



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

FAQs

Supervise a CT – Inspection records

CTIS Training Programme – Module 16

Version 1.2 – May 2022

What you will find

- Answers to questions regarding general information of inspection records.
- Answers to questions regarding the creation and submission of an inspection record.
- Answers to questions regarding the upload of inspections outcomes and reports.
- Answers to questions regarding the search, update, and cancel of inspection records.
- Answer to questions regarding the roles and permissions.

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Record of updated versions

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

Version	Version description	Date
1.2	New questions added: 2.8. Can users change the planned date? 2.13. Can Member States that do not belong to NCAs be included in the form? 3.8. Is there a redaction software provided by EMA? 4.12. Is there a page to view all the Inspection records in the public portal?	May 2022

Table of Contents

1. General information.....	6
1.1. What is an inspection?	6
1.2. What is an inspection record?	6
1.3. What types of inspection are there?	6
1.4. Which actors are involved in an inspection?.....	6
1.5. When can an inspection be performed?	7
1.6. What type of trials can be inspected?	7
1.7. What is the inspection form?.....	7
1.8. What is an inspection entry?	7
1.9. What is an inspection report?.....	7
2. Creation and submission of an inspection record	8
2.1. How can users create an inspection record in CTIS?	8
2.2. What is the EMA inspection number?.....	8
2.3. What is the National inspection number?	8
2.4. What can be the scope of an inspection record?.....	8
2.5. What happens if the inspection is conducted in the context of a Marketing authorisation application?.....	8
2.6. What types of status of an inspection record are there?	9
2.7. What types of inspection status are there?.....	9
2.8. Can users change the planned date?	10
2.9. What types of submission status are there?	10
2.10. How can Inspectors select the clinical trial for the inspection?.....	10
2.11. How many Member States Concerned can participate in an inspection?	10
2.12. How many roles for the Member States are there in an inspection?.....	11
2.13. Can Member States that do not belong to NCAs be included in the form?.....	11
2.14. Is it possible to add multiple inspection entries?	11
2.15. Can users save a draft inspection?.....	11
2.16. Who can view an inspection record that is in draft?	11
2.17. When can an inspection record be submitted?	11
2.18. How can users submit an inspection record?	12

3. Upload the inspection report and outcomes12

- 3.1. How can Inspectors complete the Overall inspection outcomes and reports sections?
12
- 3.2. Which activities of a clinical trial can be inspected?12
- 3.3. How can users select the notification which triggered an inspection?.....12
- 3.4. Can Inspectors upload more than one document in the Overall inspection outcomes and reports?.....13
- 3.5. Is it compulsory to upload an inspection report?13
- 3.6. Can Inspectors add recommendations to solve the findings identified in an inspection?.....13
- 3.7. Does the inspection report become public once submitted?13
- 3.8. Is there a redaction software provided by EMA?.....14

4. Search, update and cancel an inspection record14

- 4.1. How can users search for an inspection record?14
- 4.2. Is it possible to view all the inspection records for one specific inspectorate?14
- 4.3. How can users update an inspection?15
- 4.4. Is it possible to update a cancelled inspection record?15
- 4.5. Is it possible to update the General information section of a carried-out Inspection record?.....15
- 4.6. How can users view all the inspection entry versions submitted?15
- 4.7. Can previous versions of an inspection entry be updated?16
- 4.8. Is it possible to cancel an inspection record?16
- 4.9. Is it possible to cancel a completed inspection record?.....16
- 4.10. Are cancelled inspection records public?16
- 4.11. Is it possible to download a specific inspection record?16
- 4.12. Is there a page to view all the Inspection records in the public portal?17

5. Roles and permissions17

- 5.1. What roles and permissions are involved in an inspection record?.....17

FAQs



In this document, we list common questions regarding *Module 16: Supervise a CT – Inspection records*. They are categorised into: questions regarding general information of inspection records; questions regarding the creation and submission of an inspection record; questions regarding the upload of inspection outcomes and reports; questions regarding the search, update, and cancel of inspection records; and questions regarding the roles and permissions. The specific learning objectives of this module are:

1. Remember what an inspection record is and when an MSC can create one.
2. Understand how to create and submit an inspection record.
3. Understand how to search, view, update, and cancel an inspection record.
4. Understand which user roles are involved in the inspection record process.

