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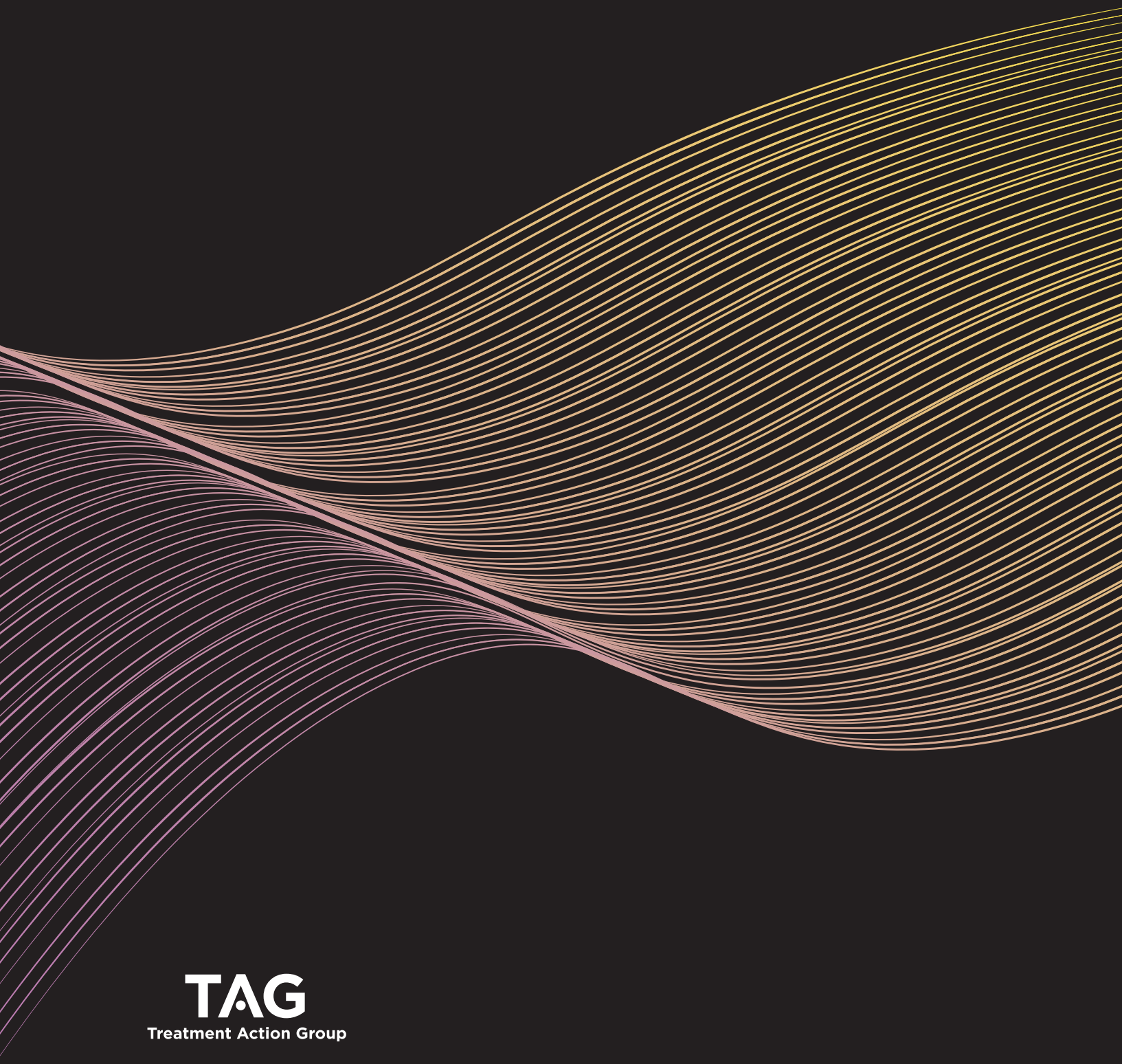
Long-Acting Therapies Trials Tracker for Malaria, Hepatitis C Virus, and Opioid Use and Overdose Prevention



