

ae-timelines - Quality Control

Details

This page provides a detailed report of the quality control documentation for ae-timelines. The source code for this page is available on [github](#).

Technical Specs

Technical documentation including, functional specifications, regressions tests and risk assessments. [see original](#)

Functional Specifications

Users can interact with an AE timeline in the following ways:

Filter by Serious Event

This drop-down menu is used to filter serious events in the data set. The default is set to include all events, but can be manipulated to include events that are only marked as serious or events that are only marked as non-serious. An open-ended black circle marks serious events so they can be viewed in the timeline at a glance.

Filter by Severity/Intensity

This drop-down menu displays a listing of the adverse event severity levels in the data set. The default is to display all severity levels. The current severity levels captured are mild, moderate, and severe, which are color coded and displayed in a legend above the timeline.

Filter by Subject Identifier

This drop-down menu displays a list of all of the subject identifiers included in the data set. Each participant is assigned a unique identifier that is associated with their adverse event data. Filtering to view a particular subject ID will only show data for that subject. The default for this filter is set to show data for all subjects.

Filter by pre-selected characteristics

The chart can be configured to have any number of data filters. Each specified filter has a drop-down menu that is used to filter the visit data that is displayed in the chart.

Sort by Subject IDs

This drop-down menu can sort the subject IDs included in the timeline data set. This option can sort the data by the participants with the earliest occurring adverse event(s) or the participants that appear first alphabetically in descending order. This option defaults to the earliest occurring events and their related participants.

Total Participants Shown

Displayed in the top right corner of the page, this statement provides the total number of participants in the data set in integers as well as the percentage of participants shown to one decimal place. In the default view, all participant data is included in the chart, or 100%, unless the project team requests otherwise. When filters are used, the data shown in the histogram is manipulated and the number of participant records shown at the top of the page may increase or decrease, depending on the variable selected.

Hover

By moving a mouse cursor over a bar in the chart, users can display metadata for some variables. Hovering the cursor over a particular bar will display the reported term of an event, the day the event started, and the day the event stopped. More information about the event can be accessed by clicking on the

Subject ID.

Show details

Clicking on the Subject ID seen to the left of the bar will load a more detailed view. This view displays the raw data for a participant's adverse events. This view shows the sequence number for the event, the day the event started, the day the event stopped, the reported term, the event's severity/intensity, and if the event is classified as serious or not.

Return to the AE Timelines

The Back button is only visible if users have clicked on the detailed view for a given participant. Clicking on this button returns users to the default AE Timelines view.

Regression Tests

- Confirm that selecting a filter manipulates the visible events
- Confirm that selecting a filter changes the ratio and percentage of affected participants
- Confirm that sorting subject IDs changes the order of the results as expected
- Confirm that hovering over event lines shows adverse event information (reported term, start day, stop day) for a participant
- Confirm that the date of an adverse event doesn't end in a circle
- Confirm that a serious AE is notated by a different mark than a normal AE
- Confirm that plot points marked as queried appear as a different color than other plot points and when clicked, display a message detailing the event and query
- Confirm that clicking on a participant ID takes the user to the detail view
- Confirm that Search works to filter the data displayed in the listing
- Confirm that Sort works in the listing by clicking on column headers
- Confirm that you can export the displayed data to a csv via via the Export: CSV button

- Confirm that clicking the Back button takes the user to the timelines chart screen
- Confirm that the population annotation (n of N participants...) is italicized.

Data Guidelines

Data Specifications for the charts. [see original](#)

AE Timelines are initialized using JSON data files that match the format created by `d3.csv()`. The chart requires a data set with one record per adverse event with placeholder rows added for participants who didn't experience any adverse events over the course of the study. The chart uses column names from the AdAM data standard by default, but can be customized to work with any column names as long as the data structure is as expected.

Default Chart

The following columns are expected in a data file used to create an instance of AE Timelines. A sample chart using this configuration is found [here](#).

Data Specification

Settings Variable	Description	Default	Required?
id_col	Unique Subject Identifier	USUBJID	Y
seq_col	Sequence Number	AESEQ	Y
stdy_col	Analysis Start Relative Day	ASTDY	Y
endy_col	Analysis End Relative Day	AENDY	Y
term_col	Reported Term	AETERM	Y
color.value_col	Severity/Intensity	AESEV	Y *
highlight.value_col	Serious Event	AESER	

* a coloring variable of some sort is required but it does not have to be

Settings

No customization is needed to initialize a chart when the data object contains all default variables above. Just pass an empty object ({}) for settings and initialize the chart like so: `aeTimelines('body', {}).init(data)`.

