



# Impact Report

Access Operations &  
Emerging Markets



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Shinyanga,  
Tanzania



## 15 years of access

When we launched our first HIV access initiative 15 years ago, we laid the foundation for a program that now brings medicines to an estimated 11.5 million people, spans four diseases, reaches more than 135 countries and is the primary focus of more than 100 Gilead employees. Our work has helped open the door to previously unimaginable public health goals – universal treatment coverage for HIV and hepatitis B virus (HBV) and the elimination of hepatitis C virus (HCV) and visceral leishmaniasis (VL). Access to our medicines has become a central tenet of Gilead’s corporate values.

While we take pride in our heritage, we know that today’s access challenges require continued evaluation and innovation. We work diligently to be flexible and responsive, regularly refining our approach to treatment scale-up. This has meant tailoring our efforts to meet the unique needs of regions, countries and communities, such as the Arkhangai Province in Mongolia and the Shinyanga and Simiyu regions of Tanzania (see pages 9 and 15).

In recent years, we have taken important steps to expand our efforts where the need is greatest. For example, we have increased our presence in emerging markets, such as Georgia, Mexico and Brazil, recognizing the distinct challenges in countries with wide gaps between rich and poor. We have moved toward a holistic approach, looking beyond medicines to the environmental factors that influence access, such as political commitment, medical workforce capacity, infrastructure and the need to focus on noncommunicable diseases. We increasingly work with nontraditional partners, such as Mastercard and the Vatican, to amplify our reach and impact.

This is the first report that comprehensively describes the work of Gilead’s Access Operations & Emerging Markets (AOEM) team. It reflects the work of not only Gilead, but also of our many partners around the world. We are deeply grateful to have such dedicated, knowledgeable collaborators. We have seen extraordinary progress over the past 15 years, and we are confident that continued collaboration and innovation in science and policy will lead to new achievements in the years to come.



Sincerely,

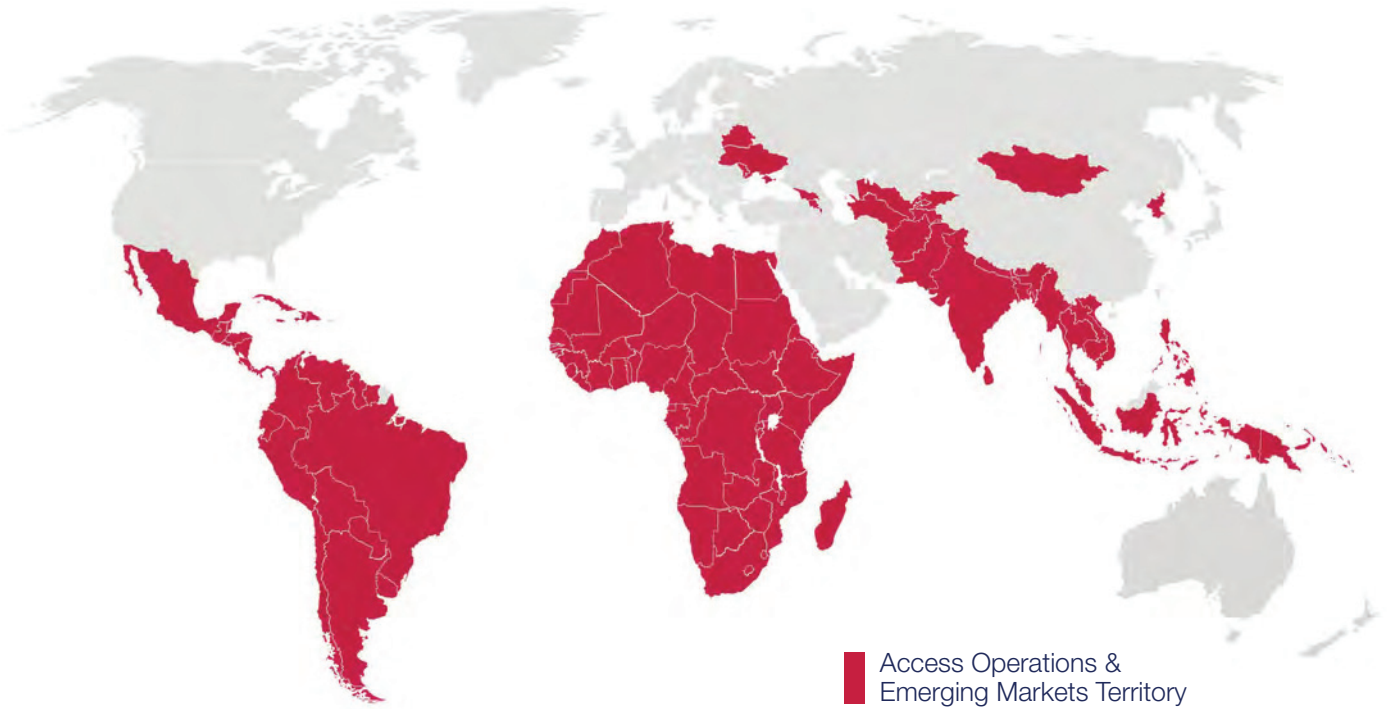
Clifford Samuel

Senior Vice President, Access Operations & Emerging Markets

# Our approach

**Every successful access initiative begins with a conversation.** Our dedicated Access team meets with public health officials, doctors and patients around the world to understand barriers and opportunities in HIV, viral hepatitis and VL treatment access.

