Addendum 1 al Contratto di sperimentazione clinica su medicinali	**Addendum 1 to clinical trial AGREEMENT for the drugs**
"Uno studio di fase 3, randomizzato, in doppio cieco, controllato con placebo, multicentrico di ABSK021 per valutare l'efficacia e la sicurezza nei pazienti con tumore tenosinoviale a cellule giganti"	"A Phase 3, Randomized, Double-blind, Placebo-Controlled, Multicenter Study of ABSK021 to Assess the Efficacy and Safety in Patients with Tenosynovial Giant Cell Tumor"
FRA	BETWEEN
Azienda USL Toscana Centro Ospedale S. Stefano di Prato (di seguito l'"Ente"), con sede legale in In Piazza Santa Maria Nuova 1, 50122 Firenze (Italia), Codice Fiscale e P.IVA n. 0006593810481, nella persona del Legale Rappresentante, Dr. Valerio Mari, in qualità di Direttore Generale, che ha munito di idonei poteri di firma del presente atto la Direttrice Staff della Direzione Sanitaria Dr.ssa Silvia Guarducci.	**Azienda USL Toscana Centro Ospedale S. Stefano di Prato (hereinafter the "Entity"),** with registered office in In Piazza Santa Maria Nuova 1, 50122 Florence (Italy) Tax Code no. and VAT no. 0006593810481, in the capacity of General Director, who has granted the Director of the Healthcare Direction Staff Dr Silvia Guarducci, the powers to enter into this Agreement.
E	AND
HongKong Tigermed Co., Limited, con sede in Unit N. 1201, 12º piano, Harbour East, 218 Electric Road, North Point, Hong Kong, Codice Fiscale: 58993572, nella persona del legale rappresentante, **Dott. Xiaoli Shi** in qualità di VP, BDPC (di seguito denominato "**CRO**"), che agisce in nome proprio e per conto di Abbisko Therapeutics Co., Ltd (di seguito denominato "Sponsor") con sede legale in N.3, 898 Lane, Halei Road, Cina (Shanghai) Pilot Free Trade Zone Shanghai, Shanghai, 201203 Cina, in virtù di apposita delega concessa il 7 giugno 2023. Il rappresentante legale di CRO HongKong Tigermed Co., Limited per l'UE è Marti Farm d.o.o. con sede legale a Lašćinska Cesta 40, Zagabria, 10000, Croazia.	**HongKong Tigermed Co., Limited**, headquartered in Unit No. 1201, 12th Floor, Harbour East, 218 Electric Road, North Point, Hong Kong, Tax Registration Number: 58993572, in the person of legal representative, **Dr. Xiaoli Shi** in their capacity as VP, BDPC (hereinafter referred to as "**CRO**"), acting in its own name and on behalf of Abbisko Therapeutics Co., Ltd (hereinafter referred to as "Sponsor") with legal office in No.3, 898 Lane, Halei Road, China (Shanghai) Pilot Free Trade Zone Shanghai, Shanghai, 201203 China, by virtue of appropriate delegation granted on 07 June 2023. The EU legal representative of CRO HongKong Tigermed Co., Limited is Marti Farm d.o.o. with its registered office in Lašćinska Cesta 40, Zagreb, 10000, Croatia.
(Individualmente anche denominati "**Parte**" e collettivamente denominati "**Parti**")	(Individually also known as "**Party**" and collectively known as the "**Parties**")
Le Parti convengono quanto segue:	It is hereby agreed by the Parties, as follows:
I. In data 22 dicembre 2023 ("Data di Decorrenza") l'Ente e la CRO hanno stipulato un Contratto per la conduzione della Sperimentazione Clinica su Medicinali (il "Contratto") per l'esecuzione della sperimentazione clinica dal titolo "Uno studio di fase 3, randomizzato, in doppio	I. On 22 December 2023 ("Effective Date") the Entity and the CRO entered into a Clinical Trial Contract on Medicinal Products (the "Contract") for the performance of the clinical trial entitled "A Phase 3, randomized, double-blind, placebo-controlled, multicenter study of

