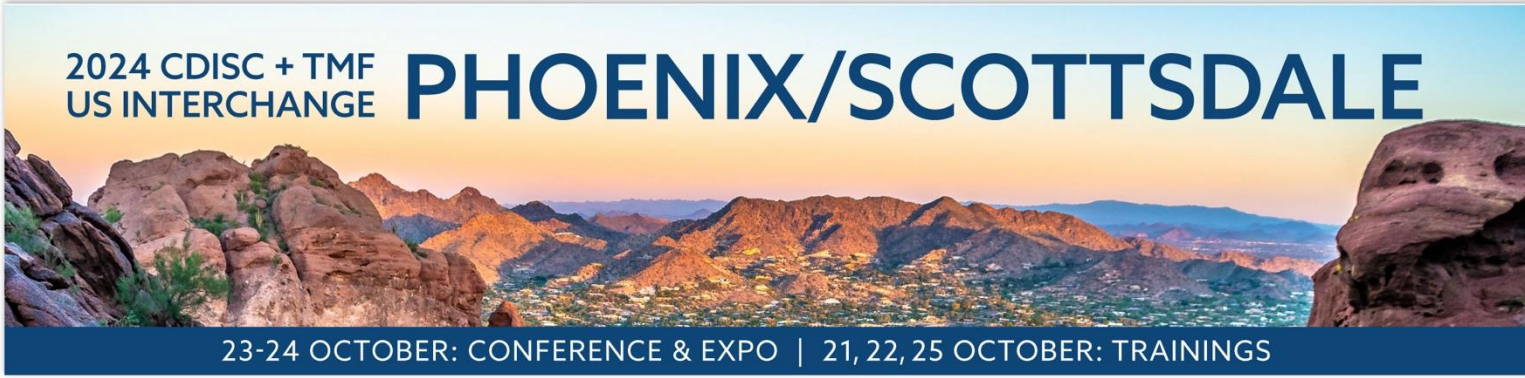


Using a Standards Library to support end-to-end CDISC automation

Stuart Malcolm
Head of Standards, Efficiency and Automation
Veramed

Meet the Speaker

Stuart Malcolm

Title: Head of Standards, Efficiency and Automation

Organization: Veramed

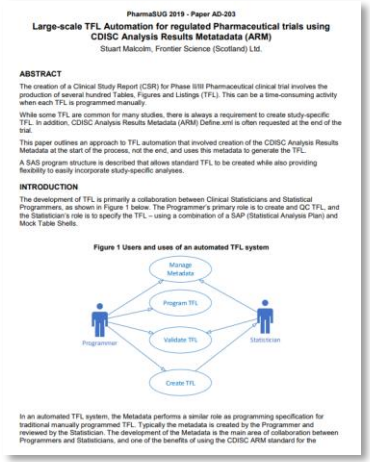
Stuart Malcolm is Head of Standards, Efficiency and Automation at Veremed where he is responsible for the delivery of software platforms, tools, and techniques to optimise the delivery of clinical trial analysis projects

Stuart has over 25 years experience delivering software-based solutions in clinical trials, and has previously worked in telecoms, finance and media.

Stuart is co-chair of PHUSE Emerging Trends & Technology Working Group

"To define the future, one must study the past"

TFL Automation using CDISC Analysis Results Metatadata (ARM)
PharmaSUG 2019



PharmaSUG 2019 - Paper AD-203

Large-scale TFL Automation for regulated Pharmaceutical trials using CDISC Analysis Results Metatadata (ARM)

Stuart Malcolm, Frontier Science (Scotland) Ltd.

ABSTRACT

The creation of a Clinical Study Report (CSR) for Phase II/III Pharmaceutical clinical trial involves the production of several hundred Tables, Figures and Listings (TFL). This can be a time-consuming activity when each TFL is programmed manually.

While some TFL are common for many studies, there is always a requirement to create study-specific TFL. In addition, CDISC Analysis Results Metadata (ARM) Define.xml is often requested at the end of the trial.

This paper outlines an approach to TFL automation that involved creation of the CDISC Analysis Results Metadata at the start of the process, not the end, and uses this metadata to generate the TFL.

A SAS program structure is described that allows standard TFL to be created while also providing flexibility to easily incorporate study-specific analyses.

