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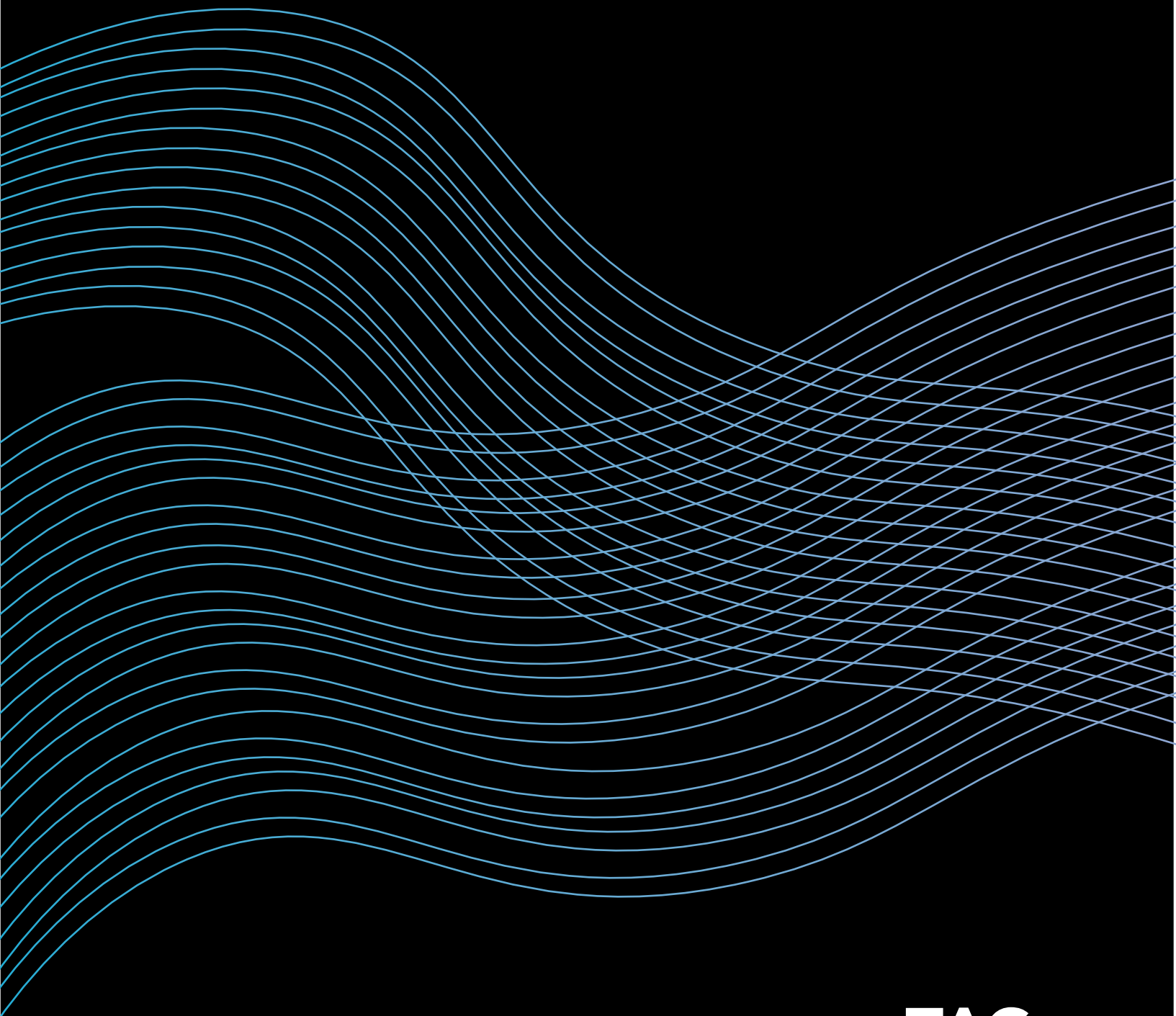
Long-Acting Therapies Trials Tracker for Hepatitis C, Opioid Use and Overdose Prevention Therapy, and Malaria



