Community Oncologist Education and Support Systems -
Renal Cell Carcinoma and Hematologic Malignancies
Request for Proposals

National Comprehensive Cancer Network and
Pfizer Independent Grants for Learning & Change

October 17, 2013

I. Background

Pfizer and National Comprehensive Cancer Network (NCCN) are collaborating to offer a new grant opportunity focused on improving care for patients with rare types of cancer such as renal cell carcinoma (RCC) and certain hematologic malignancies, where treatment options are complex and rapidly advancing.

The mission of Pfizer Independent Grants for Learning & Change (IGL&C) is to accelerate the adoption of evidence-based innovations that align the mutual interests of patients, healthcare professionals, and Pfizer, through support of independent professional education activities. The term "independent" means the initiatives funded by Pfizer are the full responsibility of the recipient organization. Pfizer has no influence over any aspect of the initiatives, and only asks for reports about the results and impact of the initiatives, which it may share publicly.

NCCN, a not-for-profit alliance of twenty-three (23) of the world's leading cancer centers, is dedicated to improving the quality and effectiveness of care provided to patients with cancer. Through the leadership and expertise of clinical professionals at NCCN Member Institutions, NCCN develops resources that present valuable information to the numerous stakeholders in the health care delivery system. NCCN has access, through its member institutions, to the world's leading thought leaders in all areas and aspects of oncology who are integral to the execution of this program.

This Request for Proposals (RFP) is being issued by both organizations. NCCN is the lead organization for review and evaluation of applications. A review committee, led by NCCN, will make decisions on which proposals will receive funding. Grant funding will be provided by Pfizer. Collectively, up to $2 million is available for the program.

II. Purpose

The intent of this RFP is to encourage organizations to submit letters of intent (LOIs) describing concepts for design and implementation of systems or programs that close clinical practice gaps and improve the care of patients with rare cancer types through the establishment of education and support mechanisms for community oncologists. Organizations may apply in one of two categories:

Category 1 – Renal Cell Carcinoma

Category 2 – Hematologic Malignancies (ALL, CML, NHL, AML and MDS)

Successful applicants will be able to describe the specific clinical practice gaps that exist for their own providers, healthcare system, or patient community, and describe what they will do to close these gaps

or problems. Site-specific obstacles to success should be identified and coupled with strategies to overcome the obstacles.

Successful proposals will likely include a clinical education component for community oncologists, identify barriers in the health care system that adversely affects patient care and potential ways to address these barriers, and/or a companion patient education strategy.

Successful proposals will include a detailed plan to generate evidence that the educational intervention has had an effect on clinician behavior that is likely to be long-lasting and that this change in behavior is associated with changes in clinical outcomes.

Programs must describe how the intervention, when implemented, will directly affect patient care and provide evidence of scalability (e.g., integration with an electronic medical record system) and sustainability (e.g., plan for dissemination/applicability beyond the proposed institution).

Pfizer and NCCN are particularly interested in supporting programs that develop and implement interventions that are followed by rigorous assessment of the efficacy of the program and examining outcomes that may include short- and long-term improvements in physician effectiveness and patient care. Partnering and collaboration between multiple departments or with other organizations is encouraged.

Gaps in Clinical Practice

A gap in clinical practice is considered to be the difference between current practice and what should be done to meet the optimal standard of care. Gaps are associated with a combination of:

- Clinician factors (e.g. knowledge, preferences, reimbursement drivers);
- Patient factors (e.g. disease factors, comorbidities, preferences, QOL, cost implications, work, family, etc.);
- Health system organization (including care process, availability of all required aspects of care);
- Payor factors;
- Policy factors.

They may relate to the ability or competencies of the healthcare professionals themselves, the abilities or competencies of the systems in which they work to promote or allow proper management, or other factors related to the external environment or patient population.

