EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Revised CTIS transparency rules, historical trials and interim period: quick guide for users

CTIS team, Data Analytics and Methods Taskforce (TDA)

An agency of the European Union

Table of contents

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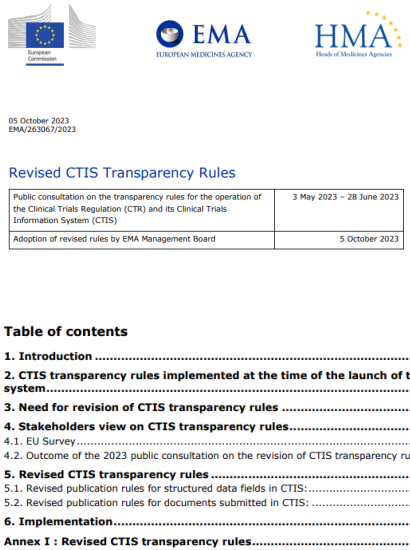
Adoption of revised rules

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



European Commission

EMA EUROPEAN MEDICINES AGENCY

HMA Heads of Medicines Agencies

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

Table of contents

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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 *(excl. integr. ph1&2)*
	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: - Public title (= title in lay terms) - Trial identifiers in registers, protocol code - Phase, medical cond., rare disease, therap. area - 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		

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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	
3rd country inspection details	

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Publication of documents

As per Revised CTIS transparency rules, applicable to all applications submitted as of launch of new public website

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Documents – what will be published & when

Documents type	Category 1		Category 2 and 3 *including integrated ph1&2*
	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		
Subject information and informed consent form			That MSC decision
Recruitment arrangements, *including procedures for inclusion and copy of advertising material*			
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, *if available*	As soon as submitted		
All other documents, including any MS document	Never		

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

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

Historical trials: what is published and when

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)

→ ***For applications* submitted in CTIS after the launch*** *of the new Public Portal the* ***documents*** *in scope of publication that it is feasible to modify through the application will be published and* ***should be redacted accordingly***

In addition, for **all** CTIS trials, including historical ones, only the latest authorized application will be made publicly available (except for non authorized trials, which are also made public)

*see following slide

Historical trials: what is published and when

When submitted after go live of the new CTIS public website, the following applications will trigger publication of all those documents that are in scope of the revised rules:

- Substantial Modifications (part I and/or part II)
- Non-Substantial Modification part II
- Additional Member State (triggering publication of part II docs only)

→ ***documents*** *in scope of publication* ***should be redacted accordingly***

NSM and AM applications will not trigger the publication of part I documents: this is because through these two kinds of applications, it is not possible for sponsors to update and therefore redact those documents in scope of publication

Example, for an initial application submitted before technical implementation of revised rules:
- the latest version of its structured data is published at the date of go live of new CTIS public website
- documents of initial application are not published

If an SM-1 is submitted after go live of new CTIS public website with the purpose of updating the IB: protocol and synopsis will be published as per revised rules
An NSM-1 submitted after go live will only trigger an update of the structured data and not of any document

Interim period: until the new CTIS public website is launched

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

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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

Revised CTIS Transparency rules: useful material

ACT EU – Implementation of clinical trial regulation website

Revised CTIS Transparency rules: useful material

The ACT EU – Implementation of clinical trial regulation website has a section dedicated to the revised transparency rules, to allow sponsors to familiarise with them during the interim period until the revised version of the public portal is launched:

- Quick guide for users
- ACT EU Q&A on the protection of Commercially Confidential Information and Personal Data while using CTIS
- CTIS Bitesize talk on the transparency rules

Details are provided on data and documents that will be published, on the interim period and on all those trials submitted before the launch ('historical trials').

Sponsors will be informed in advance the launch of the revised version of the public portal.