

**INSMED CALL FOR MEDICAL EDUCATION GRANT APPLICATIONS (CGA):
NONTUBERCULOUS MYCOBACTERIAL LUNG DISEASE (NTM-LD)**



Insmmed is committed to transforming the lives of patients with serious rare lung diseases through funding independent education programs that advance the clinical knowledge, competence, and performance of healthcare providers. This may ultimately lead to improved health outcomes in patients with these diseases and a better overall health status in the patient community.

Insmmed issues Calls for Medical Education Grant Applications (CGAs) as an additional method to notify organizations that grant funding is available for specific programs and focus areas where Insmmed has identified an unmet need addressable through education. Insmmed CGAs are publicly posted on the Alliance for Continuing Education in the Health Professions (ACEHP) website for Request(s) for Proposal (RFP), Call for Grants Notification (CGN) and CGA opportunities:

- <https://www.acehp.org/Resources/RFP-CGN-and-CGA-Opportunities>

Please refer to <https://insmed.com/culture/responsibility/grants-funding/> for medical education grant submission requirements. For additional questions about this CGA funding availability or general questions about grant processes please contact Insmmed Medical Education at grants@insmed.com.

Insmmed will have funding available to support independent medical education that reaches national audiences through Medical/Academic Society conferences and enduring programs. Insmmed is interested in receiving grant requests that align with the specifications outlined below.

Therapeutic area	Nontuberculous Mycobacterial Lung Disease (NTM-LD)
Educational format & scope	Independent medical education that addresses the needs of clinicians and researchers who have a role in the diagnosis and treatment of patients with NTM-LD who work in the pulmonology and infectious disease therapeutic areas to include live, online/enduring, or multiple components (where in-person programs may not be possible). Preference will be given to engaging and unique educational designs 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. Accreditation Council for Continuing Medical Education (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.
Meetings of interest	In addition to the educational programs above, proposals for independent satellite symposia at meetings, including, but not limited to the following, will be considered: <ul style="list-style-type: none"> • ERS 2023 • CHEST 2023 • ID WEEK 2023 • ATS 2024 <p>Hybrid participation for live programs (live simulcasts, enduring webcasts, etc.) to engage the greatest number of learners is preferred, if possible.</p>

Submission deadline	<table border="1" data-bbox="370 243 1451 415"> <thead> <tr> <th data-bbox="370 243 532 327">Focus</th> <th data-bbox="532 243 818 327">Insmmed Submission deadline</th> <th data-bbox="818 243 1451 327">Important deadline</th> </tr> </thead> <tbody> <tr> <td data-bbox="370 327 532 415">NTM-LD</td> <td data-bbox="532 327 818 415">November 22, 2022*</td> <td data-bbox="818 327 1451 415">Ensure submission at least 60 days before funding commitment is needed</td> </tr> </tbody> </table> <p data-bbox="370 428 1479 491">If your organization plans on submitting requests for more than one activity (live and/or enduring), please structure the proposal(s) to ensure:</p> <ul data-bbox="418 504 1479 604" style="list-style-type: none"> • Deadlines can be met • Cost efficiencies are clear –budget summaries should be included for each activity • Rationale/justification is clear, including relevance to potentially different audiences <p data-bbox="370 651 1479 714">*Insmmed accepts grant applications on a rolling basis. This deadline is strongly suggested for programs that begin in Q1 2023.</p>	Focus	Insmmed Submission deadline	Important deadline	NTM-LD	November 22, 2022*	Ensure submission at least 60 days before funding commitment is needed
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NTM-LD	November 22, 2022*	Ensure submission at least 60 days before funding commitment is needed					
Accreditation	Grant requests must adhere to any Medical/Academic/Scientific Society requirements regarding accreditation, if applicable.						
Budgets	When submitting detailed budgets please clearly differentiate out-of-pocket costs (i.e. direct cost) from management fees, management cost per activity, content cost per activity, and note optional costs. Please include costs associated with the continuous marketing of the enduring program and recruitment of learners throughout the posting of the enduring program. Organizations may use their own template or request a form from Insmmed.						
Intended audience	Education should address the needs of clinicians and those who have a role in the diagnosis and treatment of patients with NTM-LD, including, but not limited to, pulmonologists, infectious disease (ID) specialists (MDs, NPs, PAs and ID pharmacists) and advanced practice providers (NPs and PAs). <i>Intended audience regions should <u>only</u> include USA and/or Europe.</i>						
Areas of educational focus	<ol data-bbox="418 1155 1479 1759" style="list-style-type: none"> 1. Increase awareness of NTM-LD, associated patient risk factors/symptoms, underlying conditions (e.g., bronchiectasis) and approaches to reduce time to diagnosis and initiation of guidelines-based treatment. 2. Encourage discussion of development of individualized treatment goals based on patient factors and communication and explanation of diagnosis and treatment to patients. 3. Discuss examination of evidence and guidelines-based strategies to managing medication adverse events, adherence, and completion to improve treatment outcomes, as well as potential ways to improve efficacy and decrease drug-related toxicity. 4. Increase communication of best practices in NTM-LD current treatment including airway clearance, medication optimization, multidisciplinary approach, susceptibility testing, repeated cultures, guidelines-based duration of treatment, medication adherence, and adverse event management. 5. Assess evaluation of recent or emerging data on NTM-LD burden of illness and treatment with discussion on relevance to practice (e.g., new/revised guidelines, registry output, patient outcomes and/or research from epidemiology, health outcomes, or clinical studies). 						
Outcomes measures	Moore’s Level 4 (competence) outcomes will be the minimum expected. (Moore et al. <i>Achieving desired results and improved outcomes: integrating planning and assessment throughout learning activities</i> . JCEHP. 2009; 29 (1):1-15.)						

