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INDIA NON JUDICIAL

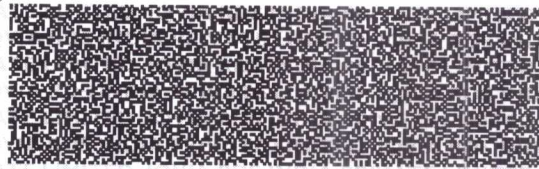
Government of Karnataka

Rs. 500

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Purchased by : IQVIA RDS INDIA PRIVATE LIMITED
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Description : CLINICAL TRIAL AGREEMENT
Consideration Price (Rs.) : 0
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First Party : IQVIA RDS INDIA PRIVATE LIMITED
Second Party : SBKS MEDICAL INSTITUTE AND RESEARCH CENTRE
Stamp Duty Paid By : IQVIA RDS INDIA PRIVATE LIMITED
Stamp Duty Amount(Rs.) : 500
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Please write or type below this line

Attested CTC

Sharaney
30/11/2023

Vice-Chancellor

Sumandeep Vidyapeeth

An Institution Deemed to be University

Vill. Piparia, Taluka Waghodia

Dist. Vadodara-391 760. (Gujarat)



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In case of any discrepancy, please inform the Competent Authority

INDIA NON JUDICIAL GOVERNMENT OF KARNATAKA

CLINICAL TRIAL AGREEMENT

The Clinical Trial Agreement ("**Agreement**") is made by and between:

- **Sumandeep Vidyapeeth Deemed to be University & Dhiraj Hospital**, having a place of business at At & Po Piparia, Ta Waghodia, Vadodara- 391760, Gujarat, India (the "**Institution**"), and
- **Dr. Punit Kumar Singh**, having a place of business at Department of Ophthalmology, SBKS MI & RC, Sumandeep Vidyapeeth Deemed to be University & Dhiraj Hospital, At & Po Piparia, Ta Waghodia, Vadodara- 391760, Gujarat, India (the "**Investigator**"), and
- **IQVIA RDS (India) Private Limited** having a place of business at Omega Embassy Tech Square Marathahalli- Sarjapur Outer Ring Road, Kadubeesanahalli, Bangalore- 560103, Karnataka, India ("**IQVIA**"),

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

Protocol Number:	AVT06-GL-C01
Protocol Title:	A Randomized, Double-masked, Parallel-group, Multicenter Clinical Study to Evaluate the Efficacy and Safety of AVT06 Compared with EU-Eylea® in Subjects with Neovascular (wet) Age related Macular Degeneration (ALVOEYE)
Protocol Date:	21 December 2021
Sponsor:	Alvotech Swiss AG, Thurgauerstrasse 54, 8050 Zürich, Switzerland
Country where Site is Conducting Study	India
Investigator:	Dr. Punit Kumar Singh, "an employee of Institution"
Key Enrollment Date:	100 Calendar Days after Site Initiation Visit (being the date by which Site must enrol at least one (1) subject as more specifically set out in section 1.7 "Key Enrollment Date" below)
IRB/IEC	Ethics Committee Name & Address- Sumandeep Vidyapeeth Deemed to be University & Dhiraj, Hospital, At & Po Piparia, Ta Waghodia, Vadodara- 391760, Gujarat, India Ethics Committee Chairperson Name : Dr. Dulari Gandhi Ethics Committee Chairperson Contact No: +91-9825282700

The following additional definitions shall apply to this Agreement:

Protocol: the clinical protocol referenced above as it may be modified from time to time by the Sponsor (defined below).

Punit Singh

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Case Report Form or CRF: case report form (paper or electronic) to be used by Site to record all of the Protocol-required information to be reported to Sponsor on each Study Subject (defined below).

Study: the clinical trial that is to be performed in accordance with this Agreement and the Protocol for purposes of gathering information about the compound/medical device identified in the Protocol.

Study Subject: an individual who participates in the Study, either as a recipient of the Investigational Product (defined below) or as a control.

Study Staff: the individuals involved in conducting the Study under the direction of the Investigator.

Investigational Product: the compound/medical device identified in the Protocol that is being tested in the Study.

Good Clinical Practices or GCPs: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Harmonised Tripartite Guideline for Good Clinical Practice as amended from time to time and the principles set out in the Declaration of Helsinki as revised from time to time.

Sponsor: the sponsor of the Study.

Medical Records: the Study Subjects' primary medical records kept by the Institution on behalf of the Investigator, including, without limitation, treatment entries, x-rays, biopsy reports, ultrasound photographs and other diagnostic images.

National Medical Commission (NMC) Act: National Medical Commission (Professional Conduct, Etiquette and Ethics) Act 2019, and any rules or regulations made thereunder as may be amended from time to time or any replacement regulations.

Study Data: all records and reports, other than Medical Records, collected or created pursuant to or prepared in connection with the Study including, without limitation, reports (e.g., CRFs, data summaries, interim reports and the final report) required to be delivered to Sponsor pursuant to the Protocol and all records regarding inventories and dispositions of all Investigational Product.

Government Official: any officer or employee of a government or of any ministry, department, agency, or instrumentality of a government; any person acting in an official capacity on behalf of a government or of any ministry, department, agency, or instrumentality of a government; any officer or employee of a company or of a business owned in whole or part by a government; any officer or employee of a public international organization such as the World Bank or the United Nations; any officer or employee of a political party or any person acting in an official capacity on behalf of a political party; and/or any candidate for political office; any doctor, pharmacist, or other healthcare professional who works for or in any hospital, pharmacy or other healthcare facility owned or operated by a government agency, ministry or department.

Item(s) of Value: should be interpreted broadly and may include, but is not limited to, money or payments or equivalents, such as gift certificates; gifts or free goods; meals, entertainment, or hospitality; travel or payment of expenses; provision of services; purchase of property or services at inflated prices; assumption or forgiveness of indebtedness; intangible benefits, such as enhanced social or business standing (e.g., making donations to government official's favored charity); and/or benefits to third persons related to government officials (e.g., close family members).

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RECITALS:

WHEREAS, IQVIA is providing clinical research organisation services to Sponsor under a separate contract between IQVIA and Sponsor. IQVIA's services include monitoring of the Study and contracting with clinical research sites;

WHEREAS, the Institution and Investigator (hereinafter jointly the "Site") are willing to conduct the Study and IQVIA requests the Site to undertake such Study.

NOW THEREFORE, the following is agreed:

1. CONDUCT OF THE STUDY

1.1. Compliance with Laws, Regulations, and Good Clinical Practices

Site agrees that Site and Study Staff shall perform the Study at Institution in strict accordance with this Agreement, the Protocol, any and all applicable local, national and international laws regulations and guidelines, including in particular, but without limitation, GCPs, MCI Regulations or NMC Act as applicable, the New Drugs & Clinical Trial Rules of 2019, and state and local tax and finance regulations. Site and Study Staff acknowledge that IQVIA and Sponsor, and their respective affiliates, need to adhere to the provisions of (i) the Bribery Act 2010 of the United Kingdom (Bribery Act); (ii) the Foreign Corrupt Practices Act 1977 of the United States of America (FCPA) and (iii) any other applicable anti-corruption legislation.

1.2. Informed Consent Form

Site agrees to use an informed consent form that has been approved by Sponsor and is in accordance with applicable regulations and the requirements of the Institutional Review Board ("IRB") or Independent Ethics Committee ("IEC") that is responsible for reviewing the Study. Site shall obtain the prior written informed consent of each Study Subject.

1.3. Medical Records and Study Data

1.3.1. Collection, Storage and Destruction: Site shall ensure the prompt, complete, and accurate collection, recording and classification of the Medical Records and Study Data.

