



IAS Corporate Partnership Programme

Global HIV Vaccine Enterprise Industry Partnership

Swinging into full gear: Strengthening industry engagement in HIV vaccine research and development

AIDS 2022, Montreal, Canada
29 July – 2 August 2022

Satellite report
4 August 2022



Background

Biomedical HIV prevention interventions are contributing to the prevention of new HIV acquisitions and are saving lives. However, the decline in HIV incidence is far from reaching the 90-90-90 UNAIDS targets. A safe and globally effective HIV vaccine remains a necessity to achieve durable control and an end to the epidemic. To develop such a vaccine, a renewed contribution from and participation by the pharmaceutical industry is necessary. The unprecedented success of research and development for COVID-19 vaccines has shown that the pharmaceutical industry, in partnership with public research institutions, can deliver on a global public health challenge in record time. As the field of vaccinology moves beyond the acute response to the COVID-19 pandemic,

there is an immediate need to recover momentum in HIV vaccine R&D by ensuring that it has the maximum interest, engagement and investment from the biopharmaceutical industry.

The IAS Corporate Partnership Programme organized a satellite at AIDS 2022, the 24th International AIDS Conference, to discuss barriers to industry involvement in HIV vaccine R&D, including recommendations for activating and optimizing industry participation in this R&D.

The event was also an opportunity to launch the IAS Global HIV Vaccine Enterprise Industry Partnership, a multi-stakeholder group aiming to support industry's contribution to HIV vaccine R&D by addressing and minimizing barriers to engagement.

Satellite programme

Welcome and introduction Carey HWANG , Vir Biotechnology, United States
Role of the pharmaceutical industry in HIV prevention and vaccine research – A researcher's perspective Linda-Gail BEKKER , Desmond Tutu Health Foundation, South Africa
Importance of community engagement with the pharmaceutical industry for HIV prevention research – A community perspective Maureen LUBA , AVAC, Malawi
What does a successful public-private partnership for HIV vaccine R&D look like? Dan BAROUCH , Center for Virology and Vaccine Research, BIDMC, United States
IAS Global HIV Vaccine Enterprise Industry Partnership launch Birgit PONIATOWSKI , International AIDS Society, Switzerland
Panel discussion Shan LU , UMASS Medical School, United States Linda-Gail BEKKER , Desmond Tutu Health Foundation, South Africa Carey HWANG , Vir Biotechnology, United States Maureen LUBA , AVAC, Malawi Valerie ORIOL MATHIEU , Janssen Vaccines & Prevention B.V., France Jan VAN LUNZEN , ViiV Healthcare, Germany Birgit PONIATOWSKI , International AIDS Society, Switzerland
Closing Linda-Gail BEKKER , Desmond Tutu Health Foundation, South Africa



Key points from the session

Role of the pharmaceutical industry in HIV prevention and vaccine research – A researcher's perspective – Linda-Gail Bekker, Desmond Tutu HIV Centre, South Africa

Linda-Gail Bekker noted the importance of re-engaging in science and HIV vaccine science at a time when HIV levels remain high in groups such as young women and with people still unable to protect themselves against HIV. She reviewed some of the recent epidemiology data and pointed to the ongoing need for a safe, effective and affordable HIV vaccine.

From the COVID-19 response, Bekker shared the learning that pandemics can cause enormous disruptions in health systems, with consequences on access to care and prevention for other infectious diseases, such as HIV. Vaccines contribute to preventing such disruptions. She also noted that when resources, academia, industry, brain power, funders and governments come together, it is possible to develop a vaccine in nine months.

The resources allocated to COVID-19 were several orders of magnitude bigger than what has ever been put towards addressing HIV, TB and malaria. However, the brain power and the vaccine platforms exist; they must be brought together with the same passion as seen with COVID-19.

Importance of community engagement with the pharmaceutical industry for HIV prevention research – A community perspective – Maureen Luba, Global Advocacy for HIV Prevention, AVAC, Malawi

Maureen Luba noted that HIV vaccine research had contributed to a better understanding of the virus and that there is a need to keep reflecting on the lessons learnt so far, especially as the research is becoming more complex.

