

# Operational Updates

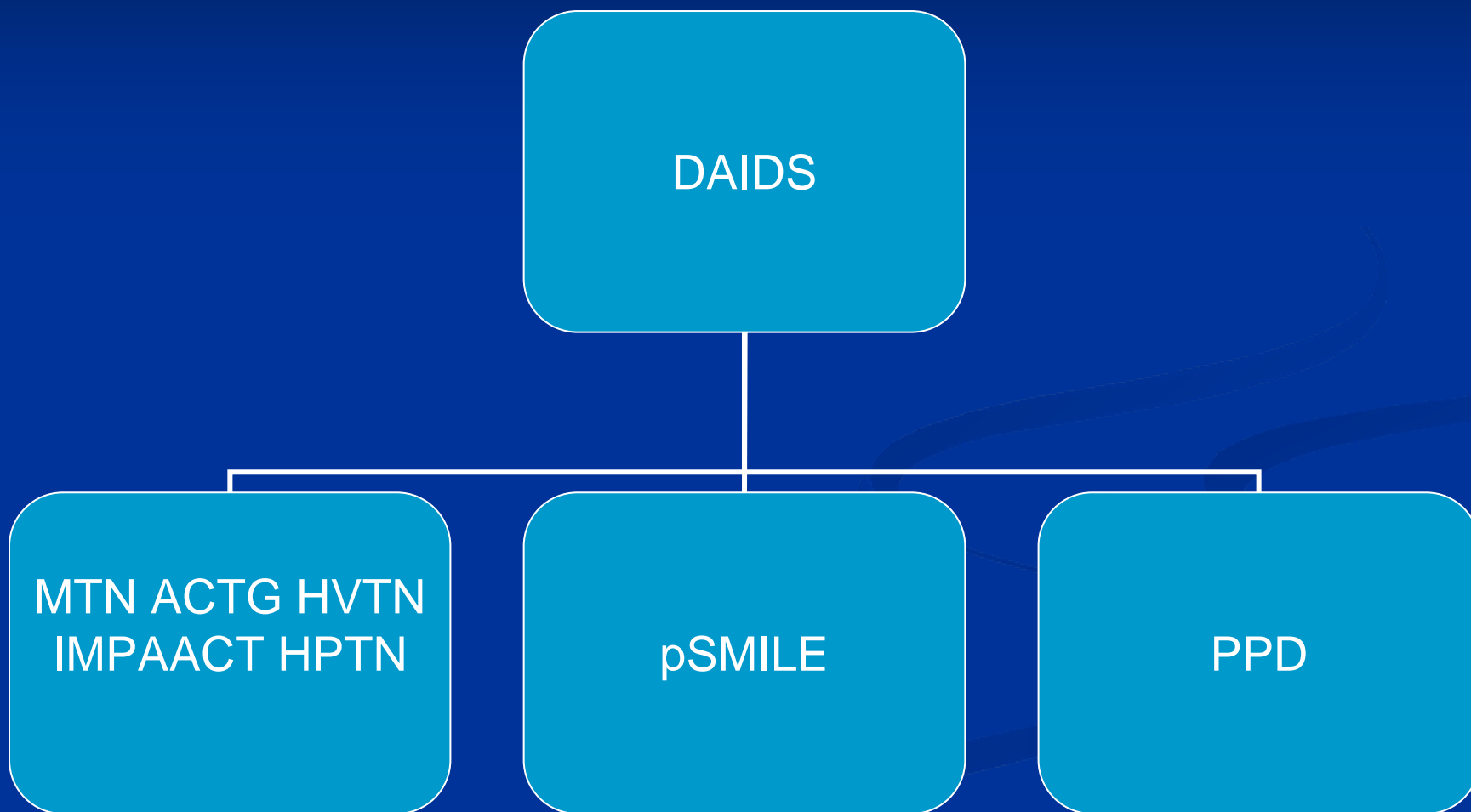
## MTN Regional Meetings

### Capetown, South Africa

### October 19-22, 2009

Edward Livant MT (ASCP), MPH  
MTN Network Laboratory

# Update 1: Review of GCLP Oversight



# Update 2: MTN Network Lab

- You can always send any lab questions to Ted and he will answer or refer them to the appropriate people.
- When in doubt on any issue, please contact MTN for clarification.
- Ted is the primary contact for MTN 001, 003, 003B, US sports related questions and 015. (*MTN 004-US only*).

# Update 2: What Questions Might Ted Refer?

- Lorna Rabe: BD Probetec, Rapid BV and TV kits, wet mounts, general microbiology (*MTN 005 US only and India MTN 006-US only.*)
- Pam Kunjara : *MTN 016 (MTN 002, 007, 008-US only)*
- Urvi Parikh: HIV resistance, HIV RNA, Virology Questions
- Charlene Dezzutti: Administrative questions, BSWG questions and some study related issues

# Update 2: What Questions Might Ted Refer?

- DAIDS/SMILE: GCLP issues
- FHI/SCHARP: Protocol Issues, documentation issues, data questions, CFR-LDMS reconciliations
- FSTRF: LDMS questions

# Update 2: Communications

- [mtnnetworklab@mtnstopshiv.org](mailto:mtnnetworklab@mtnstopshiv.org)
  - Will reach Ted, Charlene, Lorna, Pam
  - We see frequent internet problems-if you don't hear back in a reasonable time, email again.

# Update 3

- Frequency of QC for Rapid Tests

# Update 4

- Parallel Testing for Rapid Testing



# Update 5

- Validation Requirements for CLIA Waived FDA approved tests

# Update 6

- Non FDA approved kits and reagents

# Update 7

- Precision validation for qualitative tests that involve a numeric calculation

# Questions?

Who is this Clown?

