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

29.12.2023

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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.



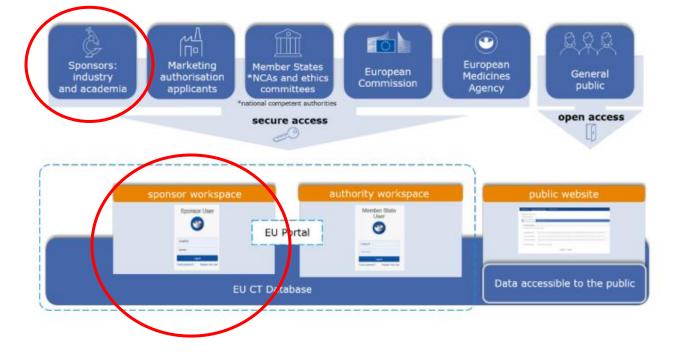
1 Introduction

1.1 What is CTIS?

The <u>Clinical Trials Regulation (Regulation (EU) No 536/2014)</u> 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 <u>clinical trial</u> 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 <u>sponsor workspace</u>, 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:

- <u>Clinical Trials Information System (CTIS): online modular training programme | European Medicines</u> <u>Agency (europa.eu)</u>
 - How to create a CTA see module 10 8 videos
- <u>Clinical Trial Information System (CTIS) Sponsor Handbook</u>
- How to access CTIS: <u>Step by step guide to access CTIS</u>
- 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

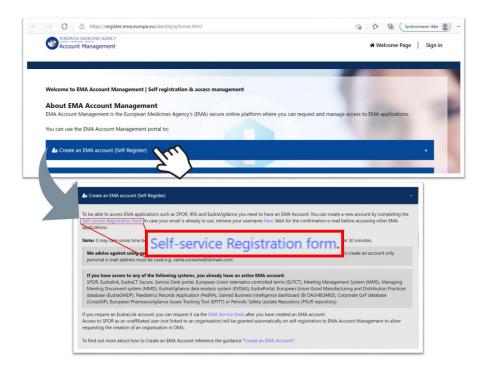
2. Register your organisation in OMS

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

3. Register your sponsor administrators

2 How to create a new EMA Account

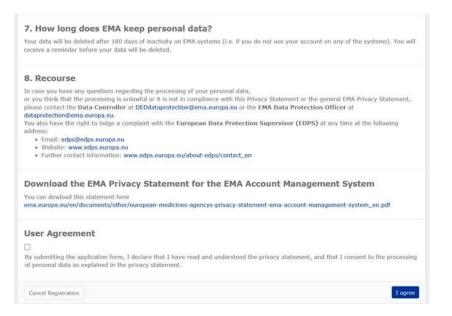
Go to EMA's Account Management portal



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.



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:

EMA - Self-service Registration Confirmation Form	
Your EMA Account Your EMA usemame is given below. Please make a note of this as you will need it to log in to EMA Usemame surname_n	EMA Registration - One-time Token register@ema.europa.eu To Calonitess
Your Details First Name Name Last Name Surname Email name.surname@domain.com Mobile (optional)	Dear Name, Thank you for your EMA Registration request. Please enter the following token value in the appropriate field when prompted. Note, once again. Your one-time token value in SHHSSP If your other token request, please contact EMA via the <u>Service Desk Portal</u> with 'Token Request not requested' as the email title stat matters please contact +31 (0) 85781 7523. Thank you.
One-time Token Please enter the value of the one-time token and have received by email in the field below. Confirm Token * SHHSSP	European Medicines Agency Domenico Scarlattilaan 6 1083 HS Amsterdam The Netherlands
Cancel	Confirm

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.

Substances	Products	Organisations	
R Home Organisations Documents			
Organisation Manageme	ent Services (OMS)		
•		Click here	
IS provides a central dictionary of organisation dat	ta in multiple languages. This covers:		
 organisation names; 	11 51 51 12 12 12 12 12 12 12 12 12 12 12 12 12		
 location address details; communication details such as email address a 	and telephone number per location		
IS supports the continuous exchange of data betw		n medicines regulatory network and across the	e pharmaceutical indus
IS provides users with the following organisation d	data management services:		
 fS provides users with the following organisation d view, search, export organisation data and cha 			

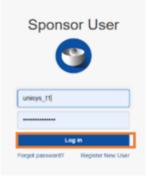
Data management and data quality processes drive the SPOR data management services to ensure that the highest quality of data is available to support EU regulatory processes.

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 <u>CTIS User Personas</u> can be used. On pages 6-8 this guide describe 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 <u>Module19 - Step-by-step guide -</u> <u>User access management and user administration (europa.eu)</u>



Ö

ASSIGN NEW ROLE

UAT CT

EN Y

Clinical trials

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

Creation Dat

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

Administration of users

Sort by: 12

Q Enter EU CT ID or ASR ID or use advanced search	SEARCH	Advanced search 🕶
Search Results		
Showing 1 - 1 of 1 items	1 of 1 pages	< 1 >

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

✓ Approve

O Reject

Revoke

ssign role(s)			×
			â
User Id:		EU CT number	
Type User Id			
Organisation name:		Organisation Id:	
Test organisation	~	ORG-100013346	
Role		Scope	
Select from list	~	Select from list	~
Authorised date:			
dd/mm/yyyy 🛱 dd/mm	/уууу 🛱		
			+ ADD ROLE
		CANCEL	ASSIGN



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.

