More Science, Less Bookkeeping: Our Path to Hyper-Efficient ADaM Program Generation via AI, Process Improvements, and Good Old-Fashioned Programming

SM04
PHUSE EU Connect 2025

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Novo Nordisk A/S
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Views and opinions expressed are those of the speakers and not necessarily Novo Nordisk

The **mighty** team

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Michael Hedegaard Thomsen

Matthew Phelps

Aksel Thomsen

What's the problem?

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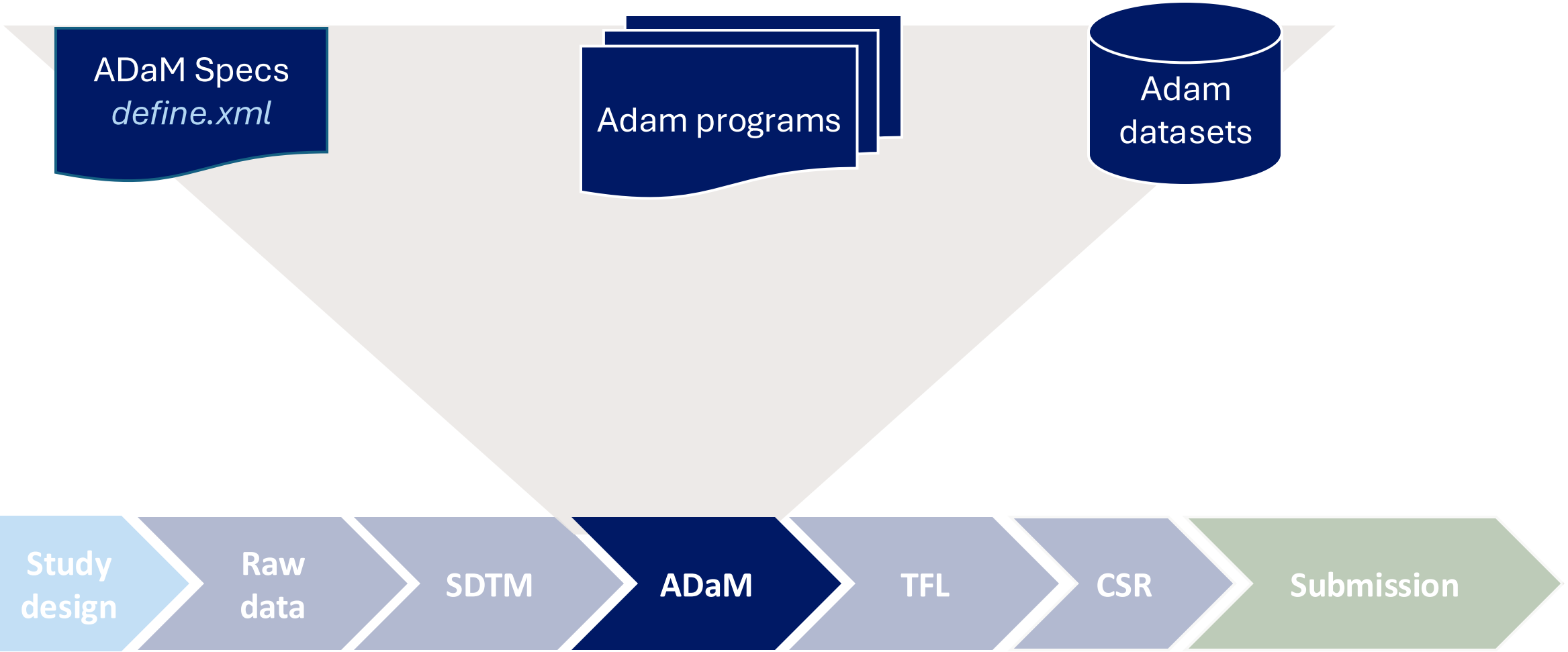
Study design → Raw data → CSR → Submission

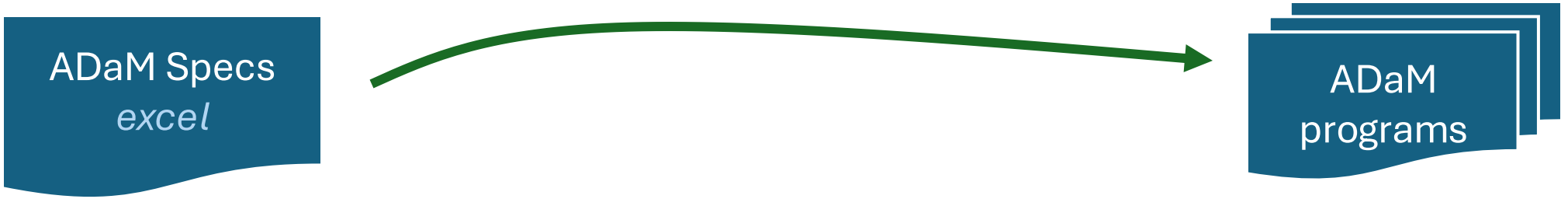
What's the problem?


Study design
Raw data
SDTM
ADaM
TFL
CSR
Submission

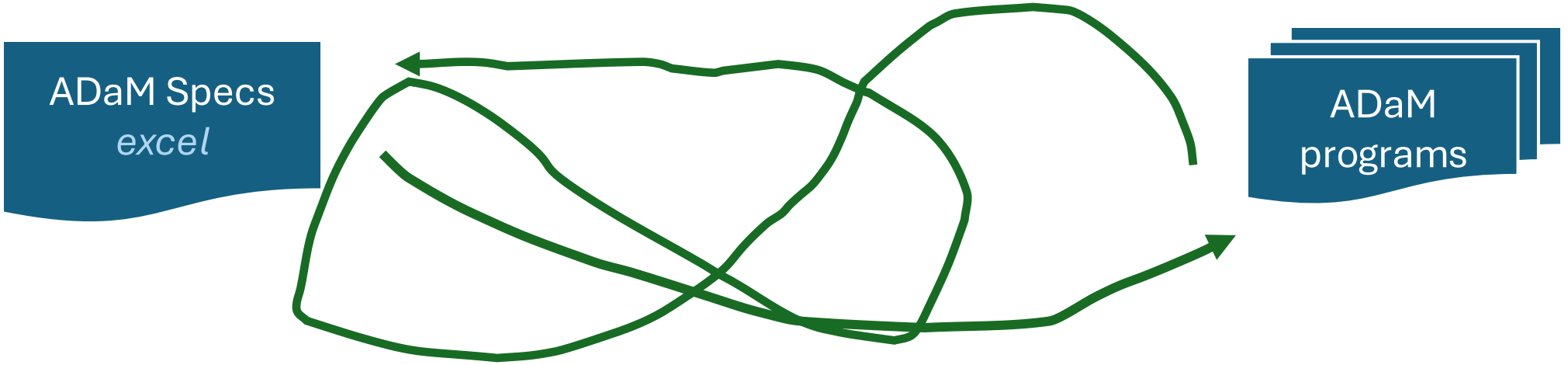
~1.7 → ~1.0


ADaM Specs
define.xml
Adam programs
Adam datasets
Study design
Raw data
SDTM
ADaM
TFL
CSR
Submission

Current state of ADaM programming



Current state of ADaM programming



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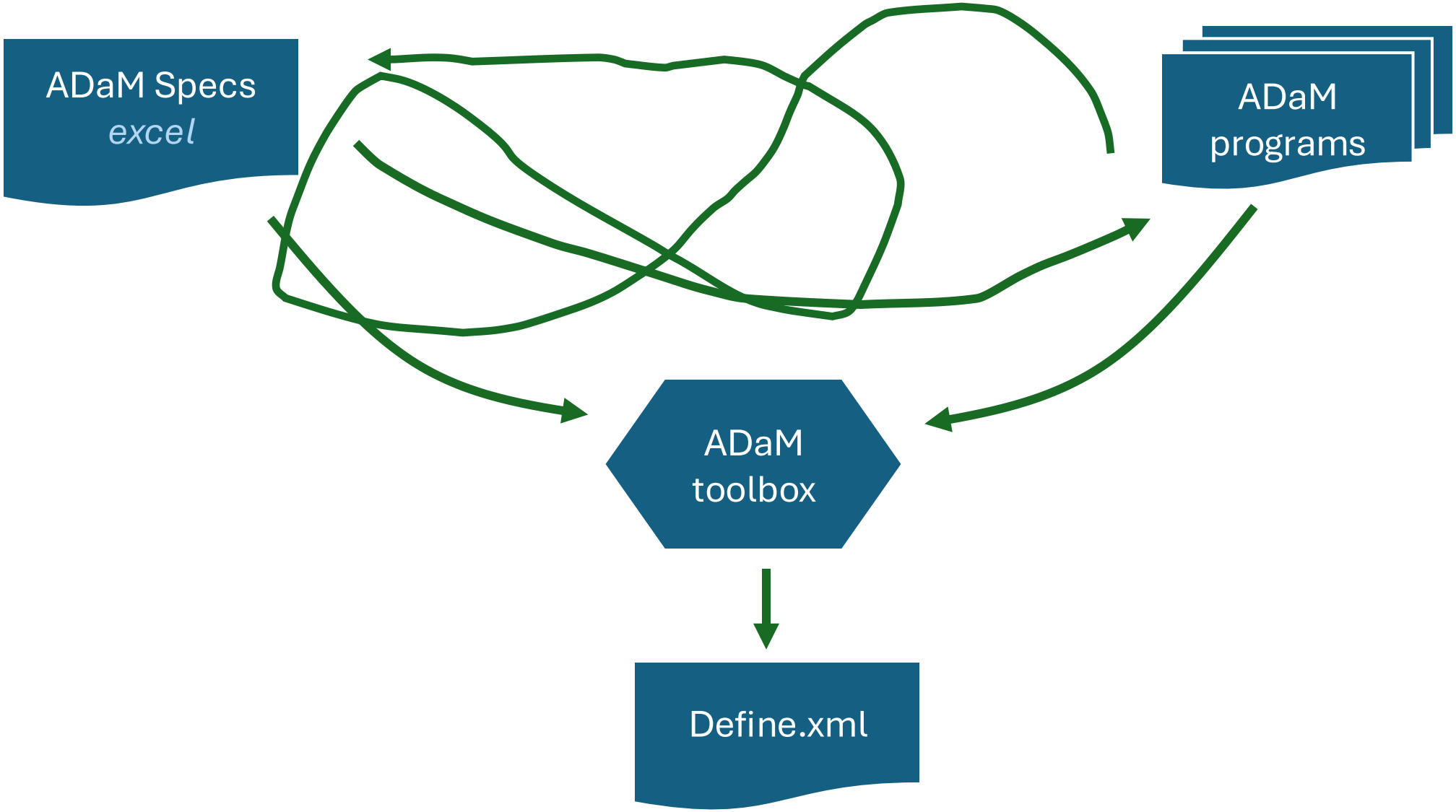

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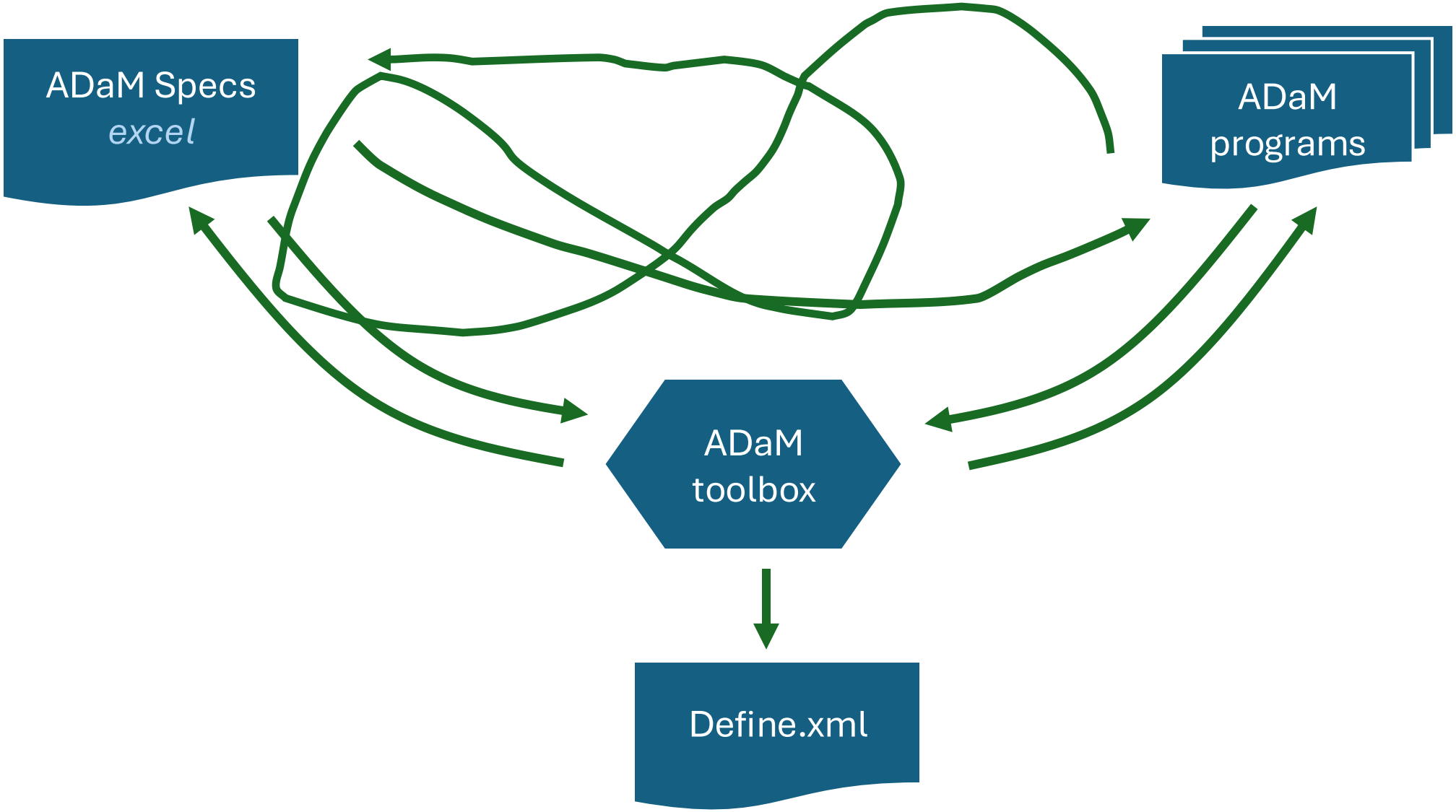

