

An abstract graphic on the left side of the slide featuring interlocking gears of various sizes and colors (blue, white, and grey) set against a background of circuitry, arrows, and geometric shapes. The graphic is partially enclosed by a curved blue border.

Connecting Tables, Listings and Figures

Stella Guo

stella.guo1@bayer.com



Clinical data analysis and reporting



Statistical analysis
plan & data/TLF
specifications



cdisc

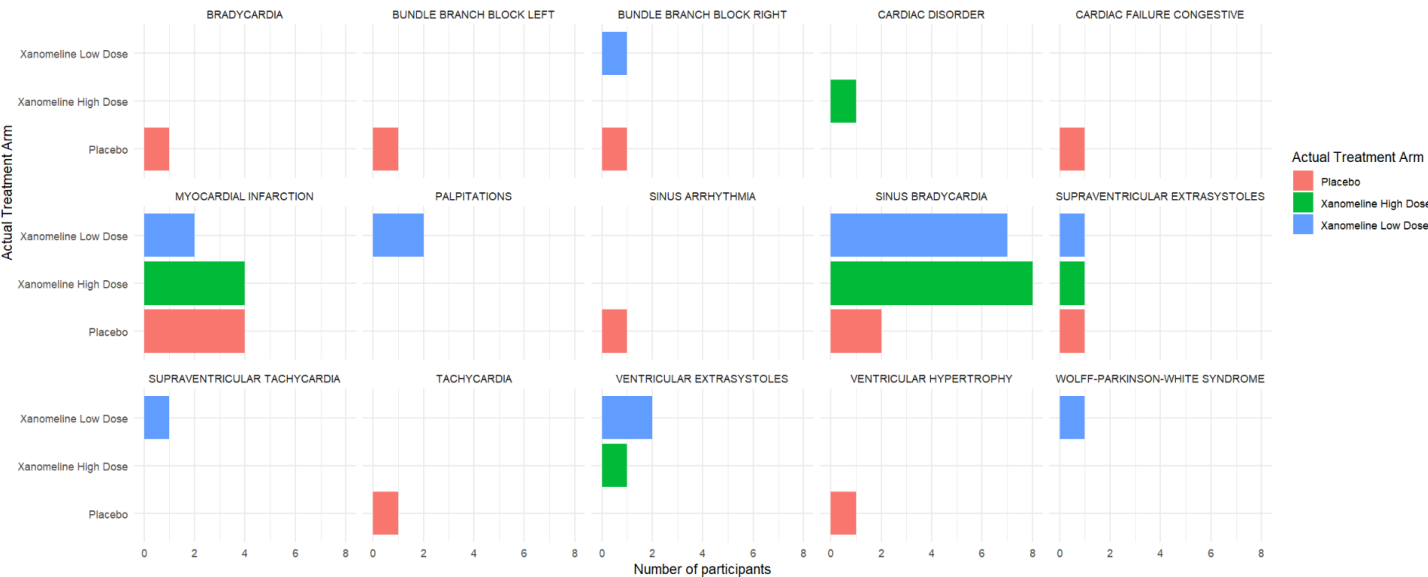
ADaM dataset



Tables, listings,
and figures

Summary of adverse events (Safety Population)

BODY SYSTEM/PREFERRED TERM	Placebo	Xanomeline High Dose	Xanomeline Low Dose
CARDIAC DISORDERS			
ATRIAL FIBRILLATION	1	3	1
ATRIAL HYPERTROPHY	1	0	0
ATRIOVENTRICULAR BLOCK FIRST DEGREE	1	0	1
ATRIOVENTRICULAR BLOCK SECOND DEGREE	2	3	0
BRADYCARDIA	1	0	0
BUNDLE BRANCH BLOCK LEFT	1	0	0
BUNDLE BRANCH BLOCK RIGHT	1	0	1
CARDIAC FAILURE CONGESTIVE	1	0	0
MYOCARDIAL INFARCTION	4	4	2
SINUS ARRHYTHMIA	1	0	0
SINUS BRADYCARDIA	2	8	7
SUPRAVENTRICULAR EXTRASYSTOLES	1	1	1



