

Request for Proposal (RFP) - Complement-Mediated Kidney Diseases (C3G, aHUS, IC-MPGN)

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.

Therapeutic Area

Complement-Mediated Kidney Diseases (C3G, aHUS, IC-MPGN)

Key Dates

RFP Issued: April 16, 2024

Applications Due to Novartis: June 7, 2024 by 5 PM EST

Notification of Grant Decisions: July-August 2024

Educational Programming Starts: Q3-Q4 2024

Educational Need

Complement-mediated kidney diseases (CMKD) are chronic, rare, complex, and progressive diseases that present with inflammatory response to the cause kidney damages in patients with an overly active immune system.¹ They include diseases such as C3 glomerulopathy (C3G), atypical hemolytic uremic syndrome (aHUS), and Immune Complex Membranoproliferative Glomerulonephritis (IC-MPGN).²⁻⁵ Activation of the alternative pathway has been implicated as a primary driver of these conditions.⁶ Although presented with similar characteristics and overall survival rate, CMKDs have differences in genetic or acquired abnormalities, and histological features, which depends on the timing of kidney biopsy and disease activity or chronicity.⁷⁻⁸

C3G has an estimated incidence of about 1-3 per 1,000,000 and prevalence as low as 5 per 1,000,000.⁹ Previous survey of patients with C3G by the National Kidney Foundation revealed that many patients were misdiagnosed and were not treated for their renal symptoms for years.¹⁰ Prognosis for patients with CMKD is poor. In the case of C3G, about half the adult patients and ~70% of children progress to end-stage kidney disease within 10 years.¹¹ Despite kidney transplantation, C3G often recur and contribute to poor allograft survival rates in nearly half of the patients.¹² Understanding the dysregulation of the alternative complement pathway and its subtypes including post-transplant recurrence, progression to end-stage kidney diseases and prevalence in children and young adults will help clinicians better identify and classify patients with a CMKD.

Patients living with CMKD can experience a variety of symptoms, which may include proteinuria, hematuria, debilitating fatigue, edema, anxiety, and chronic infections as some of the most bothersome symptoms and

complications. Improvement in quality-of-life symptoms are priorities from a patient's perspective.¹³⁻¹⁴

Optimal treatment strategy for CMKD has not been established due to multiple factors, such as difficulty carrying out large randomized controlled trials due to disease rarity, lack of availability to perform genetic testing in community settings, and heterogeneous nature of disease, but many in clinical trials are showing promise.⁹ Survey data found that while nearly 60% of patients were interested in participating in clinical trials, only 18% of patients did.¹⁰ This suggested the need for educational efforts to bring additional or previously unrecognized disease symptoms to light. Oral corticosteroids and immunosuppressants can be used in patients at high risk of disease progression, but these often come with significant side effects.¹⁴⁻¹⁵

Knowledge gaps remain in identifying which patients will benefit most from current treatment and emerging targeted therapies. Careful evaluation of clinical trial data and up to date scientific publications as they emerge, as well as the determination of the disease drive through genetic testing and complement assays are crucial for developing optimal treatment plan for patients with complement-mediated kidney diseases.

References:

1. Thurman JM. (2020) Complement and the Kidney: An Overview. *Adv Chronic Kidney Dis.* 27(2):86-94.
2. Smith R, et al. (2019) *Nat Rev Nephrol.* 15:129–43.
3. Schena F, et al. (2020) *Int J Mol Sci.* 21:525.
4. Wong EKS et al. (2018) *Semin Immunopathol.* 40(1):49-64.
5. Boyd J, et al. (2012) *Kid Int.* 81:833–43.
6. Poppelaars F, Thurman JM. Complement-mediated kidney diseases. *Mol Immunol.* 2020;128:175-187.
7. Kovala M, Seppälä M, Räisänen-Sokolowski A, Meri S, Honkanen E, Kaartinen K. Diagnostic and Prognostic Comparison of Immune-Complex-Mediated Membranoproliferative Glomerulonephritis and C3 Glomerulopathy. *Cells.* 2023;12(5):712.
8. Ravindran A, Fervenza FC, Smith RJH, De Vriese AS & Sethi S C3 glomerulopathy: ten years' experience at Mayo Clinic. *Mayo Clin. Proc* 93, 991–1008 (2018)
9. Estebanez BT, Bomback AS. C3 Glomerulopathy: Novel Treatment Paradigms. *Kidney Int Rep* (2023)
10. Feldman DL, Bomback A, Nester C. VOICE OF THE PATIENT: Report of Externally-Led Patient-Focused Drug Development Meeting on Complement 3 Glomerulopathy (C3G).; 2018.
https://www.kidney.org/sites/default/files/C3G_EL-PFDD_VoP-Report_3-29-18.pdf
11. Bomback AS, Santoriello D, Avasare RS, et al. C3 glomerulonephritis and dense deposit disease share a similar disease course in a large United States cohort of patients with C3 glomerulopathy. *Kidney Int* 2018; 93(4):977–985.
12. Mehdi A, Taliencio JJ. C3 glomerulopathy. *CCJM.* 2023;90(6 suppl 1):e1-e4.
13. Gonzalez A, et al. (2020) *Am J Kidney Dis.* S0272-6386(20)30719-8.
14. Zhao Y, et al. (2020) *J Int Med Res.* 48(1):300060519898008.
15. Rauen T, Wied S, Fitzner C, et al. After ten years of follow-up, no difference between supportive care plus immunosuppression and supportive care alone in IgA nephropathy. *Kidney Int.* 2020;98(4):1044-1052.

Project Description

The Novartis Office of Grants & Education has identified the need for innovative continuing medical education programs that strive to optimize patient outcomes through education on:

- Understand the alternative complement pathway in CMKD (C3G, aHUS, IC-MPGN) and its forms and classifications, including post-transplant recurrence
- Develop strategies to improve timely, accurate differential diagnosis in clinical practice

- Describe the safety and efficacy of current and emerging targeted therapies and construct personalized treatment plans for patients diagnosed with CMKD
- Reduce disease burden and optimize outcomes and quality of life of patients with CMKD

The Novartis Office of Grants & Education is seeking to support:

- Live/Virtual grand round series held in community hospitals, academic centers, along with an enduring component
- Live independent satellite symposium in conjunction with Nephrology-related medical congresses
- Highlights of nephrology-related scientific meetings (ie, ASN Kidney Week 2024 and ANNA Fall (Nephrology Nursing Practice, Management & Leadership Conference 2024))
- Case-based (real world examples), on-demand, expert-led programs

Note: All aspects of the Program(s) including location and placement are independent of Novartis.

Geographic Scope

Primary geography of interest: United States (National, Regional, and/or Local)

Note: Applications for this RFP must be US focused for the audience, expert faculty, educational needs, and standards of care.

Target Audience

Nephrologists, Nephrology fellows, renal pathologists, nephrology nurse practitioners and physician associates, nephrology nurses, specialty pharmacist, managed care clinicians (specialty).

Educational providers should include target number of participants. Further, please include details on proposed audience recruitment.

Please note: Novartis will not participate in the distribution of invitations to the CME/CE event(s).

Available Funding

Multiple single-support or multi-support initiatives may be funded; USD 200 000 - USD 300 000 in support is available

Submission Requirements

Grant applications must be submitted by the Accredited Provider (or the Office of CME if from an Academic Institution) electronically via the Online Portal: by **5 PM EST on June 7, 2024 to be considered**.

The grant application should include "RFP Response" within the Program Title [example: "RFP Response: Program Title"].

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 encouraged, as appropriate.

For grant request submission information, FAQs, and eligibility criteria, please visit: [Novartis external funding](#).

If you have any questions regarding this RFP, you should only contact The Novartis Office of Grants & Education via email at: grants.office@novartis.com.

[Please title the subject of your email: "RFP CMKD 2024"].

****Please submit under Complement-Mediated Kidney Diseases (C3G, aHUS, IC-MPGN) in the Grants System****

Source URL: <https://www.novartis.com/us-en/about/external-funding/educational-grants/professional-medical-education-grants/request-proposal-rfp-complement-mediated-kidney-diseases-c3g-ahus-ic-mpgn>

List of links present in page

- <https://www.novartis.com/us-en/us-en/about/external-funding/educational-grants/professional-medical-education-grants/request-proposal-rfp-complement-mediated-kidney-diseases-c3g-ahus-ic-mpgn>
- <https://www.novartis.com/us-en/us-en/about/external-funding>
- <mailto:grants.office@novartis.com>