CDISC WEBINAR

Modular by Design: The Admiral S
Transparent ADaM Programming.

Revolution ADaM creation across the industry by bringing companies together to develop one harmonized solution

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Agenda


What is Admiral?
1.
Why use Admiral?
2.
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4.

What is admiral about?

Admiral is an **open source modularized** toolbox that enables companies and communities to develop ADaM datasets in R.

Think of admiral as a toolbox of modular blocks (toolbox of R functions)

- Each block has a **stand alone purpose** (each function provides a specific functionality)
- Data Scientists can **create their own blocks** (create own R functions)

Constructing an ADaM dataset should become like building out of blocks that are based on admiral modular functions and user-created modular functions.

Why admiral?

Admiral does not exist in a vacuum.

It is the critical engine in the modern clinical data pipeline.

Across the pharmaceutical industry we all face the same challenge when it comes to analysis and creating ADaMdatasets!

- We all work on our own “standard solutions” for ADaMs
- We all face the challenge of a changing and novel data landscape
- New therapeutic areas and analysis concepts
- Individual “blackbox” solutions instead re-use , co-creation and sharing
- We tend to see siloed and hierarchical approaches as more efficient

SDTMv:
Standardized source data.

ADaM (Admiral):
The derivation layer where analysis-ready datasets are built.

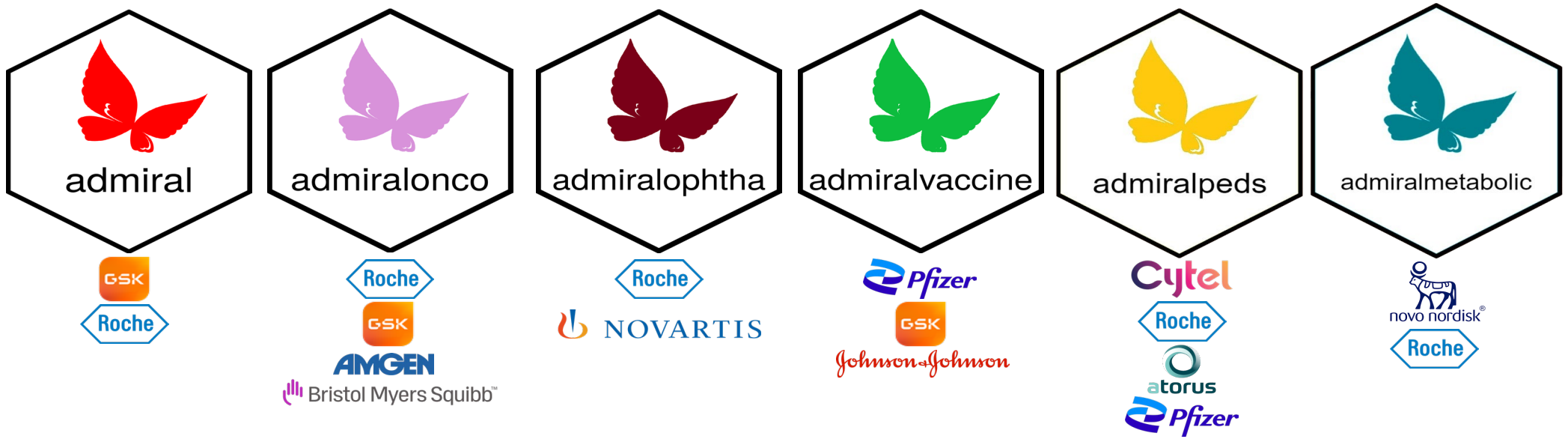
TLG:
The final output for submission.

Moving beyond silos

The industry shift

Historically, every pharma company maintained proprietary, internal SAS macro libraries to do the exact sa
thing.

The New Standard : We now compete on science, but collaborate on utilities. Admiral is co-developed by Roche, GSK, J&J, and others to create a single, robust standard for everyone.

