Call for Independent Patient Education (IPE) Notification: Roche Scientific Communications

Therapeutic Area and Disease: Haematology – Haemophilia

The Global Medical Affairs Haematology Team at Roche invites members of the educational provider community to submit applications for IPE grants subject to the terms described below. This Call for IPE 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 IPE as a means to address patients’ educational needs. This mission is achieved by supporting quality independent education that addresses evidence-based, valid educational gaps in accordance with the spirit of prevailing guidance.

Eligibility Criteria: see Appendix A

Geographical Scope: Global (ex-US, with a focus on Europe)

Submission Instructions: Providers who meet the eligibility criteria and are interested in submitting a response to this Call for IPE may submit their grant request using the Roche grant application:

http://goo.gl/forms/yX0EZKWPsW

Deadline for Submission of Applications: 31 January 2017

Award Decision Date/Mechanism: Final approvals and denials will be communicated through email no later than 31 March 2017. There have been no pre-determined approvals. All submissions will be reviewed equally.

IPE providers should only respond to this Call for IPE 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 accurate and relevantly aligned to this Call for IPE, and that can be referenced.

Call for IPE

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<tr>
<th>Therapeutic Area &amp; Disease</th>
<th>Haematology - Haemophilia</th>
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<td>Available Funding</td>
<td>There is a budget of up to CHF 200,000 available to support unsolicited grant proposal(s) for a multi-channel approach addressing one or more of the educational needs outlined in this Call for Grants Notification (CGN). This could be for one multi-</td>
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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 IPE provider believes that an IPE symposium at one or more relevant European patient congress(es), and/or educational initiatives with alternative formats, could meet the educational needs outlined in this document, vendors are expected to cover the costs within the allocated budget.

Educational providers may request up to a maximum of CHF 200,000 but are not required to design IPE that utilizes the full available amount.

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**Background**

Haemophilia A (which occurs in one in every 5000 live male births) is caused by an inherited deficiency of Factor VIII (FVIII). The modern management of haemophilia began in the 1970s with the development of lyophilized plasma concentrates of coagulation factors. Recombinant products followed after the cloning of clotting factor genes in the 1980s. Current standard treatment for haemophilia A includes regular prophylaxis and episodic treatment with recombinant or plasma-derived FVIII.

Long-term adherence to effective prophylactic therapy is the key to successful management of severe haemophilia. Determinants of adherence to prophylaxis include age, symptoms, beliefs and relationship with the healthcare provider. However, patients who experience fewer symptoms tend paradoxically to have lower adherence, which emphasizes the need for patient education on the risks of undertreatment and bleeding, and the value of sustained protection levels.

Inadequate education and poor awareness in patients with haemophilia can have serious consequences. Findings from hospital pharmacies in France showed that, although most interviewees had basic knowledge of their treatment, only 43.7% knew how clotting factor concentrates affect haemostasis, and only 12.7% of 80 patients and 30.9% of 55 caregivers referred to inhibitor formation as an adverse effect. Despite intensive home treatment training, 55.7% reported difficulties with reconstitution.
or injection, and only 17 participants were familiar with medication storage requirements. Worryingly, 29 patients and 9 caregivers had experienced an emergency which they had to treat with no medicine available at home.8

As haemophilia predominantly affects men, understanding the dynamic between men and healthcare systems can be helpful in developing services that suit their physical and psychosocial needs.9 Men value educational, social and medical services but prefer to manage their haemophilia independently in the community and access support according to their individual needs.9 Education has been shown to be important in empowering men and helping them to avoid complacency9 and the consequent low adherence.7

Home treatment of haemophilia is the standard of care for patients with severe disease, but this increases the importance of patient responsibility.10 Education raises awareness of treatment at home and provides vital information for patients and caregivers.11 The attainment of knowledge and practical skills assume critical importance in this environment, and this leads into debate over the best way to educate patients and maintain their awareness as practice changes and new treatments are introduced. For example, 'lecture' style education appears less effective in young adults,12 but e-learning yields high self-efficacy and good practical skills in patients on home treatment.10

Approximately 25% to 30% of previously untreated haemophilia patients can develop inhibitors.6,13 Episodic treatment or regular prophylaxis with bypass agents provide suboptimal control,14,15 and these patients are at heightened risk of long-term joint damage. Education, awareness and tools are needed to assist early recognition and prompt treatment of bleeds,16 and failure to recognize the importance of 'time to stop bleeding' among patients with inhibitors is a source of concern.17 Alternative treatments are under development, including bispecific antibodies that can be self-administered subcutaneously and retain efficacy regardless of FVIII inhibitor status.6,18 However, achieving the full benefit of these new therapies will require vigilance and ongoing education to ensure the correct administration and management of these treatments, and to avoid the complacency mentioned above.9 Communication between patients with so-called 'mild' haemophilia and healthcare teams is already known to be
suboptimal, with gaps in knowledge relating to bleed identification and management, and this may also be an issue in those with more severe forms of the disease.\textsuperscript{12}

**Methods**

Roche is open to support an unsolicited education grant that:

1. Supports patients’ information and learning needs as indicated by, but not limited to, the above examples.
2. Identifies further patient baseline knowledge and awareness needs, together with any gaps in understanding or application of knowledge.
3. Provides fair and balanced educational initiatives that translate into benefits for patients, caregivers and healthcare providers.
4. Is aimed at the identified areas and that embraces effective models for delivery and information/experience exchange.

Roche would encourage providers to put forward innovative proposals to facilitate and measure improved patients’ knowledge and awareness of the unmet needs and areas for improvement in haemophilia care. The exact methods of these educational activities are not proscribed and you are encouraged to consider all possible formats.

**Measures**

Roche is open to receiving grant requests from IPE providers that address specific patient knowledge and understanding 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 modifying behaviour relative to current recommendations (e.g. improving adherence/disease control). Any suggestions on how to quantify the benefit provided to the patient community by the educational activity are welcomed.

**Results**

The educational initiative should provide the participants with the latest information and techniques to enhance their treatment experience and maximize benefit. The educational provider should therefore show that learners:

1. Have demonstrated understanding of the educational activity and its implications for their own situation.
2. Have demonstrated competence and improvement in their
**Discussion**

Roche encourages IPE 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/outcome 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 detailing 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 IPE will be reviewed in accordance with all Roche policies.
2. This Call for IPE 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 IPE.
4. For compliance reasons, and in fairness to all education providers, all communications about this Call for IPE must come exclusively to global.imegrants-hematology@roche.com.
5. Failure to follow any instruction within this Call for IPE may result in a denial.

**References**