

CONSORTIUM AGREEMENT for PPP PROJECTS

THIS CONSORTIUM AGREEMENT FOR PPP PROJECTS (the “**Consortium Agreement**”) is signed on [date] (the “**Effective Date**”) by and between:

1. **[Coordinator]**, incorporated under [nationality] law, having its statutory seat [in place, country] and its address [address] and registered with the [nationality] Chamber of Commerce under number [number], hereinafter referred to as the “**Project Coordinator**”;
2. **[Research Organisation]**, incorporated under [nationality] law, having its statutory seat [in place, country] and its address [address] and registered with the [nationality] Chamber of Commerce under number [number], hereinafter referred to as the “**Research Organisation**”;
3. **[Industrial Partner X]**, incorporated under [nationality] law, having its statutory seat [in place, country] and its address [address] and registered with the [nationality] Chamber of Commerce under number [number], hereinafter referred to as the “**[Industrial Partner x]**”;

Each of the parties hereinafter also referred as “a **Party**” and together as “the **Parties**”.

WHEREAS:

- A. The Dutch Top Sector Life Sciences and Health (*‘Topconsortium voor Kennis en Innovatie’* or *‘TKI Life Sciences and Health’*) is represented by Stichting Life Sciences Health – TKI (also acting under its trade name Health-Holland, hereinafter referred to as “**Stichting LSH-TKI**”), tasked by the Dutch government to promote and stimulate new public-private partnerships to undertake research and development projects in the life sciences;
- B. To promote such partnerships, the Minister of Economic Affairs and Climate Policy has allocated certain funds to Stichting LSH-TKI, to grant allowances to projects under the TKI-programme Life Sciences & Health (each such allowance a “**PPP Allowance**”);
- C. Parties desire to start a research project titled [title] (the “**Project**”) within the scope of the TKI-programme Life Sciences & Health and have submitted an application to Stichting LSH-TKI for the grant of such PPP Allowance to the Project (the “**Project Application**”);
- D. In addition to the applicable conditions of the PPP Allowance grant agreement (the “**PPP Allowance Agreement**”) to be signed between the Parties and Stichting LSH-TKI upon approval of the Project Application, Parties desire to specify the binding commitments among themselves with regard to the project and the work to be allocated thereunder as set out in the “**Project Plan**”, all in accordance with the terms and conditions of this Consortium Agreement;
- E. The Parties agree that in case Stichting LSH-TKI does not grant the PPP Allowance as applied for, this Agreement will be terminated, except for the confidentiality provisions that will survive termination;

NOW, THEREFORE, IT IS HEREBY AGREED AS FOLLOWS:

Article 1. **Definitions**

- 1.1. “**Access Rights**” means any license and/or user rights to a Party’s Background or Foreground;
- 1.2. “**Affiliate**” means the legal entity that is either the ultimate parent company of a Party or that is under the direct or indirect control of a Party, or under the same direct or indirect control as the Party, control taking any in the following forms:
 - a. the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
 - b. the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.
- 1.3. “**Background**” means all information or material held by a Party prior to its participation to this Consortium Agreement or that has been developed or obtained by a Party after the Effective Date of this Consortium Agreement independently from the Project, as well as any intellectual property rights pertaining to such information or material;
- 1.4. “**Budget**” means the estimate of the total cost to carry out the Project Plan, pursuant to the requirements of the PPP Allowance Agreement and including an overview of the contributions of each Party to the Project, as attached to the PPP Allowance Agreement in Annex 2;
- 1.5. “**Chairperson**” means the person appointed by the Project Committee to chair the Project Committee’s meetings. The Chairperson is the Coordinator or the Coordinator’s representative unless no Coordinator is appointed or if the Coordinator is subject to a decision of the Project Meeting to replace the Coordinator or declare the Coordinator a Defaulting Party;
- 1.6. “**Consortium Agreement**” means this consortium agreement as well as all annexes hereto;
- 1.7. “**Defaulting Party**” means a Party which the Project Committee has declared to be in substantial breach of its obligations under this Consortium Agreement or the PPP Allowance Agreement in accordance with Section 6.5 of this Consortium Agreement;
- 1.8. “**Effective Date**” means the date first written in the pre-amble;
- 1.9. “**Foreground**” means any (tangible or intangible) output, such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated by a Party under the Project, as well as any rights attached to it, including intellectual property rights;
- 1.10. “**Member**” has the meaning assigned to it in Section 6.1;
- 1.11. “**Option**” has the meaning assigned to it in Section 8.5 of this Consortium Agreement;
- 1.12. “**PPP Allowance**” means the PPP Allowance applied for in the Project Application in relation to the Project;
- 1.13. “**PPP Allowance Agreement**” means the PPP Allowance grant agreement (to be) signed between the Parties and Stichting LSH-TKI, under which agreement Stichting LSH-TKI grants the PPP Allowance to the Parties subject to the terms and conditions set out in the PPP Allowance Agreement;