Needs Assessment and Healthcare Gap

Note: *It is expected that any education provider submitting a grant application conduct their own independent needs assessment when identifying gaps in patient care and learning objectives that aim to reduce those gaps.*

Background/Disease Burden

Nontuberculous mycobacteria (NTM) are opportunistic environmental pathogens that may lead to chronic and progressive lung disease (NTM-LD) in susceptible patients with certain underlying conditions such as structural lung disease, immune system deficiencies, and other host characteristics (Prevots 2015; Park 2016). While the virulence and geographic distribution of NTM species is highly variable, *Mycobacterium avium* complex (MAC) is most commonly associated with NTM-LD (Prevots 2015; Adjemian 2012; Daley 2017). Epidemiologic studies have reported a rise in the prevalence of NTM-LD globally, raising public health concerns (Adjemian 2012; Prevots 2015; Ali 2021).

NTM-LD is associated with significant clinical burden including impaired quality of life, as well as increased morbidity and mortality (Yeh 2014; Marras 2017; Mehta 2011). Most patients have moderate to severe disease at the time of diagnosis, and it is not uncommon for patients to experience significant delays in diagnosis due to a low recognition of risk factors (Khan 2010; Kotilainen 2015). Low index of suspicion, and delays in diagnosis and initiation of treatment may lead to a cycle of worsening structural lung disease and further susceptibility to destruction of lung tissue by NTM (Faverio 2016; Park 2016; Yeh 2014). Primary care providers should be educated to recognize the symptoms that may indicate NTM-LD such as unremitting cough and recurring pneumonias. NTM-LD prevalence has now surpassed tuberculosis in the US (Adjemian 2012; Winthrop 2017).

Unmet Medical Need

The 2007 ATS/IDSA guidelines (Griffith 2007) have been superseded by more recently published guidelines (Daley 2020) and outline the current standards of diagnosis, management, and treatment of NTM-LD. In a joint editorial published in CHEST, Griffith and Daley opined that the process of critically reviewing NTM medical literature could lend itself to the creation of a “living document” that could expedite the incorporation of important studies into guideline changes (Griffith and Daley 2022). For reasons that are unclear, adherence to guideline-based therapy amongst practitioners is poor perhaps due to low confidence in the data reported by small studies or in their own expertise (Ku 2022). Diagnosis is confirmed through clinical, radiographic, and microbiologic criteria that distinguishes colonization from infection. Once diagnosed, the decision to treat is complex and is dependent on clinical burden, patient factors, and disease severity (Griffith 2007; Daley 2020).

There are limited clinical trial data in NTM-LD, and only one FDA approved drug indicated for refractory NTM-LD (Flume 2021). Both the antibiotic susceptibility profile of the specific pathogen causing infection, as well as the individual patient’s tolerability for medications with known toxicity profiles, require clinical consideration and potentially medication adjustments to maximize clinical outcomes (Griffith 2007; Griffith 2012; Swenson 2020; Daley 2020). Both antibiotic and nonantibiotic treatments are currently being investigated, with no less than 80 NTM studies listed on ClinicalTrials.gov as of October 27, 2022.

Even with good adherence to guideline-based therapy, a significant number of patients have refractory disease or recurrence of NTM following sputum conversion (Wallace 2014; Miwa 2014). Real world evidence indicates that a majority of patients receive inadequate non-guideline-based therapy or require medication adjustments/discontinuation due to toxicity, putting them at risk for refractory and/or antibiotic resistant disease (Adjemian 2014; Wallace 2014). Ultimately, patients with NTM-LD who fail treatment have limited options (Griffith 2012) and are at greater risk for rapid decline in lung function and higher mortality compared with those who achieve culture conversion (Griffith 2012; Park 2016; Jenkins 2008). Patient-centered research priorities to improve screening

and earlier diagnosis of NTM-LD, and subsequently improve patient outcomes have been identified by clinical experts and the FDA (Henkle 2016; CDER 2016).

Selection Criteria

Grant requests are reviewed and prioritized for funding based on the following:

- Educational need and plan to deliver the educational activity to the intended audience
- Learning objectives that are achievable and align with the educational need and areas of focus
- Experience in designing educational programs and assessing the effectiveness of the activity
- Extension of the reach and accessibility of educational content by including plan to present, publish or use QR codes, if applicable
- Inclusion of patient(s) in development of application and/or activity or as faculty, speaker or panelist preferred
- History of timely provision of final budget reconciliation and outcomes reports in the desired format, if applicable
- Complete budget as requested above
- Accreditation and compliance with ACCME Standards for Commercial Support
- Compliance with Insmmed policies and procedures

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