

Patient Information Sheet and Consent Form

Patient Initials: _____
 (to be redacted
 for Medical Notes)

Patient number: _____
 (to be redacted
 for Medical Notes)

Main Study Title:	A Phase 3b, Multicenter, Randomized, Open-Label Study of Risankizumab Compared to Vedolizumab for the Treatment of Adult Subjects With Moderate to Severe Ulcerative Colitis Who are Naïve to Targeted Therapies
Protocol Number:	M25-540
EudraCT / EU CTEUDAMED:	EU CT Number 2024-518998-33
Sponsor:	AbbVie Deutschland GmbH & Co. KG Knollstrasse, 67061 Ludwigshafen, Deutschland
Local Representative of Sponsor	AbbVie Ltd AbbVie House, Vanwall Road, Maidenhead, Berkshire SL6 4UB
CONTACT INFORMATION:	
Study Doctor:	<<Insert investigator's name>>
Address:	<<Insert clinic and hospital>>
Telephone:	<<Insert site's contact numbers>>
After Hours Telephone:	<<Insert site's after hours contact numbers, if applicable>>
NREC reference number	<< Insert Contact details>>

PART 1

Invitation to take part

We would like to invite you to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully and talk to other friends, relatives or your GP about this study if you wish. A member of our team will go through this Patient Information Sheet with you and answer any questions you have.

- **Part 1** tells you the purpose of this study and what will happen to you if you take part; and
- **Part 2** gives you more detailed information about how this study will be conducted.

There is a consent form at the end of Part 2 that you will need to read and fill out if you would like to take part in the study. If there is anything that is not clear or if you would like more information, please ask.

The names of the sponsor for this study and its local representative are listed in the table above, and they are together referred to as “AbbVie” in this consent form.

What is the purpose of this study & why have I been invited?

The purpose of this study is to compare the efficacy and safety of risankizumab (Skyrizi®) versus vedolizumab (Entyvio®) over 48 weeks to compare how well these drugs work in patients with moderate to severe Ulcerative Colitis (UC).

You have been asked to participate in a research study with two approved drugs called risankizumab and vedolizumab to treat Ulcerative Colitis. Both study drugs risankizumab and vedolizumab are currently approved in multiple countries for the treatment of adults with moderate to severe Ulcerative Colitis (UC) and Crohn’s disease (CD).

AbbVie is sponsoring this study. AbbVie is paying the study site to perform this study.

You have been diagnosed with UC disease and are experiencing symptoms such as diarrhoea with or without blood, abdominal pain and/or a sudden and constant feeling that you have to move your bowels. Additionally, you have been never treated with some medications that help reduce the inflammation associated with your disease that are referred to as targeted therapies.

Study Information:

This study is being conducted at approximately 285 research centres worldwide and is expected to enrol approximately 530 patients in total with moderately to severely active UC.

Patients who meet eligibility criteria will be randomly assigned (by chance, like a flip of the coin) to receive either risankizumab or vedolizumab. You and your doctor will know which medication you have been assigned to.

Your study participation could be up to approximately 69 weeks if you are assigned to the risankizumab group or up to 71 weeks if you are assigned to the vedolizumab group. This includes up to a 35-day screening period followed by a primary treatment period of 44 weeks for risankizumab and 46 weeks for vedolizumab, and a 140-day follow-up call after the last dose of study drug.

If you are assigned to the risankizumab group, you will receive a 1200 mg induction dose intravenously (IV, through a vein) administered at Baseline and Weeks 4 and 8. At Week 12, depending on how you respond to treatment, you will receive risankizumab 180 mg dose or risankizumab 360 mg dose through subcutaneous (SC) injections every 8 weeks, having last dose of risankizumab SC at Week 44. Your doctor will tell you which dose you will be receiving.

Primary Trial Extension (PTE) for Trial Participants after study completion in Risankizumab arm:

If you complete the study primary treatment period in accordance with the study doctor's instructions and the study doctor confirms that you are benefiting from the study treatment, the study doctor will discuss with you and AbbVie the possibility of continuing treatment with the AbbVie risankizumab until you have reasonable access (such as through insurance or your local health system) to the drug locally or until the end of the PTE, and whichever occurs first. The PTE will last up to an additional 144 weeks.

More information about the possibility of continuing such treatment will be provided to you in a separate consent form to discuss further with the study doctor later in the study.

In addition, your study doctor might contact you 140 days after you received the last dose of risankizumab, to check if you have had any adverse event(s). This could be a visit or a call.

If you are in the vedolizumab arm, you will receive vedolizumab 300 mg intravenously (IV) at Baseline, Weeks 2 and 6, and then every 8 weeks, having the last dose of vedolizumab IV at Week 46.

At Week 48, your study doctor can identify the preferred treatment options for you once completed the study.

In addition to the 48 weeks of study participation, your study doctor will contact you 140 days after you received the last dose of the study drug, to check if you have had any adverse event(s). This could be a visit or a call.

This study will use competitive enrollment. This means that when a target number of patients begin the study, all further enrollments will be closed. Therefore, it is possible that you could be in the screening phase, ready to begin the study, and be discontinued without your consent if the target number of patients has already entered the study.

You may leave the study at any time, including before the study ends. Additionally, your study doctor may recommend that you leave the study.

AbbVie may decide to end the study early: at a site, a portion of the study, or the entire study. The study doctor may also decide to end the study at his/her site. Regardless of the reasons for stopping the study, you will be notified before the study is ended.

If you need to prematurely discontinue study drug treatment, you may still choose to continue in the study to be followed for all regularly scheduled visits, unless you fully withdraw your consent from the study participation early. Only safety data will be collected from you after study drug discontinuation. This data collection is still very important if you discontinue the study drug early.

You will be informed in a timely manner if significant new information becomes available that may be relevant to your willingness to continue participation in the study.

Use of Biological Samples

The biological samples (such as blood, urine, stool, and tissue) that we collect from you will be stored, processed and used as described in this document. Collection of some of these samples may be optional. Please refer to the "Optional Research" section to see which samples are optional.

Biological samples collected during the study will be tested by the study site, central laboratory, AbbVie, and/or companies or people working with AbbVie. Unless otherwise specified, samples will be destroyed once all required tests and analyses are completed.

AbbVie will not sell your biological samples to other people or companies. All biological samples collected from you will be given a unique code to protect the confidentiality of your Personal Data. Please refer to the section entitled, "Information, Confidentiality and Data Protection," for more details. In addition, in the "Voluntary Participation and Withdrawal" section, you can find information about what to do if you no longer want AbbVie to use your biological samples.

What is the drug being tested?

Risankizumab is made in the laboratory and is a monoclonal antibody which means that it is the same as a protein in your body, called an antibody. It works by blocking the actions of a protein known as Interleukin 23. Interleukin 23 is involved in the immune response and plays an important role in the development of chronic inflammation. Risankizumab is currently approved in multiple countries for the treatment of adults with moderate to severe UC and CD.

Vedolizumab is a monoclonal antibody which is directed against the $\alpha 4\beta 7$ heterodimer which is expressed on most leucocytes (a type of blood cell that is made in the bone marrow and found in the blood and lymph tissue) and is important for migration of leucocytes to gut-associated lymphoid tissues. Vedolizumab is approved in multiple countries for both moderately to severely active UC and CD.

Study Screening Procedures:

In order to determine if you are eligible to participate in the study you will complete the screening procedures (activities, tests and evaluations) described in this form.