- 1.14. **“PPP Allowance Regulation”** means the Dutch regulation of the Minister of Economic Affairs of July 11, 2014, published in the Staatscourant 2014, nr. 20679 including any legislative instrument superseding, amending, or replacing this regulation (‘Regeling nationale EZ-subsidies’) and the corresponding legislation, including but not limited to the Dutch decision of the Minister of Economic Affairs of November 21, 2008 published in the Staatscourant 2008, nr. 499, (‘Kaderbesluit nationale EZ-subsidies’) including any legislative instrument superseding, amending, or replacing this decision.
- 1.15. **“Project”** means the research project titled [title] first set out in the Project Application;
- 1.16. **“Project Committee”** has the meaning assigned to it in Section 6.1;
- 1.17. **“Project Plan”** means the research (and development) Project and all work to be performed as part of this Project including the allocation of the work and Budget, as set out in Annex 1 to the PPP Allowance Agreement;
- 1.18. **“Project Application”** means the research (and development) project submitted to Stichting LSH-TKI in the TKI-LSH match application form;
- 1.19. **“Stichting LSH-TKI”** means the Stichting Life Sciences and Health, also acting under its trade name Health~Holland, representing the Dutch Top Sector Life Sciences and Health (‘*Topconsortium voor Kennis en Innovatie*’ or ‘*TKI Life Sciences and Health*’);

Article 2. Purpose

- 2.1. Purpose. The purpose of this Consortium Agreement is to specify with respect to the Project the relationship among the Parties, in particular concerning the organisation of the work between the Parties as set out in the Project Plan in Annex 1 and in accordance with the Budget set out in Annex 2, the management of the Project and the rights and obligations of the Parties.
- 2.2. PPP Allowance Regulation. The Parties acknowledge that the PPP Allowance Regulation applies to the PPP Allowance and Parties agree to adhere to the terms and conditions of the PPP Allowance Regulation as applicable under this Consortium Agreement.

Article 3. Entry into force, duration and termination

- 3.1. Term. This Consortium Agreement shall enter into effect as of the Effective Date and shall continue in full force and effect until all obligations undertaken by the Parties under the Grant Agreement and under this Agreement are completed, unless the Agreement is terminated earlier in accordance with this Article 3.
- 3.2. New Party. A new entity becomes a Party to the Consortium Agreement upon written agreement of the Project Committee and the new entity’s signature of the Consortium Agreement. Such accession shall have effect from the date of signature.
- 3.3. Termination of the Agreement. This Consortium Agreement shall be automatically terminated upon rejection of the Project Application by Stichting LSH-TKI and may be terminated by the Parties upon mutual written agreement in the event that the PPP Allowance Agreement has been terminated, provided that such termination is allowed in accordance with article 3.1. of the Revised CCMO Directive on the Assessment of Clinical Trial Agreements of 30 August 2011.

Opmerking [L1]: Deze tekst dient te worden opgenomen in het geval dat het Project (gedeeltelijk) betrekking heeft op een klinische studie waarvoor toestemming dient te worden verkregen van een METC / CCMO in overeenstemming met de CCMO-richtlijn Beoordeling onderzoekscontracten. In andere gevallen is deze tekst niet relevant en dient deze te worden weggelaten.

3.4. Termination of a Party's Participation. The Project Committee is entitled to terminate a Party's participation to the Consortium Agreement with immediate effect upon written notice by the Coordinator or, if the Coordinator is subject to the termination, the Party appointed by the Project Committee, towards that Party, in the following events:

3.4.1. Insolvency. If a Party is declared insolvent or granted suspension of payments, or a insolvency / winding-up petition has been filed in respect of such Party to that end or its business is liquidated, dissolved or discontinued;

3.4.2. Decision METC. If the judgement of the competent medical research ethics committee that has assessed the Project is irrevocably revoked;

3.4.3. In the Interest of the Research Subjects. If a reasonable case can be made for terminating the Project in the interests of the health of the research subjects;

3.4.4. Scientific Purpose. If it transpires that continuation of the Project cannot serve any scientific purpose, and this is confirmed by the medical research ethics committee that has issued a positive decision on the Project;

3.4.5. Principal Investigator. If the principal investigator is no longer capable of performing the tasks of the principal investigator, and no replacement agreeable to all Parties can be found;

3.4.6. Force Majeure. If circumstances beyond the control of the Parties or investigator make it unreasonable to require the Project's continuation or a Party is in a situation of force majeure as described in Article 5.6, which has continued for a period longer than ninety (90) days.

3.5. Defaulting Party. The Project Committee is further entitled to terminate a Party's participation to the Consortium Agreement in the event that it identifies a breach by a Party of its obligations under this Consortium Agreement or the PPP Allowance Agreement (e.g. improper implementation of the project). The Coordinator or, if the Coordinator is in breach of its obligations, the Party appointed by the Project Committee, will give written notice to such Party requiring that such breach will be remedied within 30 (thirty) calendar days from the date of receipt of the written notice by the Party. If such breach is substantial and is not remedied within that period or is not capable of remedy, the Project Committee may decide to declare the Party to be a Defaulting Party and to decide on the consequences thereof, which may include termination of its participation unless failure to comply is not in reasonable proportion to the premature termination of the Project.

A Party that is declared a Defaulting Party shall bear all actual and reasonable costs incurred by the other Parties under the Project as a result of the Defaulting Party's breach of obligations, provided that the reimbursement of such cost towards the other Parties collectively shall be limited to once the Party's share of the total costs of the Project. Any excess amount shall be apportioned to the remaining Parties pro rata to their share in the total costs of the Project as identified in the Budget.

