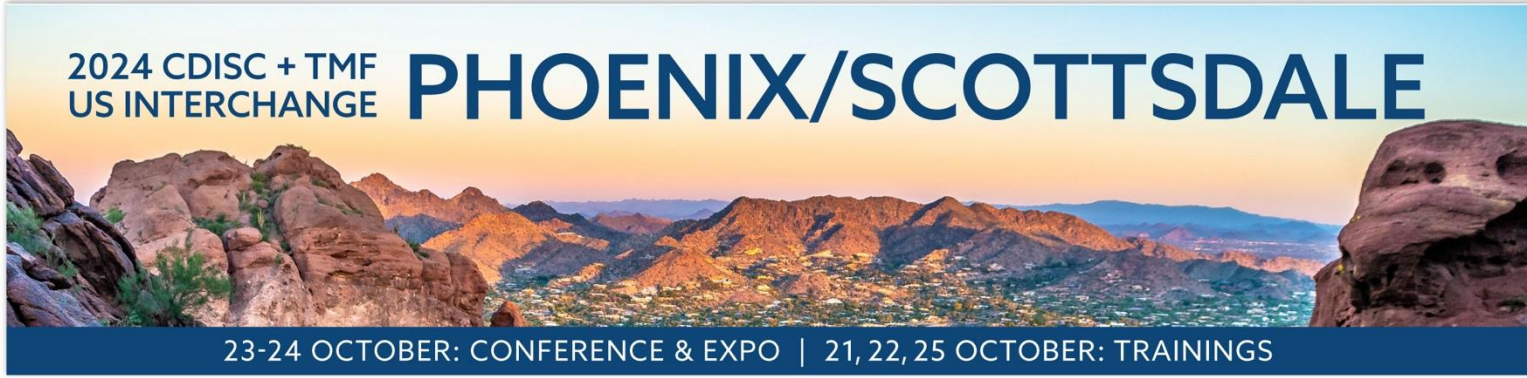

{sdtm.oak} - SDTM Programming in R V0.1 Release

Pharmaverse/ CDSIC COSA

Presented by Shiyu Chen, Data Solutions Engineer, Atorus Research

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SDTM - Challenges at Industry level

- **Raw Data structure** - Different EDC systems produce data in different structures, different variable names, dataset names etc.

- **Varying Data Collection standards** - Although CDASH is available, the companies can still develop varying eCRFs using CDASH standards.

With varying raw data structure, data collection standards it may seem impossible to come up with a common approach that can be used for programming SDTM datasets.

{sdtm.oak} attempts to overcome this problem by providing an EDC agnostic, Standards agnostic solution.

{sdtm.oak} - Introduction

- Sponsored by CDISC COSA, pharmaceutical companies, including Roche, Pfizer, Merck, GSK, Vertex and many more independent volunteers
- Part of the Pharmaverse.
- Inspired by Roche's {roak} R Package.

{sdtm.oak} will be an open-source R package

{sdtm.oak} will be EDC-agnostic, data standards agnostic & provides a framework for modular programming of SDTM in R

{sdtm.oak} can also automate SDTM dataset creation based on the metadata driven approach using standard SDTM specifications. We will pilot it standard CDASH eCRFs in the CDISC library. The concept can be extended to any sponsor MDR.

What is Roche Open-sourcing?

Core Concept - Reusable Algorithms

{roak} is based on the concept of reusable Algorithms.

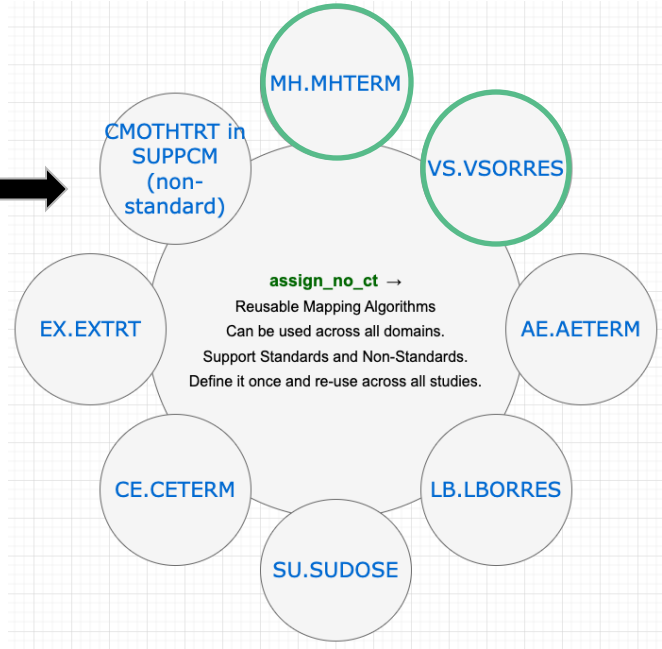
Roche has used **22 algorithms** to automate **13,000 SDTM** mappings across **6 different Therapeutic Area standards**. Each Algorithm is programmed as a function in {roak}.

