DETERMINAZIONE DEL DIRETTORE GENERALE

n. 324 **DG del** 11 AGO 2020

OGGETTO

APPROVAZIONE DELL'ACCORDO CON LA MEDIZINISCHE UNIVERSITÄT WIEN (AUSTRIA) PER LA CONDUZIONE DELLA SPERIMENTAZIONE CLINICA DI CUI AL PROTOCOLLO INT N. 101/16

Attestazione di legittimità e regolarità dell'istruttoria
Il dirigente della struttura semplice
Trasferimento Tecnologico (TTO)
(f.to dott. Antonio Cannarozzo)

In base alle attestazioni rese dal dirigente competente all'adozione del provvedimento e alle verifiche contabili svolte:

- ✓ si provvede alle registrazioni contabili.
- ☐ il provvedimento non comporta registrazioni contabili, né impegni finanziari futuri.

Il direttore della struttura complessa
Risorse Economiche e Finanziarie e Libera Professione
Firmato (dott.ssa Elena Teresa Tropiano)

CON I PARERI FAVOREVOLI DEL		
Direttore Scientifico	**Direttore Amministrativo**	**Direttore Sanitario**
dott. Giovanni Apolone	dott. Andrea Frignani	dott. Oliviero Rinaldi

L'atto si compone di 16 pagine di cui 13 pagine di allegati parte integrante
Atti n. 1.6.05 – 485/2016
/st

s.c. Affari Generali e Legali
Il Direttore

FONDAZIONE IRCCS
Istituto Nazionale Tumori
VERCOL

IL DIRETTORE GENERALE

su proposta del Responsabile del procedimento della s.s. Trasferimento Tecnologico (TTO) che, a seguito di istruttoria, attesta:

visto il D. Lgs. n. 211/2003 in tema di "Attuazione della direttiva 2001/20/CE relativa all'applicazione della buona pratica clinica nell'esecuzione delle sperimentazioni cliniche di medicinali per uso clinico";

premesso che
- in data 21 giugno 2016, il Comitato Etico della Fondazione ha approvato l'esecuzione della sperimentazione clinica dal titolo "PURE-01: Studio di Fase 2, in aperto, a singolo braccio, con anticorpo monoclonale anti-PD1 MK-3475 (Pembrolizumab) in pazienti con carcinoma uroteliale della vescica muscolo-infiltrante candidati a cistectomia radicale" promossa dalla Fondazione e da svolgersi sotto la responsabilità scientifica del dott. Andrea Necchi, Dirigente Medico presso la s.c. Oncologia Medica 1 della Fondazione, diretta dal prof. Filippo de Braud;
- con determinazione 21 dicembre 2016 n. 378DG, atti n. 485/2016, la Fondazione ha approvato un "Contratto di ricerca per sperimentazione clinica su iniziativa dello sperimentatore" con Merck Sharp & Dohme Corp., con sede in 2000 Galloping Hill Road, Kenilworth, New Jersey (USA)", per il supporto nell'esecuzione della sperimentazione in argomento;
- con determinazione 13 giugno 2019 n. 237DG, atti n. 485/2016, la Fondazione ha approvato l'Emendamento n. 1 al contratto di cui al punto precedente al fine di prorogare la durata della sperimentazione, aumentare il numero di pazienti arruolabili fino a circa 176, modificare gli aspetti economici inizialmente previsti e prevedere la partecipazione nella sperimentazione clinica in argomento della Medizinische Universität Wien, con sede in Vienna, Spitalgasse 23;

considerato che, al fine di disciplinare la partecipazione della Medizinische Universität Wien si è reso necessario predisporre apposito accordo contrattuale;

