Clinical Study Title page

Study Drug or Medical Device	Cold Plasma Device IEM
Study Code	BI – NTP – 001
Protocol Version, Date	
Protocol Title	Reducing microbial burden in acute wounds using non-thermal plasma to assess the safety and the efficacy. 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	PharmDr. Šárka Kubinová, PhD.
Sponsor´s Clinical Study Manager	
Sponsor´s Study Physician	MUDr. Břetislav Lipový, PhD.
CRO Name and Location	Bioinova, s.r.o., ÚEM AV ČR - IBC, Vídeňská 1083, Praha 4, 142 20
CRO´s Project Manager	Peter Bauer, MD, PhD
CRO´s monitor (CRA)	Peter Bauer, MD, PhD

Study Sites and Subjects Managed by CRO

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

Planned timelines of the study

CA and EC submissions	CA, EC approvals & Site Initiations	Recruitment period	Study treatment period (LPO date)	Data cleaning, Statistic & Report
11-12/2017	**01-02/2018**	**03-05/2018**	**03-05/2018**	**06/2018**

Study Specifications

	ACTIVITIES	CRO	Sponsor	NA	External provider	
A.	**STUDY DOCUMENTS**					
1	BASIC STUDY DESIGN	x				
2	PROTOCOL	x				
3	LOCAL ADAPTATION OF PROTOCOL	x				
4	PROTOCOL AMENDMENTS	x				If and when applicable
5	RANDOMIZATION SCHEDULE					
6	MASTER INFORMED CONSENT FORM (ICF)	x				Supposed to be in English
7	LOCAL ADAPTATION OF ICF	x				Including Czech translation (unless provided in Czech already by the sponsor)
8	BACK-TRANSLATION OF LOCAL ICF	x				To present and explain local modifications
9	CRF DESIGN	x				
10	EudraCT form or Med Dev. Registry (RZPRO)	x				ohlášení KZ SÚKLu v českém registru ZP
11	PATIENT DIARY					If applicable
12	PATIENT QUESTIONNAIRE (1)					If applicable
13	PATIENT QUESTIONNAIRE (2)					If applicable
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					

	ACTIVITIES	CRO	Sponsor	NA	External provider	
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				Initial submission plus communication until resolution of queries & approval/ (unless rejected]
1b	ETHICS COMMITTEE(s) - amendments	x				Amendment(s) submission, as above
2	COMPETENT AUTHORITY - initial	x				Initial submission plus communication until resolution of queries & approval/ (unless rejected]
2b	COMPETENT AUTHORITY - amendments	x				Amendment(s) submission, as above
3	INITIAL and FINAL REPORTS TO EC and CA	x				As per the local (Czech/Slovak) legal requirements

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				If CRO staff meeting needed
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

	ACTIVITIES	CRO	Sponsor	NA	External provider	
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					

