Sanofi US Medical Affairs

Request for Proposal (RFP)

Date: 11 February 2020		
Disease State: Cardiovascular		
Therapeutic Area: Cardiovascular		
Area of Interest: Diagnosis/Pharmacotherapeutic Management of Afib		
Geographic Scope: United States, National		
Internal Requestor Information:		
Name: **Title:** **Company:** **Phone:** **Email:**	Cynthia Bocchino, RN, MSN, CNL Senior National Education Manager Sanofi US 908-981-3157 Cynthia.bocchino@sanofi.com	
Due Date: By 5pm EST on 31 March 2020		
Submission Portal: https://sgrants.envisionpharma.com/vt_sgrants/		
RFP Title (to include in request): The Role of Antiarrhythmics in Atrial Fibrillation		

The Health Care Gap and Independent Background Information:

Atrial Fibrillation (AF) contributes to over 454,000 hospitalizations and 158,000 deaths each year, with an estimated $6 billion spent annually on healthcare costs related to AF and its sequelae.[1-2] The prevalence of AF in the United States is projected to more than double by 2030 to over 12 million cases.[3] Longest duration of AF episodes, number of episodes and the percentage of time spent in AF define AF burden and is associated with increased risk of cardiovascular events and death.[4] Essentially, time spent in AF is directly related to outcomes.[3-4]

Consensus statements and guidelines have been developed to aid clinicians in selecting appropriate therapies, including antiarrhythmic drugs (AAD), based on individual circumstances.[5-6] For example, recommendations for selection of AADs include consideration of underlying cardiac disease, severity of AF symptoms and AF classification (e.g. paroxysmal, persistent, or permanent AF).[4-5] A number of studies show evidence of safety, efficacy and place in treatment for antiarrhythmic drugs in appropriate patients, such as a recent Cochrane review and the CABANA trial, which provided pivotal data on the role of ablation vs medical management (i.e. rate and rhythm control).[7-10] However, despite the evidence and well-documented morbidity, mortality, and cost burdens associated with AF, many patients continue to suffer from AF, even after ablation, increasing risk of stroke, furthering left atrium remodeling and reducing quality of life.[1-9]

Understanding clinical trial outcomes and, importantly, weighing available evidence regarding antiarrhythmic drugs in the clinical decision-making process is a critical skill needed to optimize outcomes and quality of life for AF patients, while reducing costs and overall healthcare burden. Clinicians face many challenges in attaining AF management goals including: interpreting existing and emerging data, applying guidelines and best practices to their treatment strategies and tailoring these strategies to individual patients. Therefore, educational experiences should focus not only on the transfer of knowledge about the disease state, progression, and treatment strategies, but in the clinical application of knowledge through demonstration of increased skill adoption, as well as identification of barriers to optimal care, root causes for care gaps, and tools to overcome them. Engaging patients in shared decision making may also be an important key to increasing adherence and persistence.[1-15]

Sanofi US is seeking proposals for innovative independent medical education initiatives, to help clinicians address the significant morbidity and mortality associated with AF and apply current guidelines and best practices to meet their clinical challenges for improved patient outcomes, quality of life, and reduce burdens associated with hospitalizations.

- **Preference will be given to proposals that utilize a format known to improve HCP competence, performance, and/or health system changes.**

- **Innovative formats that aim to optimize patient care through collaborative approaches will be considered, with appropriate outreach for broad HCP engagement.**

Proposal should include the following information:

- **Needs Assessment/Gaps/Barriers**: Include a comprehensive needs assessment that is well referenced and demonstrates an understanding of the specific gaps and barriers of the target audiences (in alignment with ACCME criteria). **The needs assessment must be independently developed and validated by the accredited provider, as applicable.**

- **Target Audience and Audience Generation:** Proposal should indicate the target audience(s) and provide a rationale for how and why this target audience is appropriate for closing the identified healthcare gap. In addition, please describe methods for reaching the target audience including description of any rationale for recruitment and placement strategies to maximize participation according to need. Any unique recruitment efforts specific to the target audience should be highlighted.

- **Learning Objectives and Content Accuracy:** Provide clearly defined and measurable learning objectives framed as expected practice improvements in relation to the identified gaps and barriers. Include an overview of program content and explanation of criteria that will guide content selection, considering level of evidence and other variables. Sanofi US is committed to the highest standards in ensuring patient safety; the applicant should describe methods to ensure complete, accurate, evidence-based review of key safety data for any therapeutic entities discussed in the activity. Explain how content will be updated if necessary throughout the program period, and how accuracy will be ensured.

- **Educational Methods:** Sanofi US supports the ACCME guidance for educational methods to be clearly designed to address the knowledge, competence and/or performance gaps that may underlie an identified healthcare gap. Your proposal should demonstrate an understanding of instructional design as it relates to the gaps in the knowledge, competence, or performance of the targeted audience. Educational methods and design should be based on current literature in CME best practice and consistent with ACCME accreditation criteria, as applicable. For example, systematic reviews have suggested that the most effective continuing education is clearly linked to clinical practice, uses methods including interaction, reflection, strategies that ensure reinforcement through use of multiple educational interventions, and more.[12-14] Preference will be given to applications that utilize methods that have been shown to result in practice improvements, and/or with data on the effectiveness of other programs of the same type. ACCME criteria recognize that barriers may be related to systems, lack of resources, or tools etc. and these may be included if relevant in your discussion of the gap and the educational methods you propose. In addition, the educational preferences of the target audience(s) may be considered to maximize attendance/participation and lead to practice improvements.

