

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		

This document comprises of 3 parts:

- Part I: the “**Study Information**” essential for your decision to participate in the clinical study,
- Part II : your “**Consent Form**” that summarises what you might agree to,
- Part III : supplementary information in the “**Additional information for patients**” Section, including a glossary.

PART I: STUDY INFORMATION

Dear Madam/Sir,

You have been invited to participate in this study since you have been diagnosed with Biliary Tract Cancer which has spread (locally advanced or metastatic). Taking Part needs your written consent. Prior to you deciding whether you want to take part in this study, you shall be provided an explanation regarding what the study consists of.

The overall description of this study for example the gathering, storage and utilisation of **your data, biosamples** and documentation, etc. has undergone reviewed in your country by an Institutional Ethics Committee which is an independent body for ensuring that the rights, safety and well-being of study patients get protected.

Your condition may or may not get better in case you join the study. But, the information we get from this study may assist other patients having a similar condition in the future.

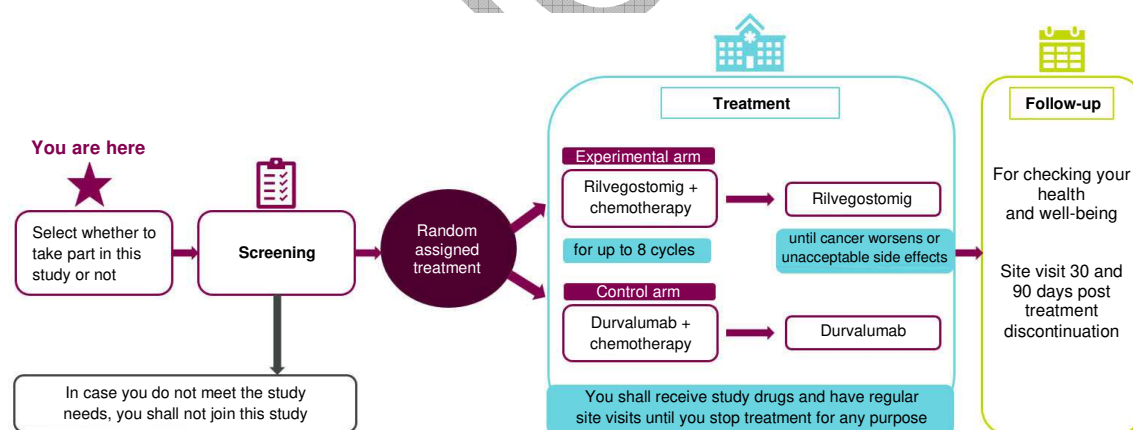
1 This study about what is it about?

We are conducting this study for learning more regarding treatment with a study drug known as rilvegostomig (also known as AZD2936), provided in combination with chemotherapy (gemcitabine and cisplatin) in patients having advanced biliary tract cancer. We shall compare the efficacy and safety of rilvegostomig combined with chemotherapy to that of standard treatment for advanced biliary tract cancer (durvalumab combined with gemcitabine and cisplatin). We are also conducting this study for a better understanding advanced biliary tract cancer and related health problems.

This study is also testing the PD-L1 diagnostic test for figuring out which advanced BTC patients might be benefitted most from rilvegostomig with chemotherapy. We are conducting this research for collecting important information which might assist in support approval of the test in countries where needed.

Few parts of this study are experimental which implies Rilvegostomig is not approved by any health authority, except for utilisation in research studies such as this.

The picture hereunder summarizes the ARTEMIDE-Biliary02 study. Every part of this study shall be explained in **Section 2**. Around 1600 patients shall undergo screening, which comprises of a series of tests which includes testing a sample of your tumor for PD-L1. Around 1100 patients shall participate in this study.



How do the study drugs function?

Rilvegostomig

Rilvegostomig might assist your immune system in fighting your cancer. It functions by blocking two proteins known as PD-1 and TIGIT on cells of your immune system. Cancer cells utilise PD-1 and TIGIT for avoiding being attacked by the immune system. By blocking PD-1 and TIGIT, rilvegostomig might assist your immune system to find and attack cancer cells. Rilvegostomig is the experimental treatment in this study.

Durvalumab

Durvalumab functions by blocking a protein known as PD-L1, that is utilised by cancer cells for evading the immune system. This enables the immune system for better recognizing and targetting the cancer cells. Immunotherapy drugs such as durvalumab are utilised for treating different kinds of cancer. In biliary tract cancer, durvalumab combined with chemotherapy (gemcitabine and cisplatin) has undergone approval for the treatment of advanced biliary tract cancer. But, not each cancer might respond to this treatment, or the response might not last long.

Chemotherapy (gemcitabine and cisplatin)

Gemcitabine and cisplatin are chemotherapy drugs utilised for treating different kinds of cancer. They are utilised together in advanced biliary tract cancer and at times called as GemCis. They function by killing or slowing the growth of cancer cells.

2 Must I participate?

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

Kindly take as much time as you require for deciding whether or not you might like to take part in this study. It might be helpful to speak with your friends and family as you make this choice.

In case you join the study, you can quit the study at any time (view “section 14” for additional details). Leaving shall not affect your care. In case you choose to quit the study, kindly let your study doctor know immediately.

Kindly consider the study time commitments and responsibilities as a research patient when you are choosing to participate.

In case you don't join the study, you shall carry on to getting care for your Biliary Tract Cancer. Your study doctor or treating physician shall speak with you regarding other possible drugs, their risks and advantages.

3 What shall occur in case I join the study?

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

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

Prior to you beginning the study treatment

You shall undergo a series of tests. This is known as screening.

You shall have around 1 to 2 visits at the study site (clinic where you must go for study visits). The length of the visit varies and is based on the tests which are required to be conducted.

In case you meet all needs, a computer shall randomly allocate you to one of two treatment arms (this is known as **randomization**). Your study Doctor shall describe in case you have been allocated with 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 utilised for ensuring patients in both treatment arms have identical characteristics and treatments may be compared as fairly as possible. Randomization implies you shall have a 50% chance of being in either the experimental or control arm (like flipping a coin).

In case you don't meet the screening criteria, the reasons shall be described. Your study doctor or treating physician shall speak with you regarding other possible treatments.

While you get study treatment

Study treatment (rilvegostomig or durvalumab combined with chemotherapy) shall be given via infusion (within the vein), as per the treatment arm you were assigned to at randomization (see above). For the initial 6 months (8 cycles), rilvegostomig or durvalumab shall be provided combined with chemotherapy – gemcitabine and cisplatin. Gemcitabine and cisplatin are provided as two infusions within the vein on days 1 and day 8 of every 3-week cycle. Once 8 cycles of chemotherapy treatment get completed you shall carry on getting rilvegostomig every 3 weeks or durvalumab every 4 weeks.

You shall carry on get treatment as a part of this study until one or more of the below mentioned happens:

- Your biliary tract cancer worsens.
- You experience side effects that require you to stop treatment.
- You choose to cease treatment.
- The study doctor and/or AstraZeneca (**Sponsor**) choose to cease your taking part.
- Applicable solely to female participants of child-bearing potential: you become pregnant or planning on become pregnant.

In case your doctor sees signs that your cancer might have gotten worse, you might be permitted to carry on getting study treatment for around 4 more weeks, as long as you are feeling well and your doctor believes you are still being benefitted from the treatment. After this time, you shall have another scan. In case the new scan confirms that the cancer is definitely worsening, you will be required to stop taking the study treatment.

In case you want to cease taking the study treatments, wish to have a modified visit schedule or in case you want to cease your participation in the study, you must inform the study doctor.