Customized Chart with Queries

The following data specs and chart settings can be used to create a chart with several custom filters, including Sex, Race and Query Status. The chart also highlights severe AEs and events under query. A sample chart using this configuration is found [here](#).

Data Specification

Settings Variable	Description	Default	Required?
id_col	Unique Subject Identifier	USUBJID	Y
seq_col	Sequence Number	AESEQ	Y
stdy_col	Analysis Start Relative Day	ASTDY	Y
endy_col	Analysis End Relative Day	AENDY	Y
term_col	Reported Term	AETERM	Y
color.value_col	Severity/Intensity	AESEV	Y *
highlight.value_col	Serious Event	AESER	
filter	AE Seriousness	AESER	Y
filter	AE Severity	AESEV	Y
filter	AE Relationship	AEREL	Y
filter	AE Outcome	AEOUT	Y
filter	Site ID	SITEID	Y
filter	Treatment Arm	ARM	Y

filter	Sex	SEX	Y
filter	Race	RACE	Y
filter	Query Flag ("Y" for yes)	QUERYFL	Y

* a coloring variable of some sort is required but it does not have to be AESEV

Settings Object

```
var settings =
  {color:
    {value_col: 'AEREL'
    ,label: 'Relationship'
    ,values:
      ['NOT RELATED'
      , 'UNLIKELY RELATED'
      , 'POSSIBLY RELATED'
      , 'PROBABLY RELATED'
      , 'DEFINITELY RELATED']}}
  ,highlight:
    {value_col: 'QUERYFL'
    ,label: 'Open Query'
    ,value: 'Y'
    ,detail_col: 'QUERY'
    ,attributes:
      {'stroke': 'black'
      , 'stroke-width': '8'
      , 'fill': 'none'
      , 'stroke-opacity': "0.2"}}
  ,custom_marks:
    [
      {type: 'circle'
      ,per: ['USUBJID', 'AESEQ', 'wc_value']
      ,tooltip: 'Serious Adverse Event'
      ,radius: 6
```

```

    ,attributes:
      {'fill-opacity': .5
      , 'fill': 'None'
      , 'stroke': 'Red'}
    ,values: {"AESER": ['Y'] , "wc_category":["ASTDY"]}}
  ]
,filters:
  [
    {value_col: 'AESER', label: 'Serious Event'}
    , {value_col: 'AEREL', label: 'Relationship'}
    , {value_col: 'AESEV', label: 'Severity/Intensity'}
    , {value_col: 'USUBJID', label: 'Subject Identifier'}
    , {value_col: 'ARM', label: 'Arm'}
    , {value_col: 'SITEID', label: 'Site ID'}
    , {value_col: 'SEX', label: 'Sex'}
    , {value_col: 'RACE', label: 'Race'}
    , {value_col: 'QUERYFL', label: 'Has query?'}

  ]};

```

API

Technical specifications for API. [see original](#)

aeTimelines(element, settings)

a factory to create a custom [Webcharts chart](#) object

returns: [chart](#)

Param	Type	Description
element	string	CSS selector identifying the element in which to create the chart
settings	object	settings object specifying options for how the chart is to appear and behave. Options defined here overwrite default values; see Configuration

Events

participantsSelected

The custom `participantsSelected` event is dispatched to the overall chart wrapper (`chart.wrap`) whenever the details for a given participant are viewed (or cleared) by clicking on the y-axis labels in the chart. The event has a custom `data` property holding an array with the selected ID when a new participant is selected (`["123-456-7"]`) or an empty array when participant details are cleared.

Chart Configuration

Technical specifications for chart configuration. [see original](#)

The most straightforward way to customize the AE Timelines is by using a configuration object whose properties describe the behavior and appearance of the chart. Since the AE Timelines is a Webcharts chart object, many default Webcharts settings are set in the [defaultSettings.js](#) file as [described below](#). Refer to the [Webcharts documentation](#) for more details on these settings.

