PRAHEALTHSCIENCES

MAKE SDTM EASIER
START WITH CDASH !

CDASH implementation, tools to ensure compliance with data collection standards

CDASH in the CRO world

- CROs are dealing with many of clients, different in size, organization and oversight management
  - Large sponsors usually have their own standards
  - Small sponsors usually trust CRO to generate compliant datasets
- “The sooner we standardize the better”
  - Very few sponsors start their standards at data collection

- Educate our sponsors about CDASH and data collection standards
- Developed PRA Data collection standards based on CDASH

Common data collection issues

Form	Study Form	Field
CP	CP	CPSTDAT
DEAT	DEATH	DTHDAT
DISP	DISPR	DISPDTE
ECOG	ECOG	ECOGDAT
EO	EOT	LDOSDAT
LLAB	LLABH	LLBDTE

No consistent naming convention used for date format

Data Dictionary Name	Coded Data	Standard User Data	Study User Data
NOYES	1		No
NOYESNA	2		No
NYxCL	N		No

Same decode cannot have different coded value. Harmonization should be put in place

Common data collection

Impact on SDTM

Data Dictionary Name	Coded Data	Standard User Data	Study User Data
CMDOSFRQCL	Q1WEEK		Every Week
CMDOSFRQCL	Q2WEEKS		Every Two Weeks
CMDOSFRQCL	Q3WEEKS		Every Three Weeks

NON COMPLIANT CODES

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)
C71127	C71113		Frequency	EVERY 2 WEEKS	Every 2 weeks; Q2S
C64535	C71113		Frequency	EVERY 3 WEEKS	Every 3 weeks; Q3S
C64529	C71113		Frequency	EVERY 4 WEEKS	Every 4 weeks; Q4S
C103390	C71113		Frequency	EVERY 5 WEEKS	Every 5 weeks; Q5S
C89788	C71113		Frequency	EVERY 6 WEEKS	Every 6 Weeks; Q6S
C116149	C71113		Frequency	EVERY 7 WEEKS	Every 7 weeks; Q7S
C103389	C71113		Frequency	EVERY 8 WEEKS	Every 8 weeks; Q8S
C67069	C71113		Frequency	EVERY WEEK	Every week; Per Week; QS

Need to re-map to SDTM CT
Hours spent causing over burn

PRA approach

Goal : 50% standards variables / study

STANDARDS

Using CDASH 1.1, develop a set of

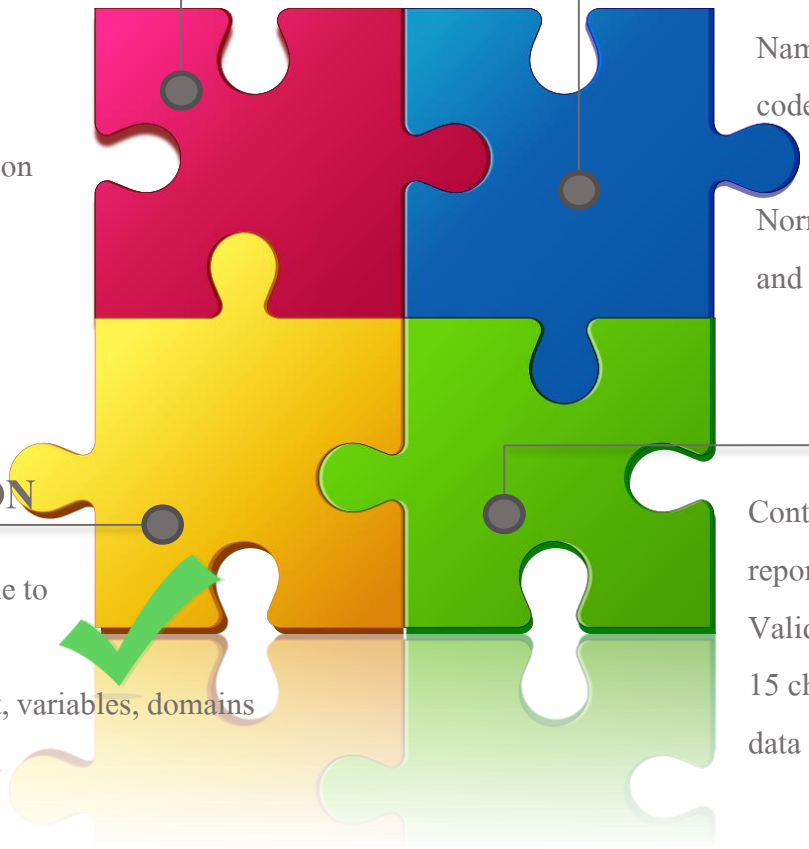
Standards forms available in Global Library