INTRODUCTION

The development of TFL is primarily a collaboration between Clinical Statisticians and Statistical Programmers, as shown in Figure 1 below. The Programmer's primary role is to create and QC TFL, and the Statistician's role is to specify the TFL – using a combination of a SAP (Statistical Analysis Plan) and Mock Table Shells.

Figure 1 Users and uses of an automated TFL system

In an automated TFL system, the Metadata performs a similar role as programming specification for traditional manually programmed TFL. Typically the metadata is created by the Programmer and reviewed by the Statistician. The development of the Metadata is the main area of collaboration between Programmers and Statisticians, and one of the benefits of using the CDISC ARM standard for the

A Language-Orientated Approach to CDISC Metadata-Driven Automation
CDISC Interchange 2023

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2023 EUROPE INTERCHANGE

COPENHAGEN | 26-27 APRIL

A Language-Orientated Approach to CDISC Metadata-Driven Automation

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Head of Standards, Efficiency and Automation, Veramed

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6

Automation of TFL Generation using CDISC 360 Enriched Metadata
CDISC EU Interchange 2020

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Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

- *The author(s) have no real or apparent conflicts of interest to report.*

End-to-End Vision

What is 360?

360 is the CDISC initiative aimed at implementing standards as linked metadata with a conceptual foundation providing the additional semantics needed to support metadata driven-automation across the end-to-end clinical research data lifecycle.

New software tools will be able to consume this new metadata to ease standards implementations while increasing data processing efficiencies.

Standards-based metadata-driven automation is a critical component in realizing the primary benefits expected of the CDISC standards: substantially improved efficiency, consistency, and re-usability across the clinical research data lifecycle.

These benefits drive the return on investment in the CDISC standards implementations expected by CDISC stakeholders.

"SUBSTANTIALLY IMPROVED
- EFFICIENCY
- CONSISTENCY
- REUSABILITY
ACROSS THE CLINICAL RESEARCH LIFECYCLE"

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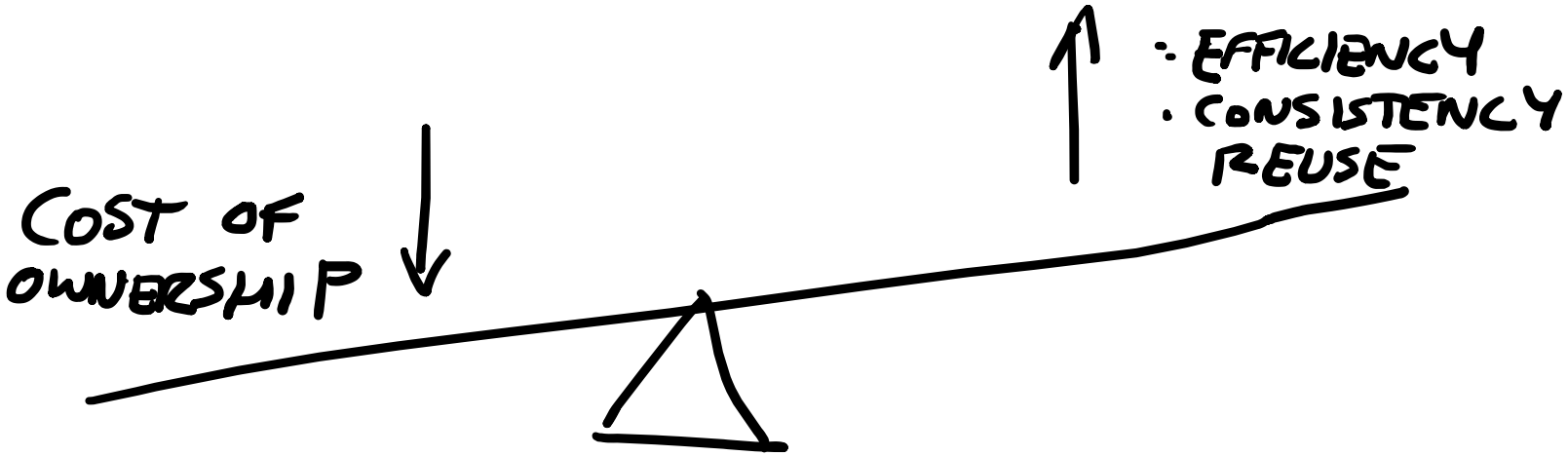
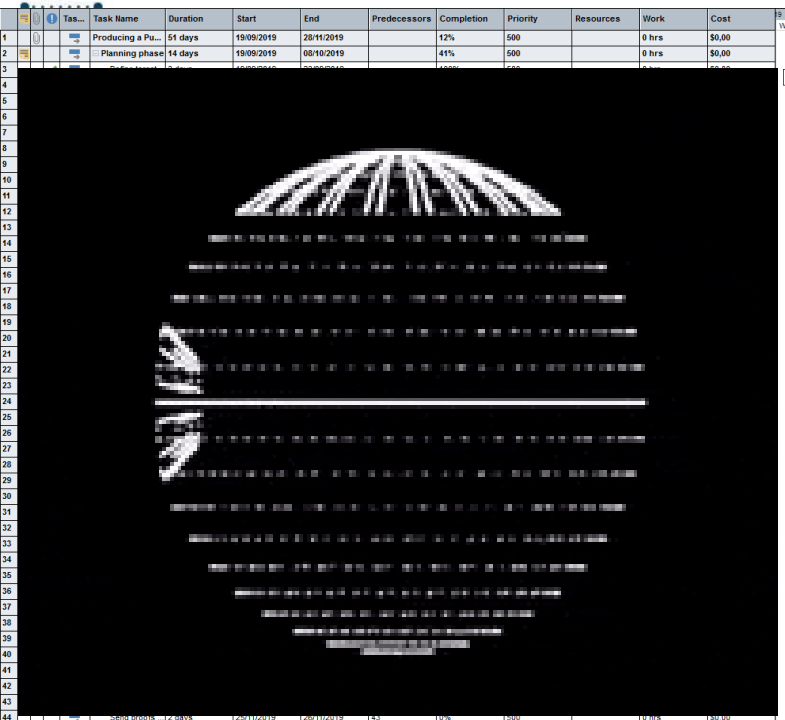
Substantially Improved…



