Forum Mission

- Public/private partnership including government agencies, industry, HIV researchers and clinicians, insurers, foundations and the HIV patient advocacy community
- Mission: to facilitate and enhance HIV research
  - Neutral & independent space
- 2007: Apply HIV collaborative model to HCV
- 2014: New Opportunities
  - CMV in transplantation
  - Anti-fibrotics for NASH and liver fibrosis/cirrhosis

www.hivforum.org
facilitating collaborative research
drug development & health policy

Translational Medicine

Discovery | Clinical Research | Approval | Post-Marketing | Implementation

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History of NGS Project

• Recognized need for discussion on regulatory pathway for NGS
  – Diagnostic tool
  – Source of data for drug submissions

• Launched NGS project in Summer 2012
  – In person meeting in December 2012

• Identified next steps
  – Proficiency panel working group
  – Bioinformatics working group
Proficiency Panel Project - Purpose and Objectives

Purpose: to advance the regulatory pathway for NGS applied to viral pathogens by collaborating with multiple industry, academic and regulatory laboratories in developing proficiency panels.

Objectives:

1. Characterize the nature and extent of inter and intra lab variation in different settings and under different conditions through a pilot proficiency panel consisting of patient derived isolates and HIV PCR products.

2. Identify and address data workflows, pipelines, and analyses issues through the project generated database (in collaboration with the Bioinformatics working group).
Proficiency Panel Project — Participating Labs

1. The laboratory aspect of the project involves five industry labs, five academic labs and CBER/FDA.

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<th>Lab/Company</th>
<th>Roche 454</th>
<th>MiSeQ</th>
<th>PacBio RS</th>
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<td>CBER/FDA - Viswanath Ragupathy</td>
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<td>CFE/VC - Richard Harrigan</td>
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<td>Harvard/BWH - Jon Li</td>
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<td>Monogram - Chris Petropoulos</td>
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<td>UCSF - Teri Liegler</td>
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<td>UNC - Shuntai Zhou</td>
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Steering Committee

Himani Bisht, PhD – Office of In Vitro Diagnostic Device Evaluation and Safety, CDRH, FDA
Andrew Dayton, MD, PhD – Medical Officer, Office of Blood Research and Review, CBER, FDA
Jules O'Rear, PhD – Lead Virologist, Division of Antiviral Products, CDER, FDA
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Richard Haubrich, MD – Professor of Medicine, Division of Infectious Diseases, UCSD
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Davey Smith, MD – Associate Professor of Medicine, UC San Diego
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Ellen Paxinos, PhD – Senior Staff Scientist, Pacific Biosciences
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Proficiency Panel Project

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All Project Members!