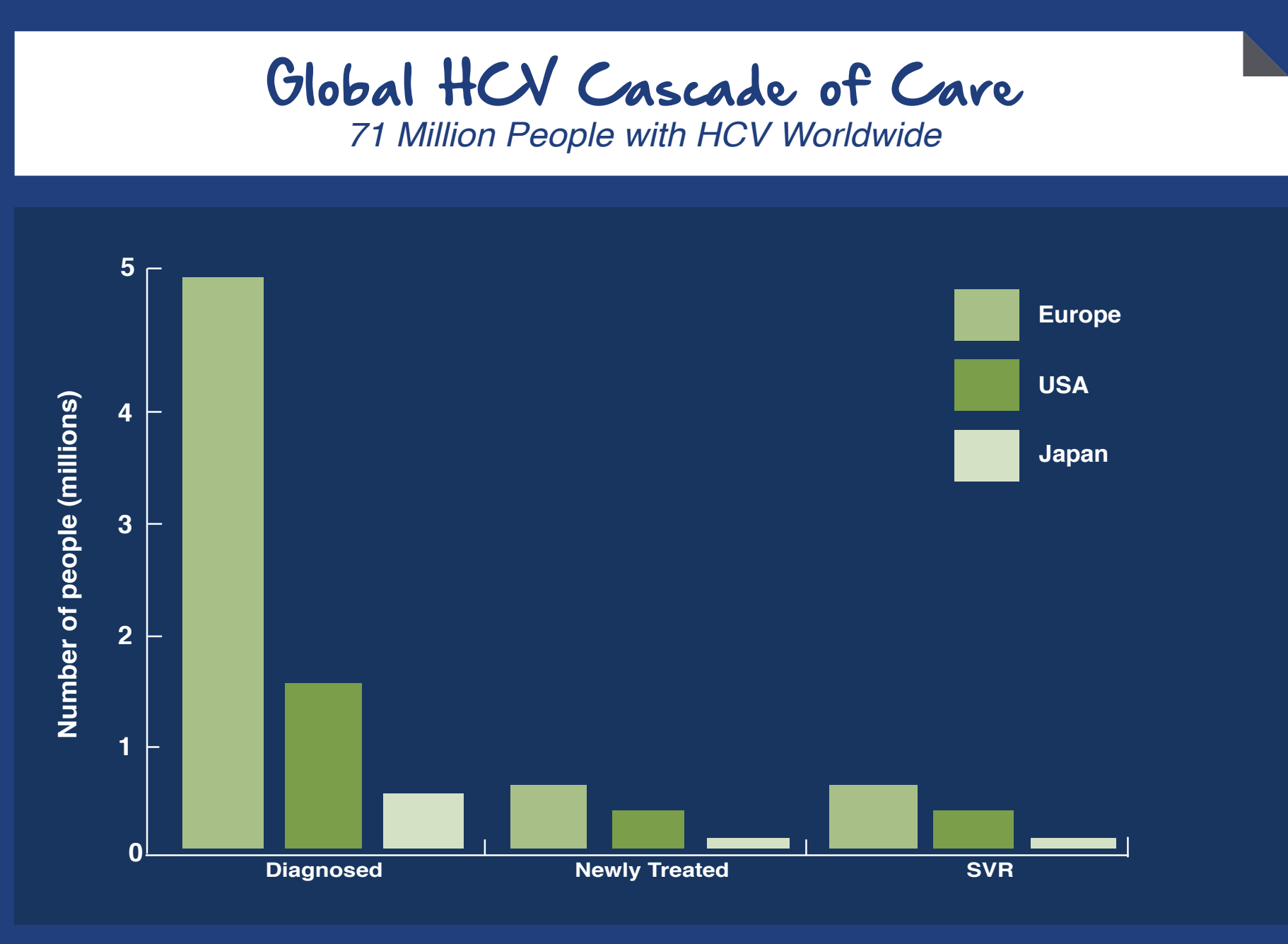




Nika Sajed, Kacy Hutchison, Lorenzo Rossaro, Diana M. Brainard, Patrick McGovern, Daniel O'Farrell, Korab Zuka, Mark Snyder, Betty Chiang, Nelson Cheinquer, Bruce Kreter

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 WHO goal of elimination of viral hepatitis around the world by 2030.