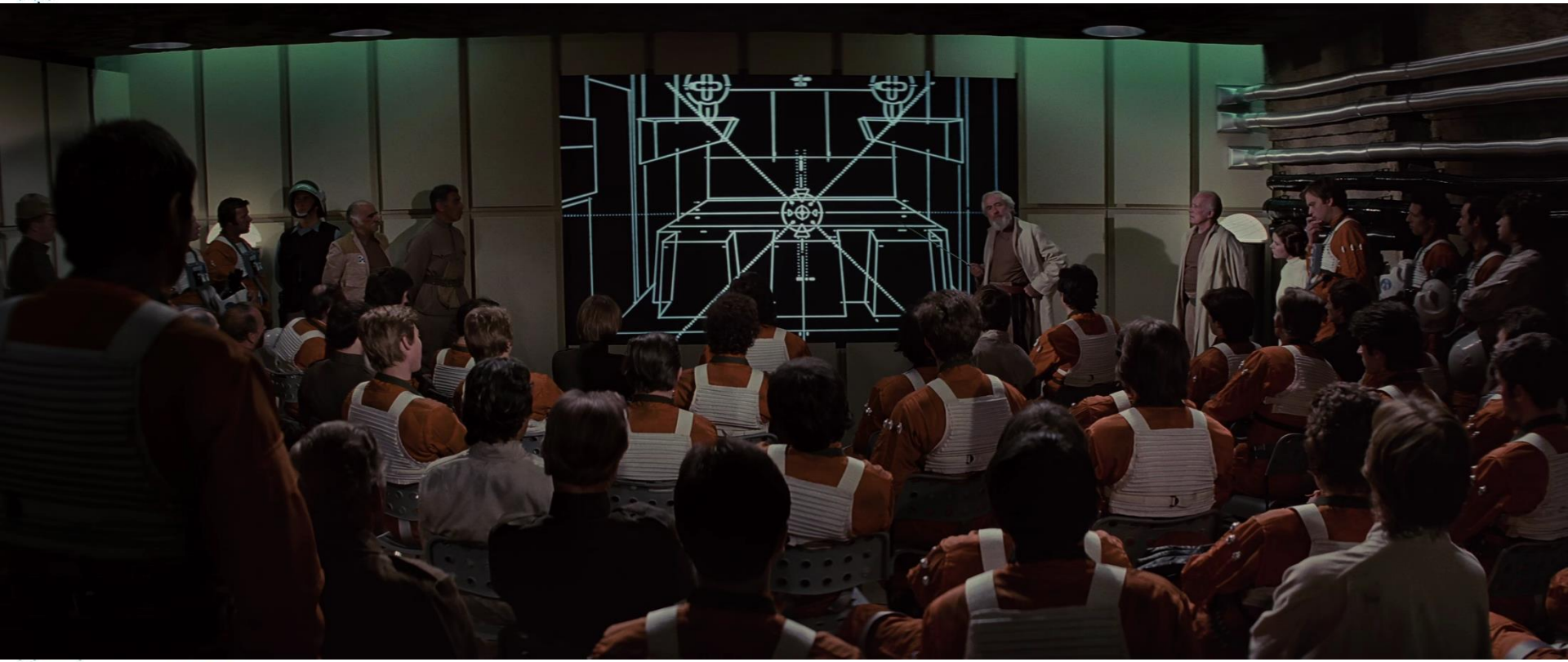
Death Stars are expensive…

…take a lot of time and effort to build, and..

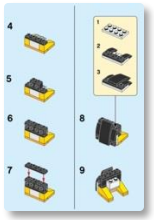


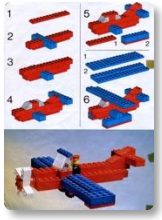
	Tas...	Task Name	Duration	Start	End	Predecessors	Completion	Priority	Resources	Work	Cost
1		Producing a Pu...	51 days	19/09/2019	28/11/2019		12%	500		0 hrs	$0,00
2		Planning phase	14 days	19/09/2019	08/10/2019		41%	500		0 hrs	$0,00
44		Send proofs ...	2 days	25/11/2019	26/11/2019	43	0%	500		0 hrs	$0,00
45		Final proofing	2 days	27/11/2019	28/11/2019	44	0%	500		0 hrs	$0,00
46		Start printing	0 days	28/11/2019	28/11/2019	45	0%	500		0 hrs	$0,00

