

ETHICS COMMITTEE



Unique Hospital

Run by Surat Lifecare Pvt. Ltd.

- multispeciality & research institute

healing with humanity

Date: 21 Apr 2026

To,

Dr. Ankit Patel

Unique Hospital – Multispeciality & Research Institute

OppKiran Motor, Nr. Canal,

Civil Hospital Char rasta-Sosyo Circle lane,

Off Ring Road, Surat-395002

Reference Study:	Study Title: Study 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) Study ID: D702NC00001
Subject:	EC approval for Study documents

Dear Dr. Ankit Patel,

We have received from you 03 hard copies and 01 soft copy on 14 Mar 2026 of above mentioned study for Ethics Committee review and opinion.

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_01 st Mar 2026 to 28 th Feb 2027 Policy Number: P1025200001/9999/106914 and Certificate No. P1025200001/9999/106914 - D702NC00001 dated 26 Feb 2026
5.	Curriculum Vitae of Principal Investigator dated 26 Nov 2025
6.	MRC_ Certificate No. G-23394_of Principal Investigators (PI)
7.	GCP training certificate_15Feb2024
8.	Investigator Undertaking by the Principal Investigator signed on 26 Nov 2025
9.	Declaration of Site Facility from PI signed on 26 Nov 2025



Unique Hospital Multispeciality & Research Institute

Nr. Kiran Motors, Opp. Unique B.R.T.S Junction, Civil Hospital Char Rasta - Sosyo Circle Lane,

Off Ring Road, Surat - 395017.

Tel.: 0261-6776666 / 00 Email : uniquehospitalsurat@yahoo.com Web.: www.uniquehospital.in





10.	Declaration of Number of Clinical Trials by PI signed on 26 Nov 2025
11.	• Toxicity Management Guidelines for Rilvegostomig (AZD2936) version 7.0_05 Feb 2026 • SUSAR_Durvalumab_01-May-2025 - 31-Oct-2025_ 04 Dec 2025 • SUSAR_Rilvegostomig_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_v02_28 Nov 2025
13.	• Clinical study Protocol 1.0 agreement page signed on 26 Nov 2025 • Clinical Study Protocol-India Addendum 01 agreement page signed on 29 Jan 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 24 Feb 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 1.0 India Master Version Date 17 Sep 2025 _ English Translation: • English to Hindi – Translated on 18 Nov 2025 • English to Gujarati - Translated on 15 Dec 2025 Back Translation: • Hindi to English – Back translated on 18 Nov 2025 • Gujarati to English - Back translated on 15 Dec 2025 Hindi Translation & Back Translation Certificates: 18 Nov 2025 • English to Hindi and Hindi to English, Gujarati Translation & Back Translation Certificates: 15 Dec 2025 • English to Gujarati and Gujarati to English
17.	Adult Study Participant Master Information and Consent Form, Master Version Number 1.0 Master Version Date 11 Aug 2025, India Version 1.0 India Version Date 19 Sep 2025 Translation:





	- English to Hindi – Translated on 03 Dec 2025 - English to Gujarati - Translated on 30 Dec 2025 Back Translation: - Hindi to English – Back translated on 03 Dec 2025 - Gujarati to English - Back translated on 30 Dec 2025 Hindi Translation & Back Translation Certificates: 03 Dec 2025 - English to Hindi and Hindi to English Gujarati Translation & Back Translation Certificates: 30 Dec 2025 - English to Gujarati and Gujarati to English
18.	Future Research Information and Informed Consent Form, India Version 1.0 India Version Date 19 Sep 2025_ EnglishDerived from Master Version Number 1.0 Master Version Date 11 Aug 2025 (Adult Study Participant Information and Consent Form) Translation: - English to Hindi – Translated on 25 Nov 2025 - English to Gujarati - Translated on 22 Dec 2025 Back Translation: - Hindi to English – Back translated on 25 Nov 2025 - Gujarati to English - Back translated on 22 Dec 2025 Hindi Translation & Back Translation Certificates: 25 Nov 2025 - English to Hindi and Hindi to English, Gujarati Translation & Back Translation Certificates: 22 Dec 2025 - English to Gujarati and Gujarati to English
19.	Optional Genomics Initiative Research Information, Master Version Number 1.0 Master Version Date 11 Aug 2025India Version Number 1.0 India Version Date 26 Sep 2025 Translation: - English to Hindi – Translated on 25 Nov 2025 - English to Gujarati - Translated on 16 Dec 2025 Back Translation: - Hindi to English – Back translated on 25 Nov 2025 - Gujarati to English - Back translated on 16 Dec 2025 Hindi Translation & Back Translation Certificates: 25 Nov 2025 - English to Hindi and Hindi to English, Gujarati Translation & Back Translation Certificates: 16 Dec 2025





