

The guide to the Clinical Trials Information System (CTIS) based on the guide made by Danish GCP-unit

26.09.2024

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Abbreviations

ASR = Annual Safety Report

AR = Assessment report

CT = Clinical Trial

CTA = Clinical Trial Application

CTIS = Clinical Trial information System

CTR= Clinical Trial Regulation

DLP=Data Lock Point

EMA =European Medicines Agency

GCP =Good Clinical Practice

IMPD=Investigational Medicinal Product Dossier

MSC = Member states concerned

OMS = Organisation Management System

RFI = Request for information

RMS = Reference member states

RSI= Reference Safety Information

SM = Substantial modification

SmPC= Summary of Product Characteristics

SAE=Serious Adverse Event

SAR=Serious Adverse Reaction

Pictures used in the document are copied from EMA's materials and are publicly available.

1 Introduction

1.1 What is CTIS?

The [Clinical Trials Regulation \(Regulation \(EU\) No 536/2014\)](#) came into application on 31 January 2022 and submission of clinical trials with medicinal products shall no longer be submitted directly to the Health Authorities and Ethics Committees, but instead the submission is taking place via a **Clinical Trial Information System (CTIS)**. CTIS is the **single entry point** for submitting clinical trial information in the EU, which is stored in the system. All communication including final decision from the authorities is received via CTIS. With CTIS, sponsors can apply for clinical trial authorisation in multiple EU/EEA countries with a single application.

CTIS is structured in two **restricted** and **secured** workspaces, only accessible to registered EMA account users, and a website with open access to the general public:

- The [sponsor workspace](#), accessible to commercial and non-commercial sponsors. It supports the preparation, compilation and submission of clinical trial data for its assessment by Member States.
- The **authority workspace**, accessible to national competent authorities, ethics committees, the European Commission, and the European Medicines Agency (EMA). It supports the activities of Member States and the European Commission in assessing and overseeing clinical trials.
- The **public website**, accessible to patients, healthcare professionals, scientists, clinical research associations, media, and members of the public. It supports the open access to clinical trials' data in the European Union, in line with the transparency goal set out in Regulation (EU) No 536/2014 (Clinical Trials Regulation, CTR).



This guidance covers the process on how to start up, complete and maintain a clinical trial application (CTA) in EU as a sponsor, using the **trial-centric approach**, as well as management of relevant notifications and information throughout the life-cycle of clinical trials.

For more specific questions you are welcome to contact the Clinicaltrials at fimea.fi or EMA helpdesk or Fimea's webpage.

This guidance is based on and can be used as a supplement to the following CTIS training guides from EMA:

- [Clinical Trials Information System \(CTIS\): online modular training programme | European Medicines Agency \(europa.eu\)](#)
 - How to create a CTA – see module 10 – 8 videos
- [Clinical Trial Information System \(CTIS\) – Sponsor Handbook](#)
- How to access CTIS: [Step by step guide to access CTIS](#)
- [European Medicine Agency \(EMA\) QUESTIONS & ANSWERS \(see section 2, 3 and 5\)](#)

1.2 Sponsor is responsible for the application via sponsors workspace

The sponsor workspace provides clinical trial sponsors with functionalities for submission of CTA's, notifications and clinical trial results to Member states authorities and the public and management of information throughout the life cycle of clinical trials.

1.3 What is needed to work in the CTIS? How to get started

If you already have an EMA account and the address of sponsor is registered in OMS – please go to section 4 in this guideline.

In order to access the CTIS Sponsor workspace, a user will need to have an active EMA Account. If the user already uses other EMA applications (e.g. Eudralink, SPOR, IRIS, EudraVigilance, OMS or the EU Clinical Trials Database), the user already has an EMA Account and could access the CTIS Sponsor workspace using his/her existing EMA Account credentials. If the user does not have an active EMA Account, (s)he needs to create one, by self-registration. In addition, organisations must be registered in EMA's Organisation Management System (OMS).

1. Register for an EMA account

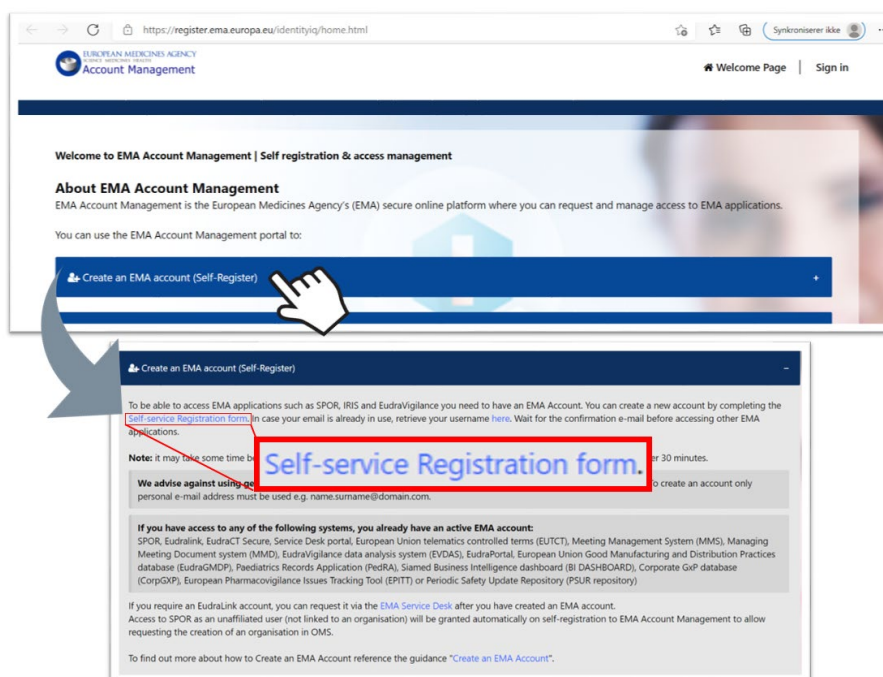
2. Register your organisation in OMS

3. Register your sponsor administrators

Only if you do not have an EMA account or your organisation is not registered in OMS already

2 How to create a new EMA Account

Go to [EMA's Account Management portal](https://register.ema.europa.eu/identityq/home.html)



Click on "Create an EMA account (Self Register)" and open the "Self-service Registration form".

Complete the "Self-service Registration Form" with the relevant information. Fields marked with red asterisks (*) are mandatory. Password is case sensitive and must be at least 8 characters long and contain 4 different character types. Now you can download and read the EMA Privacy Statement.

Tick the "User Agreement" checkbox and then click on the "I agree" button.

7. How long does EMA keep personal data?

Your data will be deleted after 180 days of inactivity on EMA systems (i.e. if you do not use your account on any of the systems). You will receive a reminder before your data will be deleted.

8. Recourse

In case you have any questions regarding the processing of your personal data, or you think that the processing is unlawful or it is not in compliance with this Privacy Statement or the general EMA Privacy Statement, please contact the Data Controller at DEDdataprotection@ema.europa.eu or the EMA Data Protection Officer at dataprotection@ema.europa.eu.

You also have the right to lodge a complaint with the European Data Protection Supervisor (EDPS) at any time at the following address:

- Email: edps@edps.europa.eu
- Website: www.edps.europa.eu
- Further contact information: www.edps.europa.eu/about-edps/contact_en

Download the EMA Privacy Statement for the EMA Account Management System

You can download this statement here
ema.europa.eu/en/documents/other/european-medicines-agencys-privacy-statement-ema-account-management-system_en.pdf

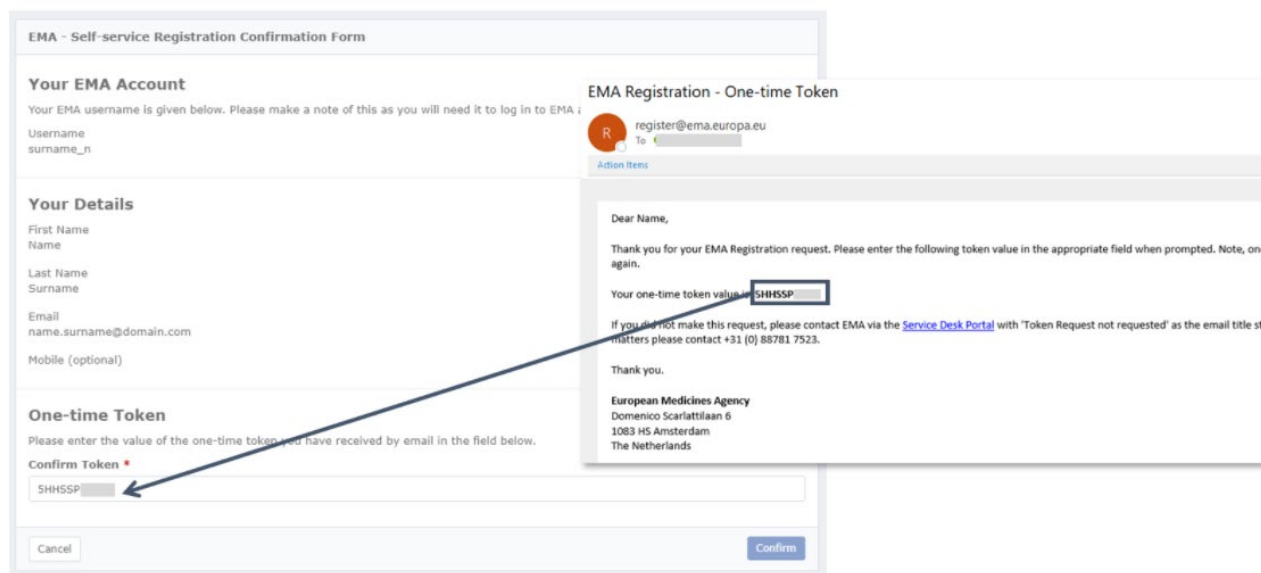
User Agreement

☐

By submitting the application form, I declare that I have read and understood the privacy statement, and that I consent to the processing of personal data as explained in the privacy statement.

[Cancel Registration](#) [I agree](#)

Set up “**Security Questions**”, answer the captcha (Completely Automated Public Turing test to tell Computers and Humans Apart) question and click the “Next” button. A “**Self-service Registration Confirmation Form**” will appear:



Complete the one-time Token received by mail and click Confirm. An automatic notification will be sent to the email address that you provided to confirm your account registration. It is recommended to save this confirmation-email.

It may take up to 30 minutes before the access is granted.

3 User access, roles and responsibilities in CTIS – Trial-centric approach

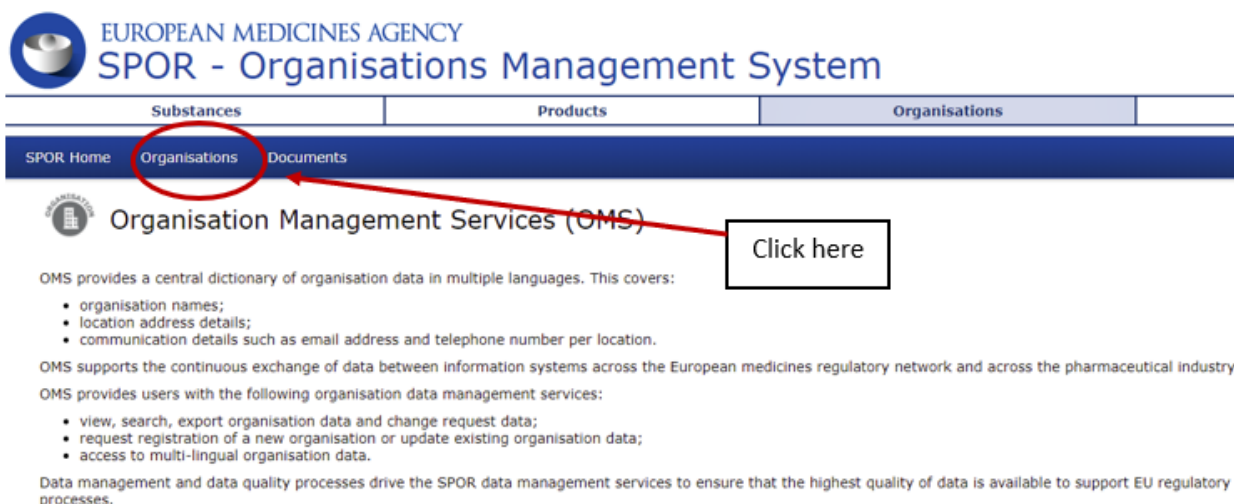
There are two general approaches to user management in CTIS: The organisation-centric approach and the trial-centric approach.

The focus of this guide is the trial-centric approach.

Trial-centric approach - Is intended to serve the needs of small organisations and specifically *academic sponsors*, which may initiate trials on an ad hoc basis. It allows for the management of a smaller number of users and one or very limited numbers of clinical trials. This approach allows a faster process (no need for registration of a high-level sponsor administrator) when submitting a first initial, and subsequent application. Further allocation of other CT Administrator (CT Admin) roles or business roles is assigned to users at the clinical trial level. The CT Admin can manage users only for the particular trial(s) of his/her concern and can perform all sponsor business activities in CTIS related only to the particular trial.

3.1 How to check for registration of the sponsor organisation in OMS

You can search [The Organisation Management System \(OMS\)](#) without an EMA account.

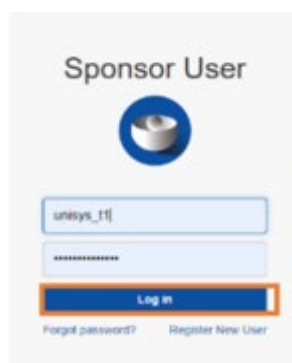


Each organisation (University Hospital, Hospital or University) has **one** Organisation ID, but can have several location ID's. Be sure you choose the right address for the specific organisation.

The sponsor details from OMS must first be added when you have logged into the CTIS database, please refer to section 4.2 in this guideline.

