

Commitment to Global Elimination of Hepatitis C Virus

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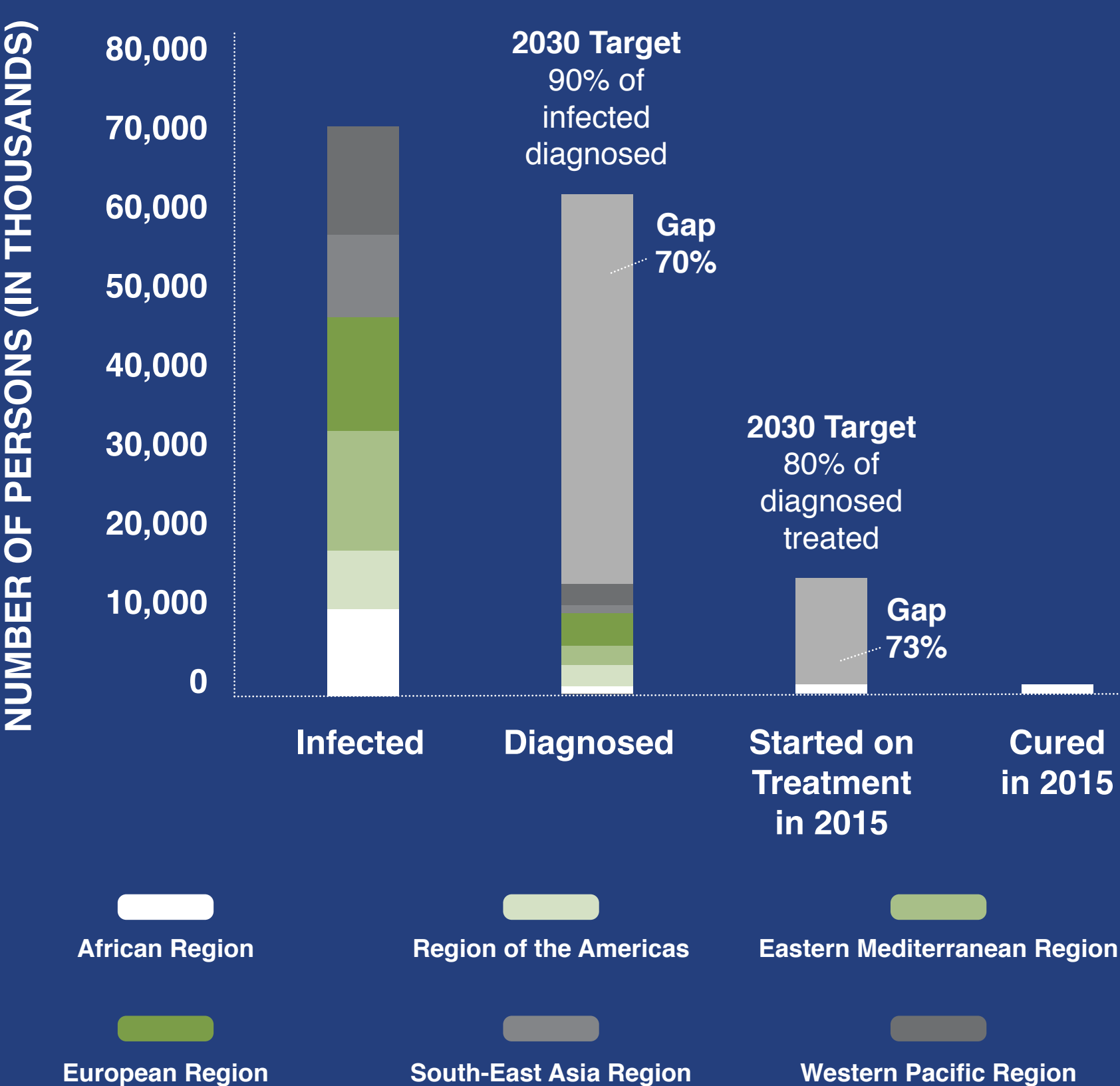
Gilead actively supports the efforts of governments and partners with professional organizations, patient advocacy groups, payers and healthcare professionals who have declared their intention and commitment to work toward the World Health Organization (WHO) goal of elimination of viral hepatitis around the world by 2030.



