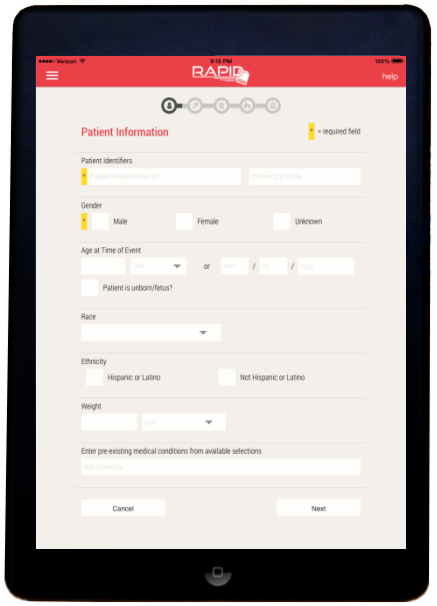
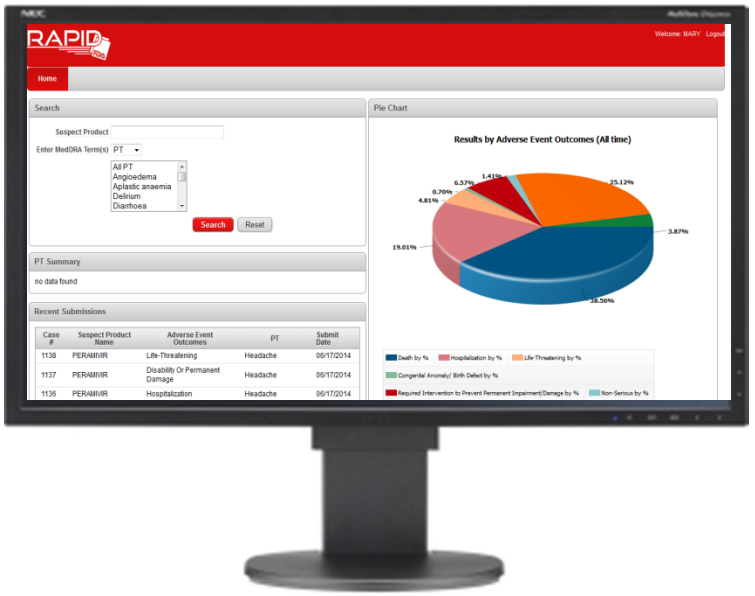
RAPID FDA


RAPID
help
Patient Information
* = required field
Patient Identifiers
Gender
Male
Female
Unknown
Age at Time of Event
Patient is unborn/fetus?
Race
Ethnicity
Hispanic or Latino
Not Hispanic or Latino
Weight
Enter pre-existing medical conditions from available selections
Cancel
Next


RAPID
Welcome MARY
Home
Search
Suspect Product
Enter MedDRA Term(s)
PT
All PT
Angioedema
Aplastic anaemia
Delirium
Diarrhoea
Search
Reset
PT Summary
no data found
Recent Submissions
Case #
Suspect Product Name
Adverse Event Outcomes
PT
Submit Date
1138 PERAMIVIR Life-Threatening Headache 06/17/2014
1137 PERAMIVIR Disability Or Permanent Damage Headache 06/17/2014
1136 PERAMIVIR Hospitalization Headache 06/17/2014
Pie Chart
Results by Adverse Event Outcomes (All time)
25.12%
3.87%
38.50%
19.01%
4.81%
0.70%
6.57%
1.41%
Death by %
Hospitalization by %
Life-Threatening by %
Congenital Anomaly/ Birth Defect by %
Required Intervention to Prevent Permanent Impairment/Damage by %
Non-Serious by %

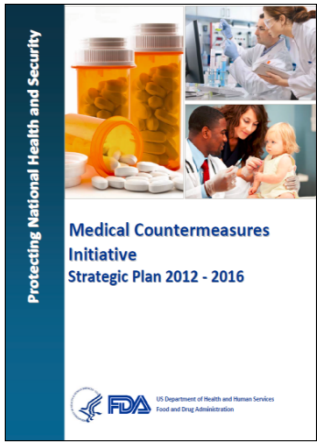
FDA launched the MCM initiative to improve our nation's capacity to respond to CBRN and pandemic threats

