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|  | Annex 12  to the Procedure for Conducting Clinical Trials of Medicinal Products and Expert Evaluation of Materials Pertinent to Clinical Trials |

**NOTIFICation ABOUT COMPLETION of clinical trial**

###### Clinical trail identification

|  |
| --- |
| Sponsor’s protocol code number: |
| EudraCT[[1]](#footnote-1) number (when available): |
| Full title of the clinical trial: |

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

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

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

|  |  |  |  |
| --- | --- | --- | --- |
| **Notification about completion of the clinical trial for the State Expert Center MoH Ukraine** | **** | **Notification about completion of the 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 notification.  In that case complete below: |  | Person or organization authorized by the sponsor to make 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: |  |
|  |  | Investigator in charge of notification: |  |
|  |  | Coordinating investigator (for multicenter clinical trial, if available) |  |
|  |  | Principal investigator (for single center clinical trial) |  |
|  |  | If investigator submits notification (complete below): |  |
|  |  | Full name: |  |
|  |  | Address: |  |
|  |  | Telephone number: |  |
|  |  | Fax number: |  |
|  |  | E-mail: |  |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Completion of clinical trial | | | | | | | Date of clinical trial completion (DD/ММ/YYYY): |
| Clinical trial completed in Ukraine only | | | Yes | | No  | | --/--/-- |
| Completion of the whole clinical trial in all countries concerned | | | Yes  | | No  | | --/--/-- |
| Premature termination of the clinical trial | | | Yes  | | No | |  |
| If “yes”, complete the following boxes: | | |  | |  | |  |
| What is (are) the reason(s) for the premature termination of clinical trial: | | |  | |  | |  |
| safety | | | Yes  | | No  | |  |
| lack of efficacy | | | Yes  | | No  | |  |
| clinical trial has not commenced | | | Yes  | | No  | |  |
| other | | | Yes  | | No  | |  |
| If “yes”, specify: | | |  | |  | |  |
| Number of patients still receiving treatment up to the time of premature termination of clinical trial in Ukraine: | | | | | | | |
| Briefly describe in the annex(free text):  justification for premature termination of the clinical trial  proposed management of patients receiving treatment at the time of the suspension or premature termination of clinical trial  consequence of premature termination of clinical trial for assessment of results of clinical trial and for overall risk/benefit assessment of the investigational medicinal product | | | | | | | |
| I, the undersigned, hereby confirm that the above information is correct. | | | | | | | |
| Applicant | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | \_\_\_\_\_\_\_\_\_ | | \_\_\_\_\_\_\_\_\_\_ | |
| (full name, in block letters) | | (date) | | (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. EudraCT (European Union Drug Regulating Authorities Clinical Trials) is the European Clinical Trials Database [↑](#footnote-ref-1)