The Project Committee is further entitled to recover any payments already paid to the Defaulting Party until the effective date of the declaration of the Party as a Defaulting Party.

3.6. Voluntary Termination by a Party. A non-Defaulting Party may request the Project Committee to terminate its participation in the Project and to this Consortium Agreement. Any Party leaving the Project shall continue to grant Access Rights pursuant to this Consortium Agreement as if it had

Opmerking [L2]: Deze tekst dient te worden opgenomen in het geval dat het Project (gedeeltelijk) betrekking heeft op een klinische studie waarvoor toestemming dient te worden verkregen van een METC / CCMO in overeenstemming met de CCMO-richtlijn Beoordeling onderzoekscontracten. In andere gevallen is deze tekst niet relevant en dient deze te worden weggelaten.

Opmerking [L3]: Toevoeging enkel in het geval dat het Project (gedeeltelijk) betrekking heeft op een klinische studie waarvoor toestemming dient te worden verkregen van een METC / CCMO in overeenstemming met de CCMO-richtlijn Beoordeling onderzoekscontracten.

remained a Party for the whole duration of the Project and such Party shall repay any payments already received by this Party until the effective date of the termination.

- 3.7. Survival. The following Sections 2.2, 3.7, 11.4 and Articles 8, 9, 10 and 12 shall survive termination of this Consortium Agreement. Termination shall not affect any rights or obligations of a Party leaving the Consortium incurred prior to the date of termination, unless otherwise agreed between the Project Committee and the leaving Party. This includes the obligation to provide all input, deliverables and documents for the period of its participation.

Opmerking [L4]: Toevoeging enkel in het geval dat het Project (gedeeltelijk) betrekking heeft op een klinische studie waarvoor toestemming dient te worden verkregen van een METC / CCMO in overeenstemming met de CCMO-richtlijn Beoordeling onderzoekscontracten.

Article 4. **Responsibilities of the Parties**

- 4.1. General Principles. Each Party agrees to take part in the efficient implementation of the Project, in accordance with the Project Plan, and to cooperate, perform and fulfil, promptly and on time, all of its obligations under this Consortium Agreement and the PPP Allowance Agreement as may be reasonably required from it and in good faith as required by Dutch law.
- 4.2. Information Obligations. Each Party undertakes to promptly notify the Project Committee through the Coordinator of any significant information, fact, problem or delay likely to affect the Project. Each Party shall promptly provide all information reasonably required by the Project Committee through the Coordinator to carry out its tasks. Each Party shall take reasonable measures to ensure the accuracy of any information (including Background and Foreground) or material it supplies to the other Parties.
- 4.3. Involvement of Third Parties. A Party is only allowed to involve third parties in the execution of its work under the Project upon prior approval thereof by the other Parties. A Party that involves third parties (including, but not limited to, Affiliates) in the Project shall at all times remain responsible for the execution of its relevant part of the Project and for such third party's compliance with the provisions of this Consortium Agreement. Such Party shall ensure that the involvement of third parties does not affect the rights and obligations of the other Parties under this Consortium Agreement.
- 4.4. Reporting. In connection with the conditions and reporting requirements as set out in the PPP Allowance Agreement and with regard to the Foreground as referred to in Section 8.3 below, Parties shall provide the Coordinator with financial, scientific and progress reports with regard to the Project.

Article 5. **Warranties and Liability**

- 5.1. Warranties. Each Party represents and warrants to the other Parties that it has full power, authority and legal capacity to execute and to perform its obligation(s) under this Agreement, and the conclusion of this Agreement does not violate any of its contractual or other obligations.
- 5.2. No Further Warranties. In respect of information or materials, Background and Foreground supplied by one Party to another under the Project, no warranty or representation of any kind is made, given or implied as to the sufficiency, accuracy or fitness for purpose of such information, nor as to the absence of any infringement of any proprietary rights of third parties. The receiving Party shall be entirely and solely liable for its use of the information and materials, Background and Foreground provided by another Party under this Consortium Agreement.

Each Party shall be fully liable for the performance of any part of its part of the Project as set out in the Project Plan, in respect of which it enters into any contract with a third party (*i.e.* a subcontractor).

- 5.3. Liability to Third Parties. Subject to such other undertakings as are provided for in this Consortium Agreement, each Party shall be solely liable for any loss, damage or injury to third parties resulting from its carrying out its parts of the Project and from its use of the Access Rights to the Background and Foreground, unless such liability on the use of Access Rights is expressly agreed upon between the Parties in writing.
- 5.4. Indemnification. Each Party shall indemnify each of the other Parties for any damages resulting from (i) gross negligent acts or omissions or willful misconduct or a breach or default by that Party (including its employees, agents and subcontractors) of its representations or obligations set forth in this Consortium Agreement, except and to the extent that such damages are caused by another Party's gross negligent acts or omissions or willful misconduct or a breach or default by another Party (including) its employees, agents and subcontractors) of any of its representations, warranties or obligations set forth in this Consortium Agreement.
- 5.5. Limitation of Liability. Any indemnification obligation as referred to under Section 5.4 shall not extend to claims for indirect or consequential loss or damages such as but not limited to loss of profit, revenue, contract or the like. The total aggregate liability of each Party under this Consortium Agreement to all of the other Partners collectively in respect of any and all such claims shall not exceed that Partner's budget as foreseen in the Budget, except for and to the extent that such damage was caused by a wilful act or gross negligence.
- 5.6. Force Majeure. No Party shall be considered to be in breach of this Consortium Agreement if such breach is caused by force majeure. Each Party will promptly notify the Coordinator of any force majeure. If the consequences of force majeure for the Project are not overcome within 90 (ninety) days after such notification, the Project Committee may decide on transfer of tasks of the Party concerned or terminate the Party's participation in accordance with Section 3.4.

