

HIV Research Update – Looking to the Future

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Southeast AETC Regional Conference 2022

Learning Objectives

By the end of this session, each participant will be able to:

- list at least 2 (of the 5) **NIH 2022 research priorities for HIV**.
- give at least 3 (of the 28) examples of **focus areas** under the 5 NIH research priorities.
- name at least 3 (of the 5) **locations of ACTG clinical research** sites in the Southeast US.
- describe in broad terms at least 2 (of many) **ACTG research studies** that are now enrolling or will open in the future.

Disclosures

- David Haas has no disclosures

This program is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) under grant number U1OHA30535 as part of an award totaling \$4.2m. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by HRSA, HHS, or the U.S. Government. For more information, please visit HRSA.gov.

“Funding for this presentation was made possible by cooperative agreement U1OHA30535 from the Health Resources and Services Administration HIV/AIDS Bureau. The views expressed do not necessarily reflect the official policies of the Department of Health and Human Services nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government. Any trade/brand names for products mentioned during this presentation are for training and identification purposes only.”



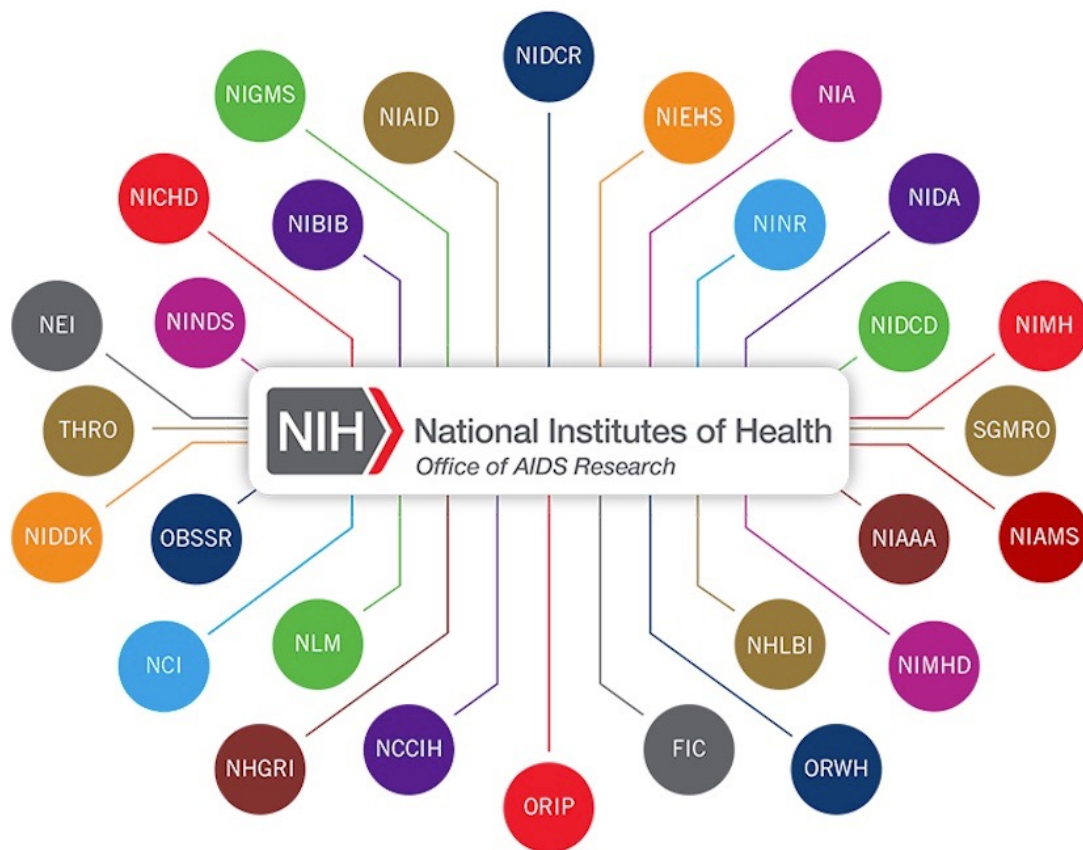
Office of AIDS Research

CONGRESSIONAL JUSTIFICATION
FY 2022

Department of Health and Human Services
National Institutes of Health

James A. Shannon
NIH National Institutes of Health
Office of AIDS Research

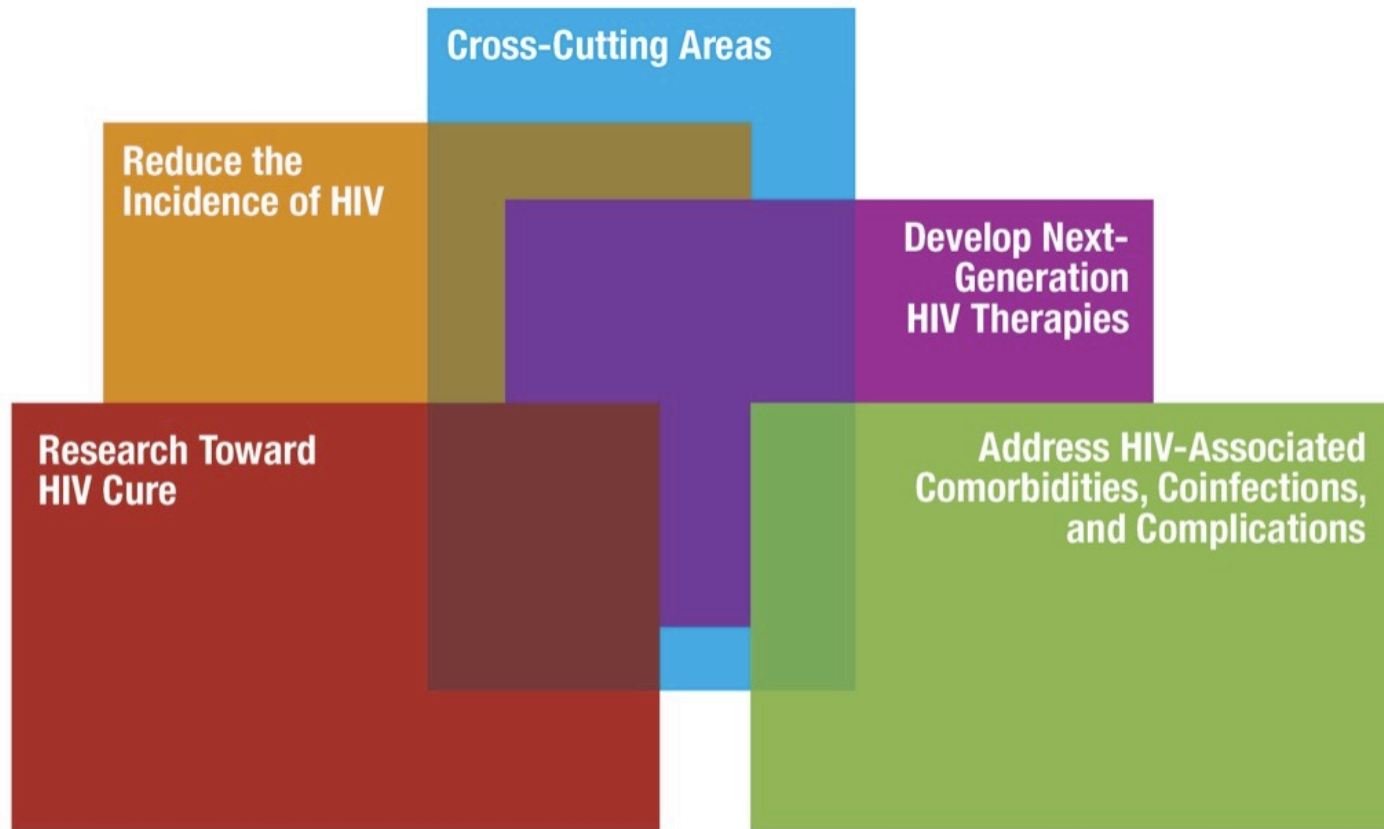
Office of AIDS Research (OAR): Coordinator of NIH's HIV Research Program



