EORTC
Avenue E. Mounierlaan 83 / 11
Brussel 1200 Bruxelles
België - Belgique
Tel : +
Fax :-
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SPECTA CONSORTIUM AGREEMENT

This SPECTA CONSORTIUM AGREEMENT ("**CONSORTIUM AGREEMENT**") is made, 19 September 2017, by and between

the **EUROPEAN ORGANISATION FOR RESEARCH AND TREATMENT OF CANCER** an international non-profit organization under Belgian law and with its registered office at 83/11 Avenue E. Mounier 1200 Brussels Belgium, VAT BE 408292992, represented by the Director General, Dr. Denis Lacombe, hereinafter referred to as the "**EORTC**"

AND

each organization signatory of the Consortium Agreement (hereinafter individually or collectively referred to as the "Institution", "**Consortium Member**" or "**Consortium Members**").

Namely, this **Consortium Member**: **MASARYKŮV ONKOLOGICKÝ ÚSTAV** (MASARYK MEMORIAL CANCER INSTITUTE), with registered offices at Zluty Kopec, 7, CZ 656 53 Brno, Czech Republic, represented by prof. Marek Svoboda, MD, Ph.D., hereinafter referred to as the "Institution" or "Participating Centre"

The Consortium Member(s) and EORTC are hereafter individually or collectively referred to as the "**Party**" or "**Parties**".

PREAMBLE

WHEREAS, the EORTC develops, conducts, coordinates and stimulates translational and clinical cancer research – which takes place in over 300 hospitals, universities and cancer centers in 32 countries – in order to facilitate the passage of experimental discoveries into state-of-the-art treatments;

WHEREAS EORTC has taken the initiative to develop SPECTA.

WHEREAS SPECTA's objectives, design, methodology, organization and responsibilities are described in the EORTC protocol 1553 entitled "SPECTA: Screening Cancer Patients for Efficient Clinical Trial Access" (hereinafter referred to as "**SPECTA Protocol**"),

WHEREAS EORTC shall act as the Sponsor in the framework of the SPECTA Protocol.

WHEREAS the Institution has facilities and personnel with requisite skills, experience, and knowledge to participate in SPECTA as a clinical site in accordance with this Consortium Agreement and the SPECTA Protocol including any amendments.

WHEREAS the Institution, MMCI, has taken the initiative to establish BBMRI-CZ - national node of Biobanking and BioMolecular resources Research Infrastructure – European Research Infrastructure Consortium (BBMRI-ERIC) whereas the tasks of BBMRI-ERIC are among other things to establish international relationships and launch joint activities with other European and non-European organisations concerned with its activities and in related fields and to improve the interoperability between biobanks as per Statutes of BBMRI-ERIC.

NOW, THEREFORE, the Parties agree to the following:

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1. Definitions.

The words and expressions herein shall be defined, as pertinent, in accordance with the definitions set forth hereunder:

"Background IP" shall mean Intellectual Property whether tangible or intangible and whether or not protectable, which is held by a Party prior to its accession to the SPECTA Consortium and which is needed for carrying out SPECTA or a SPECTA project or for using Foreground IP;

"Chain of custody" shall mean the flow of HBM between the different parties involved in collecting, handling and using HBM (e.g. the hospital/site, service providers, storage facilities and sites performing Translational Research);

"Copyrights" shall mean the exclusive rights conferred by law to the authors of an original work to protect such work, including but not limited to the exclusive right to authorize or prohibit reproduction, any communication to the public of their works, as well any form of distribution to the public by sale or otherwise;

"Commercial Use" shall mean the direct or indirect utilization of Foreground IP for developing, creating and/or marketing a product or process, or for developing, creating and/or providing a service;

"Confidential Information" shall mean and collectively include any information, in tangible or non-tangible form, and/or physical items or materials, including but not limited to know-how, ideas, data, formulae, results of experimentation, specifications, inventions, techniques, research and development plans, business strategies, software and other technical or business information whether or not marked as confidential and whether obtained or disclosed in writing, orally or otherwise;

"Consortium Agreement" shall mean this Consortium Agreement (including all its Annexes) entered into between the EORTC and the Consortium Members;

"Consortium Member(s)" shall mean a single Institution or Participating Group which is Party to this Consortium Agreement, and having rights and obligations with regard to SPECTA as specified under the terms of this Consortium Agreement;

"Coordinator of the Chain of Custody" shall mean the entity responsible for ensuring all organizations participating in the chain of custody act in compliance with the SPECTA Protocol, the applicable legislation and the existing contractual agreements;

"Custodian" shall mean the legal entity responsible for safeguarding HBM and oversight of its use.

"Data" shall mean all data from patients including but not limited to patient characteristics, images, diagnostic, prognostic, survival, QoL questionnaires, treatment response and Molecular Data collected by the Consortium Members and/or EORTC for the purpose of SPECTA or any related SPECTA Project(s);

"Database" shall mean the systematized collection of Data that can be accessed immediately and manipulated by a data-processing system for a specific purpose;

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"Default" shall mean any non-performance or shortcoming, including but not limited to an unreasonable delay in performance of a Party in respect to obligations under this Consortium Agreement;

"EORTC Peer Review Committees" shall mean generic terminology which encompasses all scientific committees which have a role for the scientific review of EORTC activities as applicable. They include but are not limited to EORTC Protocol Review Committee, EORTC New Drug Advisory committee and EORTC Translational Advisory Research Committee;

"Force Majeure" shall mean any unforeseeable and exceptional event materially affecting the fulfillment of any duty under this Consortium Agreement, which is beyond its/their control and cannot be cured or overcome despite its/their reasonable efforts. Any default of a product or service or delays in making them available for the purpose of performing this Consortium Agreement and materially affecting such performance, including for instance, anomalies in the functioning or performance of such product or service, changed circumstances making performance more difficult or expensive or other financial difficulties shall not constitute Force Majeure or relieve a Party/Parties of its/their duty to perform;

"Foreground IP" shall mean any Intellectual Property which is generated within a SPECTA Project;

"HBM" shall mean human biological material provided by Institutions to EORTC as per SPECTA Protocol or any SPECTA Project and managed according to EORTC policy POL020 "Human Biological Material Collection, Storage and Use";

