

# GOD Klinisk forskning

The Danish GCP Units guide to the Clinical Trials Information System (CTIS)

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#### Abbreviations

- AR = Assessment report
- AxMP = Auxiliary medicinal product
- CT = Clinical Trial
- CTA = Clinical Trial Application
- CTIS = Clinical Trial information System
- **CTR=** Clinical Trial Regulation
- 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 = Reporting member states
- RSI= Reference Safety Information
- SM = Substantial modification
- SmPC= Summary of Product Characteristics
- SAE=Serious Adverse Event
- SAR=Serious Adverse Reaction

#### 1 Introduction

#### 1.1 What is CTIS?

The <u>Clinical Trials Regulation, CTR (Regulation (EU) No 536/2014)</u> came into force 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 will take place via a **Clinical Trial Information System (CTIS)**. CTIS is the **single entry point** for submitting <u>clinical trial</u> information in the EU. All communication including final decision from the authorities will be 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. Link for sponsors workspace in CTIS
- 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).



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This guidance covers the process on how to submit, complete and maintain a clinical trial application (CTA) in Denmark or 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.

#### Any feedback and questions to the Danish GCP unit's Guidances is welcome:

GCP unit at Aalborg and Aarhus University hospitals: <u>gcp-unit@clin.au.dk</u>
GCP unit at Odense University hospital: <u>GCP-enheden@rsyd.dk</u>
GCP unit at Copenhagen University hospital: <u>gcp-enheden.bispebjerg-frederiksberg-hospitaler@regionh.dk</u>

This guidance is based on and can be used as a supplement to the following:

#### **CTIS training guides:**

- <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
- Clinical Trial Information System (CTIS) <u>Sponsors Handbook</u>
- How to access CTIS: <u>Step by step guide to access CTIS</u>
- How to search and create organisations in CTIS: <u>Step by step guideline</u>
- Guide for <u>CTIS common features</u>
- EMAs help desk for CTIS: <u>Service Now</u> Before submitting a ticket to Service Desk, please check information available on the EMA CTIS Support page
- EMA CTIS Support page

#### Q&As for CTR and CTIS:

- <u>Regulation CTR Q&A</u> (Question and answer document Regulation Eudralex vol. 10, Chapter V Additional documents)
- <u>EMA Q&A</u>
- Danish Medicines Agency Q&A and general information from DMA
- Danish Ethics Committee Q&A

#### 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.

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

#### 2.1 Application dossier for the initial application

Link to the CTIS database. For first time log-in see section 3.2 in the The Danish GCP Units guide – User access, roles and responsibilities in CTIS

The documents for the Clinical Trial Application dossier is described in Annex I of the CTR.

Info box: Templates for some ducuments can be found in <u>EudraLex - Volume 10 - Clinical trials guidelines</u> GO TO: Chapter I - Application and application documents

#### EudraLex - Volume 10 - Clinical trials guidelines

Chapter I - Application and application documents

Templates documents for FORM section of the CTIS

- Template statement on compliance Regulation (EU) 2016/679: PDF (EN ----)/Word (EN ----)
- Part II application document templates
  - Compensation for trial participants Template: PDF (EN | ----)/Word (EN | ----)
  - Harmonisation guidance: PDF (EN | ----)
  - Investigator Curriculum Vitae template: PDF {EN | ----}/Word {EN | ----}
  - Declaration of interest template: <u>PDF</u> {EN | •••• /<u>Word</u> {EN | ••••
  - Site suitability form: PDF (EN | ---- )/Word (EN | ----
  - Informed consent and patient recruitment procedure template: <u>PDF</u> (EN | ----) Word (EN | ----)
  - Compliance with applicable rules for biological samples: <u>PDF</u> (EN ----)/Word (EN ----)

#### Info box:

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

Overview of documents and information that are made public in CTIS public database: <u>Transparency –</u> <u>publication of clinical trial</u>

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#### Info box:

Language requirements (Part I): CTR Q&A Annex II

**National requirements** (Part II) <u>CTR Q&A Annex III (CTR Q&A:</u> *Eudralex Vol. 10: Chapter V)* List of all documents: <u>CTR ANNEX I - APPLICATION DOSSIER FOR THE INITIAL APPLICATION</u>

The asterisk \* in CTIS indicates mandatory fields. Some separate documents (e.g. recruitment) must be uploaded even though the same text is already mentioned in other documents e.g. the protocol.

#### Documents can be in Danish for trials running in Denmark only.

Part I	Part II
<ul> <li>Cover letter (for content, please go to Annex</li> </ul>	Informed consent and patient recruitment
1, section B in the <u>Regulation</u> ) – cover letter	procedure template ( <u>template in Volume 10</u> )
must be uploaded in the section "Form" in CTIS	<ul> <li>Subject information and informed consent form</li> </ul>
<ul> <li>EU Application form (structured data entered directly in CTIS)</li> </ul>	<ul> <li>Patient facing documents (e.g. recruitment)</li> </ul>
<ul> <li>Protocol and protocol synopsis (synopsis can be part of protocol or separate document)</li> </ul>	<ul> <li>Investigator CV (<u>template in Volume 10</u>) – it is not mandatory to use this template</li> </ul>
(CTR Q&A, section 5.8 for synopsis guidance)	<ul> <li>Site suitability form (<u>template in Volume 10</u>)</li> </ul>
Patient facing documents (questionnaires, diam) that are linked to the endpoints of the	- one form per site
clinical trial shall be uploaded with the	Proof of insurance cover or indemnification
protocol in Part I - vou can upload several	(Insurance: non-commercial sponsors can
documents with the protocol	upload a document stating that the trial sites
Investigators Brochure (IB)/SmPC	in DK are covered by "Patienterstatningen")
IMPD quality, safety and efficacy/ Simplified	<ul> <li>Financial and other arrangements</li> </ul>
IMPD with reference to the valid SmPC	Proof of payment of fee (not applicable for
Content of labelling of IMPD	Denmark for non-commercial trials)
Template statement on compliance with Regulation (EU) 2016/679 (GDPR) (template in Volume 10) – must be uploaded in the section "Form" in CTIS	<ul> <li>Compliance with applicable rules for biological samples (template in Volume 10)</li> </ul>

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#### Info box:

Documents in CTIS must not contain DATE and VERSION in the file name 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, also in case of substantial modifications. Or you can rename your documents in CTIS after upload.

#### 1. Uploading documents into CTIS: filename, CTIS title, version number and date

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# I. Scientific advice and pediatric investigational plan (PIP) I1\_ Scientific advice name organization I2\_ PedCo opinion I3\_ PIP decision name agency

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S. Biological samples S1\_ Compliance on the collection, use and storage of biological samples

#### 2.2 Sponsor registration in OMS

Any Sponsor can register in the Organisation Management Service (OMS). In their request to OMS, Sponsors should attach a **CT registration headed letter** available in the <u>OMS portal</u>.

