CONSORTIUM AGREEMENT

Dutch PSMA study group

CONSORTIUM AGREEMENT

This agreement is entered into on July 1, 2020 (the "Effective Date") between the undersigned:

1. Stichting Katholieke Universiteit, doing business as Radboud University Medical Center established at Geert Grooteplein 10, P.O. Box 9101, 6500 HB Nijmegen, The Netherlands, represented by its director Valorisation/ Technology Transfer acting as its legal representative, hereinafter referred to as "Radboudumc" or "Coordinator"; and

2. Universitair Medisch Centrum Groningen, an institution organized under the laws of the Netherlands, having its registered office at Hanzeplein 1, P.O. Box 30.001, 9700 RB, Groningen, The Netherlands, lawfully represented by Prof. dr. M. Joels, Dean and member of the Board of Directors, hereinafter referred to as "[UMCG"]

3. VU University Medical Center, part of Foundation VUmc, with registered address at de Boelelaan 1117, 1081 HV Amsterdam, the Netherlands, represented by dr. ir. F. Beeftink, managing director Division 7.

also referred to below individually as Party and jointly as Parties.

WHEREAS:

A. The Parties wish to constitute a consortium, in order to collect, analyze and evaluate coded patient data with the purpose to determine whether PSMA PET scans are of added value for treatment of patients with prostate cancer and to further develop treatment protocols and general guidelines, for which a general project plan has been attached hereto as Annex 1 ("Project");

B. For the purpose of the Consortium and to facilitate studies a central Database has been created in order to collect, analyze, present and publish the Data (all capitalized terms are defined in article 1);

C. The Parties will use the Data to conduct several studies as to be decided by the Steering Committee;

D. The Parties intend to disseminate the results of the studies in accordance with the contributions of each Party's researchers;

E. The Parties wish to record in this Consortium Agreement the terms and conditions under which they wish to cooperate in the Consortium;

NOW THEREFORE, IT IS HEREBY AGREED AS FOLLOWS:

1. Definitions and interpretation

1.1. Definitions

Unless defined otherwise, all capitalized terms in this Consortium Agreement shall have the following meaning.

Affiliate means, in relation to a Party, any company or other entity, whether or not a legal person, which directly or indirectly controls, is controlled by or is under joint control with that Party. For this purpose, a Party is deemed to control a company or entity if it (a) owns, directly or indirectly, more than 50 percent of the capital of the other company, or (b) in the absence of such ownership interest, substantially has the power to direct or cause the direction of the management and set the policies of such company or entity.

Background IPR means, by reference to a Party, all Intellectual Property Rights, excluding Foreground IPR, (a) owned by such Party or any of its Affiliates, or (b) licensed or made available by a third party to such Party and under which such Party is authorized to grant licenses

Confidential Information means any information of a non-public, confidential or proprietary nature, whether of commercial, financial or technical nature, customer, supplier, product or production-related or otherwise, disclosed by a Party (the Disclosing Party) to the other Party (the Receiving Party). Such information may be disclosed in any form, provided that it is disclosed reasonably in connection with this Agreement.

Consortium means the association of the Parties under this Consortium Agreement.

Consortium Agreement means this consortium agreement and all annexes, appendices and subsequent amendments to this agreement.

Contribution means the non-financial contribution (including, without limitation, human resources, materials, facilities and equipment) to be made for the benefit of the Consortium by a Party.

Data means all data collected and uploaded into the Database in relation to the Field by or on behalf of the Parties.

Database means the database containing the Data, for the Parties that will contribute to the Database. The Steering Committee of the Dutch PSMA Consortium is responsible for the database in compliance with all applicable laws and regulations

Defaulting Party means a Party in substantial breach of its obligations under this Consortium Agreement - not caused by Force Majeure ("overmacht") - which is irremediable or which is not remedied within ninety (90) days of written notice from the Steering Committee requiring that it be remedied.

Effective Date means July 1, 2020

Intellectual Property Rights means unpatented inventions, patents, trademarks, service marks, trade names, domain names, copyrights (including rights in software), moral rights, rights in designs, Know How, database rights, topography rights, mask work rights, utility models and all other intellectual property rights and forms of protection of a similar nature, licences to such rights, in each case whether registered or pending registration, and rights to apply for any such rights.

