TITLE:
Assessment of symptom patterns in Celiac disease: A prospective longitudinal survey (AG#033926)

PROTOCOL NO.:
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WCG IRB Protocol #20220731

SPONSOR:
Takeda Development Center Americas, Inc (TDCA)

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PDF version of the Informed Consent Form is available at: https://celiac.org/vcss-adult-informed-consent-form/

Informed Consent Form

Introduction

You have been invited to take part in the Virtual Celiac Symptom Study based on your answers about your experience and diagnosis with celiac disease. To help you make an informed decision on whether or not to take part, you need to understand what the study is for, what is involved, and what benefits, risks, and discomforts there may be. This process is called "informed consent."

Please take the time to read the following information carefully and discuss it with others. If there is anything that is not clear, or if you would like more information, please see the "What if I have questions?" section for contact information.

If you decide that you want to take part in the survey study, you must click "Yes" at the box at the bottom of this screen agreeing ("consenting") to participate in this study. You cannot participate in the study without signing the informed consent form. You will be able to access the information in this informed consent form in the "Study Information" part of the uMotif app.

About This Study

The purpose of this study is to learn more about the symptoms that people with celiac disease experience and how these symptoms affect different aspects of an individual's life, including social, emotional, and economic aspects and overall quality of life. You are one of about 400 participants in the United States being asked to participate in a survey about your experiences with celiac disease.

A description of this study will be available on http://www.ClinicalTrials.gov. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results.

You can search this Web site at any time. Information about this study will also be put on other Web sites, including http://www.clinicaltrials.takeda.com, but you will not be personally identified on any of these Web sites.

This study is completely virtual and consists of you answering a series of questions using the uMotif app on your mobile device (smartphone). There are no blood draws, medications, medical procedures or visits with a health care professional that are required as a part of this study.

What is involved in participating in this study and how long does it take?

In this study, you will be asked to complete questionnaires on a daily basis for three months. The questionnaires have multiple-choice questions that include, but are not limited to, specific questions about your symptoms, visits to the doctor, and overall health. The approximate time required to complete the survey is described below:

- On the first day, you will be assigned questionnaires that are estimated to take 1.5 hours to complete—these need to be completed within 4 days.
- After the first day, the questionnaires are estimated to take 5-10 minutes per day to complete.
- On a weekly basis, you will be asked to complete additional questionnaires that may take about 4-5 minutes.
- On a monthly basis during the three-month survey study, you will be asked to complete additional questionnaires that may take 30-45 minutes to complete.

Who is running this study?

This research study is being conducted by Analysis Group, Inc. ("AG") on behalf of the Sponsor Takeda Development Center Americas, Inc. ("Takeda"). Takeda is a global pharmaceutical company that develops medicines to treat various patients, including those with celiac disease (Takeda.com). AG is a research organization with headquarters in the United States (Boston, Massachusetts) (analysisgroup.com). The Celiac Disease Foundation (CDF) is helping to recruit participants, encourage participation, and coordinate participation payments for the study. CDF is an organization dedicated to medical research, patient and healthcare provider education, and public policy advocacy for celiac disease (celiac.org). Greenphire will support the reimbursement/payment process for this study. Greenphire is a clinical trial financial management company.

Please see the "What if I have questions?" section for contact information.

What technology is being used to conduct this study?

The app where you will answer questionnaires for this study was developed by and is administered by uMotif. uMotif is a company that develops modern data capture platforms for research. The app will be used to:

- administer the survey questionnaires, collect your responses, and help determine your eligibility for payment
- provide you with an easy way to provide your informed consent

To use this app, you will be required to create a username, password and to provide your email.

By providing your consent, you agree to use the uMotif app as requested. If you choose not to use the app, you will not be able to participate in the study. Please see the "What if I have questions?" section for contact information if you have any technical difficulties using the uMotif app.

What are the risks of participating in this study?

No physical risk is associated with participating in this study. The questions in this study ask you to report personal information about your physical health that might be sensitive. The questionnaires are not tests. There are no "right" or "wrong" answers. There is a small risk of a breach of confidentiality.

What are the potential benefits of participating in this study?

There are no direct health benefits to you from participating in this study. However, your responses are very important because they will help researchers understand patients' experiences with celiac disease.

What will I be paid for participating in the study?

By the end of the study, you will be eligible to be paid up to $500.00 to compensate you for your time to answer questionnaires as a study participant. In order to be paid the full amount, for the 1st milestone, you must complete all of the non-daily questionnaires and 70% of the daily questionnaires. For the other milestones you must complete at least 70% of the daily questionnaires, as well as at least 70% of the non-daily questionnaires during each time period. You will be paid after each milestone, and payments will be made within 10 calendar days after each milestone in the payment schedule described below.