TAG
Treatment Action Group

Long-Acting Therapies Trials Tracker for Malaria, Hepatitis C Virus, and Opioid Use and Overdose Prevention

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The United States government's sweeping funding cuts to global health programs have reversed decades of hard-won progress in global health. The cuts have dismantled critical systems for disease prevention, treatment, and care in numerous low-and middle-income countries (LMICs), weakened essential healthcare services, and placed millions of people at higher risk of infection and progression from diseases such as HIV/AIDS, tuberculosis (TB), malaria, and viral hepatitis, among others.[1] The funding cuts triggered further cuts in global health commitments by other high income countries (HICs), as it signaled the deprioritization of global health financing and crippled political momentum.[2] This is evident from the reductions in global health contributions that have followed from other HICs.[3]

As a direct consequence of these indiscriminate funding cuts, global health programs like the President's Emergency Plan for AIDS Relief (PEPFAR) and United States Agency for International Development (USAID) have been gutted, and major health financing institutions like the Global Fund to Fight AIDS, Tuberculosis and Malaria; Gavi, the Vaccine Alliance; and the World Health Organization (WHO) have been forced to swiftly reprogram resources to preserve core services in a bid to minimize disruptions.[4] In view of recent biomedical and technological advances in the infectious disease space, such as advances in long-acting therapies (LATs) development and their deployment in various countries, it is fair to say that these global health funding cuts could not have happened at a worse moment.

Over the last decade, advances in LATs for HIV, TB, malaria, and viral hepatitis have offered renewed hope for their elimination. Cabotegravir (Apretude), administered every two months, and lenacapavir, administered every six months, were approved by the United States Food and Drug Administration (FDA) for HIV pre-exposure prophylaxis in 2021 and 2025, respectively; and cabotegravir/rilpivirine (Cabenuva), administered every two months, and lenacapavir (Sunlenca), administered twice yearly, were approved by the FDA for HIV treatment in 2021 and 2022, respectively. Today, some of these HIV LATs have been approved in European countries and across a few LMICs, and for the very first time in history, first batches of long-acting lenacapavir (LEN) for HIV prevention were delivered in African countries like Kenya, Lesotho, Mozambique, Nigeria, Uganda, Zambia, and Zimbabwe within a few months of their approval in the United States.[5] Research and development (R&D) into LATs for TB,[6] malaria,[7] viral hepatitis,[8] and other diseases are yielding promising preclinical and clinical trial results.[9]

One of the greatest values of LATs can be their ability to close gaps where loss to follow-up has persisted for decades. Loss to follow-up remains a major barrier to controlling hepatitis C virus (HCV), TB, and malaria. In the case of malaria, people often fail to

complete the prescribed treatment and/or miss follow-up medical appointments due to initial symptom relief after the first few doses, high out-of-pocket costs, and long-distance travel and long wait times at health facilities, often resulting in lost wages. This results in unmonitored treatment failure, the emergence of drug resistance, increased transmission, and mortality. With respect to HCV, loss to follow-up occurs during both the diagnosis and the treatment phases. In most countries, the diagnosis alone requires multiple health facility visits, which are both costly and mainly available in centralized facilities. Following a positive diagnosis, people are often referred to a specialist for treatment — despite WHO recommendations on simplified service delivery, including decentralization, integration, and task sharing.

LATs have the potential to address some of these barriers by reducing — and in some cases eliminating — the need for additional clinic visits for pill refills and treatment monitoring, ensuring treatment adherence by delivering sustained and controlled drug levels in the bloodstream for weeks or months, easing the treatment burden by reducing dosing frequency, and addressing stigma by ensuring treatment privacy, all of which would make care for these diseases discreet, convenient, and more compatible with daily life. As an additional option to currently available regimens for people who need to take medications over several months, LATs also have the potential to improve quality of life by enabling greater choice and satisfaction, reducing the strain on health systems, and enabling same-day test and treat approaches, thereby resulting in better population-level health outcomes.

