



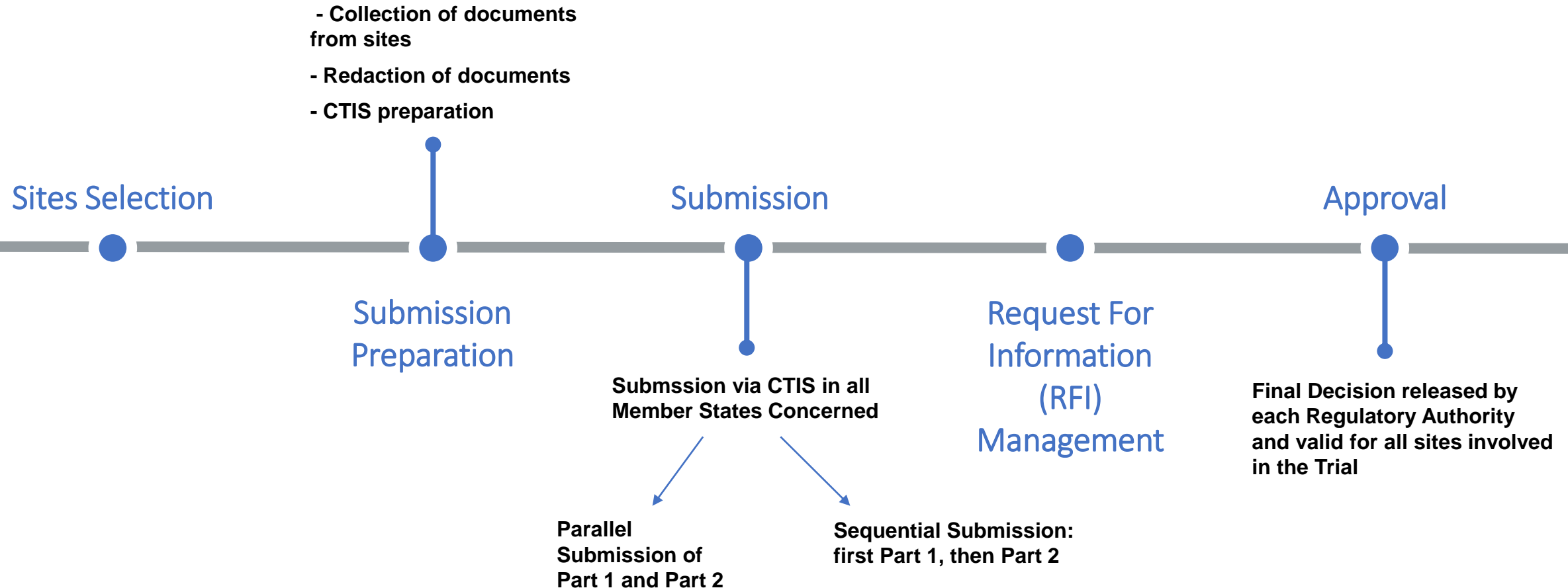
AICRO

Associazione Italiana Contract
Research Organization

UTILIZZO DEL CTIS: CLINICAL RESEARCH ORGANIZATION (CRO)

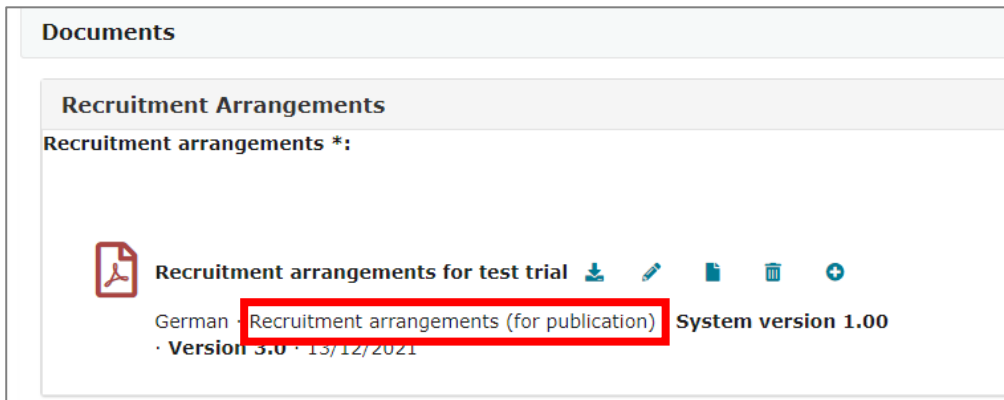
Dr Isabel Bestetti, Country Site Activation Lead, IQVIA Italia

