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

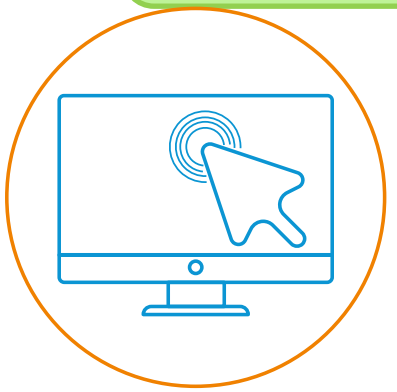
The European Medicines Agency developed this training material to enhance public access to information on the Clinical Trial Information System (CTIS). This material describes a preliminary version of CTIS and may therefore not entirely describe the system as it is at the time of use of this material. The Agency does not warrant or accept any liability in relation to the use (in part or in whole) or the interpretation of the information contained in this training material by third parties.

A few housekeeping rules

For your questions,
go to **www.sli.do**
& use event code **#july20**

Or scan
slido
QR code:

Two topics –
two questions rooms !



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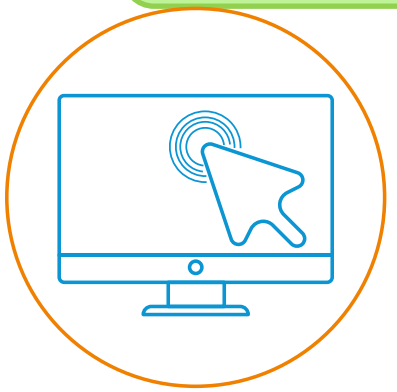

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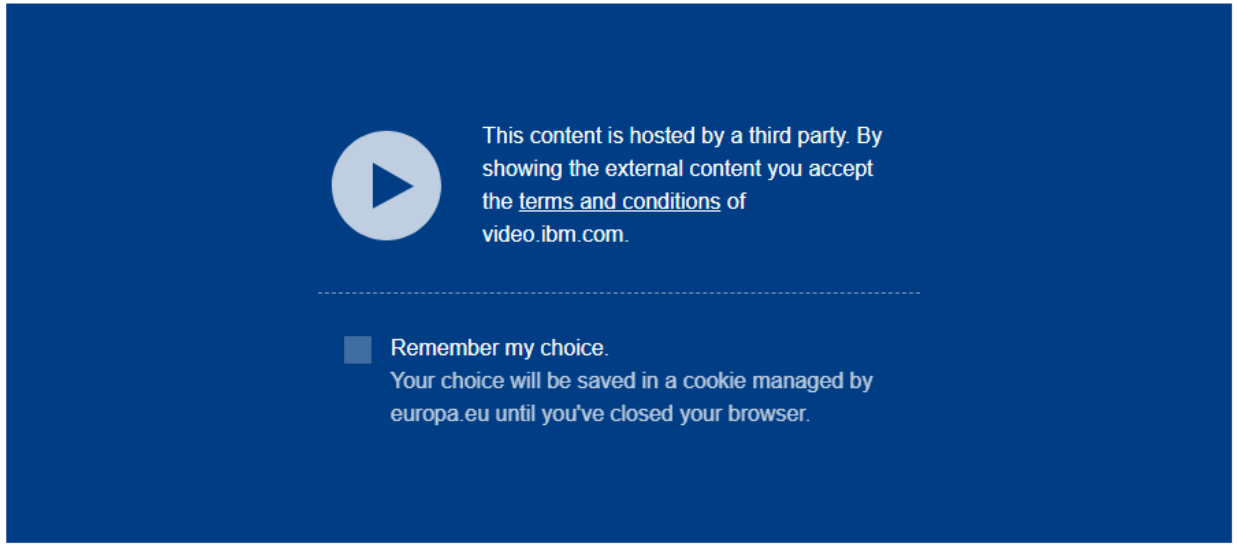
Live broadcast - 14:30 - 16:00 Amsterdam time (CET)



