Annual report / Final report for medical devices

Full Tittle of clinical trial	
Tittle	
Protocol code Number	
CRO	
Sponsor	

Principal Investigator		Investigator 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**	

CE certification		
☐ **Yes CE certificate**	☐ **No CE certificate**	☐ **Yes, off label use**

Information of clinical trial – study design		
☐ **multi-centric**	☐ **randomized**	☐ **retrospective**
☐ **First-in-human**	☐ **other:……..**	

Test product / method	Comparator	
	☐ **Yes (What):**	☐ **No:**

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	**AE and AR in relation to the test product**	**Serious Adverse Event – SAE**

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