IdISSC INSTITUTO de INVESTIGACIÓN SANITARIA Hospital Clínico San Carlos

IdISSC Hospital Clínico San Carlos
UICEC | UNIDAD DE INVESTIGACIÓN CLÍNICA Y ENSAYOS CLÍNCOS

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) Nº 536/2014 DEL PARLAMENTO EUROPEO Y DEL CONSEJO

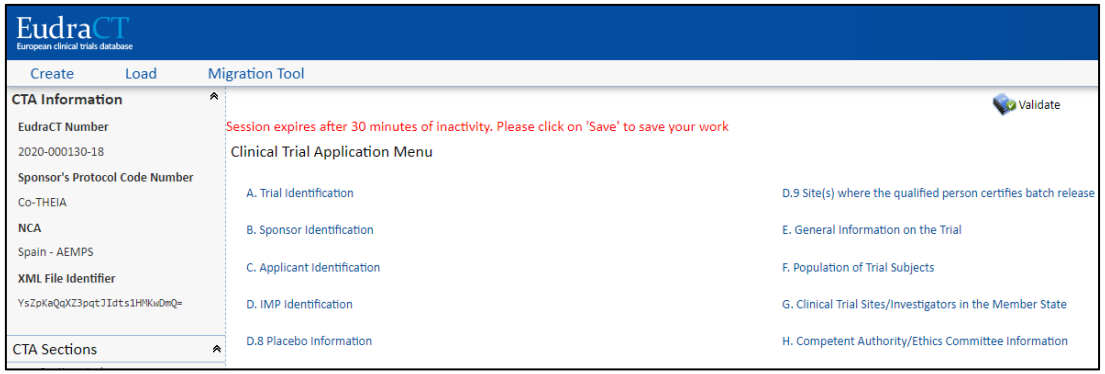
de 16 de abril de 2014

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

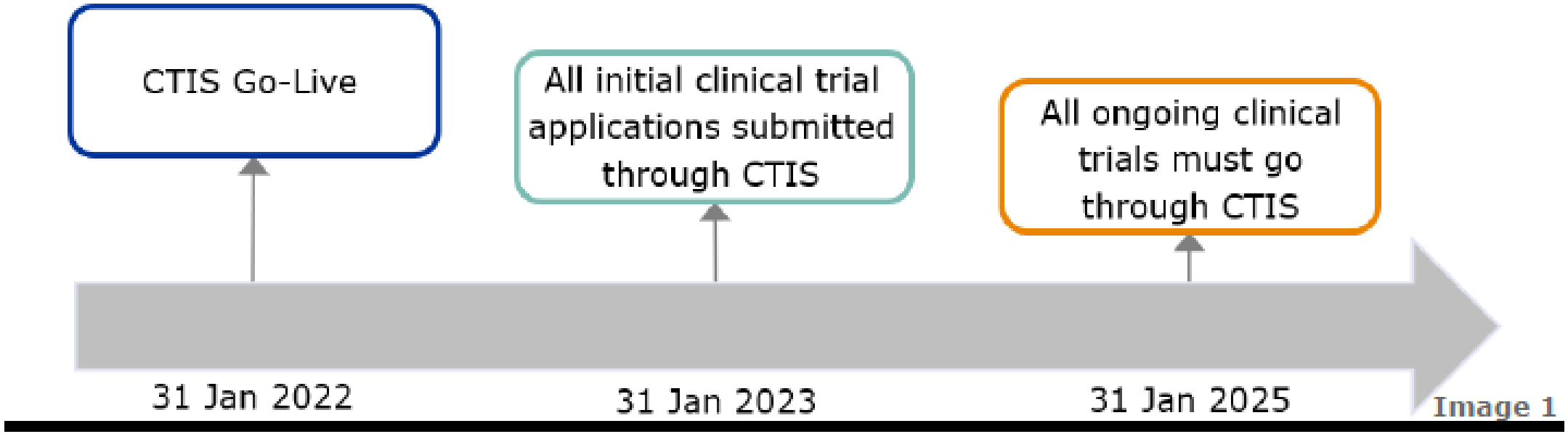
1. Introducción

Periodo Transición



1. Introducción

¿Cuándo tengo que hacerlo?

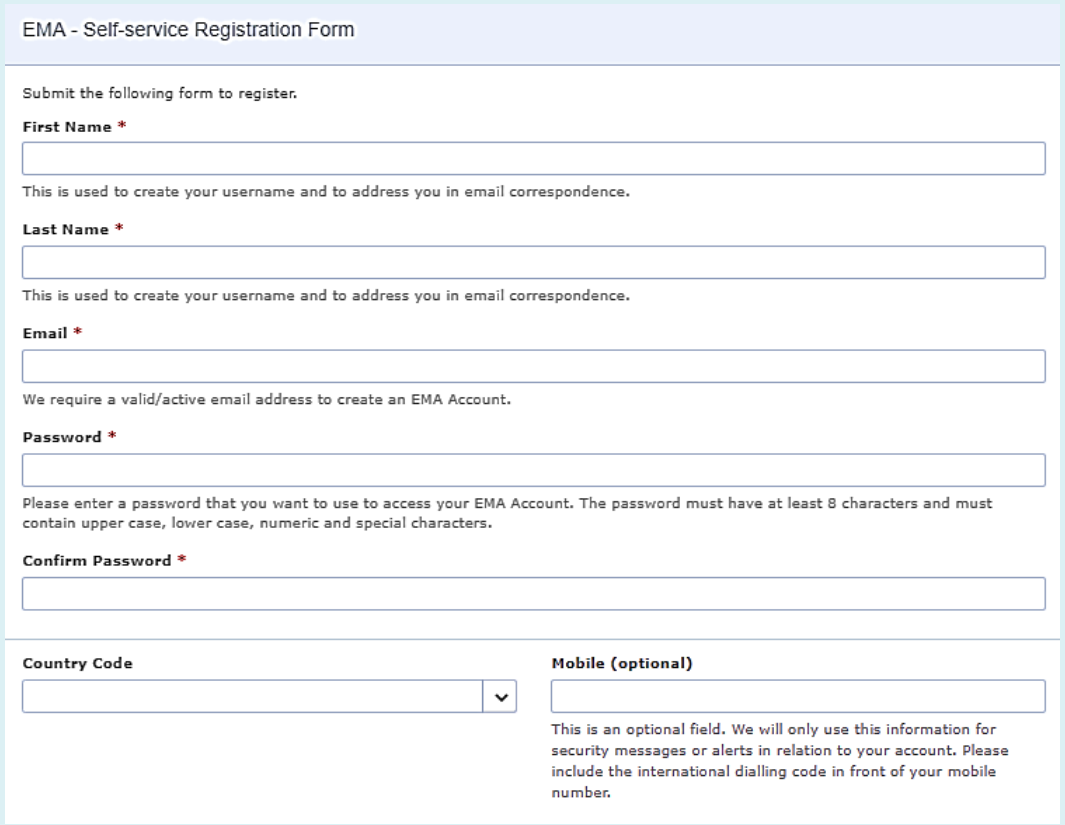


FAST TRACK para transición de EECC autorizados bajo Directiva hasta el 16 de Octubre del 2024

1. Introducción

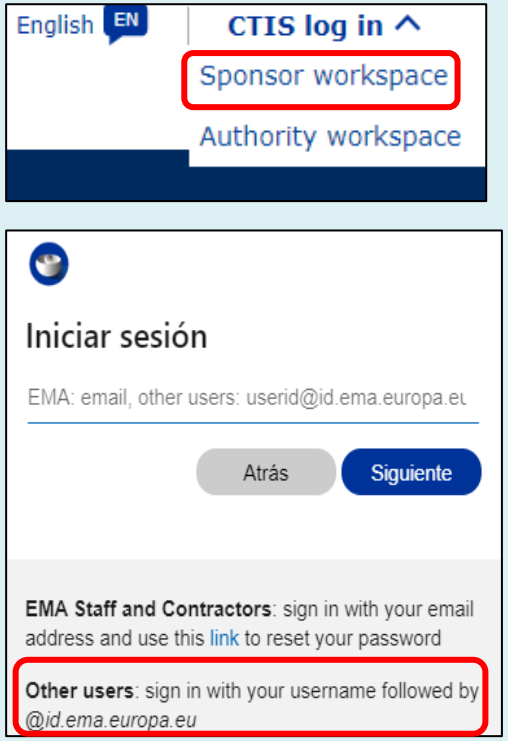
¿Cómo accedo a CTIS?