Site shall

- (i) maintain and store Medical Records and Study Data in a secure manner with physical and electronic access restrictions, as applicable and environmental controls appropriate to the applicable data type and in accordance with applicable laws, regulations and industry standards; and
- (ii) protect the Medical Records and Study Data from unauthorized use, access, duplication, and disclosure. If directed by Sponsor or IQVIA, Site will submit Study Data using the electronic system provided by Sponsor or IQVIA or their designated representative and in accordance with Sponsor's instructions for electronic data entry. Site shall prevent unauthorized access to the Study Data by maintaining physical security of the electronic system and ensuring that Study Staff maintain the confidentiality of their passwords. Investigator agrees to collect all Study Data in Medical Records prior to entering it into the CRF. Site shall ensure the prompt submission of CRFs; and
- (iii) take measures to prevent accidental or premature destruction or damage of these documents, for as long as required by applicable laws and regulations. Neither Institution nor Investigator shall destroy or permit the destruction of any Medical Records or Study Data without prior written notification to the Sponsor, and Institution shall continue to store Medical Records and Study Data, at the Sponsor's expense, for any period that the Sponsor may request in writing after retention is no longer required by any applicable law or regulation.

Punit Singh

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If the Investigator leaves the Institution, then responsibility for maintaining Medical Records and Study Data shall be determined in accordance with applicable regulations but Institution will not in any case be relieved of its obligations under this Agreement for maintaining the Medical Records and Study Data.

1.3.2. Ownership. Institution shall retain ownership of Medical Records. The Institution and the Investigator hereby assign to Sponsor all of their rights, title and interest, including intellectual property rights, to all Confidential Information (as defined below) and any other Study Data.

1.3.3. Access, Use, Monitoring and Inspection. Site shall provide original or copies (as the case may be) of all Study Data to IQVIA and Sponsor for Sponsor's use. Site shall afford Sponsor and IQVIA and their representatives and designees reasonable access to Site's facilities and to Medical Records and Study Data so as to permit Sponsor and IQVIA and their representatives and designees to monitor the Study.

Site shall afford regulatory authorities reasonable access to Site's facilities and to Medical Records and Study Data, and the right to copy Medical Records and Study Data.

The Site agrees to cooperate with the representatives of IQVIA and Sponsor, and the Site agrees to ensure that the employees, agents and representatives of the Site do not harass, or otherwise create a hostile working environment for such representatives.

The Site shall immediately notify IQVIA of, and provide IQVIA copies of, any inquiries, correspondence or communications to or from any governmental or regulatory authority relating to the Study, including, but not limited to, requests for inspection of the Site's facilities, and the Site shall permit IQVIA and Sponsor to attend any such inspections. The Site will make reasonable efforts to separate, and not disclose, all Confidential Information that is not required to be disclosed during such inspections.

1.3.4. License. Sponsor hereby grants to Institution a perpetual, non-exclusive, nontransferable, paid-up license, without right to sublicense, to use Study Data (i) subject to the obligations set forth in section 3 "Confidentiality", for internal, non-commercial research and for educational purposes, and (ii) for preparation of publications in accordance with Section 5 "Publication Rights".

1.3.5. Survival. This section 1.3 "Medical Records and Study Data" shall survive termination or expiration of this Agreement.

1.4. Duties of Investigator

Investigator is responsible for the conduct of the Study at Institution and for supervising any individual or party to whom the Investigator delegates Study-related duties and functions. In particular, but without limitation, it is the Investigator's duty to review and understand the information in the Investigator's Brochure or device labeling instructions, to ensure that all informed consent requirements are met, to ensure that all required reviews and approvals by applicable regulatory authorities and IRBs or IECs are obtained, and to review all CRFs to ensure their accuracy and completeness.

If the Investigator and Institution retain the services of any individual or party to perform Study-related duties and functions, the Institution and Investigator shall ensure this individual or party is qualified to perform those Study-related duties and functions and shall implement procedures to ensure the integrity of the Study-related duties and functions performed and any data generated.

Punit Singh

S. K. Goyal



W. Singh

W. Singh

Investigator agrees to provide a written declaration revealing Investigator's possible economic or other interests, if any, in connection with the conduct of the Study or the Investigational Product.

Investigator agrees to provide a written declaration revealing Investigator's disclosure obligations, if any, with the Institution in connection with the conduct of the Study and the Investigational Product.

Site agrees to provide prompt advance notice to Sponsor and IQVIA if Investigator will be leaving the Institution or is otherwise no longer able to perform the Study. The appointment of a new Investigator must have the prior approval of Sponsor and IQVIA.

1.5. Adverse Events

The Site shall report adverse events and serious adverse events as directed in the Protocol and by applicable laws and regulations. The Site shall cooperate with Sponsor in its efforts to follow-up on any adverse events. The Site shall comply with its IRB/IEC reporting obligations.

Sponsor will promptly report to the Site, the Site's IRB/IEC, and IQVIA, any finding that could affect the safety of participants or their willingness to continue participation in the Study, influence the conduct of the Study, or alter the Site's IRB/IEC approval to continue the Study.

1.6. Use and Return of Investigational Product and Equipment

Sponsor or a duly authorized agent of Sponsor, shall supply Institution or Investigator with sufficient amount of Investigational Product as described in the Protocol.

The Site shall use the Investigational Product and any comparator products provided in connection with the Study, solely for the purpose of properly completing the Study and shall maintain the Investigational Product as specified by Sponsor and according to applicable laws and regulations, including storage in a locked, secured area at all times.

Upon completion or termination of the Study, the Site shall return or destroy, at Sponsor's option, the Investigational Product, comparator products, and materials and all Confidential Information (as defined below) at Sponsor's sole expense.

Institution and Investigator shall comply with all laws and regulations governing the disposition or destruction of Investigational Product and any instructions from IQVIA that are not inconsistent with such laws and regulations.

The Site shall return any equipment or materials provided by Sponsor for use in the Study unless Sponsor and Site have a written agreement for Site to acquire the equipment. If there are Site facility improvements provided by IQVIA or Sponsor in relation to the Study, then Site shall enter a separate written agreement with IQVIA or Sponsor with respect to such facility improvements.

1.7. Key Enrollment Date

The Site understands and agrees that if Site has not enrolled at least one (1) Study Subject by the Key Enrollment Date then IQVIA may terminate this Agreement in accordance with Section 15 "Term & Termination" Sponsor/IQVIA has the right to limit enrollment at any time.

2. PAYMENT

In consideration for the proper performance of the Study by Site in compliance with the terms and conditions of this Agreement, payments shall be made in accordance with the provisions set forth in Attachment A, with the last payment being made after the Site completes all its obligations hereunder, and IQVIA has received all properly completed CRFs and, if IQVIA requests, all other Confidential Information (as defined below). IQVIA will received Site invoices and process

Punit Singh

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payments unless otherwise agreed. Any queries regarding Site invoices or payments should be directed at the contact details outlined in Attachment A.

3. CONFIDENTIALITY

3.1 Definition

"Confidential Information" means the confidential and proprietary information of Sponsor and includes (i) all information disclosed by or on behalf of Sponsor to Institution, Investigator or other Institution personnel, including without limitation, the Investigational Product, technical information relating to the Investigational Product, all Pre-Existing Intellectual Property (as defined in Section 4) of Sponsor, and the Protocol; and (ii) Study enrollment information, information pertaining to the status of the Study, communications to and from regulatory authorities, information relating to the regulatory status of the Investigational Product, and Study Data and Inventions (as defined in Section 4).

