

We Will be enrolling the following studies. For details on any study, call us at (615) 329-2222 or visit us online at [www.ClinicalResearchAssociates.com](http://www.ClinicalResearchAssociates.com).

**Enrolling Studies:**

Migraine  
Tdap/RSV  
Anthrax

**Compensation up to:**

\$520  
TBD  
\$725

**Upcoming Studies:**

Hot Flashes  
Migraine  
Healthy Volunteer Device  
Adolescent Obesity



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# HEALTH NOTES

Another busy Holiday Season has past! It all goes too fast and then hold on, we are into a whole new year and the pace doesn't slow down. Of course, we are thankful for the opportunity to be circling the sun again. I'm glad Clinical Research Associates and our friends are on the ride together. We are grateful for your continued interest and support of our research studies.

It is customary to make a resolution at the beginning of a new year. Popular ones in the United States might include losing weight, eating more healthy food, exercise more, stop smoking and saving money. Maybe your resolution was to add something such as volunteering, setting aside time to visit with friends or reading more books. The common thread of these resolutions is to make lifestyle changes and make us a better person. However, it's hard to change habits and lifestyles. You may have already given up on your resolution(s). According to U S News and World Report, 80% of New Year's resolutions fail by February. Each day is a new one and you can start all over again. Maybe it was an unrealistic resolution. It may be time to re-evaluate your resolution and get over the idea of being a failure.

You could be like me. I just gave up on resolutions and decided to use positive statements with the word try. I will try to do better this year. I will try to eat better and make better food choices. I am going to try to send more written cards and notes to express concern, care and appreciation. The word try gives me a little wiggle room. I am not going to feel guilty if I splurge and eat a huge hamburger but I'm not going to make it a daily thing. The next day, I will try to do better. So, if I forget to send a birthday card to my dear friend or a thank-you note ....not finished with the notes for Christmas gifts; Instead, Sending Valentine cards will be a big surprise and I'll take advantage of the surprise element. I think it's perfect to use the word "try" and finally do better! There is really no yardstick when you are trying.

Best wishes for 2019

Best,

*Linda Moore Schipani*

President & CEO

Clinical Research Associates, Inc.  
1500 Church Street  
Suite 100  
Nashville, TN 37203  
615.329.2222  
[www.ClinicalResearchAssociates.com](http://www.ClinicalResearchAssociates.com)



## Anthrax: A disease & Weapon

In the mid-nineteenth century Anthrax posed a major economic problem, particularly in France, because of its effect on horses, cattle and sheep. Robert Koch, a German scientist and physician identified the bacteria, *Bacillus anthracis*, that caused the disease in 1875 and in 1881 Louis Pasteur developed a vaccine for livestock to prevent the disease. Human Anthrax vaccines were developed in the late 1930s in the Soviet Union and in the 1950s in the United States. The current approved vaccine, BioThrax, was formulated in the 1960s but did not get full FDA approval until 2015. The vaccine causes the body to build up antibodies to fight the Anthrax bacteria and prevent illness. It is approved for prevention (pre-exposure) in adults who are at risk which includes animal workers, travelers, postal workers and military personnel.

Although a rare human disease in the US, Anthrax has been developed and used as a weapon of biological warfare. It was used in 2001, just one week after the September 11 attack. Over the course of several weeks beginning on September 18, 2001, letters were mailed containing anthrax spores to several news media offices and two senators. As a result, 22 were infected and five died.

One of the missions of the Department of Health and Human Services is to develop strategies to address public health and medical consequences after Anthrax exposure. We are conducting a vaccine study for healthy individuals 18-65 of the approved Anthrax vaccine with and without an experimental "booster". The study will evaluate the body's immune response. If you are interested in helping develop post-exposure treatment, give us a call. You cannot get Anthrax from participating and compensation up to \$725 is available.



