



To Whom It May Concern:

RE: CSR Results posting (EudraCT 2014-001863-11)

In relation to an error displayed during the validation process in section „Baseline Characteristics/Subject analysis set“, the “Safety Analysis Set”, was removed from the full data set.

The error was generated during the validation process due to the following reason: “The number of subjects in Safety analysis set (464) exceeds the number of enrolled subjects (463)”.

Please find a justification as follows:

The number of subjects included in Safety Analysis Set is corresponding with the number of subjects who were given at least one dose of study treatment – 464 subjects. It has been identified that not all of them had been randomized. The randomized subjects were 463 and they were included in ITT Analysis set.

Yours sincerely,

Eva Salapova