

WE PARTNER 4 RESEARCH

NEWSLETTER 2023

August 2023



WHO WE ARE

We are a center created to provide information on clinical trials so patients can fully consider their opportunities to get involved in research.



WHAT WE DO

We provide research information to the community and serve researchers by helping to increase participation in studies.



WHY IT MATTERS

We support increased clinical trial participation to accelerate discoveries to improve health.

Key Highlights

- **Community Research Summaries**
 - Novavax Vaccine Study
- **GHUCCTS In the Virtual Community (GITVC)**
 - Alzheimer's Awareness
 - HIV Awareness: World AIDS Day
 - COVID Conversations
- **Actively Recruiting Clinical Research Studies**
 - STEP-1 Study
 - TOPAZ Study
 - STAR & MWCCS Studies
 - MIND Study
- **Research in the Community**
 - Alzheimer's "Rock for Research"
 - Lupus walk

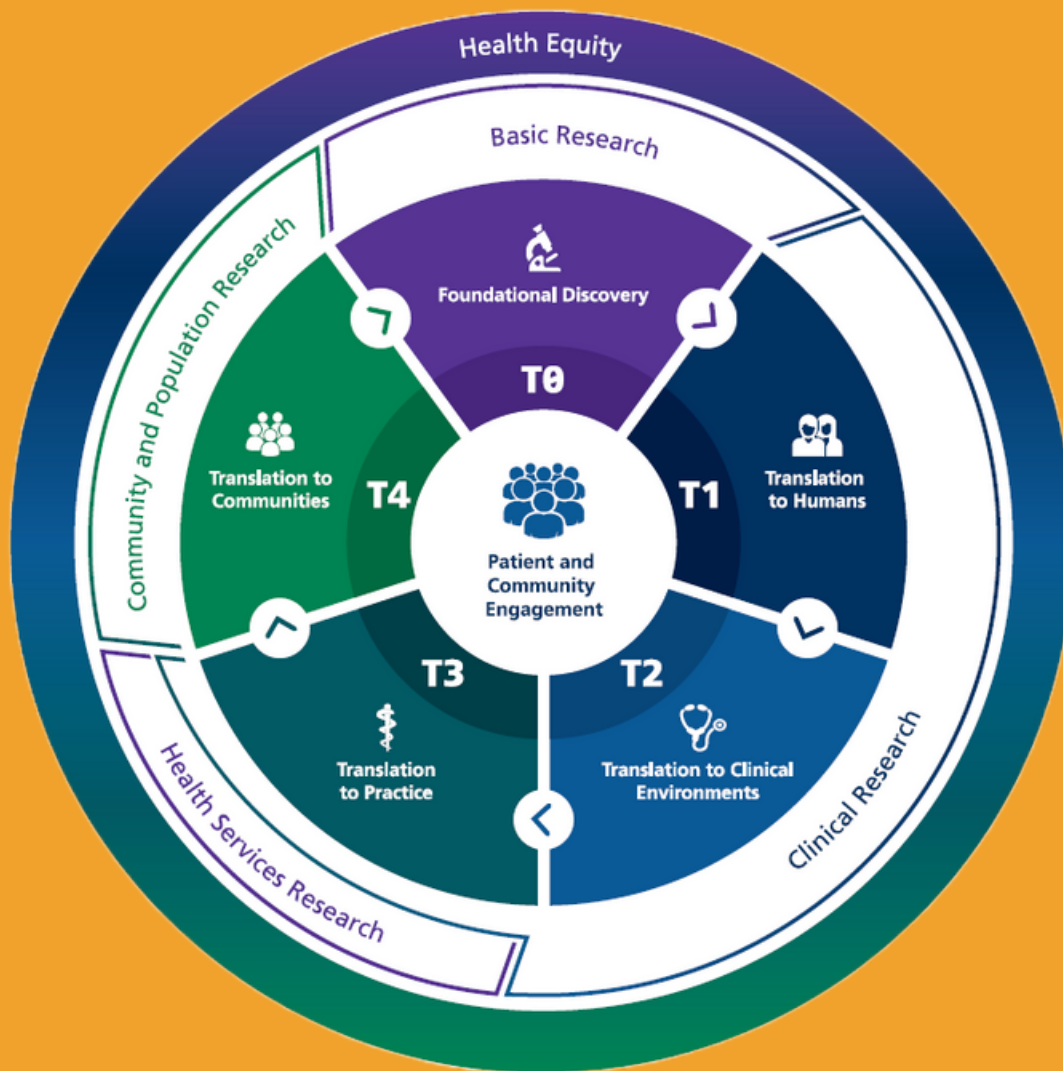
• Follow us!

