**Gilead Sciences, Inc.**

**Medical Affairs**

**Call for Proposals: COMMIT**™ **(CO**vid-19 un**M**et **M**ed**I**cal needs and associated research ex**T**ension**) COVID-19 RFP Program**

Coronavirus disease 2019 (COVID-19) was declared by the WHO as a global pandemic on March 11, 2020; with over 7 million confirmed cases and about 404,000 deaths worldwide by June 9, 2020.1 The respiratory infection, caused by the novel SARs-CoV-2 can range in severity from asymptomatic infection to severe pneumonia with multi-organ failure and death. High mortality rates have been observed in patients with severe disease especially patients requiring mechanical ventilation. Age and underlying comorbidities have been observed as strong risk factors for severe illness, complication and death.2  Critical data gaps exists in our understanding of epidemiology, clinical course, predictors of disease severity, sequelae and clinical experience of treating patients with COVID-19.

In an effort to further address the unmet medical need in COVID-19, Gilead Medical Affairs is launching the **COMMIT** program. The **COMMIT** program will support well defined individual projects of no more than $250,000 USD or equivalent sum; projects that are more than $250,000 will require approval by Gilead prior to submission.

Successful projects should demonstrate clear objectives, defined timelines, a comprehensive operational plan, and propose data that has relevance to the medical community. Note: these projects will not have objectives/endpoints that overlap with studies that are known to be currently underway as of the day of the approval of the proposal, including those studies that are sponsored by either Gilead and/or third parties.

**Gilead will not consider proposals that request COVID-19 screening costs (including test kits) or proposals that requests remdesivir or other study drug**.

**Gilead will consider support for research proposals that meet one of the following criteria:**

* Expand data on clinical course and outcome in vulnerable populations:
	+ Immune suppressed, specifically- HIV, cancer chronic inflammatory conditions (i.e., RA or IBD), and chronic liver disease, pre-existing pulmonary disease
	+ Residents of long-term care facilities/nursing homes, and older adults
	+ At risk for healthcare disparities (e.g. Black/African American, socio-economic class)
* Long-term sequelae (i.e., pulmonary fibrosis, neurologic, cardiac, quality of life)
* Real world safety and effectiveness of remdesivir used alone or with other agents (JAK inhibitors, IL-6 inhibitors, convalescent plasma and ACE inhibitors and ARBs):
	+ Viral kinetics and clinical outcomes
	+ Based on duration of treatment (e.g., 5 vs 10 days, shorter courses)
	+ Use in early (non-severe) disease
	+ Course completion in alternative (non-inpatient setting) or alternative treatment pathways

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

* Proposed budget is ≤ $250,000 USD or equivalent sum; Gilead approval will be required prior to submission for proposals with a budget of > $250,000
	+ Including overhead costs and applicable taxes
	+ Proposed overhead costs are ≤ 30% of the total budget
* The proposed study design will not take longer than 6 to 9 months to complete
* Funding request for sole purpose of screening costs is not acceptable for **COMMIT**
* Funding for or contribution of study drug is not acceptable for **COMMIT**
* No more than one sponsor for contract negotiations and/or Institutional Review Board (IRB) or Ethics Committee (EC) review
* Entered into the provided LOI form
* Research plan should not exceed 1,000 word limit

\*The letters of Intent are not binding documents on either party. The purpose of the LOI is a brief summary of the proposed study to enable Gilead to determine on a preliminary basis whether the proposed study and related budget are aligned with the criteria, timeline and scope of this RFP.

**Key Dates & Program Specifics:**

* Gilead will evaluate LOI based on the following timelines:
* Submission window:
	+ **Jul 1, 2020**: submission window opens
	+ **Aug 3, 2020**: submission window closes

Applicants should use the **LOI form** available at <https://www.gilead.com/science-and-medicine/research/investigator-sponsored-research/covid19-commit-rfp>

**LOI, curriculum vitae, and overhead policy forms should be submitted to:** <https://covid19-commit-rfp.gilead.com/>

* After Aug 3, 2020, 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 will depend on availability of funds and receipt of meritorious and complete proposals. No individual study may exceed $250,000 USD unless approved by Gilead prior to submission. Awards shall be granted solely on the merit of the research and alignment with the criteria of this RPP

Note: Gilead approval of awards does not take into account the past, present, or future volume or value of any business or referrals between the parties, and are not being given, directly or indirectly, as an inducement or reward with respect to the formulary placement of any Gilead product. Further, the awardee is not required to purchase, order, recommend or prescribe to any patients any products manufactured or available through Gilead

Questions about the **COMMIT** announcement or application process should be submitted to your local Gilead Medical Scientist. 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.

**Reference**

1. Johns Hopkins COVID-19 Dashboard. Available at: <https://coronavirus.jhu.edu/map.html> (accessed 9 June 2020)
2. CDC Interim Clinical Guidance for Management of Patients with Confirmed Coronavirus Disease (COVID-19). 2 June 2020