



CHECKLIST FOR CTA REQUEST AT CA AND EC

This checklist based on section J (formerly section K) of the Guidance ENTR CT1 rev. 2 as of OCT 2005 contains information that the [Czech](#) Competent Authority and Ethics Committees (CA and EC) are requesting.

Comments and modifications applicable for the Czech Republic have been added in blue.
("EC" applies for national EC, local EC's requirements are less)

CA	EC		INFORMATION REQUESTED
		1	General
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	1.1	Receipt of confirmation of EudraCT number
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	1.2	Covering letter (PHAMOS' SOP template)
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	1.3	Application form (web-based EMEA-form in English as hard copy and XML file)
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1.4	List of Competent Authorities within the Community to which the application has been submitted and details of decisions
<input type="checkbox"/>	<input type="checkbox"/>	1.5	Copy of ethics committee opinion in the MS concerned when available
<input type="checkbox"/>	<input type="checkbox"/>	1.6	Copy/summary of any scientific advice (optional)
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	1.7	If the applicant is not the sponsor, a letter of authorisation enabling the applicant to act on behalf of the sponsor (permission of sub-authorisations e.g. CRO 2 by CRO1 must be stated in the authorisation of the sponsor to CRO1, if applicable)
		2	Subject related
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	2.1	Informed consent form (national language)
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	2.2	Subject information leaflet (national language)
<input type="checkbox"/>	<input type="checkbox"/>	2.3	Arrangements for recruitment of subjects (only in case that any specific measures apply)
		3	Protocol related
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	3.1	Clinical trial protocol with all current amendments (English or Czech)
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	3.2	Summary of the protocol in the national language (specific format requested)
<input type="checkbox"/>	<input type="checkbox"/>	3.3	Peer review of trial when available
<input type="checkbox"/>	<input type="checkbox"/>	3.4	Ethical assessment made by the principal/coordinating investigator, if not given in the application form or protocol
		4	IMP related
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	4.1	Investigator's brochure
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	4.2	Investigational Medicinal Product Dossier (IMPD) or 4.3
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	4.3	Simplified IMPD for known products (see table 1) substituting 4.2. if applicable
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	4.4	Summary of Product Characteristics (SmPC) (for products with marketing authorisation in the Community)
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4.5	Outline of all active trials with the same IMP
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4.6	If IMP manufactured in E.U. and if no marketing authorisation in EU: Copy of the manufacturing authorization referred to in Art. 13.1. of the Directive stating the scope of this authorization
		4.7	If IMP not manufactured in E.U. and if no marketing authorisation in EU:
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4.7.1	Certification of the QP that the manufacturing site works in compliance with GMP at least equivalent to EU GMP, or that each production batch has undergone all relevant analyses, tests or checks necessary to confirm its quality
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4.7.2	Certification of GMP status of active biological substance
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4.7.3	Copy of the importers manufacturing authorization referred to in Art. 13.1. of the Directive



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			stating the scope of this authorization
<input type="checkbox"/>	<input type="checkbox"/>	4.8	Certificate of analysis for test product in exceptional cases : Where impurities are not justified by the specification or when unexpected impurities (not covered by specification) are detected
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4.9	Viral safety studies when applicable .
<input type="checkbox"/>	<input type="checkbox"/>	4.10	Applicable authorisations to cover trials or products with special characteristics (if available) e.g. GMOs, radiopharmaceuticals
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4.11	TSE Certificate when applicable
<input type="checkbox"/>	<input checked="" type="checkbox"/>	4.12	Examples of the label in the national language (if administered by the patient himself)
		5	Facilities & staff related
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	5.1	Facilities for the trial
<input type="checkbox"/>	<input type="checkbox"/>	5.2	CV of the coordinating investigator in the MS concerned (for multicentre trials)
<input type="checkbox"/>	<input type="checkbox"/>	5.3	CV of each investigator responsible for the conduct of a trial in a site in the MS concerned (principal investigator): only for local EC's, not for national
<input type="checkbox"/>	<input type="checkbox"/>	5.4	Information about supporting staff: only for local EC's, not for national
		6	Finance related
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	6.1	Provision for indemnity or compensation in the event of injury or death attributable to the clinical trial (insurance must run a national affiliate office)
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	6.2	Any insurance or indemnity to cover the liability of the sponsor or and investigator (insurance must run a national affiliate office)
<input type="checkbox"/>	<input checked="" type="checkbox"/>	6.3	Compensation to investigators (core contract with grant scheme, , may be a three-party contract site-investigator-sponsor for inv. working as employee in a hospital)
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	6.4	Compensation to subjects if applicable
<input type="checkbox"/>	<input checked="" type="checkbox"/>	6.5	Agreement between the sponsor and the trial site (core contract with grant scheme, may be a three-party contract site-investigator-sponsor in case of an investigator working as employee in a hospital)
<input type="checkbox"/>	<input checked="" type="checkbox"/>	6.6	Agreement between the investigators and the trial sites (see 6.3 and 6.5)
<input type="checkbox"/>	<input checked="" type="checkbox"/>	6.7	Certificate of agreement between sponsor and investigator when not in the protocol