



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

CTIS: functionalities and support for clinical trial sponsors, availability of clinical trial data to the public

Presented by Fia Westerholm on 21 September 2021
Programme Assurance Manager, Change Management Lead
Clinical Trials Information System (CTIS) programme
Data Analytics and Methods Task Force (TDA), European Medicines Agency

An agency of the European Union





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The presenter does not have any conflict of interests.

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CTIS Benefits

With CTIS sponsors can:

- 
- Apply for a clinical trial in up to 30 EU/EEA countries with a **single application**
 - Facilitate involvement of trial participants by allowing **easy expansion of trials to other EU/EEA countries**
 - Collaborate across borders** for better results and knowledge sharing
 - Ensure the EU/EEA remains an attractive location for **clinical research investment**
 - Fulfil all **clinical trial publication requirements** with no additional effort

The **future users of CTIS** include:

Sponsors



Commercial: large pharmaceutical companies & CROs, SMEs



Academia

Will **input clinical trial data** in CTIS

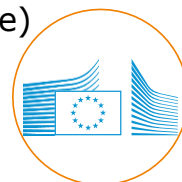
Authorities



Member States (NCA & ethics committee)



EMA



European Commission

Will **review clinical trial data** (MS/EMA) and create **Union Control Reports** (COM)

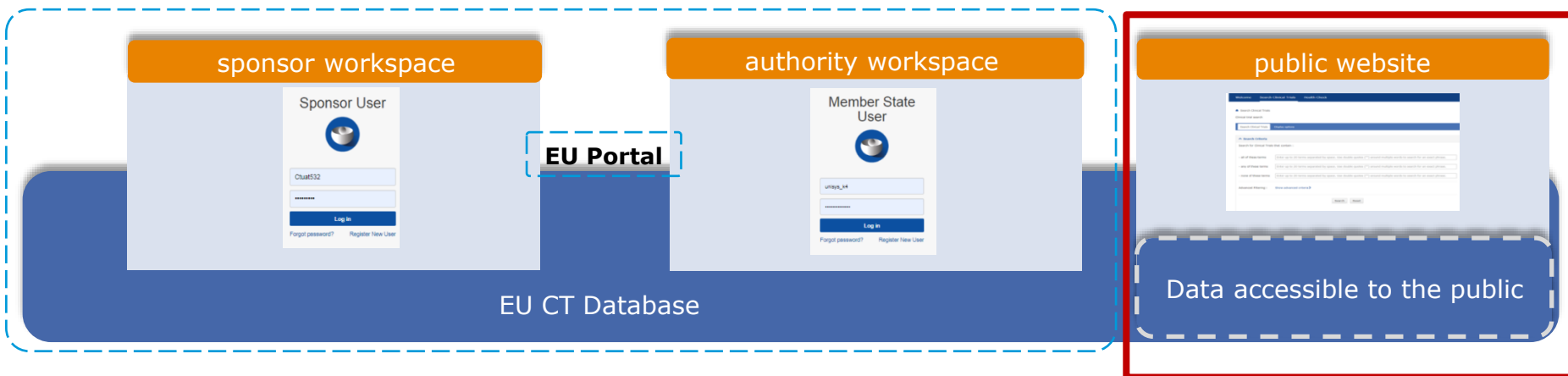
Public



Public users (Healthcare professionals, patients, other)

Will **search for publicly available clinical trial data** in CTIS

Two dedicated and secure workspaces and a public portal



CTIS offers these high-level functionalities to sponsors users. These are: Overview of Clinical Trials (search functionality), Notices & alerts, Annual Safety Reporting, Requests for Information and User administration.

Sponsor workspace

Clinical trials Notices & alerts ² Annual safety reporting RFI User administration

Search, select and monitor the status of a trial/application

Monitor the messages triggered by events occurring for a clinical trial application

Prepare and submit the ASR

Assign and manage user roles

View and respond to request for information

A view of the sponsor functionalities in CTIS – Part I

Clinical trials Notices & alerts 0 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.

