

Annual report / Final report for pharmaceuticals

Full Tittle of clinical trial					
Tittle					
Protocol code Number					
CRO					
Sponsor					
Principal Investigator			Investigators Na Homolce Hospital		
Name		Centre		Name	
				Centre/phone	
Date of approval by the Ethics Committee Na Homolce Hospital (NHH)					
The start date of the clinical trial in NHH / global			End date (also assumed) in NHH / global		
Phase of clinical trial					
☐ I. phase		☐ II. phase		☐ III. phase	
				☐ IV. phase	
Information of clinical trial					
☐ multi-centric		☐ retrospective		☐ placebo-controlled	
☐ randomized		☐ blinded		☐ double dummy	
☐ prospective		☐ double blinded		☐ cohort	
				☐ other:.....	
Test product / method			Comparator		
			☐ placebo		☐ other:
Number of enrolled patients (signed IS) in NHH / global		Number of prematurely terminated patients in NHH / global	Number of ongoing in NHH / global	Number of completed in NHH / global	Number of deaths in NHH / global
					Number of reported AE and AR in NHH / global
Adverse events (please indicate number of events in NHH / global)					
Adverse Event - AE		Adverse Drug Reaction - ADR		Serious Adverse Event - SAE	
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