Confidential Information shall not include information that:

- (i) can be shown by documentation to have been public knowledge prior to or after disclosure by Sponsor, other than through wrongful acts or omissions attributable to Investigator, Institution or any of its personnel;
- (ii) can be shown by documentation to have been in the possession of Investigator, Institution or any of its personnel prior to disclosure by Sponsor, from sources other than Sponsor that did not have an obligation of confidentiality to Sponsor;
- (iii) can be shown by documentation to have been independently developed by Investigator, Institution or any of its personnel; or
- (iv) is permitted to be disclosed by written authorization from Sponsor.

3.2 Obligations

Site and Site's personnel, including Study Staff shall not

- (i) use Confidential Information for any purpose other than the performance of the Study or
- (ii) disclose Confidential Information to any third party, except as permitted by this Section 3 or by Section 5 "Publication Rights", or as required by law or by a regulatory authority or as authorized in writing by the disclosing party.

To protect Confidential Information, Site agrees to:

- (i) limit dissemination of Confidential Information to only those Study Staff having a need to know for purposes of performing the Study;
- (ii) advise all Study Staff who receive Confidential Information of the confidential nature of such information; and
- (iii) use reasonable measures to protect Confidential Information from disclosure.

Study Data may be disclosed only as permitted by Section 5 "Publication Rights."

3.3 Compelled Disclosure

In the event that Institution or Investigator receives notice from a third party seeking to compel disclosure of any Confidential Information, the notice recipient shall provide Sponsor with prompt notice so that Sponsor may seek a protective order or other appropriate remedy. In the event that such protective order or other remedy is not obtained, the notice recipient shall furnish only that portion of the Confidential Information which is legally required to be disclosed, and shall request confidential treatment for the Confidential Information.

3.4 Return or Destruction

Upon termination of this Agreement or upon any earlier written request by Sponsor at any time, Site shall return to Sponsor, or destroy, at Sponsor's option, all Confidential Information other than Study Data.

Punit Singh

Punit Singh



Signature

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3.5 Survival

This Section 3 "Confidentiality" shall survive termination or expiration of this Agreement for ten (10) years.

4. INTELLECTUAL PROPERTY

4.1 Pre-existing Intellectual Property

Ownership of inventions, discoveries, works of authorship and other developments existing as of the Effective Date and all patents, copyrights, trade secret rights and other intellectual property rights therein (collectively, "**Pre-existing Intellectual Property**"), is not affected by this Agreement, and no Party or Sponsor shall have any claims to or rights in any Pre-existing Intellectual Property of another, except as may be otherwise expressly provided in any other written agreement between them.

4.2 Inventions

For purposes hereof, the term "**Inventions**" means all inventions, discoveries and developments conceived, first reduced to practice or otherwise discovered or developed by a Party or Sponsor or any of such entity's personnel in performance of the Study. Sponsor shall own all Inventions, that are conceived, first reduced to practice or otherwise discovered or developed by the Institution, the Investigator or any of their personnel in performance of the Study.

4.3 Assignment of Inventions

Site shall, and shall cause its personnel to, disclose all Inventions promptly and fully to Sponsor in writing, and Site, on behalf of itself and its personnel, hereby assigns to Sponsor all of its rights, title and interest in and to Inventions, including all patents, copyrights and other intellectual property rights therein and all rights of action and claims for damages and benefits arising due to past and present infringement of said rights. Site shall cooperate and assist Sponsor by executing, and causing its personnel to execute, all documents reasonably necessary for Sponsor to secure and maintain Sponsor's ownership rights in Inventions.

4.4 License

Sponsor hereby grants to Institution a perpetual, non-exclusive, non-transferable, paid-up license, without right to sublicense, to use Inventions, subject to the obligations set forth in Section 3 "Confidentiality," for internal, non-commercial research and for educational purposes.

4.5 Patent Prosecution

Site shall cooperate, at Sponsor's request and expense, with Sponsor's preparation, filing, prosecution, and maintenance of all patent applications and patents for Inventions.

4.6 Survival

This Section 4 "Intellectual Property" shall survive termination or expiration of this Agreement.

5. PUBLICATION RIGHTS

5.1 Publication and Disclosure

Institution and Investigator shall have the right to publish or present the results of Institution's and Investigator's activities conducted under this Agreement, including Study Data, only in accordance with the requirements of this Section. Institution and Investigator agree to submit any proposed publication or presentation to Sponsor for review at least thirty (30) days prior to submitting any such proposed publication to a publisher or proceeding with such proposed



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presentation. Within thirty (30) days of its receipt, Sponsor shall advise Institution and/or Investigator, as the case may be, in writing of any information contained therein which is Confidential Information (other than Study Data) or which may impair the availability of patent protection for Inventions. Sponsor shall have the right to require Institution and/or Investigator, as applicable, to remove specifically identified Confidential Information (other than Study Data) and/or to delay the proposed publication or presentation for an additional sixty (60) days to enable Sponsor to seek patent protection for Inventions.

5.2 Multi-Center Publications

If the Study is a multi-center study, Institution and Investigator agree that they shall not, without the Sponsor's prior written consent, independently publish, present or otherwise disclose any results of or information pertaining to Institution's and Investigator's activities conducted under this Agreement until a multi-center publication is published; provided, however, that if a multi-center publication is not published within eighteen (18) months after completion of the Study and lock of the database at all research sites or any earlier termination or abandonment of the Study, Institution and Investigator shall have the right to publish and present the results of Institution's and Investigator's activities conducted under this Agreement, including Study Data, solely in accordance with the provisions of Section 5.3 "Confidentiality of Unpublished Data."

5.3 Confidentiality of Unpublished Data

Institution and Investigator acknowledges and agrees that Study Data that is not published, presented or otherwise disclosed in accordance with Section 5.1 or Section 5.2 ("Unpublished Data") remains within the definition of Confidential Information, and Institution and Investigator shall not, and shall require their personnel not to, disclose Unpublished Data to any third party or disclose any Study Data to any third party in greater detail than the same may be disclosed in any publications, presentations or disclosures made in accordance with Section 5.1 or Section 5.2.

5.4 Media Contacts

Institution and Investigator shall not, and shall ensure that its personnel do not engage in interviews or other contacts with the media, including but not limited to newspapers, radio, television and the Internet, related to the Study, the Investigational Product, Inventions, or Study Data without the prior written consent of Sponsor. This provision does not prohibit publication or presentation of Study Data in accordance with this Section.

5.5 Use of Name, Registry and Reporting

No Party hereto shall use any other Party's name, or Sponsor's name, in connection with any advertising, publication or promotion without prior written permission, except that the Sponsor and IQVIA may use the Site's name in Study publications and communications, including clinical trial websites and Study newsletters. Sponsor will register the Study with a public clinical trials registry in accordance with applicable laws and regulations and will report the results of the Study publicly when and to the extent required by applicable laws and regulations.

5.6 Survival

This Section 5 "Publication Rights" shall survive termination or expiration of this Agreement.

6. PERSONAL DATA

The Site and IQVIA agree to comply with any applicable data privacy or data protection legislation in the processing of personal data, as it is defined under such applicable data privacy or data protection legislation.

7. STUDY SUBJECT INJURY

Clinical Trial Agreement – IQVIA Global template – 1 May 2019

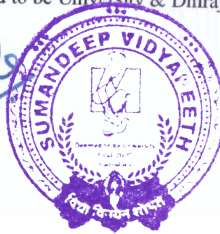
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Dr. Punit Kumar Singh _ Sumandeep Vidyapeeth Deemed to be University & Dhiraj Hospital _03Oct2022_Final

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Dr. Punit Kumar Singh

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Dr. Punit Kumar Singh

Dr. Punit Kumar Singh

The Site shall promptly notify IQVIA and Sponsor in writing of any claim of illness or injury actually or allegedly due to an adverse reaction to the Investigational Product and cooperate with Sponsor in the handling of the adverse event.

