LICENSE and SERVICE AGREEMENT

No. 2021/063

Concluded pursuant to provision of the Sec. 2358 et. seq., Act No. 89/2012 Coll., Civil Code (hereinafter as the "Act") on below stated day, month and year between the following contracting parties:

Between:

Licensee:	Statní ústav radiační ochrany, v. v. i.
Registrated seat:	Bartoškova 1450/28, 140 00 Praha
Represented by:	Mgr. Aleš Froňka, Ph.D., Institute Director
ID No:	86652052
VAT number:	CZ86652052
Data box ID:	fyy5d7d
Bank connection:	Komerční banka, a.s.
Account number:	43-8473960227/0100
Person authorized to act in technical	Ing. Pavel Solný
matters:	telephone number: +420 .; e-mail address
Person authorized to act in legal matters::	Markéta Molnárová, LL.M.
	telephone number:+420
matters	e-mail address:

Hereinafter as "Licensee,"

and

The Licensor:	ABX-CRO advanced pharmaceutical services	
The Licensor:	Forschungsgesellschaft	
Registered seat:	Blasewitzer Str. 78-80, 01307 Dresden. Germany	
Represented by:	Dr. Andreas Kluge, General Manager	
ID No:	HRB 21253	
VAT number:	DE 813528365	
Registered in the commercial	Commercial Register B of Dresden Local Court (Amtsgericht	
register:	Dresden)	
Data box ID:	N/A in Sachsen	
Telephone number:		
e-mail adress:		
Bank connection:	Commerzbank (vorm. Dresdner Bank), SWIFT/BIC	
	DRESDEFF850	
Account number:	IBAN DE67 850800000482017400	
	Name: Dr. Tobias Meyer	
Person authorized to act in technical	Position: Medical Imaging Specialist	
matters:	telefon:	
	e-mail:	

Hereinafter as "Licensor"

Together also as "Parties" as follows:

I. Meaning and purpose of the agreement

The purpose of this agreement is granting of a licence and enabling smooth operation of the software as part of the small-scale public procurement titled "SW for absorbed dose calculation in radionuclide therapy"

II. Subject of the Agreement

- 1. Pursuant to this Agreement and the terms and conditions set forth herein, Licensor licenses to Licensee the subject matter of the License specified in Article II, paragraph 2 of the Agreement and in Annex A to this Agreement (hereinafter referred to as the "SW" or "Subject of the License") and Licensee undertakes to provide the Licensor with the remuneration specified in Article IV of this Agreement (hereinafter referred to as the "Remuneration").
- 2. The Licensor undertakes to provide the SW in accordance with the requirements for the properties of the SW, including all accessories and documents that relate to the Subject of the License.
- 3. Part of the proper performance of the Agreement is the installation of the SW at the location specified in this Agreement, i.e. complete commissioning of software by the Licensor and training of Licensee's personnel according to Annex A (hereinafter referred to as "Implementation").
- 4. The Licensor further undertakes to specify the technical requirements of the hardware equipment (hereinafter referred to as "Hardware") on which the SW will be installed. The Licensee undertakes to provide the Hardware and necessary cooperation for the installation of the software using remote access. In case the Implementation using remote access is impossible, the Licensor undertakes to provide the Licensee with all necessary instructions and cooperation for a successful Implementation.
- 5. The subject of this contract is also the handover of all documentation related to SW (especially CE certificates, technical documentation, manual, maintenance instructions, etc.), which is necessary for the handling of SW and necessary for its operation or required by relevant legislation and Czech and European technical standards.
- 6. The Licensor declares that they have the right to license the SW. The license under this agreement is non-exclusive, unlimited in time, and Licensee has no right to sublicense. The license is provided in the territory of the Czech Republic.
- 7. The Licensor is also obliged to provide any related software necessary for the proper functioning of the software within the meaning of this agreement, as well as to provide licenses for such software to enable its operation throughout its lifetime, as well as regular updates of the related software. The fee for the license and the update is included in the Remuneration according to this agreement. The Licensor bears the risk of any change in the amount of remuneration for the license to the related software.

