University of Colorado **Anschutz Medical Campus**

Department of Neurology

Research Catalog | Volume 1, Issue 3

Over the years, we have talked to many individuals who are interested in Neurology Clinical Research opportunities at the University of Colorado Anschutz Medical Campus and who want to be updated on future opportunities—individuals just like you! It was your commitment to research that inspired this annual Neurology Research Catalog — a way to provide updates on our research opportunities to those whom we have seen in clinic and/or have consented into our Neurology Recruitment Database. This catalog contains a list of our currently enrolling research studies, organized by diagnosis, and the key eligibility criteria required for participation in each study. We sincerely value your time and consideration of our research and hope you find this catalog informative.

One of our goals is to offer ways for monolingual Spanish speaking people to participate in our research program. If you are not comfortable participating in English and are fluent in Spanish, please reach out to our Neurology Research Recruitment Team at NeuroResearch@CUAnschutz.edu or 303-724-4644 to learn more about our neurology research opportunities available in Spanish. We hope to continue extending our research program to more communities with additional languages.

Thank you for your passion for research and desire to help others—your consideration and generous participation is imperative to our research. Please reach out to our Neurology Research Recruitment Team by filling out our Neurology Research Interest Web Form (https://neurologyevent.ucdenver.edu/recruitment/welcome) or reach out via email (NeuroResearch@cuanschutz.edu) or phone (303-724-4644). If you are interested in research studies enclosed in this catalog and keep an eye out for future catalog issues.

University of Colorado **Anschutz Medical Campus**

Departamento de Neurología

Catálogo de Investigación | Volumen 1, Número 3

En los últimos años, hemos hablado con muchas personas que están interesadas en las investigaciones del Departamento de Neurología en la Universidad De Colorado Anschutz Medical Campus y que desean en un futuro la oportunidad de participar en estos estudios clínicos – ¡personas como usted!

Ha sido el compromiso de nuestros participantes que inspiro este catálogo semestral – una forma de proporcionar actualizaciones sobre nuestras oportunidades de investigación a aquellos a quienes hemos visto en la clínica y/o han dado su consentimiento para nuestra base de reclutamiento de datos en neurología.

Este catálogo contiene una lista sobre nuestras investigaciones que están reclutando participantes, organizada por diagnóstico, y los criterios de inclusión requeridos para participar en cada estudio. Nosotros valoramos su tiempo y su consideración para nuestros estudios de investigación. Esperamos que este catálogo sea útil para usted.

Una de nuestras metas es ofrecer oportunidad de participación a las personas que hablan español. Si usted no se siente cómodo hablando en inglés y prefiere hablar en español, por favor comuníquese con nosotros al 303-724-4644 Neurology Research Recruitment Team; o envié un correo electrónico a NeuroResearch@CUAnschutz.edu para conocer sobre nuestras oportunidades de investigación disponibles en español. Esperamos continuar nuestro programa de investigación y expandirnos a comunidades de habla hispana.

Gracias por su pasión a la investigación y deseo de ayudar a otros – su consideración y generosa participación es importante e indispensable para el éxito de las investigaciones. Comuníquese con Neurology Research Partners en **NeuroResearch@CUAnschutz.edu o 303-724-4644** si está interesado en los estudios de investigación incluidos en este catálogo y esté atento a futuras ediciones.

Neurology Research Catalog Volume 1, Issue 3

26 March 2024

Information contained in this catalog is accurate as of print date. Please confirm with the study staff for updates on studies that may not be reflected in this catalog, or visit the University of Colorado, Department of Neurology Clinical Research website: https://medschool.cuanschutz.edu/neurology/research

Please note that this catalog only includes basic eligibility requirements. The study staff will discuss the full eligibility criteria and only people who meet all criteria will be enrolled.

The information contained in this catalog is not to be used as medical advice. If you or someone you know is concerned about their brain health, please consult your health care provider.

If you think you may be eligible for one of our studies or if you would like more information, please fill out our Neurology Research Interest Web Form (https://neurologyevent.ucdenver.edu/recruitment/welcome) or contact us at NeuroResearch@CUAnschutz.edu or 303-724-4644.

If you are interested in scheduling an appointment with a neurology provider, please contact our clinic at (720) 848-2080.

Table of Contents

Navigation: click on a link below or move to the indicated page number.

Helpful Definitions

Clinical study: a research study involving human participants that is intended to add to medical knowledge. There are two types of studies: interventional and observational.

- **Interventional study:** a type of clinical study in which participants are assigned to groups that receive one or more interventions/treatments so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes.
- **Observational study:** a type of clinical study where participants are observed for biomedical or health outcomes. Participants may receive interventions, but the investigator does not assign participants to specific interventions.

Clinicaltrials.gov**:** a web-based resource that provides patients, their family members, health care professionals, researchers, and the public with easy access to information on publicly and privately supported clinical studies on a wide range of diseases and conditions.

Eligibility criteria: the key requirements that people who want to participate in a clinical study must meet or the characteristics they must have.

Informed consent: a process used by researchers to communicate to potential and enrolled participants what the trial involves. Participants must understand what will be done in the trial, how the protocol works, what risks/discomforts they may experience, and that participation in the trial is a voluntary decision.

Principal investigator: the person who is responsible for the scientific and technical direction of the study (e.g., a neurologist or PhD-level researcher).

Placebo: an inactive substance or treatment that looks the same as and is given in the same way as the active intervention/treatment being studied.

Masked: clinical trial design strategy in which one or more parties involved in the trial, such as the investigator or participants, do not know which participants have been assigned to which intervention. Types of masking include: open-label, single -blind masking, and double-blind masking.

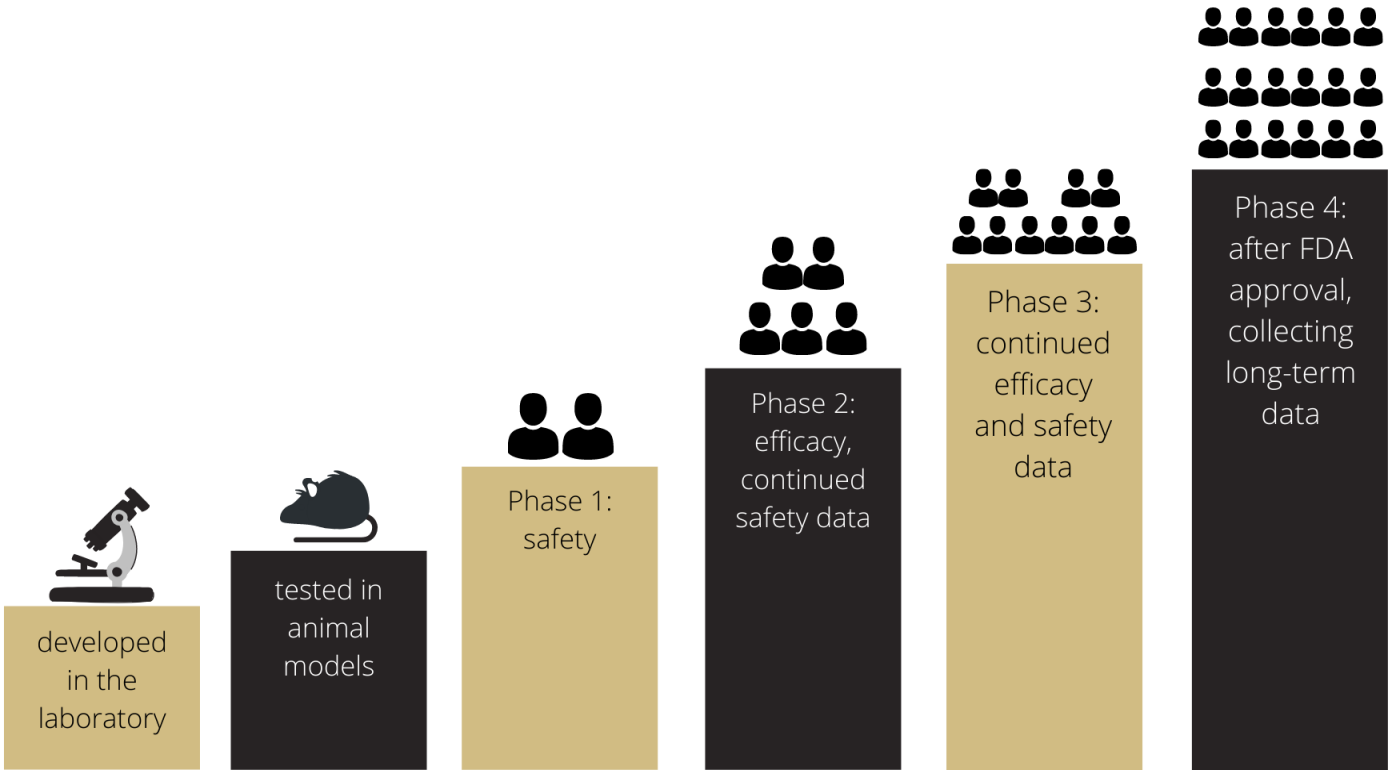
Open-label extension: a trial that follows an original randomized clinical trial. In an open-label extension study, all participants receive the study drug (rather than placebo) and additional safety data is collected. Typically only open to people who participated in the randomized trial.