~\$3 billion/year
for HIV research

<https://www.oar.nih.gov/about/organization>

NIH Priorities for HIV and HIV-Related Research - 2022



<https://www.oar.nih.gov/hiv-policy-and-research/research-priorities>

Research Toward HIV Cure

- Sustained ART-free Viral Remission
- Viral Eradication
- Viral Latency and Sanctuaries
- Cure Ethics and Acceptability

<https://www.oar.nih.gov/hiv-policy-and-research/research-priorities-overview/research-toward-hiv-cure>

Develop Next-Generation HIV Therapies

- Less Toxic and Longer Lasting ART
- Novel HIV Targets & Inhibitors
- Novel Immune-Based Therapies
- Engagement, Adherence, and Retention in Care

<https://www.oar.nih.gov/hiv-policy-and-research/research-priorities-overview/next-generation-hiv-therapies>

HIV-Associated Comorbidities, Coinfections, and Complications

- Coinfections
- Neurologic Complications
- Malignancies
- Cardiovascular Complications
- Mental Illness and Substance Use
- Metabolic Disorders
- Across the Lifespan

Reduce the Incidence of HIV

- Vaccines
- Pre-exposure Prophylaxis
- Microbicides and MPTs
- HIV Testing
- Treatment as Prevention
- Monoclonal Antibodies

<https://www.oar.nih.gov/hiv-policy-and-research/research-priorities-overview/reduce-incidence-hiv>

Cross-Cutting Areas

- Basic Virology and Immunology
- Behavioral and Social Sciences
- Epidemiology
- Health Disparities
- Information Dissemination
- Implementation Science
- Research Training, Infrastructure, and Capacity Building

<https://www.oar.nih.gov/hiv-policy-and-research/research-priorities-overview/cross-cutting-research>

OAR Listening Sessions - 2020-2021

Date(s)	Stakeholders	Hosts and Moderators
9/16/2020 Boston, MA	Area researchers, students, service providers, public health officials, and community members	Harvard Center for AIDS Research Fenway Community Health and Massachusetts Department of Public Health
9/26/2020 West Virginia	Area researchers, students, service providers, public health officials, and community members	West Virginia University Community Education Group
11/18/2020 Nashville, TN	Area researchers, service providers, public health officials, faith leaders, and community members	Tennessee Center for AIDS Research Meharry Medical College Metropolitan Interdenominational Church
4/21/2021 Nebraska	Area researchers, service providers, and community members	University of Nebraska Medical Center
5/27/2021 San Diego, CA	Area researchers, service providers, public health officials, and community members	San Diego Center for AIDS Research San Diego County Getting to Zero EHE Initiative
6/30/2021 7/7/2021 New Orleans, LA	Health care and other service providers, public health officials, people with HIV, and researchers	Southern AIDS Coalition Louisiana Public Health Institute

OAR's Second HIV Stakeholder Outreach and Engagement Report

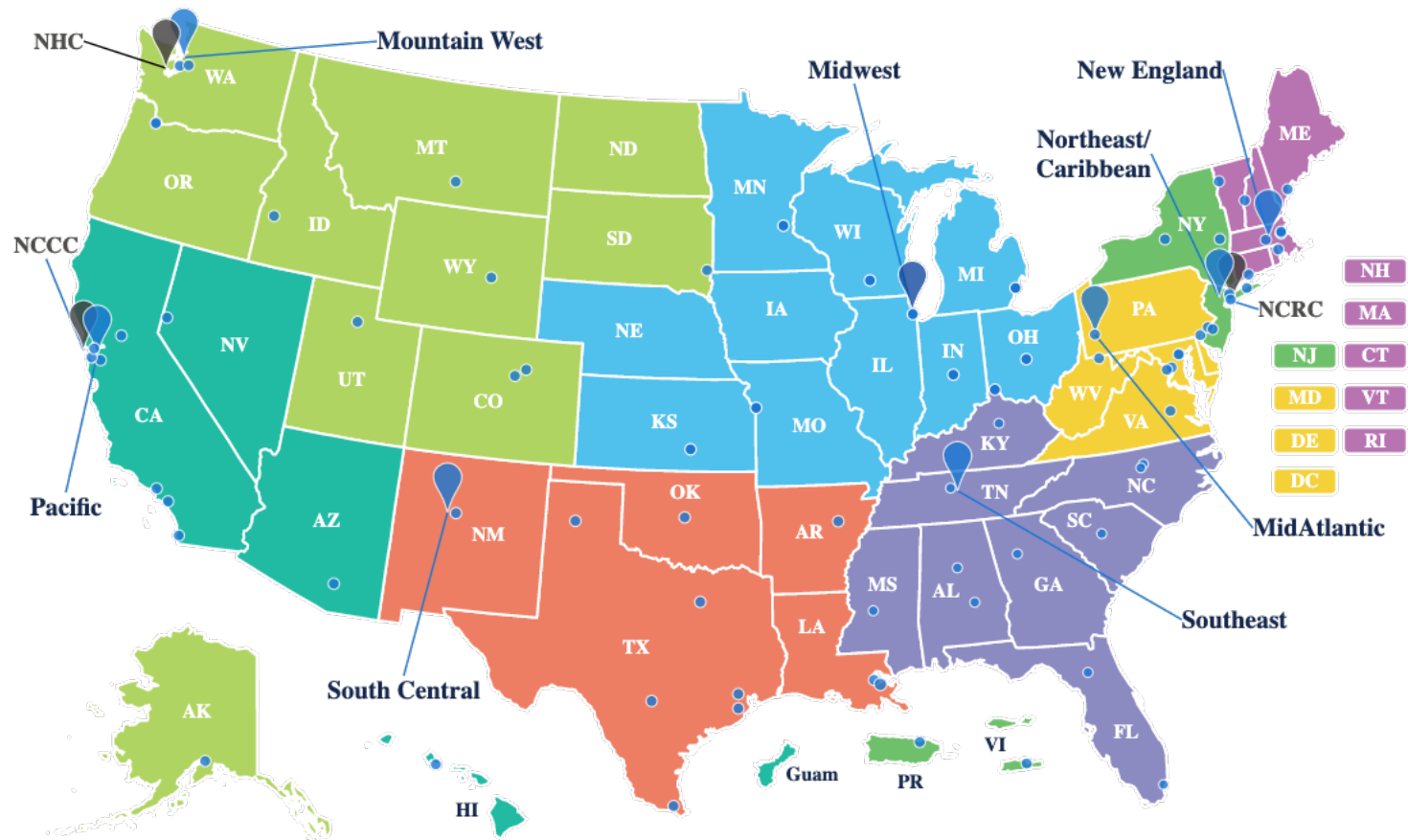
“There were two key environmental changes in early 2020 that deeply affected these listening sessions: the emergence of the **COVID-19 pandemic**, with higher disease burdens among racial and ethnic minorities, and the **resurgence of racial justice** across the United States. These developments had implications for NIH HIV research program priorities, the structure and logistics of the research enterprise, and the HIV research workforce.”

