2017 Independent Medical Education
Call for Grant Notification:
Accelerating Evidence into Practice through a
Healthcare Improvement Strategy

Release Date: January 23, 2017

A Focus on the Issues: American adults, on average, receive only 54.9% of the healthcare
recommended for their conditions.¹ Reasons for varied practices includes knowledge- and/or behavioral-
deficits and limited accessibility to emerging evidence. Embedded within this research is the time it takes
for emerging clinical evidence to get fully integrated into practice (an average of 17 years), further
complicated by an average 20% of core information guiding clinical decisions typically changing within
one year.² Furthermore the factors that determine clinical change aren’t necessarily nestled within a
traditional medical education event. There is therefore limited evidence to suggest a correlation between
general knowledge models and health care quality.³

The Learning Challenge: Through this specific Call for Grant Notification, Genentech is seeking to
support grants that consider the aforementioned issues by evolving knowledge-based medical education
into “healthcare Improvement” initiatives with the purpose of accelerating the awareness and
application of evidence-based medicine into relevant, measurable, clinical outcomes. These grants are to
remain independent, accurate, fair-balanced in nature, and must meet the highest ethical U.S. Standards
of Commercial Support; the grants are not required to be certified for credit if there are valid reasons for
that decision. 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):

<table>
<thead>
<tr>
<th>Opportunity</th>
<th>Description of the Issues/Problems</th>
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<tbody>
<tr>
<td>Therapeutic Area: Neuroscience</td>
<td>Providing effective and timely access to medical care is crucial in the pursuit of optimal health outcomes. For underserved populations with chronic conditions such as Multiple Sclerosis (MS), this becomes acutely more important.¹ Research has shown that African Americans appear to have higher incidence of MS than their counterparts, and also that they may experience a more aggressive disease course, more frequent relapses, and a more advanced transition from relapsing-remitting MS (RRMS) to secondary progressive MS.² Large-scale studies of MS patients have also shown that African American MS patients are more likely to be in lower income levels and less likely to have private insurance. Sources suggest they additionally endure disproportionately increased odds of experiencing severe disability.³ Moreover, the greatly limited representation of African Americans in clinical trials compounds the aforementioned challenges and emphasizes the need to provide effective and accessible healthcare to this patient population. Indeed, for these issues and others, <em>there exists a critical need to identify and then provide quality, accessible healthcare to African American MS patients.</em></td>
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<tr>
<td>Disease: Multiple Sclerosis</td>
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<tr>
<td>Learning Audience: Neurologists, neurology nurse practitioners, and other neurology HCPs</td>
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<tr>
<td>Support Available: Up to $350,000</td>
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<tr>
<td>Knowledge- and Competence-based Emerging Education (Understanding &amp; Addressing national</td>
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</table>

References:
1. CEOutcomes, Needs Assessment, 2015
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<table>
<thead>
<tr>
<th>Therapeutic Area: Oncology</th>
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<tbody>
<tr>
<td>Disease: Bladder Cancer</td>
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<tr>
<td>Learning Audience: Urologist &amp; Medical Oncologist</td>
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<tr>
<td>Support Available: Up to $300,000</td>
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</table>

One of the most significant barriers to the optimal treatment of patients with bladder cancer is the lack of timely referrals as described by medical and urologic oncologists. When surveyed, community medical oncologists (30%) and urologic oncologists (23%) identified lack of timely referrals from other physicians as a very significant barrier to providing optimal treatment. Furthermore, approximately only half (53%) of urologists surveyed referred their patients to a medical oncologist to administer systemic therapy. A population-based study in muscle invasive bladder cancer identified the lack of referrals to medical oncologist leads to the variation in treatment for patients; the authors suggest that this may be a result of upstream decision making by urologists. Some identified reasons for either lack of referrals or poor referral rates, include low physician awareness and/or knowledge of newer or emerging therapies, and/or the absence of an efficient infrastructure to support physician collaboration and referrals. Results from a study on personalizing bladder cancer care through a multidisciplinary team (urologic-, radiation-, and medical oncologist), show that treating complex bladder cancer patients through a team-based approach affects accurate staging and treatment decisions. Timely and more prevalent referrals along with multi-disciplinary care are needed and if addressed, may help patients with bladder cancer receive optimal treatment(s).

