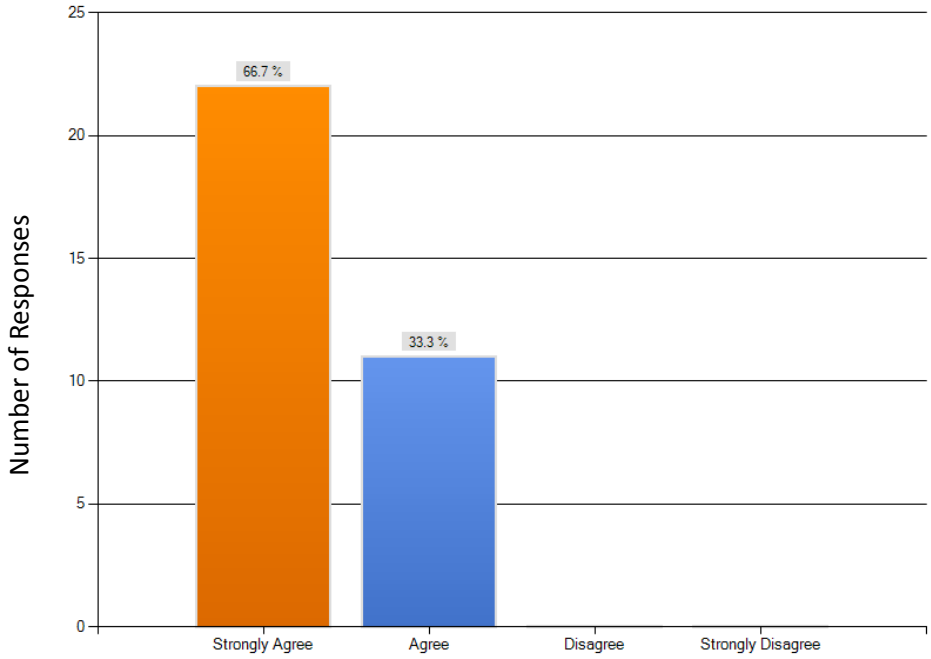
Participant Responses to Advancing HCV Drug Development: A Collaborative Approach Public Meeting

December 6, 2010

Washington DC

Would you agree that the "Advancing HCV Drug Development: A Collaborative Approach" meeting was valuable to your education, career advancement and/or work?



Overall, what did the "Advancing HCV Drug Development: A Collaborative Approach" meeting provide for you?

<u>Knowledge</u>

- An opportunity to hear what the community and the pharmaceutical industry is thinking about HCV drug development and the FDA draft guidance.
- Good understanding of knowledge, concerns, and issues in this field from many different perspectives (regulatory, patient advocates, industry, physicians, academia, etc)
- It gave me the opportunity to watch Industry and the FDA interact and to assist in framing their discussion of the issues. I also learned much more about HCV trial design.
- Multi-faceted, open and engaged insight into how to develop HCV therapies
- Insight into issues affecting clinical trials
- Latest issues, concerns and opinions that HCV treatment providers and advocacy groups have.
- The regulatory perspective on where we are.
- Recent update on FDA thinking about clinical development plans
- FDA's and experts' current thinking for HCV development and the unmet medical need
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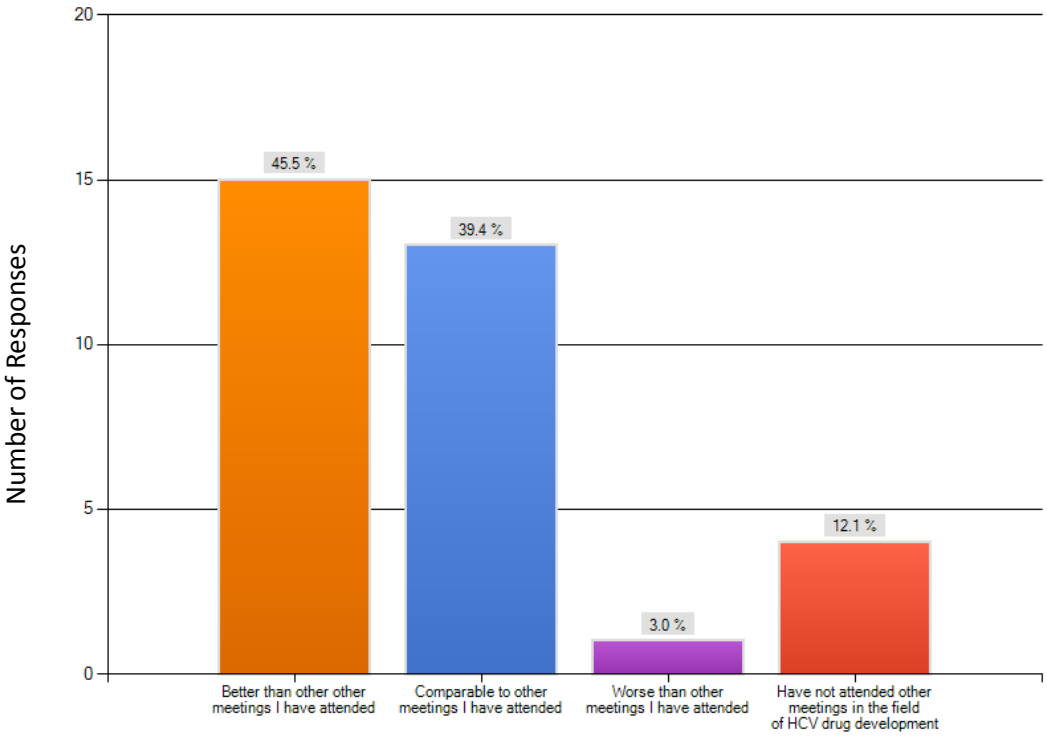
<u>Networking</u>