Gilead Sciences, Inc.  
333 Lakeside Drive  
Foster City, CA 94044  
Tel: (650) 574-3000  
Fax: (650) 578-9264



### Addressing the Global HCV Epidemic

Highly-effective, well-tolerated single-tablet regimens (STRs) have helped reduce the total burden of HCV and allow for large-scale initiatives for screening, treatment, and elimination

#### Gilead STRs

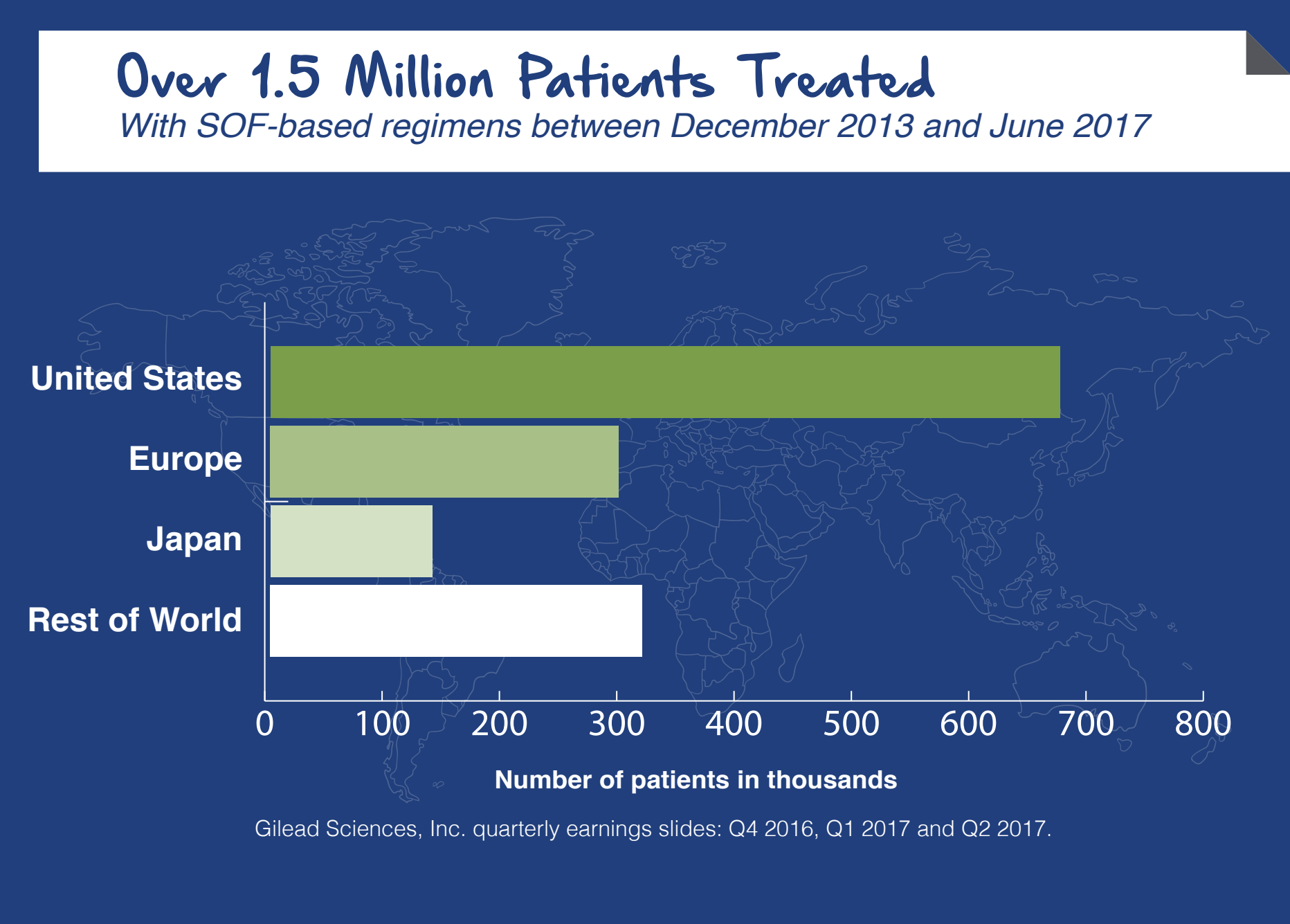
- HARVONI®** (2014): Sofosbuvir (NS5B) + Ledipasvir (NS5A)
- EPCLUSA®** (2016): Sofosbuvir (NS5B) + Velpatasvir (NS5A)
- VOSEVI™** (2017): Sofosbuvir (NS5B) + Velpatasvir (NS5A) + Voxilaprevir (PI)

