

*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.*