Over the 15 years that we have worked in resource-limited countries, we have learned that there is no one-size-fits-all solution to access challenges. We apply a variety of approaches to increase disease awareness, engage partners strategically and deliver medicines efficiently.



## Our Impact

We measure success by the impact we have on human health. More people on treatment means more people living potentially longer, healthier lives and ultimately, a decline in the number of new infections.

### HIV

**11.5M** people living with HIV estimated to be on Gilead-based treatment in developing countries

**98%** receiving licensed generics

**>85%** decline in the lowest price for tenofovir disoproxil fumarate (TDF) since 2006

**10** developing countries have registered Truvada® (emtricitabine/TDF) for pre-exposure prophylaxis (PrEP)



### Tiered pricing

We provide steep discounts on branded medicines, based on a country's disease burden and gross national income (GNI) per capita.



### Strengthening health systems

We work to strengthen health systems and overcome barriers to access by bolstering diagnostic, treatment and surveillance capacity, as well as advocacy efforts.



### Collaborative research

We support and conduct research that targets innovative therapies, informs drug delivery and helps countries to map their disease burdens.



### Advocacy

We advocate for public health initiatives and policies that maximize patient reach and prevent new infections.



### Responsible use of IP

In 2006, we became a pioneer in voluntary generic licensing, when we granted manufacturing rights to our HIV medicines on an unprecedented scale. Today, voluntary licensees in India, South Africa, Pakistan and Egypt produce high-quality, low-cost generic versions of our medicines for patients in 116 resource-challenged countries.



### Partnerships

We work closely with governments and non-governmental organizations (NGOs) to build support for developing world health and amplify our impact. We also work with more than 30 in-country distributors who, through product registration, forecasting and other efforts, help to make our medicines available locally.



### Corporate giving

Through targeted grants, we invest in programs that improve services for communities heavily affected by disease.

## CHRONIC HEPATITIS C

# 1.1M

people estimated to have been treated with Gilead medicines in developing countries

# 68%

receiving licensed generics

# 14

voluntary generic licensees

## CHRONIC HEPATITIS B

# 60+

developing countries have registered Viread® (TDF) for HBV

# 25

voluntary generic licensees

## VISCERAL LEISHMANIASIS

# 800,000+

vials of AmBisome® (amphotericin b liposome for injection) donated to the World Health Organization (WHO) over 10 years

# 39+

developing countries reached through Gilead access efforts

# Strengthening health systems

Strengthening public health systems is at the core of our strategy to expand treatment access. All too often, inadequate infrastructure creates barriers for patients, so we work with partners worldwide to improve infrastructure from the ground up.

- **Preparing the healthcare workforce:** Frontline healthcare workers are central to quality access and care. Yet in many developing countries, health professionals lack access to the latest training and resources. In addition, there may be too few qualified professionals available to meet community needs. We are working to help expand the knowledge and skills of health professionals through trainings, continuing education and long-distance learning opportunities that share the latest standards of care.
- **Educating communities:** Health education is key to preventing disease and improving patient access. We support community organizations in their efforts to develop public health education programs, such as a 2017 HIV/AIDS prevention seminar that informed 1,500 youth activists in Brazil.
- **Providing technical assistance:** Many developing world health systems urgently need medical equipment and other basic necessities. We provide financial support and technical assistance to help meet these needs. For example, we partnered with the Liver Foundation in West Bengal to help build the Indian Institute of Liver and Digestive Sciences in Kolkata, the first facility of its kind in the region. The institute will serve people living with HCV and HBV who previously had to travel almost 1,000 miles for treatment.
- **Securing the supply chain:** To help strengthen supply chain management, we have invested in tracking tools that Gilead employees and licensees can use to help forecast demand and prevent supply disruptions.

## Our Impact: 2017

**>180** medical events

**6,500** healthcare providers trained

**73** community organizations received enhanced public health education with our support


### AOEM in Action

In 2016, we began working with the PharmAccess Foundation and Gertrude's Children's Hospital to provide health services to underserved communities in Nairobi, Kenya. The program enables individuals to access healthcare, including for HIV, HBV and HCV, using a platform called M-TIBA that allows users to receive and send donated funds to use for healthcare expenses through their mobile phones. It has brought approximately 70,000 "invisible" patients into the health system and is helping local officials to better understand the region's health needs.





