DukeMedicine

Duke Adult Infectious Diseases
CLINICAL TRIALS AT A GLANCE – October 2021 (v10/12/21)

Currently Enrolling* at Duke University Hospital

***note: Tier 2 and 3 studies currently on enrollment hold. Pending COVID-19 interventional prevention and treatment studies included on this list. Quick reference to patient population highlighted. We will be updating this document frequently.**

Summary of Active Clinical Treatment COVID Trials by Patient Population				
	Prevention	**Treatment-Outpatient**	**Treatment- Moderate Hospitalized**	**Treatment- Severe Hospitalized**
		• ACTIV-2 • Regeneron mAb -Amendment 6 • ACTIV-4c • ACTIV-6		• hCT-MSCs • ACTIV-1 • ACTIV-3 • AirFLO2 • ACTIV-4a (note: this is an antithrombotic strategy) • Lyophilized Lucinactant (Surfactant) • iCO in ARDS • TESICO/ACTIV-3b

Short Name	Short Title or Purpose/ClinicalTrials.gov	Intervention(s)	Key Eligibility Criteria	Contact
COVID-19 ACTIVE				

hCT-MSC	hCT-MSCs for COVID19 ARDS https://clinicaltrials.gov/ct2/show/NCT04399889	3 daily consecutive doses of human cord tissue mesenchymal stromal cells (hCT-MSC) 1 million cells/kg (max 100 million cells)	Inclusion Criteria: • The patient or legally authorized representative (LAR) must have the ability to understand and the willingness to provide a signed and dated informed consent form. • Age 18 years and over • The patient agrees to use adequate contraception for the duration of the treatment protocol and for 6 months post treatment. • Positive RT- PCR testing for COVID-19 nucleic acid using nasopharyngeal swabbing or any other site • Patient meets ARDS criteria as defined by Berlin criteria, and is on mechanical ventilation a. Berlin criteria for ARDS are: i. bilateral opacities on chest imaging consistent with pulmonary edema ii. A need for positive pressure ventilation via endotracheal or tracheostomy tube iii. PaO2/FiO2 ratio ≤ 300mmHg with a minimum of 5 cmH20 PEEP iv. Infiltrates not fully explained by cardiac failure or fluid overload in the physician's best clinical judgement ARDS onset is considered the time that the last of criteria 1-4 is met. Infiltrates considered "consistent with pulmonary edema" include any infiltrate not due to mass, atelectasis, or effusion, or opacities known to be chronic (greater than 1 week old). Vascular redistribution or indistinct vessels or heart border alone do not qualify as opacities. Exclusion Criteria: • Evidence of multiorgan failure involving one or more organs, excluding the lungs as defined below: • Presence of shock, defined as MAP < 65 mmHg with signs of peripheral hypoperfusion, or continuous infusion of 2 or more vasopressor or inotrope	Allie Frear 919-684-8914 Raha Manyary 919-590-7452

Short Name	Short Title or Purpose/ClinicalTrials.gov	Intervention(s)	Key Eligibility Criteria	Contact
			agents to maintain MAP ≥ 65 mmHg. • Serum bilirubin > 10 mg/dl • Platelet count < 50,000/ml • Evidence of acquired or congenital immunodeficiency (due to immunosuppressive therapy, HIV, previous treatment for cancer, etc.) • History of metastatic cancer in the past 3 years • History of previous treatments with MSCs or other cell therapies • Patient is co-enrolled in any other IND-sponsored clinical trials for COVID-19 • Evidence of pregnancy or lactation • Moribund patient not expected to survive > 24 hours • Unable/unwilling to deliver lung protective ventilation • Patient is receiving Extracorporeal Membrane Oxygenation (ECMO)	

TESICO)/ACTIV-3b	Therapeutics for Severely Ill Inpatients with COVID-19 (TESICO)/ACTIV-3b https://clinicaltrials.gov/ct2/show/NCT04843761	Aviptadil vs. placebo remdesivir vs. placebo.	Inclusion Criteria: • Signed informed consent. • Requiring admission to hospital for acute medical care (not for purely public health or quarantine purposes). • Current respiratory failure (i.e. receipt of high-flow nasal cannula, non-invasive ventilation, invasive mechanical ventilation, or ECMO (extracorporeal membrane oxygenation) used to treat acute hypoxemic respiratory failure). • SARS-CoV-2 (COVID-19) infection, documented by a nucleic acid test (NAT) or equivalent testing with most recent rest within 14 days prior to randomization. • Respiratory failure is believed to be due to SARS-CoV-2 pneumonia. Exclusion Criteria: • Known allergy to investigational agent or vehicle. • More than 4 days since initiation of support for respiratory failure. • Chronic/home mechanical ventilation (invasive or non-invasive) for chronic lung or neuromuscular disease (non-invasive ventilation used solely for sleep-disordered breathing is not an exclusion). • Moribund patient (i.e. not expected to survive 24 hours). • Active use of "comfort care" or other hospice-equivalent standard of care. • Expected inability to participate in study procedures. • In the opinion of the investigator, any condition for which, participation would not be in the best interest of the participant or that could limit protocol-specified assessments. • Previous enrollment in TESICO • Agent-specific exclusion criteria	Kathleen Lane 919-720-1721

