

## Treating Primary biliary cholangitis (PBC): Unmet Needs and the Current Treatment Landscape

Posted June 26, 2024

### I. BACKGROUND

Ipsen is committed to supporting innovative, independent projects that address unmet educational needs which are aligned to Ipsen’s medical and/or scientific strategies and are intended to improve outcomes in the patient communities that Ipsen serves.

Ipsen publicly posts Requests for Proposals (RFP) that are focused on a specific area of interest and establishes timelines and other requirements for receipt and review. The grant requester (and ultimately the grantee) is responsible for the design, implementation, and conduct of the independent initiative supported by the grant, including compliance with any regulatory requirements. Ipsen must not be involved in nor have any influence over any aspect of the project.

All Ipsen-supported projects must adhere to relevant laws, codes, and regulations.

### II. ELIGIBILITY

<b>Applicant Eligibility</b>	<p>Academic institutions, disease foundations and associations, patient associations, medical education providers and other organizations committed to healthcare improvement may apply.</p> <p>Individuals (such as individual healthcare providers), healthcare provider practice groups, healthcare provider-owned clinics, managed care organizations, and pharmacy benefit managers are prohibited from applying for this grant.</p>
------------------------------	---

### III. Proposal Guidelines

<b>Gap Analysis/Needs Assessment</b>	<p>Include a comprehensive gap analysis/needs assessment that is well referenced and adequately establishes that the program is needed to benefit patient care, medical knowledge, or other public health objectives.</p> <p>Identify any potential barriers to healthcare professional (HCP) practice change and how these barriers will be addressed within the educational initiative.</p>
<b>Target Audience</b>	<p>Describe the target audience(s) and provide a rationale for why this target audience(s) is important to closing the identified healthcare gap.</p>
<b>Audience Recruitment</b>	<p>Describe the methods for reaching the target audience(s), including a description of recruitment and placement strategies to maximize</p>

	<p>participation based on need. Please also describe the planned expected reach for the program.</p>
<b>Learning Objectives</b>	<p>Provide clearly defined, specific, measurable, achievable, and relevant learning objectives for learners as a result of engaging in this activity.</p>
<b>Content Accuracy</b>	<p>Include an overview of program content and explanation of criteria that will guide content selection.</p> <p>Explain how the activity will be designed so that it is free of commercial bias for or against any product; that any product discussions are objective, balanced, and scientifically sound; and that any discussion of uses of a drug that have not been approved by the FDA are identified as such.</p> <p>Explain how content will be updated, if necessary, throughout the activity period and how accuracy will be ensured.</p>
<b>Educational Design</b>	<p>Proposed educational methods should be selected based on the professional practice gaps and educational needs of the target audience(s).</p>
<b>Innovation</b>	<p>Explain what measures you have taken to assure that this project is original and does not duplicate other projects or materials already developed.</p>
<b>Anticipated Project Timeline</b>	<p>Provide an anticipated timeline for your project including project start/end dates.</p>
<b>Faculty Recruitment</b>	<p>Provide information on the expected qualifications of contributors and description of methods to ensure recruitment of course directors and faculty who meet the qualifications.</p>
<b>Activity Evaluation and Outcomes Reporting</b>	<p>Provide a description of how the activity will be evaluated against objectives and reported. Please specify the descriptive and evaluative reporting results that will be provided. For projects that are funded for longer than six-months, interim reporting is required. A final report is due at the end of the funded activities.</p>
<b>Budget</b>	<p>Include a detailed budget, with a breakdown of costs for each line item, clear explanation of the units, and how Ipsen funds will be allocated for each of the line items. Please also include details regarding faculty honoraria and expense reimbursement.</p> <p>Include the total amount of funds requested from Ipsen, the percentage of funding requested from Ipsen to total funding for the activity, and the percentage of Ipsen’s cumulative contribution vs. the overall annual External Requestor’s budget.</p> <p>Preference will be given to programs funded by more than one sponsor.</p> <p>Budget costs should be reasonable and customary, within fair market value, and proportionate to the type and length of activity.</p>

<b>Accreditation</b>	<p>For projects offering continuing education credit, the requesting organization must be accredited. Provide proof of accreditation status in good standing.</p> <p>Activities must be accredited by the appropriate accrediting bodies and fully compliant with all standards and criteria, including the ACCME Standards for Commercial Support: Standards to Ensure the Independence of CME Activities.</p> <p>If the activity is jointly provided, the accredited provider must be involved from the concept origin and fully knowledgeable of all contents of the grant submission, and documentation should be provided on the relationship between the accredited provider and non-accredited educational partner.</p>
<b>Identification and Resolution of Conflicts of Interest</b>	Describe methods for ensuring fair and balanced content, identification, and resolution of Conflicts of Interest, and how the activity will remain free from commercial bias.
<b>Disclosure</b>	Include a description of how the provider a) discloses relevant financial relationships for all individuals in control of content, and b) discloses educational grant support for this activity.

