

**Sanofi US Medical**  
**Request for Proposal**

<b>Date: 10 November 2021</b>	
<b>Disease State: Solid Organ Transplant</b>	
<b>Therapeutic Area: Solid Organ Transplant</b>	
<b>Area of Interest: Immunosuppressive Strategies to Reduce Transplant Rejection</b>	
<b>Geographic Scope: US - National</b>	
<b>Internal Requestor Information:</b>	
<b>Name:</b>	Cynthia Bocchino
<b>Title:</b>	Medical Education Lead
<b>Company:</b>	Sanofi US
<b>Phone:</b>	908-981-3157
<b>Email:</b>	Cynthia.bocchino@sanofi.com
<b>Due Date: <a href="#">5pm on 7 January 2022</a></b>	
<b>Submission Portal: <a href="https://sgrants.envisionpharma.com/vt_sgrants/">https://sgrants.envisionpharma.com/vt_sgrants/</a></b>	
<b>RFP Title (to include in request): 2022 IME SOT RFP</b>	

**The Health Care Gap:**

The Centers for Disease Control and Prevention (CDC) estimates that more than one in seven adults in the United States have end stage renal disease (ESRD).<sup>1</sup> The only treatment options for ESRD are dialysis or kidney transplant.<sup>1</sup> Unfortunately, with approximately 37 million people suffering from ESRD, the number of people in need of transplant outweighs the number of kidneys available.<sup>1-2</sup> The ones that are fortunate enough to receive a transplant kidney may lose this life-saving gift to rejection.<sup>2</sup>

Understanding patient and donor risks associated with the possibility of rejection is an important factor in developing an aggressive monitoring plan and determining appropriate induction therapy.<sup>2</sup> Knowledge of immunobiology, mechanisms of rejection and mechanisms of action of available immunosuppressants to target specific types of post-transplant rejection are needed to optimize long term immunosuppression strategies.<sup>2,4</sup> Of course, those who are sensitized to HLA provide even greater challenges.<sup>3</sup> A team approach also helps to optimize monitoring, inclusive of the patient, as patients also play a role in prevention and monitoring for transplant rejection.<sup>2,5-6</sup> Studies show that patients do not fully understand the process of transplantation as well as the importance of adherence to their medication regimen and suggest that more innovative ways may be needed to facilitate learning.<sup>5-6</sup>

Sanofi US is seeking educational proposals to help close these independently defined healthcare gaps to enhance knowledge across the transplant team, including patients, to improve graft survival.

Sanofi US seeks cross-collaborative multi-platform initiatives to address the above gaps:

- **Preference will be given to activities that collaborate with societies that specialize in transplant medicine (e.g., American Society of Transplantation (AST), American Society of Transplant Surgeons (ASTS), etc.) and/or participate in annual meetings that target transplant clinicians (e.g., American Transplant Congress, Cutting Edge of Transplant, etc.)**
- **Priority will also be given to activities that utilize innovative approaches to educate transplant clinicians and patients, to facilitate engagement and enhance learning (e.g., innovative series at transplant centers, virtual reality, augmented reality, simulations, infographics, etc.)**
- **Preference will be given to proposals that include measured outcomes (e.g., pre- & post-test knowledge, confidence, etc.)**

**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.<sup>7-9</sup> 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.<sup>10</sup>

- **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. *Chronic Kidney Disease in the United States, 2021*. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2019. Accessed November 2, 2021.
2. Naik RH, & Shavar SH. (2020) Renal transplantation rejection. *StatPearls*. Retrieved from: <https://www.ncbi.nlm.nih.gov/books/NBK553074/>
3. Sethi, S., Choi, J., Toyoda, M., Vo, A., Peng, A., & Jordan, S. C. (2017). Desensitization: Overcoming the immunologic barriers to transplantation. *Journal of immunology research*, Article ID 6804678. doi: <https://doi.org/10.1155/2017/6804678>
4. Malhotra, P. & Shapiro, R. (Ed.) ( 2019). Immunology of transplant rejection. *Medscape*. Retrieved from <https://emedicine.medscape.com/article/432209-overview#a4>
5. Trivedi P, Rosaasen N, & Mansell H. (2016). The health-care provider's perspective of education before kidney transplantation. *Prog Transplant*, 26(4), 322-327. doi:10.1177/1526924816664081
6. Rosaasen, N., Mainra, R., Shoker, A., Wilson, J., Blackburn, D., & Mansell, H. (2017). Education before kidney transplantation: What do patients need to know? *Progress in Transplantation*, 27(1), 58–64. doi: <https://doi.org/10.1177/1526924816685862>
7. 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
8. McMahon GT. Advancing Continuing Medical Education. *JAMA*. 2015; 314(6), 561-562. doi:10.1001/jama.2015.7094.
9. Mostofian F, Ruban C, et al.(2015). Changing physician behavior: What works? *AJMC*, 21(1), 75-84
10. Moore DE, Green JS, & Gallis HA . (2009). Achieving desired results and improved outcomes: Integrating planning and assessment throughout learning activities. *JCEHP*, 29(1),1-15.