Sources:

1. CE Outcomes, Needs Assessment 2015
3. Learning & Clinical Integration, collated Outcomes Reports, 2016
Emerging immunotherapies have been shown to result in durable tumor regression in some NSCLC patient populations (1). Surprisingly a recent gap analysis found that only 30% of surveyed oncologists reported not being confident with some of the new and emerging agents and only 50% reported feeling very knowledgeable about immunotherapy clinical trial data (2). As clinical trial and publicly available consensus-driven data surrounding the sequencing of agents emerges, the need for continued education will become paramount to decreasing the average time it takes to place evidence into practice, and to tailor strategies to provide maximal benefit to all patient sub-populations with advanced NSCLC.

**References:**

2. CE Outcomes Needs Assessment, 2016

**Sources:**

**Therapeutic Area:** Oncology  
**Disease:** Chronic Lymphocytic Leukemia (CLL)  
**Learning Audience:** Medical Oncologist, Hematologist, Hem/Onc, Oncology Nurse  
**Support Available:** Up to $300,000  

Education that builds data Confidence- and Application-based continuous improvement  
*(Understanding and Addressing the national or local gaps, and/or Practicing and Extending regionalized, systems-based solutions)*

<table>
<thead>
<tr>
<th>Sources</th>
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<tr>
<td>3. CE Outcomes, Needs Assessment, 2015</td>
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</table>

Providing effective and evidence-based care to patients with CLL is crucial in the pursuit of optimal health. For patients with CLL who have a chromosomal deletion such as 17p, this becomes acutely more important. Deletion of part of chromosome 17 (17p) is linked to a poor outlook, and chromosomal aberrations are of key importance for predicting CLL outcomes. Research has shown that a substantial proportion of U.S.-based Hematologist-Oncologists aren’t appropriately ordering guideline recommended cytogenetic tests. Moreover, the greatly limited adherence to cytogenetic testing within the current CLL patient population leads to a disproportionate amount of patients receiving inadequately informed treatment selection and optimal therapy for their disease. Indeed, for this issue and others, there exists a critical need to identify and then provide quality, evidence-based healthcare to CLL patients that have the chromosomal deletion 17p.  

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3. CE Outcomes, Needs Assessment, 2016

4. Twine Analytics Assessment, 2016
### Therapeutic Area: Oncology

### Disease: Myopic CNV

### Learning Audience: General Ophthalmologists, Retinal Specialists

### Support Available: Up to $150,000

Education that builds data Confidence- and Application-based continuous improvement (Understanding and Addressing the national or local gaps, and/or Practicing and Extending regionalized, systems-based solutions)

Myopic choroidal neovascularization (CNV) is the second most common form of CNV after age-related macular degeneration. In pathologic myopia, eyes are frequently longer than the average eye. This elongation results in breaks in Bruch’s membrane, allowing an entry point for neovascularization (the growth of abnormal blood vessels into the retina). These vessels may break and leak blood or fluid into the retina, possibly causing irreversible central vision loss. Symptoms of mCNV include blurred or distorted central vision, a sudden worsening of central vision and difficulty distinguishing color.\(^1\) Given that mCNV is often bilateral and irreversible, and can result in profound visual loss in younger people, often during their working years, it is not surprising that mCNV has a significant harmful effect on quality-of-life.\(^2\) Despite the fact that anti-VEGF therapy is considered the “gold standard,” and recommended as the first-line treatment for mCNV,\(^2,3\) our needs assessment research has revealed that even retina specialists and comprehensive ophthalmologists are challenged to choose among the various agents, and lack knowledge about newly published clinical data.\(^4\) There has recently been approval for a new delivery mechanism for anti-VEGF. HCP’s need to understand the impact this can have on overall treatment and the processes involved.

### References:


### Therapeutic Area: Ophthalmology

### Disease: Advanced AMD/Geographic Atrophy

### Learning Audience: Geographical Atrophy (GA) is an advanced form of AMD; it is a progressive disease characterized by complete loss of photoreceptors, retinal pigment epithelium and choriocapillaris, which leads to irreversible loss of visual function. There are currently no approved or effective treatments for GA. Although the exact prevalence of GA is unknown, it is believed to affect over 5 million patients worldwide and over 1 million patients in the US [Boyer2016; Rudnicka 2015]. GA is responsible for approximately 20% of all cases of legal blindness in developed countries [Patel HR 2015]. While GA remains a high unmet need, the pace of GA research is increasing and there are multiple therapeutics in Phase II and III clinical development [Sadda 2016].
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<tr>
<th>Retinal Specialists Support Available:</th>
<th>Up to $250,000</th>
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</table>
| Knowledge- and Competence-based Emerging Education (Understanding & Addressing national or local gaps) | 2016; Boyer 2016].