1. Usuario EMA



EMA - Self-service Registration Form

2. Acceso CTIS



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

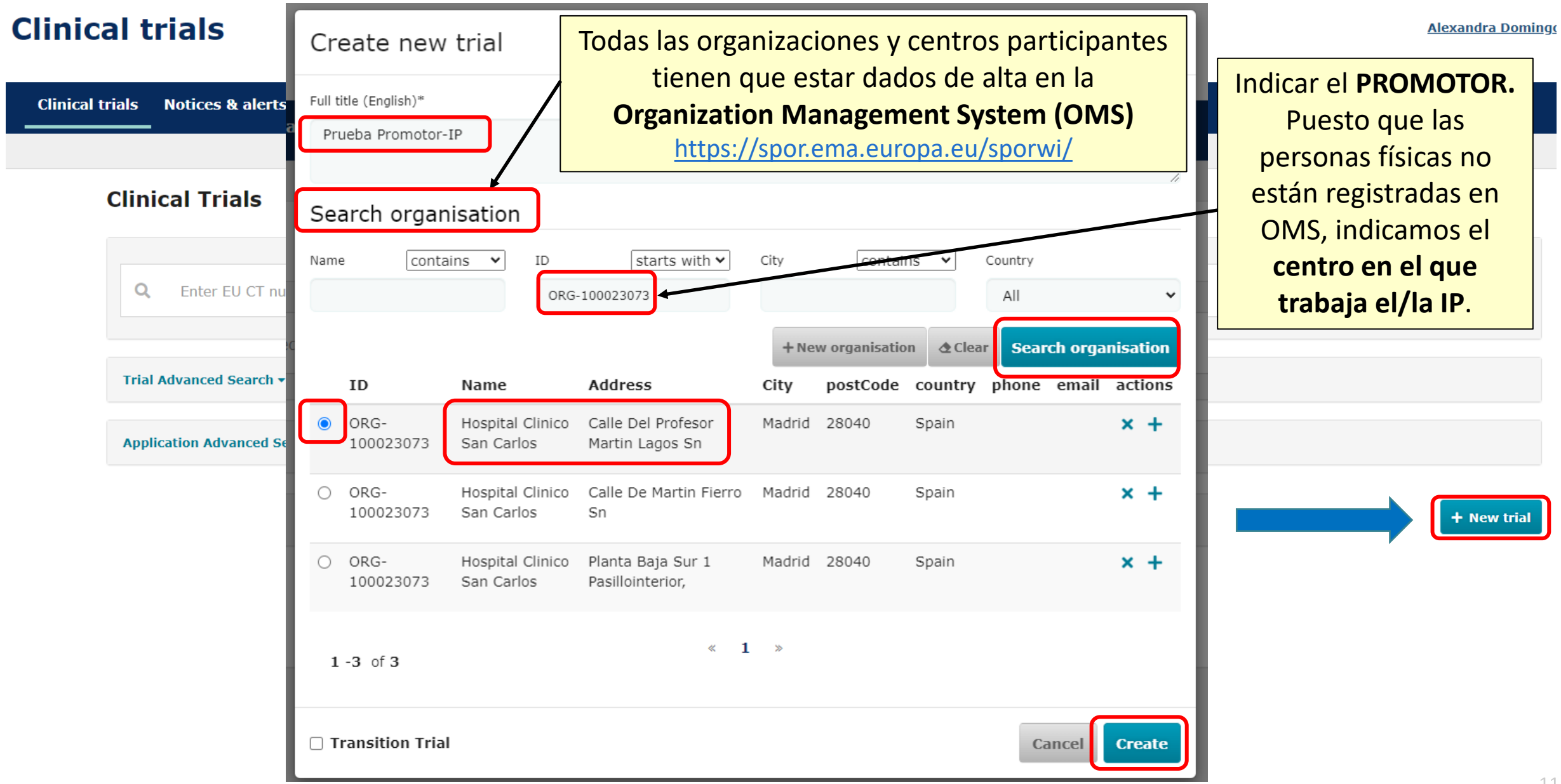
Solicitar **permiso al CEIm de referencia elegido por email*** antes de subir un estudio a CTIS para su evaluación e indicarlo en la Cover Letter.

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

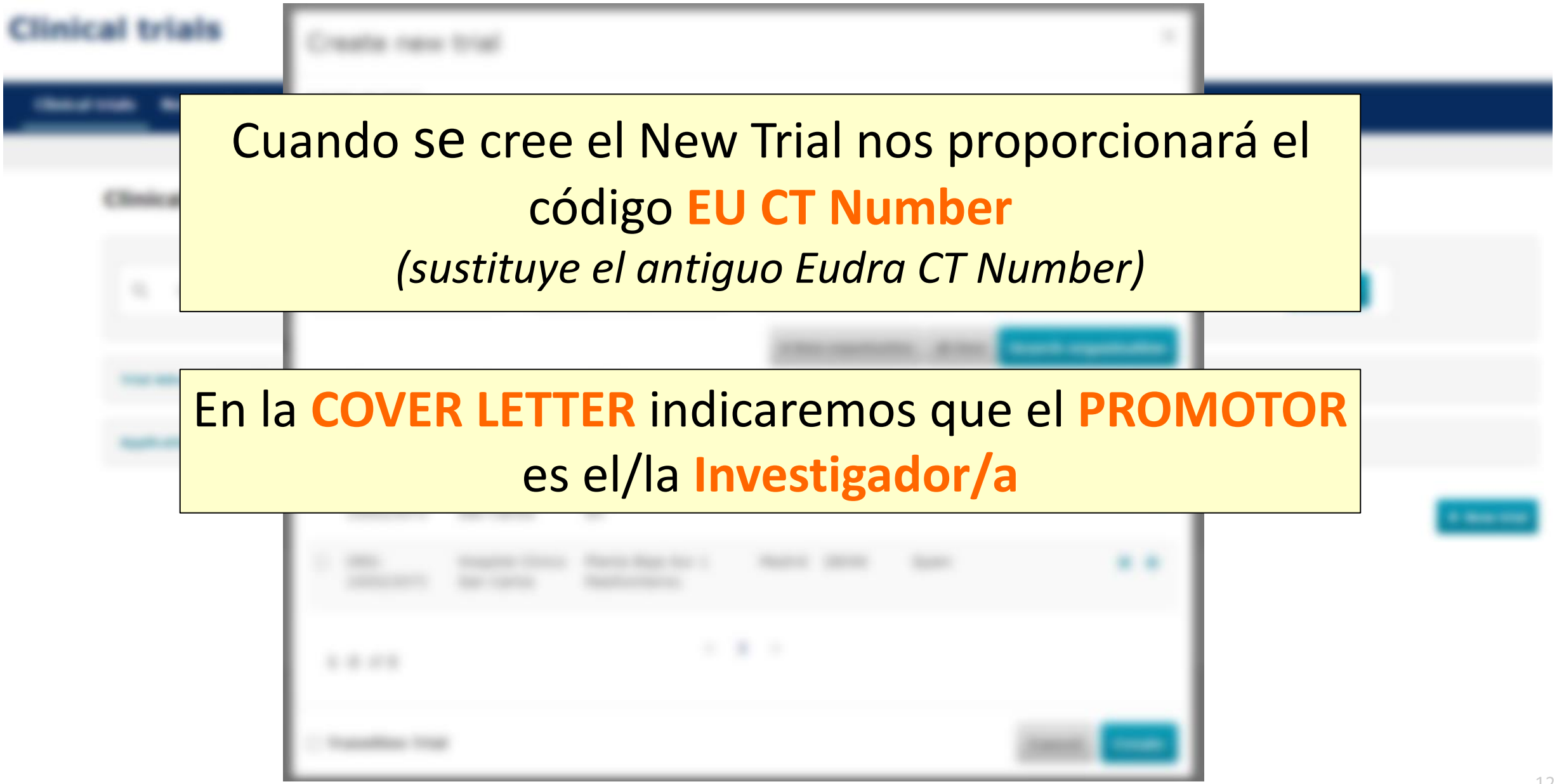
2. Nuevo Ensayo Clínico: IP Promotor

¿Cómo crear un nuevo EC?

2. Nuevo Ensayo Clínico: IP Promotor



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**

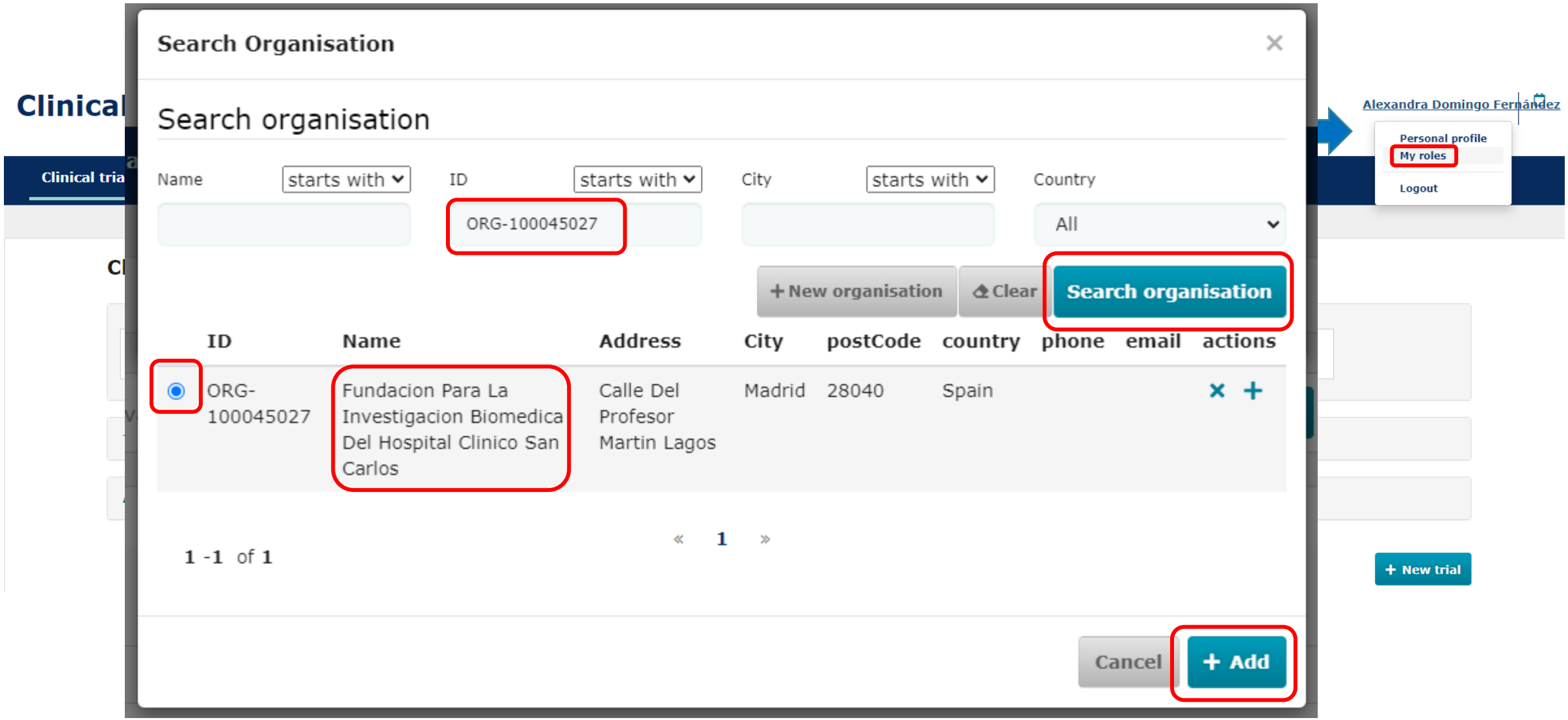
2. Nuevo Ensayo Clínico: Promotor - Organización

¿Cómo crear un nuevo EC?

