Sini Eskola

Regulation 536/2014: Status Quo from EFPIA perspective

The implementation of CTR 536/2014 will be discussed from EFPIA perspective and the latest key results of the comprehensive survey conducted by EFPIA and its national trade association members on national level Regulation implementation will be presented. The presentation will also raise the open questions still to be resolved in the implementation of the Regulation from industry perspective, including aspects of the new EU Clinical Trials Portal and Database. A short overview of the key EFPIA comments to the recent Commission consultations on the following guidelines will be presented; 1. lay summary guideline, 2. guideline on risk proportionate approach to clinical trials, 3. guideline on definition of IMP and AMP and 4. guideline for ethical considerations of trials with minors.