

Interactive Data Visualization of Clinical Trials Data with D3.js

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Background

Interactive data exploration tools can provide reviewers with instantaneous global visualization of quantitative relationships and adverse event patterns in NDA submissions. We explored the utility of open-source visualization libraries using widely implemented web standards to interactively visualize and explore SDTM datasets. D3.js is visualization library increasingly used (New York Times, NPR) by various websites as a visualization framework; facilitated by compatibility with various web standards (e.g. SVG, HTML and JavaScript) and data source formats (e.g. XML, tab-delimited, comma separated and JavaScript Object Notation (json). Here we demonstrate the use of D3.js and its extension library NVD3 to build web-based applications to support the FDA drug review process.

Initial Exploration

In our initial exploration of D3.js visualization, we first generated an adverse events summary analysis comparing risk difference and between study treatment and control treatment using the FDA internal analysis program MedDRA at a glance. This analysis program generates an excel output of subject level adverse event counts by treatment groups which could be organized by various MedDRA hierarchy levels such as system organ class and/or by various risk estimators such as risk difference, relative risk and negative log-p values.

To highlight the differences between study treatment vs. control treatment, we wrote a custom visualization to generate an interactive volcano plot using D3.js. In this volcano plot, depicting the risk difference on the y axis vs. neg log-p values of the MedDRA hierarchy in the x axis, data points in the upper right hand quadrant represents adverse events that have a higher relative risk and higher noteworthiness between the study treatment vs. control treatment, whereas data points in the lower right hand quadrant represents those that have a lower relative risk (protective effect) and higher noteworthiness between the study treatment vs. control treatment.

Adverse Events MedDRA Comparison Analysis

Treatment arm: Drug B
Control arm: Drug A

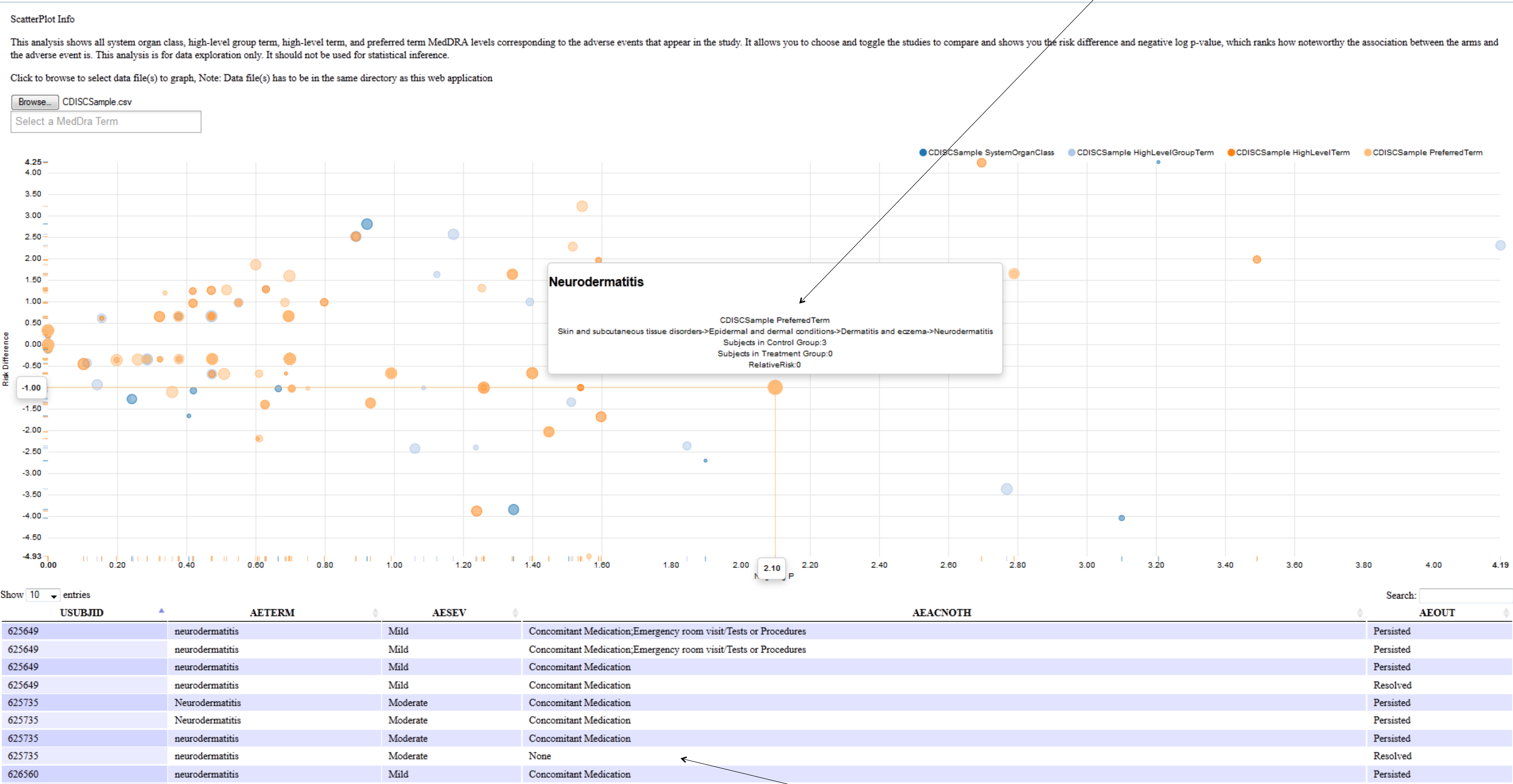
Risk difference threshold (%): 1
Relative risk threshold: 1
Negative log p-value threshold: 1