Payment milestone	**Study period**	**Payment amount** *
1	Week 1	$50.00†
2	Week 2-3	$25.00
3	Week 4-5	$100.00
4	Week 6-7	$25.00
5	Week 8-9	$100.00
6	Week 10-11	$25.00
7	Week 12	$175.00
Total		**$500.00**

*Upon completion of at least 70% of the questionnaires during the study period.

† All of the initial questionnaires (questionnaires available on day 1) must be completed to remain eligible for the study and eligible for payment.

If you do not complete all of the required questionnaires to meet the first milestone, you will not be able to continue to participate in the study and will be unenrolled. At the discretion of the investigators, if you have missed several milestone payments, you may be unenrolled from the study.

What does it cost to participate in this study?

There is no cost to you for participation in this study. However, if you choose to receive study updates, reminders or payment alerts via SMS, standard text messaging rates will apply and will not be reimbursed.

How is my personal data collected and used and how are my confidentiality and data security protected?

If you agree to take part in the study, personal information about you and your health will be gathered and stored. This may include information that may be used to identify you, such as your name, address, phone number, date of birth, as well as information collected through the questionnaires. Certain demographic information, such as your age, race, education, and gender, will also be collected to better understand how responses differ across these factors. This section describes how your information will be used and to whom it may be disclosed.

The information you provide will be used for the purposes of this research study and as described in this form. This includes, for example, to determine if you are eligible for this study; to evaluate how your health changes during the course of the study; to learn more about celiac disease; and to pay you for your time participating in this study.

All of your information related to your participation in the study will remain confidential, and confidentiality will be maintained in accessing, keeping, processing and publication of information related to your taking part in the study. All information about you which is collected through the questionnaires in this study will be identified by a code number (a Subject ID) without your name and address or other contact information. This is referred to as "coded information." We use coded information so that none of your answers will be linked to your name.

Information that can identify you (e.g., name, contact information, date of birth) will be kept separately from the research information in a list. This list will be kept securely for at least 7 years from the end of the study and then for as long as necessary to comply with applicable legal, regulatory, scientific or other requirements. The list will then be destroyed. This list will be held by CDF.

How information that can identify you will be used:

- CDF will use your name, contact information and date of birth that you provided in your iQualify account in order to contact you during the study by email to remind you to complete the questionnaires and facilitate payments with Greenphire. You may choose to receive study reminders via SMS text message. CDF will contact you by phone call to discuss your continued participation should you miss a payment milestone or not complete certain questionnaires. If in your iQualify account, you opted to have CDF send you updates and other study opportunities, your contact information will also be used for those purposes, consistent with the terms specified by CDF and your consent.
- Greenphire will use your name, contact information and date of birth to allow for payment of when milestones are completed.

- uMotif will have access to your email address in order to contact you by email and/or push notifications on your device during the study to inform you when surveys are available to complete. Push notifications are optional.

Your name, contact information, date of birth, and Subject ID will not be used for any other purposes.

Coded information (data that are not linked to your name, contact information, or date of birth) collected in connection with the study may be used by or sent to other parties to conduct the research described in this informed consent form; for scientific meetings, presentations and/or publications about the study (including those that present the results of the study); for safety-reporting; and any other study-related uses described in this form. Additionally, the coded information collected in connection with this study may also be added to research databases and used in the future by the Sponsor, their associates, and others, including independent, external researchers to develop a better understanding of the experiences of people living with celiac disease; to study therapies to conduct research unrelated to this survey study or your disease; and to improve the efficiency, design and methods of future studies. The Sponsor will do everything possible to keep your coded information confidential. The parties that may receive the coded information (data that does not identify you) includes the following:

- The Sponsor, and other companies and people acting for or with the Sponsor, including the Sponsor's business and licensing partners
- Independent, external researchers
- Regulatory agencies
- Institutional review boards and ethics committees

Coded information will be retained for as long as necessary to achieve the purposes for which it was collected, subject to local laws and regulations.

How do participants get paid?