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Cascade of Care for HCV Infection

By WHO Region, 2015



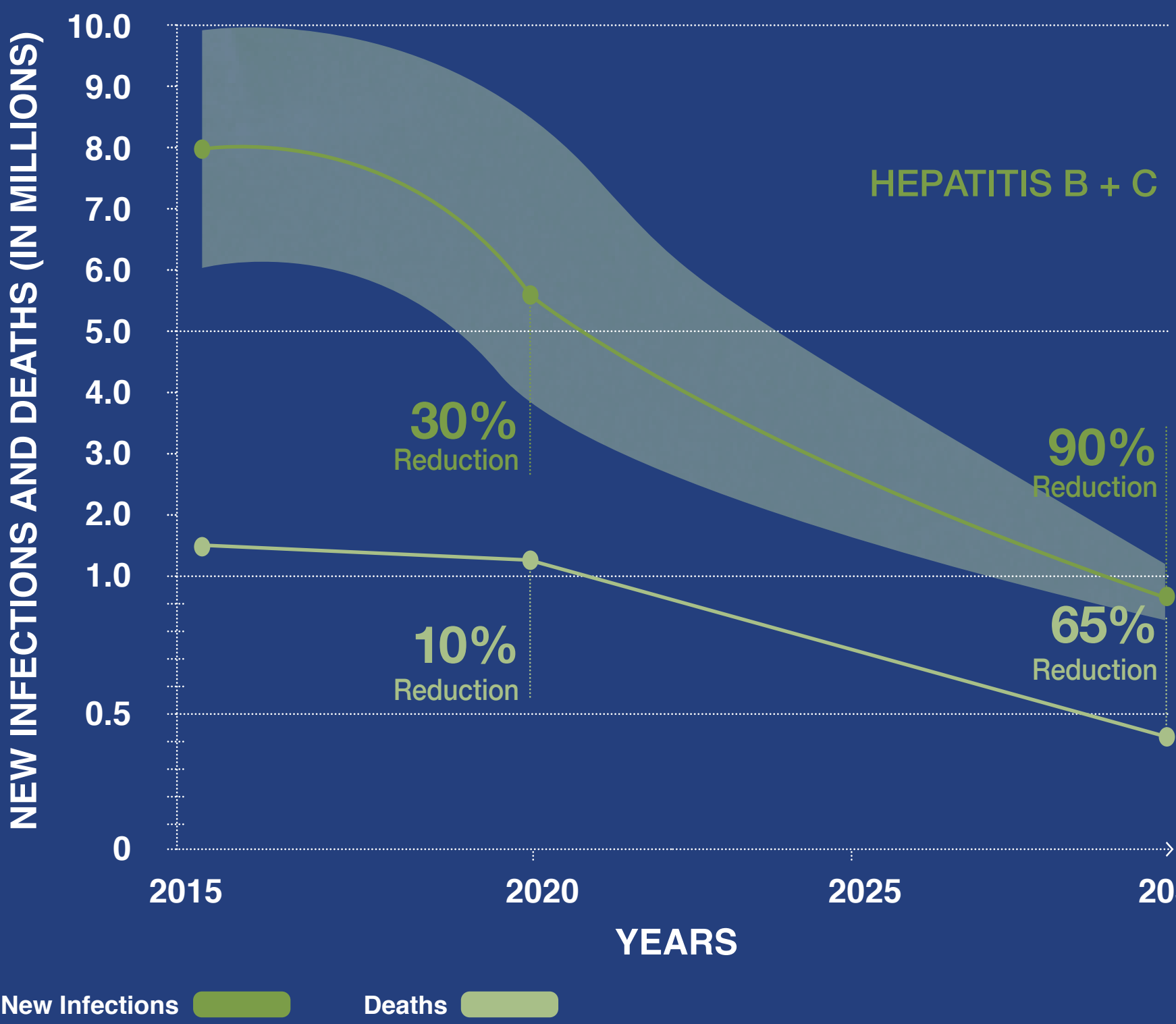
Data source: WHO estimates, conducted by the Center for Disease Analysis. Cascade details are from WHO Global Hepatitis Report 2017, p20

Addressing the Global HCV Epidemic

DAA's for the treatment of chronic hepatitis C virus have cure rates exceeding 95%

Source: WHO, Global Health Sector Strategy on Viral Hepatitis 2016-2021, June 2016.

