

GOVERNMENT OF INDIA
Directorate General of Health Services
Central Drugs Standard Control Organization
(Global Clinical Trial Division)
FDA Bhawan, Kotla Road, New Delhi-110002
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File No: CT/17/000046

To,

M/s. Quintiles Research (India) Pvt. Ltd.,
B-101-106, Shapath IV, Opp, Karnavati Club,
Sarkhej- Gandhinagar Road, Ahmedabad-380 051.

Subject: Clinical trial titled “A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Effects Of Bempedoic Acid (ETC-1002) On the Occurrence Of Major Cardiovascular Events in Patients With, Or at High Risk for, Cardiovascular Disease Who Are Statin Intolerant”– regarding.

Reference: Your Application No. GCT/Form44/FF/2017/3519 (GCT/47/17) dated 02/June/17.

Sir,

This Directorate has no objection to your conducting the subject mentioned clinical trial as per the provisions of Drugs & Cosmetics Rules under supervision of the investigators mentioned below and as per the **Protocol No: 1002-043 Version: Original Protocol dated 24/June/2016** submitted to this Directorate.

1. Dr. Shah Bhupesh Rajnikant, Dr. Jivraj Mehta Smarak Health Foundation, Bakeri Medical Research Center, Ratubhai Adani Arogyadham, Dr. Jivraj Mehta Marg, Ahmedabad-380007, Gujarat, India.
2. Dr. Ajit Raghunath Bhagwat, Kamalnayan Bajaj Hospital, Marathwada Medical & Research Institute , Gut No. 43, Satara Parisar, Bajaj Marg, Beed Bypaas Road, Aurangabad-431005, Maharashtra, India.
3. Dr. Ram Anil Raj Manni Rajagopal, Rajarajeswari Medical College & Hospital, Rajarajeshwari Heart Centre Bangalore, Department of Cardiology #202, Kambipura, Mysore Road, Bangalore-560074, Karnataka, India.
4. Dr. Harkut Pankaj Vijaykumar, Meditrina Institute of Medical Sciences, 278, Central Bazar Road, Ramdaspath, Nagpur-440010, Maharashtra, India.
5. Dr. Mahpaekar Mashhadi, Dharmsinh Desai Memorial Methodist Memorial Institute of Cardiology and Cardiovascular surgery (DDMM Heart Institute), Mission Road, Nadiad 387002, Gujarat, India.
6. Dr. Hasmukh Ravjibhai Dobariya, Apple Hospital, Udhna Darwaja, Ring Road, Surat-395002, Gujarat, India.
7. Dr. Nitin Kamalakar Ghaisas, Siddhi Hospital Multispecialty and Accidental Hospital, C/o Dr. Mutha Hospital, P-67, MIDC Satpur, Behind ITI, Near PF office, Trimbak Road, Satpur, Nashik 422007, Maharashtra, India.
8. Dr. Dhiman Kahali, “B M Birla Heart Research Center – A Unit of the Calcutta Medical Research Institute”, C K Birla Group of Hospitals, 1/1, National Library Avenue, Kolkata-700027, West Bengal, India.

