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# CLINICAL STUDY AGREEMENT

between

ASTRAZENECA PHARMA INDIA LTD

And

Mahatma Gandhi Mission Medical College & Hospital,

And

Dr. Prashant P. Udgire

# CLINICAL STUDY AGREEMENT

**between**

**ASTRAZENECA PHARMA INDIA LTD**

Block N1, 12th Floor,

Manyata Embassy Business Park,

Rachenahalli, Outer Ring Road,

Bangalore 560045, Karnataka, INDIA

Phone: +91-80- 67748600, Fax: +91-80- 67748857

**And**

**Mahatma Gandhi Mission Medical College & Hospital,**

N-6 CIDCO, Aurangabad-431003 Maharashtra, India

**And**

**Dr. Prashant P. Udgire**

Assistant Professor Department of Cardiology, Mahatma Gandhi Mission Medical College & Hospital, N-6 CIDCO, Aurangabad-431003 Maharashtra, India

Phone Number: 9503181111

**STUDY NAME:** A Study to Evaluate the Effect of Dapagliflozin on Incidence of Worsening Heart Failure or Cardiovascular Death in in Patients with Chronic Heart Failure with Reduced Ejection Fraction.

**STUDY CODE:** D1699C00001

**STUDY SITE NUMBER: 3524**

# CLINICAL STUDY AGREEMENT

## PARTIES

(1) AstraZeneca Pharma India Ltd, a company incorporated in India, whose registered office is at Block N1, 12th Floor, Manyata Embassy Business Park, Rachenahalli, Outer Ring Road, Bangalore-560045, Karnataka, India (the "**Company**");

(2) Mahatma Gandhi Mission Medical College & Hospital, N-6 CIDCO, Aurangabad-431003 Maharashtra, India (the "**Institution**"); and

(3) Dr. Prashant P. Udgire, Assistant Professor Department of Cardiology, Mahatma Gandhi Mission Medical College & Hospital, N-6 CIDCO, Aurangabad-431003 Maharashtra, India (the "**Principal Investigator**"),

together the "**Parties**" and each a "**Party**".

## BACKGROUND

(a) The Company intends to conduct the Study.

(b) The Institution has the appropriate facilities and personnel, and the Principal Investigator has the necessary qualifications, training, experience and expertise, to conduct the Study.

(c) The Company wishes to engage the Institution and the Principal Investigator to conduct the Study on its behalf.

## EFFECTIVE DATE

The effective date of this Agreement shall be the date on which the last of the Parties signs this Agreement.

## AGREED TERMS

### 1. DEFINITIONS

Unless otherwise specifically provided in this Agreement, capitalised terms shall have the meanings set forth in Appendix A.

### 2. CONDUCT OF THE STUDY

2.1 The Company hereby engages the Institution and the Principal Investigator to conduct the Study.

2.2 The Institution and the Principal Investigator shall conduct the Study at the Study Site in accordance with this Agreement, the Protocol and all Applicable Laws.

2.3 The Institution and/or the Principal Investigator will not deviate from the Protocol unless in order to eliminate an immediate hazard to Subjects. The Institution and/or Principal Investigator shall promptly notify the Company upon becoming aware of the deviation. The Company and/or Principal Investigator will notify the Ethics Committee of deviations in accordance with Applicable Laws.

## 3. RESPONSIBILITIES OF THE COMPANY

AstraZeneca AB, a company incorporated in Sweden whose registered office is at SE-151 85 Södertälje, Sweden has assumed the role of sponsor of the Study, and has engaged the Company to conduct and manage the Study in accordance with this Agreement, the Protocol and Applicable Laws, and has authorised it to enter into this Agreement.

## 4. RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR

4.1 The Principal Investigator shall be responsible for the day-to-day conduct of the Study, including training, leading and supervising Study Site Staff.

4.2 The Principal Investigator shall:

4.2.1. ensure that he/she is appropriately qualified by training and expertise, and obtain and maintain all contractual, regulatory and ethical approvals, notifications and authorisations required (including approvals from entities by which he/she is employed or to which he/she is affiliated), to enter into this Agreement and conduct the Study in accordance with Applicable Laws (and provide evidence of the same to the Company on request);

4.2.2. provide, or ensure that the Institution provides, appropriately qualified Study Site Staff, and ensure that they are supervised and are made aware of, and comply with the terms of this Agreement, and, as appropriate, with the Protocol and Applicable Laws;

4.2.3. obtain and maintain all Ethics Committee approvals required for the conduct of the Study, keep the Company informed of the progress of all applications for the same and provide Company with copies of such approval(s) on request.

4.2.4. ensure that any amendments to the Protocol are approved by the Ethics Committee and/or the Regulatory Authority prior to implementation in accordance with Applicable Laws, and ensure to maintain all approvals from the relevant Regulatory Authority, if not instructed otherwise by Company;

4.2.5. once all necessary regulatory and ethical authorisations, notifications and approvals have been obtained, use his/her reasonable endeavours to enrol the target number of Subjects into the Study. However, the Subject enrolment period may be extended or shortened and the number of Subjects that Institution

and Principal Investigator may enrol in the Study may be changed, at the Company's sole discretion;

4.2.6. ensure that informed consent is obtained from each Subject, and maintained, in accordance with the Protocol and Applicable Laws, such consent to include authorisation for the use and disclosure of the Subject's protected health information in accordance with Applicable Laws;

4.2.7. report to the Sponsor all Adverse Events in the form and within the time frame set out in the Protocol and in accordance with all Applicable Laws;

4.2.8. provide such other assistance in connection with the Study as the Company may reasonably request from time to time; and

4.2.9. ensure that each subject: a) receives patient engagement communications and ongoing study communications promptly upon receipt by the Company or its Designee prior to Study Closure; b) receives the post study communications provided by the Company or its Designee no later than 2 months after Study Closure.

4.3 Principal Investigator and/or Study Site Staff 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 Principal Investigator or any Study Site Staff. If the Principal Investigator and/or Study Site Staff 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.

