# CHALLAN
## MTR Form Number-6

| GRN | MH002568897202021P | BARCODE | | Date | 24/07/2020-11:42:50 | Form ID | |
|---|---|---|---|---|---|---|---|

| | | | |
|---|---|---|---|
| **Department** | Inspector General Of Registration | **Payer Details** | |
| **Type of Payment** | Non-Judicial Stamps<br>Duty on Imnpressing Documents SoS Mumbai only | **TAX ID / TAN (If Any)** | MUMP15856B |
| | | **PAN No.(If Applicable)** | AADCP2043E |
| **Office Name** | BOM1_MUMBAI CITY 1 SUB REGISTRAR | **Full Name** | PPD Pharmaceutical Development India PvtLtd |
| **Location** | MUMBAI | | |
| **Year** | 2020-2021 One Time | **Flat/Block No.** | 101 A wing Fulcrum |
| | | **Premises/Building** | |
| **Account Head Details** | **Amount In Rs.** | **Road/Street** | Hiranandani Business Park Sahar Road |
| 0030048201 Amount of Tax | 820.00 | **Area/Locality** | Andheri East |
| | | **Town/City/District** | |
| | | PIN | 4 0 0 0 9 9 |
| | | **Remarks (If Any)** | GSK214094_India_ MGM Medical College and Hospital_ Dr Syed Qadri_ CTA |
| | | **Amount In Words** | Eight Hundred Twenty Rupees Only |
| **Total** | 820.00 | | |

| | | | | | |
|---|---|---|---|---|---|
| **Payment Details** | SBIEPAY PAYMENT GATEWAY | **FOR USE IN RECEIVING BANK** | | | |
| **Cheque-DD Details** | | Bank CIN | Ref. No. | 10000502020072400294 | 3219067887715 |
| Cheque/DD No. | | Bank Date | RBI Date | 24/07/2020-11:43:17 | Not Verified with RBI |
| Name of Bank | | Bank-Branch | | SBIEPAY PAYMENT GATEWAY | |
| Name of Branch | | Scroll No. , Date | | Not Verified with Scroll | |

Department ID : Mobile No. : 8291277497

**NOTE:- This challan is valid for document to be registered in Sub Registrar office only. Not valid for unregistered document.**

सदर चलन केवळ दुय्यम निबंधक कार्यालयात नोदंणी करावयाच्या दस्तासाठी लागु आहे. नोदंणी न करावयाच्या दस्तांसाठी सदर चलन लागु नाही.



**Print Date 24-07-2020 11:44:28**

# CLINICAL TRIAL AGREEMENT

THIS CLINICAL TRIAL AGREEMENT ("**Agreement**"), is entered into as of DATE of last signature, ("**Effective Date**") by and between

**PPD Pharmaceutical Development India Private Limited**, Office 101, A-Wing, Fulcrum, Hiranandani Business Park, Sahar Road, Andheri (East), Mumbai-400099, Maharashtra, India **(''PPD**").

and

**Mahatma Gandhi Mission,s Medical College & Hospital**, with its principal place of business at N-6,Cidco Aurangabad,431003,Maharashtra, India, represented by **Dr. Rajendra Bohra, The Dean**, a duly authorized representative with authority to contract on behalf of the Institution ("**Institution**")

and

**Dr. Syed Umar Quadri**, with his/her offices located at Mahatma Gandhi Mission's Medical College & Hospital N-6, Cidco Aurangabad,431003 Maharashtra,India("**Principal Investigator**").

And

**Site Management Organization-Doclin Clinical Research Services** (SMO), with its principal place of business at 445, Maruti Galli, Main Road, Hangarge, Mandoli – Belagavi-590010 Karnataka India represented by Mr. Maruti Patil, a duly authorized representative with authority to contract on behalf of the **SMO** (hereinafter referred to as the "SMO")

PPD, SMO, Institution and Principal Investigator are herein referred to each as a "**Party**" and, collectively, as the "**Parties**".

**WHEREAS**

I. PPD is a global contract research organization that is currently assisting **GlaxoSmithKline Research & Development Limited,** with its registered address at 980 Great West Road Brentford Middlesex, TW8 9GS UK ("**GSK**") or one of its Affiliates in the conduct of the clinical trial in accordance with the protocol entitled "**A randomized, double-blind, placebo-controlled, study evaluating the efficacy and safety of otilimab IV patients with severe pulmonary COVID-19 related disease"** ("**Clinical Trial**"), Protocol Number: **214094** and any amendments thereto ("**Protocol**"). GSK is the sponsor of the Clinical Trial. PPD is an Affiliate of PPD International Holdings Inc. and has been engaged by PPD International Holdings Inc. to support the performance of the Clinical Trial;

II. The Institution and Principal Investigator desire to participate in the conduct of the Clinical Trial, in accordance with the Protocol;

III Institution has authorized SMO to act as a payee in this Agreement and PPD has no obligation whatsoever to pay Institution or other service providers in the event SMO fails to reimburse Institution or other service provider for payments submitted by PPD to SMO hereunder.

IV. The Parties agree to conduct the Clinical Trial in accordance with the terms and conditions hereinafter set forth.

**THEREFORE, IT IS AGREED AS FOLLOWS:**

## 1. Clinical Trial Performance

1.1 Institution and Principal Investigator shall provide certain services ("**Services**") related to the conduct of the Clinical Trial, in accordance with the Protocol and any subsequent amendments made thereto in accordance with this Agreement, and with all applicable laws, rules and

regulations relating to the Clinical Trial. The Protocol is subject to approval by the appropriate Institutional Review Board or Ethics Committee or equivalent body (collectively "**IRB**"). The informed consent ("**Informed Consent**") is subject to approval by the IRB. If there is any discrepancy or conflict between the terms contained in the Protocol and this Agreement, the terms of the Protocol shall govern and control with respect to clinical matters and the terms of the Agreement shall govern and control with respect to all other matters.

1.2 Prior to the commencement of the Services, Institution and Principal Investigator shall review the Protocol and notify PPD if they cannot comply with any of the terms contained therein. If in the course of performing the Services, in accordance with generally accepted standards of clinical research and medical practice relating to the benefit, well-being and safety of the subjects ("**Subject(s)**") a deviation from the Protocol is required, such standards will be followed. In such case, the Party aware of the need for a deviation shall immediately notify PPD and GSK of the facts supporting such deviation as soon as the facts are known to such Party. The notification shall also be confirmed in writing within three (3) working days of the original notification being made to PPD and GSK.

1.3 The Institution and Principal Investigator agree to carry out the Services in strict compliance with:

(a) all specifications and timelines established in this Agreement;

(b) the Protocol and any amendments to the Protocol;

(c) the provisions of the current version of the World Medical Association's Declaration of Helsinki, in particular, neither the Institution nor the Principal Investigator must at any time jeopardise the health or well-being of any patient by unwarranted continuation of the Clinical Trial;

(d) applicable national laws, regulations and guidelines including without limitation the "Ethical Guidelines for Biomedical Research on Human Subjects" based on the ICH-GCP laid down by Indian Council of Medical Research (**ICMR**), and the Guideline for Good Clinical Practice (**GCP**) of the International Conference on Harmonisation (**ICH**) of Technical Requirements for the Registration of Pharmaceuticals for Human Use and with other generally accepted applicable Guidelines of the ICH a copy of which has been provided to Institution and Principal Investigator. (ICH Topic E6, Consolidated Guideline 1.5.96);

(e) the Clinical Trial is conducted under an Investigational New Drug (**IND**) the conditions specified in the Agreement and in accordance with New Drugs and Clinical Trials Rules, 2019 and

(f) Indian GCP and New Drugs and Clinical Trials Rules, 2019 Rule and its amendments.

(legislation identified in clauses c, d, e and f above hereinafter referred to as **Applicable Laws**)

1.4 The Clinical Trial shall be conducted only at the following location: Mahatma Gandhi Mission's Medical College & Hospital N-6, Cidco Aurangabad,431003 Maharashtra,India

1.5 The Institution agrees that the Clinical Trial will be conducted under the direction of the Principal Investigator in accordance with the Protocol and this Agreement.

1.6 The Principal Investigator will perform Services as agreed under this Agreement personally. In the event the Principal Investigator can no longer function in such capacity, then PPD and the Institution shall attempt to agree on a replacement. PPD shall have the right to approve any new Principal Investigator designated by the Institution. The new principal investigator shall be required to agree to the terms and conditions of this Agreement. If a mutually acceptable replacement cannot be agreed upon, PPD may terminate this Agreement in accordance with Clause 16.

1.7 The Institution and the Principal Investigator shall not subcontract any Services to another person or entity without PPD's prior written approval.

1.8 Notwithstanding anything herein to the contrary, if during the term of this Agreement, information that becomes available to PPD or GSK which affects the safety or efficacy of the Clinical Trial Product (as that term is defined at Clause 3.1 below), or if the Clinical Trial Product is approved by any regulatory agency, the Parties shall negotiate, in good faith, a modification of this Agreement to either (i) reduce the number of Subjects to be studied; and/or (ii) terminate the Clinical Trial, and/or (iii) modify any other relevant provision of this Agreement.

1.9 The Clinical Trial includes the collection by Institution of human biological materials from Clinical Trial Subjects for research use, Institution will comply with all Applicable Laws, rules, regulations and codes of practice and guidance relating to the collection, storage, use, shipping, and disposal of human biological materials in the conduct of the Clinical Trial and with respect to any such human biological materials from the Clinical Trial retained in Institution's possession. Institution and GSK will mutually agree to appropriate informed consent (including, as appropriate, for any genetic analyses) for the Clinical Trial and for research use of any human biological materials, with ethics approval. Institution agrees that any human biological materials collected as part of the Clinical Trial that are transferred to GSK or a GSK contractor, or held by Institution for GSK, will be under the custodianship and control of GSK.

1.10 Clinical Trial Staff Personal Information: All Processing of the Clinical Trial Staff Personal Information shall at all times comply with, and the parties will cooperate with each other to take the necessary measures to ensure adherence to Applicable Laws. Institution is responsible for supplying the Clinical Trial Staff with sufficient information regarding the collection of, handling, and use of their Personal Information by GSK. "**Clinical Trial Staff**" as used herein means the individuals providing services on behalf of Institution with respect to the Clinical Trial at Institution, including without limitation sub investigators, Clinical Trial coordinators, and other Institution employees, agents, or subcontractor. "**Personal Information**" as used herein means any information or set of information relating to a person that identifies such person or could reasonably be used to identify such person. Clinical Trial Staff Personal Information in this section includes the work contact information, and professional experience/educational background and qualifications that is routinely provided to and held by GSK in relation to a clinical study. "**Processing**" and its conjugates, including without limitation "**Process**" as used in this section means any operation or set of operations that is performed upon Personal Information, including without limitation collection, recording, retention, alteration, use, disclosure, access, transfer, storage or destruction.

## 2. Term of Clinical Trial

2.1 This Agreement shall take effect on the Effective Date and shall continue until each Party hereto has fully fulfilled its obligations towards the other Party ("**Expiration Period**"), unless terminated in accordance with Clause 16.

2.2 In the event that the Clinical Trial is extended beyond the Expiration Period, the Parties agree that such an extension will be covered by this Agreement and shall not necessitate any

amendment to this Agreement. Any continuation of the Services under this Agreement shall be confirmed in writing by PPD, prior to the Expiration Period.

2.3 Notwithstanding the above, the Services will not commence until PPD is granted appropriate IRB and regulatory approval and the Institution has received copies of said approvals.

2.4 Patient recruitment at the Institution is scheduled to start in **AUGUST 2020** and to be completed by the **30th of OCTOBER, 2020**. The Institution shall use its best efforts to complete Subject enrolment by **the 19th of OCTOBER, 2020.** The Institution is aware that enrollment is competitive in the Clinical Trial and Institution will be informed on the maximum number of Subjects through the duration of the Clinical Trial / ("**Enrolment Maximum**"). PPD may at any time modify this Enrollment Maximum or end enrollment at Institution at any time at PPD's discretion, including, but not limited to, upon the completion of the overall Study enrollment goal across all Study centers. The Institution will not enroll more Subjects than the Enrolment Maximum and neither PPD nor GSK will be obligated to make any payment with respect to any Subject enrolled in excess of the Enrolment Maximum unless otherwise approved in writing by PPD or GSK to exceed the Enrolment Maximum. If, during the Clinical Trial, it becomes apparent that Institution and/or Principal Investigator are not able to complete the Clinical Trial on schedule, they will notify PPD immediately.

2.5 In the event the Institution is unable to complete the enrolment by such date, PPD may reassign the Institution's enrolment slots, thereby reducing the number of Subjects enrolling at the Institution in the Clinical Trial. The Institution acknowledges that the Clinical Trial is part of a multi-center clinical trial. When the enrolment goal of **800** Subjects for the Clinical Trial as a whole is reached, enrolment will be closed at all institutions, including the Institution, regardless of whether the Institution or any other institution has reached its individual enrolment goal.

