31 October 2014

Submission of comments on '<Draft Functional specifications for the EU portal and EU database to be audited>' (EMA/42176/2014 Corr.)

Comments from:

Name of organisation or individual
European Society for Paediatric Oncology - SIOPE

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF).

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	SIOPE, on behalf of the European Paediatric Oncology Clinical Research community welcomes the opportunity to comment on the draft specifications for the EU Portal and EU Database in preparation for the implementation of the Clinical Trials Regulation. Whilst it is crucial that the implementation of the Clinical Trial Regulation is not delayed, SIOPE would like to reiterate the importance of ensuring robust functionality of the EU Portal and EU Database and appreciate this public consultation on the auditable functionality. Some specific comments are included below, however greater detail on both the specifications for the auditable functionality and the broader functionality. For this reason, we feel that it is essential that further consultations will be incorporated into the on-going development of the full functionality of the EU Portal and EU Database, including those not included in the audit. We strongly support full testing of the system by stakeholders, including academic sponsors ahead of the system going live. We are pleased that as a result of the Clinical Trial Regulation there will be a uniform EU portal for submission of clinical trials but we remain concerned that there will still be a requirement to satisfy multiple national requirements in order to secure approval.	

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
Line 89 (Table 1) on Page 7, Last row - Req. 9		**Comment:** The document refers to the requirement of stakeholders who are submitting the study for a marketing authorisation to submit a Clinical Study Report. There does not appear to be any reference the requirements for trials not undertaken for marketing authorisation to upload a summary of the results (as specified in Annex 4 of the Clinical Trial Regulation) which includes a lay summary for all trials. **Proposed changes:** Functionality to upload a summary of the results (as specified in Annex 4 of the Clinical Trial Regulation) which includes a lay summary for all trials needs to be provided and the distinction needs to be made from the end of trial report submitted for marketing authorisation.	
Lines 90 – 95 and Line 134 (Table 2) on Page 12, No 1.1		**Comment:** User access management refers to the system enabling MS and the Sponsor to create and log on with their own credentials, administer their own group, assign roles, enable electronic signatures etc. and user registration and authentication. As discussed at the stakeholders meetings, academic sponsors usually consist of very few individuals and most sponsor activity is delegated to a third party (e.g. clinical trials unit or clinical research organisation). **Proposed changes:** It is therefore imperative that 1) more than one person at the sponsor's level has high level permissions to create and manage the user groups	

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		2) all activity for a trial can be easily delegated to a third party. The delegation of numerous individual tasks would be extremely laborious and time consuming and many academic sponsors will not have the man power to undertake this role. Hence it should be possible for a sponsor to delegate all tasks easily and simultaneously while maintaining read-write access themselves. This is unless it is envisaged that the "super user" resides in an organisation other than the sponsor's office in which case I would be concerned if there was no verification system in place to check that that third party has been given approval to create the trial in the database on behalf of the sponsor.	
Line 134 (Table 2) on Page 12, No 1.1, Last row in 'Details' column		**Comment and proposed changes:** Last row text states "Enable the Trial Number to be …." Please clarify - does this mean EU CT number sometimes referred to as EU trial number (e.g. page 26, No 4.5)? If so, terminology needs to be consistent.	
Line 137 (Table 2) on Page 23, No 3.10		**Comment and proposed changes:** Referring to the search functionalities to be built into the database; whilst appreciating that this is not a full list of search criteria, it is essential that the facility to search by Sponsor is included.	
Line 138 (Annex 1) on Page 27, Point 3.		**Comment:** The section seems to imply that the reporting capabilities will only be available to the Member States. **Proposed changes:** The reporting functionality should also be made available to the Sponsors	

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Line 137 (Table 2) on Page 24, No 3.11		**Comment:** We are supportive of the proposed training and help for users. **Proposed changes:** The provision of a training version of the database would be a great advantage, facilitating the training of all staff who will have to access this system.	
Line 137 (Table 2) on Pages 24-25, No's 3.13 and 4.1		**Comment:** Within the workspace functionality there is functionality specified that allows records to be altered or deleted by the system administrators. This is a concern and we would welcome information on EMA's rationale for this specification.	
Line 134 (Table 2) on Page 12, No 1.1		**Comment:** We are unclear on the definition of a 'super user' in the context of this document. It is also unclear how a super-user would be defined in the context of co-sponsorship as described in the Clinical Trial Regulation.	
Line 138 (Annex 1) on Page 27, Point 2		**Comment:** The text refers to a reduction in administrative burden for NCAs, which in itself implies that there will still be parallel systems where study sponsors will still have to deal with several different NCAs **and** the EU portal system. There are positive examples that NCAs try to harmonize their procedures, for example: http://www.pei.de/EN/information/license-applicants/clinical-trial-authorisation/electronic-submission-applications/electronic-submission-applications-node.html	

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		Proposed changes: The EU portal should replace the systems which are now in use by NCAs or will be implemented until the EU portal and the EU databases have achieved full functionality. An example is the "Electronic submission of applications for the authorisation of clinical trials for investigational medicinal products" of the Paul-Ehrlich-Institute in Germany. It should not be necessary for sponsors to use and to meet the requirements of more than one electronic submission system. Also, the requirements of different NCAs should be discussed in public. Ideally, there should be no different national requirements for submissions. In addition: In order to simplify submissions in the EC and the US the EC-portal should - as far as possible and useful - resemble or be compatible with the FDA Electronic Submissions Gateway.	
		Additional comment: There needs to be a function to add a member state to the application retrospectively.	

Please add more rows if needed.