

**Request for Proposals (RFP)**  
***Improving Health Care Capacity in Immuno-Oncology***

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**I. Introduction**

**a. About the RFP**

Pfizer - Independent Grants for Learning & Change (IGLC) and Merck KGaA, Darmstadt, Germany - Global Medical Education (GME) are collaborating to provide grant support for continuing professional education in the area of Immuno-Oncology. Immuno-Oncology is a top priority for Merck KGaA, Darmstadt, Germany, and Pfizer Inc. The global strategic alliance between our companies regarding certain products in the Immuno-Oncology field enables us to benefit from each other's strengths and capabilities.

Tumor types of current interest to our Immuno-Oncology alliance include Skin Cancer (Merkel Cell Carcinoma), Non-Small Cell Lung Cancer (NSCLC), Head & Neck Cancer, Ovarian Cancer, Gastric Cancer, Renal Cell Carcinoma and Bladder Cancer. However this RFP should be approached as pan-tumor - applicable across the entire Immuno-Oncology field.

The intent of this joint RFP is to offer organizations with a focus in health care professional education and/or quality improvement the opportunity to submit a Letter of Intent (LOI) in response to the RFP area of interest. This LOI can be related to education in a specific disease state and therapeutic area or a broader area of educational need and the system in which the education will be implemented. The RFP uses a two-stage process. Stage 1 is the submission of the LOI. After review of the LOI, applicants may be invited to submit a Full Grant Proposal. Stage 2 is the submission of the Full Grant Proposal.

Traditionally, an initiative like implementing evidence-based practice in immuno-oncology to improve the care of cancer patients is pursued through educational programming for physicians. However, the approach of this joint RFP in improving health care capacity suggests that more than traditional educational programming is necessary. The achievement of a goal to improve the health of patients is dependent on improving the capabilities of organizations and societies as well as the individual clinicians.

Current efforts in immuno-oncology education seem to be primarily limited to directly or indirectly company-sponsored online courses, satellite symposia, and live conferences. In contrast, it is our intent to support projects that focus on sustainable interventions that support the health care delivery system for

immuno-oncology. Whilst building the capacity or knowledge of individual clinicians is important, it will not, by itself, be enough to keep pace with the rapid rate of advancement of immuno-oncology.

The mission of Merck KGaA, Darmstadt, Germany GME is to help Health Care Professionals provide the very best possible care to their patients by supporting personalized learning activities addressing recognized gaps in knowledge and competence through Continuing Professional Development (CPD), Continuing Medical Education (CME) and educational collaborations. Merck KGaA, Darmstadt, Germany GME endorses the highest standards in medical education, and CPD and CME are independently developed by the grant recipient organization without any influence over any aspect of the program by Merck KGaA, Darmstadt, Germany. In order to ensure a proper assessment of the supported learning activities, Merck KGaA, Darmstadt, Germany requires the grant recipient to provide activities outcomes and impact reports.

The mission of Pfizer IGLC is to partner with the global health care 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.

When a Merck KGaA , Darmstadt, Germany and Pfizer joint RFP is issued, it is publicly posted on the Pfizer IGLC website ([www.pfizer.com/independentgrants](http://www.pfizer.com/independentgrants)) in the Request for Proposals section specifically named or listed as a joint RFP between Pfizer and Merck KGaA , Darmstadt, Germany and is sent via e-mail to all registered users in the Pfizer grants system. RFPs may also be posted on the websites of other relevant organizations, as deemed appropriate.

#### **b. External Review Panel**

The joint RFP was developed through the work of an External Review Panel (ERP). The ERP met in Copenhagen, Denmark in October 2016 and its members are listed below. The ERP will reconvene to review and make decisions on both LOIs and Full Proposals.

**Thomas Brodowicz, MD**

Associate Professor of Medicine  
Medical University Vienna, Austria

**Jan L. Ceuppens, MD, PhD**

Professor, Clinical Immunology  
University Hospital of Leuven, Belgium

**Kim Margolin, MD**

Clinical Professor and staff physician, Department of Medical Oncology  
City of Hope, Duarte, California, USA

**Donald E. Moore, Jr. PhD**

Professor, Division of Medical Education and Administration  
Vanderbilt University School of Medicine, Nashville, Tennessee, USA

**Ronald Murray, EdD**

Formerly Assoc. Director, Office of Continuing Medical Education, University of Virginia School of Medicine; Independent CME/CPD Consultant, Pickering, North Yorkshire, UK

