

## STATUS REPORT: AN UPDATE ON LAST YEAR'S RECOMMENDATIONS

| WHO                | WHAT WE SAID LAST YEAR   | WHAT HAPPENED   | WHAT MUST HAPPEN NEXT   |
|--------------------|--|---|---|
| AIDS VACCINE FIELD | Focus the preponderance of new product development resources on innovative candidates.   | Much of the field's attention had already turned in this direction prior to the disappointing performance of MRK-Ad5 in the STEP study.   | Continue work on novel concepts and articulate the key questions for human discovery and preclinical work that have come into focus post-STEP.                |
|                    | Continue to work to broaden the array of stakeholders who understand partial efficacy.   | Enterprise sponsored meetings on understanding and communicating partial efficacy. AVAC convened Enterprise working group on communications.  | Anticipate Thai prime-boost trial results expected in 2009 and ensure that all trials have communication plans for multiple scenarios in place.               |
|                    | Explore mechanisms for an advanced clinical trial commitment to strengthen and sustain industry involvement.                                   | STEP study result has prompted call for discovery-oriented human clinical trials, and industry may not take the lead in these.  | Use innovation funds (such as the new IAVI/Gates Foundation collaboration) as a mechanism for industry engagement.  |
| RESEARCHERS        | Build trial budgets to include funding for community-wide results dissemination.   | Vaccine and microbicide sites and sponsors did exemplary work in communicating unexpected research results.   | Document the best practices and long-term impact of post-trial results dissemination.   |
|                    | Dramatically expand awareness campaign around vaccine-induced seropositivity.  | Illinois court awarded US\$5000 damages to a vaccine trial participant who was tested without consent and received a false positive diagnosis. AVAC, HVTN and others drafted resource materials on the topic. | Continue follow-up with STEP and Phambili participants; prepare for expanded education should another trial of a candidate causing seropositivity go forward. |
|                    | Pilot the Good Participatory Practice (GPP) guidelines.  | Many researchers provided feedback on drafts of GPP and expressed enthusiasm for the new document.  | Train staff on GPP guidelines and implement them; work with AVAC and its GPP grantees.  |
| FUNDERS            | DAIDS: Closely monitor the on-the-ground effects of its new approach to funding prevention networks and sites.                                 | This year's events dramatically altered many sites' plans for launching or continuing trials.   | Short-term solutions to site's funding needs have been found; long term follow-up and support are needed.   |
|                    | Multiple funders: Consider community outreach and education fund for independent community oversight mechanisms.                               | Neither a fund nor an education and outreach program was created.   | Developing a fund is more important than ever, given the wide range of challenging issues on in the field of prevention research.                             |
| GLOBAL HIV VACCINE | Revisit the business strategy and scientific strategic plan; develop a two-year work plan; convene focused meetings on under-discussed issues. | Inaugural executive director Alan Bernstein assumed leadership of the Enterprise in January 2008.   | The recommended "to do" list is as critical as ever. (see page 52)  |
| AVAC               | Advocate standard definitions of levels of HIV care and treatment in trials.   | GPP guidelines and related UNAIDS ethics document include specific language on standard of prevention and level of care in trials.  | Continue to support community-level advocacy; disseminate information on approaches and outcomes for specific trials.   |
|                    | Work with partners to develop clear, realistic, and consistent messages to manage expectations of new products.                                | Published regularly-updated comprehensive prevention timeline; developed and shared messages with partners to develop consistent messages; convened the Enterprise communications working group.              | Continue current work; develop formal scenario plans in preparation for upcoming trial results.   |
|                    | Work with partners to build a strong and collaborative global movement on prevention research and implementation.                              | Convened civil society dialogues and informal discussions on a range of issues: male circumcision, STEP, Phambili, HSV-2, PrEP and others.  | Expand activity with sustained international programs.  |
| CIVIL SOCIETY      | Work in coalition to advocate for adequate, annual increases in NIH funding.   | AIDS Budget and Advocacy Coalition advocated for a 15% increase for NIH AIDS research spending in FY2009.   | Continue advocacy with a special focus on the new US Administration in 2009.  |
|                    | Pilot the GPP guidance document.   | Civil society groups worked with AVAC and UNAIDS on pilot programs.   | Document experience among initial GPP pilot project is and update the guidelines accordingly.   |
|                    | Support—and demand—developing country leadership on prevention.  | Developing country researchers and civil society leaders played an active role in disseminating and managing negative research results.   | Ensure that decisions related to PAVE 100 and other future HIV prevention trials are influenced by and responsive to these leaders.                           |