



Merck KGaA
Darmstadt, Germany

Request for Proposals (RFP) New Guidelines for Immuno-therapy in Urothelial Carcinoma (UC)

I. Background

Pfizer Global Medical Grants (GMG), Merck KGaA, Darmstadt, Germany - Global Medical Education (GME), and EMD Serono, Inc. US Medical Education 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, EMD Serono, Inc. and Pfizer Inc, and for the Global Strategic Alliance among our organizations.

This publicly posted Request for Proposal (RFP) provides detail regarding a general area of interest, sets timelines for review and approval, and uses an internal Alliance review process to make final grant decisions.

Organizations are invited to submit an application addressing the knowledge gaps as outlined in the RFP.

For all independent medical education grants, the grant requester (and ultimately the grantee) is responsible for the design, implementation, and conduct of the independent initiative supported by the grant. Our companies must not be involved in any aspect of project development, nor the conduct of the independent education program.

II. Eligibility

Geographic Scope:	<ol style="list-style-type: none">1. United States2. 5 EU (5 European Countries of France, Germany, Italy, Spain, United Kingdom)
Applicant Eligibility Criteria:	<p>The following may apply: medical, nursing, allied health, and/or pharmacy professional schools; healthcare institutions (both large and small); professional associations and medical societies; patient advocacy groups; medical education companies; other entities with a mission related to healthcare professional education and/or healthcare improvement.</p> <p>If the project involves multiple departments within an institution and/or between different institutions / organizations / associations. all institutions must have a relevant role and the requesting organization must have a key role in the project.</p> <p>For projects offering continuing education credit, the requesting organization must be accredited.</p>

III. Requirements

Date RFP Issued:	August 17, 2020
Clinical Area:	Immuno-therapy in UC
Specific Area of Interest for this RFP:	<p>Bladder Cancer treatment guidelines in the United States and Europe have recently been updated to reflect new options for patients. The intent of this RFP is to support independent education initiatives in the following categories:</p> <ol style="list-style-type: none"> 1. <u>United States (\$700K total budget available)</u> <ul style="list-style-type: none"> • Patient and caregiver education programs. Grants available to patient-focused organizations working in the bladder cancer area. Also in scope are activities for healthcare professionals that include educational materials or resources for patients or novel decision making tools to support provider-patient decision making and drive patient engagement in their care. • Local and regional education. Available to academic institutions, hospitals, community cancer centers interested in providing learning opportunities within their communities. • Local or national programs by specialty societies & professional associations based on the needs of their members (GU oncologists, nurses, NPs, PAs, pharmacists, managed care professionals etc.). 2. <u>5 EU (\$300K total budget available)</u> <p>Virtual education programs for healthcare professionals and/or patients in France, Germany, Italy, Spain, and/or United Kingdom. Funding available for new programs or expansion/extension of existing offerings such as adding multiple language translations.</p> <p>For both categories above, projects that will be considered for support will address one or more of the following objectives in locally-advanced or metastatic UC:</p> <ul style="list-style-type: none"> • Understanding current treatment options in the first line (1L) treatment of metastatic urothelial cancer (mUC) including maintenance therapy in the 1L setting • Assessing the evidence for maintenance immuno-therapy regimens in 1L mUC • Reviewing the differences between upfront treatment and sequencing strategies with immunotherapy in mUC • Reviewing the modest rate of patients receiving second-line treatment and the various reasons for that.

