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2020 Independent Medical Education Call for Grant Notification

Issue Date: **June 12th, 2020**

The *Independent Medical Education team at Genentech, a member of the Roche Group,* invites accredited educational providers to submit applications for independent, certified medical education grants subject to the terms described below. This Call for Grants Notification (CGN) provides public notice of the availability of funds in a general topic area for activities for which recognized scientific or educational needs exist and funding is available.

Purpose: As part of Genentech's scientific mission, Genentech supports grants for independent medical education that aim to improve patient care by focusing on the improved application of knowledge, competence, and performance among healthcare professionals. This mission is achieved by supporting quality independent education that addresses evidence-based, bona fide educational gaps in accordance with the ACCME, AMA, PhRMA Code, OIG and FDA guidance.

Notification: Genentech CGNs are made available through our online Genentech Funding Request System (gFRS) site (http://funding.gene.com) along with the websites for the Alliance for Continuing Education in the Health Professions (ACEhp) and the Society for Academic Continuing Medical Education (SACME). In addition, an email is distributed to all registered gFRS users who have previously applied for support of an independent education activity. *There have been no predetermined approvals, nor any identified preferred educational providers. All submissions will be reviewed equally and thoroughly.*

Terms and Conditions

1. All grant applications received in response to this CGN will be reviewed in accordance with all Genentech policies and policy guidelines. (Please refer to the publicly available criteria on http://funding.gene.com)
2. This CGN does not commit Genentech to award a grant or pay any costs incurred in the preparation of a response to this request.
3. Genentech reserves the right to approve or deny any or all applications received as a result of this request or to cancel, in part or in its entirety, this CGN.
4. For compliance reasons, and in fairness to all providers, all communications about this CGN must come exclusively to Genentech's department of Medical Education and Research Grants. Failure to comply will automatically disqualify providers.
5. Failure to follow the instructions within this CGN may result in a denial.

Instructions

Eligibility Criteria	• U.S. based education provider • Registered account in gFRS • Accredited to provide CME/CE and in good standing (e.g. ACCME, ANCC, ACPE, etc.)
Geographical Scope	• Educational initiatives must be U.S.-based only

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Submission Directions	Application Process	Deadlines
Step 1	Providers who meet the eligibility criteria and are interested in submitting a response to this CGN will have 3 weeks to complete a brief ***Executive Summary*** through the following link at https://forms.gle/5YmcZ6M3MsA23Q2t5	July 6, 2020
Step 2	After 2 weeks, respective Genentech Medical Education Managers will notify (via email) those providers whose Executive Summaries were selected for further review.	July 17, 2020
Step 3	Those providers who receive notification of potential interest will have 3 weeks to **submit full grant application(s)** online through gFRS. Further instructions will be provided in the email notification.	August 7, 2020
Step 4	Notification of final decisions will occur via email	August 21, 2020
Step 5	Funded Project Start Date: within 10-12 weeks of grant award and interim update by 4-6 weeks.	October 30, 2020

Additional Considerations

Provider(s) who are awarded grants are encouraged but not required to:

1. Demonstrate key findings via outcomes analysis and report the extent to which the education met the stated objectives and other key findings.
2. Describe how learners demonstrated competence, performance, or patient outcomes improvement as a result of the educational activity.
3. Summarize (through written analysis) the provider's understanding and interpretation of the outcomes data and identify any persistent educational gaps, unanticipated barriers and/or activity/outcomes limitations.

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Currently Available CGN Focus Area(s):