**Jan E. Patterson, MD, MS**

Associate Dean for Quality and Lifelong Learning  
University of Texas Health Science Center at San Antonio, Texas, USA

**Doris C. Quinn, PhD, MSN**

Formerly Director Cancer Network Quality, University of Texas MD Anderson Cancer Center,  
Consultant in Process Improvement, Emmitsburg, Maryland, USA

**Peter Schmid, MD, PhD**

Chair of Cancer Medicine, Honorary Consultant in Medical Oncology, Centre Lead, Centre for  
Experimental Cancer Medicine, Barts Cancer Institute, Queen Mary University London, UK

**II. Area of Interest**

**a. Background**

In 2015 there were 17.5 million cancer cases world wide and 8.7 million deaths. Between 2005 and 2015, cancer cases increased by 33%, due to a combination of population aging and population growth. Cancer caused 208.3 million DALYs worldwide in 2015 (DALYs - number of years lost due to ill-health, disability or early death). At the same time, age-standardized death rates for all cancers decreased in 140 of 195 countries from 2005 to 2015. While there has been some progress in reducing death rates, cancer incidence is expected to increase in the future as part of the general epidemiological transition from communicable diseases to non-communicable diseases.<sup>1</sup>

Increasing cancer incidence creates challenges for the oncology community. Increased emphasis on cancer prevention and early diagnosis efforts have been called for and a promising new approach to managing patients with cancer has emerged. The new approach is Immuno-Oncology.

Research in Immuno-Oncology over the past 30 years has provided convincing evidence that tumors are recognized by the body's immune system and their development can be stopped or controlled. Conceptual and technical advances in the field of immuno-oncology have provided researchers with the knowledge and techniques to develop novel immunotherapeutic approaches for the treatment of cancer. Successes in these areas lead to expectations that current and future immunotherapies used in various combinations or earlier in disease may transform cancer treatment, improving prognoses for many patients. Immunotherapy has been shown to be clinically effective in melanoma, HER2 positive breast cancer, B-cell lymphomas, and head and neck, lung, and colorectal cancers that express the epidermal growth factor receptor. Currently immuno-oncologic agents are in development for a number of tumor types in the following cancers: bladder, breast, colorectal, esophageal, head and neck, hepatocellular, leukemia, lung, lymphomas, melanoma, ovarian, pancreas, and prostate.<sup>2-6</sup>

An important challenge, however, is the typically slow advancement of research information into clinical practice. It is generally accepted that it takes approximately 17 years for new information to move from the research bench to the patient's bedside.<sup>7-9</sup> Many observers feel that diffusion, the natural spread of ideas, is partly to blame for the slow transfer of new approaches. In medicine, diffusion plays out as a process of vetting fragments of research more rigorously, summing up their strength of evidence, and pushing them through a pipeline to intended users. This process is shown in Figure 1, Conceptualization of the production and transfer of knowledge from research to practice: The pipeline as a funnel.<sup>10</sup>

