# QUALITY IMPROVEMENT GRANT AGREEMENT (ex-US Grant Recipient; ex-US Project; RFP)

This Quality Improvement Grant Agreement ("Agreement") by and between

Pfizer Inc., a Delaware corporation with a place of business at 235 E. 42<sup>nd</sup> Street. New York, NY 10017 ("Pfizer") and

Instituto Nacional de Ciencias Medicas y Nutricion Salvador Zubiran with an address of Avenida Vasco de Quiroga No.15, olonia Belisario Domingez Seccion XVI, olonia Belisario Domingez Secc Delegación Tlalpan, Tlalpan, Mexico City, Mexico 14080 ("Grant Recipient")

is effective as of the date last signed ("Effective Date").

Pfizer has contracted with The British Society for Antimicrobial Chemotherapy ("BSAC") in furtherance of an initiative to support delivery to successful grant applicant institutions, including the grant recipient identified above, of a program of work to develop local Antimicrobial Stewardship ("AMS") Centers of Excellence that seek to improve patient outcomes by addressing disparities in access.

Maria Dolores Niembro-Ortega, an employee or a contractor of Grant Recipient ("Project Lead"), intends to conduct a quality improvement project entitled "Initiative to improve healthcare and antibiotics prescription process among frontline clinicians in a third level hospital in Mexico City," Pfizer Tracking Number 74064903 (the "Project"). The parties agree as follows:

#### 1. **PROJECT**

- Project. The Project will be conducted by Grant Recipient in accordance with a project plan 1.1. developed by Project Lead (the "Project Plan"). If Project Lead modifies the Project Plan in any material way (e.g., changes to timelines, progress points) Project Lead will promptly inform Pfizer in writing.
- Sponsorship. Grant Recipient will not, and will ensure that its employees, staff, agents, 1.2. consultants or subcontractors (collectively, "Staff") will not, represent to any third party that Pfizer is a regulatory sponsor of the Project. Grant Recipient may delegate duties and responsibilities to its Staff as permitted by Applicable Requirements.
- 1.3. regulatory obligations associated with the Project.
- Regulatory Obligations. Grant Recipient is solely responsionary obligations associated with the Project.

  Compliance with Applicable Requirements. Grant Recipient will conduct the Project and the Project-related activities in accordance with Applicable Requirements and ensure aske Project-related activities in accordance with Applicable Requirements and ensure aske Project Plan; (iii) the Project Plan; (iii) the terms of any afthis Agreement; (ii) the Project Plan; (iii) the terms of any regulations guidelines or regulatory 1.4. undertake Project-related activities in accordance with Applicable Requirements and ensure compliance with Applicable Requirements by all Staff involved in the Project. "Applicable with Applicable with Requirements" means: (i) the terms of this Agreement; (ii) the Project Plan; (iii) the terms of any institutional review board ("IRB") or independent ethics committee ("IEC") approvals and any regulatory authority approvals, if applicable; (iv) all applicable laws, rules, regulations guidelines or requirements of any 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 Project in any region or regulatory jurisdiction in which the Project is conducted ("Applicable Law"); (v) all applicable good practice quality guidelines and regulations encompassing internationally recognized standards such as Good Clinical Practice, Good Laboratory Practice, and Good Review Practice; and (vi) applicable guidelines of the International Council on Harmonisation ("ICH").

- IRB/IEC Approval. If required, Grant Recipient will ensure that the Project is approved by and subject to continuing oversight by an IRB/IEC. If IRB/IEC approval is required, Grant Recipient will provide Pfizer with documentation of the initial IRB/IEC approval and any renewals, and any IRB/IEC approved amendments to the Project Plan. Grant Recipient will notify Pfizer promptly of any withdrawal or suspension of IRB/IEC approval.
- Informed Consent. If required, Grant Recipient will obtain written informed consent from 1.6. each Project subject in accordance with Applicable Requirements or a waiver of consent from the IRB or IEC. Pfizer will not participate in the development of, or to review or comment on, any informed consent document or any request for waiver.
- Duration. "Project Completion" means the completion of all Project activities including 1.7. completion of all Project Plan requirements. Project Lead expects to achieve Project Completion by July 31, 2023.
- 1.8. Status Updates. Grant Recipient will provide Pfizer with an online update of Project status at least twice a year. Each update will include publication plans, adjustments in the estimated Project Completion date, and any other information reasonably requested by Pfizer.
- Project Registration. If applicable, Pfizer encourages Grant Recipient to register the Project and post a synopsis of the Project Results on www.ClinicalTrials.gov or such other website as required by Applicable Law.

