Thank you for supporting your loved one's healthcare journey.

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Embarking on clinical research together.

Battling any medical condition can be scary, but thanks to you, your loved one doesn't have to do it alone. With every appointment you drive to and every call to the doctor you make, not only are you helping ensure your loved one gets the best care available, but you're also contributing to research that aims to advance medicine – and the greater good – for all. Thank you again for joining your loved one on this important healthcare journey.

About clinical research.

Before any medication can be made available to the general public, it must go through several phases of clinical research and regulatory approvals. A clinical research study, also known as a clinical trial, is a carefully designed study in which participants are asked to take an investigational drug or placebo, undergo investigational procedures, or use investigational medical devices under the supervision of a doctor and other research professionals. The term "investigational" means the drug, procedure, or device has not been approved as safe or effective by the regulatory authorities in your country. If a clinical research study meets its objective, it has the potential to create a new standard for caring for people with certain diseases and conditions.

Clinical research studies must be reviewed by an institutional review board (IRB) or ethics committee (EC) before anyone can participate. An IRB or EC is an independent group that is responsible for helping to protect the rights and welfare of study participants. In addition, every study participant is monitored with medical tests and study-required exams before, during, and sometimes even after the study.

Both you as a study partner and your loved one should know that study participants have the right to withdraw from the study at any time for any reason without impact to their future medical care. Please also keep in mind that the study doctor or study sponsor has the right to withdraw any participant at any time. For instance, your loved one may be withdrawn in the interest of their safety. If you have more questions regarding this, please speak to your loved one's study doctor or team.

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Because a clinical research study is helping researchers carefully collect information about an investigational drug, it is important that your loved one:

- Attends all scheduled visits
- Describes their feelings and well-being accurately and honestly to the study doctor
- Follows the study team's instructions, including using the investigational drug as prescribed
- Discusses any questions regarding the study with the study doctor

And you're a vital part of all this.

Your role in this journey.

Around the world, more than 349 million people rely on caregivers.[1] From helping with housekeeping to personal care and grooming, caregivers help improve the quality of life for their loved ones. As a caregiver in a clinical research study, however, your role may also include:

- Assistance getting to and from study appointments
- Reporting symptoms, events, or behaviors to the study team
- Advocating for your loved one
- Attending appointments and meetings with the study team
- Assisting with study drug adherence
- Administering the study drug

The success of clinical research simply wouldn't be possible without caregivers. In general, patients have shown improved adherence to dietary restrictions and medication with a caregiver present. One study also showed that a caregiver can positively impact the results of clinical research studies and the interpretations of those results.[2]

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The informed consent process.

Before your loved one participates in a study, a detailed description of the study, as well as possible risks and benefits, is provided in writing in an "informed consent form" and discussed with you both. You and/or your loved one will be asked to review and sign this form prior to participating. But before you or your loved one signs the informed consent, you should make sure you have all the information on the following important topics:

Time commitment. In addition to knowing how long the study will last, specific details about participation are important as well. What days and times are appointments available? How long will each appointment last?

Cost and compensation. Often clinical research costs are not covered by health insurance. In most cases, the investigational drug or placebo, as well as study-related medical exams, procedures, laboratory tests, and travel, are all covered by the study sponsor. Be sure to find out if reimbursement options are available and what impact study participation will have on your loved one's insurance.

Travel. How far and often will you and your loved one need to travel to appointments? Will you be reimbursed for travel costs? Based on your loved one's condition, these questions can be specifically important. For example, traveling many hours by car may not be feasible for a patient with chronic pain.

Questions from your loved one. As a study partner, you are an advocate for your loved one. Use the informed consent process as an opportunity to understand their concerns and speak up with any questions they may have.

Glossary of terms.[3]

Familiarizing yourself with these terms can help make the informed consent process and study participation easier. If you have any questions, feel free to ask the study team to elaborate.

Adverse event: An unfavorable change in the health of a participant (including abnormal laboratory findings) that happens during a clinical research study or within a certain amount of time after the study has ended. This change may or may not be caused by the study drug being researched.

Arm: A group or subgroup of participants in a clinical research study that, for example, receives a specific study drug or no intervention, according to the study's protocol.

Eligibility criteria: The key requirements that people who want to participate in a clinical research study must meet or the characteristics they must have. Eligibility criteria consist of both inclusion criteria (which are required for a person to participate in the study) and exclusion criteria (which prevent a person from participating). Types of eligibility criteria include whether a study accepts healthy volunteers, has age or age group requirements, or is limited by gender.

Informed consent: A process used by researchers to communicate to potential and enrolled participants the risks and potential benefits of participating in a clinical research study.

Informed consent form (ICF): The document used in the informed consent process.

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Glossary of terms (continued).

1. **Phase 1:** A phase of research to describe clinical research studies that focus on the safety of a drug. They are usually conducted with healthy volunteers, and the goal is to determine the drug's most frequent and serious adverse events and, often, how the drug is broken down and excreted by the body. These studies usually involve a small number of participants.