Article 6. **Project Committee and Coordinator**

- 6.1. Project Committee. The Project Committee is responsible for strategic and scientific management of the Project. The Project Committee shall consist of one representative from each Party (hereinafter referred to as "**Member**"). Each Member shall be deemed to be duly authorised to deliberate, negotiate and decide on all matters listed in Section 6.5 of this Consortium Agreement. The Coordinator shall chair all meetings of the Project Committee, unless decided otherwise by the Project Committee.

The Parties agree to abide by all decisions of the Project Committee. This does not prevent the Parties from submitting a dispute for resolution in accordance with the provisions of settlement of disputes in Article 12 of this Consortium Agreement.

- 6.2. Operational procedures for the Project Committee

6.2.1. *Representation in meetings.* Any Member shall use its best efforts to be present or represented at any meeting, and may appoint a substitute or a proxy to attend and vote at any meeting and shall participate in a cooperative manner in the meetings.

6.2.2. *Preparation and organisation of meetings.* The Chairperson shall convene ordinary meetings of the Project Committee at least once every 6 (six) months and shall also convene extraordinary meetings at any time upon written request of any Member.

6.2.3. *Notice of a meeting.* The Chairperson shall give notice in writing of a meeting including an agenda, to each Member as soon as possible and no later than 14 (fourteen) calendar days preceding an ordinary meeting and 7 (seven) calendar days preceding an extraordinary meeting.

6.2.4. *Agenda.* Any agenda item requiring a decision by the Members must be identified as such on the agenda. Any Member may add an item to the original agenda by written notification to all of the other Members no later than 7 (seven) calendar days preceding the meeting. During a meeting of the Project Committee the Members can unanimously agree to add a new item to the original agenda, provided that all Members are present or represented.

6.2.5. *Decision outside the Meeting.* Any decision may also be taken without a meeting if the chairperson circulates to all Members a written document which is then signed by the unanimity or the defined majority of Members.

6.2.6. *Binding Decisions.* Decisions will only be binding once the relevant part of the minutes has been accepted according to Article 6.4 of this Consortium Agreement.

6.3. Decision-making by the Project Committee

6.3.1. *Voting rules and quorum.* Decisions shall be taken by a majority of the votes validly cast at a meeting where at least three-quarters of the Members are present or represented, provided that decisions on the entry of new parties to the Consortium Agreement are to be taken unanimously by the Members of the Project Committee in meetings where all Members are present or represented subject to Section 6.3.3. below.

6.3.2. *Votes.* Each Member or its representative shall have one vote. Defaulting Parties have no vote.

6.3.3. A Party may not vote with regard to the decision relating to its identification to be in breach of its obligations nor to its identification as a Defaulting Party. A Party requesting to leave the consortium may not vote to decisions relating thereto.

6.4. Minutes of Meetings.

6.4.1. *Minutes of meetings.* The Chairperson shall produce written minutes of each meeting which shall be the formal record of all decisions taken. He shall send draft minutes to all Members within 14 (fourteen) calendar days of the meeting.

6.4.2. *Corrections.* The minutes shall be considered as accepted if, within 14 (fourteen) calendar days from sending, no Member has objected in writing to the Chairperson with respect to the accuracy of the draft of the minutes.

6.4.3. The Chairperson shall send the accepted minutes to all the Members of the Project Committee and to the Coordinator, who shall safeguard them. If requested, the Coordinator shall provide authenticated duplicates to Parties.

6.5. Decisions of the Project Committee. The Project Committee shall be free to act on its own initiative to formulate proposals and take decisions in accordance with the procedures set out herein. The following decisions shall be taken by the Project Committee:

- a. changes to the Project Plan;
- b. changes to the Budget;
- c. withdrawals or adjustments to the Background set out in Annex 1;
- d. determine whether certain Background or Foreground falls within the scope of the Access Rights granted under Section 9.3;
- e. entry of a new Party to the Project and approval of the settlement on the conditions of the accession of such a new Party;
- f. withdrawal of a Party from the Project and the approval of the settlement on the conditions of the withdrawal;
- g. declaration of a Party to be a Defaulting Party;
- h. remedies to be performed by a Defaulting Party;
- i. termination of a Defaulting Party's participation in the Project and measures relating thereto;
- j. change of the Coordinator;
- k. appoint or change the Chairperson;
- l. suspension of all or part of the Project;
- m. termination of the Project and the Consortium Agreement.

