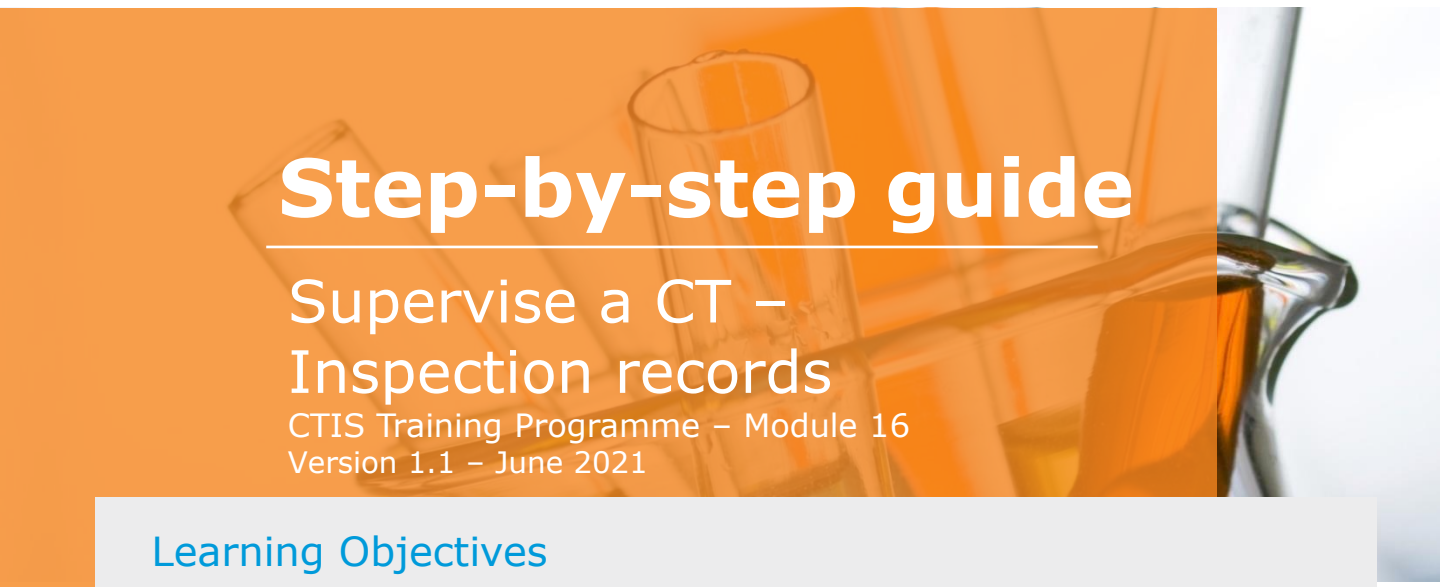
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



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.

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.

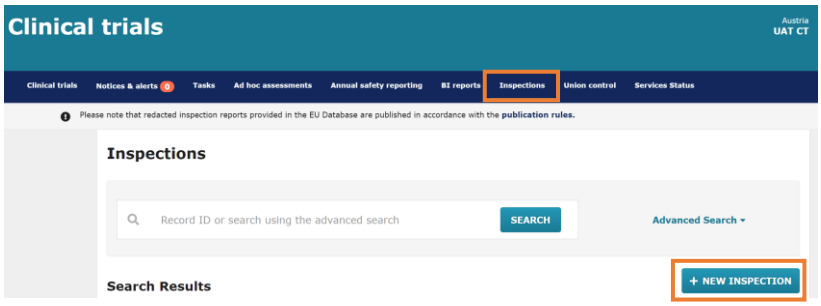
How to search, update and cancel an inspection record

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

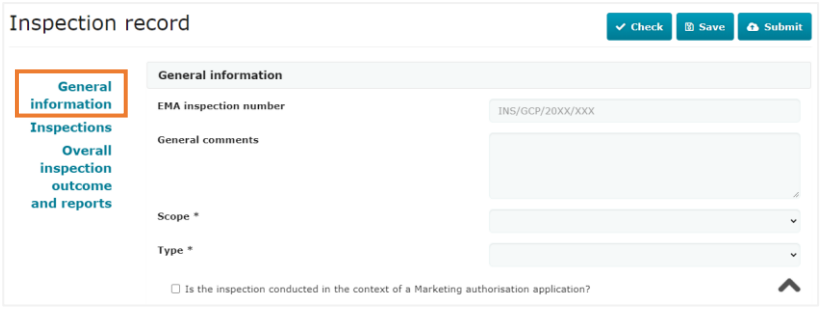
Inspection record

How to create and submit an inspection record

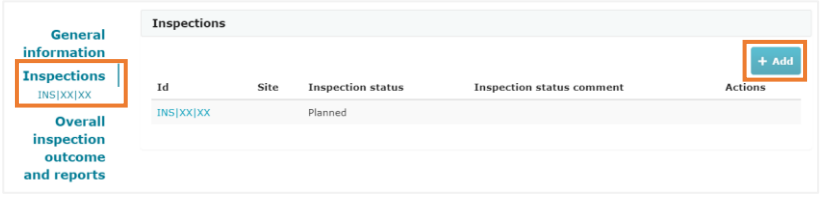
1. Open the 'Inspection' tab on a CT page and click on the '**New Inspection**' button.



