Pfizer Independent Grants for Learning & Change
Request for Proposals (RFP)

Enabling effective conversations regarding menopausal vasomotor symptoms and other conditions associated with menopause utilizing the electronic health records

I. Background

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 healthcare professionals, patients, and Pfizer, through support of independent, professional education activities. “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.

The intent of this document is to encourage organizations with a focus in healthcare professional education and/or quality improvement to submit letters of intent (LOIs) in response to a Request for Proposal (RFP) that is related to education in a specific disease state, therapeutic area, or broader area of educational need. The RFP model is a two-stage process. Stage 1 is the submission of the LOI. After review of the LOI, you may be invited to submit your Full Grant Proposal. Stage 2 is the submission of the Full Grant Proposal.

When a RFP is issued, it is posted on the Pfizer IGL&C website (www.pfizer.com/independentgrants) and is sent via e-mail to all registered organizations and users in our grants system. Some RFPs may also be posted on the websites of other relevant organizations, as deemed appropriate.

II. Eligibility

| Geographic Scope: | ☑ United States Only
☐ International(specific country/countries)______________ |
| Applicant Eligibility Criteria: | The following may apply: medical, dental, nursing, allied health, and/or pharmacy professional schools; healthcare institutions; professional associations; and other not-for-profit entities may apply. Collaborations within institutions (e.g., between departments and/or inter-professional), as well as between different institutions/organizations/associations, are encouraged. Please note all partners must have a relevant role and the requesting organization must have a key role in the project. |
### III. Requirements

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<thead>
<tr>
<th>Date RFP Issued:</th>
<th>May 20, 2014</th>
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<tr>
<td><strong>Clinical Area:</strong></td>
<td>Using electronic health records (EHR) to enable effective conversations regarding menopausal vasomotor symptoms and other conditions associated with menopause.</td>
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<tr>
<td><strong>Specific Area of Interest for this RFP:</strong></td>
<td>Design and implement a learning and change-based program which enables effective dialogue between health care providers (HCPs) and women regarding the diagnosis and management of menopausal vasomotor symptoms (VMS) and other conditions associated with menopause. The program should incorporate current treatment algorithms and guidelines, utilize electronic health record (EHR) technologies (e.g., use of patient EHR portals to identify areas of discussion prior to HCP visits), include learning and change components targeting both HCPs and women, emphasize shared decision-making, and include components aimed at improving practice management. The impact of the program should be assessed by measuring changes in relevant clinical practice and resulting outcomes (e.g., percent of mid-life women appropriately assessed for VMS and other menopausal conditions, rates of diagnosis, appropriate management and/or treatment of VMS and other menopausal conditions, and patient satisfaction with care). Applicants are encouraged to provide estimates of changes in clinical outcomes that the proposed intervention is expected to drive.</td>
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The main focus of the intervention is enabling an effective dialogue about VMS and other menopausal conditions. The successful proposal will provide an individualized, midlife woman-oriented approach promoting assessment for menopausal conditions in appropriate women and discussion of potential treatment and other options, including the benefit and risk and appropriate use of hormone therapy (HT) and other treatments and approaches. To the extent HT and other approved treatments are the focus, proposed program goals and content should be consistent with approved indications and labels and take into account labeled side effects, warnings and precautions. The program should aim to:

1. Enable discussion between the HCP and the midlife woman regarding VMS and other menopausal conditions through
   - development of tools and resources to encourage assessment for menopausal conditions and subsequent shared decision-making;
   - increasing HCPs’ and women’s knowledge of appropriate use of HT and other approved therapies in postmenopausal women; and
   - improving rates of HCP assessment of age-appropriate women for menopausal vasomotor symptoms and other menopausal conditions, and ability to track such assessment and
2. Encourage the development and availability of resources for women to understand menopausal VMS and other menopausal conditions and promote effective dialogue between themselves and their HCPs regarding these conditions.

3. Demonstrate evidence of a positive clinical impact of the program via a rigorous outcomes evaluation (see “Recommendations and Target Metrics” below).

Programs must describe how they directly impact patient care and provide evidence of scalability (e.g., integration with an electronic medical record system), and a plan for extension beyond the proposed institution.

**Target Audience:**
The focus of the program should be generating meaningful change in HCPs and in women patients with respect to effectiveness of their conversations regarding the diagnosis and management of VMS and other conditions associated with menopause. HCP audiences which may be targeted by the program are PCPs, gynecologists, endocrinologists, nurse practitioners, physician assistants, and pharmacists.

