

Tata Medical Center

14 Major Arterial Road (EW)
Newtown, Rajarhat, Kolkata - 700 160
Tel.: + 91 33 66057000, Email : info@tmckolkata.com
www.tmckolkata.com



UNDERTAKING BY THE INVESTIGATOR

1. **Full name, address and title of the Principal Investigator**

Name: Dr. Prashant Pandey
Title: Consultant medical oncologist
Tata Medical Center
Address: 14, MAR (E-W), New Town, Rajarhat, Kolkata- 700 160

2. **Name and address of the medical college, hospital or other facility where the clinical trial will be conducted:**

Name: TATA MEDICAL CENTER
Address: 14, MAR (E-W), New Town, Rajarhat, Kolkata- 700 160

Education, training & experience that qualify the Investigator for the trial: (Attach details including Medical Council registration number, and / or any other statement(s) of qualification(s))

Registration No: 60535
CV & MRC attached

3. **Name and address of all clinical laboratory facilities to be used in the study.**

Central Laboratories: Not Applicable

Local Laboratories:

DEPARTMENT OF LABORATORY SCIENCES

Tata Medical Center,
14-Mar (EW), New Town, Rajarhat,
Kolkata-700160, West Bengal, India

DEPARTMENT OF RADIOLOGY

Tata Medical Center
14-Mar (EW), New Town
Rajarhat, Kolkata-700160, West Bengal, India

OPHTHALMOLOGY FACILITY

Sankara Nethralaya
New Town (A unit of Medical Research Foundation, Chennai)
Premises No. 253333, Plot No. - DJ/16, Action Area – ID
New Town, Rajarhat, Kolkata- 700160

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4. **Name and address of the Ethics Committee that is responsible for approval and continuing review of the study.**

Name: Institutional Review Board

Address: 14, MAR (E-W), New Town, Rajarhat, Kolkata- 700 160

EC registration no.: ECR/269/Inst/WB/2013/RR-24

EC contact no: 033 6605 8147

5. **Names of the other members of the research team (Co-or sub-Investigators) who will be assisting the Investigator in the conduct of the investigation(s).**

1. **Name:** Dr. Somnath Roy
Qualification: DM
Designation: Senior Consultant Medical Oncologist
Department: Medical Oncology
2. **Name:** Dr. Deepak Dabkara
Qualification: DM
Designation: Senior Consultant Medical Oncologist
Department: Medical Oncology
3. **Name:** Dr. Arnab Bhattacharjee
Qualification: DM
Designation: Consultant Medical Oncologist
Department: Medical Oncology
4. **Name:** Dr. Susmita Sadhukhan
Qualification: DM
Designation: Consultant Medical Oncologist
Department: Medical Oncology
5. **Name:** Dr. Sayak Dey
Qualification: DM
Designation: Consultant Medical Oncologist
Department: Medical Oncology
6. **Name:** Dr. Ankur Mahajan
Qualification: MD
Designation: Fellow
Department: Medical Oncology

6. Protocol number: 61186372NSC4018

Protocol Title: A Phase 4, Open-Label Study to Evaluate Safety of Amivantamab in Combination With Chemotherapy in Indian Patients With Locally Advanced or Metastatic Non-Small Cell Lung Cancer With EGFR Exon 19del or Exon21 L858R Mutations After Progression on Osimertinib

7. Commitments:

- (i) I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct of the study. I will not begin the study until all necessary Ethics Committee and regulatory approvals have been obtained.
- (ii) I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the Sponsor and prior review and documented approval/ favorable opinion from the Ethics Committee of the amendment, except where necessary to eliminate an immediate hazard(s) to the trial Subjects or when the change(s) involved are only logistical or administrative in nature.
- (iii) I agree to personally conduct and/ or supervise the clinical trial at my site.
- (iv) I agree to inform all trial Subjects, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the New Drugs and Clinical Trial Rules, 2019 GCP guidelines are met.
- (v) I agree to report to the Sponsors all adverse experiences that occur in the course of the investigation(s) in accordance with the regulatory requirements and GCP guidelines.
- (vi) I have read and understood the information in the Investigator's brochure and/ or Prescribing Information of the drug product, including the potential risks and side effects of the drug.
- (vii) I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the trial.
- (viii) I agree to maintain adequate and accurate records and to make those records available for audit/ inspection by the Sponsor, Ethics Committee, Central Licensing Authority or their authorized representatives, in accordance with regulatory provisions and the GCP guidelines. I will fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the Sponsor.
- (ix) I agree to promptly report to the Ethics Committee all changes in the clinical trial activities and all unanticipated problems involving risks to human Subjects or others.
- (x) I agree to inform all serious adverse events to the Central Licensing Authority, Sponsor as well as the Ethics Committee within twenty-four hours of their occurrence. In case, of failure to do so, I shall furnish the reason for the delay to the satisfaction of the Central Licensing Authority along with the report of the serious adverse event.

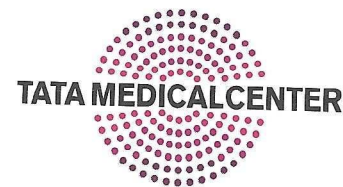
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- (xi) The report of the serious adverse event, after due analysis, shall also be forwarded by me to the Central Licensing Authority, the Chairperson of the Ethics Committee and the Head of the Institution where the trial has been conducted within fourteen days in accordance with the regulatory requirements.
- (xii) I will maintain confidentiality of the identification of all participating study patients and assure security and confidentiality of study data.
- (xiii) I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical Investigators participating in clinical trials.

8. Signature of Investigator with Date and Hospital stamp:

Prashant Pandey
8/06/24

Dr Prashant Pandey
MD, DNB (Medical Oncology) MRCP(SCE,UK), ECMO
Consultant Medical Oncologist
Tata Medical Centre