Future of PrEP and Microbicide Research: Trial Design and Regulatory Issues

January 7, 2013
Washington DC

MEETING EVALUATION

Which of the following describes your role (check all that apply): (n=22)	
Academic	36.4%
Community/Advocacy	9.1%
Federal Government	31.8%
Foreign Government	0.0%
Foundation	0.0%
Industry	4.5%
Local Government	4.5%
Professional Society	0.0%
Research	31.8%
Other	4.5%

Would you agree that the "Future of PrEP and Microbicide Research: Trial Design and Regulatory Issues" meeting was valuable to your education, work and/or career advancement? (n=22)	
Completely Agree	54.5%
Agree	40.9%
Undecided	4.5%
Disagree	0.0%
Completely Disagree	0.0%

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

- Hearing how the regulators view advancements in PrEP and its impact on future PrEP development is relevant.
- It will help as we move the PrEP research agenda forward to consider alternative trial designs and methodological strategies.
- Helpful to consider clinical trial design issues
- Discussions with colleagues working on the same topic; interactions with pharma, FDA and other regulatory agencies
- Provided a perspective on the current uptake of Truvada ---This supports programs I am developing for sustained release, etc.
- It provided a good update on the pipeline of microbicide and PrEP products and trials and a platform for discussing the complexities in trial design in the future. As an advocate, it's imperative I understand these issues in order to focus advocacy work and update in-country partners.
- Help with regulatory interactions and study design
- It affirmed a lot of the thinking we are doing internally about the issues that clinical trials for future PrEP agents will face. No answers of course, but good to know that our thinking is in line with everyone else who is grappling with these issues.
- it will inform grant proposals
- It is important to collect information about all the stakeholders' view on PrEP in order to better inform our community action in this field
- Provide background info for review of clinical trial design.
- I have a broader understanding of the issues around implementation and also the status of PrEP studies nationally and internationally
- Helped me to verify the range of opinions existing around how best to deal with the conundrum of trials becoming unfeasibly large as new prevention methods are added to the prevention package.
- Pharmaceutical represented views
- Excellent gathering of reps from the key constituencies. Great for learning and networking. I wish there was a "virtual discussion" group that could be created afterwards, to continue the dialogue and side-conversations...

How does the meeting compare to other meetings that you have attended for networking and learning new information? (n=22)	
Very favorably	45.5%
Favorably	31.8%
Neutral	22.7%
Unfavorably	0.0%
Very Unfavorably	0.0%

Will this meeting facilitate new collaborations with individuals/organizations that you have not collaborated with before? (n=22)	
Yes	63.6%
No	36.4%

Overall, what did the meeting provide for you?

- A landscape perspective.
- A place to come together with colleagues to share the most up-to-date research strategies and discuss alternatives to traditional designs.
- Good discussions with colleagues and opportunities to share our experience
- A perspective on PrEP for uptake and statistical issues around using PrEP placebo arms
- Networking opportunities and insights in study design and statistical considerations; Opportunities to learn of development work by international groups
- A good opportunity to hear the latest information in the field.
- More detailed information about how PrEP is considered worldwide and in particular in the US, the only country where it is now available
- Better understanding of differing perspectives within group of researchers.
- Discuss issues with a range of stakeholders that I would otherwise not have the opportunity to meet with.
- New information, a "temperature check" on the prevailing and minority views in the field
- Ability to meet people from other fields interested in the prep field
- The chance to meet with future collaborators; rich discussions.
- A snapshot of PrEP today.

Are there any aspects of the meeting that you believe could have been improved?

- Significant duplication of presentations and panel members remarks should be eliminated.
- Yes - I believe that 1 day for this meeting was insufficient. The meeting brought forward many ideas, but more time was needed to really wrestle with what these ideas mean to the field.
- More time for discussions during the breaks
- In general meeting was just about right
- Perhaps more time for discussion and engagement and a plans for follow-up discussion.
- No
- Sometimes there were too many presenters for the allocated time period. This did not allow to go in depth into some of the topics.
- No
- Not sure
- Would have been nice if the dinner had been better attended, but that attrition may have been unavoidable. Maybe do the dinner the night before the meeting next time?
- The meeting clearly takes a lot of work to organize and people did think a LOT about it beforehand... but in the execution, sometimes the discussion's focus seemed fuzzy / overlapping across sessions. But that may be a part of a gathering of disparate groups like this since we all have different interests and agendas.

