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>

Comments from:

Name of organisation or individual
EFPIA

1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	Guidance	
	EFPIA welcomes the publication of this draft implementing technical guidance which represents another important step forward for the policy initiative aimed at improving the transparency of clinical trials information in Europe. EFPIA fully supports this policy initiative and we would therefore like to point to some possible inadvertent consequences of this guidance that largely relate to the timing of public disclosure. We believe these are important issues that could negatively impact research and medicine in Europe.	

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	We provide some possible solutions that we believe strike the right balance between transparency and protecting the legitimate business interests of industry. We welcome and applaud the approach of seeking to harmonise this guidance with the data requirements for clinicaltrials.gov in the US. This helps ensure that patients and other stakeholders are not confused by different clinical trial information being publicly disclosed in different global databases for the same study and avoids additional significant administrative burden for sponsors. In this regard we urge the Commission to only change the wording related to the description of the data field where the regulatory terminology is different in the EU compared with the US, or where the data to be disclosed is expected to be different. Changing the wording for other reasons is likely to cause confusion amongst sponsors as to whether the same or different data is required in the EU (e.g.” Reasons not Completed” R27 requires the same information but is described slightly differently). The key difference between the US and the EU is that the Commission requires that results of trials of unapproved medicinal products be submitted and made publicly available within 6-12 months of completion as opposed to within 30 days of first	

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	approval of the medicinal product in the US for trials that support the approval. We have previously raised significant questions and concerns related to whether this proposed EU timing is the correct interpretation of primary legislation and whether the Commission has adequately assessed the possible negative impacts on the protection of regulatory data particularly in countries lacking data exclusivity legislation or where such legislation is dissimilar to that of the EU. **We still have these important and fundamental concerns relating to the timing of public disclosure of results of medicinal products before approval.** Nonetheless, we recognise that the Commission has confirmed that the results of trials of unapproved medicinal products are to be submitted and made publicly available within 6-12 months of completion. To that end we have carefully reviewed each data field to consider whether early disclosure could inadvertently have a negative impact on our ability to deliver medicines to patients by adversely limiting our ability to: protect our legitimate business interests; seek patent protection for our inventions; and conduct research in Europe. We have also carefully reviewed each difference with the data requirements for clinicaltrials.gov to consider whether the resulting lack of harmonisation - with the consequences described above - are justified. In summary:	

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	- Earlier public disclosure of data required by clinicaltrials.gov (which in the US is disclosed after approval) can have a significant negative impact on the intellectually property framework that rewards innovation and drives the delivery of medicines to patients - in part because it risks undermining regulatory data protection for future medicines (as explained above) and also because with the additional data required in EudraCT it may affect the availability of patent protection (see further below). We therefore urge the Commission to re-consider this issue as a matter of urgency. - Public disclosure of certain proposed additional data requirements in this guidance can, in some instances, prevent the sponsor from seeking patent protection for their inventions for the following reasons: o Where a patent has to be supported by data which can only be obtained during the conduct of a clinical trial, the disclosure deadline for submitting results-related data to EudraCT will not always give sponsors enough time to adequately	

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	consider the data generated in the clinical trial and prepare a quality patent application. This may preclude the possibility of obtaining patent protection for certain inventions, because publication will constitute prior art. Specifically this relates to the additional information required in "interventional details" (P12), including fields to be publicly disclosed via EudraCT only such as "Dose", "Dose unit", Dose maximum", Frequency" and "Frequency unit" and the additional detail for age ranges in Baseline Variable (R41). We recognise that this information can be considered useful to understand and interpret the results of the trial and that for R41 this aligns with policy initiatives to encourage paediatric research in Europe. Therefore we propose that the guideline clearly states that where the additional information in P12 and R41 could compromise patentability the sponsor is able to delay public disclosure of the information for 90 days with a free text field to provide the explanation and a date by which the field in the public domain is to be updated. There is a risk that without this modification the attractiveness of	