3.2 Access to CTIS

When [“EMA account Sponsor User”](#) log into the system and initiates a new CTA in CTIS, the system will automatically check if a high-level sponsor administrator has been appointed for the sponsor organisation selected.



If that is not the case, the user will be able to proceed becoming the clinical trial administrator (CT Admin) for that particular trial and can then assign other roles in the particular trial to other users also holding an EMA account.

Video on this topic in EMA training module 7:

[How to request roles and how to assign roles to register users in CTIS](#)

3.3 Considerations of which roles to assign to users within the organisation

For consideration of which roles to assign in CTIS the document [CTIS User Personas](#) can be used. On pages 6-8 this guide describes typical tasks each person in an academic institution, a hospital department or a clinical trial unit may complete in CTIS and the possible user roles they could be assigned.

The CT Administrator role is as mentioned assigned automatically to the person that initiates a new CTA, but it is recommended that at least one back up CT Admin is assigned as well. Users can also be given one of the business roles; Viewer, Preparer or Submitter.

Viewer role:

- Allows user to view structured data, documents, and includes download of document.

Preparer role (the Preparers also have Viewers permissions):

- Create permission: allows the user to edit, upload documents, save, update saved drafts. It also allows users to copy from an existing CTA to create a new one.
- Delete permission: delete refers only to eliminate/cancel draft items.

Submitter role (the Submitters also have the Viewers and Preparers permissions):

- Submit permission: allows the user to submit data/documents from their respective workspace to CTIS
- Update permission: allows updating submitted information
- Withdraw permission: refers to the withdrawal of submitted items

3.4 How to assign business role to users within the organisation

After a new CTA is created (See section 4.1), the CT Admin can assign business roles for that specific trial

1. After the CT Admin is approved, users can log in to CTIS and click the User administration tab.

Info box:

For more detailed information please refer to [Module19 - Step-by-step guide - User access management and user administration \(europa.eu\)](#)

Clinical trials

UAT CT |  | EN ▼

Clinical trials Notices & alerts 6 RFI **User administration**


2. Click on the 'Assign new role' button.




Administration of users

[Advanced search ▼](#)


Search Results

Showing 1 - 1 of 1 items
1 of 1 pages
< 1 >

Sort by: 
Creation Dat ▼

 Approve
 Reject
 Revoke

3. Fill in the information about the business role to be assigned to users within the organisation and click on the 'Assign' button.

Assign role(s)


User Id:



EU CT number

Organisation name:
 ▼

Organisation Id:
ORG-100013346

Role:
 ▼

Scope:
 ▼

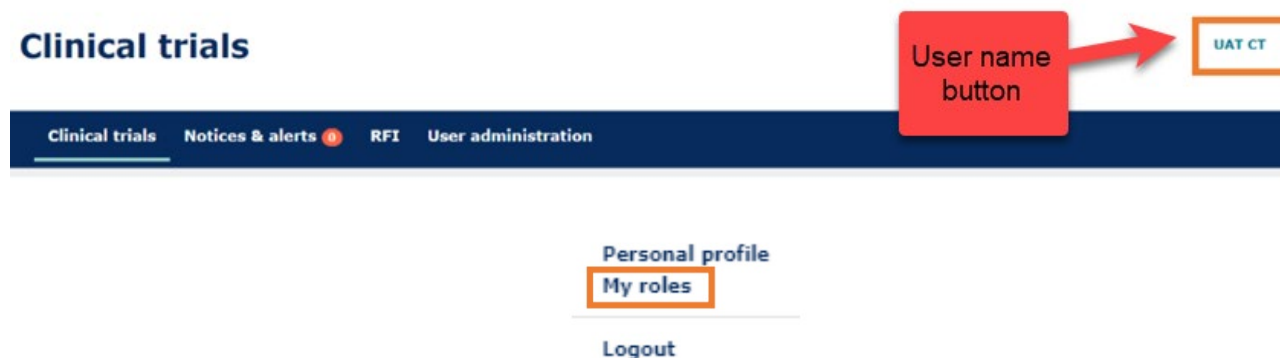
Authorised date:
 
 

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3.5 How to request a role

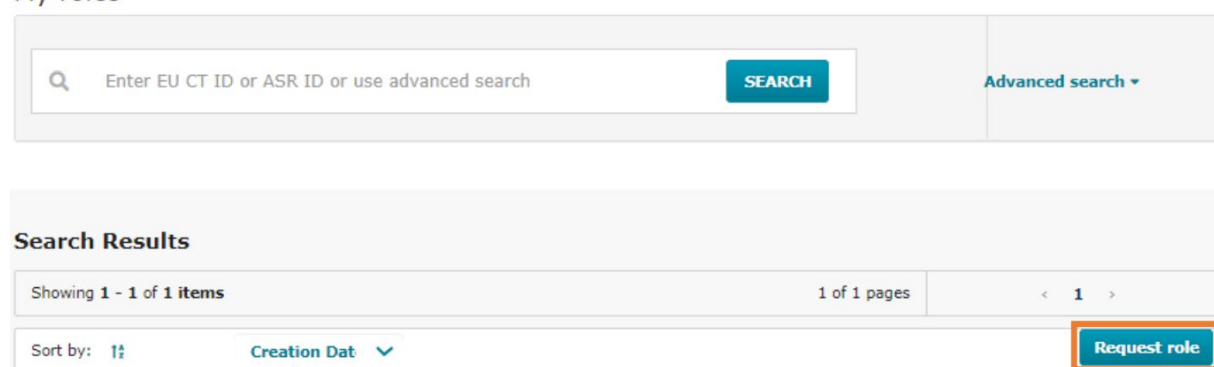
1. Users can instead choose to request a role. This is done by log in to CTIS and click the username button at the top-right corner of the CTIS start page.

2. Click on the 'My roles' button.



3. Click on the 'Request role' button.

My roles



4. Populate the information from the pop-up window and click the 'Request' button.

Request roles ×

organisationName	organisationId	Scope	EUCT Number	Role
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

5. Once users request a role, the CT admin clicks the checkbox next to the role and clicks on the 'Approve' or 'Reject' buttons. Role requests will appear in the User administration tab. No notice or alert will be generated. Therefore, CT administrators are encouraged to check the User administration tab regularly.

Administration of users

Advanced search ▾

Search Results

Showing 1 - 2 of 2 items 1 of 1 pages < 1 >

Sort by: Creation Date ▾

<input checked="" type="checkbox"/>	unisys_k4	test12@test.com	Role:	Creation date:	Assesment date:	Assigned to:
	EU CT Number:	2021-500780-21-00	ASR Submitter	19/07/2021		
	Scope:	Specific trial				
	Employer:	CTCS-8465				
	Organisation name:	Test organisation				
	Organisation Id:	ORG-100002154				

'Approve' and 'Reject' buttons.

When a role is assigned, users must log out and log in again, in order to have the role assigned to them in the system.

4 How to Create, Submit and Withdraw an initial Clinical Trial Application (CTA)

Transitio:

In accordance with the Directive clinical trials with at least one active site after 30 January 2025 must be transferred as a transitional trial to the CTIS portal in accordance with the EU Regulation. If there are no active sites in Finland in the clinical trial, no transfer will be needed for Finland.

More information on [transition](#) can be found on Fimea's website, and more [detailed instructions](#).

Fimean sivuilta löytyy tietoa [transitiotutkimuksista](#) ja tarkempi [ohje](#).

4.1 Application dossier for the initial application

Link to the CTIS database: <https://euclinicaltrials.eu/ctis-for-sponsors>

The Clinical Trial Application dossier is contained in [Annex I of the EU Regulation](#).

Templates for some of the documents can be found in [Eudralex Volume 10](#).

Please avoid any kind of signatures, both digital and wet ink signatures, in all documents, as they can be copied, when the documents are made public. You may send a public and non-public version at the same time.

Be aware not to include personal information (e.g. private addresses and telephone numbers) in investigators CV.

Info box:

Language requirements for Part I documents can be found in [Section 2 in EMAs Q&A \(updated April 2022\)](#). Documents can be in Finnish, Swedish or English for trials running only in Finland.

The asterisk * in CTIS indicates mandatory fields to be filled in and/or mandatory upload of documents. Some separate documents (e.g. recruitment arrangements) must be uploaded even though the same text is already mentioned in other documents e.g. the protocol.

[Template](#) for the the document “Proof that data will be processed in compliance with EU law on data protection (GDPR)” can be found in Volume 10.

On Fimea's website, you can find information on the [instructiontrns](#) for trilas in accordance with the regulation.

Fimean sivuilta löytyy [lisätietoa](#) asetuksen mukaisiin käytäntöihin

Part I	Part II
<ul style="list-style-type: none"> ➤ Cover letter ➤ EU Application form (data entered directly in CTIS) ➤ Protocol and protocol synopsis (synopsis can be part of protocol or separate document) ➤ Investigators Brochure (IB)/SmPC ➤ IMPD quality, safety and efficacy/ Simplified IMPD with reference to the valid SmPC ➤ Content of labelling of IMPs ➤ Proof of payment of fee (invoicing details or a request for exemption from payment, laskutettavan tiedot tai maksuvapausanomus) 	<ul style="list-style-type: none"> ➤ Recruitment arrangements (template in Volume 10) ➤ Subject information and informed consent form, National Committee on Medical Research Ethics (Tukija's) template ➤ Investigator suitability and CV (template in Volume 10) ➤ Suitability of the facilities (template in Volume 10) ➤ Proof of insurance cover or indemnification ➤ Financial and other arrangements, Tukija's template ➤ Proof that data will be processed in compliance with EU law on data protection (GDPR)

Info box:

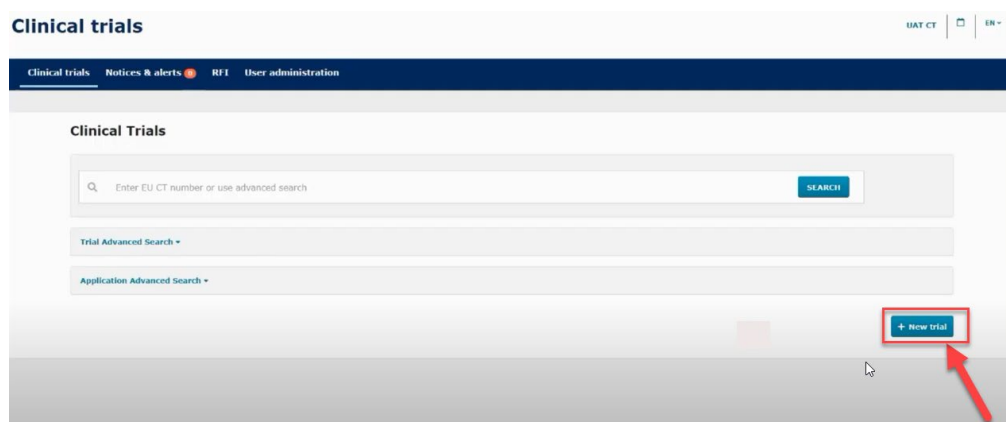
When uploading documents in CTIS be aware not to use date and version in the file name on your documents as this will be transferred to the "Title field" in CTIS and that "Title" will be the same during the entire life cycle of the clinical trial even if there comes substantial modification updates. Otherwise you can rename your documents in CTIS after upload.

4.2 Fill in the trial title and sponsor organisation in CTIS

Info box:

CTIS should be completed in English. Remember to click Save on the top of the page.

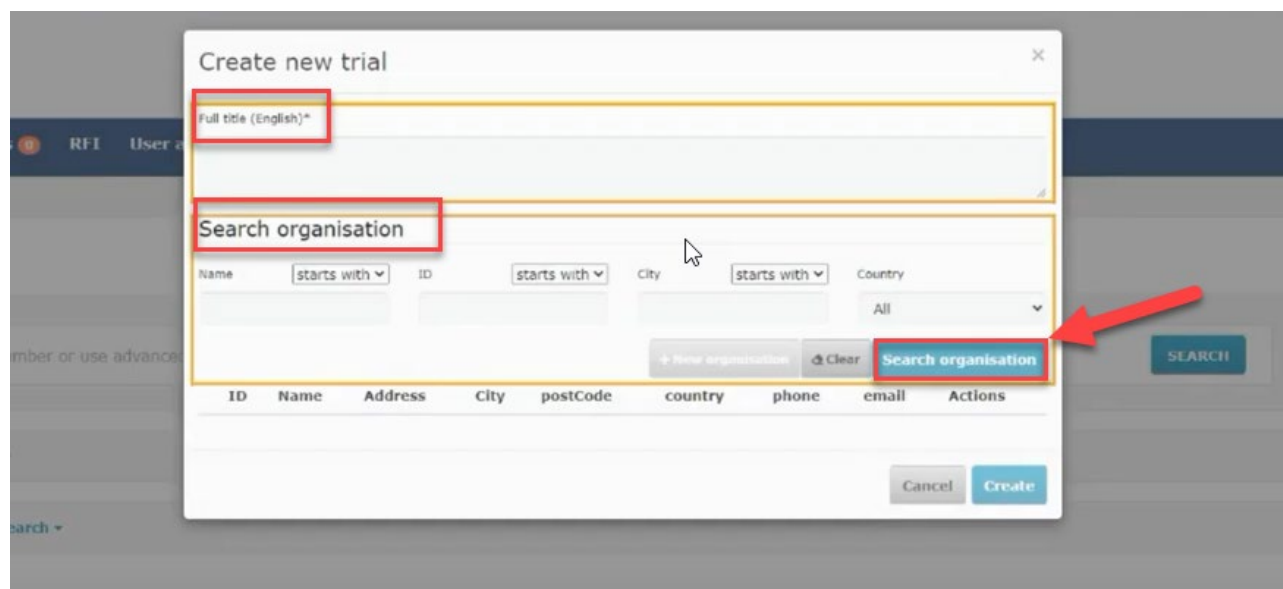
When you are logged in to the CTIS, click on the tab “New Trial”:



Type the full title of the trial.