In prior RFPs, grants have been awarded for projects that primarily focus on improving the knowledge or competence of individual clinicians. **This RFP seeks broader programs and is specifically seeking proposals that include a focus on improving systems of care to promote or allow proper management of patients.**

Management of complex or rare tumors presents several challenges to community oncologists, potentially involving both gaps in knowledge and challenges in the health care system where the patient is managed. In complex cancer types, where evidence is rapidly advancing, it may not be possible for a community oncologist to be fully informed of the most recent clinical trials reports or guidelines. In the case of RCC for example, a community oncologist may only be faced with 1-2 patients per year that have this disease. Clinicians in academic centers may see many more of these patients, but in many cases, it

may not be practical to refer a patient to an academic center that sees much larger numbers of these patients.

This RFP seeks to explore solutions to support community oncologists and the systems in which they practice as they face challenging patients with uncommon complex diseases. For example, an increasing number of agents are administered orally. These agents present complexities and issues that are different from those associated with intravenous chemotherapy. With oral therapies there are less frequent touch points between clinicians and patients, and patients often expect fewer adverse experiences. They may be surprised or alarmed by unexpected side effects or reluctant to report them to the health care team. There may also be special issues in coverage or reimbursement for costs of these agents. Projects submitted in response to this request could address issues of clinician knowledge, patient education, and/or financial issues associated with this or another aspect of management of the subject diseases.

Project ECHO® (Extension for Community Healthcare Outcomes) from the University of New Mexico School of Medicine is an example of a project with similar community-support goals. It integrates distance learning with patient-decision support in a weekly interactive format via the Internet. Experts at the University teach the case-based courses and are available to answer the questions of rural practitioners throughout New Mexico in a variety of challenging clinical areas.

Project ECHO was started to support physicians throughout rural New Mexico who were treating patients with Hepatitis C. Due to the complexities of the disease and treatment pathways, specialists at the University of New Mexico started weekly sessions that include some presentations to help increase knowledge and understanding, as well as time for rural clinicians to present a challenging patient question and receive support and advice from the medical school faculty. The interactive nature of the sessions is helpful and appealing to the audience and the project has been tremendously successful in improving care of patients with Hepatitis C. PROJECT ECHO which continues today in multiple topic areas beyond hepatitis, is one type of program that goes beyond traditional education to provide an ongoing system of support for a medical community. For more information: http://echo.unm.edu/

Applicants should consider incorporating strategies that support people at a distance such as telemedicine, academic detailing, virtual tumor boards, online resources, and online distance education. Different settings might require different solutions and proposals should be driven by local needs. Some solutions could involve multiple approaches, for example, live education sessions with ongoing remote support.

III. Needs Assessment

A gap exists in systematic support for community oncologists to optimize treatment of challenging patients and complex diseases. The needs assessment referenced below addresses the need for integration of systems of care (quality improvement) with competency (performance improvement).

"Tools and Strategies for Quality Improvement and Patient Safety," Ronda G. Hughes
http://www.ahrq.gov/professionals/clinicians-providers/resources/nursing/resources/nurseshdbk/HughesR_QMBMP.pdf

Supported by independent grants from Pfizer, the following three studies were completed in 2013 that assess the educational needs of oncologists and hematologists.

Renal Cell Carcinoma: Understanding Professional Practice Gaps and Educational Needs among Oncologists in the United States. A collaboration by The Annenberg Center for Health Sciences at Eisenhower, Clinical Care Options, AXDEV Group Inc. Link to full report:
http://www.annenberg.net/pdf/RCC_Needs_Assessment_Report.pdf

CML, ALL, and B-Cell Lymphomas: Understanding Professional Practice Gaps and Educational Needs among Hematologists and Medical Oncologists in the United States. A collaboration by The Annenberg Center for Health Sciences at Eisenhower, Clinical Care Options, AXDEV Group Inc. Link to full report:
http://www.annenberg.net/pdf/HEM_Malignancies_Needs_Assessment_Report.pdf

Educational Needs Assessment to Identify the Decision-making Patterns of Clinicians Managing Patients with Hematologic Malignancies. CE Outcomes, LLC, University of Nebraska Medical Center, Center for Continuing Education. Link to full report:
http://www.ceoutcomes.com/wp-content/uploads/2013/07/Hematologic-Malignancies.pdf

These reports identified gaps in the treatment of patients with RCC and hematologic malignancies among practicing oncologists in the US. These included challenges in the selection of therapies, monitoring of response and sequencing of agents; lack of knowledge about integration of newly available therapies; and issues managing toxicity, particularly in patients with comorbid conditions.

