***INVESTIGATOR INITIATED TRIAL SUPPORT AGREEMENT:***

THIS AGREEMENT is effective as of last signature date (“Effective Date”)

**BETWEEN:**

GE Healthcare Limited, The Grove Centre, seated at: White Lion Road, Amersham, Buckinghamshire HP7 9LL acting through and on behalf of its Affiliates (as defined below)

"Affiliate" shall mean any company controlling, controlled by or under common control where control means direct or indirect ownership of at least 50% of the voting stock or interest in a company or control of the composition of the board of directors. Affiliates of GE Healthcare Limited shall include any company which: (i) from time to time forms part of the GE Healthcare business of the group of companies (the “GEHC Group”) whose ultimate parent is General Electric Company and which (ii) is controlled by or under common control with the relevant Party (where “control” has the meaning set out above. For the purposes of this Agreement, (hereinafter referred to as “GE Healthcare”)

And

Vseobecna fakultni nemocnice v Praze (General University Hospital in Prague), Institute of Nuclear Medicine, ID.No: 00064165, seated at: U Nemocnice 499/2, 128 08 Praha 2, Czech Republic (hereinafter referred to as “Investigator”) Ge Healthcare and the Investigator together as “parties”

**INTRODUCTION:**

1. Investigator wishes to conduct the study *xxx”* (hereinafter referred to as “Trial”);
2. It is hereby acknowledged that the enrollment of patient has been already made prior to the Effective Date;
3. WHEREAS, the Investigator desires the provision of a software application called xxx which is a standalone quantification software application, in order to utilize it as part of the Trial (the “Purpose”);
4. WHEREAS GE Healthcare desires to support the Trial by providing Investigator access to xxx (hereinafter “GE Equipment”);
5. It is hereby acknowledged that GE Healthcare Limited beneficially owns all intellectual Property Rights (e.g., patents, know-how, trademarks, etc) related to the GE Equipment;
6. GE Healthcare has been asked to support the Trial and GE Healthcare has agreed to do so on the terms and conditions mentioned below. Where the GE Equipment is to be used for a Non-approved Indication, GE Healthcare makes no representations or warranties that the GE Equipment is appropriate for use in the Trial, (with or without other drugs) or that the GE Equipment will enable specific results to be obtained. GE Healthcare does not represent or warrant that the GE Equipment is authorized for such Non-approved Indication by the competent regulatory authorities in the Territory, or that the GE Equipment will not cause any loss, damage or injury as a result of such non-approved use;
7. GE Healthcare’s support of the Trial is contingent upon Investigator’s receipt of IRB/Ethics Committee approval of the Trial (amendment) and the relevant regulatory approvals in the country where the Trial is being conducted, as well as registration of the Trial in a clinical trials registry where appropriate.

**THE PARTIES HAVE AGREED AS FOLLOWS:**

1. Investigator shall conduct the Trial strictly according to the Trial protocol signed by Investigator (or his/her superior) and dated 26 of March 2019 and titled: The use of xxx to investigate the rate of impairment in patients with methanol intoxication, the project “*xxx*” (“Trial Protocol”) and Investigator shall give not less than eight [8] weeks written notice to GE Healthcare of any intended change to the Trial Protocol.
2. Investigator is the sponsor of the Trial and shall have and take full responsibility for all aspects of the conduct of the Trial (including its planning, performance, safety, reporting) and conformance at all times with the Trial Protocol. Investigator assumes all legal obligations as sponsor of the Trial, including the obligation to properly insure against all risks relating to the Trial as may be prudent or required by local law.
3. Investigator agrees to maintain liability insurance (including without limitation clinical trials liability, comprehensive general liability, property damage and workers compensation) to support their obligations in the event of any liability arising under this Agreement and the Trial. Upon GE Healthcare’s request, Investigator will provide proof of such insurance. Investigator acknowledges that GE Healthcare has no responsibility whatsoever for conducting or managing any aspect of the Trial and that GE Healthcare’s public liability insurance will not cover the Trial.
4. Investigator shall:
   1. Conduct the Trial strictly within the provisions of EU Directive 2001/20/EC if any part of the Trial is conducted in the EU and the equivalent laws of the Czech Republic (including the local Medicines Acts, namely Act No. 372/2011 Coll., on medical services); and
   2. Not start the Trial before the relevant regulatory authority and IRB/Ethics Committee have given their written approval (amendment); and
   3. Ensure safety reporting in compliance with applicable regulatory requirements.
5. The GE Equipment will be activated on the PC provided by the Investigator by a license key code that is specific to that PC.
   1. Use of GE Equipment will be restricted to personnel authorized by the Investigator under whose supervision GE Equipment will be used. Use of GE Equipment shall be confined to this Purpose and it shall not be used for patient diagnosis. The GE Equipment is provided to the Investigator subject to the terms and conditions set forth in the document attached hereto and incorporated herein as Exhibit A to this Agreement.
   2. Investigator acknowledges that the GE Equipment is to be used solely for the Purpose and may not be utilized for any other purpose and may not be shared with anyone or disclosed to a third party not involved in the secondary analysis. Investigator shall use GE Equipment solely in accordance with the instructions for use accompanying it and shall not modify or alter GE Equipment in any way.
   3. Investigator represents and warrants:

(a) that if necessary it has provided notification to its Ethics Committee of the provision of GE Equipment and its use in the Trial.

(b) Upon completion or early termination of the Trial, installation media will be returned to GE Healthcare and written evidence of the removal of GE Equipment will be provided by the Investigator to GE Healthcare.

(c) Investigator acknowledges that GE Healthcare will not charge Investigator for use of the GE Equipment and Investigator agrees that it will not include any charges for use of the GE Equipment to any third party, including but not limited to study subjects, any insurance company or governmental healthcare program.

(d) Investigator acknowledges that it is solely responsible for determining whether GE Equipment is appropriate for use in the Trial and for any treatment decision taken as a result of its use of GE Equipment. GE Equipment is not intended to be a substitute for the medical judgment of the Investigator. Investigator acknowledges that GE Equipment is provided by GE Healthcare “as is”. GE Healthcare does not give any warranty of any kind whatsoever with respect to GE Equipment and all implied or express warranties are excluded to the maximum extent permitted under applicable law, including any warranties of merchantability or satisfactory quality, non-infringement or fitness for purpose.

(e) Investigator shall notify GE Healthcare promptly if Investigator becomes aware of any malfunction or deterioration in the characteristics and/or performance of GE Equipment, or any inadequacy in its instructions for use, which might lead to or might have led to an injury or harm to any person, including any incorrect diagnosis. Investigator shall provide such assistance to GE Healthcare as GE Healthcare may reasonably request to investigate or follow-up any such incident and Investigator shall use its reasonable efforts to implement any corrective action recommended by GE Healthcare.

(f) If Investigator receives any communication from any regulatory authority concerning GE Equipment, Investigator shall promptly notify GE Healthcare and provide a copy of any such documents or correspondence. To the extent practicable, Investigator shall allow GE Healthcare a reasonable opportunity to review and comment upon any response Investigator intends to submit to such regulatory authority. Investigator will notify GE Healthcare of any meeting or teleconference to be held with any regulatory authority in connection with GE Equipment and, to the extent permissible, Investigator will allow GE Healthcare or its designee to attend and participate in such meeting and teleconference.

6. The expected start and finish dates for patient data extraction for the Trial are May 2019 and November 2019.

7. Investigator shall provide GE Healthcare with a written report on completion of the Trial which shall include the data obtained and summarize the findings and conclusions reached, yet shall not contain any personal data of the patients or any other natural persons (the “Report”). Any scientific paper, presentation or communication concerning the Trial shall be submitted to GE Healthcare before its publication so that GE Healthcare may review the manuscript for proprietary or confidential information. At GE Healthcare’s request, Investigator will remove any GE Healthcare proprietary or confidential information (except for Trial results) prior to publication and/or delay publication to protect intellectual property rights. GE Healthcare agrees to review such manuscript within thirty (30) days from receipt of the final version of the manuscript. After this deadline, Investigator can use the Report without notice from GE Healthcare.

8. GE Healthcare shall have the right to use the Report referred to above for the purposes of its own research and development and GE Equipment development and subsequent commercialization.

9. GE HEALTHCARE will support Investigator with GE Equipment software for analysis of images as requested by Investigator and approved by GE HEALTHCARE. The support will be provided as set out in **Schedule A** attached. To the extent that GE Healthcare is providing GE Equipment in support of the Trial, GE Healthcare delivers the GE Equipment under CIP Incoterms 2010 and grants Investigator the right to use the GE Equipment solely for the purpose set forth in the Trial Protocol for academic research purposes only and not for any commercial use. Investigator shall maintain accountability and responsibility for all GE Equipment, and will not transfer the GE Equipment to any third parties not under the immediate and direct control and supervision of Investigator without the prior written consent of GE Healthcare, which GE Healthcare may in its discretion reasonably withhold. Investigator shall use the GE Equipment in compliance with the relevant laws and regulations of the Czech Republic. Further Investigator shall not use the GE Equipment in research that is subject to any consulting, contractual or licensing obligations to another corporation, government agency, or other entity or person, unless prior written permission is obtained from GE Healthcare. Investigator shall delete GE Equipment at the conclusion of the Trial.