Field means diagnosis of prostate cancer using PSMA PET/CT and PET/MRI scans in relation to treatment of patients with prostate cancer.

Know How means all knowledge, drawings, specifications, samples, models, instructions, algorithms, working methods, ideas, concepts, technology, applied development engineering data, reports, notes and all other technical or commercial information, data and documents of any kind.

Personal Data means any information as defined by article 2 section (a) of the European Data Protection Directive 95/46/EC, i.e. any information relating to an identified or identifiable natural person; an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity.

Publication means the publication of an abstract, article or paper in a journal or electronic repository, its presentation at a conference or seminar, or its discussion in academic seminars, tutorials and lectures; and "to Publish" is a reference to a Publication.

Results means the results generated under a Study, including but not limited to information, Know-how, results, inventions, software and other Intellectual Property Rights identified or first reduced to practice or writing in the course of a Study.

Steering Committee means the individuals nominated by each of the Parties in accordance with the terms of this Consortium Agreement to perform the tasks mentioned in article 3 and 5.

Study means a study, initiated by a Party and carried out within the Consortium, which relates to the Field and which is approved by the Steering Committee.

1.2. Interpretation

1.2.1. Except as otherwise defined, in this Consortium Agreement:

a) references to a communication in writing shall include e-mail and electronic messages accessible and printable by commonly used software applications;

b) captions and section headings are for convenience only.

1.2.2. Schedules and Annexes are an integral part of this Consortium Agreement and references to this Consortium Agreement include its Schedules and Annexes. In the event of any ambiguity or inconsistency between the provisions of a Schedule or an Annex and in the body of this Consortium Agreement, the latter shall prevail unless otherwise provided for in this Consortium Agreement.

1.2.3. Best efforts. Where any obligation is qualified or phrased by reference to use reasonable endeavours, best efforts or wording of a similar nature, it means the efforts that a determined and reasonable person desirous of achieving a result would use in similar circumstances to ensure that such result is achieved as expeditious as possible.

2. The Consortium

2.1. The Consortium is created for the purpose of:

a) collecting Data;

b) optimizing research infrastructures through networking, cost-sharing and the sharing of academic, documentary and other researches.

c) pursuing joint Studies on the Data in relation to the Field

d) the development of protocols and policies in relation to the Field.

2.2. If this Consortium Agreement is entered into after the Effective Date, it will apply retrospectively to work carried out in relation to a Study on or after the Effective Date.

23. A new entity becomes a Party to the Consortium Agreement upon signature of the accession document (Annex 2) by the new Party and the Coordinator which is subject to a decision of the Steering Committee as mentioned in article 5.3.h. Such accession shall have effect from the date identified in the accession document.

3. Data

3.1. A Party shall be granted access to specific Data for a Study, if all the following conditions are fulfilled by said Party:

a) the Party requesting the specific Data has provided the Steering Committee with a sound Protocol, including reference to the specific Data needed ("Specified Data"), which justifies this access;

b) the Members (specified in article 5.2), in majority, have approved the Protocol and therefore approve the access to the Specified Data.
Once that Party is given access to the Specified Data ("Recipient"), it shall comply with the following clauses:

3.2. The Specified Data is considered to be proprietary to the Party uploading that Specified Data in the Database ("Provider") and this Agreement does not restrict Provider in any way to use the Specified Data and/or to make the Specified Data available to third parties or to publish any document relating to the Specified Data

3.3. As of the receipt of the Specified Data, Recipient is granted for the term of the Study, which Recipient hereby accepts, a non-exclusive, non-transferable and non-sub licensable license to use the Specified Data for the non-commercial Study, only.

3.4. Recipient shall refrain from using the Specified Data without the appropriate ethical approval and agrees not to give access to or transfer the Specified Data, in whole or part, to any third party or outside the Territory without Provider's prior written consent.

