Draft revised version of detailed guidance on the collection, verification and presentation of adverse reaction reports arising from Clinical Tials ('CT-3')

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COMMENTS FROM - F. Hoffmann-La-Roche, Basel September 7, 2010

GENERAL COMMENTS

F. Hoffmann-La Roche appreciates the possibility to comment on short-term improvements/clarifications of the detailed rules for safety reporting, although they have to be limited to what is possible under the current legal framework.

SPECIFIC COMMENTS ON TEXT

GUIDELINE SECTION TITLE

Section/Line no. + paragraph no. Or the item No.	Commission position	Suggestion/Proposed change
Point 3 under section 1.1, last line	clinical trials on medicinal products for human use (hereinafter referred to as 'delegated person'), as well as investigators, should consider this guidance when	clinical trials on medicinal products for human use (hereinafter referred to as'delegated person'), as well as investigators, are recommended to follow this guidance
Title 2.2.2.	Title - Serious event	Should be Serious adverse event
point 16 under 2.2.2	Medical events may jeopardise the clinical trial participant…	What is exactly meant by this? Either clarify or Suggest to delete, as this is very difficult to interpret.
Section 2.3 point 19	"the immediate report….should not exceed 48H"	Replace 48 H by "Two working days**".**

Section 2.3.2	Non-immediate reporting ---- [suggestion to add protocol]	In cases where reporting is not required immediately (see section 2.3) the investigator shall report within the appropriate timeframe taking account of the specificities of the trial and of the serious adverse event, as well as possible guidance in the IB and/or the protocol
Section 4.2.3. point 34	Unexpectedness	It should be stated that …..the appropriate reference document should be mentioned in the protocol
Under sections 4.3.3 point 45	…..expectedness assessment given by the investigator…….	Comment- …Investigators do not always have the complete overview of the safety profile (although most of it available is in the IB).
Section 4.4 point 46 Line 11	"sponsored by another sponsor who is either part of the same mother company or who holds a development agreement with the sponsor.	Clarify whether an investigator initiated trial for which a pharmaceutical company provides financial support and for which there is a PV agreement falls into this category (indeed, a PV agreement is not a development agreement) eventually add PV agreement if appropriate in the text.
Section 4.4 point 47	While the transitional reporting procedures still apply, additional SUSARs should be reported to Member States (cf. Section 4.7.3.3).	This is not very clear. Please explain the situation with an example of what is meant by transitional.
Section 4.5 Paragraph 48 Line 1,2,3,4	" there is no need for the sponsor to report adverse reactions not related to the IMP but related to a non IMP received by the subject"	It is clear that these cases should not be reported within the frame of Directive 2001/20/EC Clarify whether they should be reported within the frame of directive 2001/83/EC and by whom.