

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,

In addition to participating in the clinical study, we would like to know if you would be willing for your coded data (including images) and leftover biosamples collected in part 1 to be used in future research projects with appropriate ethical approval.

You are free to consent to the use of your coded data and biosamples for future research. If you decide not to do so, you may still take part in the clinical study.

1. What is future research?

Future research is important to advance science and public health. At present, 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 involves the use of your biosamples and data as outlined in part 1 of the Adult Study Participant Information and Consent Form. Some of this research may occur whilst the study is ongoing or after the study has finished.

Your coded data and biosamples may only be used for scientific health-related research to find new ways to detect, treat, prevent or cure health problems, or to

develop new technologies, diagnostic tests and approaches that will assist with this activity, including developing machine learning and artificial intelligence technologies.

They may also be used jointly with information from other sources outside typical clinical research settings, e.g. from public research databases. However, they will not be combined with other information in a way that could identify you. Your coded data and biosamples may also be anonymized for some of the future **scientific research**.

Some research projects may require the analysis of your genetic information.

AstraZeneca, research partners and service providers may use data produced from diagnostic testing and/or your unused sample(s) for future research to help develop new diagnostic tests for patients with your disease or better understand the disease itself. This includes data and biosamples collected following consent during screening period even if you do not meet the study eligibility criteria.

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

All biosamples will be securely stored on behalf of the **sponsor** for up to 15 years *and will be destroyed thereafter*. Please note that the location of the biosamples may change at the request of the **sponsor**.

Any additional data generated from your biosamples will be stored as long as necessary for scientific research objectives and allowed by law and will be destroyed or anonymised thereafter. For more information on **Sponsors** internal Document Retention policy you may go to www.astrazenecapersonaldataretention.com.

3. May my coded data and biosamples be shared?

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

Your personal data listed above (see Adult Study Participant Information and Consent Form Part 1section 11a) may also be shared with service providers or third parties including IT providers for the purposes of developing new technologies, system development and technical support.

Some of the above-mentioned recipients may be located outside your country. The data protection laws which apply in those countries may not be as stringent as the laws in your country. Nevertheless, appropriate safeguards and security measures will be taken in order to protect and maintain the confidentiality of your biosamples and coded data as described at the end of the document in Adult Study Participant Information and Consent Form in Part III: “Additional information for patients / Participants”.

4. How will my privacy be protected?

Your coded data and biosamples will be subject to appropriate safeguards, as specified in Adult Study Participant Information and Consent Form in Part III: “Additional information for patients/ Participants” . Your coded data and biosamples will only be used for the purpose of scientific health related research. This scientific health research may include developing machine learning and artificial intelligence technologies. These activities will not affect your care or any other decision affecting your life such as insurance rates or employment opportunities.

You have the same rights as the ones described in the section “What are your rights under data protection law?”.

5. What if I want to withdraw from future research?

Your participation in future research is voluntary. You are entitled to withdraw your consent for future research at any time, without giving a reason and without a negative effect on your standard of medical care. If you wish to withdraw, please inform your study doctor.

You may still continue to participate in the clinical study even if you choose to withdraw from future research.

If you withdraw from future research, your coded data and biosamples will not be used for future research and your biosamples will be destroyed as soon as possible. Your coded data (either copied from the clinical study database or newly generated) will also be destroyed unless this information is already included in analyses or used in scientific publications or if the coded data been anonymized and therefore we can't identify your data or biosamples.

6. Results from Future Research

We may have to collect study coded data and biosamples from many people over many years before we can know if the results of future research are meaningful.

Therefore, you should not expect to receive individual results from future research projects. We will not give any such data to your doctor and we will not put them in your medical record as they are not individual valid results.

You are free to consent to the use of your coded data and biosamples for FUTURE RESEARCH. If you agree, you can indicate this in the CONSENT FORM.

INFORMED CONSENT FORM

Study Code:	D702NC00001	Centre No:	3514
Investigator:	Dr. Prashant Pandey	Subject Ecode:	
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)		

I confirm that:

- The study doctor or study personnel delegated by the study doctor has / have explained the study to me comprehensively.
- I have had the opportunity to discuss the study with the study doctor and all my questions were answered.
- I have had an adequate amount of time to consider the study.
- I have truthfully answered all questions about my medical history and will follow all rules listed in the document.

I understand that my participation also entails:

- My name and contact details being collected during the study as described to me, and accessed and reviewed by listed authorised people;
- My coded data (including images) being used by the sponsor or by people or companies acting on its behalf or working with the sponsor;
- My coded data being used by persons or organisations located in countries that do not have data protection rules equivalent to those of my country. I understand that the sponsor monitors these uses and takes all possible measures to protect my privacy;
- *My biosamples being collected and analysed as described* and that this includes genetic analyses.

I further understand that I can make a choice about the topics listed below and that by ticking “Yes” I do give consent and that by ticking “No” I do not give consent:

The use of my coded data (including images), <i>biosamples and analysis of my genetic information</i> as required for future research, as described in “Future Research Information”, <i>including the collection of additional biosamples.</i>	Yes ☐	No ☐
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Sl. No	Please provide your initials (short signature or signature) or thumb impression (as applicable) against each one of the following statements to confirm your consent to these statements	
(i)	I confirm that I have read and understood the Future Research Information and Informed consent form dated 23 Jul 2026, India Version Number 1.1 for the above study and have had the opportunity to ask questions.	[]
(ii)	I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	[]
(iii)	I understand that the Sponsor of the clinical trial, others working on the Sponsor’s behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.	[]
(iv)	I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s)	[]
(v)	I agree to take part in the above study.	[]

*Signature (Or Thumb impression) of the Date of Signature
subject/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 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 the Patient Information Sheet (Future Research Information) and duly filled Informed Consent Form shall be handed over to the subject or his/her legally acceptable representative”.