Short Name	Short Title or Purpose/ClinicalTrials.gov	Intervention(s)	Key Eligibility Criteria	Contact
			• Prior receipt of any dose of remdesivir during present illness (remdesivir agent). • GFR (glomerular filtration rate) < 30 ml/min and not receiving dialysis (remdesivir agent). • ALT (alanine aminotransferase) or AST (aspartate aminotransferase) > 10 times upper limit of normal (remdesivir agent). • Unwillingness to commit to avoid sex that may result in pregnancy for at least 7 days after completion of remdesivir vs. placebo (remdesivir agent). • Refractory hypotension (aviptadil agent). • Severe diarrhea (Aviptadil agent). • Current C. difficile infection (aviptadil agent). • Pregnancy or current breast-feeding (aviptadil agent). • End-stage liver disease (aviptadil agent	

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ACTIV-4a	A Multicenter, Adaptive, Randomized Controlled Platform Trial of the Safety and Efficacy of Antithrombotic Strategies in Hospitalized Adults with COVID-19 https://clinicaltrials.gov/ct2/show/NCT04505774 (note: This is a test of antithrombotic strategies for prevention of adverse outcomes in COVID-19 positive inpatients)	Randomization to various antithrombotic strategies	Inclusion Criteria • ≥ 18 years of age • Hospitalized for COVID-19* *It is strongly recommended to confirm SARSCoV2 with a positive microbiological test prior to randomization. At centers where there is delay in confirming the diagnosis, a sufficiently high clinical suspicion is sufficient to proceed with randomization as long as confirmation is expected within 24 hours. • Enrolled within 72 hours of hospital admittance or 72 hours of positive COVID test • Expected to require hospitalization for > 72 hours •(See arm-specific Appendices for additional criteria and details) Exclusion Criteria • Imminent death • Requirement for chronic mechanical ventilation via tracheostomy prior to hospitalization • Pregnancy • See arm-specific appendices	Gloria Pinero 919 602 9568 Yemisi Mohammad - 919 641 5464

ACTIV-3			Inclusion Criteria 1. Age ≥ 18 years; 2. Informed consent by the patient or the patient's legally-authorized representative (LAR)* 3. SARS-CoV-2 infection, documented by a nucleic acid test (NAT) or equivalent testing within 3 days prior to randomization OR documented by MAT or equivalent testing more than 3 days prior to randomization AND progressive disease suggestive of ongoing SARS-CoV-2 infection per the responsible investigator; 4. Duration of symptoms attributable to COVID-19 ≤ 12 days per the responsible investigator; 5. Requiring admission for inpatient hospital acute medical care for clinical manifestations of COVID-19, per the responsible investigator, and NOT for purely public health or quarantine purposes. Exclusion Criteria 1. Prior receipt of •Any SARS-CoV-2 hIVIG, convalescent plasma from a person who recovered from COVID-19 or •SARS-CoV-2 nMAb at any time prior to hospitalization; 2. Not willing to abstain from participation in other COVID-19 trials until after Day 5; 3. In the opinion of the responsible investigator, any condition for which, participation would not be in the best interest of the participant or that could limit protocol-specified assessments; 4. Expected inability to participate in study procedures; 5. Women of child-bearing potential who are not already pregnant at study entry and who are unwilling to acknowledge the strong advice to abstain from sexual intercourse with men or practice appropriate contraception through 18 months of the study. 6. Men who are unwilling to acknowledge the strong advice to abstain from sexual	Mary Mota 804-982-0150

Short Name	Short Title or Purpose/ClinicalTrials.gov	Intervention(s)	Key Eligibility Criteria	Contact
			intercourse with women of child-bearing potential or to use barrier contraception through 18 months of the study. 7. Presence at enrollment of any of the following: a. stroke b. meningitis c. encephalitis d. myelitis e. myocardial ischemia f. myocarditis g. pericarditis h. symptomatic congestive heart failure (NYHA class III-IV) i. arterial or deep venous thrombosis or pulmonary embolism 8. Current requirement for any of the following: a. invasive mechanical ventilation b. ECMO c. mechanical circulatory support d. vasopressor therapy e. commencement of renal replacement therapy at this admission (i.e. not patients on chronic renal replacement therapy).	
ACTIV-4c	A multicenter, adaptive, prospective, randomized trial evaluating the efficacy and safety of antithrombotic strategies in patients with COVID-19 following hospital discharge note: This is a test of antithrombotic strategies for prevention of adverse outcomes in COVID-19 positive inpatients)	Anticoagulants Vs Placebo	Inclusion (key only) • Adults ≥18 years of age with COVID-19 • hospitalized for 48hours or longer and who are ready for discharge from the hospital Exclusion (key only) • Clinical requirement for anticoagulant therapy(therapeutic dose or prophylactic dose) • Contraindication to anticoagulant therapy • Anticipated life-expectancy <90 days	Yemisi Mohammed (919-641-5464) Gloria Pinero (919-602-9568)

