



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Revised CTIS transparency rules, Interim period & Historical trials: quick guide for users

1 December 2023





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Adoption of revised rules



Adoption of Revised CTIS transparency rules

- Article 81(4) of Regulation (EU) No. 536/2014: legal basis for the establishment a publicly accessible EU clinical trials database, while protecting commercially confidential information (CCI), personal data (PD) and confidential information on the assessment conducted by MSs
- Current EU public portal based on rules defined in the [Appendix on disclosure rules](#)
- [Revised CTIS transparency rules](#) were adopted on 5/10/2023, main differences:
 - publication focused on key documents of interest
 - removal of deferral functionality – documents are published earlier in time
 - use of redaction as the method to protect CCI and PD, if included in those key documents
- Applicability: [applications submitted as of launch of new CTIS public website in 2024](#)



05 October 2023
EMA/263067/2023

Revised CTIS Transparency Rules

Public consultation on the transparency rules for the operation of the Clinical Trials Regulation (CTR) and its Clinical Trials Information System (CTIS)	3 May 2023 – 28 June 2023
Adoption of revised rules by EMA Management Board	5 October 2023

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Publication of structured data

As per [Revised CTIS transparency rules](#), applicable to all applications submitted as of launch of new public website



Structured data – what will be published & when

Structured data	Category 1		Category 2 integrated ph1&2	Category 2 & 3 <i>(excl. integr. ph1&2)</i>
	Paediatrics and/or PIP	Adults		
CTA fields*	First MSC decision	First MSC decision	First MSC decision	First MSC decision
		30 months after EU/EEA End of Trial		
Product/AS details on strength, dose and treatment duration*	30 months after EU/EEA End of Trial			
MSC(s) conclusions and decision outcomes	That MSC decision			
Notifications on trial status and recruitment	As soon as submitted by sponsor			
Notifications on serious breaches, urgent safety measures, unexpected events	After MSC assessment	30 months after EU/EEA End of Trial & MSC assessment	After MSC assessment	
Corrective measures (suspension, revocation, modification request)	When applied by MSC(s)			*see following slide



Structured data – what will be published & when

Structured data	Category 1		Category 2 integrated ph1&2
	Paediatrics and/or PIP	Adults	
CTA fields populated by the sponsor, including: <ul style="list-style-type: none">- Public title (= title in lay terms)- Trial identifiers in registers, protocol code- Phase, medical cond., rare disease, therap. area<ul style="list-style-type: none">- Population age, gender- Sponsor details- Details of clinical investigator sites in MSC(s)	First MSC decision	First MSC decision	First MSC decision
Remaining CTA fields populated by the sponsor		30 months after EU/EEA End of Trial	
Product/AS details: Product & active substance strength, Maximum duration of treatment, Maximum daily dose allowed, Daily dose unit of measure, Maximum total dose allowed, Total dose unit of measure	30 months after EU/EEA End of Trial		



Structured data – what will be published & when

Structured data	All categories
Sponsor legal representative details	Never
Any request for information (RFI) and RFI responses	
Validation conclusion details, assessment decision conditions (if any)	
MSC(s) assessment(s) on notifications	
3 rd country inspection details	



Publication of documents

As per [Revised CTIS transparency rules](#), applicable to all applications submitted as of launch of new public website



Documents – what will be published & when

Category 1			Category 2 and 3 <i>including integrated ph1&2</i>
Documents type	Paediatrics and/or PIP	Adults	
Protocol, synopsis, patients facing documents	Upon results' submission	30 months after EU/EEA End of Trial	First MSC decision
SmPC, if available	Never		That MSC decision
Subject information and informed consent form			
Recruitment arrangements, <i>including procedures for inclusion and copy of advertising material</i>			
Final summary of results, Lay person summary of results	As soon as submitted	30 months after EU/EEA End of Trial	As soon as submitted
Clinical study report, <i>if available</i>	As soon as submitted		
<i>All other documents, including any MS document</i>	Never		



Interim period & Historical trials

Section 4 of [ACT EU Q&A on the protection of Commercially Confidential Information and Personal Data while using CTIS](#)

The ACT EU_Q&A on protection of CCI and PD was updated



29 November 2023
EMA/898965/2022

Q&A on the protection of Commercially Confidential Information and Personal Data while using CTIS

Question and Answers, version 1.3

This Q&A document has been created to provide preliminary guidance to CTIS users on how to protect personal data and commercially confidential information (CCI) in CTIS, the EU database established in accordance with the requirements of Regulation (EU) No 536/2014 (CTR).

The Q&A document has been produced to address a number of questions related to the transparency aspects of CTIS which were communicated by sponsors in response to the ACT EU survey on the CTR implementation under ACT EU Priority action 2 (Successful implementation of the CTR). It is foreseen that the Q&A may be updated on a regular basis as soon as new information becomes available.

The Q&A intends to provide more clarity on main aspects that have been discussed with the Clinical Trials Coordination Group (CTCG) and it should be read in conjunction with the [Guidance document on how to approach protection of personal data and commercial confidential information while using Clinical Trials Information System \(CTIS\)](#).



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Link: [ACT EU Q&A on the protection of Commercially Confidential Information and Personal Data while using CTIS](#)



Interim period: until the new CTIS public website is launched

For initial applications:

- sponsors may provide the version 'for publication' only for those documents in scope of the revised rules, and for those documents that will no longer be subject to publication, upload in the slot 'for publication' a page with wording suggested in Annex I*
- the above should translate in refraining from requesting deferral, as CCI are protected by redaction in the documents in scope of publication

For modifications/additional MS applications: sponsors should consider the preferred approach on protection of personal data and CCI, with the aim to decrease burden depending on the status of the trial, i.e. whether deferrals are already in place

For transition trial applications: sponsors should follow the principles of Q 11 of the [Guidance for the Transition of clinical trials from the CTD to the CTR](#) and submit a redacted version 'for publication' only of protocol, subject information sheet and ICF

*Annex 1 of the [ACT EU Q&A on the protection of Commercially Confidential Information and Personal Data while using CTIS](#)



Historical trials: submitted before the new CTIS public website is launched

For all those trials submitted to CTIS prior to the technical implementation of the revised rules on CTIS public website, as of new CTIS public site go-live date:

- the structured data will be published for all trials' categories as per revised rules
- documents will not be published: publication of documents in scope of the revised rules will occur only when included in **applications** submitted after the revised rules are in place (this applies to all historical trials, regardless of the previous use of deferrals or publication status)

Example: phase II trial with deferral on protocol, initial application submitted before technical implementation of revised rules in the CTIS website:

- Structured data published at the date of go live of new CTIS public website
- Documents of initial application not published on new CTIS public website
- SM-1 submitted 1 month after go live of new CTIS public website with the purpose of updating the IB: protocol and synopsis will be subject to publication as per revised rules

*→ For applications submitted in CTIS **after** the launch of the new Public Portal the documents in scope of publication will be published and should be redacted accordingly*



Thank you for your attention

