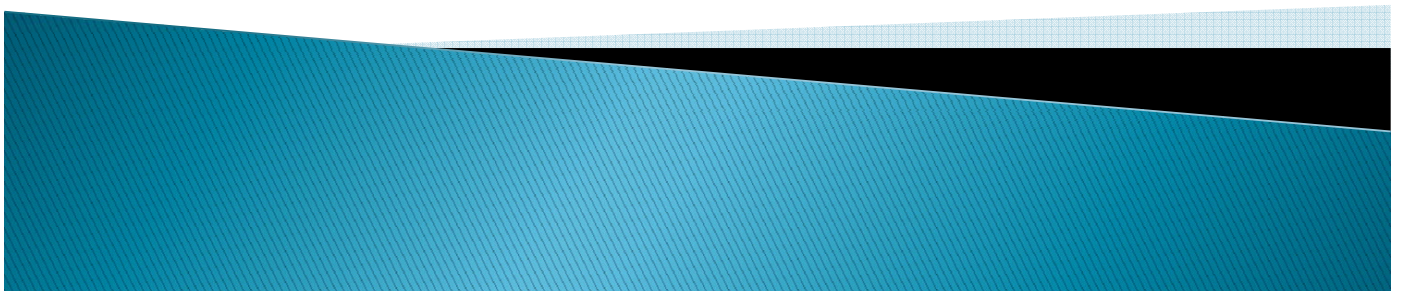


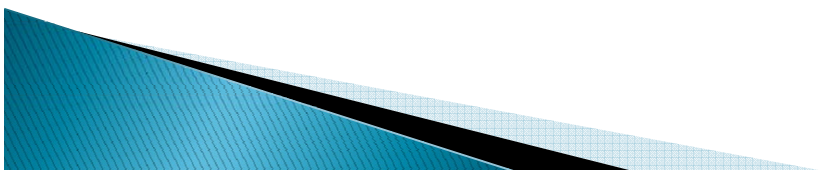
How to Use SAS to Enhance Quality in IDB Projects

Pamela Chen
2014-11-28



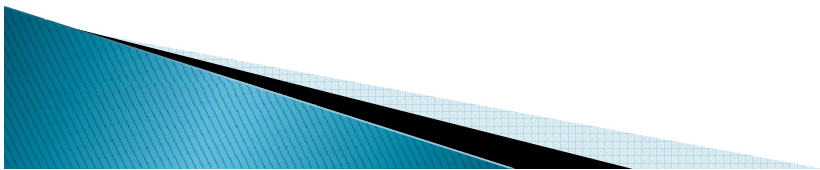
Outline

- ▶ IDB and Challenges
- ▶ Key things in quality improvement
- ▶ Share some solutions and SAS tools



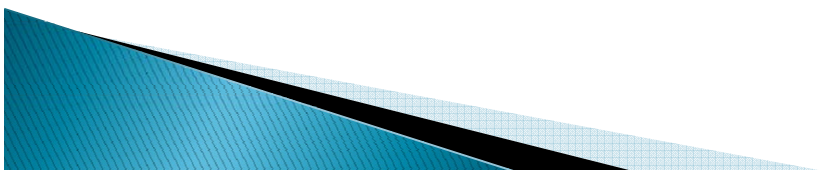
IDB and Challenges

- ▶ IDB: Integrated Database
- ▶ Challenges:
 - Datasize too big, over 1 GB etc.
 - Different methodology in individual studies
 - Too many outputs and hard to review;
 - Not easy to consistent everything



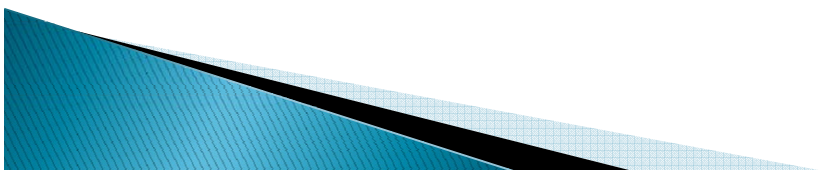
Key things in quality improvement

- ▶ What's the most important thing in quality control and project management?
 - Technical Skills (SAS, Stat Knowledge)?



