



I. Background:

Alnylam Pharmaceuticals, Inc. (Alnylam) is committed to supporting innovative, high-quality, independent medical education for healthcare professionals (HCPs) to address unmet educational needs, maintain clinical excellence, and increase HCP healthcare competence, ultimately leading to improved outcomes in the patient communities that Alnylam serves.

The intent of this Request for Grant Proposal (RGP) announcement is to notify experienced, eligible medical education providers that Alnylam is interested in receiving requests for independent medical education activities pertinent to Alnylam's areas of interest and aligned to the specifications outlined below. "Independent" means that activities are solely the responsibility of the recipient organization and Alnylam has no influence over any aspect of the activity.

Such independent medical education activities must be based on the identified professional practice gaps and educational needs of HCP learners, utilize instructional design in the planning and evaluation, be evidence-based in the aim to improve the care of patients, and must offer continuing education (CME/CE) credit. Maintenance of Certification (MOC) is encouraged, but not required. Medical education providers must adhere to relevant laws, codes, regulations, accreditation criteria, industry standards, and should align with best practices in continuing education in the health profession.

II. Grant Proposals must include the following information:

1. **Gap Analysis/Needs Assessment:** Include a comprehensive gap analysis/needs assessment that is well referenced and adequately establishes that the program is needed to benefit patient care, knowledge, or other public health objectives. The requestor must demonstrate a thorough understanding of the specific gaps and barriers of the target audience(s), delineating when applicable. The requestor must develop and validate the gap analysis/needs assessment independently of Alnylam. Gaps and needs must be distinguished from each other, and from root causes. The requestor should identify any potential barriers to healthcare professional (HCP) practice change and how these barriers will be addressed within the educational initiative.
2. **Target Audience and Audience Recruitment:** The requestor should describe the target audience(s) and provide a rationale for how and why this target audience(s) is important to closing the identified healthcare gap. In addition, please describe the methods for reaching the target audience(s), including a description of and rationale for recruitment and placement strategies to maximize participation based on need. Any unique recruitment efforts specific to the target audience should be highlighted. When describing how many individuals the activity will reach, focus should be made on those who complete the activity, not just those who are aware of the activity.
3. **Learning Objectives and Content Accuracy:** Provide clearly defined, SMART (specific, measurable, achievable, relevant, timely) learning objectives that outline what the learner will be able to know, know how to do, or do in practice as a result of attending this activity. Learning objectives should be distinct from educational objectives. Include an overview of program content and explanation of criteria that will guide content selection, considering level of evidence and other variables. The requestor must design the activity so that it is free of commercial bias for or against any product; any product discussions are objective, balanced, and



scientifically sound; and any discussion of uses of a drug that have not been approved by the FDA are identified as such. The requestor should explain how content will be updated, if necessary, throughout the activity period and how accuracy will be ensured.

4. **Educational Design:** Proposed educational methods should be selected based on the professional practice gaps and educational needs of the target audience(s) and be linked to clinical practice, utilizing instructional design and best practices in adult learning principles. Methods should be designed to change HCP competence, performance, and/or patient outcomes. Educational design must be interactive and consider appropriate target audience and learning preferences.²⁻³ Use of technology to enhance learner engagement, reinforcement, and retention is encouraged.⁴ Innovation in educational design is preferred, as well as methods that keep the learner engaged throughout the entire activity.
5. **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 faculty are fully trained in the activity expectations and any skills that may be needed to ensure effective delivery of intended education. Do not include faculty names in the proposal. Please also include the honoraria and reimbursement policy.
6. **Activity Evaluation and Outcomes Reporting:** Provide a description of how the activity will be evaluated against objectives and reported, and set out the metrics for how outcomes will be measured to assess the reach and quality of activity delivery. Descriptions should include how the healthcare gap was closed and how the intended outcomes level was achieved. Describe how outcomes will be utilized to plan future educational interventions. If utilizing multiple choice questions to assess learners, utilization of best practices in item writing, including rationales, is strongly encouraged.
7. **Budget:** Include a detailed budget, with a breakdown of costs for each line item, clear explanation of the units, and how Alnylam funds will be allocated for each of the line items. Budget costs should be reasonable and customary, within fair market value, proportionate to the type and length of activity, and in compliance with applicable laws, codes, and regulations. Include any information on support from other sources, such as additional commercial support, exhibit and advertising income, and registration fees. Final reconciliation of the budget is also due at the conclusion of the funded activity.
8. **Accreditation:** Requestors should provide proof of accreditation status in good standing. Further, activities must be accredited by the appropriate accrediting bodies and fully compliant with all standards and criteria, including the ACCME Standards for Commercial Support: Standards to Ensure the Independence of CME ActivitiesSM. If the activity is jointly provided, the accredited provider must be involved from the concept origin and fully knowledgeable of all contents of the grant submission, and documentation should be provided on the relationship between the accredited provider and non-accredited educational partner.
9. **Identification and Resolution of Conflicts of Interest:** The request should clearly describe methods for ensuring fair and balanced content, identification and resolution of conflicts of interest, and how the activity will remain free from commercial bias and utilize all available sources of data.
10. **Disclosure:** The request should include a description of how the provider a) discloses relevant financial relationships for all individuals in control of content, and b) discloses educational grant support for this activity.