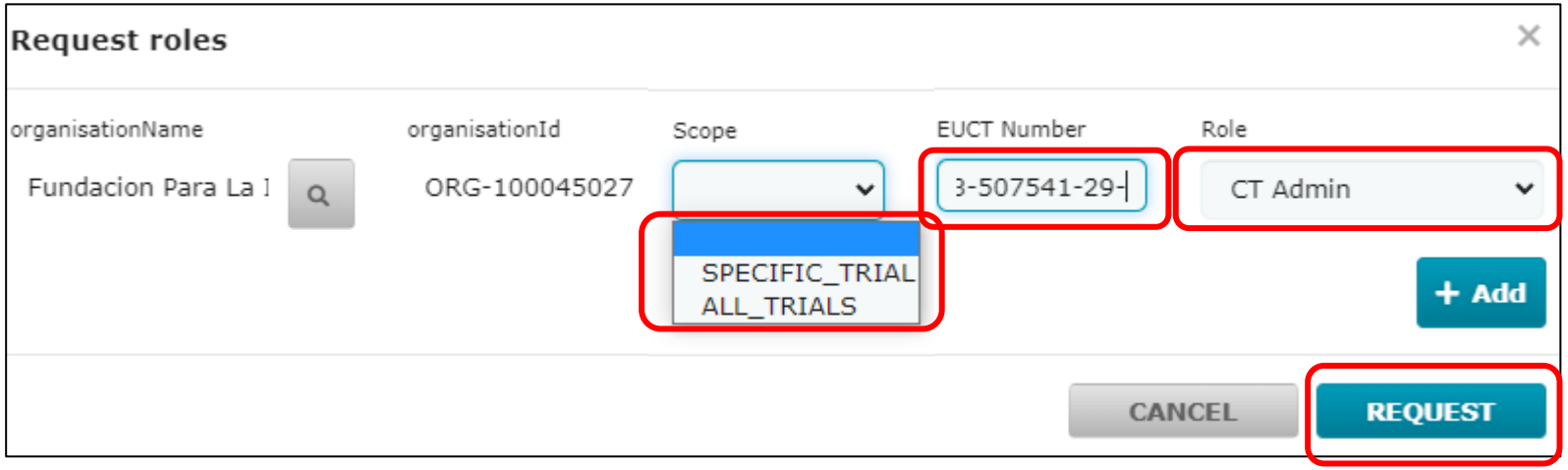
Promotor - **Organización**

Solicitar acceso al estudio

2. Nuevo Ensayo Clínico: Promotor - Organización



2. Nuevo Ensayo Clínico: Promotor - Organización



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

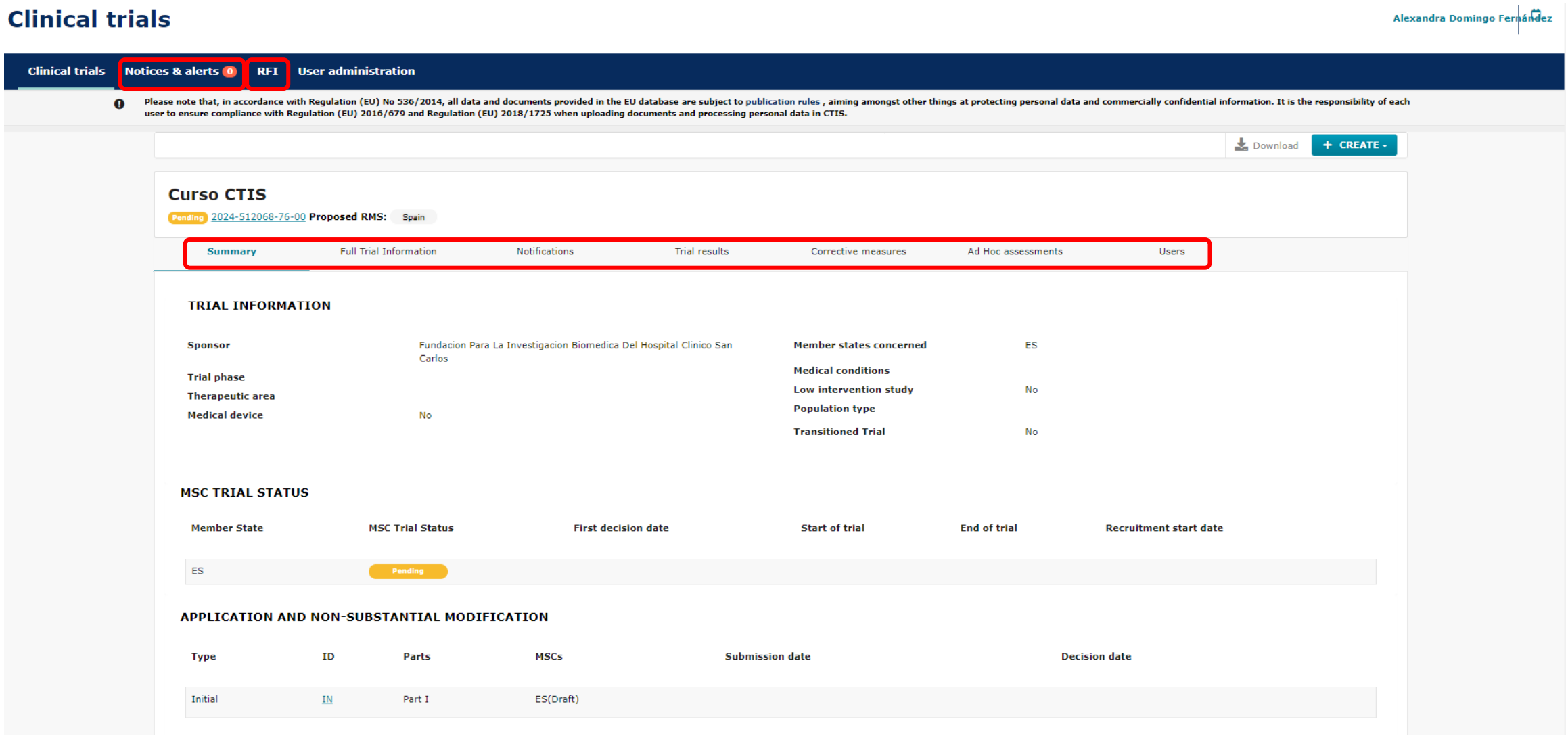
2. Nuevo Ensayo Clínico: roles

¿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**.

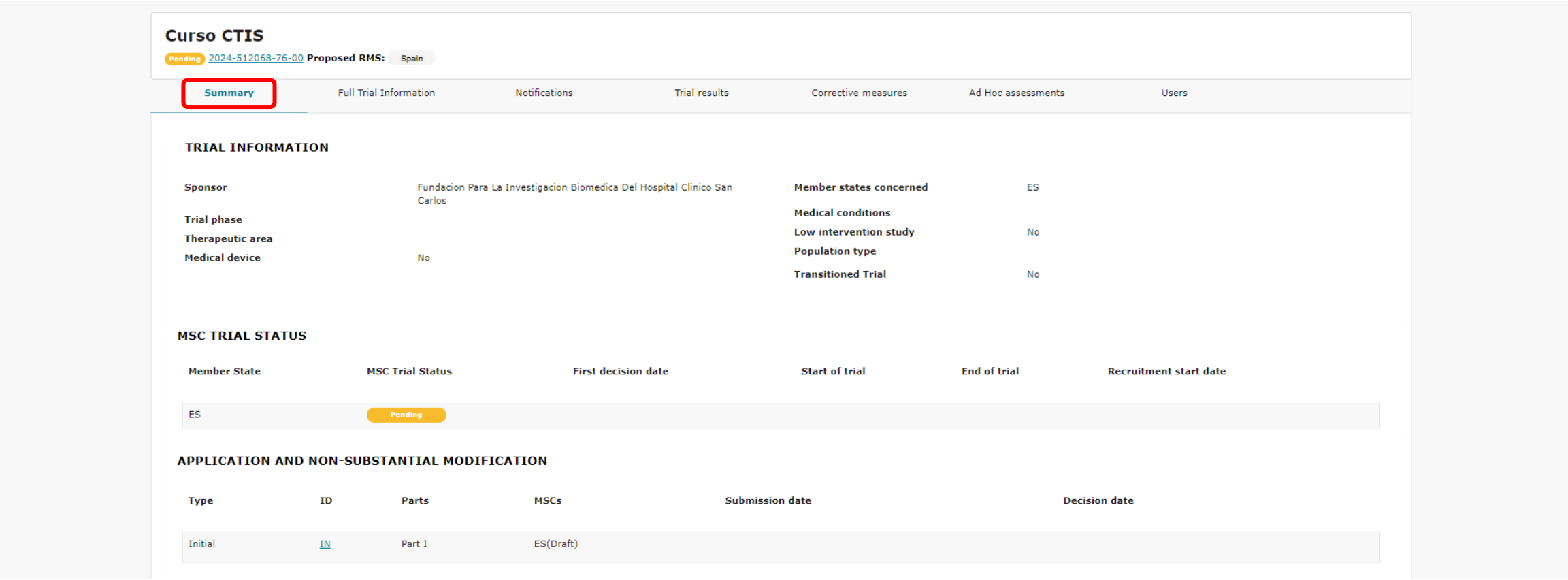
[Roles and permissions matrix summary - Sponsors workspace - CTIS Training Programme - Module 07]

