# CLINICAL STUDY AGREEMENT

## EORTC STUDY 2427-BTG

## INVOLVING

**MASARYKŮV ONKOLOGICKÝ ÚSTAV (MASARYK MEMORIAL CANCER INSTITUTE) (EORTC N°962)**
**ZLUTY KOPEC, 7**
**CZ 656 53 BRNO**
**IDENTIFICATION NUMBER: 00209808**
**CZECH REPUBLIC**

## AND

**EUROPEAN ORGANISATION FOR RESEARCH AND TREATMENT OF CANCER**
**AVENUE E. MOUNIERLAAN 83/11**
**B-1200 BRUSSELS**
**BELGIUM**

# CLINICAL STUDY AGREEMENT

**THIS CLINICAL STUDY AGREEMENT IS ENTERED INTO BY AND BETWEEN**

**The European Organisation for Research and Treatment of Cancer** (AISBL-IVSW), an international non-profit organisation under Belgian law and with its registered office at 83/11 Avenue E. Mounier, 1200 Brussels, Belgium, represented by its Chief Executive Officer, XXX ("**EORTC**")

and

**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. ("**Participating Center**")

Hereinafter, jointly or individually, referred to as "**Parties**" or "**Party**"

In the presence of **XXX** employee of Participating Center ("**Principal Investigator**"),

**WHEREAS**

A) EORTC is an academic, not-for-profit organisation and has the expertise to develop, conduct and promote clinical and translational research in the field of cancer. The subject of this Agreement is the clinical study entitled "Vorasidenib as maintenance treatment after first-line chemoradiotherapy in IDH-mutant grade 2 or 3 astrocytoma: a placebo-controlled, triple-blind, randomized phase III study (VIGOR)" with protocol number EORTC-2427-BTG (hereinafter, the "**Study**").

B) EORTC is acting as the Legal Sponsor of the Study in Europe in the framework of this Agreement.

C) The Study is an intergroup study in which EORTC is the Leading Group.

D) EORTC receives support from Servier Affaires Médicales (the "**Company**") for the conduct of the Study and Vorasidenib (and placebo) free of charge.

E) EORTC wishes to engage Participating Center and the Participating Center is willing to participate in the Study as a clinical site under the direction of the Principal Investigator.

F) This Agreement determines the terms and conditions for the Participating Center to engage in the Study, under the direction of its Principal Investigator.

## 1. DEFINITIONS

The following terms shall have the meanings set forth below:

**"Agreement":** the present clinical study agreement, its annexes and all amendments hereafter signed by the Parties.

**"Background Intellectual Property":** Intellectual Property existing prior to this Agreement or developed independently of this Agreement by any Party.

**"Case Report Forms" or "CRFs":** the paper or electronic document designed to record all of the Protocol-required information on each Study Subject.

**"Confidential Information"**: means information that one Party receives from the other Party, either directly or from any other person, disclosed by whatever means, in any medium or format, which by its nature is clearly confidential (whether or not marked as "confidential"), including the Agreement and any and all other information related to the Study, any reports, analyses, compilations, studies or other documents prepared by or on behalf of a Party, whether before or after the date of this Agreement, that contain or otherwise reflect such information.

**"Database":** the electronic medium designed for the needs of the Study and containing all Protocol-required information to be collected from the Study Subjects, including but not limited to clinical data.

**"Foreground Intellectual Property":** any and all Intellectual Property generated during or arising out of the performance of the Study.

**"Human Biological Material" or "HBM":** any tissue, body fluid, or any of their derivatives, in the form of, but not limited to, protein or nucleic acids, collected and/or used within the framework of the Study, from the Study Subject.

**"Informed Consent Form" or "IC":** A decision, which must be written, dated and signed in order to take part in the Study, taken freely after being duly informed of its nature, significance, implications and risks and appropriately documented, by any person capable of giving consent or, when the person is not capable of giving consent, by his or her legal representative; if the person concerned is unable to write, oral consent in the presence of at least one witness may be given in exceptional cases, as provided for in national legislation.

**"Intellectual Property":** means all patents, rights to inventions, discoveries, innovations, copyright and related rights, moral rights, utility models, trade-marks and service marks, business names and domain names, rights in get-up, goodwill, rights in designs, database rights, rights to use, and protect the confidentiality of, Confidential Information (including know-how and trade secrets) and all other intellectual property rights, in each case whether registered or unregistered and including all applications and rights to apply for and be granted, renewals or extensions of, and rights to claim priority from, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world, together with all rights of action in relation to the infringement of any of the foregoing.

**"Leading Group":** the group responsible for the scientific content of the Study and coordinating all involved parties (participating groups, third country sponsors, company etc.) for the conduct of the Study.

**"Legal Sponsor":** the entity which takes the responsibility for the initiation, conduct and financing of the Study, following the Protocol, and in accordance with ICH-GCP, section §5 and all legal and regulatory requirements.

**"Patient Information Sheet" or "PIS":** the written information on the Study given to the patient before deciding to take part in a Study.

**"Protocol":** the document describing all aspects and procedures of the Study, including its amendments.

**"Research Staff"**: employees, staff, agents and consultants of Participating Center involved in the conduct of the Study, and defined on the delegation of responsibilities log.

**"Results":** all results obtained within the framework of the Study including but not limited to results reproduced in (i) the final Study report(s) (including secondary endpoints as defined in the Protocol); or (ii) any reports generated for the purpose of any publication or public presentation.

**"Study Drug(s)":** all drugs, used in the framework of the Study including IMP(s) (investigational medicinal product(s)) and AMP(s) (auxiliary medicinal product(s)), as further detailed in the Protocol.

**"Study Subject":** patients selected in accordance with, and who meet, the eligibility criteria specified in the Protocol and which are recruited in the Study.

