HBV Forum 1: Evaluation Report

November 15th, 2016

Hyatt Regency Hotel Boston

Boston, MA

Facilitating Collaborative Research in Drug Development and Health Policy
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INSERM - French National Institute of Health

HBV FORUM MEETING AGENDA

1:00	**Light Lunch Reception**	
1:30	Welcoming Remarks	Veronica Miller & Bill Symonds
1:35	HBV Forum Overview	Pedro Goicochea
1:55	Update on Efforts to Get Quantitative HBsAg Assays	Timothy Block & Robert Gish
2:15	WG Update: Diagnostics & Biomarkers	Gavin Cloherty & Ed Marins
2:35	WG Update: Treatment Combinations	Bruce Given & Seng Gee Lim
2:55	WG Update: Surrogate Endpoints	Oliver Lenz & Marion Peters
3:15	Natural Disease Progression Definitions	Panel Discussion
3:45	**Break**	
4:05	Opportunities for Collaboration: ICE-HBV	Peter Revill
4:20	HBV Cure Project U of Singapore	Seng Gee Lim
4:35	Wrap-up + Next Steps	Veronica Miller & Bill Symonds
4:50	**Networking Reception**	
7:00	**Adjourn**	

BACKGROUND

The HBV Novel Therapeutic Interventions project (The HBV Forum) was launched in January of 2016 after a series of consultations with stakeholders in the field of HBV. The HBV Forum is aimed at advancing the regulatory science for HBV novel therapeutic interventions and its associated morbidities in real-time by providing an independent and neutral environment for ongoing multi-stakeholder dialogue.

The HBV Forum is currently comprised of 134 members representing different stakeholder groups, including members of academia, researchers, representatives of pharmaceutical and diagnostic companies, regulators from the US and Europe, and patient advocates/representatives.

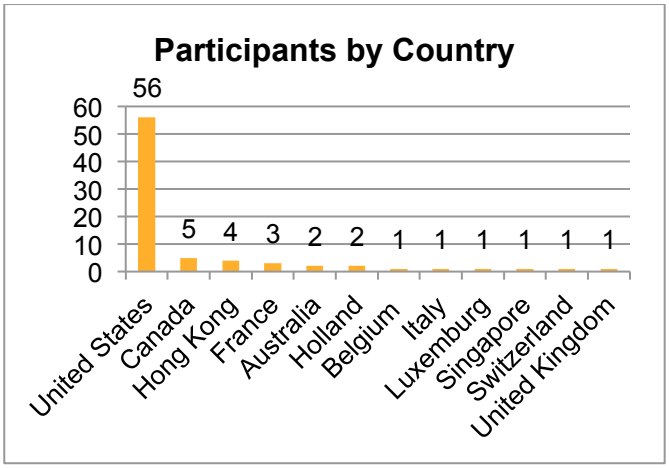
The HBV Forum has a Steering Committee (SC) consisting of 18 members that provide overall scientific leadership, suggest topics for consideration, and prioritize the research questions to be addressed in the project. The SC had its first in-person meeting in June of 2016 where members prioritized the different topics of interest for the project, and three working groups were organized:

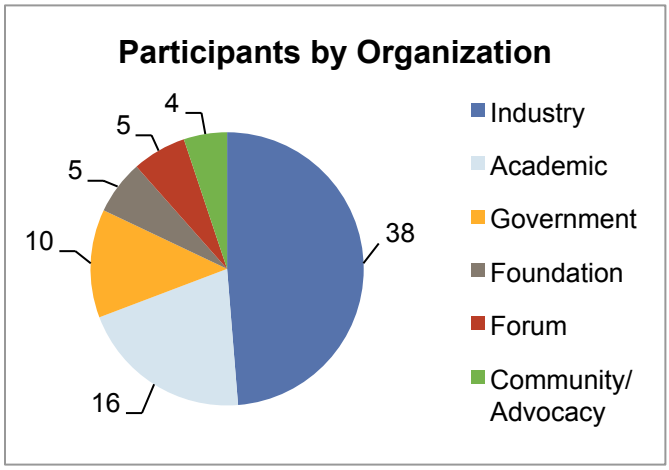
1. **Diagnostics/Biomarkers Working Group**
   Co-chairs: Ed Marins, MD and Gavin Cloherty, MD.
   Aim: Develop clarity on what is needed for biomarker acceptance and validation for HBV drug/diagnostic development
2. **Surrogate Endpoints Working Group**
   Co-chairs: Marion Peters, MD and Oliver Lenz, PhD.
   Aim: Strengthen the link of surrogate markers (endpoint in clinical studies) with long term clinical outcomes (e.g., liver disease progression/HCC)
3. **Treatment Combination Working Group**
   Co-chairs: Prof. Lim Seng Gee, MD and Bruce Given, MD.
   Aims: I.) Provide clarity on the requirements of novel agents in clinical development, and II.) identify mechanisms to speed up the development of combinations of different promising agents across companies

On November 15th, 2016, the HBV Forum held its first face-to-face meeting (HBV Forum 1) at the Hyatt Regency Hotel Boston, in Boston, Massachusetts following the AASLD Liver Meeting. This is the evaluation report of the HBV Forum 1.

PARTICIPATION IN THE HBV FORUM 1

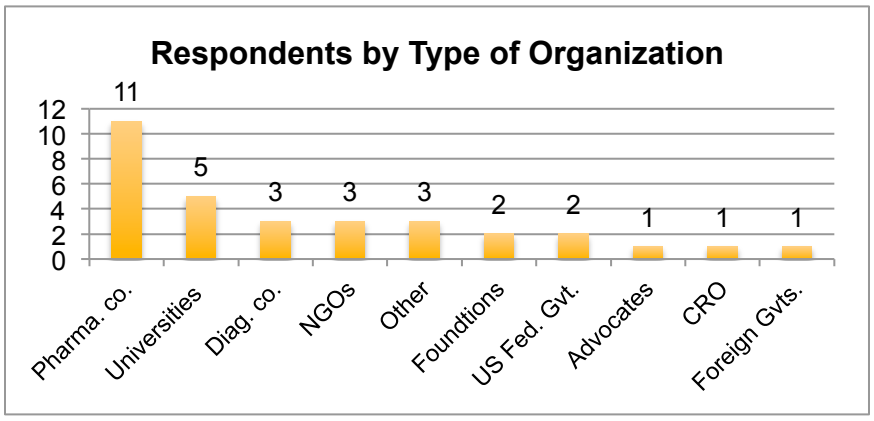
The HBV Forum 1 was attended by 78 people; 72 participated in-person, and 6 remotely via webcast. Almost half of the attendees represented industry and diagnostic companies (48.7%), and a fifth represented academia (20.5%). Other stakeholders included representatives from the US Federal Government (12.8%), Foundations (6.4%), the Forum (6.4%), and community advocates (5.1%). A majority of participants were from the United States and Canada (78.2%), followed by participants from Europe (12.8%), Asia (6.4%), and Australia (2.6%).





HBV Forum 1 Evaluation

The HBV Forum 1 Evaluation was distributed on December 5th, 2016 using SurveyMonkey, and responses were collected until December 19th, 2016. We received 32 responses, resulting in a 41% completion rate. Of all respondents, more than half (56.2%) reported that the HBV Forum 1 was the first event organized by the Forum for Collaborative Research that they had attended.