2. Nuevo Ensayo Clínico: visión general



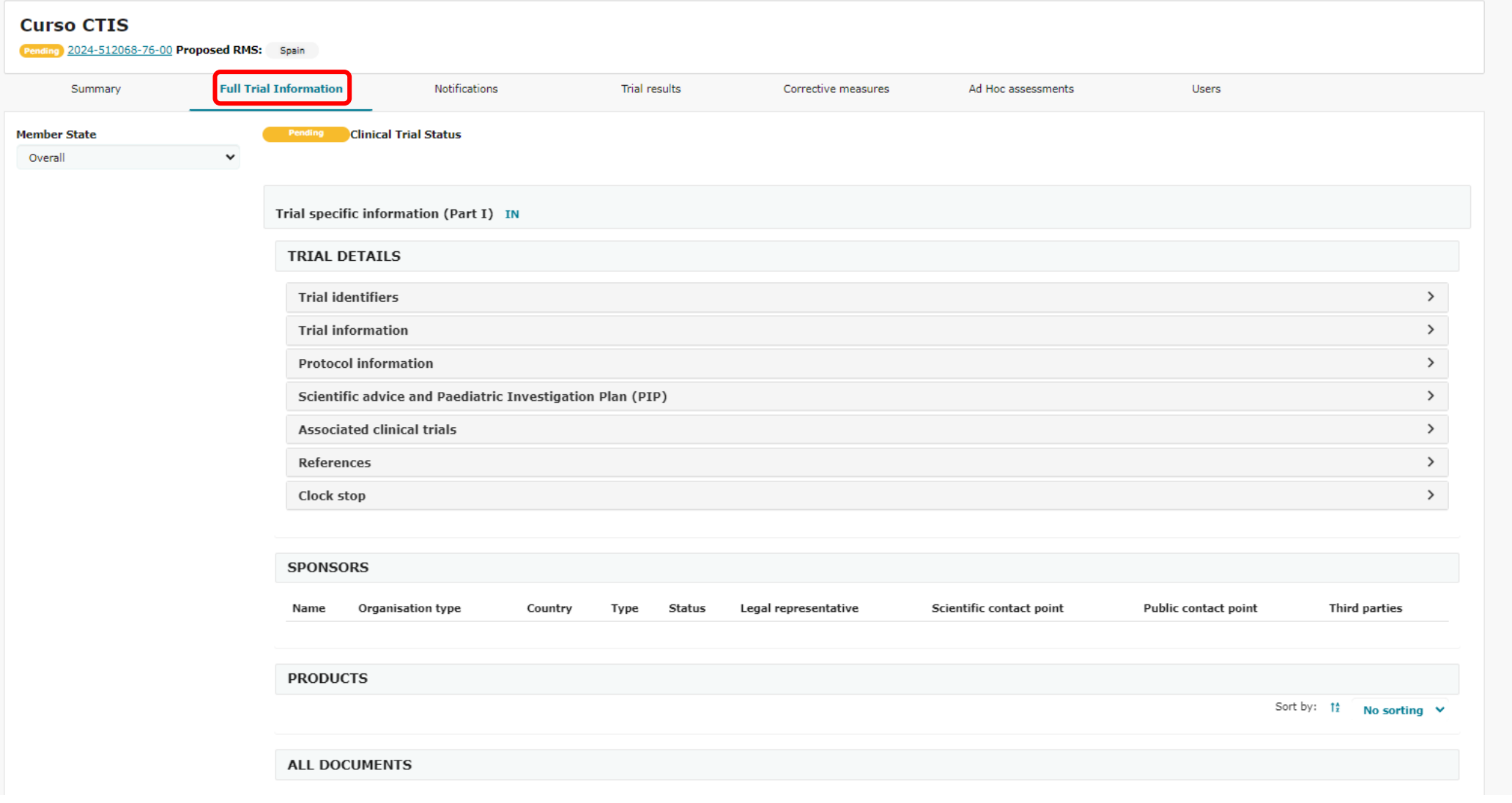
2. Nuevo Ensayo Clínico: visión general

Summary



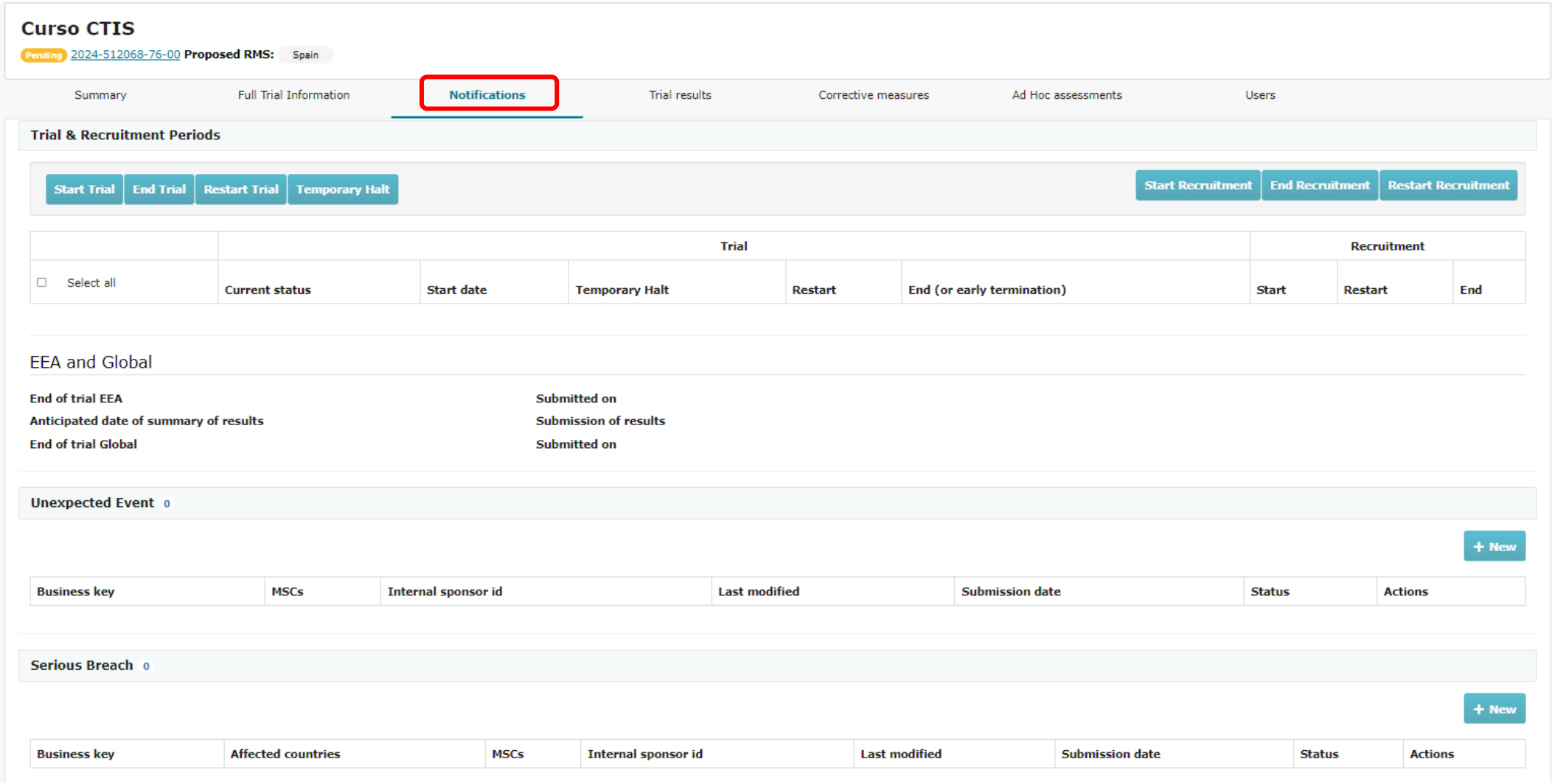
2. Nuevo Ensayo Clínico: visión general

Full Trial Information



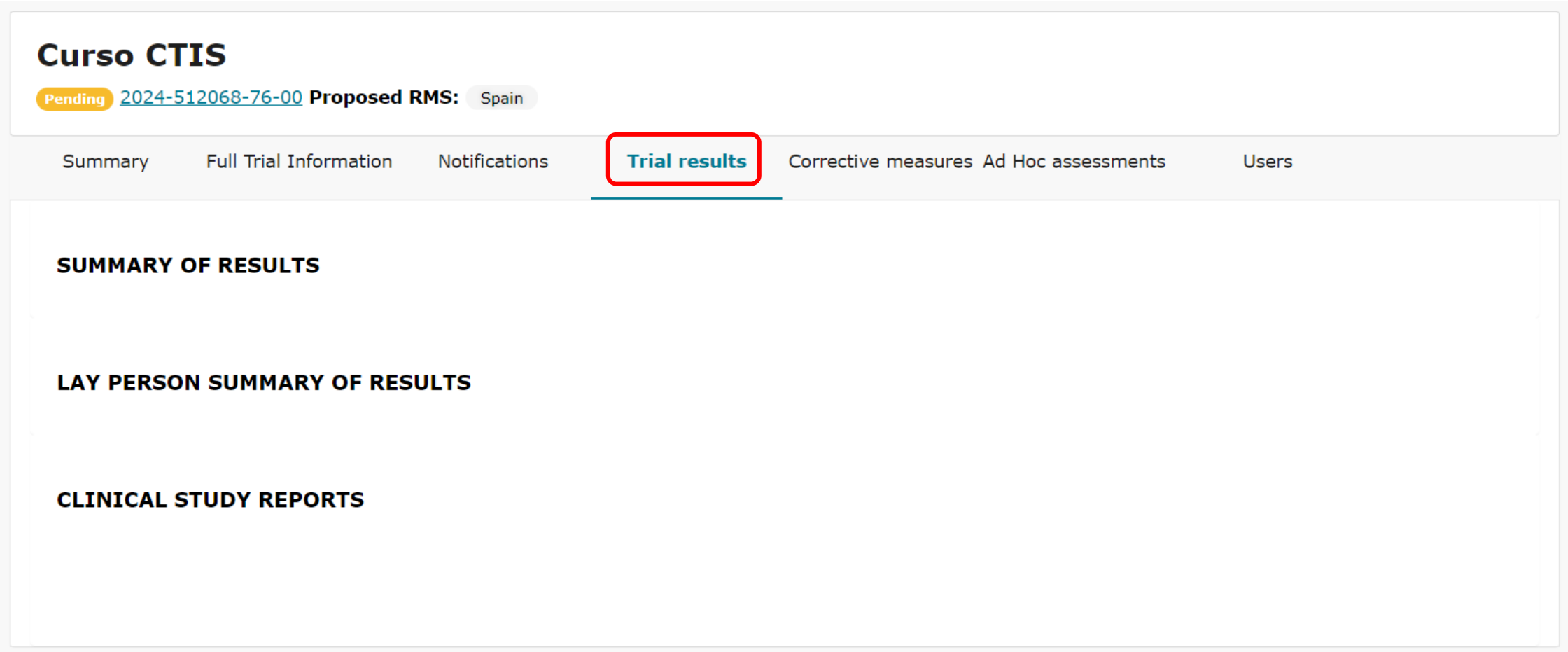
2. Nuevo Ensayo Clínico: visión general

Notifications

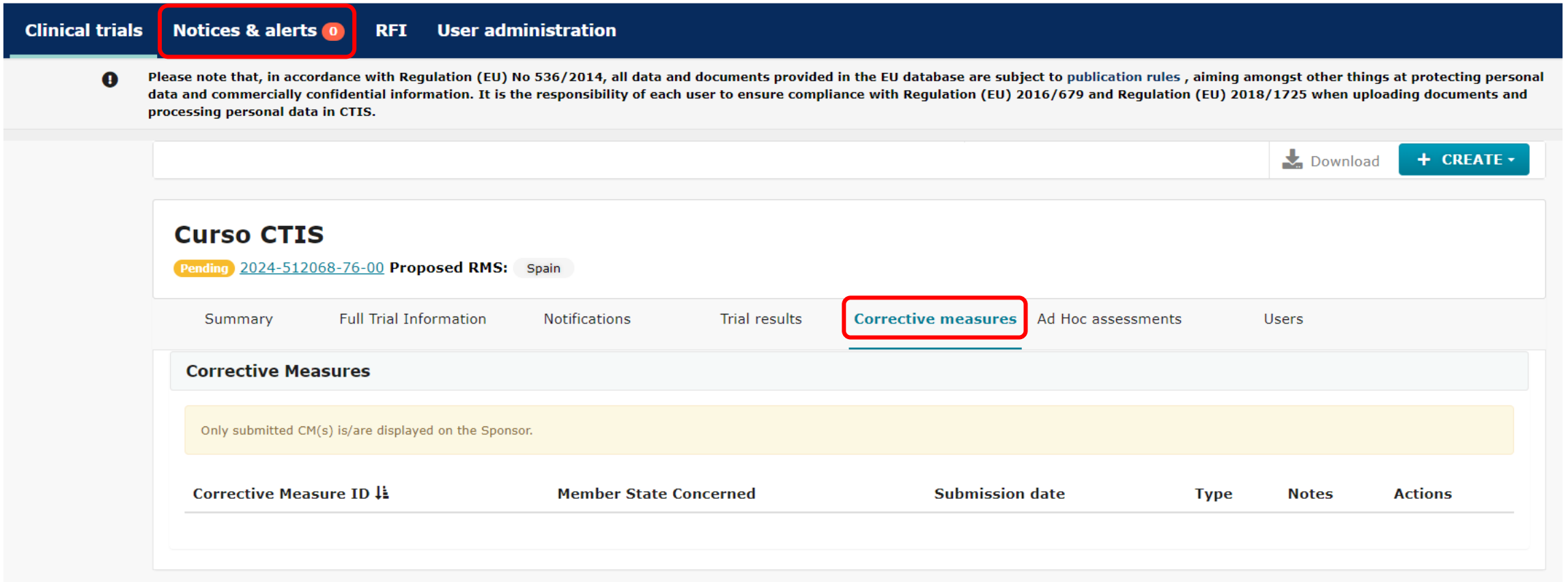


2. Nuevo Ensayo Clínico: visión general

Trial results



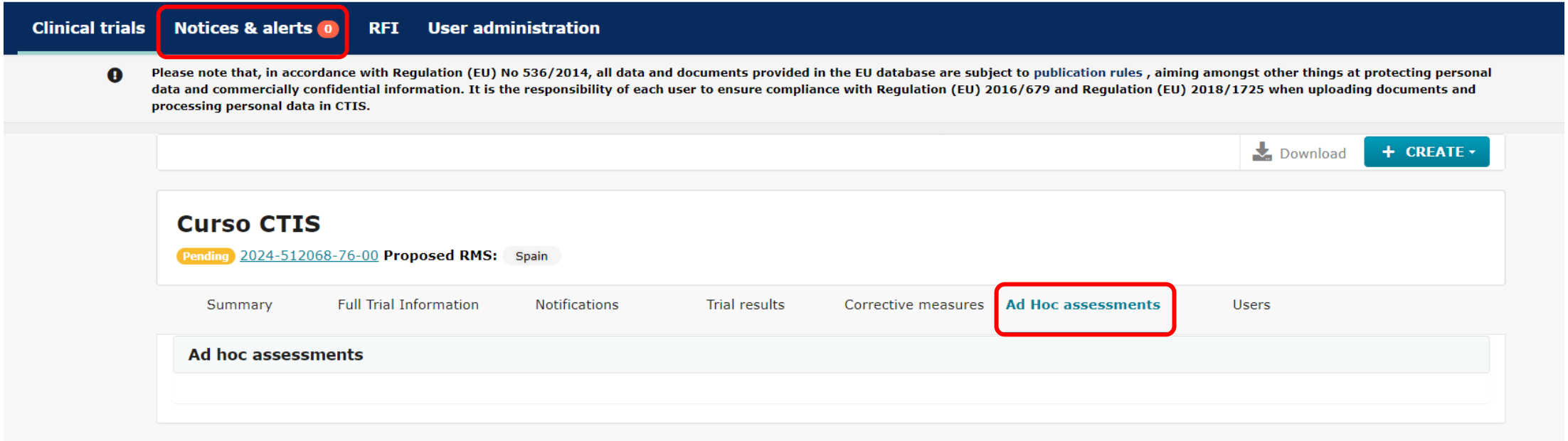
Corrective measures



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

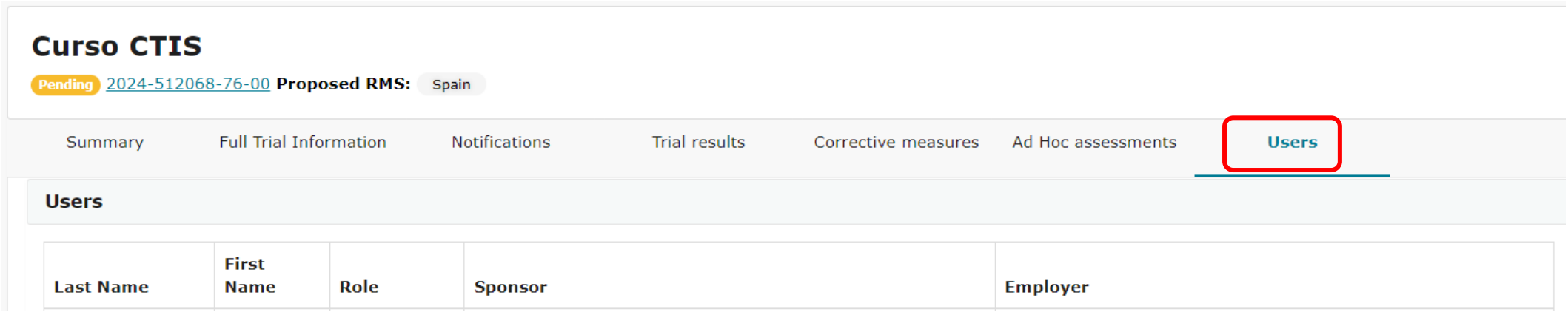
Ad Hoc assessments



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



3. Documentación