- Information and contacts
- A chance to talk about the problem of pediatric HCV

<u>General</u>

- Wonderful meeting which assembled elements of all the players necessary to make things happen - patient advocates, industry, academia, and the FDA!
- A useful dialogue between the regulatory agencies and pharma
- Great to hear discussion among thought leaders; hopefully EMA and FDA will continue to revise and harmonize their DAA guidelines as the field changes. –Tracy Swan
- A discussion from variety of stakeholders on issues that are cutting edge and do not yet have clear consensus
- The meeting provided a unique setting for critical dialogue between regulators, industry and community. Many of these conversations are already taking place in smaller groups, but it was great to have such open dialogue in the larger venue. – Michael Ninburg
- It gave an opportunity to hear the FDA's position and thinking around HCV drug development and clinical trial designs.
- Opportunity to have academics push on FDA and other HA
- A sense for how advocates, pharma and regulators thought we were going to proceed into very complicated territory: study population priorities, program strategies and study designs
- A deep multi-stakeholder discussion on many of the most relevant questions regarding HCV drug development. Very useful and update information that is crucial to empower my community treatment advocates. – Luis Mendao
- Latest discussion on relevant HCV-related topics

How does "Advancing HCV Drug Development: A Collaborative Approach" compare to other meetings that you have attended for learning new information in the field of HCV drug development?



Are there any aspects of the "Advancing HCV Drug Development: A Collaborative Approach" meeting that you believe could be improved?

<u>Content</u>

- Would have been great to have more time for some of the discussions--particularly DAA trial designs. – Tracy Swan
- Not an improvement, but it will be important to continue this kind of forum on a regular basis, as each group (regulators, industry, community) has a unique, valuable perspective to provide. HCV drug development is moving very quickly and these perspectives are necessary in order to best meet the needs of patients. – Michael Ninburg
- There should be drug company participation on every panel.
- Longer, more detailed discussion with presentation of the relevant data first would be more useful. Perhaps some small group breakouts with FDA

- I thought the FDA could be more forthcoming with various advocates that certain tests are required before a sponsor tests a drug in a patient population - for example, you can't just put a drug in people with cirrhosis without doing a hepatic impairment study first. This is part of the FDA regulations, and it doesn't foster a "partnership" with industry when they are not upfront about this with advocates. Also, is there only one community advocate in HCV? Why did one person dominate the discussion so much?
- While the views and opinions of some of the activists are important, sometimes they take up too much time away from discussions from the FDA, other regulatory authorities and experts.
- I think we have about as good as it gets. The only other forums where everyone is likely to let their guard down a tiny bit more are the like the very small one at AASLD2010
- I would only point a stronger priority on the different groups of hard to treat HCV patients. – Luis Mendao
- Perhaps, distribute "minutes" capturing all the relevant discussions. I guess that would be too much to ask since this was an all-day meeting
- Honestly, no. It was as about as open and collaborative as I've seen for a meeting its size. People's (regulatory and industry in particular) guards were about as down as can be expected and the information flow, including non-scripted information, was pretty decent.

Technical

- Needed more microphones to pass around the room so that more discussion could occur.
- Never got the email with connection information. Had to find someone in another building that had it working in order to watch it.
- Noise and voices not loud enough

How will the information presented at the meeting assist you in the work you do?

Industry

- I do HCV drug development, so it's central.

Advocacy

- It helps me know where and for what I will need to advocate. It also helped me to better understand more about the intricacies of HCV drug development. – Lynda Dee
- It will assist with advocacy efforts; knowing the FDA's priorities will assist with pushing drug companies to move in a direction that meets the needs of underserved communities. – Michael Carden
- The information received is crucial for my work in the HCV community advisory board, The European Aids Treatment Group and SOS Hepatitis. Also very relevant for the preparation of the Sitges IV meeting on hard to treat patients clinical trials and early access. – Luis Mendao

Research

- Allow for a better discussion and decision making in planning clinical development plans
- Informs phase III design
- It will facilitate the development plan for our HCV programs under development.
- In the development of studies in the field
- The information may be used to evaluate the appropriateness of certain procedures in trial protocols.

