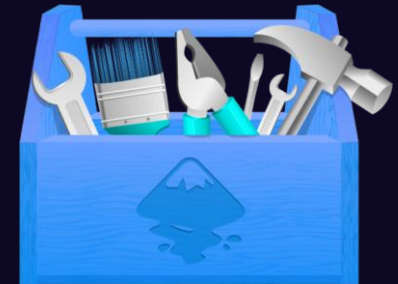

DataFax Setup Toolbox



Leanne Dyal

Manager, Data Management (Statistics)

Population Health Research Institute

Hamilton, ON, Canada



OUTLINE

- Background
- Objectives
- Tools
 - Standard Libraries
 - Schema Review Report
 - Schema Comparison Report
- Summary and Conclusion

BACKGROUND

- EDC is now the primary source of data capture, providing the ability to enter, review, and analyze real-time data
- It is essential, now more than ever, to have data that is reliable, consistent, and accurate at the time of data entry
- It is essential that study database is setup accurately, with all/most edit checks in place and validated at time of FPFV

BACKGROUND

- On average, 20-25 studies/year initiated
- ≈16 weeks to establish a large, stable, reliable, and validated study database
- To keep up with the demand and provide a more robust database, the process needed to improve by decreasing turnaround time while ensuring a robust, reliable, and validated study database
- Working longer was not the solution – working smarter was

OBJECTIVES

- Demonstrate the standardized processes and tools PHRI has available:
 1. Standard libraries
 2. Schema Review Report – schema2excel report
 3. Schema Comparison Report – schemadiff report
- Demonstrate how these tools:
 1. Accelerate study database setup (setup and testing)
 2. Reduce data processing time and discrepancy management time
 3. Facilitate needs of other functional groups
 4. Do work that is smarter, better, stronger, faster, and ultimately cheaper

STANDARD LIBRARIES



■ Standard Styles Library

- Predefined styles (variations of DataFax styles and common styles) with set properties and corresponding standard edit checks

■ Standard Edit Checks

- Edit checks that are standard across all studies
- Standardized purpose and QC message



■ Generic Edit Checks

- Edit checks common across most/all studies but that require study specific parameters
- Standardized purpose and QC message



STANDARD LIBRARIES



- Validated “Standard Study” in DataFax
 - Standard styles defined
 - Standard ECs and generic ECs programmed
 - Continuously improved
- Initiation of New Study Setup
 - Import standard styles and copy standard/generic EC files into \ecrc directory and #include in DFedit from ‘Standard Study’
 - Create study-specific styles with associated standard edit checks (if applicable)
 - Set up study based on annotated CRFs (for style)
 - Standard ECs automatically implemented

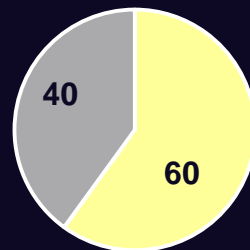
STANDARD LIBRARIES



- Identify where generic edit checks are to be implemented and with what parameters
- Specify requirements and program study-specific, detailed edit checks

Before:

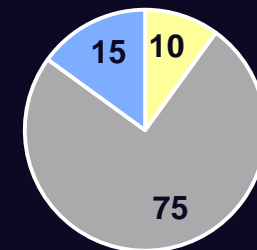
% of Type of EC on Database



■ Study Specific ■ Standard/Generic

Now:

% of Type of EC on Database



■ Study Specific ■ Standard ■ Generic

- Reduces specifications and testing substantially

SCHEMA REVIEW

- **Before:**
 - Use DFschema
 - Review Field List of each plate individually in DFSetup
 - Save Field List plate by plate to review schema in user-friendly way and redo each time setup updated
- **Now:**
 - **Schema2excel** report
 - Entire study schema in one file (xml, csv, pipe)
 - Facilitates testing
 - Statistical review
 - Easily converted to SAS dataset (sponsor)



SCHEMA COMPARISON

- Before:
 - Compile list of changes based on all change request forms, assess impact of changes based on experience
 - May underestimate impact of change, assessments may vary, may miss some changes if list is large

- Now:
 - Schemadiff report
 - Identifies changes in database by comparing two schema files
 - Classifies types of changes identified (e.g. field deleted, coding changed, edit check added)

SCHEMA COMPARISON

- Assesses the impact of each change identified as high, medium, low
- Identifies the impact rationale associated with each change type
- Comprehensively captures and assesses all changes that can guide the plan for ensuring validation of changes



SUMMARY

- Problem = more requests, less time
- Solution = work smarter, not harder and longer
- Standard tools available to:
 1. Accelerate study database setup (now \approx 10-12 wks)
 2. Provide more robust study database at time of FPFV
 3. Reduce data processing time and discrepancy management time
 4. Manage changes consistently and accurately
 5. Facilitate needs of other functional groups

CONCLUSION

“Harder, better, faster, stronger”

-Kayne West (*Stronger*)