

(for ZonMw) **Terms and Conditions First BeNeFIT call**

These Terms and Conditions set the terms and conditions applying to all Dutch Beneficiaries and shall be imposed on other recipients of the Contribution made available by ZonMw. These Terms and Conditions shall replace the General Subsidy Terms and Conditions of ZonMw. The provisions of the Dutch “Algemene wet bestuursrecht” (*Wet van 4 juni 1992, houdende algemene regels van bestuursrecht*) apply in relation to any Contribution made available by ZonMw under the First BeNeFIT call. Where in these Terms and Conditions ZonMw is mentioned, in practice the decisions will be taken jointly by ZonMw and KCE through the Call Steering Committee.

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TERMS AND CONDITIONS FIRST BENEFIT CALL

1. DEFINITIONS AND INTERPRETATION

As used in these Terms and Conditions the following terms and expressions shall have the meaning shown below:

- 1.1 **“Access Rights”** means the right to use Foreground and/or, where applicable, Background IP under the terms and conditions laid down in these Terms and Conditions.
- 1.2 **“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.
- 1.3 **“Award”** means the award letter of the Primary Funding Agency addressed to the Beneficiary, containing *inter alia* the decision of the Primary Funding Agency to select the Beneficiary for the performance of the Clinical Study and the terms and conditions governing such decision.
- 1.4 **“Background”** means any data, materials, information owned or controlled by the Beneficiary or a Collaborator, that are identified as being required for the undertaking of the Clinical Study at the Commencement Date. Background of each Beneficiary and Collaborator, including Background IP, will be listed in the Background List”
- 1.5 “Background List shall mean the list of Background attached to the Consortium Agreement and provided to the Primary Funding Agency for review. The Background List shall contain at least the following elements:

Owner	Background	Type of Background	Legal restrictions to the use of the background as described in these Terms and Conditions
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- 1.6 **“Beneficiary”** means the legal entity that is the main applicant and contact to the Primary Funding Agency and who is identified as the Beneficiary in the Award.
- 1.7 **“Beneficiary’s Representative”** means the person who is authorised to represent

the Beneficiary in respect of these Terms and Conditions.

- 1.8 “**Business Day**” means a day other than Saturday, Sunday and bank holidays in Belgium and The Netherlands.
- 1.9 “**Clinical Study**” means the First BeNeFIT non-commercial Clinical Trail (as defined in the call documents), to be conducted and coordinated by Beneficiary under these Terms and Conditions and further described in the Protocol. For the purpose of these Terms and Conditions, “Clinical Study” shall be understood as to include the activities described in the Protocol as well as any additional work to be performed by Beneficiary, before, during or after such clinical study, as agreed by the Beneficiary and Primary Funding Agency.
- 1.10 “**Collaborator**” means a third party working with the Beneficiary on the Clinical Study being formalized under these Terms and Conditions (including collaborating centres in a multicentre trial, but also third party service providers that support the performance of the Clinical Study with scientific input or certain management or logistic services).
- 1.11 “**Commencement Date**” means the commencement date of the Clinical Study as set out in the Timetable or, if later, the date upon which all necessary Authorisations have been obtained.
- 1.12 “**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 Primary Funding Agency in writing.
- 1.13 “**Confidential Information**” means information of any form, however conveyed and irrespective of the media on which it is stored, that is:

- (a) information which has been marked as confidential at the time of disclosure; or
 - (b) information that reasonably ought to be considered as confidential information of the Beneficiary or the Primary Funding Agency, 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 Primary Funding Agency or the Beneficiary.
- 1.14 “**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>.
- 1.15 “**Consortium Agreement**” means the written agreement between Beneficiary and its Collaborators covering their respective rights and obligations towards each other and the Funding Agencies in relation to the performance of the Clinical.
- 1.16 “**Consortium Partner**” means those Collaborators that have been involved in the development of the Clinical Study, that are key Collaborators and who are party to the Consortium Agreement.
- 1.17 “**Contribution**” means the total consideration payable by the Primary Funding Agency to Beneficiary, in accordance with the Payment Schedule, for the performance of the Clinical Study and the granting of the rights by Beneficiary to the Primary Funding Agency under these Terms and Conditions.
- 1.18 “**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.
- 1.19 “**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.
- 1.20 “**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.

- 1.21 **“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.
- 1.22 **“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.
- 1.23 **“Funding Agency”** means the Primary Funding Agency or the Secondary Funding Agency as the case may be.
- 1.24 **“Funding Agency Representative”** means a person authorised to represent the Primary Funding Agency in respect of these Terms and Conditions as communicated to the Beneficiary.
- 1.25 **“Law”** means any and all laws, regulations and conventions applying to the conduct of clinical studies, such as the Clinical Study, the processing of Personal Data and/or the processing of Samples in the countries where the Clinical Study is conducted.
- 1.26 **“Long Stop Date”** means 6 months after the final funding decision in the framework of the BeNeFIT Call. A Clinical Trial should be started before or on this date, which implies that the Clinical Trial is approved by an Ethics committee and if applicable, any other relevant competent authority;
- 1.27 **“Material”** means any report, executive summary, paper, abstract or other document provided by the Beneficiary under Section 4.2.2 (reporting obligations).
- 1.28 **“National Coordinator”** means a Consortium Partner responsible for subcontracting part of the Clinical Study performance to Study Sites that are not a party to the Consortium Agreement and which Consortium Partner is responsible for coordinating the performance of the Clinical Study in the Consortium Partner’s country of residence.
- 1.29 **“Payment Schedule”** means the schedule for the payment of the Contribution to be determined by the Primary Funding Agency upon the Award.
- 1.30 **“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.

- 1.31 **"Primary Funding Agency"** means the KCE or ZonMw providing the share of the Contribution to the Beneficiary: KCE shall be the Primary Funding Agency with respect to Beneficiaries residing in Belgium and ZonMw shall be the Primary Funding Agency with respect to Beneficiaries residing in The Netherlands.
- 1.32 **"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 a unique code pursuant to Section (ii)(d), provided that such code 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.
- 1.33 **"Protocol"** means the scientific document for the conduct of the Clinical Study, to be drafted by or on behalf of Beneficiary including any subsequent amendment thereto.
- 1.34 **"Quality Management System"** means the systems and processes established by Beneficiary 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.
- 1.35 **"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.
- 1.36 **"Reporting Schedule"** means the reporting schedule as indicated in Section 4 and, upon determination by the Primary Funding Agency, to be further specified in a separate document, where after the Reporting Schedule, shall constitute an integrated part of the Award.
- 1.37 **"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.
- 1.38 **"Secondary Funding Agency"** means KCE or ZonMw providing any share of the Contribution to any Collaborator: KCE shall be the Secondary Funding Agency with respect to National Coordinators residing in Belgium and ZonMw shall be the

Secondary Funding Agency with respect to National Coordinators residing in The Netherlands.

- 1.39 **“Trial Steering Committee”** shall have the meaning as set out in 4.3.1 (b).
- 1.40 **“Site-related Costs”** means all costs incurred by the Beneficiary or a Collaborator that are directly related to the recruitment, involvement and/or treatment of any Study Subject in the Clinical Study at the Beneficiary or such Collaborator’s Study Site.
- 1.41 **“Sponsor-related Costs”** means all costs in respect of the Clinical Study that are not Site-related Costs; such Sponsor-related Costs shall include, without being limited, to all costs incurred by (i) the Beneficiary in relation to the Clinical Study, including all costs paid by the Funding Agencies to the Beneficiary covering the fees for preparation of the full research proposal and for the feasibility study, performed as part of the assessment procedure, and by (ii) Collaborators that are exercising responsibilities that are delegated by the Sponsor under the Clinical Study, such as National Coordinators.
- 1.42 **“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, 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, clinical study report forms, subject diaries and adverse event reporting forms.
- 1.43 **“Study End Date”** means, unless agreed otherwise between the Beneficiary and Primary Funding Agency and detailed in the Protocol, 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.
- 1.44 **“Study Site(s)”** means any location where the Clinical Study shall be conducted.
- 1.45 **“Study Subject”** means an individual who is participating in the Clinical Study.
- 1.46 **“Study Team”** means those individuals appointed by the Beneficiary and, where applicable, a Collaborator to conduct the Clinical Study.
- 1.47 **“Terms and Conditions”** means this document, together with its Schedules attached hereto, if any.
- 1.48 **“Timetable”** means the timelines of the Clinical Trial contained in the Protocol and/or as stipulated in a separate document, which upon its establishment shall constitute an

integral part of the Award.

1.49 “**Use**” shall have the meaning as set out in Section 7.2.2.

1.50 The interpretation and construction of these Terms and Conditions 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;
- (ii) references to Sections and Schedules are to sections of and Schedules to these Terms and Conditions;
- (iii) where the context allows, references to male gender include the female gender and the neuter, and the singular includes the plural and vice versa;
- (iv) references to a Party shall include that Party's personal representatives, successors or permitted assignees; and
- (v) 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.

