CLINICAL TRIAL AGREEMENT BETWEEN ACCUTEST, PRINCIPAL INVESTIGATOR, INSTITUTE& SITE MANAGEMENT ORGANISATION

(PI Name:Dr. Ashish Deshmukh, Site Name: Mahatma Gandhi Mission's Medical College and Hospital, Protocol Number: ARL/CT/18/002)

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement is made by and between the following four parties:

1)ACCUTEST: Accutest Research Lab. (I) Pvt. Ltd. A-77, Khairne MIDC, TTC Industrial Area, Khairne, Navi Mumbai, 400 709, Tel.: +91 22- 2778 0718/19 Fax: +91 22- 2778 0720 Email ID: rajendra.talele@accutestgloabal.com **Hereinafter "ACCUTEST"**	**2) PRINCIPAL INVESTIGATOR:** Name: Dr. Ashish Ramchandra Deshmukh Address: Skin and VD Department, Mahatma Gandhi Mission's Medical College, N-6, CIDCO, Aurangabad, Maharashtra, India - 431003. Tel.: 0240-6601100 Ext- 316 Fax: +91 2772-246108 Email ID: ashish7557@gmail.com **Hereinafter "PRINCIPAL INVESTIGATOR"**
3) INSTITUTE: Name of the Authorized Signatory:Mr. Rajendra Bohra Designation: Dean Name of the Institute:MGM Medical college and Hospital. Address: MGM Medical College and Hospital, N-6, CIDCO, Aurangabad, Maharashtra, India – 431003 Tel.: 0240-6601100 Fax: 91 2772-246108 Email ID: rajbohra@msn.com **Hereinafter "INSTITUTE."**	**4) SITE MANAGEMENT ORGANISATION** Name of Authorized Signatory: Dr. Sushil Chaudhary Designation: Director Address:.Grapecity Research Solutions LLP Prakash Housing Society, Block no-D/2, Thergaon, Pune- 411033, Maharashtra, INDIA, Tel.: 020-65222284 Fax: 020-65222284 Email ID: sushilrc.chaudhary@gmail.com

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This Clinical Trial Agreement is effective from the date of last signature("**Effective Date**")

Accutest is engaged in the business of clinical trials management as a contract research organization and intends to carry out a clinical study ("the Study") with "A Randomized, Double-Blind, Placebo-Controlled, three arm, Parallel-Design, Multiple-Site Study to Evaluate the Therapeutic Equivalence and Safety of Tacrolimus Ointment, 0.1% (Encube Ethicals Private Limited) with Protopic® (tacrolimus) ointment, 0.1% (Astellas Pharma US, Inc.) in the Treatment of Moderate to Severe Atopic Dermatitis "("the Protocol") for the purpose of obtaining data for the application of the Study Drug.

The Study Protocol Number:ARL/CT/18/002
Subject to the condition of obtaining the pertinent ethics committee approval and the regulatory authorities' authorization, the parties intend to participate in the Study by rendering their services and agree to the following:

Section 1: Study Protocol
The nature and scope of the Study are ensured from the Protocol. The Protocol precisely and exhaustively describes the clinical research activities and responsibilities for careful execution by the Principal Investigator. Any changes to the Protocol are subject to Accutest's prior written consent which the Principal Investigator shall obtain, and the approval/notification of the competent ethics committee and the Drug Controller General of India ("**DCGI**"). The Protocol, including any amendments, constitutes an integral part of this Agreement ("The **Agreement**") and shall be valid upon signature of this Agreement. Inthecase of any inconsistency between this Agreement and the Protocol, this Agreement shall prevail. The Principal Investigator warrant that they have received the Protocol.

Section 2: Rules for the Conduct of the Study

2.1 Legal framework

The parties agree that the duties and obligations of the provisions of the Declaration of the Helsinki World Medical Association Recommendations Guiding Physicians in Biomedical Research Involving Human Subjects including amendments as set out in the Protocol of the "ICH Harmonised Tripartite Guideline, Guideline for Good Clinical Practice", the applicable national legislation on public health and pharmaceuticals including the Central Drugs Standard Control Organization's Good Clinical Practice Guidelines ("**GCP Guidelines**")valid at the time of the performance of this Agreement; and all other pertinent rules and regulations shall be applicable including but not limited to Schedule Y to the Drugs and Cosmetics Rules, 1945 ("**Schedule Y**"), and that the Agreement shall be construed accordingly.

2.2 General Duties and Obligations

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The Principal Investigator shall carry out the Study in a professional, competent manner in accordance with the Protocol and the terms of this Agreement.

The Principal Investigatorhereby warrants that they have sufficient resources with regard to time, adequate personnel and facilities for the performance of the Study. Unless expressly agreed otherwise, the responsibility for services of third parties (including, but not limited to sub-investigators and satellite sites) remains with the Principal Investigator. The Principal Investigator shall ensure that all personnel and third parties are bound by and comply with the terms of the Protocol and this Agreement.

The Principal Investigator will inform Accutest, about all changes of personnel, facilities and clinical research methods at the Institute that may affect the Study.

In the event the Principal Investigatorbecomes either unwilling or unable to perform the duties required by this Agreement, Principal Investigator will inform Accutest within 3 days of the Principal Investigator being unwilling or unable to perform the duties. The Principal Investigatorshall continue to be bound by the provisions referred to in Section 5.2.

The Principal Investigator is an employee, of the Institute and Investigator guarantees the proper performance by him following all obligations hereunder.