Short Name	Short Title or Purpose/ClinicalTrials.gov	Intervention(s)	Key Eligibility Criteria	Contact
ACTIV-6	COVID-19 Outpatient Randomized Trial to Evaluate Efficacy of Repurposed Medications https://clinicaltrials.gov/ct2/show/NCT04885530	Ivermectin or placebo	Inclusion • Completed Informed Consent • Age ≥30 years old • Confirmed SARS-CoV-2 infection by any authorized or approved PCR or antigen test collected within 10 days of screening • Two or more current symptoms of acute infection for ≤7 days. Symptoms include the following: fatigue, dyspnea, fever, cough, nausea, vomiting, diarrhea, body aches, chills, headache, sore throat, nasal symptoms, new loss of sense of taste or smell Exclusion • Prior diagnosis of COVID-19 infection (> 10 days from screening) • Current or recent (within 10 days of screening) hospitalization • Known allergy/sensitivity or any hypersensitivity to components of the study drug or placebo* • Known contraindication to study drug including prohibited concomitant medications (Use of CYP3A4, P-gp inhibitor drugs, or CYP3A4 substrates are contraindicated for use with ivermectin)	Lorraine Vergara 401-678-0171

Short Name	Short Title or Purpose/ClinicalTrials.gov	Intervention(s)	Key Eligibility Criteria	Contact
iCO in ARDS	A Phase II Trial of Inhaled Carbon Monoxide for the Treatment of Acute Respiratory Distress Syndrome (ARDS) https://clinicaltrials.gov/ct2/show/NCT03799874 note: This is an intervention for prevention of adverse outcomes in a subset of COVID-19 positive inpatients)	randomized in a 1:1 ratio to receive either inhaled CO or inhaled air placebo for up to 90 minutes daily for 3 days, until discontinuation of mechanical ventilation, or death, whichever comes first.	Inclusion • All intubated patients > 18 years old with ARDS according to the Berlin criteria Exclusion • Greater than 168 hours since ARDS onset • Pregnant or breastfeeding • Prisoner • Patient, surrogate, or physician not committed to full support (exception: a patient will not be • excluded if he/she would receive all supportive care except for attempts at resuscitation from • cardiac arrest) • No consent/inability to obtain consent or appropriate legal representative not available • Physician refusal to allow enrollment in the trial • Moribund patient not expected to survive 24 hours • No arterial or central line/no intent to place an arterial or central line.	Allie Frear 919-684-8914

Lyophilized Lucinactant	A Multicenter, Single-Treatment Study to Assess the Safety and Tolerability of Lyophilized Lucinactant in Adults with Covid-19 Associated Acute Lung Injury note: This is a test of adjunctive therapy for prevention of adverse outcomes in COVID-19 positive inpatients) https://clinicaltrials.gov/ct2/show/NCT04389671?term=Lucinactant&cond=Covid19&draw=2&rank=1	Lyophilized lucinactant 160 ml (~80 mg total phospholipids (TPL)/kg lean body weight).	Inclusion Criteria: 1. Signed and dated ICF by the subject or legally authorized representative; 2. Age 18-75 (inclusive); 3. Assay positive for SARS-CoV-2 virus, preferably by polymerase chain reaction (PCR); 4. Endotracheal intubation and MV, within 7 days of initial intubation; 5. In-dwelling arterial line; 6. P/F ratio < 300; 7. Mean blood pressure 65 mmHg, immediately before enrollment; 8. Bilateral infiltrates seen on frontal chest radiograph. Exclusion criteria 1. Life expectancy < 48 hours or do not resuscitate orders; 2. Severe lung disease (home O2, FEV1 < 2 liters) not likely to respond to therapy or profound hypoxemia (ie, OI ≥ 25 or P/F < 100); 3. Severe renal impairment (creatinine clearance < 30 mL/min); 4. Within the last 6 months has received, or is currently receiving, immunosuppression therapy (azothiaprine, cyclophosphamide or methotrexate) or any transplant recipient; 5. Clinically significant cardiac disease that adversely effects cardiopulmonary function: a. Acute coronary syndromes or active ischemic heart disease (as assessed by the PI using troponin and ECG) b. Cardiac ejection fraction < 40% (if known); c. Need for multiple-dose vasopressors to support blood pressure (single dose vasopressors, such as Levophed™ ≤ 0.1 mcg/kg/min are allowed); d. Cardiogenic pulmonary edema as the etiology of the current respiratory distress; e. Evidence of myocarditis or pericarditis; 6. Neuromuscular disease; 7. Neutropenia (ANC < 1000); 8. Active malignancy that impacts treatment decisions or life expectancy related to this trial;	Brittany McDowell

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			9. Suspected concomitant bacterial or other viral lung infection. Bacterial infection defined as WBC > 15k and positive blood/ urine/sputum culture results within 72 hours.	

