

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

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WHEN YOU NEED TO BE SURE



- 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

■ 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

- 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

- 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

- 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

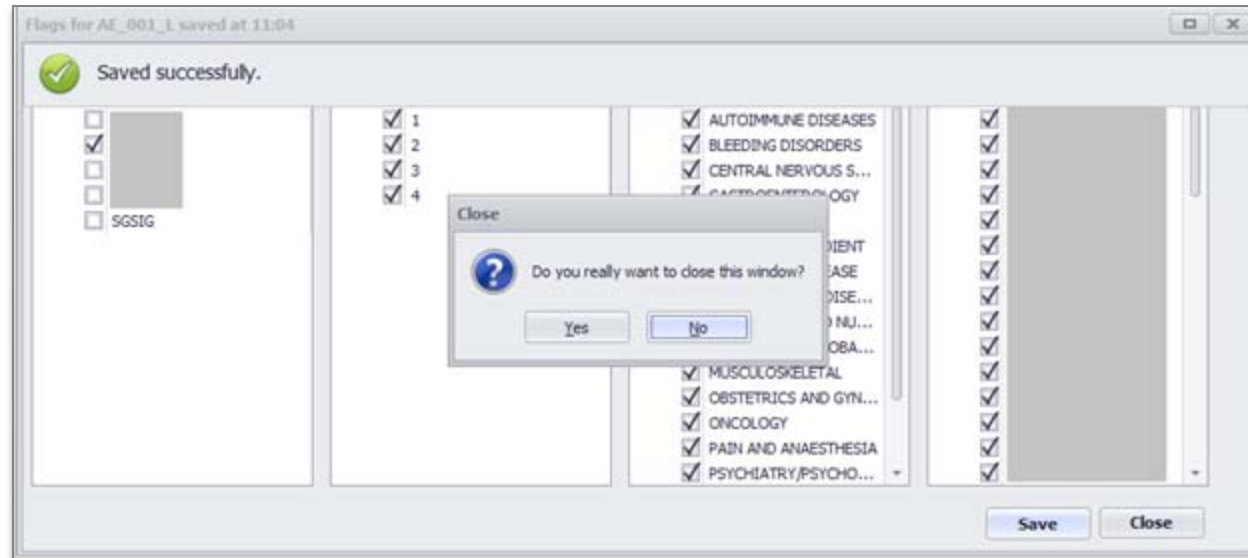
STABLE SOFTWARE AND CREATING TRAINING AND DOCUMENTATION

- 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



Print DCF

DcfType ALL

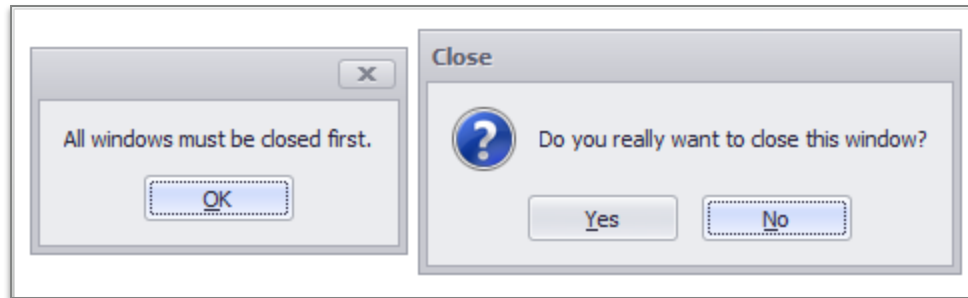
SiteId ALL DcfId ALL

USubjId ALL

Rule prefix ALL Rule name ALL

Domain ALL

Reset Print Close



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

- 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

A20 - CDM DBEN00T - [Cleaner: All Usubjids]

File Rules Cleaner DCFs ZZ Tables SDTM Rules DVP Reports Windows Help

Rule Cleaning Package (All Usubjids) DS_613_L

Drag a column header here to group by that column

row	siteid	usubjid	armcd	visit	dscat	dsstdtc#treatment	exstdtc#max	ind	message	state
1					DISPOSITION EVENT	2015-07-29	2015-06-08T15:45	*		CREATED IN EDC
2					DISPOSITION EVENT	2015-06-22	2015-06-01T11:42	*		CREATED IN EDC
3					DISPOSITION EVENT	2015-06-22	2015-06-02T12:54	*		CREATED IN EDC
4					DISPOSITION EVENT	2015-06-23	2015-06-02T13:02	*		CREATED IN EDC
5					DISPOSITION EVENT	2015-07-28	2015-07-07T13:40	*		CREATED IN EDC
6					DISPOSITION EVENT	2015-06-29	2015-06-08T13:20	*		CREATED IN EDC
7					DISPOSITION EVENT	2015-06-29	2015-06-08T13:25	*		CREATED IN EDC
8					DISPOSITION EVENT	2015-07-02	2015-06-10T09:37	*		CREATED IN EDC
9					DISPOSITION EVENT	2015-06-29	2015-06-08T13:29	*		CREATED IN EDC
10					DISPOSITION EVENT	2015-07-06	2015-06-15T14:05	*		CREATED IN EDC
11					DISPOSITION EVENT	2015-07-07	2015-06-15T14:00	*		CREATED IN EDC
12					DISPOSITION EVENT	2015-07-13	2015-06-22T14:05	*		CREATED IN EDC
13					DISPOSITION EVENT	2015-07-14	2015-06-22T14:10	*		CREATED IN EDC
14					DISPOSITION EVENT	2015-07-14	2015-06-23T13:25	*		CREATED IN EDC

Refresh In Batch Output items DCF Items Print Report

No Rows Selected TEST sync: 03/06/2015 12:09 PROD sync: 15/09/2015 16:21

- Batch processing
 - limit unnecessary waiting
 - limit idle time

Set message, state and comment for all selected records

Message, State and Comment for all selected (filtered) records will be updated as specified below, by clicking the Apply-button.
IMPORTANT: When no filter is applied all records will be updated.

Message	<input type="text"/>	Clear Message	<input type="checkbox"/>
State	<input type="text"/>	Clear State	<input type="checkbox"/>
Comments	<input type="text"/>	Clear Comments	<input type="checkbox"/>

Apply Close

Close cooperation improves dealing with

SUBOPTIMAL DESIGN DECISIONS

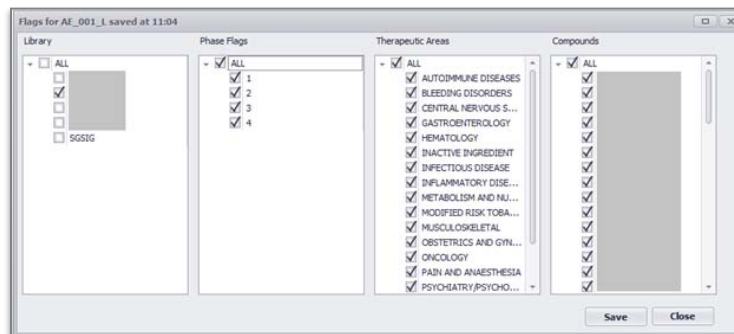
- Important A2O function: Library of validated rules
- Sponsor-specific implementation guides
 - several of the sponsors we work for have created their own implementation guidelines for CDISC SDTM

- Original solution: create 1 library per sponsor IG

- 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

- 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



SGS

THANK YOU