

Improving Knowledge in Evolving and/or New Disease Areas

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A Focus on the Issues: Informed clinicians are essential to promoting positive patient outcomes. On average 20% of the core information guiding clinical decisions typically change within one year because of the appropriate tide of consistently emerging data.¹ Healthcare practices and their clinicians are challenged with preparing to efficiently absorb new information that could impact their care decisions with patients. Clinicians often seek a more efficient information infrastructure to better connect them to data exposure, and evaluating emerging evidence-based information for their patients and families.

The Learning Challenge: Through this specific Call for Grant Notification, Genentech is seeking to support grants that are adequately designed primarily for knowledge-based medical education that enables clinicians to improve their knowledge and competence of emerging data. These grants are to remain independent, accurate, fair-balanced in nature, and must meet the highest ethical U.S. Standards of Commercial Support. To meet this request, Genentech seeks grant responses in the following disease areas (individual accredited provider organizations may, but are not required to submit a response to each identified disease area below, and are asked not to submit more than one response to each):



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Opportunity	Description of the Issues/Problems			
Therapeutic Area: Oncology Disease:	New data in Non-Hodgkin's Lymphoma was presented at the 58 th Annual Meeting & Exposition of the American Society of Hematology (ASH) highlighted new and emerging data around treatment options for patients with Follicular Lymphoma in the 11 setting ¹ Follicular Lymphoma is characterized by a			
Follicular Lymphoma	continuous risk of relapse and progression, with each event becoming less sensitive to treatment and each remission shorter than the preceding one,			
Learning Audience: Hematologist Hematologist-	making disease management challenging. ² With growing treatment options for Hematologist-Oncologists to select from, there is an increased need to educate clinicians and patients on care plan decisions, specifically around the importance of delaying progression.			
Oncologist Patients (optional)	References: 1. The ASCO Post. Selected Abstracts From the 2016 ASH Annual Meeting,			
Support Available: Up to \$350,000	Indolent Lymphomas Part 1. <u>http://www.ascopost.com/issues/january-25-</u> <u>2017/selected-abstracts-from-the-2016-ash-annual-meeting</u> . Accessed November 16, 2017. 2. NCBL Economic impact of disease progression in follicular non-Hodgkin			
Knowledge- and Competence-based Emerging Education (Understanding & Addressing national or local gaps)	lymphoma. <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3211193/</u> Accessed November 7, 2017.			
Therapeutic Area: Oncology	New Breast Cancer data was recently presented at the 2017 American Society of Clinical Oncology (ASCO) meeting highlighting new data in			
Disease: Breast Cancer	HER2+ Breast Cancer after surgery.' Despite this new data, and other major advances, the need for improved early stage treatments still exists to keep disease from reaching an incurable stage. With growing			
Learning Audience: Oncologists	treatment options, for Oncologists to select from, it is imperative to educate Oncologists on evolving treatment selection paradigms including treatment duration, and safety considerations. ²			
Hematologist- Oncologist	 BCRF: Breast Cancer Research Foundation. ASCO 2017: Clinical Trial Updates in Early Stage Breast Cancer. https://www.bcrf.org/blog/asco-2017-clinical-trial- updates.asrb.stage.broast.cancer.Accessed Nevember 16, 2017. 			
2 CGN Awards	 The Oncologist. Adjuvant Therapy for Breast Cancer: Recommendations for Management Based on Consensus Review and Recent Clinical Trials. 			
Each Up to \$300,000				
Knowledge- and				



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Competence-based Emerging Education (Understanding & Addressing national or local gaps)		
Therapeutic Area: Oncology Disease: Ovarian Cancer Learning Audience: Oncologists Gynecologists	In the United States, approximately 22,000 women are estimated to be diagnosed with Ovarian Cancer in 2017. ^{1,2} Vascular endothelial growth factor is a key promoter of angiogenesis and disease progression in epithelial ovarian cancer. ³ Currently chemotherapy is the only viable option in advanced disease, and there are limited treatment options for health care providers to choose from for patients with advanced ovarian cancer in the front-line setting. ⁴ With emerging treatment options, there exists a critical need to update and educate oncologists on emerging therapies in the front-line setting.	
Support Available: 2 CGN Awards Each Up to \$225,000 Knowledge- and Competence-based Emerging Education (Understanding & Addressing national or local gaps)	 National Cancer Institute. Surveillance, Epidemiology, and End Results Program, Cancer Facts: Ovarian Cancer. https://seer.cancer.gov/statfacts/html/ovary.html Accessed November 8, 2017. CDC: Ovarian Cancer Statistics.<u>https://www.cdc.gov/cancer/ovarian/statistics/index.htm</u> Accessed November 8, 2017. NCBI, Cancer Metastasis Reviews, Significance or vascular endothelial growth factor in growth and peritoneal dissemination of ovarian cancer. Accessed November 16, 2017. Medscape: First-line Treatment of Advanced Ovarian Cancer: Current Research and Perspectives. <u>https://www.medscape.com/viewarticle/714633</u> Accessed November 8, 2017. 	
Therapeutic Area: Rare Diseases Disease: Hemophilia A Learning Audience: Hematologist	The preferred treatment for Hemophilia is factor replacement therapy by injecting the missing factor protein into the affected patient's vein. ¹ Complications of the disease include risk of bleeding, morbidity and mortality. ² With new and emerging treatment options including new methods of delivery (subcutaneous injection versus infusion directly into the blood vain), ³ there exists a critical need to educate Hematologists on emerging therapies in patients with Hemophilia A without inhibitors.	



