Interactive clinical study visualisation in enabling the faster decision making

BBS Seminar: Graphics for decision-making in biomedical research and drug development

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Problem statement

Exploratory Biomarker Analysis

Implementation example

Demo

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- The exploratory analysis of clinical trials requires flexibility in the results exploration
- The decision making process especially based on biomarker exploratory analysis might be time consuming based on the number of potential candidates and might require the alternative hypothesis generation in the short time
- Visualisation and tabulation of those results in across different biomarkers candidates and ability of cross checking different type of analysis is a key in effective exploration

Problem statement: regulatory v. exploratory

The exploratory biomarker analysis within the clinical trial usually provides the large number of reports, which using presented flexible framework, allows to reduce the number outputs required for regulatory purposes.

Based on the saem implementation using the *R Shiny Applications within Ophthalmology* [1] :

- Efficiency gain by combining study results exploration and code generation
- Flexible and agile solution in increasingly growing complexity of studies and number of biomarker candidates
- Customisations of study specific implementations using the R packages

1 - https://www.lexjansen.com/phuse-us/2020/as/AS01.pdf

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Exploratory Biomarker analysis

- This presentation will focus on the unique capability in visualising the study results of the primary endpoints and the flexibility in exploring different baseline biomarkers, based on the randomly generated data, but reflects the real study analysis scenario.
- In the real study, there might be a good predictive biomarker candidate based on the protocol, which might fail after the study unblinding
- Exploring and finding a new good candidate in short term requires a robust hypothesis generation process

Exploratory Biomarker analysis

- In rider to explore different aspect of analysis, provided example provides a set of standard visualizations:

- *Data Table* - the raw data viewer
- *Variable Browser* - variable data browser
- *Selection Bias* - demographic analysis and selection bias
- *Cross Table* - cross tabulation of chosen variables and biomarkers
- *Uni- and Bivariate Plot* - plotting the variables
- *Response Module* - exploration of biomarker using response variable
- *Time-to-event Analysis* - exploration of biomarker using Time to event
- *Forest Response* - exploration using forest for response
- *Forest Survival* - exploration using the forest for time ti event
- *Overlap Module* - cross checking available biomarker populations

