



TMC/ IRB/ SOP-4

Standard Operating Procedure (SOP)

For,

Initial Study Submission

Annexures



**Tata Medical Center
Institutional Review Board**

SOP: TMC/IRB/SOP-13
Version No.: 13.1
Effective Date:
03-10-2025
To be reviewed (on or before):
31-03-2026

TMC/IRB/SOP-04 Standard Operating Procedure (SOP) for Initial Study Submission

Annexure 1: INITIAL STUDY SUBMISSION FORM

Section A: Title and Principal 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)	
	Name	Affiliation
Principal Investigator	Dr. Prashant Pandey	MBBS, MD, DrNB, MRCP, ESMO
Co-Principal Investigator	Dr. Sayak Dey	MBBS, MD, DM
Co-Principal Investigator	Dr. Susmita Sadhukhan	MBBS, MD, DM
Co-Principal Investigator	Dr. Ankur Mahajan	MBBS, MD, DrNB
Section B: Type of Study		
By Origin	☒ Industry Sponsored ☐ Investigator Initiated	
Sponsor Details	AstraZeneca Pvt Ltd.	
By Design	☐ Observational ☒ Interventional	
For Interventional studies only		
Phase of Study	☐ Phase I ☐ Phase II ☒ Phase III ☐ Phase IV ☐ Bioavailability/ Bioequivalence (BA/ BE) study ☐ Pre- Clinical Study ☐ None of the Above (please specify intervention below)	
Type of intervention Please select all the interventions applicable. The intervention may be an addition to or a modification of the current standard of care	☒ Drug ☐ Vaccine ☐ Device ☐ Radiotherapy ☐ Radioisotope ☐ Surgery ☐ Diagnostic test ☐ Supportive Therapy ☐ Educational Intervention ☐ Other	
Is this a regulatory trial? Regulatory trials will require DCGI permission before IRB approval. Evidence of permission or DCGI application with the current status of application has to be notified at the time of submission for review of proposal.		☒ Yes ☐ No
Is this an investigational new drug (IND) or first in human drug study?		☒ Yes ☐ No

Prepared by : Dr Indranil Mallick

IRB Member Secretary

Reviewed by: Prof Partha Pratim Majumder

TMC-IRB Chairperson

Reviewed by: Dr Pattatheyl Arun

Head of the Institution

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Section C: Centers and Participants	
Enrolling Centers	☐ Single Center ☒ Multicenter
(for multicenter studies) Number of participating centers	8
International enrolment	☒ Yes ☐ No
Total planned sample size	Global 1100 India: 44
Estimated/ Planned enrolment at Tata Medical Center	8
Will vulnerable subjects be enrolled	☐ Yes ☒ No (If Yes, Please Indicate) ☐ Children; ☐ Employees of the Institute ☐ Patients, who are in Critical Care ☐ Economically/ Socially Backward ☐ Unable to understand written documentation ☐ Others
Informed Consent All consent forms must be submitted in English, Bengali and Hindi with valid translation and back-translation certificates before IRB review.	☐ Consent Waiver Requested ☒ Standard Informed Consent form for Adult Subject ☐ Informed consent form for legally authorized representative (for all children and those adults incapable of consenting) ☐ Assent form (applicable for children between 7-15 in addition to informed consent for LAR)
If consent or assent form is to be used, it includes all the recommended components as advised in the ICMR Ethical Guidelines 2017. https://ethics.ncdirindia.org/icmr_ethical_guidelines.aspx	☒ Yes, I Confirm...
Does your study have a Data and Safety Monitoring Committee (DSMC)?	☒ Yes ☐ No



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Section D: Funding, Insurance and Indemnity

Total budget of the study (in INR)

2, 11, 500 / Per Patient
PI Grant.

Who will fund the following

Trial Intervention

☐ Subject ☒ Industry Sponsor
☐ Institute as Sponsor ☐ NA

Cost of Serious Adverse Events

☐ Subject ☒ Industry Sponsor
☐ Institute as Sponsor ☐ NA

Sponsor may avail of Clinical Trial Insurance

Compensation for Trial Related Injury

☐ Subject ☒ Industry Sponsor
☐ Institute as Sponsor ☐ NA

Sponsor may avail of Clinical Trial Insurance

If the answer to any of the above questions is 'Subject', please explain below:

Does your trial have clinical trial indemnity for investigators?

All sponsored interventional studies must provide documentation of indemnity for trial investigators and staff. All investigator-initiated interventional studies should have trial indemnity, please contact the IRB office for details.

☒ Yes ☐ No

Does the sponsor of the trial have clinical trial insurance?

All sponsored interventional studies must provide documentation of trial insurance. All investigator-initiated interventional studies of new treatments that are currently not standard of care and likely to result in SAEs in the interventional arm should consider trial insurance for cost of serious adverse events. Contact the IRB office for details.

