

Issue Date: March 3, 2014

Call for Grant Notification: Genentech Medical Education & Research Grants

The *Medical Education & Research Grants Team at Genentech, a member of the Roche Group*, invites accredited members of the educational provider community 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 transfer of knowledge, competence, and performance of 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. Genentech CGNs are posted on the Genentech website (<http://funding.gene.com>) along with the websites for the Alliance for Continuing Education in the Health Professions (ACEHP) and SACME. In addition, an email is sent out to all registered users of the Genentech Financial Request System (gFRS) who have previously submitted an application for support of an independent education activity.

Eligibility Criteria: Applicant must be U.S.-based, registered on the Genentech Financial Request System (gFRS), and in good standing and accredited to provide CME/CE by an official accrediting agency (e.g. ACCME, ANCC, ACPE, etc.)

Geographical Scope: The educational initiatives must be U.S.-based only unless specifically identified as a **Global Grant**.

Submission Instructions: Submit applications online through gFRS, which can be accessed via <http://funding.gene.com>. When submitting the application, please be sure the following are completed:

1. Select the Therapeutic Area, and the Disease State for the grant(s) that you are submitting.
2. Include "**CGN April 2014 [Insert Program Title]**" in the Program Title of the grant application
3. Complete all sections of online grant request form
4. Upload all documentation as requested by the system

Deadline for Submission of Application(s): April 7, 2014 (11:59 PM Pacific Time)

Award Decision Date/Mechanism: Approvals and denials will be communicated via standard grant-submission means (email notifications) no later than **May 16, 2014**. *There have been no pre-determined approvals, nor any identified preferred educational providers. All submissions will be reviewed equally and thoroughly.*

Educational providers should not respond to this CGN unless they have read and understand the terms, purpose, therapeutic landscape, and educational request identified below. Additionally, educational providers should not respond to any of the CGNs unless they have demonstrated expertise to successfully execute grants for independent medical education within the specified disease area(s) **AND** the recommended educational formats. Applicants will be expected to identify independent gaps that are clinically accurate and relevantly aligned to these CGNs.

Currently Available CGNs

Disease State (& Therapeutic Area)	Funding Available	Clinical Gap & Balanced Educational Gap	Requested Educational Audience and Educational Format	Quality-driven Endpoint for Consideration
Asthma (Immunology)	\$250,000	Asthma is a life long disease and can cause limitations in quality of life for millions of patients diagnosed with this disease. Approximately 25 million people have been diagnosed with asthma costing the US about \$56 billion in medical costs, lost school/work days and early deaths. ¹ The CDC has stated that better asthma education is needed...people with asthma can prevent asthma attacks if they are taught. ¹ In 2008 less than half of the people with asthma reported being taught how to avoid triggers...doctors and patients can better manage asthma by creating a personal asthma action plan that the patient follows. ¹ Allergic asthma is stated to be the most common form of asthma approximately affecting over 50% of asthma sufferers. ² It has been published since 2000 in <i>Clinical and Experimental Allergy Reviews</i> that quality-based educational programs were needed to address unmet needs. Provider/patient communication was also highlighted as an important area in need of attention and education. ³ Despite initiatives to improve asthma management, uncontrolled asthma remains highly prevalent. ⁴ There is a need to provide a fair and balanced educational initiative to increase clinician knowledge about the necessity of objective measurements to identifying levels of asthma control and effective patient management/co-management.	As such, Genentech is seeking to support an educational initiative focused on improving patients' ability to recognize the signs and symptoms of their disease, whether in the pediatric, adolescent, or adult state. Consideration will be given to ideas that include but may not be limited to a patient/physician initiative to detail communication and shared decision-making with the ultimate goal of demonstrating evidence that shows an improvement in patient care. Based on external research, Genentech believes this educational initiative is best suited for U.S.-based Primary Care Physicians, Allergists and/or Immunologists.	The initiative should aim to provide results that align to the <i>National Quality Strategy</i> priorities with a recommended focus on the following strategies: • Improved and effective communication & clinical care coordination • Patient/Family Engagement By addressing the lack of disease clarification as well as emerging evidence, the educational initiative could lead to treatment considerations that will improve personalized patient care.

