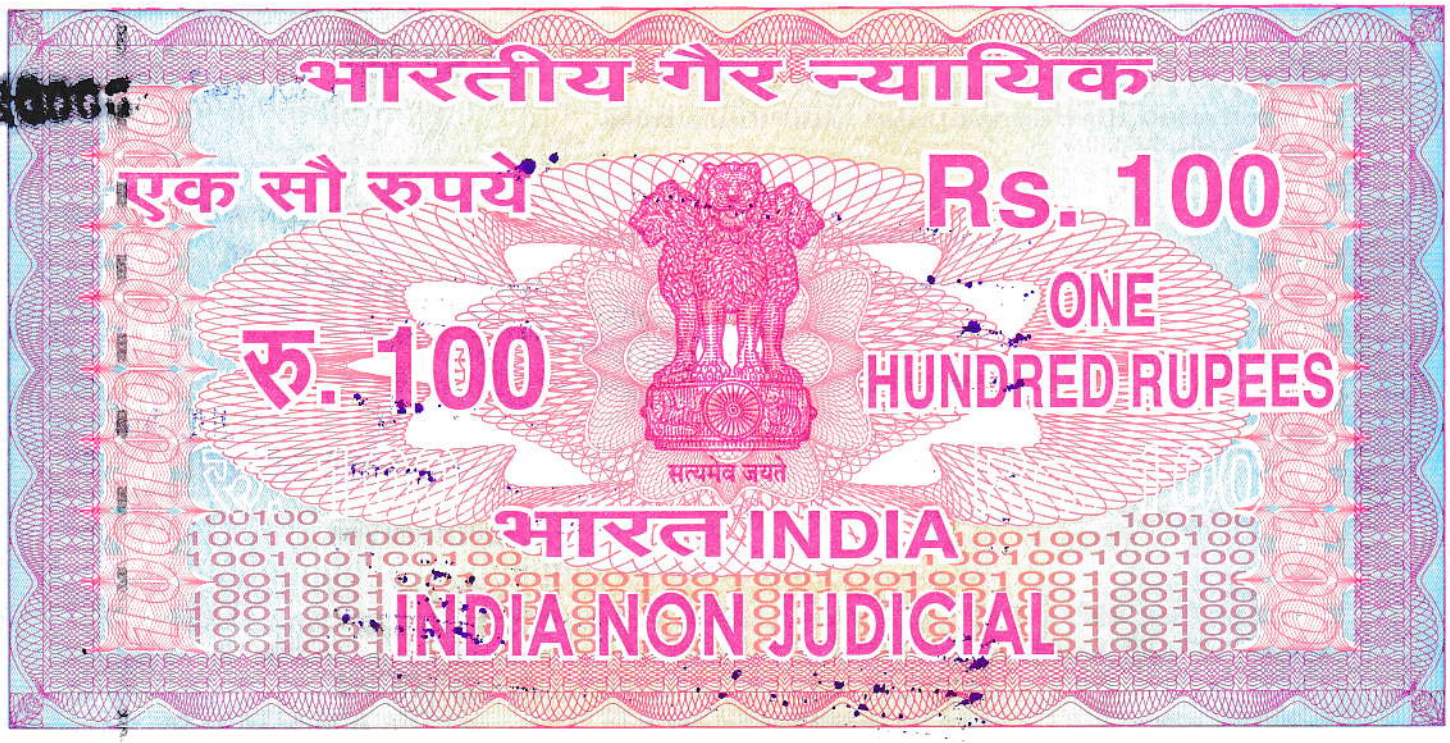

महाराष्ट्र MAHARASHTRA ◑ 2017 ◑ SE 665317

प्रधान मुद्रांक कार्यालय, मुंबई
प.म.कि.क. / 000095
- 4 JUL 2017
सक्षम अधिकारी

श्री. प्र. ना. चिंचघरे

CLINICAL TRIAL AGREEMENT

This **CLINICAL TRIAL AGREEMENT** (the "Agreement") is effective as of the date of last signature (the "Effective Date"), by and among;

Mahatma Gandhi Mission's Medical College and Hospital located at N-6, Cidco, Aurangabad-431003, Maharashtra, India (the "Institution"),

-and-

Dr. Deepak Bhosle, an employee of the Institution, acting within the scope of his/her employment, located at N-6, Cidco, Aurangabad-431003, Maharashtra, India, who shall serve as the principal investigator ("Investigator") for the Study as defined below. The Institution and the Investigator may be collectively referred to as the "Site".

11 JUL 2017

जोडपत्र - १ Annexure - I

फक्त प्रतिज्ञापत्रासाठी Only for Affidavit

मुद्रांक विकत घेणाऱ्याचे नाव _____

मुद्रांक विकत घेणाऱ्याचे रहिवाशी पत्ता _____

मुद्रांक विक्रीबाबतची नोंद वही अनु. क्रमांक _____ दिनांक _____

PHARMACEUTICAL RESEARCH ASSOCIATES INDIA PVT. LTD.
The Qube, A-609, C.T.S. No. 1498 A/2, M. V. Road, Marol, Andheri (East),
Mumbai - 400 059. India

मुद्रांक विकत घेणाऱ्याची सही

परवानाधारक मुद्रांक विक्रेत्याची सही 11 JUL 2017

परवाना क्रमांक : ८०००१५

मुद्रांक विक्रीचे ठिकाण/पत्ता : अंधेरी कोर्ट आर अशोसिएशन

एन. एल. कोर्ट, अंधेरी रेल्वे स्टेशनच्या बाजुला,

अंधेरी (पूर्व), मुंबई - ४०० ०६९.