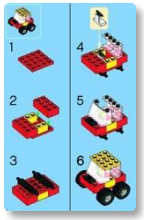
…are static and hard to change!



What if we could build trials out of components?..







It's not metadata… it's a model

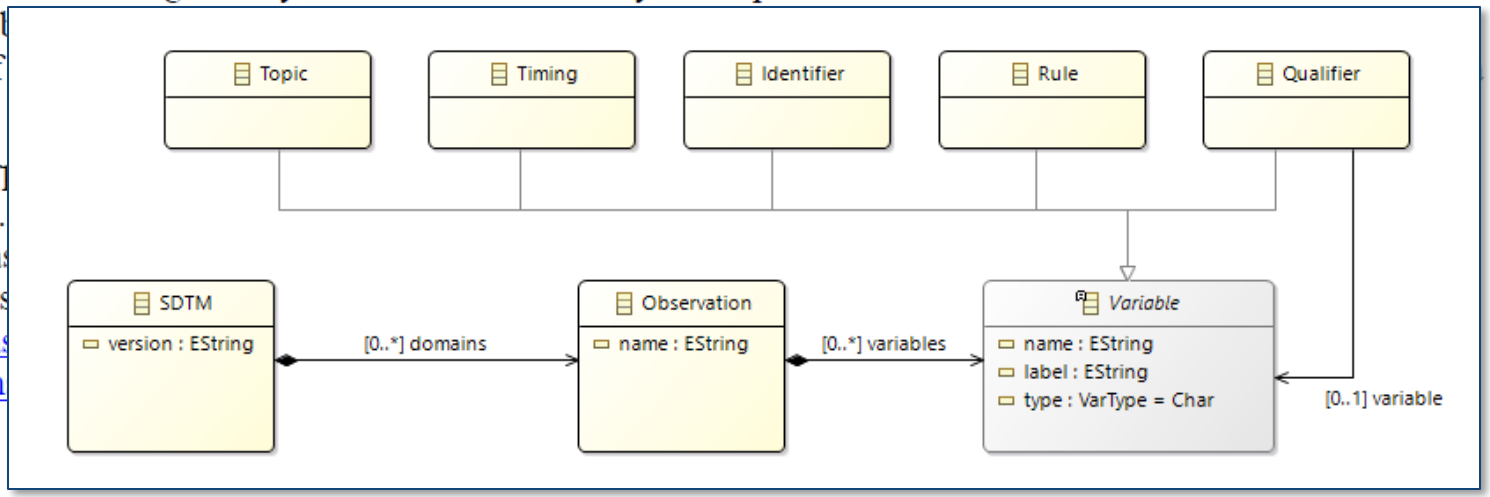
It's not metadata… it's a model

2 Model Co … d … ga … f the SDTM

Model → Grammar → Language Editor

The SDTM provides a gene… …ing t… …natio… and animal studies. The model is built around the concept of *observations*, which consist of discrete pieces of information collected during a study. Observations normally correspond to rows in a dataset. A *domain* is a collection of ob… adverse event of … clinical trial.

