CENTER FOR CLINICAL RESEARCH

Newsletter

KU SCHOOL OF MEDICINE WICHITA
The University of Kansas

BRINGING THE FUTURE OF MEDICINE TO **ALL** OF KANSAS

KU Wichita Center for Clinical Research opens **SIX** new studies in Summer 2023!

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CENTER FOR CLINICAL RESEARCH DIRECTOR

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KU Wichita Center for Clinical Research is excited to announce the opening of six new clinical trials in Summer 2023. Studies will include the investigation of medical diagnoses including **chronic cough, ALS, Alzheimer's disease and Crohn's disease.**

CALM-1 is a 52-week study that will evaluate the efficacy of a new study drug on adults with **unexplained chronic cough** ≥ one year prior to screening. Participants will receive one of two doses of the investigational drug and/or a placebo during the study. Following the initial study, all participants will receive the investigational drug for 24 weeks. Compensation for participant's time and travel will be between $50-100 per visit or $2,200 upon completion.

The Wilkins Functional Biomarkers for ALS is a 52-week study that will evaluate how mitochondria function and protein folding in the blood affects **ALS progression.** This study is looking to include both subjects who have been diagnosed with ALS and healthy subjects. Participation will include four office visits to the clinic. At each visit, participants will be asked to complete a questionnaire, provide a short medical history and complete a blood draw.

Advance-2 is an eight-week study that will evaluate the efficacy of a study drug on the effects of **agitation associated with Alzheimer's disease**. Study intervention is five weeks, and patients will have the option to enroll into an open label extension study to continue use of the study drug for an additional 24-weeks. Compensation for time and travel will be between $50-75 per visit or $500 upon completion.

Highlights

P 01 | CCR opens new studies
P 02 | Funding opportunities
P 03 | Welcome to the team
P 04 | Enrolling studies
P 05 | Enrolling studies
P 06 | Enrolling studies
P 07 | Referrals

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S-CitAD is a 31-week study that will evaluate the efficacy of an investigational drug for **agitation in Alzheimer's disease**. The study will last approximately six months and will include up to five clinic visits and eight telephone visits. Participants will be randomized to receive either the study drug or a placebo for the first 12 weeks. Following the 12-week study treatment period, participants will be followed for another 12 weeks off study drug. All participants will receive counseling and materials to help manage agitation. Compensation for time and travel will be up to $50 per visit or $650 total upon completion.

Duet is a 48-week study that will evaluate the efficacy of a combination therapy of two investigational study drugs in patients with **moderately to severely active Crohn's disease.** Study intervention is 48 weeks with an optional four-year extension. Participants will be randomized into six treatment groups. Compensation for time and travel will be up to $100 per visit or $1,700 total upon completion.

The Clinical Cohort Study is working to establish and maintain a group of potential research participants willing to allow us to follow their aging process over time. This is an **observational study** that will include both **healthy participants and participants with Alzheimer's disease.** Participation in this study would require yearly visits for as long as the participant is willing and/or able. These visits will include a clinical evaluation, memory evaluation and additional optional assessments.

Pictured: Trisha Steele, site manager, and Hannah Hancock, participant recruiter, at the 2023 Kansas Education Conference on Dementia

FUNDING OPPORTUNITIES

KU School of Medicine-Wichita Center for Clinical Research is seeking support to help solidify the center as Kansas' leader in clinical research. Increased funding will assist the center in the following ways:

- **Endowed directorship position** will allow the director to focus on professional development, expand research opportunities and launch innovative initiatives
- **Enhanced infrastructure** will allow the center the ability to study more diseases and novel drugs, in turn allowing us to help more patients and boost professional development for our faculty, residents and medical students
- **Increased space, staff and faculty** will meet the needs of an expanding facility allowing the center to provide for more patients

For more information on how you can support KU Wichita Center for Clinical Research, contact Brad Rukes at brukes@kuendowment.org or 316-293-2641.

LET'S CELEBRATE!

Pictured: CCR staff at National Clinical Trials Day Celebration

WELCOME TO THE TEAM!

KU Center for Clinical Research welcomes three new staff members to the team:

Ashley Ast, clinical research assistant, joined the team in December 2022 and comes to KU CCR with 12 years of research experience. Ashley is a Wichita native and an alumna of WSU.

John Taylor, clinical research assistant, joined the team in February 2023 following four years of clinical research experience in the hematology/ oncology setting. Raised in Wichita, John graduated from the University of Kansas in 2018 with a B.S. in behavioral neuroscience. John is currently completing his last prerequisites at Butler County Community College with plans of attending nursing school. John is hopeful that RN licensure combined with his experiences in clinical research will aid his impact in health care.