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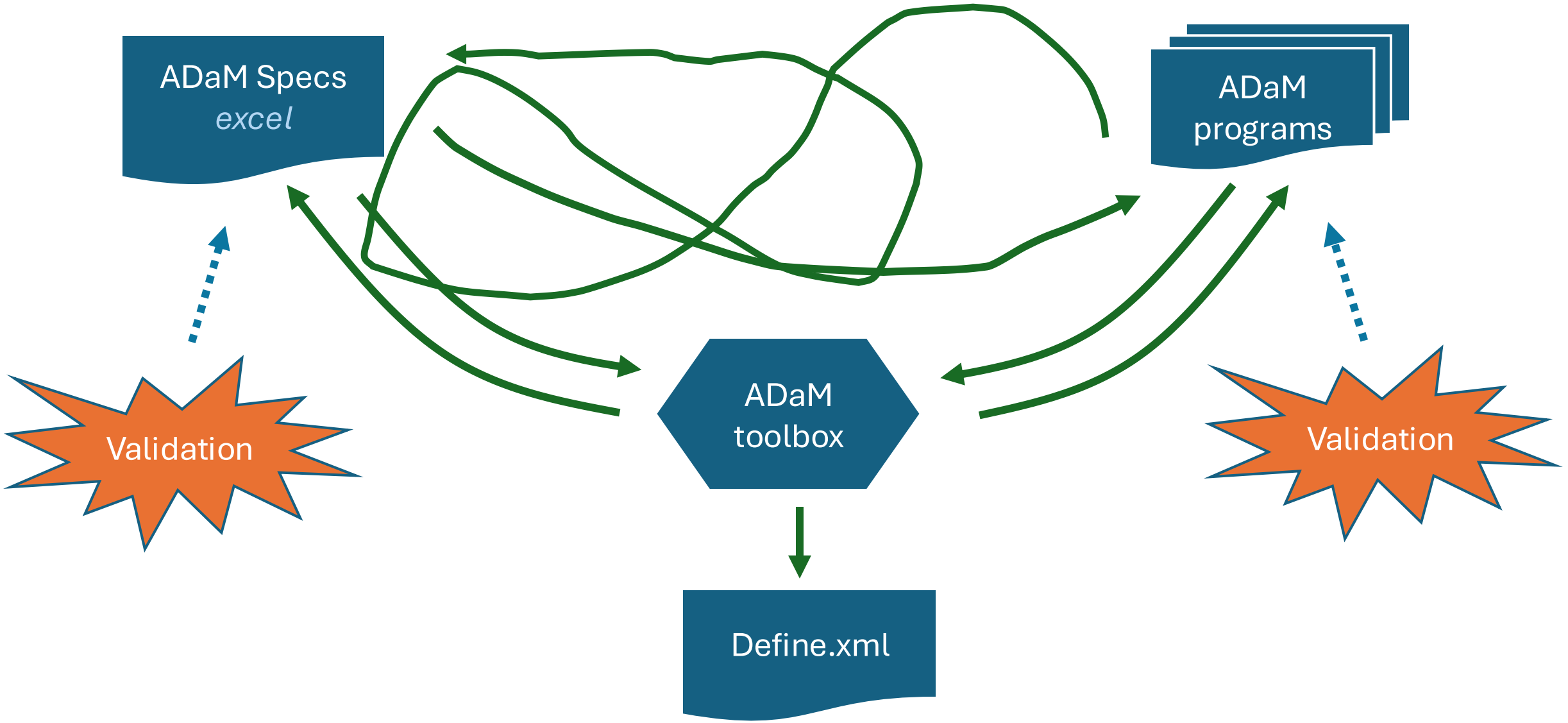

Summary of problems

- Multiple sources of truth

Summary of problems

- Multiple sources of truth
- Inefficient validation

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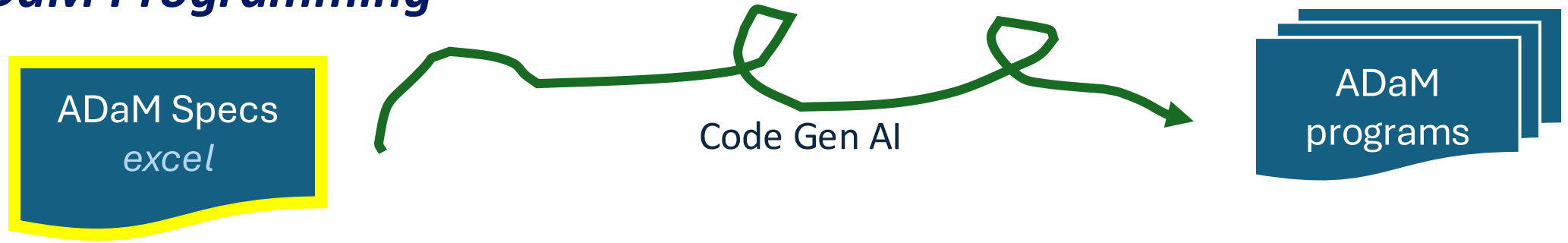
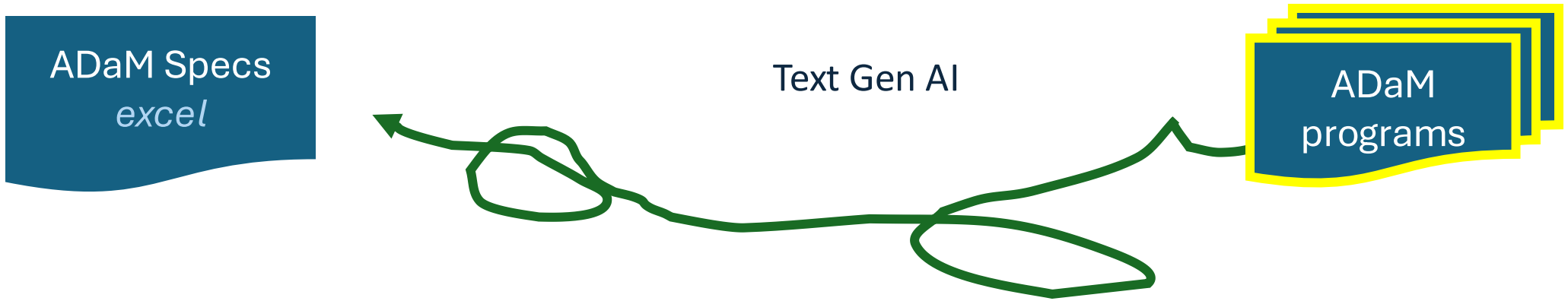
- Lack of standards

ADaM Programming





Summary of LLM-based approach

- Multiple sources of truth

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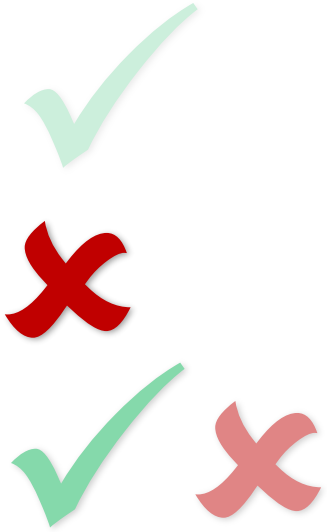

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- Inefficient validation
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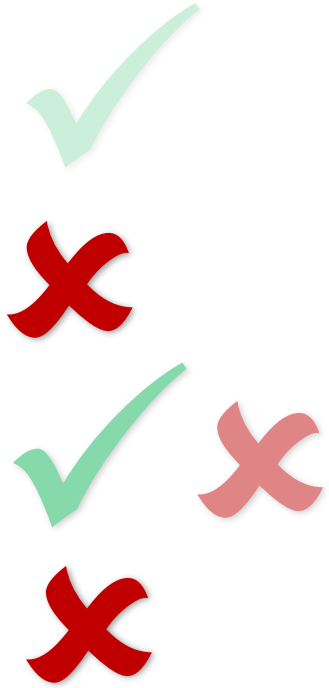

ADaM specification

- ✓ Predecessors
- ✓ Derivations
- ✓ Imputations
- ✓ Derived parameters
- ✓ …

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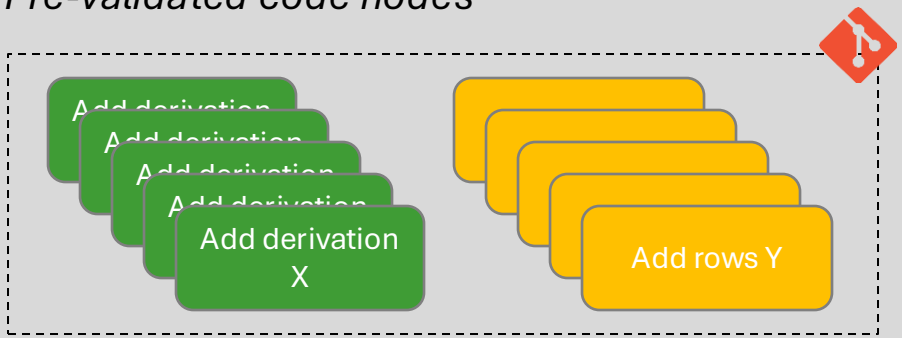
Pre-validated code nodes



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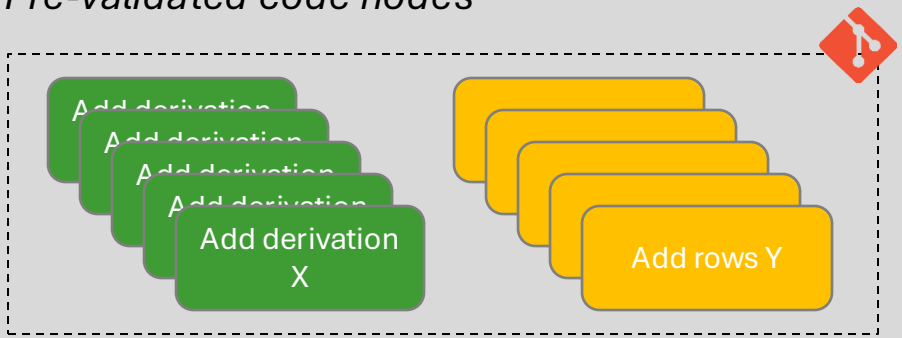
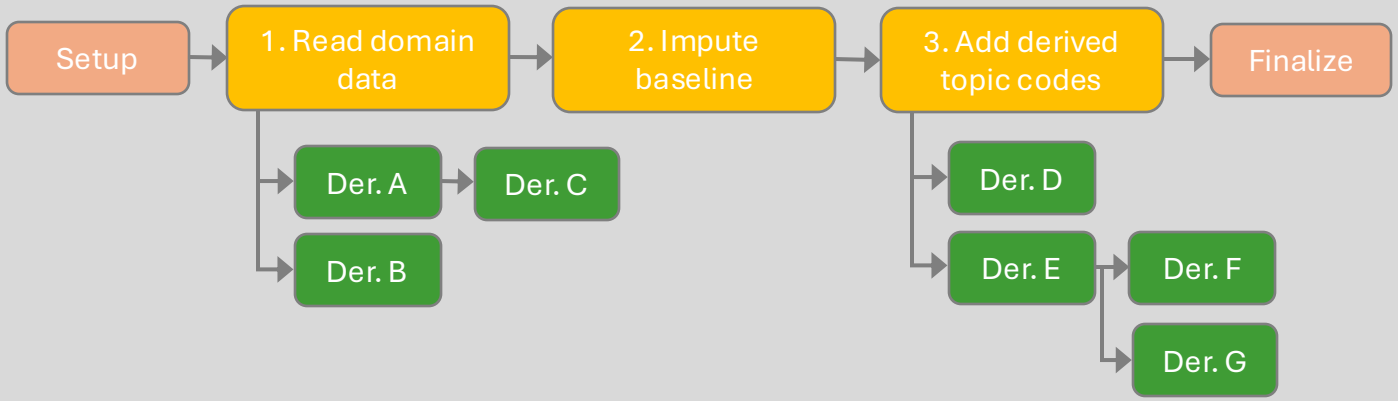


Code dependency graph (example)



ADaM specification

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Pre-validated code nodes

Add derivation X

Add rows Y

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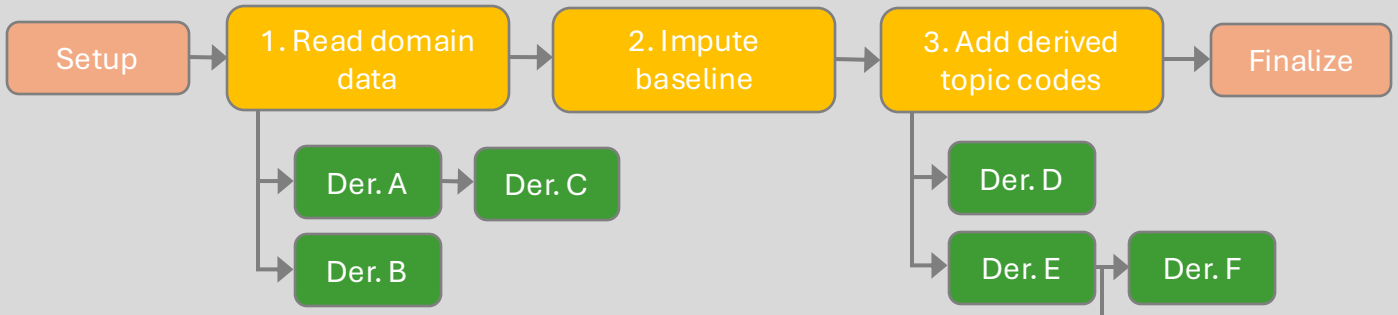
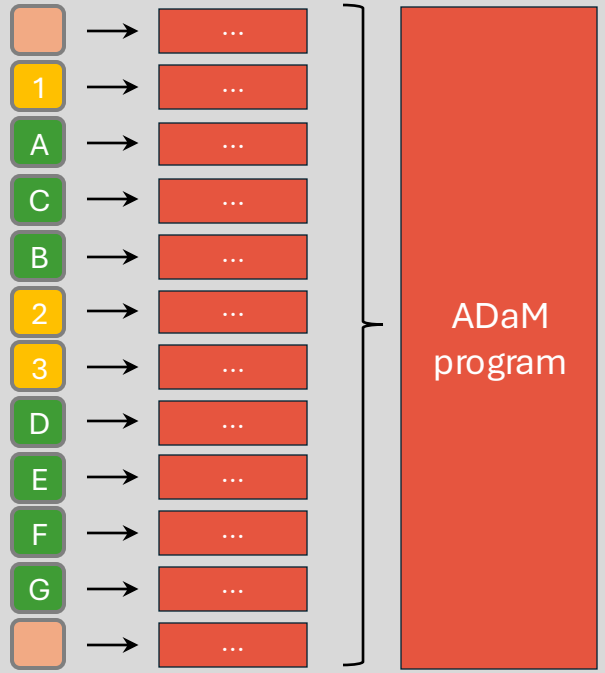


Generate program



ADaM specification

- ✓ Predecessors
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- ✓ Derived parameters
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Pre-validated code nodes

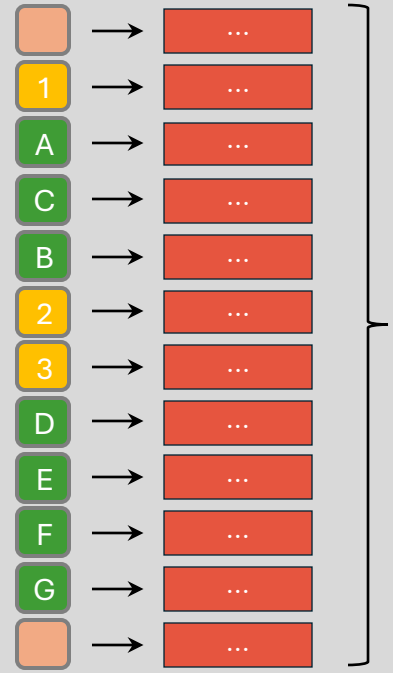
Add derivation X

Add rows Y

define.xml

ADaM table

Generate program



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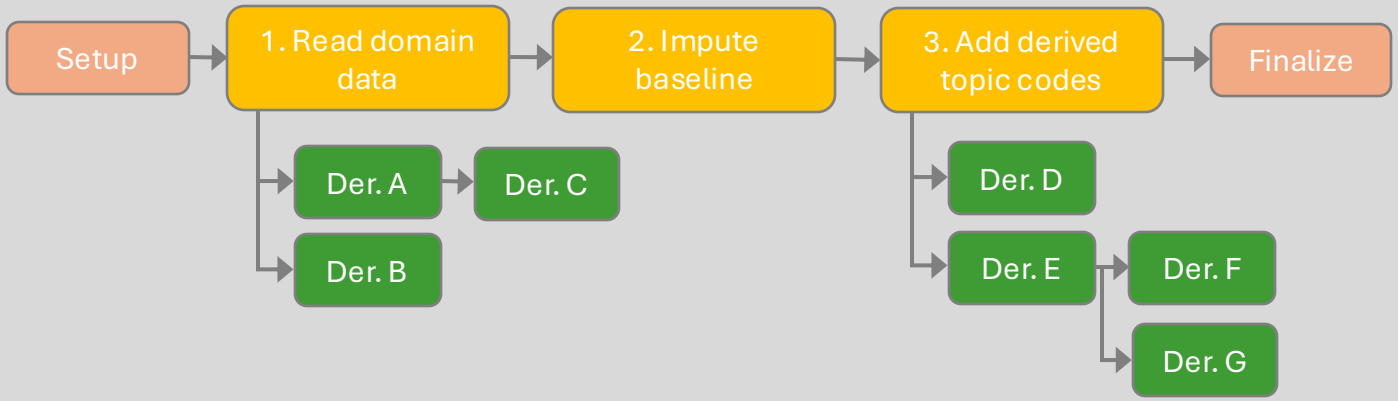

