Independent Grants for Learning & Change (IGLC)
Track 2 - Call for Grant Applications (CGA)
ROS1 Pathology Testing

I. Background

The mission of Pfizer Independent Grants for Learning & Change (IGL&C) is to partner with the global healthcare community to improve patient outcomes in areas of mutual interest through support of measurable learning and change strategies. "Independent" means that the projects funded by Pfizer are the full responsibility of the recipient organization. Pfizer has no influence over any aspect of the projects and only asks for reports about the results and the impact of the projects in order to share them publicly.

Through this CGA we encourage organizations to submit grant requests that, if funded, will support education in a specific disease state, therapeutic area, or broader area of educational need.

When a CGA is issued, it is posted on the IGL&C website (www.pfizer.com/independentgrants) in the *Grants Process* section and is sent via e-mail to all registered users in our grants system. Some CGAs may also be posted on the websites of other relevant organizations.

II. Eligibility

Geographic Scope:	☑ United States Only
Applicant Eligibility Criteria:	The following may apply: pathology laboratories or laboratory networks; medical schools; healthcare institutions (both large and small); professional associations and medical societies; and other entities with expertise in molecular diagnostics and testing. More information on organizations eligible to apply directly for a grant can be found at http://www.pfizer.com/files/IGLC_OrganizationEligibility_effJuly2015.pdf. Collaborations within institutions (e.g., between departments and/or inter-professional), as well as between different institutions/organizations/associations, are encouraged. All partners must have a relevant role, and the requesting organization must have a leadership role.

III. Requirements

Date CGA Issued:	May 24, 2016
Clinical Area:	Diagnostic Testing in NSCLC
Specific Area of Interest for this CGA:	Recent advances in the treatment of NSCLC have increased the importance of testing tumors for the biomarker ROS1. Chromosomal rearrangements of the ROS1 gene have been described and epidemiological data indicates that rearrangements of the ROS1 oncogene occur in approximately 1-2% of the NSCLC patient population[1,2,3,4]. The National Comprehensive Cancer Network (NCCN) guidelines recommend that certain patients with advanced lung cancer be considered for ROS1 testing (category 2A[6]). An FDA-approved test for the detection of ROS1 rearrangements in NSCLC is not currently available, however, laboratory developed tests are available. As a result, there is wide intra- and inter-laboratory variation in terms of the methodology (FISH, NGS, PCR, IHC, etc.) being used to diagnose ROS1 positivity. Furthermore, variation also exists in how the test results are being reported back to medical oncologists. Because of this lack of consistency and clarity, medical oncologists report having difficulty interpreting laboratory test results and often cannot determine from the diagnostic reports they receive whether their patient's tumor is positive for ROS1. The intent of this GGA is to consider and fund educational proposals from the pathology community aimed at improving this current situation. Suggested ideas and examples for grant applications: • A CLIA certified laboratory experienced in establishing the performance characteristics in accordance with 42 CFR 493.1253(b)(2) relating to analytical validity for the use of a ROS1 laboratory developed test offers a course to train other pathologists in their approach. • A medical specialty society representing pathologists develops educational activities and tools for their members to ensure accurate and reliable test results when laboratories perform ROS1 testing on patient specimens in accordance with CLIA regulations.

