

# Division of AIDS (DAIDS)

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DAIDS/NIAID/NIH

September 20, 2017

NIAID

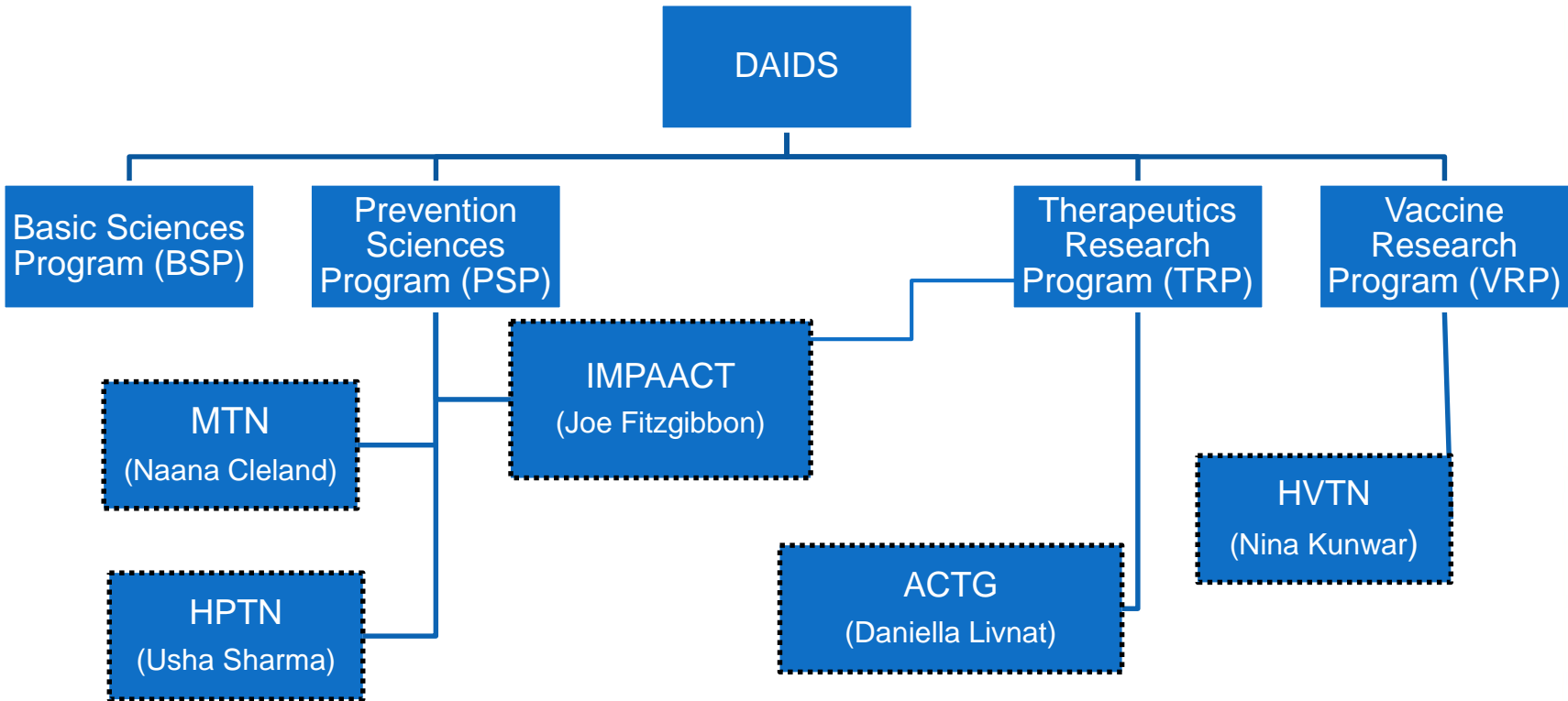


National Institute of  
Allergy and  
Infectious Diseases

# 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



- 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 15<sup>th</sup>, 2017 to November 14<sup>th</sup>, 2017

- Initiated through a Request for Proposal (RFP)

9/18/2017 NOT-AI-16-044: Request for Proposals (RFP): NIAID/Division of AIDS: Clinical Research Support Services (CRSS) NIAID-DAIDS-NIHAI2015050

Request for Proposals (RFP): NIAID/Division of AIDS: Clinical Research Support Services (CRSS) NIAID-DAIDS-NIHAI2015050

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Notice Number: NOT-AI-16-044