In addition to these assessment reports, this RFP was informed by the discussion that took place at a full-day in-person meeting of six (6) experts external to Pfizer, held on June 28, 2013. Attendees included healthcare professionals working in the specialty area of RCC and other rare cancers, including medical oncologists, hematologists, and representatives from medical education and quality improvement. In attendance were Joan McClure, NCCN, Ronit Simantov, MD, Pfizer, Robert Sweetman, MD, Pfizer, Naomi B. Haas, MD, University of Pennsylvania, Lauren C. Harshman, MD, Dana-Farber Cancer Institute, Mary Martin Lowe, PhD, President, Learning Advisors, LLC, Mark N. Stein, MD, Robert Wood Johnson Medical Group, UMDNJ, Paul A. Hamlin, MD, Memorial Sloan-Kettering Cancer Center and Weill Cornell Medical College. The group discussed gaps in evidence or education relative to:

- Provider education and provider/patient treatment decision making;
- Evidence-based recommendations for management of these diseases;
- Assessment of incorporation of education into practice;
- Information related to patient assistance programs and other patient-centered resources;
- Psychosocial programs;
- Comprehensive approaches to changing healthcare delivery systems.

The following issues and key challenges were identified and discussed.

Issues and challenges related to RCC:

Listed below are some of the key issues and challenges identified in the treatment of RCC:

- Rapidly changing practice environment and evolving data;
- Treatment sequencing;
- Dosing and administration issues;
- Toxicity management;
- Desire to use of biomarkers to personalize medicine but limited data supporting their utility;
- Access to treatments and costs of care;
- Differing knowledge bases in academic vs. community practice;
- The importance of patient preference.

Issues and challenges related to Leukemia (ALL, CML) and Lymphoma (NHL):

There are currently approximately 80 different hematologic malignancies many of them with very low incidence. Many of the issues identified for renal cell cancer are also of concern with the hematologic malignancies with some differences. One major difference is that for some of the hematologic malignancies, treatment advances have improved the outlook so significantly that they are becoming chronic rather than acute diseases. Another difference is that biomarkers are used as a cornerstone of both diagnosis and in some cases, ongoing management in the hematologic malignancies.

Gene expression profiling is used to select the most appropriate treatment. Community oncologists may see very few cases per year. Complex genetic/prognostic models are not widely available to community practice. Today, gene expression profiling is restricted to major academic centers and some central laboratories. Oncologists need to know when and how to order the tests and what to do with the results. With rapid changes in technology and its application, community oncologists should be offered ways to enhance and apply their knowledge in directing therapy to the specific biology of the disease.

Questions and issues to consider in both categories:

How do you educate when the answer is not clear and the field is rapidly advancing? Current Guidelines (NCCN, ASCO etc.) provide a range of appropriate options, but are not always helpful in making individualized treatment decisions.

Can community oncologists be offered new ways to apply biology-based science and biomarkers in making treatment decisions?

To provide patient support and education, how can oncologists promote use of independent, evidence-based resources for patient education?

How can communications between oncologists, patients and caregivers be improved?

Current gaps exist across all oncology, but especially in the use of oral therapies. Clinicians should also be providing information to patients on:

- Adherence to therapy (consequences of missing doses, use of medication logs);
- Side effects of treatment (differentiating between side effects of therapy and signs and symptoms of underlying disease, recognizing important or potentially serious side effects that should be reported to the health care team promptly);
- Support systems barriers including issues such as cost or insurance issues, transportation issues, access to home care, etc.

What is the role of the pathologist? Can we support communication between pathologists and clinicians so that appropriate, informative diagnostic tests are ordered, performed, and acted upon appropriately?

How can community oncologists be supported in their decision making when faced with:

- Uncommon, unexpected, or difficult to manage toxicities;
- Less common presentations ;
- Less common pathologies;
- Situations where options are exhausted;
- Older patients with age related changes in biology and need to tailor therapy;
- Comorbidities that limit treatment options;
- Difficult patients (e.g. anxious, comorbidities, psychological issues);
- New clinical trial publications and new drug options to be integrated into routine practice.