CLINICAL TRIAL UNDER EU-CTR



Submission Preparation

- Documents to be collected from Selected Sites for their inclusion in the Trial submission:
 - CV of Principal Investigator
 - Declaration of Interests of Principal Investigator
 - 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

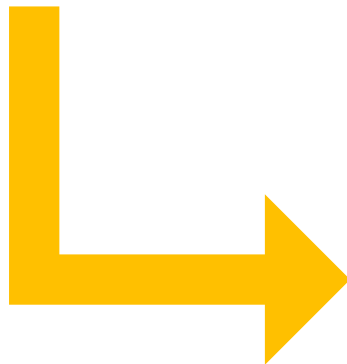
Not For Publication: the document is uploaded as it is, and all information can be seen

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

MSCs

Part I

Part II

- BE
- FR
- DE
- IT
- ES

Evaluation

Timetable

Cover Letter

Compliance with Regulation (EU) 2016/679

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

Part 1 Documents (Protocol, Synopsis, IB, IMPD, Labels, etc...)

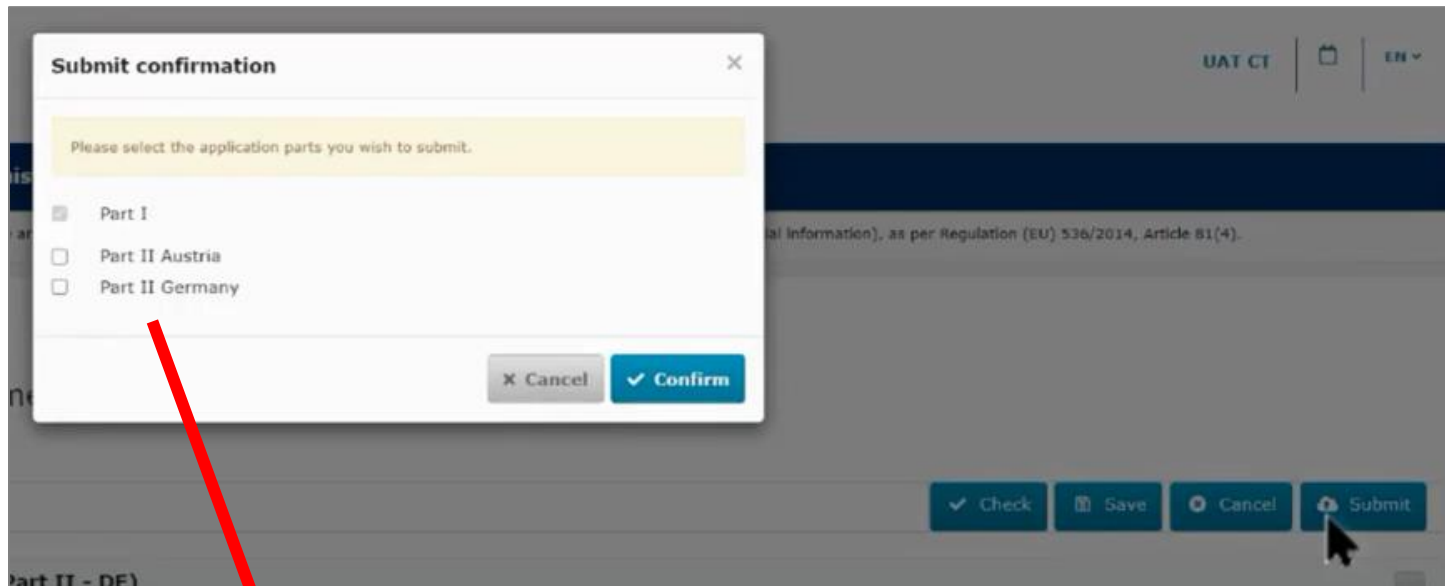
Part 2 Documents for each Member State Concerned (ICFs, Insurance, Recruitment materials, Site Documents, etc...)

