

**Novartis Office of Grants & Education  
Request for Proposal (RFP) - Professional Medical Education**

The Novartis Office of Grants & Education supports independent high-quality medical educational programs which provide fair-balanced, evidence-based, current scientific information to healthcare professionals to positively improve patient care. Activities should have an educational focus, be independent of commercial bias and be non-promotional in nature. We will perform these duties in compliance with laws, regulations and guidelines as established by the ACCME, PhRMA Code, OIG, other regulatory agencies and in compliance with Novartis guidelines and policies

<b>Key Dates:</b>	RFP Issued: June 28, 2024 <b>Applications Due to Novartis: August 23, 2024 by 5 PM EST</b> Notification of Grant Decisions: September-October 2024 Educational Programming Starts: Q4 2024-Q1 2025
<b>Therapeutic Area:</b>	IgA Nephropathy
<b>Educational Need:</b>	<p>IgA Nephropathy is a kidney disorder characterized by inflammation of the glomeruli, which are the kidneys' filtering units. IgAN can lead to blood and protein in the urine, high blood pressure, and progressive loss of kidney function. It could be the first disease with significant prevalence to be treated with therapies targeting the complement system.<sup>1</sup> The need is great for patients with this condition, as treatment has historically focused on supportive treatments addressing hypertension and proteinuria (protein in the urine), and most patients with higher residual proteinuria still progress to kidney failure, which is up to half of patients within 20 years of clinical presentation.<sup>2-3</sup> Kidney disease progression in IgAN is caused by the formation and deposition of immune complexes composed of galactose-deficient IgA1 (Gd-IgA1) and Gd-IgA1 autoantibodies (anti-Gd-IgA1 antibodies) in the glomeruli, where they trigger complement-mediated inflammation that can lead to kidney function loss.<sup>2</sup></p> <p>A definitive diagnosis of IgAN requires a kidney biopsy. Special preparations with immunofluorescence or immunoperoxidase staining demonstrating the presence of dominant or co-dominant deposition of IgA help in this process.<sup>4</sup> Because of a broad range of presentations spanning from gross hematuria to microscopic hematuria, nephrotic syndrome and acute kidney injury, diagnosis can often be delayed. Healthcare professionals (HCPs) need to better able to identify patients at high risk of developing end-stage kidney disease so that they can guide more optional treatment decisions and implement interventions at an earlier stage and prevent/halt the disease progression. Targeting complement activation could lead to important new treatments for IgAN, which is the most common glomerulonephritis worldwide.<sup>3</sup></p> <p>Current treatment approaches for IgA nephropathy primarily focus on blood pressure control, reducing proteinuria, and immunosuppression in selected cases. There is significant gap in the understanding of key mechanistic pathways of effective and targeted emerging therapies (eg, factor B, endothelin receptors and APRIL/BAFF), usage of renal biopsy scoring systems for prognosis prediction, and of clinical protocols for treating IgAN. Recent clinical developments are shifting treatment paradigms as a variety of new and emerging therapeutics with different mechanisms of action and/or targeted forms of delivery are becoming available. Given the rapidly evolving therapeutic landscape, it can be challenging for clinicians to stay up to date with the latest clinical evidence on new and emerging therapies, including their mechanism of</p>

