Specimen Management

- LDMS reconciliation Review
- Shipping
LDMS Reconciliation Review

- LDMS Reconciliations are one of our most important QA/QC processes
- Ensure SCHARP has an accurate picture of available samples
- Ensure that samples are stored with correct information
- Pick up problems early in studies to correct processes
LDMS Reconciliation Review-cont

• Remember: Reconciliations only look at CRF vs LDMS data
• Internal requisitions don’t affect the reports
• Switch from Data Fax to Medidata should improve process
• Web LDMS is coming and should also improve the process
Old/MTN-015 Reconciliation Process

- **Lab Enters Information into LDMS**
- **Clinic Enters Information on CRF**
- **Lab Exports LDMS to FTSRF**
- **Clinic Data Faxes CRF to SCHARP**
- **FSTRF Sends data to SCHARP**
- **SCHARP process CRF’s into Database**

**SCHARP Creates Reconciliation Reports**
New/MTN-025 Reconciliation Process

- Lab Enters Information into LDMS
  - Lab Exports LDMS to FTSRF
    - FSTRF Sends data to SCHARP
      - SCHARP Creates Reconciliation Reports
- Clinic Enters Info into Medidata
Future Reconciliation Process

Lab Enters Information into Web LDMS

Clinic Enters Info into Medidata

SCHARP Creates Reconciliation Reports
LDMS Reconciliation Scenarios

• Visit codes don’t match for a date
• Dates done match for a visit
• Sample in LDMS not in Medidata
• Sample in Medidata not in LDMS
• Samples with multiple dates for a visit
• Codes incorrect
Shipping

- The MTN World Courier account is only to be used for approved MTN shipments—when in doubt contact the LC.
- Fed-Ex is preferred for vaginal rings, hair and gram stains
Shipping

• Weekly IVR shipments to Parexel
  – This is required to meet mandated Turn around times
  – Sites should store IVR in a fashion that facilitates easy shipping
  – Designate one day a week to ship your samples
  – You **will NOT** receive a shipping request or shipping list from the LC for Weekly IVR shipments
Shipping

• Plasma Shipping to the USA
  – MTN-025 has same HIV endpoint verification and HIV QA requirements as MTN-020; PK TBD
  – We do not anticipate monthly shipments
  – Current plan is shipments every 6 months to coincide with SMC meetings
  – You will receive a shipping request and shipping list from the LC for all other shipments