Basal Cell Carcinoma (Oncology)	\$500,000	Basal cell carcinoma incidence rates have increased considerably. As the most common form of skin cancer approximately 2.8 million are diagnosed annually in the US. BCCs are rarely fatal, but can be highly disfiguring. ⁵⁻⁶ Advanced basal cell carcinoma and/or metastatic basal cell carcinoma diagnosis rates may be higher than actually known. While the options for addressing this disease are increasing, each option should be reviewed with patients supporting effective communication and care coordination. Equally important is the consideration of continued management of the disease. ⁷ The role of the patient is critical at all decision making points of care. It is important to ensure that healthcare providers educate patients to participate in the process of managing their care to support informed, confident decision-making, and monitor for concerning side effects to which the healthcare team should be alerted. ⁸	As such, Genentech is seeking to support an educational initiative that helps clinicians aid patients in recognizing the signs and symptoms of their disease. Consideration will be given to educational initiatives that include but may not be limited to addressing physician/patient communication, discourse surrounding treatment options, the importance of patient feedback to the management process of care, and addressing the appropriate clinician response to patient questions and concerns. Based on external research, Genentech believes this educational initiative is best suited for U.S.-based Dermatologists, Dermatologic Oncologists, Medical Oncologists, and/or all other healthcare providers who treat/manage advanced Basal Cell Carcinoma.	The initiative should aim to provide results that align to the <i>National Quality Strategy</i> priorities with a recommended focus on the following strategies: • Prevention and/or treatment to halt progression • Making care safer • Improved and effective communication & clinical care coordination By addressing the increased amount of treatment options, this educational initiative may result in improvements in personalized patient care.
Lung Cancer (Oncology)	\$500,000	For the medical oncologist community and all HCPs, treating patients diagnosed with cancer continues to be a challenge. It has been reported by the Institutes of Medicine (IOM) that approximately 4% of the US population are cancer survivors; and cancer diagnosis is only expected to increase in the coming decades. ⁹ 1.6 million people are newly diagnosed each year. Since the publication of the IOM report in 1999 <i>Ensuring Quality Cancer Care</i> , gaps in care have continued limiting the results in evidence-based care and improvements in overall cancer management. ⁹ Due to a lack of awareness of therapeutic options, comprehension of Mechanism of	As such, Genentech is seeking to support a curriculum-focused, multi-interventional initiative that considers utilizing emerging information to be presented at the upcoming ASCO 2014 Annual Meeting that focus on all emerging issues (diagnostic to treatment) related to Non Small Cell Lung Cancer (NSCLC). Consideration will be given to an educational initiative that uses a learner assessment tool(s) to collect baseline measurements that	The initiative should aim to provide results that align to the <i>National Quality Strategy</i> priorities with a recommended focus on the following strategies: • Increased affordability of healthcare • Prevention and/or