Algorithms used for SDTM automation are being open-sourced by Roche.

Source code has to be re-developed as EDC- and standards-agnostic so any company can use it.

Core Concept - Reusable Algorithms

Mapping Algorithm	Description
assign_no_ct	One to One mapping with no controlled terms.
assign_ct	One to One mapping with controlled terms.
hardcode_ct	Hard code the target based on the source with controlled terms.
hardcode_no_ct	Hard code the target based on the source without controlled terminology.
condition_add	Conditionally check a condition and apply a mapping



Read more about {sdtm.oak} algorithms/functions here

Core Concept - Reusable Algorithms

Reusable

Algorithms can be re-used across multiple SDTM domains.

Programming language-agnostic

{sdtm.oak} team implemented them in R.

Automation-ready

Algorithms can be pre-specified for data collection standards in metadata repository (MDR).

{sdtm.oak} – Modular Approach

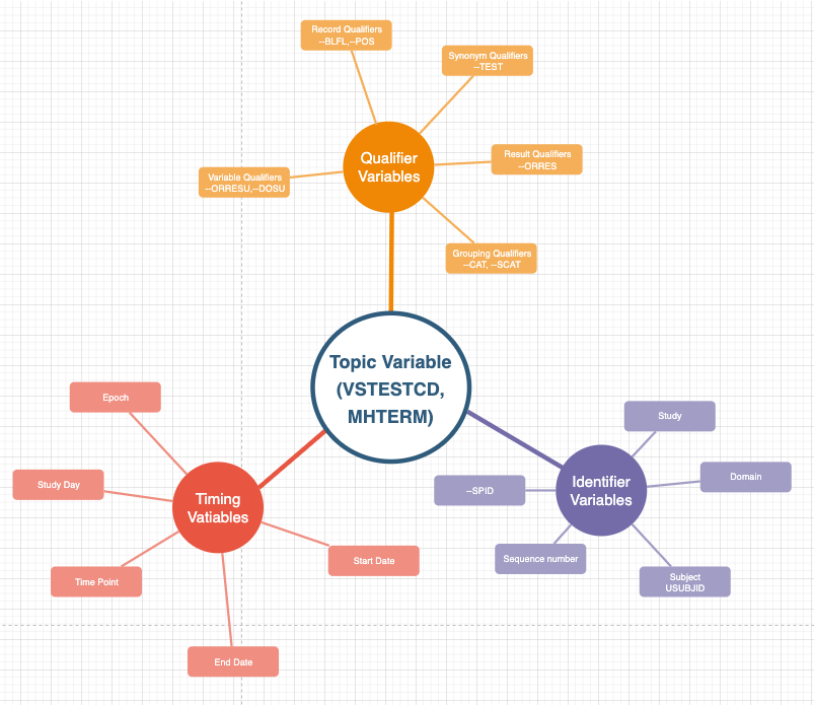
Provide a framework to modular programming of SDTM in R.

For example, a mapping of **CM.CMTRT** from raw data source cm_raw.MDRAW using **assign_no_ct** mapping algorithm which is programmed as **assign_no_ct()** function.

```
cm <-
  # Derive topic variable
  assign_no_ct(
    raw_dat = cm_raw,
    raw_var = "MDRAW",
    tgt_var = "CMTRT"
  )
```

```
cm <-
  # Derive topic variable
  assign_no_ct(
    raw_dat = cm_raw,
    raw_var = "MDRAW",
    tgt_var = "CMTRT"
  ) %>%
  # Derive CMGRPID
  assign_no_ct(
    raw_dat = cm_raw,
    raw_var = "MDNUM",
    tgt_var = "CMGRPID",
    id_vars = oak_id_vars()
  ) %>%
  # DERIVE CMINDC
  assign_no_ct(
    raw_dat = cm_raw,
    raw_var = "MDIND",
    tgt_var = "CMINDC",
    id_vars = oak_id_vars()
  ) %>%
  # Derive CMSTDTC. This function calls create_iso8601
```