2.6 All Subject visits will be completed no later than **21ST OF DECEMBER. 2020** ("**Visits Completed Date**"). All electronic case report form ("**eCRF**") information associated with a Subject's visit must be satisfactorily completed within seven (2) calendar days after the Subject's visit or, if applicable, receipt of the Subject's test results. All final eCRF data will be entered into the eCRF and submitted to PPD no later than two (2) calendar days after the Study subject's final visit or, if applicable, receipt of the subject's final test results. All data queries from GSK must be completed and returned to GSK within seven (7) calendar days or, if during final clean up, one (1) calendar day, or such other time set by GSK. In all instances described in this clause, time is of the essence.

## 3. Supply of the Clinical Trial Product and Equipment

3.1 During the course of the Clinical Trial, PPD shall procure that GSK will provide the Institution with **GSK3196165 (otilimab)** ("**Clinical Trial Product**"), or other materials as GSK determines necessary for the conduct of the Clinical Trial (collectively, the "**Materials**").

3.2 The Parties acknowledge that GSK shall be responsible for packaging, labelling and shipping the Clinical Trial Product supplies to the Institution at GSK's own expense and in full compliance with all Applicable Laws.

3.3 The Clinical Trial Product will be distributed by GSK via a distribution depot to the Institution's pharmacy, which should already be aware of storage and conservation conditions required for the Clinical Trial Product.

3.4 The Principal Investigator and the Institution: (i) shall use the Materials only to conduct the Clinical Trial in accordance with the Protocol; (ii) shall not chemically, physically, or otherwise modify the Materials, except if specifically required by the Protocol; and (iii) shall

handle, store, and ship or dispose of the Materials with appropriate care in compliance with all applicable local, state, and federal laws, rules, and regulations including, but not limited to, those governing hazardous substances.

3.5 Upon termination of the Clinical Trial or this Agreement, all unused Materials provided by GSK shall be promptly returned at GSK's expense, to an address provided by GSK or, at GSK's option and expense, destroyed with the destruction certified in writing.

3.6 Any Materials provided by GSK or by PPD in the course of the Clinical Trial may not be transferred to any other location or to any third party without the prior written consent of PPD.

3.7 Equipment

(a) Loaned Equipment ("**Loaned Equipment**") means any equipment temporarily provided to Institution by PPD or GSK pursuant to this Agreement only for use in the Clinical Trial, including, but not limited to computer hardware and software if provided for the Principal Investigator and other Clinical Trial Staff to use, collect, enter, and report Clinical Trial data to GSK.

(b) Transferred Equipment ("**Transferred Equipment**") means any equipment permanently transferred to Institution by GSK or a GSK Affiliate pursuant to this Agreement, including, but not limited to computer hardware and software if provided for the Principal Investigator and Clinical Trial Staff to use, collect, enter, and report Clinical Trial data to GSK.

(c) If applicable, with respect to Loaned Equipment provided by GSK for use in the Clinical Trial, Institution agrees that no title to nor any proprietary rights related to the Loaned Equipment is transferred to Institution, that the Loaned Equipment will be used only for the Clinical Trial and only as described in the Protocol and any other written directions provided by PPD or GSK, that the Loaned Equipment will not be transferred by Institution to the possession of any third party without the written consent of GSK, and that, at the completion of the Clinical Trial or at GSK's request, Institution will return the Loaned Equipment and all related training materials and documentation to GSK or to a vendor designated by PPD or GSK.

(d) Principal Investigator and Clinical Trial Staff will attend scheduled training to use the Loaned Equipment following reasonable advance notice of scheduling. The Loaned Equipment will be kept in a safe and secure location and Institution will be responsible for any theft, damage, or loss to the Loaned Equipment other than normal wear and tear. Institution will be responsible for arranging and paying for any required internet connection, telephone line, and/or facsimile line as necessary to use the Loaned Equipment. If Institution fails to return the Loaned Equipment within the timeframe specified by PPD or GSK, Institution will be responsible for reimbursing PPD for any penalties, late fees, and/or replacement costs.

(e) Institution acknowledges that the Loaned Equipment may involve valuable patent, trademark, trade name, trade secret, and other proprietary rights of the Loaned Equipment manufacturer. Institution will not violate and will take appropriate steps and precautions to ensure that those with access to the Loaned Equipment do not violate these proprietary rights, including, without limitation:

(i) not removing any label or notice of Loaned Equipment ownership or other rights;

(ii) not making any copy, reproduction, changes, modification, or alteration of any software or firmware included with the Loaned Equipment; or

(iii) not disassembling or decompiling any such software or firmware or otherwise attempting to discover any source code or trade secret related to such software or firmware.

## 4. Obligations of the Parties

4.1 *Institution obligations*

Institution shall:

(a) be responsible for providing, at its sole cost and expense, the premises, adequate personnel, equipment (subject to Clause 3.7) and other resources necessary to conduct the Clinical Trial, in accordance with this Agreement, the Protocol and the conditions imposed by the IRB;

(b) ensure that the Principal Investigator observes current legislation, strictly complies with this Agreement, the Protocol, ethical regulations on clinical trials with medicines and collaborates in the performance of monitoring visits by PPD, audits by auditors appointed by PPD/GSK or its Affiliates and inspections by competent health authorities;

(c) promptly advise PPD as soon as possible if Institution observes or becomes aware of: (i) material non-compliance with the Protocol, ICH Good Clinical Practice guidelines, or any Applicable Laws, rules or regulations, (ii) incomplete or inaccurate recording of data or any significant misconduct, (iii) any changes of personnel, facilities or clinical research methods at the Institution that may affect the Clinical Trial, or (iv) any other matters, events, conditions or difficulties that may jeopardize the proper conduct of the Clinical Trial;

(d) notify PPD and the IRB, in writing, of any unanticipated or serious adverse reactions to the Clinical Trial Product, in accordance with Clause 11 below and the procedures set forth in the Protocol;

(e) maintain adequate records with respect to Clinical Trial Subject identification, clinical observations, laboratory tests, and Clinical Trial Product receipt and disposition;

(f) cooperate with PPD and GSK or its Affiliates in their efforts to monitor the Clinical Trial at the Institution premises;

(g) use the data obtained from the Clinical Trial Subjects only for the purposes and in connection with the Clinical Trial and as outlined in the Protocol; and

4.2 *Principal Investigator Obligations*

Principal Investigator shall:

(a) be responsible for overseeing all medical aspects of the Clinical Trial;

(b) ensure that the Clinical Trial activities are performed in accordance with the Protocol, the guidelines provided by the correspondent IRB, the terms of this Agreement and any other local applicable legislation to the performance of clinical trials in human subjects;

(c) oversee the submission of IRB and Ethical Approval;

(d) oversee the enrolment of patients at the Institution, in accordance with the inclusion/exclusion criteria defined in the Protocol;

(e) inform all individuals to be enrolled in the Clinical Trial before they agree to participate in the Clinical Trial about the purpose(s), methods and conditions of conducting the Clinical Trial, its expected therapeutic benefit and Clinical Trial-related risk;

(f) oversee and review all eCRFs for accuracy and completeness and to provide these forms and any other Clinical Trial data or samples to PPD in accordance with Clause 2.6 and in the format and manner agreed upon by the Parties and in an anonymised form;

(g) obtain an Informed Consent from each Subject recruited for the Clinical Trial (or if permitted, their legal representative), in accordance with this Agreement, applicable local laws and regulations. The form of such Informed Consent must be the most current form approved by the IRB, GSK and PPD, and must contain language necessary to permit regulatory agencies, the IRB, GSK and its Affiliates and PPD to have full access to and use of personally identifiable information, including patient health information, as defined in applicable privacy laws, rules and regulations and according to internationally recognized standards and data protection principles;

(h) not allow a Clinical Trial Subject to be enrolled simultaneously in this Clinical Trial and another clinical trial without PPD and GSK prior written approval;

(i) ensure that all Clinical Trial data, Clinical Trial records and eCRFs, including any documents which identify and link each Clinical Trial Subject to their eCRF, are stored securely, such that they are accessible only with the knowledge of the Institution and the Principal Investigator;

(j) promptly report (in writing) any serious or unexpected adverse events to the GSK, PPD and the IRB; in accordance with Clause 11 below and following the procedures set forth in the Protocol;

(k) notify GSK, PPD, and the IRB (if applicable), in writing, of any deviations from the Protocol;

(l) engage with GSK in the collaboration of the final report of the Clinical Trial, granting approval thereto upon signing it;

(m) report on the progress of the Clinical Trial to the IRB (as appropriate);

(n) perform the Services in accordance with the highest professional standards of skill, care and diligence and in compliance with all Applicable Laws and regulations;

(o) notify PPD of any provisions in its local law, or of any changes in that law, which do or could affect the Principal Investigator's ability to conduct the Clinical Trial or to perform his/her duties as defined in this Agreement;

(p) provide PPD with the complete results of the tests and all of the data obtained during the Clinical Trial;

(q) submit all data and other information related to the Clinical Trial in a timely manner;

(r) cooperate with PPD, GSK and its Affiliates and regulatory authorities in all their efforts to monitor the Clinical Trial and conduct audits and inspections;

(s) within twenty-four (24) hours of first knowledge of any SAE (as that term is defined at Clause 11.1 below), notify PPD, and the IRB, in writing, of any unanticipated or serious adverse reactions to the Clinical Trial Product and follow the procedures set forth in the Protocol and Clause 11;

(t) if he/she is not able to continue as Principal Investigator by reason of retirement, transfer or similar reasons, he/she shall provide written notice to PPD as soon as possible and at least within three (3) weeks of such departure; and

(u) inform the patients involved in the Clinical Trial that all their personal data collected through the Informed Consent form and other means will be kept in a file whose ownership correspond solely to GSK. Principal Investigator shall collect and process all personal data in accordance with applicable local regulation on personal data on behalf of GSK and only throughout the duration of the agreement signed with GSK and only for the purposes established in the said agreement.

*4.3 PPD Obligations*

PPD shall:

(a) be responsible for obtaining regulatory approval for the Clinical Trial and register a trial on Clinical Trials Registry – India (CTRI) National Institute of Medical Statistics.

(b) be responsible for the submission to the IRB and any competent regulatory authority;

(c) be responsible for the monitoring of the Clinical Trial;

(d) provide to the Institution the Protocol, Informed Consent forms and access to eCRFs; and

(e) inform the Institution and the Principal Investigator of chemical/pharmaceutical, toxicological, pharmacological and clinical data and results to justify the design and duration of the Clinical Trial.

4.4 SMO Obligations

SMO shall

(a) act as a payee in this Agreement for payments payable to Institution/Principal Investigator

## 5. Funding of the Clinical Trial and Payments

5.1 As consideration for the performance under the terms and conditions of this Agreement, PPD will pay the Institution via SMO in accordance with **Exhibit A**. Institution will not be compensated for any Subjects who were enrolled without a properly executed informed consent form or who do not meet the inclusion/exclusion criteria for the Clinical Trial. The Institution shall be responsible for compensating all other entities and individuals who were involved in the conduct of the Clinical Trial, including (without limitation) the Principal Investigator and the Clinical Trial Staff.

5.2 Payments under this Agreement are pass-through payments from GSK. PPD shall make payment to the Institution via SMO, in accordance with **Exhibit A**.

5.3 Payments are dependent upon the reports and other information pursuant to Clauses 4.1 and 4.2 being submitted in a timely and satisfactory manner. Payment for partially completed Services, e.g, early withdrawal of Subject, shall be made on a pro-rata basis for Services performed according to **Exhibit A**. No payment will be due or paid for Services performed that are deemed violations of or deviations from the Protocol or this Agreement.

5.4 Invoices are payable within sixty (60) days following receipt of a valid invoice, as described in the payment terms of **Exhibit A**.

5.5 Payments for Services rendered under this Agreement shall be made in full in accordance with the Agreement, without deductions for taxes of any kind. Any taxes due and payable as a result of the payments by PPD to the Institution shall be Institution's sole responsibility and Institution shall pay all such taxes for which it is liable in a timely manner.

5.6 PPD will reimburse the Institution for travel costs incurred by Subjects in accordance with **Exhibit A**.

5.7 The Institution acknowledges and agrees that it shall be solely responsible for paying the appropriate amount of all local taxes/GST with respect to all fees and compensation paid pursuant to this Agreement.

5.8 SMO, Institution and Principal Investigator agree that GSK or its Affiliates may make public the amount of funding provided to the Institution by PPD for the conduct of the Clinical Trial and may identify the SMO,Institution and the Principal Investigator as part of this disclosure. Institution has obtained the Principal Investigator's consent to this disclosure.