## 5. RESPONSIBILITIES OF THE INSTITUTION

5.1 The Institution shall:

5.1.1. provide appropriate premises, facilities and equipment for the Study, including the Study Site, and provide such assistance, resources and cooperation as the Company may reasonably request in connection with the Study;

5.1.2. provide, or ensure that the Principal Investigator provides, appropriately qualified Study Site Staff and ensure that they are made aware of, and comply with, the terms of this Agreement, the Protocol, and Applicable Laws; and

5.1.3. notify the Company immediately if the Principal Investigator ceases to be employed by or associated with the Institution, or is otherwise unable to act or continue to act as the Principal Investigator.

## 6. STUDY DRUG AND MATERIALS

6.1 The Company shall use commercially reasonable efforts to supply (or procure the supply), at no cost to Institution or Principal Investigator, the quantities of Study Drug required to conduct the Study in accordance with the Protocol and Applicable Laws.

6.2 The Institution and the Principal Investigator shall ensure that the Study Drug is stored, dispensed and administered under proper conditions and in accordance with the Protocol, the Applicable Laws and, where relevant, the Company's instructions.

6.3 The Institution and/or Principal Investigator shall promptly report to the Company any adverse findings in relation to any Study Drug delivered to it, and the Company shall take such steps as are reasonably practicable in the circumstances to provide replacement Study Drug or otherwise to minimise the impact on the Study. If the Company and/or any Regulatory Authority deem that a recall of Study Drug is required, the recall strategy shall be developed by the Company and followed by the Institution and the Principal Investigator with strict regard to the requirements in terms of timing and/or any other conditions imposed.

6.4 The Study Drug must be used only for the purposes outlined in the Protocol and, neither the Institution nor the Principal Investigator shall use, supply or otherwise make available any Study Drug for any other purposes, nor engage in any promotion or commercialisation of Study Drug for any unauthorised indication.

6.5 The Principal Investigator shall maintain complete and accurate records relating to the Study Drug consistent with the Protocol and as required by Applicable Laws. At the completion or termination of the Study or earlier termination of this Agreement all remaining Study Drug shall, at the Company's option, be returned to the Company (at Company's expense) or disposed of in accordance with Applicable Laws.

6.6 The Company will provide the Institution and the Principal Investigator with the Materials required for the conduct of the Study. The Company shall retain all rights, title and interest in and to the Materials unless otherwise agreed by the Company in writing. The Materials may only be used by the Institution, the Principal Investigator and the Study Site Staff to the extent required for the conduct of the Study.

6.7 The Institution and the Principal Investigator shall be responsible for keeping any Materials in good repair and in such condition as they were on the date of delivery (fair wear and tear excepted). The Materials shall be kept and operated in a suitable environment and used only for the purpose for which they are intended, by trained staff in accordance with any instructions provided by the Company.

6.8 At Study Site Closure or at Company's earlier request, Institution and Principal Investigator shall promptly return all Materials to the Company, unless the Parties agree that Institution or Principal Investigator shall acquire the Materials for their fair market value. Any such acquisition of Materials shall be subject to a separate agreement between the relevant parties.

## 7. STUDY DOCUMENTATION

7.1 The Institution and the Principal Investigator shall compile and maintain all Study Documentation, the investigator study file (including but not limited to copies of CRFs, data queries and Adverse Event reports (if applicable)) and all other documents required under this Agreement, in accordance with this Agreement, the Protocol and Applicable Laws.

7.2 The Institution and the Principal Investigator shall make the Study Documentation available for the Company and the Regulatory Authorities in accordance with Applicable Laws. The Study Documentation shall be retained for a minimum of fifteen (15) years, or longer in accordance with the Applicable Laws, after the Study Closure.

## 8. MONITORING AND AUDIT BY THE COMPANY

8.1 The Institution and the Principal Investigator shall permit the Company or its Designee to access the Study Site during normal business hours and on reasonable notice in order for the Company to monitor that the Study has been and is being conducted in accordance with the Protocol and Applicable Laws.

8.2 The Institution and the Principal Investigator agree to cooperate fully with the Company during monitoring and audits, including making all Study Documentation available for review by the Company or its Designee (subject to reasonable safeguards for the protection of personal data and medical confidentiality as set out in Clause 13).

8.3 The Institution and the Principal Investigator shall ensure that all questions and action items arising from monitoring and audit pursuant to this Clause 8 are resolved within such reasonable period as the Parties may agree.

## 9. INSPECTION BY THE REGULATORY AUTHORITIES

9.1 A Party shall notify all other Parties as soon as reasonably possible (and in any event within two working days) following:

9.1.1. receipt of any request from a Regulatory Authority for an inspection of the Study Site (or the conduct of any inspection if without notice); or

9.1.2. receipt of any written or oral enquiries from a Regulatory Authority, regarding any aspect of the activities pursuant to this Agreement or the conduct of the Study,

and shall provide copies of all associated correspondence with the Regulatory Authority.

9.2 To the extent reasonably practicable, the Institution and the Principal Investigator shall allow the Company or its Designee to attend any inspection by a Regulatory Authority. If the Company or its Designee are not allowed to attend any such inspection, the Institution and/or Principal Investigator shall provide the Company with a detailed summary of the Inspection as soon as reasonably practicable thereafter.

9.3 The Institution and Principal Investigator shall notify the Company of any violation or deficiency noted by a Regulatory Authority. The Parties shall cooperate with each other in relation to the preparation of any response.

## 10. PAYMENTS

10.1 In consideration of the services rendered under this Agreement, the Company shall pay the Institution and/or the Principal Investigator in accordance with Appendix B.

10.2 Payment will not be made until the Company has received an invoice or such any other documentation as set out in Appendix B evidencing that the relevant services have been completed. The Company shall pay any invoices within sixty (60) days of the date of receipt by the Company, PROVIDED THAT if any amount included in the invoice is disputed, the Company shall not be required to pay the disputed amount until the dispute is resolved in accordance with this Agreement.

10.3 The Parties acknowledge that the amounts to be paid by the Company under this Agreement are reasonable, represent fair market value and are for services actually performed by the Institution, the Principal Investigator and/or Study Site Staff for the work under this Agreement and that neither the Institution, the Principal Investigator nor the Study Site Staff have received any other compensation or inducement from the Company in connection with the Agreement or their participation in the Study.

10.4 The Company shall deduct or withhold from the amounts payable any taxes that it is required by Applicable Laws to deduct or withhold. All payments made by the Company under this Agreement are inclusive of value added taxes, sales taxes or similar taxes. The Institution will be responsible for all such taxes with respect payments under this Agreement.

