



Alnylam- Request for Proposal



Identifying and evaluating patients at high risk of monogenic kidney stone disorders including Primary Hyperoxaluria Type 1
Posted: June 22, 2020

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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.

All Alnylam-supported projects must adhere to 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 ACCME-accredited, and the requestor must be the accredited provider.</p>
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III. 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.</p>
Accreditation	<p>Provide proof of accreditation status in good standing.</p>

	<p>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 Activities</p> <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.</p>
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.

IV. SCOPE

RFP (REGP) Number (include on all documents)	ALNY-ME-RFP-7
Issue Date	June 22, 2020
Submission Deadline	August 14, 2020
Notification Date	September 11, 2020
Therapeutic Area	Primary hyperoxaluria type 1 (PH1)
Educational Focus	<p>Identifying and evaluating patients at high risk of monogenic kidney stone disorders including Primary Hyperoxaluria Type 1</p> <p>Primary hyperoxaluria type 1 (PH1) is a rare genetic disorder characterized by persistent hepatic overproduction of oxalate, a renally excreted metabolite, which crystalizes with calcium, forming insoluble in urine. These toxic crystals accumulate, causing recurrent kidney stones, nephrocalcinosis, progressive renal failure, and multiorgan damage from systemic oxalosis once the disease advances. Current treatments include hyperhydration, crystallization inhibitors, and a dual liver/kidney transplant to treat the disease. Additional pharmaceutical treatments are in development.</p> <p>Prior to receiving a formal genetic diagnosis, PH1 patients present with non-specific symptoms including hematuria, abdominal pain, urinary tract infection, dysuria, and kidney stone passage. More specifically, the following symptoms are seen across age ranges:</p> <p>Infancy: Nephrocalcinosis, renal impairment, failure to thrive, urinary tract infection, ESKD</p>

	<p>Childhood: Renal colic, hematuria, urinary tract infection, recurrent urolithiasis, nephrocalcinosis, bilateral obstruction with acute renal failure</p> <p>Adulthood: Mild-to-moderate reduction in kidney function, acute renal failure, CKD, ESKD, recurrent kidney stones, nephrocalcinosis</p> <p>These non-specific symptoms are present in common conditions including kidney stone disorder due to diet or dehydration, causing physicians and patients to overlook monogenic conditions as the root cause of their condition. Because of the low suspicion for PH1, patients often have disease for over 5 years before they receive a formal diagnosis. Publications show that an earlier diagnosis can result in a better disease course by instituting hyperhydration and other supportive measures.</p> <p>Therefore, we identify a need to help physicians understand the symptoms, diagnostic framework, and management of monogenic kidney stone disorders including genetic causes like PH1.</p> <p>The objective of the program will be:</p> <ul style="list-style-type: none"> • Educate on clinical diagnosis and advances in management of monogenic kidney stone disorders including dent, cystinuria, and PH1 • HCPs understand consensus diagnostic guidelines for monogenic kidney stones, including for hyperoxaluria <p>Preference will be given to programs that:</p> <ul style="list-style-type: none"> • Can be launched no later than December 10 • Are virtual with enduring material • Incorporate a case-based approach
Geographic Scope	U.S.
Target Audience	<ul style="list-style-type: none"> • Pediatric nephrologists • Adult nephrologists interested in kidney stone disorders • Urologists • Advance practice clinicians in the field of nephrology and urology
Funding Budget	Individual requests up to \$100,000 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.

V. DIRECTIONS FOR SUBMISSION

Submissions	Requests must be submitted through Alnylam’s grant portal https://alnylam-grants.steeproekinc.com or through Alnylam’s corporate website: https://www.alnylam.com/about-alnylam/grants-and-giving/independent-medical-education-programs/
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 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 applicant organization(s) in order to facilitate disclosure reporting. Alnylam may require receipt of required information in a certain format from applicant organization(s) in order to facilitate such 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.