Critical Path to TB Drug Regimens

CPTR 2012 WORKSHOP

October 2-4, 2012
Sheraton Pentagon City Hotel
900 South Orme Street · Arlington, VA 22204 USA
Tel: 1.703.521.1900 Website: Click Here

Workshop Objectives:

- Advance TB drug regimen development through sessions on state-of-the-science, emerging issues, global and regulatory landscape, and cross-sector-perspectives
- Increase collaborative efforts
- Provide networking opportunities for workshop participants

TUESDAY, October 2

7:00 – 9:00	**Evening Reception & Buffet** ***Galaxy Ballroom***

WEDNESDAY, October 3

7:30 – 8:30	**Continental Breakfast & Networking** ***South Ballroom***
8:30 – 8:40	**Welcome & Introductions** — *Jan Gheuens*
8:40 – 9:30	**CPTR Key Accomplishments** — *Moderator: Debra Hanna* • Regulatory Science Consortium — *Debra Hanna (C-Path)* • Research Resources Group — *Jane Reese-Coulbourne (RUF)* • Drug Development Coalition — *Carl Mendel (TB Alliance)*
9:30 – 10:00	**Keynote: Dr. Edward Cox, Dir. of Office of Antimicrobial Products, Office of New Drugs, CDER, FDA** (invited)
	Break
10:15 – 12:00	**Cross-Sector Perspectives** — *Moderator: Hans-Georg Eichler* • Regulatory — *Hans-Georg Eichler (EMA)* • Industry — *Wim Parys (J&J/Tibotec)* • Global Health — *Christian Lienhardt (WHO)* • Clinical Trials — *Richard Hafner (NIH/NIAIDS)* ***Q&A panel session***
12:00 – 1:15	**Lunch** ***South Ballroom***
1:15 – 3:00	**Workgroup Breakout Sessions** • Biomarkers & Clinical Endpoints — ***North 1*** • Disease Progression Modeling — ***Mezzanine 3*** • Data Standards & Integration — ***Pentagon 1***

	• Preclinical & Clinical Sciences	***North 2***
	• Global Regulatory Pathways / Access & Appropriate Use	***South Ballroom***
	• Clinical Trial Infrastructure	***East 3***
Break		
3:30 – 5:30	**Emerging Technologies in TB Drug Regimen Development**	***South Ballroom***
	Moderator: Debra Hanna	
	• Lesion Pharmacokinetics to Guide the Design of New Drug Regimens	*Véronique Dartois (UMDNJ)*
	• Integrated Modeling & Simulation for TB Drug Regimen Development	*Tawanda Gumbo (UT-Southwestern) & Peter Vis (LAP&P Consultants)*
	• Imaging Biomarkers	*Clif Barry (NIH/NIAID)*
5:30	**Adjourn Day 1**	

THURSDAY, October 4

7:30 – 8:30	**Continental Breakfast & Networking** *South Ballroom*	
8:30 – 8:40	**Welcome Day 2**	*Jan Gheuens*
8:40 – 10:40	**TB Drug Co-Development Roundtable**	*Moderator: Carl Mendel*
	• AstraZeneca	*Scott Butler*
	• Bayer	*Martin Springsklee*
	• Janssen/J&J	*Chrispin Kambili*
	• Otsuka	*Larry Geiter*
	• Pfizer	*Bob Wallis*
	• Sanofi	*Isabelle Cieren-Puiseux*
	• Sequella	*Carol Nacy*
	• TB Alliance	*Dan Everitt & Steve Murray*
	Q&A panel session	
Break		
10:50 – 12:00	**Global Regulatory Landscape for TB Drug Development**	*Moderators: Robin Keen & Bob Clay*
	• Bill & Melinda Gates Foundation	*Vincent Ahonkai*
	Q&A panel session	
	• Bill & Melinda Gates Foundation	*Vincent Ahonkai*
	• EMA	*Hans-Georg Eichler*
	• FDA	*Edward Cox*
	• FDA	*Joseph Toerner*
12:00 – 12:15	**Closing Remarks**	*Carol Nawina Nyirenda, Treatment Advocacy and Literacy Campaign*
12:15 – 12:30	**Wrap Up & Adjourn**	*Jan Gheuens*
12:30	**Adjourn Day 2: Lunch Available** *South Ballroom*	
1:00 – 5:30	Stakeholder & Community Engagement Workgroup Meeting	***Arlington***