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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,
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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Laura Pioppo
CTIS Scientific Officer

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Mumtaz Sultani
CTIS Scientific Officer

CTIS Publication rules including deferral

Laura Pioppo

Publication Rules in CTIS

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

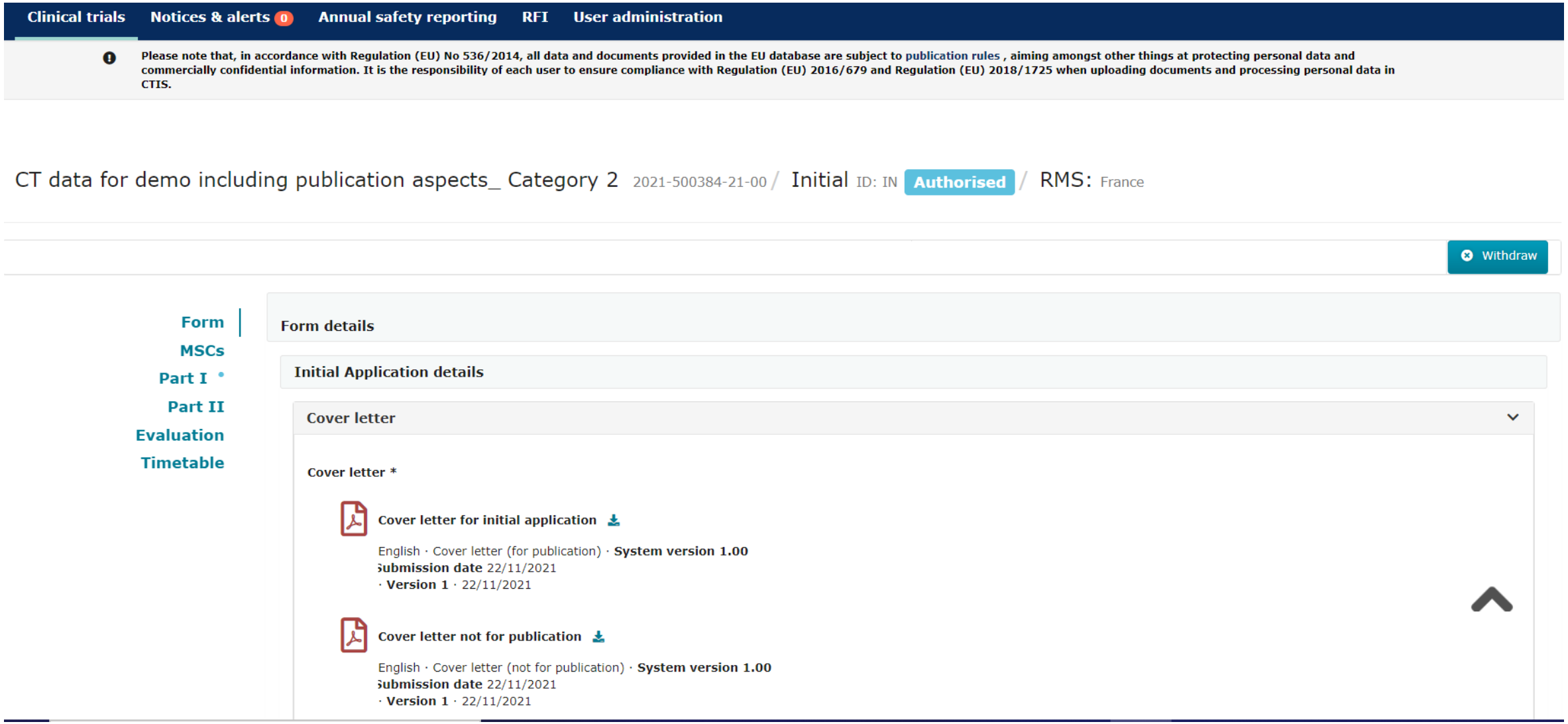
"The EU database shall be publicly accessible unless, for all or part of the data and information contained therein, confidentiality is justified on any of the following grounds:

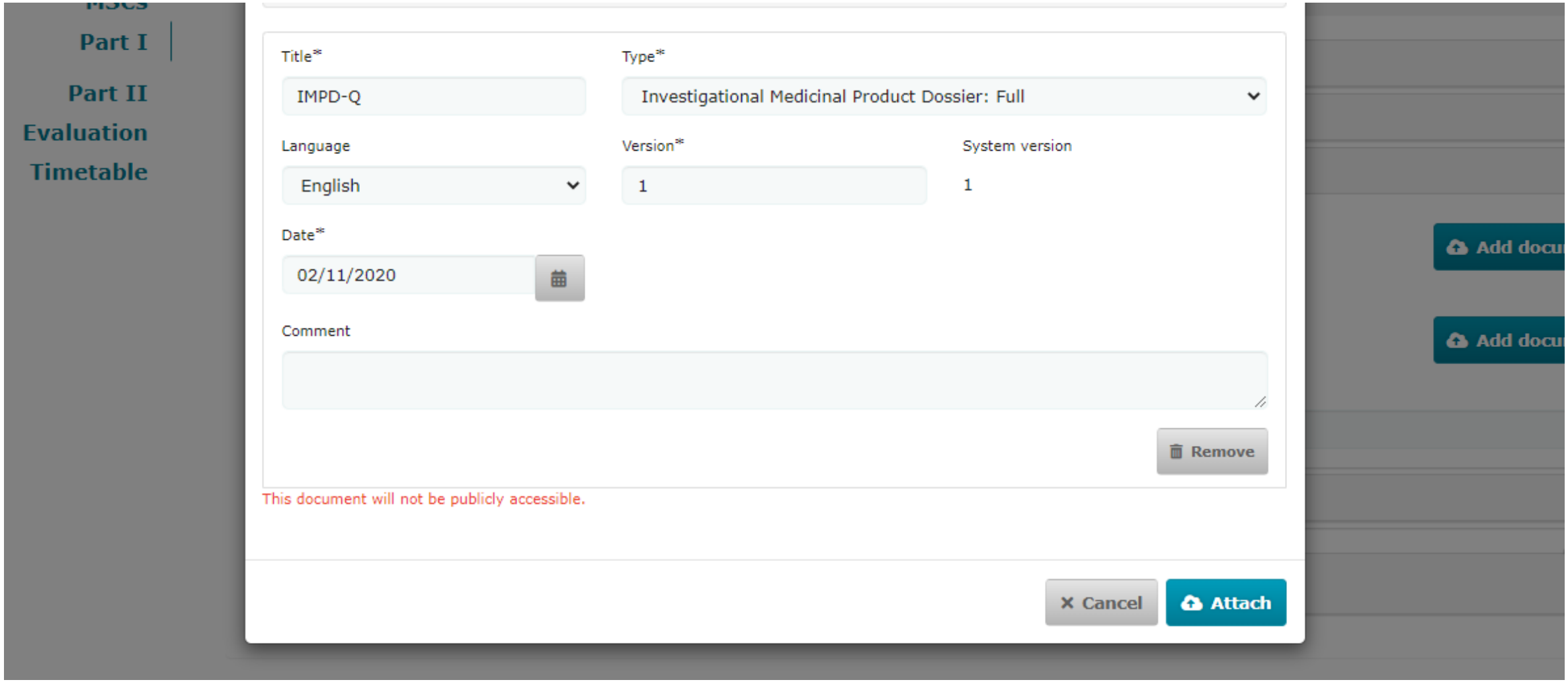
(a) protecting personal data in accordance with Regulation (EC) No 45/2001;

(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".