We encourage you to read these questions and answers carefully. If you have any questions which are not covered in this document, please contact us at CT.Training@ema.europa.eu so that we can update this document accordingly. This document will be progressively enriched with the input of the experts involved in the validation of the training material, the Master Trainers disseminating the materials, and the end-users.

1. General information

1.1. What is an inspection?

Article 2(31) of the Clinical Trial Regulation¹ (CT Regulation) refers to an inspection as the act by a competent authority of conducting 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 and that may be located at the clinical trial site, at the sponsor's and/or contract research organisation's facilities, or at other establishments which the competent authority sees fit to inspect.

An inspection has the aim to evaluate a clinical trial in terms of its compliance with the CT Regulation².

1.2. What is an inspection record?

An inspection record is the process of registration and submission of the data and documents related to an inspection in CTIS. When completing an inspection record in CTIS, users provide general information, planning or carried out information, the outcomes, and the inspection report.

1.3. What types of inspection are there?

There are two types of inspection records in CTIS:

- **Routine:** Inspections that are carried out routinely by the Inspectors, in order to verify compliance with the protocol, the CT Regulation³, and other obligations related to the conduct of the trial or activities conducted at the inspected site.
- **Triggered:** Inspections that are carried out by the Inspectors following the need to verify and address specific concerns, issues identified for the trial and/or the site.

1.4. Which actors are involved in an inspection?

Competent authorities of the Member States Concerned (MSCs) where a trial is being conducted are 'usually' responsible for carrying out the inspections. They perform the 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. CTIS

¹ European Commission, *Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC*, EU Official Journal L158. 16 of April 2014. Available at: https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf

² Idem

³ Idem

also enables to capture details of inspections carried out by the MSs in third countries.

According to Article 78 of the CT Regulation⁴, Member States shall appoint Inspectors to supervise the compliance with the CT Regulation⁵, and they shall ensure that those Inspectors are adequately qualified and trained.

1.5. When can an inspection be performed?

An inspection can be initiated after a Clinical Trial Application (CTA) has been authorised, while the clinical trial is ongoing or after the trial has ended, as part of the Member States' responsibilities to supervise the compliance of the clinical trial with the CT Regulation⁶.

1.6. What type of trials can be inspected?

Both EU and non-EU clinical trials can be inspected by the competent authorities of the Member States.

1.7. What is the inspection form?

An inspection form is a group of fields structured in sections that Inspectors can populate in order to submit and complete an inspection record in CTIS. It includes the sections: General information, Inspection entries, and Overall inspection outcomes and reports.

1.8. What is an inspection entry?

An inspection entry is an item within an inspection record that includes the details of an inspection, for example, details of the site inspected, trial inspected at the site, composition of the inspection team, and inspection dates. An inspection entry can contain details of only one site, with one or more trials inspected at the site. There can be multiple inspection entries, each with a site, within a record.

1.9. What is an inspection report?

An inspection report is a final document produced to provide a description of the outcome of the inspection and a report on the findings resulted from the inspection.

⁴ European Commission, *Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC*, EU Official Journal L158. 16 of April 2014. Available at: https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf

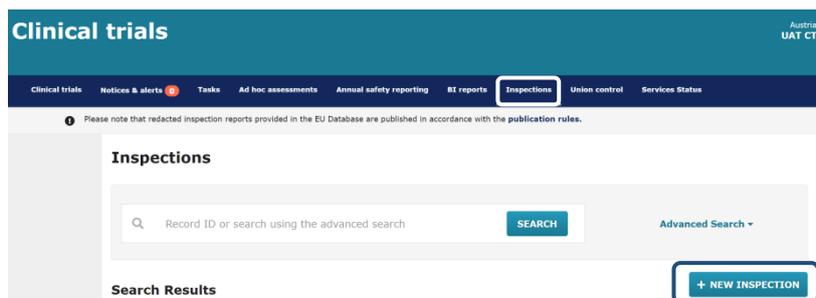
⁵ Idem

⁶ Idem

2. Creation and submission of an inspection record

2.1. How can users create an inspection record in CTIS?

An inspection record can be created through the 'Inspections' tab available on the top panel of CTIS. Once the Inspector clicks on the 'New inspection' button, it is possible to start populating each of the sections of the inspection form.



