

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)

CT sponsor's protocol code number:
CT phase:
Full title of CT:
CT sponsor:
Clinical trial sponsor's official representative for conducting the given clinical trial in Ukraine: <i>(Name of legal person/full name of natural person, full name of contact person, contact teleph, fax, e-mail)</i>
Conclusion of the State Expert Center MoH Ukraine issued <i>(date (DD/MM/YYYY) and minutes number of the related meeting)</i> :
Approval of the ethics committee at HCS issued <i>(date (DD/MM/YYYY) and minutes number of the related meeting)</i> :
If CT has been substantially amended, submit the information about each of such amendments <i>(number, date, conclusion of the Center and approval of the ethics committee at HCS)</i>

2. Date of start and end of CT

Has the trial started in Ukraine?	Yes	No
If «no», what are the reasons:		
If «yes»:		
The date of inclusion of the 1 st patient (healthy volunteer) in Ukraine <i>(DD/MM/YYYY)</i>		

The date of inclusion of the last patient (healthy volunteer) ¹ in Ukraine (DD/MM/YYYY)
Date of the end ² of the clinical trial in Ukraine (DD/MM/YYYY)

¹ Date when the informed consent signed.

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

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

Clinical trial 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:

Clinical trial 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

For the dropped out trial subjects state the reasons: (1) –informed consent withdrawn by the patient; (2) – safety; (3) – lack of efficacy; (4) – other reasons.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

Clinical trial sponsor's clinical trial site number	Suspected serious unexpected adverse reactions: (Information shall contain at least: trial subject's code, case code, start and end dates, diagnosis, consequences)

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

Clinical trial sponsor's clinical trial site number	Significant deviations from clinical trial protocol: <i>(Information shall contain at least: brief description of deviation, date, trial subject's code, consequences/measures taken)</i>

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 of 12.07.2012}*