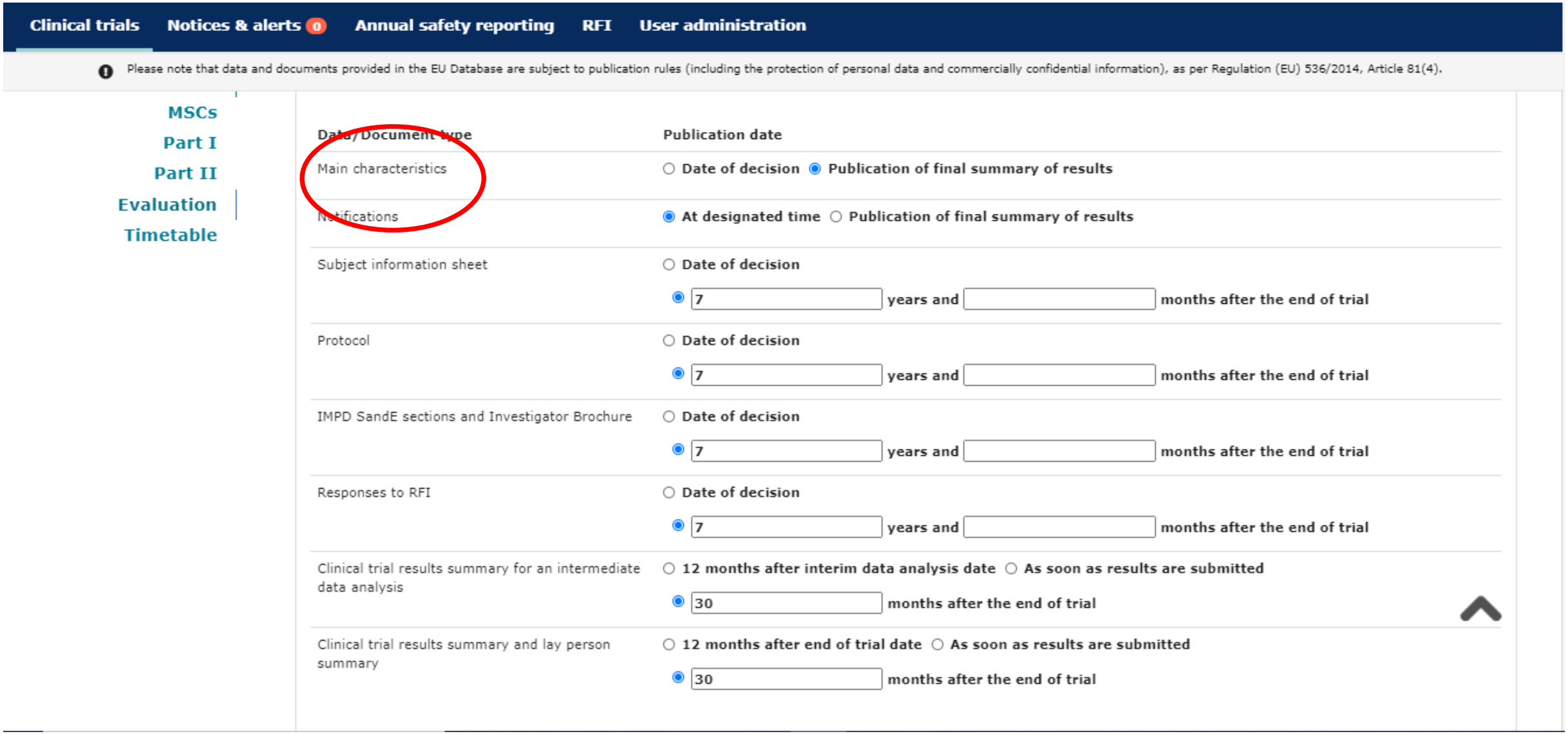




- Only applications on which a **decision** (any decision) has been reached by the Member State Concerned will be made public;
- The default is always to make public at the first opportunity, e.g. time of decision;
- Data and documents in the CTIS will be made public, with few exceptions;
- Sponsors 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"

