
ADULT INFORMED CONSENT FORM FOR AUDIO-VISUAL RECORDING OF SUBJECT'S CONSENT PROCESS IN INDIA

Study Code:	D702NC00001	Centre No:	3514
Sponsor:	AstraZeneca AB	Subject E Code:	
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)		
Principal Investigator:	Dr. Prashant Pandey		
Hospital Name:	Tata Medical Center, Kolkata		

As a new subject, we need to ask for your consent to be recorded whilst discussing the trial with the study doctor as part of your consent to participate in the trial.

If you agree to be recorded, you will then be administer trial-specific information, which describes in detail the trial and the potential risks and benefits of participation. During the recording, you can ask your doctor all the questions you have about the study, if there are aspects that are not clear to you.

If you do not agree to be recorded, you cannot participate in the trial, however, you will not be disadvantaged in any way, including medical treatment and care you are entitled to receive. Your Study Doctor can explain the other treatments that are available to you if you choose not to agree to be recorded.

What will happen to my audio-visual recordings?

The recording will be securely stored at the hospital under the supervision of your study doctor. The study site and sponsor are obliged to retain the audio-visual recordings of the informed consent process for a minimum of 5 years after the study completion or termination, if it is not possible to maintain as per timelines specified in the clinical study agreement (25 years after the end of the study). If necessary to

verify the informed consent process, sponsor representatives, auditors, the IRB/IEC, regulatory authorities, and Courts of Law may access the recordings while ensuring complete confidentiality and safeguarding your identity from disclosure to third parties or publication. Your recordings will not be used for other purposes, and you have the right to access them.

Audio-Visual recording of Informed Consent Statement

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Subject's Initials: _____ **Subject's Name:** _____

Date of Birth: _____ **Age:** _____

Sl. No.	Please provide your initials (short signature or signature) or thumb impression against each one of the following statements to confirm your consent to these statements.	
i.	I confirm that I have read this consent form to record the informed consent procedure, and have had the opportunity to ask questions, which were answered to my satisfaction.	[]
ii.	I confirm that I agree to the storage of the recording and that it may be viewed by sponsor, regulatory authority official, ethics committee member of your site and may be used in courts as explained above. However, I understand that my confidentiality will be maintained, and my identity will not be revealed in any information that is released by the Sponsor, Hospital or the Principal Investigator to third parties or published	[]
iii.	I agree to being recorded as part of the consenting procedure for the clinical trial.	[]
iv.	I agree to being recorded in future too when I have to provide my consent for my continuation in the clinical trial, which may be needed in case I have to provide re-consent for a revised informed consent form or for any other reason.	[]

A Photo ID will be collected from you, Legally Acceptable Representative, and Impartial Witness as applicable.

Signature (Or Thumb impression) of the subject/Legally Acceptable Representative (LAR)

Date of Signature

Signatory's Name (Name of the subject or LAR who has signed)

Where a subject is not able to give informed consent (e.g. an unconscious person or a minor or those suffering from severe mental illness or disability), the same may be obtained from a legally acceptable representative (a legally acceptable representative is a person who is able to give consent for or authorize an intervention in the patient as provided by the law(s) of India).

Relationship of legally acceptable representative to subject

Signature of the Investigator

Date of Signature

Study Investigator's Name

If the Subject or his/her legally acceptable representative is unable to read/write - an impartial witness should be present during the entire informed consent process who must append his/her signatures to the consent form

Impartial witness is a person who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or the subject's legally acceptable representative cannot read, and who reads the informed consent form and any other written information supplied to the subject.

Signature of Impartial Witness

Date of Signature

Name of Impartial Witness

Copy of duly filled Audio - Visual Informed Consent Form shall be handed over to the subject or his/her Legally Acceptable Representative.