



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Clinical Trial Information System (CTIS) Bitesize talk

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Transitional trials & Additional MSC application

Presented by Noémie Manent and Ana Rodriguez on 23 June 2022  
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An agency of the European Union





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# CTIS Bitesize talk: Transitional trials & Additional MSC application

14:00 - 14:05      **Introduction**

14:05 – 15:25      **CTIS Demonstration Sessions followed by live Q&A Sessions**

15:25 – 15:30      **Closing remarks**

*For questions,  
go to **www.sli.do**  
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**#23june***

## A few housekeeping rules

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## Tips for optimal screen viewing



- ❖ Make use of the instructions under the embedded video in the event page and connect directly to the **IBM channel** *for the full-screen experience*
- ❖ Increase the *video quality* from the **HD button** on the right bottom of the screen setting it to 720p (or 1080p).



# Main Session: CTIS Demo with Q&A

## Transitional trials

- Requirements for sponsors
- Sponsor Workspace - Transition a trial
- Search for a trial
- CT Summary Tab - transition trial label
- Download information about transition
- Notes for Attention

## Additional MSC application

- Introduction
- Allowed submissions whilst ongoing evaluation of an application
- Fields and Documents to be populated
- Assessment phases



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# Transitional trials

# Requirements for sponsors

- When **creating an initial CTA** to **indicate** that is in relation to a **transitional trial**, previously submitted and conducted under the umbrella of the CT Directive
- To **submit notifications** that **do not**, in all cases, **adhere to the business rules valid for a regular CTIS trial**
- **All workflow and Notice & Alerts functionality** for the initial applications marked as transition trials **will be the same as for regular CTR initial trials**. This will include all subsequent trial application submissions as substantial modifications, additional MSC applications and non-substantial modifications.
- To create and edit the transition trial data and documents, a **new permission** was created that has been **mapped** to the Sponsor roles **CT admin and application submitter**. The view form section permission can be re-used for all other Sponsor and Authority **viewer roles** to view the Transition Trial section.



# Sponsor Workspace - Transition a trial

*Sponsor users able to indicate a new trial as a Transition trial*

**Clinical trials (Training Environment)**

**Clinical Trials**

Enter EU CT number or use advanced search

**Trial Advanced Search**

**Application Advanced Search**

**Create new trial**

Full title (English)\*

Title

Search organisation

Name  ID  City  Country

ID	Name	Address	City	postCode	country	phone	email	actions
<input checked="" type="radio"/> ORG-100032441	Achilles - testcompany	Achilles Street	Ctis Test		Cyprus			<input type="button" value="x"/> <input type="button" value="+"/>
<input type="radio"/> ORG-100011446	Achilles Therapeutics Limited	Bioscience Catalyst Gunnels Wood Road,	Stevenage	SG1 2FX	United Kingdom			<input type="button" value="x"/> <input type="button" value="+"/>

1-2 of 2

☒ Transition Trial

1

2

3





- Navigate inside the Form section

1 →

Form  
MSCs  
Part I  
Part II  
Evaluation  
Timetable

Form details

Initial Application details

Cover letter

Transition Trial

☒ Transition Trial  
EUDRA CT number \*

2 →

3 →

+ Add EudraCT Trial

- Search for and register the EudraCT number (mandatory field)

EudraCT Trial Search

EUDRA CT number  
2016-002255-25

CLEAR SEARCH

4 →

Search result

Sponsor  
Department of Oncology, Herlev Hospital

Full title  
Randomized phase II study comparing electrochemotherapy with standard radiationtherapy for the treatment of basal cell carcinoma