	• An academic medical center experienced in establishing the performance characteristics in accordance with 42 CFR 493.1253(b)(2) relating to analytical validity for the use of a ROS1 laboratory developed test offers a program to visit and coach laboratories requesting this support and who wish to improve their own methods or reports related to, but not limited to: o Candidates for ROS1 testing o Sample acquisition, processing, and general diagnostic procedures o ROS1 laboratory developed Fluorescence in situ Hybridization (FISH), Immunohistochemistry (IHC), Polymerase Chain Reaction (RT-PCR), and/or Next Generation Sequencing (NGS) methodology and analytical validation o Comparison of different assay platforms for ROS1 testing o ROS1 analysis in cytology o Reporting of ROS1 test results (preanalytical/analytical selection, specimen adequacy, overall interpretation, and reporting conclusions) For proposals to be successful, applicants must have the ability to [a] present information to a broader group of pathology (and other laboratory medicine) professionals for discussion and consensus, [b] assess the anticipated changes in knowledge, competence and performance as a result of the educational interventions, and [c] develop follow-up tools for assessing practice outcomes/impact. **References:** 1. Bergethon K, Shat AT, Out S-H I, et al. ROS1 Rearrangements define a unique molecular class of lung cancers. J Clin Oncol. 2012:30(8):863-70. 2. Takeuchi K, Soda M, Togashi Y, et al. Ret, ros1 and alk fusions in lung cancer. Nat Med. 2012;18:378-381. 3. Davies KD, Le AT, Theodoro MF, et al. Identifying and targeting ROS1 gene fusions in non-small cell lung cancer. Clin Cancer Res. 2012;18(17):4570-9. 4. Scheffler M, Schultheis AN, Teixido C, et al. ROS1 rearrangement in non-small cell lung cancer: prognostic and predictive impact and genetic variability. [abstract]. J Clin Oncol. 2015;33. Abstract 389. 5. Shaw AT, Ou S-H, Bang Y-J, et al. Crizotinib in ROS-1-rearranged non-small cell lung cancer. New Engl J Med. 2014;371:1963-71. 6. NCCN Guidelines for Patients, Non-Small Cell Lung Cancer, version 6.2015. National Comprehensive Cancer Network website. Available at: http://www.nccn.org/ Accessed March 14, 2016.
Expected Approximate Monetary Range of Grant Applications:	Individual projects ranging from $10,000 to $300,000 will be considered. The total available budget related to this CGA is $300,000. The grant amount Pfizer will be prepared to fund will depend upon the evaluation of the proposal and costs involved and will be stated clearly in the approval notification.

Key Dates:	CGA release date: May 24, 2016 Grant application due date: June 27, 2016 Please note the deadline is midnight Eastern Time (New York, GMT -5). Anticipated Grant Award Notification Date: August 1, 2016 Grants distributed following execution of fully signed Letter of Agreement Period of Performance: projects should conclude no later than December 2017
How to Submit:	Please go to the website at www.pfizer.com/independentgrants and click on the button "Go to the Grant System." Registered users should select the appropriate link under Track 2 – Knowledge Gap If this is your first time visiting this site you will be prompted to take the Eligibility Quiz to determine the type of support you are seeking. Please ensure you identify yourself as a first-time user. Select the following Educational Area: CGA- ROS1 Requirements for submission: Complete all required sections of the online application and upload the completed CGA template (see Appendix). If you encounter any technical difficulties with the website, please click the "Need Support?" link at the bottom of the page
Questions:	If you have questions regarding this CGA, please direct them in writing to , Derek Warnick , at (derek.warnick@pfizer.com), with the subject line "CGA- ROS1."
Mechanism by which Applicants will be Notified:	All applicants will be notified via email by the dates noted above. Applicants may be asked for additional clarification or to make a summary presentation during the review period.

IV. Terms and Conditions

1. This CGA does not commit Pfizer or its partners to award a grant or a grant of any particular size if one is awarded, nor to pay any costs incurred in the preparation of a response to this request.

2. Pfizer reserves the right to accept or reject any or all applications received as a result of this request, or to cancel this CGA in part or in its entirety, if it determines it is in the best interest of Pfizer to do so.

3. For compliance reasons and in fairness to all applicants, all communications about the CGA must come exclusively to Pfizer IGL&C. Failure to comply will disqualify applicants.

4. Consistent with its commitment to openness and transparency, Pfizer reports education grants provided to medical, scientific, and patient organizations in the United States. Pfizer reserves the right to announce the details of successful grant application(s) by whatever means insures transparency, such as on the Pfizer website, in presentations, and/or in other public media.

5. Pfizer reserves the right to share with organizations that may be interested in contacting you for further information (e.g., possible collaborations) the title of your proposed project and the name, address, telephone number, and e-mail address of the applicant from the requesting organization.

6. To comply with 42 U.S.C. § 1320a-7h and 42 C.F.R. §§ 403.900-.914 (the Sunshine Act), Provider (sponsor) must provide to Pfizer specific information for the U.S.-licensed physicians and U.S. teaching hospitals ("Covered Recipients," as defined by applicable law) to whom Provider (sponsor) furnished payments or other transfers of value from the original independent grant awarded by Pfizer. Those payments or transfers-of-value include compensation, reimbursement for expenses, and meals provided to faculty (planners, speakers, investigators, project leads, etc.) and "items of value" (items that possess a discernable value on the open market, such as textbooks) provided to faculty and participants, if those faculty and/or participants meet the definition of Covered Recipient. Provider (sponsor) must submit the required information during the reconciliation process or earlier, upon Pfizer's request, so Pfizer can meet Sunshine Act reporting commitments. Be advised that Pfizer will not make any payments to any individuals; grant funding shall be paid directly to Provider (sponsor).

