

Investing in Research and Development



Key points:

- Gilead has broad, active programs for HIV and viral hepatitis research, investing in the development of new therapies that better meet patients' needs.
- The company is also committed to research programs in the developing world, which strengthen local research capacity in countries where HIV and hepatitis prevalence is high.
- Gilead-supported research always meets national and international standards of ethical conduct.

Ongoing investment in pharmaceutical research and development (R&D) is vital to ensure continued advances in medicine. Gilead's R&D program focuses on the treatment of life-threatening diseases and areas of unmet medical need. The company's annual R&D budget of approximately \$2 billion supports a global research program involving more than 200 Phase 2 and 3 clinical trials in a wide range of therapeutic areas, including HIV/AIDS, liver disease, cardiovascular and respiratory conditions and cancer.

Spotlight: Antiviral R&D

A priority area for Gilead is the development of new antiviral treatments for HIV and viral hepatitis. In 2011, the company was the largest funder of HIV drug discovery worldwide, investing more than \$670 million in HIV treatment R&D according to a report by the HIV Treatment Research and Development Resource Tracking Project.¹ Among Gilead's recent innovations is a complete HIV treatment regimen containing four compounds in a once-daily tablet, which received U.S. approval in August 2012. Gilead is already developing next-generation single tablet regimens that may have the potential to improve the safety and tolerability of HIV therapy even further. The company is also playing its part in the search for a cure for HIV, with early-stage research focused on identifying novel compounds for HIV eradication strategies.

Gilead is also developing new medicines for chronic hepatitis C virus (HCV) infection, devoting approximately one third of its R&D budget to this area. HCV affects about 185 million people worldwide and is the leading cause of liver cancer and transplantation in the United States.^{2,3} In 2013, the company's first hepatitis C medicine received U.S. regulatory approval, offering high cure rates and shortened duration of therapy, and reducing or eliminating the need for interferon injections for many patients. Gilead continues to develop new HCV therapies, including fixed-dose combination regimens, to further improve treatment for the disease.

Developing world research

Because a number of Gilead's medicines treat diseases, such as HIV and viral hepatitis, which disproportionately impact patients in the developing world, the company makes it a priority to support high-quality medical research conducted in resource-limited countries. By focusing research on the populations most likely to benefit from our medicines, Gilead is able to optimize treatment delivery in resource-limited settings while also building local research capacity and expertise. Through the Gilead Foundation, the company also supports mentorship programs that link scientists, medical professionals and students in the developing world with their peers in developed countries.

Compliance with research standards and guidelines

Gilead conducts research in its state-of-the-art laboratories and through numerous partnerships with well established research institutions, including government agencies such as the U.S. National Institutes of Health (NIH), leading academic centers such as Yale University and many community-based clinical research organizations around the world. In all aspects of the company's R&D programs, Gilead adheres closely to national and international guidelines for the ethical conduct of biomedical research and protection of the rights of study volunteers. These include the Declaration of Helsinki and the Good Participatory Practice (GPP) Guidelines for Biomedical HIV Prevention Trials.

References

¹ The HIV Treatment Research and Development Resource Tracking Project. *Funding Scientific Innovation: Global Investments in HIV Treatment Research and Development in 2010 and 2011*. 2013.

² WHO. Guidelines for the screening, care and treatment of persons with hepatitis C infection, April 2014. Available at: http://apps.who.int/iris/bitstream/10665/111747/1/9789241548755_eng.pdf?ua=1&ua=1

³ CDC. Hepatitis C FAQs for the Public. October 22, 2012. Available at <http://www.cdc.gov/hepatitis/c/cfaq.htm>.