

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

Study Code:	D702NC00001	Centre No.:	3514
Sponsor:	AstraZeneca AB	Subject E Code:	
Title of the study:	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 are required to ask for your consent to be recorded while having a discussion with the study doctor about the trial as part of your consent to take part in the trial.

In case you consent to be recorded, then you will be given trial-specific information, in which the trial and the potential risks and benefits of participation have been explained in detail. During the recording, you can ask all the questions that you have to your doctor in regards to the study, if any aspects are there that are not clear to you.

In case you do not agree to get recorded, you will not be able to take part in the trial, though you will not be disadvantaged in any way, including the medical treatment and care you are entitled to get. In case you decide not to agree to be recorded, then your study doctor can explain the other treatments available to you.

What will occur to my audio-visual recordings?

The recording will be securely kept at the hospital under your study doctor's supervision. The study site and sponsor are obliged to keep the audio-visual recordings of the informed consent process for at least 5 years after the completion of the study or termination if there is no possibility to maintain as per the timelines mentioned in the clinical study agreement (25 years after the end of the study). If needed to verify the informed consent process, representatives of the sponsor, auditors, the IRB/IEC, regulatory authorities, and Courts of Law might access the recordings while making sure of complete confidentiality and protecting 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

Study Code:D702NC00001
Title of the study: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)

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

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

Sl. No.	Kindly provide your initials (short signature or signature) or thumb impression against each one of the statements given below in order to confirm your consent to these statements.	
i.	I confirm that I have read this consent form to record the informed consent procedure, and I was given a chance to ask questions, for which I have received satisfactory answers.	[]
ii.	I confirm that I agree to the storage of the recording, and this can be viewed by the sponsor, regulatory authority official, member of the ethics committee of your site, and this can be used in courts as described above. However, 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 agree to be recorded as a part of the consenting procedure for the clinical trial.	[]
iv.	I agree to be recorded in the future also when I have to give my consent to continue my participation in the clinical trial, which might be required when I need to give re-consent for a revised informed consent form or for any other reason.	[]

A Photo ID will be taken from you, a legally acceptable representative, and an impartial witness, as applicable.

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

Date of Signature

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

Where a subject is unable to provide informed consent (for example, an unconscious person or a minor or those who are suffering from a severe mental disease 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 the legally acceptable representative to the subject

Signature of the investigator

Date of Signature

Name of the study investigator

In case the subject or his/her legally acceptable representative is not able to read/write, an impartial witness must be present during the complete informed consent process, who should put his/her signature on the consent form.

An impartial witness is a person who is independent of the trial, who cannot be unfairly influenced by people associated with the trial, who is present at the informed consent process in case the subject or the subject's legally acceptable representative is unable to 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

A copy of the properly filled Audio-Visual Informed Consent Form will be given to the subject or his/her Legally Acceptable Representative.