5.9 Statement of Investigator Financial Interest form

The Principal Investigator hereby acknowledges the requirements of the FDA Financial Disclosure Rule and agrees to fill in and return to PPD, upon PPD or PPD representative's request, the Statement of Investigator Financial Interest form before the start of the Clinical Trial. The Principal Investigator also consents to the disclosure of the so filled Form to the FDA if necessary.

5.10 Institution and Principal Investigator shall not charge any Subject or third-party payor for Clinical Trial procedures required by the Protocol that are paid for by PPD or GSK under this Agreement or for any Clinical Trial Product that is provided or paid for by PPD or GSK under this Agreement.

5.11 All of PPD's payment obligations are conditioned upon Institution reporting to PPD and/or GSK all data required by the Protocol and other governing documents for the Clinical Trial, including all adverse events, and upon Institution's compliance with standards identified in this Agreement.

5.12 The amounts paid under this agreement are bona fide fair market value compensation for the work conducted under this Agreement. The Parties agree that no payments by PPD pursuant to this agreement shall be passed in whole or in part, directly or indirectly, to any third party as a rebate or discount for the purchase of GSK products. Notwithstanding the foregoing, commercially reasonable payments to a subcontractor who is performing Services under the terms of this Agreement that meet the criteria for bona fide Services are not considered to be a pass-through rebate or discount payments (even if the subcontractor is a GSK customer).

## 6. Clinical Trial Subject

6.1 Informed Consent of each of the Subjects participating in the Clinical Trial shall be obtained in accordance with applicable local laws and regulations in India, including completion of the approved Informed Consent form, which has been approved by the IRB. The Institution/Principal Investigator shall administer the Clinical Trial Product only to Subjects from whom Informed Consent has been properly obtained by the Principal Investigator under Clause 4.2(g) and this Clause 6. The Institution/Principal Investigator shall maintain adequate documentation of its obtainment of the Informed Consent of each Subject.

6.2 PPD, the Institution and the Principal Investigator shall hold in confidence the identity of the Subjects and shall comply with all Applicable Laws regarding the confidentiality of their identities and their individual medical records.

6.3 The method of explanation to the patient and the obtaining of consent should be conducted in accordance with the directions of the IRB and is a Principal Investigator responsibility. Each Subject shall be provided with their own copy of the patient information sheet (hard copy or electronic copy) which they can retain for their own records.

6.4 Data Rights of Subjects

(a) The parties agree that, as between them, Institution is best able to manage requests from Subjects for access, amendment, transfer, blocking, or deletion of Personal Information. In the event GSK receives a request from a Subject for such access, amendment, transfer, blocking, or deletion, GSK shall forward the request to Institution.

(b) Institution shall respond to Subjects' requests for access, amendment, transfer, blocking, or deletion of Personal Information in accordance with Applicable Laws and the Agreement. Institution acknowledges that in order to maintain the integrity of Clinical Trial results, the ability to amend, block, or delete Personal Information may be limited, under Applicable Laws.

(c) GSK acknowledges that Subjects may withdraw their informed consent to Clinical Trial participation and consent to Processing of Personal Information at any time as described in the Informed Consent Form signed by the Subject. Institution shall promptly notify GSK of any such withdrawal that may affect the use of the Personal Information under the Agreement. Institution will use its best efforts to clarify what the Subject's expectations are if the Subject withdraws from the Clinical Trial, including what forms of communication the Institution may use to follow-up with the Subject, if any, about their Subject's status after withdrawing from the Clinical Trial.

(d) The obligations of this Section 6.4 shall survive termination of this Agreement.

## 7. Clinical Trial Results and Intellectual Property

7.1 The Parties are in agreement that all of the Materials and data gained through the conduct of the Services shall be the property of GSK.

7.2 GSK shall exclusively own all rights, title ("**Rights**") in and to any invention, and interest in and to inventions (in any clinical specimens or samples obtained from the Subject), discoveries, know-how, patents (whether patentable or not), copyright, trade secrets and other intellectual rights, including but not limited to inventions, discoveries and technology relating to the Clinical Trial Product or otherwise generated by the Clinical Trial (collectively, "**Inventions**"). The Institution and Principal Investigator hereby irrevocably transfer and assign any and all their Rights in any Invention to GSK. The Inventions will be the sole property of GSK.

7.3 The Institution and Principal Investigator agree to: (i) immediately notify in writing to PPD of any Invention, and (ii) to cooperate and assist GSK to apply for and to execute applications, assignments, affidavits, or other documents, reasonably necessary to obtain any patent, copyright, trademark or other statutory protection for the Inventions, as GSK deems appropriate, and (iii) to treat all Inventions as confidential information in accordance with Clause 8.

7.4 Neither the Institution nor the Principal Investigator shall acquire any rights of any kind with respect to the Inventions or to the Clinical Trial Product.

7.5 The obligations of this Clause shall survive after the term or termination of this Agreement.

## 8. Confidential Information

8.1 Institution/Principal Investigator and their employees and agents and third parties involved in the Clinical Trial by the Principal Investigator and/or Institution shall not disclose to any third party or use for any purposes other than for the performance of the Clinical Trial any data, records or other information (hereinafter, collectively "**Information**") disclosed to Institution/Principal Investigator by GSK or PPD or generated as a result of this Clinical Trial without the prior written consent of GSK and shall sign a written non-disclosure agreement. Such Information shall remain the confidential and proprietary property of GSK and shall be disclosed only to Institution/Principal Investigator and their employees or agents who have a "need to know". The obligation of nondisclosure shall not apply to the following Information:

(a) that is generally known to the public or that becomes publicly available through no act or omission on the part of Institution/Principal Investigator;

(b) that is disclosed to Institution/Principal Investigator by a third party legally entitled to disclose such information;

(c) which the Institution/Principal Investigator, as applicable, can demonstrate that it possessed prior to, or developed independently from, disclosure or development of this Agreement;

(d) that is required by law to a government authority or by order of a court of competent jurisdiction, provided that (i) such disclosure is subject to all applicable governmental or judicial protection available for like material; (ii) reasonable advance notice is given to GSK; and (iii) all reasonable steps to limit the scope of such disclosure have been taken.

8.2 The obligations of this Clause shall survive after the term or termination of this Agreement.

## 9. Publications

9.1 GSK will post a Clinical Trial Protocol summary on a publicly available protocol register prior to the enrollment of Subjects.

9.2 GSK will post a Clinical Trial results summary on a publicly available results register no later than twelve (12) months following completion of the Clinical Trial at all Clinical Trial sites as defined in the Clinical Trial Protocol. Posting of summary Clinical Trial results may occur prior to publication of Clinical Trial results in the peer-reviewed literature. GSK will also post full Clinical Trial Protocol and statistical analysis plan at the time of results summary posting.

9.3 GSK will seek to publish the Clinical Trial results in the searchable, peer reviewed scientific literature. First publication and all subsequent publications of the Clinical Trial results from all Clinical Trial sites ("**GSK Publication(s)**") or disclosure(s) of the Clinical Trial results shall be coordinated by GSK.

9.4 Any participation of Principal Investigator or other representatives of Institution as a named author of this GSK Publication will be determined in accordance with the International Committee of Medical Journal Editors ("**ICMJE**") Uniform Requirements for Manuscripts

(or if more stringent, the authorship criteria of the specific journal). Institution and Principal Investigator acknowledge that the enrolment of Subjects alone is not a qualification for authorship. If the Principal Investigator or other representative of Institution is a named author of the GSK Publication, as an author (s)he: (1) will enter into a written author agreement prior to the beginning of the work on the GSK Publication; (2) will have access to the Clinical Trial data from all Clinical Trial sites as necessary to fully participate in the development of the GSK Publication; and (3) will disclose as part of the GSK Publication that GSK financially supported the Clinical Trial and the GSK Publication, and will disclose any personal financial relationship with GSK. GSK will not compensate authors for authorship activities.

9.5 If considered appropriate by GSK, the Principal Investigator or other Institution personnel involved with the Clinical Trial may participate in the Publication Steering Committee ("**PSC**") or core writing team(s) for the Clinical Trial or in public presentations of the Clinical Trial results. Persons participating as a member of a PSC, in core writing team(s)' activities or in public presentation of the Clinical Trial results will not receive any payment, honorarium or other fee for participation in such activities nor ownership to nor other title or interest in work product arising out of such activities. However, GSK will reimburse such persons or the Institution (as the case may be and as advised by such persons) for their reasonable travelling and lodging expenses while travelling at GSK's request, provided that travel and lodging expenses have been authorized by GSK in writing in advance and that GSK receives proper original receipts.

9.6 Institution and Principal Investigator agree that GSK may make public the names of the Principal Investigator and the Institution as part of a list of investigators and institutions conducting the Clinical Trial when making either Protocol or results summary register postings. Institution and Principal Investigator agree that GSK may make public the amount of funding provided to Institution by GSK for the conduct of the Clinical Trial and may identify Institution and Principal Investigator as part of this disclosure. Principal Investigator agrees that when (s)he speaks publicly or publishes any article or letter about a matter related to the Clinical Trial or Clinical Trial Product or that otherwise relates to GSK, Principal Investigator will disclose that he/she was an investigator for the Clinical Trial.

9.7 Once the Clinical Trial is published in a scientific journal, GSK may list the Clinical Trial on an external website for patient-level data sharing for further research and may also make available the full Clinical Trial report on the GSK register.

9.8 Institution, consistent with scientific standards and in a scientific forum, may publish or present the Clinical Trial results from site's Clinical Trial data (an "**Institution Publication**"), provided that the Institution Publication does not also disclose any GSK Confidential Information other than the Clinical Trial results from Institution's Clinical Trial data. Institution shall submit to GSK for review and comment any proposed Institution Publication at least thirty (30) days prior to submitting the Institution Publication to any third party. If GSK requests a delay in order to file patent applications relating to new investigational product, Institution agrees to delay submitting the Institution Publication to any third party for up to one hundred twenty (120) days after GSK's request. Institution also agrees that any Institutional Publication shall only be made after the GSK Publication, and consistent with any limitations and restrictions that may apply, provided that the GSK Publication is submitted within eighteen (18) months after last subject last visit at all sites as defined in the Clinical Trial Protocol. The Institution Publication will reference the GSK Publication(s). Institution agrees that GSK's financial support of the Clinical Trial will be disclosed in any Institution Publication. Institution shall ensure that Principal Investigator complies with the obligations identified in this subsection.

9.9 Subjects' personal Information, such as name or initials, shall not be publicly disclosed at any time.

9.10 The obligations of this Section shall survive termination of this Agreement.

## 10. Data Protection and Security

10.1 Institution and Principal Investigator shall comply and shall require any of the persons or entities performing the Services on their behalf to comply, with all Applicable Laws, rules, regulations, and guidelines governing the privacy of personally identifiable information and patient health information in India.

10.2 PPD guarantees that the Protocol establishes the mechanisms that allow the disassociation of data with a personal nature of the Subjects participating in the Clinical Trial.

10.3 Institution assures PPD and GSK that the Principal Investigator shall inform the Subjects involved in the Clinical Trial that all their personal data collected through the Informed Consent form and other means will be kept in a file which is owned by GSK. All personal data collected shall be treated with the privacy, confidentiality and safety measures established by the relevant applicable regulation.

10.4 All parties shall comply with all Applicable Laws, including without limitation all Applicable Laws relating to the privacy and security of Personal Information and shall implement appropriate technical and organizational measures in such a manner that Processing will meet the requirements of the General Data Protection Regulation ("**GDPR**") and ensure the protection of the rights of the data subject.

10.5 With respect to the coded Clinical Trial data provided to GSK, the Institution and GSK are both considered data controllers for the Processing of the Personal Information and will both act in accordance with the Applicable Data Protection Law.

10.6 Before Processing any Personal Information each party shall ensure, taking into account industry good practice, the costs of implementation and the nature, scope, context and purpose of Processing, as well as the risk of varying likelihood and severity for the rights and freedoms of natural persons, that appropriate technical and organizational controls are in place to prevent unauthorized or unlawful Processing of any Personal Information it may hold and to protect any such Personal Information from accidental loss, damage or destruction.

10.7 Security Breaches

(a) Notification of Security Breaches. The parties agree to notify each other without undue delay after of discovery of a Security Breach.

i. Notice of a Security Breach to GSK, will be sent via e-mail to **csir@gsk.com**
ii. Notice of a Security Breach to Institution will be sent to **mgmmca@themgmgroup.com**

(b) In the course of notification to each other, the parties will provide, as feasible, sufficient information for the parties to jointly assess the Security Breach and make any required notification to any government authority within the timeline required by Applicable Data Protection Laws. Such information may include, but is not necessarily limited to:

i. The nature of the Security Breach the categories and approximate number of data subjects and records;
ii. The likely consequences of the Security Breach, in so far as consequences are able to be determined; and

iii. Any measures taken to address or mitigate the incident.

