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**Site Data Entry** enters the «*EVG Final Treatment outcome*» form in OpenClinica and stores the worksheet into the respective patient file

**EVG members** discuss with the site & conclude one of the following

**Site investigators do not agree with EVG members &** do not change the treatment outcome

**Site investigators** agree with **EVG members**

**EVG members** assign the outcome

***EVG members*** complete the «*EVG Final Treatment outcome*» Worksheet (in the «*Event Validation document*») on SharePoint and notify the **Site** by email

**Site investigators** modify the source document

**Discrepancy** due to incorrectly entered/missing data in OpenClinica

**Site Data Entry** modifies/adds the data in OpenClinica

**Concordant outcome**

EVG Treatment outcome

**=**

Site PI Treatment outcome

**Discordant outcome**

EVG Treatment outcome

**≠**

Site PI Treatment outcome

**EVG members** assign the outcomes based on available data and request data if needed to the Site (e.g. Chest X-rays)

**Need evaluation**

**Discordant outcome**

Algorithm Treatment outcome

**≠**

Site PI Treatment outcome

**Concordant outcome**

Algorithm Treatment outcome

**=**

Site PI Treatment outcome

**Group C: Outcomes related to the evaluation of bacteriological, radiological and clinical evolution**

**Group A: Outcomes related to death or treatment**

**Group B: Outcomes related to microbiological results only**

**Statistician:** a)runs the algorithm to classify treatment outcomes; b) creates one «*Event Validation document*» for each outcome in SharePoint and a listing of the new treatments outcomes; and notifies the **EVG members** by email (cc Trial Manager and Central Study Co).