# insmed

Insmed is committed to improving the lives of patients with serious rare lung diseases through funding independent education programs that advance clinical knowledge, competence, and performance among 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.

Insmed issues Calls for Medical Education Grant Applications (CGA) as an additional method to notify organizations that grant funding is available for specific programs and focus areas where Insmed has identified an unmet need addressable through education. Insmed CGAs are publicly posted on the ACEHP website for RFP, CGN and CGA opportunities:

## Alliance for Continuing Education in the Health Professions

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

Insmed will have funding available to support independent education that reaches national audiences through Medical Society conferences (not limited to symposia), other live regional meetings, and/or enduring programs.

Therapeutic Area	Non-Cystic Fibrosis Nontuberculous Mycobacterial Lung Disease (NTM-LD)			
Educational format & scope	<ul> <li>Independent education (symposia or other appropriate activity) that reaches clinicians who attend pulmonary and infectious disease conferences including, but not limited to:</li> <li>2021 CHEST Oct 2021</li> <li>2021 ID Week Oct 2021</li> <li>Other identified by Education Provider</li> <li>Not limited to symposia, and can include live, enduring, or multiple components</li> </ul>			
Submission deadline	Note: Medical Society conferences may require review of proposals prior to submission to Insmed or may require an executed LOA prior to a specific deadline.			
	Focus	Insmed Submission deadline	Important congress deadline	
	ID Week CHEST	Sept 1, 2020	Where required, must have approval letter from Congress/Society prior to the opening of the ID Week, CHEST sites (2021)	
	Other		Ensure submission at least 60 days before funding commitment is needed	
	If your organization plans on submitting requests for more than one activity (live and/or enduring), please structure the proposal(s) to ensure: • Congress 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			
Accreditation	Grant requests must adhere to Medical Society requirements regarding accreditation, if applicable.			

Insmed is interested in receiving grant requests that align with the specifications outlined below.

Budgets	When submitting budgets please clearly differentiate out of pocket costs from management fees and note optional costs. Organizations may use their own template or request one from Insmed.		
Intended audience	Education should address the needs of clinicians who have a role in the diagnosis and treatment of patients with NTM-LD, including Pulmonologists and Infectious Disease specialists (MDs, NPs, PAs and Infectious Disease Pharmacists).		
Areas of Education Focus	<ol> <li>Awareness of NTM-LD associated patient risk factors, underlying conditions (e.g. bronchiectasis) and approaches to reduce time to diagnosis and initiation of updated guidelines and evidence-based treatment.</li> </ol>		
	2. Discussion of development of individualized treatment goals based on patient factors and communication and explanation of diagnosis to patients.		
	3. Examination of evidence and updated guidelines-based strategies to managing medication adverse events, adherence, and completion to improve treatment outcomes.		
	4. Communication of best practices in NTM-LD current treatment including airway clearance, medication optimization, susceptibility testing, repeated cultures, duration of treatment, and medication adherence; adverse event management.		
	5. 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. Achieving desired results and improved outcomes: integrating planning and assessment throughout learning activities. 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.

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). Epidemiologic studies have reported a rise in the prevalence of NTM-LD globally, raising public health concerns (Adjemian 2012; Prevots 2015).

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).

The 2007 ATS/IDSA guidelines (Griffith 2007) have been superseded by newly published guidelines (Daley, et al 2020) and outline the current standards of diagnosis, management, and treatment of NTM-LD. 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 and Daley, et al 2020).

There are limited clinical trial data in NTM-LD, and only one FDA approved drug indicated for refractory NTM-LD. 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, et al 2020).

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; Griffith 2012). 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
- Experience in designing educational programs and assessing the effectiveness of the activity
- Requested budget
- Accreditation and compliance with ACCME Standards for Commercial Support
- Alignment with educational focus areas
- Compliance with Insmed policies and procedures

#### References

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Adjemian J et al. Lack of Adherence to Evidence-based Treatment Guidelines for Nontuberculous Mycobacterial Lung Disease. Ann Am Thorac Soc. 2014;11(1):9-16.

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Daley CL, laccarino JM, Lange Jr C, et al. Treatment of Nontuberculous Mycobacterial Pulmonary Disease: An Official ATS/ERS/ESCMID/IDSA Clinical Practice Guideline: Executive Summary. Clin Infect Dis. Epub 2020 Jul 06.

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Griffith DE, Aksamit TR. Therapy of refractory nontuberculous mycobacterial lung disease. Curr Opin Infect Dis. 2012;25(2):218-227.

Henkle E et al. Patient-centered research priorities for pulmonary nontuberculous mycobacterial (NTM) infection. An NTM Research Consortium Workshop Report. AnnalsATS. 2016;13(9): S379-S384.

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Miwa S et al. Efficacy of Clarithromycin and Ethambutol for Mycobacterium avium Complex Pulmonary DiseaseAnn Am Thorac Soc. 2014;11(1):23-29.

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Wallace RJ Jr et al. Macrolide/Azalide Therapy for Nodular/Bronchiectatic Mycobacterium avium Complex Lung Disease. Chest. 2014;146(2):276-282.

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