"Intellectual Property" shall mean any intellectual property right, including but not limited to Patents, Know How, Copyright and/or "sui generis" rights for producers of Database;

"Intergroup trials" shall mean clinical trials involving EORTC and at least one non-EORTC Academic Group;

"Institution(s)" shall mean a legal entity interested in participating in cancer research as described and agreed in this Consortium Agreement, and having rights and obligations with regard to the SPECTA network as specified under the terms of this Consortium Agreement;

"Institution Activation" shall mean first patient registered into SPECTA in the concerned Institution;

"Know How" shall mean unpatented technical information, including without limitation, materials and information relating to inventions, discoveries, concepts, methodologies, models, research, development and testing procedures, the results of experiments, tests, manufacturing processes, techniques and specifications, quality control data, analyses, reports and submissions;

"Molecular Data" means the genomic, proteomic or other type of data generated as a result of the molecular testing of the HBM, such as but no limited to biomarkers assessment;

"Participating Group" shall mean non-EORTC national/international network of investigators and/or Institutions and/or groups or structure/agency working for a group of investigators and/or Institutions and/or groups;

"Patents" shall mean Patents, Patent applications, supplementary protection certificates for medicinal products or other products for which such supplementary protection certificates may be obtained and that is not in the public domain;

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"Results" shall mean all information, data, findings, test results, discoveries, inventions, processes, methods, techniques, formulae, substances, specifications, studies, designs or improvements whatsoever (whether patentable or not) that are originated, conceived, derived, produced, discovered, invented or otherwise made in the course of or as a result of the performance of a SPECTA Project;

"SPECTA" or "SPECTA Consortium" shall mean the network of Institutions and Academic groups participating in cancer research, as described and agreed in this Consortium Agreement;

"SPECTA Project(s)" shall mean all clinical or other projects(s) that use HBM and/or Data, in the framework of SPECTA;

"SPECTA Repository" shall mean a repository for HBM collected by Consortium Members within SPECTA, contracted by EORTC;

"Steering Committee" shall mean the committee responsible for the governance of the SPECTA Consortium, as defined in the SPECTA Protocol;

2. Purpose and Scope.

The mission of SPECTA will be to offer a high quality integrated infrastructure for patients with different tumor types to support biospecimen-based translational research and biomarker discovery. The initiative will also help optimizing the timely development of high quality targeted or tailored therapies for treating cancer patients. SPECTA is designed to complement and support EORTC's current research groups.

3. Consortium Members

3.1 **Participation Criteria**. Participation in the SPECTA will be opened to any Institution or Participating Group; provided, however, that, the Institution or Participating Group meets the following criteria:

(i) Mandatory: Each Consortium Members must be a member in good standing in EORTC, or in any Participating Group to which the Institution is affiliated.

(ii) Mandatory: Each Institution, at all times, must be committed to the mission of SPECTA and must have the ability and willingness to fulfil the obligations of a Consortium Member.

(iii) Mandatory: Each Consortium Member must have a well-organized and well-functioning infrastructure for conducting SPECTA Projects, with recognized specific expertise and preferably a good track record of conducting trials with EORTC and conducting early clinical trials up to industry standards and regulatory requirements

(iv) Desirable: Each Consortium Member should actively participate in SPECTA Projects.

3.2 **Quality Assurance and Scientific Audit**. All Consortium Members shall undertake to make its reasonable efforts to ensure that appropriate quality control mechanisms and procedures are operational and that SPECTA Projects are conducted in full conformity with EORTC standard operating procedures. To ensure this commitment, EORTC can periodically require independent review and Institution visits by experts of all Institutions, as appropriate, it being understood that quality assurance and scientific audit are of major importance to the achievement of EORTC's goals. Any such audit will be performed at EORTC expense during regular business hours, arranged in advance, on reasonable notice and accompanied by an employee of the relevant Consortium Member.

EORTC
Avenue E. Mounierlaan 83 / 11
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Any issues and questions arising from the implementation of these policies shall be referred to the EORTC Board.

4. Commitments.

4.1 Each Party will
(a) be engaged actively in the mission of SPECTA;
(b) act in a spirit of cooperation and mutual trust with respect to the activities of the SPECTA;
(c) fulfil diligently and in good faith its obligations under this Consortium Agreement;
(d) obtain and furnish the HBM and the associated Data required for the Consortium, the SPECTA Protocol, SPECTA Projects.
(e) only enroll in SPECTA patients potentially eligible for SPECTA Projects.

4.2 By joining the Consortium Agreement, the Parties recognize and commit to respect the rights of patients and to comply in full with all laws, regulations, rules, ordinances, and policies applicable to its activities under this Consortium Agreement or as part of the SPECTA Consortium. This include the right of the patient to obtain clear information, including access to his/her medical records, the obligation to obtain consent from the patient prior to treatment, any other medical act or participation in scientific research, the obligation to keep the patient's data confidential and in line with the relevant applicable data privacy provisions, including but not limited to the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), the right of patients to good quality and high professional standards. Annex 3 – is describing the roles and the responsibilities of each Party insofar the data processing of personal data.

4.3 The legal representative of the Participating Center (a) authorizes the performance of SPECTA in its Institution; (b) will ensure that the personnel of the Institution who participate in the conduct of SPECTA are informed of and abide by all applicable terms of this Agreement.

4.4. Should an Institution no longer be interested in or be unable to enroll new patients in SPECTA, the Institution will ensure that follow-up data from routine visits of enrolled patients are reported until the official end of SPECTA.

4.5 The Institution shall procure that no activities related to the conduct of SPECTA will take place in another location (sub-site) other than the Institution without having obtained the approvals of the EORTC and/or, where required, Competent Authorities or Ethics Committees. All patients, including those treated in an authorized sub-site, will be registered/randomized only via the Institution.

5. Financial Contribution

5.1 EORTC will provide support to each Institution directly or through the Participating Group of which they are part (as stipulated in Annex 1, Financial Compensation).

5.2 Any potential additional Funds for SPECTA Projects to be conducted pursuant to this Consortium Agreement will be negotiated and allocated on a per project basis.

