CLINICAL TRIAL AGREEMENT

THIS AGREEMENT is made and entered into effective as of 23 Nov 2016, (hereinafter "Effective Date") by and between **BRISTOL-MYERS SQUIBB INDIA PRIVATE LIMITED,** a company incorporated under the Companies Act, 1956 having its registered office at Indiabulls Finance Centre 6th Floor, Tower 1, Senapati Bapat Marg Elphinstone (W), Mumbai-400 013 **(hereinafter "SPONSOR")**

And

MGM Medical College & Hospital, N-6, Cidco, Aurangabad, Maharashtra 431003, India **(hereinafter "INSTITUTION")**

And

PPD Pharmaceutical Development India Private Limited, 101-A Wing Fulcrum, Hiranandani Business Park, Sahar Road, Anderi East, Mumbai – 400 099 **(hereinafter "CRO")**

RECITALS

WHEREAS, SPONSOR conducts business in the research, development, manufacture and sale of pharmaceutical, nutritional and healthcare products, and

WHEREAS, SPONSOR desires INSTITUTION to conduct a clinical trial and INSTITUTION desires to conduct same, said trial being entitled:

Study Title: "A Phase IV, Open-Label, Multi-center Study to Evaluate the Safety of Apixaban in Indian Subjects Undergoing Elective Total Knee Replacement or Total Hip Repalcement Surgery"

Protocol No. CV185158

(said study, as it may be amended or supplemented from time to time in accordance with this agreement, hereinafter referred to as the "Study"), and

WHEREAS, SPONSOR has contracted with CRO to coordinate and/or perform certain activities required for the conduct of the Study and to administer and disburse payments under Article 2 of this agreement.

NOW, THEREFORE, subject to the terms, conditions and covenants hereinafter set forth, INSTITUTION and SPONSOR agree as follows:

Article 1 - The Study

1.1 The INSTITUTION shall, where required by applicable law, submit the Protocol for review and approval (i) in the case of all U.S. studies and any IND Study, to an appropriate Human Subject Institutional Review Board/Ethics Committee or equivalent body in accordance with Applicable Law (any such board, body or committee referred to hereinafter as the "IRB"), and (ii) in the case of a non-IND Study, to an appropriate independent review committee of scientists or other

For THE KAPOL CO-OP BANK LTD.
GHATKOPAR (W) BR.
Authorised Signatory

The Kapol Co-operative Bank Ltd.,
Ghatkopar Branch, Ladhorbai Kapol
Wadi, Ghatkopar (W), Mumbai-400 086.
D-5/STP(V)/C.R.1211/4/05/1998-BB

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qualified individuals as set forth under Applicable Law and in the Declaration of Helsinki (any such board, body or committee referred to hereinafter as the "IRB"). INSTITUTION shall conduct the Study in accordance with the Protocol approved by the INSTITUTION's IRB, as the same may be changed from time to time thereafter (hereinafter the "Protocol") and in accordance with prudent research practices and Applicable Law . Changes to the Protocol may be made (i) in accordance with procedures outlined in the Protocol, or (ii) by agreement of the INVESTIGATOR, INSTITUTION and SPONSOR. Changes to the Protocol shall be accompanied by such notification, review and/or approval of the IRB as may be required by Applicable Law and/or the Protocol.

For the purposes of this Agreement, Applicable Law includes all applicable statutes, enactments, acts of legislature or Parliament, laws, ordinances, rules, by-laws, regulations, notifications, guidelines, policies, directions, directives and orders of any government authority, tribunal, board, court or recognised stock exchanges including but not limited to the US FDA rules and regulations, the International Conference of Harmonization Guidelines for Good Clinical Practices, India's Drugs and Cosmetics Act, 1940 and Good Clinical Practices ("Applicable Law").

1.2 **Dr. Girish Namdeorao Gadekar** (the "INVESTIGATOR") will serve as Investigator, will supervise the conduct of the Study, and may appoint such other individuals as INVESTIGATOR, in accordance with Applicable Law and/or the Protocol, may deem appropriate as subinvestigators to assist in the conduct of the Study (such other individuals are collectively referred to hereinafter as "SUBINVESTIGATORS"). The INVESTIGATOR shall be responsible for leading and supervising any such team of SUBINVESTIGATORS. If **Dr.Girish Namdeorao Gadekar** should become unable to conduct the Study, INSTITUTION shall consult with SPONSOR regarding the appointment of a new investigator and if both parties cannot agree on a substitute, all further enrollment of subjects into the Study shall immediately cease. In the event that the Study ceases, the Investigator shall (a) forthwith inform the subjects of such, the IRB and all other regulatory authorities under Applicable Law, in writing regarding such termination of the Study; and (b) ensure all necessary therapy and follow up with the subjects as required by Applicable Law in the event INSTITUTION and SPONSOR are able to agree upon a substitute, both parties agree to work in good faith to amend this Agreement and any other documents to reflect such substitute to ensure compliance with all applicable laws, regulations and guidelines.

1.3 The INSTITUTION, SPONSOR, the INVESTIGATOR and each SUBINVESTIGATOR shall comply with the Protocol and with all Applicable Law and other governmental requirements in the performance and documentation of the Study. Without in any way limiting the foregoing, these obligations shall include the following:

(a) INSTITUTION, the INVESTIGATOR and each SUBINVESTIGATOR shall, as the same may be required of each of them by Applicable Law and the Protocol, prepare, document and maintain records and case histories on case report forms supplied by SPONSOR or CRO (as instructed or authorized by SPONSOR), retain such data and records after completion of the Study, and obtain advance informed consent from each of the subjects (or their duly authorized representatives) participating in the Study.

(b) INSTITUTION, INVESTIGATOR and each SUBINVESTIGATOR shall implement and maintain all quality assurance quality assurance systems to ensure that the clinical trial is conducted and data generated, documented and reported in compliance with

the protocol and under Applicable Law.