We **PARTNER**
for **RESEARCH**

Georgetown University | Howard University
MedStar Health Research Institute | DC Veterans Affairs Medical Center
Oak Ridge National Laboratory

COMMUNITY RESEARCH SUMMARIES

The objective of the **GHUCCTS Community Summaries** is to ensure study updates and results are communicated to the study participants and the general community. Study findings can help improve health and medicine.



NOVAVAX VACCINE EFFICACY & SAFETY

[Access Publication Here](#)

[Vaccine Info Here](#)

Efficacy and Safety of Novavax Vaccine in Adults in the U.S and Mexico

1. What?

Researchers tested the effectiveness of a novel vaccine, NVX-CoV2373, for preventing COVID-19 disease onset in individuals from North America. NVX-CoV2373, also known as the “Novavax” vaccine, is a **recombinant***, **nanoparticle*** vaccine that produced antibodies. It is similar to other established vaccinations, like those for shingles and tetanus, as it does not use mRNA technology.

2. Why?

Researchers were interested in collecting and identifying data from North America in order to compare efficacy of NVX-CoV2373 across different global regions, and diversity in race and ethnicity. The primary goal in this study was to examine the **efficacy*** of this vaccine in preventing confirmed COVID-19 infection.

3. How?

Some participants received the Novavax vaccine, while others received a **placebo***. Individuals were randomly assigned to a group and given two doses in total that were spaced 21 days apart. Viral presence was quantified one week after the second dose.



4. What?

Results: The vaccine prevented infection in 90% and prevented moderate-to-severe disease in 100% of participants: 14 of 19,714 cases of COVID-19 were reported in the vaccine group vs. 63 of 9868 in the placebo; 10 were confirmed moderate and 4 severe cases were reported, **all** of which were from the **placebo recipients**.



Key Terms*

Recombinant: A new combination of genes. Recombinant DNA technology is a very useful research tool in biology. Scientists can work with DNA fragments to study them in the lab, which can lead to the production of effective treatments for diseases like COVID-19. With this technology, proteins required for health problems can be produced safely and affordably. Some traditional vaccines that use recombinant technology include those for shingles (Shingrix), papillomavirus (HPV) and tetanus (DTaP).

Nanoparticle: Particles that are extremely small and very potent. Useful for developing new therapeutic agents or drugs in medicine.

Efficacy: The performance of an intervention under ideal and controlled circumstances

Placebo: Any substance or medical procedure with no therapeutic value. Often used in clinical trials to help understand the real effect of a new treatment- both positive benefits and possible side effects.

Why Should YOU Care?



COVID-19 studies and trials can present findings that are essential to the scientific and clinical community, given that the methods used are safe and results are applicable to a wide range of community members. It is important to understand and compare differences and benefits of various treatments being offered. This vaccine uses established recombinant technology, like more traditional vaccinations, but it does not use mRNA. Some people may want the option of this type of vaccine.

GITVC

FOLLOW OUR YOUTUBE CHANNEL OR CLICK BELOW TO LISTEN TO OUR EDUCATIONAL WEBINAR SERIES DELIVERED BY OUR INVESTIGATORS

GITVC Alzheimer's
Guest Speaker: E. Bruce Turner, MD, PhD

Dr. Turner is a Vice-Chair and Professor in the Department of Neurology and Director of the Memory Disorders Program at Georgetown University, Washington, D.C. He received his doctorate and medical degrees from Emory University, Atlanta, followed by an internship in Internal Medicine, residency in Neurology, and a Howard Hughes Medical Institute-funded fellowship in behavioral neurobiology at the University of Pennsylvania, Philadelphia. After completing his residency in neurology, Dr. Turner, Washington, DC, he was Chief of the Department of Neurology at the VA Ann Arbor Healthcare System, Ann Arbor, Michigan. He is currently Professor and Associate Chair in the Department of Neurology at the University of Michigan, Ann Arbor.

