safety-results-over-time - Quality Control Details

This page provides a detailed report of the quality control documentation for safety-results-over-time. 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

Filter by Measure

This drop-down menu is used to filter the lab variable that is displayed in the chart. The default measure is set to the first variable in the data set, but the default value can be adjusted to any measure upon the project team's request. Users can select any pre-defined measure in this filter. Selecting a measure will display the data points associated with that measure and will display the visits that the measure is collected at underneath the chart.

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.

Total Participants Shown

Displayed under the header, 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.

Set Y-axis Limits

Users are able to adjust the lower limit of the y-axis by manipulating the input within the Lower Limit box. Users are able to adjust the upper limit of the y-axis by manipulating the input within the Upper Limit box. Each limit box has up and down arrows to adjust the value of the box by 1. Users can select an arrow to change the input or delete the current value in the box and type in a new value. When typing in a value, users must click outside of the box to apply the changes. When a user manipulates a y-axis limit, the y-axis on the chart below the controls will reflect the change.

Reset Y-axis limits

Users can change the upper and lower y-axis limits back to the default values for a measure by selecting the "Reset Limits" button. Pressing the button will erase the current values in the upper and lower limit boxes and replace them with defaults. The chart below will also reflect the changes and will show the default axes.

View Visits Without Data

Users can select the checkbox to view visits that do not contain data. Checking the box will show a timepoint for the visit. Unchecking the checkbox will hide the timepoint for visits without data; visits without data are hidden on default.

View Unscheduled Visits

Users can select the checkbox to view data that is not associated with a scheduled visit. Checking the box will show a timepoint for the unscheduled visit and its associated data. Unselecting the checkbox will hide the unscheduled visit timepoint and its data; unscheduled visits are hidden on default.

Box and Whisker Plots

The chart includes box and whisker plots to show the data distribution for a given measure. These plots show the data distribution for a data measure and can be added to the chart by clicking the box to the right of the Box plots text located above the chart. To take the plots away, the user can uncheck the box by clicking in it again. The box is checked by default, so the box and whisker plots appear when the chart is rendered.

Violin Plots

The chart includes violin plots to show the data distribution for a given measure. These plots show the data distribution for a data measure and can be added to the chart by clicking the box to the right of the Violin plots text located above the chart. To take the plots away, the user can uncheck the box by clicking in it again. The box is not checked by default, so the violin plots do not appear when the chart is rendered.

Regression Tests

- Confirm that the number and percentage of participants is displayed
- Confirm that the filters are working as expected (Measure, Group): selecting a variable changes the plot values. Customize the chart to add the Group filter: {"groups":["SEX","RACE"]}
- Confirm that when a grouping is selected, the order of box/violin plots for each x-axis value match the group order in the legend.
- Confirm that checking the "Visits without data" checkbox shows a timepoint for visits with no associated data points
- Confirm that unchecking the "Visits without data" checkbox hides the

timepoint for visits with no associated data points
- Confirm that checking the "Unscheduled visits" checkbox shows a timepont for unscheduled visits and their associated data
- Confirm that unchecking the "Unscheduled visits" checkbox hides the timepoint for unscheduled visits and their associated data
- Confirm that selecting the violin plot option causes violin plots to appear around the data ranges
- Confirm that selecting the box plot option causes box plots to appear around the data ranges
- Confirm that checking the Outliers checkbox causes results outside the 5th and 9th percentiles (i.e. results outside the horizontal lines of box plots) to be displayed in the chart.
- Confirm that Outlier points are clearly visible in the chart, even with Violin plots selected and that hovering on an outlier causes it to expand.
- Confirm that unchecking the Outliers checkbox hides the outliers from the chart.
- Confirm that the # of enrolled/randomized participants is visible at the top of the page
- Confirm that hovering over a plot displays a tooltip with information about the data (N, Min, Median, etc.). Verify that Min and Max have the lowest precision; 5th %, Q1, Median, Q3, 95th %, and Mean have precision to one more decimal place than the lowest precision; and StDev has precision to two more decimal places than the lowest precision.
- Confirm that typing in a number into either the lower limit or upper limit control updates the y-axis domain accordingly.
- Confirm that the lower limit cannot be equal to or greater than the upper limit and the upper limit cannot be equal to or less than the lower limit. Entering this condition should cause the limits to flip automatically and always have the larger limit as the Upper Limit.
- Confirm that a Scale radio control appears next to the y-axis limit controls with two options, linear and log, and that selecting either radio button updates the scale of the y-axis updates as expected.
- Confirm that Y-axis tick labels do not overlap for any measure plotted on a log scale.
- Confirm that the Reset Limits button resets the y-axis to the minimum and maximum values in the data.

