



IN-GJ00990019441837X



सत्यमेव जयते

INDIA NON JUDICIAL  
Government of Gujarat  
Certificate of Stamp Duty

Certificate No. : IN-GJ00990019441837X  
Certificate Issued Date : 23-Apr-2025 11:19 AM  
Account Reference : IMPACC (SV)/ gj13334504/ GULBAI TEKRA/ GJ-AH  
Unique Doc. Reference : SUBIN-GJGJ1333450411455598189488X  
Purchased by : CLIANTHA RESEARCH LIMITED  
Description of Document : Article 5(h) Agreement (not otherwise provided for)  
Description : AGREEMENT  
Consideration Price (Rs.) : 0  
(Zero)  
First Party : CLIANTHA RESEARCH LIMITED  
Second Party : HIMALAYAN INSTITUTE OF MEDICAL SCIENCE  
Stamp Duty Paid By : CLIANTHA RESEARCH LIMITED  
Stamp Duty Amount(Rs.) : 300  
(Three Hundred only)



Dr. RESHMA KAUSHIK  
Professor & Head  
Department of Medicine  
H.I.M.S., Dehradun

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Any discrepancy in the details on this Certificate and as available on the website / Mobile App renders it invalid.  
2. The onus of checking the legitimacy is on the users of the certificate  
3. In case of any discrepancy please inform the Competent Authority.





## NOTICE



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- Any alteration to this certificate renders it invalid and would constitute a criminal offence.
- Kindly contact Stock Holding Branch / Centre in case of discrepancy.
- For information related to e-Stamping you may write to us on our email id [estamp.ahmedabad@stockholding.com](mailto:estamp.ahmedabad@stockholding.com) or visit our Branch/Centre.

સૂચના

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- આ પ્રમાણપત્રમાં કરેલ કોઈપણ ફેરફાર અમાન્ય છે અને તે કોજદારી ગુનો બને છે.
- આ ઈ-સ્ટેમ્પ પ્રમાણપત્રમાં કોઈપણ વિસંગતતા જણાય તો સ્ટોક હોલ્ડિંગની શાખા / કેન્દ્ર પર સંપર્ક કરવો.
- ઈ-સ્ટેમ્પિંગ સંબંધિત જાણકારી માટે અમને [estamp.ahmedabad@stockholding.com](mailto:estamp.ahmedabad@stockholding.com) પર ઈ-મેઈલ કરવો અથવા અમારી શાખા / કેન્દ્ર ની મલાકાત લેવી.



Dr. Reshma Kaushik, Himalayan Institute of Medical Sciences, Dehradun, Uttarakhand

**CLINICAL TRIAL AGREEMENT**

**PROTOCOL NO.: LPS17348**

This Clinical Trial Agreement (the "**Agreement**") is entered into on the 09<sup>th</sup> day of Jul, 2025 (the "**Effective Date**") by and between

**CLIANTHA RESEARCH LIMITED**, a company incorporated under the Companies Act, 1956 having its registered office at Cliantha Corporate, TP 86, FP 28/1, Off S.P. Ring Road, Sarkhej, Ahmedabad - 382 210 (hereinafter referred to as "**CRO**" which expression, unless repugnant to the context or meaning thereof shall mean and include its assignees and successors-in-interest)

**AND**

**DR. RESHMA KAUSHIK**, whose principal place of work is at Himalayan Institute of Medical Sciences, Swami Rama Himalayan University, Department of General Medicine, Jolly Grant, Dehradun – 248016, Uttarakhand, India (hereinafter referred to as the "**Principal Investigator**" which expression, unless repugnant to the subject or context therein, shall mean and include his/ her successors and permitted assigns)

**AND**

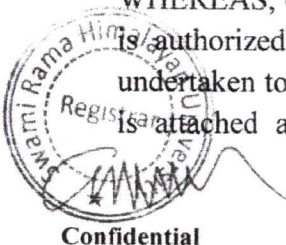
**SWAMI RAMA HIMALAYAN UNIVERSITY (SRHU)**, a University established under section 2(f) of UGC Act and enacted vide Uttarakhand Act, having its registered office at Swami Ram Nagar, Jolly Grant, Dehradun, Uttarakhand- 248016, through its Registrar, Commander Challa Venkateswar (Retd.), for its constituent unit, **HIMALAYAN INSTITUTE OF MEDICAL SCIENCES**, located at, Swami Rama Himalayan University, Department of General Medicine, Jolly Grant, Dehradun – 248016, Uttarakhand, India (hereinafter referred to as the "**Institution**" which expression, unless repugnant to the subject or context therein, shall mean and include its administrators, executors, permitted assigns & successors-in-interest)

**AND**

**KV CLINICAL RESEARCH PVT LTD**, located at, Office 617, Golden Trade Center, New Rajendra Nagar, Raipur-492001, Chhattisgarh, India (hereinafter referred to as the "**Site Management Organization/ SMO**" which expression, unless repugnant to the subject or context therein, shall mean and include its administrators, executors, permitted assigns & successors-in-interest)

**CRO, Institution, Principal Investigator and SMO** are referred to herein individually as a "**Party**" and collectively as "**Parties**".

