

TABLE – 4**UNDERTAKING BY THE INVESTIGATOR**

1.	Full Name: Dr. Prashant Pandey Address: 14 MAR(E-W), Newtown, Rajarhat, Kolkata-700160 Title of the Principal Investigator [or Investigator(s) when there is no Principal Investigator]: Title: Consultant Of Medical Oncology
2.	Name and Address of the Medical College, Hospital or other facility where the clinical trial will be conducted at: Name: Tata Medical Center Address: 14 MAR(E-W), Newtown, Rajarhat, Kolkata-700160
3.	Education, training & experience that qualify the Investigator for the clinical trial [Attach details including Medical Council registration number, and /or any other statement(s) of qualifications(s)]: Education: M.B.B.S., MD, DrNB(Medical Oncology),MRCP,ECMO MRC No.: 60535 CV and MRC are attached.
4.	Name and address of all clinical laboratory facilities to be used in the study: • Local Laboratory: Department of Laboratories(North & South Lab) Tata Medical Center, Phase I, 1st Floor 14 MAR(E-W), Newtown, Rajarhat, Kolkata-700160 • Imaging Centre: Department Of Radiology Tata Medical Center, Phase I Ground Floor, Phase II 1st Floor, 14 MAR(E-W), Newtown, Rajarhat, Kolkata-700160 • Central Laboratories: 1. LabCorp Central Laboratory Services: Labcorp (Asia) Pte. Ltd -

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	Address 01: 1 International Business Park, The Synergy, #03-14, Singapore 609917, Tel. 65-6560-8793 Fax. 65-6565-5901 Address 02: LabCorp Los Angeles, ATTN: Accessioning, 19750 S. Vermont Ave., Torrance, CA 90502, USA, Tel: 310-689-0547 2. Ventana - Address: Roche Tissue Diagnostics 2090 E Innovation Park Drive, Tucson, AZ 85755, USA 3. PPD - Address: PPD, part of Thermo Fisher Scientific, 8700 Quioccasin Rd, Henrico, VA, 23229, USA 4. Guardant Health - Address: 505 Penobscot Drive, Redwood City, CA 94063, USA 5. Q Squared Solutions Limited - Address: Q Squared Solutions Limited, The Alba Campus Rosebank, Livingston West Lothian EH54 7EG, United Kingdom 6. Rules Based Medicine - Address: 3300 Duval Road, Austin, TX 78759, USA 7. Adaptive Biotech - Address: 1165 Eastlake Ave E, Seattle, WA 98109, USA 8. ImmunAI - Address: Alexandria Center for Life Sciences, West Tower, 430 E 29th Street, Ste 1150, New York, NY 10016 9. Meso Scale Discovery - Address: Meso Scale Discovery, 16020 Industrial Drive, Gaithersburg, MD 20877 10. Discovery Life Sciences - Address: Discovery Life Sciences, 601 Genome Way, Room 1221, Huntsville, AL, US, 35806 11. AZ Biobank - Address: AstraZeneca Biocentre, 700 Progress way, Suite 4, Gaithursburg, MD 20879, US
5.	Name and address of the Ethics Committee that is responsible for approval and continuing review of the study: Name: Institutional Review Board Address: Tata Medical Center, Phase 2, 1st Floor 14 MAR(E-W) Newtown, Rajarhat Kolkata-700160 IEC Registration No.: ECR/269/Inst/WB/2013/RR-24
6.	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): Name: Dr. Sayak Dey Qualification: MBBS, MD, DM Designation: Consultant Of Medical Oncology Department: Department Of Medical Oncology

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	Name: Dr. Susmita Sadhukhan Qualification: MBBS, MD, DM Designation: Consultant Of Medical Oncology Department: Department Of Medical Oncology Name: Dr. Ankur Mahajan Qualification: MBBS, MD, DrNB Designation: Academic Senior Resident Department: Department Of Medical Oncology
7.	Protocol Title and Study number (if any) of the clinical trial to be conducted by the Investigator: Study Title: Phase III, Randomized, Open-label, Global, Multicenter Study of Rilvegostomig or Durvalumab in Combination With Chemotherapy as a First-line Treatment for Patients With Advanced Biliary Tract Cancer (ARTEMIDE-Biliary02) Study Code: D702NC00001
8.	Commitment: 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 subject, 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 Trials 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. vi. I have read and understood the information in the Investigator's brochure, including the potential risks and side effects of the drug.

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| 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 Licencing Authority or their authorised representatives, in accordance with regulatory provisions and the Good Clinical Practices guidelines. I will fully cooperate with any study related audit conducted by regulatory officials or authorised 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 Licencing 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 Licencing 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 Licencing 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. |
| xiii. | I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical Investigators participating in clinical trials. |

Signature of Investigator: P Pandey

Date: 21/07/2026