

Sponsors are reminded that investigators have to be trained according to the Curriculum of the Bundesärztekammer and the Working Party of German Ethics Committees Arbeitskreises Medizinischer Ethik-Kommissionen (cf. Bekanntmachung der Bundesärztekammer. Dtsch Arztebl. 2022;119(19):A-888). If the participation to a basic and/or advanced course dates back before 12.06.2020 the investigators need a proof of participation in the "Update course VO (EU) No. 536/2014".

Such a certificate is not needed if it can be seen from the already acquired certificates that the new legal situation [VO (EU) 536/2014, Viertes AMGÄndG] has already been comprehensively taught.

If the proof of participation in an update course or otherwise sufficient regulatory training on the CTR (see above) cannot be provided during transition process (cf. Question 5/6 "Guidance for the Transition of clinical trials from the Clinical Trials Directive to the Clinical Trials Regulation", 19 July 2023), the sponsor shall confirm that all investigators are trained accordingly.

Please note that this is an exception to facilitate uninterrupted conduct of transitioned trials. Individual training certificates including training on CTR will be required for all new / initial (non-transitioned) trials.