6.6. Stichting LSH-TKI and Project Committee. The Coordinator shall inform Stichting LSH-TKI on any decisions by the Project Committee pursuant to Section 6.5 (a) to (c), within 1 (one) week after such decisions have become final following the procedure outlined in Section 6.4.

6.7. Coordinator. The Coordinator coordinates and manages the Project and represents the Parties before Stichting LSH-TKI. Parties appoint [party] as Coordinator and authorize Mr/Mrs to carry out the tasks set forth under this Section 6.7 and Section 6.8.

6.8. In particular, the Coordinator shall be responsible for:

- a. preparing the meetings, proposing decisions and preparing the agenda of Project Committee chairing the meetings, preparing the minutes of the meetings and monitoring the implementation of decisions taken at meetings;
- b. monitoring compliance by the Parties with their obligations;
- c. keeping the address list of Members and other contact persons updated and available;
- d. collecting and reviewing information on the progress of the Project and submitting outline scientific reports and other deliverables (including financial statements and related certification), if required, to Stichting LSH-TKI and other Parties;
- e. transmitting promptly documents and information connected with the Project;
- f. administration of the Budget and fulfilling the financial tasks, all as described in Article 7;
- g. providing, upon request, the Parties with official copies or originals of documents which are in the sole possession of the Coordinator when such copies or originals are necessary for the Parties to present claims.

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

6.9. Replacement of the Coordinator. If the Coordinator fails in its coordination tasks and the Project Committee has decided to replace the Coordinator in accordance with Section 6.5, the Project Committee shall inform Stichting LSH-TKI of the change of the Coordinator.

Article 7. **Financial provisions**

- 7.1. Contribution. The contribution in cash or in kind (other than the Background) provided by each Party is set out in the Budget. The Budget shall be valued in accordance with the usual accounting and management principles and practices of the respective Parties.
- 7.2. Obligations Coordinator. Parties acknowledge that any PPP Allowance by the Stichting LSH-TKI will be allocated to the Coordinator and the Coordinator shall distribute the PPP Allowance between the Parties, if applicable, as set out in the Budget. The Coordinator shall undertake to keep the PPP Allowance for the Project separated from its normal business accounts, its own assets and property. The Coordinator shall perform diligently its tasks in the proper administration and distribution of the Project Budget and in maintaining financial accounts. The Coordinator shall provide Stichting LSH-TKI each year with an overview of the actual payments made under this Agreement, including a copy of the relevant bank account transaction or an audit certificate prepared and certified by an independent auditor, before April 1 of the following year.
- 7.3. Accounting. Each Party is solely responsible for the administration and accounting of the cost incurred with respect to the Project. In the event that an audit certificate is required, such certificate by an independent auditor shall be provided at the Party's own cost.

Article 8. **Foreground**

- 8.1. Ownership. Any Foreground generated under or in connection with the Project that is conceived solely by one Party shall be exclusively owned by that Party and that Party shall be responsible for securing ownership of such Foreground from its employees, students and other agents.
- 8.2. Joint Ownership. Any Foreground generated under or in connection with the Project that is conceived by more than one Party and for which Foreground it is not possible to (i) establish the respective contribution of each Party, or (ii) separate their contribution for the purpose of applying for, obtaining or maintaining protection of the Foreground, shall be jointly owned by such Parties.
- 8.3. Disclosing the Foreground. Each Party shall promptly disclose in confidence to the Coordinator all Foreground generated by it under the Project, during the term of this Agreement. The Coordinator shall further disclose such Foreground in confidence to the other Parties by providing a **monthly** report on such generated Foreground.
- 8.4. Exploitation of Foreground. Subject to Section 8.5 and 8.6, each Party shall have the right to exploit such Foreground solely owned by it, and each owner of joint Foreground shall be entitled to use the jointly owned Foreground, unless otherwise agreed in a joint ownership agreement to be concluded between the joint owners before any exploitation of Foreground takes place:
 - 8.4.1. for non-commercial purposes such as academic research and third party research, as well as training and teaching activities, on a royalty-free basis, and without requiring the prior consent of the other joint owner(s); and
 - 8.4.2. to grant nonexclusive licences to third parties (without any right to sublicense) for commercial purposes, if the other joint owners are given (i) at least 45 (forty-five) days advance notice and (ii) fair and reasonable compensation taking into account each joint owner's relative intellectual contribution to the joint Foreground.

- 8.5. Option. In the event that Foreground is owned by the Research Organisation, the Research Organisation shall grant the Industrial Partner that has contributed substantially to the Research Organization's activities under the Project an option to negotiate an exclusive license or transfer of ownership of such Foreground (the "**Option**"). A contribution in cash or in kind at least 5% (five percent) of the cost budgeted in the Budget for the activities of the Research Organization under the Project shall be considered 'substantial'.

In the event that the Foreground is owned jointly by the Research Organization receiving a substantial contribution and an Industrial Partner and/or Research Organization not receiving a substantial contribution, the Option shall concern the share of the first Research Organization in such joint Foreground.