3.5. Recipient acknowledges that Specified Data subjects — and/or their legal representatives on their behalf — may withdraw or change their initial informed consent. Provider shall promptly notify Recipient of any withdrawal of or changes in the informed consent of a Specified Data subject, which may affect the use of such Specified Data under this Agreement.

3.6. Serendipitous findings (if any) that may be of direct and substantial consequence for the health or wellbeing of a Specified Data subject and/or its family members will be reported by Recipient to Provider. It is the responsibility of Provider to handle such serendipitous findings in accordance with its internal policies.

3.7. It shall be the responsibility of each Party that their own use of the Specified Data shall comply with the Applicable Law.

3.8 The data will be transferred with a code and will not contain directly identifying personal data Under no circumstances will the identity of the patient or any means to derive such identity be provided. Parties shall not carry out any procedures with the Data (linking, comparison, processing) through which the identity of the patient could be derived. Parties shall have in place appropriate technical and organizational measures. Any accidental or unauthorized access to the Data or loss of Data must be reported immediately.

3.9 Coordinator shall appoint an administrator, whose task is to monitor-, maintain-, improve- and extend the database. Furthermore, the administrator shall not use the Data or Database for any other purpose than those explicitly mentioned in this article 3.9.

4. Obligations of the Parties

4.1. Each Party shall use the time and care necessary for conduct of the Study as required to achieve an optimum result. The Parties shall conduct work-related discussions and agree on the progress of the work at reasonable intervals, involving the employees entrusted with the project-related work.

4.2. Each Party ensures:

a) It has obtained the Data with due observance of the rights of the patients involved and in compliance with all applicable laws and regulations, including without limitation privacy and medical secrecy laws, and, to the extent applicable, the Declaration of Helsinki.

b) It has the authority to include the Data in the Database and, where legally required and relevant, it has obtained appropriate informed consents from all the patients involved, or approval from the applicable ethical review board has been obtained in compliance with applicable laws and regulations.

4.3. Each Party shall provide the staff and in-kind contributions required for the conduct of the Cooperation Study as is necessary on its part and bear the corresponding costs.

4.4. Each Party undertakes to notify promptly the other Parties any significant information, fact, problem or delay likely to affect the Consortium.

4.5. Each Party shall promptly provide all information reasonably required by the Steering Committee or the Coordinator to carry out its tasks.

4.6. Although each of the Parties will use reasonable endeavors to carry out its tasks under this Consortium Agreement and a particular Study, no party undertakes that any Study will lead to any particular result, nor does it guarantee a successful result of the Consortium.

5. Governance Structure

5.1. The Steering Committee is the decision making body of the Consortium.

5.2. The Steering Committee shall consist of the PI of each Party (hereinafter referred to as **"Member").** Each Party shall have the right to remove and replace its Members at its discretion from time to time, and to designate alternates for any meeting of the Steering Committee.

5.3. The Steering Committee will

a) generally coordinate the Parties' activities relating to this Consortium Agreement

b) consider new Studies to be conducted under this Consortium Agreement;

c) decide on important changes to the scientific part of a Study, such as redirecting of Study activities, in other words, decision-making concerning aims and priorities of the Study;

d) make proposals for changes to and/or amendments of this Consortium Agreement to be authorized by the official signatories of each Party in accordance with Article 18;

e) give notice requiring that a substantial breach of a Party's obligation has to be remedied according to article 9.1

f) decide whether a new party can join the Study and become a signatory/ Party to this Agreement

5.4. The Parties agree to abide by all decisions of the Steering Committee. This does not prevent the Parties from submitting a dispute for resolution in accordance with the provisions of settlement of disputes in article 22.3 of this Consortium Agreement.

5.5. Each Party will, through its Member or his alternate, have one vote in the Steering Committee. Decisions will be taken by a majority of two thirds of the Parties except where a decision necessitates a change to the Consortium, the start or change of a Study, or a change to the allocation of any funding. In either of those cases, any decision must be unanimous. The chairman will have a casting vote. Defaulting Parties may not vote.