2. PERFORMANCE OF THE CLINICAL STUDY

2.1 General

2.1.1 *General requirements.* The Beneficiary and its Collaborators shall perform the Clinical Study at the Study Site(s) in accordance with (i) Good Research Practice, (ii) the Protocol, (iii) ICH/GCP, (iv) all applicable Laws, and (vi) the terms and conditions of the Award and these Terms and Conditions. The Beneficiary shall install and maintain during the entire term of the Clinical Study an adequate Quality Management System.

2.1.2 *Responsibility as Clinical Study sponsor.* Beneficiary shall act as sponsor of the Clinical Study, as defined in any applicable Law, and shall assume all responsibilities and liabilities in connection therewith and procure and maintain, or ensure procurement and maintenance of, the mandatory liability insurance coverage in accordance with any applicable Law. Beneficiary shall ensure that it shall be mentioned in the Protocol,

the Informed Consent Forms and in other relevant communication with the Study Subjects or the Regulatory Authorities as sponsor of the Clinical Study. Beneficiary acknowledges and agrees for the avoidance of doubt that the Primary Funding Agency shall under no circumstances be considered as sponsor of the Clinical Study or assume any responsibilities or liabilities in connection therewith, and Beneficiary shall make no representations whatsoever in this respect.

2.1.3 *Conflict of interest.* (a) Beneficiary 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. Beneficiary shall notify the Primary Funding Agency 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.

(b) Without prejudice to the generality of the foregoing, Beneficiary shall, and shall ensure that any member of the Study Team and (where applicable) any Collaborator shall, during the term of these Terms and Conditions, not perform any activity for any person or organisation that substantially hinders or delays the conduct of the Clinical Study. Substantial hindrance or delay will occur where Beneficiary, or any of the Study Team members or (where applicable) Collaborators, perform services for other persons and/or organizations which, among other things, compete for resources needed for the performance of the Clinical Study and/or cause Beneficiary to fail to meet the Timetable, Study Subject enrolment requirements or data flows as agreed under these Terms and Conditions.

2.2 Administration and Direction of the Clinical Study

2.2.1 *Scope and objectives.* The scope and objectives of the Clinical Study are set out in the Protocol and any document describing the Study that underlies the Award. The management and coordination of the Clinical Study shall be under the control of Beneficiary as the Sponsor.

2.2.2 *Timetable.* In conducting the Clinical Study, Beneficiary shall use best efforts to comply with the Timetable. The Timetable may be modified upon both Beneficiary and Primary Funding Agency' written consent as a result of (i) force majeure, (ii) unforeseen requirements of the Primary Funding Agency, or (iii) delays in obtaining or rejection or revocation of or changes in the Authorisations, for reasons for which Beneficiary is not responsible; or (iv) for any other good reason agreed by the Primary Funding Agency in writing. If at any time, Beneficiary has reasons to believe that it will not be able to comply with the Timetable, Beneficiary shall inform the Primary Funding Agency as soon as possible.

2.2.3 *Authorisations.* Beneficiary shall be responsible for obtaining any and all

Authorisations before the commencement of the relevant activity which is subject to the Authorisation and for maintaining such Authorisations. Beneficiary shall keep evidence of any such Authorisations before the commencement of the relevant activity which is subject to said Authorisation and make such evidence available to the Primary Funding Agency upon the Primary Funding Agency's request.

2.2.4 *Protocol.* Before commencement of the Clinical Study, Beneficiary shall submit the Protocol to the Primary Funding Agency for approval. Any amendment of the Protocol shall also be subject to the prior approval of the Primary Funding Agency. Both Beneficiary and Primary Funding Agency shall not unreasonably withhold their consent on any amendment intended to be made by Beneficiary or requested by the Primary Funding Agency. Where required under applicable Law, Beneficiary shall obtain the Authorisations or inform the competent Regulatory Authorities in relation to such amendment. For the avoidance of doubt, no such proposed amendment to the Protocol shall be effective unless all Authorisations shall have been obtained. The Beneficiary shall comply with any amendment to the Protocol requested by a Regulatory Authority and the amended Protocol will then be provided to the Primary Funding Agency for approval (which approval the Primary Funding Agency shall not unreasonably withhold or delay).

2.2.5 *Study Subjects.* (a) Beneficiary shall ensure that the recruitment of the Study Subjects shall take place in accordance with the approved Protocol and the agreed Timetable.

(b) Beneficiary shall ensure that all Study Subjects are properly informed of the nature, implications and risks of the Clinical Study in accordance with all applicable laws and regulations, including ICH/GCP. Beneficiary shall ensure that each Study Subject has understood and signed (or that, in case of minors or protected adult, their parent(s) or guardian have signed) the required Informed Consent Forms before their participation in the Clinical Study. Beneficiary shall ensure that the Informed Consent Form states that the main purpose of the Clinical Study is to improve clinical practice and the (Belgian) health care system and provides for the consent of the Study Subject with the use of its Personal Data contained in the Study Data, including for research purposes and use in the field of health care by the Funding Agencies and/or any other governmental department, institution, body, office, public service and/or agency, as well as with the publication of aggregated and anonymized Study Data for public interests. Beneficiary shall also inform the Study Subjects in the Informed Consent Form that their Pseudonymous Personal Data may be transferred by the Beneficiary to any public health care decision making body or governmental department, institution, body or office (for example, a foreign counterpart of the any of the Funding Agencies) (each a "**Public Agency**") within or outside of the European

Economic Area for further data analyses and/or use for non-commercial research purposes and/or non-commercial use in the field of health care. Beneficiary shall submit the final draft Informed Consent Form to the Primary Funding Agency for approval (which approval the Primary Funding Agency shall not unreasonably withhold or delay). If a Funding Agency anticipates to make Pseudonymous Personal Data to a Public Agency outside the European Economic Area, the Funding Agency shall only do so if the relevant country offers at least the same level of protection in relation to such data that is usually offered by countries within the European Economic Area, and in the event the Informed Consent Form does not adequately provide for such transfer, the Primary Funding Agency and Beneficiary shall collaborate to adequately draft a subsequent, or, where applicable, amend the Informed Consent Form in this respect. For the avoidance of doubt, the Primary Funding Agency's right to share Pseudonymous Personal Data with any public health insurance agencies or governmental department, institution, body or office shall be restricted to the non-commercial uses outlined above.

(c) Beneficiary 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.

(d) Beneficiary 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 Primary Funding Agency and Beneficiary will always take into account medical and ethical considerations and the safety of the Study Subjects.

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

i) For Study Subjects participating in the Clinical Study in Belgium: Beneficiary or its BE Collaborator shall first discuss with the Belgian Primary Funding Agency and the Belgian Primary Funding Agency shall provide reasonable assistance to Beneficiary 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: Beneficiary acknowledges that such use is prohibited, except for restricted use of pseudonymous national services numbers. The Beneficiary warrants that it 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, Beneficiary 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 and legislation.

2.2.6 *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 Beneficiary at its costs, unless the costs of such clinical supplies are eventually assumed by Belgium national health insurance or the Dutch Study Subjects' health insurer.

2.2.7 *Information and reporting.* Beneficiary shall ensure that any member of the Study Team and (where applicable) any Collaborator and any other person involved in the Clinical Study, shall comply with the information and reporting requirements set out in Section 4.

2.2.8 *Transparency - Registration of the Clinical Study.* (a) Beneficiary shall comply with all transparency obligations in accordance with all applicable Laws and regulations (including the registration of the Clinical Study, Protocol related data and information and Study Data in public registers and/or databases).

(b) Without prejudice to the generality of Section 2.2.8 (a), Beneficiary shall register the Clinical Study in a WHO certified publicly accessible registry (such as clinicaltrials.gov) before the Commencement Date.

2.3 Study Team and Collaborators

2.3.1 *General.* (a) The Beneficiary shall appoint, and shall ensure (where applicable) that any of its Collaborators undertakes to appoint, the necessary personnel, facilities, equipment and supplies to perform the Clinical Study under these Terms and Conditions. In fulfilling its obligations hereunder, Beneficiary shall appoint, and shall ensure (where applicable) that any of its Collaborators undertakes to appoint, only persons with the appropriate training, skills and qualifications to perform the Clinical Study.

(b) Beneficiary shall be responsible to ensure that any member of its Study Team and (where applicable) any Collaborator shall comply with the terms of these Terms and Conditions and shall promptly advise its Study Team members and Collaborators of any changes in the scope of these Terms and Conditions or the Clinical Study. Beneficiary shall be liable vis-à-vis the Primary Funding Agency for any breach of

these Terms and Conditions by any of the aforementioned Study Team Members or Collaborators.

2.3.2 *Study Team.* (a) Before the Commencement Date, Beneficiary shall store in the trial master file a short curriculum vitae and relevant references of the key members of the Study Team and provide to the Primary Funding Agency on request. Beneficiary shall, and procures (where applicable) that any Collaborator shall, not remove or replace any key member of the Study Team (the initial list of key members shall be listed in a schedule to the Protocol and upon constitute an integral part of the Award) without the Primary Funding Agency's prior written approval (which approval the Primary Funding Agency shall not unreasonably withhold or delay), unless the person has left the employ of Beneficiary or (where applicable) any of the Collaborators. If, in the Primary Funding Agency's reasonable opinion, a key member of the Study Team is not able to perform its duties in accordance with these Terms and Conditions, the Primary Funding Agency shall have the right to request Beneficiary to replace such person and the Primary Funding Agency and Beneficiary shall meet and discuss to find a reasonable solution. In any case, Contractor shall at all times ensure that the Contractor or the National Coordinating Centre have appropriate replacement immediately available for each key member of the Study Team in the event such key member leaves the employ of Contractor or (where applicable) the National Coordinating Centre; this replacement shall be organized in such a way that a key member leaving the employ of the Contractor or (where applicable) the National Coordinating Centre, has no negative impact on the performance of the Clinical Study or on the safety of the patients.

