

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

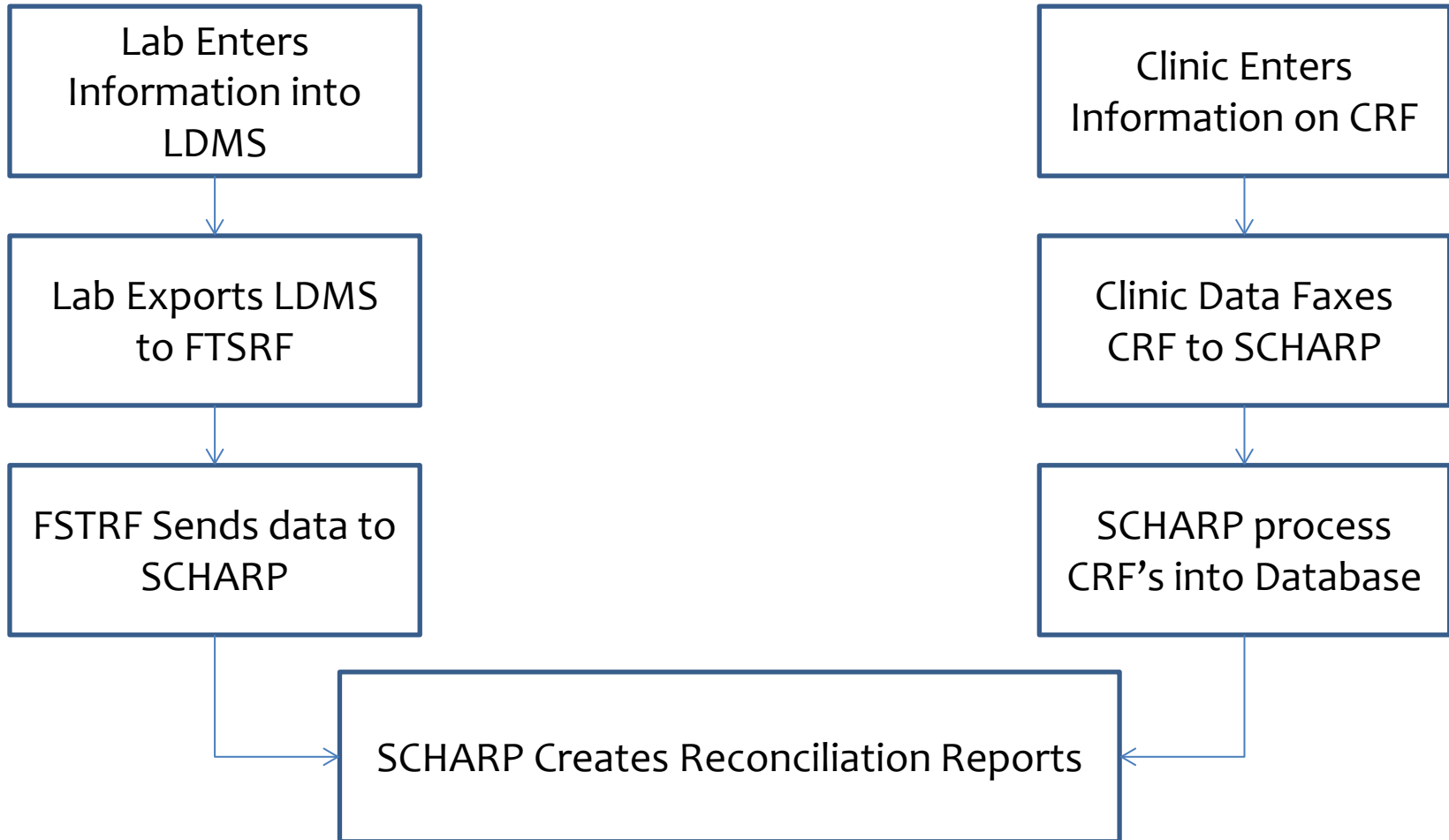
LDMS Reconciliation Review

- 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

