



Clinical Timelines Visualized

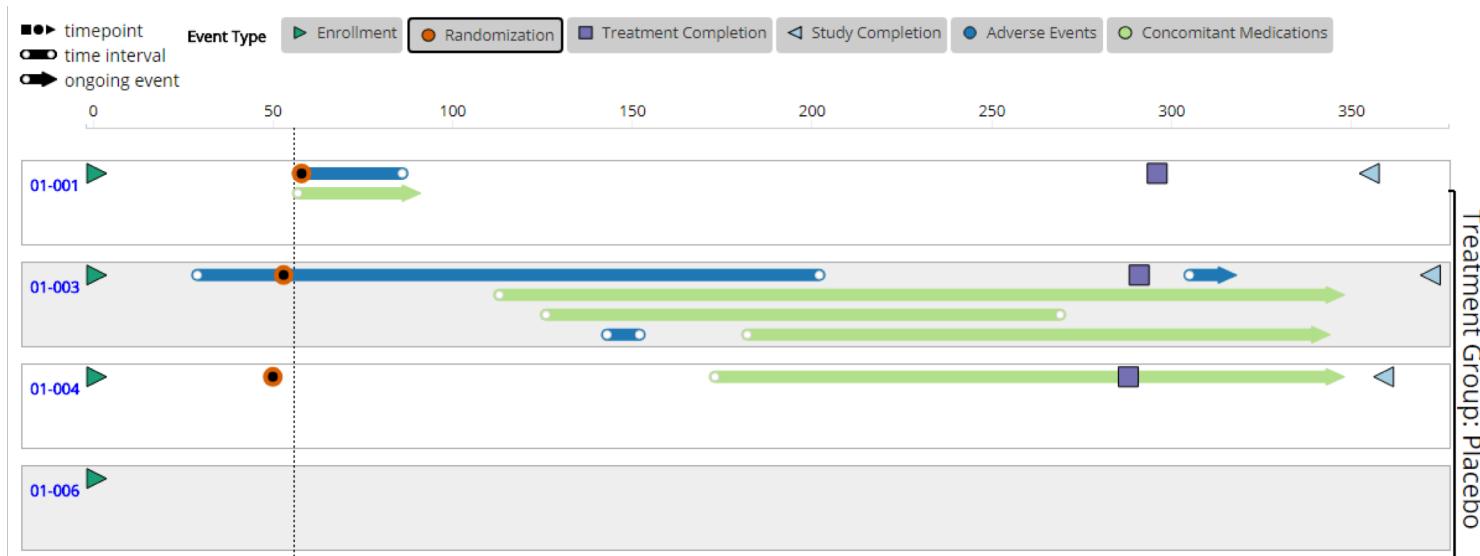
Spencer Childress
Rho, Inc.

