



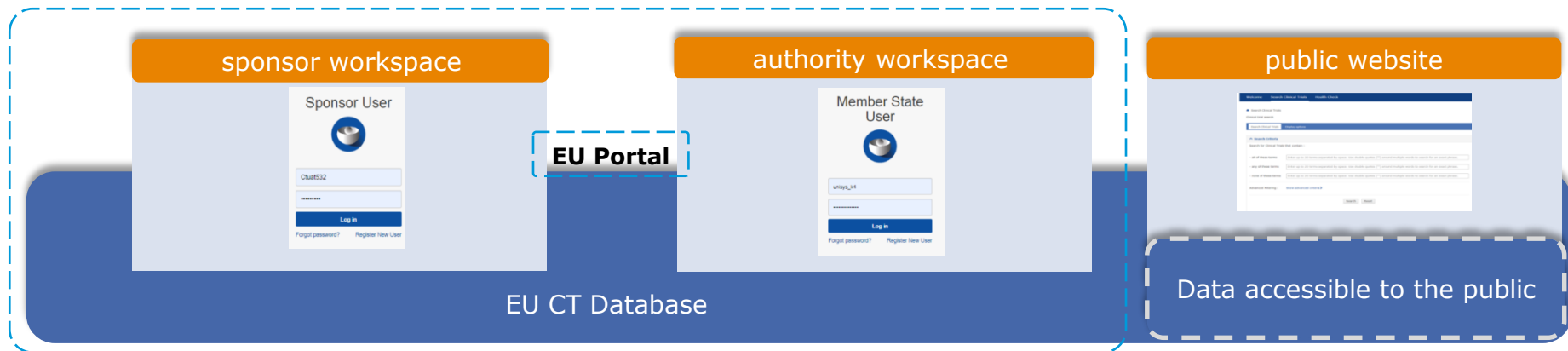
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

CTIS publication rules: How CTIS supports access to clinical trial data

Practical implications of transparency in CTIS



CTIS User groups have dedicated work spaces





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;
- Sponsors and Authority users (MSs and European Commission) will have the possibility to upload documents version 'for publication' and 'not for publication' to protect personal data, if needed;
- Commercially Confidential Information (CCI) is expected to be addressed mainly by the deferral mechanism;

Disclosure rules detailed in: https://www.ema.europa.eu/en/documents/other/appendix-disclosure-rules-functional-specifications-eu-portal-eu-database-be-audited_en.pdf



- Quality related information that include:
 - ❑ The IMPD quality
 - ❑ Quality related request of information (RFI) raised during the assessment
 - ❑ Quality Assessment reports (draft and final)
- Any draft assessment reports;
- Versions of documents that are '**not for publication**', which may include personal information identifying Member States experts, sponsor staff, MAH/applicant staff, as needed;
- Financial agreements between the sponsor and the investigator site.

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).

- [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



Sponsor document: IMPD-Q 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

Comment

This document will not be publicly accessible.

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Title* FAR part I - Quality

Type* Part I assessment report quality - Final

Language English

Version* 1

System version 1.00

Date* 02/03/2021

Comment

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This document will not be publicly accessible.

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Part I assessment report quality – Final*

Add document

- FAR part I - Quality
English · Part I assessment report quality - Final · **System version 1.00**
· **Version 1** · 02/03/2021

Part I assessment report except quality – Final*

Add document

- FAR part I exc quality
English · Part I assessment report except quality - Final (for publication) · **System version 1.00**
· **Version 1** · 02/03/2021






- FAR part I exc quality_not for publication
English · Part I assessment report except quality - Final (not for publication) · **System version 1.00**
submission date 02/03/2021
· **Version 1** · 02/03/2021

Part II assessment report – Final*

[Add document](#)

-  **Final AR part II**     

English · Part II Assessment Report - Final (for publication) · **System version 1.00**
· **Version 1** · 02/03/2021

-  **FAR not for publication**    

English · Part II Assessment Report - Final (not for publication) · **System version 1.00**
· **Version 1** · 02/03/2021

Discussion within the MSC

Austria

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Final conclusion*

Acceptable 












- An inspection record can contain information on one or more site inspected;
- Each site contains details of one or more clinical trial(s) inspected;
- At the end of the inspection process, final inspection reports can be uploaded in the system by EU MS inspectors for each site/trial combination, as applicable
(e.g. one inspection report per one site and one trial, one inspection report for one site and multiple trials)
- Like for the other documents in CTIS, a version of the inspection report 'for publication' and 'not for publication' can be uploaded in the system, as needed;
- No identifiable personal data of trial subjects should be publicly accessible.