शासकीय कार्यालयाकरिता /कोर्टासाठी सादर करण्यासाठी मुद्रांक कागदाची आवश्यकता नाही. (शासन अधि. क्र. मि. ०१/०९/२००४ दुरुस्ती)

टीप: ज्या कारणासाठी ज्यांनी मुद्रांक खरेदी केला त्यांनी त्याच कारणासाठी मुद्रांक खरेदी केल्यापासून ६ महिन्यात वापरणे बंधनकारक आहे.

PRAHEALTHSCIENCES

-and-

Grapecity Research Solutions LLP, Site Management Organization located at D/2, Prakash Hsg Society, Thergaon, Near Kalewadi Fata, Pune- 411033, Maharashtra, India, shall serve as the site management organization (the "SMO") who will provide the Institution and the Investigator certain clinical trial related services *in relation to the study as defined below.*

-and-

Pharmaceutical Research Associates India Private Limited located at The Qube, A-602 and A-603, C.T.S. No. 1498 A/2, M.V. Road, Marol, Andheri (East), Mumbai - 400 059, India ("PRA").

ASTRAZENECA AB located at 151 85 Södertälje, Sweden (the "Sponsor") will assume the role of sponsor with respect to the Study identified below and has retained PRA (under a separate written agreement) to serve as the Sponsor's contract research organization to manage the Study on its behalf.

1. STATEMENT OF WORK.

(a) The Investigator will conduct the clinical research study entitled "***A 26 Week, Multicenter, Randomized, Placebo-Controlled, Double-Blind, Parallel Group, Phase 3 Trial with a 26 Week Safety Extension Period Evaluating the Safety and Efficacy of Dapagliflozin 5 and 10 mg, and Saxagliptin 2.5 and 5 mg in Pediatric Patients with Type 2 Diabetes Mellitus who are between 10 and below 18 years of age***" (the "Study"), bearing protocol number D1680C00019, as may be amended from time to time (the "Protocol"), the provisions of which are incorporated herein by reference. The Investigator shall perform the Study in conformance with: (i) generally accepted standards of good clinical practice, (ii) an ethical manner and in a manner that appropriately protects the safety, security, and well-being of the Study subjects and any data arising from the Study (iii) the Protocol, (iv) the FDA Form 1572, and (v) all applicable laws, rules and regulations governing the conduct of the Study and the activities or interactions under this Agreement, including, but not limited to the Indian Drugs and Cosmetics Act, 1940, the Indian Drugs and Cosmetics Rules, 1945, and any other guidelines and notifications issues by the Central Drug Standard Control Organisation (as may be amended from time to time) and DCGI Guidelines on Audio Visual Recording of Informed Consent, as applicable to the conduct of the Study. The Institution shall not reassign the conduct of the Study to another investigator without Sponsor's express written consent. If the Investigator is unable to perform the duties required by this Agreement, the Institution shall promptly notify PRA and the Sponsor in writing. If a mutually acceptable replacement is not available, this Agreement may be terminated as provided herein.

(b) The Institution and SMO shall provide appropriate resources and facilities so the Investigator can conduct the Study in a timely and professional manner and according to the terms of this Agreement. The Site and SMO shall ensure that only individuals who are appropriately trained and qualified will assist in conducting the Study. The Site and SMO are responsible for ensuring that all personnel participating in the Study ("Study Team") comply with the terms of this Agreement, excluding personnel supplied by PRA or Sponsor. Institution, Investigator and SMO agree to promptly notify PRA and the Sponsor in the event any Study Team member is reported to or comes under investigation by any regulatory authority, licensing board, independent ethics committee or institutional review board, and further agrees to promptly discontinue the use of any such personnel in connection with the

PRAHEALTHSCIENCES

Study unless the Sponsor consents in writing to the continued use of such personnel. Unless otherwise agreed to in writing by the parties, the Site and SMO shall conduct the Study only at the facilities indicated in this Agreement.

(c) Investigator and/or Study Team may be invited to attend and participate in meetings relating to the Study. The parties agree that there will be no additional compensation for attendance or participation at such meetings by the Investigator or any Study Team. If the Investigator and/or Study Team are required to perform any additional tasks, over and above those required for the conduct of the Study, the terms and obligations for the provision of such services shall be subject to a separate agreement.

2. PAYMENT.

(a) PRA will pay the SMO according to the Payment Terms attached hereto as Exhibit A ("Payment Terms") and the Budget attached hereto as Exhibit B ("Budget"), upon receipt of invoices and other appropriate documentation as specified therein. Payments due hereunder are pass-through payments from Sponsor that will be sent after such payments are received by PRA from Sponsor. PRA shall exercise reasonable efforts to ensure timely receipt of pass-through payments from Sponsor.

(b) The Institution and the Investigator appoints the SMO as their duly designated payee, authorized to receive Study payment of their behalf ("Payee"). The Payee shall provide full payment instructions and bank details, in writing to PRA in the Payment Information Checklist ("PIC"), before any payment can be made. The Payee is obliged to inform PRA, in writing, of any changes or required updates of payment instructions and/or bank details. The parties agree that any change of or update to the Payee's bank details contained in the PIC may be effected through a written notice and shall not of itself require a formal Amendment to this Agreement. The Institution, Investigator and SMO agree and acknowledge that any payment made by the Sponsor or PRA to the Payee shall be deemed payment to the Institution and/or the Investigator and/or SMO and the Institution, Investigator and SMO shall have no recourse from PRA or Sponsor.