CTIS Training Demo Trial for Training event 2021-501434-60-00 / Initial ID: IN Draft

✓ Check 💾 Save ✕ Cancel 📤 Submit

Form
MSCs
Part I
Part II
Evaluation
Timetable

Trial specific information (Part I)

Trial details

Trial identifiers

Trial information

Protocol information

Scientific advice and Paediatric Investigation Plan (PIP)

Associated clinical trials

References

Countries outside the European Economic Area

Sponsors

Name	Organisation type	Country	Type	Status	Legal representative	Scientific contact point	Public contact point	Third parties
Test Organisation Spain	Pharmaceutical company	Spain	Commercial	Active				0

Products

Sort by:  No sorting 



The Regulation outlines the requirements for transparency in CTIS

Article 81(4):

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*

- Data and documents of an application that is 'under evaluation' will not be made public, unless there is an overriding public interest;
- Only applications on which a **decision** has been reached will be made public;
- All data and documents in the system will be made public with some 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 via the deferral mechanism
- Deferral will be part of CTA submission and, therefore, subject to the approval of the Member States Concerned

The data in CTIS will accumulate over time as sponsors submit their applications and results.

There is a basic search on free text and an advanced search with more options

 Search Clinical Trials

Clinical trial search

Search criteria

Search results

Display options

Basic Criteria

Contain all of these terms:

Contain any of these terms:

Does not contain any of these terms:

Basic search - Free text
fields; key words

Options for search include elements of, e.g.:

- Trial information
- Sponsor
- End point
- Therapeutic area
- Orphan status and number
- Rare disease status
- Paediatric trial (PIP)
- Trial phase
- Product
- Time ranges
- Trial events
- Country
- Age group
- Gender
- Vulnerable population
- ... etc

Trial status	<input type="text" value="--Select Multiple--"/>	Country	<input type="text" value="--Select Multiple--"/>
Trial number	<input type="text"/>	Age group	<input type="text" value="--Select Multiple--"/>
Trial title	<input type="text"/>	Therapeutic area	<input type="text" value="--Select Multiple--"/>
Conditions	<input type="text"/>	Trial phase	<input type="text" value="--Select Multiple--"/>
Sponsor/co-sponsor	<input type="text"/>	Sponsor type	<input type="text" value="--Select Multiple--"/>
End point	<input type="text"/>		
Product	<input type="text"/>	Gender	<input type="text" value="--Select Multiple--"/>
Product role	<input type="text" value="--Select Multiple--"/>	Protocol code	<input type="text"/>
Population type	<input type="text" value="--Select Multiple--"/>	Rare disease	<input type="checkbox"/>
Orphan designation number	<input type="text"/>	PIP	<input type="text"/>
Does this product have an orphan drug designation	<input type="radio"/> Yes <input type="radio"/> No	Events	
EEA clinical trial start date			
From	<input type="text"/>	Clinical trial results	<input type="checkbox"/>
To	<input type="text"/>	Clinical study report	<input type="checkbox"/>
		Low intervention trial	<input type="checkbox"/>
		Serious breach	<input type="checkbox"/>
		Unexpected event	<input type="checkbox"/>
		Urgent safety measure	<input type="checkbox"/>
EEA clinical trial end date		Inspection	<input type="checkbox"/>
From	<input type="text"/>	Trial region	<input type="text" value="--Select Multiple--"/>
To	<input type="text"/>	Vulnerable population	<input type="text" value="--Select Multiple--"/>

The results can be sorted, downloaded and a subscription to the search can be made.

Sort by: Decision date DESC Sort

Download results Subscribe to search

<input type="checkbox"/>	
<input type="checkbox"/>	<p>2021-500570-41-00 - Withdrawn - CTCS-1716_WithdrawApplicationAfterReportingAllMSCs</p> <p>Overall start date of the trial (in the EU): N/A Overall end date of the trial (in the EU): N/A Conditions: Medical_Condition Countries where the trial is taking place (EU country code): FR:Withdrawn, DE:Withdrawn Decision date: N/A</p>
<input type="checkbox"/>	<p>2021-500072-28-00 - Authorised, not started - TC1030.05 EMA-4147 Conclusion Trial Statuses in Revert Decision Screen</p> <p>Overall start date of the trial (in the EU): N/A Overall end date of the trial (in the EU): N/A Conditions: Medical_Condition Countries where the trial is taking place (EU country code): FR:Authorised, not started, DE:Not authorised, GR:Authorised, not started Decision date: FR:16/07/2021</p>

It will also be possible to choose the type of data that will be displayed.