(c) The INVESTIGATOR and each SUBINVESTIGATOR shall notify the SPONSOR, the IRB , the CRO and the relevant government bodies of all serious and unexpected adverse events in the course of the Study of which they become aware in accordance with Applicable Law and the Protocol.

(d) Upon reasonable notice and at reasonable times during the term of this Agreement, INSTITUTION, the INVESTIGATOR and each SUBINVESTIGATOR shall permit representatives of SPONSOR and CRO to examine their respective facilities, to validate case reports against original data in their files, to make copies of relevant records and monitor the work performed hereunder, and to determine the adequacy of the facilities and whether the Study is being conducted in compliance with this Agreement, the Protocol and Applicable Law; provided, that SPONSOR and CRO representatives may not review patient identifying information without proper written authorization from a Subject or except as required by law.

(e) The INVESTIGATOR will keep appropriate records of Study drug received, dispensed, used, and returned by subjects, as well as records of any Study drug returned to SPONSOR, in accordance with Applicable Law and the Protocol.

(f) INSTITUTION and INVESTIGATOR and SPONSOR acknowledge that it is possible that a regulatory or other governmental agency, acting within its scope of authority, may at some time take regulatory action against INSTITUTION because of actual or alleged deficiencies in studies not placed by SPONSOR or because of other alleged INSTITUTION defects. INVESTIGATOR and INSTITUTION agree to notify SPONSOR immediately by telephone or telefax of any such regulatory action taken or anticipated to be taken against INSTITUTION for any reason that may affect a Study governed by this Agreement and to provide a copy of any written correspondence received from a regulatory agency pertaining thereto.

INSTITUTION shall promptly notify SPONSOR of any request received by INSTITUTION from any applicable regulatory or other governmental agency to inspect or otherwise gain access to the information, data or materials pertaining to the Study performed by INSTITUTION under this Agreement. INSTITUTION shall promptly notify SPONSOR of such requests prior to permitting any third party access unless prior notice is not possible. INSTITUTION agrees to permit inspection of such information, data and materials by authorized representatives of such agencies as required by law. INSTITUTION will make reasonable efforts to segregate materials related to the Protocol, the Study and the Study Drug from any other materials that are the subject of such inquiry or inspection and will disclose only those documents and materials that are required to be disclosed during such inquiry or inspection. INSTITUTION will provide SPONSOR with copies of such notice(s) and related correspondence and permit SPONSOR representatives to attend such visits where such visits directly affect a Study governed by this Agreement. At SPONSOR's request and at a mutually agreeable time, INSTITUTION will accompany SPONSOR to such agencies to discuss relevant aspects of INSTITUTION's services performed hereunder.

1.4 SPONSOR shall provide, without cost, sufficient amounts of the Study drug to conduct the Study. INSTITUTION and INVESTIGATOR may not use or dispose of the Study drug in any way other than as specified in the Protocol.

1.5 CRO shall have such obligations and rights with respect to the Study performed under this Agreement as authorized by SPONSOR, which rights and obligations are set forth in a separate agreement between SPONSOR and CRO.

Article 2 - Compensation

2.1 In consideration of INSTITUTION's and INVESTIGATOR's participation in this Study and of their agreements hereunder, and to cover their respective costs connected with the conduct of the Study, the CRO shall pay to **"Ardent Clinical Research Services"** such amount to be determined and paid in the manner set forth in Exhibit A hereto. INSTITUTION will complete the Study within the maximum budget set forth on said Exhibit A, and will not commit to nor incur any expenses in excess of such maximum amount without SPONSOR's prior written consent. Each party agrees to discuss budgetary matters with the other party as either party may request from time to time. The parties acknowledge CRO shall, on behalf of SPONSOR, be responsible for administering and disbursing payments contemplated by this Article 2.1 in accordance with the schedule set forth in Exhibit A hereto.

2.2 The INSTITUTION and the INVESTIGATOR have elected to assign their right to receive payment under this Agreement to **"Ardent Clinical Research Services"** ("SMO") in accordance with Exhibit A. All payments made in respect of the INSTITUTION's and the INVESTIGATOR's performance under this Agreement shall be made to SMO. SMO will be responsible for compensating the INSTITUTION and all individuals and entities involved in the conduct of the Study, including the INVESTIGATOR. Neither SPONSOR nor CRO shall have any payment obligation directly to INSTITUTION, INVESTIGATOR or all such individuals and entities."

Article 3 - Institution Staff and Facilities

3.1 The Study shall be carried out at INSTITUTION under the review of its Institutional Review Board and under the supervision of the INVESTIGATOR. INSTITUTION will perform the Study in an efficient, ethical and professional manner and will use its best efforts to complete the Study within the time period estimated therefor.

3.2 INSTITUTION shall arrange and pay for all necessary laboratory and other facilities, equipment, supplies (other than the Study drug), and physicians and clinical support staff required to discharge its obligations under the Study.

3.3 All matters, terms and payment of compensation, benefits and other conditions of engagement of any nature for the INVESTIGATOR, any SUBINVESTIGATOR and any support staff used in the Study shall be solely a matter between INSTITUTION and such individuals, regardless of whether such individuals are considered employees, agents or independent contractors of INSTITUTION.

3.4 The INVESTIGATOR, each SUBINVESTIGATOR and any support staff shall comply with the terms of this Agreement to the same extent as INSTITUTION hereunder. INSTITUTION will take appropriate steps to inform each such person of his/her obligations hereunder and to obtain his/her agreement to abide by the terms and conditions of this Agreement.

3.5 The INVESTIGATOR hereby acknowledge and agree that payments due under this Agreement are pass-through payments from the SPONSOR. CRO will make said payments once funds are received by CRO from the SPONSOR. CRO shall exercise reasonable efforts to ensure timely receipt of pass-through payments from the SPONSOR.

