R/Pharma 2024

Using Shiny to Clearly Present Clinical Results with CDISC-Compliant Dataset

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Agenda

- Introduction
- Needs of different departments for clinical data
- How R and Shiny can improve data review and visualization
- Three examples in Shiny

About Me

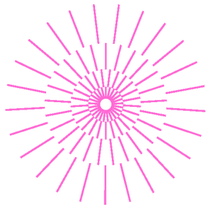
- Statistical Programmer in both CROs and pharma companies
- Potential for workflow improvement by using open-source tools like R and Python
- First experience with R
- Interest in Shiny and Tidyverse

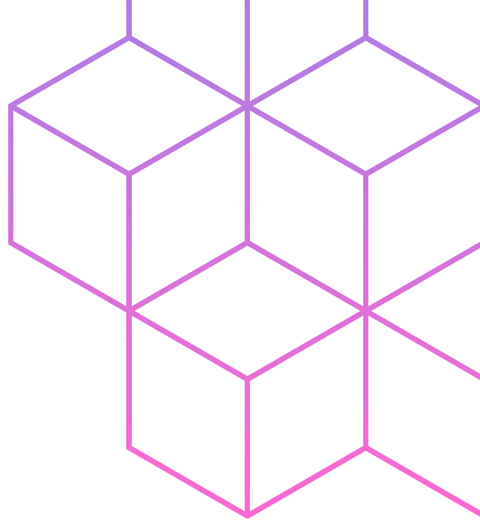
Common Process & Challenge

- Reviewers: verify numbers or individual patient data
- Programming team: trace back through ADaM, SDTM, or EDC
- Medicals: monitor patient progress
- Shiny helps by offering flexible and efficient visualizations

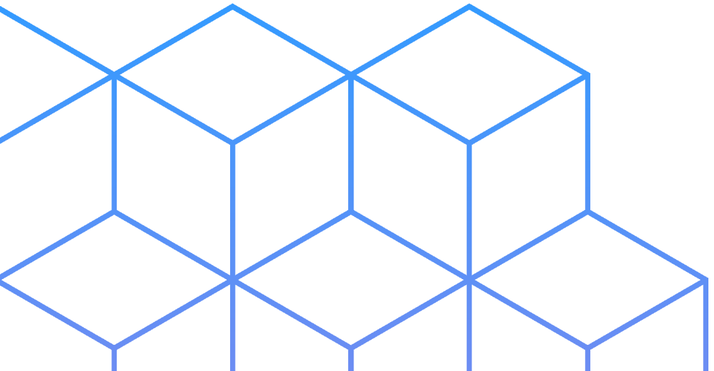
Department-Specific Needs for Clinical Data

- Different departments need varied information
  - Specific populations
  - Individual patients
  - Some lab results, etc





Need to follow the same data processing flow for everything?



What Shiny can do?

- Allows filtering data based on specific criteria
- Displaying corresponding results
- Saves time and provides real-time results

Why R/Shiny

- Growing use of R in clinical trials (e.g., Pharmaverse)

- R used successfully in regulatory submissions

- Shiny adding interactivity, allowing users to filter data and generate visual results

- R Markdown / Quarto making results accessible to non-programmers

Demonstrate

01

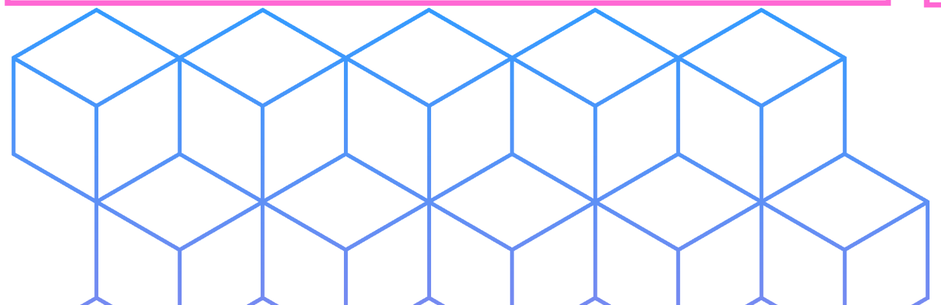
- Presenting three visualizations using simulated SDTM data in a Shiny app
  - **Tumor related analysis**
  - **Patient status overview**
  - **SDTM domain visualizations**

02

Helps to users understand clinical data results

03

Use of common R packages: tidyverse, shiny, ggplot2



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RECIST 1.1 - Tumor Related Analysis

Overall | Individual

USUBJID	Confirm_BOR	Unconfirm_BOR
Sample-001-001	CR	CR
Sample-001-002	SD	SD
Sample-001-003	CR	CR
Sample-001-004	SD	SD
Sample-001-005	SD	SD
Sample-001-006	SD	SD
Sample-001-007	PR	CR
Sample-001-008	SD	SD
Sample-001-009	PR	PR
Sample-001-012	CR	CR