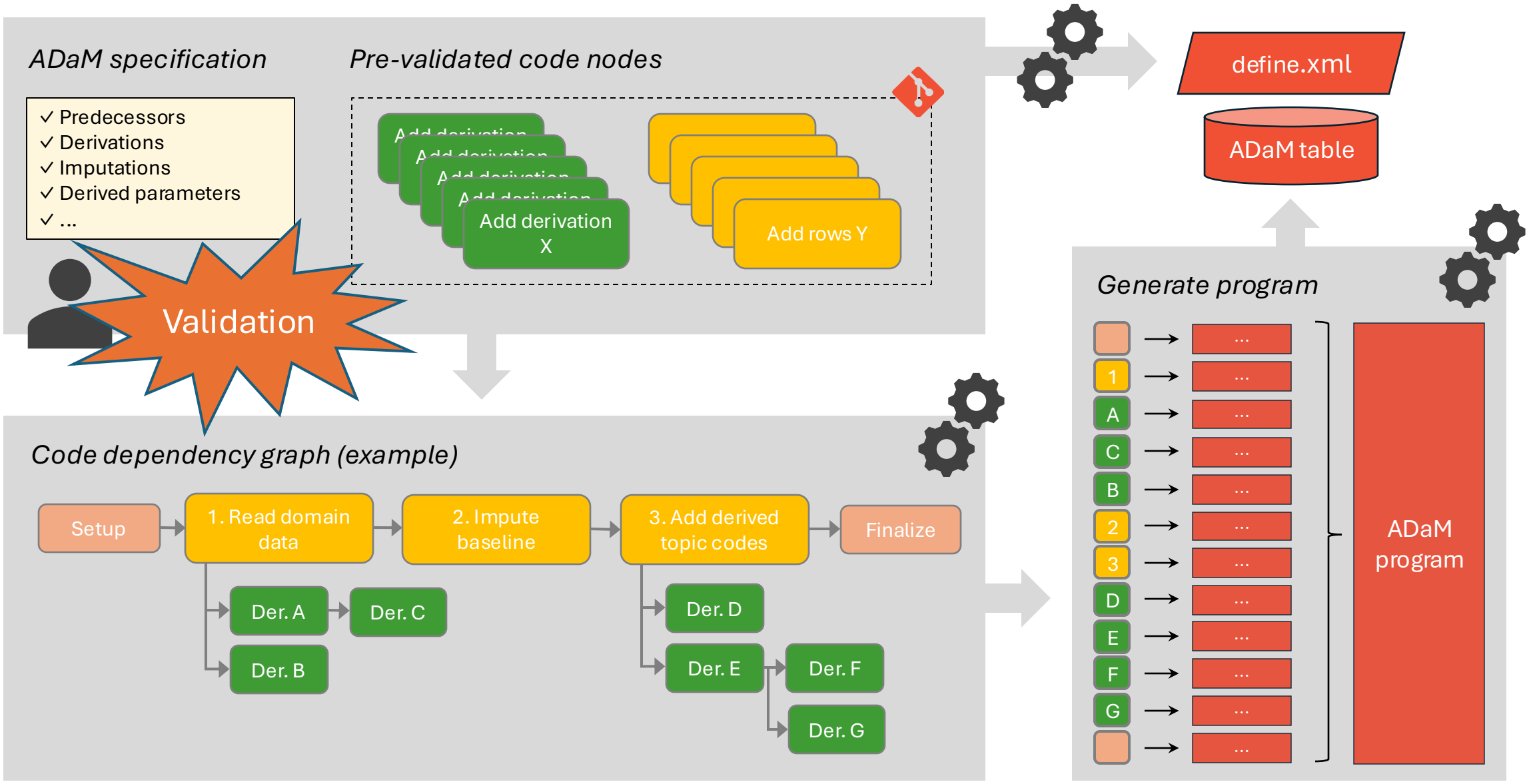
ADaM specification
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✓ ...
Validation
Pre-validated code nodes
Add derivation X
Add rows Y
define.xml
ADaM table
Generate program
ADaM program
Code dependency graph (example)
Setup
1. Read domain data
2. Impute baseline
3. Add derived topic codes
Finalize
Der. A
Der. C
Der. B
Der. D
Der. E
Der. F
Der. G

```
{{self}} <- .self |>
  dplyr::mutate(
    {{variable}} = admiral::compute_duration(
      start_date = TRTSDT,
      end_date = {{date}},
      in_unit = "days",
      out_unit = "days",
      add_one = TRUE
    )
  )
```

ADY

```
adlb <- exmapleFunction(
d_datain = bind_rows(
adlb_11_homair,
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), v_dtvar = "LBDTC",
v_dtout = "ADT")
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LBDTC

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ADLB <- ADLB |>
dplyr::mutate(
ADT = admiral::convert_dtc_to_dt(
dtc = LBDTC, highest_imputation = "M",
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ADT

```
ex %>%
 mutate(EXSTD = ymd(EXSTDTC)) %>%
 filter(!is.na(EXSTD)) %>%
 group_by(USUBJID) %>%
 summarise(TRTSDT = min(EXSTD), .groups = "drop")
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TRTSDT

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base_pick <- base_candidates %>%
group_by(USUBJID, PARAMCD) %>%
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arrange(., ADT, ADTM, .row_id, .by_group = TRUE) %>%
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transmute(USUBJID, PARAMCD, BASE = AVAL, BASEDT = ADT)
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BASE

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Standards repo

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Standards repo

Study repo

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Standards repo

```
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  BASE:
    code_id: base_std

  ADY:
    code_id: ady_std
```

Study repo

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  ADY:
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ADY

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    code_id: base_std
  ADY:
    code_id: ady_std
```

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```

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.self <- .self |>
 dplyr::mutate(
  {{variable}} = admiral::compute_duration(
   start_date = TRTSDT,
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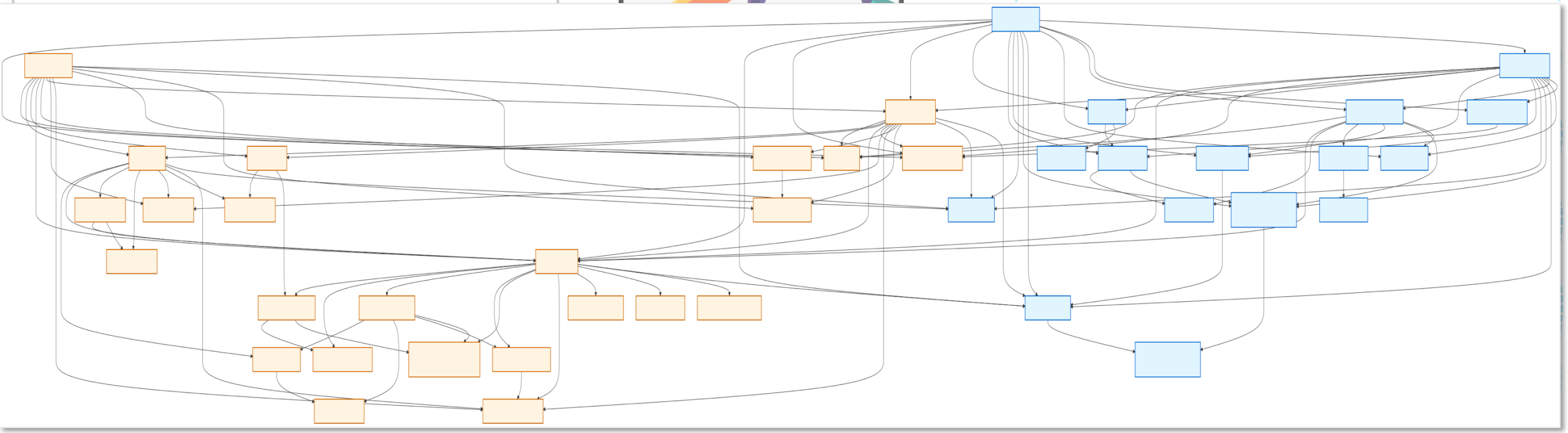
d_datain = bind_rows(
adlb_11_homair,
adlb_11_leptin
), v_dtvar = "LBDTC",
v_dtout = "ADT")
```

LBDTC

```
ADLB <- ADLB |>
dplyr::mutate(
ADT = admiral::convert_dtc_to_dt(
dtc = LBDTC, highest_imputation = "M",
date_imputation = "mid"),
ADTF = admiral::compute_dtf(
dtc = LBDTC, dt = ADT)
```

ADT

```
column:
  ADT:
    code_id: adt_std
  BASE:
    code_id: base_std
  ADY:
    code_ide: ady_std
```



```
.self <- .self |>
 dplyr::mutate(
  {{variable}} = admiral::compute_duration(
   start_date = TRTSDT,
   end_date = {{date}},
   in_unit = "days",
   out_unit = "days",
   add_one = TRUE
  )
 )
```

ADY

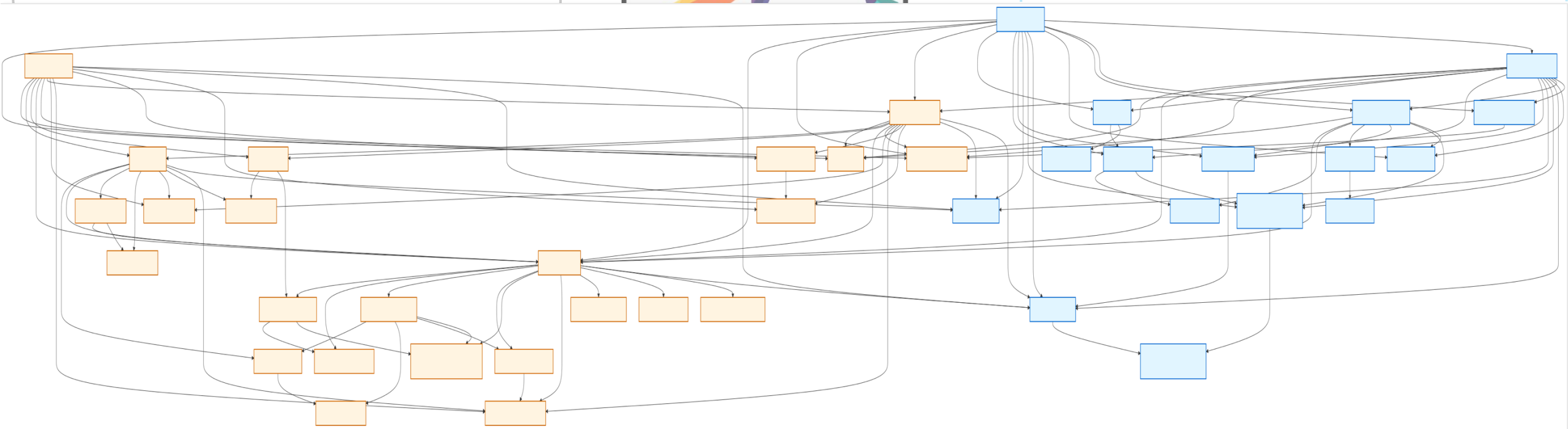
```
adlb <- exmapleFunction(
d_datain = bind_rows(
adlb_11_homair,
adlb_11_leptin
), v_dtvar = "LBDTC",
v_dtout = "ADT")
```

LBDTC

```
ADLB <- ADLB |>
dplyr::mutate(
ADT = admiral::convert_dtc_to_dt(
dtc = LBDTC, highest_imputation = "M",
date_imputation = "mid"),
ADTF = admiral::compute_dtf(
dtc = LBDTC, dt = ADT)
```

ADT

```
column:
  ADT:
    code_id: adt_std
  BASE:
    code_id: base_std
  ADY:
    code_ide: ady_std
```



```
#' @title Analysis relative day
#' @description
#' Derives the relative day compared to the treatment start date.
#' @type derivation
#' @depends ADLB ADT
#' @depends ADLB TRTSDT
#' @outputs ADY
#' @code

ADLB <- ADLB |>
  dplyr::mutate(
    ADY = admiral::compute_duration(
      start_date = TRTSDT,
      end_date = ADT,
      in_unit = "days",
      out_unit = "days",
      add_one = TRUE
    )
  )
```

```
#' @title Analysis relative day
#' @description
#' Derives the relative day compared to the treatment start date.
#' @type derivation
#' @depends ADLB ADT
#' @depends ADLB TRTSDT
#' @outputs ADY
#' @code
```

```
ADLB <- ADLB |>
  dplyr::mutate(
    ADY = admiral::compute_duration(
      start_date = TRTSDT,
      end_date = ADT,
      in_unit = "days",
      out_unit = "days",
      add_one = TRUE
    )
  )
```

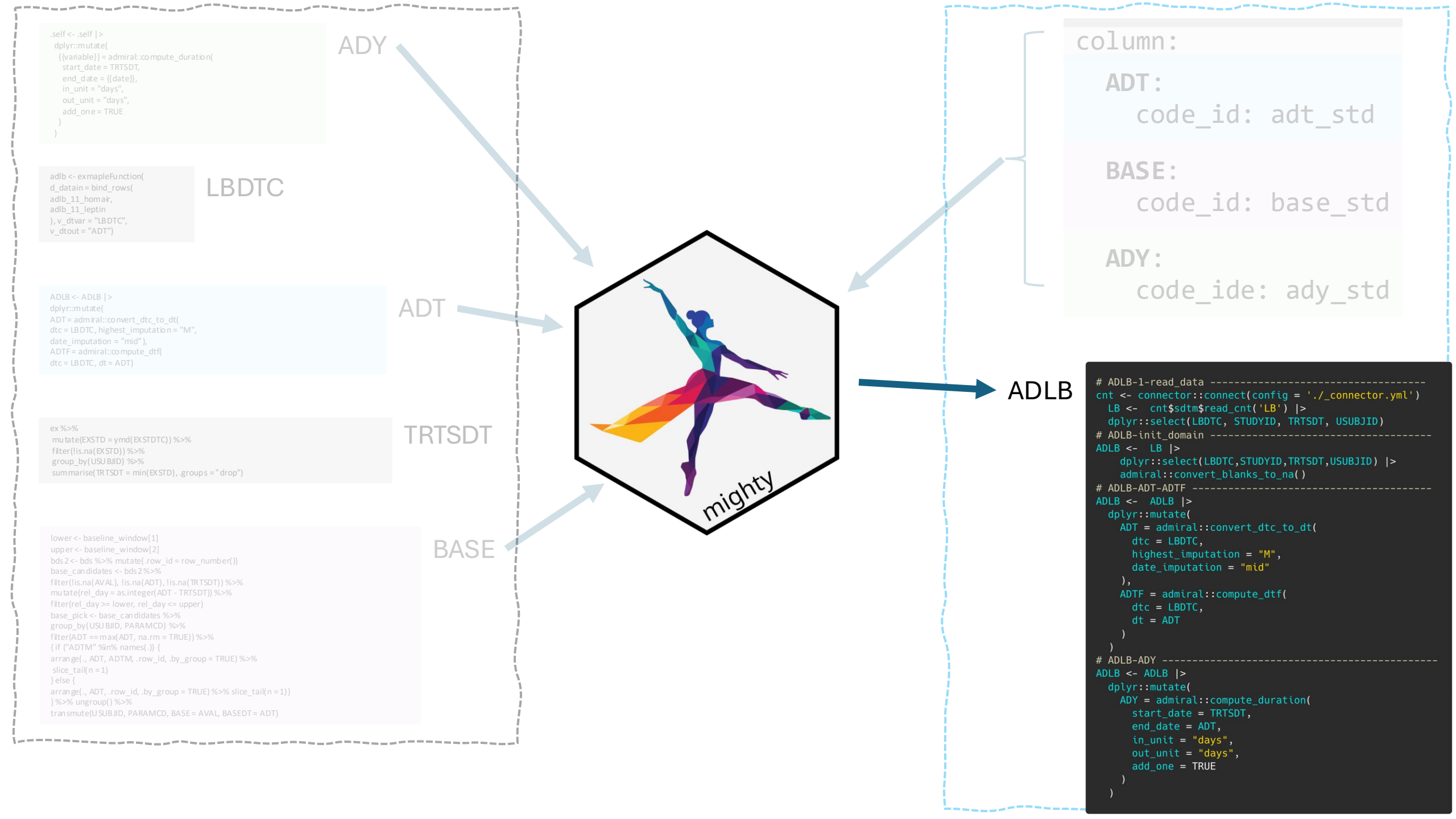
```
#' @title Analysis relative day
#' @description
#' Derives the relative day compared to the treatment start date.
#' @type derivation
#' @depends ADLB ADT
#' @depends ADLB TRTSDT
#' @outputs ADY
#' @code
```

```
ADLB <- ADLB |>
  dplyr::mutate(
    ADY = admiral::compute_duration(
      start_date = TRTSDT,
      end_date = ADT,
      in_unit = "days",
      out_unit = "days",
      add_one = TRUE
    )
  )
```

```
#' @title Analysis relative day
#' @description
#' Derives the relative day compared to the treatment start date.
#' @type derivation
#' @depends ADLB ADT
#' @depends ADLB TRTSDT
#' @outputs ADY
#' @code
```

```
ADLB <- ADLB |>
  dplyr::mutate(
    ADY = admiral::compute_duration(
      start_date = TRTSDT,
      end_date = ADT,
      in_unit = "days",
      out_unit = "days",
      add_one = TRUE
    )
  )
```

```
#' @title Analysis relative day
#' @description
#' Derives the relative day compared to the treatment start date.
#' @param variable `character` Name of new variable to create
#' @param date `character` Name of date variable to use
#' @type derivation
#' @depends {{domain}} {{date}}
#' @depends {{domain}} TRTSDT
#' @outputs {{variable}}
#' @code
{{domain}} <- {{domain}} |>
  dplyr::mutate(
    {{variable}} = admiral::compute_duration(
      start_date = TRTSDT,
      end_date = {{date}},
      in_unit = 'days',
      out_unit = 'days',
      add_one = TRUE
    )
  )
```


