RQA GCP Committee Comments on GL_1

Ethical considerations for clinical trials on medicinal products conducted with minors

Comment no.	General Comment (if any)	Outcome (if any)
1	Section 5 Definitions/Glossary contains many aspects which could be more usefully incorporated into later sections, particularly where they go beyond the immediate provision of a definitions. This would result in a more focussed and accessible document to be used as a reference by researchers. For example, 5.3 contains much guidance that could belong in Section 6; Section 5.5 seems to be a policy statement rather than a definition of ethical review.	
2	Certain detailed aspects of the document could be omitted where they are not inherent to trials with minors, resulting in a more focussed document. Examples are given in the next section (*).	
Line Number(s)	Comment and rationale; proposed changes If changes to the wording are suggested, they are highlighted	
466 – 468	Regarding actions when a subject who was a minor becomes legally competent during the trial, more guidance would be welcome to manage the transition pragmatically without unwarranted interruptions, e.g. in trial treatment. Points to consider might include the interval between routine study visits and whether an unscheduled visit would be needed.	
469 – 476	Regarding a legally-competent adolescent subject deciding to include their parent(s) in the consent process, more guidance is suggested on capturing that involvement in the trial records, even though it may not be required legally.	
482 – 490	It is not clear how this section relates to minors – is it perhaps intended to assist families supporting the minor in the informed consent process?	
772 – 774 835 – 843 863 – 882 1259 – 1265 1489 – 1519	* These are considerations for any trial, not just those involving minors or the special relevance to trials with minors is not made clear. They could be omitted from the document or the particular relevant to trials with minors stressed more clearly.	