# **MEMORANDUM OF UNDERSTANDING**

This Memorandum of Understanding ("**MOU**") is entered into at Mumbai on the 16<sup>th</sup> day of January 2023 ("**Effective Date**")

**Pfizer Limited**, a company incorporated under the Indian Companies Act, 1913 and having its registered office at The Capital, 1802, A Wing, 18<sup>th</sup> floor, Plot No. C-70, 'G' Block, Bandra Kurla Complex, Bandra (East), Mumbai 400 051 (hereinafter referred to as "**Pfizer**") which expression shall unless be repugnant to context or meaning thereof shall mean and include its successors and assigns of the **FIRST PART**;

# AND

Manipal Academy Of Higher Education (MAHE), a deemed to be University, having its registered office at Madhav Nagar, Manipal – 576 104, Karnataka, India, on behalf of its constituent unit, Kasturba Medical College, Mangalore (KMC) and represented by, Dr P Giridhar Kini, Registrar MAHE (hereinafter together referred as "MAHE") which expression shall, unless repugnant to the context or meaning thereof, be deemed to mean and include its successors and assigns of the OTHER PART.

Pfizer and the MAHE are hereinafter collectively referred to as "Parties" and individually a "Party"

## WHEREAS:

- 1. Pfizer is a leading multinational company inter alia engaged in the manufacture, sale and marketing of pharmaceutical and consumer health products.
- 2. Pfizer participates in numerous initiatives and awareness/education programs in the field of medicine and one such awareness/ initiative is Real World Evidence generation.
- 3. Pfizer understands that there is fragmented application of Real World Evidence generation in India which can be resolved by improving the capability of healthcare professionals in conducting real world evidence studies, strengthening the data generation and thereby improving patient outcomes.
- 4. MAHE is engaged in supporting research & healthcare services and endeavors to improve its data generation activities.
- 5. MAHE wishes to strengthen the Real-world evidence generation comprising of Education, Governance, Surveillance/Data Analytics & Outcomes to improve clinical outcomes and has approached Pfizer to collaborate and explore RWE study processes and framework. Pfizer has agreed to discuss and explore RWE study processes and framework with the MAHE subject to the terms and conditions contained herein.

#### NOW THEREFORE IT IS HEREBY AGREED BY AND AMONGST THE PARTIES AS UNDER:

# 1. <u>Definitions and interpretation</u>:

## 1.1 <u>Definition:</u>

In this Agreement, except where the context or subject matter is inconsistent therewith, the following terms shall have the following meanings:

"Affiliate" shall mean, with respect to any Person, any other person that directly or indirectly controls, is controlled by, or is under common control with, such Person at any time during the period for which the determination of affiliation is being made;

"**Appendix**" shall mean and include any supplemental document or schedule or set of schedules that may be attached to this MOU forming an integral part thereof.

**"Confidential Information"** may include, reports, studies, findings, inventions, ideas, data, knowhow, formulae, processes, designs, sketches, plans and specifications. To the extend practical, Confidential information shall be disclosed in documentary or tangible form marked "Proprietary" or "confidential". In case of disclosures in non-documentary form orally or visual inspection, the discloser shall have the right, or if requested in writing by the Recipient in advance of the disclosure, the obligation to confirm in writing the fact and general nature of each disclosure.

"Disclosing Party" mean Pfizer disclosing the Confidential Information.

"Intellectual Property" means any patent, patent application, copyright, moral right, business names, trade name, trademark, service mark, registered designs, trade secret, goodwill and any applications or right to apply for registration therefore, internet domain names, logos, designs, slogans, and general intangibles of like nature, computer software programs or applications, know-how, proprietary processes, formulae, algorithms, integrated circuit, topographies or any other intellectual property right available at present and/ or in future, whether registered or unregistered, and includes rights to apply and any amendments/ modifications, renewals thereto and any other similar rights in India and in any other country.

**"Law"** or **"Laws"** shall mean and include laws, treaties, ordinances, judgments, decrees, injunctions, writs, orders and stipulations of any Court, arbitrator or governmental agency or authority and statutes, rules, regulations, orders and interpretations thereof of any national, state, local, municipal, regional, environmental or other governmental body, instrumentality, agency, authority, Court or other body having jurisdiction over the Parties.

