Celgene Corporation Request for Proposal
2016 IBD Continuing Professional Educational Programming

Therapeutic Area: IBD

Disease State: IBD (Crohn’s Disease and Ulcerative Colitis)

Grant applications must be submitted through Celgene website:

www.celgene.com

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<tr>
<th>Submission Timeframe:</th>
<th>Deadline Jan 3, 2017 by 5PM EST. Please include IBD DDW (Digestive Disease Week) RFP as part of the title of application.</th>
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<td>Proposal:</td>
<td>Independent CME certified educational programming that improves HCP’s awareness of evidence based clinical information that may be used to better diagnose, treat and manage patients with IBD. (Multi–support preferred)</td>
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<td>Educational Audience:</td>
<td>Health Care Professionals that treat patients with IBD</td>
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<td>Program Format:</td>
<td>Multi supported satellite symposium to take place during DDW 2017 plus enduring activity. Independent CME certified educational programming that utilizes formats with innovative educational design that improves HCP’s awareness of evidence based clinical information that can be used to better manage patients under their care.</td>
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<td>Outcomes Measurement:</td>
<td>Submissions should include a description of measures, metrics and/or strategies for measuring impact of educational design on improving awareness of new clinical information and/or application of evidence-based medicine (if relevant) that will be incorporated into the educational design, initiative execution and/or measurement process.</td>
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Celgene Corporation is interested in providing funding to support an independent accredited satellite symposia at the annual DDW meeting taking place from May 6-9, 2017 in Chicago, IL. Proposals will be considered that address bona fide educational gaps in the diagnosis and management of patients with IBD that is evidence-based and in accordance with ACCME, AMA, PhRMA Code, OIG and FDA guidance.

Introduction and Background

Inflammatory bowel disease (IBD) primarily encompasses the conditions ulcerative colitis and Crohn’s disease. In the United States, it is currently estimated that about 1 –1.3 million people suffer from IBD.¹ Although there are few epidemiologic data from developing countries, the incidence and prevalence of IBD are increasing with time and in different regions around the world, indicating its emergence as a global disease.²

The etiology of IBD has been extensively studied in the past few decades, however, disease pathogenesis is not fully understood. Genetic polymorphism, mechanisms of genetic modification including DNA methylation, colonization with intestinal flora, and environmental factors such as diet, antibiotic and mucosal disruption play a role in intestinal inflammation.³ Crohn’s disease is characterized by a range of signs and symptoms, so there is no single test that can determine the
There are significant unmet needs in the treatment of pts with IBD. With the use of currently available therapies 40-55% of patients have no response to therapy and patients who respond to biologics may lose the response over time. In addition, treatment goals in IBD are evolving beyond the control of symptoms alone towards the sustained control of GI inflammation, objectively measured by endoscopic, radiologic, and laboratory parameters. With the advent of new agents, therapies that provide greater levels of mucosal healing and resolution of clinical symptoms may eventually modify the disease course.

With the emergence of new therapies and clinical data having an understanding of the mechanisms of action, efficacy and safety profiles of these agents supports the need for continuing education of practitioners who care for these patients. In addition, having an understanding of the pharmacology and pharmacokinetics of new oral and injectable formulations and appropriate timing of therapy may improve individual patient outcomes.

References:
3. Sandborn, W; The Present and Future of Inflammatory Bowel Disease Treatment, Gastroenterology Volume 12, Issue 7 July 2016
6. Sands, B, From symptom to diagnosis: Clinical Distinctions Among Various Forms of Intestinal Inflammation, Gastroenterology, May 2004 Volume 126, Issue 6, Pages 1518–1532

Medical Educational Grants Guidelines

Medical Educational Grants are awarded in support of high quality, independent educational programs and materials, which demonstrate the potential to improve patient care and health outcomes. Each educational grant awarded must adhere to and be compliant with:

- FDA Final Guidance on Industry-Supported Scientific and Educational Activities,
- Office of Inspector General (OIG) Guidelines,
- Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support,
- Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals,
- American Medical Association (AMA) Ethical Guidelines for Gifts to Physicians from Industry, and
- Other relevant guidelines and regulations.

Supported programs must be independent, objective, balanced and scientifically rigorous. Grants cannot be tied, in any way, to past, present, or future prescribing, purchasing or recommending
(including formulary recommendations) of any drug. Proposals which do not appear to provide a balanced view of available and/or potential future therapeutic options will not be considered.