preso atto del piano di spesa, predisposto dal dott. Andrea Necchi e pervenuto alla s.s. Trasferimento Tecnologico (TTO) in data 30 giugno 2020, e delle clausole economiche contenute nell'accordo di cui trattasi che prevedono il pagamento da parte della Fondazione alla Medizinische Universität Wien dei seguenti importi (oltre I.V.A., se ed in quanto dovuta):
- € 8.0000,00 quale compenso forfettario per l'attività di start up:
- € 2.000,00 per ogni paziente completato, per un massimo di 10 pazienti;
- € 50,00 per la spedizione di ciascun campione di tessuto;
- € 2.150,00 quale rimborso per la copertura assicurativa attivata dalla Medizinische Universität Wien per i pazienti arruolati;
- € 100,00 quale compenso forfettario per la distruzione del farmaco residuo;

considerato che la realizzazione di attività di ricerca sanitaria e la stipulazione dei correlati atti contrattuali rientrano nella missione e nelle finalità della Fondazione,

in conformità alle disposizioni degli artt. 2 e 3 dello Statuto della Fondazione, approvato con Deliberazione del Consiglio di Amministrazione n. 12F del 20 febbraio 2012;

ritenuto pertanto di approvare l'accordo di cui trattasi, precedentemente concordato con la s.s. Trasferimento Tecnologico (TTO), inoltrato dalla Medizinische Universität Wien e pervenuto in data 20 luglio 2020;

considerato altresì che nulla osta alla pubblicazione del presente provvedimento in versione integrale all'Albo Pretorio della Fondazione, per 15 giorni consecutivi, ai sensi dell'art. 32 della L. n. 69/2009 e dell'art. 17 c. 6 della L.R. n. 33/2009;

dato atto dell'attestazione di regolarità dell'istruttoria sia sotto il profilo tecnico che di legittimità nonché delle disposizioni finanziarie e contabili;

richiamata la determinazione del Direttore Generale n. 311DG del 29 settembre 2017, avente ad oggetto "Disposizioni a carattere gestionale del Direttore Generale";

visti i pareri favorevoli dei Direttori Scientifico, Amministrativo e Sanitario della Fondazione resi per quanto di competenza,

DETERMINA

1- di approvare l'accordo con la Medizinische Universität Wien, con sede in Vienna, Spitalgasse 23, nel testo allegato al presente provvedimento di cui forma parte integrante e sostanziale, per la partecipazione del citato Ateneo alla sperimentazione clinica promossa dalla Fondazione di cui al protocollo INT n. 101/16, da svolgersi sotto la responsabilità scientifica del dott. Andrea Necchi, Dirigente Medico presso la s.c. Oncologia Medica 1 della Fondazione, diretta dal prof. Filippo de Braud;
2- di dare atto che la Fondazione corrisponderà alla Medizinische Universität Wien gli importi meglio specificati in premessa, oltre IVA se ed in quanto dovuta, da imputare al codice identificativo interno Q/16/085;
3- di individuare lo Sperimentatore Principale quale Direttore dell'Esecuzione del Contratto, con particolare riferimento alla corretta tempistica della fatturazione e al relativo monitoraggio, nonché quale persona autorizzata al trattamento dei dati oggetto della sperimentazione clinica in argomento;
4- di disporre la pubblicazione del presente provvedimento all'Albo Pretorio della Fondazione, per 15 giorni consecutivi, ai sensi dell'art. 32 della L. n. 69/2009 e dell'art. 17 c. 6 della L.R. n. 33/2009.

IL DIRETTORE GENERALE
dott. Stefano Manfredi

s.c. Affari Generali e Legali
Il Direttore

s.s. Trasferimento Tecnologico (TTO)	
File no. 1.6.05 - 485/2016	*to be mentioned in reply*

Messrs.
Medical University of Vienna
Spitalgasse 23, 1090 Vienna
(Executing Department:
Department of Urology,
Währinger Gürtel 18-20, 1090
Vienna)