2.3 Ethics Committee / Review Board / Regulatory Authority Approval / Notifications

Accutest shall undertake the necessary notifications to authorities in accordance with applicable laws. The Study shall not commence until the Principal Investigator is informed by Accutest that the authorities have given authorization.
Accutest will provide the Principal Investigator with all the documentation required for submission to the pertinent ethics committee. Institute/Principal Investigator will obtain the written approval of the appropriate ethics committee prior to the commencement of the Study and will furnish Accutest or its designate with the ethics committee's letter of approval and a list of all ethics committee meeting attendees.

The Study shall not commence until receipt of the ethics committee written approval and shall follow any conditions of approval imposed by the ethics committee, and the time interval has been observed and all regulatory documents that are necessary according to the ICH – GCP,Schedule Y, and other applicable pharmaceutical regulations are available.

Should the ethics committee express objections to the content or the performance of the Study, the parties will collectively develop modifications that accommodate the objections. Should the ethics committee approval be unobtainable nonetheless, the parties shall be entitled to mutually terminate this Agreement. Amendments to the Protocol must be submitted by the Principal Investigatorto the pertinent ethics committee.

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2.4 Subject Information and Informed Consent

The Principal Investigator shall ensure that during informed consent process, information to the subjects is provided individually and not in a group (in accordance with the provisions specified in Section 2.1 above) in a language that is best understood by the subject about the nature, significance and consequences of the Study, its expected duration, and the potential benefits and risks involved in Study participation.The explanation shall at least include all points listed in theICH-GCP and Schedule Y.ThePrincipal Investigator should obtain written Informed consent fromthepatient, record necessary source data (like IC-EC, ECG, Physical Examination, Vital,etc.) and submit verify the eligibility criteriaprior to enrolling the patient in the study.The Principal Investigator shall conduct complete Informed Consent process as per current regulatory requirement and also document the written consent prior to the Study on a prepared Informed Consent Form (ICF) and shall hand out a copy of the ICF and subject information document to each subject. In accordance with the provisions specified in Section 2.1 above, Principal Investigator shall ensure that consent of the governing local health authorities and/or subject for the submission of ICF mentioned above anonymous data to and/or appropriate regulatory authorities, is obtained.

All the study related documents should be preserved safely after the completion/termination of the study for at least a period of 5 years if it is not possible to maintain the same permanently, if applicable.

Each subject will be informed accordingly, and his/her consent will be obtained

- that he/she is enrolled in the Study,
- that the subject's insurance has been effected and that each subject has obligations arising from the general insurance conditions; in particular these are:
- during the course of the Study the subject must immediately inform the Principal Investigator about any other medical treatment he/she undergoes;
- any health damage, which may be attributable to participation in the Study, must be immediately reported to the insurance company;
- that the necessary documentation of the subject's health and personal data and its distribution to Accutest, the competent health authorities, and other Institutes, as legally required, may take place.

In the event the patient or his/her legally acceptable representative is unable to read/write, an impartial witness will remain present during the entire informed consent process and who must append his/her signatures to the Study informed consent form. The Principal Investigator will obtain prior approval from the relevant ethics committee in the event of any amendments to the Study informed consent form

2.5 Enrolment Period

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The recruitment phase may not commence until the written positive decision of the ethics committee has been obtained.

The Principal Investigator will recruit a maximum of **25 subjects** for the Study, as the enrollment is competitive amongst the investigative sites.

The Principal Investigator is aware that for this multicentre study, a competitive recruitment will apply. Should the total number of subjects enrolled in the study be met prior to the end of the anticipated enrollment period, Accutest shall have the right to end further enrolment of subjects; no payment will be made for any such additionalsubjects.

2.6 Study Documents and Drug Supplies

Accutest's designee shall ensure appropriate and timely supply of the documents and Study Drugs necessary for the performance of the Study. All supplies shall be returned to Accutest by the PrincipalInvestigator/Institutein a timely manner throughout the performance of this Study, as outlined in the Protocol or when Accutest otherwise requests delivery of data, unused Drug, and clinical specimens.

The Principal Investigator hereby warrants that he/she shall:

a) account for all clinical supplies furnished by Accutest and keep a written inventory of any equipment supplied by Accutest according to guidelines provided by Accutest;

b) use the Study Drug solely for the Study, documenting each usage and to return all used and unused clinical or other supplies provided by Accutest upon conclusion of the Study;

c) collect data properly and report to Accutest all relevant information and data obtained under the Protocol;

d) submit to Accutest signed CRFs/eCRFs resulting from the Study in a timely manner;

e) retain all necessary records and documents about the Study as required by applicable regulatory requirements, this Agreement, and/or the Protocol;

Moreover, the Principal Investigatorshallupdate/maintain the investigator study file provided at the time of Site Initiation Visit (SIV)andas per ICH-GCP all relevant essential documents which are necessary for the conduct of the Study including but not limited to following:

a) Signed Protocol and amendments;

b) Investigator's Brochure and updates (If applicable);

c) Ethics Committee composition, approval(s)/opinion correspondence/reporting;

d) Notifications/Approval of regulatory authorities;

e) CVs and signature sheet for key study personnel (e.g. investigators);

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f) Approved and signed informed consent forms;
g) CRFs/eCRFs (investigator's copy) (If applicable);
h) Serious adverse events documentation and related correspondence/reporting;
i) Instructions for handling of Study Drug;
j) Screening, enrollment, and monitoring logs and subject identification code list;
k) Study related correspondence with Accutest

2.7 Adverse Events

The Principal Investigator is obliged to document and manage all Adverse Events (AEs) in accordance with the Protocol and to notify Accutest of all Serious Adverse Events according to the study instructions ("Serious Adverse Event Reporting") within the timeline specified in the Protocolor as per current regulatory requirement