Key Dates

**Release Date:** April 5, 2016

Related Announcements

None

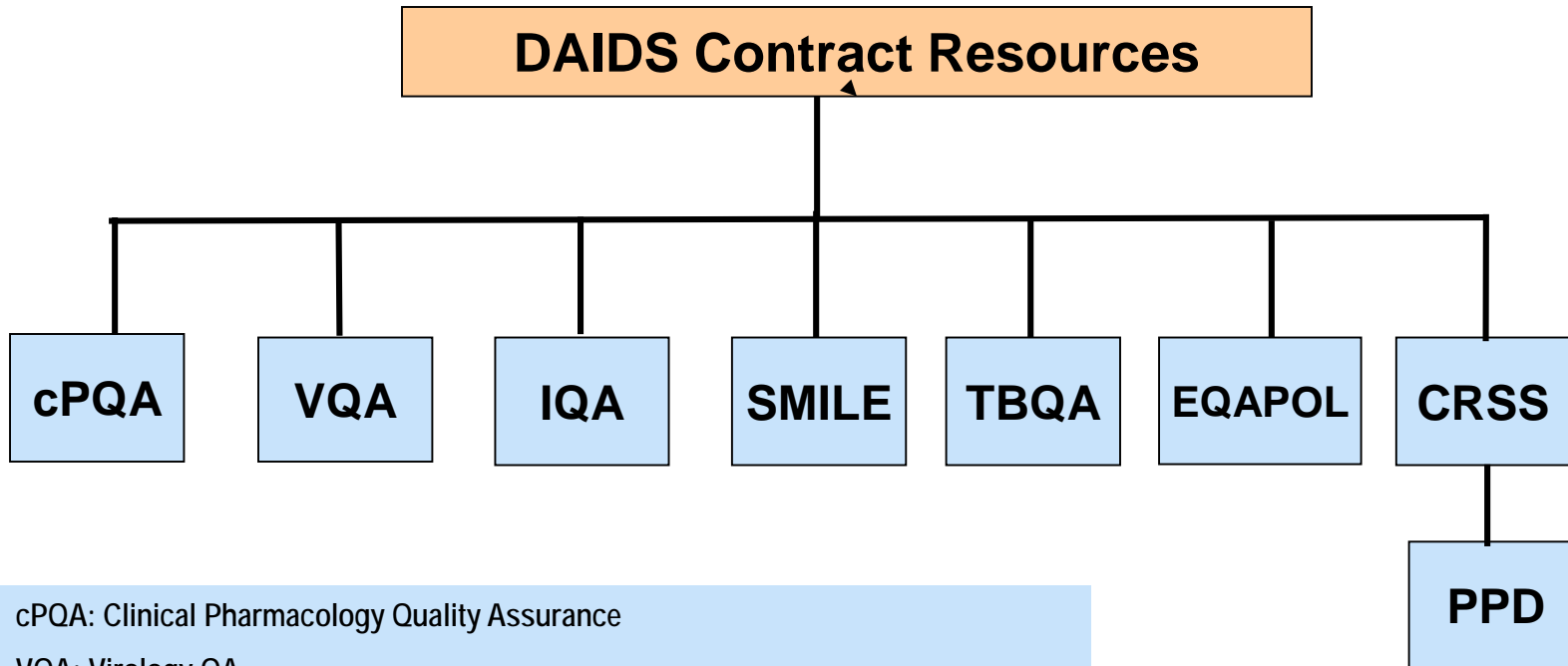
Issued by

National Institute of Allergy and Infectious Diseases ([NIAID](#))

Purpose

- 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 13<sup>th</sup>, 2017
- PPD (Current contract as of August 15<sup>th</sup>, 2017):
  - PPD audits will commence after October 13<sup>th</sup>, 2017
  - For now, all contract related laboratory oversight activities will remain the same

# DAIDS Laboratory Oversight Support



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

DAIDS Staff	DAIDS QA Contract
Joe Fitzgibbon, Team Leader	VQA
Daniella Livnat	SMILE, IQA, TPQA
Jim Lane	EQAPOL
Hao Zhang	cPQA
Jackie Burns  (Naana Cleland is the DCLOT POC for CRSS GCLP-related activities)	CRSS

COR: Contracting Officer's Representative

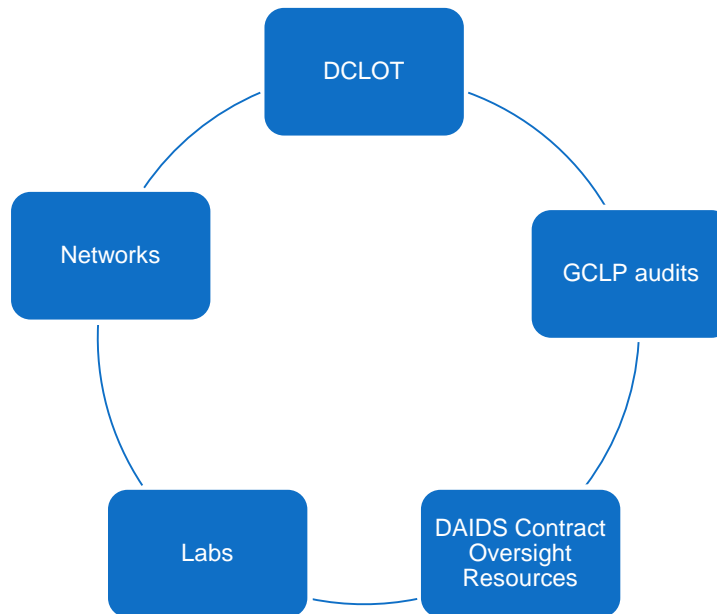
# PPD & SMILE Support Activities

- 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

# Thank You