These are examples of complex issues requiring creative approaches and solutions and are examples of the types of considerations that need to be addressed in managing these relatively uncommon diseases.

IV. Letters of Intent/Proposals

This RFP model employs a 2-stage process: Stage 1 is the submission of the LOI. If your LOI is selected, you will be invited to submit a full program proposal. Stage 2 is the submission of the Full Grant Proposal.

Successful applicants will be able to describe the specific clinical practice gaps that exist for their own providers, healthcare system, or patient community and describe what they will do to close these gaps or problems. Site-specific obstacles to success should be identified and coupled with strategies to overcome the obstacles.

The NCCN Peer Review of Proposals Committee (PRPC) has been formed to oversee this process and will utilize a formalized review procedure to accept LOIs and subsequently select the proposals of highest scientific merit. The NCCN PRPC has overseen the development of the RFP and will perform the peer review of applications.

All proposals will be considered, including those incorporating independent education of healthcare professionals and not limited to those offering traditional Continuing Education programs.

Researchers seeking funding for studies evaluating the efficacy of therapeutic interventions will not be included in this grant.

Current members of the NCCN PRPC are as follows:

Amy P. Abernethy, MD, PhD, Duke Cancer Institute

John C. Byrd, MD, The Ohio State University Comprehensive Cancer Center

Moreen M. Dudley, MSW, Fred Hutchinson Cancer Research Center

Robert D. Fox, EdD, Professor Emeritus, Adult and Higher Education, University of Oklahoma

Paul A. Hamlin, MD, Memorial Sloan Kettering Cancer Center

Lauren Christine Harshman, MD, Dana-Farber Cancer Institute

Paul B. Jacobsen, PhD, Moffitt Cancer Center

Eric Jonasch, MD, The University of Texas MD Anderson Cancer Center

Joan S. McClure, MS, National Comprehensive Cancer Network

Lillie Shockney, RN, PhD, The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins

Ronit Simantov, MD, Pfizer, Inc.

V. RFP key information

Total awards	Up to $2.0M is available to fund grants for this RFP. Grant requests should range from $50K to $500K, depending on the size and scope of the project. Individual projects can be funded for up to a maximum of 24-months' duration.
Specific area of interest	Category 1: Oncology communities – RCC Category 2: Oncology communities – Hematologic Malignancies
Certification	Projects may or may not include a component that is certified for CME/CE credit. This is not a mandatory requirement for this RFP.
Geographic scope	United States only
Target audience	Community oncologists and other members of the care team – pathologists, urologists, nurses, social workers etc.
Recommended format	Educational research or implementation science type protocol, with IRB approval if necessary. This RFP is NOT seeking basic or clinical research proposals. Interventions should be educational, or systems-based in nature.
Eligible applicants	Academic medical institutions, healthcare systems, community hospitals, professional associations, and other non-for-profit entities with a mission related to healthcare improvement.
Selection criteria	Applicant organizations will be evaluated on the basis of: • Impact of program on the health of cancer patients; • Knowledge of and experience with the area; • Capability of carrying out the work; • Collaboration if appropriate; • Potential effect and expected outcomes of the project; • Dissemination strategies.

Key dates/deadlines	**October 17, 2013**—RFP released **December 5, 2013**—Letters of Intent due **Week of February 3, 2014**—Applicants notified via email; invited to submit full proposal **March 7, 2014**—Full proposals due date **April 21, 2014**—Notification of decisions **May 2014**—Funded projects start

VI. How to Submit:

Please go to the website at www.pfizer.com/independentgrants and click on the button "Go to the Grant System".

If this is your first time visiting this site in 2013, 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 Area of Interest: Oncology Communities – RCC or Oncology Communities – Hematologic Malignancies.

Complete all required sections of the online application and upload the completed LOI template.

VII. Letter of Intent Submission Guidance

The LOI is a brief concept document that describes the proposed project at a high level. The Proposal Review Committee will select letters of intent that are best aligned with the purpose of the RFP. All applicants will be notified with either an acceptance or a declination. Successful applicants will be asked to submit a full grant proposal for funding consideration.

