Annual report / Final report for pharmaceutical

Ethics Committee Homolka

Full Tittle of clinical trial	
Tittle	
Protocol code Number	
CRO	
Sponsor	

Principal Investigator		**Investigators FNMH**	
Name	**Centre**	**Name**	**Centre/phone**
Date of approval by the Ethics Committee Homolka			
The start date of the clinical trial in FNMH / global		**End date (also assumed) in FNMH / global**	

Phase of clinical trial			
□ I. phase	□ II. phase	□ III. phase	□ IV. phase

Information of clinical trial			
□ multi-centric	□ retrospective	□ placebo-controlled	□ parallel group
□ randomized	□ blinded	□ double dummy	□ cross-over
□ prospective	□ double blinded	□ cohort	□ other:…….

Test product / method	**Comparator**	
	□ placebo	**□other:**

Number of enrolled patients (signed IS) in FNMH / global	**Number of prematurely terminated patients in FNMH / global**	**Number of ongoing in FNMH / global**	**Number of completed in FNMH / global**	**Number of deaths in FNMH / global**	**Number of reported AE and AR in FNMH / global**

Adverse events(please indicate number of events in FNMH / global)			
Adverse Event - AE	**Adverse Drug Reaction - ADR**	**Serious Adverse Event - SAE**	**Serious Adverse Drug Reaction - SADR**
Unexpected Adverse Drug Reaction - UADR	**Unexpected Serious Adverse Reactions**	**Suspected Unexpected Serious Adverse Reaction - SUSAR**	**AE and AR in relation to the test product**

Brief description of the goal and course of the study. In applicable for final report risk benefit conclusion.			
Date		**Signature**	