III. Time, Place and Manner of the Performance

1. The Licensor undertakes to draw up an Implementation plan within 60 days of the signing of this contract for The Licensee to authorize. The Implementation plan must contain a detailed description of the SW Implementation and must adequately respond to the current state of the Licensee's hardware and software detailed in Annex A of the contract and in accordance with safety policy of The Licensee. If The Licensee has reservations about the Implementation plan,

they shall provide Licensor with an additional period to modify the Implementation plan. If the Licensor fails to draw up the Implementation plan without any reservations, The Licensee may withdraw from this contract.

- 2. The Licensor's obligation to provide software is fulfilled at the time of completion of the Implementation of the complete and flawless software at the address of the State Institute of Radiation Protection, v.v.i., Bartoškova 1450/28, 140 00 Prague 4 according to the Implementation plan.
- 3. The Licensor shall issue an Implementation Protocol to the Purchaser after the successful Implementation of the SW. Completion of the Implementation for the purposes of this Agreement means the moment of signing the Implementation protocol by both the Licensee and the Licensor
- **4.** If the Licensor has reservations about the performed Implementation, they shall state these reservations in the Implementation Protocol. In the case of acceptance of the Implementation with reservations, Art. 2615 et seq. of the Civil Code will apply analogically.
- 5. The Licensor shall provide the Licensee with a license and all other performance associated with its provision shall be implemented by the SW Implementation no later than 60 days after this Agreement enters into force. The Licensor shall demonstrably (in writing, including the possibility of using e-mail addressed to the employee: pavel.solny@suro.cz) notify the Licensee of the date of performance at least three (3) working days in advance.
- **6.** In the case of Implementation by the Licensee with the cooperation of the Licensor pursuant to Article II, paragraph 4 of this Agreement, the Licensor shall always provide cooperation for individual actions according to the Implementation plan no later than the next working day after a written request is sent by the Licensee to the Licensor.
- 7. If the Licensee is not provided with performance properly and within the set due date of performance under paragraph 5 of this Article, the Licensee may withdraw from this contract without prior notice or any other actions taken against the Licensor. The Licensee is entitled not to accept the performance if the Licensor does not perform properly and on time, especially if the Licensor does not perform in the agreed quality, the Licensor does not provide the necessary documentation for the SW or does not perform activities conditional on putting the SW into operation and activities required for its proper functioning.

IV. Remuneration, Terms of Payment

1. The Licensee undertakes to pay the Licensor the following Remuneration for the subject of performance specified in Article II of this Agreement:

Remuneration excl. VAT: 1.371.600,00 CZK;

(in words: one million three hundred seventy one thousands and six hundred CZK excl. VAT)

VAT (21 %): 288.036,00 CZK

(in words: two hundred eighty eight thousand and thirty six CZK)

Remuneration (incl. VAT): 1.659.636,00 CZK

(in words: one million six hundred fifty nine thousands and six hundred thirty six CZK)

2. The total Remuneration is for the complete performance pursuant to Article II of the Agreement and includes in particular the license to the SW and related software, the

installation of the SW and related software and support for at least 36 months from the Implementation date. The remuneration stipulated above is final. The remuneration is a one-off payment and is the only and final performance that the Licensee will provide to the Licensor, except for the service remuneration pursuant to Article IV, paragraph 5 of the contract.

- 3. Payment of the Remuneration will be made by the Licensee by cashless transfer to the Licensor's account specified in this Agreement, based on the invoice issued by the Licensor after signing the installation protocol pursuant to Article III, paragraph 3 of this Agreement.
- 4. The invoice shall be payable within 28 days of its delivery. The commitment to pay the Remuneration shall be fulfilled the moment the designated amount is ordered to be transferred from the Licensee's account to that of the Licensor's.
- 5. The invoice must have all the particulars of a tax and accounting document in accordance with relevant legal regulations and must include the Licensee's agreement number; if the invoice fails to contain the particulars given above, it will be returned for correction within the maturity period, whilst a new period for payment commences after the invoice has been e-mailed again in accordance with the terms of this paragraph.

