



PRAHEALTHSCIENCES

The TFL Workbench: From Pilot to Production

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- Evolution of TFL Workbench Application Architecture ◀
- Formal Validation of TFL Workbench SAS Macro Suite
- Compliance Reporting and Associated Metrics ◀
- Process Development
- Training and Support for the User Base

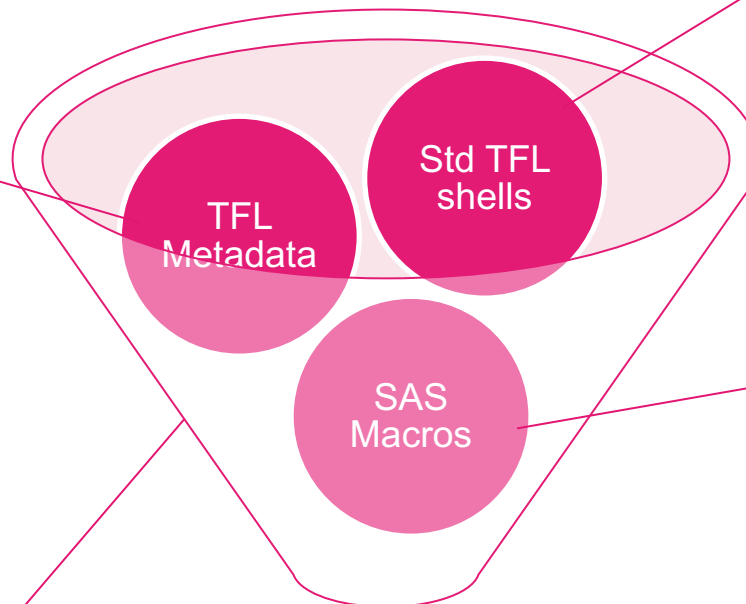


TFL Workbench components

Configuration (in Access / Excel): table templates containing machine-readable TFL metadata:

- Disposition, demography, analysis sets, enrolment
- Occurrence (AE, CM, MH)
- Labs
- Vitals
- ECG
- Exposure

Code-generation (Access/VB): reads TFL metadata and writes files containing appropriate calls to standard macros to build a TFL program



Specification: PRA or sponsor standard output layouts

Reporting: suite of modular, validated SAS “building block” macros:

- Initialisation
- Treatment columns & Population counts
- Fetch data from ADaM
- Summary statistics
- Frequency counts
- Table dataset
- [Reporting]

Auto-generated TFL program



TFL program run against ADaM data to produce output.



TFL output (RTF)

Evolution of TFL Workbench Application Architecture



Quoting Problem



Mimicking Macro Language

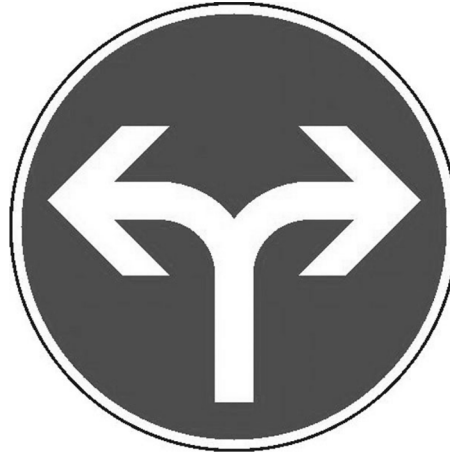


- Metadata and its structure
- Breakdown into building block macros
- Individual macro parameters and how metadata were passed to these parameters
- User Interface
- Internal mechanics of the SAS macros as well as structure of the Database (and its code) were left to the respective developers



