



CTIS Clinical Trials Information System

21-MAR-2024

¿De qué vamos a hablar hoy?



1. Introducción CTIS
2. Creación nuevo EC
3. Documentación
4. Notificaciones y Modificaciones
5. Transición EECC
6. Otros aspectos
7. Recursos EMA/AEMPS
8. Formulario solicitud

1. INTRODUCCIÓN

- CTIS: Clinical Trials Information System -

1. Introducción

¿Qué es CTIS?

REGLAMENTO (UE) N° 536/2014 DEL PARLAMENTO EUROPEO Y DEL CONSEJO

de 16 de abril de 2014

sobre los ensayos clínicos de medicamentos de uso humano, y por el que se deroga la Directiva 2001/20/CE



- Sponsor workspace
- Authority workspace
- [Public web](#)

1. Introducción

Periodo Transición

EudraCT
European clinical trials database

Create Load Migration Tool

CTA Information Validate

EudraCT Number
2020-000130-18 Session expires after 30 minutes of inactivity. Please click on 'Save' to save your work

Sponsor's Protocol Code Number
Clinical Trial Application Menu

Co-THEIA	A. Trial Identification	D.9 Site(s) where the qualified person certifies batch release
NCA	B. Sponsor Identification	E. General Information on the Trial
Spain - AEMPS	C. Applicant Identification	F. Population of Trial Subjects
XML File Identifier YsZpKaQqX23ppt7Jdts1HWkOmQ=	D. IMP Identification	G. Clinical Trial Sites/Investigators in the Member State
CTA Sections	D.8 Placebo Information	H. Competent Authority/Ethics Committee Information

Bienvenidos al Portal de Ensayos Clínicos con Medicamentos del Ministerio de Sanidad

AVISO IMPORTANTE
Les recordamos que a partir del **31 de enero de 2023** todas las nuevas solicitudes de ensayo clínico deben ir a través del sistema europeo CTIS (más información en <https://euclinicaltrials.eu/>), por lo que el envío de nuevos ensayos clínicos a través de este portal no será aceptado.

INCIDENCIAS en curso:
Para facilitar la investigación de determinadas incidencias técnicas se ha desactivado el envío simultáneo de informes a múltiples ensayos. Mientras tanto deberán enviarse de forma individual ensayo por ensayo. Rogamos disculpen las molestias.

FUNCIONALIDADES del Portal ECM versión 2
En esta aplicación podrá:

1. Preparar, modificar y validar los formularios de solicitud de EC en trámite y autorizado. El formulario europeo de una solicitud inicial se cumplimenta en el sitio web de EudraCT (ninguna Web externa: sitio web en inglés de la EMA), excepto las direcciones de los centros en las secciones G.1/G.2 y los datos del CEIC en H que se cumplimentan y validan en el portal ECM cargando el XML previamente generado en EudraCT (los Investigadores en G.1/G.2 y los datos del dictamen en H se incluirán desde EudraCT).
2. Cumplimentar y validar las cartas de presentación de las solicitudes.
3. Presentar y enviar todo tipo de solicitudes de ensayo clínico (EC) en formato electrónico con carácter oficial por vía telemática o sin firma, tanto al CEIC como a la AEMPS (excepto RAGC):
 - Nuevo Ensayo Clínico
 - Ensayo Clínico en Trámite (*)
 - Ensayo Clínico autorizado (**)



Clinical Trials English | CTIS log in

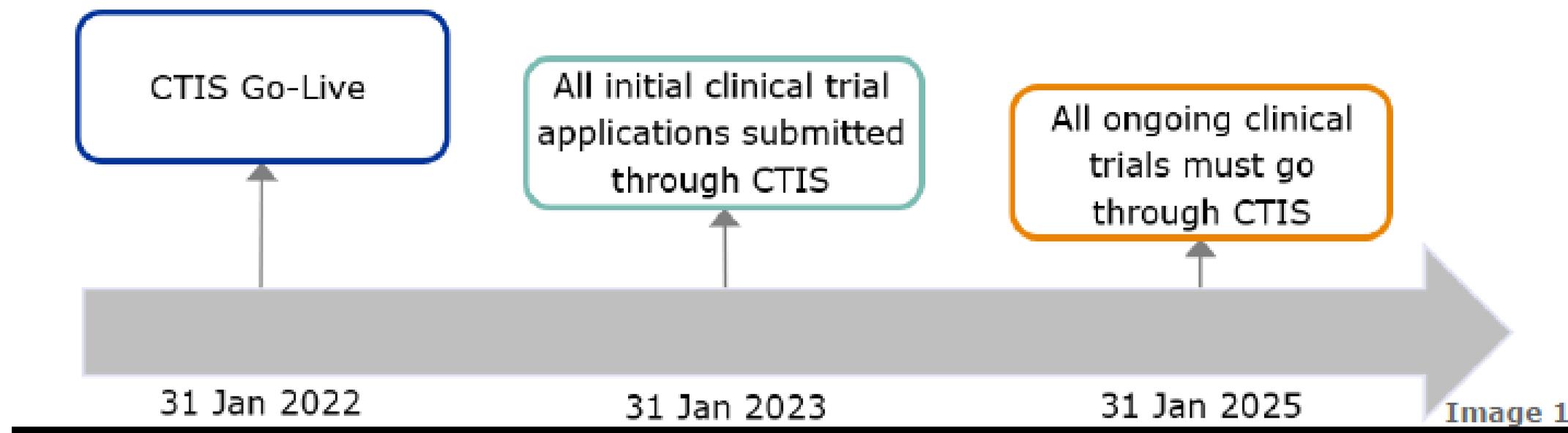
About Search clinical trials and reports CTIS for sponsors CTIS for authorities Support

CTIS for sponsors

CTIS for sponsors
The sponsor workspace in the Clinical Trials Information System (CTIS) assists clinical trial sponsors and other organisations involved in running clinical trials in preparing and compiling clinical trial applications and dossiers to submit for assessment by Member States in the European Union (EU) and European Economic Area (EEA).

1. Introducción

¿Cuándo tengo que hacerlo?



FAST TRACK para transición de EECC autorizados bajo Directiva hasta el 16 de Octubre del 2024

1. Introducción

¿Cómo accedo a CTIS?

1. Usuario EMA

EMA - Self-service Registration Form

Submit the following form to register.

First Name *

This is used to create your username and to address you in email correspondence.

Last Name *

This is used to create your username and to address you in email correspondence.

Email *

We require a valid/active email address to create an EMA Account.

