# CONSORTIUM AGREEMENT UNDER THE FIRST BeNeFIT CALL

This CONSORTIUM AGREEMENT is made as of the date of last signature below (the “**Effective Date**”), by and between:

[SPONSOR], located at [ADDRESS], [COUNTRY] (hereinafter referred to as “**Sponsor**");

[COORDINATING CENTRE], located at [ADDRESS], [COUNTRY] (hereinafter referred to as “**Coordinating Centre**");

Sponsor and Coordinating Centre may, from time to time, be hereinafter referred to collectively as the “**Coordinating Parties**””

[CONSORTIUM MEMBER], located at [ADDRESS], [COUNTRY] (hereinafter referred to as “**Consortium Member 1**");

[CONSORTIUM MEMBER], located at [ADDRESS], [COUNTRY] (hereinafter referred to as “**Consortium Member 2**");

[CONSORTIUM MEMBER], located at [ADDRESS], [COUNTRY] (hereinafter referred to as “**Consortium Member 3**");

[Consortium Member 1, Consortium Member 2 and Consortium Member 3] may, from time to time, be hereinafter referred to collectively as the “**Consortium Members**”.

Sponsor, Coordinating Centre and Consortium Member(s) may, from time to time, be hereinafter referred to individually as a “**Party**” or collectively as the “**Parties**”.

**RECITALS**

**WHEREAS**, The Parties intend to collaborate in the project [NAME] (the “**Clinical Study**” as further defined herein);

**WHEREAS**, the Clinical Study is selected for funding under the Belgium-Netherlands Funding of International Trials Programme (BeNeFIT);

**WHEREAS** [KCE/ZonMw] is the primary funding entity in respect of the Clinical Study (the “**Funding Agency**”);

**WHEREAS**, the funding principles and terms and conditions applicable between the Funding Agency and the Sponsor in respect of the Clinical Study are governed by the funding terms as set forth in Schedule 1 (the “**Funding Terms**”);

**WHEREAS**, The Parties hereby wish to set forth the rights and obligation of their cooperation in relation to the Clinical Study;

**NOW, THEREFORE,** in consideration of the premises and the mutual promises and covenants expressed herein, the Parties agree as follows:

## DEFINITIONS AND INTERPRETATION

As used in this Agreement the following terms and expressions shall have the meaning shown below:

* 1. “**Access Rights**” means the right to use Foreground and/or, where applicable, Background IP under the terms and conditions laid down in this Agreement.
	2. “**Activity-Based Clinical Study Fees**” means the part of the Budget allocated to a Party in relation to its performance of the Clinical Study.
	3. “**Agreement**” means this present consortium agreement, together with its schedules attached hereto.
	4. **“Authorisation**” means the approvals, favourable opinions or other authorisations of any Regulatory Authority, Ethics Committee and/or other authority, that are required to be obtained under applicable laws and regulations, in order to commence and/or conduct the Clinical Study.
	5. “**Background**” means any data, materials, information owned or controlled by the Parties, that are identified as being required for the undertaking of the Clinical Study at the Commencement Date as set out in Schedule 1 or that is otherwise used in the performance of the Clinical Study, including Background IP.
	6. “**Budget**” means the total amount awarded by the Funding Agencies as further detailed in Schedule 4.
	7. “**Business Day**” means a day other than Saturday, Sunday and bank holidays in Belgium and The Netherlands.
	8. “**Clinical Study**” shall have the meaning as set out in the Recitals and further described in Schedule 3.
	9. “**Commencement Date**” means the commencement date of the Clinical Study as set out in Schedule 3 or, if later, the date upon which all necessary Authorisations have been obtained.
	10. “**Completion Date**” means the date on which the Clinical Study and such other activities in relation thereto (such as the completion of the main study report and main manuscript), are completed, as confirmed by the Funding Agency in writing.
	11. “**Confidential Information**” means information of any form, however conveyed and irrespective of the media on which it is stored, that is:
1. information which has been marked as confidential at the time of disclosure; or
2. information that reasonably ought to be considered as confidential information of the Parties, including information which relates to the business, affairs, properties, assets, trading practices, goods/services, developments, trade secrets, Intellectual Property, know-how, personnel, customers and suppliers and commercial sensitive information of the Parties.
	1. “**Consort Statement**” means the Consolidated Standards of Reporting Trials 2010 guideline, intended to improve the reporting of parallel-group randomized controlled trial, enabling readers to understand a trial's design, conduct, analysis and interpretation, and to assess the validity of its results; the Consort Statement can be found at <http://www.consort-statement.org/consort-2010>.
	2. “**Effective Date**” has the meaning first stated above.
	3. “**External Site**” means an investigational site for the recruitment of patients under the Clinical Study that is not a party to this Agreement and acts as a Subcontractor of a Coordinating Party under a Site Agreement.
	4. “**Foreground**” means any Study Data, and any tangible biological, chemical and physical material and inventions, that are generated, acquired, discovered, conceived, developed, created, exemplified or derived as a result of carrying out the Clinical Study, whatever its form or nature, whether it can be protected or not, as well as any Foreground IP.
	5. “**Funding Agencies**” shall mean KCE and ZonMw collectively.
	6. “**Funding Agency**” shall have the meaning as set out in the Recitals.
	7. “**Funding Terms**” shall have the meaning as set out in the Recitals.
	8. “**Good Research Practice**” means standards, practices, methods and procedures conforming to the applicable laws and regulations and the degree of skill and care, diligence, prudence and foresight, which would reasonably and ordinarily be expected from a skilled and experienced person or body engaged in a similar type of undertaking under the same or similar circumstances.
	9. “**ICH E3 Guidelines**” means the ICH Harmonized Tripartite Guideline regarding the Structure and Content of Clinical Study Reports, a copy of which can be found at <http://www.ich.org/products/guidelines/efficacy/efficacy-single/article/structure-and-content-of-clinical-study-reports.html> or such updated versions thereof.
	10. “**Informed Consent Form**” means the document authorized by the appropriate ethics committee for obtaining the consent of a Study Subject for his/her participation in the Clinical Study, the processing of his/her Personal Data and/or Samples.
	11. “**Intellectual Property**” **(“IP”)** means all patents, copyright and related rights, trademarks and trade names, rights to goodwill or to sue for passing off, moral rights, rights in designs, database rights, and any other intellectual property rights that may apply to the protection of Background or Foreground, in each case whether registered or unregistered and including all applications (or rights to apply) for, and renewals or extensions of, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world.
	12. “**Law**” means any and all laws, regulations and conventions applying to the conduct of clinical studies, such as the Clinical Study, and including the laws applying to the processing of Personal Data and/or the processing of Samples in the countries where the Clinical Study is conducted.
	13. “**Long Stop Date**” means 6 months after the final funding decision in the framework of the Clinical Study. The Clinical Study should be started before or on this date, which implies that the Clinical Study is approved by an Ethics committee and if applicable, any other relevant competent authority. Exceptions to be discussed on a case by case base with the Funding Agencies.
	14. “**Material**” means any report, executive summary, paper, abstract or other document provided by the Parties under this Agreement.
	15. “**Payment Schedule**” means the schedule for the payment of the Clinical Study fees as set out in Schedule 4.
	16. “**Personal Data**” means any information relating to an identified or identifiable natural person (a ‘data subject’); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person, including any data that may be associated with or derived from the Samples.
	17. “**Pseudonymous Personal Data**” means Personal Data processed in such a manner that the Personal Data can no longer be attributed to a specific data subject without the use of additional information (such as a numeric or other code), provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the Personal Data are not attributed to an identified or identifiable natural person.
	18. “**Protocol**” means the scientific document for the conduct of the Clinical Study, to be drafted by or on behalf of the Sponsor including any subsequent amendment thereto.
	19. “**Quality Management System**” means the systems and processes established by Contractor to ensure that the Clinical Study is conducted and the Foreground is generated in accordance with ICH/GCP, the Protocol and applicable Laws and regulations.
	20. “**Regulatory Authority**” means a public authority or government agency responsible for exercising autonomous authority over clinical studies in a regulatory or supervisory capacity, under the laws of the territories where (any part of) the Clinical Study is conducted.
	21. “**Reporting Schedule**” means the reporting schedule as set out in Schedule 5.
	22. “**Samples**” mean biological bodily human samples obtained from the Study Subject, including human tissues and cells, gametes, embryos, foetuses, as well as any substances extracted therefrom, irrespective of the degree of processing.
	23. “**Site Agreement**” means the agreement concluded between a Coordinating Party and an External Site.
	24. “**Study Data**” means any and all (clinical) data, protocols, analyses, processes, compilations, specifications, records, case report forms, reports (including clinical study reports), specimens, clinical samples, biomarkers, lab note books, minutes of meetings, documentation, methods, know-how, discoveries, inventions, and all other information in tangible form, whether in writing or electronic form, generated during the course of the Clinical Study or otherwise arising out of the Clinical Study, including the trial master file, completed clinical study report forms, subject diaries and adverse event reporting forms.
	25. “**Study End Date**” means, unless agreed otherwise between the Funding Agency and the Sponsor, the date on which the last visit by the last Study Subject according to the Protocol (including follow-up visits) has been completed under the Clinical Study, which is anticipated to be [DATE].
	26. “**Study Site(s)**” means any location where the Clinical Study shall be conducted as listed in Schedule 3, which Schedule may be updated from time to time upon the Sponsor’s written consent.
	27. “**Study Subject**” means an individual who is participating in the Clinical Study.
	28. “**Study Team**” the group of key individuals appointed by a Party, that will perform the Clinical Study under the responsibility and supervision of that Party.
	29. “**Subcontractor**” means any party that is not a Party to this Agreement and that will perform part of the Clinical Study as a subcontractor to a Coordinating Party; Subcontractors may include External Sites or any other party involved in the performance of the Clinical Study.
	30. “**Timetable**” means the timelines listed in Schedule 3.
	31. “**Use**” shall have the meaning as set out in Section 7.2.2.
	32. The interpretation and construction of this Agreement shall be subject to the following provisions:

(i) a reference to any law, regulation or other similar instrument shall be construed as a reference to the law, regulation or instrument as subsequently amended or re-enacted unless otherwise following from or stipulated by the provisions of such law, regulation or similar instrument;

1. references to Sections and Schedules are to sections of and schedules to this Agreement;
2. where the context allows, references to male gender include the female gender and the neuter, and the singular includes the plural and vice versa; and
3. general words are not to be given a restrictive meaning because they are followed by particular examples, and any words introduced by the terms “including”, “include”, “in particular” or any similar expression will be construed as illustrative and the words following any of those terms will not limit the sense of the words preceding those terms.

## PERFORMANCE OF THE CLINICAL STUDY

## General

* + 1. *General requirements.* The Parties shall perform the Clinical Study and recruit Study Subjects in accordance with (i) Good Research Practice, (ii) the Protocol, (iii) ICH/GCP, (iv) all applicable Laws, and (vi) the terms and conditions of this Agreement. Where applicable, the Parties shall install and maintain during the entire term of the Clinical Study an adequate Quality Management System. Each Party shall be responsible to perform its part of the work in relation to the Clinical Trial, i) timely, ii) accurately, and iii) in a professional manner. It is the joint responsibility of the Parties to make every reasonable effort to complete the Clinical Study in accordance with Exhibit 3.
		2. *Compliance with Funding Terms.* The Parties shall use their best efforts to ensure that Sponsor, and the Coordinating Center as the case may be, shall at all times be able to comply with their commitments towards the Funding Agency under the Funding Terms, and the Parties shall refrain from taking any action that would in any way prevent or put at risk Sponsor’s, and the Coordinating Center’s (as the case may be), compliance with their commitments towards the Funding Agency under the Funding Terms. Moreover, the Parties acknowledge that the Funding Terms stipulate rights of the Funding Agencies that affect the rights and obligations of the Parties under this Agreement. As a consequence, in the event of discrepancy between this Agreement and the Funding Terms, the Funding Terms take precedence to the extent they will negatively affect the rights of, or obligations to, any of the Funding Agencies under the Funding Terms.
		3. *Transfer of Information to the Funding Agency*. Parties confirm that the Sponsor, and the Coordinating Center (as the case may be), is entitled to transfer any relevant information (including this Agreement) or Study Data to the Funding Agencies and to regularly report on the performance of the Clinical Study (including on the status of the Study Subject recruitment and the utilization of the funding granted by the Funding Agencies under the Funding Terms) *inter alia* to ensure that the Funding Agency can monitor Sponsor’s compliance with the Funding Terms.
		4. *Conflict of interest.* Parties must take all measures to prevent any situation where the impartial and objective performance of the Clinical Study is compromised for reasons involving any conflicting interests. Parties shall notify the Sponsor promptly in writing of any situation constituting or likely to lead to a conflict of interests and immediately take all steps to rectify this situation.

## Administration and Direction of the Clinical Study

* + 1. *Scope and objectives.* The scope and objectives of the Clinical Study are set out in Schedule 3. The management and coordination of the Clinical Study shall be under the control of the Sponsor, as appropriate, in consultation with the Funding Agency.
		2. *Timetable.* In conducting the Clinical Study, the Parties shall use best efforts to comply with the Timetable. The Timetable may be modified upon both the Sponsor’s written consent as a result of (i) force majeure, (ii) unforeseen requirements of the Funding Agency, or (iii) delays in obtaining or rejection or revocation of or changes in the Authorisations, for reasons for which the Parties are not responsible; or (iv) for any other good reason agreed by the Sponsor in writing. If at any time, any of the Parties has reasons to believe that it will not be able to comply with the Timetable, they shall inform the Sponsor (or, where applicable, the Coordinating Centre) as soon as possible.
		3. *Authorisations:* It is the responsibility of each Party to obtain the Authorisations necessary for the conduct of the Clinical Study. Each Coordinating Party engaging External Sites shall ensure that Authorisations are in place for each such External Site.
		4. *Study Subjects.* (a)The Parties shall ensure that the recruitment of the Study Subjects shall take place in accordance with the approved Protocol and the allocation of roles and responsibilities set out in Schedule 3.