		Action (MOA) and understanding prognoses to develop effective treatment plans; the current health care delivery system is poorly prepared to address increasing cancer diagnoses.⁹ Lung cancer is one of the three most common cancers in the U.S.⁹ Both diagnosing and testing are critical. The sheer number of targeted agents has increased the educational burden for the healthcare system.⁹ Barriers identified that are specific to the management of patients with Non Small Cell Lung Cancer (NSCLC) as indicated by medical oncologists consist of their belief that there is a lack of effective therapies, cost of medications, insurance coverage, and clinical trial availability.⁶ Practice-related barriers reported were patient comorbidities and side-effects of therapies. It is further important to note that the majority of medical oncologists are familiar with current guidelines and updates.¹⁰ Testing and issues with tissue samples further compound the problems in care.¹⁰ The annual meeting of the American Society of Clinical Oncology (ASCO) has historically been attended by over 30,000 medical oncology professionals yearly and is regarded as one of the key oncology conferences to attend.¹¹ Based on the review of literature and data, due to current financial barriers and increased responsibilities in practice, community oncologists are finding it increasingly difficult to attend major meetings throughout the year. The opportunity presents itself to develop an educational initiative focusing on lung cancer that will support the dissemination of information.	would indicate whether or not progress has been made after the education. Further consideration will be given to educational initiatives that include the review of difficult patient cases that include but may not be limited to issues surrounding mutations, testing, and advancements in treatment options. Based on external research, Genentech believes this educational initiative is best suited for U.S.-based medical oncologists, pulmonologists, pathologists, and/or oncology nurses.	treatment to halt progression By addressing appropriate testing topics, the lack of awareness with therapeutic options, and the referenced burdens to the cost of healthcare, this educational initiative could result in identifying the appropriate treatments at the onset of care for the lung cancer patient.
Stroke (Cardiology)	\$400,000	Every year, more than 795,000 people in the U.S. have a stroke.¹² Stroke is a leading cause of serious, long-term disability in the U.S. Stroke is the fourth leading cause of death in the U.S. and stroke kills almost 130,000 Americans each year. Strokes can and do occur at any age; nearly 25% of strokes occur in people under the age of 65.¹³ Loss of productivity costs related to stroke are projected to reach \$34.0 billion by 2020.¹⁴ It's projected that stroke prevalence will increase 3.6% by 2020. Starting January 1, 2014, hospitals will need to report two	As such, Genentech is seeking to support an online initiative to address the quality of care gaps for hospitals treating stroke patients. Based on external research, Genentech believes this educational initiative is best suited for a closed system of U.S.-based Emergency Physicians, Neurologists, and/or other health care professionals who treat stroke	The initiative should aim to provide results that align to the <i>National Quality Strategy</i> priorities with a recommended focus on the following strategies: • Making care safer • Increased

		additional stroke-related measures, in addition to the existing stroke measure set. 1) 30-day, all-cause risk-standardized rate of mortality after admission for acute ischemic stroke to any non-federal acute care hospital, and 2) 30-day, all-cause risk-standardized rate of readmission following hospitalization for acute ischemic stroke to any non-federal acute care hospital. The stroke measures will be reported to CMS on a quarterly basis via The Joint Commission-approved ORYX® vendor or through use of the CMS Abstraction & Reporting Tool (CART). Hospitals that do not report these quality measures will have their MS-DRG update reduced by 2.0% ¹⁵	patients.	affordability of healthcare • Prevention and/or treatment to halt progression This educational initiative should address the referenced burdens to the cost of healthcare and demonstrate how education hospitals can meet their expectations.
Multiple Sclerosis (Neuroscience)	\$500,000	There is limited evidence worldwide that provides a sufficient amount of discussion surrounding Multiple Sclerosis (MS) treatment options. Furthermore, little exists within the public domain to address the effective management of adverse events. As such, physicians have globally expressed concerns about the potential side effects of treatment, as well as the potential poor patient tolerance in relation to those side effects. Further research indicates a considerable lack of therapy with adequate efficacy and predictive/prognostic biomarkers. This research identifies little and/or deficient resources that are available to identify progressive MS patients early in their disease. ¹⁶	Because of limited evidence and an interest from clinicians to gather as much information as possible, Genentech is seeking to support a live interactive and engaging symposium at Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) with an online enduring component. Consideration will be given to educational initiatives that review the safety issues and profiles of biologic and emerging therapies for MS, and compliantly discuss results of recent and ongoing clinical trials of agents in late-stage development. Based on external research, Genentech believes this educational initiative is best suited for U.S.-based and non-U.S.-based neurologists, nurse practitioners, and other healthcare professionals treating patients with MS.	Providers are encouraged to aim for outcomes that demonstrate improved levels of knowledge and competence as a result of the educational initiative.

