

Tata Medical Center

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To

The Head Of the Institute

Tata Medical Center,

New Town, Rajarhat, Kolkata-700160

Date: 28-Jul-2026

Protocol No.: D702NC00001

Protocol Title: Phase III, Randomized, Open-label, Global, Multicenter Study of Rilvegostomig or Durvalumab in Combination with Chemotherapy as a First-line Treatment for Patients With Advanced Biliary Tract Cancer (ARTEMIDE-Biliary02)

Subject: Submission of Clinical Study Documents for HOI review and approval

Dear Sir,

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

Sl No	Document
1.	- Clinical Study Protocol Version 1.0 dated 08 Aug 2025 - Clinical Study Protocol Addendum version 1.0 dated 07 Oct 2025
2.	Investigator's Brochure Rilvegostomig (AZD2936), Edition 6.1 dated 07 Nov 2025
3.	Lay Summary Protocol Synopsis-v1.0 dated 12 Sep 2025
4.	Insurance certificate_1st March 2026 To 28th February 2027 Policy Number: P1025200001/9999/106914 and Certificate No.P1025200001/9999/106914 - D702NC00001 dated 23 Jul 2026
5.	Curriculum Vitae of Principal Investigator dated 21 Jul 2026
6.	MRC_of Principal Investigators (PI) valid up to 31 Dec 2026
7.	GCP training certificate of Principal investigator.
8.	Investigator Undertaking by the Principal Investigator signed on 21 Jul 2026
9.	Declaration of Site Facility from PI signed on 21 Jul 2026
10.	Declaration of Number of Clinical Trials by PI signed on 21 Jul 2026
11.	- Toxicity Management Guidelines for Rilvegostomig (AZD2936) version 7_05 Feb 2026 - SUSAR_ Durvalumab_01-May-2025 - 31-Oct-2025_04 Dec 2025 - Rilvegostomig SUSAR_06-Jul-2025 - 05-Jan-2026_21 Jan 2026
12.	eCRF (Electronic Case Report Form) Casebook (Final): - D702NC00001_ATD_Annotated- dated 20NOV2025 - D702NC00001_Unique_Non Annotated- dated 20NOV2025 - D702NC00001_eCRF Instructions 3.0_8 Jul 2026
13.	- Clinical study Protocol 1.0 agreement page signed on 21 Jul 2026 - Clinical Study Protocol-India Addendum 01 agreement page signed on 21 Jul 2026

14.	- Initial Clinical Trial Application _DCGI Screenshot Submission_ dated 24 Dec 2025 Submission number: GCT/CT04/FF/2025/53836 - DCGI submission cover letter/2025/CT/DCGI/VB/589 _dated 23 Dec 2025
15.	Clinical Study Agreement (Draft) _dated 23 Jul 2026 Please note the signed CSA will be notified once available
16.	Adult Informed Consent Form for Audio-Visual Recording for Subjects Consent Process In India, India Master Version Number 1.1 India Master Version Date 23 Jul 2026 _ English Translation: - English to Hindi – Translated on 24 Jul 2026 - English to Bengali - Translated on 24 Jul 2026 Back Translation: - Hindi to English – Back translated on 24 Jul 2026 - Bengali to English – Back translated on 24 Jul 2026 Translation & Back Translation Certificates: dated 24 Jul 2026 - English to Hindi, English to Bengali - Hindi to English, Bengali to English
17.	Adult Study Participant Master Information and Consent Form, Master Version Number 1.0 Master Version Date 11 Aug 2026 India Version Number V1.1 India Version Date 23 Jul 2026 Translation: - English to Hindi (India Version 1.1 dated 23 Jul 2026) Translated on 24 Jul 2026 - English to Bengali (India Version 1.1 dated 23 Jul 2026) Translated on 24 Jul 2026 Back Translation: - Hindi to English (India Version 1.1 dated 23 Jul 2026) Back translated on 24 Jul 2026 - Bengali to English (India Version 1.1 dated 23 Jul 2026) Back translated on 24 Jul 2026 Translation and Back translation certificates Dated 24 Jul 2026 - English to Hindi and Hindi to English - English to Bengali and Bengali to English
18.	Future Research Information and Consent Form –India Version Number V1.0 India Version Date 23 Jul 2026, Derived from Master Version Number V1.0 Master Version Date 11 Aug 2025 (Adult Study Subject Master Information and Consent Form) Translation: - English to Hindi (India Version 1.1 dated 23 Jul 2026) Translated on 24 Jul 2026 - English to Bengali (India Version 1.0 dated 23 Jul 2026) Translated on 24 Jul 2026 Back Translation: - Hindi to English (India Version 1.0 dated 23 Jul 2026) Back translated on 24 Jul 2026 - Bengali to English (India Version 1.0 dated 23 Jul 2026) Back translated on 24 Jul 2026 Translation and Back translation certificates Dated 24 Jul 2026 - English to Hindi and Hindi to English - English to Bengali and Bengali to English
19.	Optional Genomics Initiative Research Information Master Version Number 1.0 Master Version Date 11 Aug 2025 India Version Number 1.1 India Version Date 23 Jul 2026 Translation: - English to Hindi – Translated on 24 Jul 2026 - English to Bengali - Translated on 24 Jul 2026