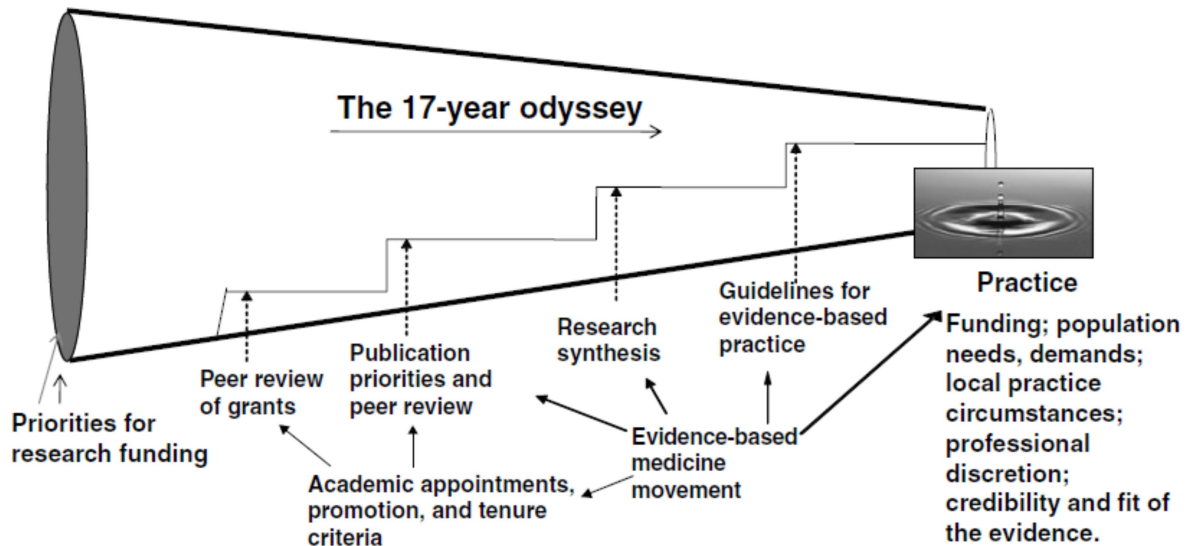


Figure 1, Conceptualization of the production and transfer of knowledge from research to practice: The pipeline as a funnel.<sup>10</sup>

## b. Gaps in education and understanding of Immuno-Oncology

Immuno-Oncology will eventually be a well-established therapy in the daily clinical setting. The potential scope of immuno-oncology therapies is very broad and will be investigated in many different patient groups and oncology indications. In general, Immuno-Oncology has special characteristics that distinguish it from cytotoxic and molecularly-targeted therapies. While there is the ongoing need for furthering research, the goal of this particular RFP is the practice of Immuno-Oncology drugs safely and intelligently delivered, with side-effects appropriately detected, assessed and monitored.

Areas of educational need include the therapeutic indications, the mechanisms of action, assessment of efficacy/effectivity, the mechanisms of resistance, recognition of toxicity and its proper management, sequencing or combinations with other classes of treatments, and the role of Immuno-Oncology in multi-modality strategies.

Educational needs of clinicians are likely to vary based on exposure and experience. All oncologists are well-trained in conventional therapy (i.e., chemo- and radiation), but some oncologists may have received less extensive training in the way of immunology science, depending on era of training and the focus of the educational and training institutions. One need may be to teach practicing clinicians enough immunology to understand the Immuno-Oncology-agents, which are rapidly emerging and evolving in their roles. Similarly, moving Immuno-Oncology seamlessly into the future means teaching the more recent trainees how best to think about the traditional approaches. They may understand immunology concepts and science but should remember that there is still a role for cytotoxic agents and molecularly targeted agents, their indications, their lines of therapy, and their expected impact on patient outcomes of survival and quality of life. Immuno-Oncology is an integrated science and medical field that is not just about T-cells, antibodies, cytokines and vaccines just as cytotoxic and molecularly-targeted drugs are not just about killing or stalling the malignant cells. The treatments interplay with other modalities and impact the host in different ways.

Another key aspect to consider in responding to this RFP is determining how much the science of immunology (which encompasses cell and molecular biology, genetics, and physiology) needs to be fully understood by the different types of clinicians and other medical professionals involved in health care. For example in the United States, the American Board of Internal Medicine has a group of people who write questions for the exams and have the elite task of deciding how much emerging fellows and test takers need to know in order to be effective and safe. Part of the task of responding to this RFP is going to be deciding how much needs to be known, and then how to best educate members of the health care teams.

- Oncologists and hematologists in academic medicine, by virtue of their teaching and research roles, would probably be expected to know more basic immunology and the related sciences listed above
- Oncologists in private and community practices likely need to know something about a broader spectrum of diseases but do not need as much depth about the mechanisms of the therapies or the unique pathophysiology of each disease. They need to know how to pick the treatment and how to keep patients safe during those treatments and when to refer to more experienced/trained institutions.

Needs are likely to vary across different countries or parts of the world. For example, in the U.S. or European countries where immunotherapies are usually first FDA-approved/EMA-approved, oncologists may be facing immediate challenges with treatment decisions, whereas in countries where access to immunotherapies is still limited, oncologists may want to increase their understanding of Immuno-Oncology mechanisms, indications and toxicity recognition and management.

### **c. Capacity development, learning, and scope of proposals**

As the results of clinical investigations are known, it is important to make the results of the trials available to clinicians in academic and community practices. The purpose of this RFP is to obtain proposals that will describe projects focused on developing the capacity to use immunotherapy to improve the broader health care of cancer patients.

