Biogen Idec Global Medical Grants Office

Multiple Sclerosis: Areas of Interest (Cycle A)
December 2, 2014
**Introduction**

The landscape for the treatment of relapsing Multiple Sclerosis ("MS") has quickly evolved over the past 5 years (and is expected to continue to rapidly evolve during the coming years) resulting in a dramatic increase in therapeutic options as well as management considerations. As the field has become more complex, the need to develop and share a framework of care in MS has become increasingly important.

Therefore, to address this unmet need, Biogen Idec is interested in comprehensive proposals that combine and synthesize the following areas of need in order to define and educate on best practices for treating patients with MS.
Educational Gap Data

MS is a chronic, inflammatory, demyelinating disease of the central nervous system (CNS).\(^1\) Its cause is unknown; however, the disease is believed to be autoimmune in origin.

A 2008 study found that approximately 70% of patients with MS see a neurologist for their care; the rest see another type of provider, usually a primary care physician (PCP).\(^2\) This study found that patients recently diagnosed and those with active disease are more likely to be under the care of a neurologist, while those with stable disease are treated by a PCP. In this study, patients with MS who are treated by a neurologist or a MS specialist, as opposed to a PCP, are more likely to undergo diagnostic and treatment-related tests and receive disease modifying agents (DMAs) and other therapies.\(^2\) These patients are also more likely to be aware of their treatment plan. The authors concluded that PCPs will need continuing education about the appropriate use of DMAs and other therapies and when to refer patients to neurologists or other specialists, like physiatrists. PCPs are also likely to need assistance with the diagnosis of MS and the use of symptomatic treatments and disability-related therapy.

A retrospective cohort study of data from 2001-2007 found that nearly 60% of newly-diagnosed patients were untreated. (Margolis 2011)\(^3\) Patients who were treated were generally younger. Reasons for the lack of DMA prescriptions for older patients included a high frequency of comorbidities and more advanced disease.

In a 2007 study of 145 patients with MS, 45% indicated that their physician discussed their emotional well-being at diagnosis, and 56% reported that their clinician discussed specific emotions (e.g., fear, sadness, anger) as a result of living with the disease.\(^4\) Discussions of emotions appeared “to be associated with several positive outcomes.”
In a recent independent study, neurologists in the United States, Canada, Brazil, Argentina, the UK, France, Germany, Italy, Spain, Scandinavia, Japan, India, and Australia were surveyed regarding their care of patients with MS. The study found:

- Less than half of neurologists were “very confident” in their management of therapeutic regimens.
- IFN and glatiramer were most commonly chosen for initial therapy of RRMS. Variability was noted with respect to second-line therapy. For a patient initially on IFN, neurologists were divided between changing therapy primarily to glatiramer, fingolimod, or natalizumab, although a sizeable minority opted to keep the patient on IFN. For third-line therapy the majority of neurologists would switch to natalizumab.
- For most countries, <30% of neurologists found MOA to be “very influential” in their DMT choice.
- Less than half of neurologists in all countries were “very confident” in managing MS symptoms, and one-third or more of neurologists were not “very confident” in communicating with patients about MS symptoms or potential medication complications.
- There was notable variability between neurologists as to how likely they were to inquire about a specific symptom. The great majority asks about quality of life, but do not use a formal survey.
- There was great variability in the use of pharmacologic and non-pharmacologic therapy used to manage MS symptoms and in referral to other healthcare providers (physical therapy, occupational therapy, psychiatrist/psychologist/counselor, urologist, continence nurse, nutritionist, social worker).
- A large majority of clinicians in all countries measured patient compliance, but most relied on patient and/or family or caregiver report.
- Clinicians in all countries wanted education on biomarkers in MS and how to use them, management of symptoms, information on new and emerging therapies, and practice guidelines.

REFERENCES

5. CEOutcomes Needs Assessment Data collected May and June 2013.
Cycle A: Areas of Interest Details

The Biogen Idec Grants Office is seeking proposals for Cycle A targeting the below 3 categories that are aimed at addressing the independently identified educational needs of the MS healthcare professional (HCP) community, referenced in the previous slides.