- Informed consent: You will sign and date a study specific IEC/IRB approved Informed Consent Form.
- Eligibility criteria
- Medical/surgical/UC history including history of alcohol and tobacco
- Adverse event assessment: You will be asked about any side symptoms you are experiencing from the time of the signature of the informed consent.
- Prior/concomitant therapy: Review of any medications you are taking or took in the past.
- Subject eDiary: The electronic diary (e-diary) for this study will be accessed using an application (app). In order to access the app, you will be asked to download the app to your personal smartphone device (Android or iPhone) during the screening visit and create a unique PIN and security question response that you enter in the app. There is no charge for you to download and use the app on your device. You will be asked to enable notifications so the app can send reminders on your device to complete the diary questionnaires. This pop-up notification is a push notification from the app and not linked to a phone number. You can disable the push notifications by turning them off. Tell your study doctor or site staff if you change your personal device during the study. If you do not have a personal device or do not want the app on your personal device, a temporary device will be provided to you for the study, and you will be asked to return it at visit Week 48. The study doctor or site staff will show you how to use the app to complete the e-diary, and you will be asked to respond to some training questions in the app. Please, ask any questions to ensure you are comfortable using the application. In order for your study doctor to confirm your eligibility at the beginning of the study, it is critical that the diary is completed daily and brought to every study visit. You will complete questions on the e-diary at home every day from screening up to visit Week 48 (336 days). The daily eDiary includes questions on stool frequency, rectal bleeding, abdominal pain, bowel urgency, nocturnal bowel movements, faecal incontinence, tenesmus (a frequent urge to go to the bathroom without being able to go), sleep-interruptions due to UC and use of anti-diarrhoeal medication. The study staff will review the e-diary entries with you as applicable at your scheduled .
- Endoscopy: During an endoscopy, you may be sedated, and a thin, flexible, lighted tube will be inserted inside the bowel through your rectum. This will allow the doctor to look for abnormal areas. A biopsy might be taken during this test.
- Mandatory intestinal biopsies: An endoscope is a long thin tube with lights that can be passed into the bowel. To perform a biopsy, a small clamp takes a small piece of superficial tissue from an abnormal area seen through the tube.
- ECG (a test which records the electrical activity of your heart)
- Vital Signs (blood pressure, heart rate, respiratory rate and temperature) as well as weight and height
- Full physical examination

- Blood testing: Blood will be taken for laboratory tests and approximately 19.8 ml (about 4 teaspoons) will be drawn. You may need to return to the study site for retesting. The screening tests are:
 - Blood test to monitor your health.
 - Blood test for hepatitis B and C - Positive hepatitis test results may be reportable to local public health department according to local laws, if applicable.
 - Blood test for HIV: You will not be eligible for study participation if test results indicate HIV infection. You may have form before testing can start (if required). The results of this test will not be shared with AbbVie.
 - FSH test: if you are assigned female and younger than age 55, to determine if you have completed menopause.
 - Pregnancy Testing: Test your blood to see if you are pregnant. You will only have pregnancy testing if you are a woman and able to become pregnant. The study doctor or study staff will tell you if the pregnancy test results are positive. The results of the pregnancy testing must be negative in order for you to be in the study.
 - PPD Skin Test or Quantiferon-TB Gold Test (or IGRA equivalent such as T-SPOT) or both tests according to local guidelines, to check for tuberculosis (TB). If latent (existing but not active infection yet developed) tuberculosis is established TB prophylaxis/treatment should be initiated prior to receiving the first treatment dose and maintained according to local country guidelines.
- Urine samples: You will be required to provide urine samples for laboratory tests to monitor your health
- Stool samples: you will be required to provide a stool sample for a laboratory test.
- Optional biomarker samples: If you agree, additional optional tissue samples may be collected during your endoscopy for biomarker research. For details, see above section on optional samples.
- HIV/AIDS Testing: The study doctor or study staff will tell you if the results are positive. HIV became a notifiable infection in Ireland in September 2011. This means that if you are given a positive HIV diagnosis, a confidential form will be completed by the study doctor, and will be submitted to the Director of Public Health/Medical Officer of Health for the area of Ireland you live in. The information provided on the form does not identify you as an individual, as a coding system is used to allow for anonymity. The purpose of making HIV a notifiable infection is to ensure that there is accurate information on the number of cases of HIV in Ireland and the number of new cases each year.

Study Procedures

If you are eligible to participate in this study, you will undergo one or more of the study procedures described in this form at each study visit.

- Updates to Eligibility criteria
- Updates to medical/surgical history including questions regarding alcohol, tobacco and drug use
- Adverse Event (AE) assessment: You will be asked about any side symptoms you are experiencing which may or may not be related to the study drug.
- Review of any medications you are taking
- Electronic Questionnaires: Instead of using paper questionnaire and pencil to understand your disease and your response to study drugs, an electronic device will be used at the site to collect your answers to questions regarding your health. This device meets all regulations for use in clinical studies, including those related to your privacy. Your answers to these questions will be transferred to a storage facility via a secure internet connection and will be viewed by site and AbbVie.
- Subject eDiary: Subject diary completion is mandatory for the entire study. In order for your study doctor to evaluate how the drug is working throughout the study, it is critical that the device is completed daily and brought to every study visit. The daily eDiary includes questions on stool frequency, rectal bleeding, abdominal pain, bowel urgency, nocturnal bowel movements, faecal incontinence, tenesmus (a frequent urge to go to the bathroom without being able to go), sleep-interruptions due to UC and use of anti-diarrhoeal medication.

- Endoscopy: During an endoscopy, you may be sedated, and a thin, flexible, lighted tube will be inserted inside the bowel through your rectum. This will allow the doctor to look for abnormal areas. A biopsy might be taken during this test.
- Endoscopic biopsy: An endoscope is a long thin tube with lights that can be passed into different body areas. To perform biopsy, a small clamp takes some material from an abnormal area seen through the tube. Biopsies may be done when performing the endoscopies to further evaluate any areas of abnormality or which could be suspicious for colon cancer.
- Abdominal Ultrasound (IUS) You might be asked to perform abdominal ultrasound (IUS) at Baseline, Weeks 4,12,28 and 48 if you are in the risankizumab arm and Baseline, Weeks 6,12,30 and 48 if you are in the vedolizumab arm.
An ultrasound uses sound waves to make pictures of the inside of your body. IUS will be required if the study investigator/site is selected as an IUS site. Please ask your doctor if you will be doing this procedure.
- Vital Signs (blood pressure, heart rate, respiratory rate and temperature) as well as weight.
- Physical Exam: You should ask the study doctor or study staff about what will happen during this exam.
- Pregnancy Testing: Test your urine to see if you are pregnant. You will only have pregnancy testing if you are a woman and can become pregnant. You may also need to have your blood tested to confirm if you are pregnant. - The study doctor or study staff will tell you if the pregnancy test results are positive. - The results of the pregnancy testing must be negative prior to dosing and in order for you to continue in the study.
- Stool samples: You will be required to provide stool samples for laboratory tests.
Blood Testing
Blood will be taken to do laboratory tests. For the blood assessments approximately 2.5 ml to 6.3 ml (from about 0.5 to 1 teaspoons) of blood will be drawn at each visit depending on visit.
 - For the assessment of your blood cells, chemistry (such as glucose, kidney function and lipids), and the assessment of the degree of inflammation in your body a total of approximately 49.1 mL (about 10 teaspoons) of blood will be drawn at dedicated visits.
 - You may need additional blood tests and to return to the study site for some follow up testing or retesting that may collect up to 27.8 mL (about 6 teaspoons) of blood to follow up abnormal laboratory tests.
 - If your study doctor feels you may be experiencing a suspected allergic reaction, you may need additional testing to collect approximately 8.5 mL (about 2 teaspoons) of blood . Your study doctor may also request other tests, as part of your immediate medical care.
- If you agree, additional optional Blood, Stool or Tissue samples may be collected for biomarker research. For details, see below section on optional samples below.
- Study Drug Administration: Give you a dose of study drug or comparator at the study center. May train you on how to self-inject study drug to proactively be prepared for subcutaneous at-home dosing in case of your participation in the Primary Study Extension (PTE). You may also be provided a subject pregnancy and dosing diary in case you have to dose at home.