(b) The Parties shall ensure to have the Clinical Study at the Study Site supervised and to have the Study Subjects monitored in such a way in order to ensure at all times the integrity, health and welfare of the Study Subjects.

(c) The Parties shall to the extent required by the Law of the country where the Clinical Study is performed, ensure that all Informed Consent Forms will contain wording that clearly specifies that (i) the Clinical Study may be discontinued at all times and with immediate effect, and that (ii) any such discontinuation shall not entitle the Study Subject to any compensation. Before deciding on discontinuation, the Parties will always take into account medical and ethical considerations and the safety of the Study Subjects.

(d) If it is anticipated in accordance with the Protocol to acquire specific Personal Data of any Study Subject, which acquisition requires the use of the national registry number (*BE-rijksregisternummer/numéro national* or *NL-burgerservicenummer*):

i) For Study Subjects participating in the Clinical Study in Belgium: the relevant Parties shall first discuss with KCE and KCE shall provide reasonable assistance to said Parties to obtain approval by the Belgian data protection supervisory authority. The engagement of a trusted third party may be required.

ii) For Study Subjects Participating in the Clinical Study in The Netherlands: the relevant Parties acknowledge that such use is prohibited, except for restricted use of pseudonymous national services numbers. The relevant Parties warrant that they shall only use such pseudonymous national service number if and to the extent permitted under Dutch law and by engaging a trusted third party.

iii) Without prejudice to i) and ii) above, the relevant Parties shall ensure that the Study Subjects have given their unambiguous consent with any use of the (pseudonymous) national registry number in the Informed Consent Form and that such use shall be implemented in strict compliance with applicable Law.

* + 1. *Clinical supplies.* Any clinical supplies, including medication or devices, Clinical Study products, comparator products (where applicable), and all technical information required to safely administer such products to the Study Subjects shall be supplied or procured by the relevant Parties at cost, unless the costs of such clinical supplies are eventually assumed by Belgium national health insurance or the Dutch Study Subjects’ health insurer.
		2. *Site Agreements*. Each Coordinating Party engaging an External Site shall conclude a Site Agreement between itself and such External Site, such Site Agreement being consistent with the terms and conditions of this Agreement.
		3. *Subcontractors*: The Coordinating Parties may subcontract part of their tasks as foreseen in Schedule 3 to a Subcontractor named in Schedule 3. The Coordinating Party shall however remain liable for the performance by the Subcontractor of the subcontracted work as if it had performed the work itself. Consortium Members may not subcontract part of their tasks to a Subcontractor.
	1. **Study Team**
		1. *General.* (a) The Parties shall appoint the necessary personnel, facilities, equipment and supplies to perform the Clinical Study under this Agreement. In fulfilling their obligations hereunder, the Parties shall appoint only persons with the appropriate training, skills and qualifications to perform the Clinical Study.

(b) The Parties shall be responsible to ensure that any member of their Study Team shall comply with this Agreement and shall promptly advise their Study Team members of any changes in the scope of this Agreement or the Clinical Study.

* + 1. *Study Team.* (a)Before the Commencement Date, the Parties shall store in the trial master file a short curriculum vitae and relevant references of the key members of the Study Team. The Parties shall not remove or replace any key member of their Study Team without the Sponsor’s prior written approval (which approval the Sponsor shall not unreasonably withhold or delay), unless the person has left the employ of the relevant Party. If, in the Sponsor’s reasonable opinion, a key member of a Study Team is not able to perform its duties in accordance with this Agreement, the Sponsor shall have the right to request the relevant Party to replace such person and the Sponsor and the relevant Party shall meet and discuss to find a reasonable solution. In any case, the Parties shall at all times ensure that they have appropriate replacement immediately available for each key member of their Study Team in the event such key member leaves the employ of said Party; this replacement shall be organized in such a way that a key member leaving the employ of said Party has no negative impact on the performance of the Clinical Study or on the safety of the patients.

(b) The Parties shall ensure that the agreements with any member of their Study Team contain provisions in respect of Intellectual Property compatible with the terms of this Agreement and in particular allow those persons to publish the Foreground in appropriate research journals.

* + 1. *Record keeping.* Without prejudice to the generality of Section 4, the Parties shall keep and shall cause, where applicable, any member of the Study Team to keep full, detailed and accurate (electronic) records of all activities performed and Foreground obtained in connection with the Clinical Study as well as, where relevant, keep laboratory notebooks recording all research, development and other work carried out in respect of the Clinical Study.

## 3. FINANCIAL TERMS

## Clinical Study Fees and Payment

* + 1. *Contribution.* In consideration of the performance of the Clinical Study in compliance with this Agreement and the granting of rights as set out in this Agreement, the Parties shall be paid their Activity-Based Clinical Study Fees (including VAT, if applicable) in accordance with the Payment Schedule, the milestones and the invoicing and payment terms set out therein. Unless specifically agreed otherwise, the Clinical Study fees shall constitute the full and complete compensation for the performance of the Clinical Study and the granting of the rights hereunder and no other or additional amounts shall be due under or in connection with this Agreement (including no pass-through costs).

## ACCESS TO STUDY DATA, REPORTING, MONITORING

##  Access to Study Data

* + 1. As from the Study End Date and for a further period of six (6) years, and subject to Section 4.1.1, the Parties shall provide the Funding Agencies upon their request with specific Study Data. Any such provision of Study Data will not require additional data analysis, unless agreed otherwise.
		2. The Parties shall ensure that the Study Data that are disclosed to the Funding Agencies or to which any of the Funding Agencies have granted access to in accordance with this Agreement will in principle be anonymized Study Data. However, where specifically requested by the Funding Agencies, Pseudonymous Personal Data shall be made available. In no event shall any of the reports, documents, information disclosed to the Funding Agencies under and in accordance with this Agreement include data that as such reveal the identity of a Study Subject through direct identifiers or otherwise. The Parties shall, or where applicable, shall ensure that their Study Team shall, keep the key to identities of all persons to whom the data relates in a separate and secure place in compliance with applicable privacy Law and legislation and such key shall not be disclosed to the Funding Agencies or unauthorized persons. In relation to the Pseudonymous Personal Data to which the Funding Agencies are granted access in accordance with this Section, the Funding Agencies shall comply with all applicable privacy Law and legislation. If so required by Law, the Party making available data to a Funding Agency and the Funding Agency shall conclude a data transfer agreement, outlining the specific data protection obligations of the Funding Agency. Such agreement shall not contain any terms and conditions that are inconsistent with the Funding Agency’s rights under the Funding Terms and this Agreement.
		3. Without prejudice to Section 8.4 and Section 9.2.2, no Party shall provide (a copy of) the Study Data to a third party without the prior written approval of the Sponsor, which approval the Sponsor shall not unreasonably withhold or delay and which the Sponsor may subject to specific conditions in order to ensure that the provision of said Study Data does not have a negative impact on the further performance of the Clinical Study in accordance with this Agreement and/or the benefit of the Clinical Study for patients and/or the public health decision making bodies.

