

FUTURE RESEARCH INFORMATION AND INFORMED CONSENT FORM

Study Code:	D702NC00001	Centre No:	3514
Sponsor:	AstraZeneca AB	Subject E Code:	
Principal Investigator:	Dr. Prashant Pandey		
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)		
Country:	INDIA		

Dear Madam/Sir,

Additionally, taking part in the clinical study, we would like to be aware of whether you would be ready for your coded data (including images) and leftover biosamples collected in part 1 to be utilized in future research projects with suitable ethical approval.

You are at liberty to consent to the use of your coded data and biosamples for future research. In case you make a decision not to do so, you might still participate in the clinical study.

1. What is future research?

Future research is important for the advancement of science and public health. Currently, however, it is not possible to foresee all details of future **scientific research** projects. These future scientific research projects are beyond the scope of the clinical study (ARTEMIDE.Biliary02 study) and the drug/device development program that includes your biosamples and data use as outlined in part 1 of the Adult Study Participant Information and Consent Form. Few of this research might take place while the study is ongoing or post the study has ended.

Your coded data and biosamples might only be used for scientific health-related research for finding new ways for detecting, treating, preventing or curing health issues, or for developing new technologies, diagnostic tests and approaches that will assist with this activity, which includes developing machine learning and artificial intelligence technologies.

They might also be utilized jointly with information from other sources out of a typical clinical research settings, for example from public research databases. But, they will not get combined with other information in a manner that might identify you. Your coded data and biosamples might also undergo anonymization for a little of the future **scientific research**.

A few research projects might need the analysis of your genetic information.

Data generated from diagnostic testing and/or your unused sample(s) for future research might be used by AstraZeneca, research partners and service providers to help develop new diagnostic tests for patients with your disease or better understand the disease itself. This consist of data and biosamples collected following consent at the time of screening period even though the study eligibility criteria is not fulfilled by you.

2. How shall my coded data and biosamples for future research be handled?

All biosamples shall be securely kept on behalf of the **sponsor** for up to 15 years *and shall undergo destruction later*. Kindly note that the biosamples location might be changed at the **sponsor's** request.

Any extra data generated from your biosamples shall be kept as long as required for scientific research objectives and permitted by law and shall undergo destruction or anonymised later. For additional information on the **Sponsor's** internal Document Retention policy, you might go to www.astrazenecapersonaldataretention.com website.

3. Can my coded data and biosamples be shared?

Sponsor might share your coded data and biosamples with research partners or **deposit** them in **scientific databases**, as explained at the end of the document in Adult Study Participant Information and Consent Form Part III: "Additional information for patients/Participants". This might be inclusive of researchers from universities, research hospitals, and companies.

Your personal data mentioned above (See Adult Study Participant Information and Consent Form Part 1 section 11a) might also get shared with service providers or third parties which

include IT providers for the objectives of developing new technologies, system development, and technical support.

A few of the above-mentioned recipients might be situated out your country. Data protection laws that are applicable in those countries might not be as strict as the laws in your country. Nonetheless, suitable safeguards and security measures shall be adopted so as to protect and maintain the confidentiality of your biosamples and coded data as explained during the end of the document in Adult Study Participant Information and Consent Form Part III: "Additional information for patients/Participants".

4. How shall my privacy be protected?

Your coded data and biosamples shall be subject to suitable safeguards, as mentioned in the Adult Study Participant Information and Consent Form in Part III: "Additional information for patients/Participants". Your coded data and biosamples shall solely be utilized for the objective of scientific health-related research. This scientific health research might be inclusive of developing machine learning and artificial intelligence technologies. These activities shall not affect your care or any other decision that affects your life, like insurance rates or job opportunities.

You possess the identical rights as the ones explained in the section "What are your right under data protection law?".

5. What in case I wish to withdraw from future research?

Your taking part in future research is on a voluntary basis. You are entitled for withdrawing your consent for future research during any time, without providing a purpose and without a negative effect on your standard of medical care. In case you want to withdraw, kindly tell your study doctor.

You might still carry on taking part in the clinical study despite you selecting to withdraw from future research.