Healthcare provider in Shinyanga, Tanzania

A large portrait of a young woman with long dark hair, wearing a black puffer jacket over a green sweater and a white hoodie. She is looking slightly to the right with a neutral expression.

Natia Shervashidze,  
Treated with Gilead medicine  
for hepatitis C, Tbilisi, Georgia



“ Not only would [eliminating HCV] have a positive impact on the lives of thousands of people across Georgia, but we hope it will also demonstrate what is possible to the rest of the world. ”

– Davit Sergeenko, Minister of Labour, Health and Social Affairs, Georgia

# Building strategic alliances

We partner with more than 2,000 NGOs, governments and academic institutions to enhance our collective impact. Together, we raise awareness, reduce stigma and deliver frontline services and care for the most vulnerable.

- **Reducing HIV among young women and girls:** Girls and young women account for 71 percent of new HIV infections among adolescents in sub-Saharan Africa. Through the DREAMS initiative, which is led by the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), we provide funding for PrEP with the goal of helping 25,000 young women to stay HIV-free. In its first year, DREAMS reached one million adolescent girls and young women and saw a 25 to 40 percent reduction in new HIV diagnoses in 65 percent of DREAMS districts.
- **Eliminating HCV in Georgia:** According to the World Health Organization, nearly eight percent of the population in the country of Georgia is infected with HCV. This is among the highest HCV prevalence in the world. We have partnered with the Georgian government and the U.S. Centers for Disease Control and Prevention (CDC) to help establish the Georgian HCV Elimination Project. To date, more than 40,000 Georgians have been treated with Gilead's HCV medicines.
- **Piloting test-and-treat in rural Tanzania:** In Tanzania, just 62 percent of people living with HIV are on treatment, while an estimated 30 percent are unaware of their infection. We partnered with the Vatican and the local Catholic diocese in the Shinyanga and Simiyu regions of northern Tanzania to reach people living with HIV and connect them to care. The program has now tested more than 112,000 people, brought treatment to more than 3,000 adults and children and helped prevent mother-to-child transmission of HIV for approximately 200 babies. Through this work, the program aims to help lower the community's viral load and slow HIV transmission.



Josephine Matiro,  
District Commissioner of Shinyanga,  
Tanzania and Anand Reddi,  
Gilead Sciences

# Supporting collaborative research

We work with investigators in low- and middle-income nations to study the efficacy and safety of our medicines, evaluate new drugs and identify optimal strategies that connect patients from screening to care. This research is critical for securing local drug approvals, helping to further our goal that future drugs meet the needs of these markets.

In addition, we invest in high-quality research facilities, such as the Institut de Recherche en Santé, de Surveillance Epidémiologique et de Formation (IRESSEF) in Senegal, that attract and support talented young researchers from developing countries.

## Our Impact: 2017

**20 demonstration projects and collaborative studies** in developing countries and emerging markets to explore how best to reach patients in need of our medicines

**12 active enrolling investigator-sponsored research programs** to study our drugs in **13 low- and middle-income countries** to understand the efficacy and safety profiles of our medicines in different patient populations

**6 research partnerships** studying the potential of the investigational agent remdesivir\* (GS-5734) to address emerging threats, such as Ebola, MERS and Marburg, that disproportionately affect low- and middle-income countries

### AOEM in Action

In 2017, we provided early financial support for the development of IRESSEF in Dakar, Senegal. IRESSEF seeks to help build capacity among young African scientists to conduct clinical research and disease surveillance throughout western Africa by providing training in epidemiology, biostatistics, clinical trials and grant writing.

In 2017, we also continued an existing collaboration with the National Institute of Allergy and Infectious Diseases and local researchers in Liberia to test the investigational agent, remdesivir (GS-5734), in Ebola survivors. In 2018, we expanded the study to include Guinea.

\*Remdesivir is not approved anywhere globally, and its efficacy and safety profile has not been established.





Vhal Lucas,  
Treated with Gilead medicine  
for hepatitis B, Manila, Philippines

# Corporate giving

Corporate giving in developing and emerging markets complements our access operations and strengthens community organizations that are working to address disease. Our approach to corporate contributions is two-pronged.

First, we award grants to organizations whose programs relate to Gilead's therapeutic areas and emphasize sustainability and impact. Second, we donate medicines to governments and organizations that are working to treat populations with the heaviest disease burdens. We believe that drug donations must work in concert with efforts to strengthen health systems if they are to have a lasting impact.