	<p>Proposals do not have to be limited to only 1L maintenance but can cover the entire continuum of care. Broader educational proposals that cover 1L treatment options or treatments in sequence for patients with mUC are also in scope.</p> <p>For educational activities that may have longer term use, organizations are encouraged to describe their process for continuous assessment of their activities for both educational effectiveness as well as how they stay current when significant new data becomes available. Innovative communication channels, digital programs, and enduring resources are all encouraged.</p>
<p>Expected Approximate Monetary Range of Grant Applications:</p>	<p>The total available budget related to this RFP is approximately \$1 million USD.</p> <p>The typical grant maximum under this RFP will be up to \$150,000 USD. However larger proposals may be considered for funding if they include a broad geography and multiple activities such as several live events, enduring activities, and supportive materials and tools.</p> <p>Smaller educational proposals are also encouraged. Organizations that would like to develop activities for a more limited regional or local group of healthcare providers should also apply. Typically grant amounts for local or regional activities should not exceed around \$50,000 USD.</p> <p>The grant amount the Global Strategic Alliance will be prepared to fund will depend upon the evaluation of the proposal and costs involved and will be stated clearly in the approval notification.</p>
<p>Key Dates:</p>	<p>RFP release date: August 17, 2020</p> <p>Grant application due date: September 30, 2020 Please note the deadline is 23:59 Eastern Standard Time (e.g., New York, GMT - 5).</p> <p>Anticipated Grant Award Notification Date: October 30, 2020 <i>*Processing time may take longer for organizations outside of the U.S.</i></p> <p>Grants distributed following execution of fully signed Letter of Agreement</p> <p>Period of Performance: December 2020 to June 2022 (projects may be shorter; 18 month project maximum)</p>

<p>How to Submit:</p>	<p>Please go to www.cybergrants.com/pfizer/knowledge and sign in. First-time users should click “Create your password”.</p> <p>In the application:</p> <ul style="list-style-type: none"> • For the question “What type of request are you submitting?” select Response to a Request for Proposal (RFP) • For the question “Are you replying to a Request for Proposal as part of the Competitive Grant Program?” select Yes • Select the following Competitive Grant Program Name: 2020 Oncology G: New Guidelines for Immuno-therapy in UC • Select the following Primary Area of Interest: Oncology - Immuno-Oncology <p>Requirements for submission: Complete all required sections of the online application and upload your project proposal (see Appendix) in the General RFP Submission field.</p> <p>If you encounter any technical difficulties with the website, please click the “Technical Questions” link at the bottom of the page.</p> <p>IMPORTANT: Be advised applications submitted after the due date will not be reviewed by the committee.</p>
<p>Questions:</p>	<p>If you have questions regarding this RFP, please direct them in writing to Jacqueline Waldrop at (Jacqueline.Waldrop@pfizer.com), with the subject line “Immuno-therapy in UC.”</p>
<p>Mechanism by which Applicants will be Notified:</p>	<p>All applicants will be notified via email by the dates noted above. Applicants may be asked for additional clarification during the review period.</p>

Appendix - General RFP Submission Requirements

Project proposals 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:

Goals and Objectives	<ul style="list-style-type: none">• Briefly state the overall goal of the project.• List the objectives you plan to meet with your project, in terms of learning and expected outcomes.
Needs Assessment for the Project	<ul style="list-style-type: none">• Include a description of your organization's needs assessment for this proposed project which may 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.
Target Audience	<ul style="list-style-type: none">• 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.
Project Design and Methods	<ul style="list-style-type: none">• Describe the planned project, the educational approach, and the way the planned methods address the established need.
Innovation	<ul style="list-style-type: none">• Explain what measures you have taken to assure that this project 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.
Evaluation and Outcomes	<ul style="list-style-type: none">• In terms of the metrics used for the needs assessment, describe how your organization will determine if the gap was addressed for the target group. Identify the sources of data your organization anticipates using to make the determination. Describe how your organization is expected 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 the target audience. Describe how your organization will determine if the target audience was fully engaged in the project.
Dissemination Plan	<ul style="list-style-type: none">• 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.
Anticipated Project Timeline	<ul style="list-style-type: none">• Provide an anticipated timeline for your project including project start/end dates.

Additional Information	<ul style="list-style-type: none"> • If there is any additional information you feel the alliance should be aware of concerning the importance of this project, please summarize here.
Organization Detail	<ul style="list-style-type: none"> • 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 institution in the proposed project.
Budget Narrative	<ul style="list-style-type: none"> • Please include a budget narrative that describes in greater detail the line items specified in the budget submitted within the application • While estimating your budget please keep the following items in mind: <ul style="list-style-type: none"> ○ Independent Medical Education Grants awarded by the alliance cannot be used to purchase therapeutic assets (prescription or non-prescription). ○ Overhead rates of up to 28% of the total proposed project budget may be supported