Capacity is a condition made up of individual competencies and collective abilities that combine and emerge into some form of a system that allows a particular type of performance to take place. Developing a capacity is a process that contributes the resources, the strategies, the motivations, and the ideas to encourage that emergence.<sup>11-12</sup> Through this RFP, the companies are interested in receiving proposals that will describe and test processes that lead to the emergence of capacities to use immunotherapy to improve the health of cancer patients.

The delivery of health care to patients with cancer takes place in clinical microsystems. At the center of a cancer microsystem are the patients and the health care professionals and teams who care for them. A clinical microsystem is embedded in a larger health care system and community which in turn interacts with a regulatory/policy environment. All these components are in dynamic interaction with each other and impact how health care is delivered.

There is a considerable amount of interest in receiving proposals that incorporate learning and quality improvement strategies in developing micro-system capacity. A recent systematic review has identified general characteristics of effective learning activities in continuing medical education settings.<sup>13</sup>

- Effective learning activities are more interactive and use more methods. Supplementing lectures with worked examples (clinical cases) and providing an opportunity to discuss the cases is

associated with improved performance outcomes of participants. Use of audience response systems in case discussions provides an opportunity for participants in a learning activity to practice retrieval of case-related knowledge. Practice retrieval in authentic case discussion facilitates transfer of what is learned to practice settings. Feedback from knowledgeable faculty is important to help learners understand what in their practice is correct, how to address an opportunity for improvement, and what may have been missed.

- Effective learning activities incorporate multiple exposures to the content that participants are intended to learn. Exposures should vary patient presentations and severity of the patients' conditions. When providing opportunities for increased exposure in case discussion, the difficulty of the cases should increase at the same time that the amount of information provided to address the case is reduced to resemble the realities of the clinical encounter.
- Effective learning activities are longer so more methods, meaningful interactivity, multiple methods, and expanded exposure can be incorporated into the learning activity. A typical day-long CME course may schedule eight lecture presentations on eight different but related topics, with some question and answer sessions. Effective learning activities reduce the number of formal presentations and replace them with a significant number of case discussions. Impromptu mini-lectures are used to address issues that emerge in case discussions. The amount of didactic informatics is decreased and more time is spent in deeper examination of case-based knowledge. Participants have an opportunity to engage in content more deeply, facilitating their ability to retrieve information in similar settings in practice.
- Effective learning activities address patient and performance outcomes that are relevant to clinicians. Quality improvement strategies can be used to identify outcomes where there are opportunities for improvement and portray gaps between what clinicians are doing and what they should or could be doing as a way to create a "teachable moment".<sup>14</sup>

### Call to Action:

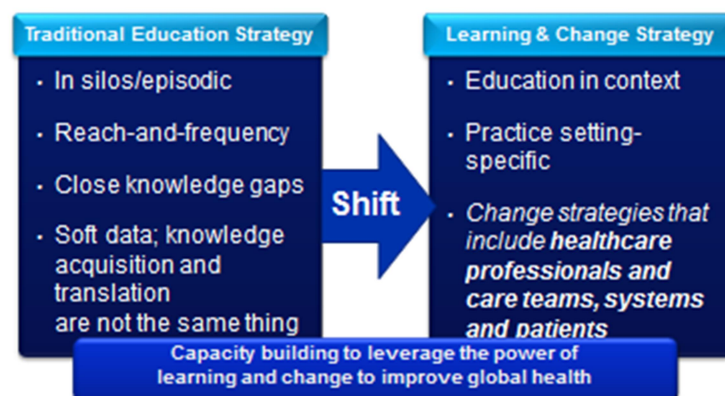


Figure 2, Call to action: Moving from a traditional education strategy to a learning and change strategy



This joint RFP is a call to action moving from a traditional education strategy to a Learning and Change strategy. On the left-hand side of the illustration, activities are in silos and episodic, they are not related in any way. Reach-and-frequency is limited, focused only on knowledge and not helping people improve their performance. Knowledge acquisition and translation are not the same thing.

This joint RFP is shifting to a model that looks at education in context. For example the practice and feedback method which in simple terms, is when you tell people what they need to do, you give them an example of it in an authentic situation, then you give them an opportunity to practice it and get feedback from experts. Give clinicians an opportunity to try out what they're supposed to be learning, get feedback from an expert and do that several times so that it is more likely that it'll be imprinted in their long-term memory.

It is expected that projects will be evidence-based (education and/or quality improvement) and the proposed research/evaluation will follow generally accepted scientific principles. During review the intended outcome of the project will be given careful consideration and, if appropriate based on the project goal, projects with the maximum likelihood of directly impacting patient care will be given high priority.