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	conducting some studies in the EU will be reduced. We do not believe such unintended consequence is in the best interests of research, medicine and patients in Europe – and for paediatric research runs counter to important policy initiatives to encourage research in this population. - Additional requirements related to "Population" and "Background therapy" R15 should remain optional for the reasons outlined above. We suggest these fields are clearly labelled as optional. - Confirmation by the Commission that results are required to be disclosed within 6-12 months of completion has brought into sharp focus the fact that the CAS number (which uniquely identifies the molecular structure of the compound) will be linked to the results for that compound at an early stage in development. We believe that this does not adequately protect the legitimate business interests of innovative companies. While we recognise that the Commission guideline on protocol related data fields requires the disclosure of this protocol data element we urgently request that the Commission adopts a position regarding	

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	the timing of inclusion of the CAS number in the EudraCT database that fosters innovation through competition. In addition there may be circumstances where disclosure of the CAS number undermines an adequate opportunity to seek patent protection Our proposed solution is for CAS numbers not to be required for phase II studies (i.e. when the compound is in early development) and for this number to be provided when the results of phase III studies are submitted. - The requirement to submit the results of paediatric studies within 6 months of completion of studies is problematic from a practical perspective (i.e. it is not routinely possible to undertake all the required activities following a trial and submit a robust data set). We believe the ability to collate, review and analyse the data is an "objective scientific reason" for delay. Nonetheless we recognise the importance of paediatric research and the results of this research from a policy perspective. Therefore we propose that the Commission adopts a framework in which there is routine acceptance that paediatric studies of non authorised products can be submitted within 8 months of completion for objective scientific reasons. The sponsor would be able to make this	

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	determination and submit data at this time point. Where there are objective scientific reasons for a longer delay of up to 12 months the sponsor would submit a justification at 6 months. - There are some differences related to the reporting of adverse events. This is clearly important information from a clinical trial. While we do not have any major concerns related to the differences in this guidance compared to the data required by clinicaltrials.gov we urge the Commission to seek agreement with the NIH in the US so that there is consistency and harmonisation in the way the data for this important information is disclosed. - There are other fields that are additional to those required by clinicaltrials.gov and while we recognise that they can be considered important we question the need to include the following fields due to the consequences related to a lack of harmonisation. In addition some of these fields are additional detail which may not be appropriate in the context of result summaries on registers and databases being a supplement, and not a replacement or substitute, for publication in the peer reviewed literature:	

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	• Blinding implementation details (P5) • Randomisation allocation implementation details (P7) • Protection of participants (R10)	
	The public may be interested to know if study results of a given study pertain to a product which has received a marketing authorisation or not. The guideline does not provide any clear information in this regard.	

Please add more rows if needed.

Specific comments on text

Guidance/ Annex Page No. Paragraph No. *(e.g. Guidance, page 4; 1st para)*	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)*
Guidance			
Section 2, page 2, final para on Submission		**Comment:** The *Submission* paragraphs of Section 2 details the process of submission of results-related data and talks about the party responsible for submitting the data having a secure user account to enable the upload/ editing of the data. However, it does not cover the process of how a responsible party would be granted access to the system/allocated a secure user account. **Proposed change** (if any): EFPIA propose that a process for gaining a secure user account, e.g. providing an email contact point from whom access can be requested, is added to the guidance.	
Section 2, page 3, first para on Processing		**Comment:** This section says that in the secure part of the system, an automated and/or manual technical validation may take place. We understand this validation relates to whether data fields have been completed and is not a review of the content of the data fields. We therefore suggest that this is made explicit in the guidance. We would also like to know whether the sponsor will be able to review any amendments made to the data, following the technical review, in order to maintain data	

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		accuracy prior to disclosure. We believe this should be a required part of the process. **Proposed change** (if any):	
Section 2, page 3, first para on Timing		**Comment:** During the Commission's consultation exercise on the draft version of Guideline 2009/C28/01, EFPIA raised serious concerns over the timelines set out in this paragraph for the submission of results-related data for paediatric studies. For many clinical trials, analyses of the data can be complex and time-consuming, and it is unrealistic to attempt to enforce the submission of the trial results within a period of 6 months from last-subject-last-visit (LSLV), when in many cases this just will not be feasible. In the case of vaccines, for example, tests such as serological analyses are performed after the end of the trials, and they may take several months to complete. Furthermore, we do not believe that there is a strong justification for the provision of the results of paediatric trials to be aggressively out of step with the requirement for non-paediatric clinical trials. Nonetheless we recognise the importance of paediatric research and the results of this research from a policy perspective. Therefore we propose that the	