You shall be requested to download UNIFY on your device, or you shall be given a device with this App already installed. Once you login into the App for the initial time you shall be requested to accept the UNIFY license agreement and privacy notice. UNIFY shall support you while in the trial and your study team shall give you with additional information on this. While and post your treatment, you shall be requested for filling out short questionnaires regarding how you are feeling and your experience in this study. UNIFY shall be given to you once available and suitable approval has been obtained.

Study interventions rilvegostomig and durvalumab shall be available post the study is over for patients who are still getting them. Kindly note that the study, and your taking part in the study, might be stopped sooner than expected, for example for scientific or safety reasons (view “section 9” for additional details).

There are various options for carrying on treatment with study drug once the study has ceased, or once your taking part in the study has ceased. You may carry on receiving treatment with the study drug as long as you are being benefitted from the study drug, in your doctor's opinion. Your doctor shall discuss the available options with you. These options might be inclusive of additional treatment within this present study, transitioning to another study, or transitioning to an alternative drug supply. In case you are transitioning to another study, you shall be provided a new study informed consent form, as applicable. In case you continue treatment within this present study, your treatment plans shall be as per the standard of care or according to local clinical practices.

Post you having received study treatment (Follow-up)

Post you stop treatment, you shall still be requested for visiting the clinic regularly until the study ceases. This is to view if you began a new treatment, assessing whether your cancer has gotten worse and confirm you are alive as part of the follow-up period. In case your cancer gets worse and study treatments have been stopped, we might follow up with you via phone rather than clinic visits. You may select to quit the study at any time.

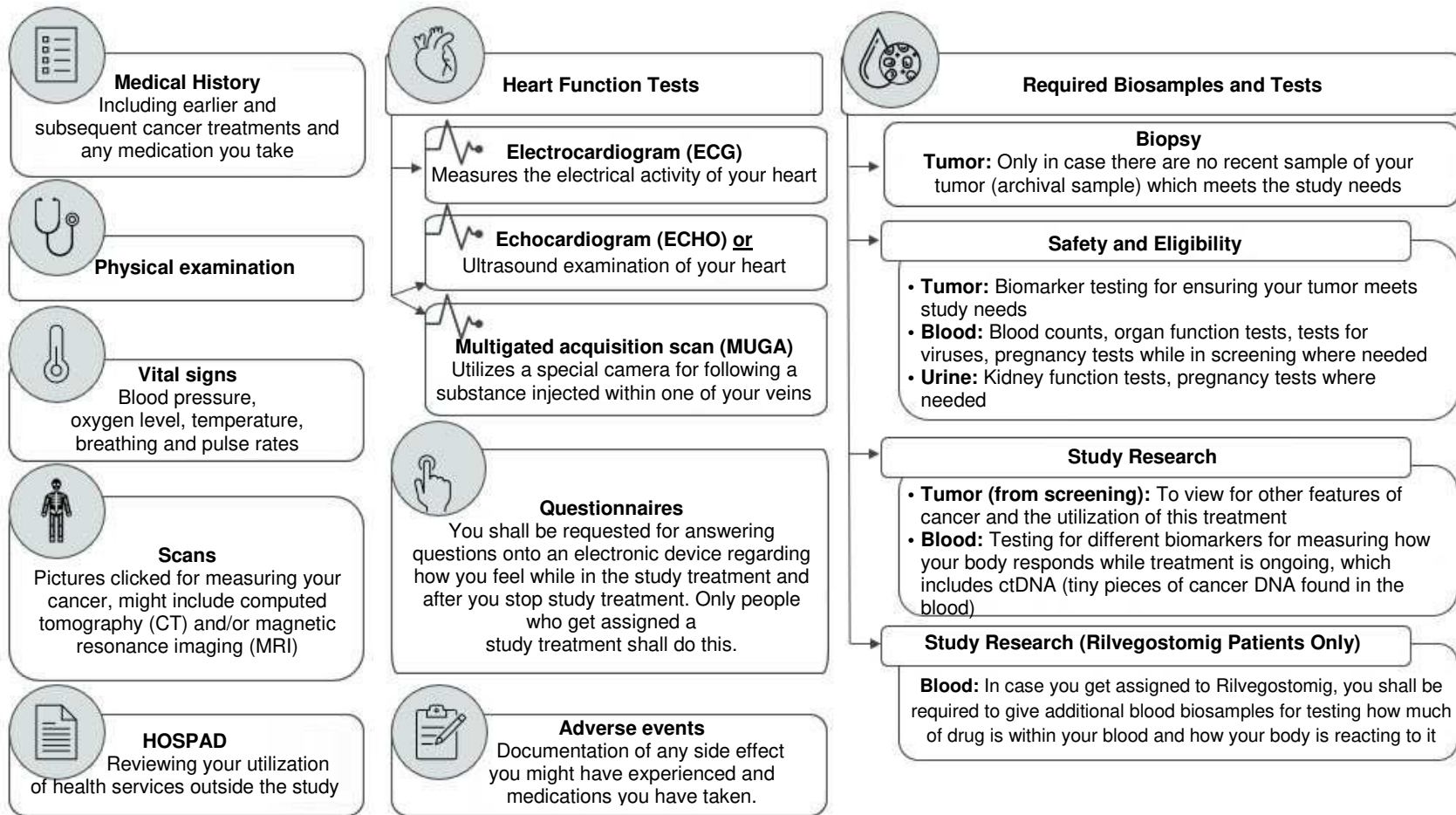
In case you cannot arrive for a visit during any part of the study, you should inform the study doctor immediately.

It is a possibility that you might have to visit another facility for undergoing a few of the assessments/procedures for this study. Your study doctor shall tell you in case you are required to go to another facility for any assessment/procedures. Your study doctor shall organize for your visit to another facility in the event it is needed.

4. The tests and procedures required what are they?

During your being in the study, we shall be required for taking a few measurements and biosamples, for example, tiny amounts of blood or urine.

This is a list of the various tests and procedures you may expect to have during participation in this study:



Complete list of study tests and procedures, which includes their detailed schedule is available in Part III section 2 “Additional information for patients”. This section also gives additional details on **biosamples** handling, collection and storage locations.

PD-L1 level testing of your tumor, To participate in this study, we require a tiny piece of your tumor tissue for testing. This is needed for everyone who joins the study. We might utilise a sample which was earlier gathered and stored from a past biopsy or surgery, as long as it was taken within the past 12 months prior to you joining the study. In case a recent sample is not available, you might be required to have a new biopsy for collecting this tissue.

PD-L1 is a protein found onto the surface of a few cancer cells. It functions like a “shield,” assisting cancer cells hide from your immune system so they are difficult for your body to find and fight. Within this study, we shall utilise a special lab test known as the investigational Ventana PD-L1 (SP263) CDx assay for checking for PD-L1 in your tumor tissue. This test is approved for assessing PD-L1 levels in a few cancer types in certain countries, however it is not approved for utilisation with rilvegostomig in biliary tract cancer. Within this study the PD-L1 test outcome is being utilised as a stratification factor that implies ensuring the two arms of the study (experimental and control arm) are balanced as per PD-L1 status. This helps in ensuring the study results are fair. We shall also investigate whether your tumor samples and study data, which includes PD-L1 results, may identify biliary tract cancer patients who may be more likely to be benefitted from the study drug.

In case your tumour sample has already been sent for central laboratory testing with the investigational VENTANA PD-L1 (SP263) CDx Assay for confirming PD-L1 status in another AstraZeneca study, then this outcome may be utilised for determining your eligibility for this study, given that the testing was conducted at the same lab and the sample meets this study's needs. By permitting to this study, you consent for the reallocation of your PD-L1 outcome, in case applicable, and any tumour samples given as part of another AstraZeneca study for the objectives of this study. In case

you do not want this outcome and tumour samples reallocated from other studies and instead might prefer giving new tumour samples, kindly tell your doctor right away.