5.6. It is understood that a Party shall have a veto in case of decision making regarding its Data

5.7 The Parties will ensure that the Steering Committee meets at least every 6 months at venues to be agreed, or at any other time at the request of any of the parties. Meetings of the Steering Committee will be convened with at least twenty-one (21) days written notice in advance. That notice must include an agenda. Draft minutes of the meetings of the Steering Committee will be prepared by the chair of the meeting and sent to each of the parties within 21 days after each meeting.

5.8 The Coordinator shall chair all meetings of the Steering Committee, unless decided otherwise by the Steering Committee.

5.9. The Coordinator shall give notice in writing of a meeting to each Member as soon as possible and no later than 31 calendar days preceding a meeting

5.10. The Coordinator is responsible for the decision making and the day-to-day management for the Study and shall consist of representatives of the Coordinator.

5.11. The Coordinator shall:

a) be responsible to the Steering Committee for the day-to-day management of the Consortium;
b) be responsible for the financial administration of the Consortium as required by the any grant agreements;
c) monitor the implementation of decisions taken by the Steering Committee;
d) prepare progress reports as required by any grant agreement; and
e) monitor the progress of any Study.

5.12. The Coordinator shall not be entitled to act or to make legally binding declarations on behalf of any other Party.

5.13. If for some reason Radboudumc at some future stage is no longer able to perform its duties as Coordinator the Steering Committee will appoint a new coordinator.

5.14. The Steering Committee may from time to time recommend the addition of other institutions. Upon the agreement of all Parties additional institutions may be invited to participate in the Consortium. If the invited institutions decide to participate the Parties will amend this Consortium Agreement to include these institutions, with all Parties sharing equally in the rights and responsibilities described in this agreement.

6. Start and execution of a Study

6.1. The Steering Committee shall give advice when, under which terms and conditions and by which Parties a Study shall be conducted **("Study Participants").**

6.2. For each individual Study an agreement ("Study **Agreement")** and a protocol **("Protocol")** shall be made by the Study Participants. Prior to the start of a Study, the Study Agreement and the Protocol need to be approved by the Steering Committee and each involved Party. Each Study Agreement and Protocol will form an annex to this Consortium Agreement.

6.3. The terms of this Consortium Agreement shall apply to the Study Agreement. However the Study Participants, may deviate from the terms of the Consortium Agreement in the Study Agreement upon prior approval of the Steering Committee.

6.4. The Study Participants shall carry out the Study in accordance with the provisions of the Study Agreement, the Protocol and the applicable grant agreement (if any).

7. Financing

7.1. Each Party shall bear its own costs and expenses incurred by it in connection with this Consortium Agreement.

7.2. The Parties may request grants. In the event a grant is awarded the Party who requested the grant, shall reimburse the Parties their justified costs in accordance to conditions and budget as specified in the relevant grant agreement.

7.3. The Parties shall carry out its obligations and activities related to a Study in accordance with the relevant grant agreement.

7.4. If there is any conflict between the terms of this Consortium Agreement and a grant agreement, this Consortium Agreement will prevail in relation to the arrangements as between the Parties, but it will not affect the Parties' respective obligations to the funding body under the grant agreement.

8. Entering into force and effect and Duration

8.1. This Consortium Agreement shall enter into force on the Effective Date.

8.2. This Consortium Agreement shall remain in full force and effect until 1 September 2022 The Consortium Agreement may be terminated prematurely in accordance with the terms of this Consortium Agreement.

8.3 The Steering Committee is entitled to terminate the Consortium Agreement with immediate effect by registered letter towards a Party:

a) that is declared bankrupt or granted suspension of payments, or for which an application to that end is filed;
b) whose business is liquidated or discontinued;
c) that is in a situation of force majeure as described in Article 5.4, which has continued for a period longer than ninety (90) calendar days.

9. Defaulting Party

9.1. The Steering Committee may decide to declare a Party to be a Defaulting Party by written notice to all Parties and decide on the consequences thereof which may include a proposal to the other parties for termination of its participation in the Consortium Agreement.

9.2 If they unanimously agree to do so, the other Parties may terminate the Consortium Agreement with regard to a Defaulting Party and treat this Defaulting Party as having withdrawn from the Consortium with immediate effect by giving notice to that party if the breach has not been remedied within 30 (thirty) calendar days after receipt of written notice specifying the breach and requiring its remedy.

