

GRANT LETTER OF AGREEMENT

September 22, 2017

David Sergeenko
Minister of Labour, Health and Social Affairs of Georgia
Ministry of Labour, Health and Social Affairs of Georgia
144 Ak. Tsereteli Ave
Tbilisi, 0119
Georgia

Dear Minister Sergeenko:

On behalf of Gilead Sciences, Inc. ("Gilead"), I am pleased to inform Georgia represented by the Ministry of Labour, Health and Social Affairs of Georgia ("Grantee") that we have approved your request to reallocate \$99,000 in funding under the Grant Letter of Agreement dated July 28, 2016 (the "**Original Grant Agreement**") to a new grant to support expanded screening for HCV in Georgia and reduce out-of-pocket costs to patients ("**Project**"), as set forth in greater detail in your carryover Grant Request Proposal provided by email on July 17, 2017, and further clarified by email on August 29, 2017. Grant Funds must be used solely to support the Project as described in the Carryover Grant Request Proposal and in accordance with the following terms ("**Letter Agreement**").

In accepting the Grant Funds, Grantee hereby agrees to the following terms and conditions:

1. **Approved Use of Grant Funds.** Grantee shall only use Grant Funds for the Project and as listed out in the Grant Request Proposal dated July 17, 2017 and further clarified on August 29, 2017 (attached to this Letter Agreement as Annexure B). Any material or substantive change in the Project must be approved by Gilead in writing before Grant Funds may be spent for such material or substantive Project change. *Please note that the Grant Funds may not be used to subsidize patient purchases of prescription medications.*

2. **Reports.** Within 30 days of the completion of the Project, Grantee shall submit a final progress report concerning the Project to Gilead, as well as the Reconciliation spreadsheet within 30 days of completion of the Project as attached as Annexure A. The completed spreadsheet (and such related information as Gilead may reasonably request) must be returned to Gilead at grants@gilead.com within 30 days of the last program event or activity date supported by this Gilead grant or by February 1 of the following calendar year for reportable transfers of value disbursed in the previous calendar year, whichever comes first (or on such earlier date as Gilead may reasonably request in light of payments reporting laws and standards to which it may be subject). The Grantees are required to submit the attached spreadsheet if some or all of Gilead grant funds are used to make payments or other transfers of value (e.g., travel expenses or meals) to one or more "Covered Recipients" (U.S.- or European-licensed M.D.s, D.O.s, licensed chiropractors, dentists, dental surgeons, podiatrists, optometrists or teaching hospitals) playing key roles in your grant program (e.g., faculty speakers or fellowship recipients). This is required

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(a) Grantee is an entity in good standing under the applicable laws of the Georgia at the time of payment of the Grant Funds;

(b) Grantee has the full right and authority to enter into and to carry out this Letter Agreement and that it has no obligations, commitments or restrictions that limit its ability to do so including, without limitation, as a condition to the receipt of any federal or state funds;

(c) Grantee is not otherwise required under any contract or agreement with any third party to carry out the activities that are part of the Project;

(d) Grantee will comply with all applicable laws and regulations applicable to the Project, including but not limited to, the U.S. Foreign Corrupt Practices Act ("FCPA") and the U.K. Bribery Act 2010;

(e) Grantee will not include as a cost in any cost report, submitted for federal or state reimbursement purposes, any items provided to the Grantee under this Letter Agreement;

(f) No third parties, including any federal or state health care programs or sources, will be billed nor will any reimbursement be sought for the cost of services or items purchased through the use of Grant Funds pursuant to this Letter Agreement, or otherwise in connection with the Project; and

(g) The Grant Funds and any ancillary support provided by Gilead are not provided as an inducement or reward for the purchase, use or recommendation of any pharmaceutical product manufactured or marketed by affiliates of Gilead or to promote such products.

(h) The Grantee further warrants that it holds or will obtain and maintain valid all necessary regulatory approvals and registrations to enable Grantee to accept the Grant Fund and/or any part thereof under this letter agreement.

8. **Publication of Research.** Any information contained in publications, studies or presentation of the research funded by the Grant Funds shall be made available to the public following such reasonable requirements or procedures as Gilead and Grantee may agree to from time to time. Gilead shall have a non-exclusive, irrevocable right to use, reproduce and distribute any publications, studies or data produced in the course of the Product.

