

Clinical Trial Facilitation and Coordination Group

CTFG

VHP procedures in preparation and in case of a no-deal Brexit

As a consequence of a possibility of a “no deal” Brexit, reflecting the still unclear status of the negotiations² between the United Kingdom and the EU, the CTFG will use the following principles for ongoing and new VHPs involving the UNITED KINGDOM.

1. Starting as of 30. March 2019 the United Kingdom will not be eligible for participation in the VHP procedure as a P-NCA.
2. Taking into account the timelines for VHP applications with conditions and the VHP-winter break 2018¹, the last day on which a VHP application with the proposal of the United Kingdom as a Ref-NCA will be accepted will be **20.12.2018**. After that date, the United Kingdom won't be accepted as a Ref-NCA.
3. Ongoing CTs after a positive VHP opinion, in which the Ref-NCA is the United Kingdom, will need a new Ref-NCA. The general mechanism on procedures, where the Ref-NCA has been lost in VHP, will be applied. This means that the VHP-A will ask the remaining P-NCAs for each VHP procedure to volunteer for the Ref-NCA function at the time of submission of VHP-substantial amendments (VHP-SA). In the light of the timelines of VHP-SA with condition¹s, this means that after **1. February 2019** all substantial amendments, in which the United Kingdom functions as a Ref-NCA will be subjected to this mechanism. In case none of the remaining P-NCAs volunteer as the Ref-NCA for this SA, the VHP will be stopped and all further SA will have to be submitted to the NCAs via the national routes only.
4. All Sponsors or applicants with ongoing VHPs should scrutinise their dossiers e.g. IMPDs for parts that might be affected by Brexit. More details are given in the document **NOTICE TO STAKEHOLDERS of the EUROPEAN COMMISSION**² section 1 and 2. Please note that VHP substantial amendments might be needed, if the manufacturing/quality person (QP) is to be changed and national amendments only might be needed, if the sponsor / legal representatives are to be changed, due to Brexit.
5. Please note that all Clinical Trial Approvals after positive VHPs will retain their approval. Changes might only be needed in cases described under 3.

1 http://www.hma.eu/fileadmin/dateien/Human_Medicines/01-About_HMA/Working_Groups/CTFG/2016_06_CTFG_VHP_guidance_for_sponsor_v4.pdf

2 **NOTICE TO STAKEHOLDERS of the EUROPEAN COMMISSION: WITHDRAWAL OF THE UNITED KINGDOM AND EU RULES IN THE FIELD OF CLINICAL TRIALS;** Brussels, 6 September 2018,
https://ec.europa.eu/info/sites/info/files/notice_to_stakeholders_brexit_clinical_trials_final.pdf