Sanofi US Medical Affairs
Request for Proposal

Date: 23 August, 2017
Disease State: Diabetes
Therapeutic Area: Diabetes
Area of Interest: Long-acting insulins with a physiologic approach to glucose control
Geographic Scope: United States

Internal Requestor Information:
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Due Date: no later than 5pm EST, September 28, 2017
Submission Portal: https://sgrants.envisionpharma.com/vt_sgrants/
RFP Title (to include in request): Diabetes RFP 2017 Long-Acting Insulins - 1

The Health Care Gap Analysis:

An estimated 30.3 million people have diabetes in the United States with 90-95% of these patients having type 2 diabetes mellitus.1 The progressive nature of type 2 diabetes mellitus leads to the requirement for initiation and persistent use of basal insulin to reach and maintain glycemic targets.2,3
While insulin remains a therapeutic standard of care, with early initiation as well as cardiovascular safety clinically validated in the ORIGIN trial, delays in insulin initiation are well documented, and the resulting exposure to long periods of poor glycemic control are believed to impact the progression and severity of microvascular and macrovascular complications.3-9 Barriers to insulin initiation and its continued use include lack of clinician education/confidence in pharmacological management, insufficient patient education in self-management, lack of interdisciplinary support, poor patient adherence, fear of hypoglycemia, fear of injections/pain, weight gain and concerns regarding regimen flexibility.9-12

Many of the available basal insulins do not optimally mimic endogenous insulin secretion and these intrinsic inadequacies and inability to mitigate the barriers described above may contribute to their suboptimal use.13-15 Optimizing diabetes management is dependent upon balancing glycemic control and hypoglycemia.17 The fear of hypoglycemia specifically has been shown to impact compliance and persistence which in turn compromises clinical control.18 Improved pharmacokinetic/pharmacodynamic (pk/pd) profiles of the newer basal insulins designed to more closely mimic endogenous insulin secretion, with flatter profiles providing less glycemic variability, may address some of these challenges.13-16 Subsequent healthcare practitioner education on the attributes of these newer basal insulins, including special considerations for older adults, will be important to ensure appropriate application for individualized treatment plans and as required, appropriate conversion from previous insulin therapies.2,3,13,14,16

Sanofi US will consider accredited and/or patient directed educational proposals to close this independently defined healthcare gap.

Preference will be given to proposals that utilize appropriately designed interventions that are likely to enhance a learner’s knowledge and ability to overcome performance gaps and barriers (i.e. likely to enhance a practitioner’s performance in mitigating delayed insulin initiation, sequencing of treatment, titration and advancement of therapy to achieve A1c
goals, avoidance of adverse events such as hypoglycemia, and familiarity with newer basal insulins to ensure appropriate application/conversion).

Organizations such as AACE, ADA, ACP, and AADE have announced the possibility of satellite symposia for accredited educational activities during their 2018 annual meetings. Sanofi US will consider proposals for these live events with enduring activity. Furthermore, various other venues and educational formats (e.g. non-symposia) are eligible for consideration.

Providers seeking multi-support of activities will also be accepted.

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. 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.  

**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:**  