The primary pur… medical devices. Within those clas… observation class… Observation Clas… purpose Domain…



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runtime-EclipseApplication - demo2/foo.sdtm - Papyrus

File Edit Navigate Search Project Run Window Help

Project Ex...

demo2
- foo.sdtm
- My.sdtm

Model Exp...

No Model Available

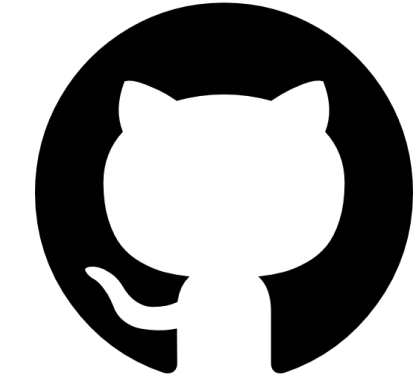
Outline

- 2.0
  - Interventions
    - TRT
    - MODIFY
    - DECOD

*foo.sdtm

```
/*
 * SDTM v2.0 example at CDISC Interchange 2023
 */
SDTM {
    version "2.0"  // version number
    domains {
        Observation "Interventions" {
            variables {
                Topic "TRT" {
                    label "Name of Treatment"
                    type Float
                },
                Qualifier "MODIFY" {
                    label "Modified Treatment Name"
                    type Char
                    variable TRT
                },
                Qualifier "DEC
                    label "Sta
                    type Char
                    variable T
                }
            }
        }
    }
```

DECOD - Interventions.DECOD
MODIFY - Interventions.MODIF
TRT - Interventions.TRT



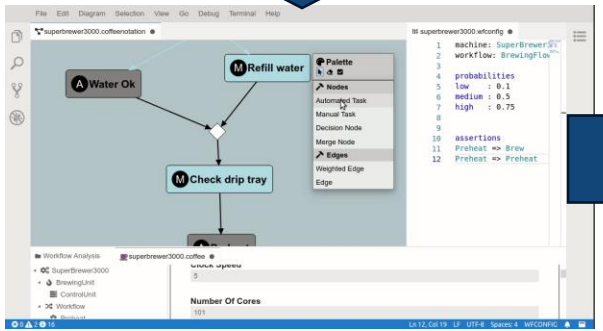
Just files
In Git

Writable Insert 16 : 33 [3]