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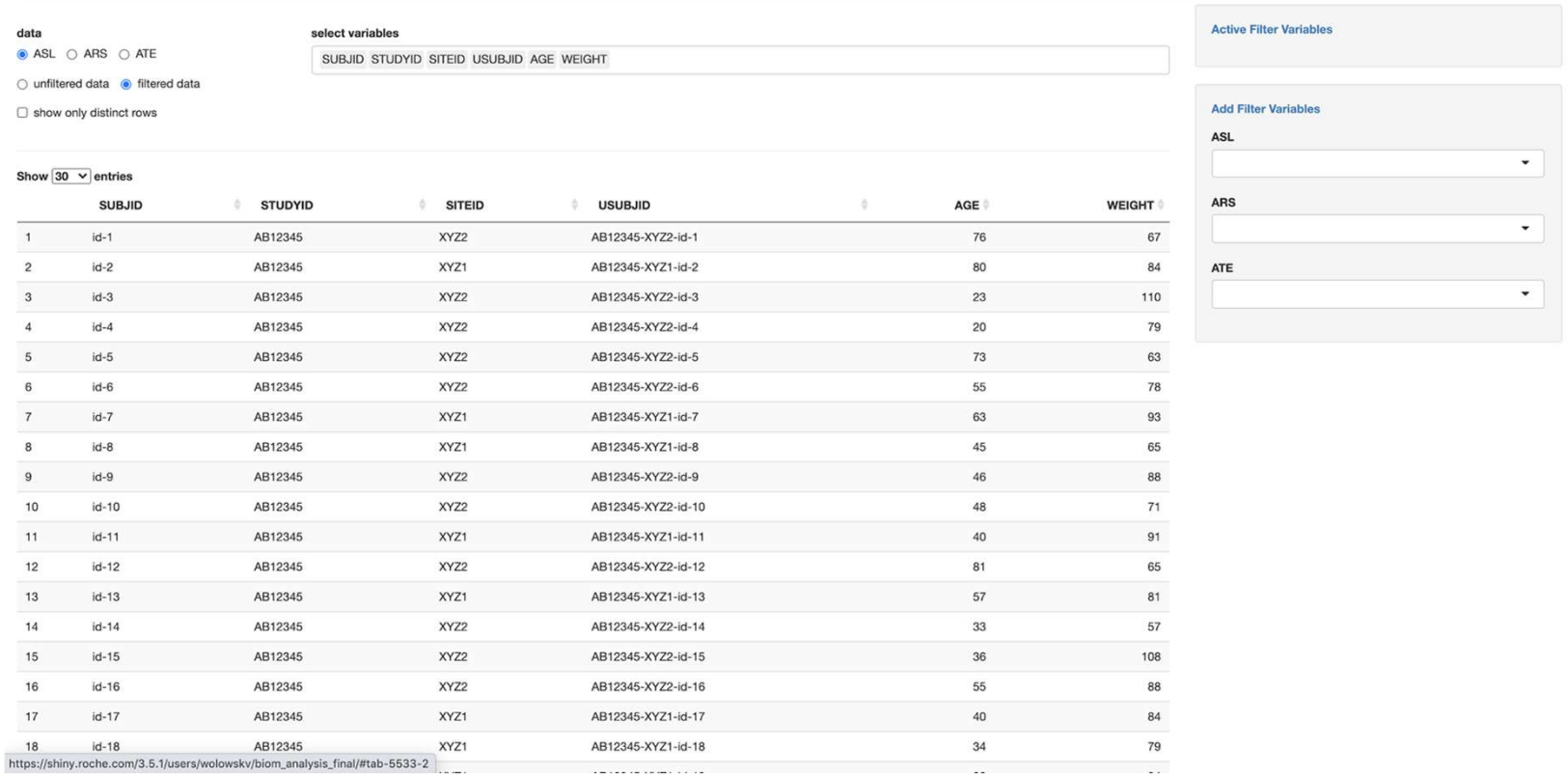