Click on the “Search organisation” to search for the sponsor which must be registered in the Organisation Management System (OMS) before the CTA is created. Be sure you choose the right address for the specific organisation. This can be the address of the hospital, university etc., where sponsor is located.

If the specific address of sponsor location, is not registered in OMS, then you must choose the overall address of the hospital/university.



services/trials

Full title (English)*
Clinical Trial for the CTIS Training Programme

Search organisation

Name contains starts with City starts with Country All

+ New organisation + Clear Search organisation

ID	Name	Address	City	postCode	country	phone	email
ORG-100023062	IAM Test Organisation	identitilaan 122	Amsterdam	1071 LT	Netherlands		
ORG-100023032	Test organisation	Test employer address			Antarctica		
ORG-100022987	Test Organisation 1	980 Great West Road Address line 2,Address line 3,Address line 4,	London		United Kingdom		
ORG-100023057	Test Organisation Demo	Berlinstrasse 12	Berlin	1045GA	Germany	004952255564645	sponsor1@e
ORG-10002305	Test Organisation Demo	Berlinstrasse 12	Berlin	1010GB	Germany	004952255564645	sponsor@er

1 - 5 of 5

Cancel Create

When the two fields are filled in, click on the create button and the draft of the CTA will be created.

On the following picture on the top right side there are four buttons:

1. Check: Identifies the mandatory fields in the sections which have not been filled in.
2. Save: Save the data which have been filled in up to that moment.
3. Cancel: To cancel your application. This can only be done while your trial is on “draft” mode.
4. Submit: Submit the application when all information is entered and it is completely ready.

Info box:

The lock button needs to be **locked** to enter data. Remember to unlock after uploading data in each section. Save the data before going to the next section.

The four different sections of the application which needs to be filled in with data and documents are:
Form, MSCs, Part I and Part II.

The screenshot shows the 'Form details' section of the CTIS application. The top navigation bar includes 'Clinical trials', 'Notices & alerts', 'RFI', and 'User administration'. A disclaimer at the top states: '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)'. The form is divided into several sections: 'Initial Application details', 'Cover letter', 'Deferral publication dates', and 'Publish dates of trial information'. Annotations include: a red box on the left listing 'Form', 'MSCs', 'Part I', 'Part II', 'Evaluation', and 'Timetable' with a note 'The four sections that need to be filled in'; a red box pointing to the 'Cover letter *' field with the text 'the asterisk * = mandatory fields'; a red box pointing to the 'lock' icon with the text 'Click on the "lock" button to be able to enter data in the form'; and a red box around the 'Add document' button.

Info box:

The "Check" button can as well be used to validate for missing sections at all times during completion.

The asterisk * in CTIS indicates mandatory fields to be filled in and/or mandatory upload of documents.

See also check list of required fields/documents:
[List of required fields per CTA \(europa.eu\).](https://eudra.ec.europa.eu/ctis/required-fields)

4.3 Fill in the Form and Member states concerned (MSCs) section

Video on this topic in EMA training module 10:

[Training video: Fill in the Form and the MSC sections](#)

Form: Add the cover letter and category of the trial. To select the trial category you must use the drop down menu. The category can be from 1- 3.

Category 1: Pharmaceutical development clinical trials.

Category 2: Therapeutic exploratory and confirmatory trials.

Category 3: Therapeutic use clinical trials.

Thereafter you need to add the “justification for the trial category”.

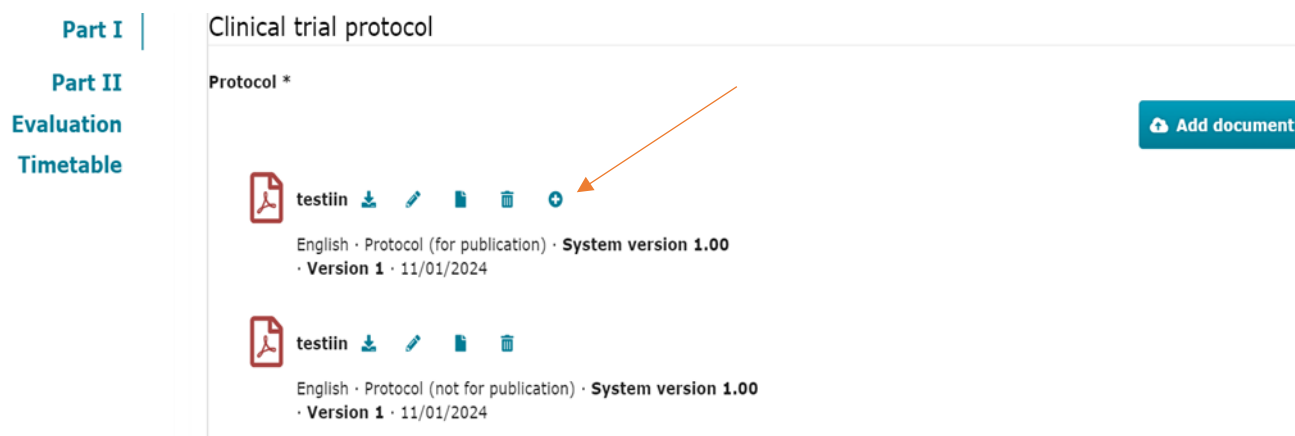
Info box:

The protocol will automatically be accessible in the public workspace after the authorisation. In case of sensitive information in the protocol according to GDPR, it is also possible to upload a second edition of the protocol not for publication.

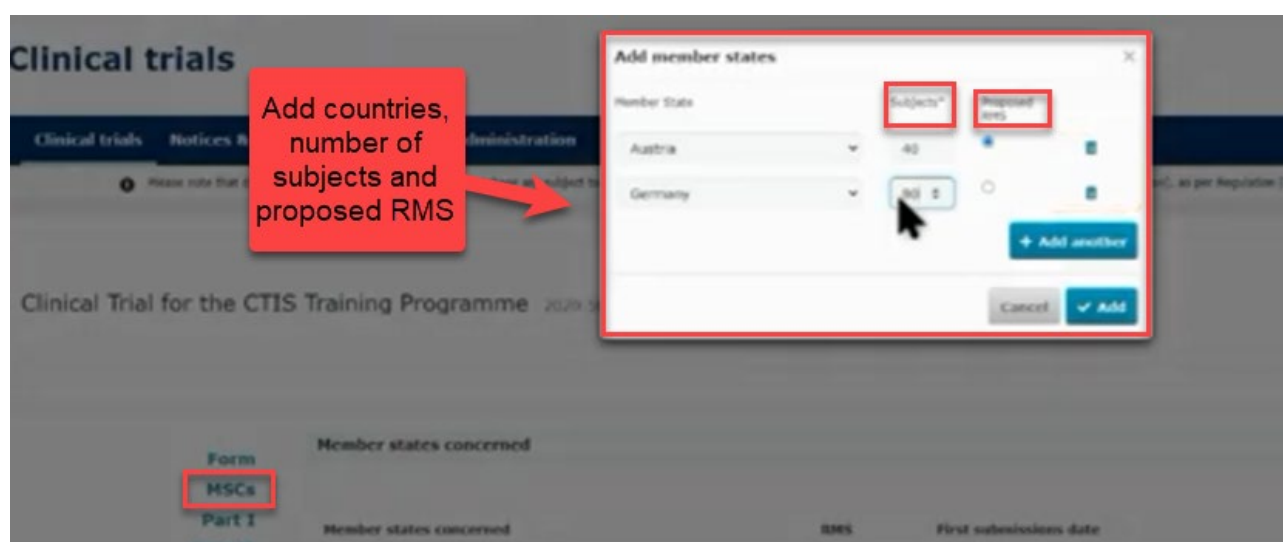
	Category 1 clinical trials (pharmaceutical development clinical trials):	Category 2 clinical trials (therapeutic exploratory and confirmatory clinical trials):	Category 3 clinical trials (therapeutic use clinical trials)
<ul style="list-style-type: none"> Protocol Investigator's brochure Responses from sponsor in relation to any aspect of the trial 	Sponsor may opt to defer this up to the time of MA using this trial or up to 7 years after the end of the trial whichever is earlier.	Sponsor may opt to defer this up to the time of MA using this trial or up to 5 years after the end of the trial whichever is earlier.	Time of decision on the trial. Sponsor may opt to up to the time when the summary of results is made public usually 12 months after the end of the trial in the EU.

Revised CTIS [transparency rules](#) were adopted on 5.10.2023, main differences: publication focused on keydocuments of interest, removal of deferral functionality, documents are published earlier in time, use of redaction as the method to protect commercially confidential information and protection of personal data, if included in those key documents.

Documents can be put into the CTIS program either as for publication-versions or not for publication-versions by adding the not for publication version via plus:



MSCs: Member states concerned. Add the countries (member states) where the trial application should be submitted. Add the number of subjects that are expected to participate in each country. If there are more than one country participating in the trial, you can suggest a country as RMS (reference member state) which is the country that are responsible for the overall scientific assessment.



4.4 Fill in the Part I section

Videos on this topic in EMA training module 10:

[Training video: Fill in the Part I section](#)

[Training video: Fill in the trial details of Part I section](#)

[Training video: Fill in the Sponsor details of Part I section](#)

[Training video: Fill in the Product details of Part I section](#)

Part I: This section contains information mainly to be assessed by the Medicines Health Authorities in each country.

Trial details

Medical condition, trial objective, inclusion- and exclusion criteria, end points, trial duration, population of trial subjects and upload of protocol. [Model](#) for the protocol can be found in Fimea's webpage.

For the main objective you can choose several “trial scopes” that are relevant for the trial.

Sponsor details

Includes sponsor information which was added when the application was first created.
All these contacts must also be registered in OMS.

The first contact point for union must be added. This person will be the contact point for sponsor.

MSCs
Part I

Part II
Evaluation
Timetable

Sponsors

Sponsor must be provided

[+ Add sponsor](#) [Change contact point for union](#)

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

Contact point for union*

Organisation name
Test Organisation Demo

Address line 1*
Berlinstrasse 12

Address line 2

Address line 3

Address line 4

Town/City*
Berlin

Post code
1045GA

Country*
Germany

Functional contact point name

Contact

First name * Last name *

Clinical trials **Notices & alerts** **RPI** **User administration**

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

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

Contact point for union*

Organisation name
Test Organisation Demo

Address line 1*
Berlinstrasse 12

Address line 2

Address line 3

Address line 4

Town/City*
Berlin

Post code
1045GA

Country*
Germany

Functional contact point name

Contact

First name * Last name *

Phone * Email *

Click on the sponsor line and add:

- the legal representative (an EU contact that only need to be added if sponsor is located outside EU),
- scientific contact point and public contact point (must be added for all trials and can be the same person) – in academic/non-commercial trials this person will often be the sponsor contact point (the contact point for union).
- third party (only if tasks or functions in the trial have been delegated to third parties). This is e.g. monitoring (the GCP unit) or laboratory facilities. All third parties must be registered in OMS.

MSCs
Part I
Part II
Evaluation
Timetable

Sponsors

Sponsor must be provided

+ Add sponsor Change contact point for sponsor

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

Test Organisation Demo

click on the sponsor line and add other contacts for the trial

the other contacts for the trial that must be added

+ Add contacts -

- Legal representative
- Scientific contact point
- Public contact point
- Third party

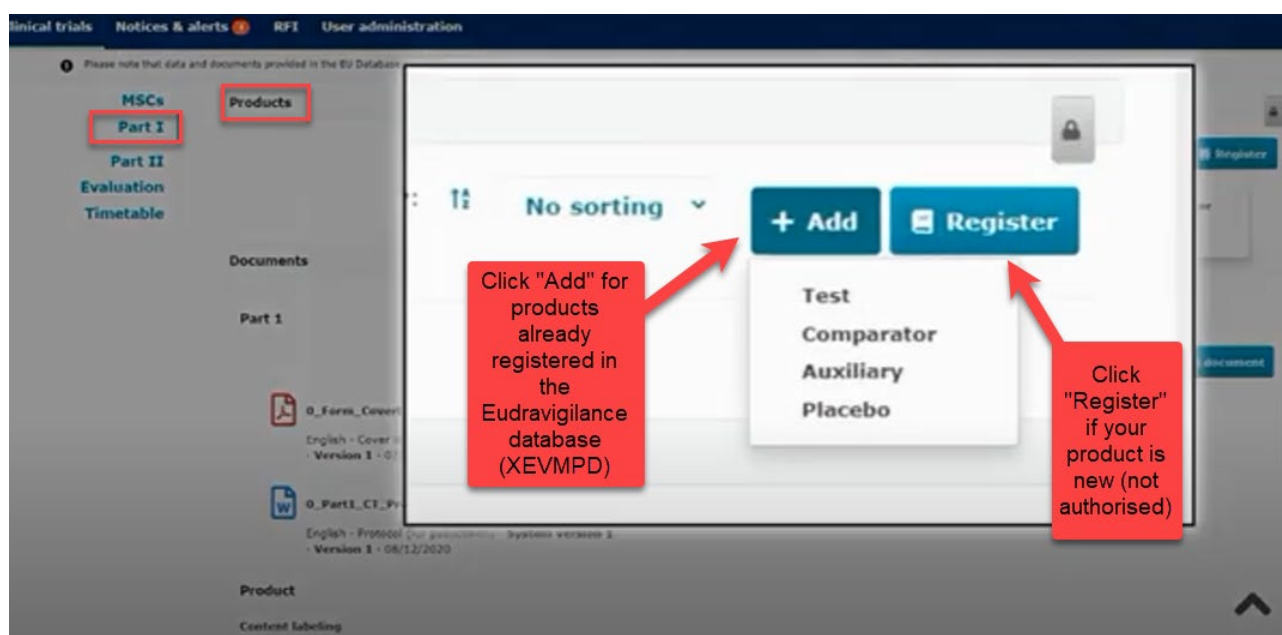
Scientific/public contact point*

Product details

Information on the medicinal products used in the trial must be added. If the products have a marketing authorisation you need to click on “Add”. Select the role (e.g. test/comparator) of the product. It is mandatory to have at least one test product (investigational medicinal product (IMP)) in the application.