Overall, how would you rate the Quality and Usefulness of Session 1-"Setting the Stage" (Kenneth Mayer, James Rooney, Jim Pickett, Trip Gulick, Sharon Hillier) (n=20)						
	Very High	High	Neutral	Low	Very Low	Did not attend
Quality	55.0%	40.0%	5.0%	0.0%	0.0%	0.0%
Usefulness	50.0%	40.0%	10.0%	0.0%	0.0%	0.0%

Overall, how would you rate the Quality and Usefulness of Session 2 - "Statistical Challenges" (Deborah Donnell, Charu Mullick, Tom Fleming, Nathalie Morgensztejn) (n=20)						
	Very High	High	Neutral	Low	Very Low	Did not attend
Quality	45.0%	50.0%	5.0%	0.0%	0.0%	0.0%
Usefulness	45.0%	35.0%	15.0%	5.0%	0.0%	0.0%

Overall, how would you rate the Quality and Usefulness of Session 3 - "Clinical trial design options for trials assessing various delivery and dosing modalities" (Veronica Miller, Deborah Donnell, Jeffrey Murray, Manju Chatani, Dave Glidden, Sheena McCormack, Jean-Michel Molina) (n=20)						
	Very High	High	Neutral	Low	Very Low	Did not attend
Quality	25.0%	50.0%	25.0%	0.0%	0.0%	0.0%
Usefulness	30.0%	45.0%	25.0%	0.0%	0.0%	0.0%

Overall, how would you rate the Quality and Usefulness of Session 4 - "Adherence vs. Efficacy and Proof-of-Concept" (Alex Carballo-Dieguez, Dianne Rausch, K. Rivet Amico, David Burns, Robert Cuffe, Robert Grant, Sybil Hosek, Peter Miele, Christina Psaros) (n=20)						
	Very High	High	Neutral	Low	Very Low	Did not attend
Quality	20.0%	40.0%	30.0%	5.0%	0.0%	5.0%
Usefulness	25.0%	35.0%	25.0%	10.0%	0.0%	5.0%

- This session would have been much better if it was focused on new approaches to get adherence, i.e. Sharon's contraception carrying Microbicides proposal in the first session

Overall, how would you rate the Quality and Usefulness of Session 5 - "How do we get to surrogacy?" (Jim Turpin, Damon Deming, Gustavo Doncel, Walid Heneine, Joseph Romano, Julie Strizki) (n=20)						
	Very High	High	Neutral	Low	Very Low	Did not attend
Quality	20.0%	30.0%	30.0%	0.0%	0.0%	20.0%
Usefulness	15.0%	35.0%	30.0%	0.0%	0.0%	20.0%

What questions remain to be addressed following this meeting?

- Funding of Prep research; involvement of NGOs
- What new paradigms do we need for adherence, what is the process from correlation to surrogacy and what is the optimal trial design
- Regulatory approach to alternatives to phase II studies
- What will clinical trials for long acting PrEP products look like?
- How can we improve PrEP demand, how can we improve PrEP products and research...
- Meeting didn't focus enough on trial design and comparators for future microbicide/intravaginal product trials.
- Are we re-considering the ethics of run-in trials that allow for selection of participants less likely to use all the elements of the prevention package?
- What [is] the path for clinical trials for PrEP

Would you attend a follow-up meeting on PrEP and Microbicide Research? (n=20)	
Yes	100.0%
No	0.0%

What meeting format would you recommend for future meetings? (n=20)	
Open workshop (panels, open invitation)	35.0%
Closed workshop (panels, invitation only)	45.0%
Roundtable (smaller meeting, invitation only)	20.0%

Please provide any comments on future meetings, meeting topics, and format

- More PK data
- Format---picked closed meeting ---but still not right---you need a more interactive format that is focused on addressing a specific gap. This meeting was good for identifying a broad [range of] gaps---now it should be what is the best and most novel thinking to fill those gaps. So limited number of people , but a goal for the end of the meeting
- Approval of Truvada by FDA set the regulatory landscape but potentially thwarted the possibility of future phase II studies for other agents. How will the agency support future research applications and support surrogacy research; Outcomes research and cost effectiveness of PrEP as a meeting topic.
- To the extent possible, as far as reps from the constituencies you selected, should be invited again. This was a rare chance to see people you wouldn't normally talk to at CROI/IAS. And having people see each other again would be a way to achieve greater impact in fostering collaborations...

	Very High	High	Neutral	Low	Very Low	Not Applicable
Overall, how would you rate the pre-meeting logistics (including such things as the registration process, arranging hotel and travel if needed, provision of relevant meeting info such as directions and agenda) (n=20)	50.0%	30.0%	10.0%	0.0%	0.0%	10.0%
Overall, how would you rate the quality of the venue for meeting? (n=20)	55.0%	30.0%	15.0%	0.0%	0.0%	0.0%

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

- Would be nice to have wifi access