

Triple-i Researcher

What is Triple-i Researcher?

Triple-i Researcher is a web based application designed to mine the U.S. Food and Drug Administration's publicly available data on drug adverse events, medical device adverse events, and medication error reports.

Powered by a variety of open-source technologies, this single page web application utilizes the openFDA data set as its model, and is designed as a tool to assist researchers in identifying anomalies (*spikes*) in aggregated data sets meeting the researchers' specified criteria. Furthermore, this tool enables researchers to delve into the details that comprise the identified anomalies.

Please note that openFDA is a beta research project and not for clinical use. While the FDA makes every effort to ensure that data and logic are accurate, you should assume all results are unvalidated.

Terms and Definitions

The following terms and definitions are used throughout this document:

- *functional prototype* means an HTML page and support files designed to run locally from the user's PC or from a web server.
- *thin client* (sometimes also called a lean, zero or slim **client**) refers to a computer or a computer program that depends heavily on another computer (its server) to fulfill its computational roles. This is different from the traditional fat **client**, which is a computer designed to take on these roles by itself.
- *API* is an acronym for Application Programming Interface. Unless otherwise stated, when used in this document, API refers to the openFDA application programming interface.

The History of Triple-i Researcher

OpenFDA is a project created in March 2013 by Taha Kass-Hout, MD, MS, the FDA's first Chief Health Information Officer. OpenFDA's goal is to create easy access to public data, to create a new level of openness and accountability, to ensure the privacy and security of public FDA data, and ultimately to educate the public and save lives.

Triple-i Researcher is a functional prototype web app intended to mine the adverse events data set made accessible by the openFDA API (<https://open.fda.gov/drug/event/>). It was designed in response to the openFDA Developer challenge, announced May 11, 2015 (<https://open.fda.gov/update/an-open-challenge-to-tap-public-data/>). Using a mix of Agile and Extreme Programming (XP) methodologies, a small team of four developers started design work for this application on June 18, 2015, with the goal of leveraging existing web technologies to deliver solid results within a short time frame.

Triple-i Researcher was developed using gitHub as its repository and version control mechanism. All code is publicly available at <https://github.com/dougboude/tripleifdachallenge/>.

The Anatomy of the Triple-i Researcher

Triple-i Researcher is a single web page application written in HTML5 which connects to the `api.fda.gov/drug/event.json` end point. While originally designed to run locally from the user's PC*, a copy of Triple-i Researcher is currently available online at <http://iiiresearch.net/>. The web page is supported by a collection of CSS, fonts, and JavaScript files, which collectively leverage the following open source technologies: jQuery, jQueryUI, charts.js, dataTables.js, and Bootstrap 3.

Triple-i Researcher is a thin client that behaves as a dynamic view to the openFDA data set. The general flow is that user defined queries are passed through to the openFDA API. The return results are then formatted for interactive display.

As of June 26, 2015, we are excited to report that this app is compatible with mobile devices.

* This web app may also be distributed via a simple zip file, to be installed and run locally. To install, unzip the file on your local PC, then open index.html with a modern browser.

Functional Areas

Product/Adverse Events Search

Triple-i Researcher permits a researcher to search a date range for adverse events associated with a drug's generic name, substance name, or both. The search may be filtered against a specific category of reaction and spike threshold percent, with an option to limit results to spikes only.

Tier1 Data Visualization

The results of a researcher's initial search will be displayed in a scrollable bar graph, with event dates on the x-axis and numbers of events on the y-axis. Spikes will be represented in red. Hovering over any bar will yield a tooltip providing details (number of reactions, percent deviation from the average) for that day's events. Clicking on any bar will open a dialog to delve into details for that day's events, which will be presented as Tier2 data visualization.

Tier2 Data Visualization

Tier2 data visualization begins with a two-tabbed dialog, with tabs named *Chart* and *Raw Data*.

- *Raw Data* allows researchers to view the underlying data as a scrollable multi-page chart. This view provides the researcher with a few options described in the Tier2 Discrete Data Interaction section that follows.
- *Chart* allows the user to segregate results by category groupings to yield new visualizations for that day's adverse events.
Researchers may group that day's adverse events according to
 - reaction type
 - drug delivery method
 - drug role
 - patient sex
 - patient age
 - patient weight

Bar graphs will be generated to display the breakdown of events according to the selected category.

Tier2 Discrete Data Interaction

Researchers may search, sort, and export the raw, charted data displayed in the Tier2 *Raw Data* tab.

Triple-i Researcher Architecture

Triple-i Researcher has been constructed using the following grocery list:

- App core framework: HTML
- Database: openFDA API (`api.fda.gov/drug/event.json` end point)
- Javascript Libraries: jQuery, jQueryUI, Bootstrap3, chars.js, Datatables, Bootstrap-datepicker, misc dependencies
- CSS Library: Bootstrap 3

Update History

June 26, 2015:

Tier 1

- Added option to group intervals by Day, Week, or Month ✓

Tier 2

- Age chart: groups by decade ✓
- Weight chart: groups in 50 lb increments ✓
- Weight chart: added option to display weight in kilograms ✓
- Orders x-axis from smallest to largest value for Age and Weight charts ✓

Application wide

- Added support for mobile devices ✓

Pending Tasks and Features

Tier 1

- Bind key press event to search button

Tier2

- Round age values to nearest whole number
- Provide ability to overlay multiple data sets

Application wide

- Refactor JavaScript