ACTIV-1	Randomized Master Protocol for Immune Modulators for Treating COVID-19 https://clinicaltrials.gov/ct2/show/NCT04593940	randomization 1:1:1:1 of remdesivir and infliximab vs abatacept vs standard of care	**Inclusion Criteria** 1. Admitted to a hospital or awaiting admission in the ED with symptoms suggestive of COVID-19. 2. Subject (or legally authorized representative) provides informed consent prior to initiation of any study procedures. 3. Subject (or legally authorized representative) understands and agrees to comply with planned study procedures. 4. Male or non-pregnant female adults ≥18 years of age at time of enrollment. 5. Has laboratory-confirmed (within 14 days prior to enrollment) SARS-CoV-2 infection as determined by PCR or other commercial or public health assay in any specimen. 6. Ongoing illness of any duration, and at least one of the following: ▯ Radiographic infiltrates by imaging (chest x-ray, CT scan, etc.), OR ▯ Blood oxygen saturation (SpO2) ≤ 94% on room air, OR ▯ Requiring supplemental oxygen, OR ▯ Requiring mechanical ventilation or ECMO. 7. Women of childbearing potential must agree to either abstinence or use at least one primary form of contraception not including hormonal contraception from the time of screening through Day 60. 8. Agrees to not participate in another interventional trial for the treatment of COVID-19 through Day 60. Exclusion Criteria 1. ALT or AST >5 times the upper limit of normal. 2. Estimated glomerular filtration rate (eGFR) <30 mL/min (including patients receiving hemodialysis or hemofiltration). 3. Neutropenia (absolute neutrophil count <1000 cells/µL) (<1.0 x 103/µL or <1.0 GI/L). 4. Lymphopenia (absolute lymphocyte count <200 cells/µL) (<0.20 x 103/µL or <0.20 GI/L) 5. Pregnancy or breast feeding.	Gloria Pinero (919-602-9568) Sally Taylor

			6. Anticipated discharge from the hospital or transfer to another hospital which is not a study site within 72 hours. 7. Known allergy to any study medication. 8. Received cytotoxic or biologic treatments (such as anti-interleukin-1 [IL-1], anti-IL-6 [tocilizumab or sarilumab], anti-IL-17, or T-cell or B-cell targeted therapies (e.g., rituximab), tyrosine kinase inhibitors including baricitinib, TNF inhibitors, or interferon within 4 weeks or 5 half-lives prior to screening. Steroid dependency defined as need for prednisone at a dose >10 mg (or equivalent) for >1 month within 2 weeks of screening is exclusionary. Note 1: Dexamethasone (at a dose of 6 mg per day for up to 10 days) is permitted for the treatment of COVID-19 in patients who are already mechanically ventilated and in patients who require supplemental oxygen at screening, but who are not mechanically ventilated in accordance with national guidelines. Note 2: Infusion of convalescent plasma is also allowed. 9. Based on medical history and concomitant therapies that would suggest infection, have suspected clinical diagnosis of current active tuberculosis (TB) or, if known, latent TB treated for less than 4 weeks with appropriate anti-tuberculosis therapy per local guidelines (by history only, no screening required). 10. Based on medical history and concomitant therapies that would suggest infection, suspected serious, active bacterial, fungal, viral (including, but not limited to, active HBV, HCV, or HIV/AIDS). 11. Have received any live vaccine (that is, live attenuated) within 3 months before screening, or intend to receive a live vaccine (or live attenuated) during the study. Note: Use of non-live (inactivated) vaccinations is allowed for all participants. 12. Severe hepatic impairment (defined as liver cirrhosis Child stage C).	

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			13. Current severe heart failure (New York Heart Association [NYHA] III-IV). 14. In the Investigator's judgment, the patient has any advanced organ dysfunction that would not make participation appropriate.	

Regeneron mAb	A Master protocol Assessing the Safety, Tolerability, And Efficacy of Anti-Spike (S) Sars-Cov-2 Monoclonal Antibodies For The Treatment Of Ambulatory Patients With Covid-19
	
	https://clinicaltrials.gov/ct2/show/NCT04425629
		Co-administered REGN10933+REGN10987 combination therapy, 1.2 g (600 mg each of REGN10933 and REGN10987) IV single dose; Co-administered REGN10933+REGN10987 combination therapy, 2.4 mg (1.2 g each of REGN10933 and REGN10987) IV single dose dose while in ED
		
		(update amendment 6)
		• For cohort 1, the REGN10933+REGN10987 8000 mg IV treatment arm will be dropped. The REGN10933 + REGN10987 2400 mg IV treatment arm and placebo arm will be retained. A new treatment arm will be added to assess REGN10933+REGN10987 1200 mg IV
		• For cohort 2, the highest dose tested will be REGN10933 + REGN10987 2400 mg IV. Weight-tiered dosing will be used in this cohort
			INCLUSION (KEY ONLY)
			• Has SARS-CoV-2-positive antigen or molecular diagnostic test (by validated SARS-CoV-2
			• antigen, RT-PCR, or other molecular diagnostic assay, using an appropriate sample such as NP, nasal, oropharyngeal [OP], or saliva) ≤72 hours prior to randomization. A historical record of positive result from test conducted ≤72 hours prior to randomization is acceptable.
			• Meets one of the following two criteria:
			  • Symptomatic Cohort (All Phases): Has symptoms consistent with COVID-19, as determined by the investigator, with onset ≤7 days before randomization or
			  • Asymptomatic Cohort (Phase 2): Meets all of the following:
			  • Has had no symptoms consistent with COVID-19 (as determined by the investigator) occurring at any time <2 months prior to randomization
			  • Has had no positive SARS-CoV-2 test results from a sample collected >7 days prior to randomization
			  • Has had no known contact (of any duration) with an individual who has confirmed COVID-19 or confirmed
			• Females who are pregnant or breastfeeding can enroll in the study
			• Patients from 0 to <18 years will be enrolled as a separate cohort (cohort 2), where permitted by local requirements. NOTE: Duke will be enrolling 12-18yr of age
			• Patients ≥18 years of age will be enrolled in cohort 1
			• Patients in cohort 1 must have ≥1 risk factor for severe COVID-19. Patients in cohort 2 must have ≥1 risk factor for severe COVID-19 or live with a housemate who has ≥1 risk factor for severe COVID-19
				Dr. John Eppensteiner
				
