

Application form
FOR CONDUCTING CLINICAL TRIAL OF MEDICINAL PRODUCT
/APPROVAL OF THE ETHICS COMMITTEE AT HCS PERTINENT TO
CONDUCTING CLINICAL TRIAL OF MEDICINAL PRODUCT

Application for conducting clinical trial of medicinal product to central executive
body (hereinafter – CEB) :

Application for approval of the ethics committee at HCS:

A. Clinical Trial Identification

Full title of clinical trial:
Clinical trial protocol code number (assigned by the clinical trial sponsor), version, and date:
For any translation of clinical trial protocol the date and version of the original document should be indicated.
EudraCT ¹ number (if any):
Name or abbreviated title of clinical trial, where available:
ISRCTN ² number, (if any):

EudraCT (European Union Drug Regulating Authorities Clinical Trials) is the European Clinical Trials Database.

² ISRCTN - International Standard Randomised Controlled Trial Number

B. CLINICAL TRIAL SPONSOR IDENTIFICATION

B1. Clinical trial sponsor

Name of legal person/full name of natural person:
Full name of contact person:
Location of legal person/address of natural person:
Contact telephone number:
Fax number:
e-mail:

B2. Legal representative of the clinical trial sponsor in Ukraine to conduct this clinical trial (if different from the clinical trial sponsor)
Name of legal person/full name of natural person:
Full name of contact person:
Location of legal person/address of natural person:
Contact telephone number:
Fax number:
e-mail:

C. APPLICANT IDENTIFICATION (please tick the appropriate box)

C1. Application to CEB:		C2. Application to the ethics committee at HCS:	
Clinical trial sponsor Official representative of the clinical trial sponsor Person or organization authorized by the clinical trial sponsor to make the application. In this case complete below: Name of legal person/full name of natural person: Full name of contact person: Location of legal person/address of natural person: Contact telephone number: Fax number: E-mail:		Clinical trial sponsor Official representative of the clinical trial sponsor Person or organization authorized by the clinical trial sponsor to make the application. In this case complete below: Name of legal person/full name of natural person: Full name of contact person: Location of legal person/address of natural person: Contact telephone number: Fax number: E-mail:	

D. Information on investigational medicinal product(s) being used in the trial: medicinal product being tested or used as comparator

Before starting clinical trial specific procedures (blinding, clinical trial specific packaging and labelling of investigational medicinal product) information on each "bulk product" should be provided in this

section for both the medicinal product being tested and the product being used as a comparator. Information on placebo (if relevant) should be provided in section E. If the clinical trial is performed with several investigational medicinal products (IMP), use extra pages and give each IMP a sequential number. Information should be given for each IMP, likewise if the IMP is a combination product, information should be given for each active substance.

Indicate which of the following is described below, then repeat as necessary for each of the numbered IMPs to be used in the clinical trial (assign numbers from 1):

Information refers to the IMP number:

IMP being tested

IMP used as comparator

D.1. Status of the investigational medicinal product to be used in the clinical trial

D.1(a) Has the IMP a registration certificate (RC)?:	Yes	No	If yes, specify the following		
			Trade name ¹	Name of the legal person/full name of natural person - RC holder	RC number ¹
• in Ukraine					
• in another country. If “yes”, please, specify:					

Available from the Summary of Product Characteristics

D.1(b) Situation where the IMP to be used in the CT has a RC in Ukraine but as per clinical trial protocol it is not possible to clearly identify the IMP(s) in advance of the trial start, go to D.2:

Has the use of this medicinal product been previously authorized in clinical trial in Ukraine?	Yes	No
--	-----	----

Has the investigational medicinal product been designated to use in this indication as an orphan drug?	Yes	No
If “yes”, give the orphan drug designation number ¹ :		

According to the Community register of orphan medicinal products or another International register (please specify).

D.2. Description of the investigational medicinal product

Medicinal product name²:

Medicinal product code (where applicable)³:

Name of each active substance (INN or proposed INN or if available, specify whether proposed or approved INN):

Other available name for each active substance (CAS⁴, current clinical trial sponsor's code(s), other descriptive names):

ATC code, if officially registered⁵:

Pharmaceutical form (use standard term):

Method of administration (use standard term):

Strength (specify all strengths to be used in clinical trial):

concentration (numerical value):

concentration unit:

concentration type (underline the appropriate: «exact numerical value», «range», «more than» or «up to»)

² In the absence of a trade name, this is the name routinely used by the clinical trial sponsor to identify the IMP in the CT documentation (protocol, investigator's brochure).

³ In the absence of a trade name, this is a code designated and used by the clinical trial sponsor to identify the investigational medicinal product in the CT documentation. This code can be used in case of combinations of medicinal products.

⁴ CAS – register of active substances of American Chemical Society.

⁵ Available from the Summary of Product Characteristics.