	Back Translation: - Hindi to English – Back translated on 24 Jul 2026 - Bengali to English – Back translated on 24 Jul 2026 Translation & Back Translation Certificates: dated 24 Jul 2026 - English to Hindi, English to Bengali - Hindi to English, Bengali to English
20.	Adult Study Information and Consent Form for Pregnant Partners of Study Participants Master Version Number 1.0 Master Version Date 11 Aug 2025 India Version Number 1.1 India Version Date 23-Jul -2026_English Translation: - English to Hindi – Translated on 24 Jul 2026 - English to Bengali - Translated on 24 Jul 2026 Back Translation: - Hindi to English – Back translated on 24 Jul 2026 - Bengali to English – Back translated on 24 Jul 2026 Translation & Back Translation Certificates: dated 24 Jul 2026 - English to Hindi, English to Bengali - Hindi to English, Bengali to English
21.	Participant Follow-up and Withdrawal of Consent Checklists v2.0 dated 12 Nov 2025
22.	Study Participation Card – English Master Version Number & Date: 1.0, 14 Aug 2025 India Version Number & Date: 1.0, 11 Dec 2025 Translation: - English to Hindi – Translated on 15 Dec 2025 - English to Bengali - Translated on 15 Dec 2025 Back Translation: - Hindi to English – Back translated on 15 Dec 2025 - Bengali to English – Back translated on 15 Dec 2025 Certificates of Accuracy: dated 15 Dec 2025 - English to Hindi, English to Bengali - Hindi to English, Bengali to English
23.	Thank You Card English - Version 1.0 dated 12 Aug 2025 Translation: - English to Hindi – Translated on 12 Sep 2025 - English to Bengali - Translated on 12 Sep 2025 Certificate of Accuracy dated 12 Sep 2025 - English to Hindi and English to Bengali
24.	D702NC00001_Study Pamphlet_version 1.0_23 Oct 2025_In-enUK Translation: - English to Hindi – Translated on 26 Nov 2025 - English to Bengali - Translated on 03 Dec 2025 Certificate of Accuracy dated 21 Oct 2025 - English to Hindi and English to Bengali Note : Translation Certificate_ Clarification on Dates_ July 2025