☒ Yes ☐ No

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Section E: Special Considerations

Does the project involve bio-banking any blood or tissue?

If bio-banking is planned at Tata Medical Center, please provide documentation that confirms that the TMC bio-bank and you are mutually aware of the requirements and SOPs.

☐ Yes☒ No

Does your project involve the use of stem cells?

If yes, please make sure you are aware of the DBT-ICMR guidelines for Stem Cell Research.

https://dbtindia.gov.in/sites/default/files/National_Guidelines_StemCellResearch-2017.pdf

☐ Yes☒ No

Does your project involve the use of infectious material?

If yes, please provide clearance from the Institutional Biosafety Committee (IBSC)

☐ Yes☒ No

Does your project involve the use of radioactive isotopes?

If yes, please provide clearance from the appropriate governmental agencies.

☐ Yes☒ No

Does your project involve the development or use of artificial intelligence tools?

If yes, please make sure you are aware of the ICMR guidelines for the application of Artificial intelligence in Biomedical Research and Healthcare.

<https://www.icmr.gov.in/ethical-guidelines-for-application-of-artificial-intelligence-in-biomedical-research-and-healthcare>

☐ Yes☒ No

Section F: Collaboration or sharing data/materials with external institutions or agencies

Does your project involve sharing of data, digital samples (images/sequencing data etc.) or biological samples of any form with any external institution/agency?

☒ Yes☐ No

If yes, I confirm that there is a **data/ material transfer agreement** in consideration between the institution and external agency covering all of the following

- ✓ Privacy Preservations
- ✓ Rights of access and use
- ✓ Safekeeping and archiving
- ✓ Disposal of digital and/ or biological material

Does your project involve funding or collaboration with any foreign agency or institution?

☐ Yes☒ No

If yes, do you have clearance from the Health Ministry Screening Committee (HMSC)?

Please check the following for details: <https://main.icmr.nic.in/content/health-ministry-screening-committee-hmsc>

☐ Yes☐ In Progress



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Signatures

By signing the document, I acknowledge that I am aware of the details of the research protocol and that all the answers to the questions above are true to the best of my knowledge.

	Name	Signature	Phone number & E-mail
Principal Investigator	Dr. Prashant Pandey		prashantpandeydr@gmail.com 9804290687
Co-PI Co-I	Dr. Sayak Dey		sayakdey240991@gmail.com 9749955500
Co-PI Co-I	Dr. Susmita Sadhukhan		Sadhukhansusmita89@gmail.com 8910788900
Co-PI Co-I	Dr. Ankur Mahajan		Ankur.mahajan98@gmail.com 8377863415
Co-PI Co-I			
Co-PI Co-I			
Co-PI Co-I			
Co-PI Co-I			
Co-PI Co-I			
Co-PI Co-I			
Co-PI Co-I			

Prepared by : Dr Indranil Mallick
IRB Member Secretary

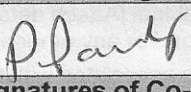
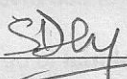
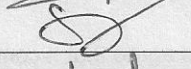
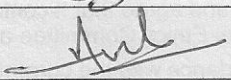
Reviewed by: Prof Partha Pratim Majumder
TMC-IRB Chairperson

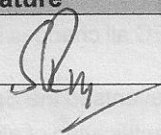
Reviewed by: Dr Pattatheyl Arun
Head of the Institution

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Statement of Compliance:

We, hereby, declare that, the information given above is true and that we will comply with the guidelines mentioned in the NDCT (Third Amendment) Rules, 2022 (Drugs and Cosmetic Act 1940), Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research (2017), Indian GCP Guidelines (2001) and the International Conference on Harmonization Good Clinical Practices (ICH GCP) Guidelines (1996) while conducting the research study.

Name and Signatures of Principal investigator with Date		
Name	Signature	Date
Dr. Prashant Pandey		28/07/26
Name and Signatures of Co-investigator(s) with Date		
Name	Signature	Date
Dr. Sayak Dey		28/7/26
Dr. Susmita Sadhukhan		28/7/26
Dr. Ankur Mahajan		28/7/26

Name and Signatures of Head of Department(s) with Date		
Name	Signature	Date
Dr. Somnath Roy		28/07/26

Stamp/ Seal of the Department(s)

Dr. Somnath Roy
MD, DM (Med Onc), ECMO
Consultant Medical Oncologist
TATA MEDICAL CENTER, KOLKATA