Listing of Adverse Events (Safety Population)

Study Identifier	Unique Subject Identifier	Actual Treatment	Analysis Start Date	Analysis End Date	Reported Term for the Adverse Event	Body System or Organ Class	Preferred Term
CDISCILOT01	01-701-1015	Placebo	2014-01-03	NA	APPLICATION SITE ERYTHEMA	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	APPLICATION SITE ERYTHEMA
CDISCILOT01	01-701-1015	Placebo	2014-01-03	NA	APPLICATION SITE PRURITUS	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	APPLICATION SITE PRURITUS
CDISCILOT01	01-701-1015	Placebo	2014-01-09	2014-01-11	DIARRHOEA	GASTROINTESTINAL DISORDERS	DIARRHOEA
CDISCILOT01	01-701-1023	Placebo	2012-08-07	2012-08-30	ERYTHEMA	SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ERYTHEMA
CDISCILOT01	01-701-1023	Placebo	2012-08-07	NA	ERYTHEMA	SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ERYTHEMA
CDISCILOT01	01-701-1023	Placebo	2012-08-26	NA	ATRIOVENTRICULAR BLOCK SECOND DEGREE	CARDIAC DISORDERS	ATRIOVENTRICULAR BLOCK SECOND DEGREE
CDISCILOT01	01-701-1023	Placebo	2012-08-07	2012-08-30	ERYTHEMA	SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ERYTHEMA
CDISCILOT01	01-701-1028	Xanomeline High Dose	2013-07-21	NA	APPLICATION SITE ERYTHEMA	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	APPLICATION SITE ERYTHEMA
CDISCILOT01	01-701-1028	Xanomeline High Dose	2013-08-08	NA	APPLICATION SITE PRURITUS	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	APPLICATION SITE PRURITUS



Open-source packages



Interactive web apps



Interactive tables



Interactive visualization



- Demographics
- Baseline Cancer Characteristics
- Disposition
- Adverse Events
- Efficacy
- Tumor Response
- Exposure
- Lab
- About

- Serious event
- Yes
 - No
- Intensity
- MILD
 - MODERATE
 - SEVERE

Summary of adverse events

Search:

BODY SYSTEM	PREFERRED TERM	Placebo	Xanomeline High Dose	Xanomeline Low Dose
All	All	All	All	All
CARDIAC DISORDERS	ATRIAL FIBRILLATION	1	3	1
CARDIAC DISORDERS	ATRIAL FLUTTER	0	1	1
CARDIAC DISORDERS	ATRIAL HYPERTROPHY	1	0	0
CARDIAC DISORDERS	ATRIOVENTRICULAR BLOCK FIRST DEGREE	1	0	1
CARDIAC DISORDERS	ATRIOVENTRICULAR BLOCK SECOND DEGREE	2	3	0
CARDIAC DISORDERS	BRADYCARDIA	1	0	0
CARDIAC DISORDERS	BUNDLE BRANCH BLOCK LEFT	1	0	0
CARDIAC DISORDERS	BUNDLE BRANCH BLOCK RIGHT	1	0	1
CARDIAC DISORDERS	CARDIAC DISORDER	0	1	0
CARDIAC DISORDERS	CARDIAC FAILURE CONGESTIVE	1	0	0
CARDIAC DISORDERS	MYOCARDIAL INFARCTION	4	4	2
CARDIAC DISORDERS	PALPITATIONS	0	0	2

Showing 1 to 242 of 242 entries

Bar chart of adverse events

Listing of adverse events

Search:



YAML configuration file – customization

- Human readable
- Key-value pairs
- Experience in R programming is not required
- Study specific information

```
pop_trt_vars:
  adsl: [FASFL, TRT01P, TRT01PN]
  adae: [SAFFL, TRT01A, TRT01AN]
  adex: [SAFFL, TRT01A, TRT01AN]
  adtte: [FASFL, TRT01P, TRT01PN]
  adbcc: [FASFL, TRT01P, TRT01PN]
  adrs: [FASFL, TRT01P, TRT01PN]

ae:
  drill_down_table:
    - STUDYID
    - USUBJID
    - AESEQ
    - ASTDT
    - AENDT

    ae_special_fl:
      - AESER
      - AESEV

sl:
  filters:
    - SEX
    - AGEGR01
    - RACE

  sum_table:
    catergorical:
      - AGEGR01
    numeric:
      - AGE
```



YAML – Filters

iAnalyze

Demographics

Baseline Cancer Characteristics

Disposition

Adverse Events

Efficacy

Tumor Response

Exposure

Lab

About

Serious event

☒ Yes

☒ No

Intensity

☒ MILD

☒ MODERATE

☒ SEVERE

ae:

ae_special_fl:

- AESER

- AESEV

Summary of adverse events

Search:

BODY SYSTEM	PREFERRED TERM	Placebo	Xanomeline High Dose	Xanomeline Low Dose
All	All	All	All	All
CARDIAC DISORDERS	ATRIAL FIBRILLATION	1	3	1
CARDIAC DISORDERS	ATRIAL FLUTTER	0	1	1
CARDIAC DISORDERS	ATRIAL HYPERTROPHY	1	0	0
CARDIAC DISORDERS	ATRIOVENTRICULAR BLOCK FIRST DEGREE	1	0	1
CARDIAC DISORDERS	ATRIOVENTRICULAR BLOCK SECOND DEGREE	2	3	0



YAML – Listing Columns

Listing of adverse events

Search:

Study Identifier	Unique Subject Identifier	Actual Treatment	Sequence Number	Analysis Start Date	Analysis End Date	Reported Term for the Adverse Event	Body System or Organ Class	Preferred Term	Severity/Intensity	Serious Event	Causality	Outcome of Adverse Event
All	All	All	All	All	All	All	All	All	All	All	All	All
CDISCPLOT01	01-704-1266	Xanomeline High Dose	4	2013-11-08	2013-12-06	ATRIAL FIBRILLATION	CARDIAC DISORDERS	ATRIAL FIBRILLATION	MILD	N		
CDISCPLOT01	01-704-1266	Xanomeline High Dose	13	2013-11-08	2013-12-06	ATRIAL FIBRILLATION	CARDIAC DISORDERS	ATRIAL FIBRILLATION	MILD	N		
CDISCPLOT01	01-708-1178	Xanomeline High Dose	7	2014-03-24	2014-03-26	ATRIAL FIBRILLATION	CARDIAC DISORDERS	ATRIAL FIBRILLATION	SEVERE	N		

```
ae:
  drill_down_table:
    - STUDYID
    - USUBJID
    - AESEQ
    - ASTDT
    - AENDT
    - AETERM
    - AEBODSYS
    - AEDECOD
    - AESEV
    - AESER
    - AEREL
    - AEOUT
```



Summary

- A shiny app is built to provide interactive tables, listings and figures
- Open-source packages DT and plotly are used to link the TLFs
- YAML configuration file is designed to set up study specific information



Acknowledgement

- Development team

Bharath Sunkavalli, Henning Lorenzen, Karl Brand, Siqi Zhang, Virginie Aris

- Management

Srinivas Veeragoni, Ankur Mathur, Richardus Wonk



Reference

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- Xie Y, Cheng J, Tan X (2022). DT: A Wrapper of the JavaScript Library 'DataTables'. <https://CRAN.R-project.org/package=DT>
- C. Sievert. Interactive Web-Based Data Visualization with R, plotly, and shiny. Chapman and Hall/CRC Florida, 2020.
- ICH E3 guidance https://database.ich.org/sites/default/files/E3_Guideline.pdf
- CDISC pilot project following ICH E3 guidance <https://github.com/cdisc-org/sdtm-adam-pilot-project>