Helpful Definitions (cont.)

Randomized: a type of trial where participants are allocated to a study group (e.g. placebo or active treatment) by chance.

Phase: the stage of a clinical trial studying a drug or biological product, based on definitions developed by the U.S. Food and Drug Administration (FDA). The phase is based on the study's objective, the number of participants, and other characteristics.

- **Phase 1**: clinical trials that focus on the safety of a drug. They are usually conducted with healthy volunteers and involve a small number of participants.
- **Phase 2**: clinical trials that gather preliminary data on whether a drug works in people who have a certain condition/disease (that is, the drug's effectiveness).
- **Phase 3:** clinical trials that gather more information about a drug's safety and effectiveness by studying different populations, different dosages, and by using the drug in combination with other drugs.
- **Phase 4**: clinical trials, occurring after the FDA has approved a drug for marketing, to gather additional information about a drug's safety, efficacy, or optimal use.



Epilepsy

The Epilepsy Subspecialty Research at the University of Colorado is a leading center for innovative research and exceptional care for patients with epilepsy and related brain disorders. Through innovative clinical research, including first-in-human studies, we aim to develop and test novel treatments to improve patient outcomes. Our research efforts focus on investigating the underlying mechanisms of epilepsy, exploring new therapeutic approaches, and enhancing the quality of life for those living with epilepsy. Our goal is to discover effective diagnostics, treatments, and cures for epilepsy and related disorders.

	Key Eligibility Requirements
Focal Epilepsy	
RISE 2 (23-1919) *Investigator*: Naveed Chaudhry, MD *Purpose*: to see the effectiveness and safety of an investigational new drug as a possible treatment for focal seizures for patients who are taking Anti-Seizure Medications (ASMs) and still experience seizures. *Intervention: 25 mg investigational drug (33% chance), 50 mg investigational drug (33% chance), or placebo (33% chance).* *Timeline*: Screening and Observational Phase: 8 weeks with 1 screening visit (in-person visit to the study site), Double-Blind Phase: 12 weeks with 5 study visits, and Follow-Up Phase: 2 weeks after the last day you take BHV-7000/placebo with 1 study visit. *ClinicalTrials.gov Identifier:* NCT06132893	• Age: 18-75 years of age at time of consent • Diagnosis: Focal Onset Epilepsy at least 1 year prior to screening visit • Ability to keep accurate seizure diaries and miss no more than 4 entries
X-TOLE2 (23-0395) *Investigator*: Nitish Harid, MD *Purpose:* to determine if XEN1101 can reduce Focal-Onset Seizure frequency and if it is safe to use. *Intervention:* XEN1101 (66% chance) or placebo (33% chance). *Timeline:* Screening/Baseline Period (up to 9.5 weeks), Double-blind Study Treatment Period (up to 12 weeks), and Post-Study Treatment Follow-Up Period (up to 8 weeks). Once you complete the Double-blind Study Treatment Period, you may be eligible to participate in the Open-label Extension (OLE) Study. *ClinicalTrials.gov Identifier:* NCT05614063	• Age: ≥18 • Diagnosis: Focal Epilepsy for ≥2 years • Weight: BMI ≤40 kg/m2 at Visit 1

Epilepsy (continued)

	Key Eligibility Requirements
Idiopathic Generalized Epilepsy (IGE)	
NAUTILUS (22-0838) *Investigator*: Naveed Chaudhry, MD *Purpose*: to find out if thalamic stimulation with NeuroPace RNS® System is safe and effective (works well) as an additional treatment in reducing the frequency of primarily generalized seizures in individuals 12 years of age or older with drug resistant Idiopathic Generalized Epilepsy (IGE). *Intervention:* NeuroPace RNS® System implantation (50% chance) or sham implantation (50% chance). *Timeline*: up to 14 in person visits over up to 2 years. *ClinicalTrials.gov Identifier:* NCT05147571	• Age: 12+ years old • Diagnosis: Idiopathic Generalized Epilepsy (IGE) • Failed treatment with 2+ antiseizure medications • Able to maintain daily electronic diary
Primary Generalized Tonic-Clonic Seizure (PGTCS)	
X-ACKT (23-0396) *Investigator*: Naveed Chaudhry, MD *Purpose*: to determine if XEN1101 can reduce Primary Generalized Tonic-Clonic Seizure (PGTCS) frequency and if it is safe to use. *Intervention:* XEN1101 (50% chance) or placebo (50% chance). *Timeline*: Screening/Baseline Period (up to 9.5 weeks), Double-blind Study Treatment Period (up to 12 weeks), and Post-Study Treatment Follow-Up Period (up to 8 weeks). Once you complete the Double-blind Study Treatment Period, you may be eligible to participate in the Open-label Extension (OLE) Study. *ClinicalTrials.gov Identifier:* NCT05667142	• Age: ≥18 • Diagnosis: probable or possible Primary Generalized Tonic-Clonic Seizure (PGTCS) (with or without other subtypes of generalized seizures) in the setting of generalized epilepsy for ≥2 years • Weight: BMI ≤40 kg/m2 at Visit 1
Temporal Lobe Epilepsy (TLE)	
NEURONA (21-3486) *Investigator*: Lesley Kaye, MD *Purpose*: to evaluate the safety and efficacy of a surgical cell therapy called NRTX-1001 in participants with drug resistant Mesial Temporal Lobe Epilepsy (MTLE). Additionally, to see if NRTX-1001 can reduce number of seizures. *Intervention:* there are two different stages of this study, described below. If eligible, you would participate in one of the stages. 1. NRTX-1001 2. NRTX-1001 (66% chance) or sham surgery (33% chance) *Timeline*: 13 visits over 24 months, then long-term follow up for 13 years (for both stages). *ClinicalTrials.gov Identifier:* NCT05135091	• Age: 18-65 years old • Diagnosis: Mesial Temporal Lobe Epilepsy (MTLE). • Seizure frequency average 2 or more per 28 day period in the previous 6 months • Has failed to achieve seizure control despite trials of at least 2 anti-seizure drugs

Headache/Migraine

At the University of Colorado Anschutz Medical Campus, we're dedicated to advancing headache and pain management through groundbreaking research and clinical trials. Collaborating with top experts, our interdisciplinary team explores innovative treatments, personalized care options, and robust support systems for patients and caregivers. By participating in our studies, you contribute to shaping the future of headache and pain management, empowering individuals with effective solutions. Join us in our mission to make a meaningful difference in the lives of those affected by headaches and pain.

Chronic Migraine	***Key Eligibility Requirements***
C-BEOND (23-1244) *Investigator:* Danielle Wilhour, MD *Purpose:* to test how well Dysport® works and how safe it is compared with placebo (dummy drug) in preventing or decreasing migraines. *Intervention:* participant will receive for 4 cycles with either one of the two doses of Dysport®, or with 2 placebo cycles followed by 2 cycles with one of the two doses of Dysport®, depending on your assigned study treatment arm. *Timeline:* Screening Period: 6-12 weeks and Study Treatment Period: 48 weeks. *ClinicalTrials.gov Identifier:* NCT06047444	• Age: ≥18 years • Diagnosis: Chronic Migraine for more than 12 months • Migraine onset occurred when participant was <50 years of age

Healthy Volunteers

Anschutz

These studies are for people with no known neurological conditions. Healthy volunteer studies provide crucial data for our researchers by creating a comparison group for neurological conditions and by helping us learn more about how the brain typically functions when unaffected by disease. These studies are a great opportunity for people with no neurological conditions to contribute to the field of neurology research.

	Key Eligibility Requirements
First-degree Relatives of People with Multiple Sclerosis (MS)	
DREAMS (19-0393) *Investigator:* Teri Schreiner, MD, MPH *Purpose*: to learn more about the risk factors for and causes of MS by studying children who are first degree relatives of people with MS. *Timeline*: a single 3-4 hour study visit (includes MRI and blood draw).	• Age: 10-17 years old • Have parent or sibling with MS • No diagnosis of MS or early symptoms of MS
RISEMS (17-1884) *Investigator*: Enrique Alvarez, MD, PhD and John Corboy, MD *Purpose*: to learn more about the risk factors for and causes of MS by studying first degree relatives of people with MS. *Timeline*: a single 2-3 hour study visit (includes MRI and blood draw). *ClinicalTrials.gov Identifier:* NCT03586986	• Age: 18-30 years old • Have a parent, sibling or child with MS • No diagnosis of MS or early symptoms of MS
Movement Disorders	
Cytokine Observational Study (18-1356) *Investigator:* Amy Amara, MD, PhD *Purpose:* to learn more about the level of inflammatory and other markers in the blood of patients with Parkinson's Disease (PD), Essential Tremor (ET), and Healthy Volunteers. *Timeline:* one time blood draw.	• Have NOT been diagnosed with Parkinson's Disease (PD) • Age: 60-75 years old
Michael J. Fox Foundation PPMI 2.0 (20-1204) *Investigator:* Michelle Fullard, MD, MSCE *Purpose:* to continue to obtain information from people with and without Parkinson's disease (PD) so that researchers may better understand how PD progresses, in order to inform better treatments. *Timeline:* 2 visits annually for up to 7 years. *ClinicalTrials.gov Identifier:* NCT04477785	• Have NOT been diagnosed with PD • Do NOT have a first degree relative with PD • Age: 30+ years old OR • Have NOT been diagnosed with PD • Have a first degree relative with PD • Age: 60+ years old

Healthy Volunteers (cont.)

