



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Clinical Trial Information System (CTIS) Bitesize talk

Deferral rules and Public website

Presented by Laura Pioppo and Mumtaz Sultani on 20 July 2022
European Medicines Agency

An agency of the European Union





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A few housekeeping rules

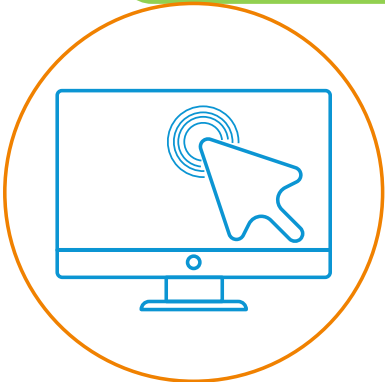
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& use event code **#july20**

Or scan
slido
QR code:



Two topics –
two questions rooms !

Tips for optimal screen viewing

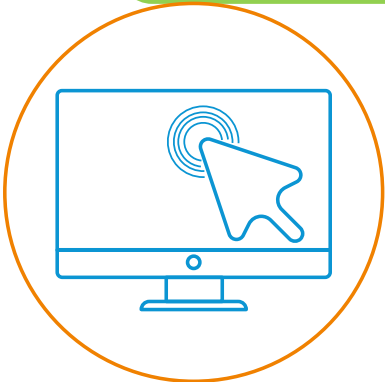


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Live broadcast - 14:30 - 16:00 Amsterdam time (CET)



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Main Sessions: CTIS Demo with Q&A

Session I :
CTIS Publication rules including
deferral (14:35-15:15)

Session II :
Public website (15:15-15:55)

*For questions,
go to **www.sli.do**
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CTIS Scientific Officer



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CTIS Publication rules including deferral

Laura Pioppo

Publication Rules in CTIS

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

"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".*

[Clinical trials](#) [Notices & alerts](#) [Annual safety reporting](#) [RFI](#) [User administration](#)

i Please note that, in accordance with Regulation (EU) No 536/2014, all data and documents provided in the EU database are subject to publication rules , aiming amongst other things at protecting personal data and commercially confidential information. It is the responsibility of each user to ensure compliance with Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 when uploading documents and processing personal data in CTIS.

CT data for demo including publication aspects_ Category 2 2021-500384-21-00 / Initial ID: IN **Authorised** / RMS: France

[Withdraw](#)[Form](#)[MSCs](#)[Part I](#)[Part II](#)[Evaluation](#)[Timetable](#)[Form details](#)[Initial Application details](#)[Cover letter](#)

Cover letter *



Cover letter for initial application



English · Cover letter (for publication) · System version 1.00
Submission date 22/11/2021
Version 1 · 22/11/2021



Cover letter not for publication



English · Cover letter (not for publication) · System version 1.00
Submission date 22/11/2021
Version 1 · 22/11/2021



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

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- Only applications on which a **decision** (any decision) has been reached by the Member State Concerned will be made public;
- The default is always to make public at the first opportunity, e.g. time of decision;
- Data and documents in the CTIS will be made public, with few exceptions;
- 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 as defined in the appendix, on the disclosure **rules**, to the "Functional Specifications for the EU Portal and DB to be audited"



Actor	Grouping	Category 1 FIH, PK/PD, BE/BA, Bio similarity	Category 2 Phase II and III	Category 3 Phase IV
Sponsor	Main Characteristics*	Publication of final summary of results		
Sponsor	Notifications*	Publication of final summary of results		
Sponsor	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	Protocol and Scientific Advice	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	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	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	Clinical trial results summary for an intermediate data analysis*	1. 12 months after interim analysis date 2. up to 30 months after the end of the trial in the EU/EEA		
Sponsor	Clinical trial results summary and lay person summary*	1. 12 months after the end of trial date in the EU/EEA 2. Up to 30 months after the end of trial in the EEA		

*not permitted if the trial includes paediatric population or it is part of a PIP



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	Publication date
Main characteristics	☐ 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



Deferral set by the Member States concerned

MSC can also set a deferral for Assessment Reports (part I and part II) and RFI at the time when they issue the decision

Clinical trialsNotices & alerts14TasksAd hoc assessmentsUser administrationAnnual safety reportingInspectionsUnion controlMember states calendarsServices Status

Please note that, in accordance with Regulation (EU) No 536/2014, all data and documents provided in the EU database are subject to publication rules, aiming amongst other things at protecting personal data and commercially confidential information. It is the responsibility of each user to ensure compliance with Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 when uploading documents and processing personal data in CTIS.