Developing the Solution

Finding Solutions and Developing Code

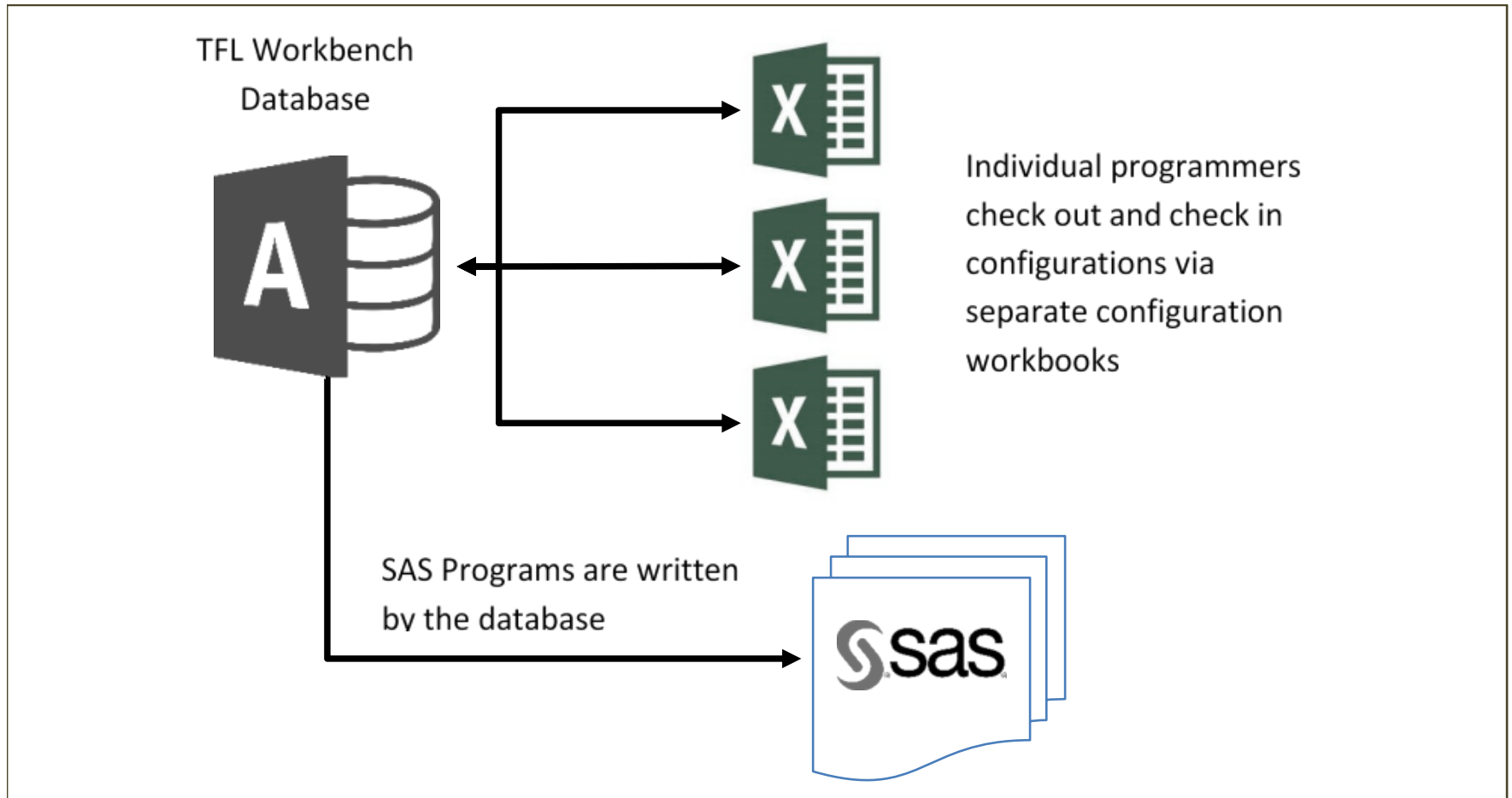


- Move from Excel to Access
- Refactoring of code
- Limiting features



