Europe and Canada Practice to Policy®
Health Awards Programme – Application Guide

The Europe and Canada Practice to Policy® Health Awards Programme
PBC awards application window closes on 8 September 2019

This document has been put together to help explain the process underlying the Europe and Canada Practice to Policy® Health Awards Programme, and to assist eligible applicants in completing their application form appropriately. We advise that all applicants read this document before they submit an application.

Programme overview
The Practice to Policy® Health Awards Programme was launched to support innovative solutions in primary biliary cholangitis (PBC), with two parallel programmes for the US and for Europe and Canada. The programme will provide financial support for short-term initiatives that are funded for up to one year. In 2019, Intercept will support six to eight new innovative projects of up to €25,000 (or local currency equivalent) per project.

In addition to this, and new in 2019, Intercept will provide up to three awards to projects which replicate previous Practice to Policy® winners (up to €15,000 per project). To find out more about funding for replicated projects, please see here.

The projects supported under this programme are independent of the use of any particular therapeutic agent. Applications will be admitted according to the eligibility criteria given below.

Eligibility criteria 2019
The Practice to Policy® Health Awards Programme in PBC encourages the development of innovative projects, which are designed to improve the lives of people living with PBC. In 2019, we are focusing on local and national projects that pioneer collaborative care between healthcare professionals and people living with PBC. Specifically, we are seeking projects that:

• Create tools or platforms that enable or encourage timely monitoring of patients
• Provide resources to improve the dialogue between people living with PBC and their healthcare professional
• Encourage collaborative care in PBC, e.g. through the appropriate use of existing or emerging best practice guidelines

The Europe and Canada Practice to Policy® Health Awards Programme is endorsed by the European Association for the Study of the Liver (EASL).
Applicants

The Practice to Policy® Health Awards Programme will consider applications from:

- Healthcare organisations
- Academic institutions
- Policy organisations
- Patient organisations

In addition to countries within Europe and Canada, the programme is open to any country outside of the US. While the programme topics and projects may largely focus on Europe and Canada, we welcome innovation and best practice learnings from across the world. For further information, please email the Practice to Policy® Health Awards team at practicetopolicy@interceptpharma.com.

General eligibility

Grants that are not eligible within the Practice to Policy® Health Awards Programme:

Investigator-initiated research grants (IIRs): If you are interested in an investigator-initiated research grant, please visit: https://research.interceptpharma.com.

Medical education grants: If you are seeking grants or other funding for medical education (either CME or IME), please visit: https://grants.interceptpharma.com.

Core funding grants: This type of funding supports an organisation’s day-to-day work and may go towards the costs of the organisation’s administration, e.g. staff costs, office rental, stationery costs, etc. and/or core initiatives. If you are seeking patient group core funding grants, please email: internationalgrants@interceptpharma.com.

Projects that are not eligible:

Patient apps: Please note, we will not be accepting project applications which focus on the development of patient apps. The Practice to Policy® Programme is supporting a separate patient app initiative to ensure that our efforts as a community can be combined. If you would be interested in becoming involved in this, please get in touch with the team via practicetopolicy@interceptpharma.com.
Recurring projects: While we will be supporting applications that seek to replicate previous winning projects, we will not be accepting applications for recurring projects from previous winners themselves. Previous winners are still eligible to apply; however, applications must act as standalone and distinct components of the organisation or institution’s activities, and clearly align with the 2019 eligibility criteria.

Application process

To start the application process, please download the application form, which can be found by selecting ‘Enter the PBC Awards’ under the PBC Awards tab on the Practice to Policy® website. Once you have completed the form, please submit via email to practicetopolicy@interceptpharma.com, along with the other supporting documentation required. Before submitting your application, please ensure that you have read through the applicant’s checklist, which you can find at the end of this document.

Applying for 100% of your project funding to come from Intercept Pharmaceuticals

Intercept Pharmaceuticals will consider applications that request 100% of their project funding through this programme. Intercept will also consider projects that have secured alternative sources of funding. If your project has an alternative source of funding, there must be a set of measurable outcomes and deliverables to be achieved by the end of the Intercept award period. Intercept also requires that applicants disclose any additional sources and amounts of funding in the application form.