WHEREAS, CRO has been contracted by Sanofi India Limited ("Sponsor") and CRO is authorized by the Sponsor to enter into the agreement on its behalf and has undertaken to abide by all the terms and condition of this Agreement. Authority letter is attached as annexure - 1 with this Agreement. having its principal/registered



Confidential



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Professor & Head  
Department of Medicine  
H.I.M.S., Dehradun  
Reg.No.UKMC-2215



Dr. Reshma Kaushik, Himalayan Institute of Medical Sciences, Dehradun, Uttarakhand

business address, Sanofi House, C.T.S. No. 117/B, L&T Business Park, Saki Vihar Road, Powai, Mumbai, Maharashtra, 400 072, India to perform one or more of Sponsor study related duties and functions for the clinical trial entitled as "A Phase IV, open label, clinical trial to assess safety and efficacy of Fexofenadine HCl + pseudoephedrine HCl fixed dose combination in Indian participants with allergic rhinitis (AR) who are 12 years and above (FAST trial)." ("Study") according to Protocol Number **LPS17348** ("Protocol") including any subsequent duly authorized amendments and which is hereby incorporated by reference; and

WHEREAS, SMO is a site management organization engaged in the business of managing services provided by its affiliated clinical research institutions and clinical investigators regarding the conduct of clinical research;

WHEREAS, the Study is of mutual interest and benefit to the Sponsor, CRO, Institution and Principal Investigator and will further the investigational and research objectives of the Institution and Principal Investigator;

WHEREAS, the Institution represents that it has the qualified personnel and facilities equipped according to Good Clinical Practices (GCP) to undertake the Study;

WHEREAS, Principal Investigator represents that he/she is appropriately qualified and experienced and has the authority and willingness to conduct the Study at the Institution;

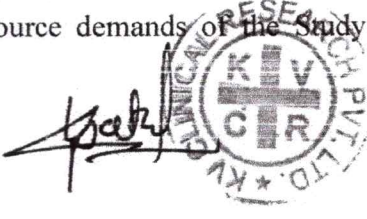
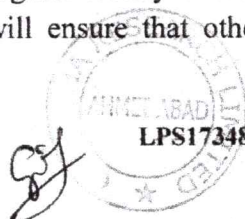
Now, therefore, in consideration of the promises and mutual covenants herein contained, the Parties agree as follows:

#### 1. THE STUDY AND THE PROTOCOL

A. The Study of Allegra-D (the "Study Drug") shall be conducted, under the direction of the Principal Investigator, in the treatment of patients ("Subjects") in accordance with this Agreement and the protocol identified as Protocol ID No. LPS17348 entitled A Phase IV, open label, clinical trial to assess safety and efficacy of Fexofenadine HCl + pseudoephedrine HCl fixed dose combination in Indian participants with allergic rhinitis (AR) who are 12 years and above (FAST trial) (the "Protocol"), including any subsequent duly authorized amendments, and which is hereby incorporated by reference (the "Study"). The Study will be monitored on behalf of Sponsor by the CRO.

B. The Principal Investigator represents and warrants that he/she is qualified by education, training and experience to assume responsibility for the proper conduct of the Study. The Principal Investigator will provide a copy of his/ her curriculum vitae and other relevant documents as and when requested by the Sponsor, the Ethics Committee, CRO and the regulatory authorities. Principal Investigator clearly understands that time is of the essence of this Agreement

and will ensure that other resource demands of the Study will be fulfilled.



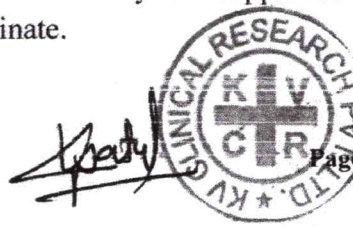
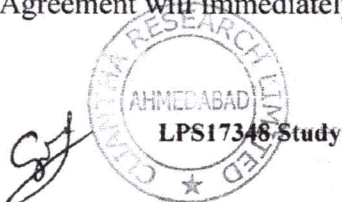
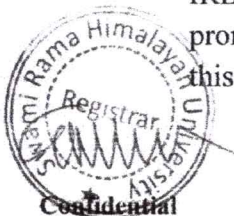
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throughout the duration of the Study. The Principal Investigator should also ensure that he/ she does not have any conflict with any other studies and shall not divert Subjects or facilities away from the Study. Principal Investigator confirms that he/she has the necessary experience, capability and resources, including, but not limited to, sufficient personnel and equipment to perform the Study in a professional and competent manner, and in strict adherence to the Protocol. The Principal Investigator shall be responsible for performing the Study in strict compliance with the specifications and timelines provided by CRO.

- C. The Institution represents and warrants that it has the necessary infrastructure, experience and expertise to conduct the Study in accordance with the terms of this Agreement and that the Institution will use all commercially reasonable best efforts to perform efficiently the Study hereunder. The Study will be conducted at Institution and will be supervised by the Principal Investigator, wherein Principal Investigator shall control any person performing any portion of the Study at the Institution. Institution and Principal Investigator will carry out certain Study-related laboratory services and investigations as may be required for the Study.
- D. The SMO represents and warrants that it has the necessary experience and expertise to provide the services under this Agreement and that it shall use all commercially reasonable best efforts to perform the required services efficiently, hereunder.
- E. **Conditions Precedent.** The Principal Investigator shall be thoroughly familiar with the safety, efficacy and appropriate use of the Study Drug as described in the Protocol, the reference-listed product with full prescribing information and other information sources relevant to the Study and as may be provided by the Sponsor from time to time. The Study shall take place at the Institution under the supervision and direction of the Principal Investigator, who will conduct the Study according to the Protocol which may be amended from time to time in writing by the Sponsor.
- F. Institution's obligation to conduct the Study is expressly conditioned upon the approval of the Protocol by an Ethics Committee / Institutional Review Board ("IRB") that complies with the requirements of Drug Controller General of India and GSR 227 (E) and applicable regulatory requirements. Principal Investigator will further ensure that the Study is subject to continuing oversight by the IRB throughout its conduct. Sponsor shall not interfere in any IRB procedures. If IRB need any assistance from Sponsor, then Sponsor shall promptly give its assistance to IRB. If the Study is disapproved by the IRB, this Agreement will immediately terminate.



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