AICRO

Associazione Italiana Contract Research Organization

UTILIZZO DEL CTIS: CLINICAL RESEARCH ORGANIZATION (CRO)

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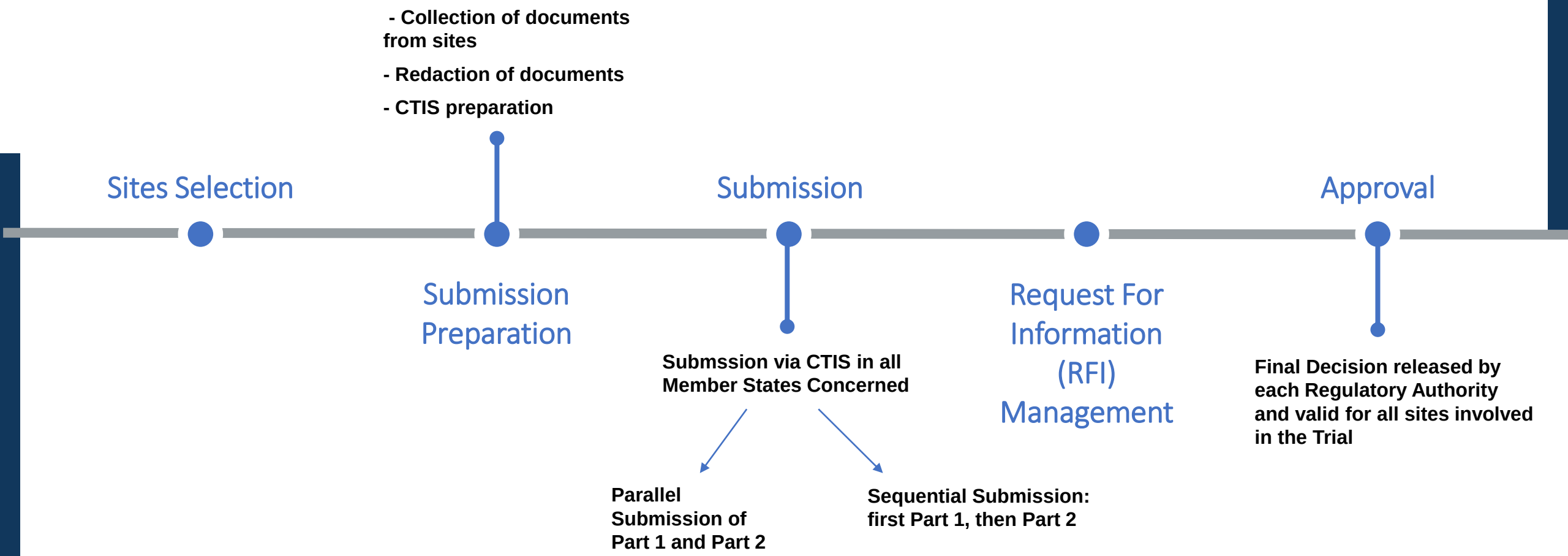
CLINICAL TRIAL UNDER EU-CTR



Submission Preparation

- Documents to be collected from Selected Sites for their inclusion in the Trial submission:
  - CV of Principal Invesitgator
  - Declaration of Interests of Principal Invesitgator
  - Site Suitability Form
- To perform the Redaction of documents before their upload in CTIS → each document can be uploaded twice:

For Publication:
Personal Protected Data (PPD) and/or Commercially Confidential Information (CCI) need to be redacted before the upload

Not For Publication: the document is uploaded as it is, and all information can be seen

The only documents that **won't** be published in any form are:

-Quality IMPD

-Financial Agreements

CLINICAL TRIAL APPLICATION DOSSIER IN CTIS

APPLICATION AND NON-SUBSTANTIAL MODIFICATION

Type	ID	Parts	MSCs	Submission date	Decision date	Reason	Scope	Link	
Substantial modification	SM-1	Part I Part I Part I	AT(Under evaluation) DE(Under evaluation)			+	+		
Additional MSC	AM-3	Part II	FR(Under evaluation)	28/10/2020		-	-	-	+ INFO
Initial	IN	Part I & Part II Part I & Part II	AT(Authorised) DE(Authorised)	22/10/2020	22/10/2020	-	-	-	+ INFO

