EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Quick guide - Introduction

How to evaluate a Clinical Trial Application: Assessment and Decision

CTIS Training Programme – Module 08

Version 1.3 – May 2022

Learning Objectives

- Remember the phases and associated timelines for evaluating an initial Clinical trial application (CTA).
- Understand the process and the user roles involved in the Assessment of Part I of an initial CTA as a Reporting Member State (RMS) and as a Member State Concerned (MSC).
- Understand the process and the user roles involved in the Assessment of Part II of an initial CTA as a MSC.
- Understand the process and the user roles involved in the Decision regarding the authorisation of an initial CTA.
- Remember the workload management functionalities in CTIS that allow users to monitor their tasks during the evaluation of an initial CTA.

The European Medicines Agency developed this training material to enhance public access to information on the Clinical Trial Information System (CTIS). This material describes a preliminary version of CTIS and may therefore not entirely describe the system as it is at the time of use of this material. The Agency does not warrant or accept any liability in relation to the use (in part or in whole) or the interpretation of the information contained in this training material by third parties.

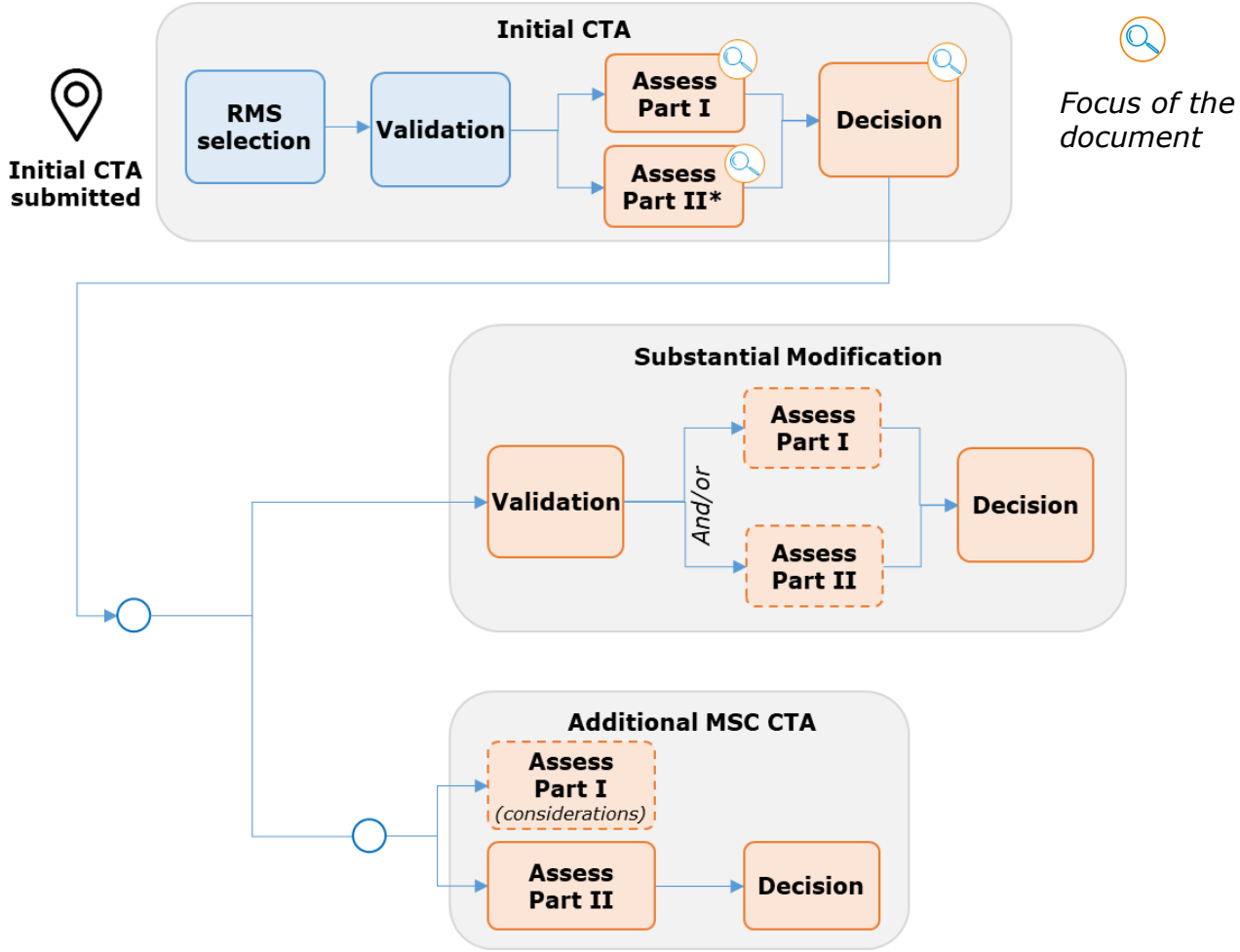
Record of updated versions

The table below describes the updated versions after CTIS go-live (January 2022):