Targets for reducing new cases of and deaths from chronic viral hepatitis B and C infection



Source: WHO Publication: GLOBAL HEALTH SECTOR STRATEGY ON VIRAL HEPATITIS 2016-2021: TOWARDS ENDING VIRAL HEPATITIS, June 2016

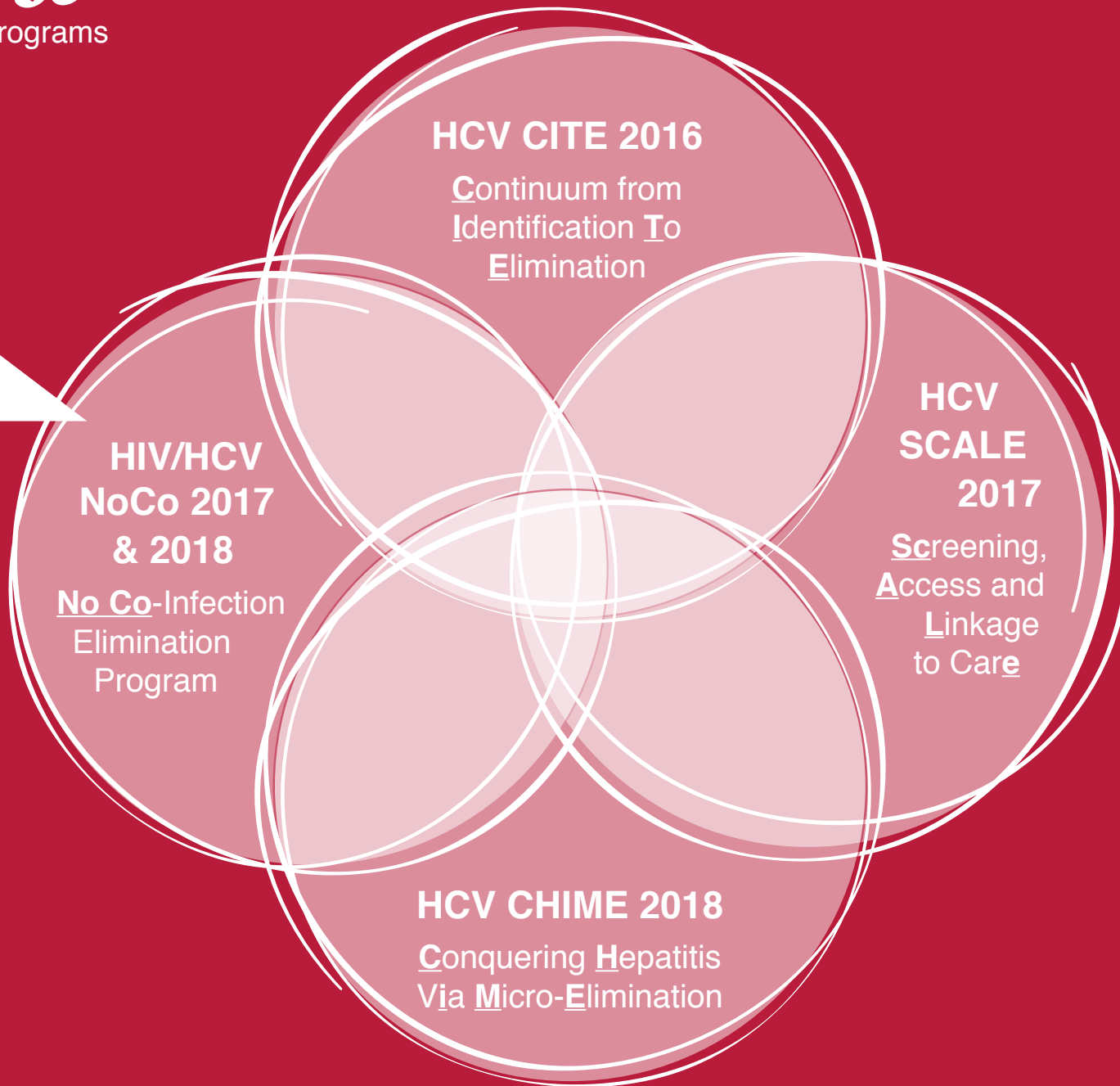


Medical Affairs

Investigator-Sponsored Research Programs

OBJECTIVE

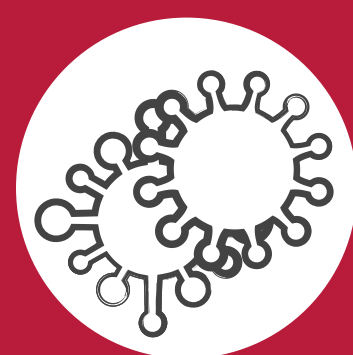
Support implementation science projects for high-risk and high-prevalence populations and geographies, including data collection or modeling and demonstration of clinical and economic value of such programs.