(c) The Site is an independent contractor, and the SMO shall be deemed an agent of the Site and neither PRA nor Sponsor is responsible for any employee benefits, pensions, workers' compensation, withholding, or employment-related taxes as to the Site, SMO or any of their personnel.

(d) The Investigator and any sub-investigators will complete and sign a financial disclosure form when reasonably requested to do so by PRA or Sponsor. These forms shall be promptly updated as needed to maintain their accuracy and completeness during the Study and for one year after its completion.

(e) The Site and SMO hereby agree that no third party will be charged for any aspect of treatment or subject care for which the Payee has invoiced or been paid under this Agreement. The Institution hereby agrees that neither participants in the Study nor any third party will be charged for **Saxagliptin, Dapagliflozin and placebo** (the "Study Drug") or any comparator drugs provided for this Study, nor shall Payee include such cost in any cost report to third-party payers.

(f) Unless otherwise agreed herein, payments will be made for evaluable subjects and for eligible subjects only. An eligible subject is one who meets all of the inclusion requirements and does not meet any of the exclusion criteria of the Protocol, who was enrolled by Investigator, and from whom informed

PRAHEALTHSCIENCES

consent has been obtained. An evaluable subject is one for whom case report forms ("CRFs") have been properly completed in accordance with the Protocol, and who has completed the appropriate Study procedures as set forth in the Protocol, and undergone the evaluations required by the Protocol.

(g) The parties acknowledge and agree that the compensation provided for Site's performance under the Agreement represents the fair market value for the services conducted by Site and has been agreed independently from any business the Institution or the Investigator has made or may make in relation to the ordering of products or services of the Sponsor.

3. RECORDKEEPING; REPORTING; ACCESS.

(a) Authorized representatives of Sponsor and/or PRA have the right, upon reasonable advance notice, and during regular business hours, to: (i) audit and examine the Site's facilities required for performance of the Study; and (ii) review all data, records and work products relating to the Study, and if necessary, make copies of such data, records and work products, provided such copies do not include any unauthorized individually-identifiable information of a Study subject. The Site shall maintain complete and accurate records related to the Study, and shall retain all such records resulting from the Study for fifteen (15) years or later if required under applicable laws and regulations.

(b) The Investigator will deliver CRFs to PRA within fourteen (14) days of Investigator's review or in accordance with PRA's reasonable written instructions, as the case may be. The Investigator shall be available at reasonable times during normal business hours to meet with Study monitors and answer questions regarding the conduct of the Study. If PRA must use or access the Site's computer systems, it will do so in accordance with the Site's instructions and will only use acquired information for the purpose of the Study and in accordance with applicable laws.

(c) The Site and SMO will promptly notify Sponsor and PRA if any regulatory authority notifies the Institution or Investigator of a pending inspection or makes any written or oral enquiries relating to the Study, and will promptly forward to Sponsor and PRA copies of any written communication received as a result of such inspection or enquiry which are related to the Study. The Site and SMO shall also provide to Sponsor and PRA copies of any documents provided to any inspector that relate to the Study.

4. CONFIDENTIALITY.

The Protocol, Study Drug(s) (including Study Documentation and Intellectual Property (as defined in Clause 7), CRFs, and any and all information, data, reports or documents, disclosed to or generated by the Site or any Study Team members regarding the work performed under this Agreement (other than subject medical records) or which otherwise relates to this Study ("Confidential Information") belong to Sponsor in accordance with clause 7 below and shall not be disclosed by the Site or SMO to any third party or be used for any purpose other than the performance of the Study without the prior written consent of Sponsor, during a period of ten (10) years after the termination of the performance of the Agreement. The above obligations of confidentiality shall not apply to the extent Confidential Information:

(a) is or becomes, through no fault of the Site or SMO, part of the public knowledge;

PRAHEALTHSCIENCES

(b) the Site or SMO can demonstrate was already lawfully in the Site or SMO's possession on the date of disclosure to the Site or SMO and not subject to prior confidentiality obligations;

(c) is acquired by the Site or SMO from any third party without restrictions on disclosure; or

(d) is developed by the Site or SMO independently, without the use or benefit of Confidential Information, and as evidenced by competent written records.

Permitted Disclosures. The Site and SMO's obligations of non-disclosure and non-use of Confidential Information shall not apply to the extent the Site and SMO are required by law to disclose Confidential Information, provided the Site or SMO promptly notifies Sponsor of such a requirement prior to disclosure to allow Sponsor the reasonable opportunity to oppose the requirement or seek an appropriate protective order. This Section 4 does not limit the Site and SMO's rights or obligations under Section 6 Publication.

5. PRIVACY AND DATA PROTECTION.

The parties agree that each will comply with their respective obligations as required under applicable privacy and data protection laws. The Institution, SMO and Investigator will obtain the consent of each Data Subject, and the Investigator will provide his/her consent and will obtain the Study Team members' consent with regard to their own personal data, to the use, processing, holding and transfer of their data to countries other than their own, that may not have the same level of data protection as their own country. . The Investigator and the Study Team have the right to access and correct their personal data. In order to exercise this right, the requests should be addressed to the Sponsor and PRA.