25.	Unify/ePRO Patient Training Material – English - Evinova study phone password and technical support card V15; Aug 2025_en-IN - Evinova study phone password and support_ Translation Certificate_ 10 Sep 2025 - OST_Patient_video_EQR_no_visits_6.0.1_July 2023_enGB (certificate not needed) - Patient welcome guide_EQRGIMT_app_nopii_July_2025_enIN_v2a - Patient Welcome Guide_EQRGIMT_app_nopii-July-2025-enIN-v2_ Translation Certificate_ 10 Sep 2025 - VO_Patient_video_EQR_no_visits_6.0.1_July_2023_enGB - VO_Patient_video_EQR_no_visits_6.0.1_July_2023_ Translation Certificate_ 10 Sep 2025
26.	Unify/ePRO Patient Training Material - Hindi - Evinova study phone password and technical support card V15; Aug 2025_hi-IN - Evinova study phone password and support_ Translation Certificate_ 25 Sep 2025 - OST_Patient_video_EQR_no_visits_6.0.1_dated July 2023_hiIN - OST_Patient_video_EQR_no_visits_6.0.1_July 2023_hiIN_ Translation Certificate dated 10 Sep 2025 - Patient welcome guide_EQRGIMT_app_nopii_July_2025_hiIN_v2a - Patient Welcome Guide_ Translation certificate dated 22 Aug 2025 - VO_Patient_video_EQR_no_visits_6.0.1_July_2023_hiIN - VO_Patient_video_EQR_no_visits_6.0.1_July_2023_v2.0_hiIN_ Translation Certificate_ 10 Sep 2025
27.	Unify/ePRO Patient Training Material – Bengali - Evinova study phone password and technical support card V15; Aug 2025_bn-IN - Evinova study phone password and support_ Translation Certificate_ 25 Sep 2025 - OST_Patient_video_EQR_no_visits_6.0.1_dated 21July 2023_bnIN - OST_Patient_video_EQR_no_visits_6.0.1_dated 21July 2023_bnIN_ Translation Certificate dated 10 sep 2025 - Patient welcome guide_EQRGIMT_app_nopii_July_2025_bnIN_v2a - Patient Welcome Guide- EQRGIMT_app_nopii_July_2025_bnIN -Translation certificate dated 22 Aug 2025 - VO_Patient_video_EQR_no_visits_6.0.1_July_2023_bnIN - VO_Patient_video_EQR_no_visits_6.0.1_July_2023_Certificate_Bengali_ 10 Sep 2025
28.	Unify/ePRO: Remote Patient Monitoring – English - Contact_doctor_Eng_14AUG2024 (Screenshot) - Contact_Doctor_ Translation Certificate_enIN_14AUG2024 - GIRPM_Screens_v2.0_India_en_IN(en_GB)_12MAY2025 - GIRPM_CoT_v2.0_India_en_IN(en_GB)_12MAY2025
29.	Unify/ePRO: Remote Patient Monitoring – Hindi - Contact_doctor_Hindi_16AUG2024 - Contact_Doctor_ Translation Certificate_hiIN_16AUG2024 - GIRPM_Screens_v2.0_India_hi_IN_12MAY2025 - GIRPM_CoT_v2.0_India_hi_IN_12MAY2025
30.	Unify/ePRO: Remote Patient Monitoring – Bengali - Contact_doctor_Marathi_14 Aug 2024 - Certification Contact doctor bnIN_14AUG2024

	- GIRPM_Screens_v2.0_India_bn_IN_12MAY2025 - GIRPM_CoT_v2.0_India_bn_IN_12MAY2025
31.	Unify/ePRO Appendix – English - Devices Label_Evinova_enIN - Device Lable_Evinova_Translation Certificate dated 28 Oct 2024 - Memo - Helpdesk Support Phone numbers_18 May 2025 (Only Available in English) - Not a patient facing document - Memo-Equivalency of eCOA Web and App modalities_21May2025 (Only Available in English) - Not a patient facing document - UTS_Memo Acknowledgement Section English_01 Aug 2025 (Only Available in English) - Not a patient facing document
32.	Unify/ePRO Appendix – Hindi - Devices Label_Evinova_hiIN - Device Lable_Evinova_Translation Certificate dated 28 Oct 2024
33.	Unify/ePRO Appendix – Bengali - Devices Label_Evinova_mrIN - Device Lable_Evinova_Translation Certificate dated 28 Oct 2024
34.	Unify: Screen-Shot -English - App Screen_Artemidebiliary02 en_IN UTS Screenshot Document V1.0 29 Oct 2025 - Patient Instruction_Patient_Login_Instructions_enIN_v3.0_with_Patient_Web (17 Oct 2025) - Patient Web_Evinova Participant Website Screenshot Document enIN_v1.0 30 Sep 2025 Note : These are the screen shots and hence COT is not applicable to this section. Paper copies of same along with COT are mentioned above in section 29, 33 and 37
35.	Unify: Screen-Shot – Hindi - App Screen_Artemidebiliary02 hi_IN UTS Screenshot Document V1.0 09-Dec-2025 - Patient Instruction_Patient_Login_Instructions_hiIN_v3.0_with_Patient_Web 17 Oct 2025 - Patient Web_Evinova Participant Website Screenshot Document hiIN V 1.0 21 Nov 2025 Note : These are the screen shots and hence COT is not applicable to this section. Paper copies of same along with COT are mentioned above in section 29, 33 and 37
36.	Unify: Screen-Shot – Bengali - App Screen_Artemidebiliary02 mr_IN UTS Screenshot Document V1.0 09 Dec 2025 - Patient Instruction_Patient_Login_Instructions_bnIN_v3.0_with_Patient_Web 17 Oct 2025 - Patient Web_Evinova Participant Website Screenshot Document bnIN_v1.0 21 Nov 2025 Note : These are the screen shots and hence COT is not applicable to this section. Paper copies of same along with COT are mentioned above in section 29, 33 and 37
37.	Study Guide – English-07-Oct-2025 - Study guide_V 1.0_Hindi_21 Jan 2026 - Study Guide_V 1.0_Translation Certificate_Hindi_12 Dec 2025 - Study Guide_V 1.0_Bengali_28 Jan 2026 - Study Guide_V 1.0_Translation Certificate_Bengali_12 Dec 2025

