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 will open **THREE** new studies to prepare for rise in COVID-19 and RSV cases.

KU Wichita Center for Clinical Research is excited to announce the opening of three new clinical trials in fall 2023. Studies will include the investigation of **prevention of COVID-19 and treatment for RSV.**

SCORPIO-PEP is a 28-day study to assess the **prevention of COVID-19 infection** in those who have been **exposed through household contact**. Both individuals with COVID-19 and those who live in the same household as someone with COVID-19 can participate in the SCORPIO study. Participants with COVID-19 will have their symptoms recorded but will not receive study intervention, and healthy participants will receive the investigational drug or placebo over a five-day treatment period before continuing with a follow-up period for the remainder of the 28 days. All participants must be 18 years or older.

SUPERNOVA is a 15-month study to assess an investigational medication that is designed to help **protect individuals with an impaired immune system from contracting COVID-19.** Participants will receive two doses of either the study drug or placebo. The doses will be six months apart, and participants will have 11 total visits throughout the study for additional assessments.

TIFFANY SCHWASINGER-SCHMIDT, M.D., Ph.D., FACP
CENTER FOR CLINICAL RESEARCH DIRECTOR

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KU Wichita Center for Clinical Research will open three new studies to prepare for rise in fall RSV and COVID-19 cases.

Pfizer RSV is a five-week study to assess the safety and efficacy of an investigational medication to **prevent severe illness in adults with respiratory syncytial virus Infection (RSV)**. Participants will receive a total of 10 doses of the investigational drug or placebo. The study population will include symptomatic participants with confirmed RSV infection who are at increased risk of progression to severe illness, as these individuals are most in need of safe and effective treatments. Participants will be considered at-risk if they have one of the following characteristics or underlying medical conditions:

- Age of 65 years or older.
- Have chronic lung disease, heart failure or an immunosuppressive disease or condition.

CCR EVENT HIGHLIGHT:

The CCR hosted the KU Alzheimer's Disease Research Center and the Alzheimer's Association on Sept. 8 for a showing of "Why," an Alzheimer's Disease Research film. Over 40 attendees learned about the barriers in recognizing and addressing early cognitive changes, as well as supporting a hopeful, empowered approach to moving forward and learning about research opportunities. After the film, participants had a Q&A session with CCR director, Tiffany Schwasinger-Schmidt, M.D., Ph.D.

Pictured: "Why" Alzheimer's Film Event attendees

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.

Pictured: CCR team at Ashlie Cornejo's, research nurse, bridal shower.

WELCOME TO THE TEAM!

KU Wichita Center for Clinical Research welcomes one new staff member to the team:

Tristan Finch, regulatory coordinator, joined the team in September 2023. Tristan graduated from the University of Kansas in 2019 with a B.A. in human biology. His previous work experience includes working as a lab technician.

LET'S CELEBRATE!

BIRTHDAYS

Sept. 21- Tristan Finch, regulatory coordinator
Sept. 28- John Taylor, clinical research assistant

CELEBRATING LGBTQ+ HISTORY MONTH

The month of October is LGBTQ+ History Month, and the CCR celebrates learning about the history of the lesbian, gay, bisexual, transgender and queer community. LGBTQ+ History Month highlights the importance of learning about LGBTQ+ historical events and standing up against bullying. The first march on Washington for Lesbian and Gay Rights took place in October 1979 and was an important step to bring awareness to the discrimination LGBTQ+ community members face. In addition, National Coming Out Day is celebrated on Oct. 11, which is the day of the second march on Washington for Lesbian and Gay Rights in 1987.

CCR ENROLLING STUDIES

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 in the last 10 days.
- Have at least two symptoms of the illness for seven days or less.

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. Eligibility includes:

- Participants aged 65 to 90 years old.
- Participants with a diagnosis of Alzheimer's disease.
- Participants who are currently exhibiting or showing signs of restlessness, aggression or irritability.
- Participants must have a dedicated caregiver who is also willing to participate in the study.