11. **Sustainability and Replicability:** Describe specific plans to broadly disseminate the proposed activity's results and ensure sustainability beyond the funding program. Explain how the proposed activity could be replicated in other geographic regions or to address other types of audiences.
12. **Reporting:** Please specify the descriptive and evaluative reporting of activity results that you will provide. Reports are required every 6 months (if enduring material) and a detailed final outcomes report is due at the conclusion of the funded activity. Final reconciliation of the budget is also due at the conclusion of the funded activity.

III. Selection Criteria:

Requests will be evaluated on:

- Ability to meet all elements in submission
- Well defined and researched gap analysis/needs assessment that specifies current practice gaps of identified learners within the educational focus indicated
- Requestor's knowledge of and experience within the therapeutic area and disease state
- Proposed activity structure and delivery options
- Linkage of educational needs to specific, achievable, and measurable learning objectives
- Incorporation of adult learning principles and instructional design method, interaction, and innovation in the educational format that reflects the preferred learning styles of the target audience
- Outcomes measures that are in alignment with learning objectives and educational format, utilizing best practices in assessment methods
- Rigor of mechanisms in place to validate content and resolve identified conflicts of interest, including review and revision of content as necessary to ensure a balanced view of therapeutic options and elimination of commercial bias
- Compliance with guidelines and regulations related to CME/CE or other local governance related to medical education
- Fiscal responsibility and fair market value
- Sustainability and replicability of initiative

Preference will be given to proposals that have or will seek funding from multiple sources.



IV. Scope:

RGP Number	ALNY-ME-REGP-3a
Posting Date	September, 2019
Submission Deadline	Due by November 5, 2019. Requests received after that date will not be considered. Requestors will be notified no later than December 16, 2019. Review is prioritized based on date of receipt, ability to meet required elements, and available budget.
Applicant Eligibility	<p>Professional associations dedicated to gastroenterology and/or motility, medical, nursing, allied health, and/or pharmacy professional schools, healthcare institutions, and other organizations committed to healthcare improvement are all encouraged to apply.</p> <p>Inter-professional development within institutions and collaboration between educational providers are encouraged. Please note that all educational partners must have an inclusive role and the requesting organization must have a key role in the development and implementation of the activity.</p> <p>For activities that are accredited to provide continuing education credit of any kind, the accredited provider must be the entity that submits the grant request.</p> <p>Individuals (such as individual healthcare providers), healthcare provider practice groups, healthcare provider-owned clinics, managed care organizations, and pharmacy benefit managers are prohibited from applying for this grant.</p>
Therapeutic Areas	Hereditary Transthyretin Amyloidosis (hATTR)
Educational Focus	<p>Differential Identification of Rare Causes of Motility Disorders</p> <p>Vomiting, nausea, early satiety, fecal incontinence, diarrhea and constipation are all common symptoms for which patients present to PCPs and gastroenterologists alike. While most instances are isolated and transient, persistent symptoms, especially in combination, are more complex to manage. On occasion, such symptoms can be attributed to common conditions (gastroenteritis, gastroparesis, gastric ulcer, GERD) or may be structural in nature (in the case of fecal incontinence); however, many times the underlying causes are not easily understood, leading physicians to consider various functional diagnoses and diagnoses of exclusion such as irritable bowel syndrome or chronic idiopathic constipation. Other rare causes for these conditions can be easily overlooked, leading to misdiagnosis.</p> <p>Hereditary TTR amyloidosis (hATTR) is a rare, autosomal dominant genetic disease, traditionally characterized by a combination of polyneuropathic and/or cardiac complications. However, gastrointestinal symptoms like those mentioned above are a</p>