In case you withdraw from future research, your coded data and biosamples shall not be utilized for future research and your biosamples shall undergo destruction immediately. Your coded data (either copied from the clinical study database or newly generated) shall also undergo destruction unless this information is already included within the analyses or utilized in scientific publications or in case the coded data has undergone anonymization and hence, we cannot identify your data or biosamples.

6. Outcomes from Future Research?

We might have to gather study-coded data and biosamples from several people over several years prior to us knowing whether the outcomes of future research are meaningful.

Hence, you must not expect to get individual outcomes from future research projects. We shall not provide any such data to your doctor and we shall not put them in your medical record as they are not individual valid outcomes.

You are free to permit the utilization of your coded data and biosamples for FUTURE RESEARCH. In case you agree, you may denote this in the CONSENT FORM.

INFORMED CONSENT FORM

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I do confirm that:

- The study doctor or study personnel delegated by the study doctor did explain the study to me in a comprehensive manner.
- I did have the chance for discussing the study with the study doctor and all my queries were replied to.
- I did have a sufficient amount of time for considering the study.
- I have honestly replied to all queries regarding my medical history and shall follow all rules mentioned in this document.

I know that my taking part also entails:

- My name and contact details being gathered while in the study as explained to me, and accessed and reviewed by the listed authorized people;
- My coded data (including images) being utilized by the sponsor or by people or companies that act on its behalf or work with the sponsor;
- My coded data being utilized by persons or organizations situated in countries that do not possess data protection rules equivalent to those of my country. I know that the sponsor monitors these utilizes and takes all possible measures for protecting my privacy;
- *My biosamples being gathered and analyzed as explained* and that this is inclusive of genetic analyses.

I further know that I can make a choice regarding the topics mentioned hereunder and that by tick-marking “Yes” I do provide consent and that by tick-marking “No” I do not provide consent:

The utilization of my coded data (which includes pictures), <i>biosamples and analysis of my genetic information</i> as needed for future research, as explained in “Future Research Information”, <i>which includes additional biosamples collection.</i>	Yes ☐	No ☐
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Sl. No.	Kindly give your initials (short signature or signature) or thumbprint (as applicable) against each one of the below mentioned statements for confirming your consent for these statements.	
(i)	I do confirm that I did read and understand the Future Research Information and Informed Consent Form dated 23 July 2026, India Version Number 1.1 for the study above and did have the chance to ask queries.	[]
(ii)	I know that my taking part in the study is on a voluntary basis and that I have the freedom to withdraw during any time, without providing any purpose, without my medical care or legal rights getting affected.	[]
(iii)	I know that the Sponsor of the clinical trial, others that work on behalf of the Sponsor, the Ethics Committee and the regulatory authorities shall not require my permission to view my health records both with respect to the present study and any additional research which might be done in association to it, despite my withdrawal from the trial. I agree to this access. But, I know that my identity shall not be disclosed in any information released to third parties or published.	[]
(iv)	I agree not to limit the utilization of any data or outcomes that emerge from this study given such a utilization is solely for scientific objective(s)	[]
(v)	I agree to participate in the study above.	[]

*Signature (Or Thumbprint) 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 does not have the ability to provide informed consent (for example an unconscious person or a minor or those suffering from severe mental illness or disability), the same might be obtained from a legally acceptable representative (a legally acceptable representative is an individual who has the ability to provide consent for or authorize an intervention in the patient as given by the law(s) of India).

Relationship of a legally acceptable representative with the subject

Investigator's Signature

Date of Signature

Name of the Study Investigator

In case the Subject or his/her legally acceptable representative is unable to read/write - an impartial witness must be present throughout the whole informed consent process who should append his/her signatures to this consent form.

An impartial witness is an individual who is free from the trial, who cannot be influenced unfairly by people involved with the trial, who attends the informed consent process in case 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.

Impartial Witness's Signature

Date of Signature

Impartial Witness's Name

"A copy of the Patient Information Sheet (Future Research Information) and properly filled Informed Consent Form will be given to the subject or his/her legally acceptable representative."