10.5 The Institution and the Principal Investigator shall keep and maintain accurate and reasonably detailed financial records in connection with the activities performed under this Agreement. Upon request, the Company shall have the right to audit such financial records to test compliance with this Agreement.

## 11. INTELLECTUAL PROPERTY

11.1 Except as expressly set out in this Agreement, no Party shall acquire any right, title or interest in or to the Intellectual Property of any of the other Parties or their licensors.

11.2 The Company 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 Principal Investigator are required to retain any Study Documentation in accordance with GCP and the Applicable Laws. The Institution and the Principal Investigator shall promptly disclose any such Intellectual Property to the Company in writing or in such other format as the parties may agree.

11.3 To the extent capable of prospective assignment, the Institution and the Principal Investigator hereby assign to the Company (or its Designee) all their rights, title and interest in and to all Intellectual Property falling within Clause 11.2 above. To the extent that any such Intellectual Property cannot prospectively be assigned, the Institution and the Principal Investigator shall assign, and shall procure that the Study Site Staff shall assign, such Intellectual Property to the Company (or its Designee) on creation.

11.4 The Institution and the Principal Investigator shall, and shall ensure that the Study Site Staff take all steps as the Company may reasonably require from time to time in order to enjoy the full benefit of the rights assigned under this Clause 11.

11.5 The Company hereby 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 provisions of Clauses 12 and 14 of this Agreement shall continue to apply in relation to any such licence.

## 12. CONFIDENTIAL INFORMATION

12.1 Subject to Clauses 12.2 and 12.3, each Party shall at all times keep confidential the Confidential Information. Each Party shall safeguard the other Party's Confidential Information with at least the same level of care as it affords to its own Confidential Information, and shall not use any other Party's Confidential Information for any purpose other than to perform its obligations under this Agreement. All Study Site Staff shall be bound by obligations of confidentiality at least as restrictive as those contained in this Agreement.

12.2 The obligations on each Party set out in Clause 12.1 shall survive for ten (10) years after the expiry or termination of this Agreement, but shall not apply to any information which:

12.2.1. was in that Party's possession (with full right to disclose) prior to receiving it from another Party, as demonstrated by written records;

12.2.2. is public knowledge otherwise than as a result of any breach of this Clause or any similar Clause in any other relevant agreement; or

12.2.3. it can demonstrate was developed independently without reference to the Confidential Information, or was received from a third party who had the right to disclose such information in a non-confidential manner.

12.3 A Party may disclose Confidential Information to the extent required by a court of competent jurisdiction, by a governmental, supervising or regulatory body, or otherwise in order to comply with Applicable Laws (including freedom of information legislation), provided always that (i) to the extent it is legally permitted to do so, the disclosing Party gives the affected Party as much notice of such disclosure as possible; and (ii) the disclosing Party complies with the affected Party's reasonable directions for taking legally available steps to resist or narrow such requirement (at the affected Party's reasonable

expense) and in any event restricts the disclosure to only those parts of the Confidential Information lawfully required to be disclosed.

12.4 The Parties acknowledge that damages alone would not be an adequate remedy for the breach of any of the terms of Clause 12, and that in the event of a breach or threatened breach the Party that initially disclosed the Confidential Information shall be entitled to seek equitable relief and/or injunctive relief concerning any threatened or actual breach (in addition to any other rights and remedies it may have under this Agreement or otherwise).

## 13. PERSONAL DATA AND BIOLOGICAL MATERIALS

13.1 The Parties agree to comply with all Applicable Laws in relation to the protection of the personal data of Subjects, the Principal Investigator and Study Site Staff. The Institution and the Principal Investigator shall maintain appropriate technical and organisational security measures to protect the confidentiality and security of Subjects' personal data.

13.2 The Institution and Principal Investigator shall ensure that any collection, handling, transportation and retention of Biological Materials in connection with the Study is carried out in accordance with the Protocol, the informed consents of Subjects, and all Applicable Laws and in such a way as to ensure that the security, integrity, quality and identity of the Biological Materials is maintained at all times.

## 14. RIGHTS TO PUBLICATION

14.1 The Institution and the Principal Investigator shall be entitled to publish the results of, or make presentations related to, the Study, as indicated in this Section 14. If this Study is part of a multi-centre clinical trial, Institution and Investigator agree not to independently publish the results of the Study until first occurrence of one of the following: (i) multi-centre primary Publication is published; (ii) no multi-centre primary publication is submitted within two years after conclusion, abandonment, or termination of the Study at all sites; or (iii) Sponsor confirms in writing there will be no multi-centre primary Publication. All such publications or presentations shall (i) be consistent with academic standards and International Committee of Medical Journal Editors (ICMJE) guidelines, (ii) not be false or misleading, (iii) comply with all Applicable Laws, (iv) not be made for any commercial purpose.

14.2 The Institution and/or the Principal Investigator shall provide the Company with copies of any materials relating to the Study, or the Developed Technologies 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.

14.3 At the request of the Company, the Institution and/or the Principal Investigator:

14.3.1. shall not include in or shall remove from any proposed publication any Confidential Information, errors or inaccuracies; and

14.3.2. shall withhold publication, submission for publication or presentation for a period of ninety (90) days from the date on which the Company receives the material to allow the Company to take such measures as the Company considers necessary to preserve its proprietary rights and/or protect its Confidential Information.

14.4 The Institution and the Principal Investigator shall include the following acknowledgement in all publications and presentations relating to the Study, the Study Documentation or the Developed Technologies, as well as in any financial disclosure information relating to the Study: "AstraZeneca sponsored this clinical trial." A copy of any publications and presentations relating to the Study, the Study Documentation and/or the Developed Technologies shall be provided to the Company on publication or presentation, and the Company shall be entitled to make copies of and distribute the publication or presentation as it considers necessary.

14.5 Subject to Clause 14.4, no Party shall mention or otherwise use the name, trade mark, trade name or logo of any other Party in any publication, press release or promotional material with respect to the Study without the prior written approval of such Party; provided, however, that the Company shall have the right to identify the Institution, the Principal Investigator and the responsible Study Site Staff in any Study recruitment activities or other Study-related meetings.

14.6 The Company has a long-standing commitment to transparency, and the Institution and the Principal 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 and in accordance with Applicable Law.