5 →

Cancel Add EudraCT Trial

- Indicate the trial was conducted under VHP - enter VHP number

Transition Trial

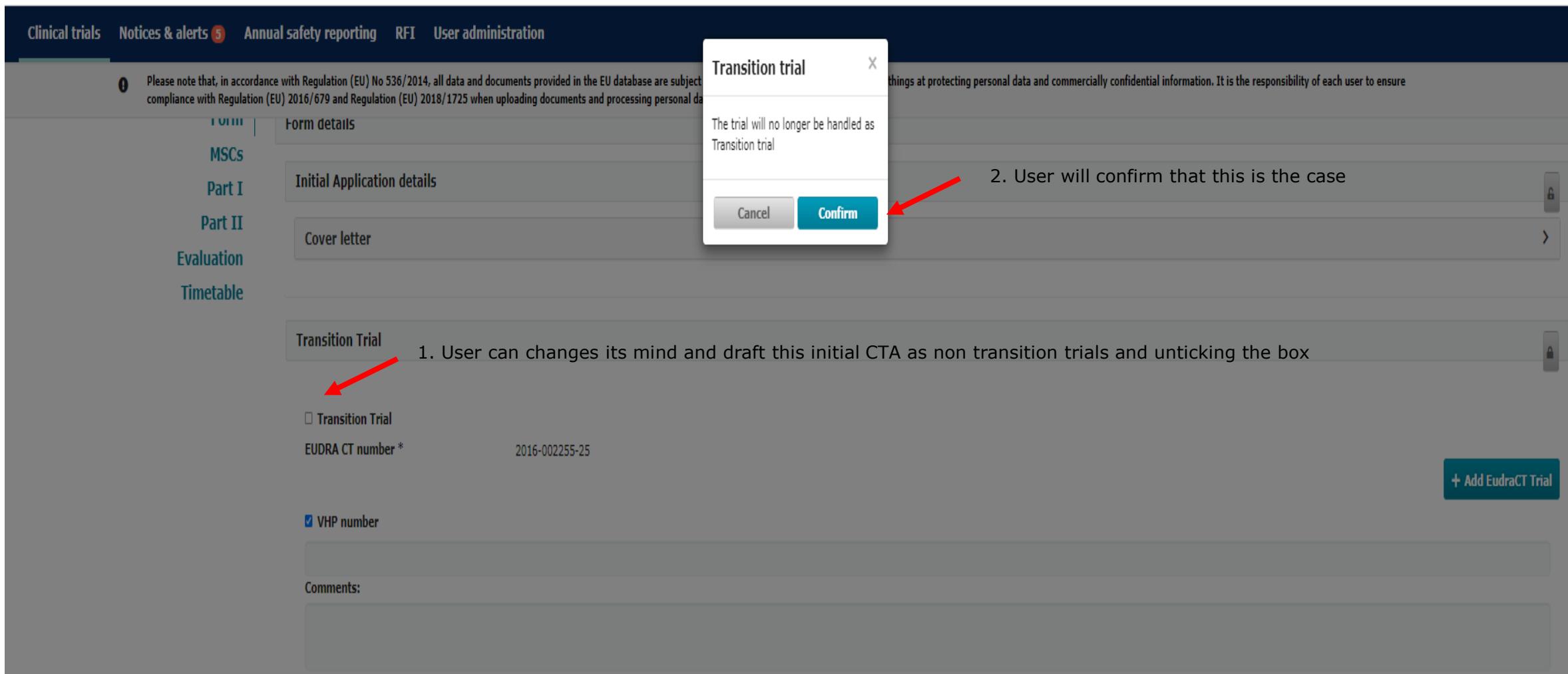
☒ Transition Trial  
EUDRA CT number \* 2016-002255-25

☒ VHP number 6 →

Comments:

+ Add EudraCT Trial

- Uncheck the Transition trial box to indicate the draft trial must NOT be considered as a Transitioned trial.



The screenshot displays the CTIS interface for a clinical trial application. A modal dialog titled "Transition trial" is open, with the message "The trial will no longer be handled as Transition trial" and "Confirm" and "Cancel" buttons. A red arrow points to the "Confirm" button. In the background, the "Transition Trial" section is visible, with a red arrow pointing to the "Transition Trial" checkbox, which is currently unchecked. The text "1. User can changes its mind and draft this initial CTA as non transition trials and unticking the box" is next to the checkbox. Another red arrow points to the "Confirm" button in the dialog, with the text "2. User will confirm that this is the case" next to it. The interface also shows a sidebar with navigation options like "Form details", "Initial Application details", "Cover letter", "Transition Trial", "EUDRA CT number", "VHP number", and "Comments".

Transition trial

The trial will no longer be handled as Transition trial

Cancel Confirm

2. User will confirm that this is the case

Transition Trial

1. User can changes its mind and draft this initial CTA as non transition trials and unticking the box

☐ Transition Trial

EUDRA CT number \* 2016-002255-25

☒ VHP number

Comments:

+ Add EudraCT Trial



## 1. When drafting the application:

- **the draft application** will be **completed the same as for an initial CTA under the umbrella of the CTR**. All mandatory fields and documents are applicable and must be part of the application check mechanism.
- there is **no limitations for adding MSC** to the CTIS application that will participate in the assessment