In addition to the standard Webcharts settings several custom settings not available in the base Webcharts library have been added to the AE Timelines to facilitate data mapping and other custom functionality. These custom settings are described in detail below. All defaults can be overwritten by users.

Renderer-specific settings

The sections below describe each `ae-timelines` setting as of version 2.1.0.

`settings.id_col`

string

unique identifier variable name

default: "USUBJID"

settings.seq_col

string

event sequence number variable name

default: "AESEQ"

settings.stdy_col

string

event start day variable name

default: "ASTDY"

settings.endy_col

string

event end day variable name

default: "AENDY"

settings.term_col

string

verbatim adverse event text variable name

default: "AETERM"

settings.color

object

an object that defines the event color stratification variable, its label, its levels, and their corresponding colors

settings.color.value_col

string

color stratification variable name, usually set to event severity

default: "AESEV"

settings.color.label

string

color stratification variable label

default: "Severity/Intensity"

settings.color.values

array

an array of stratification values

default:

```
[  
  "MILD",  
  "MODERATE",  
  "SEVERE"  
]
```

settings.color.colors

array

an array of stratification colors

default:

```
[  
  "#66bd63",  
  "#fdae61",  
  "#d73027",  
  "#377eb8",  
  "#984ea3",  
  "#ff7f00",  
  "#a65628",  
  "#f781bf",  
  "#999999"  
]
```

settings.highlight

object

an object that defines what events to highlight and how to highlight them

settings.highlight.value_col

string

event highlighting variable name

default: "AESER"

settings.highlight.label

string

a description of the highlighted event

default: "Serious Event"

settings.highlight.value

string

value of `highlight.value_col` that identifies events to highlight

default: "Y"

settings.highlight.detail_col

string

detail of highlighted event variable name

default: none

settings.highlight.attributes

object

an object of attributes that define highlighted marks

settings.filters

array

an array of filter variables and associated metadata

default: none

settings.filters[].value_col

string

the name of the filter variable

default: none

settings.filters[].label

string

a description of the filter variable

default: none

settings.details

array

an array of detail listing variables and associated metadata

default: none

settings.details[].value_col

string

the name of the detail variable

default: none

settings.details[].label

string

a description of the detail variable

default: none

settings.custom_marks

array

an array of custom Webcharts marks

default: none

settings.custom_marks[].type

string

a Webcharts mark type: point, bar, line, or text

default: none

settings.custom_marks[].per

array

an array of variables for each value combination of which a mark is drawn

default: none

settings.custom_marks[].tooltip

string

the tooltip of the custom mark

default: none

settings.custom_marks[].attributes

object

the attributes of the custom mark

Webcharts settings

The object below contains each Webcharts setting as of version 2.1.0.

```
{
  x: {
    column: 'wc_value',
    type: 'linear',
    label: null
  },
  y: {
    column: null, // set in syncSettings()
    type: 'ordinal',
    label: '',
    sort: 'earliest',
    behavior: 'flex'
  },
  marks: [
    {
      type: 'line',
      per: null, // set in syncSettings()
      tooltip: null, // set in syncSettings()
      attributes: {
        'stroke-width': 5,
        'stroke-opacity': 0.5
      }
    },
    {
      type: 'circle',
      per: null, // set in syncSettings()
      tooltip: null, // set in syncSettings()
      attributes: {
        'fill-opacity': 0.5,
        'stroke-opacity': 0.5
      }
    }
  ],
  legend: { location: 'top' },
}
```

```
gridlines: 'y',
range_band: 15,
margin: { top: 50 }, // for second x-axis
resizable: true
}
```

Testing Logs

Interactive log of QC for all code updates. Includes code reviews, feature testing and regression testing for all releases. [see original](#)

PullRequest	Requester	DateRequested	Branch
0006	jwildfire	2016-04-12T16:42:02Z	reorg
0014	jwildfire	2016-05-25T19:38:02Z	reorg-backup
0017	jwildfire	2016-06-22T20:27:11Z	v1.2.0
0018	jwildfire	2016-06-22T22:03:17Z	v1.2.1
0022	jwildfire	2016-12-17T17:21:44Z	v1.3.0
0022	jwildfire	2016-12-17T17:21:44Z	v1.3.0
0022	jwildfire	2016-12-17T17:21:44Z	v1.3.0
0022	jwildfire	2016-12-17T17:21:44Z	v1.3.0

