

GENERAL RESEARCH GRANT AGREEMENT

This General Research Grant Agreement (“Agreement”) between

Pfizer ApS/Pfizer PFE ApS, Lautrupvang 8, DK-2750 Ballerup (“Pfizer”) and

Rigshospitalet / DBCG with an address of Blegdamsvej 9, 2100 Copenhagen, Denmark (“Institution”).

when signed by the parties, is effective as of the date the Agreement is last signed (“Effective Date”).

Ann Knop, Project Coordinator an employee/contractor of Institution (“Principal Investigator”), has designed and intends to conduct a research study to build a National Database for Metastatic Breast Cancer. Pfizer Tracking Number WP2350984 (the “Study”). Pfizer wishes to provide certain funding for the Study.

Accordingly, the parties agree as follows:

1. PRINCIPAL INVESTIGATOR; PROTOCOL

- 1.1. Principal Investigator. The Study will be conducted by Principal Investigator. Principal Investigator may delegate duties and responsibilities to sub-investigators or research staff as permitted by Applicable Requirements.
- 1.2. Protocol. The Study will be conducted in accordance with a protocol developed by Principal Investigator (the “Protocol”).
- 1.3. Amendments. If Principal Investigator modifies the Protocol, Institution will promptly inform Pfizer in writing. Continued support by Pfizer will be contingent on Pfizer’s review and acceptance of the Protocol changes.

2. STUDY CONDUCT

- 2.1. Sponsorship. Institution, not Pfizer, is the sponsor of the Study. Institution will not, and will ensure that Principal Investigator and any participating sites will not, represent to any third party, including Study subjects, that Pfizer is the regulatory sponsor of the Study.
- 2.2. Regulatory Obligations. Institution is solely responsible for all safety reporting and regulatory obligations associated with the Study, including, but not limited to, obtaining and maintaining regulatory authorization for the conduct of the Study.

2.3. Compliance with Applicable Requirements.

2.3.1. *Definitions.*

2.3.1.1. “**Applicable Requirements**” means: (i) the terms of this Agreement, including, but not limited to, standard operating procedures and other documents referred to in this Agreement; (ii) the Protocol; (iii) the terms of the IRB/IEC approval(s); (iv) the terms of any regulatory authority approval; (v) all Applicable Law; and (vi) all applicable good practice quality guidelines and regulations encompassing internationally recognized standards such as Good Clinical Practice, Good Laboratory Practice, and Good Review Practice (collectively, “**GxPs**”).

2.3.1.2. “**Applicable Law**” means the applicable laws, rules and regulations, including Data Protection Legislation, applicable guidelines of the International Council on Harmonisation (“**ICH**”), and any other applicable rules, regulations, guidelines or requirements of any supranational, federal, national, state or local court, agency, authority, department, regulatory body or other governmental instrument that may be in effect during the performance of the Study in any region or regulatory jurisdiction in which the Study is conducted.

2.3.2. *Compliance.* Institution will conduct the Study and undertake Study-related activities in accordance with Applicable Requirements. Institution is solely responsible for ensuring compliance with Applicable Requirements by all employees, staff, agents and consultants of Institution and any participating sites, including Principal Investigator, or those of any subcontractor who are engaged in the provision of activities under this Agreement.

2.3.3. *Ethical Transplantation Principles.* For studies that involve human cell, tissue or organ transplantation, Pfizer supports the ethical principles articulated in the World Health Organization’s Guiding Principles for Human Cell, Tissue and Organ Transplantation. Institution agrees to abide by the ethical principles set forth in document WHA63.22, available at <http://www.who.int/transplantation/en/>, with regard to the Study.

2.4. IRB/IEC Approval. If required, Institution will ensure that the Study is approved by and subject to continuing oversight by a duly-constituted Institutional Review Board (“**IRB**”) or Independent Ethics Committee (“**IEC**”). If IRB/IEC approval is required, Institution must provide Pfizer with documentation of the initial IRB/IEC approval of the Protocol, any annual renewals of that approval, and any IRB/IEC-approved amendments to the Protocol. Institution will notify Pfizer promptly of any withdrawal or suspension of IRB/IEC approval during the term of this Agreement.