6. PUBLICATION.

(a) SMO shall have no publication rights over the Study. The Institution and the Investigator shall be entitled to publish the results of, or make presentations related to, the Study, provided that any publications or presentations to be made within 2 years of completion of the Study shall require the Sponsor's prior written consent. All such publications or presentations shall (i) be consistent with academic standards and International Committee of Medical Journal Editors guidelines, (ii) not be false or misleading, (iii) comply with all applicable laws, (iv) not be made for any commercial purpose.

(b) The Institution and/or the Investigator shall provide the Sponsor with copies of any materials relating to the Study, or the Developed Technology (defined in clause 7 below) that either intends to publish (or submit for publication) or make any presentations relating to, at least thirty (30) days in advance of publication, submission or presentation.

(c) At the request of the Sponsor and/or PRA, the Institution and/or the Investigator:

(i) shall not include in or shall remove from any proposed publication any Confidential Information, errors or inaccuracies; and

(ii) shall withhold publication, submission for publication or presentation for a period of ninety (90) days from the date on which the Sponsor receives the material to allow the Sponsor to

PRAHEALTHSCIENCES

take such measures as the Sponsor considers necessary to preserve its proprietary rights and/or protect its Confidential Information.

(iii) The Institution and the Investigator shall include the following acknowledgement in all publications and presentations relating to the Study, the Study Documentation or Developed Technology, as well as in any financial disclosure information relating to the Study: "AstraZeneca sponsored this clinical trial."

(iv) The Sponsor has a long-standing commitment to transparency, and the Institution and the Investigator acknowledge that the Sponsor shall post the Study on clinical trial registries and publish the results on clinical trial results databases in such format (including www.astrazenecaclinicaltrials.com), and/or provide such results to the regulatory authorities.

(v) If the Sponsor invites the Investigator to be an author of a Sponsor-managed publication, the Investigator shall direct, draft and/or review the proposed publication, and approve the final version of the publication to be published. No compensation shall be provided in respect of any such authorship. Any authorship, medical writing, editorial or logistical support provided to the Investigator or the Institution by the Sponsor in respect of publication shall be subject to the Sponsor's publications policy, details of which are available at www.astrazeneca.com.

7. INTELLECTUAL PROPERTY RIGHTS.

(a) Except as expressly set out in this Agreement, no party nor the Sponsor shall acquire any right, title or interest in or to the Intellectual Property of any of the other parties or the Sponsor or their licensors.

(b) The Sponsor shall own all rights and title in any Intellectual Property arising from the Study or relating to the Study Drug, any Developed Technology and the Study Documentation, except to the extent that the Institution and Investigator are required to retain any Study Documentation in accordance with the International Conference on Harmonisation Guideline for good clinical practice (including any modification or re-enactment thereto) and the applicable laws and regulations. The Institution, the Investigator and/or SMO shall promptly disclose any such Intellectual Property to the Sponsor and PRA in writing or in such other format as the parties may agree.

(c) To the extent capable of prospective assignment, the Institution, Investigator and SMO hereby assign to the Sponsor (or its Designee) all their rights, title and interest in and to all Intellectual Property falling within Clause 7(b) above. To the extent that any such Intellectual Property cannot prospectively be assigned, the Institution, Investigator and/or SMO shall assign, and shall procure that the Study Team shall assign, such Intellectual Property to the Sponsor (or its Designee) on creation.

(d) The Institution, Investigator and/or SMO shall, and shall ensure that the Study Team take all steps as the Sponsor and/or PRA may reasonably require from time to time in order to enjoy the full benefit of the rights assigned under this Clause 7.

(e) The Sponsor grants to the Institution a perpetual, royalty-free non-exclusive licence to use the Intellectual Property arising only from the Study for internal research and educational purposes only, and with no right to grant sub-licences. The SMO shall have no such rights. The provisions of Clauses

PRAHEALTHSCIENCES

4 and 6 of this Agreement shall continue to apply in relation to any such licence.

(f) The capitalised terms set out below that are referred to in this Clause or other parts of this Agreement shall have the following meanings:

(1) "**Designee**" means any person designated by the Sponsor in writing who undertakes activities on behalf of the Sponsor in relation to the Study, which may include an affiliate or PRA.

(2) "**Developed Technology**" means any inventions, discoveries, improvements or developments made by the Institution, the Investigator or any Study Team (whether solely or jointly with others) in the course of or as a result of the Study and that are directly related to the Study Drug, or the use thereof.

(3) "**Intellectual Property**" means any and all rights in and to ideas, formulae, inventions, discoveries, know-how, data, databases, documentation, reports, materials, writings, designs, computer software, processes, principles, methods, techniques and other information, including patents, trademarks, service marks, trade names, registered designs, design rights, copyrights and any rights or property similar to any of the foregoing in any part of the world, whether registered or not, together with the right to apply for the registration of any such rights.

(4) "**Study Documentation**" means all records, accounts, notes, reports, data and ethics communications (submission, approval and progress reports), collected, generated or used in connection with the Study and/or Study Drug, whether in written, electronic, optical or other form, including all recorded original observations and notations of clinical activities such as CRFs and all other reports and records necessary for the evaluation and reconstruction of the Study.