Please consult E - Change request document available in <u>SPOR portal under the documents section</u> for further clarification on the process.

#### 2.3 Fill in the trial title and sponsor organisation in CTIS

		Info box:
<u>The padlock</u> uploadin	g dat	_needs to be <b>locked</b> to enter data. Remember to unlock after a in each tab. Save the data before going to the next tab.
CTIS should b page. Th	oe coi is shc	mpleted in English. Remember to click <b>Save</b> on the top of the build be done often as there will be no automatic savings.

When you are logged into CTIS, click on the tab "New Trial":

Clinical trials	илт ст 🗖 вк
Clinical trialsNotices & alerts () RFIUser administration	
Clinical Trials	
Q. Enter EU CT number or use advanced search	SLARCH
Trial Advanced Search -	
Application Advanced Search +	
	+ 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. It is important to choose the organisation where sponsor is located if it is different from where you are located. It is not possible to correct afterwards.

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 or register the correct location in OMS – please refer to section 2.2.

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RFI User a	Full title (English)*
	Search organisation Name Starts with > ID Starts with > City Starts with > Country
	All StARCT ID Name Address City postCode country phone email Actions
	Cancel

d	inical Trial for	the CTIS Traini	ng <u>Programme</u>		1			
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					+ New o	orgenisation	dt Clear Search o	rganisatior
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1	L-5 of 5			× 1		•	-	

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 an "draft" mode.
- 4. <u>Submit:</u> Submit the application when all information is entered and it is completely ready.

#### GCP ENHEDERNE God klinisk forskning VVV

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>

Clinical trials Notices & aler	ts 📵 RF1 User administration	
Presence that data and Form MSCs Part I Part II Part II Evaluation Timetable The four sections that need to be filled in	documents provided in the EU Database are subject to publication rules (including the protection of personal data and commercial Form details Initial Application details Cover letter Cover letter the asterisk * = mandatory fields Deferral publication dates	y confidential information), as per Regulation (EU) 524/2014, Article 81(4).
	Publish dates of trial information	
	Short title / Trial category * Justification for trial category / Trial category *	~



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



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MSCs Part I	Form details Initial Application details		Add the cover	
Part II	Cover letter		letter	
Timetable	Cover letter *			A Add documents
	Deferral publication dates	Add the trial		8
	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".

	Category 1 clinical trials	Category 2 clinical trials	Category 3 clinical trials
	(pharmaceutical	(therapeutic exploratory and	(therapeutic use clinical
	development clinical trials):	confirmatory clinical trials):	trials)
<ul> <li>Protocol</li> <li>Investigator's brochure</li> <li>Responses from sponsor in relation to any aspect of the trial</li> </ul>	Sponsor may opt to defer this up to the time of MA using this trial or up to <b>7 years</b> 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 <b>12 months</b> after the end of the trial in the EU.

#### Info box: The protocol will automatically be accessible in the public workspace. 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. The first document you upload is always for publication so be sure to choose the document without sensitive information first. If you afterwards want to upload a document not for publication click on the 'Add' button (+) and upload a second protocol (not for publication) English - Protocol (for publication) - Sylender version 1.00 Submission date 16/10/2022 · Version 1.2 · 30/09/2022

The "deferral publication dates" must only be filled in if the sponsor has applied for a deferral date of the publication of the documents in the application.

<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.

<b>Clinical trials</b>			Add member states				×	
Clinical trials Notices N Press rate for a	Add countries, number of subjects and proposed RMS		Number Stats Austria Germany	*	40 40	>	E B M another	n), at per Reptieter 30
Clinical Trial for the (	CTIS Training Progr	amme 2020 5				Cancel	v Add	J
Form	Member states co	encerned						
Part	I Member states con	cented		-	Fire	at submission	ns date	

#### 2.5 Fill in the Part I section



**Part I:** This section contains information <u>mainly</u> 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.

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Form     Trial specific information (Part I)       MSCs     Trial details       Part II     Trial identifiers       Evaluation     Trial information       Timetable     Parture information	
MSCs Part I Part II Trial identifiers Evaluation Timetable Trial information	
Part II Trial identifiers Evaluation Timetable Description	
Evaluation Timetable	
Timecable	
Protocol information	
Scientific advice and Paediatric Investigation Plan (PIP)	
Associated clinical trials	
References	
Countries outside the European Economic Area	
Sameare	

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.

MSCs Part I	Sponsors									
Part II	Sponsor must be provide	ed					+ Ad	d sponsor 🖉 Ch	ange contact point	for union
Evaluation	Name	Organisation type	Country	Type	Status	Legal representative	Scientific contact point	Public contact point	Third Pr parties	Actions
	Test Organisation Demo	Pharmaceutical company	Germany	Commercial	Active				0	
	Contact point fo	er union*								
	Organisation na Test Organisation	me Demo		$\Box$						
	Address line 1*					Address lin	e 2			
	Address line 3					Address lin	ie 4			
	Town/City*					Post code				
	Berlin					1045GA				
	Country* Germany	÷				Functional	contact point name			~
	Contact									
	first name				Last	name •				

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Part II Evaluation	Test Organisation	and a second second				and a second second second	point	point	parties	Action
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		combany								
Timetable	Contact point fo	r union*								
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	Berlinstrasse 12									
	Address line J					Address lin	e 4		G	
	Town/City*					Post code				
	Berlin					1045GA				
	Country*					Functional	contact point name			
	Germany	~								
<b></b>	Contact									
	First name *				Last	name *				

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) The organization (including its email address) where the general public may obtain information about the clinical trial in academic/non-commercial trials this person will often be the sponsor contact point (the contact point for union).
- Contact point for union this is the **sponsor representative from the sponsor organisation**. This contact is used by the Union in case of required **contact to the sponsor** - in academic/non-commercial trials this person will often be the same as the scientific contact point.
- 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. If the third parties are not already registered in OMS, they can also be registered directly in CTIS without the need to register them in OMS (please refer to section 2.7).
- To search for a third party in OMS you need to use the organization number (ORG) or location number (LOC) it is not possible to search for the GCP-unit or a specific laboratory facility.

#### Only the coordinating GCP unit in Denmark needs to be added as third party.

#### The organisation numbers (ORG) and location numbers (LOC) for the three Danish GCP units are:

GCP-enheden ved Københavns Universitetshospital: ORG-100028217 Frederiksberg Hospital LOC-100045259

GCP-enheden ved Odense Universitetshospital ORG-100007716 Odense University Hospital LOC-100053630 GCP-enheden ved Aalborg og Aarhus Universitetshospitaler ORG-100028380 Aarhus Universitet Institut for Klinisk Medicin Palle Juul-Jensens Boulevard 11 LOC-100079923

When adding a third party remember to update information about the third party (duties, phone number and email) using the pencil.



