

Issue Date: **December 11, 2015**

Call for Grant Notification: Genentech Medical Education & Research Grants

The *Medical Education and 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 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 being posted on the 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 submitted an application for support of an independent education activity.

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

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

NEW! Submission Instructions for an Executive Summary:

1. Providers who meet the eligibility criteria and are interested in submitting a response to this CGN **must first complete** a brief **Executive Summary** through the following link: (<https://docs.google.com/forms/d/1HGx8UsCUJHysqxZwsUOaPOZp9cA6BPS47Gwg74DGhXU/viewform>). **Deadline for Executive Summary submission will be January 15, 2016.**
2. By January 29, 2016, Genentech's respective Medical Education Manager will contact (ie, by email) those providers whose Executive Summaries were selected for further review.
3. Those providers who receive notification of potential interest may then submit full grant proposal applications online through gFRS. Further instructions will be provided in the email notification.

Award Decision Date/Mechanism: Final approvals and denials for those who were selected to submit a full application in gFRS will be communicated via standard grant-submission means (ie, email notifications) no later than **March 18, 2016**. *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

<p>Therapeutic Area, Disease Area and Financial Support Availability</p>	<ul style="list-style-type: none"> • Oncology, Lymphoma* (Relapsed / Refractory Follicular) • Up to \$400,000. Genentech does not require, but welcomes multi-support for this initiative.
	<p>We recognize that innovation takes concerted effort and time. Although the issued CGN provides baseline considerations for educational programming, we recognize that providers who respond will likely present a wide range of innovative programming ideas. With this in mind, please consider the points and available financial amounts raised within the CGN as general guidance. We will take into account provider needs as they relate to the scale and scope of their proposed projects, including points that may not be distinctly captured within the CGN itself.</p>
<p>Introduction and Background</p>	<p>Research indicates that only 55% of U.S. adults within the United States are receiving evidence-based care whereas 45% are not^{1,2} While generalized educational models exist to measure a spectrum of outcomes associated with learning interventions, there are few to no applicable learning or measurement models identified to provide reporting of an actual, verifiable medical education impact on patients lives (e.g. how many healthy days were added to patients' lives, as a result of a particular education activity). Population analyses of health outcomes suggest that issues with access, reimbursement or process barriers of care management accounts for only 10% of the variance in outcomes, whereas approximately 50% can be attributed to behavioral and social deficits related to transferring expanded knowledge into practice fluency.² Since the 1999 IOM report publication, <i>Ensuring Quality Cancer Care</i>,³ unintended care variations persist, limiting the impact of evidence adoption into clinical practice. According to this report and the outcomes of previous educational initiatives,⁴ a disquieting proportion--around 50%--of community-based medical oncologists are only somewhat familiar with current guidelines and emerging evidence-based medicine updates.⁵ For the care of patients with follicular lymphoma (FL), healthy care providers may also be challenged due to the fact that there is no standard of care in any line of therapy.⁶</p> <p>Despite approved therapies for FL, this disease remains incurable with the course of disease comprised of responses to several lines of treatment followed by a series of subsequent relapses.^{7,8} First-line treatment for follicular lymphoma is often rituximab in combination with chemotherapy. Responders to first line therapy may receive maintenance therapy with rituximab monotherapy. The selection of treatment in the relapsed/refractory setting is based mainly on individual patient characteristics and the relative success of the last line of treatment.⁹ In patients who become refractory to rituximab-chemotherapy, the prognosis is poor and treatment options may be limited. With the evolving treatment landscape for FL, there is a need to assess new data and determine how such data can help in treatment selection based on individual characteristics of the patient.</p> <p>The aim of this CGN is to support educational programming to address gaps related to: 1) Identifying and 2) evaluating optimal treatment regimens and outcomes for patients with relapsed FL and/or Rituxan refractory FL in settings in which patients receive care. This may include, but not be limited to recommending ways to use an independent medical education activity to improve upon outcomes identified with patients receiving FL therapy, such as the impact on patients' daily lives. This may additionally include, but not be limited to, suggesting a previously published or newly proposed healthcare outcomes models</p>

and/or a potential evidence-based medicine model to deliver a reportable impact on patients.