Password *

Please enter a password that you want to use to access your EMA Account. The password must have at least 8 characters and must contain upper case, lower case, numeric and special characters.

Confirm Password *

Country Code

Mobile (optional)

This is an optional field. We will only use this information for security messages or alerts in relation to your account. Please include the international dialling code in front of your mobile number.

[EMA - Self-service Registration Form](#)

2. Acceso CTIS

English ^{EN} CTIS log in ^

Sponsor workspace

Authority workspace



Iniciar sesión

EMA: email, other users: `userid@id.ema.europa.eu`

Atrás **Siguiente**

EMA Staff and Contractors: sign in with your email address and use this [link](#) to reset your password

Other users: sign in with your username followed by `@id.ema.europa.eu`

[Acceso CTIS](#)

2. Nuevo Ensayo Clínico

- CTIS: Clinical Trials Information System -

2. Nuevo Ensayo Clínico

¿Cómo creo un nuevo EC?

Promotor - **IP**

New trial

Promotor - **Organización**

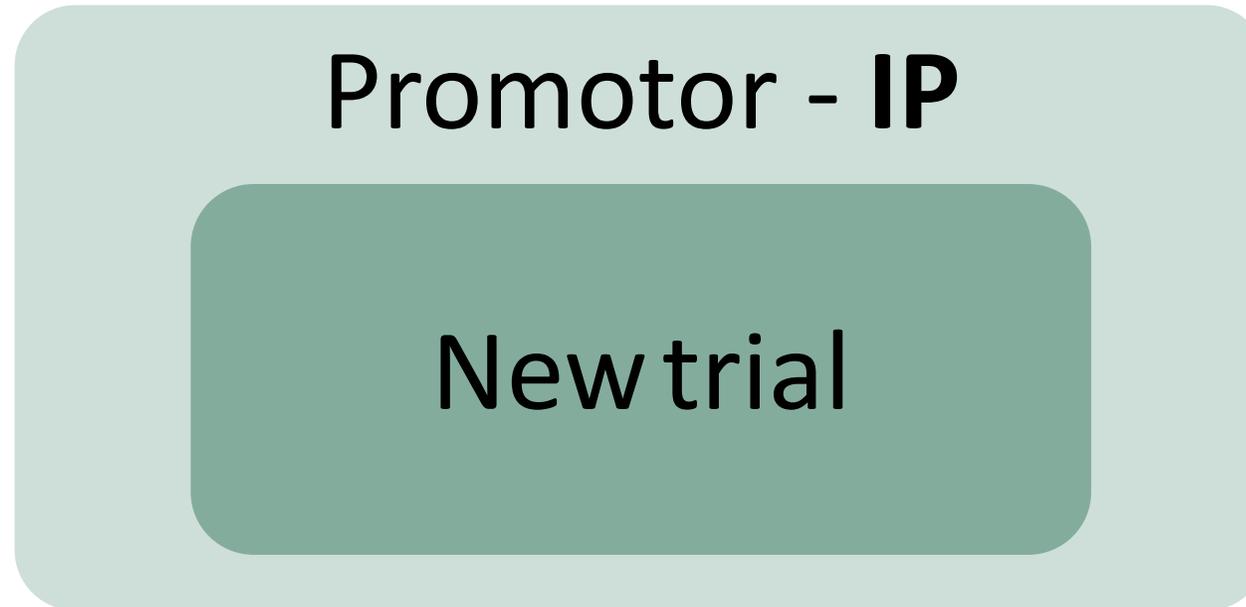
Solicitar acceso al estudio

Solicitar **permiso al CEIm de referencia elegido por email*** antes de subir un estudio a CTIS para su evaluación e indicarlo en la Cover Letter.

***ceic.hcsc@salud.madrid.org**

2. Nuevo Ensayo Clínico: IP Promotor

¿Cómo crear un nuevo EC?



2. Nuevo Ensayo Clínico: IP Promotor

Clinical trials

Clinical trials Notices & alerts

Clinical Trials

Alexandra Dominguez

Create new trial

Full title (English)*

Prueba Promotor-IP

Todas las organizaciones y centros participantes tienen que estar dados de alta en la **Organization Management System (OMS)**

<https://spor.ema.europa.eu/sporwi/>

Search organisation

Name

contains

ID

starts with

City

contains

Country

ORG-100023073

Search organisation

+ New organisation

Clear

ID	Name	Address	City	postCode	country	phone	email	actions
<input checked="" type="radio"/> ORG-100023073	Hospital Clinico San Carlos	Calle Del Profesor Martin Lagos Sn	Madrid	28040	Spain			x +
<input type="radio"/> ORG-100023073	Hospital Clinico San Carlos	Calle De Martin Fierro Sn	Madrid	28040	Spain			x +
<input type="radio"/> ORG-100023073	Hospital Clinico San Carlos	Planta Baja Sur 1 Pasillointerior,	Madrid	28040	Spain			x +

1 -3 of 3

< 1 >

Transition Trial

Cancel

Create

Indicar el **PROMOTOR**.
Puesto que las personas físicas no están registradas en OMS, indicamos el **centro en el que trabaja el/la IP**.



+ New trial

2. Nuevo Ensayo Clínico: IP Promotor

Cuando se cree el New Trial nos proporcionará el código **EU CT Number**
(sustituye el antiguo Eudra CT Number)

En la **COVER LETTER** indicaremos que el **PROMOTOR** es el/la **Investigador/a**

2. Nuevo Ensayo Clínico: Promotor - Organización

¿Cómo crear un nuevo EC?

Promotor - **Organización**

Solicitar acceso
al estudio

2. Nuevo Ensayo Clínico: Promotor - Organización

Clinical

Clinical trial

Alexandra Domingo Fernández

Personal profile
My roles
Logout

Search Organisation

Search organisation

Name starts with ID starts with City starts with Country All

+ New organisation Clear **Search organisation**

ID	Name	Address	City	postCode	country	phone	email	actions
<input checked="" type="radio"/> ORG-100045027	Fundacion Para La Investigacion Biomedica Del Hospital Clinico San Carlos	Calle Del Profesor Martin Lagos	Madrid	28040	Spain			x +

1 -1 of 1 < 1 >

Cancel **+ Add**

+ New trial

2. Nuevo Ensayo Clínico: Promotor - Organización

The screenshot shows a 'Request roles' dialog box with the following fields and values:

organisationName	organisationId	Scope	EUCT Number	Role
Fundacion Para La I	ORG-100045027	SPECIFIC_TRIAL	3-507541-29-	CT Admin

Buttons: + Add, CANCEL, REQUEST

1. Seleccionar si queremos acceso para un EC **específico** o **todos** los EECC de ese promotor.
2. Indicar **EU CT Number** en caso de ser un EC específico.
3. Seleccionar rol (normalmente **CT Admin**).
4. Clicar en **Request**.
5. Esperar **autorización** del promotor.