**"Party"** shall mean either party to this MOU when referred to individually or Parties, if referred to collectively.

**"Pfizer SOPs"** shall mean and include the Pfizer Standard Operating Procedures prescribing the expected adherence by the MAHE of the norms and ethical conduct including the Pfizer policies on business conduct, and as may be amended/deleted/replaced from time to time along with any other additional Standard Operating Procedures as may be notified by Pfizer to the MAHE, in writing from time to time.

**"Recipient"** shall mean and include the MAHE, including but not limited to, its members, directors, officers, employees and/or any other persons who work for each of the members of the MAHE jointly or severally, or those that are, whether directly or indirectly, under the control or direction of it and/ or who have access to such Confidential Information by virtue of their access, connection, engagement or relationship with the Recipient.

"Term" shall mean and include the duration of this MOU as set forth in this Agreement.

# 1.2 <u>Interpretation:</u>

In this MOU, unless the contrary is expressly stated or unless the context otherwise requires:

- 1.2.1. words in the singular shall include words in the plural and words in the plural shall include the singular;
- 1.2.2. references in this MOU to a gender shall include every gender;

- 1.2.3. the headings and sub-headings used in this MOU are inserted only for reference to the provisions hereof and shall not affect the construction or interpretation of such provisions;
- 1.2.4. the words "include", "includes" and "including" when used in this MOU are deemed to be followed by the phrase "without limitation";
- 1.2.5. references to Clauses, Parties, and Schedules are references to the Clauses of, and Parties and Schedules to, this MOU;
- 1.2.6. references in this MOU to statutory provisions shall be construed as references to those provisions as modified, amended or re-enacted from time to time; and
- 1.2.7 any word or phrase defined in the body of this MOU, as opposed to being defined in Clause 1.1 above, shall have the meaning assigned to it in such definition throughout this MOU.

# 2. <u>Understanding:</u>

The Parties wish to explore and discuss the RWE framework and processes that can be taken up by the Parties in future upon execution of a definitive agreement in this regard. The execution of this MOU does not impose an obligation on Pfizer to provide any support to the MAHE and/ or conduct any RWE workshop with the MAHE s and the Parties are executing this MOU to merely enable discussions with respect to RWE framework.

- I) Pfizer shall discuss with the MAHE and explore the possible options with respect to the following:
  - a. Supporting the MAHE to establish its own RWE study processes, if applicable, with MAHE clinical research team. This shall be with respect to broad level support for educational initiatives and developing RWE framework.
  - b. Conducting RWE educational workshop and RWE studies in therapy areas aligned with Pfizer (current and pipeline assets) with MAHE after signing of the definitive agreements. Supporting the MAHE in defining the relevant Key performance indicators (KPI) to evaluate the success of implementation of the program, however the final decision on the KPIs will be with the MAHE including but not limited to the parameters like
    - Expedited data generation within stipulated timelines in compliance to data privacy policies
    - Epidemiological/ outcomes data for the current and pipeline molecules
    - Advocates for RWE Advisory council
    - Insights on patient journey
    - Establish Center of Excellence with MAHE for Real World Evidence generation
  - c. Holding regular follow up meetings with MAHE to assess the effectiveness of the education and training on RWE, including the assessment of KPIs, on a mutually agreeable date, through a digital platform. For the purpose of reference, the broad KPIs which are required to be met as per the RWE Program shall be decided mutually between the Parties.
- II) The MAHE shall discuss with Pfizer and explore the possible options with respect to the following:
  - a. Conducting RWE studies.
  - b. MAHE 's endeavor to become a Centre of Excellence and to train their staffs in order to conduct RWE studies effectively.
  - c. Option to collaborate with a third-party solution provider of their choice and engage for the purpose of this program.
  - d. Conducting MAHE 's own due diligence and review of the contract with the vendor with whom they would engage for the purposes of conduct of RWE studies. Only on their satisfaction of the independent due diligence conducted by the MAHE , shall the MAHE enter into contract with such vendor.
  - e. Generating the real-world data and regularly monitor the KPIs, upon the RWE Program being in place.

- f. With the real-world evidence reports generated by the studies, assessment of the KPIs *versus* the data generated and formulate and/ or revise the treatment guidelines accordingly, if applicable, with the support of Pfizer's medical team.
- g. Being represented by its RWE/clinical team in follow up meetings with Pfizer's medical team to assess the effectiveness of the RWE program.
- h. Ensure that the MAHE 's RWE/clinical team, shall attend all the meetings held between MAHE and Pfizer.
- i. Dissemination of data generated through RWE Program with the collaboration of both Pfizer and MAHE relevant teams and discuss measures to improve the KPIs.
- j. Providing of update during regular quarterly meetings to Pfizer on the RWE generation activities undertaken by redacting any personal information / sensitive personal information of the patients.

# 3. <u>Representations, Warranties, Undertakings and Covenants:</u>

- 3.1 The MAHE hereby represents, warrants, undertakes and covenants with Pfizer as follows:
- 3.1.1. The MAHE is licensed, registered, or qualified under local law, regulations, policies, and administrative requirements to carry out activities as defined under this agreement, and, to the best of the MAHE 's knowledge, no regulations or other obligations prohibit it from having the same;
- 3.1.2. The MAHE has not and will not in the future directly or indirectly offer or pay, or authorize the offer or payment, of any money or anything of value in an effort to influence any Government Official or any other person in order for Pfizer to illegally obtain or retain business or to gain an improper business advantage, and, has not accepted, and will not accept in the future, such a payment;
- 3.1.3. The MAHE has been provided with a copy of Pfizer's International Anti-Bribery and Anti-Corruption Principles (Schedule A) and, to the best of the MAHE 's ability, has communicated such Principles to all persons acting on its behalf in connection with work for Pfizer, including agents or subcontractors;
- 3.1.4. Any information provided by the MAHE to Pfizer, including that related to subcontractors / agents acting on its behalf, in connection with Pfizer's anti-corruption due diligence is complete, truthful and accurate and, if the MAHE becomes aware, the MAHE agrees to inform Pfizer if any responses in the due diligence questionnaire with respect to the MAHE or any individuals identified in the due diligence questionnaire or their Family Relatives, as defined therein, change during the performance of this agreement;
- 3.1.5. The MAHE will (i) provide truthful and complete documentation supporting, in reasonable detail, the work performed and any expenses incurred, (ii) maintain true, accurate, and complete invoices, reports, statements, books, and other records; and
- 3.1.6. The MAHE will permit, during the term of the agreement and for three years after expiration of the agreement, Pfizer's internal and external auditors access to any relevant books, documents, papers, and records of the MAHE involving transactions related to the agreement. If the MAHE 's books and records are comingled with other clients of the MAHE , the audit may be conducted by an external auditor who will not share records related to such other clients with Pfizer.
- 3.1.7. The MAHE agrees to follow Pfizer's *My Anti-Corruption Policy and Procedures (MAPP)* in connection with its performance under this agreement, including requiring relevant employees of the MAHE, as determined by Pfizer, to complete training on anti-corruption and/or MAPP provided by Pfizer.
- 3.1.8. Pfizer may terminate the contract if the MAHE or his staff breaches any of the above Representations and Warranties. Further, the MAHE will indemnify and hold Pfizer harmless from any claim, liability, fine, penalty, loss or damage that arises as a result of the MAHE 's breach of the aforesaid Representations and Warranties.
- 3.1.9. The MAHE represents that the financial support provided under the terms of this MOU is not being given in exchange for any implicit or explicit agreement to use, recommend, prescribe, provide

favorable procurement decisions etc. with regard to Pfizer products by the MAHE. In addition the MAHE represents that the support provided is reasonable and appropriate to achieve the stated objectives.

#### 4. <u>Term & Termination:</u>

TERM:

- 4.1 This MOU will commence on 20<sup>th</sup> January 2023 ("Effective Date") and shall be valid for a period of Three (3) years from the start date of deployment of the digital healthcare platform and shall be extendable on mutual consent in writing, (hereinafter referred to as "**the Term**") unless terminated earlier by the Parties in accordance with the provisions mentioned.
- 4.2 Parties may renew the Term of this Agreement by way of Addendum, on such terms and conditions as shall be mutually agreed between the Parties.