If more than one Industrial Partner has made a substantial contribution, the Option shall be exclusively granted to the Industrial Partner that has contributed the Background to which the Foreground constitutes an improvement. If (i) such Industrial Partner informs the Research Organization in accordance with Section 8.6, that it declines the Option, or if (ii) the Foreground does not constitute such improvement or if (iii) there is more than one Industrial Partner that has provided such Background, the Option shall exclusively be granted to the Industrial Partner that has made the actual, substantial contribution of the highest value in cash or in kind. If such Industrial Partner informs the Research Organization in accordance with Section 8.6, that it declines the Option, or if (ii) the value of the substantial contribution by the Industrial Partners is equal, the Industrial Partners may jointly exercise the Option, unless otherwise agreed between these Industrial Partners.

- 8.6. Exercise of the Option. Each Research Organization receiving a substantial contribution as referred to under Section 8.4 shall promptly disclose in confidence to the Coordinator any Foreground conceived by it in connection with its Activities under the Project. The Coordinator shall notify the Industrial Partner(s) with an Option on the Foreground conceived. The Industrial Partner(s) may exercise the Option at any time until the earlier of (i) [1 (one) month] after the date of disclosure by the Coordinator or (ii) the completion of the Project, after which period the Option will lapse. An Option may be exercised on one or more occasions in respect of the Foreground that is subject to a separate Option.

The Option shall be deemed to be declined in respect of the Industrial Partner that has not informed the Research Organization owning (part of) such Foreground within the aforesaid term. If the Option is exercised, the Industrial Partner(s) and Research Organization shall negotiate in good faith for a period of up to 90 (ninety) calendar days, or such longer period as may be agreed upon between the Parties, all necessary commercial arrangements taking into account the stage of development and the relative contribution of the Research Organization to the Foreground and subject to the minimal conditions set out in Section 8.7. If the Parties fail to reach agreement, the Option shall lapse, and the Research Organization shall be free to exploit the Foreground

- 8.7. Minimum Conditions. Any transfer or license agreement shall contain the following minimal conditions:
- a. the Industrial Partner(s) shall pay the Research Organization a fair market price in respect of access to or assignment of ownership of the Foreground. The Industrial Partner(s) is entitled to deduct an amount from the fair market price equal to the value of its contribution under the Project as set out in the Budget;
 - b. in the case of a license, an anti-shelving clause for the Industrial Partner (*i.e.* use of

- commercially reasonable efforts to effectively commercialise or apply the Foreground);
- c. a non-exclusive license for the Research Organization for the use of the Foreground for academic research and teaching purposes;
- d. an indemnification obligation by the Industrial Partner to the Research Organization against any third party claims for damages resulting from the use of the Foreground;
- e. a warranty from the Industrial Partner(s) to respect the Access Rights of the other Parties granted under this Consortium Agreement with respect to the Foreground pursuant to Section 9.3, including a warranty that these Access Rights will not be affected by a subsequent transfer or license of the Foreground.

8.8. Maintenance and Prosecution. Each Party is responsible for any protection of the Foreground its owns pursuant to this Consortium Agreement and shall have to file patent applications for such Foreground in their own name(s) and at their own expense. Joint owners of Foreground shall agree between them on who shall be responsible for the timely prosecution and maintenance of all such Foreground and the Party that is nominated to be so responsible shall be entitled to charge the other joint owners with a percentage of the costs of so doing as agreed between the joint owners. In the absence of any agreement to the contrary between joint owners such costs shall be equally shared.

8.9. Publication. Pursuant to the publication obligations set out in Section 5.12 of the PPP Allowance Agreement, the Parties must ensure open access (free of charge, online access for any user) to all scientific publications relating to its Foreground under the Project subject to the conditions hereunder. In particular, the Parties shall ensure open access to the deposited publication at the latest: (i) on publication, if an electronic version is available for free via the publisher, or (ii) within six months of publication in any other case.

A Party or Parties that intend to publish on the Foreground (jointly) owned by it shall provide the other Parties with the draft publication at least 30 (thirty) calendar days before publication. Any objection to the planned publication shall be made in writing to the Coordinator and the Party or Parties proposing the publication within 25 (twenty-five) calendar days upon receipt of the draft publication. If no objection is made within the time limit stated above, the Publication is permitted.

For the avoidance of doubt, a Party shall **not** Publish Foreground or Background of another Party, even if such Foreground or Background is amalgamated with the Party's own Foreground, without the other Party's prior written approval.

8.10. Objections to Publication. An objection has to include a precise request for necessary modifications and shall be considered justified only, if:

- a. the proposed publication includes another Party's Background, Foreground or other Confidential Information; or
- b. the objecting Party's legitimate academic or commercial interests are harmed by the publication;
- c. the proposed publication includes patentable Foreground and the objecting Party anticipates that it wishes to exercise the Option.

Upon receipt of an objection, the Parties involved shall discuss a solution in good faith. The objecting Party can request a publication delay of an additional period of 60 (sixty) calendar days (following the 30 (thirty) day period referred to in Section 8.9). Upon expiration of the term, the publishing Party will be entitled to publish the proposed publication.

Opmerking [L5]: Partijen mogen van deze termijnen afwijken tenzij het Project (gedeeltelijk) betrekking heeft op een klinische studie waarvoor toestemming dient te worden verkregen van een METC / CCMO in overeenstemming met de CCMO-richtlijn Beoordeling onderzoekscontracten.