Each form has its automated SDTM conversion

BEST PRACTICES

Naming conventions for forms, fields, code lists

Normalize/De-normalized understanding and conventions



VALIDATION

Control usage of standards via comparison reports

Validate study specific against best practices

15 checks looking at compliance in RAW data

ACCESS TO INFORMATION

Being more compliant starts with being able to

Access CDISC information more easily

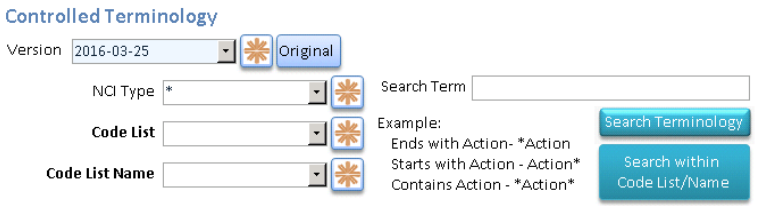
Advanced search functionality for code list, variables, domains

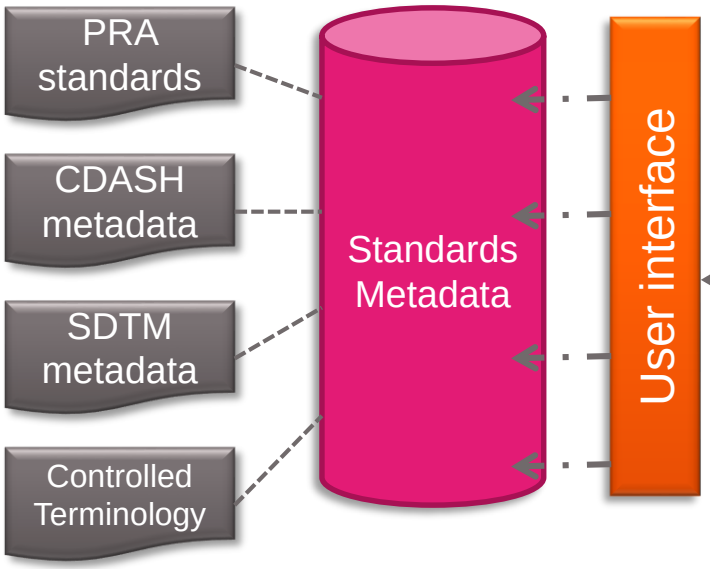
Access to CDASH and SDTM information

Provide our designer with tools to support them in compliance

Metadata Browser

- Difficult to search in PDF, in Excel files
- Study Designers may not have access to SDTM documentation





Queries
Advanced search
Finding strings

More compliant design

- Formatted similarly to a Pinnacle21 report, provides:
  - Checks on CDASH conformance
    - Variable fragments, required variables
  - Checks on PRA standard conformance
    - Naming conventions, changes in standards
  - Checks on metadata consistency
    - Consistency in codes used in code lists
- Error, Warnings
- Included in eCRF review as QC step
- Serve as support for metrics on compliance

Provide our designer with tools to support them in compliance

Validation report

Number of times issue found

CDASH checks

CALL	VAR003	Yes/No codelist used and variable name does not end with –YN	Error	1
MH	VAR004	(Highly Recommended) Variables should not be removed from standards	Error	1

PRA standards checks

ART	DDE004	Coded Data should not be numeric	Error	8
DADN	VAR005	Pre Text from standards should not be changed, if changed CSD to ensure that meaning is still the same as standard	Warning	2

Compliance checks

RDSIC	DDE003	Study specific codelist has been created. Please check that no existing CT exists.	Warning	1