#### 2. **SUPPORT**

- Support. Grant Recipient will receive support for its Project in accordance with Attachment A ("Support").
- 2.2. Basis of Support. The Support is not conditioned on: (i) any pre-existing or future business relationship between Pfizer and either Project Lead or Grant Recipient; or (ii) any business or other decisions Project Lead or Grant Recipient has made, or may make, relating to Pfizer or Pfizer products. Nothing in this Agreement will be construed in any manner as an obligation or inducement for Grant Recipient or Project Lead to purchase, order, prescribe or recommend any product of Pfizer or any Pfizer affiliate.
- Timing. Pfizer will not provide the Support until Pfizer has received documentation of IRB/IEC approval, exemption or waiver (if required), and the Project Plan.
- Use of Support. Grant Recipient will use the Support solely for purposes of the Project. 2.4.
- Project Budget. Grant Recipient represents that any Grant Recipient-provided budget upon 2.5. which the Support is based reflects an informed, reasonable, estimate of funds required to complete



and report the Project, including, if applicable, expenses relating to the publication of Project Results.

- 2.6. <u>Disclosure by Pfizer</u>. In the interest of transparency relating to its financial relationships with investigators and research sites or to ensure compliance with Applicable Law, industry codes and Pfizer policies, Pfizer may report or otherwise publicly disclose payments or other transfers of value, including if applicable, the Support, to certain health care providers, teaching hospitals and other health care organizations. These laws, policies and codes, and their implementing regulations, are collectively "**Transparency Obligations**." Pfizer may disclose in any lawful manner any information necessary for Pfizer to meet its Transparency Obligations.
  - 2.6.1. Disclosure Content. Pfizer may identify Grant Recipient and Project Lead and will differentiate clearly between payments or other transfers of value made to institutions and those made to individuals. Disclosures may include identifying information, such as name, business address, specialty, and license numbers.
  - 2.6.2. Agreement and Cooperation. Grant Recipient accepts and agrees to these disclosures on behalf of itself and its Project Lead. Grant Recipient will reasonably cooperate with Pfizer in Pfizer's collection and disclosure of information necessary to fulfill its Transparency Obligations.
- 3. CONFIDENTIALITY. Any information or materials provided to Pfizer by Grant Recipient related to the Project or the Support are non-confidential and will not contain any markings claiming confidentiality. Grant Recipient acknowledges that Pfizer will not treat such materials as confidential or assume any obligation to keep them confidential. Grant Recipient's rights with respect to such information or materials will be only those obtained under patent laws and/or under a separate written agreement between Grant Recipient and Pfizer. Grant Recipient has not, and will not, submit any confidential information to Pfizer in connection with the Project or the Support. Grant Recipient acknowledges that Pfizer may conduct ongoing or future research substantially similar or identical to the Project. Until after release of a Publication by Grant Recipient, Pfizer will not use the Project Report or Project Plan for any purpose other than internal review.

## 4. PROJECT DATA, RESULTS AND REPORT; PUBLICATIONS

#### 4.1. Definitions.

- 4.1.1. "Project Data" means non-aggregated, subject-level data collected from or about each Project subject during the course of the Project as required by the Project Plan.
- 4.1.2. "Project Results" refers to aggregated or summarized Project Data and conclusions about the Project, as would be included in a report or publication.
- 4.1.3. "Project Report" means a written report of the Project Results.
- 4.2. <u>Use of Project Results and Project Data</u>. Grant Recipient is free to publish the Project Results, subject to the provisions of this Agreement, and owns and is free to use the Project Results for any other lawful purpose. Grant Recipient owns and is free to use the Project Data for its own research, educational, and patient care purposes. In consideration of the Support, Grant Recipient



will not use, or permit others to use, the Project Data for the commercial benefit of any third party.

- 4.3. <u>Project Report</u>. Within 60 days of the earlier of Project Completion or termination of this Agreement, Grant Recipient will provide Pfizer with a Project Report which may take the form of a manuscript. If the Agreement is terminated early, the Project Report should include, at minimum, the Project Results through the date of termination.
- 4.4. <u>Publications</u>. Pfizer encourages Grant Recipient to publish the Project Results. Grant Recipient 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 and disclose Pfizer support of the Project in any Publication. "**Publication**" means any journal article, abstract, presentation or other type of public disclosure that reports any Project Results.

## 5. GLOBAL TRADE CONTROL LAWS; RESTRICTED MARKETS

## 5.1. Definitions.

- 5.1.1. "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.
- 5.1.2. "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.
- 5.1.3. "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.
- 5.1.4. "Restricted Market" means Crimean Peninsula, Cuba, Donbass Region, Iran, North Korea, and Syria.
- 5.1.5. "Restricted Party" means any individual or entity on any of the following

7

v.1.0

"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.