Article 4 - Reports

4.1 INVESTIGATOR shall keep SPONSOR advised of the status of the Study via periodic reports provided to SPONSOR or CRO (as instructed by SPONSOR). The frequency of reports shall be mutually agreed to by SPONSOR and INVESTIGATOR, in accordance with requirements specified under any Applicable Law, and set forth in Exhibit A. If required by SPONSOR, there shall also be a final report of the Study presented to SPONSOR. INSTITUTION and INVESTIGATOR shall assist the SPONSOR in submitting any status reports as may be required under any Applicable Law to any regulatory authority specified under the Applicable Law.

4.2 All case report forms and other reports submitted to SPONSOR or CRO and all data generated hereunder shall become the property of SPONSOR and may be used by SPONSOR for any purpose without further obligation or liability to INSTITUTION. INSTITUTION shall have the right to obtain and use the data in order to publish the Study results as provided in Article 5 below, for continuing academic research purposes and for the treatment and medical care of any Study subject. A subject's individual medical records shall remain the property of the INSTITUTION. INSTITUTION will, where duly authorized or within the bounds of legal requirements, provide or make such medical records and individual subject data available to SPONSOR or CRO and such governmental agencies designated by SPONSOR. Study data shall be transmitted to SPONSOR or CRO by magnetic media or other mutually agreed upon method. Study medical records and data shall be retained by INSTITUTION for such period of time required by law and/or by the Protocol. INSTITUTION shall be entitled to retain, for archival purposes, a copy of the case report forms.

4.3 INSTITUTION agrees not to provide the Study data to any third party or to use the Study data in commercially-sponsored research without SPONSOR's prior written consent. INSTITUTION also agrees not to identify, either on a blinded or unblinded basis, subjects from this Study in order to benefit research conducted or sponsored by any third party, without SPONSOR's prior written consent. The foregoing shall not affect INSTITUTION's right to publish the Study results or to use the Study data for internal academic research as set forth in this Agreement, to disclose information required by law, or to disclose or use data for the medical care of any specific Study subject.

Article 5 - Publication

5.1 INSTITUTION and INVESTIGATOR may freely publish and disseminate the results of their investigative findings hereunder and shall solely determine the authorship and contents (including scientific conclusions and professional judgments) of any such paper. INSTITUTION or

INVESTIGATOR, as the case may be, shall provide SPONSOR with a copy of the papers prepared for publication by it, him/her or any SUBINVESTIGATORs at the earliest practicable time, but in any event not less than thirty (30) days prior to their submission to a scientific journal or presentation at scientific meetings and a reasonably detailed summary or abstract of any other oral or written publication not less than thirty (30) days prior to their submission or presentation. SPONSOR may comment upon, but may not make any editorial changes to, the results and conclusions set forth in the papers; however, if identified by SPONSOR, any SPONSOR Confidential Information (as defined below) that may be contained therein shall be deleted. SPONSOR personnel shall be acknowledged in accordance with customary scientific practice. SPONSOR may freely use, copy and disseminate any such manuscript following its publication without further obligation to INSTITUTION or INVESTIGATOR.

Article 6 - Confidential Information

6.1 In furtherance of the conduct of the Study, it may be necessary or desirable for the parties hereto to disclose proprietary, trade secret and/or other confidential information (hereinafter "Confidential Information") to one another or to the INVESTIGATOR. For purposes of this Agreement, Confidential Information of SPONSOR shall include information received from either SPONSOR or CRO. All such Confidential Information shall remain the property of the party disclosing same. Such Confidential Information disclosed by CRO shall be deemed as and remain the property of SPONSOR. The INVESTIGATOR and each party hereto agrees that any such Confidential Information disclosed to him or her, or to it or its employees, agents and contractors, shall be used only in connection with the legitimate purposes of this Agreement, shall be disclosed only to those who have a need to know it and are obligated to keep same in confidence, and shall be safeguarded with reasonable care; provided, however, that the disclosing party marks the Confidential Information as such at the time of disclosure (or, if disclosed verbally, such Confidential Information is reduced to writing and so marked within a reasonable period of time thereafter).

The foregoing confidentiality obligation shall not apply when, after and to the extent the Confidential Information disclosed

(i) is now, or hereafter becomes, generally available to the public through no fault of the receiving party or its employees, agents or contractors,

(ii) was already in the possession of the receiving party without restriction as to confidentiality at the time of disclosure as evidenced by competent written records, or

(iii) is subsequently received by the receiving party from a third party without restriction and without breaching any confidential obligation between the third party and the disclosing party hereunder.

Confidential Information may also be disclosed to the extent required by Applicable Law (including without limitation the filing and prosecution of patent applications), provided that the party making such disclosure of the other party's Confidential Information shall give maximum practical advance notice of same and request such confidential treatment of such disclosure from the recipient thereof as may be afforded by the Applicable Law. The terms of this Agreement shall not be disclosed to any third party, except as required by Applicable Law or with the permission of the other party; provided, however, that, without the consent of the other party, INSTITUTION may disclose the SPONSOR's and INVESTIGATOR's name, total grant amount, and a general, nonconfidential title of

the Study without SPONSOR's consent in INSTITUTION's customary publications therefor, and SPONSOR may disclose the terms of this Agreement in connection with any governmental filing relating to the drug approval process or any business opportunity.

6.2 In addition to the above, INSTITUTION and INVESTIGATOR specifically agree that they will not discuss the Study or the Study drug with any financial, securities, or industry analyst, or with the media, except as authorized in writing by SPONSOR. This obligation extends to (a) Confidential Information supplied by the SPONSOR or CRO, (b) data produced in the Study, and (c) any opinion of INSTITUTION or INVESTIGATOR that is informed, in whole or in part, directly or indirectly, by access to the Confidential Information or Study data.

Article 7 - Independent Contractor

7.1 The relationship of SPONSOR to INSTITUTION , SPONSOR to INVESTIGATOR and SPONSOR to CRO under this Agreement is that of independent contractors. Nothing contained in this Agreement shall be construed to place the parties in the relationship of employer and employee, partners, principal and agent, or joint venturers. Neither party shall have the power to bind or obligate the other party nor shall either party hold itself out as having such authority.

