# CTIS Bitesize Talk: Implementation of revised CTIS transparency rules

20 June 2024

Event supported by Francesca Scotti and Giovanni Varricchio

(Data Analytics and Methods Task Force, EMA)

# A few housekeeping rules

Questions were collected in advance on **www.sli.do**
With event code **#bt20jun**

## Tips for optimal screen viewing

- Make use of the instructions under the **Live broadcast** section on the event page and connect directly to the **EMA's Vimeo channel 1** *for the full-screen experience*
- Have a stable internet connection

# The experts for this event are:

Moderator: Josipa Vrkljan

Francesca Scotti

CTIS Transparency Lead, EMA

Giovanni Varricchio

Scientific Specialist, EMA

# Agenda

*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*

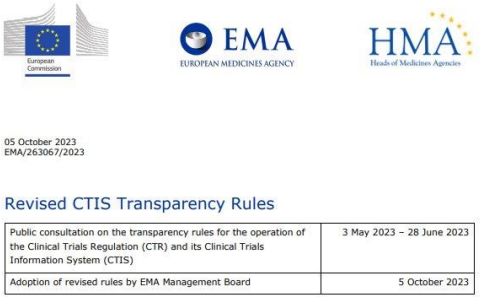
1. Implementation of revised CTIS transparency rules
2. Revised rules: modality of disclosure of CTIS trials' information
3. Publication of structured data
4. Publication of documents
5. Historical trials, submitted before 18 June 2024
6. Reference documentation

# Implementation of revised CTIS transparency rules

# Implementation of revised CTIS transparency rules

As of 18 June 2024, the Revised CTIS transparency rules are the publication rules of the Clinical Trial Information System:

- All trials submitted on or after 18 June follow the principles and timelines defined in the revised rules
- Trials submitted to CTIS before 18 June are considered 'historical' and have only their structured data published, see 'historical trials' section



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 |

Rules are summarised in the Annex 1

to the Guidance document on how to approach the protection of personal data and CCI while using the CTIS

More info are in the Q&A on the protection of CCI and Personal Data and in a dedicated CTIS bitesize talk

# Revised rules: modality of disclosure of CTIS trials' information

Chapter 2 of Guidance document on how to approach the protection of personal data and commercially confidential information while using the CTIS

# Revised rules: modality of disclosure of CTIS trials' information

The **most recent** authorised application of any trial, as well as any 'not authorised' initial application, is made publicly available as per timelines based on:

- trial category, selected in the 'Form' section as per below table
- population age
- trial phase *(in case of category 2 trials that are integrated phase 1&2)*

| Category | Trial type |
|---|---|
| Category 1<br>Pharmaceutical development clinical trials | Phase I clinical trials in healthy volunteers or patients<br>Phase 0 trial in healthy volunteers or patients<br>Bioequivalence and bioavailability trials<br>Similarity trials for biosimilars<br>Equivalence trials for combination or topical products |
| Category 2<br>Therapeutic exploratory & confirmatory clinical trials | Phase I and phase II integrated clinical trials<br>Phase II clinical trials<br>Phase II and phase III integrated clinical trials<br>Phase III clinical trials |
| Category 3<br>Therapeutic use clinical trials | Phase III and phase IV integrated clinical trials<br>Phase IV clinical trial and low interventional trials |

# Publication of structured data

Table I of Annex 1 to Guidance document on how to approach the protection of personal data and commercially confidential information while using the CTIS

# Structured data – what will be published & when

| Structured data | Category 1 | | Category 2 integrated p h1&2 | Category 2 & 3 *(excl. integr. ph1&2)* |
|---|---|---|---|---|
| | **Paediatrics and/or PIP** | **Adults** | | |
| CTIS application fields | First MSC decision | First MSC decision | First MSC decision | First MSC decision |
| | | 30 months after EU/EEA End of Trial | | |
| CTIS application fields on dose and treatment duration[1] | 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 | | | |
| Notific. on serious breaches, urgent safety measures, unexpected events | After MSC assessment | 30 months after EU/EEA EoT & MSC assessment | After MSC assessment | |
| Corrective measures (suspension, revocation, modification request) | When applied by MSC(s) | | | |

*[1]As a temporary measure, the publication of fields 'strength of product' and 'strength of active substance' has been suspended: further information will follow*

# Structured data – what will be published & when

| Structured data | Category 1 | | Category 2 integrated ph1&2 |
|---|---|---|---|
| | Paediatrics and /or PIP | Adults | |
| CTIS application fields populated by the sponsor, including:<br>•Public title (= title in lay terms)<br>•Trial identifiers in registers, protocol code<br>•Phase, medical cond., rare disease, therap. area<br>•Population age, gender<br>•Sponsor details<br>•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 | |
| CTIS application fields[1] on 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 | | |

*[1]As a temporary measure, the publication of fields 'strength of product' and 'strength of active substance' has been suspended: further information will follow*

# 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 | |

# Publication of documents

Table II of Annex 1 to Guidance document on how to approach the protection of personal data and commercially confidential information while using the CTIS

# Documents – what will be published & when

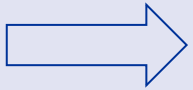
| Documents type | Category 1 | | Category 2 and 3 *including integrated ph1&2* |
|---|---|---|---|
| | **Paediatrics and/or PIP** | **Adults** | |
| Protocol, synopsis, patients facing documents | Upon results' submission | 30 months after EU/EEA End of Trial | First MSC decision |
| SmPC, if available | 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 *(requirement: 30 days from MA)* | | |
| *All other documents, including any MS document* | Never | | |