[🏠 Search Clinical Trials](#)

Clinical trial search

Search criteria

Search results

Display options

Available Search Display Options

- | | | |
|---|---|---|
| <input checked="" type="checkbox"/> Title of the clinical trial | <input type="checkbox"/> Sponsor/Co-Sponsors | <input type="checkbox"/> Primary end point |
| <input checked="" type="checkbox"/> Trial number | <input type="checkbox"/> Sponsor type | <input type="checkbox"/> Results first received |
| <input checked="" type="checkbox"/> Overall trial status | <input type="checkbox"/> Trial phase | <input type="checkbox"/> Last updated |
| <input checked="" type="checkbox"/> Countries where the trial is taking place (EU country code) | <input type="checkbox"/> End point | |
| <input checked="" type="checkbox"/> Overall start date of the trial (in the EU) | <input type="checkbox"/> Product | |
| <input checked="" type="checkbox"/> Overall end date of the trial (in the EU) | <input type="checkbox"/> Age group | |
| <input checked="" type="checkbox"/> Decision date | <input type="checkbox"/> Gender | |
| <input checked="" type="checkbox"/> Conditions | <input type="checkbox"/> Trial region | |
| <input type="checkbox"/> Therapeutic area | <input type="checkbox"/> Total number enrolled | |
| <input type="checkbox"/> Recruitment status | <input type="checkbox"/> Overall end of the trial | |

Submit

- Quality related information that include:
 - ❑ The IMPD quality
 - ❑ Scientific advice on quality
 - ❑ Quality related request of information (RFI) raised during the assessment
 - ❑ Quality Assessment reports (draft and final)
- Drafts of 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;
- Any requests for information from MS to the sponsor and responses recorded outside of an assessment of an application



Engagement

[Info events](#) (recorded & published)

Collaborative approach



Online Training

[Extensive online programme available](#)

Sponsor Master Trainer programme



Online Support

[EMA CTIS Sponsor Handbook](#)

[Supportive materials and references](#)



Research community/SME

[Targeted SME/academia trainings](#)



EMA CTIS info

[EMA CTIS Highlights Newsletters](#)

(subscribe by writing to CT.Communication@ema.europa.eu)



All above are available on www.ema.europa.eu



Events are planned to help future CTIS users prepare for CTIS Go-Live.

Find on [EMA events page](#) (search e.g. "CTIS")

26 October info event

Target audience

MS and sponsor end users

Objectives

- Ensure **awareness of CTIS** across the end-user base
- **Prepare users for the new way of working** with CTIS

Supported by DIA; fee applies

29 November training event

Target audience

SME/academia sponsors & end users

Objectives

- Ensure **awareness of CTIS** across the end-user base
- **Prepare SME/academia users** for the new way of working with CTIS

Open event, no fee



Thank you for your attention

Further information

Fia.Westerholm@ema.europa.eu

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Telephone +31 (0)88 781 6000

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A view of the sponsor functionalities in CTIS – Part II

Clinical trials Notices & alerts  Annual safety reporting RFI User administration

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CTIS Training - Testing 2021-501433-31-00 / Initial ID: IN Draft

 Check  Save  Cancel  Submit

Form

MSCs

Part I

Part II

- AT

- DE

- GR


Evaluation


Timetable

Country specific details (Part II - Austria) 


Trial sites 

Documents

Recruitment Arrangements 


Subject information and informed consent form 


Suitability of the investigator 


Suitability of the facilities 

Proof of insurance cover or indemnification 

Financial and other arrangements 

Compliance with national requirements on Data Protection 

Compliance with use of Biological samples 

All documents 

Evaluation phases of an Initial Clinical trial application



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The evaluation of an Initial application is structured in three phases: Validation, Assessment and Decision. MSCs generally have up to 60 days to complete the evaluation of an Initial application.

