

PAYMENT FORM AUTHORISATION OF CLINICAL TRIALS/ APPROVAL OF SUBSTANTIAL AMENDMENTS
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Name of the trial*

Protocol:

* Protocol – Nr./Code with minimum information necessary for identification if needed

Applicant

Sponsor

CRO**

Investigator

**Contracted Research Organisation

Name:	
Address:	
City:	
Country:	
Telephone no.:	
Fax no.:	
E-mail address:	

Medicinal product status

Authorised in Romania MA no.. /granted on.....	<input type="checkbox"/>
Not authorised in Romania, authorised in another country	<input type="checkbox"/>
Not authorised worldwide	<input type="checkbox"/>

Paying company

Name:	
Address:	
City:	
Country:	
Telephone no.:	
Fax no.:	
E-mail address:	
Fiscal Code:	
Trade Registry no.:	
IBAN Account no.:	
Bank:	

Proposed form of payment	
Lei:	<input type="checkbox"/>
Euro:	<input type="checkbox"/>

Fees for assessment of the Application for authorisation of clinical trials/approval of substantial amendments	Fee in Euro according to OMH no. 888/2014***
Authorisation of clinical trials for investigational medicinal products not authorised worldwide (new substances) Phases I-III	
Authorisation of clinical trials for investigational medicinal products not authorised in Romania, authorised in other countries or granted marketing authorisation (MA), known substances, not used according to SmPC in force in the respective trial (regarding indications, dosage, administration route, method of treatment target group etc.) Phases I-IV	
Authorisation of clinical trials for medicinal products authorised and used according to SmPC in force in Romania Phase IV	
Authorisation of bioequivalence studies	
Approval of substantial amendments (as provided for in Decision of the NAMMD Scientific Council no 22/2010)	

***Payment fee to be filled in by applicant, according to OMH no. 888/2014

Representative to Romania/Contact person	
Name:	
Address:	
City:	
Country:	
Telephone no.:	
Fax no.:	
E-mail address:	

Signatories undertake responsibility for accuracy of data in this form.

Date:

Name, signature, stamp