Original via courier

Subject: ***Scientific collaboration for the execution of the Clinical Trial entitled: "PURE-01: Studio di Fase 2, in aperto, a singolo braccio, con anticorpo monoclonale anti-PD1 MK-3475 (Pembrolizumab) in pazienti con carcinoma uroteliale della vescica muscolo-infiltrante candidati a cistectomia radicale" (english title: An Open Label, Single-arm, Phase 2 Study of Neoadjuvant Pembrolizumab (MK-3475) Before Cystectomy for Patients With Muscle-invasive Urothelial Bladder Cancer.). Principal Investigator of Fondazione: dr. Andrea Necchi.***

This Agreement is concluded between the Parties 1. Fondazione I.R.C.C.S Istituto Nazionale dei Tumori, via G. Venezian 1, 20133 Milan (Italy) (hereinafter "Fondazione"), represented by its General Manager, dr. Stefano Manfredi, Sponsor of the Study in subject, and 2. Medizinische Universität Wien, Spitalgasse 23, 1090 Vienna, Austria (Executing Department: Universitätsklinik für Urologie, Währinger Gürtel 18-20, 1090 Vienna, Austria) ("Centre"), according to § 27 UG represented by the head of the Universitätsklinik für Urologie, Univ. Prof. Dr. Shahrokh Shariat, as Participating Centre to the Study in subject.

Fondazione entrusts Centre with the task of carrying out the Clinical Trial as successively described, and the Parties therefore agree as follows (the following agreement hereinafter to be named "letter" or "Agreement"):

Centre's obligations

As agreed with the Principal Investigator of Fondazione, the Centre appoints as its Trial Investigator, Dr. Kilian Gust, in service at above mentioned Centre in the capacity of Investigator ("Investigator"). The Investigator is an employee of Centre and signs to have read and acknowledged the Agreement, but not as a party to it. For the avoidance of doubt, whenever this Agreement addresses acts, omissions or obligations of Investigator, these shall be obligations of the Centre, to assure adherence to such acts, omissions and obligations by Investigator as Investigator's employer.

Centre, through the Investigator, undertakes to carry out the following activities:

a) endeavour to enrol patients according to the inclusion and exclusion criteria described in the protocol, treat them with the experimental drug (Pembrolizumab) and follow all the patients during the whole study (included the follow-up period), both as described in the protocol (here attached as Schedule B). Fondazione acknowledges that no specific number of recruitment can be guaranteed;

b) store the experimental drug in accordance with the procedures provided by the producer and make independent arrangements for the destruction of any residual experimental drug; whereby Fondazione will pay a fixed share of € 100,00 for the destruction of any residual experimental drug;

c) develop Patient Information Sheet, Consent Form and other patient focused documents (including the processing of personal data) in accordance with Applicable Law;

d) obtain the required informed consent from each patient enrolled in the Study;

e) conduct the Study in compliance with the protocol and with the standards of "Good Clinical Practice" (GCP) issued by the European Community as well as all laws and regulations applicable to the conduct of the Study in in Austria ("Applicable Law");

f) timely fill in and complete the e-CRFs and to send them to the Principal Investigator of Fondazione, dr. Andrea Necchi, e-mail:andrea.necchi@istitutotumori.mi.it;

g) report to Fondazione SAE and SUSAR attributable to the experimental drug or to the conduct of the Study in accordance with Applicable Law;

h) collect biological material (20 unstained slides, hereinafter "Material") from enrolled patients as required by the protocol and in compliance with the existing and applicable regulations on the informed consent and to send the Material to Fondazione ensuring its quality, integrity, traceability and the respect of safeguard measures. The Centre will transmit Material identified by way of a unique reference code, which allows its traceability. If the patient withdraws his or her consent to the processing, Material shall be destructed or returned to the Centre following its instructions at Fondazione's cost;

i) if the Investigator is unable to continue performing the Study, the Institution shall promptly notify Fondazione in writing. If a mutually acceptable replacement is not available within a reasonable time, both Parties may terminate this Agreement in accordance with the provisions regarding termination as set forth below;

j) get the approvals of the competent authorities and the Ethics Committee.

