

SANOI GENZYME and REGENERON Alliance
Medical Affairs
Request for Proposal

Date: May 1, 2017		
Disease State: Immunology		
Therapeutic Area: Rheumatoid Arthritis		
Area of Interest: Rheumatoid Arthritis		
Geographic Scope: Global (including US)		
Internal Requestor Information:		
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RFP Name: <i>Gbl RA RFP-WAD – 6/17</i>		
Due Date: June 14, 2017		
Submission Portal: https://sgrants.envisionpharma.com/vt_sgrants/		

Health Care Gap

Rheumatoid arthritis (RA) is a lifelong, systemic disease with articular and systemic manifestations resulting in a reduced life span and quality of life for patients who suffer physically, emotionally, and financially making early recognition and diagnosis imperative.¹ Healthcare providers treating RA patients must have a comprehensive understanding of the disease pathogenesis and the progression to best address their patient needs.

The American College of Rheumatology (ACR) and the European League Against Rheumatism (EULAR) have identified that targeting disease remission/low disease activity is a critical success factor in the management of RA.²⁻⁴ Reduction in disease activity correlates with reduction in patient symptoms (eg, joint pain, fatigue, morning stiffness), less articular destruction, improvement in systemic manifestations, reductions in long-term disability, reductions in premature mortality, improvements in health-related quality of life and work productivity, and reductions in societal spend.

Treatment regimens vary and carry important differences between therapeutic options that are clinically relevant to healthcare providers. An understanding of the pathogenesis of RA and the role of different treatment approaches, including current and emerging therapies, will assist healthcare providers in determining the best course of therapeutic management for optimal long-term patient outcomes.

However with all of the currently available non-biologic and biologic therapies, a high proportion of RA patients do not achieve clinical remission. The remaining patients can experience continuous disease progression and disability.⁵ In addition, many patients will have an inadequate response or can become intolerant to the widely used anti-TNF therapies. Consequently, the patient's health-related quality of life may continue to be significantly reduced. New and emerging treatment strategies may offer additional therapeutic options to address the unmet needs of these patients. Comprehensive understanding of existing therapies

as well as new data on emerging therapies and treatment recommendations, including real world evidence and its impact on clinical outcomes, may assist healthcare providers to determine the best treatment options for their RA patients, taking into consideration the unmet medical needs of each individual.

Call for Grants

The Sanofi Genzyme and Regeneron Alliance is seeking to close independently identified gaps for rheumatologists and their patients in the diagnosis, treatment, and ongoing management of rheumatoid arthritis. Web-based educational proposals encompassing the spirit of World Arthritis Day, October 12, 2017, will be considered. Proposals should address important medical education gaps. The following are some gaps identified by Sanofi Genzyme and Regeneron:

1. Recognition of unmet medical needs and lack of disease control in RA patients to better develop treat-to-target strategies
2. Awareness of treatment approaches to optimize RA patient outcomes
3. Identify appropriate RA patients and clinical scenarios suited for initiation of targeted and biologic DMARDs
4. Analyze therapeutic options when individualizing RA treatment strategies, including efficacy and safety profiles, as well as tolerance and adherence issues
5. Educate on the systemic nature of RA, the full spectrum of RA manifestations and disease progression

Various distribution channels and online educational formats designed for engagement by a global audience, including US-based HCPs, are eligible. Single supported and multi-supported proposals will be considered with a maximum request not to exceed \$350,000.

Please note that proposals are expected to include an analysis of educational gap(s) and how the proposed intervention(s) would address the gap(s). 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.

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, if appropriate.
- **Target Audience and Audience Generation:** Proposals 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 Genzyme

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 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 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.^{6,7,8} 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, 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 4-6.⁹
- **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

Single supported and multi-supported proposals will be considered, with a maximum request not to exceed \$350,000. Please select "Gibl RA RFP-WAD – 6/17 " from the RFP dropdown panel within the grant portal upon submitting your applicant for this RFP.

- **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 nonaccredited 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. van Hoogmoed D et al. *Rheumatology (Oxford)*. 2010 Jul;49(7):1294-302. doi: 10.1093/rheumatology/keq043. Epub 2010 Mar 29.
2. Smolen JS et al *Ann Rheum Dis*. 2014 Mar;73(3):492-509. doi: 10.1136/annrheumdis-2013-204573. Epub 2013 Oct 25.
3. Aletaha D, Neogi T, Silman AJ, et al. *Ann Rheum Dis* 2010;**69**:1580-1588 doi:10.1136/ard.2010.138461
4. Singh, JA et al. *Arthritis Care Res (Hoboken)*. 2015 Nov 6. doi: 10.1002/acr.22783. [Epub ahead of print]
5. Hetland ML et al. *Arthritis Rheum*. 2010 Jan;62(1):22-32. doi: 10.1002/art.27227.
6. Davis, D., Barnes, B.E., Fox, R., *The Continuing Professional Development of Physicians* ed. R.t. Practice. 2003, Chicago, IL: AMA.
7. Davis, D., et al., Impact of formal continuing medical education: do conferences, workshops, rounds, and other traditional continuing education activities change physician behavior or health care outcomes? *JAMA*.1999. 282(9): p. 867-74.
8. AHRQ, Effectiveness in Continuing Medical Education, in Evidence Report No. 149. 2007.
9. Moore, D.E., Jr., J.S. Green, and H.A. Gallis, Achieving desired results and improved outcomes: integrating planning and assessment throughout learning activities. *J Contin Educ Health Prof*. 2009.29(1): p. 1-15