Applying for support for an ongoing project

It is possible to apply for support for an ongoing project. However, the project segment for which the applicant is requesting funding must act as a standalone and distinct component of the organisation or institution’s activities, and clearly align with the 2019 eligibility criteria. As part of the funding conditions, Intercept would require the methodology, results and learnings of the funded project to be disseminated through relevant channels (as appropriate in accordance with national law); the existence of ongoing components of a project must not compromise the ability to communicate best practices developed via the Intercept award. Intercept will not, however, accept recurring projects which have been previously funded by Practice to Policy®.

Please note that recurring projects differ from replicated projects. Replicated projects are projects where another organisation replicates a previous Practice to Policy® winner’s project. Recurring projects, however, are projects from previous winners who wish to repeat a project which has already been funded within their organisation. In 2019, Intercept will not accept recurring projects.
Completing the application form

The outline below indicates what should be included in your completed form:

- **Applicant details** (full name, job title, department, address, country and contact information)

- **Applicants will need to also provide:**
  - Legal proof that they are part of their organisation/institution (e.g. scanned copies of organisation/institution ID card, payment slip, official document)
  - A letter of support for the project from their organisation/institution
  - Any letters of support from external stakeholders (where applicable)
  - Overview of your organisation/institution (size, objectives, vision)
  - Project overview and objectives
  - Information regarding your capacity to initiate and implement the project in a timely manner

- **A clear methodology including:**
  - Specific, measurable, achievable, realistic and time-sensitive project milestones and actions required to meet project goals
  - Proposed process for collection and analysis of data
  - Deliverables
  - Demonstration of cost-effectiveness where applicable

- **A detailed budget table**
  - Please note, budgets should have clear justifications and should not be built to meet the upper funding limit

Please cite any statistics that you provide appropriately and list all references within your application.

Supplementary information will not be accepted. All supportive information for projects must be submitted within the application.
Completing the budget planner tool

To ensure that your application meets our funding guidelines, we have put together a budget checklist and budget planner for you. Before you start your application, please go through the checklist carefully.

Are all the budget requests that you have made permitted within the programme?

Please note that Intercept is unable to offer funding for:

- Patient apps
- Recurring projects, i.e. a project which has received an award previously, and is requesting repeat funding
- Entertainment
- Activities that are not fundamental to the delivery of the project or core funding which supports an organisation’s day-to-day work is not covered within the programme
- Costs associated with capital expenditure, e.g. funding for purchasing equipment will not be provided; however, lease costs for the duration of the project are possible
- Permanent staff costs. Only temporary staff costs directly related to the project can be funded

Have you provided a justification for every budget item?

Please provide a comprehensive budget. Be as specific as possible and provide any explanatory notes that you consider to be relevant in the appropriate field on your application form.

If you have additional sources of funding for your project, have you specified the source and the funding amount you are due to receive on your application form?

If there is more than one source of additional funding, please provide a breakdown and specify which source each amount of funding comes from.

Have you completed the funding timeline?

Please ensure you have provided a detailed timeline on when and how much funding you may require at any stage of your project.

Is your budget request at or below the €25,000 (or local currency equivalent) cap? If your project is a replicated project, is your budget request at or below the €15,000 (or local currency equivalent) cap?

Please note, budgets should have clear justifications and should not be built to meet the upper funding limit.
Budget planner tool

In order for your application to be considered, you must include full details of the amount of funding being requested, including a justification for all items in the budget planner. Applications which provide a more detailed breakdown of exactly how funds are to be used will receive greater consideration. Applications without an appropriately completed budget table cannot be considered. The budget table must be completed in EUR (€), GBP (£) or CAD (C$). Please find a sample template of the budget planner below, which is also available for download on the Practice to Policy® website.