**IV. SCOPE**

<b>RFP Number (include on all documents)</b>	Ipsen-RFP-PBC-2024-02
<b>Issue Date</b>	June 26, 2024
<b>Submission Deadline</b>	August 1, 2024
<b>Notification Date</b>	September 1, 2024
<b>Preferred Program Launch Date</b>	November 2024
<b>Therapeutic Area</b>	Primary biliary cholangitis (PBC)
<b>Educational Focus</b>	<p>Treating Primary biliary cholangitis (PBC): Unmet Needs and the Current Treatment Landscape</p> <p>Ipsen is interested in reviewing proposals for medical education programs that address the following knowledge gaps:</p> <ul style="list-style-type: none"> <li>• Increase awareness of efficacy and safety of current treatment options in second line and considerations in treatment selection</li> <li>• Provide education on strategies to assess patient response to PBC treatments and treatment goals</li> <li>• Provide education on the burden of disease, appropriate tests to perform and interpret, importance of early diagnosis , and appropriate timing for initiating treatment to slow disease progression</li> <li>• Educate on importance of symptom improvement and impact on QoL</li> </ul>
<b>Geographic Scope</b>	U.S.

<b>Target Audience</b>	Hepatologist, gastroenterologist, nurses, NPs, APs
<b>Educational Format</b>	Mix of live and virtual educational sessions with enduring component, including, but not limited to, grand rounds with case presentations.
<b>Length of proposed project</b>	Enduring component active for 12 months
<b>Funding Budget</b>	Ipsen is looking for multi-supported grants and will contribute up to \$200,000 for the grant. The amount of the grant funded may vary from the amount requested. The total budget for this RFP may be divided among multiple programs.

#### V. DIRECTIONS FOR SUBMISSION

<b>Submissions</b>	Requests must be submitted with all required documentation to <a href="mailto:ipsengrants@ipsen.com">ipsengrants@ipsen.com</a> . All submissions must be labeled with the unique RFP identifier number listed above
<b>Contact Information</b>	Direct all questions about this RFP to <a href="mailto:ipsengrants@ipsen.com">ipsengrants@ipsen.com</a> .
<b>Notification</b>	All applicants will be notified by email of a decision.

#### VI. TERMS AND CONDITIONS

1. This RFP does not commit Ipsen to award a grant of any size, nor to pay any costs incurred in the preparation of a response to this request. Ipsen reserves the right not to fund any request. Formal notifications of grant awards will be made via email to the applicant organization and supersede any prior oral or written understandings or communications between the applicant and Ipsen. No grant has been awarded until a formal grant agreement has been fully executed between Ipsen and the applicant organization(s).
2. Ipsen reserves the right to accept or reject any or all applications received as a result of this request, or to cancel this RFP in part or in its entirety.
3. Ipsen adheres to all applicable transparency laws, codes, and regulations, and, as a result, will appropriately report funding related to this grant, when and as required.
4. Ipsen may require receipt of required information in a certain format from applicant organization(s) in order to facilitate disclosure reporting.
5. Ipsen reserves the right to verify all information provided by an organization in its grant application.
6. Grant approvals are not connected to or conditioned upon the purchasing, prescribing, providing favorable recommendations for, or otherwise supporting Ipsen products. The funding of a grant request does not impose an obligation, expressed or implied, on the recipient to purchase, prescribe, provide favorable formulary status for, or otherwise support Ipsen products.
7. If accepted must agree to these terms and conditions in addition to the terms described in the Ipsen letter of agreement.
8. Only Ipsen's Grants Office is authorized to provide information related to this RFP. Any questions related to this RFP should be directed to Ipsen's Grants Office at [ipsengrants@ipsen.com](mailto:ipsengrants@ipsen.com).