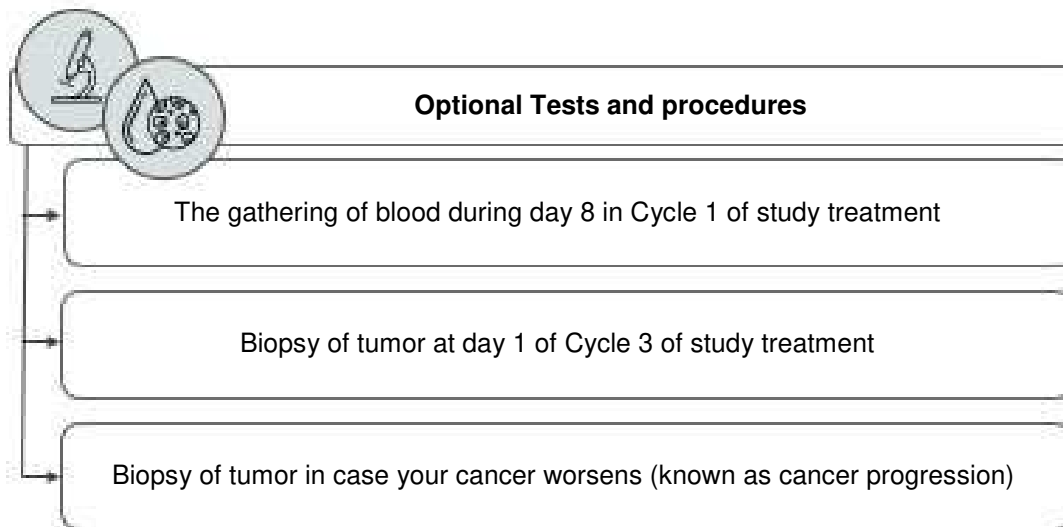
Tumor Genetic analyses

Few biosamples shall be utilised for analyzing your genetic information. You may think of genetic information as a huge instruction book which your body reads for understanding how body must be built and function. All humans possess the same instruction book in their body however few words or letters might vary from one person to another. Few of those differences have no effect on your health however others may influence the possibility of developing a disease or affect how medicine for treating a disease shall function. All your cells possess the same DNA, however tumor cells might develop alterations known as mutations. For finding these, tumor DNA may be compared with DNA from your normal blood cells, assisting us in understanding your cancer and guiding treatment. In case genetic analyses is done, they might comprise of all or part of your genetic information utilising your tumor tissue samples and circulating tumor DNA (ctDNA) which might be found in your blood, also, in case required, your normal blood cells. These analyses shall be conducted in the context of the main study objectives. The genetic analyses being done in this study are for exploratory objectives and shall be conducted retrospectively, implying the analyses are done at a later date and might not be done until after your taking part in the study has ended. Outcomes from these analyses shall not undergo sharing with you or your study doctor.

5. The optional tests and procedures what are they?

The below mentioned tests and procedures are optional in this study. In case you agree, you might give your consent by tick-marking the checkbox in the consent form. You may agree to all optional procedures and biosamples or solely one or you are not required to agree at all. The tumor and blood samples (biosamples) gathered from these optional collections might undergo analysis for extra features of your tumor and the response of your immune system to treatment. These biopsies, biosamples, and outcomes from these biosamples are not expected to directly affect your medical care. In case you do not consent for the optional procedures, you may still take part in this study. In case you want to alter your mind regarding utilising extra sample(s) for additional research, you may do so at any time and inform your study doctor.

In case you consent, biosamples might be gathered while in the study for optional tests as mentioned below:



6. The risks of joining the study what are they?

A risk exists that your biliary tract cancer shall not improve or even worsen while in the study. It is a possibility that a few patients might have side effects which we are not aware about yet. A possibility exists of failure of the investigational product to give the therapeutic effect. In case you have severe side effects from the study drug, the study doctor might ask you not to carry on treatment in the study. You might also be requested for delaying doses of study treatment to allow the side effects to get better. Management of side effects might also need the administration of drugs like steroids or other agents which may affect your immune system and lessen inflammation.

In case you suffer any side effects or injuries, or your condition worsens, inform the study doctor right away so you may get suitable care.

Possible risks linked with rilvegostomig

There is limited data on the utilisation of rilvegostomig in humans, hence the risks of rilvegostomig are not completely known during this time. You might experience side effects that might be very serious in nature (which includes the risk of death) and never disappear. Utilising information available regarding drugs which work in an identical manner to rilvegostomig and the known information from research studies with rilvegostomig, the Sponsor (AstraZeneca) has determined the below mentioned potential side effects might happen when rilvegostomig is given.

1. Identified risks:

- **Infusion-linked reactions** are side effects which happen while in or shortly post (up to 24 hours) getting a drug through the veins. These reactions might be inclusive of fever, chills, muscle ache or tenderness, nausea, vomiting, itching, rash, raised heart rate, breathing difficulty, reduced blood pressure, or light-headedness. The infusion-linked reactions seen with rilvegostomig have so far been mild, manageable and resolved.
- **Rashes** seen with rilvegostomig were mainly low-grade and responded well with treatment.

2. Potential risks:

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

- **Inflammation of the brain** (Encephalitis): you might experience confusion, problems with speech or movement.

3. Other potential risks are inclusive of, however are not limited to:

- **An acute severe allergic reaction** (known as anaphylaxis) is a rare side effect that normally happens during, within minutes, or up to 24 hours post getting a drug. Symptoms consist of swelling of the vocal cords, the face or voice box area, breathing difficulty, and/or possibly death.
- **Immune complex disease** might happen in case a patient forms antibodies to rilvegostomig. Symptoms might be inclusive of aching joints, rash, fever, a reaction in the kidneys (nephritis), or inflammation in blood vessel (vasculitis).
- **Cytokine release syndrome** is a syndrome that happens when immune cells get activated and cause raised inflammation through the entire body. Symptoms might be inclusive of fever, headache, rash, low blood pressure, low blood oxygen levels, rapid heart rate, and breathlessness. In most patients, the symptoms are mild to moderate in severity, however it may be severe and life-threatening (cytokine storm syndrome).
- **Tumor lysis syndrome** is a rare condition which happens with the rapid breakdown of cancer cells. This might cause nausea, vomiting, muscle cramps, weakness, reduced urination.
- **Abnormal laboratory results** which include elevation of triglycerides and cholesterol levels, elevation of digestive enzymes: amylase and lipase. Elevated level of potassium and reduced concentration of sodium within the blood.
- **Embryo-fetal toxicity** is an effect on the pregnant female that may lead to harm to the developing embryo or fetus.
- **Graft-versus-host disease** development post-hematopoietic stem cell transplantation is a complication when the donated cells (the graft) view your body cells as foreign and attack them. Symptoms might be inclusive of gastrointestinal tract, liver and skin problems. Few may be mild, however it may be severe and life-threatening.
- **Rejection of transplanted organs.**

Risk and side effect linked to durvalumab

Most of the possible side effects mentioned hereunder are mild to moderate. But, few side effects may be very serious and life-threatening and might even lead to death. Few side effects do not require treatment whereas others generally get better with treatment.

