

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 (or Investigators when there is no Principal Investigator):**

Dr Arnab Bhattacharjee – Consultant

Tata Medical Center, Dept. of Medical Oncology 14, Major arterial Road (E-W), Rajarhat, New Town, Kolkata, 700160

2. **Name and address of the medical college, hospital or other facility where the clinical trial will be conducted: Education, training & experience that qualify the investigator for the clinical trial (Attach details, including Medical Council registration number, or any other statements of qualifications)**

Name & Address of Clinical trial facility: Tata Medical Center, Dept. of Medical Oncology 14, Major Arterial Road (E-W) Rajarhat, New Town, Kolkata, 700160

Education: MBBS, MD(Radiation Oncology), DM (Medical Oncology)

Medical Council Registration Number: 66781

Training: ICH GCP Trained

General Experience: 14 Years, Clinical Trial Experience: 4 Years

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

Central Laboratory:

Laboratory 1: Screening safety sample analysis (India)

Metropolis Healthcare Ltd 250-D, Udyog Bhavan, Hind Cycle Marg Worli Mumbai 400030- India

Laboratory 2: PK sample holding labs (India)

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**Metropolis Healthcare Ltd 4thFloor, Kohinoor Commercial-I, A wing, Kurla West,
Mumbai-400070- India**
Laboratory 3: PK, ADA and Nab lab kits and testing (China)
**Shanghai Xihua Scientific Co., Ltd. Building 6, 118 Furonghua Road, Pudong District,
Shanghai- China**

1. For Haematology, Urinalysis, Pathology, Microbiology and Biochemistry:

- Department of Laboratory Sciences (North and South Lab) Phase I (1st floor)

Address: Tata Medical Center 14 Major Arterial Road (E-W), Newtown, Rajarhat Kolkata-700160, West Bengal, India

- Agilus Diagnostics limited Frontier ware house, 153F, S M Bose Road, 1st floor, Block C, Gate no. 4, Panihati, Agarpara, North 24 parganas, Kolkata, West Bengal, India

Local Laboratory 2: For Imaging Assessment :

Department of Radiology Phase II (1st floor) & Phase I (Ground floor)

Address:- Tata Medical Center 14 Major Arterial Road (E-W), Newtown, Rajarhat, Kolkata-700160, West Bengal, India.

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

Name: Tata Medical Center

Address: 14 MAJOR ARTERIAL ROAD(E-W), NEWTOWN, RAJARHAT KOLKATA-700160, WEST BENGAL, INDIA

EC Registration No: ECR/269/Inst/WB/2013/RR-24

EC Registration Validity: 22/APR/2029

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 investigations

Name	Qualification	Specialisation
Dr. Somnath Roy	MBBS, MD & DM	LUNG, BREAST, KIDNEY & PROSTATE (MEDICAL ONCOLOGY)
Dr. Susmita Sandhukhan	MBBS, MD & DM	LUNG, BREAST, G.I, (MEDICAL ONCOLOGY)
Dr. Prasant Pandey	MBBS, MD & DrNB,MRCP,ESMO	LUNG, BREAST, KIDNEY & PROSTATE (MEDICAL ONCOLOGY)
Dr. Sayak Dey	MBBS, MD, DM	LUNG, BREAST, G.I ((MEDICAL ONCOLOGY)
Dr. Arkaprava Sinha	MBBS, MD, DNB (Medical oncology)	LUNG, BREAST, KIDNEY & PROSTATE, G.I (MEDICAL ONCOLOGY)
Dr. Ankur Mahajan	MBBS, MD, DNB (Medical oncology)	LUNG, BREAST, KIDNEY & PROSTATE, G.I (MEDICAL ONCOLOGY)
Dr. Ritika Ubeja	MBBS, MD, DNB (Medical oncology)	LUNG, BREAST, KIDNEY & PROSTATE, G.I (MEDICAL ONCOLOGY)
Dr. Anand Bardia	MBBS, MD	Pathology
Dr. Rucha Bhalde	MBBS,MD,DNB(Radio diagnosis)	Radiology
Dr. Jagannath Mishra	MBBS, MS(O&G),MCh(Gyne-Oncology)	Gynaecological Oncology

6. Protocol Title and Study number (if any) of the clinical trial to be conducted by the

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Investigator:

Protocol Title: An Open-label, Randomised, Multicenter Phase III Clinical Trial of SHR-A1811 Versus Investigator-selected Chemotherapy for Platinum-resistant Relapsed Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

Protocol No: GSP 402-301 (SHR-A1811-315_Extension) Version No.: 1.0, Date: 03 Dec 2025

7. Commitments:

- (i) I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct 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 or favourable opinion from the ethics committee of the amendment, except where necessary to eliminate an immediate hazard to the trial subject or when the changes involved are only logistical or administrative in nature.
- (iii) I agree to personally conduct 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 and Good Clinical Practices guidelines are met.
- (v) I agree to report to the Sponsor all adverse experiences that occur in the course of the investigation(s) in accordance with the regulatory requirements and Good Clinical Practices guidelines.

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(vi) I have read and understood the information in the Investigator's brochure, 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 or inspection by the Sponsor, ethics committee, Central Licensing Authority or their authorized representatives, in accordance with regulatory provisions and Good Clinical Practices 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.

(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 subjects and assure security and confidentiality of study data.

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(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

Name of Principal Investigator: Dr Arnab Bhattacharjee

Signature of Investigator: *Arnab* Date: 16/7/26