Dr. Turner's research is focused on developing new treatments and biomarkers for neurodegenerative diseases of aging, particularly Mild Cognitive Impairment and dementia due to Alzheimer's disease. He directs numerous multi-center, randomized, placebo-controlled clinical trials and research studies.

Watch on YouTube

Georgetown University | Howard University
Veterans Affairs Medical Center | Washington DC Veterans Affairs Medical Center

ALZHEIMER'S AWARENESS

Nov 2021

+ How are Participants Protected in Research Studies?

"HIV AWARENESS: WORLD AIDS DAY"

Dec 2021

+ Clinical Trial Randomization & its Importance in Research

Understanding HIV Pre exposure a...

HIV/AIDS · HIV (human...)

PrEP: Now and the future

Watch on YouTube

MedStar Health

GiTV | COVID Conversations: Prevent...
Guest Speaker: Glenn W. Wortmann, MD

COVID-19 vaccine. Get the latest...

Glenn Wortmann, MD is currently Chief of Infectious Diseases, MedStar Washington Hospital Center and Medical Director, Infectious Disease, MedStar Health. He completed his residency in Infectious Diseases at Princeton University on a 4-year fellowship and pursued his medical education at Medical College of Virginia in Richmond, Virginia.

Dr. Wortmann fulfilled his residency, along with ID fellowship, at the Walter Reed Army Medical Center. He left the army in 2012 after a 23-year career, with tours in Germany, Ft Eustis, Walter Reed, Afghanistan and Iraq.

Watch on YouTube

Georgetown University | Howard University
Veterans Affairs Medical Center | Washington DC Veterans Affairs Medical Center

"COVID CONVERSATIONS"

May 2022

ARE YOU INTERESTED IN PARTICIPATING IN A RESEARCH STUDY?

THE FOLLOWING STUDIES ARE SEEKING PARTICIPANTS:

STEP-1

About the STEP-1 Study

The STEP-1 study is evaluating if an investigational medical device is safe and effective for reducing HbA1c and weight when used alongside lifestyle and dietary counseling in adults with type 2 diabetes who have not had success with other therapies. If you were diagnosed with type 2 diabetes less than 15 years ago and are not currently taking insulin, you may be able to participate.

What is the Investigational Device?

The investigational device is a thin, flexible sleeve called EndoBarrier®. It is designed to be a minimally-invasive alternative to insulin injections or surgery for people living with uncontrolled type 2 diabetes. The device is endoscopically placed by a physician in an outpatient procedure and can be left in place for up to 12 months.

Once in place, the device conforms to the shape and movement of the intestine. It creates a physical barrier between receptors in the intestinal wall and food that is believed to affect hormone levels. Researchers believe these possible changes in gut hormones may help to reduce:

- HbA1c
- Weight and BMI
- Cardiovascular-related metrics
- NAFLD
- Medications

Study participants may be reimbursed for expenses related to time in the study.

Who Can Participate?

This study may be an option for people who are 30 to 65 years of age and meet the following requirements:

- Type 2 diabetes diagnosed less than 15 years ago
- HbA1c between 8 – 10% despite being on a stable dose of at least 2 diabetes medications for at least 3 months
- Not currently taking insulin
- BMI between 30 – 50 kg/m²

There are other requirements to join this clinical study. A study team member will help determine if this study is right for you based on all participation criteria.



Contact Study Coordinator:

Kendra Green: kendra.s.green@medstar.net

MedStar PI: John Brebbia, MD

[More Information Here!](#)



Empowered in the fight against LUPUS

Learn about and take part in a new study enrolling eligible participants with systemic lupus erythematosus (SLE) while staying on your current treatment for SLE.



About the TOPAZ Studies: The TOPAZ Studies are evaluating the safety and potential efficacy of a study medication in people with active SLE **who are still taking their current SLE non-biologic therapy**. If you still experience symptoms even with your medication, a TOPAZ Study may be an option for you.

How do I qualify?

You may be eligible for the study if you*:

- Are 18 years or older
- Have been diagnosed with moderate-to-severe SLE for at least 6 months
- Are currently taking SLE medication

You will continue your current lupus medication during the study. You will be randomly assigned – that means selected by chance – to receive either the study drug or placebo (an inactive substance that looks like the drug being tested).

*The study team can discuss with you any additional criteria to participate. [If you don't qualify initially, you may choose to be contacted at a later time to see if you may qualify in the future.]

