

Image courtesy of Arthur Toga, Ph.D., USC

UTSouthwestern
Medical Center

Brain Summit 2020 Virtual Symposium

Saturday, October 31, 2020

Benjamin Greenberg, M.D., M.H.S.
Steven Vernino, MD, PhD



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Peter O'Donnell Jr.
Brain Institute

Disclosures

- Dr. Greenberg has received consulting fees from Alexion, EMD Serono, Novartis, Viela Bio, Roche, Greenwich Bio, Axon Advisors, Rubin Anders and Abcam. He has received grant support from the NIH, NMSS, SRNA, GuthyJackson Charitable Foundation, PCORI and CLENE Nanomedicine. He serves as an unpaid board member of the Seigel Rare Neuroimmune Association.
- *Dr. Greenberg is the PI of one of the trials mentioned today*

Disclosures

- Dr. Vernino has received consulting fees from Catalyst, Alterity, Sage Therapeutics and research support from Genentech, Grifols, Quest and Dysautonomia International
- *Dr. Vernino is a PI and co-investigator on trials mentioned below*

Research at UT Southwestern

Basic Science Research

Cellular Models

Animal Models

Translational Research

Human sample based studies

Human data based studies

Observational Clinical Research

Prospective imaging studies

Prospective outcomes research

Interventional Clinical Trials

Device studies

“Drug” studies

Research at UT Southwestern

Basic Science Research

Cellular Models

Animal Models

Translational Research

Human sample based studies

Human data based studies

Observational Clinical Research

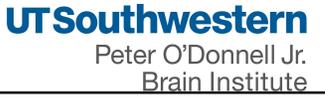
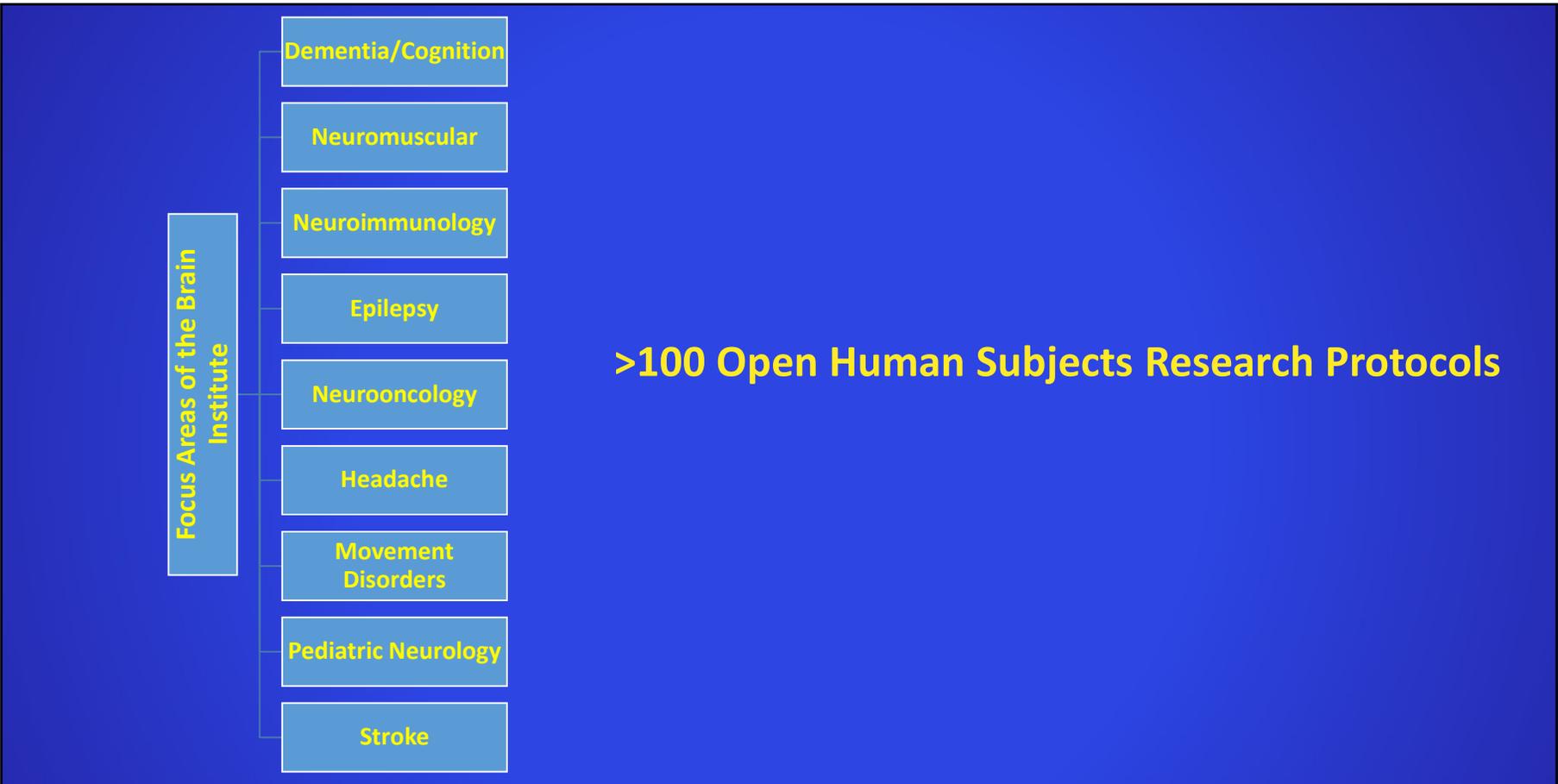
Prospective imaging studies