Regulatory

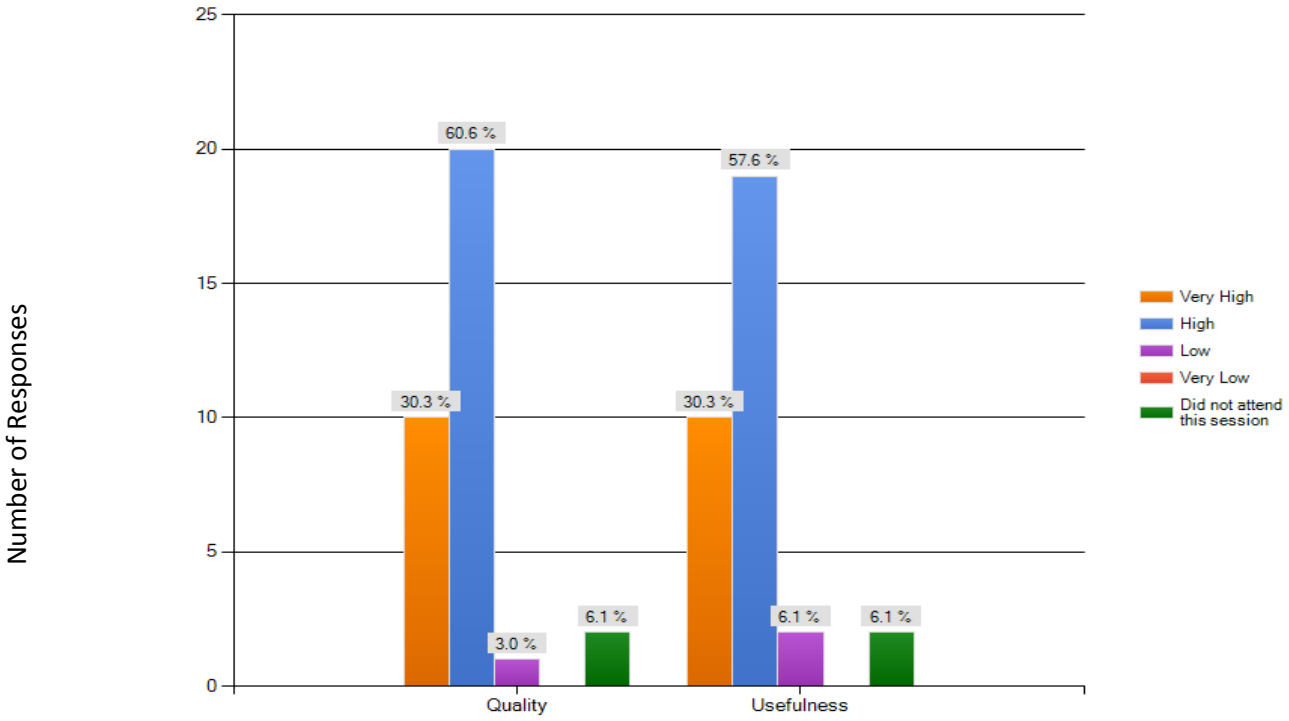
- It will help us revise the HCV guidance.
- Helps us to reconsider issues in draft guidance