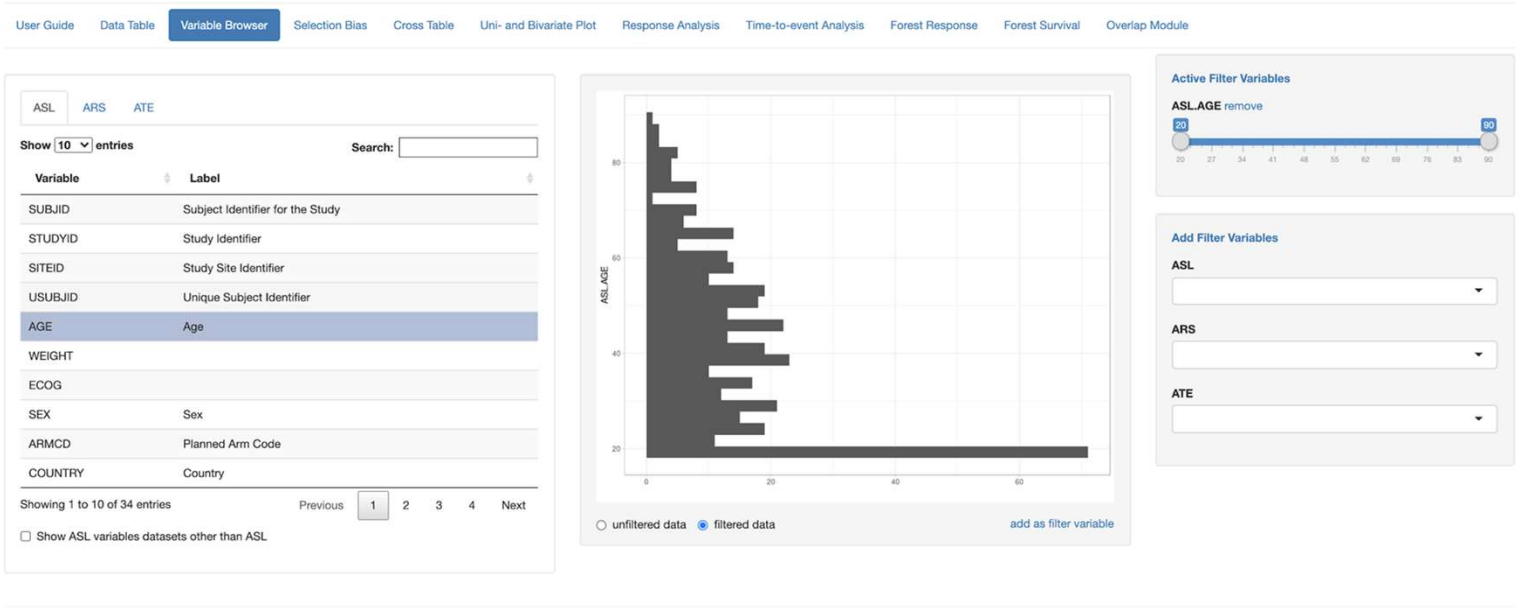
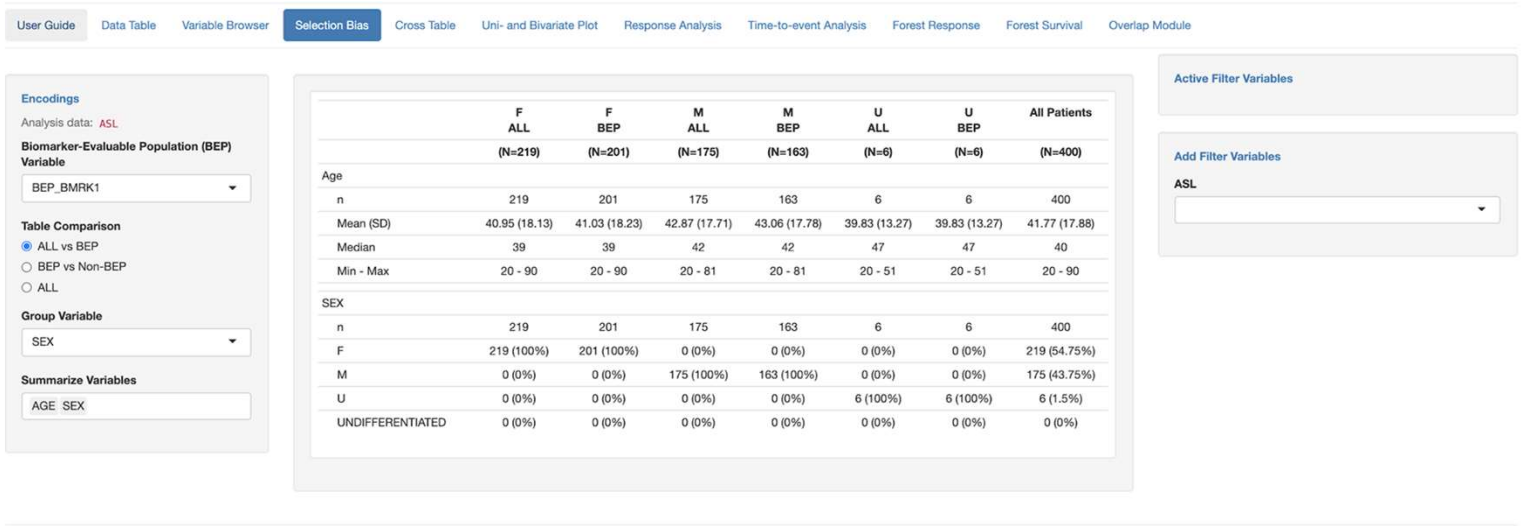
Implementation example: Data table