6. Non-financial Contribution

6.1 EORTC will offer assistance to Consortium Members with respect to (i) pertinent regulatory issues; (ii) procedures including for bio-banking purposes; (iii) novel statistical issues (in particular in

EORTC
Avenue E. Mounierlaan 83 / 11
Brussel 1200 Bruxelles
België - Belgique
Tel : +
Fax : -
E-mai
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the area of novel Phase I, II designs, biomarkers); (iv) translational research projects; and (v) practical organization aspects to limit impact on the day to day working activities of the Consortium Members.

7. Ownership and licenses on Background IP and Foreground IP.

7.1. Background IP Each Party remains the sole owner of its Background IP.

To the extent necessary for the performance of SPECTA or a SPECTA Project, each Party will grant the other Parties a royalty-free, non-exclusive, non-transferable license to use its Background IP, Data and HBM for carrying out SPECTA or a SPECTA Project, but for no other purpose.

7.2. Foreground IP Consortium Member(s) will promptly notify the EORTC and/or the other Consortium Members if applicable, in writing of any Foreground IP arising directly or indirectly in the performance of a SPECTA Project.

To the extent necessary for the performance of SPECTA or a SPECTA Project, each Party will grant the other Parties a royalty-free, non-exclusive, non-transferable license to use its Foreground IP for carrying out SPECTA or a SPECTA Project, but for no other purpose.

Ownership of the Foreground IP (solely or jointly) and/or any share in the revenues in case of Commercial Use of the Foreground IP shall be discussed in good faith in a separate agreement made between the relevant Parties, taking into account the terms and conditions as set forth in any agreements made with third parties when a SPECTA Project is supported by a third party (through the EORTC or directly to a Consortium Member) or conducted in collaboration with a third party.

8. Custody and control of HBM.

8.1 EORTC policy POL020 “Human Biological Material Collection, Storage and Use” is applicable and defines the position of the EORTC with regard to the Chain of custody of the HBM collected in EORTC clinical studies. EORTC policy POL021 “Protection of Personal Data” is applicable and defines the key principles for data protection with regard to the data being processed by EORTC in EORTC clinical studies. EORTC policy POL002 “Protection of Human Subjects Participating in Clinical and Translational Research” is applicable and defines rules to ensure the protection of the rights, safety and well-being of subjects of EORTC clinical studies

EORTC does not claim any ownership on HBM. The contributing Consortium Members shall remain the sole Custodian of the HBM collected as per SPECTA Protocol or any other SPECTA Project. EORTC shall act as the Coordinator of the Chain of Custody for all such HBM.

All logistics and management of HBM collected and/or used in the framework of the SPECTA Consortium shall be organized through the EORTC, and/or the Consortium Member(s) when applicable.

HBM will be stored in the SPECTA Repository in accordance with the requirements laid down by all laws, regulations and guidelines applicable in the European Union, in particular in accordance with the Declaration of Helsinki, the EU Clinical Trial Regulation 536/2014 and the principles of good clinical practice as laid down by the ICH topic E6, Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 and the General Data Protection Regulation (EU) 2016/679. Prior to the central storage of the HBM, the Institution will store the relevant HBM as per SPECTA Protocol without detriment and provide it for the future SPECTA Project upon request from the EORTC, within (five) 5 working days.

EORTC
Avenue E. Mounierlaan 83 / 11
Brussel 1200 Bruxelles
België - Belgique
Tel : +
Fax : +
E-mail
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EORTC shall ensure that the SPECTA Repository shall not sell, destroy or further use or distribute the HBM without the prior written consent of the EORTC. The EORTC shall remain fully liable for this subcontractor which shall take all necessary actions and commitments to protect the HBM from destruction, loss and/or theft, as set forth in this Consortium Agreement.

Access and use by Third Parties to HBM may be granted by EORTC subject to:

i) approval by the Steering Committee under the conditions stipulated in the Protocol,
ii) a separate agreement with a Third Party, which shall ensure that the rights of the patients with regard to the HBM are complied with. Furthermore, when a for-profit Third Party makes the request, access and use are subject to a reasonable financial compensation for access and for the handling cost of the HBM to the EORTC as a compensation for EORTC investment.

9. Control of the Database.

The EORTC shall centrally manage the SPECTA Databases, including the collection and analyses of the Data from SPECTA Projects and their inclusion in an EORTC database.

The EORTC is the owner of the Databases generated under this Consortium Agreement and associated SPECTA Projects, and will be responsible to decide and negotiate with third parties the terms and conditions for granting access to the Databases, provided that the patient informed consent authorizes such use by third parties of data belonging to him / her.

The Consortium Members are granted a royalty-free access to the SPECTA Database for non-commercial research use.

10. Responsibilities of the Parties and Liability.

10.1 Each Party hereby undertakes to use all reasonable efforts to perform and fulfill, diligently and in good faith, all of its obligations under this Consortium Agreement, to be actively engaged to fulfill the purpose and objectives of the Consortium Agreement and any other SPECTA Project to which it participates and to act in a spirit of cooperation and mutual trust.

10.2 Each Party undertakes to notify promptly the Steering Committee about any significant problem or delay likely to affect the success of a SPECTA Project.

10.3 All Background IP, HBM, Data supplied in the framework of SPECTA are made available by the Parties “as is”. Such Background IP, HBM and Data are experimental in nature and are made available without any representation or warranty, expressed or implied, including any implied warranty of merchantability, satisfactory quality or fitness for any particular purpose.

10.4 EORTC, as sponsor, takes the responsibility for the initiation and the management of SPECTA following the SPECTA Protocol in accordance with the legal and regulatory requirements; EORTC shall obtain an appropriate insurance valid for the whole duration of SPECTA covering the liability of the participating Consortium Members in accordance with the requirements laid down by national laws applicable in the countries where SPECTA is conducted.

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Avenue E. Mounierlaan 83 / 11
Brussel 1200 Bruxelles
België - Belgique
Tel : +
Fax : +
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10.5 The liability of any Party to the others for any breach of this Consortium Agreement, any negligence or any liability arising in any other way out of the subject matter of this Consortium Agreement, will not extend to any indirect damages or losses, or any loss of profits, loss of revenue, loss of data, loss of contracts or opportunity, whether direct or indirect, even if the Party bringing the claim has advised the other of the possibility of those losses, or if they were within the other Party's contemplation.

11. Force Majeure.

11.1 No Party shall be considered in breach of its obligations under the Consortium Agreement if it has been prevented from complying by Force Majeure. However, all necessary measures shall be taken to limit damage to the minimum.