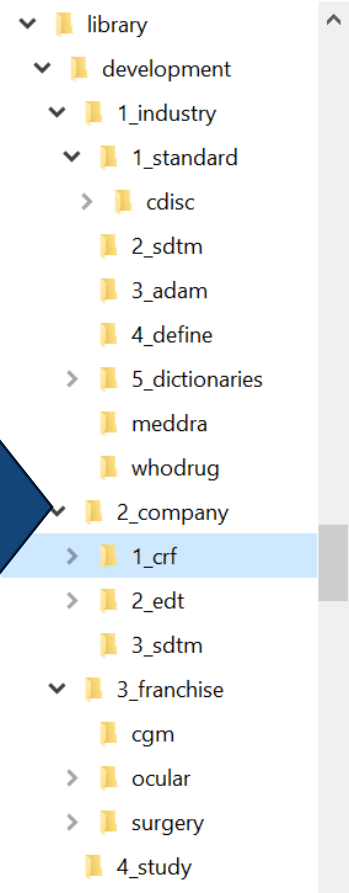
3°C Cloudy 23:00

Standards Library

Git Repo



Workbench



{JSON}

Consumer Program

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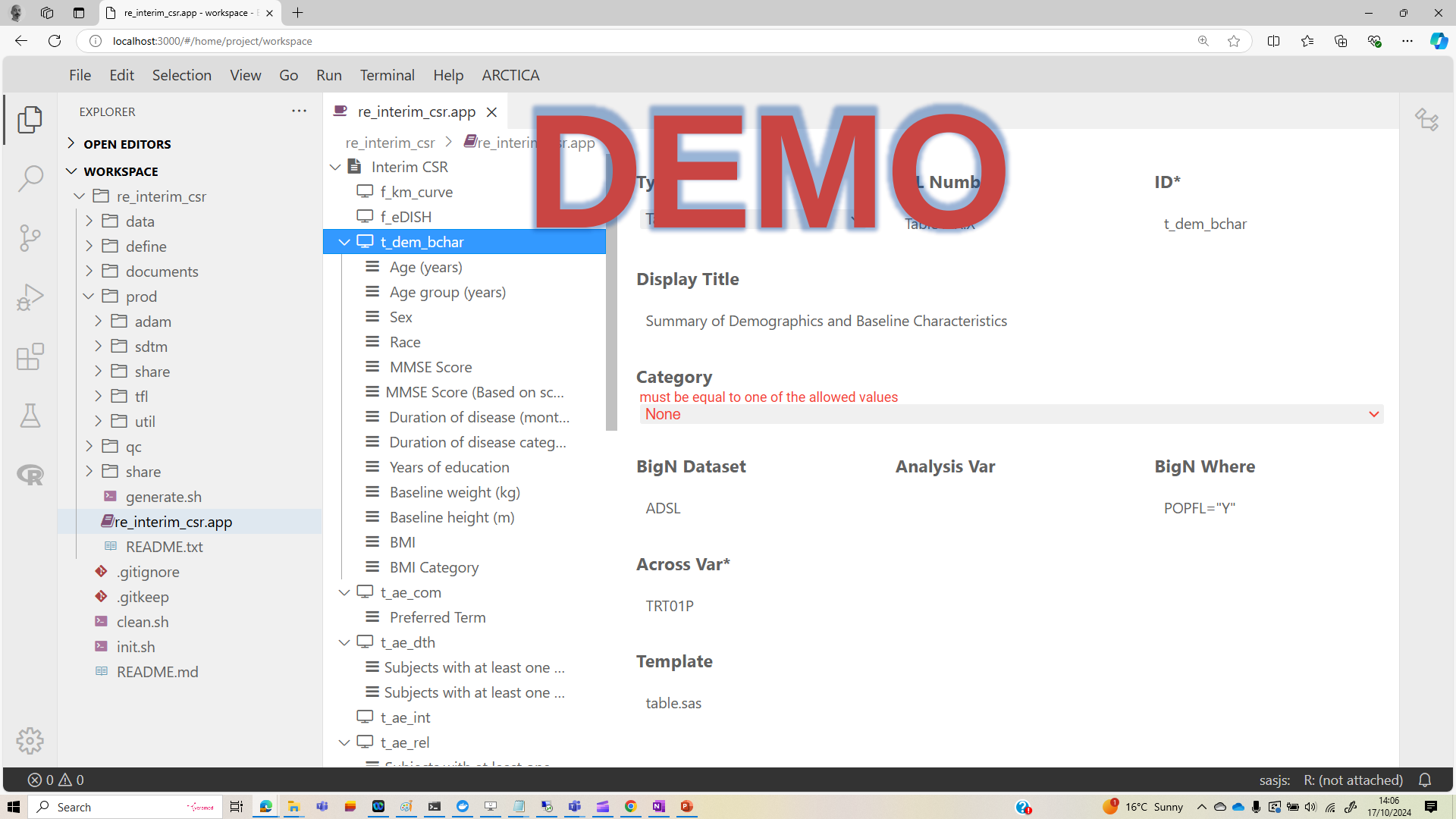
re_interim_csr.app - workspace
localhost:3000/#/home/project/workspace
File Edit Selection View Go Run Terminal Help ARCTICA
EXPLORER
OPEN EDITORS
WORKSPACE
re_interim_csr
data
define
documents
prod
adam
sdtm
share
tfl
util
qc
share
generate.sh
re_interim_csr.app
README.txt
.gitignore
.gitkeep
clean.sh
init.sh
README.md
re_interim_csr.app
re_interim_csr
Interim CSR
f_km_curve
f_eDISH
t_dem_bchar
Age (years)
Age group (years)
Sex
Race
MMSE Score
MMSE Score (Based on sc...
Duration of disease (mont...