.self <- .self |>
dplyr::mutate(
{{variable}} = admiral::compute_duration(
start_date = TRTSDT,
end_date = {{date}},
in_unit = "days",
out_unit = "days",
add_one = TRUE
)
)
ADY
adlb <- exmapleFunction(
d_datain = bind_rows(
adlb_11_homair,
adlb_11_leptin
), v_dtvar = "LBDTC",
v_dtout = "ADT")
LBDTC
ADLB <- ADLB |>
dplyr::mutate(
ADT = admiral::convert_dtc_to_dt(
dtc = LBDTC, highest_imputation = "M",
date_imputation = "mid"),
ADTF = admiral::compute_dtf(
dtc = LBDTC, dt = ADT)
ADT
ex %>%
mutate(EXSTD = ymd(EXSTDTC)) %>%
filter(!is.na(EXSTD)) %>%
group_by(USUBJID) %>%
summarise(TRTSDT = min(EXSTD), .groups = "drop")
TRTSDT
lower <- baseline_window[1]
upper <- baseline_window[2]
bds2 <- bds %>% mutate(.row_id = row_number())
base_candidates <- bds2 %>%
filter(!is.na(AVAL), !is.na(ADT), !is.na(TRTSDT)) %>%
mutate(rel_day = as.integer(ADT - TRTSDT)) %>%
filter(rel_day >= lower, rel_day <= upper)
base_pick <- base_candidates %>%
group_by(USUBJID, PARAMCD) %>%
filter(ADT == max(ADT, na.rm = TRUE)) %>%
{ if ("ADTM" %in% names(.)) {
arrange(., ADT, ADTM, .row_id, .by_group = TRUE) %>%
slice_tail(n = 1)
} else {
arrange(., ADT, .row_id, .by_group = TRUE) %>% slice_tail(n = 1)}
} %>% ungroup() %>%
transmute(USUBJID, PARAMCD, BASE = AVAL, BASEDT = ADT)
BASE
mighty
column:
ADT:
code_id: adt_std
BASE:
code_id: base_std
ADY:
code_ide: ady_std
ADLB
# ADLB-1-read_data ----------
cnt <- connector::connect(config = './_connector.yml')
LB <- cnt$sdtm$read_cnt('LB') |>
dplyr::select(LBDTC, STUDYID, TRTSDT, USUBJID)
# ADLB-init_domain ----------
ADLB <- LB |>
dplyr::select(LBDTC,STUDYID,TRTSDT,USUBJID) |>
admiral::convert_blanks_to_na()
# ADLB-ADT-ADTF ----------
ADLB <- ADLB |>
dplyr::mutate(
ADT = admiral::convert_dtc_to_dt(
dtc = LBDTC,
highest_imputation = "M",
date_imputation = "mid"
),
ADTF = admiral::compute_dtf(
dtc = LBDTC,
dt = ADT
)
)
# ADLB-ADY ----------
ADLB <- ADLB |>
dplyr::mutate(
ADY = admiral::compute_duration(
start_date = TRTSDT,
end_date = ADT,
in_unit = "days",
out_unit = "days",
add_one = TRUE
)
)

```r
# ADLB-1-read_data -----------------------------------
cnt <- connector::connect(config = './_connector.yml')
  LB <-  cnt$sdtm$read_cnt('LB') |>
  dplyr::select(LBDTC, STUDYID, TRTSDT, USUBJID)
# ADLB-init_domain -----------------------------------
ADLB <-  LB |>
    dplyr::select(LBDTC,STUDYID,TRTSDT,USUBJID) |>
    admiral::convert_blanks_to_na()
# ADLB-ADT-ADTF --------------------------------------
ADLB <-  ADLB |>
  dplyr::mutate(
    ADT = admiral::convert_dtc_to_dt(
      dtc = LBDTC,
      highest_imputation = "M",
      date_imputation = "mid"
    ),
    ADTF = admiral::compute_dtf(
      dtc = LBDTC,
      dt = ADT
    )
  )
# ADLB-ADY -------------------------------------------
ADLB <- ADLB |>
  dplyr::mutate(
    ADY = admiral::compute_duration(
      start_date = TRTSDT,
      end_date = ADT,
      in_unit = "days",
      out_unit = "days",
      add_one = TRUE
    )
  )
```

```r
# ADLB-1-read_data -----------------------------------
cnt <- connector::connect(config = './_connector.yml')
  LB <-  cnt$sdtm$read_cnt('LB') |>
  dplyr::select(LBDTC, STUDYID, TRTSDT, USUBJID)
# ADLB-init_domain -----------------------------------
ADLB <-  LB |>
    dplyr::select(LBDTC,STUDYID,TRTSDT,USUBJID) |>
    admiral::convert_blanks_to_na()
# ADLB-ADT-ADTF --------------------------------------
ADLB <-  ADLB |>
  dplyr::mutate(
    ADT = admiral::convert_dtc_to_dt(
      dtc = LBDTC,
      highest_imputation = "M",
      date_imputation = "mid"
    ),
    ADTF = admiral::compute_dtf(
      dtc = LBDTC,
      dt = ADT
    )
  )
# ADLB-ADY -------------------------------------------
ADLB <- ADLB |>
  dplyr::mutate(
    ADY = admiral::compute_duration(
      start_date = TRTSDT,
      end_date = ADT,
      in_unit = "days",
      out_unit = "days",
      add_one = TRUE
    )
  )
```

```
# ADLB-1 read_data ------------------------------------------
cnt <- connector::connect(config = './_connector.yml')
  LB <-  cnt$sdtm$read_cnt('LB') |>
  dplyr::select(LBDTC, STUDYID, TRTSDT, USUBJID)
# ADLB-2 all_domain -----------------------------------------
ADLB <-  LB |>
    dplyr::select(LBDTC,STUDYID,TRTSDT,USUBJID) |>
    admiral::convert_blanks_to_na()
# ADLB-ADT-ADTF ---------------------------------------------
ADLB <-  ADLB |>
  dplyr::mutate(
    ADT = admiral::convert_dtc_to_dt(
      dtc = LBDTC,
      highest_imputation = "M",
      date_imputation = "mid"
    ),
    ADTF = admiral::compute_dtf(
      dtc = LBDTC,
      dt = ADT
    )
  )
# ADLB-ADY --------------------------------------------------
ADLB <- ADLB |>
  dplyr::mutate(
    ADY = admiral::compute_duration(
      start_date = TRTSDT,
      end_date = ADT,
      in_unit = "days",
      out_unit = "days",
      add_one = TRUE
    )
  )
```

```r
# ADLB-1 read_data ------------------------------------------------
cnt <- connector::connect(config = './_connector.yml')
  LB <-  cnt$sdtm$read_cnt('LB') |>
  dplyr::select(LBDTC, STUDYID, TRTSDT, USUBJID)
# ADLB-2 full_domain ----------------------------------------------
ADLB <-  LB |>
    dplyr::select(LBDTC,STUDYID,TRTSDT,USUBJID) |>
    admiral::convert_blanks_to_na()
# ADLB-ADT-ADTF ---------------------------------------------------
ADLB <-  ADLB |>
  dplyr::mutate(
    ADT = admiral::convert_dtc_to_dt(
      dtc = LBDTC,
      highest_imputation = "M",
      date_imputation = "mid"
    ),
    ADTF = admiral::compute_dtf(
      dtc = LBDTC,
      dt = ADT
    )
  )
# ADLB-ADY --------------------------------------------------------
ADLB <- ADLB |>
  dplyr::mutate(
    ADY = admiral::compute_duration(
      start_date = TRTSDT,
      end_date = ADT,
      in_unit = "days",
      out_unit = "days",
      add_one = TRUE
    )
  )
```