- Confirm that the unit value for a given measure is appended to the measure in the Measure dropdown and in the y-axis label.
- Confirm that you can update the Unit (setting: unit_col) to a nonexistent variable name in CAT and re-render the chart, where the chart should behave identically, except units are not appended to the options in the Measures filter, or to the y-axis label.
- Confirm that you can update the start_value setting for a Measure to have the Measure dropdown default to displaying a measure that is not the first one alphabetically in the list.
- Confirm that you can update the start_value setting for a Measure to have a non-existent Measure and chart will handle it and display an existing measure by default instead. Verify that a warning is written to the console explaining that the specified measure does not exist.
- Confirm that you can specify a group variable (ARM, SEX, etc.) as well as a group label (Treatment Group, Sex, etc.) in CAT and that the group labels, and not the group variable names) appear in the Group dropdown, as well as in the legend label.
- Confirm that adding a non-existant group variable/label gets handled by the chart and the group label/name is not actually displayed in the Group dropdown.
- Confirm that group-by labels corresponding to duplicate group-by variables do not appear in the group-by dropdown, even if the labels differ.

Data Guidelines

Data Specifications for the charts. see original

The Safety Results Over Time accepts JSON data of the format returned by d3.csv(). The renderer visualizes clinical medical signs data with one row per participant per visit per medical sign plus the required variables specified below.

Data structure

one record per participant per visit per medical sign

Data specification

required and optional variables:

Setting	Default	Data Type	Description	Required?
`id_col`	*USUBJID*	character	unique identifier of participant	Yes
`time_settings.value_col`	*VISIT*	character	visit name	Yes
`time_settings.order_col`	*VISITNUM*	numeric	visit order	
`measure_col`	*TEST*	character	measure name	Yes
`unit_col`	*STRESU*	character	measure unit	
`value_col`	*STRESN*	numeric	measure result	Yes
`normal_col_low`	*STNRLO*	numeric	LLN of measure	
`normal_col_high`	*STNRHI*	numeric	ULN of measure	
`filters[]`		either	an array of filter variables and associated metadata	
`groups[]`		either	an array of grouping variables and associated metadata	

API

Technical specifications for API. see original

safetyResultsOverTime(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

Chart Configuration

Technical specifications for chart configuration. see original

The most straightforward way to customize the Safety Results Over Time is by using a configuration object whose properties describe the behavior and appearance of the chart. Since the Safety Results Over Time 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 Safety Results Over Time 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 safety-results-over-time setting as of version 2.3.1.

settings.id_col

`string`

name of variable that captures unique identifier of participant

default: "USUBJID"

settings.time_settings

object

visit metadata

settings.time*settings.value*col

string

name of variable that captures visit name

default: "VISIT"

settings.time_settings.label

string

Visit variable label

default: "Visit"

settings.time*settings.order*col

string

name of variable that captures visit order

default: "VISITNUM"

settings.time_settings.order

array

Visit order

default: none

settings.time*settings.rotate*tick_labels

`boolean`

Rotate tick labels 45 degrees?

default: `true`

settings.time*settings.vertical*space

`number`

Rotated tick label spacing

default: `100`

settings.measure_col

`string`

name of variable that captures measure name

default: `"TEST"`

settings.unit_col

`string`

name of variable that captures measure unit

default: `"STRESU"`

settings.value_col

`string`

name of variable that captures measure result

default: "STRESN"

settings.normal*co*low

`string`

name of variable that captures LLN of measure

default: "STNRLO"

settings.normal*co*high

`string`

name of variable that captures ULN of measure

default: "STNRHI"

settings.start_value

`string`

value of measure to display initially

default: none

settings.filters

`array`

an array of filter variables and associated metadata

default: none

settings.filters[].value_col

`string`

Variable name

default: none

settings.filters[].label

`string`

Variable label

default: none

settings.groups

`array`

an array of grouping variables and associated metadata

default: none

settings.groups[].value_col

`string`

Variable name

default: none

settings.groups[].label

`string`

Variable label

default: none

settings.color_by

`string`

grouping variable; defaults to first item in *groups* setting; set to `'srot_none'` to display chart without grouping on initialization

