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

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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-adolescent-consent-forms/

Adolescent Informed Consent Form

Introduction

Your child has been invited to take part in the Virtual Celiac Symptoms Study based on your answers about your child's experience and diagnosis with celiac disease. Your child's participation in this survey study is voluntary and your child's care will not be affected whatever you decide. Your child may refuse to participate or withdraw from the survey study, at any time, without penalty or loss of benefits to which he/she is otherwise entitled to. To help you make an informed decision on whether or not to have your child 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 your child to take part in the survey study, you must click "Yes" at the box at the bottom of this screen agreeing ("consenting") for them to participate in this study. Your child cannot participate in the study unless you provide your consent. You will be able to access the information in this informed consent form in the "Study Information" part of the uMotif app on your child's device.

What are informed consent and assent?

Informed Consent:

Informed consent is a voluntary decision made either by a participant of legally acceptable age to take part in a research project, or—as is the case here—by a parent/legal guardian(s) to enroll their child into

a research project. As a parent/legal guardian(s) considering this survey study on behalf of your child, before you sign the informed consent, you will need to make sure you:

- Have read this information and asked as many questions as you need to
- Understand as much as possible about the purpose of the research, what it requires and what the potential risks are;
- Agree to allow your child to take part in the survey study and are assured that your child wants to take part;
- Are able and willing to fulfill the required responsibilities;
- Personally provide your informed consent by selecting "Yes" at the bottom of this screen, to say that you agree that your child can take part in this study and will follow the planned research project.

Informed Assent:

Informed assent is for children who are and under the legal age to consent to research for themselves. Your child will be given age-appropriate information about the research to read and will:

- Have the opportunity to ask questions about the research to have (as much as possible) a good understanding of the research and what is required of them;
- Have the opportunity to make their own decision, without pressure from anyone that they want to take part;
- If they want to take part, have the option to agree to the assent form.

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. Your child is 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 or your child. 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 and your child will not be personally identified on any of these Web sites.

This study is completely virtual and consists of your child answering a series of questions using the uMotif app on their 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, your child 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 their symptoms, visits to the doctor, and overall health. The approximate time required to complete the survey is described below:

- On the first day, your child 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, your child will be asked to complete additional questionnaires that may take about 4-5 minutes.
- On a monthly basis during the three-month survey study, your child will be asked to complete additional questionnaires that may take 30-45 minutes to complete.

To be eligible for this study, your child should not be enrolled in a clinical trial that includes taking a medication or undergoing a procedure or a gluten challenge over the course of 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?

The app where your child 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 child's responses, and help determine your child's eligibility for payment, and
- provide you with an easy way to provide your informed consent for your child's participation and to provide your child with an easy way to provide their assent.

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

By providing your consent, you agree that your child can use the uMotif app as requested. If you choose not to have your child use the app, they 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 your child to report personal information about their 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 your child from participating in this study. However, your child's 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, up to $500.00 will be available as compensation in consideration for the time taken to answer questionnaires. In order to be paid the full amount, for the 1st milestone, your child must complete all of the non-daily questionnaires and 70% of the daily questionnaires. For the other milestones your child must complete at least 70% of the daily and weekly questionnaires, as well as at least 70% of the monthly questionnaires during each time period. Payments for your child's participation will be made to you 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 your child does not complete all of the required questionnaires to meet the first milestone, they 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 your child to participate in this study. However, if you choose to receive study updates, reminders or payment alerts about your child's participation 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 have your child take part in the study, personal information about you and personal information about your child and their health will be gathered and stored. This may include information that may be used to identify you and/or your child, such as your and your child's name, address, phone number, date of birth, as well as information about your child collected through the questionnaires. Certain demographic information, such as age, race, education, and gender, will also be collected to better understand how responses differ across these factors. This section describes how your and your child's information will be used and to whom it may be disclosed.