To promote global equity in access to LATs, the Unitaid-funded LONGEVITY project is reformulating rifapentine and isoniazid for TB prevention and glecaprevir/pibrentasvir (G/P) for HCV cure into long-acting formulations for potential use in LMICs.[10] As an agency dedicated to saving lives by making new health products available and affordable for people in LMICs, Unitaid, through LONGEVITY, aims to offer people with these chronic diseases, which require oral intake of medicines over several months, a choice and an opportunity to replace this with alternative administration routes.

Over the past six years, LONGEVITY researchers have worked hard to establish proof of concept for long-acting formulations of these three drugs with phase 1 clinical trials anticipated to begin in late 2026. As a supplement to the ongoing R&D on these LATs, LONGEVITY conducted end user,[11] health care provider,[12] and policymaker[13] surveys to understand their preferences and the acceptability and challenges of these LATs. The surveys compared currently available oral pills to long-acting injectables (LAIs), implants, and microarray patches and found very high enthusiasm for LAIs compared to implants and microarray patches.

In parallel, Treatment Action Group (TAG) and the Long-Acting Therapies Community Advisory Board (LAT CAB) have been engaging with LONGEVITY researchers and other experts to better understand the science of LATs under development and to raise awareness about their benefits, and their potential to accelerate disease control and potentially elimination.[14] Very recently, on May 7, 2026, members of the LAT CAB shared perspectives on centering community voices to overcome barriers to equitable access to LATs during the Long-Acting Learning, Innovation, Networks and Knowledge (LA LINK)

webinar organized by the Center of Excellence on Long-acting Therapeutics (CELT) Global Health.[15] TAG has developed various advocacy tools on HCV,[16] LATs,[17] and community engagement[18] and contributed to the development and dissemination of the HCV and TB surveys and their results at the International Network on Health and Hepatitis in Substance Users (INHSU) Conference and the World Hepatitis Summit, with additional conference presentations planned throughout 2026.

As these LATs enter clinical trial in 2026, continuous community engagement with the LONGEVITY researchers, Unitaid, policymakers, regulatory authorities, end users of these health technologies, potential contract development and manufacturing organizations, and other stakeholders will continue to be critical to community treatment literacy, awareness raising, and demand generation.

This trials tracker, an update of the 2025 Long-Acting Therapies Trials Tracker for Hepatitis C Virus, Opioid Use, and Overdose Prevention Therapy and Malaria,[19] provides a compilation of ongoing clinical trials on LATs for HCV, malaria, and opioid use and overdose prevention therapy in the R&D pipeline. The trials in this tracker are listed on the WHO International Clinical Trials Registry Platform website, the Pan African Clinical Trials Registry, the European Union Clinical Trials Register, and the United States clinicaltrials.gov website.

The trial registry identifier numbers link directly to trial entries, which contain more detailed information on the trial design, enrollment criteria, principal investigators, and locations. Please communicate directly with the contact listed in the individual trial registry entries for all information about the status of the research. This LATs trials tracker for Malaria, HCV, and opioid use and overdose prevention therapies clinical trials was compiled between May 8 and June 4, 2026, and will be updated on an annual basis. Please send updates, corrections, or suggestions to Joelle Dountio Ofimboudem at jdountio@treatmentactiongroup.org.

TABLE 1: Long-acting therapies for malaria, hepatitis C, and opioid use and overdose prevention in the research and development pipeline