CTIS **no envía notificaciones** por email, debemos entrar todos los días

2. Nuevo Ensayo Clínico: roles

¿Qué roles existen?

Por norma general, en EECC Independientes utilizaremos el rol **CT ADMIN** que engloba todos los permisos excepto el envío de Informe Anual de Seguridad, para el que solicitaremos rol de **ASR submitter**.

[Roles and permissions matrix summary - Sponsors workspace - CTIS Training Programme - Module 07](#)



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Roles and permissions matrix summary
Sponsors Workspace
CTIS Training Programme – Module 7
Version 2.29 – October 2022

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2. Nuevo Ensayo Clínico: visión general

Clinical trials

Alexandra Domingo Fernández

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

Please note that, in accordance with Regulation (EU) No 536/2014, all data and documents provided in the EU database are subject to publication rules, aiming amongst other things at protecting personal data and commercially confidential information. It is the responsibility of each user to ensure compliance with Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 when uploading documents and processing personal data in CTIS.

Download + CREATE

Curso CTIS

Pending 2024-512068-76-00 Proposed RMS: Spain

Summary Full Trial Information Notifications Trial results Corrective measures Ad Hoc assessments Users

TRIAL INFORMATION

Sponsor	Fundacion Para La Investigacion Biomedica Del Hospital Clinico San Carlos	Member states concerned	ES
Trial phase		Medical conditions	
Therapeutic area		Low intervention study	No
Medical device	No	Population type	
		Transitioned Trial	No

MSC TRIAL STATUS

Member State	MSC Trial Status	First decision date	Start of trial	End of trial	Recruitment start date
ES	Pending				

APPLICATION AND NON-SUBSTANTIAL MODIFICATION

Type	ID	Parts	MSCs	Submission date	Decision date
Initial	IN	Part I	ES(Draft)		

2. Nuevo Ensayo Clínico: visión general

Summary

Curso CTIS

Pending 2024-512068-76-00 Proposed RMS: Spain

- Summary**
- Full Trial Information
- Notifications
- Trial results
- Corrective measures
- Ad Hoc assessments
- Users

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2. Nuevo Ensayo Clínico: visión general

Full Trial Information

Curso CTIS
Pending [2024-512068-76-00](#) Proposed RMS: Spain

Summary **Full Trial Information** Notifications Trial results Corrective measures Ad Hoc assessments Users

Member State: Overall
Pending Clinical Trial Status

Trial specific information (Part I) IN

TRIAL DETAILS

- Trial identifiers >
- Trial information >
- Protocol information >
- Scientific advice and Paediatric Investigation Plan (PIP) >
- Associated clinical trials >
- References >
- Clock stop >

SPONSORS

Name	Organisation type	Country	Type	Status	Legal representative	Scientific contact point	Public contact point	Third parties
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PRODUCTS

Sort by: No sorting v

ALL DOCUMENTS

2. Nuevo Ensayo Clínico: visión general

Notifications

Curso CTIS

Pending [2024-512068-76-00](#) Proposed RMS: Spain

Summary Full Trial Information **Notifications** Trial results Corrective measures Ad Hoc assessments Users

Trial & Recruitment Periods

[Start Trial](#) [End Trial](#) [Restart Trial](#) [Temporary Halt](#) [Start Recruitment](#) [End Recruitment](#) [Restart Recruitment](#)

	Trial					Recruitment		
<input type="checkbox"/> Select all	Current status	Start date	Temporary Halt	Restart	End (or early termination)	Start	Restart	End

EEA and Global

End of trial EEA	Submitted on
Anticipated date of summary of results	Submission of results
End of trial Global	Submitted on

Unexpected Event 0

[+ New](#)

Business key	MSCs	Internal sponsor id	Last modified	Submission date	Status	Actions
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Serious Breach 0

[+ New](#)

Business key	Affected countries	MSCs	Internal sponsor id	Last modified	Submission date	Status	Actions
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2. Nuevo Ensayo Clínico: visión general

Trial results

Curso CTIS

Pending [2024-512068-76-00](#) Proposed RMS: Spain

Summary Full Trial Information Notifications **Trial results** Corrective measures Ad Hoc assessments Users

SUMMARY OF RESULTS

LAY PERSON SUMMARY OF RESULTS

CLINICAL STUDY REPORTS

2. Nuevo Ensayo Clínico: visión general

Corrective measures

The screenshot shows the CTIS interface for a trial. At the top, there is a navigation bar with tabs: 'Clinical trials', 'Notices & alerts' (highlighted with a red box and a '0' notification), 'RFI', and 'User administration'. Below the navigation bar is a warning message: 'Please note that, in accordance with Regulation (EU) No 536/2014, all data and documents provided in the EU database are subject to publication rules, aiming amongst other things at protecting personal data and commercially confidential information. It is the responsibility of each user to ensure compliance with Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 when uploading documents and processing personal data in CTIS.' Below the warning is a 'Download' button and a '+ CREATE' button. The main content area is titled 'Curso CTIS' and shows a 'Pending' status for trial '2024-512068-76-00' with 'Proposed RMS: Spain'. Below this, there are several tabs: 'Summary', 'Full Trial Information', 'Notifications', 'Trial results', 'Corrective measures' (highlighted with a red box), 'Ad Hoc assessments', and 'Users'. The 'Corrective Measures' section contains a yellow box with the text 'Only submitted CM(s) is/are displayed on the Sponsor.' Below this is a table with the following columns: 'Corrective Measure ID', 'Member State Concerned', 'Submission date', 'Type', 'Notes', and 'Actions'.

Permite al **MSC solicitar una modificación de un EC o modificar su estatus**. El MSC solicitará la opinión del promotor antes de aplicar la medida correctora, excepto cuando se requiera una acción inmediata.