cieco, controllato con placebo, multicentrico di ABSK021 per valutare l'efficacia e la sicurezza nei pazienti con tumore tenosinoviale a cellule giganti", Prot. ABSK021-301 (di seguito "Sperimentazione") presso l'Oncologia del Nuovo Ospedale di Prato Santo Stefano, sotto la responsabilità scientifica del Dr Giacomo Giulio Baldi, in qualità di sperimentatore principale ("Sperimentatore Principale").	ABSK021 to evaluate the efficacy and safety in patients with tenosynovial giant cell tumor", Prot. ABSK021-301 (hereinafter "Trial") at the Oncology Department of the New Hospital of Prato Santo Stefano, under the scientific responsibility of Dr Giacomo Giulio Baldi, as principal investigator ("Principal Investigator").
II. Si è reso necessario emendare il Protocollo versione 2 del 15/11/2023, presentando l'emendamento 2 al protocollo versione 2.1 che ha ottenuto parere favorevole in data 10/06/2024.	II. It was necessary to amend Protocol version 2 of 11/15/2023, by submitting amendment 2 to Protocol version 2.1 which obtained a favorable opinion on 10/06/2024.
III. Il Protocollo v. 2.1 prevede modifiche allo schema delle attività e delle visite, comportando un'ulteriore modifica al compenso riconosciuto all'Ente e stabilito nel relativo contratto.	III. Protocol v. 2.1 provides for changes to the schedule of activities and visits, resulting in a further change to the compensation recognized to the Institution and established in the originary contract.
IV. Col presente addendum le parti concordano inoltre di implementare a da € 27,00 a € 50,00 il rimborso per visita a favore dei pazienti con effetto retroattivo per tutti i pazienti.	IV. With this addendum the parties also agree to implement the reimbursement per visit for patients from €27.00 to €50.00 with retroactive effect.
V. La fatturazione dei rimborsi a favore dei pazienti saranno fatturate separatamente per motivi organizzativi interni dell'Ente.	V. Reimbursement billing for patients will be invoiced separately for internal organizational reasons of the Institution.
VI. Le disposizioni dell'Allegato A - Costi e pagamenti derivanti dall'Accordo di sperimentazione clinica qui menzionato sono modificate, aggiungendo gli importi di budget per la Parte 3 dello Studio clinico, come concordato. Il budget aggiornato è allegato al presente Addendum, (Allegato A) e costituisce parte integrante di quest'ultimo e con lo stesso valore legale.	VI. The provisions from Annex A – Costs and Payments from the Clinical Trial Agreement mentioned herein are amended, by adding the budget amounts for Part 3 of the clinical Study, as agreed. The updated budget can be found in the Annex to the present Addendum, Annex A that constitutes an integral part of the latter and with the same legal power.
VII. Le Parti concordano reciprocamente che le notifiche alla CRO saranno indirizzate (punto 6 del contratto di Sperimentazione Clinica) come di seguito: "La CRO per conto dello Sponsor fornisce i dati necessari all'emissione della fattura: Nome della società per intestazione fattura:	VII. The Parties mutually agree that the notices to the CRO shall be addressed (point 6 of the Clinical Trial Agreement) as below: "The CRO on behalf of Sponsor hereby provides the data necessary for the issuance of the invoice: Company name – invoice header:

HongKong Tigermed Co., Limited Office Unit N. 1201, 12º Piano, Hong Kong Li-Ning Building 218 Electric Road, North Point Hong Kong Indirizzo per la consegna delle fatture: Office Unit N. 1201, 12º Piano, Hong Kong Li-Ning Building 218 Electric Road, North Point Hong Kong Numero di Registrazione Fiscale: 58993572 Persona di contatto: Alexandru Nicolae Ciucur E-mail di contatto: invoices@operacro.com"	HongKong Tigermed Co., Limited Office Unit No. 1201 12th Floor Hong Kong Li-Ning Building 218 Electric Road, North Point Hong Kong Invoice delivery address: Office Unit No. 1201 12th Floor Hong Kong Li-Ning Building 218 Electric Road, North Point Hong Kong Tax Registration Number: 58993572 Contact person: Alexandru Nicolae Ciucur Contact e-mail: invoices@operacro.com"
VIII. Tutte le altre disposizioni contrattuali restano invariate.	VIII. All other contractual provisions remain unchanged.
IX. Il presente Addendum ha effetto a decorrere dalla data di ultima sottoscrizione e costituirà parte integrante del contratto originale	IX. This Addendum shall be effective from the date of last signature and shall be an integral part of the originary Agreement.
X. Lo Sponsor ha assolto l'imposta di bollo con versamento diretto tramite bonifico bancario all'Agenzia delle Entrate (codice IBAN: IT07Y 0100003245348008120501, Codice BIC: BITAITRRENT), come da risposta della stessa a interpello n. 332/2020.	X. Sponsor paid the stamp duty with direct payment via bank transfer to the Agenzia delle Entrate (Revenue Agency) (IBAN code: IT07Y 0100003245348008120501, BIC code: BITAITRRENT), as per the latter's response to request no. 332/2020.
Letto, approvato e firmato digitalmente dalle Parti	Letto, approvato e firmato digitalmente dalle Parti
Per l'Ente/For the Entity	Per l'Ente/For the Entity
Il Rappresentante Legale	Legal Representative
Dott.ssa Silvia Guarducci	Dott.ssa Silvia Guarducci
Firma digitale / Digital Signature/	Firma digitale / Digital Signature/
CRO per conto del Promotore / CRO on behalf of the Sponsor	CRO per conto del Promotore / CRO on behalf of the Sponsor
Il Legale Rappresentante / The Legal Representative	Il Legale Rappresentante / The Legal Representative
VP, Head of BDPC	VP, Head of BDPC
Dott. / Dr. Xiaoli Shi	Dott. / Dr. Xiaoli Shi
DocuSigned by: Xiaoli Shi 90A965F42BDE425...	DocuSigned by: Xiaoli Shi 90A965F42BDE425...