11.2 A Party shall notify, as soon as possible, in writing EORTC of any Force Majeure that may affect the fulfillment of its obligations under the Consortium Agreement and/or any SPECTA Project. If after six (6) weeks as from the day of notification of Force Majeure, the part of the work to be performed by the Party preventing from complying by Force Majeure is still suspended, EORTC shall propose the necessary amendments to the Consortium Agreement and/or any SPECTA Project to redress the situation.

12. Subcontracting.

12.1 Subcontracts planned by a Party in relation to its obligation under this Consortium Agreement and/or any other applicable SPECTA Project shall be reviewed and, as appropriate approved, by EORTC.

12.2 In case a Party uses a subcontractor in the performance of its obligations under this Consortium Agreement and/or any other applicable SPECTA Project, such Party shall remain fully responsible for the performance of such obligations and, unless otherwise approved by the Steering Committee and/or EORTC and such Party shall bear all costs and obligations resulting from the subcontract.

For avoidance of doubt, such Party shall also be fully responsible for the supervision of its subcontractors and shall ensure that (i) obligations of confidentiality under Article 14 are extended to such subcontractor by appropriate contractual obligations; (ii) the other Parties' ownership and licenses on Background IP and Foreground IP are fully preserved; and (iii) the Third Party shall have no access to any other Party's Background IP or Foreground IP without the latter's prior consent. Access to HBM shall be subject to Article 8.

13. Term and Termination.

The term of this Agreement will commence on the Effective Date and will remain in effect for five (5) years unless terminated earlier pursuant to this Article 13 (the "Initial Term"). The Agreement will automatically be renewed for successive five (5) year-terms unless terminated earlier pursuant to this Article 13 (each, an "Additional Term" and together with the Initial Term, the "Term"). The Consortium Members will be informed of the renewal of the Agreement.

13.1 Termination of this Agreement for Cause. This Agreement will terminate immediately for the respective party if (i) a Defaulting Party (Defaulting Party) fails to meet the requirements of this

EORTC
Avenue E. Mounierlaan 83 / 11
Brussel 1200 Bruxelles
België - Belgique
Tel : +
Fax : +
E-mail
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Agreement and this breach is not cured within sixty (60) days of being notified of the breach; or (ii) a Party is disqualified or is debarred by the government from conducting research; a Default by a Party shall be considered a breach, if such Default is not due to Force Majeure and is irremediable, or if such Default is not due to Force Majeure and is not remedied within sixty (60) calendar days of a written notice of EORTC requiring that such Default be remedied if remediable.

In the event of a breach of obligations under this Consortium Agreement by a Defaulting Party, EORTC may terminate this Consortium Agreement in relation to such Defaulting Party by a written notice of not less than sixty (60) calendar days.

13.2 If a Party enters into bankruptcy, liquidation, or any other arrangement for the benefit of its creditors, the other Parties hereto shall undertake all reasonable efforts to find an agreement to take over the fulfillment of such Party's obligations under this Consortium Agreement and/or any other applicable SPECTA Project in respect thereof. In such event, all rights of such Defaulting Party under this Consortium Agreement and any other SPECTA project shall, to the fullest extent legally possible, be assigned and transferred to the benefit of the EORTC.

13.3 Termination without Cause. Upon ninety (90) days prior written notice, any Party may terminate this Agreement without cause. A non-defaulting Party leaving voluntarily and with the other Parties' consent shall have Access Rights to the Foreground IP developed until the date of the termination of its participation to the SPECTA Consortium.

13.4 Effect of Termination of the Agreement.

i) Termination of this Agreement for any reason will not release any Party from any liability which has already accrued to that Party or which is attributable to any event occurring during the Term of this Agreement prior to such termination, nor preclude a Party from pursuing any rights and remedies it may have hereunder or at law or in equity which accrued or are based upon any event occurring during the Term of this Agreement prior to such termination.

ii) For all SPECTA Projects affected by termination of this Agreement, the Parties agree to work together and to follow the directives of all applicable supervising Institutional Review Boards to protect the safety of the then-enrolled patients.

iii) Any and all rights and licenses in relation to HBM, Data, Background IP and Foreground IP granted to a Defaulting Party by the other Parties under this Consortium Agreement and/or any other SPECTA Project shall cease immediately;

iv) Any and all rights and licenses in relation to HBM, Data, Background IP and Foreground IP granted by a Defaulting Party to the other Parties shall remain in full force and effect for the term of the SPECTA Project;

v) Work and tasks remaining to be performed by a Defaulting Party, may be assigned, by decision of the Steering Committee (without the vote of such Defaulting Party), to one or more of the other Parties or to Third Parties, which agree to be bound by the terms of this Consortium Agreement and/or an applicable SPECTA Project, subject to the approval of the other Consortium Members, which are parties to the applicable SPECTA Project.

EORTC
Avenue E. Mounierlaan 83 / 11
Brussel 1200 Bruxelles
België - Belgique
Tel : +
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14. Confidentiality.

Each Party agrees to be bound by confidentiality with respect to all projects and all activities contemplated by the Consortium Agreement, the SPECTA Protocol and SPECTA Projects.

No Party will during the SPECTA Projects and for five (5) years after the end of the last SPECTA Project under this Consortium Agreement disclose to any third party, or use for any purpose except carrying out the SPECTA Project, any of the another Party's Confidential Information, provided that the receiving Party's obligation shall not apply to information that:

a) is known to the receiving Party before its receipt from the Party making disclosure, and not already subject to any obligation of Confidentiality to the disclosing Party;

b) is or becomes publicly known without any breach of this Consortium Agreement or any other undertaking to keep it Confidential;

c) has been obtained by the receiving Party making the disclosure from a Third Party in circumstances where the Party making the disclosure has no reason to believe that there has been a breach of an obligation of Confidentiality owed to the other disclosing Party;

d) has been independently developed by the receiving Party;

e) is disclosed pursuant to the requirement of any law or regulation or the order of any Court of competent jurisdiction; or

f) is approved for release in writing by an authorized representative of the disclosing Party.

15. Publications and presentations.

Each Party agrees to be bound by the general EORTC policy on publications and presentations with respect to all projects and all activities contemplated by the EORTC Policy POL009. Authorship of publications will be determined in accordance with scientific standards and scientific input.