14.7 If the Company invites the Principal Investigator to be an author of a Company-managed publication, the Principal Investigator shall agree to comply with ICMJE authorship criteria. The Principal Investigator shall direct, draft and/or review the proposed publication, approve the final version of the publication to be published and retain full responsibility for its content. Company financial support for this research, any other financial relationship with Company, as well as any other relevant financial relationships as required by the journal or congress shall be disclosed in the publication. Any authorship, medical writing, editorial or logistical support provided to the Principal Investigator or the Institution by the Company in respect of publication shall be subject to the Company's publications policy, details of which are available at www.astrazeneca.com. No compensation shall be provided in respect of any such authorship.

## 15. INSURANCE AND INDEMNITY

15.1 Each of the Parties shall ensure that adequate provision is made by way of insurance or indemnity arrangements sufficient to meet their obligations and liabilities under this Agreement and the Applicable Laws, in particular towards Subjects for personal injury arising as a result of participation in the Study.

15.2 The Company agrees to indemnify the Institution and the Principal Investigator against all direct costs, claims, liabilities, penalties or expenses (including reasonable legal fees and disbursements), (collectively "**Losses**") arising out of or relating to the conduct of the Study.

15.3 The Company's indemnity under Clause 15.2 will not apply to the extent that such Losses arise from or relate to (a) any breach of this Agreement or Applicable Laws by the Institution and the Principal Investigator, or (b) any negligence, recklessness or willful act or omission by the Institution, the Principal Investigator or the Study Site Staff in the performance of their obligations under this Agreement.

15.4 If any third party makes a claim, or notifies an intention to make a claim, against the Institution or the Principal Investigator which may reasonably be considered likely to give rise to a liability under this indemnity (a "**Claim**"), the Institution and/or the Principal Investigator shall:

15.4.1. as soon as reasonably practicable, give written notice of the Claim to the Company, specifying the nature of the Claim in reasonable detail;

15.4.2. not make any admission of liability, agreement or compromise in relation to the Claim without the prior written consent of the Company, such consent not to be unreasonably withheld; and

15.4.3. take such action as the Company may reasonably request to avoid, dispute, compromise or defend the Claim (including granting the Company full conduct and control of the claim).

## 16. COMPLIANCE, TRANSPARENCY, ANTI-BRIBERY, ANTI-CORRUPTION AND CONFLICTS OF INTEREST

16.1 The Parties will ensure that neither they, nor any of their officers or employees, directly or indirectly offer, make, accept or request any Payments or Transfers of Value to or from any official or other person, that is intended or could be seen, to influence any decision to obtain or retain business, to gain an improper advantage, or to induce such official or other person to perform a function in violation of any statute, rule, or regulation, including but not limited to inducements, bribes, kickbacks and facilitation payments.

16.2 The Institution and the Principal Investigator warrant that neither they nor any of their Study Site Staff have engaged in any conduct that has resulted or may result in a criminal conviction, nor are currently excluded, debarred, suspended, or otherwise ineligible to participate in the Study and/or government health care programs in any country. The Institution and the Principal Investigator agree to notify the Company immediately in the event they become aware that they or any of their Study Site Staff are being investigated by any Regulatory Authority.

16.3 The Institution and the Principal Investigator acknowledge and agree (and shall be responsible for obtaining consent from the Study Site Staff) that the Company and/or its Affiliates may store, use and publicly disclose information (including personal data) about

the Institution, the Principal Investigator and the Study Site Staff and certain Payments or Transfers of Value provided to them in relation to the Study as required by Applicable Laws. Certain Payments or Transfers of Value may also be disclosed on public websites.

16.4 The Institution and the Principal Investigator declare that neither the Principal Investigator, nor any member of the Study Site Staff, 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 Principal Investigator shall inform the Company immediately upon learning of the existence of any financial arrangement or interest between the Principal Investigator and the Company.

16.5 If during the term of this Agreement or within 2 years of its termination the Principal Investigator (i) joins or participates in any committee that sets formularies or develops clinical guidelines, or (ii) is involved in any decision or recommendation relating to the adoption of any products of the Company or its Affiliates for clinical use in any local or national health care service, the Principal Investigator will disclose to such committee the existence and nature of this Agreement and will follow the disclosure obligations and procedures set forth by the committee.

## 17. TERM AND TERMINATION

17.1 This Agreement will remain in effect until (a) termination or completion of the Study, close-out of the Study Site, receipt of all Study Documentation by the Company, and completion of the obligations of the Parties under the Protocol, or (b) earlier termination in accordance with this Agreement.

17.2 Any Party may terminate this Agreement with immediate effect at any time upon written notice to all other Parties if:

17.2.1. on reasonable grounds it believes the Study should cease in the interest of the health, safety or well-being of Subjects;

17.2.2. any Party or any of their employees, agents, or sub-contractors commits any of the acts referred to in Clause 16.1 or any offence under the applicable transparency or anti-corruption laws in relation to this Agreement or the Study, or any breach of the warranty given in Clause 16.2;

17.2.3. any other Party commits a material breach of any of its obligations under the Agreement and fails to remedy such breach (where possible) within thirty (30) days of written notice from a non-defaulting Party; or

17.2.4. any step, application, order, proceeding or appointment is taken or made by or with respect to any other Party for distress, execution, composition or arrangement with creditors, winding up, dissolution, administration, receivership (administrative or otherwise) or bankruptcy, if that Party is unable to pay its debts or if any event occurs which, under the applicable law of any

jurisdiction to which it is subject, has an effect similar to that of any of the events referred to in this Clause 17.2.4.

17.3 The Company may terminate or suspend the Study and/or terminate this Agreement immediately for any reason whatsoever upon written notice to Institution and Principal Investigator.

17.4 The Company shall have no liability to the Institution or the Principal Investigator for any fees, reimbursements or other compensation or for any loss, cost, claim or damage resulting, directly or indirectly, from such termination. For the avoidance of doubt, (except in the case of termination of this Agreement as a result of an uncured breach of this Agreement by the Institution or Principal Investigator) the Company shall, upon receipt of invoices and other supporting documentation, pay to the Institution and/or Principal Investigator all costs incurred and falling due for payment up to the date of termination and all non-cancellable costs committed before receipt of notice of termination, provided that such commitments are reasonable and necessarily incurred by the Institution or Principal Investigator for the performance of the Study prior to the date of termination and agreed with the Company.