Neurobehavior

Facial Expressions Study (17-0599)

Investigator: Peter Pressman, MD

Purpose: to understand how the brain makes different facial expressions using high speed videography, learn more about how neurological disorders may impact a person's facial movements and expressions, and develop the groundwork for a diagnostic tool that would detect differences between a person's facial movements/expressions and their emotions.

Timeline: one study visit that will last approximately one hour.

CUACC Website: https://medschool.cuanschutz.edu/alzheimer/get-involved/open-studies/facial-movements-study

- Age: 18-75 years old
- Diagnosis: Mild Cognitive Impairment (MCI) or dementia or have NOT been diagnosed with a memory disorder
- Are right handed

Neuromuscular

DN (19-3004)

Study Title: Participants Needed for Research Study About Diabetes and Neuropathy.

Investigator: Vera Fridman, MD

Purpose: to learn more about the underlying causes of diabetic neuropathy by looking for the presence of abnormal molecules in the blood and skin and comparing them in people with and without Type 2 Diabetes.

Procedures: blood draw, skin biopsy, neurological and physical exam.

Timeline: 2 study visits which will occur within 30 days of each other.

- Age: 45-65 years old
- Have NOT been diagnosed with Type 2 Diabetes (T2D)

DOMYA (23-1307)

Investigator: Thomas Ragole, MD

Purpose: to assess the effectiveness and safety of an investigational digital tool called ME&MG, which allows patients with generalized Myasthenia Gravis (gMG) to self-monitor their symptoms.

Device: ME&MG smartphone application (investigational software as a medical device).

Timeline: Screening/Inclusion visit (Day 0) and an At Home Digital Test (Day 1).

ClinicalTrials.gov Identifier: NCT05564936

- Age: 18 years to 60 years
- Owning and able to use a personal smartphone which software version is above 14 for IOS and 8 for Android

Movement Disorders

The University of Colorado Movement Disorders Center (MDC) is a nationally recognized center for specialty care for those with movement disorders. The center is recognized as a Huntington's Disease Society of America Center of Excellence and a Parkinson's Foundation Center of Excellence. The mission of the MDC is to excel in providing world-class clinical care, conduct cutting-edge research, serve as a leader in educating professionals, and serve as a regional leader in community involvement.

	Key Eligibility Requirements
Ataxia	
UNIFAI (23-1196) *Investigator*: Trevor Hawkins, MD *Purpose:* to collect data on participants to understand all the ways Friedreich Ataxia (FA) affects the participant and their body, the symptoms of FA and how those symptoms change or progress over time. *Timeline:* participant will perform a number of assessments, which can be completed in a few hours during one visit, every year. Because this study would like to capture as much information as possible about FA, the study does not currently have an end date, and your participation could be over 20 years. *ClinicalTrials.gov Identifier:* NCT06016946	• Age: all ages • Diagnosis: Friedreich Ataxia (FA)
Dystonia	
Dystonia Coalition Projects-3 (20-0290) *Investigator:* Jeanne Feuerstein, MD *Purpose:* this research includes four related projects each having different but overlapping goals: (1) learn about how dystonia may progress over time and what causes dystonia (Natural History project), (2) develop tools to measure the severity of symptoms objectively (Objective Measures project), (3) create a collection of blood samples for analysis (Biobank project), and (4) develop an app to monitor symptom severity (optional Patient-Centered Outcomes project) *Website:* https://rarediseasesnetwork.org/cms/dystonia/Get-Involved/Research-Studies/6305-Dystonia-Coalition-Projects-3-CDP3	• Age: 18+ years old • Diagnosis: any isolated focal, segmental, multifocal, generalized, or hemi-dystonia ◊ For optional Patient-Centered Outcomes Project: receiving Botulinum neurotoxin (BoNT) treatments as part of regular treatment plan

Movement Disorders (cont.)

Huntington's Disease (HD)

Music Therapy Clinical Trial (16-2308)

Investigator: Isabelle Buard, PhD

Purpose: to learn more about the brain function related to fine motor skills in individuals with Huntington's Disease (HD).

Timeline: 3-4 study visits over the course of 7 weeks and 3 Neurologic Music Therapy sessions per week for 5 weeks.

Intervention: Neurologic Music Therapy (can be done at the office of a music therapist, virtually, or in home depending on location).

ClinicalTrials.gov Identifier: NCT03049033

- Diagnosis: Huntington's Disease (HD)
- Age: 30-85 years old
- Have some difficulties with fine motor skills (such as buttoning, cutting your food, or typing on a keyboard)

Multiple System Atrophy-Parkinsonian subtype (MSA-P)

Brain Imaging Research Study for Multiple System Atrophy-Parkinsonian subtype (MSA-P) (22-1462)

Investigator: Drew Kern, MD, MS

Purpose: to learn more about whether a new magnetic resonance imaging (MRI) method may reveal differences between patients with the Parkinsonian Type of Multiple System Atrophy (MSA-P) and patients with Parkinson's Disease (PD).

Assessments: clinical exam and MRI scan.

Timeline: 1 visit at University of Colorado Hospital, about 30 minutes.

- Age: 40-80 years old
- Diagnosis: meets diagnostic criteria for probable MSA-P diagnosis, as defined by the American Academy of Neurology and National Institute of Health MSA diagnosis guidelines

Parkinson's Disease (PD)

BIAL (23-0328)

Investigator: Emily Forbes, DO

Purpose: to investigate the effects, safety, and tolerability (whether side effects can be handled by a subject) of BIA 28-6156. This study is also meant to find out if the effects, safety, and tolerability are different in people with different forms of the GBA1 gene, which is a genetic characteristic that may be related to a higher risk of getting Parkinson's Disease (PD).

Treatment:
- Part A: GBA1 and LRRK2 genetic testing.
- Part B: study drug administration: either BIA 28-6156, in 1 of 2 doses (10mg or 60mg), or placebo.

Timeline:
- Part A: 1 in-person, 2-hour visit and 1 phone/video or in-person visit depending on genetic testing results. Total duration of Part A: ~5 weeks.
- Part B: 9 in-person visits and 2 phone/video visits. Total duration of Part B: ~1 year and 8 months.

ClinicalTrials.gov Identifier: NCT05819359

- Age: ≥35 and ≤80 years old
- Diagnosis: Parkinson's Disease for at least 1 year and for no longer than 7 years before initiation of screening

Movement Disorders (cont.)

Parkinson's Disease (PD) (continued)

BlueRock PD Diary (22-1234)

Investigator: Alexander Baumgartner, MD

Purpose: to study the impact of frequency of assessments on your changes and variability over time, reliability, and compliance for a Parkinson's disease diary, a 24-hour diary pertaining to your PD symptoms. This study is also intended to characterize the stability of your disease status, motor function, quality of life, and use of medications, without making any specific change to the treatment(s) selected by your doctor as a standard of care.

Timeline: 7 in-person visits over 24 months.

ClinicalTrials.gov Identifier: NCT05363046

- Age: 39-70 years old
- Diagnosis: Parkinson's Disease for 3-18 years
- Symptoms not adequately controlled with medications

Ceregate (21-5060)

Investigator: Drew Kern, MD, MS

Purpose: to find out if CereGate therapy reduces freezing of gait in participants with Parkinson's Disease (PD) with a pre-existing Gevia™ implanted deep brain stimulation (DBS) system.

Treatment: your existing Gevia DBS system is programmed with an additional stimulation program for you to use when walking. You continue to use your existing DBS program and existing medications. There are no new medications, surgeries or invasive procedures.

Timeline: 5 in-person visits over approximately 100 days.

ClinicalTrials.gov Identifier: NCT05292794

- Diagnosis: Parkinson's Disease (PD)
- Age: 21-75 years old
- Currently have implanted Gevia™ DBS system
- Currently being treated with PD medications
- Currently have freezing of gait

ExCITES-PD (22-1685)

Investigator: Amy Amara, MD, PhD

Purpose: to examine the impact of exercise on sleep and cognition in Parkinson's Disease (PD).

Procedures: 12-24 weeks of exercise rehabilitation, testing such as brain scans, sleep studies and questionnaires.

Timeline: 33 total weeks in study.

Study flyer: https://www.ucdenver.edu/docs/librariesprovider61/clinical-research-pdfs/excitespd_flyer-no-tabs_12-17-22_approved.pdf

Parkinson's Disease (PD):
- Age: 45 or older
- Diagnosis: Parkinson's Disease (PD)
- No contraindications to exercise

Study Partner:
- Age: 18 or older
- Spends at least 10 or more hours per week with the PD subject

Movement Disorders (cont.)