default: none

settings.boxplots

`boolean`

controls initial display of box plots

default: `true`

settings.outliers

`boolean`

controls initial display of outliers outside the 5th and 95th percentiles

default: `true`

settings.violins

`boolean`

controls initial display of violin plots

default: `false`

settings.missingValues

array

an array of strings that identify missing values in both the measure and result variables

default: none

settings.visits*without*data

boolean

controls display of visits without data for the current measure

default: false

settings.unscheduled_visits

boolean

controls display of unscheduled visits

default: false

settings.unscheduled*visit*pattern

string

a regular expression that identifies unscheduled visits

default: "/unscheduled|early termination/i"

settings.unscheduled*visit*values

array

an array of strings that identify unscheduled visits; overrides

unscheduled*visit*pattern

default: none

Webcharts settings

The object below contains Webcharts settings as of version 2.3.1 of the Safety Results Over Time.

```
{
    "x": {
        "column": null,
        "type": "ordinal",
        "label": null,
        "behavior": "flex",
        "sort": "alphabetical-ascending",
        "tickAttr": null
    },
    "y": {
        "column": null,
        "type": "linear",
        "label": null,
        "behavior": "flex",
        "stat": "mean",
        "format": null
    },
    "marks": [
        {
            "type": "line",
            "per": null,
            "attributes": {
                "stroke-width": 2,
                "stroke-opacity": 1,
                "display": "none"
            }
```

```
    },
    {
        "type": "circle",
        "per": null,
        "attributes": {
            "stroke": "black",
            "stroke-opacity": 0,
            "fill-opacity": 0
        },
        "values": {
            "srot_outlier": [
                true
            ]
        },
        "radius": null,
        "tooltip": null,
        "hidden": true
    },
    {
        "type": "circle",
        "per": null,
        "attributes": {
            "stroke": "black",
            "stroke-opacity": 1,
            "fill-opacity": 1
        },
        "values": {
            "srot_outlier": [
                true
            ]
        },
        "radius": 1.75,
        "tooltip": null,
        "hidden": false
    }
],
```

```
    "legend": {
        "mark": "square"
    },
    "color_by": null,
    "resizable": true,
    "gridlines": "y",
    "aspect": 3
}
```

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
0004	jwildfire	2016-04-15T17:44:50Z	adjust-ticks
0007	jwildfire	2016-05-25T20:04:26Z	reorg
0016	jwildfire	2016-12-17T16:28:29Z	v1.3.0
0018	samussiah	2017-01-25T22:20:49Z	custom-filters

0018	samussiah	2017-01-25T22:20:49Z	custom-filters
0018	samussiah	2017-01-25T22:20:49Z	custom-filters
0018	samussiah	2017-01-25T22:20:49Z	custom-filters
0018	samussiah	2017-01-25T22:20:49Z	custom-filters
0020	samussiah	2017-02-06T20:44:27Z	rotate-tick-labels
0020	samussiah	2017-02-06T20:44:27Z	rotate-tick-labels

0020	samussiah	2017-02-06T20:44:27Z	rotate-tick-labels
0020	samussiah	2017-02-06T20:44:27Z	rotate-tick-labels
0020	samussiah	2017-02-06T20:44:27Z	rotate-tick-labels
0020	samussiah	2017-02-06T20:44:27Z	rotate-tick-labels
0020	samussiah	2017-02-06T20:44:27Z	rotate-tick-labels
0021	samussiah	2017-02-08T20:13:19Z	annotate-population
0022	samussiah	2017-02-09T19:37:02Z	consistent-axes-plus-log-linea
0022	samussiah	2017-02-09T19:37:02Z	consistent-axes-plus-log-linea

0022	samussiah	2017-02-09T19:37:02Z	consistent-axes-plus-log-linear
0024	samussiah	2017-02-16T21:55:42Z	groups-default
0027	jwildfire	2017-03-07T02:28:04Z	v2.0.1
0028	samussiah	2017-03-07T22:19:35Z	log-fix
0033	jwildfire	2017-10-12T23:09:56Z	v2.0.2-dev
0035	samussiah	2017-10-20T13:58:34Z	v2.0.3-dev
0039	mhickle	2017-12-13T15:54:12Z	ReadMe
0040	samussiah	2018-01-05T14:59:25Z	v2.1.0-dev
0042	samussiah	2018-01-05T18:26:12Z	y-axis-limits
0042	samussiah	2018-01-05T18:26:12Z	y-axis-limits
0044	samussiah	2018-01-15T23:46:04Z	v2.2.0-dev