TAG
Treatment Action Group

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

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Three years after the launch of cabotegravir/rilpivirine (Cabenuva), the first long-acting HIV treatment, and cabotegravir long-acting (CAB-LA), the first long-acting PrEP, administered once a month and every two months respectively, the pipeline for these novel treatment options continues to grow. While Lenacapavir, a twice-yearly long-acting treatment option, in combination with other antiretroviral(s), was approved in 2022 by the United States Food and Drug Administration (FDA) for the treatment of HIV-1 infection in heavily treatment-experienced adults with multi-drug resistant HIV-1 infection, clinical trials on the same molecule as a twice-yearly long-acting PrEP therapy have demonstrated 100% efficacy with zero infections. In addition, a longer-acting formulation of cabotegravir for both treatment and prevention that could be administered once every four months is showing promising results. Despite the global interest in these therapies and their proven public health benefits, very few people are accessing them.

To address global inequity in access to long-acting therapies, the Unitaid-funded LONGEVITY project is developing long-acting rifapentine to treat latent tuberculosis infection and glecaprevir/pibrentasvir to cure hepatitis C virus (HCV). The goal of the project is to develop these long-acting therapies in higher volumes and at lower prices for low- and middle-income countries (LMICs). These long-acting therapies would offer people with HCV and latent TB — chronic diseases that require frequent oral intake of medicines over several months — a choice and an opportunity to replace these with alternative administrative routes to address pill/tablet fatigue. By eliminating the need for frequent oral intake of medicines, long-acting therapies could potentially improve treatment adherence, prevent relapses arising from treatment interruption, and lead to more constant plasma levels in the bloodstream. Long-acting therapies also provide privacy to people with chronic diseases who must take oral medications frequently and may be vulnerable to stigma, tablet/pill fatigue, and drug resistance.

As a partner in the LONGEVITY project, Treatment Action Group (TAG) co-founded and co-chairs the long-acting technologies community advisory board (LAT CAB) to facilitate community engagement between scientific researchers and communities. The LAT CAB also supports the development, dissemination, and implementation of research surveys among health care providers, users, and policymakers on their preferences around long-acting therapies for malaria chemoprevention, latent tuberculosis prevention, and an HCV cure in LMICs. While some of these surveys are still ongoing, based on the completed research survey results, health care providers and policymakers expressed high levels of enthusiasm for long-acting injectable formulations for an HCV cure. In fact, 93%

of providers expressed willingness to prescribe a LAT, and 72% of providers preferred a LAT if available at comparable efficacy, safety, and cost as current oral treatments. With respect to malaria, health care services users expressed equally high levels of enthusiasm for a long-acting injectable formulation, with 80% of respondents indicating that they "definitely would try" a long-acting malaria chemoprevention offered by injection instead of oral tablets/pills.

Community engagement and participation in the research and development (R&D) process is crucial to identifying and addressing potential barriers to demand and adoption of long-acting therapies once these become available. Effective community engagement in R&D is predicated on strengthening the technical capacity of research-literate activists who follow the science; advocate for community perspectives on the research needs, treatment preferences, and the acceptability of these long-acting therapies to research scientists, governments, and key decision-makers; and report back to affected communities.

While the LONGEVITY candidate treatments are still being evaluated preclinically, this trials tracker, an update of the 2023 Long-Acting Therapies Trials Tracker for Hepatitis C, Opioid Use and Overdose Prevention Therapy, and Malaria Pipeline Report, provides a compilation of ongoing and recently completed clinical trials on long-acting therapies for HCV, malaria, and opioid use and overdose prevention therapy in the R&D pipeline. The trials in this tracker are listed on the United States clinicaltrials.gov website, the European Union clinicaltrialsregister.eu registry website, the WHO International Clinical Trials Registry Platform website, and in peer-reviewed literature.