OAR's Second HIV Stakeholder Outreach and Engagement Report Key Findings

- Enhance Support for Priority Areas of Research
- Address the Impact of COVID-19 on HIV Research Activities
- Redress Structural Racism in the HIV Research Enterprise and Diversify the HIV Research Workforce
- Enhance Academic–Community Partnerships
- Focus on Early-Career Investigators

<https://oar.nih.gov/sites/default/files/OAR-Phase2-Stakeholders-Report-2021-508.pdf>

AIDS Education and Training Centers



<https://aidsetc.org/community/design-files-and-templates>

AIDS CLINICAL TRIALS GROUP

The mission of the ACTG Network is to cure HIV and reduce the burden of disease due to HIV and its complications, including tuberculosis and viral hepatitis.

Press Releases & Announcements

AUG
26

[Solicitation for ACTG Science Committee Membership Positions DUE September 21st](#)

[View Past Spotlights](#)

Publication Spotlight

DEC
01

[Cardiovascular Risk and Health Among People With Human Immunodeficiency Virus \(HIV\) Eligible for Primary Prevention: Insights From the REPRIEVE Trial](#)

Prospective Trial Participants

[About The Clinical Trials Process](#)

Interested in learning more about clinical trials? This Q&A can help explain how these trials work, how you can participate, and where you can get more information

[Trials Open For Enrollment](#)

The ACTG conducts a wide range of studies for people living with HIV. Clinical trials that are currently open for enrollment are listed by Category below. For each trial in the category, a link to more detailed information about the study will be provided.

[Clinical Trials Resources](#)

Visit this page for more information about HIV

Tweets from @ACTGNetwork

ACTG Network Retweeted



NIAID News

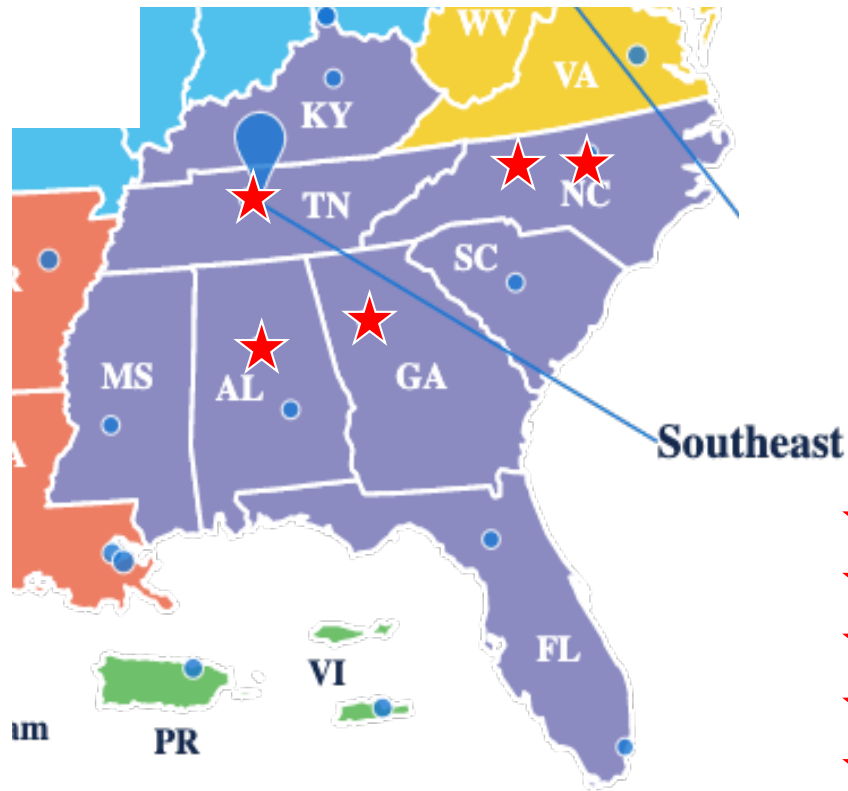
@NIAIDNews · Aug 22

MONKEYPOX NEWS: In the coming weeks, #NIAID plans to initiate clinical trials evaluating the antiviral tecovirimat (TPOXX) for #monkeypox and a clinical trial evaluating dose-sparing regimens of JYNNEOS, a vaccine approved to prevent monkeypox. Read more bit.ly/3QFfec3



7 91

ACTG Clinical Research Sites in the Southeast



- ★ Univ. Alabama Birmingham, AL
- ★ Emory (Ponce de Leon Center, Atlanta, GA
- ★ UNC Chapel Hill, NC
- ★ Greensboro, NC
- ★ Vanderbilt, Nashville, TN

A5359

A Phase III Study to Evaluate Long-Acting
Antiretroviral Therapy in Non-adherent
HIV-Infected Individuals

A Multicenter Trial of the ACTG



A5359

Long-Acting ART for Non-adherent Patients

Why are we doing this study?

- Current oral ART requires adherence to daily dosing.
- This is unachievable in some individuals because of structural, behavioral, social and clinical barriers.
- Long-acting ART has infrequent dosing and directly-observed therapy.
- Long-acting ART could improve survival and save on cost in non-adherent patients.

