Note from Dr Garcia, Chair Study Group 2

I have attached SG2 N87R7 (PD) for the consideration of the Steering Committee at their next meeting in Lübeck.

The document is unusual in that it comprises multiple parts that relate to electronic adverse event reporting by manufacturers to NCAs. Because of this the separate parts have been packaged into a single "ZIP" file bundle. The bundle contains the (cover) guidance document, an Excel spreadsheet which describes the code in detail and several files containing the code itself which can then be used in conjunction with software such as word processors and databases to "code" and "decode" the information contained in electronic reports compiled in accordance with SG2 N87R7 PD.

I hope this is clear. Computer jargon is not easy to explain in plain English

Warm regards

Jorge Garcia
Chair, GHTF SG2

1 May 2006