EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Clinical Trial Information System (CTIS) Bitesize talk

Transitional trials & Additional MSC application

Presented by Noémie Manent and Ana Rodriguez on 23 June 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.

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**

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A few housekeeping rules

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- 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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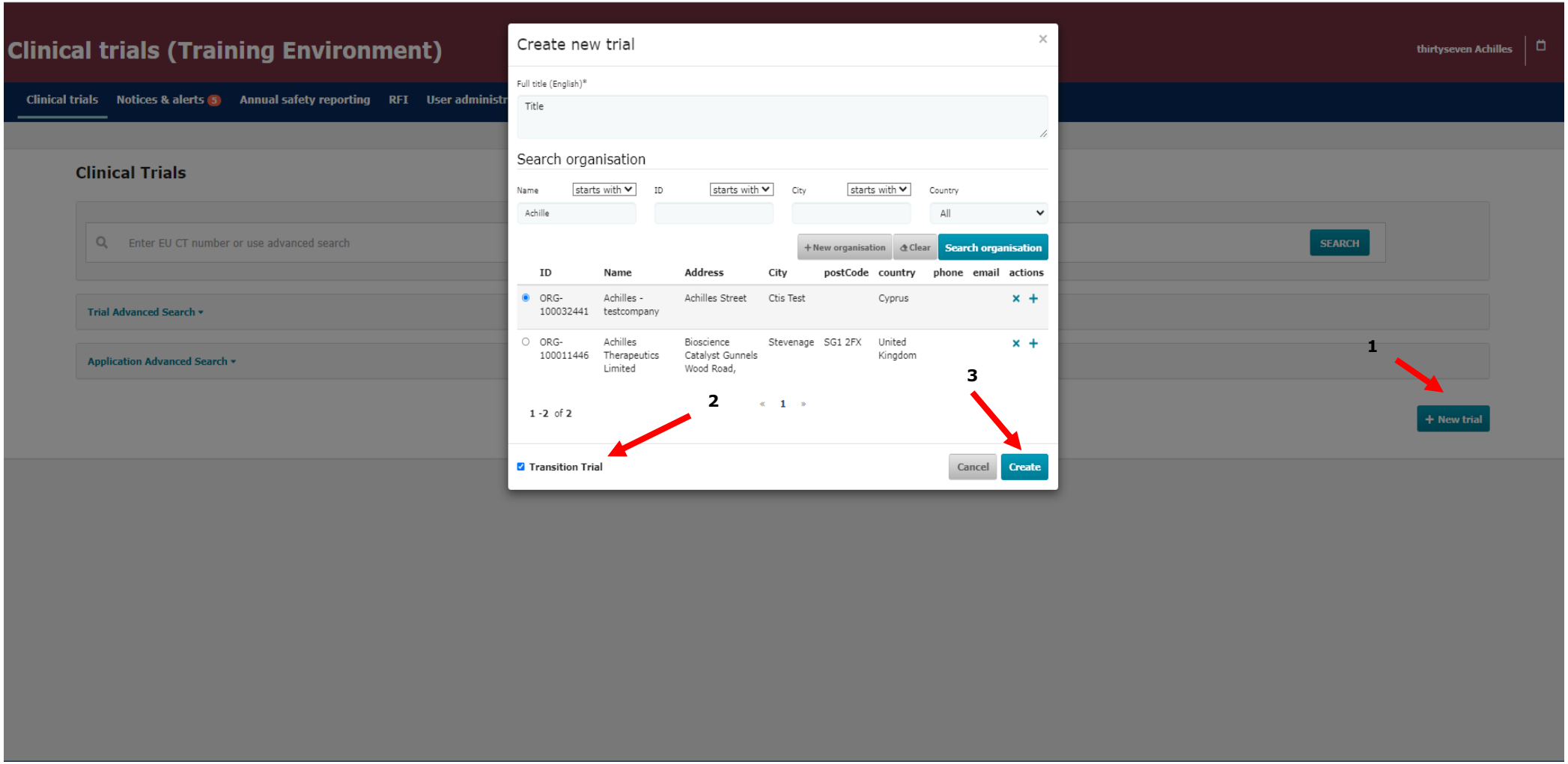
Transitional trials

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

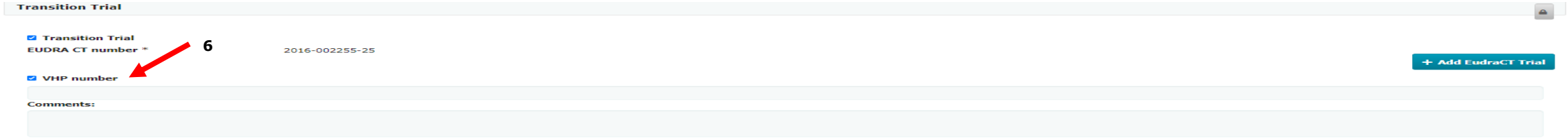
Sponsor users able to indicate a new trial as a Transition trial