A5359

Long-Acting ART for Non-adherent Patients

Who is eligible for this study?

- VL >200 within past 45 days.
- Non-adherence to ART based on at least one of the following:
 - Poor response within past 18 months (<1 log₁₀ decrease in VL, or VL >200 twice at least 4 weeks apart) despite being prescribed ART for 6 consecutive months.
 - Lost to clinical follow-up within past 18 months with ART non-adherence for ≥6 consecutive months.
- No known rilpivirine or INSTI resistance.
- At least 18 years of age.

A5359

Long-Acting ART for Non-adherent Patients

What does the study involve?

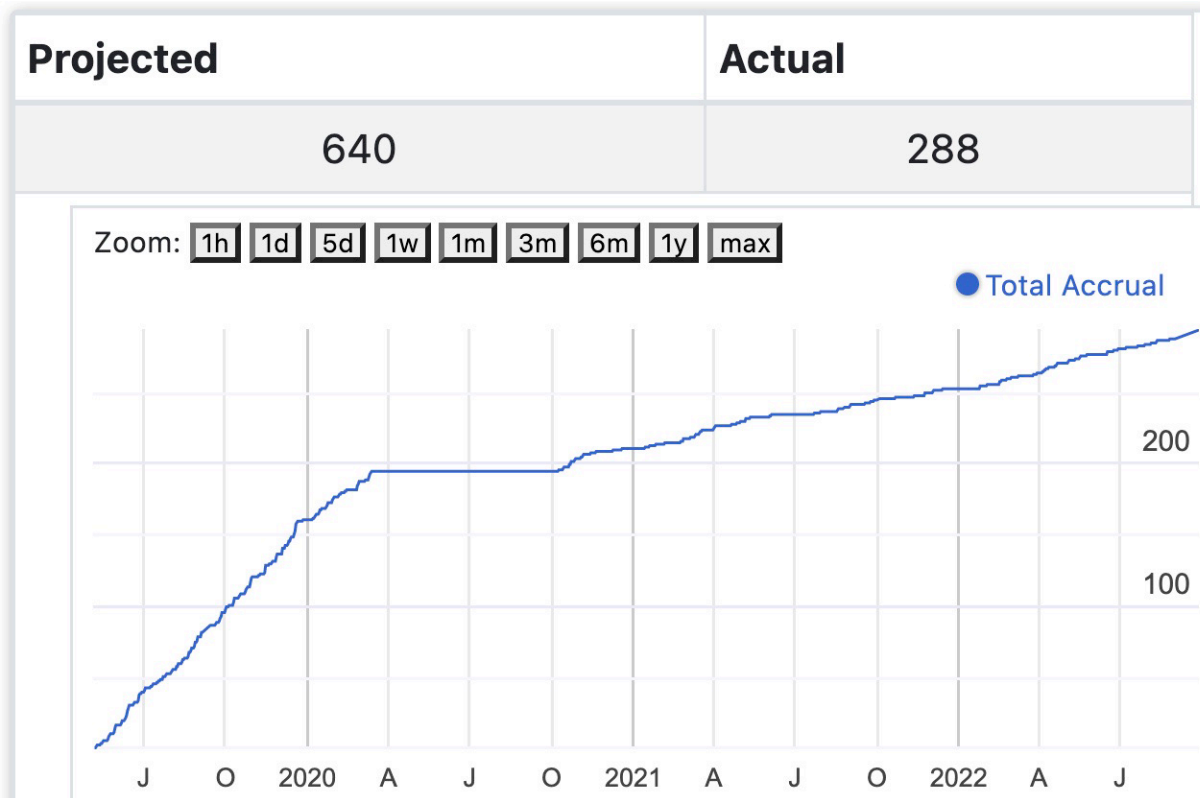
- In Step 1 – standard of care oral ART with ≥ 2 fully active including a PI and/or INSTI for **12** weeks.
- Patients who achieve VL milestones get **economic incentives** at 2, 4, 8, 12, 16 and 20 weeks.
- If VL **<200** at week **12** (before week 24), randomized (1:1) to Step 2:
 - **Arm A:** RPV-LA + CAB-LA every 4 weeks for 48 weeks, (optional oral RPV + oral CAB for 4 weeks lead-in), or
 - **Arm B:** stay on standard of care for 52 weeks*.
- After 52 weeks, standard of care arm goes to long-acting arm.
- Study can provide some ART (e.g., Triumeq, Prezcofix)



A5359

Long-Acting ART for Non-adherent Patients

How well is the study enrolling across the ACTG?



A5383

Randomized, Controlled Trial to Evaluate the Anti-inflammatory Efficacy of Letemovir (Prevymis) in Adults with HIV-1 and CMV on Suppressive ART and Its Effect on Chronic Inflammation, HIV Persistence, and Other Clinical Outcomes (ELICIT)

A Multicenter Trial of the ACTG



A5383

Letermovir to Stop Inflammation from CMV

Why are we doing this study?

- Frailty and cardiovascular disease (heart attacks & strokes) are increased with HIV despite effective ART.
- Cytomegalovirus (CMV) may drive immune activation in HIV (↑ inflamm markers, ↑ CD8 T cells, ↓ CD4/CD8 ratios)
- This may increase risk of frailty and cardiovascular disease.
- Letermovir is FDA-approved to treat and prevent CMV. It's better tolerated than valganciclovir.
- **If we “turn off” CMV, will inflammation improve?**

A5383

Letermovir to Stop Inflammation from CMV

Who is eligible for this study?

- On ART at least 48 weeks.
- VL <40 copies/mL for at least 48 weeks (blips are OK).
- At least 40 years of age.
- Encouraging enrollment of females.
- CMV antibody + (we can test, ~90% will be positive).
- Not on etravirine, lopinavir/r, or once-daily raltegravir.
- Can only enroll 1:1 with CD4 <350 vs CD4 >350

