EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

08 September 2022

Submission of comments on "[DRAFT] Guidance document on how to approach the protection of personal data and commercially confidential information in documents uploaded and published in the Clinical Trial Information System (CTIS)

(EMA/212507/2021)

Comments from:

Name of organisation or individual
Association of Clinical Research Organizations (ACRO)

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).

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1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	The Association of Clinical Research Organizations (ACRO) represents the world's leading clinical research and technology organizations. ACRO 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-human studies through post-approval, pharmacovigilance and health data research. ACRO member companies manage or otherwise support the majority of all biopharmaceutical sponsored clinical investigations worldwide. The member companies of ACRO advance clinical outsourcing to improve the quality, efficiency and safety of biomedical research. ACRO welcomes the proposed Guidance document on how to approach the protection of personal data and commercially confidential information in documents uploaded and published in the Clinical Trial Information System (CTIS) and supports the greater clarity that this document will provide to applicants. ACRO nonetheless believes that several aspects of the document may be enhanced for greater clarity and easier implementation of the CCI / PPD management	

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	principles in compliance with Clinical trial regulation (EU) 536/2014 (EU CTR), as detailed in the below general and specific comments. The complexity in operationalizing transparency and disclosure principles both in the management of documents through the product development lifecycle / study conduct, as well as managing the specificities of CTIS should be carefully balanced to ensure that the European Union remains an attractive place for conducting clinical trials, as per EU CTR.	
	Data minimization principles need to be consistently enforced throughout the document (main principles as well as examples), with a specific attention not to invite interpretation or diverse application of those principles (diverse redaction strategies from sponsors, diverse expectations in terms of submitted information or documents by MSCs).	
	The guidance may benefit from a **greater differentiation in the management of CCI / PPD depending on the nature of the information considered: Clinical Study Report** (inherited from Policy 70 principles) **versus Clinical trial documents and information exchanged in the context of a clinical trial application** (new transparency	

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	requirements introduced for those documents and information, by EU CTR). Indeed, the nature and extent of redaction on one side, as well as the timing of the processing on the other, are very different and would benefit from a greater distinction throughout the document.	
	Trial centricity of the publication deferrals: Trial- specific deferral of publication for same product documents (IB, IMPD-S&E) applies even if the same product is used across several trials. As a result: - Different legal framework between trials, e.g. trial category, trial part of PIP or includes pediatric population, or trial under REGULATION (EU) 2022/123 (crisis preparedness trial) - Sponsor's deferral justification may not be consistently accepted by different MSC(s) across trials - Deferral periods individually triggered in each trial, e.g. initial trial application is "not authorized" or "early termination" the "end of trial" deferral timing immediately triggered - Publication triggered when CSR is submitted after end of marketing authorization procedure initial MA or variation or line extension in EU in any procedure It may be beneficial to further clarify this aspect to	

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	applicants and ensure an aligned approach is taken by MSCs.	
	Deferral principles on Sponsor data / documents: - Predictability that Member States do follow sponsor proposed deferral justification when trial category in line with the correct trial phase • e.g. reliability of justification for product documents used across trials • Justification already accepted in another trial / by another MS - When multiple IMPs/AxMPs are used in trial, would the product requiring the most stringent confidentiality (e.g. test IMP) justify the overall deferral of product related data/documents for all (current CTIS behavior)? • Deferral timing of IB, IMPD-S&E per trial not per each product	
	Deferral principles on MSC data / documents: - Predictable criteria (harmonized) are needed when Member States a) follow, b) apply shorter, or c) apply no period of the sponsor proposed publication timepoint • RFI, Assessment reports, Conditions - Could MSC/RMS inform the sponsor of their envisaged publication timing already in their	

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	respective assessment reports rather than with their decision of the initial application (current CTIS behavior)? • EMA/228383/2015 Endorsed "Appendix, on disclosure rules…", Section 4.3.3: *The Member States will review and decide on the final classification of the trial in the final conclusion on Part I of the dossier.* Indeed, change in the publication timing may affect the redaction strategy that was initially considered and may require rework. - How do we ensure no CCI is disclosed in the MS final assessment report or decision supporting document, which is unaligned with sponsor's redaction / or publication timing of protocol or RFI response? • Final assessment report includes large copy/paste information extracted from protocol, statistical analysis plan, and full text of clinical and non-clinical RFI considerations / responses	
	Management of CCI / PPD in RFI section (structured data): - RFI data fields cannot be redacted and will be subject to publication. - RFI consideration text may state information of a	