#### Product details

Information on the medicinal products used in the trial must be added. If the products has 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.

An authorised product or active substance can be added by searching per product details, active substance, or ATC code, as applicable.

Non authorised medicinal products must now be registered in the Extended Eudravigilance Medicinal Product Dictionary (XEVMPD), if not already done. For IMPs not registered in XEVMPD there is no EU MP number. Please contact the manufacturer (e.g. pharmacy) regarding registration of the product in the XEVMPD database.

All medicinal products that are marketed in EU are registered in XEVMPD and can therefore be found in CTIS. Blinding, including re-encapsulation and re-packaging, of a marketed medicinal product does not need to be re-registered in XEVMPD. You can also read more about the registration in XEVMPD at the <u>DKMA</u> <u>homepage</u> (in Danish only).

#### <u>Placebo</u>

If the IMP is a placebo, the information requirements shall be limited to quality data. No additional documentation is required if the placebo has the same composition as the tested IMP (except the active substance), is manufactured by the same manufacturer, and is not sterile.



In the section "**Investigator brochure for the medicinal product**" either the Investigators Brochure (IB) or the SmPC must be uploaded. The labelling must only be uploaded if the IMP has a special label.

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

#### 2.6 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.

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MSCs Part I Part I Part I Part I Part I Part I Part I Part I Part I Part I D Crganisation Organisation ID name Site location Site street ID Site street Schopfstrase Schopfstrase Schopfstrase Innsbn Universitet Innsbruck Documents for part II Documents Subject information and informed consent form Suitability of the investigator Suitability of the facilities Proof of insurance cover or indemnification	Site post Site Site city code Country Tit Innsbruck 6020 Austria Dr.	Trial sites for each country can be added	+ Add site : Email Actions
- AT - Dt       Organisation name       Organisation site location       Site street address       Site street address	Site post Site Site city code Country Titi Innsbruck 6020 Austria Dr.	First Last Itle name name Department Phone r. First Last Chest Clinic 42342	Email Actions
Evaluation Timetable       8285       Medizinische Universität       Schopfstrase       Schopfstrase       Innsbr         In this section you need to upload the documents for part II       Documents       Schopfstrase       Schopfstrase       Innsbr         Documents       Documents       Subject information and informed consent form       Suitability of the investigator         Suitability of the facilities       Proof of insurance cover or indemnification	Innsbruck 6020 Austria Dr.	r. First Last Chest Clinic 42342	
In this section you need to upload the documents for part II Subject information and informed consent form Suitability of the investigator Suitability of the facilities Proof of insurance cover or indemnification			42424 flast@email.com 🖋
to upload an documents for part II in the section "All Compliance with national requirements on Data Protection Compliance with use of Biological samples	ection		

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

Trial sites must be added: Name, address and e-mail of trial sites and principal investigators at the trial sites.

*Please note: The first Danish site (Investigator) listed will be appointed National Coordinating Investigator in the Danish database "Nationalt Forsøgsoverblik" and so be responsible for validation and enrichment of source data in the database from the approving bodies.* 

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

The name and address of the university/hospital organisation must be registered in OMS/CTIS before you can search and add the organisation (site) to the application form. If the specific address of investigator location, is not already registered in OMS or CTIS you can add the site – please refer to section 2.7.

When the organisation is found or registered in CTIS, the details of the principal investigator at each site must be added (first and last name, department, email address, phone).

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name moto that data	and documents provided in	the EV Catabase at	Investigator infor	mation		× a antarrada
			10e		First name*	
		_	None	*		
Form	Country specif	ic details (Pa	Last name*		Department*	
MSCs	Trial sites					
Part I	Trial sites		Phone*		Enal <sup>a</sup>	
Part II - AI - DE	Organisation	Organization			× Cancel	Centime 1
imetable	6285	Medaznische Ur Innabruck	rversitat Schepfstrase Wilten	41, Schophoras 41	e 3enabruck 6020	Austria
	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	Application is valid!
Clinical trials Notices & a	lerts 🧿 RFI User administration		
O 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).
Clinical Trial for the C	TIS Training Programme 2020-501643-14-00 / Init	al ID: IN Draft	
Form	Country specific details (Part II - DE)		Check 🔯 Save O Cancel O Submit
MSCs	Trial sites		>
Part I Part II	Documents		
Evaluation Timetable	Recruitment arrangements		Add document
	2_1_Part2_Recruitment_Arrangement 🛓 🥒   English - Recruitment arrangements (for publication) - Sys - Version 1 - 10/12/2020	stem version 1	

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

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1	Submit confirmation ×	
; 📵 RFI User adminis	Please select the application parts you wish to submit.	
uments provided in the EU Database ar	<ul> <li>Part I</li> <li>Part II Austria</li> <li>Part II Germany</li> </ul>	al information), as per Regulation
Training Programme	× Cancel ✓ Confirm	<b>b</b>
		✓ Chec

#### 2.7 Site and third party registration directly in CTIS

Sites and third parties can also be registered directly in CTIS without the need to register them in OMS.

Organisations created locally in CTIS behave and function in the same way as the ones sourced from OMS and can be searched and selected once they have been registered in CTIS.

- I									
Search	organisa	ation							
Name	contains	✓ ID	s	tarts with 🛩	City	starts w	with 🛩	Country	
Agrinio								Greece	
					+ Nev	v organisatio	n 👲 Clear	Search	organisation
Search i	n oms O	Sear	rch in CTI	s 🖲	_		_		
-	Mama	Address	City	nostCode		ntry n	hone	email	actions

If users do not find the site in CTIS (red message will be displayed on the upper right corner), or if it is not listed in the search results, they can create the site in CTIS by clicking the button 'New Organisation', which will now appear enabled.

For more details of site registration in CTIS, please refer to EMA module 03 step by step guide.

#### 2.8 How to submit an additional member state 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".

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Clinical trials	Notices & alerts 💿	Annual safety report	ing RFI User admini	stration		
1	Trial title We Summary	abinar 21 09 202 5-71 00 RMS Austria full Trial Information No MATTION	0 Offications Trial resul	ts Corrective measures Ad Moc	essessments	Countral Cou
	Sponsor Trial phase Therapeutic area Medical device	Test Organisatis Therapeutic ex Diseases [C] -1 No	on I pioratory (Phase II) Respiratory Tract Diseases [CD8]	Hember states concerned Hedical conditions Low intervention study Population type	AT - 86 Apricea Yes Healthy Volunceer	
	ІМР					Expand all +

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.

ranslations	Eligibility criteria	
Part II Evaluation	Principal inclusion criteria * New ID Principal inclusion criteria (English)	Principal inclusion criteria (Languages)
	Protocol Synopsis of the protocol Data safety monitoring committee charter Dady design Investigato brochare Summary of Scentific advice Authorisation of manufacturing and import QF GMP centification DMPO Quality Simplified DMPO - failety and Efficacy Simplified DMPO - failety and Efficacy S	Principal exclusion criteria (Languages)
	1	

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

#### 2.9 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.



#### 2.10 Resubmission of an application

### Resubmission of a trial

CT applications can lapse (e.g. when the sponsor misses a response due date), be withdrawn by the sponsor, or rejected by the authorities. Lapsed, withdrawn and rejected CT applications can be <u>resubmitted</u>.