{sdtm.oak} – Programming Steps



- {sdtm.oak} is very close to the key SDTM concepts.
- Provide a straightforward way to do step-by-step SDTM programming in R, that is, mapping topic variable and its qualifiers.
- Programming steps are generic across SDTM domain classes like Events, Interventions, Findings
- The framework has the potential for automation (similar to Roche implementation)

{sdtm.oak} – Programming Steps

Read in Raw datasets	•Process one raw dataset at a time •Similar raw data sources can be stacked or merged together.
Create oak_id_vars	•Unique identifiers for each record in the raw dataset •Used to merge the qualifiers to topic variables
Read in Controlled terminology	•User prepared Controlled terminology file •Can be in CSV or excel format
Map Topic	•Map Topic variable, usually one topic Variable at a time •Using the mapping Algorithms/ functions
Map Rest	•Map Rest of the variables that defines the specific topic variable •Qualifiers, Identifiers, timing, etc •Using the mapping Algorithms/ functions
Repeat Map Topic and Map Rest	•Repeat Map Topic and Map Rest for all topic variables in the source. •Map qualifiers that are common to all topic variables.
Create SDTM Derived variables	•Create derived variables like BLFL, study day
Add Labels and Attributes.	•SDTM Variable Labels and associated attributes.

{sdtm.oak} - Code walkthrough

➔ CM domain template program walkthrough.

➔ Demonstrates **modular** SDTM programming in R.

➔ Very similar to **{admiral}** style (easier for programmers).

CM Domain Example
https://pharmaverse.github.io/sdtm.oak/articles/events_domain.html
https://github.com/pharmaverse/sdtm.oak/blob/main/inst/template/create_cm_template.R

VS Domain Example:
https://pharmaverse.github.io/sdtm.oak/articles/findings_domain.html
https://github.com/pharmaverse/sdtm.oak/blob/main/inst/template/create_vs_template.R

Package Documentations

sdtm.oak 0.1.0 Reference Articles Changelog

sdtm.oak

An EDC (Electronic Data Capture systems) and Data Standard agnostic solution that enables the pharmaceutical programming community to develop CDISC (Clinical Data Interchange Standards Consortium) SDTM (Study Data Tabulation Model) datasets in R. The reusable algorithms concept in 'sdtm.oak' provides a framework for modular programming and also can automate SDTM creation based on the standard SDTM spec.

Installation

The package is available from CRAN and can be installed with:

```
install.packages("sdtm.oak")
```

You can install the development version of 'sdtm.oak' from GitHub with:

```
# install.packages("remotes")
remotes::install_github("pharmaverse/sdtm.oak")
```

Challenges with SDTM at the Industry Level

- Raw Data Structure: Data from different EDC systems come in varying structures, with different variable names, dataset names, etc.
- Varying Data Collection Standards: Despite the availability of CDASH (Clinical Data Acquisition Standards Harmonization), pharmaceutical companies still create different eCRFs using CDASH standards.

Due to the differences in raw data structures and data collection standards, it may seem impossible to develop a common approach for programming SDTM datasets.

GOAL

'sdtm.oak' aims to address this issue by providing an EDC-agnostic, standards-agnostic solution. It is an open-source R package that offers a framework for the modular programming of SDTM in R. With future releases; it will also strive to automate the creation of SDTM datasets based on the metadata-driven approach using standard SDTM specifications.

Links

View on CRAN
Browse source code
Report a bug

License

Full license
Apache License (>= 2)

