Transparency – publication of clinical trial information contained in CTIS

SME and academia Clinical Trials Information System (CTIS) two-part training webinar

Presented by Laura Pioppo on 04 March 2021
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CTIS User groups have dedicated workspaces

- Sponsors: industry and academia
- Marketing authorisation applicants
- Member States **National competent authorities**
- European Commission
- European Medicines Agency
- General public

**secure access**

**sponsor workspace**

- Sponsor User

**authority workspace**

- Member State User

**EU Portal**

**public website**

**EU CT Database**

Data accessible to the public

Practical implications of transparency in CTIS

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Article 81(4) outlines the requirements for transparency in CTIS:

4. The EU database shall be publicly accessible unless, for all or part of the data and information contained therein, confidentiality is justified on any of the following grounds:

(a) protecting personal data in accordance with Regulation (EC) No 45/2001;

(b) protecting commercially confidential information, in particular through taking into account the status of the marketing authorisation for the medicinal product, unless there is an overriding public interest in disclosure;

(c) protecting confidential communication between Member States in relation to the preparation of the assessment report;

(d) ensuring effective supervision of the conduct of a clinical trial by Member States
General principles for disclosure of CT information in CTIS

- Only applications on which a **decision** (any decision) has been reached by the Member State Concerned will be made public;

- All data and documents in the CTIS will be made public, with few exceptions;

- The default is always to make public at the first opportunity, e.g. time of decision;

- Sponsors have options to **defer** the timing of publication of specific data/documents and MSC will have the chance to evaluate the proposal made by sponsor to defer the publication, as applicable;

- Deferral rules and maximum timelines to defer publication of data and documents will depend on the trial category [i.e. category 1 (phase I trials), category 2 (phase II and III trials) or category 3 (phase IV trials)] as defined in the appendix, on the disclosure **rules**, to the" Functional Specifications for the EU Portal and DB to be audited "
CTIS deferral rules of CT information, if not publish at the first opportunity

<table>
<thead>
<tr>
<th>Actor</th>
<th>Grouping</th>
<th>Category 1</th>
<th>Category 2</th>
<th>Category 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sponsor</td>
<td>• Main Characteristics</td>
<td>Publication of final <strong>summary of results</strong></td>
<td></td>
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<tr>
<td>Sponsor</td>
<td>• Notifications</td>
<td>Publication of final <strong>summary of results</strong></td>
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</tr>
<tr>
<td>Sponsor</td>
<td>• Subject information sheet</td>
<td>Up to <strong>7 years</strong> after the end of the trial in EU/EEA</td>
<td>Up to <strong>5 years</strong> after the end of the trial in EU/EEA</td>
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<tr>
<td>Sponsor</td>
<td>• Protocol</td>
<td>Up to <strong>7 years</strong> after the end of the trial in EU/EEA</td>
<td>Up to <strong>5 years</strong> after the end of the trial in EU/EEA</td>
<td>Publication of final <strong>summary of results</strong></td>
</tr>
<tr>
<td>Sponsor</td>
<td>• IMPD S&amp;E sections and Investigator Brochure</td>
<td>Up to <strong>7 years</strong> after the end of the trial in EU/EEA</td>
<td>Up to <strong>5 years</strong> after the end of the trial in EU/EEA</td>
<td>Publication of final <strong>summary of results</strong></td>
</tr>
<tr>
<td>Sponsor</td>
<td>• Responses to RFI</td>
<td>Up to <strong>7 years</strong> after the end of the trial in EU/EEA</td>
<td>Up to <strong>5 years</strong> after the end of the trial in EU/EEA</td>
<td>Publication of final <strong>summary of results</strong></td>
</tr>
<tr>
<td>Sponsor</td>
<td>• Clinical trial results summary for an intermediate data analysis</td>
<td>1. 12 months after interim analysis date 2. up to <strong>30 months</strong> after the end of the trial in the EU/EEA</td>
<td></td>
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</tr>
<tr>
<td>Sponsor</td>
<td>• Clinical trial results summary and lay person summary</td>
<td>1. 12 months after the end of trial date in the EU/EEA 2. Up to <strong>30 months</strong> after the end of trial in the EEA</td>
<td></td>
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</tr>
</tbody>
</table>
### Practical implications of transparency in CTIS

