# EndTB - Event Validation Document

## Study Subject ID :

**Extraction date :**

**Treatment arm :**

**Randomization date :**

## Treatment outcome at Week 39:

**Open Clinica**:

**Algorithm**:

**Conclusion**:

## Validation page

*Comments on validation process (from CAC)*:

| Week 39 Event Validation Group (EVG) final treatment outcome: | |
|---|---|
| All culture results from samples collected between weeks 36 and 39are negative; and the outcome is not classified as unfavorable | ☐ |
| In the control arm, if using the conventional regimen, addition or replacement of two or more drugs | ☐ |
| In an experimental arm or in the control arm if using the shortened regimen, addition or replacement of one or more drugs | ☐ |
| Death from any cause | ☐ |
| At least one culture result (from a sample collected between weeks 36 and 39) is positive | ☐ |
| Patient is not assessable because the last available culture result is from a sample collected before week 36 | ☐ |

| | |
|---|---|
| Concordant with Site Investigator final treatment outcome? | Yes ☐          No ☐ |
| Date of EVG W39 final treatment outcome assignment (dd/mmm/yyyy): | |
| Name of the EVG member: | |
| Signature of the EVG member: | |

NOTE: If treatment outcomes from Open Clinica and from the algorithm are concordants, please enter the following informations in Open Clinica:
- Date of EVG final treatment outcome assignment = date of extraction,
- Name of the EVG member = Algorithm,
- Presence of signature = No

# Early treatment discontinuation:

**Date of last study drug intake**:
**Reason**: *Specify other*:

# Early study discontinuation:

**Date of last visit**:
**Reason (if different from above)**:
*Specify other*:'

# Death :

**Date** :

# Treatment initiation

# Treatment change/New treatment

# Culture results

# Bacteriological, radiographic and clinical evolution

*DST results*

*Rapid molecular test for FQ resistance*

*Rapid molecular test for RIF resistance*

*Chest X-ray*

*Weight, height, BMI at screening*

*ECOG assessment*

*Weight and temperature*

*Signs and symptoms (grades)*