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		Commission considers a framework in which there is routine acceptance for objective scientific reasons that paediatric studies of non authorised products can be submitted within 8 months of completion. The sponsor would be able to make this determination and submit data at this time point. Where there are objective scientific reasons for a longer delay of up to 12 months the sponsor would submit a justification at 6 months. **Proposed change** (if any): Results-related data for all studies should be submitted to the Agency within 6-12 months of the end of the clinical trial and some fields which may preclude sponsors the possibility of obtaining patent protection for certain inventions can in these circumstances be delayed for up to an additional 90 days.	
Section 2, page 3, Follow-up submission section		**Comment:** It is not clear from the *Follow-up submission* paragraphs, what the process for updating results summaries is. In addition, the fact that follow-up submission will not be available after a period of 1 or 2 years may pose problems in case of studies with multiple time points as a sponsor would aim to post results at interim time points as well as at the last time point. In addition, some administrative fields and fields that provide citation information may require more frequent updates. We therefore propose that careful consideration is given to which individual fields that need to be locked down.	

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		Proposal: We propose that the records unlocked for a longer period and that administrative and citation fields can be updated by the sponsor as relevant information becomes available or other information changes.	
Section 2, page 4, first para on Provisions for Results of clinical trials which have ended in the past		**Comment:** The *Provisions for Results of clinical trials which have ended in the past* paragraphs of Section 2 of the draft guidance indicates that an alternative submission process (for results-related data) will be made available for those clinical trials that were completed prior to the coming into operation of this guidance and are already entered into EudraCT. This is an important issue since we understand there are now tens of thousands clinical trials entered into EudraCT. Clearly, with such a large number of Clinical Trials already in the database, our members are very concerned about the resource implications of having to transpose results information from older trials that were completed some years ago (and which are currently recorded in pre-existing formats), into the new formats as defined in the draft guidance and then having to submit them to the EMA. We welcome the fact that this issue is recognised in the draft guidance, although we would like clarity on what is meant by "which have ended	

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		more than 6 or 12 months prior to the coming into operation of systems set out in the guidance". Is this all studies where the study results have already been submitted to relevant national competent authority (i.e. via submission of a study synopsis) or just those studies where the study results have not been submitted to the relevant national competent authority, ie a study synopsis has not yet been submitted? In addition, particularly in view of the fact the result data required by EUDRACT is very similar to that required by clinicaltrials.gov, we suggest that a suitable alternative to providing a .pdf file (authorised copy of a medicinal journal article or synopsis in accordance with ICH E3) is for the sponsor to provide an internet link to the relevant record in clinicaltrials.gov. The Guidance also does not say whether sponsors have to continue submitting study synopsis to the national competent authorities or whether sponsors will have met their obligations by just submitting the resulted-related data via EudraCT. **Proposed change** (if any): For clinical trials which have ended in the past, we propose that sponsors would have to submit a pdf file (either authorised copy of medical journal article or in the format of a synopsis e.g., in ICHE3 format) or alternatively provide a link to an existing public database, such as ClinicalTrials.gov.	

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Section 3, page 4, second paragraph		**Comment**: Section 3 explains that certain fields of protocol-related data will be used to facilitate presentation of the results-related data fields and that when a sponsor submits the results-related data these protocol-related fields may be updated by means of the web interactive or via submission of updated xml with protocol-related data. If these protocol-related fields are also listed in the results-related fields, it is not clear if sponsors have to make a separate submission to update the protocol-related fields. It is also not clear if the results and protocol data will be linked at the study level or at the level of each field. Clarity on this would be helpful. **Proposed change** (if any): Our proposed process would be that the protocol-related data is automatically loaded when a sponsor goes to enter-the results-related data and therefore, can update the protocol-related data at the same time.	
Section 3, page 4, second paragraph		**Comment:** Section 3 states that certain fields of the protocol related data will be used to present the context of the trial facilitating the presentation of the results related data field. Confirmation by the Commission that results are required to be disclosed within 6-12 months of completion for unapproved medicinal products has brought into sharp focus the fact that the CAS number (which uniquely identifies the molecular structure of the	