**Disease Burden Overview:**
A survey by The Endocrine Society (TES) and its Hormone Health Network found that half of women between the ages of 45 and 60 years were experiencing symptoms of menopause. The survey found 31% of women experienced moderate to severe hot flashes. Vaginal dryness was experienced by 27%. Less than 25% of women reported receiving some type of treatment for their menopausal symptoms, despite a majority (69%) saying these symptoms negatively impacted their quality of life.¹² Conversations regarding menopausal symptoms may be difficult for a woman to broach with her HCP. Additionally, the HCP may be challenged with how to address and/or initiate this complex dialogue. However, these symptoms, as stated, are prevalent and could benefit from the dialogue between the HCP and the patient.

According to 2011 International Menopause Society (IMS) recommendations on postmenopausal HT and preventive strategies for midlife health, HT should be included in a strategy for managing VMS that focuses on lifestyle approaches like diet, exercise, smoking cessation, and moderate consumption of alcohol.³ The North American Menopause Society’s (NAMS) 2012 Position Statement on HT notes estrogen therapy (ET), with or without a progestogen, is the most effective treatment for menopausal VMS and their potential consequences including poor sleep quality, irritability, trouble concentrating, and decrease in quality of life (QOL).⁴ With the release of their most recent guidelines on menopausal treatment, the American College of Obstetrics and Gynecology (ACOG) has joined other
prominent women’s health societies in support of systemic HT as the most effective treatment for VMS. Furthermore, the 2012 consensus statement on HT from leading women’s health societies—including NAMS, TES, and the American Society for Reproductive Medicine (ASRM)—states that systemic hormone therapy, at the lowest effective dose for the shortest duration, is an acceptable option for postmenopausal women (1) up to age 59 or (2) within 10 years of menopause who report being bothered by moderate to severe menopausal symptoms. The statement also notes that the treatment approach should be individualized and that, along with a woman’s QOL priorities and, risk factors—including age; time since menopause; and personal and family history of venous thromboembolism (VTE), cardiovascular disease (CVD), and breast cancer—should also be taken into account. A WHI sub-analysis, which looked at outcomes after discontinuing conjugated estrogens (CE) in women with a prior hysterectomy, suggests there may be safety benefits related to coronary heart disease, myocardial infarction, colorectal cancer, and mortality for women who initiate HT in their 50’s or within 10 years of menopause related to coronary heart disease, myocardial infarction, colorectal cancer, and mortality. This sub-analysis also found there may be potential harm for those treated with CE in later decades with respect to the same disease states. Note HT is not indicated for CVD prevention, and the above findings on CVD, MI, colorectal cancer and mortality do not relate to approved indications for HT. The recent WHI age-stratified sub-analyses are supportive of the “timing hypothesis,” which states that there may be benefits for women who initiate HT soon after menopause instead of, compared with those who starting to taking HT at a later age. WHI sub-analyses also found a lower incidence of breast cancer in women with hysterectomy who were randomized to CE alone. This lower incidence became statistically significant with extended follow-up. It should be noted breast cancer prevention is not an approved indication for HT.

HT guidelines note that when prescribing solely for symptoms of VVA, topical vaginal products should be considered. In addition, when prescribing solely for the prevention of postmenopausal osteoporosis, hormone therapy should only be considered for only women at significant risk of osteoporosis and non-estrogen medications should be carefully considered.

HCPs who are on the front line of managing the midlife women’s health have the opportunity to offer appropriate dialogue on menopausal conditions and focus on overall well-being and QOL. Besides explaining the risks and benefits of HT when prescribed for the management of menopausal VMS and VVA and prevention of osteoporosis, HCPs can inform midlife women HT may be an acceptable option for treating their menopausal symptoms when prescribed appropriately.
Recommendations and Target Metrics:

Utilization of a control group to help assess program impact on clinical and other outcomes should be considered. The program should aim to positively impact the following target metrics:

- Assessment rates for menopausal VMS and other menopausal conditions in age-appropriate women, using validated assessment tools (e.g., MenQOL, Menopause Rating Scale (MRS), Women’s Health Questionaire (WHQ), Utian Quality of Life Scale (UQOL), Greene Climacteric Scale). Programs should integrate assessment for menopausal conditions through use of their institution’s EHR and/or other (e.g., tablet or smartphone) technologies.