Hannah Hancock, participant recruiter, joined the team in May 2023. Hannah graduated with her M.S. in biology in 2019 from Grand Canyon University. Her previous experience includes working as a recruiter for Grand Canyon University, and teaching Anatomy & Physiology at Trinity Academy.

BIRTHDAYS

6/24	Ashley Ast, Clinical Research Assistant
7/14	Tina Peck, Research Nurse
8/15	Emma Stuart-Grant, Regulatory Coordinator

WORK-IVERSARIES

7/17	Dr. Schwasinger-Schmidt, Director
7/20	Alexis Cobb, Research Nurse
7/21	Emma Stuart-Grant, Regulatory Coordinator
8/20	Caroline Inay-Park, Research Nurse
8/22	Nalina Fraser, Clinical Pharmacist

ENROLLING STUDIES

ALZHEIMER'S DISEASE

AXSOME

Axsome is seeking participants to evaluate an oral investigational medication for the treatment of agitation with Alzheimer's disease. This 10-week study also has an optional 52-week open label study. To be eligible, participants must:

- Be aged 65 to 90 years old.
- Have a diagnosis of Alzheimer's disease.
- Currently exhibit or show signs of restlessness, aggression or irritability.
- Have a dedicated caregiver who is also willing to participate.

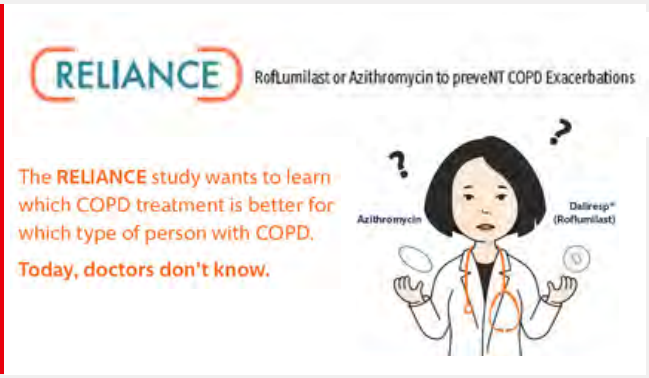
COVID-19 TREATMENT

ACTIV-6

People who test positive for COVID-19 may be eligible for a 90-day at-home study. ACTIV-6 is investigating existing medications to learn if they may help people with mild-to-moderate COVID-19 feel better faster. To be eligible, participants:

- Must be at least 30 years old.
- Have had a positive COVID-19 test within the past 10 days.
- Have at least two symptoms of the illness for seven days or less.

COPD



RELIANCE

RELIANCE is a 36-month, nationwide study that compares two investigational study drugs to determine if long-term use improves the lives of people with COPD.

To be eligible, participants should have been:

- Diagnosed with COPD.
- Hospitalized for COPD in the last 12 months.
- Discussing stronger COPD treatment with their doctor.

CONSTIPATION

SPARK-Pediatric Constipation

If the child in your care has been suffering from constipation or IBS-C, they may be eligible to take part in the SPARK-64 study. This 20-week study is looking for eligible participants who:

- Have two or fewer bowel movements per week, without laxatives.
- Are between 7-17 years old.
- Weigh more than 39lbs/18kg.

ENROLLING STUDIES

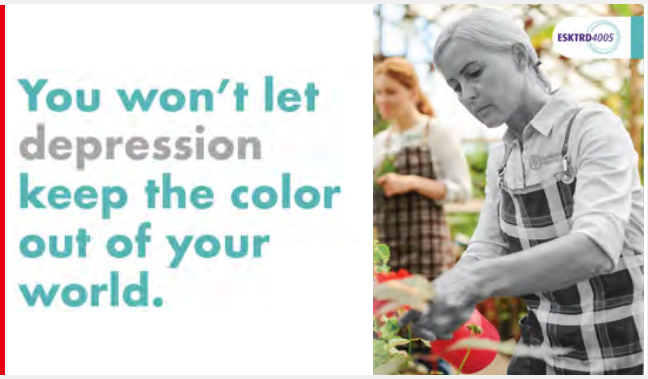
DEPRESSION

TOGETHER-BOEHRINGER-INGELHEIM

If you have major depressive disorder (MDD) that hasn't responded to antidepressant medication, this 13-week study of an investigational drug for MDD wants to help.
To qualify for this study, you must:

- Be 18 to 65 years of age.
- Have been diagnosed with MDD.
- Be in a current depressive episode for at least eight weeks but no longer than 18 months.
- Have been taking an antidepressant medication for at least the last six weeks.

