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## **Gilead Sciences, Inc.**

### **Medical Affairs**

#### **Call for Proposals PSC PACE Program - PrimAry Sclerosing Cholangitis Epidemiology Program**

Primary sclerosing cholangitis (PSC) is a rare, chronic cholestatic disease that primarily affects the bile ducts and the liver. PSC can be progressive and often lead to end stage liver failure. Patients with PSC have increased risk for cirrhosis, various types of cancer (i.e. cholangiocarcinoma) and the need for liver transplant. Currently, there is no known cure for PSC and the median survival for PSC patients is around 10-12 years after diagnosis. The overall incidence of PSC is estimated to be 1 per 100,000 person years. However, the epidemiology of PSC in general population remains unclear.

In an effort to further understand PSC epidemiology and patient outcomes from around the world, the Gilead Medical Affairs team is launching the PrimAry Sclerosing Cholangitis Epidemiology Program (PACE). The PSC PACE program will support individual projects of no more than \$150,000 USD or equivalent sum. It is Gilead's intent to support up to 5 well-defined projects.

Successful projects should demonstrate clear objectives, defined timelines, a comprehensive operational plan, and propose data that has relevance to the medical community.

#### **Gilead will consider support for research proposals that do the following:**

- ☐ Focus on a data gap for PSC patients, such as (but not limited to):
  - ☐ Prevalence and characteristics of PSC patients
  - ☐ Disease process or clinical outcomes of PSC patients
  - ☐ Understanding the cascade of care for PSC patients

#### **Letter of intent (LOI) should adhere to the following:**

- ☐ Proposed budget is  $\leq$  \$150,00 USD or equivalent sum
  - ☐ Including overhead costs and applicable taxes
  - ☐ Proposed overhead costs are  $\leq$  30% of the total budget
- ☐ The proposed study design will not take longer than 24 months to complete
- ☐ Funding request for sole purpose of screening costs is not acceptable for PACE
- ☐ Funding for or contribution of any PSC study drug is not acceptable for PACE
- ☐ No more than one subsite that will require contract negotiations and/or Institutional Review Board (IRB) or Ethics Committee (EC) review, or other barriers that will lead to delays in study start-up
- ☐ Entered into the provided LOI template
- ☐ Proposals should not exceed 1,000 word limit

#### **Key Dates & Program Specifics:**

- Gilead will evaluate and award submissions following submission deadline.
- LOI –
  - **September 16, 2019:** LOI submission window opens
  - **October 11, 2019:** LOI submission window closes



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LOI applicants should use the downloadable **LOI Form** available at [www.gilead.com/science-and-medicine/research/investigator-sponsored-research/psc-pace-rfp](http://www.gilead.com/science-and-medicine/research/investigator-sponsored-research/psc-pace-rfp) LOI forms and Overhead Policy forms should be submitted to: [PACE@gilead.com](mailto:PACE@gilead.com)

- After submission window closes, Gilead will evaluate and rank all LOIs. Top ranked LOIs will be invited to submit a full application and additional instructions will be provided to the submitter.

Gilead approval of awards for research proposals depend on availability of funds and receipt of meritorious applications. Gilead anticipates that approximately 5 awards will be granted. No individual study may exceed \$150,000 USD or equivalent sums. Awards shall be for research purposes only.

Questions about the PSC PACE Program announcement or application process should be submitted to your local Gilead Medical Scientist or [PACE@gilead.com](mailto:PACE@gilead.com). Gilead reserves the right to approve or decline any application. 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 therapeutics 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.