A5383

Letermovir to Stop Inflammation from CMV

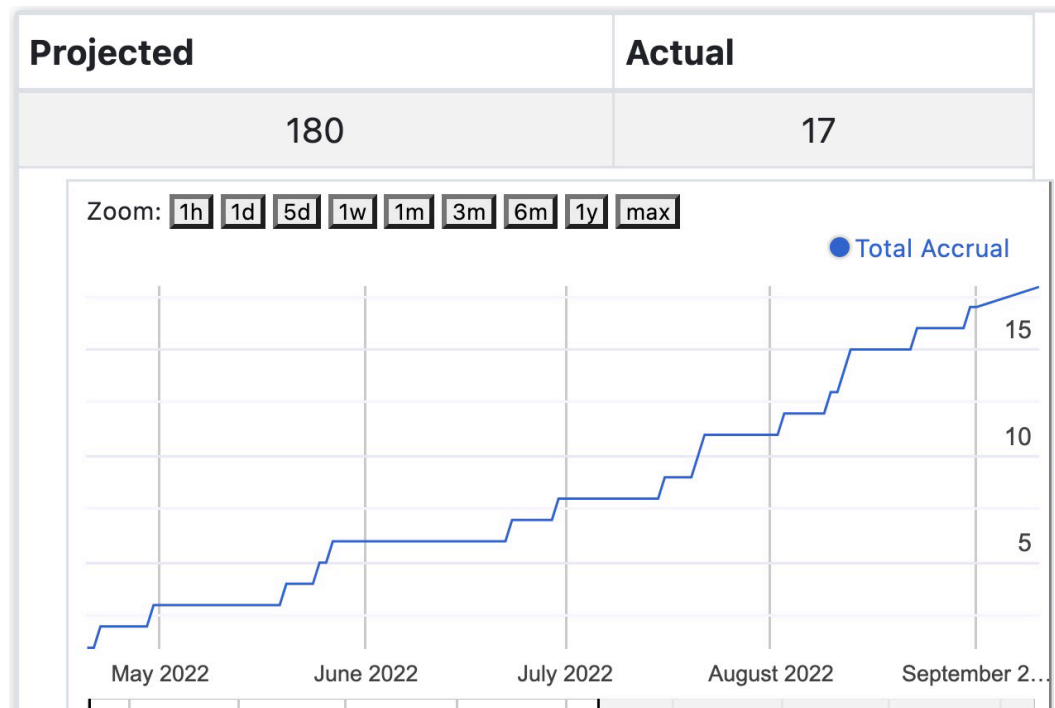
What does the study involve?

- About 10 study visits over 1 year.
- Blood draws, genital & oral secretion collection, rectal swabs, physical function testing, brief neuropsych testing, questionnaires.
- 180 participants will be randomized 1:1 to:
 - **Arm A:** open-label letermovir 480 mg once daily
 - **Arm B:** no anti-CMV treatment
- 60 weeks (48 weeks on treatment + 12 weeks of follow-up).
- Pause for fertility analysis after first 40 patients reach week 8.

A5383

Letermovir to Stop Inflammation from CMV

How well is the study enrolling across the ACTG?



A5379

Enhancement of HBV Vaccination in Persons
Living with HIV (BEe-HIVe): Evaluation of
HEPLISAV-B

A Multicenter Trial of the ACTG



A5379

Enhanced Hepatitis B Vaccination

Why are we doing this study?

- In HIV+ persons, response to standard HBV vaccine regimens is suboptimal.
- No approach to improve responses is universally accepted.
- HIV+ persons without protective HBsAb titers (≥ 10 mIU/mL) are a decision point for clinicians.
- Goal is protective antibody with fewest doses/injections, best durability.
- HEPLISAV-B is HBsAg + CpG1018, an adjuvant Toll-like receptor 9 (TLR9) agonist, given at 0 and 1 months. Superior to 3-doses of ENGERIX-B.

A5379

Enhanced Hepatitis B Vaccination

Who is eligible for this study?

- On ART for at least past 2 months days.
- CD4 count ≥ 100 , viral load < 1000 .
- Documented HBV vaccine at least 168 days before study entry.
 - Completion of vaccination series is not required.
- Never received HEPLISAV-B vaccine.
- HBV antibody < 10 mIU/mL, negative, or indeterminate.
- No prior HBV infection (no HBsAg+ or HBVcAb+).
- Age ≥ 18 and ≤ 70 years.

A5379

Enhanced Hepatitis B Vaccination

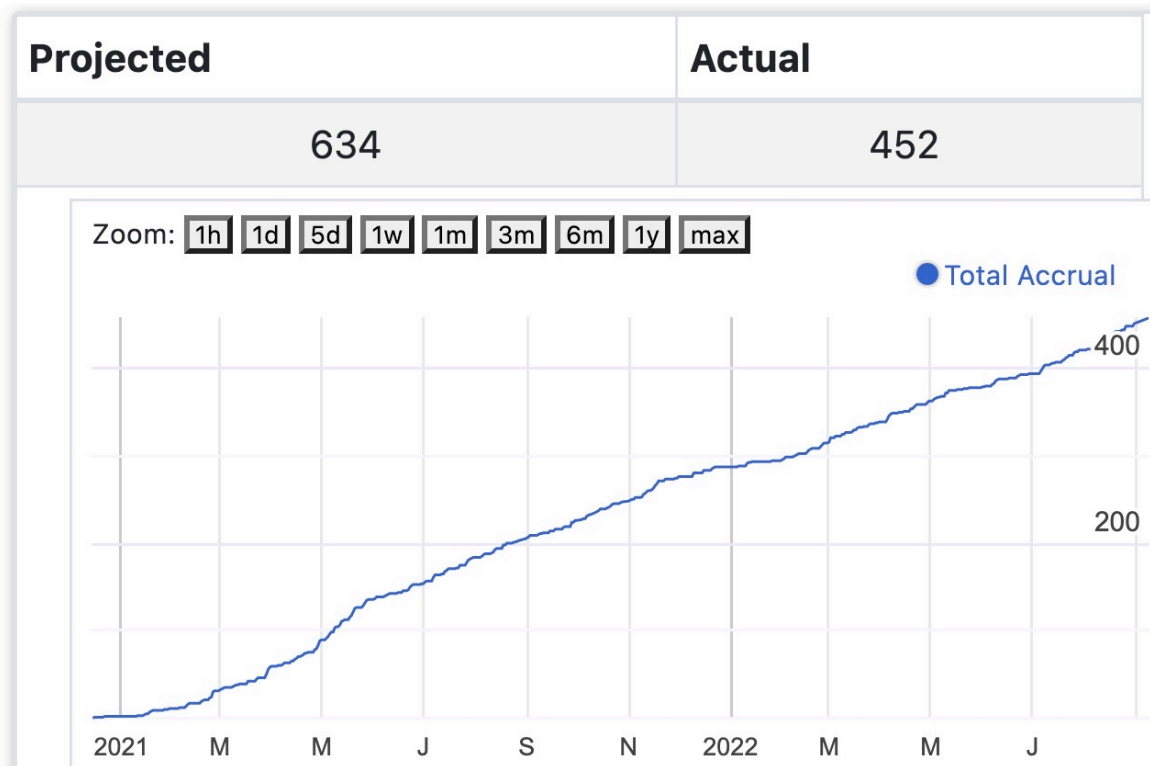
What does the study involve?

- Patients are randomized (1:1) to:
 - **Arm 1:** HEPLISAV-B three doses (weeks 0, 4, and 24)
 - **Arm 2:** ENGERIX-B three doses (weeks 0, 4, and 24)
- Patients stay on study for 72 weeks.

