

If your child or teenager struggles with constipation,

#2 may often be the #1 topic...



A CLINICAL RESEARCH STUDY FOR CONSTIPATION IN CHILDREN AND TEENAGERS

If you have tried other treatments and haven't found a solution to get things moving, we invite you to learn more about a research study that is evaluating the safety and effectiveness of a study medication for constipation in children and teenagers.

SEE IF YOUR CHILD QUALIFIES →

Your child may be eligible to take part in the 2Go Study if they:

- ✓ Are between 6 months and 17 years old and weigh at least 12 lbs (5.5 kg)
- ✓ Have fewer than 3 bowel movements per week
- ✓ Have at least one of the following symptoms for a month or longer:
 - Inability to control bowel movements (BMs) causing poop to leak unexpectedly
 - Retentive Posturing (holding the body in such a way as to purposely prevent a BM)
 - Painful or hard BMs
 - Large stools that can clog a toilet or that are large in diameter
 - A history of voluntarily withholding stool (purposely trying not to poop)

Additional study criteria will apply.



Study-related care will be provided at no cost.


SEE IF YOUR CHILD QUALIFIES →

About Constipation in Children and Teenagers


Constipation is a common condition and one of the main reasons for a visit to a gastroenterologist. The majority of children and teenagers experiencing symptoms of constipation are eventually diagnosed with "functional constipation" — a term that means there is no underlying disease causing their symptoms. In most cases, constipation is successfully treated with laxatives and dietary changes.

However, for approximately 1 in 3 children and teenagers, the symptoms persist and cannot be fully managed with regular enemas and even maximum laxative intake.


Further research is needed to understand and treat their symptoms. If your child or teenager has functional constipation and has not found relief from standard treatment, you may want to consider enrolling them in the 2Go Study.

Constipation affects up to 30 percent of children and teenagers



Constipation accounts for an estimated 3 to 5 percent of all visits to pediatricians



Functional constipation is responsible for more than 95 percent of cases of constipation in healthy children one year and older and is particularly common among preschool-aged children

Sources: www.ncbi.nlm.nih.gov | www.uptodate.com

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Call: 1-800-807-6524

Hi 👋 I am Takeda 2Go Bot (and not a real person!). I am here to help you submit information to prescreen and participate in our 2Go Study! Your information will be recorded, but will only be used for the purposes of this study.

How can I assist?

Get started with screener

FAQs on screener





About Clinical Research Studies

Clinical research studies aim to advance the treatment of all conditions, including Constipation in Children and Teenagers.

The main objective of a clinical research study is to answer questions about the safety and effectiveness of potential new medications. These studies must be completed before a new treatment can be offered to the public. **Right now, there are over 300,000 clinical studies in progress all over the world.**

For each research study, researchers develop eligibility criteria, such as age, gender, previous treatment history, and other medical conditions. It is important to test medications and medical products in the people they are meant to help, and to conduct research in a variety of people because different people may respond differently to treatments.

Participation in the 2Go Study will give your child access to study medications that may regulate their bowel movements and alleviate constipation symptoms.



Study participants will receive the following at no cost:

Study-related medications

Study-related care and monitoring

Study-related visits with a team of medical professionals

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About the 2Go Study

This study is evaluating the safety and effectiveness of a study medication, called *prucalopride*, for children and teenagers with constipation. *Prucalopride* has already been approved in the United States for the treatment of constipation in adults.



The study is divided into three phases:



Phase One

Screening

This phase is devoted to determining if your child is eligible to participate in the study.



Phase Two

Study Treatment

If your child is eligible to participate in the 2Go Study, they will begin the Study Treatment Phase, which is broken into two parts, Part A and Part B.

- For Part A, which lasts for 12 weeks, your child will be randomly assigned to 1 of 3 study treatment groups: high dose, low dose, and placebo
- After Part A is completed, study participants who were in the placebo group for 12 weeks will be re-randomized into either the high- or low-dose group for Part B of the Study Treatment Phase, which lasts for 36 weeks
- Part B of the Study Treatment Phase will measure the long-term safety of the study medication



Phase Three

Follow-up Phase

After Part A and Part B of the Study Treatment Phase are completed, there will be one follow-up visit to complete the study that takes place approximately 4 weeks after the last dose of the study medication is taken.

Please consider enrolling your child in the 2Go Study today.

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Frequently Asked Questions

Who can participate in the 2Go Study?