Data/document type

Responses to RFIs

Publication timepoint

Date of Decision (set by sponsor)

Data/document type

RFIs sent to the sponsor

Publication timepoint

Date of Decision (set by sponsor)

Publication of assessment reports and conditions

Data/document type

Protocol

Publication timepoint

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

Data/document type

IMPD S&E and Investigator Brochure

Publication timepoint

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

Data/document type

Assessment reports and conditions

Publication timepoint

4

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

Create subtaskComplete

12 CTIS bitesize talk 20 July 2022 - Deferral rules and Public website

Classified as public by the European Medicines Agency

Publication rules in CTIS

- The use of a deferral is per trial
- The timing for deferrals is set by the sponsor at the time of initial application
- The Member States documents and the RFI raised to the sponsors can also be deferred
- It would be preferable to have alignment between the publication timelines of sponsor documents and MSC documents
- A document submitted in an application for which a decision has been issued, but not yet published because of deferral, cannot be modified in the context of that application
- A [guidance document](#) is currently on public consultation to address the topic on protection of personal data and CCI in the documents uploaded in CTIS



Demo and QA session on publication and deferrals



Public website

Mumtaz Sultani



Public website sections



Clinical Trials

English **EN**

CTIS log in **▼**

About **▼**

Search clinical trials and reports **▼**

CTIS for sponsors

CTIS for authorities

Support **▼**

[🏠 Search clinical trials and reports](#)

About searching for clinical trials and reports

This website allows you to search clinical trials in the European Union (EU) and European Economic Area (EEA), entered since its launch on 31 January 2022.





How to search for a clinical trial?

Two search

functionalities:

- Basic Criteria
- Advanced Criteria

The screenshot shows the CTIS (Clinical Trial Information System) search interface. At the top is a dark blue navigation bar with links: 'About', 'Search clinical trials and reports', 'CTIS for sponsors', 'CTIS for authorities', and 'Support'. Below this is a breadcrumb trail: 'Search clinical trials and reports > Search for clinical trials'. The main section is titled 'Clinical trial search' and contains three tabs: 'Search Criteria' (active), 'Search results', and 'Display options'. Under the 'Search Criteria' tab, there is a 'Basic Criteria' section with three input fields: 'Contain all of these terms:', 'Contain any of these terms:', and 'Does not contain any of these terms:'. Below these fields is a link 'Show Advanced Criteria'. At the bottom of the search area are two buttons: 'Search' and 'Reset'.



Information that can be viewed

European DisCoVeRy for Solidarity: An Adaptive Pandemic and Emerging Infection Platform Trial (SolidAct)
EUCT number: 2022-500385-99-00

Download CT

Summary				Full trial information	Events	Trial Results	Corrective measures	Inspection records
Trial information								
Conditions(s)	SARS-CoV II infection (Coronavirus disease)				Member states concerned		AT BE CZ FR DE GR HU IE IT LU PT ES NO SK	
Sponsor	Oslo University Hospital Hf				Low intervention study		No	
Trial Phase	Therapeutic confirmatory (Phase III)				Population type		Incapacitated population, Subjects in emergency situation, Subjects incapable of giving consent personally, Patients Yes	
Therapeutic area	Diseases [C] - Virus Diseases [C02]				Transition Trial			
First submitted	15/03/2022							
Last update	15/07/2022							
Medical device	No							
Overall Trial status								



- **Summary** (2 subsections – 1. trial information of the CT including condition(s), sponsors, trial phase, therapeutic area, date of submission, date of last update, MSC(s) etc. – 2. overall status in each MSC including decision date, last update, the start date of the trial, recruitment status etc.)
- **Full trial information** (displays of data and documents of each CTA, including Trial specific information of Part I and country specific details).
- **Events** (events that may have accrued during the conduct of the CT including unexpected events, serious breaches, urgent safety measures, inspection reports from countries outside the EEA etc.)
- **Trial Results** (summary of results, layperson summary of results etc.)
- **Corrective measures** (possible measures taken by the MSC as part of their supervision activities to ensure adherence to the CTR)
- **Inspection records** (information related to the inspections performed to the trial and/or system and facilities

[Download CT](#)

What will not be made public in a CTA?

- Quality related information that includes:
 - ☐ the IMPD quality
 - ☐ Scientific advice on quality
 - ☐ Quality related request for information (RFI) raised during the assessment
 - ☐ Quality Assessment Reports (draft and final)
- Draft of assessment reports
- Versions of documents that are 'not for publication', which may include personal information
- Financial agreements between sponsors and investigator sites



Demo and QA session on public website



Questions & Answers



For questions,
go to **www.sli.do** & use event code **#july20**
or scan **slido QR code**



We ask for *your feedback* on this event

A brief **poll is now open** in Slido

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or scan slido **QR code:**





Info on upcoming events



Upcoming CTIS events – Save the date

Date	CTIS event
21/07/2022	<u>OMS Trouble Shooting Session for CTIS users</u>
22/08/2022	<u>CTIS Walk-in clinic</u>
22/09/2022	<u>OMS Trouble Shooting Session for CTIS users</u>
28/09/2022	<u>CTIS bitesize talk: Notifications - Part 1</u>

*For satisfaction feedback,
Please go to **www.sli.do**
& use event code **#july20***



CTIS training environment Survey 3.0

A new survey (Survey 3.0) has been published where new potential users of CTIS can express interest to access the CTIS training environment (CTIS Sandbox).

CTIS Sandbox Survey 3.0

The deadline for participation in Survey 3.0 is **23 September 2022.**

*For satisfaction feedback,
Please go to **www.sli.do**
& use event code **#july20***



Thank you for attending today's event

*Next CTIS bitesize talk
on 28 September*

Further information

For CTIS communication, training & change management queries, e-mail CT.Communication@ema.europa.eu

For the [Clinical Trials Newsletter](#) sign up at CT.NewsletterSubscriptions@ema.europa.eu.

For upcoming CTIS events, visit the [EMA event page](#).

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