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ALLEGATO A – BUDGET	ANNEX A – BUDGET
COSTI E COMPENSI	COSTS AND PAYMENTS
Parte 1 - Oneri fissi e Compenso per paziente coinvolto nello studio	Part 1 – Fixed costs and payments per patient involved in the study
Fornitura del/i Medicinale/i Sperimentale/i e/o di ogni altro materiale in sperimentazione o necessario allo svolgimento della stessa affinché non vi sia aggravio di costi a carico del S.S.N. (kit diagnostici, dispositivi medici, ecc.).	Supply of the Trial Drug(s) and/or of any other materials required for the trial provided that there are no extra costs for the National Health Service (diagnostics kits, medical devices, etc.).

Oneri fissi in euro/Fixed costs in euro

Fixed Cost

Code	**Site Costs**	**Budget**
SC003	Study Start-Up Fee/Site Set-Up Fee	1’497
SC008	Pharmacy: Set-Up Fee	615
SC009	Pharmacy: Close-Out Fee	308
SC023	Study Close out: including all activities related to closing out the site	543
SC020	Document Storage, Archiving Total Cost	494
SC150	Drug Destruction Fee - Per Occurrence	138
SC130	Re-consent, Informed consent performed again with the same patient	39
SC090	Log and File Serious Adverse Event (SAEs) Reports/Forms: per incident	33
	Total Site Costs (€)	€ 3’667

Code	Procedure	Quantity	Budget	ISV	SV	C1D1	C1D15	C2D1	C2D15	C3D1	C4D1	C5D1	C6D1	C7D1	EoT	Safety FU	Pro FU	Part 2	C1D1.1	C2D1.1	C3D1.1	C4D1.1	C7D1.1	EoT.1	Safety FU.1	Pro FU.1
INCON	Informed consent	1	40	40																						
INCEX	Eligibility criteria	1	37	37																						
T9210	Medical History with Demographics	1	72	72																						
99205	Physical examination	15	172		172		172	172		172	172	172	172	172	172				172	172	172	172	172	172		
99211	Vital Signs	17	28		28	28	28	28	28	28	28	28	28	28	28				28	28	28	28	28	28		
S0042	ECOG Score	15	18		18		18	18		18	18	18	18	18	18				18	18	18	18	18	18		
84702	Serum pregnancy	5	24		24									24	24								24	24		
84703	Urine pregnancy	7	17					17		17	17	17	17						17			17				
85025	Hematology	16	23		23	23	23	23		23	23	23	23	23	23				23	23	23	23	23	23		
T9999	Blood Chemistry	17	36		36	36	36	36	36	36	36	36	36	36	36				36	36	36	36	36	36		
82550	Myocardial Enzyme Test - CK	17	7		7	7	7	7	7	7	7	7	7	7	7				7	7	7	7	7	7		
82553	Myocardial Enzyme Test - CK-MB	17	19		19	19	19	19	19	19	19	19	19	19	19				19	19	19	19	19	19		
84484	Myocardial Enzyme Test - Cardiac Troponin I (cTnI) or Cardiac Troponin T (cTnT)	1	33		33																					
85610	Coagulation - Prothrombin time (PT)	7	9		9						9			9	9							9	9	9		
T5209	Coagulation - Fibrinogen	7	20		20						20			20	20							20	20	20		
INR	Coagulation - International Normalized Ratio (INR)	7	18		18						18			18	18							18	18	18		