Supported HCV Elimination Study Locations



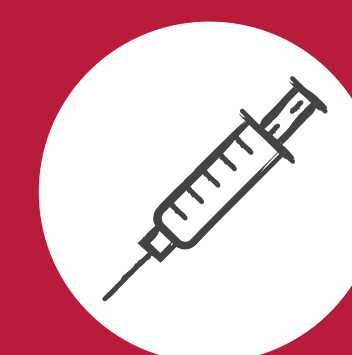
79 HCV Elimination Studies Supported



HIV/HCV Co-infection: 19



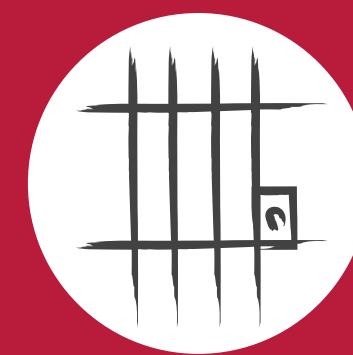
Regional: 18



People Who Inject Drugs: 14



Health System: 12



Prisons: 9



Special Populations: 7

The above list of investigator-sponsored HCV elimination studies is not exhaustive.



Public Affairs

Corporate Giving



Reducing Disparities

Addressing differences in healthcare that are closely linked with social or economic disadvantages



Advancing Education

Working to improve disease awareness among patients and healthcare professionals



Improving Access

Enabling access to care that achieves the best health outcomes



Supporting Local Communities

Backing initiatives to promote betterment of communities where we live and work

In 2017, Gilead provided almost \$400 million in cash donations to address unmet needs and lessen the impact of life-threatening diseases faced by communities around the world.

Corporate Contributions - Examples



Countdown to the elimination of viral hepatitis by 2030: 2017-2018 strategic plan and add-on activities

Provided funding to support the WHA's vision of a world free from viral hepatitis

Core organizational activities include: raising awareness of viral hepatitis, advocating for viral hepatitis and ending the social injustices of viral hepatitis. Additional activities include: development and implementation of national elimination plans in European and African regions, increasing the understanding and knowledge among governments of how to finance hepatitis C elimination programs and expanding the scope and impact of the NOnpe campaign.



Correlation Hepatitis C Initiative

Gilead's Grants Programme supported founding of the Hepatitis C Initiative, a European Platform for HCV and Drug Use led by the Correlation Network to monitor, support and implement research-related activities in order to improve access to, and quality of effective HCV service delivery in people who inject drugs (PWID).

In January 2018, a new paper was published on the importance of HCV testing in the Community in which the urgency of screening and testing amongst the PWID population was highlighted.



Clinical and Collaborative Research

Iceland



The TraP Hep C study is an ongoing nationwide elimination programme in Iceland. In this 3-year programme started in December 2015, Gilead is providing DAAs free of charge in an epidemiological study setting for all HCV-positive individuals covered by the Icelandic health insurance system.

TRA-P-C study

Eliminating HCV

Objective: Elimination of HCV through intensive test & treat strategy

Results: 72% reduction in proportion of viremic HCV and 53% reduction in new HCV infections among people who inject drugs (PWID)*

Olaussen et al. J Intern Med 2016; 263: 500-507

For the Iceland program, under an agreement signed in December 2015, Gilead provides DAAs in an epidemiological study setting for 36 months for all HCV-positive individuals covered by the Icelandic health insurance system. The Icelandic government provided special funding for the overall organization of the project, diagnostic tests and other services related to the nationwide elimination campaign.

Australia



A combination of micro- and macro-elimination projects in Australia have demonstrated that universal access to DAAs combined with expanded screening programmes has increased uptake of treatment and reduced the prevalence of HCV, paving the way for its elimination.