Section 3: Documentation and Monitoring

3.1 Documentation and CRF/eCRFs handling

The Principal Investigator shall keep all original medical files (paper and print-outs of electronic files) of every subject participating in the Study in addition to the Case Report Forms(CRFs)/electronic Case Report Forms (eCRFs). The medical file is the documentation containing all demographic and medical data of a subject. This medical file will clearly identify each Study subject and where the medical files are termed the source; entries on the CRFs/eCRFs must be traceable to entries in the medical file. In the course of the Study, the Principal Investigator undertakes to express medical data in writing using medical terminology where necessary, the status of the Study for the respective subject and be completed expeditiously following a subject visit. The Principal Investigator must sign all eCRFs/CRFs. The Principal Investigator should inform the general practitioner and, if applicable, any other physicians, treating the subject about his participation in this clinical Study. The Principal Investigator warrants that all eCRFs/CRFs submitted to Accutest are true, complete and correct and accurately reflect the results of the Study with respect to each person participating as a subject.

The Principal Investigator undertakes to cooperate with Accutest and acknowledges Accutest's right, upon a request, to be granted direct access to all requested trial-related records (including patient medical files).

3.2 Monitoring

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The parties agree to frequent monitoring visits to the institute by Accutest. The monitor (CRA) will visit the Institute to discuss study progress with the Principal Investigator who will allow inspection of all study data including medical files requested by the monitor.

The CRAs will check the data entered in the eCRFs/CRFs. CRAs and possibly representatives of Accutest shall perform source data verification, comparing the CRFs/eCRFs with the medical records to validate the data. Despite the CRA's and other representatives' efforts, the Principal Investigator remain primarily responsible for the accurate and complete data entry in the CRFs/ eCRFs. All persons who obtain knowledge of medical records are subject to professional secrecy.

Such monitoring will be carried out during the study, but may also be demanded by the pertinent regulatory authorities after completion of the study. The Principal Investigator are obliged to inform Accutest immediately of any notification of an inspection by the pertinent regulatory authorities.

3.3 Audit and Regulatory Inspection

Audits or inspections may be carried out during the Study, but may also be demanded by the regulatory authorities after completion of the Study. In the event thatAccutest or authorities perform an audit, the Institute,PrincipalInvestigatorwill allow access to the facilities, make documents available and if necessary provide information. Should a governmental or regulatory authority request or carry out an inspection of the Institute's or Principal Investigator's facilities, Principal Investigator has to immediately notify Accutestby telephone, mail or fax and allow Accutestto be present. The Principal Investigatorshall provide to Accutest copies of all materials, correspondence, statements, forms and records that Principal Investigator receives, obtains, or generates pursuant to any such inspection.

Section 4: Confidentiality and Subject Data

4.1 Protection of Subject Data

On the CRFs/eCRFs, which will be used for evaluation of the Study, patient data will be documented in anonymous form only, i.e. without naming the subject, and passed on to Accutest and the DCGIand/or foreign regulatory authorities. The name of the subject, as well as other person-related data, will not be divulged by the Principal Investigator, or by Accutest. Accutest shall ensure that the protection of the data concerning subjects is safeguarded.

When, for reasons ofthefulfilment of professional obligations or verification purposes, person-related data concerning the Principal Investigator or the subjectare stored or handled, reliable organizational measures must be employed to ensure that these data are not divulged to unauthorized third parties.

Exception: When IEC or DCGI or any other regulatory authorities require the subject details then Principal investigator shall share photocopy and maintain the record in the file.

4.2 Confidentiality

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Principal Investigator shall receive copies of the Study documents and the investigator site file. Principal Investigator/Institute is obliged to retain the documents facilitating identification of the Study patients, and all other Study Documentation disclosed by Accutest, for at least 15 years after the end or the premature termination of the Study or as communicated during site close-outvisit.Institute has no part to play in the closeout of the trial.Accutest is responsible for informing the Principal Investigator when it is no longer necessary to conserve all the Study documentation (ICH 4.9.5).

The Principal Investigator/Institute is obliged to maintainthesecrecy of all information related to the Study and the Study Drug ("the **Information**"). The Principal Investigator shall procure that any co-workers assisting the Principal Investigator in the Study shall keep all such Information secure and strictly confidential as well. The Principal Investigator agrees not to use the Information for any purpose other than the performance of the Study.

The information shall not include:

- Information that enters the public domain and only then where this has occurred other than through unauthorized disclosure by the Principal Investigator or his co-workers.
- Information that is properly requestedforby the ethics committee responsible for approvingthe Study may proceed or is requested by the pertinent regulatory authorities in accordance with prevailing legislation, provided that the Principal Investigator shall give prior written notice to Accutest of any such request for disclosure.

The above obligations of confidentiality shall remain in full force and effect.

4.3 Proprietary information

All documents, data, know-how, formulas and unused Study Drug provided to the Principal Investigator for purposes of the Study ("**Data**") are and will remain Accutest's property and will be returned to Accutestor their respective designates upon request. Notwithstanding the preceding, Accutest shall retain full ownership rights in and to all templates, programs and other materials developed or licensed by Accutestprior to or apart from the commencement of this Agreement, regardless of whether such materials are used in connection with this Agreement.ThePrincipal Investigator hereby transfers and assigns to Accutestthe Principal Investigator's worldwide right and title to all Data in perpetuity and agrees to undertake such actions reasonably requested by Accutest to give effect to such ownership and agrees to sign, execute, affirm all documents, including, without limitation, all applications, forms, instruments of assignment and supporting documentation and perform all other acts as may be required for this purpose.