- Rates of dialogue between the HCP and patient regarding menopausal VMS and other menopausal conditions
  - Rates of menopausal symptom counseling in EHR.

- Rates of diagnosis and appropriate management of menopausal VMS and other menopausal conditions symptoms. Assessment may include:
  - Patient satisfaction scores related to the management of menopausal symptoms;
  - Chart or EHR documentation of patient counseling related to menopause and menopausal conditions; and
  - Utilization of validated tools to measure program impact on menopausal condition treatment

- Women’s understanding of menopause and of VMS and other menopausal conditions, and related treatment options. For example:
  - Measure rates of “hits” on practice or institutional websites for consumer menopause education resources
  - Results of a patient post-appointment survey to measure whether women feel the EHR intervention led to more focused discussion of their VMS and other menopausal conditions
  - Results of a patient post-appointment survey to measure whether women feel they have a better understanding of their VMS and other menopausal conditions and the treatment options available following the dialogue with the HCP or receiving materials on menopause.

The program’s impact on the following may also be assessed:

- HCP’s understanding of the burden of menopausal symptoms on women’s QOL;
### Gaps Between Actual and Target, Possible Reasons for Gaps:

In the previously mentioned survey conducted by The Endocrine Society, more than four in ten women 45 to 60 years old said information about managing and treating symptoms of menopause was confusing (45%) or they were not sure who to trust (41%). Only about half (52%) of patients claim to be very satisfied with their menopause discussion; and those dissatisfied with the dialogue often report feeling dismissed by their HCP or not receiving enough information beyond diagnosis. Thus, there is a need for increased HCP-initiated dialogue with a postmenopausal patient regarding her symptoms.

### Barriers:

Barriers for effective conversations regarding menopausal conditions exist for both HCPs and for women. The program should aim to address the following barriers in menopausal care:

1. **Difficulty and/or discomfort with discussions regarding VMS and other menopausal conditions in HCPs and postmenopausal women, and inadequate proactive HCP assessment and diagnosis of such conditions**
   
   HCP’s may not be aware of the burden of menopausal VMS and other conditions on a woman’s quality of life. Additionally, they may have inadequate knowledge about or lack access to efficient approaches and tools to screen for these conditions. These factors could contribute to suboptimal assessment, diagnosis, and management of these conditions, especially in the primary care setting.

   There is often a lack of ample time for menopause discussions during office visits, particularly for HCPs who often must address a number of conditions in a limited time. Focusing on practice management improvements may help streamline these discussions. In addition, the menopause discussion can be awkward for many HCPs and patients.

   Effective discussion, assessment, diagnosis, and appropriate management of VMS and other menopausal conditions should be incorporated into the routine healthcare of the midlife woman.

2. **Discomfort with HT and/or inadequate understanding of appropriate use of HT in HCPs and postmenopausal women**
   
   Since the initial results of the Women’s Health Initiative (WHI) study were released over 10 years ago, there have been numerous publications and opinions about the benefits and risks of menopausal
hormone therapy. Analyses show that in the year immediately following WHI Study, HT use dramatically decreased 25% to 72%. Others (Steinkellner et al.) showed HT utilization decreased approximately 18% within the first 3 months after the release of the WHI trial results. By July 2003, 12 months after the initial WHI publication, HT use had decreased between 32% and 38%; and by 18 months post-WHI Study, HT use was nearly 45% below mid-2002 levels. Another analysis utilizing the IMS Health National Disease and Therapeutic Index physician survey data obtained from 2000 to 2009 found, for visits in which menopausal hormone therapy use was reported by US office-based physicians, use of oral estrogen therapy dropped by 62%, from 7.4 M in 2001 to 2.8 M in 2009, while an estrogen plus a progestin therapy declined by 76%, from 6.9 M in 2001 to 1.6 M in 2009.