1. MS Thought Leader Steering Committee
2. 2015 National/Regional Congresses
3. General MS Medical Education
Biogen Idec is interested in supporting programs that bring together MS Experts/Thought Leaders (patient and/or physician organizations or academic institutions) to participate in an educational initiative designed to assess and discuss best practices in managing patients’ health during the treatment span of MS from onset onward.

- For example: guidelines and education on decisions around treatment initiation, best practices for disease monitoring, considerations and shared decision-making in the choice of disease modifying therapies, assessing the psychological aspect of the patient (i.e. depression), and managing symptoms (e.g. fatigue and cognitive dysfunction).

The MS Thought Leader Steering Committee should promote stimulating discussions with the end goal of reporting outcomes that:

- Seek to collect and synthesize current evidence in a scientifically rigorous, evidence-based manner under the guidance of a panel of experts
- Approach the solution with a multi-faceted methodology
- Offer creative approaches to deliver and reinforce content to the HCP community (for example, interactive interventions that reinforce the relevance of the presented content to real-world practice through case scenarios)
- Feature collaboration across organizations and/or academic institutions to ensure a wide representation of stakeholder viewpoints
General MS Medical Education

We are seeking proposals for accredited educational programs to address the below areas:

- Current clinical trial data on new therapies.
- Latest evidence-based therapeutic regimens for relapsing MS.
- Risks and benefits of available therapies.
- Mechanisms of action for MS therapies and its impact on efficacy and safety.
- Best practices in managing patients’ health during the treatment span of MS from onset onward. For example: guidelines and education on decisions around treatment initiation, best practices for disease monitoring, considerations and share decision-making in the choice of disease modifying therapies, assessing the psychological aspect of the patient (i.e. depression), and managing symptoms (e.g. fatigue and cognitive dysfunction).
- How to evaluate disease activity and identify treatments to get the best long term outcomes.

The Biogen Idec Grants Office supports independently developed educational programming designed to address knowledge and performance practice gaps (levels 3-6) of the healthcare professional community, ultimately directed at enhancing patient care and community health. Special consideration will be given to multi-component initiatives that offer scientifically rigorous formats, unique delivery methods, and incorporates adult learning principles (for example, interactive interventions that reinforce the relevance of the presented content to real-world practice through case scenarios).
We acknowledge the value physicians, nurses, and other healthcare professionals place on professional meetings, as they provide them with the opportunity to stay up to date on advancements in clinical practice, specifically within their specialty. Therefore, we are seeking requests to fund live activities (face-to-face meetings) at major national/regional congresses.

**Cycle A:** Please reference the following cycle code on your grant application/proposal: MSCYCLEA-2015

- **Open Date:** December 11, 2014
- **Close Date:** February 27, 2015
- **Activity Start Date:** Cycle A-2015 is for grants with start dates on or after May 30, 2015
- **Submission Deadline:** 5:00pm Friday, February 27, 2015
Special Note

Preference is given to multi-component initiatives (for example, live activity with enduring spin-off).

Consistent with Biogen Idec policy and our commitment to conduct business ethically, all proposals for continuing medical education programs and initiatives must comply with ACCME criteria and Standards for Commercial Support™ as well as the AMA, PhRMA Code, FDA, and OIG guidance’s. In addition:

• Proposals must be fair, balanced, and scientifically sound;
• Data must be objectively selected;
• Content must be independently developed;
• Biogen Idec will not provide input relating to content, presenters, moderators, or program format; and
• Biogen Idec will not support proposals that are linked to prescribing, purchasing, formulary status, or reimbursement activities.
Contact Information

If there are any questions please contact:

<table>
<thead>
<tr>
<th>Name:</th>
<th>Amy Funkhouser</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title:</td>
<td>Associate Director</td>
</tr>
<tr>
<td>Phone:</td>
<td>617-914-4099</td>
</tr>
<tr>
<td>Email:</td>
<td><a href="mailto:grantsoffice@biogenidec.com">grantsoffice@biogenidec.com</a></td>
</tr>
</tbody>
</table>