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

2.3.3 *Collaborators and Consortium Agreement.* (a) Beneficiary and the Consortium Partners shall conclude between them a Consortium Agreement that complies with the terms and conditions of these Terms and Conditions, in particular in respect of arrangements in relation to dissemination and exploitation of, and ownership and access rights to, Foreground. The Consortium Agreement shall be executed no later than 6 months upon the start of the Clinical Study. Beneficiary shall submit to the Primary Funding Agency the final (draft) Consortium Agreement at least 30 days prior to its execution.

(b) The Consortium Agreement shall provide for the creation of governance structure to decide on the collaboration and synchronisation of activities, including on data management, common approaches towards standardisation, links with regulatory

activities and commonly shared dissemination activities, and for the settlement of internal disputes.

(c) Each Consortium Partner may serve as a National Coordinator, who may involve Study Sites located in the country of such National Coordinator, which Study Sites are not a party to the Consortium Agreement, for the performance of the Clinical Study at such Study Sites.

(c) Beneficiary may not involve any new Collaborators in the Clinical Study without the prior written approval of the Primary Funding Agency (which approval the Primary Funding Agency shall not unreasonably withhold or delay).

2.3.4 *Subcontracts.* The Beneficiary or any of the Consortium Partners shall subcontract any work performed by a Collaborator that is not a Consortium Partner in accordance with these Terms and Conditions.

2.3.5 *Record keeping.* (a) Without prejudice to the generality of Section 4, the Beneficiary shall keep and shall cause any member of the Study Team and (where applicable) any Collaborator 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

3.1 Contribution and Payment

3.1.1 *Contribution.* In consideration of the performance of the Clinical Study in compliance with these Terms and Conditions and the granting of rights as set out in these Terms and Conditions, the Funding Agencies shall pay the Contribution (including VAT, if applicable) in accordance with the Payment Schedule and the milestones set out therein. Unless otherwise specifically agreed between the Beneficiary and Primary Funding Agency, the Contribution 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 by the Primary Funding Agency under or in connection with these Terms and Conditions (including no pass-through costs), unless otherwise agreed between the Beneficiary and Primary Funding Agency.

3.2 Belgian Beneficiary

3.2.1 *Contribution:* If the Beneficiary is a Belgian legal entity, KCE shall be the Primary Funding Agency and ZonMw shall be the Secondary Funding Agency. KCE shall pay to the Beneficiary the share of the Contribution allocated to the Beneficiary and the Belgian

Collaborators pursuant to the Clinical Study Budget. ZonMw shall pay to the National Coordinator the share of the Contribution a) allocated to Dutch National Coordinator (including its subcontracted Study Sites and, where applicable other Collaborators residing in the Netherlands) and b) 50% of the Sponsor-related Costs allocated to the Beneficiary. The National Coordinator shall transfer the Sponsor-related Costs to the Beneficiary upon receipt of a specified invoice from the Beneficiary.

- 3.2.2 *Payment terms and conditions:* Beneficiary, or in case of a Dutch Beneficiary the Belgian National Coordinator, shall issue invoices within six (6) months of achievement of the relevant milestone event or milestone date as set out in the Payment Schedule. Prior to issuing any invoice, Beneficiary shall submit a draft invoice to the Primary Funding Agency for the Primary Funding Agency's prior approval (which approval the Primary Funding Agency shall not unreasonably withhold or delay). Beneficiary shall send the final invoice to the following address **the Primary Funding Agency Trials - Financial Service; Kruidtuinlaan 55, Doorbuilding (10th floor); 1000 Brussel; the Primary Funding Agency.Finances@kce.fgov.be**. KCE shall pay the invoice in EURO within thirty (30) days from the date of receipt of the invoice.

3.3 Dutch Beneficiary

- 3.3.1 *Contribution:* If the Beneficiary is a Dutch legal entity, ZonMw shall be the Primary Funding Agency and KCE shall be the Secondary Funding Agency. ZonMw shall pay to the Beneficiary the share of the Contribution allocated to the Beneficiary and the Dutch Collaborators pursuant to the Clinical Study Budget. KCE shall pay to the Belgian National Coordinator the share of the Contribution a) allocated to Belgian National Coordinator (including its subcontracted Study Sites and, where applicable other Collaborators residing in the Belgium) and b) 50% of the Sponsor-related Costs allocated to the Beneficiary. Subject to the KCE terms and conditions applying to the National Coordinator, the National Coordinator shall transfer the Sponsor-related Costs to the Beneficiary upon receipt of a specified invoice from the Beneficiary.

- 3.3.2 *Payment terms:* The payments by ZonMw to the Beneficiary, and in case of a Belgian Beneficiary, to the Dutch National Coordinator, shall be made in accordance with the Payment Schedule.

3.4 Other terms and conditions

- 3.4.1 *Suspension.* The Primary Funding Agency may suspend its payment obligations under these Terms and Conditions in the event Beneficiary (or any other person or organisation involved in the Clinical Study) does not comply with its material obligations under these Terms and Conditions after a remediation period of thirty (30) days following the date of receipt of a written notice by the Primary Funding

Agency specifying the non-compliance and requiring its remedy.

3.4.2 *Payments to third parties.* Without prejudice to Sections 3.2 and 3.3, the Beneficiary is responsible to pay from the Contribution received from the Primary Funding Agency, costs incurred by third parties involved in (the performance of) the Clinical Study in the Beneficiaries country of residence, including Collaborators, Regulatory Authorities, Study Subjects, the relevant data protection supervisory authority. The National Coordinator shall pay from the Contribution received from the Secondary Funding Agency costs incurred by to third parties involved in (the performance of) the Clinical Study in the National Coordinator's country of residence, including Collaborators, Regulatory Authorities, Study Subjects, the relevant data protection supervisory authority. The Beneficiary shall, and shall ensure that the National Coordinator shall, be responsible and ensure that such payments are made promptly and in accordance with applicable laws and regulations.

3.4.3 *Final payment.* The final payment due by the Funding Agencies under Sections 3.2 and 3.3, upon the Completion Date as set out in the Payment Schedule, shall be subject to the following conditions:

- (i) the reports (including the trial report) and the main manuscript required under Section 4 and the Reporting Schedule have been submitted by the Beneficiary to the Primary Funding Agency, and have been accepted by the Primary Funding Agency according to the procedure set forth in Section 4.2.2(c); and
- (ii) agreement has been reached in respect of any items remaining for disposal.

4. ACCESS TO STUDY DATA, REPORTING, MONITORING

4.1 Access to Study Data

4.1.1 As from the Study End Date and for a further period of six (6) years, and subject to Section 4.1.2, Beneficiary shall provide the Funding Agencies upon the Primary Funding Agency's request with specific Study Data in the format to be agreed between the Beneficiary and Primary Funding Agency. Any such provision of Study Data will not require additional data analysis, unless agreed otherwise.

4.1.2 Beneficiary 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 these Terms and Conditions, will in principle be anonymized Study Data. However, where specifically requested by the Primary Funding Agency, Pseudonymous Personal Data shall be made available. In no event shall any of the reports, documents, information disclosed to the Primary Funding Agency under and in accordance with these Terms and Conditions include data that as such reveal the

identity of a Study Subject through direct identifiers or otherwise. The Beneficiary shall, or where applicable, shall ensure that the Study Team and/or Collaborators shall, keep the key to personal identities of all persons to whom the data relates in a separate and secure place in compliance with applicable data privacy Law and legislation and such key shall not be disclosed to the Primary Funding Agency or unauthorized persons. In relation to the Pseudonymous Personal Data to which the Primary Funding Agency is granted access in accordance with this Section, the Primary Funding Agency shall comply with all applicable data privacy Law and legislation.

- 4.1.3 Except if the procedure for publication as set forth in Section 8.4 has been followed, Beneficiary shall not provide (a copy of) the Study Data to a third party without the prior written approval of the Primary Funding Agency, which approval the Primary Funding Agency shall not unreasonably withhold or delay and which the Primary Funding Agency 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 these Terms and Conditions, the rights granted to the Primary Funding Agency under these Terms and Conditions and/or the benefit of the Clinical Study for patients and/or the public health decision making bodies.

