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|  | Annex 13  to the Procedure for Conducting Clinical Trials of Medicinal Products and Expert Evaluation of Materials Pertinent to Clinical Trials |

Periodical report on status of clinical trial in Ukraine

*Submitted to:*

The State Expert Center MoH Ukraine

The Ethics Committee at HCS

1. Information about clinical trial (hereinafter - CT)

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| --- |
| Sponsor’s protocol code number: |
| Clinical trial phase: |
| Full name of CT: |
| CT sponsor: |
| Sponsor’s official representative for conducting the given clinical trial in Ukraine:  *(Name of legal person/full name of natural person, full name of contact person, telephone number, fax, e-mail)* |
| Conclusion of the State Expert Center MoH Ukraineissued *(date (DD/MM/YYYY) and minutes number of the related meeting)*: |
| Approval of the Ethics Committee at HCSissued *(date (DD/MM/YYYY) and minutes number of the related meeting)*: |
| If CT has been substantially amended, submit the information about each of such amendments *(number, date, conclusion* *of the Center and**approval of the Ethics Committee at HCS)* |

2. Date of start and completion of CT

|  |
| --- |
| Has the trial started in Ukraine? Yes No |
| If «no», what are the reasons: |
| If «yes»: |
| The date of inclusion of the 1st patient (healthy volunteer)in Ukraine (*DD/MM/YYYY)* |
| The date of inclusion of the last patient (healthy volunteer) 1 in Ukraine (*DD/MM/YYYY)* |
| Date of completion2 of clinical trial in Ukraine *(DD/MM/YYYY)* |

1 *Date when the informed consent signed.*

2 *Date of completion of clinical trial or planned completion of current clinical trials, if the date has changed after submitting the application.*

3. Information about clinical trial sites, which applied for the clinical trial in Ukraine:

|  |  |  |
| --- | --- | --- |
| Sponsor’s clinical trial site number | Identification of clinical trial site (name, address, principal investigator) | Status:  (1) started and at least one patient recruited;  (2) started but no one patient recruited;  (3) in reserve/waits for start;  (4) excluded/dropped out/ closed without start  (5) excluded/dropped out/ closed after start |
|  |  |  |

4. Information about trial subjects in Ukraine:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Sponsor’s clinical trial site number | Number of trial subjects at clinical trial site: | | | | |
| screened | randomized | Continue to participate in clinical trial | Participation in clinical trial completed | Dropped out[[1]](#footnote-1) |
|  |  |  |  |  |  |

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

For the dropped out trial subjects state the reasons: (1) –informed consent withdrawn by the patient; (2) – safety; (3) – lack of efficacy; (4) – other reasons.

**5. Information about suspected serious unexpected adverse reactions in Ukraine:**

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| --- | --- |
| Sponsor’s clinical trial site number | Suspected serious unexpected adverse reactions**:**  (*Information shall contain at least: trial subject’s code, case code, start and completion dates , diagnosis, consequences)* |
|  |  |

**6. Information about significant deviations1 from clinical trail protocol in Ukraine:**

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| --- | --- |
| Sponsor’s clinical trial site number | Significant deviations from clinical trail protocol:  (*Information shall contain at least: brief description of deviation, date, trial subject’s code, consequences/measures taken)* |
|  |  |

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

All significant deviations pertinent to safety of trial subject are subject to reporting*.*

**7. Other important information (if any)**

**8. Information about the person, submitting the report** *(full name, organization, position, contact telephone)***:**

**9. Date of making the report, signature:**

{Annex in wording of MoH Ukraine Order [№ 523 as of 12.07.2012](http://zakon4.rada.gov.ua/laws/show/z1235-12/paran388#n388)}

1. [↑](#footnote-ref-1)