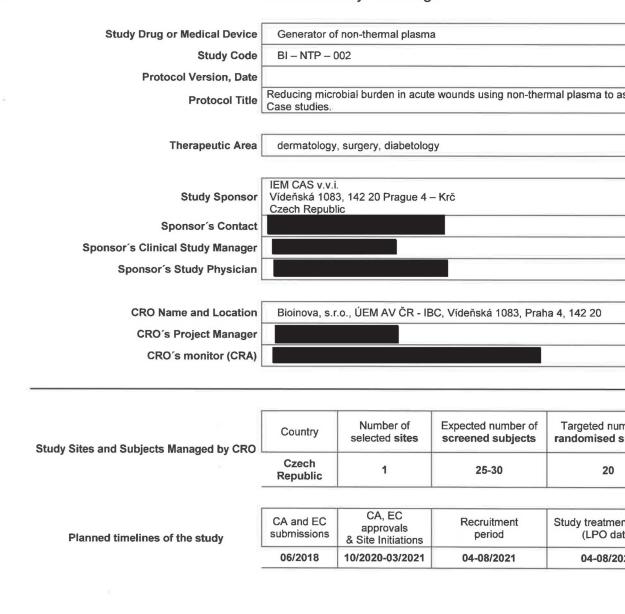
Příloha č. 1

Clinical Study Title Page





Study Specifications

,*	ACTIVITIES	CDO	C	
	ACTIVITIES	CRO	Sponsor	

S	TUDY DOCUMENTS		
1	BASIC STUDY DESIGN	х	
2	PROTOCOL	x	
3	LOCAL ADAPTATION OF PROTOCOL	х	
4	PROTOCOL AMENDMENTS	х	
5	RANDOMIZATION SCHEDULE		
6	MASTER INFORMED CONSENT FORM (ICF)	х	
7	LOCAL ADAPTATION OF ICF	х	
8	BACK-TRANSLATION OF LOCAL ICF	х	
9	CRF DESIGN	х	
10	EudraCT form or Med Dev. Registry (RZPRO)	х	
11	PATIENT DIARY		
12	PATIENT QUESTIONNAIRE (1)		==
13	PATIENT QUESTIONNAIRE (2)		
14	INVESTIGATOR FILE	х	
15	USER MANUAL TO IP / MEDICAL DEVICE		
16	PRINTING OF STUDY DOCUMENTS		
17	DOCUMENT DELIVERY TO SITE / TO SPONSOR		

18	TRANSLATION IN LOCAL LANGUAGE of any document provided in other language		
19	STUDY MANUAL - if applicable		
20	MONITORING PLAN	x	
21	NEWSLETTERS		
22	ADVERTISING TOOLS		
23	PHARMACIST FILE		

1	SUPPLY TEST DRUG / MEDICAL DEVICE	
2	PACKAGE DRUG / ASSEMBLY DEVICE	
3	LABEL DRUG	
4	LOCAL LAB management	
5	COORDINATION OF BIOLOGICAL SAMPLES SHIPMENT BETWEEN SITES AND CENTRAL DEPO	
6	SHIP USED/UNUSED DRUGS FROM SITES TO SPONSOR, PERFORM IP ACCOUNTABILITY	

C. R	EGULATORY ACTIVITIES	
1	ETHICS COMMITTEE(s) - initial	x
1b	ETHICS COMMITTEE(s) - amendments	x
2	COMPETENT AUTHORITY - initial	x
2b	COMPETENT AUTHORITY - amendments	x

3	INITIAL and FINAL REPORTS TO EC and CA	х	

S	TUDY SET-UP ACTIVITIES		
1	IDENTIFY INVESTIGATIONAL SITE(S)	х	
2	NEGOTIATE and/or CONCLUDE Clinical Trial AGREEMENTS	x	x
3	SET UP INVESTIGATOR FILES	x	
4	ICF printing and distribution	х	
5	SITE PRE-SELECTION CONTACT AND VISIT	х	x

1	INTERNAL MEETING	X	
2	CRO/SPONSOR MEETING	x	
3	INVESTIGATOR MEETING (Start up)	x	
4	GCP Trainings (site staff)	x	
5	CRA TRAINING		
6	TELECONFERENCEs, WEBINARS		
7	General study local supervision	x	

N	MONITORING	
1	CONDUCT QUALIFICATION SITE VISITS	x

6	Sites oversight/communication between MVs	x	х
5	INVESTIGATORS FEE AND INVOICING MNGMT.		x
4	CONDUCT STUDY CLOSURE VISITS	x	
3	CONDUCT INTERIM MONITORING VISITS	х	
2	CONDUCT ON-SITE STUDY INITIATION VISITS	X	

GLOBAL PROJ	ECT MANAGEMENT	
1 GLOBAL PR	ROJECT MANAGEMENT	х

SAFETY REPORTING	
1 SAE reporting	x

(CLINICAL DATA MANAGEMENT + CRF	
1	CLINICAL DATA MANAGEMENT + CRF	x

PROGRAMMING AND STATISTICS		
x		

K. STUDY CLOSURE ACTIVITIES

1	ARCHIVE, RETAIN, AND RETURN STUDY DOCUMENTATION AND STUDY DATABASE		x
2	CLINICAL STUDY REPORT	x	х
3	END OF STUDY REPORT TO EC AND CA	х	

	OTHER ACTIVITIES			
T	1 OFFICE OVERHEAD costs			