UT Southwestern
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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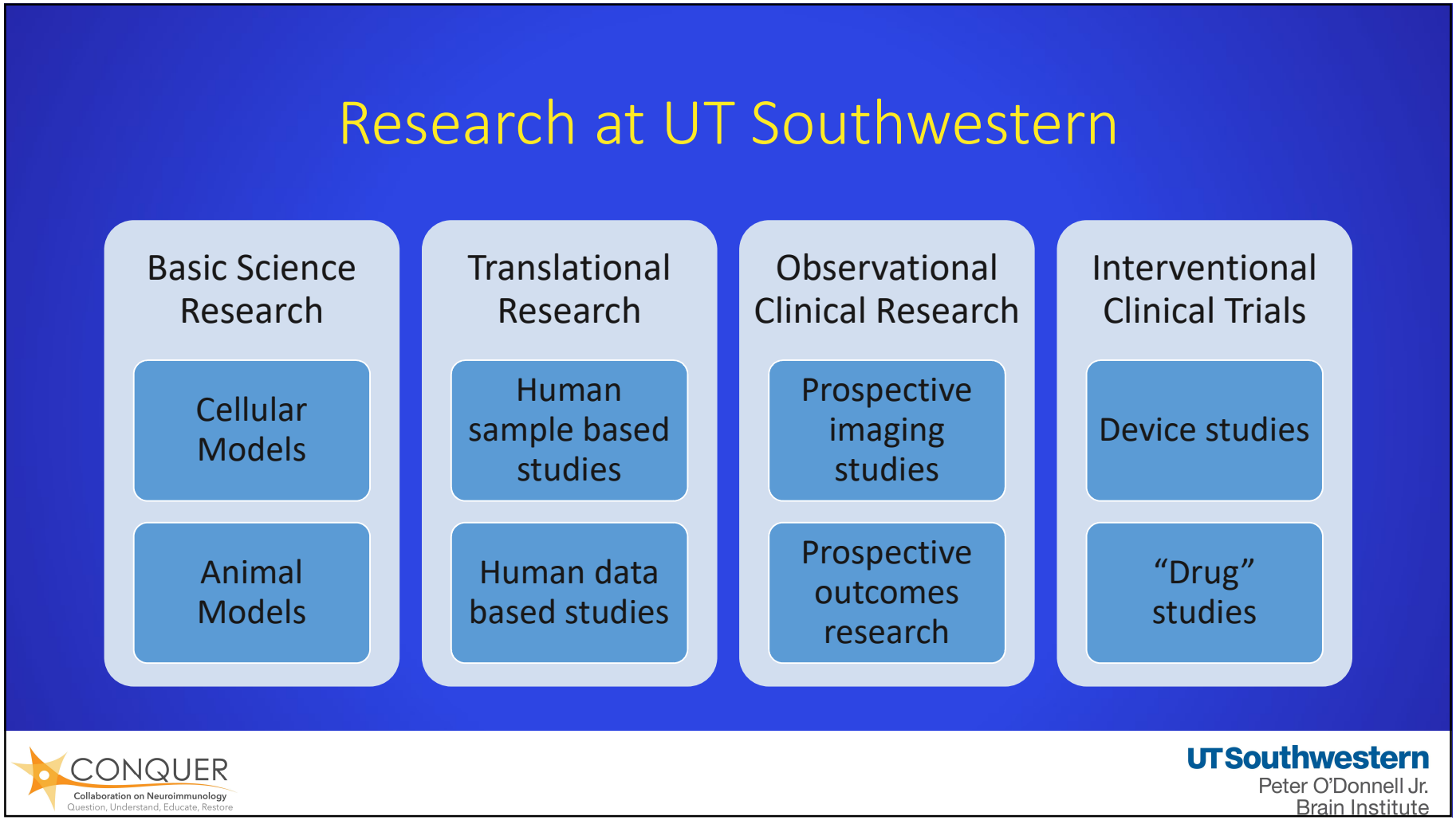
Disclosures

