

Global HIV Vaccine Enterprise Funders' Meeting

Summary, Themes and Recommendations

Meeting Information

Saturday, 08 September 2012

12:00 – 5:00 p.m./12h00 – 17h00 EDT

Westin Waterfront Hotel, 425 Summer Street, Boston, MA

Summary

Bill Snow, director of the Global HIV Vaccine Enterprise, opened the meeting and welcomed 11 of the top institutions around the world who are funding HIV vaccine research and development (see [Appendix A](#) for a listing of participants). The Enterprise exists to help move HIV vaccine research and development forward faster. This meeting was a first step in information sharing; identifying opportunities to ensure that existing resources are most effectively utilized; and ensuring that the most critical areas of HIV vaccine research advance the fastest. The meeting intended to get key funding institutions to understand one another's plans and priorities, capacities to respond to new research developments, common interests and potential areas for collaboration.

Each participant was asked to consider their own goals for the meeting and how they would like to proceed in the future, noting the day's discussion may help to set the strategic priorities of the Enterprise Secretariat in the next 12 – 24 months.

The meeting kicked off with presentations by each institution that provided an overview of their funding plans in the form of six slides covering the following areas:

- Top five organizational priorities;
- Process to create/fund initiatives;
- Flexibility/capacity to respond to new developments in future funding years;
- Recent changes in funding directions and expected shifts;
- Areas they would like to see being funded (either through the participants' institution or another source);
- Ideas to discuss with this group, including possible areas to collaborate.

Participants were then assigned to one of three groups ([see Appendix C](#) for break out groups) and asked to consider all funders' presentations and to discuss the following questions:

- What intrigued you and what of importance did you learn?
- What "topics" proposed as opportunities seem most amenable to collaboration?
- Are there any new ideas?
- What should this group, with the support of the Enterprise Secretariat, focus on in the future?

Siobhan Malone of the Bill & Melinda Gates Foundation, Margaret McCluskey of the United States Agency for International Development and Kevin Ryan of the National Institute of Allergy and Infectious Diseases served as rapporteurs for each group.

Summary of Break-out Group Discussions

It became very clear that flat and restrained budgets create more reasons to work together and begin to force efficiencies. Participants recognized the importance of information sharing so as not to duplicate efforts and to ensure that priority areas are funded to their maximum potential -- there was a willingness and interest among all participants to collaborate and reconvene. Therefore, the Enterprise Secretariat will plan to bring such a group together annually or semi-annually, to continue to share updates on funding plans, assess and plan for new developments and more complex issues on the horizon.

The group also recognized the importance of engaging new funders and those poised to contribute more. They discussed the potential of the meeting to serve as a platform to create new partnerships between new and existing funders, between regions and between public and private partners. They also noted the significance of flexible funding to allow for more creativity and risk taking and to enable more rapid response emerging opportunities. In addition, several common themes emerged, which are captured below.

Clinical Trial Site Management

The group discussed the importance of having accurate and timely information on clinical trial site capacity to plan future efficacy trials. New approaches that promote more efficient use or sharing of clinical trial sites among funders and research organizations could help eliminate clinical trial bottlenecks. It was suggested that a catalogue of existing clinical trial sites describing different factors such as availability, populations, trials history, facilities, plans, etc., be created to promote sharing. An online catalogue would be a living document that could be updated by the trial sites and addresses the needs of shifting timelines in trial implementation as well as the need to do multiple phase I – III trials at the same sites.

Accelerating GMP product manufacturing

Timely GMP product manufacturing has repeatedly proven to be costly and difficult to manage and control. Products need to be available more rapidly in order to test vaccine approaches efficiently and to accelerate the iterations of vaccine development. The group agreed that there are several issues to consider such as the wide diversity of products used in current vaccine candidates (proteins, DNA, viral vectors etc.) or the unfamiliarity of investigators with the product development process. With support from the Gates Foundation, IAVI now provides guidance to some researchers within CAVD. However, even with such support, academic groups need strong industry partners because production guidelines will vary depending on the specific product being manufactured. The group discussed surveying the field to define the bottlenecks in GMP manufacture of proteins, vectors, small molecules, etc. and options to have either a central service facility to manufacture products or to develop a process that would connect researchers with identified contract manufacturing organizations. Coincidentally, the Enterprise Secretariat is working on a Timely Topic proposal to create a tool that maps the different steps in GMP product manufacturing for researchers to understand and prepare for it properly.

Adjuvant comparison

Access to multiple adjuvants for optimal use with vaccine products, while mitigating the risks to IP owners has been one of the goals for the field for a long time. As new adjuvants are being developed in parallel with vaccine approaches, comparing their role in increasing vaccine responses is critical. Funders discussed how to create a framework that would help achieve optimal pairings and consider engagement with what others are doing such as the PHARVAT consortium (<http://www.pharvat.eu/>) on a platform for harmonization of vaccine adjuvants and the ADITEC consortium on advanced immunization technologies (<http://www.aditecproject.eu/>), both initiatives funded by the European Commission.).

Harnessing industry expertise

The group agreed that continued and increased engagement of private enterprise and increased collaboration between academia and the private sector are paramount to HIV vaccine discovery and development. Industry expertise has contributed to much of the progress we are seeing in the field, and the group supported recommendations to develop strategies to maximize the scientific value of partnerships with industry. The Enterprise Secretariat will begin planning around the creation of advisory group comprised of industry partners in 2013 and continue efforts to garner advice on how the field can harness industry platforms and leverage their expertise in the meantime.

Advancement criteria for efficacy trials

Defining criteria that will help inform strategic funding decisions as to which a limited number of products can move forward is of concern to all, even though each funder will make their own decisions based on organizational priorities. The Secretariat is currently working with an ad hoc group of Clinical Collaborators to create an immune space framework that will map immune responses induced by different vaccine candidates in early phase clinical trials. The immune space frameworks may be used as one of the criteria, along with safety profile, protection data in non-human primate trials and product/production characteristics. It may be advisable to devise additional tools to support advanced decision-making.

Tools to maintain funding

The group discussed the creation of a common set of tools about the field overall to put their own meetings, discussions, presentations, etc. in context to help maintain HIV vaccine research funding levels. These tools could provide a big picture overview of the field [and recent advances, as would help] to advocate for ongoing support of key areas of HIV vaccine research and development. The Enterprise Secretariat will be gathering information to propose tools that would meet the general need.

Next Steps

The Enterprise Secretariat will develop recommendations to follow up on the above themes and other various recommendations that came out of the meeting.

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