10. This Agreement may be terminated in accordance with the following provisions:

* 1. By either party without cause with sixty (60) days written notice to the other party;
  2. GE Healthcare may, at its discretion, suspend or terminate its duties under this Agreement if it becomes aware that Investigator is in material breach of this agreement and, if capable of remedy, Investigator fails to remedy the breach within 30 days upon being requested to do so by notice in writing from GE Healthcare.
  3. If the Trial is terminated early by either party, a final report shall be required from the Investigator in accordance with Section 7 of this Agreement.
     + 1. Investigator shall indemnify and hold harmless GE Healthcare and its Affiliates from and against any claim, liability, loss or damage suffered or incurred by GE Healthcare or its Affiliates due to any negligent act or omission of, or any breach of this Agreement by, Investigator, its staff or representatives, to the extent that this was not caused by GE Healthcare’s negligent performance of this Agreement.
       2. GE Healthcare shall indemnify the Investigator from and against any claim, liability, loss or damage suffered or incurred by the Investigator or patients due to any negligent act or omission of, or any breach of this Agreement by, GE Healthcare, its staff or representatives, to the extent that this was not caused by Investigator’s negligent performance of this Agreement.
       3. This Agreement may only be amended by the mutual written amendment signed by the Investigator and GE Healthcare.
       4. In the course of this Agreement, it may be necessary for GE Healthcare to disclose certain confidential or proprietary information to Investigator. Accordingly, during the term of this Agreement and for a period of five (5) years thereafter, Investigator shall not disclose or use Confidential Information except as permitted in this Agreement or in writing by GE Healthcare. Confidential Information shall include all information concerning the GE Equipment that is disclosed to Investigator by GE Healthcare, including any business information relating to GE Healthcare or its affiliates.
       5. All Trial data, medical and other clinical records generated hereunder by Investigator during the Trial shall be and remain the sole and exclusive property of Investigator. Investigator shall allow GE Healthcare and its authorized representatives access to the anonymized data, with advance notice and during regular business hours, so that GE Healthcare may review the Trial results (including correspondence with IRB/Ethics Committee and regulatory authorities), depending on the approval of the IRB/Ethics Committee (amendment) examine the facilities where the Trial is conducted and communicate with staff and personnel involved with the Trial, including any sub-investigators. GE Healthcare will not have access to any patient health information obtained from review of the Trial data or patient records for any purpose other than defined in Protocol and informed consent of the patients.
       6. The parties agree that they shall comply with any and all applicable laws and regulations and industry guidance and standards, including but not limited to the Data Protection Act 1998 of the UK ("DPA"), the Medicines Act 1968 of the UK, the Bribery Act 2010 of the UK and The Association of British Pharmaceutical Industry (ABPI) Code of Practice (the "Code") as well as the mandatory Czech law In connection with this Agreement, the Investigator hereby consent to the disclosure by GE Healthcare to other members of the GE Healthcare group of companies and to medicines regulatory authorities where required under any applicable laws and regulations or codes of practice, of the nature and scope of the support provided by GE Healthcare to Investigator.
       7. This Agreement is governed by the laws of the Czech Republic and the parties shall submit to the jurisdiction of the Czech Republic Courts in connection with any dispute or claim arising under it.Limitation of Damages, except in the event of personal injury, death or fraud, IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER FOR ANY SPECIAL, INCIDENTAL, INDIRECT, PUNITIVE, OR CONSEQUENTIAL DAMAGES (INCLUDING, BUT NOT LIMITED TO LOST PROFITS AND LOST BUSINESS), WHETHER BASED ON BREACH OF CONTRACT, TORT (INCLUDING NEGLIGENCE), GE EQUIPMENT LIABILITY, OR OTHERWISE ARISING OUT OF OR RELATED TO THIS AGREEMENT, AND WHETHER OR NOT ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.
       8. Investigator may not assign any right or delegate any duty under this Agreement without GE Healthcare’s prior written consent. GE Healthcare may assign this Agreement to any of its Affiliates upon written notice sent to the Investigator
       9. Other than as specifically provided for in this Agreement, Investigator may not, without GE Healthcare’s prior written consent, issue any press release or announcement, advertise or publish, or disclose information relating to this Agreement, or use GE Healthcare’s name or trademarks, or the names or trademarks of any of GE Healthcare’s affiliates or customers.
       10. The relationship of the parties hereunder shall be that of independent contractors. Nothing in this Agreement shall be deemed to create a partnership, joint venture, or similar relationship between the parties and no party shall be deemed to be an agent of the other party.
       11. Investigator and GE Healthcare agree and acknowledge that their existing inventions and technologies as of the Effective Date are their separate, respective property and are not affected by this Agreement, and neither party shall have any claims to or rights in such existing inventions and technologies of the other party. Investigator agrees to give GE Healthcare notice of all inventions and discoveries arising under this Agreement (“Inventions”). Regardless of inventorship, GE Healthcare shall own all Inventions needed by GE Healthcare to exploit (e.g. make, have made, use, offer for sale, sell, or otherwise distribute, import, and export) the GE Equipment (“GE Healthcare Inventions”). Investigator shall own all Inventions that are not GE Healthcare Inventions (“Investigator Inventions”).
       12. This Agreement (including all Schedules hereto) is intended by the parties as a final and complete expression of their agreement on the subject hereof, and supersedes any and all prior and contemporaneous agreements and understandings. No other agreements, oral or otherwise, on the subject matter hereof shall be deemed to exist or to bind any of the parties.
       13. This Agreement may not be modified and none of its terms may be waived, except in writing and signed by authorized representatives of both parties. To the extent that any term in any document, other than a writing signed by both parties that expressly purports to amend this Agreement, is contrary to, or conflicts with this Agreement, the terms of this Agreement shall control. A waiver by a party of any default shall not be deemed a waiver of a prior or subsequent default of the same or other provisions of this Agreement. The failure of a party to enforce, or the delay by a party in enforcing any of its rights, shall not be deemed a continuing waiver or a modification of this Agreement.
       14. The termination of this Agreement for any reason shall not affect the continued operation or enforcement of the provisions hereof which by their terms are to survive termination, including, without limitation, the enjoyment by GE Healthcare of any and all fully-vested rights. If any part of this Agreement is declared invalid or unenforceable by a court of competent jurisdiction, it shall not affect the validity or enforceability of the remainder of this Agreement, unless the Agreement so construed fails to meet the essential business purposes of the parties as manifested herein.
       15. This Agreement is executed in two counterparts, each of which will be deemed to be an original copy of the Agreement, and all of which when taken together shall be deemed to constitute one and the same agreement.
       16. GE Healthcare hereby acknowledges that Investigator is obliged to publish information in accordance with Act No. 340/2015 Sb., on Agreements Register. The Parties agree that the Agreement will be published by Investigator only on the relevant register in compliance with applicable laws. The version of this Agreement intended for publication (excluding trade secrets) will be prepared by Investigator and published the day of the signature of this Agreement.

