European Commission Public consultation on Draft Revision 3 of ‘Detailed guidance for the request for authorisation of a clinical trial on a medicinal product for human use to the competent authorities, notification of substantial amendments and declaration of the end of the trial’

CTRU Leeds Response

Pages 13 – 17 IB/IMPD/Simplified IMPD.Page 13 states that an IB must accompany a request for authorisation, but may be replaced by the SmPC if the IMP is authorised in any Member State and is used according to the terms of the marketing authorisation.However, no guidance is given on when an IMPD is required, or perhaps more relevant: under what circumstances one is not required. Also the guidance on when a simplified IMPD is required is also unclear, e.g ‘a simplified IMPD may be submitted if the information relating to the IMP is contained in the IB’ - but this only explains that a full IMPD is not required, but does not specify whether a simplified IMPD is required in all applications. We need to know under what circumstances will a SmPC alone suffice, when will an IB (alone or with SmPC) suffice and when is an IMPD (full or simplified) required? Also, the current application form does not contain provision for saying that an IB has been submitted (the only options are full IMPD, simplified IMPD and SmPC).

Pages 13 – 17 would benefit from additional information regarding preparation of an IMPD / summary IMPD for placebos and additionally what documentation should accompany an application for over-encapsulated IMPs when being used in a placebo controlled trial.