

Notes from Breakout Session on Data Analysis/Signal Detection,
MedDRA User Group Meeting, 20 June 2002

led by T. Moraleda Garcia;

Tomas opened the session with his slide of “Topics for Discussion” (see his slide for specific topics displayed).

The first issue discussed was decisions to code symptoms *vs.* diagnoses. One user commented that the decision to code symptoms *vs.* diagnosis was made by the medical monitors at her company. Patty reminded the users of the coding principles in the “MedDRA Term Selection: Points to Consider” (PTC) document, and she asked if users knew of and used this document. Some users indicated that they do use it, but they noted that the document sometimes presented choices rather than one way to do it. JoAnn related to the users some of the philosophy behind the PTC document and why it is like that.

Users were asked if they felt MedDRA makes medical help more necessary when coding. To emphasize the point, Tomas showed a series of slides which reinforced the greater specificity/granularity of MedDRA. Some users felt that it did require more medical input.

Another issue brought up was whether the granularity of the PTs helps or hinders signal detection. An experienced MedDRA user from a large pharmaceutical company indicated that it both helps and hinders signal detection. It helps because the specificity of the PT points to the specific issue of concern. To overcome the hinderance at signal detection, this individual described how his company has grouped terms in a way to make it work better for them.

The discussion above led to the description of the MSSO’s current initiatives for MedDRA Analytical Groups (MAGs). After this was introduced, it was clear that this had enthusiastic support from the users. Some even suggested new MAGs after Tomas showed a slide of the proposed MAGs under development (e.g., one for “lack of effect” concept, one for “death”, one for “hypertension”, etc.). It was clear from the discussions that the users either do not use the current Special Search Categories at all or use them in a very limited capacity. One concern raised by a user was that the MAGs would add a new field to the MedDRA files, but Jim indicated his commitment to keeping the file structure more or less intact as it is.

A user had a very specific question that she posed to the other users, namely, how would one handle the term “bereavement” as an adverse event. Other users responded that MedDRA does allow for coding of that concept, but that most would recommend a query to the investigator/reporter to clarify if this was really an adverse event. A general discussion of the issue of internal coding conventions also ensued.

Another user asked if people have a re-look at legacy data after conversion to MedDRA. Some answered that they do an analysis to check for differences in coding, but the

differences are not usually surprising. Tomas showed some slides that reinforced this concept.

The issue of labels using MedDRA was also brought up. Another experienced MedDRA user from a biopharmaceutical company indicated that, at his company, there had been some resistance to the idea of changing labels to MedDRA due to the greater specificity of the terms. It was also noted that the FDA and EMEA seem to be uncoordinated in their approach to using MedDRA in product labels.

Another user noted that we should consider having MedDRA linked to terminologies used in computer based medical records.

Finally, in reference to signal detection, the users were asked if the HLT had any role to play in signal detection. It was indicated that the HLT has been used to further investigate a potential signal that was not analyzable at the PT level, but that HLTs in general are not useful for signal detection.