Implementation example: Variable browser



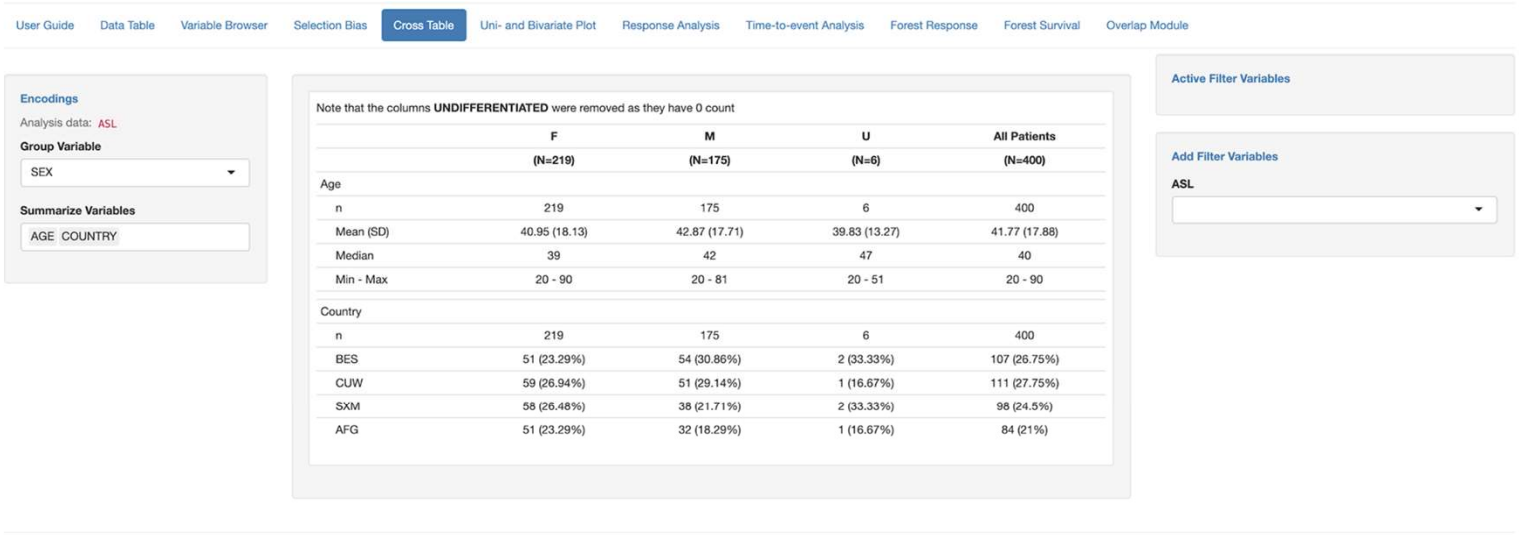
Implementation example: Selection bias



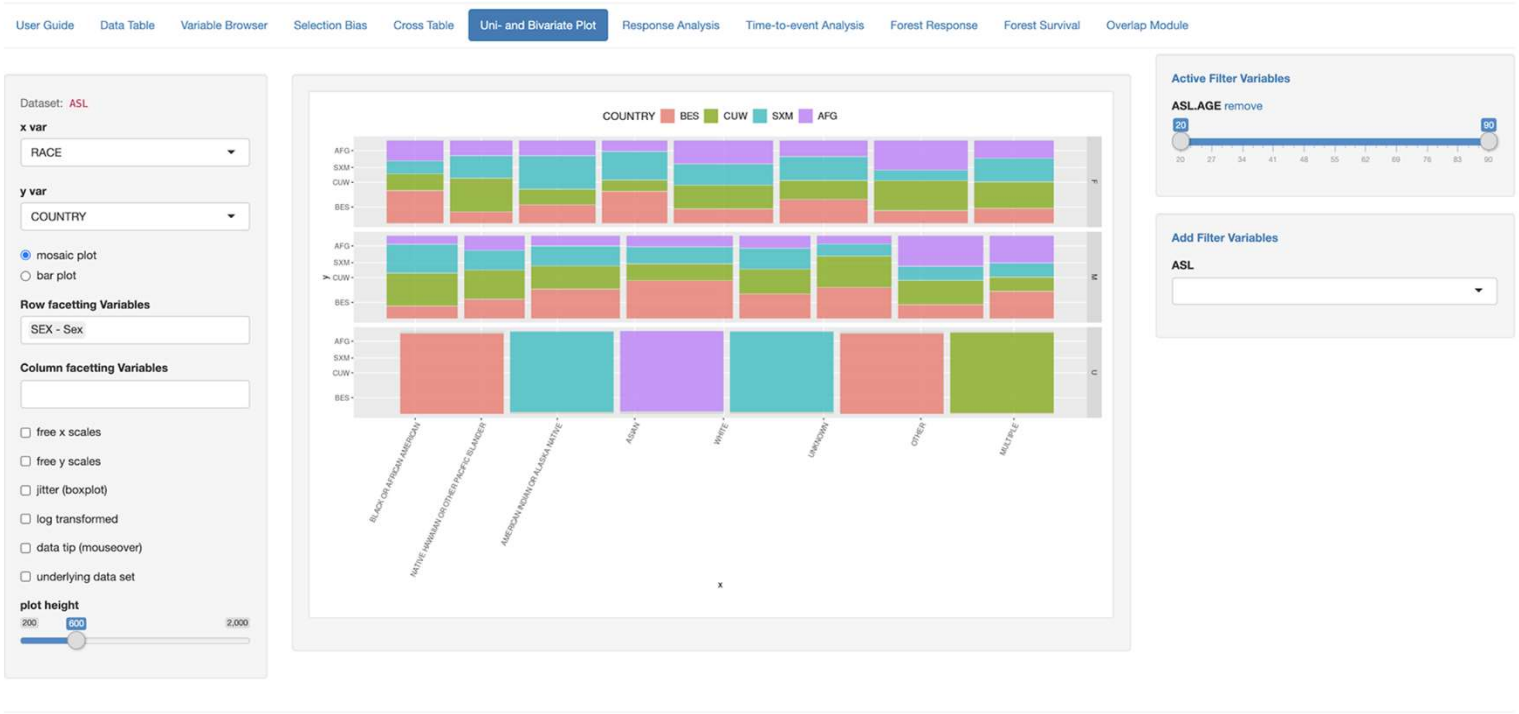
	F ALL (N=219)	F BEP (N=201)	M ALL (N=175)	M BEP (N=163)	U ALL (N=6)	U BEP (N=6)	All Patients (N=400)
Age							
n	219	201	175	163	6	6	400
Mean (SD)	40.95 (18.13)	41.03 (18.23)	42.87 (17.71)	43.06 (17.78)	39.83 (13.27)	39.83 (13.27)	41.77 (17.88)
Median	39	39	42	42	47	47	40
Min - Max	20 - 90	20 - 90	20 - 81	20 - 81	20 - 51	20 - 51	20 - 90
SEX							
n	219	201	175	163	6	6	400
F	219 (100%)	201 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	219 (54.75%)
M	0 (0%)	0 (0%)	175 (100%)	163 (100%)	0 (0%)	0 (0%)	175 (43.75%)
U	0 (0%)	0 (0%)	0 (0%)	0 (0%)	6 (100%)	6 (100%)	6 (1.5%)
UNDIFFERENTIATED	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

