

U.S. Practice to Policy[®] Health Awards Program Application Guide

Program Overview and Application Process

- **Purpose of the U.S. Practice to Policy[®] Health Awards Program**

The Practice to Policy[®] Health Awards Program is designed to support initiatives that aim to improve health outcomes for people living with progressive non-viral liver diseases. The awards program encourages innovation as well as providing a platform for best practice sharing in the liver community. For 2019, the program will provide financial support (of up to \$30,000 USD) to short-term initiatives that are only funded for up to one year. The projects supported under this program are independent of the use of any particular therapeutic agent.

- **Eligibility criteria**

The U.S. Practice to Policy[®] Health Awards Program in primary biliary cholangitis (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 programs 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 providers
- Explore new ways to enhance local PBC communities or networks

- **Applicants**

The Practice to Policy[®] Health Awards Program will consider applications from:

- Healthcare providers and organizations
- Academic institutions
- Policy organizations
- Patient organizations

- **The following grants are not eligible within the Practice to Policy[®] Health Award Program:**

- Investigator-initiated research (IIR) grant
- Medical education grant
- Core funding grant

- **The process of applying for an award**

To apply for an award, please download the application form and submit the completed application via email to practicetopolicy@interceptpharma.com.

- **Applying for 100 percent of your project funding to come from Intercept Pharmaceuticals**

Intercept Pharmaceuticals will consider applications that are requesting 100 percent of their project funding through this program. Intercept will also consider projects with additional sources of funding; however, there must be an appropriate project deliverable associated with the Intercept one-year funding timeline.

- **Applying for support for an ongoing project**

It is possible to apply for support for an ongoing project. However, the new component for which you are requesting funding must have distinct and measurable outcomes. The existence of ongoing projects must not compromise the ability to communicate best practices specific to the individual components of the project.

Completing an Application Form

- **What to include in your application**

The application form provides a structure to follow. The outline below also indicates what should be included in your completed form:

- Applicant details
- Upload supporting documents:
 - Legal proof that you are part of their organization/institution (e.g. scanned copy of ID card, payment slip, official document) - **required**
 - A letter of recommendation for the project from your organization/institution - **required**
 - Any letters of recommendation from external stakeholders (where applicable) should also be submitted at this stage of the online application – **optional, but recommended**
- Overview of your organization/institution
- Project overview and objectives
- A clear methodology including:
 - Specific, measurable, achievable, realistic action steps required to meet project goals
 - A clear timeline for project milestones
 - Proposed process for collection and analysis of data
 - Deliverables
 - Demonstration of cost-effectiveness (where applicable)
- Clear details of the budget (please refer to the budget checklist for more information)

- **Completing the budget planner**

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 table. 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 USD (\$). Please find a sample template of the budget planner below.

Sample budget table from the application form:

Project/resource type	Total cost of resource within project (USD, \$)	Amount requested from Intercept (USD, \$)	Justification for Intercept funding requested
Staffing (describe roles, grades and full time equivalent)			
Production (e.g., of materials)			
Equipment *			
Expenses and travel			
Other (specify if applicable)			
TOTALS			

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

Please note that Intercept is unable to offer funding for:

- Activities that are not fundamental to the delivery of the project
- Entertainment
- Costs associated with capital expenditure

Additionally, funding will only cover staff-time specifically dedicated to this project and not duplicative of existing staff time.

- If temporary staff is hired and 100% of their time is resourced to the project, it can be included in the budget.
- If part-time staff is contributing to the project, only their hours dedicated to this project that are above and beyond their regular working hours will be covered (i.e., they normally work 4 days/week but planning to work an additional day every week to specifically manage this project).
- If full-time permanent staff will be contributing to the project, it must be clearly documented that time dedicated to this project will be outside of regular working hours (i.e., evenings, weekends).

- **Ensuring application forms are complete**

Please ensure your application form is complete before submission. All received applications will be reviewed prior to official consideration to ensure quality and identify important missing information.

Should any missing information be identified in advance of the judging meeting, the U.S. Practice to Policy®

Health Award Program 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 by emailing practicetopolicy@interceptpharma.com. To be reconsidered for an award, the application must be re-submitted by the deadline of September 8, 2019.

Judging of Applications

- **The judging committee**

A judging committee will be responsible for voting on which applications should receive awards. This committee consists of senior Intercept representatives and external judges representing perspectives from the medical and patient communities, who are familiar with the objectives of the program.

- **The judging criteria**

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?
 - Completed budget planner with a clear, detailed budget specific to the project
 - Legal proof that they are part of the organization
 - A letter of recommendation for the project from the organization
- 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 program that:
 - Creates tools or platforms that enable or encourage timely monitoring of patients
 - Provides resources to improve the dialogue between people living with PBC and their providers
 - Explores new ways to enhance local PBC communities or networks
- Can the project be completed within the one-year timeframe?
- Does the project have clear and measurable outcomes? Does it follow the SMART (specific, measurable, achievable, realistic, timely) methodology?
- Does the project have 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 to the above criteria. Decisions by the judges are made without reference to, or any intent to influence, prescribing practices.

Successful Applicants

- **Next steps for successful applicants**

Successful applicants will be notified by October 2019 and asked to sign an award agreement letter in line with the PhRMA Code on Interactions with Health Care Professionals and the PhRMA Principles on Interactions with Patient Organizations, as well as any applicable laws and regulations. Successful applicants will be required to engage with members of Intercept in relation to providing an interim report on the project's progress at times to be determined.

- **Timeline for provision of funding**

The program may provide financial support to short-term initiatives (of up to \$30,000 USD) that are funded for up to one year. Upon confirmation of an award from the U.S. Practice to Policy[®] Health Awards Program, Intercept will engage with the successful party to create a written agreement detailing the terms of the project.

- **Publishing the details of awards**

Details of all successful projects from the U.S. Practice to Policy[®] Health Awards Program may be included on the program's [website](#). Intercept reserves the right to utilize project materials, project summaries, organizations' logos and presentations for the purpose of sharing best practices externally.

- **Commitments required from successful applicants**

It is a requirement that successful applicants:

- Provide Intercept with interim and final reports on the project detailing the methodologies and results
- Work with Intercept to share project results and showcase learnings via written, live, or digital channels (e.g. webinar or live event)
- Permit the sharing of their organization/institution's details in addition to their funded project being highlighted on the practice to policy 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 organization/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.

Unsuccessful applicants

- **Re-applying for future programs**

Applicants who are unsuccessful in this application window are able to apply to future programs.

For all specific application queries, please email the U.S. Practice to Policy[®] Health Awards Program team at practicetopolicy@interceptpharma.com.