Nutrition - LUXEMBOURG

Competent author	'ity
Contact Details	Contact Name 1
	Ministry of Health
	Phone
	+352 247-85592 / 96
	Fax
	+352 24795615
	Email General
	info@ms.etat.lu
	Address
	Allée Marconi - Villa Louvigny
	ZIP/City
	2120 Luxembourg
	Country
	Luxembourg (LU)
	Web address
	http://www.ms.etat.lu
	Additional Information
	CA = Ministry of Health No local / regional CA.
Trial Authorisation /	Regulatory and ethics bodies involved in approval process
Registration / Notification	Ethics committee(s) Agency for data protection
	CA - Registration requirements for clinical trials
	Registration recommended
	CA - Submission required to
	not required
	Additional Information
	The Luxemburg clinical trial law only refers to drug trials. Observational studies must not be submitted to CA but if it is an interventional nutrition study we would recommend to notify the Competent Authorities.
Submission Format	Standard application form available
	No
Language of Submission	Language(s) of application
	National languages: French and German, English
	Preferred language of application
	_

	English accepted
	Yes
	Documents mandatory to be in official national language
	_
	Documents mandatory to be in local language of study site
	-
	Documents mandatory to be in language of the study participant
	-
Timelines Authorisation	Additional Information
	not indicated
Ethics committee	
Contact Details	Contact Name 1
	Comité National d'Ethique de Recherche (CNER)
	Contact Name 2
	Dr Georges MICHEL, Président
	Address
	Rue Thomas Edison 1A
	ZIP/City
	L-1445 Strassen
	Country
	Luxembourg (LU)
	Additional Information
	There is only 1 national EC committee
Ethical Review - General	Submission for Ethical review mandatory for
	-
	Submission of study mandatory
	Yes
	Submission to CA and EC to be performed in the following order
	-
	National declaration on Ethical requirements exists
	Yes
	National declaration
	 Deontology code, chap V Hospital act, article 25
Single-Centre Studies -	Ethical approval (favourable opinion) to be obtained from
Ethical Review	National EC
Multi-Centre Studies - Ethical Review	Ethical approval (favourable opinion) required from
	Central EC (authorised to issue a single opinion)

Submission of Application	Entitled to study submission Sponsor Principal Investigator Investigator Industry Prerequisites for submission / approval	
Submission Format	Standard application form available	
	Yes	
	Standard application form	
	Standard application form	
Language of Submission	Language(s) of application	
	National languages: French and German, English	
	Preferred language of application	
	-	
	English accepted	
	-	
	Documents mandatory to be in local language of study site	
	-	
	Documents mandatory to be in language of study participant	
	-	
Timelines Ethical Review	Time in weeks from submission to positive approval (minimum)	
	4	
	Time in weeks from submission to positive approval (maximum)	
	13	
	Time in weeks from submission to positive approval (average)	
	8	
	Additional Information	
	Meeting every 2 months, but documents have to be submitted at the latest 3 weeks before the meeting	
Safety Reporting	Investigator shall report SAE to	
	Sponsor	
Study specific Req	Study specific Requirements	
Sponsor	Sponsorship mandatory	
	Yes	
	Sponsorship mandatory - Additional information	
	There must be a sponsor but not always funding	
	Co-Sponsor - Definition available in national law	
	No	

	Co-sponsorship allowed
	Yes
	Co-sponsorship allowed - Additional information
	Not mentioned in law but co-sponsorship possible
	Contracts with external sponsor
	Yes
Investigator	Entitled to be principal investigator
	Dietitian Nutritionist PhD
	Entitled to be principal investigator for trials with patients
	-
	Entitled to be principal investigator for trials with healthy participants
	-
	Entitled to be principal investigator for trials with vulnerable population
	-
	Additional Information
	Not defined in law, but Primary Investigator has to be experienced in the related domain
Study Participants -	Standard IC form (ICF) available
Informed Consent (IC)	No
	Accepted format of Informed Consent (IC) form
	Written consent
	Accepted format of IC form for studies including patients —
	Accepted format of IC form for studies including healthy participants
	Accepted format of IC form for studies including vulnerable population
	_
Study Participants -	Considered as vulnerable population
Vulnerable Population	Children Incapacitated adults Other
	Vulnerable population - Additional information
	No definition for vulnerable population in law but minors and incapable adults are specifically mentioned
	Regulations concerning the inclusion or exclusion available
	Yes
	Regulations concerning the inclusion or exclusion
	only for pharmaceuticals

	Applicable ethical regulations
	National
	Additional Information
	Law for CT with drugs (30.05.2005) mention minors and incapable adults
Study Participants - Compensation & Reimbursement	Reimbursement for study participants
	Optional
	Compensation is limited to/provided for
	-
	Additional Information
	No incentives or financial benefit are allowed except compensation
Funding	Trials generally financially supported by industry
ý	Yes
	Name of industry company/institution supporting financially
	Pharma companies
	Funding is an issue during the approval process
	Yes
	Additional Information
	only pharmaceutical studies are generally sponsored by industry
	CA submission: free EC submission (initial submission 500€ for academic studies, 1000€ for
	commercial trials)
	EC ensure the Investigator fees and patient compensation are reasonable and are not incentives to join the trial
Study Participants -	Regulations on recruitment process exist
Recruitment & Trial Outcome	No
	Mandatory to inform participant of clinical trial outcome
	No
Insurance	Liability insurance or alternative arrangements for damages mandatory for
	Patients/Volunteers
	Researchers Sponsor
	Name and contact insurance companies insuring clinical research
	Zurich Global Corporate Benelux
	Zurich Insurance plc, Belgium branch
	Avenue Lloyd Georgelaan 7 B-1000 Brussels
	Insurance fee in € value indicated as
	Insurance fee in € value indicated as
	– Insurance fee for lowest risk research - Additional Information
	not indicated
	Insurance fee in € value indicated as
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		No
No	Blood & Tissue Samples	Tissue samples permitted
		No

Data Protection	Specific Requirements
	Yes
	Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files)
	-
Invasive Catheters	Invasive catheters permitted
	Yes
	Additional Information
	as long as there is a favourable opinion from EC
Definition	
Clinical Research	Definition in national law
	The existing law in Luxemburg in clinical trials is the "Grand-Ducal Regulation of 30 May 2005 regarding the implementation of good clinical practice in the conduct of clinical trials with medicinal products for human use". Therefore the below definitions are related to clinical trials with drugs. There is no definition for "interventional studies" or "observational study". The law defines "clinical trials and "non-interventional trials".
Observational Study	Definition in national law
	"non-interventional trial": a study where the medicinal products are prescribed in the usual manner in accordance with the terms of the marketing authorization. The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the medicine is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures shall be applied to the patients and epidemiological methods shall be used for the analysis of collected data.