Rheumatoid Arthritis (Immunology)	\$250,000 Global Grant <i>Joint funding from Genentech and Roche</i>	The American College of Rheumatology (ACR) and the European League Against Rheumatism (EULAR) guidelines recommend measurement of disease activity and adjustment of therapy to optimize outcomes.¹⁷ Yet most Rheumatoid Arthritis (RA) patients are not evaluated objectively for disease activity.¹⁸ There are inconsistencies in treatment decisions and limited knowledge of the relative efficacy/safety/dosing profile of new biologics therapy in the context of established RA.¹⁹ ACR/EULAR recommendations for the treatment of RA have both recently been updated.²⁰⁻²¹ Guidelines for treatment have recently been changed thereby fueling ACR to add to their recommendations. World wide, there are Rheumatologists focused on the treatment of patients with RA. 66% of these Rheumatologists use their judgment rather than validated instruments to evaluate disease activity, and only one-third believe Mechanisms of Action (MoA) to be important when making treatment decisions. Patients have become complacent, with many expressing satisfaction with their treatment despite abnormal disease activity. Rheumatologists have poorly adhered to consensus recommendations¹⁸⁻¹⁹ suggesting that further education may be necessary in order for clinicians to make practice changes based on the updated ACR/EULAR recommendations.	As a result, Genentech is seeking to support an educational initiative that addresses the immediate knowledge and competence of clinicians who manage patients with RA specifically regarding selection of appropriate treatments—with a theme surrounding an understanding of the treatment patterns of patients intolerant or non-adherent to all available and emerging therapies—monotherapy and combination therapy regimens included. Consideration will be given to educational initiatives that provide fair/balanced discussion based on treatment safety, efficacy, Mechanisms of Action (MoA), and the characteristics of patient disease. There is a need to provide educational activities for those treating RA to appropriately interpret data in order to manage the disease in patients and in turn make appropriate treatment decisions based on evidence. Based on further external research, Genentech believes this educational initiative is best suited for <u>U.S.-based and non-U.S.-based</u> Rheumatologists (specifically those within France, Spain, Italy and Germany) who manage patients with RA.	The initiative should aim to provide results that align to the <i>National Quality Strategy</i> priorities with a recommended focus on the following strategies: • Making care safer • Increased affordability of healthcare By addressing the referenced burdens to the cost of healthcare, the educational initiative could result in helping clinicians to follow guidelines and gain consensus, specifically around treatment (mono- or combination-therapy) efficacy, safety, and dosing.
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Vasculitis (Immunology)	\$300,000	Vasculitis (AAV) is defined as inflammation and necrosis of the blood vessel wall. The annual incidence of AAV is estimated to be 38.6 cases per million, with a greater incidence in women (50.4 cases per million) than in men (26.0 cases per million). ²² Given the relative rarity of the disease, there is a paucity of literature and educational opportunities in the area of AAV. Those that do exist most commonly focus on the rheumatologic manifestations of the disease. As a result, practice gaps in diagnosis and treatment of AAV, further complicated by varying clinical presentations depending on the localization, degree, and type of organs involved, are rampant. In particular, renal manifestations of the disease have aided in many diagnosis and treatment gaps. Research to improve treatment and better understand the etiology and pathogenesis of these diseases has been limited or not widely disseminated, creating additional knowledge gaps. ²³	As a result, Genentech is seeking to support a satellite symposium at the Annual Society of Nephrologists (ASN) focused on the fair/balanced, appropriate treatment and management of renal manifestations of AAV. Based on external research, Genentech believes this educational initiative is best suited for U.S.-based Nephrologists.	Providers are encouraged to aim for outcomes that demonstrate improved levels of knowledge and competence as a result of the education as a result of the educational initiative.
Diabetic Macular Edema (Ophthalmology)	\$500,000	Research indicates there are increasing early diagnosis rates of Diabetic Macular Edema (DME) though many clinicians are unaware of how to consider and then discuss the most effective prevention and treatment practices with their patients. Further research has suggested the need to immediately address and improve the care coordination and communications between those who diagnose and manage the diabetic patient as paramount to the improvement of patient outcomes. Data suggest that such efforts may best be accomplished within a network of clinicians who are taught how to address these issues in a collaborative and relevant way. ²⁴⁻²⁷	As a result, Genentech is seeking to support a live regional meeting series with an online educational enduring component that identifies and discusses issues related to DME detection within underserved patient populations. Based on external research, Genentech believes this educational initiative is best suited for U.S.-based Primary Care Physicians, Optometrists, Endocrinologists and/or other Diabetic Specialists.	The initiative should aim to provide results that align to the <i>National Quality Strategy</i> priorities with a recommended focus on the following strategies: • Improved and effective communication & clinical care coordination • Prevention and/or treatment to halt progression • Health & Wellness This educational initiative