	Other information	Trial registry identifier	Manufacturer/sponsor	Location	Phase	Status/estimated completion date
Malaria						
A Phase 1b, Randomized, Double-Blind, Placebo-Controlled Trial to Assess the Safety, Tolerability, and Pharmacokinetics of Monoclonal Antibody L9LS in Infants in Mali and to Evaluate the Impact of L9LS on Subsequent R21/Matrix-MTM Vaccine Immunogenicity	Injectable Sample size: 180 Objective: to assess the safety, tolerability, and pharmacokinetics (PK) of L9LS in infants in Mali and to evaluate the impact of L9LS on subsequent R21/Matrix-MTM vaccine immunogenicity	NCT06461026	National Institute of Allergy and Infectious Diseases (NIAID) National Institutes of Health (NIH) University of Washington Harvard School of Public Health (HSPH) Indiana University School of Medicine, Indiana University	Mali	1	Estimated study completion date: 06/2026
A First-in-Human, Single-Centre, Single Ascending Dose Study to Assess the Safety, Tolerability and Pharmacokinetics of a Single Intramuscular Injection of MMV371 Long-Acting Injection Formulation in Healthy Participants	Depot injection Sample size: 32 Objective: to assess the safety, tolerability, and PK of a single intra-muscular depot injection of MMV371 LAI formulation in healthy participants	NCT06558643	Medicines for Malaria Venture	United Kingdom	1	Estimated study completion date: 09/2025
Single Ascending Dose Study to Assess the Safety, Tolerability and Pharmacokinetics of LAI MMV055 Alone and in Combination with MMV371 in Healthy Participants	Depot injection Sample size: 72 Objective: to assess the safety, tolerability, and PK of a single dose of IM depot injection of LAI formulations of MMV055 administered alone (Part A) and in combination with MMV371 (Part B) in healthy participants.	NCT07011511	Medicines for Malaria Venture Quotient Sciences The Doctors Laboratory Ltd	United Kingdom	1	Recruiting Estimated study completion date: 12/2027

	Other information	Trial registry identifier	Manufacturer/sponsor	Location	Phase	Status/estimated completion date
Malaria						
A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Safety, Tolerability and Pharmacokinetics of MMV371 Long-Acting Injection in Healthy Adults and Adolescents	Injectable Sample size: 80 Objective: to assess the safety, tolerability, and PK of a single injection of MMV371 in healthy adult and adolescent participants in Rwanda	NCT07548021	Medicines for Malaria Venture Rinda Ubuzima, Rwanda Swiss BioQuant Swiss Tropical & Public Health Institute ACE Research	Rwanda	1	Not yet recruiting Estimated study completion date: 03/2028
Single-Use Antimalarial Monoclonal Antibodies for Post-Discharge Malaria Prevention in Children with Severe Anemia or Severe Malaria in Kenya: A Multi-Centre, Parallel-Group, Two-Arm Randomized Placebo-Controlled Non-Inferiority Trial	Injectable Sample size: 398 Objective: to assess the efficacy of a single dose of L9LS versus post-discharge malaria chemoprevention against microscopy or RDT-confirmed clinical malaria in hospitalized children with severe anemia or severe malaria by six months after investigational product administration	NCT07082205	Liverpool School of Tropical Medicine NIAID Centers for Disease Control and Prevention	Kenya	3	Recruiting Estimated study completion date: 04/2027
Hepatitis C virus						
Nothing found						
Opioid use and overdose prevention therapy						
A Phase II Multi-center Safety Study Examining the Use of the O'Neil Long-Acting Naltrexone Implant (OLANI) in Opioid Dependent Persons Receiving Repeat Dosing	Implant Sample size: 250 Objective: to evaluate the safety profile and efficacy of the OLANI when used in participants who meet the diagnosis of opioid use disorder and who will be voluntarily seeking relapse-prevention treatment using the naltrexone (NTX) implant	NCT05382091	Go Medical Industries Pty Ltd National Institute on Drug Abuse (NIDA) New York State Psychiatric Institute Columbia University The Emmes Company, LLC University at Buffalo	United States	2	Estimated study completion date: 07/2029