Sponsor shall reimburse Institution for the direct, reasonable and necessary medical expenses incurred by Institution for the treatment of any adverse event experienced by, illness of or bodily injury to a Study Subject that is caused by treatment of the Study Subject in accordance with the Protocol, except to the extent that such adverse event, illness or personal injury is caused by:

- (a) failure by Institution, Investigator or any of their respective personnel to comply with this Agreement, the Protocol, any written instructions of Sponsor concerning the Study, or any applicable law, regulation or guidance, including GCPs, issued by any regulatory authority, or
- (b) negligence or willful misconduct by Institution, Investigator or any of their respective personnel, or
- (c) failure of the Study Subject to follow the reasonable instructions of the Investigator relating to the requirements of the Study.

This Section 7 "Study Subject Injury" shall survive termination or expiration of this Agreement.

8. IQVIA DISCLAIMER

IQVIA expressly disclaims any liability in connection with the Investigational Product, including any liability for any claim arising out of a condition caused by or allegedly caused by any Study procedures associated with such product except to the extent that such liability is caused by the negligence, willful misconduct or breach of this Agreement by IQVIA.

This Section 8 "IQVIA Disclaimer" shall survive termination or expiration of this Agreement.

9. CONSEQUENTIAL DAMAGES

Neither IQVIA nor Sponsor shall be responsible to the Site for any lost profits, lost opportunities, or other consequential damages, nor shall Site be responsible to IQVIA or Sponsor for any lost profits, lost opportunities, or other consequential damages.

Nothing herein is intended to exclude or limit any liability of any party for death or personal injury caused by the negligence of such party.

This Section 9 "Consequential Damages" shall survive termination or expiration of this Agreement.

10. DEBARMENT

The Site represents and warrants that neither Institution nor Investigator, nor any of Institution's or Investigator's employees, agents or other persons performing the Study at Institution, have been debarred, disqualified or banned from conducting clinical trials or are under investigation by any regulatory authority for debarment or any similar regulatory action in any country, and the Site shall notify IQVIA immediately if any such investigation, disqualification, debarment, or ban occurs.

This Section 10 "Debarment" shall survive termination or expiration of this Agreement.

Clinical Trial Agreement – IQVIA Global template – 1 May 2019
Alvotech Swiss AG_AVT06-GL-C01_India_21Apr2022

Dr. Punit Kumar Singh _ Sumandeep Vidyapeeth Deemed to be University & Dhiraj Hospital _03Oct2022_Final

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11. FINANCIAL DISCLOSURE AND CONFLICT OF INTEREST

Upon Sponsor's or IQVIA's request, Site agrees that, for each listed or identified investigator or sub-investigator who is directly involved in the treatment or evaluation of Study Subjects, it shall promptly return to IQVIA a financial and conflict of interest disclosure form that has been completed and signed by such investigator or sub-investigator, which shall disclose any applicable interests held by those investigators or sub-investigators or their spouses or dependent children.

IQVIA may withhold payments if it does not receive a completed form from each such investigator and sub-investigator.

Site shall ensure that all such forms are promptly updated as needed to maintain their accuracy and completeness during the Study and for one (1) year after Study completion. Site agrees that the completed forms may be subject to review by governmental or regulatory agencies, Sponsor, IQVIA, and their agents, and the Site consents to such review.

The Site further consents to the transfer of its financial disclosure data to the Sponsor's country of origin and to the U.S., even though data protection may not exist or be as developed in those countries as in the Site's own country.

This Section 11 "Financial Disclosure and Conflict of Interest" shall survive termination or expiration of this Agreement.

12. ANTI-KICKBACK AND ANTI FRAUD

Institution and Investigator agree that their judgment with respect to the advice and care of each Study Subject will not be affected by the compensation they receive from this Agreement, that such compensation does not exceed the fair market value of the services they are providing, and that no payments are being provided to them for the purpose of inducing them to purchase or prescribe any drugs, devices or products.

If the Sponsor or IQVIA provides any free products or items for use in the Study, Institution and Investigator agree that they will not bill any Study Subject, insurer or governmental agency, or any other third party, for such free products or items.

Institution and Investigator agree that they will not bill any Study Subject, insurer, or governmental agency for any visits, services or expenses incurred during the Study for which they have received compensation from IQVIA or Sponsor, or which are not part of the ordinary care they would normally provide for the Study Subject, and that neither Institution nor Investigator will pay another physician to refer subjects to the Study.

13. ANTI-BRIBERY

Institution and Investigator agree that the fees to be paid pursuant to this Agreement represent fair compensation for the services to be provided by Site. Institution and Investigator represent and warrant that it will not make payments or convey items of value to Government Officials to assist Sponsor or IQVIA to secure and improper advantage.

Institution and Investigator further represent and warrant that neither they nor any of their respective owners, directors, employees, agents, or consultants, nor any payee under this Agreement, will, in order to assist Sponsor or IQVIA to secure an improper advantage or obtain or retain business, directly or indirectly pay, offer or promise to pay, or give any Items of Value to

Punit Kumar Singh

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any person or entity for purposes of (i) influencing any act or decision; (ii) inducing such person or entity to do or omit to do any act in violation of their lawful duty; (iii) securing any improper advantage; or (iv) inducing such person or entity to use influence with the government or instrumentality thereof to affect or influence any act or decision of the government or instrumentality.

In addition to other rights or remedies under this Agreement or at law, IQVIA may terminate this Agreement if Site breaches any of the representations or warranties contained in this Section or if IQVIA or Sponsor learns that improper payments are being or have been made to or by Institution or Investigator or any individual or entity acting on its or their behalf.

14. INDEPENDENT CONTRACTORS

The Investigator and Institution and Study Staff are acting as independent contractors of IQVIA and Sponsor and shall not be considered the employees or agents of IQVIA or Sponsor.

Neither IQVIA nor Sponsor shall be responsible for any employee benefits, pensions, workers' compensation, withholding, or employment-related taxes as to the Investigator or Institution or their staff.

15. TERM & TERMINATION

15.1 Term

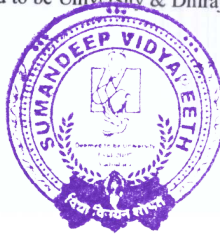
This Agreement will become effective on the date of approval of the Study by Drugs Controller General India or the date on which it is last signed by the parties, whichever date is later, (the "Effective Date") and shall continue until completion or until terminated in accordance with this Section 15 "Term & Termination". IQVIA shall attach a copy of the approval from the Drugs Controller General India approving the Study to this Agreement as Attachment B, and the Parties agree that such approval shall be incorporated by reference herein. If such approval has not been received as of the date the Parties sign this Agreement, IQVIA shall keep the original signed Agreements until receipt of such approval, and upon receipt of such approval, IQVIA shall attach a copy of the approval to each original Agreement as Attachment B and forward an original Agreement to each other Party thereafter, while retaining one original Agreement in its files. If such approval was received prior to the signatures of the Parties, IQVIA shall attach a copy of the approval hereto as Attachment B, and upon signature of all Parties, each Party shall receive an original of the Agreement, which shall include such approval as Attachment B.

15.2 Termination

IQVIA may terminate this Agreement for any reason effective immediately upon written notice. The Site may terminate upon written notice if circumstances beyond the Site's reasonable control prevent completion of the Study, or if it reasonably determines that it is unsafe to continue the Study. Upon receipt of notice of termination, the Site shall immediately cease any subject recruitment, follow the specified termination procedures, ensure that any required subject follow-up procedures are completed, and make all reasonable efforts to minimize further costs, and IQVIA shall make a final payment for visits or milestones properly performed pursuant to this Agreement in the amounts specified in Attachment A; provided, however, that ten percent (10%) of this final payment will be withheld until final acceptance by Sponsor of all CRF pages and all data clarifications issued and satisfaction of all other applicable conditions set forth herein. If a material breach of this Agreement appears to have occurred and termination may be required, then, except to the extent that Study Subject safety may be jeopardized, IQVIA may suspend performance of all or part of this Agreement, including, but not limited to, subject enrollment.

