Annex 8

Semmelweis University Checklist for Clinical Trials

PARTNER	1 START-UP PHASE	2 CONTRACT PHASE	3 CONDUCT OF THE RESEARCH PHASE	4 CONCLUSION OF THE RESEARCH
Documents to be provided by the SPONSOR	1. Copy of the valid license from the competent authority or copy of the letter requesting the license 2. Study protocol in an electronic format approved by the competent authority 3. A short summary of the study protocol in Hungarian 4. Copy of the liability insurance policy 5. Full budget for the study in electronic format 6. Related contracts 7. for the Principal Investigtor: trial site and IKEB authorization documents	Comments on the draft contract	Certificate of completion for invoicing	Certificate of completion for invoicing
Documents to be submitted by the PRINCIPAL INVESTIGATOR	1. Declaration of admission - **Annex 1** 2. Personnel and equipment for the inspection - **Annex 2** 3. Notification form for the Chief Pharmacist of the initiation of a clinical trial of a medicinal product - **Annex 3** 4. Excluded costs estimate (if applicable) - **Annex 5** 5. Principal Investigator's declaration for clinical trials - remuneration, NEAK reporting requirements - **Annex 7** 6. Copy of the Principal Investigator's information letter to IKEB		1. Quarterly report on the number of patients enrolled in the trial 2. Sponsor audit and regulatory inspection results/report to 4K	1. Conclusion of the investigation - **Annex 11** 2. Final report 3. Summary for 4K
Documents to be submitted by 4K		1. Request for documents, verification of documents **according to Annex 8** 2. Consultation with the Economic and Legal Department	Quarterly report of the Centre	1. REGISTRATION in the POSEIDON system 2. ARCHIVING 3. Closure with the economic and legal department 4. Preparation of a final summary
Documents to be submitted by the PHARMACIST	1. Delegation of the pharmacist responsible for quality assurance - **Annex 4** 2. Declaration of the pharmacist responsible for quality assurance - **Annex 10**		Transfer protocol for the delivery of clinical trial products **Annex 9**	Completion of the trial