Type of medicinal product		
Does the investigational medicinal product contain an active substance:		
of chemical origin?	Yes	No
of biological/biotechnological origin ¹ ?	Yes	No
Is this:		
1) a gene therapy medicinal product ¹ ?	Yes	No
2) a radiopharmaceutical medicinal product?	Yes	No
3) an immunological medicinal product ¹ ?	Yes	No
4) a herbal medicinal product?	Yes	No
5) a homeopathic medicinal product?	Yes	No

6) another type of medicinal product?	Yes	No
If “yes”, specify:		

Complete also sections D.3 and D.4.

D.3. Biological or biotechnological investigational medicinal products

Type of medicinal product		
Extractive	Yes	No
Recombinant	Yes	No
Blood and plasma derived products	Yes	No
Others	Yes	No
If others, specify:		

D.4. Gene therapy investigational medicinal product

Gene(s) of interest:

<i>In vivo</i> gene therapy:	<i>Ex vivo</i> gene therapy:
------------------------------	------------------------------

Type of gene transfer product		
Nucleic acid (e.g., plasmid):	Yes	No
If “yes”, specify		
if naked:	Yes	No
or complex:	Yes	No
Viral vector:	Yes	No
If “yes”, specify the type: adenovirus, retrovirus, AAV, etc.:		
Other:	Yes	No
If other, specify:		

E. Information on placebo (if more than one used – repeat for each)

Is there a placebo used:	Yes	No
--------------------------	-----	----

Information refers to placebo number:	
Specify number of investigational product from D which is it a placebo for	
Pharmaceutical form:	
Method of administration:	
Composition apart from the active substance(s):	
is it identical to the IMP?	Yes No
if “not”, specify major ingredients:	

F. Information on manufacturing site responsible for the release of the investigational medicinal product

This section deals with investigational medicinal product and comparator product, manufactured for use in clinical trial (released, randomized, packaged, labelled). If there is more than one site or more than one IMP is released, use extra pages and give each IMP its number from D or E (for placebo) and indicate which investigational medicinal product is released by each site.

Responsible for the release of the finished IMP (please tick the appropriate box):	
This manufacturing site is responsible for release of such IMP (specify the number(s) from D for the IMP and E - for the placebo):	
☐ Manufacturer ☐ Importer ☐ Both manufacturer and importer	
Name of organization:	
Location:	
Please give the manufacturer’s or importer’s authorization number:	
If no authorization available, give the reason:	
Has the manufacturing site been inspected by competent authorities?	Yes No
If “yes”, date of most recent inspection and who performed it:	

G. General information on the clinical trial

<i>Pathological condition or disease under investigation</i>

Specify pathological condition (free text):

ICD classification code (ICD-10)¹:

MedDRA classification code¹:

Rare disease

Yes

No

¹ The information on the ICD-10 and MedDRA (the Medical Dictionary for Regulatory Activities) classification is optional. When both classification codes are available only one should be provided; in this case it is recommended to provide the MedDRA classification code.

Objective of the trial

Main objective:

Secondary objectives:

Principal inclusion criteria *(list most important)*

Principal exclusion criteria *(list most important)*

Primary end point(s):

Scope of the trial — tick all the boxes where applicable

Diagnosis

Prophylaxis

Therapy

Safety

Efficacy

Pharmacokinetics

Pharmacodynamics

Bioequivalence

Dose response

Pharmagenomics

Pharmacoeconomics

Other

If “other”, specify:

Human pharmacology (Phase I)	Therapeutic exploratory (Phase II)	Therapeutic confirmatory (Phase III)	Therapeutic use (Phase IV)
Is the trial:			
First administration to humans			
Bioequivalence study			
Comparative pharmacodynamic study			
Comparative clinical trial (generics)			
Other: please specify:			

Design of the trial									
Randomized:	Yes	No							
Controlled:	Yes	No	If “yes”, specify:						
			Open:	Yes	No				
			Single blind:	Yes	No	Double blind:			
							Yes	No	
			Parallel group:			Cross over:	Yes	No	
				Yes	No				
			Other:	Yes	No	If “yes”, specify:			
			Specify the comparator:						
			(an) other medicinal product(s)						
							Yes	No	
			placebo				Yes	No	
			other				Yes	No	
			If other, specify:						
Single site (see also section I):	Yes	No							
Multiple site (see also section I):	Yes	No							
Multinational clinical trial:	Yes	No							

Maximum duration of treatment of a trial subject according to the clinical trial protocol:

Female	Male

<i>Population of trial subjects</i>		
Healthy volunteers	Yes	No
Patients	Yes	No
Specific vulnerable populations of trial subjects		
Women of childbearing age	Yes	No
Pregnant women	Yes	No
Nursing women	Yes	No
Emergency situation	Yes	No
Trial subjects incapable of giving informed consent personally	Yes	No
	If “yes”, specify:	
Other	Yes	No
	If “yes”, specify:	

Planned number of trial subjects to be included in clinical trial:
in Ukraine
for a multinational clinical trial:
in the whole clinical trial

Plans for treatment or care after the trial subject has ended the participation in the clinical trial¹ (if different from the expected normal treatment of that pathological condition):
Specify:

¹ If not specified previously in the clinical trial protocol .

