

FORM CT-04**(See rule 21)****APPLICATION FOR GRANT OF PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUG**

I/We, Ms. Sneha Vajresh Thakur of M/s Johnson & Johnson Pvt. Ltd., HIGI House, L.B.S. Marg, Mulund Mulund West (India) - 400080 Telephone No.: 0124-4647000 FAX: 0124-4647000 E-Mail : RA-JNJIN-REGJJMI@ITS.JNJ.COM hereby apply for grant of permission to conduct clinical trial on new drug or investigational new drug.

The details of the application are as under:

1. Name of Applicant: Ms. Sneha Vajresh Thakur
2. Nature and constitution of applicant: Private Limited
3. (i) Sponsor Address : M/s Johnson and Johnson Private Limited, Higi House, LBS Marg, Mulund West , Maharashtra (India) - 400080 Telephone No.: 912225644441 FAX: 912225643410
- (ii) Clinical trials site address : M/s Johnson and Johnson Private Limited, Higi House, LBS Marg, Mulund West , Maharashtra (India) - 400080 Telephone No.: 912225644441 FAX: 912225643410
- (iii) Name and Address of person responsible for payment of compensation, if any : Dr. Sanish Davis
Johnson and johnson Private Limited, Higi house L.B.S. Marg, Mulund (west), Maharastra, Maharashtra (India) - 400080
Telephone No.: 9820958943 Email: SDavis20@its.jnj.com
- (iv) Address for correspondence : M/s Johnson and Johnson Private Limited, Higi House, L.B.S. Marg, Mulund (W), Mumbai, Maharashtra (India) - 400080
Telephone No.: 912225936700 FAX: 912225936700

4.Details of new drugs or investigational new drugs and clinical investigation site [As per Annexure].

Names of the new drug or investigational new drug:	Therapeutic class:	Dosage form:	Composition:	Indications:
Ramantamig (JNJ-79635322)	Trispecific T cell engaging antibody	Solution for injection	JNJ-79635322 5.0000 mg/ml In House Specification Active	Relapsed or Refractory Multiple Myeloma after 1 to 3 Prior Lines of Therapy
Ramantamig (JNJ-79635322)	Trispecific T cell engaging antibody	Solution for injection	JNJ-79635322 50.0000 mg/ml In House Specification Active	Relapsed or Refractory Multiple Myeloma after 1 to 3 Prior Lines of Therapy

Names and address of clinical trial site:	Ethics committee details:	Name of investigator:	Clinical
N. R.S. Medical College And Hospital, Centernary building, 138, 4th floor, A.J.C Bose Road Kolkata West Bengal - 700014	Ethics Committee, N.R.S. Medical College, Kolkata West Bengal - 700014 ECR/609/Inst/WB/2014/RR-25	Dr Tuphan Kanti Dolai	Suraksha Diagnostic Limited, P-118 CIT Road Scheme VIM, Kolkata Kolkata West Bengal - 700054

LMMFs Deenanath Mangeshkar Hospital and Research Centre, Erandwane, Pune Maharashtra - 411004	Institutional Ethics committee of Deenanath Mangeshkar Hospital And Research Centre, Pune, Maharashtra - 411004 ECR/15/Inst/Maha/2013/RR-22	Dr Sameer R Melinkeri	Department of Pathology LMMFs Deenanath Mangeshkar Hospital and Research Centre, Erandwane, Pune . Pune Pune Maharashtra - 411004
M S Ramaiah Medical College And Hospitals, M S Ramaiah Nagar, MSRIT Post Bengaluru Bengaluru Karnataka - 560054	Ethics Committee,MS Ramaiah Medical College And Hospitals, Bengaluru (Bangalore) Urban. Karnataka - 560054 ECR/215/Inst/KA/2013/RR-22	Dr Santhosh Kumar Devadas	Ramaiah Memorial Hospital Central laboratory, Basement , Ramaiah Memorial Hospital . M S Ramaiah Nagar , MSIRT Bengaluru Bengaluru (Bangalore) Urban Karnataka - 560054
Fortis Memorial Research Institute, Sector-44, Opp. Millenium city center Gurugram Haryana - 122002	IEC, Fortis Memorial Research Institute, Gurugram Haryana - 122002 ECR/223/Inst/HR/2013/RR-22	Dr Rahul Bhargava	Agilus Diagnostics, 1st Floor Fortis Memorial Research Institute Sector-44 Gurugram - India Haryana Gurugram Haryana - 122002
TATA Medical Center, 14 Major Arterial Road EW, Rajarhat, Newtown. Kolkata West Bengal - 700160	INSTITUTIONAL REVIEW BOARD, TATA MEDICAL CENTER, Kolkata West Bengal - 700160 India ECR/269/Inst/WB/2013/RR-24	Dr Jeevan Kumar	Department of laboratory Science, TATA Medical Center 14 Major Arterial Road EW Rajarhat New Town Kolkata Kolkata West Bengal - 700160
Dr B.R.A. Institute Rotary Cancer Hospital, Room 218, second floor, All India Institute of Medical Science, Ansari Nagar, New Delhi Delhi - 110029	Institute Ethics Committee All India Institute of Medical Sciences, New Delhi, Delhi - 110029 India ECR/538/Inst/DL/2014/RR-25	Dr Ranjit Kumar Sahoo	Agilus Diagnostics, Unit 306, Tower A ,Unitech Cyber Park , sector 39 Gurugram Gurugram Haryana - 122002
Bhagwan Mahaveer Cancer Hospital and Research Center, Jawahar Lal Nehru Marg Jaipur Rajasthan - 302017	Institutional Ethics Committee Bhagwan Mahaveer Cancer Hospital and Research Center Jaipur Rajasthan - 302017 India ECR/19/Inst/RJ/2013/RR-25	Dr Prakash Singh Shekhawat	Pathological Department Bhagwan Mahaveer Cancer Hospital and Research Center, Jawahar Lal Nehru Marg Jaipur Jaipur Jaipur Rajasthan - 302017
Rajiv Gandhi Cancer Institute and Research, D-18, Sector 5, Rohini Delhi Delhi - 110085	Institutional Review Board Rajiv Gandhi Cancer Institute and Research Centre Delhi - 110085 India ECR/10/Inst/DC/2013/RR-24	Dr Dinesh Bhurani	Department of Lab Services Rajiv Gandhi Cancer Institute and Research Sector, Rajiv Gandhi Cancer Institute and Research Sector 5, Rohini Delhi delhi New Delhi Delhi - 110085

5. Phase of the Clinical Trial **Phase 3**

6. Clinical trial protocol number with date: **Protocol No.: 79635322MMY3002 Version No. Amendment 1 Protocol**

Date 19-FEB-2026

7. Fee paid on **27-FEB-2026** Rs **200000.00** receipt/challan/transaction id **2702260062026**.

8. I have enclosed the documents as specified in the Second Schedule of the New Drugs and Clinical Trials Rules, 2019.

9. I hereby state and undertake that:

(i) I shall comply with all the provisions of the Drugs and Cosmetics Act, 1940, and the New Drugs and Clinical Trials Rules, 2019.

Date: 15-Mar-26

Place: Mumbai

Signature

Darshana Dholakia
Senior Manager, GCO, India