V. Penalties

- 1. If the Licensor fails to comply with the deadline set for the performance under Article III. para. 5 and 6 of this Agreement or the Licensor fails to comply with the deadline for removal of defects under Article VI. of this Agreement, or the Licensor does not rectify the defect against which the Licensee has had reservations in the Implementation protocol, the Licensor is entitled to demand payment of a contractual penalty in the amount of 0.1 % of the Remuneration for each commenced day of delay. The Licensee's right to compensation for damage which exceeds the penalty shall not be affected by this provision.
- 2. If the Licensee fails to meet the due date of the Remuneration referred to in Article IV. para. 4 of this Agreement, the Licensor shall be entitled to demand payment of default interest of 0.1 % of the Remuneration for each commenced day of delay.
- 3. In case of delay in commencement of support operations according to the requirement specified in Article VI. of the Agreement after prior due notification of the Licensor by the Licensee pursuant to Article VI. para. 5 of the Agreement, the Licensor shall pay the Licensee a contractual penalty in the amount of CZK 1,000 for each commenced day of delay under this provision.

VI. Support

- 1. The Licensor provides a warranty for the quality of the SW. The Licensor must ensure that the object of the contract corresponds to the contract, its annexes and legal regulations. The length of the warranty period is 6 months starting from the date of completion of the Implementation in according to Article III, paragraph 3 of the contract. After having been notified of the defect, the Licensor undertakes to eliminate the defect within a reasonable period of time specified by them.
- 2. The warranty does not cover defects caused by force majeure.
- 3. The Licensor undertakes to provide the Licensee with free (i.e., at their own expense and at their own risk) support for the provided SW. This support is paid within the Remuneration, the Licensor cannot demand any further performance for this support. The duration of the

- provision of free support is set at a minimum of 36 months from the date of completion of the Implementation in the sense of Article III, paragraph 3 of the Agreement.
- 4. Free support includes, in particular, the performance of all inspections, updates, checks and revisions of the SW. As part of the support, the Licensor undertakes to enable the Licensee to use the hotline in the form of telephone support and system of reporting an error. Free support also includes the provision of services at the request of the Licensee, who in such case invokes support by submitting a request for support.
- 5. The Licensee shall send the service request to the Licensor in writing, ie. explicitly also by a data message (e-mail), even without an electronic signature, with a technical description of the defect. In the written request, the Licensee shall state the deadline for the elimination of the defect. In the event that the nature, severity and extent of the defect do not allow the Licensor to meet the deadline for the elimination of the defect, a reasonably longer period may be agreed upon in writing.
- 6. Travel costs, material costs and other costs incurred by the Licensor in connection with the provision of support shall be paid in full by the Licensor.
- 7. The Licensor guarantees the availability of post-warranty support (paid SW support for a period of 72 months (but at least 72 months) since the end of the period of free support).
- 8. Remuneration for post-warranty support is not included in the Remuneration. The Licensor undertakes to provide post-warranty support for prices specified in technical specification.
- 9. The Licensor will issue an invoice for the provided post-warranty support by the 15th day of the month following the month in which this support was provided. This invoice will be due in 30 days.

VII. Final Provisions

- 1. The Licensor will be obliged to cooperate in the performance of a financial inspection, in accordance with Section 2 (e) of the Act No. 320/2001 Coll., on Financial Inspection and on Amending Certain Acts.
- 2. The Licensor states that they have no payables overdue towards public authorities and that Licensor's right to provide a license to the SW has been neither questioned nor challenged legally, and that there has been no attachment imposed on the Licensor or his rights.
- 3. As regards matters not explicitly regulated under this Agreement, the contractual relationship established herein shall be governed by Act No. 89/2012 Coll., Civil Code, as amended, this particularly involving the relevant provisions on license agreements, and by other legislation of the Czech Republic.
- 4. The invalidity of any provision of this agreement does not invalidate the entire agreement. Any condition of this Agreement which by its nature extends beyond the terms of this Agreement shall remain in full force and take effect until fulfilled and apply to any party's successor.
- 5. The contracting parties undertake to settle all disputes arising from this contract primarily amicably. All disputes arising under this contract will finally be resolved before the Czech courts and in accordance with Czech law.
- 6. The Licensor declares that they are aware of the fact that they are not entitled to condition this offer with any counter-offer, even if the standard offered license would require immanently for installation or proper operation launching of other SW (e.g. so-called EULA). The Licensor is aware that such provisions will not be taken into account by the Licensee and the contracting parties will act as if these provisions are non-existent.

- 7. The Licensor declares that they are aware of the fact that any business terms and conditions attached by the Licensor will not be taken into account. This Agreement may be amended and supplemented only by written and numbered amendments signed by person authorised to act on behalf of the Parties. All amendments, which will be marked as amendments to this Agreement, are integral part of this agreement.
- 8. This Agreement has been made in:

Two written paper counterparts, one of which shall be kept by the Licensee and one by the Licensor.