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		compound) will be linked to the results for that compound at an early stage in development we do not believe that this adequately protects innovation and may undermine the competitive forces that drive innovation and research investment. This is because other research sponsors may be able to utilise the results which are uniquely linked to the molecular structure for the compound in real-time without any investment. While we agree that the information should be available to other researchers, we believe that the innovator company should be afforded the opportunity to utilise the results as they relate to specific compounds prior to disclosure to other researchers. In addition there may be circumstances where disclosure of the CAS number undermines an adequate opportunity to seek patent protection. **Proposed change** (if any): Our proposed solution is for CAS numbers not to be entered into the EudraCT database for phase II studies (i.e. when the compound is in early development) and for sponsors to provide this number when the results of phase III studies are submitted.	
Section 3, page 4, final paragraph		**Comment**: Our member companies are very concerned at the possibility of having to enter the same data into potentially multiple databases (in the global context), with the associated risks of inaccurate transcription (which are inherent for multiple re-keying of data), and the potential for inaccurate	

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and Page 5, first 4 paras		or conflicting information reaching the public. Consequently, we welcome the acknowledgement here that coherence of EudraCT with other global databases containing the same or similar data sets is an important objective. Nonetheless, we have carefully reviewed each data field to consider whether early disclosure (compared with that required in the US) could inadvertently have a negative impact on our ability to deliver medicines to patients by adversely limiting our ability to: protect our legitimate business interests; seek patent protection for our inventions; and conduct research in Europe. We have also carefully reviewed each difference with the data requirements for clinicaltrials.gov to consider whether the resulting lack of harmonisation is justified. In conclusion: - Some of the proposed additional data requirements in the guidance can, in some instances, prevent the sponsor from seeking patent protection for their inventions. The disclosure deadline for submitting results-related data to EudraCT will not always give sponsors enough time to adequately consider the data generated in the clinical trial and prepare a quality patent application which must contain supporting data obtained during the clinical trial. This may preclude the possibility of	

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		obtaining patent protection for certain inventions, because publication will constitute prior art. Specifically this relates to the additional information required in "interventional details" (P12) and the additional detail for age ranges in Baseline Variable (R41). We recognise that this information can be considered useful to understand and interpret the results of the trial and that for R41 this aligns with policy initiatives to encourage paediatric research in Europe. We therefore propose that the guideline clearly states that where the additional information in P12 and R41 could compromise patentability the sponsor is able to delay posting for 90 days with a free text field to provide the explanation and a date by which the field is to be updated. There is a risk that without this modification some studies may be conducted outside the EU which we do not believe is in the best interests of research, medicine and patients in Europe – and for paediatric research runs counter to important policy initiatives to encourage research in this population. - Additional requirements related to "Population" and "Background therapy" R15 should remain optional for the reasons outlined above. We suggest these fields are clearly labelled as optional.	

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		Proposed change (if any): (see text above)	
Annex			
P5 How Blinding was realised in practice		**Comment:** It is not clear if this information is uploaded from the protocol submission or if this is additional required information. **Proposed Change:** While this can be important information we do not consider that it should entered as additional information to that required by clinicaltrials.gov	
P7 Randomised allocation details		**Comment:** It is not clear if this information is uploaded from the protocol submission or if this is additional required information. **Proposed change:** While this can be important information we do not consider that it should entered as additional information to that required by clinicaltrials.gov	
Section A, Page 5, Row P12		**Comment:** Re field "Interventional details": The level of detail required concerning the nature of the intervention, and especially that required by the fields proposed to be included in EudraCT which go beyond those in ClinicalTrials.gov (e.g. dose, dose unit, dose maximum, frequency, frequency unit, route of administration, type of dosing), is likely to preclude the possibility of obtaining patent protection for certain inventions.	