Your child or teenager may be eligible to take part in the 2Go Study if they:

- Are between 6 months and 17 years old and weigh at least 12 lbs (5.5 kg)
- Have fewer than 3 bowel movements per week
- Have at least one or more of the following symptoms for a month or longer:
 - Inability to control bowel movements (BMs) causing poop to leak unexpectedly
 - Retentive Posturing (holding the body in such a way as to purposely prevent a BM)
 - Painful or hard BMs
 - Large stools that can clog a toilet or that are large in diameter
 - A history of voluntarily withholding stool (purposely trying not to poop)

There are additional criteria that are reviewed by the study team at the study center at the first appointment.



What's involved with study participation?

If your child qualifies for the 2Go Study, it will involve taking the study medication, visiting the study center or attending study visits by phone, recording your child's bowel movement and study medication dosing information in an eDiary (an electronic diary that captures data), and completing study procedures.

If pre-qualified, what can I and my child expect on the first visit to the study center?

This initial appointment is an opportunity to:

- **Learn more about the 2Go Study.** Your child will be speaking with a study coordinator at the study center to learn more regarding their participation in this study.
- **Ask any important questions.** These can be any questions you or your child may have about this study or clinical research in general.
- **Determine if the 2Go Study may be right for your child.** After speaking with the study coordinator and learning details about this study, the research staff will perform a series of screening tests to determine if your child pre-qualifies to participate. If they pre-qualify, they will be given an opportunity to decide if participation is right for them. If they agree to take part, the center will ask them to review and sign an assent form.

How long is this study? / How many appointments are there?

If eligible, your child will be in the study for a little over 1 year, during which time participants will be required to attend approximately 25 study visits. During the first part of the study, there will be weekly visits and some of these visits will be conducted over the phone. During the second part of the study, there will be monthly visits, and some of these visits will be also conducted over the phone. The final study visit will be conducted over the phone.

My child isn't toilet trained / my child is in the middle of being toilet trained. Can they participate?

If your child pre-qualifies during this online questionnaire, you can discuss these details with the study center.

What is the medication being tested?

This study is evaluating the safety and effectiveness of a study medication, called prucalopride, in treating children and teenagers with constipation. Prucalopride has already been approved in the United States for the treatment of constipation in adults.

Is it possible that my child may be given placebo? / Is there a placebo?

If your child qualifies for the 2Go Study, there is a one in three chance they may receive a placebo during the first part of the study. You, your child, and the study team won't know which study treatment group your child is in. In the second part of the study, all participants will receive the study medication. The study coordinator can answer any questions you or your child have about the 2Go Study.

What is a placebo?

A placebo is a substance with no active medication. In this case, the placebo looks like the study medication but does not contain the active ingredient.

Will my child have to discontinue any current medication?

Do not discontinue any medication unless your child is advised to do so by the study center staff or your child's primary care physician.

Where are the study centers located?

The study centers are located throughout the United States.

Does participating in this study cost me anything?

Qualified participants will receive study-required medical care and study medication at no cost. The study will not pay for other medical care or current medication(s) needed to support your child's daily health care routine. You may receive reimbursement for study-related expenses. If your child pre-qualifies, they can speak with the study center for more information.

Does my child need health insurance to participate?

No, health insurance is not required in order to participate.

Why hasn't my child pre-qualified for the study?

Research studies are designed in specific ways to test the study medication for safety and effectiveness. One or more of the answers that you provided about their health status were outside of the eligibility criteria for this study. This does not mean your child will not qualify for different research studies.



About Research Studies

What is a research study?

A research study (also known as a clinical trial) is a medical study that is designed to answer questions about the safety of potential new medications and to find out how well they work. These studies must be performed before a potential new medication or treatment can be approved for use in patients and sold to the general public.

It is important to test medications and medical products in the people they are meant to help. It is also important to conduct research in a variety of people because different people may respond differently to treatments.

For each research study, researchers develop eligibility criteria, such as age, gender, previous treatment history, and other medical conditions. Not everyone who applies for a research study will be accepted. Participants will be selected based on the eligibility criteria and the number of participants needed by the researchers.

Why are research studies important?

Research studies are used to test medications before they are available to the general public. The testing that takes place during the studies provides information regarding the safety and effectiveness of the potential medication. By participating in a study, you may help bring new and improved treatments to patients in need.

Where can people find out about research studies?

One way to find information about clinical trials is by searching this website: www.clinicaltrials.gov. ClinicalTrials.gov is an interactive online database, managed by the National Library of Medicine. It provides information about both federally and privately supported clinical research. ClinicalTrials.gov is updated regularly and offers information on each trial's purpose, who is qualified to participate, locations, and phone numbers to call for more information.