## 99.6%

**ESTIMATED TOTAL CURE RATE**

When Sofosbuvir-based Single Tablet Regimens Harvoni or Epclusa are First-Line, followed by Vosevi Re-Treatment

5763 publications citing "sofosbuvir"  
Ovid® search of BIOSIS Previews, Current Contents/Life Sciences, Embase, Ovid MEDLINE® In-Process & Other Non-Indexed Citations & Ovid MEDLINE® resources on September 29, 2017.



The ODA Foundation. Available from: [http://polarisobservatory.org/polaris\\_view/bccascade.htm](http://polarisobservatory.org/polaris_view/bccascade.htm). Accessed: September 28, 2017  
SVR = sustained virologic response | Global Hepatitis Report 2017. Geneva: World Health Organization; 2017.

## Medical Affairs

Investigator-Sponsored Research Programs

**HCV CITE 2016**

Continuum from Identification to Elimination

**HM/HCV NoCo 2017**

No-Co-Infection Elimination Program

**HCV SCALE 2017**

Screening, Access and Linkage to Care

**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.

### 27 HCV Elimination Studies Approved

#### Health System

- Community Pharmacy Led Treatment in an OST Population
- Promoting Inter-Hospital Referral System to Hepatologists
- Universal HCV Screening and Linkage with Therapy
- Direct to Patient Messaging for HCV Screening and Care
- Patient and Health System Outcomes Following Structured Interventions
- Comparing Two Novel Interdisciplinary Care Models
- Cascade of Care in a Provider Network vs Private Practice vs University

#### HIV Co-infection

- Curing HCV in HIV/HIV Co-infection and T2 Diabetes
- Modeling Interventions in HIV/HIV Co-infection
- Eliminating HCV in HIV+ MSMs
- Universal Access to DAAs and Counseling in Special Populations
- Behavioral Patterns and Incident HCV Infection in HIV+ MSMs
- Expand Treatment and Detect, Navigate, Educate
- Eliminating HCV in Canada's Co-Infected Population

#### Corrections

- Linkage vs In Prison Treatment
- Decreasing Recidivism Through Treatment
- Testing and Linkage to Care for Probationers and Parolees
- Cascade of Care in Prison Population

#### Regional

- HCV Elimination in the Netherlands
- HCV Identification and Linkage to Care in British Columbia
- City Wide HCV Screening and Linkage to Care in Seattle
- Models for HCV Elimination in Philadelphia

#### Special Populations

- HCV in Hemophilia and Bleeding Disorders
- Preventing HCV Post-Liver Transplant with DAAs
- HCV Elimination in the Urban Native American population
- HCV Elimination in Migrants and Low-Income Refugees
- OST and HCV Elimination

## Government Affairs and Policy

### FOCUS (Frontlines of Communities in the United States)

In 2010, the FOCUS program, was created to develop and share best practices in screening, diagnosis, and linkage to care in accordance with the US CDC's recommended screening guidelines. First launched to address HIV, FOCUS expanded its scope in 2014 to integrate HCV screening & linkage to care and in 2016 incorporated HBV as well. FOCUS is helping to meet the challenge of identifying and linking the nearly 2M undiagnosed patients living with HCV in the U.S., which requires screening at an unprecedented scale across health care systems and the creation of novel LTC networks to address the high volume of patients.