Article 8 - Term and Termination

8.1 This Agreement shall commence on the Effective Date of this Agreement and shall, unless sooner terminated as herein expressly provided, continue until completion of the Study as provided in the Protocol.

8.2 This Agreement (or any Study conducted hereunder) may be terminated and/or further enrollment of subjects in a Study may be suspended:

(a) by SPONSOR, with or without cause, effective as of such date as SPONSOR may specify in such notice (which shall be not less than thirty (30) days prior notice for any termination of this Agreement without cause) to INSTITUTION, without penalty or liability therefor and payment of any further compensation hereunder except as may be provided in Exhibit A, provided, however, that SPONSOR shall have no obligation to pay for the Study if SPONSOR terminates this Agreement for material failure of INSTITUTION or INVESTIGATOR to follow the Protocol or breach of any material obligation under this Agreement;

(b) by INSTITUTION, either (i) if it believes such termination is necessary to protect the best interests of the Study subjects, or (ii) for a breach of a material provision hereof by SPONSOR, which breach is not cured by SPONSOR within thirty (30) days following receipt of written notice thereof from INSTITUTION;

(c) CRO may remove itself as a party to this Agreement upon thirty (30) days prior written notice to the other parties, if the agreement pursuant to which PPD Development LLC is providing services to Sponsor in connection with the Study is terminated or cancelled; or

(d) by written mutual agreement.

Upon such termination or suspension, the parties will meet and confer promptly to determine an appropriate phase-out for subjects already enrolled in the Study. Further, in the event of termination due to any reason, INVESTIGATOR shall assist SPONSOR in submitting any reports or meeting any requirements as may be required under Applicable Law.

8.3 Articles 1.3, 1.4, 2, 3, 4, 5.1, 6 and 9 shall survive any termination or expiration of this Agreement, as well as any other terms which by their intent or meaning are intended to so survive. No termination hereunder shall constitute a waiver of any rights or causes of action that either party may have based upon events occurring prior to the termination date.

Article 9 - General

9.1 Distinct from any medical expenses covered by Article 9.2 below, SPONSOR will indemnify and hold harmless INVESTIGATOR, any SUBINVESTIGATOR, INSTITUTION, its IRB, its affiliated corporations, and its and their directors, trustees, officers, employees and agents (collectively, the "Indemnitees") , from and against any amounts paid or payable by an Indemnitee to a Study subject resulting from claims, legal proceedings or causes of actions (collectively, "Claims") asserted or initiated by such subject based upon personal injury (including death) to such Study subject, which injury is sustained as a result of the administration of the Study drug in accordance with the Protocol, except to the extent such Claims, are attributable to:

(i) the failure of INSTITUTION, the INVESTIGATOR, any SUBINVESTIGATOR or any other INSTITUTION personnel involved in the performance of the Study to adhere to the terms of the Study protocol or any written instructions (including, without limitation, package inserts, where appropriate) relative to the use of any drugs or devices used in the performance of the Study, or comply with Applicable Law, or

(ii) any negligent or wrongful act or omission, or willful malfeasance, of INSTITUTION, the INVESTIGATOR, any SUBINVESTIGATOR or any other INSTITUTION personnel (including employees, agents or independent contractors) involved in the performance of the Study.

It is a condition precedent to SPONSOR's indemnification obligations under this article 9.1 that each such Indemnitee seeking indemnity hereunder must (i) promptly notify SPONSOR of the assertion of any such Claims against it/him/her, (ii) authorize and permit SPONSOR to conduct and exercise sole control of the defense and disposition (including all decisions relative to litigation, appeal or settlement) of such Claims and (iii) fully cooperate with SPONSOR regarding any such Claims (including access to pertinent records and documents and provision of relevant testimony) and in determining the scope of SPONSOR's obligations hereunder. Subject to the foregoing, each Indemnitee may participate in any such Claims at its/his/her own cost and expense.

9.2 In the event of an injury occurring to the Study subject, such Study subject shall be provided free medical management in accordance with applicable laws as may be amended from time to time. In the event of a Study-related injury or death, the SPONSOR shall reimburse the costs of and to provide financial compensation in accordance with applicable laws as may be amended from time to time (except to the extent such costs are covered by the Study subject's

insurance or other third party coverage in accordance with applicable laws as may be amended from time to time). In the event of no permanent injury, the quantum of compensation shall be commensurate with the nature of the non-permanent injury and loss of wages in accordance with applicable laws as may be amended from time to time.

9.3 No right or license is granted under this Agreement by one party to the others either expressly or by implication, except those specifically set forth herein. Nothing contained within this Agreement shall impose an obligation of exclusivity on one party by the others. The parties reserve the right to enter into and participate in other activities (either alone or with another party) including, but not limited to, clinical trials and sponsored research projects.

9.4 All matters affecting the interpretation, validity and performance of this Agreement shall be governed by the laws of India, without regard or giving effect to its conflict of laws principles. Parties agree and irrevocably submit to the exclusive jurisdiction of the Mumbai courts to hear and determine any suit, action or proceeding and to settle any disputes which may arise out of or in connection with this Agreement. This Agreement, including the annexed Exhibit(s), sets forth the entire understanding between the parties herein, and there are no other understandings or promises, written or verbal, not set forth herein, relating to the subject matter hereof This Agreement may not be assigned by one party without the prior written consent of the other parties (not to be unreasonably withheld). This Agreement may not be changed or supplemented, except by a writing executed by INSTITUTION, SPONSOR and CRO. No failure or delay in exercising any right hereunder will be considered a waiver thereof unless expressly waived in writing by the party to be charged therewith. No waiver on one occasion will be considered a continuing or subsequent waiver. The person signing below on behalf of a corporation or other entity represents that he or she has the full power and authority to enter into this Agreement on behalf of such entity.