A5379

Enhanced Hepatitis B Vaccination

How well is the study enrolling across the ACTG?



A5391

Doravirine for Persons with Excessive Weight Gain on Integrase Inhibitors and Tenofovir Alafenamide (The Do IT Study)

A Multicenter Trial of the ACTG



A5391

Doravirine for Weight Gain on INSTIs

Why are we doing this study?

- Persons living with HIV starting or switching to INSTIs gain more weight compared to PI and NNRTI regimens.
- There may be more weight gain with TAF.
- It is unknown whether change to different ART could attenuate or reduce body weight.
- Addressing excess weight gain could improve cardiometabolic outcomes.

A5391

Doravirine for Weight Gain on INSTIs

Who is eligible for this study?

- On a BIC, DTG, or RAL +TAF/FTC (or TAF/3TC) regimen with ≥ 48 weeks INSTI+TAF/FTC (or TAF/3TC) before entry.
- BMI ≥ 27.5 kg/m².
- Unintentional $>10\%$ weight gain within first 3 years after starting or switching to INSTI-based ART, with ≥ 48 weeks of TAF (being amended).
- Viral load <50 copies/mL.
- No past K65R/E/N, M184V/I, or NNRTI mutations.
- No past virologic failure.
- No diagnosis of osteoporosis or osteopenia
- Age ≥ 18 years.

A5391

Doravirine for Weight Gain on INSTIs

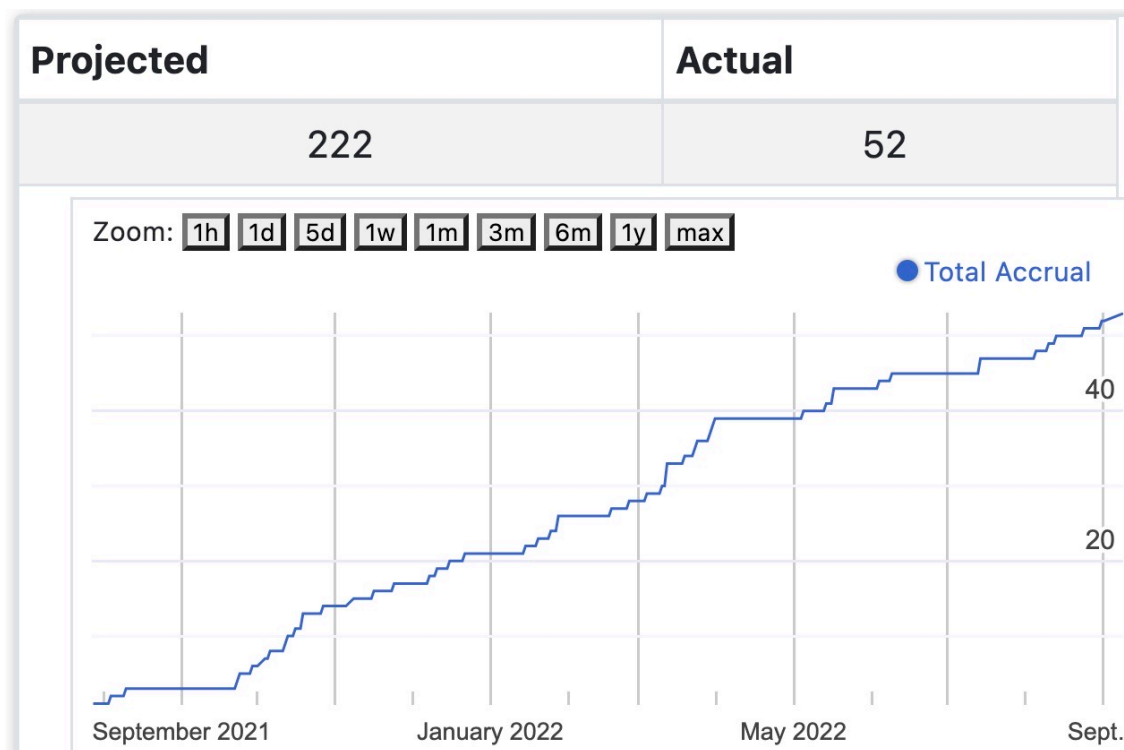
What does the study involve?

- Patients are randomized (1:1:1) to:
 - **Arm 1:** DOR + TAF/FTC (or TAF/3TC)
 - **Arm 2:** DOR + TDF/FTC (or TDF/3TC)
 - **Arm 3:** stay on current INSTI+TAF/FTC (or TAF/3TC)
- Follow-up for 48 weeks.
- Includes close monitoring for bone and kidney safety.

A5391

Doravirine for Weight Gain on INSTIs

How well is the study enrolling across the ACTG?



A5418

A Randomized, Placebo-Controlled, Double-Blinded
Trial of the Safety and Efficacy of Tecovirimat for the
Treatment of Human Monkeypox Virus Disease

A Multicenter Trial of the ACTG

(to open in 2022)

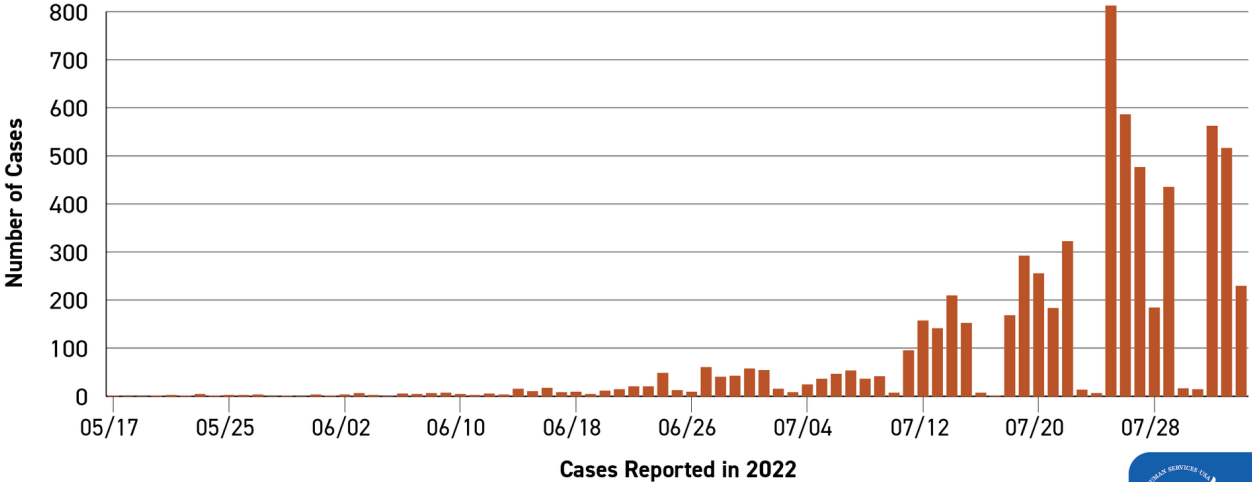


A5418

Tecovirimat for Monkeypox

MONKEYPOX UPDATE

U.S. Monkeypox Case Trends Reported to CDC as of August 3, 2022



Learn more: www.cdc.gov/monkeypox

CS333164A 08/03/2022



A5418

Tecovirimat for Human Monkeypox (HMPXV)

Why are we doing this study?