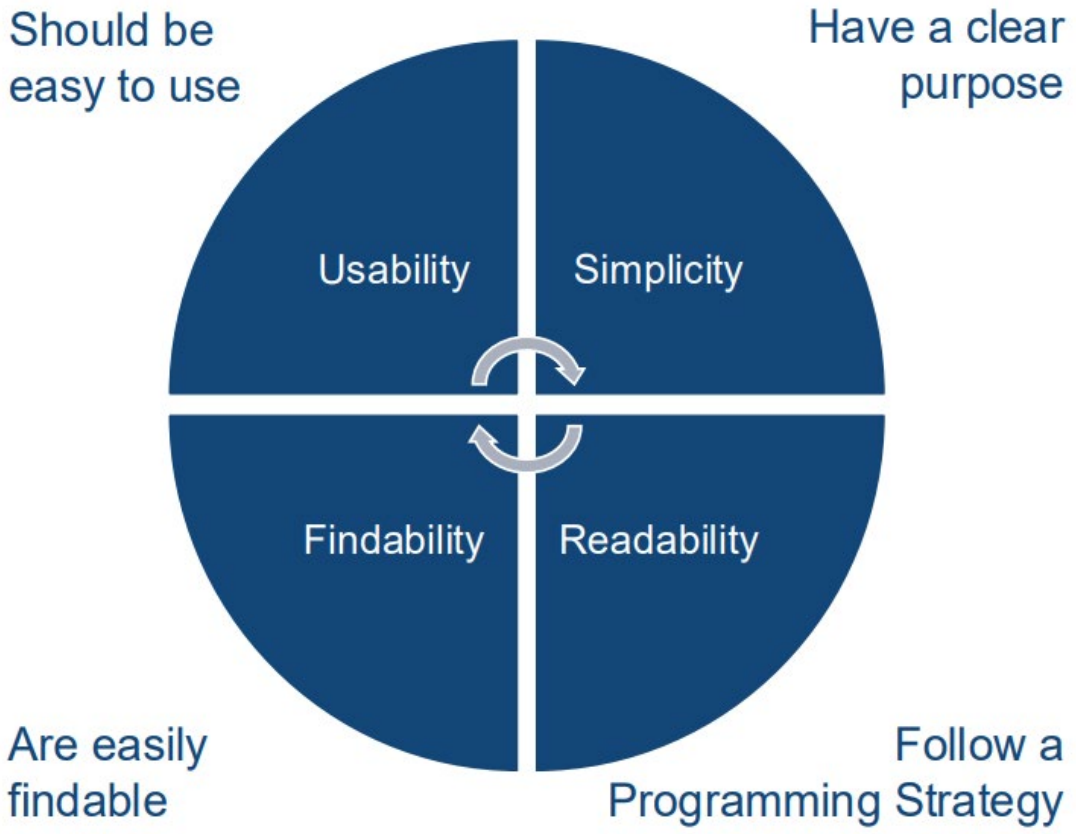


Admiral core values

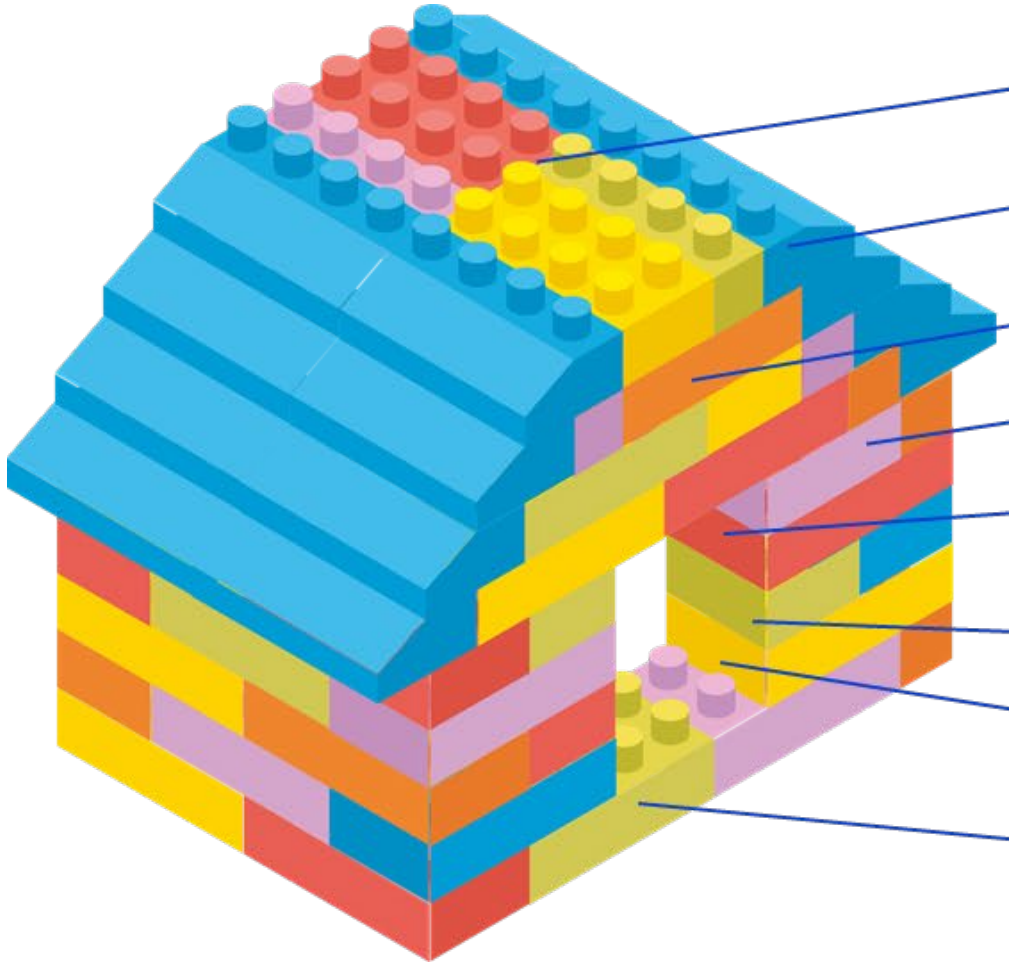
Not a black box, but a modular toolbox

Unlike rigid legacy macros that force an "all-nothing" approach, Admiral functions act like precision tools.

You pick exactly the tool you need for the specific derivation at hand.



Programming flow examples: ADSL



- Add Labels and Attributes
- Derive Other Variables
- Derive Groupings and Populations
- Derive Death Variables (DTHDT, DTHCAUS, LSTALVDT)
- Derive Disposition Variables (EOSDT, DCSREAS, DCSREASP)
- Derive/Impute Date/Time and Duration
- Derive Period, Subperiod, Phase, and Treatment Variables
- Read in Data, load ADSL template

https://pharmaverse.r-universe.dev/articles/admiral/adsl.html

Your essential toolkit

The derivation engine

These 4 functions cover 80% of daily ADaM programming tasks:

- derive_vars_dt():

Character ISO dates (DTC) to numeric (DT).

- derive_vars_merged():

The workhorse for joins (like SQL JOIN).

- derive_vars_merged_lookup():

Maps codes (e.g., VSTESTCD → PARAMCD).

- derive_param_computed():

Creates new parameter rows (e.g., BMI).

The "piping" Paradigm

