ANNEX IV OF REGULATION (EU) No 536/2014

CONTENT OF THE SUMMARY OF THE RESULTS OF THE CLINICAL TRIAL

The summary of the results of the clinical trial shall contain information on the following elements:

A. CLINICAL TRIAL INFORMATION:

1. Clinical trial identification (including title of the trial and protocol number);
2. Identifiers (including EU trial number, other identifiers);
3. Sponsor details (including scientific and public contact points);
4. Paediatric regulatory details (including information whether the clinical trial is a part of a Paediatric Investigation Plan);
5. Result analysis stage (including information about intermediate data analysis date, interim or final analysis stage, date of global end of the clinical trial). For clinical trials replicating studies on already authorised investigational medicinal products and used in accordance with the terms of the marketing authorisation, the summary of the results should also indicate identified concerns in the overall results of the clinical trial relating to relevant aspects of the efficacy of the related medicinal product;
6. General information about the clinical trial (including information about main objectives of the trial, trial design, scientific background and explanation of rationale for the trial; date of the start of the trial, measures of protection of subjects taken, background therapy; and statistical methods used);
7. Population of subjects (including information with actual number of subjects included in the clinical trial in the Member State concerned, in the Union and in third countries; age group breakdown, gender breakdown).

B. SUBJECT DISPOSITION:

1. Recruitment (including information on the number of subjects screened, recruited and withdrawn; inclusion and exclusion criteria; randomisation and blinding details; investigational medicinal products used);
2. Pre-assignment Period;
3. Post Assignment Periods.

C. BASELINE CHARACTERISTICS:

1. Baseline Characteristics (Required) Age;
2. Baseline Characteristics (Required) Gender;
3. Baseline Characteristics (Optional) Study Specific Characteristic.

D. END POINTS:

1. End point definitions [(1)]
2. End Point #1

   Statistical Analyses
3. End Point #2

   Statistical Analyses

E. ADVERSE EVENTS:

1. Adverse events information;
2. Adverse event reporting group;
3. Serious adverse event;
4. Non-serious adverse event.

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.

[(1)] Information shall be provided for as many end points as defined in the protocol