Code	Procedure	Quantity	Budget	ISV	SV	C1D1	C1D15	C2D1	C2D15	C3D1	C4D1	C5D1	C6D1	C7D1	EoT	Safety FU	Pro FU	Part 2	C1D1.1	C2D1.1	C3D1.1	C4D1.1	C7D1.1	EoT.1	Safety FU.1	Pro FU.1
85730	Coagulation - activated partial thromboplastin time (aPTT)	**7**	**14**		**14**						**14**			**14**	**14**							**14**	**14**	**14**		
85670	Coagulation - Thrombin time(TT)	**7**	**27**		**27**						**27**			**27**	**27**							**27**	**27**	**27**		
81005	Urinalysis	**16**	**7**		**7**	**7**	**7**	**7**		**7**	**7**	**7**	**7**	**7**	**7**				**7**	**7**	**7**	**7**	**7**	**7**		
T0060	Thyroid panel	**7**	**73**		**73**						**73**			**73**	**73**							**73**	**73**	**73**		
T0703	Virology	**1**	**51**		**51**																					
93000	12-lead ECG: Includes tracing, interpretation and report	**17**	**56**		**56**	**56**	**56**	**56**	**56**	**56**	**56**	**56**	**56**	**56**	**56**				**56**	**56**	**56**	**56**	**56**	**56**		
78473	Echocardiography / MUGA	**7**	**611**		**611**						**611**			**611**	**611**							**611**	**611**	**611**		
ADEVT	Adverse events	**19**	**23**	**23**		**23**	**23**	**23**	**23**	**23**	**23**	**23**	**23**	**23**	**23**	**23**			**23**	**23**	**23**	**23**	**23**	**23**	**23**	
CONMD	Concomitant medications	**19**	**21**	**21**		**21**	**21**	**21**	**21**	**21**	**21**	**21**	**21**	**21**	**21**	**21**			**21**	**21**	**21**	**21**	**21**	**21**	**21**	
RANDM	Randomization	**1**	**46**			**46**																				
T0299	PK Sample Collection	**8**	**22**			**22**	**22**				**22**			**22**	**22**							**22**	**22**	**22**		
73222	Tumor imaging (MRI) with contrast material(s)	**9**	**606**		**606**						**606**			**606**	**606**		**606**					**606**	**606**	**606**		**606**
R3222	MRI Interpretation and Report	**9**	**82**		**82**						**82**			**82**	**82**		**82**					**82**	**82**	**82**		**82**
88399	Tissue Specimen Collection	**1**	**774**	**774**																						
95851	Range of motion (ROM) of affected joints (incl. report)	**7**	**26**		**26**						**26**			**26**	**26**							**26**	**26**	**26**		

Code	Procedure	Quantity	Budget	ISV	SV	C1D1	C1D15	C2D1	C2D15	C3D1	C4D1	C5D1	C6D1	C7D1	EoT	Safety FU	Pro FU	Part 2	C1D1.1	C2D1.1	C3D1.1	C4D1.1	C7D1.1	EoT.1	Safety FU.1	Pro FU.1
S0005	Worst Stiffness NRS and BPI Worst Pain NRS	**14**	**14**		**14**	**14**		**14**		**14**	**14**	**14**	**14**	**14**	**14**					**14**	**14**	**14**	**14**	**14**		
S0034	PROMIS Physical Functioning Scale	**14**	**32**		**32**	**32**		**32**		**32**	**32**	**32**	**32**	**32**	**32**					**32**	**32**	**32**	**32**	**32**		
S0034	European Quality of Life Questionnaire (EuroQol) (EQ-5D)	**14**	**32**		**32**	**32**		**32**		**32**	**32**	**32**	**32**	**32**	**32**					**32**	**32**	**32**	**32**	**32**		
S0034	NCI-PRO-CTCAE	**11**	**32**		**32**	**32**	**32**	**32**	**32**	**32**	**32**	**32**	**32**	**32**	**32**											
	Procedures Sub Total (€)			**967**	**2070**	**398**	**464**	**537**	**222**	**537**	**2.045**	**537**	**537**	**2.052**	**2.052**	**44**	**688**	**0**	**427**	**488**	**488**	**2.013**	**2.020**	**2.020**	**44**	**688**