## **TERMINATION**:

- 4.3 Either Party shall have the right to terminate this MOU by providing 30 (thirty) days' notice in writing to the other Party.
- 4.4 Pfizer shall have the right to forthwith terminate this MOU in the event of a material breach of the provisions of this MOU by the MAHE, including representations and warranties provided herein.

## 4.5. **Consequences and Obligations on Termination**:

Upon any termination or determination of this MOU by Pfizer in accordance with clause 6.3 and 6.4 above the MAHE shall:

- (a) Furnish to Pfizer an undertaking that it has removed all Confidential Information belonging to Pfizer from its computer systems and / or any hard copies/files;
- (b) Cease and desist using any Pfizer information and materials or any part thereof in any manner whatsoever.

#### 5. <u>CONFIDENTIALITY:</u>

- 5.1 The Recipient agrees and undertakes that they shall:
- 5.1.1 Hold the Confidential Information in strict confidence in accordance with the provisions hereof.
- 5.1.2 Not disclose any Confidential Information to any third party, agent or affiliate, whether directly or indirectly, for any purpose whatsoever, except as expressly permitted under this Agreement, without the prior written approval of the Disclosing Party.
- 5.1.3 Not use the Confidential Information, whether directly or indirectly, for any purpose(s) whatsoever, except as expressly permitted under this Agreement.
- 5.1.4 Protect the Confidential Information by using the highest degree of care and highest security precautions, to prevent the unauthorized use, dissemination, or publication of the Confidential Information.
- 5.1.5 Take all necessary actions to impose the Confidentiality obligations on all its directors, officers, employees, agents and/ or any other persons who work for the party or are under its direct or indirect control and direction and who shall have access to such confidential information. In any event, the

Recipient shall be responsible for any breach of the terms of this MOU by any of its directors, officers, employees and/ or any of its representatives.

- 5.1.6 Return all originals, copies, reproductions and summaries of Confidential Information in its control as and when requested by the Disclosing Party or as per the terms of this MOU.
- 5.1.7 Notwithstanding any other provision of this Clause, Recipient may disclose the terms of this MOU (other than Confidential Information of a technical nature) to its solicitor, accountant, insurer and auditor or as may be required by any statutory body or governmental authority having jurisdiction over the Disclosing Party.
- 5.1.8 Confidential Information shall not be deemed to mean and include any information that (i) is or becomes generally available to or known to the public other than as a result of a breach of this MOU, (ii) was within the Recipient's possession prior to its being furnished to it by or on behalf of the Disclosing Party pursuant hereto, (iii) becomes available to the Recipient on a non-confidential basis from a source other than the Disclosing Party or any of its representatives, and in the case of (ii) and (iii) the source of such information was not bound by a confidentiality agreement with or other contractual, legal or fiduciary obligation of confidentiality to the Disclosing Party or any other party with respect to such information.
- 5.1.9 If the Recipient or any of its permitted affiliates, successors, group companies, subsidiaries and assigns believe that it will be compelled by a Court or other authority to disclose any Confidential Information, it agrees and undertakes to give the Disclosing Party, prompt and timely written notice so as to allow the other party to take steps to oppose such disclosure, but in any event the Recipient shall not be prohibited from complying with such requirement; and

## 5.2 ACTION ON BREACH:

- 5.2.1 The Recipient shall notify the Disclosing Party, immediately upon discovery of any breach of its obligations under this MOU and shall co-operate in every reasonable way to help the Disclosing Party in taking steps to regain possession of the Confidential Information and to prevent further disclosure.
- 5.2.2 The Disclosing Party shall be entitled, without waiving or limiting any other rights in laws or remedies to seek such injunctive or equitable relief as may be deemed proper by a Court of competent jurisdiction.
- 5.2.3 The provisions of this Clause and the Parties' obligations hereunder shall survive the expiration or termination of this MOU for any reason whatsoever for a period of 7 years after the expiration or termination of this MOU.