**NOW THEREFORE, THE PARTIES AGREE AS FOLLOWS:**

## 2. CONFORMANCE WITH LAW AND ACCEPTED PRACTICE

2.1. The Study will be performed by both Parties, as applicable to either Party, in accordance with:

- the Declaration of the Helsinki World Medical Association Recommendations Guiding Physicians in Biomedical Research Involving Human Subjects including amendments thereto;
- the "ICH Harmonised Tripartite Guideline, Guideline for Good Clinical Practice" and the "Notes for Guidance on Good Clinical Practice" CPMP/ICH/135/95 ("ICH-GCP");
- 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 (General Data Protection Regulation or "GDPR"). To that extent Parties shall process Personal Data in accordance with terms defined in Annex 3 "Data Processing Agreement";
- the Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use "CTR", repealing Directive 2001/20/EC. To that extent, Participating Center shall obtain or has obtained the OMS ORG and LOC number, required under CTR and will maintain the OMS portal up to date (e.g. address changes). Participating Center will inform EORTC of any changes made in the OMS portal;
- all applicable national laws and regulations;
- the Protocol and its amendments (attached by reference as Annex 1 to this Agreement);
- any specific Study instructions issued by the EORTC; and
- any other pertinent recommendations and guidelines, if applicable.

## 3. FINANCIAL PROVISIONS

3.1. EORTC shall provide financial compensation to the Participating Center according to the budget and payment schedule set forth below in Annex 2. The Participating Center is responsible to distribute the funds further internally (e.g. to individual departments, or the Principal Investigator) as applicable.

3.2. All invoices shall be sent to EORTC, only by email to accounting@eortc.org, stating the Participating Center legal address and the VAT number. The invoice should also state the following information:

EORTC
Accounting Department
Avenue Mounier 83/11
B-1200 Brussels
Belgium
VAT: BE0408292992
Reference: EORTC Study 2427

3.3. Undisputed invoices will be paid within thirty (30) days of the date of the invoice.

3.4. In case of early termination of the Agreement in accordance with clause 13, payments shall be made to Participating Center for Study Subjects enrolled up until the date of termination and in accordance with the amounts and conditions defined in Annex 2.

## 4. OBLIGATIONS OF PARTIES

4.1. The Participating Center authorizes the performance of the Study in its center and ensures that the facilities where the Study is being conducted are suitable for the Study and its computerized systems are validated, throughout the full conduct of the Study.

4.2. The Principal Investigator is responsible for the conduct of the Study at the Participating Center, including supervision of the Research Staff.

4.3. The Principal Investigator and Research Staff will fully comply with the Protocol, the obligations under this Agreement and any instructions provided by EORTC.

4.4. The Principal Investigator shall ensure that all Research Staff is adequately qualified, trained (including but not limited to ICH-GCP training) and informed of and abides by all applicable terms and conditions of this Agreement and the Protocol.

4.5. The Participating Center shall inform EORTC as soon as becoming aware of a change of Principal Investigator and shall ensure the continuation of the enrolled Study Subjects as per Protocol requirements. The Participating Center shall follow the instructions from EORTC with respect to the continuation of Study Subjects enrolment under the new Principal Investigator.

4.6. The Principal Investigator shall promptly notify EORTC of any withdrawal of a Study Subject, which may affect the use of the Study Subject's data and HBM under this Agreement.

4.7. The Participating Center and Principal Investigator shall comply with requirements for conflict of interest disclosure as per applicable legislation.

4.8. The Protocol and EORTC "Policy on Investigational Site Participation" (in its latest version, available at https://www.eortc.org/policies-guidelines/) defines the process by which EORTC will grant authorization to Participating Center to join the Study and to monitor site performance until the first Study Subject is included.

4.9. EORTC shall obtain all legal, regulatory or other approvals in Participating Center´s country in accordance with the requirements laid down by applicable laws and regulations. EORTC may request support from Participating Center in order to properly comply with its obligations.

4.10. EORTC is responsible for the development and maintenance of the Protocol including its amendments, as endorsed through the relevant EORTC approval process.

4.11. EORTC shall be responsible for the central management of all data collected in the scope of the Study ("**Study Data**") including the collection and analysis of the Study Data and its inclusion in the Study Database. The EORTC shall ensure the collected data is kept as required by ICH-GCP.

4.12. The Principal Investigator agrees to provide the Study Subject data by completing the CRF's (including responses to queries, and any reports and/or summary for Serious Adverse Events reporting data) as required by the Study Protocol and instructions provided by EORTC. Such data shall be transferred to EORTC in English, in a coded form and in a timely manner.

4.13. EORTC will apply its procedures relating to receipt of persistently overdue data. EORTC will inform the Principal Investigator through email about their form compliance and overdue queries (including related to Serious Adverse Events if applicable). The Principal Investigator shall take measures to improve the situation. If no improvement occurs, the EORTC can renegotiate the terms and conditions of this Agreement and has the right to exclude or put on hold the Participating Center for further participation in the Study.

4.14. Should any activity related to the conduct of the Study (e.g. radiotherapy, surgery, chemotherapy, tissue storage, sample analysis etc.) take place in a location other than the Participating Center

(hereinafter referred to as 'service facility'), the Participating Center shall inform EORTC, and request EORTC's approval. Participating Center shall ensure that it has adequate arrangements in place with the service facilities to cover such activities and shall ensure that such service facility shall comply with the terms of this Agreement, the Protocol and/or any instructions from EORTC. Participating Center shall be responsible for distribution of funds to service facilities if applicable. Any such arrangements shall not conflict with the terms and conditions of this Agreement. All Study Subjects, including those being treated in an authorized service facility, will be registered/randomized only via the Participating Center. For the sake of clarity, the final responsibility for the conduct of the Study and for all treatment-related issues at the Service Facility (-ies) will remain with the Participating Center and/or Principal Investigator.