MCMi Overview

- FDA launched its medical countermeasure initiative (MCMi) in response to a comprehensive, year-long review conducted by the HHS assessing the nation's ability to respond to public health emergencies
- Mission: Strengthen and transform the MCM enterprise by augmenting FDA's activities in review, regulatory science, and policy to expedite its ability to respond to CBRN and EID threat

Three Pillar Strategy

- Enhance FDA's product review and approval processes for the highest priority MCMs and related technologies
- Build the necessary science base for MCM regulatory review and identify clear, efficient regulatory pathways for developing critical MCMs
- Modernize the legal, regulatory, and policy framework to facilitate MCM development and ensure an effective public health response



The cloud-based RAPID Bio-surveillance System will support collaboration between FDA and other Federal agencies to enhance monitoring emerging health threats

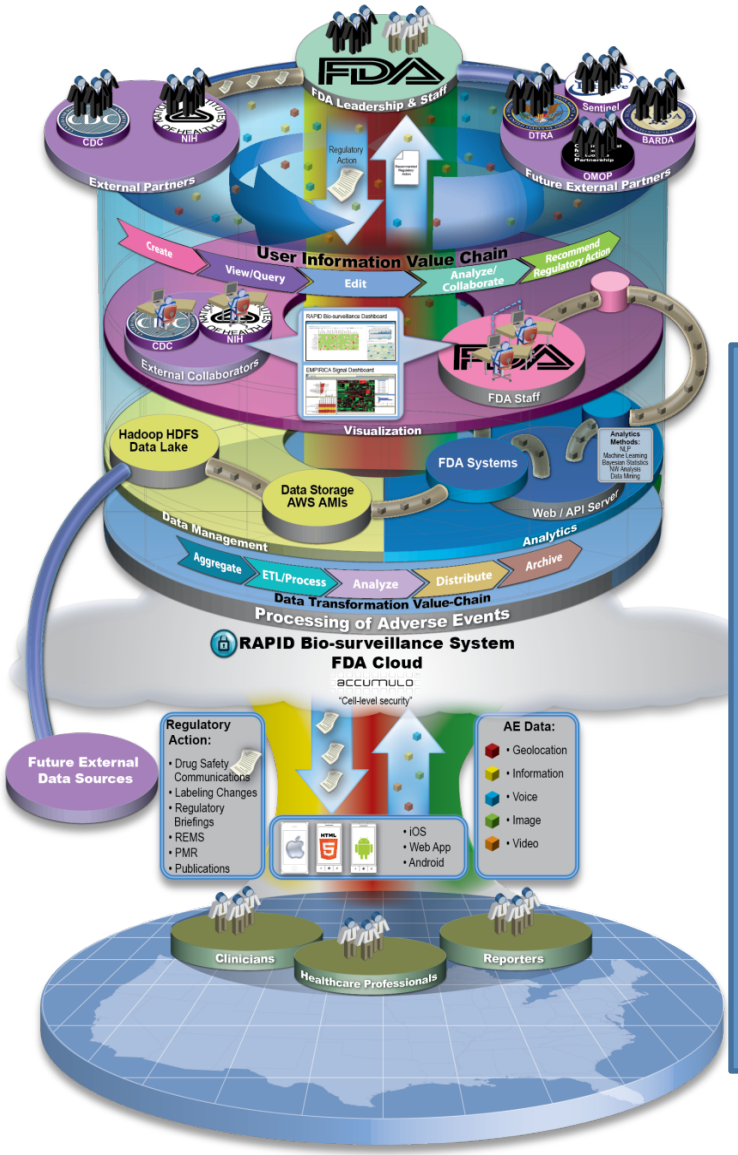
RAPID Biosurveillance System

Tier 1: Regulatory Action/Guidance
- FDA and external partners issue guidance to ensure patient safety

