Forum for Collaborative HIV Research

Global Surveillance of Antiretroviral Drug Safety

Perspectives from Different Stakeholders

June 11, 2010
Washington, DC

Meeting Agenda

	June 10, 2010	
6:30 p.m.	Session moderators briefing at Ceiba	
7 p.m.	Dinner at Ceiba	
	June 11, 2010	
	Session I: Welcome and Meeting Goals Moderator: Veronica Miller	
8:00–8:30 a.m.	Breakfast	
8:30-8:40 a.m.	Welcome, meeting goals and objectives	Veronica Miller
8:40-8:45 a.m.	Forum work and meeting background	Nyasha Bakare
8:45-8:50 a.m.	Update from WHO	Alex Dodoo
	Session II: Evolving Science of Drug Safety Surveillance **Objective: To discuss new developments in drug safety surveillance** Moderators: Judy Aberg & Gerald Dal Pan	
8:50-9:00 a.m.	New initiatives at FDA	Gerald Dal Pan
9:00-9:10 a.m.	New initiatives at EMA	June Raine
9:10-9:20 a.m.	UMC – adapting to new challenges	Marie Lindquist
9:20-9:35 a.m.	Industry perspective on safety surveillance & Antiretroviral Pregnancy Registry: Lessons learned	Fabio Lievano
9:35-10:00 a.m.	Discussion	
10:00-10:15 a.m.	Coffee Break	
	Session III: Pitfalls and pearls in resource-limited settings **Objective: To provide perspectives on current experiences in ARV safety surveillance** Moderators: Andy Stergachis & Alex Dodoo	
10:15-10:25 a.m.	Opening remarks	Andy Stergachis
10:25-10:35 a.m.	Case study - Namibia	Jude Nwokike
10:35-10:45 a.m.	Case study – an industry experience	Barbara da Silva
10:35-11:30 a.m.	Panel discussion What are the strengths, weaknesses, opportunities, challenges? What about special populations (children, pregnant women)?	Panelists Chris Duncombe Ricardo Kuchenbecker Albert Mwango Praphan Phanuphak Ian Sanne Lulu Oguda Mwangi

Session IV: Current and planned support for global surveillance activities **Objective: To determine commitments from organizations supporting global surveillance activities** Moderator: Veronica Miller		
11:30-12:30 p.m.	Questions: What are the commitments and priorities? What are the barriers? How do these relate to other ongoing activities? Where are the gaps?	Panelists: Caroline Ryan Serge Xueref Stephen Becker Carlie Williams Chris Duncombe David Ripin
12:30-1:30 p.m.	Lunch	
Session V: Thinking outside the box **Objective: To identify opportunities to achieve sustainable systems for global surveillance of ARV drug safety** Moderators: Ian Sanne, & Nyasha Bakare		
1:30-2:10 p.m.	*Topic 1: Role of industry in non-ICH regions* - Best use of industry expertise - Safety databases - Models for collaboration	Lead discussants: Rob Dintruff Vijaya Kuppa Joel Novendstern
2:10-2:50 p.m.	*Topic 2: Role of regulatory authorities* - Strengthening national PV centers - Opportunities for collaboration (regional, with industry, other)	Lead discussants: Alex Dodoo Albert Mwango Gerald Dal Pan
2:50-3:30 p.m.	*Topic 3: Active surveillance: Identifying common elements that can be leveraged for progress* - Cohort studies as sentinel sites - Registries - Surveillance technology (data collection software, background event databases, pharmacy linkages, approaches to improving documentation and reporting at sites, etc.) - Proposals for research and evaluation	Lead discussants: Ralph Edwards Carlie Williams Ngozi Erondu
3:30-3:45 p.m.	**Coffee Break**	
Session VI: Wrap up and Next Steps Moderator: Jur Strobos		
3:45-4:00 p.m.	Recap	
4:00-4:50 p.m.	What is the big picture? Common goals? Recommended next steps?	
5:00 p.m.	Final comments, meeting adjourn	