

**Comment of the Network of Coordinating Centers for Clinical Trials
(KKS-Network), Germany**

on the

**Consultation document “Definition of Investigational Medicinal Products (IMPs)
and use of Auxiliary Medicinal Products (AMPs)” (01/06/2016)**

Recommendations of the expert group on clinical trials for the implementation of Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use

General remarks:

We thank the expert group very much for the above mentioned document. The document is well structured, clear and precise. The relevant content is easy to understand also for people with little precognition.

Technical comments:

Chapter 3.1, last paragraph: The sentence does not seem to be complete.

Köln / Berlin, 31.08.2016