DEPRESSION

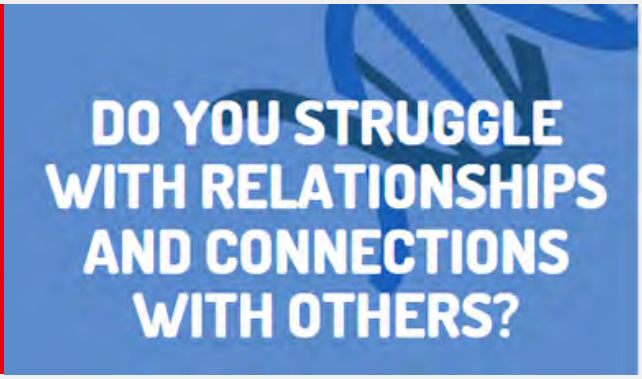


JANSSEN-ESKETAMINE

Do you have treatment-resistant depression (TRD)? The purpose of this 24-week study is to evaluate the effectiveness, safety and tolerability of an investigational medication in people with TRD.
You may be eligible to participate if you:

- Are 18 years of age or older.
- Have been diagnosed with major depressive disorder.
- Have not responded to at least two different antidepressant treatments.

PERSONALITY DISORDER



PERSONALITY DISORDER

KU School of Medicine-Wichita Center for Clinical Research is recruiting participants who have personality disorder features, traits or characteristics. Participants will have one clinic visit that will include questionnaires and a saliva sample, which will be sent to 23andMe for analysis. The participants will receive 23andMe results at no charge.

AMYOTROPHIC LATERAL SCLEROSIS (ALS)

AMYOTROPHIC LATERAL SCLEROSIS (ALS)

The Wilkins Functional Biomarkers for ALS is a multicenter, longitudinal study with no intervention to address multiple issues for clinical trial readiness in ALS. The study is looking for both healthy subjects and subjects who have been diagnosed with ALS. Subject participation will include four clinic visits over an 8-12 month time frame.

ENROLLING STUDIES

CHRONIC COUGH (RCC)

CALM-1

If you have a refractory chronic cough (RCC) that seriously impacts your quality of life and social interactions, the 52-week CALM-1 study wants to help "calm the cough."
To qualify for this study, you must:

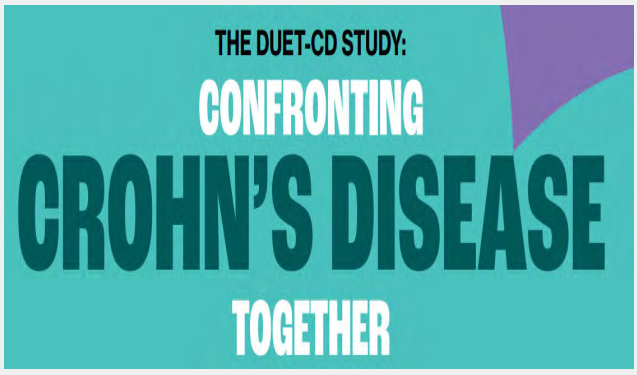
- Be 18 to 80 years of age.
- Had refractory chronic cough (RCC) for at least one year.
- Medical evaluations and prescribed or over-the-counter treatments have not greatly improved your symptoms.

ALZHEIMER'S DISEASE

COHORT

The purpose of the Clinical Cohort Study is to establish and maintain a group of well-characterized, potential research participants willing to allow us to follow their aging process over time, as well as participate in future research related to brain aging and thinking abilities. Participation is available to both individuals who are or are not experiencing memory loss and will include yearly clinical evaluations. The clinical cohort is an observational study, meaning there are no interventions or medications.

CROHN'S DISEASE



DUET-CD

The 48-week DUET-CD study is being conducted to determine whether a combination of two investigational medications are safe and effective in individuals with moderately to severely active Crohn's disease.
DUET-CD is looking for participants who:

- Are 18-65 years of age.
- Have had moderately to severely active CD for at least three months.
- Have not responded to treatment for CD.

ALZHEIMER'S DISEASE

S-CitAD

The Escitalopram for Agitation in Alzheimer's disease (S-CitAD) study is a 12-week trial of the study drug for the treatment of agitation in participants with Alzheimer's Disease (AD). The S-CitAD study is looking for participants who:

- Have been diagnosed with Alzheimer's disease.
- Experience irritability, restlessness, frustration or anger.
- Have a study partner who can participate in the study.

PARTICIPANTS NEEDED

Participants of clinical research have access to:

- Investigational research trials
- Expert clinical assessment and care
- Medication
- Time/Travel reimbursement
- And more

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EMAIL clinicaltrialunit@kumc.edu

INSURANCE NOT REQUIRED

PROVIDER REFERRAL?

• SUBMIT ONLINE •

bit.ly/KUCCRreferral

For more information:

HANNAH HANCOCK | Participant Recruiter

HHANCOCK@KUMC.EDU