- 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
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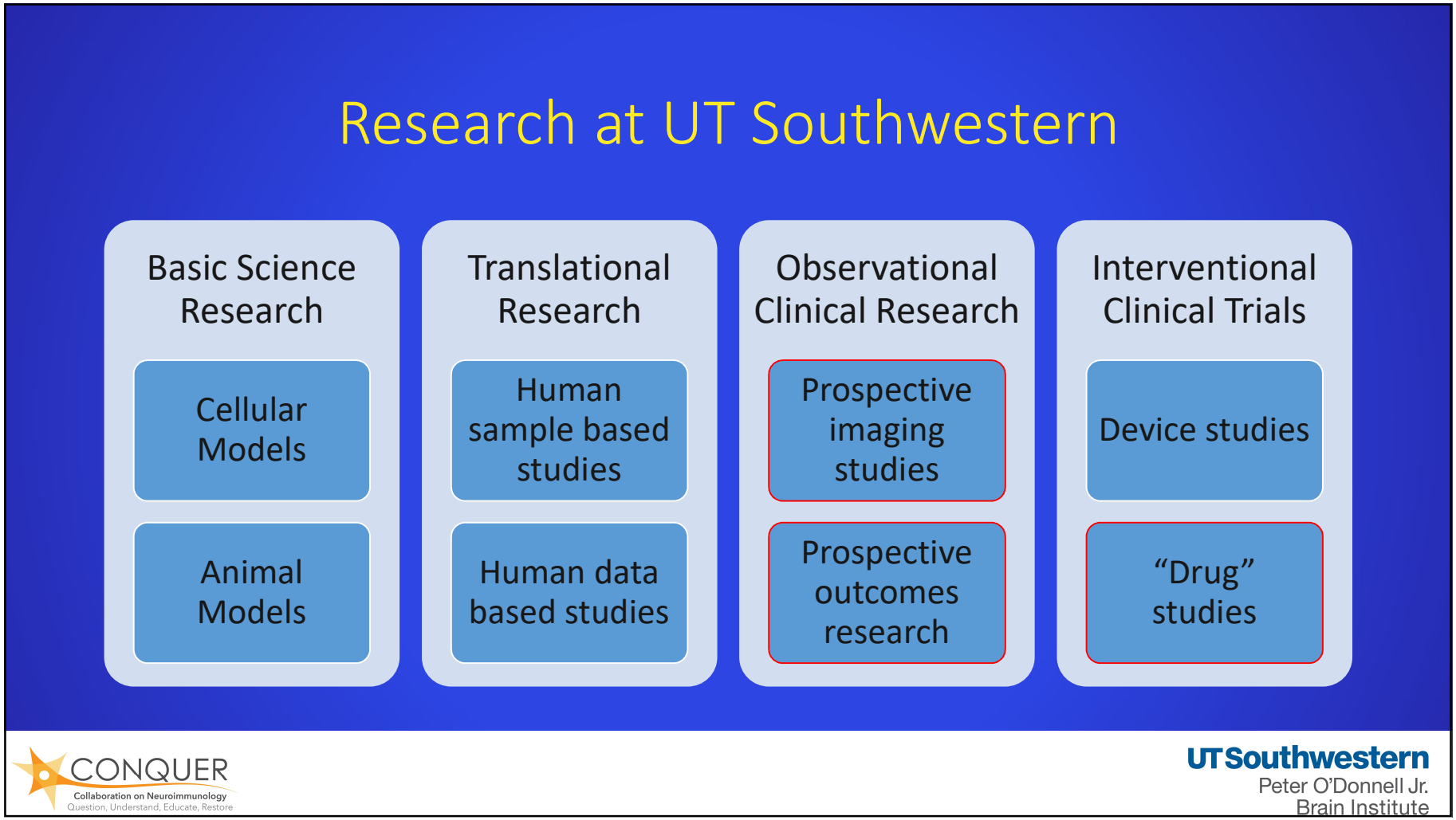
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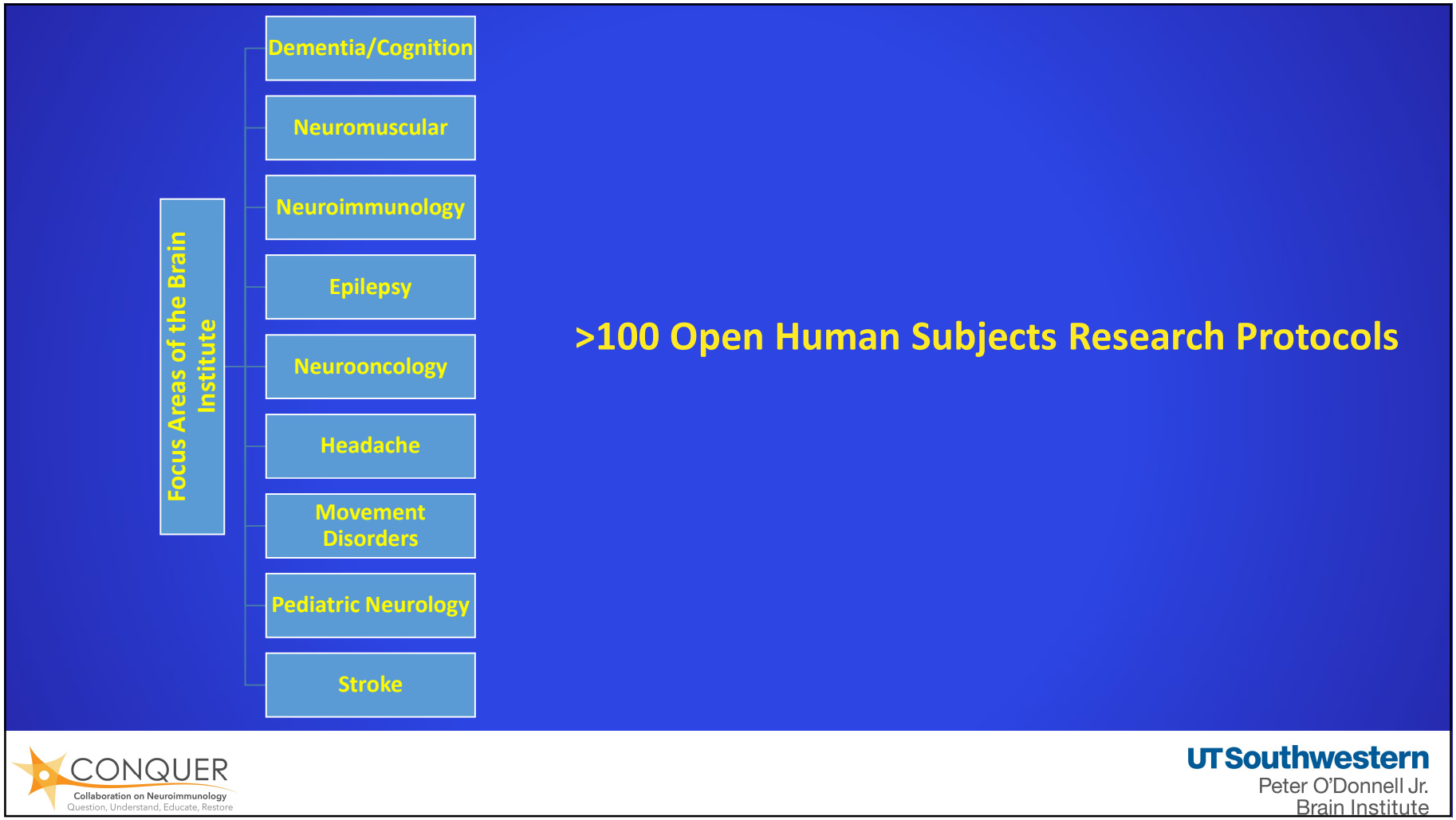
Focus Areas of the Brain Institute
Dementia/Cognition
Neuromuscular
Neuroimmunology
Epilepsy
Neurooncology
Headache
Movement Disorders
Pediatric Neurology
Stroke
>100 Open Human Subjects Research Protocols
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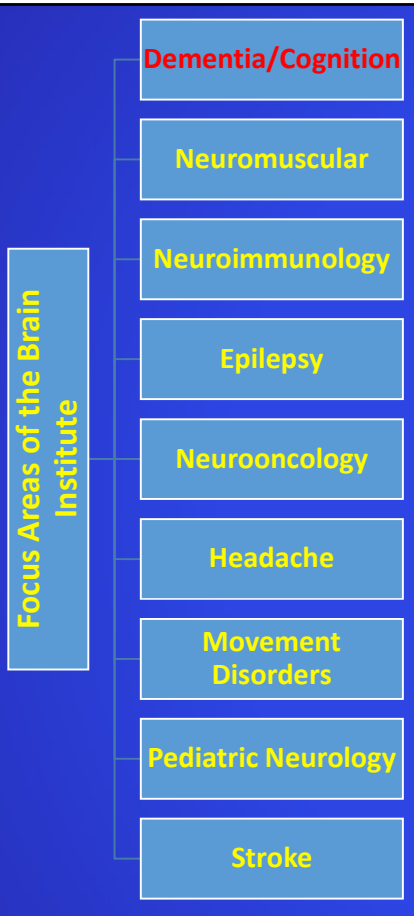

