BASG / AGES
Institut Überwachung
Traisengasse 5, 1200 Wien, Österreich

Classification of Amendments for Clinical Trials with Medicinal Products according to the Austrian Medicinal Products Act (AMG)

Example	substantial	non-substantial
Change of main objective	**X**	
Change of primary or secondary endpoint	**X**	
Use of new measurements (methods) for the primary endpoint	**X**	
Change in the definition of the end of the trial	**X**	
Addition of a trial arm or placebo group	**X**	
Change of in-/exclusion criteria	**X**	
Reducing number of monitoring visits	**X**	
Withdrawal of independent data monitoring board (DSMB)	**X**	
Change of IMP	**X**	
Change of dosing of IMPs	**X**	
Change of mode of administration of IMPs	**X**	
Change of study designs with impact on statistical analysis or the risk/benefit assessment	**X**	
Change of sponsor or the sponsor's legal representative	**X**	
Revocation or suspension of the IMP's MA	**X**	
Changes in the manufacturing process and/or specifications of an active substance /IMP (exception: Shelf life extensions*)	**X**	
Change of the reference safety information (RSI) during the conduct of a clinical trial.	**X**	
Addition of a study site	**X**	
Change of investigator	**X (EC)**	**X (BASG)**
Changes to the patient information	**X (EC)**	**X (BASG)**
Change of the applicant		**X**
Change of contact details of the applicant		**X**
Change of CRA (Clinical Research Associate) for monitoring		**X**
Change of CRO		**X**
Change of internal organization of the sponsor		**X**
Change of logistical arrangements for storing/transporting samples		**X**
Change of technical equipment		**X**
Closing of a study site		**X**
Change of main objective	**X**	
Change of case report forms		**X**
Minor changes of duration of the trial (< 10 %)		**X**

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Example	substantial	non-substantial
Increase in duration of the trial > 10 % provided that… 1. the exposure to treatment with the IMP is not extended, 2. the definition of the end of the trial is unchanged, and 3. monitoring arrangements are unchanged		**X**
Change in the number of clinical trial participants per trial site (if the total number of participants in the Member State concerned is identical)		**X**
Insignificant increase/ decrease in view of the absolute number of participants		**X**
Minor clarifications to the protocol		**X**
Correction of typographical errors		**X**
Shelf life extensions according to protocol		**X**

* see also Guidance for submission of a clinical trial (L_Z109_Guidance_CT_submission_en.pdf)

Please note:

- Non-substantial amendments can be appended to subsequent substantial amendments.
- Changes of the protocol on request of the Ethics Committee are regarded as **non-substantial** amendments (exception) and have to be **immediately** communicated to the CA. However, the updated protocol is to be submitted to the Competent Authority.
- If non-substantial changes result in the modification of the Clinical trial application (CTA) file, the updated xml-file is to be submitted to the BASG.

Shelf-life extensions:

Shelf-life extensions are not substantial amendments if the applicant has outlined a detailed plan on the intended stability protocol in the original Clinical Trial Application, with a clear description of the intended frequency of testing and on the planned submission of stability data. Further, the methods or specifications set for the stability protocol must not be changed from the original application – additional methods and time-points may be included.
This implies, for example, that the replacement of one test method by another would require the submission of a substantial amendment. Deviations from the stability programme detected during ongoing routine stability monitoring have to be reported to the BASG.