She called for a more coordinated strategy to unlock the challenges of developing an HIV vaccine. She noted that despite many failures, there is a glimmer of hope, with new trials being launched. At the same time, she stressed the importance of communication and engagement with communities and avoiding raising false hope.

Community-industry partnerships are critical to the success of clinical research, as demonstrated in the past. The relationship with industry has not always been good, but has improved, and community advisory boards are now an essential component of clinical research. Still, there is much to do to achieve a meaningful engagement with communities that goes beyond window dressing.

Engagement should move away from a top-down approach, and researchers need to acknowledge that community members are experts in their own ways. Engagement should start with communities identifying their own problems and contributing to finding solutions through an iterative process. True collaboration at each stage of the research is needed and building



community research literacy must be financially supported. Tension is inevitable, but can lead to candid and meaningful conversation. Not engaging can contribute to vaccine hesitancy. HIV vaccine research has been the engine driving the COVID-19 response. Recent developments are bringing us closer to an HIV vaccine. There is a need to learn from our mistakes and critically analyse what we aim to achieve. Carey Hwang noted that building trust from the very beginning is very important.

What does a successful public-private partnership for HIV vaccine R&D look like? – Dan Barouch, Center for Virology and Vaccine Research, BIDMC, United States

Ban Barouch noted that there are many structures that public-private partnerships (PPP) can follow and that he would be sharing his experience of the partnership that led to the development of the Ad26 platform from the bench to efficacy studies. Although success is still pending, the partnership has been successful.

The partnership started between his lab and a small biotech (Crucell), with the research funded by a U19 NIH grant specifically designed to fund PPP work. It was triggered by the failure of the Ad5 platform in the STEP study and led to the development of the Ad26 platform. DB also collaborated with other academics (Bette Korber, Los Alamos, USA) for the design of the mosaic antigen used in the Ad26 vector.

When Johnson & Johnson bought Crucell, the collaboration accelerated, leading to a partnership with the HVTN for conducting clinical studies, including the Imbokodo (HVTN 705) and MOSAICO (HVTN 706) studies. Imbokodo has been discontinued but MOSAICO is ongoing.

For Barouch, elements for a successful partnership include:

- Aligned scientific goals: an affordable and thermostable vaccine, deliverable to low- and middle-income countries
- Mutual respect and complementary expertise: in this case, the academic partner brought innovation, preclinical and immunology expertise while the industry partner brought manufacturing and regulatory expertise
- Rigorous decision-making process
- Early engagement of the industry partner in the research so that it is scientifically invested in the research and prepared to take risks

There were some challenges along the way. It was important not to avoid them, but rather to figure out how to solve them, acknowledging mutual opinions and working through differences. This was facilitated by the trust that developed from a long-term collaboration with the same individuals. Technical and scientific challenges were also addressed by bringing in other partners and adapting the research to the latest science as it arises.

This successful partnership led to another successful partnership to develop a vaccine against COVID-19 with an agreement signed in a record four days.

Looking forward, Barouch noted that the field is back to discovery, and he remains optimistic. There is a critical need for industry engagement as academia alone cannot bring a vaccine to the market. Respectful, shared decision-making processes between academia, industry,



government, communities and all other stakeholders are important for the success of the partnership and for delivering on the goal of developing a safe and effective HIV vaccine.

IAS Global HIV Vaccine Enterprise Industry Partnership launch

The satellite was an opportunity to formally launch the IAS HIV Vaccine Industry Partnership; it had a soft launch in May 2022. Birgit Poniatowski provided a brief history of IAS engagement with the biomedical industry, highlighting the successes of the Industry Liaison Forum and the Towards an HIV Cure Industry Collaboration Group.

The IAS Corporate Partnership Programme aims to catalyse and engage industry and non-industry partners in a dialogue towards addressing topical issues with the IAS acting as a neutral convener. The IAS HIV Vaccine Industry Partnership is the third group in the Corporate Partnership Programme. The activities of each group are steered by their members and two co-chairs, one to represent the industry and one to represent non-industry members. These groups are united by their convening power and need for collaboration to achieve a common goal. Although each has a distinct focus, there will be opportunities for cross-group engagement and work.

