observer)	No known electronic submission standard

All VICH members and observers are awaiting the final decision by ICH on whether the ISO/HL7 ICSR messaging standard for exchange of health care information will be adopted. The US FDA has been accepting electronic adverse event reports for humans with the ICH E2B standard for many years, but will transition to the HL7 ICSR. In the EU, mandatory electronic reporting (in line with modified E2B standards) is in place since November 2005. The messaging standards being developed within ISO 27953-1 are considered as the basis for the messaging standards of pharmacovigilance information through a consortium aiming to harmonize the relevant HL7 ICSR standards up to International Organization for Standardization (ISO)/European Committee for Standardization (CEN) level. The message format is XML.

Following the completion of its mandate and sign-off of the package of pharmacovigilance GLs by the EWG and the SC (GL 35 at step 4) it is considered appropriate to dissolve the PhV EWG and establish a new group (ESI EWG) ~~be established~~ concentrating on implementation of the guidelines on electronic reporting.

Mandate

The proposed mandate of the ESI EWG is as follows:

- Provide for a continuous dialogue between VICH partners to ensure harmonized implementation of VICH GLs 24, 29, 30, 35 and 42.
- Incorporate collected comments into an implementation plan for the above guidelines for submission to the VICH SC for the 25th SC meeting
- Finalise GL 35 following public consultation at step 4.

- Creation of a VICH implementation guide for GL35 which will be in line with ISO 27953-1 Health informatics – pharmacovigilance – individual case safety reports.
- Maintenance of the standard lists of terms under GL 30.

Action Plan:

The ESI EWG will differ considerably from the ~~existing~~ previous Pharmacovigilance EWG, in that a practical understanding of the technical issues and Guidelines will be an essential component for a successful implementation. Although the ESI EWG will need experienced business members, the technical representatives must be hands-on experts knowledgeable of HL7 ICSR standard and Information Technology (IT) development with the authority to negotiate and enact decisions such that emerging issues and problems may be addressed in an efficient and timely manner.

- Each regional industry and Regulatory Authority participant will appoint at least one dedicated business expert and one dedicated technical expert, where possible and resources allow.
- Each region should ensure adequate ISO/HL7 expertise and its application to veterinary AERs and knowledge of VICH pharmacovigilance guidelines of its expert(s).

Outreach and Education Component for Industry and RAs:

Each region will need a domestic outreach and education component to be available to all interested parties. The purpose will be to provide training materials and procedures for implementing the guidelines. It is recommended that each region ensure for sufficient interaction and support for implementation to the relevant stakeholders.

Anticipated issues and problems that might arise:

- Unique descriptive wrappers will be needed to allow information to be accepted by regionally different IT systems
- Implementation and interpretation of technical documents, including ISO 27953-1
- Specific needs for regional business rule validations or if implementation issues arise for lists of values that have regional only implication with an primary emphasis on domestic reports, e.g.,
    - computerized validation of regional application numbers and registration identifiers
    - formatting differences of telephone numbers
    - validation of states and provinces
    - dictionary list choices vs. text fields
    - confusion in identification of third party reports
- Implementation of various Guidelines, such as reporting on domestic and foreign reports pursuant to GL24