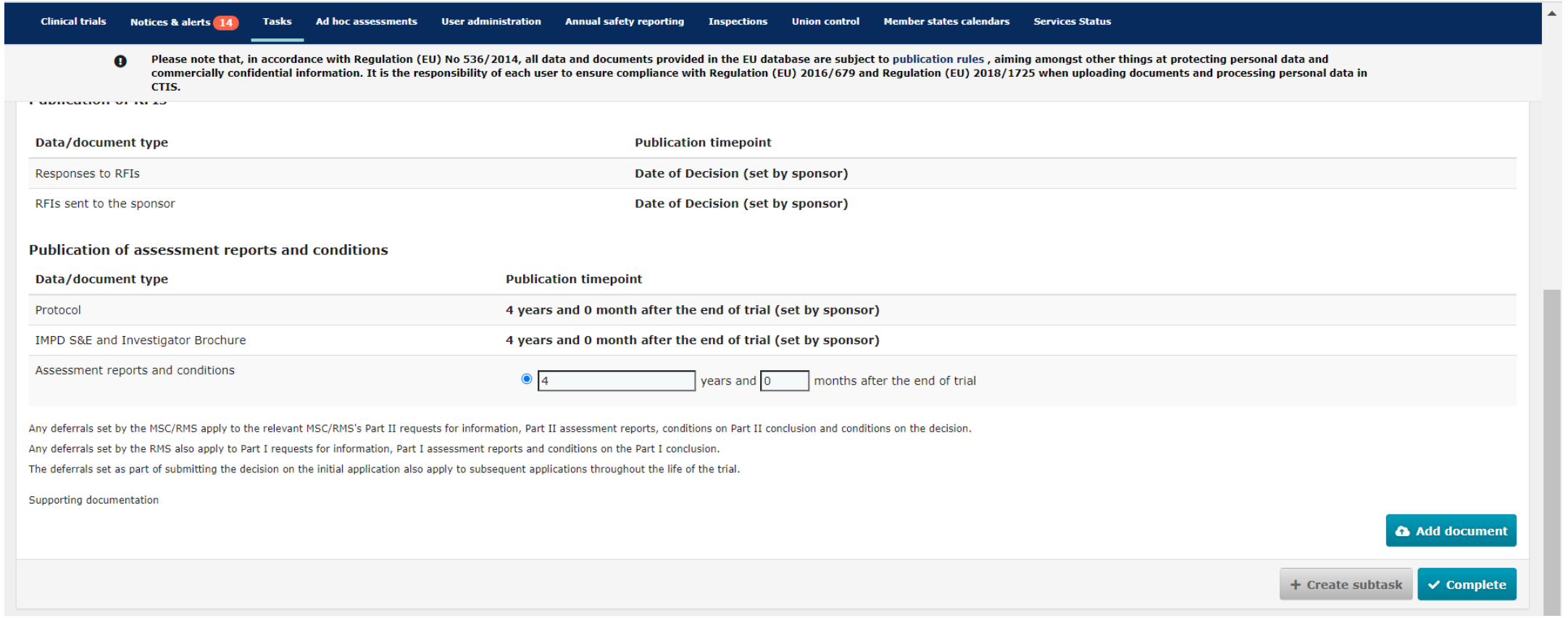
Actor	Grouping	Category 1 FIH, PK/PD, BE/BA, Bio similarity	Category 2 Phase II and III	Category 3 Phase IV
Sponsor	Main Characteristics*	Publication of final **summary of results**		
Sponsor	Notifications*	Publication of final **summary of results**		
Sponsor	Subject information sheet	Up to **7 years** 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