- **Faculty Recruitment and Development:** Provide Information on the expected qualifications of contributors and description of methods to ensure recruitment of course directors and faculty who meet the qualifications. Explain any methods that will be used to ensure that faculty are fully trained in the program expectations and any skills that may be needed to ensure effective delivery of intended education.

- **Program Evaluation and Outcomes:** Provide a description of the approach to evaluate the reach and quality of program delivery; methods for monitoring individual activities and for ensuring ongoing quality improvements. For ACCME accredited programs, refer to accreditation elements and criteria, as applicable. Describe methods that will be used to determine the extent to which the activity will close the identified healthcare gap, and the qualifications of those involved in the design and analysis of the outcomes. Preference will be given to programs with Objectives and Outcomes Plans with objective measures of changes in knowledge, and/or additional measures of improvements in competence, performance, patient health, population health, and/or system improvements, as aligned with the design of the intervention.[15]

- **Budget:** Include a detailed budget with rationale and breakdown of costs, per unit, and description of each budget line item. In addition, please include any registrations fees paid by the learner, and how the fees will be applied.

- **Accreditation**: If proposal involves an accredited program, the accreditation must be provided by an appropriate accrediting body and fully compliant with the accrediting body's criteria and applicable government guidelines and regulations.

- **Fair Balance:** The proposal should briefly describe methods for ensuring fair and balanced content, identification and resolution of conflict of interest, in alignment with applicable ACCME criteria.

- **Communication and Publication Plan**: Provide a description of how the provider will keep Sanofi US informed of progress. If applicable, include description of how the results of this educational intervention will be presented, published or disseminated.

1. Centers for Disease Control and Prevention (2019). *Atrial fibrillation*. Retrieved from https://www.cdc.gov/heartdisease/atrial_fibrillation.htm. Accessed on January 21, 2020.
2. Kim M, Johnston S, Chu B, Dalal M, Schulman K. Estimation of Total Incremental Health Care Costs in Patients with Atrial Fibrillation in the United States. *Circulation: Cardiovascular Quality and Outcomes*, 4(3):313-320. doi:10.1161/circoutcomes.110.958165
3. Marinigh R, Lip G, Fiotti N, Giansante C, Lane D. Age as a Risk Factor for Stroke in Atrial Fibrillation Patients. *J Am Coll Cardiol*., 56(11):827-837. https://doi.org/10.1016/j.jacc.2010.05.028
4. Chen, L., Chung, M., allen, L., Ezekowitz, M., Furie, K.,…Turakhia, M. and On behalf of the American Heart Association Council on Clinical Cardiology; Council on Cardiovascular and Stroke Nursing; Council on Quality of Care and Outcomes Research; and Stroke Council. (2018). Atrial fibrillation burden: Moving beyond atrial fibrillation as a binary entity: A scientific statement From the American Heart Association. *Circulation*, 137: e623-e644. https://doi.org/10.1161/CIR.0000000000000568
5. Dan, A. et al. (2018). Antiarrhythmic drugs-clinical use and clinical decision making: A consensus document from the European Heart Rhythm Association (EHRA) and European Society of Cardiology (ESC) Working Group on Cardiovascular Pharmacology, endorsed by the Heart Rhythm Society (HRS), Asia-Pacific Heart Rhythm Society (APHRS) and International Society of Cardiovascular Pharmacotherapy (ISCP). *Europace,* 20(5). DOI: 10.1093/europace/eux373
6. January CT, et al. 2014 AHA/ACC/HRS Guideline for the management of patients with atrial fibrillation: executive summary. *Journal of the American College of Cardiology*., 64(21), 2246-2280.
7. Connolly S., Camm A., Halperin J. et al. Dronedarone in High-Risk Permanent Atrial Fibrillation. *N Engl J Med*., 365:2268-76.
8. Packer DL, Mark DB, Robb RA, et al. (2019). Effect of catheter ablation vs antiarrhythmic drug therapy on mortality, stroke, bleeding, and cardiac arrest among patients with atrial fibrillation: The CABANA randomized clinical trial. *JAMA.*, 321(13):1261–1274. doi:10.1001/jama.2019.0693
9. Stabile, G., Iuliano, A., Agresta, A., La Rocca, V., D'Ascia, S., De Simone, A. (2013). Antiarrhythmic therapy following ablation of atrial fibrillation. *Expert Rev Cardiovasc Ther*., 11(7):837-42. doi: 10.1586/14779072.2013.811982
10. Marrouche NF, Brachmann J, Andresen D et al. (2018). Catheter ablation for atrial fibrillation with heart failure. *N Engl J Med.,* 378(5):417-427. doi: 10.1056/NEJMoa1707855
11. Dan G. A. (2019). Rhythm control in AF: Have we reached the last frontier?. *European cardiology*, 14(2), 77–81. doi:10.15420/ecr.2019.8.h
12. Cervero RM, Gaines JK. (2015). The impact of CME on physician performance and patient health outcomes: An updated synthesis of systematic reviews. *J. Contin. Educ. Health Prof*., 35: 131–138. doi:10.1002/chp.21290
13. McMahon GT. (2015). Advancing continuing medical education. *JAMA*., 314(6):561-562. doi:10.1001/jama.2015.7094
14. Mostofian F, Ruban C, et al. (2015). Changing physician behavior: What works? *AJMC*, 21(1):75-84.
15. Moore DE, Green JS, and Gallis HA. (2009). Achieving desired results and improved outcomes: Integrating planning and assessment throughout learning activities. *JCEHP*, 29(1):1-15.