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		Details with respect to specific dose and/or administration regimen can be the subject of a patentable invention. In order to obtain a patent directed to a dose/formulation/regimen, we are typically required to demonstrate with data a superior technical effect of the claimed dose/formulation/ regimen. This data most often is produced in the course of clinical trials (e.g., Phase II, multiarm, multidose). It is therefore not possible to file a patent application to the specific dose/formulation/ regimen until the data is complete and fully analysed. The proposed timelines for submitting results-related data to EudraCT does not give enough time to adequately consider the data and prepare a quality patent application and so may preclude patenting, because publication will constitute prior art and prevent sponsors from getting a patent directed to the dose/formulation/ regimen. Sponsors who are unable to garner an adequate opportunity to seek patent protection on inventions discovered during the conduct of clinical trials are inadvertently discouraged from investigating new uses of medicine and improved treatment regimens. **Proposed change** (if any): We propose that the requirement to provide in the public domain data in additional fields which go beyond those in ClinicalTrials.gov is delayed by 90 days, in those instances where public disclosure would prevent the sponsor from seeking patient protection. In	

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		addition a free text field could be provided to enable the sponsor to provide a reason for the delay and the date by which the information will be made publicly available. EPFIA believes that this proposal strikes an appropriate balance that informs the public regarding clinical research while maintaining an environment that protects innovation and supports intellectual property	
Section B R10 Protection of Participants		**Comment:** While this can be important information we do not consider that it should entered as additional information to that required by clinicaltrials.gov **Proposed change:** This should be an optional field	
Section B Page 14, Row R15		**Comment:** Re field "Background Therapy": Providing details of background therapy upon which an investigational drug is being tested has the potential to preclude the possibility of obtaining patent protection for certain inventions, for example combination therapies. For this reason, EFPIA members are pleased that this field is optional. **Proposed change** (if any): EPFIA would like to emphasise the necessity of background therapy remaining an optional field and this field should be clearly labelled as being optional	

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Section B, Page 15, Row R23		**Comment**: re field "Is this the baseline period?": It is not clear how this question would be answered in certain circumstances. What if there is only an "overall study" period, so no baseline period? Is it OK to have a study with no baseline period? Or do we need to identify a separate baseline period (meaning all studies will have at least 2 periods)? **Proposed change** (if any): We understand that the intent is to capture baseline data more generally. We suggest that this is made clear in the descriptions for this field.	
Section B, Page 16, Row R27		**Comment:** re field "Reason not completed type": There are differences in the description text compared with the description of this field in clinicaltrials.gov. We understand that the same information would be submitted to the two databases and therefore suggest any differences in the description is kept to a minimum to avoid confusion. In addition, the mixture of commas and semi-colons for punctuation leaves confusion about what the choices actually are. It could be read as: • Serious adverse event(s), non-fatal; • Adverse Event(s), not serious; • Serious Adverse Event, Fatal (mandatory • reporting);	

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		• Physician Decision, Pregnancy, Withdrawal by Subject, not due to adverse event; • Lack of Efficacy, Protocol Violation, specify; • Lost to Follow-up ,Other(s), specify (repeat). OR as: • Serious adverse event(s), non-fatal; • Adverse Event(s), not serious; • Serious Adverse Event, Fatal (mandatory • reporting); • Physician Decision, • Pregnancy, • Withdrawal by Subject, not due to adverse event; • Lack of Efficacy, • Protocol Violation, specify; • Lost to Follow-up , • Other(s), specify (repeat). **Proposed change (if any):** We request that there are no or only minimal differences from the description in clinicaltrials.gov. If it is considered necessary to retain the additional text we request that some other method of separation of the possible choices is used.	

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Section B, Page 17, Title row for Population		**Comment:** field "Population": We agree that this section should be optional and suggest that this is made clear in the guidance. **Proposed change (if any):** We propose the optional nature of this section is made clear.	
Section B, Page 18, Row R37		**Comment:** field "Not included in this population reasons": Same comment as for R27, the mixture of commas and semi-colons for punctuation leaves confusion about what the choices actually are. **Proposed change (if any):** We request that some other method of separation of the possible choices is used.	
Section B, Page 18, Title row for Baseline Characte-ristics		**Comment:** field "Baseline Characteristics": Publication of detailed information concerning baseline characteristics has the potential to preclude the possibility of obtaining patent protection for certain inventions, for example, new uses based on characteristics of a population, e.g. contributing to differential efficacy. For this reason, EFPIA members are therefore pleased that providing such characteristics is optional and we request that this is made clear in the guidance. **Proposed change (if any):** EPFIA would like to emphasise the necessity	

