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

**Therapeutic Area and Disease:** Immunology – Giant Cell Arteritis (GCA)

Roche invites members of the educational provider community (IME providers) to submit applications for a grant for IME (Independent Medical Education) subject to the terms described below. This call for grant for IME provides public notice of the availability of funds in the area of Giant Cell Arteritis (GCA) 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:** US and EU5

**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: https://goo.gl/forms/r2T2VjPU73uKPtbm1

**Deadline for Submission of Applications:** 16th November, 2016 (23:59 Central European Time)

**Award Decision Date/Mechanism:** Final approvals and denials will be communicated through email no later than 9th December, 2016. There is no pre-determined approvals or rejections. All applications and submissions will be reviewed thoroughly and equally.

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

**Call for grant for IME**

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<tr>
<th>Therapeutic Area &amp; Disease</th>
<th>Immunology – Giant Cell Arteritis (GCA)</th>
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<td><strong>Available Funding</strong></td>
<td>There is a budget of up to CHF 300,000 (three hundred thousand Swiss Francs) available for a multichannel approach addressing one</td>
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or more of the educational needs outlined in this Call for Grants Notification (CGN). Based on external research, Roche believes that an online education format and a multi-modular approach would meet the educational needs outlined in this document, but is also open to proposals for educational initiatives with alternative format.

Educational providers may request up to a maximum of CHF 300,000 but are not required to design IME that utilizes the full available amount.

Background

Giant Cell Arteritis (GCA) is an autoimmune disease causing systemic vasculitis of medium and large sized arteries. It affects adults over the age of 50 and is two to three times more likely to affect women1. GCA has a global impact with a known geographical difference in the prevalence2,3. The incidence increases from 23 per 100,000 people per year in the sixth decade of life to 44.7 per 100,000 people per year in the ninth decade of life and older1.

GCA commonly affects the cranial arteries (e.g. temporal and ophthalmic arteries) where inflammation leads to stenosis or occlusion, resulting in ischemic symptoms such as headache, scalp tenderness, jaw pain and visual problems. GCA also affects large vessels outside the head, particularly the aorta and its branches resulting in ischemic symptoms such as upper limb pain and risk of aortic aneurysm. Frequent systemic constitutional symptoms are polymyalgia rheumatica (PMR), fatigue, malaise, fever and weight loss4,5. The inflammatory markers ESR and CRP are elevated in the majority of cases during active disease1.

GCA is characterised by an often elusive presentation to a wide and variable spectrum of signs and symptoms that the patient may present with1. This can make diagnosis difficult. Symptom overlap with other conditions can also mean delayed or incorrect diagnosis4. GCA patients can present with symptoms to general practitioners and different specialists such as rheumatologists, ophthalmologists, neurologists, or geriatricians for example. The specialists that patients see first when experiencing symptoms of GCA influence the time it takes for them to be correctly diagnosed. Increasing awareness of the symptomatology to ensure early identification and
Diagnosis of GCA is important. Diagnosis is based on a range of elements including a patient’s symptoms, clinical examination, blood tests (to check for elevated inflammatory markers), a temporal artery biopsy, and/or imaging techniques such as computed tomography angiography (CTA), magnetic resonance angiography (MRA) or positron emission tomography–computed tomography (PET-CT). With the variety of tools there is a need to identify effective diagnostic approaches for adult patients with GCA.

Early recognition and diagnosis of GCA is paramount to avoid vision loss and limit long term side effects. Permanent visual loss affects ~15% of patients. Once visual loss is established, it is almost always permanent, but it can be prevented by early intervention.

Current treatment of GCA is long-term high doses of glucocorticoids. They are effective for remission induction and have been the mainstay of GCA therapy for the past 50 years, but generally fail to cure GCA or maintain sustained glucocorticoid-free remission.

During glucocorticoid tapering, over 50% patients will experience a flare of their GCA, with approximately one third of patients experiencing two or more flares. For those GCA patients able to stop treatment with glucocorticoids, tapering off can take 1-3 years. In addition, 80% of GCA patients will experience glucocorticoid related adverse events/toxicities, and the cumulative dose of glucocorticoid has a corresponding increase in the risk of related adverse events. There is an unmet medical need to reduce the cumulative glucocorticoid dose.

**Methods**

Roche is seeking to support an education grant that:

1. Identifies clinician baseline knowledge and awareness needs, together with competence gaps across the disease, the diagnosis and treatment
2. Provides fair and balanced educational initiatives that translate into benefits for patients, their care givers and healthcare providers
3. Is aimed at the identified areas and embraces both effective
and innovative models for delivery and scientific exchange.

On the basis of external research, Roche believes that these educational initiatives would be best suited to physicians who see patients in the disease pathway (these include but not limited to rheumatologists, ophthalmologists, primary care physicians, neurologists, geriatricians).

Although not specifically required, Roche also believes that an online education format and a multi-modular approach to address the specific educational needs of the varying physician groups might need to be considered.

**Measures**

Roche encourages IME providers to submit grant requests that address specific clinician 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 knowledge gaps and assessing healthcare providers’ behaviour relative to disease management.

**Results**

The educational initiative should provide the participants with the latest data to help with the evaluation and utilization of evidence that leads to appropriate decision making and enhancement of patient care. The educational provider should therefore demonstrate that learners:

1. Have demonstrated understanding of the educational activity
2. Have demonstrated competence improvement as a result
3. Will use evidence-based concepts to consider changing behaviour where appropriate or relevant
4. Will use evidence of supporting knowledge and competency retention

**Discussion**

Roche encourages IME provider(s) who are awarded approval to:

1. Consider whether or not the educational intervention(s) reduced on average the time taken 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 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.

*Roche is also committed to providing non-solicited grant support in these therapeutic areas.

**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 grant for IME will be reviewed in accordance with all Roche policies.
2. This call for grant 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 grant for IME.
4. For compliance reasons, and in fairness to all education providers, all communications about this call for grant for IME must come exclusively to global.ime-immunologygca@roche.com.
5. Failure to follow any instruction within this call for grant for IME may result in a denial.

**References**

5. Dasgupta, B. Concise guidance: diagnosis and management of giant cell arteritis. Royal College of Physicians. 2010
16. Sun GH. Corticosteroid-Related Adverse Events in Patients with Giant Cell Arteritis: A Claims-Based Analysis. Presented at the American College of Rheumatology Annual Scientific Meeting; 14-19 November 2014; Boston, MA
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:
   a. Funding for healthcare professional partners or guests.
   b. Faculty lodging and/or expense reimbursement out of proportion with the number of days that the faculty is presenting
   c. Gifts/prizes for faculty or attendees
   d. Request for food only
   e. Funding for faculty dinners not related to content review
   f. 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
   g. 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