Re-engaging with industry in HIV vaccine R&D is critical in a fast-changing prevention landscape; this R&D is at a turning point in history, with only two ongoing efficacy trials. The field is back to a discovery stage with a rich pipeline of products entering early clinical testing using new platforms for both vaccine products and clinical testing.

The partnership is launched with a renewed awareness of the barriers to industry's engagement in HIV vaccine research, but also with mechanisms to support this engagement. Working with industry and non-industry stakeholders, the group has identified mechanisms that cover all stages of product development from start to end, as well as new ways of working and funding strategies, to strengthen industry's engagement.

The HIV Vaccine Industry Partnership will work to promote entrepreneurship and innovative funding mechanisms, create demand and prepare for success. It aims to "push and pull" at various stages in the development of HIV vaccines. The group's ways of working will be informed by the success of the IAS Industry Liaison Forum and by providing a neutral space for interactions between industry and non-industry members. Areas of work have already been identified and actions will be informed by members with the aim of delivering tangible outcomes.

The partnership expects other benefits for both industry and non-industry members, including increased visibility and better understanding of academic vaccine R&D and a facilitated engagement with community-based organizations. This will also be an opportunity for members to share information and potentially initiate new partnerships. Overall, with this partnership, the IAS aims to add value to all stages of product development.

Panel discussion

Inda-Gail Bekker opened the panel by remembering the power of convening stakeholders in a safe place to accelerate product development, using the example of the GAP-f as a previous success.



It was noted that no infectious disease has been eradicated without a vaccine. There is a need for industry to commit to developing a vaccine in addition to the commitment to developing treatment and other interventions. The following themes were discussed:

Challenges for industry

- Industry commitment is framed by industry financial objectives and constraints. But it was recognized that industry could lose public trust by not investing in HIV vaccine R&D.
- More incentives are needed for industry to participate. The Barouch and Janssen partnership was possible because it was supported by a specific NIH funding scheme.
- In addition to scientific barriers, the conducting of clinical trials is a major challenge because of their size, cost and low incidence and the availability of other HIV prevention tools.
- There is a gap between early-phase studies and efficacy studies.
- Much talked-about experimental medicine may not be the answer.
- There is a need to develop better biomarkers to replace infection as the primary outcome of efficacy studies.

Partnership building and management

- Each partnership is an adventure that requires a lot of effort to make it work. This is also an ongoing and long-term effort.
- Building trust between industry and academic partners is important, especially regarding IP protection that may later lead to access problems.
- IP management mechanisms can be agreed on in advance using marketing mechanisms.
- A careful approach to IP is needed to ensure that participation remains attractive to the industry partner.
- Collaborations between companies that are developing different products are also important (for example, vaccine developers and adjuvant developers).

Product development

- There is a need for greater diversity in approaches to vaccine development as there is no clear path towards an HIV vaccine (unlike COVID-19).
- There is a need for more vaccine candidates and for more companies to engage in the development of vaccine candidates.
- Some participants thought that companies dedicated to HIV vaccines would be in a better position to develop new products and approaches, especially biotech, as they can do so with reduced risks. (It was noted that this had been the case for RNA.)

Manufacturing and access

- It was thought important and conceivable to manufacture vaccines in the countries where the epidemic is found.
- Access and equity, as exemplified by COVID-19, are issues to consider now, even if there is no HIV vaccine yet.
- IP management should be considered from an early stage of product development.

Community engagement



- Vaccines create hope. It is important to keep the community informed of the status of the research and not raise false hope.
- Building trust by engaging early with communities is essential to the successful conduct of the research, product acceptability and rollout.
- It was thought important to build community capacity to understand how research and vaccine works.
- VISP is thought to be a potential obstacle to rollout and it should be addressed now.
- Vaccine characteristics are important for product acceptability and communities can advise on what is suitable and acceptable.
- It is important to engage communities and nurture peer educators.