

Pre-admission (registration) request for a clinical trial

Investigator:	
Test site:	
Name of the contact person of the investigator:	
Telephone number of the contact person of the investigator:	
Contact email address of the investigator:	
Title of the study:	
Protocol number:	
Phase:	
Type of study (drug, device, non-interventional, IIT)	
Name of the contact person of the principal/CRO:	
Telephone number of the contact person of the client/CRO:	
E-mail address of the contact person of the client/CRO:	

1. The investigation will require the involvement of service provider(s):

- Imaging study
- Pathology examination
- Laboratory test
- University pharmacy services
- Name of other subspecialty/clinic:

The planned duration of the study:

(Planned) date of submission of the NNGYK licence application:

Number of patients planned for clinic:

2. Declaration by the Principal Investigator: (Select the appropriate section!)

- The material and personnel conditions for the study are fully available at the clinic, so no additional collaborator is required.
- University block coordinator assistance required: Click or tap here to enter text.
- The material and personnel conditions for the study are not fully available at the clinic, so additional collaborators are needed. Name and function of external collaborator: Click or tap here to enter text.
- The study is low-cost, so the **cost** per patient enrolled is **less than 12%** of the total **study fee revenue** per patient.
- The study involves high-cost diagnostic or therapeutic procedures, so the **cost** per patient included **exceeds 12%** of the total **study fee revenue** per patient.

Regulations for clinical research trials

[] The study involves low-cost diagnostic or therapeutic procedures (the per-patient **cost of the study**, excluding staff costs, is **less than 12% of** the total per-patient **fee income**), but the institutional part of the study is intended to cover additional **staff costs**.

[] The study involves high-cost diagnostic or therapeutic procedures, so the **out-of-pocket costs** per patient included, excluding personnel costs, **exceed 12% of** the total **study fee revenue** per patient. The institutional share of the out-of-pocket costs **is** intended to cover **personnel costs in** addition to the out-of-pocket costs.

The following VAT refund declaration is only required for single-contract or hybrid models (where the revenue to the University is not only for the cost of the study).

[] The proceeds of the clinical trial are used only to purchase the materials and equipment necessary to conduct the trial and are not used or exploited in the provision of basic healthcare.

[] The proceeds from the clinical trial are also used to purchase materials and equipment used in the provision of healthcare which is also a core activity (VAT is not recoverable)

As stipulated in the Clinical Research Trials Regulations, separate records of investigational medicinal products received for clinical trials and used in the treatment of patients must be kept in the institutional pharmacy. The person responsible for keeping these records is the Institutional Pharmacist. The pharmacy registration fee, which is fixed at an uniform amount of EUR 250, is assigned to this task and must be provided by the investigational site (the investigational site's own („out-of pocket”) costs for the trial). Accordingly, the test site acknowledges by this declaration that the amount of the pharmacy registration fee will be transferred in one lump sum from the test site's health operating budget to the University Pharmacy Pharmacy Service Institute, which will perform the task, at the same time as the invoice for the first test fee is issued, if no patient enrolment takes place, at the close of the test.

Budapest,

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Clinical Director
(if not the Principal Investigator)

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Head of Investigation

A synopsis of the study in Hungarian must be attached to this registration application.
The completed and signed registration form must be sent electronically in PDF format to klinikaikutatas@semmelweis.hu.