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16. NOTICE

Any notices required or permitted to be given hereunder shall be given in writing and shall be delivered

- (a) in person,
- (b) by certified mail, postage prepaid, return receipt requested,
- (c) by e-mail of .pdf/scan or other non-editable format notice with confirmed transmission report, or
- (d) by a commercial overnight courier that guarantees next day delivery and provides a receipt, and such notices shall be addressed as follows:

To Sponsor:	Name: Alvotech Swiss AG Address: Thurgauerstrasse 54, 8050 Zürich, Switzerland Tel: +41 443139570
To IQVIA	Name: IQVIA RDS (India) Private Limited Address: Omega Embassy Tech Square Marathahalli- Sarjapur Outer Ring Road, Kadubeesanahalli Bangalore KA 560103, India. And to IQVIA Inc. Global Legal Department 100 IMS Drive Parsippany, NJ 07054 USA Attention: General Counsel Email: officeofgeneralcounsel@iqvia.com
To Institution	Name: Dr. Avinash Seth Address: Sumandeep Vidyapeeth Deemed to be University & Dhiraj Hospital, At & Po Piparia, Ta Waghodia, Vadodara- 391760, Gujarat, India Tel: +91-99749 00278
To Investigator	Name: Dr. Punit Kumar Singh Address: Department of Ophthalmology, SBKS MI & RC, Sumandeep Vidyapeeth Deemed to be University & Dhiraj Hospital, At & Po Piparia, Ta Waghodia, Vadodara- 391760, Gujarat, India Tel: +91-9879946599

17. FORCE MAJEURE

The performance by either Party of any obligation on its part to be performed hereunder shall be excused by floods, fires or any other Act of God, accidents, wars, riots, embargoes, delay of carriers, inability to obtain materials, failure of power or natural sources of supply, acts, injunctions, or restraints of government or other force majeure preventing such performance, whether similar or dissimilar to the foregoing, which are unforeseeable and beyond the reasonable control of the Party bound by such obligation, provided, however, that the Party affected shall exert its reasonable efforts to eliminate or cure or overcome any of such causes and to resume performance of its obligations with all possible speed.

Clinical Trial Agreement – IQVIA Global template – 1 May 2019

Alvotech Swiss AG_AVT06-GL-C01_India_21Apr2022

Dr. Punit Kumar Singh _ Sumandeep Vidyapeeth Deemed to be University & Dhiraj Hospital _ 03Oct2022_Final

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18. MISCELLANEOUS

18.1 Entire Agreement

This Agreement, including its attachment(s), constitutes the sole and complete agreement between the Parties and replaces all other written and oral agreements relating to the Study.

18.2 No Waiver/Enforceability

Failure to enforce any term of this Agreement shall not constitute a waiver of such term.

If any part of this Agreement is found to be unenforceable, the rest of this Agreement will remain in effect.

18.3 Assignment of the Agreement

This Agreement shall be binding upon the Parties and their successors and assigns.

The Site shall not assign or transfer any rights or obligations under this Agreement without the written consent of IQVIA and Sponsor.

Upon Sponsor's request, IQVIA may assign this Agreement to Sponsor or to a third party, and IQVIA shall not be responsible for any obligations or liabilities under this Agreement that arise after the date of the assignment, and the Site hereby consents to such an assignment. Site will be given prompt notice of such assignment by the assignee.

18.4 Third Party Beneficiary

The Parties agree that Sponsor shall have the right to enforce any of the provisions of this Agreement as a third party beneficiary.

Each Party to this Agreement acknowledges that except for the Sponsor, there are no third party beneficiaries with any rights to enforce any of the provisions of this Agreement.

18.5 Applicable Law

This Agreement shall be interpreted under the laws of the state or province and country in which Site conducts the Study.

18.6 Survival:

The terms of this Agreement that contain obligations or rights that extend beyond the completion of the Study shall survive termination or completion of this Agreement, even if not expressly stated herein.

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P. K. Singh



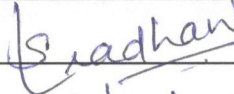
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Sumandeep Vidyapeeth

ACKNOWLEDGED AND AGREED BY IQVIA RDS (INDIA) PRIVATE LIMITED

By: Shweta Pradhan

Title: Director & Head Site Management

Signature: 

Date: 8/11/2022

ACKNOWLEDGED AND AGREED BY THE INVESTIGATOR:

By: Dr. Punit Kumar Singh

Signature: 

Date: 18/11/22


ACKNOWLEDGED AND AGREED BY SUMANDEEP VIDYAPEETH DEEMED TO BE UNIVERSITY & DHIRAJ HOSPITAL:

By: Dr. Chandramani B More

Title: Registrar

Signature: 

Date: 08/11/22



Research Cell Sumandeep Vidyapeeth as the payees in this Agreement, agrees to abide by all obligations placed on Institution in the provisions of this Agreement concerning Confidentiality (Section 3); Intellectual Property (Section 4); Publication Rights (Section 5); Debarment (Section 10); Anti Kickback and Anti Fraud (Section 12); and Anti-Bribery (Section 13)

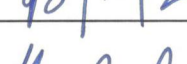
ACKNOWLEDGED AND AGREED BY RESEARCH CELL SUMANDEEP VIDYAPEETH:

By: Dr. Chandramani B More

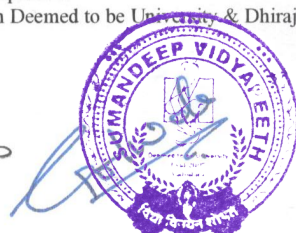
Title: Registrar

Signature: 

Date: 08/11/22







**ATTACHMENT A
BUDGET & PAYMENT SCHEDULE**

A. PAYEE DETAILS

The Parties agree that the payee designated below is the proper payee for this Agreement, and that payments under this Agreement will be made only to the following payee ("Payee"):

Institution and Investigator acknowledge and confirm that the Payee named hereunder, is authorized to receive payment under this Agreement, and; certify, represent and agree that such payment arrangement is in accordance with the modalities, rules or policies laid down by the Institution for receipt of funding for the Study and is not in violation of any applicable national, state or local laws or regulations.

Payee

Payee Name (Must match name in the contract)	Research Cell Sumandeep Vidyapeeth
Payee Address	Sumandeep Vidyapeeth Deemed to be University & Dhiraj Hospital, At & Po Piparia, Ta Wadhodia, Vadodara- 391760, Gujarat, India
GST Number	24AAATK4485H1ZK
PAN Card Number	AAATK4485H

Banking Information:

Bank Name	Indian Overseas Bank
Bank Street	Piparia Branch(1788) K M Shah Dental College Campus, Waghodia Road, Piparia
Bank City	Vadodara
Bank State/Province	Gujarat
Bank Postal Code	391760
Bank Country	India
Receiving Account Currency	INR
Bank Account #	178802000000131
IFSC Code	IOBA0001788
Swift Code (8 or 11 Characters)	Not Applicable
If the contracted Payment Currency does not match your bank account, you may need to provide an intermediary bank. Please contact your financial institution for details. If an Intermediary bank is required, please provide Bank Name, Account Number if applicable and SWIFT Code of intermediary bank along with all other required wire instructions	

Contact Information	
Name of Institution's Point of Contact	Dr Avinash K Seth
Phone number & Email	+91-9824466105 & director.research@sumandeepvidyapeethdu.edu.in
Language Preference	English
Name of Institution's Point of Contact payment recipient to receive payment notification and details	Dr Avinash K Seth

Clinical Trial Agreement – IQVIA Global template – 1 May 2019
Alvotech Swiss AG_AVT06-GL-C01_India_21Apr2022

Dr. Punit Kumar Singh _ Sumandeep Vidyapeeth Deemed to be University & Dhiraj Hospital _03Oct2022_Final

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Punit Kumar Singh



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Phone number & Email	+91-9824466105 & director.research@sumandeepvidyapeethdu.edu.in
Language Preference	English

In case of changes in the Payee's bank details, Site is obliged to inform IQVIA in writing by sending an email, through which Site shall provide supporting documents evidencing the changes to: apac@ctp.solutions.iqvia.com.