	English to Gujarati and Gujarati 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 1.0 India Version Date 23-Sep-2025_English Translation: - English to Hindi – Translated on 25 Nov 2025 - English to Gujarati - Translated on 22 Dec 2025 Back Translation: - Hindi to English – Back translated on 25 Nov 2025 - Gujarati to English - Back translated on 22 Dec 2025 Hindi Translation & Back Translation Certificates: 25 Nov 2025 - English to Hindi and Hindi to English Gujarati Translation & Back Translation Certificates: 22 Dec 2025 - English to Gujarati and Gujarati 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 Gujarati – Translated on 15 Dec 2025 Back Translation: - Hindi to English – Back translated on 15 Dec 2025 - Gujarati to English – Back translated on 15 Dec 2025 Certificates of Accuracy: dated 15 Dec 2025 - English to Hindi, English to Gujarati - Hindi to English, Gujarati 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 Gujarati – Translated on 12 Sep 2025 Certificate of Accuracy dated 12 Sep 2025
24.	- English to Hindi, English to Gujarati D702NC00001_Study Pamphlet_version 1.0_23 Oct 2025_In-enUK Translation: - English to Hindi – Translated on 26 Nov 2025 - English to Gujarati – Translated on 26 Nov 2025 Certificate of Accuracy dated 21 Oct 2025 - English to Hindi, English to Gujarati Note : Translation Certificate_ Clarification on Dates_ July 2025
25.	ePRO Questionnaire Paper English - EQORTC IL172_HandHeld_English - EORTC IL444_HandHeld_English - EORTC IL444_Translation Certificate dated 05 Sep 2025 - EORTC IL445_Handheld English - EORTC IL445_Translation Certificate dated 05Sep2025 - EORTC IL446_Handheld English - EORTC IL446_Translation Certificate dated 05 Sep 2025 - PGI-TT_cv1_Trans_WS_Paper_English-IN_31Jan2019 - PGI-TT_cv1_Trans_Certificate_WS_Paper_English-IN_31Jan2019 - PGIC-Standard_Health_Status_7pt_v1.0_Trans_Paper_English-IN_08Jul2024 - PGIC-Standard_Health_Status_7pt_v1.0_Trans_Certificate_Paper_English-IN_08Jul2024 - PGIS_Standard_Cancer_4pt_cv1_Trans_Paper_English-IN_21Jun2024 - PGIS_Standard_Cancer_4pt_cv1_Trans_Certificate_Paper_English-IN_10Jul2024 - PROMIS SF v2.0 - Physical Function - 8c 7-Day_Eng_20May2022 - EQ5D5L_Health Questionnaire_v3.00_HandHeld_English-IN - EQ5D5L_Certificate_English-IN_dated 15 Nov 2023
26.	ePRO Questionnaire Paper – Hindi - EORTC IL172_HandHeld_Hindi - EORTC IL172_Handlehd_Hindi_Translation Certificate_08 Sep 2025 - EORTC IL444_HandHeld_Hindi - EORTC IL444_Translation Certificate dated 05 Sep 2025 - EORTC IL445_HandHeld_Hindi - EORTC IL445_Translation Certificate dated 05Sep2025 - EORTC IL446_HandHeld_Hindi - EORTC IL446_Translation Certificate dated 05 Sep 2025 - PGI-TT_cv1_Trans_WS_Paper_Hindi -IN_25Jan2019 - PGI-TT_cv1_Trans_Certificate_WS_Paper Hindi-IN_31Jan2019