Tier 2: Data Visualization
- Dashboards summarizing key information provide safety alerts
- Disproportionality metrics and detailed analyses allow FDA and collaborators to understand emerging issues

Tier 3: Data Management & Analytics
- RAPID data is combined with existing MedWatch and Medwatcher reports and data from external collaborators
- Advanced analytics support AE signal detection

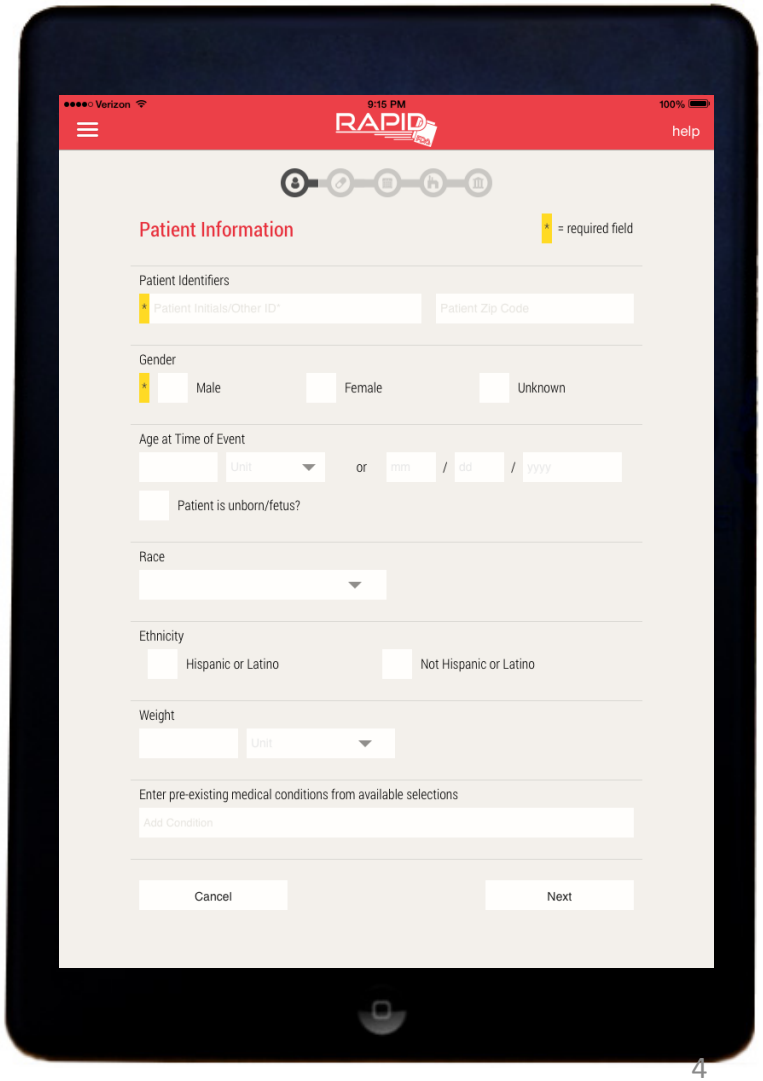
Tier 4: Processing of Adverse Events
- Healthcare professionals submit AE data via the RAPID mobile app
- AE data is stored in a "data lake" to support real-time access



FDA requires a real-time active surveillance application to support pharmacovigilance and adverse event reporting in MCM situation

The Solution

- Real-time Application for Portable Interactive Device (RAPID) will facilitate the real-time collection, analysis, and communication of MCM product and health information during national public health emergencies
- Flexible Mobile platform to use during MCM events
- Flexible FDA cloud design complementary to FAERS
- Adaptable data management and analysis system
- Bidirectional CDER multimedia communications
- Decision maker data work bench



RAPID

Home

Home > Summary > Case Details > **Send Message**

Selected Drug: Peramivir ×

To: **Case #1114 Reporter** | All Peramivir Reporters

Enter Message:

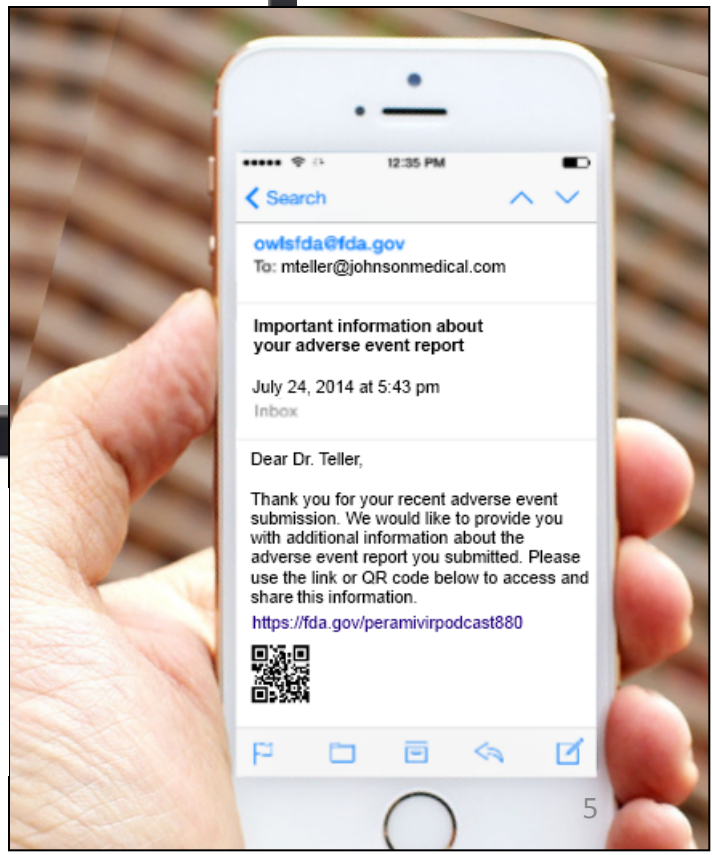
Dear Dr. Teller,

Thank you for your recent adverse event submission. We would like to provide you with additional information about the adverse event report you submitted. Please use the link or QR code below to access and share this information.

https://fda.gov/peramivirpodcase880

Thank you,
FDA

Cancel | **Send Message**



Visual Look at RAPID Stakeholders

RAPID MOBILE APPS

FDA RAPID LEADERSHIP
- Dr. Henry Francis
- Richard Zhang
- Bruce Weaver

FDA RAPID Team
- Joseph Tonning, Thomas Ly, Sanjay Sahoo, Suranjan De

FDA RAPID Contractor Team:
Booz Allen Hamilton, Project Manager Lauren Neal

NIH National Library of Medicine:
George Thoma, Sameer Antani, Stacey Arnesen, Whitney Quesenbery

Office of Communications
- Paul Buckman
- Sherunda Lister
- Mary Kremzer
- Catherine Chew

DRISK
- Amarilys Vega with Cynthia LaCivita

DPV
- Scott Proestel and Robert Levin

DMEPA
- Jo Wyeth

RAPID CLOUD ENVIRONMENT

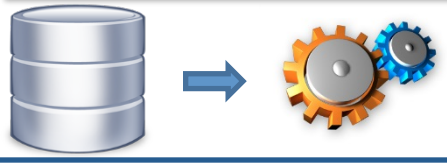
Cloud Infrastructure
- Farhan Khan
- Accenture/AWS Team

Security
- Kristen Wayne (CISO)

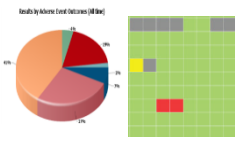
MedDRA / Data SMEs
- Sonja Brajovic
- Roger Goetsch
- Krishna Chary (E2B)
- Mitra Roca (HL7)

Web Services, Database, Dashboards, Empirica, ArcGIS
- FDA RAPID Contractor Team

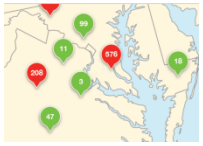
RAPID EXTERNAL DATA SOURCES



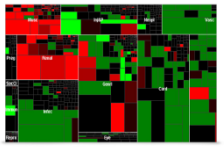
RAPID ANALYTICAL TOOLS



RAPID Dashboard & Data
- OSE
- USCIITG
- RAPID Contractor Team



Geovisualization
- Martha O'Connor
- Wayne Gorski
- Nathan Beck
- Newland Agbenowosi (RAPID Contractor Team)