```
# Readable data flow
adlb %>%
  derive_vars_dt     (DTC) %>%
  derive_vars_dy     (ref_date = TRTSDT) %>%
  derive_anrind     ( ... ) %>%
  add_labels    ()
```

Programming flow examples: ADVS

- Read in Data
- Derive/Impute Numeric Date/Time and Analysis Day (ADT, ADTM, ADY, ADTF, ATMF)
- Assign PARAMCD, PARAM, PARAMN, PARCAT1
- Derive Results (AVAL, AVALC)
- Derive Additional Parameters (e.g. BSA, BMI, or MAP for ADVS)
- Derive Timing Variables (e.g. APHASE, AVISIT, APERIOD)
- Timing Flag Variables (e.g. ONTRTFL)
- Assign Reference Range Indicator (ANRIND)
- Derive Baseline (BASETYPE, ABLFL, BASE, BASEC, BNRIND)
- Derive Change from Baseline (CHG, PCHG)
- Derive Shift (e.g.SHIFT1)
- Derive Analysis Ratio (e.g. R2BASE)
- Derive Analysis Flags (e.g. ANL01FL)
- Derive Criterion Variables (CRITy, CRITyFL, CRITyFN)
- Derive New Rows
- Assign ASEQ
- Add ADSL variables
- Add Labels and Attributes

https://pharmaverse.r-universe.dev/articles/admiral/bds_finding.html

Programming flow examples: ADVS

Read in Data

To start, all data frames needed for the creation of `ADVS` should be read into the environment. This will be a company specific process.