Why should my child or teenager consider participating in a research study?

For those who are qualified, taking part in research studies offers several benefits:

- Getting actively involved in their own health care
- Having access to potentially new research treatments
- Having access to expert medical care for the condition being studied, since investigators are often specialists in the disease area being studied
- Helping others by contributing to medical research

It is important to test medications and medical products in the people they are meant to help. It is also important to conduct research in a variety of people because different people may respond differently to treatments.

For each research study, researchers develop eligibility criteria, such as age, gender, previous treatment history, and other medical conditions. Not everyone who applies for a research study will be accepted. Volunteers may be excluded based on the eligibility criteria and/or the number of participants needed by the researchers.

Where are research studies conducted?

Research studies can be sponsored by an organization such as a pharmaceutical company, a federal agency such as the Veterans Administration, or an individual, such as a physician or health care provider. The sponsor determines the location(s) of the trials, which are usually conducted at universities, medical centers, clinics, doctor's offices, and/or at hospitals.

What is "informed consent"?

The government requires researchers to give prospective participants complete and accurate information about what will happen during the study. Participants must sign an "informed consent" form before joining the study, indicating they understand that the study is research, and that they can leave the research study at any time. This informed consent helps ensure that a prospective research study participant understands what's involved.



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Privacy Policy

Clinical Trial Media, Inc. (CTM)
Privacy Policy
Effective January 22, 2021

INTRODUCTION

CTM is committed to respecting and protecting your privacy. This privacy policy sets out how we look after your personal data, how we will use your personal data, and tells you about your privacy rights and how the law protects you.

This privacy policy sets out our approach to protecting personal data on a worldwide basis and we recognize that different jurisdictions and legal systems will apply:

- (i) In the United States, the Federal Trade Commission has jurisdiction over our compliance regarding personal data. If you do not agree to the terms of this privacy policy, you should not access or use any CTM website or service.
- (ii) In the rest of the world, different legal rules apply and, in particular, we will be using and protecting personal data in a way which is in accordance with the rules operating in the European Economic Area ("EEA") which has adopted the General Data Protection Regulation ("GDPR") and the United Kingdom ("UK") which has adopted its own version of the GDPR. In the EEA, the relevant national supervisory authority will have jurisdiction over our compliance in the relevant country. If you do not agree to the terms of this privacy policy, please do not access or use any CTM website or service.

TABLE OF CONTENTS

- PURPOSE
- THE DATA WE COLLECT ABOUT YOU
- HOW YOUR PERSONAL DATA IS COLLECTED
- HOW WE USE AND DISCLOSE YOUR PERSONAL DATA
- INTERNATIONAL TRANSFERS
- DATA SECURITY
- DATA RETENTION
- YOUR DATA PRIVACY RIGHTS UNDER GDPR AND UK PRIVACY LAW
- YOUR CALIFORNIA PRIVACY RIGHTS
- DEFINITIONS

1. PURPOSE

This privacy policy describes how CTM collects, uses, processes and protects your personal data and informs the choices available to you regarding how you can choose and manage your personal data.

It is important that you read this privacy policy together with any other privacy policy or fair processing notice we may provide on specific occasions when we are collecting or processing personal data about you so that you are fully aware of how and why we are using your data. This privacy policy supplements the other notices and is not intended to override them.

1.1 CONTROLLER

This privacy policy is issued on behalf of CTM so when "we", "us" or "our" is mentioned in this privacy policy, we are responsible for processing your data.

We have appointed a data protection officer who is responsible for dealing with questions in relation to this privacy policy. If you have any questions about this privacy policy, including any requests to exercise your legal rights, please contact the data protection officer using the details set out below:

1.2 CONTACT DETAILS

Our contact details for privacy rights requests and information about our privacy practices are:

Full name of legal entity: Clinical Trial Media, Inc.
 Name or title of data protection officer: Henry Shinn
 Email address: privacy@clinicaltrialmedia.com
 Telephone number: 516-470-0720

Postal address: 100 Motor Parkway, Suite 528, Hauppauge, NY 11788, USA

URL: <https://www.clinicaltrialmedia.com/request-form>

1.3 COMPLAINTS

You have the right to make a complaint at any time to the relevant national supervisory authority in the country where you reside. To find more about this right and to locate the appropriate Data Privacy Authority, go to the European Commission website (https://ec.europa.eu/info/privacy/justice-and-fundamental-rights_en) or the UK, go to the Information Commissioner's Office ("ICO") website (<https://ico.org.uk>). If you are in the United States, you may contact the US Federal Trade Commission regarding your concerns. For more information, please see <https://www.ftc.gov/consumer-protection/submit-consumer-complaint-form>.