- CTIS: Clinical Trials Information System -

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 2.0[1], 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

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

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		

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.

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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

Transparency rules

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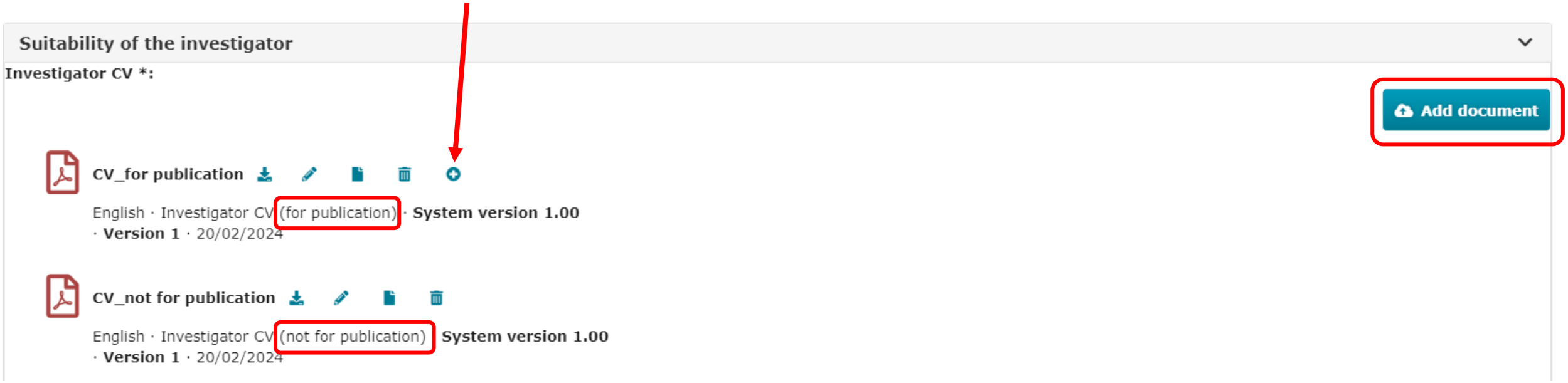
Structured data – what will be published & when
Documents – what will be published & when

3. Documentación

¿Cómo se suben los documentos?