(c) The parties will jointly decide on the basis of all available information and Applicable Laws if the Security Breach will be considered a reportable Security Breach and arrange for notification to data subjects and/or government authorities if required by Applicable Laws. Where the parties decide that notification is required by Applicable Data Protection Laws, the party that incurred the Security Breach shall be responsible for providing such notification.

(d) Assistance in Event of Security Breach. In the event of a Security Breach relating to the Personal Information and/or GSK Confidential Information collected or received by a party under this Agreement, the receiving party agrees to assist and fully cooperate with the sending party with any internal investigation or external investigation by third parties, such as law enforcement, through the provision of information, employees, interviews, materials, databases, or any and all other items required to fully investigate and resolve any such incidents and provide information necessary to provide required notifications. The breached party agrees to take such remedial actions as the parties mutually agree is warranted.

(e) Neither party shall disclose, without the other party's prior written approval, any information related to the suspected Security Breach to any third party other than a vendor hired to investigate/mitigate such Security Breach and bound by confidentiality obligations, except as required by Applicable Laws.

(f) Institution agrees to indemnify GSK, for all losses resulting from any Security Breach due to negligence or wilful misconduct by Institution, its agents, its Affiliates, or any vendor retained by Institution, including but not limited to legal damages, government penalties, and/or mitigation expenses.

## 11. Adverse Events Reporting

11.1 For the purposes of this Agreement an Adverse Event ("**AE**") shall mean any untoward medical occurrence whether thought to have been caused by the Materials or the Clinical Trial or not and Serious Adverse Event ("**SAE**") shall mean any adverse event which is fatal, life threatening, disabling or incapacitating, requires in-patient treatment or prolongs existing hospitalization, is a congenital anomaly in the off-spring of the patient or which may require intervention to prevent the previously stated outcomes.

11.2 Any SAE must be reported as defined in the Protocol within twenty-four (24) hours of first knowledge of any SAE and using the eCRF. This applies also for any event that could affect the safety of the Clinical Trial participants or the conduct of the Clinical Trial.

11.3 The Institution is responsible for ensuring that the Principal Investigator notifies GSK, the Institution and the Responsible Ethics Committee of any Adverse Events (including Serious Adverse Events) that occur during the course of the Clinical Trial in accordance with the Protocol, and relevant ethical and regulatory guidelines, and in the case of the Institution and the Responsible Ethics Committee with their policies and procedures.

11.4 Nothing in this Agreement shall remove or restrict any obligation on Institution and/or Principal Investigator to report clinical safety information arising during the Clinical Trial to the regulatory authorities in India, in accordance with the local requirements or comply with any other legal or administrative obligation in connection with the Clinical Trial.

11.5 The Institution shall monitor the Subjects in accordance with the Protocol. The Institution shall require the Principal Investigator to promptly (within twenty-four (24) hours of the occurrence of any SAE) report via the electronic eCRF all SAEs that may be associated with the administration of the Clinical Trial Product that occurs during the course of the Clinical

Trial. Failure to comply with this Clause shall constitute reasonable grounds for PPD to terminate this Agreement as provided in Clause 16.

11.6 GSK maintains its own Investigator Brochure(s) ("**IB(s)**") for the Clinical Trial Product(s) being investigated under the Clinical Trial, so GSK will provide these IB(s), and any updates and/or supplements to these IB(s), to the Institution during the course of the Clinical Trial for information purposes.

11.7 GSK agrees to reimburse the Institution/Principal Investigator for reasonable and necessary medical expenses incurred as a direct result of diagnosing and treating of an SAE related to the Clinical Trial Product and Clinical Trial related procedure and incurred during the course of the Clinical Trial, provided that the Clinical Trial Product was administered in accordance with the Protocol and the SAE did not occur as a direct result of the Institution or Principal Investigator's negligence or misconduct. The Institution/Principal Investigator agrees to treat any such illness or injury. Payments will be made following an invoice per treatment and confirmation by GSK or PPD that the treatment has been performed as a result of such SAE. Institution or Principal Investigator will provide all information reasonably requested by GSK or PPD to confirm such treatment.

11.8 Without prejudice to the foregoing if injury is suffered by a Subject while participating in the Clinical Trial, the GSK agrees to operate in good faith in accordance with the guidelines entitled "GlaxoSmithKline's – Clinical Trial Compensation Guidelines" (refer **Exhibit C**) and New Drugs and clinical trials rules, 2019, and the Principal Investigator shall make clear to the Subjects that the Clinical Trial is being conducted subject to these Guidelines.

## 12. Recordkeeping and Audits

12.1 The Institution and Principal Investigator shall keep complete and systematic data related to the Clinical Trial and the Services performed and any other records generated as a part of this Agreement for a minimum period of twenty-five (25) years from the issue date of the Clinical Trial report/summary or equivalent. GSK will inform the Principal Investigator of the date on which the GSK required retention period will expire.

12.2 Upon the expiration of the above time period, Institution is responsible for complying with any remaining relevant local, organizational, state, national and/or regulatory guidelines for records retention. If, at any time during the retention period, Investigator and/or Institution are unable to comply with the record retention responsibilities in this Section (e.g., Principal Investigator retirement; Principal Investigator is no longer employed by or associated with Institution; or, Institution site closure), Principal Investigator or Institution shall transfer responsibility for record retention to another party at the Institution or to a third party off-site archive facility. Principal Investigator or Institution must provide written notice to PPD and/or GSK prior to such transfer which specifies the name and address of the new responsible party and, if applicable, the new file location address.

12.3 During the Institution's regular business hours and with reasonable advance notice, PPD, GSK or its Affiliates or their designee may audit the Institution's records, facilities, equipment, or procedures related to Institution's obligations under this Agreement. Such audits may include, without limitation, Institution's records related to the Clinical Trial and the performance of the Services, in order to verify Institution's compliance.

12.4 If any governmental or regulatory authority notifies the Institution/Principal Investigator that it will inspect Institution's records, facilities, equipment, or procedures, or otherwise take action related to the Clinical Trial and/or the Services under this Agreement, Institution/Principal Investigator shall co-operate with the authority and notify PPD and GSK as soon as is practicable (to the extent possible, within two (2) business days and prior to the inspection or action), allow

the authority to conduct an inspection or take other legal action, allow PPD and GSK to be present at the inspection or participate in any response to the action, and provide PPD with copies of any reports issued by the authority and Institution's proposed response for GSK's prior review and approval (such approval not to be unreasonably withheld).

## 13. Insurance

13.1 PPD declares that an insurance policy to cover the conduct of the Clinical Trial, in pursuance of current national laws, is in place. Said policy shall be maintained and updated throughout the duration of the Clinical Trial.

13.2 The insurance of the GSK does not relieve the Investigator, Institution and/or their agents participating in the Clinical Trial from their obligation to be liable and responsible to GSK and PPD for their own negligence and wilful misconduct, or their failure to adhere to the terms of the Protocol or any laws or regulation applicable to the Clinical Trial. The Principal Investigator and Institution each represent and warrant that they possess, through insurance or otherwise sufficient financial resources to meet their obligations under this Agreement. The Institution shall provide evidence of its insurance upon request by PPD.

## 14. Representations and Warranties

14.1 Institution and Principal Investigator represent and warrant to the best of their knowledge, that the Institution and the Principal Investigator are not bound by any other agreement which could prevent, or be violated by, or under which there would be a default as a result of, the execution and performance of this Agreement, and that each will not enter into any such conflicting agreements during the term of this Agreement.

14.2 Institution represents and warrants that all persons involved in the Clinical Trial and the Principal Investigator (i) have not been debarred or convicted of a crime which could lead to debarment under any applicable law, rule or regulation; (ii) have not been disqualified as a testing facility under applicable local regulation; or (iii) are not disqualified as a clinical investigator under applicable local regulation. If such persons later become debarred or receive notice of any action or threat of action with respect to debarment and Institution/Principal Investigator gain knowledge thereof, PPD will immediately be notified.

14.3 Institution shall indemnify GSK and PPD against all direct losses, damages, liabilities and expenses (including legal expenses) incurred by PPD and/or GSK as a result of any breach of the warranties contained in this Clause.

14.4 Principal Investigator hereby warrants that he is authorized to perform the Services at the Institution premises under his/her own name and that the performance of the correspondent agreement and the acceptance of any payments is not in violation of legal or internal regulations of the Institution or other entity to which Principal Investigator is associated or any agreement to which Principal Investigator is bound. Likewise, Principal Investigator further warrants that he/she has obtained all required consents from and/ or filed all required notifications to/from the Institution board or other regulatory or self-regulatory authority, board or committee.

## 15. Limitation of Liability and Indemnification

15.1 Institution and Principal Investigator shall indemnify, defend and hold harmless PPD and GSK and its Affiliates from any and all losses, injuries, harm, costs or expenses, including without limitation, reasonable attorney's fees, incurred by PPD or GSK or its Affiliates as a result of the negligence or wilful misconduct of Institution and/or Principal Investigator**.**

15.2 A Party shall give written notice to the other Parties as soon as is practicable of the details of any claim or proceedings brought or threatened against it by a third party in respect of which a claim will or may be made under Clause 15.1 above.

15.3 Upon request by Institution and/or Principal Investigator, indemnification of Institution and Principal Investigator by GSK shall be governed by a separate letter agreement between GSK, Institution and Principal Investigator.

15.4 Nothing in this Clause 15 or otherwise in this Agreement shall exclude or in any way limit Institution' liability for (i) fraud, (ii) death or personal injury caused by its negligence; and (iii) any liability to the extent the same may not be excluded or limited as a matter of law.

15.5 No Party shall be liable to the other Parties for any punitive, exemplary damages or for an indirect or consequential loss or damage resulting from any breach of this Agreement even if the other Parties have been advised of the possibility of such damages.

15.6 Each Party's agreement to indemnify and hold the other Party or Parties harmless is conditional on the indemnified Party (i) providing written notice to the indemnifying Party of any claim, demand or action arising out of the indemnified activities within ten (10) days after the indemnified Party has knowledge of such claim, demand or action, (ii) permitting the indemnifying Party to assume full responsibility to investigate, prepare for and defend against any such claim or demand, (iii) assisting the indemnifying Party, at the indemnifying Party's reasonable expense, in the investigation of, preparation for and defence of any such claim or demand, and (iv) not compromising or settling such claim or demand without the indemnifying Party's written consent.

15.7 The obligations of this Clause shall survive termination of this Agreement.

## 16. Termination

16.1 PPD may terminate this Agreement at any time, without cause, by giving thirty (30) days written notice to the Institution and Principal Investigator if any of the following conditions occur:

(a) the authorization and approval to perform the Clinical Trial in India is withdrawn by the IRB or any other competent authority;

(b) if PPD's agreement with GSK is terminated;

(c) if available data indicate that it is not safe to continue to administer the Clinical Trial Product to Subjects;

(d) if overall Clinical Trial enrolment has not been met, even if the enrolment at the Institution has not been completed;

(e) the Principal Investigator is unable to continue, and an acceptable successor is not agreed upon;

(f) adherence to the Protocol is poor, or Clinical Trial data recording is chronically inaccurate or incomplete;

(g) the Clinical Trial is terminated;

(h) material breach of this Agreement; or

(i) by mutual agreement of the Parties.

16.2 In the event this Agreement is terminated for any reason prior to the end of the Clinical Trial, the Institution shall take all reasonable steps required by PPD, including communicating with the Subjects, to facilitate completion of the Clinical Trial at an alternative clinical site designated by PPD. In such event, PPD will (except where the termination was as a result of the breach by the Institution of its obligation under this Agreement) reimburse the Institution for its reasonable direct costs incurred in connection with such transfer, as well as for reasonable non-reimbursed costs incurred and non-cancellable commitments made prior to the receipt by the Institution that the Agreement will be terminated.

16.3 Termination of this Agreement by any Party shall not affect the rights and obligations of the Parties that have accrued prior to the effective date of the termination.

## 17. Effect of Termination

17.1 In the event of termination, the sum payable under this Agreement shall be limited to prorated fees based on actual Services performed pursuant to the Protocol as determined in accordance with **Exhibit A**.

17.2 Upon completion of the Clinical Trial or earlier termination thereof, Institution and/or Principal Investigator shall ensure that all data, information, reports and Clinical Trial results are properly recorded in eCRFs and submitted to PPD, and shall return to PPD all Information.

17.3 Upon completion of the Clinical Trial or early termination thereof, all unused Clinical Trial Product, and/or Materials furnished to Institution and/or Principal Investigator by or on behalf of GSK or PPD shall be returned to PPD or GSK, as described in Clause 3.