Parkinson's Disease (PD) (continued)

Jazz PD (23-0784)

Investigator: Jeanne Feuerstein, MD

Purpose: to see if a test drug not yet approved for market, named suvecaltamide, will help in the treatment of moderate to severe residual tremor in people with Parkinson's Disease (PD) and how safe it is to use.

Intervention: suvecaltamide (50% chance) or placebo (50% chance).

Timeline: Screening Period (up to 4 weeks), Baseline Visit (up to 5 hours), Dose Titration and Optimization Period (5 weeks), Maintenance Period (12 weeks), Safety Follow-up Period (2 weeks).

ClinicalTrials.gov Identifier: NCT05642442

- Age: 40-85 years (inclusive)
- Diagnosis: Parkinson's Disease (PD)
- Participants must also be on a stable dosing regimen of their permitted PD and/or other tremor medications for the treatment of motor symptoms for at least 6 weeks prior to Screening and do not anticipate the need to make any changes for the duration of the study.

LUMA (22-0285)

Investigator: Emily Forbes, DO

Purpose: to look at whether the study drug (BIIB122) works in people with early-stage Parkinson's Disease (PD) , how safe it is in terms of medical problems known as "side effects", and how the body handles taking it (tolerability).

Treatment: BIIB122 (50% chance) or placebo (50% chance).

Timeline: 20 in-person visits during a period of up to 152 weeks.

ClinicalTrials.gov Identifier: NCT05348785

- Age: 30-80 years old
- Diagnosis: Parkinson's Disease (PD) (diagnosis received within the past 2 years and at least 30 years old at time of diagnosis)
- Never treated with PD medications OR treated with PD medications for less than 1 year

Michael J. Fox Foundation PPMI 2.0 (20-1204)

Investigator: Michelle Fullard, MD, MSCE

Purpose: to continue to obtain information from people with and without Parkinson's Disease (PD) so that researchers may better understand how PD progresses, in order to inform better treatments.

Timeline: 2 visits annually for up to 7 years.

ClinicalTrials.gov Identifier: NCT04477785

- Diagnosis: Parkinson's Disease (PD) for ≤ 2 years
- Age: 30+ years old
- NOT currently being treated with PD medications or expected to require PD medications within 6 months

Movement Disorders (cont.)

Parkinson's Disease (PD) (continued)

Music Therapy Clinical Trial (16-2308)

Investigator: Isabelle Buard, PhD

Purpose: to learn more about the brain function related to fine motor skills in individuals with Parkinson's Disease (PD).

Timeline: 3-4 study visits over the course of 7 weeks and 3 sessions per week for 5 weeks for either music therapy intervention, or occupational therapy (OT) intervention, or no intervention (location options available for interventions).

Intervention: (1) musical intervention group A, (2) musical intervention group B, (3) standard of care OT, or (4) a waitlist group for 5 weeks.

ClinicalTrials.gov Identifier: NCT03049033

- Diagnosis: Parkinson's Disease (PD)
- Age: 45-85 years old
- Have some difficulties with fine motor skills (such as buttoning, cutting your food, or typing on a keyboard)

PD GENEration: Mapping the Future of Parkinson's Disease

Investigator: Jeanne Feuerstein, MD

Purpose: a Parkinson's Foundation initiative to help scientists advance their understanding of PD by offering genetic testing and genetic counseling at no cost for people with Parkinson's Disease (PD).

Assessment: one-time, home-delivered genetic testing kit.

Study flyer: https://ucdenver.edu/docs/librariesprovider61/clinical-research-pdfs/pdgene_general-flyer_v1_english_02dec2022.pdf

ClinicalTrials.gov Identifier: NCT04994015

- Age: 18 and older
- Diagnosis: meet Movement Disorder Society (MDS) Clinical Diagnostic Criteria for Parkinson's Disease (PD): probable diagnosis

Resistance Training Study (22-2333)

Investigator: Mark Mañago, DPT, PhD, PT, NCS

Purpose: this research study proposes to investigate a strengthening program using blood flow restriction to improve strength and mobility in people Parkinson Disease (PD) who have walking limitations.

Timeline: participants must be willing and able to participate in twice weekly intervention for 8 weeks (in-person), and participate in strength and mobility assessments before and after the exercise program.

Procedures: strength training exercises using blood flow restriction performed in-person 2x/ week under supervision of physical therapist for 8 weeks.

Study flyer: https://www.ucdenver.edu/docs/librariesprovider61/clinical-research-pdfs/bfr-pd-ad.pdf

- People with Parkinson's Disease (PD) who have at least some difficulties with walking, Hoehn and Yahr Stage II or higher

Movement Disorders (cont.)

Anschutz

Parkinson's Disease (PD) (continued)

SHINE (22-1962)

Investigator: Trevor Hawkins, MD

Purpose: to determine if investigational treatment, JM-010, is safe and effective in the treatment of levodopa-induced dyskinesia.

Treatment:
- Part 1: receive either one of 3 dose combinations of one component of JM-010 (active drug) and 1 placebo, or 2 placebos.
- Part 2: receive either one of 2 dose combinations JM-010 (active drug) and 1 placebo, one component of JM-010 and 1 placebo, or 2 placebos.

Timeline:
- Part 1: 5-6 in-person visits during a period of 6 to 11 weeks.
- Part 2: 7 in-person visits during a period of 15 to 20 weeks.

ClinicalTrials.gov Identifier: NCT04377945

- Age: 18-85 years old
- Diagnosis: Idiopathic Parkinson's Disease (PD)
- Experienced dyskinesia over a period of at least 3 months prior to Screening Visit

Sleep Research Study (22-1244)

Investigator: Jeanne Feuerstein, MD

Purpose: to learn more about abnormal sleep in Parkinson's and Post-Traumatic Stress Disorder (PTSD).

Timeline: 1 in-person study visit to the Anschutz campus and 7 days of wearing a sleep and motion monitor.

Study flyer: https://ucdenver.edu/docs/librariesprovider61/clinical-research-pdfs/parkinson's-ptsd-flyer_31oct2022-approved.pdf

- Age: 35-80 years old
- Diagnosis: Post-Traumatic Stress Disorder (PTSD) OR Parkinsonism
- Diagnosis: REM sleep behavior disorder (i.e., acting out dreams in your sleep)

SPARX3 (20-1854)

Investigator: Cory Christiansen, PT, PhD

Purpose: to learn more about the effects of aerobic exercise on people with Parkinson's Disease (PD) who have not yet started medication for their PD.

Intervention: moderate to high intensity exercise on a treadmill

Timeline: exercise 4x/week with periodic study visits for 24 months.

ClinicalTrials.gov Identifier: NCT04284436

- Diagnosis: PD ≤ 3 years
- Age: 40-80 years old
- NOT currently being treated with Parkinson's Disease (PD) medications or expected to require PD medications within 6 months

Movement Disorders (cont.)

Parkinson's Disease (PD) (continued)

Swallow Strength Study

Investigator: Elizabeth Cuadrado, MS

Purpose: a new study is looking at a device that would strengthen the muscles of your mouth to make eating and drinking easier for individuals with Parkinson's Disease (PD).

Study flyer: https://www.ucdenver.edu/docs/librariesprovider61/clinical-research-pdfs/swallow-strenght-19-1850-cosd-flier-without-tabs-8-19-2022.pdf

For more information, please call 303-724-8335 or email (preferred) quinlyn.axelson@cuanschutz.edu.

- 18 years or older
- willing to go to Anschutz branch of University of Colorado for 5 visits
- Willing to exercise the muscles of your mouth outside of study visits

Trial of Parkinson's and Zoledronic Acid (TOPAZ)

Investigator: Michelle Fullard, MD, MSCE

Purpose: to learn if a medicine called Zoledronic Acid (ZA) can reduce fractures and deaths in people with Parkinson's Disease (PD) or parkinsonism.

Intervention: one-time dose of the study treatment (either ZA or a placebo).

Timeline: 1 in-person exam with a nurse at home and a study check-in (by email, mail, or phone) every 4 months to ask if you have any fractures for 2-5 years.

Study flyer: https://www.ucdenver.edu/docs/librariesprovider61/clinical-research-pdfs/topaz-postcard_v2-1_8-18-20_u-of-colorado-denver-(colorado).pdf

ClinicalTrials.gov Identifier: NCT03924414

- Age: 60 years or older
- Diagnosis: Parkinson's Disease (PD) or parkinsonism
- Have not had a hip fracture

Neurobehavior

The **University of Colorado Alzheimer's and Cognition Center (CUACC)** is part of the School of Medicine, Department of Neurology. Their mission is to discover effective early diagnostics, preventions, treatments, and ultimately cures for Alzheimer's disease and related dementias, through research and clinical care. They believe there is as much to learn from individuals who are healthy as they do from individuals with Alzheimer's disease.

