### Independent Medical Education

**Request for Education: Community-based small group educational initiative**

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| RFE Requestor Information | Name: Laurie Connor, PhD  
Title: Associate Director, Global Medical Education, Lymphoma  
E-mail: Laurie.Connor@bms.com |
| RFE Code              | RFE-23-HEME-200   |
| Therapeutic Area      | DLBCL             |
| Area of Interest      | BMS would like to support an educational initiative related to:  
Providing Community-based clinicians an educational experience that will enhance their ability to navigate the CAR-T process more effectively and overall improve patient outcomes.  
- Identify DLBCL patients who may be a candidate for CAR T therapy, earlier in their treatment journey.  
- Monitoring and managing adverse effects of post-CAR T therapy.  
- Coordination of care between community site and CAR T academic center.  
- Ability of community HCPs to discuss CAR T as an option for DLBCL patients. |
| Educational Design    | BMS is interested in supporting a comprehensive educational initiative that includes the following:  
- Small group learning experiences that bring together a subject matter expert from a CAR T center (group leader) with community-based HCPs from the surrounding area (group participants).  
- Group participants will work together to create site-specific action plans to address barriers to the CAR T process.  
- Development of training materials (self-paced videos, other downloadable reference materials) that can be used to educate the multi-disciplinary care team at the community sites.  
- Development of downloadable patient education tools that HCPs can use to educate patients.  
- Providers are expected to develop a well-conceived, evidence-based framework/implementation plan.  
- Confirmed commitment of the partners to implement the project successfully.  
- Include how you will recruit both CAR T subject matter experts and community clinicians.  
- Provide details on how you will evaluate and report the impact of the initiative at each community site.  
- Provide a detailed timeline of number activities and milestones, including start and end dates for each program component.  
- Include a plan to sustain the program beyond grant funding, ex: how will the information/learnings be leveraged to a broader audience?  
- Outline MEC experience in executing community-based small group educational initiatives. |
### Intended Audience
Community based hematologists, hematologist-oncologists and community based advanced practice providers in hematology-oncology who care for DLBCL patients

### Budget/Budget Range
The maximum amount of funding available for this RFE is $1,000,000. Multi-support requests will be considered.

### Accreditation
ACCME, ACPE, ANCC and ACPE

### Geographic Coverage
United States

### Deadline for Submission
1/18/2024 by 5:00PM EST

### Expected Grant Approval
2/02/2024 by 5:00PM EST

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**Background**

Non-Hodgkin lymphomas (NHL) are a heterogeneous group of lymphoproliferative diseases made up of both indolent and aggressive subtypes.\(^1\) Diffuse large B-cell lymphoma (DLBCL) makes up 30% of newly diagnosed Non-Hodgkin lymphomas. Its annual incidence is estimated at 5.1 cases per 100,000, with an annual mortality rate of 1.6 per 100,000.\(^2\) DLBCL has an aggressive course and requires timely treatment to ensure optimal outcomes. The standard first-line regimen for DLBCL is R-CHOP, a regimen consisting of rituximab in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone.\(^3\) While over 60% of newly diagnosed patients achieve a complete response with this regimen, 10-15% of patients have primary refractory disease and an additional 20-25% experience a relapse within the first two years of achieving a complete response.\(^2,4\)

The addition of novel targeted and cellular therapies to DLBCL treatment algorithms has provided an improved survival outlook for the relapsed/refractory population. Among these second-line-and-beyond treatment options is CAR T cellular therapy, which involves genetically modifying a patient’s own T-cells to identify and eliminate cancer cells expressing a target antigen.\(^5\) There are currently four anti-CD19 CAR T-cell therapies approved for DLBCL in the second, third, and later lines of therapy.\(^6-8\) The advent of CAR T-cell therapy gives relapsed/refractory patients the potential to achieve deep and durable responses with a one-time treatment.\(^5\) Studies of two CAR T-cell therapies in patients with DLBCL, axicabtagene ciloleucel (axi-cel) and lisocabtagene maraleucel (liso-cel), in the second line setting demonstrated statistically significant improvements in both overall and complete response rates versus standard of care regimens, highlighting the importance of early identification of CAR T candidates.\(^9,10\)

CAR T-cell therapy represents a fundamental shift in the way DLBCL is managed, but providing this therapy for patients can be a complex process requiring extensive education and care coordination across involved parties. Clinicians have identified several barriers to the optimal use of CAR T-cell therapy, which may preclude eligible patients from benefitting from these therapies. Among these barriers are a lack of knowledge of the clinical trial landscape and adverse event profiles of each CAR T-cell therapy, difficulties in identifying appropriate candidates for therapy, and a lack of understanding of the logistical considerations involved.\(^11,12\)

