

Tata Medical Center

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



To,
The Head of Institute,
Institutional Review Board, Tata Medical Center,
14, MAR (EW), New Town, Rajarhat, Kolkata 700160

Date: 31-July-2026

Protocol number: 61186372NSC4018

Study 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.

Subject: Submission of study documents to Head of Institute for Review and Approval.

Dear Sir,

Please find enclosed one copy of below mentioned documents for Head of Institute submission review and approval.

Sr.no	Document Name	Version .no	Date
1.	Clinical Protocol 61186372NSC4018	Amendment 1	29-Apr-2026
2.	Amivantamab Prescribing information	NA	03-Sept-2025
3.	Insurance certificate; Insurance number: 4067/429217801/00/000 Valid From 01Mar2026 Until 28Feb2027	NA	11-Mar-2026
4.	Form-CT-04	NA	24-Dec-2025
5.	DCGI - Application Number BIO/CT04/FF2025/53853	NA	24-Dec-2025
6.	DCGI -Approval letter	NA	16-Jul-2026
7.	Draft CTA	5	NA
8.	61186372NSC4018_eCRF_Unique forms_v 0.1 _RW_ generated on 19 Nov 2025	0.1	29-May-2026
9.	IB Signature Page	NA	08-Jun-2026
10.	Investigator Undertaking_ Dr. Prashant	NA	08-Jun-2026
11.	Protocol Signature Page	NA	08-Jun-2026
12.	Principal Investigator Curriculum Vitae	NA	03-Dec-2025
13.	GCP Certificate of PI	NA	03-Dec-2025
14.	MRC of PI	NA	03-Dec-2025
15.	Master Clinical ICF Version Date: 04 May 2026 Version Number 2.0 Site Clinical ICF Version date 17-Jun -2026 Version Number 2.1.0 PI:Dr Prashant Pandey, Site :TMC, Kolkata	2.1.0	17-Jun-2026
16.	Master Clinical ICF Version Date: 04 May 2026 Version Number 2.0 Site Clinical ICF Version date 17-Jun -2026 Version Number 2.1.0 PI:Dr. Prashant Pandey, Site: TMC, Kolkata Translated from English to Hindi on 29 Jun 2026	2.1.0	29-Jun-2026

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17.	Master Clinical ICF Version Date: 04 May 2026 Version Number 2.0 Site Clinical ICF Version date 17-Jun -2026 Version Number 2.1.0 PI: Dr. Prashant Pandey, Site: TMC, Kolkata Back Translated from Hindi to English on 29 Jun 2026	2.1.0	29-Jun-2026
18.	Master Clinical ICF Version Date: 04 May 2026 Version Number 2.0 Site Clinical ICF Version date 17-Jun -2026 Version Number 2.1.0 PI:Dr. Prashant Pandey, Site: TMC, Kolkata Translated from English to Bengali on 29 Jun 2026	2.1.0	29-Jun-2026
19.	Master Clinical ICF Version Date: 04 May 2026 Version Number 2.0 Site Clinical ICF Version date 17-Jun -2026 Version Number 2.1.0 PI :Dr. Prashant Pandey, Site: TMC, Kolkata Back Translated from Bengali to English on 29 Jun 2026	2.1.0	29-Jun-2026
20.	Master Pregnancy in Clinical Study ICF Version Date: 04 May 2026, ICF Version Number: 2.0 Site Pregnancy in Clinical Study ICF Version Date: 17-June-2026 , ICF Version Number: 2.1.0 PI : Dr Prashant Pandey, Site :TMC, Kolkata	2.1.0	17-Jun-2026
21.	Master Pregnancy in Clinical Study ICF Version Date: 04 May 2026 , ICF Version Number: 2.0 Site Pregnancy in Clinical Study ICF Version Date: 17-June-2026 , ICF Version Number: 2.1.0 PI : Dr. Prashant Pandey, Site: TMC, Kolkata Translated from English to Hindi on 29 Jun 2026	2.1.0	29-Jun-2026
22.	Master Pregnancy in Clinical Study ICF Version Date: 04 May 2026 , ICF Version Number: 2.0 Site Pregnancy in Clinical Study ICF Version Date: 17-June-2026 , ICF Version Number: 2.1.0 PI : Dr. Prashant Pandey, Site: TMC, Kolkata Back Translated from Hindi to English on 29 Jun 2026	2.1.0	29-Jun-2026
23.	Master Pregnancy in Clinical Study ICF Version Date: 04 May 2026 , ICF Version Number: 2.0 Site Pregnancy in Clinical Study ICF Version Date: 17-June-2026 , ICF Version Number: 2.1.0 PI : Dr. Prashant Pandey, Site: TMC, Kolkata Translated from English to Bengali on 29 Jun 2026	2.1.0	29-Jun-2026
24.	Master Pregnancy in Clinical Study ICF Version Date: 04 May 2026 , ICF Version Number: 2.0 Site Pregnancy in Clinical Study ICF Version Date: 17-June-2026 , ICF Version Number: 2.1.0 PI : Dr. Prashant Pandey, Site: TMC, Kolkata Back Translated from Bengali to English on 29 Jun 2026	2.1.0	29-Jun-2026
25.	FT & BT CERTIFICATE _Dr. Prashant Pandey	NA	29-Jun-2026

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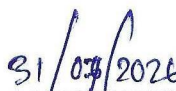
26.	Patient accrual methods: Patient will be recruited from OPD, who are coming for treatment at Tata Medical Center, Kolkata. PI and Sub-I choose the patients for trial as per specific trial criteria.
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Please revert me back if you have any queries.

Thanking you.
Yours Sincerely,


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Dr. Prashant Pandey
Consultant Medical Oncologist,
Department of Medical Oncology.

I acknowledge the receipt of above mentioned document on behalf of the Head of Institute.

 Date Received	 Signature	 Name of the personnel
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