# 6. <u>Intellectual Property Rights:</u>

- 6.1 In the event Pfizer shares any educative / awareness content on AMS with the MAHE to generate disease awareness at the MAHE, it is expressly understood that Pfizer shall be the owner and be entitled to the Intellectual Property Rights in the said educative / awareness content. The MAHE hereby declares that it shall not except, with due permission from Pfizer as provided in this Agreement:
- (a) use the Intellectual Property Rights shared by Pfizer on its own account or otherwise or for any other purpose other than for creating awareness at the MAHE.
- (b) permit the use of its intellectual property by any other person, firm or body corporate through it.

# 7. <u>Independent Relation</u>:

- 7.1 Nothing contained herein shall be deemed to create any joint venture or relationships of principal and agent or master and servant, or employer and employee between Pfizer and the MAHE or provide either Party with the right, power or authority, whether expressed or implied, to create any such duty or obligation on behalf of any of them.
- 7.2 The MAHE , any employees of the MAHE , its personnel, its agents, or any other person shall have no authority/right to bind Pfizer in any manner.

# 8. <u>Indemnity</u>:

8.1 The MAHE agrees to indemnify, keep indemnified and save harmless Pfizer against all claims, demands, damages, losses, expenses, suits or proceedings made against, incurred, or suffered in connection with, resulting from or arising out of (whether or not involving a third party claim) the material breach by the MAHE or by any of any of its representations and warranties, covenants, and undertakings under this MOU.

## 9. Assignment:

Neither party shall not assign or transfer any of their rights or interest or benefits under this MOU without the prior written consent of the other party.

## 10. **<u>Resolution of Disputes</u>**:

- 10.1 All disputes under this MOU shall be referred to arbitration under the Arbitration & Conciliation Act, 1996 (or any amendments thereof).
- 10.2 The parties shall appoint its own arbitrators and the two arbitrators shall in turn appoint the third arbitrator, who shall preside over the arbitration. The place of such arbitration shall be Mumbai. It is expressly stated that the Courts of Mumbai shall have the exclusive jurisdiction with respect to matters relating to the arbitration including the enforcement of awards and injunctive relief. The language of arbitration shall be English
- 10.3 Awards relating to any dispute shall be final and binding on the Parties to such dispute as from the date they are made. The Parties agree and undertake to carry out any decision or award of the arbitrator relating to such dispute without delay and further agree that there will be no appeal to any court of law or other judicial authority.
- 10.4 The language of arbitration shall be English. The arbitrator shall give a reasoned decision or award.

## 11. <u>Binding Nature:</u>

The provisions of this MOU shall be legally binding on the Parties hereto.

#### 12. <u>Governing laws and Jurisdiction:</u>

This MOU shall be governed by, and construed in accordance with the laws of India. Further, the Parties agree that the competent courts at New Delhi only shall have jurisdiction on all matters relating to this Agreement including for grant of injunctive relief and enforcement of arbitral awards.

**IN WITNESS WHEREOF**, the Parties have executed this MOU as of the date first above written.

By:

DocuSigned by: PGCuuc 07F640CADD4C462... January 17, 2023

Name: Dr P Giridhar Kini

1.\_\_\_\_\_

Name: \_\_\_\_\_

2.\_\_\_\_\_

Title: Registrar

Witnesses

In the presence of:

For and on behalf of **Pfizer Limited** 

For and on behalf of **Manipal Academy of Higher Education**, **Manipal** 

	DocuSigned by:
By:	Komal Gaus
	January 16, 2023

Name: Dr Komal Gaur

Title: Real World Evidence Medical Lead

In the presence of:

Witnesses

1.			

ame:
ame:

2.	

Name: \_\_\_\_\_ Name: \_\_\_\_\_

## Annexure A



## Pfizer's International Anti-Bribery and Anti-Corruption Business Principles

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. We expect the same commitment from the consultants, agents, representatives or other companies and individuals acting on our behalf ("Business Associates"), as well as those acting on behalf of Business Associates (e.g., subcontractors), in connection with work for Pfizer.

## **Commercial Bribery**

Bribery and corruption can also occur in non-Government, business to business relationships. Most countries have laws which 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 could include, but are not limited to, providing expensive gifts, lavish hospitality, kickbacks, or investment opportunities in order to improperly induce 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.

# 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:

- 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.
- 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.
- 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 only permitted if they are received on an infrequent basis and only at appropriate gift-giving occasions.

#### 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 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 <u>corporate.compliance@pfizer.com</u>.