LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

Checklist for joint application of clinical trials

Below you can see which documents you need to submit via the DKMAnet portal when you apply to conduct a new clinical trial of medicines. All documents must be dated and bear a version number.

If you need more information about the required content of the individual documents, please consult the respective guidelines of the Danish Medicines Agency and the Research Ethics Committee System here:

Guidelines of the Danish Medicines Agency
Guidelines of the Research Ethics Committee System (in Danish)

	Mandatory for all trials	Dependent on the specific trial	Documentation to be submitted to	No. of attachments allowed
Covering letter - e.g. including: List of appendices, information about who is monitoring the trial in Denmark, information about reference document.	X		Research Ethics Committee System and Danish Medicines Agency	1
EudraCT form Application form in PDF downloaded from the EudraCT website	X		Danish Medicines Agency	1
Trial protocol Complete with amendments incorporated in the applicable version, including Danish protocol supplement and e.g. procedure for giving oral information	X		Research Ethics Committee System and Danish Medicines Agency	5
Participant information Consent form(s) Power of attorney Power of attorney if the trial may be subjected to inspection by foreign authorities, e.g. the FDA.	X		Research Ethics Committee System and Danish Medicines Agency	2 0
Documentation for investigational medicinal products Investigational Medicinal Product Dossier (IMPD) and Investigator's brochure (IB), manufacturing authorisations and QP declarations, as well as scientific advice, Paediatric Investigation Plan (PIP), documentation that the manufacturer has been informed of the trial. If the investigational medicinal product is marketed, the summary of product characteristics may replace IMPD and IB.	X		Danish Medicines Agency	1 0
Danish protocol summary (replaces lay person summary)	X		Research Ethics Committee System and Danish Medicines Agency	1 5
Material for recruitment of participants		X	Research Ethics Committee System	1 0

Questionnaires and other distributed material		X	Research Ethics Committee System	10
Documentation of the investigator's identity (health insurance card/passport), education (certificate of authorisation) and clinical and research-related experience (CV)	X		Research Ethics Committee System	10
Relevant sections (clauses) of the contract between the sponsor and investigator regarding financial arrangements/funding (Danish translation) and the investigator's access to trial data and publication	X		Research Ethics Committee System	10
Signature page If sponsor/applicant is not the same as the investigator		X	Research Ethics Committee System	10
Other		X	Research Ethics Committee System and Danish Medicines Agency	20
Text for advertising on Sundhed.dk (link) – text must be in Danish.		X	Research Ethics Committee System	No attachment – part of the form.