Call for Independent Medical Education (IME) Notification: Roche Scientific Communications

Therapeutic Area and Disease: CNS-Multiple Sclerosis

The Global Medical Affairs Multiple Sclerosis Team at Roche invites members of the educational provider community to submit applications for IME grants subject to the terms described below. This Call for IME provides public notice of the availability of funds in a general topic area for activities for which recognized scientific or educational needs exist and funding is available.

**Purpose:** As part of its scientific mission, Roche supports grants for IME as a means to enhance the medical community’s ability to care for patients. This mission is achieved by supporting quality independent education that addresses evidence-based, valid educational gaps in accordance with the spirit of prevailing IME guidance, e.g. UEMS-EACCME and ACCME.

**Eligibility Criteria:** Appendix A

**Geographical Scope:** Global, ex-US

**Submission Instructions:** Providers who meet the eligibility criteria and are interested in submitting a response to this Call for IME may submit their grant request using the Roche grant application: [link](#)

**Deadline for Submission of Applications:** March 31, 2016 (23:59 Central European time)

**Award Decision Date/Mechanism:** Final approvals and denials will be communicated through email no later than April 29, 2016. *There have been no pre-determined approvals. All submissions will be reviewed equally.*

IME providers should only respond to this Call for IME if they have read and understand the terms, purpose, therapeutic landscape and educational request identified below. Applicants will be expected to identify independent gaps that are clinically accurate, relevantly aligned to this Call for IME, and that can be referenced.

**Call for IME**

<table>
<thead>
<tr>
<th>Therapeutic Area &amp; Disease</th>
<th>CNS – Multiple Sclerosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Available Funding</td>
<td>There is a budget of up to CHF 800k available for a multichannel medical education approach addressing one or more of the educational needs outlined in this Call For Grant Notification</td>
</tr>
</tbody>
</table>
Multiple sclerosis (MS) is a chronic inflammatory, autoimmune, demyelinating, and neurodegenerative disease of the central nervous system (CNS)\(^1\). Approximately 85% of the patients present with relapsing remitting MS (RRMS), while a minority (10%) presents with primary progressive MS (PPMS)\(^2\), while the classification of the disease keeps on evolving\(^3\). Although a lot of progress has been done in revealing the role of the immune system in MS\(^4\), the understanding of the role of T- and B-cells in the pathophysiology of the disease, relapsing or progressive, is not widely understood by neurologists\(^5\). Hence there is a persistent difficulty for healthcare professionals to effectively and safely manage MS, starting with diagnosing the disease (especially differentiating RRMS from PPMS)\(^6\), and deciding when to initiate and adapt available treatment options \(^6,7,8\). Roche believes there is then a substantial unmet educational need for healthcare professionals to understand and use evidence-based information on MS into their day-to-day clinical practice decisions with the aim of providing the best of care to patients.

Roche is seeking to support educational grants that:

1. Further identify the clinician baseline knowledge/awareness & competence gaps that lead to impact on the care of MS patients that may include but are not limited to those mentioned in the Background section of this Call for IME.

2. Align the identified gaps to a relevant, fair/balanced educational initiative(s) that can address the gaps through
learning intervention(s).

3. Provide fair/balanced education on the identified areas, embracing innovative models for delivery and scientific exchange, where possible. Programs can be conveyed through a single or multichannel approach (e.g. live symposia at congresses and/or online educational programs) using impactful educational formats and patient based cases, where applicable.

Based on external research, Roche believes these educational initiatives would be best suited for ex-US based neurologists and neurology nurses with a focus on MS.

Measures

A wide variety of measures have been used for managing patients with MS.

Roche encourages accredited providers to submit educational grants that identify the connection between relevant measures and the specific systemic/clinician-based knowledge and competence gaps that lead to awareness of current and emerging areas of MS. Roche encourages IME providers to submit grant requests that address specific HCP knowledge, competence, and performance gaps. Although not specifically required, consideration will be given to those grant requests intended to demonstrate how the educational initiative(s) will improve patient care by closing the gaps and assessing the healthcare providers’ behavior relative to standard of care and best available evidence.

Results

The educational initiatives should provide the participants with the data to help with the evaluation and utilization of evidence that leads to appropriate decision-making. The educational provider should therefore show that learners have 1) demonstrated understanding of the educational activity, 2) demonstrated a competence improvement as a result of it, and 3) will use evidence-based concepts to consider changing behavior where appropriate or relevant.