PROJECTS SUPPORTED BY GILEAD SCIENCES

SIMPLIFY
Evaluating treatment efficacy in people with chronic HCV infection who currently inject drugs

STOP-C
Surveillance and treatment of prisoners with HCV

TAP
Assessing treatment of PWIDs through network-based approach

EC
Establishing an HCV elimination program for the state of Victoria

CEASE
Aiming to eliminate HCV infection from the Australian HIV positive population

I-STEP
Inner Sydney Treatment HCV Elimination Project in People with HIV Confection

REACT
Treatment for Recently Acquired HCV in PWID and People with HIV Confection

OPERA-C
Observational, Prospective Epidemiological Registry in Australia of HCV Liver Disease

DARE C-II
Investigating whether treatment of acute chronic HCV can be shortened

Access Operations and Emerging Markets

Efforts Towards HCV Elimination

Multiple strategies to expand access to HCV medicines in LMICs
Flat pricing with minimal profit that is re-invested in support activities



Mongolia
Partnership with MoH for a micro-elimination program in the Arkhangai Province



India
MoU Collaboration with Tata Trust Foundation on the public health challenges posed by viral hepatitis

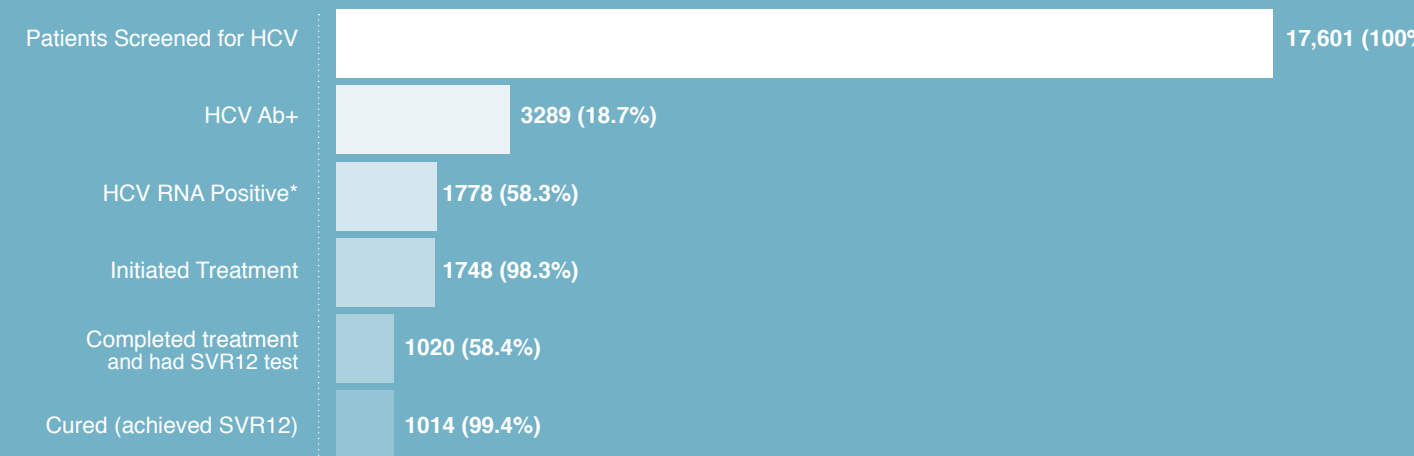


Georgia
Donations made to the Georgia HCV Elimination Program with over 25,000 HCV patients cured to date

LMIC = low and middle income countries | MoH = Ministry of Health | MoU = memorandum of understanding

Mongolia Elimination Program

In 2017, the Arkhangai Department of Health Hepatitis Elimination Program screened all eligible patients between 40-65 years of age in the Arkhangai province.