##  Obligation to inform and report

* + 1. *Information*. The Parties shall inform each other promptly of (i) any event which is likely to affect significantly or delay the performance of the Clinical Study, (ii) changes in its legal, financial, technical, organisational situation, circumstances affecting compliance with the requirements under this Agreement, (iii) significant developments, including developments in relation to the safety of Study Subjects or to the scientific direction of the Clinical Study.
		2. *Reporting*. (a) The Parties shall comply with the Reporting Schedule as set out in Schedule 5 and shall use the format as determined by the Sponsor.

(b) The Sponsor shall strictly comply with its obligations under Law in view of maintaining complete and up-to-date all required files and documentation in respect of the Clinical Study. To ensure that the Sponsor can at all times fulfil its obligations in this respect, the Parties shall timely transfer all relevant files and documentation (such as Authorisations, local ICFs, progress reports, financial reports, etc) to the Sponsor.

## 4.3 Follow-up and governance

4.3.1 *Governance.* The Consortium shall comprise of the following Consortium bodies (each a “**Consortium Body**”): (a) The Trial Steering Committee (“TSC”) shall oversee the performance of the Clinical Study and discuss important topics in relation thereto. The TSC shall be chaired by Sponsor. The TSC shall meet once every four months during the first year and every six months thereafter (“ordinary meetings”) or at such other time as reasonably requested in advance by the Funding Agencies or deemed necessary by 1/3 of the TSC members (“extraordinary meetings”) and shall be at least composed of an independent clinical expert, a representative of a recruitment site, up to 2 patients or members of the public, 1 representative of each of the two Funding Agencies. The Funding Agencies shall have the right (but not the obligation) to be present at each TSC meeting. The chair shall provide the members of the TSC and the Funding Agencies with a proposed agenda for such meetings at the latest ten (10) Business Days in advance of the meeting; the Funding Agencies shall have the right to add additional items to the agenda. The chair of the TSC shall provide draft meeting minutes to each member and the Funding Agencies at the latest ten (10) Business Days for approval. Except for changes in the Budget, the meeting minutes shall be deemed to be accepted if no comments are raised by a member or the Funding Agencies in writing within fifteen (15) Business Days after receipt of the minutes.

4.3.2 *Audits*. (a) The Parties shall provide, and shall ensure that any member of their Study Team undertakes to provide, all reasonable cooperation and assistance at all times during the term of this Agreement and for a period of six (6) years after termination or expiry of this Agreement for the purposes of allowing the Sponsor or any of the Funding Agencies to obtain the information as is necessary to fulfil any obligations to supply information for parliamentary, governmental, judicial or other regulatory or administrative purposes.

(b) The Parties shall provide, and shall ensure that any member of their Study Team shall provide, all reasonable cooperation and assistance at all times during the term of this Agreement and for a period of two (2) years after termination or expiry of this Agreement to allow the Sponsor, any of the Funding Agencies, or any of their designees (the “**Auditors**”) to carry out an audit of the relevant Party’s compliance with this Agreement (including all activities, performance, security and integrity in connection therewith), and its Quality Management System. In this respect, the relevant Party shall ensure, during business hours and upon giving reasonable prior notice, free access to the Auditors to its facilities and Study Sites, and all relevant information, data and records relevant to the Clinical Study, including the trial master file.

The Auditors shall have access only to such information as strictly required to verify the compliance with this Agreement. It is the responsibility of the Sponsor or any of the Funding Agencies to ensure that the Auditors are bound by confidentiality provisions and restrictions at least as stringent as those stated in Section 6 below.

(c) If, during the term of this Agreement and six (6) years thereafter a Party is notified of a scheduled inspection of the Clinical Study at any study Site by a Regulatory Authority, said Party will immediately inform the Sponsor in writing. At its discretion, the Sponsor may choose to be present during such inspection, unless such inspecting Regulatory Authority opposes to the Sponsor being present during the inspection. Any inspection report made by a Regulatory Authority, relevant to the performance of the Clinical Study, will promptly be shared with the Sponsor.

(d) Nothing contained in this Section 4.3.2 shall entitle the Parties to a Budget increase or to any other compensation.

## DATA PROTECTION

##  General obligations

* + 1. The terms displayed in ***italic and bold*** as used in this Section 5 have the meaning under Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation - GDPR).
		2. In relation to any ***processing*** of Personal Data in connection with the Clinical Study, the Parties shall be deemed to be individual and/or joint ***controllers***. The Parties are responsible for any obligations of the ***controller*** under the GDPR, including:
1. They will only lawfully ***process*** Personal Data as meant under Article 6 of the GDPR;
2. Processing shall be in accordance with all applicable Law, regulations and where applicable, ***codes of conduct***.
3. They will ensure integrity and confidentiality of the Personal Data by implementing appropriate organisational and technical measures to prevent any breach of security leading to the accidental or unlawful destruction, damages, loss, alteration, unauthorised disclosure of, or access to, Personal Data transmitted, stored or otherwise processed by it.
4. They will ensure that the ***data subjects*** are enabled to exercise their rights under Chapter III of the GDPR.
5. In case of a ***personal data breach***, or any other incident that may affect the processing of Personal Data, the Party experiencing the ***personal data breach*** or incident shall promptly inform the Party from which the Personal Data was obtained and the Sponsor and Parties will provide each other any assistance needed and/or required to enable them to meet their obligations under the applicable privacy Law.

##

## CONFIDENTIALITY

## Confidentiality and non-use

* + 1. *General.* In respect of any Confidential Information that a Party may receive (the “Recipient”) from any other Party (the “Discloser”), the Recipient undertakes to keep secret and strictly confidential and shall not disclose any such Confidential Information to any third party other than those involved in the Clinical Study, who are bound by similar confidentiality obligations, without the Discloser’s prior written consent provided that nothing herein shall be so construed as to prevent Recipient from using data processing techniques, ideas, know-how and the like gained in the course of this Agreement in the furtherance of its normal business, to the extent that this does not result in a disclosure of any Confidential Information or infringement of any valid Intellectual Property rights of the Recipient or the unauthorised ***processing*** of any Personal Data.
		2. *Exception.* The obligation of confidentiality and non-use shall not apply to any information to the extent such information:
1. is or becomes public knowledge (otherwise than by breach of Section 6.1.1);
2. was in the possession of the Recipient, without restriction as to its disclosure, before receiving it from the Discloser;
3. is received from a third party who lawfully acquired it and who is under no obligation restricting its disclosure;
4. is independently developed without access to the Confidential Information of the Discloser; or
5. must be disclosed pursuant to a statutory, legal or parliamentary obligation imposed upon the Recipient, in which case the Recipient shall inform the Discloser promptly to allow the Discloser to challenge or limit, the disclosure of its Confidential Information.
	* 1. *Term.* The obligations of each of the Parties contained in this Section shall continue for a period of ten (10) years after the expiration or termination of the Agreement. A failure to comply with this Section 6, shall constitute a material breach of this Agreement.

