

Disclaimer:

The table below was compiled by information submitted by member state competent authorities.

Whilst CTFG endeavor to ensure that the information is accurate and up to date some inaccuracies may occur.

If you have any matters for clarification in the table below regarding competent authority assessment please contact the relevant member state competent authority.

22 DECEMBER 2008

CTA ASSESSMENT IN MS : Who assesses what ?

	INFORMATION BEING ASSESSED*	AT		BE		DK		FI		FR		DE (PEI)		DE (Bfarm)		GR	
		CA	EC	CA	EC	CA	EC	CA	EC	CA	EC	CA	EC	CA	EC	CA	EC
1	Subject related																
1.1	Informed consent form	X	X		X	X	X	X	X		X		X		X		
1.2	Subject information leaflet	X	X		X	X	X	X	X		X		X		X		
1.3	Arrangements for recruitment of subjects	X	X		X		X	(X)	X		X		X		X		
2	Protocol											X	X	X	X		
2.1	CT design methodology - statistics	X	X		X	X	X	X			X	X	X	X	X		
2.2	Security of subjects (inclusion/exclusion criteria ; follow-up measures...)	X	X		X	X	X	X		X	X	X	X	X	X		
2.3	Choice of dose, posology	X	X	X	X	X	X	X		X	X	X	X	X	X		
2.4	Choice of comparator	X	X		X	X	X	X		X	X	X	X	X	X		
2.5	Need for a DSMB					X		X		X	X						
3	IMP dossier											X		X			
3.1	Quality part (including viral safety part)	X		X		X		X		X		X		X			
3.2	Non clinical part	X		X		X		X		X		X		X			
3.3	Clinical part	X		X		X		X		X	X	X	(X)	X	(X)		
3.4	Labelling	X1		X				X				X		X			
4	Facilities & staff related	X1					X	X	X		X		X		X		
5	Finance / Insurance related								X		X						
5.1	Provision for indemnity or compensation in the event of	X	X		X		X		X		X	(X)	X	(X)	X		

	injury or death attributable to the clinical trial																
5.2	Any insurance or indemnity to cover the liability of the sponsor or investigator	X	X		X		X		X		X	(X)	X	(X)	X		
5.3	Compensations to investigators	X	X		X		X	(X)	(X)	(X)			X		X		
5.4	Compensations to subjects	X	X		X		X		X		X		X		X		

CA : competent authority

EC : Ethics committee

(*) Further comments at the end of the document

CTA ASSESSMENT IN MS : Who assesses what ?

	INFORMATION BEING ASSESSED*	IT		IE		LU		NL		PT		ES		SE		UK	
		CA	EC	CA	EC	CA	EC	CA	EC	CA	EC	CA	EC	CA	EC	CA	EC
1	Subject related												X				X
1.1	Informed consent form		X	X	X	X	X		X		X		X	X	X		X
1.2	Subject information leaflet		X	X	X	X	X		X	(X)	X		X	X	X		X
1.3	Arrangements for recruitment of subjects		X		X	(X)	X		X		X		X		X		X
2	Protocol					X						(X)	X	X	X	X	X
2.1	CT design methodology - statistics		X	X	X	X	X		X	(X)	X	X	X	X	X	(X)	X
2.2	Security of subjects (inclusion/exclusion criteria ; follow-up measures...)	(X)	X	X	X	X	X		X	X	X	X	X	X	X	X	X
2.3	Choice of dose, posology	(X)	X	X	X	X	X		X	X	X	X	X	X		X	X
2.4	Choice of comparator		X	X	X	X	X		X	(X)	X	X	X	X	X	(X)	X
2.5	Need for a DSMB			(X)	X	X	X		X	(X)	X	X	X	X	X	X	X
3	IMP dossier					X						X		X		X	
3.1	Quality part (including viral safety part)	(X)	X	X		X	(X)		X	X	(X)	X		X		X	
3.2	Non clinical part	(X)	X	X		X	(X)		X	X	(X)	X		X		X	
3.3	Clinical part	(X)	X	X		X	X	(X)	X	X	X	X		X	X	X	
3.4	Labelling		X	X		(X)			X	X		(X)		X		X	
4	Facilities & staff related		X	X		X	X				X		X		X	(X)	
5	Finance / Insurance related					X	X				X		X		X		X
5.1	Provision for indemnity or compensation in the event of injury or death attributable to the clinical trial		X		X	X	X		X	(X)	X		X		X		X
5.2	Any insurance or indemnity to cover the liability of the sponsor or investigator		X		X	X	X		X	(X)	X		X		X		X
5.3	Compensations to investigators		X		X	X	X		X		X		X		X		X
5.4	Compensations to subjects		X		X	(X)	X		X		X		X		X		X

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(*) Further comments at the end of the document

CTA ASSESSMENT IN MS : Who assesses what ?