Clinical trials	User name button
Clinical trials Notices & alerts 👩 RFI User administration	
Personal profile My roles Logout	
3. Click on the 'Request role' button.	
My roles	
Q Enter EU CT ID or ASR ID or use advanced search SEARCH	Advanced search 🕶
Search Results	
Showing 1 - 1 of 1 items 1 of 1 p	ages < 1 >
Sort by: 1 [*] Creation Dat V	Request role

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

Request roles							×
organisationName		organisationId	Scope		EUCT Number	Role	
	۹			~			~
							+ Add
					CA	NCEL	REQUEST

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

Q Enter EU CT ID or ASR ID or use advanced search			SEARCH	Advanced search +
thowing 1 - 2 of 2 items Creation Date			1 of 1 pages ✓ Approve ◎ Reject	< 1 > Revoke ASSIGN NEW ROL
unisys_k4 test12@test.com Commenter EU CT Number: 2021-500780-21-00 Scope: Specific trial Employer: CTCS-8465 Organisation name: Test organisation Organisation Id: ORG-100002154	Role: ASR Submitter	Creation date: 19/07/2021	Assesment date:	'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 webside, 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 <u>Annex I of the EU Regulation</u>.

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 <u>Section 2 in EMAs</u> <u>Q&A (updated April 2022)</u>. 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.

<u>Template</u> 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 <u>instructiotrns</u> for trilas in accordance with the regulation.

Fimean sivuilta löytyy lisätietoa asetuksen mukaisiin käytäntöihin

Part I	Part II
 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) 	 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) 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 <u>not</u> 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.

Clinical trials

 Image: Section 2.1
 Market 2.1</td

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.

. 🍘 RFI User a	Create new trial		
mber or use advance:	Search organisation Name starts with v ID starts with v City starts with v Country All v + New organisation Clear Search organisation	SEARCH	
sarch +	ID Name Address City postCode country phone email Actions Cancel Create		

	arch orga		2					
Nam	est Organisation	itains 👻 I		arts with 💙	City	starts with	Country	
-					+ New o	organisation	d Clear Search o	rganisation
	ID	Name	Address	City	postCode	country	phone	email
0	ORG- 100023062	IAM Test Organisation	identitylaan 122	Amsterdam	1071 LT	Netherlands		
0	ORG- 100023032	Test organisation	Test employer address	45		Antarctica		
0	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
0	ORG- 10002305	est rganisation	Berlinstrasse 12	Berlin	1010G8	Germany	004952255564645	sponsor@

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

Info box: <u>The lock button</u> 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: <u>Form, MSCs, Part I and Part II.</u>

Please note that data and	s RFI User administration documents provided in the EU Database are subject to publication rules (including the protection of personal data and commerci advances of the EU Database are subject to publication rules (including the protection of personal data and commerci advances of the EU Database are subject to publication rules (including the protection of personal data and commerci advances of the EU Database are subject to publication rules (including the protection of personal data and commerci advances of the EU Database are subject to publication rules (including the protection of personal data and commercial advances of the EU Database are subject to publication rules (including the protection of personal data and commercial advances of the EU Database are subject to publication rules (including the protection of personal data and commercial advances of the EU Database are subject to publication rules (including the protection of personal data and commercial advances of the EU Database are subject to publication rules (including the protection of personal data and commercial advances of the EU Database are subject to publication rules (including the protection of personal data and commercial advances of the EU Database are subject to publication rules (including the protection of personal data and commercial advances of the EU Database are subject to publication rules (including the protection of personal data and commercial advances of the EU Database are subject to publication rules (including the protection of the personal data and commercial data	ally confidential information), as per Regulation (EU) 536/2014, Article 81(4).
Form MSCs Part I Part II Evaluation The four sections that need to be filled in	Form details Initial Application details Cover letter cover letter * the asterisk * = mandatory fields	Click on the "lock button" to be able to enter data in the form
	Deferral publication dates Publish dates of trial information Short title / Trial category *	*
	Justification for trial category / Trial category *	^

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).

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 MSCs Part I	Form details Initial Application details		Add the cover	
Part II aluation metable	Cover letter *		letter	Add docum
	Deferral publication dates	Add the trial		
	Publish dates of trial information Short litle / Trial category *	category and justification for the category		
	Justification for trial category / Trial category *			~

<u>Form:</u> 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)
Resp from in re any	ocol stigator's hure ponses n sponsor elation to aspect of 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.

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Revised CTIS <u>transparency rules</u> 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:

Part I	Clinical trial protocol
Part II	Protocol *
Evaluation	Add document
Timetable	testiin English · Protocol (for publication) · System version 1.00 · Version 1 · 11/01/2024 testiin Image: Content of the system is the system
	English · Protocol (not for publication) · System version 1.00 · Version 1 · 11/01/2024

<u>MSCs</u>: 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.

Clinical trials			Add member states				×	
Clinical trials Notices I	number of	Residut ration	Number State Austria Germany		42 42	-	a another	u), at per Repulsion (D
Clinical Trial for the	Member states o					Canod	¥ 848	J
HSC		corned		axes	tie	t submission	s date	

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

<u>**Part I:**</u> 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. <u>Model</u> for the protocol can be found in Fimea's webpage.