				should address the referenced burdens to understanding and identifying the treatment options for this disease as well as the need to improve collaborative communication with the DME patient.
Age-related Macular Degeneration (Ophthalmology)	\$260,000	Vision impairment affects 3.3 million Americans over age 40. ²⁸ If detected early, some of the underlying disease causing vision loss, such as neovascular eye disease, can be reversed. ²⁹ Yet specialists often lack familiarity with the current body of evidence supporting early detection and treatment of Age-Related Macular Degeneration (AMD). ³⁰ While 95% of Retina Specialists report being extremely confident in diagnosing and treating retinal disease, only 40-50% are very familiar with current clinical trial results that would elucidate efficacy and safety of available treatments for these diseases. ³¹	As a result, Genentech is seeking to support an online educational initiative that helps to maximize the analysis of current evidence. Consideration will be given to educational initiatives that discuss the criteria for diagnosing retinal diseases, the strategies for establishing that diagnosis, and discussions around safety and efficacy considerations in selecting appropriate AMD therapy. Further consideration will be given to educational activities that address appropriate dosing and maintaining patient management for patients who have demonstrated improved vision and overall quality of life since initial treatment. Based on external research, Genentech believes this educational initiative is best suited for U.S.-based Retinal Specialists / Comprehensive Ophthalmologists.	The initiative should aim to provide results that align to the <i>National Quality Strategy</i> priorities with a recommended focus on the following strategies: • Prevention and/or treatment to halt progression • Health & Wellness • Patient/Family Engagement This educational initiative should address the referenced burdens to understanding and identifying the treatment options for this disease as well as the need to improve collaborative communication with the AMD patient.

**Genentech is also committed to providing non-solicited grant support in all disease areas.*

Through the preferred educational formats, the identified audiences should have availability to the latest data that helps them evaluate and manage safety concerns in their patients while considering the evidence that leads to appropriate decision making. The selected educational provider must therefore show that learners 1) have demonstrated reflection upon the educational activity, 2) demonstrated a competence improvement as a result of it, and 3) will use evidence-based concepts to consider changing behavior where appropriate or relevant.

The Expected Outcomes Measurement Process

All grant submissions should provide a description of the proposed methodology that evaluates the reach and quality of program delivery, including methods for measuring each activity identified within the proposals and for ensuring ongoing improvements to the activities (Accreditation elements 12,13,14,15).

All grant submissions should describe how the educational provider plans to determine the extent to which the initiatives have met the stated objectives and closed the identified clinical/educational gap(s) (Accreditation Elements 10,11,12) including the qualifications of those involved in the design and analysis of the outcomes.

While not required, it is strongly recommended that the results of these educational initiatives aim to increase understanding around the elements identified within the chart within this CGN. Genentech will review ways the aforementioned information ties into the following components:

- Education that results in an improvement of quality metrics, quality of care, and/or quality of life
- Education that results in a way the helps to inform or better engage patients with their caregivers
- Additionally, a plan for publishing the results detailing the lessons learned would be welcomed

Genentech's Grant Decision-Making Criteria

Please refer to the publicly available criteria, which can be found at <http://funding.gene.com>.

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.
2. This CGN does not commit Genentech to award a grant or to 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 reason, and in fairness to all providers, all communications about this CGN must come exclusively to Genentech's department for Medical Education & Research Grants. Failure to comply will automatically disqualify providers.
5. Failure to follow instruction within this CGN may result in a denial.

Transparency

Genentech, at its sole discretion, has the right to disclose the details of funded independent medical education activities, including those that may be required by federal, state, and/or local laws and regulations. This disclosure may include, but shall not be limited to, details of the activity and the grant amount. The information may be disclosed to the public in a manner including, but not limited to, disclosure on the Genentech website.

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