Fondazione's obligations

Fondazione undertakes to carry out the following activities:

a) send to the Centre all the necessary material and documentation for the evaluation of the

Study by the competent Ethics Committee and the approvals of the competent authorities;

b) act for set up and initiation visit of the Centre and give the support during the execution of the Study;
c) develop of Case Report Form (including AEs forms) in accordance with Applicable Law and ICH-GCP;
d) perform telephonic monitoring of the Centre in accordance with GCP, protocol, monitoring plan and Applicable Law, upon prior written notification and during Center's normal business hours;
e) guarantee the supply of the Study drug without additional costs for Centre;
f) support the Centre with Pharmacovigilance service;
g) monitor the data of the Study through queries;
h) coordinate biological material collection and transmission, according to the Protocol;
i) provide Centre the payments for the executed activities as set forth in the Protocol and this Ageement as detailed in the attached budget Schedule A;
j) communicate to the Centre if it is necessary to archive the documentation of the Study for longer than 15 years, and bear the expense for such archiving exceeding 15 years;
k) report SAE and SUSAR to the competent Authorities;
l) provide reimbursement for insurance obtained by Centre on behalf of Sponsor;
m) in general adhere to any requirements Fondazione as sponsor of the Study has to fulfil pursuant to Applicable Law.

Duration

This Agreement shall be effective as of the date of the last signature and shall remain in force until the date of formal closure or termination of the Study at Centre. The duration of the Study is foreseen in 40 months or at the fulfilment of the target recruitment as per protocol.

Both Parties can terminate this Agreement,

a. immediately if necessary for patient safety reasons,
b. if the other Party is in breach of this Agreement, and such breach cannot be remedied by the breaching Party within 30 days of corresponding notice by the non-breaching Party,

In case of an early termination, Fondazione shall pay for activities that have been properly performed up to such date of termination on a pro rata basis as per Schedule A and shall reimburse Centre for reasonable costs incurred in connection with the safe withdrawal of patients from the Study without medical impact to such patients and for non-cancellable expenses after the termination date accrued as a result of meeting obligations reasonably entered into by Centre

for the performance of the Study prior to the effective date of termination.

Processing of personal data

Fondazione and Centre are both considered controllers, as defined in Article 4 subsection 7 of the European Union General Data Protection Regulation ("GDPR"), for the processing of personal data and will both act in accordance with applicable data protection laws (including but not limited to the GDPR). Fondazione and Centre hereby determine their respective responsibilities for compliance with the obligations under the GDPR.

Fondazione and Centre are joint controllers for the following data processing:

- the collection of personal data from study subjects in accordance with the study protocol

Fondazione, acts as independent controller for:

- the processing of pseudonymized personal data of study subjects that are reported or transferred by Centre or Principal Investigator to Fondazione under the study protocol
- the processing of personal data of Investigator and Study Personnel collected in accordance with the Agreement and study protocol

Centre acts as independent controller for:

- the pseudoynimization and transmission of the collected personal data of study subjects to Fondazione
- medical records processed by Centre with respect to source data and/or disclosed by study subject in the course of the study, which pursuant to medical standard of care and applicable legal obligations
- personal data collected or generated in the course of the study for the purpose of exercising independent medical judgement in line with this Agreement and the study protocol.

Fondazione agrees only to process personal data in accordance with research purposes and this Agreement and to ensure compliance with the Data Protection Legislation. Compliance includes but is not limited to ensuring a legal basis study subjects' informed consent ICF shall include the necessary content to allow the processing of the study subject's personal data for research purposes and this Agreement as well as providing approval of the ethics committee. Fondazione is responsible for the content and completeness, legality and representation of the actual circumstances thereof in the ICF.

Centre or Investigator will report or transfer the personal data of study subjects in pseudonymous form only to the Fondazione under the study protocol. Fondazione will maintain the personal data of study subjects in such de-identified form and shall not attempt to re-identify any study

subject (e.g. by collecting data) or attempt to contact those persons. In the event any study subject, for whatever reason, becomes identifiable to Fondazione , Fondazione agrees to preserve, at all times, the confidentiality of information pertaining to such study subjects.