General

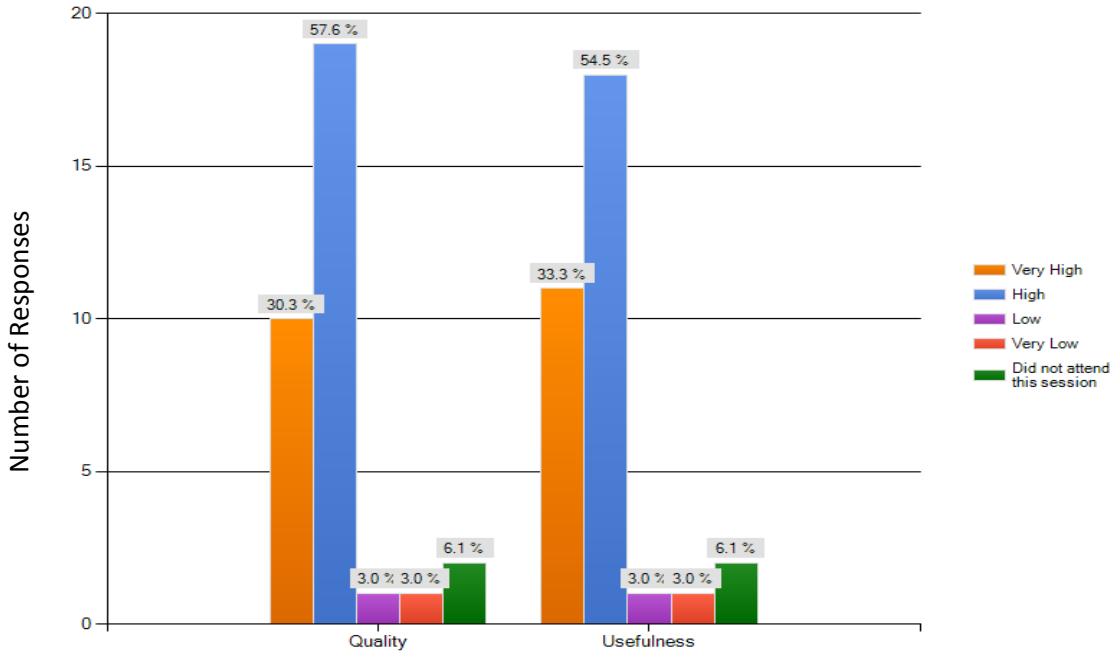
- Hopefully it will continue to advance the field of DAA drug development, make a framework for sponsors to evaluate drugs that may be less effective but great backbones for regimens, facilitate early access and push for trials--particularly phase III--in "real-life" populations so that their results are clinically relevant. –Tracy Swan
- Provides an understanding on perspectives from different groups.
- Better informed for subsequent discussions.
- Informative to think of the relevant issues to design optimal clinical trials
- Just starting to work in the area of HCV clinical drug development--the forum provided overview of the area which was very helpful.
- Better understanding of FDA position

- Important to know what the new clinical trial requirements will be and see how Clinicians/drug companies are incorporating new scientific discoveries into their studies.
- Please send us meeting minutes, so, we can compare with what we believe to have heard

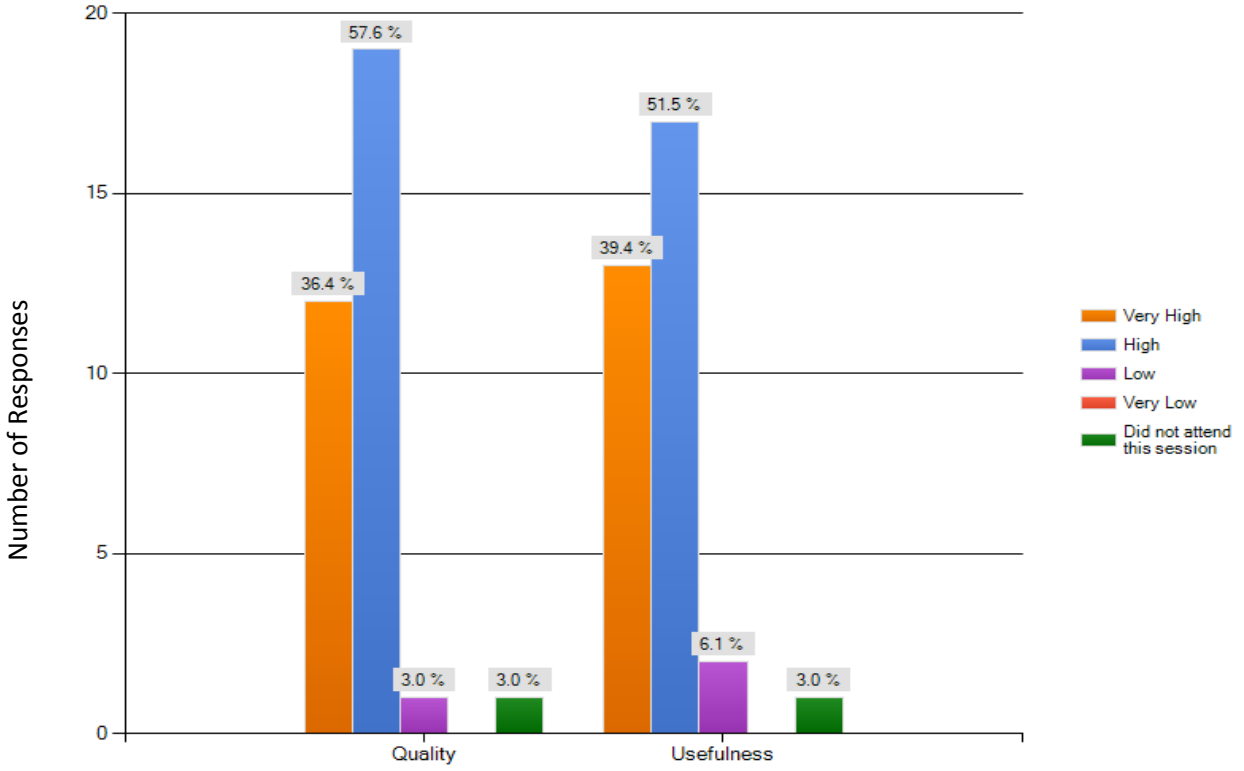
Overall, how would you rate the QUALITY and USEFULNESS of *Session1: DDAs for HCV in Development: Current Status and Need* at the "Advancing HCV Drug Development: A Collaborative Approach" meeting?