The trial registry identifier numbers link directly to trial entries, which contain more detailed information on 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. These HCV, malaria, and opioid use and overdose prevention long-acting therapies clinical trials were compiled between February 15 and May 30, 2024, 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 Hepatitis C, Malaria, and Opioid Use and Overdose Prevention on the research and development pipeline

	Other information	Trial registry identifier	Manufacturer/ sponsor	Location	Phase	End date	Published/presented data
Malaria							
An Open-label, Single Ascending Dose Study of the Safety, Tolerability, and Pharmacokinetics of Long-acting Oral Ivermectin (LYN-163) in Healthy Volunteers	Oral Sample size: 25 Objective: To evaluate the safety, tolerability, pharmacokinetics of long-acting oral ivermectin (LYN-163) in healthy individuals	ACTRN12621001218886	Lyndra®Therapeutics, Inc. (Lyndra)	USA	Phase 1	2023	https://drj.com/industry_news/lyndra-therapeutics-doses-first-clinical-trial-participant-in-study-of-oral-biweekly-ivermectin-lyn-163-as-a-tool-in-the-fight-to-eradicate-malaria/
HCV							
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 (in abdominal region) 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	National Institute on Drug Abuse (NIDA) New York State Psychiatric Institute Columbia University The Emmes Company, LLC University at Buffalo Go Medical Industries Pty Ltd	USA	Phase 2	April 2027	https://www.cdek.liu.edu/trial/NCT05382091/

	Other information	Trial registry identifier	Manufacturer/ sponsor	Location	Phase	End date	Published/presented data
Long-acting Buprenorphine vs. Naltrexone Opioid Treatments in Criminal Justice System–involved Adults	Injectable Sample size: 796 Objective: To compare the effectiveness of extended-release buprenorphine (XR-B) vs extended-release naltrexone (XR-NTX)	NCT04219540	NYU Langone Health National Institute on Drug Abuse (NIDA)	USA	Phase 4	December 2024	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8384640/
Anchoring Intermittent Long-acting Antimicrobials to Medication for Opioid Use Disorder Treatment to Facilitate Structured Transitions of Care for People Who Use Drugs Admitted to the Hospital with Invasive Infections	Injectable Sample size: 25 Objective: To determine the efficacy of an alternative strategy using intermittent outpatient oritavancin therapy dosed weekly combined with initiation and continuation of medication assisted treatment for opioid use disorder for completion of antimicrobial therapy in a 12 week prospective, open-label study	NCT05521880	University of Maryland, Baltimore	None provided	Phase 4	May 2025	https://synapse.patsnap.com/clinical-progress-detail/a05884a38a5ad528ad528e5525a552ea
A Randomized, Open-label, Single Dose Pharmacokinetic and Safety Study of Implantable Long-acting 3-month Naltrexone Subcutaneous Pellets Compared to Naltrexone IM Injection (Vivitrol) in Healthy Volunteers	Implant (subcutaneous) Sample size: 24 Objective: To evaluate the pharmacokinetics and safety of implantable subcutaneous naltrexone pellets (BICX104) vs Vivitrol intramuscular depot naltrexone injection	NCT04828694	BioCorRx Inc National Institute on Drug Abuse (NIDA)	USA	Phase 1	March 2023	https://ichgcp.net/clinical-trials-registry/NCT04828694

	Other information	Trial registry identifier	Manufacturer/ sponsor	Location	Phase	End date	Published/presented data
CSP #2014 - Comparative Effectiveness of Two Formulations of Buprenorphine for Treating Opioid Use Disorder in Veterans (VA-BRAVE)	Injectable and sunlingual Sample size: 952 Objective: To determine whether a 28-day long-acting injectable sub-cutaneous 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	USA	Phase 4	November 2025	Addiction Science & Clinical Practice (2022) 17:6
A Pragmatic, Multi-centre, Open-label, Randomized, 12-month, Parallel Group, Superiority Study to Compare the Effectiveness of Subcutaneous Buprenorphine Depot (Sublocade®) vs Daily Sublingual Buprenorphine with Naloxone (Suboxone®) for the Treatment of Opioid Use Disorder	Injectable and sublingual Sample size: 90 Objective: To demonstrate the superior benefits of Sublocade® on important clinical outcomes to demonstrate its cost-effectiveness and justify expanded insured access across Canada	NCT05594121	Royal Victoria Hospital, Canada	Canada	Phase 4	December 2024	https://classic.clinicaltrials.gov/ProvidedDocs/21/NCT05594121/Prot_SAP_000.pdf