

Note on data collection timelines:

Study start: The official study start was December 2nd, 2011 when the service contract with EMA was signed.

Start of data collection, locally at each center, was June 26th. As the ENCePP seal application was delayed for logistic reasons (holidays and mail delivery delays) the data are held locally until the application is submitted.

Start of data collection, in terms of sending the aggregated research files from the local center to the central server for analysis, is now planned for **August 22** but will be postponed until **confirmation of our submission**. The original documents were sent by regular mail to EMA on **August 15, 2012**.

The signed original declaration of interest form from UNIMIB has not yet been received by PHARMO, who submits the seal application, and research file transfer is postponed until submission of this original to EMA.