- It is a requirement that any unused funds are returned to Intercept
- The total amount requested cannot be more than 40% of an organisation’s total funding

<table>
<thead>
<tr>
<th>Project/resource costs</th>
<th>Total cost of resource within project EUR (€), GBP (£) or CAD (C$)</th>
<th>Amount requested from Intercept EUR (€), GBP (£) or CAD (C$)</th>
<th>Justification for Intercept funding requested</th>
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<tr>
<td>Staffing (please describe roles, grades and whole time equivalent (WTE))*</td>
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<td>Production (e.g. of materials)</td>
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<td>Travel expenses and equipment†</td>
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<td>Other (please specify if applicable)</td>
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<td><strong>TOTALS</strong></td>
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*Funding will only cover temporary staff required for the timelines of the project, where 100% of their time is resourced to the funded project. Costs for existing or new permanent staff will not be covered.

†Only leasing of equipment will be covered. Please note capital expenditure for equipment that could be used after the project is not permitted.

Demonstrating support from your organisation or institution

All applications should be signed by a senior member of the organisation. For applications submitted on behalf of an institution, we require applicants to demonstrate support in the form of a signed and dated letter from a senior staff member when submitting the application. Please ensure the letter is scanned and sent to practicetopolicy@interceptpharma.com together with the completed application form before the application window closes on 8 September 2019. Please ensure the letter is written in English; quotes the full name of the applicant; includes the project title; and states that the institution endorses the proposed project.
Demonstrating support from stakeholders associated with your project

If you have gained endorsement from any relevant organisations, institutions or project stakeholders, please ensure any relevant documents are scanned and sent to practicetopolicy@interceptpharma.com together with the completed application form before the application window closes on 8 September 2019.

Ensuring application forms are complete

Please ensure that your application form is complete before submission. All received applications will be reviewed prior to official consideration to identify any important missing information. Should any missing information be identified in advance of the judging meeting, the Practice to Policy® Programme team may contact you to seek clarification. If you do not submit the information quickly upon request, your application may be rejected.

Recalling a submitted application

An application can be recalled on the condition that it is re-submitted by the application deadline of 8 September 2019. To recall an application, email practicetopolicy@interceptpharma.com.

Judging of applications

We are incredibly thankful to our judges for taking the time to participate in this programme! Our team of judges will use the criteria below to evaluate applications and will be responsible for voting on which proposed projects should receive awards.

The judging panel comprises Intercept representatives from Corporate and Medical Affairs, alongside external advisors representing the perspectives of the medical and patient communities. Any conflicts of interest are declared by the judges. If a judge has a conflict, he or she is excluded from any discussions that pertain to the conflict. Applicants will be notified of the outcome of their application by January 2020. To view this year’s Practice to Policy® judging panel, please visit interceptpracticetopolicy.com.

Applications will be judged on the extent to which they satisfy the criteria set out below:

• Does the application contain all of the necessary details and supporting documents within the application?
  o Completed budget planner with a clear, detailed budget specific to the project
  o Legal proof that they are part of the organisation
  o A letter of support for the project from the organisation

The Europe and Canada Practice to Policy® Health Awards Programme is endorsed by the European Association for the Study of the Liver (EASL).
• Does the project demonstrate innovation within PBC?*
• Does the project demonstrate a clear purpose and rationale?
• Does the project intend to support or improve the lives of people living with PBC and does it meet the 2019 eligibility criteria to pioneer collaborative care between healthcare professionals and people living with PBC?* Specifically, a programme that:
  o Creates tools or platforms that enable or encourage timely monitoring of patients
  o Provides resources to improve the dialogue between people living with PBC and their healthcare professional
  o Encourage collaborative care in PBC, e.g. through the appropriate use of existing or emerging best practice guidelines
• Does the project have clear and measurable outcomes? Does it follow the SMART (specific, measurable, achievable, realistic, timely) methodology?
• Does the project have an impact in terms of creating valuable insights, evidence and learning for the wider healthcare community?*

All awards given are based on the merits of the application in accordance with the above criteria. Decisions by the judges are made without reference to, or any intent to influence, prescribing practices.
*Does not apply to applications which are seeking to replicate a previous Practice to Policy® project.