- 8.11. Use of Names, Logos or Trademarks. Nothing in this Consortium Agreement shall be construed as conferring rights to use in advertising, publicity or otherwise the name of the Parties or any of their logos or trademarks without their prior written approval.

Article 9. **Ownership Background and Access Rights**

- 9.1. Background identification. Each Party has identified in Annex 1 to this Consortium Agreement certain of its Background that it is willing to grant Access Rights to, if any, and has also indicated, where relevant, whether the Access Rights to specific Background are subject to legal restrictions or limits. Anything not identified in Annex 1 shall not be the object of Access Right obligations with respect to the Background. Background remains the sole property of the Party disclosing Background under the Project. Unless expressly agreed otherwise in writing, the disclosure of any Background does not imply the grant of Access Rights by the disclosing Party. Each Party will have the right to add Background to Annex 1 by written notice to the Coordinator, who will be responsible to inform the other Parties of such addition. In the event that a Party desires to withdraw or modify any Background or restrict the Access Rights provided under this Agreement, such Party will request the Project Committee to do so by written notice.

- 9.2. Request for Additional Background. A Party (or Parties) is entitled to request another Party to add certain Background to Annex 1 if, without Access Rights to such Background, carrying out the tasks assigned to the recipient Party would be technically or legally impossible, significantly delayed, or require significant additional financial or human resources. The Party (or Parties) receiving such request may decide to add such Background in its sole discretion.

- 9.3. Standard Access Rights. Each Party hereby grants to the other Parties such non-exclusive Access Rights as required for the execution of the Project and the Project Plan and for this purpose only, for the term of this Consortium Agreement and subject to the restrictions set out in Annex 1 with regard to the Access Rights to a Party's Background. Any Access Rights granted under this Section 9.3 shall exclude any obligation to pay royalties and/or the right to sublicense.

If a Party requires Access Rights as set out in this Section, such Party shall request the relevant Party in writing to make such Background or Foreground under the Access Rights available. The Party receiving such request shall provide the requesting Party with the relevant Background and/or Foreground within [5 (five)] calendar days of the receipt of such notice. If the Party receiving such request disagrees with the requesting Party that the requested Background or Foreground falls within the Access Rights, the requesting Party shall have to show its need for such Access Rights. Access Rights shall be free of any administrative transfer costs.

In the event that Parties disagree on whether the requested Background and/or Foreground falls within the Access Rights granted under this Section 9.3, each of the Parties may request the Project Committee to decide the matter in accordance with Article 6.5 (d).

- 9.4. Access Rights for Use or Exploitation. Each Party shall have the right to request Access Rights to a Party's Background and/or Foreground in addition to the Access Rights granted under Section 9.3, from another Party for (i) internal research purposes, or (ii) if without the Access Rights the use of a Party's own or jointly owned Foreground would be technically or legally impossible or (iii) for the commercial exploitation of a Party's (or that other Party's) own or jointly owned Foreground.

A request for Access Rights shall be made in writing ultimately within six (6) months after expiration or termination of this Consortium Agreement. The granting of Access Rights will be at

a Party's own discretion and may be made conditional on the acceptance of specific conditions aiming at ensuring that these rights will be used only for the intended purpose and that appropriate confidentiality obligations are in place. Any Access Rights under this Section 9.4 under (i) shall be granted on a royalty-free basis and under (ii) and (iii) shall be granted on fair and reasonable market conform conditions.

- 9.5. Use of Access Rights. Background and Foreground shall be used only for the purposes for which Access Rights to it have been granted.
- 9.6. New Parties entering the Consortium Agreement. All Foreground developed before the accession of the new Party shall considered to be Background listed in Annex 1 with regard to said new Party.
- 9.7. Parties leaving the Consortium Agreement. Access Rights granted to a Defaulting Party and such Party's right to request Access Rights shall cease immediately upon receipt by the Defaulting Party of the formal notice of the decision of the Project Committee to terminate its participation in the Project. A non-Defaulting Party leaving voluntarily and with the other Parties' consent shall continue the Access Rights it has granted with respect to its Background and Foreground under this Consortium Agreement as if it had remained a Party for the whole duration of the Project.

Article 10. **Non-disclosure of Confidential Information**

- 10.1. Non-disclosure of information. All information in whatever form or mode of communication, which is disclosed by a Party (the "**Disclosing Party**") to any other Party (the "**Recipient**") in connection with the Project during its implementation and (i) which has been explicitly marked as "confidential" at the time of disclosure, or (ii) when disclosed orally has been identified as confidential at the time of disclosure and has been confirmed and designated in writing within 15 calendar days from oral disclosure at the latest as confidential information by the Disclosing Party or (iii) when the confidential or proprietary character is or should reasonably have been known to the receiving Party is "**Confidential Information**".