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, participants must:

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

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 medication for MDD wants to help. To qualify for this study, participants must:

- Be 18 to 65 years of age.
- Have a diagnosis of MDD.
- Be in a current depressive episode for at least eight weeks but no longer than 18 months.
- Currently take an antidepressant medication and have been on a stable dose for the last six weeks.

CCR ENROLLING STUDIES

ALZHEIMER'S DISEASE

COHORT

You can help advance the research on memory and aging by participating in the Clinical Cohort. Participation contributes to local and national efforts to advance science to eliminate Alzheimer's disease. Participation is available to both individuals who are and are not experiencing memory loss and will include yearly 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:

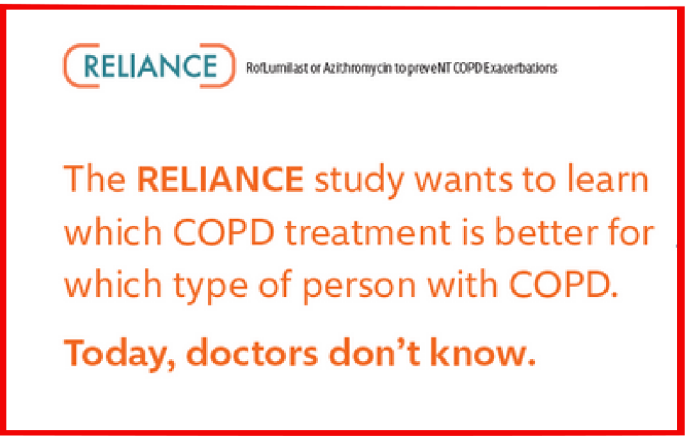
- Are 18 to 65 years of age.
- Have had moderately to severely active CD for at least three months.
- Have not responded to previous treatment for CD.

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 participant will receive the 23andMe results at no charge.

COPD



RELIANCE-COPD

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 treatments with their doctor.

CCR ENROLLING STUDIES

COVID-19 PREVENTION

SCORPIO-PEP

The SCORPIO-PEP study is being done to learn whether an investigational medicine can prevent COVID-19 in those exposed to it. Both individuals with COVID-19 and those who live in the same household as someone with COVID-19 can participate. All participants must be 18 years or older. The study will last for a total of 28 days and will include seven study visits.

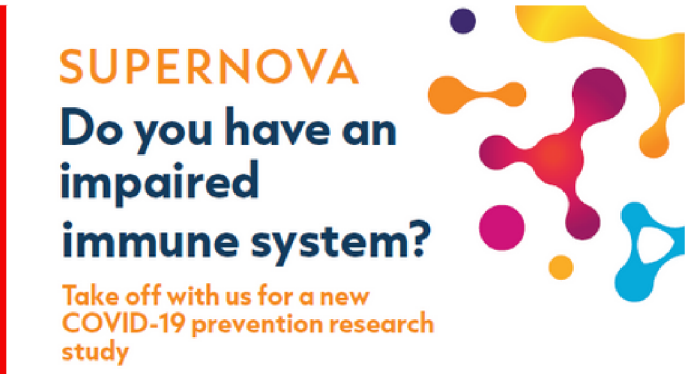
ALZHEIMER'S DISEASE

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, anger or other symptoms of agitation.
- Have a study partner.

COVID-19 PREVENTION



SUPERNOVA

The SUPERNOVA study is a 15-month study that is looking at an investigational medication designed to help protect people with an impaired immune system from contracting COVID-19. Participants must:

- Be 18 years of age or older.
- Not currently have COVID-19.
- Have immune risk factors (cancer patients, liver/kidney transplant patients, HIV patients, etc.)
- Have not received a COVID-19 vaccine in the last three months.

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.

KU WICHITA CENTER FOR CLINICAL RESEARCH

PARTICIPANTS NEEDED

Clinical research participants have access to:

- Investigational research trials
- Expert clinical assessment and care
- Medication
- Time/travel reimbursement
- No insurance required
- And more!

SCAN ME!

CONTACT US

1010 N. Kansas
Wichita, KS 67214
P: 316-293-1833
F: 316-293-1829
E: clinicaltrialunit@kumc.edu

FOR MORE INFORMATION:

Hannah Hancock, participant recruiter
hhancock@kumc.edu