
Demystifying Laboratory Data Reconciliation

Heather M. Irish and Huiming (Sam) Tu
Premier Research Group, plc



The issues at hand...

- Why lab data is a necessary evil
- Why lab data gives us nightmares
- Holes in our attempts to handle lab data
- Possible solutions to our woes
- Could it really be that simple? (examples)



A Necessary Evil

- Almost every clinical trial requires collection of Laboratory Samples
 - Blood Chemistry
 - Hematology
 - Urinalysis
 - Pharmacokinetic
 - Pharmacodynamic
 - Specialized testing per protocol...
- Important data for statistical analysis
 - Safety
 - Efficacy



Nightmares

- Central versus Local sample analysis
- Lab Normal Ranges (variable)
- Test Units
- Clinical Significance of Results
- CTC Grading
- Data Reconciliation



Issues



- **Local Lab data**
 - Normal Ranges
 - Obtaining from sites
 - Programming Edit Checks
 - Varying Units between sites
 - Normalizing for analysis
 - Programming Edit Checks
- **Central Lab data**
 - Merging study database with external transfers
 - CRF/External data reconciliation process
 - Obtaining Clinical Significance of Results



Solutions?



- **Local Labs**
 - Designing the “perfect” CRF
 - Look-up Tables to support Edit Checks
 - Squeezing information from your study sites
- **Central Labs**
 - To import or not to import: lab report images
 - Populating external data onto barcoded pdfs
 - Extra programming up front saves time in the end



Lab Range Programming

- Why we need a site-specific plate (versus only patient specific plates)?
- Why use look-up tables?
 - CRFs versus look-up tables
 - Excel versus web application
- How we program consistency checks to compare normal ranges and actual results?



Example: Lab CS/NCS (1)

Sponsor Protocol: DataFax #1247 Plate #102 PRG: 86OCT2004

Premier Research Group: DataFax Demonstration Study

Subject ID: [] [] [] [] Initials: [] [] [] [] Scheduled Retest Additional Visit No. [] []

Accession Number: [] [] [] [] [] [] [] []

Collection Date: [] [] [] [] [] [] [] [] [] [] Collection Time: [] [] [] [] (24-hour clock)

Are There Out of Range Analyses Yes No

Clinically Significant: Yes No		Clinically Significant: Yes No	
HCT	<input type="checkbox"/> <input type="checkbox"/>	Bands	<input type="checkbox"/> <input type="checkbox"/>
HGB	<input type="checkbox"/> <input type="checkbox"/>	Lymphocyte	<input type="checkbox"/> <input type="checkbox"/>
RBC	<input type="checkbox"/> <input type="checkbox"/>	Monocyte	<input type="checkbox"/> <input type="checkbox"/>
RBC Morph	<input type="checkbox"/> <input type="checkbox"/>	Eosinophile	<input type="checkbox"/> <input type="checkbox"/>
WBC	<input type="checkbox"/> <input type="checkbox"/>	Basophile	<input type="checkbox"/> <input type="checkbox"/>
Neutrophil	<input type="checkbox"/> <input type="checkbox"/>	Platelets	<input type="checkbox"/> <input type="checkbox"/>

Principal Investigator's Signature: _____ Date: [] [] [] [] [] [] [] []

Immediately following each patient visit, fax completed CRFs to 1-800-693-5765

DO NOT TRY THIS AT HOME!

- Forcing Central Lab Reports into DataFax without Barcodes
 - Possible, but not without a boatload of problems



Conclusions

Still searching for the perfect solution...

- Local labs required for many studies (oncology, etc.)
- Impossible to control every factor in the equation (unless you're the sponsor!)
- The importance of good communication and cooperation amongst all study roles
- Regular reconciliation throughout trial ensures quicker database lock



Questions?

Thank you!



Heather M. Irish

215 282 5441

Heather.irish@premier-research.com

