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Gilead Sciences, Inc.
Medical Affairs
Request for Proposals for STAT Program (Simplification and Test and Treat Strategies Towards Hepatitis C Elimination)

The development of highly-effective direct-acting antivirals (DAAs) have revolutionized the care of patients with hepatitis C virus (HCV) over the last few years, providing cure rates greater than 95% with few side effects and rare treatment discontinuations. This advancement in HCV care, combined with increased access to treatment, have led many countries to implement strategies toward HCV elimination in alignment with the World Health Organization (WHO) goal of eliminating viral hepatitis as a public health threat globally by 2030[1].

HCV screening, linkage to care, and treatment access still remain a challenge due to health system, provider, societal, and patient barriers. According to the WHO, key success factors for large-scale HCV treatment and care delivery include the use of simplified and standardized HCV treatment algorithms and decentralized care in primary care settings in the community, in addition to collaboration and commitment of all involved stakeholders[2].

Gilead 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 goal of eliminating viral hepatitis.

The LEGA-C platform, "Local Elimination Programs Leading to Global Action in HCV", including the ongoing programs CITE, SCALE, CHIME, and NoCo, 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 a fifth program, **Simplification and Test and Treat Strategies Towards Hepatitis C Elimination** (STAT), which will support projects that focus on ways to overcome barriers in hepatitis C care. The new once-daily, pan-genotypic treatment regimens enable treatment simplification and decentralization that could lead to expansion in hepatitis C care and additional progress towards the elimination goal[1,3].

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

- Simplification
    - Innovative approaches to simplify HCV treatment & HCV care delivery (e.g. minimal monitoring, alternative models of care)
    - Innovative elimination strategies through simplification of the patient care cascade
    - Use of technology to address digital patient solutions
- Test and Treat
    - Strategies using pan-genotypic regimens as well as diagnostic tools that allow for rapid treatment initiation

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The STAT program aims to fund approximately 15 projects worldwide, with a total budget of US $10,000,000. Any proposal greater than $750,000 should be discussed with your Gilead Medical Scientist prior to submission.

Gilead retains the right to accept or deny any proposal and will attempt to ensure accepted submissions fulfill a data need and represent geographic distribution across the world.

Letter of Intent (LOI) should adhere to the following:

- ☐ Sponsoring institution is not currently receiving support from a Gilead Medical Affairs LEGA-C Program (i.e., CITE, SCALE, NoCo, CHIME) or from Gilead's Government Affairs FOCUS program (US and Europe only)
- ☐ Indirect (i.e., overhead) costs are ≤ 30% of the total budget
- ☐ Enrollment for the proposed study should be completed within 30 months
- ☐ Funding requests for the sole purpose of screening costs or free drug programs will not be considered

Key Dates & Program Specifics

- **11 April 2019**: LOI submission window opens
- **30 June 2019**: LOI submission window closes
- LOI should be entered into the provided template, available at www.gilead.com/science-and-medicine/research/investigator-sponsored-research/hcv-stat-rfp, and submitted to STAT@gilead.com
- Proposals should not exceed 1,000 words

After the submission window closes, Gilead will evaluate and rank all LOIs. Top ranked LOIs will be invited to submit a full application. Based on prior programs, approximately 20% of LOIs are expected to be selected as full proposals and instructions will be provided.

Gilead plans to approve awards for these research proposals, dependent upon availability of funds and receipt of meritorious applications. Awards shall be for research purposes only.

Questions about the announcement or application process should be submitted to your local Gilead Medical Scientist or STAT@gilead.com. Applications are reviewed by an internal review committee.

About Gilead Sciences

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.

1. WHO. Global Hepatitis Report 2017 Available at: http://www.who.int/hepatitis/publications/global-hepatitis-report2017/en/ (accessed April 2018)
2. WHO. Global Health Sector Strategy on Viral Hepatitis 2016-2021 towards ending viral hepatitis Available at: https://www.who.int/hepatitis/strategy2016-2021/ghss-hep/en/ (accessed January 2019)
3. Kapadia SN and Marks KM. Hepatitis C Management Simplification From Test to Cure: A Framework for Primary Care Providers. Clin Ther. 2018 Aug; 40(8):1234-45