Version	Version description	Date
1.3	Minor changes applied (e.g. tittle, reference links, format, etc.).	May 2022
1.2	Training material version published at CTIS go-live.	September 2021

Introduction

The process of evaluation of Clinical Trial Applications (CTAs) by Member States is established in the Clinical Trials Regulation[1] (CT Regulation). This process starts once the sponsor has submitted an initial Clinical Trial Application (CTA). The MSCs can evaluate the documentation provided by the sponsor to ensure the compliance with the CT Regulation. The evaluation is performed for the following types of CTAs: Initial CTA, Substantial Modification (SM) and Additional MSC CTA (Add MSC).



Content included in module 06 eLearning | Step-by-step guide RMS selection.

Content included in module 08 Quick guide | Step-by-step guide SM | Step-by-step guide Add MSC.

Step in the process that may occur depending on the CTA submitted. An SM CTA can include Part I and Part II, Part I only or Part II only. For an Add MSC CTA users may rise considerations.

**In case of applications limited to Part I, the sponsor has two years from the notification of the conclusion of Part I to submit an application limited to Part II.*

[1] Regulation (EU) No 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use, *EU Official Journal* L158. Available at: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf

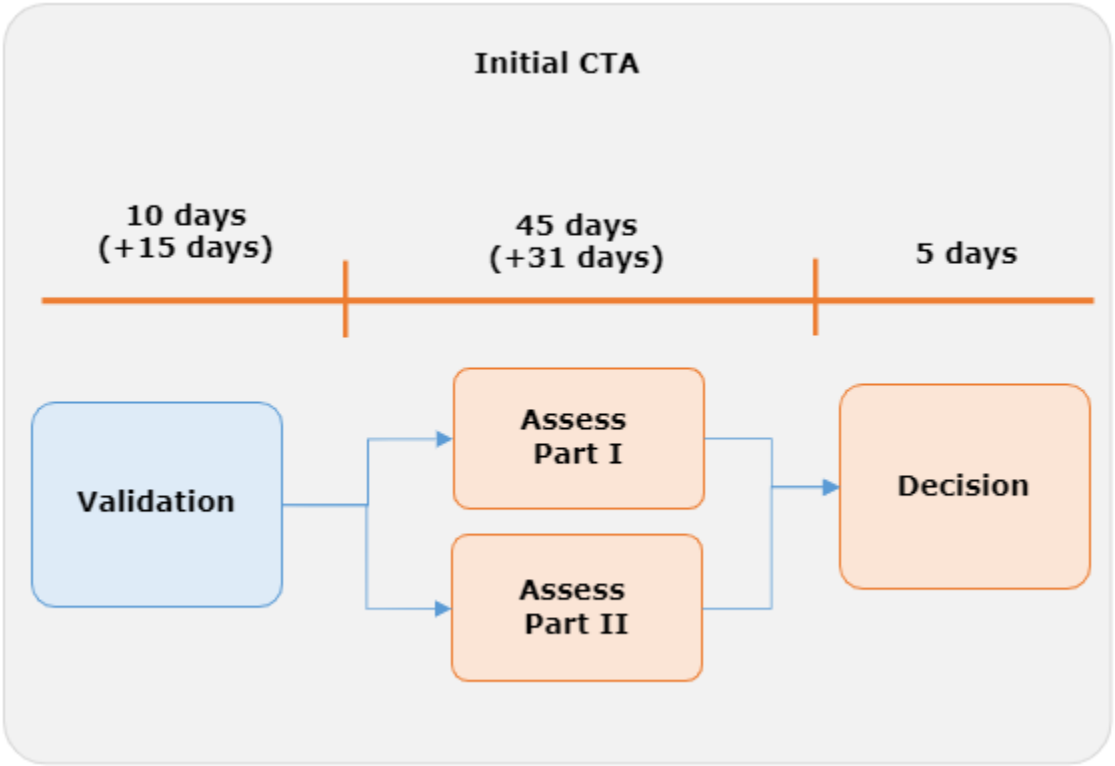
Assessment and decision of an Initial clinical trial application

