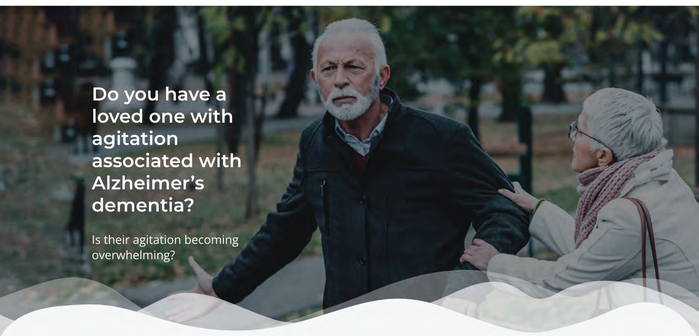


Do you have a loved one with agitation associated with Alzheimer's dementia?

Is their agitation becoming overwhelming?

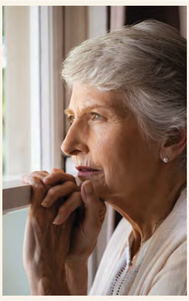
Is someone you care for with Alzheimer's dementia exhibiting excessive motor activity, verbal and/or physical aggression?

If so, they may qualify for the ASPECT™ clinical research study. The purpose of this study is to evaluate the safety and effectiveness of an investigational drug for agitation associated with Alzheimer's dementia.

The ASPECT study can help us learn more about a potential treatment for agitation in patients with Alzheimer's dementia.

See If You/Your Loved One May Qualify

A clinical research study for agitation associated with Alzheimer's dementia



To be eligible for this study, a potential participant must:

- **Be between the ages of 50 and 90 [inclusive]**
- **Have a diagnosis of probable Alzheimer's dementia**
- **Have moderate-to-severe agitation that interferes with their daily life**
- **Have a reliable caregiver who spends a minimum of 2 hours per day, 4 days per week with them and is willing and able to comply with all study procedures**

Other eligibility criteria will apply.

If you are caring for someone with moderate-to-severe agitation associated with Alzheimer's dementia, see if they are eligible to participate in the ASPECT™ clinical research study.

Those who qualify will receive study-required medical care and study drug at no cost.

See If You/Your Loved One May Qualify

About Agitation associated with Alzheimer's Dementia

Alzheimer's Dementia (AD) is a progressive neurodegenerative disease. [3]

Agitation is widely recognized by clinicians as a common and important clinical feature of Alzheimer's dementia. Symptoms of agitation place a serious burden on the individuals with Alzheimer's dementia and their caregivers, significantly affecting their health-related quality of life for all concerned. [5]

Over the course of the disease, **many patients with Alzheimer's dementia will likely experience agitation.** [4]

Agitation is characterized by **excessive motor activity, verbal aggression, and physical aggression** that causes emotional distress to the patient. [1]

Agitation has also been associated with **increased risk of institutionalization and earlier progression** to severe dementia. [2,6,7]

These are just some of the many reasons why more **research on the disease is needed.**

Sources:

[1] Cummings J, et al. "Agitation in cognitive disorders: International Psychogeriatric Association provisional consensus clinical and research definition." International Psychogeriatrics, 27:1, 7–17. 2015. https://www.ncbi.nlm.nih.gov/pubmed/25311499

[2] Knapp M, et al. "Predictors of care home and hospital admissions and their costs for older people with Alzheimer's disease: findings from a large London case register." BMJ Open, 6:11, 1-15. 2016. https://bmjopen.bmj.com/content/bmjopen/6/11/e013591.full.pdf

[3] DeTure MA, et al. The neuropathological diagnosis of Alzheimer's disease. Molecular Neurodegeneration. 2019;14:32;doi.org/10.1186/s13024-019-0333-5

[4] Alzheimer's Association. "2017 Alzheimer's Disease Facts and Figures." Alzheimer's & Dementia, 13: 325-373. April 2017. https://www.sciencedirect.com/science/article/pii/S1552526017300611?viewFullText=true

[5] Laybourne A, et al. "Carer coping and resident agitation as predictors of quality of life in care home residents living with dementia: Managing Agitation and Raising Quality of Life (MARQUE) English national care home prospective cohort study." International Journal Of Geriatric. Psychiatry, 34:106-113. 2018. https://www.ncbi.nlm.nih.gov/pubmed/30276865