## 2. After submitting the application:

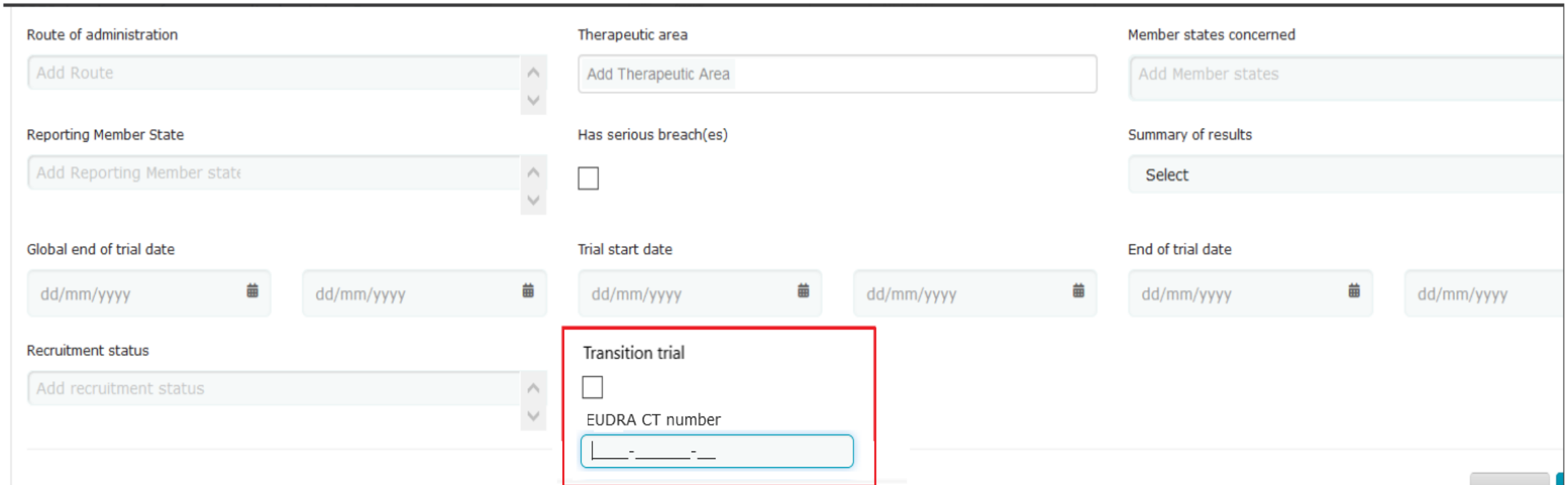
- the **transition trial checkbox** in the Form sections can not be unchecked and will become **read-only**.
- the Sponsor **cannot make changes to the transition trial section data as part of the response to the RFI**. The section will be **read-only**.

### 3. After the transitioned trial related application is decided by the MSC

- The Sponsor **cannot make changes to the transition trial section** data as part of **subsequent CTAs** (SM, AMS, NSM). The section will be **read-only**.
- Sponsors can submit the notifications as already implemented, but **some business rules** should be **adapted** for **only** the trials selected as Transition Trial.
  - When sponsors create a notification to **start** or **end** the trial for an MSC, it must be possible to select a date **before** the registered CTIS Decision date (change to the existing business rule).
  - Notifications, such as Start of recruitment, Temporary halt, Summary of Results, can also be submitted with a date before the decision date registered in CTIS due to the dependency with the start of trial and end of trial date.
  - Transition trials can expire for any MSC, as with regular CTIS applications, when recruitment has not started 2 years after the **decision date** registered for that MSC in CTIS. Also, the trial will expire for an MSC with status halted when the restart of trial was not started 2 years after the **temporary halt date** registered for that MSC in CTIS.

# Search for a transitional trial

- Possibility in both, sponsor and authority workspace, to **search** and find only trials that are checked as **Transitioned trials** in the Trial and Application advanced search .
- Possibility to search by the EudraCT number. This field 'demands' from the user to enter the correct format: YYYY-012345-01



The screenshot displays the EMA search interface with the following sections:

- Route of administration:** Add Route
- Therapeutic area:** Add Therapeutic Area
- Member states concerned:** Add Member states
- Reporting Member State:** Add Reporting Member state
- Has serious breach(es):** ☐
- Summary of results:** Select
- Global end of trial date:** dd/mm/yyyy (calendar icon)
- Trial start date:** dd/mm/yyyy (calendar icon)
- End of trial date:** dd/mm/yyyy (calendar icon)
- Recruitment status:** Add recruitment status
- Transition trial:** ☐ (highlighted with a red box)
- EUDRA CT number:**  (highlighted with a red box)



# CT Summary Tab - transition trial label

Added label on **Transitioned trial** with value **Yes** in the **summary tab** of the trial, to make the users aware. If the trial is not a transitioned trial, the label will show **No**.  
The same applies for the **Full trial information** tab.