4.4 Rights to results

Accutest shall have the right to use the results of the Study in any manner deemed appropriate to Accutest's business interests. All data attained duringtheperformance of the Study are Accutest's property. The Principal Investigator assign worldwide rights and title to alldata obtained in the Study in

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perpetuity to Accutest and agree to undertake such actions reasonably requested by Accutest to give effect to such ownership and agree to sign, execute, affirm all documents, including, without limitation, all applications, forms, instruments of assignment and supporting documentation and perform all other acts as may be required for this purpose. Principal Investigatorshall notify Accutest of the results immediately, separately and in writing.

4.5 Intellectual Property

Neither the Principal Investigator nor hisemployees or agents shall acquire any rights of any kind whatsoever with respect to the Study Drug as a result of their performance under this Agreement. All inventions, discoveries, and technology relating to the Study Drug conceived by the Institute or its Principal Investigator, solely or jointly with others as a result of work done under this Agreement, shall be, and remain, at all times the sole and exclusive property of Accutest (subject to the right expressly reserved under Section 4.3).

The Principal Investigator hereby assign worldwide rights and title to the Intellectual Propertyin perpetuity to Accutest and agree to undertake such actions reasonably requested by Accutest to give effect to such ownership and agree to sign, execute, affirm all documents, including, without limitation, all applications, forms, instruments of assignment and supporting documentation and perform all other acts as may be required for this purpose.

The Principal Investigatorwarrant, by the execution of this Agreement, that they have not entered, and will not enter, into any contractual agreement or relationship which would in any way conflict with or compromise Accutest's rights to, any inventions, discoveries, or technology arising out of or related to their performance thereunder.

4.6 Publications

It is the general policy of the ARL&Sponsorto encourage publication of results of Clinical Trial on a case to case basis. However, according to good scientific practice, no interim data should be published by the Principal Investigator/ Institute unless agreed by the Parties in writing. It is further agreed that when the Principal Investigator/ Institute request for publications, the manuscript shall be based on final report of the Study and before any publication it shall be sent to the ARL &Sponsorfor its perusal, comments, and approval. The ARL or Sponsor may at its discretion either refuse the publication or forward it to the Principal Investigator/ Institute/ along with its comments or modifications which shall be final and binding on the Principal Investigator/ Institute.

4.7 Publicity

No party to this Agreement shall use Accutest's name or the name of any party hereto in connection with any advertising or promotion of any product or service without the prior written permission of such party or Accutest, as appropriate.

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Section 5: Term and Termination of the Agreement

5.1 This Agreement commences on the Effective Date provided that Accutest has received from the pertinent ethics committees and the DCGI, as required by law, approval to carry out the Study. This Agreement shall remain in force to the full conclusion of the Study according to the Study Protocol unless terminated prematurely. Accutest may terminate this Agreement immediately upon written notice to the Institute/Principal Investigator.

5.2 Termination of this Agreement by any party shall not affect the rights and obligations of the parties accrued prior to the effective date of termination of this Agreement.

Neither termination of this Agreement, however, effectuated, nor the end of the term shall cause the parties hereto to be released from their rights and obligations under Sections 3, 4, 6, 7 and 8, or under any other provisions of this Agreement that by their terms are understood to survive termination.

Upon completion of the Study, the Principal Investigator and the Institute shall return to Accutest, or its designee, all unused Study Drug, compounds, Comparator Drugs (when used), equipment as specified in Section 2.6 that were furnished to the Institute other than the investigator site file documents.

5.3 Should the Principal Investigator recognise within reasonable discretion that continuation of the Study is no longer possible, due to unexpected results medically not justifiable, due to severity of serious adverse events not justifiable or efficacy of the treatment with the Study Drug insufficient, he/she will immediately notify Accutest as well as the ethics committee. Should continuation not be justifiable, the Principal Investigator may arrange for immediate termination of the Study.In the event that the Study is terminated with the consent of Accutest,the Principal Investigator shall receive payment pro rata temporis basis for the efforts of the Study, in accordance with Appendix A.

5.4 Accutest may terminate its cooperation with the Principal Investigator prematurely, provided that:

a) one month after shipment of the Study material, no subjectshavebeen enrolled or the Principal Investigator recruits no subjectsor recruits such a low number of subjectsthat it can be assumed that the agreed number of patients will not be reached during the planned recruitment phase,

b) Accutest terminates the Study for the Study Drug or the indication is discontinued,

c) it is proved that the dosage used for the Study does not seem to be justified any more,

d) regulatory authorities or other pertinent institutions decide to terminate the Study in this center or as a whole,

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e) the Principal Investigator fails to sufficiently adhere to the conditions of the Protocol and the need to exact and complete data documentation and the GCP Guidelines and Schedule Y.

5.5 Consequences of Termination: Upon the effective date of termination, the Principal Investigator shall:

a) terminate all services as efficiently and quickly as possible, except to the extent Institute/Principal Investigator is required to continue to follow the procedures and perform such services with respect to the ongoing Study, as may be necessary, until the appointment by Accutest of another Institute/Principal Investigator for the purpose of continuing the Study;

b) within 7 business days, provide copies of all information, data, documents (including but not limited to IPs, ICFs(blank copies), CRFs/eCRFs, Study related material & documents, and any clinical samples obtained with regard to the Study) prepared, conceived, generated or delivered by Principal Investigator as a result of or in connection with the conduct of the Study;

c) Provide an accounting of all clinical supplies, which is subject to verification by Accutest. If Accutest objects to any charge, the parties shall use reasonable efforts to resolve expeditiously any disagreement.