9. Dr. Sanjay Kumar, Fortis Escorts Hospital, Neelam Bata Road, Faridabad-121001, Haryana, India.
10. Dr Nirav Chandulal Bhalani, Rhythm Heart Institute-A Unit of Synergy Lifecare Pvt. Ltd., Nr Siddharth Bungalows-Sama-Savli Road, Vadodara-390022, Gujarat, India.
11. Dr. Sunita Aggarwal, Department of Medicine Maulana Azad Medical College And Associated Lok Nayak, Govind Ballabh Pant Hospital, Guru Nanak Eye Center, New Delhi-110 002, India.
12. Dr. Sanjay Mittal, Medanta-The Medicity, Sector 38, Gurgaon, Haryana-122001, India.
13. Dr. Abid Hussain, Fortis Flt. Lt. Rajan Dhall Hospital, Sec B-1, Aruna Asaf Ali Marg, Vasant Kunj, New Delhi-110070, India.
14. Dr. Jugal Bihari Gupta, Eternal Hospital, Unit of Eternal Heart Care Centre & Research Institute Pvt. Ltd., 3A, Jagatpura Road, Near Jawahar Circle, Jaipur-302017, Rajasthan, India,
15. Dr. Bipin Kumar Sethi, Care Hopsitals, Care Outpatient Centre, #8-2-620/A-E, Road No: 10, Banjara Hills, Hyderabad-500034, Telangana, India.
16. Dr. Karandikar Neelkanth Gopalrao, Sassoon General Hospital, Pune, Jayprakash Narayan Road, Pune Railway Station Near, Pune,411001, Maharashtra, India.
17. Dr. Kothiwale Veerappa Annasaheb, KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi-590010, Karnataka, India.
18. Dr. Dhurjati Prasad Sinha, Institute of Post-Graduate Medical Education & Research, 244, Acharya Jagadish Chandra Bose Road, Kolkata-700020, West Bengal, India.
19. Dr. Kajal Ganguly, Nilratan Sircar Medical College & Hospital, 138, AJC Bose Road, Kolkata-700014, West Bengal, India.
20. Dr. Jaishankar Krishnamoorthy, The Madras Medical Mission, Department of Clinical Research, #4-A, Dr. J.J. Nagar, Mogappair, Chennai-600037, Tamilnadu, India.
21. Dr. Anup Kumar Boro, Department of Cardiology, GNRC Ltd., GNRC Complex, Dispur, Guwahati, Assam, India-781006.
22. Dr. Amit Kumar Chaurasia, BLK Super Speciality Hospital, Pusa Road, New Delhi-110005, India.
23. Dr. Choudhary Dinesh, Department of Cardiology, Haldiram Moolchand Cardiology Govt. Centre of Research & Science, S.P.Medical College & AG of Hospitals, Bikaner 334003, Rajasthan, India.
24. Dr. Srikanth. K.V, Narayana Institute of Cardiac Sciences-Unit of Narayana Health, NH Health City, #258/A, Bommasandra Industrial Area, Anekal Taluk, Bangalore-560099, Karnataka, India.
25. Dr. Selvamani. S, Meenakshi Mission Hospital and Research Centre, Lake Area, Melur Road, Madurai, 625107, Tamil Nadu, India.
26. Dr. Aravind S R, Diacon Hospital (Diabetes Care & Research Centre), 359-360, 19th Main, 1st Block, Rajajinagar, Bangalore: 560010, Karnataka, India.
27. Dr. Arneja Jaspal Singh, Arneja Heart & Multispeciality Hospital, Department of Cardiology, 123, Ramdaspath, Nagpur-440010, Maharashtra, India.
28. Dr. Raghavendra N. Belgaonkar, Sushruta Multispecialty Hospital & Research Centre Private Limited., P. B. Road, Vidyanagar, Hubli- 580021, Karnataka, India.
29. Dr. Deshpande Atul Vaman, Lata Mangeshkar Medical Foundation's Deenanath Mangeshkar Hospital & Research Centre, Erandwane, Pune- 411004, Maharashtra, India.
30. Dr. Chavan Chandrakant Bhagwat, Rajasthani and Gujarati Charitable Foundation's, Poona Hospital and Research Centre, 27, Sadashiv Peth, Pune- 411030, Maharashtra, India.
31. Dr. Prajapati Vipulkumar Bachubhai, GCS Medical College, Hospital and Research Centre, Opp. DRM Office, Nr. Chamunda Bridge, Naroda Road, Ahmedabad-380025, Gujarat, India.
32. Dr. Gaikwad Vijay Bansidharrao, Government Medical College, Department of Medicine Aurangabad-431001, Maharashtra, India.
33. Dr. Sunil Ishwarchand Agarwal, Oyster and Pearl Hospitals, 1671-75, Ganeshkhind Road, Shivaji Nagar, Pune-411005, Maharashtra, India.
34. Dr. Nikhil D. Parikh, S R Kalla Memorial Gastro & General Hospital 78-79, Dhuleshwar Garden, Behind HSBC Bank, Sardar Patel Marg, C-Scheme, Jaipur- 302001 Rajasthan, India.