4.15. When using a medical device ("MD") or an in vitro diagnostic medical device ("IVD"), for any local procedures that are performed in the scope of the Study (i.e. determine patient eligibility, allocation or administration of treatment and/or safety assessment), Participating Center shall ensure compliance with the applicable requirements as defined in the EU Regulations 2017/745 and 2017/746 of 5 April 2017 on medical devices ("MDR") and in vitro diagnostic medical devices ("IVDR"). These include, but are not limited to, compliance with CE marking requirements for the MDs and IVDs used, any vigilance reporting. For the sake of clarity, in-house devices developed and used solely by the laboratory, shall be exempt from IVDR, but have to meet the requirements of art. 5.5 and Annex I of IVDR.

4.16. EORTC is responsible to manage all suspicions of serious breach as applicable to the Study. The Principal Investigator shall, upon awareness, inform EORTC (at quality@eortc.org) of any potential serious breach as applicable to Participating Center related to the Study (including activities at service facilities). EORTC will lead the investigation of such issues in accordance with its SOP(s). Principal Investigator shall provide the necessary further support to EORTC or regulatory bodies in any such investigation process and ensure corrective and preventive measures are put in place. Unless objective evidence is obtained that it was not a serious breach, the EORTC is required to report to the appropriate regulatory bodies according to applicable regulations or national legislation and within the timelines requested by that authority. For the sake of clarity, a serious breach is any deviation from the approved Protocol or applicable regulations likely to affect to a significant degree the safety and rights of a Study Subject or the reliability and robustness of the data generated in the Study.

4.17. Participating Center shall not subcontract any third party in the framework of the Study without prior approval of EORTC. Notwithstanding EORTC's approval for such delegation, Participating Center shall remain liable to EORTC for the tasks delegated to subcontractor(s). Any agreement with subcontractors shall reflect and be in line with the terms and conditions of this Agreement.

4.18. If circumstances or events have occurred or will occur that will substantially delay or are likely to substantially delay the progress of recruitment of the Study Subjects at Participating Center, the Principal Investigator shall without undue delay inform EORTC in writing. In each such event Parties shall discuss the consequences of the delay and each Party shall undertake reasonable endeavours to agree on measures to handle the delay.

4.19. Parties are responsible for maintaining a file that contains all Study-essential documents. This file must be kept by all Parties in a secure location for the duration of the Study and further kept after the end of the Study (as defined in the Protocol), for a minimum of 25 years in accordance with the Regulation (EU) No 536/2014, or as otherwise required by the national laws, whichever period is longer.

## 5. DRUG SUPPLY

5.1. Vorasidenib (and placebo) will be packaged and labelled complying with applicable local laws and regulations, and made available to Participating Center, free of charge as defined in the Protocol. The Participating Center shall store and handle this supplied Study Drug in accordance with the Protocol, the terms and conditions of this Agreement and as per additional study drug management guidelines provided by EORTC. Participating Center shall not use the supplied Study Drug outside of the scope of the Study and the Protocol.

5.2. At the end of the Study, after Study Drug reconciliation, approval of EORTC and as per study drug management guidelines, all unused, damaged, and expired Study Drug supplied by EORTC as part of the Study, will be returned, as instructed and at EORTC's expenses, (i) to the Company or; (ii) to the distributing pharmacy for destruction in compliance with the relevant Good Clinical Practices.

5.3. For the sake of clarity, any other drugs not covered by the above, shall be taken from the shelf by the Participating Center, at own cost, and the Participating Center is responsible for adequate accountability, labeling (if applicable), reconciliation, record maintenance and destruction in accordance with all applicable regulatory requirements.

## 6. HUMAN BIOLOGICAL MATERIAL

6.1. Participating Center shall collect, store, process, and ship HBM as per the Protocol, PIS-IC signed by the Study Subject, and any additional guidelines provided by EORTC.

6.2. EORTC will provide all necessary laboratory and packaging material (laboratory kits, packaging material, dry ice if applicable) and ensure the transportation to central laboratory.

6.3. EORTC will ensure that the HBM shall be stored, processed and shared as defined in the Protocol, PIS-IC and in accordance with all applicable laws, regulations and good practices, including but not limited to the Good Clinical Laboratory Practice (GCLP) guidelines.

6.4. EORTC policy "Human Biological Material collection and use" (in its latest version, available at: https://www.eortc.org/policies-guidelines/) is applicable and defines the position of the EORTC with regards to the collection, storage and use of HBM collected in EORTC studies, including further access to HBM for future research.

## 7. OWNERSHIP OF STUDY DATA AND RESULTS

7.1. EORTC is the owner of all Study Data and Results. Participating Center shall as far as legally possible assign all interest and rights in Study Data and Results to EORTC, who accepts this assignment. For the sake of clarity, the medical files remain under the control of the Participating Center.

7.2. EORTC shall be entitled to use the Study Data and Results for any purposes, including but not limited to sub-licensing and transferring to third parties, as permitted by applicable legislation, and in compliance with any stipulations in the Protocol and the PIS-IC.

## 8. INTELLECTUAL PROPERTY RIGHTS

8.1. Each Party remains the sole owner of its Background Intellectual Property. To the extent necessary for the performance of the Study and to the extent that a Party is legally able to do so, each Party participating in the Study will grant the other Parties and any third parties participating in the Study a royalty-free, non-exclusive, non-transferable license to use its Background Intellectual Property for the purpose of carrying out the Study, but for no other purposes.

8.2. With the exception of medical records, the sole and exclusive right to any inventions, discoveries or innovations, whether patentable or not, and all Foreground Intellectual Property ("**IPRs**") shall vest in EORTC. EORTC shall be entitled to transfer, assign or grant any license under these IPRs and execute all actions and deeds related thereto. Participating Center hereby transfers, and EORTC hereby accepts the transfer of, any and all IPRs to EORTC. The Principal Investigator and the Participating Center shall execute such documents as are necessary to give effect to this provision.