All written and oral public disclosures concerning information gained in the course of SPECTA shall be submitted to the Steering Committee at least 30 days before the date of the proposed disclosure and shall include a statement that it has been developed within the SPECTA Consortium. The Steering Committee may, by giving written notice to the Party which wishes to publish, require that Party to delay the proposed Publication for a maximum of 60 days after receipt of the written notice if, in the Steering Committee's reasonable opinion, that delay is necessary in order to seek Intellectual Property protection for any Foreground IP that is to be disclosed.

16. Choice of Law, Dispute Resolution.

This Consortium Agreement shall be construed and enforced in accordance with the laws of Belgium, without regard to its conflict of law's provisions. Any dispute arising hereunder shall be resolved amicably by the Parties. If an agreement cannot be reach, the dispute will be heard before the competent courts of Brussels.

17. Language.

EORTC
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This Consortium Agreement and any SPECTA Projects shall be in English, which language shall govern all documents, notices, and meetings for its application and/or extension or in any other way relative to this Consortium Agreement or the other SPECTA Projects.

18. Severability.

Should any provision of this Consortium Agreement prove to be invalid or incapable of fulfillment, or subsequently become invalid or incapable of fulfillment, whether in whole or in part, the invalidity or incapability shall not affect the validity of the remaining provisions of this Consortium Agreement. In such a case, the Party concerned shall be entitled to demand that a valid and practicable provision be negotiated which most nearly fulfills the purpose of the invalid or impracticable provision.

19. No Partnership, Agency or Exclusivity.

19.1 This Consortium Agreement is not intended to and nothing in this Consortium Agreement shall be deemed to constitute, create, give effect to, or otherwise recognize such creation of a joint venture, agency, interest grouping or any other kind of formal business grouping or entity between the Parties.

19.2 Non-Exclusivity Provision. This Agreement does not create an exclusive relationship between the Parties, and any activities in furtherance of a SPECTA Project requiring exclusivity will be specifically defined and agreed upon by the Parties as an amendment to this Agreement or in a separate agreement.

20. Notices.

20.1. Notices in writing shall be deemed to be valid and effective, if the notice
- i) has been personally served,
- ii) sent by registered prepaid airmail, or
- iii) sent by recorded delivery mail

to the representatives of the Parties at their addresses listed in the most current address list to be kept by the EORTC Secretariat.

If not explicitly stated in this Consortium Agreement that a notice shall be in writing, any notices, requests, consents and other communications to be given by a Party under this Consortium Agreement may also be effected by e-mail. Notices by e-mail shall be deemed to be valid and effective, if sent to representatives of the Parties and if delivery was recorded and a transmission report has been received by the sender.

21. Assignment, Amendments.

21.1 No rights or obligations of a Party arising from this Consortium Agreement may be assigned, conveyed, or transferred in whole or in part to any Third Party without the prior written approval of the Steering Committee, such approval to be in the sole discretion of the Steering Committee.

21.2 Any and all amendments and modifications to this Consortium Agreement require consent in writing between all Parties, duly signed by respectively authorized representatives of the Parties.

21.3 In the event of an inconsistency between the terms and conditions of this Consortium Agreement and any other Agreement concluded in relation to a SPECTA Project, the terms and conditions of this Consortium Agreement shall prevail except where expressly stipulated and agreed otherwise hereunder.

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België - Belgique
Tel : +
Fax : +
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Web :

22. Counterparts.

The Parties may execute this Consortium Agreement in counterparts, each of which is deemed an original and all of which constitute one agreement.

23. Authority.

Each individual signing this Consortium Agreement on behalf of a Party represents and warrants to the other Parties that he or she has the authority to sign this Consortium Agreement on behalf of such Party and to bind such Party to the terms and conditions of this Consortium Agreement.

SIGNATURES ON THE NEXT PAGE

EORTC
Avenue E. Mounierlaan 83 / 11
Brussel 1200 Bruxelles
België - Belgique
Tel : +3
Fax : +3
E-mail :
Web : h

Authorized to sign on behalf of EORTC

Family Name, first Name, Title: Denis Lacombe, Director General

Signature: _____

Date: 21. 8. 2019

Stamp:

Authorized to sign on behalf of Masaryk Memorial Cancer Institute (EORTC Site n° 962)

Family Name, first Name, Title: prof. Marek Svoboda, M.D., Ph.D.

Signature: _____

Date: 28. 8. 2019

EORTC
Avenue E. Mounierlaan 83 / 11
Brussel 1200 Bruxelles
België - Belgique
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ANNEX 1

FINANCIAL COMPENSATION

All payments shall be made by the EORTC to the Institutions according to the budget and payment schedule set forth below.

This financial support might be subject to changes in the future.

Initial compensation at Institution Activation as defined in Article 1 of the agreement

START-UP FEE	3000€, FIXED AMOUNT, PAID ONCE PER INSTITUTION AT INSTITUTION ACTIVATION

Per patient/data entry compensation:

INSTITUTION COMPENSATION (ICOM)	250€, FIXED AMOUNT, PAID ONCE PER PATIENT ENROLLED IN STEP 2 AND FOR WHOM BASELINE CLINICAL AND PATHOLOGICAL DATA HAS BEEN PROVIDED

The costs related to the shipment of the patient material to the SPECTA REPOSITORY will be prepaid by the EORTC.

The Consortium Members are informed that the EORTC will not provide any additional financial support to their Institutions. The figures mentioned in this section are inclusive of any taxes and/or levies imposed the Institutions (e.g. overhead fees, archiving costs) and/or authorities, except VAT if applicable.

Based on Directive 2006/112/EC, since January 2010, the place of supply of services to a taxable person acting as such shall be the place where that person has established his business. As EORTC is established in Belgium, the Institutions shall not charge any VAT on the invoice if they are not located in Belgium.

The internal allocation of these payments within the Institutions is entirely within the Institutions discretion and shall have no effect on the total amount payable by EORTC.

All invoices shall be sent to EORTC, twice yearly, and based on actuals:

EORTC AISBL/IVZW
Accounting & Finances Reporting Office
VAT: BE 0408292992
Avenue Mounierlaan 83/11
B-1200 Brussels
Belgium
Reference: SPECTA –1553

The EORTC will send every six months a payment request to the Institution with a summary of all eligible compensations (excluding startup fee) during the reference period. Upon agreement with the payment request form, the Institution will draw up an invoice at the attention of the EORTC.