\*Remainder of the page intentionally left blank\*

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| --- | --- |
| PLACE  DATE | Prague  DATE |
| Duly authorized for and on behalf of  **GE HEALTHCARE** (or other legal entity) | Duly authorized for and on behalf of  (Investigator) |
| (Signature) | (Signature) |
| Name and title: | Name and title: |
|  | I, xxx., Head of Institute of Nuclear Medicine, hereby confirm that I have become acquainted with this contract and I shall comply with the duties stipulated therein for the investigator and duties following for the investigator from Good Clinical Practice.    In Prague, on      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  xxx |
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**Schedule A**

**Study Support**

In accordance with the Investigator Initiated Trial Agreement dated 14 March 2019 between Institute of Nuclear Medicine (the “Investigator”) and GE Healthcare:

1. GE Healthcare agrees that it shall provide to Investigator, at no cost, GE Equipment for analysis of images to be used in connection with the Study. Upon receipt of a signed Agreement and confirmation of IRB/Ethics Committee approval, GE Equipment shall be delivered as set out below:

|  |  |  |
| --- | --- | --- |
| **Software Description** | **CE Mark** | **Approx. Value** |
| xxx | No 7927 | The value of xxx is likely to be approximately $3,250.00 (USD) per year |

Upon completion or early termination of the Study all GE Equipment must be returned to GE Healthcare.