Associated Neurologists, P.C.
Danbury • Waterbury • New Milford, CT

Associated Neurologists'

"The NeuroTransmitter" Newsletter

Spring Edition, May 2017

L to R, Top Row: Drs. Neil Culligan, Behzad Habibi, Robert Bonwetsch, Diane Wirz, David Greco, William Yorns Jr., and Samuel Markind

Bottom Row: PA-Cs Loralee Richter, Margaret Cavino, Amy Drabik, Courtney Kennedy, Danielle Centone, and Dr. Charles Guardia III

Clinical Studies at Associated Neurologists: Your Frequently Asked Questions

**We've included several hyperlinks below for those who are interested in going to our web site to learn further information. Please be sure to click on these links to visit!*

The ***Connecticut Chapter of the Alzheimer's Association*** held its **20th Annual Education Conference** on April 6, 2017, in Cromwell, CT. This full-day conference is designed for both professionals and family caregivers to share best practices and creative interventions for the care, treatment, and preservation of the quality of life of persons with **Alzheimer's and related dementias.**

Our Clinical Research Coordinators, **Janet Mauro** and **Dawn Morsey**, had the great pleasure of representing Associated Neurologists at this year's conference. They were the presenters for the learning session, *"Connecticut Clinical Trials and Research."* During their presentation, they explored what it means for patients to be enrolled in a clinical trial. Janet and Dawn emphasized that the potential for finding effective treatments and cures for Alzheimer's disease and other forms of dementia is not possible without researchers and volunteers. They also shared information with the audience concerning **specific clinical trials that are currently being conducted at Associated Neurologists.**

Janet Mauro and Dawn Morsey

Associated Neurologists' Certified Clinical Research Coordinators (CCRCs)

This was a wonderful opportunity for Dawn and Janet to continue fulfilling their shared goal of educating the community on the importance of research overall and clinical trials, since without such research, innovations in medical and behavioral treatments and interventions would not occur. Unfortunately, the reality is that many misconceptions remain concerning participating in clinical trials. But the hope is that through educating the public on how trial participants' safety and privacy are protected, many of these negative notions can be dispelled--a goal that is critical in overcoming these common barriers to successful trial enrollment, retention, and completion and ultimately translating safe and effective treatments to the clinic.

Frequently Asked Questions

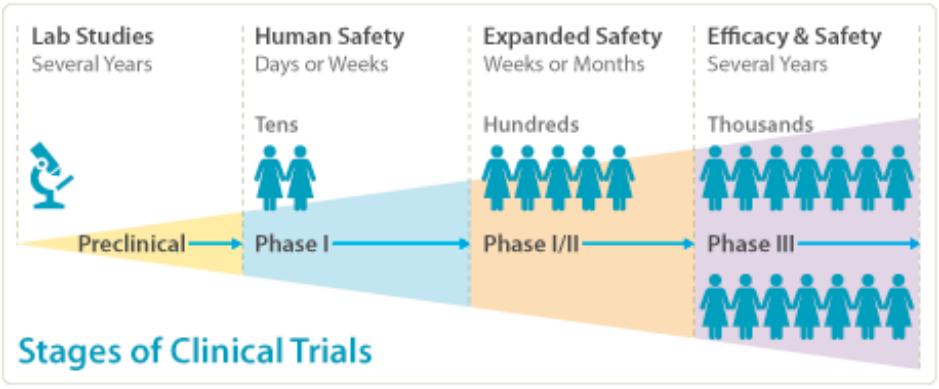
Would you like to participate in a clinical trial? At some point in our lives, many of us have been asked this simple question. If so, you might not have known how to answer, since this undoubtedly raised multiple questions of your own. Dawn's and Janet's hope is that they can answer a few of these important questions

for you today!

So, what *is* a clinical trial? A clinical trial is a type of research in which people participate as volunteers to help investigators study the safety and effectiveness of a medical or behavioral intervention or treatment. Clinical trials may help us to:

- Test a new medication or device for a particular disease.
- Learn whether a new medication or device is more effective than and/or has fewer harmful side effects than current standard treatment(s).
- Show that a new treatment or intervention may enhance the quality of life for people living with a life-threatening disease or chronic health problem.
- Prevent, diagnose, and/or increase understanding of a particular disease or health problem.

