ANNEX IV

CONTENT OF THE SUMMARY OF THE RESULTS OF THE CLINICAL TRIAL F.ADDITIONAL INFORMATION:

1. Global Substantial Modifications;
2. Global Interruptions and re-starts;
3. Limitations, addressing sources of potential bias and imprecisions and Caveats;
4. A declaration by the submitting party on the accuracy of the submitted information.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EU) No 536/2014 of the European Parliament and of the Council, Division F..