**Call for Grant Notification Topic:** Tethered Patient-Provider and/or Stand Alone Patient Education

**Identifier to enter into the title of the grant application:** CGA Patient Education IBD

**Therapeutic Area:** Gastroenterology, IBD

**Issue Date:** June 29th, 2017

**Deadline for Submission:** August 8th, 2017

**Award Decision Date:** Approvals and denials will be communicated via standard email notifications no later than August 14th, 2017

1. **Purpose:** Takeda is seeking to support independent educational grants for tethered patient-provider and/or stand alone patient education programs designed to improve clinical decisions, patient care and outcomes for people with Inflammatory Bowel Disease (IBD). The programs supported should focus on addressing challenges that exist in the management of IBD for patients with moderate to severe disease.

2. **Focus Area:**

The care of IBD is complex. There are a number of challenges that exist including: chronicity and recurring nature of IBD flares, varied management of disease for each patient, increased availability of medical therapeutic options which are difficult to navigate, barriers of access to treatment and financial burden. Patients with IBD can be part of the solution by being more engaged in their care, becoming their own advocate at large and by being part of the dialogue with their clinician. (1)

Variations in care could be addressed by examining real world data and following established guidelines. Published care pathways for IBD provide a more systematic approach for assessing patients with IBD and making treatment recommendations. (6-11) Patients should be aware of care pathways and understand the severity and prognosis of their disease in the clinic setting. Real world data plays a significant role in personalized medicine to treat IBD and may provide both patients and their clinician’s patterns of additional therapeutic choices not outlined in dated guidelines that could lead to more effective treatment and attain the goal of long term maintenance of remission. (12,13) The availability of many choices of immunomodulators and biologic therapies for patients with moderate to severe IBD makes disease management difficult for both the patient and the clinician. (2, 3) Insights from large scale analysis of social media platforms reveals a wide range of themes governing patient experience and choice with IBD biologics. The complexity of navigating their risk-benefit profiles suggests merit in creating and/or utilizing existing tailored decision tools to support IBD patients' decision-making with biologic therapies. (4)
Even when appropriate decisions are made for treatment, patients may not be able to receive the treatment they need due to difficulties with access to care and financial constraints. One study demonstrated that patients responded to such challenges by making personal sacrifices, substituting with informal care and resigning to system constraints. Appropriate and supportive services are needed to help patients overcome such barriers. (5)

Ideally, patients should be able to navigate their own insurance plans, understand patient assistance programs, and be part of the dialogue with their clinician effectively.

Being aware of existing treatment paradigms, risks and benefits of available therapies and navigating access issues will help patients be fully engaged in their own care and be their own advocates. (5)

3. Funding: Individual awards requesting up to $300,000 will be considered.

4. Criteria applied to assess applications:

- Quality of needs assessment, educational design and evaluation plan
- Project scope alignment with proposal objectives
- Plan for Dissemination of findings and sustainability of interventions
- Budget

5. Submission process and requirements:

The education must be accredited by the appropriate accrediting bodies, be fully compliant with ACCME criteria and the Standards for Commercial Support and must be in accordance with the U.S. Food and Drug Administration’s Guidance on Industry-Supported Scientific and Educational Activities. If accepted, must attest to the terms, conditions and purposes of an educational grant as described in the Takeda letter of agreement.

Proposals should be structured based on below format to ensure standardization and evaluation of all responses. All the sections listed below must be included in the proposal, in the order presented, with the Section Number listed.

The responses shall be submitted in the following format:

- Section 1 – Executive Summary
- Section 2 – Your Organizational Profile: This section should provide a brief overview of your organization, past experience, and pertinent information.
- Section 3 – Background: This section must include a well-referenced needs assessment that demonstrates the specific gaps and barriers of the intended target audience; where appropriate demonstration of need using real world data and established national measures used in national quality programs such as the Merit-Based Incentive Payment System (MIPS). Additionally, information about the how the needs were identified must be presented.
- Section 4 – Proposed Activities: This section should clearly define the target audience,
measurable learning objectives or measures and rationale for the program design. Proposals should outline how the content will be developed, by whom, and the methods to ensure complete, accurate and evidence-based information. The activities should be linked to specific gaps identified in the guidance provided in Section 3.

- Section 5 – Implementation Plan: This section should include roles and responsibilities of all parties, selection criteria, identification of partners or outside vendors for any part of the implementation plan, Letters of Support from partners if applicable, and timeline of key milestones of the program.

- Section 6 -- Outcomes and Evaluation Plan: This section should describe specifically the outcomes model utilized (i.e. Moore’s, TELMS or other): measures, methodology, measurement design, statistical analysis, and reporting. At minimum, the educational evaluation plan must be designed to objectively measure improvements in knowledge and competence. Preference will be given to programs that align
  - To objectives, outcomes, and measures properly and provide as much detail regarding the metrics that will be captured and reported.
  - To the national quality strategies and national quality programs such as the Merit-Based Incentive Payment System (MIPS)

- Section 7- Reporting & Dissemination Plan – This section should include information about the potential contents of the report, frequency of reporting throughout the funding period (interim and final reports) as well as a plan for disseminating findings as best practices (journal articles, newsletters, conference abstracts etc.).

- Section 8- Sustainability/Scalability Plan- This section should describe how you plan on sustaining, supporting or maintaining the intervention/activities beyond the project period.

- Section 9 – Budget: This section should include a detailed budget with rationale including breakdown of costs associated with management of the program, content development and out-of-pockets.

- Section 10 – Appendices: Any additional and relevant information should be attached as an appendix. This may include results of similar programs or examples of previous programs or contingency plan for implementation.

6. References:


2. Ryan Ungaro, MDa, Saurabh Mehandru, MDa, b, Patrick B Allen, MDc, Prof Laurent Peyrin-Biroulet, MDd, Professor Jean-Frédéric Colombel, MDa, Ulcerative colitis. The Lancet. Volume 389, Issue 10080, 29 April–5 May 2017, Pages 1756–1770 https://doi.org/10.1016/S0140-6736(16)32126-2

3. Joana Torres, MDa, Saurabh Mehandru, MDa, Prof Jean-Frédéric Colombel, MDa, Prof Laurent Peyrin-Biroulet, MD Crohn's diseaseThe Lancet. Volume 389, Issue 10080, 29 April–5 May 2017, Pages 1741–1755 https://doi.org/10.1016/S0140-6736(16)31711-1


