

Gilead Sciences, Inc.

Medical Affairs - Request for Research Proposals



No Co-Infection (NoCo) Program: HCV Elimination in Specific Populations and Regions with High Prevalence or Risk of HIV and HCV Infection

Gilead Sciences supports the research efforts of academic institutions, clinical investigators, community organizations and research networks to help inform the scientific community about barriers and facilitators of HCV elimination, including elimination in people living with HIV. Targeting elimination of HCV in sub-populations, including co-infected or high-risk individuals, is a feasible and a more proximate short-term goal and a positive step toward more global HCV elimination.

The LEGA-C platform, “Local Elimination Programs Leading to Global Action in HCV”, including the ongoing Request for Proposal (RFP) programs CITE, SCALE, CHIME, NoCo and STAT, demonstrates Gilead’s commitment to support local actions in HCV elimination. More than 100 investigator-sponsored research (ISR) studies have been funded by Gilead, focused on screening, linkage to care and micro-elimination.

To further strengthen this support and commitment, the Gilead Medical Affairs team is launching the third year of the No Co-Infection (NoCo) RFP Program: HCV Elimination in Specific Populations and Regions with High Prevalence or Risk of HIV and HCV Infection. This program is calling for ISR proposals with objectives to develop and perform implementation science projects, including data collection or modeling that may include, but are not limited to, the following populations, geographies and topics:

- Population: Injection drug use, opioid addiction, poverty, homeless, women and children, migrants, men who have sex with men, people in HIV pre-exposure prophylaxis (PrEP) care
- Geography: Rural communities (ie, Appalachia, several countries in Latin America, Africa and Asia), urban cities (ie, Washington DC, Baltimore, Glasgow) and other regions (ie, Eastern Europe and the former Soviet Union) with high HIV and HCV prevalence, poverty, high rates of substance abuse, minimal access to clean syringes, and/or limited access to harm reduction services and medical care
- Research topics:
 - Transmission networks (ie, real-time surveillance tracking emerging threats)
 - Novel methods to address stigma and increase screening
 - Innovative approaches to simplify HCV diagnosis algorithm
 - Rapid initiation of treatment initiatives (ie, test and treat)
 - Access to health care and coordinated care services (ie, collocated care)
 - Interventions by HCPs and/or technology
 - Integrating models within hardest-to-treat populations
 - Evaluation of cost effectiveness
 - HCV re-infection
 - Correction settings (ie, prison, jails, including release from these settings)
 - Joined efforts within the Fast Track Cities network (or other NGOs)
 - Treatment in conjunction with successful harm-reduction measures

Successful projects should demonstrate clear scientific objectives, defined timelines, a comprehensive operational plan, and proposed data generation which has relevance to the medical community and policy makers, and include the following information:

- Potential scalability and sustainability of program to other practice settings and geographies
- Plan to publish and present results in scientific forums and to other organizations*
- Plan to complete the research within 2-3 years

Awards shall be for research purposes only; ***requests that include costs for routine medical care, screening or study drug will not be considered.*** Proposals should not require treatment with any specific drug regimen. Awards will not be granted to a sponsoring institution that currently has an active grant from a Gilead Medical Affairs HCV or HIV/HCV Co-Infection RFP Program (ie, CITE, NoCo, SCALE, CHIME, STAT) or is currently receiving support from FOCUS.

Key Dates & Program Specifics:

Letter of Intent (LOI): 2-page concise overview of proposed project and draft budget, using the form available at <https://www.gilead.com/science-and-medicine/research/investigator-sponsored-research/co-infection-noco-rfp>

27 June 2019: LOI submission window opens

9 August 2019: LOI submission window closes

LOIs and questions about the application process should be submitted to NoCo@Gilead.com

Full Application: Selected LOIs will be invited to submit a full ISR application. The timelines below will be followed for those full ISR submissions.

16 September 2019: Notice of LOI outcome, either approved for full application submission or declined

25 October 2019: Deadline for receipt of full ISR application

27 November 2019: Notice of full application outcome, either approved provisionally or declined

Investigators who meet criteria for a standard Gilead ISR are encouraged to apply. There are no geographic limitations to applications.

Gilead reserves the right to approve or decline any proposal and will attempt to ensure accepted submissions fulfill a data need and represent geographic distribution across the world. Applications are reviewed by an internal review committee. Award of a grant in any one cycle does not imply that a subsequent grant will be awarded without further application and approval.

Budget Considerations: Gilead plans to award up to \$3,000,000 in funds for these research proposals, dependent upon availability of funds and receipt of meritorious applications.

- Gilead anticipates that 4-6 awards will be granted
- Each proposal will be capped at \$600,000

About Gilead Sciences, Inc.

Gilead Sciences, Inc. is a research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of unmet medical need. The company strives to transform and simplify care for people with life-threatening illnesses around the world. Gilead has operations in more than 35 countries worldwide, with headquarters in Foster City, California.

*Investigator has discretion whether and where to publish/present results