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		of detailing baseline characteristics beyond age range and gender remaining optional. We believe this strikes an appropriate balance that benefits the public health while maintaining an environment that protects inventions and intellectual property.	
Section B, Page 20, Title row for Baseline Variable		**Comment:** field "Baseline Variable": Publication of detailed information concerning baseline variables has the potential to preclude the possibility of obtaining patent protection for certain inventions. Please see our comments against Section B, Page 18, Title row for "Baseline Characteristics". **Proposed change (if any):**	
Section B, Page 20, Title row for Baseline Variable		**Comment:** field "Baseline Variable": In the description it says "All variables measured at baseline used for endpoint should be included". We would like clarity on what endpoint is being referred to? **Proposed change (if any):** We propose the categories of endpoints required are clarified in the guidance.	
Section B, Page 20, Row R41		**Comment:** field "Baseline Variable title": The proposal to provide more specific age categories has the potential to preclude the possibility of obtaining patent protection for certain inventions. Please see our comments	

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		against Section B, Page 18, Title row for "Baseline Characteristics". **Proposed change (if any):** We recognise that this detail can be considered important in being able to understand and interpret the results of the trial and that for this field it aligns with policy initiatives to encourage paediatric research in Europe. We therefore propose that where the additional information could compromise patentability the sponsor is able to delay posting for up to 90 days with a free text field to provide the explanation and a date by which the field is to be updated. We believe that this proposal strikes an appropriate balance of informing the public regarding clinical trials while maintaining an environment that protects innovation and supports intellectual property.	
Section B, Page 25, Row R51		**Comment:** field "Number of participants analysed": In the description it states "Can be associated with the participant flow table of selected arm(s)/group(s) and period(s) or with "population". We would like clarity on what is meant by this? How is the association noted? Or does this simply mean that the number of participants can be based on treatment arm or population? **Proposed change (if any):** We would like to propose using a word other	

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		than "associated", such as "based on".	
Section B, Page 26, Row R60		**Comment:** field "Safety variable": It is not clear whether the definition of "safety issue" in the "description" for the field "Safety variable" in EudraCT is consistent with that for the field name "Outcome Measure Safety Issue in ClinicalTrials.gov. Therefore we are not sure the mapping of "Safety variable" in EudraCT to "Outcome Measure Safety Issue" in ClinicalTrials.gov is appropriate. The ClinicalTrials.gov field asks if the outcome measure is assessing a safety issue. It is necessary to clarify whether the term "Safety variable" in the EudraCT field corresponds to a variable assessing a specific safety issue the study was designed to monitor (e.g. liver toxicity, cardiac effect) or to routine safety reporting. **Proposed change (if any)**: The definition of "Safety variable" needs to be amended to bring the necessary clarification and avoid any misunderstanding and to ensure the mapping of "Safety variable" in EudraCT to "Outcome Measure Safety Issue" in ClinicalTrials.gov is appropriate.	
Section B,		**Comment:** fields "Safety variable" and "Efficacy variable": We can see	

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Page 26, Rows R60 and R61		nothing that will preclude a variable having "Y" for both safety and efficacy. Is this assumption correct? **Proposed change (if any):** We propose this is clarified in the guidance.	
Section B, Page 37, Row R112		**Comment:** field "Event severity": To enter the event severity is a major concern raised by EFPIA members. There is no universal scale for describing or measuring the severity of an adverse drug reaction. Assessment is largely subjective. Unless a severity scale has been very precisely defined in advance for a given adverse event (to the extent it is possible) and the way to collect this information has been precisely defined too, the assessment will depend on individuals (assessors and assessed) and the variability will increase with the number of centres involved in the trial, the number of countries/cultures under consideration etc. Severity may also vary in a single individual. In addition it is not clear if % cut-off applies to overall for the adverse event regardless of event severity. If so, likely will need an "all severity" entry also. This will have a big impact on the quantity of data uploaded. EPFIA members fully support the provision of relevant information to the public in the interests of public health, however the potential public health benefits of disclosure with regards to this field which is not in ClinicalTrials.gov is less clear. We feel the results-related information needs to be consistent with other international clinical trial	

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		disclosures like ClinicalTrials.gov. This will help reduce the administrative burden for sponsors and avoid confusion among patients and others who may access the information. **Proposed change (if any):** We suggest further discussing this matter with the NIH in the US so that there is consistency and harmonisation in the way the data for this important information is disclosed before the field and its description may be included in the system	

Please add more rows if needed.