	Key Eligibility Requirements
Alzheimer's Disease (AD)	
Conversational Speech Analysis (CSA) (18-0456) *Investigator:* Peter Pressman, MD *Purpose:* to learn more about how speech changes over time in adult populations, understand how those changes reflect changes in cognition, and develop new ways of detecting MCI and dementia using everyday speech. *Timeline:* two study visits, one year apart. *Study flyer: https://www.ucdenver.edu/docs/librariesprovider61/clinical-research-pdfs/csa-a.pdf*	• Age: 40-95 years old • Diagnosis: Mild cognitive impairment (MCI) or dementia *OR* • Have NOT been diagnosed with a memory disorder
Facial Expressions Study (17-0599) *Investigator:* Peter Pressman, MD *Purpose:* to understand how the brain makes different facial expressions using high speed videography, learn more about how neurological disorders may impact a person's facial movements and expressions, and develop the groundwork for a diagnostic tool that would detect differences between a person's facial movements/ expressions and their emotions. *Timeline:* one study visit that will last approximately one hour. *CUACC Website:* https://medschool.cuanschutz.edu/alzheimer/get-involved/open-studies/facial-movements-study	• Age: 18-75 years old • Diagnosis: Mild Cognitive Impairment (MCI) or dementia or have NOT been diagnosed with a memory disorder • Are right handed

Neurobehavior (continued)

Anschutz

Alzheimer's Disease (AD) (continued)

SESAD (19-2727)

Investigator: Peter Pressman, MD

Purpose: to learn more about the safety and effectiveness of a drug called sargramostim for improving cognitive function and memory in people with Alzheimer's Disease (AD).

Intervention: if determined to be eligible during screening, you will be assigned to one of two arms of the study: 1) receives study medication; 2) receives placebo (a pill or a liquid that looks like medicine but is not real).

Timeline: after initial screenings at the CU Anschutz campus in Aurora, CO, participants will be able to have weekly home nursing visits to provide supplies and draw blood. Occasional visits to campus during the study will be required for procedures that cannot be done at home. Including screening and follow-up, study participation last up to 9-1/2 months with up to 55 visits.

- Screening period will last up to 8 weeks
- Treatment period will last 24 weeks
- Follow-up visit occurs 45 days after end of treatment

Compensation: study related care and medication at no cost.

Study Flyer: https://www.ucdenver.edu/docs/librariesprovider61/clinical-research-pdfs/sargramostim-ad-26sep2023_approved.pdf

ClinicalTrials.gov Identifier: NCT04902703

Key Eligibility Requirements

- Age: between 60-85 years old
- Diagnosis: mild-to-moderate Alzheimer's Disease (AD)
- Have a study partner with whom you at least 12 hours of contact a week, is willing to attend scheduled visits, can report changes in your thinking and memory, and is willing to be trained to give daily injections of study drug
- Willing to have testing of sample collected from a lumbar puncture/ spinal tap or an amyloid PET scan to confirm diagnosis of Alzheimer's disease
- Must not have a first degree relative diagnosed with AD before 55 years of age

Neurobehavior (continued)

Anschutz

	Key Eligibility Requirements
Frontotemporal Dementia (FTD)	
ALLFTD (21-2833) *Investigator:* Peter Pressman, MD *Purpose:* the ARTFL LEFFTDS Longitudinal Frontotemporal Dementia (ALLFTD) study aims to evaluate sporadic (s-) and familial (f-) frontotemporal lobar degeneration (FTLD) patients and asymptomatic family members of f-FTLD patients, characterizing the cohorts longitudinally and informing clinical trial design (Biofluid-Focused and Longitudinal arms available). *ALLFTD Biofluid Timeline:* one-time visit with questionnaires, neurological exam, blood drawn, and optional lumbar puncture. *ALLFTD Longitudinal Timeline:* annual visit to the clinic, each lasting 2–3 days, with questionnaires, thinking and memory questions, neurological exam, blood drawn, and an MRI. *ClinicalTrials.gov Identifier:* NCT04363684	**ALLFTD Biofluid Study:** • Diagnosis: FTLD syndrome like bvFTD, bvFTD with ALS, PPA, PSP, or CBD • Age: 18+ years old **ALLFTD Longitudinal Study:** • Diagnosis: FTLD syndrome like bvFTD,bvFTD with ALS, PPA, PSP, or CBD • Age: 18+ years old ***OR*** • Are from a family with a mutation in a gene known tocause FTLD (such as C9orf72, MAPT, and GRN) • Age: 18+ years old ***OR*** • Have a significant family history of FTLD suggesting a familial genetic mutation • Age: 18+ years old
Conversational Speech Analysis (CSA) (18-0456) *Investigator:* Peter Pressman, MD *Purpose:* to learn more about how speech changes over time in adult populations, understand how those changes reflect changes in cognition, and develop new ways of detecting Mild Cognitive Impairment (MCI) and dementia using everyday speech. *Timeline:* two study visits, one year apart. *Study flyer: https://www.ucdenver.edu/docs/librariesprovider61/clinical-research-pdfs/csa-a.pdf*	• Age: 40-95 years old • Diagnosis: Mild Cognitive Impairment (MCI) or dementia *OR* • Have NOT been diagnosed with a memory disorder
Facial Expressions Study (17-0599) *Investigator:* Peter Pressman, MD *Purpose:* to understand how the brain makes different facial expressions using high speed videography, learn more about how neurological disorders may impact a person's facial movements and expressions, and develop the groundwork for a diagnostic tool that would detect differences between a person's facial movements/ expressions and their emotions. *Timeline:* one study visit that will last approximately one hour.	• Age: 18-75 years old • Diagnosis: Mild Cognitive Impairment (MCI) or dementia or have NOT been diagnosed with a memory disorder • Are right handed

Neurobehavior (continued)

	Key Eligibility Requirements
Lewy Body Dementia (LBD)	
Facial Expressions Study (17-0599) *Investigator:* Peter Pressman, MD *Purpose:* to understand how the brain makes different facial expressions using high speed videography, learn more about how neurological disorders may impact a person's facial movements and expressions, and develop the groundwork for a diagnostic tool that would detect differences between a person's facial movements/ expressions and their emotions. *Timeline:* one study visit that will last approximately one hour. *CUACC Website:* https://medschool.cuanschutz.edu/alzheimer/get-involved/open-studies/facial-movements-study	• Age: 18-75 years old • Diagnosis: Mild Cognitive Impairment (MCI) or dementia or have NOT been diagnosed with a memory disorder • Are right handed
RewinD-LB (23-0426) *Investigator*: Samantha Holden, MD *Purpose:* to determine whether neflamapimod can improve learning skills, problem solving skills, and memory loss in people diagnosed with Dementia with Lewy Bodies (DLB). More specifically, the aim of this study is to find out if the participant experiences any improvement in verbal learning, memory, attention, and cognitive and functional performance. *Intervention:* neflamapimod (50% chance) or placebo (50% chance). *Timeline:* 8 in-person clinic visits (or 9 visits if an additional Screening Visit is scheduled) over approximately 21 weeks. Participant will be asked to return to the clinic for a Follow-Up Visit 2 weeks after their last dose of study drug. If the participant decides to participate in the Open-Label Extension Phase, where all subjects will receive neflamapimod, they will have 5 additional clinic visits over 34 weeks. *ClinicalTrials.gov Identifier:* NCT05869669	• Age: ≥ 55 years old • Diagnosis: Dementia with Lewy Bodies (DLB)
SHIMMER (22-0669) *Investigator:* Samantha Holden, MD *Purpose:* to learn about the safety of CT1812 and how well your body tolerates a once-a-day dose of CT1812. The study will also test how well CT1812 will treat mild to moderate dementia with Lewy Bodies (DLB). *Intervention:* low dose of CT1812 (33% chance), high dose of CT1812 (33% chance) or placebo (33% chance). *Timeline:* 12 in-person study visits over 210 days. *Clinicaltrials.gov:* NCT05225415	• Age: 50-85 years old • Diagnosis: Dementia with Lewy Bodies (DLB) • Have a reliable support person or caregiver willing to participate • Willingness to undergo 2 lumbar punctures

Neurobehavior (continued)

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	Key Eligibility Requirements
Mild Cognitive Impairment (MCI)	
Conversational Speech Analysis (CSA) (18-0456) *Investigator:* Peter Pressman, MD *Purpose:* to learn more about how speech changes over time in adult populations, understand how those changes reflect changes in cognition, and develop new ways of detecting Mild Cognitive Impairment (MCI) and dementia using everyday speech. *Timeline:* two study visits, one year apart. *Study flyer: https://www.ucdenver.edu/docs/librariesprovider61/clinical-research-pdfs/csa-a.pdf*	• Age: 40-95 years old • Diagnosis: Mild Cognitive Impairment (MCI) or dementia *OR* • Have NOT been diagnosed with a memory disorder
Facial Expressions Study (17-0599) *Investigator:* Peter Pressman, MD *Purpose:* to understand how the brain makes different facial expressions using high speed videography, learn more about how neurological disorders may impact a person's facial movements and expressions, and develop the groundwork for a diagnostic tool that would detect differences between a person's facial movements/ expressions and their emotions. *Timeline:* one study visit that will last approximately one hour. *CUACC Website:* https://medschool.cuanschutz.edu/alzheimer/get-involved/open-studies/facial-movements-study	• Age: 18-75 years old • Diagnosis: Mild Cognitive Impairment (MCI) or dementia or have NOT been diagnosed with a memory disorder • Are right handed

Neuroimmunology/MS

The Rocky Mountain Multiple Sclerosis Center at the University of Colorado's cutting-edge research program — one of the largest in the world — conducts basic science, clinical trials and translational research to find effective MS treatments. The results from this work are driving our medical care approach to maximize lifelong brain health through comprehensive care, which supports the brain's ability to protect and repair itself and promotes quality of life for patients and their families. Our physicians and scientists play a critical role in the development of current and emerging MS therapies, as well as studies to determine the biological basis of the disease.

