2014 Global HIV Vaccine Enterprise Funders' Meeting

Summary, Themes, and Recommendations

Meeting Information

Thursday, 10 July 2014
8:45AM – 4:00 PM EDT
Bill & Melinda Gates Foundation, Washington DC, USA

Bill Snow opened the meeting and welcomed the representatives from many of the top institutions funding HIV vaccine research and development around the world (see Appendix A for a listing of participants). He noted that US government agencies missed last year's meeting due to the US government shutdown and expressed his pleasure that they were able to attend this year. As in past years, 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.

The meeting started with presentations by funders (see Appendix B for all slides presented). Each organization was asked to describe their current programs following a set of seven slides covering:

- Top five organizational priorities;
- Allocation of funding among different areas;
- Recent changes in funding directions and reasons for change;
- Any programs specifically targeted at facilitating manufacturing of candidate vaccines for clinical testing;
- Any programs specifically targeted at improving or maintaining clinical trial site capacity;
- Ideas to discuss with this group, including possible areas to collaborate.

After the presentations, participants divided into three groups to discuss the state of the field, opportunities for collaboration, and potential focus areas for the Enterprise Secretariat. Reports from the groups as well as general discussion identified several common areas of interest among funders:

- Tracking current HIV incidence rates and incidence trends in various geographic and demographic populations is an ongoing challenge critical to planning efficacy trials. A mismatch likely exists between places with highest incidence and the best established trial sites. Gathering the latest information on incidence and on the capacity of existing sites to conduct trials can help address this challenge. US DHHS maintains a website (http://worldreport.nih.gov) that collects (from funders) trial site information for multiple diseases. Gates Foundation has a similar website and discussions began about potentially merging the two sites into one. Also, EDCTP maintains a database of clinical trials, which spans multiple diseases. Thus, a concern was raised that multiple efforts exist that are not well-coordinated and it was suggested that the Enterprise Secretariat explore opportunities to make these efforts better coordinated and more relevant to the HIV field. Mitchell Warren pointed out that AVAC explored the idea of maintaining a database of trial sites, but found it extremely difficult to maintain the information current. Charles Mgone suggested that a Wikipedia-style database could remain current by allowing trial sites themselves to update their information.
- In the area of regulatory approval of clinical trials, it also became clear that multiple efforts exist that are not well coordinated or communicated across the field. Mitchell Warren shared a landscape analysis of regulatory efforts done by AVAC for IAVI/USAID (see Appendix C). It was suggested that the Enterprise Secretariat explore how information in this area can be better communicated. There was a general

agreement that regulatory approvals can be effectively secured in developing countries that have a history of HIV clinical trials. Efforts are needed to improve regulatory environment in countries that have not been engaged so far. The area of experimental medicine trials also requires attention and focused efforts.

- In the area of clinical trial site capacity, while current capacity is sufficient for ongoing and forthcoming trials, it will be critical to sustain sites in the long run, with better coordination across all prevention modalities and even non-HIV diseases. Charles Mgone commented that training and retaining the next generation of people in all roles associated with the conduct of clinical trials is another associated capacity need.
- In the area of manufacturing vaccine candidates for clinical trials, the ability to manufacture human-grade material is available, but it is not well supported with expertise in producing and characterizing HIV-specific products (such as subunit Env vaccines). Various efforts are already under way by multiple stakeholders to address this challenge.

Kevin Fisher presented the 2013 HIV vaccine funding data from the Resource Tracking Working Group (RTWG). He noted that the funding for HIV vaccines went down again this year to $818 US million. When adjusted for inflation in biomedical research, this represents 70% of the funding level in 2007. New this year, RTWG attempted to break down the funding by the area of research, and the participants discussed the challenges in gathering and presenting such information.

Yegor Voronin presented three funder-relevant issues that were raised in the past convenings by the Enterprise Secretariat:

- The meeting on VISR (http://www.vaccineenterprise.org/content/timely-topic-VISP) raised the challenge of long-term support to volunteers in cases where trial sponsors don't have the resources for long-term support. The group discussed the fact that the challenge will become more pressing as more candidates aim to elicit broader antibodies. Margie McGlynn pointed to the Vaccine Injury Act as a possible model, where every vaccine dose has an associated fee going into a common fund that is used to address the issue field-wide.
- The meeting on Durability of Antibody Responses (http://www.vaccineenterprise.org/timely-topic-antibody-durability) identified the need to conduct long-term studies in non-human primates (NHPs). The group agreed that this question needs to be answered in humans. Nina Russell pointed out that the Bill & Melinda Gates Foundation is planning to fund a program that will address some of the questions raised during the meeting and look at durability of antibody responses in NHPs and humans in parallel.
- The meeting on Therapeutic Vaccines (http://www.vaccineenterprise.org/content/timely-topic-therapeutic-vaccines) was organized to enable a better communication between the preventative and therapeutic fields and the group was asked to comment on how it can be facilitated. Everyone agreed that there's already a lot of activity and communication between the two fields. Mitchell Warren suggested writing a short paper that would lay out the growing connections.

Overall, the common theme from these discussions was the need to better collect and disseminate relevant information to all stakeholders. These yearly meetings serve this goal and can be used to develop a comprehensive picture of the field. The Enterprise Secretariat was encouraged to play a more active role in summarizing these discussions and disseminating them to the field and also in facilitating regular communication among stakeholders.