#### 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

### Overview of FOCUS in the US

165 Current Partnerships in 72 Cities/Countries

\*As of September 2017  
\*\*Other includes health departments, substance use, training, and corrections.

Dissemination of information by FOCUS

- 415 Abstracts Accepted At Major Conferences
- 47 Journal Articles Published In Peer-reviewed Journals

Sample Settings	Partners	HCV Ab tests	HCV Ab+
Emergency Departments	55 partners	280,000	8.3%
Community Health Centers	74 partners	485,000	3.6%
Substance Use Tx	31 partners	40,000	16.3%
Corrections	10 partners	9,000	13.2%

Data through Q2 2017

## 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

#### Registration & Partnerships

Registration of Gilead HCV medicines for inclusion on the WHO Essential Medicines List: Sovaldi, Harvoni and Epclusa are all currently approved

#### Health System Strengthening

Support government efforts to build sustainable systems for HCV screening and treatment

**Mongolia**

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

**India**

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

**Georgia**

Donation of Sovaldi and Harvoni for the Georgia's HCV Elimination Program with over 43,000 patients to date started on HCV treatment

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

### Georgia Elimination Program

#### ELIMINATION GOALS

- Cure 122,000 persons living with chronic hepatitis C
- Reduce prevalence of HCV infection by 90% (to 0.5%)

#### 7% HCV prevalence

Developing nation  
STOP-C study

Eliminating HCV  
Total Population: 3,700,000  
Anti-HCV+: 259,000  
Chronic HCV: 185,000

- Challenged with limited healthcare infrastructure
- Lack of screening, surveillance, infection control measures
- Small country size and commitment from Georgia government, CDC and Gilead makes eradication feasible

Plan  
Prevention and expanding access to care  
Phase 2 (2016-2020): treating 20,000 patients/year