9.5 All legal notices to be given by one party to the others shall be made in writing by hand delivery or by registered or certified mail, return receipt requested or by other method reasonably capable of proof of receipt thereof and addressed to the parties at their respective addresses first set forth above to the attention of:

If to the INSTITUTION,
to:
MGM Medical College & Hospital ,
N-6 CIDCO, Aurangabad-431003,
MH India.
Telephone no:- 0240 660 1100
Attn:Dr.A .G Shorff

If to the SPONSOR,
to:
Indiabulls Finance Centre 6th Floor,
Tower 1, Senapati Bapat Marg
Elphinstone (W), Mumbai-400 013

If to the CRO,
to:
PPD Pharmaceutical Development India Pte Ltd
101-A Wing Fulcrum,
Hiranandani Business Park,Sahar Road
Anderi East,Mumbai – 400 099
Attn.:Rashmi Chitgupi

or to such other address as either may designate from time to time to the other. Any notice shall be effective as of its date of receipt.

9.6 SPONSOR will not use the name of INSTITUTION, or a variant thereof, in any advertising or promotional material or make any representation relative to the Study drug which would constitute an express or implied endorsement by INSTITUTION of any commercial product or service (and will not authorize others to do so), except as may be required by law or with the INSTITUTION'S written permission. INSTITUTION will not use SPONSOR's name, or a variant thereof, for any advertising or promotional purpose without SPONSOR's prior written consent.

9.7 INSTITUTION shall promptly disclose to SPONSOR any discovery or invention ("Invention") made by INSTITUTION, the INVESTIGATOR, any SUBINVESTIGATOR or other Study personnel in the performance of the Study. All such Inventions shall be the exclusive property of the SPONSOR, and INSTITUTION and INVESTIGATOR shall assign, and shall take appropriate steps to ensure that all of its Study personnel are obligated to assign, to SPONSOR all rights, title and interests each may have in any such Invention and will cooperate to effect the foregoing.

9.8 INSTITUTION hereby certifies to SPONSOR that INSTITUTION has not used, and will not use the services of any person debarred under the Generic Drug Enforcement Act of 1992, as amended, in any capacity in connection with any of the services or work provided hereunder or for or on behalf of SPONSOR or any of its affiliates, subsidiaries or divisions and that this certification may be relied upon in any applications to the Federal Food and Drug Administration for drug approval. It is understood and agreed that this certification imposes a continuing obligation upon INSTITUTION to notify SPONSOR of any change in the truth of this certification.

9.9 So that SPONSOR may fulfill its certification and other financial disclosure obligations under 21 CFR Part 54 to the United States Food and Drug Administration and such other Applicable Laws and regulations as may from time to time be or become applicable with respect thereto, the INVESTIGATOR and each SUBINVESTIGATOR shall provide such financial disclosures to SPONSOR or CRO as SPONSOR or CRO may request, on such forms as SPONSOR may supply or as SPONSOR may approve. During the time the Study is being conducted and for one (1) year thereafter, the INVESTIGATOR and each SUBINVESTIGATOR shall update such forms promptly and provide same to SPONSOR as may be requested by SPONSOR or whenever any material change occurs in the information disclosed by a previous form.

9.10 Data Protection

(a) For Studies conducted in India, INSTITUTION and each INVESTIGATOR agree, and shall cause its agents to agree, at all times:

(i) to collect and process all data collected and relating to a Study subject ("Study Data") in accordance with the provisions of this Agreement, each Study Letter or as otherwise instructed by SPONSOR from time to time;

(ii) to comply with all Applicable Law with respect to the processing of Study Data;

(iii) to ensure that they do not collect any data relating to individuals other than the categories of data specified in the relevant Protocols and Study Letters;

(iv) to collect and process Study Data solely for the purposes of a Study and in the manner specified in the relevant Protocol and Study Letter and not to further process such data in any other manner;

(v) not to transfer Study Data collected in the European Economic Area to any person or persons located outside the European Economic Area; provided, however, that INSTITUTION or an INVESTIGATOR may transfer such Study Data in the event that it has received written notice from SPONSOR that such transfer is required or permitted by any Applicable Law or any regulatory or governmental authority;

(vi) to ensure that all Study Data are accurate and, where necessary, kept up to date and to use best efforts to ensure that Study Data which are inaccurate or incomplete are corrected or completed;

(vii) to comply with all written instructions issued by SPONSOR to anonymize the Study Data from time to time:

(viii) to ensure that it notifies SPONSOR promptly (and, in any event, within five days of receipt) of any communication received from a Study subject relating to such subject's rights to access, modify or correct Study Data and to comply with all instructions of SPONSOR in responding to such communications; and

(ix) to ensure that the technical and organizational measures specified in a Protocol and/or Study Letter are taken to protect Study Data against accidental or unlawful destruction or accidental loss or damage, alteration, unauthorized disclosure or access and against all other unauthorized disclosure or access and against all other unauthorized or unlawful forms of processing.

For the avoidance of doubt, all Study Data is Confidential Information hereunder and all of the non-disclosure and non-use obligations set forth in Article 6 shall apply to all Study Data.

INSTITUTION and each INVESTIGATOR agree to comply with its obligations (if any) under Applicable Law to notify any regulatory or governmental authority of its collection and processing activities under this Agreement and further agrees to take all such steps as SPONSOR may reasonably require from time to time in order to enable SPONSOR to comply with any such

notification obligation applicable to SPONSOR.

9.11 COMPLIANCE WITH THE LAWS.

The parties shall comply with all Applicable Laws, including the federal false claims statute (31 USC 3729) and anti-kickback statute (42 U.S.C. 1320a-7(b)) and the related safe harbor regulations and/or their respective equivalent in the country where the Study is conducted.. Accordingly, no part of any consideration paid hereunder is a prohibited payment for the recommending or arranging for the referral of business or the ordering of items or services. Further the parties understand and agree that neither this Agreement nor any consideration paid hereunder is contingent upon INSTITUTION'S use or purchase of any of SPONSOR's products. If any portion of this Agreement is found by any court or agency with jurisdiction over the subject matter hereof not to be in compliance, that portion of the Agreement shall be deemed retroactively amended and reformed as necessary to comply and the parties shall cooperate in taking such action as are necessary and desirable to ensure such compliance.