Your safety is our highest priority while participating. If you have questions or concerns at any point throughout the study, a study staff member is available. The study staff can also tell you about their COVID-19 safety protocols.

Your participation is voluntary, and you are free to withdraw at any time for any reason. Your privacy will be maintained throughout the study.

Why take part?

If you qualify and decide to take part, you will receive:

- All study-related care and study medication at no charge
- Regular monitoring of your SLE and overall health by physicians who specialize in SLE
- Reimbursement for transportation and other expenses such as childcare to attend study visits, as needed
- The opportunity to contribute to learning more about SLE

For more information or to see if you qualify:

Ms. Destiny Barksdale db1619@georgetown.edu 202-444-6206	Dr. Megan Lockwood mml157@georgetown.edu 202-444-6200	TOPAZLupusStudy.com
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Biogen-117821

TOPAZ Studies_Patient Flyer_US English_V1_0UUL2021

MIND

MIND Website

a two-year clinical study testing whether the safe use of nicotine, delivered via a patch, can improve memory and functioning in people who have been diagnosed with mild memory loss or mild cognitive impairment (MCI)

IS YOUR MEMORY NOT WHAT IT USED TO BE?

Memory loss associated with aging can be mild cognitive impairment (MCI), a precursor to Alzheimer's disease.

The MIND Study is testing whether the safe and innovative use of nicotine, delivered through a patch, can improve memory and functioning in people who have been diagnosed with MCI.

If you are a healthy, non-smoking adult over the age of 55, please visit MINDStudy.org or call **1-866-MIND-150** (1-866-646-3150) to learn more.

Funded by the National Institutes of Health and the Alzheimer's Drug Discovery Foundation.





Study of Treatment and Reproductive Outcomes



MACS/WIHS COMBINED COHORT STUDY



MACS/WIHS COMBINED COHORT STUDY



Study of Treatment and Reproductive Outcomes



NIH/Georgetown University HIV Studies

MWCCS

Help understand HIV infection!

WE ARE LOOKING FOR:

- ◆ HIV POSITIVE women 30-70 years old
- ◆ HIV NEGATIVE women 30-70 years old

MWCCS is a long-term study involving a physical exam, lab work and an interview annually.

You will be compensated for your time!

For more information contact:

DC: 202-784-2687

VA: 703-321-2674

mwccsstudy@georgetown.edu

STAR

Help understand HIV infection in young women!

WE ARE LOOKING FOR:

- ◆ HIV POSITIVE women 18-45 years old
- ◆ HIV NEGATIVE women 18-45 years old

STAR is a long-term study involving a physical exam, lab work and an interview annually.

You will be compensated for your time!

For more information contact:

DC: (202) 384-7815

VA: 703-321-2674

starstudy@georgetown.edu

MWCCS:

mwccsstudy@georgetown.edu

STAR:

starstudy@georgetown.edu



ROCK FOR RESEARCH!

AN ALZHEIMER'S EVENT

September 24 at 5PM - 9PM

**The State Theatre
Falls Church, VA 22046**

DANCE • DONATE • DEFEAT ALZ

A night of rockin' and rollin' with Uncle Jesse Band, auction and more, in honor of the millions of Americans living with Alzheimer's. All funds raised will go directly to **Georgetown University Memory Disorders Program!**

Casual cocktail attire and all ages welcome!

Price of admission is a suggested donation of \$100 per person ages 15 and up.

Donate at (give.georgetown.edu/memorydisorders) to attend!



[Admissions Details Here](#)

WALK TO END LUPUS NOW[®]

Saturday, September 30th 2023

Please join the Georgetown University Hospital Rheumatology Team in the Walk to End Lupus! You can make a difference by simply showing up to walk with us and/or donating to help us reach our fundraising goal to support the Lupus Foundation's efforts to improve the quality of life for all people affected by lupus.

This will be a great opportunity to meet other people living with lupus and speak directly with healthcare professionals from the Lupus Program at Georgetown University Hospital.

The Lupus Program at Georgetown University Hospital is dedicated to the comprehensive care of patients with lupus, which includes opportunities for patients to participate in clinical research trials to investigate therapies for lupus.

We hope to see you! You can read more and join our team:

[Join Georgetown Study Team Here!](#)

Thank You!

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&

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