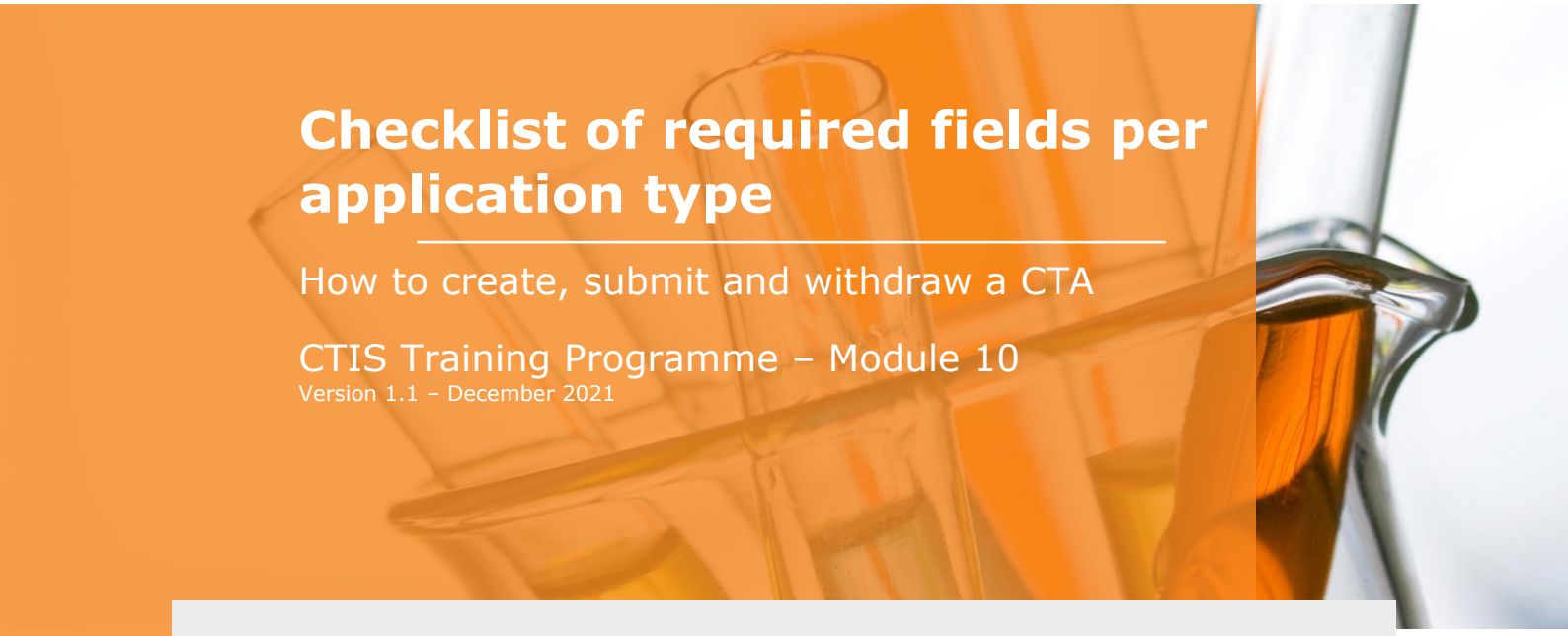
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



Checklist of required fields per application type

How to create, submit and withdraw a CTA

CTIS Training Programme – Module 10

Version 1.1 – December 2021

Learning Objectives

- In this support document you will find a list of the data and documents that are requested as a minimum in CTIS to be able to proceed with the submission of the different application types.

General information

This document is composed of three sections below, listing the sections, sub-sections and required fields on each type of clinical trial applications (CTA). Find below the legend of the elements included in each section:

- A cloud icon ( ) indicates that users need to upload a pre-populated document to CTIS.
- A 'button' indicates that when users click on that specific button, a pop-up window will allow users to populate the indicated information.
- A 'check box' indicates that, if clicked, the user will need to populate specific information.
- A 'pencil' indicates that users should click this icon to open a pop-up window where they will be able to edit or complete the specific information.
- An 'example' field refers to instances of the particular required field e.g. an authorised product.