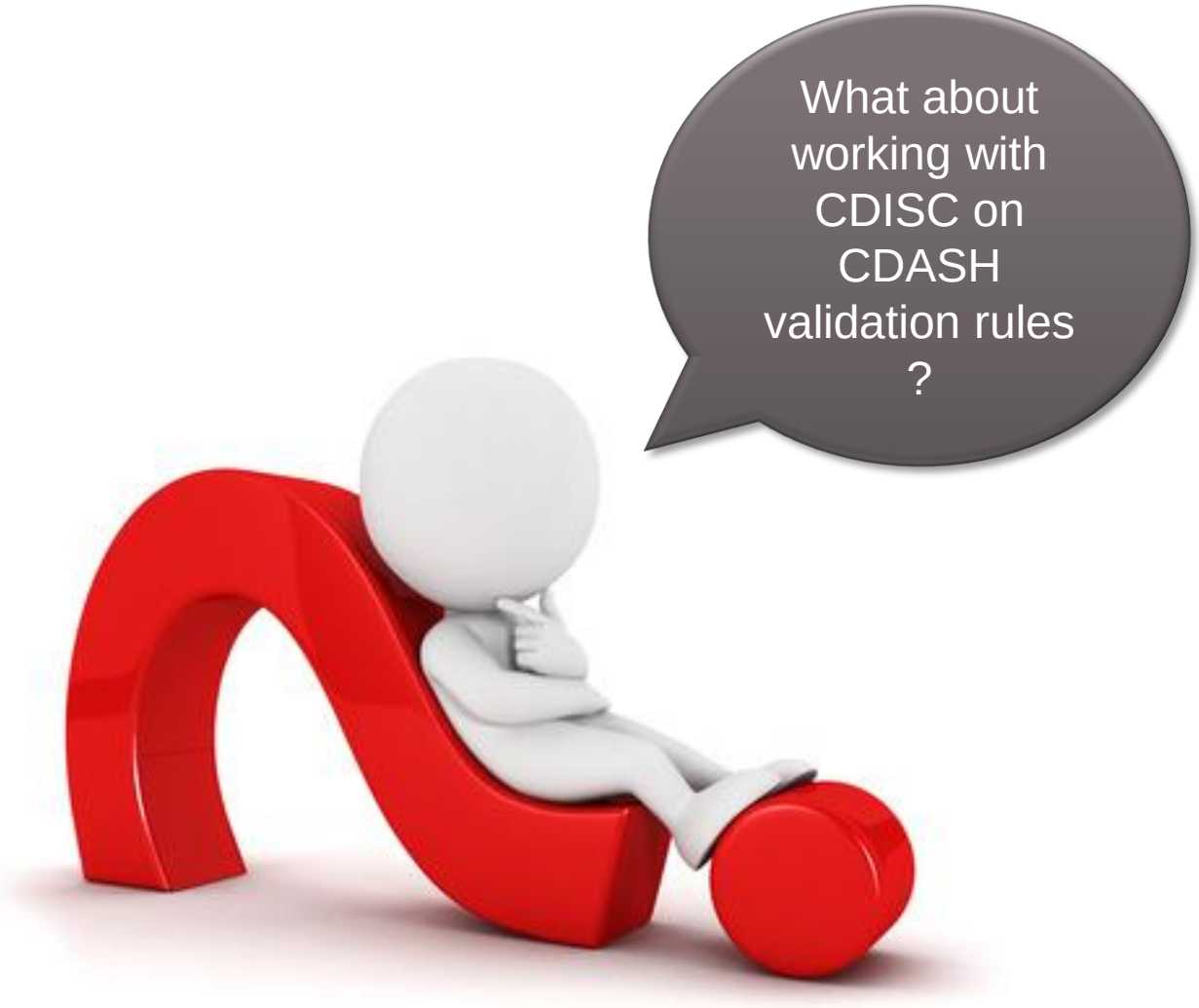
Consistency checks

VSYN	DDE005	Decoded value has multiple coded values	Error	1

Conclusion

- Pilot study
  - 50% target of variables from standards achieved
  - 85% of fields reused from standards without changes
  - 95 % compliance to CDASH and PRA best practices
  - SDTM expectation
    - 50 % of auto mapping
    - Decreased number of hours spent
- Pitfalls
  - A huge number of validation checks fire (a lot are warning but should be addressed)
    - Some time is needed from Designer perspective
    - May discourage people
  - Sometimes difficult to truly measure the compliance to best practices
- Potential improvement
  - Try to find a way to limit the number of checks (group them together)
  - Improve usability of the report to manage comments and actions performed from report to report
    - False positive checks to be identified and should not fire again
    - Identify new checks since previous run

One question to you



WE ARE DEDICATED TO THE FUTURE OF CLINICAL DEVELOPMENT AND TO EVERY LIFE IT SAVES.

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