

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		

In this document, there are 3 parts:

- Part I: The “**Study Information**” is important to your decision to participate in the clinical study.
- Part II: your “**Consent Form**” which summarises what you may consent to,
- Part III: supplementary information in the “**Additional information for patients**” Section, including a glossary.

PART I: STUDY INFORMATION

Dear Madam/Sir,

You are invited to participate in this study as you have been diagnosed with Biliary Tract Cancer, which has spread (locally advanced or metastatic). Your written consent is needed for participation. Before you decide whether you wish to take part in this study, you will be given an explanation about what is included in the study.

An Institutional Ethics Committee, which is an independent body, have reviewed the overall explanation of this study, for example, the collection, storage, and use of **your data, biosamples**, and documentation, etc. in your country to make sure that the rights, safety, and well-being of study patients are safeguarded.

Your condition may or may not improve if you participate in the study. However, the information we receive from this study may help other patients having the same condition in the future.

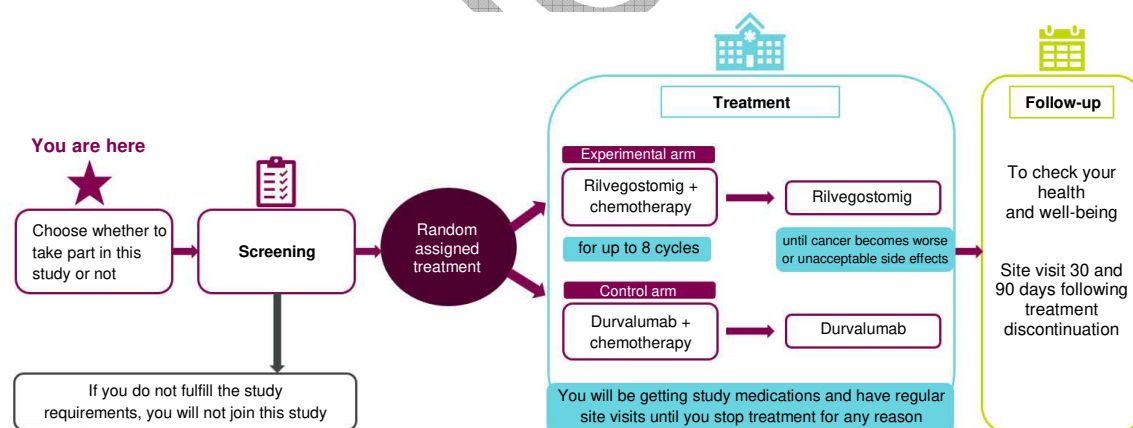
1 What is this study regarding?

This study is being conducted by us to learn more about treatment with a study medication known as rilvegostomig (also known as AZD2936), administered in combination with chemotherapy (gemcitabine and cisplatin) in patients with advanced biliary tract cancer. We will compare the efficacy and safety of rilvegostomig in combination with chemotherapy to that of standard treatment for advanced biliary tract cancer (durvalumab in combination with gemcitabine and cisplatin). This study is also conducted by us to better understand advanced biliary tract cancer and associated health problems.

This study is also testing the PD-L1 diagnostic test to find out which advanced BTC patients might benefit most from rilvegostomig with chemotherapy. This research is being conducted by us to gather important information that can help support approval of the test in countries where needed.

Some parts of this study are experimental which means Rilvegostomig has not been approval by any health authority, except for use in research studies such as this.

The picture below summarizes the ARTEMIDE-Biliary02 study. Every part of this study will be explained in **Section 2**. Approximately 1600 patients will be screened, which contains a series of tests that include testing your tumor sample for PD-L1. Approximately 1100 patients will participate in this study.



How do the study medications work?

Rilvegostomig

Rilvegostomig may help your immune system fight your cancer. It works by blocking two proteins known as PD-1 and TIGIT on cells of your immune system. Cancer cells use PD-1 and TIGIT to avoid being attacked by the immune system. By blocking PD-1 and TIGIT, rilvegostomig may help your immune system to find and attack cancer cells. The experimental treatment in this study is Rilvegostomig.

Durvalumab

Durvalumab works by blocking a protein known as PD-L1, which is used by cancer cells to evade the immune system. This allows the immune system to better identify and target the cancer cells. Immunotherapy medications such as durvalumab are used for treating various types of cancer. In biliary tract cancer, durvalumab in combination with chemotherapy (gemcitabine and cisplatin) have been given approval for treating advanced biliary tract cancer. However, not every cancer would react to this treatment, or the response might not take long.

Chemotherapy (gemcitabine and cisplatin)

Gemcitabine and cisplatin are chemotherapy drugs used to treat different types of cancer. They are used together in advanced biliary tract cancer and at times referred to as GemCis. They work by killing or slowing the growth of cancer cells.

2 Do I need to participate?

You have a choice whether you wish to take part or not.

Kindly take as much time as you need to decide whether you wish to take part in this study or not. It might be helpful to speak with your friends and family as you decide.

If you participate in the study, you may withdraw from it at any time (see “section 14” for additional details). Your care will not be affected by withdrawal. If you decide to withdraw from the study, kindly inform your study doctor immediately.

Kindly think about the study time commitments and responsibilities as a research patient when you are making a decision to participate.

If you do not participate in the study, you will carry on to get care for your Biliary Tract Cancer. Other possible drugs, their risks and benefits will be discussed with you by your study doctor or treating physician.

3 What will occur if I participate in the study?

You will be in the study for up to 4 years. Your taking part in the study might require it to be longer to get better answers to the study queries.

A screening period, treatment period, and follow-up period are included in this study.

Before you start the study treatment

You will have a series of tests. This is known as screening.

You will have about 1 to 2 visits at the study site (clinic where you need to go for study visits). The length of the visit is different and based on the tests that need to be conducted.

If you fulfill all requirements, a computer will randomly assign you to one of two treatment arms (this is known as **randomization**). Your study doctor will explain if you have been assigned to the combination of rilvegostomig plus gemcitabine and cisplatin (the experimental arm) or durvalumab plus gemcitabine and cisplatin (the control arm). Randomization in a clinical trial is used to ensure patients in both treatment arms have similar characteristics and that treatments may be compared as fairly as possible. Randomization means you will have a 50% possibility of being in either the experimental or control arm (such as tossing a coin).

If you do not fulfill the screening criteria, the reasons will be explained. Other possible treatments will be discussed with you by your study doctor or treating physician.

While you get study treatment

Study treatment (rilvegostomig or durvalumab in combination with chemotherapy) will be given through infusion (into the vein), as per the treatment arm you were allotted to at randomization (see above). For the first 6 months (8 cycles), rilvegostomig or durvalumab will be given in combination with chemotherapy – gemcitabine and cisplatin. On days 1 and day 8 of each 3-week cycle, gemcitabine and cisplatin are administered as two infusions into the vein. After 8 cycles of chemotherapy treatment are completed, you will carry on to get rilvegostomig every 3 weeks or durvalumab every 4 weeks.

You will carry on to get treatment as a part of this study until one or more of the following occurs:

- Your biliary tract cancer gets worse.
- You have side effects that need you to stop treatment.
- You decide to stop treatment.
- The study doctor and/or AstraZeneca (*Sponsor*) decide to stop your participation.
- Applicable only to female participants able to bear a child: you get pregnant or intend to get pregnant.

If your doctor observes signs which your cancer may have worsened, you may be permitted to continue getting study treatment for about 4 more weeks, provided you are feeling well and your doctor considers you are still benefiting from the treatment. You will undergo another scan after this time. If the new scan confirms that the cancer is definitely worsening, you will require to stop taking the study treatment.

If you wish to stop taking the study treatments, wish to have a modified visit schedule, or if you wish to stop your participation in the study, you must inform the study doctor.

You will be asked to download UNIFY on your device, or a device will be given to you with this App previously installed. You will be asked to accept the UNIFY license agreement and privacy notice once you log in into the App for the first time. You will be supported by UNIFY during the trial, and you will be given further information about this by your study team. You will be asked during and after your treatment to complete short questionnaires about how you are feeling and your experience in this study. You will be given UNIFY once available and appropriate approval has been obtained.

After the study is completed, study interventions rilvegostomig and durvalumab will be available for patients who are still getting them. Kindly note that the study, and your taking part in the study, might be stopped earlier than expected, for example, for scientific or safety reasons (see “section 9” for more details).

There are different options for continuing treatment with study medication after the study has completed, or after your taking part in the study has completed. You may continue getting study drug treatment as long as you are benefiting from the study

drug, in the opinion of your doctor. The available options will be discussed with you by your doctor. These options may involve further treatment within this present study, transitioning to another study, or transitioning to an optional drug supply. If you are transitioning to another study, a new study informed consent form will be given to you, as applicable. If you carry on treatment within this present study, your treatment plans will be as per the standard of care or according to local clinical practices.

After you have obtained study treatment (Follow-up)

After you stop treatment, you will still be asked to regularly visit the clinic until the completion of the study. This is to find out whether you have begun a new treatment, evaluate whether your cancer has become worse, and confirm you are alive as part of the follow-up period. If your cancer becomes worse and study treatments have been discontinued, we might follow-up with you by phone instead of clinic visits. At any time, you may decide to withdraw from the study.

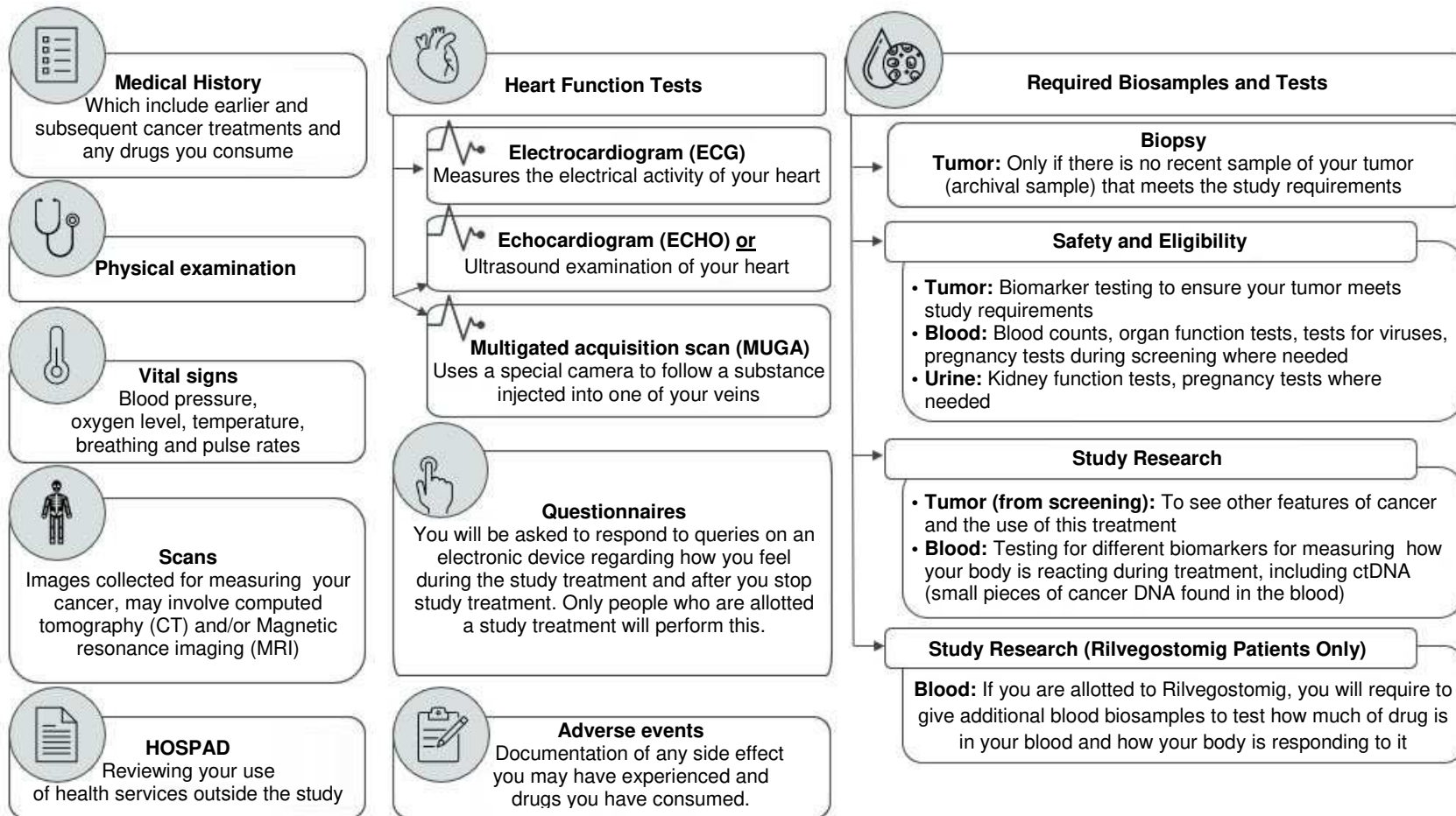
If you are not able to come to a visit during any part of the study, you should inform the study doctor immediately.

There is a possibility that you may need to go to another facility to have some of the evaluations/procedures for this study. You will be informed by your study doctor in case you require to go to another facility for any evaluations/procedures. Your visit will be organized to another facility by your study doctor in case it is needed.

4. What are the needed tests and procedures?

While you are on the study, some measurements and biosamples, for example, small amounts of blood or urine, will need to be taken by us.

This is a list of the various tests and procedures you may expect to have while taking part in this study:



The complete list of study tests and procedures, which includes their detailed schedule, is available in Part III, section 2, “Additional information for patients”. More details about **biosamples** handling, collection, and storage locations are also given in this section.

PD-L1 level testing of your tumor, To participate in this study, we require a small piece of your tumor tissue for testing. This is needed for everybody who joins the study. We might use a sample that was earlier taken and stored from a past biopsy or surgery, provided it was collected within the last 12 months before you join the study. If a recent sample is unavailable, you may need to have a new biopsy to gather this tissue.

PD-L1 is a protein found on the surface of some cancer cells. It works like a “shield,” which helps cancer cells hide from your immune system in order they are harder for your body to find and fight. We will use a special lab test called the investigational Ventana PD-L1 (SP263) CDx assay in this study to check for PD-L1 in your tumor tissue. This test is given approval to evaluate PD-L1 levels in some cancer types in some countries, but it is not given approval for use with rilvegostomig in biliary tract cancer. The PD-L1 test result is being used in this study as a stratification factor, which means making sure of the two arms of the study (experimental and control arm) are balanced as per PD-L1 status. This helps to make sure that the study results are fair. We will also be investigating if your tumor samples and study data, which include PD-L1 results, may identify biliary tract cancer patients who may be more likely to benefit from the study medication.

If your tumour sample have previously been sent for central laboratory testing with the investigational VENTANA PD-L1 (SP263) CDx Assay to confirm PD-L1 status in another AstraZeneca study, then this result might be used to determine your suitability for this study, provided that the testing was conducted at the same lab and the sample meets the requirements of this study. By agreeing to this study, you agree to the reallocation of your PD-L1 result, if applicable, and any tumour samples given as part of another AstraZeneca study for the objectives of this study. If you do not

wish this result and tumour samples reassigned from other studies, and instead would prefer to give new tumour samples, kindly let your doctor know right away.

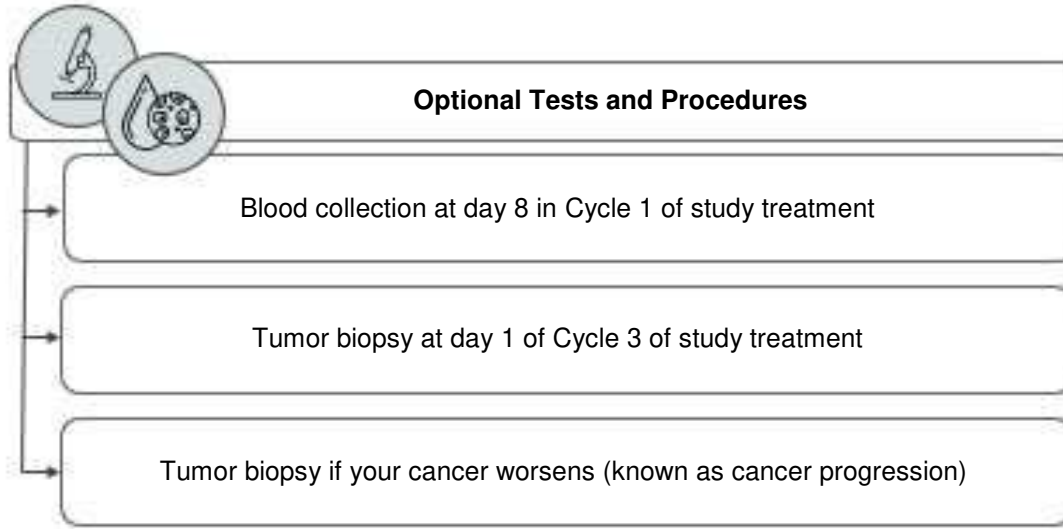
Tumor Genetic Analyses

Some biosamples will be used to analyse your genetic information. 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 bodies have the same instruction book, but some words or letters may vary from one individual to the other. Some of those variations have no effect on your health, but others may influence the possibility of developing an illness or affect how a drug for treating a disease will work. All your cells have the same DNA, but tumor cells might develop changes known as mutations. To find these, tumor DNA may be in comparison to DNA from your normal blood cells, helping us understand your cancer and guide treatment. If genetic analyses are conducted, they might include all or part of your genetic information using your tumor tissue samples and circulating tumor DNA (ctDNA) that might be found in your blood, as well as, if needed, your normal blood cells. These analyses will be done in the context of the main study objectives. In this study, the genetic analyses being performed are for exploratory purposes and will be done retrospectively, which means the analyses are performed at a later date and may not be done until after the completion of your participation in the study. Outcomes from these analyses will not be shared with you or your study doctor.

5. What are the optional tests and procedures?

In this study, the following tests and procedures are optional. If you consent, you may give your consent by marking the checkbox in the consent form. You may agree to all optional procedures and biosamples, or only one, or you do not need to agree at all. The tumor and blood samples (biosamples) taken from these optional collections may be reviewed for additional features of your tumor and the reaction of your immune system to treatment. These biopsies, biosamples, and results obtained from these biosamples are not expected to affect your medical care directly. If you do not agree to the optional procedures, you may still take part in this study. If you would like to change your mind about using additional sample(s) for further research, you may do so at any time and let your study doctor know.

If you agree, biosamples may be taken during the study for optional tests as follows:



6. What are the risks of participating in the study?

There is a risk that your biliary tract cancer will not improve or even worsen at the time of the study. There is a possibility that some patients may experience side effects that we are not aware of as yet. It is possible that there could be a failure of the investigational product to give the intended therapeutic effect. If you experience severe side effects from the study medication, you may be asked by the study doctor not to continue treatment in the study. You might also be asked to delay study treatment doses to allow the side effects to improve. Managing side effects can also need the administration of drugs like steroids or other agents, which may affect your immune system and decrease inflammation.

If you have any side effects or injuries, or your condition worsens, let the study doctor know right away so you may get proper care.

Potential risks related to rilvegostomig

There are limited data on rilvegostomig use in humans, hence the risks of rilvegostomig are not completely known currently. You may have side effects that may be very serious in nature (which include the risk of death) and never get better. Using information available about medications that work in a similar manner to rilvegostomig and the known information from research studies with rilvegostomig, the Sponsor (AstraZeneca) have determined the following possible side effects may happen when rilvegostomig is given.

1. Identified risks:

- **Infusion-related reactions** are side effects that happen during or shortly after (up to 24 hours) getting a drug intravenously. Fever, chills, muscle pain or tenderness, nausea, vomiting, itching, rash, increase in heart rate, breathing difficulty, decrease in blood pressure, or light-headedness may be included in these reactions. The infusion-related reactions observed with rilvegostomig have so far been mild, manageable, and resolved.
- **Rashes** seen with rilvegostomig were particularly low-grade and reacted well to treatment.

2. Possible Risks:

- **Skin related reactions:** you may observe itching, blisters, and/or hair loss.
- **Large Intestinal Inflammation (Colitis):** You may have diarrhoea.
- **Endocrine abnormalities** (inflammation of the hormone-producing glands in your body): you might have tiredness, weight changes, abnormal blood sugar levels/ diabetes, nausea, and skin changes.
- **Lung Inflammation (Pneumonitis):** You may have a cough and/or breathlessness. When measured, your blood oxygen levels can be reduced.
- **Liver Inflammation (Hepatitis):** This can be without symptoms, or you might have symptoms, which include jaundice and itching.
- **Kidney Inflammation (Nephritis):** you can observe changes to the amount and colour of your urine and/or observe swelling of the face and ankles.
- **Muscle Inflammation (Myositis):** a reaction of your muscles that causes muscle pain.
- **Pancreatic Inflammation (Pancreatitis):** mild forms may be without symptoms. You may have fever, nausea, abdominal pain, tiredness, or jaundice.
- **Inflammation of your heart muscle (Myocarditis):** you might have chest pain and irregular heartbeats.
- **Brain Inflammation (Encephalitis):** You can have confusion,

problems associated with speech or movement.

3. Other possible risks involve, but are not limited to the following:

- **An acute severe allergic reaction** (which is known as anaphylaxis) is a rare side effect that generally happens during, within minutes, or up to 24 hours after taking a drug. Symptoms involve swelling of the vocal cord, the face or voice box area, breathing difficulty, and/or possibly death.
- **Immune complex disease** might happen if a patient forms antibodies to rilvegostomig. Symptoms can involve aching joints, rash, fever, a reaction in the kidneys (nephritis), or blood vessels inflammation (vasculitis).
- **Cytokine release syndrome** is a syndrome occurring when immune cells are activated and causes an increase in inflammation all through the body. Symptoms might involve fever, headache, rash, low blood pressure, low blood oxygen levels, rapid heart rate, and breathlessness. In the majority of patients, the symptoms are mild to moderate in severity, but it may be severe and life threatening (cytokine storm syndrome).
- **Tumor lysis syndrome** is a rare condition occurring with the rapid breakdown of cancer cells. This can cause nausea, vomiting, muscle cramps, weakness, decrease in urination.
- **Abnormal laboratory results**, which include increased triglycerides and cholesterol levels, increased digestive enzymes: amylase and lipase. Increased potassium level and a decrease in the concentration of sodium in the blood.
- **Embryo-fetal toxicity** is an effect on the pregnant female that may cause harm to the developing embryo or fetus.
- **Graft-versus-host disease** development after hematopoietic stem cell transplantation is a complication when the donated cells (the graft) see your body cells as foreign and they are attacked. Symptoms might involve the gastrointestinal tract, liver and skin problems. Some might be mild, but it may be severe and life threatening.
- **Rejection of transplanted organs.**

Risk and side effects associated with durvalumab

Most of the possible side effects mentioned below are mild to moderate. However, some side effects may be too serious and life threatening, and may even lead to death. Some side effects do not require treatment, while others usually improve with treatment.

Very common (observed in over 1 in 10 people)

Diarrhea
Rash/Dry itchy skin
Pain in the abdomen
Upper respiratory tract infections
Cough
Fever
An underactive thyroid gland, which can cause tiredness or weight gain (Hypothyroidism)

Common (observed in over 1 in 100 people)

Lung Inflammation (pneumonitis)
An overactive thyroid gland, which may cause a fast heart rate or weight loss (Hyperthyroidism)
Changes in laboratory tests associated with kidney and liver function
Infusion-related reactions
Pain in Muscles and joints (Myalgia)
Pneumonia
Influenza
Hoarse voice
Pain while urinating
Night sweats
Fungal infection in the mouth (Oral candidiasis)
Dental and oral soft tissue infections
Fluid accumulation, which causes swelling, e.g., in the legs

Uncommon (observed in less than 1 in 100 people)

Decrease in secretion of hormones produced by the adrenal glands (Adrenal insufficiency)

Scarring of lung tissue (Interstitial lung disease)

Liver Inflammation (Hepatitis)

Kidney Inflammation (Nephritis)

Inflammation of the skin (dermatitis)

Muscle Inflammation (Myositis)

Intestinal Inflammation (Colitis)

Thyroid gland inflammation (Thyroiditis)

Pancreatic Inflammation (pancreatitis)

Rare (seen in less than 1 in 1,000 people)

Type 1 Diabetes Mellitus

Multiple muscle inflammation (polymyositis)

Muscle Weakness (myasthenia gravis)

Underactive function of the pituitary gland (Hypophysitis/Hypopituitarism)

Heart Inflammation (Myocarditis)

Blistering rash (Pemphigoid)

Imbalance in body fluids and electrolytes (Diabetes Insipidus)

Reduction in cells that help your blood clot (Immune thrombocytopenia)

Brain Inflammation (encephalitis)

Inflammation inside the eye (Uveitis)

Nervous system disorder (Guillain-Barré syndrome)

Joint Inflammation (Immune-mediated arthritis)

Risk of combination of chemotherapy with rilvegostomig or durvalumab

The possible risks and side effects of chemotherapy plus rilvegostomig or durvalumab depend on the identified risks of each individual drug. No Additional risks are not currently anticipated when chemotherapy is a combination with either rilvegostomig or durvalumab, beyond what is expected for each individual drug. It is common for patients having advanced biliary tract cancer to get chemotherapy (gemcitabine plus cisplatin). The risks and possible side effects of chemotherapy will be explained to you by the study doctor.

Potential risks of study procedures

Some of the study procedures might have potential side effects, risks, and discomforts. You may have none, some, or all. The procedures conducted as part of this study are standard and routine procedures; you might have these procedures more often if you participate in this study. These can be explained to you in detail by the study doctor, and information about any risks and/or side effects related to these can be given to you.

Risks related to biopsy

If a sample of your tumor is not available (for example, taken from the time you were diagnosed) that meets the requirements of the study, your new tumor sample will need to be taken by biopsy. Based on where a biopsy is collected from, risks might involve pain, bleeding, injury of the liver or bile ducts, and infection. In very rare instances, serious complications may occur that may even result in death. In addition, there is a hypothetical risk of regional spread of cancer cells when the needle is taken out from your tumor. Your study doctor will discuss with you the most appropriate manner to get a biopsy from your tumor and other possible risks. You might be asked to separately agree to the biopsy procedure.

Risks related to PD-L1 testing

A valid PD-L1 result is compulsory to join the study.

There is a minor risk that the sample you give will not provide us with a result; it is a failed or invalid test. In this instance, we might ask your doctor if another sample is available to be tested. The possibility of a successful test result will be increased by this.

There is a minor risk that your test result can be delayed, but measures have been put in place to reduce the risk of a delayed test result. It's also essential to understand that the PD-L1 test is conducted in the laboratory using your tumor sample. The equipment used for the test does not come into direct contact with you, so no risk of harm or injury will occur to you from the testing itself.

7. Are there any other considerations or risks I need to understand?

Pregnancy, contraception, and nursing

As there are unknown effects of the study drugs on an unborn child or infant, you (or your female partner if you are a male) should not become pregnant or breastfeed from entering the study until 60 days after the last rilvegostomig dose, 90 days after the last durvalumab dose, and 6 months after the last chemotherapy dose, whichever is longer.

There might be other things to think about, and the needed time of contraception might be longer while you are getting chemotherapy as well. You will be informed by your study doctor if this is the case.

For female patients:

Females who can get pregnant and intend to be sexually active with a male partner who is of childbearing potential (are non-sterilized) should use at least 1 highly effective contraceptive method from entering the study until 60 days after the last rilvegostomig dose, 90 days after the last durvalumab dose or 6 months after the last chemotherapy dose, whichever is longer. In some instances, local guidelines may need a longer period, and you will be informed by your doctor if this is the case. Your male partner should also use a male condom plus spermicide throughout this period.

If you get pregnant, you should inform the study doctor immediately. You will need to stop consuming the study drug right away until you have discussed it with your study doctor. You will be asked to give information regarding you and your baby. This might include a separate consent to allow us to monitor the health and development of your baby.

For male patients:

Men who can father a child (are non-sterilized) and intend to be sexually active with a female partner who can get pregnant should use a male condom plus spermicide from enrolling in the study until 60 days after the last rilvegostomig dose, 90 days after the last durvalumab dose, or 6 months after the last chemotherapy dose, whichever is longer. In some instances, local guidelines may need a longer period, and you will be informed by your doctor if this is the case. Your female partner should also use a highly effective contraceptive method throughout this period. If your partner gets pregnant, you should inform the study doctor right away. Your partner will be asked, under a separate consent, to give information about their health and the health of your baby.

Note that some methods of contraception are not considered highly effective. Kindly see the table below for examples of highly effective contraceptive methods.

Examples of highly effective contraceptive methods (<1% failure rate):

Non-hormonal methods	Hormonal methods
Intrauterine device (provided coils are copper-banded)	- Injection: Medroxyprogesterone injection (eg, Depo-Provera[®]) - Levonorgestrel-releasing intrauterine system (eg, Mirena[®]) - Implants: Etonogestrel-releasing implants (eg, Implanon[®] or Nexplanon[®]) - Intravaginal devices: Ethinylestradiol/etonogestrel-releasing intravaginal devices (eg, NuvaRing[®]) - Combined pill: Normal and low-dose combined oral contraceptive pill - Patch: Norelgestromin/ethinylestradiol-releasing transdermal system (eg, Xulane[®], Ortho Evra[®]) - Mini pill: Progesterone-based oral contraceptive pill using desogestrel: Cerazette[®] is presently the only highly effective progesterone-based pill

The study doctor may speak with you more about the acceptable methods of birth control.

Other drugs and remedies you may be consuming

You require to inform the study staff regarding any other drugs, vitamins, or herbal remedies (which include recreational medications like marijuana) which you are consuming.

The way certain drugs are managed by your body may be changed by rilvegostomig or durvalumab. Particularly, you will be advised against the use of immunosuppressive drugs (medications that dampen your immune system), like systemic (taken by mouth or by injection) corticosteroids, whilst on study. If relevant, your study doctor will discuss this further with you and think about optional drugs as appropriate.

Blood, sperm, and egg donation

You should not donate blood or blood components, sperm or ova (egg cells) from screening until 60 days after the last rilvegostomig dose, 90 days after the last durvalumab dose or 6 months after the last chemotherapy dose, whichever is longer.

Vaccines

You must not be given certain kinds of vaccines (known as live attenuated vaccines) from 30 days before the first treatment dose on the study until 30 days after the last study treatment dose. You must not get a COVID-19 vaccination in the 3 days before getting the first study treatment dose. You may be informed by your study doctor more about vaccines that are permitted whilst you are getting study treatment.

8. What are the potential benefits of participating?

We are not aware whether participating will help your condition, but we hope that it will.

The information the study **Sponsor** gets from this study might help to better treat patients suffering from biliary tract cancer.

It is uncertain that you will benefit directly from the participation in the study. However, your participation may help other patients in the future by making the knowledge of diseases better and improving medical care.

9. What occurs if something changes during my participating in the study, e.g., if new information is found?

Changes may occur in the study that may make you change your mind about continuing to participate in the study. We will inform you immediately if something changes.

At any time, you may decide to withdraw from the study. For additional details, see section 14 below.

The study doctor may also decide to remove you from the study if they believe that it is beneficial for you.

When the **Sponsor**, health authorities, the ethics or regulatory agencies decide that the study must be stopped, your participation in the study also stops.

10. What will occur if I am harmed or have an injury during the study, and in such instances, who will pay financial compensation?

In case there is an emergency, contact your study doctor immediately or go to the closest emergency room and get in touch with your study doctor as soon as you can. All relevant contact details may be found in part 3: "Additional information for patients".

If you become sick or have an injury while you are in this research study, you should let your study doctor know immediately.

Injuries that have been due to the study medication, tests, or procedures are known as "trial-related injuries". Injuries caused by your usual medical care or your biliary tract cancer are not trial-related injuries.

COMPENSATION FOR TRIAL-RELATED INJURIES

If you have an injury during the clinical trial, AstraZeneca, the clinical trial sponsor, shall give you medical management free of cost as long as needed or till such time it is established that the injury is not associated with the clinical trial, whichever is earlier, as per rule 40 of G.S.R.227(E).

In case of a trial-related injury or death, the sponsor or the investigator or centre, as the case might be, as per the rule 39 (i.e., Indian regulation for Compensation in case of injury or death in clinical trial of new drug or investigational new drug), as the case might be, shall give financial compensation for the injury or death.

The financial compensation will be in addition to any costs incurred on the medical management of an injury that occurs to you as a clinical trial subject. In case of a study-related injury, the health authority of India determines the compensation to be given to you or your nominee. Therefore, in case you suffer from a study-related injury or death, according to the directive of the health authority of India, AstraZeneca will pay compensation to you or your nominee.

An insurance has been taken out by AstraZeneca to cover clinical study-related injuries or death. In order for AstraZeneca to get proceeds from this insurance for your study-related injury or death, the insurance company may request for your medical records and/or your signed informed consent form for this study. There is also a possibility that the health authority of India would ask for your medical records and/or your signed informed consent form to assess a study-related injury. If your medical records and/or your signed ICF have to be shared by AstraZeneca with the insurance company or the health authority, proper care will be taken to safeguard your privacy.

If you are having medical insurance, kindly check with your insurance company that your coverage will not be affected by participating in this research study.

11. What will occur to my data and biosamples collected in the study?

a. Which data and biosamples are taken?

In order to perform the study, information about your identity (like your name, address, telephone number, and health insurance number) also data that is needed to evaluate your health conditions like your medical condition and medical history (this may involve information from your physicians / available in your medical records), your lifestyle, your demographics (age, gender, ethnic and racial background), your images and data generated from the images (for example scans) and your genetic information will need to be collected and registered by the **study site**.

Data taken through devices or apps on a smartphone, website, or other tool will also be part of your coded data. Your answers to questionnaires using a smartphone or handheld device will also be taken. For additional details about which data that is taken in the study, see additional details at the end of this document in part 3: "Additional information for patients".

Also, biosamples will be collected from you (like blood or body tissue) by the study site. These will be analyzed, and the data obtained from the analysis will be part of your **coded data**, which will also involve genetic data and images.

b. What are my data and biosamples are required for?

Your data and biosamples are needed for the **sponsor** to develop the drug and associated diagnostic devices (together with Ventana Medical Systems Inc), get permission to introduce and keep it on the market, monitor its safety, and get it

reimbursed, for example, by governments i.e., throughout the drug development program. Hence, they will be used as planned in this study and also within related research activities needed for this drug development program, in order to:

- Know about how the study drug(s) and similar drugs work in the body (i.e., assess the study drug's mode of action, alone or combined with other study medications),
- understand the studied disease and associated health problems in a better way,
- *develop diagnostic tests for the disease by evaluating whether the diagnostic tests may identify patients who will most likely benefit from the study drug in a clinical performance study, future diagnostic development, and diagnostic approval in countries where needed.*
- learn from previous studies to plan new studies or make scientific analysis methods better,
- publish research results in scientific journals, or use them for educational purposes.

c. Who may access my data and biosamples?

To conduct the study, your name and contact details will be accessible to the study doctor and the study team only at the study site. Personnel that act on the **sponsor's** behalf and being bound by a duty of confidentiality, and also **Health authorities** and Ethics Committees, might also be given access to this data only to verify that the study is conducted in compliance with legal and quality requirements. Some of your data might be accessed remotely, where permitted.

Your data and biosamples will be shared by the study site with the **sponsor**, but only after they have been coded (meaning that your name, contact details, or health insurance number have been replaced by a code. For additional information about coding, see details at the end of this document in the Glossary in part 3: "Additional information for patients". This involves coded data and biosamples taken following consent during the screening period, even if you will not be enrolled in the study.

Your coded data and biosamples may be shared by the **sponsor** with its **Research partners** and **Service providers** for the objectives of the drug and diagnostic device development program. To get permission to market the drug and diagnostic test, your coded data and biosamples will also be shared by AstraZeneca with the manufacturer of the test/device (Ventana Medical Systems, Inc.) as well as health authorities, and possibly with Ethics Committees to make sure of appropriate conduct and accurate results of the study.

In order to make sure of appropriate conduct and accurate results of the study and to get permission to market the drug and diagnostic device, your coded data will be shared by the **sponsor** with health authorities and possibly with Ethics Committees. They can also be shared with scientific journals, so that the study results may be reviewed by independent scientists and to make sure of the accuracy of the results.

In the event of adverse events or device deficiencies associated with the investigational test, your coded data may be shared by the sponsor with health authorities and ethics committees as per applicable regulations. This involves any serious adverse events that threaten your life, need an emergency visit to the hospital, prolong your hospital stay, result in disability or death, which are connected with the diagnostic test or a study procedure connected with the test – For example, a complication in a study related biopsy procedure required for study eligibility which needs you or prolongs your stay in hospital.

In none of these cases your identity will be disclosed.

Some of the persons mentioned above may be situated outside your country. If this other country does not have equivalent personal data protection standards as your country, appropriate **safeguards** (like contracts and technical **security measures**) will be adopted to safeguard and keep the confidentiality of your data and biosamples, as further explained at the end of the document in part 3: “Additional information for patients”.

In case development or commercialisation of the study drug is taken over by another organisation, your coded data or biosamples may be sent to them. They will then need to safeguard your data and biosamples in the same manner as explained herein.

d. Who else can have access to my contact information, and why?

Your name or contact details might be shared with service providers, in order to:

- Reimburse you for your time, effort, and certain costs associated with your participation.
- Set up and manage your accounts for any apps or other devices which are used in the study. The data that is taken and processed in the study via the App is detailed in Part 3, Section 3 of this document.
- Give technical support for any mobile application which is used in the study. If you contact the App provider support helpdesk, your name and phone number may be taken (with your permission) if a follow-up contact is needed,

for example, your issue is not resolved, and Helpdesk needs to get in touch with you. The information will be removed after your ticket is resolved. Your name or contact details must be kept confidential by the service providers, and any information that may directly identify you will NOT be shared with the Sponsor.

Your contact details may be taken when you use the Unify App, but will be used only for technical support purposes and are subject to the same data protection standards as other personal information.

The data that is taken and processed in the study via the Unify App is detailed in Part 3, Section 3 of this document.

Your name or contact details must be kept private by the service providers, and any information that can directly identify you will NOT be shared with the **sponsor**.

e. How long will my coded data and biosamples be stored?

All study data are obliged to be kept by the study site and the **sponsor** for 25 years after the completion of the study, unless there is a legal requirement for keeping them longer. Your coded data will be removed or anonymised at the end of this retention period.

For additional details about anonymizing, see part 1 section 11g: "What does anonymised data mean?".

Your biosamples taken during the study will be given back to your study doctor or destroyed immediately after the tests mentioned in part 1, sections 4 and 5, for the drug development program are completed, unless you give consent for future research.

If you authorize the **sponsor** to use your samples for future research (In a separate "Future Research ICF a tick-box" that will let you to make this decision), your biosamples will be stored for a maximum of 15 years.

f. What are my rights under data protection law?

You have the right to review which of your data is taken and being used; you may also ask for a copy of this data, ask for restriction of use of this data, or ask to have a rectification of incorrect data.

In case you agree to Future Research (In a separate "Future Research ICF), you can also ask the study doctor to get a copy of the data you have provided for the future

research in a standardised electronic format or to have them sent to another person of your choice.

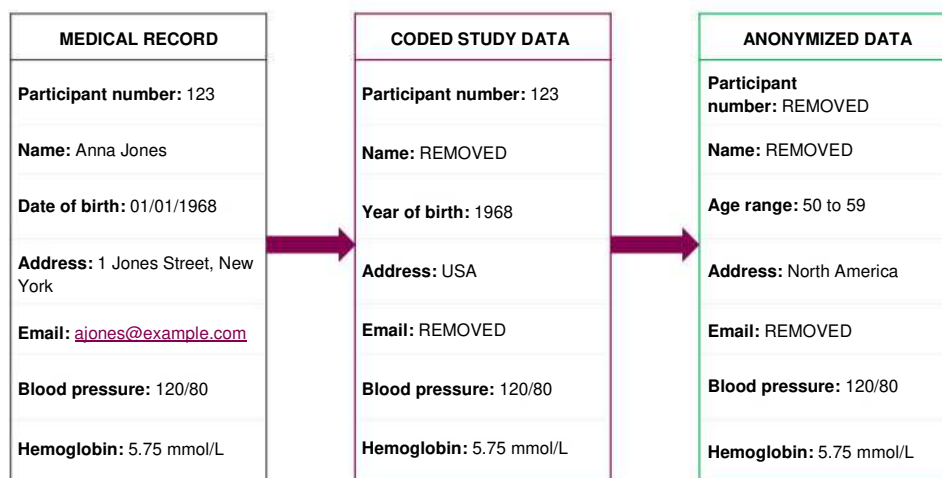
To make sure that the scientific integrity of the study, you cannot review some of the data or get a copy of it until the completion of the study.

To use these **restricted rights**, kindly get in touch, preferably with the study doctor.

Contact details of the **Data Protection Officer (DPO)** are given in part 3: “Additional information for patients”. If there are issues associated with the use of your data, you have the right to file a complaint with your local data protection authority or with the **Sponsor’s** and Ventana Medical System’s data protection authority.

g. What does anonymised data mean?

Health authorities as well as pharmaceutical companies believe that access to clinical studies data advances clinical science and medical knowledge and is in the best interest of patients and public health, provided that the privacy of the patients is safeguarded. Hence, the **sponsor** might generate and share internally or with other researchers an anonymized set of your data taken in the study (e.g., on www.vivli.org). This means your coded data will be stripped of your patient code as well as of any other information that may reasonably be used to recognize you, like your date of birth.



12. What are the costs of participating?

You will not have to bear any costs for taking part in this study. Study medication, study visits, tests, and examinations are free of cost.

Payment will not be given to you for participating in this study. However, you would get Rs 2000/- per visit towards your reasonable and needed costs in connection with the study, like travel conveyance. If you have any side effects or injury, your study doctor must be informed right away so that you may get proper medical treatment.

13. How to get more information after the study?

Trial Result Summaries are a short and easy way to know about summary of the results of this study. Within 1 year of the last study patient's last site visit, these will be added to www.trialssummaries.com. You may visit the www.trialssummaries.com website anytime to sign up to be informed through email when the trial results summary of your study is available. Or, kindly inform your study doctor if you require a printed copy of the document.

Trial Result Summaries will also be posted on <http://euclinicaltrials.eu>.

An explanation of this clinical trial will be available on <http://www.clinicaltrials.gov>, as needed by U.S. Law. Information that may identify you will not be included in this website. Mostly, a summary of the results will be included in the website. At any time, you may search this website.

Information in the technical language associated with the study protocol and the results will be posted on <http://astrazenecaclinicaltrials.com> and, <https://www.clinicaltrialsregister.eu>, and <http://euclinicaltrials.eu>. An explanation of this study is also available on <http://ctri.nic.in>. Any information about you is not contained in these websites.

14. What will occur if I would like to quit the study?

Your taking part in the study is voluntary, meaning you may stop your participation at any time. If you would like to stop consuming the study medication, would like to have a modified visit schedule, or if you would like to stop your participation, you must let the study doctor know and speak about available options.

If you stop taking part in the study (keep in mind that this is a “study discontinuation”, and not a withdrawal of / objection to consent for processing personal data), the collection of your data will be stopped by the study doctor, but your earlier collected data and biosamples will be stored and used to guarantee the validity of the study and to follow regulatory requirements, as permitted by law. You will then be invited by the study doctor to have an end of study examination to check your health. If you do not come for a planned visit, the study doctor will try to contact you. If the study doctor is not able to contact you, where permitted, help will be taken from public

sources like a patient organization registry to verify your health. This is essential for study results. It is not compulsory, but it would be helpful for the study if you explain to your study doctor why you would like to stop your participation, especially if you have been experiencing discomfort.

Your data and collected samples will continue to be used by us as originally consented, unless you wish your data or biosamples not to be used after you leave the study. In such an instance, you should notify the study doctor, and your leftover biosamples will be destroyed or (if requested) given back to the study doctor immediately, but your coded data, earlier collected, will be stored as needed by clinical regulations.

15. Who may answer any queries I might have?

Keep in mind, there are no silly queries! Do not hesitate to ask any queries at ANY TIME! It is your right to get complete information before making a decision to participate in this study, as well as in the future research proposed in part 2. You may get in touch with the study doctor at any time at the address given in part 3: "Additional information for patients".

PART II: 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)		

Subject's Initials:			
Subject's Name:			
Date of Birth:		Age:	
Address of the Subject:			
Qualification:			
Occupation: <i>(Kindly tick which is appropriate)</i>	Student ☐ Self-Employed ☐ Service ☐ Housewife ☐ Others _____		
Annual Income of the subject:			
Name and address of the nominee(s) and his/her relation to the Subject: <i>(For the purpose of compensation in the event of trial-related death)</i>			

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.
- The standard of care procedures conducted before informed consent can be used for screening purposes.

I know that my participation will also involve the following:

- During the study, my name and contact details will be taken as explained to me, and accessed and reviewed by the listed authorised people;
- My coded data (which include images) will be used by the sponsor and Ventana Medical Systems Inc., or by people or companies that act on behalf of the sponsor or that 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 analyzed as explained, and that this involves genetic analyses.
- If applicable, my PD-L1 result and/or tumour samples submitted for screening procedures as part of another AstraZeneca study can be used for the objectives of this study.

I further know that I can decide about the below mentioned topics and that by marking “Yes” I do provide consent, and that by marking “No” I do not provide consent:

My taking part in the optional blood test as mentioned in part 1 section 5.	Yes ☐	No ☐
My taking part in the optional biopsy on the first day of cycle 3 of study treatment as mentioned in part 1 section 5.	Yes ☐	No ☐
My taking part in an optional biopsy if my cancer worsens (disease progression) as mentioned in part 1 section 5.	Yes ☐	No ☐
Your physician may be informed by the study doctor of your participation in the study, and relevant medical information may be shared with him/ her if needed to manage your health and safety throughout the study. If you agree, kindly mention your physician's name and contact details here: You agree, Yes ☐ No ☐ Not Applicable ☐ If yes, kindly mention your physician's name and contact details here: Name of your physician: Contact Details:		

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 Study 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 study participation 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 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

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 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.

Signature of Impartial Witness

Date of Signature

Name of Impartial Witness

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

PART III: ADDITIONAL INFORMATION FOR [PATIENTS / PARTICIPANTS]

WHO CAN I GET IN TOUCH WITH FOR INFORMATION AND HELP?

1. Contact details

In case of any study-related injury or whenever you have queries about the study or your study drug, kindly get in touch with the following:

Principal Investigator:	Dr. Prashant Pandey
Phone Number:	+91-9804290687
Email:	prashantpandeydr@gmail.com
Sub-Investigator/Study coordinator:	
Phone Number:	
Hospital name and Address:	Tata Medical Center 14 MAR(E-W), Newtown, Rajarhat, Kolkata-700160

Sponsor contact details stated in glossary section below:

If you have any queries about your rights as a research subject, you can get in touch with the following:

Name of Ethics Committee:	Institutional Review Board
Name of Ethics Committee's Member Secretary/ Chairperson: <i>(Member Secretary or Chairperson, as applicable as per EC SOP)</i>	Dr. Indranil Mallick (Member Secretary)
Phone Number:	+91-9831171235

2. Detailed list of visits and Test/Procedures

Mandatory tests and procedures:

- **Signature on Informed Consent Form:** before any study-related procedures are done, you will be asked to put a signature on the consent form in Part II "Consent Form" of this document to give your permission for the tests and procedures to be done.
- **General health:** information will be taken from you about your age, gender, and race, and your medical, surgical, and lifestyle history. Your medical history will be looked at by the study doctor to find out whether you fulfill the requirements to participate in this study.
- **Drugs/side effects:** Any drugs that you may be consuming will be discussed with you by the doctor. Kindly notify them about all the medications that you are consuming, which include prescriptions, over-the-counter drugs, vitamins, supplements, and any herbal or recreational medicines. You will also be asked whether you have been feeling sick or have observed any changes in your well-being. You must let the study staff know about any changes that have happened since your last visit.
- **Safety monitoring and performance status:** Your safety and well-being will be monitored by your study doctor during the entire study. Your doctor will assess your performance status (PS). This performance status is a measurement of your general health and daily life activities. Kindly make sure you inform your study doctor of any discomfort or deterioration in your health at any time.
- **Physical examination (which includes weight and height):** You will be examined by your study doctor, which will involve monitoring your general health, looking for any signs of new or worsening abnormalities, and measurement of your weight and height.

- **Vital signs measurement:** Your blood pressure, oxygen level in your blood, heart rate, breathing rate, and body temperature will be evaluated by your study doctor.
- **Healthcare resource use (HOSPAD)** - Your healthcare records will be used by us to find out how many times you have required to use health services, outside of the study
- **Electrocardiogram (ECG):** Your chest and shoulders will be attached with sticky patches or electrodes and linked to wires which go to a machine. The electrical activity of your heart is measured by this.
- **Echocardiogram (ECHO)/Multi-gated Acquisition (MUGA) Scan:** ECHO or MUGA scans check whether your heart is pumping blood properly. An ECHO is a type of ultrasound test to determine the pumping function of your heart. A MUGA scan is a test using a radioactive tracer (called a radionuclide) and a special camera to capture images of your heart as it pumps blood.
- **Evaluation for Tuberculosis infection:** your study doctor will evaluate whether you are having active tuberculosis infection, in line with local practice.
- **Tumor imaging by computed tomography (CT) or magnetic resonance imaging (MRI):** these will be used to check if there are signs of cancer regression/progression. X-rays are used in CT scans to create detailed images of your body, while magnetic fields are used in MRI scans to produce similar images. Body areas that will be scanned involve the chest/thorax, abdomen, and pelvis. Any other areas might be additionally imaged as required.
- **X-ray:** may be done to check if there are any signs of cancer regression/progression, like in the bones. X-rays are a type of radiation which may pass through the body and produce images of the inside of the body.

- **Whole body bone scans (Scintigraphy):** may be done to check if there are any signs of cancer regression/progression, including in the bones.
- **Positron emission tomography/computed tomography (PET/CT) scans:** may be done to check any signs of cancer regression/progression. A radioactive tracer is used in PET/CT scans to show more detailed images of your body.
- **Blood and urine collections:** Blood counts, organ function tests, tests for viruses.
- **Pregnancy Test / Nursing:** if you are a female and are able to have children, you will undergo a pregnancy test (from blood) at screening and a blood or urine pregnancy test before every cycle of study treatment, at the end of treatment, and during safety follow-up. You are not permitted to participate in this study if you are pregnant or are trying to get pregnant. You are not permitted to participate in this study if you are nursing or intend to breastfeed.
- **Blood sample for exploratory biomarkers research.** A biomarker is a biological molecule which is a sign of a normal or abnormal condition. Some biomarkers may help predict how well somebody will react to a specific treatment for a disease and help understand how the drug works. During the treatment period, these samples will be taken to evaluate any changes in reaction to the drug in comparison to baseline throughout the study.

These blood samples will be used for the following:

- Study the reaction of the immune system and immune-associated biomarkers (soluble proteins and gene expression) to the drug to understand why some patients may react to treatment better than others or develop side effects.
- Test circulating DNA shed by the tumour (ctDNA) to understand why some patients may react to treatment better than others, and why sometimes treatment may stop working, and to help develop diagnostic tests (tests to choose the right drugs for various people)

and to find out early recurrence of cancer. Furthermore, DNA sequencing might be done on white blood cells remaining from blood processing before ctDNA testing. A further description of genetic analyses is given in Part I, Section 4 of this document.

- **Blood sample during Rilvegostomig treatment.** Blood samples during Rilvegostomig treatment. If you get Rilvegostomig, additional blood samples will be taken during your treatment cycles. These samples help us measure how much of the medication is in your blood (pharmacokinetics) to understand how the drug is processed by your body and gets rid of it. We will also check whether antibodies against the drug (immunogenicity) are produced by your immune system.
- **TIGIT level testing of your tumor:** Leftover tumor samples taken at screening from each participant will be tested for another protein known as TIGIT.
- **Exploratory tests using your tumor:** Leftover tumor samples after the end of PD-L1 and TIGIT testing will be assessed for exploratory biomarker analysis and future diagnostic development.
- **Images of your tumor tissue** (sections or stained slides) might be collected and kept to conduct computer-aided analysis.
- **Electronic Clinical Outcome Assessment (eCOA):**

You will be asked to fill out a number of questionnaires at different times during the study, either on a handheld device that your study team will give or, if applicable to you, on your own electronic device (tablet, smartphone). These evaluations are used to know how you feel and function during and following treatment. During the evaluations, the following data about your symptoms and health will be taken through sets of queries:

- Experience with symptoms from treatment through sets of queries
- Digestive symptoms through a set of questions
- Weight measurement

The electronic handheld device, or, if applicable, your own device, is what you will primarily use to respond to these queries through the UNIFY App, but under some circumstances, you might complete a web-based version of these questionnaires. The expected time to fill out questionnaires ranges from 5 to 15 minutes, but you may respond to these queries at your own pace. You will be asked queries regarding side effects that you experience, but your responses will not always be monitored by your study doctor. If you have severe side effects, kindly let your study doctor know right away. You will be given instructions to bring the device to all visits.

Optional tests:

- ***Blood sample at day 8 in Cycle 1 of study treatment:***

We want you to give an additional blood sample in order that these blood samples may be studied to better understand the treatment effects of the drug and what occurs in biliary tract cancer after patients get the treatments, and their results are not expected to benefit you directly.

- ***Tumor biopsy at day 1 of Cycle 3 of study treatment:*** We want you to give a tumor biopsy sample for research. These samples are very precious, and they allow us to test the effect of treatment on your cancer. Your doctor will ask for a new tumor sample if it is safe to take sample. We will ask for your consent to use the sample for biomarker research. Also, images of your tumor tissue images may be collected and kept to conduct computer-aided analysis. It is totally up to you whether you would like to donate this samples (s).

- ***Tumor biopsy at disease progression:*** If your tumor worsens, we want you to give a tumor biopsy sample for research. These are very precious samples, and they allow us to test why, despite treatment, cancers have become worse. Your doctor will ask for a new tumor sample if it is safe to take sample. We will ask for your consent to use the sample for biomarker

research. Also, your tumor tissue images may be collected and kept to conduct computer-aided analysis. It is totally up to you whether you would like to donate these samples (s).

Schedule of activities:

Evaluations	Screening	Cycle 1	Cycle 2-8	Cycle 9+	End of treatment visit ^a	Follow up: safety ^b	Follow up: Survival ^c
Consent	X						
Eligibility	X						
Complete Physical Examination, Vital signs & other wellness evaluations	X	X					
Targeted physical examination, Vital signs & other wellness evaluation		X	X	X	X	X	
ECG	X	X	As clinically indicated				
ECHO/MUGA	X	As clinically indicated			X	As clinically indicated	
Collection of Information associated with any changes in your health and any drugs that you may be consuming	X	X			X	X	
Documentation of health and survival status						X	X
Documentation of other anticancer therapies					X	X	X
Review of Adverse Events	X	At every visit, and might be conducted by phone if not connected to a visit				X	
Laboratory Evaluations							
Safety blood tests ^d	X	X	X	X	X	X	
Research blood tests	X	X	X	X	X	X	
Urine collection (Urinalysis)	X	X	As clinically indicated		X		
Pregnancy Test ^e	X (from blood)	X	X	X	X	X	

Evaluations	Screening	Cycle 1	Cycle 2-8	Cycle 9+	End of treatment visit ^a	Follow up: safety ^b	Follow up: Survival ^c
Mandatory Tumor sample (archival or from a new biopsy)	X						
On study tumor sample (optional) ^g			X				
Tumor sample on cancer progression (optional) ^g		Only if your cancer worsens					
Imaging							
CT or MRI Scan	X	X ^f					
Clinical outcomes evaluations							
Fill out questionnaires at home.		X	X	X	X	After disease progression, 3 times every 4 weeks for selected questionnaires	
Administration of Study Treatment							
Rilvegostomig or Durvalumab dosing		X	X	X			
Gemcitabine and Cisplatin dosing		X	X				

^a After 30 days post the last study treatment dose

^b After 90 days post the last study treatment dose

^c Every 12 weeks +/- 14 days from the safety follow-up visit until end of the study

^d During screening period: complete blood count, clinical chemistry (calcium [total], magnesium, creatinine, sodium, blood urea nitrogen/urea, glucose, potassium, total bilirubin, amylase, lipase, troponin T or I, creatinine phosphokinase, aspartate aminotransferase, alanine aminotransferase, alkaline phosphatase, albumin, total protein, chloride, phosphate), CEA, CA19-9, coagulation tests, hepatitis tests, HIV tests (as per local regulation), tuberculosis tests (if applicable), thyroid function test. You will also have blood tests during trial participation.

^e Females are able to bear a child only. Taken Blood sample at screening and from blood or urine afterward.

^f Every 6 weeks (with approximately a week of flexibility) until 24 weeks. Then every 8 weeks (with approximately a week of flexibility) until 56 weeks. Thereafter, every 12 weeks (with approximately a week of flexibility) until the end of the study or until your cancer worsens. If your cancer worsens, you will have 1 additional scan for this study.

^g Optional biopsy, only if additional consent is given and conducted at Cycle 3 Day 1 visit and/or at disease progression

3. Complete List of Personal Data taken

In addition to the personal data taken during the study mentioned in Part I, section 11, below, you may find a list of all personal data taken when using the UNIFY App.

Kindly note that using the UNIFY App is a mandatory part of the study. You will be asked to confirm that you agree with the App Privacy Notice. Kindly see all personal data taken via the App below:

- **Health-related information** depends on your answers to the queries. This data is taken to learn about your experience with the treatment and your overall health during the study. The data is available to your clinical site and is part of your coded data and will be shared with AstraZeneca.
- **Personal characteristics like year of birth or language spoken.** This data is not part of your coded data and will not be shared with AstraZeneca.
- The App does not conduct any activity in the background with regard to activity usage, except for any use of the App itself if you consent to usage analytics in the App.
- **IP address** (a unique string of numbers that identifies a device on the internet or a local network, which may be used to determine general location - note location is not transmitted or shared in the study). The IP address is taken for technical purposes in case the App needs any update or remote support. The data is not part of your coded data and will not be shared outside of the provider databases.
- **Information about the usage of this application.** As part of our ongoing improvement of the App, at some time during the study, you may be asked by us to allow us to use your usage data to improve the App. Usage data is information collected automatically about how you use the App, like what time of day you use it, how long you spend on various questionnaires in the App, or what App features or content you use the most. If we would like to use your usage data, we will ask for your consent via the app itself. The data will be a portion of the coded data and will be shared with AstraZeneca. It will not be shared with third parties.
- **Account information like User ID, PIN, and/or password.** These are taken as part of the App management and outside of the provider databases.

4. Glossary

PD-L1 Assay Details	Name of the PD-L1 Assay: VENTANA PD-L1 (SP263) CDx Assay Manufacturer and Sponsor of the study to evaluate performance of the diagnostic test outside EU/EEA and UK: Ventana Medical Systems, Inc. (Roche Tissue Diagnostics) 1910 E. Innovation Park Drive, 85755, Tucson, AZ, USA Intended purpose: PD-L1 is a stratification factor in this study. It is also used to assess the association of PD-L1 expression with the effectiveness of rilvegostomig in combination with chemotherapy in comparison to durvalumab in combination with chemotherapy. Approval status: VENTANA PD-L1 (SP263) CDx Assay is CE-marked under IVDD (In Vitro Diagnostic Directive) for EU and approved in countries including but are not limited to the US, Japan, and China. The on-market assay does NOT involve the intended objective of this study. The methods used to assess PD-L1 status in the context of this study are investigational.
Your biosamples	All your biological samples taken during this study and associated with you, like blood, urine, biopsy, as appropriate and mentioned in section 4: “<i>What are the needed tests and procedures?</i>” and in section “Which extra biosamples do I need to give?”. All your biosamples are coded, meaning that your name will not be linked to them.
Your coded data	All your data taken at the study site with your name and contact details have been replaced by a code. This is conducted by the study doctor who maintains the link between your name/ contact details and the code to make sure of your safety and confidentiality. Coded information cannot identify you unless your study doctor provides your name or contact details, where permitted by applicable law.

Sponsor details	The ARTEMIDE-Biliary02 clinical study is sponsored by AstraZeneca AB, s-151 85 Södertälje, Sweden The overall responsibility for a clinical study remains with the sponsor. Local Contact: AstraZeneca Pharma India Ltd. Block N1, 12th floor, Manyata Embassy Business Park, Rachenahalli, Outer Ring Road, Bengaluru – 560045, India
Study site details	The place where the clinical study is occurring and where you will need to go for the planned visits.
Health authorities	Authorities supervising the study, who give approval for the medicine to be available commercially or who get adverse event reporting, whether in your country or in other countries.
Research partners	Any organisation collaborating with the sponsor within the drug development program or for future research.
Service providers	Any organisation bound to the sponsor by a contract that may perform activities on the sponsor's behalf under its strict instructions. This might involve other researchers, including so-called "contracted research organisations" (CROs) and IT companies hosting clinical data or providing IT services including developing new systems and services.

Safeguards	Appropriate safeguards will be implemented to safeguard coded data during and following the study, and it can involve the following: • Access to the coded data will be limited to specific individuals subject to confidentiality obligations (which include the obligation not to attempt to re-identify individuals/decode the clinical data). • The coded data will be safeguarded with security measures to prevent data alteration, loss, and unauthorised accesses, and further de-identification techniques can be applied. • A data protection impact assessment (DPIA) will apply to identify and mitigate privacy risks, if any, related to each scientific research. • When needed by applicable law, scientific research is subject to the Ethics Committee's approval. • The coded data will not be shared for direct marketing purposes or other purposes which are not legal duties or are not considered scientific research as per the applicable data protection legislation. Particularly, it will not be used to decide about future services available to you, like insurance.
Security measures: How is my data safeguarded in other countries?	The processing of your data begins at the study site. Your data will then be transferred to several data experts to be verified and for the results to be calculated. Other than having your data and biosamples coded, your data is also safeguarded by high-standard technical security means like strong access control and encryption. You may get additional information as well as a copy of these measures, by asking your study doctor.

Restricted rights	Kindly note that the rights given by the GDPR and UK Privacy Law to get data destroyed (i.e., the right to be forgotten) as well as to get data transmitted in a standard electronic format (i.e., right of portability), are not applicable to such studies.
DPO (Data Protection Officer) details	If you want to get in touch with the DPO of the sponsor, kindly be aware that your name is not known there. You would need to link your identity to your study participant number, which may compromise the coding of your data. Sponsor DPO: AstraZeneca has assigned a data protection officer responsible to oversee AstraZeneca's compliance with EU and UK data protection law, which you may get in touch with at privacy@astrazeneca.com, or at the Global Data Protection Officer, 1 Francis Crick Avenue, Cambridge Biomedical Campus CB2 0AA Cambridge, UK.
Scientific research	Scientific research involves technological development and demonstration, fundamental research, applied research, and privately funded research as well as studies performed in the public interest in the area of public health. This means that the data may be used by us to advance our understanding of how to produce new drugs, medical devices, diagnostic products, tools, and/or other therapies for treating illnesses. This data may also be used by us to improve the design and execution of future clinical studies, services, and medications, for outcome research activities, and to help in pricing and reimbursement activities.

Deposit in scientific databases	To conduct more powerful research, it is helpful for researchers to share data by putting data into one or more scientific databases. The data combined from several research projects may then be studied by the researchers, and get even more information about health and illness. If you consent to participate in future research, some of your coded data, which include genetic data, may be put into one or more scientific databases. Researchers with an approved scientific research project might be able to look at and use your coded data, together with data obtained from many other people. Your name and other information by which you may be directly identified (like address or social security number) will never be put into such a scientific database. Researchers will always have a duty to safeguard your privacy and to maintain the confidentiality of your information.
Trial Result Summaries	Also referred to by the EU as Lay Language Summaries.
Legal basis	You will take part in the clinical study only if you give consent to it. If you do so, data associated with your health and the study drug must be taken and processed to assess the effectiveness and the safety of the tested drug, as per legal requirements given below: Any other applicable law including UK laws and statutory instruments associated with clinical studies. The use of your coded data and biosamples for future research will be possible only if you give your optional consent for it.
Biomarker	A biological molecule found in blood, other body fluids, or tissues, which is a sign of a normal or abnormal process, or of a condition or illness. A biomarker might be used to look at how well the body reacts to a treatment for an illness or condition.

Diagnostic test	A test used to help figure out what illness or condition a person is having based on their signs and symptoms
Clinical Performance Study	Samples taken for this study will be tested using a diagnostic test (known as a diagnostic device) to evaluate whether it may be used to predict patients who are most expected to react better to the study medication. Data obtained from this study data may be used to indicate whether patients with your disease benefit or not. Ventana Medical Systems, Inc. (Roche Tissue Diagnostics) 1910 E. Innovation Park Drive, 85755, Tucson, AZ, USA will be the Sponsor of the Clinical performance study and has the overall responsibility of the clinical performance study.
Research partners	Any organization collaborating with AstraZeneca (the Sponsor) within the drug development program or for future research.