Overview

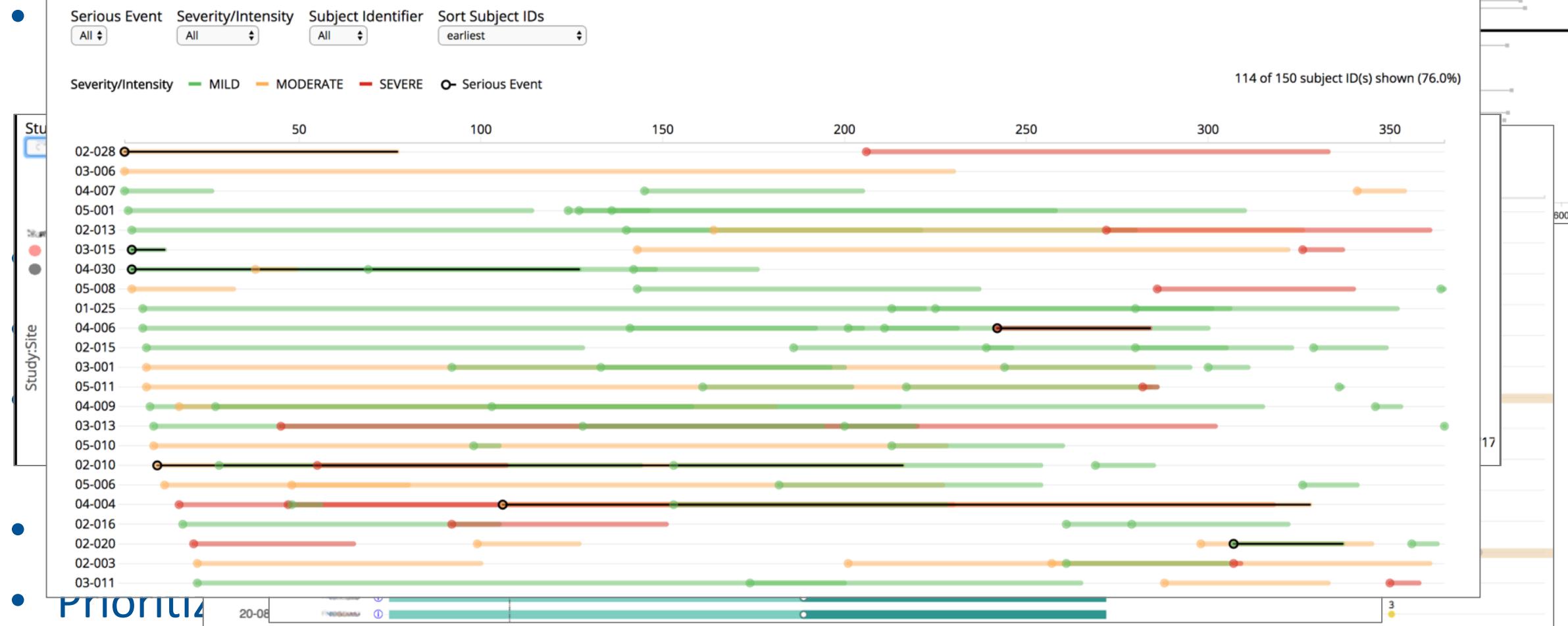
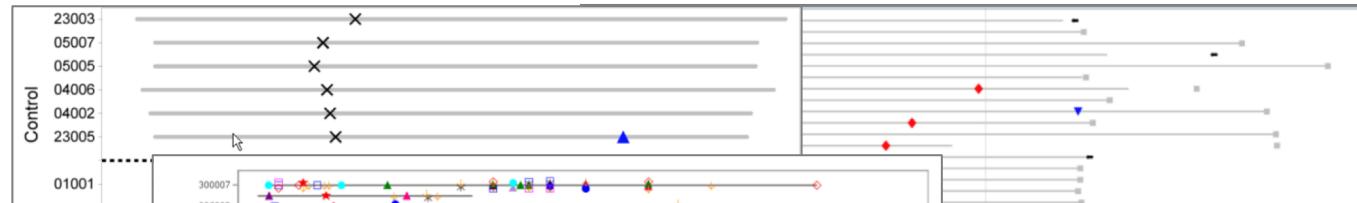
- The Clinical Timelines Library
- Use Cases
- Software-driven vs Data-driven
- Data Structure
- Clinical Timelines
 - Population view
 - Individual view
- Web Technology
- Demo(s)

The Clinical Timelines Library

- Longitudinal data visualization of events over time
 - Faceted by an identifier variable, e.g. participant, site, or study ID
 - Events plotted chronologically from left to right
- Open-source and fully interactive
- Example with test data



Use Cases



- Allow robust customization

Use Cases – Clinical Outcomes

- Enrollment duration
- Visit patterns
- Compliance
- Adverse events
- Concomitant medications
- Abnormal medical signs

Use Cases – Clinical Operations

Site-level

- Site activation
- Participant enrollment
- Monitoring visits
- Protocol deviations
- Database lock

Study-level

- Protocol development
- FPFV
- FDA submissions
- DSMB/DMCs
- LPLV
- Database lock
- ClinicalTrials.gov

Software-driven vs Data-driven

Software-driven

- User defines events
- Highly manual
- More platform-specific
- Less shareable
- Susceptible to human error