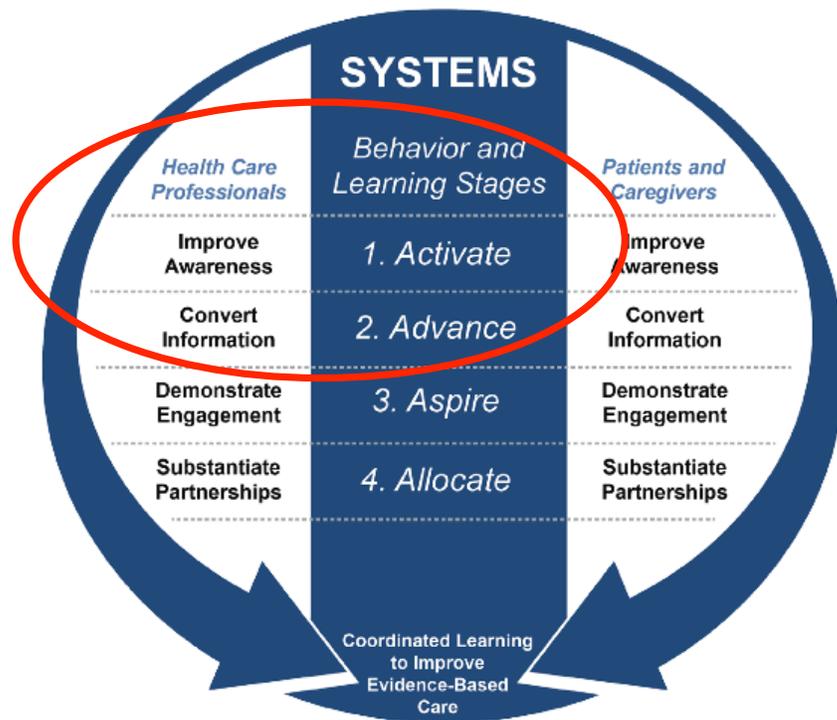
Methods

The clinical gaps, described above, could potentially be addressed through educational initiatives that are targeted to community-based oncologists and hematologist/oncologists.

Further, the clinical gaps described are aligned with gaps for health care professionals that may be addressed through behavior and/or learning interventions aimed at:

1. **Activating** the educational audience to “**improve their awareness**” about the current problem, purpose and culture of the gap; and/or
2. **Advancing** the educational audience to “**convert the information**” to demonstrate where and when improvements will be implemented and whether or not these improvements can be replicated.

The circled area within the graphic below identifies the potential intervention target for education that may address the described clinical gaps.^{10**}



Measures and Results

Submissions should include a description of any identified measures, such as referenced, endorsed or geographically relevant tools, metrics and/or strategies for measuring and improving the quality of care and/or application of evidence-based medicine (if relevant) that will be incorporated into the educational design, initiative execution and/or measurement process.

Through the submitter’s 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.

Submissions should include a description of how learners are expected to 1) demonstrate reflection upon or engagement with the educational activity's content and concepts, 2) demonstrate a competence improvement as a result of the educational activity, and 3) use evidence-based approaches to consider changing behavior where appropriate or relevant. Submissions should provide a description of how the potential grant will aim (if all / some / none are relevant)

- to activate learners,
- to advance learning or behavior change,
- to advance application of evidence based medicine,
- to provide tools to serve as aspirational resources for learners to commit to further engagement, and/or
- to have learners allocate the necessary resources or engage in collaborations to further expand upon learning and change.¹⁰

Discussion

Provider(s) who are awarded approval are encouraged to:

1. Consider whether or not the educational intervention(s) reduced the average time it takes for the educational audience to adopt emerging information, demonstrating how this was achieved.¹¹
2. Demonstrate key findings via outcomes analysis (please see Measures and Results section immediately above).
3. Summarize (through written analysis) the provider's understanding of the metrics, identifying the association between the intervention and the outcomes, identifying any comparison of the results with findings from other identified interventions or publications (if relevant).
4. Identify any unanticipated *barriers* and *activity/outcomes limitations*, explaining the reasons for them, and describing the efforts that were/are being made to adjust them as necessary.
5. Be available for discussion and/or presentation, if requested by Genentech's respective Medical Education Manager.

****Genentech is also committed to providing non-solicited grant support in all disease areas; however, a proportion of disease areas will have limited budgets outside of funding allocated to support grant decisions related to CGNs.***

*****While this particular model for education planning and assessment is identified within the CGN for descriptive purposes, all submitters may choose the model or framework that is most appropriate for their particular education design and/or plan as well as choose to apply no model or framework at all.***

Additional Considerations

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 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 that helps to inform or better engage patients with their care providers; or
- Optionally, education that includes a plan for publishing or disseminating the results, detailing the lessons learned.

Optionally and if appropriate, grant submissions and/or outcomes reporting may be organized in accordance with the SQUIRE model.¹²

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 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 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.

References

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7. Hainsworth JD, et al. Maximizing therapeutic benefit of rituximab: Maintenance therapy versus re-treatment at progression in patients with indolent non-Hodgkin's lymphoma—a randomized Phase II

trial of the Minnie Pearl Cancer Research Network. *Journal of Clinical Oncology*, 2005; 23(6): 1088-1095.

8. Friedberg JW, et al. Bendamustine in patients with rituximab-refractory indolent and transformed non-hodgkin's lymphoma: Results from a Phase II multicenter, single-agent study. *Journal of Clinical Oncology*, 2008; 26(2): 204-210.

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10. Ruggiero JE, et al. Coordinated learning to improve evidence-based care: A model for continuing education for the new healthcare environment. Abstract presented at: 2016 ACEhp Quality Symposium; September 28-30, 2015; Chicago, IL.

11. Balas EA and Boren SA. Managing clinical knowledge for health care improvement. *Yearbook of Medical Informatics*. 2000.

12. Ogrinc G, et al. *BMJ Journal of Quality and Safety* 2015;0:1–7. doi:10.1136/bmjqs-2015-004411.