								🗸 Olea	B Save O C	mod 🗅 Subm
Form	Trial specific informati	on (Part I)								
MSCs Part I	Trial details									
Part II	Trial identifiers									>
Evaluation	Trial information									>
Timetable	Protocol informatio	m								>
	Scientific advice an	d Paediatric Investiga	tion Plan	(PIP)						>
	Associated clinical	trials								>
	References									>
	Countries outside t	he European Economi	c Area							>
					-					
	Sponsors									
	Name	Organisation type	Country	Type	Status	Legal representati	ve Scientific co	intact point	Public contact point	Third parties
	Test Organisation Demo	Pharmaceutical company	Germany	Commercial	Active					. ^

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

Sponsor details

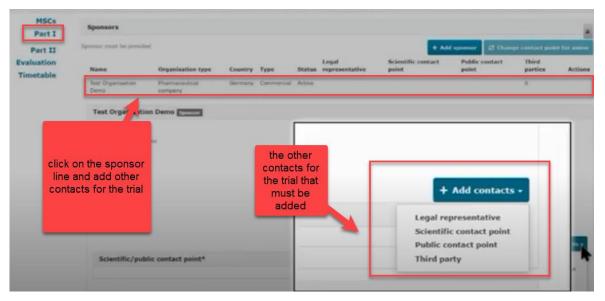
Includes sponsor information which was added when the application was first created. All these contacts must also be registered in OMS.

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

Part I	Sponsors							_		_
Part II	Sponsor must be provided				5	egal	+ Ad Scientific contact	Public contact	ge contact poir	nt for a
Timetable	Name	Organisation type	Country	Туре		epresentative	point	point	parties	A
	Test Organisation Demo	Pharmaceutical company	Germany	Commercial	Active				0	
	Contact point for	union*								
	Organisation name									
	Test Organisation De	emo		63						
	Address line 1*					Address	line 2			
	Berlinstrasse 12									
	Address line 3					Address	line 4			
	Town/City*					Post code				
	Berlin					1045GA				
	Country*					Function	al contact point name			
	Germany									
	Contact									
ical trials Noti	ices & alerts 🍘 RFI 🛛	User administration			Last na	me*				
and the second second second	First some *		publication rules (including the prot			erclarly confidential information), a	s per Regulation (EU) 536/201	14, Article #1(4).	
0 Plases octa	that data and documents provided in t	the EU Database are subject to p			ection of per	sonal data and comm Legal	Scientific contact	Public contact	Third	
O Plazas nota	that data and documents provided in t ICs t I Name	the EU Database are subject to p Organisation typ	pe Coun	try Type	ection of per Statu	sonal data and comm tegal s representative	Scientific contact	and the second second second	Third parties	Ac
Plase outs MS Par Par	that data and documents provided in t iCs t I Name II Test Organisatio Derro	the EU Database are subject to p Organisation typ	pe Coun		ection of per Statu	sonal data and comm tegal s representative	Scientific contact	Public contact	Third	Ac
Plases note MS Par	tur data and documents provided in T T T Name Test Organisatio Derrie	the EU Database are subject to p Organisation typ n Pharmaceutical	pe Coun	try Type	ection of per Statu	sonal data and comm tegal s representative	Scientific contact	Public contact	Third parties	
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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.



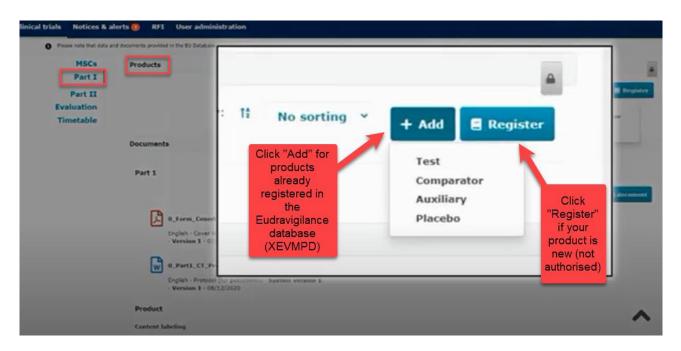


Product details

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 (XEVMPD) if this is not already done.

EMA's <u>handbook</u> item 6 tells how to enter not authorised product into the XEVMPD 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.

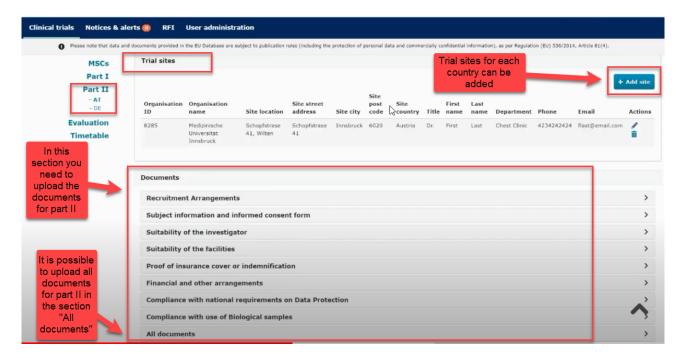
If you scroll down in the end you see all the uploaded documents for Part I.

4.5 Fill in the Part II section



<u>Part II:</u> 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: <u>Local documents</u> from each country needs to be uploaded. Tukijan sivulta löytyvät <u>ohjeet</u> paikallisesti toimitettaviin asiakirjoihin.



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.

