

Celgene Corporation Request for Proposal
2018 AML Continuing Professional Educational Programming

Therapeutic Area: Hematology

Disease State: Acute Myelogenous Leukemia (AML)

Grant applications must be submitted through Celgene website:

www.celgene.com

Submission Timeframe:	Deadline November 20, 2017 by 5PM EST. Please include AML RFP as part of the title of application.
Proposal:	Independent CME/CE certified educational initiative for the interdisciplinary AML care team on how to incorporate new clinical evidence into the management of patients with AML in order to optimize their treatment experience. Multi-support is preferred.
Educational Audience:	Interdisciplinary healthcare team treating AML patients in community setting including: <ul style="list-style-type: none">• Hematologists and oncologists• Advanced Practice Providers including NP's, PAs• Oncology nurses and members of healthcare team who are presently active in patient care.
Program Format:	Independent CME/CE programming that is designed to address the unique learning needs of members of the oncology clinical care team involved in the management of patients with AML.
Outcomes Measurement:	Submissions should include a description of all measures, metrics and/or strategies that are going to be utilized to measure the impact of the education and closing the educational gaps for which the programming was designed.

Celgene Corporation is interested in providing funding to support quality independent education that addresses bona fide educational gaps in the diagnosis and management of patients with AML that is evidence-based and in accordance with ACCME, AMA, PhRMA Code, OIG and FDA guidance.

Introduction and Background

Acute myeloid leukemia (AML) will be diagnosed in approximately 19,950 people in the US in 2016, and 10,430 patients will die from this disease. It is the most common acute leukemia in adults, and its incidence increases with age.^{1,2} About half of patients are treated outside of academic institutions and relative to other cancer types, oncologists see AML as one of the most difficult to manage because it is both acute and rare. For the past decades, chemotherapy has been a cornerstone of treatment. Many patients however, have been unable to tolerate standard chemotherapy or transplant and much dismay has been expressed over the lack of progress in the management of this disease. Fortunately, recent years have brought much progress in understanding the pathophysiology of AML, and new targeted pathways are being identified.³ As a result, new treatments are being developed. In 2017 the

FDA approved several new targeted therapies, these are now being made available to patients in the US and the approvals have taken the treatment of AML into the era of personalized medicine. To adapt to these major advancements, the World Health Organization (WHO) recently updated its classification system for myeloid neoplasms,⁴ and the National Comprehensive Cancer Network (NCCN) in 2017 revamped its guidelines for clinical management.⁵ In 2017, several new agents were approved by the FDA for different subgroups of patients with AML, including patients with specific mutations. Each of the most recently approved agents works by a different mechanism of action and is associated with unique adverse event and safety profiles. It is critical that hematologists/oncologists are knowledgeable about these agents and the mechanisms of action, as well as how to identify patients who would potentially benefit from these targeted therapies.

The importance of educating the interdisciplinary care team is supported by a 2014 report on the state of cancer care in America. The American Society for Clinical Oncology (ASCO) indicated that by 2025, there will be a shortage of oncology clinicians due to the aging population and the increased demand for oncology visits.⁶ One response to the projected shortage is that the number of advanced practice clinicians (APCs)—including nurse practitioners (NPs) and physician assistants (PAs)—in oncology practice is on the rise, and their responsibilities are increasing.⁷ Currently, 75% of oncology practices employ APCs, including NPs and PAs—a substantial increase from the 52% of practices that reported doing so in 2014.⁸ Collaborative practices involving physicians and APCs are becoming increasingly critical to the delivery of oncology care and services. As team-based care becomes more prevalent, it is important for APCs and physicians work together with shared goals and clearly defined roles.⁹ APCs play important clinical roles, including ordering and administering treatment and managing pain and symptoms. ASCO and the National Cancer Institute both recognize the importance of team-based care that includes APCs, specifically in oncology, as well as the importance of interprofessional education.¹⁰ Since oncology APCs have high-level patient responsibilities and advanced degrees, education should be tailored to provide the background needed to derive maximum educational benefit. “Increasing attention should be paid to developing additional oncology-specific continuing medical education material for non-physician providers.”¹¹

In summary, the treatment of AML is experiencing evolutionary change from decades where standard chemotherapy and transplant were cornerstones of treatment, to a new era where new genomic discoveries and mutational testing are leading to personalized approaches to disease management. In light of this, several new therapies have recently received approval by the FDA, the WHO guidelines have been updated and NCCN guidelines have been revamped. Education related to all recent advancements for the oncology clinical care team who treat patients with this disease is warranted. The goal of the RFP is to provide programming designed to educate the clinical care team so that the latest evidence based advancements can be incorporated into practice safely and effectively with the goal to improve the outcomes of patients suffering with this disease.

References:

- ¹ National Comprehensive Cancer Network. Clinical practice guidelines. Acute myeloid leukemia. Version 1.2017
- ² E., *Molecularly targeted therapies for acute myeloid leukemia*. ASH Education Book; December 5, 2015 vol. 2015 no. 1 579-583.
- ³ Vakana E, Altman JK, Plataniias LC. Current treatments and future targeted treatments for acute myeloid leukaemia. *Clin Pharm*. 2016;8(3)
- ⁴ Arber DA, Orazi A, Hasserjian R, et al. The 2016 revision to the World Health Organization classification of myeloid neoplasms and acute leukemia. *Blood*. 2016;127(20):2391-405.)
- ⁵ National Comprehensive Cancer Network. Clinical practice guidelines. Acute myeloid leukemia. Version 1.2017.
- ⁶ American Society of Clinical Oncology. The state of cancer care in America, 2014: a report by the American Society of Clinical Oncology. *J Oncol Pract*. 2014;10: 119-142.
- ⁷ American Society of Clinical Oncology. The state of cancer care in America, 2016: a report by the American Society of Clinical Oncology. *J Oncol Pract*. 2016;12: 339-383.
- ^{8,9} American Society of Clinical Oncology. The state of cancer care in America, 2017: a report by the American Society of Clinical Oncology. *J Oncol Pract*. 2017;13: e353-e394.
- ¹⁰ Kosty MP, Bruinooge SS, Cox JV. Intentional approach to team-based oncology care: evidence-based teamwork to improve collaboration and patient engagement. *J Oncol Pract*. 2015;11: 247-248.
- ¹¹ Oncology education for nurse practitioners and physician assistants. *J Oncol Pract*. 2007;3:269-270.

Medical Educational Grants Guidelines

Medical Educational Grants are awarded in support of high quality, independent educational programs and materials, which demonstrate the potential to improve patient care and health outcomes. Each educational grant awarded must adhere to and be compliant with:

- FDA Final Guidance on Industry-Supported Scientific and Educational Activities,
- Office of Inspector General (OIG) Guidelines,
- Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support,
- Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals,
- American Medical Association (AMA) Ethical Guidelines for Gifts to Physicians from Industry, and
- Other relevant guidelines and regulations.

Supported programs must be independent, objective, balanced and scientifically rigorous. Grants cannot be tied, in any way, to past, present, or future prescribing, purchasing or recommending (including formulary recommendations) of any drug. Proposals which do not appear to provide balanced view of available and/or potential future therapeutic options will not be considered.