Non authorised medicinal products must now be registered to the Extended Eudravigilance Medicinal Product Dictionary (XEVMPPD) if this is not already done.

EMA’s [handbook](#) item 6 tells how to enter not authorised product into the XEVMPPD system.



The reference safety information (RSI) which can be either the Investigators Brochure (IB) or the SmPC must also be uploaded. The labelling must also be uploaded.

If you scroll down in the end you see all the uploaded documents for Part I.

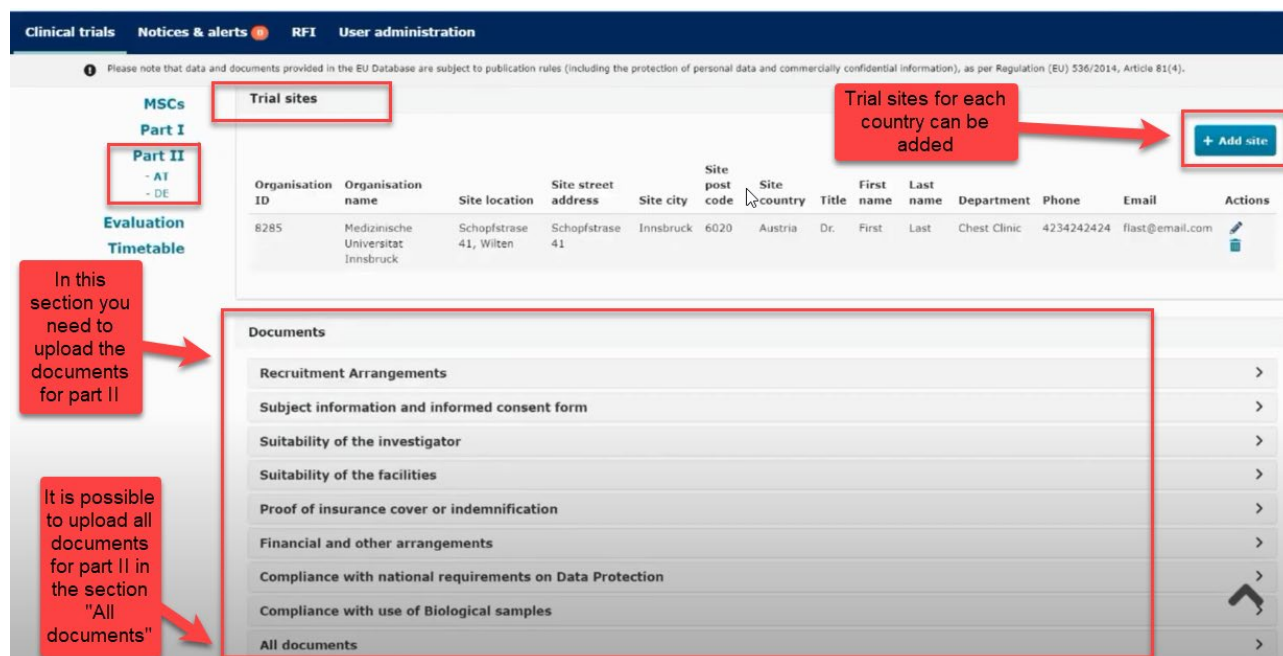
4.5 Fill in the Part II section

Video on this topic in EMA training module 10:

[Training video: Fill in the Part II section](#)

Part II: Individual information for each country, mainly to be assessed by the Ethics Committees in each country. Local documents from each country needs to be uploaded.

Finnish EC requirements: [Local documents](#) from each country needs to be uploaded.
Tukijan sivulta löytyvät [ohjeet](#) paikallisesti toimitettaviin asiakirjoihin.



The screenshot shows the Fimea OMS system interface. The top navigation bar includes 'Clinical trials', 'Notices & alerts', 'RFI', and 'User administration'. A sidebar on the left contains 'MSCs', 'Part I', 'Part II', 'Evaluation', and 'Timetable'. The main content area is divided into two sections: 'Trial sites' and 'Documents'.

Trial sites section: A table lists trial sites with columns: Organisation ID, Organisation name, Site location, Site street address, Site city, Site post code, Site country, Title, First name, Last name, Department, Phone, Email, and Actions. A red box highlights the 'Trial sites' header, and another red box highlights the '+ Add site' button. A red arrow points from the text 'Trial sites for each country can be added' to the '+ Add site' button.

Documents section: A list of document types is shown, including 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, and All documents. A red box highlights the 'Documents' header and the list of document types. A red arrow points from the text 'In this section you need to upload the documents for part II' to the 'Documents' header. Another red arrow points from the text 'It is possible to upload all documents for part II in the section "All documents"' to the 'All documents' link.

Documents listed and uploaded in chronological order is recommended in the section "All documents".

Trial sites must be added: Name and address of trial sites and primary investigators at the trial sites.

Be aware not to include personal information (e.g. personal ID numbers, private addresses and telephone numbers) in investigators CV for public.

The name and address of the university/hospital organisation must be registered in OMS before you can search and add the organisation to the application form. If the organisation is not already part of the OMS system, the organisation must be added to OMS (see section 3.1). This must be done by sponsor or the organisation itself.

Select trial site

Search organisation

Name: (contains) ID: (starts with) City: (starts with) Country:

ID	Name	Address	City	postCode	country	phone	email	Actions
<input checked="" type="radio"/> ORG-100007200	Department of Nuclear Medicines, MU Innsbruck	Anichstrasse 35	Innsbruck	6020	Austria			<input type="button" value="X"/> <input type="button" value="+"/>
<input type="radio"/> ORG-100022556	Medizinische Universität Innsbruck	Schopfstrasse 41 Wilten,	Innsbruck	6020	Austria			<input type="button" value="X"/> <input type="button" value="+"/>

1 - 2 of 2

When the organisation is found via the search function, the details of the investigators must be added (first and last name, department, email address, phone).

Investigator information

Title: First name*:

Last name*: Department*:

Phone*: Email*:

Supporting documents: Upload documents in each separate section or upload all the documents in the section "All documents" and specify in the document title what the document contains.

Click on the “Save” button to save all uploaded documents and click on the “Check” to see if any documents or information are missing. The green message shows when the application is valid.

The screenshot shows the 'Clinical trials' application form. At the top, there is a green message box that says 'Application is valid!'. Below this, there is a red box highlighting the 'Check' button. A red arrow points from the text 'Green message shows when the application is valid' to the green message box. Another red arrow points from the 'Check' button to the same green message box. The form includes sections for 'Country specific details (Part II - DE)', 'Trial sites', and 'Documents'. A red box highlights the 'Add document' button in the 'Documents' section.

Remember to upload the Part II information relevant for each country. Part I is always included by default in the submission for all countries.

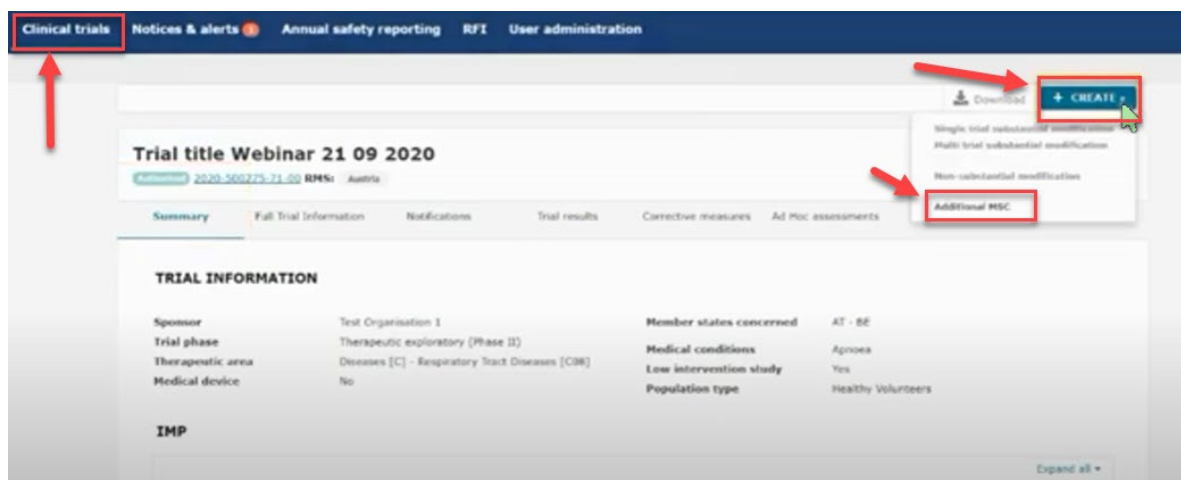
The screenshot shows the 'Submit confirmation' dialog box. It contains a list of application parts with checkboxes: 'Part I' (checked), 'Part II Austria' (checked), and 'Part II Germany' (checked). A red box highlights the 'Part II Austria' and 'Part II Germany' options. A red arrow points from the text 'Remember to upload the Part II information relevant for each country' to the 'Part II Austria' and 'Part II Germany' options. The dialog box also has 'Cancel' and 'Confirm' buttons. A red box highlights the 'Confirm' button.

4.6 How to submit an additional member states concerned (MSC) application (add a new country)

Video on this topic in EMA training module 10:

[Training Video: How to submit an additional MSC application in the CTIS Sponsor workspace](#)

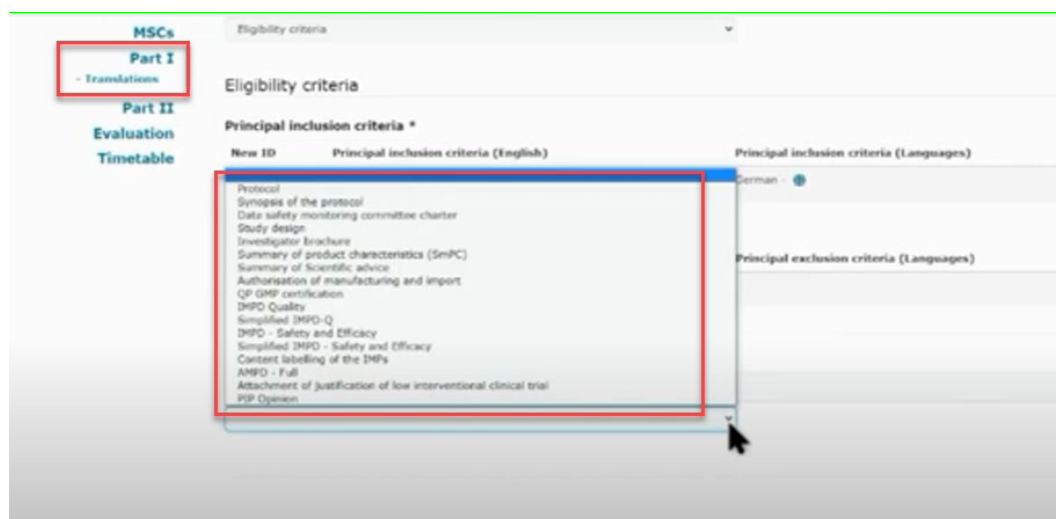
To add a new member state (MSC) to an already approved application. In the page of the authorised clinical trial click on the “create” button and choose “Additional MSC”.



In the next pop-up window you can select one or several MSCs to add on the same time and specify for each country the number of subjects. Each application will be assessed individually by the country that has received the new application.

In the Form section a new cover RMS letter must be uploaded for each added MSC.

In the Part I section you can provide translations if required by the new MSC. If you need to upload translations for documents you can choose the document type on a list and thereafter upload the new document and add the language.



In the Part II you can add the site details for the new MSC.

4.7 Withdrawal of an application

After opening the initial trial application which is under evaluation, select the “withdraw” button. A justification for the withdrawal should be provided.

CT for training test 2021-501399-27-00 / Initial ID: IN Under evaluation



5 Validation, Request for Further Information (RFI) and Authorisation

5.1 How to access and view a request for further information (RFI)

Videos on this topic in EMA training module 11:

[Training Video: How to access and view a request for further information \(RFI\) in CTIS \(Sponsors\)](#)

RFI: Questions from authorities to sponsor.

In the sponsors workspace you will be able to see incoming RFIs in the “Notices and alerts” tab.

Access the RFIs by click on each of them

Alert	RFI sent to sponsor	Ref number	Source type	Evaluation process	Received	IMP	RMS	Sponsor
An RFI has been sent by Austria for the Initial application, Validation .	2021-500027-47-00	Initial	Validation	03/02/2021	Paracetamol Tablets 500mg	Austria	Test Organisation Demo	
An RFI has been sent by Austria for the Initial application, Validation .	2021-500027-47-00	Initial	Validation	03/02/2021	Paracetamol Tablets 500mg	Austria	Test Organisation Demo	

You can access the RFI by clicking on each of the alerts. They can also be accessed from the RFI tab next the “Notices and alerts” tab.

Click on the RFI and you will be redirected to the “Evaluation” section where the Request for further information (RFI) is shown.

CTIS Training Programme test CT for Demo 2021-500027-47-00 / Initial ID: IN **Under evaluation** / RMS: Austria

Validation section shows the number of RFIs

Click on the lock to be able to upload response to RFI

RFI-CT-2021-500027-47-00-IN-001 Due: 15/02/2021

MSC: Austria Submission date: 03/02/2021 Due date: 15/02/2021

Reason: Incomplete

No changes have been made to the application.