0022	jwildfire	2016-12- 17T17:21:44Z	v1.3.0
0022	jwildfire	2016-12- 17T17:21:44Z	v1.3.0
0022	jwildfire	2016-12- 17T17:21:44Z	v1.3.0
0022	jwildfire	2016-12- 17T17:21:44Z	v1.3.0
0022	jwildfire	2016-12- 17T17:21:44Z	v1.3.0
0022	jwildfire	2016-12- 17T17:21:44Z	v1.3.0
0022	jwildfire	2016-12- 17T17:21:44Z	v1.3.0
0022	jwildfire	2016-12- 17T17:21:44Z	v1.3.0
0022	jwildfire	2016-12- 17T17:21:44Z	v1.3.0
0022	jwildfire	2016-12- 17T17:21:44Z	v1.3.0
0022	jwildfire	2016-12- 17T17:21:44Z	v1.3.0

[illegible]

0022	jwildfire	2016-12-17T17:21:44Z	v1.3.0
0022	jwildfire	2016-12-17T17:21:44Z	v1.3.0
0022	jwildfire	2016-12-17T17:21:44Z	v1.3.0
0022	jwildfire	2016-12-17T17:21:44Z	v1.3.0
0023	jwildfire	2016-12-17T17:23:50Z	SAEs
0027	samussiah	2017-01-19T22:40:41Z	custom-marks
0027	samussiah	2017-01-19T22:40:41Z	custom-marks
0027	samussiah	2017-01-19T22:40:41Z	custom-marks
0030	jwildfire	2017-03-07T02:10:51Z	v2.0.1
0030	jwildfire	2017-03-07T02:10:51Z	v2.0.1
		2017-03-	

0030	jwildfire	07T02:10:51Z	v2.0.1
0038	jwildfire	2017-10-16T18:16:05Z	v2.0.3-dev
0038	jwildfire	2017-10-16T18:16:05Z	v2.0.3-dev
0042	samussiah	2017-12-04T17:49:28Z	v2.0.4-dev
0043	samussiah	2017-12-04T18:52:06Z	listing-bug
0050	samussiah	2018-04-02T14:16:03Z	v2.1.0-dev
0051	samussiah	2018-04-03T18:11:24Z	test-page
0052	samussiah	2018-04-03T19:15:45Z	settings-schema
0053	samussiah	2018-04-03T19:36:52Z	italicize-population-annotation
0053	samussiah	2018-04-03T19:36:52Z	italicize-population-annotation
0054	samussiah	2018-04-03T19:46:13Z	fix-color-domain
0055	samussiah	2018-04-03T20:52:19Z	add-settings-merge
0058	samussiah	2018-04-24T15:31:39Z	v2.1.0-dev
0059	samussiah	2018-04-24T15:32:07Z	test-page
0060	brittsikora	2018-04-27T18:19:31Z	brittsikora-patch-1
0061	rtbailey	2018-08-09T19:45:12Z	rtbailey-patch-1
0065	samussiah	2018-12-18T15:56:04Z	dev-v2.1.3
0066	samussiah	2018-12-18T15:56:54Z	security-vulnerabilities

0066	samussiah	2018-12-18T15:56:54Z	security-vulnerabilities
0067	samussiah	2018-12-18T15:57:43Z	fix-test-page
0067	samussiah	2018-12-18T15:57:43Z	fix-test-page
0068	samussiah	2018-12-18T15:58:13Z	scale-y-axis
0068	samussiah	2018-12-18T15:58:13Z	scale-y-axis
0069	samussiah	2018-12-18T15:58:38Z	ignore-placeholder-rows
0069	samussiah	2018-12-18T15:58:38Z	ignore-placeholder-rows
0069	samussiah	2018-12-18T15:58:38Z	ignore-placeholder-rows
0069	samussiah	2018-12-18T15:58:38Z	ignore-placeholder-rows
0071	jwildfire	2019-03-27T19:48:24Z	dev-v2.1.4
0073	samussiah	2019-04-30T17:24:15Z	dev-v2.1.5
0075	dependabot[bot]	2019-07-12T04:09:52Z	dependabot/npm_and_yarn/lo4.17.14
0077	jwildfire	2019-08-09T16:50:12Z	dev-v2.1.6
0078	jwildfire	2019-08-09T16:50:44Z	addCustomEvent