INSTITUTION agrees that it will not seek or collect, and will not assist the Study Subject in seeking or collecting, reimbursement from any health insurance plan, PPO, or governmental medical plan or other government provided health coverage available to the Study Subject for any medical expenses paid by SPONSOR pursuant to this Agreement.

9.12 INSTITUTION'S ELECTRONIC SYSTEMS

(a) SPONSOR has implemented electronic systems that assist in its analysis of data generated by clinical trials and the submission of such data to regulatory authorities. An important requirement in this process is the ability of the INSTITUTION to electronically enter, review, approve and transmit data. As part of this Study, SPONSOR will, in cooperation with INSTITUTION, evaluate INSTITUTION's electronic equipment and communication capabilities (the "Electronic Systems") to determine if they are sufficient to perform the Protocol and are compatible with SPONSOR's systems. If SPONSOR determines that INSTITUTION's Electronic Systems are either not sufficient to perform the Protocol or incompatible with SPONSOR's systems, SPONSOR will provide INSTITUTION with a laptop computer (the "Computer") and/or hi-speed internet access ("Internet Access", collectively with the Computer, the "Technology"), as applicable.

(b) The Computer shall be the property of SPONSOR. Upon completion of the Study, SPONSOR and INSTITUTION shall make arrangements for the prompt return of the Computer to the SPONSOR. For the duration of the Study INSTITUTION shall (i) take all reasonable steps to maintain the Computer in good operating condition, and (ii) keep the Computer in a secure environment. INSTITUTION shall take such precautions as are necessary to avoid damage or loss to the Computer.

(c) The Computer provided to INSTITUTION will contain all software and operating systems necessary to permit INSTITUTION to perform the Study according to the Protocol and in a manner compatible with SPONSOR's systems. At no time during the term of this Agreement may INSTITUTION install or use any additional software programs on the Computer. Further, INSTITUTION shall neither during the pendancy of this Agreement or thereafter, claim any rights

over such software and operating systems nor permit any third party access to the same, unless permitted in writing by the SPONSOR.

(d) SPONSOR shall provide INSTITUTION with Internet Access for the duration of the Study if deemed necessary for the conduct of the Study. If Internet Access is provided, SPONSOR shall, during the term of the Study, either (i) pay the selected internet service provider directly for such access or (ii) reimburse INSTITUTION for costs actually incurred by INSTITUTION provided such reimbursement is limited to the amount SPONSOR would have paid to the internet service provider had SPONSOR paid internet service provider directly. Upon completion of the Study or expiration or termination of the Agreement, SPONSOR's/CRO's obligation to pay for or reimburse INSTITUTION for such services shall cease and INSTITUTION shall have full and sole liability for such costs. Notwithstanding the foregoing, any costs incurred by INSTITUTION in excess of the basic Internet access fee shall be the sole responsibility of the INSTITUTION.

(e) INSTITUTION may not use the Technology for any purpose other than performance of the obligations required by the Protocol, as set forth in this Agreement and the Protocol. INSTITUTION shall allow only those people directly involved in the conduct of the Study access to the Technology. SPONSOR agrees to provide INSTITUTION with maintenance and repair service for the Technology during the Study. At no time shall INSTITUTION attempt to repair, fix or correct any errors or technical problems related to the Technology.

Shilpi

IN WITNESS WHEREOF, INSTITUTION , SPONSOR and CRO have caused this Agreement to be executed in multiple counterparts by their duly authorized representatives.

Bristol-Myers Squibb India Private Limited

By: Shilpi

Name: SHILPI SINHA

Title: SR. SITE MANAGER

Date: 23/11/2016

MGM Medical College & Hospital

By:

Name: Dr. A G Shrotri

Title: Dean

Date: 09-11-2016

MGM's Medical College * Aurangabad *

PPD Pharmaceutical Development India Private Limited

By: 21NOV2016

Name: Rashmi Chitgupi
Associate Director - Clinical Management
PPD Pharmaceutical Development India Pvt. Ltd.
01- Dynasty, B-wing (Kanakia Spaces)
Andheri - Kurla Road, Andheri East
Mumbai - 400 059. India.

Title:

Date:

I HAVE READ AND UNDERSTAND THE ABOVE AGREEMENT AND AGREE TO ABIDE BY THE TERMS THEREOF:

Dr. Girish Namdeorao Gadekar (INVESTIGATOR)

DATE 22/09/2016

DR. GIRISH N GADEKAR
D-ORTHO. M.S. (ORTHO)
ASSO. PROF. & HOD
MGM HOSPITAL,AURANGABAD
Reg. No.2001020830

Shilpi

EXHIBIT A

PAYMENT SCHEDULE

CV185-158

TITLE OF STUDY:	"A Phase IV, Open-Label, Multi-center Study to Evaluate the Safety of Apixaban in Indian Subjects Undergoing Elective Total Knee Replacement or Total Hip Replacement Surgery"
SPONSOR:	BRISTOL-MYERS SQUIBB COMPANY
INVESTIGATOR:	Dr.Girish Namdeorao Gadekar, Consultant Orthopedician
PAYEE & ADDRESS	Ardent Clinical Research Services Regus, Level-2, Connaught Place, Bund Garden Road Pune, India, 411001

This Payment Schedule includes all costs associated with the conduct of the Study, including, but not limited to, all procedures as presented in the Protocol's Time & Event Schedule; administrative fees; pharmacy fees; laboratory fees; Investigator & Study Coordinator work effort; and overhead costs.