On the CT page, in the Summary tab, scroll down to the application section. Click the application you want to resubmit: IN = initial application

Clinical trials Notices & alerts 2000 Annual safety reporti			
Study title	Then, in the top	p-right corner, click Resubmit	
Summary Full Trial Information			Copy C Resubmit
	Form Tria	l specific information (Part I)	
	Part I * Tri	ial details	
(Sevell down)	→ Part II 1	Frial identifiers	>
(scroll down)	Evaluation	Frial information	>
	F	Protocol information	>
	5	Scientific advice and Paediatric Investigation Plan (PIP)	>
APPLICATION AND NON-SUBSTANTIAL MODIFICATIO	1	Associated clinical trials	>
Type ID Barts	F	References	>
		Countries outside the European Economic Area	>
Initial IN Part I & Part II			

The documents of the original submission will be copied to the resubmission. Documents can be replaced if necessary (e.g. cover letter). <u>Please note</u>: the version and date of all documents is reset to v1 and today, so click Edit (pencil icon) to enter the correct version and date for all documents. The resubmission will keep the original CT-number, but ending with -01.

#### 3 Validation, Request for Further Information (RFI) and Authorisation

#### 3.1 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)

#### Info box:

Please be aware to regularly check for Request for Information (RFI) from the authorities **in CTIS**. It is not possible to receive any mails or reminders in your mail box.

RFI: Questions from authorities to sponsor.

# Sponsor must check for Request for Information (RFI) from the authorities during both validation and assessment. As some RFIs can have a very short deadline for responding, the GCP units recommend that sponsors or delegated personal check for RFI on a daily basis.

#### Info box:

**GCP** ENHEDERNE

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In case the sponsor does not respond to a RFI before the given deadline, it will cause the lapse of the application - there is no second change. RFI must be answered within the specified deadline for each RFI. Sponsors do only have one change to answer each RFI. When sponsor submits the answer to RFI, all questions from the authorities must be answered.

If the application is rejected, use the "re-submission".

If in doubt about anything – call the Danish Medicines Agency or EC before submitting the answer to the RFI.

A timetable (see section 3.4) for estimated timelines will be generated and available in CTIS for each CTA, but it is important for sponsors to notice that the workflow in CTIS is dynamic. This means that the timelines shown in CTIS correspond to the maximum deadlines foreseen for each task/action. If a task/action is completed before its deadline, the corresponding deadlines for the following tasks/actions are recalculated.

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

You can access the RFI by clicking on each of the alerts. The RFI can also be accessed from the RFI tab next to the "Notices and alerts" tab, this is a more direct path to respond to each RFI.

It is possible to	download the RFI's - see section 3.7
-------------------	--------------------------------------

Clinical trials	Notices & alerts  RFI User administration						
-	E.						
	Notices & alerts () Access RFIs via the RFI tab	_					
/	Q Enter EU CT ID or ASR ID (Business Keys) or use advanced	Search. Access by click	the RFIs on each hem	SEAR	сн	Advance	ed Search <del>+</del>
)	Showing 1 - 8 of 8 items			1 of 1 p	ages	< 1	*
	Sort by: 11 Received ~						
	Newl 🚺 All 💟		1				
	Alert RFI sent to sponsor	Ref number	Source Evalu type pro	ation Received	IMP	RMS	Sponsor Test Organisation
	An RFI has been sent by Austria for the Initial application, Validation .	2021-500027-47-00	Initial Valid	ation 03/02/2021	Tablets 500mg	Austria	Demo
	Alert RFI sent to sponsor	Ref number	Source Evaluty	ation Received	ІМР	RMS	Sponsor
	An RFI has been sent by Austria for the Initial application, Validation .	2021-500027-47-00	Initial Valid	ation 03/02/2021	Paracetamol Tablets 500mg	Austria	Test Organisation Demo

Every single RFI must be opened by clicking on 'RFI- CT-xxxx-xxxxxx-xx-IN-001 IN' (black text):

#### GCP ENHEDERNE God klinisk forskning VVV

In most cases there will be several RFIs and often in both Part I and Part II. The due date for responding to each RFI is stated in "Due" column in the RFI 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 as will be made publicly as	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 available in accordance with these rules.
	$\searrow$
CTIS Training Programm	e test CT for Demo 2021-500027-47-00 / Initial ID: IN Under evaluation / RMS: Austria
Form MSCs Part I	Evaluation Validation Validation RFIs
Evaluation	Expand all V
Click on the lock to be able	REI-CT-2021-500027-47-00-IN-001         Tom: 1:/(42/2023)           MSC: Austria Submission date: 03/02/2023 Due date: 15/02/2023           Reason         Incomplete
to upload response to RFI	No changes have been made to the application.  Supporting documentation

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

Clinical trials Notices & alerts	0 RFI User administration	
Please note that data an will be made publicly ava	d documents provided in the EU Database are subject to publication rules, which take into account the need to protect personal data and ilable in accordance with these rules.	d commercially confidential information. Once available, a redacted version of the document
MSCs Part I Part II Evaluation Timetable	RFI-CT-2021-500027-47-00-IN-001         Owe: 15/02/2021           MSC: Austria Submission date: 03/02/2021         Due date: 15/02/2021	Expand all V Change application
RFIs from	Supporting documentation HS: Quality RF1_Submission_Quality  English - Supporting document from MS - Quality - System version 1.00 iutbmission date 03/02/2021 - Version 1 - 03/02/2021 Non-Quality	It is possible to change/update the application if required in RFI
Ethics commitees	RFI_Submission_nonQuality         English - Supporting document from MS - Non Quality (for publication) - System version 1.00         Submission date 03/02/2021         Spensor:	
	General documentation Quality related documentation	Add document     Add document     Add document

In the "Add document" tab you can upload supporting documentation to the RFI. If the RFI requires, you must as well click on the "Change application" and then change information in documents that have previously been uploaded or entered for the CTA. Be aware that besides responding to each RFI, changes to

the CTA is most often required as revised documents like for example an edited protocol with a new version must be uploaded.

Please remember to upload a <u>protocol with track changes</u>, please refer to the info-box in section 2.4 to see how to upload a document "not for publication".