The Parties agree that in case of changes in bank details which do not involve a change of Payee, tax numbers, or tax-exempt status no further amendments are required. Neither IQVIA nor Sponsor shall be liable for any delay in payment to the Payee that results from Site's failure to promptly notify IQVIA of such changes.

The Parties acknowledge that the designated Payee is authorized to receive all of the payments for the services performed under this Agreement.

If the Investigator is not the Payee, then the Payee's obligation to reimburse the Investigator, if any, is determined by a separate agreement between Investigator and Payee, which may involve different payment amounts and different payment intervals than the payments made by IQVIA to the Payee.

Investigator acknowledges that if Investigator is not the Payee, IQVIA will not pay Investigator even if the Payee fails to reimburse Investigator.

B. MINIMUM ENROLLMENT GOAL

Investigator acknowledges that Investigator's minimum enrollment goal is 3 Study Subjects and that Site will use its best efforts to reach the enrolment goal within a reasonable timeframe after commencement of the Study at Site. If Site fails to adhere to this principle, IQVIA may reconsider Site's suitability to continue participation in the Study.

C. PAYMENT TERM

IQVIA will pay the Payee *every 3 months*, on a completed visit per subject basis in accordance with the attached budget. Ninety percent (90%) of each payment due, including any Screening Failure that may be payable under the terms of this Agreement, will be made based upon prior 3 months' enrollment data received from the Site supporting subject visitation.

The balance of monies earned, up to ten percent (10%), will be pro-rated upon verification of actual subject visits, and will be paid by IQVIA to the Payee upon final acceptance by Sponsor of all data entry, all data clarifications issued, the receipt and approval of any outstanding regulatory documents as required by IQVIA and/or Sponsor, the return of all unused supplies to IQVIA, and upon satisfaction of all other applicable conditions set forth in the Agreement.

Site represents that the services it provides under this Agreement are taxable services under the tax laws in India, and that it is required to charge applicable taxes for the services rendered to IQVIA at the prevailing rate. Site represents that it is entitled to require such payment of the applicable taxes under the laws of India. Site undertakes to provide IQVIA with an invoice, to be sent to IQVIA at the address mentioned in Section L of this Attachment A, in respect of such taxable services and such invoice shall be in accordance with the terms of the applicable tax laws in India as may be amended from time to time or any successor legislation.

It should be noted that all payments made to the Payee are subject to Tax Deducted at Source (**TDS**) in accordance with India tax laws, as amended from time to time. IQVIA will deduct the tax at the time of making payments unless a valid Certificate of no deduction or NIL deduction is obtained from tax authority is made available to IQVIA.

All fees set forth in the Agreement are exclusive of any taxes and duties (other than employment-related taxes, corporate income taxes) ("**Taxes**"). Institution shall pay any and all Taxes that are imposed by legislation in connection with the provision of services.

Clinical Trial Agreement – IQVIA Global template – 1 May 2019

Alvotech Swiss AG_AVT06-GL-C01_India_21Apr2022

Dr. Punit Kumar Singh _ Sumandeep Vidyapeeth Deemed to be University & Dhiraj Hospital _03Oct2022_Final

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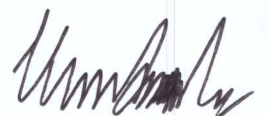
All amounts specified in this Agreement are in Indian Rupees (INR) and are exclusive of GST. IQVIA will pay to the Payee any amount of GST that the Payee is required to pay in addition to the amounts set out in this Attachment A and in accordance with GST legislation.

Any expense or cost incurred by Investigator in performing this Agreement that is not specifically designated as reimbursable by IQVIA or Sponsor under the Agreement (including this Budget and Payment Schedule) is the sole responsibility of the Institution.









Major, disqualifying Protocol violations are not payable under this Agreement

D. BUDGET TABLE

Procedure	SV	D1/BL	SPC 1	SPC 2	W4	SPC 3	W8D1	SPC 4	W16	SPC5	W24	SPC 6	W32	SPC 7	W40	SPC 8	W48	SPC 9	W52/ EOS/ ET	UV	TV **	
Informed consent	Yes																					
Demographics	Yes																					
Inclusion and exclusion criteria	Yes	Yes																				
Prior and concomitant procedures and medications	Yes	Yes			Yes		Yes		Yes		Yes		Yes		Yes		Yes		Yes	Yes	Yes	Yes
In vivo physical examination : Includes a comprehensive medical history (including ophthalmic history), a comprehensive physical examination including one set of vital signs,	Yes																					

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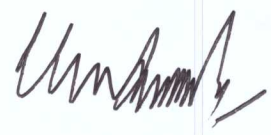
height and weight																																																				
Medical history (including ophthalmic history)	Yes																																																			
Complete physical examination includes a comprehensive physical examination ; one set of vital signs and weight			Yes																																																	
Vital signs	Yes																																																			
Single 12-lead ECG: Includes tracing, interpretation, and report	Yes																																																			

Clinical Trial Agreement – IQVIA Global template – 1 May 2019
 Alvotech Swiss AG_AVT06-GL-C01_India_21Apr2022
 Dr. Punit Kumar Singh _ Sumandeep Vidyapeeth Deemed to be University & Dhiraj Hospital _ 03Oct2022_Final

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Indirect ophthalmoscopy, extended, with retinal drawing, Fundoscopy . Optic Nerve Examination ; initial, unilateral: Includes interpretation and report	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Spectral domain Humphrey visual field (SD-VF), or HIE segment, with interpretation and report, unilateral only; retina	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Punit Kumar Singh

Study Coordinator, Interactive Web Response System (IWRs) - Per Hour	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Study Coordinator, Electronic Data Capture (EDC) - Per Hour	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Pharmacy, Complex (for Intra-treatment injection) - Per Hour	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Preparation of sterile (area); dispense drug	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Unmasked Physician - for Study Treatment Administration - Per Hour	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Daily Facility Charge - Sterile Room for Intravitreal	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Clinical Trial Agreement – IQVIA Global template – 1 May 2019
Alvotech Swiss AG_AVT06-GL-C01_India_21Apr2022

Dr. Punit Kumar Singh _ Sumandeep Vidyapeeth Deemed to be University & Dhiraj Hospital _ 03Oct2022_ Final

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Injection - Per Day	Yes	4571	4519	155	4039	155	155	50158	15	3537	1559	5164	155	347	1559	357	155	3471	1559	3428	398	53
		0	0	9	2	9	9	0	59	2		0	11	9	1	20	9	1	6		9	65
Submission/ transfer of ophthalmic imaging data (SD- OCT, FA, color FP) to central reader	Yes		Yes		Yes		Yes			Yes		Yes		Yes		Yes		Yes				
Visit Amount including institutional overhead		421921																				

**FOLLOWING SCREENING AND BASELINE (RANDOMIZATION), TELEVISIT CAN BE CONDUCTED IN PLACE OF A SCHEDULED ON-SITE VISIT IN THE EVENT THAT STUDY CENTERS ARE CLOSED.

