European Medicines Agency

SUBMISSION OF COMMENTS ON : Guideline on GCP specific to Advanced Therapy Medicinal Products , Draft Version 2 July 2008-10-01

Public Consultation: 15 October 2008

COMMENTS FROM Paul Ehrlich Institut
GENERAL COMMENTS

SPECIFIC COMMENTS ON TEXT

GUIDELINE SECTION TITLE

Line no[1]. + paragraph no.	**Comment and Rationale**	**Proposed change (if applicable)**
2.3.2 Responsibilities (p5/14)	2.3.2.1. Responsibility of the sponsor Comment: To ensure prompt action of the overall responsible sponsor in urgent cases (e.g. serious adverse events) he must have all data on traceability available at any time. We refer to the responsibilities laid down for blood products.	Proposal to add the following sentence: The sponsor must have all data available at any time
2.3.3. Archiving responsibilities of the sponsor, manufacturer and the investigator/institution for traceability (p.6/14)	Donation identification that will include at least: • Identification of the procurement organisation… • Unique Donation ID number • …. Comment: It should be added the bullet point "Unique Donor/animal number" as a donation can include several donors which has to be identified	Additional bullet point: Unique Donor /animal number

[1] Where available

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2.4.1. Notification of Adverse Events and Reactions (p. 8/14)	" New events related to the conduct of the trial or the development of the ATIMP and likely to affect the safety of the subjects should be reported" Comment: It must be clear that the reporting lines for serious adverse events must be the same as already regulated generally.	" New events related to the conduct of the trial or the development of the ATIMP and likely to affect the safety of the subjects should be reported" according to the existing timelines for expedited reporting
2.4.1. Notification of Adverse Events and Reactions (p. 8/14)	" a significant hazard to the subject population such as lack of efficacy of an investigational medicinal product used for the treatment of a life-threatening disease." Comment: The wording should be clarified. The development of an ATIMP is usually discontinued if there is a lack of efficacy. This applies not only to life-threatening disease. An example would be helpful to clarify this.	
2.8 Protocol	Instructions to ensure the blinding of the trial where the person involved at the clinical site in the preparation of the ATIMP cannot to be **unblinded** whilst the person responsible for the administration of the ATIMP needs to be blinded;	Should this read "blinded"?

Please feel free to add more rows if needed.