Cervan Girard

Vladimir Obucina

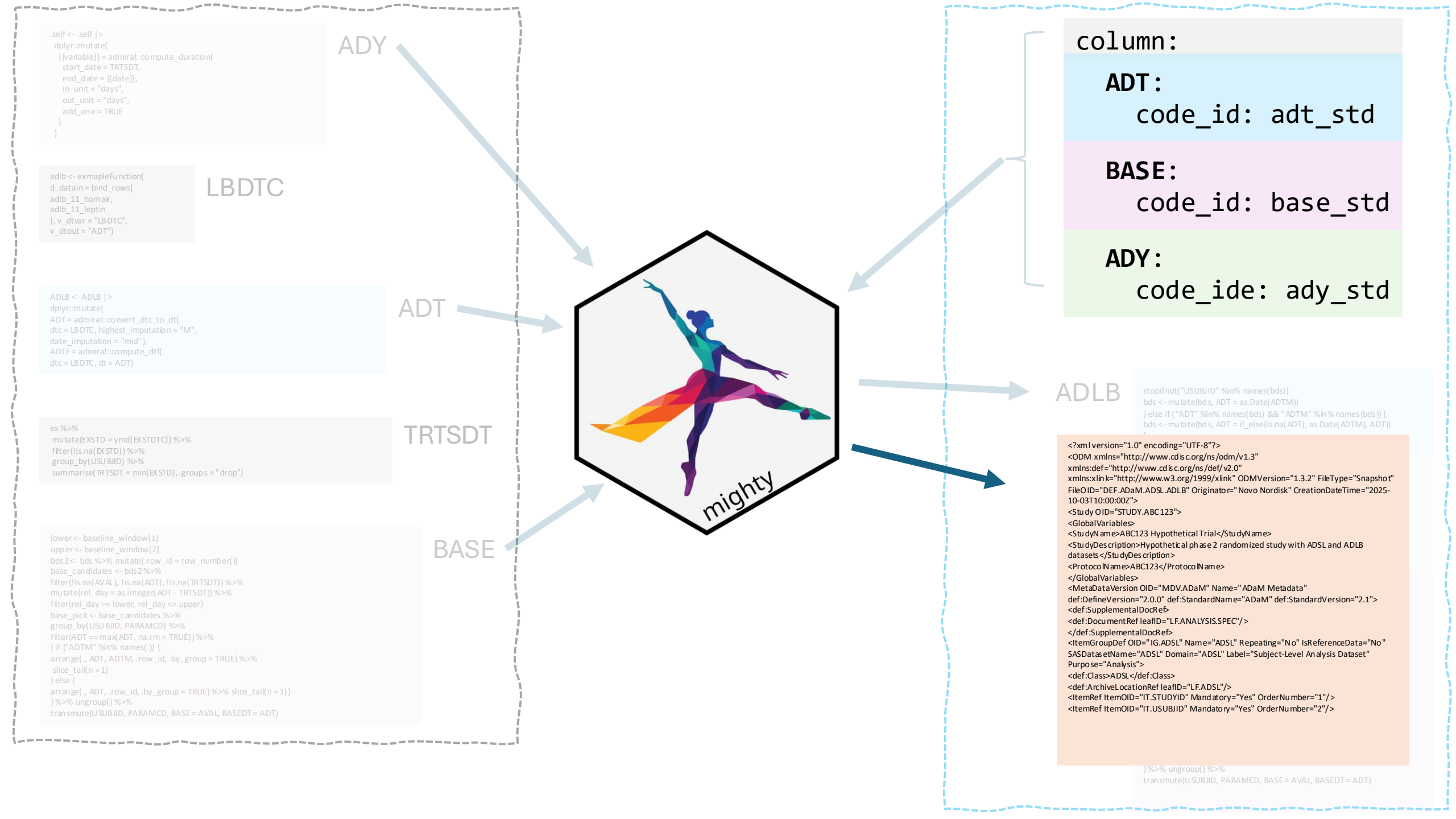
Aksel Thomsen

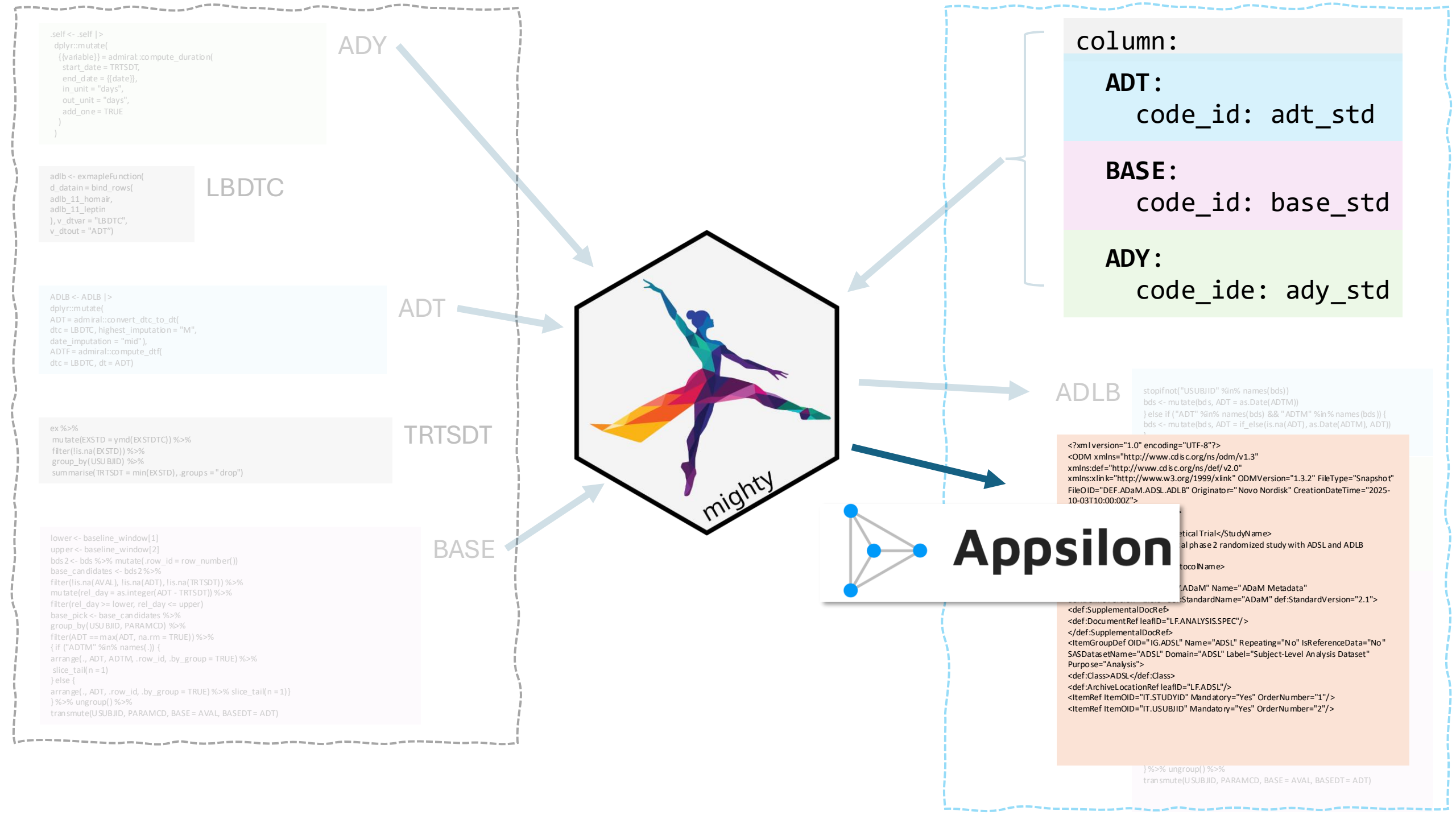
```r
# ADLB-1-read_data -----------------------------------
cnt <- connector::connect(config = './_connector.yml')
  LB <-  cnt$sdtm$read_cnt('LB') |>
  dplyr::select(LBDTC, STUDYID, TRTSDT, USUBJID)
# ADLB-init_domain -----------------------------------
ADLB <-  LB |>
    dplyr::select(LBDTC,STUDYID,TRTSDT,USUBJID) |>
    admiral::convert_blanks_to_na()
# ADLB-ADT-ADTF --------------------------------------
ADLB <-  ADLB |>
  dplyr::mutate(
    ADT = admiral::convert_dtc_to_dt(
      dtc = LBDTC,
      highest_imputation = "M",
      date_imputation = "mid"
    ),
    ADTF = admiral::compute_dtf(
      dtc = LBDTC,
      dt = ADT
    )
  )
# ADLB-ADY -------------------------------------------
ADLB <- ADLB |>
  dplyr::mutate(
    ADY = admiral::compute_duration(
      start_date = TRTSDT,
      end_date = ADT,
      in_unit = "days",
      out_unit = "days",
      add_one = TRUE
    )
  )
```

```r
# ADLB-1-read_data -----------------------------------
cnt <- connector::connect(config = './_connector.yml')
  LB <-  cnt$sdtm$read_cnt('LB') |>
  dplyr::select(LBDTC, STUDYID, TRTSDT, USUBJID)
# ADLB-init_domain -----------------------------------
ADLB <-  LB |>
    dplyr::select(LBDTC,STUDYID,TRTSDT,USUBJID) |>
    admiral::convert_blanks_to_na()
# ADLB-ADT-ADTF --------------------------------------
ADLB <-  ADLB |>
  dplyr::mutate(
    ADT = admiral::convert_dtc_to_dt(
      dtc = LBDTC,
      highest_imputation = "M",
      date_imputation = "mid"
    ),
    ADTF = admiral::compute_dtf(
      dtc = LBDTC,
      dt = ADT
    )
  )
# ADLB-ADY -------------------------------------------
ADLB <- ADLB |>
  dplyr::mutate(
    ADY = admiral::compute_duration(
      start_date = TRTSDT,
      end_date = ADT,
      in_unit = "days",
      out_unit = "days",
      add_one = TRUE
    )
  )
```

```r
# ADLB-1-read_data ------------------------------------
cnt <- connector::connect(config = './_connector.yml')
  LB <-  cnt$sdtm$read_cnt('LB') |>
  dplyr::select(LBDTC, STUDYID, TRTSDT, USUBJID)
# ADLB-init_domain ------------------------------------
ADLB <-  LB |>
    dplyr::select(LBDTC,STUDYID,TRTSDT,USUBJID) |>
    admiral::convert_blanks_to_na()
# ADLB-ADT-ADTF ---------------------------------------
ADLB <-  ADLB |>
  dplyr::mutate(
    ADT = admiral::convert_dtc_to_dt(
      dtc = LBDTC,
      highest_imputation = "M",
      date_imputation = "mid"
    ),
    ADTF = admiral::compute_dtf(
      dtc = LBDTC,
      dt = ADT
    )
  )
# ADLB-ADY --------------------------------------------
ADLB <- ADLB |>
  dplyr::mutate(
    ADY = admiral::compute_duration(
      start_date = TRTSDT,
      end_date = ADT,
      in_unit = "days",
      out_unit = "days",
      add_one = TRUE
    )
  )
```

```r
# ADLB-1-read_data ---------------------------------
cnt <- connector::connect(config = './_connector.yml')
  LB <-  cnt$sdtm$read_cnt('LB') |>
  dplyr::select(LBDTC, STUDYID, TRTSDT, USUBJID)
# ADLB-init_domain ---------------------------------
ADLB <-  LB |>
    dplyr::select(LBDTC,STUDYID,TRTSDT,USUBJID) |>
    admiral::convert_blanks_to_na()
# ADLB-ADT-ADTF ------------------------------------
ADLB <-  ADLB |>
  dplyr::mutate(
    ADT = admiral::convert_dtc_to_dt(
      dtc = LBDTC,
      highest_imputation = "M",
      date_imputation = "mid"
    ),
    ADTF = admiral::compute_dtf(
      dtc = LBDTC,
      dt = ADT
    )
  )
# ADLB-ADY -----------------------------------------
ADLB <- ADLB |>
  dplyr::mutate(
    ADY = admiral::compute_duration(
      start_date = TRTSDT,
      end_date = ADT,
      in_unit = "days",
      out_unit = "days",
      add_one = TRUE
    )
  )
```


.self <- .self |>
dplyr::mutate(
{{variable}} = admiral::compute_duration(
start_date = TRTSDT,
end_date = {{date}},
in_unit = "days",
out_unit = "days",
add_one = TRUE
)
)
ADY
adlb <- exmapleFunction(
d_datain = bind_rows(
adlb_11_homair,
adlb_11_leptin
), v_dtvar = "LBDTC",
v_dtout = "ADT")
LBDTC
ADLB <- ADLB |>
dplyr::mutate(
ADT = admiral::convert_dtc_to_dt(
dtc = LBDTC, highest_imputation = "M",
date_imputation = "mid"),
ADTF = admiral::compute_dtf(
dtc = LBDTC, dt = ADT)
ADT
ex %>%
mutate(EXSTD = ymd(EXSTDTC)) %>%
filter(!is.na(EXSTD)) %>%
group_by(USUBJID) %>%
summarise(TRTSDT = min(EXSTD), .groups = "drop")
TRTSDT
lower <- baseline_window[1]
upper <- baseline_window[2]
bds2 <- bds %>% mutate(.row_id = row_number())
base_candidates <- bds2 %>%
filter(!is.na(AVAL), !is.na(ADT), !is.na(TRTSDT)) %>%
mutate(rel_day = as.integer(ADT - TRTSDT)) %>%
filter(rel_day >= lower, rel_day <= upper)
base_pick <- base_candidates %>%
group_by(USUBJID, PARAMCD) %>%
filter(ADT == max(ADT, na.rm = TRUE)) %>%
{ if ("ADTM" %in% names(.)) {
arrange(., ADT, ADTM, .row_id, .by_group = TRUE) %>%
slice_tail(n = 1)
} else {
arrange(., ADT, .row_id, .by_group = TRUE) %>% slice_tail(n = 1)}
} %>% ungroup() %>%
transmute(USUBJID, PARAMCD, BASE = AVAL, BASEDT = ADT)
BASE
mighty
column:
ADT:
code_id: adt_std
BASE:
code_id: base_std
ADY:
code_ide: ady_std
ADLB
stopifnot("USUBJID" %in% names(bds))
bds <- mutate(bds, ADT = as.Date(ADTM))
} else if ("ADT" %in% names(bds) && "ADTM" %in% names(bds)) {
bds <- mutate(bds, ADT = if_else(is.na(ADT), as.Date(ADTM), ADT))
<?xml version="1.0" encoding="UTF-8"?>
<ODM xmlns="http://www.cdisc.org/ns/odm/v1.3"
xmlns:def="http://www.cdisc.org/ns/def/v2.0"
xmlns:xlink="http://www.w3.org/1999/xlink" ODMVersion="1.3.2" FileType="Snapshot"
FileOID="DEF.ADaM.ADSL.ADLB" Originator="Novo Nordisk" CreationDateTime="2025-10-03T10:00:00Z">
<Study OID="STUDY.ABC123">
<GlobalVariables>
<StudyName>ABC123 Hypothetical Trial</StudyName>
<StudyDescription>Hypothetical phase 2 randomized study with ADSL and ADLB datasets</StudyDescription>
<ProtocolName>ABC123</ProtocolName>
</GlobalVariables>
<MetaDataVersion OID="MDV.ADaM" Name="ADaM Metadata"
def:DefineVersion="2.0.0" def:StandardName="ADaM" def:StandardVersion="2.1">
<def:SupplementalDocRef>
<def:DocumentRef leafID="LF.ANALYSIS.SPEC"/>
</def:SupplementalDocRef>
<ItemGroupDef OID="IG.ADSL" Name="ADSL" Repeating="No" IsReferenceData="No"
SASDatasetName="ADSL" Domain="ADSL" Label="Subject-Level Analysis Dataset"
Purpose="Analysis">
<def:Class>ADSL</def:Class>
<def:ArchiveLocationRef leafID="LF.ADSL"/>
<ItemRef ItemOID="IT.STUDYID" Mandatory="Yes" OrderNumber="1"/>
<ItemRef ItemOID="IT.USUBJID" Mandatory="Yes" OrderNumber="2"/>
} %>% ungroup() %>%
transmute(USUBJID, PARAMCD, BASE = AVAL, BASEDT = ADT)


ADY
LBDTC
ADT
TRTSDT
BASE
mighty
column:
ADT:
code_id: adt_std
BASE:
code_id: base_std
ADY:
code_ide: ady_std
ADLB
Appsilon

Did we solve the problem

- Multiple sources of truth

Did we solve the problem

- Multiple sources of truth
- Inefficient validation

Did we solve the problem

- Multiple sources of truth
- Inefficient validation
- Burdensome bookkeeping

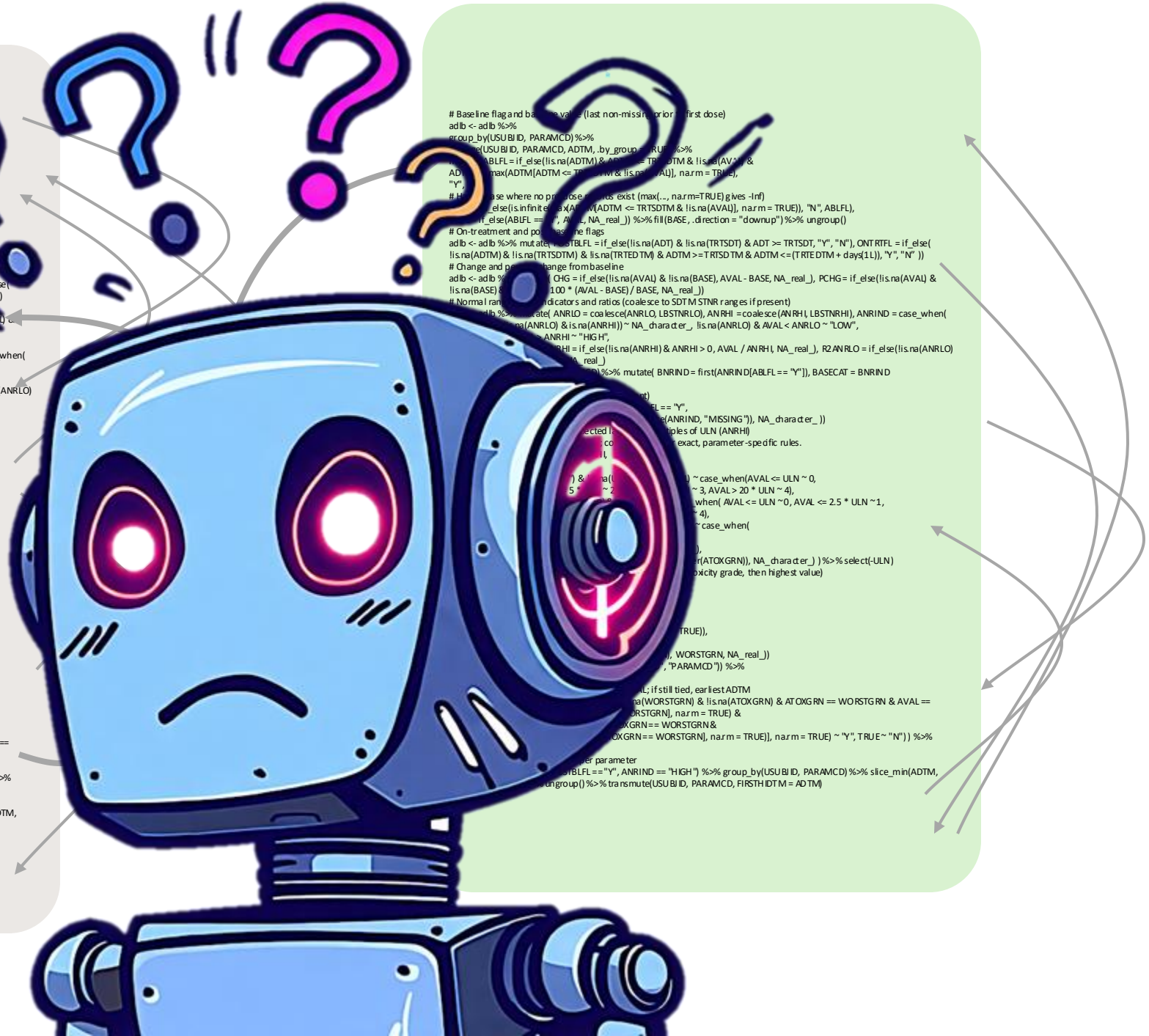
Did we solve the problem

- Multiple sources of truth
- Inefficient validation Burdensome bookkeeping
- Lack of standards