Form → *Cover Letter*
Compliance with Regulation (EU) 2016/679

MSCs → *List of **Member States Concerned** with the number of expected patients*

Part I → *Part 1 Documents (Protocol, Synopsis, IB, IMPD, Labels, etc…)*

Part II
- BE
- FR
- DE
- IT
- ES

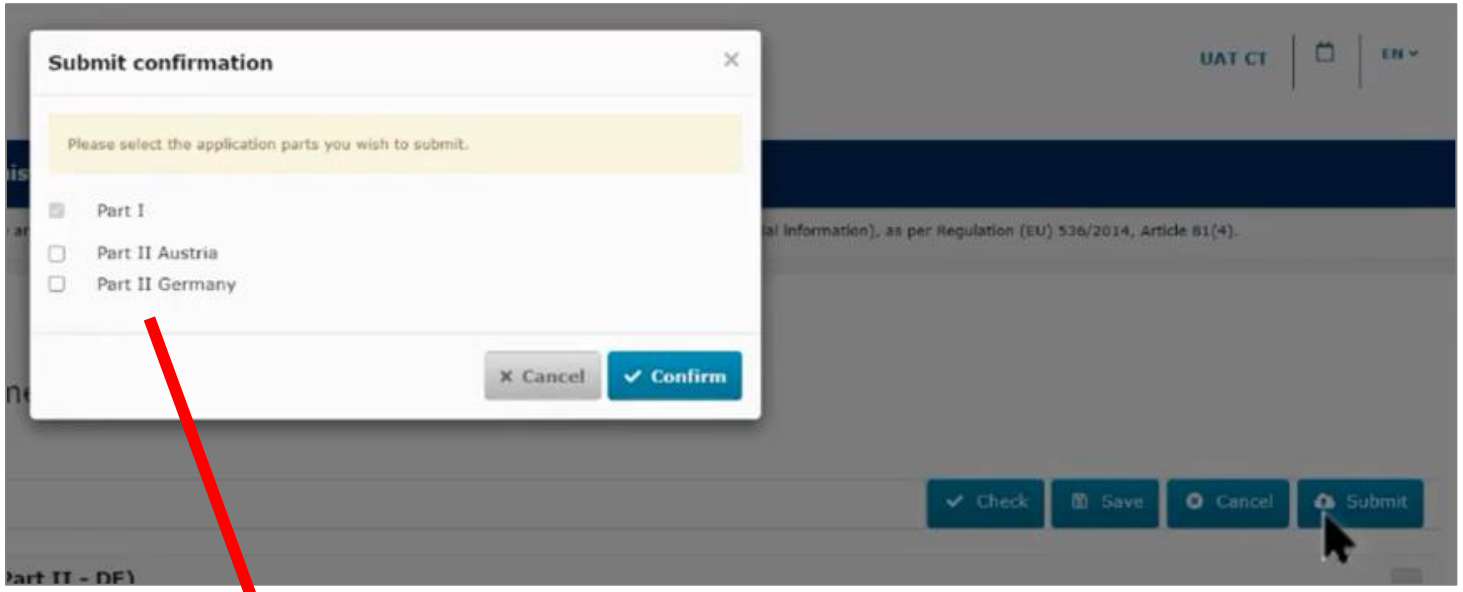
→ *Part 2 Documents for each Member State Concerned (ICFs, Insurance, Recruitment materials, Site Documents, etc…)*

Evaluation → *Section to receive RFI, Approvals and to upload the Sponsor's replies*