# 7. RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

## Ownership of Background

* + 1. *Principle.* Nothing in this Agreement shall affect a Party’s rights in Background nor imply grant of any license to such Background, unless expressly set out herein.
		2. *Identification.* In the event that Background will be used for the performance of the Clinical Study, such Background shall be identified in Schedule 2, including the legal restrictions of which it is aware that may affect the use of the Background for the purpose of the Clinical Study. The relevant Party shall on a best effort’s base procure that it will not use any Background that was not identified in Schedule 2 for the performance of the Clinical Study.

## Use of Background

* + 1. *General.* In respect to the Background, each Party shall remain free to license, assign, or otherwise dispose or transfer ownership (“Use”) of its Background, provided that such Party shall pass on its obligations specified under this Agreement regarding such Background, to the appropriate licensee, assignee, transferee or acquirer, including the obligation to pass those obligations where appropriate, on to any subsequent licensee, assignee, transferee or acquirer of that Background.
		2. *Notification and objection.* Each Party shall, during the term of the Agreement, notify the Sponsor of any Use in advance and the Sponsor shall be entitled to object to such Use if, in the Sponsor’s reasonable opinion, the Use prevents or limits such Party’s performance under this Agreement. The foregoing obligation to notify the Sponsor of such Use, shall be without prejudice to the obligation of each Party set forth in Section 7.2.1, which obligation shall continue to apply for a period of six (6) years after the term of the Agreement.

## RIGHTS AND OBLIGATIONS RELATED TO RESULTS

## Ownership of Foreground

* + 1. *Principle.* Foreground is owned by the Party that has generated such Foreground.

## Protection of Foreground

* + 1. *Information.* Each Party shall inform the Sponsor in a timely manner of any Foreground, whether patentable or not, which is capable of exploitation either by direct implementation into the health care service or, subject to Section 8.3, via commercialisation.
		2. *IP policy.* Each Party will identify, protect and maintain Intellectual Property in accordance with its standard institutional policy. If available, each Party will provide a copy of any applicable IP policy on the request of the Sponsor (or any of the Funding Agencies). Each Party shall take due consideration of the Funding Agencies’ attitude to the clearly inappropriate use of patents which the Funding Agencies consider detrimental to scientific endeavour or to advances in healthcare. In the event a Party decides not to protect any Foreground invention by filing a patent application or to abandon prosecution of any patent in the Foreground invention, such Party shall communicate such decision to the Sponsor and the Funding Entities, which shall discuss in good faith how to proceed in the best interest of patients and the public health decision making bodies without protecting said invention by filing a patent.

Alternatively, each Party shall have the right, before taking any decision on the protection and maintenance of Intellectual Property, to discuss with the Funding Entities first on the feasibility and appropriateness of the protection of the Foreground through Intellectual Property, in the best interest of patients and the public payers.

* + 1. *Records.* Each Party shall keep proper records showing the description of the Background IP and Foreground IP.

## Exploitation of Foreground

* + 1. *General.* Parties acknowledge that the main purpose of the research performed under this Agreement is to generate results that will serve the general public interests, and specifically the interests of the patients and public healthcare decision making bodies, and, therefore, undertake not to exploit the Foreground in any way that is or could be detrimental to such interests. In this respect, Parties acknowledge the importance of the dissemination of the Foreground and the Access Rights in accordance with the principles set forth herein. Parties shall ensure that to the maximum extent possible under privacy Law, the Foreground shall be made available for further research activities with the purpose to generate additional results that could further support the aforementioned interests.
		2. *Commercialisation.* In accordance with the acknowledgements and the principles set forth or referred to in Section 8.3.1, the commercialization of the Foreground is not and should never be the main aim of Parties under this Agreement. Without prejudice to Section 8.4, in the event that a commercialization opportunity nevertheless arises, the Parties shall inform the Sponsor thereof in advance. The Parties acknowledge that any such commercialization may lead to the scenario where any of the Dutch or Belgian government may have to pay twice (e.g. for the research under this Agreement and the Funding Terms, and for the reimbursement of commercial products incorporating or making use of one or more Foreground) or where such commercialisation may lead to direct or indirect state aid, and may therefore result in a claim by the Funding Agencies for the reimbursement of the Budget. Accordingly, Parties shall refrain from taking any steps that may result in such commercialization.

## Dissemination of Foreground – Open Access

* + 1. *General .* (a) the Parties acknowledge and agree the principle that Foreground should be disseminated to the public as soon as possible by appropriate means, including in scientific publications (in any medium). The Parties agree that any dissemination of Foreground shall be in accordance with this Section 8, provided that any publication arrangements shall be without prejudice of the rights of the Funding Agencies under the Funding Terms.

(b) The foregoing does not change the right to protect Foreground through patent applications in accordance with Section 8.2, the confidentiality obligations in Section 6 and the obligations to protect Personal Data further to Section 5, all of which still apply.

(c) The Parties shall always consult with each other prior to independently publishing or otherwise disclosing any findings resulting from the Clinical Study. The Parties confirm that they will ensure that the first publication in respect of the findings resulting from the Clinical Study and its primary endpoint shall emanate from the Parties as a whole.

* + 1. Any dissemination shall acknowledge the Funding Agencies’ financial support and carry a disclaimer as the Funding Agencies may require or in the absence of direction from the Funding Entities a notice as follows:

“*This report is independent research funded by ZonMw and the Belgian Health Care Knowledge Centre ([PROGRAMME NAME, TITLE AND REFERENCE NUMBER]). The views expressed in this publication are those of the author(s) and not necessarily those of ZonMw or the Belgian Health Care Knowledge Centre or the Department of Health*.”

* + 1. *Open access to scientific publications.* The Parties shall ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to the Foreground. In particular the Parties shall:
1. As soon as possible and at the latest on publication, deposit a machine readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications; moreover, Parties must aim to deposit at the same time the research data needed to validate the Foreground presented in the deposited scientific publications; and
2. Ensure open access to the deposited publication, via the repository at the latest on publication (if an electronic version is available for free via the publisher). In case certain high impact journals require a lock-up period (which may under no circumstances be higher than 6 months) before open access may be granted, Parties shall use their best endeavors to eliminate this lock-up period, which may include the payment of a financial compensation. Parties acknowledge that the final payment set forth in Schedule 4 provides sufficient financial means for the payment of this financial compensation by the Parties.

## ACCESS RIGHTS

## Background

* + 1. *Access Right*. Regarding the Background listed in Schedule 2 as per Section 7.1.2, or any Background not listed in Schedule 2 which was used in the performance of the Clinical Study in contravention of Section 7.1.2,, the Parties hereby grant to each other *and* to the Funding Agencies a non-exclusive, worldwide, irrevocable, unlimited, royalty-free and transferable Access Rights to Background, with the right to sub-license, to the extent such Background is needed to use the Foreground in accordance with the license grant in accordance with Section 9.2.1. Each Party shall ensure that any of its sub-licensees complies with the terms and conditions of the Access Rights set forth herein.