Prepared by : Dr Indranil Mallick
IRB Member Secretary

Reviewed by: Prof Partha Pratim Majumder
TMC-IRB Chairperson

Reviewed by: Dr Pattatheyl Arun
Head of the Institution

TMC/IRB/SOP-04 Standard Operating Procedure (SOP) for Initial Study Submission

Annexure 2: Undertaking by the investigator as per Schedule III, Table 4 of NDCT (Third Amendment) Rules, 2022

Protocol Name:

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)

1. Full name, Address and Title of the Principal Investigator/ (Investigator(s) when there is no Principal Investigator)
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 Curriculum Vitae, Good Clinical Practice Certificate & Medical Council Registration Certificate and/or any other statement(s) of qualification(s)].
3. Name and Address of all clinical laboratory facilities to be associated with the study.
4. Name and Address of the Ethics Committee that is responsible for approval and continuing review of the study.
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).
6. Protocol Title and Study number (if any) of the clinical trial to be conducted by the Investigator.
7. Commitments:
 - ❖ 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.
 - ❖ 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/favourable 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.
 - ❖ I agree to personally conduct and/or supervise the clinical trial at my site.
 - ❖ I agree to inform all Subjects that the drugs are being used for investigation purposes and I will ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the GCP guidelines are met.
 - ❖ I agree to report to the Sponsor all adverse experiences that occur in the course of the study in accordance with the regulatory and GCP guidelines.
 - ❖ I have read and understood the information in the Investigator's brochure, including the potential risks and side effects of the drug.
 - ❖ 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.
 - ❖ I agree to maintain adequate and accurate records and to make those records available for audit/inspection by the Sponsor, Ethics Committee, Licensing Authority or their authorized representatives, in accordance with regulatory and GCP provisions. I will fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the Sponsor.
 - ❖ I agree to promptly report to the IRB/EC all changes in the clinical trial activities and all unanticipated problems involving risks to human Subjects or others.
 - ❖ I agree to inform all serious adverse events to the Sponsor as well as the IRB/EC within 24hrs of their occurrence.
 - ❖ I will maintain confidentiality of the identification of all participating study patients and assure security and confidentiality of study data.
 - ❖ I have/do not have any conflicts of Interest (COI) in the study i.e. Financial/Personal or others.
 - ❖ I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical Investigators participating in clinical trials.

8. Signature of the Investigator with Date

Name of the Investigator:
Dr. Prashant Pandey

Prepared by : Dr Indranil Mallick	Reviewed by: Prof Partha Pratim Majumder	Reviewed by: Dr Pattatheyl Arun
IRB Member Secretary	TMC-IRB Chairperson	Head of the Institution


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Annexure 3: Check List of Documents for Protocol Submission (by the study team)

S/N	Document	Yes	No	Date/ if pending	NA
1)	Project submission application duly filled	☒	☐		☐
2)	Letter to Member Secretary/Chairperson	☒	☐		☐
3)	Summary of protocol (in not more than 500 words)	☒	☐		☐
4)	Protocol	☒	☐		☐
5)	Amendments to protocol	☒	☐		☐
6)	Informed consent document in English	☒	☐		☐
7)	Informed consent document in Regional languages (Total No. : 2) Bengali & Hindi	☒	☐		☐
8)	Back translations of Informed consent documents	☒	☐		☐
9)	Translation and Back translation certificates of Informed consent documents	☒	☐		☐
10)	Amendments to the Informed consent documents	☐	☐		☒
11)	Case Record Form	☒	☐		☐
12)	Subject recruitment procedures : advertisements, notices	☒	☐		☐
13)	Patient instruction card, identity card, diary etc.	☒	☐		☐
14)	Patient/subject questionnaire(s) (No.: ____)	☒	☐		☐
15)	Insurance policy (only one copy is needed for submission)	☒	☐		☐
16)	Investigator's undertaking to DCG(I) (one copy)	☒	☐		☐
17)	DCG(I) approval (one copy)	☒	☐		☐
18)	Investigator's agreement with sponsor (copy of final signed document)	☒	☐		☐
19)	DCG(I) marketing/manufacturing licence for herbal formulations/nutraceuticals (one copy)	☐	☐		☒
20)	Health Ministry Screening Committee (HMSC) approval, in case the study involves collaboration with any foreign laboratory/clinic/institution (one copy)	☐	☐		☒
21)	Bhaba Atomic Research Centre (BARC) approval in case study involves use of radioisotopes/ionizing radiations (one copy)	☐	☐		☒
22)	Genetic Engineering Advisory Committee (GEAC) approval in case study involves use of gene therapy (one copy)	☐	☐		☒