2.5. Informed Consent. Institution will obtain valid written informed consent from each Study subject in accordance with Applicable Requirements. Institution will be responsible for the adequacy of the informed consent document and for compliance with Applicable Requirements. Pfizer has no obligation to participate in the development of, or to review or comment on, any informed consent form or any request for waiver. Institution will ensure that the informed consent document.

- 2.6. Duration of Study Conduct. “**Study Completion**” means the completion of all Study activities, including safety follow-up of all Study subjects and completion of all Protocol requirements with respect to each Study subject. Principal Investigator expects to achieve Study Completion by 1 August 2023.
- 2.7. Status Updates. Institution will provide Pfizer with an update of Study status, in the form requested by Pfizer, at least twice a year during the term of this Agreement, or more frequently if agreed by the parties. Each status update will include subject enrollment, publication plans, any adjustments in the estimated Study Completion date, and any other information reasonably requested by Pfizer.
- 2.8. Study Registration. Pfizer encourages Institution and Principal Investigator to register the Study and any synopsis of Study Results on www.ClinicalTrials.gov or such other website as required under Applicable Law before enrollment of the first Study subject or before commencement of data collection.

3. FUNDING

- 3.1. Funding. Pfizer will provide funding in support of the Study up to a maximum amount of DKK 600.000, in accordance with the schedule set forth in Attachment A (“**Funding**”). No portion of the Funding may be used to purchase capital equipment. Examples of capital equipment include, but are not limited to: Computers, iPhones, tablets, appliances, machinery, camera equipment, sensors etc.
- 3.2. Responsible persons at the Institution

The Grant will be given to the Institution and is approved by Per Jørgensen, Deputy Director on behalf of the Hospital.

Furthermore the support is approved by Bent Ejlersen, Professor, Senior Consultant and Ann Knop, Senior Consultant, who are responsible for the hospital account to which the funding is paid to.
- 3.3. Basis of Support. The Funding is not conditioned on: (i) any pre-existing or future business relationship between Pfizer and Principal Investigator or Institution, or (ii) any business or other decisions Principal Investigator or Institution has made, or may make, relating to Pfizer or Pfizer products. Nothing contained in this Agreement will be construed in any manner as an obligation or inducement for Institution or Principal Investigator to purchase, order, prescribe or recommend any product of Pfizer or any Pfizer affiliate.
- 3.4. Submission of Required Documents. Pfizer will not provide the Funding until Pfizer has received the documents identified in Attachment B.
- 3.5. Use of Funding. Institution will, and will ensure that Principal Investigator will, use the Funding solely for purposes of the Study. At the completion of the Study, Institution

will confirm in writing that the Funding has been used only to support the Study by completing a *Certification of Study Closure* form provided by Pfizer. The Funding may not be used to pay physicians or other health care providers or health care institutions for referring potential subjects for enrollment in the Study. If a government agency is providing funding for the Study, Institution will use the Funding only for those Study activities that are not covered by such government funding.

- 3.6. No Charge to Third Parties. Institution will ensure that no Study subject, insurer, governmental entity or other third party payor is charged for any Study-related activities carried out by Institution using the Funding.
- 3.7. Study Budget. The Institution-provided Study budget upon which the Funding is based reflects an informed estimate of all funds required to complete and report the Study, including, if applicable, expenses relating to the publication of Study Results.
- 3.8. Disclosure by Pfizer. In the interest of transparency relating to its financial relationships with investigators and study sites or to ensure compliance with Applicable Law, industry codes and Pfizer policies, Pfizer may, and (in certain cases) is required to, report or otherwise disclose publicly payments or other transfer of value to certain health care providers, teaching hospitals and other health care organizations, including Funding provided under this Agreement. These laws and codes, and their implementing regulations, collectively are referred to as “**Transparency Obligations**.” Pfizer may disclose in any lawful manner the terms of this Agreement and any other information to the extent necessary for Pfizer to meet its Transparency Obligations. The terms of the Agreement shall be publicly disclosed on Pfizer’s webpage (www.pfizer.dk) when the Agreement is made and for a period of 2 years thereafter.
 - 3.8.1. *Disclosure Content*. Pfizer may identify Institution and Principal Investigator, and will differentiate clearly between payments or other transfers of value made to institutions and those made to individuals. Disclosures may include identifying information for institutions and investigators, such as name, business address, specialty, license numbers.
 - 3.8.2. *Agreement and Cooperation*. Institution accepts and agrees to these disclosures on behalf of itself and its Principal Investigator. Institution will reasonably cooperate with Pfizer in Pfizer’s collection and disclosure of information necessary to fulfill its Transparency Obligations, and to ensure such cooperation by its Principal Investigator and other affected personnel.
- 3.9. Notification. Notification of co-operation for the Danish Health and Medicines Authority.