## Foreground

* + 1. *Access Right.* (a) In furtherance of the main purpose and interests set forth in Section 8.3.1 above, the Parties hereby grant each other *and* the Funding Agencies a non-exclusive, worldwide, irrevocable, unlimited, royalty-free and transferable Access Right to the Foreground and to Background needed for the use of such Foreground, with the right to sub-license, for any non-commercial research purposes, public health care services purposes, and/or for designing, evaluating, and/or implementing policies or programmes in connection with or related to health care, health economics, pharmacoeconomics and/or social security.

(b) The Funding Agencies’ right to sub-license include the right to grant non-exclusive and royalty-free access rights to the Foreground and to Background needed to use such Foreground, to EU or EU member state’s institutions, bodies, offices, public services and/or agencies, for any non-commercial research purposes, public health care services purposes and/or for designing, evaluating and/or implementing policies or programmes in connection with or related to health care, health economics, pharmacoeconomics and/or social security.

(c) The foregoing access rights shall include the right to publish, upon notification of the relevant Party that owns the Foreground, any Foreground for any non-commercial purpose, including any entry in a register of research findings or an individual issue of or a review article in a monograph series prepared on any of the Funding Agencies’ behalf. The content and timing for such publication will take into account the publication timetables in other peer-reviewed journals and the need to make research findings publicly available as soon as practicable.

* + 1. *Access right to third parties.* After the Completion Date, subject to the provisions of this Agreement (including Clauses 5 and 6), the Parties shall grant Access Rights to the Foreground to third parties on a non-exclusive basis and at fair and reasonable terms. In this respect, the Parties shall establish a data access plan managing the access by third parties to the Foreground subject to the third party entering into a data use agreement with the Party that owns the Foreground providing the terms and conditions for such access.

## PUBLICATION BY the Funding Agencies

## General

* + 1. The Clinical Study funded by the Funding Agencies under the Funding Terms is open and the Parties acknowledge and agree that the Funding Agencies are entitled to publish details of the selection process, the research objectives, plan and costs of the Clinical Study.

## REPRESENTATIONS

* + 1. Each Party represents that, to its reasonable knowledge at the Effective Date:
1. the Party’s execution, delivery and performance of this Agreement (a) have been authorised by all necessary corporate action, (b) do not violate the terms of any law, regulation, research standards, or court order to which such Party is subject or the terms of any agreement to which the Party may be subject and (c) are not subject to the consent or approval of any third party;

(ii) this Agreement is the valid and binding obligation of the representing Party, enforceable against such Party in accordance with its terms; and

1. such Party is not subject to any pending or threatened litigation or governmental action which could interfere with such Party’s performance of its obligations hereunder.
	* 1. Except as expressly provided in this Agreement, none of the Parties give any warranties or make any representations with respect to any of the Foreground (IP) and/or Background (IP) or any products derived from them, or their fitness for any purpose, or that any material produced or supplied by any Party and any processes or techniques used, proposed or recommended by any Party will not infringe the Intellectual Property rights of any person in any country.
		2. The Parties warrant that:
2. they shall use best efforts to devote all resources and efforts as may be necessary for the satisfactory and timely completion of the Clinical Study in compliance with the Timetable;
3. they have full capacity, power and authority and all necessary licences, permits and consents to assume and fully perform all of their obligations under this Agreement;
4. there are no actions, suits or proceedings pending or, to each Party’s knowledge, threatened against or affecting the Contractor before any court or administrative body or tribunal that might affect the ability of said Party to meet and carry out its obligations under this Agreement;
5. they shall comply with their obligations under this Agreement, including with the standards for performing the Clinical Study set out in Section 2.1.1.
6. at the Effective Date they are not a party to an agreement which would prevent said Party from fulfilling their obligations under this Agreement;
7. they shall during the term of the Clinical Study not enter into any agreement or arrangement which would substantially restrict a Party’s ability to perform the Clinical Study;
8. they shall during the term of the Clinical Study not do any other act which may have a substantial adverse effect on the availability of Study Subjects, including providing services to third parties in relation to a study which would or could recruit the same Study Subjects;
9. they shall not enter into any agreement in which the Intellectual Property arrangements would adversely affect a Party’s ability to comply with the terms of this Agreement.
10. their Study Teams will have the expertise in the disease and patient population relevant to the Clinical Study and will have the training, information, licenses, approvals or certifications necessary for safely, adequately and lawfully conducting the Clinical Study;
11. none of their Study Teams shall be subject to any conflicting obligation that may interfere with the performance of the Clinical Study or that might impair the validity of the Study Data;
12. they shall perform the Clinical Study in compliance with all ethical principles, including avoiding fabrication, falsification, plagiarism or other research misconduct;
13. none of them obtained or will obtain during the term of the Clinical Study any other (EU, federal, regional, local or foreign) public or private funding for the performance of the Clinical Study;
14. to the best of their knowledge and belief:
	1. subject to the declaration set out in Schedule 2 they have the right to use and provide licenses to any Background under this Agreement, and if applicable shall obtain the consent of any legal and beneficial owner that has any right, title and interest in and to the Background listed in Schedule 2 prior to entering such Background into the Clinical Study;
	2. they will be the legal and beneficial owner(s) of all right, title and interest in and to the Foreground and the Collaborator will own and manage Foreground IP in accordance with, and subject to the terms of this Agreement; and
	3. they have not granted any third party any right in respect of the Foreground IP (other than in accordance with the provisions of this Agreement), and has not charged or encumbered and will not charge or encumber any of the same.

## LIABILITY

## Limitations

* + 1. *Exclusion indirect damages.* Except and to the extent caused by third party claims or for breaches of a Party’s obligations set out in Section 8.3, neither Party shall be liable towards the other for any consequential, special, indirect or punitive damages whatsoever, including but not limited to financial loss, lost profits, loss of opportunity or damage to reputation.
		2. *No exclusion or limitation.* Nothing in this Agreement shall exclude or limit a Party’s liability for personal injury or death or for fraud, fraudulent misrepresentation, wilful misconduct and/or gross negligence.
		3. *Obligation to mitigate.* Notwithstanding any other provision of this Agreement, each Party shall use its reasonable endeavours to mitigate losses it may incur that are covered by indemnities provided by the other Party.

## INSURANCE

* 1. Without prejudice to Section 12, each Party (a defaulting Party) shall, or shall ensure, throughout the duration of this Agreement effect and maintain with a reputable insurance company a policy or policies of insurance providing an adequate level of cover in respect of all risks which may be incurred by another Party arising out of the defaulting Party's performance of this Agreement.
	2. It is the responsibility of the Sponsor and the Coordinating Center to arrange for adequate insurance required pursuant to applicable Law in relation to the part of the Clinical Study performed in their country of residence.
	3. Each Party shall produce on demand by the Sponsor documentary evidence that any insurance policies required by Sections 13.1 and 13.2 are in force.
	4. Except for the Clinical Study insurance under section 13.2 The terms or the amount of cover of any insurance shall not relieve any Party of any liabilities under the Agreement.