Code	Procedure	Quantity	Budget	Part 3	C1D1.2	C4D1.2	C7D1.2	C13D1	C19D1	EoT.2	Safety FU.2	Pro FU.2
INCON	Informed consent	0	40									
INCEX	Eligibility criteria	0	37									
T9210	Medical History with Demographics											
99205	Physical examination	6	172		172	172	172	172	172	172		
99211	Vital Signs	6	28		28	28	28	28	28	28		
S0042	ECOG Score	6	18		18	18	18	18	18	18		
84702	Serum pregnancy	0										
84703	Urine pregnancy	0										
85025	Hematology	6	23		23	23	23	23	23	23		
T9999	Blood Chemistry	6	36		36	36	36	36	36	36		
82550	Myocardial Enzyme Test - CK	6	7		7	7	7	7	7	7		
82553	Myocardial Enzyme Test - CK-MB	6	19		19	19	19	19	19	19		
84484	Myocardial Enzyme Test - Cardiac Troponin I (cTnI) or Cardiac Troponin T (cTnT)	0										
85610	Coagulation - Prothrombin time (PT)	5	9		9	9	9	9	9			
T5209	Coagulation - Fibrinogen	5	20		20	20	20	20	20			
INR	Coagulation - International Normalized Ratio (INR)	5	18		18	18	18	18	18			
85730	Coagulation - activated partial thromboplastin time (aPTT)	5	14		14	14	14	14	14			
85670	Coagulation - Thrombin time(TT)	5	27		27	27	27	27	27			
81005	Urinalysis	6	7		7	7	7	7	7	7		
T0060	Thyroid panel	5	73			73	73	73	73	73		
T0703	Virology											
93000	12-lead ECG: Includes tracing, interpretation and report	6	56		56	56	56	56	56	56		
78473	Echocardiography/ MUGA	5	611			611	611	611	611	611		
ADEVT	Adverse events	6	23		23	23	23	23	23	23	23	
CONMD	Concomitant medications	6	21		21	21	21	21	21	21	21	
RANDM	Randomization	0										
T0299	PK Sample Collection	0										
73222	Tumor imaging (MRI) with contrast material(s)	6	606			606	606	606	606	606		606
R3222	MRI Interpretation and Report	6	82			82	82	82	82	82		82
88399	Tissue Specimen Collection											
95851	Range of motion (ROM) of affected joints (incl. report)	5	26			26	26	26	26	26		
S0005	Worst Stiffness NRS and BPI Worst Pain NRS	6	14		14	14	14	14	14	14		
S0034	PROMIS Physical Functioning Scale	6	32		32	32	32	32	32	32		
S0034	European Quality of Life Questionnaire (EuroQol) (EQ-5D)	6	32		32	32	32	32	32	32		

Code	Procedure	Quantity	Budget	Part 3	C1D1.2	C4D1.2	C7D1.2	C13D1	C19D1	EoT.2	Safety FU.2	Pro FU.2
S0034	NCI-PRO-CTCAE	**0**										
	Procedures Sub Total (€)				**488**	**1974**	**1974**	**1974**	**1974**	**1974**	**44**	**688**

Sub-Total: 32,428.00 euro

Code	Procedure	Quantity	Budget	ISV	SV	C1D1	C1D15	C2D1	C2D15	C3D1	C4D1	C5D1	C6D1	C7D1	EoT	Safety FU	Pro FU	Part 2	C1D1.1	C2D1.1	C3D1.1	C4D1.1	C7D1.1	EoT.1	Safety FU.1	Pro FU.1
NP004	Physician - Per Hour	20	84	84	168	84	84	84	84	84	84	84	84	84	84	42	42	**0**	84	84	84	84	84	84	42	42
NP022	Study Coordinator, Complex - Per Visit	20	79	79	158	79	79	79	79	79	79	79	79	79	79	40	40	**0**	79	79	79	79	79	79	40	40
NP006	Pharmacy, Simple (e.g. tablets, cream tubes) - Per Preparation (formerly Per Visit); dispense drug	10	29			29		29		29	29	29	29					**0**	29	29	29	29				
	Non Procedures Sub Total (€)			163	326	192	163	192	163	192	192	192	192	163	163	82	82	**0**	192	192	192	192	163	163	82	82