#### 3.2 How to upload documents into CTIS in response to an RFI: change application

Clinical trials Notices & alerts (33) Annual safety reporting RFT User administration

2016/679 and Reg	ulation (EU) 2018/1725 when uploading documents and processing personal data in CTIS.	
MSCs	Validation	
Part I *	RELO	
Part II		Collarse al /
imetable	REI-CT-2022-501381-22-00-IN-001 Date 07/02/2022	
	to:: Hetherlands Subamassion date: 37/93/2022 Due date: (7/02/2022 Resorr     supporting documentation	For any changes to the application (documents or data) requested in the RFI. E.g. missing documents requested during validation, requests to modify document title/data/ursion during validation, or a new protocol
	MS: Quality	version requested during assessment
	No document available	version requested during assessment.
	Non-Quality	
	No document available	
	Sprear	Q Add documer
	Please notice that in this sector on v supporting documentation to the response should be u	Add docume
	<ul> <li>Freque necles one in this accession only appearing documentation to the response another of a</li> </ul>	овое и и пот такот и поту у посаколни повеси и посетност и перемили (соу зодеретност о се региску люми се времена и посторости акоет от поструктов о беле и на тот пост
	Response to consideration	Sort by 🗸 🗸
	Consideration number RFI-CT-2022-501381-22-00-IN-001-01	Application section parts Part 1 - Clrical Application section and document Protocol
	Consideration Please submit	
	Response	•
	Textual response	
	Documents related to the response	Optional, only for documents containing the response to this specific consideration. If the consideration requests a missing or updated

Clicking 'Change application' and confirming it, leads you back to the dossier, where documents can be added similarly to the initial submission. Click the lock and navigate to the location of the dossier where the change should be made.

		🗸 Check 🛛 🖻 Save 🖉 🛛 Withdraw
Trial specific information (Part I)		
Trial details		
Trial identifiers		>
Trial information Protocol information	<u>Update</u> : for uploading a new version of an existing document, e.g. protocol v2 with changes requested by	>
Clinical trial protocol	the MS. You are asked to enter the version number and date, but the document title in CTIS cannot be changed!	
Protocol & Protocol er publication Submission date 3/01/2022 - Version 1 - 22/01/2022	• • System version 1.00	
it: for changing the title, vers ocument contained a version o atch the documents, then you	ion or date of an existing document. If by mistake an uploaded or date in its title, or the indicated version and/or date do not will likely be asked to correct this in the Validation RFI.	Add document: for adding fully new documents, e.g. missing documents requested by the MS during validation. The System version will be 1.00. Please use document codes and titles as explained earlier.

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a identifiers	>
l information	>
otocol information	Newest version is shown on the left
ical trial protocol	previous versions are shown here
CTIS system version, does not necessarily	previous versions are shown here.
match own version number	Add document
🔎 Protocol 🛓 🥒 🗎 🧯 💿 🔪	Previous versions () ^
English - Protocol (for publication) - System version 2.00 Submission date 27/01/2022	
Version 2 · 27/01/2022     Own version num	ber and date, as entered during the upload.
Comment v2 uploaded in response to RFI	
n finished adding new/changed documents to the applica	tion, navigate back to the RFI response.
en finished adding new/changed documents to the applica	tion, navigate back to the RFI response.
en finished adding new/changed documents to the applica	tion, navigate back to the RFI response.
en finished adding new/changed documents to the applica Form Evaluation MSCs Validation Part I	tion, navigate back to the RFI response.
n finished adding new/changed documents to the applica Form SCs Validation Vari I RF1	tion, navigate back to the RFI response.
n finished adding new/changed documents to the applica Form MSCs Validation art I ation	tion, navigate back to the RFI response.
en finished adding new/changed documents to the applica Form MSCs Validation Part I art II RF1  RF1  RF1  RF1  RF1  RF1  RF1  RF1	tion, navigate back to the RFI response.
en finished adding new/changed documents to the applica Form MSCs Validation Part I Validation RfT-CT-2022-501381-22-00-TN-001 [cm=07/07/2022] MSC: http://diref.to/fabe/skdw.dbr/m.27/01/2022 Dec date: 07/02/2022	tion, navigate back to the RFI response.
en finished adding new/changed documents to the applica Form MSCs Validation Part I Part I etable RF1-CT-2022-501381-22-00-TN-001 [bcs:57/61/27222] Etable RF1-CT-2022-501381-22-00-TN-001 [bcs:57/61/27222] Etable RF1-CT-2022-501381-22-00-TN-001 [bcs:57/61/27222] Etable RF1-CT-2022-501381-22-00-TN-001 [bcs:57/61/2722] Etable RF1-CT-202-501381-22-00-TN-001 [bcs:57/61/272] Etable RF1-CT-202-501381-22-00-TN-001 [bcs:57/61/272] Etable RF1-CT-202-501381-22-00-TN-001 [bcs:57/61/272] Etable RF1-CT-202-501381-20-00-TN-001 [bcs:57/61/272] Etable RF1-CT-202-501381-20-00-TN-001 [bcs:57/61/272] Etable RF1-CT-202-501 Etable RF1-CT-202-5	tion, navigate back to the RFI response.
en finished adding new/changed documents to the applica	tion, navigate back to the RFI response. Cotage at A Cotage at A Cotage at A Cotage at A
en finished adding new/changed documents to the applica Form MSCs Part I Part I Pattel RF1-CT-2022-501381-22-00-IN-001 0mm 07/07/072  MSC: Includes Application changes Campete In the spatiation = Campete Interview of Spatiation = Campete Interv	tion, navigate back to the RFI response. Collapse at A thecard changes
en finished adding new/changed documents to the applica Form MSCs Validation Part I Part I Part I RF1-CT-2022-501381-22-00-TH-001 [See 87/02/2022] RF5-CtT-2022-501381-22-00-TH-001 [See 87/02/202] RF5-CtT-2022-501381-22-00-TH-001 [See 87/02/202] RF5-CtT-2022-501381-200 RF5-CtT-2022-501381-200 RF5-CtT-2022-501381-200 RF5-CtT-2022-501381-200 RF5-CtT-2022-501381-200 RF5-CtT-2022-501381-200 RF5-CtT-2022-501381-200 RF5-CtT-202 RF5	tion, navigate back to the RFI response.

#### 3.3 How to change a Clinical Trial Application as part of a 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.

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.

