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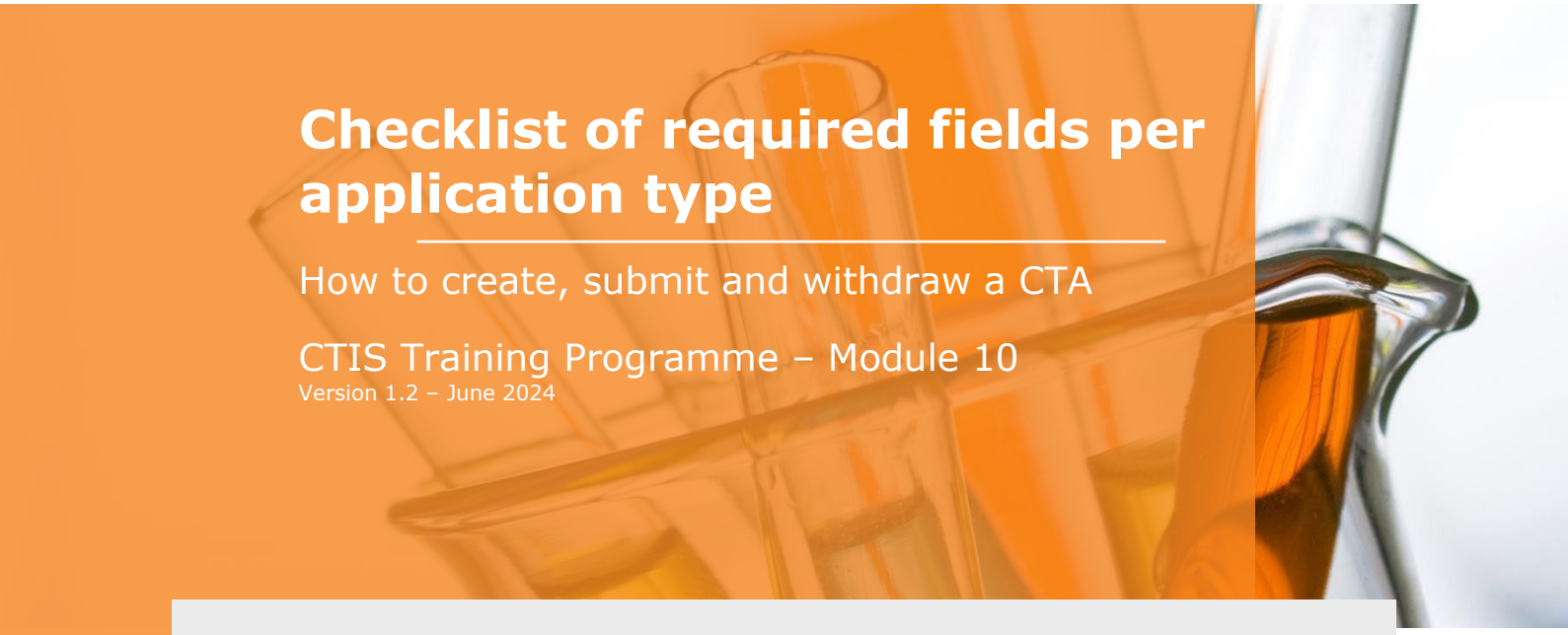

Checklist of required fields per application type

How to create, submit and withdraw a CTA

CTIS Training Programme – Module 10

Version 1.2 – June 2024

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.

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Record of updated versions

The table below describes the updated versions after December 2021.

1.2	"Individual Participant Data (IPD) Sharing Statement" has been added in Part I Section – Trial Details Reference for Deferrals from the form section of the clinical trial initial application deleted	June 2024
1.1	First version of "Checklist of required fields per application type" published	December 2021

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

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 category	• If Low intervention trial (check box) / Justification for the low intervention trial • Trial phase
	Trial information	***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
		Individual Participant Data (IPD) Sharing Statement	• 'Plan to share IPD', is mandatory • Selection from a drop-down list of pre-defined values
		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

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Clinical Trials Information System (CTIS).

Support document – Checklist of mandatory fields per application type.

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