				S. Michelle Griffin/ Andrew Bouffler

Short Name	Short Title or Purpose/ClinicalTrials.gov	Intervention(s)	Key Eligibility Criteria	Contact
			EXCLUSION (KEY ONLY) • Has been admitted to a hospital prior to randomization, or is hospitalized (inpatient) at randomization, due to COVID-19 • Has participated, or is participating, in a clinical research study evaluating COVID-19 convalescent plasma, mAbs against SARS-CoV-2, or intravenous immunoglobulin (IVIG) within 3 months or less than 5 half-lives of the investigational product (whichever is longer) prior to the screening visit • Prior, current, or planned future use of any of the following treatments: COVID-19 convalescent plasma, mAbs against SARS-CoV-2, intravenous Immunoglobulin (IVIG) (any indication), systemic corticosteroids (any indication), or COVID-19 EUA-approved treatments, where prior use is defined as the past 30 days or less than 5 half-lives of the investigational product (which is longer) from screening • Patients with a known positive SARS-CoV-2 serology test will be excluded • Patients with a positive SARS-CoV-2 antigen test or molecular diagnostic test from a sample collected >72 hours prior to randomization will be excluded • Patients with active infection with influenza or other non-SARS-CoV-2 respiratory pathogen, confirmed by a diagnostic test, will be excluded	

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ACTIV-2	Adaptive Platform Treatment Trial for Outpatients with COVID-19 (Adapt Out COVID) https://clinicaltrials.gov/ct2/show/NCT04518410 https://www.dukehealth.org/clinical-trials/directory/pro00106671	Single-dose infusion of 700mg of bamlanivimab for treatment of COVID-19 (infused over 1 hour) OR matching placebo	INCLUSION • Age 18 years or older • Positive SARS-CoV-2 test within 7 days of enrollment (Patients can be retested if they are out of window) • Onset of symptoms ≤ 10 days prior to enrollment • Presence of symptoms within 48 hours prior to enrollment EXCLUSION • Prior or current hospitalization for COVID-19 • Current need for hospitalization in the opinion of treating clinician • Receipt of COVID-19 vaccine in the past • Receipt of any COVID-19 investigational therapeutics in the past • Receipt of steroids in the last 30 days • Currently pregnant	Dr. Lance Okeke lance.okeke@duke.edu or 919-321-7474 Caroline Sanner

ACTIV-3	A Multicenter, Adaptive, Randomized, Blinded Controlled Trial of the Safety and Efficacy of Investigational Therapeutics for Hospitalized Patients with COVID-19 https://clinicaltrials.gov/ct2/show/NCT04501978	AZD8895/AZD1061 (known collectively as AZD7442) or placebo	**Inclusion** • Age ≥ 18 years; • Informed consent by the patient or the patient's legally-authorized representative (LAR)* • SARS-CoV-2 infection, documented by PCR or other nucleic acid test (NAT) within 3 days prior to randomization OR documented by NAT more than 3 days prior to randomization AND progressive disease suggestive of ongoing SARS-CoV-2 infection per the responsible investigator; • Duration of symptoms attributable to COVID-19 ≤ 12 days per the responsible investigator; • Requiring admission for inpatient hospital acute medical care for clinical manifestations of COVID-19, per the responsible investigator, and NOT for purely public health or quarantine purposes. • *Continuing consent • Participants for whom consent was initially obtained from a LAR, but who subsequently regain decision-making capacity while in hospital will be approached for consent for continuing participation, including continuance of data acquisition. The consent form signed by the LAR should reflect that such consent should be obtained. **Exclusion** • Prior receipt of Any SARS-CoV-2 hIVIG, convalescent plasma from a person who recovered from COVID-19 or SARS-CoV-2 nMAb at any time prior to hospitalization; • Not willing to abstain from participation in other COVID-19 treatment trials until after Day 5; • In the opinion of the responsible investigator, any condition for which, participation would not be in the best interest of the participant or that could limit protocol-specified assessments;	Mary Motta 804-982-0150 (mobile)

Short Name	Short Title or Purpose/ClinicalTrials.gov	Intervention(s)	Key Eligibility Criteria	Contact
			• Expected inability to participate in study procedures; • Pregnant or breastfeeding • High flow nasal cannula (optiflow) • Women of child-bearing potential who are not already pregnant at study entry and who are unwilling to abstain from sexual intercourse with men or practice appropriate contraception through Day 90 of the study. • Men who are unwilling to abstain from sexual intercourse with women of child-bearing potential or who are unwilling to use barrier contraception through Day 90 of the study. • [stage 1 only] Presence at enrollment of any of the following: stroke, meningitis, encephalitis, myelitis, myocardial infarction, myocarditis, pericarditis, symptomatic congestive heart failure (NYHA class III-IV), arterial or deep venous thrombosis or pulmonary embolism • [stage 1 only] Current or imminent requirement for any of the following: invasive mechanical ventilation; ECMO, mechanical circulatory support, vasopressor therapy, commencement of renal replacement therapy at this admission (i.e. not patients on chronic renal replacement therapy).	