- 9. This Agreement shall become valid upon its signature by the authorized representatives of both Parties and the Agreement shall enter into force by its publication in the Contracts Register pursuant to Act No. 340/2015 Coll., Contracts Register Act. The Parties agree to its publication in this register, which the Licensee will be authorized to ensure; for the purpose of its publication, the Parties shall not treat any of the contents of this Agreement nor any metadata related to it as being excluded from disclosure.
- 10. The contracting Parties declare that this Agreement is concluded in accordance with their true and free will, not under duress or under conspicuously disadvantageous conditions, which they affirm by their signatures. The following annexes are an integral part of this agreement:

Annex A – Technical specifications (Filled in by the economic operator and attached to the tender)

Parties confirm with their signature the authenticity of this Agreement:

On behalf of the Licensee:

On behalf of the Licensor:

In Prague on 5.11.2021

In Dresden on

Mgr. Aleš Froňka, Ph.D. Dr. Andreas Kluge

Institute Director of SÚRO, v.v.i. General Manager of ABX-CRO, mbH



Annex A

Technical specifications

1) Description and the purpose of the technology:

Software is used for calculation of absorbed doses in radionuclid therapy.

2) <u>Technical parameters specified by the contracting authority:</u>

Requirements	Guaranteed by the economic operator
Technical parameters:	
The Licensor: a) shall implement SW using remote access OR, b) shall provide the necessary cooperation in the implementation by the Licensee	YES, via remote access
SW which guarantees fast DICOM (including 3D) data processing and storage	YES
Standardised absorbed dose calculation SW based on image (DICOM)/ patient examination for multiple radionuclides and radiopharmaceuticals (mainly using: 131I, 90Y, 177Lu).	YES. 10 (ten) nuclides of choice, see attached the ABX-CRO official quotation. 131I, 90Y, 177Lu nuclides are included.
Time-activity curve fitting and analysis (of activity during time) – time-activity curve imaging including curve parameters read-out and saving, (user being able to adjust curve parameters would be an advantage) for different body parts.	YES, user adjustment of curve parameters is available
SW must include S-values or/and dose coefficients based on up-to-date ICRP/ICRU recommendations. A possibility to choose from various types of phantoms/models and ICRP 103 would be an advantage.	YES, values from ICRP 110, various phantoms and effective dose according to ICRP 103 are included
MIRD formalism or other acceptable calculation (Monte Carlo) must be included.	YES
SW should enable easy absorbed dose comparison using different model-dependent S-values.	YES
The possibility of DICOM format processing (modification of DICOM head etc. would be an advantage) or SW enabling conversion of DICOM data to SW processed format.	YES, certain information from the DICOM header can be modified (e.g. acq. date and time)
3D image and volumetric analysis – calculation of counts in VOI (volume of interest) from SPECT and/or SPECT/CT and PET/CT.	YES, activity and volume in VOI is calculated
Therapeutic administered activity calculation based on diagnostic dosimetry.	YES, via dose extrapolation and nuclide replacement
Functionality independent of gamma cameras/ hybrid systems producers (SIEMENS, GE, DDD, Philips)	YES
Guarantee requirements:	

At least 36 months warranty on the functionality	YES, see attached official quotation of
of the SW	ABX-CRO.
	20210824_Quote_Purchase_QDOSE_2108-
	1
Requirements for warranty service	YES, see attached official quotation of
	ABXCRO.
	20210824_Quote_Purchase_QDOSE_2108-
	1
Guaranteed availability of SW updates post-warranty	YES, 72 months
(including paid) for a period of at least 72 months	
post-warranty (but not exceeding 20 years), including	
the pricing conditions of this guarantee	
Requirement for post-warranty service including	YES, see attached official quotation of
prices. The Licensor guarantees to provide post-	ABX-CRO. 20210824_Quote_Post-
warranty service for these prices. The price for 1 Man-	Warranty_QDOSE_2108-2.pdf
hour of post-warranty support is specified in point 2.1.	
of price calculation.	
The price for 1 Man-hour of post-warranty support	1250,- CZK
according to Chapter VI para. 8 of the Agreement in	
CZK excluding WAT	