|  |  |
| --- | --- |
|  | Annex 4  to the Procedure for Conducting Clinical Trials of Medicinal Products and Expert Evaluation of Materials Pertinent to Clinical Trials  (Section VII, 7.1 (7.1.2)) |

#### 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: |  |

# А. Clinical Trial Identification

|  |
| --- |
| Full title of clinical trial: |
| Clinical trial protocol code number (assigned by the Sponsor), version, and date:  \_\_\_\_\_\_\_\_\_\_\_\_  For any translation of clinical trial protocol the date and version of the original document should be indicated. |
| EudraCT1 number (if any): |
| Name or abbreviated title of clinical trial, where available: |
| ISRCTN2 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. sponsor Identification

|  |
| --- |
| **B1. 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 sponsor in Ukraine to conduct this clinical trial** (if different from the 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: |

**С. APPLICANT IDENTIFICATION (please tick the appropriate box)**

|  |  |  |  |
| --- | --- | --- | --- |
| **С1. Application to CEB:** |  | **С2. Application to the Ethics Committee at HCS:** |  |
| Sponsor |  | Sponsor |  |
| Official representative of the sponsor |  | Official representative of the sponsor |  |
| Person or organization authorized by the sponsor to make the application. In this case complete below: |  | Person or organization authorized by the sponsor to make the application. In this case complete below: |  |
| Name of legal person/full name of natural person: |  | Name of legal person/full name of natural person: |  |
| Full name of contact person: |  | Full name of contact person: |  |
| Location of legal person/address of natural person: |  | Location of legal person/address of natural person: |  |
| Contact telephone number: |  | Contact telephone number: |  |
| Fax number: |  | Fax number: |  |
| E-mail: |  | 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]](#footnote-1)** | **Name of the legal person/full name of natural person - RC holder** | **RC number1** |
| **•** 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 number1:** | | |

**\_\_\_\_\_\_\_\_\_\_\_\_**

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 sponsor’s code(s), other descriptive names):** |
| **АТС 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 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 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 origin1? | Yes  | No |
| **Is this:** |  |  |
| 1) a gene therapy medicinal product1? | Yes  | No  |
| 2) a radiopharmaceutical medicinal product? | Yes  | No  |
| 3) an immunological medicinal product1? | 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:** |

|  |  |  |  |
| --- | --- | --- | --- |
| ***In vivo* gene therapy:** | **** | ***Ex vivo* 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: |  |  |

**Е. 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?  if “not”, specify major ingredients: |  Yes  No | |

**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**

|  |  |  |
| --- | --- | --- |
| Pathological condition or disease under investigation | | |
| 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)*  8 Продовження додатка 4 |
|  |

|  |
| --- |
| **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)  Is the trial:   First administration to humans   Bioequivalence study   Comparative pharmacodynamic study |  Therapeutic exploratory  (Phase II) |  Therapeutic confirmatory  (Phase III) |  Therapeutic use  (Phase IV) |
|  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: | | Yes | | No  | Cross over: | 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 subject according to the clinical trial protocol:** |
| **Maximum IMP dose allowed (specify: per day or total):** |

|  |
| --- |
| **Determination of the end of clinical trial and justification in case it is not the last visit of the last subject undergoing the clinical trial1:**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  If not provided in the clinical trial protocol. |
| **Initial estimate of the duration of the clinical trial (years and months)1:**  in Ukraine years months  in all countries, in which clinical trial is conducted years months |

\_\_\_\_\_\_\_\_\_\_\_\_\_

1from the 1st inclusion until the last visit of the last subject.

**Н. Population of trial subjects**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Age span**: | | | | | |
|  |  under 18 years  If “yes”, specify: | | |  Adult (18–65 years) |  Elderly (> 65 years) |
|  |  In utero   Preterm newborn infants (up to gestational age ≤ 37 weeks)   Newborns (0–27 days)   Infants (28 days – 24 months)   Children (2 – 11 years)   Juveniles (12–14 years)   Minors (14–18 years) | |
| **Gender:** | | | | | |
|  Female | | |  |  Male | |

|  |  |  |
| --- | --- | --- |
| Population of trial subjects | | |
| Healthy volunteers | Yes  | No  |
| Patients | Yes  | No |
| Specific vulnerable populations |  |  |
| Women of childbearing age | Yes  | No  |
| Pregnant women | Yes  | No  |
| Nursing women | Yes  | No  |
| Emergency situation | Yes  | No  |
| Subjects incapable of giving informed consent personally | Yes   If “yes”, specify: | No  |
| Other | Yes   If “yes”, specify: | No  |

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

|  |
| --- |
| **Plans for treatment or care after the trial subject has ended the participation in the clinical trial[[2]](#footnote-2)1 (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  1.1.2. Location | Principal investigator | | |
| 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 sponsor or his legal representative have transferred clinical trial-related duties and functions (repeat as needed for multiple organizations)** | | |
| The 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[[3]](#footnote-3)** | | |  | |
|  | | | |  | | | 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 HCSapproval (where available) |
|  | | | | |  | | | Letter of authorization enabling to act on behalf of the sponsor (if applicant is not the 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 Ukrainian | | |
|  | |  | | | | 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 MOЗУ 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 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 MOЗУ 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 HCSabout the effective date of start of clinical trial[[4]](#footnote-4) (when it has become known);  I will submit a summary study report to the Center and the Ethics Committee at HCSwithin 1 year after the end of clinical trial (in all countries if clinical trial is multinational). | |
| Applicant to CEB  Date: | Applicant to the Ethics Committee at HCS  Date: |
| Signature: | Signature: |
| Full name in block letters: | 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 Ukraine Order* [*№ 523 as of 12.07.2012*](http://zakon3.rada.gov.ua/laws/show/z1235-12/paran391#n391)*, amended by MoH Ukraine Order* [*№ 304 as of 06.05.2014*](http://zakon3.rada.gov.ua/laws/show/z0739-14/paran49#n49)*; in wording of the MoH Ukraine Order* [*№ 966 as of 18.12.2014*](http://zakon3.rada.gov.ua/laws/show/z0062-15/paran15#n15)*}*

1. [↑](#footnote-ref-1)
2. [↑](#footnote-ref-2)
3. [↑](#footnote-ref-3)
4. [↑](#footnote-ref-4)