The parties shall maintain appropriate administrative, technical and organizational measures to meet the requirements of Art 32 GDPR to protect the study data from misuse and unauthorized access or disclosure.

Fondazione and Centre agree that all data processing agreements will be in writing and in compliance with applicable data protection laws (as the Art 28 GDPR) and that data processors will be required to comply with the terms of this Agreement before any personal data of study subjects or Principal Investigator and Study Personnel, is provided to them. The parties ensure that any agents, contract partners including subcontractors, to whom it provides personal data, agree to the same restrictions and conditions listed in this Agreement.

The parties shall use the personal data exclusively through personnel under its supervision. Information related to the study data shall be disclosed only to such persons who have a need to know for the purpose of the study protocol and this Agreement and who are bound by similar obligations of confidentiality and restrictions on use as contained in this Agreement to have access to the personal data.

Fondazione will provide a personal information form required by the Art 13 and 14 GDPR for Principal Investigator and Study Personnel advising them of the collection, use, processing, holding and transfer of their personal data.

Centre and Fondazione shall each maintain a written record of all processing activities that are carried out under this Agreement as required by Article 30 of the GDPR.

The parties shall cooperate with each other with respect to any data protection impact assessments and/or consultations or inspections with government or semi-governmental authorities that may be required under applicable law in respect of data processing carried out under this Agreement.

Fondazione and Centre agree that, as personal data of study subjects will be reported or transferred to Fondazione, as between them, Centre is best able to manage requests from study subjects for access, amendment, correction, transfer, restriction, or deletion of their personal data. Therefore Centre is designated as the first point of contact for the study subjects whose personal data is being processed hereunder. In the event when Centre acts as a controller and Fondazione receives a request from a study subject to exercise their rights as a study subject according to the GDPR, Fondazione will immediately inform the Centre and refer the study subject to Centre.

Centre will respond to study subjects' requests in accordance with applicable law. Fondazione acknowledges that study subjects may withdraw their informed consent to study participation and their consent to processing of their personal data at any time.
Nevertheless Fondazione should support the Centre as much as possible in fulfilling the rights of data subjects (natural person who´s personal data is being processed).
The parties shall notify each other promptly if either party becomes aware of a personal data breach (as defined under Art 4 subsection 12, Art 33 and 34 of the GDPR) related to the personal data that is processed under this Agreement. Each party is responsible for any personal data breach that falls into the sphere of such party and shall comply with the obligations as set forth under Article 33 GDPR.

The parties are liable to data subjects according to Art 82 GDPR. Each party is liable for violations of the GDPR which it has committed in their sphere.

Each controller is responsible and legally obligated to ensure a secure transmission of personal data to third countries that are not obligated to the same standard of data protection as required by the GDPR. The parties shall ensure prior to transferring personal data outside of the European Economic Area compliance with Art 45 to 49 GDPR. If the standard contractual clauses of the European Commission are the legal basis for the transfer, Centre must ensure that they are signed before personal data can be transmitted.

The data protection provisions shall continue to apply even after termination or expiry of this Agreement.

Intellectual Property

According to applicable laws and regulation on copyright and intellectual property, data and results created during the performance of the Study in accordance with the protocol are Fondazione's property, excluding patient identification lists and medical files, which will remain Centre's property.

In case such intellectual property, data and results contain inventions, those shall be Fondazione's property too, however Fondazione will reimburse Centre for costs occurred for the transfer of such inventions, including but not limited to notary costs and employee invention remunerations Centre is obliged to pay according to applicable laws.

However, the Centre shall be entitled to use said intellectual property, data and results including inventions for its own research and teaching activities and patient care.

Nothing contained in the letter shall be deemed to grant either directly or by implication, estoppel, or otherwise any license under any patents, patent applications, or other proprietary interests to any other inventions, discovery or improvement of either party. The Centre shall remain the owner of all its knowledge, concepts, research results, inventions, softwares and other information obtained before, after or outside the performance of the Study in accordance with the protocol.