## TERM AND TERMINATION

##

## Term and surviving Sections

*14.1.1 Term.* Unless otherwise terminated in accordance with the provisions hereof, this Agreement shall be effective as from the Effective Date and shall, subject to Sections 14.2 and 14.3, automatically expire on the Completion Date.

*14.1.2 Surviving provisions.* Notwithstanding Section 14.1.1, the following provisions shall survive the expiration or termination of the Agreement: Section 4.1 (*Access to Study Data*), Section 4.3.2 (*Audits*), Section 6 (*Confidentiality*), Section 7 (*Background IP*), Section 8 (*Foreground*), Section 9 (*Access Rights*), Section 10 (*Publication*), Section 12 (*Liability and Indemnification*), Section 14.4 (*Termination Consequences*) and Section 17 (*Applicable Law*), including any cross-references set out in these Sections. The foregoing shall be without prejudice to any other provision of the Agreement that by its nature survives expiration or termination of the Agreement.

## 14.2 Termination of a Party’s participation in the Agreement

This Agreement or the participation of one or more Parties to it, may be terminated in accordance with the terms of this Agreement.

*14.2.1 Termination by the Funding Agency*. Subject to Section 14.3 (*Consequences of Termination*), if the Funding Agency terminates the funding of the Clinical Study this Agreement shall automatically terminate in respect of all Parties at the same date as the effective date of termination indicated by the Primary Funding Agency.

*14.2.2 Termination at request of a Party:* A Party may request termination of its participation in the Clinical Study and this Agreement for unforeseen urgent circumstances that prevent the Party from further participation.

The Party that intends to cancel its participation (the “***Cancelling Party***”) pursuant to Section 14.1.1, shall inform the Sponsor in writing no later than 60 days prior to the projected cancellation date, providing at least i) a rationale for its cancellation, and ii) a proposal for winding up its activities in re0lation to the Clinical Study and the transfer of its activities taking into account the interests of the Clinical Study and iii) any information requested under Section 14.4.4 (*Cancellation Notice*).

The Sponsor, having consulted the Steering Committee, shall inform the Cancelling Party within 30 days’ notice upon receipt of the Cancellation Notice of the consequences of the termination, covering at least the financial consequences, Access Rights of the Cancelling Party after termination and a plan for winding up and transfer of the Cancelling Party’s activities.

*14.2.3 Termination for cause.* The Sponsor, having consulted the Steering Committee, may terminate the participation of a Party in the Clinical Study for material breach of the Agreement by such Party. “Material Breach” means i) a breach of a Party’s obligations under this Agreement that is substantial and is not remedied within the period stated in the formal notice (Section 14.2.3.1) or that is not capable of remedy, or ii) numerous breaches committed by a Party in respect of its obligations under this Agreement.

*14.2.3.1 Procedure*. A Party identifying a potential breach of the Agreement by another Party shall promptly notify the Sponsor. If the Sponsor confirms the breach or itself identifies a breach, it shall provide formal notice to the Party being in breach of its obligations under this Agreement, specifying the nature of the breach and requiring that such breach will be remedied within the term stated in the formal notice.

In case of a Material Breach, Sponsor may decide to declare the Party to be a defaulting Party (the “**Defaulting Party**”). The Sponsor shall inform and consult with the Steering Committee on the consequences thereof, which may include termination of the Defaulting Party’s participation in the Clinical Study and this Agreement.

*14.2.4 Other grounds for termination.*

*14.2.4.1 By the Sponsor*. The Sponsor may terminate this Agreement with respect to a Party

1. if such Party is dissolved or liquidated, files or has filed against it a petition under any bankruptcy or insolvency law, makes an assignment for the benefit of its creditors or has a receiver appointed for all or substantially all of its property, or experiences an event analogous to any of the foregoing in any jurisdiction in which any of its assets are situated; and/or
2. that is not a Defaulting Party, in case a force majeure event suffered by such Party, that continues in effect for a period of more than three (3) months.
3. if any key member of the Study Team of such Party is no longer available (for whatever reason) for the Clinical Study and no mutually acceptable replacement can be found provided that the Sponsor will not unreasonably withhold its approval to the proposed qualified replacement of key personnel.

**14.3 Termination of the Clinical Study**

The Clinical Study and this Agreement may further be terminated

1. if a Regulatory Authority directs that the Clinical Study be terminated or refuses, revokes or cancels any Authorisation or in the event any Authorisations for the commencement of the Clinical Study is not given within a period of 12 months after the final funding decision in the framework of the Clinical Study (except in case double blind medication cannot be delivered within this timeframe notwithstanding the Parties using commercial reasonable efforts); and/or
2. if the safety of the Study Subjects cannot be guaranteed and such is confirmed by a Regulatory Authority and/or the Steering Committee.

**14.4 Consequences of termination with respect to one, several or all Parties**

*14.4.1 Surviving provisions.* Upon termination under Sections 14.2 and 14.3, the provisions mentioned in Section 14.1.2 shall survive and be effective with respect to any Party whose participation in the Clinical Study and this Agreement is terminated.

*14.4.2 Minimize harm.* In all circumstances causing the termination of this Agreement, the Sponsor shall confer with the Party or Parties concerned and each of them will use their best endeavors to minimize any inconvenience or harm to Study Subjects.

*14.4.3 Recruitment stop*. Upon given or receipt of notice of termination of this Agreement, the Party/Parties concerned will not recruit and/or enroll additional Study Subjects, and will cooperate with the Sponsor in the orderly discontinuation of the Clinical Study, including, without limitation, discontinuing of the administration of Clinical Study supplies (made available pursuant to Section 2.2.5) as soon as medically appropriate, allowing Sponsor access to records and facilities as required for Clinical Study close-out procedures at mutually agreed times, and requiring the principal investigators (as defined in ICH GCP) to complete any actions required by the role principal investigator.

*14.4.4 Financial Reporting* In case of early termination of this Agreement, the Party/Parties concerned shall provide the Sponsor in accordance with Schedule 4, with i) a breakdown of its costs already incurred up until the date of the notice of termination, and ii) an overview of expected costs to be reasonably incurred up until the date of termination of its participation in the Agreement.

*14.4.5 Return of Confidential Information.* At close-out of the Clinical Study site following termination or expiration of this Agreement, the Party/Parties concerned shall upon request immediately deliver, or destroy with confirmation thereof, if requested, to the other Party all Confidential Information of the Disclosing Party, except for copies to be retained in order to comply with mandatory law or needed for the purposes of evidence.

*14.4.6 Access Rights granted to a leaving Party*: A Cancelling Party shall have Access Rights to the Foreground developed until the date of the termination of its participation. Access Rights granted to a Defaulting Party shall cease immediately upon receipt by the Defaulting Party of the formal notice of the decision of the Sponsor to terminate the Defaulting Party’s participation in the consortium.