[6] Rabins P, et al. "Neuropsychiatric symptoms at baseline predict shorter time to severe dementia in a population-based sample of incident Alzheimer's disease: The Cache County dementia progression study." Alzheimer's and Dementia, supplement, 8:4 126-127. 2012. https://www.alzheimersandidementia.com/article/S1552-5260(12)00466-7/abstract

[7] Peters M, et al. "Neuropsychiatric symptoms as predictors of progression to severe Alzheimer's dementia and death: The Cache County Dementia Progression Study."172(5): 460-5. 2015. https://www.ncbi.nlm.nih.gov/pubmed/25585033

A clinical research study for agitation associated with Alzheimer's dementia

See If You/Your Loved One May Qualify

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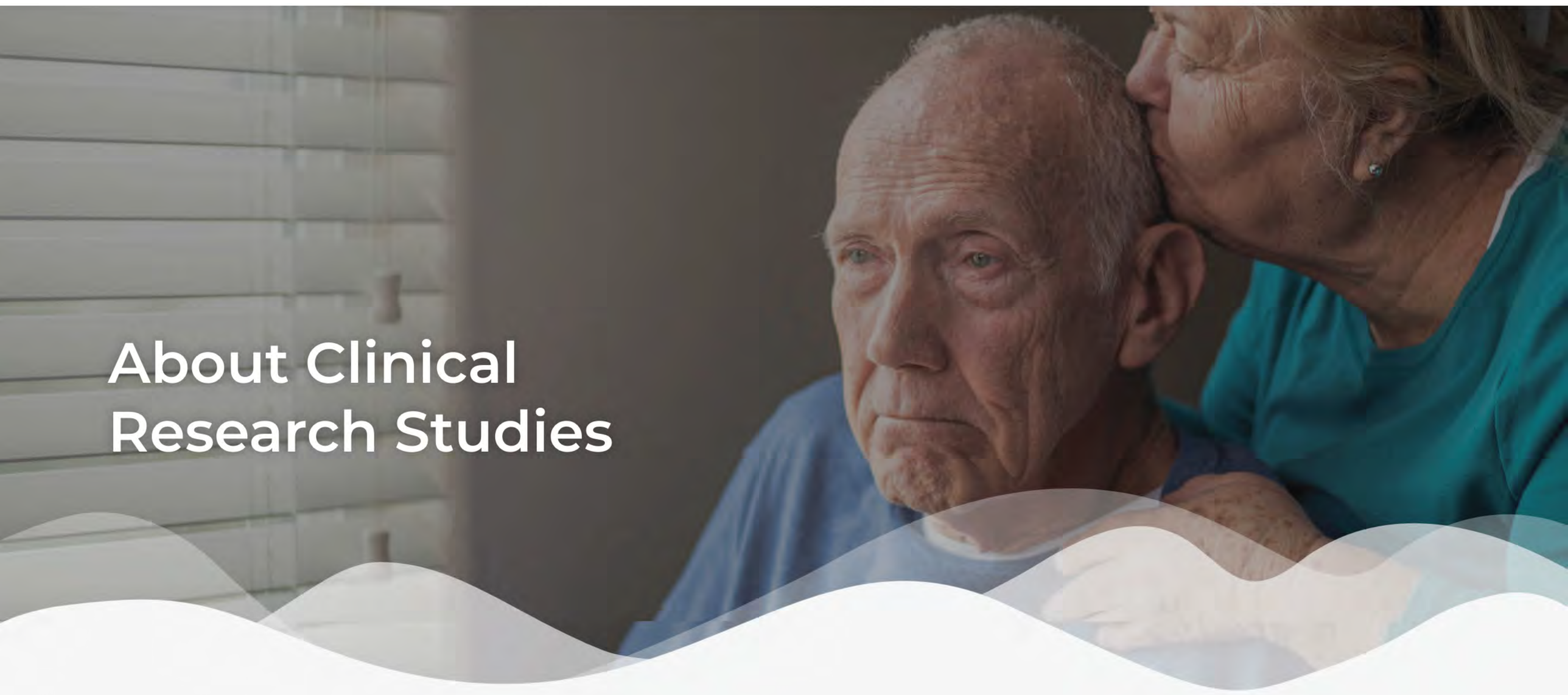

About Clinical Research Studies

Clinical research studies aim to evaluate the investigational treatment of conditions, like agitation associated with Alzheimer's dementia.

Clinical research helps doctors and scientists determine if an investigational drug or therapies are safe and/or effective for use in humans to potentially treat a condition, disease or disorder. Clinical studies often require a large number of volunteers to participate in a single study, sometimes thousands are needed to obtain reliable information.