Clinical assessments utilizing noninvasive imaging technologies such as color fundus photography (CFP), spectral-domain optical coherence tomography (SD-OCT), fundus autofluorescence (FAF), and near-infrared reflectance (NIR) are being used to aid GA diagnosis, measure areas of atrophy and monitor disease progression over time[Sadda 2016; Holts 2014; Pilotto 2016; Zarbin 2014]. Because the fovea is often not involved until late GA, best corrected visual acuity (BCVA) is often a poor indicator of visual dysfunction in GA, underrepresenting patients' deficit. Even with good BCVA, GA patients can experience debilitating functional impairment affecting their everyday life. To capture a more representative understanding of patients' visual function deficits many ongoing clinical trial programs include other measures of visual function in addition to BCVA. These additional assessments can include low-luminance VA (LLVA), microperimetry, reading speed, and patient reported outcome measures (PROs) like the NEI VFQ-25 and the Functional Reading Independence Index (FRI Index) [Sadda 2016].

Recent updates to AMD clinical classification (Ferris et al, 2013) and ICD-10CM AMD diagnostic coding (AAO.org) reflect clarifications by the retina community to better define the stages of AMD (early, intermediate, late) and distinguish GA from earlier stages of non-neovascular (dry) AMD. These tools may be used to determine appropriate treatment, and/or referral to a specialist; therefore the use of consistent nomenclature is critical to improve patient management and access as emerging treatment options are approved and become available.

While there are currently no approved or effective treatments to reduce or halt the progression of GA various mechanisms of action are being evaluated in ongoing clinical development programs [Sadda 2016, Holz 2014]. There is strong genetic evidence for complement dysfunction in AMD and researchers are evaluating different target points in the complement cascade [Boyer 2016]. Retina specialists and comprehensive ophthalmologists would benefit from education on ongoing clinical trial efforts to contextualize this data, to help set appropriate expectations for what emerging treatment options might deliver in terms of visual preservation vs. visual restoration, and to understand how to critically evaluate trial results as they become available [Pilotto 2016, Sadda 2016].

References


**Therapeutic Area:** Ophthalmology  
**Disease:** Diabetic Retinopathy  
**Learning Audience:** General Ophthalmologists, Retina Specialists

While the systemic impact of diabetes is well established, it is the leading cause of new cases of blindness among adults aged 20–74 years. Of the ocular complications caused by diabetes, diabetic retinopathy (DR) occurs in approximately 28% of patients over the age of 40, and 14% of those with DR will also develop diabetic macular edema (DME). Many patients with DR and DME are undiagnosed or undertreated, and approximately 50% of patients report not having timely examinations. Moreover, 45% of patients are unaware that diabetes can affect their eyes.

It is projected that by 2020, five million people will have visual impairment due to age-related macular degeneration and diabetic macular edema. There has recently been approval for a new delivery mechanism for anti-VEGF. HCP’s need to understand the impact this can have on overall treatment and the processes involved. Retina specialists and comprehensive ophthalmologists have difficulties identifying management strategies for their patients with DR including considerations...
Support Available:
Up to $200,000

Education that builds data confidence and application-based continuous improvement (Understanding and Addressing the national or local gaps, and/or Practicing and Extending regionalized, systems-based solutions)

for cost-effective treatment options. Diabetic retinopathy and DME will continue to become a national health problem with millions of lives affected, that the importance of addressing barriers to optimal treatment, including timely examinations, diagnosis and cost-effective treatment need to be addressed.

References:

The healthcare improvement initiative(s) can exist in a local geography, intra-institution/system, or in a national setting so long as the learning initiative uses your most suitable intervention recommendations that meet relevant learner needs. (Recommended guidance for initiative planning can be viewed at the Revised Standards for Quality Improvement Reporting Excellence, SQUIRE 2.0. Please note we welcome partnerships if appropriate; and we understand the development/cultivation of systems-based or other partnerships takes time. We consider your grant submission to be an intended proposal based on progressing partnership conversations, and should scope changes be necessary after a grant approval, we are open to considering them. Genentech also welcomes multi-support, though it is not required.

