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

Therapeutic Area and Disease: Hematology – Lymphoma

The Global Medical Affairs Hematology 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

**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: http://goo.gl/forms/yX0EZKWPsw

**Deadline for Submission of Applications:** 22 July, 2016 (23:59 Central European Time)

**Award Decision Date/Mechanism:** Final approvals and denials will be communicated through email no later than 17 August, 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**

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<tr>
<th>Therapeutic Area &amp; Disease</th>
<th>Hematology - Lymphoma</th>
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<td>Available Funding</td>
<td>There is a budget of up to CHF 280,000 available for a multi-channel approach, to be completed before the end of 2017, addressing one or...</td>
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more of the educational needs outlined in this Call for Grants Notification (CGN). This could be for one multi-channel activity, or more than one linked activities or independent activities addressing the identified unmet needs for the target audience. Budget submissions should be broken down per activity if more than one approach is proposed.

Please note that if the IME provider believes that an IME symposium at one or more relevant European congress(es) could meet the educational needs outlined in this document, vendors are expected to cover the costs within the allocated budget*. Roche is also open to proposals to educational initiatives with alternative formats.

Educational providers may request up to a maximum of CHF 280,000 but are not required to design IME that utilizes the full available amount.

Roche is also committed to providing non-solicited grant support in this therapeutic area.

*Please note, there is a requirement that any proposals submitted for activities taking place in Spain are multi-sponsored.

Background

Non Hodgkin Lymphoma (NHL) includes a group of clinically and biologically diverse diseases that arise from mature T- or B-lymphocytes in secondary lymphoid organs.1,2 About 85% of cases of NHL are of B-cell origin, and include indolent forms (iNHL) such as follicular lymphoma (FL) and marginal zone lymphoma (MZL), and more aggressive presentations such as diffuse large B-cell lymphoma (DLBCL), Burkitt’s lymphoma (BL) and mantle cell lymphoma (MCL).2

FL is the most common type of iNHL, with an incidence that has risen from 2 to 3 per 100,000 in the 1950s to 5 to 7 per 100,000 more recently in Western Europe.3 Approximately 50% to 70% of patients have bone marrow involvement, which indicates advanced disease, at presentation.4-6 DLBCL is the most prevalent aggressive subtype,1 and accounts for between 30% and 58% of cases of NHL.7 Incidence increases with age, and there are a variety of risk factors.7

Patients with B-cell NHL represent a heterogeneous disease
population with diverse clinical outcomes and unmet needs. Management of NHL depends on stage, tumor burden and other patient factors. Patients with early (stage I–II) iNHL can achieve good initial outcomes, but most patients are incurable and experience successive relapses and increasing resistance to treatment. Over half of DLBCL patients can achieve long and durable responses with current therapy based on anti-CD20 MAb + anthracycline-based chemotherapy. MCL is considered incurable, although median overall survival in these patients has improved since the introduction of rituximab.

Prolonging survival and delaying relapse in iNHL: Despite high response rates with initial therapy, FL is characterized by frequent relapses. A continuous pattern of relapse is common after good initial responses, and FL remains incurable for many patients.

Increasing safety and improving tolerability for first-line agents in iNHL: The short- and long-term toxicities of chemotherapy-based regimens continue to be a source of concern, and there is a need for new strategies that might preclude these toxicities.

Improving cure rates and survival in first-line DLBCL: DLBCL is an aggressive but potentially curable malignancy. However, more than 30% of DLBCL patients will eventually relapse after first line treatment, after which the majority of patients die from the disease.

Methods

Roche is seeking to support an education grant that:

1. Supports clinicians’ information and learning needs as outlined, but not limited to, those outlined above.
2. Identifies further clinician baseline knowledge and awareness needs, together with competence gaps.
3. Provides fair and balanced educational initiatives that translate into benefits for patients, their care givers and healthcare providers.
4. Is aimed at the identified areas and that embraces effective models for delivery and scientific exchange.

Roche believes on the basis of external research that this educational
Roche encourages IME providers to submit grant requests that address specific clinician knowledge, competence, and performance gaps. Consideration will be given to those grant requests intended to demonstrate how the educational initiative(s) will improve patient care by closing gaps and assessing healthcare providers’ behavior relative to standards of care and best available evidence.

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 show 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 behavior where appropriate or relevant.

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, and demonstrate 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.
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.imegrants-hematology@roche.com.
5. Failure to follow any instruction within this Call for IME may result in a denial.

References


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