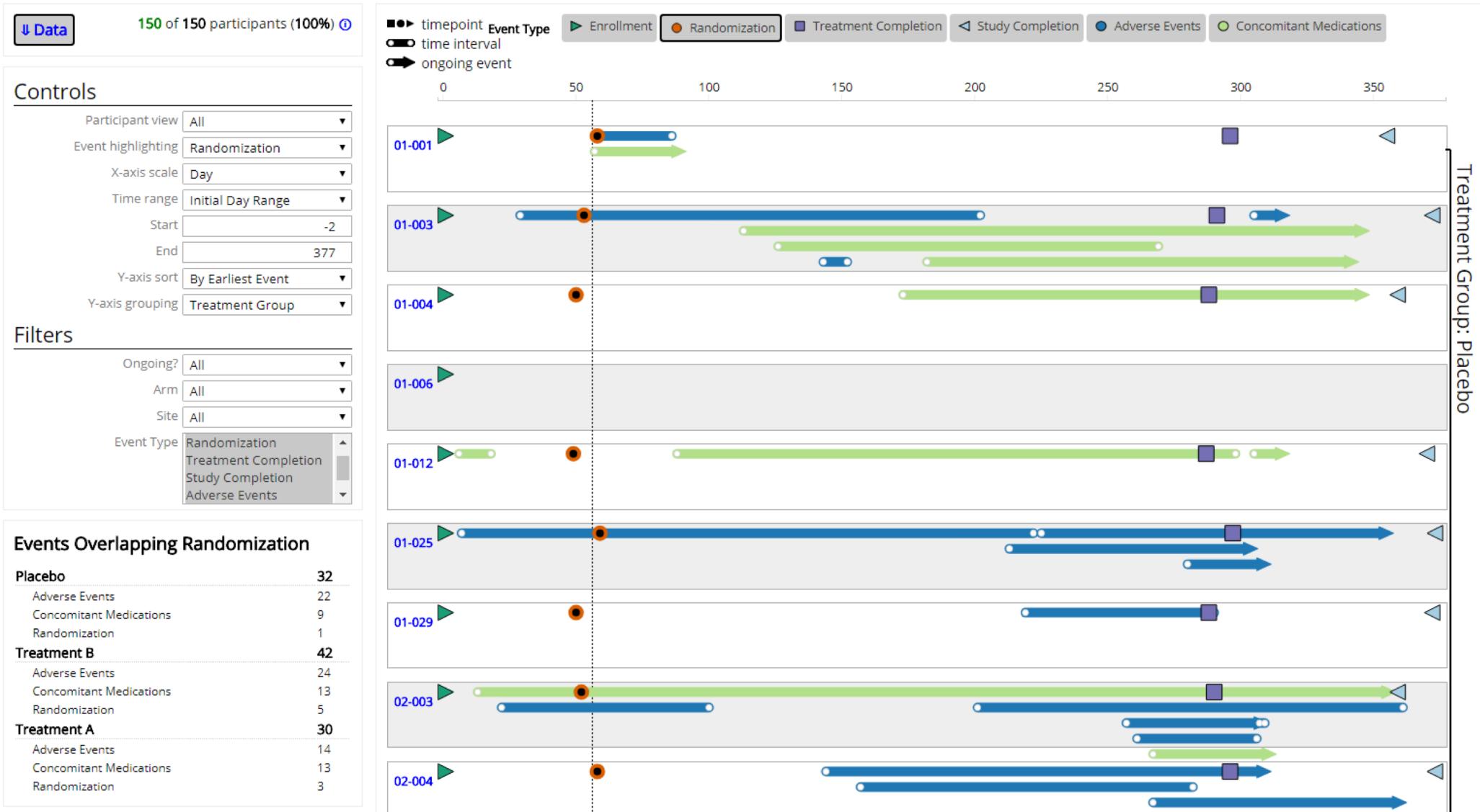
Data-driven

- Links to the database
- Easier to automate
- Platform-agnostic
- Easily shared
- What you see is what you have

Data Structure

- One record per individual per event
- Event type
- Timing variables
 - Date
 - Reference day
- Modeled after SDTM
 - Stack domains
 - Remove variable prefixes
 - #standardized