Submission requirements

1. The letter of intent should be no more than three (3) pages, single spaced, using Calibri 12-point font and 1-inch margins. It should contain the following information about the proposed project:
    a. Project title
    b. Organization(s) involved
    c. Principal investigator
    d. High-level project description, including
        i. Primary goal(s)
        ii. Description of how the proposal builds on existing work, projects, or programs
        iii. Anticipated challenges and solutions
        iv. Expected outcome and how the impact of the project will be evaluated
    e. Deliverables and dissemination strategies
2. A letter of intent longer than three pages will be **RETURNED UNREVIEWED**
3. Submit the letter of intent online via the Pfizer IGL&C website
    a. Please go to the website at www.pfizer.com/independentgrants and click on the button "Go to the Grant System."
    b. If this is your first time visiting this site in 2013 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.

   c. Submit your letter of intent in the Oncology Communities – RCC or Oncology Communities – Hematologic Malignancies clinical area.
4. Complete all required sections of the online application and upload the completed letter of intent template.

VIII. Full proposals

A limited number of applicants will be invited to submit for consideration a full proposal of no more than 10 pages, accompanied by a line-item budget. The full proposal format will be shared with the invitation to submit.

IX. Questions

If you have questions regarding this RFP, please direct them in writing to the Grant Officer for this clinical area, Jacqueline Waldrop at Jacqueline.waldrop@pfizer.com with the subject line, "**Oncology Communities RFP**."

X. Terms and conditions

1. Complete **TERMS AND CONDITIONS** for Certified and/or Independent Professional Healthcare Educational Activities are available on submission of a grant application on the IGLC website at www.pfizer.com/independentgrants.
2. This RFP does not commit Pfizer or NCCN to award a grant or to pay any costs incurred in the preparation of a response to this request.
3. NCCN and Pfizer reserves the right to accept or reject any or all applications received as a result of this request or to cancel in part or in its entirety this RFP, if it is in the best interest of NCCN and Pfizer to do so.
4. NCCN and Pfizer reserve the right to announce the details of successful grant application(s) by whatever means ensures transparency, such as on their websites, in presentations, and/or in other public media.
5. For compliance reasons and in fairness to all applicants, all communications about this RFP must come exclusively to the IGLC team at Pfizer or from NCCN. Members of the Advisory Panel may not be contacted directly.
6. Failure to comply will automatically disqualify applicants.
7. All output (e.g., products, research, data, software, tools, processes, papers, and other documents) from funded projects will reside in the public domain.
8. Sunshine Act: To comply with the Federal Physician Payments Sunshine Act, Provider (sponsor) must provide names and other required information of the US-licensed physicians and US teaching hospitals (Covered Recipients, as defined by Centers for Medicare and Medicaid Services) to whom the Provider (sponsor) furnished payments or other transfers of value stemming from the original independent grant awarded by Pfizer. This includes compensation, reimbursement for expenses, and meals provided to faculty (planners, speakers, investigators, project leads, etc.) and "items of value" (items that possess a value on the open market, such as textbooks) provided to faculty and participants, if such faculty and/or participants meet the definition of „Covered Recipient". Such required information is to be submitted during the reconciliation process or earlier upon Pfizer's request in order to meet certain Sunshine Act reporting commitments. The parties agree that, pursuant to this Agreement, Pfizer will not make any payments directly to any physician, and all payments shall be directed to Institution.

The parties further agree that all payments made pursuant to this Agreement will be considered research payments under the Federal Physician Payments Sunshine Act.

9. Food and Beverage Clause: No portion of a Pfizer independent grant will be used for food and/or beverage for learners and/or participants in any capacity. Provider (sponsor) will be required to certify during final grant reconciliation that the funds were not used for food and/or beverage for learners and/or participants.

XI. Transparency

Consistent with our commitment to openness and transparency, Pfizer publicly reports its medical educational grants and support for medical and patient organizations in the United States. A list of all LOIs selected to move forward may be publicly disclosed, and whatever emanates from this RFP is in the public domain. In addition, all approved full proposals, as well as all resulting materials (e.g., status updates, outcomes reports, etc.) may be posted on the website. Grantees will be required to submit quarterly reports and/or updates.