17.4 Immediately upon receipt of a notice of termination, Institution and Principal Investigator shall cease entering Subjects into the Clinical Trial, cease conducting procedures to the extent medically permissible on Subjects already entered into the Protocol, and refrain from incurring additional costs and expenses to the extent possible

17.5 All provisions of this Agreement that by their nature would be expected to survive termination of this Agreement shall survive such termination, including - but not limited to – Clauses 1, 2, 3, 4, 5, 7, 8, 9, 10, 11, 12, 14, 15, 16, 17, 18, 19 and 20.

## 18. Compliance with Laws and Human Rights

18.1 Each Party shall perform its obligations under this Agreement in a manner that complies with all applicable international, national and local laws in relation to, or otherwise relevant to, its obligations under this Agreement and shall promptly notify the other Parties if it receives a written allegation of non-compliance with any such law by any person which relates to its performance of such obligations.

18.2 Institution and the Principal Investigator (the "**Site**") agree to the terms of **Exhibit B**.

18.3 Each Party expressly agrees that this Agreement is the result of arms-length negotiations, and that neither Party has entered into this Agreement with a corrupt motive to obtain or retain business or to secure an unfair business advantage.

18.4 Each Party hereby warrants and undertake that they shall at all material times keep and maintain accurate and up to date accounting records to ensure that all transactions relating to this Agreement are sufficiently documented.

18.5 Respectful of its employees right to freedom of association, Institution represents and warrants, to the best of its knowledge, that in connection with this Agreement, it respects the human rights of its staff and does not employ child labor, forced labor, unsafe working conditions, discrimination of protected characteristic or cruel or abusive disciplinary practices in the workplace; and that it pays each employee at least the minimum wage, provides each employee with all legally mandated benefits, and complies with the Applicable Laws on working hours and employment rights in the countries in which it operates. Institution shall be respectful of its employee's right to freedom of association, and Institution shall encourage compliance with these standards by any supplier of goods or services that it uses in performing its obligations under this Agreement.

## 19. Applicable law and competent jurisdiction

19.1 This Agreement shall be governed by and interpreted in accordance with the laws of India.

19.2 The Parties, expressly waiving any other jurisdiction to which they might be entitled, agree to submit any disputes arising out or in connection with this Agreement (whether of a contractual or non-contractual nature) to the Courts of India.

## 20. Miscellaneous

20.1 Independent Contractor

The Institution, including its agents and employees, shall be an independent contractor at all times, and shall not be an agent of PPD or GSK and shall have no actual, apparent or implied authority to bind PPD or GSK in any manner or to any obligation whatsoever. The Principal Investigator shall not be or be deemed to be an employee of PPD or GSK and shall not be entitled to any benefits available to employees of PPD or GSK.

20.2 Assignment

Institution shall not assign this Agreement in whole or in part to any other Party and shall not appoint any other person as Principal Investigator without PPD's written consent. PPD may assign this Agreement in whole or in part, including to any corporate parent, affiliate or subsidiary of PPD, without the Principal Investigator's/Institution's consent.

This Agreement shall be binding upon the Parties, their legal representatives, successors and permitted assigns. Institution and Principal Investigator acknowledge and agree that GSK and each of its Affiliates is a third party beneficiary to this Agreement and shall be entitled to enforce all of the rights and benefits of this Agreement at all times as if it were a party to this Agreement.

20.3 Use of Name

No Party shall make (or have made on its behalf) any oral or written release of any statement, information, advertisement or publicity in connection with this Agreement which uses the other Parties names, symbols, or trademarks without the other Parties prior written approval.

20.4 Notices

(a) All notices under this Agreement shall be sent by registered or certified mail, postage prepaid, or by overnight courier service. Notices may be sent by facsimile or e-mail, if confirmed by also sending as described above.

(b) Notices pertaining to this Agreement shall be sent to:

**If to Institution:**
Attn.:**Dr. Rajendra Bohra**
Title: The Dean
Mahatma Gandhi Mission's Medical College & Hospital
N-6,Cidco,
Aurangabad,431003,Maharashtra,
India
Tel.:0240-2481437,0240-2482235
Fax: 0240-2482235
E-mail address:
mgmmca@themgmgroup.com

**If to PPD:**
Attn.: Rashmi Chitgupi
Title: Associate Director, Clinical Management
**PPD Pharmaceutical Development India Private Limited**
101, A-Wing, Fulcrum, Hiranandani Business Park, Sahar Road, Andheri (East), Mumbai-400099, Maharashtra, India
Tel.: +91 22 4247 2900
Fax: +91 22 4248 6900
E-mail address: Rashmi.Chitgupi@ppdi.com

**If to the Principal Investigator:**
Attn.: **Dr Syed Umar Quadri**
Mahatma Gandhi Mission's Medical College & Hospital
N-6,Cidco,
Aurangabad,431003,Maharashtra,
India
Tel.: 9923798702
Fax: 0240-2482235
E-mail address:
umarazmed@gmail.com

**If to the SMO**:
Attn.: Mr. Maruti Patil
Doclin Clinical Research Services
445,Maruti Galli,Main Road, Hangrage Mandoli Belagavi-590008 Karnataka
Tel.: 9591358733
E-mail :maruti.patil171@gmail.com

20.5 Severability

If any provision(s) of this Agreement should be illegal or unenforceable in any respect, the legality and enforceability of the remaining provisions of this Agreement shall not in any way be affected.

20.6 Waiver; Modification of Agreement

No waiver, amendment, or modification of any of the terms of this Agreement shall be valid unless in writing and signed by authorized representatives of all Parties. Failure by any Party to enforce any rights under this Agreement shall not be construed as a waiver of such rights nor shall a waiver by any Party in one or more instances be construed as constituting a continuing waiver or as a waiver in other instances.

20.7 Force Majeure

If any Party is delayed in performing an obligation under this Agreement by strike, lockout, or other labor troubles of a third party; by restrictive governmental or judicial order not directly related to this Agreement; or by riots, insurrection, war, inclement weather, or Acts of God; performance is excused for the period of such delay. The delayed Party shall promptly notify the other Parties in writing of the delaying event.

20.8 Entire Agreement

This Agreement and its exhibits constitute the entire agreement and understanding between the Parties with respect to the subject matter hereof and supersedes any prior agreement, understanding or arrangement between the Parties, whether oral or in writing. No representation, undertaking or promise shall be taken to have been given or be implied from

anything said or written in negotiations between the Parties prior to this Agreement except as expressly stated in this Agreement.

20.9 Miscellaneous

(a) For the purposes of this Agreement, "Affiliate" means any entity that controls, is controlled by, or is under common control with, a party to this Agreement. In this context, "control" shall mean (i) ownership by one entity, directly or indirectly, of at least forty percent (40%) of the voting stock of another entity; (ii) power of one entity to direct the management or policies of another entity, by contract or otherwise; or (iii) any other relationship between GSK or Institution and an entity which GSK and Institution have agreed in writing may be considered an "Affiliate" of GSK or Institution (as the case may be).

(b) PPD or GSK may provide supportive measures to strengthen the Institution's research capacity for the benefit of the community. PPD, GSK and the Institution agree that any of these measures that may be provided by PPD or GSK are not intended to be for the exclusive benefit of the Clinical Trial or of GSK studies generally, or to induce the Institution to participate in the Clinical Trial or to induce or reward any use, purchase, recommendation, or prescription of GSK products. GSK and the Institution also agree that any of these measures that may be provided by PPD or GSK are intended to be sustainable by the Institution and the local community following the Clinical Trial.

(c) GSK and/or PPD and the Institution have sought agreement with key interested external parties, including ethics committees, research investigators, national government, health ministry, local health authorities, ethics groups, non-governmental organisations, or representatives of the communities who might participate in the Clinical Trial, that it is appropriate to conduct the Clinical Trial at the Institution, including discussion of the standard of care to be provided during the Clinical Trial, the scientific rationale for interventions (including placebo), the provision of healthcare for subjects after the Clinical Trial, and the fate of any capacity built for the conduct of the Clinical Trial.

(d) The Institution agrees that any nationally-licensed medicinal products that are not the subject of the Clinical Trial but are required for the routine care of a Clinical Trial subject during and after the Clinical Trial for the disease or condition to which the Clinical Trial relates are expected to be available to the Clinical Trial Subject and funded through the usual operations of the local healthcare system independently from the Clinical Trial and without expectation of GSK support.

20.10 **Counterparts and Electronic Signatures.:** This Agreement and all associated amendments may be executed in counterparts, each of which shall be deemed an original and all of which together shall constitute one and the same instrument. Each party may execute this Agreement and all amendments by electronic signature (whatever form the electronic signature takes) or in Portable Document Format (or other file format) sent by electronic means. Signatures of authorized signatories of the parties completed by electronic signature or sent by electronic means in Portable Document Format shall have the same force and effect as manual signatures, shall be valid and binding, and, upon delivery, shall constitute due execution of this Agreement any amendments hereunder.

**IN WITNESS WHEREOF,** the Parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

**FOR INSTITUTION – Mahatma Gandhi Mission's Medical College & Hospital**

Name: Dr. Rajendra Bothra
Position: Dean
Date: 31 Jul 2020

DEAN
MGM'S MEDICAL COLLEGE
AURANGABAD

**FOR PPD - PPD Pharmaceutical Development India Private Limited**

Name:
Position:
Date:

**BY PRINCIPAL INVESTIGATOR**

Name: Dr. Sayed Umar Quadri
Position: Associate Professor
Date: 31st Jul 2020

Dr. SYED UMAR QUADRI
M.B.B.S. M.D. (MED.)
Asst. Prof. of Medicine
MGM Medical College & Hospital A'bad.
REG NO. 2005/02/0904

**BY SMO- Doclin Clinical Research Services**

Name: Mr. Maruti Patil
Position: Managing Director
Date: 27-Jul-2020

## EXHIBIT A

### BUDGET AND PAYMENT SCHEDULE

Payment by PPD shall be made payable to the payee and at the address indicated on the PAF form or other applicable form provided to PPD prior to the execution of this Agreement ("Payee") as follows:

| | |
|---|---|
| Payee Name: | Doclin Clinical Research Services |
| Payee Address: | 445, Maruti Galli, Main Road, Hangarge, Mandoli – Belagavi 590008<br>Karnataka India |
| Bank Information and Routing number as applicable: | Bank Name: Axis Bank,<br>Nehrunagar Belagavi-590010 Karnataka India<br>Account Number:919020049795418<br>IFSC Code- UTIB0001690<br>Swift Code: CHASUS33 |
| GST Number: | 29AZXPP8818R1ZP |

Institution may request to revise the payee details provided herein during the course of the Study. In such cases, the parties agree that no amendment to this Agreement shall be required provided that Institution provides written notification to PPD with the revised payee details and, if applicable, a revised PAF(Payment Authorization Form). The parties further agree that PPD assumes no liability for incorrect payee details provided by Institution.

**Cost per Subject**: The amount to be paid to the Payee per completed subject is outlined on the Exhibit A-1, less ten percent (10%) withholding. Payments will be made on a quarterlybasis in Indian Rupees and will be based on completed visits, verified as applicable in the subject electronic case report forms (eCRFs).

**Enrollment**: Institution shall apply best efforts for enrollment in accordance with the Study subject eligibility criteria specified in the Protocol for up to a maximum of thirty (30) Study subjects. With the express, written pre-approval of the Sponsor, the Institution may enroll beyond these thirty (30) randomized subjects into the study

**Study Start-Up Fee:** A one-time non-refundable Start-Up Payment at the rate set forth in Exhibit A-1, for Study Start-Up Activities, will be payable to SMO based on full execution of this document, proper completion and submission to GSK or GSK designated vendor of all regulatory documents as defined by the GSK Study team for the Study, including, but not limited to, and financial disclosure documents as well as IRB submission. The receipt of a correct and itemized invoice must be received prior to payment.

**Screen Failures:** The Payee will be paid for twenty (20) screen fails (as defined below) without pre-approval from Sponsor and may be paid up to a maximum of thirty (30) with express pre-approval from Sponsor. Payee will be reimbursed in accordance with the rates set forth for the Screening visit in the Budget, as verified in the CRF. For purposes of this Agreement, a Screen Failure shall mean any subject, who initially appears to meet the criteria for pre-screening, signs the informed consent form, completes the pre-screening and/or screening visit but does not randomize into the Study.

**IRB Fees:** Central IRB is defined as the IRB selected and paid by the Sponsor. Local IRB Fees will be submitted to PPD by the Institution and reimbursed by PPD directly to the Payee upon the receipt of correct and itemized invoices.

**Record Storage and Archiving:** A one-time record storage and archiving fee at the rate set forth in Exhibit A-1 will be paid to the SMO for purposes of compliance with this Agreement. SMO will be paid

this fee upon execution of this Agreement, confirmation of IRB meeting and approval, and completion of pre-Study requirements as specified by Sponsor or PPD/its designee.