Empirica (Signal Detection)
- Ana Szarfman
- Michael Johnston
- Luda Gittes (RAPID Contractor Team)

Mobile Data Collection: Clinicians, Reporters, and Patients enter AE information, attach digital files (ex. photo), capture geolocation, and respond to REMS survey

Data Transferred to FDA: Data is submitted from mobile device and sent over Cellular network or WiFi to FDA's Cloud Environment via web services

Data Processed in Cloud: Data is processed and stored in FDA Cloud. Adhering to FDA Security and Data best practices. Dashboards provide leadership, comm staff and QC views into AE Data

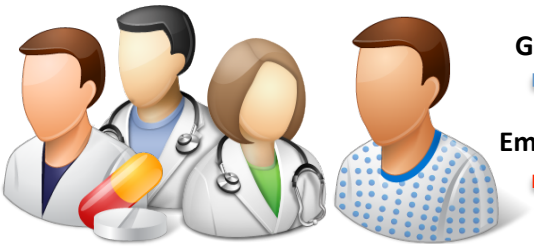
Response Sent to Reporter: Within 24 hours a targeted response is sent via email containing link to digital file (ie, Podcast) with additional information

Perform Analytics : Utilize RAPID Dashboard, ArcGIS (location-based analysis) , and Empirica (signal detection) for analysis

Obtain External Data: Data will be shared from external sources via web services (ex. HL7 ICSR) and increase the effectiveness of analysis performed using RAPID analytical tools

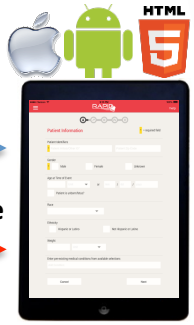
DPV - Adverse Event Report Use Case

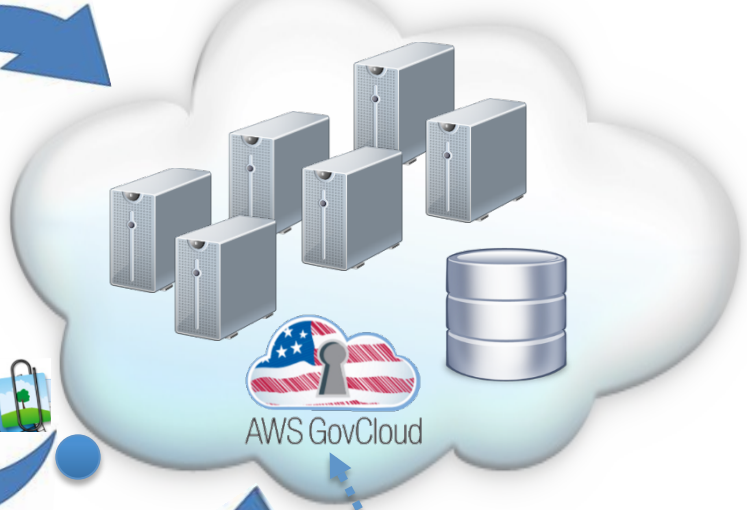
Healthcare Professionals and consumers submit regular and emergency surveillance adverse event reports



General Surveillance

Emergency Surveillance



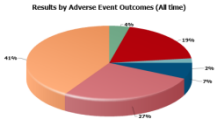
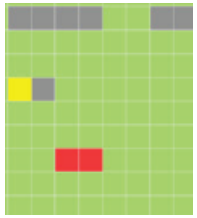
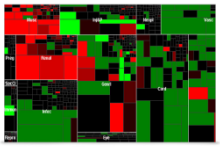


DPV Stakeholders

- Scott Proestel
- Robert Levin
- Samantha Cotter

RAPID External Data (Future)