	Key Eligibility Requirements
Autoimmune Encephalitis	

CIELO (22-0449)
 	
Investigator: Amanda Piquet, MD
 	
Purpose: to evaluate the efficacy, safety, pharmacokinetics, and pharmacodynamics of an investigational drug in patients with anti N-methyl-D-aspartic acid receptor (NMDAR) or anti leucine-rich glioma-inactivated 1 (LGI1) encephalitis.
 	
Intervention: Investigational drug (50% chance) vs. placebo (50% chance)
 	
Timeline: screening period
• Part 1: primary interventional period of 52 weeks
• Part 2: an optional extension period lasting ~2 years
  • Option 1: continue on randomized, double-blind investigational drug or placebo
  • Option 2: start open-label investigational drug
  • Option 3: stop investigational drug or placebo and continue follow-up assessments within Part 2
 	
ClinicalTrials.gov Identifier: NCT05503264
	• Onset of autoimmune encephalitis symptoms less than or equal to 9 months before randomization
	• Reasonable exclusion of tumor or malignancy
	• NMDAR Cohort:
	  • Age: 12 and older
	  • Diagnosis of probable or definite NMDAR encephalitis
	• LGI1 Cohort:
	  • Age: 18 and older
	  • Diagnosis of LGI1 encephalitis

First-degree Relatives of People with Multiple Sclerosis (MS)	
DREAMS (19-0393) *Investigator*: Teri Schreiner, MD, MPH *Purpose*: to learn more about the risk factors for and causes of MS by studying children who are first degree relatives of people with MS. *Timeline*: a single 3-4 hour study visit (includes MRI and blood draw).	• Age: 10-17 years old • Have parent or sibling with MS • No diagnosis of MS or early symptoms of MS

Neuroimmunology (cont.)

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	Key Eligibility Requirements
First-degree Relatives of People with Multiple Sclerosis (MS) (continued)	
RISE-MS (17-1884) *Investigator*: Enrique Alvarez, MD, PhD and John Corboy, MD *Purpose*: to learn more about the risk factors for and causes of MS by studying first degree relatives of people with MS. *Timeline*: a single 2-3 hour study visit (includes MRI and blood draw) *ClinicalTrials.gov Identifier:* NCT03586986	• Age: 18-30 years old • Have a parent, sibling or child with MS • No diagnosis of MS or early symptoms of MS
Primary Progressive Multiple Sclerosis (PPMS)	
We are asking people with multiple sclerosis (MS) to be a part of our study at the University of Colorado by filling out a survey. Please Join us! Study flyer: https://ucdenver.edu/docs/librariesprovider61/clinical-research-pdfs/23-1095.pdf	
Relapsing and Secondary Progressive Multiple Sclerosis (RSPMS)	
BEAT-MS (19-1621) *Investigator*: John Corboy, MD *Purpose*: to compare efficacy and safety of autologous hematopoietic stem cell transplantation (AHSCT) to best available therapy (BAT) in treatment resistant relapsing MS. *Intervention:* best available therapy (50% chance) or AHSCT cell transplant (50% chance) *Timeline*: up to 17 study visits over 6 years (not including stem cell transplantation procedures, if randomized to AHSCT group). *ClinicalTrials.gov Identifier:* NCT04047628	• Age: 18-55 years old • Diagnosis: highly active, treatment resistant MS • 2 clinically confirmed episodes of treatment failure in the past 36 months • Insurance or public funding available to cover the cost of an MS DMT
De-Escalation Study (21-4993) *Investigator*: Enrique Alvarez, MD, PhD *Purpose*: to learn more about how "de-escalation" therapy affects outcomes in patients with relapsing forms of multiple sclerosis (MS). "De-escalation" means switching from an anti-CD20 treatment to Vumerity or Tecfidera. *Timeline*: 6 in-person visits over 24 months.	• Age: 18+ years old • Diagnosis: relapsing MS • Taking an anti-CD20 (Ocrevus, Rituxan) for at least 1 year • Planning to initiate Vumerity or Tecfidera treatment

Neuroimmunology (cont.)

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	Key Eligibility Requirements
Relapsing and Secondary Progressive Multiple Sclerosis (RSPMS) (continued)	
DELIVER-MS (18-1633) *Investigator*: Enrique Alvarez, MD, PhD *Purpose*: to learn whether there is a difference between two common treatment approaches for people who have recently been diagnosed with relapsing remitting MS: escalation approach (start out by using a lower-risk, moderately effective medication) vs early highly effective treatment approach (start out with one of the stronger, but potentially more risky, medications). *Timeline:* 13 study visits over 3 years. *ClinicalTrials.gov Identifier:* NCT03535298	• Age: 18-60 years old • Recently diagnosed with MS • Not currently taking any MS medication (but plan to start one soon)
FUSION (22-2421) *Investigator*: Enrique Alvarez, MD, PhD *Purpose*: • Part 1: to find out how safe and effective a investigational drug called BIIB091 is when given to people with RMS, and how well the body can handle taking it (tolerability). • Part 2: to know whether a specific dose of the investigational drug (BIIB091) works and whether it is safe for people with relapsing forms of multiple sclerosis or "RMS" when given with DRF. *Intervention:* BIIB091 or DRF or a combination of both. *Timeline*: The study will be done in 2 parts: Part 1 and Part 2. The participant will only be invited to participate in one part. Regardless of part, there will be 3 different periods: • Screening period – up to 4 weeks • Study treatment period – about 48 weeks • Follow-up period – about 2 weeks *ClinicalTrials.gov Identifier:* NCT05798520	• Age:18-55 years old (inclusive) at the time of informed consent. • Diagnosis: Relapsing Remitting Multiple Sclerosis (RRMS) or active Secondary-Progressive Multiple Sclerosis (SPMS) • Time since MS symptom onset is <20 years.

Neuroimmunology (cont.)

Anschutz

	Key Eligibility Requirements
Relapsing and Secondary Progressive Multiple Sclerosis (RSPMS) (continued)	
REMODEL 2 (21-4825) *Investigator*: Enrique Alvarez, PhD, MD *Purpose*: to provide efficacy, safety and tolerability data for an investigational drug to support regulatory approval worldwide as a treatment for RMS. *Intervention:* Investigational drug and placebo (50% chance) -or– an approved drug and placebo (50% chance). *Timeline*: 15 in-person visits for up to 2.5 years followed by an Open Label Extension (OLE) which involves 13 in-person visits for up to 5 years. *ClinicalTrials.gov Identifier:* NCT05156281	• Age: 18-55 • Diagnosis: RRMS • 1 documented relapse in previous year OR 2 documented relapses in previous 2 years OR 1 active Gd-enhancing lesion in past year • Neurologically stable within 1 month

We are asking people with multiple sclerosis (MS) to be a part of our study at the University of Colorado by filling out a survey. Please Join us!

Study flyer:
https://ucdenver.edu/docs/librariesprovider61/clinical-research-pdfs/23-1095.pdf

Neuromuscular

The Neuromuscular Division provides care for a large and diverse group of rare diseases including Amyotrophic Lateral Sclerosis (ALS), Muscular Dystrophies, Myasthenia Gravis, inherited neuropathies, and many others. We are a quaternary care center meaning we handle the highest level of complexity in medical care, and we are a Muscular Dystrophy Association Care Center providing weekly multi-disciplinary care clinics. The goal of the Neuromuscular Clinical Research Program is to help patients with neuromuscular diseases in the Rocky Mountain Region gain access to cutting-edge therapies.

