CLOSE COOPERATION BETWEEN DEVELOPERS AND END-USERS IS VITAL TO DEPLOYMENT OF CDISC STANDARD SOFTWARE

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SOFTWARE DEVELOPMENT AND USAGE

- Process improvement plan
  - Software is an important aspect

- Homemade software
  - developed by:
    - Application Developers
    - Clinical Data Programmers
  - used by:
    - Clinical Data Programmers
    - Clinical Data Managers

- Benefits of end users and developers working closely together
Close cooperation between developers and end-users improves staggered deployment.
EXAMPLE SOFTWARE

- All 2 One
  - setup and maintain the study rule package (the collection of checks and listings used to clean the database)
  - create new rules
  - perform the data cleaning
  - log and follow-up on review issues
  - maintain a library of validated rules, which can be used in new trials
  - maintain library of SDTM checks, which are run on all trials
  - creation of the data validation plan
FIRST DEPLOYMENT OF A2O

- Initial deployment
  - smaller scale Phase I trial
  - highly motivated early adopter as lead CDM
  - backup in the previous software system
  - go/no-go
  - library creation is pivotal point
LESSONS LEARNED

- Interaction between developer and end user
  - CDM involvement in testing and validation provided valuable early knowledge
  - AD and CDP availability during initial deployment smoothed over encountered problems

- Examples
  - dragging or batch filling review state
  - retrieving disappeared review state

- AD and CDP acutely aware of problems or the effect of changes
GRADUALLY EMBEDDING THE NEW WORKFLOW

- **Reduction in**
  - backup scenarios
  - reserve personnel
  - go/no-go points

- Shift in privileges to improve the workflow
Close cooperation between developers and end-users affects

TRAINING USERS
EXAMPLE SOFTWARE

- QC Tool
  - perform the quality control on the conversion of incoming source data from (e)CRF, esource, external vendor data,... to CDISC SDTM format
  - logging and following up on any encountered issues
TRAINING AN EVOLVING TOOL

- Digitizing the QC on the conversion
  - originally a paper-based process
  - paperless, guided, unified workflow

- Monthly exchange meetings
  - all stakeholders: CDM, AD
  - quick turnover between issue recognition and issue resolution

- Developing early training and documentation
  - swift development
  - not often performed process
  - difficult to train and keep users up to date

- Screenshot-based presentation
  - kept up to date by the project lead
  - refresh on new information available via document or meeting attendants
STABLE SOFTWARE AND CREATING TRAINING AND DOCUMENTATION

- QC on conversion is not performed often
  - training gets forgotten

- Now
  - initial group training
  - refresh course via presentation/meeting attendants
  - work instructions

- Future plans
  - automated self-training module with work instructions included, developed by training responsible, CDM and AD
  - initial training
  - refresh course
  - new items highlighted
Close cooperation between developers and end-users improves

USER INTERFACE AND INTERACTION
CLEAR FEEDBACK ON PERFORMED ACTIONS
DECLUTTER
All windows must be closed first.

Do you really want to close this window?

OK

Yes
No
EMPOWERING USERS

- Gradually delegate permissions to end users
- Continuous workflow per function
Close cooperation between developers and end-users improves PERFORMANCE
OBJECTIVE SPEED INCREASE

- Large datasets require optimisation to keep the program running smooth
  - rendering to screen
  - column width calculation
  - row coloring
  - row numbering

- Database connections used more efficiently
PERCEIVED SPEED INCREASE

- Visual feedback
  - limit unnecessary waiting
  - idle time

- Reorganisation of menu item
  - re-evaluation of menu structure after usage period

- Uncluttering screen
  - make everything as discoverable as possible
  - focus on important elements
  - difficult and hard to predict
### PERCEIVED SPEED INCREASE

![Table showing data related to perceived speed increase]
PERCEIVED SPEED INCREASE

- **Batch processing**
  - limit unnecessary waiting
  - limit idle time
Close cooperation improves dealing with SUBOPTIMAL DESIGN DECISIONS
INTRODUCTION

- Important A2O function: Library of validated rules
- Sponsor-specific implementation guides
  - several of the sponsors we work for have created their own implementation guidelines for CDISC SDTM

- Original solution: create 1 library per sponsor IG
COPING WITH SUBOPTIMAL DESIGN

- Several libraries worked very well, until
  - new implementation guides
  - new versions of implementation guides

- Coping by copying
  - labour intensive
  - error prone
  - not futureproof
  - dependent on name availability in copy-to library
  - loss of version control
  - end users (CDM) dependent on AD and CDP
CORRECTING THE SUBOPTIMAL DESIGN

- Master library with metadata flags
  - creation of sub-library by adding the correct flag
  - rule can be part of multiple sub-libraries
  - version control maintained
  - future proof
  - end users (CDM) maintain the system themselves, freeing up time for AD and CDP
THANK YOU