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EORTC reply to the public consultation
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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

General comment: major issues

1) Following the document, results are to be made public 5 days after submission (so, 1 year and 5 days after the end of the trial) – In our opinion and given a quite exhaustive list of items to be collected, which include primary endpoints this delay is too short in case a publication is under submission to a journal or to any symposium (such as ASCO). Indeed, organizers / publishers frequently ask to be the first source of release of results. Some publications may partially lose their interest if results are already made public. Moreover, some results need careful interpretation and should not be released without comments. We suggest sponsor should have a possibility to extend this delay of 5 days by a maximum of 1 year (for justified reasons, which should include publication).

2) Language: it is essential to mention allow English-only entries as being sufficient for international trials". It should also be prohibited member states construct their own databases for result collection.

3) List of required fields is very extensive:
    1. it is essential that for protocol related information fields are populated automatically from EudraCT without any re-formulation or re-encoding;
    2. we would also like to suggest to extent the possibility of attaching pdf of a publication instead of coding results to future trials (currently this is only envisaged for trials which will be already ended for more than 6 months/ 1 year prior to this system being functional);
    3. the risk this step will lead again to the increase of costs of clinical trials instead of simplifying should be taken into consideration (given the time the one would need to spend to correctly complete all fields required)
    4. the worthwhile of some fields (e.i R10: measures to protect participants being communicated at the end of the trial when everybody is already treated) is doubtful
    5. some of results may concern endpoints, not yet mature data at time of reporting. Disclosure of such a data prematurely may lead readers to an erroneous conclusion. Sponsor should have a possibility to complete "not yet mature" instead of real results.

In details:

Page& section	Text	Comment
p. 3 “processing”	“They will be linked to the protocol related data, where the later are available in EudraCT”	Given publication of results is applicable to clinical trials run in EU, it is not clear how protocol related data may not be available
p. 3 “timing”	“… within 5 working days…”	We would propose to add: “in dully justified cases (including publications or presentation of abstracts) an extension of this delay by a maximum of 1 year may be requested by the sponsor”
p. 3 “language”		At the end of the section we would propose to add: “For multi-national trials, entries only available in English will be accepted as valid. No translation will be asked to the sponsor”
p. 3 “follow-up submission”	“the results-related data of a given trial may be locked …. after a period to be established…”	It is not clear where the responsibility for the update of results stops, nor is it clear on who establishes the necessity to lock and the period when it should happened. We propose to modify as follows: “the results-related data of a given trial <u>will</u> be locked …. after a period to be established <u>by the sponsor</u>…. No further update will be required, unless sponsor would request an unlock for justified reasons.” It is also not clear how the 5 working days upload will take place if data are not locked… Moreover, previous versions may be just a result of a human error – we do not see the pertinence of keeping it available for review.
p.4		Before the non-compliance section we would like to add another section “Alternative submission process” to allow all or part of fields is replaced by a pdf file of a publication <u>for all trials</u>
Annex A p1		It is not clear why this field is asked at the time of results as it is already part of the protocol related information (may be not fully “lay” language is used, but the information is present)
Annex A p3		Title of the section “date of global end of the trial” is inconsistent with the description “when the data was collected” – sometimes it is the same date, sometimes not. Proposal of description “date declared to CA/EC as date of the end of the trial”
Annex A p4		The aim of this section is not clear, the description sound like a definition. The information on whether or not trial is open or blinded is part of the protocol related

		information and explanation would be more appropriate to be provided as a general glossary (maintained by the agency) and not trial by trial.
Annex A p6		Same remark as above – already part of protocol related information or needs to be explained in a general glossary to be maintained by the agency
Annex A p7		This information is protocol related, though is not collected through EudraCT – this question is frequently asked by ECs – harmonizing and centralizing EC submissions would make this field available earlier and potentially through EudraCT – if for instance module II of EudraCT (in English for multi-national trials) would be imposed to all ECies with a given format and with xml behind
Annex A p8-11		Should be extracted from EudraCT (for p11 – EudraCT instructs not to put INN if trade name is available…)
Annex A p12		Partially duplicated with EudraCT and quite duplicated with most of EC forms so same comment as above – see p7)
Annex A p14		This guidance is about fields to be made public 5 days after the 1 year post end of trial – so how is this compatible with a day-to-day update of status of recruitment?
Annex A p15		We suggest allowing an attachment of the list of publications instead of completion. It is not clear up to when sponsor is required to complete this field (some trials may have additional publications decades after its ned)
Annex A p16		The difference with p15 is not clear.
Annex B R-11 & R-12		How this can be completed for a trial with more than 200 locations with 350 characters?
Annex B R-13 & R-14		Already part of protocol related information
Annex B R-15		Information on NIMPs is required in the cover letter – why not incorporating this into EudraCT (protocol related)
Annex B R60-61		Fields should appear only of in EudraCT this was mentioned as applicable to the trial.
Annex B R-115		What is the possibility of the sponsor to react if not in agreement with CA comments?
Annex B R-128		The relevance of listing amendments is not clear at the end of the trial.