Workload & Costs

	ACTIVITIES	Work capacity allocation: Resources	Number of units	Unit	Unit Cost	Total Cost	Pass-Through Costs (PTC): Number of units	Unit	Unit Cost	Total PTC (max. estimated)
A.	**STUDY DOCUMENTS**					**35 200 Kč**				**0 Kč**
1	BASIC STUDY DESIGN - consultation & updating	CRM		hour	1 100 Kč	0 Kč				0 Kč
2	PROTOCOL	CRM	15	hour	1 100 Kč	16 500 Kč				0 Kč
3	LOCAL ADAPTATION OF PROTOCOL	CRM		hour	1 100 Kč	0 Kč				0 Kč
4	PROTOCOL AMENDMENTS	CRM		hour	1 100 Kč	0 Kč				0 Kč
5	RANDOMIZATION SCHEDULE	NA		hour	1 100 Kč	0 Kč				0 Kč
6	MASTER INFORMED CONSENT FORM (ICF) in Czech	CRM	5	hour	1 100 Kč	5 500 Kč				0 Kč
7	LOCAL ADAPTATION OF ICF	CRM		hour	1 100 Kč	0 Kč				0 Kč
8	ENGLISH TRANSLATION OF the Czech MASTER ICF	CRM		hour	1 100 Kč	0 Kč				0 Kč
9	CRF (Case Report Form) DESIGN	CRM	5	hour	1 100 Kč	5 500 Kč				0 Kč
10	CRF INSTRUCTIONS FOR INVESTIGATOR	CRM	1	hour	1 100 Kč	1 100 Kč				0 Kč
11	SUBJECT DIARY	CRM		hour	1 100 Kč	0 Kč				0 Kč
12	SUBJECT QUESTIONNAIRE (1)	CRM		hour	1 100 Kč	0 Kč				0 Kč
13	SUBJECT QUESTIONNAIRE (2)	CRM		hour	1 100 Kč	0 Kč				0 Kč
14	INVESTIGATOR STUDY FILE (ISF)	CRM	3	hour	1 100 Kč	3 300 Kč				0 Kč
15	USER MANUAL TO IP / MD	CRM		hour	1 100 Kč	0 Kč				0 Kč
16	PRINTING OF STUDY DOCUMENTS	CRA		hour	930 Kč	0 Kč				0 Kč
17	DOCUMENT DELIVERY TO SITE / TO SPONSOR	CRA		hour	930 Kč	0 Kč				0 Kč
18	TRANSLATION of documents - if applicable	CRM		hour	1 100 Kč	0 Kč				0 Kč
19	STUDY MANUAL - if applicable	CRA		hour	930 Kč	0 Kč				0 Kč
20	MONITORING PLAN	CRM	3	hour	1 100 Kč	3 300 Kč				0 Kč
21	NEWSLETTERS	CRM		hour	1 100 Kč	0 Kč				0 Kč
22	ADVERTISING TOOLS	CRM		hour	1 100 Kč	0 Kč				0 Kč
23	PHARMACIST FILE	CRM		hour	1 100 Kč	0 Kč				0 Kč
B.	**DRUG SUPPLY AND INVENTORY MANAGEMENT, BIOLOGICAL SAMPLE**					**0 Kč**				**0 Kč**
1	SUPPLY TEST IP/ MD	CRA		hour	930 Kč	0 Kč				0 Kč
2	PACKAGE DRUG / ASSEMBLY DEVICE	CRA		hour	930 Kč	0 Kč				0 Kč
3	LABEL DRUG	CRA		hour	930 Kč	0 Kč				0 Kč
4	LOCAL LAB management, start up and management	CRM		hour	1 100 Kč	0 Kč				0 Kč
5	COORDINATION OF BIOLOGICAL SAMPLES SHIPMENT BETWEEN SITES AND CENTRAL DEPO	CRA		hour	930 Kč	0 Kč				0 Kč
6	SHIP USED/UNUSED DRUGS FROM SITES TO SPONSOR, PERFORM IP ACCOUNTABILITY	CRA		hour	930 Kč	0 Kč				0 Kč
C.	**REGULATORY ACTIVITIES**					**18 100 Kč**				**0 Kč**
1	ETHICS COMMITTEE (EC) initial submission	CRM	3	hour	1 100 Kč	3 300 Kč				0 Kč
1	Communication before/during EC review process	CRM	1	hour	1 100 Kč	1 100 Kč				0 Kč
1b	ETHICS COMMITTEE amendment submission	CRM		hour	1 100 Kč	0 Kč				0 Kč
2	COMPETENTY AUTHORITY (CA) initial submission	CRM	3	hour	1 100 Kč	3 300 Kč				0 Kč
2	Communication before/during CA review process	CRM	1	hour	1 100 Kč	1 100 Kč				0 Kč
2b	COMPETENT AUTHORITY amendment submission	CRM		hour	1 100 Kč	0 Kč				0 Kč
3	INITIAL and FINAL REPORTS TO EC and CA	CRA	10	hour	930 Kč	9 300 Kč				0 Kč