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Part I	Assessment Part I	Draft 1 for	
Part II	RFI	Assessment Part I	
Timetable	Conclusion		
	Intended Disagreements		
plication in	Assessment Part II	Draft 2 for Assessment	
ft for Part I	AT	Part II - Austria	
id Part II.	RFI 🕗		
be one	Conclusion		
swer from ach RFI.	DE	Draft 3 for Assessment	
	RFI 🚯	Part II - Germany	
	Conclusion		
	Decision		
	Part I Disagreements		



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

#### 3.4 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.

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will be made public	ata and documents provided in the EU Database are sub cly available in accordance with these rules.	ject to publication rules, which take into account the need to protect pe	ersonal data and commercially confidential information. Once available, a redacted version of the
MSCs			
Part I	Assessment Part I		
Part II *			
Evaluation	RFI 🚯		
Timetable			open the RFI Expand a
	RFI-CT-2021-500027-47-00-IN-	003 Responded: 03/02/2021	
		The second secon	
	RFI-CT-2021-500027-47-00-IN-	004 Due: 15/02/2021	-
			✿ Discard char
	MSC atria Submission date: 03/02/202	21 Due date: 15/02/2021	
	Includes application changes		
all all and the second	Changes to the application -		
CIICK ON THE			
CIICK on the			Add docum
ock button to	No document has been uploaded.	Remember to	🛆 Add docum
click on the ock button to be able to	No document has been uploaded. Supporting documentation	Remember to tick the "includes	C Add docum
click on the ock button to be able to answer the	No document has been uploaded. Supporting documentation MS:	Remember to tick the "includes application	Add docum
click on the ock button to be able to answer the RFI	No document has been uploaded. Supporting documentation MS: Quality	Remember to tick the "includes application changes" if there	Add a response
click on the ock button to be able to answer the RFI	No document has been uploaded. Supporting documentation MS: Quality No document available	Remember to tick the "includes application changes" if there are changes to	Add a response document
click on the ock button to be able to answer the RFI	No document has been uploaded. Supporting documentation MS: Quality No document available	Remember to tick the "includes application changes" if there are changes to sections in the	Add a response document
click on the ock button to be able to answer the RFI	No document has been uploaded. Supporting documentation MS: Quality No document available Non-Quality	Remember to tick the "includes application changes" if there are changes to sections in the application	Add a response document
click on the ock button to be able to answer the RFI	No document has been uploaded. Supporting documentation MS: Quality Non-Quality Non-Quality No document available	Remember to tick the "includes application changes" if there are changes to sections in the application	Add a response document
click on the bock button to be able to answer the RFI	No document has been uploaded. Supporting documentation MS: Quality No document available Non-Quality No document available	Remember to tick the "includes application changes" if there are changes to sections in the application	Add a response document

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	a continue parte first L. Man elizioni	Austinita endia and demand factori
Timetable	Consideration Austria - Part I Assessment consideration nr3 Sponsor response Response Austria - Part I Assessment consideration nr3 Documents related to the response	Consideration	
	ResponseRFI1 🛓 English - Supporting documentation for Consideration (for public submission date 05/02/2021 - Version 1 - 05/02/2021	Here you can upload additional documents for the consideration	
	Consideration number RFI-CT-2021-500027-47-00-IN-004-02 Applicate Consideration Germany - Part I Assessment consideration nr5 Response	on section parts Part I - Non-clinical	Application section and document Cover letter
	Documents related to the response	Type your response in the field	Add docure A

The "Submit response" button will be active when the changes have been saved on "save response".

#### 3.5 Timetable

In the timetable tab on the left side of the page in CTIS it shows the dates for the assessment schedule. All timelines will be in calender days, however the due dates must never fall on a weekend or official holiday. A time period will not be shorter than two consecutive working days. It is important for sponsors to notice that the workflow in CTIS is **dynamic** which means that timelines can be changed.



The figure below shows an overview of the general timetable and deadlines for authorities and sponsors. <u>CTIS Evaluation Timelines</u>

Process	Task	Timers for an initial application	Shorten the due date of the next workflow if completed earlier?
Validate Application	Submit validation conclusion	Day 10 + 15	Yes
Assess Part I	Submit part I conclusion	Day 45 + 31	Yes, if the assess part II is also completed earlier
Assess Part II	Submit part II conclusion	Day 45 + 31	Yes, if the assess part I is also completed earlier
Submit Decision	Submit decision	Day 5	-

#### 3.6 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.

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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	nts provided in the EU Da	tabase are subject to publica	ition rules (inclu	ding the protectio	n of personal data	a and commercially confidential in	nformation), as per Regulation (	EU) 536/2014, Article 81(4).
	MSCs	Dec	cision							
	Part I	P	art I Disagreeme	nts						
_	Part II									
	Evaluation	Pa	art I conclusion	·	Acceptable			· · · ·		
	Timetable	De	ecision		Authorised			•		
			ASSESSMENT OV	ERVIEW						
		P	4SCs	Validation		Assessment	Part 1	Assessment Part II	Decision	+AII
		A	USTRIA	Valid		Acceptable		Acceptable	Authorised	+
			RHS	(30/10/2020)		(04/11/2020)		(04/11/2020)	(05/11/2020)	
•										
								10002110		
		G	ERMANY					Acceptable (05/11/2020)	Authonsed (05/11/2020)	+

An overview of all documents and the approval date is shown at the end of "full trial information". Some countries do send "approval letters" but Denmark is not, and the approval date can only be seen in CTIS "Decision – authorised".

ALL DOCUMENT	rs											
Section	11	Document type	11	Document	Document	Document	Document Submission	System	Language	Authorisation	Application	
	~		~	Title II	Version 1	Comment 11	Date II	11	11	date If	*	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	A
Roles: Test Name:DENUBIL 250 mg/180 mg solución oral		Summary of Produ Characteristics (SmPC) (for publication)	ct	SmPC - NaCl 09 - Braun Melsungen DE	1		17/01/2022	1.00	English	17/01/2022	INITIAL - IN	ß
Part I		Content labelling o 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	ß

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#### 3.7 How to find the "Report for the Application Evaluation Decision" in CTIS:

**Go to front page** -> "Summary" -> 1 ("Download") -> "Applications " -> mark "Initial" -> mark "Form, MSC, Part 1, Part 2 and Evaluation" select all -> mark "structured data in PDF"

Click the Start download button. Will be downloaded as a ZIP file.

Go to evaluation and then decision

T Poseidon	DAMS. Deamark							
Summary	Full Trial Information	Notifications	Trial results	Corrective measures	Ad Hoc assessments	Users		
						Start Download	Cancel	
Applications 1								
Application type	Application ID	Member s	tates concerned	Application Part	Submission da	ate	Decision date	
INITIAL IN	3662	DK (Under	evaluation)	Part I Part II	21 Mar 2023			
ontents for Downl	oad:			Include the following	1:			
				Structured data in I	PDF*			
Z Form				Documents*				
				* these only include the	e latest version related t	to the		
MSC				application				
🗹 Part I								
Part II			~					
Select all								
Denmark								
Evaluation			~					
✓Select all								
✓Validation								
Assessme	nt Part I							
Assessme	nt Part II							
Decision								

#### How to find the "Report for the Application Evaluation Decision" in public space in CTIS:

**Go to front page** -> "Summary" -> "Download CT" -> Full Trial Information -> mark application type "Initial" -> Click download clinical trial -> Export file.