9. **Publicity.** Neither party shall use the name of the other party, or its affiliates, or the name of Gilead's or its affiliates' employees, agents or assigns in any form of advertisement or publicity without first obtaining Gilead's or its affiliates' written approval for such use. Gilead and its affiliates reserve the right to use Grantee's name in publicly-available materials describing Gilead grant disbursements.

10. **Assignment.** Grantee may not assign or subcontract all or any material part of its obligations under this Letter Agreement without the prior written consent of Gilead.

11. **Governing Law.** All questions relating to the execution, interpretation and performance of this Letter Agreement shall be governed by the laws of the State of Delaware.

Please sign below to indicate agreement to this Letter Agreement, make a copy for your files and return a signed copy to us, via email to grants@gilead.com.

Ministry of Labour, Health and Social Affairs of Georgia

Signature: _____

Print name: _____

Title: _____

Acknowledged and Agreed to:

Gilead Sciences, Inc.

Signature: _____

Print name: _____

Title: _____

Solutions:

We have already made significant efforts and continue to work in the direction of screening expansion to increase number of people screened for Hepatitis C. Intensive information-communication campaign is underway to increase the population awareness about Hepatitis C program and its importance.

To address a financial barrier, there are two options: A) completely cover the first (post-screening confirmatory) PCR test through the additional budget, thus completely removing patient co-payment; or B) to replace the PCR test with other, more cost-effective technology, such as HCVcoreAg or using GeneXpert system.

Ideas for consideration:

Within the provided grant, there are unused resources in the amount of 99 000\$. We propose to utilize unused resources for addressing financial barrier. Considering the above mentioned options of influencing financial barrier, utilization of the remaining grant funds in the option A will be sufficient for up to 3000 patients during this year.

The option B, will be able to fund the confirmative testing of approximately 10 000 patients by the end of this year.

Taking into consideration cost-effectiveness of the HCVcore Ag/ GeneXpert studies, the PCR test can be completely replaced, while the unused resources within the grant utilized for purchasing test systems, required for the HCVcore Ag/ GeneXpert studies. This will significantly reduce the cost of the confirmative testing and, accordingly, increase the patients' inflow in the program.

By this approach we would cover co-payment cost for "First Confirmation Test" for up to 6000 patients.

Also, reducing Ministry's expenditures for this test (by replacing PCR by HCVcore Ag/ GeneXpert method, we could increase co-payment % which will give possibility to cover totally more than 10 000 patients need for "Confirmation Test" for current year.

Table 2

	Unit cost (GEL)	Number of patients	Total budget (GEL)
Medical facilities' service reimbursement	5	11700	58 500,00
Transportation costs	1,2		14 040,00
CORE ag test	60		702 000,00
TOTAL			774 540,00

Currently, HCV program budget includes 550 000 GEL for confirmative tests. The difference between existing and required resources will be covered by the Gilead grant resource which amounts to 224 540 GEL ($=774\,540 - 550\,000 = 224\,540$).

Option 2. Replacement of the PCR test with HCVcore Ag testing, the unused resources within the grant will be used for purchasing test systems.

In this option, it will be able to purchase about 10 000 test systems (cost of test system – 10 USD), which will reduce the cost of CORE ag test by 24 GEL and total price of the test will become 36 GEL. In this case, it will be able to cover about 11 400 patients' confirmative tests (table 3)

Table 3

	Unit cost (GEL)	Number of patients	Total budget (GEL)
Medical facilities' service reimbursement	5	11400	57 000,00
Transportation costs	1,2		13 680,00
CORE ag test (-cost of test)	36	8500	306 000,00
CORE ag test	60	2900	174 000,00
TOTAL			550 680,00

Conclusion:

There is no significant difference between the 1st and 2nd options. In the first case, the grant resources will be used for funding the medical service and in the second case - for procurement test systems through centralized purchasing.

In both cases, patient's co-payment on confirmative test will be 0 GEL and the copayment of patient on diagnostic tests (for inclusion in treatment component) will be reduced by 22 per cent.

Therefore, in the first case, it will be able to cover about 11 700 patients' confirmative tests and in the second case – 11 400 patients.