Genentech
A Member of the Roche Group

2017 Independent Medical Education Call for Grant Notification:

Improving Knowledge in Emerging Areas with Shared Decision Making

Release Date: April 14, 2017

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. With emerging data in therapeutic areas offering preference sensitive treatments, shared decision making (SDM) and patient engagement is a valuable method that can help improve satisfaction and ultimately improve[2] patient outcomes, and lower costs of care.[3-5] Unfortunately, while SDM is supported in the reformed healthcare marketplace focused on developing higher quality care, it is poorly adopted by clinicians today, and the care patients receive may not necessarily align to their preferences.[6-7]

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 in the context of SDM, thereby potentially impacting improvements in practice. 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):

Genentech
A Member of the Roche Group

2017 Independent Medical Education Call for Grant Notification:

Improving Knowledge in Emerging Areas with Shared Decision Making

Opportunity	Description of the Issues/Problems
Therapeutic Area: Oncology **Disease:** Non-Hodgkin's Lymphoma (NHL) **Learning Audience:** Hematologist Hematologist-Oncologist Patients (optional) **Support Available:** Up to $375,000 Knowledge- and Competence-based Emerging Education *(Understanding & Addressing national or local gaps)*	New NHL data (specifically in diffuse large B-cell lymphoma and follicular lymphoma) presented at the most recent American Society of Hematology meeting highlighted current treatment routes including intravenous infusion and orally available options, as well as new and updated data on sub-cutaneous treatment options that add to the complexity of the treatment armamentarium for NHL.[1] With growing treatment options for Hematologist-Oncologists to select from, there is an increased need to incorporate the patients' voice in education that utilizes SDM tools and resources in care plan decisions. There also exists a critical need to identify patient preferences while providing evidence-based healthcare to NHL patients. References: 1. ASH. 58th Annual Meeting and Exposition website. https://ash.confex.com/ash/2016/webprogram/start.html. Accessed March 22, 2017.
Therapeutic Area: Rare Diseases **Disease:** Hemophilia A **Learning Audience:** Hematologists Patients (optional) **Support Available:** Up to $375,000 Knowledge- and Competence-based Emerging Education *(Understanding &*	The preferred treatment for Hemophilia is factor replacement therapy by injecting the missing factor protein into the affected patient's vein.[1] The most serious complication of replacement therapy is the development of antibodies (proteins) that attack the clotting factor which prevents the main treatment for hemophilia from working and occurs in approximately 30% of people with Hemophilia A.[2-3] Complications of the disease include risk of bleeding, morbidity and mortality. With current and emerging treatment options that have varying degrees of treatment burden and impact on quality-of-life, clinicians and patients will need to seek alignment in treatment decisions (i.e., SDM).[4] The United States is divided into 10 separate Hemophilia Treatment Center (HTC) regions.[5] Today, there are approximately 141 federally-funded treatment centers across the country.[6] About 70% of people with Hemophilia in the United States receive multidisciplinary care in a HTC.[7] With the advent of new medicines, there exists a critical need to educate