	- PGIC-Standard_Health_Status_7pt_v1.0_Trans_Paper_Hindi-IN_09Jul2024 - PGIC-Standard_Health_Status_7pt_v1.0_Trans_Certificate_Paper_Hindi-IN_09Jul2024 - PGIS_Standard_Cancer_4pt_cv1_Trans_Paper_Hindi-IN_21Jun2024 - PGIS_Standard_Cancer_4pt_cv1_Trans_Certificate_Paper_Hindi-IN_10Jul2024 - PROMIS SF v2.0 - Physical Function - 8c 7-Day_Hindi_03Aug2021 - PROMIS SF v2.0 - Physical Function - 8c 7-Day_Hindi_Translation Certificate 30 Nov 2020 - BC02_NU Note to File - Date Discrepancy between Questionnaires and CoT_16May2024 - EQ5D5L_v2.1_HandHeld_Hindi-IN - EQ5D5L_Certificate_Hindi-IN_dated 15 Nov 2023
27.	ePRO Questionnaire Paper – Gujarati - EORTC IL172_HandHeld_Gujarati - EORTC IL172_Handlehd_Gujarati_Translation Certificate_08Sep2025 - EORTC IL444_HandHeld_Gujarati - EORTC IL444_Translation Certificate dated 05Sep2025 - EORTC IL445_HandHeld_Gujarati - EORTC IL445_Translation Certificate dated 05Sep2025 - EORTC IL446_HandHeld_Gujarati - EORTC IL446_Translation Certificate dated 05Sep2025 - PGI-TT_cv1_Trans_WS_Paper_Gujarati -IN_25 Jan 2019 - PGI-TT_cv1_Trans_Certificate_WS_Paper_Gujarati -IN_31Jan2019 - PGIC-Standard_Health_Status_7pt_v1.0_Trans_Paper_Gujarati -IN_12 Jul 2024 - PGIC-Standard_Health_Status_7pt_v1.0_Trans_Certificate_Paper_Gujarati -IN_12 Jul 2024 - PGIS_Standard_Cancer_4pt_cv1_Trans_Paper_Gujarati-IN 21 Jun 2024 - PGIS_Standard_Cancer_4pt_cv1_Trans_Certificate_Paper_Gujarati -IN_04 Jul 2024 - PROMIS SF v2.0 - Physical Function - 8c 7-Day_Gujarati_07 Jul 2021 - NU_PROMIS certification of translation_Physical Function 8c 7-Day_Gujarati 07 Jul 2021 - NU Note to File - Date Discrepancy between Questionnaires and CoT_16May2024 - EQ5D5L_v1.0_HandHeld_Gujarati-IN - EQ-5D-5L Translation Certificate v_2.0_15 Nov 2023
28.	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





29.	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
30.	Unify/ePRO Patient Training Material – Gujarati - Evinova study phone password and technical support card V15; Aug 2025_Gu-IN - Evinova study phone password and support_ Translation Certificate_ 25 Sep 2025 - OST_Patient_video_EQR_no_visits_6.0.1_dated 21July 2023_GuIN - OST_Patient_video_EQR_no_visits_6.0.1_dated 21July 2023_GuIN_Translation Certificate dated 10 sep 2025 - Patient welcome guide_EQRGIMT_app_nopii_July_2025_GuIN_v2a - Patient Welcome Guide- EQRGIMT_app_nopii_July_2025_GuIN -Translation certificate dated 22 Aug 2025 - VO_Patient_video_EQR_no_visits_6.0.1_July_2023_GuIN - VO_Patient_video_EQR_no_visits_6.0.1_July_2023_Certificate Gujarati_ 10 Sep 2025
31.	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
32.	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
33.	Unify/ePRO: Remote Patient Monitoring – Gujarati - Contact_doctor_Gujarati_14 Aug 2024 - Certification_Contact_doctor_GuIN_14AUG2024 - GIRPM_Screens_v2.0_India_Gu_IN_12MAY2025.pdf - GIRPM_CoT_v2.0_India_Gu_IN_12MAY2025
34.	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
35.	Unify/ePRO Appendix – Hindi • Devices Label_Evinova_hiIN • Device Lable_Evinova_Translation Certificate dated 28 Oct 2024
36.	Unify/ePRO Appendix – Gujarati • Devices Label_Evinova_GuIN • Device Lable_Evinova_Translation Certificate dated 28 Oct 2024
37.	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
38.	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
39.	Unify: Screen-Shot – Gujarati • App Screen_Artemidebiliary02 Gu_IN UTS Screenshot Document V1.0 05-Nov-2025 • Patient Instruction_Patient_Login_Instructions_GuIN_v3.0_with_Patient_Web 17 Oct 2025 • Patient Web_Evinova Participant Website Screenshot Document GuIN_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
40.	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