Confidentiality

Upon signature of this letter and for a period of five (5) years from the termination of this letter, Centre will keep the Clinical Trial-related information in the strictest confidence and will not disclose such confidential information to third parties without Fondazione's written consent, except as otherwise expressly stipulated in this Agreement. Centre guarantees that the obligation of confidentiality will be extended to the Investigator and co-Investigators and to any other person, outside the Centre, who, for any reason, becomes aware of the confidential information.

Notwithstanding the foregoing, confidential information shall not include information that:

a) was in the public domain or open to the public at the time it was transmitted to the Centre, or
b) became public or open to the public after the date of disclosure to the Centre otherwise than as a result of an action or omission attributable to the Centre, or
c) was in Centre's possession, without any limitation regarding its disclosure at the time it was disclosed to Centre, provided that such prior possession is supported by written evidence, or
d) was obtained in good faith by Centre and without any restriction relating to confidentiality from a third party entitled to disclose it, or
e) is independently developed by Centre without use of or access to the confidential information, as supported by written evidence, or
f) is required to be publicly disclosed pursuant to a requirement of law or a court order.

Publication

As the Study is a multicenter Trial, any publication by the Investigator may only take place after the multicenter publication performed by Fondazione. In this multicenter publication, the Investigator will be acknowledged as co-author. If, within twelve (12) months of the end of the multicenter trial, such multicenter publication has not been published by Fondazione, the Investigator may publish the results achieved at Centre, in compliance with the provisions of this letter.

Insurance

Each Party warrants and represents that it has adequate liability insurance, such protection being applicable to all its officers and employees while acting within the scope of their employment with said Party, as well as property damage insurance.

Indemnification, Warranty

Fondazione agrees to indemnify and hold harmless Centre, its agents and employees from all liabilities, claims, damages and losses resulting out of the performance of the Study in accordance with the protocol, unless caused by Centre's (including its employees') gross negligence or wilful misconduct.

Centre shall not be liable for slight negligence, except in case of personal injury or bodily harm.

The Parties are aware of the risk of success or failure associated with scientific research. Centre makes no warranties, express or implied, regarding the achievement of any particular results. There are no warranties of merchantability or fitness for a particular purpose for any of the results or that the use of the results will not infringe any patent rights of a third party.

Debarment and compliance

The Parties declare that (a) have not been debarred or is under consideration to be debarred, by a competent regulatory authority from working in, or providing services to, any pharmaceutical or biotechnology company; and (b) are not disqualified by any government or regulatory authorities from performing clinical trials or specific services, and are not subject to a pending disqualification proceeding. Each Party will notify the other Party immediately if it is or is proposed to be debarred or disqualified.

Governing law and jurisdiction

This letter and the conduct of the Study by Centre shall be governed by Austrian law. Any dispute between the Parties in relation with this letter shall be submitted exclusively to the jurisdiction of the competent courts in Vienna, Austria.

Miscellaneous

In case of discrepancies, the protocol shall govern in medical aspects, while this Agreement shall govern in all other aspects.

If a provision of this Agreement is or becomes (i) illegal under any applicable law or regulation, (ii) invalid or (iii) otherwise unenforceable, such illegality, invalidity or

unenforceability shall not affect the validity or enforceability of any other term or provision of this Agreement. All waivers of the terms of this Agreement shall be in writing. Failure to insist upon compliance with any of the terms and conditions of this Agreement shall not constitute a general waiver or relinquishment of any such terms or conditions, but the same shall remain at all times in full force and effect.

This Agreement, including Schedule A and B, contains the whole agreement between the Parties; there are no side-letters or verbal arrangements. Any amendment of this Agreement has to be in writing and has to be signed by both Parties.

Each Party agrees to not use the other Party's name or logo without the other Party's prior written explicit approval.