Role of Traumatic Brain Injury in AD

We are enrolling patients with amnestic 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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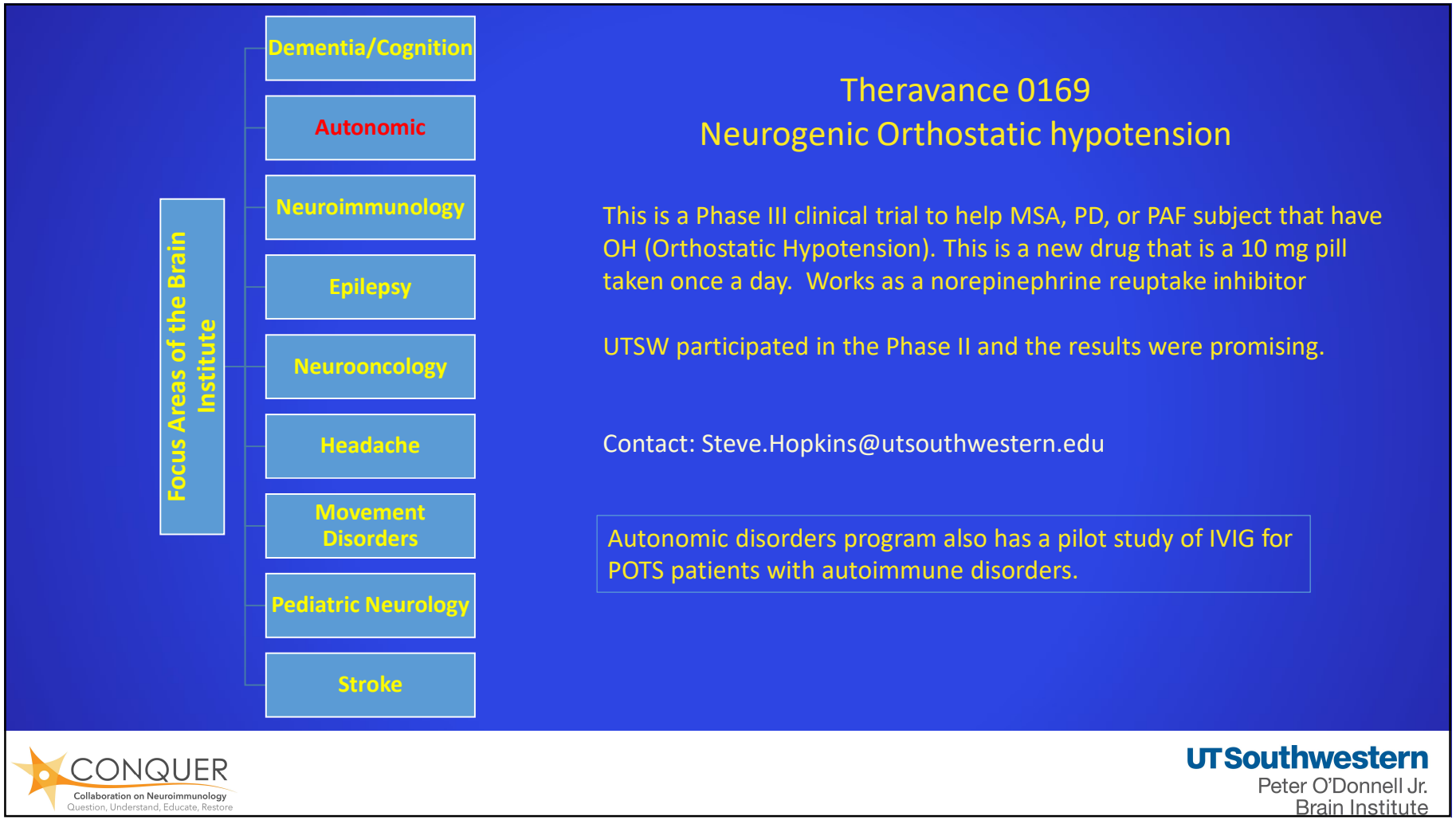
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Theravance 0169
Neurogenic Orthostatic hypotension
This is a Phase III clinical trial to help MSA, PD, or PAF subject that have OH (Orthostatic Hypotension). This is a new drug that is a 10 mg pill taken once a day. Works as a norepinephrine reuptake 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.
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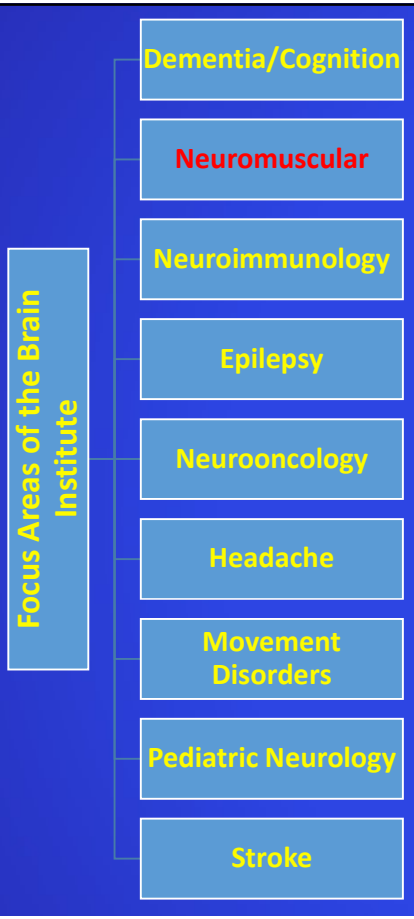

