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

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<thead>
<tr>
<th>Geographic Scope:</th>
<th>☑ United States Only</th>
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Applicant Eligibility Criteria:
The following may apply: medical, dental, nursing, allied health, and/or pharmacy professional schools; healthcare institutions (both large and small); professional associations and medical societies; medical education companies; and other entities with a mission related to healthcare professional education and/or healthcare improvement.

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

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<tr>
<th>Date CGA Issued:</th>
<th>June 6, 2016</th>
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Clinical Area: Biosimilars
Specific Area of Interest for this CGA:

|   | The second biosimilar in the US received approval in April 2016 and there are several other approvals on the horizon. Biosimilars represent a new approach to biological product evaluation and approval that is supported by complex science. Clinicians will need to stay abreast of new developments related to biosimilars as they occur, such as updates to FDA guidance documents, new biosimilar approvals, data from post-approval studies with biosimilars, decisions regarding naming for biosimilars in the US, and state legislation related to interchangeability/substitution.\(^2\)

|   | The difference between biosimilars and their reference biological products is sometimes incorrectly paralleled to generic small molecule drugs and their reference products. The misconceptions surrounding biosimilars may impact physician and patient confidence. This is seen as an important barrier to the uptake of biosimilars. Additionally, a low level of understanding of differences between biosimilars and generics and biosimilars and reference biologics presents a key knowledge gap that if reduced, could positively impact patient care.\(^3\)

|   | Education leading to a clear understanding of the appropriate use of biosimilars and other emerging concerns is critical for US physicians and pharmacists preparing for their use in clinical practice. The intent of this CGA is to support educational programs that seek to improve clinician knowledge and competence in the use of biosimilars in the US across multiple therapeutic areas.

|   | Preference will be given to projects that incorporate learning and change principles consistent with the sentiment expressed in the following quote: “CME leads to greater improvement in physician performance and patient health if it is more interactive, uses more methods, involves multiple exposures, is longer, and is focused on outcomes that are considered important by physicians.”\(^4\)

| References: |

| Expected Approximate Monetary Range of Grant Applications: |
| Grant applications requesting up to $250,000 will be considered. The total available budget related to this CGA is $500,000. The grant amount Pfizer will be prepared to fund will depend upon the evaluation of the proposal and budget and will be stated clearly in the approval notification. |
Key Dates:

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
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<tbody>
<tr>
<td>CGA release date</td>
<td>June 6, 2016</td>
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<tr>
<td>Grant application due date</td>
<td>August 5, 2016</td>
</tr>
<tr>
<td>Please note the deadline is midnight</td>
<td>Eastern Time (New York, GMT -5)</td>
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<tr>
<td>Anticipated Grant Award Notification</td>
<td>September 19, 2016</td>
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<tr>
<td>Grants distributed following execution of</td>
<td></td>
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<tr>
<td>fully signed Letter of Agreement.</td>
<td></td>
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<tr>
<td>Project start date</td>
<td>On or after November 1, 2016</td>
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How to Submit:

- Please go to the website at [www.cybergrants.com/pfizer/knowledge](http://www.cybergrants.com/pfizer/knowledge) and log in to select the “CGA – Use of Biosimilars in the US” to apply.

- 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- Use of Biosimilars in US](#)

- 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. Please note that submissions entered into the incorrect portal may not be reviewed by the committee.

Questions:

- If you have questions regarding this CGA, please direct them in writing to Amanda Solis, Senior Manager at amanda.solis@pfizer.com with the subject line “CGA – Use of Biosimilars in the US.”

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](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.