		Search orga	anisation	starts with ~) cey	starts	with w	Country			
Form MSCs	Country sp	Innebruck			* 24	is imposively	a di Chu	Austria er Secar		nisati	Stim
Part I	Trial site	ID	Name	Address	City	postCode	country	phone	of all	Actie	0.95
Part II - AT - DE		ORG- 100007200	Department of Nuclear Medicines, MU Densbruck	Anichstrasse 35	Innsbruck	6020	Austria			×	÷
raluation imetable	Organisat ID	ORG- 100022556	Medizinische Universität Trinsbruck	Schopfstrase 41 Wilter,	Innsbruck	6020	Austria			×	+
	Documina	1-2 0/2		۰.	1						

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).

oue note that data	and documents previded in	the EV Database at	Investigator infor	mation		× a stand
			Title None	-	First name*	
Form	Country specifi	c details (Pa	Last name*		Department*	_
MSCs Part I Part II	Trial sites Trial sites		Phone ²		(mal ^{ar}	
- A1 + DE	Organisation ID	Organisation			× Cancel	title :
limetable	6285	Medicinische Un Innabruck	oversitet Schopfstrave Wilten	41, Schophore 41	ar Jenabruck 6020	Auttria
	Documents					

<u>Supporting documents</u>: 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.

Clinical trials		Green message shows when the application is valid	\rightarrow	Application is valid!
Clinical trials Notices &	alerts 😳 RFI User administration			
Please note that data	and documents provided in the EU Database are subject to publication rules (including the protection of persona	l data and commercially confidential informati	on), as per Regulation (EU)) 536/2014, Article 81(4).
	TIS Training Programme 2020-501643-14-00 / Initial ID: IN Dra	ft		
			✓ Check	🕅 Save 🔹 Cancel 🏠 Submit
Form	Country specific details (Part II - DE)		-	
MSCs Part I	Trial sites			>
Part II	Documents			
- DE	Recruitment Arrangements			~
Evaluation Timetable	Recruitment arrangements *:			Add document
	2_1_Part2_Recruitment_Arrangement 🛓 🥓 📱 🍵 🔘			
	English · Recruitment arrangements (for publication) · System version 1 · Version 1 · 10/12/2020			

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

	Submit confirmation ×	
🐽 RFI User adminis	Please select the application parts you wish to submit.	
uments provided in the EU Database ar	Part I Part II Austria	al information), as per Regulation
	Part II Germany	
Training Programme	* Cancel Confirm	
		6
		 Check

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



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".

				A :	+ CREATE
				Single 14	and particulars and an annual states of
Trial title We	binar 21 09 2020			Phalite brief	el substantial multilization
2020-50027	71-00 RMS: Austria			Non-cale	stantial modification
				Addition	al MSC
Summary P	all Trial Information Notifica	ations Trial results	Corrective measures Ad P	foc assessments	al MSC
Summary P	d Trial Information Notifica	ations Trial results	Corrective measures Ad 8	foc assessments	al HSC
TRIAL INFORM		etions Tinal results	Corrective measures Ad M	toc assessments	el MSC
			Corrective measures Ad #	toc assessments	d MSC
TRIAL INFORM	ATION			AT - 86	d MSC
TRIAL INFORM Sponsor Trial phase Therapeutic area	Test Organisation 1 Therapeutic explore Dreames [C] - Resp		Member states concerned	toc assessments	d MSC
TRIAL INFORM Sponsor Trial phase	Test Organisation 1 Therapeutic explora	tory (Phase II)	Hember states concerned Hedical conditions	roc assessments	d MSC
TRIAL INFORM Sponsor Trial phase Therapeutic area	Test Organisation 1 Therapeutic explore Dreames [C] - Resp	tory (Phase II)	Hember states concerned Healical conditions Low intervention study	AT - BE Aproea Yes	d 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 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.

Part II	Eligibility	criteria			
Evaluation	Principal in	clusion criteria *			
Timetable	New 1D	Principal inclusion criteria (English)	Principal inclusion criteria (Languages)		
	Study desig Investigation Summary of Authorisation OP OMP con DIPO Quality Simplified 19 Cantent labs Cantent labs AMPO - Full	monitoring committee charter brochure product characteristics (SmPC) Sopertific advoce nof manufacturing and import tricuton of manufacturing and import tricuton 490-Q 490-Q 490-Biology 490-Salety and Officacy ding of the IMPs of justification of low interventional clinical trial	Principal exclusion criteria (Languages)		
			•		
			•		

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.



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

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



RFI: Questions from authorities to sponsor.

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

Clinical trials	Notices & alerts RFI User administration						
1	Notices & alerts 👩						
/	Q Enter EU CT ID or ASR ID (Business Keys) or use advanced search.	Access to by click of th	on each	SEA			ed Search +
	Showing 1 - 8 of 8 items	_	_	1 of 1	pages	< 1	>
	Sort by: 11 Received ~ New! All		1				
	Alert RFI sent to sponsor An RFI has been sent by Austria for the Initial application, Validation .	Ref number 2021-500027-47-00	type p	Idation Received	IMP Paracetamol Tablets 500mg	RMS Austria	Sponsor Test Organisation Demo
	Alert RFI sent to sponsor	Ref number	type p	aluation Received	IMP Paracetamol	RMS	Sponsor Test Organisation
	An RFI has been sent by Austria for the Initial application, Validation .	2021-500027-47-00	Initial Va	lidation 03/02/2021	Tablets 500mg	Austria	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.

Clinical trials Notices & alert	s 🕘 RF1 User administration
Please note that data a will be made publicly an	nd 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 railable in accordance with these rules.
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CTIS Training Programm	e test CT for Demo 2021-500027-47-00 / Initial ID: IN Under evaluation / RMS: Austria
Form MSCs Part I	Evaluation shows the number of RFIs
Part II Evaluation	RFI 🕑
Timetable	BEI-CT-2021-500027-47-00-IN-001 Iber: 15/02/2021 V MSC: Autoria Submission date: 03/02/2021 Due date: 15/02/2021 V
Click on the lock to be able to upload	Reason Incomplete No changes have been made to the application.
response to RFI	Supporting documentation M5:

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".