RAISE – myasthenia gravis

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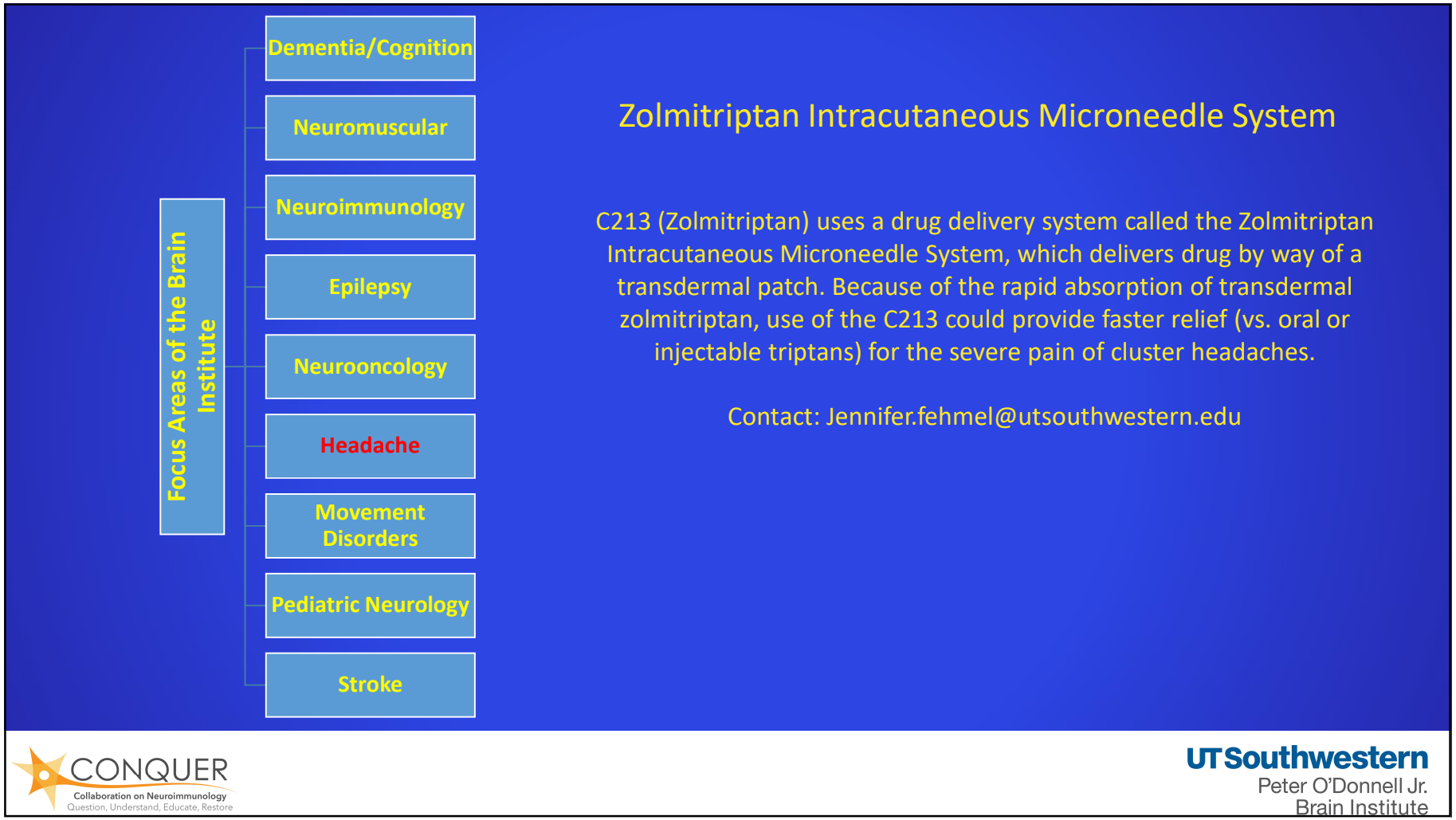
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Zolmitriptan Intracutaneous Microneedle System
C213 (Zolmitriptan) uses a drug delivery system called the Zolmitriptan Intracutaneous Microneedle System, which delivers drug by way of a transdermal patch. Because of the rapid absorption of transdermal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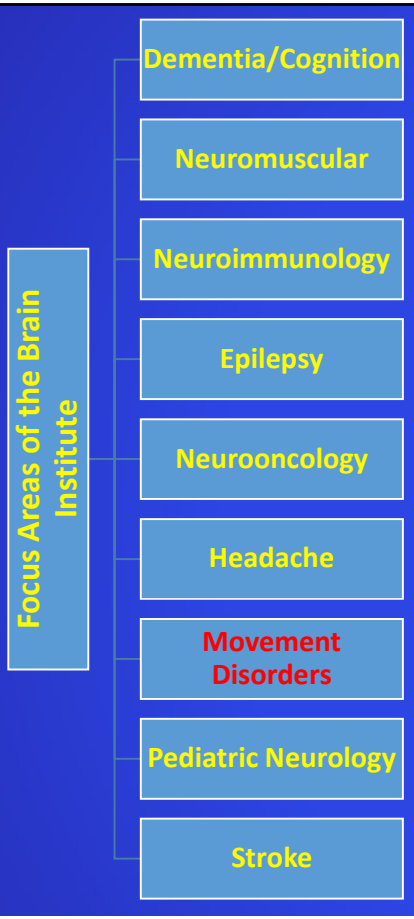

REPAIR PD

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).

