8th International Conference on HIV TREATMENT AND PREVENTION ADHERENCE

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"New Frontiers" Pre-Conference Symposia: Novel Technologies and Assays for Adherence Assessment and Support

Moderators:
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Novel Technologies and Assays for Adherence Assessment and Support

Presenters/Panelists:

- Ariane van der Straten, PhD, MPH, Director, Women's Global Health Imperative, Research Triangle Institute (RTI), San Francisco, CA, *PrEP Adherence: Innovations towards its optimization.*
- Donn Dennis, Xhale Inc. *SMART®: A Breath-Based Technology to Definitively Document Adherence to HIV Medications (Oral and Microbicide Gels).*
- Maya Petersen, MD, PhD, Div. of Biostatistics and Epidemiology, University of California Berkeley: *Analytic Challenges and Tools.*

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The Office of HIV/AIDS Network Coordination's BSWG Data Capture Technologies Focus Group

Context and Goals:

- Provide recommendations for networks using (A)CASI and other electronic data capture technologies - particularly guidance on why, whether, and how trials might adopt these approaches.
- Identify key considerations for a cost/benefit analysis when protocols are considering new tools.
- Address the limits of "validation" given questions about transferability and challenges with self-report.
- Consider developing an electronic data capture technologies implementation costing tool applicable to a variety of clinical trial settings.

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www.hanc.info/behavioral/Pages/reportLibrary.aspx
October 11, 2012 – Bethesda, MD

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Key Recommendations:

- Create a vendor/technology table for researchers to reference as they consider adopting a tool.
- Identify funds to pilot novel technologies and cognitive testing of questions.
- Conduct a cost/benefit analysis and develop a budgeting tool and best practices guidance document modeled on the HANC "Recommendations for Standardizing Budgets for Clinical Trial Sites".
- Create a cross-network "Technology and Measures Task Force" to develop standards and recommendations.

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Key Considerations:

- Participant self-report is not reliable (e.g. VOICE, FemPrEP, etc.)
- Real-time monitoring would compliment and potentially enhance the reliability of self report.
- Real-time monitoring would complicate trial conduct and design.
- Current trials have no objective means to access adherence in placebo recipients. This complicates an analysis of efficacy based on adherence (i.e. drug exposure) in only the active trial arm(s).
- No point of care testing exists for drug exposure monitoring.
- The FDA is considering new rules for Electronic Source Data in Clinical Investigations.*
- All new technologies are bio-behavioral interventions.

*www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf

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