|  |  |
| --- | --- |
|  | Annex 8  to the Procedure for Conducting Clinical Trials of Medicinal Products and Expert Evaluation of Materials Pertinent to Clinical Trials |

##### NOTIFICation ABOUT the start of clinical trial in Ukraine

###### CLINICAL Trial identification

|  |
| --- |
| Sponsor’s protocol code number: |
| EudraCT[[1]](#footnote-1) number (when available): |
| Full title of clinical trial: |
| The State Expert Center MoH Ukraine conclusion:  *date* --/--/-- (DD/ММ/YYYY) |
| Approval of the Ethics Committee at HCS:  *date* --/--/-- (DD/ММ/YYYY) |

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

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

**Applicant identification (please tick the appropriate box)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Notification about the start of clinical trial for the State Expert Center MoH Ukraine** | **** | **Notification about the start of clinical trial for 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 notification.  In that case complete below: |  | Person or organization authorized by the sponsor to make the notification.  In that 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: |  |
| Address of legal person/address of natural person: |  | Address of legal person/address of natural person: |  |
| Telephone number: |  | Telephone number: |  |
| Fax number: |  | Fax number: |  |
| E-mail: |  | E-mail: |  |

|  |  |
| --- | --- |
| **Start of clinical trial in Ukraine** | (DD/ММ/YYYY) |
| Date of inclusion of the first trial subject in Ukraine | --/--/---- |
|  |
| Indicate the clinical trial site, where the first trial subject has been included: | |
| Name: | |
| Location: | |
| Principal investigator: | |

|  |  |
| --- | --- |
| I, the undersigned, hereby confirm (on behalf of the sponsor) that the above information is correct. | |
|  |  |
| Applicant submitting the notification about the start of clinical trial for the State Expert Center MoH Ukraine: | Applicant submitting the notification about the start of clinical trial for the Ethics Committee at HCS: |
| Date: | Date: |
| Signature: | Signature: |
| Full name (block letters): | Full name (block letters): |

{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)