Prospective outcomes research

Interventional Clinical Trials

Device studies

“Drug” studies



Focus Areas of the Brain Institute

- Dementia/Cognition
- Neuromuscular
- Neuroimmunology
- Epilepsy
- Neurooncology
- Headache
- Movement Disorders
- Pediatric Neurology
- Stroke

Role of Traumatic Brain Injury in AD

We are enrolling patients with amnesic MCI with a history of at least one concussion to learn if safe, noninvasive brain stimulation might lessen memory difficulties in this population. Patients will wear a soft head cap where 10 sessions of low level stimulation is applied for a brief duration while relaxing (lasting ~30 minutes each). Brief memory testing will be completed at baseline, after the last stimulation session, and then a 3-month follow-up.

Eligibility for inclusion in the studies is:

- Diagnosis of aMCI (single, or multiple domain)
- Over 50 years of age
- Fluent in English
- Has at least a high school education

Contact: Jan.Garcia@utsouthwestern.edu

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Focus Areas of the Brain Institute

Dementia/Cognition

Autonomic

Neuroimmunology

Epilepsy

Neurooncology

Headache

Movement Disorders

Pediatric Neurology

Stroke

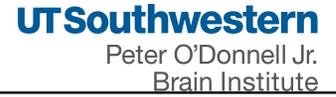
Theravance 0169 Neurogenic Orthostatic hypotension

This is a Phase III clinical trial to help MSA, PD, or PAF subject that have OH (Orthostatic Hypotension). This is a new drug that is a 10 mg pill taken once a day. Works as a norepinephrine reuptake inhibitor

UTSW participated in the Phase II and the results were promising.

Contact: Steve.Hopkins@utsouthwestern.edu

Autonomic disorders program also has a pilot study of IVIG for POTS patients with autoimmune disorders.



Focus Areas of the Brain Institute

Dementia/Cognition

Neuromuscular

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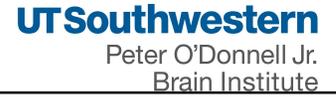
Stroke

RAISE – myasthenia gravis

This is a Phase III clinical trial for generalized MG. This is an entirely new class of drug that suppresses antibody levels without general immunosuppression.

UTSW participated in early studies of this class of medication

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Focus Areas of the Brain Institute

Dementia/Cognition

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Movement Disorders

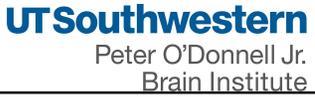
Pediatric Neurology

Stroke

REPAIR MS

This study is enrolling RRMS patients, stable on Natalizumab to take an oral agent that is thought to be neuroprotective and/or remyelinating. The agent does not suppress the immune system.

Contact: Monae.Carpenter@utsouthwestern.edu



Focus Areas of the Brain Institute

- Dementia/Cognition
- Neuromuscular
- Neuroimmunology
- Epilepsy**
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- Stroke

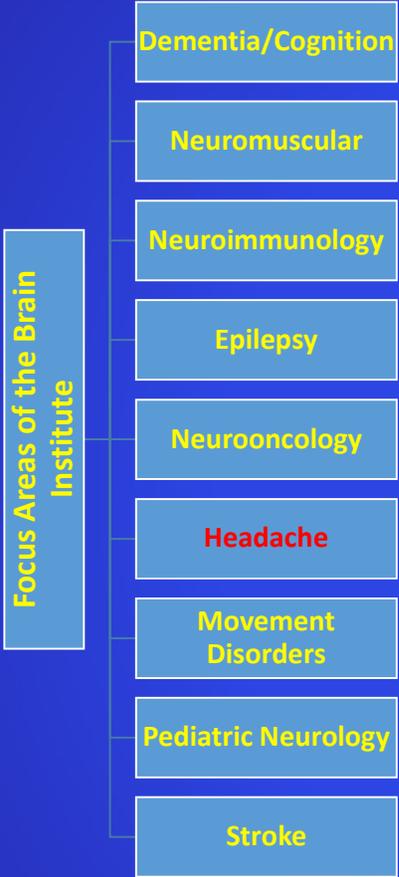
XEN1101 as Adjunctive Therapy in Focal-onset Epilepsy