4.2 Obligation to inform and report – acceptance of the final Clinical Study report

- 4.2.1 *Information.* Subject to Section 4.1.2, Beneficiary shall during the term of the Clinical Study provide all information on any aspect of the Clinical Study as reasonably requested by the Primary Funding Agency, allowing the Primary Funding Agency to be informed on the progress of the Clinical Study and any important event in relation therewith. In addition, Beneficiary shall inform the Primary Funding Agency promptly of (i) any event which is likely to affect significantly or delay the performance of the Clinical Study or the Primary Funding Agency's interests, (ii) changes in its legal, financial, technical, organisational situation, circumstances affecting compliance with the requirements under these Terms and Conditions, (iii) significant developments, including developments in relation to the safety of Study Subjects or to the scientific direction of the Clinical Study taking into account the research objectives of the Clinical Trial. For the avoidance of doubt, safety data reporting obligations in accordance with the applicable laws and regulations shall vest in the Beneficiary.

- 4.2.2 *Reporting.* (a) Without prejudice to this Section 4.2, the Beneficiary shall comply with the Reporting Schedule and shall use the format as determined by the Primary Funding Agency or published on its dedicated website (as the Primary Funding Agency may amend from time to time). Beneficiary shall provide the Primary Funding Agency with high-level progress reports every two (2) to four (4) weeks and at least once a month.

Trial Steering Committee will report at least every four (4) to six (6) months.

(b) Each progress report shall detail all relevant information relating to the Clinical Study (including the recruitment of Study Subjects) up to the relevant date.

(c) The final report(s) identified in the Reporting Schedule shall include the (anonymized and aggregated) Foreground, methods and final conclusions together with management information and any other information relating to the Clinical Study up to the Study End Date, and shall be in compliance with the ICH E3 Guidelines or similar format acceptable to the Primary Funding Agency and with the CONSORT Statement (unless the Primary Funding Agency has confirmed that said report(s) may be set up pursuant to adapted or simplified standards). Beneficiary shall use the template final report provided by the Primary Funding Agency or placed on any of the Funding Agency's website. The Beneficiary shall also provide, in a form to be agreed with the Primary Funding Agency, a draft summary final report of the findings of the Clinical Study. If within one (1) year of the Study End Date the Beneficiary has not produced a final report which satisfies the Primary Funding Agency, the Primary Funding Agency may prepare and publish, or arrange for the preparation and publication of such a report.

The Primary Funding Agency has the possibility to object in writing against or provide written comments on the draft final Clinical Study report and/or the draft summary final report of the findings of the Clinical Study during a period of two (2) months from the date of receipt. Following objections or comments received from the Primary Funding Agency within that two (2) month period, the Primary Funding Agency and Beneficiary shall discuss in good faith on any adjustments to be made to the draft report(s); in any case, Beneficiary shall, and shall ensure that any of its Collaborators shall, make those adjustments to the final report which are required to ensure compliance with the Protocol. The Primary Funding Agency is also allowed to give suggestions for adjustment of the final report from a scientific point of view, and Beneficiary, resp. Collaborator will use its best efforts to take into account such reasonable suggestions as long as such suggested adjustments do not change the scientific conclusion of the findings and do not interfere with the scientific integrity of the findings. Beneficiary shall, and shall ensure that its Collaborators shall, implement the agreed upon adjustments to said reports as soon as possible after the Primary Funding Agency and Beneficiary having agreed on the adjustments. For the avoidance of doubt, if Beneficiary has not received any written objections or comments within the above-mentioned two (2) month period, the draft final Clinical Study report and the draft summary final report of the findings of the Clinical Study, as previously submitted to the Primary Funding Agency, will be deemed to be accepted by the Primary Funding Agency.

(d) The Funding Agencies reserve the right to reproduce the findings of the final report or to publish a summary of the findings with a reference to the final report. In any case, the Funding Agencies shall not change the scientific conclusions of the findings; notwithstanding the foregoing, a Funding Agency, or any party appointed by it, shall be entitled to perform additional analysis as it deems appropriate; as the case may be, if the Funding Agency's analyses may result in different conclusions or findings than the conclusions or findings set forth in the final report submitted by (or on behalf of) the Beneficiary to the Primary Funding Agency, the Funding Agency shall present these different conclusions or findings as its own conclusions or findings.

4.3 Follow-up and governance

4.3.1 *Governance.* (a) The Beneficiary Representative and the Funding Agency Representative shall review and discuss the conduct and progress of the Clinical Study once a month by phone and email. A face to face meeting at the Primary Funding Agency will be planned within one month if requested by either Party.

(b) Beneficiary shall install and organise a steering committee ("**Trial Steering Committee**") that shall oversee the performance of the Clinical Study and discuss important topics in relation thereto. The Trial Steering Committee 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 Primary Funding Agency or deemed necessary by Beneficiary ("extraordinary meetings"). The Beneficiary shall propose to the Primary Funding Agency the composition of the Trial Steering Committee for the Primary Funding Agency's prior approval. The Primary Funding Agency shall have the right (but not the obligation) to be present at each Steering Committee meeting. Beneficiary shall provide the Primary Funding Agency with a proposed agenda for such meetings at the latest ten (10) Business Days in advance of the meeting; the Primary Funding Agency shall have the right to add additional items to the agenda. Beneficiary shall provide draft meeting minutes at the latest ten (10) Business Days after the meeting to the Primary Funding Agency for review (irrespective whether the Primary Funding Agency participated or not to said meeting). The meeting minutes shall be deemed to be accepted by the Primary Funding Agency if no comments are raised by the Primary Funding Agency in writing within fifteen (15) Business Days after receipt of the minutes.

4.3.2 *Audits.* (a) The Beneficiary shall provide, and shall ensure that any member of the Study Team and (where applicable) any Collaborator undertake to provide, all reasonable cooperation and assistance at all times during the term of these Terms and Conditions and for a period of six (6) years after termination or expiry of these Terms and Conditions for the purposes of allowing the Primary Funding Agency to obtain the information as is necessary to fulfil the Primary Funding Agency's

obligations to supply information for parliamentary, governmental, judicial or other regulatory or administrative purposes.

(b) Beneficiary shall provide, and shall ensure that any member of the Study Team or (where applicable) any Collaborator shall provide, all reasonable cooperation and assistance at all times during the term of these Terms and Conditions and for a period of two (2) years after termination or expiry of these Terms and Conditions to allow the Primary Funding Agency or its designee (the "**Auditors**") to carry out an audit of the Beneficiary's or (where applicable) any of its Collaborators' compliance with these Terms and Conditions (including all activities, performance, security and integrity in connection therewith), and Beneficiary's Quality Management System. In this respect, Beneficiary shall ensure, during business hours and upon giving reasonable prior notice, free access to the Auditors to Beneficiary's and (where applicable) any of its Collaborators' facilities and Study Sites, and all relevant information, data and records relevant to the Clinical Study, including the trial master file, taking into account Collaborator's and Collaborator's facilities and Study Sites' procedures for access.

The Auditors shall have access only to, and only be allowed to report to the Primary Funding Agency, such information as strictly required to verify the compliance with these Terms and Conditions. It is the responsibility of the Primary Funding Agency that the Auditors are bound by confidentiality provisions and restrictions at least as stringent as those stated in Section 6.1 below.

(c) If, during the term of these Terms and Conditions and six (6) years thereafter the Beneficiary is notified of a scheduled inspection of the Clinical Study at any study Site by a Regulatory Authority, Beneficiary will immediately inform the Primary Funding Agency in writing. At its discretion, the Primary Funding Agency may choose to be present during such inspection, unless such inspecting Regulatory Authority opposes to the Primary Funding Agency being present during the inspection. Any inspection report made by a Regulatory Authority, relevant to the performance of the Clinical Study or the Contribution made available, will promptly be shared by Beneficiary with the Primary Funding Agency.

4.3.3 *Measures.* The Beneficiary shall take all measures reasonably requested by the Primary Funding Agency in order to ensure compliance with these Terms and Conditions and performance of the Clinical Study within its research objectives.

5. **DATA PROTECTION**

5.1 **General obligations**

5.1.1 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).

5.1.2 In relation to any **processing** of Personal Data in connection with the Clinical Study, the Beneficiary and its Collaborators shall be deemed to be individual and/or joint **controllers**. The Primary Funding Agency **processing** Pseudonymous Personal Data, as set forth in these Terms and Conditions, shall be deemed a **controller** with respect to such Pseudonymous Personal Data. The Primary Funding Agency and the Beneficiary (and any of its Collaborators) are responsible for any obligations of the **controller** under the GDPR, including:

- (ii) It will only lawfully **process** Personal Data as meant under Article 6 of the GDPR;
- (iii) Processing shall be in accordance with all applicable Law, regulations and where applicable, **codes of conduct**.
- (iv) It 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.
- (v) It will ensure that the **data subjects** are enabled to exercise their rights under Chapter III of the GDPR.

5.1.3 Without prejudice to the Primary Funding Agent's obligations as a **controller** under the GDPR, the Primary Funding Agents will report any **data security breach** to the Beneficiary, to allow the Beneficiary and/or any of its Collaborators to comply with their obligations to report and inform such breach, under the GDPR.

5.2 Specific obligations

(a) Beneficiary shall at all times ensure that only anonymous Study Data or, where requested by the Primary Funding Agency, Pseudonymous Personal Data are made available to the Primary Funding Agency. Beneficiary shall at all times ensure that (i) the unique code concerning such Pseudonymous Personal Data will only be in the possession of the members of the Study Team who are in direct contact with the relevant Study Subjects, that (ii) such Pseudonymous Personal Data can only be traced or linked back by said Study Team members, and that (iii) said Study Team members shall treat these codes as strictly confidential.