Focus	Opportunity
Therapeutic Area: Rare Diseases **Disease:** Hemophilia A **Learning Audience:** Hematologists Nurses Pharmacists Patients and caregivers (optional) **Support Available:** Up to $375,000 Knowledge- and Competence-based Emerging Education *(Understanding & Addressing national or local gaps)*	The hemophilia A treatment landscape has evolved over the past 5 years with the advent of extended half-life factor replacement therapies, innovative therapeutic approaches, and the potential of novel therapies that have recently come to the market or are under development.[1] With the emergence of novel therapies for the management of hemophilia A, there exists a need for comprehensive and consistent capture of safety reporting to better enable the benefit-risk profile assessment over the life of a therapy, from preapproval to the postmarketing setting.[2] Surveillance of safety in the post-marketing setting is a vital mechanism to better understand the overall safety profile of any new intervention beyond what can be captured in a clinical trial setting. Industry and health regulatory authorities have standardized methods to collect and analyze safety information, as well as standardized approaches to communicate with the public when new safety information changes to the benefit-risk profile of a particular intervention.[3] Many channels exist for healthcare providers, patients and caregivers to inform industry and health regulatory authorities of adverse events that are observed or experienced post-marketing; however, adverse events are often not reported for various reasons.[4,5] There is an opportunity to educate the hemophilia community on their role in the pharmacovigilance process and the differences between preapproval and postmarketing safety reporting. Genentech seeks to support independent medical education activities designed to enhance the understanding of the pharmacovigilance process throughout the preapproval and postmarketing life of a therapeutic treatment. For example: how adverse event reports gathered pre-and-post-marketing are analyzed in the context of the disease state and used to inform the overall safety profile of a medication. References: 1. Weyand AC and Pipe SW. New therapies for hemophilia. Blood 2019 Jan 31;133(5):389-398. doi: 10.1182/blood-2018-08-872291 https://pubmed.ncbi.nlm.nih.gov/30559264/ 2. van Vulpen LFD, Saccullo G, Iorio A et al. The current state of adverse event reporting in hemophilia. Expert Review of Hematology 2017; 10:2: 161-168, DOI: 10.1080/17474086.2017.1272410 https://pubmed.ncbi.nlm.nih.gov/28013565/ 3 U.S. Food and Drug Administration, Center for Drug Evaluation and Research: Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment. 2005. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/good-pharmacovigilance-practices-and-pharmacoepidemiologic-assessment 4. Lassila R and Makris M. Safety surveillance in haemophilia and allied disorders (Review Symposium). J Intern Med 2016; 279: 515–523. https://pubmed.ncbi.nlm.nih.gov/27001233/ 5. Weinstein M, Makris M, and Ludlam CA. Biovigilance and pharmacovigilance for haemophilia. Haemophilia 2010; 16(Suppl 5): 17–21. https://pubmed.ncbi.nlm.nih.gov/20590851/
Therapeutic Area: Oncology **Disease:**	Acute myeloid leukemia (AML) is the most common form of acute leukemia among adults and accounts for the largest number of annual deaths from leukemia in the U.S.[1] The disease is clinically and genetically heterogeneous, and recent advances have improved our understanding of the cytogenetic abnormalities and molecular mutations, aiding in prognostication and risk

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Acute myeloid leukemia (AML) **Learning Audience:** Hematologist Hematologist-Oncologist Community Oncologist Nurses Pharmacists Patients (optional) **Support Available:** Up to $375,000 Knowledge- and Competence-based Emerging Education *(Understanding & Addressing national or local gaps)*	stratification.[2,3] AML is characterized by features of bone marrow failure including fatigue, anemia, recurrent infections due to neutropenia and increased risk for bleeding due to thrombocytopenia.[4] If left untreated, death usually ensues within months of diagnosis secondary to infection or bleeding.[5] Most of the clinical manifestations of AML reflect the accumulation of malignant, poorly differentiated myeloid cells within the bone marrow, peripheral blood and infrequently in other organs. The majority of patients presents with a combination of leukocytosis and signs of bone marrow failure such as anemia and thrombocytopenia.[5] Treatment of AML is divided into induction, consolidation, and maintenance. Induction and consolidation treatment is typically treated with chemotherapy, which may result in myelosuppression.[6] Since 2017, the FDA has approved eight new drugs in AML, including novel treatments.[7] Genentech is seeking to support medical education activities (CME/CE) designed to enhance HCP's understanding of the practical management of AML patients including management of myelosuppression (i.e. dose modifications/dose reductions), drug-drug interactions, and supportive care measures to ensure appropriate treatment management in the era of new and emerging AML therapies. **References:** 1. Siegel RL, et al. Cancer statistics, 2019. CA Cancer J Clin 2019;69:7-34. 2. Papaemmanuil, E, et al. "Genomic Classification and Prognosis in Acute Myeloid Leukemia." New England Journal of Medicine, vol. 374, no. 23, 2016, pp. 2209–2221. 3. Döhner, H, et al. "Diagnosis and Management of AML in Adults: 2017 ELN Recommendations from an International Expert Panel." Blood, vol. 129, no. 4, 2017, pp. 424–447., doi:10.1182/blood-2016-08-733196. 4. Khwaja, A, et al. "Acute Myeloid Leukaemia." Nature Reviews Disease Primers, vol. 2, no. 1, Oct. 2016, doi:10.1038/nrdp.2016.10. 5. Kouchkovsky, I De, and Abdul-Hay, M. "Acute Myeloid Leukemia: a Comprehensive Review and 2016 Update." Blood Cancer Journal, vol. 6, no. 7, 1 July 2016, p. e441., doi:10.1038/bcj.2016.50. 6. Taylor SJ, Duyvestyn JM, Dagger SA et al. Preventing chemotherapy-induced myelosuppression by repurposing the FLT3 inhibitor quizartinib. Sci Transl Med. 2017;9. https://stm.sciencemag.org/lookup/doi/10.1126/scitranslmed.aam8060. Accessed May 26, 2020. 7. Burnett, A, and Richard S. "AML: New Drugs but New Challenges." Clinical Lymphoma Myeloma and Leukemia, vol. 20, no. 6, 2020, pp. 341–350., doi:10.1016/j.clml.2020.02.005.