



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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

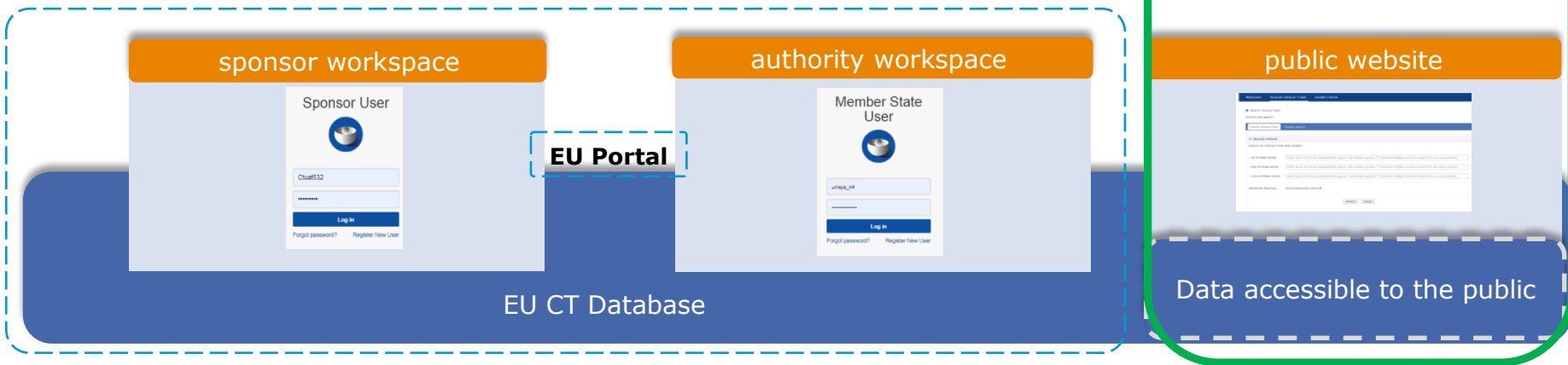


*National competent authorities

secure access



open access





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*

- 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



Actor	Grouping	Category 1 FIH, PK/PD, BE/BA, Bio similarity	Category 2 Phase II and III	Category 3 Phase IV
Sponsor	<ul style="list-style-type: none"> Main Characteristics 	Publication of final summary of results		
Sponsor	<ul style="list-style-type: none"> Notifications 	Publication of final summary of results		
Sponsor	<ul style="list-style-type: none"> Subject information sheet 	Up to 7 years after the end of the trial in EU/EEA	Up to 5 years after the end of the trial in EU/EEA	
Sponsor	<ul style="list-style-type: none"> Protocol 	Up to 7 years after the end of the trial in EU/EEA	Up to 5 years after the end of the trial in EU/EEA	Publication of final summary of results
Sponsor	<ul style="list-style-type: none"> IMPD S&E sections and Investigator Brochure 	Up to 7 years after the end of the trial in EU/EEA	Up to 5 years after the end of the trial in EU/EEA	Publication of final summary of results
Sponsor	<ul style="list-style-type: none"> Responses to RFI 	Up to 7 years after the end of the trial in EU/EEA	Up to 5 years after the end of the trial in EU/EEA	Publication of final summary of results
Sponsor	<ul style="list-style-type: none"> Clinical trial results summary for an intermediate data analysis 	<ol style="list-style-type: none"> 12 months after interim analysis date up to 30 months after the end of the trial in the EU/EEA 		
Sponsor	<ul style="list-style-type: none"> Clinical trial results summary and lay person summary 	<ol style="list-style-type: none"> 12 months after the end of trial date in the EU/EEA Up to 30 months after the end of trial in the EEA 		



i Please note that data and documents provided in the EU Database are subject to publication rules (including the protection of personal data and commercially confidential information), as per Regulation (EU) 536/2014, Article 81(4).

- MSCs
- Part I
- Part II
- Evaluation
- Timetable

Data/Document type

Main characteristics

Publication date

Date of decision Publication of final summary of results

Notifications

At designated time Publication of final summary of results

Subject information sheet

Date of decision

7 years and months after the end of trial

Protocol

Date of decision

7 years and months after the end of trial

IMPD SandE sections and Investigator Brochure

Date of decision

7 years and months after the end of trial

Responses to RFI

Date of decision

7 years and months after the end of trial

Clinical trial results summary for an intermediate data analysis

12 months after interim data analysis date As soon as results are submitted

30 months after the end of trial

Clinical trial results summary and lay person summary

12 months after end of trial date As soon as results are submitted

30 months after the end of trial





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**.*



- 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***

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Display options

1 results found

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Decision date

DESC

Sort

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<input type="checkbox"/>	
<input type="checkbox"/>	2020-500226-34-00 - On-going, recruiting - Trial title_publication category 1 with no deferral
	Overall start date of the trial (in the EU): 02/11/2020 Overall end date of the trial (in the EU): N/A Conditions: Medical condition Countries where the trial is taking place (EU country code): AT:On-going, recruiting Decision date: AT:02/11/2020

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Trial title_publication category 1 with no deferral

EUCT number: 2020-500226-34-00

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Summary

Full trial information

Events

Trial results

Corrective measures

Inspection Record

Trial information

Conditions(s)	Medical condition	Member states concerned	AT
Sponsor	Test Organisation Demo1	Low intervention study	No
Trial Phase	Human Pharmacology (Phase I)- First administration to humans	Population type	Healthy Volunteers
Therapeutic area	Diseases [C] - Musculoskeletal Diseases [C05]		
First submitted	02/11/2020		
Last update	02/11/2020		
FIH	Yes		
Medical device	No		

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Clinical trial search

Search criteria Search results Display options

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<input type="checkbox"/>	
<input type="checkbox"/>	2020-500228-68-00 - On-going, recruiting - 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

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EUCT number: 2020-500228-68-00

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- Summary
- Full trial information
- Events
- Trial results
- Corrective measures
- Inspection Record

Trial information	
Conditions(s)	Member states concerned
Sponsor	Test Organisation Demo1
Trial Phase	Low intervention study
Therapeutic area	Population type
First submitted	No
Last update	02/11/2020
Medical device	No



- 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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- Form
- MSCs
- Part I
- Part II
- Evaluation
- Timetable

Form details

Initial Application details

Cover letter

Cover letter *

Add document

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

Some data/documents are never published

Part I
Part II
Evaluation
Timetable

Title* IMPD-Q Type* Investigational Medicinal Product Dossier: Full

Language English Version* 1 System version 1

Date* 02/11/2020

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▶ **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

Number	Period title	Period Description	Allocation method	Blinding used	Roles blinded	Blinding implementation details	Arm details
There are no attached documents							

▶ **Scientific Advice and Paediatric Investigation Plan**



Any questions?

Further information

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