Clinical trials Notices & alerts 0 Tasks Ad hoc assessments Annual safety reporting BI reports Inspections Union control Services Status

General information
Inspections
Overall inspection outcome and reports

Overall Inspection Outcomes

+ Add report

Related site	Related EU trials	Related Non EU trials	Document upload	Actions
Test Hospital FBL	2021-500408-31-00 Add trials	Add trials	 Inspection report for publication English · Inspection report (for publication) · System version 1.00 Submission date 02/03/2021 · Version 1 · 02/03/2021	    
			 Inspection report not for publication English · Inspection report (not for publication) · System version 1.00 Submission date 02/03/2021 · Version 1 · 02/03/2021	   

Publication rules:

- Publication of the inspection report(s) will occur when all the sites and the trials in the inspection record have a corresponding inspection report ;
- In case of inspections done in the context of a marketing authorisation application, inspection report(s) will be published when the Clinical study report (CSR) will be provided in CTIS by the Marketing authorisation applicant;
- Publication of inspection reports cannot be deferred;
- Sponsors are responsible to provide in CTIS also inspection reports for inspections carried out by third countries authorities. These reports are published as soon as they are submitted and publication cannot be deferred.



Deferral rules in CTIS



- By completing the CTA sponsors can apply for a request for deferral, to delay publication of certain clinical trial data and documents;
- If the sponsor applies for a deferral, then RMS/MSD can also defer publication of certain documents up to the same period of time as selected by the sponsor or for a shorter period;
- **RMS** can defer the publication of information related to **part I**, for request for information (RFI), final assessment reports and conclusions;
- **MSD** can defer the publication of information related to **part II**, for request for information (RFI), final assessment reports and conclusions.

Deferral rules for sponsors



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 		

Example: sponsor can request deferral for publication of CT information

Clinical trials Notices & alerts **0** Annual safety reporting RFI User administration

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***

Decision

Authorised



Publication of RFIs

Data/document type

Publication timepoint

Responses to RFIs

4 years and 0 month after the end of trial (set by sponsor)

RFIs sent to the sponsor

Date of Decision

4 years and 0 months after the end of trial

Publication of assessment reports and conditions

Data/document type

Publication timepoint

Protocol

7 years and 0 month after the end of trial (set by sponsor)

IMPD S&E and Investigator Brochure

6 years and 0 month after the end of trial (set by sponsor)

Assessment reports and conditions

7 years and 0 months after the end of trial

Any deferrals set by the MSC/RMS apply to the relevant MSC/RMS's Part II requests for information, Part II assessment reports, conditions on Part II conclusion and conditions on the decision.

Any deferrals set by the RMS also apply to Part I requests for information, Part I assessment reports and conditions on the Part I conclusion.

The deferrals set as part of submitting the decision on the initial application also apply to subsequent applications throughout the life of the trial.

Supporting documentation

Add document



CTIS public website- publication aspects

Welcome Search Clinical Trials Union Control Reports Help Predefined Reports

🏠 Search Clinical Trials

Clinical trial search

Search criteria

Search results

Display options

1 results found

Modify my search

Sort by:

Decision date

DESC

Sort

Download results

Subscribe to search

<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

[Welcome](#) [Search Clinical Trials](#) [Union Control Reports](#) [Help](#) [Predefined Reports](#)

[View Clinical Trial](#)

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		

Home Search Clinical Trials

Clinical trial search

Search criteria Search results Display options

1 results found [Modify my search](#)

Sort by: Decision date DESC Sort

Download results Subscribe to search

<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

- Welcome
- Search Clinical Trials
- Union Control Reports
- Help
- Predefined Reports

[View Clinical Trial](#)

EUCT number: 2020-500228-68-00

Download CT

- 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	
Last update	02/11/2020
Medical device	No



▶ [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](#)

View Clinical Trial

EUCT number: 2021-500392-23-00

Download CT

Inspection record

Inspection record INS|08 - Austria -24/02/2021

Related Trials 2021-500392-23-00

Title	File type	Document Type
TEST	PDF	Inspection report (for publication)

Request removal of public information

Node: uv1268.emea.eu.int:80



Conclusions

Transparency builds public trust and confidence in clinical trials, in the regulatory process and in trial results

- **Publication** of clinical trial data and information about medicines, their development and authorisation, helps to:
 - To generate trust – information is available
 - To build confidence – I understand what is happening
 - To empower – knowledge enables decision-making
 - Empowerment enables patients, consumers, their carers and treating physicians make good decisions for their healthcare

More information on Regulation (EU) No 536/2014 and CTIS can be found on:

<https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/regulation>





Thank you for your attention

Any questions?

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