

Tool should be
online.
Preference is for
R-shiny

Include SDTM
& SEND

- free scripts \Rightarrow either
desktop or SAS
- DM, EX, efficacy

* Open source
* Simple UI
* ~~Start~~ SEND
since it is simple
& less domain

Yes! I see the need.
I'm wondering about the
scope. Is it to provide
the use of the same test
data across users? Or
to help users generate
custom test data that
meet their needs?

- A user-friendly interface
where one can input
population
characteristics based on
study I/E criteria.
- in SDTM format
- assessments, events based on
protocol SOA

① Desktop or SaaS

② Paid & Maintained

③ Most important datasets
DM (ADSL)
AE (ADAE)

Many Rules:

Analysis should be
realistic

~~Web b:~~

Desktop
usable.
not cloud

Not proprietary
R/
Shiny preferred

Most imp domains ②

2) Disposition (w/ different
trial milestones)

~~ECG~~ 3) ECG

1) EC/EX - w/ varying
dose forms
& scenarios

Top 3 features: ①

- Provide general
specs on study
design that can be
modeled in ~~real~~
relationships across
variables / visits

(eg. crossover
combinatorial treatment
arms)

User interface Preference

Simple front end (e.g. enter values for specific fields)

Output

- CSV or other non-Proprietary format

What I would use:

- time-to-event simulated dataset where I can control a treatment effect
- A simulated ADAE dataset linked to ~~ADAE~~ DM data

SDTM + ADaM

Tool → Test New
Standard
Therapeutic
Are

Open Source

- Ready to use ~~and~~
~~can be added to~~
- desktop

- open source - let others add to it

SDTM
would start w/ DM,
probably EX after that.

Had no idea there was (→)

→ So much to consider

Priority - SDTM (1)
ADaM (2)

Ready to use would be awesome but scripts would be OK

- If Ready-to-use, company would be willing to pay reasonable amt (depends on cost)