Summary

Full Trial Information

Notifications

Trial results

Corrective measures

Ad Hoc assessments

TRIAL INFORMATION

Sponsor

Panpharma

Member states concerned

AT · ES · FR

Trial phase

Human Pharmacology (Phase I)- First administration to humans

Medical conditions

test

Therapeutic area

Diseases [C] - Bacterial Infections and Mycoses [C01]

Low intervention study

Yes

FIH

Yes

Population type

Healthy Volunteers

Medical device

No

Start of trial

31/03/2021

IMP

Transitioned trial

Yes



# Download information about transition on the Form

Trial Information	
Transition Trial	
EudraCT number: 2018-123456-01	
VHP number: 12345	
Comments: VHP coordinator Austria should be RMS	

# Notes for Attention

- In case the sponsor cannot provide certain documents listed in Annex I of the Regulation, which were not required under the Directive, the sponsor should upload a blank document clarifying that this aspect was assessed by National Competent Authority (NCA) and/or Research Ethics Committee (REC) and therefore is covered by the conclusion of the assessment. Updates to those documents will be required in line with [Q&A 11.11](#).
- At the moment of the first application submitted after the a clinical trial has transitioned and therefore submitted under the rules of the Regulation (i.e. the next substantial modification or addition of a new Member State) the sponsor should, in principle, complete the application dossier in accordance with the requirements of Annex I of the Regulation, at least with regard to that part of the application dossier which will be assessed in the procedure).
- Clinical trials that were initially started under the Directive and switched to the Regulation have to comply with all the obligations of the Regulation e.g. the publication of summary of results, notifications and, if applicable, the Clinical Study Report (CSR).





# **Additional MSC application**

# Introduction

An Additional MSC application can only be submitted once the initial CTA has been authorised by at least one Member State Concerned (MSC).

The sponsor can select a new MSC to which they wish to extend the authorised clinical trial.

**NOTE:** *Sponsors can withdraw an Additional MSC and must provide a justification for the withdrawal.*

*The withdrawal of an Additional MSC can only be done before the MSC has issued a decision.*
























## Allowed submissions whilst ongoing evaluation of an application



		Submission of a substantial modification to Part I and Part II	Submission of a substantial modification to Part I	Submission of a substantial modification to Part II	Submission of a non substantial modification	Submission of an application for an additional member state
	<b>Initial application</b>	Not until a decision is issued by all MSC	Not until a decision is issued by all MSC	Not until a decision is issued by all MSC	Not until a decision is issued by all MSC	Not until a decision is issued by all MSC
<b>Ongoing activity</b>	<b>Evaluating Part I &amp; Part II substantial mod application</b>	No	No	No	No	No
	<b>Evaluating Part I only substantial mod application</b>	No	No	No	No	No
	<b>Evaluating Part II only substantial mod application</b>	No	No	Only to MS who did not receive the Part II SM	No	yes
	<b>Evaluating add additional member state</b>	No	No	Only to MS who are not evaluating the application to add an additional MSC	No	Only to MS that is not an MSC or evaluating an assessment to become an MSC



# Fields and Documents to be populated

Users can only modify the documents and data of the Form, MSC and Part II sections as Part I has already been evaluated. However, translations of the documents of Part I can be added.

Form	MSCs	Part I	Part II
 Cover letter	 Add MSC	 Data	 Trial site
 Modification description	 # of subjects per MSC	 Data translations	 PI contact details
 Supporting information		 Documents	 Documents
 Supporting information		 Document translations	 Document translations
 SM reason		 3 <sup>rd</sup> party entity	
 SM scope		 Entity contact details	
 Proof of payment of fee		 Description of changes	
 Deferrals			

 = Structured data field  
 = Document uploaded

Highlighted in **green**:  
The possible field and document options that may be populated with an additinal MSC application.



# Assessment Phases

## Additional MSC

Assessment of Part I \*

Assessment of Part II

Decision

*\* **NOTE:** Additional MSC can create considerations on Part I and RMS can create RFIs, but no hard task is generated*



# Questions & Answers



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# Upcoming CTIS events

- 30/06/2022: [Organisation Management System \(OMS\) Trouble Shooting Session for CTIS users](#)
- 01/07/2022: [Clinical Trials Information System \(CTIS\) webinar: Six months of CTIS and looking forward](#)
- 20/07/2022: [Clinical Trials Information System \(CTIS\) bitesize talk: Deferral rules and Public website](#)

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# Thank you for attending today's event

*Next CTIS bitesize talk  
on 20 July*

## Further information

For CTIS communication, training & change management queries, e-mail [CT.Communication@ema.europa.eu](mailto:CT.Communication@ema.europa.eu)

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

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