Developing the Architecture

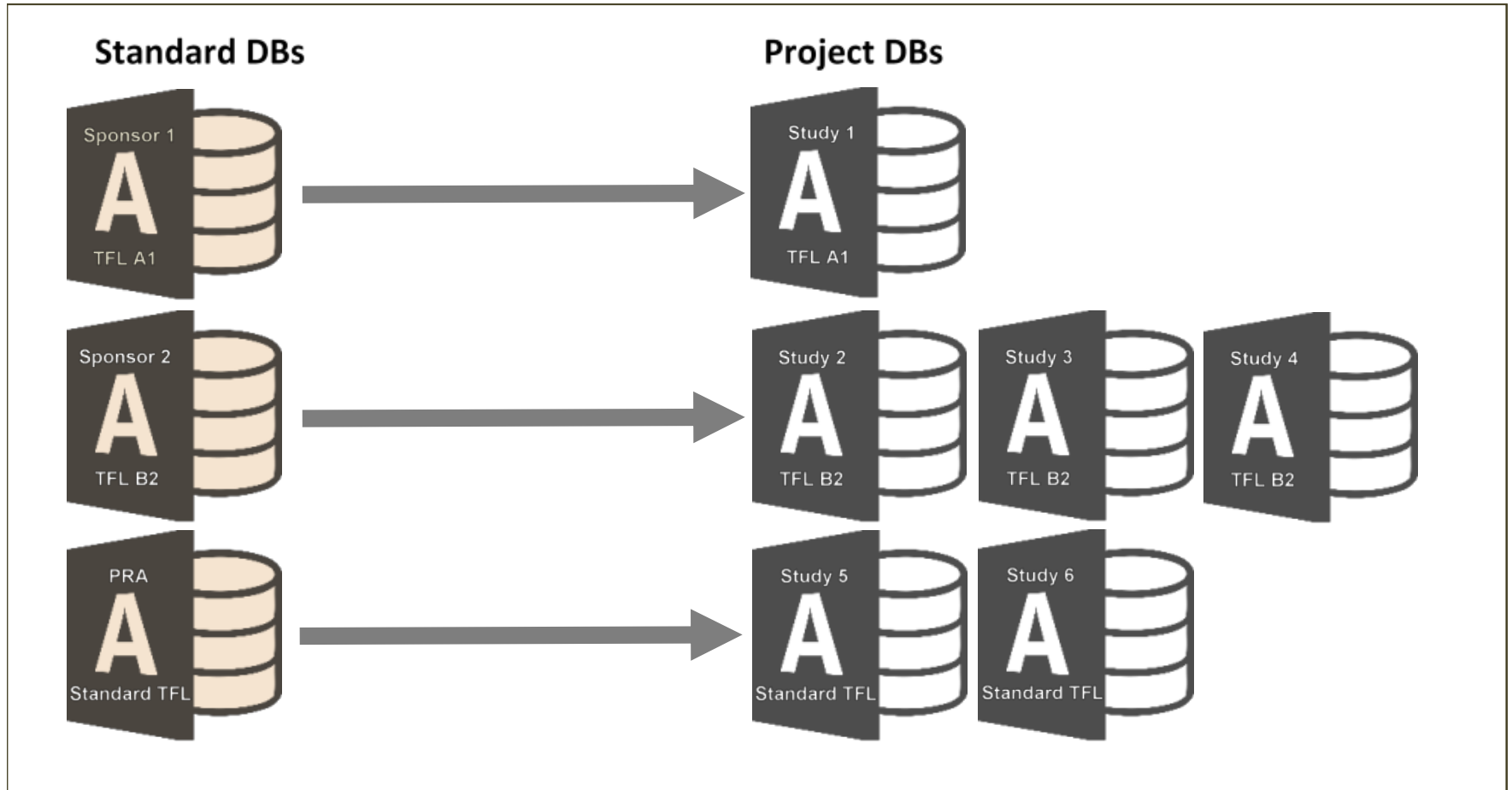
Architecture at Study Level





Developing the Architecture

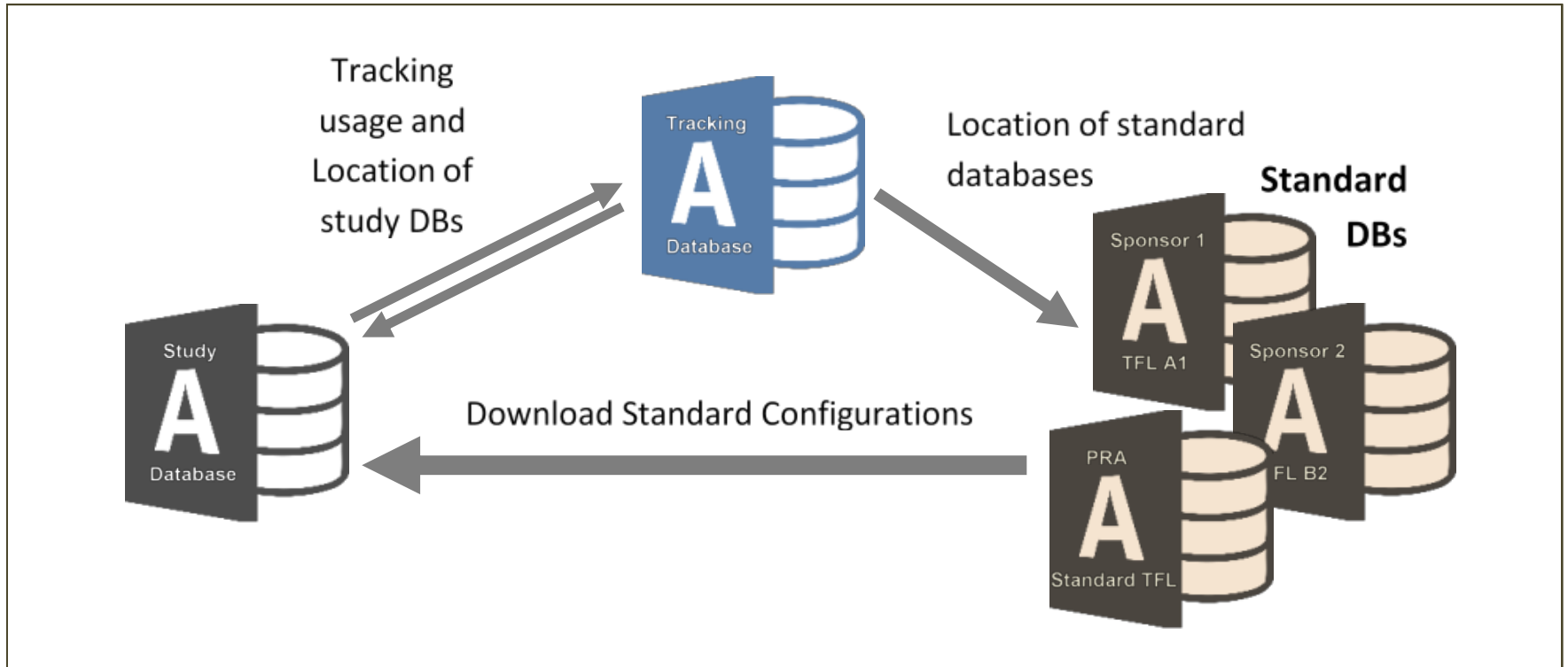
Distributing Standard Configurations