2.2. What is the EMA inspection number?

The EMA inspection number is an optional field in the 'General Information' section of an inspection record, and it is populated if the inspection is conducted on behalf of the EMA. The details of the EMA inspection number are provided to the inspectors by EMA outside of CTIS.

2.3. What is the National inspection number?

The National inspection number is a national identifier for the inspections done by a Member State. It is expected that each MSC keep track of the inspections that they do nationally (they have a list) and would include this number for reference in CTIS.

2.4. What can be the scope of an inspection record?

An inspection record can have one of the following scopes: Trial specific; System or Facility specific; Trial and System/Facility specific; and other.

2.5. What happens if the inspection is conducted in the context of a Marketing authorisation application?

If the inspection will or/ has been carried out for a clinical trial used for obtaining marketing authorisation for an investigational medicinal product, users need to provide the related information to the marketing authorisation procedure: the type (centralised procedure; mutual recognition procedure; decentralised procedure; or national procedure) and the procedure number or the reference ID. Moreover, users can select the applicant organisation

by selecting the '+Add applicant' button. The information is retrieved from OMS.

2.6. What types of status of an inspection record are there?

An inspection record can have two status indicators in CTIS:

- **Inspection status:** Indicates the timing and the completion of the inspection.
- **Submission status:** Indicates if the data entry and documents of the inspection record are saved as draft or they have been submitted to CTIS. This status has an impact on the publication of the documents.

2.7. What types of inspection status are there?

An entry can have four possible inspections 'status':

- **Planned (future inspections):** At the time of completion of the inspection record, the inspection is yet to be performed, and the last date of inspection indicated in the inspection form is in the future. Inspectors can populate and submit the information of the planned inspection via CTIS. Once that the inspection has been carried out, the Inspectors can then update the details and populate the section of the inspection outcome and upload the inspection report.
- **Carried-out (past inspections):** At the time of completion of the inspection record, the inspection has already been performed, and the date indicated in the inspection form is in the past. Inspectors can populate all the information of the performed inspection, including the outcome and they can upload the inspection report.
- **Completed:** The inspection has been carried out, the inspection outcome has been populated and each site/trial combination in an inspection entry has a corresponding inspection report provided.
- **Cancelled:** Inspection that has been cancelled by the inspector. Only possible if the inspection report has not been uploaded.

The overall status of the inspection record is dependent on the status of the individual inspection entries:

- If the record contains an entry with the status 'Planned' and another that is 'Carried-out', the Overall status of the inspection record is 'Planned'.
- If the record contains an entry with the status 'Completed' and another that is 'Carried-out', the Overall status of the inspection record is 'Carried-out'.

2.8. Can users change the planned date?

Users can change the dates when the inspection record is in draft (before submission). Users are not advised to change the date for inspection records that have been already submitted.

2.9. What types of submission status are there?

The submission of an inspection in CTIS can have two possible additional status(es), referring to its data entry and submission in the system:

- **Draft:** Indicates that the data of the inspection has been saved but not submitted yet. Users can save a draft inspection and continue populating it at a later stage. The inspection information will only be visible to the user and other users with the same profile within the Member State.
- **Submitted:** Indicates that the data of the inspection has been populated and has been submitted. The inspection information will be visible to other users with the same profile across the different Member States.

2.10. How can Inspectors select the clinical trial for the inspection?

When populating the inspection entry, the Inspectors can populate manually the clinical trial to be inspected, by searching through the EU CT number of the clinical trial or using any of the search fields, for example, selecting their MSC, the Overall trial status (authorised, ongoing or ended trials).