(b) No mention shall be made of individual officers of any of the Funding Agencies,

nor shall information be included which might lead to their identification, without the prior written agreement of the relevant Funding Agency.

(c) Beneficiary shall ensure that the **processing** of Personal Data under these Terms and Conditions shall be duly notified to the **supervisory authority** directly or through the relevant **data protection officer**.

6. CONFIDENTIALITY

6.1 Confidentiality and non-use

6.1.1 *General.* In respect of any Confidential Information the Beneficiary or Primary Funding Agency may receive (the "Recipient") from the other (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:

- (i) 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 these Terms and Conditions, 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; and
- (ii) nothing herein shall be construed as to prevent the Primary Funding Agency from exercising its rights granted under these Terms and Conditions provided that it complies with all applicable Laws and regulations.

6.1.2 *Exception.* The obligation of confidentiality and non-use shall not apply to any information to the extent such information:

- (i) is or becomes public knowledge (otherwise than by breach of Section 6.1.1);
- (iii) was in the possession of the Recipient, without restriction as to its disclosure, before receiving it from the Discloser;
- (iv) is received from a third party who lawfully acquired it and who is under no obligation restricting its disclosure;
- (v) is independently developed without access to the Confidential Information of the Discloser; or

(vi) 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.

6.1.3 *Term.* The obligations of each of the Beneficiary and Primary Funding Agency contained in this Section shall continue for a period of ten (10) years after the expiration or termination of these Terms and Conditions. A failure to comply with this Section 6, shall constitute a material breach of these Terms and Conditions.

7. RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

7.1 Ownership of Background

7.1.1 *Principle.* Nothing in these Terms and Conditions shall affect Beneficiary's or, where applicable, any of its Collaborators' rights in Background nor imply grant of any license to such Background, unless expressly set out herein.

7.1.2 *Identification.* In the event that Background will be used for the performance of the Clinical Study, such Background shall be identified in the Background list, including the legal restrictions of which it or its Collaborators are aware that may affect the use of the Background for the purpose of the Clinical Study or the rights granted to the Primary Funding Agency under these Terms and Conditions. Beneficiary shall on a best effort's base procure that neither itself nor any of its Collaborators will use in the performance of the Clinical Study any Background that was not identified in the Background List.

7.2 Use of Background

7.2.1 *General.* In respect to the Background, Beneficiary shall, and procures (where applicable) that any Collaborator shall, remain free to license, assign, or otherwise dispose or transfer ownership ("Use") of its Background, provided that Beneficiary (and, where applicable, any Collaborator) shall pass on its obligations specified under these Terms and Conditions (or the Consortium 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.

7.2.2 *Notification and objection.* Beneficiary shall, during the term of these Terms and Conditions, notify the Primary Funding Agency of any Use in advance and the Primary Funding Agency shall be entitled to object to such Use if, in the Primary Funding Agency's reasonable opinion, the Use prevents or limits Beneficiary's performance under these Terms and Conditions. The foregoing obligation to notify the Primary

Funding Agency of such Use, shall be without prejudice to the obligation of Beneficiary (and its Collaborators) set forth in Section 7.2.1, which obligation shall continue to apply for a period of six (6) years after the term of these Terms and Conditions.

8. RIGHTS AND OBLIGATIONS RELATED TO RESULTS

8.1 Ownership of Foreground

8.1.1 *Principle.* Foreground is owned by the Beneficiary and/or Collaborator who has generated such Foreground.

8.2 Protection of Foreground

8.2.1 *Information.* The Beneficiary shall inform the Primary Funding Agency in a timely manner, and shall ensure (where applicable) that any Collaborator informs the Beneficiary, 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.

8.2.2 *IP policy.* The Beneficiary (and/or the appropriate Collaborator) will identify, protect and maintain Intellectual Property in accordance with its standard institutional policy. If available, the Beneficiary will provide a copy of any applicable IP policy on the request of the Primary Funding Agency. Beneficiary shall take due consideration of the Primary Funding Agency's attitude to the clearly inappropriate use of patents which the Primary Funding Agency considers detrimental to scientific endeavour or to advances in healthcare. In the event the Beneficiary (or where applicable) any Collaborator decides not to protect any Foreground invention by filing a patent application or to abandon prosecution of any patent in the Foreground invention, the Beneficiary shall communicate such decision to the Primary Funding Agency and both Beneficiary, if appropriate the Collaborator, and the Primary Funding Agency 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, Beneficiary shall have the right, before taking any decision on the protection and maintenance of Intellectual Property, to discuss with the Primary Funding Agency 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.

8.2.3 *Records.* Beneficiary shall keep proper records showing the description of the Background IP and Foreground IP.

8.3 Exploitation of Foreground

8.3.1 *General.* Beneficiary acknowledges that the main purpose of the research performed under these Terms and Conditions 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, undertakes not to exploit the Foreground in any way that is or could be detrimental to such interests. In this respect, Beneficiary acknowledges the importance of the dissemination of the Foreground and the Access Rights in accordance with the principles set forth herein. Beneficiary and its Collaborators 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 as outlined in Section 9.2.3 below.

8.3.2 *Commercialisation.* (a) 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 Beneficiary under these Terms and Conditions. Without prejudice to Section 8.4, in the event that a commercialization opportunity nevertheless arises, the Beneficiary shall or shall procure (where applicable) that any Collaborator shall inform the Primary Funding Agency thereof in advance and shall seek the prior written consent of the Primary Funding Agency before it or (where applicable) any Collaborator, as the case may be, makes any commercial use of, or grants to any third party any exploitation rights over the Foreground and/or transfer, dispose or assigns the Foreground to a third party. Beneficiary shall, and shall procure (where applicable) that any Collaborator shall, provide all appropriate details of any proposed commercialisation, licensing, transfer or assignment arrangements, including but not limited to any deal sheet or commercial terms in circulation, which information the Primary Funding Agency shall keep confidential.

(b) the Primary Funding Agency shall evaluate such intended commercialization against the purpose and interests set forth in section 8.3.1. the Primary Funding Agency shall, acting reasonably, have the right to withhold such approval in the event the Primary Funding Agency reasonable believes that the intended commercialisation, licensing or assignment is likely to have a negative impact on the further performance of the Clinical Study in accordance with these Terms and Conditions, the rights granted to the Primary Funding Agency under these Terms and Conditions and/or on the main purpose and/or interests set forth in Section 8.3.1. For example and without limiting the foregoing, such right of withholding approval, shall apply in the event the Beneficiary intends to grant exclusive rights to third parties hindering or limiting the Access Rights granted to the Primary Funding Agency hereunder; or in the event the 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 these Terms and Conditions 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. In this respect, the Primary Funding Agency shall have the right to subject its approval to specific terms which are reasonable and appropriate in the specific case and which should ensure that the intended commercialization has no negative impact on the further performance of the Clinical Study in accordance with these Terms and Conditions, the rights granted to the Primary Funding Agency under these Terms and Conditions and/or on the main purpose and/or interests set forth in Section 8.3.1. For example, and without limiting the foregoing, such specific terms could include the payment to the Primary Funding Agency of a fair compensation and/or conditions concerning the pricing of the commercial product or service incorporating or making use of one or more Foreground.

8.4 Dissemination of Foreground – Open Access

8.4.1 *General obligation.* (a) Unless otherwise agreed between the Beneficiary and Primary Funding Agency, Beneficiary (and its Collaborators) must as soon as possible disseminate the Foreground owned by it and/or (where applicable) any Collaborator, by disclosing them to the public by appropriate means, including in scientific publications (in any medium). Beneficiary shall inform and discuss its dissemination strategy with the Primary Funding Agency in advance.

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

(c) Notwithstanding the foregoing, the final Clinical Study report as referred to in Section 4.2.2 should be made available for review and comment by the Primary Funding Agency in accordance with Section 4.2.2, before the Foreground are disseminated in accordance with this Section 8.4.

(d) The Beneficiary must notify the Primary Funding Agency prior to any dissemination (including publication) (whether in oral, written or other form) of any Foreground or of matters arising from the Clinical Study. The Beneficiary shall send one draft copy of the proposed dissemination to the Primary Funding Agency at least ten (10) days for an abstract and thirty (30) days for a manuscript before the date intended for dissemination. For the avoidance of doubt, this obligation continues after the end of the Clinical Study, for a further period of six (6) years. The Primary Funding Agency may object to such dissemination, by giving written notice to the Beneficiary (a “Confidentiality Notice”) (ii) to prevent the dissemination of its Confidential Information, or (iii) to delay the proposed dissemination for a maximum ninety days after the date of submission to the Primary Funding Agency of the first draft

publication if, in its reasonable opinion, such delay is necessary in order to seek patent or similar protection for any Foreground which are the subject of the intended dissemination. In the event Beneficiary or (where applicable) any Collaborator intends not to protect the Foreground that is capable of IP protection, Beneficiary requires to formally notify the Primary Funding Agency thereof before the dissemination takes place and Beneficiary and Primary Funding Agency shall act as per Section 8.2.2.