We would, however, appreciate the chance to deal with your concerns before you approach one of the national supervisory authorities, so please contact us in the first instance.

1.4 CHANGES TO THE PRIVACY POLICY AND YOUR DUTY TO INFORM US OF CHANGES IN YOUR PERSONAL DATA

We reserve the right to amend this privacy policy and will notify you by updating this notice, so please check it from time to time, especially if you have ongoing dealings with us. It is important that the personal data we hold about you is accurate and current. Please keep us informed if your personal data changes during your relationship with us.

1.5 THIRD-PARTY LINKS

This website may include links to third-party websites, plug-ins and applications. Clicking on those links or enabling those connections may allow third parties to collect or share data about you. We do not control those third-party websites and are not responsible for their privacy statements. When you leave our website, we encourage you to read the privacy policy of every website you visit.

2. THE DATA WE COLLECT ABOUT YOU

Personal data, or personal information, means any information related to an identified or identifiable natural person. It does not, however, include data where the identity has been removed (anonymized data).

We may collect, use, store and transfer different categories of personal data about you which we have grouped together as follows:

- **Identity Data** includes first name, maiden name, last name, username and/or similar identifier, date of birth, and gender.
- **Contact Data** includes billing address, delivery address, email addresses and telephone numbers.
- **Financial Data** includes banking details of clients, suppliers, and agents for the making of payments by us and to us in relation to the services we provide.
- **Transaction Data** includes details of products and services you have received or purchased from us and/or affiliates.
- **Technical Data** includes internet protocol ("IP") address, your login data, browser type and version, time zone setting and location, browser plug-in types and versions, operating system and platform, and other technology on the devices you use to access this website.
- **Profile Data** includes your username and password, purchases or orders made by you, your interests, preferences, feedback, and survey/questionnaire responses.
- **Usage Data** includes information about how you use our website, products, and services.
- **Marketing and Communications Data** includes your preferences in receiving marketing from us and/or affiliates.
- **Health Data** includes information in relation to any aspect of your health and/or consequences of taking part in any clinical trials organized by our clients.

We may also collect, use and share **Aggregated Data** such as general statistical or demographic data for any purpose. Aggregated Data may be derived from your personal data but is not considered personal data in law as this data does not directly or indirectly reveal your identity. For example, we may aggregate your Usage Data to calculate the percentage of users accessing a specific website feature. However, if we combine or connect Aggregated Data with your personal data so that it can directly or indirectly identify you, we treat the combined data as personal data which will be used in accordance with this privacy policy.

Apart from Health Data and industry-wide or governmental survey/questionnaire where we are obliged to take part, we do not normally collect any **Special Categories of Personal Data** about you (this includes details about your race or ethnicity, religious or philosophical beliefs, sex life, sexual orientation, political opinions, and trade union membership).

2.1 IF YOU FAIL TO PROVIDE PERSONAL DATA

Where we need to collect personal data by law, or under the terms of a contract we have with you and you fail to provide that data when requested, we may not be able to perform the contract we have or are trying to enter into with you (for example, to provide you with our services). In this case, we may have to cancel a product or service you have with us but we will notify you if this is the case at the time.

3. HOW YOUR PERSONAL DATA IS COLLECTED

We use different methods to collect the categories of data described above from and about you including through:

- **Direct interactions.** You may give us your personal data by filling in forms or by corresponding with us by mail, phone, and email, or otherwise. This includes personal data you provide when you:
 - apply online or otherwise for our services or products;
 - contract to receive our services; or
 - request marketing material to be sent to you.
- **Automated technologies or interactions.** As you interact with our website, we may automatically collect Technical Data about your equipment, browsing actions and patterns. We collect this personal data by using cookies, log files, and other similar technologies. We may also receive Technical Data about you if you visit our websites employing our cookies. This aggregate data gives a "macro-view" of the visitor traffic patterns and might to what sections of the website users visits most. We use this information to determine what kind of technology is available on the visitors' computers so that we can better serve them by utilizing more advanced technologies (e.g., Macromedia Flash). None of this information is linked to any Personal Information.
- We passively collect and log the following information from visitors to our site such as:
 - Browser type
 - IP Address
 - Domain Name
 - Access time
 - Operating System
- **Third parties or publicly available sources.** We may receive personal data about you from various third parties and public sources as set out below:
 - We may receive **Technical Data** from the following parties:
 - analytics providers such as Google;
 - advertising networks;
 - search information providers;
 - portals.
 - **Contact and Transaction Data** from providers of technical, payment and delivery services.
 - **Identify and Contact Data** from data brokers or aggregators.