17.5 Upon notice of termination of this Agreement:

17.5.1. the Parties shall take all reasonable steps to minimise any inconvenience or harm to the Subjects; and

17.5.2. the Institution and the Principal Investigator shall:

17.5.2.1 immediately -cease enrolment of Subjects into the Study; and

17.5.2.2 promptly provide to the Company all Study Documentation (except where required to be retained pursuant to Applicable Laws), the Company's Confidential Information and any Materials provided by the Company in connection with the Study.

17.6 The following Clauses shall survive the termination or expiry of this Agreement to the extent necessary to preserve such rights and obligations: Clause 4.2.9 (Study Communication); Clause 6 (Study Drug and Materials); Clause 7 (Study Documentation); Clause 8 (Monitoring and Audit by Company); Clause 9 (Inspection by the Regulatory Authorities); Clause 10 (Payments), in respect of any rights to payment arising prior to termination; Clause 11 (Intellectual Property); Clause 12 (Confidential Information); Clause 13 (Personal Data and Biological Samples); Clause 14 (Rights to Publication); Clause 15 (Insurance and Indemnity); Clause 16 (Compliance, Transparency, Anti-Bribery, Anti-corruption and Conflicts of Interest); Clause 17.3 (Term and Termination); and Clause 18 (General).

## 18. GENERAL

18.1 **Force Majeure** - No Party shall be liable to any other for any delay or non-performance of its obligations under this Agreement arising from any Force Majeure Event. In the

event of a Party being so delayed or prevented from performing its obligations, such Party shall: (i) give notice in writing of such delay or prevention to the other Parties as soon as reasonably possible, stating the commencement date and extent of such delay or prevention, the cause of such delay or prevention and its estimated duration; (ii) use commercially reasonable efforts to mitigate the effects of such delay or prevention upon the performance of its obligations under this Agreement; and (iii) resume performance of its obligations as soon as reasonably possible after the removal of the cause of the delay or prevention.

18.2 **Assignment, Subcontracting** - The Principal Investigator and the Institution may not assign, delegate, subcontract, sublicense or otherwise transfer any or all of their rights and obligations under this Agreement without the prior written consent of the other Parties. The Company shall be entitled to assign, delegate, sublicense or otherwise transfer its rights and obligations under this Agreement to any Affiliate, any external service providers such as contract research organisations retained to assist the Company in managing and monitoring the Study, and to any successor in interest to all or substantially all of the business to which this Agreement relates. The Company shall always have the right to perform any or all of its obligations and exercise any or all of its rights under this Agreement through any of its Affiliates. Any assignment in violation of this Agreement shall be null and void.

18.3 **No Partnership** - Nothing in this Agreement shall create, or be deemed to create a partnership, joint venture, employer/employee, contractor/contractee, or other relationship between the Parties other than the contractual relationship expressly provided for in this Agreement.

18.4 **Waiver** - No failure or delay by a Party to exercise any right or remedy provided under this Agreement or by law shall constitute a waiver of that (or any other) right or remedy, nor shall it preclude or restrict its further exercise. In addition, no single or partial exercise of any such right or remedy shall preclude or restrict the further exercise of that (or any other) right or remedy.

18.5 **Construction** - The Parties acknowledge and agree that they have reviewed, negotiated and jointly drafted this Agreement and that it should be construed without regard to the Party or Parties responsible for its preparation.

18.6 **Invalidity** - If any provision of this Agreement is held by any court or other competent authority to be illegal, invalid or unenforceable in whole or in part, this Agreement shall continue to be valid as to its other provisions, and if possible the affected provision should be modified to the minimum extent necessary to make it valid, legal and enforceable.

18.7 **Inconsistency** - In the event of any inconsistency between this Agreement and the Protocol, the terms of the Protocol shall prevail with respect to the conduct of the Study and the treatment of Subjects in connection therewith; in all other respects, the terms of this Agreement shall prevail.

18.8 **Notices** - Any notice to be given by any Party under or in connection with this Agreement must be in writing and shall be: (a) delivered by hand or by courier; (b) sent by pre-paid recorded (i.e. signed for) post; or (c) sent by fax, to the addresses set out at the start of this Agreement or such addresses or numbers as may be notified to the other Parties from time

to time. Notices sent in accordance with this Clause are to be deemed to have been received (i) if delivered by hand or by courier, when left at the address referred to above; (ii) if sent by post, three business days after posting; (iii) if sent by fax, when transmitted.

18.9 **Entire agreement** - This Agreement together with the Appendices (all of which are incorporated by reference) constitutes the entire agreement between the Parties with respect to the subject matter of this Agreement and supersedes all prior agreements, whether written or oral, with respect to that subject matter.

18.10 **Amendments** - Any amendment or modification to this Agreement must be in writing and signed by authorised representatives of each Party.

18.11 **Counterparts** - This Agreement may be executed in two or more counterparts, each of which shall be deemed an original and all of which shall together be deemed to constitute one and the same agreement. The Parties agree that execution of this Agreement by industry standard electronic signature software and/or by exchanging PDF signatures shall have the same legal force and effect as the exchange of original signatures, and that in any proceeding arising under or relating to this Agreement, each Party hereby waives any right to raise any defence or waiver based upon execution of this Agreement by means of such electronic signatures or maintenance of the executed agreement electronically.

18.12 **Governing law** - This Agreement and any dispute or claim arising out of or in connection with it or its subject matter (including non-contractual disputes or claims) shall be governed by and construed in accordance with the laws of India without regard to the conflicts of law principles thereof. The Parties irrevocably agree that the courts of India shall have exclusive jurisdiction to settle any dispute or claim that arises out of or in connection with this Agreement or its subject matter (including non-contractual disputes or claims).

