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

PROTOCOL NO.:
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SPONSOR:
Takeda Development Center Americas, Inc (TDCA)

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PDF version of the Adolescent Reconsent Form is available at: https://celiac.org/vcss-adolescent-consent-forms/

Adolescent Reconsent Form

Introduction

Previously, before you started the Virtual Celiac Symptoms Study, your parent/legal guardian consented to your participation in the study by signing an informed consent form on your behalf, and you provided your own agreement to participate in the study by signing an assent form. As you have now reached the age to consent to participate in the study, you can decide whether you would like to continue to take part in the study.

To help you make an informed decision on whether or not to continue 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.” This informed consent form is a version of the informed consent form that was signed by your parent/legal guardian. The form has been updated to obtain your informed consent to continue to take part in this study since reaching the legal age of 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 continue 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 continue to 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 participating 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?

So far, you have been completing questionnaires on a daily basis for this study. For the remaining time left in this three-month study, you will continue to be asked to complete questionnaires on a daily basis. 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 of the study, the questionnaires 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.

At the discretion of the investigators, if you have missed several milestone payments, you may be unenrolled from the study.

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?

When you started this study, you were asked to answer questions on a mobile app that was developed by and is administered by uMotif. uMotif is a company that develops modern data capture platforms for research. For the remainder of the study, you will continue to use the app to:

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

By providing your consent, you agree to continue to use the uMotif app as requested. If you choose not to use the app, you will not be able to continue 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.

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 does it cost to participate in this study?

There is no cost to you for your continued participation in this study.

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

If you agree to continue 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, may 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 (and that your parent/legal guardian previously provided) will be used for the purposes of this research study and as described in this form. This includes, for example, to determine if you were eligible for this study; to evaluate how your health changes during the course of the study; to learn more about celiac disease; and to process payment.

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 your parent/legal guardian provided in their iQualify account in order to contact you during the study by email to remind you to complete the questionnaires and to facilitate payments with Greenphire. CDF may also contact your parent/legal guardian via phone or SMS text about study information and participation, based on the information they previously provided to CDF and in their informed consent.
- uMotif will have access to your date of birth and 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 and to collect your informed consent. Push notifications are optional.

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.

What are your rights?

Your decision to continue 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 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 to 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 continue 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. 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, please send an e-mail to celiacsymptoms@analysisgroup.com.

If you have a question about payment 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.

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 continue to participate, please click the **Yes** button.

By clicking "Yes", you (or your legal representative) 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 continue to participate, click the **No** button.

If you would like more information before deciding whether to participate, please view the study website 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.