# Standard Operating Procedure for

# Chest X-ray Reporting

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# Standard Operating Procedure for

# Chest X-ray Reporting

## PURPOSE

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| To describe the procedure for reporting chest X-ray results in the endTB clinical trials. |

## SCOPE

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| This SOP describes how to report chest X-ray findings in the source document and in the endTB clinical trial electronic Case Report Form (eCRF). |

## RESPONSIBLE FUNCTIONS

|  |  |
| --- | --- |
| **Function** | **Activities** |
| **Site Principal Investigator (Site PI)** | Support the Site Clinical Investigator in interpreting the chest X-ray findings and ensures that chest X-rays are performed according to the study protocol. |
| **Site Study Coordinator (Site SC)** | Ensure that the chest X-ray findings are reported in the source document and in the eCRF according to the SOP and that chest X-rays are performed according to the study protocol. |
| **Site Clinical Investigator (Site CI)** | Prescribe chest X-ray, read the chest X-ray and report chest X-ray findings in the source document. |
| **Delegated external expert (as needed)** | Where possible, chest X-ray will be accompanied by a radiologist’s reading and report. Additional support from a radiologist may be requested. |
| **Delegated data entry personnel** | Report the chest X-ray finding from the patient’s file (source document) in the chest X-ray component of the eCRF. |

## DEFINITIONS and ABBREVIATIONS

In the endTB clinical trials, chest X-ray will be used to characterise pulmonary tuberculosis (TB). This includes the types of lesions, extent of lesions, and potential risks of complication. It is also used to document patient treatment response, especially when evaluation of the bacteriological response is not possible. A posterior-anterior chest X-ray is systematically prescribed. A lateral chest X-ray may be added according to the Site Clinical Investigator’s judgement. Chest X-ray reporting should be done systematically each time it is performed.

## PROCEDURE:

### Material

* Source document, including ***Chest X-Ray Worksheet*** (Form 11)
* eCRF
* X-ray viewer
* SOP ***SP-009-ET Chest X-ray reading***

### Reading

The Site CI will:

* Ensure that there is a date and study identification number that corresponds to the study subject ID of the participant being evaluated on the X-ray film.
* Systematically read the chest X-ray according to the ***SOP*** ***SP-009-ET Chest X-ray reading,*** even if there is a report from a radiologist.
* Look systematically for presence of cavities, fibrosis, bullae, pleural disease, and infiltrates.

Image 1:



* The overall extent of the disease should be classified as follows :
* **Limited**: presence of lesions with slight to moderate density, but no cavitations. Lesions may be present in a small portion of one or both lungs but the total extent of the lesions should not exceed the size of the apex of the lung (area above the first chondrosternal junction).
* **Moderate**: lesions present in one or both lungs, with a total extent which does not exceed the following:
  + Scattered lesions of slight to moderate density that may extend throughout the total volume of one lung or may partially involve both lungs.
  + Dense, confluent lesions that extend up to 1/3 of the volume of one lung.
  + Cavitation with a diameter of < 4 cm in any single cavity.
* **Extensive**: lesions that are more extended than those defined as moderate.

If the Site CI has different findings than indicated in the report from the radiologist or has any question, s/he should contact the radiologist and/or the Site PI directly to discuss the reading conclusions.

### Reporting

The Site CI will:

* Systematically report in the source document:
  + The date of the chest X-ray and the corresponding trial follow-up time (refer to the Schedule of Events of the endTB clinical trial protocols) for scheduled follow-up visits or the corresponding follow-up week for unscheduled visit.
  + The quality of the X-ray as adequate or inadequate, according to the ***SOP SP-009-ET Chest X-ray reading.***
  + The presence or absence of each of the following findings: cavities, fibrosis, bullae, pleural disease, and infiltrate.
  + The presence of any other abnormality(ies).
  + For any finding, report the location (left, right or both lungs) (See ***SOP SP-009-ET Chest X-ray reading***).
  + The number of lung zones affected by disease.
  + In case of abnormal X-ray findings, report the extent of the lesions (limited, moderate, or extensive) using the definitions given above in section 5.2 and define the number of lung zones affected by the disease.
  + For cavity(ies) and bullae, report the length in cm.
  + For any follow-up chest X-ray, report if the radiological findings are new or were already present on the previous X-ray. If they were already present, specify if there is a worsening or improvement in term of size and/or extent.
  + Reports from the radiologist and from the Site Clinical Investigator will be included in the source document.

The delegated data entry personnel will:

* Enter in the eCRF from the source document report of the Site CI:
  + The quality of the X-ray
  + The presence of any abnormal chest X-ray finding
  + The presence or absence of each of the following: cavities, fibrosis, bullae, pleural disease and infiltrate. Report location (left, right or both lungs) indicated for each finding
  + The presence of any other finding
  + The extent of disease as limited, moderate, or extensive
  + The number of lung zones affected by disease
* Systematically request clarification from the Site CI if the information is not well reported in the source document before data entry.

## REFERENCES

None

## SUPPORTING DOCUMENTS

* endTB Clinical Trial Protocols (specifically section Schedule of Events).
* Chest X-Ray Worksheet (Form 11) (endTB Site Study Document).
* SOP SP-009-ET Chest X-ray reading (endTB Site Study Document).

## APPENDIX

None