## 19. SUB – CONTRACTOR

The Institution and Principal Investigator shall be permitted to use SMO as its Sub-contractor to [manage Study Site staff, Investigator grant, Institutional overhead and process payments made by AstraZeneca under this Agreement per APPENDIX B]. Except for the foregoing, the Institution and Principal Investigator shall not engage or make use of Subcontractors for the purpose of performing its obligations under this Agreement except as expressly authorized by AstraZeneca in writing, provided that any such authorization by AstraZeneca shall not be deemed to be a waiver of AstraZeneca rights with respect to any failure of the Institution and Principal Investigator to conduct its activities under this Agreement. Any such permitted subcontract shall be subject to the applicable terms and conditions of this Agreement, including Clause 12, Clause 16, Clause 17 and Clause 18, and, upon AstraZeneca request, the Institution and Principal Investigator shall require any such Subcontractor to enter into an undertaking, pursuant to which the terms and conditions of this Agreement shall apply directly between such Subcontractor and AstraZeneca prior to disclosing to such Subcontractor any of AstraZeneca's Confidential Information; provided, however, that no such subcontract shall release the Institution and Principal Investigator from any of its obligations under

this Agreement except to the extent such obligations are satisfactorily performed by such Subcontractor in accordance with this Agreement. The Institution and Principal Investigator shall remain at all times responsible to AstraZeneca for the performance and observance of all its obligations under this Agreement (including by Subcontractors). The Institution and Principal Investigator shall procure that all Subcontractors comply with this Agreement. The Institution and Principal Investigator shall adequately assess and provide ongoing oversight of Subcontractors, in order to ensure that the Subcontractor complies with this Agreement. The express reference to a Subcontractor in any provision of this Agreement is for emphasis only and shall not mean that the absence of an express reference to a Subcontractor in another provision means that the provision does not apply to a Subcontractor.

**AGREED** by the Parties on the dates indicated below.

SIGNED for and on behalf of
**AstraZeneca Pharma India Ltd**

Signature

Name: Tapankumar M Shah

Title: SMM-India Country Head

Date: 05 July 2017

SIGNED for and on behalf of
**Mahatma Gandhi Mission Medical College & Hospital, Aurangabad**

Signature

Name: DR. RAJENDRA B. BOHRA

Title: DEAN

Date: 27 July 2017

SIGNED by
**Principal Investigator**

Signature

Name: DR PRASHANT PRABHAKAR UDGIRE

Title: P.I.

Date: 12/07/2017

## APPENDIX A - DEFINITIONS

"**Adverse Event**" shall have the meaning set out in the Protocol.

"**Affiliate**" means any business entity that, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with, a Party, with "control" meaning in the case of a company, direct or indirect ownership of 50% or more of the voting interest in such company, and in the case of a partnership the right to a share of more than half the assets, or of more than half the income of the partnership.

"**Applicable Laws**" means all applicable international, national, regional and local laws, rules, regulations and guidance including without limitation Regulatory Authority rules and regulations, decisions and industry codes (including any modification or re-enactment thereto) applicable to the Study and the activities or interactions under this Agreement, including Good Clinical Practice, and all generally accepted standards of good laboratory practice, good clinical practice and good medical practice.

"**Biological Materials**" means any human biological materials, including but not limited to blood, body tissue, plasma and any other material containing human cells.

"**Confidential Information**" means (i) the terms of this Agreement; and (ii) any business, employee, patient or customer information or data in any form which is disclosed or otherwise comes into possession of a Party, directly or indirectly, as a result of this Agreement and which is of a confidential or proprietary nature (including, without limitation, the Study Documentation, any information relating to business affairs, operations, products, processes, methodologies, formulae, plans, intentions, projections, know-how, Intellectual Property, trade secrets, market opportunities, suppliers, customers, marketing activities, sales, software, computer and telecommunications systems, costs and prices, wage rates, records, finances and personnel).

"**Case Report Form**" or "**CRF**" means a printed document ("pCRF"), optical or electronic document ("eCRF") or database designed to record all of the information to be reported to the Company on each Subject, as required by the Protocol.

"**Designee**" means any person designated by the Company in writing who undertakes activities on behalf of the Company in relation to the Study, which may include an Affiliate.

"**Developed Technology**" means any inventions, discoveries, improvements or developments made by the Institution, the Principal Investigator or any Study Site Staff (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.

"**Ethics Committee**" means the independent institutional, regional, national or supranational committee or review board-responsible for ensuring the protection of rights, safety and well-being of human subjects in a clinical study, and for reviewing and approving/providing an opinion on the Protocol, the suitability of the investigator(s), the Study Site(s), the Subject recruitment materials and methods, and informed consent forms.

**"Force Majeure Event"** means any circumstance beyond a Party's reasonable control, including acts of war or other action of military forces, terrorism, riot, civil commotion, sabotage, vandalism, accident, fire, flood, acts of God, strike, lock-out or other industrial disputes (whether or not involving employees of the relevant party) or legislative or administrative interference and which could not have been avoided or mitigated by the exercise of reasonable care by that Party.

"**Good Clinical Practice**" or "**GCP**" means the International Conference on Harmonisation Guideline for good clinical practice (including any modification or re-enactment thereto).

"**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.

"**Materials**" means any equipment, materials (excluding Study Drug), documents, data, software and information supplied by or on behalf of, or purchased at the expense of, the Company, in connection with the Study, as described and set out in the Protocol and this Agreement.

"**National Coordinating/Lead Investigator**" means the Principal Investigator who, by the Company, has been assigned the responsibility to coordinate all principal investigators across all Study Sites within one country>>

"**Payment or Transfer of Value**" means a direct or indirect transfer of *anything* of value, whether cash or in kind in connection with the development or sale of medical products. "Value" shall mean the discernible economic value on the open market. A direct Payment or Transfer of Value is one made directly by a company for the benefit of a recipient. An indirect Payment or Transfer of Value is one made by a third party on behalf of a company for the benefit of a recipient where the identity of the company is known to, or can be identified by, the recipient.

"**Protocol**" means the clinical study protocol that has been approved by the relevant Ethics Committee, which describes the Study, including all amendments thereto as the Parties may from time to time agree in writing.

"**Regulatory Authority**" means any international, national, regional or local agency, authority, department, inspectorate, minister, ministry official, parliament, public or statutory person (whether autonomous or not) of any government of any country having jurisdiction over any of the activities contemplated by this Agreement, the Study, or the Parties.

"**Site Closure**" means the date of receipt by the Principal Investigator of the site closure visit report from the Company.

"**Study Closure**" the date of publishing the Clinical Study Report as communicated by the Company.

"**Sponsor**" means the company, as identified in Clause 3, which takes responsibility for the initiation, management or conduct of the Study in accordance with Applicable Laws.

