

NOTIFICATION of the end of clinical trial

Clinical trial identification

Clinical trial sponsor's protocol code number:
EudraCT 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 of the end of the clinical trial for the State Expert Center MoH Ukraine	Notification of the end of the clinical trial for the Ethics Committee at HCS
Clinical trial sponsor	Clinical trial sponsor
Official representative of the clinical trial sponsor	Official representative of the clinical trial sponsor
Person or organization authorized by the clinical trial sponsor to make notification.	Person or organization authorized by the clinical trial sponsor to make notification.
In that case complete below:	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:
Location of legal person/address of natural person:	Location of legal person/address of natural person:
Contact phone:	Contact phone:
Fax:	Fax:
E-mail:	E-mail:

¹ EudraCT (European Union Drug Regulating Authorities Clinical Trials) is the European Clinical Trials Database

	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: Contact phone: Fax: E-mail:
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End of clinical trial			Date of the end of the clinical trial (DD/MM/YYYY):
Clinical trial completed in Ukraine only	Yes	No	--/--/--
End of the complete clinical trial in all countries concerned by the clinical trial	Yes	No	--/--/--
Early termination of the clinical trial	Yes	No	
If "yes", complete the following boxes:			
What is (are) the reason(s) for the early 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 early termination of clinical trial in Ukraine:			
Briefly describe in the annex (free text):			
justification for early termination of the clinical trial			
proposed management of patients receiving treatment at the time of the suspension or early termination of clinical trial			
consequences of early termination of clinical trial for assessment of results of clinical trial and for overall assessment risk and expected benefit 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 Order № 523 of
12.07.2012}*