AirFLO2	AirFLO2 Treatment for Hypoxia and/or Tachypnea in Patients with COVID-19 https://clinicaltrials.gov/ct2/show/NCT04649775	unblinded, randomized, controlled trial for use of the AirFIO2 device	Inclusion criteria: •Adults ≥18 years of age with confirmed COVID-19 infection •Patient must be able to complete consent and hold mask •Room air oxygen saturation </=94%, patient with new supplemental oxygen requirement, or patient on supplemental oxygen at baseline and requiring up-titration of oxygen setting •Patient must have access to an internet-connected device Exclusion criteria: •Tracheostomy (current) •History of pneumothorax or known bullous lung disease •Recent cataract surgery •Patient receiving NIV (Noninvasive Ventilation) or HFNC (High Flow Nasal Cannula) •Patient receiving mechanical ventilation •Active TB •Seizures •Delirium preventing patient from providing informed consent or self-applying mask	Cathy Foss

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Fungal				
Candidemia (Scynexis)	Open–Label Study of SCY-078 in Patients with Invasive and/or Severe Fungal Infections Refractory to or Intolerant of Standard Antifungal Treatment https://clinicaltrials.gov/ct2/show/NCT03059992	SCY-078 -301	▪ ≥ 18 years of age with a documented eligible invasive and/or severe fungal disease ▪ refractory to/intolerant of/ or not feasible to receive available antifungal treatment	Caroline Questell 668-5142 Pager 970-4949
AMPLYX 2 IMI Caused by Aspergillus or Rare Molds	A Phase 2, Open-Label Study to Evaluate the Safety and Efficacy of APX001 in the Treatment of Patients with Invasive Mold Infections Caused by Aspergillus Species or Rare Molds https://clinicaltrials.gov/ct2/show/NCT04240886?term=APX001&cond=Aspergillus+Infection&draw=2&rank=1	IV APX001 with Oral Step-down available after Day 3	▪ Aged 18 + w/ confirmed IMI ▪ Documented/anticipated resistance, contraindication, intolerance so SOC antifungal therapy ▪ Cannot have treatment with systemic antifungal therapy w/ mold-active azole or polyene for > 120 hours immediately before first dose ▪ Significant hepatic dysfunction ▪ Ongoing history of neurologic disorders	Ashley Pifer 668-0166 Pager 970-4134
REFUND	REpository for FUNgal Diagnostics (REFUND)	No Intervention	▪ ≥ 18 years of age ▪ Subject listed for lung transplant and/or admitted to an ICU for at least 48hours and expected to stay an additional 48hours (and with additional risks ▪ Subject with suspected or diagnosed with proven, probable or possible IFI based on MSG/EORTC definitions	Kelly Stanly 668-9324 Diane Wright 668-5571

Short Name	Short Title or Purpose/ClinicalTrials.gov	Intervention(s)	Key Eligibility Criteria	Contact
F2G invasive fungal diseases	An open-label single-arm Phase IIb study of F901318 as treatment of invasive fungal infections due to Lomentospora prolificans, Scedosporium spp., Aspergillus spp., and other resistant fungi in patients lacking suitable alternative treatment options. https://clinicaltrials.gov/ct2/show/NCT03583164?term=F901318&rank=1	F901318 for invasive fungal diseases	▪ Patients with confirmed IFD: Lomentospora (Scedosporium) prolificans (LoPro), Scedosporium spp., Aspergillus spp. ▪ Patients have limited alternative treatment options.	Shuqin Li 668-0165
HIV Treatment-Experienced				
IMMUNE	Pathogenesis of Neuroinflammation and Neurocognitive Impairment in HIV-infected Young Adult Cannabis Users	No treatment provided	■ Ages 18-29 ■ HIV+ ■ HIV RNA (viral load) contained ■ Stable ART for >6 months ■ Last CD4 count above 350	Dominick Bresson 668-9324 (On hold)

Short Name	Short Title or Purpose/ClinicalTrials.gov	Intervention(s)	Key Eligibility Criteria	Contact
HIV Biorepository	Database repository that allows archived clinical specimens and data to be stored and used for future research	No treatment provided	■ ≥ 18 years ■ Current or former patient in the Duke Infectious Diseases Clinic	Rebecca Mangus 668-3199
Lipidomic	The purpose is to develop new tools to monitor patients with liver disease from hepatitis C infection before/after treatment	No treatment provided	■ HIV/HCV co-infection initiating a course of all-oral, DAA therapy as part of standard of care	Rebecca Mangus 668-3199
Hepatitis B Virologic Failure	Study of blood samples from people with both HIV and hepatitis B to investigate causes of virologic failure to tenofovir-based combinations.	No treatment provided	■ Adults 18 years of age with HIV and HBV co-infection on cART that includes TDF ■ Obtainable plasma samples ■ No change in cART therapy that can explain the failure of HBV therapy	Rebecca Mangus 668-3199 (On hold)

