CRITICAL PATH INSTITUTE

CPTR 2017 Workshop: Day 4 – March 23, 2017

The 8th Annual CPTR Initiative Workshop drew more than 150 participants to Washington, D.C. to learn and share information critical to the rapid advancement of new TB combination therapies, drug susceptibility tests (DST), and the tools and models necessary to develop and implement them. Participants represented a diverse group of global stakeholders, including product developers, regulators, health systems workers, and TB survivors and patient advocates. Detailed summaries and content from Day 4 of the 2017 CPTR Workshop is provided below.

AGENDA

8:15 – 8:30 am	**Welcoming Remarks** *Marco Schito (Critical Path Institute)*
How Regulators and Policymakers are Evolving the TB Diagnostic Landscape ***Moderator: Heike Sichtig (Food and Drug Administration)***	
8:30 – 8:35 am	**Session Introduction** *Heike Sichtig (Food and Drug Administration)*
8:35 – 8:50 am	**Validation Strategies for Novel In Vitro Diagnostic Assays** *Kristian Roth (Food and Drug Administration)*
8:50 – 9:05 am	**The Role of Whole Genome Sequencing in Antimicrobial Susceptibility Testing of Bacteria: Report from the EUCAST Subcommittee** *Claudio Köser (University of Cambridge)*
9:05 – 9:20 am	**WHO Support to the Evolving TB Diagnostic Landscape** *Chris Gilpin (World Health Organization)*

9:20 – 10:00 am	**Panel Discussion** *Moderator: Heike Sichtig (Food and Drug Administration)* *Panelists: Kristian Roth (Food and Drug Administration), Claudio Köser (University of Cambridge), Chris Gilpin (World Health Organization), Richard Compton (Nanopore), Joshua Trotta (Thermofisher), Simon Travers (Hyrax Bio), Christiane Honisch (Illumina)*
10:00 – 10:15 am	**Break**
Developing a Global Health Business Case Solution for Drug Susceptibility Testing and Antimicrobial Resistance ***Moderator: Jim Gallarda (Bill & Melinda Gates Foundation)***	
10:15 – 10:25 am	**Session Introduction** *Jim Gallarda (Bill & Melinda Gates Foundation)*
10:25 – 10:40 am	**Business Models for Sustaining Biomedical Databases: The Case for ReSeqTB** *Anita Suresh (McGill University)*
10:40 – 10:55 am	**Does a Sustainable Business Model Need a New Global Health Institution? Lessons from the GAVI-Alliance** *Kristin Ingstad Sandberg (Fridtjof Nansen Institute)*
10:55 – 11:10 am	**Adoption of Real-time, Low Cost, Portable Whole Genome Sequencing for Point-of-care Drug Susceptibility and Antimicrobial Resistance Testing** *Richard Compton (Nanopore)*
11:10 – 11:45 am	**Question & Answer**
11:45 – 12:15 pm/td>	**Closing Remarks** *Jim Gallarda (Bill & Melinda Gates Foundation)* *Steve Bradley (TB Alert)*

Welcoming Remarks

Marco Schito (Critical Path Institute)

Marco Schito kicked off the final day of CPTR's 2017 Workshop by affirming the essential role of diagnostics in effective TB treatment, and contrasting that importance with a lack of corresponding investment in the field, despite such a compelling value proposition. Schito outlined reasons why diagnostic development has stalled resulting in few new products. Schito culminated his remarks by reiterating the need for collaboration between developers, implementers, regulators, and all stakeholder groups, to overcome the silos and catalyze innovation and progress.

- Presentation

How Regulators and Policymakers are Evolving the TB Diagnostic Landscape

Moderator: Heike Sichtig (Food and Drug Administration)

Session Introduction

Heike Sichtig (Food and Drug Administration)

Heike Sichtig reminded the audience that the FDA published new draft guidance around diagnostics in May 2016 and comments, including those from the CPTR group have been received and are being processed. Sichtig stated that the FDA is generally interested in streamlining policies and integrating efforts across offices and divisions.
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Validation Strategies for Novel In Vitro Diagnostic Assays

Kristian Roth (Food and Drug Administration)

Kristian Roth presented on the FDA's regulatory framework for In Vitro Diagnostic Assays (IVDs). Roth's presentation began by laying out the definition of and levels of risk associated with IVDs. He continued by covering the case of GeneXpert and the need for further evolution in the field and shifting trends of the disease. Roth went on cover ideas for moving forward into biomarker models, and concluded by explaining the principles of a successful IVD premarket submission.

- Presentation

The Role of Whole Genome Sequencing in Antimicrobial Susceptibility Testing of Bacteria: Report from the EUCAST Subcommittee

Claudio Köser (University of Cambridge)

Claudio Köser reminded the group that in DST, it remains critical to accurately determine phenotype and that phenotypic testing is not free of assumptions. Köser discussed technical issues relating to MIC concentration and epidemiological cutoff value, noting that epidemiological breakpoints can differ from clinical breakpoints. He concluded by noting that the path toward progress requires transparency and accountability, with clear documentation of assumptions and open questions; this is what fosters critical and high-quality research.

- Presentation

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WHO Support to the Evolving TB Diagnostic Landscape

Chris Gilpin (World Health Organization)

Chris Gilpin covered the evolution of TB diagnostic techniques through the prism of WHO policy. Gilpin discussed new concepts and technologies and the WHO's corresponding analysis plan(s). The presentation concluded with a review of a non-inferiority study comparing the current GeneXpert Omni against Xpert Ultra, which showed favorable results.

- Presentation

Panel Discussion

Moderator: Heike Sichtig (Food and Drug Administration)

Panelists: Kristian Roth (Food and Drug Administration),

Claudio Köser (University of Cambridge), Chris Gilpin (World Health Organization), Richard Compton (Nanopore), Joshua Trotta (Thermofisher), Simon Travers (Hyrax Bio), Christiane Honisch (Illumina)

- Presentation

Developing a Global Health Business Case Solution for Drug Susceptibility Testing and Antimicrobial Resistance

Moderator: Jim Gallarda (Bill & Melinda Gates Foundation)

Session Introduction

Jim Gallarda (Bill & Melinda Gates Foundation)

- Presentation

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Business Models for Sustaining Biomedical Databases: The Case for ReSeqTB

Anita Suresh (McGill University)

Anita Suresh offered a case study of ReSeqTB and discussed dynamics like costs, proprietary restrictions, donor infrastructure, and access by stakeholders as elements of the sustainability equation for biomedical databases. Suresh's presentation compared other databases as well. Suresh discussed various business models to support such databases including grants, philanthropic funds, usage fees, partnerships with joint funding, corporate sponsorships, as well as hybrids of the above models.

- Presentation

Does a Sustainable Business Model Need a New Global Health Institution? Lessons from the GAVI-Alliance

Kristin Ingstad Sandberg (Fridtjof Nansen Institute)

Kristin Ingstad Sandberg presented on GAVI's experience providing an infrastructure enabling low income countries to be able to develop vaccines, and the determinants of the success of those efforts in different settings and contexts. The model could be replicated for TB diagnostics as many of the issues and challenges were what vaccines faced a decade ago.

- Presentation

Adoption of Real-time, Low Cost, Portable Whole Genome Sequencing for Point-of-care Drug Susceptibility and Antimicrobial Resistance Testing

Richard Compton (Nanopore)

Richard Compton presented on the benefits of real time, low cost whole genome sequencing for point of care drug susceptibility and antimicrobial resistance testing, articulating the features of Nanopore's technologies.

- Presentation

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