Learning Objectives

- Understand how to create and submit an inspection record.
- Understand how to search, update and cancel an inspection record.
Inspection record

An inspection allows Inspectors to conduct an official review of documents, facilities, records, quality assurance arrangements, and any other resources that are deemed by the competent authority to be related to the clinical trial.

Within CTIS, the inspector shall create and submit inspection records with all the information concerning the inspection and the outcomes obtained. Inspectors can also view, update or cancel an inspection record already submitted.

Inspections shall be conducted under the responsibility of the Member State where the inspection takes place.

• This section outlines the steps that inspectors need to follow to create an inspection record and populate an inspection form.

• This section outlines the steps that inspectors need to follow to search, update and cancel an inspection record.
1. Open the ‘Inspection’ tab on a CT page and click on the ‘New Inspection’ button.

2. Populate the General information section with the corresponding data concerning the inspection.

3. In the Inspections section, click on the ‘Add’ button to create a new inspection entry and complete each of the sections. Inspection records can include multiple individual inspection entries.

4. In the Overall inspection outcome and reports section, upload an inspection report by selecting the ‘Add report’ button once the inspection has been carried-out.

5. Once all the information is provided for the inspection record, Inspectors must submit it by selecting the ‘Submit’ button.

In case an inspection record has been conducted in the context of a Marketing authorisation application, a marketing authorisation procedure must be added.

Planned inspections can be submitted before uploading the inspection report. Once the inspection is carried-out, inspectors will upload the inspection report.
1. Search for an inspection record by indicating the record ID or, alternatively, using the ‘Advanced Search’ button.

![Search for an inspection record](image)

2. Update the information of an inspection record by clicking on the ‘Padlock’ button.
   a) General information
   ![General information](image)

   b) Inspection entry
   ![Inspection entry](image)

   c) Overall inspection outcome and report
   ![Overall inspection outcome and report](image)

   d) Once the information is updated, submit it by selecting the ‘Submit’ button.
   ![Submit](image)

3. Cancel a draft inspection record/entry by clicking on the ‘Cancel’ button, selecting the record or a specific entry in the pop-up window and clicking on the ‘Confirm’ button.
   ![Cancel draft inspection record/entry](image)
Clinical Trials Information System (CTIS)
Step-by-step guide: Supervise a CT – Inspection record

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