Supporting documentation

MS:

When you have clicked on the lock button you can see the documents that the authorities have attached to the RFI. The RFI can be related to “quality” or “non quality”.

RFIs from authorities or Ethics committees

It is possible to change/update the application if required in RFI

Change application

RFI-CT-2021-500027-47-00-IN-001 Due: 15/02/2021

MSC: Austria Submission date: 03/02/2021 Due date: 15/02/2021

Reason: Incomplete

Supporting documentation

MS:

Quality

RFI_Submission_Quality

English · Supporting document from MS - Quality · System version 1.00

submission date 03/02/2021

Version 1 · 03/02/2021

Non-Quality

RFI_Submission_nonQuality

English · Supporting document from MS - Non Quality (for publication) · System version 1.00

submission date 03/02/2021

Version 1 · 03/02/2021

Sponsor:

General documentation

Quality related documentation

Add document

Add document

In the “Add document” tab you can upload supporting documentation. If the RFI requires, you can click on the “Change application” and then change information which is previously uploaded or entered for the CTA.

5.2 How to change a Clinical Trial Application as part of a RFI response (Sponsors)

Videos on this topic in EMA training module 11:

[Training Video: How to change a Clinical Trial Application as part of an RFI response \(Sponsors\)](#)

If the RFI requires changes to the application you must click on the change application button. Then a new version of the application has been drafted. Each RFI must be answered separately. You can make changes in the sections Form, Part I and Part II.

Clinical trials **Notices & alerts** **RFI** **User administration**

Please note that data and documents provided in the EU Database are subject to publication rules, which take into account the need to protect personal data and commercially confidential information. Once available, a redacted version of the documents will be made publicly available in accordance with these rules.

MSCs
Part I *
Part II *
Evaluation
Timetable

RFI 1

Consideration number RFI-CT-2021-500027-47-00-IN-004-01 Application section parts Part I - Non-clinical Application section and document Protocol

Consideration Austria - Part I Assessment consideration nr3

Sponsor response Response Austria - Part I Assessment consideration nr3

Documents related to the response

ResponseRFI1

English - Supporting documentation for Consideration (for publication) - System version 1.00

Submission date 05/02/2021

Version 1 - 05/02/2021

RFI 2

Consideration number RFI-CT-2021-500027-47-00-IN-004-02 Application section parts Part I - Non-clinical Application section and document Cover letter

Consideration Germany - Part I Assessment consideration nr5

Response

Response to Austria - Part I Assessment consideration nr5

Documents related to the response

Add document

Save response

Response to RFI. Each consideration must be answered

If there are RFIs from different countries it is necessary to make a draft application for each RFI. There can for example be one RFI for Part I and one RFI for Part II from each member state.

The screenshot shows the EMA RFI response interface. On the left, a sidebar contains links for 'Clinical trials', 'Notices & alerts', 'RFI', and 'User administration'. Below these, a list of 'MSCs' includes 'Part I', 'Part II', 'Evaluation', and 'Timetable'. The main area displays three drafts for Assessment Part I and Part II. Draft 1 for Assessment Part I is highlighted in orange. Draft 2 for Assessment Part II - Austria is highlighted in blue. Draft 3 for Assessment Part II - Germany is highlighted in green. A red box with an arrow points to the 'Evaluation' link in the sidebar, containing the text: 'Application in draft for Part I and Part II. There must be one answer from each RFI.'

The screenshot shows the 'Protocol information' section of the EMA RFI response interface. It displays a list of documents, including '0_Part1_CT_Protocol' and '0_Part1_CT_Protocol'. Annotations with red boxes and arrows point to specific elements: 'New version of the protocol' points to the '0_Part1_CT_Protocol' document; 'Previous version of the protocol' points to the 'Version 1' document; 'click on the upload button to upload new versions of the documents' points to the 'Add document' button; and 'Add new document' points to the 'Add document' button. A 'Previous versions' dropdown menu is also visible.

Remember to unlock each section when you are done answering the RFI and uploading new documents.

5.3 How to respond to RFI considerations and submit an RFI response

Videos on this topic in EMA training module 11:

[Training Video: How to respond to RFI considerations and submit an RFI response \(Sponsors\)](#)

Sponsor must reply to each of the RFI received from the authorities. You can upload a response document that describes the changes to the application.

clinical trials Notices & alerts RFI User administration

Please note that data and documents provided in the EU Database are subject to publication rules, which take into account the need to protect personal data and commercially confidential information. Once available, a redacted version of the documents will be made publicly available in accordance with these rules.

MSCs
Part I *
Part II *
Evaluation
Timetable

Assessment Part I

RFI 3

RFI-CT-2021-500027-47-00-IN-003 Responded: 03/02/2021

RFI-CT-2021-500027-47-00-IN-004 Due: 15/02/2021

Discard changes

Add document

click on the lock button to be able to answer the RFI

Remember to tick the "includes application changes" if there are changes to sections in the application

Add a response document

open the RFI

Below the RFI, there can be considerations which also must be answered. You can respond separately to each consideration.

MSCs
Part I *
Part II *
Evaluation
Timetable

Click on the lock button

Consideration 1

Consideration 2

Type your response in the field

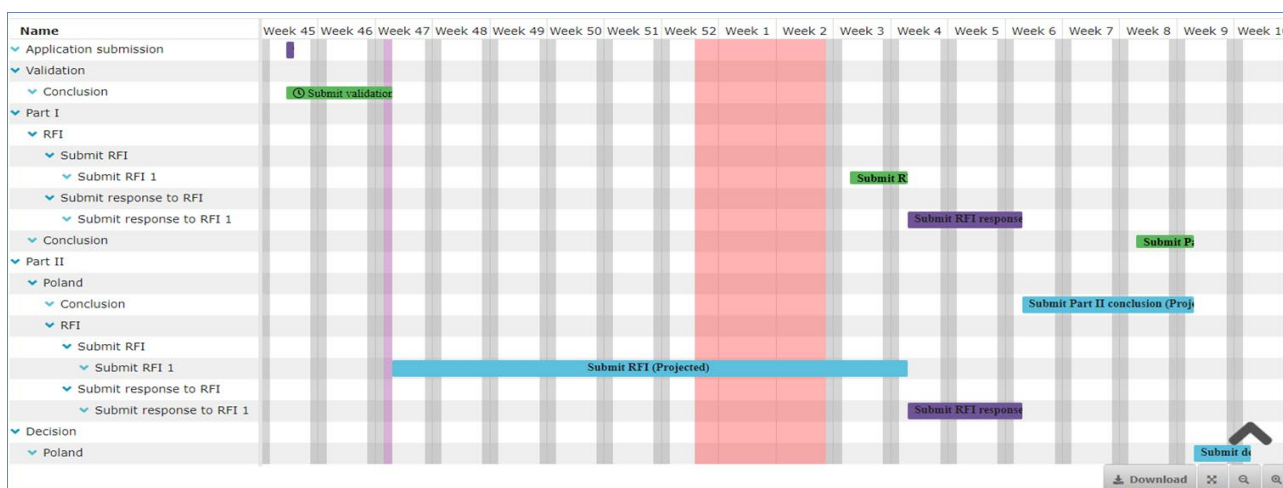
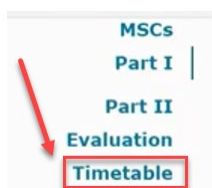
Here you can upload additional documents for the consideration

Save response

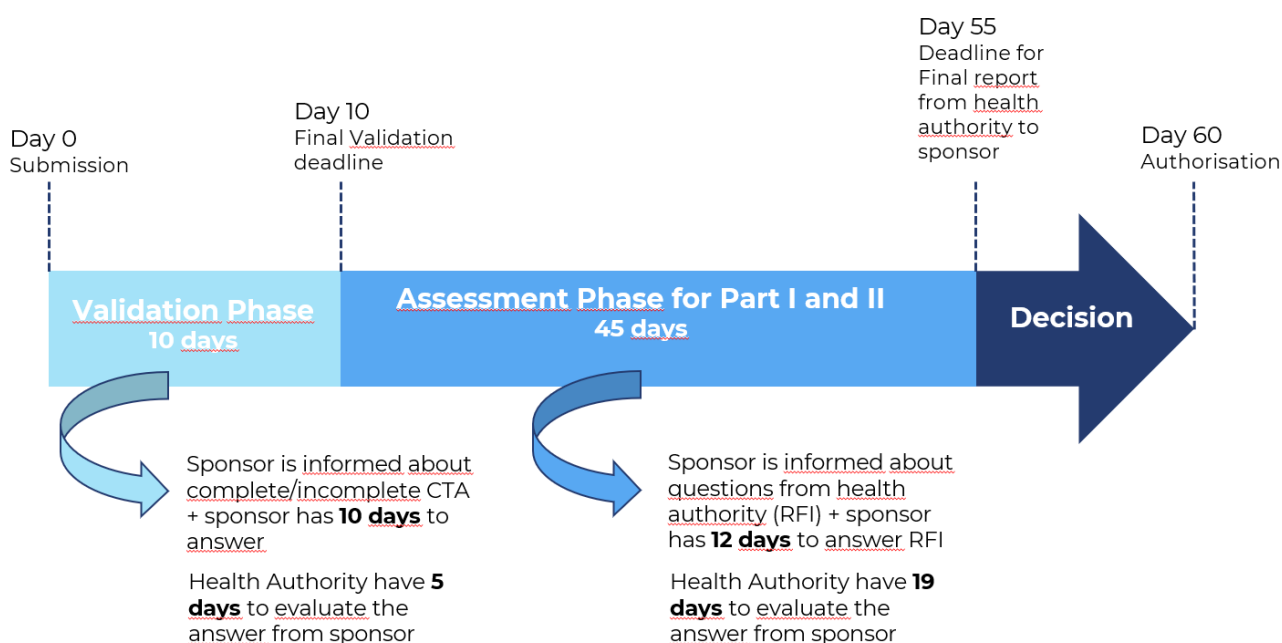
The "Submit response" button will be active when the changes have been saved on "save response". Please check that the top lock is locked and the other locks are open, then the "submit response" button is available in the bottom of the page. It is advisable to include the track changes document if there are many changes (in protocol, ICF etc.)

T5.3 Timetable

In the timetable tab on the left side of the page in CTIS it shows the dates for the assessment schedule.



The figure below shows an overview of the general timetable and deadlines for authorities and sponsors.



5.4 Authorisation

Info box:

The trial must include patients in the member state within 2 years from authorisation date in order to keep the trial authorised in that member state.

In the assessment overview at the “Evaluation” page it is shown which countries have authorised the trial.

MSCs	Validation	Assessment Part I	Assessment Part II	Decision	
AUSTRIA	Valid (30/10/2020)	Acceptable (04/11/2020)	Acceptable (04/11/2020)	Authorised (05/11/2020)	+
GERMANY			Acceptable (05/11/2020)	Authorised (05/11/2020)	+

An overview of all documents and the approval date is shown at the end of “full trial information”.

ALL DOCUMENTS										
Section	Document type	Document Title	Document Version	Document Comment	Document Submission Date	System version	Language	Authorisation date	Application	Download
Part I	Cover letter (for publication)	Cover letter	1		17/01/2022	1.00	English	17/01/2022	INITIAL - IN	
Part I	Protocol (for publication)	Protocol for publication	1		17/01/2022	1.00	English	17/01/2022	INITIAL - IN	
Roles: Test Name: DENUBIL 250 mg/180 mg solución oral	Summary of Product Characteristics (SmPC) (for publication)	SmPC - NaCl 09 - Braun Melsungen DE	1		17/01/2022	1.00	English	17/01/2022	INITIAL - IN	
Part I	Content labelling of the IMPs (for publication)	Labelling	1		17/01/2022	1.00	English	17/01/2022	INITIAL - IN	
Part I	Compliance with Regulation (EU) 2016/679 (for publication)	Compliance with Reg 2016_679	1		17/01/2022	1.00	English	17/01/2022	INITIAL - IN	

6 15 days Notifications after Authorisation

Video on this topic in EMA training module 5:

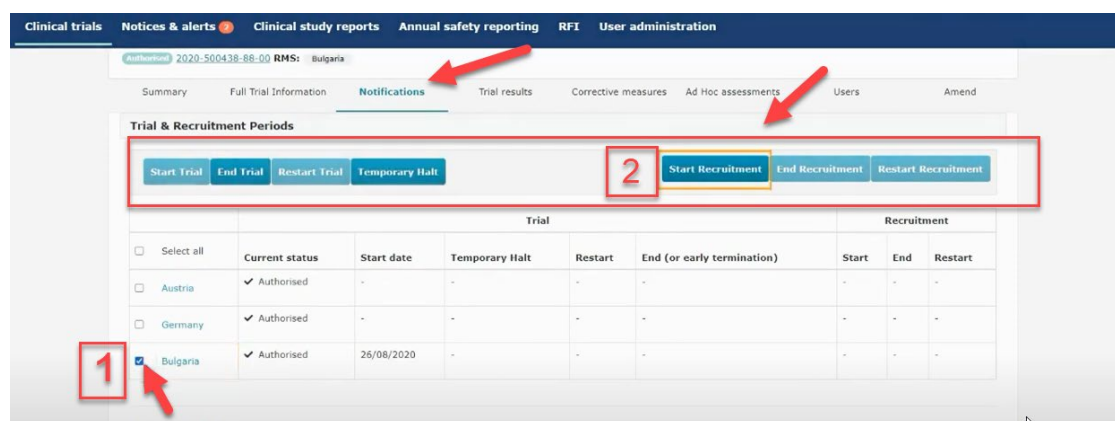
[Training Video: How to manage a CT in the CTIS sponsors workspace – Trial and recruitment periods notifications](#)

The **notification tab** can be found in each clinical trial in the sponsor workspace. Sponsors use the notification tab to inform each member state of important milestones in the clinical trial:

- Start of recruitment
- Start of inclusion
- Temporary halt of the clinical trial
- Temporarily halted clinical trial is resumed
- End of recruitment
- End of inclusion
- End of trial

The **deadline** for reporting these notifications in CTIS is **15 days**. The notifications should be made for each member state where the clinical trial is approved. The specific country must be selected and then click on the notification tab you want to enter.