- 5.2. <u>Global Trade Control Laws</u>. 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 Global Trade Control Laws.
- 5.3. Restricted Parties; Restricted Markets. Grant Recipient 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. Grant Recipient represents 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, Grant Recipient confirms that neither Grant Recipient 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. Grant Recipient will screen the parties listed above against the relevant Restricted Party Lists. In the event that any part of this representation changes, Grant Recipient will promptly inform Pfizer and suspend all related activities under this Agreement until Pfizer agrees in writing to move forward.

#### 6. TERM AND TERMINATION

6.1. <u>Term.</u> This Agreement will commence on the Effective Date and will continue until the later of one year or until terminated in accordance with this Agreement.

#### 6.2. Termination.

- 6.2.1. *Termination Upon Project Completion*. This Agreement will terminate upon Project Completion and each party's receipt of all deliverables and payments owed.
- 6.2.2. Termination by Grant Recipient. Grant Recipient may terminate this Agreement: (i) immediately on written notice to Pfizer when, as confirmed by the IRB/IEC, continued performance of the Project poses risks to the health or well-being of Project subjects; or (ii) without cause upon 30 days prior written notice to Pfizer.
- 6.2.3. Termination by Pfizer. Pfizer may terminate this Agreement (A) upon 30 days prior written notice to Grant Recipient if: (i) the Project Plan is materially modified in a way unacceptable to Pfizer, (ii) the Project is not completed within six months after the expected Project Completion Date, (iii) the Project does not start within six months of the Effective

VALIDAD

Date, or (iv) if applicable, the Subject enrollment rate is significantly slower than outlined in the Project Plan or needed to complete the Project by the Project Completion Date; or (B) immediately upon written notice to Grant Recipient if (i) Project Lead becomes unavailable or withdraws from the Project and Pfizer and Grant Recipient are unable to agree upon a successor within 30 days after Pfizer is notified, or (ii) BSAC becomes unavailable or withdraws from its relationship with Pfizer.

6.2.4. *Termination for Cause*. This Agreement may be terminated by either party upon written notice that specifically identifies the breach and gives the alleged breaching party 30 days in which to cure it. Notwithstanding the foregoing, Pfizer may terminate this Agreement immediately upon notice to Grant Recipient, with no cure period, if Grant Recipient violates Global Trade Control Laws or breaches Section 7.3.

#### 7. REPRESENTATIONS

- 7.1. Representations of the Parties. Each party represents 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.
- 7.2. <u>Representations of Grant Recipient</u>. Grant Recipient represents that Grant Recipient, its affiliates and Staff involved in the Project:
  - 7.2.1. are licensed, registered or otherwise qualified and suitable (without restrictions) under Applicable Law to act as a regulatory sponsor, Project site or investigator, as applicable;
  - 7.2.2. are not debarred under subsections 306(a) or (b) of the U.S. Federal Food, Drug, and Cosmetic Act or any other similar Applicable Law and will not use the services of any person debarred under Applicable Law in the Project;
  - 7.2.3. are not the subject of any material past (within the past three years) or pending governmental or regulatory investigation, warning or enforcement action related to its conduct of clinical research that has not been disclosed to Pfizer;
  - 7.2.4. as applicable, are not excluded from, or prohibited from participating in, any national or federal health care program;
  - 7.2.5. have the authority to share business contact information; and
  - 7.2.6. will maintain true, accurate and complete reports, statements, books and other records related to the Project.
- 7.3. Anti-Bribery and Anti-Corruption Representations. Grant Recipient represents that:
  - 7.3.1. the Support will not cause Grant Recipient or its Staff to do anything that would result in Pfizer improperly obtaining or retaining business or gaining any improper business advantage;



- 7.3.2. it will not use any portion of the Support 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 Pfizer to improperly obtain or retain business or to gain an improper business advantage, and, it has not accepted, and will not accept in the future, such a payment; and
- 7.3.3. Pfizer will be entitled to revoke the Support if Pfizer learns that Grant Recipient or its Staff has used or intends to use any portion of the Support to improperly seek to influence any Government Official or any other person in order to obtain or retain business or gain a business advantage.
- 7.3.4. For the purpose of this Agreement, "Government" includes all levels and subdivisions of governments (i.e., local, regional, and national; administrative, legislative, and executive) and "Government Official" includes (i) any elected or appointed non-US Government official (e.g., a legislator or a member of a non-US Government ministry), (ii) any employee or individual acting for or on behalf of a non-US Government Official, non-US Government agency, or enterprise performing a function of, or owned or controlled by, a non-US Government (e.g., a healthcare professional employed by a non-US Government hospital or university), (iii) any non-US political party officer, candidate for non-US public office, or employee or individual acting for or on behalf of a non-US political party or candidate for public office, (iv) any employee or individual acting for or on behalf of a public international organization, and (v) any member of a royal family or member of a non-US military.
- 7.4. <u>Amendment</u>. Grant Recipient will notify Pfizer promptly if any of these representations require amendment during the term of this Agreement.