**Pharmacy Start-Up Fees:** Payee will receive a one-time fee at the rate set forth in Exhibit A-1 to cover set-up of the pharmacy services on this Study. The pharmacy start-up fees will be payable upon PPD's receipt of a correct and itemized invoice from Payee.

**Unscheduled visits:** An "Unscheduled Visit" shall be defined as a Study subject visit which is not expressly set forth in the Protocol, but is otherwise required for the Study. Unscheduled Visits will be paid at the rates set forth in Exhibit A-1 upon PPD's receipt of correct and itemized invoices.

**Loaned Equipment:** Loaned Equipment described as follows:
eConsent logpads will be provided to sites by vendor, DrugDev (IQVIA) and must be returned to vendor at Institution close out.

**Invoices:** All correct and itemized invoices pertaining to this Study should be addressed to PPD and submitted quarterly for reimbursement to the following:

PPD Pharmaceutical Development India Private Limited, Office 101, A-Wing, Fulcrum, Hiranandani Business Park
Sahar Road, Andheri (East)
Mumbai-400099, Maharashtra
INDIA
GSKROWInvestigatorPayments@ppdi.com

All invoices must include the following:

- Institution Name and Address
- Protocol Number
- Investigator Name
- Invoice Date
- Invoice Number
- Clear description of items being invoiced, subject numbers, date of service, and if applicable supporting documentation (including but not limited to receipts, to and from addresses, invoices from vendors, etc.)
    - NOTE! DO NOT include any subject identifiers, other than subject numbers, in the invoice or back-up details. Subject names, initials, addresses, phone numbers, ages, and birthdates will need to be redacted on back-up details, receipts, and vendor forms to ensure patient privacy before sending to PPD
- Correct amount listed for each invoiced item
- Total amount being invoiced
- Payee information including name and address for sending payment (this should match the payment information listed in this Agreement)

All invoices for Study payments, as outlined in this budget and payment schedule, must be submitted to PPD within ninety (90) days of the Institution's Study close-out visit. Invoices received after this time will not be reimbursed.

**GST:** All fees payable by PPD will be exclusive of GST and similar indirect taxes as per the existing rules in India. PPD will pay the vendor on receipt of a legal tax invoice raised according to the terms of this agreement and the indirect tax / GST laws applicable in India

**Final Payment:** The final payment, which corresponds to the remaining ten percent (10%) of costs, shall be made upon completion of the close-out visit and upon receipt of (i) all completed and corrected case report forms and queries, of (ii) all Study documentation, of (iii) all unused Study drug

has been accounted for and (iv) all study equipment and supplies returned as specified by PPD and Sponsor. PPD must be notified of any discrepancies within ninety (90) days from receipt of final payment.
If at the completion of the Study, PPD has advanced sums under the terms of this Agreement that exceed the earned amount for all Study subject visits completed, Payee shall reimburse PPD within sixty (60) days any amount by which amounts advanced by PPD exceed the fees earned.

No other additional funding requests will be considered without the prior written consent of GSK.

# Exhibit A-1

**Budget Information**

**Total Cost per Patient:** 727,291.50

**Location:** India

**Institution:** MGM medical College and Hospital

**Overhead Percent:** 30.00%

**PI:** Dr.Syed Umar Quadri

**Currency:** INR - Indian Rupee

**Procedures**

| Name | OH? | Selected Cost | Screening | Day 1 | Day 2 | Day 3 | Day 4 | Day 5 | Day 6 | Day 7 | Day 8 | Day 9 | Day 10 | Day 11 | Day 12 | Day 13 | Day 14 | Day 15 | Day 16 | Day 17 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Informed consent | Y | 3,000.00 | 3,000.00 | | | | | | | | | | | | | | | | | |
| Eligibility assessment | Y | 1,500.00 | 1,500.00 | | | | | | | | | | | | | | | | | |
| Thoracic CT scan or Chest X-Ray | Y | SOC | SOC | | | | | | | | | | | | | | | | | |
| Demography | Y | 900.00 | 900.00 | | | | | | | | | | | | | | | | | |
| Medical history | Y | SOC | SOC | | | | | | | | | | | | | | | | | |
| Daily clinical features of COVID-19 (for non-mechanically ventilated participants) | Y | 2,300.00 | | 2,300.00 | 2,300.00 | 2,300.00 | 2,300.00 | 2,300.00 | 2,300.00 | 2,300.00 | 2,300.00 | 2,300.00 | 2,300.00 | 2,300.00 | 2,300.00 | 2,300.00 | 2,300.00 | 2,300.00 | 2,300.00 | 2,300.00 |
| Initial Full physical examination | Y | SOC | SOC | | | | | | | | | | | | | | | | | |
| Follow up Full physical examination | Y | SOC | | | | | | | | | | | | | | | | | | |
| 12-lead ECG | Y | 500.00 | 500.00 | 500.00 | | | | | | | | | | | | | | | | |
| Blood pressure and pulse | Y | SOC | SOC | SOC | | | | | | | | | | | | | | | | |
| Respiratory Rate and temperture | Y | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC |
| SpO2 (for participants not on invasive mechanical ventilation) | Y | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC |
| Concentration of inspired oxygen (FiO2) and / or oxygen flow rate (L/min) | Y | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC |
| Ordinal scale | Y | 2,000.00 | 2,000.00 | 2,000.00 | 2,000.00 | 2,000.00 | 2,000.00 | 2,000.00 | 2,000.00 | 2,000.00 | 2,000.00 | 2,000.00 | 2,000.00 | 2,000.00 | 2,000.00 | 2,000.00 | 2,000.00 | 2,000.00 | 2,000.00 | 2,000.00 |
| SOFA score (for ICU) | Y | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC |
| AE review | Y | 1,000.00 | | 1,000.00 | 1,000.00 | 1,000.00 | 1,000.00 | 1,000.00 | 1,000.00 | 1,000.00 | 1,000.00 | 1,000.00 | 1,000.00 | 1,000.00 | 1,000.00 | 1,000.00 | 1,000.00 | 1,000.00 | 1,000.00 | 1,000.00 |
| Concomitant medication review | Y | 700.00 | 700.00 | 700.00 | 700.00 | 700.00 | 700.00 | 700.00 | 700.00 | 700.00 | 700.00 | 700.00 | 700.00 | 700.00 | 700.00 | 700.00 | 700.00 | 700.00 | 700.00 | 700.00 |
| Survival follow-up | Y | 2,000.00 | | | | | | | | | | | | | | | | | | |
| Hematology | Y | 500.00 | 500.00 | 500.00 | 500.00 | | 500.00 | | | 500.00 | | | | | | | 500.00 | | | |
| Chemistry | Y | 3,000.00 | 3,000.00 | 3,000.00 | 3,000.00 | | 3,000.00 | | | 3,000.00 | | | | | | | 3,000.00 | | | |
| Lactate | Y | 900.00 | 900.00 | 900.00 | 900.00 | | 900.00 | | | 900.00 | | | | | | | 900.00 | | | |
| Troponin | Y | 1,200.00 | 1,200.00 | 1,200.00 | 1,200.00 | | 1,200.00 | | | 1,200.00 | | | | | | | 1,200.00 | | | |
| D-dimer | Y | 1,400.00 | 1,400.00 | 1,400.00 | 1,400.00 | | 1,400.00 | | | 1,400.00 | | | | | | | 1,400.00 | | | |
| CRP | Y | 1,103.00 | 1,103.00 | 1,103.00 | 1,103.00 | | 1,103.00 | | | 1,103.00 | | | | | | | 1,103.00 | | | |
| Ferritin | Y | 2,800.00 | 2,800.00 | | | | | | | 2,800.00 | | | | | | | 2,800.00 | | | |
| Procalcitonin | Y | 2,378.00 | 2,378.00 | | | | | | | 2,378.00 | | | | | | | 2,378.00 | | | |
| ESR | Y | 519.00 | 519.00 | | | | | | | 519.00 | | | | | | | 519.00 | | | |
| Coagulation | Y | 1,355.00 | 1,355.00 | 1,355.00 | 1,355.00 | | 1,355.00 | | | 1,355.00 | | | | | | | 1,355.00 | | | |
| Pregnancy Test - Serum | Y | 800.00 | 800.00 | | | | | | | | | | | | | | | | | |
| PD Sample (Cytokines) | Y | 3,000.00 | 3,000.00 | | 3,000.00 | | 3,000.00 | | | 3,000.00 | | | | | | | | | | |
| PK sample | Y | 3,000.00 | | 3,000.00 | 3,000.00 | | | | | 3,000.00 | | | | | | | 3,000.00 | | | |
| Spec Handling (simple) | Y | 1,500.00 | | 1,500.00 | 1,500.00 | | | | | 1,500.00 | | | | | | | 1,500.00 | | | |
| IV dosing with otilimab or placebo | Y | 9,000.00 | | 9,000.00 | | | | | | | | | | | | | | | | |
| Per Patient Activity Totals: | | | 27,555.00 | 29,458.00 | 22,958.00 | 6,000.00 | 18,458.00 | 6,000.00 | 6,000.00 | 28,655.00 | 6,000.00 | 6,000.00 | 6,000.00 | 6,000.00 | 6,000.00 | 6,000.00 | 25,655.00 | 6,000.00 | 6,000.00 | 6,000.00 |

| Name | OH? | Selected Cost | Day 18 | Day 19 | Day 20 | Day 21 | Day 22 | Day 23 | Day 24 | Day 25 | Day 26 | Day 27 | Day 28 | Discharge/Early Withdrawal | Follow-up Phone call (Day 42)/ Early Withdrawal | Follow-up Phone call (Day 60)/ Early Withdrawal | Day 14 Phone Visit if Subject is discharged | Day 28 Phone Visit if Subject is discharged |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Informed consent | Y | 3,000.00 | | | | | | | | | | | | | | | | |
| Eligibility assessment | Y | 1,500.00 | | | | | | | | | | | | | | | | |
| Thoracic CT scan or Chest X-Ray | Y | SOC | | | | | | | | | | | | | | | | |
| Demography | Y | 900.00 | | | | | | | | | | | | | | | | |
| Medical history | Y | SOC | | | | | | | | | | | | | | | | |
| Daily clinical features of COVID-19 (for non-mechanically ventilated participants) | Y | 2,300.00 | 2,300.00 | 2,300.00 | 2,300.00 | 2,300.00 | 2,300.00 | 2,300.00 | 2,300.00 | 2,300.00 | 2,300.00 | 2,300.00 | 2,300.00 | 2,300.00 | 2,300.00 | 2,300.00 | 2,300.00 | 2,300.00 |
| Initial Full physical examination | Y | SOC | | | | | | | | | | | | | | | | |
| Follow up Full physical examination | Y | SOC | | | | | | | | | | | | SOC | | | | |
| 12-lead ECG | Y | 500.00 | | | | | | | | | | | | 500.00 | | | | |
| Blood pressure and pulse | Y | SOC | | | | | | | | | | | | SOC | | | | |
| Respiratory Rate and temperture | Y | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | | | | |
| SpO2 (for participants not on invasive mechanical ventilation) | Y | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | | | | |
| Concentration of inspired oxygen (FiO2) and / or oxygen flow rate (L/min) | Y | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | | | | |
| Ordinal scale | Y | 2,000.00 | 2,000.00 | 2,000.00 | 2,000.00 | 2,000.00 | 2,000.00 | 2,000.00 | 2,000.00 | 2,000.00 | 2,000.00 | 2,000.00 | 2,000.00 | 2,000.00 | 2,000.00 | 2,000.00 | 2,000.00 | 2,000.00 |
| SOFA score (for ICU) | Y | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | SOC | | | | |
| AE review | Y | 1,000.00 | 1,000.00 | 1,000.00 | 1,000.00 | 1,000.00 | 1,000.00 | 1,000.00 | 1,000.00 | 1,000.00 | 1,000.00 | 1,000.00 | 1,000.00 | 1,000.00 | 1,000.00 | 1,000.00 | 1,000.00 | 1,000.00 |
| Concomitant medication review | Y | 700.00 | 700.00 | 700.00 | 700.00 | 700.00 | 700.00 | 700.00 | 700.00 | 700.00 | 700.00 | 700.00 | 700.00 | 700.00 | 700.00 | 700.00 | 700.00 | 700.00 |
| Survival follow-up | Y | 2,000.00 | | | | | | | | | | | | 2,000.00 | 2,000.00 | 2,000.00 | 2,000.00 | 2,000.00 |
| Hematology | Y | 500.00 | | | | | | | | | | | 500.00 | 500.00 | | | | |
| Chemistry | Y | 3,000.00 | | | | | | | | | | | 3,000.00 | 3,000.00 | | | | |
| Lactate | Y | 900.00 | | | | | | | | | | | 900.00 | 900.00 | | | | |
| Troponin | Y | 1,200.00 | | | | | | | | | | | 1,200.00 | 1,200.00 | | | | |
| D-dimer | Y | 1,400.00 | | | | | | | | | | | 1,400.00 | 1,400.00 | | | | |
| CRP | Y | 1,103.00 | | | | | | | | | | | 1,103.00 | 1,103.00 | | | | |
| Ferritin | Y | 2,800.00 | | | | | | | | | | | | | | | | |
| Procalcitonin | Y | 2,378.00 | | | | | | | | | | | | | | | | |
| ESR | Y | 519.00 | | | | | | | | | | | | | | | | |
| Coagulation | Y | 1,355.00 | | | | | | | | | | | 1,355.00 | 1,355.00 | | | | |
| Pregnancy Test - Serum | Y | 800.00 | | | | | | | | | | | | 800.00 | | | | |
| PD Sample (Cytokines) | Y | 3,000.00 | | | | | | | | | | | | | | | | |
| PK sample | Y | 3,000.00 | | | | | | | | | | | | | | | | |
| Spec Handling (simple) | Y | 1,500.00 | | | | | | | | | | | | | | | | |
| IV dosing with otilimab or placebo | Y | 9,000.00 | | | | | | | | | | | | | | | | |
| Per Patient Activity Totals: | | | 6,000.00 | 6,000.00 | 6,000.00 | 6,000.00 | 6,000.00 | 6,000.00 | 6,000.00 | 6,000.00 | 6,000.00 | 6,000.00 | 15,458.00 | 18,758.00 | 8,000.00 | 8,000.00 | 8,000.00 | 8,000.00 |

