This application has been submitted as a "transitional trial". The clinical trial is already approved and ongoing under the national legislations based on Directive 2001/20/EC and the sponsor is now applying for the clinical trial to be governed under the rules set out in the Regulation (EU) 536/2014.

The application fulfils the requirements of a transitional trial. The sponsors proposed category for publication of documents and data (according to EMA/228383/2015) is considered acceptable.

In light of this initial transition submission, no further assessment is performed.

Accordingly to Best practices, the application is approvable with the following condition :

"The sponsor must update the application dossier in line with Regulation (EU) No 536/2014 in a Part I substantial modification application BEFORE any additional MSC is added to the trial. Information on whether any additional MSC(s) will be added in line with Article 14 of the regulation, should be announced in the cover letter to the SM Part I application to allow the RMS to make a meaningful summary of the trial assessment accessible for the additional MSC. For details on the first SM after transition, see CTCG guidance and annexes I-III, published on the CTCG website (part of hma.eu) under Key documents."