

Highlights of the SG2 meeting held Oct 18-20, 1999 in Minneapolis, Minnesota

Several updates were given on various projects, including the status of:

- the document review process: now under the direction of Beth Pieterston, Health Canada and Chair GHTF
- SG2 N27 R2: Terms and Definitions document: because of universal application to other study groups, SG2 will invite other SGs to participate in the development of the document. This will prevent conflicts of definitions of terms found in multiple SG documents. SG2 will take lead in taking the document through the proper GHTF clearances
- Dating of web postings: suggestion to date when postings are placed on GHTF website were forwarded to Health Canada, and will be followed up by HC representative.
- GMDM project update given. Project completion now anticipated by spring 2000.

Feedback received by FDA on the SG2 N21 R8:Manufacturers Reporting guidance (title abbreviated) reviewed with members. NO other feedback received. All members encouraged to make sure the document is well disseminated and available for public comment.

Implementation of N21 was reviewed by each NCA in attendance. It was recognized that implementation within the European countries (including those awaiting inclusion into the EU, and the EFTA countries) is dependent on translation of the guidance into a MedDev document. This process has not been initiated. It is unclear what process must take place, or who has actual responsibility for assuring progress of this goal. European industry and NCA representatives agreed that it may be helpful for them to collectively put forward a request for action to the European Commission. Otherwise, Australia, Canada, Japan, and the US also acknowledge that changes are necessary in order within current regulatory structures or guidelines in order to get to the harmonization recommendations, and are being pursued.

A lively discussion was held on the topic of "Use Error". Public comments received by FDA and other nations was presented and discussed, as were some examples of definitions of "use error". Several NCA representatives expressed concern that failure to receive reports on malfunction reports associated with use error mean the NCA will not learn about problems until they are associated with more serious outcomes, such as serious illness or death. That seems contrary to our stated SG2 mission and goals, in addition to being potentially politically dangerous. Industry representatives also expressed strong concerns over the anticipated over-reporting of "useless reports". After several hours of debate and discussion, it was recognized that no consensus could be reached during this meeting.

A report was given on the status of the Vigilance Report exchange pilot. A majority of respondents indicated that the reports received were considered valuable, however not all reports had been evaluated by all participant NCAs. Several changes were suggested to minimize duplication of information on the report form, and it was agreed that we need to continue the pilot for another six months, to further refine the process.

Projects presented and discussed:

- Reporting timeframes: a new sub-group was formed to define "immediate report", and clarify guidance for general timeframes and 'immediate' timeframes
- The concept of a "universal report format" was discussed. Reporting elements from SG2 N7 R2: Manufacturer Minimum Data Set serve as the basis for a universal format. The FDA 3500A form and the EU Reporting form were reviewed to identify which elements were included within the minimum data set. Other elements reviewed and discussed how they might be addressed. It was generally agreed that reporting guidance will help clarify what information is needed, and where the information should be provided on the form.

- SG2 N30:Common and Well-characterized Adverse Event : new format and data presented. Originally it was anticipated that the posting of the document would illustrate where various reporting alternatives currently exist, and could serve as a reference or resource for others interested in similar options. Following discussions at the meeting, it was decided that it is premature to post such a list, since the reporting alternatives are not harmonized, but found mainly in FDA. The information will be provided to SG2 members, but will not be made public until such time as there is greater global involvement.
- Review of what we are trying to accomplish within our vigilance exchange program, and where we are going was presented and discussed. It was determined that we need to continue our current processes for the present, and revisit potential future ideas at a later date.

It was announced that TC210 agreed to develop a coding manual for device problem codes associated with medical device related adverse event reports.

A brief report was given to help clarify the current activities of ISO 9000. Apparently, newly released information about the project is not clear, and was found by some to be disappointing.

SG2 will meet next in London. Exact dates to be confirmed, but anticipated in March 2000. Agenda to be developed at a later date.

Deb Blum, Exec Sec, SG2