Timetable → *Study-specific Timetable*

CLINICAL TRIAL SUBMISSION IN CTIS

Create, submit, and withdraw a clinical trial – Submission confirmation

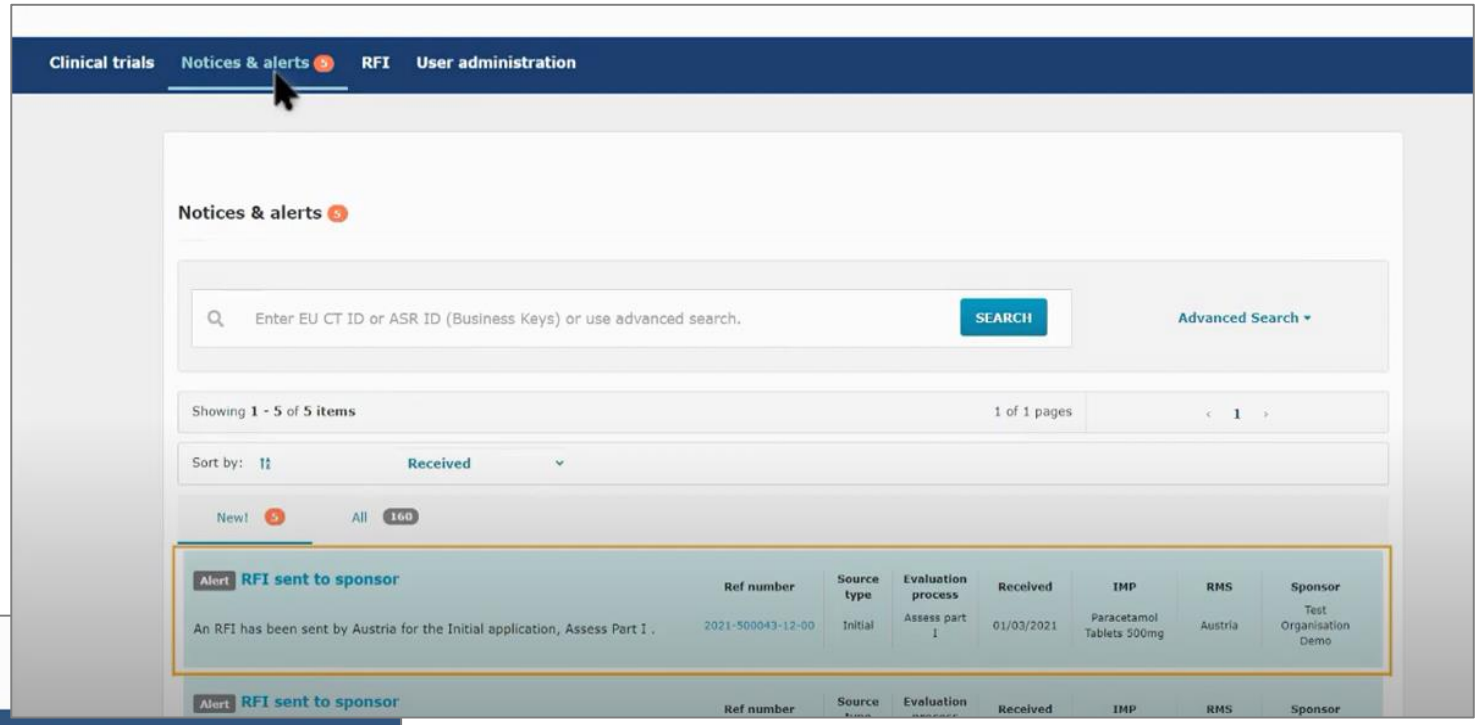


