2023 Independent Medical Education Call for Grant Applications

"CGA-PDT-PID-IPIC-2023: Digital health technology to improve treatment burden in Primary Immunodeficiency"

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) describes a heterogenous group of more than 400 rare genetic diseases wherein part of the immune system is missing or not functioning properly.[1] Due to their impaired immune system, patients with PID may be more susceptible to infections, such as sinusitis, bronchitis, pneumonia, or gastrointestinal infections.[2] They also often present with chronic or recurrent infections, and infections that are rarely found in people with fully functioning immune systems[3] besides other non-infectious complications such as increased risk of cancer, autoimmune diseases and allergies.[4] If left untreated, PID-related infections and conditions may lead to even further health complications, including organ damage and mortality.[5-9]

In general, treatments for PID aim to prevent and treat infections, improve the immune system, and/or treat the underlying cause of the immune deficiency. Milder forms of PID might be managed by prophylactic antimicrobials (e.g., antibiotics and antifungals), however, treatment is complex, and the specific therapy depend on the type of immunodeficiency and clinical needs of the individual patient. Most forms of PID involve impaired antibody production and/or function[10] where substitution with functional antibodies (i.e. immunoglobulin replacement therapy) is the standard of care in patients with more severe forms with increased susceptibility of and/or persistent

Date of preparation: January 2023
MARV code: VV-MEDMAT-80479

infection. This involves an often life-long, regular (weekly to monthly) administration of therapy via the intravenous or subcutaneous route, adding to the overall burden of the disease (e.g. due to complexities related to the administration),[11] and highlighting the need for a comprehensive/holistic yet individualized therapy approach.

While home treatment via self-administered subcutaneous therapy enables increased independence for patients, many opportunities remain around optimizing therapy management to further ease associated administrative burden. Digital health technology including solutions for remote patient monitoring have been shown to support treatment personalization and to improve patient outcomes for the treatment of other chronic diseases – especially when interactive or combining digital with device.[12] Likewise, patient-centric digital health technology shows promise to optimize therapy for PID e.g. by simplifying the therapeutic administration process, promoting remote monitoring and supporting therapy management. Thereby such tools might ultimately help to enhance treatment experience and patient outcomes.

Educational initiatives discussing the challenges and needs of patients to reduce treatment burden, as well as informing about new developments in digital and device solutions are thus important to increase the awareness thereof among HCPs. Frontline providers and HCPs caring for PID patients can support the treatment journey by ensuring high standard for patient training and by engaging patients who are willing and able to use digital health and novel device solutions.

Therefore, Takeda is interested in proposals for a continuing medical educational symposium at the International Primary Immunodeficiency Congress 2023 and subsequent enduring activity on the impact of overall administration burden of therapy and novel digital and device approaches aimed to overcome these.

2023 Independent Medical Education Call for Grant Applications

"CGA-PDT-PID-IPIC-2023: Digital health technology to improve treatment burden in Primary Immunodeficiency"

CGA Details:

Educational Focus:	Primary Immunodeficiency (PID) – Patient integrated care solutions
Educational Design	Symposium at the International Primary Immunodeficiencies Congress 2023 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 March 2023
Anticipated Decision Date:	1st May 2023

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.

Date of preparation: January 2023
MARV code: VV-MEDMAT-80479

2. Please select "Yes" from the drop down in response to the question "Are you responding to a CGA?"
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: Jan 2023)

2. Immune Deficiency Foundation, "About Primary Immunodeficiencies: Infections." http://primaryimmune.org/about-primary-immunodeficiencies/relevant-info/infections/. (Accessed: Jan 2023)

3. ESID Clinical Working Party: "10 Warning Signs of PID - General" https://esid.org/Working-Parties/Clinical-Working-Party/Resources/10-Warning-Signs-of-PID-General (Accessed Jan 2023)

4. Blaese RM, Stiehm ER, Bonilla FA, Younger ME, eds. The Immune Deficiency Foundation Patient & Family Handbook for Primary Immunodeficiency Diseases. 6th ed. Towson, MD: Immune Deficiency Foundation; 2013. Reprint 2019.

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

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

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

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

9. 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.

10. Kobrynski L, Powell RW, Bowen S. Prevalence and morbidity of primary immunodeficiency diseases, United States 2001-2007. J Clin Immunol. 2014;34(8):954–961.

11. Jones GL, Vogt SK, Chambers D, Clowes M, Shrimpton A. What Is the Burden of Immunoglobulin Replacement Therapy in Adult Patients With Primary Immunodeficiencies? A Systematic Review. Front Immunol. 2018 Jul 2;9:1308

12. Mosnaim, Giselle, Guilherme Safioti, Randall Brown, Michael DePietro, Stanley J. Szefler, David M. Lang, Jay M. Portnoy, Don A. Bukstein, Leonard B. Bacharier, and Rajan K. Merchant. "Digital health technology in asthma: a comprehensive scoping review." The Journal of Allergy and Clinical Immunology: In Practice 9, no. 6 (2021): 2377-2398.