The Investigator will be responsible for notifying the Danish Health and Medicines Authority for this co-operation with reference to of the Executive order concerning Health professionals related to pharmaceutical and medical device companies and specialist retailers with medical equipment.

Please be aware of the following requirement derived from the executive order of health professionals related to pharmaceutical and medical device companies and specialist retailers with medical equipment;

By notification, the Danish Health and Medicines Authority publish the following information about the Investigator at the Danish Health and Medicines Authority's website;

- a. Identification of the Investigator, e.g. name and authorization ID
- b. Identification of the company or business
- c. Type of affiliation and duration
- d. The Investigators total payment per calendar from Pfizer
- e. For securities: Number and value and the time for acquisition

The above mentioned information will be deleted after 2 years from end date of the affiliation. It is the Investigators responsibility to inform The Danish Health and Medicines Authority about when the affiliation will or has ended.

4. CONFIDENTIALITY

All materials and other information provided to Pfizer by employees, staff, agents or consultants of Institution including Principal Investigator, and any participating sites, are non-confidential and do not and will not contain any markings claiming confidentiality. By submitting any materials or other information to Pfizer for review at the grant application stage, or subsequently, Institution acknowledges that Pfizer will not treat such materials as confidential or proprietary. Pfizer assumes no obligation to keep them confidential. Institution and Principal Investigator's rights with respect to such material and other information shall be only those obtained under the patent laws and/or under any written contract to which the submitter and Pfizer may mutually agree.

Institution agrees that it has not and will not submit any confidential information to Pfizer in connection with the Study and the Funding. Institution agrees to be bound by the terms and conditions set forth in this Section. Institution further acknowledges that Pfizer may conduct ongoing or future research identical to the Study. In consideration for the Funding, to the fullest extent allowed, Institution releases Pfizer from any and all liability for use of all or any portion of material or information provided by all employees, staff, agents and consultants of Institution including Principal Investigator, and any participating sites, in connection with the Study and the Funding, other than infringing uses that are protected by patent.

5. STUDY DATA, STUDY RESULTS AND STUDY REPORT

5.1. Definitions.

- 5.1.1. "Study Data" means non-aggregated, subject-level data collected from or about each Study subject during the course of the Study as required by the Protocol.
- 5.1.2. "Study Results" refers to aggregated or summarized Study Data and conclusions about the Study, as would be included in a study report or publication.