Community

Contributing guide
Code of conduct

Citation

Citing sdtm.oak

Developers

Rammprasad Ganapathy
Author, maintainer

Adam Forys
Author

Edgar Manukyan
Author

Rosemary Li
Author

Preetesh Parikh
Author

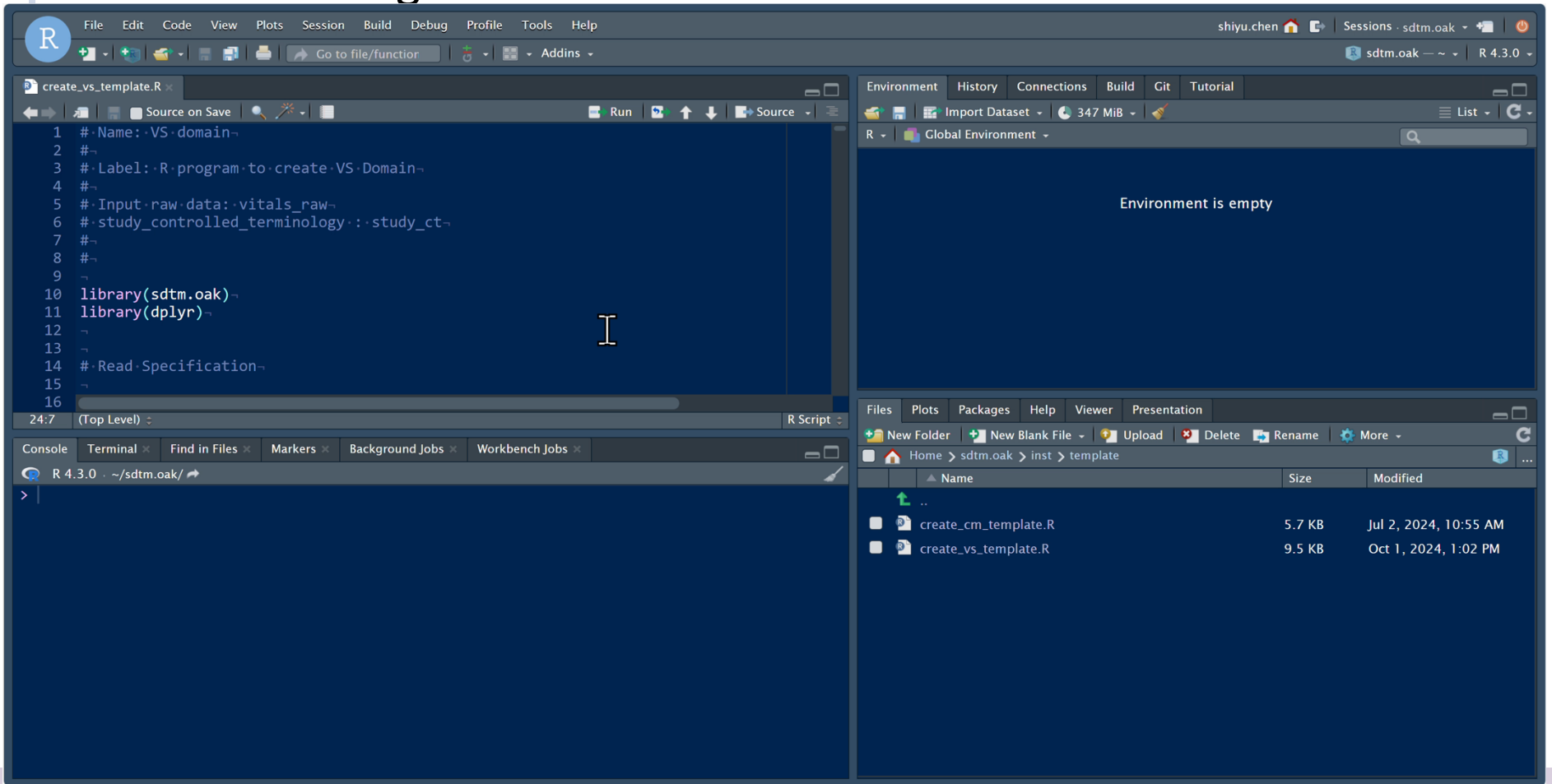
Lisa Houterloot
Author

Yogesh Gupta
Author

Omar Garcia
Author

Ramiro Magno

Code Walkthrough



{sdtm.oak} – V0.1 – In this Release

- Product documentation - https://pharmaverse.github.io/sdtm.oak/index.html
- Functions for Mapping Algorithms and required SDTM functions like sequence number, study day, baseline flag.
- Template program and Vignette to create CM domain and VS domain
- Ability program majority of the domains (Events, Interventions and Findings) . Not supported domains/Concepts - DM, RELREC, SE, SV, TDDs, metadata driven unit conversions

{sdtm.oak} V0.1 – Community can try and give us feedback via

Slack - oakgarden.slack.com

GitHub - https://github.com/pharmaverse/sdtm.oak

{sdtm.oak} – Path to Open-source SDTM Automation

SDTM specification where users can define, raw data source, target sdtm domain, target sdtm variables and algorithms used for automation. A template is available in the Gitlab Repo (under development).