This Agreement, or any obligation or right contained herein, cannot be assigned to a third Party, except with the express written approval of the other Party.

Fondazione IRCCS "Istituto Nazionale dei Tumori"	***MEDIZINISCHE UNIVERSITÄT WIEN***
_____	_____
(signature)	(signature)
Name: Dr. Stefano Manfredi	Name: Univ.- Prof. Dr. Shahrokh Shariat
Title: General Manager	Title: Head of the Department of Urology
Date: _____	Date: 10. JULI 2020
Read and acknowledged	**Read and acknowledged**
DR. ANDREA NECCHI	**DR. KILIAN GUST**
_____	_____
(signature)	(signature)
Date: 11/7/2020	Date: 13. JULI 2020

Responsabile del procedimento: dott. Antonio Cannarozzo, Responsabile s.s. Trasferimento Tecnologico (TTO)
(tel. 02/2390.3332; fax 02/2390.3132)
Pratica trattata da Silvia Taverna
N.B.: Nell'eventuale corrispondenza successiva si prega di indicare il n° di protocollo e di atti riportato nell'intestazione della presente, indirizzandola a Fondazione IRCCS Istituto Nazionale dei Tumori – s.s. Trasferimento Tecnologico (TTO), via G. Venezian, 1 20133 Milano

s.c. Affari Generali e Legali
Il Direttore

Schedule A - Budget

Protocol number: PURE-01

Site Dr. Gust

In consideration of Centre's services provided under this Agreement in carrying out the Study, Fondazione agrees to provide payment as follows:

This Schedule A is for completed records for up to 10 valid study subjects. This figure is given as an indication only and may be revised upwards or downwards as the Study progresses.

By mutual agreement between the parties, the total provisional net sum of such fees have been valued at €2.000,00 (two thousand EURO) per completed evaluable study subject in accordance with the requirements of the Protocol.

This sum is based on the following rates:

Visit		Amount in Euro
Screening		400
treatment phase	Cycle 1, Day 1	300
	Cycle 2, Day 1	300
	Cycle 3, Day 1	300
Precystectomy visit		400
Cystectomy Week 9		0
Visits Post Cystectomy	Week 4	100
	Week 12	100
	Week 24	100
	2 years	0
Sum:		**2000**

Fondazione will make a one time start up payment of €8.000 (eight thousand Euro) to Centre to cover administration costs borne by Centre to obtain the relevant approvals and perform necessary preparation activities to start the Study. This fee will only be paid if all applicable approvals have been obtained. The start up payment is non-refundable.

EC/RA costs will be reimbursed by Fondazione on a pass through basis upon receipt of a formal invoice from Centre issued by the EC/RA and are not included in the above Budget. Any subsequent re-submissions or renewals, will be reimbursed upon receipt of appropriate documentation.

Costs for FFPE samples staining and preparation of slides including shipping and handling will be € 50 (fifty Euro) per sample.

These sums are understood to be exclusive of tax, and the Centre shall be responsible for the invoicing of VAT if acceptable, depending on the taxation system to which it is subject.

Subject to the foregoing, payment shall take place in proportion to the completed and e-CRF forms actually conducted in accordance with the requirements of the protocol.

Payment of these fees will be made semi annually, within sixty (60) days upon receipt of the corresponding invoice to the following bank account of Centre:

Bank:	ERSTE BANK
Payee:	Medizinische Universität Wien
IBAN-Code:	AT362011140410070700
BIC-Code:	GIBAATWW
Reference:	See invoice

It is hereby stipulated that, on no account shall the sums paid to the Centre permit healthcare professionals, in particular, the Investigator, to derive advantages which they are prohibited from receiving directly or indirectly. Given the scientific interest of this research for the interested party, it should be noted that the Investigator shall not derive any advantage by virtue of this agreement. Fondazione agrees that no employee of Centre, including Investigator, will receive direct payment from Fondazione.

s.c. Affari Generali e Legali
Il Direttore

Schedule B - Protocol