4. HOW WE USE AND DISCLOSE YOUR PERSONAL DATA

We will only use your personal data when the law allows us to. Most commonly, we will use your personal data in the following circumstances:

- Where it is necessary for the contract we are interested to enter into or have entered into with you, or to perform other legal obligations.
- Where it is necessary for our legitimate interests (or those of a third party) and your interests and fundamental rights do not override those interests (this applies in the EEA and UK).
- Where we need to comply with a legal or regulatory obligation.

In the EEA, in relation to sending direct marketing communications to you via email or text message, we will only do so by contacting (i) we have your express consent or (ii) you are an existing client. You have the right to withdraw consent to marketing at any time by contacting us.

4.1 PURPOSES FOR WHICH WE WILL USE YOUR PERSONAL DATA

We have set out below, in table format, a description of the ways we plan to use your personal data, and which of the legal basis we rely on to do so. We have also identified what our legitimate interests are, where appropriate.

Note that we may process your personal data for more than one lawful ground depending on the specific purpose for which we are using your data. Please contact us if you need details about the specific legal ground we are relying on to process your personal data where more than one ground has been set out in the table below:

Purpose/Activity	Category of data	Lawful basis for processing including basis of legitimate interest
To register you as a new customer	(a) Identity(b) Contact	Performance of a contract with you(b)
To process and deliver services and/or perform contractual obligations for you, including collecting and recovering money owed to us	(a) Identity(b) Contact(c) Financial(d) Transaction(e) Marketing and Communications	(a) Performance of a contract with you(b) Necessary for our legitimate interests (to recover funds due to us)
To manage our relationship with you which will include (a) Notifying you about changes to our terms or privacy policy(b) Asking you to leave a review or take a survey/questionnaire	(a) Identity(b) Contact(c) Profile(d) Marketing and Communications	(a) Performance of a contract with you(b) Necessary to comply with a legal obligation(c) Necessary for our legitimate interests (to keep our records updated and to study how customers use our products/services)
To enable you to complete a survey/questionnaire	(a) Identity(b) Contact(c) Profile(d) Usage(e) Marketing and Communications	(a) Performance of a contract with you(b) Necessary for our legitimate interests (to study how customers use our products/services, to develop them and grow our business)
To consider whether you are eligible/suitable for taking part in a specific clinical trial, related clinical investigation, or clinical support program carried out, or clients	(a) Identity(b) Contact(c) Health	(a) Necessary for our legitimate interests to develop our products/services(b) Necessary in order to comply with contractual obligations with our end-clients
To administer and protect our business and this website (including troubleshooting, data analysis, testing, system maintenance, support reporting, and hosting of data)	(a) Identity(b) Contact(c) Technical	(a) Necessary for our legitimate interests (for running our business, provision of administration and IT services, network security, to prevent fraud and in the context of a business reorganization or group restructuring activity)(b) Necessary to comply with a legal obligation(c) Necessary to resolve disputes
To deliver relevant website content and advertisements to you and measure or understand the effectiveness of the advertising we serve to you	(a) Identity(b) Contact(c) Profile(d) Usage(e) Marketing and Communications(f) Technical	Necessary for our legitimate interests (to study how customers use our products/services, to develop them, to grow our business and to inform our marketing strategy)
To produce data analytics to improve our website, products/services, marketing, customer relationships and experiences; provide audit records for consent	(a) Technical(b) Usage	Necessary for our legitimate interests (to define types of customers for our products and services, to keep our website updated and relevant, to develop our business and to inform our marketing strategy)
To make suggestions and recommendations to you about goods or services that may be of interest to you	(a) Identity(b) Contact(c) Technical(d) Usage(e) Profile	Necessary for our legitimate interests (to develop our products/services and grow our business)
To comply with legal obligations, including proper government investigations, subpoenas, or other legal process or as otherwise necessary to prevent physical or financial harm or to prevent crime and fraud	(a) Identity(b) Contact(c) Technical(d) Usage(e) Profile	(a) Necessary for our legitimate interests (to protect our business, employees, customers, and the public)(b) Necessary to comply with a legal obligation(c) Necessary to resolve disputes

4.2 DISCLOSING INFORMATION TO THIRD-PARTIES

We generally do not share your personal clinical data with any company outside CTM except for our trusted clients and service providers where needed for investigations and trials.

