



THE HBV FORUM OPERATING PRINCIPLES

Introduction

The HBV Novel Therapeutics Interventions – **The HBV Forum** – is an independently funded project of the Forum for Collaborative Research (The Forum) and operates in accordance with The Forum’s guiding principles, which include:

- neutrality and independence;
- transparency and accessibility;
- inclusiveness;
- collaboration, and
- efficiency and productivity,

as documented in the report¹ describing the establishment of The Forum for Collaborative HIV Research. This document describes the operating principles and the working process of the HBV Forum.

The HBV Forum provides a sustained, disease-specific focus for stakeholder engagement and deliberation to clarify and advance the regulatory process for therapeutics to treat and cure HBV infection. The HBV Forum activities include providing a proactive mechanism to survey and synthesize current knowledge, including ongoing studies, and to actively catalyze stakeholders to develop and implement new studies and other activities to fill the gaps and address the barriers that impede progress in this field.

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Neutrality and Independence

Ownership. The HBV Forum is owned collectively by its members, with each stakeholder group having an equal voice. By including all interested parties and ensuring that no one particular entity dominates, we provide a neutral, independent and safe space for discussion, dialogue and deliberation among expert scientists from government, industry, academia, professional societies, community and other relevant entities. Identified priorities are considered important and of value to all stakeholder groups.

¹ The Keystone Centre. "The Keystone National Policy Dialogue on Establishment of Studies to Optimize Medical Management of HIV Infection." Annals of the Forum for Collaborative HIV Research 1, no. 1 (August 2 1996): 14



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Credibility. The HBV Forum members have a strong record of leadership and experience in viral hepatitis and in particularly, hepatitis B infection, and the resources needed to follow through with their commitment. All participants are equal partners. Recommendations are based on sound ethical principles and scientific evidence and designed to protect the public's health. The HBV Forum does not force consensus, but publishes consensus-based recommendations only when the science supports those recommendations.

We restrict participation to experts with the necessary scientific knowledge from organizations or entities with a clear commitment to advancing the therapeutic field of HBV, whether they be from government, academia, industry or community. Only in this way can we achieve the effectiveness and productivity needed to add value to the field.

The HBV Forum is not a venue for marketing and/or investment experts.

Leadership. A Steering Committee consisting of project members from all stakeholder groups representing US, Europe and Asia provides overall guidance. As is traditional for The Forum, the HBV Forum is led by an academic and industry co-chairs. Industry members will be rotated on an annual basis.

Steering committee members are listed on the project's webpage (<http://www.hivforum.org/projects/drug-development/hbv-forum/1243-hbv-forum>).

Transparency and Accessibility

Funding. We invite participating organizations such as professional societies and regulated industry to make financial contributions to The HBV Forum. The contributions are voluntary; whether, and if so, what level of contribution is made does not impact the ability of the organization to participate either as a general project member or a member of the steering committee. The contributions are used to offset the cost of running the project. The HBV Forum is an ongoing process, requiring dedicated staff time, office expenses, and logistics costs for in-person meetings.

We make every effort to obtain grants from foundations and public funding agencies. We publicly acknowledge all supporters, no matter the contribution level, on the project's webpage and in all written materials.

Accountability. The HBV Forum is accountable to the major member stakeholder groups. Frequent evaluations determine whether the HBV Forum is responsive to their needs. The HBV Forum will continue to operate for as long as the Steering Committee continues to see value in its existence.

Publication and Dissemination. The project members bring their individual expertise and perspective to the table rather than formally represent their respective organization, agency or company. All comments are off-the-record and not for attribution. Documents are not made public until members



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agree to their release. We publish white papers and recommendations in peer-reviewed journals when appropriate.

Inclusiveness

The HBV Forum is open to all organizations with an authentic commitment to the scientific advancement of the field of hepatitis B and hepatocellular carcinoma, including U.S. and European government representatives, academic experts, regulated industry, and patients/patient representatives and/or advocates. We value diversity in stakeholder representation. Our process ensures that expert input representing all stakeholder perspectives contributes to the outcome.

Collaboration

No one stakeholder group, member organization or individual has all of the information and resources needed to effect progress in this field. Collaboration helps optimize resource utilization, share information, and avoid unintended duplication of efforts. Collaborative activities may include information and data sharing; analysis of databases resulting from shared data; sub-studies within existing studies; and engaging in the process of biomarker acceptance. The volunteered contributions by members from different sectors within the HBV Forum network, steering committee, specific working groups, and other activities represent the cornerstone for collaboration.

Efficiency and Productivity

The HBV Forum increases efficiency and productivity through a sustained, disease-specific focus and synchronous work process which allows all parties engaged in the deliberation to be exposed to the same information in real time. This promotes and facilitates cross-pollination of ideas, standardization of research practices, and the design of more efficient clinical trials. The collaborative and open environment links silos by decreasing traditional tension and competition and improving cross-sector communication.

THE HBV FORUM WORKING PROCESS

Administration

The HBV Forum operates under the organizational leadership of The Forum for Collaborative Research. The Forum is housed within the University of California Berkeley, School of Public Health, and receives funds under the 501(c)(3) of the University of California Berkeley Foundation.



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Member Selection

The Forum staff recruits HBV Forum project members meeting the scientific expertise criteria from the various stakeholder groups, with input and guidance from members of the Steering Committee. Steering Committee members are appointed by their own agency (e.g. FDA, EMA), or recruited by The Forum staff (e.g. academia). Industry representatives on the Steering Committee will rotate off on a staggered basis to allow broader participation in leadership. Forum members volunteer for participation in working groups.

Member Roles and Expectations

HBV Forum members bring their own expertise and the perspectives of their stakeholder group to the table. Members help disseminate and bring discussion points back to their own networks for further discussion and input. Members volunteer their time; the Forum does not provide honoraria or any items of value (e.g. gifts) to HBV Forum members or to invited speakers. All organizations, agencies, and companies should send members with the appropriate scientific expertise. We request that regulated industry limit their attendance at in-person meetings to two individuals per company in order to keep the size manageable and the discussion focused.

Convening Schedule

The HBV Forum Steering Committee convenes by phone and e-mail as required to provide overall leadership and guidance to the project. The HBV Forum project members meet twice a year, in conjunction with the AASLD and EASL conferences. Working Groups established to focus on specific questions convene by phone and email as needed in between the two annual meetings.

Meeting Agendas and Facilitation

In-person meeting agendas rely heavily on moderated discussions allowing broad input from all project members. When necessary, overview presentations help to bring everyone on the same page with respect to current scientific and policy state-of-the-art. We maintain diversity in leadership by distributing leadership opportunities among the HBV Forum project and steering committee members. We expect all meeting participants to engage in discussion, and discourage the presence of passive observers.