Developing the Architecture

Tracking Databases and Publishing Standards



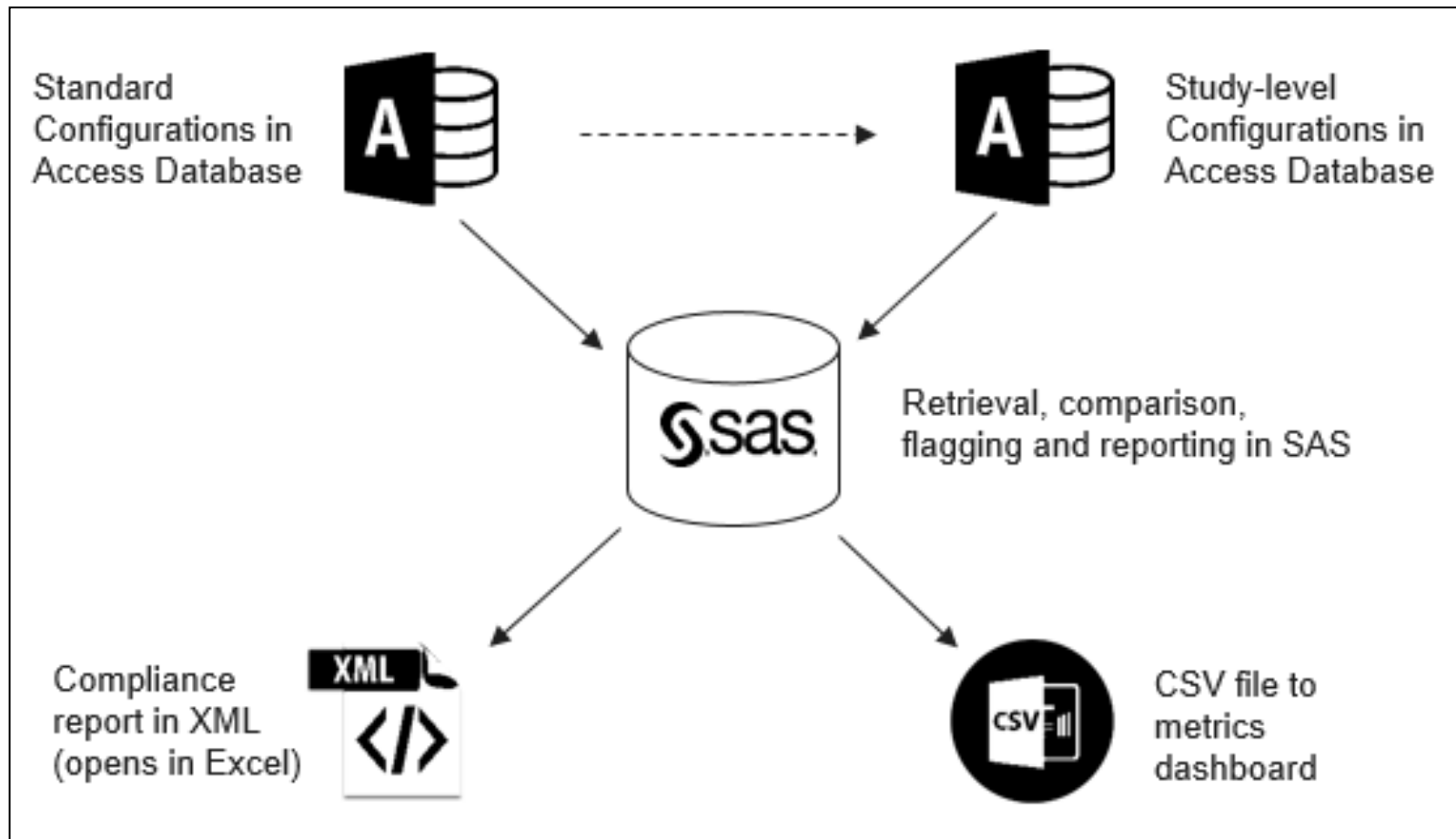
Compliance Reporting and Associated Metrics



- Standards are key
- Compliance is the extent to which a standard is being followed
- 2 reasons for measuring
 - Assist QC at individual study level
 - Governance at overall standard level



