

Gilead Sciences, Inc.

Medical Affairs - Request for Applications

HIV/HCV No Co-Infection (NoCo) Program: Micro-Elimination of HCV in HIV-Infected and High-Risk HIV-Uninfected Populations

Through Medical Affairs, 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 micro-elimination in people living with HIV. Gilead intends to support investigators focused on addressing the challenges associated with HCV elimination for individuals co-infected with HIV or in people at high risk for HIV infection, ie, HIV-negative men who have sex with men (MSM) on pre-exposure prophylaxis (PrEP). Many people living with HIV or on PrEP are linked and engaged in care. Thus, targeting micro-elimination of HCV in HIV-infected or high-risk HIV-uninfected individuals is a feasible and a more proximate short-term goal and a positive step toward more global HCV elimination.

This Request for Applications, via the Investigator-Sponsored Research (ISR) process, will evaluate proposals with objectives to develop and perform implementation science projects, including data collection or modeling, of HCV in HIV-infected populations that may include, but are not limited to, the following elements:

- Clearly defined populations such as a clinic, a health system, a geographic location (city) or other micro-environments
- Epidemiology of treated-HCV populations: those left to treat; differences across regions or countries, and changes with time
- Epidemiology of HCV in HIV-uninfected MSM (especially MSM on PrEP)
- Molecular epidemiology and transmission risks associated with HCV transmission
- Evaluation of cost effectiveness of treatment of acute HCV
- Programs to enhance HCV screening in HIV-negative MSM on PrEP
- Assessment of immediate treatment after HCV rapid test diagnosis
- Evaluation of the incidence of new HCV infection in an HIV population, including re-infection rates and change in incidence over time
- Transmission of HCV in HIV-infected pregnant women

Proposals must contain the following:

- Clear scientific objectives based on a scientific hypothesis
- Potential scalability and sustainability of program to other practice settings
- 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 routine medical care, HCV or HIV screening costs or HCV or HIV study drug will not be considered.** Proposals should not require treatment with any particular HCV or HIV medication or drug regimen. Awards will not be granted to a sponsoring institution that has already received a screening/linkage to care grant from a Gilead Medical Affairs Program (ie, CITE, NoCo, SCALE, CHIME) 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 attached form

03 July 2018: LOI submission window opens

20 August 2018: LOI submission window closes

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

Full Application

A review of the LOIs will result in invitations for selected LOI applicants to submit a full application. The timelines below will be followed for those full submissions.

04 October 2018: Notice of LOI outcome, either approved for full application submission or declined

16 November 2018: Deadline for receipt of full application

12 December 2018: 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 application. 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 a total of approximately \$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. Proposals 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.