Code	Procedure	Quantity	Budget	Part 3	C1D1.2	C4D1.2	C7D1.2	C13D1	C19D1	EoT.2	Safety FU.2	Pro FU.2
NP004	Physician - Per Hour	**8**	84		84	84	84	84	84	42	42	42
NP022	Study Coordinator, Complex - Per Visit	**8**	79		79	79	79	79	79	40	40	40
NP006	Pharmacy, Simple (e.g. tablets, cream tubes) - Per Preparation (formerly Per Visit); dispense drug	**3**	29		29	29	29					
	Non Procedures Sub Total (€)				**192**	**192**	**192**	**163**	**163**	**82**	**82**	**82**

Sub-Total: 4,863.00 euro

Invoiceable Procedure	**Budget**
Serum pregnancy test	24
Urine pregnancy test	17
Blood Chemistry	36
Thyroid panel	73
Myocardial Enzyme Test - CK	7
Myocardial Enzyme Test - CK-MB	19
Myocardial Enzyme Test - Cardiac Troponin I (cTnI) or Cardiac Troponin T (cTnT)	33
12-lead ECG: Includes tracing, interpretation and report	56
MUGA	611
MRI with contrast	606
Virology	51
Hematology	23
Coagulation - Prothrombin time (PT)	9
Coagulation - Thrombin time(TT)	27
Coagulation - International Normalized Ratio (INR)	18
Coagulation - Fibrinogen	20
Urinalysis	7
Tissue Specimen Collection	774
ECOG	18
Blood Draw	22
Range of motion measurements and report; each extremity or each trunk section (spine)	26
NCI-PRO-CTCAE	32
Scripps Neurological Rating Scale (SNRS) (NRS)	14
Bristol Activities of Daily Living Scale (BADLS); 20-item scale, caregiver-administered	7
Echocardiograph	388
Patient Reimbursement, Expenses, Patient Travel - Per Visit	50

Quantity	**Budget**	**ISV**	**SV**	**C1D1**	**C1D15**	**C2D1**	**C2D15**	**C3D1**	**C4D1**	**C5D1**	**C6D1**	**C7D1**	**EoT**	**Safety FU**	**Pro FU**
Overhead (all costs €)	19%	215	455	112	119	139	73	139	€ 425	139	139	421	421	24	146
Total Cost Per Visit with Overhead (€)		1’345	2’851	702	746	868	458	868	2’662	868	868	2’636	2’636	150	916

Quantity	**Budget**	**Part 2**	**C1D1.1**	**C2D1.1**	**C3D1.1**	**C4D1.1**	**C7D1.1**	**EoT.1**	**Safety FU.1**	**Pro FU.1**
Overhead (all costs €)	19%	0	118	129	129	419	415	415	24	146
Total Cost Per Visit with Overhead (€)		0	737	809	809	2’624	2’598	2’598	150	916

Quantity	Budget	Part 3	C1D1.2	C4D1.2	C4D1.2	C13D1	C19D1	EoT.2	Safety FU.2	Pro FU.2
Overhead (all costs €)	19%	0	129	412	412	406	406	391	24	146
Total Cost Per Visit with Overhead (€)		0	809	2'578	2'578	2'543	2'543	2'447	150	916

