

Update from SCHARP

ASPIRE Protocol Team
Meeting

February 10, 2013

The logo for ASPIRE, featuring the word "ASPIRE" in a bold, purple, sans-serif font. A thin, light-colored ring is positioned around the letter "A".

A Study to Prevent Infection
with a Ring for Extended Use

Data Update

- Over 30,000 CRF pages received
- Over 1,000 QCs applied
- 96% of QCs are resolved
- 96% of CRF pages are received within 7 days
- AE Logs are received within 3 days
- Overall, data quality and timeliness goals are being met/exceeded

iDataFax Update

- Missed Visit CRFs:
 - 29% entered electronically
- Protocol Deviations Log CRFs (new version):
 - 33% entered electronically
- Most “active” sites
 - Umkomaas
 - Isipingo
 - Tongaat
 - eThekweni

Routine Reports

- Screen Out
- Enrollment
- Retention
- Retention Graph
- Contraceptives Use
- Procedure Completion
- Data Management Quality
- Unresolved AE, Product Hold, Social Harms
- Missed Visit Listings
- Coming soon: Product Adherence, Data Summary

Upcoming SMC & DSMB Reviews

- SMC review call – April 1, 11:30-13:00 US EDT
- QC Reports - Feb 26, March 6
- Specimen Shipping – per NL
- Open SMC Report – on Atlas by March 26
- DSMB Review - May 15/16

Data Goals for Coming Months

- Continue with accurate and timely data submission, QC resolution
- Be extra responsive to Feb 26 and March 6 QC Reports
- Try to increase electronic data entry of MV and PDL forms – 80% or higher
- Continue to use/review routine reports to improve site processes
- Let SCHARP know how we can help you meet these goals

Questions & Discussion