

Tata Medical Center

14 Major Arterial Road (EW)
Newtown, Rajarhat, Kolkata - 700 160
Tel.: + 91 33 66057000, Email : info@tmckolkata.com
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To,
The Head of the Institute
Institutional Review Board
Tata Medical Center,
14, MAR (EW), Rajarhat, New Town,
Kolkata-700160

Date: 05-MAY-2026

Subject: Initial Study documents for EC submission and approval for referenced protocol.

Protocol Number: TAK-226-3001

Protocol Title: A Phase 3, Multicenter, Open-Label, Randomized Trial to Compare the Efficacy and Safety of Elritrecept versus Epoetin Alfa for the Treatment of Anemia Due to IPSS-R Very Low, Low, or Intermediate Risk Myelodysplastic Syndromes in ESA-naïve Adult Participants Who Require Red Blood Cell Transfusions.

Dear Sir,

Please find the enclosed soft copies of below mentioned documents for EC review and approval.

S. No.	Document Name
1	Takeda_TAK-226-3001_QAB41954_Protocol dated 01Sep2025
1.1	Takeda_TAK-226-3001_QAB41954_Site 24003_Dr. Arijit Nag_Protocol Signature page_10Dec2025
2	Takeda_TAK-226-3001_QAB41954_Investigator's Brochure Edition 08 dated 01 July 2025
3	Takeda_TAK-226-3001_QAB41954_Draft CTA Template_22Dec2025
4	Master India Participant Information Sheet and Consent Form Version 1.0_20Jan2026
4.1	Master India Participant Information Sheet and Consent Form Version 1.0 (Hindi)_20Jan2026
4.2	Translation Certificate (Hindi)_04Feb2026
4.3	Back Translation (Hindi)
4.4	Back Translation Certificate (Hindi)_04Feb2026
4.5	Master India Participant Information Sheet and Consent Form Version 1.0 (Bengali)_20Jan2026
4.6	Translation Certificate (Bengali)_04Feb2026
4.7	Back Translation (Bengali)
4.8	Back Translation Certificate (Bengali)_04Feb2026
5	Master India Pregnant Partner Authorization for Pregnancy Follow-up 1.0_20Jan2026
5.1	Hindi Version
5.2	Hindi Translation Certificate_04Feb2026
5.3	Hindi Back Translation
5.4	Bengali Back Translation Certificate_04Feb2026
5.5	Bengali Version
5.6	Bengali Translation Certificate_04Feb2026
5.7	Bengali Back Translation
5.8	Bengali Back Translation Certificate_04Feb2026

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6	Other_V9.0IND(en)1.0_20Jan2026
6.1	Hindi Version
6.2	Hindi Translation Certificate_05Feb2026
6.3	Hindi Back Translation
6.4	Hindi Back Translation Certificate_05Feb2026
6.5	Bengali Version
6.6	Bengali Translation Certificate_05Feb2026
6.7	Bengali Back Translation
6.8	Bengali Back Translation Certificate_05Feb2026
7	Audio Visual (A-V) Recording Declaration_V6.0IND(en)_20Jan2026
8	Participant ID Card (English)_11 Nov 2025
8.1	Translation Certificate_24 Nov 2025
8.2	Hindi Version
8.3	Hindi Translation Certificate_10Dec2025
8.4	Bengali Version
8.5	Bengali Translation Certificate_15Dec2025
9	EORTC QLQ-C30 English v3.0_31Jul2025
9.1	Hindi Version
9.2	Bengali Version
9.3	Translation Certificate
10	EQ-5D-5L (Interviewer & Self Versions – EN/HI/BN)
10.6	Translation Certificates (EN/HI/BN)
11	FACT-An Paper (EN/HI/BN Versions)
11.2	Hindi Translation Certificate
11.4	Bengali Translation Certificate
12	PGIC Anemia Symptoms (EN/HI/BN + Certificates)
13	PGIC Fatigue (EN/HI/BN + Certificates)
14	PGIC Physical Function Limitations (EN/HI/BN + Certificates)
15	PGIS Anemia Symptoms (EN/HI/BN + Certificates)
16	PGIS Fatigue (EN/HI/BN + Certificates)
17	PGIS Physical Function Limitations (EN/HI/BN + Certificates)
18	Transfusion Burden Patient Question (EN/HI/BN + Certificates)
19	Dr. Arijit Nag CV_25Sep2025
20	Dr. Arijit Nag GCP Certificate_24Sep2025
21	Dr. Arijit Nag MRC
22	Investigator's Undertaking_30Jan2026
23	Insurance Certificate_19Jan2026
23.1	Insurance Policy
24	Self-Administration Diary Card (EN/HI/BN)_31Dec2025
25	Self-Administration Instructions to Patients (EN/HI/BN)_31Dec2025
26	Translation Certificates (EN/HI/BN)_31Dec2025
27	Mock CRF_30Apr2025
28	RA Submission Cover Letter_04Feb2026

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28.1	AOR Email_GCT_CT04_FF_2026_54744
28.2	AOR Email Screenshot
29	Budget Sheet
30	RSD Form (Applied)
31	Institutional Biosafety Committee checklist and Form
32	CO.Investigators' CV, GCP & MRC
33	EC meeting slide for presentation

Thanking you

Arijit Nag

Dr. Arijit Nag

(Principal Investigator)

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

05/05/2026

Date received

[Signature]

signature

Abcendra Narayan Choudhary

Name of the personnel

Seal of the Ethics Committee:

