

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		

There are 3 parts to this document:

- Part I: the “**Study Information**” essential to your decision to take part in the clinical study,
- Part II: your “**Consent Form**” which summarises what you may agree 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 take part in this study because you have been diagnosed with Biliary Tract Cancer that has spread (locally advanced or metastatic). Participation requires your written consent. Before you decide whether you want to participate in this study, you will be given an explanation about what the study involves.

The overall description of this study e.g. the collection, storage and use of **your data**, **biosamples** and documentation, etc. has been reviewed in your country by an Institutional Ethics Committee which is an independent body to ensure that the rights, safety and well-being of study patients are protected.

Your condition may or may not improve if you join the study. However, the information we get from this study might help other patients with the same condition in the future.

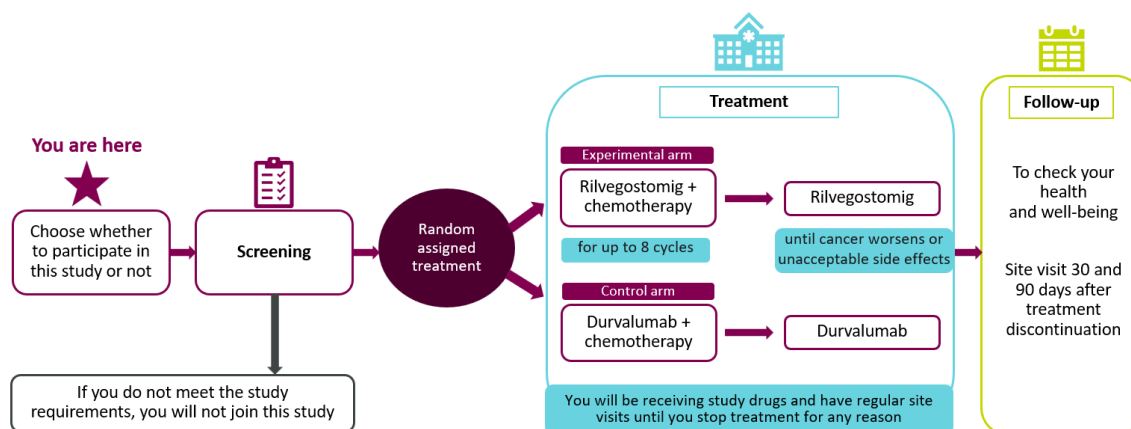
1 What is this study about?

We are doing this study to learn more about treatment with a study drug called rilvegostomig (also called AZD2936), given in combination with chemotherapy (gemcitabine and cisplatin) in patients with advanced biliary tract cancer. We will compare the effectiveness 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). We are also performing this study 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 may benefit most from rilvegostomig with chemotherapy. We are carrying out this research to collect important information that may help support approval of the test in countries where required.

Some parts of this study are experimental which means Rilvegostomig is not approved by any health authority, except for use in research studies like this.

The picture below summarizes the ARTEMIDE-Biliary02 study. Each part of this study will be described in **Section 2**. About 1600 patients will be screened, which consists of a series of tests including testing a sample of your tumour for PD-L1. About 1100 patients will take part in this study.



How do the study drugs work?

Rilvegostomig

Rilvegostomig may help your immune system fight your cancer. It works by blocking two proteins called 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. Rilvegostomig is the experimental treatment in this study.

Durvalumab

Durvalumab works by blocking a protein called PD-L1, which is used by cancer cells to evade the immune system. This enables the immune system to better recognize and target the cancer cells. Immunotherapy drugs like durvalumab are used to treat different types of cancer. In biliary tract cancer, durvalumab in combination with chemotherapy (gemcitabine and cisplatin) has been approved for treatment of advanced biliary tract cancer. However, not every cancer would respond to this treatment, or the response may not last 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 sometimes referred to as GemCis. They work by killing or slowing the growth of cancer cells.

2 Do I have to take part?

You have a choice whether or not you would like to participate.

Please take as much time as you need to decide whether or not you would like to participate in this study. It may be helpful to talk with your friends and family as you make this decision.

If you join the study, you can leave it at any time (see “section 14” for more details). Leaving will not affect your care. If you choose to leave the study, please let your study doctor know as soon as possible.

Please consider the study time commitments and responsibilities as a research patient when you are deciding to take part.

If you don't join the study, you will continue to receive care for your Biliary Tract Cancer. Your study doctor or treating physician will talk to you about other possible drugs, their risks and benefits.

3 What will happen if I join the study?

You will be in the study for up to 4 years. Your participation in the study may need to be longer to get better answers to the study questions.

This study involves a screening period, treatment period and follow-up period.

Before you begin the study treatment

You will undergo a series of tests. This is called screening.

You will have approximately 1 to 2 visits at the study site (clinic where you have to go for study visits). The length of the visit varies and depends on the tests that need to be done.

If you meet all requirements, a computer will randomly allocate you to one of two treatment arms (this is called **randomization**). Your study Doctor will explain if you have been allocated 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 make sure patients in both treatment arms have similar characteristics and treatments can be compared as fairly as possible. Randomization means you will have a 50% chance of being in either the experimental or control arm (like flipping a coin).

If you don't meet the screening criteria, the reasons will be explained. Your study doctor or treating physician will talk to you about other possible treatments.

While you receive study treatment

Study treatment (rilvegostomig or durvalumab in combination with chemotherapy) will be administered via infusion (into the vein), according to the treatment arm you were assigned 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. Gemcitabine and cisplatin are given as two infusions into the vein on days 1 and day 8 of each 3-week cycle. Once 8 cycles of chemotherapy treatment are completed you will continue to receive rilvegostomig every 3 weeks or durvalumab every 4 weeks.

You will continue to receive treatment as a part of this study until one or more of the following happens:

- Your biliary tract cancer gets worse.
- You experience side effects that require 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 of child-bearing potential: you become pregnant or intend to become pregnant.

If your doctor sees signs that your cancer may have gotten worse, you may be allowed to continue receiving study treatment for approximately 4 more weeks, as long as you are feeling well and your doctor thinks you are still benefitting from the treatment. After this time, you will have another scan. If the new scan confirms that the cancer is definitely getting worse, you will need to stop taking the study treatment.

If you want to stop taking the study treatments, want to have a modified visit schedule or if you want to stop your participation in the study, you should tell the study doctor.

You will be asked to download UNIFY on your device, or you will be provided with a device with this App already installed. Once you login into the App for the first time you will be asked to accept the UNIFY license agreement and privacy notice. UNIFY will support you during the trial and your study team will provide you with further information on this. During and after your treatment, you will be asked to fill out short questionnaires about how you are feeling and your experience in this study. UNIFY will be provided to you once available and appropriate approval has been obtained.

Study interventions rilvegostomig and durvalumab will be available after the study is over for patients who are still receiving them. Please note that the study, and your participation in the study, may 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 drug once the study has ended, or once your participation in the study has ended. You can continue receiving treatment with study drug as long as you are benefiting from the study drug, in your doctor's opinion. Your doctor will discuss the available options with you. These options may include further treatment within this current study, transitioning to another study, or transitioning to alternative drug supply. If you are transitioning to another study, you will be given a new study informed consent form, as applicable. If you continue treatment within this current study, your treatment plans will be according to standard of care or as per local clinical practices.

After you have received study treatment (Follow-up)

After you stop treatment, you will still be asked to visit the clinic regularly until the study ends. This is to see if you started a new treatment, assess if your cancer worsened and confirm you are alive as part of the follow-up period. If your cancer worsens and study treatments have been stopped, we may follow up with you by phone instead of clinic visits. You can choose to leave the study at any time.

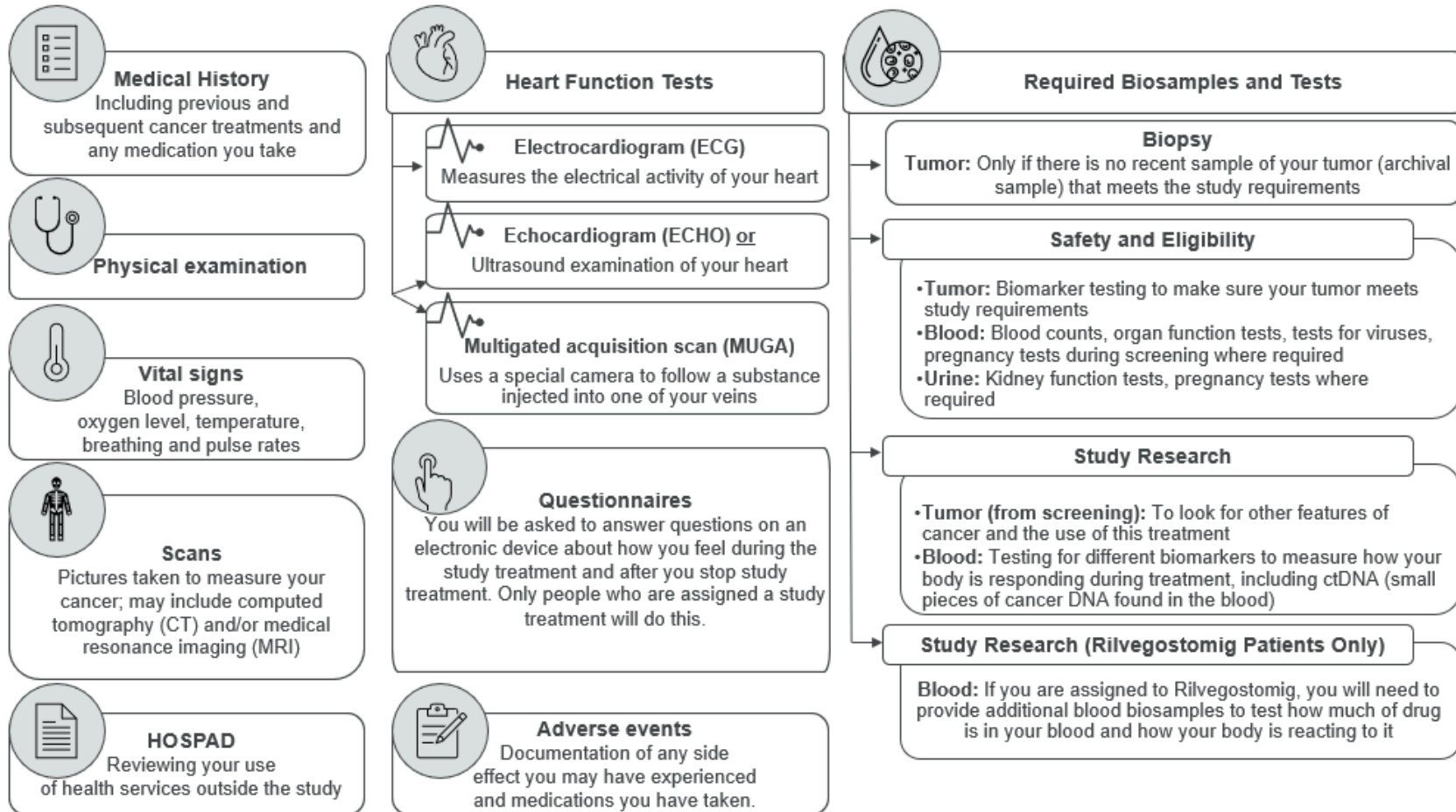
If you cannot come to a visit during any part of the study, you must tell the study doctor as soon as possible.

It is possible that you may have to visit another facility to undergo some of the assessments / procedures for this study. Your study doctor will inform you in case you need to go to another facility for any assessment / procedures. Your study doctor will organize for your visit to another facility in case it is required.

4. What are the required tests and procedures?

While you are on the study, we will need to take some measurements and biosamples, e.g. small amounts of blood or urine.

This is a list of the different tests and procedures you can expect to have while participating in this study:



The complete list of study tests and procedures, including their detailed schedule is available in Part III section 2 “Additional information for patients”. This section also provides more details on **biosamples** handling, collection and storage locations.

PD-L1 level testing of your tumour: To take part in this study, we need a small piece of your tumour tissue for testing. This is required for everyone who joins the study. We may use a sample that was previously collected and stored from a past biopsy or surgery, as long as it was taken within the last 12 months before you join the study. If a recent sample is not available, you may need to have a new biopsy to collect this tissue.

PD-L1 is a protein found on the surface of some cancer cells. It works like a “shield,” helping cancer cells hide from your immune system so they are harder for your body to find and fight. In this study, we will use a special lab test called the investigational Ventana PD-L1 (SP263) CDx assay to check for PD-L1 in your tumour tissue. This test is approved to assess PD-L1 levels in some cancer types in some countries, but it is not approved for use with rilvegostomig in biliary tract cancer. In this study the PD-L1 test result is being used as a stratification factor which means ensuring the two arms of the study (experimental and control arm) are balanced according to PD-L1 status. This helps ensure the study results are fair. We will also be investigating whether your tumour samples and study data, including PD-L1 results, can identify biliary tract cancer patients who may be more likely to benefit from the study drug.

If your tumour sample has already 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 may be used to determine your eligibility for this study, provided that the testing was performed at the same lab and the sample meets this study's requirements. By consenting to this study, you consent to the reallocation of your PD-L1 result, if applicable, and any tumour samples provided as part of another AstraZeneca study for the purposes of this study. If you do not want this result and tumour samples reallocated from other studies and instead would prefer to provide new tumour samples, please tell your doctor immediately.

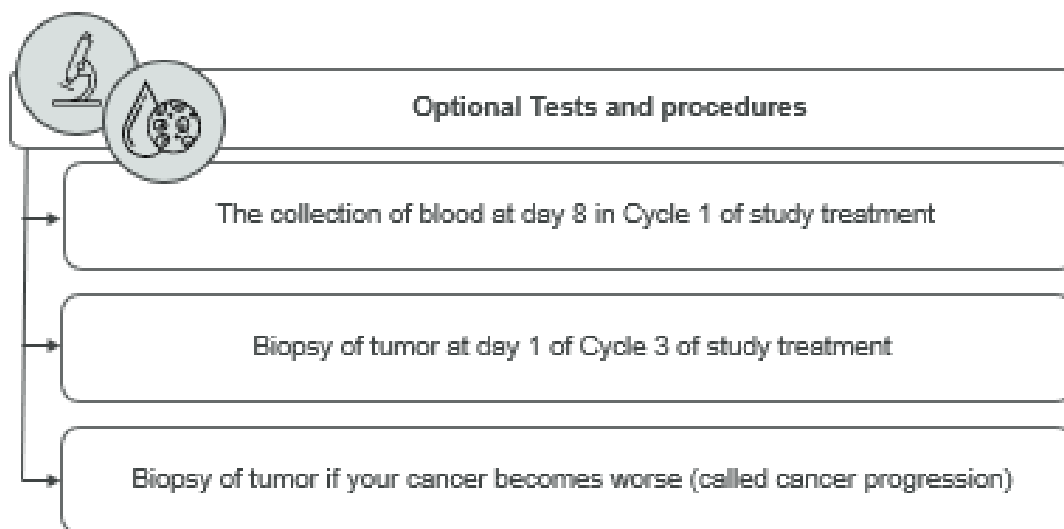
Tumour Genetic analyses

Some biosamples will be used to analyse your genetic information. You can think of genetic information as a large instruction book that your body reads to understand how it should be built and function. All humans have the same instruction book in their body but some words or letters may be different from one person to the other. Some of those differences have no effect on your health but others can influence the likelihood of developing a disease or affect how medicine to treat a disease will work. All your cells have the same DNA, but tumour cells may develop changes called mutations. To find these, tumour DNA can be compared to DNA from your normal blood cells, helping us understand your cancer and guide treatment. If genetic analyses are done, they may involve all or part of your genetic information using your tumour tissue samples and circulating tumour DNA (ctDNA) that may be found in your blood, as well as, if required, your normal blood cells. These analyses will be performed in the context of the main study objectives. The genetic analyses being conducted in this study are for exploratory purposes and will be performed retrospectively, meaning the analyses are conducted at a later date and may not be conducted until after your participation in the study has ended. Results from these analyses will not be shared with you or your study doctor.

5. What are the optional tests and procedures?

The following tests and procedures are optional in this study. If you agree, you may provide your consent by ticking the checkbox in the consent form. You can agree to all optional procedures and biosamples or only one or you don't need to agree at all. The tumour and blood samples (biosamples) collected from these optional collections may be analyzed for additional features of your tumour and the response of your immune system to treatment. These biopsies, biosamples, and results from these biosamples are not expected to directly affect your medical care. If you don't consent to the optional procedures, you can still participate in this study. If you want to change your mind about using extra sample(s) for further research, you can do so at any time and tell your study doctor.

If you consent, biosamples may be collected during the study for optional tests as follows:



6. What are the risks of joining the study?

There is a risk that your biliary tract cancer will not get better or even get worse during the study. It is possible that some patients could have side effects that we do not know about yet. There is a possibility of failure of investigational product to provide intended therapeutic effect. If you have severe side effects from the study drug, the study doctor may ask you not to continue treatment in the study. You may also be asked to delay doses of study treatment to allow the side effects to get better. Management of side effects may also require the administration of drugs such as steroids or other agents that can affect your immune system and reduce inflammation.

If you suffer any side effects or injuries, or your condition gets worse, tell the study doctor immediately so you can receive appropriate care.

Possible risks associated with rilvegostomig

There are limited data on the use of rilvegostomig in humans, therefore the risks of rilvegostomig are not fully known at this time. You may experience side effects which could be very serious in nature (including risk of death) and never go away. Using information available about drugs that work in a similar way to rilvegostomig and the known information from research studies with rilvegostomig, the Sponsor (AstraZeneca) has determined the following potential side effects may occur when rilvegostomig is administered.

1. Identified risks:

- **Infusion-related reactions** are side effects that occur during or shortly after (up to 24 hours) receiving a drug via the veins. These reactions may include fever, chills, muscle pain or tenderness, nausea, vomiting, itching, rash, increased heart rate, difficulty breathing, decreased blood pressure, or light-headedness. The infusion-related reactions seen with rilvegostomig have so far been mild, manageable and resolved.

- **Rashes** observed with rilvegostomig were mainly low grade and responded well to treatment.

2. Potential risks:

- **Skin reactions:** you may notice itching, blisters and/or hair loss.
- **Inflammation of the large intestine (Colitis):** you may experience diarrhoea.
- **Endocrine abnormalities** (inflammation of the hormone-producing glands in your body): you may experience fatigue, weight changes, abnormal blood sugar levels/ diabetes, nausea and skin changes.
- **Inflammation of the lungs (Pneumonitis):** you may experience a cough and/or shortness of breath. When measured, your blood oxygen levels may be low.
- **Inflammation of the liver (Hepatitis):** this may be without symptoms, or you may develop symptoms including jaundice and itching.
- **Inflammation of the kidneys (Nephritis):** you may notice changes to the amount and colour of your urine and/or notice swelling of the face and ankles.
- **Inflammation of the muscles (Myositis):** a reaction of your muscles causing muscle pain.
- **Inflammation of the pancreas (Pancreatitis):** mild forms can be without symptoms. You may experience fever, nausea, pain in the abdomen, fatigue, or jaundice.
- **Inflammation of your heart muscle (Myocarditis):** you may experience chest pain and irregular heartbeats.
- **Inflammation of the brain (Encephalitis):** you may experience confusion, problems with speech or movement.

3. Other potential risks include, but are not limited to:

- **An acute severe allergic reaction** (called anaphylaxis) is a rare side effect that usually occurs during, within minutes, or up to 24 hours after receiving a drug. Symptoms include swelling of the vocal cords, the face or voice box area, difficulty breathing, and/or possibly death.
- **Immune complex disease**, may occur if a patient forms antibodies to rilvegostomig. Symptoms may include aching joints, rash, fever, a reaction in the kidneys (nephritis), or inflammation in blood vessel (vasculitis).
- **Cytokine release syndrome** is a syndrome that occurs when immune cells are activated and cause increased inflammation throughout the body. Symptoms may include fever, headache, rash, low blood pressure, low blood oxygen levels, rapid heart rate, and shortness of breath. In most patients, the symptoms are mild to moderate in severity, but it can be severe and life threatening (cytokine storm syndrome).
- **Tumour lysis syndrome** is a rare condition that occurs with rapid breakdown of cancer cells. This may cause nausea, vomiting, muscle cramps, weakness, decreased urination.
- **Abnormal laboratory results** including elevation of triglycerides, and cholesterol levels, elevation of digestive enzymes: amylase and lipase. Elevated level of potassium and decreased concentration of sodium in the blood.
- **Embryo-fetal toxicity** is an effect on the pregnant female which can 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 attack them. Symptoms may include gastrointestinal tract, liver and skin problems. Some may be mild, but it can be severe and life threatening.
- **Rejection of transplanted organs.**

Risk and side effect related to durvalumab

Most of the possible side effects listed below are mild to moderate. However, some side effects can be very serious and life-threatening and may even result in death.

Some side effects do not need treatment while others generally get better with treatment.

Very common (seen in more than 1 in 10 people)

Diarrhoea
Rash/Dry itchy skin
abdominal pain
Upper respiratory tract infections
Cough
Fever
Underactive thyroid gland that can cause tiredness or weight gain (Hypothyroidism)

Common (seen in more than 1 in 100 people)

Inflammation in the lungs (pneumonitis)
Overactive thyroid gland that can cause fast heart rate or weight loss (Hyperthyroidism)
Changes in lab tests related to kidney and liver function
Infusion related reactions
Pain in muscles and joints (Myalgia)
Pneumonia
Influenza
Hoarse voice
Painful urination
Night sweats
Fungal infection in the mouth (Oral candidiasis)
Dental and oral soft tissue infections
Accumulation of fluid causing swelling e.g. in the legs

Uncommon (seen in less than 1 in 100 people)

Decreased secretion of hormones produced by the adrenal glands (Adrenal insufficiency)
Scarring of lung tissue (Interstitial lung disease)
Inflammation of the liver (Hepatitis)
Inflammation of the kidneys (Nephritis)

<i>Rare (seen in less than 1 in 1,000 people)</i>	Inflammation of the skin (dermatitis) Inflammation of the muscles (Myositis) Inflammation of the intestines (Colitis) Inflammation of the thyroid gland (Thyroiditis) Inflammation of the pancreas (pancreatitis) Type 1 Diabetes Mellitus Inflammation of multiple muscles (polymyositis) Weakness of the muscles (myasthenia gravis) Underactive function of pituitary gland (Hypophysitis/Hypopituitarism) Inflammation of the heart (Myocarditis) Blistering rash (Pemphigoid) Imbalance in body fluids and electrolytes (Diabetes Insipidus) Decrease in cells that help your blood clot (Immune thrombocytopenia) Inflammation of the brain (encephalitis) Inflammation inside the eye (Uveitis) Nervous system disorder (Guillain-Barré syndrome) Inflammation of the joints (Immune-mediated arthritis)
Risk of combining chemotherapy with rilvegostomig or durvalumab The potential risks and side effects of chemotherapy plus rilvegostomig or durvalumab are based on the identified risks of each individual drug. No additional risks are currently anticipated when chemotherapy is combined with either rilvegostomig or durvalumab, beyond what is expected for each individual drug . It is common for patients with advanced biliary tract cancer to receive chemotherapy (gemcitabine plus cisplatin). The study doctor will explain the risks and potential side effects of the chemotherapy with you.	

Possible risks of study procedures

Some of the study procedures may have possible side effects, risks, and discomforts. You may experience none, some, or all. The procedures performed as part of this study are standard and routine procedures; you may have these procedures more often if you join this study. The study doctor will be able to explain these to you in detail and provide you with any risks and/or side effects associated with these.

Risks associated with biopsy

If there is no sample of your tumour available (for example, collected from the time you were diagnosed) that meets the study requirements, a new sample of your tumour will need to be collected by biopsy. Depending on where a biopsy is taken from, risks may include pain, bleeding, injury of the liver or bile ducts, and infection. In very rare cases, there can be serious complications which may even lead to death. Also, there is a hypothetical risk of regional spread of cancer cells when the needle is removed from your tumour. Your study doctor will discuss the most appropriate way to obtain a biopsy from your tumour and other possible risks with you. You may be asked to separately consent to the biopsy procedure.

Risks associated with PD-L1 testing

A valid PD-L1 result is mandatory to enter the study.

There is a small risk the sample you provide does not give us a result; it is a failed or invalid test. In this case, we may ask your doctor if another sample is available to be tested. This will increase the chance of a successful test result.

There is a small risk your test result may be delayed, but measures have been put in place to minimise the risk of a delayed test result. It's also important to know that the PD-L1 test is done in the laboratory using your tumour sample. The equipment used for the test does not come into direct contact with you, so there is no risk of harm or injury to you from the testing itself.

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

Pregnancy, contraception, and breast-feeding

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

There may be other things to consider and the required time of contraception may be longer while you are receiving chemotherapy as well. Your study doctor will tell you if this is the case.

For female patients:

Women who are able to become pregnant and intend to be sexually active with a male partner who is able to have children (are non-sterilized) must use at least 1 highly effective method of contraception from entering the study until 60 days after the last dose of rilvegostomig, 90 days after the last dose of durvalumab or 6 months after the last dose of chemotherapy, whichever is longer. In some cases, local guidelines may require a longer duration and your Doctor will tell you if this is the case. Your male partner must also use a male condom plus spermicide throughout this period.

If you become pregnant, you must tell the study doctor straight away. You will have to stop taking the study drug immediately until you have spoken to your study doctor. You will be asked to provide information about you and your baby. This may involve a separate consent to allow us to monitor your baby's health and development.

For male patients:

Men who are able to father a child (are non-sterilized) and intend to be sexually active with a female partner who is able to become pregnant must use a male condom plus spermicide from entering the study until 60 days after the last dose of rilvegostomig, 90 days after the last dose of durvalumab or 6 months after the last dose of chemotherapy, whichever is longer. In some cases, local guidelines may require a longer duration and your Doctor will tell you if this is the case. Your female partner must also use a highly effective method of contraception throughout this period. If your partner becomes pregnant, you must tell the study doctor immediately. Your partner will be asked, under a separate consent, to provide information about their health and your baby's health.

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

Examples of Highly effective methods of contraception (<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 currently the only highly effective progesterone-based pill

The study doctor can discuss more about the acceptable birth control methods with you.

Other medicines and remedies you may be taking

You need to tell the study staff about any other medicines, vitamins or herbal remedies (including recreational drugs such as marijuana) that you are taking.

Rilvegostomig or durvalumab may change the way certain drugs are handled by your body. In particular, you will be advised against the use of immunosuppressive medications (drugs that dampens your immune system), such as systemic (taken orally or by injection) corticosteroids whilst on study. If relevant your study doctor will discuss this further with you and consider alternative drugs as appropriate.

Blood, sperm and egg donation

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

Vaccines

You should not be given certain kinds of vaccines (called live attenuated vaccines) from 30 days before the first dose of treatment on the study until 30 days after the last dose of study treatment. You should not receive a COVID19 vaccination in the 3 days before

receiving the first dose of study treatment. Your study Doctor can tell you more about vaccines that are allowed whilst you are receiving study treatment.

8. What are the possible benefits of taking part?

We do not know if taking part will help your condition, but we hope that it will.

The information the study **Sponsor** receives from this study may help to better treat patients with biliary tract cancer.

It is not certain that you will directly benefit from the participation in the study. Your participation may, however, help other patients in the future by improving the knowledge of diseases and improving medical care.

9. What happens if something changes while I am in the study, e.g. if new information is found?

Changes may happen in the study that could make you change your mind about continuing to take part in the study. If something changes, we will tell you as soon as possible.

You can choose to leave the study at any time. For more details see section 14 below.

The study doctor can also choose to take you out of the study if they believe that it is best for you.

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

10. What happens if I am harmed or injured during the study and in such cases who will pay financial compensation?

If there is an emergency, call your study doctor right away or go to closest emergency room and contact your study doctor as soon as you can. All relevant contact details can be found in part 3 : “Additional information for patients”.

If you become ill or are injured while you are in this research study, you must tell your study doctor straight away.

Injuries that have been caused by the study drug, tests or procedures are called “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

In case of an injury occurring to you during the clinical trial, AstraZeneca, the clinical trial sponsor shall provide you free medical management as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier in accordance with the rule 40 of G.S.R.227(E).

In the event of a trial related injury or death, the sponsor or the investigator or centre, as the case may be, in accordance with 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 may be, shall provide financial compensation for the injury or death.

The financial compensation will be over and above any expenses incurred on the medical management of an injury occurring to you as a clinical trial subject. The health authority of India determines the compensation to be given to you or your nominee in case of a study related injury. Hence, AstraZeneca will pay compensation to you or your nominee in case you suffer from a study related injury or death per the directive of the health authority of India.

AstraZeneca has taken out an insurance to cover clinical study-related injuries or death. In order for AstraZeneca to obtain proceeds from this insurance for your study related injury or death, insurance company may request for your medical records and/or your signed informed consent form for this study. It is also possible that the health authority of India would ask for your medical records and/or your signed informed consent form to evaluate a study related injury. If AstraZeneca has to share your medical records and/or your signed ICF to the insurance company or the health authority, appropriate care will be taken to protect your privacy

If you have medical insurance, please check with your insurance company that taking part in this research study will not affect your coverage.

11. What will happen to my data and biosamples gathered in the study?

a. Which data and biosamples are collected?

In order to conduct the study, the **Study site** will have to collect and register information about your identity (such as your name, address, telephone number, and health insurance number) as well as data that is necessary to assess your health conditions such as your medical condition and medical history (this may include 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 (e.g. scans) and your genetic information.

Data collected via 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 collected. For more details about which data that is collected in the study, see further details at the end of this document in part 3: "Additional information for patients".

In addition, the study site will collect biosamples from you (such as blood or body tissue). These will be analysed and the data derived from the analysis will be part of your **coded data** which will also include genetic data and images.

b. What are my data and biosamples needed 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 e.g. by governments i.e., throughout the drug development programme. Therefore, they will be used as planned in this study as well as within related research activities necessary for this drug development programme in order to:

- understand how the study drug(s) and similar drugs work in the body (i.e., evaluate the study drug mode of action, alone or in combination with other study drugs),
- better understand the studied disease and associated health problems,
- *develop diagnostic tests for the disease by assessing whether the diagnostic tests can 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 required.*
- learn from past studies to plan new studies or improve scientific analysis methods,
- publish research results in scientific journals or use them for educational purposes,

c. Who can access my data and biosamples?

Only at the study site, your name and contact details will be accessible to the study doctor and the study team to conduct the study. Personnel acting on behalf of the **Sponsor** and being bound by a duty of confidentiality as well as **Health authorities** and Ethics Committees may also be given access to this data only to verify that the

study is carried out in compliance with legal and quality requirements. Some of your data may be accessed remotely where allowed.

The study site will share your data and biosamples with the **Sponsor** but only after they have been coded (which means that your name, contact details or health insurance number, have been replaced by a code. For more information about coding, see details at the end of this document in Glossary in part 3: “Additional information for patients”). This includes coded data and biosamples collected following consent during the screening period even if you will not join the study.

The **Sponsor** may share your coded data and biosamples with its **Research partners** and **Service providers** for the purposes of the drug and diagnostic device development programme. To get permission to market the drug and diagnostic test, AstraZeneca will also share your coded data and biosamples with the manufacturer of the test/device (Ventana Medical Systems, Inc.) as well as health authorities and possibly with Ethics Committees to ensure proper conduct and accurate results of the study

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

In the case of adverse events or device deficiencies related to the investigational test, the Sponsor may share your coded data to health authorities and ethics committees in accordance with applicable regulations. This includes any serious adverse events which threaten your life, requires an emergency visit to hospital, prolongs your hospital stay, results in disability or death which are linked with the diagnostic test or a study procedure linked with the test – For example a complication in a study biopsy procedure needed for study eligibility which requires you or prolongs your stay in hospital.

In none of these cases your identity will be revealed.

Some of the above-mentioned persons may be located outside your country. If this other country does not have equivalent personal data protection standards as your country, appropriate **Safeguards** (such as contracts and technical **Security measures**) will be adopted to protect and maintain the confidentiality of your data and biosamples as further described at the end of the document in part 3: “Additional information for patients”.

In case another organisation takes over development or commercialisation of the study drug, your coded data or biosamples may be transmitted to them. They will then have to protect your data and biosamples in the same way as described herein.

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

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

- Reimburse you for your time, effort and certain expenses related to your participation.
- Set up and manage your accounts for any apps or other devices that are used in the study. The data that is collected and processed in the study through the App is detailed in Part 3, Section 3 of this document.
- Provide technical support for any mobile application that is used in the study. If you call the App provider support helpdesk, your name and phone number may be collected (with your permission) in case a follow-up contact is required, e.g. your issue isn't resolved, and Helpdesk needs to contact you. The information will be deleted after your ticket is resolved. The service providers must keep your name or contact details private and will NOT share any information that can directly identify you with the Sponsor.

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

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

The service providers must keep your name or contact details private and will NOT share any information that can directly identify you with the **Sponsor**.

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

The study site and the **Sponsor** are obliged to keep all study data for 25 years after the end of the study, unless there is a legal requirement for keeping them longer. At the end of this retention period your coded data will be deleted or anonymised.

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

Your biosamples collected during the study will be returned to your study doctor or destroyed as soon as possible after the tests listed in part 1 section 4 and 5 for the

drug development program are completed unless you provide consent for future research.

If you authorise the **Sponsor** to use your samples for future research (In a separate “Future Research ICF a tick-box” that will allow you to make this choice), your biosamples will be kept 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 collected and being used; you can also ask for a copy of this data, ask for restriction of use of this data, or ask to have incorrect data rectified.

In case you consent to Future Research (In a separate “Future Research ICF”), you may also ask the study doctor to receive a copy of the data you have provided for the future research in a standardised electronic format or to have them transmitted to another person of your choice.

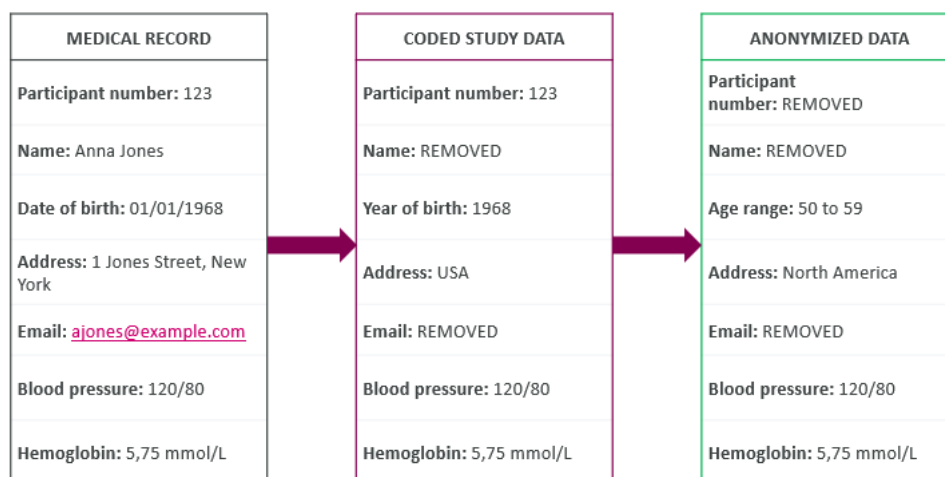
To ensure the scientific integrity of the study, you will not be able to review some of the data or receive a copy of it until the study ends.

To exercise these **restricted rights**, please contact preferably the study doctor.

Contact details of the **Data Protection Officer (DPO)** are provided in part 3: “Additional information for **patients**”. If there are issues related to 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 one

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 patient privacy is protected. Therefore, the **Sponsor** may generate and share internally or with other researchers an anonymised set of your data collected 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 could reasonably be used to identify you such as your date of birth.



12. What are the costs of taking part?

Participating in this study will not cost you anything. Study drug, study visits, tests and examinations are free of charge.

You will not be paid for taking part in this study. However, you would receive Rs 2000/- per visit towards your reasonable and necessary expenses in connection with the study, such as travel conveyance. If you suffer any side effect or injury, notify your Study Doctor immediately so that you can receive appropriate medical treatment

13. How to find out more after the study?

Trial Result Summaries are a short and easy to understand summary of the results of this study. These will be added to www.trialssummaries.com within 1 year of the last study patients last site visit. You can visit www.trialssummaries.com website anytime to sign up to be notified via email when the trial results summary of your study is available. Or, please let your study doctor know if you need a printed copy of the document.

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

A description of this clinical trial will be available on <http://www.clinicaltrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Information in technical language related to study protocol and the results will be posted on <http://astrazenecaclinicaltrials.com> and <https://www.clinicaltrialsregister.eu> and

<http://euclinicaltrials.eu>. A description of this study is also available on <http://ctri.nic.in>. These websites do not contain any information about you.

14. What will happen if I want to quit the study?

Your participation in the study is voluntary which means you can stop your participation at any time. If you want to stop taking the study drug, want to have a modified visit schedule or if you want to stop your participation, you should tell the study doctor and discuss available options.

If you stop participating in the study (be aware that this is a “study discontinuation”, and not a withdrawal of / objection to consent for processing personal data), the study doctor will stop the collection of your data, but your previously collected data and biosamples will be kept and used to guarantee the validity of the study and to comply with regulatory requirements, as allowed by law. The study doctor will then invite you to have an end of study examination to check your wellbeing. If you don’t show up at a planned visit, the study doctor will try to reach you. If the study doctor cannot reach you, where allowed public sources such as patient organization registry will be consulted to verify your wellbeing. This is important for study results. It is not mandatory but would be helpful for the study if you explain to your study doctor why you wish to stop your participation, in particular if you have experienced discomforts.

We will continue to use your data and collected samples as originally consented, unless you would like your data or biosamples not to be used after you quit the study. In such case, you must inform the study doctor and your remaining biosamples will be destroyed or (if requested) returned to the study doctor as soon as possible, but your coded data previously collected will be kept as required by clinical regulations.

15. Who can answer any questions I may have?

Remember, there are no silly questions! Feel free to ask at ANY TIME! It is your right to be fully informed before deciding to take part in this study as well as in the future research proposed in part 2. You can contact the study doctor at any time at the address indicated in part 3: “Additional information for patients”.

PART II: INFORMED CONSENT FORM

Study Code:	D702NC00001	Centre No:	3514
Investigator:	Dr. Prashant Pandey	Subject Ecode :	
Study Title:	Phase III, Randomized, Open-label, Global, Multicenter Study of Rilvegostomig or Durvalumab in Combination With Chemotherapy as a First-line Treatment for Patients With Advanced Biliary Tract Cancer (ARTEMIDE-Biliary02)		

Subject's Initials:			
Subject's Name:			
Date of Birth:		Age:	
Address of the Subject:			
Qualification:			
Occupation: (Please tick as appropriate)	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: (For the purpose of compensation in case of trial related death)			

I confirm that:

- The study doctor or study personnel delegated by the study doctor has / have explained the study to me comprehensively.
- I have had the opportunity to discuss the study with the study doctor and all my questions were answered.
- I have had an adequate amount of time to consider the study.
- I have truthfully answered all questions about my medical history and will follow all rules listed in the document.
- The standard of care procedures performed prior to informed consent may be used for screening purposes.

I understand that my participation also entails:

- My name and contact details being collected during the study as described to me, and accessed and reviewed by listed authorised people;
- My coded data (including images) being used by the sponsor and Ventana Medical Systems Inc or by people or companies acting on its behalf or working with the sponsor;
- My coded data being used by persons or organisations located in countries that do not have data protection rules equivalent to those of my country. I understand that the sponsor monitors these uses and takes all possible measures to protect my privacy;
- My biosamples being collected and analysed as described and that this includes genetic analyses.
- If applicable, my PD-L1 result and/or tumour samples submitted for screening procedures as part of another AstraZeneca study may be used for the purposes of this study.

I further understand that I can make a choice about the topics listed below and that by ticking “Yes” I do give consent and that by ticking “No” I do not give consent:

My participation to optional blood test as detailed in part 1 I section 5.	Yes ☐	No ☐
My participation to optional biopsy at first day of cycle 3 of study treatment as detailed in part 1 I section 5.	Yes ☐	No ☐
My participation to optional biopsy if my cancer become worse (disease progression) as detailed in part 1 I section 5.	Yes ☐	No ☐
The study doctor may notify your physician of your participation in the study and may share relevant medical information with him/ her if necessary for managing your health and safety throughout. If you agree, please indicate name and contact details of your physician here: You agree, Yes ☐ No ☐ Not Applicable ☐ If yes, please indicate name and contact details of your physician here: Name of your physician: Contact Details:		

Sl. No	Please provide your initials (short signature or signature) or thumb impression (as applicable) against each one of the following statements to confirm your consent to these statements	
(i)	I confirm that I have read and understood the Study Information and Informed Consent Form dated 23 Jul 2026, India Version Number 1.1 for the above study and have had the opportunity to ask questions.	[]
(ii)	I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	[]
(iii)	I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.	[]
(iv)	I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s)	[]
(v)	I agree to take part in the above study.	[]

*Signature (Or Thumb impression) of the
subject/Legally Acceptable Representative (LAR)*

Date of Signature

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

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

Relationship of legally acceptable representative to subject

Signature of the Investigator

Date of Signature

Study Investigator's Name

If the Subject or his/her legally acceptable representative is unable to read/write - an impartial witness should be present during the entire informed consent process who must append his/her signatures to the consent form

Impartial witness is a person who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or the subject's legally acceptable representative cannot read, and who reads the informed consent form and any other written information supplied to the subject.

Signature of Impartial Witness

Date of Signature

Name of Impartial Witness

“Copy of the Patient Information Sheet (Adult Study Participant Master Information) and duly filled Informed Consent Form shall be handed over to the subject or his/her legally acceptable representative”.

PART III: ADDITIONAL INFORMATION FOR [PATIENTS / PARTICIPANTS]

WHO CAN I CONTACT FOR INFORMATION AND HELP?

1. Contact details

In case of any study-related injury, or whenever you have questions about the study or your study medication, please contact:

Principal Investigator:	Dr. Prashant Pandey
Phone No:	+91-9804290687
Email:	prashantpandeydr@gmail.com
Sub-Investigator/Study coordinator:	
Phone No:	
Hospital name and Address:	Tata Medical Center 14 MAR(E-W), Newtown, Rajarhat, Kolkata-700160

Sponsor contact details mentioned in glossary section blow:

If you have questions about your rights as a research subject, you may contact:

Name of Ethics Committee	Institutional Review Board
Name of Ethics Committee's Member Secretary/Chairperson <i>(Member Secretary or Chairperson as applicable per EC SOP)</i>	Dr. Indranil Mallick (Member Secretary)
Phone No:	+91-9831171235

2. Detailed list of visits and Test/Procedures

Mandatory tests and procedures:

- **Sign Informed Consent Form:** before any study-related procedures are performed, you will be asked to sign the consent form in Part II “Consent Form” of this document to give your permission for the tests and procedures to be performed.
- **General health:** information will be collected from you regarding your age, gender and race, and your medical, surgical and lifestyle history. The study doctor will look at your medical history to see if you meet the requirements to take part in this study.
- **Medications/side effects:** doctor will discuss with you any medications that you may be taking. Please inform them about all the drugs that you are taking including prescriptions, over-the-counter medications, vitamins, supplements and any herbal or recreational drugs. You will also be asked if you have been feeling unwell or have noticed any changes in your health. You must tell the study staff about any changes that have occurred since your last visit.
- **Safety monitoring and performance status:** your study doctor will monitor your safety and wellbeing throughout the study. Your performance status (PS) will be evaluated by your doctor. This performance status is a measurement of your general well-being and activities of daily life. Please ensure you notify your study doctor of any discomfort or deterioration in your health at any time.
- **Physical examination (including weight and height):** your study doctor will examine you, which will include checking your general health, looking for any signs of new or worsening abnormalities and measuring your weight and height.

- **Measurement of vital signs:** your study doctor will assess your blood pressure, oxygen level in your blood, heart rate, breathing rate and body temperature.
- **Healthcare resource use (HOSPAD)** - we will use your healthcare records to see how many times you have needed to use health services, outside of the study
- **Electrocardiogram (ECG):** Sticky patches or electrodes are attached to your chest and shoulders and connected to wires that go to a machine. This measures the electrical activity of your heart.
- **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 take pictures of your heart as it pumps blood.
- **Assessment for Tuberculosis infection:** your study doctor will assess if you have active tuberculosis infection, in line with local practice.
- **Tumour imaging by computed tomography (CT) or magnetic resonance imaging (MRI):** these will be used to check if there are signs of the cancer regression/progression. CT scans use X-rays to create detailed images of your body, while MRI scans use magnetic fields to produce similar images. Body areas that will be scanned include chest/thorax, abdomen and pelvis. Any other areas may be additionally imaged as needed.
- **X-ray:** may be performed to check if there are any signs of the cancer regression/progression, like to the bones. X-rays are a type of radiation that can pass through the body and produce images of the inside of the body.
- **Whole body bone scans (Scintigraphy):** may be performed to check if there are any signs of the cancer regression/progression, including to the bones.

- **Positron emission tomography/computed tomography (PET/CT) scans:** may be performed to check any signs of the cancer regression/progression. PET/CT scans use a radioactive tracer to show more detailed images of your body.
- **Blood and urine collections:** Blood counts, organ function tests, tests for viruses.
- **Pregnancy Test / Breastfeeding:** if you are a woman and are able to have children, you will have a pregnancy test (from blood) at screening and a blood or urine pregnancy test before each cycle of study treatment, at the end of treatment and during safety follow-up. You are not allowed take part in this study if you are pregnant or are trying to become pregnant. You are not allowed take part in this study if you are breastfeeding or intend to breastfeed.
- **Blood sample for exploratory biomarkers research.** A biomarker is a biological molecule that is a sign of a normal or abnormal condition. Some biomarkers can help predict how well someone will respond to a specific treatment for a disease and understand how the drug is working. These samples will be collected during the treatment period to assess any changes in response to the drug compared to baseline during the study.

These blood samples will be used to:

- Study the response of the immune system and immune associated biomarkers (soluble proteins and gene expression) to the drug to understand why some patients may respond to treatment better than others or develop side effects.
- Test circulating DNA shed by the tumour (ctDNA) to understand why some patients may respond to treatment better than others, and why sometimes treatment can stop working, and to help develop diagnostic tests (tests to choose the right medicines for different people) and to detect early recurrence of cancer. Furthermore, DNA sequencing may be performed on white blood cells leftover from blood processing prior

to ctDNA testing. A further explanation of genetic analyses is provided in Part I, section 4 of this document.

- **Blood sample during Rilvegostomig treatment.** Blood samples during Rilvegostomig treatment. If you receive Rilvegostomig, extra blood samples will be collected throughout your treatment cycles. These samples help us measure how much of the drug is in your blood (pharmacokinetics) to understand how your body processes and gets rid of the drug. We will also check whether your immune system makes antibodies against the drug (immunogenicity).
- **TIGIT level testing of your tumour:** Remaining tumour samples collected at screening from each participant will be tested for a protein called TIGIT.
- **Exploratory tests using your tumour:** Remaining tumour samples following completion of PD-L1 and TIGIT testing will be evaluated for exploratory biomarker analysis, and future diagnostic development
- **Images of your tumour tissue** (sections or stained slides) may be taken and stored to perform computer-aided analysis.
- **Electronic Clinical Outcome Assessment (eCOA):**
You will be asked to complete a number of questionnaires at different times during the study either on a handheld device that your study team will provide or, if applicable to you, on your own electronic device (tablet, smartphone). These assessments are used to understand how you feel and function during and after treatment. During the assessments the following data about your Symptoms and well-being will be collected via sets of questions:
 - Experience with symptoms from treatment via sets of questions
 - Digestive symptoms via sets of questions
 - Weight measurement

The electronic handheld device, or, if applicable your own device, is what you will primarily use to answer these questions via the UNIFY App, but under some circumstances you may complete a web-based version of these

questionnaires. The estimated time to complete questionnaires ranges from 5 to 15 minutes, but you can answer these questions at your own pace. You will be asked questions about side effects that you experience, but your responses will not always be monitored by your study doctor. If you experience severe side effects, please tell your study doctor immediately. You will be instructed to bring the device to all visits.

Optional tests:

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

We would like you to provide an additional blood sample so these blood samples can be studied to better understand the treatment effects of the drug and what happens in biliary tract cancer after patients receive the treatments, and their results are not expected to benefit you directly.

- ***Tumour biopsy at day 1 of Cycle 3 of study treatment:*** We would like you to provide a tumour 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 tumour sample if it's safe to collect one. We will ask for your consent to use the sample for biomarker research. Additionally, images of your tumour tissues may be taken and stored to perform computer-aided analysis. It is entirely up to you whether you wish to donate this sample(s).

- ***Tumour biopsy at progression:*** If your tumour becomes worse, we would like you to provide a tumour biopsy sample for research. These samples are very precious, and they allow us to test why cancers have progressed despite treatment. Your doctor will ask for a new tumour sample if it's safe to collect one. We will ask for your consent to use the sample for biomarker research. Additionally, images of your tumour tissues may be taken and stored to perform computer-aided analysis. It is entirely up to you whether you wish to donate this sample(s).

Schedule of activities:

Assessment	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						
Full Physical Examination, Vital signs & other wellness assessments	X	X					
Targeted physical examination, Vital signs & other wellness assessment		X	X	X	X	X	
ECG	X	X	As clinically indicated				
ECHO/MUGA	X	As clinically indicated			X	As clinically indicated	
Collection of information related to any changes in your health, and any medications that you may be taking	X	X			X	X	
Documentation of health and survival status						X	X
Documentation of other anticancer therapies					X	X	X
Adverse Events review	X	At every visit and may be done by phone if not tied to a visit				X	
Laboratory Assessments							
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	
Mandatory Tumour sample (archival or from new biopsy)	X						
On study tumour sample (optional) ^g			X				
Tumour sample on cancer progression (optional) ^g		Only if your cancer gets worse					

Assessment	Screening	Cycle 1	Cycle 2-8	Cycle 9+	End of treatment visit ^a	Follow up: safety ^b	Follow up: Survival ^c
Imaging							
CT or MRI Scan	X		X ^f				
Clinical outcomes assessment							
Completing questionnaires at home		X	X	X	X	After disease progression, 3 times every 4 weeks for chosen questionnaires	
Study Treatment administration							
Rilvegostomig or Durvalumab dosing		X	X	X			
Gemcitabine and Cisplatin dosing		X	X				

^a After 30 days post last dose of study treatment

^b After 90 days post last dose of study treatment

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

^d During screening period: full 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 (per local regulation), tuberculosis tests (if applicable), thyroid function test. You will also have blood tests during the trial participation.

^e Women of childbearing potential only. Taken from blood sample at screening and from blood or urine later on.

^f Every 6 weeks (with about a week of flexibility) until 24 weeks. Then every 8 weeks (with about a week of flexibility) until 56 weeks. After that, every 12 weeks (with about a week of flexibility) until completion of the study or until your cancer gets worse. If your cancer gets worse, you will undergo 1 additional scan for this study.

^g Optional biopsy, only if additional consent provided and performed at Cycle 3 Day 1 visit and/or at progression of the disease

3. Complete List of Personal Data collected

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

Please 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. Please see all personal data collected via the App below:

- **Health related information** based on your answers to the questions. This data is collected to learn about your experience with the treatment and your overall wellbeing

during the study. The data is available to your clinical site and are part of your coded data and will be shared with AstraZeneca.

- **Personal characteristic such as 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 perform any activity in the background with regards to activity usage, except for any use of the App itself if you agree to usage analytics in the App.

- **IP address** (a unique string of numbers that identifies a device on the internet or a local network that can be used to determine general location - note location is not transmitted or shared in the study). The IP address is collected for technical purposes in the case that the App requires 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 on usage of this application.** As part of our ongoing improvement of the App, at some time during the study we may ask you to let us use your usage data to improve the App. Usage data is automatically collected information about how you use the App, such as what time of day you use it, how long you spend on different questionnaires in the App, or what App features or content you use the most. If we want to use your usage data, we will ask for your consent through the app itself. The data will be part of the coded data and will be shared with AstraZeneca. It will not be shared with third parties.

- **Account information such as User ID, PIN and/or password.** These are collected as a 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 assess 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 evaluate the association of PD-L1 expression with the efficacy of rilvegostomig in combination with chemotherapy compared 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 not limited to the US, Japan and China. The on-market assay does NOT include the intended purpose of this study. The methods used to evaluate PD-L1 status in the context of this study are investigational.
Your biosamples	All your biological samples collected during this study and related to you, such as blood, urine, biopsy, as appropriate and listed in section 4: “<i>What are the required tests and procedures?</i>” and in section “Which additional biosamples do I have to provide?”. All your biosamples are coded which means that your name will not be associated with them.
Your coded data	All your data collected at the study site with your name and contact details have been replaced by a code. This is done by the study doctor who keeps the link between your name/contact details and the code to ensure your safety and confidentiality. Coded information cannot identify you unless your study doctor provides your name or contact details, where allowed by applicable law.

Sponsor details	The ARTEMIDE-Biliary02 clinical study is sponsored by AstraZeneca AB, s-151 85 Södertälje, Sweden] The sponsor has the overall responsibility for a clinical study. 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 taking place and where you will have to go for the planned visits.
Health authorities	Authorities who supervise the study, who approve the commercialisation of the drug or who receive the adverse events reporting, whether in your country or in other countries.
Research partners	Any organisation which collaborates with the sponsor within the drug development programme or for future research.
Service providers	Any organisation bound to the sponsor by a contract, which may conduct activities on behalf of the sponsor under its strict instructions. This may include 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 protect coded data during and after the study and may include that: • Access to the coded data will be limited to specific individuals subject to confidentiality obligations (including the obligation to not attempt to re-identify individuals/decode the clinical data). • The coded data will be protected with security measures to avoid data alteration, loss and unauthorised accesses and further de-identification techniques may be applied. • A data protection impact assessment (DPIA) will apply to identify and mitigate privacy risks, if any, associated with each scientific research. • When required by applicable law, scientific research is subject to the approval of Ethics Committees. • The coded data will not be shared for direct marketing purposes or other purposes that are not legal duties or are not considered scientific research according to the applicable data protection legislation. In particular, it will not be used to make decisions about future services available to you, such as insurance.
Security measures: How is my data protected in other countries?	The processing of your data starts at the study site. Your data will then be transferred to several data experts to be verified and for results to be calculated. In addition to having your data and biosamples coded, your data is also protected by high standard technical security means such as strong access control and encryption. You may obtain further information as well as a copy of these measures by asking your study doctor.

Restricted rights	Please note that the rights provided by the GDPR and UK Privacy Law to get data discarded (i.e., the right to be forgotten) as well as to get data transmitted in a standard electronic format (i.e., right of portability)] do not apply to such studies.
DPO (Data Protection Officer) details	If you wish to contact the DPO of the sponsor, please 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 for overseeing AstraZeneca's compliance with EU and UK data protection law, which you may contact 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 includes technological development and demonstration, fundamental research, applied research and privately funded research as well as studies conducted in the public interest in the area of public health. This means that we may use the data to advance our understanding of how to make new medicines, medical devices, diagnostic products, tools and/or other therapies, to treat diseases. We may also use this data to improve the design and execution of future clinical studies, services and drugs, for outcome research activities and to aid in pricing and reimbursement activities.

Deposit in scientific databases	To do more powerful research, it is helpful for researchers to share data by placing data into one or more scientific databases. Researchers can then study the data combined from several research projects and learn even more about health and disease. If you agree to take part in future research, some of your coded data including genetic data might be placed into one or more scientific database. Researchers with an approved scientific research project may be able to see and use your coded data, along with that from many other people. Your name and other information that could directly identify you (such as address or social security number) will never be placed into such a scientific database. Researchers will always have a duty to protect your privacy and to keep your information confidential.
Trial Result Summaries	Also referred to by the EU as Lay Language Summaries
Legal basis	You will participate in the clinical study only if you consent to it. If you do so, data related to your health and to the study drug must be collected and processed to evaluate the efficacy and the safety of the tested drug, in accordance with legal requirements from: Any other applicable law including UK laws and statutory instruments relating to clinical studies The use of your coded data and biosamples for future research will only be possible if you provide optional consent for it.
Biomarker	A biological molecule found in blood, other body fluids, or tissues that is a sign of a normal or abnormal process, or of a condition or disease. A biomarker may be used to see how well the body responds to a treatment for a disease or condition.

Diagnostic test	A test used to help figure out what disease or condition a person has based on their signs and symptoms
Clinical Performance Study	Sample collected for this study will be tested using a diagnostic test (called a diagnostic device) to assess whether it can be used to predict patients who are most likely to respond better to the study drug. Data from this study may be used to show 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 which collaborates with AstraZeneca (the Sponsor) within the drug development program or for future research.