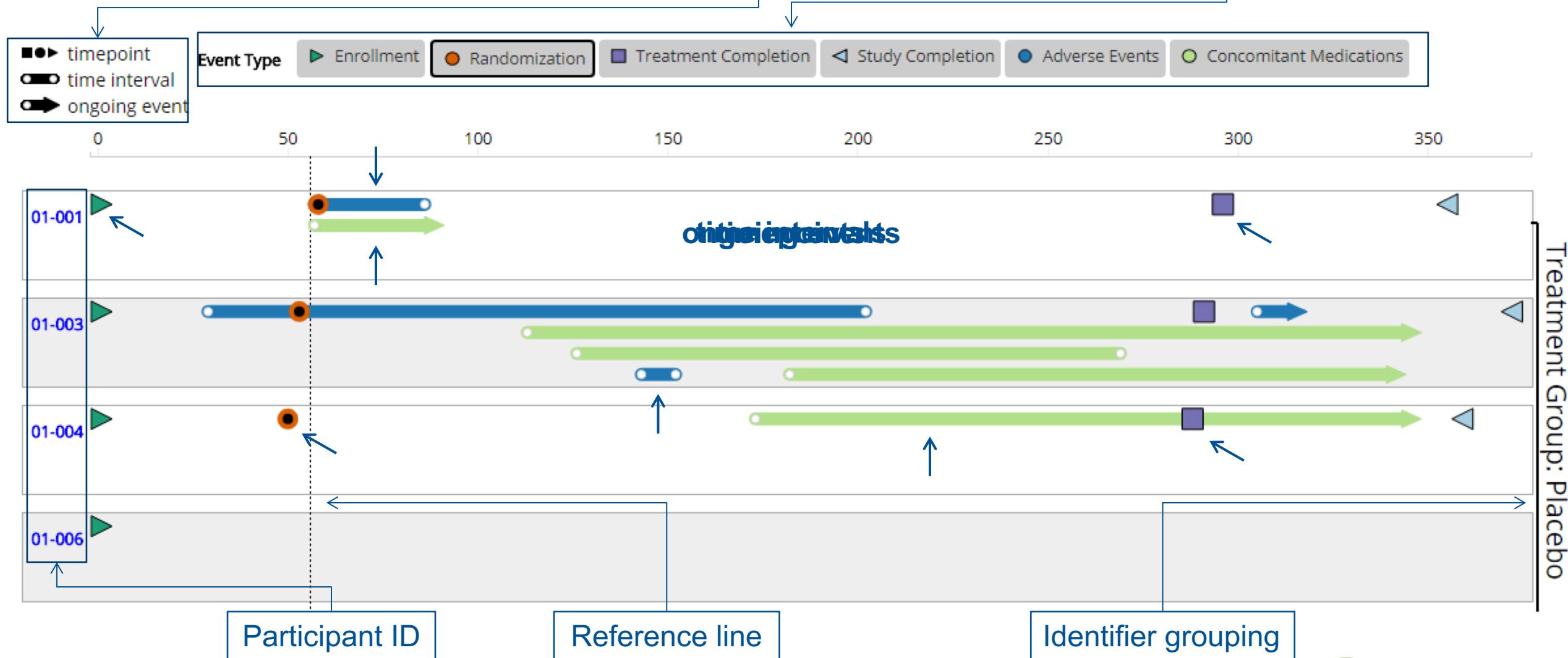
Clinical Timelines – Population View



Timelines Chart

Explanatory legend

Stratification legend



Data and Population Summary

↓ Data

150 of 150 participants (100%) ⓘ
135 of 150 displayed (90%) ⓘ
15 of 150 hidden (10%) ⓘ

- Data export
 - Includes data that match the current time range and filters
- Population summary
 - Population count
 - Number of individuals that meet current filter criteria
 - Number of individuals with events that occur/occurred in the current time range

Controls and Filters

Controls

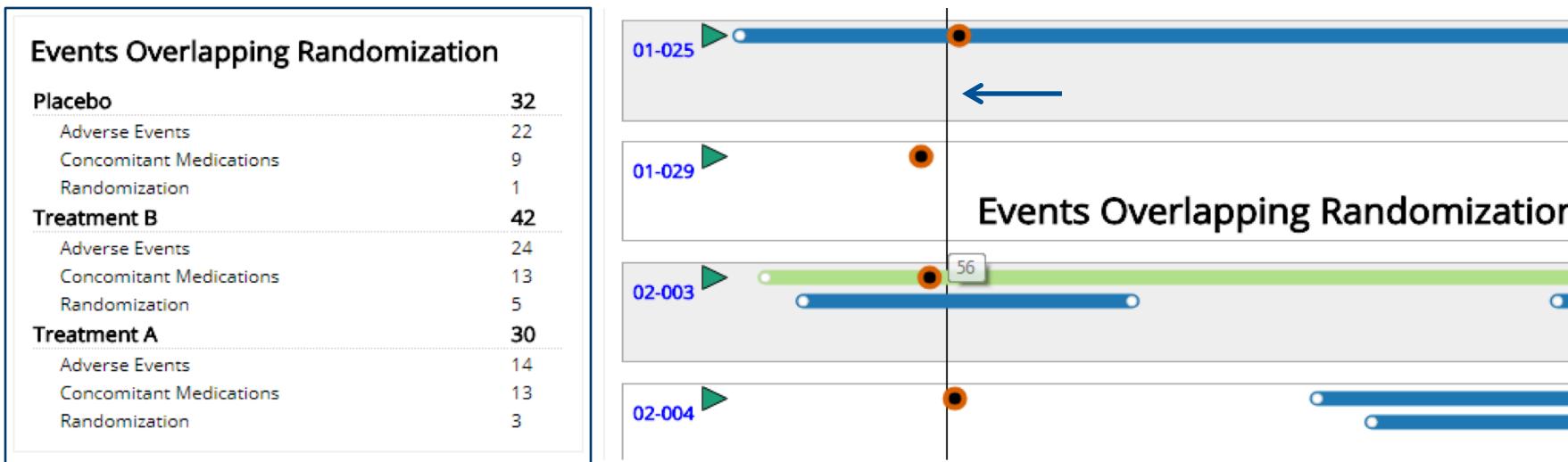
Participant view	All
Event highlighting	Randomization
X-axis scale	day
Time range	full
Start	1
End	375
Y-axis sort	by earliest event
Y-axis grouping	Treatment Group