"**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.

"**Study**" means the clinical study stated on the front page of this Agreement, as further described in the Protocol.

"**Study Drug**" means the investigational medicinal product(s), any placebo and any comparator drug(s) being studied or tested in the Study as set out in the Protocol.

"**Study Site(s)**" means the premises where Study related activities are conducted, as identified in the Protocol.

"**Study Site Staff**" means all those investigators, sub-investigators, employees, agents, students, sub-contractors and others who are engaged by the Institution and/or the Principal Investigator in the conduct of the Study, including any such persons at Study Site.

"**Subject**" means a person recruited to participate in the Study in accordance with the Protocol and Applicable Laws.

## APPENDIX B - PAYMENT

The Company shall compensate the Institution for each Subject that completes the Study in accordance with the Component table below.

**1: Per Subject Compensation:**

| **Activity** | **Compensation per Subject** |
|---|---|
| Visit 1: Enrolment | 17000 |
| Visit 2: Randomization | 20000 |
| Visit 3: | 15000 |
| Visit 4: | 15000 |
| Visit 5: | 15000 |
| Visit 6: | 15000 |
| Visit 7: | 17000 |
| Visit 8: | 17000 |
| Visit 9: | 15000 |
| Visit 10: | 14000 |
| Visit 11: | 14000 |
| Visit 12: | 14000 |
| Premature Treatment Discontinuation Visit ( PTDV): | 11000 |
| Study Closure Visit (SCV) | 12000 |
| **TOTAL RESEARCH GRANT** (if all on-site, in-person, 12 visits and PTDV/SCV visits are completed per protocol. | **2,11,000/-** (this amount would vary based on actual number of on-site, in-person, visits completed by each patient per protocol.) |
| modified follow-up visit i.e. less frequent visits and or regular telephone contacts and or a contact at study closure and or other means (per protocol in case the patient refuses to continue on-site, in-person, study visits in case of premature treatment discontinuation but agrees to undergo modified telephonic follow- | **1500** (this is an optional component and payment for this will be provided if it is actually performed. This is not payable for routine telephonic follow up calls made to the patient.) |

| | |
|---|---|
| up per protocol section **3.9.3.2**) | |

| **2. MEDICAL MANAGEMENT AND COMPENSATION FOR TRIAL RELATED INJURIES AND RESCUE THERAPY** | |
|---|---|
| Medical management of trial related injuries per schedule Y. | On actuals against original bills. This is towards the cost that patient may have incurred for the management of a trial related injury. |
| Compensation for trial related injuries per schedule Y. | As directed by the Drugs Controller General (India) |

The Company shall be entitled to withhold compensation in respect of Subjects whose visit data is incomplete, missing in eCRF or 'lost to follow-up' as a result of any failure by the Institution or the Principal Investigator to comply with their obligations under this Agreement.

Reimbursement will not be given for Subjects enrolled who do not meet all inclusion and exclusion criteria, unless otherwise approved by the Company, and the Institution will not be compensated for any Protocol violations, unless otherwise approved by the Company.

The Company shall additionally compensate the Institution and the Principal Investigator for the activities set out in the table below.

activities set out in the table below.

| **3. ADDITIONAL COSTS** | |
|---|---|
| **Additional Fees** | **Amount in INR** |
| **Subject expenses for travelling and/or reimbursement:** | Up to a maximum of INR 2000 per visit |
| **Study Co-ordinator fees:** | INR 30,000 per randomized patient |
| **Sub-Investigator Fee** | INR 2,000/ per subject per actual visit completed (only applicable for Onsite visits and not applicable for modified follow up visits) |
| **Laboratory Investigations** | As per actuals |
| **Internet Charges** | INR 2,000 per month (From First Subject in to Data Base Lock) |
| **Administrative costs (eg: phone/fax and courier etc.):** | INR 2,000 per randomized subject. |
| **Equipment support (eg: AV recording,** | INR 30,000 upon submission of original bill. |

| | |
|---|---|
| **storage devices etc., which is study specific.)** | |
| **Archival of Documents at end of study (to be archived for 15 years):** | 1,50,000 One Lac Fifty Thousand (This amount will be paid at the end of the study) |

| **4. INSITITIONAL OVERHEADS** | |
|---|---|
| **Institutional Overhead Charges:** | 25% on component 1 (per subject compensation based on actual visits completed). This is not applicable on components 2 (medical management and compensation of trial related injuries, and component 3 (additional costs). |

The Parties agree that payments made for this Study per appendix B will be made to the SMO. AstraZeneca will make the payment to the SMO upon receipt of duly signed invoice for the study related activities per appendix B from the investigator/institution. The services provided by the SMO (payee) to the investigator/institution for this study are governed by a separate agreement between the SMO and investigator/institution that includes the financial obligations between those parties as well. AstraZeneca is not and will not be a party to the agreement between SMO and investigator/institution. AstraZeneca's only responsibility is to make payment per appendix B of this agreement to the SMO on the basis of the invoices raised by the investigator/institution. Investigator and institution release AstraZeneca from any financial obligations and/or disputes that arise in between SMO and investigator/institution concerning this study.

## 5. PAYMENT TERMS

Payments will be made to: **Payee Name: Ardent Clinical Research Services**

Account details:
Bank Name: HDFC
Bank Branch: Hingre Khurd Pune
PAN: APQPD7018M
Account No: 50200007013912
ISFC: HDFC0000825

All invoices should be clearly marked with the "D" code for the Study, and Subject. "E" code wherever applicable.

