

OPTIONAL GENOMICS INITIATIVE 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 Participant,

In addition to participating in the main study, we would like to know if you would be willing to donate additional **biosamples** for use along with your coded data in an optional multi-omics research project, as part of AstraZeneca's Genomics Initiative.

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

1 What is optional multi-omics research?

Multi-omics research is important to advance science and public health. 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 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 such as the UK Biobank or patient

groups collected by academic researchers. However, they will not be combined with other information in a way that could identify you.

This research project will include the analysis of your genetic, and complementary protein, metabolite and lipid information. These can be referred to as genomics, proteomics, metabolomics and lipidomics and are collectively called “omics” i.e **multi-omics**.

You can think of genetic information as a large instruction book that your body reads to understand how it should be built and function. All humans have the same instruction book in their body but some words or letters may be different from one person to the other. Genetic information is stored in your DNA and this research will include analysis of your DNA and may involve looking at part, or all your genetic information i.e your whole genome. Whole exome or whole genome sequencing technologies may be used.

Proteomics, metabolomics and lipidomics, provide insight into the make-up of biological molecules at the time your biosamples are collected and are complementary to the genomic analysis. Multi-omics analyses provide a comprehensive view of the role these biological molecules play within your body, how they work and how they link together. Much of the multi-omics information is common in all people but some differences can influence the likelihood of developing a disease or can be used to guide individualised treatment options to increase the likelihood of the medicine working.

2 Which additional biosamples do I have to provide?

If you consent to optional multi-omics research, we will collect additional biosamples from you as follows:

- One 3mL blood sample (approximately 1 teaspoon) for genomic analyses and one 3 mL blood sample (approximately 1 teaspoon) for multi-omics analyses at the first day of study treatment (prior to receiving any study drug) or at a later visit.

There are no additional risks involved in this blood collection procedure further to those explained in the main study information and informed consent form.

Your additional biosamples will be coded like the ones collected for the purposes of the main study and as an added level of security will be labelled with a different code than in the main study before we use them for this research project.

3 How will my coded data and biosamples be handled?

All biosamples will be securely stored by AstraZeneca or by another organisation working with AstraZeneca for up to 15 and will be destroyed thereafter. Please note that the location of the biosamples may change at the request of the sponsor.

Any 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. Further information can be found at <https://www.astrazenecapersonaldataretention.com>.

4 May my coded data and biosamples be shared?

The sponsor may share your coded data and biosamples with research partners and/ or deposit them in scientific databases as described in the main study information and informed consent form in Part III: Additional Information for Patients. This may include researchers, as well as universities, research hospitals, and drug- or health-related companies. In addition, the sponsor and its designated organisations may conduct further research where they will share summary data (not your individual data) with other researchers, from other companies or universities, for example. This summary data may be combined with data from other studies, for example as part of scientific databases. The researchers can only use this information for medical and healthcare-related research.

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 in “Part III: Additional Information for Patients” in the main informed consent.

5 How will my privacy be protected?

Your coded data and biosamples will be subject to appropriate safeguards, as described in the main study information and informed consent form “Part III: Additional Information for Patients” and will only be used for the purpose of scientific health-related research to find new ways to detect, treat, prevent or cure health problems. They will not be used to contact you or to 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 main study information and informed consent form section “What are your rights under data protection law?”.

6 What if I want to withdraw from optional multi-omics research?

Your participation in multi-omics research is voluntary. You are entitled to withdraw your consent 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 continue to participate in the main study even if you choose to withdraw from optional multi-omics research.

If you withdraw from optional multi-omics research, your coded data and biosamples will not be used for further research and will be destroyed as soon as possible. Your coded data

(either copied from the main study database or newly generated) will also be destroyed unless this information is already included in analyses or used in scientific publications.

7 What happens if there are unexpected findings?

The data generated from this optional multi-omics research will not be used to diagnose any disease or sickness, or inform your treatment plan, as it is for research purposes only. We may also have to study coded data and biosamples from many people over many years before we can know if the results are meaningful. Therefore, you should not expect to receive individual results from this optional multi-omics research. We will not give any such data to your doctor and we will not put them in your medical record as they are only for research purposes and not valid for medical care.

8 Who can answer any questions I may have?

Remember, there are no stupid questions! Feel free to ask at ANY TIME! It is your right to be fully informed before deciding to take part in this optional multi-omics research. You can contact the study doctor at any time.

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

INFORMED CONSENT FORM FOR OPTIONAL GENOMICS INITIATIVE RESEARCH

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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 optional multi-omics research (part of AstraZeneca's Genomics Initiative) to me comprehensively.
- I have had the opportunity to discuss the optional multi-omics research with the study doctor and all my questions were answered.
- I have had an adequate amount of time to consider the optional multi-omics research.
- 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 optional multi-omics research as described to me, and accessed and reviewed by listed authorised people;
- My coded data 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 herein.
- My coded data being summarised with other participants data and shared by the sponsor and its designated organisations with other researchers, from other companies or universities for medical and healthcare related research.

I further understand that I can make a choice about the topic 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 and biosamples for optional multi-omics research including the analyses of my genomic information, as described in this consent form.	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 Optional Genomics Initiative 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
subject/Legally Acceptable Representative (LAR)*

Date of Signature

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 (Optional Genomics Initiative Research Information) and duly filled Informed Consent Form shall be handed over to the subject or his/her legally acceptable representative”.