All buttons found in the notification tab will be active once the clinical trial is authorized.

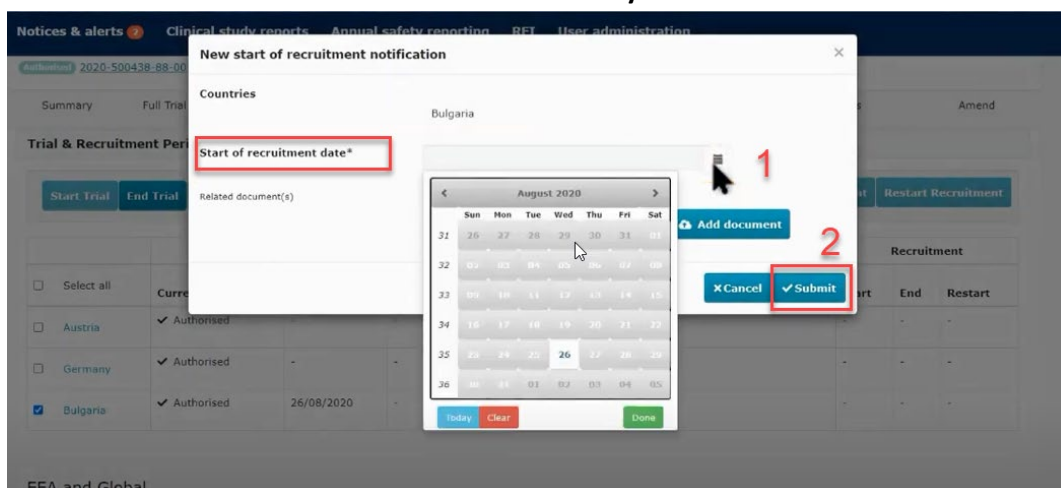


Select the specific country where you want to make a notification

Click on the notification tab you want to enter either **Start Trial**, **End Trial**, **Restart trial**, **Temporary Halt**, **Start recruitment**, **End recruitment** or **Restart recruitment**.

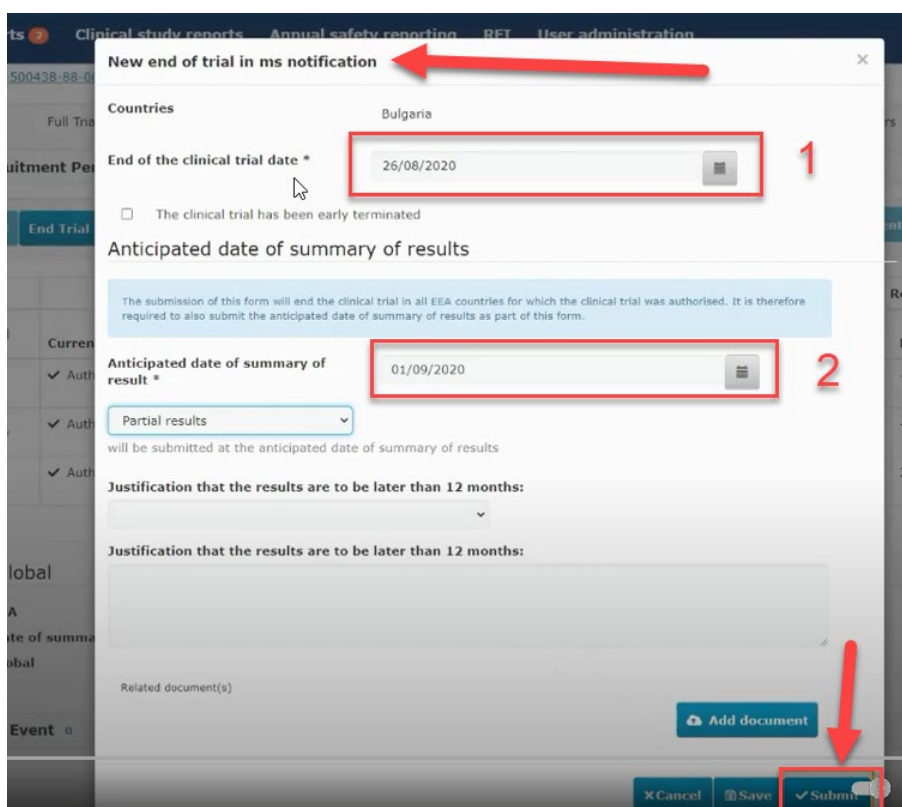
Examples:

Start of recruitment notification at the latest 15 days after start:



Choose the country where you want to notify about recruitment start. Enter the date where the recruitment will start and then click submit.

End of trial notification at the latest 15 days after the trial ended:

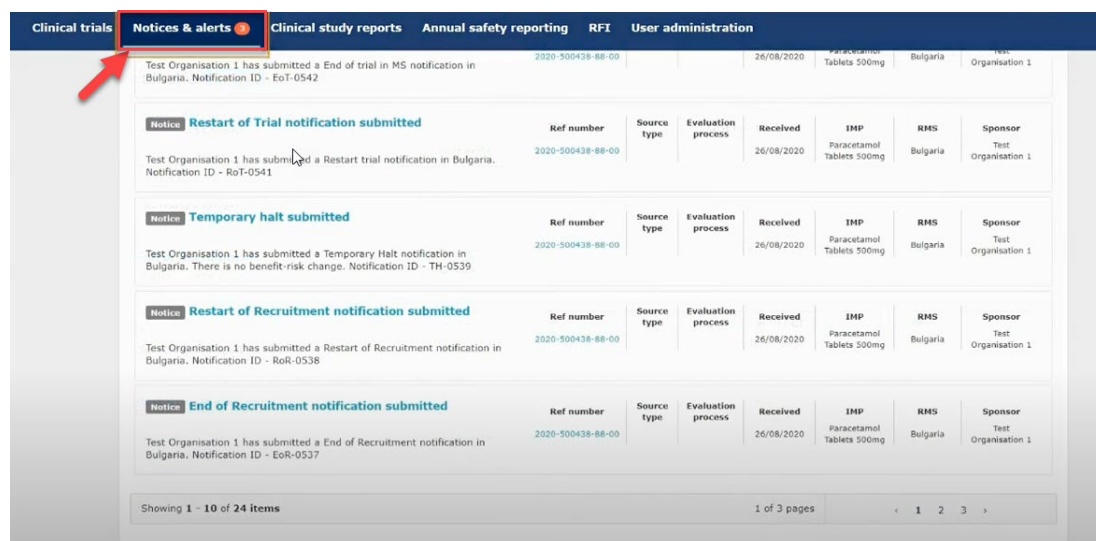


Enter the date where the clinical trial ended according to the protocol or if it was terminated early.

Enter the anticipated date of where the summary of results will be available.

By clicking on the country link you can go to the notification history for that specific country.

Each time you submit a notification a notice is created on the “notices & alerts” tab.



Clinical trials						
Notices & alerts						
Test Organisation 1 has submitted a End of trial in MS notification in Bulgaria. Notification ID - EoT-0542						
Notice Restart of Trial notification submitted						
Test Organisation 1 has submitted a Restart trial notification in Bulgaria. Notification ID - RoT-0541						
Notice Temporary halt submitted						
Test Organisation 1 has submitted a Temporary Halt notification in Bulgaria. There is no benefit-risk change. Notification ID - TH-0539						
Notice Restart of Recruitment notification submitted						
Test Organisation 1 has submitted a Restart of Recruitment notification in Bulgaria. Notification ID - RoR-0538						
Notice End of Recruitment notification submitted						
Test Organisation 1 has submitted a End of Recruitment notification in Bulgaria. Notification ID - EoR-0537						
Showing 1 - 10 of 24 items						
1 of 3 pages						

7 How to create and submit a Substantial Modification (SM)

Video on this topic in EMA training module 10:

[Training Video: How to submit a substantial modification in the CTIS sponsor workspace](#)

There are three types of changes to a clinical trial:

1. Substantial Modification (SM)
2. Non Substantial Modifications (NSM)
3. 81.9 Non Substantial Modification (81.9 NSM)

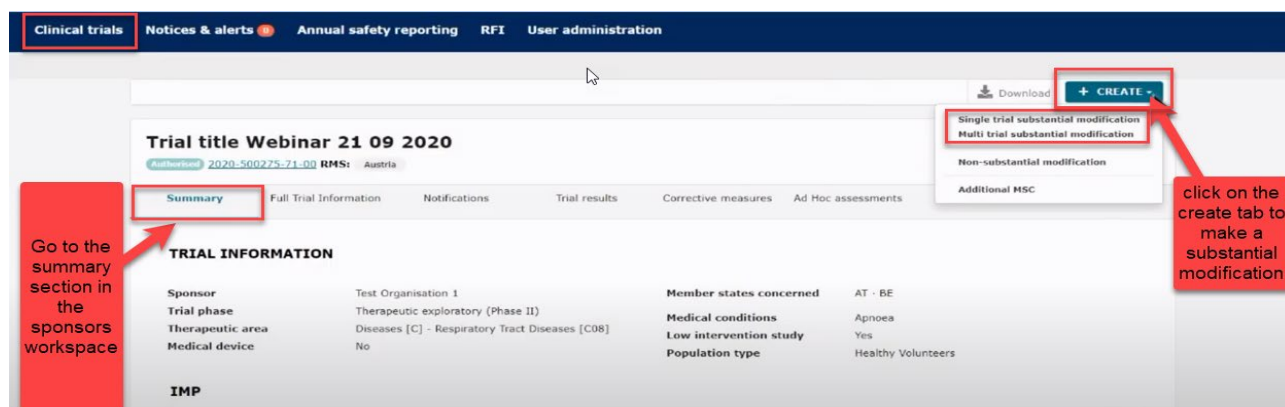
Classification of changes to ongoing trials can be found in [EMA Q&A](#) Annex IV “Classification of changes to ongoing clinical trial”.

All non substantial changes, both CTR’s 81.9 NSM and NSM, do not require an approval before implementation.

The CTR’s 81.9 NSMs must be updated by sponsor regularly in CTIS during the trial period. These are changes that are relevant to the member states concerned.

Other NSMs must be updated in CTIS with next SM or latest at end of trial, if no SMs have been submitted meantime.

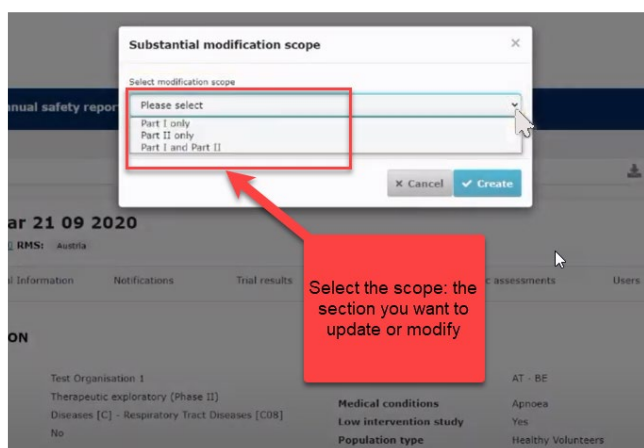
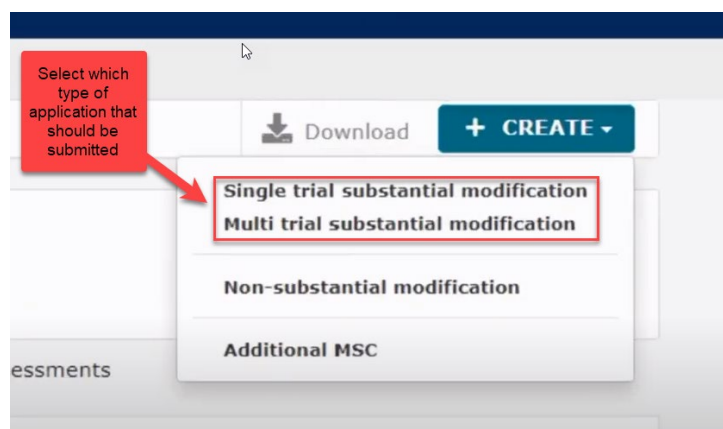
To create and submit a substantial modification after the clinical trial has been authorised, users can select the ‘+ CREATE’ button in the sponsors workspace at the top-right corner of the Clinical Trail page.



This will enable you to select which type of modification you want to submit:

Single trial substantial modification: to update information for *only one trial*.

Multi trial substantial modification: to update information for trials that have the same investigational medicinal product (IMP) and the same sponsor. In this case it is possible to submit *a single application covering several trials*.



If you click on the **“Single trial substantial modification”** you will be redirected to a window where you need to enter the scope of the substantial modification. Thereby you will define the part which will be modified (Part I and/or II).

In the **“Form”** section, cover letter etc. should be uploaded and you can add details about the substantial modification.

Clinical trials Notices & alerts Annual safety reporting RFI User administration

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).

Trial title Webinar 21 09 2020 / RMS: Austria / Substantial modification ID: SM-1 Draft New version draft SM-1 View submitted application

Check Save Cancel Submit

Form MSCs Part I Part II Evaluation Timetable

Form details

Substantial modification details

Cover letter Add document

Modification description Add document

Supporting information

If you scroll down, the reason for the substantial modification must be added here.