	Key Eligibility Requirements
Becker Muscular Dystrophy (BMD)	
CANYON (22-0354) *Investigator*: Matthew Wicklund, MD *Purpose:* to learn about the safety, and effectiveness of EDG-5506 when compared to placebo in individuals diagnosed with Becker Muscular Dystrophy (BMD). *Intervention:* EDG-5506 (at least 66% chance) or placebo (no greater than 33% chance). *Timeline:* 10 in-person study visits over 14 months. *ClinicalTrials.gov Identifier:* NCT05291091	• Age: 12-50 years old • Diagnosis: Becker Muscular Dystrophy (BMD) • Gender: male at birth • Able to walk 100m without assistance
GRASP BMD (22-1278) *Investigator*: Stacy Dixon, MD, PhD *Purpose:* to learn more about Becker Muscular Dystrophy (BMD) by measuring how your muscles change over time. This information will help plan future studies and drug development for people with BMD. *Timeline:* 5 in-person study visits over 24 months. *ClinicalTrials.gov Identifier:* NCT05257473	• Age: 8+ years old • Diagnosis: Becker Muscular Dystrophy (BMD)
Charcot Marie Tooth Disease (CMT)	
Genetics of CMT (20-1525) *Investigator*: Vera Fridman, MD *Purpose*: to look for new genes that cause Charcot Marie Tooth disease (CMT) and to look for genes that don't cause CMT, but may modify the symptoms a person has. *ClinicalTrials.gov Identifier:* NCT01193088	• Diagnosis: Charcot Marie Tooth Disease (CMT) *or* have a relative with CMT

Neuromuscular (continued)

	Key Eligibility Requirements
Charcot Marie Tooth Disease (CMT) (continued)	
Natural History of CMT (18-2537) *Investigator*: Vera Fridman, MD *Purpose*: observational, longitudinal study to determine natural history and genotype-phenotype correlations of disease causing mutations in Charcot Marie Tooth disease (CMT). *ClinicalTrials.gov Identifier:* NCT01193075	• Diagnosis: Charcot Marie Tooth Disease (CMT) *or* have a relative with CMT
Diabetic Neuropathy (DN)	
DN (19-3004) *Study Title:* Participants Needed for Research Study About Diabetes and Neuropathy. *Investigator*: Vera Fridman, MD *Purpose:* to learn more about the underlying causes of diabetic neuropathy by looking for the presence of abnormal molecules in the blood and skin and comparing them in people with and without Type 2 Diabetes. *Procedures:* blood draw, skin biopsy, neurological and physical exam, autonomic nervous system testing, nerve conduction study, questionnaires and balance, coordination, and agility tests. *Timeline:* 2 study visits which will occur within 30 days of each other.	• Age: 45-65 years old • Diagnosis: Type 2 Diabetes (T2D)
Facioscapulohumeral Muscular Dystrophy (FSHD)	
MOVE FSHD (20-0405) *Investigator*: Matthew Wicklund, MD *Purpose*: to collect motor and functional outcomes specific to Facioscapulohumeral Muscular Dystrophy (FSHD) over time to ensure the best level of clinical care and to speed up drug development by gaining a better understanding of how having FSHD impacts motor function and other health outcomes. *Timeline*: 1 study visit per year for 3 years. *ClinicalTrials.gov Identifier:* NCT04635891	• Diagnosis: Facioscapulohumeral Muscular Dystrophy (FSHD) Type 1 or 2, genetically confirmed or family history and functionally affected

Neuromuscular (continued)

	Key Eligibility Requirements
Limb Girdle Muscular Dystrophy (LGMD)	
Fortify (23-0309) *Investigator*: Thomas Ragole, MD *Purpose:* to learn more about the safety of BBP-418 and to find out what effects (both good and bad) it has on people with Limb Girdle Muscular Dystrophy Type 2I (LGMD2I/R9). *Intervention:* BBP-418 (66% chance) or placebo (33% chance). *Timeline:* Screening and Baseline period (approx. 7-28 days), Double-Blind Study Treatment period (approx. 36 months) and Follow-up Visit (approx. 30 days following last dose of study drug). *ClinicalTrials.gov Identifier:* NCT05775848	• Age: 12-60 years (inclusive) • Diagnosis: Limb Girdle Muscular Dystrophy Type 2I (LGMD2I/R9) • Body Weight: >30 kg
GRASP LGMD (19-0506) *Investigator*: Stacy Dixon, MD, PhD *Purpose*: to learn more about Limb Girdle Muscular Dystrophy (LGMD) by measuring how your muscles change over time. *Timeline:* 4-5 study visits over 12 months. *ClinicalTrials.gov Identifier:* NCT03981289	• Age: 4-65 years old • Diagnosis: clinically affected Limb Girdle Muscular Dystrophy (LGMD) (weakness in limb girdle pattern or in distal extremity)
TREATing-LGMDR1 (23-1472) *Investigator*: Stacy Dixon, MD, PhD *Purpose:* to learn more about Limb Girdle Muscular Dystrophy type R1 (LGMDR1) and what effects it has on you during disease progression. *Procedures:* blood draw, urine sample collection, spirometry, physical tasks, physical exam, MRI and questionnaires. *Timeline:* 4 clinic visits for 3 study visits (Baseline Day 1, Baseline Day 2, Month 12, Month 24). *ClinicalTrials.gov Identifier:* NCT05618080	• Age: between 12-50 at enrollment • Diagnosis: Limb Girdle Muscular Dystrophy type R1 (LGMDR1)

Neuromuscular (continued)

	Key Eligibility Requirements
Myasthenia Gravis (MG)	
DOMYA (23-1307) *Investigator*: Thomas Ragole, MD *Purpose:* to assess the effectiveness and safety of an investigational digital tool called ME&MG, which allows patients with generalized Myasthenia Gravis (gMG) to self-monitor their symptoms. *Device:* ME&MG smartphone application (investigational software as a medical device). *Timeline:* Screening/Inclusion visit (Day 0), Follow-up Visit at 3 months (Day 90), and End-of-study Visit at 12 months (Day 365). *ClinicalTrials.gov Identifier:* NCT05564936	• Age: 18 years to 60 years • Diagnosis: generalized Myasthenia Gravis (gMG) • Owning and able to use a personal smartphone which software version is above 14 for IOS and 8 for Android (included)
FLEX (22-2391) *Investigator:* Thomas Ragole, MD *Purpose*: to learn how well batoclimab works and how safe it is, when compared with placebo (an inactive material that looks like batoclimab but does not have any active drug). *Intervention*: batoclimab or placebo (chance of receiving batoclimab will vary between Periods). *Timeline*: Screening Period of up to 4 weeks, two 12-week Treatment Periods (referred to as Period 1 and Period 2), a 52-week Long-Term Extension Period (referred to as Period 3), and a 4 week Follow-up Period. Total study duration: approximately 84 weeks (1 ½ years), approximately 34 study visits. *ClinicalTrials.gov Identifier:* NCT05403541	• Age: ≥ 18 years • Diagnosis: mild to severe Generalized Myasthenia Gravis (gMG) • Have diagnostic autoantibody (AChRAb+, anti-MuSK+, or anti-LRP4+) confirmation of gMG at the Screening Visit
Prevail (22-1330) *Investigator*: Thomas Ragole, MD *Purpose:* to determine if the study medication (ALXN1720) is safe and effective in the treatment of generalized Myasthenia Gravis (gMG). *Intervention:* ALXN1720 (50% chance) or placebo (50% chance). *Timeline:* 24 in-person visits over 2.5 years. *ClinicalTrials.gov Identifier:* NCT05556096	• Age: 18+ years old • Diagnosis: generalized Myasthenia Gravis (gMG)

Neuromuscular (continued)

Anschutz

	Key Eligibility Requirements
Myotonic Dystrophy Type 1 (DM1)	
END-DM1 (21-4907) *Investigator*: Thomas Ragole, MD *Purpose:* to determine the best ways to assess how people are affected by Myotonic Dystrophy Type 1 (DM1). The study will examine the effects of DM1 on your muscles, heart, blood, and nervous system. *Timeline:* up to 4 in person study visits over 2 years. *ClinicalTrials.gov Identifier:* NCT03981575	• Age: 18-70 years old • Diagnosis: Myotonic Dystrophy Type 1 (DM1)
Spinal Muscular Atrophy (SMA)	
WeSMA (22-0296) *Investigator:* Stacy Dixon, MD, PhD *Purpose*: to follow patients receiving Evrysdi (risdiplam) for a long time. This will add to the body of evidence about the safety and effectiveness of Evrysdi. *Intervention:* Evrysdi. *Timeline*: visits every 6 months for up to 5 years. *ClinicalTrials.gov Identifier:* NCT05232929	• Diagnosis: spinal muscular atrophy • Currently prescribed Evrysdi

Neuro-Ophthalmology

The Neuro-Ophthalmology Research Section at the University of Colorado is a leading center for investigating disorders that affect the visual system and brain. Founded in 1967, the section has a long history of excellence in patient care, education, and research. Its faculty members are internationally recognized experts in the field, and their research focuses on a wide range of topics, including optic nerve disease, Neuromyelitis Optica Spectrum Disorder (NMOSD) and Myelin Oligodendrocyte Disorder (MOG), cerebral visual impairment, and neuroimaging. The section is committed to advancing our understanding of these conditions and developing new treatments that improve the lives of patients.