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	dossier section fully protected from publication while the related contents of the RFI consideration will be disclosed. A short-term solution is needed: • how MSC(s) describe information not appropriate to be disclosed (supporting doc?). • Possible CTIS enhancements to protect these RFI's (e.g. RFIs on Part II financial arrangements) like Part I – Quality RFI's to be considered *Note: there is no way for MS to withdraw an RFI in CTIS once raised, hence it is critical to have ways to edit / redact information is leak of CCI / PPD occurs via that route (prior clinical trial decision.*	
	Management of structured data: Further details on the specific management of structured data in CTIS should be included throughout the document as the options to redact that information are more limited. List of structured data text fields (e.g. Evaluation page RFI consideration text, or RFI response text), that cannot be redacted should be added for further clarification. Indeed, if personal data is either inadvertently entered or if it is required in the context of addressing the RFI/RFI response such personal data in a structured data text field could become an issue. Similarly, there in some lack of clarity on the deferral	

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	rules that may apply to some of those fields depending on where located in the clinical trial application form (unclear relationship between certain fields / sections of the application form and the corresponding disclosure / rules to apply).	
	CCI / PPD justification for redaction or deferral: There is currently no way for clinical trial applicants to provide granular justification per field or section of document to justify redaction or deferral, nor is there a formal requirement detailed in EU CTR Annex I to provide such information to MSCs. That opens up several question on the overall management of PPD / CCI by the different stakeholders and through the study lifecycle. For example: - During study lifecycle (initial submission and subsequent submissions), how deferred CCI can be identified to inform MSCs so that this is maintained confidential by MSCs (no inclusion in assessment reports for publication)? - For Full clinical study report (CSR) posting, how redaction execution as established within the remit of Policy 70 will evolve, in particular in relation to redaction strategy and its supportive documentation to be prepared by the marketing authorization holder (anonymisation report	

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	template, how to identify and redact commercially confidential information in clinical reports, template for justifications for redactions of commercially confidential information) in absence of legal basis in the regulation for provision of such information, or CTIS functionality (or publication rules) to manage those documents if necessary? Careful impact assessment of the administrative burden some of those considerations may cause will be required in order to ensure that the European Union remains an attractive place for conducting clinical trials.	

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)*
Lines 342 to 458 Section 2.2.2		**Comment:** For category 1 trials the main characteristics of the trial may be deferred up to the submission of the final summary of results, but unclear which data fields and documents in each section of the application (Form, MSC, Part I, Part II, Evaluation) belong to main characteristics and, if yes, whether they are belonging to the limited ones that will be made public immediately despite of deferrals. For instance, EMA/42176/2014 table 1 footnote e includes "nature of clinical trial (e.g. bioequivalence in 24 healthy volunteers)" as belonging to those restricted fields, but unclear, which part I data fields affected. Other application sections include Forms, e.g. cover letter, modification description, proof of payment etc. or data fields; Part I, Part II or Evaluation, which data fields related to validation or assessment conclusion, assessment report or supporting documents to disagreement or decisions. **Proposed Change (if any):** Provide detailed list of all CTIS data fields and document types within all areas of the CT, i.e. application Form, MSC, Part I, Part II and Evaluation page, notifications (data and documents for each notification type), results (data and documents for each results submission).	
Lines 342 to 458 Section 2.2.2		**Comment:** Main Characteristics data fields in part of the application allowed to be deferred for category 1 trials follow a	

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		different maximum publication deferral timing than what may be agreed for the protocol (max. 7 years), while the data they contain comes from the protocol. **Proposed Change (if any):** Add paragraph in this chapter in the guidance with explanation.	
Lines 342 to 458 Section 2.2.2		**Comment:** Appendix, on disclosure rules, to the "Functional specifications for the EU portal and EU database to be audited - EMA/42176/2014 (e.g. footnotes h), and its implementation in CTIS requires additional justification for deferral of certain information when the sponsor selects category 1 or 3 trials. However, this guidance does not explain what additional justification in addition to the trial phase and legislation in line with the trial category would be expected. **Proposed Change (if any):** Add paragraph in this chapter in the guidance with explanation.	
Lines 342 to 458 Section 2.2.2		**Comment:** While EMA/42176/2014 describes general specifications of publication and deferral rules, further clarification how these are applied for relevant business situations: What is the impact for publication of main characteristics, notifications or results for a category 1 trial, when sponsor adds PIP or paediatric population subsequently via SM?	

