DATE: 30 September 2010

SUBMISSION OF COMMENTS ON:

Draft 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 (SANCO/C/8/SF D(2010) 326416)

Submitted by:

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1. General comments

Stakeholder number	General comments	Outcome (if applicable)
	EuropaBio welcomes the draft guidance which will facilitate public disclosure of the results of clinical trials conducted in Europe and conducted outside Europe when part of a paediatric investigation plan. We thank the European Commission for the extensive mapping of EudraCT fields to existing fields in ClinicalTrials.gov which facilitates preparation for the implementation. While overall we very much support this policy objective we do have some important concerns over the manner in which the Commission is proposing to implement certain technical aspects, as set out in the draft guidance. We would like to emphasise that our concerns are not related to the act of publication of these data, indeed we fully support the principle of making this information publicly available. We believe that there should be an appropriate balance that benefits public health while maintaining an environment that protects inventions and intellectual property.	
	1. Our concerns largely relate to the unconditional timing of publication. We are concerned about the potential consequences of the publication of some clinical trial results on **non-authorised medicines** in the context of the current data and marketing exclusivity framework in Europe. Our concern is that the mandatory and systematic publication of all clinical trial results on unauthorised products within 12 months of the end of the trial, might lead to attempts to use these results as bibliographic references in applications submitted under the "mixed marketing" or "well-established medicinal use" authorisation routes, and this could undermine the current level of regulatory data protection that is established in Europe. In addition, we are concerned that the publication of such information via the EudraCT database could also undermine the level of protection available in countries outside Europe. 2. We welcome the efforts to seek harmonisation with the data requirements for ClinicalTrials.gov in the US. This will minimise administrative burdens for sponsors (particularly SMEs) and help ensure that	

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	there is not a confusing picture of clinical trials in the public domain. However we are concerned that disclosure of some of the information proposed as being required for EudraCT but which is not required for ClinicalTrials.gov - particularly as public disclosure is required prior to product authorisation - will on some occasions not give sponsors sufficient time to take the actions necessary to protect their intellectual property interests. This is because there may not be enough time to submit a patent application which includes supporting findings from the trial. Public disclosure via EudraCT may prevent patentability as it will be considered prior art. This is a concern for additional requirements related to the dosage in P12 (interventional details) and age ranges in R41 (Baseline variable). In those circumstances where there is an issue with regard to patentability we strongly suggest that the sponsor is able to delay the submission of this information. In addition, it is important that "Population" and "Background Therapy" information described as "optional" remains optional for the same reason. We recommend that these fields are clearly labelled as optional. 3. The timing of the public disclosure of results for unauthorised medicines raises a concern that the molecular structure of the investigational medicinal product will be disclosed (via the CAS number) with the results of the trial at an early stage of development. We believe that this does not provide sufficient protection for innovator companies who are leading or pioneering research in particular areas. Furthermore, there may be instances where disclosure of the CAS number prevents the sponsor from obtaining patent protection. We recommend that it should be possible to delay disclosure of the CAS number until phase III results are submitted. 4. The adverse event data required by the guidance differs in some aspects from that required by ClinicalTrials.gov. We urge the Commission to seek consensus on the information required. 5. We welcome the recognition that retrospective submission of results of completed studies would be overly burdensome for sponsors. We therefore support the approach of being able to provide a .pdf file of a medical journal article or a synopsis that is in accordance with ICH E3 guidance. We suggest that as an alternative it should be possible to provide a hypertext link to a result summary which may exist on	

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	another database. 6. We request that duplicate data entry (i.e. same data entry in more than one field) is avoided in the database design. 7. Clarification of Section 2 sub-section 'Language' in the draft guidance is required. An alternative wording for this sub-section is proposed: *"In order to enable search and reporting functions, data will be entered in English whenever possible. Where feasible dropdown menus/picklists may be provided in the official languages. It is recognised that not all dictionaries will be available in all official languages and may initially exist only in English. Translations of dictionaries will only be used where the originators of the dictionaries make full and current versions available." (The source of this alternative text is an extract of that originally used in ENTR/CT5).*	