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

Therapeutic Area and Disease: Oncology – Ovarian Cancer

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 recognised scientific or educational needs exist and funding is available.

Purpose: As part of its scientific mission, Roche supports grants for Independent Medical Education 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 (except USA)

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://docs.google.com/a/roche.com/forms/d/e/1FAIpQLSfO5QpWwaw6yA-tocuxHDl5yzqByVJQA7Ldfz0Y1_3qyK15TIA/viewform

Deadline for Submission of Applications: 20 January 2017 (23:59 CET)

Award Decision Date/Mechanism: Conditional approvals and denials will be communicated through email no later than 17 February 2017. 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>
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<tr>
<th>Therapeutic Area &amp; Disease</th>
<th>Oncology / Ovarian Cancer</th>
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<td>Available Funding</td>
<td>There is a budget of up to CHF 150'000 available for a multi-channel approach addressing one or more of the educational needs outlined in this Call for Grants Notification (CGN). Educational providers may request up to a maximum of CHF 150'000 but are not required to design independent medical education that utilizes the full available amount. Budget submissions should be broken down by type of activity. Roche is committed to providing non-solicited grant support to enhance medical and scientific knowledge in the areas described below.</td>
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<td>Background</td>
<td>Ovarian cancer</td>
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<td>Ovarian cancer is one of the most common gynecological cancers in Europe and the United States. The incidence of ovarian cancer varies by geographic region, with the highest rates observed in North America, Europe, and other developed countries (<a href="http://globocan.iarc.fr">http://globocan.iarc.fr</a>). Based on data published by IARC, there were 65,500 new cases of ovarian cancer, yielding an age-standardized incidence rate of 13.1 cases per 100,000 women in Europe [1,2]. Ovarian cancer has a higher fatality-to-case ratio than any other gynaecologic malignancy [3]. It is the fifth leading cause of cancer mortality among European women [1]. In Europe, the age-adjusted 2012 mortality rate is 7.6 deaths per 100,000 women per year (42,700 deaths), with the highest rates in Northern Europe (8.7 per 100,000) and the lowest rates in Southern Europe (6.4 per 100,000) [1]. The median age at diagnosis for ovarian cancer is 63 years, with peak incidence occurring at age 60 [3]. Women who develop ovarian cancer are most commonly white and peri- or postmenopausal (<a href="http://seer.cancer.gov/statfacts/html/ovary.html">http://seer.cancer.gov/statfacts/html/ovary.html</a>).</td>
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Major risk factors include: older age, nulliparity, older age at first birth, post-menopausal treatment with estrogens or clomiphene, family history of breast cancer or colorectal cancer and mutations in BRCA1 and BRCA2 genes. Due to asymptomatic early stage disease, most women are diagnosed with already advanced ovarian cancer. The relative 5-year survival of patients with distant disease is 27.4%.

The standard of care for ovarian cancer includes surgery with the aim of complete cytoreduction. Standard therapy for all patients with advanced disease following surgery is a taxane/platinum combination, usually carboplatin and paclitaxel. Antiangiogenic therapy in front-line ovarian cancer is approved in several countries, including the EU [4].

In order to fully embrace the importance of frontline treatment of ovarian cancer, healthcare providers need sufficient multidisciplinary knowledge and support to be confident in making the best disease management decision by also using the approved treatments in clinical practice. Multiple insights sources have shown that although healthcare providers are familiar with the antiangiogenic treatment of frontline ovarian cancer, many still lack of understanding on which patients benefit more and better from which treatment sequence.

The educational programme should address the multidisciplinarity of a patient’s management with advanced ovarian cancer, from first diagnosis to first relapse, by addressing the following educational gaps.
1. Ovarian cancer front-line treatment
The healthcare providers need to understand:
• the multidisciplinary disease management for an optimal individualized treatment strategy [11].
• optimal surgical plan for newly diagnosed patients
  • management of inoperable patients [5]
  • management of operable patients
• how surgical outcomes impact on treatment options

2. Ovarian cancer front-line treatment in special populations
The healthcare providers need to understand the management options of:
• elderly patients [6,7,8]
• patient with poor performance status [10]
• patients with multimorbid conditions (e.g. hypertension, proteinuria, GI issues,) and symptoms (e.g. pleural effusion, ascites) [10].

3. Ovarian cancer frontline treatment: risks and side effects
The healthcare providers need to understand how to address and manage identified risks of antiangiogenic treatment such as but not limited to haemorrhagic events, GI side effects, hypertension, and how to follow guidance of chemotherapy adjustment [5,7,10].

4. Understanding frontline ovarian cancer treatment landscape
To address a knowledge gap, an identified education may include, but is not limited to
• Understanding of drugs in development as PARP inhibitors and checkpoint inhibitors and the rationale in combination with current disease management options including antiangiogenic treatment [9,12,13].

The format of the initiative should ensure an optimal gain of knowledge by addressing the gaps that are mentioned in this section above.

Methods

Roche is seeking to support an education grant that:
1. Further identifies clinician baseline knowledge and awareness needs, together with competence and performance gaps that lead to impact on the care of patients that may include but are not limited to those mentioned in the Background section of this Call for IME.

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 that embraces effective models for delivery and scientific exchange.

Based on external research, Roche believes these educational initiatives would benefit, but would not limit to, medical oncologists, gynecological oncologists, gynecological surgeons, and oncology nurses.

**Measures**

Roche encourages IME providers to submit grant requests that address specific clinician knowledge and competence gaps. Although not specifically required, consideration will be given to those grant requests intended to demonstrate how the educational initiative(s) would improve patient care by closing knowledge gaps and assessing healthcare providers’ behaviour relative to standards of care and best available evidence. Although not specifically required, consideration will also be given to use of an approach that encompasses multiple learning platforms and methods (i.e. a ‘multi-channel’ approach), as well as innovative ideas. Providers should consider how the needs of learners with different levels of knowledge and different cultural challenges will be addressed and how any content proposals will meet identified knowledge gaps.

Consideration will be given to providers who can demonstrate an understanding of the types, channels and methods of learning that fulfil the criteria outlined in the Results section below.
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 have:

1. Demonstrated understanding of the educational activity and have gained knowledge;
2. Demonstrated competence improvement as a result.

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. Summarise (through written analysis) their understanding of the outcomes metrics, identifying the association between the intervention and outcomes;
4. Identify any further knowledge gaps and 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.
   For compliance reasons, and in fairness to all education providers, all communications about this Call for IME must come exclusively to global.cgn-floc@roche.com
4. Failure to follow any instruction within this Call for IME may result in a denial.
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 centre, 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. Description of why the event / activity is necessary (unmet educational need);
      ii. Background of the request including objectives and expected result of the event / activity;
      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
Transparency

As a matter of corporate responsibility Roche reserves itself the right to publicly disclose, for example via reports published on its website, its grants or contributions to third-party organizations. In such case Roche will report information such as the name of the grantee, a brief description of the program/project, and the amount of the grant award.

References

4. EU SPC and PIL EMEA/H/C/000582/II/0087 (Avastin)
6. Mustea A, Wimberger P, Oskay-Özcelik G et al. Impact of age on the safety and efficacy of bevacizumab-containing therapy In patients with primary ovarian cancer: second interim analysis of the OTILIA German non-interventIonal study on behalf of the north-eastern German society of gynaecological oncology (NOGGO) ovarian cancer working group. Poster #867P presented at ESMO 2016 Annual meeting