- 5.1.3. **“Study Report”** means a written report of the Study Results.
- 5.2. **Use of Study Data and Study Results.** Institution owns and is free to use the Study Data for its own research, educational, and patient care purposes. Institution and Principal Investigator are free to publish the Study Results, subject to the provisions of this Agreement, and to use the Study Results for any other lawful purpose.
- 5.3. **Study Report.** Within six months of the earlier of Study Completion or termination of this Agreement, Institution will provide Pfizer with a Study Report. Unless otherwise agreed in writing by the parties, the Study Report may take the form of a manuscript for publication. If the Agreement is terminated early, the Study Report should include, at minimum, the results of the Study through the date of Agreement termination
6. **PUBLICATIONS.** Pfizer supports the exercise of academic freedom and encourages Institution to publish the Study Results. Institution will ensure that Principal Investigator will comply with standard academic practices regarding authorship of scientific publications and recognition of the contribution of other parties in any Publication, including the authorship guidelines promulgated by the International Committee of Medical Journal Editors (“**ICMJE**”) in effect at the time and disclose Pfizer support of the Study in any Publication. “**Publication**” means any journal article, abstract, presentation or other type of public disclosure that reports any Study Results.
7. **GLOBAL TRADE CONTROL LAWS; RESTRICTED MARKETS**
- 7.1. **Definitions.**
- 7.1.1. “*Global Trade Control Laws*” means the US Export Administration Regulations; US International Traffic in Arms Regulations; economic sanctions rules and regulations implemented under statutory authority and/or the President’s Executive Orders and administered by the US Treasury Department Office of Foreign Assets Control (“**OFAC**”); EU Council Regulations on export controls and sanctions, including regulation nos. 428/2009 and 267/2012; other EU Council sanctions regulations, as implemented in EU Member States; United Nations sanctions policies; other relevant economic sanctions, export and import control laws, and other laws, regulations, legislation, orders, and requirements imposed by a relevant Governmental Entity.
- 7.1.2. “*Governmental Entity*” means any court, tribunal, or arbitral body with competent jurisdiction; any military, quasi-military, or law enforcement agency; or any other entity agency, department, authority, or other instrumentality of any supra-national, federal, national, state, county, local, municipal, other political subdivision, administrative authority, agency, commission, instrumentality, or other governmental, regulatory body.
- 7.1.3. “*Government Official*” means (1) any elected or appointed government official (e.g., a legislator or a member of a government department or ministry), (2) any employee or individual acting for or on behalf of a government official, government agency, or enterprise performing a function of, or owned or controlled by, a government (e.g., a

healthcare professional or researcher employed by a public hospital or university), (3) any political party officer, candidate for public office, or employee or individual acting for or on behalf of a political party or candidate for public office, (4) any employee or individual acting for or on behalf of a public international organization, and (5) any member of a royal family or member of a military.

7.1.4. “*Restricted Market*” means Crimean Peninsula, Cuba, Donbass Region, Iran, North Korea, Sudan, and Syria.

7.1.5. “*Restricted Party*” means any individual or entity on any of the following “Restricted Party Lists:” the list of sanctioned entities maintained by the United Nations; the Specially Designated Nationals List and Sectoral Sanctions Identifications List administered by OFAC; the US Denied Persons List, US Entity List, and US Unverified List all administered by the US Department of Commerce; the Consolidated List of Persons, Groups and Entities Subject to EU Financial Sanctions implemented by the EU Common Foreign and Security Policy; the List of Excluded Individuals/Entities published by the US Department of Health and Human Services, Office of Inspector General; any lists of prohibited or debarred parties established under the US Federal Food, Drug, and Cosmetic Act; the list of persons and entities suspended or debarred from contracting with the US Government; and similar lists of restricted parties maintained by the Governmental Entities of the countries that have jurisdiction over activities under this Agreement.

7.2. Global Trade Control Laws. The parties and their agents, employees, affiliates and contractors involved in activities under this Agreement, will perform the activities under this Agreement in full compliance with all applicable Global Trade Control Laws.

7.3. Restricted Parties; Restricted Markets. Institution acknowledges that activities under this Agreement will not (i) be in a Restricted Market; (ii) involve individuals ordinarily resident in a Restricted Market; or (iii) include companies, organizations, or Governmental Entities from or located in a Restricted Market. Institution represents and warrants that it is not a Restricted Party and is not owned or controlled by a Restricted Party. With respect to activities performed under this Agreement, Institution confirms that neither Institution nor affiliates, agents, employees, or subcontractors directly or indirectly involved in the activities contemplated under this Agreement are Restricted Parties and that no Restricted Parties will be engaged in any activities contemplated under this Agreement or delegated any responsibilities contemplated under this Agreement. Institution will screen the parties listed above against the relevant Restricted Party Lists. In the event that any part of this representation changes, Institution will immediately inform Pfizer and suspend all related activities under this Agreement until Pfizer agrees in writing to move forward. Notwithstanding any other provision herein, such Restricted Party designation or involvement will be grounds for immediate termination of this Agreement by Pfizer, for cause, with no cure period.