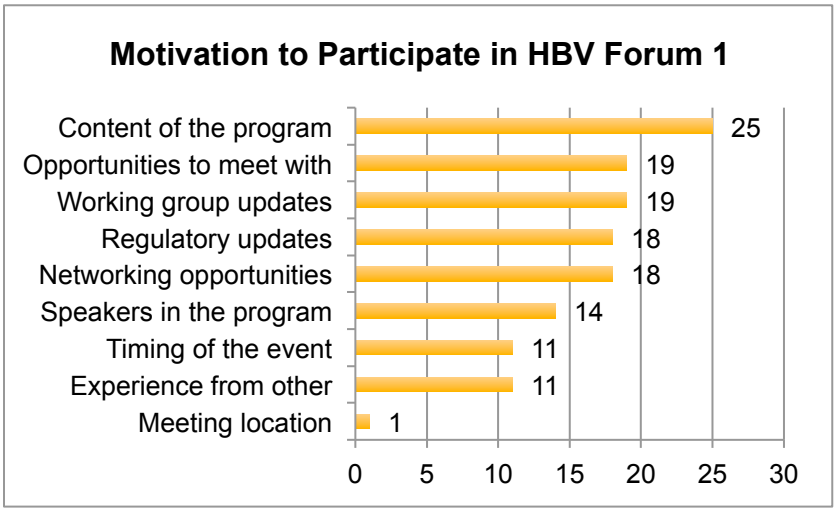
More than a third of respondents (34.38%) represented pharmaceutical companies and 16% reported working at universities. Other respondents represented diagnostic companies, non-governmental organizations, foundations, the US Federal

Government, foreign government, patient advocates, and contract research organization (CRO).

Of those from pharmaceutical and diagnostic companies, 14 respondents reported their role in their organizations as either Project Lead or Director (71%) or Chief Medical or Scientific Officer (29%).

The three motivations that respondents most frequently indicated as relevant to their decision to participate in the HBV Forum 1 were:

1. The content of the program
2. Working group updates
3. Opportunities to meet with colleagues.



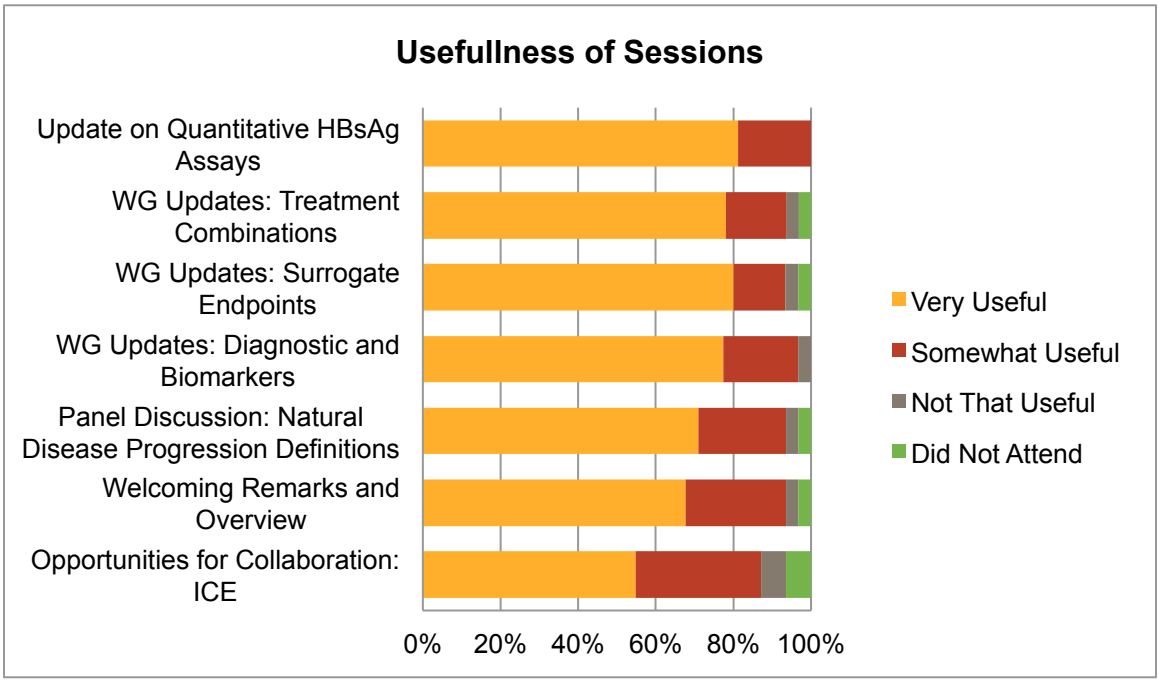
Opinions about the HBV Forum

The majority of evaluation respondents agreed that the discussions at the HBV Forum will help guide the work of their organizations (91%), that their participation is valuable for their work (96%), and that they would recommend other colleagues or peers to join the HBV Forum (90%). All respondents agreed that the HBV Forum provided opportunities to network with collaborators, hear from different perspectives, and learn about developments in the field.