8.3. Participating Center and/or Principal Investigator shall promptly disclose to EORTC in writing any inventions and IPRs of which they become aware and shall assign their rights in all IPRs.

## 9. CONFIDENTIALITY

9.1. The Party receiving Confidential Information (the "Receiving Party") shall keep strictly confidential any and all Confidential Information and shall not disclose Confidential Information publicly or to any third party without the prior written consent of the Party disclosing Confidential Information (the "Disclosing Party"), except as explicitly permitted by this Agreement and solely for the purposes directly related to this Agreement (the "Permitted Purpose").

9.2. The Receiving Party shall restrict access to Confidential Information to only those of its affiliates employees, directors, members, employees or consultants (the "Representatives") required by their duties to have knowledge thereof or otherwise having a need to have knowledge of such information for the Permitted Purpose, which persons shall be entitled to use Confidential Information, but only to the same extent as the Receiving Party is permitted to do so under this Agreement. The Receiving Party shall ensure that (i) its Representatives are bound in writing by confidentiality terms at least as strict as those of this clause 9; and (ii) its Representatives will act in accordance with the provisions of this Agreement as if each of them was a party hereto. Any non-compliance with any of the provisions of this clause 9 by its Representatives shall be deemed a breach of this Agreement by the Receiving Party.

9.3. The provisions of clause 9.1 shall not apply to:

i. any of the Confidential Information which at the time of receipt by the Receiving Party is in the public domain, other than as a result of breach of confidentiality;

ii. any of the Confidential Information that was known to, or in the possession of, the Receiving Party (without restriction on disclosure) before it was disclosed by the Disclosing Party, as established by written records;

iii. any of the Confidential Information which was developed independently or acquired directly or indirectly, as established by written records, from a source wholly independent of the Disclosing Party, before disclosure by the Disclosing Party;

iv. any of the Confidential Information that the Parties mutually agree can be disclosed;

v. any of the Confidential Information whose disclosure is required by applicable laws, regulations (including information legally required to be disclosed to regulatory bodies and/or national/international portals as applicable for submission or other purposes), or by final judicial decision, provided that the Receiving Party shall (i) inform promptly the Disclosing Party so as to allow it to take all possible steps to protect the Confidential Information, including protective order(s); (ii) take all reasonable steps, to the extent possible, to ensure the confidentiality of such Confidential Information; and (iii) disclose only that part of the Confidential Information required by the applicable laws, regulations, regulatory bodies, or final judicial decision.

9.4. The terms and conditions of these obligations of confidentiality and restricted use contained herein are applicable during the term of the Agreement and shall survive ten (10) years from its date of termination, whether by expiration or by earlier termination.

9.5. Notwithstanding the above the Parties acknowledge that this Agreement, and its amendments if applicable, shall be published at the Registry of Agreements ("Registry") pursuant to Act No. 340/2015 Coll., on Registry of Agreements. The Parties further undertake not to publish at the Registry any information which can be considered as a trade secret of Parties within the meaning of Sec. 504 of Act No. 89/2012 Coll., Civil Code, as amended. EORTC considers mainly the following to be their trade secret: the study Protocol, the Investigator Brochure.

## 10. ON-SITE MONITORING, AUDITS AND INSPECTIONS

10.1. <u>On-site monitoring</u>

The Participating Center shall permit monitoring visits by EORTC (or its delegate). The Principal Investigator and Participating Center shall allow access to monitor the facilities and all Study-related documents (including its computerized systems). Monitoring visits will be conducted during standard working hours and days (Monday - Friday 7:00-15:30), and according to the monitoring

plan. Monitoring visits will be carried out by qualified and trained Study monitors. The Participating Center will ensure that the monitor has access to the relevant medical records of the Study Subjects (either paper, electronic or printouts of electronic documents).

10.2. Audits

The Participating Center hereby allows EORTC (or its delegate) to audit the facilities (including approved service facilities if applicable) and all related documents being used for the Study (including its computerized systems), as defined in the Protocol. The Participating Center and the Principal Investigator will be notified at least four (4) weeks in advance, except in case of triggered audits that can take place as soon as possible after the detection of a suspected non-conformity. The Participating Center shall take appropriate actions to address any irregularities or findings, as mutually agreed with EORTC.

10.3. Inspections

The Participating Center and the Principal Investigator hereby allow any regulatory bodies to inspect the facilities (including approved service facilities if applicable) and all related documents being used for the Study (including its computerized systems).

The Participating Center shall inform EORTC as soon as becoming aware of any such inspection (to 2427@eortc.org). The Participating Center will not provide, and shall require that no Research Staff (including the Principal Investigator) provides, any regulatory body with any response related to findings or other questions that relate to the Study, without EORTC's review which will be provided in a timely manner. The Participating Center shall provide EORTC with a copy of the inspection report and details of any steps taken to comply with the recommendations and measures imposed by the regulatory body. Participating Center shall also provide copies of the final version of any communication with regulatory bodies related to the Study to EORTC.

## 11. DISCLOSURE OF STUDY DOCUMENTS, RESULTS AND PUBLICATION

11.1. EORTC shall ensure that the required reporting of the Study-related documents and Results to regulatory bodies and/or portals are done as applicable (i.e. EUDRACT, EU CTIS portal, ct.gov, etc.). For the sake of clarity EORTC is not responsible for any reporting to regulatory bodies for obtaining marketing authorization.

11.2. The results of all EORTC studies are published, irrespective of the findings (both positive and negative, statistically significant or not).