Duration of disease categ...
Years of education
Baseline weight (kg)
Baseline height (m)
BMI
BMI Category
t_ae_com
Preferred Term
t_ae_dth
Subjects with at least one ...
Subjects with at least one ...
t_ae_int
t_ae_rel
DEMO
ID*
t_dem_bchar
Display Title
Summary of Demographics and Baseline Characteristics
Category
must be equal to one of the allowed values
None
BigN Dataset
ADSL
Analysis Var
BigN Where
POPFL="Y"
Across Var*
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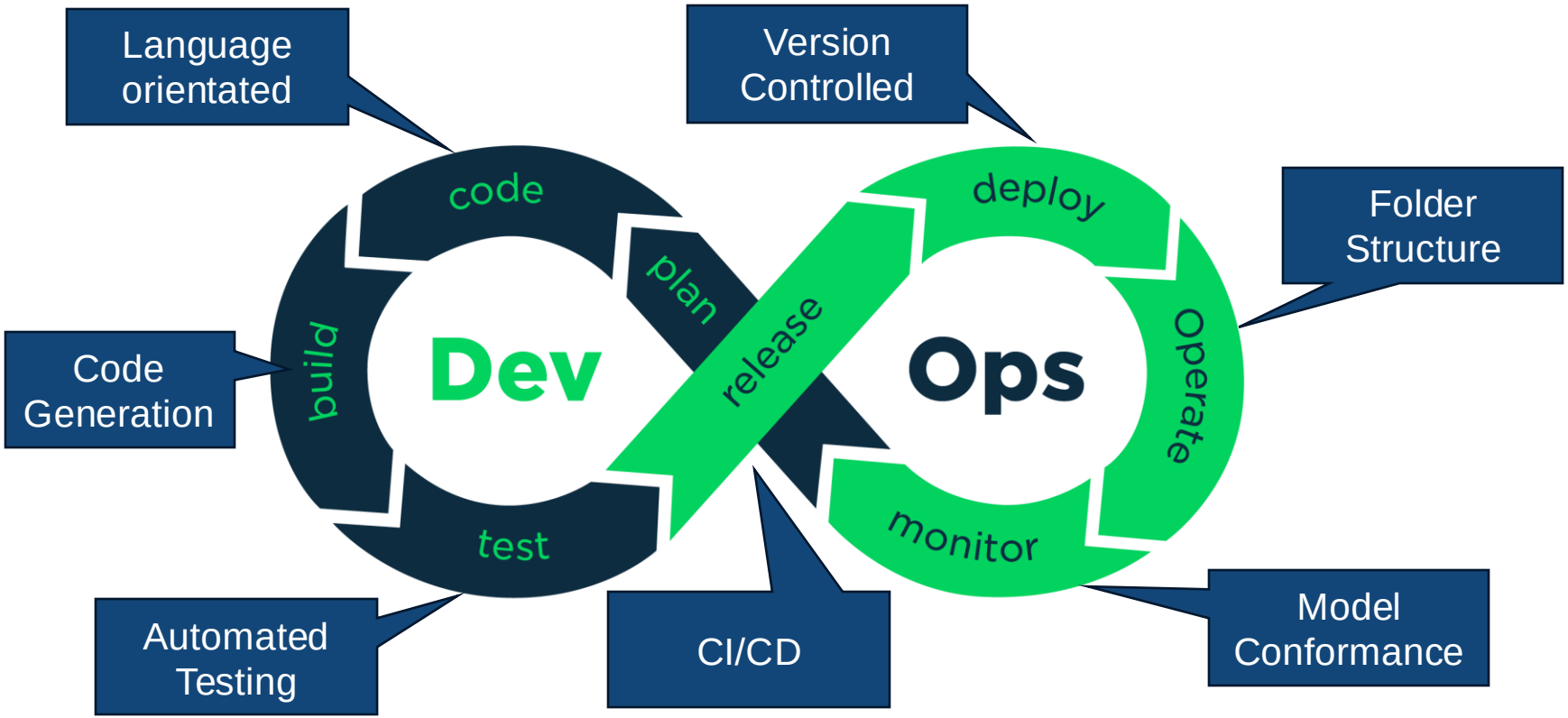
An agile approach to standards management



https://imranqureshi.co.uk/devops-for-dummies-3rd-ed-notes/

A New Hope? Agile, Decentralised and Automated

Thank you!

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