9.3. Any Defaulting Party terminating its participation in the Consortium Agreement shall continue to grant access to any of its Background IPR as if it had remained a Party for the whole duration of the Project.

10. Confidentiality

10.1. With due observance of article10.2 and article 10.3, a Receiving Party hereby undertakes to observe strict confidentiality in respect of the Confidential Information that it receives from a Providing Party, and to refrain from disclosing or using this Information without the prior written consent of the Providing Party.

10.2. A Receiving Party shall not use Confidential Information for purposes other than in direct relation with this Consortium Agreement. The Receiving Party shall treat the Disclosing Party's Confidential Information with at least the same degree of care as it would use in respect of its own confidential information of similar importance, but in any event a reasonable level of care. In particular, the Receiving Party shall not disclose, publish, disseminate or make accessible the Disclosing Party's Confidential Information, in whole or in part, in any way or form, to third parties other than to its employees or employees of Affiliates who have a need-to-know in connection with the performance of the Receiving Party's obligations under this Consortium Agreement.

10.3. In accordance with article 10.1 each Receiving Party undertakes that:

a) it shall not use any Confidential Information for any purpose other than the performance of its obligations or its enjoyment of rights under terms of this Agreement; and

b) it shall not disclose any confidential Information to any third party except with the Disclosing Party's prior written consent; and the receiving Party shall ensure that such confidential Information is disclosed only on a "need to know" basis; and

c) Confidential Information shall neither be copied, nor otherwise reproduced nor duplicated in whole or in part where such copying, reproduction or duplication have not been specifically authorized in writing by the disclosing Party.

10.4. The obligations contained in article 10.1 and 10.2 shall not apply if and to the extent that the Confidential Information:

a) has come into the public domain prior to, or after the disclosure thereof and in such case throug h no wrongful act of the receiving Party; or,

b) is already known to the receiving Party, as evidenced by written documentation in the possession of the receiving Party;

c) has been lawfully received from a third Party without restrictions or breach of this Consortium Agreement;

d) has been or is published without violation of this Consortium Agreement;

e) is acquired by the Receiving Party through independent discovery or creation;

f) this is required or permitted by or pursuant to the law or is ordered by a competent authority, whereby the receiving Party will notify the providing Party about the disclosure - if permitted - prior to this disclosure.

10.5. The Receiving Party is permitted to provide the Confidential Information to a professional advisor of the Receiving Party or one or more of its Affiliates if and to the extent that: (i) this information is reasonably necessary for the professional adviser or Affiliate in question in order to carry out his or her work; (ii) the professional adviser or Affiliate in question is bound by a duty of confidentiality that is equal to or extends beyond the duties of confidentiality stipulated in

this article 10; and (iii) the professional adviser of Affiliate in question is informed about the confidential nature ot the Confidential Information.

11. Intellectual Property Rights

11.1. This Consortium Agreement does not affect the ownership of any Intellectual Property in any Background IPR or in any other technology, design, work, invention, software, data, technique, Know-how, or materials that are not Results. The Intellectual Property in them will remain the property of the Party that contributes them to the Study (or its licensors). No license to use any Intellectual Property is granted or implied by this Agreement except the rights expressly granted in this Consortium Agreement.

11.2. All Results are available to all Parties for the purpose of execution of the relevant Study and for non-commercial research and education purposes.

11.3. Rights to Results shall be owned by the Party who carried out the work generating the Results, or on whose behalf such work was carried out.

11.4. If the work generating particular Results is carried out by more than one Party and if their intellectual contributions to such Results form an indivisible part thereof, these Parties shall have joint ownership of such Results **("Joint Results").** The share of ownership of each of the joint owners shall be determined in good faith, taking into account each owner's relative intellectual contribution to the joint Results.

11.5. In the event a Result is capable of protection by Intellectual Property Rights and one or more of the Parties wish to protect such Result, the Parties will, through the Steering Committee, consult and agree who will bear the cost of such protection. Intellectual Property Rights are applied for in the name of the owning Party or Parties.