Right now, there are over 300,000 clinical studies in progress all over the world.

Taking part in a clinical research study can offer benefits including:

- Helping others by possibly progressing medical research
- Getting actively involved in your own healthcare

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About the ASPECT™ Study

Agitation associated with Alzheimer's dementia can be difficult and unpredictable to manage, as well as very challenging for patients and their loved ones.

Examples of some easily identifiable agitated behaviors are:[4]

- Restlessness
- Screaming
- Shouting
- Throwing things
- Resistiveness
- Constant unwarranted requests for attention or help
- Pacing/aimless wandering
- Kicking
- Hitting others or self
- Pushing people
- Hurting self or others
- Tearing things or destroying property

The purpose of the ASPECT™ study

Currently, there is no approved treatment in the US for agitation associated with Alzheimer's dementia.

In this study, an investigational drug called AVP-786 will be compared to placebo in patients with agitation associated with Alzheimer's dementia. Researchers want to find out if this investigational drug is safe and effective (useful) in managing agitation in patients with Alzheimer's dementia.

Source:

[4] Cummings J, et al. Agitation in cognitive disorders: International Psychogeriatric Association provisional consensus clinical and research definition. International Psychogeriatrics. 2015;27:7-17

What can study participants and their caregivers expect?

THE STUDY WILL LAST 20 WEEKS

Eligible participants enrolled into this study will be randomly assigned (by chance, like drawing straws) into groups receiving either the investigational drug or placebo.

This study is blinded, which means that the participant, their caregiver, the research staff, and even the study doctor will not know if the participant is receiving the investigational drug or placebo.

It is very important that both the participant and their caregiver attend all study visits and complete all study procedures.

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Frequently Asked Questions

About this Research Study:

Open All FAQs

Who can participate in the ASPECT™ Study?

The ASPECT Study is looking for participants to evaluate the safety and effectiveness of an investigational drug for agitation associated with Alzheimer's dementia. In order to be eligible for this study, a potential participant must:

- Be between the ages of 50 and 90 [inclusive]
- Have a diagnosis of probable Alzheimer's dementia
- Have moderate-to-severe agitation that interferes with their daily life
- Have a reliable caregiver who spends a minimum of 2 hours per day, 4 days per week with them and is willing and able to comply with all study procedures

There are additional criteria that are included in the questionnaire on this website and some that are reviewed by the study team at the study site at the first appointment.

What's involved with study participation?

The ASPECT Study involves attending study appointments, completing study procedures, taking the study drug (investigational drug or placebo), and reporting on the participant's behaviors.

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

This initial appointment is an opportunity for you to:

- **Learn more about the ASPECT Study.** You'll be speaking with a study coordinator at the study site to learn more regarding your participation in this study.
- **Ask any important questions you may have.** These can be any questions you may have about this study or clinical research in general.
- **Determine if the ASPECT Study may be right for you**. After speaking with the study coordinator and learning details about this study, the research staff will evaluate if you pre-qualify to participate. If you pre-qualify, you will be given an opportunity to decide if participation is right for you. If you agree to take part, the site will ask you to review and sign a consent form.

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

If qualified, participation can last up to 20 weeks with up to 10 appointments with the study site. The study coordinator can answer any questions you have about the ASPECT Study.

What is the drug being tested?

The investigational drug being studied in the ASPECT Study is a capsule taken orally.

What is a placebo?

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

Will I have to discontinue any current medication?

Do not discontinue any medication unless you are advised to do so by the study site staff or your primary care physician.

Are there any precautions being taken due to COVID?

The health and safety of study participants are always top priority of clinical research study centers. The precautions taken may vary by study center.

Where are the study sites located?

The study sites are located throughout the United States and Canada.

Does participating in this study cost me anything?

There is no cost to you for participating in this study. If you qualify for this study, study-related care will be provided at no cost to you and participants may be compensated for their time.

Why have I not pre-qualified for the study?

Research studies are designed in specific ways to test the investigational drug for safety and effectiveness. One or more of the answers that you provided were outside of the eligibility criteria for this study. This does not mean you 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 and efficacy of potential new drugs 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 drugs and medical products in the people they are meant to help. It is also important to conduct research in a variety of people because each individual 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 sold to the general public. The testing that takes place during the studies provides information regarding the safety and effectiveness of the potential medication.

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 I consider participating in a research study?