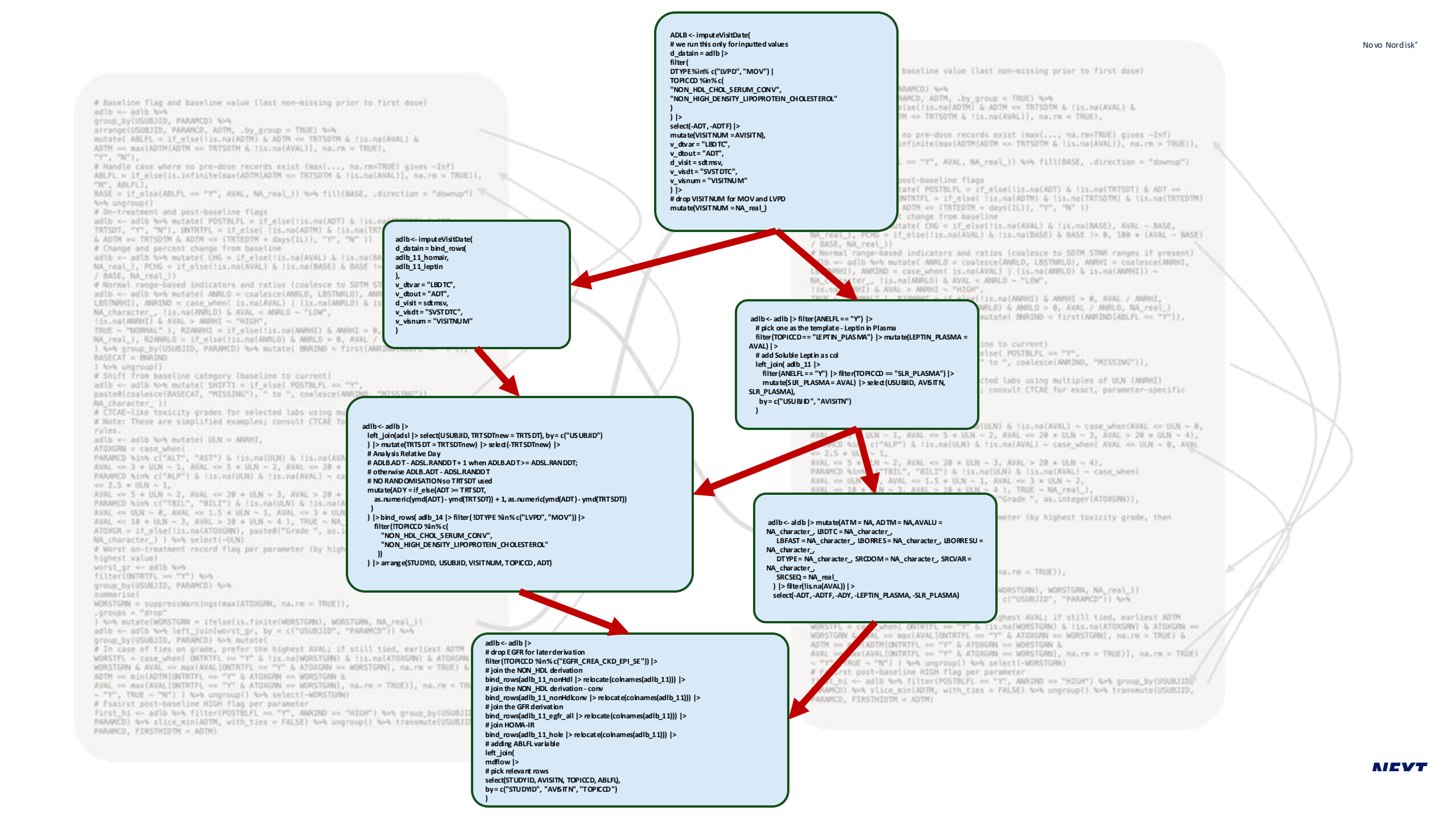
```
# Baseline flag and baseline value (last non-missing prior to first dose)
adlb <- adlb %>%
group_by(USUBJID, PARAMCD) %>%
arrange(USUBJID, PARAMCD, ADTM, .by_group = TRUE) %>%
mutate( ABLFL = if_else(!is.na(ADTM) & ADTM <= TRTSDTM & !is.na(AVAL) &
ADTM == max(ADTM[ADTM <= TRTSDTM & !is.na(AVAL)], na.rm = TRUE),
"Y", "N"),
# Handle case where no pre-dose records exist (max(..., na.rm=TRUE) gives -Inf)
ABLFL = if_else(is.infinite(max(ADTM[ADTM <= TRTSDTM & !is.na(AVAL)], na.rm = TRUE)), "N", ABLFL),
BASE = if_else(ABLFL == "Y", AVAL, NA_real_)) %>% fill(BASE, .direction = "downup") %>% ungroup()
# On-treatment and post-baseline flags
adlb <- adlb %>% mutate( POSTBLFL = if_else(!is.na(ADT) & !is.na(TRTSDT) & ADT >= TRTSDT, "Y", "N"), ONTRTFL = if_else(
!is.na(ADTM) & !is.na(TRTSDTM) & !is.na(TRTEDTM) & ADTM >= TRTSDTM & ADTM <= (TRTEDTM + days(1L)), "Y", "N" ))
# Change and percent change from baseline
adlb <- adlb %>% mutate( CHG = if_else(!is.na(AVAL) & !is.na(BASE), AVAL - BASE, NA_real_), PCHG = if_else(!is.na(AVAL) &
!is.na(BASE) & BASE != 0, 100 * (AVAL - BASE) / BASE, NA_real_))
# Normal range-based indicators and ratios (coalesce to SDTM STNR ranges if present)
adlb <- adlb %>% mutate( ANRLO = coalesce(ANRLO, LBSTNRLO), ANRHI = coalesce(ANRHI, LBSTNRHI), ANRIND = case_when(
is.na(AVAL) | (is.na(ANRLO) & is.na(ANRHI)) ~ NA_character_, !is.na(ANRLO) & AVAL < ANRLO ~ "LOW",
!is.na(ANRHI) & AVAL > ANRHI ~ "HIGH",
TRUE ~ "NORMAL" ), R2ANRHI = if_else(!is.na(ANRHI) & ANRHI > 0, AVAL / ANRHI, NA_real_), R2ANRLO = if_else(!is.na(ANRLO)
& ANRLO > 0, AVAL / ANRLO, NA_real_)
) %>% group_by(USUBJID, PARAMCD) %>% mutate( BNRIND = first(ANRIND[ABLFL == "Y"]), BASECAT = BNRIND
) %>% ungroup()
# Shift from baseline category (baseline to current)
adlb <- adlb %>% mutate( SHIFT1 = if_else( POSTBLFL == "Y",
paste0(coalesce(BASECAT, "MISSING"), " to ", coalesce(ANRIND, "MISSING")), NA_character_ ))
# CTCAE-like toxicity grades for selected labs using multiples of ULN (ANRHI)
# Note: These are simplified examples; consult CTCAE for exact, parameter-specific rules.
adlb <- adlb %>% mutate( ULN = ANRHI,
ATOXGRN = case_when(
PARAMCD %in% c("ALT", "AST") & !is.na(ULN) & !is.na(AVAL) ~ case_when(AVAL <= ULN ~ 0,
AVAL <= 3 * ULN ~ 1, AVAL <= 5 * ULN ~ 2, AVAL <= 20 * ULN ~ 3, AVAL > 20 * ULN ~ 4),
PARAMCD %in% c("ALP") & !is.na(ULN) & !is.na(AVAL) ~ case_when( AVAL <= ULN ~ 0, AVAL <= 2.5 * ULN ~ 1,
AVAL <= 5 * ULN ~ 2, AVAL <= 20 * ULN ~ 3, AVAL > 20 * ULN ~ 4),
PARAMCD %in% c("TBIL", "BILI") & !is.na(ULN) & !is.na(AVAL) ~ case_when(
AVAL <= ULN ~ 0, AVAL <= 1.5 * ULN ~ 1, AVAL <= 3 * ULN ~ 2,
AVAL <= 10 * ULN ~ 3, AVAL > 10 * ULN ~ 4 ), TRUE ~ NA_real_),
ATOXGR = if_else(!is.na(ATOXGRN), paste0("Grade ", as.integer(ATOXGRN)), NA_character_) ) %>% select(-ULN)
# Worst on-treatment record flag per parameter (by highest toxicity grade, then highest value)
worst_gr <- adlb %>%
filter(ONTRTFL == "Y") %>%
group_by(USUBJID, PARAMCD) %>%
summarise(
WORSTGRN = suppressWarnings(max(ATOXGRN, na.rm = TRUE)),
.groups = "drop"
) %>% mutate(WORSTGRN = ifelse(is.finite(WORSTGRN), WORSTGRN, NA_real_))
adlb <- adlb %>% left_join(worst_gr, by = c("USUBJID", "PARAMCD")) %>%
group_by(USUBJID, PARAMCD) %>% mutate(
# In case of ties on grade, prefer the highest AVAL; if still tied, earliest ADTM
WORSTFL = case_when( ONTRTFL == "Y" & !is.na(WORSTGRN) & !is.na(ATOXGRN) & ATOXGRN == WORSTGRN & AVAL ==
max(AVAL[ONTRTFL == "Y" & ATOXGRN == WORSTGRN], na.rm = TRUE) &
ADTM == min(ADTM[ONTRTFL == "Y" & ATOXGRN == WORSTGRN &
AVAL == max(AVAL[ONTRTFL == "Y" & ATOXGRN == WORSTGRN], na.rm = TRUE)], na.rm = TRUE) ~ "Y", TRUE ~ "N") ) %>%
ungroup() %>% select(-WORSTGRN)
# Fsairst post-baseline HIGH flag per parameter
first_hi <- adlb %>% filter(POSTBLFL == "Y", ANRIND == "HIGH") %>% group_by(USUBJID, PARAMCD) %>% slice_min(ADTM,
with_ties = FALSE) %>% ungroup() %>% transmute(USUBJID, PARAMCD, FIRSTHIDTM = ADTM)
```

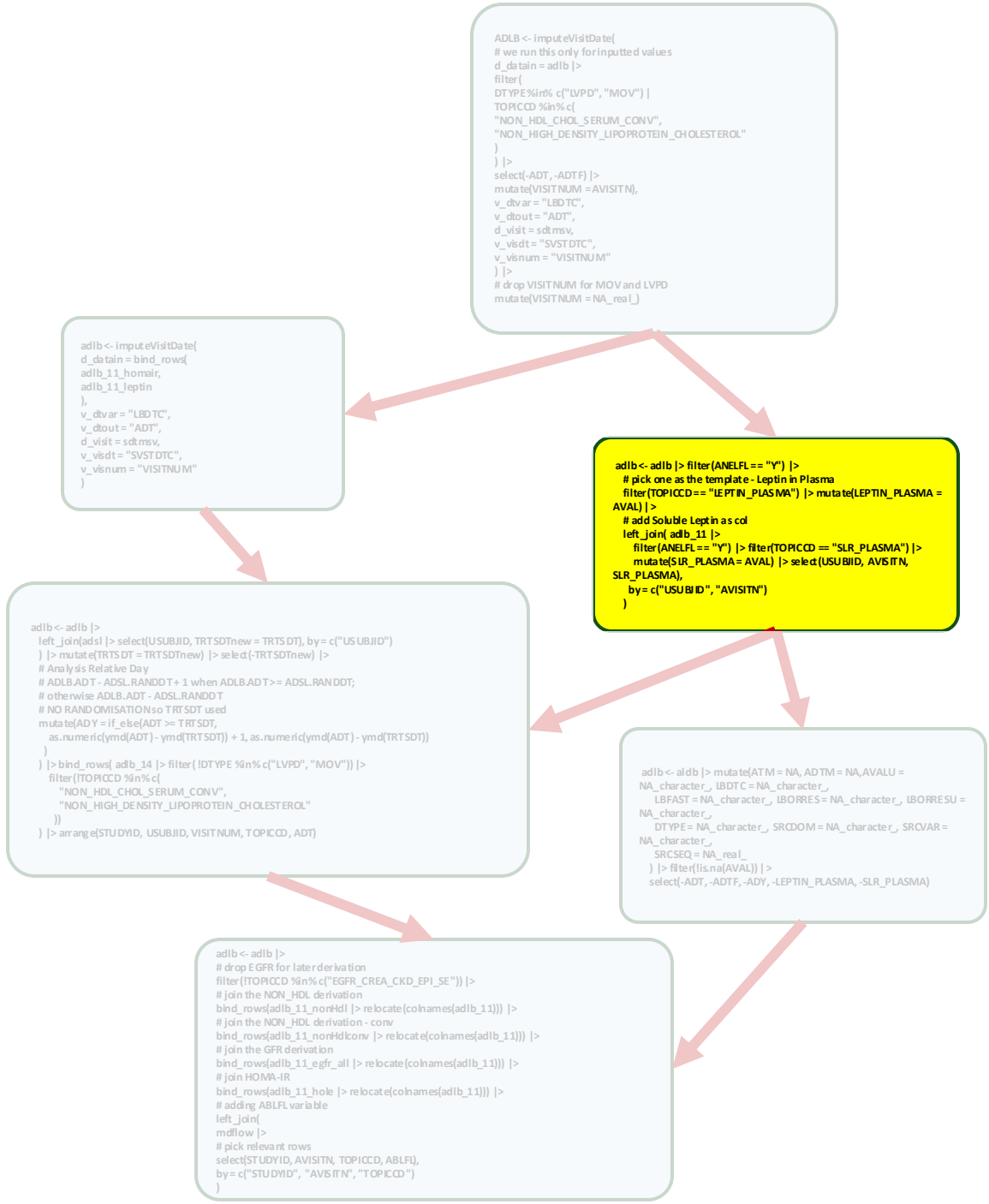

```
# Baseline flag and baseline value (last non-missing prior to first dose)
adlb <- adlb %>%
group_by(USUBJID, PARAMCD) %>%
arrange(USUBJID, PARAMCD, ADTM, .by_group = TRUE) %>%
mutate( ABLFL = if_else(!is.na(ADTM) & ADTM <= TRTSDTM & !is.na(AVAL) &
ADTM == max(ADTM[ADTM <= TRTSDTM & !is.na(AVAL)], na.rm = TRUE),
"Y", "N"),
# Handle case where no pre-dose records exist (max(..., na.rm=TRUE) gives -Inf)
ABLFL = if_else(is.infinite(max(ADTM[ADTM <= TRTSDTM & !is.na(AVAL)], na.rm = TRUE)), "N", ABLFL),
BASE = if_else(ABLFL == "Y", AVAL, NA_real_)) %>% fill(BASE, .direction = "downup") %>% ungroup()
# On-treatment and post-baseline flags
adlb <- adlb %>% mutate( POSTBLFL = if_else(!is.na(ADT) & !is.na(TRTSDT) & ADT >= TRTSDT, "Y", "N"), ONTRTFL = if_else(
!is.na(ADTM) & !is.na(TRTSDTM) & !is.na(TRTEDTM) & ADTM >= TRTSDTM & ADTM <= (TRTEDTM + days(1L)), "Y", "N" ))
# Change and percent change from baseline
adlb <- adlb %>% mutate( CHG = if_else(!is.na(AVAL) & !is.na(BASE), AVAL - BASE, NA_real_), PCHG = if_else(!is.na(AVAL) &
!is.na(BASE) & BASE != 0, 100 * (AVAL - BASE) / BASE, NA_real_))
# Normal range-based indicators and ratios (coalesce to SDTM STNR ranges if present)
adlb <- adlb %>% mutate( ANRLO = coalesce(ANRLO, LBSTNRLO), ANRHI = coalesce(ANRHI, LBSTNRHI), ANRIND = case_when(
is.na(AVAL) | (is.na(ANRLO) & is.na(ANRHI)) ~ NA_character_, !is.na(ANRLO) & AVAL < ANRLO ~ "LOW",
!is.na(ANRHI) & AVAL > ANRHI ~ "HIGH",
TRUE ~ "NORMAL" ), R2ANRHI = if_else(!is.na(ANRHI) & ANRHI > 0, AVAL / ANRHI, NA_real_), R2ANRLO = if_else(!is.na(ANRLO)
& ANRLO > 0, AVAL / ANRLO, NA_real_)
) %>% group_by(USUBJID, PARAMCD) %>% mutate( BNRIND = first(ANRIND[ABLFL == "Y"]), BASECAT = BNRIND
) %>% ungroup()
# Shift from baseline category (baseline to current)
adlb <- adlb %>% mutate( SHIFT1 = if_else( POSTBLFL == "Y",
paste0(coalesce(BASECAT, "MISSING"), " to ", coalesce(ANRIND, "MISSING")), NA_character_ ))
# CTCAE-like toxicity grades for selected labs using multiples of ULN (ANRHI)
# Note: These are simplified examples; consult CTCAE for exact, parameter-specific rules.
adlb <- adlb %>% mutate( ULN = ANRHI,
ATOXGRN = case_when(
PARAMCD %in% c("ALT", "AST") & !is.na(ULN) & !is.na(AVAL) ~ case_when(AVAL <= ULN ~ 0,
AVAL <= 3 * ULN ~ 1, AVAL <= 5 * ULN ~ 2, AVAL <= 20 * ULN ~ 3, AVAL > 20 * ULN ~ 4),
PARAMCD %in% c("ALP") & !is.na(ULN) & !is.na(AVAL) ~ case_when( AVAL <= ULN ~ 0, AVAL <= 2.5 * ULN ~ 1,
AVAL <= 5 * ULN ~ 2, AVAL <= 20 * ULN ~ 3, AVAL > 20 * ULN ~ 4),
PARAMCD %in% c("TBIL", "BILI") & !is.na(ULN) & !is.na(AVAL) ~ case_when(
AVAL <= ULN ~ 0, AVAL <= 1.5 * ULN ~ 1, AVAL <= 3 * ULN ~ 2,
AVAL <= 10 * ULN ~ 3, AVAL > 10 * ULN ~ 4 ), TRUE ~ NA_real_),
ATOXGR = if_else(!is.na(ATOXGRN), paste0("Grade ", as.integer(ATOXGRN)), NA_character_) ) %>% select(-ULN)
# Worst on-treatment record flag per parameter (by highest toxicity grade, then highest value)
worst_gr <- adlb %>%
filter(ONTRTFL == "Y") %>%
group_by(USUBJID, PARAMCD) %>%
summarise(
WORSTGRN = suppressWarnings(max(ATOXGRN, na.rm = TRUE)),
.groups = "drop"
) %>% mutate(WORSTGRN = ifelse(is.finite(WORSTGRN), WORSTGRN, NA_real_))
adlb <- adlb %>% left_join(worst_gr, by = c("USUBJID", "PARAMCD")) %>%
group_by(USUBJID, PARAMCD) %>% mutate(
# In case of ties on grade, prefer the highest AVAL; if still tied, earliest ADTM
WORSTFL = case_when( ONTRTFL == "Y" & !is.na(WORSTGRN) & !is.na(ATOXGRN) & ATOXGRN == WORSTGRN & AVAL ==
max(AVAL[ONTRTFL == "Y" & ATOXGRN == WORSTGRN], na.rm = TRUE) &
ADTM == min(ADTM[ONTRTFL == "Y" & ATOXGRN == WORSTGRN &
AVAL == max(AVAL[ONTRTFL == "Y" & ATOXGRN == WORSTGRN], na.rm = TRUE)], na.rm = TRUE) ~ "Y", TRUE ~ "N") ) %>%
ungroup() %>% select(-WORSTGRN)
# Fsairst post-baseline HIGH flag per parameter
first_hi <- adlb %>% filter(POSTBLFL == "Y", ANRIND == "HIGH") %>% group_by(USUBJID, PARAMCD) %>% slice_min(ADTM,
with_ties = FALSE) %>% ungroup() %>% transmute(USUBJID, PARAMCD, FIRSTHIDTM = ADTM)
```