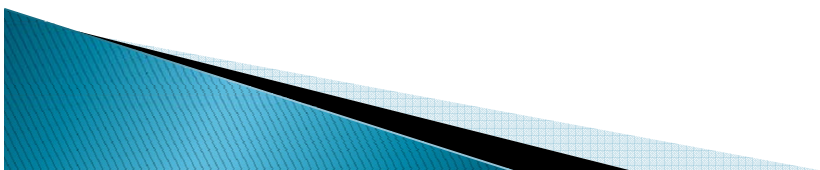
Key things in quality improvement

- ▶ What's the most important thing in quality control and project management?
 - Technical Skills (SAS, Stat Knowledge)?
 - Regulatory knowledge (ICH Ex, CDISC etc..)?



Key things in quality improvement

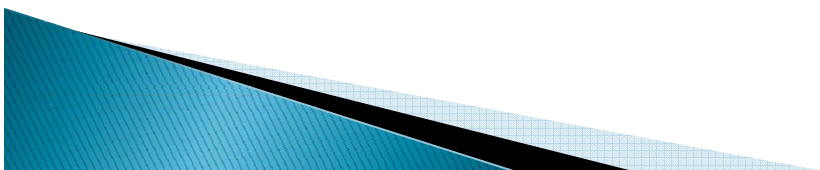
- ▶ What's the most important thing in quality control and project management?
 - Technical Skills (SAS, Stat Knowledge)
 - Regulatory knowledge (ICH Ex, CDISC etc..)
 - Thinking!



Key things in quality improvement

▶ Thinking

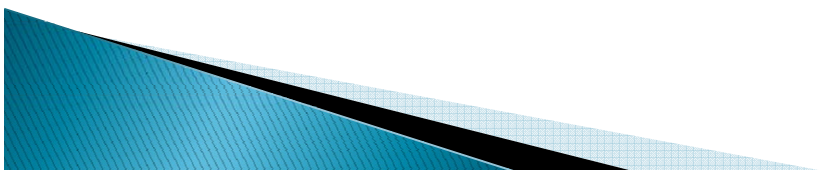
- Everything serves thinking!
- Thinking is for solution!
- You can't change the world, but can change yourself.



Challenges – Solutions I

► Challenge:

- Datasize too big, hard to QC
- Each run cost too much time and efforts



Challenges – Solutions I

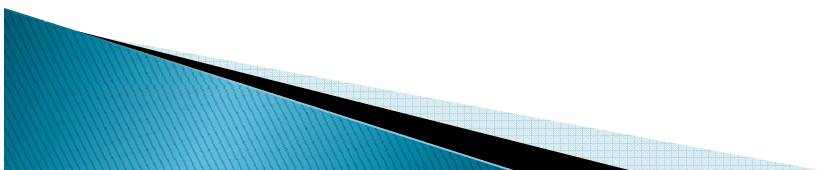
► Solutions:

◦ SAS:

- Compress function
 - data b(**compress** = "Y");
 - set a;
 - run;
- Thread in sort step:
 - proc sort data = a out = b **thread**;
 - by usubjid;
 - run;
- SQL

◦ Ideas:

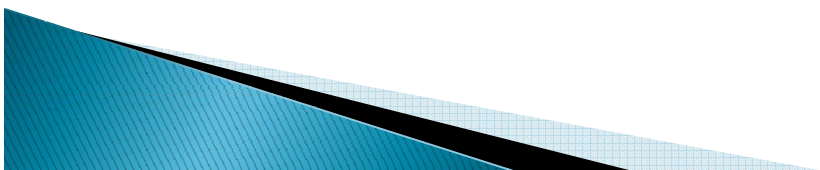
- Split data before read source data (SDTM)
- Batch Run
- Same People do same thing
- Piece by piece QC



Challenges – Solutions II

- ▶ Challenge:

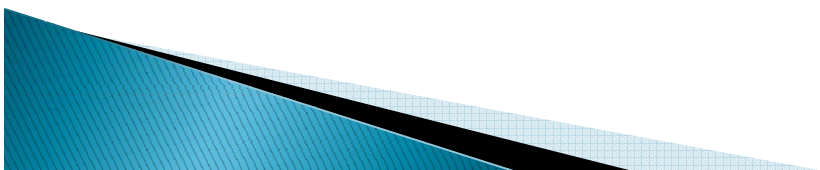
- ▶ Too many variables, attributions easy to mess up