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

- Getting actively involved in their own health care
- Helping others by contributing to medical research

It is important to test drugs and medical products in the people they are meant to help. It is also important to conduct research in a variety of people because each individual 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 the "informed consent" process?

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 is involved.

A clinical research study for agitation associated with Alzheimer's dementia

See If You/Your Loved One May Qualify

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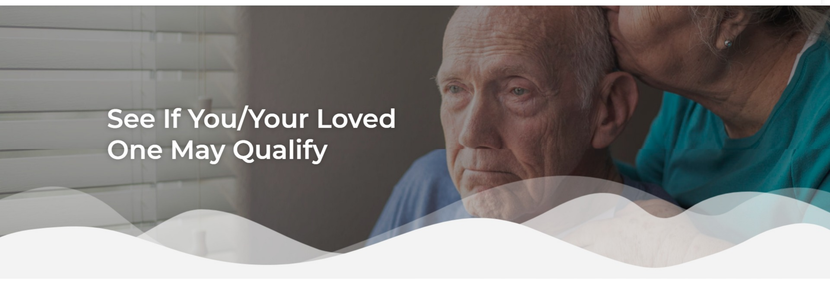

See If You/Your Loved One May Qualify

1. Are you taking this questionnaire for yourself, or on behalf of someone else?

   - ○ Myself
   - ◉ Someone Else

2. Who are you taking this questionnaire for?

   - ○ My Relative
   - ○ My Partner
   - ○ Someone I Care For
   - ◉ Someone Else

   Please enter their first name: First Name

3. Do you have permission to submit the answers to these questions on behalf of the patient?

   - ○ Yes
   - ○ No

4. Please enter First Name's date of birth:

   mm/dd/yyyy

5. Please select First Name's gender:

   - ○ Male
   - ○ Female

6. Has First Name been diagnosed with probable Alzheimer's Dementia? In order to be diagnosed, First Name would have been evaluated by a doctor or other specialists where they would have run blood tests, memory tests or quizzes, and/or imaging test such as: MRI/PET scans.

   - ○ Yes
   - ○ No

7. Is First Name currently taking medication for Alzheimer's Dementia? If yes, has First Name been on the same dose over the past 3 months?

   Some examples of Alzheimer's Dementia medications include but are not limited to: Aricept® (donepezil), Exelon® (rivastigmine), Razadyne®, formerly Reminyl™ (galantamine), or Namenda® (memantine).

   - ○ Yes, Currently Taking Medication, And The Dose Has Been The Same Over The Past 3 Months
   - ○ Yes, Currently Taking Medication, But The Dose Has Changed In The Past 3 Months
   - ○ Yes, Currently Taking Medication, But Started Taking It Less Than 3 Months Ago
   - ○ Not Currently Taking Medication For Alzheimer's Dementia

8. Has First Name experienced moderate-to-severe agitation?

   Examples include: pacing, rocking, restlessness, yelling or shouting, using profanity, or physical aggression such as grabbing, pushing, or hitting others.

   - ○ Yes
   - ○ No

9. This study requires a caregiver, defined as a person who spends at least 2 or more hours per day for at least 4 days per week with the participant, to comply with all study procedures. The caregiver must be available to attend study appointments with the participant, help administer the study drug, and report on the participant's behaviors. If First Name pre-qualifies the study site can review these requirements in more detail.

   Does First Name have someone who would fill this role?

   - ○ Yes
   - ○ No
   - ○ Unsure

10. Has First Name been diagnosed with any of the following:

    - ☐ Parkinson's Disease Dementia
    - ☐ Schizophrenia
    - ☐ Schizoaffective Disorder
    - ☐ Bipolar I Disorder
    - ☐ Bipolar II Disorder
    - ☐ Generalized Anxiety Disorder (GAD)
    - ☐ Obsessive-Compulsive Disorder (OCD)
    - ☐ Panic Disorder
    - ☐ None Of The Above

11. **User Agreement:** By selecting "I Agree" below, I understand that the personal information I am providing may be collected, shared, used and/or transferred by the study team for the sole purpose of enabling me or the study candidate to be contacted to learn more about the study, see if I am/the study candidate is suitable to take part in this study, and if appropriate, to assist me/the study candidate in enrolling in this study. I understand there is no guarantee that I will be contacted by a member of the study team as a result of submitting this information. I also understand that I may be contacted in the future about other studies for which I/the study candidate may qualify. I acknowledge that I/the study candidate may withdraw interest in participating in the study at any time by speaking with a member of the study team or representative.
    By selecting "I Agree" below, I verify that:
    - The name and phone numbers I have provided belong to me or the study candidate and are correct, and that I am/the study candidate is interested in being contacted (by Text, Email, or Phone).
    - I am 18 years or older.
    - I have read and understood the Legal Notice and Privacy Policy.