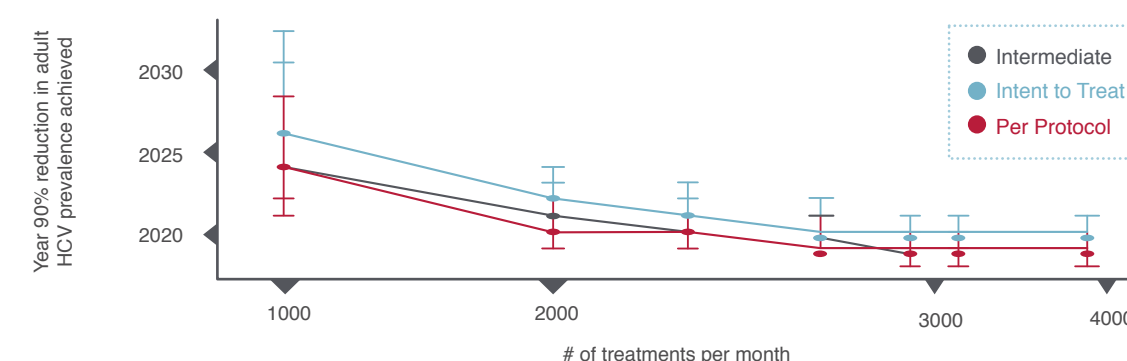
Nearly 99% of HCV positive patients began treatment with DAAs, and of those who completed treatment, 99.6% were cured

*HCV RNA positive among 3053 individuals who received a viral load test

Scale up of treatment has already reduced prevalence by 26% and incidence by 25%, and prevented 1845 new infections and 93 HCV-related deaths.

However, extensive scale up to 4000 treatment initiations/month is needed to achieve a 90% reduction in prevalence by 2020.

Year in which 90% prevalence reduction will be reached for levels of treatment scale up from November 2017:

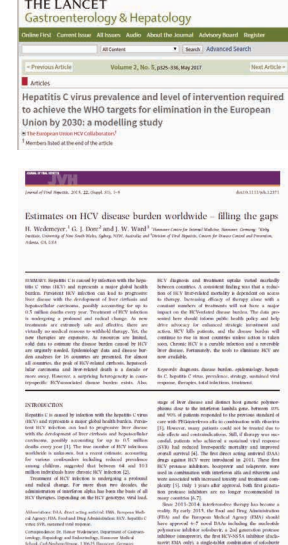


References: Progress Towards Hepatitis C Elimination in the Country of Georgia, EASL 2017; Walker J, et al. EASL 2017; Teetsovadze T, PHC 2016; Walker J, et al. <https://www.biorxiv.org/content/early/2018/02/24/270079> Accessed April 15, 2018; Teetsovadze T, EASL 2018



Government Affairs and Policy

INTERNATIONAL EFFORTS



Generating evidence for policy-makers: elimination is possible

Financially supported CDA to develop hepatitis health policy model, assessing country opportunity to eliminate. Model rolled out over 40 countries with the involvement of multidisciplinary experts.

All plans published in peer reviewed journals; catalysed discussions about priorities to address HCV challenge in national elimination plans.

Facilitating policy advocacy: priorities to achieve elimination

Partnering with advocacy groups, professional organisations and industry to advocate for HCV elimination at European level. Political engagement at EU level and country policy summits.

Sharing best practices and solutions with policy makers: progress towards the WHO elimination goal

'Road to Elimination' report assessed best practices and barriers towards each step of care cascade across 11 countries.

Financial support provided to Catolica Instituto de Ciências da Saúde, to develop the Let's End Hep C Dashboard – an online, cross-country policy dashboard comparing countries on their actions towards the elimination of hepatitis C until 2030. <http://www.letsendhepc.com/index.html>

FOCUS (Frontlines of Communities in the United States)

Established in 2010, the FOCUS Program is a public health initiative within Gilead's Government Affairs Department that enables FOCUS Partners to bring their HIV, HCV, and HBV screening, diagnosis, and linkage to care into alignment with CDC, USPSTF, and state and local health department guidelines.

First launched in 2010 to implement HIV screening guidelines in the United States, FOCUS Partnerships integrated HCV screening in 2013 and HBV in 2016. Later, in 2018, FOCUS expanded to Portugal and Spain. Through Q3 2018, 250 FOCUS partners have conducted 2.6 million HCV antibody screening tests in 94 cities/counties in the United States. Additionally, FOCUS partners have conducted over 165,000 HbsAg tests through Q3 2018.

FOCUS Partners are helping to meet the challenge of screening and linking undiagnosed individuals to care, which requires FOCUS Partners to develop and share their best practices, including systems-level changes to screen, diagnose, and link patients to care.

FOCUS' guiding model - TEST: Four Pillars of Routine Screening



Integrate Testing Into Normal Clinical Flow



Electronic Medical Record (EMR) Modification



Systemic Policy Change



Training, Feedback & Continuous Quality Improvement