	INFORMATION BEING ASSESSED*	CY		CZ		EE		HU		LV		LT	
				CA	EC	CA	EC	CA	EC	CA	EC		
1	Subject related			X	X								
1.1	Informed consent form			X	X	X	X	(X)	X	X	X		
1.2	Subject information leaflet			X	X	X	X	X	X	X	X		
1.3	Arrangements for recruitment of subjects				X		X	(X)	X		X		
2	Protocol			X	X								
2.1	CT design methodology - statistics			X	X	X		X	X	X	X		
2.2	Security of subjects (inclusion/exclusion criteria ; follow-up measures...)			X	X	X		X	X	X	X		
2.3	Choice of dose, posology			X	X	X		X	X	X	X		
2.4	Choice of comparator			X	X	X		X	X	X	X		
2.5	Need for a DSMB			X	X	X		X	X	X	X		
3	IMP dossier			X	X			X					
3.1	Quality part (including viral safety part)			X		X		X		X			
3.2	Non clinical part			X		X		X		X			
3.3	Clinical part			X		X		X		X			
3.4	Labelling			(X)		X		X		X			
4	Facilities & staff related			(X)	X	X	X	(X)	X				
5	Finance / Insurance related			(X)	X	X	X						
5.1	Provision for indemnity or compensation in the event of injury or death attributable to the clinical trial				X	X	X	(X)	X	X	X		
5.2	Any insurance or indemnity to cover the liability of the sponsor or investigator				X	X	X	(X)	X	X	X		
5.3	Compensations to investigators				X		X	(X)	X				
5.4	Compensations to subjects				X		X	(X)	X	X	X		

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(*) Further comments at the end of the document

CTA ASSESSMENT IN MS : Who assesses what ?

	INFORMATION BEING ASSESSED*	MT		PL		SK		SI		NO		IS	
		CA	EC	CA	EC	CA	EC	CA	EC	CA	EC	CA	EC
1	Subject related												
1.1	Informed consent form			X	X			X				X	X
1.2	Subject information leaflet			X	X			X				X	X
1.3	Arrangements for recruitment of subjects				X							X	X
2	Protocol	X											
2.1	CT design methodology - statistics	X		X	X			X				X	X
2.2	Security of subjects (inclusion/exclusion criteria ; follow-up measures...)	X		X	X			X				X	X
2.3	Choice of dose, posology	X		X	X			X				X	X
2.4	Choice of comparator	X		X	X			X				X	X
2.5	Need for a DSMB	X		X	X								X
3	IMP dossier												
3.1	Quality part (including viral safety part)	X		X	X			X				X	
3.2	Non clinical part	X		X	X			X				X	
3.3	Clinical part	X		X	X			X				X	
3.4	Labelling	X		X				X				X	
4	Facilities & staff related	X			X								
5	Finance / Insurance related												
5.1	Provision for indemnity or compensation in the event of injury or death attributable to the clinical trial			X	X							(X)	X
5.2	Any insurance or indemnity to cover the liability of the sponsor or investigator			X	X			(X)					X
5.3	Compensations to investigators			X	X								X
5.4	Compensations to subjects			X	X								X

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() Further comments at the end of the document

Further comments

AT: Labelling (3.4) and Facilities and staff (4) are assessed by the Inspection unit of the CA

FI: Ethical and scientific assessments are overlapping. There is no legal or other obstacle for EC or CA to comment any aspect of the trial. For example, when assessing paediatric clinical trials, at least one member of the EC is an expert in paediatrics. She or he often comments also the protocol.

The answers given are thus not exclusive but merely describe the present practice.

Assessment of compensation to investigators is not mentioned in Finnish law as a duty of EC or CA. However, EC and CA have commented it, when it may have had inappropriate effect on recruitment.

FR:

2.: protocol is assessed by both EC and AC ; Afssaps is mainly responsible for insuring the safety of participants in the trial and the quality/and safety of the IMP. Statistical and methodology/design is, among others, a specific mission of ECs.