2. Nuevo Ensayo Clínico: visión general

Ad Hoc assessments

The screenshot displays the CTIS (Clinical Trials Information System) interface. At the top, there is a navigation bar with tabs for 'Clinical trials', 'Notices & alerts' (highlighted with a red box and a notification icon), 'RFI', and 'User administration'. Below the navigation bar, a warning message is visible: 'Please note that, in accordance with Regulation (EU) No 536/2014, all data and documents provided in the EU database are subject to publication rules, aiming amongst other things at protecting personal data and commercially confidential information. It is the responsibility of each user to ensure compliance with Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 when uploading documents and processing personal data in CTIS.' The main content area shows a card for 'Curso CTIS' with a status of 'Pending' and a reference number '2024-512068-76-00'. Below the card, there is a horizontal menu with tabs: 'Summary', 'Full Trial Information', 'Notifications', 'Trial results', 'Corrective measures', 'Ad Hoc assessments' (highlighted with a red box), and 'Users'. A 'Download' button and a '+ CREATE' button are also visible in the top right corner of the main content area.

Permite al **MSC discutir y evaluar información relacionada con una notificación presentada**, una sospecha de RAGI, un IMP o cualquier otra información relevante para la supervisión de un ensayo. El MSC puede solicitar información adicional al promotor y consultar con los demás Estados miembros.

2. Nuevo Ensayo Clínico: visión general

Users

Curso CTIS
Pending [2024-512068-76-00](#) Proposed RMS: Spain

Summary Full Trial Information Notifications Trial results Corrective measures Ad Hoc assessments **Users**

Users

Last Name	First Name	Role	Sponsor	Employer
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3. Documentación

- CTIS: Clinical Trials Information System -

3. Documentación

Evaluación EECC con medicamento



[Requisitos documentales](#) para la validación y **evaluación de un EC con medicamento** en el CEIm HCSC.



[Requisitos documentales](#) para la tramitación de la **Idoneidad de las instalaciones** del HCSC.

3. Documentación

Templates específicos CTIS

FORM:

- [Compliance with regulation template](#)

PART II:

- Subject information and informed consent form: [Informed consent and patient recruitment procedure template](#)
- Suitability of the investigator: [Declaration of interest template](#)
- Financial and other arrangements: [Compensation for trial participants template](#)
- Compliance with use of Biological samples: [Compliance with Spanish rules for human biological samples](#)

3. Documentación

¿Como nombro los documentos?

[Best Practice Guide for Sponsors of document naming in CTIS](#)

CTCG best practice guide naming of documents, version 2.0¹, 9 March 2023

CTCG has set up a best practice for the naming of documents in CTIS. The purpose of this naming convention is to provide a harmonised structured overview of the documents in the clinical trial application dossier, in alignment with the document types referred to in the sections of CTR annex I and II. Please note that this naming convention refers to the document title in CTIS, and that the documents as uploaded into CTIS may have any desired filename, except for the special characters (/,.,;|[]). Each document uploaded in CTIS, especially multiple documents of the same document type, must have a CTIS title that is unique, self-explanatory including relevant identification when applicable, short and concise (not exceeding 100 characters).

Incluir el **EU CT Number sin los 2 últimos dígitos**, ya que estos identifican las modificaciones.

3. Documentación

Transparency rules

Protection of personal data and commercially confidential information

Page contents

Also on this topic

Handbook for clinical trial sponsors

Evaluation timelines

Additional reference materials for CTIS users

Training and information events

Master trainers

Protection of personal data and commercially confidential information

Related EU legislation

Related content

Contact point

Protection of personal data and commercially confidential information

Guidance is available for CTIS users on the protection of **personal data** and **commercially confidential information** while using CTIS.

This aims to assist sponsors and authorities in fulfilling the **transparency** obligations set out in the [Clinical Trials Regulation](#).

The guidance is based on the outcome of a public consultation concluded in 2022. It will apply until the revised CTIS transparency rules are implemented, which is expected in the second quarter of 2024.

The European Commission, EMA and the Heads of Medicines Agency (HMA) have also prepared a questions and answers document on data protection.

Both documents can be found on the Accelerating [Clinical Trials](#) in the EU website, at the link listed below.

For more information, see:

- [Clinical Trials Information System: Processing of personal data](#)
- [Development of the Clinical Trials Information System: Transparency requirements](#)
- [Accelerating Clinical Trials in the EU \(ACT EU\): Implementation of the Clinical Trials Regulation](#)

Documents on ACT EU website:

- [Guidance on transparency rules in CTIS](#)
- [Annex I - Guidance document on how to approach the protection of personal data and commercially confidential information while using the Clinical Trials Information System \(CTIS\)](#)
- [Annex II](#) [Annex II to the guidance document of protection of personal data and commercially confidential information while using CTIS](#)
- [Q&A on the protection of commercially confidential information and personal data while using CTIS](#)
- [User guide: Revised CTIS transparency rules, Interim period & Historical trials](#)

3. Documentación

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Page contents

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- **Mecanismos para hacerlo**
- **Datos personales e información confidencial que deben ocultarse**

3. Documentación

Transparency rules - Mecanismos

Documentos

- **For publication:** se ocultan los datos personales o información confidencial y serán los documentos que se hagan públicos.
- **Not for publication:** en el que las agencias evaluadores y comités podrán conocer esta información.

Deferral o aplazamiento

- Depende de la categoría del EC

Grouping	Category 1 FIH, PK/PD, BE/BA, Bio similarity	Category 2 Phase II and III	Category 3 Phase IV Low interventional CT
• Main Characteristics	Publication of final summary of results		
• Notifications	Publication of final summary of results		
• Subject information sheet	Up to 7 years after the end of the trial in EU/EEA	Up to 5 years after the end of the trial in EU/EEA	
• Protocol	Up to 7 years after the end of the trial in EU/EEA	Up to 5 years after the end of the trial in EU/EEA	Publication of final summary of results
• IMPD S&E sections and Investigator Brochure	Up to 7 years after the end of the trial in EU/EEA	Up to 5 years after the end of the trial in EU/EEA	Publication of final summary of results
• Responses to RFI	Up to 7 years after the end of the trial in EU/EEA	Up to 5 years after the end of the trial in EU/EEA	Publication of final summary of results
• Clinical trial results summary for an intermediate data analysis	1. 12 months after interim analysis date 2. up to 30 months after the end of the trial in the EU/EEA		
• Clinical trial results summary and lay person summary	1. 12 months after the end of trial date in the EU/EEA 2. Up to 30 months after the end of trial in the EEA		

3. Documentación

Transparency rules - Información que hay que ocultar

Datos personales

- Si son **necesarios durante la revisión científica y regulatoria**, se proporcionará en la versión *“not for publication”*.
- En la versión *“for publication”* deben ser anónimos, **excepto** el nombre y apellido investigador/es/as principal/es, persona responsable de la emisión de la idoneidad de las instalaciones, del representante legal del promotor y de las personas que firman los informes del EC.
- Las **firmas no deben revelarse** en la versión *“for publication”*.