    Select

12. Unfortunately you do not qualify for this study. If you would like to be contacted about other study opportunities, please continue.

    User Agreement: By selecting "I Agree" below, I understand that the personal information I am providing may be collected, shared, used and/or transferred by the study team for the sole purpose of enabling me to be contacted to learn more about other study opportunities, see if I am suitable to take part in other study opportunities, and if appropriate, to assist me in enrolling in other study opportunities. I understand there is no guarantee that I will be contacted by a member of a study team as a result of submitting this information. I also understand that I may be contacted in the future about other studies for which I may qualify. I acknowledge that I may withdraw interest in participating in any study at any time by speaking with a member of the study team or representative.
    By selecting "I Agree" below, I verify that:
    - I am providing my own name and contact information and I am interested in being contacted (by Text, Email, or Phone).
    - I am 18 years or older.
    - I have read and understood the Legal Notice and Privacy Policy.

    Select

Candidate Information

First Name :	*
Middle Name :	
Last Name :	*
Cell Phone Number :	*
Home Phone Number :	
Preferred Callback Time :	Select preferred callback time *
Email Address :	*
Address :	Enter a location *
Zip Code :	*
Caregiver Name:	
Caregiver Phone Number:	
Caregiver Email:	

Submit

A clinical research study for agitation associated with Alzheimer's dementia

ASPECT

A clinical research study for agitation associated with Alzheimer's dementia

Explore The Site

- About Agitation Associated with Alzheimer's Dementia
- Clinical Research
- ASPECT Study
- FAQs

More Info

- Privacy Policy
- Legal Notice

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See If You/Your Loved One May Qualify

Site Locator Result

Based on the answers you provided, you may qualify to take part in the ASPECT™ Study.

The following study centers are currently open and accepting new participants. Please select the center that is most convenient. If you do not want to select a current study center, you can have your information saved. We will contact you if another center opens in your area; however, there is no guarantee that new locations will be added for this study.

- ◯ Tech Ops Test (Airport Jct Rd, Wales, AK 99783, USA) (Zip - 99783) (4 Miles)
- ◯ The Study site(s) listed above are not convenient.

If you choose to continue, the information we collected will be sent to the study site that you have selected. A staff member from the study site will contact you within the next few days to discuss this study further and schedule an appointment, if appropriate. Please rest assured that all efforts to contact you are handled discreetly and confidentiality is always strictly protected, unless you have given permission or except as required by law.

Submitting this information is not a commitment to participate in this study, but rather simply exploring an opportunity to join the study if pre-qualified. We may also forward this contact information to a different study site in this area if the original study site is unavailable.

CONTINUE

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See If You/Your Loved One May Qualify

Thank you

The information has been sent to the study site. Please expect a pre-screening call to the telephone number you entered within the next 2 days.

Thank you for your interest in the ASPECT™ study and helping advance clinical research for Agitation associated with Alzheimer's dementia.

A clinical research study for agitation associated with Alzheimer's dementia

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See If You/Your Loved One May Qualify

Screener Assessment Result

Based upon the information you have provided, it appears that you may qualify for the ASPECT™ Study, however there are no study sites in the area at this time. Study sites may become available in this area in the future, or you may qualify for a future research study. With your permission, the information you have provided will be kept on file.

Privacy is very important to us. The information you provided will only be used to inform you of clinical research studies for which you may qualify, and any information you provide will be retained and used in accordance with our privacy policy.

Do we have permission to retain this information in our files? If you choose "No", we will not store the information and will not be able to notify you about new study sites or future clinical trials.

Yes No

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See If You/Your Loved One May Qualify

Thank you for your interest in the ASPECT™ study and helping advance clinical research.