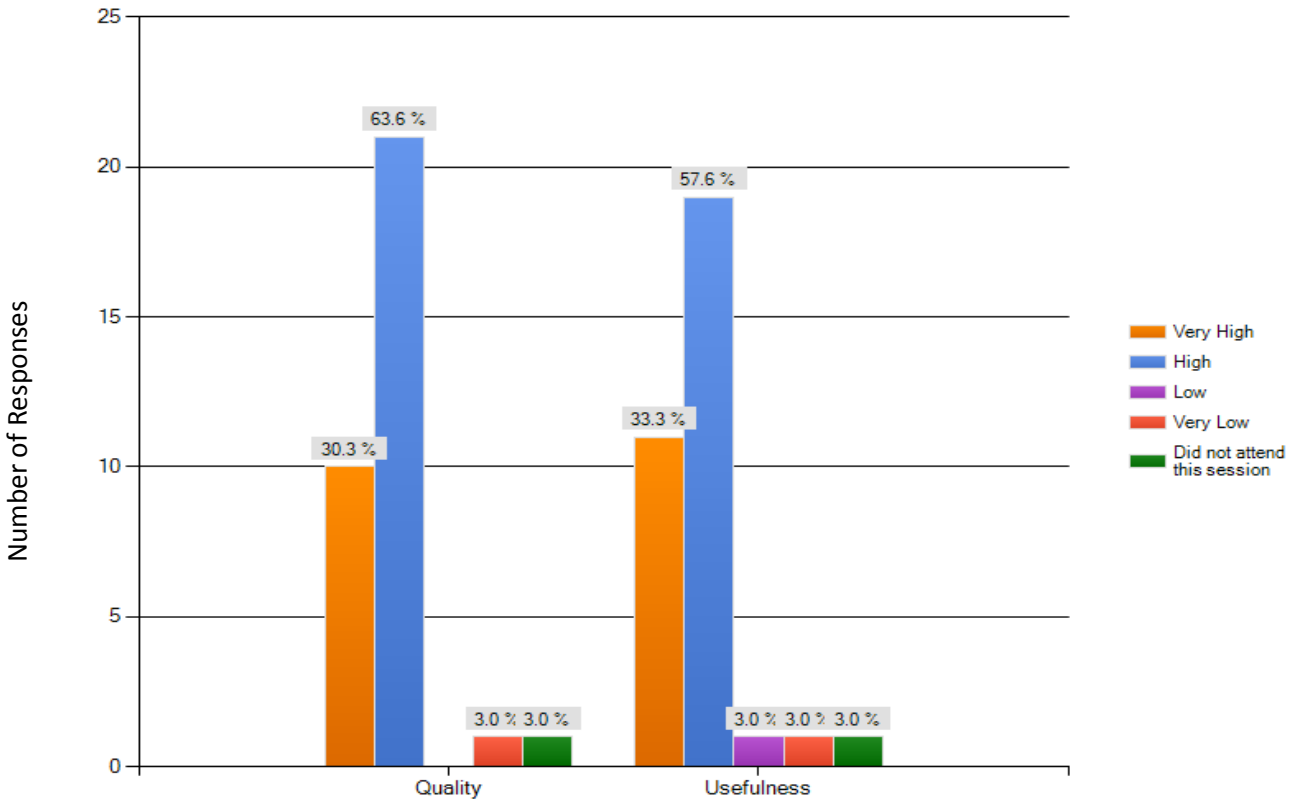
Overall, how would you rate the QUALITY and USEFULNESS of *Session 2: General Clinical Design Considerations* at the "Advancing HCV Drug Development: A Collaborative Approach" meeting?



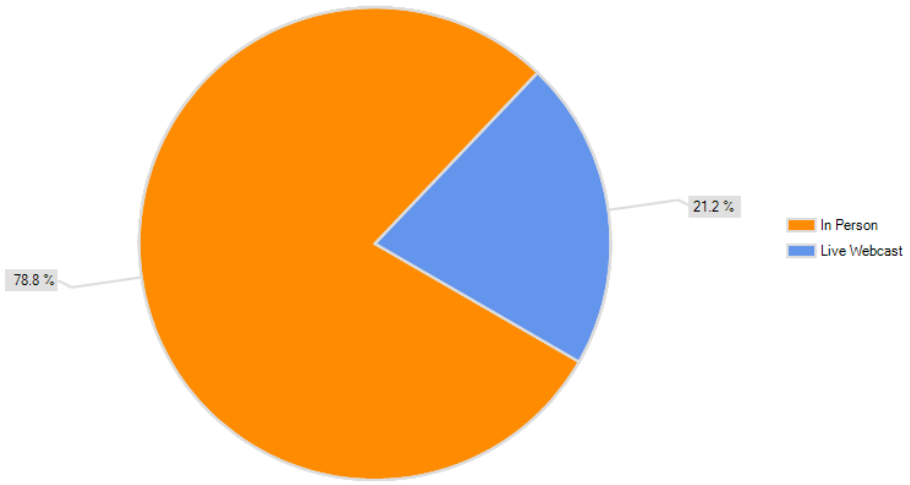
Overall, how would you rate the QUALITY and USEFULNESS of *Session 3: Future Directions of DAAs* at the "Advancing HCV Drug Development: A Collaborative Approach" meeting?