8. TERM AND TERMINATION

- 8.1. Term. This Agreement will commence on the Effective Date and will continue until terminated in accordance with this Agreement.
- 8.2. Termination.
- 8.2.1. *Termination Following Study Completion and Satisfaction of Obligations*. This Agreement will terminate after all of the following have occurred: (i) Study Completion; (ii) each party's receipt of all deliverables and payments owed to each party under this Agreement and in accordance with the Protocol; and (iii) each party's satisfaction of all other obligations under this Agreement.
- 8.2.2. *Early Termination by Institution*. Institution may terminate this Agreement (i) immediately on written notice to Pfizer when, as confirmed by the IRB/IEC, continued performance of the Study poses risks to the health or well-being of Study subjects; (ii) without cause upon 30 days written prior notice to Pfizer; or (iii) as otherwise permitted expressly under this Agreement.
- 8.2.3. *Early Termination by Pfizer*. Pfizer may terminate this Agreement (i) without cause upon 30 days prior written notice to Institution; (ii) immediately upon written notice to Institution if Principal Investigator becomes unavailable or withdraws from the Study and Pfizer and Institution are unable to agree upon a successor within 30 days after Pfizer is notified; (iii) as otherwise permitted expressly under this Agreement.
- 8.2.4. *Termination for Cause*. This Agreement may be terminated by either party, with written notification to the other party of an uncured breach by the other party. The party alleging breach must first provide to the other party written notice that specifically identifies the breach and must provide the alleged breaching party 30 days in which to cure it. Notwithstanding the foregoing, Pfizer may terminate this Agreement immediately upon notice to Institution, with no cure period, in the event that Institution violates Global Trade Control Laws or anti-corruption obligations set forth herein.
- 8.3. Payment upon Early Termination. The terms in this Section 8.3 apply only if the Agreement is terminated early for a reason other than for cause. Upon early termination, Pfizer will pay a pro rata portion of the total funding, less payments already made. Institution will refund to Pfizer any funding already received in excess of this calculated amount except to the extent that such funds have already been used, or committed and unable to be canceled, in a manner consistent with the Study budget upon which the Funding is based.
- 8.4. Reconciliation upon Study Completion. At Study Completion, the parties will cooperate to perform a financial reconciliation to confirm consistency between total Pfizer milestone payments and the agreed-upon milestones and deliverables. The parties agree to make any adjustment (e.g., refund or additional payment) that is revealed by this analysis to be warranted.

9. REPRESENTATIONS AND WARRANTIES

- 9.1. Representations and Warranties of Both Parties. Each party represents and warrants that it: (i) has the requisite power and authority to enter into this Agreement and that this Agreement constitutes a legal and valid obligation binding upon such party, enforceable in accordance with its terms; and (ii) is not a party to any agreement that would prevent it from fulfilling its obligations under this Agreement.
- 9.2. Representations and Warranties of Institution. Institution hereby represents and warrants that:
- 9.2.1. Institution, its affiliates, employees, staff, agents and consultants, including Principal Investigator: (i) are licensed, registered or otherwise qualified and suitable under Applicable Law to act as a regulatory sponsor, Study site or Investigator, as applicable; (ii) are not debarred any Applicable Law under any applicable jurisdiction. For the avoidance of doubt, this includes investigators not having any restrictions on their license to practice medicine, including restrictions on practicing certificates or other authorizations from professional bodies; (iii) are not the subject of any past or pending governmental or regulatory investigation, inquiry, warning or enforcement action (each an “Agency Action”) related to its conduct of clinical research that has not been disclosed to Pfizer. Institution will notify Pfizer promptly anyone listed above receives notice of or becomes the subject of any Agency Action regarding its compliance with ethical, scientific or regulatory standards for the conduct of clinical research if the Agency Action relates to events or activities that occurred prior to or during the period in which the Study is conducted; and (iv) will not use in any capacity the services of any person debarred under Applicable Law under any applicable jurisdiction with respect to activities to be performed by or on behalf of Institution under this Agreement;
- 9.2.2. Conducting the Research and receiving the Funding is not inconsistent with any other obligation of the Institution.
- 9.2.3. Any information provided by Institution to Pfizer as part of Pfizer’s anti-corruption due diligence process is complete and accurate.
- 9.2.4. The Funding will not cause Institution or any individual affiliated with Institution to do anything that would result in Pfizer improperly obtaining or retaining business or gaining any improper business advantage.
- 9.2.5. Institution has not, will not, and will take measures to ensure that individuals affiliated with Institution have not and will not, use any portion of the Funding to directly or indirectly offer or pay any money or anything of value in an effort to influence any Government Official or any other person in order for
- 9.2.6. Pfizer to improperly obtain or retain business or to gain an improper business advantage, or