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

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

Information that can identify you or your child (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 and your child's name, contact information, and date of birth that you provided in your iQualifyCeliac account in order to contact you and your child during the study by email to remind you to complete the questionnaires and facilitate payments with Greenphire. You may have the option to choose to receive study reminders about your child's participation via SMS text message. CDF may contact you by phone call to discuss your child's continued participation should your child miss a payment milestone or not complete certain questionnaires. Your child will not be contacted by phone. If in your iQualifyCeliac account, you opted to have CDF send you or your child updates and other study opportunities, your contact information and your child's contact information will also be used for those purposes, consistent with the terms specified by CDF and your consent.

- Greenphire will use your name, address, and date of birth and your child's email address to allow for payment when milestones are completed.
- uMotif will have access to your child's date of birth and email address in order to contact your child by email and/or push notifications on their device during the study to inform them when surveys are available to complete and to allow for password resets. Push notifications are optional.

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

Coded information (data that are not linked to your or your child's 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 the coded information confidential. The parties that may receive the coded information (data that does not identify you or your child) 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 provide payment for your child's participation, a virtual ClinCard from Greenphire will be issued to you. A virtual ClinCard is a digital representation of a debit card that funds are loaded onto. The virtual card will be activated once registration and identity verification are complete. Greenphire's terms of use and conditions may apply. When a milestone is completed, funds will be approved and loaded onto the virtual card. The funds will be available within 10 calendar days. In order to assign a virtual ClinCard and load funds onto the ClinCard, CDF will provide Greenphire with your child's Subject ID and email address, and your name, address, and date of birth based on the data that you entered into your iQualifyCeliac account.

Greenphire has administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of your and your child's personal information. Greenphire will only use or disclose your and/or your child's 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 or your child's personal information for any other purpose. Greenphire will retain your and your child's 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?

Participation in this study is completely voluntary. Even if you agree to allow your child to participate in this study, your child can stop taking part at any time. Your child may also decline to answer any question. If your child chooses to decline to answer a question, your child can just exit that questionnaire and move on to the following questionnaire. Please know that an incomplete questionnaire may affect the study compensation for your child's participation. For you or your child to withdraw your consent for data processing or to withdraw from the study, please see the section below on "How does my child leave the study or withdraw consent for data processing?"

You and your child have the right to request access, rectification, and deletion of your and your child's 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 or your child's request cannot be or can only partially be honored, you or your child 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 does my child leave the study or withdraw consent for data processing?

Participation in this study is totally voluntary. Even if you agree to allow your child to participate in this study, your child can stop taking part at any time. If you choose for your child not to take part or you agree to have your child to take part but then withdraw them from the study, this will not affect your child's present or future medical care and there will be no penalty or loss of benefits that you and your child may otherwise be entitled to. If you or your child choose to withdraw your child from the research study, any data about you and/or your child (including your child's 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, you or your child may email CDF at Virtualstudy@celiac.org.

If you or your child withdraw consent for data processing, your child will no longer be able to take part in the study, and your and your child's 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 or your child withdrew consent. No new information about your child will be added to the study, but the Sponsor can still use and distribute any information it received before you or your child withdrew 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 payment or would like to withdraw your child 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 child's participation in this survey and agree to have your child 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 and your child, including your child's 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 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 have considered this study carefully, and I have asked any questions I have about my child participating in this study. My questions have been answered to my satisfaction.
- I understand that taking part in this study voluntarily and I can withdraw my child from the study at any time without penalty or losing any benefits or medical care my child is entitled to.
- My and my child's personal data, including contact information, can be used (by Sponsor and those working with the Sponsor) in the ways described previously.
- My child and I can be contacted for purposes of this study in the ways described previously.

- My child's 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 for my child 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 for my child to participate.

I am 18 years or older and I am the parent/legal guardian of a child (a minor) who has been invited to participate in this study.

❑ **Yes**
❑ **No**

I confirm that my child is between the ages of 12 and 17 and has been invited to participate in this study.

❑ **Yes**
❑ **No**

- All children are required to assent.
- Documentation of assent is not required