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		Will application of end of trial deferral rules (see EMA/42176/2014 footnote c) be reset, if trial is first not authorized, but decision later reverted by the MSC to authorize? What application of end of trial deferral rules (see EMA/42176/2014 footnote c) be applied on publication timing for Part II information of MSC that refuses trial and for Part I information refused in one but not all MSC(s)? Will the end of trial deferral rules be generally taken as the EEA end of trial, even if trial is globally ongoing in third countries? **Proposed Change (if any):** Add paragraph in this chapter in the guidance with explanation.	
Section 2.2.2 and lines 366 – 367		**Comment:** Appendix, on disclosure rules, to the "Functional specifications for the EU portal and EU database to be audited - EMA/42176/2014 section 4.3.3. specifies that the Member States will review and decide on the final classification of the trial in the **final conclusion** on Part I of the dossier. However, in CTIS, sponsors will find out only at the time of decision, whether the RMS/MSC follow the same or shorter	

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		publication deferral timing for those documents they produce, and this may already be inconsistent with the required publication timing required to protect the confidentiality of dossier content. **Proposed Change (if any):** Align with what is stated in the EMA/42176/2014 section 4.3.3., that RMS/MSC should specify the deferral timing for the documents they produce at the time of conclusion, e.g. included in the assessment report.	
Section 2.2.2 and lines 366 – 367		**Comment:** Appendix, on disclosure rules, to the "Functional specifications for the EU portal and EU database to be audited - EMA/42176/2014 footnote c on table 1 explains function how a deferral timing of the original trial, that was rejected by all Member States concerned is reset in case of a resubmission. However, in the current draft guidance, nothing is explained in this respect and how this is functionally operationalized in CTIS. Also, it is unclear, how the two trials would be linked in CTIS, e.g. via the "Associated Trials" section in part I, and what would prevail in case the publication deferral timings differ between the original trial and the resubmission trial. **Proposed Change (if any):** Add paragraph in this chapter in the guidance documents with explanation.	

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Lines 420 – 423 and 432 - 449		**Comment 1 on CTIS structured data fields** Text entered in CTIS structured data fields cannot be redacted (see also comment in general section). Wording of a consideration RFI may include PPD needed for context so that Sponsor may appropriately respond as needed for the context, but such information may not be appropriate to be published even at the end of any deferral period. This includes natural person's names included for legal roles such as proposed investigators before they are authorized. **Proposed Change (if any):** Solution needed to ensure that RFIs do not include any personal data or natural person's name in the RFI consideration text field (best practices on MS side and technical solution within CTIS to redact such information in case PPD / CCI was included in an RFI sent to the Sponsor, as no way to withdraw a submitted RFI once sent to the Sponsor).	
Lines 420 – 423 and 432 - 449		**Comment 1 on CTIS structured data fields** Text entered in CTIS structured data fields cannot be redacted (see also comment in general section). RFIs sent to the sponsor may include considerations relating to any documentation within a given part and the wording of a consideration text may require stating content related information of the documentation it refers to, needed for context reasons. As each documentation within a given part follows individual publication (deferral) timing, the contents	

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		mentioned in the consideration may not be appropriate to be published at the time of RFI publication, if the MSC/RMS defers the timing for RFIs sent to the sponsor for a shorter period than the documentation with the longest deferral timing within that part. **Proposed Change (if any):** Simplify the publication deferral timing and only allow one deferral timing for RFIs sent to sponsor for all part(s) and for documents produced by the RMS/MSC (RFIs, assessment reports, conditions) consistently follow the publication period of the documentation requiring the longest publication deferral in the dossier.	
Lines 420 – 423 and specifically 436 - 449		**Comment:** MSC can defer the publication of information related to part II, in relation to request for information (RFI), while the RMS also for part I. Validation RFIs sent by the RMS (e.g. initial applications or SMs affecting part I and II) may also include considerations related to MSC specific part(s) II documentation. If such validation RFIs then follow the RMS RFI deferral timing. The deferral period related to an individual part II consideration would follow different publication timing, depending on whether it is included in a validation RFI sent by the RMS, or in an RFI send by the MSC, e.g. during assessment. On the other hand, if each consideration contained therein follows the specific deferral timing of the part and MSC it	