Seleccionar: **“Add document”**

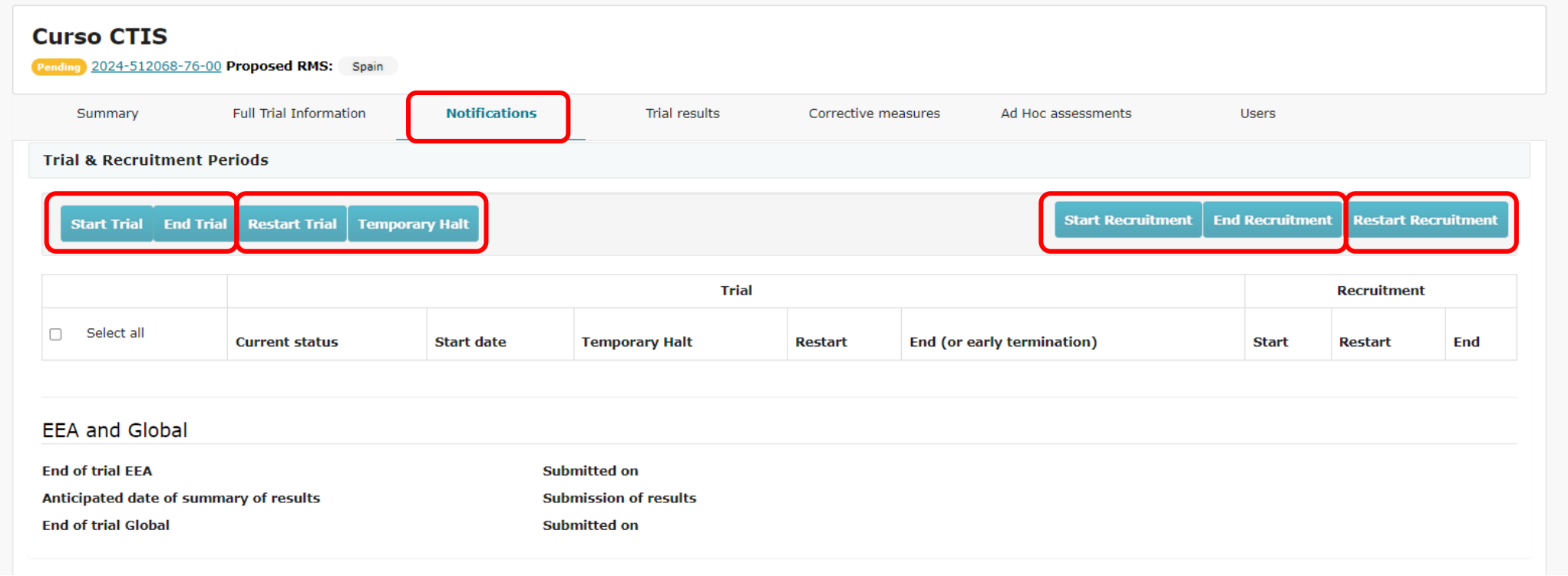
- Por defecto, la primera version del documento subida es **“for publication”**
- Después de incluir la version “for publication”, se da la posibilidad de subir la version **“not for publication”** seleccionando el icono “+” que esta al lado de la primera version



4. Notificaciones y Modificaciones

- CTIS: Clinical Trials Information System -

Notificaciones del ciclo del EC

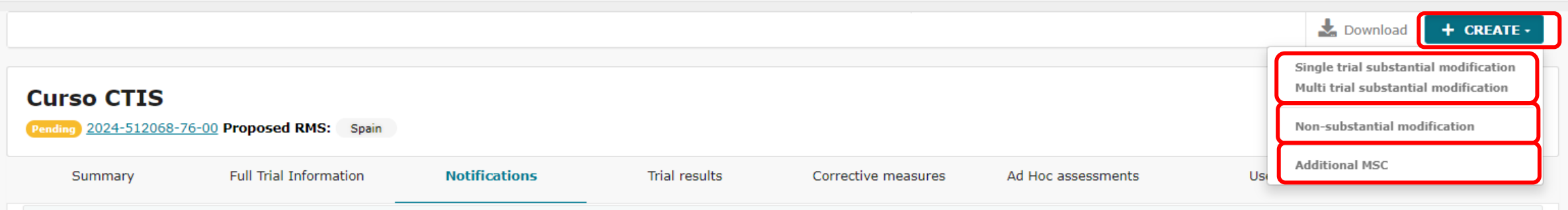


Este tipo de notificaciones deberán realizarse dentro de los **15 días** siguientes al inicio del evento.

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.

Modificaciones del EC



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?

Substancial modification: Se notifica como modificación sustancial

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

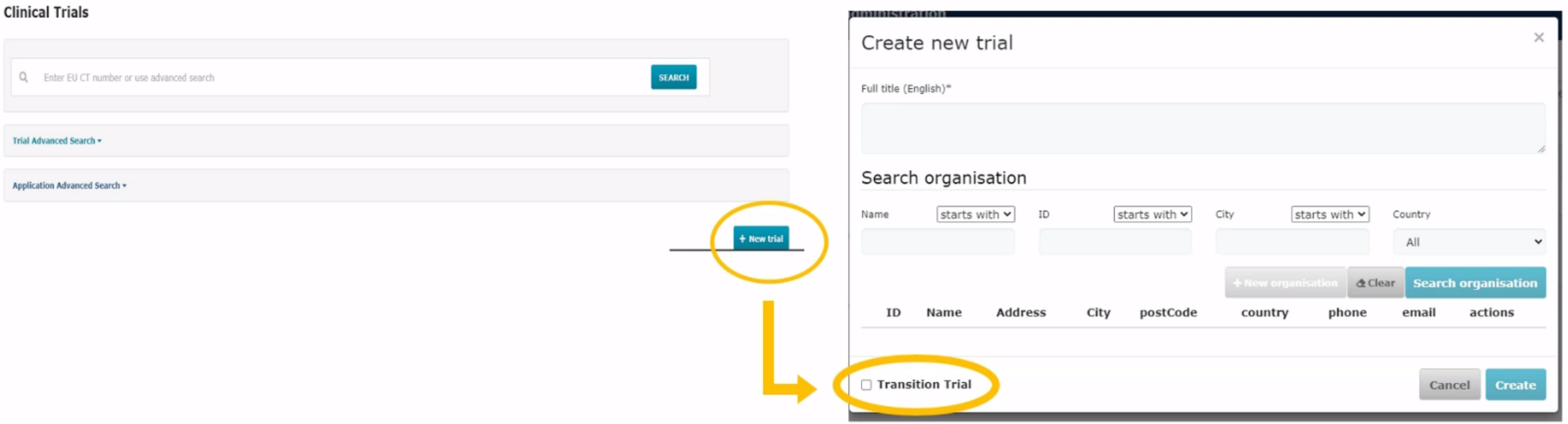
Non-substancial modification: Modificaciones no sustanciales que no cumplen los criterios anteriores y que se acumulan para notificarlas en la siguiente modificación sustancial.

5. Transición EECC

- CTIS: Clinical Trials Information System -

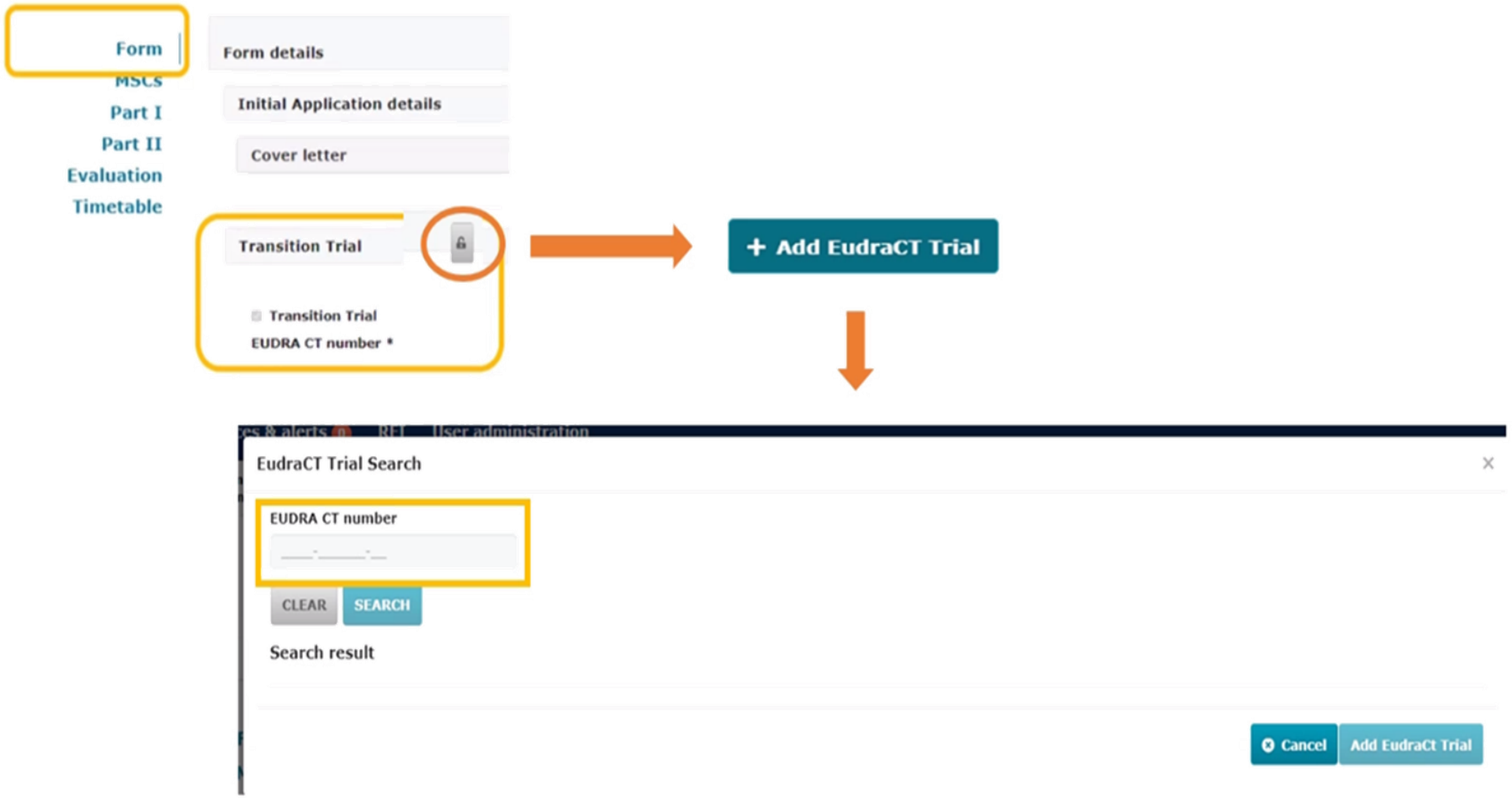
Cómo solicitar la transición:

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



5. Transición EECC

Cómo solicitar la transición:

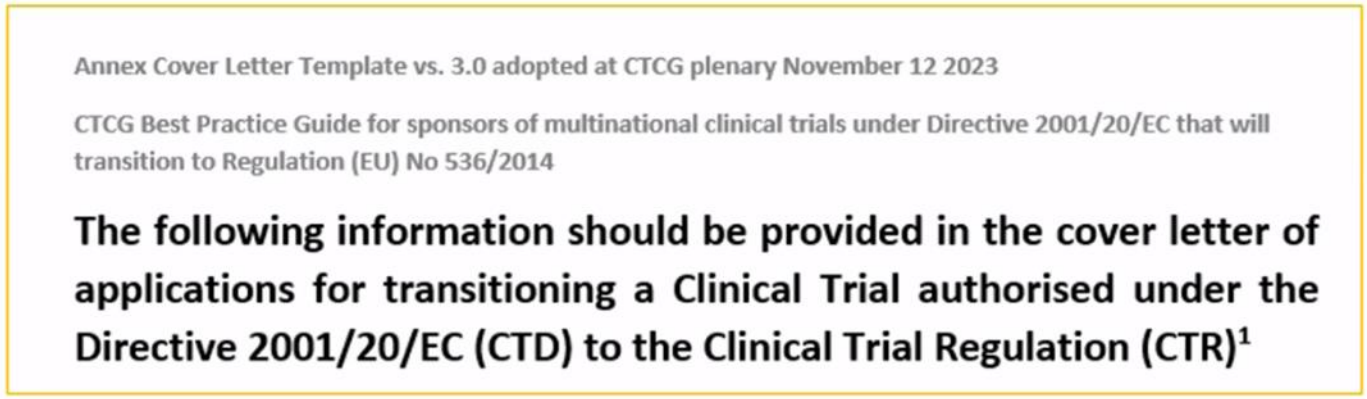


EC nacional: documentos

- **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 responsable 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) 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 €***

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

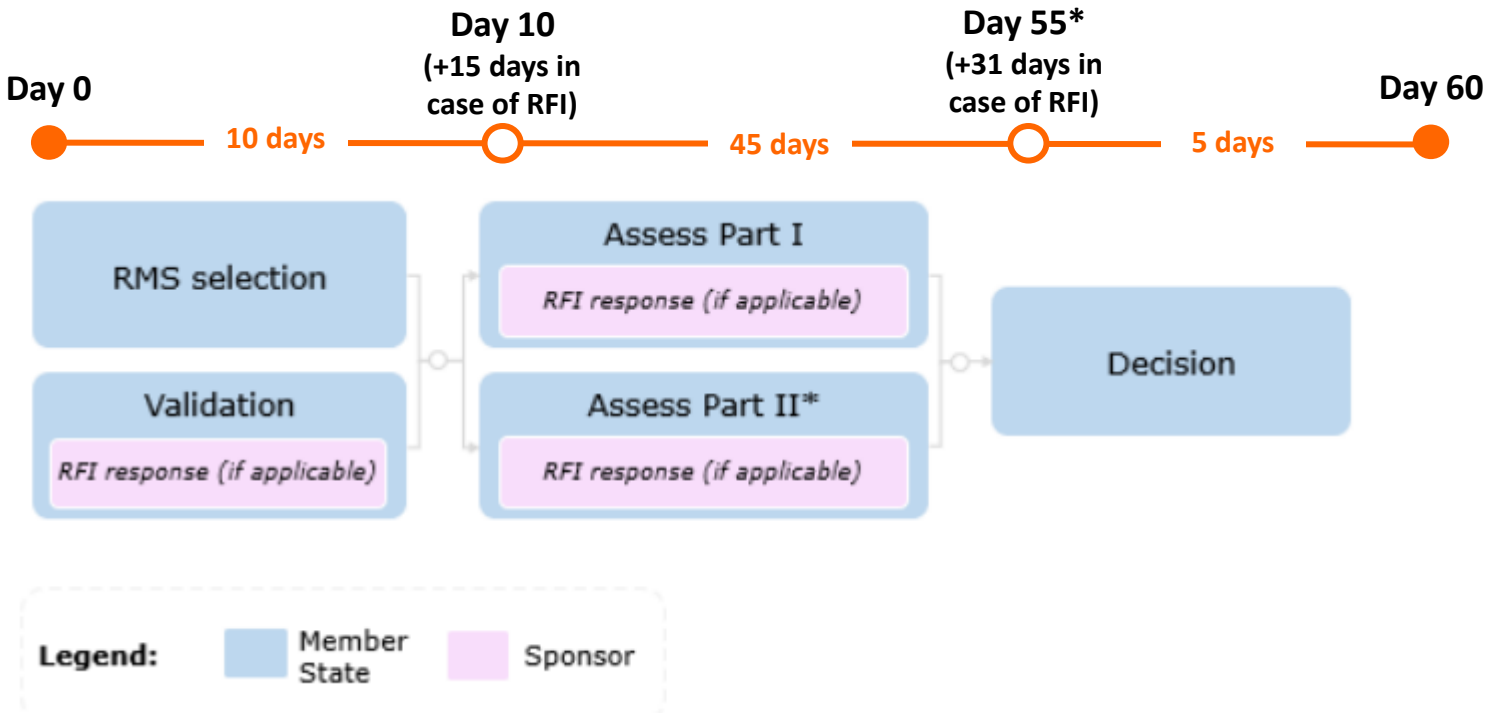
- **E-learning** (videos and step-by-step guides): requiere una evaluación (3 intentos) ***Gratuita***