Compliance reporting process





Compliance report example – concomitant medication configuration

Source	Section	Row	Metadata	RowLabel1	Indent1	Statistic	Class Var	Analysis Vars	Where	Denominator
1	-1	.	row label hdr	Therapeutic Class!Preferred Term	0!2					
1	10	1	statistic	_Row_Label_From_TOO_	0	n_pct		UNIQUE (_USUBJID_)		_BigN_
1	20	1	statistic	_CLASS1_	0	n_pct	CMCLAS	UNIQUE (_USUBJID_)		_BigN_
1	20	5	statistic	_CLASS2_	2	n_pct	CMCLAS#CMDECOD	UNIQUE (_USUBJID_)		_BigN_
2	-1	.	row label hdr	Preferred Term	0					
2	10	1	statistic	_Row_Label_From_TOO_	0	n_pct		UNIQUE (_USUBJID_)		_BigN_
2	20	5	statistic	_CLASS1_	0	n_pct	CMDECOD	UNIQUE (_USUBJID_)		_BigN_

Cosmetic
change

Data-
related
change



Standard configuration



Study-level configuration



- Metrics

Measure	Significance
Number and percent of tables produced by the TFL Workbench, versus those traditionally programmed	A measure of coverage: the extent to which TFLs can be produced by the TFL Workbench
Number and percent of TFL Workbench-produced tables based on standard templates, versus those based on custom templates	A measure of the degree to which the standard templates met the study reporting requirements
Number and percent of TFL Workbench-produced tables based on standard templates that are unmodified, versus those with cosmetic changes, versus those with data-related changes	A measure of the degree to which standard templates needed study-specific amendment
Number of tables requiring pre-processing and post-processing code	A measure of the need to overcome a constraint of either the TFL Workbench or the source data

