Quick guide
How to evaluate a Clinical Trial Application: Assessment and Decision
CTIS Training Programme – Module 08
Version 1.3 – March 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 a n initial CTA.
• Remember the workload management functionalities in CTIS that allow users to monitor their tasks during the evaluation of an initial CTA.

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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.

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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 established 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.

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

<table>
<thead>
<tr>
<th>Assessment Part I Conclusion</th>
<th>Assessment Part II Conclusion</th>
<th>Application Status (System Set)</th>
</tr>
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Clinical Trials Information System (CTIS).
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