0 RFI User administration	
documents provided in the EU Database are subject to publication rules, which take into account the need to protect personal data and o lable in accordance with these rules.	commercially confidential information. Once available, a redacted version of the documen
RFI-CT-2021-500027-47-00-IN-001 over: 15/02/2021 Image: Submission date: 03/02/2021 Due date: 15/02/2021 Reason Incomplete Supporting documentation MS:: Quality Image: RFI_Submission_Quality \$ English - Supporting document from MS - Quality - System version 1.00 Submission date o3/02/2021	Expand all Change application It is possible to change/update the application if required in RFI
Non-Quality RF1_Submission_nonQuality English - Supporting document from MS - Non Quality (for publication) - System version 1.00 Usersion 1 - 03/02/2021 Spensor: General documentation Quality related documentation	Add document
	dockennets provided in the EU Database are subject to publication rules, which take into account the need to protect personal data and RFI-CT-2021-500027-47-00-IN-001 [over 15/02/2021] MSC: Austria Submission date: 03/02/2021 Due date: 15/02/2021 Reson Incomplete Supporting documentation Vis: Quality RFI_Submission quality RFI_Submission document from MS - Quality - System version 1.00 isobimission document from MS - Quality - System version 1.00 version 1 - 03/02/2021 Nor-Quality RFI_Submission_nonQuality RFI_Submission_document from MS - Non Quality (for publication) - System version 1.00 version 1 - 03/02/2021 Supporting document from MS - Non Quality (for publication) - System version 1.00 version 1 - 03/02/2021 Supporting document from MS - Non Quality (for publication) - System version 1.00 version 1 - 03/02/2021 Supporting document from MS - Non Quality (for publication) - System version 1.00 version 1 - 03/02/2021 Supporting document from MS - Non Quality (for publication) - System version 1.00 version 1 - 03/02/2021 Supporting document from MS - Non Quality (for publication) - System version 1.00 version 1 - 03/02/2021 Supporting document from MS - Non Quality (for publication) - System version 1.00 version 1 - 03/02/2021

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 d will be made publicly availa	ocuments provided in the EU Database are subject to publication rules, which take into account the need to protect personal data and com ble in accordance with these rules.	nercially confidential information. Once available, a redacted version of the docume
MSCs		
Part I *		
Part II *	-	
Evaluation	Consideration number RFI-CT-2021-500027-47-00-IN-004-01 Application section parts Part I - Non-clinical	Application section and document Protocol
Timetable	Consideration Austria - Part I Assessment consideration nr3	
RFI 1	Sponsor response Response Austria - Part I Assessment consideration nr3	
	Documents related to the response	
Response to		
RFI. Each	kesponseRFI1 🛓	
consideration must be	English - Supporting documentation for Consideration (for publication) - System version 1.00 submission date 05/02/2021 - Version 1 - 05/02/2021	
answered		
	La 19	
	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	
DELO	Response	
RFI 2	Response to Austria - Part I Assessment consideration nr5	
	Documents related to the response	
		Add docume A
		D Save response

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.

	rts 🔘 RFI User administration		3
Please note that data will be made publicly	and documents provided in the EU Database are subject to available in accordance with these rules.	to publication rules, which take into account the need to protect personal data and commercially confidential in	formation. Once available, a redacted versio
MSCs	Assessment Part I		
Part I Part II		Draft 1 for	
Evaluation	RFI 🕤	Assessment Part I	
Timetable	Conclusion		
	Intended Disagreements		
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or Part I	AT	Part II - Austria	
Part II.	RFI 🕖		
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_	RFI 1	Part II - Germany	
	Conclusion		
	Provide and		
	Decision		
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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



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.

	ject to publication rules, which take into account the need to protect per	sonal data and commercially confidential information. Once available, a redacted version of the docume
vallable in accordance with these rules. Assessment Part I RFI RFI RFI-CT-2021-500027-47-00-IN RFI-CT-2021-500027-47-00-IN RFI-CT-2021-500027-47-00-IN CT-2021-500027-47-00-IN Tricludes application changes Changes to the application management of the application	-003 Responded: 03/02/2021 -004 Texe: 15/02/2021	open the RFI Expand all ~
Sponsor: General documentation		

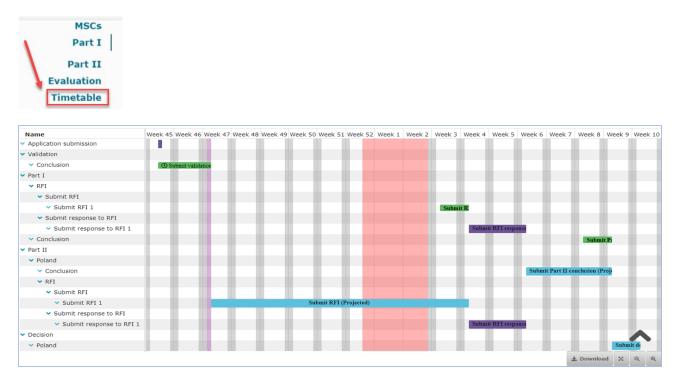
Below the RFI, there can be considerations which also must be answered. You can respond separately to each consideration.

