



सत्यमेव जयते

GOVERNMENT OF INDIA  
CENTRAL DRUGS STANDARD CONTROL  
ORGANISATION (Headquarter)  
(Directorate General of Health Services)  
Ministry of Health & Family Welfare  
FDA Bhavan  
ITO, Kotla Road  
New Delhi - 110002 (Delhi)  
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**File No. CT/25/000059**

To,

M/s. AstraZeneca Pharma India Limited,  
Block N1, 12th Floor Manyata Embassy,  
Business Park, Rachenahalli Outer Ring Road,  
Bangalore, Karnataka (India) – 560045.

Sir,

With reference to your application No. GCT/CT04/FF/2025/49542 dated 14-May-2025, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled **“A Phase III, Randomised, Double-blind, Placebo-controlled, Parallel-group Study to Assess the Effect of AZD0780 on Major Adverse Cardiovascular Events in Patients with Established Atherosclerotic Cardiovascular Disease (ASCVD) or at High Risk for a First ASCVD Event” Protocol No. D7960C00015 Version No. 1.0 Protocol dated 11-APR-2025; Local CSP Addendum IND-1: Version 1.0, dated 14 Apr 2025 with a total of up-to 600 subjects from India** under the provisions of New Drugs and Clinical Trial Rules, 2019

The permission granted by the Central Licensing Authority to conduct clinical trial shall be subject to following conditions, namely:-

- (i) **Human biological samples i.e. Whole blood, serum and urine samples related to clinical trial shall be permitted to be exported for analysis subject to the clearance by port offices of CDSCO. Further, ICMR/DHR permission shall be obtained for export of optional biological samples as per DGFT notification number 72/2023 dated 11.03.2024.**
- (ii) Clinical trial at each site shall be initiated after approval of the clinical trial protocol and other related documents by the Ethics Committee of that site, registered with the Central Licencing Authority under rule 8;
- (iii) where a clinical trial site does not have its own Ethics Committee, clinical trial at that site may be initiated after obtaining approval of the protocol from the Ethics Committee of another trial site; or an independent Ethics Committee for clinical trial constituted in accordance with the provisions of rule 7:

Provided that the approving Ethics Committee for clinical trial shall in such case be responsible for the study at the trial site or the centre, as the case may be:

Provided further that the approving Ethics Committee and the clinical trial site or the bioavailability and bioequivalence centre, as the case may be, shall be located within the same city or within a radius of 50 kms of the clinical trial site;

- (iv) in case an ethics committee of a clinical trial site rejects the approval of the protocol, the details of the same shall be submitted to the Central Licensing Authority prior to seeking approval of another Ethics Committee for the protocol for conduct of the clinical trial at the same site;
- (v) the Central Licencing Authority shall be informed about the approval granted by the Ethics

Committee within a period of fifteen working days of the grant of such approval;

- (vi) clinical trial shall be registered with the Clinical Trial Registry of India maintained by the Indian Council of Medical Research before enrolling the first subject for the trial;
- (vii) clinical trial shall be conducted in accordance with the approved clinical trial protocol and other related documents and as per requirements of Good Clinical Practices Guidelines and the provisions of these rules;
- (viii) status of enrolment of the trial subjects shall be submitted to the Central Licencing Authority on quarterly basis or as appropriate as per the duration of treatment in accordance with the approved clinical trial protocol, whichever is earlier;
- (ix) six monthly status report of each clinical trial, as to whether it is ongoing, completed or terminated, shall be submitted to the Central Licencing Authority electronically in the SUGAM portal;
- (x) in case of termination of any clinical trial the detailed reasons for such termination shall be communicated to the Central Licencing Authority within thirty working days of such termination;
- (xi) any report of serious adverse event occurring during clinical trial to a subject of clinical trial, shall, after due analysis, be forwarded to the Central Licencing Authority, the chairperson of the Ethics Committee and the institute where the trial has been conducted within fourteen days of its occurrence as per Table 5 of the Third Schedule and in compliance with the procedures as specified in Chapter VI;
- (xii) in case of injury during clinical trial to the subject of such trial, complete medical management and compensation shall be provided in accordance with Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licencing Authority within thirty working days of the receipt of order issued by Central Licencing Authority in accordance with the provisions of the said Chapter;
- (xiii) in case of clinical trial related death or permanent disability of any subject of such trial during the trial, compensation shall be provided in accordance with Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licencing Authority within thirty working days of receipt of the order issued by the Central Licencing Authority in accordance with the provisions of the said Chapter;
- (xiv) the premises of the sponsor including his representatives and clinical trial sites, shall be open for inspection by officers of the Central Licencing Authority who may be accompanied by officers of the State Licencing Authority or outside experts as authorised by the Central Licencing Authority, to verify compliance of the requirements of these rules and Good Clinical Practices Guidelines, to inspect, search and seize any record, result, document, investigational product, related to clinical trial and furnish reply to query raised by the said officer in relation to clinical trial;
- (xv) where the new drug or investigational new drug is found to be useful in clinical development, the sponsor shall submit an application to the Central Licencing Authority for permission to import or manufacture for sale or for distribution of new drug in India, in accordance with Chapter X of these rules, unless otherwise justified;
- (xvi) the laboratory owned by any person or a company or any other legal entity and utilised by that person to whom permission for clinical trial has been granted used for research and development, shall be deemed to be registered with the Central Licencing Authority and may be used for test or analysis of any drug for and on behalf of Central Licencing Authority;
- (xvii) the Central Licencing Authority may, if considered necessary, impose any other condition in writing with justification, in respect of specific clinical trials, regarding the objective, design, subject population, subject eligibility, assessment, conduct and treatment of such specific clinical trial;
- (xviii) the sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.
- (xix) Merely granting permission to conduct the **clinical trial** with the Investigational Drug Product does not convey or imply that, based on the **clinical trial study data** generated with the investigational drug, permission to market this drug in the country will automatically be granted to you;
- (xx) The permission to initiate clinical trial granted under rule 22 in form CT-06 or automatic approval under rule 23 in Form CT 4A shall remain valid for a period of **two years** from the date of its issue, unless extended by the Central Licencing Authority.

