

ADULT INFORMED CONSENT FORM FOR AUDIO-VISUAL RECORDING OF THE CONSENT PROCEDURE OF THE PARTICIPANT 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 participant, it is required for us to ask for your consent to be recorded during the discussion of the trial with the study doctor as part of your consent to participate in the trial.

In case you agree to be recorded, then you will be provided with trial-specific information that explains in detail the trial and the possible risks and benefits of participating. During the recording, if there are any aspects that are not clear to you then you may ask your doctor all queries that you have related to the study.

In case you do not agree to be recorded then you will not be able to take part in the trial; however, you will not be disadvantaged in any way, which includes the medical treatment and care that you are entitled to get. In case you choose not to agree to be recorded then your study doctor will explain the other treatments available to you.

What will occur to my audio-visual recordings?

The recording will be stored securely at the hospital under your study doctor's supervision. The study site and sponsor are obliged to retain the audio-visual recordings of the informed consent process for a minimum of 5 years following the completion or termination of the study, in case it is not possible to keep according to timelines indicated in the clinical study agreement (25 years after the end of the study). In case required to scrutinize the informed consent process, sponsor representatives, auditors, the IRB/IEC, regulatory authorities, and Courts of Law might access the recordings while making sure complete confidentiality and safeguarding your identity from disclosure to third parties or publication. Your recordings will not be used for other objectives, and you have the right to access them.

Audio -Visual Recording of the Informed Consent Statement

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Initials of the Subject: _____ Name of the Subject: _____

Date of birth: _____ Age: _____

Sl. No.	Kindly give your initials (short signature or signature) or thumb impression near each of the given below statements to confirm your consent to these statements.	
i.	I confirm that I have read this consent form for recording of the informed consent procedure, and have got the chance to ask questions, for which answers were given to my satisfaction.	[]
ii.	I confirm that I agree to the storage of the recording and that the sponsor, official of the regulatory authority, member of the ethics committee of your site can view it and it can be used in courts as per the explanation given above. Though, I understand that my confidentiality will be maintained and my identity will not be disclosed in any information that is released by the Sponsor, Hospital, or the Principal Investigator to third parties or published.	[]
iii.	I consent to be recorded as part of the consenting procedure for the clinical trial.	[]
iv.	I consent to be recorded in the future also when I have to give my consent for my continuation in the clinical trial that can be required if I have to give consent again for a revised informed consent form or for any other reason.	[]

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

Signature (or Thumb impression) of the Subject / Date of Signature
Legally Acceptable Representative (LAR)

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 the patient or authorize an intervention as provided by the law(s) of India).

Relationship of legally acceptable representative with subject

Signature of the investigator Date of Signature

Name of the study Investigator

An impartial witness should be present during the entire informed consent process who must add his/her signatures to the consent form, if the subject or his/her legally acceptable representative is unable to read/write.

Impartial witness is an individual 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 given to the subject.

Signature of the Impartial Witness

Date of Signature

Name of the Impartial Witness

The properly filled audio-visual informed consent form's copy shall be handed over to the subject or his/her Legally Acceptable Representative.