11.6. To the extent not limited by pre-existing obligations towards third parties each Party grants the others a royalty-free, non-exclusive license to use its Background IPR and any Intellectual Property Rights subsisting therein, for the purpose of carrying out the Study, but for no other purpose.

11.7. All intellectual property rights relating to the software / database itself (including but not restricted to copyright, database law and trademark law) shall vest in the party who generated that database or software, unless it concerns rights on Data, specified in article 3.2.

12. Publication

12.1. Parties agree that it is the intention to publish the results of the Study. As a general rule regarding Publications on results of the Study, all Parties which contributed to the generation of specific results shall be granted the opportunity to be a co-author to the respective Publication. In all Publications authorship shall be subject to accepted academic standards for authorship as described in "Defining the Role of Authors and Contributors" (which can be found on http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html).

12.2. For the avoidance of doubt, no Party shall have the right to publish or allow the publishing of any data which constitutes Results, Background, IPR or Confidential Information of another Party, even where such data is amalgamated with such first Party's Foreground, Background, IPR or other information, document ormaterial.

12.3. A copy of any proposed Publication in connection with or relating to the Study shall be sent to the Steering Committee and by the Steering Committee to the Parties at the earliest time possible but ultimately 14 calendar days prior to the submission for Publication. Any of the Parties may object to the Publication within those fourteen (14) calendar days after receipt of a copy of the proposed Publication on any of the following grounds: (i) that the proposed Publication includes the Confidential Information of the objecting Party, or (ii) the Publication includes patentable matter. The proposed Publication shall not take place until the expiry of the above-mentioned period of 14 calendar days. In the absence of any objection within the above-mentioned period, it is deemed that the Parties agree to the proposed Publication. Following the end of the above-mentioned period, the Steering Committee shall inform the Parties whether or not any objection has been received.

12.4. A Publication can only be delayed, not withheld. In case of a situation as mentioned under i the objecting Party may delay (not block) the publication for a maximum of thirty (30) days, and to request the publishing Party to delete the confidential information. In case of a situation as mentioned in article ii the Publication can be delayed (not blocked) with a maximum period of thirty (30) days

13. Liability and Indemnification

13.1. None of the Parties makes any representation or gives any warranty to the other that any advice or information given by it or any of its employees who work on a Study, or the content or use of any Results, Background IPR or materials, works or information provided in connection with a Study, will not constitute or result in any infringement of third-party rights.

13.2. No Party shall be liable to any other Party for any costs or damages. In any event no Party shall be liable to any other Party for any indirect or consequential loss or similar damage such as, but not limited to, loss of profit, loss of revenue or loss of contracts.

13.3. Each Party shall be solely liable for any loss, damage or injury to third parties resulting from the performance of said Party's obligations under this Consortium Agreement or from its use of IPR, Knowhow, Background IPR or Data unless such loss, damage or injury is caused by gross negligence and/or willful misconduct of another Party.

14. Involvement of third parties

14.1. A Party that involves third parties (including, but not limited to, Affiliated Entities) to conduct certain tasks shall at all times remain responsible for the execution of its relevant part of a Study and for such third party's compliance with the provisions of this Consortium Agreement. It has to ensure that the involvement of third parties does not affect the rights and obligations of the other Parties under this Consortium Agreement. In addition, a Party is only allowed to involve third parties in the execution of its work under a Study upon prior approval thereof by the other Parties.

15. Termination **with regard to a Party/Right to Withdraw**

15.1. Any individual Party can terminate its participation to this Consortium Agreement by giving each of the other parties thirty (30) days prior written notice.

15.2. A terminating or terminated Party may not recover from any of the other parties any of its costs incurred in connection with the Project to the extent that those costs were incurred after the date of its withdrawal from any of the other Parties.

15.3. Any Party terminating its participation or whose participation has been terminated shall have no rights whatsoever with regard to Results created after the moment the termination of its participation becomes effective, unless the Steering Committee unanimously decides otherwise.

15.4. All rights to use any other Party's Intellectual Property granted under this Agreement to a Party that withdraws or that is treated as having withdrawn from the Project in accordance with clause 10.1, will cease immediately.