https://shiny.roche.com/3.5.1/users/wolowskv/biom_analysis_final/#tab-5533-1

Implementation example: Cross table

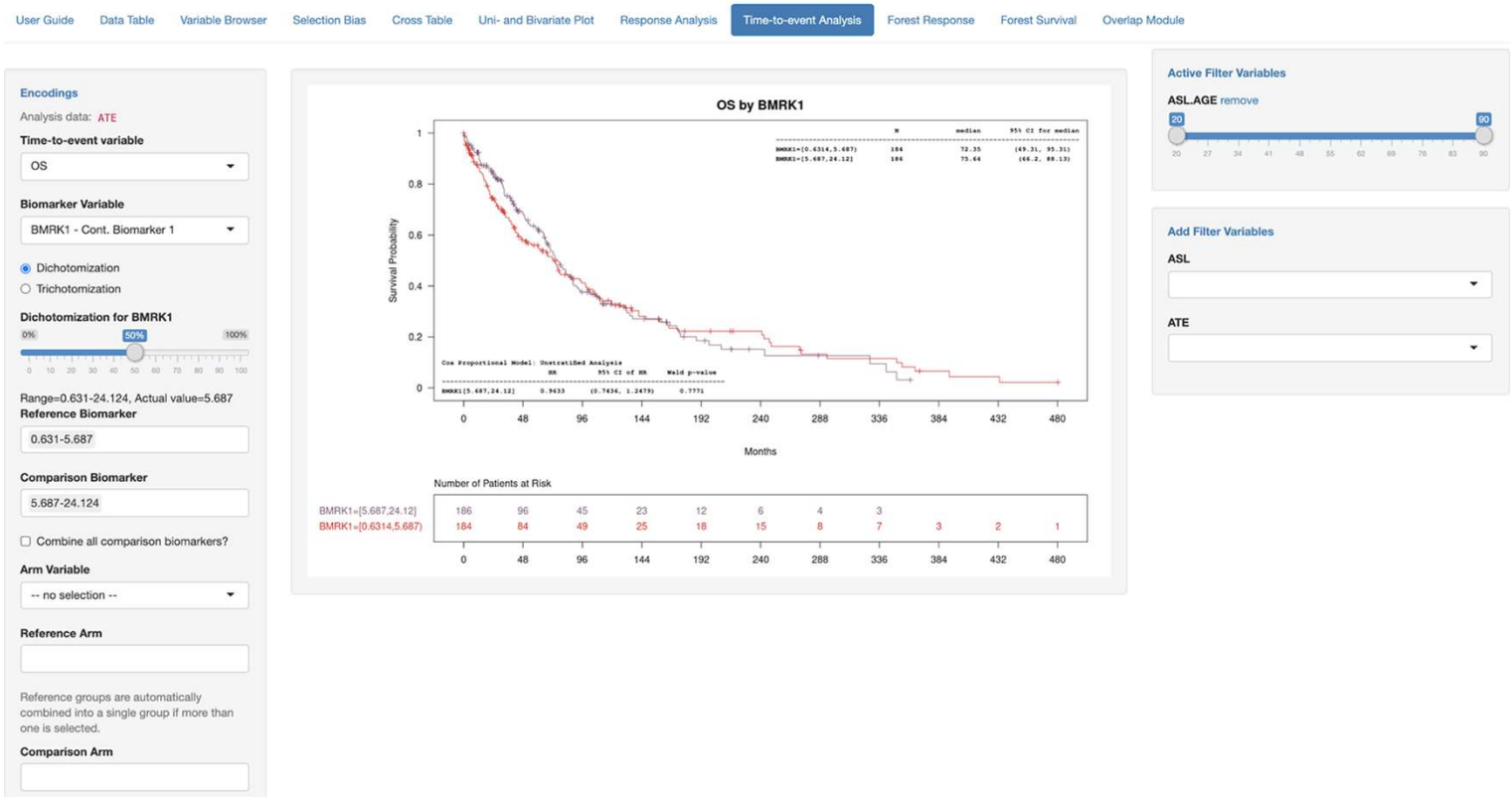


Implementation example: Uni- and Bivariate plot

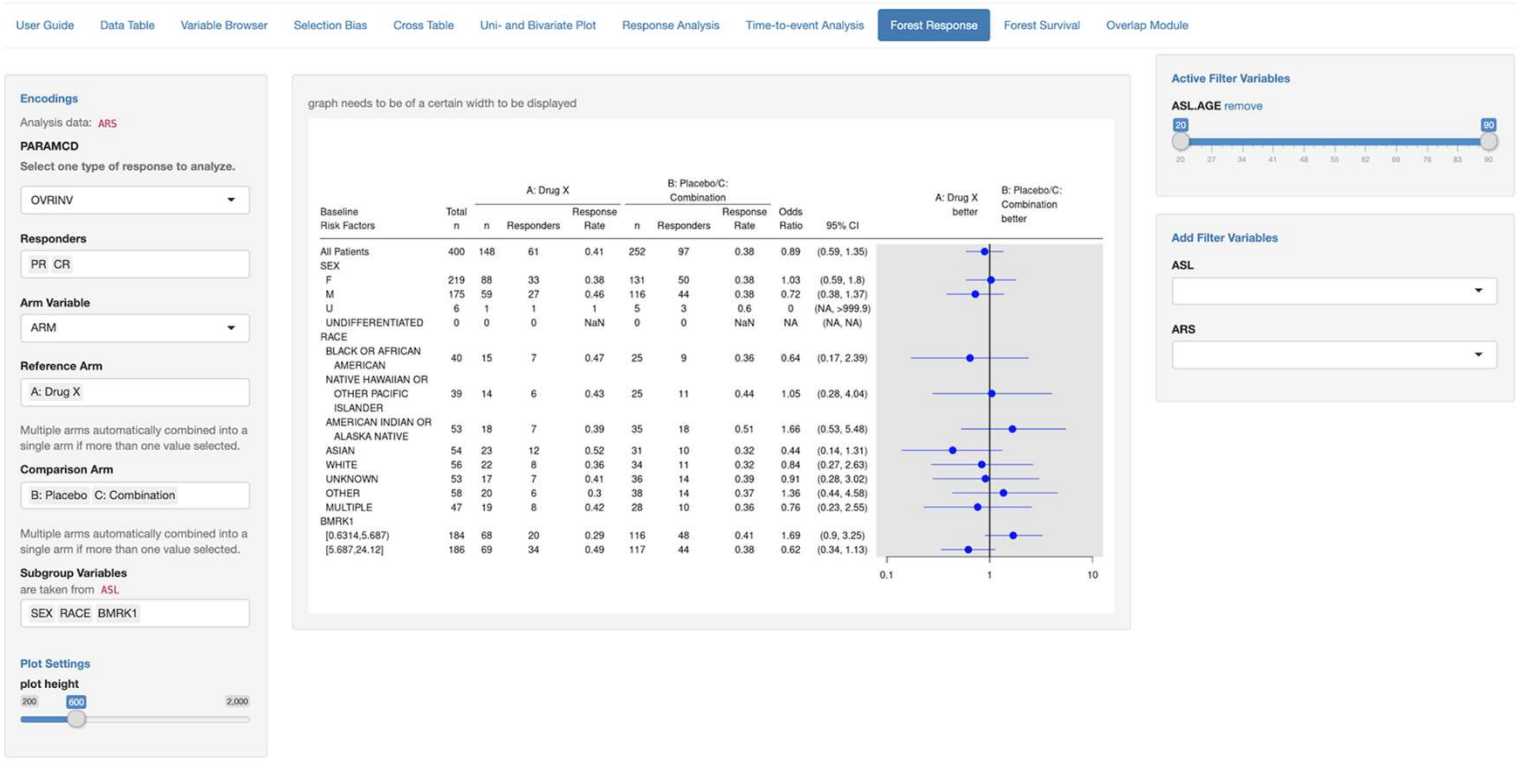