Among those involved in the care of patients receiving CAR T-cell therapy, the community clinician plays a key role in each patient’s treatment journey. Community clinicians must be armed with the knowledge and experience to identify at what point in a patient’s disease course to discuss CAR T-cell therapy, and to utilize shared decision making with patients and caregivers before ultimately sending patients to an authorized treatment center.\(^13\)
| Many community clinicians do not have clear enough guidance on patient eligibility for CAR T cell therapy and may be unaware of the timing of treatment which affects their likelihood to refer in a timely manner. | Community clinicians will identify DLBCL patients who may be candidates for CAR T cellular therapy and will consider these patients for evaluation earlier in their treatment journey. |
| Community HCPs learning opportunities on CAR T adverse event management are often limited and they are unsure how to recognize and manage patients’ symptoms, post-infusion. | Members of the community multi-disciplinary care team will be better equipped to manage long-term adverse events related to CAR T cellular therapy. |
| Communication between community clinicians and treating institutions varies by site and directly impacts the effective coordination of care throughout a patients’ treatment journey. | There will be a more streamlined coordination of care between CAR T treatment center and community clinics. |
| Community clinicians may not be equipped to have conversations with their DLBCL patients about CAR T as a therapeutic option for their care. | Community clinicians will be more comfortable discussing the potential benefits of CAR T therapy as an option with their patients. |

**Specific Area of Interest:**

BMS is interested in funding an innovative, interactive, educational activity that addresses the above educational needs and professional practice gaps. The content and/or the format of the CME/CE activity and its related
materials must be current and designed in such a way that it addresses the educational needs of the intended audiences as described in this RFE.

Grant Proposals should include, but not be limited to, the following information:

- **Executive Summary**: The Executive Summary should consist of 1-2 pages and highlight the key areas as described below. Describe how the leaders of your organization and partnering organizations will provide support to the interventions. Include letters of support from your key partners as part of your grant request. Clearly list the roles and responsibilities of each partner.

- **Needs Assessment/Gaps/Barriers**: Needs assessment should be referenced and demonstrate an understanding of the specific gaps and barriers of the target audiences. The needs assessment must be independently developed and validated by the educational provider.

- **Target Audience and Audience Generation**: Target audience for educational program must be identified within the proposal. In addition, please describe methods for reaching target audience(s) and any unique recruitment methods that will be utilized. The anticipated or estimated participant reach should also be included, with a breakdown for each modality included in the proposal, as applicable (e.g., number of participants for the live activity, the live webcast, and enduring activity).

- **Learning Objectives**: The learning objectives must be written in terms of what the learner will achieve because of attending. The objectives must be clearly defined, measurable, and attainable and address the identified quality gaps and barriers. If the initiative is geared for the multidisciplinary care team, please specify learning objectives for each learner if applicable.

- **Program Evaluation and Outcomes Reporting**: Description of the approach to evaluate the quality of the educational program. Describe methods used for determining the impact of the educational program on closing identified healthcare gaps. Please include how you plan to calculate measures and what data sources will be used to support the measurement of your project. The specific measurement plan should specify anticipated outcomes in terms of improved patient safety/quality or patient care and a plan if the target/goal cannot be or is not achieved.
  - Please refer to “Guidance for Outcomes Report” (on the BMS grants website) for a detailed explanation of preferred outcomes reporting methods and timelines.
  - Remember that knowledge, performance, and competency-based outcome measures according to Moore’s Level 4 is required. Level 5 and 6 outcomes are highly favored and recommended when possible.

- **Educational Design and Methods**: Describe the approach used to address knowledge, competence, and performance and quality gaps that underlie identified healthcare gaps. Activities should include strategies that ensure reinforcement of learning through use of multiple educational interventions and include practice resources and tools, as applicable. Proposals should outline how the interventions will be developed, by whom, and the methods to ensure complete, accurate and evidence-based information. Clearly define the population, measures and indicators, and rationale for the intervention design.
• **Communication and Publication Plan:** It is highly recommended to describe how the results of the activity will be presented, published, or disseminated. Include a plan to sustain the program beyond grant funding, ex: how will the information/learnings be leveraged to a broader audience?

• **Innovation:** Describe how this project is innovative and engages the learners to improve knowledge, competence and/or performance. Further describe how this project might build on existing work, pilot projects or ongoing projects developed either by your institution or other institutions related to this topic.

• **Budget:** Detailed budget with rationale of expenses, including breakdown of costs, content cost per activity, out-of-pocket cost per activity, and management cost per activity.

**Note:** The accredited provider and, if applicable, the medical education partner or other third party executing the activities, are expected to comply with current ethical codes and regulations. They must have a conflict-of-interest policy in place to identify and resolve all conflicts of interest from all contributors and staff involved in developing the content of the activity prior to delivery of the program and must have a separate company providing/accrediting independent medical education if they are also performing promotional activities.

*If your organization wishes to submit an educational grant request, please use the online application available on the Bristol Myers Squibb Independent Medical Education website.*


**References:**

11. Mahmoudjafari Z, Hawks KG, Hsieh AA, Plesca D, Gatwood KS, Culos KA. American Society for Blood and Marrow Transplantation Pharmacy Special Interest Group Survey on Chimeric Antigen Receptor T Cell