2. **Phase 2:** A phase of research to describe clinical research studies that gather preliminary data on whether a drug works in people who have a certain condition/disease (that is, the drug's effectiveness). For example, participants receiving the drug may be compared to similar participants receiving a different treatment, usually an inactive substance (called a placebo) or a different drug. Safety continues to be evaluated, and short-term adverse events are studied.

3. **Phase 3:** A phase of research to describe clinical research studies that gather more information about a drug's safety and effectiveness by studying different populations and different dosages, and by using the drug in combination with other drugs. These studies typically involve a larger number of participants.

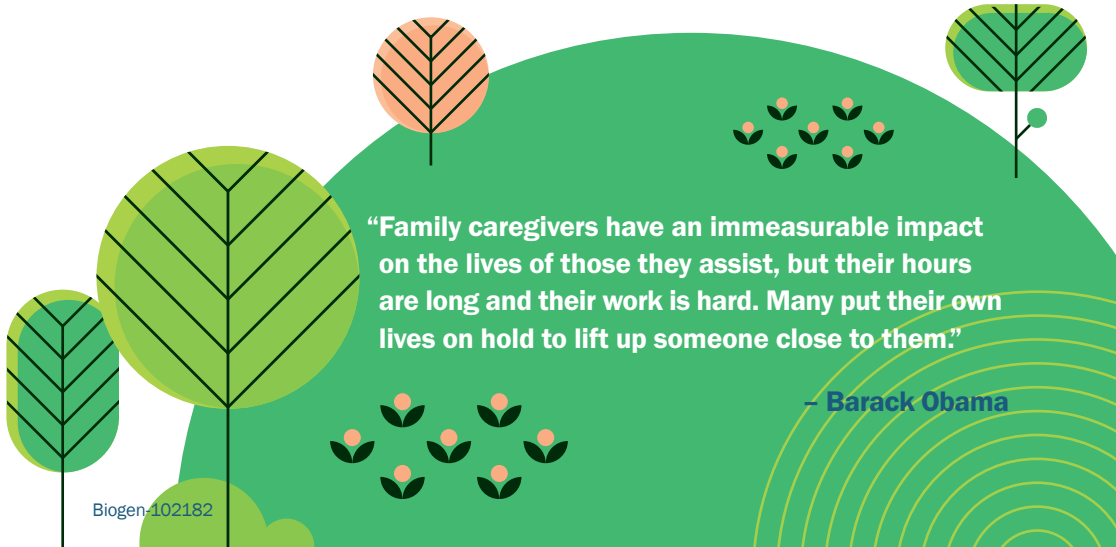
4. **Phase 4:** A phase of research to describe clinical research studies occurring after a drug has been approved for marketing by regulatory authorities such as the US FDA. They include post-market requirement and commitment studies that are required or agreed to by the study sponsor. These studies gather additional information about a drug's safety, effectiveness, or optimal use.

Placebo: An inactive substance or treatment that looks the same and is given the same way as the active drug or intervention/treatment being studied.

Principal investigator (PI): The person, usually a doctor, who is responsible for the scientific and technical direction of the clinical research study.

Protocol: The written description of a clinical research study. It includes the study's objectives, design, and methods. It may also include relevant scientific background and statistical information.

Sponsor: The organization or person who initiates the study and who has authority and control over the study.



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Caring for yourself.

While caring for a loved one throughout a research study, it is important to take time for yourself. We understand you may find it difficult to justify this, but not taking time to care for yourself can lead to a feeling of exhaustion known as "caregiver burnout," which can make the situation even more difficult.

To help you avoid caregiver burnout, we'd like to share the following tips:

Get enough sleep. The average adult needs at least seven hours of sleep each night, but it's something care partners often sacrifice. Strive for those seven hours, because sleep is vital to your health.

Take advantage of waiting room downtime. You may have a lot of downtime waiting for your loved one's appointments or procedures. You can take advantage of this time by creating your shopping list, catching up on emails, or even relaxing by reading a book or listening to a podcast.

Pay attention to your eating and exercise habits. If you don't keep your body active and fueled with the right foods, you will become more easily fatigued. Stay energized with a little yoga or take an exercise class. (Please discuss any diet or exercise changes with your physician.)

Plan your meals. At the end of a long day, making a meal in the kitchen is likely not how you want to spend your time. Create a meal schedule or use a slow cooker. Having meals ready checks one more thing off your to-do list.

1. who.int/ageing/health-systems/icope/evidence-centre/ICOPE-evidence-profile-caregiver.pdf
2. blog.longboat.com/caregivers-the-unseen-force-behind-clinical-trials
3. clinicaltrials.gov/ct2/about-studies/glossary

Take time for you. When you're a care partner, your day is filled with tending to the needs of others. It's perfectly okay for you to take some time in the day to do something you enjoy. Whether it's reading, watching television, or sitting in silence, it's important to spend time on yourself.

Acknowledge your feelings. Building up your emotional walls may serve a purpose in public, but being your authentic self at home can be a huge beneficial release. Don't forget to acknowledge what you are feeling about yourself and how you feel about your situation. When you can admit your feelings to yourself, you'll find they become less of a mental burden.

Thank you.

Clinical advancements and new medications do not happen without study participants like your loved one and the love and support they receive from important people like you.

To find more clinical research opportunities, visit biogentriallink.com.

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