C l i n i c a l D r u g T r i a l s

INFORMATION to be provided to the Ethics Committee of Medical University Innsbruck (MUI)

☐ boxes show **information to be provided** to the EC
☐ information **not usually required** for ethics committee application

	1	**General**
☐	**1.1**	Receipt of confirmation of EudraCT number
☐	**1.2**	Covering letter
☐	**1.3**	Application form - EudraCT
☐	~~1.4~~	~~List of Competent Authorities within the Community to which the application has been submitted and details of decisions~~
☐	**1.5**	Copy of ethics committee opinion in the MS concerned when available
☐	**1.6**	Copy/summary of any scientific advice
☐	**1.7**	If the applicant is not the sponsor, a letter of authorisation enabling the applicant to act on behalf of the sponsor
	2	**Subject related**
☐	**2.1**	Informed consent form
☐	**2.2**	Subject information leaflet
☐	**2.3**	Arrangements for recruitment of subjects **(e.g. during hospital stay, via G.P., advertisment etc)**
	3	**Protocol related**
☐	**3.1**	Clinical trial protocol with all current amendments
☐	**3.1A**	Amendments (if separate)
☐	**3.1B**	CRF (Case Report Form)
☐	**3.2**	Summary of the protocol in the national language **(= Section 7 of the EC application form)**
☐	**3.3**	Peer review of trial **when available**
☐	**3.4**	Ethical assessment made by the principal/coordinating investigator, if not given in the application form or protocol
	4	**IMP related**
☐	**4.1**	Investigator's brochure
☐	~~4.2~~	~~Investigational Medicinal Product Dossier (IMPD)~~
☐	~~4.3~~	~~Simplified IMPD for known products (see table 1)~~
☐	~~4.4~~	~~Summary of Product Characteristics (SmPC) (for products with marketing authorisation in the Community)~~
☐	~~4.5~~	~~Outline of all active trials with the same IMP~~
☐	~~4.6~~	~~If IMP manufactured in E.U. and if no marketing authorisation in EU:~~
☐	~~4.6.1~~	~~Copy of the manufacturing authorisation referred to in Art. 13.1. of the Directive stating the scope of this authorisation~~
☐	~~4.7~~	~~If IMP not manufactured in E.U. and if no marketing authorisation in EU:~~
☐	~~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~~
☐	~~4.7.2~~	~~Certification of GMP status of active biological substance~~
☐	~~4.7.3~~	~~Copy of the importers manufacturing authorisation referred to in Art. 13.1. of the Directive stating the scope of this authorisation~~
☐	~~4.8~~	~~Certificate of analysis for test product in exceptional cases :~~
☐	~~4.8.1~~	~~Where impurities are not justified by the specification or when unexpected impurities (not covered by specification) are detected~~
☐	**4.9**	Viral safety studies when applicable.
☐	~~4.10~~	~~Applicable authorisations to cover trials or products with special characteristics (if available) e.g. GMOs, radiopharmaceuticals~~
☐	~~4.11~~	~~TSE Certificate when applicable~~
☐	~~4.12~~	~~Examples of the label in the national language~~
	5	**Facilities & staff related**
☐	**5.1**	Facilities for the trial
☐	**5.2**	CV of the coordinating investigator in the MS concerned (for multicenter trials)
☐	**5.3**	CV of each investigator responsible for the conduct of a trial in a site in the MS concerned (principal investigator)
☐	**5.4**	Information about supporting staff
	6	**Finance related**
☐	**6.1**	Provision for indemnity or compensation in the event of injury or death attributable to the clinical trial
☐	**6.2**	Any insurance or indemnity to cover the liability of the sponsor or investigator
☐	**6.3**	Compensation to investigators
☐	**6.4**	Compensation to subjects
☐	**6.5**	Agreement between the sponsor and the trial site **("Sponsoringvertrag" – inquiries: Fr. Innerhuber/LKI – F:++43-512-504-22040)**
☐	**6.5a**	Compensation to trial sites
☐	~~6.6~~	~~Agreement between the investigators and the trial sites~~
☐	**6.7**	Certificate of agreement between sponsor and investigator when not in the protocol
	7	**Any other material provided**
☐	**7.1**	Miscellaneous (including additional correspondence)