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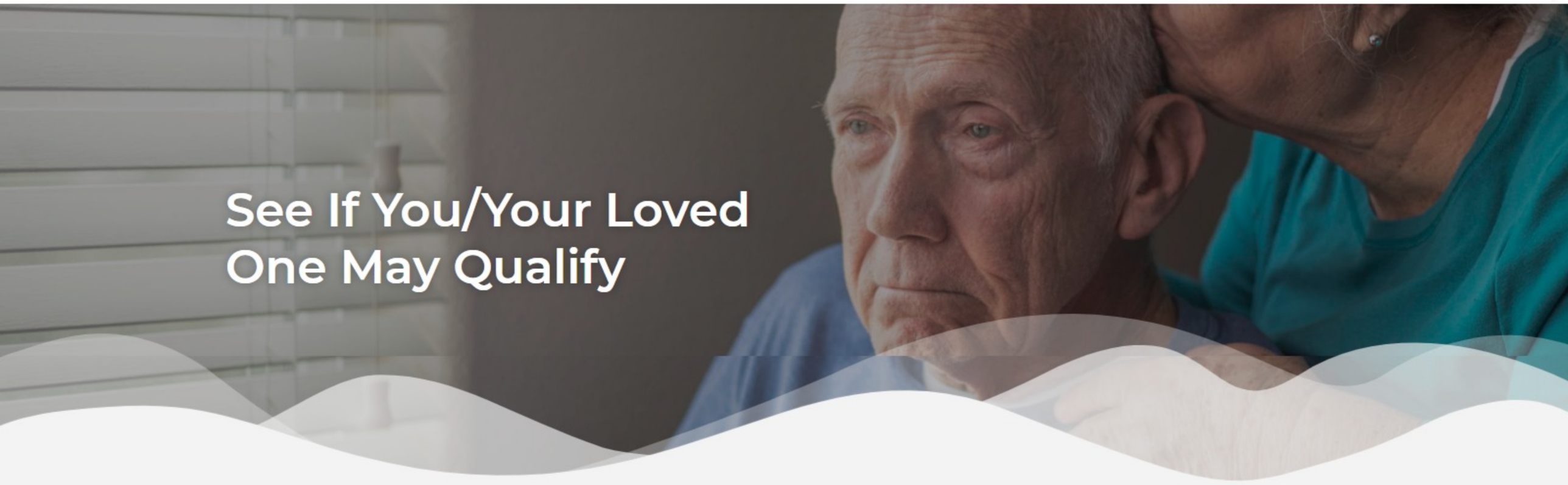

See If You/Your Loved One May Qualify

Site Locator Result

At this time there does not appear to be a study site in the area. This is based on the zip code you entered, which was used to identify study site locations within 100 miles.

Would you like to expand the search radius?

- ○ Yes
- ○ No

PROCEED

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See If You/Your Loved One May Qualify

Screener Assessment Result

Based upon the information you have provided, it appears that you do not qualify for the ASPECT™ Study at this time. Thank you for responding to the study questionnaire. With your permission, the information you have provided will be kept on file.

Privacy is very important to us. The information you provided will only be used to inform you of future clinical research studies for which you may qualify, and any information you provide will be retained and used in accordance with our privacy policy.

Do we have permission to retain this information in our files? If you choose "No", we will not store the information and will not be able to notify you about future clinical trials.

Yes No

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See If You/Your Loved One May Qualify

Thank you for your interest in the ASPECT™ study and helping advance clinical research.

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See If You/Your Loved One May Qualify

Screener Assessment Result

Based on the information you provided it looks like you have already taken the questionnaire for this study. If you believe you received this message in error, please email us at rescreen@clinicaltrialmedia.com.

CONFIRM

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See If You/Your Loved One May Qualify

Thank you for your interest in the ASPECT™ study and helping advance clinical research.

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Privacy Policy

Clinical Trial Media, Inc. ("CTM")
Privacy Policy
Effective January 23, 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 recognizes that different jurisdictions and legal systems will apply.

1. 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.
2. In the rest of the world, different legal rules apply and in particular, we will be using and processing personal data in a way which is in accordance with the rules governing the European Economic Area ("EEA") where we are based and the United Kingdom ("UK") where we are based. The General Data Protection Regulation ("GDPR") which has adopted in law several aspects of the GDPR, in the EEA, the relevant national supervisory authority will have jurisdiction over our compliance. In the European Economic Area we act as the legal entity responsible for the collection and use of personal data under the GDPR in relation to:

CONTENTS

1. THE DATA WE COLLECT ABOUT YOU
2. HOW YOUR PERSONAL DATA IS COLLECTED
3. HOW WE USE YOUR PERSONAL DATA AND THE LAW
4. INTERNATIONAL TRANSFERS
5. DATA SECURITY
6. DATA RETENTION
7. YOUR LEGAL RIGHTS UNDER GDPR AND OF PRIVACY LAW
8. YOUR PRIVACY RIGHTS IN THE UNITED STATES
9. 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 access and control this 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.