Choose your arms and type in your thresholds in the yellow input cells
Look below to see which terms have signals; you may have to scroll down
The colors in the signal columns tell you about the signal:
This term shows a signal
A term above or below in MedDRA shows a signal

Level	System Organ Class	High-Level Group Term	High-Level Term	Preferred Term	DME	Signal	At	Signal	At	Treatment: Drug B N=303	Control: Drug A N=300	Risk Difference	Relative Risk	Negative Log P-value
										Subject Count	%	Subject Count	%	
1	Blood and lymphatic system disorders									4	1.3	5	1.7	-0.3
2	Blood and lymphatic system disorders	Anaemias nonhaemolytic and marrow depression								4	1.3	4	1.3	0.0
3	Blood and lymphatic system disorders	Anaemias nonhaemolytic and marrow depression	Anaemia deficiencies							3	1.0	2	0.7	0.3
4	Blood and lymphatic system disorders	Anaemias nonhaemolytic and marrow depression	Anaemia deficiencies	Iron deficiency anaemia						3	1.0	2	0.7	0.3
3	Blood and lymphatic system disorders	Anaemias nonhaemolytic and marrow depression	Anaemia NEC							1	0.3	2	0.7	-0.3
4	Blood and lymphatic system disorders	Anaemias nonhaemolytic and marrow depression	Anaemia NEC	Anaemia						1	0.3	2	0.7	-0.3
3	Blood and lymphatic system disorders	Haematological disorders NEC								0	0.0	1	0.3	-0.3
4	Blood and lymphatic system disorders	Haematological disorders NEC	Haematological disorders							0	0.0	1	0.3	-0.3
4	Blood and lymphatic system disorders	Haematological disorders NEC	Haematological disorders	Mastocytosis						0	0.0	1	0.3	-0.3
1	Congenital, familial and genetic disorders									8	2.6	3	1.0	1.6
2	Congenital, familial and genetic disorders	Eye disorders congenital								2	0.7	0	0.0	0.7
3	Congenital, familial and genetic disorders	Eye disorders congenital	Lacrimal system disorders congenital							2	0.7	0	0.0	0.7
4	Congenital, familial and genetic disorders	Eye disorders congenital	Lacrimal system disorders congenital	Dacryostenosis congenital						2	0.7	0	0.0	0.7
3	Congenital, familial and genetic disorders	Metabolic and nutritional disorders congenital								1	0.3	0	0.0	0.3
4	Congenital, familial and genetic disorders	Metabolic and nutritional disorders congenital	Inborn errors of carbohydrate metabolism (excl glucose)							1	0.3	0	0.0	0.3
4	Congenital, familial and genetic disorders	Metabolic and nutritional disorders congenital	Inborn errors of carbohydrate metabolism (excl glucose)	Hereditary fructose intolerance						1	0.3	0	0.0	0.3
2	Congenital, familial and genetic disorders	Metabolic and nutritional disorders congenital								3	1.0	1	0.3	0.7

Figure 1. Output from MedDRA at a glance shows risk difference, relative risk and neg-log P values for different MedDRA hierarchy terms.

Additional interactive features of the developed web application include the ability to show detailed information on mouse over.



Detailed information relating to each MedDRA AE term is displayed here.

Future Exploration

This preliminary work demonstrates the ability to create interactive data exploration web applications using the open source visualization library D3. This flexible resource enabled creation of a variety of interactive visualizations adapted for review use. We are currently exploring using D3's capabilities to create additional data exploration tools including various chart types as well as animated visualizations.

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