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



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

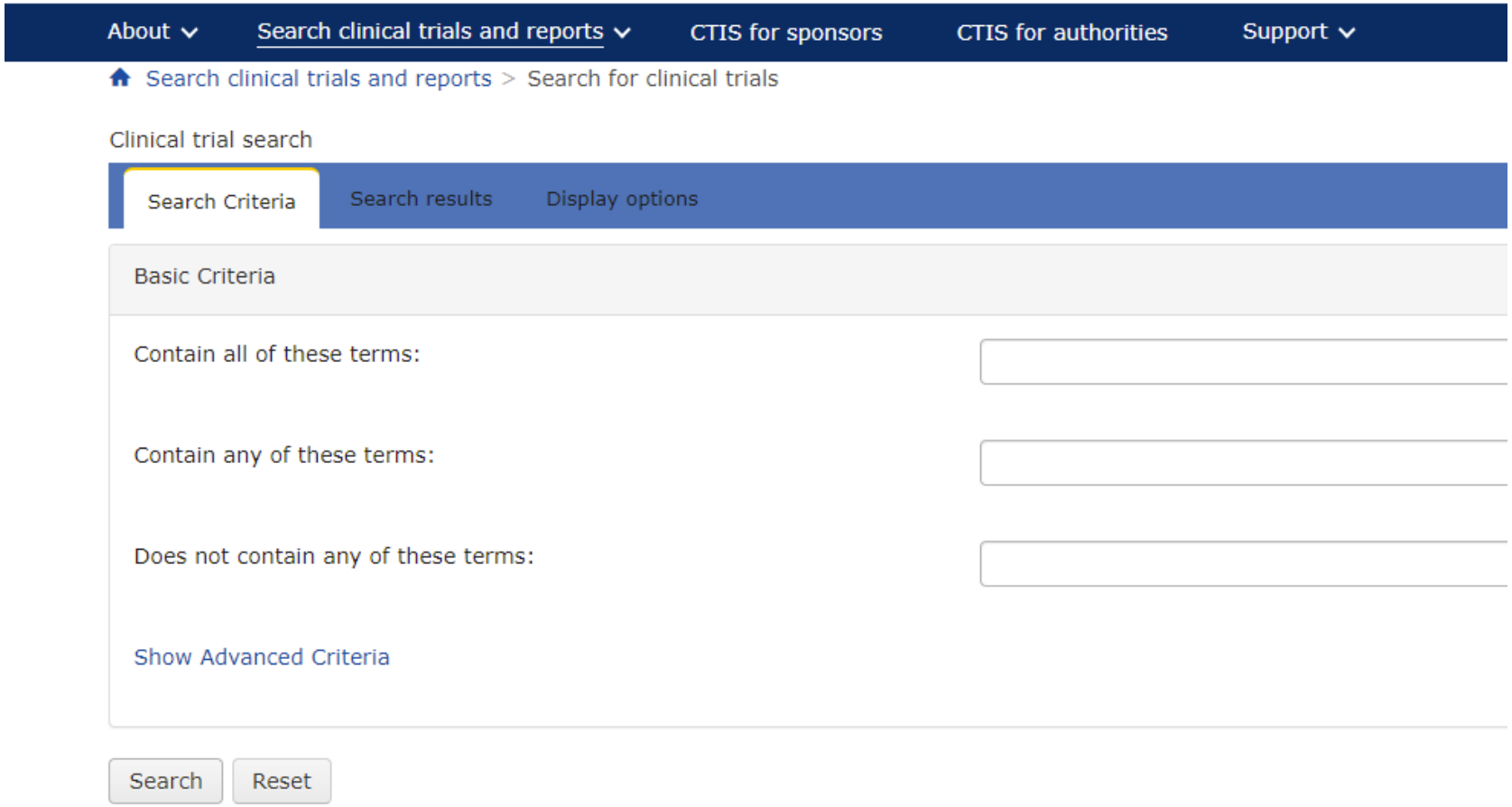
About searching for clinical trials and reports

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



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
Therapeutic area	Diseases [C] - Virus Diseases [C02]	Transition Trial	Yes
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

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**

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We ask for *your feedback* on this event

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

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Info on upcoming events

Upcoming CTIS events – Save the date

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

*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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