*14.4.7 Access Rights to be granted by any leaving Party*: Any Party leaving the Consortium shall continue to grant Access Rights pursuant to the Funding Terms and this Agreement as if it had remained a Party for the whole duration of the Clinical Study.

*14.4.8* *Other.* Termination of this Agreement will be without prejudice to the accrued rights and liabilities of the Parties under this Agreement*.*

## FORCE MAJEURE

* 1. In the event that any of the Parties is delayed in the performance of its obligations under this Agreement by an event of Force Majeure (as defined hereafter), the obligations of said Party under this Agreement shall remain in suspense until the cause thereof has ceased. *"***Force Majeure***"* shall include, without being limited to, any of the following: riots, sabotage, acts of war, terrorism or piracy, destruction of essential equipment by fire, explosion, storm, flood or earthquake, and delay caused by failure of power supplied or transport facilities or any other cause beyond the control of a Party which renders performance of this Agreement impossible.
	2. Neither of the Parties shall be liable to the other for any loss including but not limited to any damages or abatement of charges whether directly or indirectly caused or incurred by any failure or delay in the performance of its obligations due to Force Majeure.
	3. If either of the Parties shall become aware of Force Majeure which give or are likely to give rise to any failure or delay on its part it shall forthwith notify the other by the most expeditious method then available and shall say how long it is estimated that such failure or delay shall continue.
	4. Any failure by a Party to perform or any delay by a Party in performing its obligations under the Agreement which results from any failure or delay in the performance of its obligations by any person, firm or company with which said Party shall have entered into any contract, supply arrangement or sub-contract or otherwise, shall be regarded as a failure or delay due to Force Majeure only in the event that person, firm or company shall itself be prevented from or delayed in complying with its obligations under such contract, supply arrangements or sub-contract or otherwise as a result of Force Majeure.

## 16. GENERAL PROVISIONS

## Severability

* + 1. If any of the provisions of this Agreement are held to be or rendered void or unenforceable, the Parties agree that the same shall not result in the nullity or unenforceability of the remaining provisions of this Agreement, but that they shall use their best efforts to replace such provision with a valid and enforceable provision which shall achieve, to the extent possible, the economic, business or other purpose of said void or unenforceable provision.

## Relationship

* + 1. This Agreement does not make any Party the employee, agent, partner or legal representative of the other Party for any purpose whatsoever. No Party is granted any right or authority to assume or create any obligation or responsibility, expressed or implied, on behalf of or in the name of the other Party. In fulfilling obligations pursuant to this Agreement each Party shall be acting as an independent contractor.

## Entire Agreement

* + 1. No amendment or variation of this Agreement shall be valid unless made in writing and with the consent of all the Parties.
		2. In the event of any inconsistencies between the terms of this Agreement and the terms of the Protocol or the Schedules or other documents referred to in this Agreement, and with exclusion of the Funding Terms, that will prevail as stipulated in Section 2.1.3, the terms of this Agreement shall prevail except to the extent that any conflict relates to a clinical or medical matter, in which case the Protocol shall prevail.

## Headings

* + 1. The Section and sub-section headings in this Agreement are for convenience only and shall not in any way affect the meaning or interpretation of this Agreement.

## Further Assurance

* + 1. Each Party shall at the reasonable request of the other do or procure the doing of all such further acts, and execute or procure the valid execution of all such documents, as may from time to time be necessary in the requesting Party’s reasonable opinion to give full effect to this Agreement and to vest in the requesting Party the full benefit of the assets, rights and benefits to be transferred to the requesting Party under this Agreement.

## Waiver

* + 1. No delay or omission by either Party hereto to exercise any right occurring upon any non-compliance or default by the other Party with respect to any of the terms of this Agreement shall impair any such right or power or be construed to be a waiver of such right. A waiver by any Party hereto of any of the covenants, conditions or agreements to be performed by the other shall not be construed to be a waiver of any succeeding breach of this Agreement or of any covenant, condition or agreement contained in this Agreement.

## Costs

* + 1. Each Party shall pay its own costs incurred in connection with the negotiation, preparation and implementation of this Agreement.

## Notices

[*PARTIES TO FILL IN THEIR NOTICE DETAILS*]

## Anti-corruption

* + 1. *Prevention of fraud.* The Parties shall take all reasonable steps, in accordance with Good Research Practice, to prevent fraud in connection with the receipt of monies under this Agreement.

## APPLICABLE LAW, ESCALATION PROCEDURE AND DISPUTE RESOLUTION

## Applicable law

* + 1. This Agreement shall be governed by and construed in accordance with the substantive laws of [Belgium / the Netherlands], without taking into account its conflict-of-law rules.

## Dispute resolution

* + 1. In the event that any attempts to resolve a dispute between the Parties amiably fails or in the event that any delay would cause irreparable harm to a Party, then the relevant Parties hereto agree to submit such dispute to the exclusive jurisdiction of the […].
		2. Notwithstanding the foregoing, any Party may seek immediate injunctive or other interim relief from any court of competent jurisdiction with respect to any matter for which monetary damages would not adequately protect such Party’s interests.

*[REMAINDER OF THE PAGE INTENTIONALLY LEFT BLANK]*

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed on [date] in […] originals by their respective duly authorized officers.

**[SPONSOR]**

By \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ By \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Print Name: Print Name:

Title: Title:

**[COORDINATING CENTRE]**

By \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ By \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Print Name: Print Name:

Title: Title:

**[CONSORTIUM MEMBER 1]**

By \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ By \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Print Name: Print Name:

Title: Title:

**[CONSORTIUM MEMBER 2]**

By \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ By \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Print Name: Print Name:

Title: Title:

**[CONSORTIUM MEMBER 3]**

By \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ By \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Print Name: Print Name:

Title: Title:

**[CONSORTIUM MEMBER 4]**

By \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ By \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Print Name: Print Name:

Title: Title:

LIST OF SCHEDULES:

1. **Schedule 1: Funding Terms**
2. **Schedule 2: Parties’ Background IP**
3. **Schedule 3: Description of the Clinical Study and Timetable**
4. **Schedule 4: Payment Schedule**
5. **Schedule 5: Reporting Schedule**

# SCHEDULE 1: FUNDING TERMS

# SCHEDULE 2: PARTIES’ BACKGROUND IP

|  |  |  |  |
| --- | --- | --- | --- |
| **Owner**  | **Background**  | **Type of Background** | **Legal restrictions to the use of the background as described in this Agreement** |
|  |  |  |  |
|  |  |  |  |

# SCHEDULE 3: Description of the Clinical Study and Timetable \_- Description of roles and responsibilities of the Parties

[Detailed description of the research objectives, scope of work, Clinical Study, Study Site(s)]

* + - 1. **Research Objectives**

**[Describe in detail]**

* + - 1. **[Clinical Study]**

**[Describe in detail]**

* + - 1. **[Timetable]**

**[Describe in detail]**

***[Parties may include the Protocol synopsis instead of filling in this Schedule, provided that said synopsis contains any of the abovementioned data]***

# SCHEDULE 4: Budget and Payment Schedule

# SCHEDULE 5: Reporting Schedule

#