This dramatically decreased prescription of HT has resulted in many women who may be appropriate for hormone therapy treatment for moderate to severe menopausal symptoms remaining untreated. Inadequate management of menopausal symptoms can lead to a substantial decrease in quality of life. Regarding the observed decrease in appropriate use of HT, Dr. Wulf Utian notes, “Women progressing through and beyond menopause in the next decade need to be spared the unnecessary harm inflicted upon their sisters of the previous decade”. Providers and women need to be educated about how HT may be appropriately used to manage menopausal symptoms.

| Current National Efforts to Reduce Gaps: | The North American Menopause Society and the Association of Professors of Gynecology and Obstetrics (APGO) partnered in 2012 to develop menopause learning and case study modules for current practitioners and residents to learn about menopausal symptoms identification and management. |
| Expected Approximate Monetary Range of Grant Applications: | Individual grants requesting up to $500,000 will be considered. The total available budget related to this RFP is $2,000,000. The amount of the grant Pfizer will be prepared to fund for any full proposal will depend upon the external review panel’s evaluation of the proposal and costs involved, and will be stated clearly in the grant approval notification. |
| Key Dates: | RFP release date: May 20, 2014
Letter of Intent due date: June 24, 2014
Review of LOIs by External Review Panel: June 24 to July 30, 2014
Anticipated LOI Notification Date: July 31, 2014 |
| **Full Proposal Deadline:** | *September 10, 2014*  
*Only accepted LOIs will be invited to submit full proposals* |
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<tbody>
<tr>
<td><strong>Review of Full Proposals by External Review Panel:</strong></td>
<td>September 11 to October 23, 2014</td>
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<td><strong>Anticipated Full Proposal Notification Date:</strong></td>
<td>October 27, 2014</td>
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<td><strong>Anticipated award delivered following execution of fully signed Letter of Agreement</strong></td>
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<td><strong>Period of Performance:</strong></td>
<td>November 2014 to May 2017</td>
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**How to Submit:**

Please go to the website at [www.pfizer.com/independentgrants](http://www.pfizer.com/independentgrants) and click on the button “Go to the Grant System.”

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 Area of Interest: Menopause: Enabling Effective Conversations

Requirements for submission:

Complete all required sections of the online application and upload the completed LOI 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 RFP, please direct them in writing to the Grant Officer, Robert Kristofco, at (robert.kristofco@pfizer.com), with the subject line: “Enabling Effective Conversations.”

**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.

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References:
9. Corbelli JA and Hess R. Hormone therapy prescribing trends in the decade after the Women’s Health Initiative: how patients and providers have found a way to sleep better at night. Menopause 2012;19(6):600-601.
15. NAMS personal communication.
**IV. Terms and Conditions**

1. This RFP 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 RFP 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 RFP must come exclusively to Pfizer Independent Grants for Learning & Change. 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. 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 IGL&C website and/or any other Pfizer document or site.

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 for the requesting organization.

6. To comply with the Patient Protection and Affordable Care Act (“Sunshine Act”), Provider (sponsor) must provide names and other required information for 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. Be advised Pfizer will not make any payments to any individuals; grant funding shall be paid directly to Provider (sponsor).

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 final grant reconciliation that the 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: Letter of Intent Submission Guidance

LOIs should 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 not meeting these standards will not be reviewed.**

LOIs should include the following sections

Main Section (not to exceed 3 pages):

A. Title

B. Goal
   1. Briefly state the overall goal of the project. Describe how this goal aligns with the focus of the RFP, the goals of the applicant organizations, and the proposed project.

C. Objectives
   1. List the overall objectives you plan to meet with your project both in terms of learning and expected outcomes. Do not include individual activity objectives.
      • Objectives should describe the population as well as the outcomes you expect to achieve as a result of conducting the project.

D. Assessment of Need for the Project
   1. 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. The RFP includes a national assessment of the need for the project. Please do not repeat this information within the LOI (you may reference the RFP, if necessary). Only include information that impacts your specific project, linking regional or local needs to those identified on the national basis, if appropriate.
   2. 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
   1. 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
   1. Explain what measures you have taken to assure that this project idea is original and does not duplicate other projects or materials already developed.
   2. 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. Design of Outcomes Evaluation
1. 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.
   - 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).

2. Quantify the amount of change expected from this project in terms of your target audience.

3. Describe how you will determine if the target audience was fully engaged in the project.

4. Describe how the project outcomes might be broadly disseminated.

H. Project Timeline

I. Requested Budget
   1. A total amount requested is the only information needed at this time.
   2. The budget amount requested must be in U.S. dollars (USD).
   3. 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.
      - 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
   1. 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.

LOIs should be single-spaced using Calibri 12-point font and 1-inch margins. 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).

Make every effort to submit as few documents as possible—you are encouraged to include all required sections in one document. There is no need to submit the organization detail or references in a document separate from the main section of the LOI.
Please note the formatting and page limit for the LOI. The LOI is inclusive of additional information of any kind. A submission exceeding the page limit WILL BE REJECTED and RETURNED UNREVIEWED.