We may have to share your personal data with the parties set out below for the purposes set out in the table in section 4.1 above:

- Third party sub-contractors who provide services for us and/or help to provide services to you. In the event that we use sub-contractors who have access to your personal data, we ensure that there are strict contractual terms in place to ensure that they only process personal data to the extent that we instruct them to do so in writing and that there are suitably worded confidentiality and data protection clauses in all such contracts.
- Third parties to whom we may choose to sell, transfer, or merge parts of our business or our assets. Alternatively, we may seek to acquire other businesses or merge with them. If a change of control arises in relation to our business, then the new owners may use your personal data in the same way as set out in this privacy policy.
- We may disclose personal information to law enforcement, government authorities or otherwise in response to legal subpoenas or process as required by applicable law or in circumstances involving the possibility of physical or financial harm, fraud, or crime.

We require all third parties to respect the security of your personal data and to treat it in accordance with the law. We do not allow our third-party service providers to use your personal data for their own purposes and only permit them to process your personal data for specified purposes and in accordance with our instructions.

We do not sell your personal data to any third party. Our use and disclosure of Personal Identifiable Health Information ("PHI") is limited to the minimum amount of personal data needed to accomplish the intended purpose of the specific clinical investigation or clinical trial and is used in relation to pre-screening activities for such clinical research projects. This includes using study questionnaires that only ask health and medical related questions that are directly associated with the relevant clinical research project as specified in approved protocols.

PHI will generally not be used by us or disclosed by us to any third party unless we have clear consent from you to do so.

Exceptionally, PHI may be disclosed by us or disclosed by us to any third party if you do so by a relevant law or regulation. In particular, this includes, but is not limited to, situations where we are required to disclose such PHI in relation to requests by public authorities to meet national security or law enforcement requirements. This will include use and/or disclosure in order to:

- prevent or control disease, injury or disability;
- report disease, injury or disability;
- assist public health surveillance, investigations or interventions;
- report child abuse or neglect or domestic violence;
- avert a serious threat to individual(s) or public health or safety;
- to coroners and/or medical examiners or for tissue donation;
- in response to legal proceedings and relevant court orders or subpoenas;
- for specialized government functions and worker's compensation;
- by workforce members who are whistle-blowers or victims of a criminal act;
 - when we believe in good faith that disclosure is necessary to protect our rights or to protect your safety, the safety of others or investigate fraud.

4.3 OPTING OUT

You can ask us or third parties to stop sending you information/reminders/messages at any time by contacting us.

When you opt out of receiving these information/reminders/messages, this will not apply to personal data provided to us as a result of a product/service purchase, warranty registration, product/service experience or other transactions.

4.4 COOKIES

We only use cookies to record user-specific information on what pages users' access or visit, record past activity, and session management and personalization. Use of cookies allows a better user experience when visitors return to the website.

You can set your browser to refuse all or some browser cookies, or to alert you when websites set or access cookies. If you disable or refuse cookies, please note that some parts of the website may become inaccessible or not function properly.

4.4.1 Cookie Control. CTM's interactive cookie statement prevents cookies from being placed on and controls their use until consent via granting and revoking consent. The user has the control to clearly choose from being placed on their computer until consent via an affirmative act.

4.5 CHANGE OF PURPOSE

We will only use your personal data for the purposes for which we collected it, unless we reasonably consider that we need to use it for another reason and that reason is compatible with the original purpose.

If we need to use your personal data for an unrelated purpose, we will notify you and we will explain the legal basis which allows us to do so.

Please note that we may process your personal data without your knowledge or consent, in compliance with the above rules, where this is required or permitted by law.

4.6 USE OF HEALTH DATA IN THE UNITED STATES

The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and subsequent regulations published by the Department of Health and Human Services ("DHHS") impose restrictions on other organizations (Covered Entities) which may be covered under HIPAA with respect to your relationship with CTM. CTM may, in providing subject recruiting call center services for one of these organizations, be required to comply with certain aspects of HIPAA in their conduct of human subject research activities.

Although CTM is not a Covered Entity as defined in the HIPAA, privacy regulations, our policies and procedures, which govern the privacy rights of research participants included in this privacy policy, are compatible with those required by HIPAA for Covered Entities and will become standard for research activities involving PHI.