Short Name	Short Title or Purpose/ClinicalTrials.gov	Intervention(s)	Key Eligibility Criteria	Contact
HNC-001	Prevalence and Predictors of Hepatic Steatosis in Persons Living with HIV (Steatosis in HIV Study)	No treatment provided	■ 18 years or older ■ On ART for ≥6 months prior to screening with HIV RNA <200 copies/mL at entry ■ Patients are excluded if there is evidence of current or prior chronic HBV or recent or current HVC ■ Patients are excluded if known other chronic liver disease	Rebecca Mangus 668-3199
GS-US-380-5310	A Phase 1b, Open-label study to Evaluate the PK, Safety and Efficacy of B/F/TAF in HIV-1 infected, Virologically Suppressed, Pregnant Women in their Second and Third Trimesters ClinicalTrials.Gov	B/F/TAF 50/200/25 mg administered orally, once daily	■ Female participants of age >/= 18 to < 40 years with singleton pregnancy, at least 12 weeks but not more than 31 weeks pregnant at the time of screening ■ Currently on a stable antiretroviral regimen for ≥ 6 months preceding the screening visit ■ Documented plasma HIV-1 RNA levels of < 50 copies/mL for ≥ 6 months preceding the screening visit and have HIV-1 RNA < 50 copies/mL at the Screening Visit ■ Patients cannot Have chronic hepatitis B virus (HBV) or active hepatitis C virus (HCV) infection ■ Excluded if treated with immunosuppressant therapies or chemotherapeutic agents within 3 months of study screening	Laura Farrow 668-0176
EXTRA-CVD	Innovative prevention nurse intervention to extend the HIV/AIDS treatment cascade for hypertension and hyperlipidemia among PLHIV on suppressive antiretroviral therapy. https://clinicaltrials.gov/ct2/show/NCT03643705?term=extra+cvd&draw=2&rank=1	No medication intervention, will provide nurse intervention or education control	■ Age ≥18 years ■ Confirmed HIV+ diagnosis (HIV+ ELISA with confirmatory PCR). ■ most recent HIV viral load <200 copies/ml, checked within the past year. ■ systolic BP >130 mmHg on ≥ 2 occasions in the past 12 months or on antihypertensive medication. ■ non-HDL cholesterol >130 mg/dL or on cholesterol lowering medication.	Kiran Grover 668-1095 Caroline Questell 668-5142

Short Name	Short Title or Purpose/ClinicalTrials.gov	Intervention(s)	Key Eligibility Criteria	Contact
SWOBI-CVD	A Clinic-Based Case Manager Administered Telephone Intervention to Reduce Cardiovascular Disease Risk in Persons Living with HIV https://clinicaltrials.gov/ct2/show/NCT03839394?term=A+Clinic-Based+Case+Manager+Administered+Telephone+Intervention+to+Reduce+Cardiovascular+Disease+Risk+in+Persons+Living+with+HIV&draw=2&rank=1	No medication intervention	■ Age 40-75 years ■ In care at the Duke ID clinic for at least 24 months ■ HIV+ and on antiretroviral therapy for at least one year, with six consecutive months of documented viral suppression (HIV-1 RNA <50 copies/ml at time of enrollment. ■ Diagnosis of hypertension or hyperlipidemia	Kiran Grover 668-1095 Caroline Questell 668-5142
HIV Treatment Naïve				
BANNER	A Phase 2a Multicentre, Randomized, Open-Label, Two-Part Adaptive Design Study to Evaluate the Antiviral Effect, Safety and Tolerability of GSK3810109A, an HIV-1 Specific Broadly Neutralizing Human Monoclonal Antibody in Antiretroviralnaïve HIV-1-Infected Adults https://clinicaltrials.gov/ct2/show/NCT04871113?term=GSK3810109A&draw=2&rank=1	GSK3810109A	▪ 18-65 years of age with Plasma HIV-1 RNA ≥5000 c/mL ▪ Antiretroviral naïve: No ARTs (in combination or monotherapy) received after the HIV diagnosis ▪ Body weight ≥50 kg to ≤115 kg ▪ Participants with primary HIV infection evidenced by acute retroviral syndrome and/or evidence of recent (within 3 months) documented viremia without antibody production and/or evidence of recent documented seroconversion are excluded	Ashley Pifer 668-0166

Short Name	Short Title or Purpose/ClinicalTrials.gov	Intervention(s)	Key Eligibility Criteria	Contact
FLU / Parainfluenza / RSV/CMV				
Ansun DAS 181	Phase III DAS 181 Lower Tract PIV Infection in Immunocompromised https://clinicaltrials.gov/ct2/show/NCT03808922?term=DAS+181&rank=7	DAS181 for PIV	■ Currently requires supplemental oxygen ≥2 LPM at the time of randomization. ■ Immunocompromised: HSCT; SOTR; Patients with Chemo treatment. ■ Confirmed PIV lower tract disease.	Shuqin Li 668-0165
Tuberculosis				
LTBI Biomarkers Methodist Study	Immune Response to TB during treatment of Latent Infection	None	Positive IGRA, HIV-, Contact from high incidence country	Laura F 668-0176 (On hold)
Staphylococcus Bloodstream Infections				