A Confidentiality Notice must contain a precise and motivated request for necessary adaptations to the intended dissemination/publication. If such objection has been raised, the Primary Funding Agency and the Beneficiary will discuss how to overcome the justified grounds for the objection on a timely basis (for example by adapting the planned publication and/or by protecting Foreground before publication). The opposition to the intended dissemination will not be unreasonably continued if both Beneficiary and Primary Funding Agency agree that appropriate actions have been taken following the discussion. Confidentiality Notices must be sent within thirty (30) calendar days after receipt of the draft dissemination/publication. The Beneficiary shall have the right to proceed with the proposed dissemination/publication if it has not received a Confidentiality Notice within that thirty calendar days' period.

Furthermore, Beneficiary will use its best efforts to take into account any reasonable scientific suggestions from the Primary Funding Agency as long as such suggested adjustments do not change the scientific conclusion or the findings and do not interfere with the scientific integrity of the findings.

(e) Beneficiary shall ensure that any dissemination is scientifically correct, objective and unbiased (taking into consideration the primary endpoint(s)).

(f) Beneficiary shall ensure that the manuscript for publication includes references to the data access plan, as well as the contact details of the person responsible within Beneficiary for the management of third party access to the Study Data, as further set forth in Section 9.2.3.

(g) In the event of a multicentre Clinical Study, Beneficiary shall not, and shall use its best efforts to ensure that its Collaborators shall not, independently publish or otherwise disclose any findings resulting from the Clinical Study before publication of the main multicentre publication. In the event the main multicentre publication is not published within twelve (12) months from the date the final Clinical Study report as referred to in Section 4.2.2 is accepted by the Primary Funding Agency in accordance with Section 4.2.2.(c), the Beneficiary and/or the Collaborators shall be entitled to publish the site-specific publication, subject to the procedure and conditions set forth in Section 8.4.1 (d) and (f) above.

- 8.4.2 The Beneficiary shall ensure that any dissemination shall acknowledge the Funding Agencies' financial support and carry a disclaimer as the Primary Funding Agency may require or in the absence of direction from the Primary Funding Agency a notice as follows:

"This report is independent research funded by 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 Belgian Health Care Knowledge Centre or the Department of Health."

- 8.4.3 *Open access to scientific publications.* Beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed scientific publications relating to the Foreground owned by it and/or the Collaborators. In particular it must:

- (i) 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, Beneficiary must aim to deposit at the same time the research data needed to validate the Foreground presented in the deposited scientific publications; and
- (ii) 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) or, within six (6) months of publication in any other case.

9. ACCESS RIGHTS

9.1 Background

- 9.1.1 *Access Right.* Regarding the Background listed in Background List as per Section 7.1.2, or any Background not listed in therein, which was used in the performance of the Clinical Study in contravention of Section 7.1.2, Beneficiary hereby grants, and procures (where applicable) that any Collaborator grants, 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. Each Funding Agency shall ensure that any of its sub-licensees complies with the terms and conditions of the Access Rights set forth herein.

9.2 Foreground

- 9.2.1 *Access Right.* (a) In furtherance of the main purpose and interests set forth in Section 8.3.1 above, Beneficiary hereby grants, and procures (where applicable) that any Collaborator grants, to the Funding Agencies at the end of the Clinical Study, 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 consultation with Beneficiary, 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 a Funding Agency's behalf. The content and timing for such publication will be subject to consultation with the Beneficiary and 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. The Funding Agencies shall each ensure that such dissemination shall be in accordance with privacy Law and acknowledge Beneficiary as the sponsor (in the sense of any applicable Law) of the Clinical Study.

9.2.2 *Publication.* In addition to the foregoing, the Funding Agencies shall have the right to publish any Material, (aggregated) Study Data or other information in relation to the Clinical Study received from the Beneficiary for communication and publicising activities as set out in Section 10.

9.2.3 *Access right to third parties.* After the Completion Date, subject to the provisions of these Terms and Conditions (including Clauses 5 and 6), Beneficiary shall grant, and procures (where applicable) that any Collaborator shall grant, Access Rights to the Foreground to third parties on a non-exclusive basis and at fair and reasonable terms. In this respect, Beneficiary 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 Beneficiary (or the person appointed by it) providing the terms and conditions for such access. Beneficiary shall appoint a contact person that shall manage the third party access on its behalf. In the event Beneficiary and the relevant third party are unable to agree on the terms and conditions for the access to the Foreground, Beneficiary may request the Primary Funding Agency to facilitate the

discussions.

10. PUBLICATION BY the Funding Agencies

10.1 General

10.1.1 The Clinical Study funded by the Funding Agencies under these Terms and Conditions is open and, subject to the provisions of these Terms and Conditions, the Primary Funding Agency is entitled to publish details of the selection process, the research objectives, plan and costs and these Terms and Conditions.

10.2 Publishing activities

10.2.1 *Communication and publishing activities.* (a) without prejudice to the Funding Agencies' rights under Section 9 and subject to Sections 5 and 6, the Funding Agencies may use, for their communication and publicising activities, the Materials and all (aggregated) Study Data or other information in relation to the Clinical Study provided by Beneficiary to the Primary Funding Agency.

(b) However, if the Funding Agencies' use of these Materials, documents and information, would risk compromising Beneficiary's legitimate interests, the Beneficiary may request the Primary Funding Agency not to use it for said purposes and the Beneficiary and Primary Funding Agency shall discuss in good faith an acceptable way to proceed, considering at all times the purpose and the objective of the Clinical Study.

(c) The Funding Agencies' right to use the Materials, documents and information includes: (i) for its own purposes, in particular making them available to persons working for the Funding Agencies or any other federal, regional, EU or other EU member state institution, body, public service, office or body, and copying or reproducing them in whole or in part, in unlimited numbers; (ii) distribution to the public, in particular publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services or inclusion in widely accessible databases or indexes; (iii) editing or redrafting for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation; (iv) translation; (v) giving access in response to individual requests in furtherance of the applicable legislation on freedom of information act ('*Wet openbaarheid van bestuur*'); (vi) storage in paper, electronic or other form; (vii) archiving; and (viii) the right to authorise third parties to act on its behalf or sub-license the modes of use set out above to third parties if needed for the communication and publicising activities of the any of the Funding Agencies. In any case, the Funding Agencies' right to use the Materials, documents and information set forth in this Section 10.2.1(c) does in no case allow the any

Funding Agency to change the scientific conclusion of the findings notwithstanding the foregoing, the foregoing without the Funding Agencies' rights under Section 4.4.2(d).

(d) Beneficiary shall ensure it obtains all necessary approvals from third parties concerned in order to comply with its obligations under this Section 10. In this respect, Beneficiary shall, and shall ensure that its Collaborator shall, before the commencement of the Clinical Study, have entered into appropriate (employment) agreements with its employees, representatives, agents and personnel, in which such employees, representatives, agents or personnel have assigned or granted to Beneficiary, resp. Collaborator, such rights in order for Beneficiary to comply with its obligations under this Section 10.

(e) Where requested by Beneficiary, the Funding Agencies will insert the following information:

" © - [year] - [name of the copyright owner]. All rights reserved. Licensed to Belgian Health Care Knowledge Centre and ZonMw under conditions."

11. REPRESENTATIONS

11.1 Both Beneficiary and Primary Funding Agency representations

11.1.1 Except as expressly provided in these Terms and Conditions, none of the Beneficiary and Funding Agencies give any warranties or makes 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.

11.2 Beneficiary warranties

11.2.1 The Beneficiary warrants that:

- (i) it 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;
- (ii) it has full capacity, power and authority and all necessary licences, permits and consents to assume and fully perform all of its obligations under these Terms and Conditions;
- (iii) there are no actions, suits or proceedings pending or, to the Beneficiary's knowledge, threatened against or affecting the Beneficiary before any court or administrative body or tribunal that might affect the ability of the

Beneficiary to meet and carry out its obligations under these Terms and Conditions;

- (iv) it shall comply with its obligations under these Terms and Conditions, including with the standards for performing the Clinical Study set out in Section 2.1.1.
- (v) it is not a party to an agreement which would prevent Beneficiary from fulfilling its obligations under these Terms and Conditions;
- (vi) it shall during the term of the Clinical Study not enter into any agreement or arrangement which would substantially restrict Beneficiary's ability to perform the Clinical Study;
- (vii) it 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;
- (viii) it shall not enter into any agreement in which the Intellectual Property arrangements would adversely affect the Beneficiary's ability to comply with the terms of these Terms and Conditions without the prior consent of the Primary Funding Agency, such consent not to be unreasonably withheld or delayed.
- (ix) the Beneficiary's Study Team 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;
- (x) none of the Study Team 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;
- (xi) it shall perform the Clinical Study in compliance with all ethical principles, including avoiding fabrication, falsification, plagiarism or other research misconduct;
- (xii) unless otherwise agreed in writing by the Primary Funding Agency, neither the Beneficiary nor any of its Collaborators has obtained or will obtain during the term of the Clinical Study any other (EU, federal, regional, local or foreign) public (other than from the Primary Funding Agency) or private funding for the performance of the Clinical Study;
- (xiii) to the best of its knowledge and belief:
 - a. subject to the declaration set out in the Background List, it is (or, where

applicable, any Collaborator is) has the right to use and provide licenses to any Background under these Terms and Conditions, 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 Background List prior to entering such Background into the Clinical Study;

- b. it and/or (where applicable) a Collaborator 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 these Terms and Conditions; and
- c. it has not granted any third party any right in respect of the Foreground IP (other than in accordance with the provisions of this Terms and Conditions), and has not charged or encumbered and will not charge or encumber any of the same.