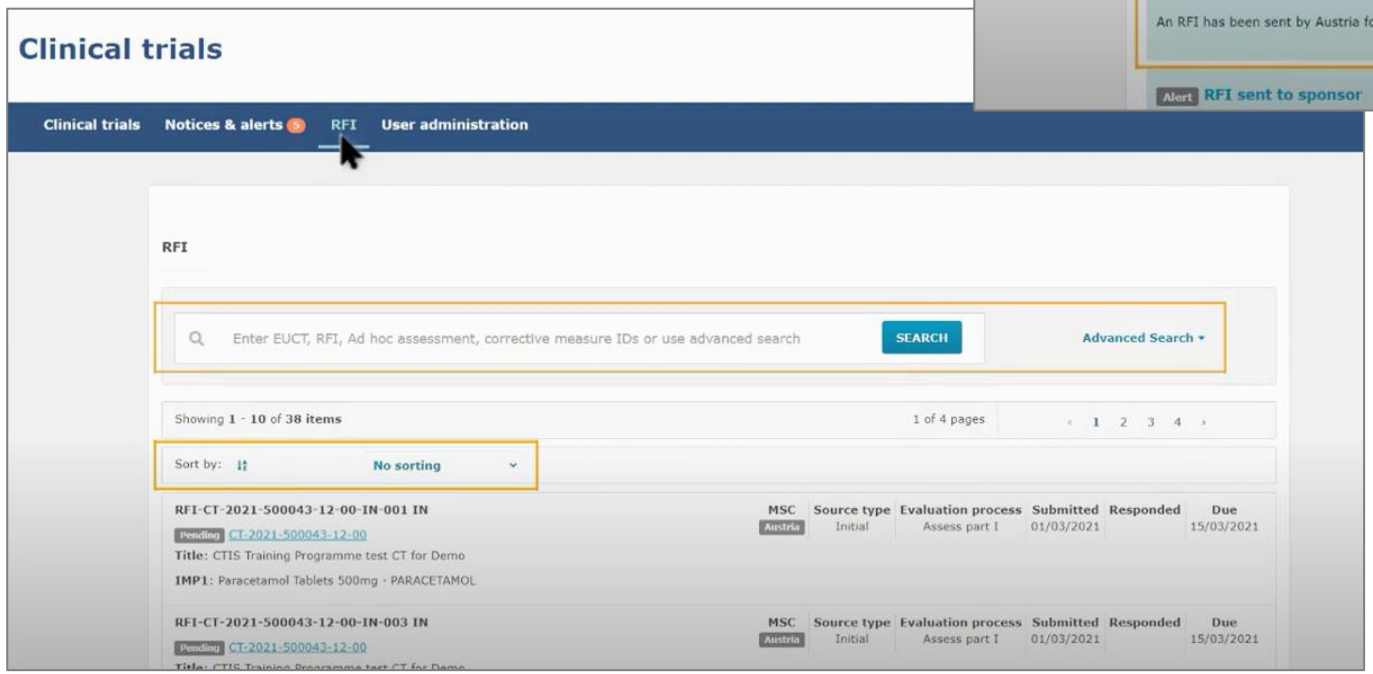
You can choose to submit Part 2 in parallel for all MSCs or just to some of them

HOW TO MANAGE RFIs

RFIs can be found in two tabs:

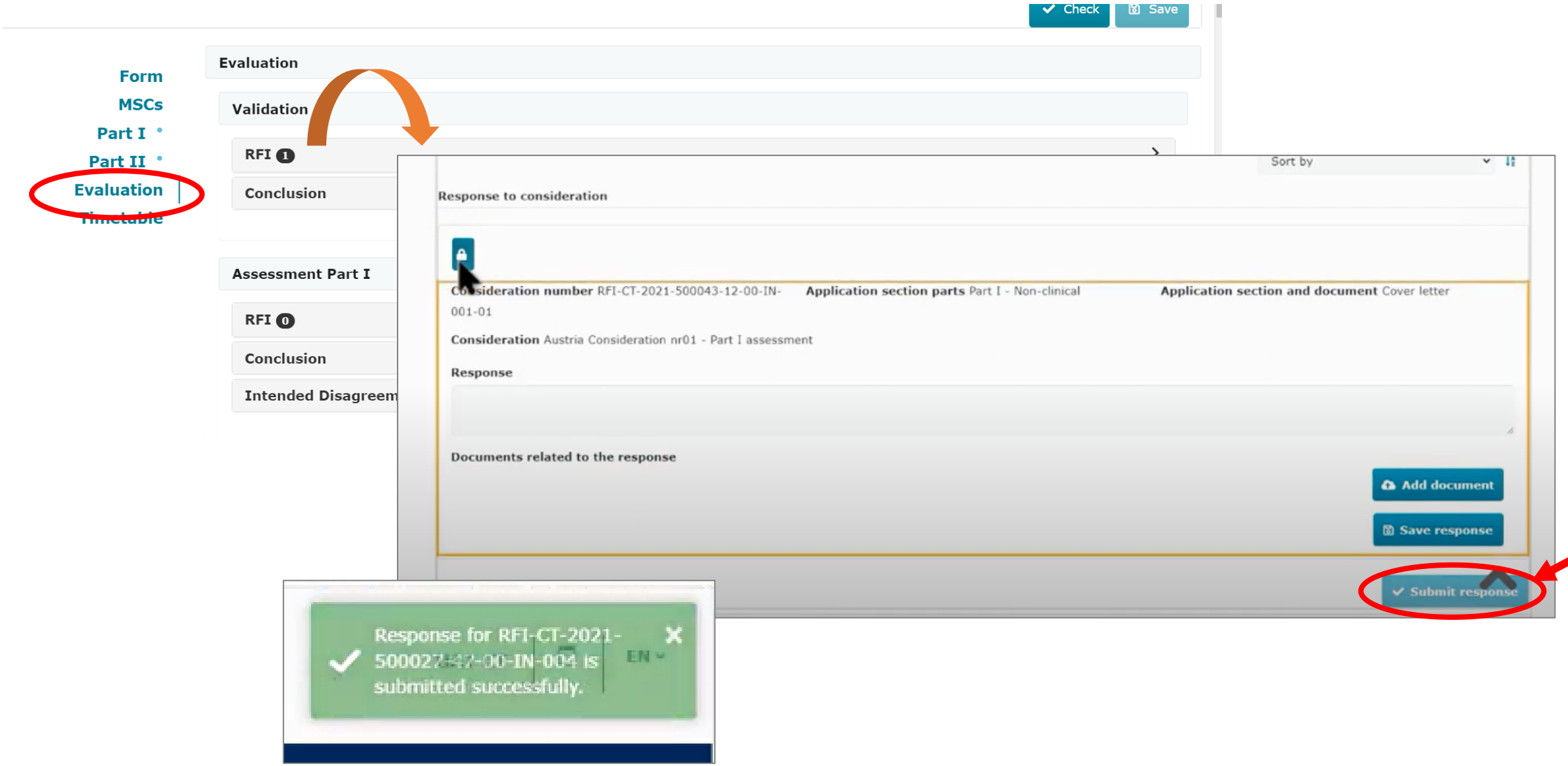
- Notices & alerts tab





- RFI Tab

HOW TO MANAGE RFIs



Assessment Overview

- Part I
- Part II
- Evaluation
- Timetable

ASSESSMENT OVERVIEW

MSCs	Validation	Assessment Part I	Assessment Part II	Decision	+All
SPAIN			Acceptable (12/01/2023)	Authorised (23/02/2023)	+
ITALY RMS	Valid (14/11/2022)	Acceptable (20/02/2023)	Acceptable (20/02/2023)	Authorised (23/02/2023)	+

Assessment Report Part 1 – released by RMS

Assessment Report Part 2 – released by EC

Final Decision – released by each RA for each country (AIFA for Italy)

CONCLUSION

- CTIS is the single-entry point for clinical trials information in the European Union (also with the public section)
- CTIS allows the submission of clinical trials simultaneously in the Member States Concerned
- CTIS is a user-friendly system for many aspects

BUT

- Many bugs became apparent in the system during 2022, impacting operational efficiencies which resulted in the opening of many tickets to the helpdesk
- Challenges continue into 2023, particularly in relation to creation of new applications and bugs within Modifications and Additional Member State applications

Thank you

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