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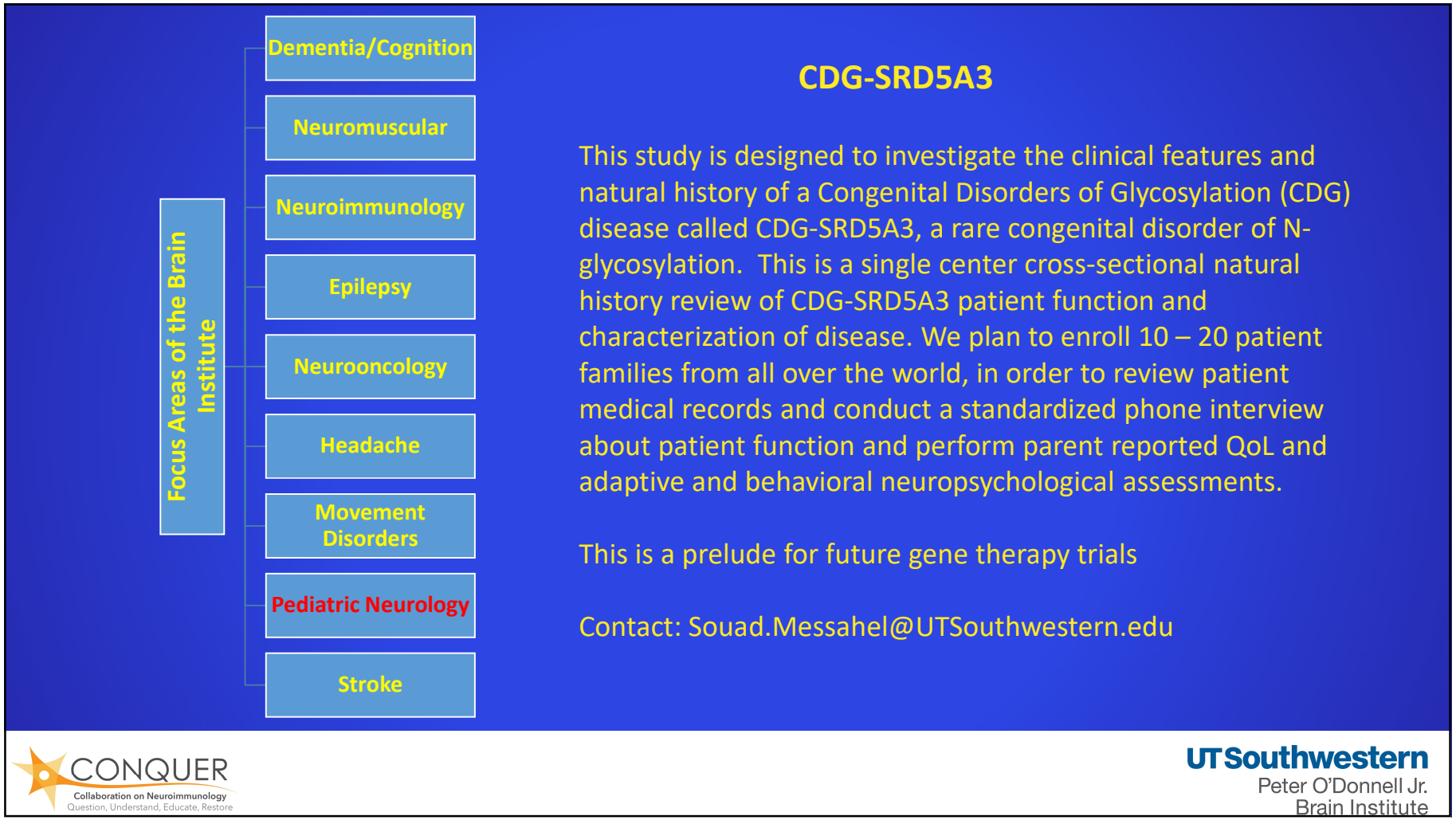
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CDG-SRD5A3
This study is designed to investigate the clinical features and natural history of a Congenital Disorders of Glycosylation (CDG) disease called CDG-SRD5A3, a rare congenital disorder of N-glycosylation. This is a single center cross-sectional 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
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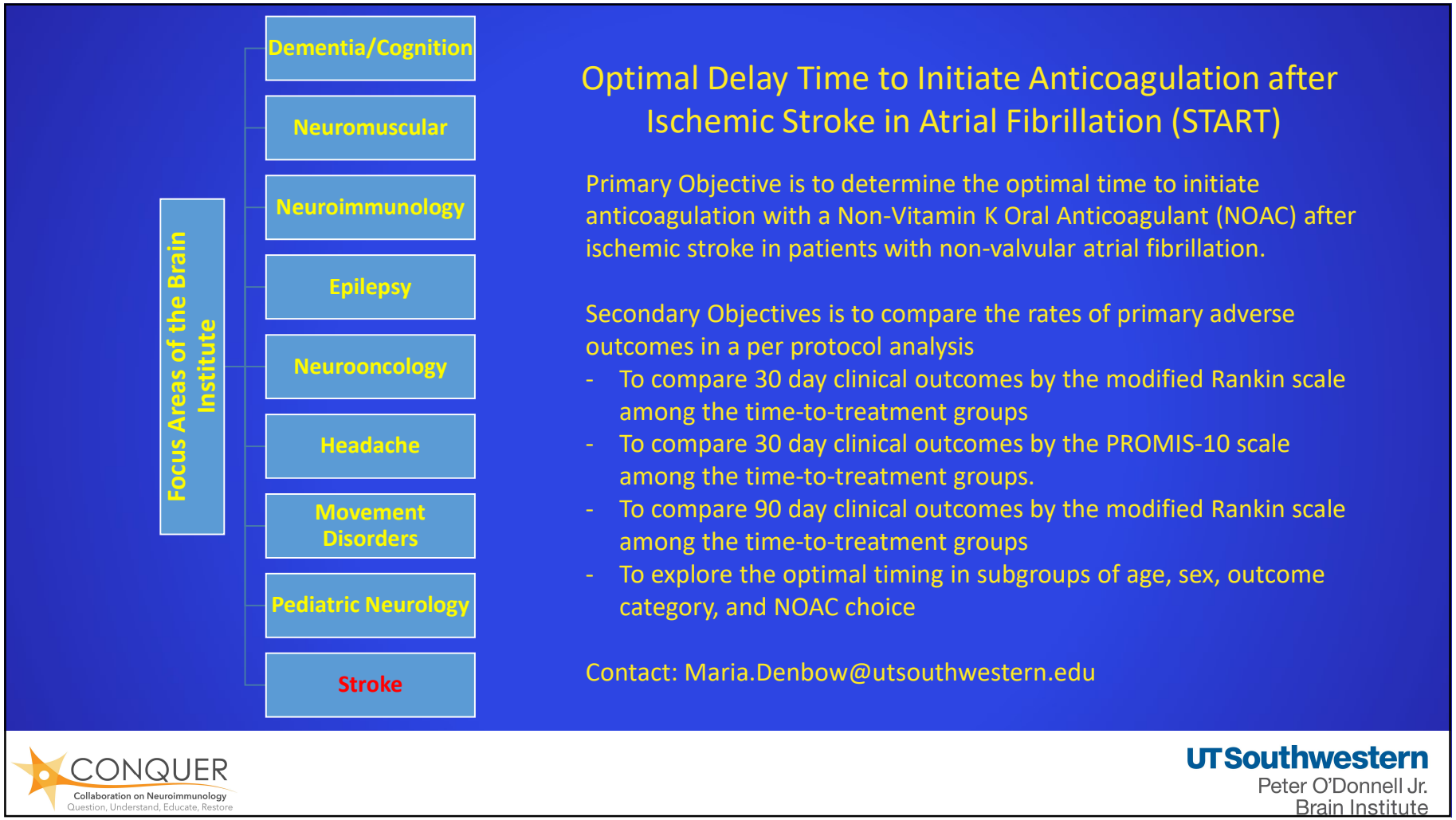