D.	**STUDY SET-UP ACTIVITIES**					**4 400 Kč**				**0 Kč**
1	IDENTIFY INVESTIGATIONAL SITE, PERFORM QUALIFICATION VISIT, PREPARE REPORT	CRM	1	hour	1 100 Kč	1 100 Kč				0 Kč
2	NEGOTIATE and CONLUDE INVESTIGATOR AGREEMENT	CRM		hour	1 100 Kč	0 Kč				0 Kč
2	INVESTIGATOR'S FEE (payment for the study, to be included in agreement)	CRM		hour	1 100 Kč	0 Kč				0 Kč
3	SET UP INVESTIGATOR FILE	CRM	3	hour	1 100 Kč	3 300 Kč				0 Kč
4	ICF printing and distribution	CRA		hour	930 Kč	0 Kč				0 Kč
5	SITE PRE-SELECTION CONTACT AND VISIT	CRM		hour	1 100 Kč	0 Kč				0 Kč
E.	**MEETINGS / STUDY UPDATES**					**8 800 Kč**				**0 Kč**
1	INTERNAL MEETING	CRM/CRA		hour	930 Kč	0 Kč				0 Kč
2	CRO/SPONSOR MEETING	CRM	3	hour	1 100 Kč	3 300 Kč				0 Kč
3	INVESTIGATOR MEETING (Start up)	CRM/CRA		hour	930 Kč	0 Kč				0 Kč
4	GCP Training (site staff)	CRM	5	hour	1 100 Kč	5 500 Kč				0 Kč
5	CRA TRAINING	CRA		hour	930 Kč	0 Kč				0 Kč
6	TELECONFERENCES / WEEKLY UPDATES	CRA		hour	930 Kč	0 Kč				0 Kč
7	General local study & site supervising	CRA		hour	930 Kč	0 Kč				0 Kč
F.	**MONITORING**					**16 740 Kč**				**0 Kč**
1	CONDUCT QUALIFICATION SITE VISIT	CRA		hour	930 Kč	0 Kč		km		0 Kč
2	CONDUCT ON-SITE STUDY INITIATION VISIT	CRA	5	hour	930 Kč	4 650 Kč				0 Kč
3	CONDUCT INTERIM MONITORING VISITS	CRA	10	hour	930 Kč	9 300 Kč				0 Kč
4	CONDUCT STUDY CLOSURE VISITS	CRA	3	hour	930 Kč	2 790 Kč				0 Kč
5	MANAGEMENT of INVESTIGATOR FEE & INVOICING	CRA		hour	930 Kč	0 Kč		per 1 subject		0 Kč
6	Site oversight/communication between MVs	CRA		hour	930 Kč	0 Kč				0 Kč
G.	**GLOBAL PROJECT MANAGEMENT**					**11 000 Kč**				
	PROJECT MANAGEMENT	CRM	10	hour	1 100 Kč	11 000 Kč				0 Kč
H.	**SAFETY REPORTING**					**0 Kč**				
	SAE reporting	CRA		hour	930 Kč	0 Kč				0 Kč
I.	**CLINICAL DATA MANAGEMENT**					**0 Kč**				**0 Kč**
	CLINICAL DATA MANAGEMENT	DE/DM		hour	640 Kč	0 Kč				0 Kč
J	**PROGRAMMING AND STATISTICS**					**0 Kč**				**0 Kč**
	PROGRAMMING AND STATISTICS - if CRO is charged to ensure this task	NA				0 Kč				
K.	**STUDY CLOSURE ACTIVITIES**					**5 160 Kč**				
1	ARCHIVE, RETAIN, AND RETURN STUDY DOCUMENTS AND STUDY DATABASE	CRA		hour	930 Kč	0 Kč				0 Kč
2	CLINICAL STUDY REPORT (CSR)	CRM	3	hour	1 100 Kč	3 300 Kč				0 Kč
3	END OF STUDY REPORT TO EC AND CA	CRA	2	hour	930 Kč	1 860 Kč				0 Kč
L.	**OTHER ACTIVITIES**					**0 Kč**				**0 Kč**
	Office overhead	office						month	4 900 Kč	0 Kč
	GRAND TOTAL					**99 400 Kč**				**0 Kč**
						CRO staff work				pass-through costs

RESOURCES		HOURLY RATES	DAILY RATES	COMMENTS
Clinical Research Manager	CRM	1 100 Kč	8 800 Kč	8 working hours per 1 day
Clinical Research Associate	CRA	930 Kč	7 440 Kč	8 working hours per 1 day
Study Assistant / Data management	SA/DM	640 Kč	5 120 Kč	8 working hours per 1 day

PASS-THROUGH COSTS		
Mileage (company car) per 1 km	10 Kč	
Office overhead costs per month	4 900 Kč	for 1 FTE (full-time equivalent)