MSCs Part I * Part II *	Click on the lock button		
Evaluation Timetable	Consideration number RFI-CT-2021-500027-47-00-IN-004-01 Application Consideration Austria - Part I Assessment consideration nr3 Sponsor response Response Austria - Part I Assessment consideration nr3 Documents related to the response	Consideration 1	lication section and document Protocol
	ResponseRFI1 L English - Supporting documentation for Consideration (for public submission date 05/02/2021 · Version 1 · 05/02/2021	cation) - System version 1.00	Here you can upload additional documents for the consideration
	Consideration number RFI-CT-2021-500027-47-00-IN-004-02 Applicati	ion section parts Part I - Non-clinical App	lication section and document Cover letter
	Consideration Germany - Part I Assessment consideration nrS Response Response to Austria - Part I Assessment consideration nrS	Consideration 2	2
	Documents related to the response	Type your response in the field	Add docum

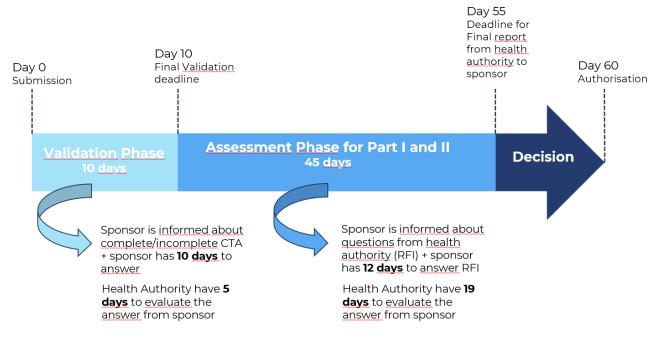
The "Submit response" button will be active when the changes have been saved on "save response". Please check that the top lock is open and the other locks are closed, then the "submit response" button is available. It is advisable to include the track changes document if there are many changes (in protocol,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

Clinical trials	Notices & alerts 🧿	Tasks	Ad hoc assessments	Annual safety reporting	BI reports	Inspections	Union control	Services Status		
0	Please note that data a	nd docume	ints provided in the EU Da	tabase are subject to public	ation rules (inclu	iding the protection	on of personal data	a and commercially confidential i	nformation), as per Regulation (I	EU) 536/2014, Article 81(4).
	MSCs	De	cision							
	Part I	P	art I Disagreeme	nts						
	Part II		-					· · · ·		
	Evaluation		art I conclusion		Acceptable			•		
	Timetable		art II conclusion ecision		Acceptable Authorised					
		0	ecision		HULHUISEU					
			ASSESSMENT OV	ERVIEW				1	•	
									_	
			MSCs	Validation		Assessment	t Part I	Assessment Part II	Authorised	+All
			AUSTRIA RMS	Valid (30/10/2020)		Acceptable (04/11/2020	3	Acceptable (04/11/2020)	Authorised (05/11/2020)	+
			GERMANY					Acceptable	Authorised	+
			JERMANT					(05/11/2020)	(05/11/2020)	Ŧ

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

Section 4		Document type	11	Document	Document	Document	Document Submission	System		Authorisation	Application	
	~		*	Title If	Version 11	Comment 11	Date 41	version 11	Language 11	date If	~	Download
Part I		Cover letter (for publication)		Cover letter	1		17/01/2022	1.00	English	17/01/2022	INITIAL - IN	A
Part I		Protocol (for publication)		Protocol for publication	1		17/01/2022	1.00	English	17/01/2022	INITIAL - IN	A
Roles: Test Name:DENUBIL mg/180 mg sole oral		Summary of Produ Characteristics (SmPC) (for publication)	ict	SmPC - NaCl 09 - Braun Melsungen DE	1		17/01/2022	1.00	English	17/01/2022	INITIAL - IN	ß
Part I		Content labelling of the IMPs (for publication)	đ	Labelling	1		17/01/2022	1.00	English	17/01/2022	INITIAL - IN	A
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	ß

6 15 days Notifications after Authorisation

Video on this topic in EMA training module 5:

<u>Training Video: How to manage a CT in the CTIS sponsors workspace – Trial</u> <u>and recruitment periods notifications</u>

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.

	5ummary	Full Trial Information	Notifications	Trial results	Corrective r	measures Ad Hoc assessments	Users		Amend
Tr	ial & Recruitn	nent Periods		_		-			
						2 Start Recruitment End R	cruitment		Recruitment
	Start Trial	ind Trial Restart Tria	I Temporary Ha	lt.		2 Start Recruitment End R	cruitment	Restart	Recruitment
				Trial				Recruit	ment
						unent			
0	Select all	Current status	Start date	Temporary Halt	Restart	End (or early termination)	Start	End	Restart
		Current status	Start date	Temporary Halt	Restart -	End (or early termination)	Start	End	Restart
	Austria			Temporary Halt			Start -		Restart -

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:

	2020-50043		t of recruitment	notifica	tion												
Sumn	nary	Full Trial	1			aria											Amend
ial &	Recruitme	ent Peri Start of re	cruitment date*										£ 1				
	rt Trial Em	d Trial Related docur	ment(s)		<			Augus	t 2020			>			+t		Recruitment
					31			Tue 28			Fri 31	Sat	Add document	2		Recruit	
					32				l	3		-	-			Recruit	ment
S	elect all	Curre			33								×Cancel ×	Submit	art	End	Restart
A	ustria	✓ Authonsed			34							22		-			
	ermany	✓ Authorised	•	22	35				26			-				•	-
в	ulgaria	✓ Authorised	26/08/2020		36	-	Clear	01	83	83	-	0.5					

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.