#### 8. GENERAL PROVISIONS

- 8.1. <u>Liability</u>. Each party will be responsible, to the extent permitted by law, for any negligent acts or omissions by itself, its Staff, officers or directors. The Project is not designed, sponsored, or managed by Pfizer and Pfizer provides no indemnification of any type.
- 8.2. <u>Assignment and Delegation</u>. Grant Recipient may not assign any rights or delegate any duties under this Agreement without written permission from Pfizer. If Pfizer authorizes any delegation of duties, Grant Recipient remains responsible to Pfizer for the performance of those duties. Since Pfizer's only obligation hereunder is to provide the Support, Pfizer may assign and delegate any and all of its rights or obligations under this Agreement to a third party.
- 8.3. Entire Agreement. This Agreement, its Attachments and the Project Plan represent the entire understanding, and supersede all previous agreements, between the parties relating to the Project. This Agreement may be amended only by a written instrument signed by both parties.
- 8.4. <u>Survival</u>. Sections 3, 4, and 8 will survive Agreement termination, along with any other provision of this Agreement that, by its nature and intent, remains valid after termination.
- 8.5. Use of Names. Neither party will use the name or logos of the other or any of its Staff for DADO



promotional or advertising purposes without prior written consent. Grant Recipient is free to identify Pfizer as providing support for the Project in Publications or in publicly available reports of ongoing research studies. Pfizer is free to identify Grant Recipient and the Project in non-promotional listings or reports of Pfizer-supported projects.

- 9. **EDUCATION SPECIFIC TERMS**. If the Project has a medical education component, the following terms apply:
- 9.1. <u>Standards</u>. Grant Recipient will ensure the Project conforms to all applicable medical education standards and guidelines (such as the Accreditation Council for Continuing Medical Education's "Standards for Commercial Support" or its successor guidance, or relevant standards enacted by the European Accreditation Council for Continuing Medical Education). Grant Recipient will adhere to the International Academy for Continuing Professional Development Accreditation's Consensus Statement (<a href="https://academy4cpd-accreditation.org/">https://academy4cpd-accreditation.org/</a>) even if the Project is not an accredited or certified continuing medical education program.
- 9.2. <u>Content; Faculty</u>. Grant Recipient is solely responsible for the content of any medical education content and the selection of any presenters, authors, moderators and/or faculty (collectively, "Faculty"). Pfizer will not direct or influence the content of the medical education and will not participate in the selection of the Faculty.
- 9.3. <u>Disclosure of Support.</u> Grant Recipient will ensure meaningful disclosure to the Project participants of: (i) Pfizer's support of the Project; and (ii) any financial relationships or potential conflicts of interest between Grant Recipient or Faculty and Pfizer.
- 9.4. Use of Funds.

9.4.1. Grant Recipient may not use the Support to: (i) pay travel, lodging, registration fees, or personal expenses for Project participants; or (ii) purchase and distribute items to Faculty or Project participants that possess a discernible value on the open market (e.g., textbooks).

[signature page follows]



# ATTACHMENT A Support

Grant Recipient will receive a supported program of work with the goal of achieving accreditation of its AMS program. The program of work may include one or more of the following:

- 1. Gap analyses;
- 2. Customized training; or
- 3. Development (or assistance with development) of an impact evaluation program.

No monetary funds will be transferred to Grant Recipient under the Agreement. Grant Recipient is responsible for: (i) the submission of requested information (whether to Pfizer, BSAC, or a third party) in connection with the Project or the Agreement; (ii) participation in the AMS accreditation process; and (iii) implementation of identified improvement actions relevant to the Project or otherwise supported by the Agreement. Pfizer will not conduct or monitor any aspect of the relevant AMS accreditation process.

<u>Inquiries</u>: To inquire about a deliverable above, e-mail <u>GlobalMedicalGrants@pfizer.com</u> and include Pfizer Tracking No. 74064903.





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

PFIZER	GRANT RECIPIENT
	O Santa Oscrnio
Authorized Representative	Authorized Representative
	2 José Sountes Osovnio
Printed Name	Printed Name
	3 Hangging Director
Title	Title
	1) August 24,2022
Date	Date

Read and Acknowledged by:

Maria Doloves Niembro Ortega. August 24, 2022
Project Lead Date

Marra Doloves Nyembro Ortega
Printed Name