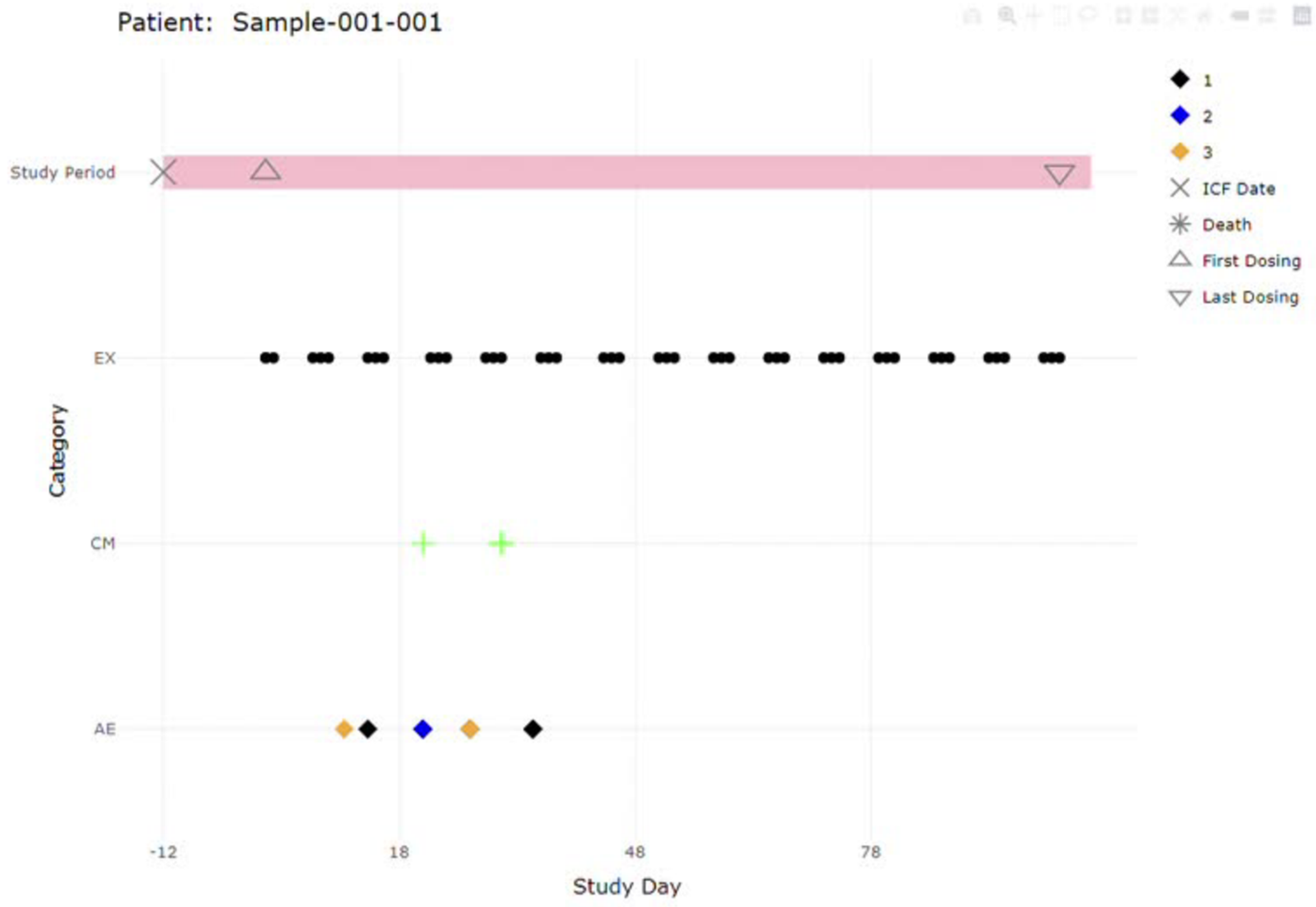
Download Excel

Trial Status Overview Plot

Patient ID :

Sample-001-001

Download Excel



SDTM Domain Listing

Unique Subject :

Sample-001-001

Class :

All

Domain :