There are many types of trials that take place in the United States and internationally, with the most common being **interventional trials.** These trials focus on evaluating whether an experimental drug or device is safe and effective for treatment of a disease or condition. An experimental (study) drug typically goes through years of development and clinical research, averaging approximately 12 years once tested with human subjects before it may be approved and become available for public use. There are several different phases a study drug goes through, involving many different trials.



Before an experimental drug is tested in humans, **preclinical studies** are required to collect data that demonstrate the safety of the new drug treatment, procedure, or intervention. Preclinical studies may include computer models, lab work conducted with living organisms as small as cells, and experimentation using animals to answer basic questions of safety. If such preclinical studies do support the safety of the intervention, a **New Investigational Drug Application** is then submitted to the **Food and Drug Administration (FDA)**, who will review and potentially approve the intervention for testing in humans.

Once approved for "first in human" testing, the study drug enters the **clinical phase of testing**, which comprises three main phases of development:

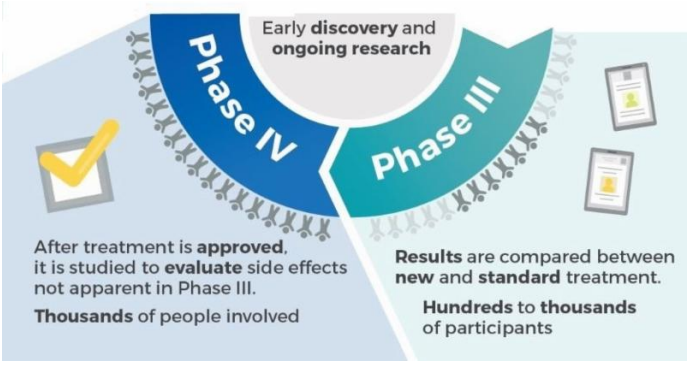
- **Phase I clinical trials** are designed to determine that people can be safely treated with the study drug. During these trials, the dose of the agent being studied is slowly increased to confirm the highest dose that is most effective without causing severe side effects (dose escalation). Data is also obtained on

how the body absorbs and uses the drug.

- **Phase II clinical trials** provide further information on the agent's safety as well as whether it is effective. If the trial results demonstrate that the new intervention is as safe as standard treatment and is likely to be effective, research on the study drug can progress to Phase III.
- **Phase III clinical trials** compare the safety and effectiveness of a new treatment that has worked well in a small number of people with a particular disease against current standard treatment for that disease. These trials include a large number of patients, ranging from several hundred to thousands, and are often conducted at multiple sites across the country and possibly internationally. Because it is not known whether the study drug or standard treatment is more effective, study patients are frequently selected at random to receive either the new treatment or the standard treatment in a process called **randomization.** If possible, the study is designed as a **double-blind study,** meaning that neither study patients nor those conducting the trial know which treatment each patient is receiving.

By the last stage of development, approximately 1,000 or more people have received the study drug. Once all of the research data from the trials have been obtained and analyzed, the data is then submitted to the FDA for review. If the data meet FDA standards, the agency will then approve the treatment for a particular **indication**, meaning the use of the drug for treating a specific disease.

Importantly, research on a particular drug does not stop after the FDA's approval for marketing and consumer use. The product's safety is always being monitored, whether through additional trials focused on particular research questions (known as Phase IV studies) or post-marketing surveillance, which monitors the safety of the medication based on reported adverse events experienced by patients. Such surveillance is crucial, since all potential adverse effects of a treatment cannot be anticipated despite the FDA's premarket review and drug approval process based on the number of patients included in the clinical trials. The FDA evaluates and uses this information to update the drug's labeling and, in some cases, to reassess the treatment's approval.



Why participate? The most common reasons one might participate in a clinical trial are to play an active role in your own health, to help future patients, to contribute toward furthering medical knowledge, and/or to potentially receive access to a new treatment and the hope it may result in therapeutic improvement that is more effective than the current standard of care. However, it's important to recognize that no matter the reason one participates, major breakthroughs could not happen without the generosity of clinical trial participants.