Will be downloaded as a ZIP file

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About 🗸	Search clinical trials and report	CTIS for sponse	ors CTIS for authorities	Support 🗸					
<ul> <li>Search</li> </ul>	clinical trials and reports > Search	ch for clinical trials							
Please sele	ect information you would like to d	ownload for clinical trial v	vith EUCT Number: 2022-5022	50-14-00					
• Ti	rial Summary								
🗆 Tr	Trial Summary will be included in the downloaded file								
• F	ull Trial Information								
🗹 Fu	II Applications Information wil	l be included in the do	wnloaded file						
	Application type	Status	Member states concerned		Submission date	Decision date			
	INITIAL	Authorised	DK:Authorised, not started		13/01/2023	22/03/2023			
• A	ttached documents								
	l attached documents will be in	cluded in the downloa	ded file						
			D	ownload clinical trial	Cancel				
			Zip file has bee	n created. Click here to	o download: Export file				

**How to see in CTIS how long the trial is approved:** Go to "Full trial information" -> "Trial details" -> "Trial information" -> "Trial duration".

In case of increased trial duration, the sponsor is expected to update the 'estimated end of trial date' field.

This is a non-substantial modification and require no approval from the authorities.

Trial duration *	
Estimated recruitment start date in	Estimated end of trial date in EEA
<b>EEA</b> 01/09/2022	01/09/2028

#### 4 15 days notifications from start to end of trial

#### 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:

#### Notifications that need to be submitted for every clinical trial:

• **Start trial:** the first act of recruitment of a potential subject for a specific CT, unless defined differently in the protocol.

- Start recruitment: the first visit of the first subject. The date could be the same one as for start trial.
- End recruitment: act of not recruiting subjects anymore in an MSC.
- End trial: last visit of the last subject, or a later point in time as defined in the protocol.

# Notifications that need to be submitted only when the sponsor needs to interrupt a CT on specific grounds with a view to resuming it afterwards:

• **Temporary halt:** An interruption not provided in the protocol of the conduct of a CT with the intention of the sponsor to resume it.

• **Restart trial:** The act of restarting the trial, after a temporary halt or after a suspension of the CT as part of a corrective measure by an MSC.

• **Restart recruitment**: The act of restarting the recruitment of subjects. The trial must have been restarted to be able to restart the recruitment.

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.

2020-5004	555-86-00 KMS: Buigan								
Summary	Full Trial Information	Notifications	Trial results	Corrective r	neasures Ad Hoc assessments	Users		Amend	
Trial & Recruitm	ent Periods								_
Sur Trial	nd Trial Bout at Tria	Townson Us			3 Start Recruitment End Re	cruitment	Restart I	Recruitment	
Stan That	na triat Restart tria	тетрогагу на							
-			Trial				Recruit	ment	_
<ul> <li>Select all</li> </ul>	Current status	Start date	Trial Temporary Halt	Restart	End (or early termination)	Start	Recruit End	ment Restart	
Select all	Current status	Start date	Trial Temporary Halt	Restart -	End (or early termination)	Start	Recruit End	ment Restart	
Select all     Austria     Germany	Current status <ul> <li>Authorised</li> <li>Authorised</li> </ul>	Start date	Trial Temporary Halt .	Restart -	End (or early termination)	Start - -	Recruit End	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:** 

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

Summary	Full Trial		_	Bulg	aria										Amend
Start Trial	End Trial Related docu	ment(s)	-	<			Augus	1 2020		_	>	<b>1</b>		Restart	Recruitment
					Sun	Mon	Tue	Wed	Thu	Pri	Set	Add document		-	
				31	26	27	28	29	30				2	Recruit	ment
Colora all	and the second se			32	.02										
J Jelect an	Curre			33								× cancel ✓ Subm	art	End	Restart
Austria	✓ Authorised			34											
Germany	✓ Authorised			35	20			26							
Bulgaria	✓ Authorised	26/08/2020		36		C1034	01	0.3	03	.04	0.5				

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

ts 👩 🛛 Clir	nical study reports Annual sa	fety reporting RFT User admin	istration	
500438-88-0	New end of trial in ms notificat	tion		~
Full Tria	Countries	Bulgaria		rs
litment Pei	End of the clinical trial date *	26/08/2020		1
End Trial	The clinical trial has been early	terminated		
	Anticipated date of summa	ary of results		
	The submission of this form will end the cli required to also submit the anticipated dat	nical trial in all EEA countries for which the clinical tr e of summary of results as part of this form.	ial was authorised. It is the	refore
Curren	Anticipated date of summary of			
✓ Auth	result *	01/09/2020		2
✓ Auth	Partial results			
	will be submitted at the anticipated dat	e of summary of results		_
✓ Auth	Justification that the results are to	be later than 12 months:		
		~		_
	Justification that the results are to	be later than 12 months:		_
lobal				
A				_
te of summa				
obal	Related document(s)			_
Event o			Add docu	ment
			X Cancel Save	✓ 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.

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1	Test Organisation 1 has submitted a End of trial in MS notification in Bulgaria. Notification ID - EoT-0542	2020-500438-88-00			26/08/2020	Tablets 500mg	Bulgaria	Organisation 1
,	Notice Restart of Trial notification submitted Test Organisation 1 has submited a Restart trial notification in Bulgaria. Notification ID - RoT-0541	Ref number 2020-500438-88-00	Source type	Evaluation process	Received 26/08/2020	IMP Paracetamol Tablets S00mg	RMS Bulgaria	Sponsor Test Organisation 1
	Temporary halt submitted Test Organisation 1 has submitted a Temporary Halt notification in Bulgaria. There is no benefit 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
	Notice Restart of Recruitment notification submitted Test Organisation 1 has submitted a Restart of Recruitment notification in Bulgaria. Notification ID - 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
	Notice End of Recruitment notification submitted Test Organisation 1 has submitted a End of Recruitment notification in Bulgaria. Notification ID - E6R-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

Info box: To be able to see the "Annual safety reporting tab" and to perform ASR related activities, the CT administrator should assign the "ASR submitter role" to him/herself.

Please refer to <u>The Danish GCP Units guide - Submission of Annual Safety</u> <u>Report (ASR) in CTIS</u> for more information.

#### 5 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>CTR Q&A, Annex IV</u>: "Classification of changes to ongoing clinical trial".

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

# 

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The 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 Trial page.

Clinical trials	Notices & alerts 💿 🛛 Ann	ual safety reporting RFI User administra	tion		
	Trial title Webina	⊊ <b>1 09 2020</b>		Download + CRLA Single trial substantial modificat Huiti trial substantial modificati	NTE -
Go to the summary	Summary Full Trial In TRIAL INFORMATION	MS: Austria	Corrective measures Ad Hoc	Additional MSC	click on the create tab to make a substantial modification
section in	Sponsor	Test Organisation 1	Member states concerned	AT · BE	
the sponsors workspace	Trial phase Therapeutic area Medical device	Therapeutic exploratory (Phase II) Diseases [C] - Respiratory Tract Diseases [C08] No	Medical conditions Low intervention study Population type	Apnoea Yes Healthy Volunteers	
	IMP				

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*.