## Our Impact: 2017

**\$300M**

in cash donations to address unmet medical needs throughout the world

nearly  
**80%**

of that total focused on improving access to medicines

For four years in a row, Funders Concerned About AIDS has ranked Gilead the leading corporate funder helping to address the HIV/AIDS epidemic

### AOEM in Action

VL is the second-largest parasitic killer in the world after malaria, responsible for approximately 40,000 deaths each year. We have worked closely with the WHO and NGOs since 1992 to provide our antifungal medication, AmBisome, to those in need, and since 2011, we have donated more than 800,000 vials of AmBisome to countries where VL is endemic. Three of these countries have seen substantial decreases in incidence – Bangladesh, India and Nepal are making progress toward eliminating VL by 2020.

We are funding an Extension for Community Healthcare Outcomes (ECHO®) project to improve the lives of the 10,000 to 20,000 people living with HBV in the Patagonia region of Argentina. The program uses telehealth technology to connect specialist clinicians in Buenos Aires to non-specialist providers in Patagonia. Clinicians in Buenos Aires use 90-minute sessions to share best practices in HBV care. The ECHO model was developed by the University of New Mexico Health Sciences Center Department of Internal Medicine and was used successfully in Patagonia to help train 40 non-specialists on HCV diagnosis and care.

# Fostering global support

We work with partners around the world to make an evidence-based case for policies that seek to improve access to health services in resource-challenged countries.

The prevention, screening and treatment standards established by the World Health Organization, International AIDS Society and other organizations play a critical role in driving progress against disease. To inform these guidelines, we share up-to-date scientific and cost-effectiveness data. We work with national governments to demonstrate the benefits of health investment, commissioning epidemiological and economic modeling to inform public health and disease elimination programs.

We also convene high-level meetings in which policymakers from around the world share best practices and make new commitments. Past Gilead-organized events have examined such topics as the challenges of addressing HBV in Africa, managing HIV-HCV co-infection among people who inject drugs and strengthening HIV prevention in sub-Saharan Africa.



At the 2018 International AIDS Conference, Gilead and global partners launched MenStar, a coalition to expand HIV diagnosis and treatment among men in developing countries.



## Our Impact

In 2017, we reaffirmed our commitment to the London Declaration, a **global pledge** to combat 10 key neglected tropical diseases by 2020. Cases of VL, one of these neglected diseases, have dropped significantly in endemic countries, and several of these countries are poised to potentially eliminate the disease by 2020.

In early 2017, we co-organized a Wilton Park symposium in Swakopmund, Namibia, which brought together government officials, scientists, patient advocates and program implementers to **identify ways to strengthen the HIV prevention movement** in sub-Saharan Africa.

We brought our chronic HCV medicines to the developing world **less than 12 months after U.S. approval** – including to Egypt, which has the highest HCV prevalence worldwide – because of proactive collaborations with national governments.


### AOEM in Action

Mongolia has one of the highest rates of viral hepatitis in the world. We worked with Yo Baatarbileg, a Member of Parliament in Mongolia to design a broad screening and treatment pilot program in the Arkhangai Province, which serves as a model for the rest of the country. To start, the program screened individuals ages 40 to 65 and treated 99.7 percent of those diagnosed. In the next phase, the province intends to screen 13,000 Mongolians under 40. The country's government has shown a steady commitment to addressing the national epidemic: it has established national health insurance subsidies for HCV and HBV treatments and diagnostics, as well as accelerated regulatory approvals for innovative treatments.

Gilead has been working with governments around the world to expand HIV prevention strategies, including PrEP scale-up. Our engagement has been met with impressive HIV leadership in Brazil. On World AIDS Day of 2017, the Brazilian Ministry of Health announced it was introducing its first-ever national HIV PrEP program. As part of this initiative, the government is providing free PrEP medications to 9,000 Brazilians at high risk for HIV in the first year. In addition, the health ministry is working with local NGOs that represent men who have sex with men and transgender people to develop videos and messages to reach at-risk communities that can benefit most from PrEP as part of a comprehensive prevention strategy. Over the next five years, the ministry aims to offer PrEP medications to 54,000 people and have at least one clinic that provides PrEP in each of Brazil's 27 states.



 Kenneth Kabagambe,  
HBV advocate, Uganda

A man with glasses and a black shirt is sitting on a floral-patterned sofa. The background features patterned wallpaper, a large framed picture at the top, and a smaller framed picture on the wall behind him.

Temur Radiani,  
Treated with Gilead  
medicine for hepatitis C,  
Tbilisi, Georgia

“ The prime minister announced that anybody with the virus [hepatitis C] would be treated. The feeling was like rebirth. ”

- Temur Radiani





[access@gilead.com](mailto:access@gilead.com)

[www.gilead.com](http://www.gilead.com)