Section 6: Payment Terms and Conditions

It shall be the Principal Investigator's/ Institute's responsibility to comply with all obligations in respect of taxes and social security contributions, if applicable, which relate to the subject matter of this Agreement, including without limitation, those which relate to the Principal Investigator, the Institute, and its employees and/or collaborators.

Payment of investigator grants on behalf of Accutest will be equatedwith respect to the number of subjectsrecruited and the services performed as set out in detail in the APPENDIX-I & II entitled "Investigator Grants."

Inthecase of any inconsistency between this Agreement and the APPENDIX, this Agreement shall prevail. For the avoidance of doubt, if any obligation is specified in one of these documents but not in the other, this shall not constitute an inconsistency.

In the event thatAccutest or the Principal Investigator/Institute terminates the Agreement prematurely in accordance with Section 5.4, Accutest shall not pay grants for performance on subjects that do not conclude the Study provided that:

- where a subjecthasbeen recruited to the Study in violation of the Protocol, there shall be no obligation of payment;

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- where failure by a subjectto complete the Study is due to the omission of tests or assessments by the Principal Investigator, there shall be no obligation of payment;
- where failure by a subjectto complete the Study is due to adverse effect, lack of effect, concomitant illness, non-compliance or non-attendance, provided that full data is available up to the time of the subject'sdropout and the event is satisfactorily recorded, payment shall be made in accordance with the above-referenced APPENDIX proportionately according to the amount of work carried out by the Principal Investigator pursuant to the Protocol;
- any sums advanced to the Principal Investigator prior to termination of this Agreement will be taken into account in calculating any sum due to the Institute or Principal Investigator and any balance outstanding and due to Accutest shall be paid to by the Principal Investigator;
- "Completed Patients" are subjectswho have completed the Study in accordance with the Protocol, and for whom full case report forms and any ancillary documentation required have been completed by the Principal Investigator to Accutest's satisfaction.

Section 7: Standard of Care, Insurance, Indemnity

7.1 Subject Insurance

Thishas been obtained and will be provided to the site personnel before the initiation of the trial.

7.2 Product liability

Study Insurance will be provided to the site personnel before the initial of the trial.

7.3 Standard of care

In no event shall Accutest be held responsible for any controversy, demand or claim for the payment of damages deriving from Principal Investigator for-

(a) injuries or damages incurred if they are the result of or are alleged to be the result of negligence or willful misconduct on the part of the Instituteor agents or the Principal Investigator;

(b) activities contrary to the Protocol;

(c) unauthorized warranties made by the Principal Investigator concerning the product being tested;

(d) in any case, in which written, informed consent was not obtained for the subjectinvolvedin accordance with the Protocol.

The Principal Investigator hereby represent and warrant that they have obtained a professional liability insurance policy from a reputed and creditworthy insurance company, covering their liability for any damage, which may be caused as a result of fault or negligence, which they may commit in the performance of this Agreement. The Principal Investigator shall provide evidence of its

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insurance upon request by Accutest. The Principal Investigator shall be liable under this Agreement for direct damages resulting from negligence or wilful misconduct in the execution of the Study.

The Principal Investigator shall defend and hold harmless, and be responsible for losses suffered byAccutestand any agent and employees of Accutest from any and all liabilities, claims, actions or suits for personal injury or death directly arising out of the improper or negligent administration or use of the Study Drug during the course of the Study.

The Principal Investigator shall also indemnify, defend, and hold Accutest and its affiliates, directors, officers, employees and other representatives ("Accutest Indemnified Parties") harmless from and against any and all loss, costs, claims, actions, liability and/or suits, including without limitation, interest, penalties and reasonable attorneys' fees ("Accutest's Claims"), incurred by Accutest that arose from or was a result of following:

(a) any material breach by Principal Investigator under this Agreement;

(b)the failure, or act, error, deviation, omissions, negligence, gross negligence or intentional misconduct of the Principal Investigator in connection with its performance of the services, obligations, responsibilities and undertakings under this Agreement;

(c) Principal Investigator's violation of any and all applicable laws rules and regulations of India;

(d) Principal Investigator's breach or default in performance of its obligations in connection with the Study;

(e) Principal Investigator's material deviation from the Protocol;

(f) Principal Investigator's failure to complete the Study and any such delay attributable solely to Principal Investigator's willful misconduct, or failure to comply with its obligations under this Agreement.

Section 8: Parties

8.1 Conflict of Interests

ThePrincipalInvestigatorwarrant that they, as well as all their support personnel, are not presently under any agreement or obligation which conflicts with the duties and obligations owed to Accutest under this Agreement, and further agree not to undertake any such obligations or agreement during the course of the Study.

Where (if applicable) it is intended that the Study Drug will be the subject of a submission to the regulatory authorities for a New Drug Application, the Principal Investigator certifies that he/she shall, in any form or manner reasonably requested by Accutest, disclose, and shall use his/her reasonable best efforts to cause any sub-investigators for the Study to disclose, all of the following that they and their spouses, domestic partners and dependent children own or possess directly, indirectly, or equitably (all collectively "Financial Interests"):

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(a) All compensation, payments (including other research grants, consulting or director's fees, honoraria, speaking and meeting travel fees and reimbursement) and items or services of value provided by or on behalf of Accutest (excluding compensation received under this Agreement);

(b) All licenses, assignments, or other conveyances of rights or interests in real, personal or intellectual property ofAccutest or relating to the Study Drug;

(c) All forms of interests in the equity (including stock, options, and warrants) or debt of Accutestor of other entities having a financial interest in the Study Drug; and

(d) All other financial interests, payments, and other compensation.