Initial Clinical Trial Application

Form section	Sub-sections	Required fields
Initial application details	**Cover letter**	• Cover letter
Compliance with regulation	**Compliance with Regulation (EU) 2016/679**	• Compliance with Regulation (EU) 2016/679
Deferral publication dates	**Deferral of clinical trial information**	• Short title / Trial category • Justification for trial category / Trial category

MSC section	Required fields
Member State Concerned	• +Add member states (button) • Member states • Subjects • Select Proposed RMS

Part I section	Sub-sections		Required fields
Trial details	**Trial identifiers**		• Full title • Public title
	Trial information	***Trial category***	• If Low intervention trial (check box) / Justification for the low intervention trial • Trial phase
		Medical condition	• Add condition (button) / Medical condition(s) • Therapeutic area
		Main objective	• Trial scope • Main objective
		Eligibility criteria	• Add inclusion criteria (button) • Add exclusion criteria (button)
		End points	• Add primary endpoint (button)
		Trial duration	• Estimated recruitment start date in EEA • Estimated end of trial date in EEA
		Population of trial subjects	• Age range • Gender • Clinical trial group • (if check box 'Vulnerable group' is clicked) Recruitment population group
	Protocol information	***Clinical trial protocol***	• Protocol
Sponsors	**Contact point for Union**		• Add contact point for Union (button) • Scientific Contact Point • Public Contact Point
Products	**Products**		• +Add (button)
	Role: Test (example)		• +Add (button) / Authorised product (example)
	Dosage and administration details		• Route of administration • Maximum duration of treatment • Maximum daily dose allowed • Total dose unit of measure
	Information about the modification of the medicinal product		• Has the medicinal product been modified in relation to its Marketing Authorisation? (check box)
	Investigator brochure for the medicinal product		• Investigator brochure • Summary of product characteristics (SmPC)
	IMPD Quality*		• IMPD-Q • Simplified IMPD-Q • Justification for no IMPD upload
	IMPD - Safety and efficacy*		• IMPD - Safety and Efficacy • Simplified IMPD - Safety and Efficacy • Justification for no IMPD upload
	Content labelling		• Content labelling of the IMP's

* To view the required fields per IMP please refer to question 2.12 What types of IMP can be added as a test role on the Frequently Asked Questions document of this module.

Part II section	Sub-sections	Required fields
Country specific details	**Trial sites**	• +Add sites (button) • Search organisation (or create an organisation) • Edit information (pencil) • First name / last name / department / phone / email
	Documents	• Recruitment arrangements • Subject information and informed consent form • Investigator CV • Suitability of the facilities • Proof of insurance cover or indemnification • Financial and other arrangements

Additional MSC Clinical Trial Application

Form section	Sub-sections	Required fields
Initial application details	**Cover letter**	• Cover letter

MSC section	Required fields (if users wish to add MSCs which have not been populated in the pop-up screen after the Add MSC CTA has been created, but not yet submitted)
Member states concerned	• +Add member states (button) • Member states • Subjects

Part II sections	Sub-sections	Required fields
Country specific details	**Trial sites**	• +Add sites (button) • Search organisation (or create organisation) • Edit information (pencil) • First name / last name / department / phone / email
	Documents	• Recruitment arrangements • Subject information and informed consent form • Investigator CV • Suitability of the facilities • Proof of insurance cover or indemnification • Financial and other arrangements

Substantial Modification Clinical Trial Application

When users create a Substantial Modification, the scope must be selected (Part I only, Part II only, or Part I and Part II) from the dropdown menu in the pop-up screen.

Form section	Sub-sections	Required fields
Substantial Modification details	**Cover letter**	• Cover letter
	Modification description	• Modification description

European Medicines Agency

Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Telephone +31 (0)88 781 6000

Send a question

www.ema.europa.eu/contact

Clinical Trials Information System (CTIS).

Support document – Checklist of mandatory fields per application type.