Presentation Outline

- DAIDS Programs & Funded Networks
  - DAIDS Clinical Laboratory Oversight Team (DCLOT) POCs

- DAIDS Laboratory Oversight Support
  - Contract Re-competition Process
  - CRSS Contract (WESTAT/FHI & PPD)
  - Patient Safety Monitoring in International Laboratories (SMILE)

- DAIDS GCLP Audit Process Working Group (DGAPWG)
  - Site Laboratory Survey Results

- Discussion Session
DAIDS Programs and Funded Clinical Networks and DCLOT POCs

DAIDS

- Basic Sciences Program (BSP)
  - MTN (Naana Cleland)
  - HPTN (Usha Sharma)

- Prevention Sciences Program (PSP)
  - IMPAACT (Joe Fitzgibbon)

- Therapeutics Research Program (TRP)
  - ACTG (Daniella Livnat)

- Vaccine Research Program (VRP)
  - HVTN (Nina Kunwar)

Microbicide Trials Network (MTN)
HIV Prevention Trials Network (HPTN)
International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT)
AIDS Clinical Trials Group (ACTG)
HIV Vaccine Trials Network (HVTN)
CRSS Contract Award
Transition Period August 15th, 2017 to November 14th, 2017

- Initiated through a Request for Proposal (RFP)

- Westat/FHI (Previous contract now in transition period):
  - Contract activities will continue during the transition period
    - Including all direct communications with laboratories
  - Contract conducted audits will end on October 13th, 2017

- PPD (Current contract as of August 15th, 2017):
  - PPD audits will commence after October 13th, 2017
  - For now, all contract related laboratory oversight activities will remain the same
cPQA: Clinical Pharmacology Quality Assurance
VQA: Virology QA
IQA: Immunology Quality Assessment
SMILE: Patient Safety Monitoring & International Laboratory Evaluation
TBQA: TB Quality Assessment
EQAPOL: External Quality Assurance Program Oversight Laboratory
CRSS: Clinical Research Support Services
## QA COR Assignment

<table>
<thead>
<tr>
<th>DAIDS Staff</th>
<th>DAIDS QA Contract</th>
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<tr>
<td>Joe Fitzgibbon, Team Leader</td>
<td>VQA</td>
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<tr>
<td>Daniella Livnat</td>
<td>SMILE, IQA, TPQA</td>
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<td>Jim Lane</td>
<td>EQAPOL</td>
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<td>Hao Zhang</td>
<td>cPQA</td>
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<td>Jackie Burns</td>
<td>CRSS</td>
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(Naana Cleland is the DCLOT POC for CRSS GCLP-related activities)
PPD & SMILE Support Activities

- **PPD GCLP-related activities**
  - Conduct GCLP audits and generate associated reports
  - Support GCLP training activities

- **SMILE (key support activities)**
  - Create audit report action plans and oversee report resolution activities
  - Coordinate and oversee EQA related activities
  - Provide guidance on GCLP standards compliance
  - Provide on-site or remote trouble-shooting/training support
Laboratory Oversight Team

Laboratory oversight is a collaborative team effort involving all stakeholders

To promote reliability, quality, consistency and integrity of clinical data; and the safety of participant & lab staff
DAIDS GCLP Audit Process Working Group (DGAPWG)

- **DGAPWG** (members: DCLOT, SMILE, FHI/PPD, Network, Site lab)
  - Overarching goal
    - To improve the effectiveness of the DAIDS GCLP audit process

- Highlights from site laboratory survey
  - SMILE support is highly valued
  - Audit and report resolution process very beneficial but suggested improvements needed
    - Request for trend analysis
    - Request to reduce audit report resolution timelines
  - Auditor-related concerns
    - Knowledge of GCLP and relevant local standards
    - Audit debriefing information
  - GCLP training preference
  - Harmonization of network laboratory activities