11.3. Participating Center and/or Principal Investigator will not independently publish its own site-specific results (i.e. any abstract, publication, whether oral or written) before the publication of the multi-center investigational paper, nor before 12 months have passed following the lock of the Database in case EORTC has not published. Any publication arising from such use of the site-specific results by Participating Center and/or Principal Investigator shall be provided to EORTC for review at least 30 calendar days ahead of the submission for publication (or 15 calendar days in case of abstracts).

11.4. Participating Center acknowledges and agrees that the publication and/or communication of Results could be delayed for a period which should not be longer than six (6) months from the request of the delay, in order to enable EORTC to take steps to protect Confidential Information and/or intellectual property rights and/or know how of EORTC (or a relevant third party), it being understood that the EORTC shall make reasonable efforts to limit such period to three (3) months.

11.5. Participating Center and/or Principal Investigator shall have a non-exclusive, irrevocable, paid-up right to use the data from its own Study Subjects for teaching and for internal research purposes, in accordance with the applicable laws and regulations and subject to this Agreement's provisions regarding confidentiality and publication rights.

## 12. INSURANCE, LIABILITY AND INDEMNIFICATION

12.1. EORTC shall obtain appropriate clinical trial insurance for the country of the Participating Center, valid for the whole duration of the Study at the Participating Center and its approved service facilities (if applicable), covering damages to the Study Subjects resulting from the Study in accordance with the requirements laid down by national laws applicable in such country.

12.2. If applicable, the Participating Center declares that it has adequate professional liability insurance as laid down by the national law and shall provide evidence of such insurance coverage upon request of the EORTC.

12.3. EORTC shall indemnify and hold harmless the Participating Center and its agents and employees, including Principal Investigator and Research Staff ("Participating Center Indemnitees"), against any claims, damages, costs and expense, suits, or proceedings (including reasonable legal costs) (a "Claim") arising out of the participation of the Participating Center Indemnitees in the Study, except to the extent that the Claim results from (i) the failure of a Participating Center Indemnitee to comply with the Agreement, the Protocol or any written instructions from EORTC or with any applicable law, regulation or directive; or (ii) any negligent act or material breach or omission or willful misconduct by a Participating Center Indemnitee.

12.4. Participating Center shall indemnify and hold harmless EORTC, its agents and employees against any Claims, arising out of, or in connection with, (i) the injury or death to a Study Subject caused by a Participating Center Indemnitee(s); (ii) any negligent act, omission or willful misconduct on the part of the Participating Center Indemnitees; or (iii) any breach by Participating Center Indemnitee(s) of this Agreement, the Protocol, or any instructions from EORTC. The indemnification shall not apply to the extent that any such Claim is the result of (i) negligence or willful misconduct on the part of EORTC, its agents or employees; or (ii) a material breach of its obligations by EORTC, its agents or employees.

12.5. The Party seeking indemnification ("Indemnified Party") shall (a) promptly notify the Party due to indemnify ("Indemnifying Party") in writing of any Claim for which indemnification is requested, (b) permit the Indemnifying Party to collaborate with Indemnified Party on control any negotiations or defense, (c) assist the Indemnifying Party at such Party's request and reasonable expense, (d) take all reasonable steps to mitigate any potential damages that may result from the applicable Claim, and (e) not compromise or otherwise settle the applicable Claim without the Indemnifying Party's prior written consent. In any event, the Indemnifying Party shall not accept liability, settle, admit or accept fault, dispose of, cease to defend, or otherwise compromise any Claim made against the Indemnified Party without such Indemnified Party's prior written consent.

12.6. No Party shall be responsible to any other Party for loss of profit.

12.7. Nothing in this clause 12 shall operate so as to restrict or exclude the liability of a Party in relation to death or personal injury caused by the negligence of that Party or its servants, agents or employees or appointed third parties or to restrict or exclude any other liability of either Party which cannot be so restricted or excluded in law.

## 13. TERM AND TERMINATION OF THE AGREEMENT AND STUDY

13.1. This Agreement commences on the date of the last signature by the Parties to this Agreement ("Effective Date") and shall continue in force until the earlier of:

i. completion of all Parties' obligations under this Agreement; or

ii. early termination in accordance with the clauses below;

13.2. Each Party may terminate this Agreement:

i. with immediate effect, if the other Party commits a breach of this Agreement, which, in the case of a breach capable of remedy, shall not have been remedied within sixty (60) days of the receipt to the Party in default of a written notice identifying the breach and requiring its remedy;

ii. upon thirty (30) days´ prior written notice if the other Party is declared insolvent or a petition in bankruptcy has been filed against it or if it is dissolved; or

13.3. EORTC shall have the right to terminate the Study in general or at the Participating Center specifically, with immediate effect, in the following cases:

i. if the Study does not receive official approval from the regulatory bodies, or this approval is permanently revoked;

ii. if it can be reasonably assumed that the Study must be terminated in the interests of the health of the Study Subjects or the Study may no longer reach its scientific purpose;

iii. in the event that the Agreement entered into between EORTC and Company is terminated;

iv. if no mutually agreeable qualified successor is found in case of the leave of Principal Investigator, as per terms of clause 4.5;

v. in case of unresponsiveness of the Participating Center or absence of patient recruitment, following the conditions as set out in the Protocol and EORTC "Policy on Investigational Site Participation"; or

vi. for duly justifiable reasons or reasons beyond EORTC's reasonable control.

For the sake of clarity, should EORTC terminate the Study as per this clause 13.3, it shall be entitled to also terminate the Agreement upon thirty (30) days´ prior written notice to Participating Center.