This RFP intends to support projects such as:

- Those that enable immuno-oncology treatment decision-making through trusted resources such as from national societies or associations or collaborations between member organizations or cooperative study groups.
- Protocol or pathway development that can be implemented, measured and shared with others
- Programs, forums or helplines that encourage direct interaction with or access to experts
- Capacity development programs that lead to improved governance around immuno-oncology
- Innovative technology-based solutions such as mobile device applications
- Patient (and patient advocacy groups) education programs
- Initiatives where plans exist for the results of the knowledge and the processes to be transferred and replicated by others

There is a considerable amount of interest in receiving responses from applicants whose projects utilize system-based changes. Although educational efforts for grantees and patients may be entirely appropriate components in responses to this RFP, projects that include an overt description of system changes will be given high priority. System-based changes begin with process mapping so that all steps are clearly identified as well as the roles of those working in these processes. Once all the care processes are clear, the bigger system can be addressed, the metrics designed and put into place, and the system changed.

Collaborations between multiple organizations are also encouraged because they have proven to be more efficient and effective than organizations working alone. For example, a 2008 publication "Guideline for Treating Tobacco Use and Dependence" was the trigger for nine organizations to come together in a collaborative effort to implement this updated guideline. The collaboration CS2Day – Cease Smoking Today was supported by a grant from Pfizer. The partner organizations included academic medical centers, non-profit societies, and medical education and consulting companies. The initial educational effort reached more than 43,000 clinicians from all 50 states in the USA and 10 foreign countries via certified education and derivative resources. The collaboration benefited from shared curricula and teaching resources and continued for many years with spin-off projects and additional collaborators.<sup>15</sup>

It is not the companies' intent to support clinical research projects through this RFP. Projects evaluating the efficacy of therapeutic or diagnostic agents will not be considered. Information on how to submit requests for support of clinical research projects can be found at [www.Pfizer.com/iir](http://www.Pfizer.com/iir) or at [www.ist.emdserono.com](http://www.ist.emdserono.com) for US and Canada or at [www.iss.merckbiopharma.com](http://www.iss.merckbiopharma.com) for all other countries.

## References

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### III. Requirements

<b>Date RFP Issued:</b>	March 16, 2017
<b>Clinical Area:</b>	Immuno-Oncology: Pan-tumor
<b>Target Audience:</b>	Medical Oncologists and all members of health care team involved in the care of cancer patients. Urologists who may be treating bladder, renal, and prostate cancers are also included.
<b>Geographic Scope:</b>	<input checked="" type="checkbox"/> North America (United States and Canada) <input checked="" type="checkbox"/> European Union (including Switzerland and Israel)
<b>Applicant Eligibility Criteria:</b>	<p>Health care institutions, large and small; health care professional organizations and other organizations with a mission related to health care improvement. More information on organizations eligible to apply directly for a grant can be found at <a href="http://www.pfizer.com/files/IGLC_OrganizationEligibility_effJuly2015.pdf">http://www.pfizer.com/files/IGLC_OrganizationEligibility_effJuly2015.pdf</a>.</p> <p>Collaborations within institutions (e.g., between departments and/or inter-professional), as well as between different organizations, are strongly encouraged. All partners must have a relevant role and the requesting organization must have a key role in the project. For programs offering CME/CPD credit, the requesting organization must be the accredited grantee. Government agency partners are also encouraged although typically in a collaboration with others where another partner is the lead requesting organization.</p>
<b>Expected Approximate Monetary Range of Grant Applications:</b>	<p>Individual projects of all scope and size will be considered. For example smaller single-site projects could be in the \$20,000 to \$100,000 USD range. Multiple-organization international collaborations could be as high as \$1 million USD. Applicants are encouraged to develop concepts most appropriate to their organization's area of responsibility when it comes to improving patient care.</p> <p>The total available budget related to this RFP is up to \$2 million USD</p> <p>The amount of the grant Pfizer and Merck KGaA, Darmstadt, Germany will be prepared to fund for any project will depend upon the external review panel's evaluation of the proposal and costs involved, and will be stated clearly in the approval notification.</p>

