2024 Independent Medical Education Call for Grant Applications

"CGA-PDT-PID-ESID-2024: The many faces of PID- challenges in diagnosis and management"

Takeda is committed to supporting high-quality, un-biased, evidence-based independent medical education for healthcare professionals, teams, patients, payers, and systems designed to:

- Improve knowledge, enhance skills, and support behavior change
- Close clinical and practice gaps
- Improve the quality and delivery of patient care
- Enable patients to take an active role in their healthcare

Independent Medical Education is defined as education that is evidence-based, fair-balanced, unbiased educational programs, planned and implemented independent of industry influence, free of bias and not influenced by Takeda or its Alliance partners.

Takeda is issuing the following Call for Grant Applications (CGA) and invites accredited educational providers to submit applications for independent, certified medical education grants that align with the educational needs outlined below.

Statement of Need:

Primary Immunodeficiency (PID), also referred to inborn errors of immunity (IEI), is a group of disorders characterized by defects in the immune system. To date, more than 480 primary immunodeficiencies have been identified.[1,2] Due to their impaired immune system, patients with PID may be more susceptible to infections.[3] However, primary immunodeficiencies are highly heterogenous and complex, exhibiting diverse phenotypes and symptom onset that can manifest at any point in a patient's life. With the ongoing expansion of genetic diagnostics, the field has transitioned from primarily studying infection-dominated phenotypes to unraveling diverse manifestations across various medical disciplines.[4]

Patients with PID face an increased risk cancer, inflammatory and autoimmune diseases, and allergies.[5] Additionally, aside from infections and immune system disorders, manifestations of PID include dysregulation of the central nervous, intestinal, renal and pulmonary systems, growth delays, endocrine disease and dysmorphic features.[6] Individuals exhibiting disease symptoms may display a range of phenotypes with varying degrees of severity, a phenomenon commonly referred to as variable expressivity, which can be attributed to extrinsic/environmental influences or intrinsic factors such as (epi)genetics.[7] Thus, the initial presentation can be misleading harboring high risk of misdiagnosis and consequently mismanagement of the underlying PIDs.[8,9] Delayed diagnosis and inappropriate management may lead to even further health complications, including

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irreversible organ damage and mortality.[10-14] This highlighs the need to enhance the recognition of these conditions and (clinical) phenotypes to facilitate both, accurate and timely diagnosis and appropriate management.[15]

Considering these challenges, Takeda is inviting proposals for a medical educational symposium at the 21st biennial meeting of the European Society for Immunodeficiencies (ESID) in October 2024, as well as enduring activities. The symposium should highlight the wide range of PID manifestations in both pediatric and adult patients, and discuss associated diagnostic challenges as well as barriers to effective and individualized management inherent to present care pathways. It should cover the latest understanding of both infectious and non-infectious presentations and complications, including their (clinical) features, pathophysiology, epidemiology, and unmet needs to facilitate accurate and timely diagnosis. Furthermore, the symposium should cover innovative and individualized therapy management enabled by new technologies as part of digital health, emphasizing a holistic approach to patient care. The aim is to assist clinicians in developing comprehensive knowledge frameworks that can support the accurate diagnosis and personalized management of PID in the future. Takeda is particularly interested in innovative and patient-centric proposals. We encourage to think outside the box and consider creative ways that can efficiently deliver scientific and practical knowledge in a highly engaging and progressive format.

Symposium (format) details:

- 90 min medical symposium (slot secured by Takeda)
- Creative, innovative and interactive format with audience engagement
- Keynote speakers should be renowned experts and thought leaders in the field
- Ensure that symposium agenda, content, and activities are designed with patient experience and perspective in mind
- Post-enduring element to keep momentum and allow for continuing the engagement

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CGA Details:

Educational Focus:	Infectious and non-infectious manifestations in primary immunodeficiency- implications for diagnosis and management
Educational Design	Symposium at the European Society for Immunodeficiency (ESID) 2024 ***(Notably, 90 min symposium slot is secured by Takeda)*** and subsequent enduring activity
Support Available:	Up to $300,000.00
Learning Audience:	HCPs managing patients with PID (e.g. pediatricians, immunologists, nurses)
Intended Outcomes Level:	knowledge/competence
Submission Deadline:	15th April 2024
Anticipated Decision Date:	31st May 2024