HBV FORUM 1 SESSIONS AND MEETING LOGISTICS

The majority of respondents (69%) reported that they received an invitation to participate in the HBV Forum 1 directly from the Forum for Collaborative Research. Others reported that they were referred to the meeting by a colleague from their organization (12%) or learned about it from word-of-mouth (9%). Other sources of information about the meeting included having participated in other projects of the Forum for Collaborative Research, such as the HCV project.

The HBV Forum 1 was organized into seven sessions, with over 93% of respondents (of those who attended) reporting that each session was either “Very Useful” or “Somewhat Useful”. The Working Group Updates and the Update on Quantitative HBsAg Assays were rated by the most respondents as “Very Useful”.



Respondents indicated that the HBV Forum 1 facilitated new collaboration or extended existing collaboration with individuals and organizations (59.4%) and fostered partnerships with other colleagues and organizations to further scientific interests (58%). However, a few respondents (18.8%) indicated that it was too early to say.

Suggestions from respondents to facilitate collaboration in future meetings included:

- Forum should take a leading role to help define regulatory paths
- Having clear action items at the end of each meeting
- Partners that are doing community based work can help inform the community about what the developments are, creating an advocacy platform to move the efforts towards a cure and better care for HBV individuals
- Encourage monitoring cure advances to patients quickly
- Consider regulatory challenges for sponsors considering collaboration in development trials
- Prevent “doing business” during HBV Forum meetings

Meeting Logistics

The Hyatt Regency Hotel Boston as the meeting venue was rated “Excellent” or “Good” by most respondents (93.1%). Some respondents suggested hosting the meeting in a venue closer to the main conference venue, or with easier access to the airport.

For respondents that attended in-person, 100% reported that asking questions and engaging in the meeting was easy. However, one participant noted that there were a small number of participants that dominated the conversation.

For respondents that participated remotely, 66.7% reported that of the technical aspects of the meeting were “good” or excellent (16.7%). The primary complaint was the limitation in the ability of remote attendees to participate in the discussions; however, this is a general Forum policy for events.

Overall, over 80% of respondents reported the level of satisfaction with the meeting logistics as “Very Satisfactory” or “Satisfactory”.

RECOMMENDATIONS FOR HBV FORUM 2 – APRIL 2017, AMSTERDAM

Topics suggested by respondents to be considered for HBV Forum 2 included:

- FDA's opinion on medical need for HBV
- Feasibility of regulatory approval of quantitative HBsAg in the US and regulatory path for submission to FDA
- Bioinformatics and relevance to research and clinical applications
- EMA and FDA regulatory framework and their perspectives
- Definitions and discussions about DILI
- Progress on drug development and regulatory updates
- Overview of HBV therapeutic pipeline and assays required to support clinical trials
- Continue updates on working groups:
    - Revalidate priorities the Forum should be focusing on
    - Endpoints and regulatory path and discussion of promising endpoints currently being evaluated
    - Follow up for trials development including polypharmacy i.e. perhaps more compounds need to be closer to Phase 2 development, but planning should be happening now
    - Advances and treatment and biomarkers: planning for clinical trials and establishing protocols appropriate to specific patient groups
    - Discussions on strategies for combination therapy and biomarkers to support them

In terms of remote participation, respondents suggested that people participating over the phone should be allowed to actively participate in the discussions.

Patient advocates/representatives requested to have a more active role in the meeting and discussions, which should be taken into account during the development of the agenda and presentations.