

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,

Additionally, taking part in the main study, we would like to know whether as part of AstraZeneca's Genomics Initiative you would be ready to donate additional **biosamples** for use together with your coded data in an optional multi-omics research project.

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

1 What is optional multi-omics research?

Multi-omics research is vital for advancing science and public health. 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 and approaches that will assist with this activity, which includes developing machine learning and artificial intelligence technologies.

They might also be used jointly with information from other sources outside typical clinical research settings, for example, from public research databases like the UK Biobank or patient groups collected by academic researchers. Though, they will not be combined with other information in a manner that could recognize you.

The analysis of your genetic, and complementary protein, metabolite and lipid information will be included in this research project. These can be mentioned as genomics, proteomics, metabolomics and lipidomics and are collectively known as “omics” that is, **multi-omics**.

You can imagine genetic information as a huge book of instruction that your body reads to understand how your body must be built and function. All humans in their body have the similar instruction book however few words or letters might be different from one individual to the other. Genetic information is stored in your DNA and this research will consist of your DNA analysis and might involve looking at part, or all your genetic information that is, your whole genome. Whole exome or whole genome sequencing technologies might be utilized.

Proteomics, metabolomics and lipidomics, give insight into the make-up of biological molecules during your biosamples are collected 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 link together. In all individuals, much of the multi-omics information is common however few differences can influence the possibility of developing a disease or can be used to guide individualised treatment choices to raise the medicine working possibility.

2 Which additional biosamples do I have to give?

In case you consent to optional multi-omics research, additional biosamples will be collected by us from you as follows:

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

There are no extra risks involved in this method of blood collection additionally to those described in the main study information and informed consent form.

Your additional biosamples will be coded like the ones collected for the main study's objective and as an added level of security will be labelled with a different code than in the main study prior to 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 working with AstraZeneca for up to 15 years and after that will be discarded. Kindly note that the biosamples storage location might be changed at the sponsor's request.

Any data produced from your biosamples will be stored as long as required for scientific research purposes and permitted by law and will be discarded or anonymised after that. Additional information can be found at <https://www.astrazenecapersonaldataretention.com>.

4 Might my coded data and biosamples be shared?

Your coded data and biosamples might be shared by the sponsor with research partners and/ or deposit them in scientific databases as explained in the main study information and informed consent

form in Part III: Additional Information for Patients. Researchers, as well as universities, research hospitals, and drug- or health-related companies might be included in this. Additionally, the sponsor and its appointed organisations might carry out additional research where summary data (not your individual data) will be shared by them with other researchers, researchers from other companies or universities, e.g., This summary data might be combined with data from other studies, e.g., as part of scientific databases. This information can only be used by the researchers for medical and healthcare-related research.

Few of the recipients mentioned above might be situated outside your country. The data protection laws, which are applicable in those countries, might not be as strict as the laws in your country. Nonetheless, in order to secure and maintain your biosamples and coded data's confidentiality as explained in "Part III: Additional Information for Patients" in the main informed consent, suitable safeguards and security measures will be taken.

5 How will my privacy be secured?

Your coded data and biosamples will be subject to suitable safeguards, as explained in the main study information and informed consent form "Part III: Additional Information for Patients" and will only be used for the scientific health-related research's objective for finding new ways for detecting, treating, preventing or curing health issues. They will not be used to get in touch with you or to impact your care or any other decision impacting your life like insurance rates or employment chances.

You have the similar 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 in case I want to leave optional multi-omics research?

In multi-omics research, your participation is voluntary. At any time, you are entitled to take back your consent, without providing a reason and without a negative effect on your standard of medical care. Kindly inform your study doctor, in case you wish to leave. Even though you make a choice to leave optional multi-omics research, you might carry on to take part in the main study.

In case you leave optional multi-omics research, your coded data and biosamples will not be used for additional research and will be discarded as early as possible. Your coded data (either copied from the main study database or newly produced) will also be discarded unless this information is already included in analyses or utilized in scientific publications.