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Optimal Delay Time to Initiate Anticoagulation after Ischemic Stroke in Atrial Fibrillation (START)
Primary Objective is to determine the optimal time to initiate anticoagulation with a Non-Vitamin K Oral Anticoagulant (NOAC) after ischemic stroke 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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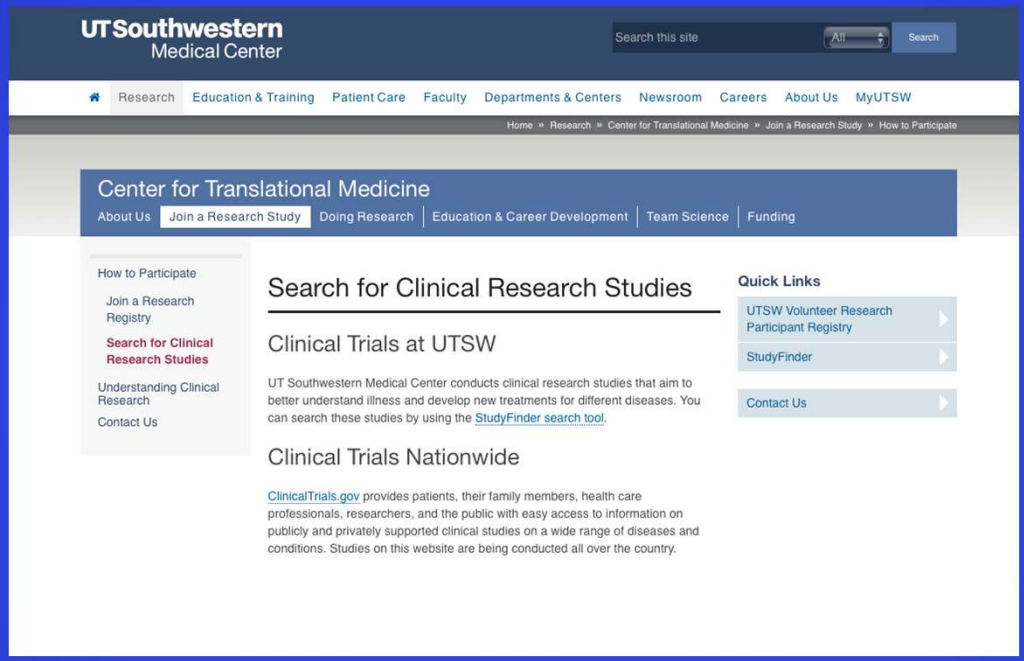
Searching for Trials at UT Southwestern