8. MATERIAL TRANSFER; RETURN OF MATERIALS; EQUIPMENT.

(a) During the Study, Sponsor or Sponsor's designee shall provide to the Site, at Sponsor's expense, the Study Drug, placebo and other compounds, or agents for the performance of the Study (collectively, the "Materials"). The Materials will be used only by the Site for performance of the Study in accordance with the Protocol and this Agreement. The Site shall handle, store, and ship or dispose of Materials in accordance with the Protocol and any reasonable written instructions provided by Sponsor (or Sponsor's designee), and in compliance with all applicable, local and national laws, rules and regulations including, but not limited to, those governing hazardous substances.

(b) Unless otherwise agreed by the parties, in the event that the Protocol for a Study requires the collection of blood, tissue or other biological materials from subjects ("Biological Materials") the site and SMO agree that the use of such Biological Materials shall be limited to those tests, analyses or procedures identified in the Protocol and informed consent as approved by the IRB/EC.

(c) Upon completion or termination of the Study, all Materials furnished to the Site by Sponsor or Sponsor's designee shall be promptly returned or destroyed as directed by PRA. Shipping costs relating thereto will be paid by PRA.

PRAHEALTHSCIENCES

(d) If Sponsor provides equipment to the Site, such equipment shall be used only by the Site for the performance of the Study and in accordance with any written instructions of use provided by the equipment manufacturer or Sponsor. Such equipment is property of the Sponsor or Sponsor's designee and shall be returned, at Sponsor's expense, to Sponsor (or Sponsor's designee), upon Sponsor's written request or upon completion of the Study. The equipment to be provided is listed at Exhibit C. Site will use reasonable care to maintain such equipment while in its possession, provided that Sponsor shall be responsible for maintenance and repair costs due to normal wear and tear. If Institution and/or Investigator do not return the equipment, the fair market value of the equipment, as determined by Sponsor or Sponsor's designee, will be deducted from the final payment.

9. TERM; TERMINATION.

(a) This Agreement shall commence on the Effective Date and shall continue in force until the Study has been completed at the Site.

(b) This Agreement may be terminated by the Sponsor or PRA at any time and for any reason upon thirty (30) days written notice, or immediately upon written notice by any party where such party, on reasonable grounds, believes the Study should cease in the interests of health, safety or well-being of Study subjects.

(c) Upon the effective date of termination of this Agreement, an accounting shall be conducted by the Site, subject to verification by PRA. Following PRA's receipt of adequate documentation, PRA will pay for:

(i) all services properly rendered and monies properly expended by the Site, through the effective date of termination which have not yet been paid by PRA; and

(ii) non-cancelable obligations properly incurred for the Study by the Site prior to receipt of notice of termination.

(d) If the Site has been paid any amounts which have not been earned hereunder as of the date of termination, the Institution shall promptly return to PRA all such unearned funds within 30 days.

(e) Immediately upon receipt of a notice of termination, the Investigator shall stop screening and enrolling subjects into the Study and shall, as directed by PRA, cease conducting Study procedures on subjects already enrolled in the Study, to the extent medically permissible, and to cease, to the extent reasonably feasible, from incurring any additional Study expenses.

(f) The SMO shall have no termination rights over this Agreement.

10. INSURANCE.

The parties acknowledge that Sponsor will ensure adequate provision is made by way of insurance or indemnity arrangements sufficient to meet its obligations and liabilities under applicable laws as the sponsor of the Study, in particular towards Study subjects for personal injury arising as a result of

PRAHEALTHSCIENCES

participation in the Study.

11. STATUS OF SPONSOR.

In order to satisfy pre-existing contractual obligations owed by PRA to the Sponsor, the parties agree that the Sponsor and its affiliates are the intended third-party beneficiaries of the rights under this Agreement, and accordingly has concomitant enforceable rights in relation to this Clause. The parties acknowledge that conferring third-party beneficiary status upon the Sponsor and its affiliates is a direct and material purpose of the parties entering into this Agreement. Rights under this Clause 12 cannot be modified without the Sponsor's consent. To the extent applicable law does not allow vesting of any rights directly in Sponsor under this Agreement, such rights will vest in PRA, on Sponsor's behalf and PRA may grant licenses to the Sponsor to effect such rights.

12. CERTIFICATIONS.

(a) The Institution, Investigator and SMO hereby individually certify that they have not been debarred or disqualified from participating in clinical research under any laws or regulations. If during the term of this Agreement, the Institution, Investigator or SMO (i) becomes debarred or disqualified or (ii) receives notice or threat of an action with respect to its debarment or disqualification, the Institution, Investigator or SMO, as the case may be, shall notify PRA immediately.

(b) The Institution, Investigator and SMO hereby individually certify that they have not and will not use in any capacity the services of any individual or entity which has been debarred or disqualified from participating in clinical research under any laws or regulations. In the event that the Institution, Investigator or SMO becomes aware of the debarment, threatened debarment, disqualification or threatened disqualification of any such individual or entity, the Institution and/or the Investigator and/or SMO, as the case may be, shall notify PRA immediately.

(c) The Institution, Investigator and SMO declare that neither the Investigator nor any member of the Study Team is subject to any conflicting obligations or legal impediments and/or has any financial, contractual or other interests in the outcome of the Study that might interfere with the performance of the Study or that is likely to affect the reliability and robustness of the data generated in the Study. The Investigator shall inform the Sponsor immediately upon learning of the existence of any financial arrangement or interest between the Investigator or member of the Study Team and the Sponsor.