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

Study-specific Timetable

CLINICAL TRIAL SUBMISSION IN CTIS

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



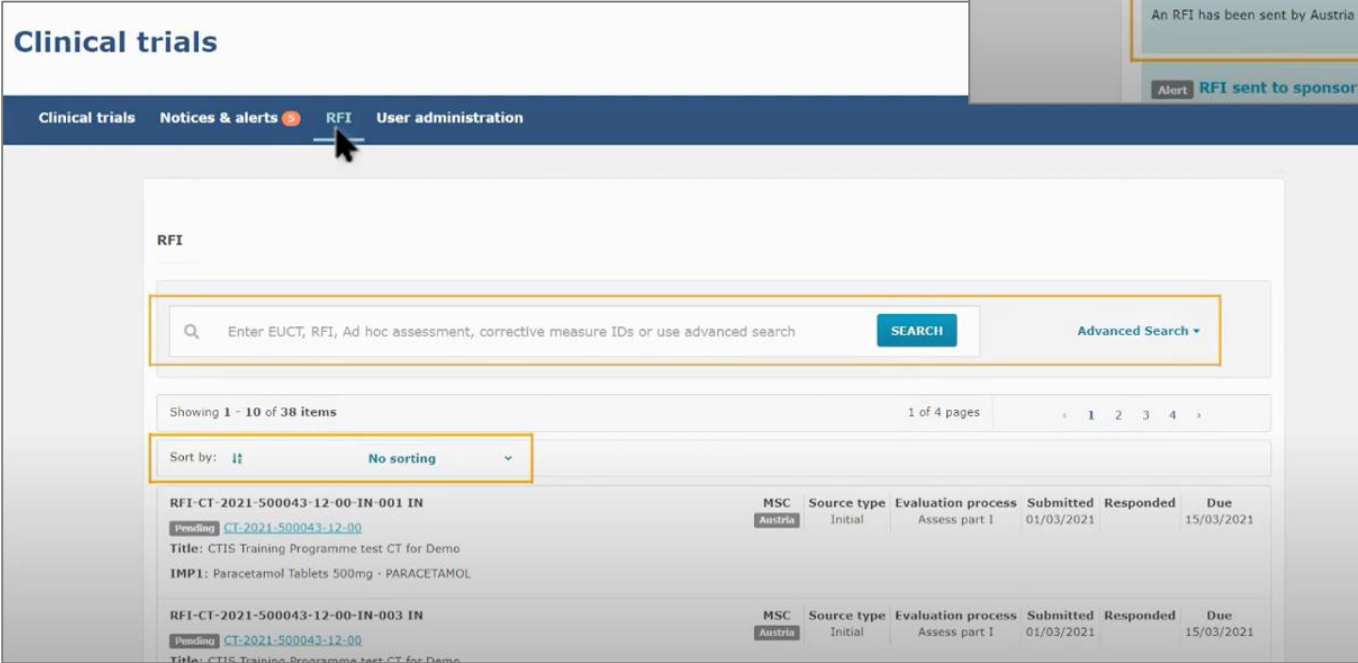
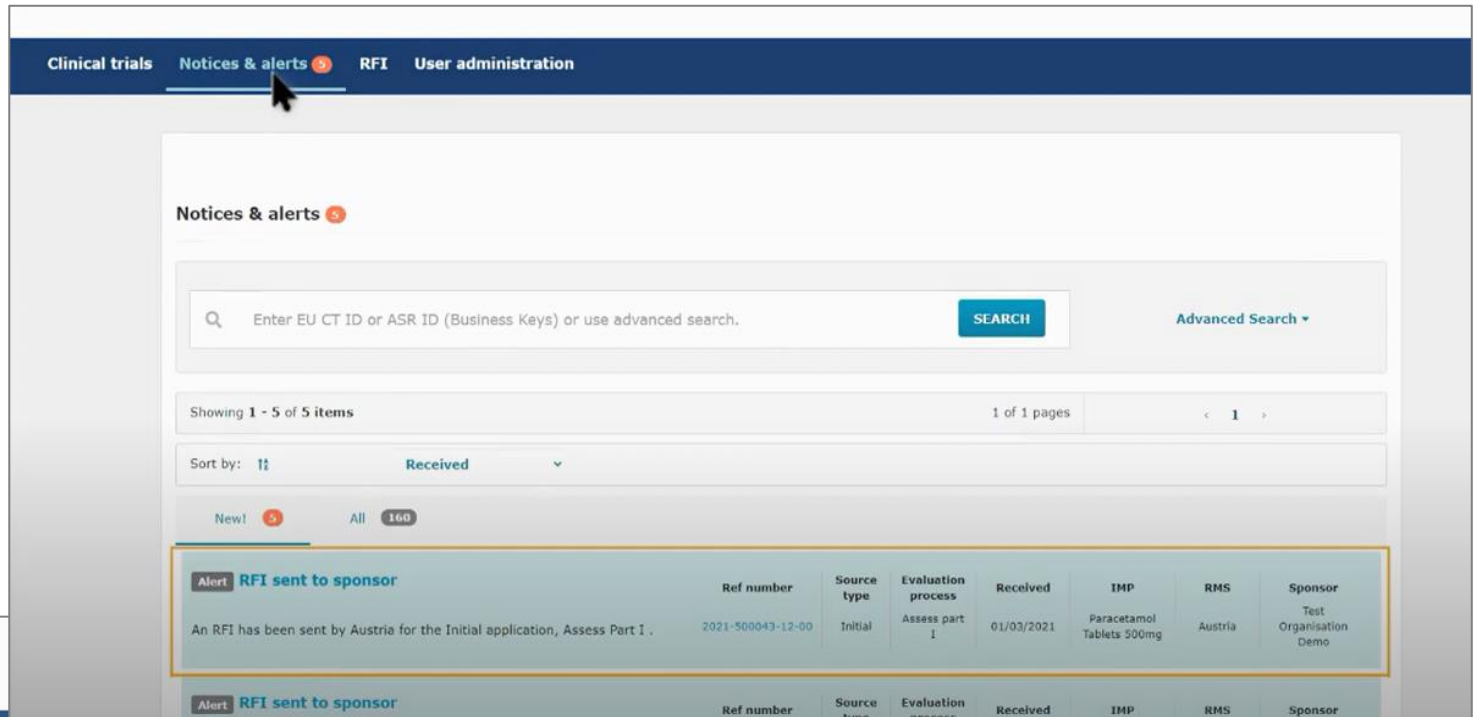
You can choose to submit Part 2 in parallel for all MSCs or just to some of them



HOW TO MANAGE RFIs

RFIs can be found in two tabs:

- Notices & alerts tab 



- RFI Tab 

HOW TO MANAGE RFIs

The screenshot displays the AICRO RFI management interface. On the left, a navigation menu includes 'Form', 'MSCs', 'Part I', 'Part II', 'Evaluation' (circled in red), and 'Timetable'. The main content area shows a 'Response to consideration' form for RFI-CT-2021-500043-12-00-IN-001-01. The form includes fields for 'Consideration number', 'Application section parts', and 'Application section and document'. A 'Response' text area is present, along with 'Documents related to the response' and buttons for 'Add document', 'Save response', and 'Submit response' (circled in red). A green notification box at the bottom left states: 'Response for RFI-CT-2021-500043-12-00-IN-001-01 is submitted successfully.' An orange arrow points from the 'Evaluation' menu item to the 'RFI 1' tab, and a red arrow points from the 'Submit response' button to the notification box.

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)	+



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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