Información comercial confidencial (ICC)

- Preferentemente, mecanismo de **aplazamiento**.
- Alternativamente, ocultar la ICC en la versión del documento *“for publication”* aunque, en general, los datos incluidos no deben considerarse confidenciales.
- En el documento *“not for publication”* se marcará el texto que se consideran CCI.

3. Documentación

Transparency rules

Page contents

Also on this topic

Handbook for clinical trial sponsors

Evaluation timelines

Additional reference materials for CTIS users

Training and information events

Master trainers

Protection of personal data and commercially confidential information

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Table I – Data and documents uploaded by the trial sponsor to identify easily data and documents that might contain personal data.
Table III – Trial categories

3. Documentación

Transparency rules

Page contents

Also on this topic

Handbook for clinical trial sponsors

Evaluation timelines

Additional reference materials for CTIS users

Training and information events

Master trainers

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Structured data – what will be published & when
Documents – what will be published & when

3. Documentación

¿Cómo se suben los documentos?

Seleccionar: “Add document”

- Por defecto, la **primera version** del documento subida es “for publication”
- Después de incluir la version “for publication”, se da la posibilidad de subir la version “not for publication” seleccionando el icono “+” que esta al lado de la primera version

Suitability of the investigator

Investigator CV *:

CV_for publication     

English · Investigator CV (for publication) · System version 1.00
· Version 1 · 20/02/2024

CV_not for publication    

English · Investigator CV (not for publication) · System version 1.00
· Version 1 · 20/02/2024

Add document

4. Notificaciones y Modificaciones

- CTIS: Clinical Trials Information System -

4. Notificaciones y Modificaciones

Notificaciones del ciclo del EC

The screenshot displays the 'Curso CTIS' interface. At the top, it shows the course title 'Curso CTIS' and a status 'Pending' with a reference number '2024-512068-76-00' and 'Proposed RMS: Spain'. Below this is a navigation bar with tabs: 'Summary', 'Full Trial Information', 'Notifications' (highlighted with a red box), 'Trial results', 'Corrective measures', 'Ad Hoc assessments', and 'Users'. The main content area is titled 'Trial & Recruitment Periods' and contains two groups of buttons: 'Start Trial', 'End Trial', 'Restart Trial', and 'Temporary Halt' (all highlighted with red boxes); and 'Start Recruitment', 'End Recruitment', and 'Restart Recruitment' (all highlighted with red boxes). Below the buttons is a table with columns for 'Trial' and 'Recruitment'. The 'Trial' section includes a 'Select all' checkbox, 'Current status', 'Start date', 'Temporary Halt', 'Restart', and 'End (or early termination)'. The 'Recruitment' section includes 'Start', 'Restart', and 'End'. At the bottom, there is a section for 'EEA and Global' with fields for 'End of trial EEA', 'Anticipated date of summary of results', 'End of trial Global', 'Submitted on', and 'Submission of results'.

Este tipo de notificaciones deberán realizarse dentro de los **15 días** siguientes al inicio del evento.

4. Notificaciones y Modificaciones

Notificaciones circunstanciales

Unexpected events

Acontecimiento inesperado **que pueda influir en la relación beneficio-riesgo** del medicamento, o que pueda dar lugar a **cambios en la administración de un medicamento** o en la **realización general** de un EC. Notificar sin demoras indebidas y a más tardar dentro de los **15 días siguientes** a la fecha en que el promotor tuvo conocimiento del evento.

Serious breach

Incumplimiento grave que pueda afectar de manera significativa a la **seguridad y los derechos de un sujeto** o a la **fiabilidad y solidez de los datos**. Notificar sin demoras indebidas y a más tardar en un plazo de **7 días** a partir de la fecha en que el promotor tuvo conocimiento del incumplimiento.

Urgent Safety Measure

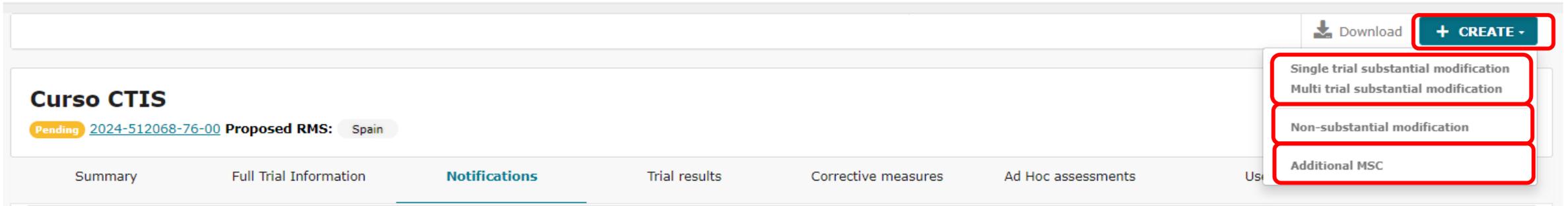
Medidas urgentes de seguridad que se han tomado para proteger a los sujetos. Notificar sin demora indebida y a más tardar dentro de los **7 días** siguientes a la fecha en que se tomaron las medidas.

3rd Country Espectorate Inspection

Presentación de **informes de inspección de las autoridades de terceros países** relacionados con el EC.

4. Notificaciones y Modificaciones

Modificaciones del EC



Curso CTIS

Pending 2024-512068-76-00 Proposed RMS: Spain

Summary Full Trial Information **Notifications** Trial results Corrective measures Ad Hoc assessments Usi

Download + CREATE -

- Single trial substantial modification
- Multi trial substantial modification
- Non-substantial modification
- Additional MSC

[Q&A Document – Regulation \(EU\) 536/2014](#)

Anexo IV “**Classification of changes to ongoing clinical trials**”

¿Qué se considera Modificación Sustancial y a qué parte del EC afecta?

Substantial modification: Se notifica como modificación sustancial

Non-substantial modification importantes para la supervisión del EC: Se notifican como modificación no sustancial.

Non-substantial modification: Modificaciones no sustanciales que no cumplen los criterios anteriores y que se acumulan para notificarlas en la siguiente modificación sustancial.