For a trial conducted outside of the EU, the Inspectors can search for previously entered details of the trial in CTIS or populate directly in CTIS the NON-EU trials details and include them manually in an inspection entry.

2.11. How many Member States Concerned can participate in an inspection?

There is no limit to the number of MSCs which can participate in an inspection. MSCs will appoint roles to the participants of the inspection outside of CTIS. Inspections are usually conducted under the responsibility of the MSC where the inspection takes place. There must be a leading inspectorate per inspection entry recorded in CTIS.

In case of inspections carried out on behalf of the EMA, the Reporting Inspector will be responsible to populate the details of the inspection record and provide the details of the inspections conducted at the sites, indicating the Leading Inspector per each site.

2.12. How many roles for the Member States are there in an inspection?

There are four roles of Inspectors that can participate in the inspection and recorded in CTIS: Leading Inspectorate, Supporting Inspectorate, Expert, and Observer. There is no limit to the number of participants in an inspection. However, it is compulsory to have at least one Leading Inspectorate in each inspection.

2.13. Can Member States that do not belong to NCAs be included in the form?

Under the 'Member State' tile, users can select only EU / EEA MSs from the drop-down list. If there were third parties authorities also taking part in the inspection it can be captured in the 'General comments' free text available on the 'General information' section.

2.14. Is it possible to add multiple inspection entries?

Yes. It is possible to add multiple inspection entries within an inspection record. One or more trials can be inspected at the site.

2.15. Can users save a draft inspection?

Yes. Users can save a draft inspection entry and resume populating at a later stage. To do that, users can select the 'Save' button located at the upper-right corner of the inspection form .

It is only possible to save an inspection record/entry once the details of the site and/or trials are included in the form.

2.16. Who can view an inspection record that is in draft?

If an inspection record is in draft (not submitted), only the inspectorate that created and populated the information of the inspection record can see the information. After submitting an inspection record, other Member States will be able to view the information of the inspection record.

2.17. When can an inspection record be submitted?

An inspection record can be submitted after the users populate all the required sections of the inspection form, according to the status of the inspection entries. If the status of the inspection entry is carried-out, the Inspectors must populate the outcome section and submit the inspection report in order to submit the inspection record.

Users can use the 'Check' button to see which sections are not populated .

2.18. How can users submit an inspection record?

Users can submit an inspection record by selecting the 'Submit' button on the upper-right corner of the inspection form .

3. Upload the inspection report and outcomes

3.1. How can Inspectors complete the Overall inspection outcomes and reports sections?

Inspectors can select an inspected activity (*refer to question 3.2 for more information on the list of activities*) and sub-activity. Each activity will include a predefined list of sub-activities that can be selected by the Inspector. They can also add comments on each activity and sub-activity in order to describe more specifically what has been inspected. Lastly, Inspectors can document the number of findings identified in an inspection. These can be 'critical findings' or 'major findings'.

3.2. Which activities of a clinical trial can be inspected?

In CTIS, users have a predefined list of activities of a clinical trial that can be inspected. The predefined list will be displayed in a drop-down menu and includes the following options:

- Operational resources; Administrative aspects of the trial; Trial master file (sponsor and investigator); Clinical conduct of the trial; Management of the trial by the sponsor/CRO; Safety reporting; Investigational medicinal product/pharmacy; Clinical data Management; Source data Review/Verification; Clinical trial monitoring; Instrument-based diagnosis/examinations; Clinical sample Management; Laboratory – not PK; Bioanalysis (PK) laboratory; Pharmacokinetic analysis; Statistical analysis; Reports; and Quality Management system.

3.3. How can users select the notification which triggered an inspection?

If an inspection has been carried out because of a notification reported by the sponsor, the users must select the appropriate notification in the section 'Sponsor notification related to the trials inspections'. To do that, users must click on the 'Add' button. This will display all the notifications linked to the clinical trial included in the entry, from which the users can select the notification in question. Inspectors can also add recommendations on how to address the notified event.

