

43636/20.10.14

GOVERNMENT OF INDIA

Directorate General of Health Services
Central Drugs Standard Control Organization
Office of Drugs Controller General (India)
(Global Clinical Trial Division)
FDA Bhawan, Kotla Road, New Delhi-110 002
Tel No: 01123236965, Fax: 01123236971
E-mail: dci@nic.in

File No: CT/48/14 - DCG (I)

Dated: 16/04/15

To,

M /s. Boehringer Ingelheim India Pvt. Ltd.,
1102, 11th Floor, Hallmark, Business Plaza,
Gurunanak Hospital Rd, Near Gurunanak Hospital,
Bandra (East), Mumbai - 400 051.

Subject: Permission for conducting a Phase III clinical trial entitled
"Randomized, double-blind, evaluation in secondary stroke
prevention comparing the efficacy and safety of the oral thrombin
inhibitor dabigatran etexilate (110 mg or 150 mg, oral b.i.d.) versus
acetylsalicylic acid (100 mg oral q.d.) in patients with embolic stroke
of undetermined source (RESPECT ESUS)"- regarding.

Clinical Trial NOC No.: GCT/11/15

Reference: - Your letter No. BI/DCGI/CT/128/2014 dated 17 Oct 2014 on the subject
mentioned above.

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 following investigators and as per the **Protocol No: 1160.189 version 1.0 dated
27 Jun 2014** submitted to this Directorate.

1. Dr. Uma Sunder, LTMMC & GH Medical College, Dr. Baba Saheb Ambedkar Road, Sion West, Jain Society, Mumbai - 400 022, Maharashtra.
2. Dr. R Srinivasa, M. S. Ramaiah memorial Hospital, Dept of neurology, M.S.R. Nagar, MSRIT Post, Bangalore- 560054, Karnataka.
3. Dr. Rupam Borgohain, Department of Neurology Nizams Institute of Medical Sciences, Punjagutta, Hyderabad - 500 082, Telangana.
4. Dr. Vikram Sharma, St. Theresa's Hospital, Sanath nagar, Opp. Raithu Bazar, Erragadda, Hyderabad, Pin: 500 018, Telangana.
5. Dr. Sudhir Kothari, Dept. of Neurology, Poona Hospital and Research Centre, 27, Sadashiv Peth, Pune - 411 030.
6. Dr. GRK Sarma, Department of Neurology, St. Johns Medical College & Hospital, Sarjapur Road, Bangalore 560 034, Karnataka.
7. Dr. Prashantha D K, Nanjappa Hospital, #660, Kuvempu Road, Shivamogga - 577 201, Karnataka.
8. Dr. Vijaya P, Lalitha Super Specialities Hospital (P) Ltd., Kothapet, Guntur, Pin: 522001, Andhra Pradesh.
9. Dr. Rajashekar Reddi, Max Super Speciality Hospital. 1-press enclave road, Saket, New Delhi-110017.

10. Dr. Vikram Huded, Mazumdar Shaw Medical Centre, Narayana Hrudayalaya Private Limited, Narayana Hrudayalaya Private Limited, #258/A, Bommasandra, Hosur Road, Bangalore – 560 099, Karnataka.
11. Dr. Sebastian Joseph, Caritas Hospital, Thellakom PO, Kottayam, Kerala-686 016.
12. Dr. Arvind Sharma, Dept. of Neurology, B J Medical College and Civil Hospital, Asarwa, Ahmedabad 380 016, Gujarat.
13. Dr. Dheeraj Khurana, Post Graduate Institute of Medical Education and Research, Sector 12, Chandigarh - 160 012.
14. Dr. Tapas Kumar Banerjee, National Neurosciences Centre Calcutta, Peerles Hospital Campus (2nd Floor) 360, Panchasayar, Kolkata – 700 094, West Bengal.
15. Dr. Rahul Baviskar, Chopda Medicare and Research Centre Pvt Ltd, Magnum Heart Institute, 3/5, Patil Lane No 1, Laxmi Nagar, Near K B H Vidyalaya, Canada Corner, Nashik 42205.
16. Dr. M V Padma Srivastava, All India Institute of Medical Sciences, Room No 708, 7th Floor, Ansari Nagar, Delhi 110 029.
17. Dr U K Misra, C Block, Dept of Neurology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Rae Bareli Road, Lucknow.
18. Dr. Anand Alurkar, KEM Hospital, 5th Floor, Diamond Jubilee Building, Sardar Moodliar Road, Pune 411 011.
19. Dr. Prahlad Sethi, Sir Gangaram Hospital, Sir Gangaram Hospital Road, New Rajinder Nagar, New Delhi-110 060.
20. Dr. Vijay Anand T C, Meenakshi Mission Hospital & Research Centre, Lake Area, Melur Road, Madurai- 625 107, Tamil Nadu.
21. Dr. Zanzmera, New Civil Hospital and Government Medical College, New Civil Hospital Campus, Majura Gate, Surat – 395 001.
22. Dr. Soaham Desai, Shree Krishna Hospital and Medical Research Centre, Gokal Nagar, Karamsad-388 325.
23. Dr. Sunil K Narayan, Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), II Floor, IP Building, SS Block, Dhavanthri Nagar, Puducherry – 605 006.
24. Dr. Rahul Kulkarni, Deenanath Mangeshkar Hospital and Research Center, Erandwane, Pune – 411 004.
25. Dr. Nilesh Palasdeokar, Dept. of medicine, B.J. Govt. Medical College and Sassoon Hospital, Camp, Pune, Maharashtra – 411 001.
26. Dr. Suresh Kumar, Research Cell, Room No. 18, Vijaya Health Centre, 175 N.S.K Salai, Vadapalani, Chennai, Tamil Nadu 600 026.

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

- a. 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;
- b. Approval of the Ethics Committee shall be obtained before initiation of the study;
- c. Clinical trials shall be registered at Clinical trials Registry of India before enrolling the first patient for the study;
- d. 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;

- e. Any report of serious adverse event occurring during clinical trial study to the subject, after due analysis, shall be forwarded within ten days of its occurrence as per Appendix XI and in compliance with the procedures prescribed in Schedule Y;
- f. 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;
- g. 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;
- h. 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.
- i. Clinical trial shall be conducted only at those sites which are institutes/hospitals having adequate emergency facilities and duly registered Institutional Ethics committees.
- j. The sponsor shall ensure that the number of clinical trials an investigator can undertake should be commensurate with the nature of the trial, facility available with the Investigator etc. However, under no circumstances the number of trials should be more than three at a time.
- 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. In addition to the requirement of obtaining written informed consent, audio - visual recording of the informed consent process of each trial subject, including the procedure of providing information to the subject and his/her understanding on such consent is required to be done while adhering to the principles of confidentiality. Such audio-visual recording and related documentation shall be preserved. This is applicable to the new subjects to be enrolled in all clinical trials including Global Clinical Trials. All the Sponsors /Investigators /Institutes/Organizations and other stake holders involved in conduct of clinical trials in the country are required to adhere to this requirement of audio-visual recording of informed consent process of trial subjects.

- 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. V.G. Somani)
Joint Drugs Controller (India)