2. COMPLIANCE

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

We have appointed a data privacy manager 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.

3. 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 Shron

Email address: privacyofficer@ctmedia.com

Telephone number: 646-464-3030

Postal address: 100 Motor Parkway, Suite 525, Hauppauge, NY 11788, USA

URL: http://www.clinicaltrialmedia.com/Research/Contact.php

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, or, where deem it from time to time, especially if you have provided us with your e-mail address, by e-mail notification. 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.

5. THIRD PARTIES LINKS

This privacy policy does not cover links to other 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 these 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.

6. THE DATA WE COLLECT ABOUT YOU

Personal data, or personal information, means any information about an identifiable or identifiable individual person. It does not include, include data where the identity has been removed (anonymous 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 or similar identifier, date of birth and gender.
- **Contact Data** includes billing address, delivery address, email address and telephone numbers.
- **Financial Data** includes banking details of clients, suppliers, and agents for the making of payments to 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 purchases or orders, your interests, preferences, feedback, and survey 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 relating to your health, including the collection of vaccine status or proof of being immune to 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 related vaccine or governmental vaccine(s)/passport(s) information, 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) and genetic and biometric data).

7. 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.

8. 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:
1. apply for our products or services;
2. contract to receive our services; or
3. 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 other websites employing cookies or pixels. We aggregate some Usage Data such as number of visitors to a particular website and other statistics of the website users visits most. We use this information to determine what kind of marketing material is most relevant to our customers. It can better serve our Priority Marketing Data and technological improvements.
- **Third parties or publicly available sources.** We may receive personal data about you from various third parties and public sources as set out below:
1. Technical Data from the following parties:
2. analytics providers such as Google;
3. advertising networks;
4. search information providers;
5. and partners.
- **Contact and Transaction Data** from providers of technical, payment and delivery services.
- **Identity and Contact Data** from data brokers or aggregators.

9. 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:

1. Where we need to perform the contract we are about to enter into or have entered into with you, or to perform other legal obligations.
2. 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).
3. 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 where (i) we have your express consent or (ii) where we have a legitimate interest in sending such marketing communications to you.

9.1 PURPOSES FOR WHICH WE WILL USE YOUR PERSONAL DATA

We have set out below, in a table format, a description of the ways we plan to use your personal data, and which of the legal bases 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.

Purposes/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
To process and deliver services and/or perform transactions including: (a) Manage payments, fees and charges (b) Collect 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 debts 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 Specimen	(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 Specimen	(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, to grow our business and to inform our marketing strategy)
To consider whether you are eligible suitable for taking part in a specific clinical trial, including: (a) Identity verification, (b) Medical, (c) Vaccination, (d) Immunization, (e) Medical history, (f) Medical testing, (g) Medical treatment, (h) Medical diagnosis	(a) Identity(b) Contact(c) Health	(a) 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 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 to respond to any request made pursuant to a Federal law or to prevent loss of life or injury. Fraud	(a) Identity(b) Contact(c) Technical(d) Usage(e) Profile	(a) Necessary for our legitimate interests (business or business transfer, provided that your interests or fundamental rights do not override those interests) (b) Necessary for our legitimate interests (to comply with a legal obligation) (c) Necessary to resolve disputes
9.2 DISCLOSURE INFORMATION TO THIRD PARTIES

We may have to share your personal data with the parties set out below for the purposes set out in the table in section 7.1 above.

1. Third party sub-contractors who provide services for us and/or help to provide services to you. In the event that we sub-contractors who have access to our personal data, we will use our best efforts to ensure such third parties have in place appropriate security measures to ensure that your personal data is not lost, stolen or misused by such third parties.
2. 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.
3. We may disclose personal information to law enforcement, government authorities or otherwise in response to legal subpoenas or process, or requests, including but not limited to, civil and criminal subpoenas, court orders, or other legal process, or to law enforcement requests.

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 third parties. Our use and disclosure of Personal Identifiable Health Information ("PIHI") 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 strictly for research purposes. We do not share your PIHI with any third parties for their marketing purposes. We may share your Health and medical related questionnaire and medical information with our clients and third parties as specified in agreements between us.

PIHI will generally not be used by or disclosed to or by any third parties unless we have their consent from you to do so.