0046	samussiah	2018-01-16T19:22:01Z	visitnum-order
0046	samussiah	2018-01-16T19:22:01Z	visitnum-order
0046	samussiah	2018-01-16T19:22:01Z	visitnum-order
0047	samussiah	2018-01-18T00:01:04Z	unscheduled-visits
0047	samussiah	2018-01-18T00:01:04Z	unscheduled-visits
0047	samussiah	2018-01-18T00:01:04Z	unscheduled-visits
0047	samussiah	2018-01-18T00:01:04Z	unscheduled-visits

0047	samussiah	2018-01-18T00:01:04Z	unscheduled-visits
0047	samussiah	2018-01-18T00:01:04Z	unscheduled-visits
0048	samussiah	2018-01-18T21:27:40Z	settings-schema
0048	samussiah	2018-01-18T21:27:40Z	settings-schema
0048	samussiah	2018-01-18T21:27:40Z	settings-schema
0048	samussiah	2018-01-18T21:27:40Z	settings-schema
0051	samussiah	2018-02-27T14:56:32Z	v2.2.1-dev
0051	samussiah	2018-02-27T14:56:32Z	v2.2.1-dev

0055	samussiah	2018-04-02T14:19:20Z	v2.2.2-dev
0056	samussiah	2018-04-02T17:49:34Z	add-test-page
0059	brittsikora	2018-05-01T19:58:07Z	brittsikora-patch-1
0063	rtbailey	2018-08-09T19:47:07Z	rtbailey-patch-1
0064	samussiah	2018-10-23T19:27:59Z	v2.2.3-dev
0066	samussiah	2018-12-18T17:06:26Z	dev-v2.3.0
0068	samussiah	2019-01-02T19:14:30Z	legend-order
0068	samussiah	2019-01-02T19:14:30Z	legend-order
0069	samussiah	2019-01-02T19:14:52Z	tooltip-precision
0069	samussiah	2019-01-02T19:14:52Z	tooltip-precision
0070	samussiah	2019-01-02T19:15:15Z	outliers

0070	samussiah	2019-01-02T19:15:15Z	outliers
0071	samussiah	2019-01-02T19:15:36Z	log-axis
0071	samussiah	2019-01-02T19:15:36Z	log-axis
0071	samussiah	2019-01-02T19:15:36Z	log-axis
0071	samussiah	2019-01-02T19:15:36Z	log-axis
0071	samussiah	2019-01-02T19:15:36Z	log-axis
0071	samussiah	2019-01-02T19:15:36Z	log-axis
0071	samussiah	2019-01-02T19:15:36Z	log-axis
0071	samussiah	2019-01-02T19:15:36Z	log-axis
0071	samussiah	2019-01-02T19:15:36Z	log-axis
0072	samussiah	2019-01-02T19:15:57Z	group-labels
0072	samussiah	2019-01-02T19:15:57Z	group-labels
0072	samussiah	2019-01-	group-labels

		02T19:15:57Z	
0073	samussiah	2019-01-02T19:21:18Z	optionalize-variables
0074	pburnsdata	2019-01-08T21:17:01Z	pburnsdata-patch-1
0078	samussiah	2019-01-18T15:35:12Z	miscellany
0078	samussiah	2019-01-18T15:35:12Z	miscellany
0078	samussiah	2019-01-18T15:35:12Z	miscellany
0081	samussiah	2019-01-29T16:47:21Z	bug-fixes
0081	samussiah	2019-01-29T16:47:21Z	bug-fixes
0085	samussiah	2019-02-07T16:31:29Z	dev-v2.3.1
0085	samussiah	2019-02-07T16:31:29Z	dev-v2.3.1
0087	samussiah	2019-03-11T22:16:07Z	add-color_by-to-schema
0088	samussiah	2019-03-27T20:22:33Z	dev-v2.3.2
0088	samussiah	2019-03-	dev-v2.3.2

		27T20:22:33Z	
0091	jwildfire	2019-05-16T03:35:31Z	dev-v2.3.3
0093	dependabot[bot]	2019-07-12T04:22:54Z	dependabot/npm_and_yarn/lo 4.17.14