https://clinicaltrials.utswmed.org

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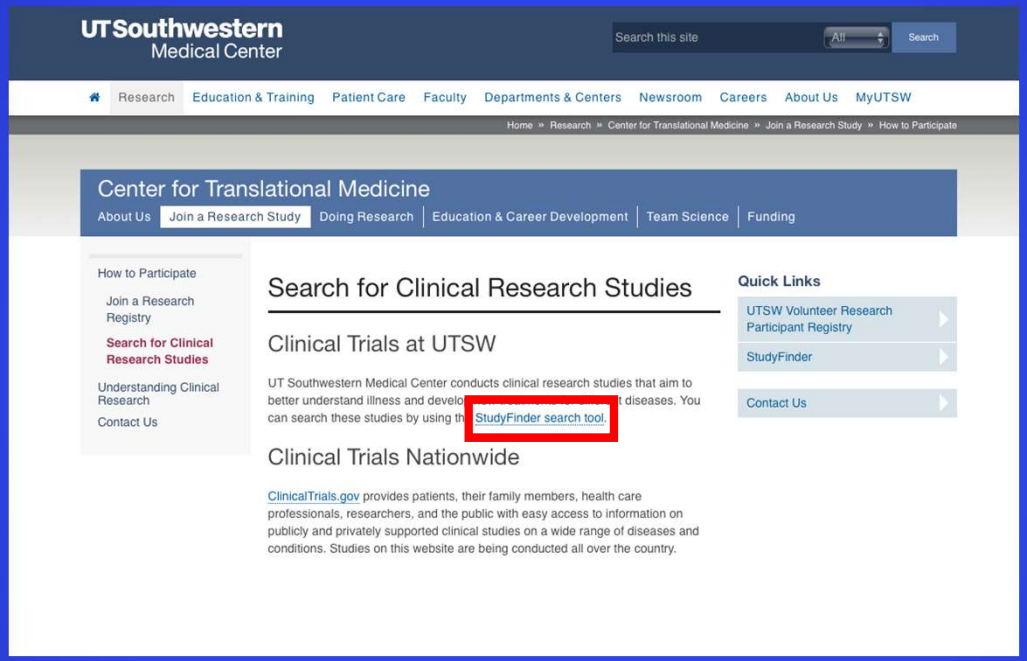

