

**Meeting Summary**  
**Study Group 2 Meeting**  
**March 16-17, 2000 (London, United Kingdom)**

The meeting was attended by twenty members of SG2 and three observers. Dr. Larry Kessler, Chair of SG2, presided over an equal number of representatives from the national competent authorities (NCAs) and medical devices industry (including ECRI). Of special note, the members bid farewell to Jacob Nordan of Norway, and Mr. Ron Dale of the United Kingdom. In addition, several new SG2 participants attended, including:

- Mr. Bo Hojdefors, representing the European Commission
- Mr. Thomas Colson, representing the French
- Mr. Philippe Auclair, representing EUCOMED

The primary discussions centered around four main SG2 projects. Those projects, in random order, are:

- 1) SG2 N20 and N25: Guidance for NCA reporting to other NCAs, also called Vigilance Reports, and the NCA report form
- 2) SG2 N32: Universal Format for Manufacturers Medical Device Adverse Event Report to the NCA
- 3) SG2 N 33: Harmonization of Timeframes for Manufacturer Postmarket Medical Device Adverse Event Reporting to the NCA
- 4) SG2 N36: Manufacturers Medical Device Adverse Event Report Trending

**1) SG2 N20 and N25: Guidance for NCA reporting to other NCAs, also called Vigilance Reports, and the NCA report form**

In summary, the discussion about SG2 N20 and N25 was focused on review of the current criteria used to generate a NCAR, and the actual format of the NCAR. No change was made to the criteria elements, but additional clarification will be added to the guidance on how to complete the form itself. NCAR numbering conventions have been clarified and will now reflect an annual cumulative number so that it will be easier for recipients to determine if they are missing any reports. Additionally the GHTF web site for SG2 will be amended to include a list of the reference numbers of all NCARs issued.

Various aspects of the NCARs were presented. Evaluations indicate the NCARs are useful and have triggered additional action by some recipient NCAs. Most evaluations indicate a preference for “active exchange” verses “passive exchange”, so we will continue the active exchange via internet email. The NCARs currently use Microsoft Word. It was decided to retain that format so NCAs can readily cut, copy and paste the data as desired for internal purposes.

One concern noted is the potential increased workload and resource drain after we get out of the pilot phase and more NCAs want to participate.

SG2 recommends that the NCAR pilot end as scheduled in June 2000. In order to overcome some of the resource issues associated with an expanded resource needs, SG2 recommends the creation of an application process for joining the NCAR program. SG2 suggests the applicant will agree to certain pre-requisites. Some of the pre-requisites include: be an active participant of GHTF, have an active postmarket medical device adverse event reporting program, participate in training, and financially support the program. SG2 will prepare a formal proposal on the application process and present it to the GHTF under the SG2 Chair's signature.

**2) SG2 N32: Universal Format for Manufacturers Medical Device Adverse Event Report to the NCA**

The discussion about SG2 N32 was very specific to the individual data elements which are part of universal data set. The universal data set is a set of data on a medical device related adverse event, prepared by the manufacturer, and that is universally accepted by all NCAs to whom the report is submitted. The universal data set *is not* a maximum data set, and does not necessarily include all information the NCA might require on a specific event.

The universal data set is considered by some to be too inclusive, and by others to be too dependent on guidance. Subsequently, SG2 industry members are tasked with evaluating the data elements to identify which ones are particularly difficult to obtain or are not applicable to a particular product line. The SG2 regulator members are tasked with evaluating the data elements to determine which ones are critical to internal job requirements. This topic will be further discussed at the next SG2 meeting.

**3) SG2 N 33: Harmonization of Timeframes for Manufacturer Postmarket Medical Device Adverse Event Reporting to the NCA**

This document proposes guidance on the maximum number of days that might elapse before a manufacturer must file a reportable event to the NCA. This project focuses on a single or first report to the NCA. New terms and definitions were added to the draft document. This guidance document is in the working draft phase, and is not ready to be disseminated publicly.

**4) SG2 N36: Manufacturers Medical Device Adverse Event Report Trending**

Discussion on this document was greatly facilitated by the efforts that were accomplished between SG2 meetings. Members received and commented on the guidance document prior to the London meeting.

Thus at this meeting the document reflected the previous suggestions, and the new changes were limited to minor clarifications rather than substantial changes to content. SG2 recommends a

proposal to GHTF to move this guidance forward as to “Proposed Document” status, so that we may release it for public comment.

Other topics were discussed that do not represent areas of general public interest, but are of importance to SG2 members. These other topics will be presented in the future should they become of broader interest.

Meeting Record prepared and submitted by Deb Blum, SG2 Executive Secretary  
March 30, 2000