



Transthyretin Amyloidosis (ATTR) – Clinical implementation of best practices to optimize patient care

Posted August 17, 2022

I. BACKGROUND

Alnylam Pharmaceuticals, Inc. (Alnylam) is committed to supporting innovative, independent projects that address unmet educational needs and are intended to improve outcomes in the patient communities that Alnylam serves.

Alnylam publicly posts Requests for Proposals (RFP) that are focused on a specific area of interest and establishes timelines and other requirements for receipt and review. All proposals are the sole responsibility of the requesting organization, and Alnylam has no influence over any aspect of the project.

NOTE: The RFP process is separate from the Alnylam review and approval pathway for investigator-initiated studies (IIS). To submit an IIS request, please refer to <https://www.alnylam.com/about-alnylam/investigator-initiated-studies/>.

All organizations carrying out Alnylam-supported projects must adhere to the below terms and conditions as well as relevant laws, codes, and regulations.

II. ELIGIBILITY

<p>Applicant Eligibility</p>	<p>Professional associations, patient advocacy organizations, healthcare institutions, medical education companies and other organizations committed to healthcare improvement may apply.</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> <p>Medical education providers must be Accreditation Council for Continuing Medical Education (ACCME)-accredited, and the requestor must be the accredited provider.</p>
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III. SCOPE

<p>RFP Number (include on all documents)</p>	<p>ALNY-RFP-TTR-12</p>
<p>Issue Date</p>	<p>August 17, 2022</p>
<p>Submission Deadline</p>	<p>October 21, 2022</p>
<p>Notification Date</p>	<p>November 9, 2022</p>
<p>Therapeutic Area</p>	<p>Transthyretin Amyloidosis (ATTR)</p>

Educational Focus	<p>Overall Educational Focus</p> <p>Transthyretin Amyloidosis (ATTR) - Addressing existing knowledge gaps in the awareness and understanding of ATTR amyloidosis that enables and enhances patient diagnosis, prognosis, management, and ongoing assessment of disease burden. Strong consideration will be given for programs that effectively translate educational content into real-world operationalization within relevant clinical settings.</p> <p>Potential Areas of Focus Could Include:</p> <ul style="list-style-type: none"> • The real-world development and implementation of various clinical decision modalities supporting recognition, accurate diagnosis with multi-system workup and assessing / addressing ongoing disease burden. Some examples are EMR-based technologies, multi-disciplinary teams, and cross-specialty referral networks. • Real-world implementation of recent guidelines and expert consensus on assessing and addressing ongoing disease burden through post-diagnostic monitoring of disease course with focus on performing and interpreting assessments with both high clinical utility and high clinical feasibility (e.g., standard clinical and functional assessments, patient reported outcomes, imaging, and biomarkers) in a typical clinical practice setting. • Information on up-to date management options <p>Program should also provide:</p> <ul style="list-style-type: none"> • Pre- and post-assessments of program efficacy • Enduring accessibility (hosted or links) to references and associated clinical materials (algorithms, guidelines, etc.) • Publicly accessible, HCP-gated, work-product (e.g.: comprehensive PowerPoint slides, videos, etc.) for use by HCPs in building other independent (non-accredited) educational programs
Preferred Launch Date for Educational Content	February 20, 2023
Geographic Scope	U.S.
Target Audience	Specialists that may manage ATTR or have an interest in the disease, including: <ul style="list-style-type: none"> • Cardiologists or cardiology nurse practitioners, Nuclear cardiologists, echocardiographers, cardiac imaging specialists • Neurologists or neurology nurse practitioners, electromyographers (EMG) • Clinical pharmacists with a focus on neurology and/or cardiology
Funding Budget	Individual requests up to \$150,000 USD 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.

IV. Proposal Guidelines

Gap Analysis/Needs Assessment	<p>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.</p> <p>Identify any potential barriers to healthcare professional (HCP) practice change and how these barriers will be addressed within the educational initiative.</p>
Target Audience	<p>Describe the target audience(s) and provide a rationale for why this target audience(s) is important to closing the identified healthcare gap.</p>
Audience Recruitment	<p>Describe the methods for reaching the target audience(s), including a description of recruitment and placement strategies to maximize participation based on need.</p>
Learning Objectives	<p>Provide clearly defined, SMART (specific, measurable, achievable, relevant, timely) learning objectives for learners as a result of attending this activity.</p>
Content Accuracy	<p>Include an overview of program content and explanation of criteria that will guide content selection.</p> <p>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.</p> <p>Explain how content will be updated, if necessary, throughout the activity period and how accuracy will be ensured.</p>
Educational Design	<p>Proposed educational methods should be selected based on the professional practice gaps and educational needs of the target audience(s).</p> <p>Educational format must be interactive and consider appropriate target audience and learning preferences. Use of technology to enhance learner engagement, reinforcement, and retention is encouraged.</p>
Faculty Recruitment	<p>Provide information on the expected qualifications of contributors and description of methods to ensure recruitment of course directors and faculty who meet the qualifications.</p>
Activity Evaluation and Outcomes Reporting	<p>Provide a description of how the activity will be evaluated against objectives and reported.</p>
Budget	<p>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.</p> <p>Budget costs should be reasonable and customary, within fair market value, and proportionate to the type and length of activity. Grant funds may not be used for meals for attendee HCPs.</p>
Accreditation	<p>Provide proof of accreditation status in good standing.</p> <p>Activities must be accredited by the appropriate accrediting bodies (e.g., ACCME) and fully compliant with all standards and criteria, including the ACCME Standards for Commercial Support: Standards to Ensure the Independence of CME Activities.</p>

	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.
Identification and Resolution of Conflicts of Interest	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.
Disclosure	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.
Sustainability	Describe specific plans to broadly disseminate the proposed activity's results and ensure sustainability beyond the funding program.
Honoraria Policy	Provide documentation that describes the honoraria and reimbursement policies.
Project Timeline	Provide a detailed timeline that includes but is not limited to dates for development, launch, interim report, and final report.

V. DIRECTIONS FOR SUBMISSION

Submissions	Requests must be submitted through Alnylam's grant portal https://alnylam-grants.steeproclinc.com or through Alnylam's corporate website: https://www.alnylam.com/about-alnylam/grants-and-giving
Contact Information	Direct questions about this RFP to grants@alnylam.com
Notification	All applicants will be notified by email of a decision.

VI. TERMS AND CONDITIONS

1. Alnylam may request supplemental information from applicants, and Alnylam reserves the right to reject incomplete applications.
2. This RFP 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 RFP 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 related to this grant, when and as required.
5. Alnylam may require receipt of required information in a certain format from recipient organization(s) in order to facilitate disclosure reporting.
6. Alnylam reserves the right to verify all information provided by an organization in its grant application.
7. Only the Grants and Giving Office is authorized to provide information related to this RFP. Please contact the office at grants@alnylam.com.