All PHI data collected by CTM in connection with subject recruiting for a clinical research study is captured electronically and transmitted through a secure network connection to a secure database. CTM's data security policies are consistent with Good Clinical Practices, HIPAA and GDPR standards. CTM maintains separate Security Policies for Physical Security, Network Security and Application Security.

5. INTERNATIONAL TRANSFERS

Some personal data may be held on servers in the US. This will involve transferring your data outside the European Economic Area ("EEA") or the UK. In addition, we use third parties who have IT servers located in the United States which hold your personal data. You consent to the transfer of your personal information to the United States.

Whenever we transfer and/or process your personal data outside of the EEA or UK, we ensure a similar degree of protection is afforded to it by:

- using specific contracts approved by the European Commission for UK (ICD) which give personal data the same protection it has in Europe.

6. DATA SECURITY

We and our third party hosting partners have put in place appropriate security measures to prevent your personal data from being accidentally lost, used or accessed in an unauthorized way, altered or disclosed. In addition, we limit access to your personal data to those employees, agents, contractors and other third parties who have a business need to know. They will only process your personal data on our instructions and they are subject to a duty of confidentiality.

We have put in place procedures to deal with any suspected personal data breach and will notify you and any applicable regulator of a breach where we are legally required to do so.

7. DATA RETENTION

We will only retain your personal data for as long as necessary to fulfill the purposes we collected it for, including for the purposes of satisfying any legal, accounting, or reporting requirements.

To determine the appropriate retention period for personal data, we consider the amount, nature, and sensitivity of the personal data, the potential risk of harm from unauthorized use or disclosure of your personal data, the purposes for which we process your personal data and whether we can achieve those purposes through other means, and the applicable legal requirements.

In some circumstances in the EEA and UK you can ask us to delete your data; see the section below entitled "Your Data Privacy Rights Under GDPR and UK Privacy Law" for further information.

We may also anonymize your personal data (so that it can no longer be associated with you) for research or statistical purposes in which case we may use this information indefinitely without further notice to you.

8. YOUR DATA PRIVACY RIGHTS UNDER GDPR AND UK PRIVACY LAW

Under certain circumstances in the EEA and UK, you have the following rights under data protection laws in relation to your personal data:

Request access to your personal data (commonly known as a "data subject access request"). This enables you to receive a copy of the personal data we hold about you and to check that we are lawfully processing it.

Request correction of the personal data that we hold about you. This enables you to have any incomplete or inaccurate data we hold about you corrected, though we may need to verify the accuracy of the new data you provide to us.

Request erasure of your personal data. This enables you to ask us to delete or remove personal data where there is no good reason for us continuing to process it. You also have the right to ask us to remove or disable your personal data where you have successfully exercised your right to object to processing (see below), where we may have processed your information unlawfully or where we are required to erase your personal data to comply with local law. Note, however, that we may not always be able to comply with your request as erasure for specific legal reasons which will be notified to you, if applicable, at the time of your request.

Object to processing of your personal data where we are relying on a legitimate interest (or those of a third party) and there is something about your particular situation which makes you wish to object to processing on this ground as you feel it impacts on your fundamental rights and freedoms. You also have the right to object where we are processing your personal data for direct marketing purposes. In some cases, we may demonstrate that we have compelling legitimate grounds to process your information which overrides your rights and freedoms.

Request restriction of processing of your personal data. This enables you to ask us to suspend the processing of your personal data in the following scenarios: (a) if you want us to establish the data's accuracy; (b) where our use of the data is unlawful but you do not want us to erase it; (c) where you need us to hold the data even if we no longer require it as you need to establish, exercise or defend legal claims; or (d) if you have objected to our use of your data but we need to verify whether we have overriding legitimate grounds to use it.

Request the transfer of your personal data to you or to a third party. We will provide to you, or a third party you have chosen, your personal data in a structured, commonly used, machine-readable format. Note that this right only applies to automated information which you initially provided consent for us to use or where we used the information to perform a contract with you.

Withdraw consent at any time where we are relying on consent to process your personal data. However, this will not affect the lawfulness of any processing carried out before you withdraw your consent. If you withdraw your consent, we may not be able to provide certain products or services to you. We will advise you if this is the case at the time you withdraw your consent.

If you wish to exercise any of the rights set out above, please contact us.

In the EEA, you have the right to make a complaint at any time to the relevant national supervisory authority. For example, in the UK this would be the Information Commissioner's Office ("ICO"), the UK supervisory authority for data protection issues (www.ico.org.uk). We would, however, appreciate the chance to deal with your concerns before you approach one of the national supervisory authorities so please contact us in the first instance.