Yours faithfully,

(Dr. Rajeev Singh Raghuvanshi)  
Drugs Controller General (India) &  
Central Licencing Authority  
Stamp

**FORM CT-06**  
(See rules 22,25,26,29 and 30)  
**PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR  
INVESTIGATIONAL NEW DRUG**

1. The Central Licensing Authority hereby permits **M/s. AstraZeneca Pharma India Limited, Block N1, 12<sup>th</sup> Floor, Manyata Embassy Business Park, Rachenahalli, Outer Ring Road, Bangalore, Karnataka (India) - 560045** to conduct clinical trial of the new drug or investigational new drug as per **Protocol No. D7960C00015 Version No. 1.0 Protocol dated 11-APR-2025; Local CSP Addendum IND-1: Version 1.0, dated 14 Apr 2025** in the below mentioned clinical trial sites [As per Annexure].
2. Details of new drug or investigational new drug and clinical trial site [As per Annexure].
3. This permission is subject to the conditions prescribed in part A of Chapter V of the New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act, 1940.

Place: New Delhi

Date \_\_\_\_\_

(Dr. Rajeev Singh Raghuvanshi)  
Drugs Controller General (India) &  
Central Licencing Authority  
Stamp

**Note:** The permission to initiate clinical trial granted under rule 22 in form CT-06 shall remain valid for a period of **two years** from the date of its issue, unless extended by the Central Licencing Authority.

**Annexure:**

Details of new drug or investigational new drug:

<b>Names of the new drug or investigational new drug</b>	AZD0780 30mg Tablet or Placebo
<b>Therapeutic class:</b>	PCSK9 inhibitor
<b>Dosage form:</b>	Tablets
<b>Composition:</b>	AZD0780=30.0000 milligram (mg) In House Specification Active
<b>Indications:</b>	Assess the Effect of AZD0780 on Major Adverse Cardiovascular Events in Patients with Established Atherosclerotic Cardiovascular Disease

**Annexure:**

Details of clinical trial site:

<b>Sr. No.</b>	<b>Names and address of clinical trial site</b>	<b>Ethics committee details</b>	<b>Name of investigator</b>
1.	KLES Dr Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi -590010, Karnataka	Institutional Ethics Committee, KLE University KLE Dr. PK Hospital and MRC, Nehru Nagar, Belagavi, Karnataka -590010  ECR/211/Inst/KA/2013/RR-24	Dr. Prasad Murigendrappa Renuka
2.	Shri Guru Ram Rai (SGRR) Institute of Medical & Health Sciences and Shri Mahant Indires Hospital, Patel Nagar, Dehradun -248001, Uttarakhand	Institutional Ethics Committee SGRR Institute Of Medical Health Sciences IEC, Administrative Building, Patel Nagar, Dehradun, Uttarakhand - 248001  ECR/710/Inst/UK/2015/RR-21	Dr. Tanuj Bhatia
3.	Max Super Speciality Hospital Saket (East Block) (A Unit of Devki Devi Foundation), 2, Press Enclave Road, Saket, New Delhi -110017, India	Institutional Ethics Committee, Devki Devi Foundation, 2 Press Enclave Road, Saket, New Delhi -110017  ECR/110/Inst/DL/2013/RR-24	Dr. Vijay Kumar Chopra
4.	Batra Hospital and Medical Research Centre, 1, Tughlakabad Institutional Area, Mehrauli Badapur Road, New Delhi -110062	The Chairman Scientific Research and Ethical review Committee, Batra Hospital And Medical Research Centre, 1, Tughlakabad Institutional Area, Mehrauli Badarpur Road, New Delhi South Delhi, Delhi -110062  ECR/295/Inst/DL/2013/RR-22	Dr. Upendra Kaul
5.	Govind Ballabh Pant Institute of Postgraduate Medical Education and Research, First Floor, Academic Block, Department of Cardiology, Jawahar Lal Nehru Marg, New Delhi -110002, Delhi	Institutional Ethics Committee MAMC, Maulana Azad Medical College, 3rd Floor, Room No 306B, Bahadur Shah Zafar Marg, New Delhi, Delhi -110002  ECR/329/Inst/DL/2013/RR-24	Dr. Vimal Mehta

6.	LPS Institute of Cardiology and Cardiac Surgery, G.S.V.M Medical College, G.T. Road, Swaroop Nagar, Kanpur -208002, Uttar Pradesh	IEC LPS Institute of Cardiology, LPS Institute Of Cardiology And Cardiac Surgery, G.T. Road , Kanpur, Uttar Pradesh – 208002  ECR/2062/Inst/UP/2025	Dr. Santosh Kumar Sinha
7.	Dayanand Medical College & Hospital, Unit - Hero DMC Heart Institute, Tagore Nagar, Civil Lines, Ludhiana - 141001, Punjab	Drug Trial Ethics Committee Dayanand Medical College and Hospital, Tagore Nagar, Civil Lines, Ludhiana Punjab –141001  ECR/101/Inst/PB/2013/RR-24	Dr. Gurpreet Singh Wander
8.	Govt. Siddhartha Medical College, Ring road, Gunadala, Vijayawada - 520008, Andhra Pradesh	Institutional Ethics Committee SMC and GGH, Siddhartha Medical College and Govt. General Hospital, Ring Road, Gunadala, Vijayawada NTR Andhra Pradesh -520008  ECR/633/Inst/AP/2014/RR-24	Dr. Srinivasu Yalaga
9.	Topiwala National Medical College & B.Y.L Nair Charitable Hospital, Dr. A.L. Nair Road, Mumbai -400008, Maharashtra, INDIA	Institutional Ethics Committee TNMC NAIR HOSPITAL, Topiwala National Medical College Nair Hospital, Dr A L Nair Road, Mumbai, Maharashtra – 400008  ECR/22/Inst/Maha/2013/RR-24	Dr. Ajay Chaurasiya
10.	Sri Jayadeva Institute of Cardiovascular Sciences and Research, Bannerghatta Road, 9th block, Jayanagar, Bengaluru Urban, Karnataka -560069	Sri Jayadeva Ethics Committee, Sri Jayadeva Institute Cardiovascular Sciences Research, Bannerghatta Road, 9th block, Jayanagar, Bangalore Urban Karnataka – 560069  ECR/423/Inst/KA/2013/RR-19	Dr. Sriranga R
11.	Lisie Hospital, P.B. No. 3053, Kochi -682018	Institutional Ethics Committee, Lisie Hospital, P.B No 3053, Ernakulam, Kerala –682018  ECR/40/Inst/KL/2013/RR-25	Dr. Jabir Abdullakutty
12.	Malla Reddy Narayana Multispeciality Hospital, Suraram 'X' Roads, Jeedimetla, Hyderabad, Telanagana -500055	MRMCW-Institutional Ethics Committee Malla Reddy Medical College For Women Suraram X Road Qutbullapur, Municipality, Jeedimetla Hyderabad, Telangana – 500055  ECR/981/Inst/AP/2017/RR-20	Dr. P. S. Gautam
13.	Kasturba Hospital, an associate Hospital of MAHE, Madhav Nagar, Manipal - 576104, Karnataka	MAHE Ethics Committee Manipal Academy of Higher Education, manipal.edu bldg, Madhav Nagar, Manipal, Udupi, Karnataka –576104  ECR/191/Inst/KL/2013/RR-24	Dr. Tom Devasia