5. Transición EECC

- CTIS: Clinical Trials Information System -

5. Transición EECC

Cómo solicitar la transición:

- Crear el borrador de un **EC nuevo**
- Indicar que es un **EC a transicionar**. Proceso de evaluación “express”

Clinical Trials

Enter EU CT number or use advanced search

[Trial Advanced Search](#)

[Application Advanced Search](#)

Create new trial

Full title (English)*

Search organisation

Name starts with ID starts with City starts with Country All

ID	Name	Address	City	postCode	country	phone	email	actions
----	------	---------	------	----------	---------	-------	-------	---------

Transition Trial

5. Transición EECC

Cómo solicitar la transición:



The screenshot shows a dialog box titled 'EudraCT Trial Search'. It features a search input field labeled 'EUDRA CT number' with a yellow border. Below the input field are two buttons: 'CLEAR' and 'SEARCH'. The 'SEARCH' button is highlighted in blue. Below the input field, the text 'Search result' is visible. At the bottom right of the dialog, there are two buttons: 'Cancel' and 'Add EudraCT Trial', both highlighted in blue.

5. Transición EECC

EC nacional: documentos

- **Cover Letter** (template)
- **Compliance with Regulation** (template)
- **GDPR Statement** (template) *Part-II*
- **Patient recruitment procedure** (template) *Part-II*
- **Part-I**. Las últimas versiones autorizadas de:
 - Protocolo
 - IB/IMPD
 - Documentos relativos a NCF
 - Documentos del medicamento auxiliar
- **Part-II**. Las últimas versiones autorizadas de HIP-CI, seguro, memoria económica, CVs IPs, Idoneidades de las instalaciones centros, idoneidad del investigador....

5. Transición EECC

Annex Cover Letter Template vs. 3.0 adopted at CTCG plenary November 12 2023

CTCG Best Practice Guide for sponsors of multinational clinical trials under Directive 2001/20/EC that will transition to Regulation (EU) No 536/2014

The following information should be provided in the cover letter of applications for transitioning a Clinical Trial authorised under the Directive 2001/20/EC (CTD) to the Clinical Trial Regulation (CTR)¹

- Indicar que se trata de una transición, declaración de que cumple criterios para transición y cuál es el CEIm de referencia:

“The CT above referenced is a CT in line with the requirements for transitional trials, from Directive 2001/20/EC (CTD) to the Regulation (EU) No 536/2014 (CTR), and is still in line with the authorization given under the CTD.

All documents for Part I and Part II, respectively, have been approved by the MSC (Spain) under CTD and are described in detail below. The EC responsible for this trial is the CEIm Hospital Clínico San Carlos”.

5. Transición EECC

- Listado de versiones actuales de **Part-I**, aprobadas bajo CTD:

Documents included in the Part I transition dossier approved in the MSC under the CTD

Member State	Type of document	Version and Date of the document approved per Member State	Date of Approval		Comment
			National Competent Authority	Ethics Committee	
SPAIN					

- Listado de versiones actuales de **Part-II**, aprobadas bajo CTD:

Documents included in the Part II transition dossier approved in the MSC under the CTD

Member State	Type of document	Version and Date of the document approved per Member State	Date of Approval		Comment
			National Competent Authority	Ethics Committee	
SPAIN					

5. Transición EECC

- Listado de versiones actuales de Parte I, aprobadas bajo el CTD:

Documents included in the Part I transition dossier approved in the MSC under the CTD

El RMS comprobará si se han presentado el GDPR statement y la lista de versiones aprobadas, pero no comprobará la lista en detalle.

Se trata de una VALIDACIÓN, no de una EVALUACIÓN.

- Listado de versiones actuales de Parte II, aprobadas bajo el CTD:

Documents included in the Part II transition dossier approved in the MSC under the CTD

Member State	Type of document	Version and Date of the document approved per Member State	Date of Approval		Comment
			National Competent Authority	Ethics Committee	
Spain					

6. Otros aspectos a tener en cuenta

- CTIS: Clinical Trials Information System -

6. Otros aspectos a tener en cuenta

¿CTIS envía notificaciones?

CTIS **NO envía notificaciones** por email, tenemos que **entrar todos los días** para confirmar si ya tenemos acceso, si nos han enviado aclaraciones, etc... ¡OJO! Los plazos para contestar **aclaraciones (RFI)** son entre **7 y 15 días naturales** → **SIN PRÓRROGA**

¿Qué pasa con REec?

Hay que contactar con la AEMPS ([reec incidencias@aemps.es](mailto:reec_incidencias@aemps.es)) indicando quien será el responsable de la actualización de la información.

6. Otros aspectos a tener en cuenta

¿Qué es XEVMPD?

Extended EudraVigilance Medicinal Product Dictionary

Todas las sustancias tienen que estar registradas en esta BD. En caso de utilizar una sustancia nueva no registrada, es necesario hacer una formación ([XEVMPD training](#))

- **Short training** (1 día): Promotores comerciales y no comerciales de EECC **350 €**
- **E-learning** (videos and step-by-step guides): requiere una evaluación (3 intentos) **Gratuita**