Prepared by : Dr Indranil Mallick

IRB Member Secretary

Reviewed by: Prof Partha Pratim Majumder

TMC-IRB Chairperson

Reviewed by: Dr Pattatheyl Arun

Head of the Institution



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23)	Director General of Foreign Trade (DGFT) approval in case study samples are to be sent abroad for analysis (one copy)	☐	☐	☒
24)	Administrative sanction from the Head of the Institution in case of collaborative studies with other institutions (one copy)	☐	☐	☒
25)	Signed and dated brief current curriculum vitae of the study team members (principal investigator, co-investigator, study coordinator) (one copy)	☒	☐	☐
26)	Ethics Committee clearance of other centres (Total No. : _____) (one copy)	☐	☐	☐
27)	Log of delegation of responsibility of the study team members – sample format enclosed	☒	☐	☒
28)	Document Receipt Form (one copy)	☒	☐	☐
29)	Current status of ongoing studies conducted by Principal Investigator	☒	☐	☐
30)	Documentation of CTIRI registration/any other WHO platform registry (whenever applicable) (one copy)	☒	☐	☐
31)	GCP training certificates of principal investigator and co-investigator(s)	☒	☐	☐
32)	Any other documents submitted	☒	☐	☐

*Study Specific
Not applicable
but details attached
in SOP 4.*

Attached.

Prepared by : Dr Indranil Mallick
 IRB Member Secretary

Reviewed by: Prof Partha Pratim Majumder
 TMC-IRB Chairperson

Reviewed by: Dr Pattatheyl Arun
 Head of the Institution



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Checklist for EC form:

DOCUMENTS	RESPONSE		
	YES	NO	NA
Submission Letter	✓		
Complete Submission Dossiers	✓		
Summary of Protocol	✓		
Undertaking by Investigator	✓		
Patient Information Sheet	✓		
Case Record Form	✓		
Updated CV, GCP and MRC of PI and all the respective Co-I's	✓		
Completed SOP 4	✓		
Draft CTA (if available)	✓		
RSD Approval	✓		
Study Budget (detailed budget sheet)	✓		
IBSC Checklist (for projects handling with micro- organisms)			✓
CTRI Registration Sheet	✓		
CDSCO Submission	✓		
DCGI Approval	✓		
Study Presentation (min 5 slides; max 7 slides)	✓		

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TMC-IRB Chairperson

Reviewed by: Dr Pattatheyl Arun
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Annexure 4: Delegation Log/ Roles and Responsibility

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)						
	Name	Role	No.				
	Dr. Prashant Pandey	Principal Investigator	1				
	Dr. Sayak Dey	Co-Investigator	2				
	Dr. Susmita Sadhukhan	Co-Investigator	3				
	Dr. Ankur Mahajan	Co-Investigator	4				
	Souhita Pal	Study coordinator	5				
	Krishnendu Dutta	Study coordinator	5				
	Sayanika Bhattacharjee	Study coordinator	5				
		Laboratory Technician	6				
Roles and Responsibilities assigned to Study Team							
CODE	TASKS	ROLE 1	ROLE 2	ROLE 3	ROLE 4	ROLE 5	ROLE 6
A.	All relevant documents pertaining to protect blinding	✓	✓	✓	✓	✓	
B.	Subject selection / screening	✓	✓	✓	✓		
C.	Obtain informed consent	✓	✓	✓	✓		
D.	Evaluate inclusion/exclusion criteria	✓	✓	✓	✓		
E.	Conduct the visit assessments	✓	✓	✓	✓		
F.	Physical examination	✓	✓	✓	✓		
G.	Complete the source documents					✓	
H.	Complete and correct CRF	✓				✓	
I.	Final review and sign CRF	✓					
J.	Collect laboratory safety test samples					✓	
K.	Processing blood samples					✓	
L.	Preparing aliquots & keeping a tract of the samples sent					✓	
M.	Review and signing of the laboratory reports	✓	✓	✓	✓		
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IRB Member Secretary		TMC-IRB Chairperson		Head of the Institution			

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N.	Receive the study drug, document drug, dispensing, storage & accountability					✓	
O.	Persons with whom subject should contact in case of adverse event					✓	
P.	Report all Serious Adverse Events (SAE)	✓					
Q.	Follow up of SAE	✓				✓	
R.	Maintaining study site master file					✓	
S.	In-charge of inventory & supplies					✓	
T.	Archiving of study documents					✓	
U.	Resolution of queries					✓	
V.	Overall coordination and supervision					✓	

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Annexure 5: Document Receipt form

Receipt No.			
Protocol Name			
Protocol No.		Submission Date	
Principal Investigator			
Department			
Communication	E-mail address:		
Documents submitted	Complete Incomplete, Will submit on:		
Documents to be submitted later	Final signed clinical trial agreement Informed consent form Case report forms (CRF) Study budget Investigator's brochure Insurance document Others (Please Mention)		

Name of Receiver

Signature:

Date:

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IRB Member Secretary	TMC-IRB Chairperson	Head of the Institution