13.4. In all circumstances causing early termination of the Study or this Agreement, Parties shall protect the health and safety of the Study Subjects and integrity of the Study Data. Parties agree that they will in good faith make arrangements concerning the continuation of the treatment of the enrolled Study Subjects if such is in their medical best interest and any other actions needed for a proper discontinuation of the Study at the Participating Center. Participating Center will follow any further EORTC instructions and will continue providing the data as required per Protocol for the enrolled Study Subjects. Any financial arrangements following early termination shall follow the conditions set up in clause 3.4.

13.5. Clauses 4.19, 6.3, 7, 8, 99, 11, 12 and any other clauses that by nature would survive of this Agreement shall remain in force after early termination or expiration of this Agreement.

## 14. LEGAL NOTICES AND CONTACT DETAILS

14.1. Any legal notices, requests, consents and other communications to be given by a Party under this Agreement ("Legal Notices") may be executed in writing or by email:

i. Legal Notices in writing shall be deemed to be valid and effective if the notice has been personally served or sent by registered mail.

ii. Legal Notices by email shall be deemed to be valid and effective upon the acknowledgement of receipt.

14.2. Such Legal Notices shall be addressed to:

| EORTC | Participating Center |
|---|---|
| Contracts Department<br>Avenue E. Mounier 83/11<br>B-1200 Brussels<br>Belgium<br>Email: contracts@eortc.org with a copy to 2427@eortc.org | Masaryk Memorial Cancer Institute:<br>XXX<br>Zluty kopec 7<br>656 53 Brno, CZ<br>E-mail: XXX |

## 15. FORCE MAJEURE

15.1. Neither Party to this Agreement shall be liable to the other for any delay or non-performance of its obligations under this Agreement arising from any circumstance beyond a Party's reasonable control and which could not reasonably have been foreseen or provided against, including acts of war or other action of military forces, terrorism, riot, civil commotion, sabotage, vandalism, accident, fire,

flood, strike, pandemic event, lockdown or other industrial disputes (whether or not involving employees of the relevant Party) or legislative or administrative interference and which could not have been avoided or mitigated by the exercise of reasonable care by that Party (a "Force Majeure Event").

15.2. In the event of a Party being so delayed or prevented from performing its obligations due to Force Majeure Event, such Party shall:

(i) give notice in writing of such delay or prevention to the other Party as soon as reasonably possible, stating the commencement date and extent of such delay or prevention, the cause of such delay or prevention and its estimated duration;

(ii) use commercially reasonable efforts to mitigate the effects of such delay or prevention upon the performance of its obligations under this Agreement; and

(iii) resume performance of its obligations as soon as reasonably possible after the removal of the cause of the delay or prevention.

15.3. If a Party is prevented from performing its obligations by a Force Majeure Event for more than eight (8) consecutive weeks the remaining Party may terminate this Agreement immediately upon written notice to the other Parties.

## 16. MISCONDUCT AND DEBARMENT

16.1. For the purposes of this clause 16, "Debarred or Disqualified Person" means any person subject to limitations or any form of enforcement imposed upon clinical investigators or clinical study sites by the United States Food and Drug Administration (FDA), the European Medicines Agency (EMA), or any regulatory authority or other recognized national, multi-national, or industry body.

16.2. The Participating Center declares that neither the Principal Investigator, nor any Research Staff, has ever been and is not currently a Debarred or Disqualified Person, nor will the Participating Center employ any Debarred or Disqualified Person. If during the term of this Agreement, the Participating Center, the Principal Investigator or any Research Staff (i) comes under investigation by FDA, the EMA or other regulatory authority for debarment action or disqualification, (ii) is debarred or disqualified, or (iii) engages in any conduct or activity which could lead to any of them being rendered a Debarred or Disqualified Person, the Participating Center will immediately notify EORTC. Upon the receipt of any such notice, EORTC shall have the right to terminate this Agreement immediately.

## 17. GOVERNING LAW AND DISPUTE RESOLUTION

17.1. This Agreement shall be governed by and construed in accordance with the laws of Czech Republic. The Parties agree that in case of dispute which is not amicably resolved, the decision is taken by the courts of Brno, Czech Republic.

## 18. MISCELLANEOUS

18.1. If any provision of this Agreement is determined to be invalid or void, the remaining provisions shall remain in effect. In such a case, invalid provisions will be replaced by provisions being legally acceptable and in compliance with the objective of the invalid provision.

18.2. In case of any inconsistency between the terms and conditions of this Agreement and those contained in the Protocol, the terms and conditions of this Agreement shall prevail except with respect to medical, scientific or clinical matters for which the provision of the Protocol shall take precedence.

18.3. This Agreement and all annexes hereto constitute the entire Agreement between the Parties with respect to the subject matter included herein and no variation, modification or waiver of any terms or conditions hereof shall be deemed valid unless made in writing and signed by the Parties hereto.

This Agreement supersedes any and all prior agreements and understandings, whether oral or written, between the Parties with respect to the subject matter included herein.

18.4. Any work performed by the Principal Investigator and the Participating Center under this Agreement shall be considered to be performed as independent contractors and not as employees, partners or agents of the EORTC.

18.5. Each person signing this Agreement represents and warrants that he or she is duly authorized and has legal capacity to execute and deliver this Agreement.

18.6. The Parties agree that execution of this Agreement by e-Signatures (as defined below, e.g. DocuSign) shall have the same legal force and effect as the exchange of original signatures.

e-Signature shall mean a signature that consists of one or more letters, characters, numbers or other symbols in digital form incorporated in, attached to or associated with the electronic document, that (i) is unique to the person executing the signature; (ii) the technology or process used to make the signature is under the sole control of the person making the signature; (iii) the technology or process can be used to identify the person using the technology or process; and (iv) the electronic signature can be linked with an electronic document in such a way that it can be used to determine whether the electronic document has been changed since the electronic signature was incorporated in, attached to or associated with the electronic document.