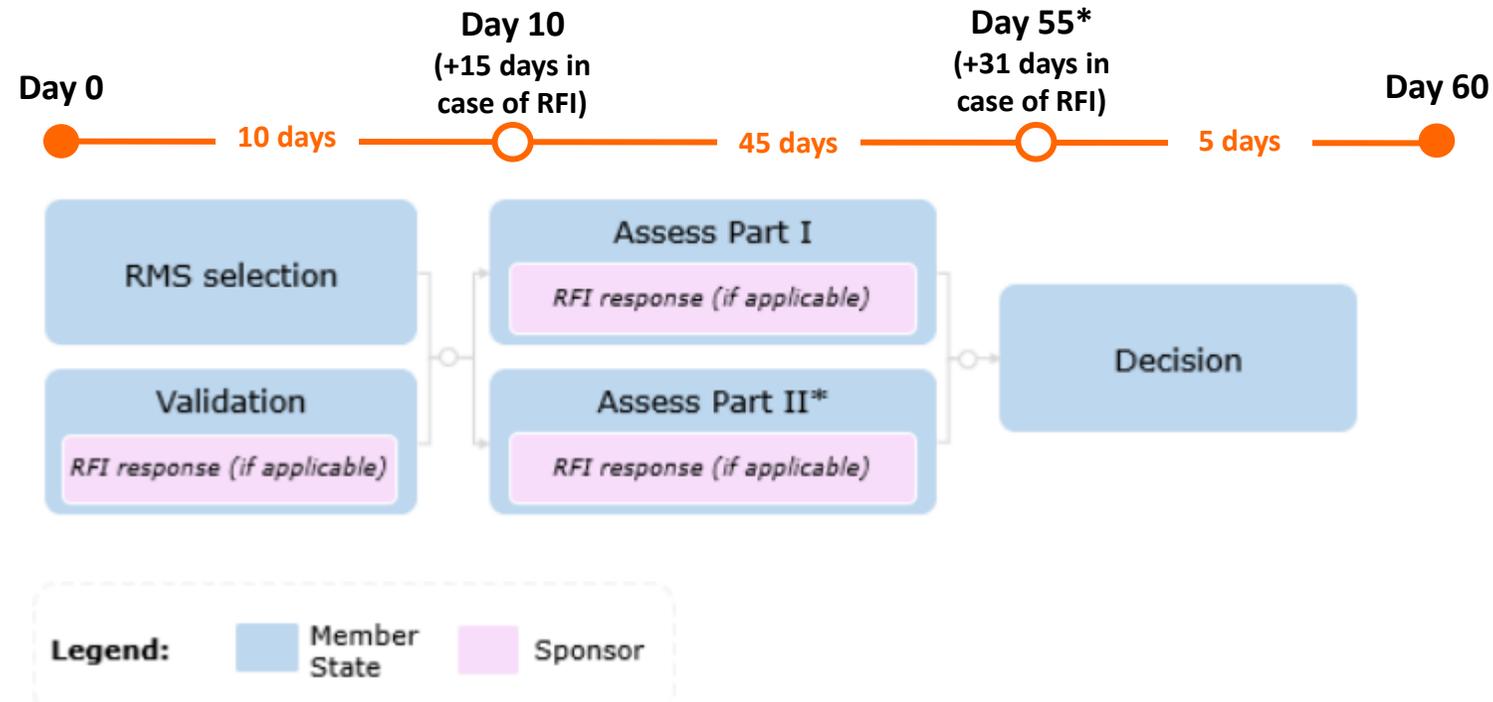
*Próxima convocatoria:
12 – 13 Junio 2024
(repetición cada 4 meses)*

Newsletter CTIS

Para suscribirse a los **CTIS Highlights**, contactar con ct.communication@ema.europa.eu

6. Otros aspectos a tener en cuenta

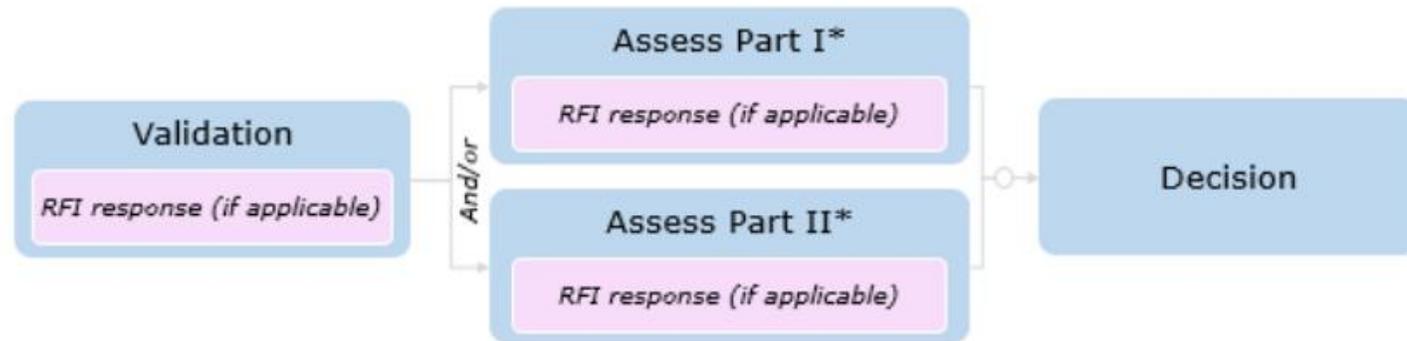
Tiempos de evaluación: autorización inicial



(*) Estos plazos no pueden ampliarse, salvo en el caso de un EC de **terapia avanzada** o de un medicamento definido en el punto 1 del anexo del Reglamento (CE) 726/2004, con el fin de consultar a expertos. En tales casos, el RMS podrá **ampliar la fase de evaluación un máximo de 50 días**.

6. Otros aspectos a tener en cuenta

Tiempos de evaluación: Modificación sustancial



Legend:

Member State

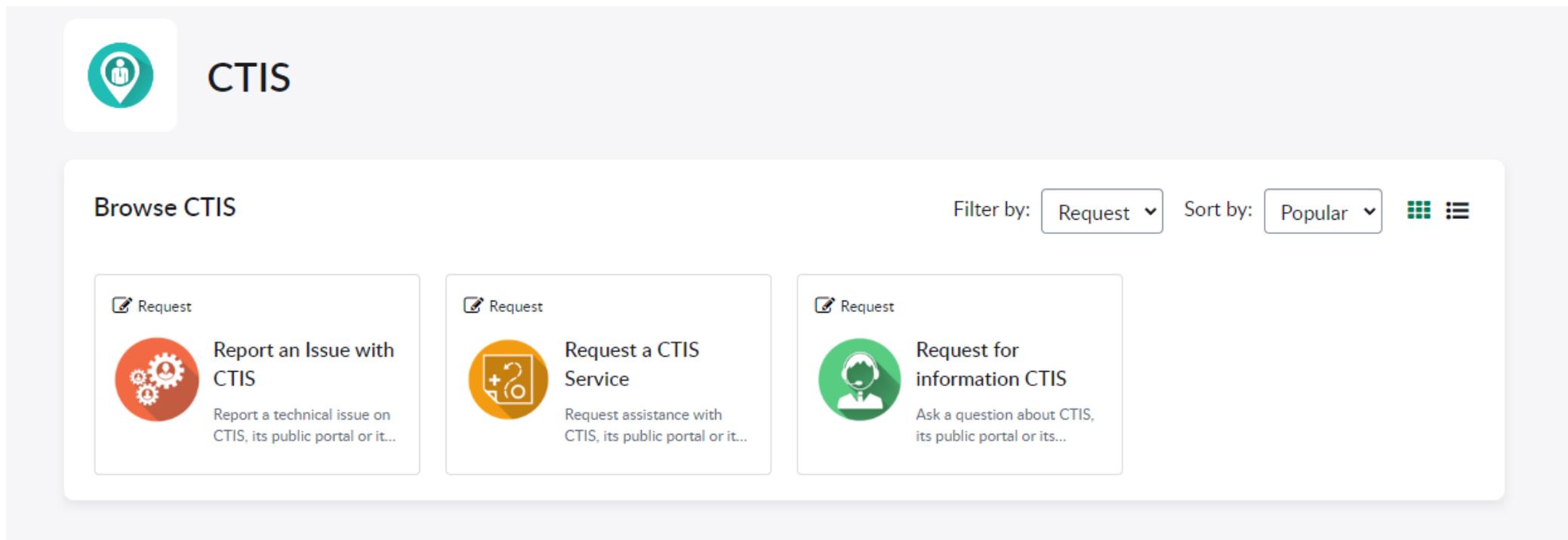
Sponsor

Entre 50 a 96 días naturales

6. Otros aspectos a tener en cuenta

¿Y si tengo algún problema?