Addressing national or local gaps)	the multidisciplinary care team and patients on emerging therapies and SDM in Hemophilia A.[8] References: 1. Hemophilia Federation of America. Treatment of Hemophilia. http://www.hemophiliafed.org/bleeding-disorders/hemophilia/treatment/. Accessed March 22, 2017. 2. National Institute of Health: National Heart, Lung, and Blood Institute. https://www.nhlbi.nih.gov/health/health-topics/topics/hemophilia/treatment. June 13, 2013. Accessed March 22, 2017. 3. Hemophilia Federation of America. Bleeding Disorders. Inhibitors. http://www.hemophiliafed.org/bleeding-disorders/inhibitors/. Access March 22, 2017. 4. Athale, A., et al. "Developing a two-sided intervention to facilitate shared decision-making in haemophilia: decision boxes for clinicians and patient decision aids for patients." *Haemophilia* 20.6 (2014): 800-806. 5. Brenda Riske, MS, MBA, MPA; Regina Butler, RN, MSN; Jim Munn, RN. Hemophilia 101 for non-clinicians. American Thrombosis & Hemostasis Network Website. https://athn.org/downloads/files/2011%20ATHN_DS_RISKE_FINAL%20245 1648-2451648-database-structure%2009%2012%2011.pdf. Accessed March 22, 2017. 6. Hemophilia Federation of America. Advocacy-temp. Hemophilia Treatment Centers. http://www.hemophiliafed.org/advocacy-temp/access-old/hemophilia-treatment-centers-old/. Accessed March 22, 2017. 7. Centers for Disease Control and Prevention. Hemophilia. Data & Statistics. https://www.cdc.gov/ncbddd/hemophilia/data.html. Last updated July 11, 2016. Accessed March 22, 2017. 8. Business Wire: A Berkshire Hathaway Company. Chugai's Bispecific Antibody "ACE910/Emicizumab" Phase 1 Data in Patients with Hemophilia A Published in The New England journal of Medicine Online. First NEJM Publication of Chugai's Drug Candidate. http://www.businesswire.com/news/home/20160525006575/en/Chugais-Bispecific-Antibody-ACE910Emicizumab-Phase-Data-Patients. Published.May 25, 2016. Accessed March 22, 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

Genentech
A Member of the Roche Group

2017 Independent Medical Education Call for Grant Notification:

Improving Knowledge in Emerging Areas with Shared Decision Making

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

Moore's et al.	The Expanded Learning Model for Systems (TELMS)
Levels 1-2: Participation & Satisfaction	**Understand the Gap**: Learning should ***activate*** a collective improved awareness: • 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

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

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	**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://goo.gl/forms/HK4GinjnT1oWB0uh1	May 5, 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.	May 19, 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.	June 9, 2017
Step 4	Notification of decisions via email will occur*	June 23, 2017
Step 5	Funded Project Start Date: within 8 weeks of decision date with the goal to have baseline interim outcomes before the end of 2017.	Aug 4-Aug 18, 2017

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

Genentech
A Member of the Roche Group

2017 Independent Medical Education Call for Grant Notification:

Improving Knowledge in Emerging Areas with Shared Decision Making

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.

Genentech
A Member of the Roche Group

2017 Independent Medical Education Call for Grant Notification:

Improving Knowledge in Emerging Areas with Shared Decision Making

References

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

2. King, Jaime, and Benjamin Moulton. "Group Health's participation in a shared decision-making demonstration yielded lessons, such as role of culture change." *Health Affairs* 32.2 (2013): 294-302.

3. Mitchell SE, Gardiner PM, Sadikova E, et al. Patient Activation and 30-Day Post-Discharge Hospital Utilization. *Journal of General Internal Medicine*. 2014;29(2):349-355. doi:10.1007/s11606-013-2647-2.

4. Arterburn, David, et al. "Introducing decision aids at Group Health was linked to sharply lower hip and knee surgery rates and costs." *Health Affairs* 31.9 (2012): 2094-2104.

5. Veroff, David, Amy Marr, and David E. Wennberg. "Enhanced support for shared decision making reduced costs of care for patients with preference-sensitive conditions." *Health Affairs* 32.2 (2013): 285-293.

6. Braddock III, Clarence H., et al. "Informed decision making in outpatient practice: time to get back to basics." *Jama* 282.24 (1999): 2313-2320.

7. Oshima Lee, Emily, and Ezekiel J. Emanuel. "Shared decision making to improve care and reduce costs." *New England Journal of Medicine* 368.1 (2013): 6-8.

8. Baddeley, Michelle. "Herding, social influence and economic decision-making: socio-psychological and neuroscientific analyses." *Philosophical Transactions of the Royal Society B: Biological Sciences* 365.1538 (2010): 281-290.