Payment Summary

Payment For All Completed Study Subjects	**INR 1,920,000**

Other Payments

Screen Failure (SF) Payment	same as Screening visit fee
Final Payment	10% of Total Cost Per Subject

Items Paid By Invoice

Symptomatic VTE (PE/DVT) Assessments	Per Invoice
Audio-Video Consenting Equipment	Per Invoice
Unscheduled Visit Payment	Per Invoice
Payment for Recruitment and Retention Activities	Per Invoice
Additional Travel Reimbursement	Per Invoice
IRB Fees	Per Invoice

Payment Details

Subject Care Payment (excludes other payments and invoice-driven payments):

I. **Subject Care** (based on visit driven payments as described below)

a. 30 Subjects X INR 64,000 per Completed Subject = INR 1,920,000

b. **Written permission must be obtained from Sponsor or its designee prior to enrolling additional Study Subjects beyond 30 (thirty)**. The budget will be adjusted for any decrease or agreed-upon increase in the contracted number of Subjects enrolled according to the per Subject cost herein.

c. Payments for Subject care will be made **Quarterly** (i.e. every 90 days) for each Subject visit after source document verification for the visit by Sponsor or its designee for the visits, as noted below.

i. The first quarterly payment will be made 90 days after the First Patient First Visit (FPFV-based on visits occurred and eCRFs completed. Quarterly payments will continue to be generated every 90 days thereafter, provided that eCRFs are received by Sponsor or its designee and there is an amount owed.

ii. Each completed eCRF is noted in TAO as "Save Complete" under the Summary tab. (Note: marking the eCRF as being complete implies that you have met the requirements of the form and consider your responses complete).

iii. Data entry into TAO eCRFs should be completed within **5** business days of a Subject completing each visit.

iv. Queries must be resolved within **5** business days of receipt (both during the Study and after completion of the Study). Queries must be resolved within 48 hours during database lock and interim data cuts.

v. Ten percent (10%) of the amount per visit stated in the visit schedule below will be withheld from each payment. The total withheld amount will be paid pending resolution of all outstanding items as described in the section of the budget titled "Final Payment".

Visit Name	Cost (Rs)
Pre Randomization	15,000
Randomization/Pre Surgery	10,000
Surgery Day 1	6,000
Day 2	6,000
Hospital Discharge	7,000
Day 7 +/- 2 Days	6,000
Day 12 (or Day 35 for THR subj.)	7,000
Follow up Day 42 (or 65 for THR subj.)	7,000
Total Cost Per Completed Patient with 20% OH	64000

All visits above are inclusive of study personnel work effort.

d. For enrolled Subjects who discontinue from the Study early, payments will be made according to the above visit schedule based on Sponsor's or its designee's receipt of completed eCRFs.

Other Payments (Paid by eCRFs, Report, etc.)

II. **Screen Failure Payment**

a. Compensation for Screen Failures will be at the same rate as Screening visit amount per Screen Failure. A Screen Failure is defined as any Subject who signs an Informed Consent Form and completes the screening procedures, but fails to meet the criteria for entry into the next phase of the Study, as set forth in the Protocol.

b. The maximum number of Screen Failures allowed is based on the following table:

Total No. of Subjects Randomized	Number of Screen Failures Paid
0 - 10 Subjects	1
11 - 20 Subjects	2
21 - 30 Subjects	3
31 - 40 Subjects	4
41 - 50 Subjects	5
51 - 60 Subjects	6
61 - 70 Subjects	7
71 - 80 Subjects	8

81 - 90 Subjects	9
91 - 100 Subjects	10

c. All Screen Failure payments will be made upon the completion of the Randomized phase of the Study and based on a Sponsor's or its designee's internal report. As per prevailing service tax regulation, PPD India will not be able to make any payments for screen failures until a service tax valid invoice is received.

III. **Final Payment**

a. The Final Payment will be made upon completion of the last patient, last visit, but only after (1) all eCRFs are completed and have been approved by the Investigator, and submitted to Sponsor or its designee; (2) unused clinical supplies have been returned to Sponsor or its designee, or destroyed on site, or transferred to another Study or Study Site by Sponsor or its designee; (3) the Study Site has duly completed and submitted all required forms and logs reconciling receipt, dispensing, and use and return of the Study drug; and (4) all data queries/questions have been resolved. Final financial reconciliation will occur within 60-90 days after completion of the Study.

b. Final Payment is automatically generated by Sponsor or its designee. As per prevailing service tax regulation, PPD India will not be able to make any payments for final payment until a service tax valid invoice is received.

IV. **Study Drug(s)**

a. All Study Drug(s) will be provided by Sponsor or its designee to the participating Institution.

Items Paid By Invoice

V. **SOC (Standard of Care) and Invoice Requirements**

a. All procedures listed below this section may or may not be considered as SOC (Standard of Care). If for any reason these procedures listed below are not considered SOC at your site, a detailed **Invoice** must be forwarded to the Sponsor or its designee in order to receive payment

b. The Sites must submit detailed **Invoices** to reflect the exact visit where procedures/scans have been performed for Clinical Team's review/approval and for check payment description purposes.

VI. **Symptomatic VTE (PE/DVT) Assessments**

a. If the following Assessments are performed, as required by the Protocol or, as clinically indicated, the Site will be paid at the fixed amounts indicated below upon Sponsor's or its designee's receipt of a clear and itemized invoice:

PROCEDURE	COST (Rs)
CT of Chest/Thorax	33321.60
Pulmonary Ventilation and Perfusion Scan (Lung Scan)	33321.60
Duplex Scan of Lower Extremity arteries (femoral or other) Complete Bilateral Study (B mode Ultrasonography with integrated color flow doppler.	20048.40
Pulmonary Angiogram	2797.92
Venography	39021.75
Complete Extremity Ultrasound	9205.17
Bilateral Extremity Angiography	33321.60
ECG	720.00

VII. **Audio-Video Consenting Equipment**

a. One time charges for Audio-Video consenting equipment up to and not exceeding **INR 50,000** (Rupees fifty thousand only) would be paid to the site upon receipt of invoice. In case the Audio-Video consenting equipment is provided by Sponsor or its designee this amount cannot be claimed by the site.