Invoices will be paid within thirty (30) days of receipt.

EORTC
Avenue E. Mounierlaan 83 / 11
Brussel 1200 Bruxelles
België - Belgique
Tel : -
Fax : -
E-mai
Web

ANNEX 2

For the sake of clarity, the Parties agree to include certain understandings with site 962 (Masaryk Memorial Cancer Institute) in this Annex 2, complementing the provisions set forth in this Consortium Agreement:

The Agreement, for site 962, starts and is effective as of the day of publishing the Agreement in Czech registry of contracts according to Contracts Register Act. Institution shall proceed and manage such registry request.

At Clause 2:

The contracting parties mutually agree that the purpose of this Consortium Agreement is NOT systematic testing of one or more investigational medicinal product(s) with the objective of ascertaining its (their) safety or efficacy conducted on trial subjects intended to (1) discover or verify the clinical, pharmacological or other pharmacodynamic effects, (2) identify any adverse reactions, (3) study absorption, distribution, metabolism or excretion

At Clause 8:

EORTC takes into account that the relevant HBM is stored in its BBMRI-CZ affiliated biorepository which is organizational part of the Institution. Institution will provide HBM following applicable quality policies of Accrediting bodies such as ISO, BBMRI-ERIC and EORTC and provide it upon request from the EORTC, in accordance with the SPECTA Protocol. The organizational part of the Institution releasing the HBM for the SPECTA Repository is the Institution BBMRI-CZ affiliated biobank.

EORTC will not contact or make any effort to identify individuals who are or may be the sources of HBM.

HBM is provided as it is. The Institution makes no representations and extends no warranties of any kind, either expressed or implied. There are no express or implied warranties of merchantability or fitness for a particular purpose, or that the use of HBM will not infringe any patent, copyright, trademark or other proprietary rights.

The Parties will indemnify each other against all losses (whether direct or indirect, reasonably foreseeable or specifically contemplated by the parties), damages, costs, expenses (including but not limited to reasonable legal costs and expenses) that it incurs as a result of: (i) the use, storage or disposal of HBM of the other party; or (ii) any negligence or willful default of the other party, provided that the other party agrees to use its reasonable endeavours to mitigate any loss.

When all SPECTA Projects are completed and the last archiving period has ended, HBM will be returned to the Institute to be used under their sole responsibility for patient's own needs or to be fully anonymized or to be destroyed. Shall Institute not wish to receive this material back, EORTC may either fully anonymize or destroy it, in compliance with all applicable statutes and regulations.

At Clause 16 Choice of Law, Dispute Resolution is complemented as follows:

Without prejudice of the foregoing, disputes arising out from the activities performed by site 962 under this Consortium Agreement shall be resolved in compliance with the Czech law, by the courts of Brno.

EORTC
Avenue E. Mounierlaan 83 / 11
Brussel 1200 Bruxelles
België - Belgique
Tel : +
Fax : +
E-mail
Web :

The Parties acknowledge that this Agreement, and its amendments if applicable, shall be published, by site 962, at the Registry of Agreements ("Registry") pursuant to Act No. 340/2015 Coll., on Registry of Agreements.

In the event of conflict between this Annex 2 and the Consortium Agreement, the text of this Annex 2 shall prevail for the interpretation in respect of the site 962 (Masaryk Memorial Cancer Institute).

EORTC
Avenue E. Mounierlaan 83 / 11
Brussel 1200 Bruxelles
België - Belgique
Tel : +
Fax : +
E-mail
Web :

Annex 3 – Data Processing Agreement (DPA)

The terms Data Controller and/or Controller, Data Processor and/or Processor, Data Subjects, Personal Data and any other terms as they are defined in article 4 of GDPR shall have the meaning set out in GDPR. Terms not otherwise defined in GDPR, when capitalized, shall have the meanings set forth below:

"**Sub-processor**": means any other Data Processor engaged by any Party in its role of Data Processor or by any of its Sub-processors in the scope of activities under this agreement;

"**Data Processing Agreement**" or "**DPA**": means this agreement binding the Data Processor to the Data Controller, setting out the subject, matter and duration of the processing, the nature and purposes of the processing, the type of Personal Data and categories of Data Subjects, taking into account the specific tasks and responsibilities of the processor in the context of the processing to be carried out and the risk to the rights and freedoms of the Data Subject

"**Sponsor**": means the organisation which takes the full responsibility for initiation, management and financing of Projects in accordance with the legal, regulatory requirements ;

"**Professional Contacts' Data**": means Personal Data of Parties' employees, fellows, interim workers, students, directors, officers, consultants, agents, affiliates and (if applicable) experts, legal or other professional advisers, members, vendors and subcontractors. The list is not exhaustive.

"**Research Subject's Data**": means Personal data of patients and other research participants, as relevant to the applicable Stud(y)(ies).

Now therefore, the Parties agree as follows:

1. Scope of the DPA

1.1. This DPA covers all data processing activities, including archiving.

1.2. For the sake of clarity and except when agreed otherwise, the DPA does not intend to limit in any way the liberty of both Parties to use Personal Data for other legitimate purposes in a lawful way and independently from each other. Shall any Party use Personal Data described in DPA for any other purpose than purposes covered by the Study Agreement or in a way that differs from agreed terms, including when resulting from the breach to this DPA, it shall be deemed independent controller in that scope.

1.3. Specifically, this DPA is without prejudice to Participating Center's obligations and rights as controller of the patient medical file, from which some data are copied into the Study databases in a pseudonymous form.

2. Processing activities and categories of data processed

2.1. In the scope of the Studies, both Parties agree on the list of processing activities and their respective roles, as controller and/or processor as specified below:

2.1.1. EORTC, as Data Controller:

(i) process pseudonymous Research Subject's Data for the purpose of performing research described in the Study, perform further scientific research and share data with other researchers, including outside EU, in compliance with applicable legislation

(ii) process Research Subject's Data for the purpose of on-site source data verification

(iii) process Participating Center's Professional Contacts' data, their relevant vendor's and sub-contractor's data, for the purpose of (a) management and control of Studies, (b) its evaluation, (c) audit and supervision, (d) to ensure its legal, regulatory and administrative compliance, (e) to ensure appropriate training and information of involved individuals and

EORTC
Avenue E. Mounierlaan 83 / 11
Brussel 1200 Bruxelles
België - Belgique
Tel : +
Fax : +
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(f) in the scope of sharing of pseudonymous Research Subject's Data with other researchers, including outside EU, in compliance with applicable legislation;

2.1.2. EORTC may delegate partially or entirely any of the processing activities described in the section 2.1.1 to subcontractors.