<b>Key Dates:</b>	<p>RFP release date: March 15, 2017</p> <p><b>LOI due date: May 1, 2017</b> Please note the deadline is midnight Eastern Time (New York, GMT -5).</p> <p>Anticipated LOI Notification Date: June 13, 2017</p> <p>Full Proposal Deadline: July 25, 2017* *Only accepted LOIs will be invited to submit full proposals Please note the deadline is midnight Eastern Time (New York, GMT -5).</p> <p>Anticipated Full Proposal Notification Date: September 26, 2017</p> <p>Grants distributed following execution of fully signed Letter of Agreement</p> <p>Period of Performance: December 2017 to December 2019 (projects may be shorter, but may be no longer than 2 years)</p>
<b>How to Submit:</b>	<p>Please go to <a href="http://www.cybergrants.com/pfizer/loi">www.cybergrants.com/pfizer/loi</a> and sign in. First-time users should click "REGISTER NOW".</p> <p>Select the following Area of Interest: Immuno-Oncology Capacity Development</p> <p>Requirements for submission: Complete all required sections of the online application and upload the completed LOI template (see Appendix).</p> <p>If you encounter any technical difficulties with the website, please click the "Need Support?" link at the bottom of the page.</p> <p><b>IMPORTANT:</b> Be advised applications submitted through the wrong application type and/or submitted after the due date will not be reviewed by the committee.</p>
<b>Questions:</b>	<p>If you have questions regarding this RFP, please direct them in writing to the Grant Officer, Jacqueline Waldrop (<a href="mailto:Jacqueline.Waldrop@pfizer.com">Jacqueline.Waldrop@pfizer.com</a>), with the subject line "Immuno-Oncology Capacity Development."</p>
<b>Mechanism by which Applicants will be Notified:</b>	<p>All applicants will be notified via email by the dates noted above.</p> <p>Applicants may be asked for additional clarification or to make a summary presentation during the review period.</p>

#### **IV. Terms and Conditions**

1. This RFP does not commit Pfizer, Merck KGaA, Darmstadt, Germany or their affiliates and 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 and Merck KGaA, Darmstadt, Germany reserve the right to accept or reject any or all applications received as a result of this request, or to cancel this RFP in part or in its entirety, if it determines it is in the best interest of Pfizer or Merck KGaA, Darmstadt, Germany to do so.
3. For compliance reasons and in fairness to all applicants, all communications about the RFP must come exclusively to Pfizer IGLC. Applicants should not contact other departments within Pfizer or Merck KGaA, Darmstadt, Germany regarding this RFP. 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. Merck KGaA, Darmstadt, Germany also reports grants in accordance with applicable laws. Pfizer and Merck KGaA, Darmstadt, Germany reserve the right to announce the details of successful grant application(s) by whatever means insures transparency, such as on the their websites, in presentations, and/or in other public media. In the case of this RFP, a list of all LOIs selected to move forward may be publicly disclosed. In addition, all approved full proposals, as well as all resulting materials (e.g., status updates, outcomes reports, etc.) may be posted on the IGLC website and/or any other company document or site.
5. Pfizer and Merck KGaA, Darmstadt, Germany reserve 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 ensure compliance with applicable local law, Pfizer and Merck KGaA, Darmstadt, Germany may publicly disclose the support they provide. Pfizer and Merck KGaA, Darmstadt, Germany may disclose in any lawful manner the terms of the letter of agreement, the support or funding that they are providing under the letter of agreement, and any other related information, to the extent necessary for Pfizer and/or Merck KGaA, Darmstadt, Germany to meet their obligations under those laws, regulations and industry codes that require them to report payments or other transfers of value to certain health care professionals and teaching hospitals (collectively, the "Transparency Laws"). Transparency Laws include, without limitation, section 6002 of the U.S. Affordable Care Act and the EFPIA Code on Disclosure of Transfers of Value. Disclosures may include identifying information for organizations and U.S. physicians, such as name, business address, specialty, National Provider Identifier (NPI), and licensure numbers. Grantee will agree to (and will cause other agents, employees and contractors to) reasonably cooperate with Pfizer and Merck KGaA, Darmstadt, Germany in their collection and disclosure of information to fulfill their Transparency Law obligations. Grantee will provide Pfizer and Merck KGaA, Darmstadt, Germany with complete and accurate information about payments or other transfers of value reportable under Transparency Laws.