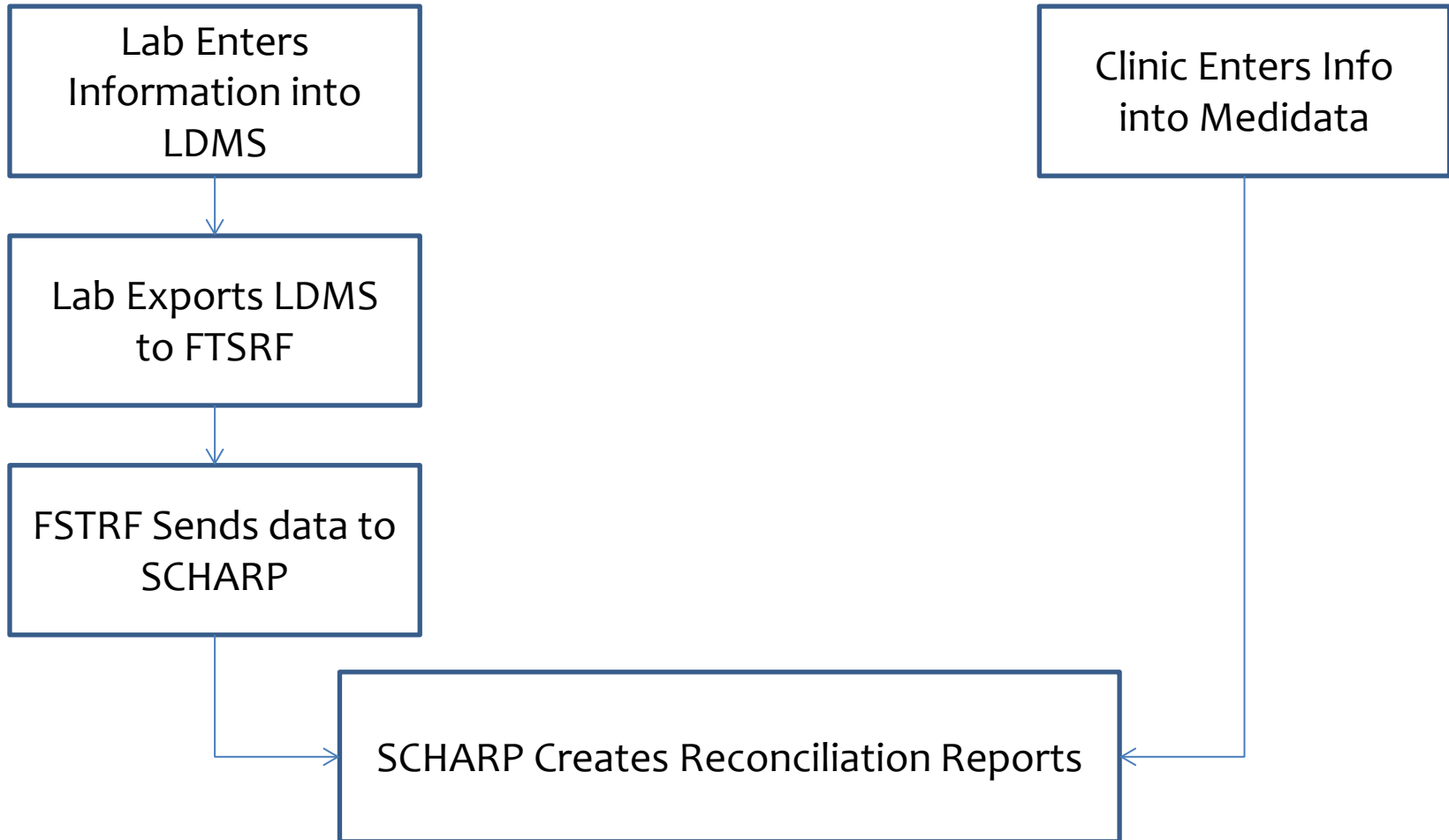
LDMS Reconciliation Review-cont

- 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

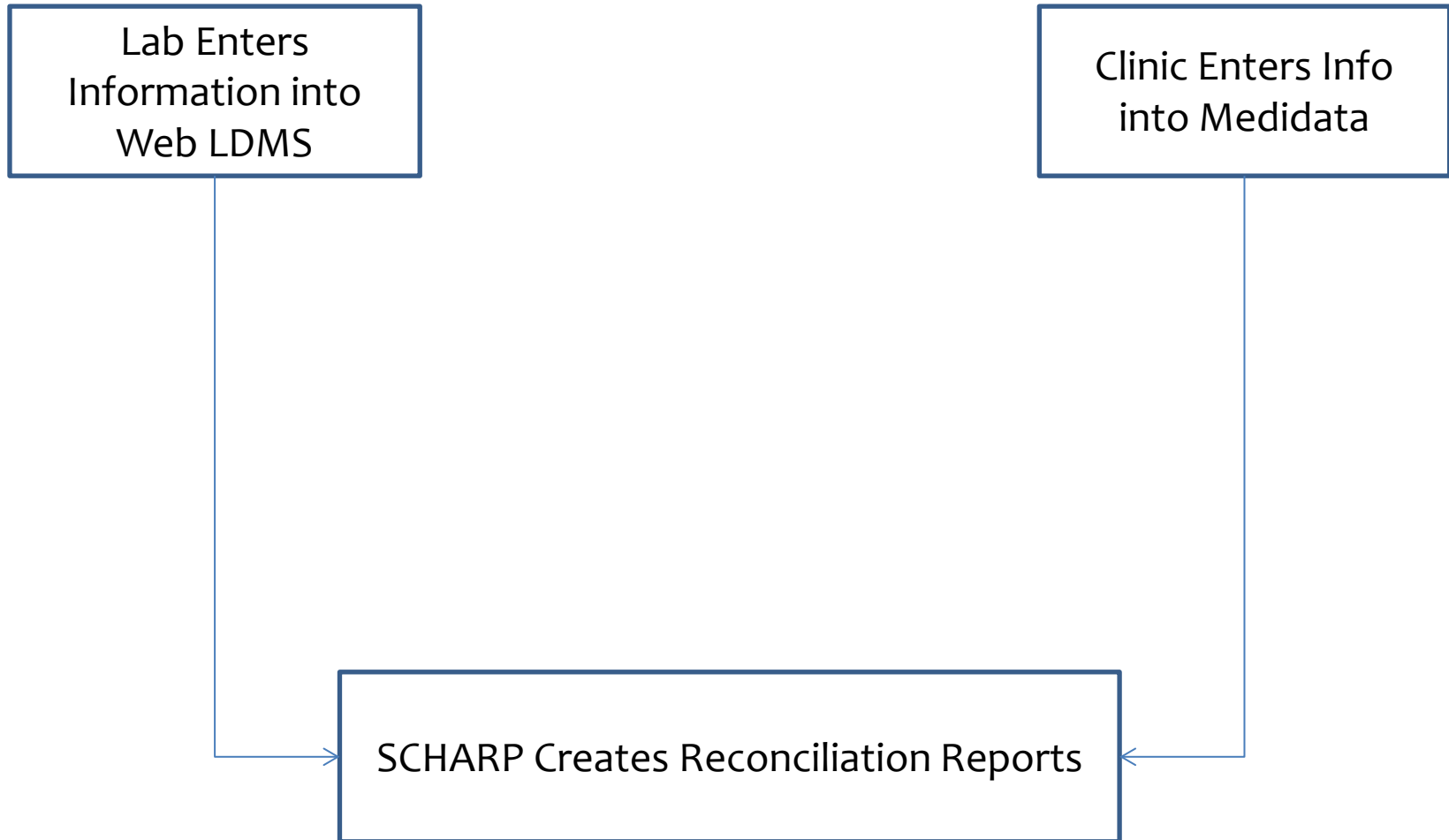
Old/MTN-015 Reconciliation Process



New/MTN-025 Reconciliation Process



Future Reconciliation Process



LDMS Reconciliation Scenarios

- Visit codes don't match for a date
- Dates don't 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?