Are there potential benefits and harms that may result from participating in a clinical trial? Yes, there are, just as there are possible benefits and harms that can be associated with routine medical care. The specific potential benefits and harms differ based on the study design and particular agent being studied and will be described to each participant before enrolling in a clinical trial. There are measures in place in each trial to protect participants and to minimize any potential harms.

Why is a placebo included in clinical trials? Why can't you give me the real thing? This is the most common question we hear, and if we could do so, we would. However, including a placebo is a critical component in obtaining robust data and considered the most reliable way to compare whether or not an experimental drug is safe and effective. In fact, randomized controlled trials are considered the "gold standard" for reliably determining the safety and efficacy of a treatment and demonstrating its superiority over existing standard of care or a placebo. A placebo is an inactive substance or "sugar pill" that does not contain active drug ingredients in the product. To accurately assess whether the experimental treatment is effective in improving the condition, a control group is needed. Most studies use a placebo for the control group. However, others use a comparison drug that is already on the market for the condition in cases where it would unethical to leave a patient untreated while in a placebo-controlled study (e.g., epilepsy studies).

In conclusion, Janet's and Dawn's shared goal is to educate people on the importance of clinical trials, since without such studies, medications for **Alzheimer's disease**, **Parkinson's disease**, multiple sclerosis, high blood pressure, cancer, and many other diseases and conditions would not be available. Novel treatments that are approved today after going through the clinical trial process may not only benefit you, but your children, your grandchildren, and your grandchildren's children; your friends; your work colleagues; your neighbors; your community; and every community today and tomorrow.

If you have any questions about research and clinical trials, or if you would like to learn more about our **enrolling clinical trials here at Associated Neurologists,** please feel free to reach out to Janet or Dawn at (203) 748-2551, extension 351 or 377, respectively. They would love to hear from you!

Sources and Additional Resources on Clinical Trials

"Clinical Trials and Older People." (2009, September; last updated 2017, May 4.) National Institute on Aging. ***https://www.nia.nih.gov/health/publication/clinical-trials-and-older-people.***

"Are Clinical Trials for You?" (Last updated 2017, February 21.) NIH Clinical Center. ***https://www.cc.nih.gov/participate/studies1.html.***

"Healthy Aging and Participating in Research" Powerpoint presentation. (2016, May 19.) National Institute on Aging. ***https://www.nia.nih.gov/health/publication/roar-toolkit?utm_source=201601024_clintrials&utm_medium=email&utm_campaign=ealert***.

"The Drug Development Process." (Last updated 2017, April 26.) U.S. Food & Drug Administration. ***https://www.fda.gov/ForPatients/Approvals/Drugs/ucm405658.htm***

"NIH Clinical Research Trials and You: The Basics." (Last reviewed 2017, January 18.) National Institutes of Health. ***https://www.nih.gov/health-information/nih-clinical-research-trials-you/basics***

"Learn about Clinical Studies." (Last reviewed 2017, January.) ClinicalTrials.gov. ***https://clinicaltrials.gov/ct2/about-studies/learn***

"Understanding Clinical Trials." Fox Trial Finder, The Michael J. Fox Research Foundation for Parkinson's Research. ***https://foxtrialfinder.michaeljfox.org/understanding-clinical-trials/clinical-trials-101/***

"What are the Different Types of Clinical Research?" (Last updated, 2016, February 24.) U.S. Food & Drug Administration. ***https://www.fda.gov/ForPatients/ClinicalTrials/Types/default.htm***

"Overview of Clinical Trials." CenterWatch. ***http://www.centerwatch.com/clinical-trials/overview.aspx***

Associated Neurologists, P.C. | 69 Sand Pit Road, Suite 300, Danbury, CT 06810 | (203) 748-2551 | **www.associatedneurologists.com**

See What's Happening on Our Social Sites!

Like us on Facebook | Follow us on twitter | FOLLOW US ON Pinterest