Association of Clinical Research Organizations Comments in Response to the European Commission Public Consultation on the "Implementing Technical Guidance- List of Fields for Result-Related Information to be Submitted to the 'EudraCT' Clinical Trials Database, and to be made Public, In Accordance with Article 57(2) of Regulation (EC) NO 726/2004 and Article 41 of Regulation (EC) NO 1901/2006 and their Implementing Guidelines 2008/C168/02 AND 2009/C28/01"

30 September 2010

I. Introduction

The Association of Clinical Research Organizations (ACRO) represents the world's leading clinical research organizations (CROs). Our member companies provide a wide range of specialized services across the entire spectrum of development for new drugs, biologics and medical devices, from pre-clinical, proof of concept and first-in-man studies through postapproval and pharmacovigilance research. Each year, ACRO member companies conduct more than 9,000 clinical trials involving nearly 2 million participants in 115 countries. With more than 66,000 employees engaged in research activities around the world, of which over 23,000 are located in the European Union/European Economic Area (EEA), ACRO advances clinical outsourcing to improve the quality, safety, and efficiency of biomedical research.

The European Commission's Public Consultation on the draft Implementing Technical Guidance on the list of fields for result-related information to be submitted to the EudraCT clinical trials database provides a welcome opportunity to help shape the manner in which key result-related information will be made accessible on EudraCT. As a stakeholder in the clinical trials process, ACRO is pleased to submit comments on the above-referenced Guidance during the public consultation on behalf of the global CRO industry.

II. General Comments

1. ACRO welcomes the high degree of consistency that is seen between the ClinicalTrials.gov and EudraCT database in relation to public access of protocol and results data for clinical trials. Review of the EudraCT fields to be made public was facilitated by the format that the commission used to publish the fields, showing them in comparison to the ClinicalTrial.gov fields that are currently in use. We feel that Industry should be informed of any updates or changes that will be made to ClinicalTrials.gov to further align the two systems.

2. ACRO understands the information will be uploaded into the database by uploading an XML file, via the web interface or using a gateway technology. It would be useful to better understand in layman's terms how this would be achieved. We believe the first two options are consistent with current practice for preparing the clinical trial application, but it would be useful to have clarification on this as well as explanation of the gateway technology and what this would mean for end users.

3. ACRO requests clarification on whether the results will be submitted/uploaded on a per trial basis or a per country basis.

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4. ACRO feels that it would be helpful to consider how uploading of results data from EudraCT would fit in with the currently employed practices of results publication (e.g. Clinical Study Report). As most Competent Authorities only require the synopsis, will the requirement for the Clinical Study Report submission continue to be a requirement as well?

5. ACRO believes that Sponsors will need to employ diligent Quality Control (QC) processes to ensure that the results loaded onto the EudraCT database are aligned with that loaded on Clinicaltrials.gov.

III. Specific Comments

B.5 Further information contact (R1-R5)

- New for EudraCT (although we note that France has something similar for their national database)
- What are the requirements for this contact?
    I. Telephone number & e-mail is requested – what are the language capabilities required (e.g. EudraCT database is in English for many countries, therefore is English sufficient or must other languages be included?)
    II. Is it necessary to provide both email and telephone? We believe that the requirement to provide a telephone helpdesk may be an onerous undertaking for smaller Sponsors

Certain agreements (R6- …)

- ClinicalTrials.gov allows declaration of financial interest to be made (e.g. does Investigator work for Sponsor).
    I. Does the EudraCT system make provision for this?

R10 Protection of participants

- The sponsor is required to report paediatric populations and other vulnerable groups participating in the clinical trial are protected against various sources of harm. Measures to minimise distress, pain, risk, etc. are required for inclusion
    I. As the trial must be approved by an Ethics committee, we would expect that all of these issues had been adequately addressed during the review process. Can the Commission expand on the rationale for publishing this information?

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