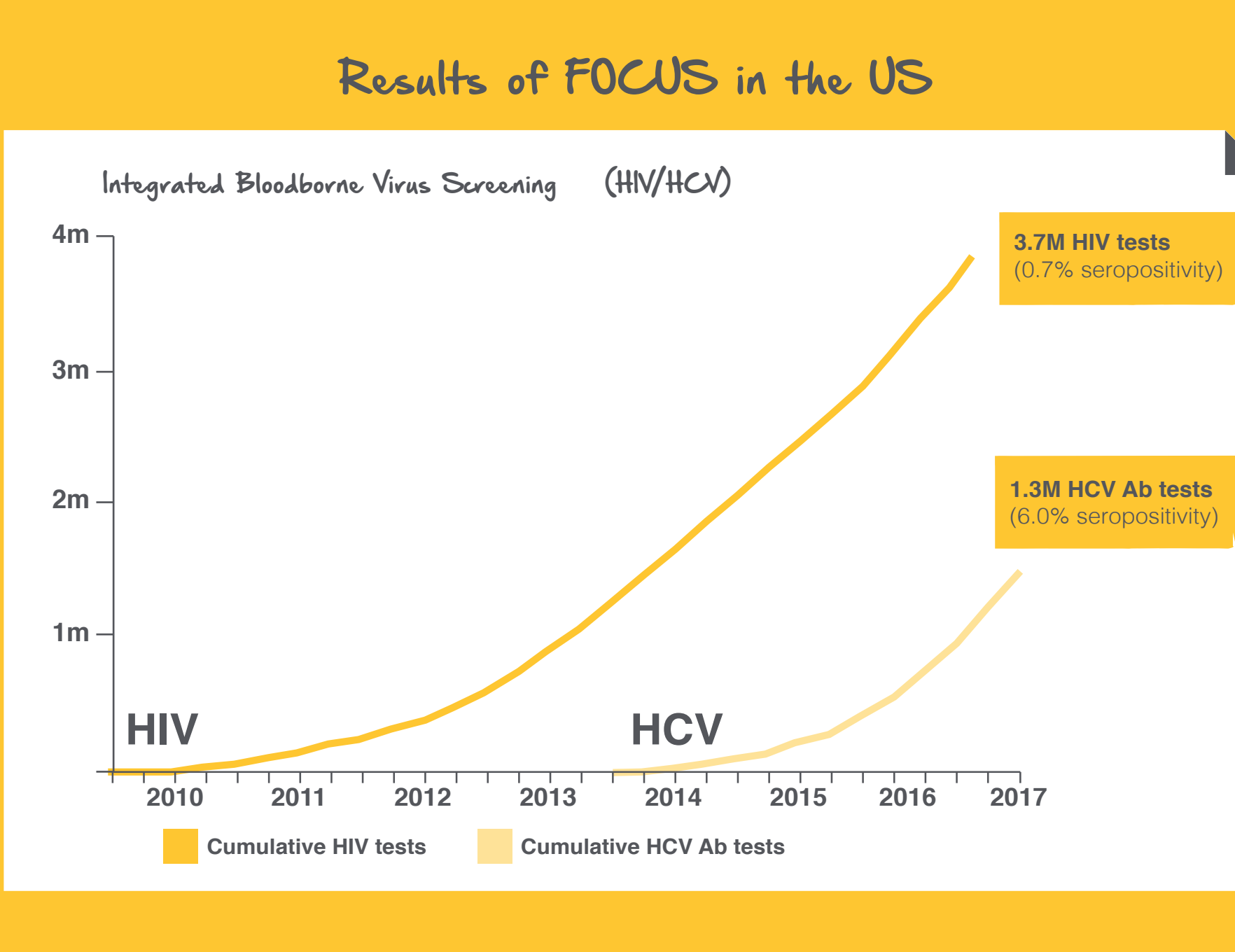
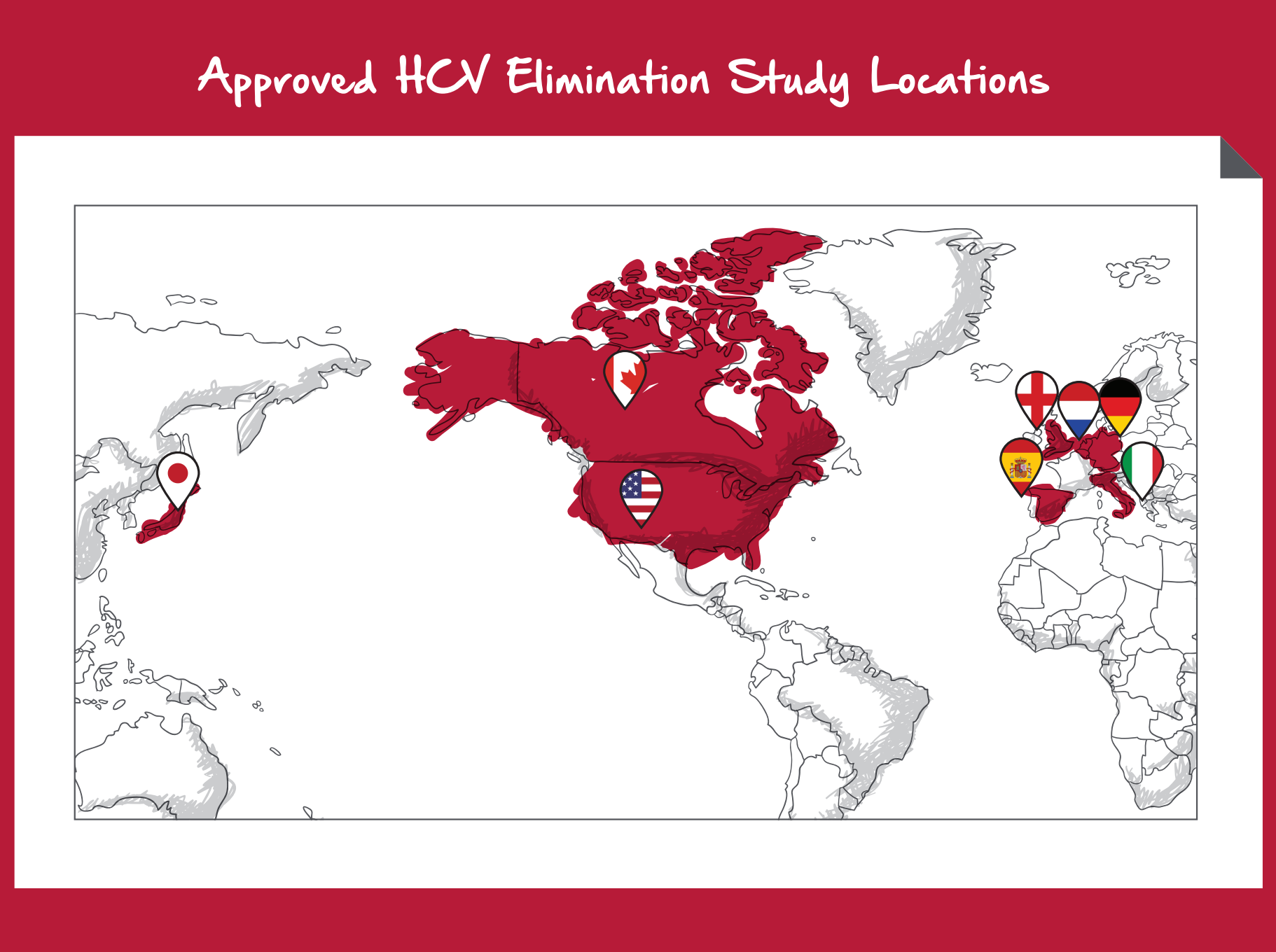
Since May 2015: >37,000 patients completed treatment; 98% cured with LDV/SOF