An adjunctive anticonvulsant trial seeking those who continue to have focal seizures despite having tried 2 anticonvulsant medications or more in the past. Participants must have more than 6 seizures per month.

Contact is Xiaohong Xu (xiaohong.xu@UTSouthwestern.edu)

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The diagram shows a vertical list of focus areas for the Brain Institute, connected to a central vertical bar. The focus areas are: Dementia/Cognition, Neuromuscular, Neuroimmunology, Epilepsy, Neurooncology, Headache, Movement Disorders, Pediatric Neurology, and Stroke.

Zolmitriptan Intracutaneous Microneedle System

C213 (Zolmitriptan) uses a drug delivery system called the Zolmitriptan Intracutaneous Microneedle System, which delivers drug by way of a transdermal patch. Because of the rapid absorption of transdermal zolmitriptan, use of the C213 could provide faster relief (vs. oral or injectable triptans) for the severe pain of cluster headaches.

Contact: Jennifer.fehmel@utsouthwestern.edu

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Focus Areas of the Brain Institute

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Neuromuscular

Neuroimmunology

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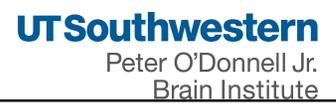
Pediatric Neurology

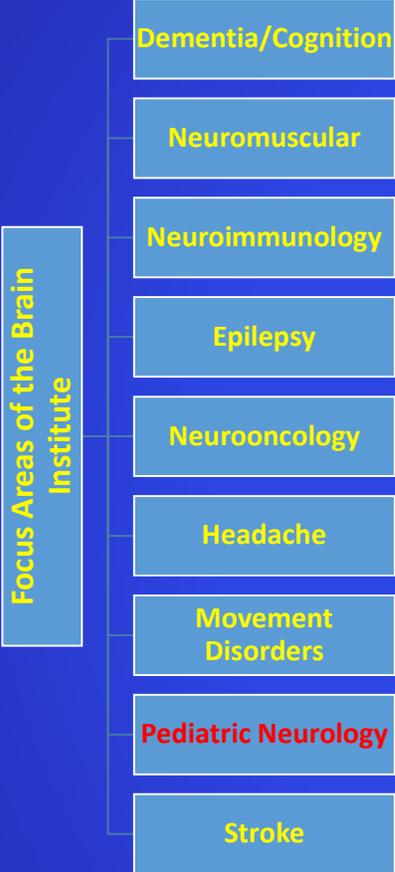
Stroke

REPAIR PD

REPAIR-PD is a single-center open label pilot, sequential group, investigator and patient blinded study to assess the CNS metabolic effects, safety, pharmacokinetics, and pharmacodynamics of CNM-Au8 (an oral agent) in patients who have been diagnosed with Parkinson's Disease (PD) within three (3) years of Screening. The primary endpoint is the ratio of the oxidized to reduced form of nicotinamide adenine dinucleotide (NAD+:NADH) measured non-invasively by 31phosphorous magnetic resonance spectroscopy (31P-MRS).

Contact: Nasreen.sayed@utsouthwestern.edu





The diagram shows a vertical list of focus areas for the Brain Institute, connected to a central vertical bar. The focus areas are: Dementia/Cognition, Neuromuscular, Neuroimmunology, Epilepsy, Neurooncology, Headache, Movement Disorders, Pediatric Neurology, and Stroke. The text 'Pediatric Neurology' is highlighted in red.