Overall, how would you rate the QUALITY and USEFULNESS of *Session 4: Unmet Needs in HCV Therapy* at the "Advancing HCV Drug Development: A Collaborative Approach" meeting?

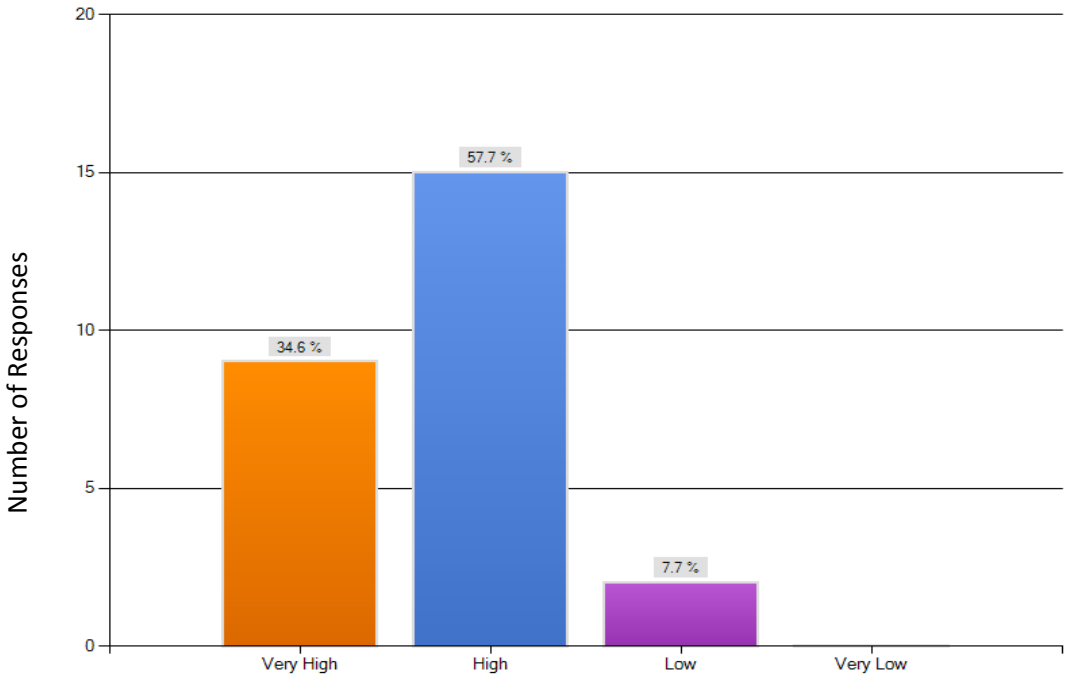


Did you choose to participate in "Advancing HCV Drug Development: A Collaborative Approach" In-Person or *via* Live Webcast?



<u>In person responses:</u>

Overall, how would you rate the quality of the Venue for "Advancing HCV Drug Development: A Collaborative Approach"?