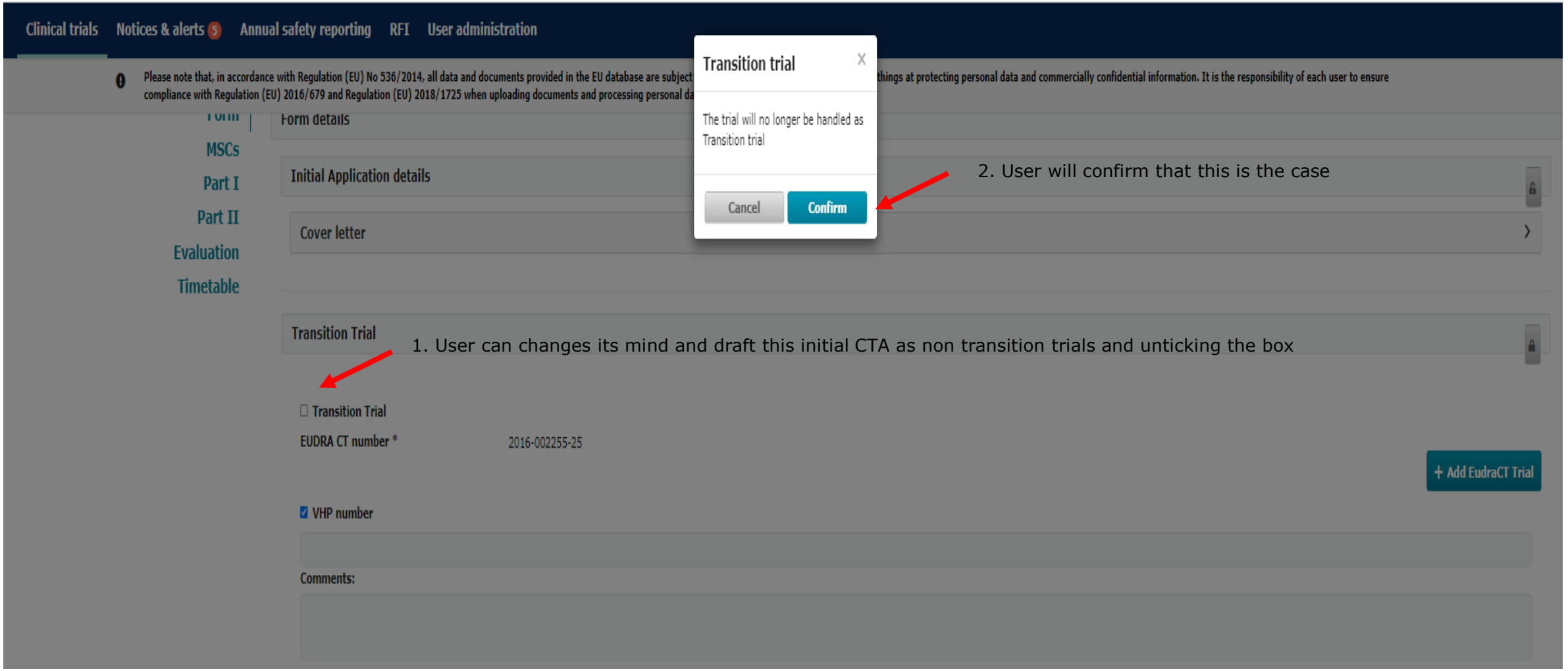
- Navigate inside the Form section

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

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



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

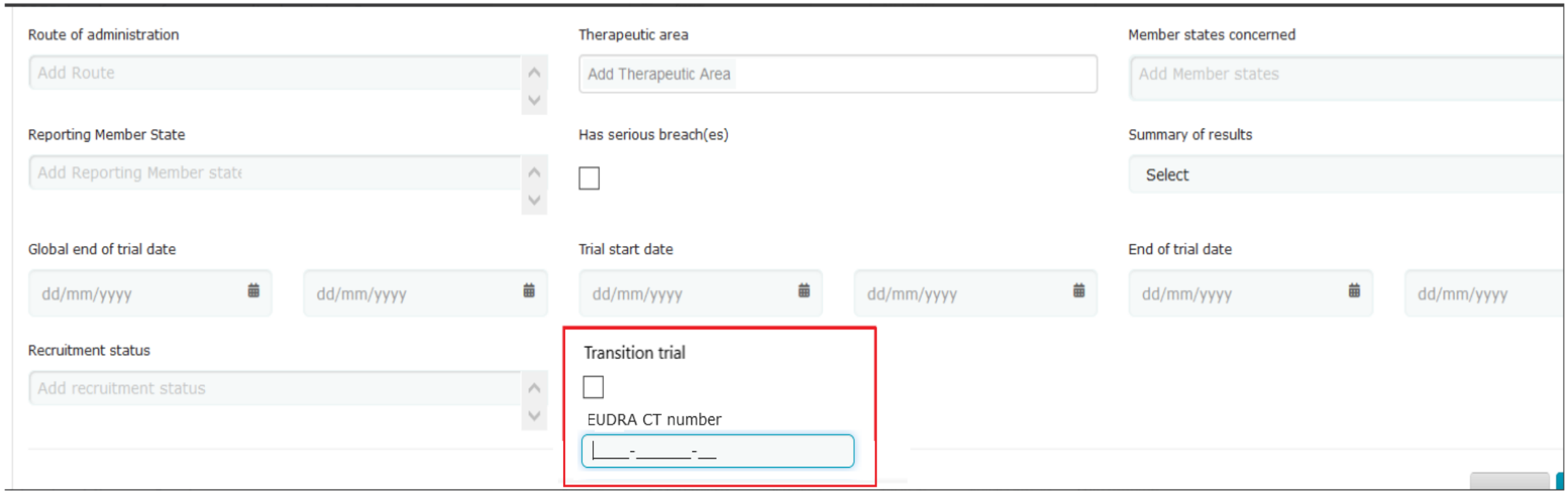
    - When sponsors create a notification to **start** or **end** the trial for an MSC, it must be possible to select a date **before** the registered CTIS Decision date (change to the existing business rule).

    - 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.

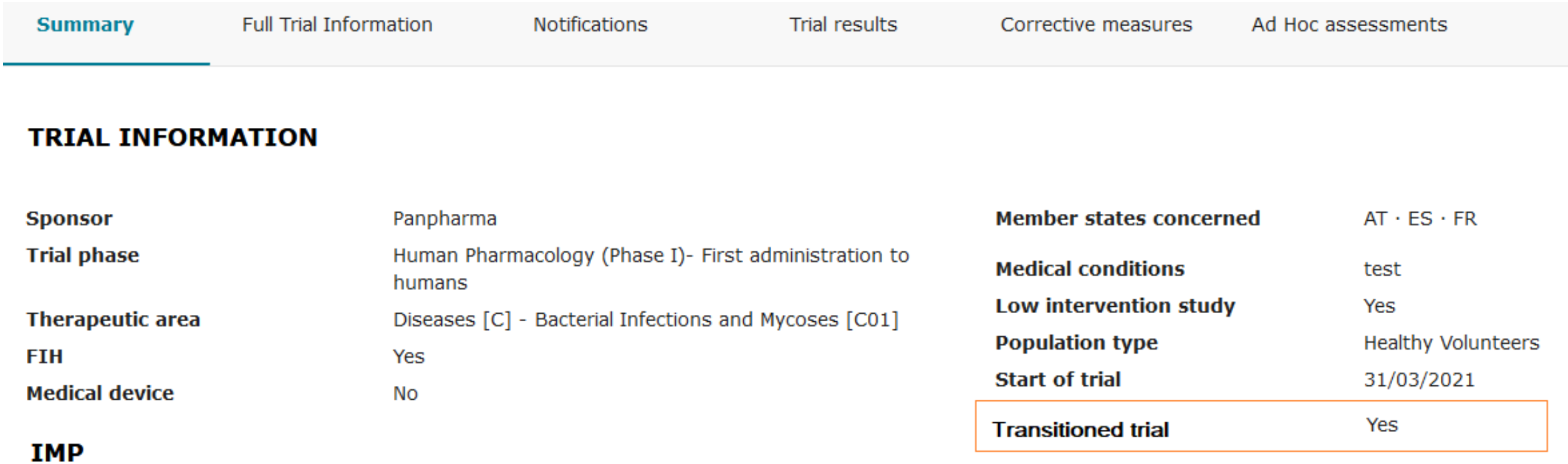
Search for a transitional trial

- 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



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.



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
	Initial application	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
Ongoing activity	**Evaluating Part I & Part II substantial mod application**	No	No	No	No	No
	Evaluating Part I only substantial mod application	No	No	No	No	No
	Evaluating Part II only substantial mod application	No	No	Only to MS who did not receive the Part II SM	No	yes
	Evaluating add additional member state	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

- Cover letter
- Modification description
- Supporting information
- Supporting information
- SM reason
- SM scope
- Proof of payment of fee
- Deferrals

MSCs

- Add MSC
- # of subjects per MSC

Part I

- Data
- Data translations
- Documents
- Document translations
- 3rd party entity
- Entity contact details
- Description of changes

Part II

- Trial site
- PI contact details
- Documents
- Document translations

= 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

For the Clinical Trials Newsletter sign up at CT.NewsletterSubscriptions@ema.europa.eu.

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