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

Diarrhea
Rash/Dry itchy skin
abdominal pain
Upper respiratory tract infections
Cough
Fever
Underactive thyroid gland which can lead to weariness or weight gain (Hypothyroidism)

Common (seen in more than 1 in 100 people)

Inflammation in the lungs (pneumonitis)
Overactive thyroid gland which may lead to rapid heart rate or loss of weight (Hyperthyroidism)
Alterations in lab tests linked to kidney and liver function
Infusion-linked reactions
Pain in muscles and joints (Myalgia)
Pneumonia
Influenza
Hoarse voice
Painful urination
Night sweats
Fungal infection inside the mouth (Oral candidiasis)
Dental and oral soft tissue infections
Accumulation of fluid that causes swelling for example in the legs

Uncommon (seen in less than 1 in 100 people)

Reduced secretion of hormones produced via the adrenal glands (Adrenal insufficiency)
Scarring of lung tissue (Interstitial lung disease)
Liver Inflammation(Hepatitis)
Kidneys Inflammation (Nephritis)
Skin Inflammation(dermatitis)
Inflammation of the muscles (Myositis)
Inflammation of the intestines (Colitis)
Inflammation of the thyroid gland (Thyroiditis)
Inflammation of the pancreas (pancreatitis)

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

Type 1 Diabetes Mellitus
Inflammation of multiple muscles (polymyositis)
Weakness in the muscles (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 assist your blood in clotting (Immune thrombocytopenia)
Brain Inflammation (encephalitis)
Inflammation inside the eye (Uveitis)
Nervous system disorder (Guillain-Barré syndrome)
Inflammation of the joints (Immune-mediated arthritis)

Risk of combining chemotherapy using rilvegostomig or durvalumab

Potential risks and side effects of chemotherapy plus rilvegostomig or durvalumab are on the basis of the identified risks of every individual drug. No additional risks are at present anticipated when chemotherapy is combined with either rilvegostomig or durvalumab, beyond what is expected for every individual drug. It is common for patients having advanced biliary tract cancer for getting chemotherapy (gemcitabine plus cisplatin). The study doctor shall describe the risks and potential side effects of the chemotherapy with you.

Possible risks of study procedures

Few of the study procedures might have possible side effects, risks, and discomforts. You might experience few or all, none. The procedures conducted as part of this study are standard and routine procedures; you might have these procedures more frequently in case you join this study. The study doctor shall have the ability to explain these to you in detail and give you any risks and/or side effects linked with these.

Risks linked with biopsy

In case there is no sample of your tumor available (for example, gathered from the time you were diagnosed) which meets the study needs, a new sample of your tumor shall be required to be gathered by biopsy. Based on where a biopsy is taken from, risks might be inclusive of pain, bleeding, injury of the liver or bile ducts, and infection. In extremely rare cases, there may be serious complications that might even result in death. Also, a hypothetical risk exists of the regional spread of cancer cells when the needle is taken out from your tumor. Your study doctor shall discuss the most suitable way for obtaining a biopsy from your tumor and other possible risks with you. You might be asked to separately consenting to the biopsy procedure.

Risks linked with PD-L1 testing

A valid PD-L1 outcome is mandatory for entering the study.

There is a tiny risk the sample you give does not provide us with a result; it is a failed or invalid test. In this case, we might ask your doctor in case another sample is available for being tested. This shall raise the chance of a successful test outcome.

There is a tiny risk your test outcome might be delayed, however measures have been kept in place for minimising the risk of a delayed test outcome. It is also important to know that the PD-L1 test is conducted in the laboratory using your tumor sample. The equipment utilised for the test does not come into direct contact with you, so there exists no risk of harm or injury to you from the testing itself.

7. Do any other considerations or risks exist that I need to know about?

Pregnancy, contraception, and breastfeeding

Since the effects of the study drugs on an unborn child or infant are not known, you (or your female partner in case you are a male) should not become pregnant or breastfeed by entering the study until 60 days post the final dose of rilvegostomig, 90 days post the final dose of durvalumab, and 6 months post the final dose of chemotherapy whichever is longer.

There might be other things for considering and the required time of contraception might be longer while you are getting chemotherapy as well. Your study doctor shall tell you whether this is the case.

For female patients:

Women who have the ability to get pregnant and intend to be sexually active with a male partner who have the ability to father a child (are non-sterilized) should utilize a minimum of 1 highly efficacious method of contraception from entering the study until 60 days post the final dose of rilvegostomig, 90 days post the final dose of durvalumab or 6 months post the final dose of chemotherapy, whichever is longer. In a few cases, local guidelines might need a longer duration and your Doctor shall tell you whether this is the case. Your male partner should also utilize a male condom plus spermicide through this entire period.

In case you get pregnant, you should tell the study doctor immediately. You shall have to cease taking the study drug right away until you have spoken with your study doctor. You shall be requested to give information regarding you and your baby. This might comprise of a separate consent for allowing us for monitoring your baby's health and development.

For male patients:

Men who have the ability to father a child (are non-sterilized) and intend to be sexually active with a female partner who has the ability to get pregnant should utilize

a male condom plus spermicide from entering the study until 60 days post the final dose of rilvegostomig, 90 days post the final dose of durvalumab or 6 months post the final dose of chemotherapy, whichever is longer. In few cases, local guidelines might need a longer duration, and your Doctor shall tell you whether this is the case. Your female partner should also utilize a highly efficient method of contraception through this entire period. In case your partner becomes pregnant, you should inform the study doctor right away. Your partner shall be asked, under a separate consent, to give information regarding their health and your baby's health.

Note that a few contraception methods are not considered highly efficient. Kindly view the table hereunder for examples of highly efficient methods of contraception.

Examples of highly efficient methods of contraception (<1% failure rate):

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

The study doctor may discuss more regarding the acceptable birth control methods with you.

Other medicines and remedies you might be taking

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

Rilvegostomig or durvalumab might alter the way specific drugs are handled by your body. Specifically, you shall be advised against the utilisation of immunosuppressive medications (drugs which dampens your immune system), like systemic (taken orally

or via injection) corticosteroids whilst on study. In case relevant your study doctor shall discuss this further with you and consider alternative drugs as suitable.

Blood, sperm and egg donation

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

Vaccines

You must not be provided specific types of vaccines (known as live attenuated vaccines) from 30 days prior to the initial dose of treatment on the study until 30 days post the final dose of study treatment. You must not get a COVID 19 vaccination in the 3 days prior to getting the initial dose of study treatment. Your study Doctor might inform you more about vaccines which are allowed whilst you are getting study treatment.

8. What are the possible benefits of participating?

We are not aware if participating in the study shall assist your condition, however we hope that it shall.

The information the study **Sponsor** gets from this study might assist in better treating patients having biliary tract cancer.

It is not specific that you shall directly benefit from taking part in the study. Your taking part might, but, assist other patients in the future by improving the knowledge of diseases and improving medical care.

9. What occurs in case something alters while I am in the study, for example in case new information is found?

Alterations might occur in the study which might make you alter your decision regarding carrying on participating in the study. In case something alters, we shall tell you immediately.

You may choose to quit the study during any time. For additional details view section 14 hereunder.

The study doctor may also select to withdraw from the study in case they trust that it is best for you.

Your taking part in the study also ceases when the **Sponsor**, health authorities, the ethics or regulatory agencies choose that the study should be stopped.

10. What occurs in case I get harmed or injured while in the study and in such cases who shall pay monetary compensation?

In case there is an emergency, call your study doctor immediately or go to the nearest 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".

In case you become ill or get injured while you are in this research study, you should tell your study doctor immediately.

Injuries which have been caused due to the study drug, tests or procedures are known as "trial-related injuries". Injuries caused due your regular medical care or your biliary tract cancer are not trial-linked injuries.

COMPENSATION FOR TRIAL-LINKED INJURIES

In the event of an injury happening to you while in the clinical trial, AstraZeneca, the clinical trial sponsor will give you free medical management as long as needed or till such time it is established that the injury is not associated with the clinical trial, whichever is sooner 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 rule 39 (that is Indian regulation for Compensation in the event of injury or death in clinical trial of new drug or investigational new drug), as the case might be, will give monetary compensation for the injury or death.

The monetary compensation shall be over and above any expenses incurred on the medical management of an injury happening to you as a clinical trial subject. The health authority of India decides the compensation to be provided to you or your nominee in the event of a study-linked injury. Hence, AstraZeneca shall pay compensation to you or your nominee in the event you suffer from a study-linked injury or death according to the directive of the health authority of India.