- Since spring 2022, HMPXV has rapidly spread throughout the world.
- Highest risk of infection in men who have sex with men (MSM).
- Antivirals FDA-approved for smallpox should be active against HMPXV.
- Tecovirimat targets a protein (p37) conserved across orthopoxviruses.
- Tecovirimat has only been studied in 359 healthy adults, in animal models. Looks safe and active.

A5418 is for everyone, not just for people living with HIV



A5418

Tecovirimat for Human Monkeypox (HMPXV)



Who is eligible for this study?

- Illness onset <14 days prior to study entry.
- Lab-confirmed (PCR, culture, or antigen) from skin, oropharynx, or rectal swab within 7 days prior to entry.

OR

- Presumptive diagnosis:
 - Skin lesions, mucosal lesions or proctitis likely HMPXV
- AND**
- Sexual contact in the 21 days prior to symptom onset or close exposure to another person known to be infected with HMPXV.
- At least 1 active (not yet scabbed) skin lesion, mouth lesion, or proctitis with or without visible ulcers.

A5418

Tecovirimat for Human Monkeypox (HMPXV)

What does the study involve?

- Patients are randomized (1:1) to Arms A and B:
 - **Arm A:** Tecovirimat pills every 8-12 hours x14 days
 - **Arm B:** Placebo pills every 8-12 hours
- High-risk assigned to Arm C:
 - **Arm C:** open-label Tecovirimat pills every 8-12 hours x14 days
- High-risk defined by:
 - severity of HMPXV, location of lesions, underlying diseases, skin conditions
- Follow-up for 2 months.

A5403

Giving Standardized Estradiol Therapy In
Transgender Women to Research Interactions
with HIV Therapy: the GET IT RIGHT Study

A Multicenter Trial of the ACTG

(to open in 2022)



A5403

Standardized Estradiol In Transgender Women (TW)

Why are we doing this study?

- Feminizing hormone therapy (FHT) is part of gender-affirming care for TW.
- 17- β estradiol is preferred for FHT due to lower risk of thromboemboli.
- Concerns about drug interactions between ART and FHT have been raised by providers and patients, but few data exist.
- No studies of relationships of modern ART and estrogen therapies at the doses used for FHT.

A5403

Standardized Estradiol In Transgender Women (TW)

Who is eligible for this study?

- Assigned male sex at birth, identifies as a TW, female or transfeminine.
- Desire to initiate or restart FHT.
- Viral load <200 copies/mL.
- Serum estradiol <75 pg/mL within 60 days prior to entry.
- Age ≥ 18 years.
- On specific ART:
 - **Group 1:** bicitgravir (BIC) + TAF + FTC
 - **Group 2:** dolutegravir (DTG) + TDF + (FTC or 3TC)
 - **Group 3:** darunavir + (cobicistat or ritonavir) + other ARVs
- May switch regimen to be on study.

A5403

Standardized Estradiol In Transgender Women (TW)

What does the study involve?

- Oral 17- β estradiol 2 mg once daily.
- At weeks 4, 12, 24, and 36, may titrate 17- β estradiol to achieve the desired participant goals and target hormone concentrations.
- Participant goals influence titration decisions.
- Titration above recommended therapeutic range not allowed.
- The study will assess whether TW maintain therapeutic ART levels, and whether estradiol concentrations on FHT vary between ART regimens.

A5371

A Single-Arm, Open-Label, Pilot Study of Semaglutide for Non-Alcoholic Fatty Liver Disease (NAFLD), a Metabolic Syndrome with Insulin Resistance, Increased Hepatic Lipids, and Increased Cardiovascular Disease Risk (The SLIM LIVER Study)

A Multicenter Trial of the ACTG



A5371

Semaglutide for Non-Alcoholic Fatty Liver Disease (NAFLD)

Why are we doing this study?

- ~35% of adults with HIV also have NAFLD ($\geq 5\%$ hepatic steatosis without other demonstrable causes).
- May progress to non-alcoholic steatohepatitis (NASH), cirrhosis, liver failure, and hepatocellular carcinoma.
- Most excess morbidity and mortality with NAFLD is cardiovascular dz.
- NAFLD pathogenesis may be worse in people living with HIV.
- Semaglutide is a glucagon-like peptide (GLP)-1 receptor agonist approved for diabetes and weight loss.

A5371

Semaglutide for Non-Alcoholic Fatty Liver Disease (NAFLD)

Who is eligible for this study?

- Viral load <200 copies/mL on ART.
- Central adiposity but no diabetes
- At least 5% intra-hepatic triglyceride (IHTG) content
- At least 1 indicator of insulin resistance or pre-diabetes:
 - fasting glucose 100-125 mg/dL
 - HbA1c between 5.7 and <6.5%
 - HOMA-IR >3.0
- Age \geq 18 years.

A5371

Semaglutide for Non-Alcoholic Fatty Liver Disease (NAFLD)

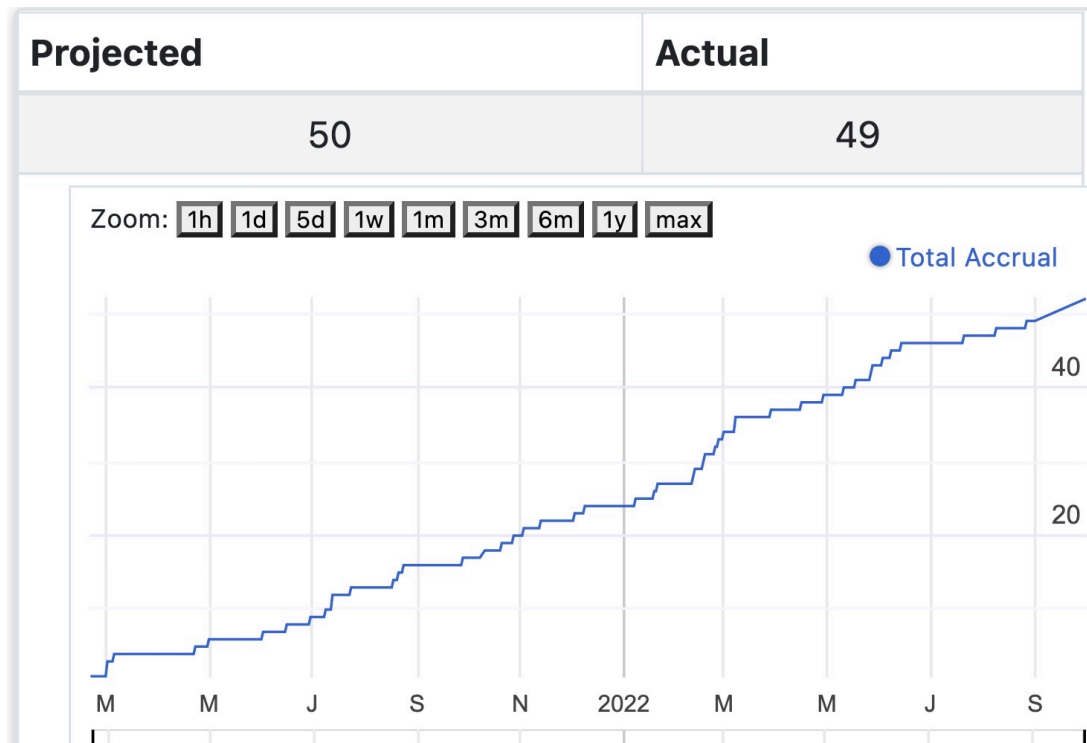
What does the study involve?