VIII. **Local Taxes**

a. All payments will be made after deduction of tax at source as applicable and subjected to receipt of original invoices.

b. Service tax as per prevailing government regulation will be applicable on the visit based payment and must be included in a separate, valid invoice.

IX. **Unscheduled Visit Payment**

a. Unscheduled safety visits arising as a result of Subject's participation in the Study will be paid at the maximum rate of **INR 3,625.00** per Subject, per visit.

b. Payments for unscheduled safety visits described above will be made upon Sponsor's or its designee's **receipt of invoice from the Site.**

X. **Additional Travel Reimbursement** ***(For Subjects Traveling over 150 Miles or 240 Kilometers, Round-Trip)***

a. Study-related travel expense for a scheduled Site visit is already included in the total cost per visit. However, for Subjects who may be traveling over 150 miles (240 km) round-trip or more than 75 miles (120 km) each way, the Site may be reimbursed additionally for reasonable travel expenses directly related to the Subject's

participation in the Study (such as air transportation, additional meals, overnight lodging, etc.). The reimbursement amount (per mile/km) will be based on the current IRS' medical-research-rate.

b. In order to be reimbursed for these travel expenses, Sponsor or its designee must receive reasonably detailed invoice(s) (including all supporting documentation or receipts) for actual travel expenses incurred by the Subject.

c. Prior approval from Sponsor or its designee must be secured before allowing any study –related travel expenses for Subjects traveling 150 miles (240 km) round-trip.

XI. Payment and Submission of Invoices

a. Invoice driven payments shall be made within 50 days of receipt of an invoice.

b. All outstanding invoices must be submitted to Sponsor or its designee no later than 50 days of the last patient, last visit at the Site.

c. To avoid delay in payment processing, **all** invoices must contain the following information:

- Invoice Number
- Protocol Number
- Site Number
- Institution Name
- Investigator Name
- Payee Name & Address
- Service tax number of the Institution
- Category of the Service

d. All invoices must be submitted to Sponsor via:

PPD Pharmaceutical Development India Private Limited,
101-A Wing Fulcrum,
Hiranandani Business Park,Sahar Road
Andheri East,Mumbai – 400 099

XII. Additional Terms and Conditions:

a. Enrollment/Recruitment will end once this Study's Enrollment/Recruitment goals have been achieved. If the Study is prematurely terminated, the total payment hereunder will be made only for those enrolled/recruited/randomized and evaluable Subjects who were enrolled/recruited/randomized in accordance with the above fee schedule for Study visits completed at the time of the termination notice and upon receipt of completed eCRFs by Sponsor or its designee. Payee agrees to refund any excess amount previously paid, and Sponsor agrees to pay any amount owed based

on the receipt of acceptable eCRFs by Sponsor or its designee along with the resolution of all queries/questions relating to the Study.

b. No additional funding requests will be considered without the prior written consent of Sponsor or its designee.

APPENDIX B

PPD

Payment Authorisation Form for Vendors

To be completed by the investigator or payee

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 (CTMS Field) (Finance Field)	**Payee or Investigator Information**	Max Chars for Finance Field Incl. Spaces
Payee Name *(in terms of the provisions of the Statement of Agreement):*	**Ardent Clinical Research Services**	80
(To whom should the cheque or transfer be made payable to?) **N.B. This must be the exact payee as it appears on the bank account**		
Street Address of Payee (Address Line 1) (Address 1)	**Regus, Level-2**	30
Department Name (if applicable): (Address Line 2) (Address 2)	**Connaught Place**	30
Room / Floor (if applicable) (Address Line 3) (Address 3)	**Bund Garden Road**	30
Other Address Details (if applic.) (Address Line 4) (Address 4)	**Pune**	30
Country (Country) (Country)	**India**	2 *ISO Code*
State / Province (if Applicable) (State / Province) (State or Province)	**Maharashtra**	2
Town/City (City) (City or Address 5)	**Pune**	18
Postal Code (Zip/Postal Code) (Postal Code)	**411001**	10
Contact name for payee if different from above	**Mr. Chandu Devanpally**	30
Telephone	**09545817447**	27
Fax		27

E-mail	**cdevanpally@ardent-cro.com**	60
Web page	**www.ardent-cro.com**	60

Service / VAT / Tax Withholding Details

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

Service / VAT / Sales Tax

Are you Service Tax / VAT / Sales Tax registered?	**YES**		*Delete where applicable*

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

Service Tax / VAT number, if known	**APQPD7081MSD001**
At what % rate will Services Tax / VAT / Sales Tax be charged?	**15% or as applicable**

Tax Withholding

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

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

PAN ID number Please provide a copy of the PAN Card. In case you are exempt from TDS please provide IT certificate	APQPD7081M

Payment Method required

What is your preferred payment method?	**Cheque**		*Delete where applicable*

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

Preferred

IBAN Number	
BIC Number	

Or

PPD

APPENDIX B

Payment Authorisation Form for Vendors

To be completed by the investigator or payee

Bank Account Number	**50200007013912**		
Sorting Code *(For UK only)*		**Branch number/Bank code**	
RTGS/NEFT code:	**HDFC0000825**		

Bank Details

Bank name:	**HDFC Bank**		
Address:	SUVIDHA RESIDENCY, UNIT NO 101,102 SHOP NO 1,2,AND 3,HISSA NO 5/1 TO 5/6,PLOT NO 1,HINGRE KHURD PUNE MAHARASHTRA		
City	**Pune**	**Postal Code**	**411051**
Country:	**India**	**Private or Public Bank Account:** *(Belgium and France only)*	

Declaration

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

Investigator/Institutional Signatory	
Name in print	DR GIRISH N. GADEKAR
Date (dd/mmm/yyyy)	22/09/2016

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)*	**India**
In what currency is the Statement of Agreement defined	**INR**

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 *Contact/Account – More Info View*	**Vendor Number** *Contact/Account – Addresses View*	**Remittance Code** *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		