Clinical trials Notices & alerts Annual safety reporting RFI User administration

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

0_Modification_Description_Details English - Modification Description (for publication) - System version 1 - Version 1 - 13/09/2020

Supporting information

Supporting information documents Add document

Substantial modification reason

- ☐ End of trial in MS
- ☐ End of trial in EEA
- ☐ Global end of trial
- ☐ Anticipated date of summary of results
- ☐ Unexpected Event Change in B/R
- ☐ Serious Breach
- ☐ Urgent Safety Measure
- ☐ 3rd Country Inspectorate Inspection
- ☐ EEA Inspections
- ☐ Change of sponsor or sponsor's legal representative
- ☐ Extension to start trial recruitment beyond 2 years
- ☐ Extension to restart trial beyond 2 years

Substantial modification scope

In the "MSCs section" only subject numbers (number of planned trial subject) can be modified.

Clinical trials Notices & alerts Annual safety reporting RFI User administration

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).

Trial title Webinar 21 09 2020 / RMS: Austria / Substantial modification ID: SM-1 Draft New version draft SM-1 View submitted application

Check Save Cancel Submit

Form MSCs Part I Part II Evaluation Timetable

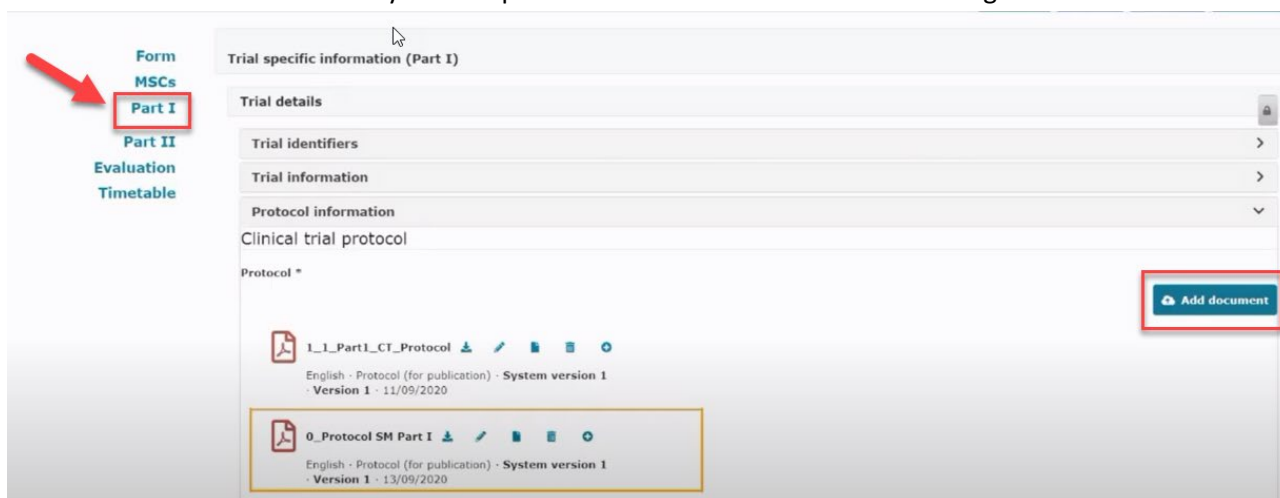
Member states concerned

Member states concerned	RMS	First submissions date
Austria	Selected	
Belgium		

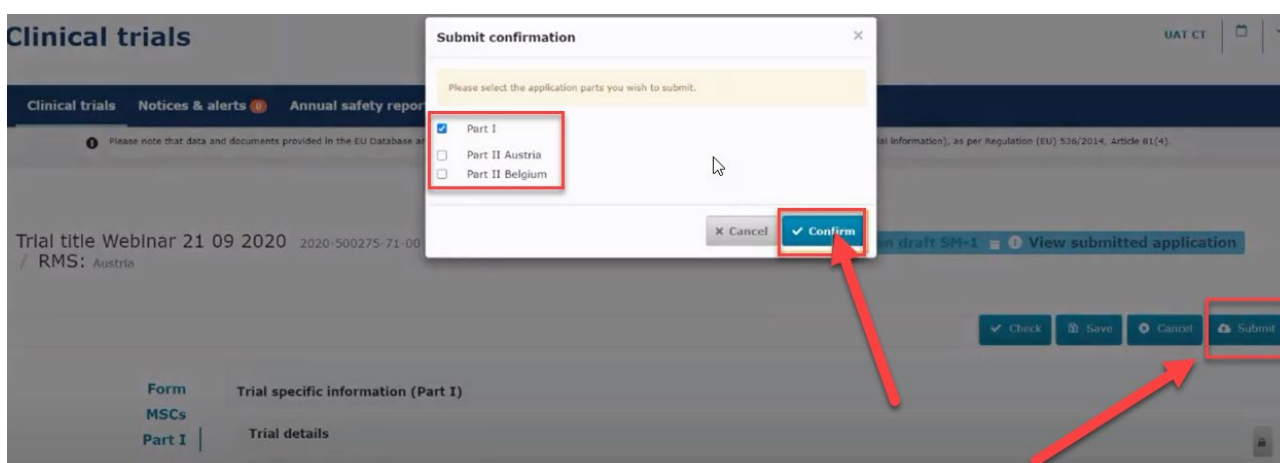
Subjects 20 20

+ Add member states

In the “Part I or Part II” section you can upload the relevant documents with changes.



When all data and documents have been modified and uploaded, click on “Submit”. Then select the parts of the application you want to submit and click on the “confirm” button.



In the Summary page you can scroll down and see the status of the substantial modification.

Clinical trials Notices & alerts Annual safety reporting RFI User administration

Paracetamol Tablets 500mg

OVERALL TRIAL STATUS

Member State	Overall Trial Status	First decision date	Start of trial	End of trial	Recruitment start date
AT	Authorised	11/09/2020			
BE	Authorised	11/09/2020			

It is shown whether the substantial modification has been authorised and by which member states

It is possible to view additional information

APPLICATION AND NON-SUBSTANTIAL MODIFICATION

Type	ID	Parts	MSCs	Submission date	Decision date	Reason	Scope	Link	
Substantial modification	SM-1	Part I Part I	AT(Authorised) BE(Authorised)	13/09/2020	13/09/2020	+	+		+ INFO
Initial	IN	Part I & Part II Part I & Part II	AT(Authorised) BE(Authorised)	11/09/2020	11/09/2020	-	-	-	+ INFO

8 Create and submit an Annual Safety Report (ASR)

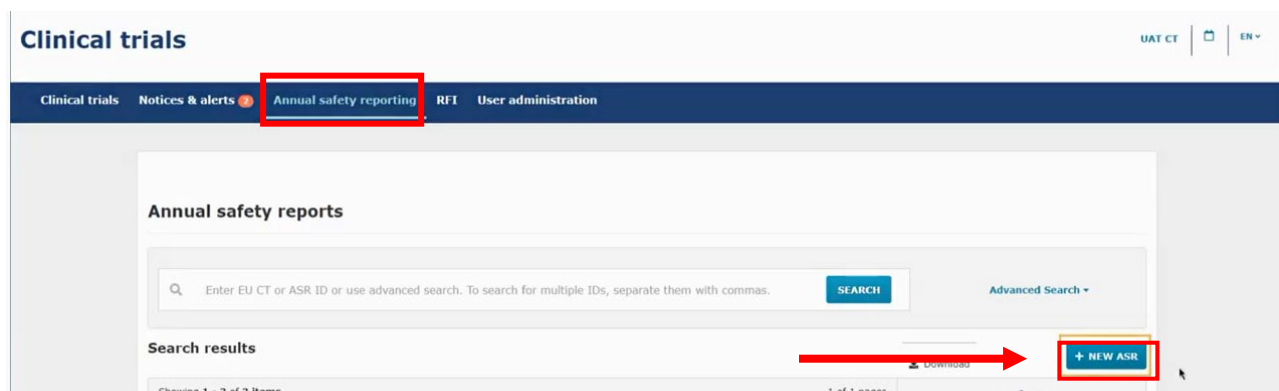
Video on this topic in EMA training module 18:

[Training Video: How to create, cancel or clear and submit an Annual Safety Report](#)

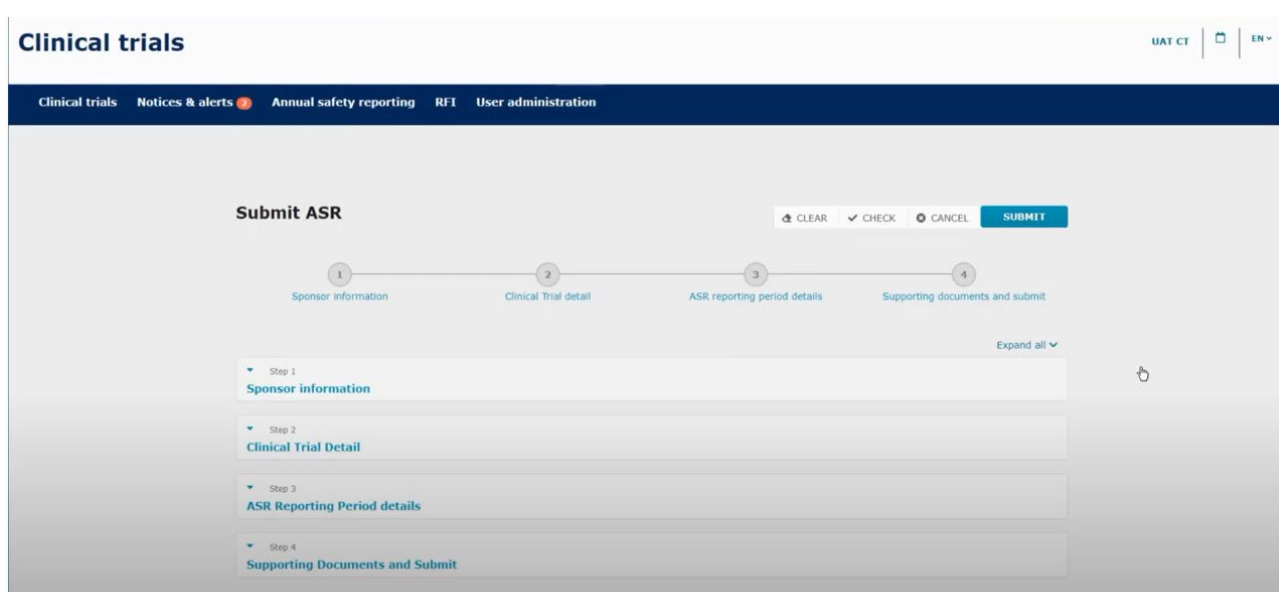
Info box:

Make sure to have the ASR document in PDF prepared.
You also need to have all the relevant information ready (e.g. Investigational medicinal products, relevant events that occurred, reporting period, etc) before you start.

To create and submit an Annual Safety Report users can open “the Annual Safety Reporting form” by clicking on the ‘+New ASR’ button in the sponsor’s workspace.

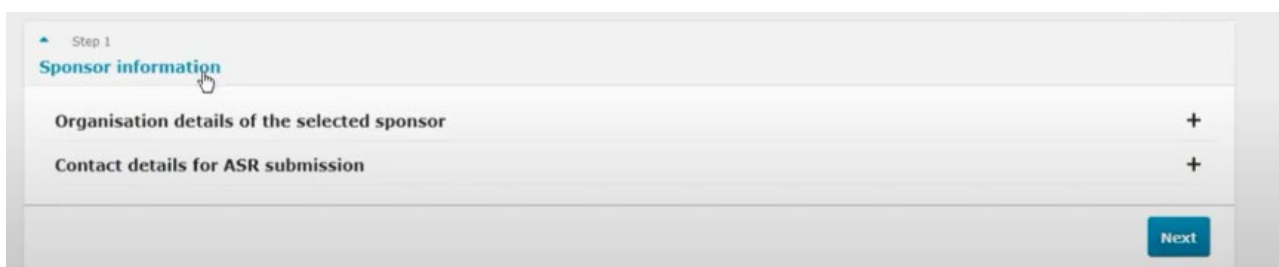


An ASR form opens:



Fill in the information for the four steps (**Sponsor information**, **Clinical trial details**, **ASR reporting period details** and **supporting documents**) and submit on the "Submit" button. The ASR form has to be filled in and submitted in one go. You need to have all information ready because it cannot be saved.

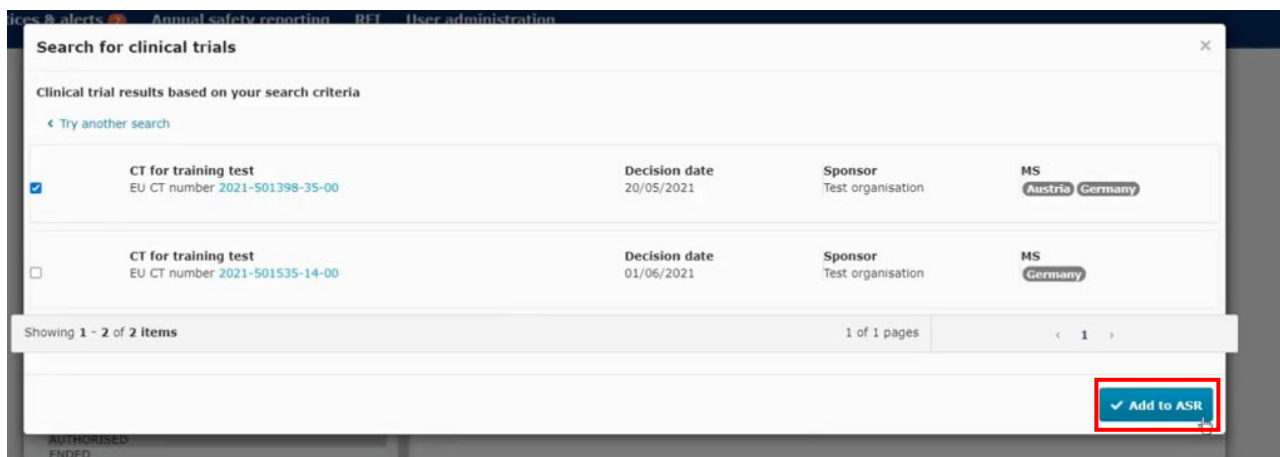
Step 1: Sponsor information



Fill in Organisation details of the selected sponsor and the contact details for the person who is responsible for the submission and can be contacted with an email address and / or phone number.

