

EndTB - Event Validation Document

Study Subject ID :

Extraction date :

Treatment arm :

Randomization date :

Treatment outcome at Week 104:

Open Clinica:

Algorithm:

Conclusion:

Validation page

Comments on validation process (from CAC):

Week 104 Event Validation Group (EVG) final treatment outcome:	
The last two culture results are negative. These two cultures must be from sputum samples collected on separate visits, the latest between weeks 97 and 104	<input type="checkbox"/>
The last culture result (from a sputum sample collected between weeks 97 and 104) is negative; and either there is no other post-baseline culture result or the penultimate culture result is positive due to laboratory cross contamination; and bacteriological, radiological and clinical evolution is favorable	<input type="checkbox"/>
There is no culture result from a sputum sample collected between weeks 97 and 104 or the result of that culture is positive due to laboratory cross contamination; and the most recent culture result is negative; and bacteriological, radiological and clinical evolution is favorable.	<input type="checkbox"/>
Replacement or addition of one or more investigational drugs in an experimental arm or in the control arm if using the shortened regimen(failure)	<input type="checkbox"/>
Replacement or addition of two or more investigational drugs in the control arm if using the conventional regimen (failure)	<input type="checkbox"/>
Initiation of a new MDR-TB treatment regimen after the end of the allocated study regimen and before week 104 (relapse)	<input type="checkbox"/>
Death from any cause	<input type="checkbox"/>
At least one of the last two cultures, the latest being from a sputum sample collected between weeks 97 and 104, is positive in the absence of evidence of laboratory cross contamination (failure/relapse)	<input type="checkbox"/>
The last culture result (from a sputum sample collected between weeks 97 and 104) is negative; AND there is no other post-baseline culture result or the penultimate culture is positive due to laboratory cross contamination; and bacteriological, radiological or clinical evolution is unfavorable (failure/relapse)	<input type="checkbox"/>
There is no culture result from a sputum sample collected between weeks 97 and 104 or it is positive due to laboratory cross contamination; AND the most recent culture is negative; and bacteriological, radiological or clinical evolution is unfavorable (failure/relapse)	<input type="checkbox"/>
There is no culture result from a sputum sample collected between weeks 97 and 104 or it is positive due to laboratory cross contamination; AND there is no other post-baseline culture or it is positive or, the most recent culture is negative and bacteriological, radiological and clinical evolution is not assessable	<input type="checkbox"/>
Previously classified as unfavorable in the present study, except not assessable at week 73	<input type="checkbox"/>
Loss to follow-up	<input type="checkbox"/>

Concordant with Site Investigator final treatment outcome?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Date of EVG W104 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)