The evaluation process of an Initial application includes three main phases: Validation, Assessment, and Decision. It generally takes up to 60 days, and it aims at determining if a clinical trial is fit to be performed in a Member State of the EU.

The Assessment phase includes two parts: Part I and Part II. Both parts are similar in terms of workflow, and they may or may not occur simultaneously. The main difference lies in the fact that Part I consists in a joint assessment by the MSCs led by the Reporting Member State (RMS), who submits Part I conclusion; whereas Part II consists in a separate assessment performed by each MSC, each of which results in the submission of an individual conclusion. The Assessment phase can take up to 45 days. In case that Requests for Information (RFIs) are raised by the Reporting Member State (RMS) for Part I or by the Member State Concerned (MSC) for Part II, the deadline of the Assessment phase is extended by a maximum period of 31 days.

Up to five days after the Assessment phase, each MSC decides if the application is complete and adequate, and therefore if the clinical trial can be conducted in its territory.

Within these timelines, the RMS and MSCs must perform a number of actions, which are referred to hereafter as 'tasks'. Some of these tasks are mandatory ('hard tasks' that need to be performed for the process to move forward), while others are not ('soft tasks').



How to use this quick guide

This document focuses on the tasks to be performed by the RMS (for Part I) and MSCs (for Part I and II) in the **Assessment** and **Decision** phases of the evaluation process of an Initial Clinical Trial Application[2]. For information on the previous phase, the Validation phase, please refer to *Module 6: How to evaluate a CT application (types of applications, evaluation process, RMS selection, and Validation)* of the CTIS Training Programme.

This Quick Guide is structured into three independent documents that focus on: Assessment of Part I; Assessment of Part II; and the Decision. These documents are embedded in this quick guide for easier navigation, so users can consult the relevant materials according to their role in the evaluation process. **Users can double click on the icons below to access the evaluation phase they are interested in**. Users need to open the file once again to go back to this introduction document.

Assessment Part I

This document outlines the main purpose and overview of the Assessment of Part I, the related tasks that Member States users, including RMS, will perform, and the roles and permissions involved.

Assessment Part II

This document outlines the main purpose and overview of the Assessment of Part II, the roles and permissions involved, and the related tasks that Member States users will perform.

Decision

This document outlines the main purpose and overview of the Decision, the roles and permissions involved, and the related tasks that Member States users will perform.

[2] For specific information about the evaluation process performed for CTAs other than initial applications, please refer to the FAQs document, Step-by-step guide of Additional MSC and Step-by-step guide of Substantial Modification of Module 08.

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Clinical Trials Information System (CTIS).

Quick guide – Introduction: How to evaluate a Clinical Trial Application: Assessment and Decision.