

Annex 3

Notification form for the Chief Pharmacist of the University about the start of a clinical trial

..... (name) Principal Investigator I declare that I am familiar with the procedures of the Central Coordinating Office for Clinical Research and the Institute for Pharmaceutical Organization of the University Pharmacy. I want to inform the Chief Pharmacist of the following newly initiated drug clinical trial under the terms and conditions set out therein:

1. Basic data

Title of test	
Test unique SE identifier	
Protocol number	
Clinical trial phase	
Name of manufacturer or conducting company	
Address of manufacturer or conducting company	
Name of Principal Investigator	
Name of the test site and department	
Name of the investigational medicinal product	
Name of control medicine	
Name of premedication	
Storage conditions of the test product	
OGYÉI decision number	

The Chief Pharmacist will delegate a pharmacist responsible for quality assurance for each new clinical trial of a medicinal product, who will be responsible for recording the data required by Article 33 of Decree 41/2007 (9.IX.) of the Hungarian Medicines Control Act. According to the legislation, a register must be available in the institute pharmacy containing the name of the investigational medicinal product, the manufacturing number, the trial number, the expiry date, and the storage instructions for each consignment received. The Chief Pharmacist shall inform the Principal Investigator and the Central Clinical Trials Coordination Office of the identity of the pharmacist assigned to the trial employing a declaration of acceptance at the end of the registration procedure.

2. Arrival of the test product

- University Pharmacy premises
- Clinic department

If the Principal Investigator wishes to have the investigational medicinal product delivered to the clinic department, it is the responsibility of the Principal Investigator to store the

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investigational medicinal product separately from the patient care medicinal product and to follow the protocol.

In addition, the Principal Investigator shall provide the quality assurance pharmacist assigned to the study by the Institute for Pharmaceutical Organisation of the University Pharmacy with access to the data according to Article 33 of Decree 41/2007 (IX. 9.) EüM. The use of the clinical trial product submitted is subject to registration in the pharmacy register of the institute following Regulation No. 41/2007 (IX. 9.) of the EüM.

3. Providing a control preparation

- Sponsored by University Pharmacy premises
- Sponsor by clinic department
- By sponsor through a wholesaler to the University Pharmacy site
- Purchased from University Pharmacy [In this case, please fill in point 5]

4. Pharmacist delegation

The Principal Investigator declares that they are responsible for the pharmacist's part of the protocol

- wishes to employ a pharmacist employed by EGYGYSZI

[In this case, please fill in point 5]

- You wish to employ a university staff member with a different qualification

If the Principal Investigator does not wish to delegate a university pharmacist to a clinical trial, they are personally responsible for the pharmacist's part of the trial protocol. Person to be delegated

- Name:
- Availability:

5. Tasks related to investigational medicinal products

- Delivery and storage of the test product
- Issue of the test product (factory box)
- Preparation of test formulation (aseptic conditions)
- Preparation of test formulation (aseptic section)
- Preparation of test formulation (cytostatic)
- Purchase of control medicine

The pharmaceutical registration fee is provided from the clinical share of the trial fee.

The completed and signed notification form must be sent electronically in PDF format to klinikaikutatas@semmelweis-univ.hu and kkgyogyszertar@semmelweis.hu.

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Budapest,

Investigator in charge