During the conduct of the Study and for one (1) year after its completion, the Principal Investigator agrees to execute and update such forms, disclosures, and certifications now or subsequently required by Accutest related to the Financial Interests. The Principal Investigator hereby warrants that he/she has implemented a "Conflicts of Interests" disclosure and management policy and program that complies with the requirements and regulations issued or administered by the pertinent regulatory authorities, and the Principal Investigator warrants that he/she has and will continue to comply with such policies and programs.

8.2 Independent Contractor, Employees

The Institute and the Principal Investigatorshall perform services under this Agreement only as independent contractors for Accutest, and nothing contained herein shall be construed to be inconsistent with that relationship or status. The Principal Investigator and his respective employees shall not be considered employees or agents of Accutest. This Agreement shall not create a business organization of any kind.

The parties agree that they shall not directly or indirectly solicit for employment, employ or otherwise retain staff of the other party during the term of this Agreement or within the period of three (3) years following termination of this Agreement.

The Study is performed independently from any business transactions and decision on supply purchases with Accutest. The Institute and the Principal Investigator will not receive any benefits from the conduct of the Study beyond the remuneration agreed herein.

8.3 Assignment

Principal Investigator shall not assign his rights or obligations out of this Agreement to any third parties without Accutest's prior written consent. The Institute and the Principal Investigator understand and agree that this Agreement is being entered into to perform services for Accutest and that accordingly, Accutest may freely assign its rights and obligations out of this Agreement.

Initial (ACCUTEST):	Initial (PI):	Initial (INSTITUTE):	Initial (SMO)
	Ashish		

ACCUTEST RESEARCH LABORATORIES (I) Pvt. LTD. NAVI MUMBAI

M. G. M. Hospital Aurangabad.

CLINICAL TRIAL AGREEMENT BETWEEN ACCUTEST, PRINCIPAL INVESTIGATOR, INSTITUTE& SITE MANAGEMENT ORGANISATION

(PI Name: Dr. Ashish Deshmukh, Site Name: Mahatma Gandhi Mission's Medical College and Hospital, Protocol Number: ARL/CT/18/002)

The Institute/Principal Investigator shall not retain any subcontractor to perform any of its obligations under this Agreement without the prior written consent of Accutest. Any such consent shall not relieve the Institute and/or the Principal Investigator of its obligations hereunder.

Section 9: Communications

The Parties undertake to notify each other of all cases that influence the performance of this Agreement.Correspondences shall be made to the following addresses:

1)ACCUTEST: Accutest Research Lab. (I) Pvt. Ltd. A-77, Khairne MIDC, TTC Industrial Area, Khairne, Navi Mumbai, 400 709, Tel.: +91 22- 2778 0718/19 Fax: +91 22- 2778 0720 Email ID: rajendra.talele@accutestgloabal.com **Hereinafter "ACCUTEST"**	**2) PRINCIPAL INVESTIGATOR:** Name: Dr. Ashish Deshmukh Address: Skin and VD Department, Mahatma Gandhi Mission's Medical College, N-6, CIDCO, Aurangabad, Maharashtra, India - 431003. Tel.: 0240-6601100 Ext- 316 Fax: +91 2772-246108 Email ID: ashish7557@gmail.com **Hereinafter "PRINCIPAL INVESTIGATOR"**
3) INSTITUTE: Name of the Institute: MGM Medical college and Hospital. Address: MGM Medical College and Hospital, N-6, CIDCO, Aurangabad, Maharashtra, India – 431003 Tel.: 0240-6601100 Fax: +91 2772-246108 Email ID: rajbohra@msn.com **Hereinafter "INSTITUTE."**	**4) SITE MANAGEMENT ORGANISATION** Name of Authorized Signatory: Dr. Sushil Chaudhary Designation: Director Address:.Grapecity Research Solutions LLP Prakash Housing Society, Block no-D/2, Thergaon, Pune- 411033, Maharashtra, INDIA, Tel.: 020-65222284 Fax: 020-65222284 Email ID: sushilrc.chaudhary@gmail.com

Section 10: Contractual

10.1 Entire Agreement

This Agreement (including the Protocol and the APPENDIX) represents the entire understanding between the parties with respect to the subject matter hereof. No amendment to this Agreement will be effective or binding unless it is in writing signed by all parties and refers to this Agreement.

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CLINICAL TRIAL AGREEMENT BETWEEN ACCUTEST, PRINCIPAL INVESTIGATOR, INSTITUTE& SITE MANAGEMENT ORGANISATION

(PI Name: Dr. Ashish Deshmukh, Site Name: Mahatma Gandhi Mission's Medical College and Hospital, Protocol Number: ARL/CT/18/002)

10.2 Applicable Law, Place of Venue

The parties agree that this Agreement shall be governed by Indian Law, without regard to the conflicts of laws provisions thereof.

The parties will endeavor to settle amicably any dispute having its origin in this Agreement. In case a dispute is brought before a court of law, the courts of Mumbai, India will have sole jurisdiction over the litigation

10.3 Severability

Should any of the provisions of this Agreement be declared entirely or in part invalid or unenforceable by the pertinent authorities according to the applicable laws, the remaining terms of this Agreement shall not be affected by such declaration. Such invalid provision shall be replaced by a valid provision reflecting - to the extent possible - the intent of the original provision.

10.4 Waiver

No waiver of any term, provision 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 any such term, provision or condition, or of any other term, provision or condition of this Agreement.

