MTN 017 Real-Time PK Testing

Pam Kunjara, MT ASCP
MTN Network Laboratory
Magee-Womens Research Institute
Pittsburgh, PA
Objectives

- Specimen Handling
- Specimen Management
- Specimen Shipping
- Test Results
- Q&A
MTN Network Lab Contacts

♦ MTN Network lab
  ♦ Pam Kunjara 412-641-6393
    pkunjara@mwri.magee.edu

♦ MTN Pharmacology Core Lab
  ♦ James Johnson jjohnso6@jhmi.edu
  ♦ Mark Marzinke mmarzin@jhmi.edu
  ♦ Craig Hendrix chendrix@jhmi.edu
Specimen Handling

- **Plasma for PK**
  - Collected at every Mid Period and End Period visit (Visits 3, 4, 6, 7, 9, and 10)
  - Whole blood (EDTA) will be spun down to obtain plasma and stored at -80°C within 8 hours of collection.
  - Specimens will be accompanied by an LDMS Tracking sheet and logged into LDMS.
Specimen Management

♦ All specimens must be tracked according to site Chain of Custody.
♦ CRFs are required for specimens reported to SCHARP.
♦ All collected samples will be reported from SCHARP to the MTN NL to assure that samples are being shipped for testing in a timely manner.
Specimen Shipping

- One month after the first participant enrolls **biweekly** shipments of plasma for PK should be initiated.
- All shipping staff must be IATA certified.
- All shipments must be accompanied by an LDMS Shipping Manifest.
Specimen Shipping cont.

- Specimens will be shipped on dry ice to the MTN Pharmacology Core to arrive by **Thursday** for testing on Friday.

- Prior to shipping sites must notify the MTN NL and Pharmacology Core by e-mail with tracking details along with LDMS generated and excel batch files.
Specimen Shipping cont.

- Shipping costs will be billed directly to the MTN NL. World Courier and FedEx accounts numbers will be available.
- Please reference MTN-017-9231 for all PK shipments
PK Test Results

- Results will be available within 10 business days of specimens being received at the Pharmacology Core.
- The MTN Pharmacology Core will report qualitative results to the sites on a spreadsheet in pdf format via e-mail. Quantitative results will be sent to SCHARP.
Specimen Flow Chart

Specimen collected in clinic

Specimen processed and stored within 8 hrs

Ship biweekly for arrival on Thursdays

Results sent via e-mail within 10 business days

Results reported to participant

PK assays performed on Fridays
Any Questions?