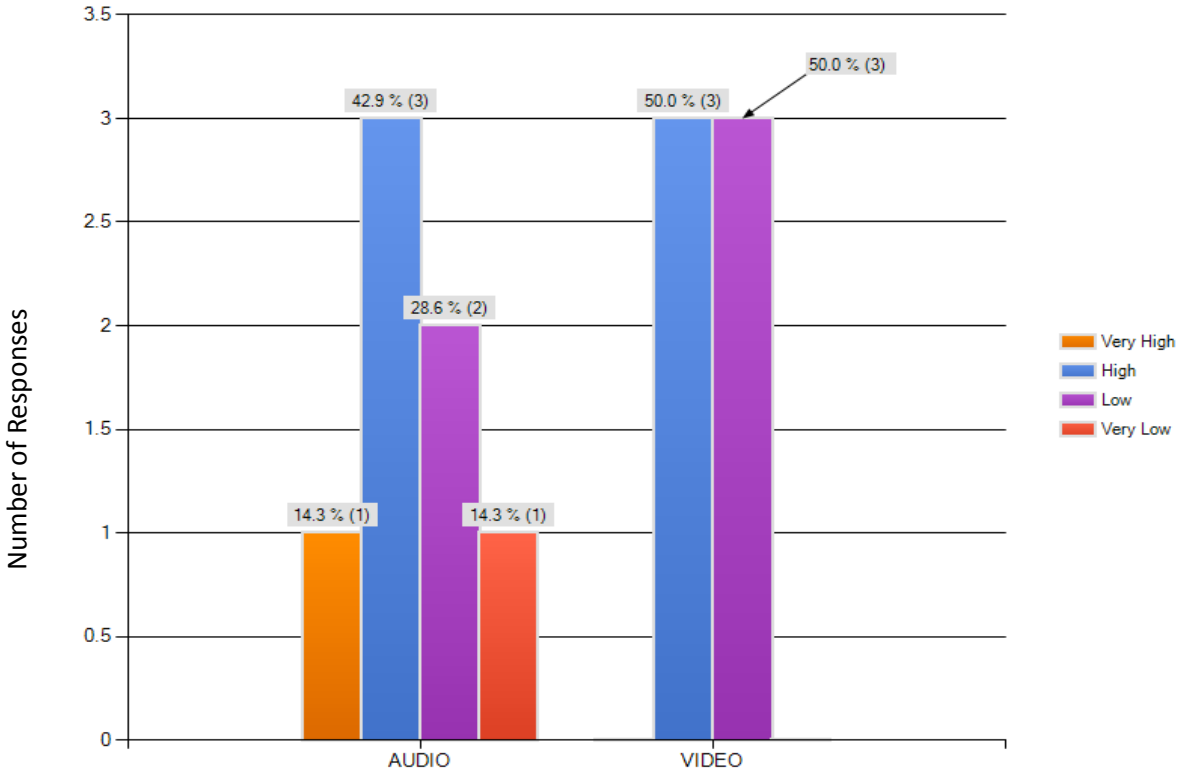


Do you have any comments on the venue that would help us to make future meetings a greater success?

- Great job!
- The venue was suitable and appropriate.
- Better acoustics
- Could we spend a bit more to have lunch on site? ask everyone to pay 10 bucks if they want lunch
- The places for eating could be closer, but we were Ok with what was available this time.

<u>Live webcast responses:</u>

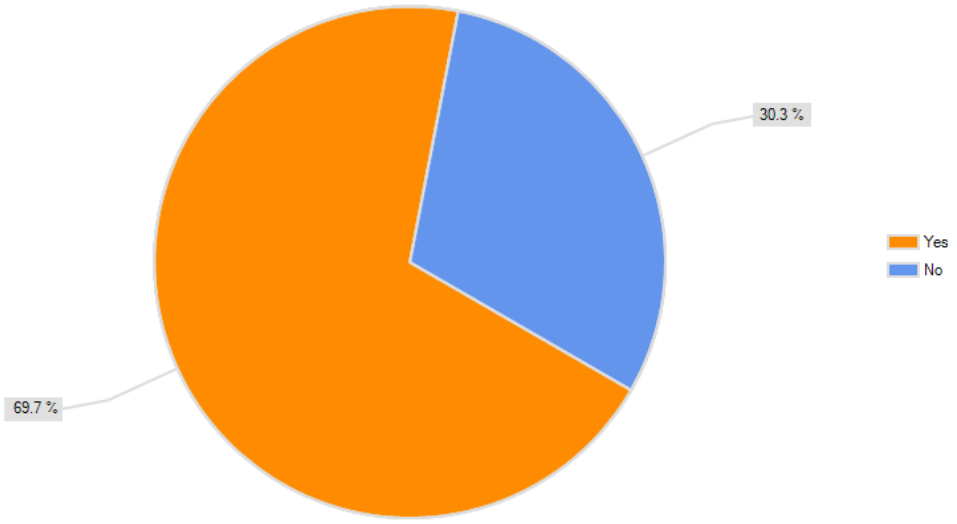
Overall, how would you rate the Quality of the AUDIO and VIDEO of the live webcast?