Step 2: Clinical trial details

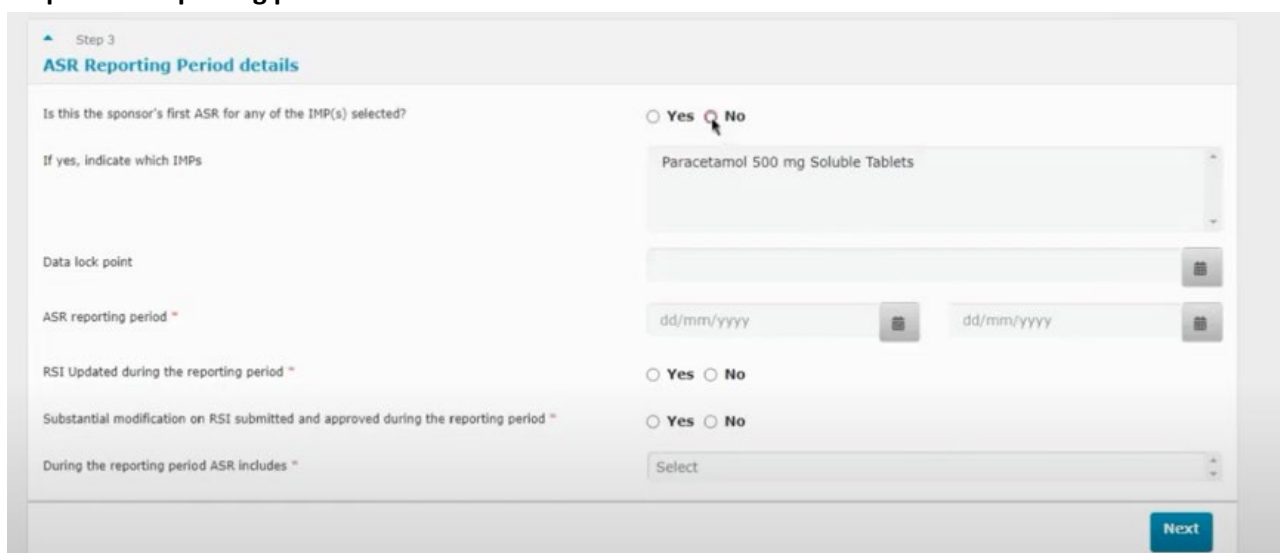
Search for the Clinical Trial (CT) to which you want to submit an ASR. You search for clinical trials that are authorised for the selected sponsor organisation and select the trial(s) for which you want to submit an ASR.



Search for clinical trials			
Clinical trial results based on your search criteria			
Try another search			
<input checked="" type="checkbox"/>	CT for training test EU CT number 2021-501398-35-00	Decision date 20/05/2021	Sponsor Test organisation MS Austria Germany
<input type="checkbox"/>	CT for training test EU CT number 2021-501535-14-00	Decision date 01/06/2021	Sponsor Test organisation MS Germany
Showing 1 - 2 of 2 items		1 of 1 pages	Add to ASR

When the form opens you click on the related IMP or IMP's for the clinical trial you want to submit an ASR.

Step 3: ASR reporting period details



Step 3

ASR Reporting Period details

Is this the sponsor's first ASR for any of the IMP(s) selected? ☐ Yes ☒ No

If yes, indicate which IMPs

Paracetamol 500 mg Soluble Tablets

Data lock point

ASR reporting period *

dd/mm/yyyy dd/mm/yyyy

RSI Updated during the reporting period *

☐ Yes ☐ No

Substantial modification on RSI submitted and approved during the reporting period *

☐ Yes ☐ No

During the reporting period ASR includes *

Select

Next

In this section you need to select and fill in the **data lock point (DLP)**. That is the cut-off date of selecting data for the ASR. The DLP must be as close as possible to the approval date.

If this is the first ASR in the clinical trial the **ASR reporting period** starts with the date where the clinical trial is first authorised and ends with the selected DLP (approximately after one year).

The deadline for submission of ASR is every year 60 calendar days after the DLP.

The following should also be answered:

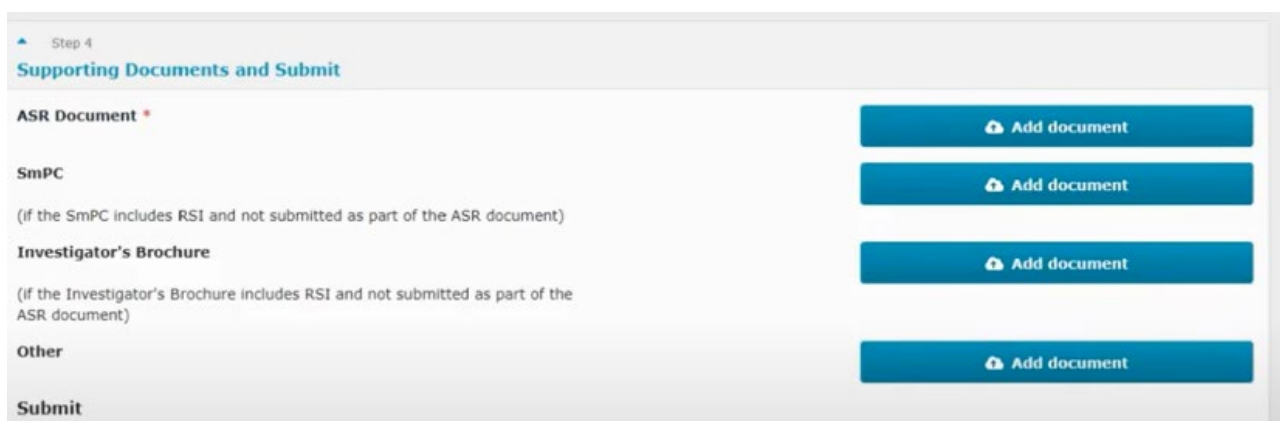
- Has the RSI (reference safety information) been updated during the reporting period?

- Has a Substantial modification on the RSI been submitted and approved during the reporting period?

In most cases the answer would be no.

From the drop down menu it is possible to choose what the ASR includes.

Step 4: Supporting documents and submit



Step 4
Supporting Documents and Submit

ASR Document * [Add document](#)

SmPC [Add document](#)
(If the SmPC includes RSI and not submitted as part of the ASR document)

Investigator's Brochure [Add document](#)
(If the Investigator's Brochure includes RSI and not submitted as part of the ASR document)

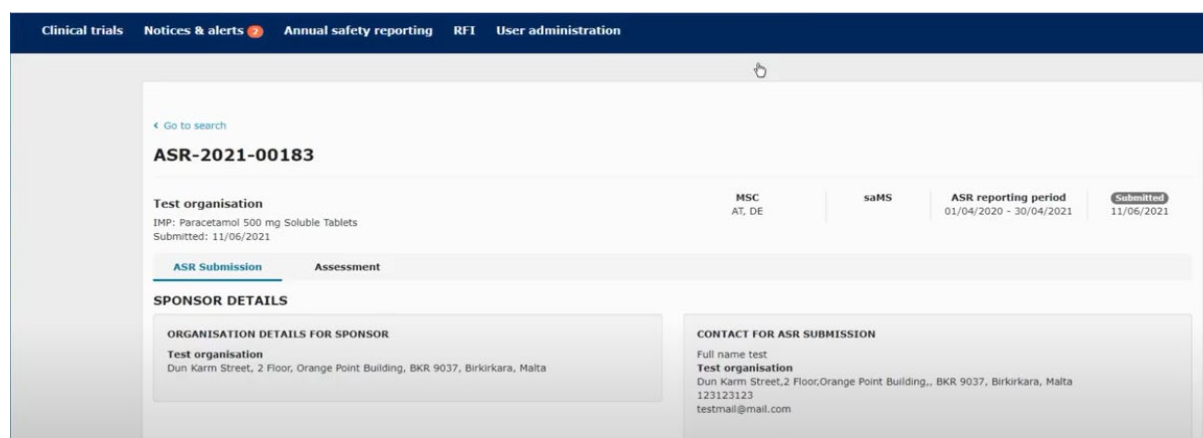
Other [Add document](#)

Submit

In step 4 you add the ASR report document and you can also add other supporting documents. The ASR report should be uploaded as a PDF.

Then you can check if all information is valid or anything is missing by using the **check button** and then you can submit.

Once submitted you see this page where all the information that was populated will appear.



Clinical trials Notices & alerts Annual safety reporting RFI User administration

Go to search

ASR-2021-00183

Test organisation
IMP: Paracetamol 500 mg Soluble Tablets
Submitted: 11/06/2021

MSC
AT, DE

sAMS

ASR reporting period
01/04/2020 - 30/04/2021

Submitted
11/06/2021

ASR Submission Assessment

SPONSOR DETAILS

ORGANISATION DETAILS FOR SPONSOR
Test organisation
Dun Karm Street, 2 Floor, Orange Point Building, BKR 9037, Birkirkara, Malta

CONTACT FOR ASR SUBMISSION
Full name test
Test organisation
Dun Karm Street, 2 Floor, Orange Point Building, BKR 9037, Birkirkara, Malta
123123123
testmail@mail.com

9 Summary of Results and Summary for Layperson

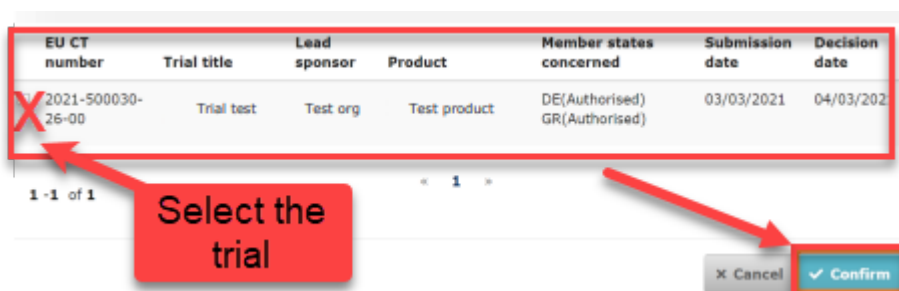
The sponsor shall submit a summary of the results of the Clinical Trial. The deadline for uploading the results in CTIS is 1 year after end of trial.

The content of the summary of results is set out in [Annex IV of the regulation](#). It shall be accompanied by a summary written in a manner that is understandable to laypersons. The content of lay person summary of results is described in [Annex V of Regulation](#).

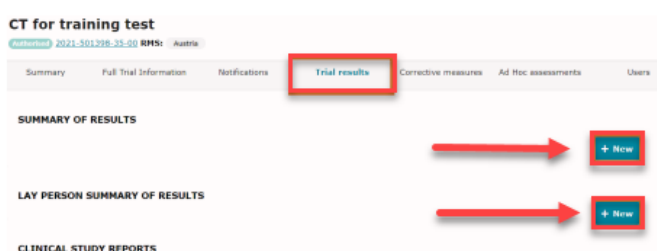
To submit the summary of results go to Clinical Trial page and search for the clinical trial by entering the “EU CT number” or use advanced search.



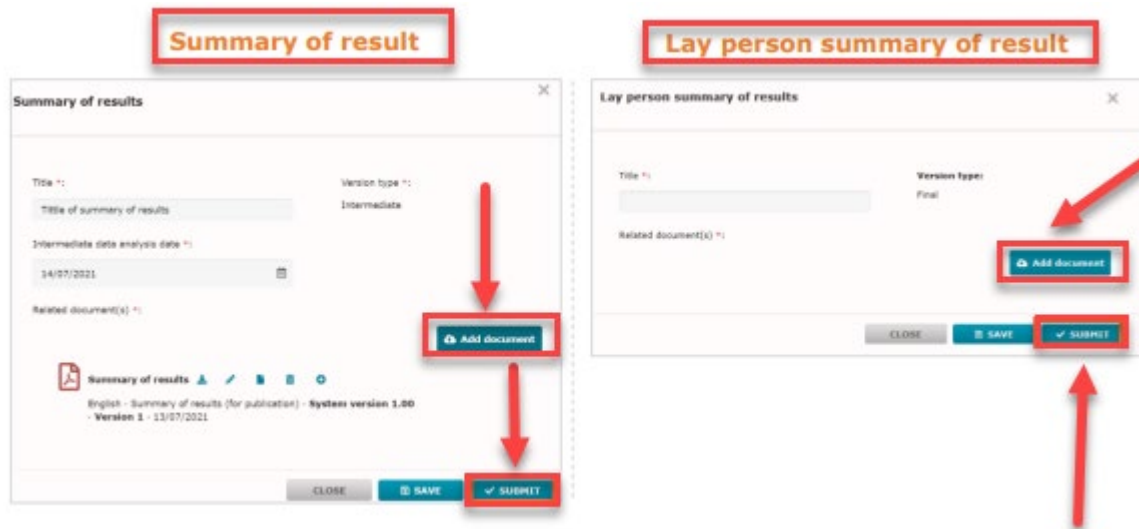
Select the trial from the results page and click on the ‘Confirm’ button.



When the trial is selected a window will show where the “summary of results” and “layperson summary of results” can be uploaded.



Select the “Add document”. Then “Save” and “Submit”.



10 Changes log

Version 1.0

Version 1.2 Links corrected

Version 1.3 Updated according to comments from users

Version 1.4 updated modifications of Finland, 03.05.2022

Version 1.5 updated modifications of Finland 29.12.2023