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E. STUDY START-UP FEE

A one-time, non-refundable payment will be paid in the amount of **One Lakh Indian Rupees (100000 INR)** to cover Study start-up activities upon completion and receipt by IQVIA of all contractual and regulatory documentation and receipt of invoice.

F. SCREENING FAILURE

Reimbursement for screen failures will be at the amount indicated on the screening visit of the attached budget, not to exceed 1 screen failure(s) paid per 1 Study Subject(s) randomized.

To be eligible for reimbursement of a screening visit, supporting data entry must be completed and submitted to IQVIA along with any additional information, which may be requested by IQVIA to appropriately document the Study Subject screening procedures.

G. DISCONTINUED OR EARLY TERMINATION STUDY SUBJECTS

Reimbursement for discontinued or early termination Study Subjects will be prorated based on the number of confirmed completed visits.

H. UNSCHEDULED VISITS

Payment for unscheduled visits will be reimbursed in the amount of **Three Thousand Nine hundred and Eighty Nine Indian Rupees (3989 INR)** which includes overhead, as denoted in the Budget Table above. To be eligible for reimbursement for unscheduled visits, supporting data entry must be completed and submitted to IQVIA, along with any additional information which may be requested by IQVIA, to appropriately document the unscheduled visit.

I. CONDITIONAL PROCEDURES (WITH INVOICE)

The following conditional procedure costs will be reimbursed on a pass-through basis upon receipt of an invoice in the amount indicated in the table below (which includes overhead). Study Subject number and procedure dates must be included on the invoice for payment to be issued.

Conditional Procedure	<u>AMOUNT INCLUDING INSTITUTIONAL OVERHEAD</u> <u>(INR)</u>
Pregnant female partner informed consent	846
Volunteer consent <i>for the certification process</i>	846
Complete physical examination: includes a comprehensive physical examination; one set of vital signs and weight - <i>for Unscheduled visit</i>	6,137
Vital signs - <i>for Unscheduled visit and/or to allow more frequent measurements as clinically indicated</i>	1,117
Single 12-lead ECG: Includes tracing, interpretation and report - <i>for W4 and W8 for the first 10 subjects randomized into the study globally, and for repeat and/or unscheduled assessments</i>	1,134
Best-corrected visual activity (BCVA) using ETDRS chart, quantitative, bilateral - <i>for Unscheduled visit</i>	604
Biomicroscopy, slit lamp examination, including external examination of the eyes, bilateral - <i>for Unscheduled visit</i>	1,608
Single intraocular pressure (IOP), bilateral, tonometry: Includes interpretation and report - <i>for Unscheduled visit</i>	803









Spectral domain optical coherence tomography (SD-OCT), posterior segment, with interpretation and report, unilateral only; retina - <i>for Unscheduled visit and/or for the certification process</i>	2,742
Color fundus photography, retinal photography, color stereo photography; bilateral: Includes interpretation and report - <i>for additional measurements if any significant change in the posterior pole is detected and/or for the certification process</i>	3,239
Fluorescein angiography (includes multiframe imaging): Includes interpretation and report; unilateral - <i>for D1/BL if baseline visit is scheduled more than 14 days from screening visit and /or for additional measurements if any significant change in the posterior pole is detected and/or for the certification process</i>	6,527
Submission/transfer of ophthalmic imaging data (SD-OCT, FA, color FP) to central reader - <i>for Unscheduled visit and/or for the certification process</i>	1,807
Lab handling and/or shipping of specimen(s) to central laboratory, simple - <i>for repeat and/or unscheduled samples (safety reasons or for technical issues with the samples)</i>	450
Blood draw, phlebotomy, routine venipuncture for collection of specimen(s) for central (hematology, clinical chemistry, coagulation, immunogenicity, serum pregnancy test/FSH if applicable) laboratory , as needed, simple: Includes preparation of specimen - <i>for repeat and/or unscheduled samples (safety reasons or for technical issues with the samples)</i>	211
Hematology: includes the measurement of erythrocytes (red blood cells or RBC), leukocytes (white blood cells or WBC), hemoglobin, hematocrit (volume of packed red blood cells or VPRC), platelet or thrombocyte count, and indices (mean corpuscular hemoglobin or MCH, mean corpuscular volume or MCV). Includes automated differential of the white blood cells: neutrophils or granulocytes, lymphocytes, monocytes, eosinophils, and basophils (local lab) - <i>in case laboratory samples cannot be shipped to central laboratory due to pandemic related restrictions</i>	637
Hematology: Blood count; reticulocyte count, manual (local lab) - <i>in case laboratory samples cannot be shipped to central laboratory due to pandemic related restrictions</i>	551
Clinical Chemistry: Includes Albumin; Bilirubin, total; Calcium; Carbon Dioxide (bicarbonate); Chloride; Creatinine; Glucose; Phosphatase, alkaline; Potassium; Protein, total; Sodium; Transferase, alanine amino (ALT); Transferase, aspartate amino (AST); Urea Nitrogen (BUN) (local lab) - <i>in case laboratory samples cannot be shipped to central laboratory due to pandemic related restrictions</i>	1,429
Clinical Chemistry: Glutamyl transferase, gamma (GGT) (local lab) - <i>in case laboratory samples cannot be shipped to central laboratory due to pandemic related restrictions</i>	592

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Clinical Chemistry: Hemoglobin, haemoglobin (HbA1C) (Hgba 1c); glycated, glycosylated (local lab) - <i>in case laboratory samples cannot be shipped to central laboratory due to pandemic related restrictions</i>	1,010
Clinical Chemistry: Bilirubin; direct (local lab) - <i>in case laboratory samples cannot be shipped to central laboratory due to pandemic related restrictions</i>	338
Coagulation: Prothrombin time (PT) (local lab) - <i>in case laboratory samples cannot be shipped to central laboratory due to pandemic related restrictions</i>	708
Coagulation: Thromboplastin time, partial (aPTT); plasma or whole blood, serum (local lab) - <i>in case laboratory samples cannot be shipped to central laboratory due to pandemic related restrictions</i>	944
Coagulation: International Normalized Ratio (INR) (local lab) - <i>in case laboratory samples cannot be shipped to central laboratory due to pandemic related restrictions</i>	996
Serum pregnancy, gonadotropin chorionic (hCG) (BetahCG); quantitative (local lab) - <i>as needed for women, in case laboratory samples cannot be shipped to central laboratory due to pandemic related restrictions</i>	2,081
Gonadotropin; follicle stimulating hormone (FSH) (local lab) - <i>as needed to confirm post menopausal status, in case laboratory samples cannot be shipped to central laboratory due to pandemic related restrictions</i>	2,154
Urine collection for local (urine pregnancy test if applicable) and/or central (routine urinalysis) laboratory - <i>for repeat and/or unscheduled samples (safety reasons or for technical issues with the samples)</i>	348
Urinalysis, by dip stick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; automated, with microscopy (local lab) - <i>in case laboratory samples cannot be shipped to central laboratory due to pandemic related restrictions</i>	473
Urinalysis; microscopic only (local lab) - <i>if blood or protein is abnormal, in case laboratory samples cannot be shipped to central laboratory due to pandemic related restrictions</i>	324
Urine pregnancy; qualitative (local lab) - <i>for women of childbearing potential only</i>	876
Collection of samples from throat, nose, nares, sputum by swab or brushing - <i>in case of suspicions for SARS-CoV-2 infection</i>	377
Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique (local lab) - <i>for RT-PCR testing</i>	1,318
Intravitreal injection of a pharmacologic agent (EU-Eylea): includes ophthalmoscopy or ultrasound for needle location, post treatment observation and post injection tonometry; unilateral - <i>for Eylea administration for the treatment of the fellow eye</i>	14,045
Pharmacy, Complex (intravitreal injection) - Per Preparation (EU-Eylea); dispense drug - <i>for Eylea administration for the treatment of the fellow</i>	1,337