38.	IL172 – Screens - EORTC_IL_172_v1.00_Trans_App_Evinova_English-IN_03Dec2025_D702NC00001 - EORTC_IL_172_v1.00_Trans_App_Evinova_Hindi-IN_17Nov2025_D702NC00001 - EORTC_IL_172_v1.00_Trans_App_Evinova_Bengali-IN_26Jan2026_D702NC00001 Translation Certificate - EORTC_IL_172_v1.00_Trans_Cert_App_Evinova_English-IN_03Dec2025_D702NC00001 - EORTC_IL_172_v1.00_Trans_Cert_App_Evinova_Hindi-IN_17Nov2025_D702NC00001 - EORTC_IL_172_v1.00_Trans_Cert_App_Evinova_Bengali-IN_26Jan2026_D702NC00001
39.	IL444- Screens - EORTC_IL_444_v1.0_Trans_App_Evinova_English-IN_03Dec2025_D702NC00001 - EORTC_IL_444_v1.00_Trans_App_Evinova_Hindi-IN_04Feb2026_D702NC00001 - EORTC_IL_444_v1.00_Trans_App_Evinova_Bengali-IN_26Jan2026_D702NC00001 Translation Certificate - EORTC_IL_444_v1.0_Trans_Cert_App_Evinova_English-IN_03Dec2025_D702NC00001 - EORTC_IL_444_v1.00_Trans_Cert_App_Evinova_Hindi-IN_04Feb2026_D702NC00001 - EORTC_IL_444_v1.00_Trans_Cert_App_Evinova_Bengali-IN_26Jan2026_D702NC00001
40.	IL445- Screens - EORTC_IL_445_v1.0_Trans_App_Evinova_English-IN_03Dec2025_D702NC00001 - EORTC_IL_445_v1.00_Trans_App_Evinova_Hindi-IN_04Feb2026_D702NC00001 - EORTC_IL_445_v1.00_Trans_App_Evinova_Bengali-IN_26Jan2026_D702NC00001 Translation Certificate - EORTC_IL_445_v1.0_Trans_Cert_App_Evinova_English-IN_03Dec2025_D702NC00001 - EORTC_IL_445_v1.00_Trans_Cert_App_Evinova_Hindi-IN_04Feb2026_D702NC00001 - EORTC_IL_445_v1.00_Trans_Cert_App_Evinova_Bengali-IN_26Jan2026_D702NC00001
41.	IL446- Screens - EORTC_IL_446_v1.0_Trans_App_Evinova_English-IN_03Dec2025_D702NC00001 - EORTC_IL_446_v1.00_Trans_App_Evinova_Hindi-IN_04Feb2026_D702NC00001 - EORTC_IL_446_v1.00_Trans_App_Evinova_Bengali-IN_26Jan2026_D702NC00001 Translation Certificate - EORTC_IL_446_v1.0_Trans_Cert_App_Evinova_English-IN_03Dec2025_D702NC00001 - EORTC_IL_446_v1.00_Trans_Cert_App_Evinova_Hindi-IN_04Feb2026_D702NC00001 - EORTC_IL_446_v1.00_Trans_Cert_App_Evinova_Bengali-IN_26Jan2026_D702NC00001
42.	EQ-5D-5L – Screens - EQ-5D-5L_v1.00_Trans_App_Evinova_English-IN_03Dec2025_D702NC00001 - EQ-5D-5L_v1.00_Trans_App_Evinova_Hindi-IN_22Dec2025_D702NC00001 - EQ-5D-5L_v1.00_Trans_App_Evinova_Bengali-IN_12Feb2026_D702NC00001