Filters

Ongoing?	All
Site	01
Event Type	Randomization Treatment Completion Study Completion Adverse Events

- Controls
 - Toggle between population and identifier view
 - Highlight events
 - Change time scale/range
 - Sort/group y-axis
- Filters
 - Event-level filters
 - Ongoing event
 - Event type
 - Individual-level filters
 - Treatment group
 - Site

Reference Line



Clinical Timelines – Individual View

[Back](#)

Participant: 01-003
Treatment Group: Placebo
Site: 01
Age: 43
Gender: F
Race/Ethnicity: Hispanic

Event Type: timepoint time interval ongoing event Enrollment Randomization Treatment Completion Study Completion Adverse Events Concomitant Medications

Controls

Participant view: 01-003
Event highlighting: Randomization
X-axis scale: Day

Filters

Event Type: Randomization Treatment Completion Study Completion Adverse Events

Enrollment

Randomization

Treatment Completion

Study Completion

Adverse Events

Concomitant Medications

Click column headers to sort.

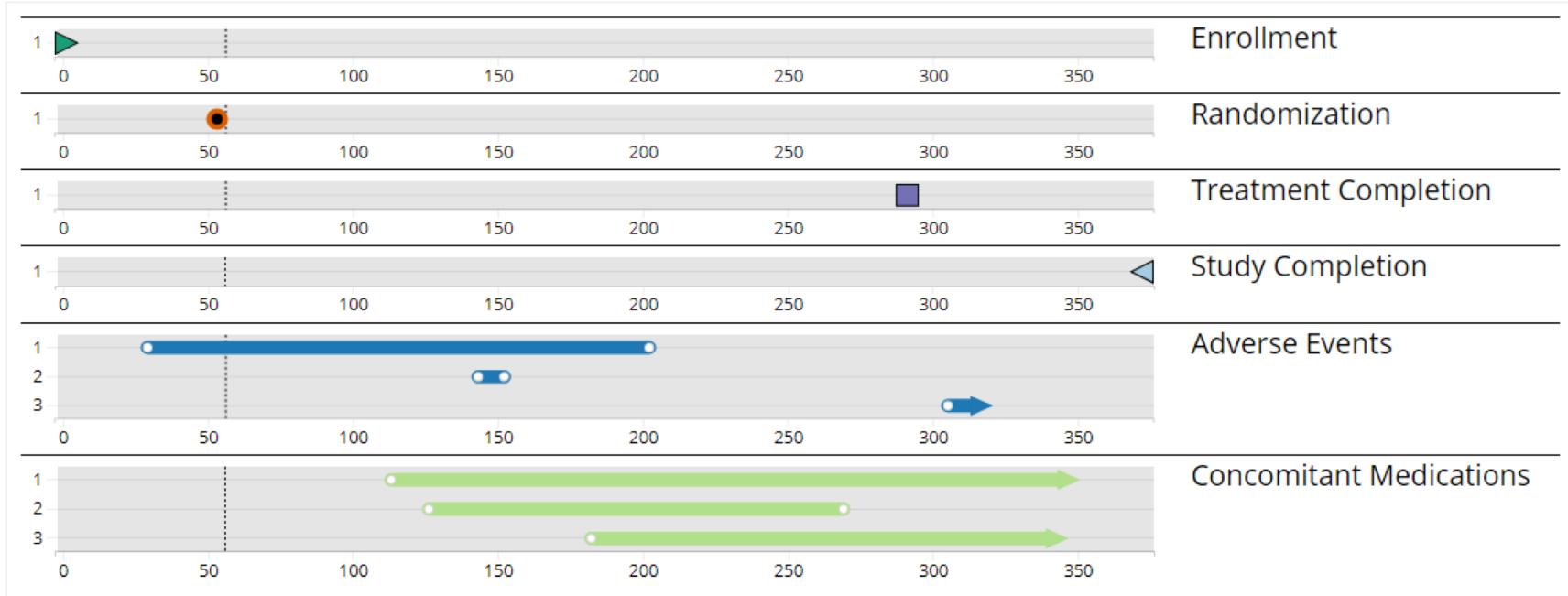
Search: 10 records displayed

Event Type	Start Date (Day)	Stop Date (Day)	Sequence Number	Ongoing?	Details
Adverse Events	2015-09-11 (29)	2016-03-02 (202)	1	N	This mark definitely represents the Adverse Events domain
Adverse Events	2016-01-03 (143)	2016-01-12 (152)	2	N	This mark definitely represents the Adverse Events domain
Adverse Events	2016-06-13 (305)	2016-06-21 (313)	3	Y	This mark definitely represents the Adverse Events domain
Concomitant Medications	2015-12-04 (113)	2016-07-21 (343)	1	Y	This mark definitely represents the Concomitant Medications domain
Concomitant Medications	2015-12-17 (126)	2016-05-08 (269)	2	N	This mark definitely represents the Concomitant Medications domain
Concomitant Medications	2016-02-11 (182)	2016-07-17 (339)	3	Y	This mark definitely represents the Concomitant Medications domain
Enrollment	2015-08-14 (1)	2015-08-14 (1)	1		This mark definitely represents the Enrollment domain
Randomization	2015-10-05 (53)	2015-10-05 (53)	1		This mark definitely represents the Randomization domain
Study Completion	2016-08-19 (372)	2016-08-19 (372)	1		This mark definitely represents the Study Completion domain
Treatment Completion	2016-05-30 (291)	2016-05-30 (291)	1		This mark definitely represents the Randomization domain

Export:

Timelines Charts

Faceted by event type



Domain fitted to individual

Back Button and Individual Characteristics

