



# R&D for HIV/AIDS

How new tools can transform the fight

Since emerging in the 1980s, the HIV/AIDS pandemic has claimed the lives of more than 42 million people around the world—reversing gains in life expectancy and economic development in the world's most under-resourced places. The development of antiretroviral drugs (ARVs) turned the trajectory of the global pandemic, extending the life expectancy of people living with HIV and preventing transmission between mothers and children and people of different HIV statuses.

Yet, progress toward ending the HIV pandemic has slowed in recent years, and major gaps remain in our arsenal of treatment and prevention tools. We will not bring about an end to the HIV pandemic without new and improved technologies.

**3.79** million  
people living with HIV/AIDS

**1.3** million  
people became newly infected with HIV  
in 2023

**250** children  
die every day from AIDS-related causes

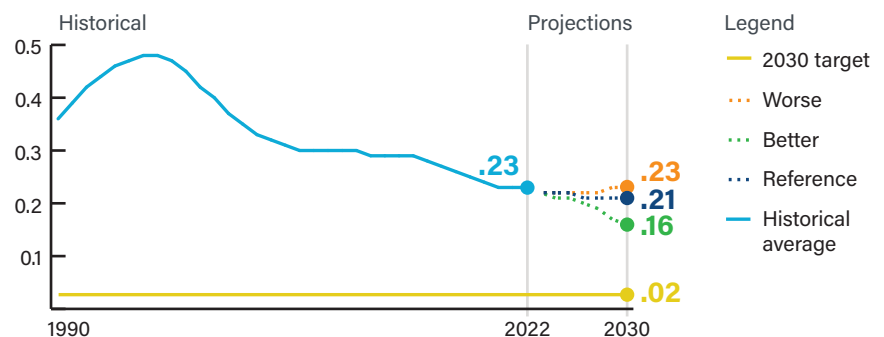
## 🔍 Research successes

Technologies have transformed the fight against HIV/AIDS:

- **ARVs**—developed with NIH support—are today used to treat 30.7 million people globally and have cumulatively averted 16.5 million AIDS-related deaths since 2001.
- **Pre-exposure prophylaxis (PrEP)**—the use of ARVs to prevent infection—was shown to be effective through NIH, CDC, and USAID research and is now widely used globally.
- Approaches to **prevent mother-to-child HIV transmission**—developed with NIH support—have contributed to a 62% decline in new infections in children since 2010.
- New **long-acting PrEP options**, including a monthly vaginal ring and an every-two-month injectable, developed with NIH and USAID support, now offer an alternative for those who struggle to take daily pills.
- **Child-friendly therapies**—including a sweet-tasting, heat-stable combination therapy—are improving care for HIV-positive children.
- New **diagnostic innovations**, such as rapid tests, urine and oral tests, and at-home tests, have increased the percentage of people aware of their HIV status.
- **Recency tests**, which distinguish if an infection occurred in the last year or before, are enabling health programs to identify HIV transmission clusters and better target services.

## 📈 Continued progress is possible, not inevitable

New cases of HIV per 1,000 people



## 🔑 Key missing tools

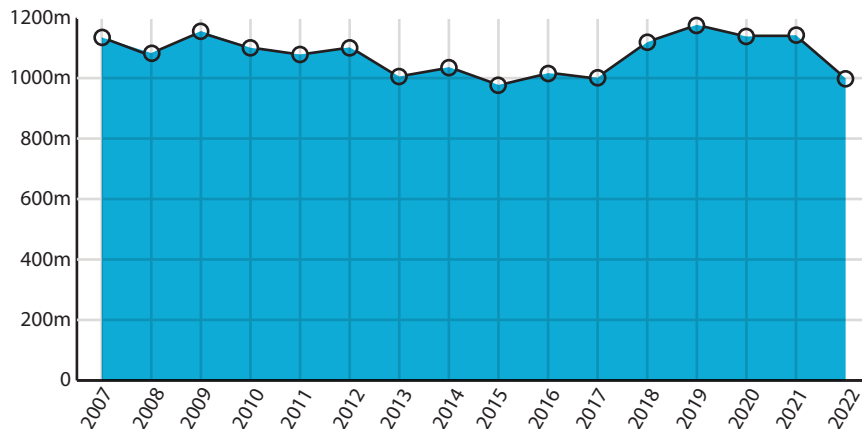
To end HIV/AIDS, we need new prevention and treatment tools, including:

- **Vaccines** to prevent and reduce new infections.
- A **cure** to control infection or eliminate it from the body.
- **New treatment and PrEP regimens** to help expand choice and improve adherence, including additional long-acting options, fixed-dose combinations, and simplified treatments with fewer side effects.
- Additional **microbicide options** to prevent infections in women and men who have sex with men—populations disproportionately impacted by the pandemic.
- **Expanded therapies for young children** that are safe, palatable, and easy to administer.
- Additional **treatment options to combat resistance** to existing regimens.
- Additional **multipurpose prevention technologies** that simultaneously prevent HIV, other sexually transmitted infections, and/or unintended pregnancy.

## 💡 Breakthroughs on the brink

- **Long-acting biomedical products** that could revolutionize both HIV treatment and prevention in hard-to-reach populations by reducing frequency of use and providing a more discreet, convenient alternative to daily pills. Products now in development include a **once-weekly ARV pill, a three-month vaginal ring, injectable preventative drugs taken every four or six months, and implants** that slowly release anti-HIV drugs over time for continuous protection.
- **Multipurpose prevention products**—including pills, injections, and vaginal rings that combine HIV protection with contraception—could provide more convenient options for women. The two products furthest in development are a **dual prevention pill** and a **multipurpose vaginal ring**, both of which were developed with USAID support.
- Many clinical trials are underway to test **broadly neutralizing antibodies (bNAbs)**—proteins shown to neutralize many different genetic variants of HIV—as treatment and prevention products delivered via infusion or injection. These include trials of several bNAbs developed or isolated at NIH labs.
- Several **mRNA-based HIV vaccine candidates** have advanced into first-in-human trials, including candidates supported by NIH, USAID, and PEPFAR, bringing new hope to the quest for an HIV vaccine. Additionally, **new vaccine research strategies** are reinvigorating the field, including **approaches to induce bNAbs** such as **germline targeting**, which uses a series of stepwise shots to coax the immune system to create bNAbs, and **T-cell approaches**, which induce T cells that act as either killer cells to directly attack the virus or helper cells that support other B cells that generate antibodies against HIV.
- **Seven patients appear to have been effectively cured of HIV or are in long-term remission**, demonstrating that a cure for HIV infection, while difficult, is scientifically possible. Several **cure strategies** are also advancing in the research pipeline including a **“kick and kill” approach** to prompt latent HIV to reactivate so it can be targeted and neutralized and **gene modification approaches** to change human DNA in immune cells to produce cells that are resistant to HIV.

US government investment in HIV/AIDS R&D for low-resource settings (in 2022) US\$ millions



### 🇺🇸 US Government R&D efforts

The US government is leading efforts to advance research and development (R&D) to end the HIV/AIDS epidemic through a whole-of-government approach:

- **National Institutes of Health (NIH)** conducts basic science and clinical research to advance products to prevent, diagnose, and treat HIV/AIDS, as well as social behavioral research to improve the use of existing interventions.
- **US Agency for International Development (USAID)** advances R&D for HIV/AIDS technologies designed for low-resource settings, including research for a vaccine, microbicides, and multipurpose prevention products, and helps accelerate the introduction of and access to new tools.
- **Department of State** oversees the President’s Emergency Plan for AIDS Relief (PEPFAR), which finances certain HIV/AIDS research programs, alongside delivering health products and services.
- **Centers for Disease Control and Prevention (CDC)** develops improved diagnostics and conducts research to inform the use of existing tools and the risk factors influencing the spread of HIV/AIDS to better target interventions to those in need.
- **Department of Defense** undertakes research to protect US service members, including vaccine research.
- **Food and Drug Administration** operates a tentative regulatory approval program to allow PEPFAR to distribute generic ARVs for use outside the United States.

