

Executive Summary

The template EPAD LCS Agreement's main purpose is to provide a legal framework for contracting the Trial Delivery Centers which will perform part of the EPAD Cohort study.

Janssen and UEDIN jointly initiated work on this template, which became more complicated (and time consuming) as initially expected for the following reasons:

- The sponsorship role for the EPAD Cohort study needed to be determined. Ultimately, it was decided to adopt a “one-sponsor” approach for all Trial Delivery Centers in the EPAD Cohort study, with UEDIN as the sponsor.
- The relationship between UEDIN and Lothian Health Board, the entity with which it regularly co-sponsors trials needed to be clarified. For the EPAD Cohort study, no such co-sponsorship structure will be adopted.
- The EPAD Cohort study consists of different “waves” of contracting Trial Delivery Centers, and the template needs to be usable for all these waves. First UEDIN will contract the Trial Delivery Centers which are also involved as participants in EPAD (i.e. the National/Regional Leads). This triggers less of discussion as matters such as liability and intellectual property have already been agreed in the EPAD Project Agreement. In a second stage, however, UEDIN will contract Trial Delivery Centers which are not a participant in EPAD. For this reason, the template needs to foresee more detailed language to safeguard the EPAD participants' interests, as well as more detailed financial arrangements.

After agreement between Janssen and UEDIN, the template was reviewed, revised, and approved by the EPAD Legal & IP Committee on February 18, 2016.

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