Implementation example: Response analysis

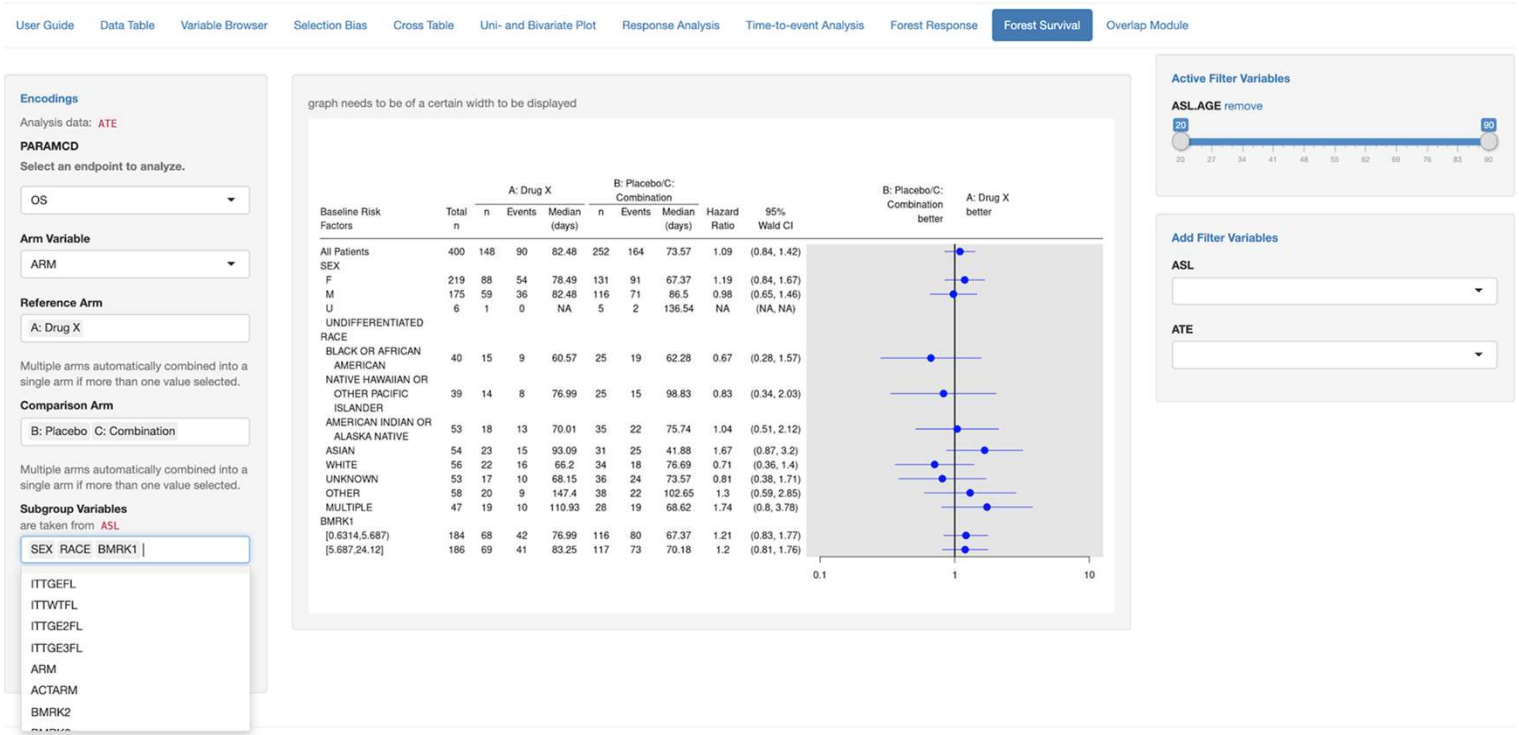
Implementation example: Time to Event analysis