To receive payment, you will be issued a virtual ClinCard from Greenphire. A virtual ClinCard is a digital representation of a debit card that your funds are loaded onto and can be used at your discretion. Your virtual card will be activated once registered to you, initiating an email to be sent, containing a link to access your virtual card online after the successful verification of your identity. Greenphire's terms of use and conditions may apply. When a milestone is completed, funds will be approved and loaded onto your virtual card. The funds will be available within 10 calendar days and can be used at your discretion. In order to assign a virtual ClinCard to you and load funds onto the ClinCard, CDF will provide Greenphire with your Subject ID, name, address, date of birth, and e-mail address based on the data that you entered into your iQualify account.

Greenphire has administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of your personal information. Greenphire will only use or disclose your personal information to support the activities described in this informed consent, including to service providers who assist in managing, administering or delivering the services. Greenphire will not use your personal information for any other purpose. Greenphire will retain your personal information for as long as necessary to provide the activities described in this informed consent form and for compliance with applicable laws.

What are your rights?

Your decision to take part in this research study is completely voluntary. You may decline to answer any question. If you choose to decline to answer a question, please just exit that questionnaire and move on to the following questionnaire. Please know that an incomplete questionnaire may affect your study compensation. To withdraw your consent for data processing or withdraw from the study, please see the section below on "How do I leave the study or withdraw consent for data processing?"

You have the right to request access to, rectification, and deletion of your personal data or that its use be restricted. It may not always be possible to immediately and completely honor any of these requests described above. If your request cannot be or can only partially be honored, you will be informed and given the reason(s).

Who is overseeing this research?

This research is being overseen by an Independent Review Board (IRB). An IRB is a group of people who perform independent review of research studies. The IRB works to ensure that the rights of all participants in research are protected. The IRB that is overseeing this study is the WCG IRB. You may contact the WCG IRB at (855) 818-2289, or clientservices@wcgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.

How do I leave the study or withdraw consent for data processing?

You can stop taking part in this study or withdraw your consent for data processing at any time. If you choose not to take part in the study or you agree to take part but then withdraw from the study, this will not affect your present or future medical care, and there will be no penalty or loss of benefits to which you are otherwise entitled. If you choose to withdraw from the research study, any data about you (including your health information) that has already been collected may remain part of the study data in order to satisfy regulatory requirements and/or safeguard scientific integrity. To withdraw from the study, please email CDF at Virtualstudy@celiac.org.

If you withdraw your consent for data processing, you will no longer be able to take part in the study, and your information will no longer be used or shared under this consent, unless doing so is necessary to make sure that the study is scientifically reliable, and/or to record when you withdrew your consent. No new information about you will be added to the study, but the Sponsor can still use and distribute any information it received before you withdrew your consent for the purposes described in this informed consent.

What if I have questions?

If you have questions about the study, including any comments, questions, or complaints about how your information is handled, or about the research, or you think you have been harmed by this research, please send an e-mail to celiacsymptoms@analysisgroup.com.

If you have a question about how you are paid or would like to withdraw from the study, please send an e-mail to Virtualstudy@celiac.org.

If you have questions about the uMotif app, please send an email to VirtualCeliac@uMotif.com.

Conflict of Interest Disclosure
The principal investigator has a financial relationship with the sponsor. Please feel free to ask any questions you may have about this.

Statement of Consent to Take Part in the Research Study:

If you have read the previous screens and completely understand the information regarding your participation in this survey and agree to participate, please click the **Yes** button.

By clicking "Yes", you are authorizing the Sponsor, its affiliates and business partners to use and share personal information about you, including information about your health and treatment, as specified in the informed consent form. This consent does not have an end date.

If you do not agree to participate, click the **No** button.

If you would like more information before deciding whether to participate, please view the study Web site at virtual.celiac.org or contact the study team by sending an e-mail to celiacsymptoms@analysisgroup.com.

By selecting "Yes", you are declaring the following:

- I am 18 years of age or older.
- I have considered this study carefully, and I have asked any questions I have about participating in this study. All of my questions have been answered to my satisfaction.
- I understand that I am taking part in this study voluntarily and I can withdraw from the study at any time without penalty or losing any benefits or medical care I am entitled to.
- My personal data, including contact information, can be used (by Sponsor and those working with the Sponsor) in the ways described previously.
- I can be contacted for the purposes of this study in the ways described previously.
- My coded health information can be used (by Sponsor, those working with the sponsor, and independent researchers) and transferred in the ways described previously and may be added to research databases in order to:
    - develop a better understanding of celiac disease;
    - perform research unrelated to celiac disease; and
    - improve the efficiency, design and methods of future clinical studies.

- ❑ **Yes**, I agree to participate. I confirm that by selecting "Yes," I am providing the legal equivalent of my handwritten signature on this consent form.
- ❑ **No**, I do not agree to participate.