

Tata Medical Center

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UNDERTAKING BY THE INVESTIGATOR

(Per Table 4, Third Schedule of New Drugs and Clinical Trials Rules, 2019, dated 19 March 2019)

1. Full Name, address and title of Principal Investigator:

Dr. Arijit Nag
Senior Consultant
Tata Medical Center,
14, MAR (E-W), Newtown, Rajarhat, Koljata-700160, West Bengal, India

2. Name & Address of medical college, hospital or other facility where clinical trial will be conducted:

Tata Medical Center,
14, MAR (E-W), Newtown, Rajarhat, Koljata-700160, West Bengal, India

NOTE: Education, training & experience that qualify the Investigator for the clinical trial (Attach details including Medical Council registration number, or any other statements of qualifications)

3. Name and address of all clinical laboratory facilities to be used in the study:

Central Laboratory:

IQVIA Central Laboratories 301-A, Leela Business Park, Andheri East, Mumbai, India	IQVIA Central Laboratories 438B Alexandra Road #07-01/04 Alexandra Technopark Singapore 119968
IQVIA Central Laboratories 28454 Livingston Avenue, Valencia, CA 91355 USA	IQVIA Central Laboratories The Alba Campus Rosebank Livingston West Lothian, EH54 7EG Scotland, UK
Q2 Solutions - Innovation Labs 2400 Ellis Road Durham, NC 27703 USA	PPD 2246 Dabney Road Richmond, VA 23230 USA
Quest Diagnostics Nichols 33608 Ortega Highway, San Juan Capistrano, CA 92675 USA	Quest Diagnostics Chantilly 14225 Newbrook Dr, Chantilly, VA 20153-0841 USA

CERBA 12 Avenue Roland Moreno ZAC des Epineaux Frépillon, France 95740	
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Local Laboratory:

**Department of Laboratory Sciences,
Tata Medical center,
14, MAR (E-W), Newtown, Rajarhat, Kolkata-700160, West Bengal, India**

4. **Name and address of the Ethics Committee that is responsible for approval and continuing review of the study:**

**Institutional Review Board,
Tata Medical center
14, MAR (E-W), Newtown, Rajarhat, Kolkata-700160, West Bengal, India**

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 investigations:**

**Dr. Shouriyo Ghosh
Dr. Debranjani Chattopadhyay
Dr. Saswata Saha**

6. **Protocol Title and Study Number (if any) of the clinical trial being conducted by the Investigator:**

Protocol Title: A Phase 3, Multicenter, Open-Label, Randomized Trial to Compare the Efficacy and Safety of Elriterccept 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

Study Number: TAK-226-3001

7. **Commitments:**

- (i) I have reviewed the clinical protocol, and I 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 / favorable 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.

- (iii) I agree to personally conduct and/or supervise the clinical trial at my site.
- (iv) I agree to inform all trial subjects 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.
- (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 / inspection by the Sponsor, Ethics Committee, Central Licensing Authority or their authorized representatives, in accordance with regulatory and the Good Clinical Practices guidelines. I will fully cooperate with any study related audit conducted by regulatory officials or authorized 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 Licensing Authority, Sponsor or his representative, 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 Central Licensing 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 Central Licensing Authority, the Chairperson of the Ethics committee and the Head of the Institute 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 study 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.

8. Signature of Principal Investigator with date:

Anjit Nag .

30.01.2026.

Dr. ARIJIT NAG
MD, MRCP, DM
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TATA MEDICAL CENTER, KOLKATA
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