Study Activities for Subjects Enrolled in the Risankizumab Arm

Activity Visit window ± 7 days	Screening	Baseline	Week 4	Week 8	Week 12	Week 20	Week 28	Week 36	Week 44	Unscheduled	Week 48/PD	140-day Follow-up Visit / Call
INTERVIEWS & QUESTIONNAIRES												
Informed consent	X											
Eligibility criteria	X	X										
Medical/surgical/UC history including history of alcohol and tobacco	X	X										
Adverse event assessment	X	X	X	X	X	X	X	X	X	X	X	X
Prior/concomitant therapy	X	X	X	X	X	X	X	X	X	X	X	X
mMS (*if needed to confirm inadequate response)		X			X					X*	X	
Partial mMS		X	X	X	X	X	X	X	X	X	X	
Dispense Subject eDiary	X											
Subject eDiary Review		X	X	X	X	X	X	X	X	X	X	
Latent TB risk assessment form	X											
LOCAL LABS & EXAMS												
Endoscopy (*if needed to confirm inadequate response)	X				X					X*	X	
Mandatory intestinal biopsies	X				X						X	
Abdominal Ultrasound (if relevant) remove this row if the site is not participating		X	X		X		X				X	
12-lead ECG	X											
Height (screening only) and weight	X	X	X	X	X	X	X	X	X	X	X	
Vital signs	X	X	X	X	X	X	X	X	X	X	X	
Full physical examination	X	X			X						X	
Targeted physical examination			X	X		X	X	X	X	X		
Urine pregnancy test		X	X	X	X	X	X	X	X		X	
CENTRAL LABS												
Hepatitis B, Hepatitis C Screening and HIV Test	X											

Activity Visit window ± 7 days	Screening	Baseline	Week 4	Week 8	Week 12	Week 20	Week 28	Week 36	Week 44	Unscheduled	Week 48/PD	140-day Follow-up Visit / Call
Serum pregnancy test	X											
QuantiFERON-TB Gold test (and/or local purified protein derivative TB skin test)	X											
Faecal calprotectin		X			X			X		X	X	
hs-CRP		X			X			X		X	X	
Clinical chemistry, Haematology (CBC)	X	X	X	X	X		X	X		X	X	
Urinalysis	X											
<i>C. difficile</i>	X											
Tryptase		In the event of a suspected systemic post-dose hypersensitivity reaction, tryptase samples should be obtained between 15 minutes and 3 hours of symptom onset and no later than 6 hours, and another sample is requested a minimum of 2 weeks after the recorded event or at the next study visit.										
Serum risankizumab, serum ADA and nAb		Only for subjects randomized to the risankizumab treatment group, in the event of a suspected systemic post-dose hypersensitivity reaction, samples should be collected once within 24 hours of the reaction.										
TREATMENT												
Randomization/Drug assignment		X			X							
Administer risankizumab study treatment		X	X	X	X	X	X	X	X			
Perform drug accountability			X	X	X	X	X	X	X			
OPTIONAL SAMPLES												
Optional biomarker sample: Whole-blood DNA PG		X										
Optional biomarker sample: Serum/Plasma		X	X		X			X			X	
Optional biomarker sample: Whole-blood DNA Epi		X	X		X			X			X	
Optional biomarker sample: Whole-blood RNA		X	X		X			X			X	
Optional biomarker sample: Stool		X			X						X	
Optional biomarker sample: Tissue biopsies (RNA)	X				X						X	
Optional biomarker sample: Tissue biopsies (Formalin)	X				X						X	
Optional biomarker sample: PBMCs (at limited sites)		X	X		X						X	

Study Activities for Subjects Enrolled in the Vedolizumab Arm

Activity Visit window ± 7 days	Screening	Baseline	Week 2	Week 6	Week 12	Week 14	Week 22	Week 30	Week 38	Week 46	Unscheduled	Week 48/PD	140-day Follow-up
INTERVIEWS & QUESTIONNAIRES													
Informed consent	X												
Eligibility criteria	X	X											
Medical/surgical/UC history including history of alcohol and tobacco	X	X											
Adverse event assessment	X	X	X	X	X	X	X	X	X	X	X	X	X
Prior/concomitant therapy	X	X	X	X	X	X	X	X	X	X	X	X	X
mMS (*If needed to confirm inadequate response)		X									X*	X	
Partial mMS		X	X	X		X	X	X	X	X	X	X	
Dispense Subject eDiary	X												
Subject eDiary Review		X	X	X		X	X	X	X	X	X	X	
Latent TB risk assessment form	X												
LOCAL LABS & EXAMS													
Endoscopy (*If needed to confirm inadequate response)	X				X						X*	X	
Intestinal biopsies	X				X							X	
Abdominal ultrasound (if relevant) Remove this row if the site is not participating		X		X	X			X				X	
12-lead ECG	X												
Height (screening only) and weight	X	X	X	X		X	X	X	X	X	X	X	
Vital signs	X	X	X	X		X	X	X	X	X	X	X	
Full physical examination	X	X										X	
Targeted physical examination			X	X		X	X	X	X	X	X		
Urine pregnancy test		X	X	X		X	X	X	X	X		X	

Activity Visit window ± 7 days	Screening	Baseline	Week 2	Week 6	Week 12	Week 14	Week 22	Week 30	Week 38	Week 46	Unscheduled	Week 48/PD	140-day Follow-up
CENTRAL LABS													
Hepatitis B, Hepatitis C Screening and HIV Test	X												
Serum pregnancy test	X												
QuantiFERON-TB Gold test (and/or local purified protein derivative TB skin test)	X												
Faecal calprotectin (**to be collected at home prior to endoscopy preparation)		X			X**						X	X	
hs-CRP		X				X					X	X	
Clinical chemistry, Hematology (CBC)	X	X	X	X		X		X	X		X	X	
Urinalysis	X												
<i>C. difficile</i>	X												
Tryptase		In the event of a suspected systemic post-dose hypersensitivity reaction, tryptase samples should be obtained between 15 minutes and 3 hours of symptom onset and no later than 6 hours, and another sample is requested a minimum of 2 weeks after the recorded event or at the next study visit. Plasma histamine should be obtained, optimally, within 5 to 15 minutes of the onset of symptoms, and no later than 1 hour.											
TREATMENT													
Randomization/Drug assignment		X											
Administer vedolizumab study treatment		X	X	X		X	X	X	X	X			
Perform drug accountability			X	X		X	X	X	X	X			
OPTIONAL SAMPLES													
Optional biomarker sample: Whole-blood DNA PG		X											
Optional biomarker sample: Serum/Plasma		X		X		X						X	
Optional biomarker sample: Whole-blood DNA-Epi		X		X		X						X	
Optional biomarker sample: Whole-blood RNA		X		X		X						X	
Optional biomarker sample: Stool		X			X							X	

Activity Visit window \pm 7 days	Screening	Baseline	Week 2	Week 6	Week 12	Week 14	Week 22	Week 30	Week 38	Week 46	Unscheduled	Week 48/PD	140-day Follow-up
Optional biomarker sample: Tissue biopsies (RNA)	X				X							X	
Optional biomarker sample: Tissue biopsies (Formalin)	X				X							X	
Optional biomarker sample: PBMCs (at limited sites)		X		X		X						X	

Optional Biomarker research

In addition to the main study, you are being asked if you would like to take part in optional biomarker research. You can take part in the main study without agreeing to take part in any of the below optional research sub-studies.

If you decide to participate in the optional research, the following optional samples will be collected for biomarker research during the study as described below in the corresponding study visits:

Risankizumab arm

- Optional Blood Samples: additional samples blood be taken:
 - Approximately 30.5 mL (approximately 6 teaspoons) at Baseline
 - Approximately 26.5 mL (approximately 5 teaspoons) at Weeks 4, 12, 36, 48 or Premature Discontinuation Visit
- Optional Blood Sample for peripheral blood cell profile: 16 mL (about 3 teaspoons) of blood will be taken at Baseline and Weeks 4, 12, 48 or Premature Discontinuation Visit only
- Optional Tissue Samples - During your endoscopy procedure, additional biopsy samples will be taken at:
 - Screening and Weeks 12, 48 or Premature Discontinuation Visit
- Optional Stool Samples – Will be collected at:
 - Baseline, Weeks 12, 48 or Premature Discontinuation Visit

Vedolizumab arm

- Optional Blood Samples: additional samples blood be taken:
 - Approximately 30.5 mL (approximately 6 teaspoons) at Baseline
 - Approximately 26.5 mL (approximately 5 teaspoons) at Weeks 6, 14, 48 or Premature Discontinuation
- Optional Blood Sample for peripheral blood cell profile: 16 mL (about 3 teaspoons) of blood will be taken at Baseline and Weeks 6, 14, 48 or Premature Discontinuation Visit only
 - Optional Tissue Samples - During your endoscopy procedure, additional biopsy samples will be taken at: Screening and Weeks 12, 48 or Premature Discontinuation Visit
- Optional Stool Samples – Will be collected at:
 - Baseline, Weeks 12, 48 or Premature Discontinuation Visit

Samples collected for biomarker research may be retained and studied for up to 20 years from the end of the study and then destroyed. Biomarker research can help us better understand:

- How to diagnose, monitor, and treat moderate to severe Ulcerative Colitis (and related conditions);
- Why and how some patients with moderate to severe Ulcerative Colitis respond to the study product(s) or products of the same or similar class; and/or
- How the study product(s) being studied may affect and/or interact with your body.