SOF/VEL provided since 2017; outcome data pending

SVR Results:

Genotype	All	Cirrhosis (n=597)	No cirrhosis (n=991)
Genotype 1	97%	97%	98%
Genotype 2	98%	98%	99%
Genotype 3	99%	100%	98%

References: Progress Towards Hepatitis C Elimination in the Country of Georgia, EASL 2017; Walker J, et al. EASL 2017; Teetsvatze T, PHC 2016 | PWID = people who inject drugs



## Public Affairs

### Corporate Giving

**Reducing Disparities**

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

**Improving Access**

Enabling access to care that achieves the best health outcomes

**Advancing Education**

Working to improve disease awareness among patients and healthcare professionals

**Supporting Local Communities**

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

In 2016, Gilead provided almost \$460 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

#### World Hepatitis Alliance

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 injustice 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 NOhep campaign.

#### Cherokee Nation Health Services HCV Elimination Project

Cherokee Nation Health Services HCV Elimination Project. The program has increased patient screenings from 500 a month in September 2015 to more than 2,500 a month in January 2016. The number of HCVs who can manage HCV patients has increased from seven in 2014 to 27 by the end of 2015.

#### NIH R IOM Report

Institute of Medicine (IOM) Report  
Sponsorship of Phase Two of the IOM process to develop a report with goals and strategies to eliminate hepatitis B and C in the United States. Following the release of the first report, Eliminating the Public Health Problem of Hepatitis B and C in the United States: Phase One Report, which concluded that both hepatitis B and C could be eliminated as a public health problem in the United States, Gilead supported the development of a second report, A National Strategy for the Elimination of Hepatitis B and C: Phase Two Report. This second report recommended specific actions to bring about the end of these diseases and identified five areas—information, interventions, service delivery, financing, and research—to include in the national plan.

## Clinical Research

### Iceland

0.3% HCV prevalence

TRaP HepC study

Eliminating HCV  
Total Population: 340,000  
Chronic HCV: 880-1300

Iceland represents a unique setting to pilot a nationwide HCV elimination program

- "Closed system": little immigration in/out of country
- National healthcare system tracks all new HCV; allows long-term monitoring of clinical outcomes, burden of disease

