

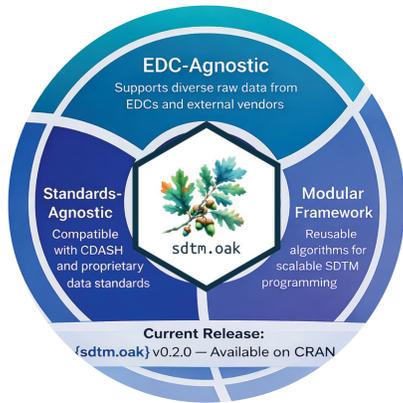
R You Ready for SDTM? Let {sdtm.oak} Do the Heavy Lifting



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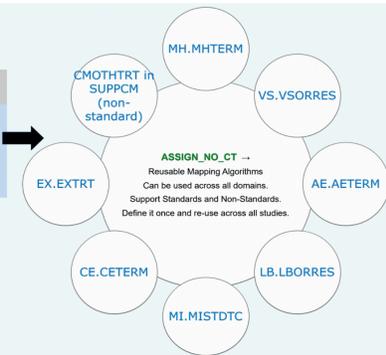
What is {sdtm.oak}?

Open-Source R Package - A flexible and modular solution for automating SDTM dataset creation in R.



Sample Algorithms

Algorithm	Description
<code>assign_no_ct</code>	One-to-one mapping between the raw source and a target variable with controlled terminology restrictions.
<code>assign_datetime</code>	One-to-one mapping between the raw source and a target variable that involves a date or time or datetime component.
<code>condition_add</code>	Filtering the source data and/or target domain based on a condition.

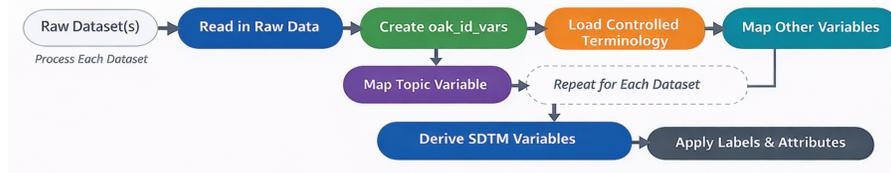


Concept

- {sdtm.oak} aligns closely with core SDTM concepts.
- Enables step-by-step SDTM programming in R by mapping topic variables and qualifiers
- Uses a generic workflow across SDTM domains (Events, Interventions, Findings)
- Designed with strong potential for automation (e.g., Roche-like implementations)



Programming Workflow



```

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 CMSTRPT Annotation text is IF MDPRIOR == 1 then CM.CMSTRPT = 'BEFORE'
hardcode_ct(
  raw_dat = condition_add(cm_raw, MDPRIOR == "1"),
  raw_var = "MDPRIOR",
  tgt_var = "CMSTRPT",
  tgt_val = "BEFORE",
  ct_spec = study_ct,
  ct_clst = "C66728",
  id_vars = oak_id_vars()
) %>%
# Derive qualifier CMSTTPT Annotation text is IF MDPRIOR == 1 then CM.CMSTTPT = 'SCREENING'
hardcode_no_ct(
  raw_dat = condition_add(cm_raw, MDPRIOR == "1"),
  raw_var = "MDPRIOR",
  tgt_var = "CMSTTPT",
  tgt_val = "SCREENING",
  id_vars = oak_id_vars()
)
    
```

Core Concept: Reusable Algorithms

Mappings transforming the collected source data into the target SDTM data model are grouped into algorithms

- Backbone of {sdtm.oak}
- R functions to represent each algorithm



Roadmap

Reference Date Variables

Metadata Automation

EPOCH Derivation

Standard Units & Results

SUPP Domains

CDISC eCRF Portal

About the package

- Sponsored by **CDISC COSA**, pharmaceutical companies, including **Roche, Pfizer, GSK, Vertex, Atorus Research, Pattern Institute, Transition Technologies Science**
- Part of the Pharmaverse Group of packages
- Inspired by the Roche's {roak} package

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