SDTM Controlled Terminology where the users can define the SDTM Controlled terms applicable to the study. A template is available in the Gitlab Repo.

Prepare SDTM Spec & Controlled Terminology in the format OAK expects

Automated way to read the spec and make {sdtm.oak} function calls automatically.

LLM is good in generating the code based on prompts.

{sdtm.oak} - Open-source SDTM Automation Vision

Modular Programming

```
cm_raw <- read.csv(system.file("raw_data/cm_raw_data.csv",
  package = "sdtm.oak"
)) %>%
  generate_oak_id_vars(
    pat_var = "PATNUM",
    raw_src = "cm_raw"
  )

dm <- read.csv(system.file("raw_data/dm.csv",
  package = "sdtm.oak"
))

# Create CM domain. The first step in creating CM domain is to create the topic variable

cm <-
  # Derive topic variable
  assign_no_ct(
    raw_dat = cm_raw,
    raw_var = "MDRAW",
    tgt_var = "CMTRT"
  ) %>%
  # Derive CMGRPID
  assign_no_ct(
    raw_dat = cm_raw,
    raw_var = "MDNUM",
    tgt_var = "CMGRPID",
    id_vars = oak_id_vars()
  ) %>%
  # DERIVE CMINDC
  assign_no_ct(
    raw_dat = cm_raw,
    raw_var = "MDIND",
    tgt_var = "CMINDC",
    id_vars = oak_id_vars()
  ) %>%
  # Derive CMSTDTC. This function calls create_iso8601
  assign_datetime(
    raw_dat = cm_raw,
    raw_var = c("MDBDR", "MDBTM"),
    tgt_var = "CMSTDTC",
    raw_fmt = c(list(c("d-m-y", "dd mmm yyyy")), "H:M"),
    raw_unk = c("UN", "UNK")
  ) %>%
  # Derive qualifier CMSTRTPT  Annotation text is If MDPRIOR == 1 then CM.CMSTRTPT = 'BEFORE'
  hardcode_ct(
```

Create SDTM spec & automate

Prepare SDTM Spec in the format {sdtm.oak} expects

```
library(sdtm.oak)

cm <- create_domain(
        domain = ”cm",
        spec = ”~/study_sdtm_spec.csv",
        ct = "~/study_ct.csv")
```

Initial focus is to develop {sdtm.oak} and pave way for SDTM programming in R.

{sdtm.oak} – Upcoming Events

- Oct 24th- 25th - BBSW (Bay Area BioTech Pharma Workshop)
- Oct 28th - Virtual Workshop at R in Pharma
- Q1-2025 - CDISC Hackathon event
- Q1-2025 - PHUSE Connect (Tentative)

{sdtm.oak} – Roadmap

- Functions to create the DM domain.
- User Feedback.
- Explore pathways for automation/code generation (LLM) based on a standard spec.
- Metadata driven unit conversions for applicable like LB, MB, PC, IS
- Explore approaches to handle QS domain

{sdtm.oak}
How to stay connected?

R package developers, Testers,
SDTM SMEs

Slack - oakgarden.slack.com

GitHub -

https://github.com/pharmaverse/sdtm.oak

Open to everyone to try {sdtm.oak} V0.1 and share your feedback in Slack or GitHub.

Thanks to Volunteers – Top Code/Review Contributors

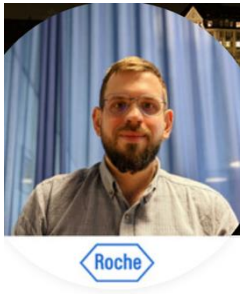
Rammprasad Ganapathy – Roche/Genentech

Ramiro Magno – Director Pattern Institute / Research Software Engineer

Kamil Sijko - TTSI

Rosemary Li – Roche/Genentech

Edgar Manukyan – Roche/Genentech



Adam Forys – Roche/Genentech

Venkata Maguluri – Pfizer
Yogesh Gupta – Pfizer
Preetesh Parikh – Pfizer
Aditya Parankusham – GSK
Susheel Arkala – Vertex
Phani Tata - Bayer
Omar Garcia – CDISC
Charles Shadle - CDISC

Thank You!