<table>
<thead>
<tr>
<th>Data/Document type</th>
<th>Publication date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Main characteristics</strong></td>
<td>Date of decision ○ Publication of final summary of results</td>
</tr>
<tr>
<td>Notifications</td>
<td>○ At designated time ○ Publication of final summary of results</td>
</tr>
<tr>
<td>Subject information sheet</td>
<td>○ Date of decision ○ 7 years and ______ months after the end of trial</td>
</tr>
<tr>
<td>Protocol</td>
<td>○ Date of decision ○ 7 years and ______ months after the end of trial</td>
</tr>
<tr>
<td>IMPD SendE sections and Investigator Brochure</td>
<td>○ Date of decision ○ 7 years and ______ months after the end of trial</td>
</tr>
<tr>
<td>Responses to RFI</td>
<td>○ Date of decision ○ 7 years and ______ months after the end of trial</td>
</tr>
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<td>Clinical trial results summary for an intermediate data analysis</td>
<td>○ 12 months after interim data analysis date ○ As soon as results are submitted</td>
</tr>
<tr>
<td>Clinical trial results summary and lay person summary</td>
<td>○ 12 months after end of trial date ○ As soon as results are submitted</td>
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Sponsor data/documents that can be deferred for category 1 trials

A non-exhaustive list of the clinical trial main characteristics for which publication can be deferred, include, but is not limited to:

• trial title,
• protocol code, trials design, therapeutic intent,
• main objective,
• secondary objective,
• endpoints,
• inclusion and exclusion criteria,
• treatment arms, treatment population and number of subjects,
• identification of the investigational medicinal products (IMPs).

Of note, deferral of main characteristics is possible only for category 1 trials.
Fields always published, even in case of deferral

- EU Clinical Trial Number,
- Sponsor name and address,
- Nature of clinical trial (e.g. bioequivalence in 24 healthy volunteers),
- Decision outcome on the trial application and date of decision,
- Date of start of the trial,
- Dates of start and end of recruitment,
- Date of end of the trial in the Member State(s) in the EEA, and globally (including early termination of the trial),
- Principal Investigator Curriculum Vitae,
- Suitability of the facilities

*Of note, these fields are always published at time of decision and regardless of trial category*
Practical implications of transparency in CTIS
### Summary

<table>
<thead>
<tr>
<th>Trial Information</th>
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<tbody>
<tr>
<td>Conditions(s)</td>
<td>Medical condition</td>
</tr>
<tr>
<td>Sponsor</td>
<td>Test Organisation Demo1</td>
</tr>
<tr>
<td>Trial Phase</td>
<td>Human Pharmacology (Phase I) - First administration to humans</td>
</tr>
<tr>
<td>Therapeutic area</td>
<td>Diseases [C] - Musculoskeletal Diseases [C05]</td>
</tr>
<tr>
<td>First submitted</td>
<td>02/11/2020</td>
</tr>
<tr>
<td>Last update</td>
<td>02/11/2020</td>
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<tr>
<td>FIH</td>
<td>Yes</td>
</tr>
<tr>
<td>Medical device</td>
<td>No</td>
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<tr>
<td>Member states concerned</td>
<td>AT</td>
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<tr>
<td>Low intervention study</td>
<td>No</td>
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<tr>
<td>Population type</td>
<td>Healthy Volunteers</td>
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### Practical implications of transparency in CTIS

**Overall start date of the trial (in the EU):** 02/11/2020  |  **Overall end date of the trial (in the EU):** N/A  |  **Conditions:** N/A  |  **Countries where the trial is taking place (EU country code):** On-going, recruiting  |  **Decision date:** N/A
Practical implications of transparency in CTIS

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What will not be made public

- Quality related information that include:
  - The IMPD quality
  - Quality related request of information (RFI) raised during the assessment
  - Quality Assessment reports (draft and final)
- Draft assessment reports;
- Personal information identifying Member States experts, sponsor staff, MAH/applicant staff
- Financial agreements between the sponsor and the investigator site;
Examples of CTIS functionalities

How data confidentiality and data protection is enabled via CTIS
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Practical implications of transparency in CTIS

Upload a doc version for publication and not for publication, to protect personal data, as applicable

Form details

Initial Application details

Cover letter

Cover letter for initial

- English
- Cover letter (for publication)
- System version 1
- Version 1 · 02/11/2020

Cover letter with signature

- English
- Cover letter (not for publication)
- System version 1
- Version 1 · 02/11/2020

Add document
Some data/documents are never published
Deferral of some documents

- Trial identifiers
- Trial information
- Protocol information

Clinical Trial Protocol

Protocol:
There are no attached documents.
Synopsis of the protocol:
There are no attached documents.
Data safety monitoring committee charter:
There are no attached documents.

Study design

Period details

<table>
<thead>
<tr>
<th>Number</th>
<th>Period Title</th>
<th>Period Description</th>
<th>Allocation Method</th>
<th>Blinding Used</th>
<th>Roles Blinded</th>
<th>Blinding Implementation Details</th>
<th>Arm Details</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>

There are no attached documents.

Scientific Advice and Paediatric Investigation Plan
Any questions?

Further information

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