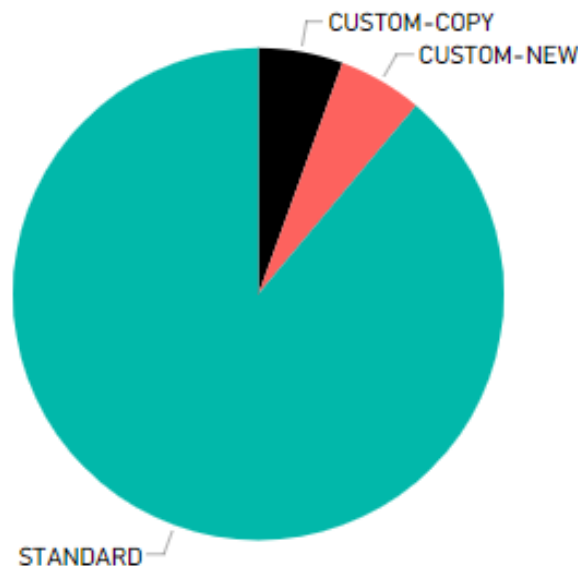


Metrics dashboard example – standard vs. custom templates

Unique tables produced by TFL Workbench: Usage of standard vs custom templates

Count of Tables by Template Source

● CUSTOM-COPY ● CUSTOM-NEW ● STANDARD



Count of Unique Tables

18

PRAproject

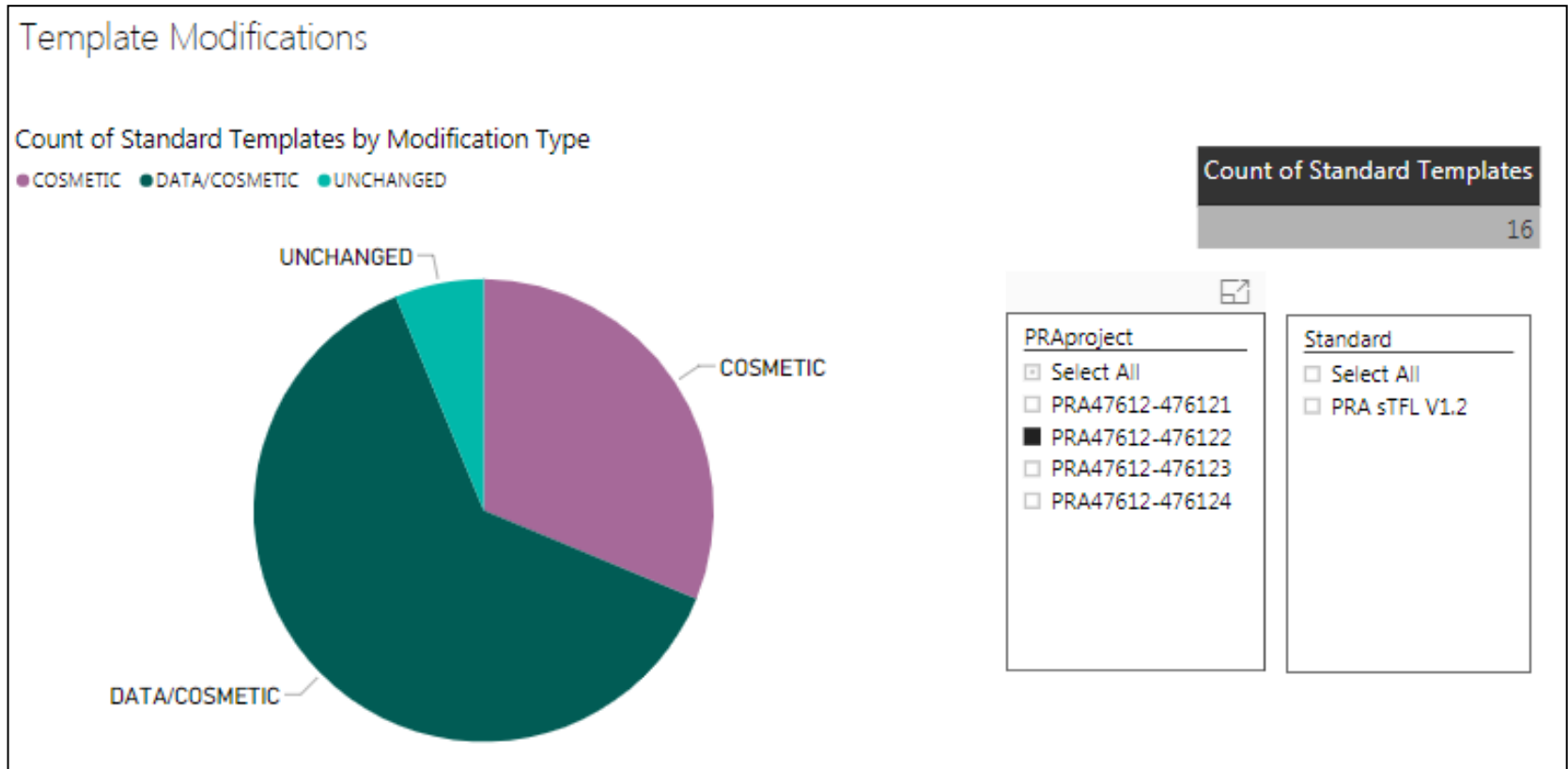
- ☐ Select All
- ☐ PRA47612-476121
- ☒ PRA47612-476122
- ☐ PRA47612-476123
- ☐ PRA47612-476124

Standard

- ☐ Select All
- ☐ PRA sTFL V1.2



Metrics dashboard example – template modification types



Conclusions



- Pre-requisites to successful deployment
 - Robust multi-user platform
 - Architectural change with migration to Access
 - Reduction in independent double-programming
 - Formal validation of TFL Workbench SAS macro suite
 - Adoption of standards
 - Compliance reporting and performance metrics
 - Incorporate new tool and working practices into existing SOP
 - Process development
 - Achieve optimal use of the tool and maximum efficiency gain
 - Training and support for the user base
- Part of the broader applications development landscape
 - Extending the horizons of Biostatistical Programming
 - Stakeholders, resources, methods, skills

Questions