Your biological samples collected for biomarker research may be studied for genetic material (instructions for cells to work that is in the form of DNA and RNA), proteins or parts of proteins (a part of all cells), and/or other molecules of cell metabolism (such as sugars and fats). All of this research is an effort to develop new therapies, diagnostic tests, research methods, and/or technologies.

Your biological samples collected for biomarker research will only be used by AbbVie (and/or people or companies working with AbbVie) for the purposes described in this document. AbbVie will not sell your samples to other people or companies, nor will AbbVie use them for future, unspecified research.

Biomarker research is exploratory in nature and cannot help your doctor or the study doctor treat your disease or condition. For this reason, you will not get the results of any testing that is done as part of biomarker research.

Do I have to take part?

No. It is totally up to you to decide whether or not to take part. We will discuss this study and the optional research with you and if you agree to take part, we will ask you to read and sign a consent form to show that you have agreed to take part in this study and if you have agreed or not agreed to take part in the optional research. You will be given a copy of this Patient Information Sheet and a signed copy of the consent form to keep.

What do I have to do?

Taking part in a research study can be an inconvenience to your daily life. For this study to be successful and to collect accurate information about how risankizumab or vedolizumab works in moderately to severely active Ulcerative Colitis (UC) it is important that you follow the following responsibilities as a study patient:

- Come to your study visits as scheduled.
- Provide truthful, accurate and complete information about your past and current medical conditions.
- Provide your study doctor and study staff with a complete list of all the medication you are taking.
- Fill out the electronic questionnaires and diaries completely and honestly and bring the device to the study doctor at each visit.
- Tell the study staff of any side effects or health problems you are having even if you don't think they are important or related to study drug.
- Follow the directions of the study doctor and research team
- Tell the study staff if you wish to stop taking part in this study or any of the optional research. You should come back for the end of study visit and return all study supplies.
- Tell the study staff if you are invited to receive a new vaccine (e.g. for COVID-19).
- Refrain from participation in other research studies while you are subject in this study
- **IMPORTANT:** Please do not change any of your medicines or take any new medication without checking with your study doctor. Certain medications may result in an increase in side effects with the study drug.

You will be given a “Patient **Information Card**” describing that you are participating in a clinical study. This will contain your study doctor’s contact details and inform other medical personnel that you are participating in a research study. Remember to carry this card with you at all times whilst you are on this study. You should show this card to anyone who gives you medical treatment.

If you feel that this study would take up too much of your time or you do not think you can meet the responsibilities highlighted in this section, you should not agree to be in this study. Please let your doctor know so they can discuss alternative treatments with you.

What are the alternative treatments?

You do not have to take part in this research study or optional research to receive treatment for your condition. Alternatives to this study for the treatment of your condition may include drugs already approved or being used for treatment of your condition, surgery or other experimental drugs. Examples of these alternative treatments may include other biologic therapies such as adalimumab, infliximab, ustekinumab, etc.; or conventional therapies such as aminosalicylates, immunomodulators or antibiotics used to treat Ulcerative Colitis; or surgical resections of the compromised part of the intestine. Your study doctor will review treatment options that are appropriate for you together with the potential risks and benefits of each treatment.

What are the possible benefits of taking part?

We hope that the treatment will help you, however this cannot be guaranteed. No one can know whether you will benefit from the treatment. It is possible that your condition may not improve or may worsen while taking part in this study. The information from this study may help researchers learn more about the study medication and may help to improve the treatment of people with this condition in the future.

What are the possible side effects of treatment with Risankizumab ?

Risankizumab has been given to healthy volunteers and patients with psoriasis, erythrodermic psoriasis, generalized pustular psoriasis, psoriatic arthritis, Crohn’s disease, ulcerative colitis, palmoplantar pustulosis, ankylosing spondylitis, asthma, atopic dermatitis, and hidradenitis suppurativa. Risankizumab has been given either by intravenous infusion (IV, slowly injected into a vein in the arm) or by subcutaneous injection (SC, injection into the deepest skin layer). It has been tested in repeated doses as high as 1800 mg IV and 360 mg SC. No new or different side effects were seen with higher doses of risankizumab.

As of 25 March 2024, safety data were available for over 10,000 patients in both completed and ongoing studies.

Crohn’s disease

Over 1800 adults (including 16-18yrs adolescents) with moderate to severe Crohn’s disease were treated with IV (200 mg, 600 mg, 1200 mg) and SC risankizumab (180 mg, 360 mg). The rates of overall side effects and serious side effects were similar between risankizumab treatment and placebo treatment (an inactive substance) throughout 52-week treatment. The most frequently reported side effects considered related to risankizumab in patients with Crohn’s disease who received risankizumab through 52 weeks of treatment were:

Very common ($\geq 10\%$): may affect more than 1 in 10 people

- upper respiratory infections with symptoms such as sore throat and stuffy nose (15.4%)

Common ($\geq 1\%$ and $< 10\%$): may affect up to 1 in 10 people

- headache (5.6%)
- injection/ infusion site reactions (5.6%)
- feeling tired (4.2%)
- fungal skin infection (1.1%)

Ulcerative Colitis

Over 1500 adults with ulcerative colitis were treated with IV (600 mg, 1200 mg, 1800 mg) and SC risankizumab (180 mg, 360 mg). The rates of overall side effects and serious side effects were similar between risankizumab treatment and placebo treatment (an inactive substance) throughout 52-week treatment. The most frequently reported side effects considered related to risankizumab in patients with ulcerative colitis who received risankizumab through 52 weeks of treatment were:

Very common ($\geq 10\%$): may affect more than 1 in 10 people

- upper respiratory tract infections with symptoms such as sore throat and stuffy nose (14.7%)

Common ($\geq 1\%$ and $< 10\%$): may affect up to 1 in 10 people

- feeling tired (4.4%)
- headache (4.4%)
- injection/infusion site reactions (3.1%)
- rash (2.3%)
- eczema (1.8%)
- urticaria (hives) (1.8%)
- fungal skin infection (1.0%)

Uncommon ($\geq 0.1\%$ and $< 1\%$): may affect up to 1 in 100 people
folliculitis (inflammation of hair follicles) (0.3%)

Other Possible Risks

Some drugs that affect the immune response have been associated with side effects such as serious allergic reactions, and possible increased risk of malignancy (cancer).

Infections:

Risankizumab therapy is associated with an increased risk of certain infections. Serious infections leading to hospitalization (most frequent of which were pneumonia, appendicitis, and sepsis (blood infection)) have been reported in patients receiving risankizumab. Drugs that affect the body's immune system may increase the risk of infections, including tuberculosis (TB).

You will be screened for signs of active infection before you start on risankizumab.

Always tell your doctor before and during use of risankizumab if you:

- currently have an infection or if you have an infection that keeps coming back
- have TB
- have recently received or plan to receive an immunization (vaccine). You should not be given certain types of vaccines while using risankizumab.
 - You should not receive a vaccine that is described as "live" while taking risankizumab (an exception may be made for the JYNNEOS monkeypox vaccine after discussion with your doctor).
 - There is no data available on the effects of live vaccines in patients receiving risankizumab. Non-live vaccines may be given while participating in the study. However, the effect of the risankizumab on the response to non-live vaccines, including various COVID-19 vaccines, is not known. Prior to receiving any vaccination, check with your study doctor.