CDG-SRD5A3

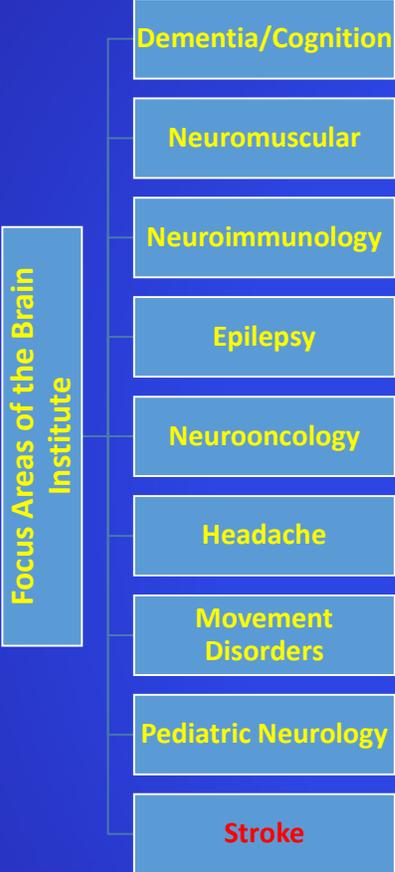
This study is designed to investigate the clinical features and natural history of a Congenital Disorders of Glycosylation (CDG) disease called CDG-SRD5A3, a rare congenital disorder of N-glycosylation. This is a single center cross-sectional natural history review of CDG-SRD5A3 patient function and characterization of disease. We plan to enroll 10 – 20 patient families from all over the world, in order to review patient medical records and conduct a standardized phone interview about patient function and perform parent reported QoL and adaptive and behavioral neuropsychological assessments.

This is a prelude for future gene therapy trials

Contact: Souad.Messahel@UTSouthwestern.edu

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The diagram shows a vertical list of focus areas for the Brain Institute, connected to a central vertical bar labeled 'Focus Areas of the Brain Institute'. The focus areas are: Dementia/Cognition, Neuromuscular, Neuroimmunology, Epilepsy, Neurooncology, Headache, Movement Disorders, Pediatric Neurology, and Stroke.

Optimal Delay Time to Initiate Anticoagulation after Ischemic Stroke in Atrial Fibrillation (START)

Primary Objective is to determine the optimal time to initiate anticoagulation with a Non-Vitamin K Oral Anticoagulant (NOAC) after ischemic stroke in patients with non-valvular atrial fibrillation.

Secondary Objectives is to compare the rates of primary adverse outcomes in a per protocol analysis

- To compare 30 day clinical outcomes by the modified Rankin scale among the time-to-treatment groups
- To compare 30 day clinical outcomes by the PROMIS-10 scale among the time-to-treatment groups.
- To compare 90 day clinical outcomes by the modified Rankin scale among the time-to-treatment groups
- To explore the optimal timing in subgroups of age, sex, outcome category, and NOAC choice

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Searching for Trials at UT Southwestern

The screenshot shows the website for the Center for Translational Medicine at UT Southwestern Medical Center. The main heading is "Search for Clinical Research Studies". Below this, there is a section titled "Clinical Trials at UTSW" with a sub-heading "Clinical Trials Nationwide". The text explains that the center conducts clinical research studies to better understand illness and develop new treatments. It mentions the use of the "StudyFinder search tool" and provides a link to "ClinicalTrials.gov".

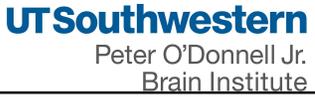
On the left side of the page, there is a sidebar with the following items:

- How to Participate
 - Join a Research Registry
 - Search for Clinical Research Studies**
 - Understanding Clinical Research
 - Contact Us

On the right side, there is a "Quick Links" section with the following items:

- UTSW Volunteer Research Participant Registry
- StudyFinder
- Contact Us

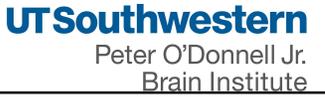
<https://clinicaltrials.utswmed.org>



Searching for Trials at UT Southwestern

The screenshot shows the UT Southwestern Medical Center website. At the top, there is a search bar and a navigation menu with links for Research, Education & Training, Patient Care, Faculty, Departments & Centers, Newsroom, Careers, About Us, and MyUTSW. Below this is the 'Center for Translational Medicine' section with sub-links for About Us, Join a Research Study, Doing Research, Education & Career Development, Team Science, and Funding. The main content area is titled 'Search for Clinical Research Studies' and includes a sub-section 'Clinical Trials at UTSW'. In this section, a link for 'StudyFinder search tool' is highlighted with a red box. Other links include 'How to Participate', 'Quick Links' (with sub-links for 'UTSW Volunteer Research Participant Registry', 'StudyFinder', and 'Contact Us'), and 'Clinical Trials Nationwide'.

<https://clinicaltrials.utswmed.org>



Searching for Trials at UT Southwestern

UT Southwestern Medical Center studyFINDER

Clinical Trials Home Search for a Study For Researchers Contact Us

Search Study Opportunities

Healthy Volunteers

Please Select

Gender

Any

Children (age < 18 years)

Adults (age ≥ 18 years)

Search (Keyword, condition, treatment, etc.)

