# IAS Corporate Partnership Programme

## HIV Vaccine Industry Partnership

*Workshop on "Biomarkers and clinical trial design"*

*Tuesday 15 November 2022 – 4PM-7PM CET*

IAS

## Background

HIV prevention is evolving rapidly with the roll out of prevention tools such as pre-exposure prophylaxis (PrEP) and with treatment making a significant contribution towards controlling the epidemic.

As a result, the design and conduct of HIV prevention trials is becoming challenging and is further affected by the outcomes of ongoing efficacy trials – including injectable antiretrovirals and passively infused monoclonal antibodies.

The window of opportunity for conducting double-blind placebo-controlled randomized clinical trials, the gold standard of epidemiology studies, is closing. New counterfactual approaches are required to evaluate product efficacy.

Biomarkers, as surrogate endpoints of vaccine efficacy, are one approach under evaluation. If one or more biomarkers, probably of immune nature, could reliably predict the efficacy of a vaccine in a clinical trial, replacing HIV infection as primary clinical endpoint, such marker(s) could alleviate the need for a placebo group.

Biomarker(s), if measurable shortly after immunization, could also be useful to quickly screen vaccine candidates for further improvement and reduce time and cost of efficacy trials, accelerating iterative research.

The use of biomarkers as surrogate endpoint for clinical efficacy come with challenges and limitations including identifying and validating, biomarkers. Regulatory and community perspectives on the use of biomarkers in clinical trials are also important to understand.

The workshop conducted in partnership with the Global HIV Vaccine Enterprise follows from the series of events on design approaches for current and future HIV prevention efficacy trials.

This workshop will bring together industry and non-industry representatives with a stake in HIV vaccine R&D to explore how biomarkers could be used as surrogate markers of clinical efficacy in counterfactual vaccine trials.

By debating the design of future efficacy trials, the workshop aims to contribute to addressing the industry's concern that, in a changing prevention landscape, conducting efficacy trials can be an obstacle to investment in HIV vaccine R&D.

*The mission of the IAS HIV Vaccine Industry Partnership is to encourage and facilitate the full contribution of the pharmaceutical industry to HIV vaccine research and development*

# Workshop on "Biomarkers and clinical trial design"

**15 November 2022 – 16:00 -19:00 CET**

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| 1600 – 1602 | **Welcome** – Tuuli Reissaar, Project Manager, IAS, Switzerland |
| 1602 – 1610 | **Opening – HIV vaccine efficacy trials today**<br>Co-chairs: Linda-Gail Bekker – Carey Hwang |
| ***PART 1*** | ***Understanding the role and potential of biomarkers of efficacy for HIV vaccine trials*** |
| 1610 – 1615 | **A short introduction to biomarkers and surrogate endpoints in clinical trials** |
| 1615 – 1630 | **Evaluating the surrogacy of multiple vaccine-induced immune response biomarkers in HIV vaccine trials**<br>*Sayan Dasgupta – Vaccine and Infectious Disease Division, Fred Hutchinson Cancer Research Center* |
| 1630 – 1640 | **Q&A – Lead by co-chairs** |
| 1640 – 1730 | **What biomarkers for HIV vaccine efficacy trials?**<br>**Perspectives (3 minutes each)**<br>1. *Larry Corey, HVTN, USA*<br>2. *Tomas Hanke, University of Oxford*<br>3. *Hanneke Schuitemaker, Janssen Vaccine Prevention, Netherlands.*<br><br>**Group Discussion** |
| 1730 – 1740 | ***Break*** |
| ***PART 2*** | ***Using biomarkers as surrogate endpoints in HIV prevention efficacy studies - Challenges and opportunities.*** |
| 1740 – 1755 | **PT80: A neutralization titer biomarker for antibody-mediated prevention of HIV-1 acquisition**<br>*Yunda Huang*<br>*Fred Hutchinson Cancer Research Center, University of Washington* |
| 1755 – 1805 | **A regulator perspective on the use of biomarkers as surrogate endpoints**<br>*EMA- Marco Cavaleri* |
| 1805 – 1820 | **Q&A – Lead by co-chairs** |
| 1820 – 1855 | **Can biomarkers of efficacy be included in the design of efficacy trial and how?**<br>**Perspectives (3 minutes each)**<br>1. *Myron Cohen, The University of North Carolina at Chapel Hill, USA (TBC)*<br>2. *Moupali Das, Gilead Sciences, USA.*<br>3. *Daisy Ouya, AVAC, Kenya*<br><br>**Discussion** |
| 1855 – 1900 | **Closing** |