Transition Trials

Which documents have to be provided for part II in case of "transition trials"?

In accordance with questions 7 and 8 of the "Guidance for the Transition of clinical trials from the Clinical Trials Directive to the Clinical Trials Regulation", March 2024 the sponsor is requested to submit the latest authorised versions of the subjects' information sheet(s) and the informed consent as a minimum set for Part II. No additional part II documents are required for validation of the transitioning application. No other documents should be submitted. Additional documents would not be part of the validation . Be reminded that during the transitioning application no changes to already approved documents, trial sites, investigators etc. are allowed.

Only the clinical trial sites which are active need to be included in the application form. For any previously approved and not yet deregistered trial site that is not being transitioned, the sponsor should clarify in the cover letter that this site shall be deregistered.

Unless stated otherwise in the cover letter and CTIS, trial sites will be deemed to proceed under CTR with only their principal investigator (“Prüfer”) and not the former deputy (“Stellvertreter” named in the site suitability form) as investigator.

For further details we refer to the Guidance mentioned above.

What needs to be considered concerning part II in the event of a subsequent substantial modification after the clinical trial has been transferred to the CTIS as a transition trial?

With the first substantial modification of part II, the sponsor should complete **all** elements related to Part II of the dossier (i. e. all documents required for part II according to Annex I CTR). E. g., for all named investigators the CV, FDF and training certificates have to be uploaded.

In transitioned trials, no formal evidence (“update” certificate) is required to show that investigators previously approved under CTD have been trained up to the standards of CTR. According to ICH E6 5.6.1 it is the sponsor’s responsibility to ensure that investigators are qualified to properly conduct the trial under CTR. In general, the CVs, FDF and certificates approved under CTD do not have to be updated. The site suitability statement does not have to be updated retrospectively, the version approved under CTD should be uploaded.

Please note that formal evidence on regulatory training including training on CTR (https://www.akek.de/curriculare-fortbildungen/) is required for any new investigators added after transition.

In the course of a substantial modification application, the sponsor should clearly state in the cover letter or by way of a “Summary of Changes”-document:

- which documents in part II are only being supplemented and have not changed since their approval under CTD, and

- which documents in part II have been amended since their approval under CTD and are now being submitted for approval as part of the substantial modification application.
- If during the SM documents are replaced by new versions, it is sufficient to provide the new version.

The sponsor should provide a document with a list of the trial sites including the names of investigators. Any changes to trial sites and/or investigators that are being submitted for approval as part of the substantial modification application should be highlighted.