Search Browse by category

Find the Right Clinical Trial. For You. For a Loved One.

Participating in research is one of the most powerful things you can do to be part of tomorrow's health care breakthroughs. UT Southwestern is always looking for people who are willing to participate in studies so that our researchers can better understand how to diagnose, treat, and prevent diseases and conditions.

Use this StudyFinder website to quickly and easily identify UT Southwestern studies that need volunteers. Every study is different – some need healthy volunteers, while others are looking for people with a specific condition – so we've created search filters to help you find the study that's right for you. You can also filter by age and search by keyword to find studies focused on specific conditions and diseases.

By getting involved with research, you can help transform the lives of millions.

Find more ways to get involved with research:

Join Our Registry Contact Us

StudyFinder was developed by the Clinical and Translational Science Institute (CTSI), and is supported by the NIH Clinical and Translational Science Award at the University of Minnesota. UL1TR001114. Sign In

Search Study Opportunities

Healthy Volunteers

Please Select

Gender

Any

Children (age < 18 years)

Adults (age ≥ 18 years)

Search (Keyword, condition, treatment, etc.)

Search Browse by category

Searching for Trials at UT Southwestern

The screenshot shows the 'studyfinder' interface for UT Southwestern Medical Center. At the top, there are navigation links: 'Clinical Trials Home', 'Search for a Study', 'For Researchers', and 'Contact Us'. Below this is a search bar with the text 'multiple sclerosis' and a 'Search' button. To the right of the search bar are filters for 'Healthy Volunteers' (with a dropdown menu), 'Children (age < 18 years)', and 'Adults (age ≥ 18 years)'. There is also a 'Gender' dropdown menu set to 'Any'. Below the search bar, there are 'Search' and 'Clear' buttons.

The 'Search Results' section indicates that there are 6 study matches. The first study listed is 'Ciidribine Tablets After Treatment With Natalizumab (CLADRINA)'. The description states: 'The purpose of this study is to generate hypotheses regarding the safety, efficacy, and immunological impact of cladribine tablets after treatment with natalizumab in patients with relapsing-remitting multiple sclerosis (RRMS) and active secondary progressive multiple sclerosis (active SPMS)'. The contact information includes: 'Call 214-648-5005', 'studyfinder@utsouthwestern.edu', 'Principal Investigator: Claf Svbe', 'Principal Investigator ID: 58631', 'Gender: All', 'Age: 18 Years to 50 Years old', and 'Phase: Phase 4'. A warning icon indicates 'This study is NOT accepting healthy volunteers'. The system ID is NCT04178005 and the IRB number is STU-2019-1618. There is a 'Show full eligibility criteria' button.

The second study listed is '31P-MRS Imaging to Assess the Effects of CNM-Au8 on Impaired Neuronal Redox State in Multiple Sclerosis (REPAIR-MS)'. The description states: 'REPAIR-MS is a single-center open label, sequential group, investigator and patient blinded study to assess the CNS metabolic effects, safety, pharmacokinetics, and pharmacodynamics of CNM-Au8 in patients who have been diagnosed with Multiple Sclerosis (MS) within fifteen (15) years of Screening. The primary endpoint is the ratio of the oxidized to reduced form of nicotinamide adenine dinucleotide (NAD+ / NADH) measured non-invasively by 31phosphorous magnetic resonance spectroscopy (31P-MRS)'. The contact information includes: 'Call 214-648-5005', 'studyfinder@utsouthwestern.edu', 'Principal Investigator: Benjamin Greenberg', and 'Principal Investigator ID: 105091'.



Other resources

- Clinicaltrials.gov

COVID-19 is an emerging, rapidly evolving situation.
 Get the latest public health information from CDC: <https://www.coronavirus.gov>.
 Get the latest research information from NIH: <https://www.nih.gov/coronavirus>.

U.S. National Library of Medicine
ClinicalTrials.gov Find Studies ▾ About Studies ▾ Submit Studies ▾ Resources ▾ About Site ▾ [PRS Login](#)

ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world.

Explore 356,000 research studies in all 50 states and in 217 countries.

See [listed clinical studies related to the coronavirus disease \(COVID-19\)](#)

ClinicalTrials.gov is a resource provided by the U.S. National Library of Medicine.

IMPORTANT: Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our [disclaimer](#) for details.

Before participating in a study, talk to your health care provider and learn about the [risks and potential benefits](#).

Find a study (all fields optional)

Status

Recruiting and not yet recruiting studies
 All studies

Condition or disease (For example: breast cancer) X

Other terms (For example: NCT number, drug name, investigator name) X

Country X

[Search](#) [Advanced Search](#)