Invoices to be sent electronically to Or by post to: **AstraZeneca Pharma India Ltd**
**Central Mail Room**
Block N1, 12th Floor, Manyata Embassy Business Park,

Rachenahalli, Outer Ring Road,
Bangalore – 560045, Karnataka, India
T: + 91 80 67748000

| | |
|---|---|
| Time for payments: | The Research Grants, the patient travel expenses and the reimbursements will be paid within a month (30 days) of receipt of a Invoice issued by the Institution or the Principal Investigator (starting from the date of site initiation till Close Out Visit has been performed) against the patients recruited and the visits, relevant activity has been completed.<br>No payment will be made before the Principal Investigator has signed the protocol and before all authorisations required to proceed with the study have been obtained including approval of the relevant ethics committee.<br>Payment is only due if the Principal Investigator/institution has fulfilled his/her obligations under this contract |

## APPENDIX C- FACILITIES, RECORDS and RESOURCES

### 1. PLANNED SUBJECT ENROLMENT

| | |
|---|---|
| **Number of enrolled subjects:** | Approximately 30 subjects |
| **Number of randomised subjects:** | Approximately 15 subjects |
| **First Subject enrolled by:** | First Subject to be enrolled within 60 days from Investigator's receipt of written approval by Sponsor |
| **Last Subject completed before/ LSLV:** | Planned date 05 December 2019 |

### 2. MATERIALS PROVIDED BY COMPANY

| | |
|---|---|
| **Equipment:** | ePRO devices (TrialMaxSlate®) to be provided by CRF Health and to be returned to CRF Health by study closure |
| **Other materials:** | Lab kits provided by Central lab Covance |

### 3. MATERIALS PROVIDED BY STUDY SITE

**Equipment:** Calibrated weighing balance, height scale, sphygmomanometer, Centrifuge for samples, -20 freezer for samples, 12-lead ECG machine.

**Other materials:**

- A computer with high speed internet connection
- An on-line fax machine equipped with archive proof papers (if archive proof papers are not available, fax reports from the Central Laboratory and IVRS/IWRS reports/alerts should be copied)
- Scales for weight and height measurements
- Standard pulse and blood pressure measurement device
- Thermometer
- Thermometer for min./max. temperature monitoring in the rooms where Investigational Products will be stored/ Pharmacy.
- Local lab supplies for safety laboratory assessments such as dipsticks for urinalysis, vacutainers, etc.
- Power bar (for ePRO charging)
- Wi-Fi or good cellular phone signal (for ePRO transmitting)
- Stationary Items like Patient files, plastic sleeves,

papers for printing etc.,

# 4. SOURCE DATA, RECORDS AND STORAGE

## 4.1. Web-based Data Capture ('WBDC') and Electronic Patient Reported Outcome ('ePRO') System

Company may require the completion of a technical site assessment survey to determine that the computer and its associated hardware are technically capable for use in a Web-based Data Capture Study.

To meet key milestones and ensure integrity and completeness of study data, each Subject data should be entered into the electronic Case Report Form within 72 hours of each completed visit. Data queries shall be reviewed and responded to within 72 hours. Timelines for data entry and responses to queries may be shorter when the Study approaches an interim analysis or Data Base Lock. Data related to SAEs/AEs and/or Endpoints must be reported as defined in the Clinical Study Protocol.

### 4.1.1 WBDC, ePRO and/or other system access controls

Access to electronic systems used in the study will be strictly restricted to these (Study Site Staff, Company employees, Company data management centre staff, Subjects depending on the system) who have been appropriately trained. Each user will be allocated access to the system for their sole use only. Principal Investigator and/or his Study Site Staff understand that access codes/tokens and passwords are for personal use only and not to be shared with others, and that an electronic signature, when used, is the legally binding equivalent of a traditional handwritten signature.

### 4.1.2 ePRO training of Subjects

Principal Investigator and/or Study Site Staff are responsible for training Subjects on how to use the ePRO device, using the materials and training provided by the ePRO vendor.

### 4.1.3 Back-up procedures for system unavailability

ePRO; If the network is down, and the data has been saved on the ePRO device the data is stored on the device until next time data is sent.

WBDC; Back-up procedures for WBDC according to the Protocol.

## 4.2. Records and Documents

### 4.2.1 Medical Records

The medical (hospital/practice) records for each Subject should contain information which is important for the Subject's safety and continued care and to fulfil the requirement that critical Study data should be verifiable. To achieve this, the medical records of each Subject should clearly describe at least:

- that the Subject is participating in the Study, eg, by including the enrolment and/or the randomisation code and the Study code or other Study identification
- the Subject's general practitioner/family doctor was informed of the Subject's Study participation/was not informed and why
- date when Informed Consent was obtained
- diseases (past and current; both the disease studied and others, as relevant)
- treatments withdrawn/withheld due to participation in the Study
- treatments given, including Investigational Product, changes in treatments during the Study, and the time points for the changes.
- visits to the clinic during the Study, including those for Study purposes only
- Serious Adverse Events (if any) including causality assessments
- date of and reason for discontinuation; and
- additional information according to local regulations and practice.

Company will have the right to assess the validity of the electronic system used for medical records in order to ensure proper Source Data Verification ('SDV').

### 4.2.2 Case Report Form as source document

The following variables may be directly recorded in the CRF and need not be present in Subject medical records (electronic/paper CRF = source document), provided that data is recorded in the CRF at once. Please specify in this section or add an annex where source data is listed.

- Ethnic group and race
- Criteria of SAE met or not
- AstraZeneca aware of SAE
- Reason of concomitant medication
- Date and results of local laboratory reports

- The laboratory reports received via fax/e-mail from the Central Laboratory should be signed and dated by the Principal Investigator or delegate and should be filed in the Investigator's Study File (ISF).
- Reports from the IWRS/IVRS (faxed or e-mail-printouts) will be considered as source data and should be filed in the ISF.
- ECG printouts or duplicates, should be signed and dated by the Investigator or delegate
- Biological sample logs provided by AstraZeneca.

#### 4.2.3 Electronic Patient Reported Outcome Source Data

Sites are responsible for ensuring that patients complete the correct assessments at the correct time. Sites are responsible for managing the device and selecting subject identifier (E-code) on the device which corresponds to the patient who is completing the assessment.

The ePRO source data are recorded electronically in a central database hosted by the ePRO service provider and are available for review and maintenance during the Study. Principal Investigator maintains control of the data and must authorise all ePRO data changes.

### 4.3. Storage of Study Documents

The Study Documentation shall be retained and stored during the Study and for 15 years after Study Closure in accordance with this Agreement.

When a WBDC/ ePRO system is used for the Study, Company will provide Principal Investigator with copies of the Study Site's electronic Case Report Forms, ePRO and associated data on an optical media eg, Compact Disc ('CD') or digital versatile disc ('DVD'). The media should be regarded as part of the Investigator's study file, but may be stored separately.

### 4.4. Emergency Unblinding Tools

Treatment codes are accessible according to the Protocol.