AstraZeneca did take out an insurance to cover clinical study-linked injuries or death. So that AstraZeneca obtains proceeds from this insurance for your study-linked injury or death, insurance company might ask for your medical records and/or your signed

informed consent form for this study. It is also a possibility that the health authority of India might ask for your medical records and/or your signed informed consent form for evaluating a study-linked injury. In case AstraZeneca has to share your medical records and/or your signed ICF to the insurance company or the health authority, suitable care shall be taken for protecting your privacy

In case you have medical insurance, kindly check with your insurance company that participating in this research study shall not affect your coverage.

11. What shall happen to my data and biosamples collected in the study?

a. Which data and biosamples are gathered?

So as to conduct the study, the **Study site** shall have to gather and register information regarding your identity (like your name, address, telephone number, and health insurance number) as well as data which is required for assessing your health conditions like your medical condition and medical history (this might be inclusive of information from your physicians / available in your medical records), your lifestyle, your demographics (age, sex, ethnic and racial background), your images and data generated from the images (for example scans) and your genetic information.

Data gathered through devices or apps on a smartphone, website, or other tool shall also be part of your coded data. Your answers to questionnaires utilising a smartphone or handheld device shall also be gathered. For additional details regarding which data is collected in the study, view further details at the end of this document in part 3: "Additional information for patients".

Additionally, the study site shall gather biosamples from you (like blood or body tissue). These shall undergo analysis and the data derived from the analysis shall be part of your **coded data** that will also be inclusive of genetic data and images.

b. My data and biosamples what are they required for?

Your data and biosamples are required by the **Sponsor** for developing the drug and associated diagnostic devices (along with Ventana Medical Systems Inc), get permission for introducing and keeping it on the market, monitoring its safety and getting it reimbursed e.g. by governments that is, through the entire drug development programme. Hence, they shall be utilised as scheduled in this study as well as within associated research activities required for this drug development programme so as to:

- understand how the study drug(s) and identical drugs function in the body (that is, evaluating the study drug's mode of action, solo or combined with other study drugs),
- better understand the studied disease and linked health problems,
- *develop diagnostic tests for the disease by assessing if the diagnostic tests may identify patients who shall most likely be benefitted from the study drug in a clinical performance study, future diagnostic development, and diagnostic approval in countries where needed.*
- learn from previous studies for planning new studies or improving scientific analysis methods,
- publish research outcomes in scientific journals or utilise them for educational objectives,

c. My data and biosamples who can access it?

Solely at the study site, your name and contact details shall be accessible to the study doctor and the study team for conducting the study. Personnel who act on behalf of the **Sponsor** and being bound by a duty of confidentiality, as well as **Health authorities** and Ethics Committees might also be provided access to this data solely for verifying that the study is conducted in compliance with legal and quality needs. Few of your data might be accessed remotely where permissible.

The study site shall share your data and biosamples with the **Sponsor** however, only post they have been coded (which implies that your name, contact details or health insurance number have been substituted by a code. For additional information regarding coding, view details at the end of this document in Glossary in part 3: "Additional information for patients"). This is inclusive of coded data and biosamples gathered following consent while in the screening period, despite you not joining the study.

The **Sponsor** might share your coded data and biosamples with its **Research partners** and **Service providers** for the objectives of the drug and diagnostic device development programme. To get permission for marketing the drug and diagnostic test, AstraZeneca shall 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 for ensuring proper conduct and precise outcomes of the study.

So as to ensure proper conduct and precise results of the study and to get permission for marketing the drug and diagnostic device, the **Sponsor** shall share your coded

data with health authorities and possibly with Ethics Committees. They might also be shared with scientific journals, so the study outcomes can be reviewed by independent scientists and for ensuring the precision of the outcomes.

In the event of adverse events or device deficiencies linked with the investigational test, the Sponsor might share your coded data with health authorities and ethics committees as per applicable regulations. This is inclusive of any serious adverse events that threaten your life, needs an emergency visit to the hospital, prolongs your hospital stay, leads to disability or death that are associated with the diagnostic test or a study procedure associated with the test – For example a complication in a study biopsy procedure required for study eligibility which needs you or prolongs your stay within hospital.

In neither of these cases shall your identity be disclosed.

Few of the above-mentioned persons might be situated out your country. In case this other country does not possess equivalent personal data protection standards as your country, suitable **Safeguards** (like contracts and technical **Security measures**) shall be adopted for protecting and maintaining the confidentiality of your data and biosamples as further explained at the end of the document in part 3: “Additional information for patients”.

In the event another organisation takes over the development or marketing of the study drug, your coded data or biosamples might be transmitted to them. They shall then have to protect your data and biosamples in a similar manner as explained herein.

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

Your name or contact details might undergo sharing with service providers, so as to:

- Reimburse you for your time, effort and specific expenses associated with your taking part.
- Setting up and managing your accounts for any apps or other devices which are utilised in the study. The data which is gathered and processed in the study through the App is detailed in Part 3, Section 3 of this document.
- Give technical support for any mobile application which is utilised in the study. In case you call the App provider support helpdesk, your name and phone number might be gathered (with your permission) in the event a follow-up contact is needed, for example your issue isn't resolved, and Helpdesk requires getting in touch with you. The information shall be deleted post your

ticket gets resolved. The service providers should store your name or contact details private and shall NOT share any information which may directly identify you with the Sponsor.

When you utilise the Unify App, your contact details might be gathered but shall solely be utilised for technical support purposes and are subject to similar data protection standards as other personal information.

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

The service providers should store your name or contact details private and shall NOT share any information which may directly identify you with the **Sponsor**.

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

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

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

Your biosamples gathered while in the study shall be returned to your study doctor or destroyed immediately post the tests mentioned in part 1 section 4 and 5 for the drug development program are completed unless you give consent for future research.

In case you authorise the **Sponsor** for utilising your samples for future research (In a separate "Future Research ICF a tick-box" which shall allow you for making this choice), your biosamples shall be stored for a maximum of 15 years.

f. My rights under data protection law what are they?

You possess the right for reviewing which of your data is gathered and being utilised; you may also request a copy of this data, request for restriction of utilisation of this data, or request for having incorrect data corrected.

In the event you consent to Future Research (In a separate "Future Research ICF), you might also request the study doctor to get a copy of the data you have given for the future research in a standardised electronic format or for having them transmitted for another person of your choice.

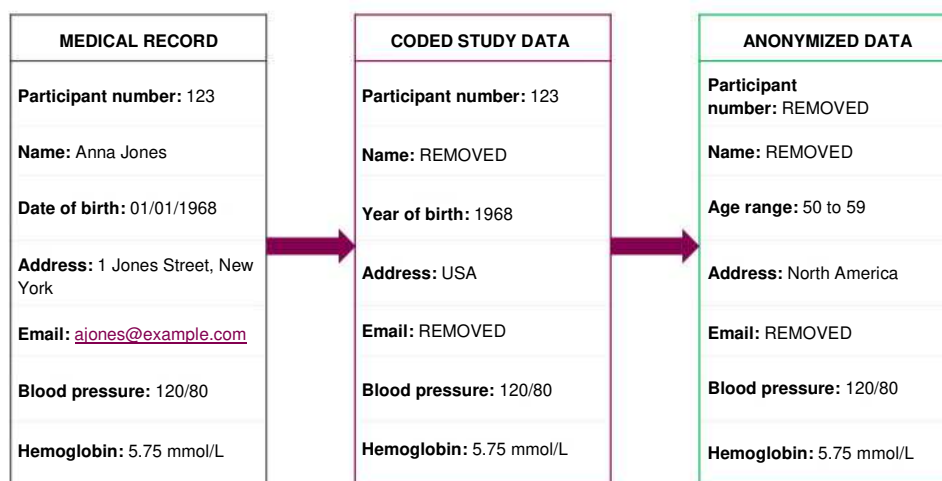
For making sure the scientific integrity of the study, you shall not have the ability to reviewing some of the data or getting a copy of it until the study ceases.