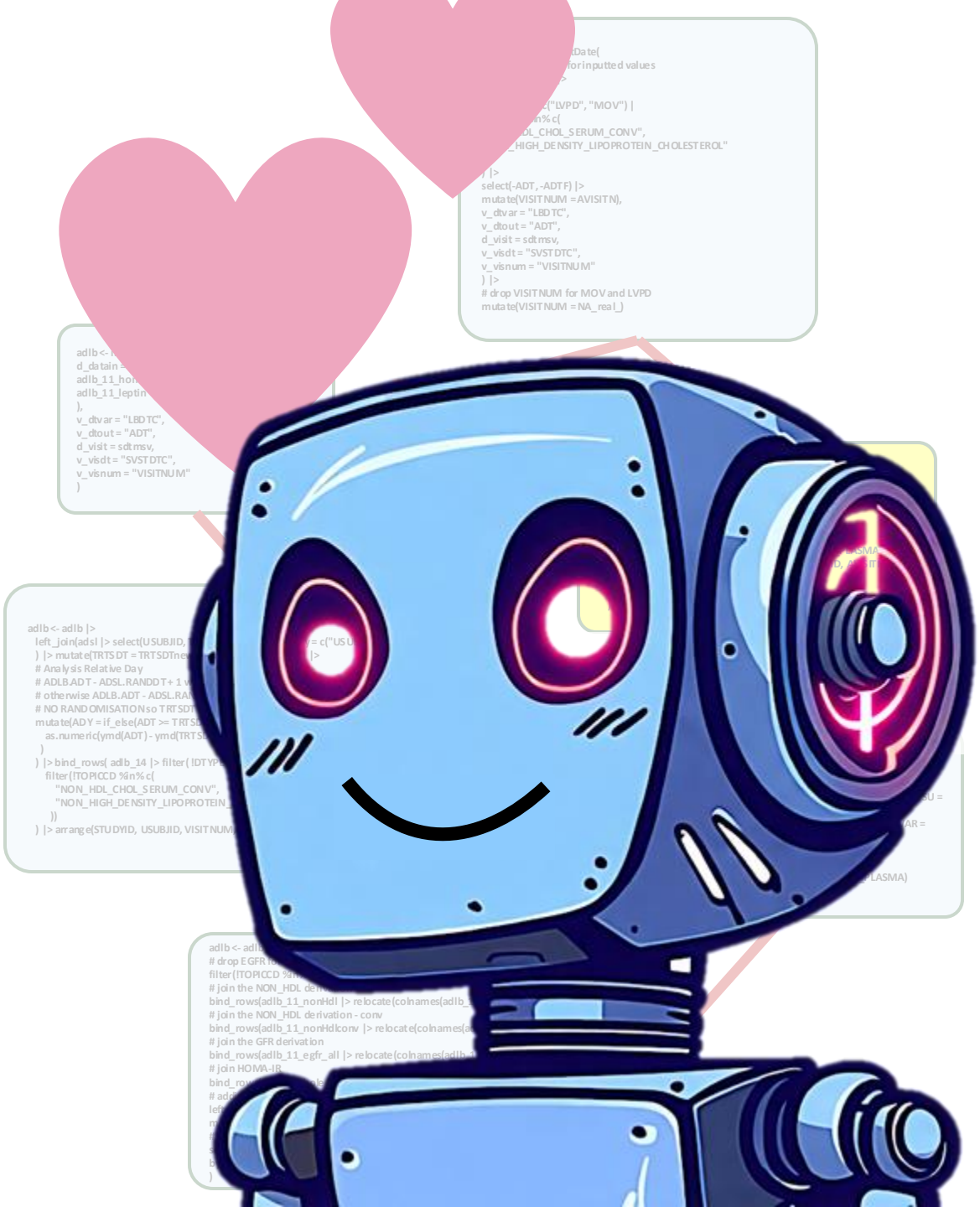
```
# Baseline flag and baseline value (last non-missing prior to first dose)
adlb <- adlb %>%
group_by(USUBJID, PARAMCD) %>%
arrange(USUBJID, PARAMCD, ADTM, .by_group = TRUE) %>%
mutate( ABLFL = if_else(!is.na(ADTM) & ADTM <= TRTSDTM & !is.na(AVAL) &
ADTM == max(ADTM[ADTM <= TRTSDTM & !is.na(AVAL)], na.rm = TRUE),
"Y", "N"),
# Handle case where no pre-dose records exist (max(..., na.rm=TRUE) gives -Inf)
ABLFL = if_else(is.infinite(max(ADTM[ADTM <= TRTSDTM & !is.na(AVAL)], na.rm = TRUE)), "N", ABLFL),
BASE = if_else(ABLFL == "Y", AVAL, NA_real_)) %>% fill(BASE, .direction = "downup") %>% ungroup()
# On-treatment and post-baseline flags
adlb <- adlb %>% mutate( POSTBLFL = if_else(!is.na(ADT) & !is.na(TRTSDT) & ADT >= TRTSDT, "Y", "N"), ONTRTFL = if_else(
!is.na(ADTM) & !is.na(TRTSDTM) & !is.na(TRTEDTM) & ADTM >= TRTSDTM & ADTM <= (TRTEDTM + days(1L)), "Y", "N" ))
# Change and percent change from baseline
adlb <- adlb %>% mutate( CHG = if_else(!is.na(AVAL) & !is.na(BASE), AVAL - BASE, NA_real_), PCHG = if_else(!is.na(AVAL) &
!is.na(BASE) & BASE != 0, 100 * (AVAL - BASE) / BASE, NA_real_))
# Normal range-based indicators and ratios (coalesce to SDTM STNR ranges if present)
adlb <- adlb %>% mutate( ANRLO = coalesce(ANRLO, LBSTNRLO), ANRHI = coalesce(ANRHI, LBSTNRHI), ANRIND = case_when(
is.na(AVAL) | (is.na(ANRLO) & is.na(ANRHI)) ~ NA_character_, !is.na(ANRLO) & AVAL < ANRLO ~ "LOW",
!is.na(ANRHI) & AVAL > ANRHI ~ "HIGH",
TRUE ~ "NORMAL" ), R2ANRHI = if_else(!is.na(ANRHI) & ANRHI > 0, AVAL / ANRHI, NA_real_), R2ANRLO = if_else(!is.na(ANRLO)
& ANRLO > 0, AVAL / ANRLO, NA_real_)
) %>% group_by(USUBJID, PARAMCD) %>% mutate( BNRIND = first(ANRIND[ABLFL == "Y"]), BASECAT = BNRIND
) %>% ungroup()
# Shift from baseline category (baseline to current)
adlb <- adlb %>% mutate( SHIFT1 = if_else( POSTBLFL == "Y",
paste0(coalesce(BASECAT, "MISSING"), " to ", coalesce(ANRIND, "MISSING")), NA_character_ ))
# CTCAE-like toxicity grades for selected labs using multiples of ULN (ANRHI)
# Note: These are simplified examples; consult CTCAE for exact, parameter-specific rules.
adlb <- adlb %>% mutate( ULN = ANRHI,
ATOXGRN = case_when(
PARAMCD %in% c("ALT", "AST") & !is.na(ULN) & !is.na(AVAL) ~ case_when(AVAL <= ULN ~ 0,
AVAL <= 3 * ULN ~ 1, AVAL <= 5 * ULN ~ 2, AVAL <= 20 * ULN ~ 3, AVAL > 20 * ULN ~ 4),
PARAMCD %in% c("ALP") & !is.na(ULN) & !is.na(AVAL) ~ case_when( AVAL <= ULN ~ 0, AVAL <= 2.5 * ULN ~ 1,
AVAL <= 5 * ULN ~ 2, AVAL <= 20 * ULN ~ 3, AVAL > 20 * ULN ~ 4),
PARAMCD %in% c("TBIL", "BILI") & !is.na(ULN) & !is.na(AVAL) ~ case_when(
AVAL <= ULN ~ 0, AVAL <= 1.5 * ULN ~ 1, AVAL <= 3 * ULN ~ 2,
AVAL <= 10 * ULN ~ 3, AVAL > 10 * ULN ~ 4 ), TRUE ~ NA_real_),
ATOXGR = if_else(!is.na(ATOXGRN), paste0("Grade ", as.integer(ATOXGRN)), NA_character_) ) %>% select(-ULN)
# Worst on-treatment record flag per parameter (by highest toxicity grade, then highest value)
worst_gr <- adlb %>%
filter(ONTRTFL == "Y") %>%
group_by(USUBJID, PARAMCD) %>%
summarise(
WORSTGRN = suppressWarnings(max(ATOXGRN, na.rm = TRUE)),
.groups = "drop"
) %>% mutate(WORSTGRN = ifelse(is.finite(WORSTGRN), WORSTGRN, NA_real_))
adlb <- adlb %>% left_join(worst_gr, by = c("USUBJID", "PARAMCD")) %>%
group_by(USUBJID, PARAMCD) %>% mutate(
# In case of ties on grade, prefer the highest AVAL; if still tied, earliest ADTM
WORSTFL = case_when( ONTRTFL == "Y" & !is.na(WORSTGRN) & !is.na(ATOXGRN) & ATOXGRN == WORSTGRN & AVAL ==
max(AVAL[ONTRTFL == "Y" & ATOXGRN == WORSTGRN], na.rm = TRUE) &
ADTM == min(ADTM[ONTRTFL == "Y" & ATOXGRN == WORSTGRN &
AVAL == max(AVAL[ONTRTFL == "Y" & ATOXGRN == WORSTGRN], na.rm = TRUE)], na.rm = TRUE) ~ "Y", TRUE ~ "N") ) %>%
ungroup() %>% select(-WORSTGRN)
# Fsairst post-baseline HIGH flag per parameter
first_hi <- adlb %>% filter(POSTBLFL == "Y", ANRIND == "HIGH") %>% group_by(USUBJID, PARAMCD) %>% slice_min(ADTM,
with_ties = FALSE) %>% ungroup() %>% transmute(USUBJID, PARAMCD, FIRSTHIDTM = ADTM)
```