Total Cost Per Patient (€)	**€ 44,378**

- Tutti i costi rimborsabili relativi allo studio, inclusi quelli coperti dal contributo per paziente coinvolto nello studio, non comporteranno aggravio di costi a carico del SSN. - Gli esami di laboratorio verranno effettuati con kit diagnostici forniti da Lab Connect ed inviati presso un unico laboratorio centralizzato esterno, con spese a carico del Promotore.	- All the reimbursable costs of the stud - y, including those covered by the contribution per patient involved, shall not lead to any extra cost payable by the National Health Service. The lab tests will be carried out with diagnostic kits supplied by Lab Connect and shipped to a unique centralized Lab at Sponsor's expenses.
Parte 2 - Costi aggiuntivi per esami strumentali e/o di laboratorio da effettuarsi sulla base del Tariffario dell'Ente (o in difetto sulla base del nomenclatore tariffario della Regione dove è situato il Centro di sperimentazione) vigente al momento dell'erogazione delle rispettive prestazioni.	**Part 2 – Additional costs for instrumental tests and/or lab tests to be carried out according to the Tariff of the Entity (or over cost on the basis of the tariff nomenclator of the Region where the Trial Center is located) in force at the time of the provision of the respective services.**
Non sono previsti costi aggiuntivi.	No additional costs are planned.
Parte 3 - Indennità per i pazienti/accompagnatori coinvolti nello studio clinico:	**Part 3 – Payment Allowance for patients/carers involved in the clinical trial:** (*if applicable*)
- Si fa rinvio al modello "Indennità per i partecipanti alla sperimentazione", incluso nel dossier della domanda ai sensi del Regolamento (UE) n. 536/2014, da intendersi richiamato nel presente Contratto come sua parte integrante e sostanziale. La relativa fatturazione sarà emessa separatamente da tutte le altre attività.	Reference is made to the model "Compensation for participants in the trial", included in the application dossier pursuant to Regulation (EU) no. 536/2014, to be understood as referred to in this Agreement as an integral and substantial part. The related invoicing will be issued separately from all other activities.
LIQUIDAZIONE E FATTURE	**PAYMENTS AND INVOICES**
- Il compenso deve essere liquidato entro 30 giorni dalla ricezione della fattura.	The payment must be made within 30 days from receipt of the invoice.
- Le fatture devono essere emesse con cadenza prevista semestrale secondo quanto maturato nel periodo di riferimento, sulla base di apposita richiesta di emissione fattura da parte del Promotore da inviare al seguente indirizzo: Azienda USL Toscana Centro Task Force sperimentazione clinica Presidio Ospedaliero "Piero Palagi" Viale Michelangelo 41 - 50125 Firenze	The invoices must be issued at the required six-month intervals *half yearly* based on the amounts accruing during the reference period and the request for invoice by the Sponsor. Azienda USL Toscana Centro Task Force sperimentazione clinica Presidio Ospedaliero "Piero Palagi" Viale Michelangelo 41 - 50125 Firenze e-mail: taskforceclinica@uslcentro.toscana.it

e-mail: taskforceclinica@uslcentro.toscana.it Tramite bonifico bancario alle Coordinate Bancarie: Banco B.P.M. Spa – Piazza Davanzati n. 3 50123 Firenze Cod. BIC/Swift: BAPPIT21N25 IBAN: IT04S0503402801000000009615 Si precisa che nella causale dell'eventuale bonifico è importante indicare anche il numero e la data della fattura. Nel caso in cui le coordinate bancarie subissero eventuali variazioni, faranno fede quelle riportate sulle fatture emesse dall'Azienda.	By bank transfer to Bank Details: Banco B.P.M. Spa – Piazza Davanzati n. 3 50123 Firenze Cod. BIC/Swift: BAPPIT21N25 IBAN: IT04S0503402801000000009615 Please note that in the case of a bank transfer it is important to indicate also the number and date of the invoice. In the event that the bank details undergo any changes, those indicated on the invoices issued by the Company will prevail.
Compenso a paziente coinvolto nello studio (solo visita di screening): **€ 4,196.00 + IVA** *(se applicabile)* .	Payment per patient involved in the study (screening visit only): **€ 4,196.00 + VAT** *(if applicable).*
Compenso per screening failure e unscheduled visit: calcolato caso per caso sulla base delle procedure effettuate.	Compensation for screening failure and unscheduled visit: calculated for each case based on the procedures performed.
Compenso massimo per il Centro sperimentale a paziente completato *(Compenso a paziente coinvolto – overhead aziendale - tutti i costi sostenuti dall'Ente per la sperimentazione)*: **€ 44,378.00** + IVA (se applicabile).	Maximum payment per trial Centre for each completed patient (Payment for enrolled patient - company overheads - all the costs incurred by the Entity *for the trial)*: **€ 44,378.00** + VAT (if applicable).

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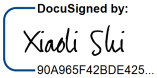
Xiaoli Shi xiaoli.shi@tigermedgrp.com VP Security Level: Email, Account Authentication (None)	DocuSigned by:  90A965F42BDE425... Signature Adoption: Pre-selected Style Using IP Address: 210.57.36.126	Sent: 21/11/2024 | 11:18 Viewed: 21/11/2024 | 11:56 Signed: 21/11/2024 | 11:57

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In Person Signer Events	Signature	Timestamp

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Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	21/11/2024 | 11:18
Certified Delivered	Security Checked	21/11/2024 | 11:56
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