Based on post marketing data (data that comes from real-world use of risankizumab), rash, eczema (dry, itchy skin and rashes) and urticaria (hives, red and sometimes itchy bumps on the skin) are considered known side effects.

Severe Allergic Reactions: All drugs have a potential for severe reactions such as anaphylaxis (which may include difficulty breathing, swelling of the face or throat, low blood pressure, or loss of consciousness). A severe allergic reaction requires immediate medical treatment and could result in permanent disability or death. It is important to tell your study doctor about any past allergic reactions that you may have had to other drugs including antibody drugs (which are usually given directly into the vein or injection under the skin).

Malignancy (cancer): When an immune system pathway is blocked, there is a possibility of a decreased immune defence against malignancies. In the completed studies to date, risankizumab has not been associated with an increased risk of malignancies but the risk with long term therapy is not known.

Cardiovascular Events: Patients with inflammatory diseases such as psoriasis, psoriatic arthritis and inflammatory bowel disease have an increased risk of major cardiovascular events (such as heart attacks, strokes or cardiovascular death). In the completed studies to date, risankizumab has not shown an increased risk of these events. However, any new or worsening signs or symptoms such as chest, neck, or arm pain, shortness of breath, sensation of rapid heart rate, new visual symptoms, or muscle weakness should be immediately reported to your study site and/or primary health care provider.

Infusion Reactions: You will get risankizumab through an intravenous infusion (IV). This means that the medicine will be sent directly into your vein using a needle or tube. This may cause an infusion reaction such as a fever, warmth and redness (flushing) of your skin, itching, rash, or a decrease in blood pressure. Your study doctor will watch you closely for signs of a reaction during your infusions of the study drug.

There is no antidote to risankizumab. Any side effects occurring as a result of risankizumab will be treated symptomatically.

What are the possible side effects of treatment with Vedolizumab

Like all medicines, vedolizumab can cause side effects, although not everybody gets them. Most of the following side effects (also known as adverse reactions) are mild to moderate. If you experience any of these side effects or the side effect becomes severe, tell your study doctor or study nurse immediately. The most common adverse reactions (>3%) with vedolizumab treatment are nasopharyngitis (sore throat), headache, arthralgia, nausea and upper respiratory infection. The most serious side effect that has been reported is serious hypersensitivity reactions including anaphylaxis.

Infusion-related reactions and hypersensitivity reactions have been reported, including anaphylaxis, dyspnea, bronchospasm, urticaria, flushing, rash, and increased blood pressure and heart rate. These reactions may occur with the first or subsequent infusions of vedolizumab and may vary in their time of onset from during infusion or up to several hours post-infusion.

If anaphylaxis or other serious infusion-related reactions or hypersensitivity reactions occur, your study doctor will discontinue administration of vedolizumab immediately and will initiate appropriate treatment.

It is known that patients treated with vedolizumab are at increased risk for developing infections. The most commonly reported infections reported in clinical trials at a rate greater on vedolizumab than placebo were infections that involved the upper respiratory and nasal mucosa (e.g., nasopharyngitis, upper respiratory tract infection). Serious infections have also been reported in patients treated with vedolizumab, including anal abscess, sepsis, tuberculosis, salmonella sepsis, Listeria meningitis, giardiasis and cytomegaloviral colitis. You will be screened for signs of active infection before you start on vedolizumab.

Always tell your study doctor before and during use of vedolizumab if you:

- currently have an infection or if you have an infection that keeps coming back
- have TB
- have recently received or plan to receive a vaccine.

You should not be given certain types of vaccines while receiving vedolizumab. You may receive non-live vaccines (e.g., influenza vaccine injection) and may receive live vaccines if the benefits outweigh the risks. Please, let your study doctor know if you have a history of recurring severe infections or if you currently have an active, severe infection that is not controlled because vedolizumab is not recommended to be taken in case of such conditions. Your study doctor will consider withholding treatment with vedolizumab in case you develop a severe infection while on treatment with vedolizumab. Your study doctor will perform screening for tuberculosis (TB) according to the local practice.

Your study doctor will monitor you for any new onset, or worsening, of neurological signs and symptoms while you are in the study and receiving vedolizumab. The reason is because a rare and often fatal opportunistic infection of the central nervous system (CNS) which is called Progressive Multifocal Leukoencephalopathy (PML) was reported while receiving vedolizumab. Your study doctor will monitor you for typical signs and symptoms associated with PML like progressive weakness on one side of the body or clumsiness of limbs, disturbance of vision, and changes in thinking, memory, and orientation leading to confusion and personality changes. In case of suspected PML, your study doctor will withhold dosing with vedolizumab; if PML is confirmed, your study doctor will discontinue vedolizumab immediately.

There have been reports of elevations of transaminase (liver enzymes) and/or bilirubin (substance formed when red blood cells are broken down), in patients receiving vedolizumab. Your study doctor will discontinue vedolizumab in case that you develop a jaundice or other evidence of significant liver injury.

Pregnancy risks, risk to nursing infant and contraceptive precautions

Risankizumab and vedolizumab have not been adequately studied in pregnant or breastfeeding individuals. We do not know if these drugs are safe for pregnant individuals, unborn babies, or infants or children who are breastfeeding.

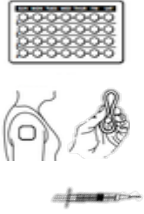





You may not take part in this study if:

- You are pregnant or think that you may be pregnant
- You and your partner are trying to get pregnant.
- You are breastfeeding.

If you are an individual who can get pregnant:

- Before you can take part in the study, you will get a pregnancy test to make sure you're not pregnant.
- You must take contraception while in the study and for at least 20 weeks after your last dose of study drug in the study. Your study doctor will talk to you about your options and which method may be right for you.

The contraceptive methods below are used to prevent pregnancy in the study. These should be used consistently and correctly as described by your study doctor

Method	What it includes	
Combined hormonal contraception with oestrogen and progestogen that stops ovulation when started at least 30 days before day 1 of the study (baseline)	Contraception: <ul style="list-style-type: none"> • Taken by mouth (orally) • Placed in the vagina (intravaginal) • Placed on the skin (transdermal) • Taken as an injection (injectable) 	
Hormonal contraception with only progestogen that stops ovulation when started at least 30 days before day 1 of the study (baseline)	Contraception: <ul style="list-style-type: none"> • Taken by mouth (orally) • Placed in the body (implantable) • Taken as an injection (injectable) 	
Bilateral tubal occlusion/ligation or Bilateral tubal occlusion/ligation by hysteroscopy with a hysterosalpingogram to confirm the procedure's success	A surgery that blocks or cuts the fallopian tubes to prevent the egg from being fertilised (also called having the "tubes tied")	
Intrauterine device (IUD) or Intrauterine hormone-releasing system (IUS)	A small device inserted into a woman's uterus to prevent pregnancy	
Vasectomised partner	An operation to make a man permanently unable to get a woman pregnant (as long as the partner verbally confirms the medical success of the surgery and is the sole sexual partner of the participant).	
Abstinence	Not having sex at all (as long as this is a part of the participant's long-term life choice). This doesn't include periodic abstinence (such as the calendar, ovulation, symptothermal, or post-ovulation methods) or the withdrawal method.	

Once you're enrolled in the study, if you become pregnant or think you could be pregnant or are trying to get pregnant, it is important for you to tell the study doctor or staff immediately.

If you become pregnant during the study, you will no longer get the study drug. Even if you are no longer taking the study drug, your study doctor will contact you to ask questions about your pregnancy and pregnancy outcome.

Unknown risks

You may experience side effects that are not listed in this informed consent. Administration of risankizumab and vedolizumab may involve risks that are currently unknown, including life threatening reactions or the remote possibility of death.

You should notify the study doctor of any changes in your health or new symptoms you are experiencing, even if you think these changes are not related to study drug.

