SANOFI US
Medical Affairs
Request for Proposal

Date: July 21, 2015
Disease State: Anaphylaxis
Therapeutic Area: Anaphylaxis
Area of Interest: RFP Response

Internal Requestor Information:
Name: William Daley
Title: VP Med Affairs Business Dev & Licensing, Specialized Therapeutics Group
Phone: 908-981-5464
E-Mail: William.Daley@sanofi.com
TAG ID: PL-AZ34K
Due Date: 09/08/2015

Health Care Gap
Anaphylaxis is a severe, potentially life-threatening medical emergency. Diagnosis and treatment of anaphylaxis are challenging since reactions are often unexpected, and progress rapidly.\(^1\) In the US, in 2012, 7.8 million children reported respiratory allergies.\(^3\) Increases in the prevalence of food allergy, the most common cause of anaphylaxis in community health settings, has been documented, particularly among children.\(^4-5\) About 25% of anaphylaxis reported at schools occurred in children with no previous diagnosis of food allergy.\(^6-7\)

It has been noted that anaphylaxis is often underdiagnosed and underreported.\(^8\) In the event that anaphylaxis is properly diagnosed, epinephrine administration is first-line treatment, according to guidelines.\(^3-10\) Delay or failure to administer epinephrine and lack of medical attention have contributed to many fatal anaphylaxis cases.\(^8-16\) However, guidelines are complex,\(^9-10\) and studies have shown inconsistent management of anaphylaxis in the emergency room.\(^17\) Diagnosis and treatment gaps persist for emergency physicians and primary care physicians, often on the front line in treatment for anaphylaxis.\(^16-18\)

Due to the nature of anaphylaxis, patients/caregivers often make initial judgments regarding recognition of signs and symptoms of anaphylaxis. Additional education is required for patients and caregivers to recognize symptoms of anaphylaxis and ensure appropriate administration of epinephrine.\(^16\) Patients with known prior anaphylactic events may not receive adequate education to develop preventive strategies or adequate preparation for future events.\(^16\) After an acute event, appropriate follow-up care and development of an emergency action plan may prove critical to successful management of severe allergy and may minimize fatal outcomes.\(^17\)

Clinical and scientific data regarding dosing and overcoming barriers to care continue to evolve.\(^19\) Additionally, novel epinephrine delivery systems may address auto-injection utilization errors and provide safe, effective treatment options.\(^18\) Due to the emergent nature of anaphylaxis, a synergistic approach to education and support is required to recognize the onset of anaphylaxis and enhance immediate, appropriate response from patients, family/community caregivers, emergency clinicians, as well as primary care and allergists.

SANOFI US is seeking proposals to close this independently defined healthcare gap: to advance knowledge in accurate diagnosis of anaphylaxis, treatment strategies, as well as to increase confidence and competence among emergency clinicians, primary care physicians, patients, and caregivers to optimize patient outcomes. The IME grant committee will consider independent medical education applications designed to close these gaps according to well-referenced learner preferences.
Single supported and multi-supported proposals will be considered, with a maximum request from Sanofi US not to exceed $150,000.

Please note that proposals are expected to include an analysis of the barriers and root causes for this gap and how the educational intervention would address this gap.

**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 (i.e., 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 rational 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. SANOFI 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:** 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 continuing education 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 description of the approach to evaluate the reach and quality of program delivery; methods for monitoring individual activities and for ensuring ongoing quality improvements (Accreditation elements 12, 13, 14). 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 4-6.25

- **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 Support16. **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.

2. World Health Organization. *White Book on Allergy 2011-2012 Executive Summary*. By Prof. Ruby Pawankar, MD, PhD, Prof. Giorgio Walkter Canonica, MD, Prof. Stephen T. Holgate, BSc, MD, DSc, FMed Sci and Prof. Richard F. Lockey, MD.