For exercising these **restricted rights**, kindly get in touch with preferably the study doctor.

Contact details of the **Data Protection Officer (DPO)** are given in part 3: “Additional information for patients”. In case there are issues linked with the utilisation of your data, you possess 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 trust that access to clinical studies data advances clinical science and medical knowledge and is in the best interest of patients and public health, given that patient privacy is protected. Hence, the **Sponsor** might generate and share internally or with other researchers an anonymised set of your data gathered in the study (for example, on www.vivli.org). This implies your coded data shall be stripped of your Patient code as well as of any other information which might reasonably be utilised for identifying you, like your date of birth.



12. What are the costs of taking part?

Taking part in this study shall not cost you anything. Study drug, study visits, tests and examinations are free of cost.

You shall not get paid for participating in this study. But, you might get Rs 2000/- per visit towards your valid and necessary expenses connected with the study, like travel

conveyance. In case you suffer any side effect or injury, inform your Study Doctor right away so that you may get suitable medical treatment.

13. How to figure out more post the study?

Trial Result Summaries are a short and easy-to-understand summarization of the outcomes of this study. These shall be added to www.trialssummaries.com within 1 year of the last study patient's last site visit. You may visit www.trialssummaries.com website anytime for signing up to be notified through email when the trial results summary of your study is available. Or, kindly let your study doctor know whether you require a printed copy of the document.

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

Description of this clinical trial shall be available on <http://www.clinicaltrials.gov> website, as needed by U.S. Law. This website shall not be inclusive of information that may identify you. At most, the website shall be inclusive of a summarisation of the outcomes. You may search this website during any time.

Information in technical language associated with the study protocol and the outcomes shall be posted on <http://astrazenecaclinicaltrials.com> and <https://www.clinicaltrialsregister.eu> and <http://euclinicaltrials.eu> website. Description of this study is also available on <http://ctri.nic.in> website. These websites do not consist of any information regarding you.

14. What shall happen in case I want to quit the study?

Your taking part in the study is on a voluntary basis which implies you may stop your taking part during any time. In case you want to cease taking the study drug, wish to take a modified visit schedule or in case you want to cease your taking part, you must inform the study doctor and discuss available options.

In case you cease taking part in the study (know that this is a “study discontinuation”, and not a withdrawal of / objection to consent for processing personal data), the study doctor shall cease the collection of your data, however your earlier gathered data and biosamples shall be kept and utilized for guaranteeing the validity of the study and for complying with regulatory needs, as permissible by law. The study doctor shall then invite you for having an end-of-study examination for checking your wellbeing. In case you don't show up at a scheduled visit, the study doctor shall try to reach you. In case the study doctor cannot reach you, where permissible, public sources like patient organization registry shall be consulted for verifying your wellbeing. This is important for study outcomes. It is not mandatory however might be helpful for the study in case

you describe to your study doctor why you want to cease your taking part, in particular in case you did experience discomforts.

We shall carry on utilising your data and gathered samples as originally consented, unless you might like your data or biosamples not to be utilised post you quitting the study. In such an event, you should tell the study doctor and your leftover biosamples shall undergo destruction or (in case requested) returned to the study doctor immediately, however your coded data gathered earlier shall be stored as needed by clinical regulations.

15. Who may reply to any queries I might have?

Do bear in mind, there are no silly queries! Feel free to enquire at ANY TIME! It is your right to be completely informed prior to deciding to participate in this study also in the future research proposed in part 2. You may get in touch with the study doctor during any time at the address denoted 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)		

Initials of the Subject:			
Name of the Subject:			
Date of Birth:		Age:	
Address of the Subject:			
Qualification:			
Occupation: (Kindly tick-mark as suitable)	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 objective of compensation in the event of trial-linked death)			

I do confirm that:

- The study doctor or study personnel delegated by the study doctor has / have described the study to me in a comprehensive manner.
- I did have the chance to discuss the study with the study doctor and all my queries were replied to.
- I did have sufficient quantity of time for considering the study.
- I have honestly replied to all queries regarding my medical history and shall follow all rules mentioned in the document.
- The standard of care procedures done before the informed consent might be utilised for screening purposes.

I know that my taking part also entails:

- My name and contact details are being gathered while in the study as explained to me, and accessed and reviewed by the mentioned authorised people;
- My coded data (which includes images) being utilised by the sponsor and Ventana Medical Systems Inc., or by people or companies that act on its behalf or work with the sponsor;
- My coded data being utilised by persons or organisations situated in countries which do not have data protection rules equivalent to those of my country. I know that the sponsor monitors these uses and takes all possible measures for protecting my privacy;
- My biosamples being gathered and analysed as explained and that this includes genetic analyses.
- In case applicable, my PD-L1 result and/or tumour samples submitted for screening procedures as part of another AstraZeneca study might be utilised for the objectives of this study.

I further understand that I can make a choice regarding the topics mentioned hereunder and that by tick-marking “Yes” I do provide consent and that by tick-marking “No” I do not provide consent:

My taking part in optional blood test as detailed in part 1 I section 5.	Yes ☐	No ☐
My taking part in the optional biopsy during the first day of cycle 3 of study treatment as detailed in part 1 I section 5.	Yes ☐	No ☐
My taking part in the optional biopsy in case my cancer worsens (disease progression) as detailed in part 1 I section 5.	Yes ☐	No ☐
Study doctor might notify your physician regarding your taking part in the study and might share relevant medical information with him/ her in case required for managing your health and safety throughout. In case you agree, kindly indicate the name and contact details of your physician here: You agree, Yes ☐ No ☐ Not Applicable ☐ In case yes, kindly indicate the name and contact details of your physician here: Name of your physician: Contact Details:		

Sl. No.	Kindly give your initials (short signature or signature) or thumbprint (as applicable) against every one of the below-mentioned statements for confirming your consent for these statements	
(i)	I do confirm that I did read and understand the Study Information and Informed Consent Form dated 23 July 2026, India Version Number 1.1 for the study above and did have the chance to ask queries.	[]
(ii)	I know that my taking part in the study is voluntary and that I have the freedom for withdrawing at any time, without providing any reason, without affecting my medical care or legal rights.	[]
(iii)	I know that the Sponsor of the clinical trial, others who work on behalf of the Sponsor , the Ethics Committee and the regulatory authorities shall not require my permission for looking at my health records both with respect to the present study and any additional research which might be done in association with it, despite my I withdrawal from the trial. I agree to this access. But, I know that my identity shall not be disclosed in any information shared with third parties or published.	[]
(iv)	I agree not to limit the utilisation of any data or outcomes that emerge from this study given such utilisation is solely for scientific objective(s).	[]
(v)	I agree to participate in the study above.	[]

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

Date of Signature

Signatory's Name (Name of the subject or LAR who did sign)

Where a subject does not have the ability to provide informed consent (for example an unconscious person or a minor or those suffering from severe mental illness or disability), the same might be obtained from a legally acceptable representative (a legally acceptable representative is an individual who is has the ability to provide consent for or authorize an intervention in the patient as given by the law(s) of India).

Relationship of legally acceptable representative with the subject

Signature of the Investigator

Date of Signature

Name of the Study Investigator

In case the Subject or his/her legally acceptable representative is unable to read/write an impartial witness must be present while the entire informed consent process is ongoing who should append his/her signatures to the consent form.

An impartial witness is an individual who is free from the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process in case the subject or the subject's legally acceptable representative cannot read, and who reads the informed consent form and any other written information given to the subject.