12. INDEMNIFICATION

- 12.1 Beneficiary shall indemnify, defend and hold the Funding Agencies or any other governmental institution, body, public service or agency and its or their respective officers, directors, employees and agents harmless from and against any and all claims, liabilities, lawsuits, threats of lawsuits or other governmental action, or losses suffered, incurred or sustained by any Funding Agency Indemnified Party, by reason of any claim or proceeding to the extent arising out of or resulting from (a) any non-compliance of Beneficiary with any of its obligations or warranties under these Terms and Conditions; (b) any breach by Beneficiary of any agreement between Beneficiary and Collaborator and/or Study Team; (c) any claims arising out of or in connection with or as a result of the performance of the Clinical Study.

13. INSURANCE

- 13.1 Without prejudice to Section 12, the Beneficiary shall, or shall ensure, throughout the duration of these Terms and Conditions 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 the Beneficiary arising out of the Beneficiary's performance of these Terms and Conditions, including the insurance that is required to be taken out as sponsor the Clinical Study as set out in any applicable Law.
- 13.2 The Beneficiary shall produce on demand by the Primary Funding Agency documentary evidence that any insurance policies required by Section 13.1 are in force.
- 13.3 Subject to the limitations set out herein, the terms or the amount of cover of any

insurance shall not relieve the Beneficiary of any liabilities under these Terms and Conditions.

14. TERM AND TERMINATION

14.1 Term

14.1.1 *Term.* Unless otherwise terminated in accordance with the provisions hereof, these Terms and Conditions shall be effective as from the date of the Award and shall, subject to Section 14.1.2, 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 these Terms and Conditions: Section 4.1 (*Access to Study Data*), Section 4.3.2 (*Audits*), Section 6 (*Confidentiality*), Section 7 (*Background*), Section 8 (*Foreground*), Section 9 (*Access Rights*), Section 10 (*Publication*), Section 12 (*Indemnification*), Section 14.3 (*Termination Consequences*) and Section 19 (*Applicable Law*), including any cross-references set out in these Sections. The foregoing shall be without prejudice to any other provision of these Terms and Conditions that by its nature survives expiration or termination of these Terms and Conditions.

14.2 Termination

14.2.1 Both Beneficiary and Primary Funding Agency shall have the right to terminate the Clinical Study, and ZonMw may terminate the Contribution, immediately upon written notice, in the event:

- (ii) The other 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
- (iii) In case an event force majeure that exceeding a period of three (3) months; and/or
- (iv) Immediately upon giving notice 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 at the latest six (6) months after the Award for reasons outside the reasonable control of the Party wishing to terminate these Terms and Conditions; and/or
- (v) Immediately upon giving notice if the safety of the Study Subjects cannot be

guaranteed anymore for reasons outside the reasonable control of the Party wishing to terminate these Terms and Conditions.

14.2.2 In addition to the termination rights provided herein, Articles 4:48 and 4:49 of the General Administrative Law Act (Algemene wet bestuursrecht) contain provisions that govern the revocation or a retroactive change to the allocation of a Contribution and the determination of the amount of the grant. The following are the most important grounds pursuant to those articles.

(a) ZonMw may revoke the allocation of the Contribution or change the Contribution to the detriment of the Beneficiary in the event that:

- the activities for which the Contribution has been allocated have not been carried out or will not be carried out in whole or in part;
- the grant recipient has failed to comply with the obligations that have been attached to the Contribution;
- the Beneficiary has provided incorrect or incomplete information and the provision of correct or complete information would have led to a different decision in respect of the application for the Contribution; or
- the Contribution was otherwise allocated incorrectly and the grant recipient knew that should have known it.

14.2.3 ZonMw may revoke the allocation of the Contribution or change the Contribution to the detriment of the Beneficiary

- (a) on the ground of facts or circumstances of which it reasonably could not have been aware at the time at which the amount of the Contribution was determined and on the ground of which the amount of the Contribution would have been lower than the amount determined in accordance with the allocation of the grant;
- (b) in the event that the determination of the amount of the Contribution was incorrect and the grant recipient knew that or should have known it; or
- (c) in the event that after the determination of the amount of the Contribution, the grant recipient has failed to comply with the obligations that have been attached to the Contribution.
- (d) ZonMw may lower the amount of the Contribution (to nil) on the basis of

the provisions contained in the first or second subsection. In addition, any abuse or misuse will be reported.

14.3 Suspension

14.3.1 The Primary Funding Agency, upon its sole discretion, may require the Beneficiary or a Dutch National Coordinator to suspend until further notice the performance of the Clinical Study for any of the reasons set out in Sections 14.2.1 to 14.2.3 and in accordance with the notice periods (if any) set out therein..

14.4 Termination consequences

14.4.1 *General.* Subject to Section 14.3.2, termination of these Terms and Conditions in accordance with Section 14.2 shall not entitle Beneficiary of Dutch National Coordinator to receive any compensation or indemnity by the Primary Funding Agency in relation to such termination. Termination or expiration of these Terms and Conditions in accordance with the provisions hereof shall be without prejudice to the surviving obligations of the Beneficiary and Primary Funding Agency as set out in Section 14.1.2.

14.4.2 *Accrued rights.* The termination or expiration of these Terms and Conditions shall be without prejudice to or affect any rights, action or remedy which shall have accrued before termination or expiration or shall accrue thereafter to any Party.

14.4.3 *Closing-down obligations.* Upon receipt of the termination notice, Beneficiary shall use best efforts to incur no further expense and to perform no further work except as is reasonably necessary to close down the Clinical Study within the given period. In addition, Beneficiary shall:

- (i) take all necessary steps to cease the conduct of the Clinical Study in an orderly and professional manner, without compromising quality, and to minimise the further costs and expenses payable by the Primary Funding Agency hereunder; and
- (ii) make any declaration to or notify any Regulatory Authority in respect of the completion or early termination of the Clinical Study if such declaration is required under any applicable Law; and
- (iii) within six (6) months of the effective date of expiry or termination, prepare and submit to the Primary Funding Agency a report on the Clinical Study in the form and containing the particulars specified by the Primary Funding Agency.

14.4.4 Upon receipt of the termination notice to a Dutch National Coordinator, the National Coordinator shall consult with ZonMw whether the Dutch National Coordinator's tasks

shall be transferred to another Collaborator or third party, subject to the decision of the Beneficiary to the Clinical Study. Furthermore, the Dutch National Coordinator shall use best efforts to incur no further expense and to perform no further work except as is reasonably necessary to close down or transfer the Clinical Study within the given period. The terms of Section 14.4.3 shall apply.

14.5 FINANCIAL ACCOUNTS AND AUDIT

- 14.5.1 In the event of termination or completion of the Clinical Study, in order to determine the amount of the Contribution, the Beneficiary must submit to ZonMw both a substantive and a financial final report within 13 weeks after the termination of the Award (in case of termination of the Contribution) or the Completion Date (in case of completion of the Clinical Study). The person who is responsible for the Beneficiary's finances must sign the financial final reports (and, if necessary, the party that is responsible for administrative purposes must co-sign the financial reports to indicate that they have been read). ZonMw will provide guidelines in advance in which it will indicate the manner in which the finances must be accounted for.
- 14.5.2 In the financial accounts the Beneficiary must give ZonMw sufficient insight to enable ZonMw to form a sound opinion with respect to the budget and the realisation. Significant differences between the budget and the realisation must be explained. In the financial final report the actual costs must be compared with the cost items that were included in the budget that ZonMw approved.
- 14.5.3 The Beneficiary must immediately give written notice of any circumstances that could affect the decision with respect to the amount of the Contribution to be determined

15. FORCE MAJEURE

- 15.1 In the event that the Beneficiary is delayed in the performance of its obligations under these Terms and Conditions by an event of Force Majeure (as defined hereafter), the obligations of the Beneficiary and Primary Funding Agency under these Terms and Conditions 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 the Beneficiary which renders performance of these Terms and Conditions impossible.
- 15.2 If Beneficiary becomes 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 ZonMw by the most expeditious method then available and shall say how long it is estimated

that such failure or delay shall continue.

- 15.3 Any failure by the Beneficiary to perform or any delay by either of the Beneficiary in performing its obligations under these Terms and Conditions which results from any failure or delay in the performance of its obligations by any person, firm or company with which the Beneficiary 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. FINANCIAL ACCOUNTS AND AUDIT IN RELATION TO THE CONTRIBUTION

- 16.1 In order to determine the amount of the Contribution, the Beneficiary must submit both a substantive and a financial final report within 13 weeks after the date on which the Clinical Trial ends. The person who is responsible for the Beneficiary's finances must sign the financial final reports (and, if necessary, the party that is responsible for administrative purposes must co-sign the financial reports to indicate that they have been read). ZonMw will provide guidelines in advance in which it will indicate the manner in which the finances must be accounted for.