Plan  
Treat all HCV patients according to Icelandic guidelines over 3 years

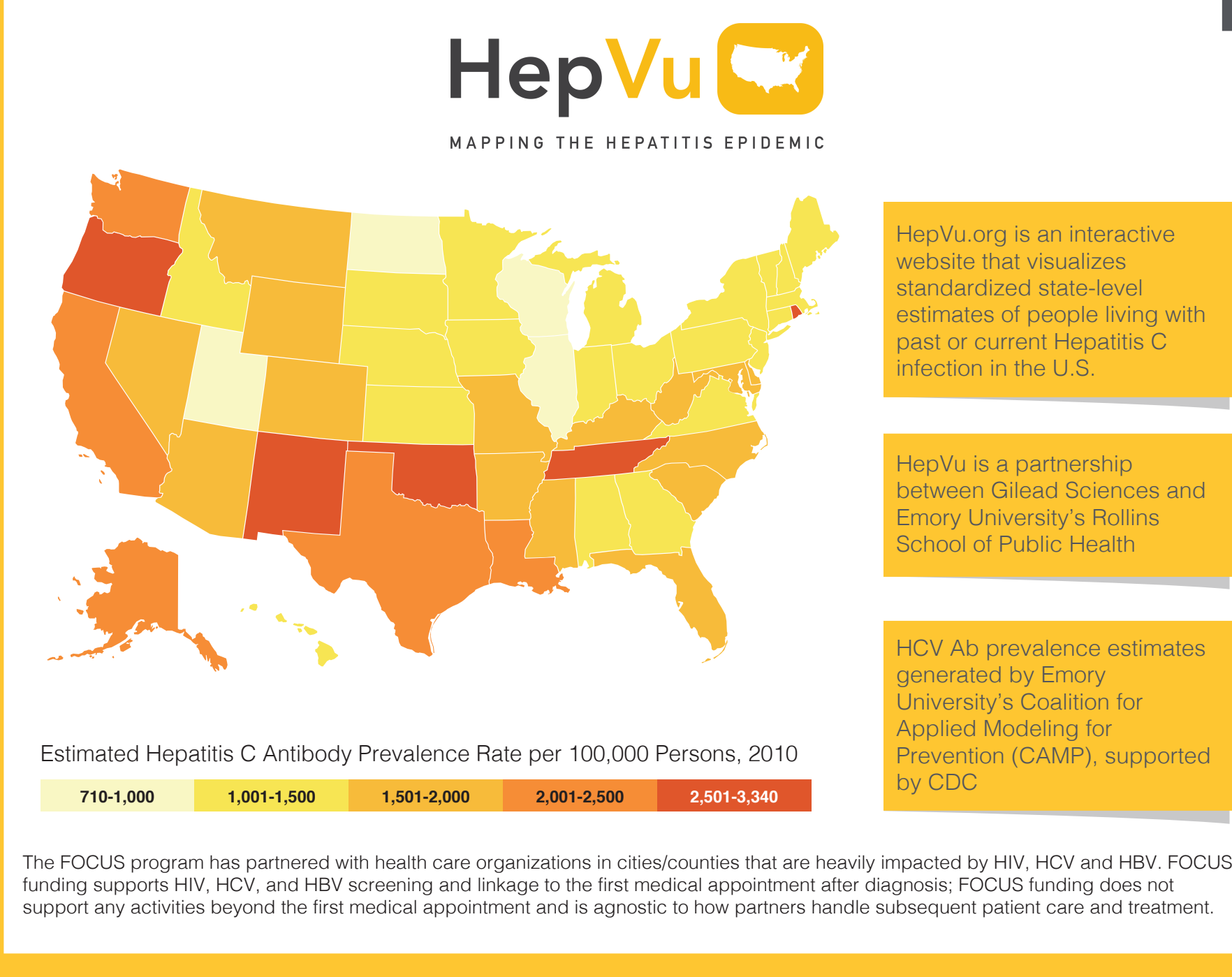
### Australia

0.9% HCV prevalence

SToP-C (Prisons)  
TAP (PWID)  
CEASE (HIV/HCV+)  
SIMPLIFY (PWID)  
REACT (PWID, HIV/HCV+)  
EC Partnership (PWID in Community & Prisons)  
OPERA-C (National HCV Registry)

Treatment in Prisons  
SToP-C Study Surveillance and Treatment of Prisoners with Hepatitis C

- Evaluate impact of SOF/VEL treatment on HCV incidence and prevalence
- Assess behavioral factors associated with exposure and infection



## World Hepatitis Alliance

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