Sanofi US Medical

Request for Proposal (RFP)

Date: 15 November 2021		
Disease State: Atrial Fibrillation		
Therapeutic Area: Cardiovascular		
Area of Interest: The role of AADs in Early Rhythm Control and the Management of Atrial Fibrillation		
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 on 9 December 2021		
Submission Portal: https://sgrants.envisionpharma.com/vt_sgrants/		
RFP Title (to include in request): 2022 Early Rhythm Control		

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.[2] 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.[3] Essentially, time spent in AF is directly related to outcomes.[3-8]

Consensus statements and guidelines have been developed to aid clinicians in selecting appropriate therapies, including antiarrhythmic drugs (AAD), based on individual circumstances.[4,7] For example, recommendations for selection of AADs include consideration of severity of AF symptoms, AF classification (e.g. paroxysmal, persistent, or permanent AF), and underlying cardiac disease.[3,4,8] Attention has been called to the relationship of AF with heart failure (HF) due to the increasing numbers of patients with each of these conditions; risk for both increases with age and each has a high risk of leading to the other condition.[11-12] In fact, people with AF have a 5-fold increased risk for both HF with preserved ejection fraction (HFpEF) and HF with reduced ejection fraction (HFrEF).[11-12] However, HFpEF makes up approximately half of all HF diagnoses and has a higher rate of comorbidity as well as hospitalization, morbidity and mortality than heart failure with reduced ejection fraction (HFrEF).[12]

A number of studies show evidence of safety, efficacy and place in treatment for antiarrhythmic drugs in appropriate patients, such as the Cochrane review and the CABANA trial, which provided pivotal data on the role of ablation vs medical management (i.e. rate and rhythm control).[9-10] Data suggests that earlier initiation of rhythm control strategies can slow progression of AF.[4-8] The EAST-AFNET4 trial tested the hypothesis of whether a strategy of early rhythm control would be associated with better outcomes in patients with early atrial fibrillation than contemporary evidence-based usual care, leading to an update of the European Society of Cardiology (ESC) guidelines with enhanced grade recommendation for early rhythm control for both symptoms and quality of life improvements[4,6] ESC guidelines also provide recommendations for management of the combination of AF with HFpEF and AF with HFrEF.[4] The American College of Cardiology (ACC) and the European Society of Cardiology (ESC) guidelines both suggest considering early intervention with rhythm control strategies to prevent AF progression.[4, 7-8]

Sanofi US is seeking proposals for innovative, independent medical education initiatives that engage general cardiologists, internal medicine and primary care physicians to understand the safety and

efficacy of available AADs to individualize treatment, address the importance of early identification of AF and early management of rhythm control, including AF with HF, applying these new knowledge gains to decrease symptoms and increase quality of life for people afflicted with AF, reduce economic burdens associated with hospitalizations to help improve patient outcomes.

- **Preference will be given to proposals delivered at cardiology conferences (e.g. American Heart Association, American College of Cardiology, Heart Rhythm Society), live/virtual and endured, that are innovative and utilize a format designed to engage learners (e.g. cardiologists, internal medicine, etc.) to improve knowledge, competence/confidence and/or performance.**

- **Preference will also be given to proposals that are unique and innovative utilizing methodologies designed for the busy practitioner**

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.[13-15] 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.[16]

- **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.

References

1. Centers for Disease Control and Prevention (2020). *Atrial fibrillation*. Retrieved from https://www.cdc.gov/heartdisease/atrial_fibrillation.htm#:~:text=What%20are%20the%20consequences%20of,year%20in%20the%20United%20States.&text=The%20condition%20contributes%20to%20about%20158%2C000%20deaths%20each%20year.&text=The%20death%20rate%20from%20AFib,for%20more%20than%20two%20decades. Accessed November 20,2020.
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. 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
4. Hindricks, G. et al.(2020). 2020 ESC Guidelines for the diagnosis and management of atrial fibrillation developed in collaboration with the European Association of Cardio-Thoracic Surgery (EACTS): The Task Force for the diagnosis and management of atrial fibrillation of the European Society of Cardiology (ESC) Developed with the special contribution of the European Heart Rhythm Association (EHRA) of the ESC. *European Heart Journal*, ehaa612, https://doi.org/10.1093/eurheartj/ehaa612
5. 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
6. Kirchhoff, P. et al. (2020). Early Rhythm-Control Therapy in Patients with Atrial Fibrillation. *N Engl J Med.* 383, 1305-1316. DOI: 10.1056/NEJMoa2019422
7. January, C., et al. (2019). 2019 AHA/ACC/HRS Focused Update of the 2014 AHA/ACC/HRS Guideline for the Management of Patients with Atrial Fibrillation: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society in Collaboration with the Society of Thoracic Surgeons
8. January C., et al. (2014). 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.
9. Valembois L, Audureau E, Takeda A, Jarzebowski W, Belmin J, Lafuente-Lafuente C. (2019). Antiarrhythmics for maintaining sinus rhythm after cardioversion of atrial fibrillation. *Cochrane Database of Systematic Reviews* Issue 9. Art. No.: CD005049. DOI: 10.1002/14651858.CD005049.pub5. Accessed 25 November 2020.
10. 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
11. Gopinathannair R, Chen LY, Chung MK, Cornwell WK, Furie KL, Lakkireddy DR, Marrouche NF, Natale A, Olshansky B, Joglar JA; on behalf of the American Heart Association Electrocardiography and Arrhythmias Committee and Heart Failure and Transplantation Committee of the Council on Clinical Cardiology; Council on Arteriosclerosis, Thrombosis and Vascular Biology; Council on Hypertension; Council on Lifestyle and Cardiometabolic Health; and the Stroke Council. Managing atrial fibrillation in patients with

heart failure and reduced ejection fraction: a scientific statement from the American Heart Association. *Circ Arrhythm Electrophysiol* 2021;14:e000078. doi: 10.1161/HAE.0000000000000078
12. Dunlay SM, Roger VL, Redfield MM (2017). Epidemiology of heart failure with preserved ejection fraction. *Nat Rev Cardiol.*,14(10):591-602. doi: 10.1038/nrcardio.2017.65. Epub 2017 May 11. PMID: 28492288.
13. 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
14. McMahon GT. (2015). Advancing continuing medical education. *JAMA*., 314(6):561-562. doi:10.1001/jama.2015.7094
15. Mostofian F, Ruban C, et al. (2015). Changing physician behavior: What works? *AJMC*, 21(1):75-84.
16. 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.