

**Regulatory Capacity Building Workshop:
Vaccine Clinical Trial Review from Ebola to HIV
Agenda**

Dates: March 18-20, 2015

Location: Kivu Ballroom

Hôtel des Mille Collines by Kempinski
2KN 6th Ave

Pre-Workshop Reception at La Terrasse restaurant – March 17, 2015	
15:30	Networking reception for participants of Considerations for a Pan-African HIV Vaccine Development Agenda Meeting and Regulatory Capacity Building Workshop
DAY 1 – March 18, 2015	
8:30	Registration
<u>Session 1</u>	
9:00	<ul style="list-style-type: none"> • Welcome and overview of the workshop objectives: Beno Yakubu (NAFDAC) and Dean Smith (HC) • Welcome to Rwanda
<u>Session 2</u>	
9:30	<ul style="list-style-type: none"> • Mapping out regulatory capacity building in Africa: Moderators Beno Yakubu, Amapola Manrique (the Enterprise) and Dean Smith • Presentations from agencies and organizations engaged with regulatory capacity building: David Mukanga (the Gates Foundation), Fran Priddy (US IAVI), Angelo Kaggwa-Katumba (AVAC & GHTC), Annalene Nel (IPM Global), Thomas Nyirenda (EDCTP), Miga Chultem (HC), Ahmed Bellah (WHO), Jane Mashingia (EAC) and Christoph Conrad (PEI)
10:30	HEALTH BREAK
10:45	<ul style="list-style-type: none"> • Facilitated group discussion: lessons learned with regulatory capacity building • Next steps
12:30	LUNCH La Terrasse Restaurant
<u>Session 3</u>	
13:30	<ul style="list-style-type: none"> • Lessons learned from recent African joint reviews for clinical trials through WHO/AVAREF and other frameworks, experiences from Ebola, TB, Malaria and HIV: Moderators Beno Yakubu and Dean Smith • Overview: David Mukanga
15:15	HEALTH BREAK
15:30	<ul style="list-style-type: none"> • Facilitated group discussion on best practices with the recent joint reviews
16:30	<ul style="list-style-type: none"> • Wrap up and next steps

DAY ENDS AT 17:00

DAY 2 – March 19, 2015

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| 9:00 | <p>Session 4</p> <ul style="list-style-type: none"> • Highlights from the Regulatory Satellite at 2014 HIVR4P Cape Town Conference: Moderators Beno Yakubu and Dean Smith |
| 9:20 | <ul style="list-style-type: none"> • Facilitated breakout discussions on key issues from Cape Town <ol style="list-style-type: none"> 1) National regulatory frameworks versus international guidance and, 2) Strategies to enhance expertise available to support regulatory review by resource limited agencies |
| 10:30 | HEALTH BREAK |
| 10:45 | <ul style="list-style-type: none"> • Break out discussions continued • Next steps |
| 13:00 | LUNCH at La Terrasse Restaurant |
| 14:00 | <p>Session 5</p> <ul style="list-style-type: none"> • Risk benefit assessment when making regulatory decisions: Moderators Beno Yakubu and Dean Smith • Selected case studies and group discussion |
| 15:30 | HEALTH BREAK |
| 15:45 | <ul style="list-style-type: none"> • Selected case studies and group discussion continued |
| 16:45 | <ul style="list-style-type: none"> • Wrap-up and preview for Day 3 |

DAY ENDS AT 17:00

DAY 3 – March 20, 2015

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| 9:00 | <p>Session 6</p> <ul style="list-style-type: none"> • Good Review Practice Guidance: Moderators Beno Yakubu and Dean Smith |
| 10:30 | HEALTH BREAK |
| 10:45 | <p>Session 7</p> <ul style="list-style-type: none"> • AVAREF draft guidance on joint review: Moderators Beno Yakubu and Dean Smith • Overview, key issues in the current draft guidance: David Mukanga • Facilitated group discussion • Next steps |
| 12:30 | LUNCH at La Terrasse Restaurant |
| 13:30 | <p>Session 8</p> <ul style="list-style-type: none"> • AVAREF and regional regulatory capacity building: Moderators Beno Yakubu and Dean Smith |



Global HIV Vaccine
Enterprise



Government
of Canada

Gouvernement
du Canada

Bureau de coordination de
l'Alliance
L'association des vaccins contre le VIH



Alliance
Coordinating Office
Advancing HIV Vaccines

- **Opportunities and challenges:** Beno Yakubu and David Mukanga
- **Facilitated group discussion**
- **Next steps**
- **Workshop recommendations and next steps**

DAY ENDS AT 15:00