Signatures to this Agreement transmitted by facsimile, email, portable document format (or .pdf) or by any other electronic means intended to preserve the original graphic and pictorial appearance of this Agreement shall have the same effect as the physical delivery of the paper document bearing original signature.

18.7. The Participating Center shall not use EORTC's name and/or the logo or its employees' name for any purpose without the prior written consent of EORTC.

## 19. ANNEXES

Annex 1 – Protocol

Annex 2 – Budget and Payment Schedule

Annex 3 – Data Processing Agreement

**IN WITNESS THEREOF, the Parties hereto have caused this Agreement to be duly executed, as of the Effective Date, by the proper persons duly authorized:**

**Authorized representative of the EORTC**

Name: XXX

Title: Head of Contracts Department

Date: 8. 9. 2025

Signature:

**Authorized representative of the Participating Center**

Name: Prof. Marek Svoboda, MD, Ph.D.

Title: Director

Date: 17. 9. 2025

Signature:

**Principal Investigator**

I have read and understood this Agreement and I accept my obligations hereunder.

Name: XXX

Date: 15. 9. 2025

Signature:

# ANNEX 1- PROTOCOL

This page is intentionally left blank as the Protocol is incorporated by reference.

# ANNEX 2 – BUDGET AND PAYMENT SCHEDULE

| | |
|---|---|
| Site Startup/Administration Fee<br>(fixed amount, paid once upon receipt of an invoice after agreement signature) | 7.500 € |
| Compensation per Study Subject<br>(fixed amount, paid once per enrolled Study Subject) | 12.000 € |

The internal allocation of these payments is entirely within the Participating Center's discretion hence the Participating Center shall invoice EORTC for the full amounts as stated in the table above and in the Request for invoice and from one single entity.

EORTC will pay compensations per Study Subject at least twice per year upon receipt of an invoice from Participating Center, matching the amount specified on the EORTC request for invoice. For this purpose, EORTC will provide a document named "Request for invoice" to the Participating Center twice a year (approximately in January and July) with the number of Study Subjects that fit the payment criteria and amounts that are allowed to be invoiced by Participating Center, as per table above.
EORTC shall send the requests for invoice electronically to the following email address of the Participating Center: fakturace-studie@mou.cz.

Additionally, EORTC will reimburse the Participating Center for fees from regulatory bodies and any fixed fees incurred in the framework of inspections by regulatory bodies upon receipt of a valid invoice from the Participating Center and a copy of the original invoice from the Ethics Committee and/or regulatory body. For the sake of clarity, inspection fees will only be reimbursed if the said inspection is directly targeted to the performance of Study.

The Participating Center shall be informed that the EORTC will not be able to provide any additional financial support to the Participating Center, Research Staff or Study Subjects, with the exception of provisions set out in this Annex. For the sake of clarity, Participating Center shall ensure that the Study Subject does not bear any expenses related to the Study. Any compensation to the Study Subjects for such expenses needs to be taken from the amounts provided to the Participating Center as defined in the table above and shall be entirely managed by the Participating Center with the Study Subject as per local procedures and regulations.

The amounts mentioned in this Annex are inclusive of any taxes and/or levies imposed by the Participating Center (overhead fees, archiving costs) and/or authorities, except for value added tax (VAT), if applicable. All payments for the Study are subject to any applicable value added taxes or other applicable taxes, which shall be payable in addition at the rate and in the manner for the time being prescribed by law.

If your Participating Center is not located in EU, the services under this Agreement are considered outside the scope of Directive 2006/112/CE and VAT shall not be charged.

If your Participating Center is located in EU, the Directive 2006/112/CE applies and Article 44 stipulates that the place of supply of services to a taxable person acting as such shall be the place where that person has established his business. Hence since EORTC is established in Belgium, your Participating Center should not charge any VAT on the invoice if it is not located in Belgium.

## ANNEX 3 – DATA PROCESSING AGREEMENT

**Definitions:**

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 the GDPR shall have the meaning set out in the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 (GDPR).

Terms not otherwise defined in the GDPR or the main Agreement, 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 the main Agreement(s);

**"Data Processing Agreement" or "DPA":** means this Data Processing 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;

**"Data Subjects"**: as defined in GDPR and for the purpose of this DPA shall mean Professional Contacts and Research Subjects.

**"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 Study.

"**Pseudonymised data":** personal data that was subjected to pseudonymisation as per definition in GDPR.

**Now therefore, the Parties agree as follows:**

### 1. Scope of the DPA

1.1. This DPA intends to replace any arrangement previously in place in the scope of Study in relation to the data protection compliance. All other sections of such arrangements remain unchanged thereof. In the absence of any existing arrangement, this DPA shall govern the relationship between both Parties as Data Controller or Data Processor.

1.2. In case of any inconsistency between the terms and conditions of this DPA and those contained in the main Agreement already in place, the terms and conditions of this DPA shall prevail.

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

1.4. 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 this DPA for any other purpose than purposes covered by the main Agreement or in a way that differs from agreed terms, including when resulting from the breach to the main Agreement, it shall be deemed independent controller in that scope.

1.5. 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's database(s) in a pseudonymous form.

1.6. Parties will amend this DPA in the event of changes to data protection requirements or the interpretation of data protection regulations by regulatory bodies and/or jurisdiction.

### 2. Processing activities and categories of data processed

2.1. In the scope of the Study, 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. processes pseudonymous Research Subject's Data for research purposes described in the Study, performs further scientific research and share data with other researchers, including outside the EU, in compliance with the applicable legislation;

ii. processes Research Subject's Data for the purpose of on-site source data verification;

iii. processes Participating Center's Professional Contacts' Data, its relevant vendor's and sub-contractor's data, for the purpose of (a) management and control of Study, (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 (f) in the scope of sharing of pseudonymous Research Subject's Data with other researchers, including outside the EU, in compliance with the applicable legislation;

iv. EORTC may delegate partially or entirely any of the processing activities described in the section 2.1.1. to vendors and sub-contractors.