9.2.7. Institution or affiliated entities or individual(s) to improperly obtain or retain business or gain a business advantage.

9.2.8. Pfizer will be entitled to revoke the Funding if Pfizer learns that Institution or any individuals affiliated with Institution entity or the Funding, has used or intend[s] to use any portion of the Funding to improperly seek to influence any Government Official or any other person in order to obtain or retain business or gain a business advantage.

9.2.9. Pfizer may at any time publicly disclose that it has provided Institution with the Funding, including the amount of such support.

9.2.10. Failure to comply with, or a demonstrated intent to fail to comply with, any of the warranties in this Section will constitute adequate cause for Pfizer to immediately terminate the Agreement, for cause, with no cure period.

9.2.11. Institution will (i) provide truthful and complete documentation supporting, in reasonable detail, the work performed and any expenses incurred; and (ii) maintain true, accurate and complete invoices, reports, statements, books and other records.

Institution will notify Pfizer immediately if any of these representations and warranties require amendment during the performance of this Agreement. Pfizer may terminate this Agreement immediately if Institution, its affiliates, employees, staff, agents and consultants, including Principal Investigator, fails to comply with, or demonstrates an intent to fail to comply with, any of the above representations and warranties.

10. GENERAL PROVISIONS

10.1. Indemnification. Research supported by the Funding are not designed, sponsored, or managed by Pfizer and Pfizer provides no indemnification of any type. Institution will indemnify, defend, and hold harmless Pfizer and its affiliates, and its/their employees, contractors, agents, officers, and directors from and against any loss, liability, damage, cost, fine, penalty, or expense, including reasonable attorneys' fees, arising out of an audit, investigation, administrative proceeding, or litigation related to the Funding or any study or research supported by the Funding. This Section will survive the termination or expiration of this Agreement.

10.2. Assignment and Delegation.

10.2.1. *By Institution.* Institution may not assign any rights or delegate or subcontract any duties under this Agreement without written permission from Pfizer. If Pfizer authorizes any delegation of duties, Institution remains responsible to Pfizer for the performance of those duties.


10.2.2. *By Pfizer.* Pfizer may assign and delegate any and all of its rights or obligations under this Agreement to a third party.

- 10.3. Entire Agreement. This Agreement (including Attachments) along with the Protocol represent the entire understanding between the parties relating to this subject matter. This Agreement supersedes all previous agreements between the parties (oral and written) relating to this Study, except for any obligations that, by their terms, survive independent of this Agreement.
- 10.4. Survival of Obligations. Sections 3, 4, 5, 6, 9, and 10 will survive Agreement termination, along with any other provision of this Agreement that, by its nature and intent, remains valid after termination.
- 10.5. Public Disclosures: Use of Names. Neither party will use the name or logos of the other party in any public announcement, advertising or other public disclosure regarding the relationship of the parties, the existence or contents of this Agreement, or this Study without the prior written approval of the other party, and Institution will ensure that each subcontractor will not make any such disclosure. Institution will provide Pfizer reasonable advance notice, and in any event at least 14 days' notice, before publicly releasing any information about this Agreement or the Study (including, but not limited to, listings on clinical trial registries, website postings, press releases or presentations at scientific congresses) such that Pfizer may review and comment, and Institution will incorporate any reasonable Pfizer comments before releasing publicly.
- 10.6. Institution Personnel Notice. Institution and Principal Investigator acknowledge that they have received a Pfizer data privacy notice, as available at <https://privacycenter.pfizer.com/dk/hcp>, with respect to the processing of Personal Data of the Principal Investigator and Institution personnel, and that Institution personnel have or will receive a copy of such notice.
- 10.7. Law and venue. This Agreement shall be governed by Danish law. The parties hereby submit any dispute or controversy arising out of or in connection with this Agreement to the jurisdiction of the Maritime and Commercial Court of Copenhagen.