	<p>action, efficacy and safety data, and their potential impact on IgAN disease progression. Innovative, engaging educational activities are needed to deliver the essential scientific evidence and latest updates.</p> <p><b>References:</b></p> <ol style="list-style-type: none"> <li>1. Rajasekaran A, Green TJ, Renfrow MB, Julian BA, Novak J, Rizk DV. Current Understanding of Complement Proteins as Therapeutic Targets for the Treatment of Immunoglobulin A Nephropathy. <i>Drugs</i>. 2023 Nov;83(16):1475-1499. doi: 10.1007/s40265-023-01940-2.</li> <li>2. Maixnerova D, El Mehdi D, Rizk DV, Zhang H, Tesar V. New Treatment Strategies for IgA Nephropathy: Targeting Plasma Cells as the Main Source of Pathogenic Antibodies. <i>J Clin Med</i>. 2022;11(10):2810. doi: 10.3390/jcm11102810.</li> <li>3. Kwon CS, Daniele P, Forsythe A, Ngai C. A Systematic Literature Review of the Epidemiology, Health-Related Quality of Life Impact, and Economic Burden of Immunoglobulin A Nephropathy. <i>J Health Econ Outcomes Res</i>. 2021;8(2):36-45. doi: 10.36469/001c.26129.</li> <li>4. Wyatt RJ, Julian BA. IgA nephropathy. <i>N Engl J Med</i>. Jun 20 2013;368(25):2402-14.</li> </ol>
<p><b>Geographic Scope:</b></p>	<p>Primary geography of interest: United States (National, Regional, and/or Local)</p> <p>Note: Applications for this RFP must be US focused for the audience, expert faculty, educational needs, and standards of care.</p>
<p><b>Project Description:</b></p>	<p>The Novartis Office of Grants &amp; Education has identified the need for innovative continuing medical education programs that strive to optimize patient outcomes through education on:</p> <ul style="list-style-type: none"> <li>• Assess the pathophysiology of the disease progression of IgAN and outline the multi-hit hypothesis</li> <li>• Design a treatment strategy based on the goal of reducing proteinuria in patients with IgAN to delay disease progression and improve prognosis</li> <li>• Summarize novel mechanisms of action and the role of the complement, endothelin, and APRIL/BAFF in IgAN</li> <li>• Apply recent efficacy and safety clinical trial data on new and emerging treatments for IgAN and clinical protocols to guide individualized treatment plans for patients with IgAN</li> <li>• Design patient-centric strategies to empower and help patients better understand IgAN and overcome barriers to disease management</li> </ul> <p>The Novartis Office of Grants &amp; Education is seeking to support:</p> <ul style="list-style-type: none"> <li>• Live grand round series held in community hospitals, academic centers, along with an enduring component</li> <li>• Case-based (real world examples), on-demand, expert-led programs</li> <li>• Peer-to-peer activities</li> </ul> <p>Note: All aspects of the Program(s) including location and placement are independent of Novartis.</p>
<p><b>Target Audience:</b></p>	<p>Primary audience: Nephrologists, renal pathologists, transplant nephrologists, primary care physicians, nephrology nurses</p> <p>Secondary audience: Nephrology nurse practitioners and physician associates, specialty pharmacist, managed care clinicians (specialty).</p>

	<p>Educational providers should include target number of participants. Further, please include details on proposed audience recruitment.</p> <p>Please note: Novartis will not participate in the distribution of invitations to the CME/CE event(s).</p>
<b>Available Funding:</b>	<p>Multiple single-support or multi-support initiatives may be funded; In total, \$300,000 - \$400,000 in support is available.</p>
<b>Submission Requirements:</b>	<p>Grant applications must be submitted by the Accredited Provider (or the Office of CME if from an Academic Institution) electronically via the Novartis Grants Central Station website: <a href="http://www.ngcs.novartis.com">www.ngcs.novartis.com</a> by <b>5 PM EST on August 23, 2024 to be considered.</b></p> <p>The grant application should include “RFP Response” within the Program Title [example: “RFP Response: <i>Program Title</i>”].</p> <p>Multi-support proposals that include collaborations with third parties, including (but not limited to), medical societies, health education companies/centers, not-for-profit organizations, and academic institutions, are preferred, as appropriate.</p>
<p style="text-align: center;"><b>For grant request submission information, FAQs, and eligibility criteria, please visit:</b>  <a href="https://www.novartis.us/corporate-responsibility/external-funding">https://www.novartis.us/corporate-responsibility/external-funding</a></p> <p style="text-align: center;"><b>If you have any questions regarding this RFP, you should only contact The Novartis Office of Grants &amp; Education via email at:</b> <a href="mailto:grants.office@novartis.com">grants.office@novartis.com</a> or <a href="mailto:Sofia.Yang@novartis.com">Sofia.Yang@novartis.com</a>.          [Please title the subject of your email: “RFP IgAN 2024”].  <b>**Please submit under IgA Nephropathy in the Grants System**</b></p>	