5.3. Compensations to investigators are assessed by a French competent authority which is not Afssaps.

DE (PEI and Bfarm):

3.3 quality, preclinical parts may be discussed by Ethics Committees as part of the IB clinical documentation is often presented to the Ethics Committees outside of an IMPD; when presented within the IMPD it is assessed also by the Ethics Committees

5.1/5.2 insurances are in the responsibility of the Paul-Ehrlich Institute only in the case of xenogenic cell therapeutics, all other insurances are in the responsibility of the Ethics Committees

IT: The Security of subjects (2.2) , Choice of dose, posology (2.3) Quality part (3.1) non clinical (3.2) and clinical(3.3) aspects are assessed by the CA only for phase I trials, cell/gene therapies and OGM medicinals.

LU: The CA requires on request only the information on arrangements of recruitment of subjects and compensations to subjects. Examples of the label are requested in French or German.

The EC assesses parts of the IMP dossier (quality part and non clinical part) through the Investigator's Brochure.

NL: The CA within the Netherlands only perform a very marginal assessment of the clinical trial, involving only a check of the Clinical trial Module of the Eudravigilance

database for suspected unexpected serious adverse reactions (SUSARs) and a check of EudraCT database on inspections. The assessment of the complete research file/dossier (including IB and IMPD) is done by accredited ECs.

PT: All items of “1-Subject related” and “2-Protocol” information marked both for the EC and by the CA, are assessed in different perspectives, which avoid overlapping. EC assessment encompasses the overall scientific value and related ethical assessment whilst CA assessment is focused in the safety of the IMP use in the proposed trial. Therefore brackets were added to differentiate information which is not the focus of the assessment, although taken into consideration/referred to for that purpose. Non clinical and clinical parts are generally reviewed by EC as part of the IB, although if deemed necessary the IMPD may be requested by the EC. Indemnity/insurance matters (section 5.1/5.2), CA has responsibility for its consideration (to enable checking that related legal aspects are covered) in accordance with National CT legislation. Please note that Portuguese Central EC has been consulted for the purpose of their information/column.

ES: National legislation does not differentiate the aspects to be assessed by the CA or the EC for those documents such as protocol to be received by both of them. The CA often accepts the EC opinion without further protocol assessment for those CT referring to the use of medicinal products authorised in the UE (In Spain the favourable EC opinion is a pre-requisite for the authorisation by the AEMPS of the CT. In parenthesis are aspects which are sometimes but not systematically assessed; for example sample size is assessed in some bioequivalence clinical trials which are known to be intended to support the application for marketing authorisation of a generic, and in order to avoid inappropriate trials in healthy volunteers. Compliance with labelling requirements of GMP annex 13 is a mandatory requirement in national legislation.

UK: When assessing the CT design methodology, the competent authority does not assess the statistical basis of the trial or its potential to lead to a successful marketing authorisation application, but rather the safety of the trial. When considering the comparator, the competent authority considers the safety of the comparator whereas the ethics committee may consider whether this is the most suitable comparator. Whilst the ethics committees in the UK make their considerations in different ways, in general they will consider the information indicated to a greater or lesser degree. The competent authority assesses the facilities and staff related to the trial at inspection rather than at the trial authorisation stage.

CZ: Labelling (3.4) – the requirements on the labelling are given by the Czech legislation. Should the sponsor intend to implement any deviation, this would be assessed on a case-by-case basis.

Facilities & staff related (4) – the Agency does not comment on the particular facilities and investigators that should take part in the trial. However, should there be concerns about the type of the facilities (e.g. in-patient vs out-patient facilities i.e. need for hospitalisation); these could also be raised by the Agency.

Finance/ Insurance (5)– Finance/ Insurance related matters are assessed by the Agency only as part of the PIF/ICF review process /i.e. it is checked whether the subjects are informed of any incentives/ expenses (related to the participation) and of the fact that the subjects are insured for participation in a clinical trial. Insurance certificates are not required.

EE: EC evaluates only short overview of the protocol.

HU: In cases signed with * the Hungarian competent authority only verifies if the documents are present, because sponsors are allowed to communicate with EC only via NIP.

Preclinical parts and clinical part discussed by Ethics Committees as part of the IB.

SI: Clarification of point 5.2.: insurance of the sponsor is required.