

Conclusion of VHP Procedure

Deadline for submissions to VHP in the context of the Christmas Break 2021/2022 and transition to CTIS/CTR starting with the CTR application

Dear VHP-applicants

The full implementation of the CTR 536/2014 is planned for the 31.1.2022. In order to organise a smooth transition of the VHP-Processes into CTIS and the CTR, especially in the light of the VHP-Christmas break the following deadlines were defined.

The VHP Christmas break 2021/2022 will take place between 22.12.2021 and 7.1.2022 (including). All VHPs procedures should be finalised in January 2022. In order to achieve this goal and to offer clear guidance

the last day for any VHP submission (initial, substantial amendment, 2nd round) will be 15 October 2021.

This deadline ensures that the initial assessments, sending of GNA and response to GROUNDS FOR NON-ACCEPTANCE will be finalised before the Christmas Break. Final assessments, decisions and fulfilments of conditions, if needed, will be done after the Christmas break in January. Sponsor could decide afterwards either to file national submission (after the VHP as usual) or to transfer the Clinical trial directly to the CTIS/CTR. When pursuing the latter path, the involvement of Ethics Committees or others involved in the CTRs part II assessment has to be ensured outside of VHP and in CTIS! Questions on this topic cannot be answered by the VHP-A or Clinical Trials Facilitation Group, please check with responsible national bodies.

In order to harmonise VHP-Processes, the last day to submit any new VHP-substantial amendments or second round will be 15 October 2021 too.

Submission after the Deadline (15 October midnight) will not be accepted without further notice (neither initial, nor substantial amendment nor addition of MS). No exceptions will be considered.

**All VHP-Administrators at the Paul-Ehrlich-Institute and
the whole Clinical Trials Facilitation and Coordination Group
want to THANK YOU for using VHP for 12 years and for giving us the opportunity to
experience international harmonisation of clinical trials in Europe!**