Section 11: Miscellaneous

Principal Investigator/Instituteherebyconfirms,

A. that he/she has never been subject to debarment proceedings indicted, convicted, or otherwise engaged in conduct for which a person can be debarred by law,

B.To have received a copy of the Investigator's Brochure and to be informed of its contents.

The Investigator consents that his/her contact data, as well as information about the conduct of the Study, may be stored and processed for evaluation purposes during and after the completion of the Study by Accutest.

1) ACCUTEST: For Accutest Research Lab. (I) Pvt. Ltd: Signature and Date	**2) PRINCIPAL INVESTIGATOR:** Signature and Date

Initial (ACCUTEST):	Initial (PI):	Initial (INSTITUTE):	Initial (SMO)
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INICAL TRIAL AGREEMENT BETWEEN ACCUTEST, PRINCIPAL INVESTIGATOR, INSTITUTE& SITE MANAGEMENT ORGANISATION

(PI Name: Dr. Ashish Deshmukh, Site Name: Mahatma Gandhi Mission's Medical College and Hospital, Protocol Number: ARL/CT/18/002)

Mr. Rajendra Talele, Head- Clinical Development Services 19 Oct 2018	**Name: Dr. Ashish Deshmukh** Ashish 01/11/2018
3) INSTITUTE: For MGM Medical College and Hospital Signature and Date 1/11/18 **Name & Designation: Dr. Rajendra Bohra - Dean**	**4) SITE MANAGEMENT ORGANISATION** For Grapecity Research Solutions LLP Signature and Date 01/11/18 **Name & Designation: Dr Sushil Chaudhary - Director**

APPENDIX I

Financial Support for Investigator:

(a) Total payment, compliance, completed patients, inclusion Criteria:

Payment of remuneration will only be made under the condition that the Study is conducted in accordance with the Protocol, the Study documentation is complete and evaluable, can be verified from the subject medical files, and is submitted to Accutest at the stipulated points in time. Should these prerequisites not be fulfilled, the remunerations are forfeited, particularly for patients who are included in the Study despite non-compliance with the inclusion or exclusion criteria.

Unless expressly agreed otherwise in writing, total payment will not exceed the amount set out below.

For each evaluable patient who completes the study visits in accordance with the Protocol, GCP, and application regulatory requirement, Accutest will compensate the Investigator remuneration as specified in Appendix II.

Payments for any costs not expressly specified herein, including but not limited to hospital overhead fees, staff costs, pharmacy fees, other tests,(if applicable) and travel costs, must come from the per patient enrolment fee.

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CLINICAL TRIAL AGREEMENT BETWEEN ACCUTEST, PRINCIPAL INVESTIGATOR, INSTITUTE& SITE MANAGEMENT ORGANISATION

(PI Name: Dr. Ashish Deshmukh, Site Name: Mahatma Gandhi Mission's Medical College and Hospital, Protocol Number: ARL/CT/18/002)

(b) Payments will be made based upon the completed CRF/eCRFscollected by Accutest

(Please refer Appendix II for payment detail).

(c) Pro rata temporis payment

Should the Study be prematurely discontinued, the remuneration will be calculated on a pro rata temporis basis. For patients who do not complete the Study, remuneration may be paid on pro rata temporis basis. Payment will include only those patients participating in the Study whose date of joining the Study is not later than the date of the premature termination of the Study.

(d) Protocol violators, exclusion

For Protocol violators due to missed or delayed visits or in the event of a violation on the part of a patient of a Protocol resolution or the Regulations for Good Clinical Practice, no compensation will be paid for that patient /payment may be made at Accutest's sole discretion.

(e) Income tax

All the payments made to the payee are subject to Tax Deducted at Source (TDS) as per the applicable existing tax laws in the country. Accutest will deduct the tax at the time of making payments unless a valid certificate (Form 15 AA – for no TDS) from tax authority is made available in advance.

(f) Payment details

Accutest, on behalf of the Sponsor, shall pay the relevant cost and fee as set out in this Payment Agreement to following payees through A/C Payee Cheque as agreed by all signatories. Full of the grant shall be paid to the PI/ institute according to the payment milestones provided in APPENDIX II.

PI/ Institute payment
Payee Name: Grapecity Research Solutions LLP
PAN number: AAPFG8186L
GST Number: 27AAPFG8186L1ZH

Initial (ACCUTEST):	Initial (PI):	Initial (INSTITUTE):	Initial (SMO)
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M. G. M. Hospital Aurangabad.

CLINICAL TRIAL AGREEMENT BETWEEN ACCUTEST, PRINCIPAL INVESTIGATOR, INSTITUTE& SITE MANAGEMENT ORGANISATION

(PI Name: Dr. Ashish Deshmukh, Site Name: Mahatma Gandhi Mission's Medical College and Hospital, Protocol Number: ARL/CT/18/002)

Note:

1. Provide legible scan/photocopy of the PAN cards at the time of the signing of this agreement.
2. All local investigations (local lab tests, radiological scans,any diagnostic assessments etc.) are included in PI grants
3. All Services provided by the site under this Agreement are taxable under the laws related to Goods & Service tax in India (GST) and it is required to be charged at the rate of 18%, as may be amended from time to time. The Sponsor / CRO (applicable word as per agreement should be used) undertakes to provide Patient Visit Tracker on monthly basis (on last day of the month) to CRCs for the trial and on the basis of the tracker site shall raise invoice for the month. The invoice shall be in accordance with the terms of Rule 5 of the Tax Invoice, Debit and Credit Notes Rules of Goods & Service Rules 2017.