[User support service](#)



The screenshot displays the CTIS user support service interface. At the top left, there is a CTIS logo featuring a person icon inside a location pin, followed by the text "CTIS". Below the logo, the heading "Browse CTIS" is visible. To the right of the heading, there are two dropdown menus: "Filter by: Request" and "Sort by: Popular". Further right, there are icons for a grid view and a list view. The main content area contains three request cards, each with a "Request" icon and a "Request" label. The first card is titled "Report an Issue with CTIS" and includes the subtext "Report a technical issue on CTIS, its public portal or it...". The second card is titled "Request a CTIS Service" and includes the subtext "Request assistance with CTIS, its public portal or it...". The third card is titled "Request for information CTIS" and includes the subtext "Ask a question about CTIS, its public portal or its...".

7. Recursos EMA/AEMPS

- CTIS: Clinical Trials Information System -

7. Recursos EMA

[Clinical Trials Information System: training and support](#)

Clinical Trials Information System: training and support Share

Training and supporting materials are available from the European Medicines Agency (EMA) to help users of the [Clinical Trials Information System \(CTIS\)](#) comply with their legal obligations.

[Human](#) [Clinical trials](#)

Page contents

Also on this topic

[Handbook for clinical trial sponsors](#)

[Evaluation timelines](#)

[Additional reference materials for CTIS users](#)

[Training and information events](#)

[Master trainers](#)

[Protection of personal data and commercially confidential information](#)

[Related EU legislation](#)

[Related content](#)

[Contact point](#)

For information on CTIS, the [Clinical Trials Regulation](#), and EMA's **online training modules** for CTIS users, see:

- [Clinical Trials Regulation](#)
- [Clinical Trials Information System \(CTIS\): online training modules](#)

Also on this topic

- [Clinical Trials Information System \(CTIS\): online training modules](#)

Handbook for clinical trial sponsors

The **CTIS sponsor handbook** covers priority topics identified with the help of [clinical trial sponsors](#), with references and links to further supporting materials.

It is aimed at pharmaceutical companies, contract research organisations (CROs), small and medium-sized enterprises (SMEs), academic sponsors and other organisations working on [clinical trials](#).

EMA regularly updates the handbook.



Clinical Trial Information System (CTIS) - Sponsor handbook

First published: 29/07/2021

Last updated: [10/11/2023](#)

Reference Number: EMA/923413/2022 v. 3.03

English (EN) (1.61 MB - PDF)

[View](#)

7. Recursos EMA

[Clinical Trials Information System \(CTIS\): online training modules](#)

Page contents

[Introduction to CTIS](#)

[Sponsor workspace](#)

[Common functionalities for all registered users](#)

[Authority workspace](#)

[Searching CTIS as a public user](#)

[Related EU legislation](#)

[External links](#)

[Related content](#)

[Contact point](#)

Introduction to CTIS

[Introduction to the Clinical Trials Regulation \(Regulation \(EU\) No 536/2014\) \(Module 01\)](#) ▾

[High-level overview of CTIS workspaces and common system functionalities \(Module 02\)](#) ▾

Sponsor workspace

[Create, submit and withdraw a clinical trial \(Module 10\)](#) ▾

[Respond to requests for information received during the evaluation of a clinical trial application \(Module 11\)](#) ▾

[Manage a clinical trial through CTIS \(Module 05\)](#) ▾

[How to create and submit an annual safety report and respond to related requests for information \(Module 18\)](#) ▾

[Clinical study reports submissions \(Module 13\)](#) ▾

[Search, view and download information on clinical trials and clinical trial applications \(Module 09\)](#) ▾

[CTIS for SMEs and Academia \(Module 19\)](#) ▾

Common functionalities for all registered users

[User access management \(Module 03\)](#) ▾

[Management of registered users and role matrix \(Module 07\)](#) ▾

[Data protection in CTIS \(Module 12\)](#) ▾

[Support with workload management \(Module 04\)](#) ▾

[Transitional trials \(Module 23\)](#) ▾

7. Recursos AEMPS

[AEMPS Normativa de EECC con medicamento](#)

GOBIERNO DE ESPAÑA
MINISTERIO DE SANIDAD

agencia española de medicamentos y productos sanitarios

Castellano

La AEMPS ▾ Medicamentos de uso humano ▾ Medicamentos veterinarios ▾ Productos sanitarios ▾ Cosméticos ▾ Biocidas y cuidado personal ▾

Comunicación ▾ Industria farmacéutica ▾ Profesional Sanitario ▾ Ciudadanía ▾ CNCps

Normativa sobre Ensayos Clínicos con Medicamentos de Uso Humano

Inicio > [Legislación de la Unión Europea](#) > Normativa sobre Ensayos Clínicos con Medicamentos de Uso Humano

Última actualización: 22 de mayo de 2023

Española

Europea

Guías

Publicación en Web	Título del documento
27/06/2023	CTIS Guidance for Sponsors
27/11/2023	Documento de instrucciones de la Agencia Española de Medicamentos y Productos Sanitarios para la realización de ensayos clínicos en España. Versión en español – Versión en inglés

8. FORMULARIO

- CTIS: Clinical Trials Information System -

8. Formulario

Curso CTIS 2024-512068-76-00 / Initial ID: IN **Draft**

[Acceso CTIS](#)

✓ Check 📄 Save ✕ Cancel ☁ Submit

Form |
MSCs
Part I
Part II
Evaluation
Timetable

Form details

Initial Application details



Cover letter >

¡OJO con los candados!

El candado no describe el estado del apartado, sino la **acción a realizar**



Apartado cerrado, clicar para abrir



Apartado abierto, clicar para cerrar



MUCHAS GRACIAS