New end of trial in ms notification Countries Bulgaria End of the clinical trial date * 26/08/2020 itment Pe -2 The clinical trial has been early terminated Anticipated date of summary of results The submission of this form will end the clinical trial in all EEA countries for which the required to also submit the anticipated date of summary of results as part of this form Curre Anticipated date of summary of result * 01/09/2020 = - Aut Partial results ~ will be submitted at the anticipated date of summary of results Justification that the results are to be later than 12 months: Justification that the results are to be later than 12 months: lobal Related document(s) Add doc vent p

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.

1	Test Organisation 1 has s Bulgaria. Notification ID -	ibmitted a End of trial in MS notification in EoT-0542	2020-500438-88-00			26/08/2020	Tablets 500mg	Bulgaria	Organisation 1
Ĩ	Contraction of the local division of the loc	al notification submitted	Ref number 2020-500438-88-00	Source type	Evaluation process	Received 26/08/2020	IMP Paracetamol Tablets 500mg	RMS Bulgaria	Sponsor Test Organisation 1
		alt submitted ubmitted a Temporary Halt notification in fit-risk change. Notification ID - TH-0539	Ref number 2020-500438-88-00	Source type	Evaluation process	Received 26/08/2020	IMP Paracetamol Tablets 500mg	RMS Bulgaria	Sponsor Test Organisation 1
		cruitment notification submitted ibmitted a Restart of Recruitment notification in RoR-0538	Ref number 2020-500438-88-00	Source type	Evaluation process	Received 26/08/2020	IMP Paracetamol Tablets 500mg	RMS Bulgaria	Sponsor Test Organisation 1
		tment notification submitted ubmitted a End of Recruitment notification in EoR-0537	Ref number 2020-500438-88-00	Source type	Evaluation process	Received 26/08/2020	IMP Paracetamol Tablets 500mg	RMS Bulgaria	Sponsor Test Organisation 1
	Showing 1 - 10 of 24 item					1 of 3 pages		1 2	

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 <u>EMA Q&A</u> 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.

Clinical trials	Notices & alerts 💿 Ann	ual safety reporting RFI U	ser administra	tion			
Go to the	Trial title Webina	r 21 09 2020 RMS: Austria Information Notifications	Trial results		assessments	Download CREATE - Single trial substantial modification Hulti trial substantial modification Non-substantial modification Additional MSC	click on the create tab to make a substantial
summary section in the sponsors workspace	Sponsor Trial phase Therapeutic area Medical device	Test Organisation 1 Therapeutic exploratory (Phase II Diseases [C] - Respiratory Tract D No		Member states concerned Medical conditions Low intervention study Population type	AT - BE Apnoea Yes Healthy Volun	iteers	modification

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

<u>Single trial substantial modification:</u> to update information for *only one trial*.

<u>Multi trial substantial modification</u>: 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.*

Select which type of application that should be	Lownload + CREATE -
submitted	Single trial substantial modification Multi trial substantial modification
	Non-substantial modification
sments	Additional MSC

	Substantial modification so	cope	×
	Select modification scope		
inual safety repor	Please select		-
	Part I only Part II only Part I and Part II		
ar 21 09 202	.0	× Cancel 🗸 Cr	cate
RMS: Austria	otifications Trial results	Select the scope: the	assessments Us
ON		section you want to update or modify	
ON Test Organisat	on 1	section you want to	AT - BE

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 & a	lerts 📵 Annual safety reporting RFI User administration
Please note that data a	nd 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 (/ RMS: Austria	In the form section you can upload cover letter and description of the modification and other supporting information
Form	Form details
Part I	Substantial modification details
Part II Evaluation Timetable	Cover letter
Timetable	Modification description
	Supporting information

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

MSCs				Add docu
Part I Part II Evaluation Timetable	■ Modification_Description_Details ▲ ■ English - Modification Description (for publication - Version 1 - 13/09/2020 Supporting Information) - System version 1	Choose a reason for the substantial modification. It none of the reasons are applicable you can choose "other".	
	Supporting information documents			
	Substantial modification reason		Substantial modification scope	Add doc
	Substantial modification reason I Gend of trial in MS Gend of trial in EEA Gend of trial in EEA	1 2 -	Substantial modification scope	Add doc
	I I tind of trial in HS I nd of trial in HS Cabol end of trial Cabol end of trial Anticipated date of summary of results Discrepated Event Change in B/R Serious Breach	l∳ -	Substantial modification scope	🛆 Add doc
		3	Substantial modification scope	🕰 Add do:

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

Clinical trials Notices & a	lerts 💿 Annual safety reporting RF	I User administration			The button "add member state" is
Please note that data ar	nd documents provided in the EU Database are subject to p	ublication rules (including the protect	ion of personal data and commercially confidential inf	formation), as per Regulation (EU) 5:	inactive as this requires a new
In the MSCs section only					application.
the number of Inar 21 (subjects can be changed	09 2020 2020-500275-71-00 / Subst	tantial modificatior	I ID: SM-1 Draft New version	draft SM-1 📄 🕕 View s	submitted ap lication
				🗸 Check 🛛 🕅	Save 🛇 Cance 🕰 Submit
Form	Member states concerned			<u>\</u>	+ Add member states
Part I	Member states concerned	RMS	First submissions date	Subjects	victions
Part II	Austria	Selected		20 -	
Evaluation	2.1.1				
Timetable	Belgium			20	

Form	Trial specific information (Part I)	
MSCs Part I	Trial details	a
Part II	Trial identifiers	>
Evaluation Timetable	Trial information	>
Imetable	Protocol information	~
	Clinical trial protocol	
	Protocol *	Add document
	L_l_Partl_CT_Protocol 🛓 🥒 🖿 📑 O English - Protocol (for publication) - System version 1 - Version 1 - 11/09/2020	
	O_Protocol SM Part I ▲ ✓ ■ ■ O English - Protocol (for publication) - System version 1 - Version 1 - 13/09/2020	

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.

