



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Step-by-step guide

Supervise a CT – Inspection records

CTIS Training Programme – Module 16
Version 1.1 – June 2021

Learning Objectives

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

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| 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**.



How to create and submit an inspection record

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



How to search, update and cancel an inspection record

- This section outlines the steps that inspectors need to follow to search, update and cancel an inspection record.

Inspection record

How to create and submit an inspection record

1. Open the 'Inspection' tab on a CT page and click on the '**New Inspection**' button.

The screenshot shows the 'Clinical trials' dashboard with the 'Inspections' tab selected. A search bar is visible with the text 'Record ID or search using the advanced search' and a 'SEARCH' button. The '+ NEW INSPECTION' button is highlighted with a red box.

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

The screenshot shows the 'Inspection record' form with the 'General information' section highlighted. The form includes fields for 'EMA inspection number' (value: INS/GCP/20XX/XXX), 'General comments', 'Scope *', and 'Type *'. There is also a checkbox for 'Is the inspection conducted in the context of a Marketing authorisation application?'.

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**.

The screenshot shows the 'Inspections' table with the '+ Add' button highlighted. The table has columns for 'Id', 'Site', 'Inspection status', 'Inspection status comment', and 'Actions'. One entry is visible with 'Id' INS|XX|XX and 'Inspection status' Planned.

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.

The screenshot shows the 'Report' section with the '+ Add report' button highlighted. The form includes fields for 'Overall Inspection Outcomes', 'Overall recommendation' (value: Add recommendation), and 'Overall outcomes comments'.

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

The screenshot shows the 'Inspection record' form with the 'Submit' button highlighted. The form includes 'Check', 'Save', and 'Submit' buttons.

Inspection record

How to search, update and cancel an inspection record

1. Search for an inspection record by indicating the **record ID** or, alternatively, using the **'Advanced Search'** button.

2. Update the information of an inspection record by clicking on the **'Padlock'** button.

- a) General information

- b) Inspection entry

Id	Site	Inspection status	Inspection status comment	Actions
INS 138 01		Carried out		✕ -
INS 138 02		Cancelled		✕ -
INS 138 03		Planned		✕ -

- c) Overall inspection outcome and report

- d) Once the information is updated, submit it by selecting the **'Submit'** button.

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.

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Clinical Trials Information System (CTIS)

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