# Network Structure, Operational Updates
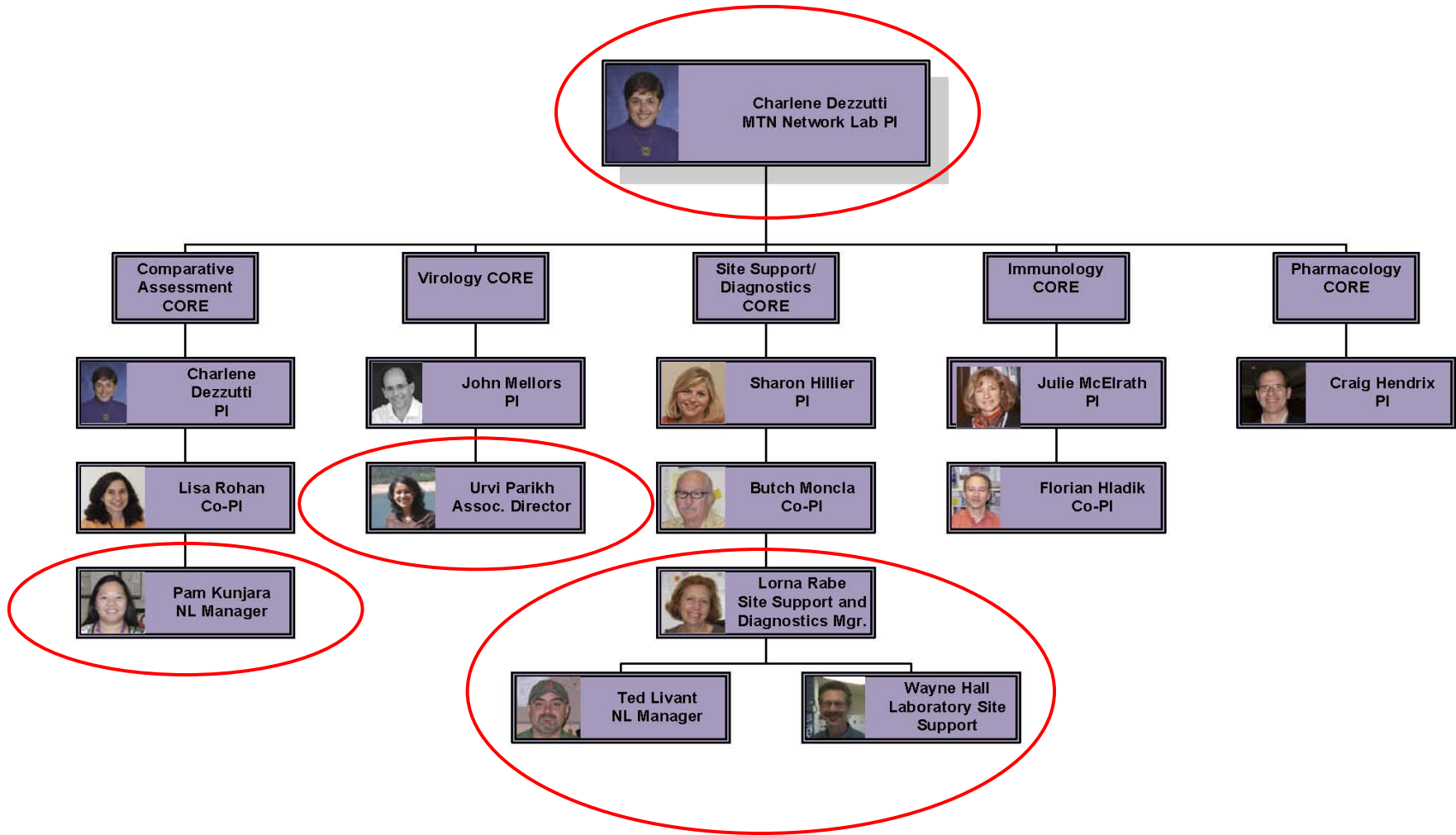
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MTN Network Laboratory

# Goals for this session

- Review Network Laboratory Structure
- Review the relationship between DAIDS, NL's, SMILE and PPD
- Operational updates/reminders

MTN Network Laboratory

9/8/2010

Urvi Parikh
Assoc. Director

Charlene Dezzutti
MTN Network Lab PI

# Primary Study Contacts

- Ted: MTN 003, 003B, 015.
- Pam: MTN 016.

