2023 Independent Medical Education Call for Grant Applications
"CGA-CICCOM-2023: Effective Communication for Improving the Diagnosis and Management of Chronic Idiopathic Constipation"

Takeda is committed to supporting high-quality, unbiased, 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:

Chronic idiopathic constipation (CIC) has an estimated prevalence of 16% in the United States and has a significant impact on both patient lives and the healthcare system.[1,2] CIC affects approximately 35 million adults in the United States, resulting in 2.8 million ambulatory and emergency room visits annually.[3,4] CIC creates a significant burden on patients, such as psychological stress and impaired health-related quality of life.[1,5]

Effective communication is foundational to optimal diagnosis and treatment, especially to close gaps associated with healthcare disparities,[6] and foster optimal disease management. Diagnosing CIC can be challenging for healthcare providers (HCPs),[3] especially since only about half of patients who have CIC report actually discussing their constipation with an HCP.[4] However, effective communication encouraging trust and a positive patient-provider relationship can motivate patients to share important clinical and psychosocial information while providing a picture of the full impact of the illness on their daily lives.[7] Such information can be used by HCPs to distinguish CIC from other illnesses that share similar symptoms and therefore direct treatment recommendations.

Managing CIC can be challenging, and patients often report dissatisfaction with treatment.[3,7] In fact, only approximately half of patients receiving prescription medication for CIC refill those

prescriptions.[8] HCPs agree there continue to be unmet needs in the treatment of CIC.[3,9,10] Improving management for both patients and HCPs is rooted in improving communication around the disease and its treatment.[9] Patients are seeking information about their condition and available treatment options,[7] many remain dissatisfied with the explanations they receive from HCPs.[10] Good communication contributes to a strong therapeutic HCP-patient relationship and facilitates shared decision-making (SDM).[7,11]

Evidence indicates SDM fosters appropriate care, improves health outcomes, and reduces health-care costs, yet it is not routinely implemented in practice.[11-13] Barriers include limited time during clinical visits, HCP indifference, and lack of confidence in SDM resources.[11,13] Furthermore, HCPs are often unaware of their own implicit bias that impacts their interactions with patients, impacting trust and contributing to disparities in care.[6]

HCPs would benefit from education on how to best engage in meaningful, culturally competent communication with patients, preferably education that provides experiential learning.[7] Improvements in HCP communication behaviors may disrupt the negative association between HCP implicit bias and patient trust and satisfaction, and improving patient trust and satisfaction can lead to better patient health-related behaviors and clinical outcomes.[6] Regarding SDM, educational interventions have shown to improve HCP skills and attitudes.[13] Such interventions can provide ongoing support, encouragement and motivation which are significant influences for implementing SDM.[11] Patients must also be prepared to make the best decisions for their care.[12] They need and desire education regarding basic pathophysiology, rationale for treatment, and further understanding of treatment options to set treatment goals.[7] Ideally, this education takes place one-on-one with their HCP and involves the use of aids or tools to illustrate the information discussed.[7] Use of such aids improve patient knowledge, increase confidence and clarify personal values in making decisions.[13]

Therefore, Takeda is interested in supporting educational initiatives that measure demonstrable improvements in communication, including cultural competence that addresses disparities in care and SDM, between HCPs and patients with CIC. Initiatives should be designed to report real-world outcomes. Please include a description of any plans for publication or presentation of the outcomes of the initiative.

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CGA Details:

Educational Focus:	Improving communication between healthcare providers and patients with CIC to facilitate better diagnosis and management
Educational Design	Educational initiatives that will demonstrate real-world outcomes or quality improvement related to communication, cultural competence, disparities in care and SDM.
Support Available:	Up to $250,000
Learning Audience:	Healthcare providers and patients managing chronic idiopathic constipation
Intended Outcomes Level:	Behavior or Patient Health Include a description of any plans to publish or present outcomes from the initiative.
Submission Deadline:	June 2, 2023
Anticipated Decision Date:	June 30, 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 "Gastroenterology" as the Therapeutic Area and "Chronic Idiopathic Constipation" 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?"
3. Please select "CGA-CICCOM-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 personnel 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:

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3. Lacy BE. Update on the management of chronic idiopathic constipation. *Am J Manag Care*. 2019;25(4 Suppl):S55-S62.
4. Oh SJ, Fuller G, Patel D, et al. Chronic Constipation in the United States: Results From a Population-Based Survey Assessing Healthcare Seeking and Use of Pharmacotherapy. *Am J Gastroenterol*. 2020;115(6):895-905. doi:10.14309/ajg.0000000000000614
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6. Hagiwara N, Elston Lafata J, Mezuk B, Vrana SR, Fetters MD. Detecting implicit racial bias in provider communication behaviors to reduce disparities in healthcare: Challenges, solutions, and future directions for provider communication training. *Patient Educ Couns*. 2019;102(9):1738-1743. doi:10.1016/j.pec.2019.04.023
7. Drossman DA, Ruddy J. Improving Patient-Provider Relationships to Improve Health Care. *Clin Gastroenterol Hepatol*. 2020;18(7):1417-1426. doi:10.1016/j.cgh.2019.12.007.
8. Cash B, Lu M, Schoenfeld PS, et al. A real-world study of persistence and adherence to prescription medications in patients with chronic idiopathic constipation. *Gastroenterology*. 2022;162:S-921–S-922. https://doi.org/10.1016/S0016-5085(22)62189-9.
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10. Bielefeldt K. Perceived barriers to treatment in persons treated for functional gastrointestinal disease with constipation. *Digestive Diseases and Sciences.* 2021;66:739-750.
11. Alsulamy N, Lee A, Thokala P, Alessa T. What influences the implementation of shared decision-making: an umbrella review. *Patient Education and Counseling*. 2020. 103:2400-2407.
12. Coronado-Vázquez V, Canet-Fajas C, Delgado-Marroquín MT, Magallón-Botaya R, Romero-Martín M, Gómez-Salgado J. Interventions to facilitate shared decision-making using decision aids with patients in primary health care: A systematic review. *Medicine (Baltimore)*. 2020;99(32):e21389. doi:10.1097/MD.0000000000021389.
13. Amell F, Park C, Sheth P, Elwyn G, LeFrancois D. A shared decision-making communications workshop improves internal medicine resident skill, risk-benefit education, and counseling attitude. *Patient Education and Counseling.* 2022;105:1018-1024.