

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 taking part in the clinical study, we wish to know whether you agree for your coded data (including images) and remaining biosamples taken in Part 1 to be used in future research projects with proper ethical approval.

You have the liberty to give consent to the use of your coded data and biosamples for future research. If you decide not to do so, you can still participate in the clinical study.

1. What is future research?

Future research is essential to advance science and public health. However, at present, it is not possible to predict 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 involving the use of your biosamples and data as mentioned in Part 1 of the Adult Study Participant Information and Consent Form. Some of this research might occur whilst the study is ongoing or after the completion of the study.

Your coded data and biosamples can be used only for scientific health-related research to find new methods for detecting, treating, preventing, or curing health related problems, or to develop new technologies, diagnostic tests, and approaches

that will help with this activity, which includes developing machine learning and artificial intelligence technologies.

They can also be used jointly with information obtained from other sources outside typical clinical research settings, for example, from public research databases. However, they will not be combined with other information in a method by which you may be identified. Your coded data and biosamples might also be anonymized for some future **scientific research**.

The analysis of your genetic information may be needed for some research projects.

Data obtained from diagnostic testing and/or your unused sample(s) may be used by AstraZeneca, research partners, and service providers for future research to help develop new diagnostic tests for patients having your disease or understand the disease in a better way. This involves data and biosamples collected following consent during the screening period, even if you do not fulfill the study eligibility criteria.

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

All biosamples will be stored securely on the **sponsor's** behalf for up to 15 years *and will later be destroyed*. Kindly note that the location of the biosample can change at the **sponsor's** request.

Any additional data created from your biosamples will be kept as long as needed for scientific research objectives and permitted by law, and will later be destroyed or anonymised. For more information about the **Sponsor's** internal Document Retention policy, you can visit www.astrazenecapersonaldataretention.com.

3. Can my coded data and biosamples be shared?

Your coded data and biosamples may be shared with research partners by the **sponsor**, or they can be **deposited** 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". Researchers from universities, research hospitals, and companies may be included in this.

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

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

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

4. How will my privacy be safeguarded?

Your coded data and biosamples will be subject to appropriate safeguards, as mentioned in Part III: “Additional information for patients/Participants” in the Adult Study Participant Information and Consent Form. Your coded data and biosamples will be used only for the purpose of scientific health-related research. This scientific health research might involve developing machine learning and artificial intelligence technologies. Your care or any other decision that affects your life, like insurance rates or employment opportunities, will not be affected by these activities.

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

5. What will happen if I would like to withdraw from future research?

Your taking part in future research is voluntary. You are entitled to withdraw your consent for future research at any time, without providing any reason and without a negative effect on your standard of medical care. If you want to withdraw from the research, kindly notify your study doctor.

You can still continue to take part in the clinical study even if you decide to withdraw from future research.

In case you withdraw future research, your coded data and biosamples will not be used for future research, and your biosamples will immediately be destroyed. Your coded data (either copied from the clinical study database or newly created) will also be destroyed unless this information is previously included in analyses or used in scientific publications, or if the coded data has been anonymized, and hence, your data or biosamples cannot be identified by us.

6. Results obtained from Future Research?

Study coded data and biosamples may need to be collected by us from many people over many years before we can know whether the results of future research are meaningful.

Hence, you must not expect to get individual results from future research projects. Any such data will not be given to your doctor by us, and as they are not individual valid results, we will not place them in your medical record.

You have the liberty to agree to the use of your coded data and biosamples for FUTURE RESEARCH. In case you agree, you may mention this in the CONSENT FORM.

INFORMED CONSENT FORM

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

I confirm that:

- The study has/have been explained to me comprehensively by the study doctor or study personnel delegated by the study doctor.
- I have had the chance to speak about the study with the study doctor and received answers to all my queries.
- I have had a sufficient amount of time to think about the study.
- I have honestly answered all queries about my medical history and I will comply with all rules mentioned in the document.

I know that my participation will also involves the following:

- During the study, my name and contact details will be taken as explained to me, and accessed and reviewed by listed authorized people;
- My coded data (including images) will be used by the sponsor or by people or companies acting on the sponsor's behalf or working with the sponsor;
- My coded data will be used by persons or organizations situated in countries where the rules for data protection are not equivalent to the rules present in my country. I know that these uses are monitored by the sponsor, and all possible measures are taken to secure my privacy;
- *My biosamples will be taken and analysed as explained*, and that this involves genetic analyses.

I further know that I can make a choice about the below-listed topics and that by marking “Yes” I do provide consent, and in the same way by marking “No” I do not provide consent:

The use of my coded data (which includes images), <i>biosamples</i> , and <i>analysis of my genetic information</i> as needed for future research, as explained in “Future Research Information”, <i>which includes the collection of further biosamples</i> .	Yes ☐	No ☐
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Sl. No.	Kindly put your initials (short signature or signature) or thumb impression (as applicable) against each one of the following statements to confirm your consent to the given below statements.	
(i)	I confirm that I have read and understood the Future Research Information and Informed Consent Form dated 23 July 2026, India Version Number 1.1 for the study mentioned above and I have had the chance to ask queries.	[]
(ii)	I know that my taking part in the study is voluntary and that I have the liberty to withdraw from this at any time, without giving any reason, without affecting my medical care or legal rights.	[]
(iii)	I know that the clinical trial sponsor, others who work on behalf of the sponsor, the Ethics Committee, and the regulatory authorities will not need my permission to see my health records, both in respect of the present study and any further research that might be performed in relation to it, even if I withdraw from the trial. I agree to this access. However, I know that my identity will not be disclosed in any information released to third parties or published.	[]
(iv)	I agree not to put restrictions on the use of any data or results arising from this study, provided such use is only for the scientific purpose(purposes).	[]
(v)	I agree to participate in the study mentioned above.	[]

*Subject's/Legally Acceptable Representative's
(LAR) Signature (Or Thumb impression)*

Date of Signature

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

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

Relationship of a legally acceptable representative to the subject

Investigator's Signature

Date of Signature

Name of the Study Investigator

If the Subject or his/her legally acceptable representative is unable to read/write, an impartial witness must be there during the entire informed consent process, who must put his/her signature on the consent form.

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

"The Patient Information Sheet (Future Research Information) and properly completed Informed Consent Form copy shall be given to the subject or his/her legally acceptable representative."