EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Quick guide - Decision

How to evaluate a Clinical Trial Application: Assessment and Decision

CTIS Training Programme – Module 08

Version 1.5 – 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.

Record of updated versions

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

Version	Version description	Date
1.5	Minor changes applied (e.g. tittle, reference links, format, etc.).	May 2022
1.4	Possible scenarios in case of a tacit Decision.	May 2022
1.3	Training material version published at CTIS go-live.	December 2021

Decision

The purpose of the Decision is to communicate to a sponsor who submitted an initial CTA the outcome of the evaluation phase. This can either be: authorisation, authorisation with conditions, or refusal to start a clinical trial in an EU Member State or an EEA country.

Overview of the Decision

The Decision phase consists of the notification to the sponsor of the authorisation, the authorisation with conditions, or the refusal to conduct a given trial.
To submit a Decision, a conclusion regarding Part I and Part II must have been previously issued. Therefore, the Decision phase comes always after the Assessment phase.

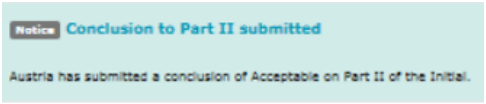
Ultimately, each MSC shall notify the sponsor whether the clinical trial is authorised, authorised subject to conditions, or whether the authorisation is refused within its territory. This must be notified within five days from the end of the Assessment phase.

Timelines

Each MSC has a maximum of 5 days to submit its Decision after the conclusions of Part I and Part II assessment have been submitted.

Process to submit the Decision

The Decision phase starts after the conclusion of the Assessment (Part I and Part II) has been submitted. The MSC will receive the following notice:



Once the application has been assessed, each MSC can **submit their Decision regarding the authorisation (or refusal)** of the clinical trial in their particular territory.

However, as per Article 8(4) of the CT Regulation[1], an MSC can decide not to authorise a trial if it disagrees with the conclusion of the Reporting Member State for Part I, or on any of the grounds specified in the Regulation:

- If it considers that the aspects addressed in Part II of the assessment report are not complied with;
- If an ethics committee has issued a negative opinion in accordance with the law of that MSC.

To do so, the MSC can access 'Evaluation' section and click on the 'Intended Disagreements' tile from the 'Assessment Part I' form.

#CTIS insights

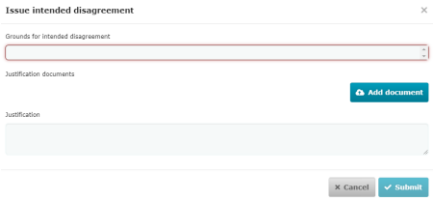
If the decision outcome is 'authorised with conditions', the MSC must indicate the conditions.

[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

Decision

If the decision task is not completed by the due date, the system applies a tacit decision. For example, if there is no conclusion submitted for, the system applies a decision taking into account the conclusion of Part I.

The MSC will need to provide a justification.



To submit the Decision, MSC users with appropriate permissions (*see section Roles and Permissions*) need to follow these steps:

1. Access the Tasks tab and click on the 'Authorise'.

2. The system will redirect the user to the Decision section of the evaluation of a CTA where the MSC user can issue a decision regarding the authorisation.

3. Moreover, the MSC user can add supporting documentation. Additionally, in case a sponsor has applied for a deferral, the RMS/MSC can also defer the publication of their evaluation documents or RFIs within the period of time stablished by the sponsor's deferral.
4. After the Decision has been issued, the MSCs and the sponsor who submitted the application will receive a notice stating that an MSC has submitted a Decision. The status of the decision from each MSC may be checked within the summary page of the CT.

#CTIS insights

MSCs can revert the decision already submitted on an application. It is only possible through a legal procedure enabling to change a refusal decision to an authorisation (with or without conditions).

Roles and permissions

Only users with the decision maker-submitter role can submit and revert the Decision of the MSC.

Possible scenarios in case of a tacit Decision

If an MSC does not submit a Decision by the deadline, CTIS will apply a tacit decision for that MSC. As a general rule, whenever the conclusion of Part I has been positive (*acceptable or acceptable with conditions*), the Decision will be to authorise the trial. On the contrary, if the conclusion of Part I has been negative, the application will not be authorised, irrespective of the outcome of the assessment Part II.

Finally, if no conclusion was submitted for Part I by the given deadline, and the user does not take any action in issuing the Decision, the application will be considered as 'Under evaluation'. *Please refer to the table on the Possible scenarios of the tacit Decision in the Annex or to question 4.8 of the FAQs of Module 8: How to evaluate a CTA: Assessment and Decision for more information.*

Annex Part II

Assessment Part I Conclusion	Assessment Part II Conclusion	Application Status (System Set)
Acceptable/Acceptable with conditions	Acceptable/Acceptable with conditions	Authorised
Acceptable/Acceptable with conditions	Not Acceptable	Authorised
Acceptable/Acceptable with conditions	No Conclusion	Authorised
Not Acceptable	Acceptable/Acceptable with conditions	Not Authorised
Not Acceptable	Not Acceptable	Not Authorised
Not Acceptable	No Conclusion	Not Authorised
No Conclusion	Acceptable/Acceptable with conditions	Under Evaluation
No Conclusion	Not Acceptable	Under Evaluation
No Conclusion	No Conclusion	Under Evaluation
Acceptable/Acceptable with conditions No Conclusion	None	Lapsed
Acceptable/Acceptable with conditions (Disagreed)	None	Not Authorised

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Clinical Trials Information System (CTIS).

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