You will be told of important new information about this study or the study drug that becomes available and that may affect your willingness to participate in this study.

What are the other possible disadvantages and risks of taking part?

Risks related to Study Procedures:

- Blood Draw for blood testing: Blood tests may cause pain, bleeding, and/or bruising. You may feel faint or pass out. There is a risk of bleeding or bruising at the puncture site and/or development of a small scar or an infection with redness and irritation of the vein at the site where blood is drawn. Frequent blood collection may cause anaemia (low red blood cell count), which may create a need for blood transfusions. Fasting for up to 8 hours could cause dizziness, headache, stomach discomfort, or fainting.
- Electrocardiogram (ECG): Skin irritation is rare but could occur during an ECG from the electrodes or gel that is used. To do the ECG, you will have pads placed on different parts of your body. There is no pain or discomfort during an ECG; however, removing the pads may cause some irritation to your skin.
- Physical Exam: There are no special risks with an exam. It will be similar to examinations you have had in your doctor's in the past.
- Serum Pregnancy Testing: The risks are similar to any blood test.
- Intravenous infusion of risankizumab or vedolizumab: a thin needle is placed inside the vein and could cause similar risks to the ones described in the blood draw in addition to allergic and infusion related reactions (reactions that can happen when medicine is infused in your vein) as described below in the risankizumab risks.
- Subcutaneous injection of risankizumab: a needle is used to inject the study drugs under the skin. This can cause skin irritation and/or itching.
- PPD skin test (to test for TB infection) - there may be slight discomfort where injection is administered. Rarely people can have a larger skin reaction at the site. This may require treatment for a couple of days.
- Blood tests for TB infection: The risks are similar to any blood tests.
- Endoscopy/ Biopsy: A full endoscopy and biopsy of the colon are standard and commonly performed medical procedures to examine the large bowel and parts of the small bowel. This procedure may involve some pain and discomfort. Rare complications include tearing of the colon and/or bleeding that may require surgical repair. When a biopsy (removal of a small piece of tissue) is performed during the endoscopy, bleeding from the biopsy site may occur. Other complications that may occur include infection at the biopsy site and bacteria in the blood. If sedation is to be given for the procedure, your study doctor will discuss with you the risks of sedation. You will not be permitted to drive immediately after the procedure and, therefore, will need someone to drive you home. You may be asked to sign a separate consent for the endoscopy. Additional risks for the procedure include the rare occurrence of bowel perforation (creation of a hole in the bowel) and/or bleeding which might require surgery and/or the use of antibiotics. Following the removal of tissue for biopsy, you may see a small amount of blood in your stools.
- Abdominal ultrasound (IUS): There are no special risks. You may be placed in an uncomfortable position for a short period to get the best images. **Remove text if the site is not participating in the abdominal Ultrasound substudy**

Safety Monitoring

Blood tests to check your numbers of white, red blood cells and platelets will be done throughout the study. Blood levels of lipids (such as cholesterol), kidney function and liver function will be conducted. Measurements of heart rate and blood pressure will be checked throughout the study and electrocardiograms (looking at the electrical conduction of the heart) will be done. Physical examinations including checking your lymph nodes will be performed.

What happens when the research study stops?

If you must leave this study or optional research for medical reasons or AbbVie or your doctor wishes to withdraw you from this study, you will be asked to visit your study doctor for an end of treatment visit to be performed.

Following completion of this study, your doctor will discuss treatment options available to you.

Payments, expenses and costs

You will not be paid for taking part in this study or any of the optional research or for the use of your biological samples but you, and your carer if applicable, will be reimbursed for reasonable travel expenses, meals and hotel accommodation you incur to attend study visits you complete. All expenses must be supported by original receipts or tickets.

You will not have to pay for the study product or for any tests, procedures or medications that are required by this study while participating in the study.

AbbVie is not required to share any profits in relation to the development of new tests, procedures and commercial products with you.

Third-Party Services:

AbbVie hired a company to assist in providing certain services to support your participation in this study. In order to provide these services, the company will need to process certain personal information about you, as described below. The legal basis under data protection laws for processing this personal information is AbbVie's legitimate interests in supporting your participation in this study. Additional information on how your personal information will be used and shared as part of your participation in this study, including your data protection rights, can be found in PART 2 of this consent form in the **Information, Confidentiality and Data Protection** section. The personal information that is needed by the company will depend upon the services being provided:

There are 2 options for reimbursement:

Option 1: Reimbursement/Payment via Debit Card

To provide your study-related reimbursements/payments described in this form, you will receive a debit card. After you complete a study visit, funds will be loaded onto the debit card. The funds will be available within 1 business day. In order to assign a debit card to you and load funds on the card, the company will need your name, address, and date of birth. The company will retain transactional debit card data for at least 7 years from study close out, if there is no balance available on the card and you are not associated with any active cards.

Option 2: Reimbursement/Payment via Direct Deposit

To provide your study-related reimbursements/payments described in this form, the company will directly deposit funds into your bank account. In order to transfer funds, the company will need your name, address, date of birth, and bank account details.

Study-Related Travel

For approved travel, you or the site staff will book your travel arrangements through a designated travel agent, and the costs for such travel arrangements will be paid directly by AbbVie. In order to book travel and provide you with itineraries, the company and travel agent will need your name, address, date of birth, and email. Additional information may be required by the travel agent to complete the booking.

What if there is a problem?

Any complaint about the way you have been dealt with during this study is addressed in Part 2 of this Patient Information Sheet.

If the information in Part 1 has interested you and you are considering participating in this study, please read the additional information in Part 2 before making any decision.

PART 2

What if relevant new information becomes available?

Sometimes we get new information about the treatment being studied. If this happens, your study doctor will tell you and talk to you about whether you should stay in the study. If you decide not to carry on, or your study doctor thinks it is better for you to stop the study, your study doctor will make arrangements for your care to continue. If you decide to stay in this study, your study doctor will ask you to sign an updated consent form.

If this study is stopped for any other reason, you will be told why, and your continuing care will be arranged.

What if there is a problem?

If you have a concern about any aspect of this study, you should speak with the study staff who will do their best to answer your questions. Their contact details are found on the first page, with additional details at the end of this Patient Information Sheet.

In the event of you becoming ill or injured as a result of your taking part in this study, AbbVie will compensate you in accordance with Irish Law (statutory or otherwise). Participation in this study is covered by an approved insurance policy in the name of AbbVie. In addition, the study doctors have current medical malpractice coverage. In the event that you are not happy with treatment conducted by a member of the study staff, the normal health service complaints mechanisms are available to you. By signing this form, you are not losing any of your legal rights.

INFORMATION, CONFIDENTIALITY AND DATA PROTECTION

This confidentiality section describes your rights and explains how personal information about you, including information derived from your biological samples, and other information about your health, as well as any images collected during the study, will be used, shared and protected. This type of information is referred to as “**Personal Data**” and it is protected by data protection law. AbbVie and the study doctor and staff working on this study and optional research must comply with this law. Before Personal Data is transferred to AbbVie, the study doctor and staff will replace any information that could directly identify you (such as your name, address, and contact information) with a generic code which AbbVie cannot link to your identity. In addition, any features that can identify you on images taken of you as part of your participation in the study will be blocked/masked when maintained by AbbVie. Such Personal Data without directly identifying information is referred to as “**Coded Data**”.

Who is the controller of my Personal Data?

Sponsor is the data controller of the Personal Data collected or created for the purposes of the study because the Sponsor is responsible for deciding what Personal Data will be collected for the study and how it will be used. This includes the Coded Data shared with AbbVie, as well as Personal Data contained in the study documents controlled by the study site. The study site and study doctor will continue to be the data controllers of Personal Data contained in your medical records because they are responsible for deciding how your Personal Data will be used for your medical care that is unrelated to this study.

In this section we explain how we collect, use and share your Personal Data with others if you participate in the study. If you don't agree, you will not be able to participate in the study or the optional research.

What Personal Data about me will be Collected?

To help answer the research questions, the study doctor and staff will collect Personal Data about you from you and your existing medical records so that they can understand your medical history. In addition, they may collect your Personal Data from available public records. Also, during the study, they will collect information self-reported by you as well as their observations of you.