Signature of Impartial Witness

Date of Signature

Name of Impartial Witness

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

PART III: ADDITIONAL INFORMATION FOR [PATIENTS / PARTICIPANTS]

WHO MAY I GET IN TOUCH WITH FOR INFORMATION AND ASSISTANCE?

1. Contact details

In the event of any study-linked injury, or whenever you have queries regarding the study or your study medication, kindly get in touch with:

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

Sponsor contact details specified in glossary section hereunder:

In case you have queries regarding your rights as a research subject, you might contact:

Name of Ethics Committee	Institutional Review Board
Name of Ethics Committee's Member Secretary/Chairperson <i>(Member Secretary or Chairperson as applicable, according to 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:** prior to any study-linked procedures are conducted, you shall be requested for signing the consent form in Part II “Consent Form” of this document to provide your permission for the tests and procedures for being performed.
- **General health:** information shall be gathered from you about your age, gender and race, and your medical, surgical and lifestyle history. The study doctor shall view your medical history for viewing whether you meet the requirements to participate in this study.
- **Medications/side effects:** The doctor shall discuss with you any medications which you might be taking. Kindly inform them regarding all the drugs which you are taking which includes prescriptions, over-the-counter medications, vitamins, supplements and any herbal or recreational drugs. You shall also be questioned whether you have been feeling unwell or did notice any alterations in your health. You should inform the study staff regarding any alterations which have happened since your last visit.
- **Safety monitoring and performance status:** your study doctor shall monitor your safety and well-being through the entire study. Your performance status (PS) shall get evaluated by your doctor. This performance status is a measurement of your general well-being and activities of everyday life. Kindly make sure you notify your study doctor of any discomfort or deterioration in your health during any time.
- **Physical examination (which includes weight and height):** your study doctor shall examine you, that shall be inclusive of 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 shall assess your blood pressure, oxygen level in your blood, heart rate, breathing rate and body temperature.
- **Healthcare resource use (HOSPAD)** - We shall utilise your healthcare records to view how many times you required utilisation of health services, out of the study
- **Electrocardiogram (ECG):** Sticky patches or electrodes are fixed to your chest and shoulders and connected to wires which go to a machine. This measures the electrical activity of your heart.
- **Echocardiogram (ECHO)/Multi-gated Acquisition (MUGA) Scan:** ECHO or MUGA scans check if your heart is pumping blood in a proper manner. An ECHO is a kind of ultrasound test for determining the pumping function of your heart. A MUGA scan is a test utilising a radioactive tracer (known as a radionuclide) and a special camera for taking pictures of your heart as it pumps blood.
- **Assessment for Tuberculosis infection:** your study doctor shall assess whether you are having active tuberculosis infection, in line with local practice.
- **Tumor imaging by computed tomography (CT) or magnetic resonance imaging (MRI):** these shall be utilised for checking whether there are signs of cancer regression/progression. CT scans utilise X-rays for creating detailed images of your body, while MRI scans utilize magnetic fields for producing identical images. Body areas which shall be scanned comprise of chest/thorax, abdomen and pelvis. Any other areas might be additionally imaged as required.
- **X-ray:** might be conducted for checking whether there are any signs of cancer regression/progression, such as in the bones. X-rays are a kind of radiation that may pass through the body and create images of the within of the body.

- **Whole body bone scans (Scintigraphy):** might be conducted for checking whether there are any signs of cancer regression/progression, which includes the inside the bones.
- **Positron emission tomography/computed tomography (PET/CT) scans:** might be conducted for checking any signs of the cancer regression/progression. PET/CT scans utilise a radioactive tracer for showing more detailed images of your body.
- **Blood and urine collections:** Blood counts, organ function tests, tests for viruses.
- **Pregnancy Test / Breastfeeding:** in case you are a woman and have the ability for having children, you shall take a pregnancy test (from blood) during screening and a blood or urine pregnancy test prior to every cycle of study treatment, during the end of treatment and while in the safety follow-up. You are not permitted to participate in this study in case you are pregnant or are trying to get pregnant. You are not permitted to participate in this study in case you are breastfeeding or plan on breastfeeding.
- **Blood sample for exploratory biomarkers research.** A biomarker is a biological molecule which is a sign of a normal or abnormal condition. A few biomarkers may help in predicting how well someone will respond to a specific treatment for a disease and for understanding how the drug is functioning. These samples shall be gathered while in the treatment period for assessing any alterations in response to the drug compared to baseline while in the study.

These blood samples shall be utilised for:

- Studying the response of the immune system and immune associated biomarkers (soluble proteins and gene expression) with the drug for understanding why few patients might respond with the treatment better than others or develop side effects.
- Test circulating DNA shed by the tumour (ctDNA) for understanding why few patients might respond to treatment better than others, and why at times treatment may cease functioning, and for helping develop

diagnostic tests (tests for choosing the right medicines for different people) and for detecting early recurrence of cancer. Additionally, DNA sequencing might be conducted on white blood cells leftover from blood processing before ctDNA testing. A further explanation of genetic analyses is given in Part I, section 4 of this document.

- **Blood sample while in Rilvegostomig treatment.** Blood samples while in Rilvegostomig treatment. In case you get Rilvegostomig, extra blood samples shall be gathered through your treatment cycles. These samples assist us in measuring how much of the drug is within your blood (pharmacokinetics) for understanding how your body processes and gets rid of the drug. We shall also check if your immune system makes antibodies against the drug (immunogenicity).
- **TIGIT level testing of your tumor:** Leftover tumor samples gathered during screening from each participant shall be tested for protein known as TIGIT.
- **Exploratory tests utilising your tumor:** Leftover tumor samples after completion of PD-L1 and TIGIT testing shall undergo evaluation for exploratory biomarker analysis, and future diagnostic development.
- **Images of your tumor tissue** (sections or stained slides) might be taken and kept for performing computer-aided analysis.

- **Electronic Clinical Outcome Assessment (eCOA):**

You shall be asked for completing a number of questionnaires during different times while in the study either on a handheld device that your study team shall provide or, in case applicable for you, on your own electronic device (tablet, smartphone). These assessments are utilised to understand how you feel and function while in and post-treatment. While in the assessments the below-mentioned data regarding your Symptoms and well-being shall be gathered via sets of queries:

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

Electronic handheld device, or, in case applicable your own device, is what you shall primarily utilise for answering these queries through the UNIFY App, however under some circumstances you might complete a web-based version of these questionnaires. The estimated time for completion of questionnaires ranges from 5 to 15 minutes, however you may reply to these queries at your own pace. You shall be asked questions regarding side effects which you experience, however your responses shall not always be monitored by your study doctor. In case you experience severe side effects, kindly inform your study doctor right away. You shall be instructed for bringing the device to all visits.

Optional tests:

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

We would like you to give an extra blood sample so these blood samples may be studied for better understanding of the treatment effects of the drug and what happens in biliary tract cancer post patients getting the treatments, and their outcomes are not expected to benefit you directly.

- ***Tumor biopsy during day 1 of Cycle 3 of study treatment:*** We would like you to give a tumor biopsy sample for research. These samples are very precious, and they permit us to test the effect of treatment on your cancer. Your doctor shall ask for a new tumor sample in case tumor sample is safe for collecting one. We shall ask for your consent to utilise the sample for biomarker research. In addition, images of your tumor tissues might be taken and kept for performing computer-aided analysis. It is completely up to you if you want to donate this sample(s).

- ***Tumor biopsy during progression:*** In case your tumor worsens, we would like you to give a tumor biopsy sample for research. These samples are very precious, and they permit us for testing why cancers have progressed inspite of treatment. Your doctor shall ask for a new tumor sample whether the tumor sample is safe to collect one. We shall ask for your consent for utilizing the

sample for biomarker research. In addition, images of your tumor tissues might be taken and stored for performing computer-aided analysis. It is completely up to you whether you want 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 associated with any alterations in your health, and any medications that you might 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 each visit and might be done via phone in case 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	

Assessment	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		Solely in case your cancer worsens					
Imaging							
CT or MRI Scan	X	X ^f					
Clinical outcomes assessment							
Completion of questionnaires at home		X	X	X	X	Post 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 Post 30 days after the last dose of study treatment

^b Post 90 days after the final dose of study treatment

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

^d While in the 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 (in case applicable), thyroid function test. You shall also take blood tests while in the trial participation.