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		belongs to, then individual deferral timing would be required for any RFI supporting documentation sent by the Member States. **Proposed Change (if any):** Simplify the publication deferral timing and only allow one deferral timing for RFIs sent to sponsor for all part(s) consistently follow the publication period of the documentation requiring the longest publication deferral in the dossier.	
Lines 436 - 442		**Comment:** Unclear how documents produced by the RMS/MSC which include the contents from various documentation sources within the dossier respect those documentation individual publications rules (or deferral of timing of publication). **Proposed Change (if any):** Documents produced by the RMS/MSC (assessment reports, conditions) should not repeat e.g. copy and paste information already provided elsewhere in the dossier and align with the documentation requiring the longest publication deferral timing.	
Section 4.3 Lines 823-852		**Comment:** Section 4.3 focuses exclusively on CCI related to the medicinal product/s under investigation. An example of this focus being the linkage of the publication deferral timeline to the date of decision on marketing authorisation for the product involved in the trial. In addition, all examples	

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		provided in section 4.3.1 refer directly or indirectly to the product/s. Policy 0070 incorporates a similar focus throughout. This focus is problematic for ACRO members, as information relating to the processes, products and technologies owned by organisations other than clinical trial sponsors and marketing authorisation holders such as Clinical Research Organisations (CROs) are also likely to be described within documentation submitted to Regulatory Authorities and Ethics Committees via CTIS. It is therefore necessary for such organization to propose redactions within the versions of these documents that are destined for publication in accordance with the requirements of the EU CT Regulation, to protect such CCI and prevent harm. **Proposed Change (if any):** By extension of information within section 4.3 of draft guidance 212507, CCI is considered to mean any information provided during the clinical trial lifecycle which is not in the public domain or publicly available, and where disclosure may undermine the legitimate economic interest or competitive position of the clinical trial sponsors, marketing authorisation holders and/or other organisations involved in the management of the clinical trial. When redacting such information all of these organisations should consider the option for deferral of such documents and assess whether an available deferral may appropriately protect the CCI; however, in cases where deferral is not an option, any such organisation involved in the management of a clinical	

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		trial may redact information that meets the definition of CCI. Prior to applying redaction, the organisations involved should consider the information already available in the public domain in relation to the commercially sensitive information or product, and the likelihood that an available deferral may be sufficient to protect the information, given the anticipated progression in knowledge or technology in the interim. Examples of information that may carry commercially confidential value for organisations other than clinical trial sponsors and marketing authorisation holders such as CROs: - Descriptions and names of technologies utilised on clinical trials - Detailed descriptions or information relating to the processes employed by an organisation in the management of an activity within a clinical trial - Detailed descriptions of innovative approaches being applied to the conduct of clinical trials - Names of additional third parties and suppliers that are not already included within the clinical trial application, - [etc…]	
Lines 963 - 964		**Comment:** Guidance explains that unit measurement values may be considered as CCI, but unclear how this confidentiality is ensured in current implementation of CTIS: - Structured data fields of the product section within part I, e.g. in subsections "Medicinal Product Details"	

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		or "Dosage Administration Details", - Structured data fields of RFI considerations text sent to sponsor, or - Assessment reports completed by RMS/MSC **Proposed Change (if any):** Add paragraph in the guidance with explanation with reference link in this section.	
Lines 1092-1095		**Comment:** Reference is made in this paragraph to "When a sponsor has justified a piece of information as CCI", but such information is neither part of EU CTR Annex I submission requirements nor has a structured data or supportive documentation placeholder field allowing to specify individually which field or section document may contain CCI in CTIS. **Proposed change (if any):** Guidance should consistently align with CTIS capabilities in terms of how and when information may be provided, as nothing currently exists to define what justifications a sponsor should develop when managing CCI / PPD via redaction or deferral, how this information is provided to MSCs or how this information would then be managed by MSCs (for example deferred CCI will not be redacted, but should not be included in MSC assessment report or similar document in an unredacted manner).	