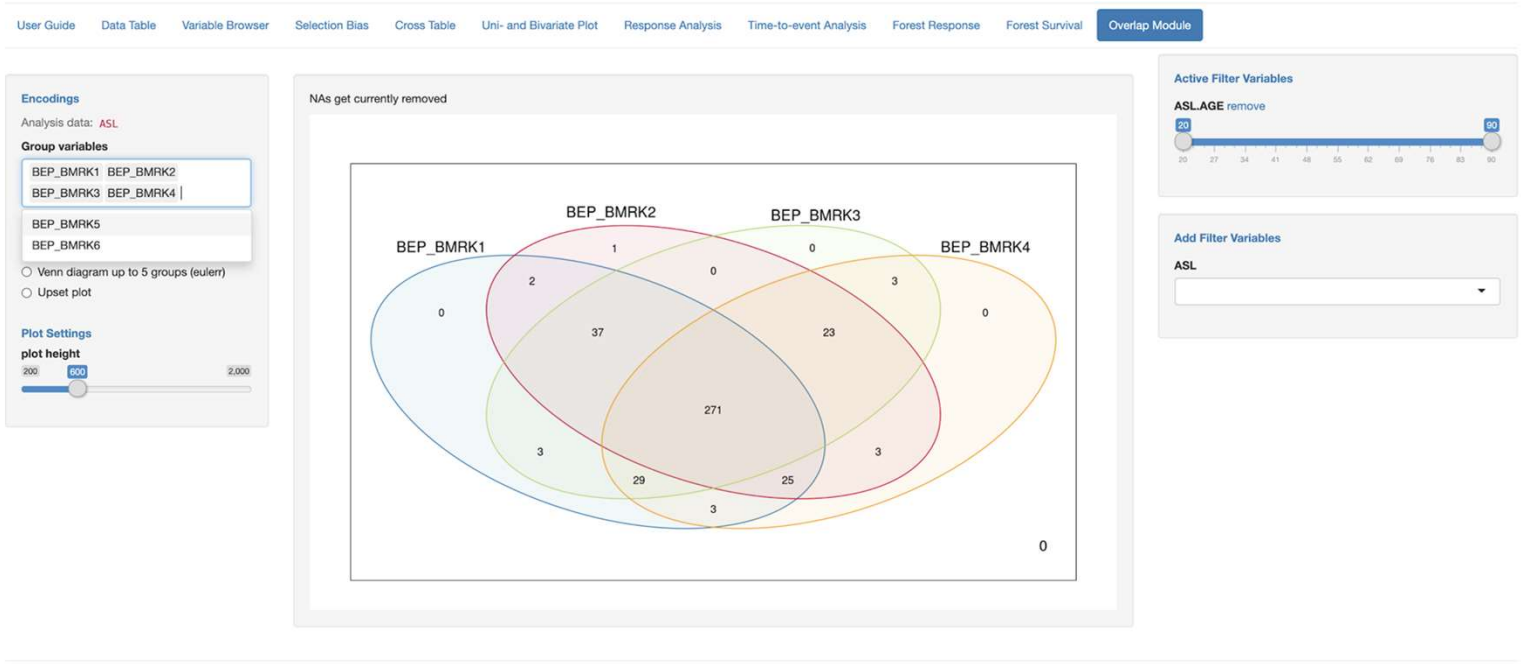
Implementation example: Forest response



Implementation example:Forest Survival



Implementation example: Overlap module



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Acknowledgments

Internal software development team for providing the flexible framework and author of presented shiny implementation based on the random data: Vincent Wolowski

Doing now what patients need next