- Weekly subcutaneous injection of semaglutide x24 weeks.
- MRIs to measure intra-hepatic triglycerides (IHTG) at weeks 0 and 24.
- Other evaluations during monthly visits
- Participants stay on their ART.

A5371

Semaglutide for Non-Alcoholic Fatty Liver Disease (NAFLD)

How well is the study enrolling across the ACTG?



A5415

A Limited-Center, Prospective, Double-Blind, Placebo-Controlled Study to Evaluate the Effects of Cenicriviroc Mesylate on Arterial Inflammation in People Living with HIV

A Multicenter Trial of the AIDS Clinical Trials Group (ACTG)

(to open in 2022)



A5415

Cenicriviroc for Arterial Inflammation in HIV

Why are we doing this study?

- Cardiovascular disease is increased with HIV despite ART.
- Atherosclerosis is an inflammatory disease where immune mechanisms interact with metabolic factors.
- MCP-1 (the ligand for CCR2) is important for monocyte migration into the vascular intima during atherogenesis
- Cenicriviroc inhibits CCR5 and CCR2 antagonist, is being developed to treat liver fibrosis in nonalcoholic steatohepatitis.

A5415

Cenicriviroc for Arterial Inflammation in HIV

Who is eligible for this study?

- On stable NNRTI- or unboosted INSTI-based ART.
- At least 1 cardiovascular risk factor
- VL below limit of quantification.
- CD4 T-cells > 200
- At least 45 years of age.

A5415

Cenicriviroc for Arterial Inflammation in HIV

What does the study involve?

- About 6 study visits over 6 months.
- 93 participants will be randomized 2:1 to:
 - **Arm A:** Cenicriviroc 150 mg pill daily x24 weeks.
 - **Arm B:** placebo pill daily x24 weeks.
- Measure aorta inflammation by FDG-PET/CT at baseline & 24 weeks.
- Also measures of metabolic, immune and inflammation markers.

A5402

Randomized Controlled Trial of Pramipexole
versus Escitalopram to Treat Major Depressive
Disorder (MDD) and Comorbid MDD with HIV-
Associated Mild Neurocognitive Disorders (MND)
in Persons Living with HIV Infection

A Multicenter Trial of the ACTG

(to open in 2023)



A5402

Treating Major Depression and HAND in HIV

Why are we doing this study?

- HIV associated neurocognitive disorders (HAND) and depressive disorders affect many PLWH.
- Major depressive disorder (MDD) may co-occur with HAND.
- Pramipexole is a dopaminergic (DA) agonist approved for Parkinson's disease and restless legs syndrome
- There is rationale that pramipexole will be effective for PLWH with MDD, and comorbid mild neurocognitive disorders MND and MDD.

A5402

Treating Major Depression and HAND in HIV

Who is eligible for this study?

- On ART
- Viral load <200 copies/mL on ART.
- Major depressive disorder
- Can be on antidepressant or DA agonist (will taper off)
- Age ≥ 18 – 65 years.

A5402

Treating Major Depression and HAND in HIV

What does the study involve?

- Patients will be randomized (1:1) to:
 - **Arm A:** Pramipexole ER pills daily
 - **Arm B:** Escitalopram pills daily
- Comprehensive visits at baseline, 6 months, and 12 months.
- Briefly visits monthly.
- Monitoring for toxicity, response, assess for dose changes.

Upcoming Phase 1 Studies Working Toward Cure

- A5364, A5374, (A5377), A5388, A5389
- Small sample sizes (~30-50 people each)
- Involve broadly-neutralizing antibodies (bNAbs)
- May also involve therapeutic vaccine, adjuvants
- May require analytic treatment interruption
- Frequent and intensive study visits
- Most are for people who started ART during acute infection

Multicenter Trials of the ACTG



A5364

A Phase I, Open-Label Study of the Safety and Ability of Broadly Neutralizing Antibodies 3BNC117-LS and 10-1074-LS in Combination to Durably Prevent Viral Relapse During a Monitored Analytical Treatment Interruption

A Multicenter Trial of the ACTG



A5374

A Double-blind, Randomized, Placebo-controlled
Phase I/IIa Trial of Conserved-mosaic T-cell
Vaccine in Combination with Vesatolimod and
Broadly Neutralizing Antibodies in Adults Initiated
on Suppressive Antiretroviral Therapy during
Acute HIV-1

A Multicenter Trial of the ACTG)



A5377

A Phase I, First-in-human Study of SAR441236, a
Tri-specific Broadly Neutralizing Antibody, in
Participants with HIV

A Multicenter Trial of the ACTG



A5388

A Double-Blind, Randomized, Placebo-Controlled
Clinical Trial of Combination HIV-Specific Broadly
Neutralizing Monoclonal Antibodies Combined
with ART Initiation during Acute HIV Infection to
Induce HIV Remission

A Multicenter Trial of the ACTG



A5389

A Phase I Study to Evaluate the Safety and Antiviral Activity of Two Human Monoclonal Antibodies (VRC07-523LS and PGT121.414.LS) During Analytic Treatment Interruption in Participants Living with HIV Who Initiated ART During Acute HIV-1 Infection

A Multicenter Trial of the ACTG



Learning Objectives

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- give at least 3 (of the 28) examples of **focus areas** under the 5 NIH research priorities.
- name at least 3 (of the 5) **locations of ACTG clinical research** sites in the Southeast US.
- describe in broad terms at least 2 (of many) **ACTG research studies** that are now enrolling or will open in the future.