Roentgenova 2, 150 30 Praha 5
Tel.: +420 257 271 111
IČO: 00023884

Annual report / Final report

Full Title of clinical trial	
Tittle	
Protocol code Number	
CRO	
Sponsor	

Principal Investigator		**Investigators Hospital Na Homolce**	
Name	**Center**	**Name**	**Center/phone**
Date of approval by the Ethics Committee			
The start date of the clinical trial		**End date (also assumed)**	

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)	**Number of prematurely terminated patients**	**Number of ongoing**	**Number of completed**	**Number of deaths**	**Number of reported AE and AR**

Adverse events (please indicate number of events at Na Homolce Hospital)			
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			
Date		Signature	