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Section 5.2 (inspection reports) Lines 1203-1215		**Comment:** Not all types of inspected facilities in third countries will generate findings relevant to the conduct of a trial in the EU (e.g. inspection of a single Investigator trial site in a third country being conducted under different national legislation would be of limited relevance to the conduct of the trial within the EU). **Proposed Change (if any):** Additional information would be welcomed within section 5.2 (or reference to expected guidance on the matter, i.e. EU Commission Q&A upcoming updates) for determining the need to submit such reports as a preliminary step to determining to which extent CCI / PPD then needs to be addressed.	
Annex 1 Line item: Sponsor Legal representative in the Union		**Comment:** According to 4.2.2 personal information identifying them is included for those persons with legal roles including the legally designated representative of the sponsor, or where the sponsor is a natural person (e.g. an investigator who is also the sponsor). A sponsor may be a legal person and the related mandatory field to identify that sponsor's contact point for the Union is not made public. However, when a legal representative of the sponsor is added that may also be in the form of a legal person (entity) rather than a natural person, CTIS requires to enter a natural person's first and last name plus contact phone/email for this legal representative, and this information is made public.	

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		Proposed change (if any): Allow the legal representative of the sponsor to be a legal entity and not mandate provision of a natural person's first / last name, but only a functional contact, or make the contact details (first/last name, phone, email) not public.	
Annex 1		**Comment:** The Annex provides an exhaustive list of the CTIS document types and their potential of identifying elements, However, for the CTIS data fields only a few are listed (e.g. sponsor legal representative contacts), while others may also have the potential to contain personal identifying elements, while they cannot be redacted. Those include e.g. application RFI considerations or sponsor responses, conditions, or data fields related to notifications. **Proposed change (if any):** Include data fields where potential they could contain personal identifying elements (or CCI). Should also provide a business approach, whereby any actor required to enter personal identifying elements (or CCI) information into any data field, that rather a supporting document must be supplemented which should be provided in two versions (public, i.e. redacted, and non-public).	
Annex 1 Auxiliary medicinal product dossier (AMPD)		**Comment:** AMPD specified as Not Public, while the CTIS field for this document type is "For Publication".	

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		Proposed change (if any): Change Auxiliary medicinal product dossier (AMPD) column "Disclosed" to Yes.	
Annex 1 Study design		**Comment:** While the timing of publication of the protocol may be deferred according to the trial category, the information entered into the CTIS Part I sub-section "Study Design" into the "Period Details" (Data fields) or "Study Design" (Document) cannot. This is inconsistent, since the information entered in this sub-section results from protocol information. **Proposed change (if any):** Align the publication timing of the sub-section "Study Design" with the publication (or deferral of publication) of the protocol.	
Annex 1 Table 1: Document Types listed under Form Section and Part I Documents (Clinical Trial Documents + Medicinal Product Documents)		**Comment:** Several entries refer to "may include identifying elements e.g. signature". For those that are common Part I (Trial / Product) documents, provision of signature or DSMB member listings cannot depend on individual MSC expectations or preferences. In view of a harmonization and as the composition of MSCs vary between trials, there should be an aligned EU/EEA expectation whether or not MS expect signatures or names of DSMB to be provided for trial and product specific documents. If not aligned, sponsors could be faced with challenge to add an MSC later that has different expectations. The Add MSC application only allows providing new language translations, but does not allow changing / updating the parent part I	

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		documents, e.g. adding signatures etc. **Proposed Change (if any):** Harmonize EEA MSC approach for signature expectations and for DSMB member listing inclusion in Part I documents (data minimization principle).	
Annex 1 Table 1: Subject information, informed consent form and informed consent procedure		**Comment:** Only document specified under EU CT Annex I, item L62 are listed, but this line item misses to list other document types different from Informed Consent, under this document type, as specified in EU CTR Annex I, items L61 or L63, which may also include CCI / PPD information. **Proposed Change (if any):** Add to this list the documents as specified by Annex I, items L61 and L63.	
Annex 1 Table 1: Suitability of the principal investigator - Principal Investigator Curriculum Vitae (CV)"		**Comment:** The description of the qualification of the principal investigators in a current CV (e.g. basic personal information, contact details, academic background, professional experience etc), any previous training in the principles of good clinical practice or experience obtained from work with clinical trials and patient care, that is included in the column "Categories of personal data captured in CTIS" is not in line with data minimization principle for what information relevant for the public should be made public (degree of redaction / published CV template). **Proposed Change (if any):** Please consider narrowing down	

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		the scope of information to be made public (e.g. include only name, site, and info on ICH GCP certification).	
		ACRO thanks the Agency for this opportunity to provide input on this draft guidance. Please do not hesitate to contact ACRO (knoonan@acrohealth.org) if we can answer any questions or provide additional details.	

Please add more rows if needed.