14.	Medanta - The Medicity, Sector -38, Gurgaon, Haryana -122001	Medanta Institutional Ethics Committee, Medanta -The Medicity, Sector 38, Gurugram, Haryana – 122001  ECR/282/Inst/HR/2013/RR-20	Dr. Rajneesh Kapoor
15.	Crescent Hospital & Heart Centre, Behind Old Mount Carmel School, Near Lokmat Square, Dhantoli, Nagpur - 440012, Maharashtra	Ethics Committee of Crescent Hospital Heart Centre, Crescent Hospital and Heart Centre, Plot No 25, Behind Old Mount Carmel School, Near Lokmat Square, Dhantoli, Nagpur, Maharashtra – 440012  ECR/682/Inst/MH/2014/RR-21	Dr. Mohd Aziz Khan
16.	Marengo CIMS Hospital, Plot no. 67/1, Opp. Panchmrut Bungalows, Near Shukan Mall, Off. Science City Road, Ahmedabad -380060, Gujarat	Ethics Committee of CIMS Care Institute of Medical Sciences, Near Shukan Mall, Off Science City Road, Sola, Ahmedabad, Gujarat –380060  ECR/206/Inst/GJ/2013/RR-24	Dr. Anish Chandarana
17.	Fortis Escorts Heart Institute, Okhla Road, New Delhi - 110025	Institutional Ethics Committee, Fortis Escorts Heart Institute, Room No A - 22, 23, 2nd Floor, RC Building, Okhla Road, New Delhi, Delhi – 110025  ECR/261/Inst/DL/2013/RR-24	Dr. Peeyush Jain
18.	Atal Bihari Vajpayee Institute of Medical Sciences, Dr. Ram Manohar Lohia Hospital, Baba Kharak Singh Marg, New Delhi -110001	Ethics Committee, PGIMER, Dr. RML Hospital PGIMER, Dr Ram Manohar Lohia Hospital, Baba Khadakh Singh Marg, New Delhi, Delhi –110001  ECR/78/Inst/DL/2013/RR-24	Dr. Puneet Aggarwal
19.	Venkateshwar Hospital, Sector 18A, Dwaraka, New Delhi -110075	IEC VENKATESHWAR HOSPITAL UNIT OF ASHA, Venkateshwar Hospital, Sec 18 A, Dwarka, Delhi – 110075  ECR/1275/Inst/DL/2019/RR-24	Dr. Karan Chopra
20.	All India Institute of Medical Sciences (AIIMS), Ansari Nagar, New Delhi -110029	Institute Ethics Committee, All India Institute of Medical Sciences, Old OT Block, Room No. 102, AIIMS Hospital, Ansari Nagar, New Delhi, Delhi –110029  ECR/1275/Inst/DL/2019/RR-24	Dr. Sandeep Seth
21.	Care Hospitals, 6-3-248/2, Road No.1, Banjara Hills, Hyderabad -500034, Telangana	CARE Hospitals, Institutional Ethics Committee, 6-3-248/2, Care Hospital, In-Patient building, 4th Floor, Room No. 401, Road No-1, Banjara Hills, Hyderabad, Telangana-500034  ECR/94/Inst/AP/2013/RR-21	Dr. Praneeth Polamuri

22.	Lakeshore Hospital and Research Centre Ltd., XVII/612, Maradu, Nettoor, PO-682040, Kochi, Kerala	Lakeshore Ethics Committee, Lakeshore Hospital and Research Centre Limited, XXIV/477, NH 47 by Pass Nettoor P.O, Maradu, Kochi, Ernakulam Kerala –682040  ECR/115/Inst/Ker/2013/RR-24	Dr. Anand Valsakumar
23.	Rabindranath Tagore International Institute of Cardiac Sciences, Premises No 1489, 124 Mukundapur, E.M. Bypass, Kolkata - 700099	NHRTIICS Ethics Committee, RTIICS, 124, Mukundapur, E. M. Bypass Kolkata Kolkata West Bengal –700099  ECR/316/Inst/WB/2013/RR-24	Dr. Ayan Kar
24.	Rhythm Heart Institute, Near Siddharth Bungalows, Sama Savli Road, Vadodara - 390022, Gujarat	Rhythm Heart Institute Ethics Committee Rhythm Heart Institute, Near Siddharth Bungalows, Sama-Savli Road, Vadodara, Gujarat – 390022  ECR/224/Inst/GJ/2013/RR-24	Dr. Nirav Chandulal Bhalani

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