The following are examples of Personal Data that may be collected and disclosed by the study doctor and staff responsible for your treatment:

- your name, address, telephone number, date of birth, gender/sex, ethnicity, medical record numbers and/or other identifying information
- results of examinations and laboratory tests including blood tests, medical imaging, genetic tests, tissue sample tests or other medical procedures
- information regarding your health and medical history, including information derived from your biological samples (for example, blood, urine, and tissue) , health conditions, treatments and medical procedures, and survival status, including related dates.
- your images,

As described earlier in this document, AbbVie will only receive Coded Data and will not be able to directly identify you.

How will my Personal Data be used?

Listed below are examples of how your Personal Data may be used for the purposes of this study and optional research (if you agree to participate):

- to determine if you can participate in this study or optional research ;
- to evaluate how your health or condition changes during the study and compare it to other study participants;
- to find out if treatment with the study product(s) is/are safe and effective and to follow up with you if needed for safety reasons after the study is completed;
- to learn more about the disease(s) or condition(s) that are the participant of the study or optional research ;
- to report safety data, such as adverse reactions or events, product complaints, or pregnancies, related to a medical product and/or device used in this study to its manufacturer;
- to provide you with reimbursement of your travel expenses for attending study visits; and
- to provide you with treatment and reimbursement of medical expenses in the event of a study-related illness or injury.

AbbVie may use your Personal Data, including your Coded Data, based on your consent, AbbVie's legitimate interests in the scientific research described in this document, or to comply with a legal obligation.

Your Coded Data is very important to help us continue development of therapies, diagnostic tests, research methods, and technologies for your disease, condition and similar diseases and conditions. If you agree, your Coded Data, collected for this study and the optional research may also be used for continued research that is compatible with the study, the specific details of which may not be known at present. They could include:

- further examination of the safety or efficacy of risankizumab and vedolizumab
- identification of new medical uses of risankizumab and vedolizumab ;
- further examination of moderate to severe ulcerative colitis or similar diseases or conditions; and
- analysis of how AbbVie can improve its clinical research processes.

This is optional. At the end of this document, you can let us know if you agree to this continued use of your Coded Data.

Who will receive my Personal Data and biological samples?

The study doctor and staff will share your Coded Data and biological samples with AbbVie and its representatives for the purposes described above. The study doctor and staff and AbbVie may share your Coded Data and biological samples with AbbVie's affiliates, as well as with its service providers and research partners in countries around the world. The study doctor and staff may also share your Personal Data and Coded Data with their service providers helping conduct the study.

The study doctor and staff may share your Personal Data and AbbVie may share your Coded Data with regulatory authorities in countries around the world and with the ethics committee responsible for oversight of this study and optional research. These bodies are responsible for ensuring that the research is being conducted properly, in accordance with laws and ethical requirements, and they may use your Personal Data/Coded Data in order to fulfil their duties. Regulatory authorities may also use your Personal Data/Coded Data to evaluate and confirm the validity of the study findings.

AbbVie may share Coded Data contained in safety data with the manufacturer of the medical product and/or device used in this study. AbbVie shares safety data with the manufacturer based on its legitimate interest in supporting safety reporting requirements.

The results of this study and optional research, including Coded Data, may be published in study reports or scientific presentations and publications. They may also be used in educational, promotional, marketing, and commercial materials distributed publicly worldwide relating to the study product(s) or disease(s) or condition(s) that are the participant of the study. **Information or features that identifies you or that reasonably could be used to identify you will be removed to protect your identity.**

How will my Personal Data and biological samples be protected?

The study doctor and staff will store your Personal Data in a limited-access, secure storage space. They are required by law to protect the confidentiality of your Personal Data and to use and disclose it only as described in this document. Representatives of AbbVie, regulatory authorities, and the ethics committee overseeing this study and the optional research may be provided with access to Personal Data controlled by the study site to verify that the study data is being reported accurately and that the study and optional research is being conducted properly. The study doctor will retain your Personal Data for as long as required by local laws and regulations or for a longer period if required by an agreement with AbbVie.

AbbVie will store the Coded Data and biological samples that it receives in a limited-access, secure storage space. AbbVie has implemented security measures to prevent unauthorised individuals from accessing your Coded Data and biological samples. AbbVie will only use your Coded Data and biological samples for the purposes described in this document. Before sharing your Coded Data, AbbVie will require each of its affiliates, service providers and research partners to sign a written agreement requiring them to protect your Coded Data and use it only for the purposes described in this document. AbbVie may also employ anonymisation and de-identification techniques to further reduce the ability to identify individuals from Coded Data. AbbVie may retain the Coded Data reported to it for as long as the study product(s) is used or longer if required by local laws and regulations, consistent with Good Clinical Practices (GCP) and clinical trial related laws and regulations.

Some of AbbVie's affiliates, service providers or research partners may be located outside your country where data protection laws may offer less protection. Any Coded Data that is transferred to AbbVie's parent company, AbbVie Inc., in the United States, or other AbbVie affiliates is done under internal privacy agreements. A copy can be obtained by sending an email to privacyoffice@abbvie.com. Any transfers of Coded Data to AbbVie's service providers or research partners outside your home country will be made in compliance with the international data transfer restrictions that apply.

Can I See My Study Records; what rights do I have?

A description of this clinical trial and the results when they are available, can be found at euclinicaltrials.eu & <http://www.ClinicalTrials.gov>. These websites will not include information that can identify you. At most, the website will include a summary of the results. You can search these websites at any time.

A summary of the study results, along with a layperson summary of the results, will also be available in the EU database and portal known as the Clinical Trial Information System (CTIS) approximately one year or more after the study is fully completed. The exact timing will vary based on the study type and regulatory timelines. This information will be available no matter what the study's outcome is and will not include information that can identify you.

You will be able to access these summaries in the EU database soon after they become available using the following EU trial number for the study: 2024-518998-33. If you need assistance understanding these Web Sites or have questions about the study information, please ask the study doctor or staff.

You may have the right to see and get a copy of your study records, or to request correction if you believe your Personal Data is not accurate or complete. Please note that your access to your study records may be suspended during your participation in the study. If you want to immediately access your study records, you may not be able to continue participating in the study. The optional research cannot help your doctor, or the study doctor treat your disease or condition. For this reason, the optional research test results may not be sent to you or put into your medical records.

In addition, you have the right to request information on how the Coded Data reported to AbbVie and your Personal Data collected by the study doctor and staff is being used and shared. You can also request the deletion or restriction of use of any Personal Data that are not required to comply with regulatory requirements and are no longer needed. Please be aware that because AbbVie only maintains Coded Data, AbbVie may not be able to fully respond to your request. You should direct your request about Coded Data that AbbVie maintains to the study site and ask the study site to forward your request to AbbVie. If AbbVie cannot meet your request, it will provide the reason.

You also have a right to take back your permission to collect, use and share your Personal Data. Please refer to the “Voluntary Participation and Withdrawal” section below for more details.

Please note that you are entitled to lodge a complaint with the German Data Protection Authority as the main data protection authority for AbbVie or the data protection authority in your country if you have concerns with how AbbVie or the study doctor or staff are using your Personal Data.

In the “Contacts” section below, you can find information about who to contact if you want to request a copy of your study records, have access to them to correct your Personal Data, or to request information or have questions or concerns regarding how your Personal Data is being used and shared.

VOLUNTARY WITHDRAWAL

Do I have to participate?

Participation in the study or any of the optional research is voluntary. You may still participate in the study if you decide not to participate in the optional research. The study and/or the optional research may be stopped early by AbbVie, the study doctor, the ethics committee, or organisations that regulate research in Ireland or other countries. You could be withdrawn from the study or the optional research without your consent, at any time and for any reason.

Can I change my mind?

If you start the study or any of the optional research, you may stop at any time without further explanation. You may also request that we stop collecting and sharing your Personal Data, but you will not be able to continue in any of the research.