2.1.3. Participating Center, as Data Controller: process Data Controller Professional Contacts' Data, vendor's and sub-contractor's data, exclusively for the purpose of the execution of this DPA, performance of activities as allocated, legal, regulatory and administrative compliance as specifically required by the Study Sponsor and Data Controller

2.1.4. Participating Center, as Data Processor process coded Research Subject's Data for the purpose of performing research as planned in the Studies as specifically required by as the Data Controller

2.2. Both Parties agree on the categories of data that may be processed in the scope of this DPA as relevant to activities allocated to each Party and described in the table below.

Data categories	Type of Data Subjects	
	Professional contacts	Patients and other research participants
Direct Identification data (e.g. name, surname, date of birth)	Yes	Yes (limited*)
Indirect Identifiers (eg. code)	No	Yes
Contact data (e.g. address, phone, e-mail etc…)	Yes (professional)	No
Technical data (e.g. IP address, event logs)	Yes	No
Professional data (e.g. qualification & training, including in a form of curriculum vitae(s)	Yes	No
Economic and financial data (e.g. accounting details)	Yes	No, except for health economics research if part of the Studies
Legal data (e.g. any suspicion of fraud or bribery)	Yes	No
Data conveying information about personal life (e.g. quality of life questionnaires, potentially including questions about sex life, etc…)	No	Yes
Data conveying information about origins (e.g. ethnicity etc…)	No	Yes
Health data (e.g. disease, treatments, health images etc…)	No	Yes

EORTC
Avenue E. Mounierlaan 83 / 11
Brussel 1200 Bruxelles
België - Belgique
Tel : +
Fax : +
E-mail
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Genetic data (e.g. somatic or germ line mutations etc…)	No	Yes

*Collection of identification data related to patients and other research participants at EORTC is limited to the date of birth (only if allowed by the national law); otherwise the access to fully identifiable information is possible only in the scope of the on-site source data verification.

3. Obligations of both Parties

3.1 Both Parties shall process Personal Data in compliance with GDPR and all applicable laws, enactments, regulations, orders, standards and other similar instruments; specifically, both Parties shall:

3.1.1. process Personal Data lawfully, fairly and in transparent manner

3.1.2. collect Personal Data only for purposes referred to in the section 2.1 and to limit the data collection to what is needed for achieving these purposes

3.1.3. provide each other with accurate and up to date Personal Data

3.1.4. process personal data in a way that ensures appropriately security of Personal Data and maintains their integrity and confidentiality

3.2 EORTC, in its role of Sponsor of the Studies and in relation to the Research Subject's Data, shall not be reasonably likely able to identify or directly contact any patients and other research participants, or their living relatives. Participating Center will not transfer to EORTC any information that would enable direct identification of any patient or research participant, such as but not limited to patient or research participant's name, surname or initials, ID number or hospital chart number.

3.3 By way of exception to the section 3.2, Participating Center shall grant EORTC or its subcontractors access to relevant parts patient or research participant's medical file, for the sole purpose of the on-site source data verification in the scope of the Studies. This to enable the Study' Sponsor, to comply with Good Clinical Practice (GCP) principles and its legal obligations and to ensure compliance with the requirements of GDPR article 5 (1.d) ("data accuracy").

3.4 EORTC will ensure it appropriately selects and trains subcontractors and/or individuals performing on-site source data verification, including but not limitedby putting in place stronger confidentiality clauses.

3.5 Both Parties may exchange the Professional Contacts' Data as relevant for the performance of this DPA. Therefore, each Party hereby gives permission to the other Party and their designees to process received and to transfer received to other parties if relevant to the scope of this DPA and Studies.

3.6 Both Parties represent that, Professional Contacts whose Personal Data are provided to the other Party, has been appropriately informed about and consented (unless other legal basis applies), to the collection and use of their data by the other Party, its Participating Centers, subcontractors in the scope of this DPA.

4. Obligations of Participating Center

4.1 Participating Center, confirms that:

4.1.1 it has no reason to believe that the legislation applicable to it prevents it from fulfilling the instructions received from Data Controller and its obligations under this DPA and that in the event of a modification of this legislation which is likely to have a substantial adverse effect on the warranties and obligations of this DPA, it will promptly notify this modification to the Data Controller as soon as it is aware of it, in

EORTC
Avenue E. Mounierlaan 83 / 11
Brussel 1200 Bruxelles
België - Belgique
Tel : +
Fax : +
E-mail
Web :

which case the Data Controller is entitled to suspend the transfer of data and/or terminate this DPA and any other contract concluded in the scope of the Studies; and

4.1.2 it has implemented and keep up to date the technical and organizational security measures before processing the Personal Data (pursuant to the article 32 of GDPR) and, specifically the measure that any natural person acting under its authority, such as principalinvestigator or any other individual(s) involved in the Studies acting under Participating Center's authority process the data in compliance with this DPA.