(d) The Institution, Investigator and SMO individually warrant and promise that, in connection with this Agreement, it/he/she has not and will not (directly or indirectly) make any improper payment or offer (or authorizing another to pay or offer) money or anything of value to a government official or any other person connected with the provision of services under this Agreement, in order to improperly influence any act or decision of such official or person, to induce such official or person to do or omit to do any act in violation of his or her relevant duty, to obtain any improper advantage, to procure improper performance of a function or activity associated with this Agreement or in the case of a government official, to induce such official to use his or her influence improperly to affect or influence any act or decision of a government.

PRAHEALTHSCIENCES

13. ASSIGNABILITY.

Site and SMO may not assign any of its rights or delegate any performance under this Agreement, voluntarily or involuntarily, whether by merger, consolidation, dissolution, operation of law, or any other manner except with the prior written consent of PRA, and any purported assignment or delegation without PRA's written consent is void. Except for the third-party beneficiary rights granted to the Sponsor and its affiliates in this Agreement, any person who is not a party to this Agreement shall not have any rights under it and shall not be able to enforce any term of this Agreement.

14. NOTICES.

With the exception of Study funds paid by PRA pursuant to Section 2 hereof, all notices required or permitted to be given under this Agreement shall be in writing and shall be (a) delivered personally, (b) sent by certified mail, or (c) sent by a nationally-recognised courier guaranteeing next-day delivery, to the recipients below. The parties agree that changes to the addresses below for receipt of notices under this Section may be effected by a letter signed by the relevant party and does not require an amendment to this Agreement signed by all parties:

If to PRA:	**Pharmaceutical Research Associates India Private Limited** The Qube, A-602 and A-603 C.T.S. No. 1498 A/2 M.V. Road, Marol, Andheri (East), Mumbai 400 059 India Attention: Clinical Operations Director
If to the Sponsor:	**AstraZeneca AB** 151 85 Södertälje, Sweden Attention: Legal Department
If to the Institution:	**Mahatma Gandhi Mission's Medical College and Hospital** N-6, Cidco, Aurangabad-431003, Maharashtra, India Attention: Dr. Deepak Bhosle
If to the Investigator:	**Dr. Deepak Bhosle** N-6, Cidco, Aurangabad-431003, Maharashtra, India
If to the SMO:	**Grapecity Research Solutions LLP** D/2, Prakash Hsg Society, Thergaon, Near Kalewadi Fata, Pune- 411033, Maharashtra, India Attention: Dr. Sushil Chaudhary

15. USE OF NAMES.

The Institution, Investigator and SMO shall not use the name, symbols and/or trademarks of PRA or the Sponsor in any form of publicity in connection with the Study unless explicitly approved by PRA or the Sponsor in advance or specifically allowed under the terms of this Agreement. Institution, Investigator and SMO agree that, in accordance with applicable laws, Sponsor may make public the amount of funding

PRAHEALTHSCIENCES

provided hereunder for the conduct of the Study and may identify Institution, Investigator and SMO as part of this disclosure or as part of any Study recruitment activities or other Study-related meetings.

16. WAIVER; SEVERABILITY.

No waiver of any term or condition of this Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver of such term or condition, or of any other term or condition of this Agreement. If any terms or conditions of this Agreement are held to be invalid, illegal or unenforceable the remaining terms and conditions contained herein shall not be affected.

17. ENTIRE AGREEMENT; EXHIBITS; COUNTERPARTS.

This Agreement, including the Exhibits attached hereto, constitutes the full understanding of the parties with respect to the subject matter hereof and a complete and exclusive statement of the terms of their agreement, and no terms, conditions, understanding or agreement purporting to amend, modify, vary or waive the terms of this Agreement shall be binding unless made in writing and signed by an authorised representative of each party hereto. This Agreement and any amendment hereto may be executed in several counterparts, each of which shall be deemed an original but taken together shall constitute one and the same instrument.

18. CONTINUING OBLIGATION; SURVIVAL OF PROVISIONS.

Except as otherwise specifically provided herein, termination of this Agreement shall not relieve any party hereto from any obligation under this Agreement that accrued or arose from facts and circumstances in existence prior thereto. In addition, the provisions of this Agreement that by their nature contemplate continuing obligations shall survive expiration or termination of this Agreement.

19. GOVERNING LAW.

This Agreement shall be governed by the laws of the country where the services are performed excluding conflict of law rules.

SIGNATURES APPEAR ON FOLLOWING PAGE

PRAHEALTHSCIENCES

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorised representatives on the date(s) indicated below, but effective for all purposes as of the Effective Date.

PHARMACEUTICAL RESEARCH ASSOCIATES INDIA PRIVATE LIMITED

By : _____
Authorised Signature

Name : Sachin Narkhede

Title : Associate Director, Clinical Operations

Date : 03/AUG/2017

INSTITUTION

DEAN
MGM'S MEDICAL COLLEGE
AURANGABAD

By : _____
Authorised Signature

Name : _____

Title : _____

Date : _____

SMO

By : _____

Name : Dr. Sushil Chaudhary

Title : Director

Date : _____

INVESTIGATOR

By : _____

Name : Deepak Bhosle

Title : Principal Investigator

Date : _____

PRAHEALTHSCIENCES

EXHIBIT A
PAYMENT TERMS

Sponsor:	AstraZeneca
Protocol No:	D1680C00019
PRA Project Id:	AZUC1375-CV137

1. **Payee**. The SMO, **Grapecity Research Solutions LLP**, shall be the Payee for this study in accordance with paragraph 2 of this Agreement. It is understood and agreed that although PRA shall direct all payments to SMO, SMO shall disburse any and all payments to Institution and/or Investigator and/or Study Team members as applicable. Pursuant to the Payment Terms, Budget, this Agreement, and in accordance with any applicable agreement between Institution, Investigator and SMO; neither PRA nor Sponsor shall be responsible for any payments directly to Institution, Investigator and SMO.