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

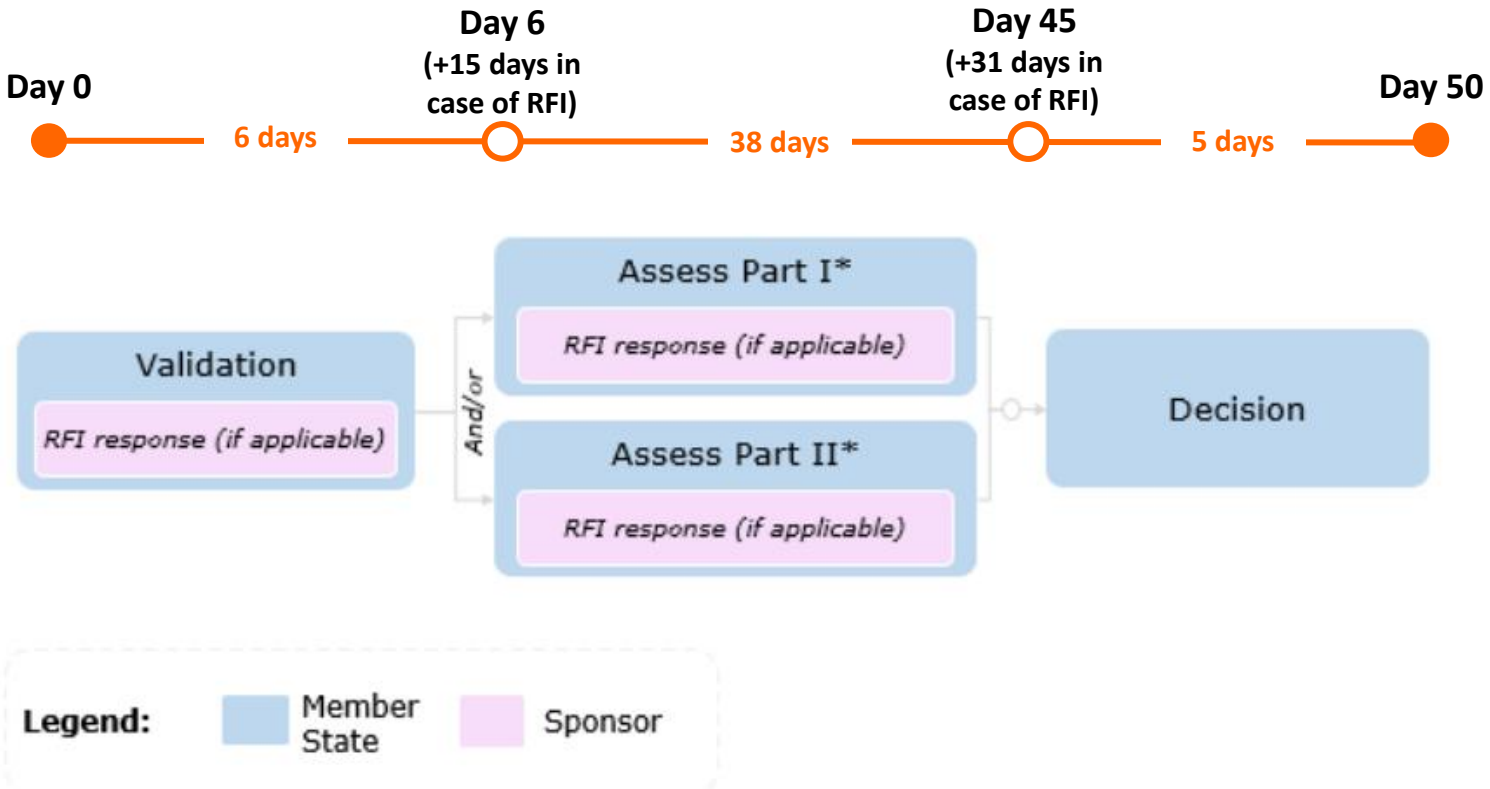


Entre 60 a 106 días naturales

(*) 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

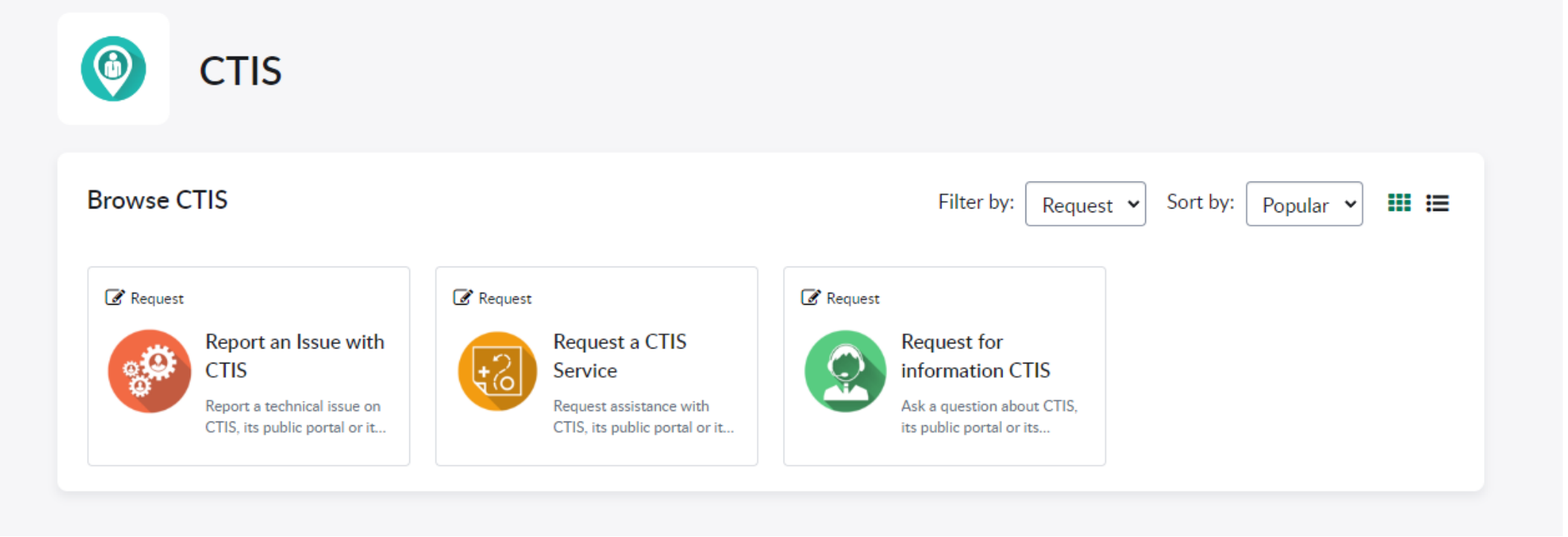


Entre 50 a 96 días naturales

6. Otros aspectos a tener en cuenta

¿Y si tengo algún problema?

User support service



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

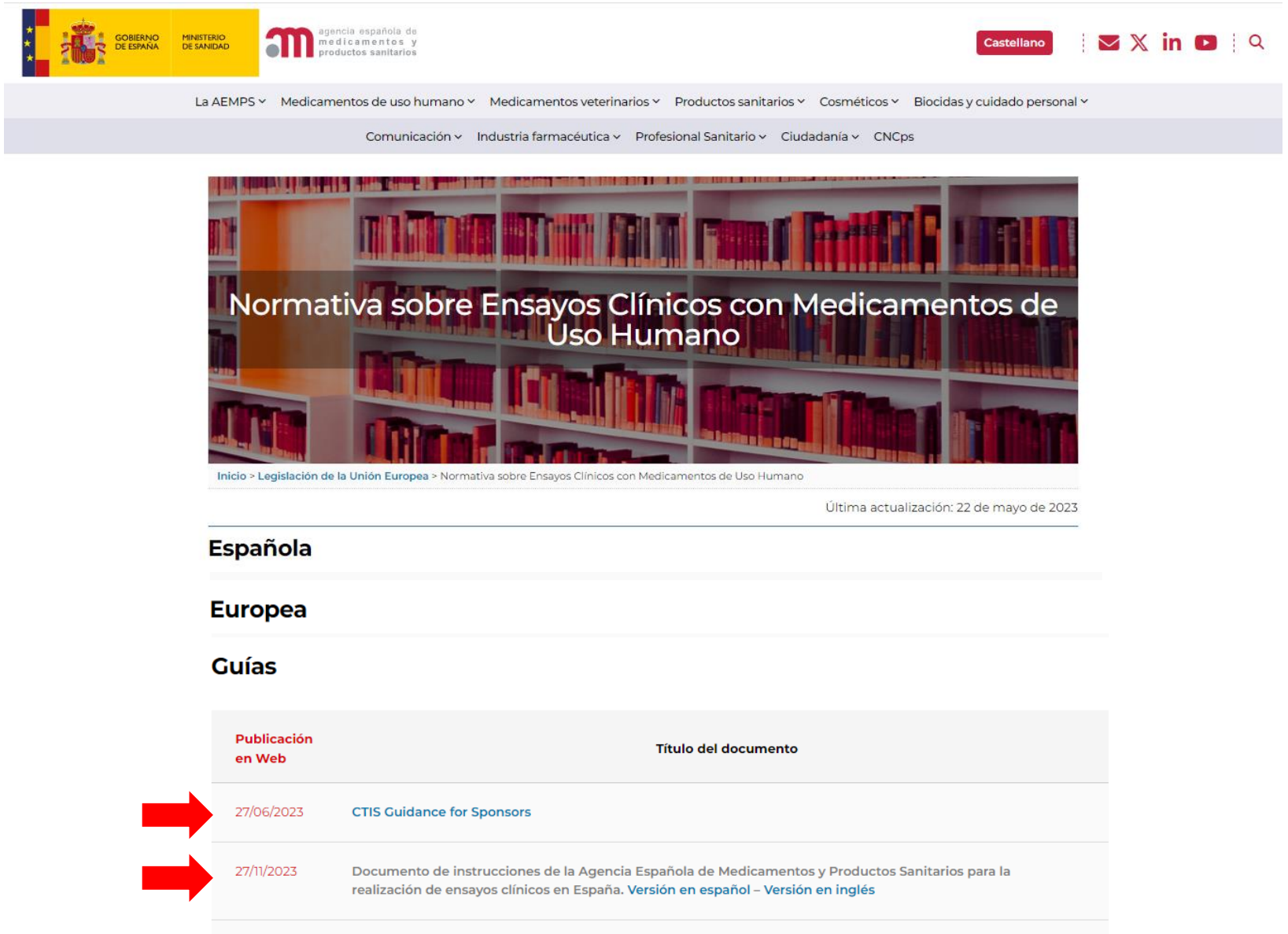
- Create, submit and withdraw a clinical trial (Module 10)
- Respond to requests for information received during the evaluation of a clinical trial application (Module 11)
- Manage a clinical trial through CTIS (Module 05)
- How to create and submit an annual safety report and respond to related requests 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

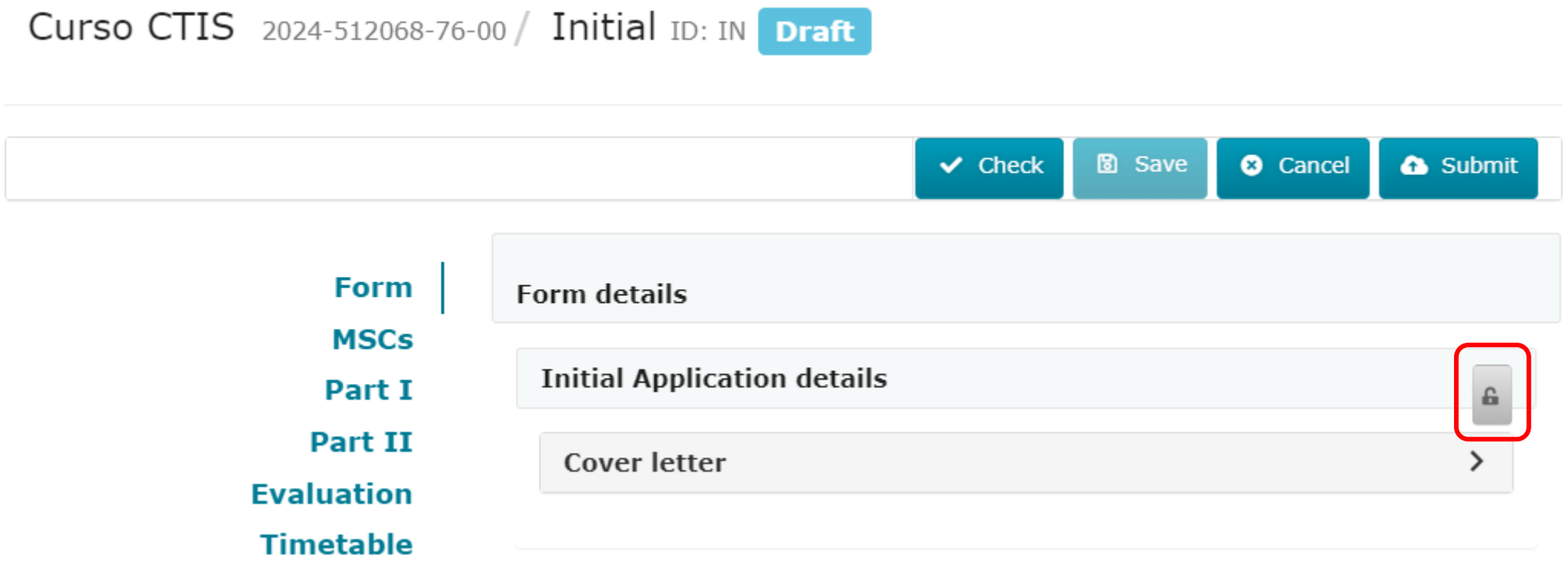
[AEMPS Normativa de EECC con medicamento]



8. FORMULARIO

- CTIS: Clinical Trials Information System -

8. Formulario



[Acceso CTIS]

¡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