	Other information	Trial registry identifier	Manufacturer/sponsor	Location	Phase	Status/estimated completion date
Opioid use and overdose prevention therapy						
A Randomized Controlled Trial Examining Extended-Release Injectable Buprenorphine in Those Who Use High Potency Synthetic Opioids	Injectable Sample size: 60 Objective: to compare buprenorphine formulations (sublingual buprenorphine versus LAI buprenorphine) for treating opioid use disorder among individuals who use fentanyl and/or other high potency synthetic opioids	NCT06726200	Rachel R. Luba National Institute on Drug Abuse (NIDA)	United States	Early phase 1	Estimated study completion date: 01/2029
A Randomized, Active-Comparator Controlled, Two-Dose-Level Study of iSTEP-N in Healthy Adults with Long-Term Safety and PK Follow-Up	Implant Sample size: 33 Objective: to measure blood levels of naltrexone over time after administration of two different doses of the iSTEP-N implant and to compare those levels with the blood levels achieved by Vivitrol®, an FDA-approved injectable extended-release naltrexone given once every month	NCT07064564	Akyso Therapeutics LLC National Institute on Drug Abuse (NIDA) Cenexel JBR Fast-Track Drugs & Biologics, LLC Aliri Bioanalysis Ardena Element Analytics	United States	1	Not yet recruiting Estimated study completion date: 03/2029
A Sequential Dose Cohort Pharmacokinetic and Safety Study of Implantable Long-Acting Naltrexone Subcutaneous Pellets with or Without Bupropion Compared to Naltrexone IM Injection (Vivitrol®) in Healthy Normal Volunteers	Implant Sample size: 30 Objective: to assess the safety and PK of a subcutaneous implantable pellet drug product containing Naltrexone base anhydrous administered through a minor surgical procedure	NCT07269873	BioCorRx Pharmaceuticals Inc National Institute on Drug Abuse (NIDA)	United States	1	Estimated study completion date: 12/2026

	Other information	Trial registry identifier	Manufacturer/sponsor	Location	Phase	Status/estimated completion date
Opioid use and overdose prevention therapy						
Comparative Effectiveness of Two Formulations of Buprenorphine for Treating Opioid Use Disorder in Veterans (VA-BRAVE)	Injectable and sublingual Sample size: 952 Objective: to determine whether a 28-day LAI subcutaneous formulation of buprenorphine is superior in retaining veterans in opioid treatment and in sustaining opioid abstinence compared to the daily sublingual buprenorphine formulation	NCT04375033	VA Office of Research and Development	United States	4	Estimated study completion date: 05/2029

L9LS is an investigational lab-made monoclonal antibody derived from a natural antibody developed by scientists at the NIH in partnership with the Medicines for Malaria Venture (MMV). L9LS targets and neutralizes Plasmodium falciparum parasites — a parasitic protozoan that causes the most severe and deadly form of human malaria — before they can infect the human liver and cause illness. By neutralizing these parasites, L9LS prevents them from reaching and infecting liver cells, thereby stopping the infection from developing.

R21/Matrix-MTM Vaccine is a malaria vaccine developed to prevent Plasmodium falciparum malaria, which is the deadliest form of the disease and is most common in Africa. It was developed by the University of Oxford in partnership with the Serum Institute of India and Novavax and is primarily intended for young children in malaria-endemic regions, particularly in sub-Saharan Africa.

MMV371 is an LAI antimalarial drug candidate developed by MMV, in partnership with Scripps Research and Janssen Pharmaceuticals. It is designed to provide at least three months of protection against malaria with a single intramuscular injection. As a prodrug of the approved antimalarial drug atovaquone, MMV371 can circulate in the bloodstream for a significantly longer period compared to standard oral atovaquone. MMV371 is designed to be effective against both Plasmodium vivax and Plasmodium falciparum, the two most prevalent malaria parasites.

MMV055 is a potential new antimalarial drug candidate developed by MMV. MMV055 is being investigated as a potential partner drug for MMV371 to create an LAI for malaria prevention. MMV055 is intended to target multiple life stages of the malaria parasite, including liver (preerythrocytic), blood (asexual stage), and possibly vector stages.

iSTEP-N is an investigational long-acting bioabsorbable subcutaneous implant for opioid use disorder that progressively releases naltrexone into the bloodstream to block opioid receptors, effectively preventing the euphoric effects of opioids and reducing cravings. Developed by Akyso Therapeutics, iSTEP-N aims to support long-term recovery by providing continuous opioid blockade for 6 to 12 months from a single, in-office procedure. Given its bioabsorbable nature, surgical removal would not be required.

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