

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,

As well as taking part in the main study, we wish to know whether you agree to donate further **biosamples** for use along with your coded data in an optional multi-omics research project, as part of AstraZeneca's Genomics Initiative.

You have the liberty to agree to the use of your coded data and biosamples for this optional research. If you make a decision not to do so, you can still participate in the main study.

1 What is optional multi-omics research?

Multi-omics research is essential to advance science and public health. Your coded data and biosamples can be used only for scientific health-related research to find new methods to detect, treat, prevent or cure health related problems, or to develop new technologies and approaches that will help with this activity, which include 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 like the UK Biobank or patient groups taken by academic researchers. However, they will not be combined with other information in a way by which you may be identified.

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

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

Proteomics, metabolomics and lipidomics, give insight into the make-up of biological molecules at the time your biosamples are taken and are complementary to the genomic analysis. Multi-omics analyses give a comprehensive view of the role these biological molecules play within your body, how they work and how they are connected together. Much of the multi-omics information is common in all people but some variations may influence the possibility of developing a disease or may be used to guide individualised treatment options to raise the possibility of the drug working.

2 Which further biosamples do I need to give?

If you agree to optional multi-omics research, additional biosamples will be collected from you by us as follows:

- One 3ml blood sample (about 1 teaspoon) for genomic analyses and one 3 ml blood sample (about 1 teaspoon) for multi-omics analyses at the first day of study treatment (before getting any study drug) or at a later visit.

No additional risks are included in this blood collection procedure further to those described in the main study information and informed consent form.

Your further biosamples will be coded like the ones taken for the objectives of the main study and as an added level of security will be labelled with a different code than in the main study before they are used by us for this research project.

3 How will my coded data and biosamples be handled?

All biosamples will be stored securely by AstraZeneca or by another organisation that work with AstraZeneca for up to 15 years and will be later destroyed. Kindly note that the location of the biosamples can change at the sponsor's request.

Any data created from your biosamples will be kept as long as needed for scientific research purposes and permitted by law and will later be destroyed or anonymized. Additional information may be found at <https://www.astrazenecapersonaldataretention.com>.

4 Can my coded data and biosamples be shared?

Your coded data and biosamples may be shared by the sponsor with research partners and/ or they will be deposited in scientific databases as explained in the main study information and informed

consent form in Part III: More Information for Patients. This may involve researchers from universities as well as research hospitals, and drug- or health-related companies. Also, further research may be conducted by the sponsor and its designated organisations where they will share summary data (not your individual data) with other researchers, from other companies or universities, for example. This summary data can be combined with data from other studies, for example as part of scientific databases. This information may only be used by the researchers for medical and healthcare-related research.

Some of the recipients mentioned above may 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, appropriate safeguards and security measures will be taken in order to safeguard and keep your biosamples and coded data confidential as explained in “Part III: More Information for Patients” in the main informed consent.

5 How will my privacy be safeguarded?

Your coded data and biosamples will be subject to appropriate safeguards, as explained in the main study information and informed consent form “Part III: More Information for Patients” and will be used only for the objective of scientific health-related research to find new methods to detect, treat, stop or cure health related problems. They will not be used to get in touch with you or to affect your care or any other decision that affect your life like insurance rates or employment opportunities.

You have the same rights as the ones explained in the main study information and informed consent form section “What are your rights under data protection law?”.

6 What will occur if I would like to leave optional multi-omics research?

Your taking part in multi-omics research are voluntary. You are entitled to take back your consent at any time, without providing a reason and without a negative effect on your standard of medical care. If you would like to leave, kindly let your study doctor know. You may carry on to take part in the main study even if you decide to leave optional multi-omics research.

If you leave optional multi-omics research, your coded data and biosamples will not be used for additional research and will immediately be destroyed. Your coded data (either copied from the main study database or newly created) will also be destroyed unless this information is previously included in analyses or used in scientific publications.

7 What will occur if there are unexpected findings?

The data created from this optional multi-omics research will not be used to diagnose any disease or sickness, or explain your treatment plan, as it is only for research purposes. We may also need to study coded data and biosamples from many people over many years before we can understand whether the results are meaningful. Hence, you must not expect to get individual results from this optional multi-omics research. Any such data will not be given to your doctor by us and we will not place them in your medical record as they are only for research objectives and not valid for medical care.

8 Who may respond to any queries I might have?

Keep in mind, there are no stupid queries! Do not hesitate to ask any questions at ANY TIME! It is your right to get complete information before making a decision to participate in this optional multi-omics research. At any time, you may get in touch with the study doctor.

You have the liberty to agree to the use of your coded data and biosamples for OPTIONAL GENOMICS INITIATIVE RESEARCH. If you consent, you may mention this in the CONSENT FORM

DO NOT USE

INFORMED CONSENT FORM FOR OPTIONAL GENOMICS INITIATIVE RESEARCH

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Investigator:	Dr. Prashant Pandey	Subject E code:	
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I confirm that:

- The optional multi-omics research (part of AstraZeneca's Genomics Initiative) has 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 this optional multi-omics research with the study doctor and all my queries were answered to me.
- I have had a sufficient amount of time to think about this optional multi-omics research.
- 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 involve the following:

- My name and contact details will be taken during the optional multi-omics research as explained to me, and accessed and reviewed by listed authorised people;
- My coded data will be used by the sponsor or by people or companies that act on behalf of the sponsor or who work with the sponsor;
- My coded data will be used by persons or organisations situated in countries that do not have data protection rules equal to rules present in my country. I know that the sponsor monitors these uses and takes all possible measures to safeguard my privacy;
- My biosamples will be taken and analysed as explained herein.
- My coded data will be summarised with other participant's 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 know that I can decide about the below listed topic and that by marking “Yes” I do give consent and that by marking “No” I do not give consent:

The use of my coded data and biosamples for optional multi-omics research which includes the analyses of my genomic information, as explained in this consent form.	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 statements given below.	
(i)	I confirm that I have read and understood the Optional Genomics Initiative 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 leave at any time, without providing 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 require my permission to see my health records both in respect of the present study and any additional research that may be performed in relation to it, even if I leave 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.	[]

*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 cannot give informed consent (for example, an unconscious person or a minor or those with severe mental disease or disability), the same might be obtained from a legally acceptable representative (a legally acceptable representative is a person who can 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 cannot read/write - an impartial witness should be there during the entire informed consent process who must put his/her signatures on the consent form

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.

Signature of Impartial Witness

Date of Signature

Name of Impartial Witness

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