4.2 Participating Center will:

4.2.1 process the Personal Data only to the extent, and in such a manner as is necessary for it to perform its obligations under this DPA in relation to execution of Studies, and not for any other purpose; it will process strictly in accordance with documented instructions and/or request made by the Data Controller, including with regard to amendment, transfer or deletion of Personal Data, or any decision to communicate with Data Subjects in such terms and by such method as the Data Controller shall reasonably require;

4.2.2 in the event of subcontracting any of processing activities, inform the Data Controller and obtain its prior written authorization for any Sub-processor selected specifically for the purpose of the performance of the Studies;

4.2.3 in the event of any other sub-processing relevant to this DPA, but not sub-contracted specifically for the purpose of the performance of the Studies, inform the Data Controller about any such Sub-processor(s) upon request;

4.2.4 send promptly, upon Data Controller's request, a copy of any Sub-processor agreement relevant to activities falling under the scope of this DPA to the Data Controller (whether specifically subcontracted for the purposes of this DPA or not);

4.2.5 enter into a written agreement with any Sub-processor, which imposes the same obligations on the Sub-processor as those imposed on Data Processors under this DPA, so that the processing by the Sub-processor is carried out in accordance with conditions set out in this DPA;

4.2.6 restrict access to the Personal Data to those of its employees who need access to the Personal Data to meet obligations under this DPA;

4.2.7 deal promptly and properly with all inquiries from the Data Controller relating to processing of the Personal Data in the scope of this DPA, to the transfer and to abide by the advice of any supervisory authority concerned with regard to the processing of the data transferred;

4.2.8 submit, at the request of the Data Controller, sufficient information about its data-processing facilities for audit of the processing activities covered by this DPA to be carried out by the Data Controller, supervisory authority concerned or an inspection body;

4.2.9 assist Data Controller in addressing Data Subject's requests, specifically in relation to the right of access and portability;

4.2.10 assist Data Controller in ensuring compliance with the obligation of the GDPR articles 32 and 36 within the limits of information available to the Participating Center

4.2.11 assit Data controller for the fulfillment of Data Controller's obligations to respond to requests for exercising Data Subject's rights

4.2.12 inform the Data Controller about any request received directly from the Data Subjects without responding to that request, unless it has been otherwise authorized to do so;

4.2.13 without prejudice to the section 4.2.12, make available to the Data Subject or regulatory bodies upon request (i) a copy of this DPA, or any existing contract for sub-processing, unless any such contract contain commercial information, in which case it may remove such commercial information, and (ii) a summary description of the security measures in those cases where the Data Subject is unable to obtain a copy from the Data Controller;

4.2.14 promptly notify the other Party (in its role of Controller) about any legally binding request for disclosure of the Personal Data by a law enforcement authority unless otherwise prohibited, such as a prohibition under criminal law to preserve the confidentiality of a law enforcement investigation.

EORTC
Avenue E. Mounierlaan 83 / 11
Brussel 1200 Bruxelles
België - Belgique
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Web :

4.2.15 make available to the Data Controller all information necessary to demonstrate compliance with the article 28 of GDPR and contribute to relevant audits and inspections

4.3 for the sake of clarity and specifically in relation to patients, any communication that would normally occur between Participating Center's Professional Contacts' Data and patients outside the Study shall not be subject to requirements set in the section 4.2.1

4.4 In the event of any complaint, notice or communication relating directly or indirectly to the processing of the Personal Data or to either party's compliance with the GDPR (including without limitation a request from a Data Subject for access to that person's Personal Data) Participating Center shall:

4.4.1 immediately inform Data Controller of any such complaint, notice or communication; and

4.4.2 provide Data Controller with full co-operation and assistance and comply with all Data Controller's instructions in the handling of any such complaint, notice or communication.

5 Reporting of Personal Data breaches

5.1 Data Controller shall be responsible for the evaluation of the risk of any data breach.

5.2 Participating Center shall promptly notify Data Controller about any suspicion of the Personal Data breach and within twenty-four (24) hours of becoming aware of it, by e-mail, to the DPO of Data Controller; in particular, but not limited to:

5.3 if any Personal Data is lost or destroyed or becomes damaged, corrupted, unusable, or inaccessible, in which case processor will arrange and bear the cost of restoring such Personal Data on Data Controller's request and in accordance with it instructions; and/or

5.4 if processor becomes aware of any unauthorized or unlawful processing of the Personal Data, in which case Processor will provide Data Controller with full co-operation and assistance and comply with all Data Controller's instructions in the handling thereof.

5.5 Without prejudice to the section 3.3 shall EORTC become a recipient of Research Subject's Personal Data which are not properly coded or which shall not be otherwise provided to EORTC, such a situation will be considered by EORTC as Participating Center's own data breach.

5.6 When section 5.3 applies, EORTC will notify any suspicion of the Personal Data breach and within twenty-four (24) hours of becoming aware of it to the Participating Center's DPO); Participating Center shall evaluate the reported event and, if deemed relevant by the Participating Center, send relevant notification(s) in compliance with GDPR.

6 Data retention period

6.1 Both Parties shall not store Personal Data any longer than permitted by this DPA. In order to comply with the legislation applicable in the field of clinical research, both Parties shall keep Personal Data being part of the trial master file for the period set by applicable legislation (e.g. 15 years after the end of the Study pursuant to applicable law in Czech Republic, eventually in the future at least twenty-five (25) years after the end of the Study pursuant to Regulation (EU) 536/2014 on clinical trials on medicinal products for human use and repealing Directive 2001/20/EC).

6.2 Further research projects performed in compliance with the section 2.1, data will be archived for ten (10) years after the end of related research projects, unless a longer archiving period is imposed by the applicable legislation;

6.3 For the sake of clarity , the same Personal Data may be subject to multiple agreements and used in the framework of different scopes or projects; without prejudice to the section 6.1, EORTC, as Data Controller, will not delete or fully anonymise any Personal Data and specifically Research Subject's

EORTC
Avenue E. Mounierlaan 83 / 11
Brussel 1200 Bruxelles
België - Belgique
Tel : +
Fax : +
E-mail
Web :

Data without careful verification of all agreements in place in the view of its legal obligations and limitation at the time of expected end of Personal Data storage;

6.4 Insofar Research Subject's Data are concerned, Participating Center shall notify EORTC 60 days prior to the end of the retention period referred to in the section 6.2 and it shall not delete any data without EORTC's specific authorisation for doing so.

7 Liability and indemnification

The Parties agree that any liability in relation to the protection of Personal Data under the Study Agreement and this DPA shall be governed by the rules set-up in GDPR and specifically its article 82 ("Right to compensation and liability"). The Parties may not rely on a breach of its obligations by a Sub-processor to avoid their own liabilities.

8 Survival

This DPA shall survive the termination of the Study Agreement insofar as any Party is still processing Personal Data in accordance with this DPA.

9 Notices and administrative/legal contact persons

9.1 To exercise rights of individuals under data protection laws , for the reporting of data breaches or for any other communication in relation to the data protection, Parties can contact:

- EORTC's data protection officer at dpo@eortc.org

- Participating Center's data protection officer at dpo@mou.cz