# When in Doubt, don't look about!

- You can reach Ted, Lorna, Wayne and Pam at this address which can be found on the MTN Website:

  People →Email Groups →Laboratory

- mtnnetworklab@mtnstopshiv.org

# Overall Lab Oversight

- What is the role of DAIDS?

- What is the role of PPD?

- What is the role of SMILE?

- What is the role of the networks?

# DAIDS

- Funds go from DAIDS to the CTU which covers site laboratory costs.

- Site questions sent to MTN will be discussed among ourselves and possibly other networks.

- Some questions sent to MTN may be referred to DAIDS.

- Usha Sharma is the Laboratory Point of Contact For MTN studies

# PPD

- Clinical Research Site monitor - external contractor.

- Performs audits and sends these reports to DAIDS.

# SMILE

- **EQA oversight**
  - Investigation reports from deficiencies
- **PPD Audit follow up**
  - Action Plans
- **Guidance and Support-many great resources and great staff**

# Network Laboratories

- Study Specific Guidance and Oversight
- Partnering with SMILE on EQA oversight and Action Plans
  - PNL vs NL

# Operational Updates/Reminders

- **MTN 015 activation is upon us!**
  - MTN 015 Training was conducted over the weekend
  - The expectation now will be that sites activate as soon as possible
  - I will be in contact with relevant sites-some documents have already been received

# Operational Updates/Reminders

- LDMS Reconciliations
  - Error Reports
  - Discrepancies
  - Reports come from SCHARP
  - Corrective action goes to Ted
  - How to clear citations

# Operational Updates/Reminders

- Wet Mount Testing in MTN 015
  - Flexibility has been written into the protocol
  - You can do the same testing as VOICE
    - Rapid Trich
    - BV Blue and KOH as indicated
  - Alternatively, you can do standard Wetmount
  - Suggest for sites doing VOICE, follow same testing as VOICE
  - You need to notify NL and FHI if switching
  - Updates to SSP soon after this meeting

# Operational Updates/Reminders

- Notify the NL of any discordant HIV rapids
  - Why?
  - What info is needed?
- Notify the NL of any short storage for MTN 003 Plasma archive
  - Why?
  - What info is needed?

# Operational Updates/Reminders

- **Recent Updates to MTN 003 SSP**

| Dipstick Glucose Result | CRF Result |
|---|---|
| Negative | Negative |
| 100 mg/dl | Trace |
| 250 mg/dl | 1+ |
| 500 mg/dl | 2+ |
| 1000 mg/dl | 3+ |
| 2000 mg/dl | 4+ |

# Operational Updates/Reminders

- Recent Updates to MTN 003 SSP
- Plasma archive is allowable in the protocol at any visit after enrollment "as indicated". Any positive HIV test results after enrollment may be considered an indication for plasma archive. Sites are encouraged to store a plasma archive for any post enrollment positive HIV result even if not required by the protocol.

# Operational Updates/Reminders

- Recent Updates to MTN 003 SSP

- In cases where a mandatory archive is not stored or is less then 50% of the required minimum volume, sites may recall the participant to collect the plasma archive without prior approval from the MTN NL. Sites must always notify the MTN NL in these situations.

# Operational Updates/Reminders

- Recent Updates to MTN 003 SSP
- Leftover Specimens:  Leftover specimens may be temporarily stored for site QA purposes and problem resolution. This process must be described in an SOP or policy onsite which indicates how long the samples will be stored. Local guidelines and regulations must be followed in these situations.

# Thank You-Questions?