3.4. Can Inspectors upload more than one document in the Overall inspection outcomes and reports?

Yes. Inspectors can add more than one document in the section 'Overall inspection outcomes and reports' if they wish to do so. CTIS enables to add one or more documents, as applicable, for each site/trial combination.

3.5. Is it compulsory to upload an inspection report?

Yes. At least one report must be uploaded to CTIS for each site/trial combination in order to be able to complete the inspection record.

3.6. Can Inspectors add recommendations to solve the findings identified in an inspection?

Yes. Inspectors can write the recommendation or select one or more of the recommendations provided in a predefined drop-down list. This list includes:

- Acceptance of data for evaluation and assessment of the application.
- Exclusion of data for evaluation and assessment of the application (specify data).
- Re-inspection recommended (specify scope/timeline).
- CAPA requested.
- Inspection of another site recommended.
- Revoke authorisation.
- Suspend trial.

3.7. Does the inspection report become public once submitted?

Yes. Inspection reports will be published on the Public website of CTIS the moment that the inspection record status changes to 'Completed' (i.e., once the inspection report has been submitted for each site/trial combination). Please consider that:

- Publication of the inspection report(s) will occur when all the sites and the trials in the inspection record have a corresponding inspection report.
- In case of inspections done in the context of a marketing authorisation application, inspection report(s) will be published when the Clinical Study Report (CSR) will be provided in CTIS by the Marketing authorisation applicant.

In relation to the publication of inspection reports, it should be noted that as per the

Appendix, on disclosure rules, to the 'Functional specifications for the EU portal and EU database to be audited - EMA/42176/2014' section 4.5.1:

'Inspection reports should be made public once the inspection process is completed and the final inspection report signed off and issued by the Member State(s) inspectorate. This may be deferred where its publication would be prohibited by ongoing legal proceedings in the Member State, in which case this will be recorded in the database by that Member State'⁷.

Therefore, in case of an inspection procedure that has led to a legal proceeding, the inspection report should be uploaded in CTIS and published only when the legal proceeding has been concluded. The fact that a legal proceeding has taken place and the upload of the inspection report in CTIS has been delayed, can be recorded by the users in the general comments free text in the general information section.

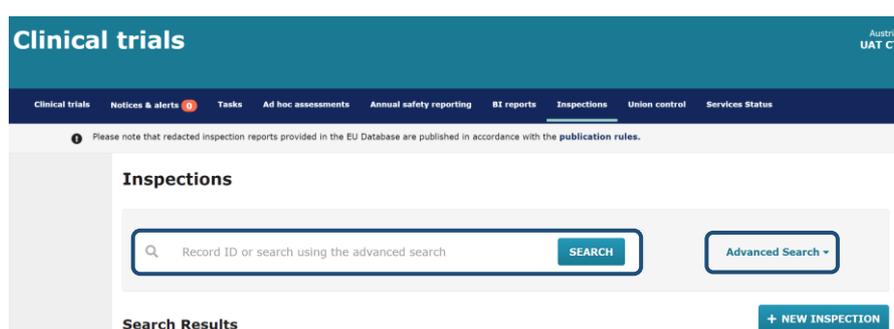
3.8. Is there a redaction software provided by EMA?

There is not an automated redaction tool available in CTIS. If a redaction of documents is needed in CTIS for inspection reports this will have to be applied outside of CTIS.

4. Search, update and cancel an inspection record

4.1. How can users search for an inspection record?

Users can search for an inspection record in the 'Inspections' tab. Inspectors can search for a specific inspection record by indicating the record ID or, alternatively, using the 'Advance Search' button which includes fields such as EU CT number, EMA inspection number, Trial protocol code, etc.



4.2. Is it possible to view all the inspection records for one specific inspectorate?

Users of a Member State can see all the inspection records (both submitted and in draft) that

⁷ EMA, *Appendix on disclosure rules to the Functional specifications for the EU portal and EU database to be audited - EMA/42176/2014*, 2 of October 2015.

their Member State is involved in. To search for a specific inspection record, users can use an advanced search functionality and populate the specific parameters of the inspection record that they are looking for.