7 What occurs in case there are unexpected findings?

The data produced from this optional multi-omics research will not be used to diagnose any disease or sickness, or inform your treatment plan, as it is only for research purposes. We might also have to study coded data and biosamples from many individuals over many years prior to we can know 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 provided by us to your doctor and we will not put them in your medical record as they are for research purposes only and not valid for medical care.

8 Who can answer any queries I might have?

Keep in mind, that there are no stupid queries! Feel at liberty to ask at ANY TIME! It is your right to be completely informed prior to making a decision to participate in this optional multi-omics research. At any time, you can get in touch with the study doctor.

You are at liberty to consent to your coded data and biosamples use for OPTIONAL GENOMICS INITIATIVE RESEARCH. In case you consent, you can specify this in the CONSENT FORM

DO NOT USE

INFORMED CONSENT FORM FOR OPTIONAL GENOMICS INITIATIVE RESEARCH

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I affirm that:

- The study doctor or study staff appointed by the study doctor has/ have described the optional multi-omics research (part of AstraZeneca's Genomics Initiative) to me in detail.
- I have had the chance to discuss the optional multi-omics research with the study doctor and answers were given to all my questions.
- I have had a sufficient amount of time to think about the optional multi-omics research.
- I have honestly answered all queries regarding my medical history and will comply with all rules listed in the document.

I am aware that my participation also includes:

- At the time of the optional multi-omics research, my name and contact details being gathered as explained to me, and accessed and reviewed by listed authorised individuals;
- My coded data being used by the sponsor or by individuals or companies acting on behalf of it or working with the sponsor;
- My coded data being used by individuals or organisations situated in countries that do not have data protection rules equal to those of my country. I am aware that these uses are monitored and all possible measures are taken to secure my privacy by the sponsor;
- As explained in this, my biosamples being collected and analysed.
- My coded data being summarised with other participants' data and shared by the sponsor and its appointed organisations with other researchers, from other companies or universities for medical and healthcare related research.

I additionally understand that I can make a choice regarding the topic listed below and that by putting a tick on “Yes” I do provide consent and that by putting a tick on “No” I do not provide consent:

The utilization of my coded data and biosamples for optional multi-omics research which includes my genomic information analyses, as explained in this consent form.	Yes ☐	No ☐
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Sl. No.	Kindly give your initials (short signature or signature) or thumb impression (as applicable) besides each one of the given below statements to affirm your consent to these statements	
(i)	I affirm 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 have had the chance to ask queries.	[]
(ii)	I am aware that my participation in the study is voluntary and that at any time I am at liberty to leave, without providing any reason, without my medical care or legal rights being impacted.	[]
(iii)	I am aware that even though I leave the trial, the clinical trial's Sponsor, others working on behalf of the Sponsor, the Ethics Committee and the regulatory authorities will not require my permission to look at my health records both in respect of the present study and any additional research that might be carried out concerning it. I consent to this access. Though, I acknowledge that my identity will not be disclosed in any information released to third parties or published.	[]
(iv)	I consent not to limit the use of any data or results that emerge from this study given such a use is only for scientific reason(s)	[]
(v)	I consent 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 is unable to provide informed consent (for example, an unconscious individual or a minor or those suffering from severe mental illness or disability), the similar might be acquired from a legally acceptable representative (a legally acceptable representative is an individual who is able to provide consent for or authorize an intervention in the patient as given by the law(s) of India).

Relationship of legally acceptable representative to subject

Signature of the Investigator

Date of Signature

Study Investigator's Name

In case the Subject or his/her legally acceptable representative is not able to read/write - an impartial witness must be present at the time of the complete informed consent process who should put his/her signatures on the consent form

Impartial witness is an individual who is independent of the trial, who cannot be influenced unfairly by individuals involved with the trial, who is present during the informed consent process in case 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

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