15.5. All rights to use the withdrawing Party's Intellectual Property and Data granted under this Agreement to any of the other Parties, will continue to exist until the termination of this Agreement or termination of the PSMA Consortium. On termination of this Agreement the Party terminating the Agreement shall withdraw its Data from the Database for future projects.

16. Notices

16.1. Any notices required to be given or which shall be given under this Consortium Agreement shall be in writing delivered by registered mail addressed to the Parties.

17. Assignment

17.1. This Consortium Agreement shall not be assignable by any Party without the prior written consent of all of the other Parties.

18. Independent Contractors

18.1. For the purposes of this Consortium Agreement and all services to be provided hereunder, each of the Parties shall be, and shall deemed to be, an independent contractor and not an agent or employee of any of the other Parties. None of the Parties shall have authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on any of the other Parties, except as may be explicitly authorized by any of the other Parties in writing.

19. Entire Agreement

19.1. Unless otherwise specified, this Consortium Agreement (including the annexes thereto) embodies the entire understanding between the Parties, and any prior or contemporaneous representations, agreements and/or understandings, either oral or written, are hereby superseded.

20. Amendments

20.1. This Consortium Agreement may not be amended, supplemented, or otherwise modified except by a unanimous decision of the Steering Committee in accordance with Article 5 of this Consortium Agreement and made in writing and signed by an authorized signatory of each of the Parties.

21. Force Majeure

21.1. A failure in the performance of this Consortium Agreement cannot be imputed or assumed to a Party to the extent it is due to Force Majeure. Each Party will notify the other Parties in writing of any situation of Force Majeure as soon as possible. The Parties shall discuss in good faith the

possibilities of a transfer of tasks affected by the event. Such discussions shall commence as soon as reasonably possible. If such Force Majeure event is not overcome within 60 (sixty) days after such notification, the transfer of tasks shall be carried out, unless an extension is agreed by the Parties

22. Governing Law and Dispute Resolution

22.1. This Consortium Agreement and all subsequent agreements arising from this Consortium Agreement is exclusively governed by the laws of the Netherlands excluding the conflict of law provisions.

22.2. In the event a dispute arises between the Parties in connection with this Agreement, then the Parties, represented by their designated contact persons, will initially attempt to arrive at an amicable settlement to the dispute within 30 (thirty) working days. In the event the Parties do not succeed in arriving at an amicable settlement within the aforementioned period, at the request of one Party, the dispute will be escalated to the management level, and the representatives from the Parties' board of directors will consult with one another and attempt again to arrive at an amicable settlement to the dispute within 30 (thirty) working days. During the aforementioned stages of consultation, the Parties will conduct themselves in accordance with the rules of reasonableness and professionalism. If the Parties still fail to arrive at an amicable settlement during the aforementioned consultation activities and within the aforementioned period, the Parties are permitted to submit the dispute to the court referred to in article 22.3. This article 22.2 does not limit the Parties in their option to petition the preliminary relief court judge for injunctive relief ("kort geding').

22.3. All disputes arising out of or in connection with this Consortium Agreement or any agreement arising from this Consortium Agreement that cannot be settled amicably, shall be referred exclusively to the competent courts of The Hague, the Netherlands

23. Severability

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

SIGNED BY EACH PARTY ON A SEPARATE PAGE

Authorised to sign on behalf of: VU University Medical Center

Signature

Name: dr. ir. F. Beeftink

Title: managing director Division 7

Date: 10/2/2010

For Read & Agreed

Principal Investigator Daniela E. Oprea-Lager

Sign

Name

10-2-2010

TTO-file A18-0529

Authorised to sign on behalf of: **Radboud University Medical Center**

Signature:

Name: Joram Sjoens Msc i/a Dr E. Caldenhoven

Title: Director Valorisation Head QSO

Date: 04.06.2019

Sign:

Prof. dr. M. Prokop

Head of the Department of Radiology and Nuclear Medicine

Date: 9-6-2020

For Read & Agreed

Principal Investigator

Sign:

Name: Professor Fred Verzijbergen

26-05-2020

Authorized to sign on behalf of: Universitair Medisch Centrum Groningen

Signature:

Name: Prof. Dr. M. Joels

Title: Dean and member of the Board of Directors

Date: 19-05-2020

For Read & Agreed

Principal Investigator

Sign:

Name: Mrs. Dr. A.H. Brouwers

Annex I: General Project Plan

Gallium-68 (Ga-68)-/Fluor-18-PSMA PET/CT prostate cancer registration study

1. **Introduction:** prostate cancer (PCa) is the most frequently diagnosed cancer in males with 11,000 new cases in the Netherlands per year. PET/CT with emerging radiopharmaceuticals promises accurate staging of primary disease, restaging of recurrent disease, detection of metastatic lesions and, ultimately, prediction of aggressiveness of disease. Prostate-specific membrane antigen (PSMA) is a well-characterized imaging biomarker of PCa. Because PSMA levels are directly related to androgen independence, metastases and progression, PSMA could prove an important target of new radiopharmaceuticals for PET. The ^{68}Ga-(HBED- CC)-PSMA and ^{18}F-PSMA-1007/^{18}F-PSMA-DCFPyL compounds were recently developed in Heidelberg. The PSMA-scan is both sensitive and specific for localizing even small amounts of cancer cells in different stages of prostate cancer. Contrary to anatomical imaging techniques PSMA-scan provides functional and anatomical findings, not only in the pelvic area but also in bone and visceral structures in the rest of the body.

   Although PSMA PET/CT imaging is hardly represented in current guidelines, the scans are already increasingly applied in different stages of prostate cancer, but the consequences of the results of the scan are not fully understood yet, especially when it comes to impact on disease free survival, survival as such and quality of life.

2. Aim of the study: despite the fact that PSMA-scans were recently introduced and are not fully recommended in recent guidelines many patients are already imaged throughout the country each day.

   We aim at registering all PSMA-scans in the Netherlands with the intention to gain a better understanding of the indications for and the consequences of implementation of the scans. Primary outcome measures: what is the impact of the PSMA-scan on the treatment strategy during primary staging and during PSA-recurrence after radical prostatectomy. One of the most important secondary outcome measures: what are the detection rates of the PSMA-scan at different levels of PSA.

   Moreover, registration of all PSMA studies in a database facilitates prostate cancer trials related to different clinical questions. These trials will be performed by the participating centres.

3. **Study design:** registration study without any direct consequences for the patient.

4. Method: the registry-database is called imPRINT. The clinician delivers the desired clinical information and is requested to give a description of the expected consequences of the scan findings.

   Only after informed consent, patient data will be copied into the **imPRINT** registry-database. All data in the database are encrypted and fully anonymized. Parties that are authorized to have insight in the registered data are the research team, monitoring committees, authorized members of the Medical Ethical Committees of the participating hospitals and authorized members of the Inspection of Healthcare.

5. Nature **and extent of the burden and risks associated with participation:** The patient is requested to read the Patient Information Form of the imPRINT study. Only after written informed consent, the data of the patient will be registered. Participation in the study does not influence the procedure of the application, the planning nor the result of the PSMA PET/CT scan. There are no extra questionnaires to be filled in by the patient.

   Participation in the imPRINT study does not generate extra costs for the patient.

Annex II: Accession Document

ACCESSION

of a new Party to

PSMA **Consortium Agreement, version** 1 July 2020

[OFICIAL NAME OF THE NEW PARTY]

hereby consents to become a Party to the Consortium Agreement identified above and accepts all the rights and obligations of a Party starting [date].

{OFFICIAL NAME OF THE COORDINATOR]

hereby certifies that the consortium has accepted in the meeting held on [date] the accession of [the name of the new Party] to the consortium starting [date1

This Accession document has been done in 2 originals to be duly signed by the undersigned authorized representatives.

Date: [Date and Place]

[INSERT NAME OF THE NEW PARTY]

Signature(s)
Name(s)
Title(s)

Date: [Date and Place]

[INSERT NAME OF THE COORDINATOR]

Signature(s)
Name(s)
Title(s)