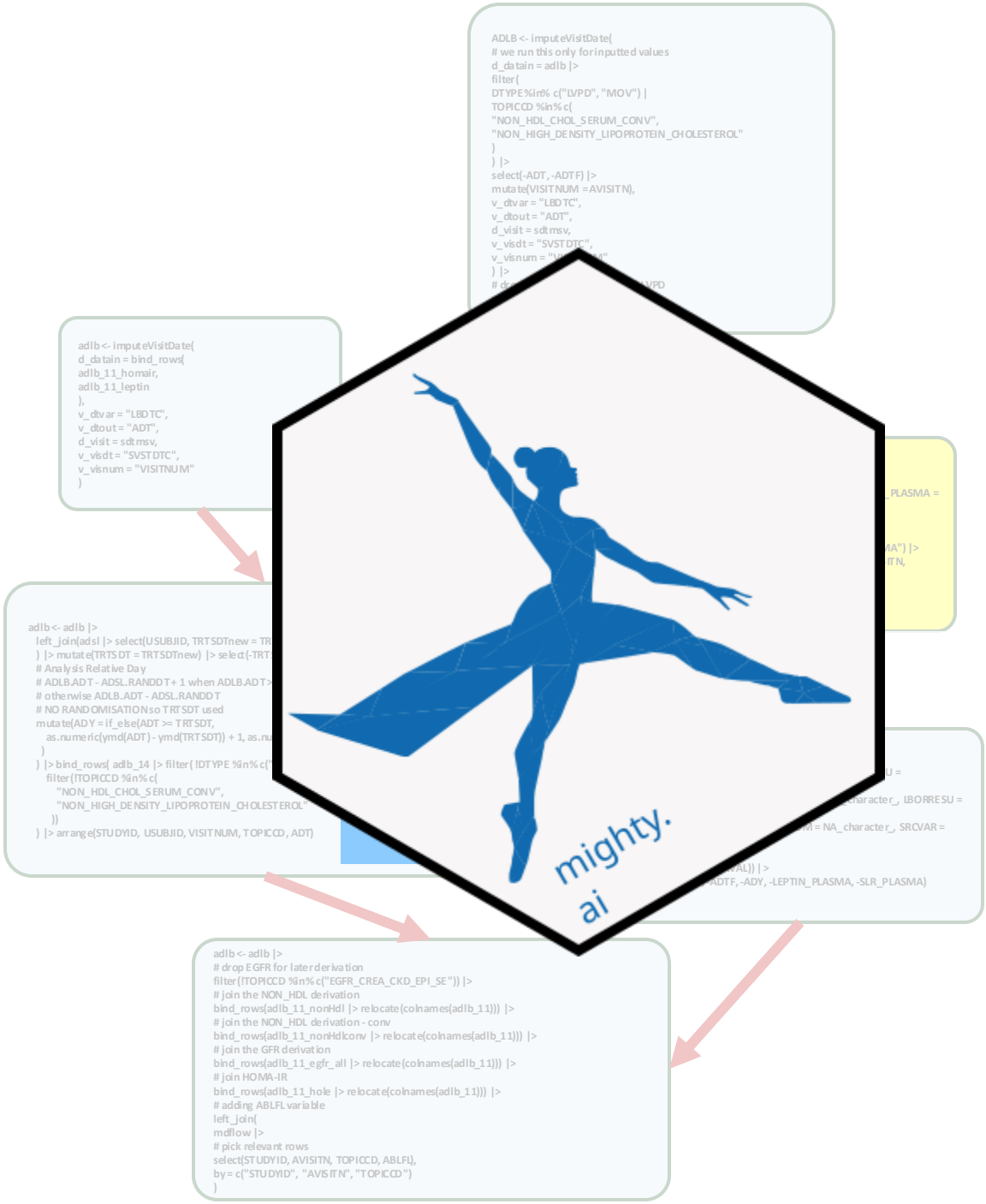


```
# Baseline flag and ba      e value (last non-missing prior to first dose)
adlb <- adlb %>%
group_by(USUBJID, PARAMCD) %>%
      e(USUBJID, PARAMCD, ADTM, .by_group = TRUE) %>%
      ABLFL = if_else(!is.na(ADTM) & ADTM <= TRTSDTM & !is.na(AVAL) &
ADTM == max(ADTM[ADTM <= TRTSDTM & !is.na(AVAL)], na.rm = TRUE),
"Y", "N"),
# Handle case where no pre-dose records exist (max(..., na.rm=TRUE) gives -Inf)
ABLFL = if_else(is.infinite(max(ADTM[ADTM <= TRTSDTM & !is.na(AVAL)], na.rm = TRUE)), "N", ABLFL),
BASE = if_else(ABLFL == "Y", AVAL, NA_real_)) %>% fill(BASE, .direction = "downup") %>% ungroup()
# On-treatment and post-baseline flags
adlb <- adlb %>% mutate( POSTBLFL = if_else(!is.na(ADT) & !is.na(TRTSDT) & ADT >= TRTSDT, "Y", "N"), ONTRTFL = if_else(
!is.na(ADTM) & !is.na(TRTSDTM) & !is.na(TRTEDTM) & ADTM >= TRTSDTM & ADTM <= (TRTEDTM + days(1L)), "Y", "N" ))
# Change and p      change from baseline
adlb <- adlb %>%      CHG = if_else(!is.na(AVAL) & !is.na(BASE), AVAL - BASE, NA_real_), PCHG = if_else(!is.na(AVAL) &
!is.na(BASE) &      100 * (AVAL - BASE) / BASE, NA_real_))
# Normal ran      ndicators and ratios (coalesce to SDTM STNR ranges if present)
adlb <- adlb %>%      ate( ANRLO = coalesce(ANRLO, LBSTNRLO), ANRHI = coalesce(ANRHI, LBSTNRHI), ANRIND = case_when(
      na(ANRLO) & is.na(ANRHI)) ~ NA_character_, !is.na(ANRLO) & AVAL < ANRLO ~ "LOW",
      ANRHI ~ "HIGH",
      RHI = if_else(!is.na(ANRHI) & ANRHI > 0, AVAL / ANRHI, NA_real_), R2ANRLO = if_else(!is.na(ANRLO)
      A_real_)
      ) %>% mutate( BNRIND = first(ANRIND[ABLFL == "Y"]), BASECAT = BNRIND
      t)
      FL == "Y",
      (ANRIND), "MISSING")), NA_character_ ))
      ected l      co      exact, parameter-specific rules.
      l,
      ) & !      ) ~ case_when(AVAL <= ULN ~ 0,
      5 *      ~ 3, AVAL > 20 * ULN ~ 4),
      when( AVAL <= ULN ~ 0, AVAL <= 2.5 * ULN ~ 1,
      4),
      ~ case_when(
      ),
      r(ATOXGRN)), NA_character_) ) %>% select(-ULN)
      oxicity grade, then highest value)
      TRUE)),
      ), WORSTGRN, NA_real_))
      , "PARAMCD")) %>%
      L; if still tied, earliest ADTM
      na(WORSTGRN) & !is.na(ATOXGRN) & ATOXGRN == WORSTGRN & AVAL ==
      ORSTGRN], na.rm = TRUE) &
      XGRN == WORSTGRN &
      OXGRN == WORSTGRN], na.rm = TRUE)], na.rm = TRUE) ~ "Y", TRUE ~ "N") ) %>%
      er parameter
      STBLFL == "Y", ANRIND == "HIGH") %>% group_by(USUBJID, PARAMCD) %>% slice_min(ADTM,
      ungroup() %>% transmute(USUBJID, PARAMCD, FIRSTHIDTM = ADTM)
```


ADLB <- imputeVisitDate(
# we run this only for inputted values
d_datain = adlb |>
filter(
DTYPE %in% c("LVPD", "MOV") |
TOPICCD %in% c(
"NON_HDL_CHOL_SERUM_CONV",
"NON_HIGH_DENSITY_LIPOPROTEIN_CHOLESTEROL"
)
) |>
select(-ADT, -ADTF) |>
mutate(VISITNUM = AVISITN),
v_dtvar = "LBDTC",
v_dtout = "ADT",
d_visit = sdtmsv,
v_visdt = "SVSTDTC",
v_visnum = "VISITNUM"
) |>
# drop VISITNUM for MOV and LVPD
mutate(VISITNUM = NA_real_)
adlb <- imputeVisitDate(
d_datain = bind_rows(
adlb_11_homair,
adlb_11_leptin
),
v_dtvar = "LBDTC",
v_dtout = "ADT",
d_visit = sdtmsv,
v_visdt = "SVSTDTC",
v_visnum = "VISITNUM"
)
adlb <- adlb |> filter(ANELFL == "Y") |>
# pick one as the template - Leptin in Plasma
filter(TOPICCD == "LEPTIN_PLASMA") |> mutate(LEPTIN_PLASMA = AVAL) | >
add Soluble Leptin as col
left_join(adlb_11 |>
filter(ANELFL == "Y") |> filter(TOPICCD == "SLR_PLASMA") |>
mutate(SLR_PLASMA = AVAL) |> select(USUBJID, AVISITN, SLR_PLASMA),
by = c("USUBJID", "AVISITN")
)
adlb <- adlb |>
left_join(adsl |> select(USUBJID, TRTSDTnew = TRTSDT), by = c("USUBJID")
) |> mutate(TRTSDT = TRTSDTnew) |> select(-TRTSDTnew) |>
Analysis Relative Day
ADLB.ADT - ADSL.RANDDT + 1 when ADLB.ADT >= ADSL.RANDDT;
otherwise ADLB.ADT - ADSL.RANDDT
NO RANDOMISATION so TRTSDT used
mutate(ADY = if_else(ADT >= TRTSDT,
as.numeric(ymd(ADT) - ymd(TRTSDT)) + 1, as.numeric(ymd(ADT) - ymd(TRTSDT))
)
) |> bind_rows(adlb_14 |> filter(!DTYPE %in% c("LVPD", "MOV")) |>
filter(!TOPICCD %in% c(
"NON_HDL_CHOL_SERUM_CONV",
"NON_HIGH_DENSITY_LIPOPROTEIN_CHOLESTEROL"
))
) |> arrange(STUDYID, USUBJID, VISITNUM, TOPICCD, ADT)
adlb <- aldb |> mutate(ATM = NA, ADTM = NA, AVALU = NA_character_, LBDTC = NA_character_,
LBFAST = NA_character_, LBORRES = NA_character_, LBORRESU = NA_character_,
DTYPE = NA_character_, SRCDOM = NA_character_, SRCVAR = NA_character_,
SRCSEQ = NA_real_
) |> filter(!is.na(AVAL)) | >
select(-ADT, -ADTF, -ADY, -LEPTIN_PLASMA, -SLR_PLASMA)
adlb <- adlb |>
# drop EGFR for later derivation
filter(!TOPICCD %in% c("EGFR_CREA_CKD_EPI_SE")) |>
join the NON_HDL derivation
bind_rows(adlb_11_nonHdl |> relocate(colnames(adlb_11))) |>
join the NON_HDL derivation - conv
bind_rows(adlb_11_nonHdlconv |> relocate(colnames(adlb_11))) |>
join the GFR derivation
bind_rows(adlb_11_egfr_all |> relocate(colnames(adlb_11))) |>
join HOMA-IR
bind_rows(adlb_11_hole |> relocate(colnames(adlb_11))) |>
adding ABLFL variable
left_join(
mdflow |>
pick relevant rows
select(STUDYID, AVISITN, TOPICCD, ABLFL),
by = c("STUDYID", "AVISITN", "TOPICCD")
)


ADLB <- imputeVisitDate(
# we run this only for inputted values
d_datain = adlb |>
filter(
DTYPE %in% c("LVPD", "MOV") |
TOPICCD %in% c(
"NON_HDL_CHOL_SERUM_CONV",
"NON_HIGH_DENSITY_LIPOPROTEIN_CHOLESTEROL"
)
) |>
select(-ADT, -ADTF) |>
mutate(VISITNUM = AVISITN),
v_dtvar = "LBDTC",
v_dtout = "ADT",
d_visit = sdtmsv,
v_visdt = "SVSTDTC",
v_visnum = "VISITNUM"
) |>
# drop VISITNUM for MOV and LVPD
mutate(VISITNUM = NA_real_)
adlb <- imputeVisitDate(
d_datain = bind_rows(
adlb_11_homair,
adlb_11_leptin
),
v_dtvar = "LBDTC",
v_dtout = "ADT",
d_visit = sdtmsv,
v_visdt = "SVSTDTC",
v_visnum = "VISITNUM"
)
adlb <- adlb |> filter(ANELFL == "Y") |>
# pick one as the template - Leptin in Plasma
filter(TOPICCD == "LEPTIN_PLASMA") |> mutate(LEPTIN_PLASMA = AVAL) | >
add Soluble Leptin as col
left_join(adlb_11 |>
filter(ANELFL == "Y") |> filter(TOPICCD == "SLR_PLASMA") |>
mutate(SLR_PLASMA = AVAL) |> select (USUBJID, AVISITN, SLR_PLASMA),
by = c("USUBJID", "AVISITN")
)
adlb <- adlb |>
left_join(adsl |> select(USUBJID, TRTSDTnew = TRTSDT), by = c("USUBJID")
) |> mutate(TRTSDT = TRTSDTnew) |> select(-TRTSDTnew) |>
Analysis Relative Day
ADLB.ADT - ADSL.RANDDT + 1 when ADLB.ADT >= ADSL.RANDDT;
otherwise ADLB.ADT - ADSL.RANDDT
NO RANDOMISATION so TRTSDT used
mutate(ADY = if_else(ADT >= TRTSDT,
as.numeric(ymd(ADT) - ymd(TRTSDT)) + 1, as.numeric(ymd(ADT) - ymd(TRTSDT))
)
) |> bind_rows(adlb_14 |> filter(!DTYPE %in% c("LVPD", "MOV")) |>
filter(!TOPICCD %in% c(
"NON_HDL_CHOL_SERUM_CONV",
"NON_HIGH_DENSITY_LIPOPROTEIN_CHOLESTEROL"
))
) |> arrange(STUDYID, USUBJID, VISITNUM, TOPICCD, ADT)
adlb <- aldb |> mutate(ATM = NA, ADTM = NA,AVALU = NA_character_, LBDTC = NA_character_,
LBFAST = NA_character_, LBORRES = NA_character_, LBORRESU = NA_character_,
DTYPE = NA_character_, SRCDOM = NA_character_, SRCVAR = NA_character_,
SRCSEQ = NA_real_
) |> filter(!is.na(AVAL)) | >
select(-ADT, -ADTF, -ADY, -LEPTIN_PLASMA, -SLR_PLASMA)
adlb <- adlb |>
# drop EGFR for later derivation
filter(!TOPICCD %in% c("EGFR_CREA_CKD_EPI_SE")) |>
join the NON_HDL derivation
bind_rows(adlb_11_nonHdl |> relocate(colnames(adlb_11))) |>
join the NON_HDL derivation - conv
bind_rows(adlb_11_nonHdlconv |> relocate(colnames(adlb_11))) |>
join the GFR derivation
bind_rows(adlb_11_egfr_all |> relocate(colnames(adlb_11))) |>
join HOMA-IR
bind_rows(adlb_11_hole |> relocate(colnames(adlb_11))) |>
adding ABLFL variable
left_join(
mdflow |>
pick relevant rows
select(STUDYID, AVISITN, TOPICCD, ABLFL),
by = c("STUDYID", "AVISITN", "TOPICCD")
)




ADLB <- imputeVisitDate(
# we run this only for inputted values
d_datain = adlb |>
filter(
DTYPE %in% c("LVPD", "MOV") |
TOPICCD %in% c(
"NON_HDL_CHOL_SERUM_CONV",
"NON_HIGH_DENSITY_LIPOPROTEIN_CHOLESTEROL"
)
) |>
select(-ADT, -ADTF) |>
mutate(VISITNUM = AVISITN),
v_dtvar = "LBDTC",
v_dtout = "ADT",
d_visit = sdtmsv,
v_visdt = "SVSTDTC",
adlb <- imputeVisitDate(
d_datain = bind_rows(
adlb_11_homair,
adlb_11_leptin
),
v_dtvar = "LBDTC",
v_dtout = "ADT",
d_visit = sdtmsv,
v_visdt = "SVSTDTC",
v_visnum = "VISITNUM"
)
adlb <- adlb |>
left_join(adsl |> select(USUBJID, TRTSDTnew = TR
) |> mutate(TRTSDT = TRTSDTnew) |> select(-TRT
Analysis Relative Day
ADLB.ADT - ADSL.RANDDT + 1 when ADLB.ADT >
otherwise ADLB.ADT - ADSL.RANDDT
NO RANDOMISATION so TRTSDT used
mutate(ADY = if_else(ADT >= TRTSDT,
as.numeric(ymd(ADT) - ymd(TRTSDT)) + 1, as.nu
)
) |> bind_rows(adlb_14 |> filter(!DTYPE %in% c("
filter(!TOPICCD %in% c(
"NON_HDL_CHOL_SERUM_CONV",
"NON_HIGH_DENSITY_LIPOPROTEIN_CHOLESTEROL"
))
) |> arrange(STUDYID, USUBJID, VISITNUM, TOPICCD, ADT)
_PLASMA =
MA") |>
ITN,
U =
character_, LBORRESU =
M = NA_character_, SRCVAR =
VAL)) | >
ADTF, -ADY, -LEPTIN_PLASMA, -SLR_PLASMA)
adlb <- adlb |>
# drop EGFR for later derivation
filter(!TOPICCD %in% c("EGFR_CREA_CKD_EPI_SE")) |>
join the NON_HDL derivation
bind_rows(adlb_11_nonHdl |> relocate(colnames(adlb_11))) |>
join the NON_HDL derivation - conv
bind_rows(adlb_11_nonHdlconv |> relocate(colnames(adlb_11))) |>
join the GFR derivation
bind_rows(adlb_11_egfr_all |> relocate(colnames(adlb_11))) |>
join HOMA-IR
bind_rows(adlb_11_hole |> relocate(colnames(adlb_11))) |>
adding ABLFL variable
left_join(
mdflow |>
pick relevant rows
select(STUDYID, AVISITN, TOPICCD, ABLFL),
by = c("STUDYID", "AVISITN", "TOPICCD")
)
mighty.
ai

5 May, 2012,
https://www.reddit.com/r/funny/comments/t8gjh/instructions_for_my_new_undies_just_in_case/

@davie_dave 24 April 2020, https://www.instagram.com/p/B_YHfJiJ_9j/

Matthew Phelps

mewp@novonordisk.com

Nocialai Skov Jensen