01.06.2016

CLEAR; Uni-Köln-1667

Annex 1: referred to D.2.2 *Declaration of the End of Trial Form*

D.2.2.1 The justification for early termination of the trial;

In the conducted trial three already authorized medicinal products have been used. After Colistin was unavailable in the formulation as a powder for several months, the manufacturer finally decided to discontinue the production of Colistin powder permanently. The use of another formulation is not feasible as the production of a suitable placebo can not be ensured. Consequently the study had to be terminate on May 31st 2016.

D.2.2.2 Number of patients still receiving treatment at time of early termination in the MS concerned by the declaration and their proposed management;

At the time of early termination no patient received any treatment.

D.2.2.3 The consequences of early termination for the evaluation of the results and for overall risk benefit assessment of the investigational medicinal product.

Despite the early termination study data generated during the study, will be evaluated and published. We expect that the results and findings from the study will further contribute to the available knowledge in this research area. The investigational medicinal products conisted of three approved and marketed medicinal products. During the study no new safety issues have been identified.