For example purpose, the CDISC Pilot SDTM and ADaM datasets—which are included in `{pharmaversesdtm}`—are used.

```
library(admiral)
library(dplyr, warn.conflicts = FALSE)
library(pharmaversesdtm)
library(lubridate)
library(stringr)
library(tibble)

vs <- pharmaversesdtm::vs
adsl <- admiral::admiral_adsl
vs <- convert_blanks_to_na(vs)
```

Join `ADSL` to `VS` domain.

```
adsl_vars <- exprs(TRTSDT, TRTEDT, TRT

advs <- derive_vars_merged(vs,
  dataset_add = adsl,
  new_vars = adsl_vars,
  by_vars = exprs(STUDYID, USUBJID))
```

USUBJID	VSTESTCD	VSDTC	VISIT	TRTSDT	TRTEDT	TRT01A	TRT01P
01-701-1015	DIABP	2014-01-16	WEEK 2	2014-01-02	2014-07-02	Placebo	Placebo
01-701-1015	DIABP	2014-01-16	WEEK 2	2014-01-02	2014-07-02	Placebo	Placebo
01-701-1015	DIABP	2014-01-16	WEEK 2	2014-01-02	2014-07-02	Placebo	Placebo
01-701-1023	DIABP	2012-08-27	WEEK 2	2012-08-05	2012-09-01	Placebo	Placebo
01-701-1023	DIABP	2012-08-27	WEEK 2	2012-08-05	2012-09-01	Placebo	Placebo
01-701-1023	DIABP	2012-08-27	WEEK 2	2012-08-05	2012-09-01	Placebo	Placebo
01-703-1086	DIABP	2012-09-16	WEEK 2	2012-09-02	2012-12-04	Xanomeline Low Dose	Xanomeline Low Dose
01-703-1086	DIABP	2012-09-16	WEEK 2	2012-09-02	2012-12-04	Xanomeline Low Dose	Xanomeline Low Dose
01-703-1086	DIABP	2012-09-16	WEEK 2	2012-09-02	2012-12-04	Xanomeline Low Dose	Xanomeline Low Dose
01-703-1096	DIABP	2013-02-09	WEEK 2	2013-01-25	2013-03-16	Placebo	Placebo

Programming flow examples: ADVS

Derive/Impute Numeric Date and Analysis Day (`ADT`, `ADY`, `ADTF`, `ATMF`)

1. The function `derive_vars_dt()` can be used to derive `ADT`.

```
advs <- derive_vars_dt(advs,

new_vars_prefix = "A", dtc = VSDTC)
```

2. If imputation is needed and the date is to be imputed to the first of the month, the call would be:

```
advs <- derive_vars_dt(advs,
  new_vars_prefix = "A",
  dtc = VSDTC,
  highest_imputation = "M")
```

3. Once `ADT` is derived, the function `derive_vars_dy()` can be used to derive `ADY`.

```
advs <- derive_vars_dy(advs,
  reference_date = TRTSDT,
  source_vars = exprs(ADT))
```

USUBJID	VISIT	VSDTC	ADT
01-701-1015	SCREENING 1	2013-12-26	2013-12-26
01-701-1015	SCREENING 1	2013-12-26	2013-12-26
01-701-1015	SCREENING 1	2013-12-26	2013-12-26
01-701-1015	SCREENING 2	2013-12-31	2013-12-31
01-701-1015	SCREENING 2	2013-12-31	2013-12-31
01-701-1015	SCREENING 2	2013-12-31	2013-12-31

USUBJID	VISIT	VSDTC	ADT	ADTF
01-716-1024	SCREENING 1	2012-07	2012-07-01	D
01-716-1024	SCREENING 1	2012-07	2012-07-01	D
01-716-1024	SCREENING 1	2012-07	2012-07-01	D

USUBJID	VISIT	ADT	ADY	TRTSDT
01-716-1024	SCREENING 1	2012-07-06	-3	2012-07-09
01-716-1024	SCREENING 1	2012-07-06	-3	2012-07-09
01-716-1024	SCREENING 1	2012-07-06	-3	2012-07-09
01-716-1024	SCREENING 2	2012-07-07	-2	2012-07-09
01-716-1024	SCREENING 2	2012-07-07	-2	2012-07-09
01-716-1024	SCREENING 2	2012-07-07	-2	2012-07-09
01-716-1024	BASELINE	2012-07-09	1	2012-07-09
01-716-1024	BASELINE	2012-07-09	1	2012-07-09
01-716-1024	BASELINE	2012-07-09	1	2012-07-09
01-716-1024	AMBUL ECG PLACEMENT	2012-07-22	14	2012-07-09

Programming flow examples: ADVS

Assign `PARAMCD`, `PARAM`, `PARAMN`, `PARCAT1`

1. To assign parameter level values such as `PARAMCD`, `PARAM`, `PARAMN`, `PARCAT1`, etc., a lookup can be created to join to the source data.