2. **Subject Recruitment**. Enrollment for this study is competitive. PRA anticipates that the Site and SMO will recruit approximately 2 subjects, but makes no guarantees regarding this number. Site and SMO shall not recruit more, without the prior written approval of PRA or Sponsor, and neither PRA nor Sponsor will be liable for compensation for unauthorized subjects in excess of the number specified above. PRA will advise on recruitment progress and notify sites when recruitment is complete.

3. **Payment Method**. PRA will make payments in Indian Rupee by electronic bank transfer in accordance with Exhibit B Budget as attached. PRA will not make any additional payments to Payee pursuant to this Agreement without the prior written approval of Sponsor. Nor will PRA pay for any procedures performed or treatments given in violation of the Protocol unless approved in writing by Sponsor.

4. **Payment Timing.** PRA will make payments on a quarterly basis, in accordance with Exhibit B Budget. These payments will be made within 45 days of the acceptance criteria outlined below:

   a) **Start-Up Payments**. Upon site activation and the receipt of a completed Payment Information Checklist. Start-Up fees will be paid in accordance with Exhibit B Budget.

   b) **Subject Visit Payments**. PRA will make payments based on subject visits that have been source document verified by Study Monitor, in accordance with Exhibit B Budget. PRA will withhold 10% of each subject visit payment until the Final Payment, as defined below.

5. **Other Payments**. All other payments will be made within the agreed timing, as defined in section 3 above, upon receipt by PRA of a valid invoice, in the amounts specified in Exhibit B Budget, and according to the following criteria.

   a) **IRB Fees or Ethics Committee Fees.** If Site will be using the central IRB or Ethics Committee designated for this Study, PRA will be responsible for the Task Order and fees associated with this service provider. PRA will reimburse the relevant IRB or Ethics Committee for fees in accordance with an invoice issued to PRA by the IRB or Ethics Committee. PRA will not reimburse Site for IRB fees incurred in connection with the Study.

PRAHEALTHSCIENCES

b) **Screen Failures**. PRA will pay for subjects who fail screening based on a pre-determined flat fee. The Site or SMO must document all screening procedures completed prior to screen failure and must ensure that the subject has signed an informed consent form. PRA will not pay for any procedures carried out after the subject has failed screening.

c) **Subject Travel Reimbursement**. PRA will reimburse the Site for subject travel expenses per subject visit in accordance with Exhibit B Budget and the study subject Informed Consent Form.

Invoicing. All invoices must contain the Protocol title and number, a detailed summary of the payment to be made, supporting documents (if any), and be addressed to the following:

PRA Entity Address	**Pharmaceutical Research Associates India Private Limited** ATTN: Accounts Payable The Qube, A-602 and A-603, C.T.S. No. 1498 A/2, M.V. Road, Marol, Andheri (East), Mumbai 400 059
Email	Invoices may be emailed to: PRA Email: investigatorinvoices@prahs.com Protocol Number : D1680C00019

*Invoices missing any of the above information may result in delayed payment.

All invoices should be received by PRA within forty-five (45) days following the incurrence of the applicable expense or database lock, whichever is earlier. Site and SMO understands once PRA has reconciled and closed Study internally that PRA reserves the right to no longer accept invoices.

6. **Final Payment**. PRA will perform a reconciliation of the Site's payments before issuing a final payment to the Payee to account for all previous Study payments, remaining payments due and if applicable this shall include the withholding from Subject Visit Payments and the fair market value of any equipment provided under this Agreement which the Site purchases. The reconciliation will result in either a final payment due to the Payee ("Final Payment") or a request for reimbursement due to PRA ("Reimbursement").

7. **Taxes**. Payments shown in the Exhibit B Budget do not include tax of any type. If the Payee is VAT/GST registered, and if VAT/ GST or other applicable taxes are required under the Payee's country law, the applicable tax should be added and shown on the invoice at the local applicable VAT rate. The Site and Payee each acknowledge and agree that Payee shall be solely responsible for paying the appropriate amount of any applicable federal, state, and local taxes with respect to all payments made pursuant to this Agreement, and PRA shall have no responsibility whatsoever for withholding or paying any such taxes on behalf of the Site or Payee.

PRAHEALTHSCIENCES

8. **Payment Dispute**. Payee and Institution will have thirty (30) days from the receipt of final payment to dispute any payment discrepancies.

PRAHEALTHSCIENCES

EXHIBIT B
BUDGET

AstraZeneca
Protocol: AZUC1375-CV1375
Investigational Product: Dapagliflozin, Saxagliptin, or Placebo
Budget Based on Protocol dated: 04-4-17
Investigator: Deepak Bhosle
Study Center: Mahatma Gandhi Mission's Medical College and Hospital
Country: India
Currency: INR - Indian Rupee
Overhead: 20%

Terms Defined

Per Patient Budget – The items in the Budget include all fees payable and will be paid in accordance with the Payment Terms attached to the Agreement.
Section 1. Administrative Costs: costs incurred regardless of patient enrollment or activity. To be paid upon receipt of invoice.
Section 2. Cost Per Visit: costs incurred due to patient activity while participating in the Study and in accordance with the Protocol.
Section 3. Direct Cost: costs incurred due to patient activity and in accordance with the Protocol but are not paid with the Cost Per Visit or by a third party payor. To be paid upon receipt of invoice.