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**Next steps for successful applicants**

*Successful applicants will be notified by end of January 2020*

Successful applicants will be required to engage with members of Intercept and/or service providers appointed by Intercept in relation to providing results of the project, including allocation of funding and plans for publication, and encouraging best practice sharing.

**Intercept’s commitment**

We commit to ensure that all activity in connection with the project/funding is compliant with both the European Federation of Pharmaceutical Industries and Associations (EFPIA) and local Codes of Practice, in addition to any further applicable laws and regulations. In particular, we understand that the provision of an award is not intended to and shall impose no obligation upon the awardee to promote or otherwise encourage the prescription, recommendation, purchase, supply, sale or administration of the products of Intercept or its affiliates.

Intercept will not provide funding for projects it would consider to be non-compliant or in breach of the EFPIA code or Intercept's other legal obligations. Applicants will be required to ensure that their activities in connection with any funding received comply with the requirements of the code.
Timeline for provision of funding

Upon confirmation of an award from the Practice to Policy® Health Awards Programme, Intercept will engage with the successful party to create a written agreement detailing project milestones and terms of payment release along a project timeline.

Publishing the details of awards

Details of all successful projects from the Practice to Policy® Health Awards Programme may be included on the Practice to Policy® Programme website. Intercept reserves the right to utilise project materials, project summaries and presentations for the purpose of sharing best practice externally. Consent for use of winning organisations’ logos on the Practice to Policy® Programme website and programme materials, may be included in the final award agreement.

Commitments required from successful applicants

It is a requirement that successful applicants:

- Conduct a final review of the project, including allocation of funding and plans for publication
- Permit the sharing of their organisation/institution details in addition to their funded project being highlighted on the Intercept Europe and Canada Practice to Policy® Health Awards Programme website
- Commit to the dissemination of their methodologies and results through the relevant channels, including but not limited to: publications, manuscripts and toolkits to ensure education around best practices within and beyond their organisation/institution’s network. Intellectual property rights would remain in the ownership of the project leads. It is Intercept’s policy in line with transparent disclosure requirements that any publication acknowledges financial support from Intercept and that Intercept will publish details of funding provided as required by applicable laws and industry codes

Next steps for unsuccessful applicants

The judging panel will supply feedback for unsuccessful applicants within six weeks of the judging decision.

Re-applying for future programmes

Applicants who are unsuccessful in this application window are able to apply to future programmes.
Applicant's checklist
To ensure you are ready to complete the application form, we have put together a 'final checklist' for you. If you are unable to answer any of the questions included, please refer to our other materials before you start your application.

<table>
<thead>
<tr>
<th>Question</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have you checked that you are eligible?</td>
<td>Eligibility criteria change every year.</td>
</tr>
<tr>
<td>Have you read and understood this Application Guide in detail?</td>
<td>The Application Guide contains all relevant information for the 2019 PBC awards cycle.</td>
</tr>
<tr>
<td>Have you thought about your project timeline and milestones?</td>
<td>The more detailed and clear your application is, the higher your chance of receiving an award.</td>
</tr>
<tr>
<td>Can you provide details on funding?</td>
<td>Applications which provide a more detailed breakdown of exactly how funds are used will receive greater consideration.</td>
</tr>
<tr>
<td>Do you have all relevant documents ready and at hand to upload with your application?</td>
<td>You may need documents to upload as proof of statements.</td>
</tr>
</tbody>
</table>

If you can tick all the boxes, you are ready to start your application! To start the application, please download the application form, which can be found by selecting ‘Apply’ under the PBC Awards tab on the Practice to Policy® website. Once you have completed the form, please submit via email at practicetopolicy@interceptpharma.com, along with the other supporting documentation required.

Good luck and we look forward to receiving your application!

Should you have any questions about completing the application form, please email the Practice to Policy® Health Awards Programme team at practicetopolicy@interceptpharma.com.