1) ACCUTEST: For Accutest Research Lab. (I) Pvt. Ltd: Signature and Date 19.07.2018 **Mr. Rajendra Talele, Head- Clinical Development Services**	**2) PRINCIPAL INVESTIGATOR:** Signature and Date Ashish 01/11/2018 **Name: Dr. Ashish Deshmukh**
3) INSTITUTE: For MGM Medical College and Hospital Signature and Date 1-11-18 **Name & Designation: Dr. Rajendra Bohra - Dean**	**4) SITE MANAGEMENT ORGANISATION** For Grapecity Research Solutions LLP Signature and Date 01/11/18 **Name & Designation: Dr Sushil Chaudhary - Director**

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APPENDIX II

Visit	**Amount (INR)**
Visit 1 Screening	10000
Visit 2 Baseline	7000
Visit 3 Interim Visit	7000
Visit 4 End of study/ Early Termination	7000
Safety Follow	5260
Total PI Grant (a)	36260
Institutional overhead (10%) (b)	3626
TOTAL (a+b)	**39886**
GST 18% (c)	3988.6
Grand Total (a+b+c)	**43874.6**
TOTAL PI GRANT	**43880**

Payment Details & Milestone:

1. Principal Investigator Fees will be **INR 43880/-** per completed patient (including institutional overhead and goods and service tax and/or other taxes if applicable). The taxes may be revised and shall be applicable as per the Government norms from time to time.

   All local investigations (local lab tests, radiological scans, any diagnostic assessments etc.) are included in total PI grants

The above payment also includes following charges:

a) Investigator(s) and other team members fees
b) Stationary, cupboard, courier, telephone, fax, internet and electricity bills, etc.
c) Patient recruitment
d) Electronic Case Report Form/Case Report Forms (CRF/ eCRFs) completion and correction
e) Data Clarification Form (DCF) resolution
f) Consultation charges
g) Document archival

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(PI Name: Dr. Ashish Deshmukh, Site Name: Mahatma Gandhi Mission's Medical College and Hospital, Protocol Number: ARL/CT/18/002)

2. Ethics Committee fee will be paid on actual on the production of Bill/proof/invoice.
3. Institutional Overhead will be paid on production of Bill/proof/invoice
4. Per patient cost will be paid as mentioned above upon confirmation by site monitor of receipt of legible and accurately completed CRF/eCRF for a properly qualified subject.
5. INR 5000/- for 6 screen failure patients (which includes all laboratory investigation charges) against 25 completed patients will be reimbursed.
6. Expense towards themedical management of serious adverse events will be made as per actual.

The following are the milestone for the payments:

1. Every month from SIV, site personnel is supposed to raise invoice.
2. Invoice should be 90% of the SDV completed at the site by the ARL monitor.
3. Rest 10% of study payment will be made after study close out visit once all documents and activities (related to site) are completed.

NOTE: *If above milestones are not achieved than proportionate amount will be paid based on patient randomized and visit completed by the patient.*

Principal Investigator agrees that before incurring any of the aforesaid expenses it shall obtain prior written approval from the Accutest. Accutest will generally provide procedural material required by the protocol for the study. However, in the event Sponsor and Accutest requires Principal Investigator to procure aforesaid items, it shall reimburse the actual cost incurred by Principal Investigator in connection in addition to that.

The parties hereto agree as follow on the basis of the Clinical Trial Agreement:

a) Accutest will pay a sum for every complete and evaluable patient.

b) A complete and evaluable patient is defined as follows:

- All procedures must be performed according to the protocol
- A patient will only be included according to the inclusion/exclusion criteria
- All data are documented completely and accurately

c) All payments will be on a pro rata basis as mentioned in budget above. For patients who do not complete (early termination, drop-out, etc.), the budget will be evaluated according to the number of days completed as per protocol. If any investigation is not performed during a visit, then an equivalent amount mentioned in the above budget will be deducted.

d) An invoice will be generated/ requested for payment on a monthly basis according to the actual work performed (after source data verification and CRF/eCRFs review for completed visits). An invoice will be generated/ requested according to days completed by the patient

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as specified above. The credit period of releasing the payment will be two months after receiving invoice.

e) If the patient was randomized in the study deviating from protocol inclusion and exclusion criteria (without a waiver, if applicable), then payment will not be made for such wrong randomization and subsequent visits, however screening visit can be paid, if performed according to protocol.

f) Patient conveyance/ compensation will be paid by Accutest on behalf of the Sponsor and is included in the budget as mentioned. The TDS will not be deducted on payment released for patient compensation.

g) The investigator grant includes payment of meals provided to patient and patient's relative (if applicable) during the study.

h) If the trial terminates prematurely, any payments made by Accutest exceeding the amount earned will be promptly refunded to Accutest (minus Ethics Committee fees, and patient conveyance/compensation).

i) Payment would be done on the basis of invoices generated by the site in consultation with site CRA on every monitoring after checking the CRF/eCRF completion.

NOTE: Site should generate a monthly invoice and should consider completed milestone from above at the time of invoicing.

1) ACCUTEST: For Accutest Research Lab. (I) Pvt. Ltd: Signature and Date 19-Oct-2018 **Mr. Rajendra Talele, Head- Clinical Development Services**	**2) PRINCIPAL INVESTIGATOR:** Signature and Date 01/11/2018 **Name: Dr. Ashish Deshmukh**
3) INSTITUTE: For MGM Medical college and Hospital Signature and Date 1/11/18 **Name & Designation: Dr. Rajendra Bohra - Dean**	**4) SITE MANAGEMENT ORGANISATION** For Grapecity Research Solutions LLP Signature and Date 01/11/18 **Name & Designation: Dr Sushil Chaudhary - Director**

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