## Common cold or RSV?

Respiratory Syncytial Virus often referred to as RSV, is a specific virus that causes inflammation of the bronchioles, the smallest air passages in the lungs. Symptoms are similar to the common cold in older children and adults but infants have such small airways, RSV can be very serious. It is one of the main causes of infant hospitalization and mortality. Outbreaks for RSV in our area are usually in the fall and winter. The virus spreads through tiny droplets that goes into the air when infected people cough, sneeze or blow their nose. The virus can also be on surfaces as well. There are no specific treatments for RSV. Researchers are working to develop a vaccine for prevention. We have conducted three RSV vaccine studies. For the approximate 350 adults who participated, THANK YOU. The work continues.

Our upcoming RSV vaccine study will be focusing on young healthy women of childbearing age, 18 to 40. As you may know, Tdap (tetanus, diphtheria and pertussis/whooping cough) vaccine is recommended during the third trimester of each pregnancy. Our study will seek to determine if an investigational RSV vaccine and Tdap can be co-administered. During the study, the immune response will be evaluated over approximately two months. This may have implications for the prevention of infant RSV by maternal immunity. Consider volunteering for this important study. Compensation is available.

## Migraine Treatment and Prevention

A new class of medications has been a game changer for how migraines are treated. The new drug class called calcitonin gene-related peptide or simply CGRP works by preventing CGRP from dilating blood vessels which are believed to be something that can start or intensify migraine headaches. The FDA has approved three drugs in this class, all in 2018. Clinical Research Associates was involved in studies related to two of the three. Thank you to all who participated. You have made a difference in the lives of migraine sufferers.

We have several upcoming migraine studies. If you have at least two migraines per month, give us a call. We would be glad to give you the details and see if one of these studies might be right for you.

## Alzheimer's Drug Development Update

You may know that we have been very involved in studies of drugs to treat or prevent Alzheimer's Disease (AD). These are the most complex studies we have attempted and the screening process has been quite a challenge. We had more than 300 volunteers screen in-clinic (and about 10 times that number prescreen by phone) for studies that expected only 5% to qualify for enrollment. If you have been following the medical news, you know these drugs did not work.

What these drugs have in common is that they all treat the same possible cause of AD. Maybe a different drug could treat that cause or maybe damage is underway long before we can detect any problem. Maybe AD has a completely different cause. There is so much we still don't know.

The last AD drug to be approved by the FDA was marketed in 2003, and the AD drugs we do have don't work very well. There have been more than 500 clinical studies of AD drugs, costing many billions of dollars. So it might look bleak, but there is an upside.

When Thomas Edison was trying to invent the light bulb, one of his critics noted that he had tried 10,000 different types of filament without success and branded him a failure; Edison replied, "I have not failed. I've just found 10,000 ways that won't work." Now a variety of other causes of AD are being considered with drugs in development to treat them. Looking in a number of different directions seems a good approach when searching for a destination.



The majority of our staff enjoys cooking so we headed out to a cooking class for a Multi-Cookers appliance. There are several brands but probably the most recognizable one is the Instant Pot. These single electric cookers can do the function of seven appliances: pressure cooker, slow cooker, rice cooker, yogurt maker, saute'/browning pot and warm pot. We had hoped to have a tutorial on the use of the pot to help us best utilize our appliance or decide if we wanted to purchase one. We didn't learn a lot about "hands-on" use but certainly had a good time.

Our take away points: If you are making stews, soups and one-pot dishes, it will be worth your while to own one as it takes about 1/3 or less time as traditional cooking on the stove or oven. These pressure cookers take about 10 minutes to come to pressure and another 10 minutes to release. Food with short cooking times may be quicker with traditional methods. For the novice cook who doesn't own lots of small appliances, this could be your best deal. After all, this is a multi-function cooker. A one pot meal completed with little prep and hands-on allows you to dump meats and vegetable in the pot and walk away. Dinner is served quickly!

If you own a multi-cooker, look on our website for a couple of recipes. This time of year, we are missing our grill. Our instant pot ribs may become a favorite.