Adverse Event Analytical Tools

RAPID AE Dashboard & Data	Geovisualization
	
RAPID Heatmap	**Empirica**
	

Mobile Data Collection:
Clinicians, reporters, and patients create general surveillance and emergency surveillance reports

Perform Analytics :
Utilize RAPID Dashboard, location based data, and Empirica (signal detection) for analysis

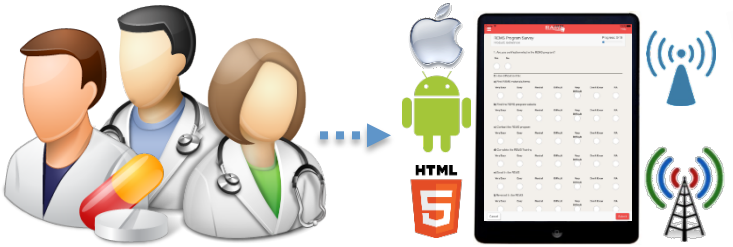
Obtain External Data:
Data will be shared from external sources via web services (ex. HL7 ICSR) and increase the effectiveness of analysis performed using RAPID analytical tools

Data Transferred to FDA:
Data is submitted from mobile device and sent over Cellular network or WiFi to FDA GovCloud via web services

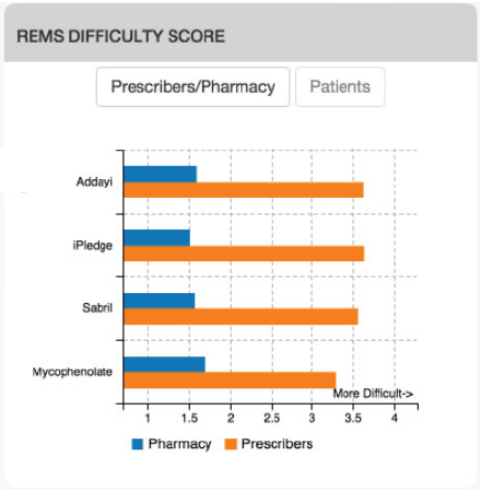
Response Sent to Reporter:
Within 24 hours a targeted response is sent via email containing links to multimedia files like images and podcasts

DRISK - REMS Assessment Use Case

Prescribers & Pharmacists submit REMS Program Assessment



REMS Program Dashboard



Mobile Data Collection:
Prescribers, pharmacists, and patients complete the REMS Assessment using the RAPID app on their mobile device

Data Transferred to FDA:
Data is submitted from mobile device and sent over Cellular network or WiFi to GovCloud via web services

Perform Analytics :
Utilize the REMS Dashboard to view composite scores, results by domain, and to perform additional analysis

Response Sent to Reporter:
Send email containing information about the REMS Program back to the user

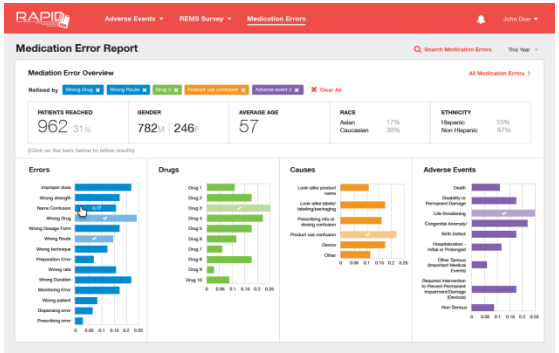
DRISK Stakeholders

- Cynthia LaCivita
- Lisy Vega
- Gita Toyserkani
- Doris Auth
- Shelly Harris

DMEPA – Medication Error Use Case

Prescriber submits medication error report

Medication Error Dashboard



Mobile Data Collection:
Prescriber completes a Medication Error Report and attaches an image using the RAPID app on their mobile device

Data Transferred to FDA:
Data is submitted from mobile device and sent over Cellular network or WiFi to GovCloud via web services

Perform Analytics :
Utilize the Medication Error Dashboard to view overview of the medication error reports that are being submitted

Response Sent to Reporter:
Send email containing information about the Medication Error back to the user