1. Administrative Costs, per invoice

	Unit Cost	Unit Type	Overhead	SubTotal	Total Cost
Start-up Fees	30,000	One time, non-refundable fee	NA	30,000	30,000
Start-up Fee	27,846	One time fee at Initial Payment	5,569	33,415	33,415
Pharmacy Start-up Fee					
PreScreening Fee	1,438	Per completed pre-screen entry up to 200 pre-screen	288	1,726	1,726
Local IRB Fees	Amount invoiced	Recurring fee	NA	Amount invoiced	
Local IRB Review Fee					
Close-out Fees	150,000	One time fee at end of study	30,000	180,000	180,000
Archiving/Document Storage for 15 years (Third Party)				**Estimated Total Administrative Costs:**	**246,141**

All administrative costs will be paid upon receipt of invoice

2. Patient Costs per Visit

	Unit Cost	Unit Type	Overhead	SubTotal	Expected Number of Occurences	Total Cost
Screening	22,538	each	4,508	27,046	1	27,046
Re-Screening (1 re-screen permitted per subject)	22,538	each	4,508	27,046	1	27,046
Lead-In Period	17,451	each	3,491	20,942	1	20,942
Short Term Treatment	26,496	each	5,300	31,796	1	31,796
Day 1	3,978	each	796	4,774	1	4,774
Week 2 Phone	24,934	each	4,987	29,921	1	29,921
Week 6	23,464	each	4,693	28,157	1	28,157
Week 12	16,204	each	3,241	19,445	1	19,445
Week 14	24,934	each	4,987	29,921	1	29,921
Week 20	27,650	each	5,530	33,180	1	33,180
Week 26	25,250	each	5,050	30,300	-	30,300
Early Treatment Discontinuation*	25,250	each	5,050	30,300	-	30,300
Rescue Visit**						
Long Term Treatment	21,510	each	4,302	25,812	1	25,812
Week 32	3,978	each	796	4,774	1	4,774
Week 36	21,510	each	4,302	25,812	1	25,812
Week 40	3,978	each	796	4,774	1	4,774
Week 46	21,787	each	4,358	26,145	1	26,145
Week 52/ETD/Rescue***	3,978	each	796	4,774	1	4,774
Week 56/Followup	3,978	each	796	4,774	3	14,322
Quarterly Phone between Week 56 to Week 104	15,568	each	3,114	18,682	1	18,682
Week 104 Post Study						
Non-Treatment Followup Period	14,757	each	2,952	17,709	-	17,709
NonTx Week 26	14,757	each	2,952	17,709	-	17,709
NonTx Week 52	3,978	each	796	4,774	-	4,774
NonTx Phone Followup	3,978	each	796	4,774	-	4,774
Quarterly Phone between Week 56 to Week 104	15,568	each	3,114	18,682	-	18,682
Week 104 Post Study		**Estimated Total Visit Cost per Patient assuming Treatment through Week 104 (No ET, Rescue, or NonTx):**				**377,323**

Sites will be paid for either Week 26 or ETD depending on the subject's status; not both.
* Subjects who discontinue study medication should have all ETD visit procedures performed and will continue in the study with non-treatment visits and followup.
** Subjects who qualify for rescue should have all rescue visit procedures performed prior to rescue medication is administered and will then continue on treatment from last completed visit. Sponsor will not provide rescue medication or reimbursement.
*** Long-term ETD and long-term rescue visit should follow same guidelines as short-term ETD and short-term rescue visits.

3. Ad Hoc Patient Costs, per invoice

	Unit Cost	Unit Type	Overhead	SubTotal	Total Cost
Screening Failure*	22,538	each	4,508	27,046	27,046
Unscheduled Visit**	28,500	per visit	5,700	34,200	34,200
Travel Reimbursement					
Caregiver Travel Reimbursement	1,385	per travel visit	277	1,662	1,662
Patient Travel Reimbursement	600	per travel visit	120	720	720
Rescue Medication and/or Background Therapy Reimbursement					
3mL Vial	1,677	per vial	335	2,012	2,012
Conditional Procedures					
Urine Pregnancy Test (females of childbearing potential only); At home test provided and should be used on days specified in protocol	326	each	66	392	392
Serum Pregnancy Test (females of childbearing potential only)	300	each	60	360	360
Repeat Laboratory Analysis (may be repeated once per subject; initial sample costs included in the visit total of all applicable visits as indicated in protocol and should not be invoiced additionally)					
Venipuncture plus handling to central laboratory for analysis (must be performed within 10 days from original Screening Visit)	2,229	each	446	2,675	2,675

All Direct Costs will be paid upon receipt of invoice
*Screen Failures will be reimbursed as a ratio of 3 per 1 randomized subjects; no site maximum limit
**Procedures completed at an unscheduled visit will be paid upon receipt of itemized invoice up to a maximum as defined by the unit cost plus any conditional items completed

PRAHEALTHSCIENCES

EXHIBIT C
EQUIPEMT TO BE PROVIDED

1. -70 Freezer
2. Minimum-maximum thermometer
3. -70C Freezer thermometer
4. Filing cabinet