35. Dr. Washimkar Sunil Nilkantharao, Department of Cardiology, Super Speciality Hospital, Government Medical College & hospital, Tukdoji Square, Nagpur- 440009, Maharashtra, India.
36. Dr. Ravikumar Gurugubelli, King George Hospital, Maharanipecta, Visakhapatnam- 530002, Andhra Pradesh, India.
37. Dr. Parneesh Arora, Fortis Hospital, B- 22, Sector-62, Noida- 201301, U.P., India.

Kindly note that the clinical trial permission is subject to the following conditions:

- a. **Statin intolerance criteria as submitted to this Directorate is applicable for screening and randomization to the study.**
- b. Clinical trial shall be conducted in compliance with the approved protocols, requirements of Schedule Y, Good Clinical Practice Guidelines issued by this Directorate and other applicable regulations.
- c. Approval of the Ethics Committee shall be obtained before initiation of the study.
- d. Clinical trials shall be registered at Clinical trials Registry of India before enrolling the first patient for the study.
- e. Annual status report of each clinical trial, as to whether it is ongoing, completed or terminated, shall be submitted to the Licensing Authority, and in case of termination of any clinical trial the detailed reasons for the same shall be communicated to the said Licensing Authority.
- f. Any report of serious adverse event occurring during clinical trial study to the subject, after due analysis, shall be forwarded within fourteen days of its occurrence as per Appendix XI and in compliance with the procedures prescribed in Schedule Y.
- g. In case of an injury or death during the study to the subjects, the applicant shall provide complete medical management and compensation in the case of trial related injury or death in accordance with rule 122 DAB and the procedures prescribed under Schedule Y, and the details of compensation provided in such cases shall be intimated to the Licensing Authority within thirty days of the receipt of the order of the said authority.
- h. The premises of Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical trial study sites shall be open to inspection by the officers authorized by the Central Drugs Standard Control Organization, who may be accompanied by an officer of the State Drug Control Authority concerned, to verify compliance to the requirements of Schedule Y, Good Clinical Practices guidelines for conduct of clinical trial in India and other applicable regulations.
- i. The Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical trial study sites and the Investigator shall allow officers authorized by the Central Drugs Standard Control Organization, who may be accompanied by an officer of the State Drug Control Authority concerned, to enter with or without prior notice, any premises of Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical trial sites to inspect, search and seize any record, data, document, books, investigational drugs, etc. related to clinical trial and provide adequate replies to any queries raised by the inspecting authority in relation to the conduct of clinical trial.
- j. Clinical trial shall be conducted only at those sites which are institutes/hospitals having adequate emergency facilities and duly registered Institutional Ethics committees.

- k. The details of payment/honorarium/financial support/fees paid by the Sponsor to the Investigator(s) for conducting the study shall be made available to this directorate before initiation of each of the trial sites.
- l. An audio-video recording of the informed consent process in case of vulnerable subjects in clinical trials of New Chemical Entity or New Molecular Entity including procedure of providing information to the subject and his understanding on such consent, shall be maintained by the investigator for record. Provided that in case of clinical trial of anti-HIV and anti-Leprosy drugs, only audio recording of the informed consent process of individual subject including the procedure of providing information to the subject and his understanding on such consent shall be maintained by the investigator for record.
- m. It may kindly be noted that merely granting permission to conduct clinical trials with the drug does not convey or imply that based on the clinical trial data generated with the drug, permission to market this drug in the country will automatically be granted to you.

Yours faithfully,

(Dr. G. N. Singh)
Drugs Controller General (India)