Short Name	Short Title or Purpose/ClinicalTrials.gov	Intervention(s)	Key Eligibility Criteria	Contact
DISRUPT	A Randomized, Double-Blind, Placebo-Controlled Study of the Efficacy and Safety of a Single Dose of Exebacase in Patients Receiving Standard-of-Care Antibiotics for the Treatment of *Staphylococcus aureus* Bloodstream Infections (BSI), Including Right-Sided Infective Endocarditis https://clinicaltrials.gov/ct2/show/NCT04160468?term=exebacase&draw=2&rank=1	IV Exebacase	▪ ≥ 18 years of age and >72 hours from blood culture positive for Staphylococcus aureus ▪ Subject has not received Exebacase and has at least two signs and/or symptoms attributable to *S. aureus* BSI ▪ Subject must have known or suspected right-sided infective endocarditis, **or** known or suspected complicated BSI **or** at least one risk factor for complicated BSI ▪ Subject may not have known or suspected left-sided infective endocarditis or >72 hours of effective systemic antistaphylococcal antibiotics prior to randomization	Alyssa McGowan 684-8634 Pager 970-4568
Nontuberculous Mycobacterium (MAC, etc)				

ENCORE	ENCORE - A Randomized, Double-Blind, Placebo-Controlled, Active Comparator, Multicenter Study to Evaluate the Efficacy and Safety of an Amikacin Liposome Inhalation Suspension (ALIS)-Based Regimen in Adult Subjects with Newly Diagnosed Nontuberculous Mycobacterial (NTM) Lung Infection Caused by *Mycobacterium avium* Complex (MAC) https://www.clinicaltrials.gov/ct2/show/NCT04677569	amikacin Liposome Inhalation Suspension + azithromycin + ethambutol or empty liposome control (placebo) + azithromycin + ethambutol X 12 months.	**Inclusion** ▪ ≥18 years of age ▪ Current diagnosis of MAC lung infection ▪ Positive sputum culture for MAC within 6 months prior to Screening ▪ In the Investigator's opinion, documented respiratory signs/symptoms at Screening that are attributable to the current MAC lung infection ▪ Ability to produce (spontaneously or with induction) approximately 2 mL of sputum for mycobacteriology at Screening ▪ Be able to comply with study drug use, study visits, and study procedures as defined by the protocol **Exclusion** ▪ Cystic fibrosis (CF) ▪ History of lung transplantation ▪ Acquired and primary immunodeficiency syndromes (eg, HIV) ▪ Received any mycobacterial antibiotic treatment for current MAC lung infection ▪ Relapse of prior MAC lung infection, defined as positive sputum culture for MAC ≤ 6 months of cessation of prior treatment ▪ Any pulmonary cavity ≥ 2 cm in diameter, as determined by chest CT scan within 6 months prior to Screening ▪ Active pulmonary malignancy or any malignancy requiring chemotherapy or radiation therapy within 1 year prior to Screening or anticipated during the study ▪ Acute pulmonary exacerbation (eg, COPD or bronchiectasis) requiring treatment with antibiotics, or corticosteroids within 4 weeks prior to and during Screening ▪ FEV1 < 35%, pre-bronchodilator use ▪ Current smoker ▪ Prior exposure to ALIS (including clinical study) ▪ Serum creatinine > 2 times ULN ▪ Current alcohol, medication, or illicit drug abuse	April Wittman (919) 668-1220 april.hawkins@duke.edu Kathy Foy (919) 668-3833 katherine.foy@duke.edu

ARISE	ARISE - A Randomized, Double-Blind, Placebo-Controlled, Active Comparator, Multicenter Study to Validate Patient-Reported Outcome Instruments in Adult Subjects with Newly Diagnosed Nontuberculous Mycobacterial (NTM) Lung Infection Caused by *Mycobacterium avium* Complex (MAC) https://clinicaltrials.gov/ct2/show/NCT04677543	amikacin Liposome Inhalation Suspension + azithromycin + ethambutol or empty liposome control (placebo) + azithromycin + ethambutol X 6 months	**Inclusion** ▪ ≥18 years of age ▪ Current diagnosis of MAC lung infection ▪ Positive sputum culture for MAC within 6 months prior to Screening ▪ In the Investigator's opinion, documented respiratory signs/symptoms at Screening that are attributable to the current MAC lung infection ▪ Ability to produce (spontaneously or with induction) approximately 2 mL of sputum for mycobacteriology at Screening ▪ Be able to comply with study drug use, study visits, and study procedures as defined by the protocol **Exclusion** ▪ Cystic fibrosis (CF) ▪ History of lung transplantation ▪ Acquired and primary immunodeficiency syndromes (eg, HIV) ▪ Received any mycobacterial antibiotic treatment for current MAC lung infection ▪ Relapse of prior MAC lung infection, defined as positive sputum culture for MAC ≤ 6 months of cessation of prior treatment ▪ Any pulmonary cavity ≥ 2 cm in diameter, as determined by chest CT scan within 6 months prior to Screening ▪ Active pulmonary malignancy or any malignancy requiring chemotherapy or radiation therapy within 1 year prior to Screening or anticipated during the study ▪ Acute pulmonary exacerbation (eg, COPD or bronchiectasis) requiring treatment with antibiotics, or corticosteroids within 4 weeks prior to and during Screening ▪ FEV1 < 35%, pre-bronchodilator use ▪ Current smoker ▪ Prior exposure to ALIS (including clinical study) ▪ Serum creatinine > 2 times ULN ▪ Current alcohol, medication, or illicit drug abuse	April Wittmann (919) 668-1220 april.hawkins@duke.edu Kathy Foy (919) 668-3833 katherine.foy@duke.edu