

Tata Medical Center

14 Major Arterial Road (EW)
Newtown, Rajarhat, Kolkata - 700 160
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To
The Head Of the Institute ,
Tata Medical Center,
New Town, Rajarhat, Kolkata-700160

Date: 02-Jun-2026

Protocol No.: D9106R00007

Protocol Title: A prospective, observational, multicenter, post marketing surveillance study to assess safety of Durvalumab in Indian adult patients with resectable Non-Small Cell Lung Cancer (NSCLC).

Subject: Submission of Clinical Study Documents for Ethics Committee review and approval

Dear Sir,

Please find the below listed documents for your review and approval to the Ethics Committee:

S. No.	Table of Content
1.	Investigational Study Protocol Version 1.0 Dated 22-Dec-2024
2.	Consent Letter dated 31 Jan 2026.
3.	Declaration Letter dated 31 Jan 2026.
4.	Investigator Undertaking dated 16 Feb 2026.
5.	Informed Consent Document 5.1 English ICD version 1.0 dated 09-Mar-2026 5.2 Hindi ICD Version 1.0 dated 16 -Mar-2026 5.3 Bengali ICD Version 1.0 dated 16 -Mar-2026 5.4 Back Translated Hindi to English ICD Version 1.0 dated 16-Mar-2026 5.5 Back Translated Bengali to English ICD Version 1.0 dated 16-Mar-2026 5.6 Hindi ICD Translation and Back Translation Certificate Dated 16-Mar-2026 5.7 Bengali ICD Translation and Back Translation Certificate Dated 16-Mar-2026
6.	Prescribing Information sheet dated 09-Feb-2026.
7.	Final Case Report Form version 2.0 13-Feb-2026.
8.	Investigator Documents 8.1 Curriculum Vitae of Investigator signed on 02-Feb-2026

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	8.2 MRC of Investigator signed on 25-Apr-2025 Valid till 31-Dec-2026 8.3 GCP of Investigator signed on 25-Apr-2025 Valid till 22-Apr-2027 8.4 Curriculum Vitae of CO-I signed on 03-Dec-2025 8.5 MRC of CO-I Signed on 03-Dec-2025 Valid till 31-Dec-2026 8.6 GCP of CO-I signed on 03-Dec-2025
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If you require further information or need any clarifications, please revert to me.

Thanking You,

Sincerely,

Dr. Somnath Roy
Principal Investigator

I acknowledge the receipt of above mentioned document on behalf of the Ethics Committee

Date Received

Signature

Name of the personnel

Seal of the ethics Committee