4.3. How can users update an inspection?

Inspectors can update a draft inspection record by clicking on the 'Padlock' button at the upper-right corner of the Inspections section. If the inspection is completed, only certain fields can be updated. Cancelled inspections cannot be updated.



4.4. Is it possible to update a cancelled inspection record?

If the inspection record is cancelled, it is not possible to update any of the sections of the cancelled inspection record. A new inspection record will need to be created.

4.5. Is it possible to update the General information section of a carried-out Inspection record?

Yes. If the inspection entry status is carried-out, it is possible to update the General information section. However, the inspection entry's site, trial, and product details cannot be changed when the inspection report has already been uploaded.

4.6. How can users view all the inspection entry versions submitted?

When there is more than one version of an inspection entry (e.g., if the Inspector has updated it), they can be found in the 'Inspections' section of the Inspection record form. Inspectors can click on the versions icon and all the versions will be displayed.



4.7. Can previous versions of an inspection entry be updated?

No. Users are only able to view previous versions of an inspection entry in read-only mode. Only the latest version of an inspection entry can be subject to update.

4.8. Is it possible to cancel an inspection record?

Yes. Inspectors are able to cancel an inspection record or an inspection entry, by clicking on the 'Cancel' button. This will cancel all the entries. Also, inspection entries can be cancelled by selecting the 'Padlock' button at the upper-right corner of the Inspections section and selecting the 'X' button on the right side of each inspection entry.

It is only possible to cancel an inspection record when the inspection report has not been submitted.

Inspection record
INS|138

Submission date: 26/04/2021 | Overall Status: Planned | MS who created the Inspection Record: AT

Check Cancel Submit

General information
Inspections
INS|138|01
INS|138|02
INS|138|03
Overall inspection outcome and reports

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

4.9. Is it possible to cancel a completed inspection record?

No. It is not possible to cancel an inspection with the status 'Completed' (i.e. the inspection report is uploaded). If the report has not been submitted, it is possible to cancel an inspection.

4.10. Are cancelled inspection records public?

No. Cancelled inspection records are not published. Only inspection records that are submitted and completed will be published. Only the inspection report will be publicly available and can be downloaded.

4.11. Is it possible to download a specific inspection record?

Yes. To download the inspection records related to a trial, users can:

1. Search for the trial in the clinical trials tab.
2. Click on the EU CT number of the trial.
3. Select the 'download' button on the upper-right corner of the CT page.

4. Check the section 'Inspections'.
5. Select the 'Start download' button.

This will download a zip file that contains the inspection reports and any other document of the inspections related to that specific clinical trial.

The inspection report can be downloaded by the users within the MSCs who performed the inspection.

4.12. Is there a page to view all the Inspection records in the public portal?

No, the Inspection reports will be available in the Public portal but there is not a specific tab to view them listed. Users can access all the inspection records by clicking on the 'Search clinical trials and reports' tab and then using the advance criteria filters from the 'Search Criteria' sub-tab.

5. Roles and permissions

5.1. What roles and permissions are involved in an inspection record?

Below you can see the distribution of roles by type of activity:

- **Submit/update an inspection record:** Inspector Submitter.
- **Create/Cancel an inspection record:** Inspector Preparer; Inspector Submitter.
- **View an inspection record:** Viewer Part I Full rights/Restricted rights; Viewer Part II; Validator (Preparer/Submitter) Full rights (Part I and Part II); Validator Preparer restricted rights (Part I exc IMPD and Part II); Validator Part II (Preparer/Submitter); Assessor Part I (Preparer/Submitter) Full rights/Restricted rights; Assessor Part II (Preparer and Submitter); Decision Maker-Submitter; Supervisor (Preparer/Submitter); Inspector (Preparer/Submitter).

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Clinical Trials Information System (CTIS)
FAQs: Supervise a CT – Inspection records.

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