DMEPA Stakeholders

- Jo Wyeth
- Mishale Mistry
- Hina Mehta

Duke University Medical Center

Brigham and Women's Hospital

University of Southern California Hospital

University of Maryland Medical Center

Trigger examples: influenza order, blood culture order, sputum culture order, CXR order

(ESP) Safety or Clinical data

FHIR®©

Smart on FHIR API
Clinical Data Element Profile for Severe Acute Respiratory Infection data elements

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Secure Data Broker
HHS & Booz Allen Hamilton
Data Aggregated & De-identified

U.S. Department of Health & Human Services

Geolocation, case and site reporting, resource deployment overlay

RAPID FDA

Regulatory-case level or patient level

Visualization layer with streaming data for research case and patient level

Clinical Registry case level and patient level

RAPID Phase II

The proposed RAPID Biosurveillance Platform includes a cloud-based open source big data analytic tool to facilitate detection of adverse event signals in near real-time

[Alerts] Display Drugs with > 50% increase in the number of reports in the last 2 weeks

My Projects
- Project 1
- Project 2
- Project 3

Create Project

Drug-AE Filter:
- All drugs in which 1 or more cases are fatal
- All drugs in which 50% of the adverse event cases are reported in pediatrics

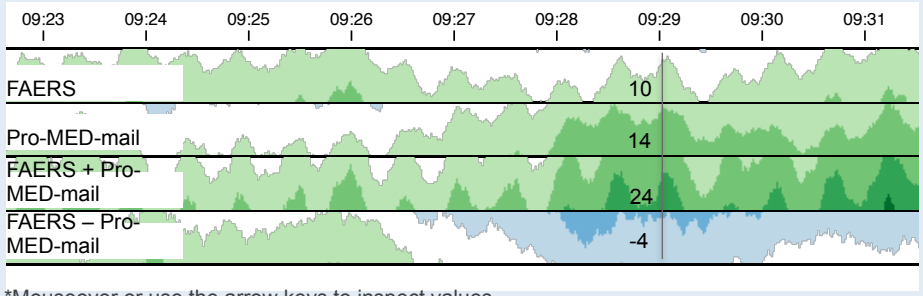
Disproportionality Metric Filter:
- ROR
- PRR
- GPS
- IC
- Corresponding Ranking statistic: e.g., 5 per cent quantile $Q_{0.05}$ of the posterior distribution

Drug-Event Tracker

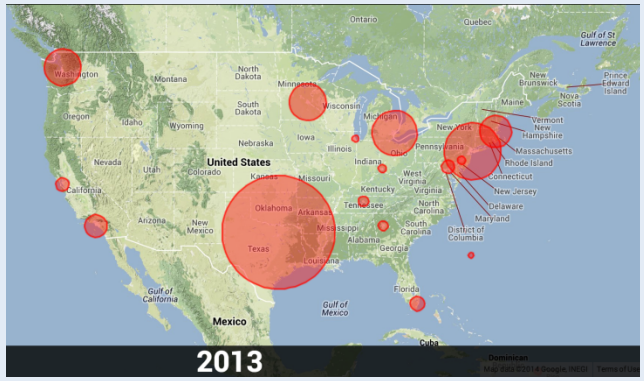
Drug	% Change in Number of Reports (daily)	Algorithm & Ranking Statistic (all data)
Paramivir-H1N1	+ 3	2.0
Avandia-Diabetes	0.17	1.05
MPA-Steroid Injections	*1.0*	1.3
Zanamivir-H1N1	0.17	1
ALL	+ 10	2.5

Clicking on a drug in the list above activates the time series and geographic visualization

Time Series Visualization for Number of Reports for Drug of Interest: Adverse Event Data and Social Media Data



*Mouseover or use the arrow keys to inspect values



*Mouseover bubbles to view information on adverse events reported at different geographic locations

RAPID II Summary

- Bidirectional cloud based system
- Capable of real time information and analytics
- Flexible data and analytic platform
- Beginning multimedia information analysis
- **Key issues**
  - Who owns the data?
  - How would the transdisciplinary group work?
  - What data, not quantity of data is important?