

Passive Immunization Trials to Inform Vaccine Design

8 August 2014, New York

Location

New York Marriott Downtown
85 West Street
Salon C
New York, New York 10006

Agenda

Meeting objectives: Define how passive immunization studies can answer questions relevant to the design of a preventive HIV vaccine: what data will be available, how definitive will it be, what are the implications for setting the goalposts for vaccine candidates?

8:30 – 8:40 **Welcome** (Bill Snow)

8:40 – 9:00 **What can we expect to learn from passive immunization trials?** (Mary Marovich)

9:00 – 9:20 **The landscape of passive immunization efforts** (Pervin Anklesaria)

9:20 – 10:20 **Clinical Trials**

Objectives: Discuss ongoing and planned trial designs including target population, PK, safety, biological activity measurements and novel exploratory assessments. Also discuss the criteria used to select specific bNabs for clinical study.

Speakers:

- Barney Graham – Clinical Evaluation the HIV-1 CD4 Binding Site-Specific Monoclonal Antibody VRC01
- Michel Nussenzweig – Anti-HIV antibodies in prevention and therapy
- Phil Johnson – Immunoprophylaxis by gene transfer – Shortcut to an HIV vaccine

10:20 – 10:35 **Coffee break**

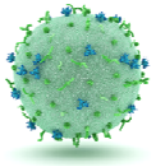
10:35 – 11:10 **Clinical Trials (continued)**

Speakers:

- Merlin Robb – MHRP passive antibody transfer studies in African and THai cohorts
- Peter Gilbert – Statistical issues for assessing treatment efficacy and correlates of protection in mAb efficacy trials

*Disclaimer:

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11:10 – 12:30 Panel: Impact of clinical trials of passive immunization on vaccine design
(Moderator: Barney Graham)

Objectives: Discuss the vaccine-relevant questions that will be answered in the course of these studies, the commonalities and differences of various clinical trial designs. What questions can be uniquely answered in each study and how multiple studies can complement each other?

Panel:

- Michel Nussenzweig
- Phil Johnson
- Merlin Robb
- Peter Gilbert

12:30 – 13:30 Lunch break

13:30 – 14:15 Alternate antibody formats and delivery methods

Speakers:

- David Baltimore – Gene-based Ab Delivery
- Gepi Pantaleo – Antibody-based therapeutic strategies to purge the HIV cell reservoir
- David Ho – Novel passive immunization approaches to HIV prevention

14:15 – 14:35 General discussion: What additional information can be obtained from these alternate approaches?
(Moderator: Coleen Cunningham)

14:35 – 14:50 Coffee break

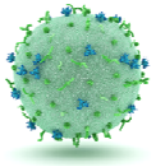
14:50 – 16:10 NHP studies: Discuss key findings from past NHP studies. What NHP studies are needed to inform clinical trials and how they can address questions unanswerable in humans.

Speakers:

- Malcolm Martin – Administration of potent anti-HIV neutralizing monoclonal antibodies to macaques prior to or following challenge with SIV/HIV chimeric viruses
- Nancy Haigwood – Post-exposure mAb prophylaxis in macaques as a model for preventing infection in HIV-exposed newborns
- Gregory Del Prete – Identification and application of CCR5-tropic SHIVs with transmitted/founder HIV-1 Envs
- Dan Barouch – Establishment and Targeting of the Viral Reservoir in Rhesus Monkeys

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16:10 – 17:10 Panel: Impact of NHP studies of passive immunization on planning clinical trials and considerations for vaccine design
(Moderator: Michel Nussenzweig)

Objectives: Discuss how NHP studies can best complement clinical work in informing vaccine design and their role in advancing new approaches to the clinic. What key findings in NHP need to be validated in clinical studies? How preclinical studies will define the correlation of *in vitro* potency PK and tissue penetrance, and other antibody functional properties applicable to prevention, therapeutic, and cure strategies.

Panel:

- Malcom Martin
- Nancy Haigwood
- Dan Barouch
- Gregory Del Prete
- David Montefiori

17:10 – 17:20 Wrap up

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