CGA Eligibility:

The educational programs submitted in response to the CGA must be accredited by the appropriate accrediting bodies, be fully compliant with ACCME criteria and the Standards for Integrity and Independence and must be in accordance with the U.S. Food and Drug Administration's Guidance on Industry-Supported Scientific and Educational Activities. If approved, requestors must attest to the terms, conditions and purposes of an educational grant as described in the Takeda letter of agreement (LOA).

Providers who meet the eligibility criteria and are interested in submitting a response to this CGA will need to complete a full submission through the Takeda Support system by the submission deadline listed above in the CGA Details area.

CGA Submission Instructions:

Submissions in response to a CGA's need to be made through the Takeda Support system at (https://takeda.envisionpharma.com/ienv_takeda/visiontracker/portal/login.xhtml?pgm=CME).

1. Submissions should be made designating "Immunology" as the Therapeutic Area and "Primary Immunodeficiency (PID)" as the disease state of interest.
2. Please select "Yes" from the drop down in response to the question "Are you responding to a CGA?"

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3. Please select "CGA-PDT-PID-IPIC-2023" from the drop down in the "CGA Number" field.

Terms and Conditions:

1. All grant applications received in response to this CGA will be reviewed in accordance with all Takeda policies and guidelines.
2. This CGA does not commit Takeda to fund any CGA submission, or the costs associated with such submissions.
3. Takeda reserves the right to cancel, in part or in its entirety, this CGA.
4. For compliance reasons, and in fairness to all providers, all communications about this CGA must come exclusively to Takeda's Department of Medical Education. Failure to comply will automatically disqualify providers.
5. Failure to follow the instructions within this CGA will result in a denial.
6. Takeda Medical Education personal will notify (via email) the requestor whose submission was selected for up to 2 weeks from the anticipated decision date as listed in the CGA details above.

References:

1. Immune Deficiency Foundation. Specific Disease Types. Available at: https://primaryimmune.org/about-primary-immunodeficiencies/specific-disease-types (Accessed: Feb 2024)

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3. European Society for Immunodeficiencies, "10 Warning Signs of PID." https://esid.org/Working-Parties/Clinical-Working-Party/Resources/10-Warning-Signs-of-PID-General (Accessed: Feb 2024)

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7. Gruber, C. & Bogunovic, D. Incomplete penetrance in primary immunodeficiency: a skeleton in the closet. Hum. Genet. 139, 745–757 (2020).

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10. Seymour B, Miles J, Haeney M. Primary antibody deficiency and diagnostic delay. J Clin Pathol. 2005;58(5):546–547.

11. Jiang F, Torgerson TR, Ayars AG. Health-related quality of life in patients with primary immunodeficiency disease. Allergy Asthma Clin Immunol. 2015;11:27.

12. Buckley RH, ed. Immune Deficiency Foundation Diagnostic and Clinical Care Guidelines for Primary Immunodeficiency Diseases. 3rd ed. Towson, MD: Immune Deficiency Foundation; 2015.

13. Verbsky JW, Grossman WJ. Cellular and genetic basis of primary immune deficiencies. Pediatr Clin North Am. 2006;53(4):649-684.

14. Bonilla FA, Khan DA, Ballas ZK, et al. Members of the Joint Task Force on Practice Parameters for the American Academy of Allergy, Asthma and Immunology; American College of Allergy, Asthma and Immunology; Joint Council of Allergy, Asthma and Immunology. Practice parameter for the diagnosis and management of primary immunodeficiency. J Allergy Clin Immunol. 2015;136(5):1186–1205.e1-e78.

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15. Cunningham-Rundles C, Casanova JL, Boisson B. Genetics and clinical phenotypes in common variable immunodeficiency. Front. Genet., 11 January 2024, Sec. Genetics of Common and Rare Diseases Volume 14 - 2023