- 16.2 In the financial accounts the Beneficiary must give ZonMw sufficient insight to enable ZonMw to form a sound opinion with respect to the budget and the realisation. Significant differences between the budget and the realisation must be explained. In the financial final report the actual costs must be compared with the cost items that were included in the budget that ZonMw approved.

- 16.3 The Beneficiary must immediately give written notice of any circumstances that could affect the decision with respect to the amount of the Contribution to be determined.

17. AUDITS

- 17.1 The Beneficiary's accountant – who must have certification authority – must conduct an investigation within the context of the audit of the annual accounts to ensure that the Contribution has been spent correctly, in accordance with ZonMw's audit protocol. The costs related to the audit cannot be subsidised. Nonetheless, ZonMw is authorised to audit the books and records or to conduct an investigation at the institution in order to ensure that the Beneficiary has complied with the obligations attached to the Contribution.

18. GENERAL PROVISIONS

18.1 Severability

- 18.1.1 If any of the provisions of these Terms and Conditions are held to be or rendered

void or unenforceable, the Beneficiary and Primary Funding Agency agree that the same shall not result in the nullity or unenforceability of the remaining provisions of these Terms and Conditions, 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.

18.1.2 The Beneficiary shall be responsible to the Funding Agency from which it receives directly or indirectly any Contribution, for the acts and omissions of its sub-contractors or Collaborators as though they were its own.

18.1.3 The Beneficiary shall ensure that, to the extent that they are relevant, and where reasonable to do so, the terms and conditions of these Terms and Conditions are incorporated into any sub-contract and that all reasonable steps are taken by it to ensure that its sub-contractors and Collaborators are aware of and adhere to the terms and conditions of these Terms and Conditions.

18.2 Publicity

18.2.1 Before and after the Commencement Date, and prior to the publication of the Foreground or of matters arising from the Clinical Study in accordance with Section 10, the Beneficiary shall not without the prior written consent of the Primary Funding Agency, which shall not be unreasonably refused or delayed, release, or otherwise make available to third parties, any information relating to the Clinical Study by means of any public statement, in particular any media announcement or display or by putting on any website or oral presentation to meetings where the Foreground are likely to be reported by the media. This condition shall not apply where the Beneficiary has a contractual, legal or similar obligation to publish specific details about these Terms and Conditions or the Clinical Study.

18.3 Inconsistencies

18.3.1 In the event of any inconsistencies between the terms of these Terms and Conditions and the terms of the Protocol or the schedules or other documents referred to in these Terms and Conditions (including the Award Letter), the terms of these Terms and Conditions shall prevail except to the extent that any conflict relates to a clinical or medical matter, in which case the Protocol shall prevail.

18.4 Further Assurance

18.4.1 Beneficiary shall at the reasonable request of ZonMw 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 ZonMw's reasonable opinion to give full

effect to these Terms and Conditions and to vest in ZonMw the full benefit of the assets, rights and benefits to be transferred to ZonMw under these Terms and Conditions.

18.5 the Primary Funding Agency approval of consent

18.5.1 Where the Primary Funding Agency's approval or consent is requested as per these Terms and Conditions, the Primary Funding Agency shall use reasonable efforts to communicate its position to Beneficiary within fifteen (15) Business Days as per Beneficiary's request, except where these Terms and Conditions explicitly provides for a different timeframe for such communication to be given by the Primary Funding Agency.

18.6 Language and Notices

18.6.1 *Language.* Beneficiary explicitly agrees that these Terms and Conditions is made in the English language and hereby waives any claim in relation to the use of the English language in any communication or correspondence from the Primary Funding Agency to Beneficiary in relation to these Terms and Conditions.

18.6.2 *Notices.* (a) Any notice required under these Terms and Conditions shall be made in English, either by registered mail or an internationally recognised overnight courier to the Primary Funding Agency and to Beneficiary at their respective addresses first above written or as subsequently changed by notice duly given in writing at such addresses.

(b) Notices by registered mail are deemed to be given upon receipt. Notices by internationally recognised overnight courier are deemed to be given one business day following delivery with such courier.

18.7 Anti-corruption

18.7.1 *Prevention of fraud.* The Beneficiary shall take all reasonable steps, in accordance with Good Research Practice, to prevent fraud in connection with the receipt of monies from the Primary Funding Agency.

(i) The Beneficiary shall notify the Primary Funding Agency immediately if it has reason to suspect that any fraud has occurred or is occurring or is likely to occur.

(ii) If the Beneficiary or their staff (or any staff of a sub-contractor or Collaborator) commits fraud in relation to this or any other contract with a governmental institution, body or agency (including the Primary Funding Agency), the Primary Funding Agency may: (a) terminate these Terms and Conditions immediately by giving notice in writing and recover from the

Beneficiary the amount of any proven loss suffered by the Primary Funding Agency (or such other governmental institution, body or agency) resulting from the termination, including the cost reasonably incurred by the Primary Funding Agency of making other arrangements for the performance of the Clinical Study and any additional expenditure incurred by the Primary Funding Agency throughout the remainder of the term of the Clinical Study; or (b) recover in full from the Beneficiary any other proven loss sustained by the Primary Funding Agency (or any such governmental institution, body or agency) in consequence of any breach of this Section 18.7.

18.8 Freedom of Information (“Openbaarheid van Bestuur”)

18.8.1 The Beneficiary acknowledges that the Primary Funding Agency is subject to the requirements of the relevant Belgian legislation on the freedom of information *Openbaarheid van Bestuur*, hereafter “FoI”) and shall assist and reasonably cooperate with the Primary Funding Agency to enable the Primary Funding Agency to comply with these requirements.

18.8.2 The Beneficiary shall and shall procure that its sub-contractors and Collaborators shall:

- (i) transfer to the Primary Funding Agency all requests for information that it receives under FoI that in its opinion are for the Primary Funding Agency;
- (ii) consult the Primary Funding Agency where it has any doubt whether the request is for the Primary Funding Agency as soon as practicable and in any event within two working days of receiving a request for information;
- (iii) provide the Primary Funding Agency with a copy of all information in its possession or power in the form that the Primary Funding Agency requires to be provided within a reasonable period time (and in any case within the timeframe that is required for the Primary Funding Agency to comply with its obligations under the FoI) in relation to the Primary Funding Agency’s request; and
- (iv) provide all necessary assistance as reasonably requested by the Primary Funding Agency to enable the Primary Funding Agency to respond to the request for information within the time for compliance set out in the FoI.

18.8.3 The Primary Funding Agency shall be responsible for determining at its absolute discretion, and notwithstanding any other provision in these Terms and Conditions or any other agreement, whether commercially sensitive information and/or any other information is exempt from disclosure in accordance with the relevant provisions of FoI.

18.8.4 In no event shall the Beneficiary respond directly to a request for information unless expressly authorised to do so by the Primary Funding Agency, unless obliged by law or regulation.

18.8.5 The Beneficiary acknowledges that the Primary Funding Agency may, acting in accordance with the FoI request, have to disclose information concerning the Beneficiary or the Clinical Study:

- (i) in certain circumstances without consulting the Beneficiary; or
- (ii) following consultation with the Beneficiary and having taken their views into account;

provided always that the Primary Funding Agency takes reasonable steps, where appropriate, to give the Beneficiary advance notice, or failing that, to draw the disclosure to the Beneficiary's attention after any such disclosure.

18.9 Transparency

18.9.1 The Primary Funding Agency shall be responsible for determining at its absolute discretion whether any of the content of these Terms and Conditions is exempt from disclosure in accordance with the provisions of FoI.

18.9.2 The Primary Funding Agency may consult with the Beneficiary to inform its decision regarding any redactions but the Primary Funding Agency shall have the final decision at its absolute discretion.

18.9.3 The Primary Funding Agency may, at its sole discretion, redact information from these Terms and Conditions prior to publishing for one or more of the following reasons:

- (i) national security;
- (ii) Personal Data;
- (iii) information protected by intellectual property law;
- (iv) third party or Collaborator confidential information;
- (v) IT security; or
- (vi) prevention of fraud.

18.9.4 The Beneficiary shall assist and cooperate with the Primary Funding Agency to enable the Primary Funding Agency to publish these Terms and Conditions.

18.9.5 Notwithstanding any other term of these Terms and Conditions, the Beneficiary hereby gives consent for the Primary Funding Agency to publish these Terms and Conditions in its entirety, including from time to time any agreed changes to these Terms and Conditions, to the general public.

19. APPLICABLE LAW AND DISPUTE RESOLUTION

19.1 Applicable law

19.1.1 This Terms and Conditions shall be governed by and construed in accordance with the substantive laws of The Netherlands.

19.2 Dispute resolution

19.2.1 The terms of the Dutch General Administrative Law Act shall apply. However, the Beneficiary and Primary Funding Agency shall first use their best efforts to amicably resolve any dispute or claim arising out of or relating to these Terms and Conditions.

19.2.2 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.

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