A participant profile card with a 'Back' button. The card displays the following information:
Participant: 01-003
Treatment Group: Placebo
Site: 01
Age: 43
Gender: F
Race/Ethnicity: Hispanic

- Back button
 - Returns to the population timelines
- Individual characteristics
 - Like a participant profile
 - Individual-level information
 - Adds context to events
 - Configurable

Data Listing

- Lists out events
- Interactive
- Exposes the raw data

Click column headers to sort.					
Event Type	Start Date (Day)	Stop Date (Day)	Sequence Number	Ongoing?	Details
Adverse Events	2015-09-11 (29)	2016-03-02 (202)	1	N	This mark definitely represents the Adverse Events domain
Adverse Events	2016-01-03 (143)	2016-01-12 (152)	2	N	This mark definitely represents the Adverse Events domain
Adverse Events	2016-06-13 (305)	2016-06-21 (313)	3	Y	This mark definitely represents the Adverse Events domain
Concomitant Medications	2015-12-04 (113)	2016-07-21 (343)	1	Y	This mark definitely represents the Concomitant Medications domain
Concomitant Medications	2015-12-17 (126)	2016-05-08 (269)	2	N	This mark definitely represents the Concomitant Medications domain
Concomitant Medications	2016-02-11 (182)	2016-07-17 (339)	3	Y	This mark definitely represents the Concomitant Medications domain
Enrollment	2015-08-14 (1)	2015-08-14 (1)	1		This mark definitely represents the Enrollment domain
Randomization	2015-10-05 (53)	2015-10-05 (53)	1		This mark definitely represents the Randomization domain
Study Completion	2016-08-19 (372)	2016-08-19 (372)	1		This mark definitely represents the Study Completion domain
Treatment Completion	2016-05-30 (291)	2016-05-30 (291)	1		This mark definitely represents the Randomization domain

Export: [CSV](#)

Web Technology

- Webpage
 - Accessible anywhere via browsers
 - Collections of elements
 - Display properties
 - Event listeners
- D3
 - Binds data to elements in the webpage
- Webcharts
 - Built on top of D3
 - Simplifies data visualization with settings that define charts

Demos

- Treatment of Multiple Sclerosis With Copaxone and Albuterol
- [live demo](#)
- Promoting Tolerance to Peanut in High-Risk Children
- [live demo](#)

Questions and References

GitHub repository github.com/Rholnc/clinical-timelines

Rho data viz rhoinc.github.io/viz-library/

My handle [@samussiah](https://twitter.com/@samussiah)

Big thanks to [@RyanResearches](#), [@brittsikora](#), and [@jwildfire](#) for their contributions to this endeavor!