Clinical Trial Agreement – IQVIA Global template – 1 May 2019

Alvotech Swiss AG_AVT06-GL-C01_India_21Apr2022

Dr. Punit Kumar Singh _ Sumandeep Vidyapeeth Deemed to be University & Dhiraj Hospital _03Oct2022_Final

Page 30 of 34

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eye	
Physician - Per Hour - for Eylea administration for the treatment of the fellow eye, max. 1 hour	2,769
Daily Facility Charge - Sterile Room for Intravitreal Injection - Per Day - for Eylea administration for the treatment of the fellow eye	1,972
Pharmacy, Simple - Per Preparation (mydriatic drops / topical anaesthetics / topical antiseptics / florescein strips); dispense drug	570
Meal - Per Meal	642
Patient Travel - Per Visit	1500
Patient Travel (for the volunteers for the image certification) - Per Visit	1500
Serious adverse events (SAE)	2,474
Re-consent, Informed consent performed again with the same patient	1,538

J. EQUIPMENT

All materials and equipment provided ("**Equipment**") by the Sponsor or IQVIA/vendors contracted by the Sponsor shall remain the sole property of the Sponsor/IQVIA/vendor, as the case may be.

Therefore, it is hereby agreed that such Equipment shall:

- a) be subject to removal at any time upon the Sponsor's or, IQVIA' demand provided that such removal does not prevent the Site from conducting the Study and carrying out their obligations under this Agreement;
- b) be used only for the purposes of the Study;
- c) be used in accordance with any manuals or instructions while in possession of the Site;
- d) shall remain in the same condition, ordinary wear and tear excepted. As long as the Equipment are in the possession of the Site, it is liable for maintenance or any risk of loss in connection with the Equipment during the conduct of the Study;
- e) be clearly identified as the sole property of the Sponsor/IQVIA/vendor, as applicable, by clearly stating "BELONGS TO "Name of legal owner" in order to notify any third parties, including creditors, that the legal owner retains title thereto; and
- f) upon completion or termination of the Study, IQVIA or Sponsor, together with Site assistance, shall arrange the return of all equipment provided for the Study within one (1) month of request to return, or if requested by the Sponsor or IQVIA in writing, arrange for the disposal of the Equipment as soon as reasonably practicable.

K. PAYMENT DISPUTES

Site will have thirty (30) days from the receipt of final payment to dispute any payment discrepancies during the course of the Study.

L. INVOICES

Payments will be issued by IQVIA based on the agreed budget, Visit Budget, payment frequency and payment terms as described above. Payments will be made only upon receipt of corresponding invoices, including back-up documentation, in the specified currency, as described below. Undisputable invoices will be payable within **sixty (60) days** from the date of receipt by IQVA of the invoice, including any applicable back-up documentation.







Invoices for any additional payments to those stated in this Agreement (i.e., additional reimbursements) must also be sent to IQVIA and approved by Sponsor. All invoices shall be raised in the following manner:

Invoices to be billed and ORIGINAL copies to be sent to:

IQVIA RDS (India) Private Limited

Omega Embassy Tech Square Marathahalli - Sarjapur Outer Ring Road,
Kadubeesanahalli Bangalore- 560103, Karnataka, India

**Invoices to be emailed to: scanned copy of the Invoices to be emailed to:
apac@ctp.solutions.iqvia.com**

The following information should be included on the invoice:

- Complete INVESTIGATOR name, address and phone number
- Invoice Date
- Invoice Number
- Payee Name (must match Payee indicated in CTA)
- Payment Amount
- Complete description of services rendered
- Study Number:
- Sponsor Name
- Invoices should be printed on site/institution letterhead

All invoice and payment related inquiries shall be addressed directly to the payments team at apac@ctp.solutions.iqvia.com.

Invoices and any accompanying documentation must not include any personally identifying information of any Study Subject, including but not limited to Study Subject first or last name, initials, date of birth, address, telephone, passport number, email address, or credit card information. If invoices or any accompanying documentation do contain this information IQVIA will notify Payee. Payee will need to resubmit a redacted invoice and accompanying documentation that does not include any personally identifying information of any Study Subject.

M. SITE COST

• **Pharmacy Set-Up Fee**

A one-time, non-refundable Pharmacy Set-Up payment will be paid in the amount of **Twenty Four Thousand Eight Hundred and Eleven Indian Rupees (24811 INR)** upon completion and receipt by IQVIA of all original contractual and regulatory documentation and receipt of an original invoice.

• **Pharmacy Storage Fee**

Pharmacy storage payment will be paid in the amount of **Twelve Thousand Three Hundred and Five Indian Rupees (12305 INR)** for the storage of Investigational Product per year. Site will be eligible for reimbursement upon receipt of Investigational Product by Institution and upon receipt of invoice. Invoice must include year in which reimbursement request is for.

• **Pharmacy Close-Out Fee**

A one-time, non-refundable Pharmacy Close-out payment will be paid at the end of the Study on a pass-through basis upon receipt of invoice, up to **Thirteen Thousand Three Hundred and Fifty Five Indian Rupees (13355 INR)** and are not included in the attached Budget.

• **Record Storage Fee/Archiving Fee**

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A one-time record storage payment will be paid in the amount of **Seventy Five Thousand Indian Rupees (75000 INR)** upon receipt of invoice and are not included in the attached Budget. In accordance with Sponsor's Protocol requirements, Institution shall maintain all Site Study records in a safe and secure location for period of 15 years after study is completed to allow easy and timely retrieval, when needed.

- **Study Close-Out Fee**

A one-time, non-refundable Study Close-Out payment will be paid in the amount of **Ten Thousand Five hundred and Four Indian Rupees (10504 INR)** upon completion and approval by IQVIA of any outstanding data documentation (eCRFs and data clarifications issued) and regulatory documentation and upon receipt of original invoice.

- **Eylea Reimbursement**

If the fellow eye (the non-study eye) develops age-related macular degeneration (AMD) and requires treatment of Eylea. Site will buy comparator itself and the costs will be reimbursed on a pass-through basis upon receipt of invoices up to **Fifty Thousand Indian Rupees (50000 INR)** per Eylea. Study Subject numbers and procedure date must be included on the invoice. (1 Eylea up to 50000 INR)

- **Intravitreal injection items**

Intravitreal injection items cost up to **Five Thousand Indian Rupees (5000 INR)** per interatrial injection item will be paid on a pass-through basis upon receipt of invoices and are not included in the Budget. Study Subject numbers and procedure date must be included on the invoice. (1 Intravitreal injection items up to 5000 INR)

NO OTHER ADDITIONAL FUNDING REQUESTS WILL BE CONSIDERED

All amounts include all applicable taxes except GST.

All payments for this Study will be paid by IQVIA electronically in accordance with Attachment A of this Agreement.

JS

Routrson



Procedure Date

Singh

Handwritten signature

**ATTACHMENT B
APPROVAL LETTER**

Attested CTC

Sharaney
30/11/2023

Vice-Chancellor

Sumandeep Vidyapeeth

An Institution Deemed to be University

Vill. Piparia, Taluka: Waghodia.

Dist. Vadodara-391 760. (Gujarat)

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Alvotech Swiss AG_AVT06-GL-C01_India_21Apr2022

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Page 34 of 34

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Manoj Kumar Singh