Clinical trials	Submit confirmation	×		UAT CT	
Clinical trials Notices & alerts () Annual safety repor	Please select the application parts you wish to submit.		_		
Please note that data and documents provided in the EU Database are	 Part I Part II Austria Part II Belgium 	\square	ai information], as per Regulation (EU) 53	6/2014, Article 81(4).	
Trial title Webinar 21 09 2020 2020-500275-71-00 / RMS: Austria		× Cancel ✓ Confirm	m draft SM-1 🗉 🛈 View	submitted applica	tion
			🛩 Check	1 Save	A Submit
Form Trial specific information (Pa	urt I)			1	
MSCs Part I Trial details			/		

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

 Paracetamol T 	ablets 500	img							
OVERALL TRIAL STATUS									
Member State	Overall Tria	Status	First decision date	Start of tr	ial End of	rial	Recruitme	nt start d	ate
AT	Authorised	0	11/09/2020	It is shown the subs	A REAL PROPERTY OF A READ PROPERTY OF A REAL PROPER				
BE	Authorises	0	11/09/2020	modificati	Contraction of the second s		It is no	ssible	e to view
4				been auth	and the second	_			ormation
APPLICATION AND	NON-SUB	STANTIAL MO	DIFICATION	and by v member					_
Туре	ID	Parts	MSCs	Submission date	Decision date	Reason	Scope	Link	
Substantial modification	<u>SM-1</u>	Part I Part I	AT(Authorised) BE(Authorised)	13/09/2020	13/09/2020	+	+	ß,	+ INFO

8 Create and submit an Annual Safety Report (ASR)

Video on this topic in EMA training module 18: <u>Training Video: How to create, cancel or clear and submit an Annual Safety</u> <u>Report</u>

Info box: Make sure to have the <u>ASR document in PDF</u> 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.

Clinical t	rials				UAT CT
Clinical trials	Notices & alerts 🧑	Annual safety reporting	RFI	User administration	
	Annual safet		search.	To search for multiple IDs, separate them with commas. SEARCH Advanced Search •	st
	Showing 1 - 3 of 3 ite	ems		1 of 1 pages (1)	- ·

An ASR form opens:

Clinical trials	UAT CT
Clinical trials Notices & alerts 🥑 Annual safety reporting RFI User administration	
Submit ASR CLEAR V CHECK © CANCEL SUBMIT Sponsor information Clinical Trial detail ASR reporting period details Supporting documents and submit Expand all V	
• See 1 Sponsor information	ð
 Step 2 Clinical Trial Detail 	
Step 3 ASR Reporting Period details	
Step 4 Supporting Documents and Submit	

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

47	
Organisation details of the selected sponsor	+
Contact details for ASR submission	+

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.

	trial results based on your search criteria another search			
2	CT for training test	Decision date	Sponsor	MS
	EU CT number 2021-501398-35-00	20/05/2021	Test organisation	(Anstria) (Germany)
2	CT for training test	Decision date	Sponsor	MS
	EU CT number 2021-501535-14-00	01/06/2021	Test organisation	(Cermany)
howing 1	- 2 of 2 items		1 of 1 pages	

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 Q 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 $\ensuremath{^\circ}$	⊖ Yes ⊖ No	
During the reporting period ASR includes "	Select	¢

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.

Notices & alerts 🧑 Annual safety reporting RFI User administratio	n
	6
(Co to search	
ASR-2021-00183	
Test organisation IMP: Paracetamol 500 mg Soluble Tablets Submitted: 11/06/2021	MSC saMS ASR reporting period committee AT, DE 01/04/2020 - 30/04/2021 11/06/2021
ASR Submission Assessment SPONSOR DETAILS	
ORGANISATION DETAILS FOR SPONSOR	CONTACT FOR ASR SUBMISSION
Test organisation Dun Karm Street, 2 Floor, Orange Point Building, BKR 9037, Birkirkara, Maita	Full name test Test organisation Dun Karm Street,2 Floor,Orange Point Building,, BKR 9037, Birkirkara, Malta 123123123 testmail@mail.com
	Coto search ASR-2021-00183 Test organisation IMF: Paracetamol 500 mg Soluble Tablets Submitted: 11/06/2021 ASR Submission Assessment SPONSOR DETAILS ORGANISATION DETAILS FOR SPONSOR Test organisation

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 <u>Annex IV of the regulation</u>. 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 <u>Annex V of Regulation</u>.

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.

Clinical trials	Notices & alerts 👩	Annual safety reporting	RFI	User administration	
Clinic	al Trials				
٩	Q Enter EU CT number or use a		SEARCH		
Trial Ad	vanced Search =		E	nter the C	T number or
Applica	tion Advanced Search +			use advar	nced search

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

EU CT number	Trial title	Lead sponsor	Product	Member states concerned	Submission date	Decision date
2021-500030- 26-00	Trial test	Test org	Test product	DE(Authorised) GR(Authorised)	03/03/2021	04/03/202
1 -1 of 1	Calast	the	< 1 >			
	Select trial	me				

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

	ining test			_		
Summary	Full Trial Information	Notifications	Trial results	Corrective measures	Ad Hoc assessments	Users
SUMMARY OF	FRESULTS			_		+ New
LAY PERSON	SUMMARY OF RESULTS			_		+ New
CLINICAL ST	UDY REPORTS					

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