Data:

1. rawdata: data directly entered into database by medical staff from clinical trial sites

-      ae: adverse events

-      dm: demographics

-      enroll: enrollment

-      pk: pharmacokinetic sample collection time

-      pk\_ex: drug dosing time

-      sdrgcomp: study drug completion status

-      studcomp: study completion status

-      visdt: subject visit dates

1. SDTM: built from rawdata, rawdata are converted into this standard data structure that are to be submitted to FDA as part of a product application

* ae: adverse events
* dm: demographics
* ds: subject disposition
* ex: treatment information
* suppae: supplemental information for adverse events
* suppdm: supplemental information for demographics
* suppex: supplemental information for treatment
* sv: subject visits
* ta: trial arms
* te: trial elements
* ts: trial summary
* tv: trial visits

1. ADaM: built from SDTM data, it contains derived variables to be used for analysis, e.g., variables related to efficacy or safety. Most of the tables and figures that are generated for writing study report use variables from the ADaM data.

* adae: dataset for adverse events
* adsl: dataset for subject level information

Outputs:

1. t-demog.rtf: table for subject demographics, generated from adsl
2. t-disp.rtf: table for subject disposition, generated from adsl
3. t-teae.rtf: table for treatment-emergent adverse events, generated from adae and adsl
4. g-med-alt: an example graph for ALT lab value versus study day, which is \***not\*** generated from these dummy data

Specs:

1. ADaM Specification: describes the name, type and meaning of each variable in the adsl and adae datasets
2. SDTM specs: describes how rawdata are converted into SDTM data. Each form corresponds to a dataset in the rawdata, e.g., the adverse event form on Page 1-3 matches the ae dataset in rawdata. Variable names in the orange boxes correspond to the variables in the SDTM data.