Exceptionally, PIHI may be disclosed by us when we are required to do so by law. For example, in particular, this includes, but is not limited to, situations where we are required to disclose PIHI in relation to requests by public authorities to meet national security or law enforcement requirements. This will include one and/or disclosure in order to:

1. prevent or control disease;
2. report disease, injury or disabilities;
3. assist public health surveillance/investigations or interventions;
4. report child abuse or neglect or domestic violence;
5. notify a person regarding potential exposure to a disease or at risk of being infected or spreading a disease or condition;
6. or to respond to a request pertaining to a foreign disease;
7. in response to legal proceedings and relevant court orders or subpoenas;
8. for operational government functions and national security;
9. to healthcare members who are reliable disclosers or victims of a criminal act;
10. where we believe that disclosure is necessary to lessen or prevent a serious threat to protect your safety, the safety of others or investigate fraud.

9.3 OPTING OUT

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

Where you opt out of receiving these information/marketing 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.

9.4 COOKIES

We do not use cookies to record user specific information or what pages users' access or visit, record post entry, and session management and personalization. Use of website 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.

9.5 Cookie Control. CTM's interactive cookie management closely replicates those used in Google's product and offers easy-to-use functionality for granting and revoking consent. You can turn the control to prevent cookies from being placed on their computer and consent as or otherwise.

9.6 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.

10. USE OF DATA OUTSIDE THE UNITED STATES

Clinical Trials Research Inc. (CTRI) is a Delaware corporation and as of 1994 CTRI(CT) and subsequent regulations published by the Department of Health and Human Services ("DHHS") regarding human research subjects (Common Rule) and Clinical trials and research in the United States, we are required to provide our parent company CTM. CTM may, in providing subject recruiting and called services for one of these organizations, be required to comply with certain aspects of HIPAA in their conduct of human 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 our clinical trials, are based on the HIPAA privacy regulations. Our policies and procedures are intended to be equivalent to those required of Covered Entities.

All PIHI 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 a Business Associate Agreement with its parent Clinical Trials Research Inc. (CTRI).

11. INTERNATIONAL TRANSFERS

Our personal data may be sent or access to the USA. This will include transferring your data outside the European Economic Area ("EEA") or the UK. In addition, we share personal data with our IT service 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 safeguards. Specifically, we will only transfer your personal data to countries that have been deemed to provide an adequate level of protection.

12. DATA SECURITY

We have put in place appropriate security measures and 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.

13. 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, regulatory, tax, 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 anonymise 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.

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

Under certain circumstances in the EEA and UK you have rights that relate to your 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 delete or remove 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 of 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 want 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 override 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) the accuracy of the data is contested by you, and it requires a period of time for us to verify the accuracy of the data; (b) the processing is unlawful but you do not want us to hold the data even if we no longer require it as you need it to establish, exercise or defend legal claims; or (d) 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 refer to 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.

Use of Supervisory Authority data: http://ec.europa.eu/justice/data-protection/bodies/authorities/index_en.htm

15. 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).

16. 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 (or to exercise any of your other rights). This is a security measure to ensure that personal data is not disclosed to any person 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 our response.

17. 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.

18. YOUR LEGAL/VITAL 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 may also request that we provide a copy of your personal data.

"The right to request that we delete any Personal Information we have collected from you. To submit a request to delete, please contact us. You may also request that we delete your personal data.

"The right to opt-out of the sale of your Personal Information. To submit a request to opt-out, please contact us.

"The right to not be discriminated against for exercising your rights.

We will not discriminate against you for exercising any of your privacy rights. We may charge a fee or offer a reduced or enhanced service if a consumer's data is of a different value than we are unable to reasonably value.

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

If you would like to exercise any of the rights of the Privacy Policy, CTM has not sold any Personal Information collected about you, nor does it have plans to do so in the future.

19. 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 by law). 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: (1) health plans, (2) healthcare clearinghouses and (3) healthcare providers who transmits any personal identifiable health information in electronic form in connection with a transaction covered by HIPAA.

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

1. relates to the past, present or future physical or mental health or condition of an individual, the provision of healthcare to an individual, or (3) the past, present, or future payment for the provision of healthcare to the individual, and
2. identifies the individual or there is reasonable basis to believe it can be used to identify the individual, and
3. PIHI does not include education records or medical 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.

THIRD PARTY

Third Parties means:

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

A clinical research study for patients associated with Alzheimer's dementia

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A clinical research study for agitation associated with Alzheimer's dementia

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