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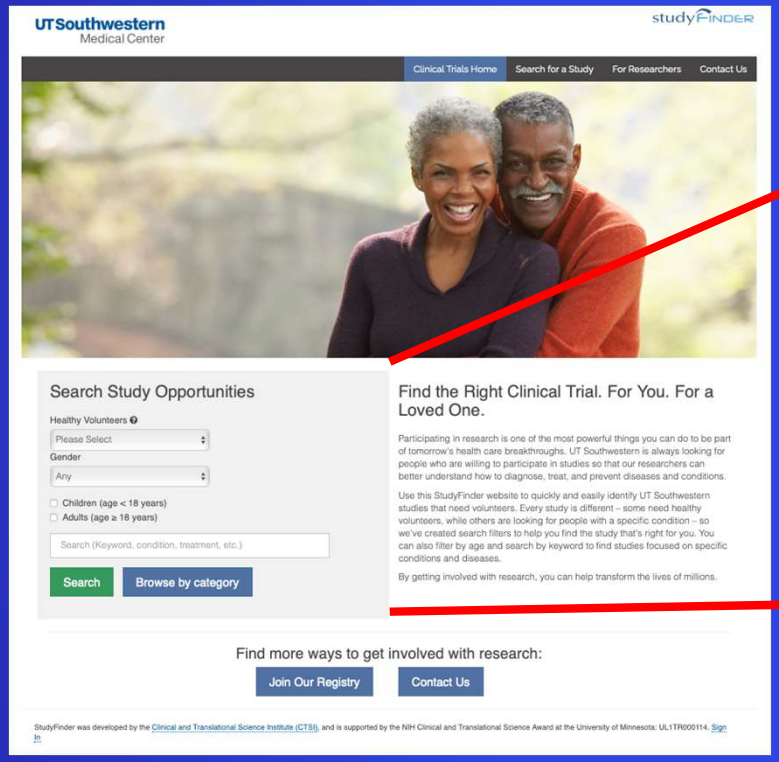

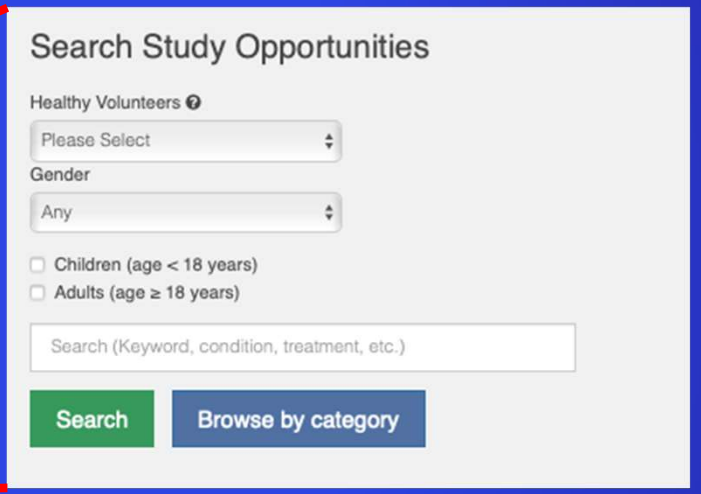

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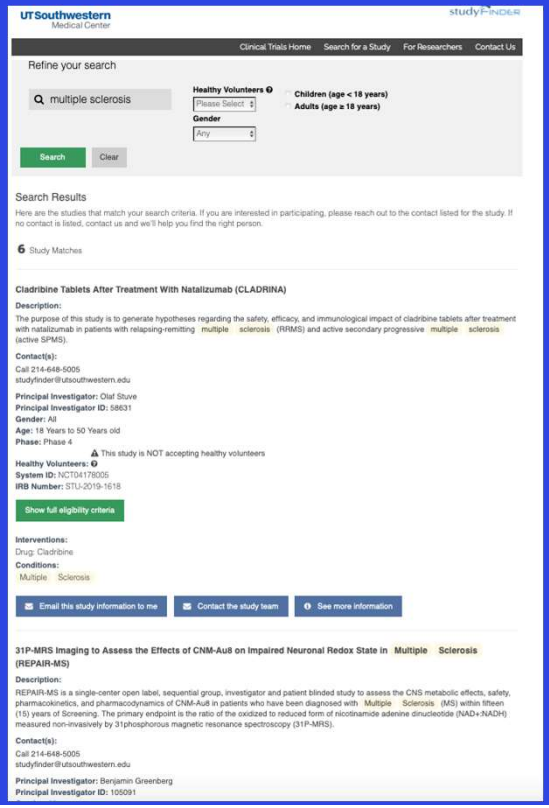

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Other resources

- Clinicaltrials.gov