Příloha č. 1

Clinical Study Title Page

Study Drug or Medical Device	Generator of non-thermal plasma
Study Code	BI – NTP – 002
Protocol Version, Date	
Protocol Title	Reducing microbial burden in acute wounds using non-thermal plasma to as Case studies.
Therapeutic Area	dermatology, surgery, diabetology
Study Sponsor	IEM CAS v.v.i. Vídeňská 1083, 142 20 Prague 4 – Krč Czech Republic
Sponsor´s Contact	[redacted]
Sponsor´s Clinical Study Manager	[redacted]
Sponsor´s Study Physician	[redacted]
CRO Name and Location	Bioinova, s.r.o., ÚEM AV ČR - IBC, Vídeňská 1083, Praha 4, 142 20
CRO´s Project Manager	[redacted]
CRO´s monitor (CRA)	[redacted]

Study Sites and Subjects Managed by CRO

Country	Number of selected **sites**	Expected number of **screened subjects**	Targeted num **randomised s**
Czech Republic	**1**	**25-30**	**20**

Planned timelines of the study

CA and EC submissions	CA, EC approvals & Site Initiations	Recruitment period	Study treatmen (LPO dat
06/2018	**10/2020-03/2021**	**04-08/2021**	**04-08/20**

Study Specifications

	ACTIVITIES	CRO	Sponsor
A.	**STUDY DOCUMENTS**		
1	BASIC STUDY DESIGN	x	
2	PROTOCOL	x	
3	LOCAL ADAPTATION OF PROTOCOL	x	
4	PROTOCOL AMENDMENTS	x	
5	RANDOMIZATION SCHEDULE		
6	MASTER INFORMED CONSENT FORM (ICF)	x	
7	LOCAL ADAPTATION OF ICF	x	
8	BACK-TRANSLATION OF LOCAL ICF	x	
9	CRF DESIGN	x	
10	EudraCT form or Med Dev. Registry (RZPRO)	x	
11	PATIENT DIARY		
12	PATIENT QUESTIONNAIRE (1)		
13	PATIENT QUESTIONNAIRE (2)		
14	INVESTIGATOR FILE	x	
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		

B.	DRUG SUPPLY AND INVENTORY MANAGEMENT, BIOLOGICAL SAMPLES		
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.	REGULATORY 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	x	

D.	STUDY SET-UP ACTIVITIES		
1	IDENTIFY INVESTIGATIONAL SITE(S)	x	
2	NEGOTIATE and/or CONCLUDE Clinical Trial AGREEMENTs	x	x
3	SET UP INVESTIGATOR FILEs	x	
4	ICF printing and distribution	x	
5	SITE PRE-SELECTION CONTACT AND VISIT	x	x

E.	MEETINGS		
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	

F.	MONITORING		
1	CONDUCT QUALIFICATION SITE VISITS	x	

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

G.	GLOBAL PROJECT MANAGEMENT		
1	GLOBAL PROJECT MANAGEMENT	x	

H.	SAFETY REPORTING		
1	SAE reporting	x	

I.	CLINICAL DATA MANAGEMENT + CRF		
1	CLINICAL DATA MANAGEMENT + CRF	x	

J	PROGRAMMING AND STATISTICS		
1	PROGRAMMING AND STATISTICS	x	

K.	STUDY CLOSURE ACTIVITIES

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

L.	OTHER ACTIVITIES		
1	OFFICE OVERHEAD costs		