   Frequently Asked Questions related to IGLC's Sunshine Act Reporting Requirements are available on our website (http://www.pfizer.com/files/IGLCsunshineFAQ_updatedJan2016.pdf).

7. No portion of a Pfizer independent grant may be used for food and/or beverages for learners and/or participants in any capacity. Provider (sponsor) will be required to certify during the reconciliation process and/or the periodic collection of Sunshine reporting that funds were not used for food and/or beverages for learners and/or participants.

8. In the performance of all activities related to an independent grant, the Provider (sponsor) and all participants must comply with all applicable Global Trade Control Laws. "Global Trade Control Laws" include, but are not limited to, U.S. Export Administration Regulations; the International Traffic in Arms Regulations; EU export controls on dual-use goods and technology; Financial Sanctions Laws and Restrictive Measures imposed within the framework of the CFSP - Treaty on European Union; and the economic sanctions rules and regulations administered by the U.S. Treasury Department's Office of Foreign Assets Control.

Appendix: CGA Grant Submission Template

Grant Applications should be single-spaced using Calibri 12-point font and 1-inch margins. Note there is a **15-page limit** exclusive of references. Please include the following:

A. Title
B. Organizational Detail: Describe the attributes of the institutions/organizations that will support and facilitate the execution of the project, the leadership of the proposed project, and the specific role of each partner in the proposed project.
C. Goal: Briefly state the overall goal of the project.
D. Objectives: List the objectives you plan to meet with your project, in terms of learning and expected outcomes.
E. Assessment of Need: Include a quantitative baseline data summary, initial metrics, or a project starting point (please cite data on gap analyses or relevant patient-level data that informs the stated objectives) in your target area.
F. Target Learner Audience: Describe the primary audience(s) targeted for this project. Indicate whom you believe will directly benefit from the project outcomes. Describe the overall population size as well as the size of your sample population.
G. Project Design and Methods: Describe the planned project, the educational approach, and the way the planned methods address the established need.
H. Innovation: Explain what measures you have taken to assure that this project idea is original and does not duplicate other projects or materials already developed. Describe how this project builds upon existing work,

pilot projects, or ongoing projects developed either by your institution or other institutions related to this project.

I. Outcomes Evaluation: In terms of the metrics used for the needs assessment, describe how you will determine if the gap was addressed for the target group. Identify the sources of data you anticipate using to make the determination. Describe how you expect to collect and analyze the data. Explain the method used to control for other factors outside this project (e.g., use of a control group or comparison with baseline data). Quantify the amount of change expected from this project in terms of your target audience. Describe how you will determine if the target audience was fully engaged in the project.

J. Dissemination Plan: Describe how the project may have extended benefit beyond the grant. Will the teaching materials be made available to others to use? Will there be tools or resources that are made publicly available beyond the initial project. Describe how the project outcomes might be broadly disseminated.

K. Timeline

L. Additional Information: If there is any additional information you feel Pfizer should be aware of concerning the importance of this project, please summarize it in within the page limitations.

M. References (outside the 15-page limit)
    - There is no designated format for references

N. Budget (See template available in application)
    - While estimating your budget please keep the following items in mind:
        - Grants awarded by IGLC cannot be used to purchase therapeutic agents (prescription or non-prescription).
        - Pfizer maintains a company-wide, maximum allowed overhead rate of 28% for projects.
        - A separate Excel file should be uploaded. This does not count toward the page limit.
            - An example of the budget template can be found here: http://cybergrants.com/pfizer/docs/KnowledgeGapBudgetTemplate2015.xls
            - At the conclusion of your program, a reconciliation of expenses is required using the original budget file submitted.

Grant Applications should be single-spaced using Calibri 12-point font and 1-inch margins. There is a **15-page limit** exclusive of references. If extensive, references may be included on 1-2 additional pages.