Discussion

Roche encourages IME provider(s) who are awarded approval to:
1. Consider whether or not the educational intervention(s) reduced the average time it takes for the educational audience to adopt information, demonstrating how this was achieved.
2. Demonstrate key findings via outcomes analysis (see Measures and Results sections above).
3. Summarize (through written analysis) their understanding of the outcomes metrics, identifying the association between the intervention and the outcomes.
4. Identify any unanticipated barriers and/or activity/outcomes limitations; explain the reason(s) for them, and describe the efforts made to address them as necessary.

Additional Considerations

All grant submissions should describe how the educational provider plans to determine the extent to which the initiatives have met the stated objectives and closed the identified clinical/educational gap(s) including the qualifications of those involved in the design and analysis of the outcomes.

Terms and Conditions

1. All grant applications received in response to this Call for IME will be reviewed in accordance with all Roche policies.
2. This Call for IME does not commit Roche to award a grant or to pay any costs incurred in the preparation of a response to this request.
3. Roche reserves the right to approve or deny any or all applications received as a result of this request or to cancel, in part or in its entirety, this Call for IME.
4. For compliance reasons, and in fairness to all education providers, all communications about this Call for IME must come exclusively to global.imegrantsms@roche.com
5. Failure to follow any instruction within this Call for IME may result in a denial.

References

6. CEOOutcomes Needs Assessment, 2015

Appendix A

Eligibility Criteria for Independent Medical Education (IME) Grant Recipients

Roche Grants for Independent Medical Education (IME) to Healthcare-Related Entities Grants can only be provided for the purpose of supporting healthcare-related education and must always ultimately benefit patients and / or public health.

IME is generally defined as a healthcare-related educational activity for HCPs initiated and organized independently from Roche by an IME Provider such as a hospital, academic center, society or association, or medical education company, and where Roche has no influence on the content of the program.

The IME Provider must be an independent third party that has full control over the development and selection of all aspects of the activity, including content, presenters, moderators and audience.

Roche is not providing Grants for IME to the following:
1. Individual HCPs or individual patients or organisations owned or controlled by individual HCPs
2. Small business associations of HCPs, e.g. private physician offices, private group practices, small private hospitals (comprising, as a general rule, less than 10 HCPs)
3. Not-for-profit foundations formed by a small number of HCPs (as a general rule less than 50 HCPs)

In order to be eligible, the funding must not be used:
1. To improperly induce or to reward the prescription, recommendation, purchase, order, supply, use, administration, sale or lease of a Roche Product or Service;
2. For the purpose of Pre-approval or Off-label Promotion of a Roche Product;
3. To inappropriately influence regulatory, pricing, formulary or reimbursement decisions;
4. To influence the content of Clinical Practice Guidelines;
5. For relationship building purposes.
6. For standalone entertainment or social events
Firewall requirements for IME Providers
Organisations that provide services to Roche, e.g. in the areas of strategy, promotion, market research, publication or Roche initiated medical education, must have a proper firewall in place between their sections providing these services to Roche and their section receiving the IME Grant and realizing the IME activities.

Provision for an independent specific activity or event
1. Grants are provided for a specific activity or event that may not be organized nor influenced in any way by Roche. Additionally, Roche cannot receive any direct benefit in return when providing a Grant.
2. The specific activity or event must be described in the application form link and the description must be sufficiently complete in order for Roche to be able to evaluate whether or not to provide the support.
   a. It should usually contain at least the following information:
      i. Background of the request including objectives and expected result of the event / activity
      ii. Description of why the event / activity is necessary (unmet educational need)
      iii. Intended audience of the event / activity
      iv. Whether or not other companies have been invited to support the event / activity
      v. In case of live event additionally: Proposed agenda and description of the planned location.
      vi. Requested amount of support, including cost breakdown for event / activity;

3. Grant requests that contain unacceptable budget line items will be ineligible such as:
   1. Funding for healthcare professional partners or guests.
   2. Faculty lodging and/or expense reimbursement out of proportion with the number of days that the faculty is presenting
   3. Gifts/prizes for faculty or attendees
   4. Request for food only
   5. Funding for faculty dinners not related to content review
   6. Honoraria or costs not according to Fair Market value FMV and the applicable local laws, regulations and industry codes, in the country where the attending HCP has his/her primary practice
   7. Lavish venues and venues that detract from the educational activity as the primary purpose.

4. Grants are provided for a fixed period of time and cannot be self-renewing

General
1. The organization will provide an official receipt and full cost reconciliation upon request that meets applicable accounting standards.
2. If a Grant is approved, the organization must enter into a written agreement with Roche