[signature page follows]


IN WITNESS WHEREOF, this Agreement has been duly executed by the parties.

Date: November 14, 2019
For and on behalf of Pfizer ApS

DocuSigned by:

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Anne Bloch Thomsen, MD, Ph.D
Country Medical Director, Denmark &
Iceland

Date: 19/11 2019
For and on behalf of Rigshospitalet



Per Jørgensen
Deputy Director

Date: 20-11-2019
Read and Acknowledged for
Rigshospitalet /DBC



Bent Ejlersen, Professor
Senior Consultant, Principal
Investigator

Date: 20/11/19
Read and Acknowledged for
Rigshospitalet /DBC



Ann Knop
Senior Consultant

ATTACHMENT A

PAYMENT SCHEDULE

Support Details and Payment Schedule

A.1 Study Details

The start date of the Study is: The Effective Date
The completion date is: 1 August 2023

A.2 Payment Schedule

Total General Research Grant funding support from Pfizer is DKK 600.000

Milestone	Payment amount DKK
Initial & Total payment within 30 days after signing of the contract	600.000
Total	600.000

Pfizer's commitment to provide funding is in Danish currency (DKK).

Initial & Total payment Pfizer will make no payment until Pfizer received
(1) Executed copy of the Agreement and
(2) The required documents identified in Attachment B,
Study Documentation Requirements

ATTACHMENT B

STUDY DOCUMENTATION REQUIREMENTS

In order to release the requested grant, Pfizer requires the following documents in addition to the executed agreement:

1. Documentation of IRB/IEC Approval (or Exemption)
2. Final Protocol

ATTACHMENT C

PFIZER'S INTERNATIONAL ANTI-BRIBERY AND ANTI-CORRUPTION BUSINESS PRINCIPLES

1. Pfizer's Policy

Pfizer has a long-standing policy forbidding bribery and corruption in the conduct of our business in the United States or abroad. Pfizer is committed to performing business with integrity, and acting ethically and legally in accordance with all applicable laws and regulations. Pfizer expects the same commitment from the consultants, agents, representatives or other companies and individuals acting on Pfizer's behalf ("**Business Associates**"), as well as those acting on behalf of Business Associates (*e.g.*, subcontractors), in connection with work for Pfizer.

2. Bribery of Government Officials

Most countries have laws that forbid making, offering or promising any payment or anything of value (directly or indirectly) to a Government Official when the payment is intended to influence an official act or decision to award or retain business. "**Government Official**" will be interpreted broadly and means: (a) any elected or appointed Government official (*e.g.*, a legislator or a member of a Government ministry); (b) any employee or individual acting for or on behalf of a Government Official, agency or enterprise performing a governmental function, or owned or controlled by, a Government (*e.g.*, a health care professional employed by a Government hospital or researcher employed by a Government university); (c) any political party officer, candidate for public office, officer, or employee or individual acting for or on behalf of a political party or candidate for public office; (d) any employee or individual acting for or on behalf of a public international organization; (e) any member of a royal family or member of the military; and (f) any individual otherwise categorized as a Government Official under law. "**Government**" means all levels and subdivisions of Governments (*i.e.*, local, regional or national and administrative, legislative or executive). Because the definition of Government Official is so broad, it is likely that Business Associates will interact with a Government Official in the ordinary course of their business on behalf of Pfizer. For example, doctors employed by Government-owned hospitals are considered Government Officials.

3. The FCPA

The U.S. Foreign Corrupt Practices Act (the "**FCPA**") prohibits making, promising or authorizing a payment or providing anything of value to a non-U.S. Government Official to improperly or corruptly influence that official to perform any governmental act or make a decision to assist a company in obtaining or retaining business, or to otherwise gain an improper advantage. The FCPA also prohibits a company or person from using another company or individual to engage in any such activities. As a U.S. company, Pfizer must comply with the FCPA and could be held liable as a result of acts committed anywhere in the world by a Business Associate.