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

^f Every 6 weeks (with around a week of flexibility) until 24 weeks. Later every 8 weeks (with around a week of flexibility) until 56 weeks. Post that, every 12 weeks (with around a week of flexibility) until completion of the study or until your cancer worsens. In case your cancer worsens, you shall undergo 1 extra scan for this study.

^g Optional biopsy, solely in case additional consent given and conducted at Cycle 3 Day 1 visit and/or at progression of the disease

3. Complete List of Personal Data gathered

Addition to the personal data gathered while in the study mentioned in Part I section 11, hereunder you may find a list of all personal data gathered while utilising the UNIFY App.

Kindly note that utilising the UNIFY App is a mandatory part of the study. You shall be requested for confirming that you agree with the App Privacy Notice. Kindly view all personal data gathered through the App hereunder:

- **Health related information** on the based on your answers to the queries. This data is gathered for learning regarding your experience with the treatment and your overall well-being while in the study. The data is available to your clinical site and are part of your coded data and shall be shared with AstraZeneca.
- **Personal characteristic like year of birth or language spoken.** This data is not part of your coded data and shall not be shared with AstraZeneca.
- The App does not conduct any activity in the background with regards to activity utilisation, except for any utilisation of the App itself in case you agree for usage analytics in the App.
- **IP address** (a unique string of numbers which identifies a device on the internet or a local network which may be utilised for determining general location - note location is not transmitted or shared in the study). The IP address is gathered for technical purposes in the event that the App needs any update or remote support. The data is not part of your coded data and shall not be shared out of the provider databases.
- **Information regarding the usage of this application.** As part of our ongoing improvement of the App, during some time while in the study we might ask you for letting us utilise your usage data for improving the App. Usage data is automatically gathered information regarding how you utilise the App, like what time of day you utilise it, how long you spend on various questionnaires in the App, or what App features or content you utilise the most. In case we want to utilise your usage data, we shall ask for your consent via the app itself. The data shall be part of the coded data and shall be shared with AstraZeneca. It shall not get shared with third parties.
- **Account information like User ID, PIN and/or password.** These are gathered as part of the App management and out 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 utilised for evaluating the association of PD-L1 expression with the efficiency of rilvegostomig combined with chemotherapy in comparison to durvalumab combined 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 which include however, is not limited to the US, Japan and China. The on-market assay does NOT include the intended objective of this study. The methods utilised for evaluating PD-L1 status in the context of this study are investigational.
Your biosamples	All your biological samples gathered while in this study and associated with you, like blood, urine, biopsy, as appropriate and mentioned in section 4: “<i>What are the tests and procedures required?</i>” and in section “Which additional biosamples must I provide?”. All your biosamples are coded which implies that your name will not be linked with them.
Your coded data	All your data gathered at the study site with your name and contact details have been substituted by a code. This is done by the study doctor who stores the link between your name/ contact details and the code for ensuring your safety and confidentiality. Coded information cannot identify you unless your study doctor gives your name or contact details, where permissible 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 happening and where you shall have to go for the scheduled visits.
Health authorities	Authorities who supervise the study, who approve the marketing of the drug or who get the adverse events reporting, whether in your country or in other countries.
Research partners	Any organisation that collaborates with the sponsor within the drug development programme or for future research.
Service providers	Any organisation bound with the sponsor by a contract, that might conduct activities on behalf of the sponsor under its stringent instructions. This might be inclusive of other researchers that include so-called “contracted research organisations” (CROs) and IT companies hosting clinical data or provide IT services that include developing new systems and services.

Safeguards	Appropriate safeguards shall be implemented for protecting coded data while in and post the study and might include that: • Access to the coded data shall be limited to specific individuals subject to confidentiality obligations (which includes the obligation not to try to re-identify individuals/decode the clinical data). • The coded data shall be protected using security measures for avoiding data alteration, loss and unauthorised accesses and further de-identification techniques might be applied. • Data protection impact assessment (DPIA) shall apply for identifying and mitigating privacy risks, in case any, linked with each scientific research. • When needed by applicable law, scientific research is subject to the approval of Ethics Committees. • The coded data shall not be shared for direct marketing objectives or other objectives that are not legal duties or are not considered scientific research as per the applicable data protection legislation. In particular, it shall not be utilised for making decisions regarding future services available to you, like insurance.
Security measures: How is my data protected in other countries?	The processing of your data begins at the study site. Your data shall then be transferred to many data experts for being verified and for outcomes to be calculated. In addition to getting your data and biosamples coded, your data is also protected by high-standard technical security measures like strong access control and encryption. You might obtain further information as well as a copy of these measures by enquiring with your study doctor.

Restricted rights	Kindly note that the rights given by the GDPR and UK Privacy Law for discarding data (i.e., the right for being forgotten) as well as for getting data transmitted in a standard electronic format (that is, right of portability) are not apply to such studies.
DPO (Data Protection Officer) details	In case you wish to get in touch with the DPO of the sponsor, kindly know that your name is not known there. You shall require linking your identity with your study participant number which might 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, that 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 is inclusive of technological development and demonstration, fundamental research, applied research and privately funded research as well as studies done in the public interest in the area of public health. This implies that we might utilise the data for advancing our understanding regarding how to make new medicines, medical devices, diagnostic products, tools and/or other therapies, for treating diseases. We might also utilise this data for improving the design and execution of future clinical studies, services and drugs, for outcome research activities and for aiding in pricing and reimbursement activities.

Deposit in scientific databases	For doing more powerful research, it is helpful for researchers for sharing data by placing data in one or more scientific databases. Researchers may later study the data combined from several research projects and learn even more regarding health and disease. In case you agree for taking part in future research, a little of your coded data which includes genetic data may be kept into one or more scientific database. Researchers with an approved scientific research project might have the ability for seeing and utilizing your coded data, along with the information from several other people. Your name and other information which might directly identify you (like address or social security number) shall never be kept into such a scientific database. Researchers shall always have a duty for protecting your privacy and for keeping your information confidential.
Trial Result Summaries	Also called by the EU as Lay Language Summaries
Legal basis	You shall take part in the clinical study solely in case you consent for it. In case you do so, data associated with your health and to the study drug should be gathered and processed for evaluating the efficiency and the safety of the tested drug, as per legal needs from: Any other applicable law which includes UK laws and statutory instruments related to clinical studies. The utilisation of your coded data and biosamples for future research shall only be possible in case you give optional consent for it.
Biomarker	A biological molecule found within blood, other body fluids, or tissues that is a sign of a normal or abnormal process, or of a condition or disease. A biomarker might be utilised for seeing how well the body responds to a treatment for a disease or condition.
Diagnostic test	A test utilised to help figure out what disease or condition a person has on the basis of their signs and symptoms

Clinical Performance Study	Sample gathered for this study shall undergo testing utilising a diagnostic test (known as a diagnostic device) to assess whether it may be utilised for predicting patients who are most likely to respond better to the study drug. Data from this study might be utilised to show whether patients having your disease benefit or not. Ventana Medical Systems, Inc. (Roche Tissue Diagnostics) 1910 E. Innovation Park Drive, 85755, Tucson, AZ, USA shall be the Sponsor of the Clinical performance study and has the overall responsibility of the clinical performance study.
Research partners	Any organization that collaborates with AstraZeneca (the Sponsor) within the drug development program or for future research.