AE

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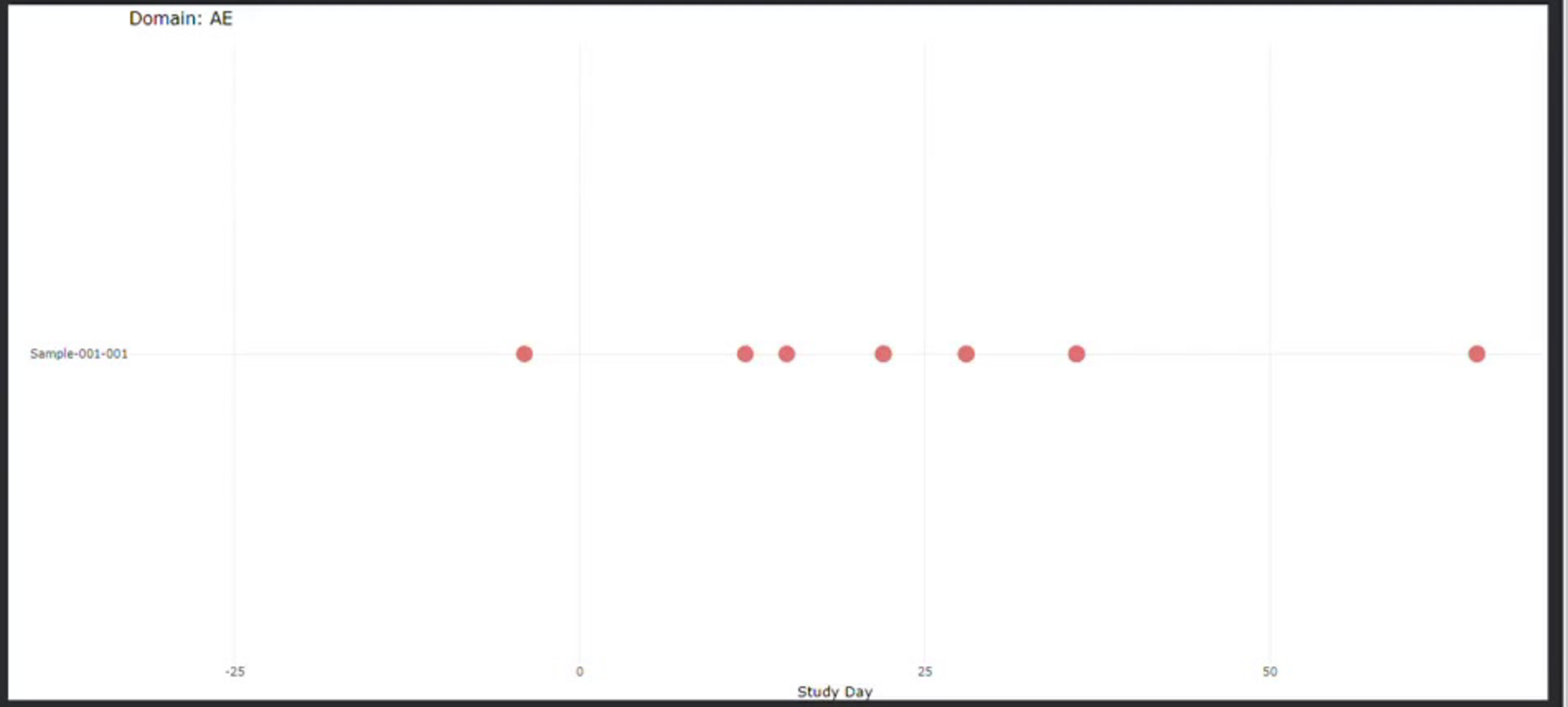

Unique Subject	Topic Variable	Category	Subcategory	Start Date	End Date	Dat/Time
Sample-001-001	ALANINE AMINOTRANSFERASE INCREASED	NA	NA	2019-01-28	2019-03-19	NA
Sample-001-001	ALOPECIA	NA	NA	2019-01-14		NA
Sample-001-001	ASPARTATE AMINOTRANSFERASE INCREASED	NA	NA	2019-01-28		NA
Sample-001-001	ALKALINE PHOSPHATASE INCREASED	NA	NA	2018-12-20	2018-12-31	NA
Sample-001-001	COUGH	NA	NA	2019-01-20	2019-02-26	NA
Sample-001-001	DIARRHEA	NA	NA	2019-01-04	2019-01-05	NA
Sample-001-001	DIARRHEA	NA	NA	2019-01-14	2019-01-17	NA
Sample-001-001	DYSGEUSIA	NA	NA	2019-02-26		NA

Why CDISC

- **Standardized Data**: CDISC (e.g., SDTM, ADaM) offers a unified format for clinical trial data, reducing the need for additional data reformatting.

- **Effective Communication**: CDISC standards facilitate easier communication across departments and organizations.

- **Time-Saving**: Standardized variables and attributes simplify the visualization process, saving time and effort.

Conclusion

Shiny and R improve data flexibility and interactivity

CDISC-compliant data simplifies communication and reduces reformatting

Shiny + Quarto for empowering non-programming teams

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Thank you

HALLOWEEN