I. Proposed investigators and clinical trial sites in Ukraine

I.1. Clinical trial site and principal investigator	
1.1.1. Name and address of the clinical trial site	Principal investigator

1.1.2. Location	Full name	Qualification
-----------------	-----------	---------------

I.2. Coordinating investigator, if any	
Full name	Qualification

I.3. Central technical facilities to be used in the conduct of the clinical trial (laboratory or other technical facility), in which the measurement or assessment of the main evaluation criteria are centralized (repeat as needed for multiple organizations)
Organization: Full name of contact person: Location: Telephone number: Duties subcontracted:

I.4. Organizations to whom the clinical trial sponsor or his legal representative have transferred clinical trial-related duties and functions (repeat as needed for multiple organizations)	
The clinical trial sponsor or his legal representative has transferred any clinical trial-related duties and functions to another organization or third party	
	Yes No
If “yes”, specify: Name of legal person: Full name of contact person: Location: Telephone number: Duties/functions subcontracted:	

J. CEB / Ethics Committee at HCS

If this application is addressed to the CEB, please, tick the “Ethics committee at HCS” box and provide information pertinent to ethics committee at HCS and vice versa	
CEB Ethics committee at HCS	
Name and location:	
Date of submission:	
Conclusion /Approval: pending to be requested	

issued If conclusion/approval issued, specify: Date of conclusion /approval: accepted/approved: not accepted /not approved. If not acceptable /not approved, give: reasons eventual anticipated date of resubmission
--

K. Checklist of the information to be attached to the application form

Information that the Center and the ethics committee at HCS require according to item 1 section VII and item 3 section VIII of this Procedure		
Ethics committee at HCS	Center ¹	
		Cover letter
		Application form
		Confirmation of receipt of EudraCT number (when available)
		Clinical trial protocol with all amendments
		Investigator's brochure
		Investigational Medicinal Product Dossier (IMPD)
		Simplified IMPD
		Summary of Investigational Medicinal Product Characteristics
		Case report form (except for multinational clinical trials)
		Copy of ethics committee at HCS approval (where available)
		Letter of authorization enabling to act on behalf of the clinical trial sponsor (if applicant is not the clinical trial sponsor)

Trial subject-related information¹
Trial subject information leaflet and informed consent form Other trial subject-related information (diary, checklists, case histories, list appropriate): Arrangement for recruitment of trial subjects
Clinical trial protocol-related information¹
Summary of the clinical trial protocol Expert evaluation of clinical trial (when available) Ethical assessment of clinical trial made by the principal/coordinating investigator Signed and dated CVs of principal investigators of each clinical trial site
IMP-related information¹
Examples of label with product information in the state language Applicable approvals to cover clinical trials or products with special characteristics (if available) e.g. radiopharmaceutical products TSE certificate (when applicable) Certificate of analysis for batch of IMP Statement that the manufacturing is conducted at manufacturing or investigational site in compliance with Guidance “Medicinal products. Good manufacturing practice. CT-H MO3Y 42-4.0:2008” approved by MoH Ukraine Order of 16.02.2009 №95, with GMP certificate or written statement of the qualified person for quality (of the manufacturer) Copy of manufacturing authorization issued by the authorized body of the manufacturing country; Information about IMP manufacturing site Certificate of IMP origin Information about production technique and documentation for manufacturing and quality control of medicinal product
Documents related to healthcare settings, investigators and clinical trial site¹:
Application from principal investigator Information about healthcare setting and clinical trial site Signed and dated CVs of investigators
Finance-related information¹
Documents establishing amount and conditions of payment (except for insurance) Other documents

Tick all boxes to show information provided to the Center and the ethics committee at HCS.

L. Signature of the applicant

I, the undersigned, hereby confirm (on behalf of the clinical trial sponsor) that (cross out inappropriate): the information given in this application is correct; the clinical trial will be conducted according to the clinical trial protocol, national regulations and Guidance “Medicinal products. Good clinical practice. CT-H MO3Y 42-7.0:2008” approved by MoH Ukraine Order of 16.02.2009 №95; it is reasonable for the clinical trial to be undertaken; I will notify the Center and the ethics committee at HCS about the effective date of start of clinical trial¹ (when it has become known); I will submit a summary study report to the Center and the ethics committee at HCS within 1 year after the end of clinical trial (in all countries if clinical trial is multinational).	
Applicant to CEB Date: Signature: Full name in block letters:	Applicant to the ethics committee at HCS Date: Signature: Full name in block letters:

Inclusion of the 1st patient in clinical trial in Ukraine (inclusion starts with the informed consent signature).

{annex in wording of the MoH Order № 523 of 12.07.2012, amended by MoH Order № 304 of 06.05.2014; in wording of the MoH Order № 966 of 18.12.2014}