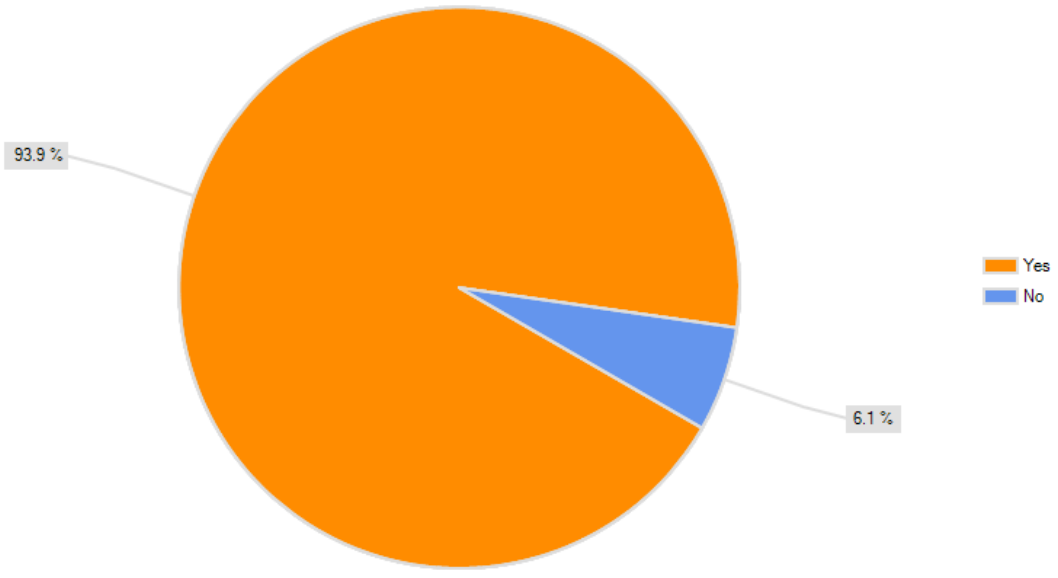
Are there any aspects of the live webcast that you believe could be improved?

- Earlier dissemination of dial-in information
- Audibility, more close-ups please

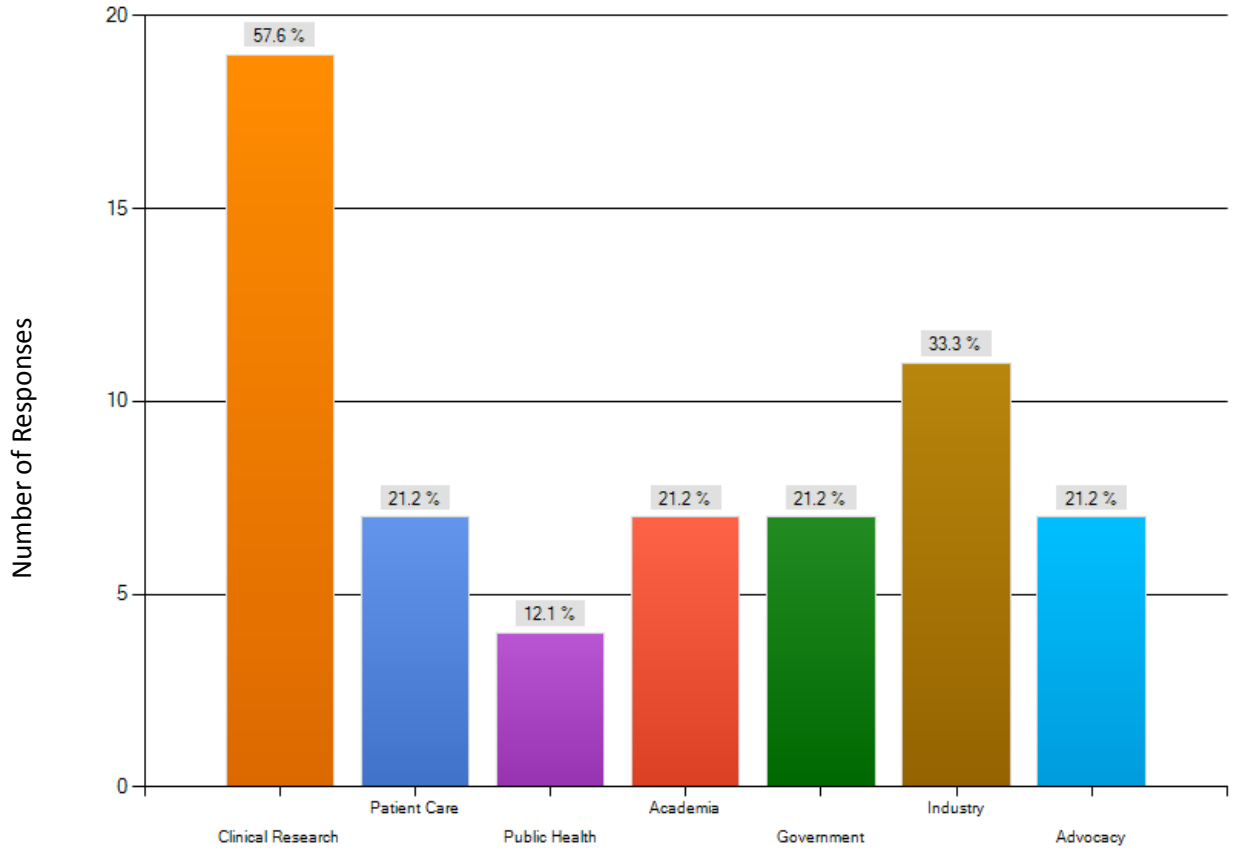
Will this meeting facilitate new collaborations with individuals/organization that you have not collaborated with before?



Would you be interested in participating in future Forum meetings *via* live webcast?



I am involved in (check all that apply*):



*= Responses are not mutually exclusive