	<p>common and often overlooked complication of hATTR, which may predate the onset of neuropathic symptoms.</p> <p>As such, patients in the early stages of hATTR often go undiagnosed. Helping health care providers recognize the early constellation of hATTR symptoms will raise clinical suspicion for more accurate diagnoses, and ultimately more timely intervention.</p>
Geographic Scope	United States
Target Audience	Gastroenterologists, motility experts and advanced practice providers who encounter patients with persistent or worsening GI conditions such as vomiting, nausea, early satiety, fecal incontinence, diarrhea and constipation. Multidisciplinary and/or interprofessional education that focuses on the healthcare team is encouraged.
Educational Format	<p>A wide range of activity types will be considered through this RGP, including live activities, sessions within an agenda, satellite symposia, workshops, and/or online enduring materials.</p> <p>Submissions should include interactive strategies, incorporate patient case discussions, and provide opportunities to enhance change and reinforce learning. Innovation in educational delivery is preferred.</p>
Available Support	Individual requests up to \$75,000 will be considered for funding. The amount of the grant funded may vary from the amount requested. Therefore, Alnylam encourages submission of grant requests with multiple sources of funding support, including registration fees or other funding allocations.
Outcomes Measures	Moore's Level 4 Outcomes ¹ are expected. Proposed outcomes that do not align with the learning objectives and educational format will not be given preference.
Submission Directions	<p>Requests will be accepted from accredited CME/CE providers in good standing (e.g. ACCME, ANCC, ACPE, etc.).</p> <p>Requests must be submitted through alnylam.com/grants and include all attachments that align with the conditions above in Section II.</p>
Contact Information	For questions about this RGP, please direct them in writing to the Alnylam Grants and Giving office at grants@alnylam.com with the subject line "{Name of RGP and Date}". Failure to communicate directly with grants@alnylam.com may result in disqualification.
Notification	<p>All applicants will be notified by email of a decision.</p> <p>Applicants may be asked for additional information or clarification as needed during the review period.</p>



Terms and Conditions:

1. Alnylam reserves the right to not review incomplete applications.
2. This RGP does not commit Alnylam or its affiliates to award a grant of any size, nor to pay any costs incurred in the preparation of a response to this request. Alnylam reserves the right not to fund any request. No grant has been awarded until a formal grant agreement has been fully executed between Alnylam and the applicant organization(s).
3. Alnylam reserves the right to accept or reject any or all applications received as a result of this request, or to cancel this RGP in part or in its entirety.
4. Alnylam adheres to all applicable transparency laws, codes, and regulations, and, as a result, will appropriately report funding from any awarded grant in accordance with the foregoing. Alnylam may require receipt of required information in a certain format from applicant organization(s) in order to facilitate such reporting.
5. Alnylam reserves the right to verify all information provided by an organization in its grant application.
6. In fairness to all requestors, all communications about grants must come exclusively to Alnylam's Grants and Giving office at grants@alnylam.com. Failure to comply may disqualify applicants.

References:

1. Moore D., Green J., & Gallis H. (2009). Achieving desired results and improved outcomes: Integrating planning and assessment throughout learning activities. *JCEHP*, 29(1), 1-15
2. McMahon G. (2015). Advancing continuing medical education. *JAMA*, 314(6), 561-562. doi:10.1001/jama.2015.7094
3. Mostofian F., Ruban C., Simunovic, N. & Bhandari, M. (2015). Changing physician behavior: What works? *AJMC*, 21(1),75-84.
4. Cervero R. & Gaines J. (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