4. Anti-Bribery and Anti-Corruption Principles Governing Interactions with Governments and Government Officials

Business Associates must communicate and abide by the following principles with regard to their interactions with Governments and Government Officials:

- 4.1 Business Associates, and those acting on their behalf in connection with work for Pfizer, may not directly or indirectly make, promise or authorize the making of a corrupt payment or provide anything of value to any Government Official to induce that Government Official to perform any governmental act or make a decision to help Pfizer obtain or retain business. Business Associates, and those acting on their behalf in connection with work for Pfizer, may never make a payment or offer any item or benefit to a Government Official, regardless of value, as an improper incentive for such Government Official to approve, reimburse, prescribe, or purchase a Pfizer product, to influence the outcome of a clinical trial, or to otherwise benefit Pfizer's business activities improperly.
- 4.2 In conducting their Pfizer-related activities, Business Associates, and those acting on their behalf in connection with work for Pfizer, must understand and comply with any local laws, regulations or operating procedures (including requirements of Government entities, such as Government-owned hospitals or research institutions) that impose limits, restrictions or disclosure obligations on compensation, financial support, donations or gifts that may be provided to Government Officials. If a Business Associate is uncertain as to the meaning or applicability of any identified limits, restrictions or disclosure requirements with respect to interactions with Government Officials, that Business Associate should consult with his or her primary Pfizer contact before engaging in such interactions.
- 4.3 Business Associates, and those acting on their behalf in connection with work for Pfizer, are not permitted to offer facilitation payments. A "facilitation payment" is a nominal payment to a Government Official for the purpose of securing or expediting the performance of a routine, non-discretionary governmental action. Examples of facilitation payments include payments to expedite the processing of licenses, permits or visas for which all paperwork is in order. In the event that a Business Associate, or someone acting on their behalf in connection with work for Pfizer, receives or becomes aware of a request or demand for a facilitation payment or bribe in connection with work for Pfizer, the Business Associate will report such request or demand promptly to his or her primary Pfizer contact before taking any further action.

5. Commercial Bribery

Bribery and corruption also can occur in non-Government, business to business relationships. Most countries have laws that prohibit offering, promising, giving, requesting, receiving, accepting or agreeing to accept money or anything of value in exchange for an improper business advantage. Examples of prohibited conduct include, but are not limited to, providing expensive gifts, lavish hospitality, kickbacks or

investment opportunities to induce improperly the purchase of goods or services. Pfizer colleagues are not permitted to offer, give, solicit or accept bribes, and we expect our Business Associates, and those acting on their behalf in connection with work for Pfizer, to abide by the same principles.

6. Anti-Bribery and Anti-Corruption Principles Governing Interactions with Private Parties and Pfizer Colleagues

Business Associates must communicate and abide by the following principles with regard to their interactions with private parties and Pfizer colleagues:

- 6.1 Business Associates, and those acting on their behalf in connection with work for Pfizer, may not directly or indirectly make, promise or authorize a corrupt payment or provide anything of value to any person to influence that person to provide an unlawful business advantage for Pfizer.
- 6.2 Business Associates, and those acting on their behalf in connection with work for Pfizer, may not directly or indirectly, solicit, agree to accept or receive a payment or anything of value as an improper incentive in connection with their business activities performed for Pfizer.
- 6.3 Pfizer colleagues are not permitted to receive gifts, services, perks, entertainment or other items of more than token or nominal monetary value from Business Associates, and those acting on their behalf in connection with work for Pfizer. Moreover, gifts of nominal value are permitted only if they are received on an infrequent basis and only at appropriate gift-giving occasions.

7. Reporting Suspected or Actual Violations

Business Associates, and those acting on their behalf in connection with work for Pfizer, are expected to raise concerns related to potential violations of these International Anti-Bribery and Anti-Corruption Business Principles or the law. Such reports can be made to a Business Associate's primary point of contact at Pfizer or, if a Business Associate prefers, to Pfizer's Compliance Group by e-mail at corporate.compliance@pfizer.com or by phone at 1-212-733-3026.