	Key Eligibility Requirements
Myelin Oligodendrocyte Glycoprotein Antibody Disease (MOG-AD)	
METEOROID (23-0648) *Investigator*: Jeffrey Bennett, MD, PhD *Purpose*: to compare the effects, good or bad, of satralizumab with placebo alone or in combination with current treatment (baseline/background therapy) on participants with Myelin Oligodendrocyte Glycoprotein Antibody-associated Disease (MOGAD). *Intervention:* satralizumab (50% chance) or placebo (50% chance). *Timeline*: Screening Period (approx. 28 days), Double-Blind Period, Open-Label Period (approx. 2 years), and Follow-Up Period (12 weeks if you are an adult and 24 weeks if you are an adolescent (12 to 17 years old)). Total study participation: up to 5 years. *ClinicalTrials.gov Identifier:* NCT05271409	• Age: ≥ 12 • Diagnosis: Myelin Oligodendrocyte Glycoprotein Antibody-associated Disease (MOGAD) • Body weight: 20kg at Screening
UCB MOG (21-3747) *Investigator*: Jeffrey Bennett, MD, PhD *Purpose:* to assess how safe, tolerable (acceptable to you) and effective rozanolixizumab (referred to as "the study drug" hereafter) is in treating Myelin Oligodendrocyte Glycoprotein Antibody Disease (MOG-AD). *Intervention:* study drug (50% chance) or placebo (50% chance). *Timeline:* Screening Period (approx. 4 to 6 weeks) followed by a Double-Blind Study Treatment Period (up to 132 weeks) followed by a Open-Label Extension (OLE) Study Treatment Period (approx. 51 weeks) followed by a Safety Follow-Up (SFU) Period (8 weeks after the last dose of study treatment). *ClinicalTrials.gov Identifier:* NCT05063162	• Age: ≥18 to ≤89 years old • Diagnosis: Myelin Oligodendrocyte Glycoprotein Antibody Disease (MOG-AD) • Weigh at least 35kg at Screening

Neuro-Ophthalmology (cont.)

Anschutz

	Key Eligibility Requirements
Neuromyelitis Optica Spectrum Disorder (NMOSD)	
HORIZON (23-0315) *Investigator*: Amanda Piquet, MD *Purpose:* to assess pregnancy and birth outcomes in women with Neuromyelitis Optica Spectrum Disorder (also known as NMOSD), who received inebilizumab (commercially available as "UPLIZNA") during pregnancy, or within 6 months before getting pregnant. *Procedure:* during the study, the following information will be collected: contact information, medical and family history, pregnancy data (lifestyle, how you got pregnant, last menstrual period, estimated date of delivery, etc.), current NMOSD disease status and your baby's data (date of birth, general health status, weight, etc.). *Timeline:* in order to collect this data, you and/or the doctor taking care of your pregnancy and/or your baby will be contacted approximately 4 times by the site.	• Diagnosis: Neuromyelitis Optica Spectrum Disorder (NMOSD) • Are a female of reproductive potential • Have been exposed to UPLIZNA during pregnancy as defined by receipt of any dose during pregnancy or within 6 months preceding conception
SAkuraPEAK (22-1981) *Investigator*: Jeffrey Bennett, MD, PhD *Purpose:* to test satralizumab at a higher dose (180 mg) in Neuromyelitis Optica Spectrum Disorder (NMOSD) participants weighing more than 100 kg to find out if this dose is safe and to understand the way their body processes the study drug. *Intervention:* satralizumab. *Timeline:* Screening Visit followed by a 24-week study treatment period (~10 in-person visits) followed by a 12-week follow-up (~2 telephone visits + 1 final in-person visit). *ClinicalTrials.gov Identifier:* NCT02073279	• Age: 18+ years old • Diagnosis: AQP4 antibody-positive NMOSD • Body Weight: over 100kg (~220 lbs)

Neurovascular/Stroke

The Neuro-Hospitalists team at the University of Colorado is a highly specialized group of physicians who provide expert care for patients with a wide range of acute neurological conditions. We provide timely and effective interventions to improve patient outcomes, and our team is available around the clock to issue rapid responses to stroke emergencies. Our clinical research program aims to advance the field of neurovascular medicine, with a particular focus on investigating new diagnostic and treatment approaches for stroke. Our goal is to provide the highest quality of care for our patients and improve outcomes for those with neurovascular and stroke-related conditions.

Cerebral Autosomal Dominant Arteriopathy with Subcortical Infarcts and Leukoencephalopathy (CADASIL)

CADASIL (22-0235)

Investigator: Karen Orjuela, MD

Purpose: Cerebral Autosomal Dominant Arteriopathy with Subcortical Infarcts and Leukoencephalopathy (CADASIL) is the most common heritable cause of vascular dementia, but many of the early symptoms of the disease remain poorly understood. This study is designed to look at how a person's body, brain, and behavior change throughout the stages of this disease, and what factors might serve as additional risks or protective factors.

Timeline: 3 in-person study visits over 5 years.

ClinicalTrials.gov Identifier: NCT05677880

Key Eligibility Requirements

CADASIL Participants:

- Age: 18+ years old
- positive NOTCH3* genetic testing; or a positive skin biopsy; or willingness to have a NOTCH3 genetic test prior to enrolling and are a -risk for, or diagnosed clinically, with CADASIL

CADASIL Participant Chosen Companion:

- Same criteria as CADASIL participants except are or were at risk for CADASIL but have Negative NOTCH3* genetic testing

Additional Resources

Finding Current Studies:

- University of Colorado Anschutz Medical Campus Department of Neurology Clinical Research: https://medschool.cuanschutz.edu/neurology/research
    - Epilepsy: https://medschool.cuanschutz.edu/neurology/research/studies/epilepsy
    - Headache/Migraine: https://medschool.cuanschutz.edu/neurology/research/studies/headache-migraine
    - Healthy Volunteers: https://medschool.cuanschutz.edu/neurology/research/studies/healthy-volunteers
    - Movement Disorders: https://medschool.cuanschutz.edu/neurology/research/studies/movement-disorders
    - Neurobehavior: https://medschool.cuanschutz.edu/neurology/research/studies/neurobehavior
    - Neuroimmunology/Multiple Sclerosis (MS): https://medschool.cuanschutz.edu/neurology/research/studies/neuroimmunology
    - Neuromuscular: https://medschool.cuanschutz.edu/neurology/research/studies/neuromuscular
    - Neuro-Ophthalmology: https://medschool.cuanschutz.edu/neurology/research/studies/neuro-ophthalmology
    - Neurovascular/Stroke: https://medschool.cuanschutz.edu/neurology/research/studies/stroke
- Neurology Research Interest Web Form: https://neurologyevent.ucdenver.edu/recruitment/welcome
- Clinicaltrials.gov: https://clinicaltrials.gov

More Information on Research and Upcoming Events:

- University of Colorado Movement Disorders Center: https://cumovement.org
- Rocky Mountain Multiple Sclerosis (MS) Center: https://mscenter.org
- University of Colorado Alzheimer's and Cognition Center: https://medschool.cuanschutz.edu/alzheimer

Learning More about Clinical Research:

- The National Institutes of Health (NIH) - Clinical Trails and You: https://nih.gov/health-information/nih-clinical-research-trials-you
- The Center for Information and Study on Clinical Research Participation (CISCRP) (https://ciscrp.org) is first-of-its-kind nonprofit organization dedicated to educating and informing the public, patients, medical/research communities, the media, and policy makers about clinical research and the role each party plays in the process.
    - The CISCRP Community Resources webpage (https://ciscrp.org/education-center/community-organizations) contains a number of contact information-containing resources available to anyone seeking information about clinical research, both general and disease-specific.
- PubMed (https://pubmed.ncbi.nlm.nih.gov) is a free resource supporting the search and retrieval of biomedical and life sciences literature with the aim of improving health–both globally and personally.
- Office for Human Research Participants: https://hhs.gov/ohrp/education-and-outreach/about-research-participation/index.html
- Clinicaltrials.gov Glossary of Common Site Terms: https://clinicaltrials.gov/ct2/about-studies/glossary

Frequently Asked Questions

Anschutz

I am interested in participating in research, but I don't know where to start. What should I do?

Please visit the New to Clinical Research (https://medschool.cuanschutz.edu/neurology/research#new-to-clinical-research) section of our Neurology Clinical Research webpage and contact our Neurology Research Recruitment Team by filling out our Neurology Research Interest Web Form (https://neurologyevent.ucdenver.edu/recruitment/welcome) or reach out via email (NeuroResearch@cuanschutz.edu) or phone (303-724-4644).

A Recruitment Specialist will contact you with more information about clinical research and will see if there are any studies you may be a good fit for. If you don't qualify for any studies at this time, the Recruitment Specialist will provide you with follow up resources so you can stay up-to-date on clinical research.

I think I might be eligible for one or more of these studies. What is the next step in the process?

Please contact our Neurology Research Recruitment Team by filling out our Neurology Research Interest Web Form (https://neurologyevent.ucdenver.edu/recruitment/welcome) or reach out via email (NeuroResearch@cuanschutz.edu) or phone (303-724-4644).

A Recruitment Specialist will contact you to discuss the studies further and potentially complete a brief prescreening questionnaire with you over the phone to see if you are a good fit. If you meet the prescreening requirements, the Recruitment Specialist with connect you with the Study Coordinator who will work with you to schedule a more in-depth, in-person screening visit.

I have contacted the Neurology Research Recruitment Team and have not heard back yet. How long will I have to wait?

A Recruitment Specialist will reach out to you via phone or email within 5 business days. We receive a high volume of inquiries, so thank you in advance for your patience!

University of Colorado **Anschutz Medical Campus**

Department of Neurology