Documentation Standards

• Key issues
  – GCP Error Corrections
  – Comments on Corrections
  – Initials and Dates on Corrections
  – Correction based on assumptions
  – Source Documents
  – Date Format
Specimen Management
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

1. Lab Enters Information into LDMS
2. Lab Exports LDMS to FTSRF
3. FSTRF Sends data to SCHARP
4. SCHARP Creates Reconciliation Reports
5. Clinic Enters Information on CRF
6. Clinic Data Faxes CRF to SCHARP
7. SCHARP process CRF’s into Database
New/MTN-025 Reconciliation Process

Lab Enters Information into LDMS

Lab Exports LDMS to FTSRF

FTSRF 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
MTN-025 Ring Processing

- Ring Codes: be aware of this system
- Ring rinsing-possible source of labelling error
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
Biocair

• Possible competitor to World Courier
• Looking for possible shipment to try them out
• Any site experience?