Non-Interventional Study Informed Consent

P15-325: Impact of adalimumab on patient-reported outcomes (PROs) in Canadian patients suffering from moderate-to-severe ulcerative colitis (UCanADA)

Study Number: P15-325

Study Sponsor: AbbVie Corporation

Study Doctor: **«PiFullName»**

Telephone: **«IcfPhoneNumber»**

Additional Contact(s): **«AdditionalStaffMemberContacts»**

Address: **«PiLocations»**

Dear Patient,

You are being treated for ulcerative colitis with the approved medication HUMIRA® (adalimumab). The manufacturer of this drug and sponsor of this research, AbbVie Corporation, is interested in collecting information to assess the real-life effect of HUMIRA® on psychological distress/depression symptoms in moderate-to-severe patients with ulcerative colitis. The research explained below deals with the collection and storage of data only and is not designed for drug testing.

Your treating doctor is participating in this project to collect data about the standard treatment of your disease with the approved medication.

For a period of 52 weeks, information about your demographics data, medical history, disease history, your medications, your disease progression and your quality of life will be documented by your doctor and by yourself via questionnaires during your routine doctor visits. As part of this research, the company is hoping to obtain information from approximately 100 patients with ulcerative colitis, across Canada, of which up to 30 patients would have been already been prescribed a biologic medication for their ulcerative colitis.

The study consists of 4 to 5 visits (inclusion, week 8, follow-up (1 and/or 2) and week 52 visits). Each visit will last about 1 hour. The questionnaires will take about 35 minutes to complete.

These should coincide with your routine doctor appointments. You might be seen more often, at your doctor's request if he/she thinks it's necessary.

The following information will be collected for the study:

- Physical examination
- Medical & surgical history
- Disease characteristics, prior and current treatments
- Medications associated with ulcerative colitis & other diseases
- Clinical laboratory tests, if requested by your doctor

Non-Interventional Study Informed Consent

- Fecal Calprotectin test
- Other tests or procedures for treatment management
- Compliance to the treatment
- Changes in your health

This is not a complete list, as your doctor could decide other examinations or tests are required to better evaluate your health.
At each visit, you will have a series of 7 questionnaires to complete. These questionnaires were developed to assess the psychological distress/depression symptoms, disability, fatigue, pain, impact on work life and sleep quality in moderate-to-severe patients with ulcerative colitis. Some of the questions are of a personal and sensitive nature. All questionnaires should take about 35 minutes to complete.

BENEFITS
There is no benefit to you from taking part in this study.

If any new information about this study becomes available that may affect your decision to continue your participation, you will be informed as soon as possible.

YOUR COSTS & EXPENSES - REIMBURSEMENT FOR PARTICIPATION

There will be no cost to you, your private medical insurance (if any) or the public health insurance plan for participating in this study.

You will not be paid for your participation in this study. IRB Services - an independent ethics committee that reviewed the ethical aspects of this study to help protect the rights and welfare of study participants, agreed that you may be reimbursed for parking expenses due to a longer routine doctor visit in order to complete the study questionnaires. You will be reimbursed the exact amount of your expense, to a maximum of twenty ($20.00) dollars for each visit. You will receive reimbursement at each completed visit and only for the visits you have completed.

DATA WE COLLECT FROM YOU:
Your health information from your original medical records and data resulting from your participation in this study will be collected. Your health information includes health related details, as well as the results of questions you are asked by the study doctor or by filling out questionnaires.

HOW YOUR DATA WILL APPEAR:
Your identity and contact details will not be disclosed. Rather, your identity and contact details will be replaced by a code, such as a number.

WHY WE COLLECT THIS DATA:
Your health information will be used in study reports or for scientific presentations, but in a way that will not identify you by name. Your health information will be kept confidential at a secure location and, unless required by law, will not be made publicly available. After the study has been completed, it is possible that your coded health information will be used for future studies on the drug/condition covered by the current protocol.