2.1.2. Participating Center, as Data Processor:

i. pseudonymises Research Subject's Data prior to sending them to EORTC in compliance with the applicable legislation and Study requirements as approved by relevant regulatory bodies;

ii. processes Research Subject's Data for the research purposes as stipulated in the Study as specifically required by EORTC as the Data Controller;

iii. processes safety data provided by EORTC (in its role of Study Sponsor) as legally required, concerning Study Subjects from other participating sites;

iv. processes Data Controller Professional Contacts' Data for the purpose of the execution of this Agreement, performance of activities as allocated, legal, regulatory and administrative compliance as specifically required by the Study Sponsor and Data Controller;

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

| Data categories | Data Subjects categories | |
|---|---|---|
| | Professional Contacts | Research Subjects |
| Identification data (e.g. name, surname, date of birth) | Yes | No* |
| Indirect identification data (e.g. patient 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 Study |
| 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 origin (e.g. ethnicity, etc.) | No | Yes |
| Health data (e.g. disease, treatments, health images etc.) | No | Yes |
| Genetic data (e.g. somatic or germ line mutations, etc.) | No | Yes |

*Access to fully identifiable information by EORTC is possible only in the scope of the on-site monitoring for the source data verification.

## 3. Obligations of the Parties

3.1. Parties shall process Personal Data in compliance with the 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 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 Study and in relation to the Research Subject's Data, shall not be "reasonably" able to identify or directly contact any Research Subjects, or their living relatives. Participating Center will not transfer to EORTC any information that would enable direct identification of any research subject, such as but not limited to Research Subject's name, surname or initials, ID number or hospital chart number.

3.3. When applicable, in case of prospective data collection, EORTC, in its role of Study Sponsor shall ensure the Research Subjects are adequately informed about the processing of their data, including but not limited to purposes of processing personal data, mechanisms of transfer to third countries and legal basis.

3.4. Participating Center, will allow EORTC to access source data at the site for exercising the ICH-GCP and legal obligations, eg. the purpose of verification during monitoring.

3.5. By way of exception to the section 3.2, Participating Center shall grant EORTC or its sub-contractors access to relevant parts of Research Subject's medical file, for the sole purpose of the on-site source data verification in the scope of the Study. This will enable EORTC to comply with Good Clinical Practice (GCP) principles.

3.6. EORTC will ensure it appropriately selects and trains sub-contractors and/or individuals performing on-site source data verification, including but not limited to, by putting in place stronger confidentiality clauses.

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

3.8. Both Parties represent that Professional Contacts whose Personal Data are provided to the other Party have been appropriately informed about and consented (unless other legal basis applies), to the collection and use of their data by the other Party, its partners, vendors and sub-contractors in the scope of this Agreement.

## 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 Agreement 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 Agreement, it will promptly notify this modification to the Data Controller as soon as it is aware of it, in which case the Data Controller is entitled to suspend the transfer of data and/or terminate this Agreement and any other contract concluded in the scope of the Study; and

4.1.2. it has implemented and keeps 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 Principal Investigator or any other individual(s) involved in this Study acting under Participating Center's authority process the data in compliance with this Agreement.

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 Agreement, 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. when applicable, not collect excessive amount of personal data, in the scope of verification of identity of the monitors/auditors acting on behalf of EORTC;

4.2.3. when applicable, provide relevant privacy notice in relation to 4.2.2. to monitors / auditors prior their visit to the Participating Center's site;

4.2.4. prospectively inform EORTC about any change in the staff members involved in the key Study-related activities (e.g. listed in the delegation log / part of the Study essential documents); where prospective information is impossible, EORTC shall be made aware within the two working days from the change of staff;

4.2.5. in the event of sub-contracting 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 Study;

4.2.6. in the event of any other sub-processing relevant to this Agreement, but not sub-contracted specifically for the purpose of the performance of the Study, inform the Data Controller about any such sub-processor(s) upon Data Controller's request;

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

4.2.8. 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 Agreement, so that the processing by the Sub-processor is carried out in accordance with conditions set out in this Agreement;

4.2.9. restrict access to the Personal Data to those of its employees who need access to the Personal Data to meet obligations under this Agreement;

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

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

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

4.2.13. 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;

4.2.14. assist Data controller for the fulfillment of Data Controller's obligations to respond to requests for exercising Data Subject's rights;

4.2.15. 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;

4.2.16. without prejudice to the section 4.2.15, make available to the Data Subject or regulatory bodies upon request (i) a copy of DPA, the Agreement, 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;

4.2.17. 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;

4.2.18. 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 and Research Subjects outside the Study shall not be subject to requirements set in the section 4.2.1;

4.4. In the event of <u>any complaint, notice or communication</u> 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. <u>Reporting of Personal Data breaches</u>

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) business hours of becoming aware of it (having the confirmation), by e-mail, to the DPO of Data Controller; in particular, but not limited to:

5.2.1. 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

5.2.2. 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.

5.3. Without prejudice to the section 3.4 shall EORTC become a recipient of Research Subject's Personal Data which are not properly pseudo-anonymized or which shall not be otherwise provided to EORTC, such a situation will be considered by EORTC as Participating Center's own data breach.

5.4. 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 Agreement.

6.2. 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 at least twenty-five (25) years after the end of the Study.

6.3. Further research projects performed in compliance with the section 1.4, shall comply with the archiving period imposed by the applicable legislation;

6.4. 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 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.

6.5. 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

The Parties agree that any liability in relation to the processing of Personal Data under this 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 Agreement insofar as any Party is still processing Personal Data in accordance with this Agreement.

## 9. Notices and 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 or contact for data protection queries at dpo@mou.cz