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.* 

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





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 & al	erts 🕘 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 E1(4).
Trial title Webinar 21 ( / RMS: Austria	In the form section you can upload cover letter and description of the modification and other supporting
	Check D Save Cancel Submit
Form	Form details
Part I	Substantial modification details
Part II	Cover letter
Evaluation	C Add document
Timetable	Modification description
	Supporting information

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

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MSCs				Add d
Part I Part II Evaluation Timetable	0_Modification_Description_Details 🛓 🥒 🖡 English - Modification Description (for publication) - Syst - Version 1 - 13/09/2020 Supporting Information	tem version 1	Choose a reason for the substantial modification. If none of the reasons are applicable you can choose "other".	
	Supporting information documents			🕰 Add d
	Supporting information documents Substantial modification reason		Substantial modification scope	Add do
	Supporting information documents Substantial modification reason		Substantial modification scope	Add de
	Supporting information documents Substantial modification reason		Substantial modification scope	Add de
	Supporting information documents Substantial modification reason  I  C and of trial in MS C a		Substantial modification scope	Add de
	Supporting information documents  Substantial modification reason  Cond of trial in MS Cond of trial in EA Colobal and of trial		Substantial modification scope	Add d
	Supporting information documents Substantial modification reason           I           I           Ind of trial in HS           End of trial in EEA           I clobal and of trial           I clobal and of trial           I clobal and of trial		Substantial modification scope	Add d
	Supporting information documents  Substantial modification reason  I  End of trial in B4S End of trial in B4S Clabal end of trial Anticipated date of summary of results Unspected types (Change in B/R	_	Substantial modification scope	Add d
	Supporting information documents  Substantial modification reason  I I I end of trial in MS End of trial in EA Global end of trial Anticipated date of summary of results Unexpected (vent Change in E/R Serious Breach		Substantial modification scope	Add d
	Supporting information documents  Substantial modification reason  I  I Ind of trial in MS Ind of trial in EEA Indebal and of trial Anticipated date of summary of results Unsequected Event Change in E/R Serious Breech Urgent Setey Neasure		Substantial modification scope	Add d
	Supporting information documents  Substantial modification reason  I  Cond of trial in MS Cond of trial in MS Cond of trial Colobel end		Substantial modification scope	Add d

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

Clinical trials Notices & al	erts 🛑 Annual safety reporting I	RFI User administration			The button "add member state" is
Please note that data an	d documents provided in the EU Database are subject to	publication rules (including the protect	ion of personal data and commercially confidential inf	ormation), as per Regulation (EU) 5:	inactive as this requires a new
In the MSCs					application.
section only the number of Inar 21 0	09 2020 2020-500275-71-00 / Sub	stantial modificatior	ID: SM-1 Draft New version (	draft SM-1 🝵 🕕 View :	submitted ap lication
subjects can be changed					
			\	🗸 Check 🔯	Save 🛿 Cance 🗗 Submit
	₹.				
Form	Member states concerned				
MSCs					+ Add member states
Part I	Member states concerned	RMS	First submissions date	Subjects	victions
Part II	Austria	Selected		20 2	
Evaluation	Relation				
Timetable	Deignan			20	

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

Form	Trial specific information (Part I)	
Part I	Trial details	
Part II	Trial identifiers	>
Evaluation	Trial information	>
Timetable	Protocol information	~
	Clinical trial protocol	
	Protocol *	Add document
	English - Protocol (for publication) - System version 1 - Version 1 - 11/09/2020	
	0_Protocol SM Part I       Image: Constraint of the second	

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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 0 ~
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 as	Part I Part II Austria Part II Belgium	2	el information), as per Regulation (EU) \$38/2014, Article 61(4).
Trial title Webinar 21 09 2020 2020-500275-71-00 / RMS: Austria		× Cancel  Confirm	n draft SM-1 = O View submitted application
Form Trial specific information (Pa MSCs Part I   Trial details	ırt I)		

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

▼ Paracetamol	Tablets 500	img							
OVERALL TRIAL STATUS Member State	Overall Tria	Status	First decision date	Start of tr	rial End of t	rial	Recruitme	nt start d	ate
AT	Authorised	0	11/09/2020	It is shown the subs	whether				
BE	Authorised	0	11/09/2020	modificati	on has		It is no	-	to view
•				been auth and by v	orised which		additio	nal info	ormation
APPLICATION AND	NON-SUB	STANTIAL MO Parts		been auth and by v member Submission date	orised which states	Reason	additio	nal info	ormation
APPLICATION AND Type Substantial modification	NON-SUB ID <u>SM-1</u>	Parts Part I Part I	DIFICATION MSCs AT(Authorised) BE(Authorised)	been auth and by v member Submission date	Decision date	Reason +	additio scope		+ INFO

#### 6 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 🔞 Ann	ual safety reporting RFI	User administration
Clinical Trials		-
Q Enter EU CT number or Lee		MARCH.
Trial Advanced Search •	Er	nter the CT number or
Application Advanced Search +	u	se advanced 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	Select	the	< <b>1</b> >			
	trial				× Cancel	✓ Confirm

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

I results Corrective measures Ad Hoc assessments Users
+ New

Select the "Add document". Then "Save" and "Submit".

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mmary of results		×	Lay person summary of results	3
Title 1:	Version type - Intermediate		Title *i	Version Type: Final
Intermediate data analysis data "i			Related document(x) *:	
14/07/2021 Related document(s) *1	8			
		Add document		CLOSE E SAVE
Brigish - Summary of results A Brigish - Summary of result - Version 1 - 13/07/2021	s (for publication) - System version 1.4	10		t

#### 7 Changes log

Version 1.0

Version 1.2 Links corrected.

Version 1.3 Updated according to comments from users.

Version 1.4 Updated with new experiences from authorities and users and links corrected.

Version 1.5 Updated with information of resubmission and other small corrections.

Version 2.0 Updated section on how to respond to RFI, removal of section on how to create an EMA account, roles and responsibilities and ASR.

Version 2.1 Updated with information of sponsor, third party and site registration directly in CTIS, updated list of documents and templates and new links.

Version 2.2 Updated according to comments from users and how to find and download Report for evaluation decision in CTIS and in public space. Location number is updated for the GCP-unit in Aalborg and Aarhus.

Version 2.3 Added comment from Trial Nation regarding the first mentioned investigator in CTIS will be named "coordinating investigator" in the database Danish National Trial Overview (Nationalt Forsøgsoverblik).

Version 2.4 Further explanation about log in to CTIS