7. Frequently Asked Questions related to IGLC's Sunshine Act Reporting Requirements are available on our website ([http://www.pfizer.com/files/IGLCsunshineFAQ\\_updatedJan2016.pdf](http://www.pfizer.com/files/IGLCsunshineFAQ_updatedJan2016.pdf)).
8. No portion of an independent grant may be used for food and/or beverages for learners and/or participants in any capacity. Grantee 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.
9. In the performance of all activities related to an independent grant, the Grantee 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.
10. For all Dissemination and Implementation research projects the institution(s) must agree to assume all responsibilities as sponsor of the study as outlined in the proposal, which includes:
  - Obtaining institutional review board (IRB)/independent ethics committee (IEC) approval for studies involving human subjects or human tissue and obtaining a subsequent renewal of this approval as required by local regulations (e.g., yearly, biannually, etc.). In addition, obtaining any IRB/IEC approval for amendments to protocol as they pertain to the research.
  - Obtaining all required personal data privacy or informed consent documentation (as appropriate).
  - Obtaining all required regulatory approval(s) per local regulations.
  - Assuming all reporting obligations to local regulatory authorities.
  - A statement that the research will be conducted in compliance with relevant provisions of the International Conference on Harmonisation, Good Clinical Practice, or Good Pharmacoepidemiology Practice guidelines and all applicable local legal and regulatory Requirements

## **V. Letter of Intent Submission Guidance**

LOIs should be in English and be single-spaced using Calibri 12-point font and 1-inch margins. Note there is a 3-page limit in the main section of the LOI. LOIs should include the following sections

### Main Section (not to exceed 3 pages):

- A. Title
- B. Goal and Objectives
  - Briefly state the overall goal of the project. Also describe how this goal aligns with the focus of the RFP and the goals of the applicant organization(s).
  - List the *overall* objectives you plan to meet with your project both in terms of learning and expected outcomes. Objectives should describe the target population as well as the outcomes you expect to achieve as a result of conducting the project.
- C. Assessment of Need for the Project

- Please include a quantitative baseline data summary, initial metrics (e.g., quality measures), 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. Describe the source and method used to collect the data. Describe how the data was analyzed to determine that a gap existed. If a full analysis has not yet been conducted, please include a description of your plan to obtain this information.

D. Target Audience

- Describe the primary audience(s) targeted for this project. Also 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

E. Project Design and Methods

- Describe the planned project and the way it addresses the established need.
- If your methods include educational activities, please describe succinctly the topic(s) and format of those activities.

F. 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.

G. Evaluation and Outcomes

- In terms of the metrics used for the needs assessment, describe how you will determine if the practice gap was addressed for the target group. Describe how you expect to collect and analyze the data.
- Quantify the amount of change expected from this project in terms of your target audience.
- Describe how the project outcomes will be broadly disseminated.

H. Anticipated Project Timeline

I. Requested Budget

- A total amount requested is the only information needed for the LOI stage. Full Budget is not required. This amount can be adjusted at the Full Proposal stage as applicable.
- The budget amount requested must be in U.S. dollars (USD).
- While estimating your budget please keep the following items in mind:
  - Institutional overhead and indirect costs may be included within the grant request. Examples include human resources department costs, payroll processing and accounting costs, janitorial services, utilities, property taxes, property and liability insurance, and building maintenance as well as additional project expenses such as costs for publication, IRB / IEC review fees, software license fees, and travel. Please note: Pfizer does not provide funding for capital equipment.
  - The inclusion of these costs cannot cause the amount requested to exceed the budget limit set forth in the RFP.
  - It should be noted that grants awarded through IGLC cannot be used to purchase therapeutic agents (prescription or non-prescription).
  - Pfizer maintains a company-wide, maximum allowed overhead rate of 28% for independent studies and projects.

J. 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.

Organizational Detail (not to exceed 1 page)

Describe the attributes of the institutions/organizations/associations that will support and facilitate the execution of the project and the leadership of the proposed project. Articulate the specific role of each partner in the proposed project. Letters of support from partner organizations will be required at the Full Proposal stage only and should not be included with the LOI.

Please note that any project partners listed in this section should also be listed within the online system. Tax-IDs of partner organizations will be requested when entering this information. If a partnership is only proposed, please indicate the nature of the relationship in the Organizational Detail section of your LOI.

There is a 3-page limit for the main section and a 1-page limit for organizational detail. If extensive, references may be included on 1 additional page. Final submissions should not exceed 5 pages in total (3 pages for the main section, 1 page for organizational detail, and 1 page for references). All required sections should be combined in one document (MS Word or Adobe PDF). There is no need to submit the organization detail or references in a document separate from the main section of the LOI.