WHO WILL SEE YOUR DATA:
The only people with access to your health information in identifiable form will be your doctor and personnel helping your doctor conduct the study, sponsor representatives who are checking that the study is conducted properly, and ethics committee(s) (IRB Services) and local and foreign regulatory authorities where required by law.

By signing this document, you are allowing your doctor and personnel at the facility to permit AbbVie and/or

Non-Interventional Study Informed Consent

AbbVie's representatives to have access to your health information for the purpose of collecting data, verifying the data is correct, and checking that the study is conducted properly.

Some of these organizations may be located outside of the country or region in which you live, including in countries where data protection requirements may be different or less restrictive than in your home country or region. However, AbbVie will take reasonable measures to keep your health information confidential. By signing this document, you agree to the transfer of your health information to such countries, including the United States of America.

TAKING BACK YOUR PERMISSION TO USE OR DISCLOSE YOUR PERSONAL HEALTH INFORMATION:
To take back your permission to use or disclose your health information, you must inform your doctor conducting this study. Any information that has already been collected at the time you take back your permission will be kept and, where the law allows, your health information, will continue to be used by your doctor or AbbVie or other parties involved with the study. No new data will be collected about you after you withdraw your permission.

RIGHTS TO YOUR DATA:
You may have the right to access, correct and make a copy of your medical records as allowed by applicable privacy laws. You may ask to see your records by requesting such records from your doctor.

When you sign this document, you agree to the access, collection, processing and transfer of your health information as described in this consent document.

This study has no influence on the nature of the treatment for your disease. You will neither be subject to additional check-ups nor will you receive any other therapy than the therapy your doctor intended for you. Participation is voluntary. In case you decide against participating or if you withdraw your agreement later on, this will not have any detrimental effect on you.

QUESTIONS

If you have questions, concerns or complaints regarding this study or adverse effects of study medication, you should contact the study doctor or the study staff at the telephone number listed on the first page of this form.

Please contact IRB Services, which is not affiliated with the research or the research team, if you have questions about your role and rights as a research participant, or have concerns, complaints or general questions about the research, by phone: 1-866-449-8591 or by email: subjectinquiries@irbservices.com

Please reference the following number when contacting IRB Services: Pro00011211.

Non-Interventional Study Informed Consent

I agree that my health information may be used for this study as described in this document.

I agree to take part in this research study.

_____
Patient Printed Name

_____ _____
Signature Date

_____
Name of Person Obtaining Consent

_____ _____
Signature Date

Non-Interventional Study Informed Consent

PATIENTS AT HEART EDUCATIONAL WEBSITE (*OPTIONAL*)

The Patients at Heart (PaH) program has been in place in Canada since 2009 and reflects AbbVie's desire to put patients at the heart of clinical research. The Web site (www.patientsatheart.com) is designed to support and inform patients who are participating or considering taking part in a clinical trial. This program will be made optional and complementary to the UCanada study.

The Web site includes a public section that contains information about all essential aspects of clinical trials and the best ways to prepare for them, patient testimonials as well as detailed information on various conditions. The Web site also has a study-specific section for patients participating in the UCanada study, which will include a personal account giving patients access to a study journal and timeline as well as additional information regarding the trial.

If you are interested in this optional part of the study, you will receive a code and password from your doctor or nurse in order to register on the Web site and create a personal account to access your journal, trial timeline, and other trial details. In order to create a personal account, the only mandatory information to be provided will be an email address, which you will use to access your account. Other personal information can be added in your account, but are optional.

By providing your information on the website, you acknowledge and confirm that the Internet is not a secure medium where privacy of your personal information and confidentiality can be guaranteed. While every effort will be made to ensure that reasonable measures are in place to protect the privacy and confidentiality of your personal information, complete security is not possible.

All data registered on the Web site will remain confidential as per AbbVie's Privacy Policy and to the extent of the limitations imposed by a Web site.

I agree to take part in this optional part of study.

❒ YES ❒ NO

_____
Patient Printed Name

_____ _____
Signature Date

_____
Name of Person Obtaining Consent

_____ _____
Signature Date