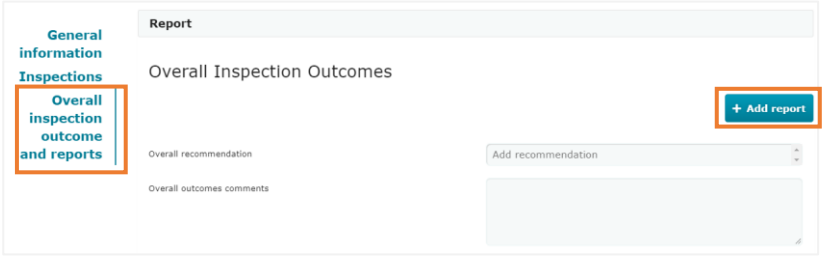
2. Populate the **General information section** with the corresponding data concerning the inspection.



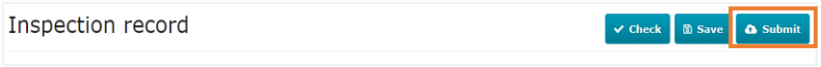
3. In the **Inspections section**, click on the **'Add'** button to create a **new inspection entry** and complete each of the sections. Inspection records can include **multiple individual inspection entries**.



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.



#CTIS insights

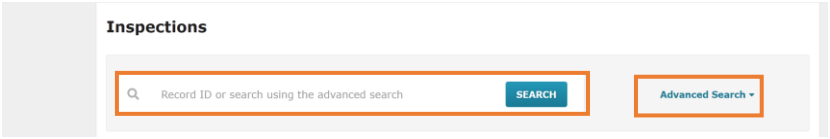
In case an inspection record has been conducted in the context of a **Marketing authorisation application**, a marketing authorisation procedure must be added.

Planned inspections can be submitted **before uploading the inspection report**. Once the inspection is carried-out, inspectors will upload the inspection report.

Inspection record

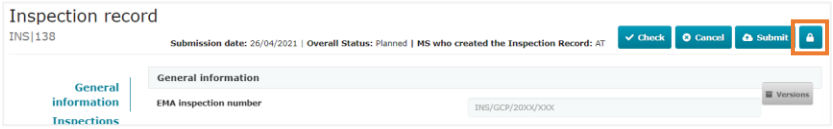
How to search, update and cancel an inspection record

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

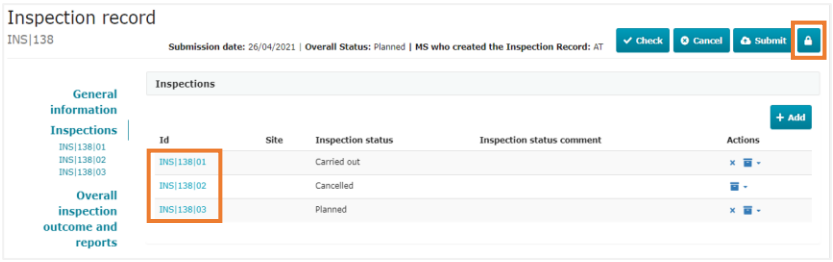


2. Update the information of an inspection record by clicking on the **'Padlock'** button.

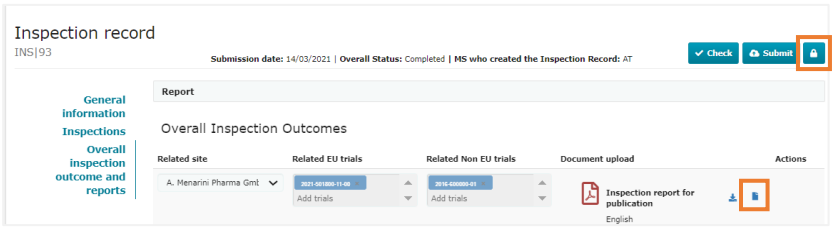
   a) General information



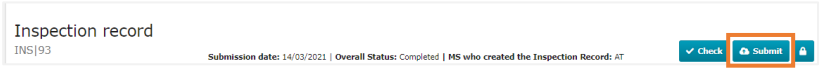
   b) Inspection entry



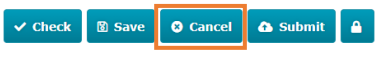
   c) Overall inspection outcome and report

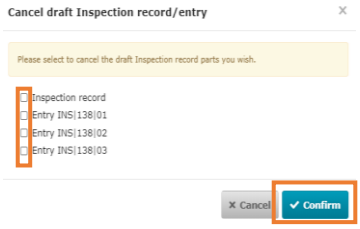


   d) Once the information is updated, submit it by selecting the **'Submit'** button.



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.





#CTIS insights

When any of the sections of the inspection record is updated, a **new version** will be created.

Old versions of any of the sections can be access in **Read-only mode**.

European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands
Telephone +31 (0)88 781 6000
Send a question
www.ema.europa.eu/contact

Clinical Trials Information System (CTIS)
Step-by-step guide: Supervise a CT – Inspection record