Challenges – Solutions II

▶ Solution:

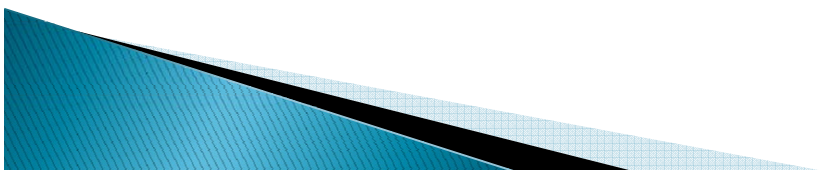
- Use SAS to create shells to automatically assign the attributions.
- Idea: create a blank shell, no value, but with all variables there, all label, length and format are created in the shell. Set the final dataset with this blank shell to get all the attribution



Challenges – Solutions III

- ▶ **Challenge:**

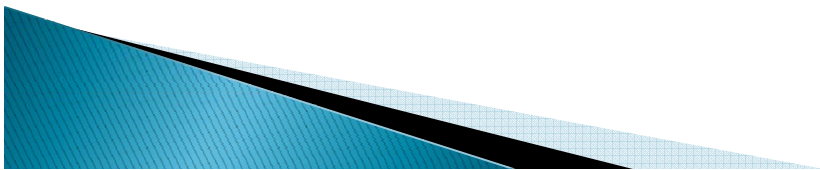
- Too many outputs, hard to review and hard to locate the outputs



Challenges – Solutions III

► Solutions:

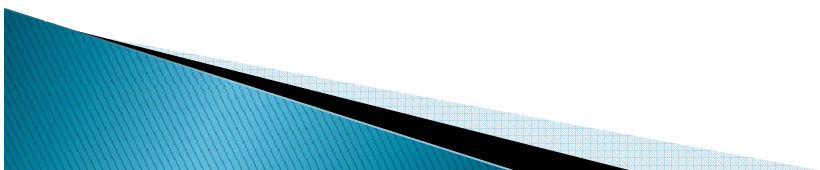
- Create a SAS tool to help distribute the outputs.
 - Step 1: Master the outputs/authors/assignment in a excel file.
 - Step 2: SAS reads in this excel file, copy the required outputs into destination folder.
- Create a SAS macro to generate key consistency for each output, N (population) for example.
- Create a SAS tool to check the consistency between tables, N (population) for example.
- Create a SAS tool to compare two different version of excel file, for example ADaM spec, to improve efficiency and accuracy.



Challenges – Solutions IV

- ▶ **Challenge:**

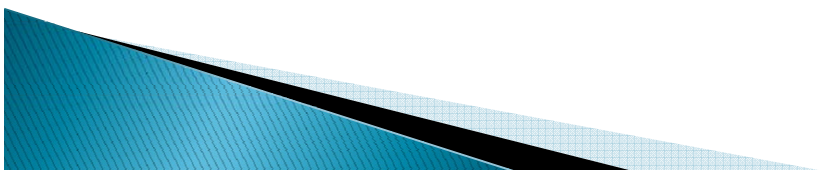
- ▶ Different methodology in individual studies



Challenges – Solutions IV

► Solutions:

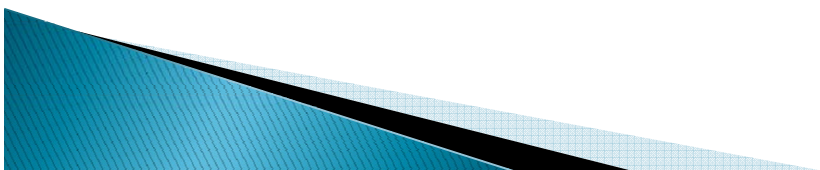
- Systematically check the study design, seek common ground while reserving differences
- Pay attention unexpected discrepancy from different data cut. Selected period cut may bring different derivation of left periods.



Summary

▶ Try to do:

- Automatic
- Systematic
- Time less, Quality more



► Thanks!

