Health Care Gap

Coronary heart (CHD) is the leading cause of morbidity and mortality in the United States and accounts for about 1 in 6 deaths annually [1,2]. Elevated low-density lipoprotein cholesterol (LDL-C) is a major risk factor for CHD. According to NHANES data, it is estimated that 71 million Americans aged ≥20 years have high LDL-C but only 34 million are being treated, of which 23 million have their LDL-C controlled [3,4]. Statin therapy has been the gold standard for treating dyslipidemia. Their powerful effect on lowering LDL cholesterol and improving outcomes has been widely documented [5,6].

Despite the significant success of CV risk reduction with statins, a significant percentage of patients do not achieve LDL-C targets with statin monotherapy, even with high doses of statins [6]. This is especially important for patients with higher cardiovascular risk, where LDL targets may be lower (<100 mg/dL, and <70 mg/dL in some cases based on ATP III), and standard therapy with a statin alone or in combination with other available lipid-lowering therapy is often insufficient [5,7,8]. Further, statin therapy discontinuation rates ranging from 9% to 20% have been observed in clinical practice due to therapy intolerance [12,13]. Consequently, patients with uncontrolled hypercholesterolemia remain at a high risk for atherosclerotic CVD[9-11].

New cholesterol treatment guidelines, recommendations and position statements have been released from key societies and organizations, but there are differences among them and they lack consensus on LDL-C management [14-22].

There are limited treatment alternatives for patients who are at high risk for CVD and in whom LDL-C is not sufficiently controlled with statins. To address this persisting health care gap, novel mechanisms of action and emerging agents (including mAbs) are being studied for lipid reduction. Research targeting LDL continues to provide evidence linking LDL reduction with improved CVD outcomes [23]. Recent and ongoing research investigating new potential mechanisms for LDL lowering, including PCSK9 inhibition, MTP inhibition and Apo-B inhibition continue. New and emerging treatment strategies may offer additional therapeutic options as a complement to statin therapy or as a standalone therapy [23-28]. Furthermore, these emerging treatments carry important differences from other molecules that may be clinically/ intellectually relevant to health care professionals, including such things as their development history and how they differ from other (e.g., small) molecules. In addition, these differences
may involve such things as practical treatment considerations that may need to be addressed educationally, such as special storage or handling and injection requirements.

The Sanofi-Regeneron Alliance will consider accredited educational proposals to close this independently defined healthcare gap.

The American Heart Association (AHA) has announced the possibility of satellite symposia for accredited educational activities during the AHA Annual Meeting in November 2015; the Sanofi and Regeneron Alliance will consider proposals for this and other venues.

The Sanofi and Regeneron Alliance will also consider proposals for accredited web-based, print and/or live educational activities that address the described educational gaps above. Preference will be given to proposals that recommend appropriately designed interventions that are likely to enhance a learner’s knowledge of the unmet needs and employ proven strategies to overcome knowledge and performance gaps and barriers.

Providers seeking multi-support of activities will also be strongly considered.

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 (ie, ACCME accreditation element 2). The needs assessment must be independently developed and validated by the accredited provider.

- **Target Audience and Audience Generation:** Proposal should describe the target audience(s) and provide a rationale for how and why this target audience is important to closing the identified healthcare gap. In addition, please describe methods for reaching the target audience(s) including description of and 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. The Sanofi and Regeneron Alliance 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 and efficacy 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:** The ACCME calls for educational methods that are 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 issues as they relate to the gaps in the knowledge, competence, or performance of the targeted audience. Education methods and design should be based on current literature in CME best practice and consistent with ACCME accreditation elements 3,4,5,6. 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. 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 detailed description of the approach to evaluate the reach and quality of program delivery; objective methods for monitoring individual activities and for ensuring ongoing quality improvements (Accreditation elements 12, 13, 14, 15). Describe methods that will be used to determine the extent to which the activity has served to close the identified healthcare gap. (Accreditation Elements 10, 11, 12), 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 of Moore level 4-6 that utilize at a minimum objective and tangible data measures (e.g.; matched pre-and post-tests) of knowledge gain/educational impact as outcomes methodologies.

- **Budget:** Include a detailed budget with rationale including breakdown of costs, clear explanation of the units, and calculations of:
  - Content cost per activity
  - Out-of-pocket cost per activity
  - Management cost per activity

- **Accreditation:** Programs must be accredited by the appropriate accrediting bodies and fully compliant with all ACCME criteria and Standards for Commercial Support™. If you are a non-accredited provider, the accredited provider must be involved from the concept origin, fully knowledgeable of the grant submission and documentation should be provided on the website grant application section entitled, “Other Information”.

- **Resolution of Conflict:** The proposal should briefly describe methods for ensuring fair and balanced content, identification and resolution of conflict of interest, with particular emphasis on ACCME criteria 7, 8, 9.

- **Communication and Publication Plan:** Provide a description of how the provider will keep the supporter informed of progress. Include description of how the results of this educational intervention will be presented, published or disseminated.
References:
1. CDC, NCHS. Underlying Cause of Death 1999-2013 on CDC WONDER Online Database, released 2015. Data are from the Multiple Cause of Death Files, 1999-2013, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. Accessed Feb. 3, 2015.