For example, when creating `ADVS`, a lookup based on the SDTM `--TESTCD` value may be created:

2. This lookup may now be joined to the source data:

```
advs <- derive_vars_merged_lookup(
  advs,
  dataset_add = param_lookup,
  new_vars = exprs(PARAMCD),
  by_vars = exprs(VSTESTCD)
)
```

* Please note, it may be necessary to include other variables in the join. For example, perhaps the `PARAMCD` is based on `VSTESTCD` and `VSPOS`, it may be necessary to expand this lookup or create a separate look up for `PARAMCD`.

VSTESTCD	PARAMCD	PARAM	PARAMN	PARCAT1	PARCAT1N
HEIGHT	HEIGHT	Height (cm)	1	Subject Characteristic	1
WEIGHT	WEIGHT	Weight (kg)	2	Subject Characteristic	1
DIABP	DIABP	Diastolic Blood Pressure (mmHg)	3	Vital Sign	2
MAP	MAP	Mean Arterial Pressure	4	Vital Sign	2
PULSE	PULSE	Pulse Rate (beats/min)	5	Vital Sign	2
SYSBP	SYSBP	Systolic Blood Pressure (mmHg)	6	Vital Sign	2
TEMP	TEMP	Temperature (C)	7	Vital Sign	2

USUBJID	VSTESTCD	PARAMCD
01-701-1015	DIABP	DIABP
01-701-1015	HEIGHT	HEIGHT
01-701-1015	PULSE	PULSE
01-701-1015	SYSBP	SYSBP
01-701-1015	TEMP	TEMP
01-701-1015	WEIGHT	WEIGHT
01-701-1023	DIABP	DIABP
01-701-1023	HEIGHT	HEIGHT
01-701-1023	PULSE	PULSE
01-701-1023	SYSBP	SYSBP

Programming flow examples: ADVS

Derive New Rows

Use function `derive_param_computed()` to create a new `PARAMCD`. Below is an example of creating `Mean Arterial Pressure` (`PARAMCD = MAP2`) with an alternative formula.

```
advs <- derive_param_computed(advs,
  by_vars = exprs(USUBJID, VISIT, ATPT),
  parameters = c("SYSBP", "DIABP"),
  set_values_to = exprs(AVAL = (AVAL.SYSBP - AVAL.DIABP) / 3 + AVAL.DIABP,
  PARAMCD = "MAP2", PARAM = "Mean Arterial Pressure 2 (mmHg)"))
```

USUBJID	PARAMCD	VISIT	ATPT	AVAL
01-701-1015	DIABP	AMBUL ECG PLACEMENT	AFTER LYING DOWN FOR 5 MINUTES	67.00000
01-701-1015	MAP2	AMBUL ECG PLACEMENT	AFTER LYING DOWN FOR 5 MINUTES	90.33333
01-701-1015	SYSBP	AMBUL ECG PLACEMENT	AFTER LYING DOWN FOR 5 MINUTES	137.00000
01-701-1015	DIABP	AMBUL ECG PLACEMENT	AFTER STANDING FOR 1 MINUTE	61.00000
01-701-1015	MAP2	AMBUL ECG PLACEMENT	AFTER STANDING FOR 1 MINUTE	83.00000
01-701-1015	SYSBP	AMBUL ECG PLACEMENT	AFTER STANDING FOR 1 MINUTE	127.00000
01-701-1015	DIABP	AMBUL ECG PLACEMENT	AFTER STANDING FOR 3 MINUTES	65.00000
01-701-1015	MAP2	AMBUL ECG PLACEMENT	AFTER STANDING FOR 3 MINUTES	92.00000
01-701-1015	SYSBP	AMBUL ECG PLACEMENT	AFTER STANDING FOR 3 MINUTES	146.00000
01-701-1015	DIABP	AMBUL ECG REMOVAL	AFTER LYING DOWN FOR 5 MINUTES	72.00000

Ready to build?

pharmaverse.github.io/admiral

Your single source of truth for all documentation.

Thank you.

Reference

Admiral R-universe Package
https://pharmaverse.r-universe.dev/admiral

CRAN Release Documentation
https://pharmaverse.github.io/admiral/cran-release/

Admiral GitHub Repository
https://pharmaverse.github.io/admiral/cran-release/

ADSL Guide
https://pharmaverse.r-universe.dev/articles/admiral/adsl.html

BDS Finding Guide
https://pharmaverse.r-universe.dev/articles/admiral/bds_finding

Pharmaverse Slack
https://pharmaverse.r-universe.dev/admiral