Submissions that may be given higher priority: Preference will be given to organizations that frame the grant development, suggested learning implementation, and outcomes assessment in the context of an improvement framework, such as the following:

- Identifying the nature and significance of the clinical problem, demonstrating how the learning initiative helps participants recognize why they are participating to begin with
- Demonstrating how the learning will help participants form collective, sustainable solutions that adjust and/or rectify that problem
- If relevant to the problem, reducing variation in the care of patients which therefore demonstrates maximum likelihood to directly impact patient care

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. 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. As institutions continue to bear risk, preference will be given to learning initiatives that frame the grant development and suggested learning implementation in a way that provides outcomes that are useful not to just individual learners but to the needs of an overall system(s).

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
4. Improved clinical endpoints
To that end, Genentech encourages the use of existing and/or expanded outcomes measurement models, for example:

<table>
<thead>
<tr>
<th>Moore’s et al.</th>
<th>The Expanded Learning Model for Systems (TELMS)</th>
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<tbody>
<tr>
<td><strong>Levels 1-2: Participation &amp; Satisfaction</strong></td>
<td><strong>Understand the Gap:</strong> Learning should <em>activate</em> a collective improved awareness:</td>
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<tr>
<td></td>
<td>• 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?</td>
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<td></td>
<td>• What is the intended improvement if these learners participate?</td>
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<tr>
<td><strong>Level 3: Procedural &amp; Declarative Knowledge Improvement</strong></td>
<td><strong>Address the Gap:</strong> Learning should <em>advance</em> participants toward a conversion of information that helps inform the collective system:</td>
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<td>• Post-learning metrics that show an improvement in awareness of that specified local problem</td>
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<tr>
<td><strong>Level 4: Competence Improvement</strong></td>
<td><strong>Practice the Solution:</strong> Learning should enable participants to <em>aspire</em> toward a collective solution:</td>
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<td></td>
<td>• Post-learning metrics that describe how the system intends to address/correct the problem to improve the baseline problem</td>
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<td></td>
<td>• Describes new commitments to long-term project plans that address previously identified barriers</td>
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<td></td>
<td>• Demonstrate collective practice improvements by using available system tracking techniques</td>
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<td></td>
<td>• Give examples of how the learning initiative helped identify a change in process that addresses the original identified problem</td>
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<tr>
<td><strong>Levels 5-7: Potential individual clinician performance improvement, potential individual patient improvement, and potential community-level improvement</strong></td>
<td><strong>Extend the Solution:</strong> Learning should enable participants to <em>allocate</em> solutions that are sustainable over time:</td>
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<td>• 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</td>
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<td></td>
<td>• Post-learning metrics that demonstrate how a change in process of care specific to evidence and system requirements were met</td>
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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 клиническо г ap. While these listed models for learning planning and assessment are identified within the CGN for descriptive purposes, all submitters may choose the model or framework that is most appropriate for their particular educational plan.
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Instructions to apply:

| 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 Global Grant.

Submission Directions

<table>
<thead>
<tr>
<th>Application Process</th>
<th>Deadlines</th>
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<tr>
<td><strong>Step 1</strong> Providers who meet the eligibility criteria and are interested in submitting a response to this CGN will have 4 weeks to complete a brief <strong>Executive Summary</strong> through the following link at <a href="https://goo.gl/forms/M2SK795XhjlwLV922">https://goo.gl/forms/M2SK795XhjlwLV922</a></td>
<td>February 20, 2017</td>
</tr>
<tr>
<td><strong>Step 2</strong> After 2 weeks, respective Genentech Medical Education Managers will notify (via email) those providers whose Executive Summaries were selected for further review.</td>
<td>March 6, 2017</td>
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<tr>
<td><strong>Step 3</strong> Those providers who receive notification of potential interest will have 3 weeks to submit full <strong>grant application(s)</strong> online through gFRS. Further instructions will be provided in the email notification.</td>
<td>March 27, 2017</td>
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<td><strong>Step 4</strong> Notification of decisions via email will occur*</td>
<td>April 10, 2017</td>
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<td><strong>Step 5</strong> Funded Project Start Date: within 6-8 weeks of decision date.</td>
<td>May 22, 2017—June 5, 2017</td>
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</table>

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

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 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.

Genentech’s Grant Decision-Making Criteria: Please refer to the publicly available criteria, which can be found at http://funding.gene.com. 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.
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
2. Balas EA and Boren SA. Managing clinical knowledge for health care improvement. Yearbook of Medical Informatics. 2000
3. IOM Report, 2013; HealthAffairs