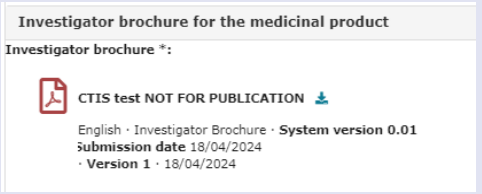
# As of 18 June 2028, for any application created before this date

For all those documents that are no longer published (e.g. IB), the system had to remove the former version 'for publication', unless no 'not for publication' version was linked to it

*workspace view*


*before 18/6/24*






*as of 18/6/24*

*Examples, placeholder with:*

A. *1 doc version 'for publication' + its version 'not for pub'* → *only former 'not for publication' version can now be seen*

B. *Only 1 doc 'for publication' (no 'not for pub')* → *this version (formerly 'for publication') is kept*

C. *3 docs 'for pub' and 1 'not for pub' linked to 1 of them* → *3 docs are kept: 2 former 'for pub' (that had no 'not for pub' linked) + 1 former 'not for pub' (which was linked to the third 'for pub')*

# Examples

| Before 18 June, sponsor had uploaded: | | As of 18 June, Sponsor/MS will see, in the same placeholder: |
|---|---|---|
| In slot 'for publication' | and linked to 'not for publication' | |
| Doc 1 'for publication' | - | Doc 1 (formerly 'for publication') |
| Doc 1 'for publication' | Doc 1 not for publication | Doc 1 (formerly 'not for publication') |
| Doc 1 'for publication' | 2 or more docs 'not for publication', linked to the same unique document for pub | All 'not for publication' docs *(doc 'for publication' removed)* |
| Doc 1 For publication<br>Doc 2 For publication (e.g. translation) | Doc 1 'not for publication'<br>Doc 2 'not for publication' (e.g. translation) | Doc 1 (formerly 'not for publication')<br>Doc 2 (formerly 'not for publication' ,e.g. translation) |
| Doc 1 For publication<br>Doc 2 For publication | Doc 1 'not for publication' linked to doc 1<br>- | Doc 1 (formerly 'not for publication')<br>Doc 2 (formerly 'for publication') |
| Doc 1 'for publication'<br>Doc 2 'for publication'<br>Doc 3 'for publication'<br>Doc 4 'for publication' | Doc 1 'not for publication'<br>Doc 2 'not for publication'<br>-<br>- | Doc 1 (formerly 'not for publication')<br>Doc 2 (formerly 'not for publication')<br>Doc 3 (formerly 'for publication')<br>Doc 4 (formerly 'for publication') |
| Doc 1 'for publication' English<br>Doc 2 'for publication' German | Doc 3 'not for publication' Spanish<br>Doc 4 'not for publication' Italian | Doc 1 (formerly 'for publication' English)<br>Doc 2 (formerly 'for publication' German)<br>Doc 3 (formerly 'not for publication' Spanish)<br>Doc 4 (formerly 'not for publication' Italian) |

*In some cases, users could still see both 'for publication' and 'not for publication' versions. Note that also in these cases the document is not published.*

# Historical trials, submitted before 18 June 2024

Section 2.3 of Guidance document on how to approach the protection of personal data and commercially confidential information while using the CTIS

# Historical trials: what is published and when

For all those CTIS applications **submitted*** before 18 June 2024:

- the structured data will be published for all trials' categories as per revised rules
- **documents will not be published** *(this applies to all historical trials, regardless of the previous use of deferrals or publication status)*

The following kinds of CTIS applications **submitted*** on or after 18 June 2024 will trigger publication of those documents that are in scope of the application and 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***

**the date determining whether a trial is 'historical' or not, is the submission date, not the date of creation of your draft*

# Historical trials: what is published and when

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

→ ***for an application that is submitted to CTIS on and after 18 June,*** *the* ***documents*** *in scope of publication that are feasible to be modified through the application are going to be published and* ***should be redacted accordingly***

Example, for an initial application submitted before 18 June 2024:

- 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

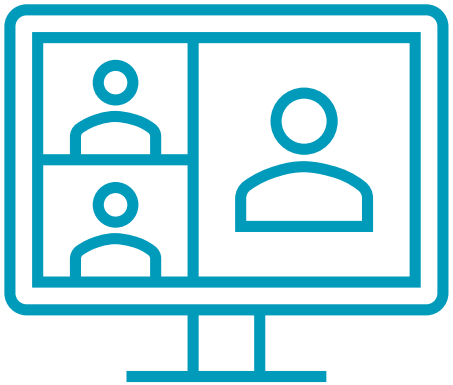
# Reference documentation

ACT EU – Implementation of clinical trial regulation website

# Reference documentation

- Revised transparency rules
- Quick guide for users
- Guidance document on how to approach the protection of personal data and commercially confidential information (CCI) while using CTIS and its Annex I
- Q&A on the protection of CCI and Personal Data while using CTIS
- CTIS Bitesize talk on the transparency rules

# Upcoming CTIS events



- **10 July 2024**, 16:00 – 17:00 CET – CTIS Walk-in Clinic
- **18 September 2024,** 16:00 – 17:00 CET – CTIS Bitesize talk
- For 2024 CTIS events, please consult Clinical Trials Information System: training and support | European Medicines Agency (europa.eu) and EMA events pages

# Thank you for attending today's event

Please provide your feedback for this event in our **Slido survey**

Use the passcode: **#bt20jun** or scan the QR code

## Further information

For the CTIS Newsletter sign up at https://ec.europa.eu/newsroom/ema/user-subscriptions/3201/create

For upcoming CTIS events visit the EMA event page.

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