**Non Procedures**

| Name | OH? | Selected Cost | Screening | Day 1 | Day 2 | Day 3 | Day 4 | Day 5 | Day 6 | Day 7 | Day 8 | Day 9 | Day 10 | Day 11 | Day 12 | Day 13 | Day 14 | Day 15 | Day 16 | Day 17 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Physician's Fees without Exam Costs | Y | 5,000.00 | 7,500.00 | 7,500.00 | 7,500.00 | 5,000.00 | 6,250.00 | 5,000.00 | 5,000.00 | 10,000.00 | 5,000.00 | 2,500.00 | 2,500.00 | 2,500.00 | 2,500.00 | 2,500.00 | 10,000.00 | 2,500.00 | 2,500.00 | 2,500.00 |
| Study Coordinator Fee Per Visit | Y | 3,000.00 | 4,500.00 | 4,500.00 | 4,500.00 | 3,000.00 | 4,500.00 | 3,750.00 | 3,000.00 | 6,000.00 | 3,000.00 | 1,500.00 | 1,500.00 | 1,500.00 | 1,500.00 | 1,500.00 | 6,000.00 | 1,500.00 | 1,500.00 | 1,500.00 |
| Pharm Disp p/visit (use w/infusion) | Y | 1,000.00 | | 1,000.00 | | | | | | | | | | | | | | | | |
| Per Patient Other Direct Cost Totals: | | | 12,000.00 | 13,000.00 | 12,000.00 | 8,000.00 | 10,750.00 | 8,750.00 | 8,000.00 | 16,000.00 | 8,000.00 | 4,000.00 | 4,000.00 | 4,000.00 | 4,000.00 | 4,000.00 | 16,000.00 | 4,000.00 | 4,000.00 | 4,000.00 |

**Overall Patient Cost**

| | Screening | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Screening | Day 1 | Day 2 | Day 3 | Day 4 | Day 5 | Day 6 | Day 7 | Day 8 | Day 9 | Day 10 | Day 11 | Day 12 | Day 13 | Day 14 | Day 15 | Day 16 | Day 17 |
| **Costs Charged before overhead** | 39,555.00 | 42,458.00 | 34,958.00 | 14,000.00 | 29,208.00 | 14,750.00 | 14,000.00 | 44,655.00 | 14,000.00 | 10,000.00 | 10,000.00 | 10,000.00 | 10,000.00 | 10,000.00 | 41,655.00 | 10,000.00 | 10,000.00 | 10,000.00 |
| **Overhead at 30%** | 11,866.50 | 12,737.40 | 10,487.40 | 4,200.00 | 8,762.40 | 4,425.00 | 4,200.00 | 13,396.50 | 4,200.00 | 3,000.00 | 3,000.00 | 3,000.00 | 3,000.00 | 3,000.00 | 12,496.50 | 3,000.00 | 3,000.00 | 3,000.00 |
| **Selected Cost Per Visit** | 51,421.50 | 55,195.40 | 45,445.40 | 18,200.00 | 37,970.40 | 19,175.00 | 18,200.00 | 58,051.50 | 18,200.00 | 13,000.00 | 13,000.00 | 13,000.00 | 13,000.00 | 13,000.00 | 54,151.50 | 13,000.00 | 13,000.00 | 13,000.00 |

**Non Procedures**

| Name | OH? | Selected Cost | Day 18 | Day 19 | Day 20 | Day 21 | Day 22 | Day 23 | Day 24 | Day 25 | Day 26 | Day 27 | Day 28 | Discharge/Early Withdrawal | Follow-up Phone call (Day 42)/ Early Withdrawal | Follow-up Phone call (Day 60)/ Early Withdrawal | Day 14 Phone Visit if Subject is discharged | Day 28 Phone Visit if Subject is discharged |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Physician's Fees without Exam Costs | Y | 5,000.00 | 2,500.00 | 2,500.00 | 2,500.00 | 2,500.00 | 2,500.00 | 2,500.00 | 2,500.00 | 2,500.00 | 2,500.00 | 2,500.00 | 6,250.00 | 6,250.00 | 6,250.00 | 6,250.00 | 5,000.00 | 5,000.00 |
| Study Coordinator Fee Per Visit | Y | 3,000.00 | 1,500.00 | 1,500.00 | 1,500.00 | 1,500.00 | 1,500.00 | 1,500.00 | 1,500.00 | 1,500.00 | 1,500.00 | 1,500.00 | 3,750.00 | 3,750.00 | 3,750.00 | 3,750.00 | 3,000.00 | 3,000.00 |
| Pharm Disp p/visit (use w/infusion) | Y | 1,000.00 | | | | | | | | | | | | | | | | |
| Per Patient Other Direct Cost Totals: | | | 4,000.00 | 4,000.00 | 4,000.00 | 4,000.00 | 4,000.00 | 4,000.00 | 4,000.00 | 4,000.00 | 4,000.00 | 4,000.00 | 10,000.00 | 10,000.00 | 10,000.00 | 10,000.00 | 8,000.00 | 8,000.00 |

**Overall Patient Cost**

| | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Treatment | Discontinuation | Follow Up | Follow Up | Treatment | Treatment |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Day 18 | Day 19 | Day 20 | Day 21 | Day 22 | Day 23 | Day 24 | Day 25 | Day 26 | Day 27 | Day 28 | Discharge/Early Withdrawal | Follow-up Phone call (Day 42)/ Early Withdrawal | Follow-up Phone call (Day 60)/ Early Withdrawal | Day 14 Phone Visit if Subject is discharged | Day 28 Phone Visit if Subject is discharged |
| **Costs Charged before overhead** | 10,000.00 | 10,000.00 | 10,000.00 | 10,000.00 | 10,000.00 | 10,000.00 | 10,000.00 | 10,000.00 | 10,000.00 | 10,000.00 | 25,458.00 | 28,758.00 | 18,000.00 | 18,000.00 | 16,000.00 | 16,000.00 |
| **Overhead at 30%** | 3,000.00 | 3,000.00 | 3,000.00 | 3,000.00 | 3,000.00 | 3,000.00 | 3,000.00 | 3,000.00 | 3,000.00 | 3,000.00 | 7,637.40 | 8,627.40 | 5,400.00 | 5,400.00 | 4,800.00 | 4,800.00 |
| **Selected Cost Per Visit** | 13,000.00 | 13,000.00 | 13,000.00 | 13,000.00 | 13,000.00 | 13,000.00 | 13,000.00 | 13,000.00 | 13,000.00 | 13,000.00 | 33,095.40 | 37,385.40 | 23,400.00 | 23,400.00 | 20,800.00 | 20,800.00 |
| | | | | | | | | | | | | | | 727,291.50 | | |

## Site Level Other Direct Costs

| Name | OH? | Selected Cost |
|---|---|---|
| Archiving/Document storage/per site | N | 200,000.00 |
| Pharmacy set-up fee | N | 60,000.00 |
| Site Start-up Costs | N | 75,000.00 |

## Invoiceable Procedures

| Name | Selected cost | Overhead | Total incl OH |
|---|---|---|---|
| Re-consent Process, per patient | 3,000.00 | 900.00 | 3,900.00 |
| SAE Review | 5,907.00 | 1,772.10 | 7,679.10 |
| Pregnancy Test -Urine | 500.00 | 150.00 | 650.00 |
| Hospitalisation Fees(ICU)/day | 9,000.00 | 2,700.00 | 11,700.00 |

## EXHIBIT B

## GSK ANTI-BRIBERY AND ANTI-CORRUPTION TERMS

1. Institution agrees that it shall comply fully at all times with all applicable laws and regulations, including but not limited to anti-corruption laws, and that it has not, and covenants that it will not, in connection with the performance of this Agreement, directly or indirectly, make, promise, authorise, ratify or offer to make, or take any act in furtherance of any payment or transfer of anything of value for the purpose of influencing, inducing or rewarding any act, omission or decision to secure an improper advantage; or improperly assisting it or GSK in obtaining or retaining business, or in any way with the purpose or effect of public or commercial bribery, and warrants that it has taken reasonable measures to prevent subcontractors, agents or any other third parties, subject to its control or determining influence, from doing so. For the avoidance of doubt this includes facilitating payments, which are unofficial, improper, small payments or gifts offered or made to Government Officials to secure or expedite a routine or necessary action to which we are legally entitled.

2. Institution shall not contact, or otherwise knowingly meet with any Government Official for the purpose of discussing activities arising out of or in connection with this Agreement, without the prior approval of GSK and, when requested by GSK, only in the presence of a GSK designated representative.

   For the purpose of this Agreement "Government Official" (where 'government' means all levels and subdivisions of governments, i.e. local, regional, national, administrative, legislative, executive, or judicial, and royal or ruling families) means: (a) any officer or employee of a government or any department, agency or instrumentality of a government (which includes public enterprises, and entities owned or controlled by the state); (b) any officer or employee of a public international organisation such as the World Bank or United Nations; (c) any officer or employee of a political party, or any candidate for public office; (d) any person defined as a government or public official under applicable local laws (including anti-bribery and corruption laws) and not already covered by any of the above; and/or; (e) any person acting in an official capacity for or on behalf of any of the above. "**Government Official**" shall include any person with close family members who are Government Officials (as defined above) with the capacity, actual or perceived, to influence or take official decisions affecting GSK business.

3. Institution shall inform GSK in writing, if, during the course of this Agreement, it is convicted of or pleads guilty to a criminal offense involving fraud or corruption or becomes the subject of any government investigation for such offenses, or is listed by any government agency as debarred, suspended, proposed for suspension or debarment, or otherwise ineligible for government programs.

4. Institution represents and warrants that except as disclosed to GSK in writing prior to the commencement of this Agreement: a) none of their significant shareholders (>25% shareholding) or senior management have influence over GSK's business; (b) no significant shareholders (>25% shareholding), members of senior management team, members of the Board of Directors, or key individuals who will be responsible for the provision of goods / services are currently or have been in the past two years, a Government Official with actual or perceived influence which could affect GSK business; (c) it is not aware of any immediate relatives (e.g. spouse, parents, children or siblings) of the persons listed in the previous clause (b) having a public or private role which involves making decisions which could affect GSK business or providing services or products to, or on behalf of GSK; (d) it does not have any interest which directly or indirectly conflicts with its proper and ethical performance of this Agreement; and (e) it shall maintain arm's length relations with all third parties with which it deals for or on behalf of GSK in performance of this Agreement. Institution shall inform GSK in writing at the earliest possible opportunity of any conflict of interest as described in this subsection #4 that arises during the performance of this Agreement.

5. GSK shall have the right during the term of this Agreement to conduct an audit of Institution's activities under this Agreement to monitor compliance with the terms of this Agreement.

Institution shall cooperate fully with such audit, the scope, method, nature and duration of which shall be at the sole reasonable discretion of GSK.

6. Institution shall ensure that all transactions under the Agreement are properly and accurately recorded in all material respects on its books and records and each document upon which entries such books and records are based is complete and accurate in all material respects. Institution must maintain a system of internal accounting controls reasonably designed to ensure that it maintains no off-the-books accounts.

7. Institution agrees that in the event that GSK believes that there has been a possible violation of the terms of this **Exhibit B**, GSK may make full disclosure of such belief and related information at any time and for any reason to any competent government bodies and its agencies, and to whomsoever GSK determines in good faith has a legitimate need to know.

