



## Product Development Boot Camp – Agenda

5-6 November 2015, New York

### Location

New York Marriott Downtown  
Room - Financial 2 & 3  
85 West St  
New York, NY 10006

### DAY 1

**07:45 – 08:30** Continental Breakfast – Financial 1

**08:30 – 08:50** Welcome and Opening Remarks (Bill Snow, Ryan Wiley)

### Pipeline and Portfolio Considerations – Module 1

**Description:** Overview of principles behind portfolio management by governmental agencies, foundations, and industry; discussion of approaches to a more coordinated field-wide portfolio management; review and discussion of “Immune Landscape” Timely Topic deliverables.

#### Presentations:

**8:50 – 9:00** Principles of portfolio management in industry (Jerry Sadoff)

**9:00 – 9:10** Principles of portfolio management in foundations (Penny Heaton)

**9:10 – 9:20** Principles of portfolio management in governments (Mary Marovich)

**9:20 – 9:30** Integrated approaches to portfolio management (Carlos DiazGranados)

#### Panel Discussion:

**9:30 – 10:30** Moderator: Sanjay Phogat

Panelists: Jerry Sadoff, Penny Heaton, Mary Marovich, Carlos DiazGranados

#### Presentation:

**10:30 – 11:10** Outcomes of the "Visualizing Immune Landscape" Timely Topic (Yegor Voronin)

**11:10 – 11:30** *Coffee break*



## Target Product Profile (TPP) – Module 2

**Description:** Introductory training on why and how to create a TPP; early- vs. late-stage TPP development; challenges of developing TPPs for HIV vaccine candidates; hands-on training in small teams by developing TPPs for fictitious vaccine candidates; comparing and contrasting different approaches.

### Presentation:

**11:30 – 11:45** Overview of TPP: why and how to create a TPP (Jane Halpern)

### Panel Discussion:

**11:45 – 12:15** Moderator: Sanjay Phogat

Panelists: Jane Halpern, Carlos DiazGranados, Tom Hassell, Jerry Sadoff

**12:15 – 12:45** *Lunch break - Financial 1*

### 12:45 – 13:45 Breakout Sessions

Moderators: Jane Halpern, Carlos DiazGranados, Tom Hassell, Jerry Sadoff, Sanjay Phogat

**13:45 – 14:00** *Coffee break*

**14:00 – 15:00** Reports from breakout groups and discussion

## Moving Vaccine Candidates from Bench to Clinic – Module 3

**Description:** Challenges of advancing candidates from preclinical to first-in-human trials; preclinical data requirements, manufacturing, and clinical considerations; case studies to compare and contrast alternative models.

### Presentations:

**15:00 – 15:15** Phase and goal-appropriate product development (Michael Pensiero)

**15:15 – 15:30** Preclinical data and regulatory considerations (Jim Ackland)

**15:30 – 16:00** Compare and contrast case studies: Research- and product-oriented development (Robin Shattock, Dan Barouch)

### Panel Discussion:

**16:00 – 17:00** Moderators: Tom Hassell, Michael Pensiero

Panelist: Jim Ackland, Michael Pensiero, Robin Shattock, Dan Barouch

**17:30 – 19:30** *Reception with food - IAVI Board Room, 125 Broad St (see map for instructions)*



## DAY 2

**08:15 – 09:00** Continental Breakfast – Financial 1

**09:00 – 09:20** Recap of Day 1 and Introduction to Day 2 (Ryan Wiley)

### Planning for Trial Success – Module 4

**Description:** Planning for various outcomes of late-stage trials; concept overview and main considerations; case study using Dengue vaccine development; considerations for ongoing late-stage HIV trials.

#### Presentations:

**9:20 – 9:40** Concept overview of planning for success (Anne Mullin)

**9:40 – 9:55** Dengue vaccine late stage development (Sanjay Phogat)

**9:55 – 10:10** P5 development plans (Nina Russell)

**10:10 – 10:20** *Coffee break*

#### Panel Discussion:

**10:20 – 11:20** Moderator: Tom Hassel

Panelists: Anne Mullin, Sanjay Phogat, Nina Russell, James Kublin

### Product Development Partnerships: Best Practices – Module 5

**Description:** Best practices in cross-sector collaboration; lessons learned from key partnerships; multi-sector panel discussion.

#### Presentation:

**11:20 – 11:50** Product Development Partnerships (PDP): Overview (Ryan Wiley)

**11:50 – 12:30** *Lunch break - Financial 1*

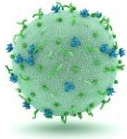
#### Presentation:

**12:30 – 13:00** Contrast and compare the different approaches of Janssen and P5 (Jerry Sadoff, Robert O'Connell)

#### Panel Discussion:

**13:00 – 14:00** Moderators: Ryan Wiley, Nina Russell

Panelists: James Kublin, Tom Denny, Jerry Sadoff, Robert O'Connell



**TIMELY TOPICS**  
in HIV Vaccines



Global HIV Vaccine  
**Enterprise**



## Wrap-up Session

**Description:** A high-level discussion among all speakers and participants summarizing PD Boot Camp topics and brainstorming on how they can be applied to improve current product development practices in the HIV vaccine field.

**14:00 – 15:00** Moderators: Yegor Voronin, Ryan Wiley, Tom Hassell

**15:00 – 15:15** **Closing Remarks** (Bill Snow)

**15:15 – 15:45** **Coffee and snacks available – Financial 1**