Improving Knowledge in Evolving and/or New Disease Areas

Primary Care Physician	Becaus much i	se of limited evidence and an interest from clinicians to gather as nformation as possible, Genentech is seeking to support a live	
Support Available: Up to \$350,000 Knowledge- and Competence-based Emerging Education (Understanding & Addressing global and national educational gaps)	sympos 2018 w Consid and em results develo educat based patiem	much information as possible, Genentech is seeking to support a live symposium at World Federation of Hemophilia (WFH) Congress in May 2018 with an online enduring component to target US based clinicians. Consideration will be given to educational initiatives that review the new and emerging therapies for Hemophilia A, and compliantly discuss the 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.Sbased and non-U.S based Hematologists, and other healthcare professionals treating patients with Hemophilia A.	
caddalonal gapoj	1.	Hemophilia Federation of America Treatment of Hemophilia	
Combined US and	••	http://www.hemophiliafed.org/bleeding-disorders/hemophilia/treatment	
Non-US education		Accessed November 8, 2017.	
Mayo Clinic. Diseases and Conditions: Hemophili		Mayo Clinic. Diseases and Conditions: Hemophilia.	
		https://www.mayoclinic.org/diseases-	
		conditions/hemophilia/basics/complications/con-20029824?p=1	
	2	Accessed November 8, 2017.	
	э.	Revolution http://www.hematology.org/Thehematologist/Vears-	
		Best/6993.aspx Accessed November 20, 2017	

Measuring Impact: Research indicates that there are two identified care decision processes: 1) care decisions made fast and intuitive, 2) care decisions that require a deliberate analytical approach to locate information that is not instantly recalled.⁸ To add complexity to the decision making process, healthcare has been reformed so that care decisions should be a result of team-based care, a collective planning process with the entire system including the patient, not via an individual decision-maker.

Genentech encourages the consideration of an outcomes measurement strategy that contains the following measurements **when relevant to the applicable problem**:

- 1. Improved utilization of evidence based data (i.e. efficacy and/or safety management) when making clinical decisions
- 2. Increased rate of care coordination and/or timely referrals
- 3. Utilization of shared decision making between clinicians and patients measured by the OPTIONs tool, and if applicable, patient engagement as measured by the patient activation measure



Improving Knowledge in Evolving and/or New Disease Areas

To that end, Genentech encourages the use of existing <u>and/or</u> expanded outcomes measurement models, for example:

Moore's et al.	The Expanded Learning Model for Systems (TELMS)	
Levels 1-2: Participation & Satisfaction	 Iderstand the Gap: Learning should activate a collective improved vareness: What are the nature, severity and context of the identified problem and why are these specific participants invited to be part of the healthcare improvement initiative? What is the intended improvement if these learners participate? 	
Level 3: Procedural & Declarative Knowledge Improvement	 Address the Gap: Learning should advance participants toward a conversion of information that helps inform the collective system: Post-learning metrics that show an improvement in awareness of that specified local problem 	
Level 4: Competence Improvement	 Practice the Solution: Learning should enable participants to aspire toward a collective solution: Post-learning metrics that describe how the system intends to address/correct the problem to improve the baseline problem Describes new commitments to long-term project plans that address previously identified barriers Demonstrate collective practice improvements by using available system tracking techniques Give examples of how the learning initiative helped identify a change in process that addresses the original identified problem 	
Levels 5-7*: Potential individual clinician performance improvement, potential individual patient improvement, and potential community-level improvement	 Extend the Solution*: Learning should enable participants to allocate solutions that are sustainable over time: Post-learning observations that identify systemic collaborations, such as documented improved communication, improved patient satisfaction scores, improved adherence of evidence-based care, improved measures patients take to make better healthy living decisions away from the clinic Post-learning metrics that demonstrate how a change in process of care specific to evidence and system requirements were met 	

*Please note that the clinical gap, the identified problem, and the identified necessary participants drive the expected outcome. Not all staged levels and/or embedded examples are necessary or required; selected stages will depend on what was identified as the issue/clinical gap. While these listed models for learning planning and assessment are identified within the CGN for descriptive purposes, all



Improving Knowledge in Evolving and/or New Disease Areas

submitters may choose the model or framework that is most appropriate for their particular educational plan.

Instructions to apply:

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Eligibility Criteria	 U.S. based provider Registered on the Genentech Financial Request System (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, unless specifically identified as a <i>Global Grant.</i>		
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 <i>Executive</i> <i>Summary</i> through the following link at https://goo.gl/forms/LFK338EIfTXV0m6G2	December 15, 2017	
Step 2	After 2 weeks, respective Genentech Medical Education Managers will notify (via email) those providers whose Executive Summaries were selected for further review.	December 22, 2017	
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.	January 19, 2018	
Step 4	Notification of decisions via email will occur*	February 2, 2018	
Step 5	Funded Project Start Date: within 8 weeks of decision date with the goal to have baseline interim outcomes before the end of 2018.	June 2018	

* There have been no pre-determined approvals, nor any identified preferred educational providers. All submissions will be reviewed equally and thoroughly.



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<u>Purpose</u>: 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.

<u>Notification:</u> Genentech CGNs are made available through being posted on the online gFRS site (<u>http://funding.gene.com</u>) 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.

<u>Genentech's Grant Decision-Making Criteria</u>: Please refer to the publicly available criteria, which can be found at <u>http://funding.gene.com</u>. 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 funding allocated to support grant decisions related to CGNs.

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.
- 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.

<u>Transparency</u>: 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.



Improving Knowledge in Evolving and/or New Disease Areas

References

- 1. Balas EA and Boren SA. Managing clinical knowledge for health care improvement. Yearbook of Medical Informatics. 2000
- Baddeley, Michelle. "Herding, social influence and economic decision-making: sociopsychological and neuroscientific analyses." *Philosophical Transactions of the Royal Society B: Biological Sciences* 365.1538 (2010): 281-290.