If you want to take back your permission to use or disclose your Personal Data, or biological samples or if you want to stop participating in the study and/or optional research for any reason you must let the study doctor know. You will not be punished or lose any benefits to which you are otherwise entitled.

What will happen to my biological samples and Personal Data?

Biological Samples

If you withdraw or are withdrawn from the study, the biological samples we have collected from you as part of the study or optional research will continue to be stored and analysed as described in this document unless you specifically withdraw your permission. If you withdraw your permission to use your biological samples, no new research work will be started, and your biological samples will be destroyed unless a regulatory authority requires AbbVie to keep them. If AbbVie and/or other researchers did any testing of your biological samples before you withdrew your permission, AbbVie will still use and disclose the test results and keep the data generated from your biological samples due to regulatory requirements that are designed to safeguard scientific integrity.

Personal Data

If you withdraw or are withdrawn from the study, the study doctor and staff may continue to follow up with you regarding your health status.

You can always withdraw your permission for the collection of your Personal Data or withdraw your permission to participate in the follow up. You should inform your study doctor about this when you withdraw or are withdrawn from the study.

If you are withdrawn because you become pregnant, the study doctor and staff will also collect information about your pregnancy, unless you specifically withdraw your permission. This information will include:

- Your date of last menstrual period
- General information about your past pregnancies which may include:
 - Number of pregnancies and their outcome
 - Number of elective or spontaneous abortions
- Information about your current pregnancy which may include:
 - Forms of contraception used
 - Estimated and actual date of delivery
 - Complications during pregnancy, labour or delivery
- After the baby is born:
 - Your baby's birth weight and length
 - Your baby's gender
 - Information about any birth defects that your baby has and any tests or procedures that were performed to diagnose them.

Even if you withdraw your permission to participate in follow up, or you withdraw your permission for the collection of your Personal Data, we may still collect a limited amount of new Personal Data (i) information about your survival status from available public records, and (ii) safety information that may be related to your participation in the study. We need to continue to collect this type of information because of legal and regulatory requirements and AbbVie's legitimate interests in the scientific research described in this document.

Personal Data that has already been collected prior to your withdrawal cannot be deleted from study records to ensure the scientific integrity of the study.

Even after your withdrawal, the study doctor and staff and AbbVie may be required to include your information in analysis and aggregate study results, but in a way that will not identify you.

Involvement of your General Practitioner/family doctor (GP)

If you decide to take part in this study or optional research your study doctor will inform your GP about your participation. This is done to make sure all doctors having anything to do with your care are aware of the medicines or treatments you are taking. They can also tell your doctor if there is any medical reason why you should not take part in this study.

Who is organising and funding the research?

The research study is being organised and funded by AbbVie. AbbVie will pay your hospital for their services in conducting this study.

Who will review this study?

All research is looked at by an independent group of people, called the Research Ethics Committee to protect your safety, rights well-being and dignity. A favourable opinion has been obtained from **National Office for Research Ethics Committees Ireland (NREC)** for this study.

Further information and contact details

Please contact the study doctor below if you would like more information about any part of this study, the optional research your rights as a participant or in the case of a study related injury.

Doctor: _____

Address: _____

Telephone: _____

➔ In the event of an emergency please contact:

Telephone: _____

You can find out more about how your Coded Data and Personal Data is being used and shared by contacting the study site at Contact Person at [Study Site] at [Contact Information].

To request a copy of your study records, to make a request to exercise your rights of access, deletion, objection, transfer, restriction, or correction, to request information on how the Coded Data reported to AbbVie is being used and shared, or to raise questions, concerns, or complaints as to how AbbVie is using your Coded Data, you may contact [Contact Person at Study Site] at [Contact Information]. In addition, you are entitled to lodge a complaint with the German Data Protection Authority as the main data protection authority for AbbVie or the data protection authority in your country.

You have the right to object to the Personal Data processing activities described in this consent form that are based on AbbVie’s legitimate interests.

AbbVie’s Data Protection Officer can be contacted by going to abbvie.com/privacy-inquiry.html or by sending an e-mail to privacyoffice@abbvie.com.

If you are harmed by the research or have any questions or concerns about the study product(s) you should contact the study doctor immediately for further instructions.

This Patient Information Sheet and Consent Form is governed by the laws of Ireland.

Thank you for taking the time to read this Patient Information Sheet.

Please let us know if you have any questions or if you would like further information.

USE HOSPITAL HEADED PAPER

Patient Initials: _____	Patient number: _____
(to be redacted for Medical Notes)	(to be redacted for Medical Notes)

CONSENT FORM

Study Title: M25-540 A Phase 3b, Multicenter, Randomized, Open-Label Study of Risankizumab Compared to Vedolizumab for the Treatment of Adult Subjects With Moderate to Severe Ulcerative Colitis Who are Naïve to Targeted Therapies

Principal Investigator: <INSERT NAME>

Please
initial
each
box

- 1 I confirm that I have read the Patient Information Sheet version 2 19Jun2025 and all my questions regarding participation in this research study and the optional research have been answered.
- 2 I understand that relevant sections of my medical notes and data collected during this study and the optional research may be looked at by the study doctor, personnel helping the study doctor to conduct this study and optional research, individuals from AbbVie, their representatives/ agents, and regulatory authorities.
- 3 I acknowledge that my biological samples will be accessed, collected, processed and transferred as described in the Patient Information Sheet.
- 4 I understand that I *or my witness* will receive a copy of this signed and dated Patient Information Sheet and Consent Form.
- 5 I understand that my participation in this study and the optional research is voluntary and that I am free to withdraw at any time without giving any reason and without my medical care or legal rights being affected.
- 6 I agree to my GP being informed that I am taking part in this study and for my GP to provide personal health information that is relevant to my participation in this study, such as other medicines I am taking.
- 7 I agree to take part in this study and the optional research I have selected below
- 8 If I become pregnant during the study, I understand that the study doctor and staff will collect information about my pregnancy as described in the Patient Information Sheet and that I may be withdrawn from the study and the optional research.

I have read the above pregnancy consent and acknowledge this is not applicable

- 9 **Privacy Acknowledgement:**
 - I acknowledge the collection, use and sharing of my Personal Data as described in this document.

****Optional Blood Samples**

- Yes, I volunteer to provide optional blood samples for the biomarker research described in this form.
- I **DO NOT** volunteer to provide optional blood samples for the biomarker research described in this form.

****Optional Stool Samples**

- Yes, I volunteer to provide optional stool samples for the biomarker research described in this form.
- I **DO NOT** volunteer to provide optional stool samples for the biomarker research described in this form.

****Optional Tissue Samples**

- Yes, I volunteer to provide optional tissue samples for the biomarker research described in this form.
- I **DO NOT** volunteer to provide optional tissue samples for the biomarker research described in this form.

Continued Use of Mandatory Tissue Samples

- Yes, I volunteer to allow the storage and use of collected tissue samples taken during the main study endoscopies for optional research
- I **DO NOT** volunteer to provide optional tissue samples for the biomarker research described in this form

Patient Name (print)

____/____/_____
Date

Patient Signature

I have fully informed and discussed with the participant this study, optional research Procedures and possible benefits and risks. The patient has been given enough time to read the information and understand the nature and purpose of this study

Investigator Name (print)
(Investigator conducting informed consent discussion)

____/____/_____
Date

Investigator Signature

Additional Signature if applicable:

Add role and reason for additional signature requirement (e.g. Translator, impartial witness)

_____/_____/_____
Name (print) Date Signature

When completed; 1 for patient [or 1 for Witness]; 1 for medical notes; original to be kept in Investigator Site File

Consent Form

Use of Coded Data for Continued Research

Use of Coded Data for Continued Research - Select One Option

Yes, I agree for my Coded Data to be used for continued research as described in this document.

No, I do not agree for my Coded Data to be used for continued research as described in this document.

Patient Name (print)
[or witness]

___/___/___
Date

Patient Signature
[or witness]

Additional Signature if applicable:

Add role and reason for additional signature requirement (eg. Translator, impartial witness)

Name (print)

___/___/___
Date

Signature

When completed; 1 for patient ; 1 for medical notes; original to be kept in Investigator Site File