Notwithstanding the foregoing, Confidential Information of a Party shall not include information that the other Party can establish by written documentation:

- a. to have been publicly known prior to disclosure of such information by the Disclosing Party to the Receiving Party;
- b. to have become publicly known, without the fault of the Receiving Party, subsequent to disclosure of such information by the Disclosing Party to the Receiving Party;
- c. to have been received by the Receiving Party at any time from a source, other than the Disclosing Party, rightfully having possession of and the right to disclose such information;
- d. to have been otherwise known by the receiving Party prior to disclosure of such information by the Disclosing Party to the receiving Party; or
- e. to have been independently developed by employees and/or agents of the Receiving Party, on its behalf, without access to or use of such information disclosed by the Disclosing Party to the Receiving Party.

- 10.2. Non-Disclosure. During the term of this Consortium Agreement, and for a period of ten (10) years following the expiration or termination of this Consortium Agreement, each Party shall maintain in confidence all Confidential Information disclosed by the other Parties, and agrees:
- a. not to use the Confidential Information for any other purpose for which it was disclosed;
 - b. not to disclose Confidential Information to any third party without the prior written consent by the Disclosing Party;
 - c. to ensure that internal distribution of Confidential Information by a Recipient shall take place on a strict need-to-know basis; and
 - d. to return to the Disclosing Party on demand all Confidential Information which has been supplied to or acquired by such Recipient including all copies thereof. If needed for the recording of on-going obligations, such Recipient may however keep a copy for archival purposes only.

Each Recipient shall apply the same degree of care with regard to the Confidential Information disclosed within the scope of the Project as with its own confidential and/or proprietary information, but in no case less than reasonable care.

- 10.3. Mandatory Disclosure. If any Party is required to disclose Confidential Information in order to comply with applicable laws or regulations or with a court or administrative order, nothing herein shall restrict the Recipient from disclosing Confidential Information, but only to the extent of such order, law or regulation and it shall, to the extent it is lawfully able to do so, prior to any such disclosure (i) promptly notify the Disclosing Party, and (ii) comply with the Disclosing Party's reasonable instructions to maximally protect the confidentiality of the information.
- 10.4. Obligations Recipient. Notwithstanding Section 10.2 (c), Parties will have the right to disclose Confidential Information of another Party to any of its Affiliates, provided that prior consent of the Disclosing Party is obtained and such Affiliates are bound by confidentiality obligations not less stringent than the ones of the Consortium Agreement. Each Recipient shall further be responsible for the fulfilment of the above obligations on the part of its employees and its Affiliate employees and shall ensure that its employees remain so obliged, as far as legally possible, during and after the end of the Project and/or after the termination of employment.
- 10.5. Unauthorized Disclosure. Each Party shall promptly advise the other Party in writing of any unauthorized disclosure, misappropriation or misuse by any person of Confidential Information as soon as practicable after it becomes aware of such unauthorized disclosure, misappropriation or misuse.

Article 11. **Miscellaneous**

- 11.1. Inconsistencies and severability. If conflicts appear between the annexes and the body text of this Consortium Agreement, the latter shall prevail. Should any provision of this Consortium Agreement become invalid, illegal or unenforceable, it shall not affect the validity of the remaining provisions of this Consortium Agreement. In such a case, the Parties concerned shall be entitled to request that a valid and practicable provision be negotiated which fulfils the purpose of the original provision and given the contents and purpose of this Agreement, is, to the greatest extent possible, similar to that of the invalid or unenforceable part.

- 11.2. No representation, partnership or agency. The Parties shall not be entitled to act or to make legally binding declarations on behalf of any other Party. Nothing in this Consortium Agreement shall be deemed to constitute a joint venture, agency, partnership, an offer by, or creating any obligation of either Party to enter into any form of agreement other than stated in this Consortium Agreement or interest grouping or any other kind of formal business grouping or entity between the Parties.
- 11.3. Assignment. Except as allowed under this Consortium Agreement, no rights or obligations of the Parties arising from this Consortium Agreement may be assigned or transferred, in whole or in part, to any third party without the other Parties' prior formal approval.
- 11.4. Amendment. Pursuant to the PPP Allowance Agreement, any amendments or modifications of the text of this Consortium Agreement approved by all Parties require the prior written approval of Stichting LSH-TKI if, and to the extent that the PPP Allowance Agreement is still in effect. For the avoidance of doubt, any amendment of the Agreement without the prior written consent of Stichting LSH-TKI is null and void, if and to the extent that the PPP Allowance Agreement is still in effect.

Article 12. **Governing Law and Dispute Resolution**

- 12.1. Governing Law. This Agreement is governed by, and is to be construed exclusively in accordance with the laws of the Netherlands without regard to the conflict of laws provisions thereof.
- 12.2. Dispute Resolution. In the event of any disputes arising out of or in connection with this Agreement, including disputes concerning the existence and validity thereof, the Parties shall first make reasonable efforts to settle the dispute between themselves. Any legal actions or proceedings arising out of this Agreement which cannot be settled by good faith efforts and shall be brought exclusively to the court of Amsterdam, the Netherlands.

Ref no <insert Postdossiernummer>

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IN WITNESS WHEREOF, the Parties hereto have signed this Consortium Agreement in fold by their authorized representatives.

On behalf of

Place

Date

On behalf of

Place

Date

Name

Position

Name

Position

On behalf of company

Place

Date

On behalf of company

Place

Date

Name

Position

Name

Position

Ref no <insert Postdossiernummer>

<Type document title>

Annex 1 – Background