8. GSK shall be entitled to terminate the Agreement immediately on written notice to Institution, if Institution fails to perform its obligations in accordance with this **Exhibit B**. Institution shall have no claim against GSK for compensation for any loss of whatever nature by virtue of the termination of this Agreement in accordance with this **Exhibit B**.

## EXHIBIT C

## GLAXOSMITHKLINE'S – CLINICAL TRIAL COMPENSATION GUIDELINES

GlaxoSmithKline (GSK) will adhere to the following broad guidelines in the event of injury caused to the patient attributable to participation in the trial in question.

1. **Basic Principles**

1.1 Notwithstanding the absence of legal commitment, GSK will pay compensation to the patient-volunteers suffering Clinical Trial related injury (including death) in accordance with these guidelines.

1.2 Compensation will be paid when, on the balance of probabilities, the injury was attributable to the administration of a medicinal product under study or any clinical intervention or procedure provided for by the protocol that would not have occurred but for the inclusion of the Subject in the Clinical Trial.

1.3 Compensation will be paid to the child injured in utero through the participation of the Subject's mother in a clinical trial as if the child were a patient-volunteer with the full benefit of these guidelines.

1.4 Compensation will only be paid for the more serious injuries of an enduring and disabling character (including exacerbation of an existing condition) and not for temporary pain or discomfort or less serious or curable complaints.

1.5 Where there is an adverse reaction to a medicinal product under study and injury is caused by the procedure adopted to deal with the adverse reaction, compensation will be paid for such injury as if it were caused directly by the medicinal product under study.

1.6 Neither the fact that the adverse reaction causing the injury was foreseeable or predictable, nor the fact that the patient has freely consented (whether in writing or otherwise) to participate in the Clinical Trial should exclude a patient from consideration for compensation under these guidelines, although compensation may be abated or excluded in the light of the factors described in paragraph 4.2 below.

1.7 For the avoidance of doubt, compensation will be paid regardless of whether the Subject is able to prove that GSK has been negligent in relation to research or development of the medicinal product under study or that the product is defective and therefore, as the producer, GSK is subject to strict liability in relation of injuries caused by it.

2. **Types of Clinical Research Covered**

2.1 These guidelines apply to injury caused to patients involved in Phase II and Phase III trials, that is to say, patients under treatment and surveillance (usually in hospital) and suffering from the ailment which the medicinal product under trial is intended to treat but for which the product license does not exist or does not authorize supply for administration under the conditions of the trial.

2.2 These guidelines do not apply to injuries arising from studies in non-patient volunteers (Phase I), whether or not they are in hospital, for which separate guidelines for compensation already exist at the facility where the Clinical Trial is carried out

2.3 These guidelines do not apply to injury arising from clinical trials on marketed products (Phase IV) where a product licence exists authorising supply of administration under the conditions of the trial, except to the extent that the injury is caused to a patient as a direct result of procedures undertaken in accordance with the protocol (but not any product administered) to which the patient would not have been exposed had treatment been other than in the course of the trial. These guidelines do not apply to post-marketing surveillance and ancillary care.

2.4 These guidelines do not apply to clinical trials which have not been initiated or directly sponsored by GSK. Where trials of products are initiated independently by doctors, responsibility for the health and welfare of patients rests with the doctor alone (see also paragraph 5.2 below).

## 3. Limitations

3.1 Compensation will not be paid to research participants receiving placebo in consideration of its failure to provide a therapeutic benefit.

3.2 Compensation will not be paid for natural progression of an underlying disease.

3.3 Compensation will not be available for adverse effects due to concomitant medications allowed as per protocol/routine procedures as part of standard of care.

3.4 No compensation should be paid for the failure of a medicinal product to have its intended effect or to provide any other benefit to the patient.

3.5 No compensation should be paid for injury caused by other licensed medicinal products administered to the patient for the purpose of comparison with the product under trial.

3.6 No compensation should be paid (or it should be abated as the case may be) to the extent that the injury has arisen:

(a) through a significant departure from the agreed protocol;

(b) through a wrongful act or default of a third party, including a doctor's failure to deal adequately with an adverse reaction;

(c) through a contributory negligence by the patient.

3.7 Compensation may not be provided if it is determined (by the Investigator and the IEC) that the injury has arisen through:

(a) wrongful act or default of a third party;

(b) contributory negligence by the research participant (e.g. wilful or reckless non-adherence to protocol procedures/instructions by the research participants as described in the ICDs).

## 4. Assessment of Compensation

4.1 The amount of compensation paid should be appropriate to the nature, severity and persistence of the injury and should in general terms be consistent with the quantum of damages commonly awarded for similar injuries by the Indian Courts in cases where legal liability is admitted.

4.2 Compensation may be abated, or in certain circumstances excluded, in the light of the following factors (on which will depend the level of risk the patient can reasonably be expected to accept):

(a) the seriousness of the disease being treated, the degree of probability that adverse reaction will occur and any warnings given;

(b) the risks and benefits of established treatments relative to those known or suspected of the trial medicine.

This reflects the fact that flexibility is required given a particular patient's circumstances. As an extreme example, there may be patient suffering from a serious or life-threatening disease who is warned of a certain defined risk of adverse reaction. Participation in the trial is then based on an expectation that the benefit/risk ratio associated with participation may be better than that associated with alternative treatment. It is, therefore, reasonable that the patient accepts the high risk and should not expect compensation for the occurrence of the adverse reaction of which he or she was told.

4.3 In any case where GSK concedes that a payment should be made to a Subject but there exists a difference of opinion between GSK and patient as to the appropriate level of compensation, GSK shall seek at its own cost (and make available to the patient) the opinion of a mutually acceptable independent expert, and that his/her opinion should be given substantial weight by GSK in reaching its decision on the appropriate payment to be made.

5. **Miscellaneous**

5.1 Claims pursuant to the guidelines should be made by the Subject to GSK, preferably via the Principal Investigator, setting out details of the nature and background of the claim and, subject to the Subject providing on request an authority for GSK to review any medical records relevant to the claim. GSK should consider the claim expeditiously.

5.2 The undertaking given by GSK extends to injury arising (at whatever time) from all administration, clinical interventions or procedures occurring during the course of the Clinical Trial but not to treatment extended beyond the end of the Clinical Trial at the request of the Principal Investigator. The use of unlicensed products beyond the trial period is wholly the responsibility of the treating doctor.

5.3 The fact that GSK has agreed to abide by these guidelines in respect of a Clinical Trial does not affect the right of a Subject to pursue a legal remedy in respect of injury alleged to have been suffered as a result of participation. Nevertheless, patients will normally be asked to accept that any payment made under the guidelines will be in full settlement of their claims.

5.4 GSK should encourage the investigator to make clear to participating Subjects that the Clinical Trial is being conducted subject to GSK's guidelines relating to compensation for injury arising in the course of clinical trials and the copy of these guidelines should be made available to the participating Subjects.

**EXHIBIT D**
**PAYMENT AUTHORIZATION FORM**

All fields are **mandatory** unless indicated otherwise

**NB** **IF YOU HAVE COMPLETED THIS FORM BEFORE, YOU NEED ONLY COMPLETE IT AGAIN IF ANY OF YOUR DETAILS HAVE CHANGED**

## Payee or Investigator Details

| **Description**<br>(CTMS Field) (Finance Field) | **Payee or Investigator Information** | Max Chars for Finance Field Incl. Spaces |
|---|---|---|
| **Payee Name**<br>*(in terms of the provisions of the Statement of Agreement):* | **Doclin Clinical Research Services** | 80 |
| **(To whom should the transfer be made payable to?)**<br>**N.B. This must be the exact payee as it appears on the bank account** | | |
| **Street Address of Payee**<br>(Address Line 1) (Address 1) | **445, Maruti Galli, Main Road, Hangarge, Mandoli** | 30 |
| **Department Name** (if applicable):<br>(Address Line 2) (Address 2) | **NA** | 30 |
| **Room / Floor** (if applicable)<br>(Address Line 3) (Address 3) | **NA** | 30 |
| **Other Address Details** (if applic.)<br>(Address Line 4) (Address 4) | **NA** | 30 |
| **Country**<br>(Country) (Country) | **India** | 2<br>*ISO Code* |
| **State / Province** (if Applicable)<br>(State / Province) (State or Province) | **Karnataka** | 2 |
| **Town/City**<br>(City) (City or Address 5) | **Belagavi** | 18 |
| **Postal Code**<br>(Zip/Postal Code) (Postal Code) | **590008** | 10 |
| **Contact name for payee**<br>if different from above | **Mr. Maruti Patil** | 30 |
| **Telephone** | **+91-9591358733** | 27 |
| **Fax** | **NA** | 27 |
| **E-mail** | **Maruti.patil171@gmail.com** | 60 |
| **Web page** | **NA** | 60 |

## Service / VAT / Tax Withholding Details

(Please note that payments cannot be made without these fields being completed):

**Service / VAT / Sales Tax**

| | | | |
|---|---|---|---|
| Are you GST Registered | **YES** | | *Delete where applicable* |
| If no Reason | | | |

If **YES**, please provide the following information

| | |
|---|---|
| GST No, | 29AZXPP8818R1ZP |
| At what % rate GST be charged? | 18% |

**Tax Withholding**

| | | | |
|---|---|---|---|
| Is PPD required to withhold Tax from Payments? | **YES** | | *Delete where applicable* |

If **YES**, please provide the following information

| | |
|---|---|
| PAN ID number<br>Please provide a copy of the PAN Card.<br>In case you are exempt from TDS please provide IT certificate | **AZXPP8818R**<br>**Attached** |

## Payment Method required

| | |
|---|---|
| What is your preferred payment method? | Bank transfer |

If **Bank Transfer**, please complete the following details:

Preferred

| | | | |
|---|---|---|---|
| **Bank Account Number** | | | |
| **Sorting Code** *(For UK only)* | | **Branch number/Bank code** | **1690** |
| **RTGS/NEFT code:** | **UTIB0001690** | | |

## Bank Details

| | | | |
|---|---|---|---|
| **Bank name**: | **Axis Bank** | | |
| **Address**: | **Nehru Nagar, Ratna Plaza, CTS No. 10593, Kolhapur Circle** | | |
| **City** | **Belagavi** | **Postal Code** | **590010** |
| **Country**: | **India** | **Private or Public Bank Account**:<br>*(Belgium and France only)* | |

**Declaration**

I have provided the above details and confirm they are correct:

| | |
|---|---|
| **Investigator/Institutional Signatory** |  |
| **Name in print** | Dr. Sayed Umar Quadri |
| **Date** (dd/mmm/yyyy) | 31st Jul 2020 |

Dr. SYED UMAR QUADRI
M.B.B.S. M.D. (MED.)
Asst. Prof. of Medicine
MGM Medical College & Hospital A'bad.
REG NO. 2005/02/0904

**TO BE COMPLETED BY THE PPD CRA/CONTRACT SPECIALIST**

## Other Financial Data

| | |
|---|---|
| **PPD CRA/CONTRACT SPECIALIST name** | **Kathrine Joy** |
| **Location** | **Mumbai** |
| **Paying Country** *(if in doubt, contact the Financial Analyst for the study)* | |
| **In what currency is the Statement of Agreement defined** | |

## CASCADE Interface Data

- If the Investigator is the payee, please enter the CASCADE **Contact** number.
- If the Hospital/R&D etc is the payee, please enter the CASCADE **Account** number.
- It may be that the Payee listed above already has a Vendor number (Contact/Account Screen and More Info View) and Remittance code (Contact/Account Screen and Addresses View).
- Please note that these fields are crucial to correct payments being made. Please confirm the correct numbers with your CASCADE Super User or the cascade business support team via the helpdesk.

**NOTE: DO NOT USE THE CTMS SITE NUMBER HERE**

| **CTMS Number**<br>*Contact/Account – More Info View* | **Vendor Number**<br>*Contact/Account – Addresses View* | **Remittance Code**<br>*Contact/Account – Addresses View* |
|---|---|---|
| | | |

If the Account or Contact has a vendor number, please identify the purpose of this form, if you are **certain** of the correct option.

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| New Vendor | ☐ | Amend Vendor | ☐ | New Remittance Address Required | ☐ | Amend Remittance Address | ☐ |

## Lawson Data

**TO BE COMPLETED BY PPD FINANCE DEPARTMENT**

| | | | |
|---|---|---|---|
| **Vendor Name *(used in Lawson)*** | | | |
| **Vendor Number:** | | **Vendor Location** | |
| **Vendor Group** | | **Distribution Code** | |
| **Vendor Class** | INV | **Separate Payment** | Y |
| **Search Name *(used in LAWSON):*** | | | |
| **Tax Code *(dependent on Service Tax / VAT Reg)*** | | | |
| **Cash Code *(dependent on country and currency)*** | | | |
| **Payment Code *(dependent on method of payment)*** | | | |
| **Next Available User Field *(AP10.1)*** | | CTMS | |