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	• Study guide_ V 1.0_ Gujarati_ 21 Jan 2026 • Study Guide_ V 1.0_ Translation Certificate_ Gujarati_ 12 Dec 2025
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We have received from you documents of patient accrual method on 30-Mar -2026 of above mentioned study for Ethics Committee review and opinion.

Patient accrual method	The patients in current study will be identified by PI from his own OPD including institutional data base and IPD. Patients may approach the site team voluntary and can come in walking for another opinion. Even referral patients will be taken by PI from Sub-I (s). Moreover, for recruitment in into the study patients will be referred by other oncologist from same city or from other cities too.
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The following members of the Ethics Committee were present at the meeting held on 17-04-2026, 01:00 PM, at Doctor's Room, Unique Hospital - Multispecialty & Research Institute and voted:

Sr. No	Name	Role/ Designation in Ethics committee
1	Dr. Milan Jiyani, MD (Intensivist, Pulmonary Chest Physician)	Chairperson
2	Dr. Divyesh Patel MBBS, MD (TB & Chest Disease), IDCCM	Member Secretary
3	Dr. Mahesh Sutariya, M.D., IDCCM (Critical Care Physician & Intensivist)	Clinician
4	Dr. Tirthesh Mehta (MBBS, MS (Orthopedics)	Clinician
5	Mr. Bhavin Modi, B.Com, LLB(General), LLB(Special)	Legal Expert
6	Mr. Tushar Bhalani, B.Com	Lay Person
7	Dr. Parikshit Vashi, Ph.D (Chemistry), M.Phil, M.Sc. (Organic Chemistry), B.Ed. (Maths-Science)	Social Scientist
8	Dr. Khushbu Vaghasiya (MD Pharmacology)	Basic Medical Scientist
9	Mr. Rakesh Pathak, ITI, Electronics	Theologian
10	Dr. Jinesh Desai, BPT, MBA (Healthcare Management)	Member
11	Mrs. Kochumol. V. A	Woman Member



ETHICS COMMITTEE



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None of the study team members were a part of the voting procedure.

DECISION

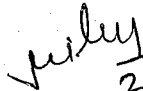
- We approve the study to be conducted in its presented form.
- Applicable mandatory regulatory and other permissions to be obtained prior to commencement of the study.
- The investigator team members should be trained on the protocol & protocol related procedures and the Good Clinical Practices (GCP) Guidelines prior to commencing the study.
- Participating subjects should not be put to additional financial burden due to participation in the study.

The Ethics Committee Unique Hospital expects to be informed about the following:

- Progress of the study to be reported six monthly from date of approval to the EC-UNIQUE HOSPITAL.
- To provide an abridged copy of the final report after completion of the study.

Ethics Committee-Unique hospital is working in accordance to ICH-GCP, New Drug and Clinical Trials Rules-2019 and ICMR guidelines and other applicable regulation.

Yours sincerely,


21/4/26
Dr. Milan Jiyani

Chairperson- Ethics Committee,
Unique Hospital-Multispecialty
& Research Institute, Surat.