A list of Supervisory Authorities is available here: http://ec.europa.eu/justice/data-protection/bodies/authorities/index_en.htm.

8.1 NO FEE USUALLY REQUIRED

You will not have to pay a fee to access your personal data or to exercise any of the other rights.

8.2 WHAT WE MAY NEED FROM YOU

We may need to request specific information from you to help us confirm your identity and ensure your right to access your personal data to exercise any of your other rights). This is a security measure to ensure that personal data is not disclosed to anyone who has no right to receive it. We may also contact you to ask you for further information in relation to your request to speed up our response.

8.3 TIME LIMIT TO RESPOND

We try to respond to all legitimate requests within 30 business days. Occasionally it may take us longer than 30 business days if your request is particularly complex or you have made a number of requests. In this case, we will notify you and keep you updated.

9. YOUR CALIFORNIA PRIVACY RIGHTS

If you are a resident of California, you have the following rights with respect to your Personal Information:

- the right to know what Personal Information we have collected, used, disclosed and sold about you. To submit a request to know, please contact us. You also may designate an authorized agent to make a request for access on your behalf.
- the right to request that we delete any Personal Information we have collected about you. To submit a request for deletion, please contact us. You also may designate an authorized agent to make a request for deletion on your behalf.

When you exercise these rights and submit a proper request to us, we will verify your identity by asking you for identifying information such as your email address, telephone number, and/or information about your account with us. We also may use a third party verification provider to verify your identity. Please note that we are not obligated to honor such requests twice in a 12-month period.

Your exercise of these rights will have no adverse effect on the price and quality of our goods or services.

For the 12-month period prior to the date of this Privacy Policy, CTM has not sold any personal information collected about you, nor does it have any plans to do so in the future.

10. DEFINITIONS

EEA AND UK

Legitimate Interest means, in the EEA or UK, the interest of our business in conducting and managing our business to enable us to give you the best service/product and the best and most secure experience. We make sure we consider and balance any potential impact on you (both positive and negative) and your rights before we process your personal data for our legitimate interests. We do not use your personal data for activities where our interests are overridden by the impact on you unless we have your consent or are otherwise required or permitted to do so. You can obtain further information about how we assess our legitimate interests against any potential impact on you in respect of specific activities by contacting us.

Performance of Contract means processing your data where it is necessary for the performance of a contract to which you are a party or to take steps at your request before entering into such a contract.

Comply with a legal or regulatory obligation means processing your personal data where it is necessary for compliance with a legal or regulatory obligation that we are subject to.

GDPR is the European Union General Data Protection Regulation.

UNITED STATES

Covered Entity means an institution, organization or other entity that is subject to the rules of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Covered Entities include: (i) a health plan, (ii) a healthcare clearinghouse and, (iii) a healthcare provider who transmits any personal identifiable health information in electronic form in connection with a transaction covered by HIPAA.

Personal Identifiable Health Information (PHI) means any information including demographic information collected from an individual that:

- (i) relates to (a) the past, present or future physical or mental health or condition of an individual, (b) the provision of healthcare to an individual; or (c) the past, present or future payment for the provision of healthcare to the individual; and
- (ii) identifies the individual or is a reasonable basis to believe it can be used to identify the individual; and

(iii) PHI does not include education records covered by the Family Education Rights and Privacy Act or employment records held by CTM in its role as an employer.

CALIFORNIA

Personal Information means any information that identifies, relates to, describes, is reasonably capable of being associated with, or could reasonably be linked, directly or indirectly, with a particular consumer or household.

FOR ANY JURISDICTION

Third Parties means:

- Service providers acting as processors and who provide services to us.
- Professional advisers acting as processors or joint controllers including lawyers, bankers, auditors and insurers who provide consultancy, banking, legal, insurance and accounting services to us.
- Regulators and other state authorities acting as processors or joint controllers in any jurisdiction in which we are operating and who require reporting of processing activities in certain circumstances.

If your child or teenager struggles with constipation, #2 may often be the #1 topic

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If your child or teenager struggles with constipation, #2 may often be the #1 topic

SEE IF YOUR CHILD QUALIFIES

Call: 1-800-807-6524

Hi 👋 I am Takeda 2Go Bot (and not a real person!). I am here to help you submit information to prescreen and participate in our 2Go Study! Your information will be recorded, but will only be used for the purposes of this study.

How can I assist!

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