Bundesamt für Sicherheit
im Gesundheitswesen

List of documentation required *(former „J-Checklist“)*

List of documentation to be provided to the national competent authority of the Member State concerned in accordance with the CT-1 document[1], sections 2.3 to 2.10:

1. **Cover letter**
   (see CT-1, section 2.3)
2. **Clinical trial application form**
   (EudraCT form, see CT-1, section 2.4 and https://eudract.ema.europa.eu/)
3. **Protocol**
   (see CT-1, section 2.5 and *Guideline For Good Clinical Practice, ICH E6*)
4. **Investigator's Brochure (IB)** or document replacing the IB
   (see CT-1, section 2.6)
5. **Investigational Medicinal Product Dossier (IMPB)/simplified IMPD**
   (see CT-1**,** sections 2.7)
6. **Non-Investigational Medicinal Product (NIMP) dossier**
   (see CT-1, section 2.8)

Additional documentation as set out in Section 2.9, CT-1:

7. A copy of the opinion of the Ethics Committee (if already available)
8. If available, a copy of the summary of scientific advice from any Member State or the EMA with relevance for the clinical trial.
9. If the clinical trial is part of an agreed PIP (Paediatric Investigation Plan), a copy of the EMA's Decision on the agreement on the PIP, and the opinion of the Paediatric Committee, unless these documents are fully accessible via the internet. In the latter case, the link to this documentation in the cover letter is sufficient (see Section 2.3).

The applicant is further asked to submit a single draft of the informed consent form. It is regarded as supportive documentation and will not be reviewed by the Competent Authority.

The EudraCT application form (in PDF and XML) and the documents required for the assessment need to be submitted electronically on a data medium (e.g. CD). The application should then be sent to the BASG together with a covering letter by post.

Attention!
The primary contact information for correspondence and requests by the Austrian competent authority is the person indicated as applicant in the application form under C.1.

If the invoice address differs from the address of the applicant indicated in section C of the EudraCT application form, this needs to be clearly stated in the cover letter.

[1] Communication from the Commission — Detailed guidance on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and the declaration of the end of the trial (CT-1).