	Translation Certificate - EQ-5D-5L_v1.00_Trans_Cert_App_Evinova_English-IN_03Dec2025_D702NC00001 - EQ-5D-5L_v1.00_Trans_Cert_App_Evinova_Hindi-IN_22Dec2025_D702NC00001 - EQ-5D-5L_v1.00_Trans_Cert_App_Evinova_Bengali-IN_12Feb2026_D702NC00001
43.	PGIC – Screens - PGIC-Health-Status_v1.00_Trans_App_Evinova_English-IN_03Dec2025_D702NC00001 - PGIC-Health-Status_v1.00_Trans_App_Evinova_Hindi-IN_17Nov2025_D702NC00001 - PGIC-Health-Status_v1.00_Trans_App_Evinova_Bengali-IN_30Jan2026_D702NC00001 Translation Certificate - PGIC-Health-Status_v1.00_Trans_Cert_App_Evinova_English-IN_03Dec2025_D702NC00001 - PGIC-Health-Status_v1.00_Trans_Cert_App_Evinova_Hindi-IN_17Nov2025_D702NC00001 - PGIC-Health-Status_v1.00_Trans_Cert_App_Evinova_Bengali-IN_30Jan2026_D702NC00001
44.	PGIS4P – Screens - PGIS4P-Cancer_v1.00_Trans_App_Evinova_English-IN_03Dec2025_D702NC00001 - PGIS4P-Cancer_v1.00_Trans_App_Evinova_Hindi-IN_17Nov2025_D702NC00001 - PGIS4P-Cancer_v1.00_Trans_App_Evinova_Bengali-IN_30Jan2026_D702NC00001 Translation Certificate - PGIS4P-Cancer_v1.00_Trans_Cert_App_Evinova_English-IN_03Dec2025_D702NC00001 - PGIS4P-Cancer_v1.00_Trans_Cert_App_Evinova_Hindi-IN_17Nov2025_D702NC00001 - PGIS4P-Cancer_v1.00_Trans_Cert_App_Evinova_Bengali-IN_30Jan2026_D702NC00001
45.	PGI-TT – Screens - PGI-TT_v1.00_Trans_App_Evinova_English-IN_03Dec2025_D702NC00001 - PGI-TT_v1.00_Trans_App_Evinova_Hindi-IN_17Nov2025_D702NC00001 - PGI-TT_v1.00_Trans_App_Evinova_Bengali-IN_30Jan2026_D702NC00001 Translation Certificate - PGI-TT_v1.00_Trans_Cert_App_Evinova_English-IN_03Dec2025_D702NC00001 - PGI-TT_v1.00_Trans_Cert_App_Evinova_Hindi-IN_17Nov2025_D702NC00001 - PGI-TT_v1.00_Trans_Cert_App_Evinova_Bengali-IN_30Jan2026_D702NC00001
46.	PROMIS – Screens - PROMIS_v1.00_Trans_App_Evinova_English-IN_03Dec2025_D702NC00001 - PROMIS_v1.00_Trans_App_Evinova_Hindi-IN_17Nov2025_D702NC00001 - PROMIS_v1.00_Trans_App_Evinova_Bengali-IN_26Jan2026_D702NC00001 Translation Certificate - PROMIS_v1.00_Trans_Cert_App_Evinova_English-IN_03Dec2025_D702NC00001 - PROMIS_v1.00_Trans_Cert_App_Evinova_Hindi-IN_17Nov2025_D702NC00001 - PROMIS_v1.00_Trans_Cert_App_Evinova_Bengali-IN_26Jan2026_D702NC00001
47.	App Screens - Artemidebiliary02 en_IN UTS Screenshot Document V1.0 2025-10-29 11.38 - Artemidebiliary02 hi_IN UTS Screenshot Document V2.0 2026-02-13 12.40

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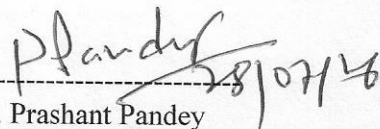


	Artemidebiliary02 bn_IN UTS Screenshot Document V2.0 2026-02-13 14.35
48.	Website Screens - Evinova Participant Website Screenshot Document enIN (2025-09-30) - Evinova Participant Website Screenshot Document hiIN (2025-11-21) - Evinova Participant Website Screenshot Document bnIN (2025-11-21)
49.	CTRI Registration--CTRI/2026/06/112376 (Registered on: 10/06/2026)

If you require further information or need any clarifications, please revert to me.

Thanking You,

Sincerely,



Dr. Prashant Pandey
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		