



The image shows a tablet displaying the RAPID mobile application. The interface is titled "Patient Information" and includes a progress bar at the top with steps 1 through 5. The form contains the following fields and options:

- Patient Identifiers:** A text field for "Patient Identifier (e.g., ID)" and a text field for "Patient Zip Code".
- Gender:** Radio buttons for Male, Female, and Unknown.
- Age at Time of Event:** A dropdown menu for "Unit" (years, months, days, weeks) and input fields for "Age", "Month", "Day", and "Week".
- Patient is unborn/fetus?** A checkbox.
- Race:** A dropdown menu.
- Ethnicity:** Radio buttons for "Hispanic or Latino" and "Not Hispanic or Latino".
- Weight:** A text field and a dropdown menu for "Unit" (pounds, kilograms).
- Enter pre-existing medical conditions from available selections:** A text field with a "Add Condition" button below it.
- Buttons:** "Cancel" and "Next" buttons at the bottom.



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

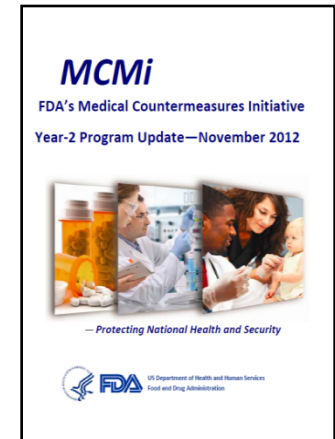
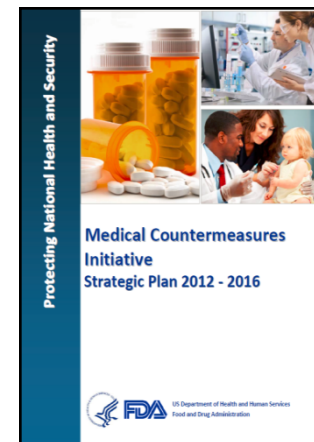
MCMi Overview

- 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

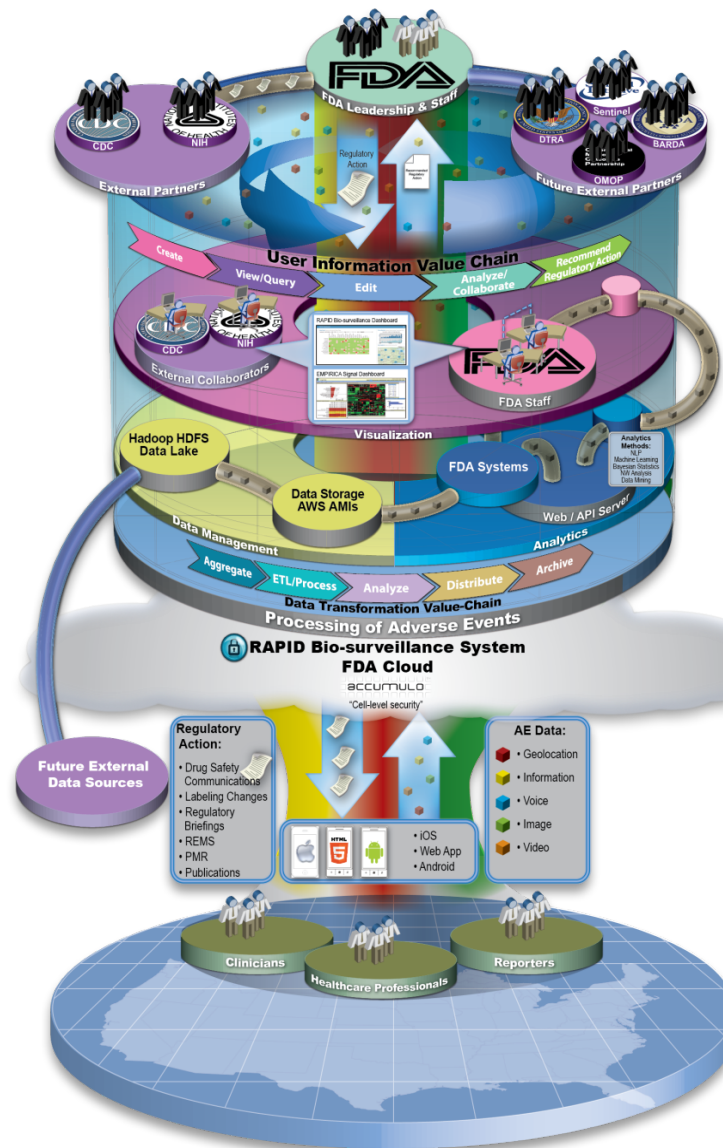
- Dashboards summarizing key information provide safety alerts
- Disproportionality metrics and detailed analyses allow FDA and collaborators to understand emerging issues

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



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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

The screenshot shows the RAPID mobile application interface on a tablet. The top status bar displays "Verizon", "9:15 PM", and "100%". The app header is red with the "RAPID" logo and a "help" link. Below the header is a navigation bar with icons for home, add, edit, view, and list. The main content area is titled "Patient Information" and includes a legend indicating that a yellow asterisk (*) denotes a required field. The form contains several sections: "Patient Identifiers" with a required field for "Patient Initials/Other ID*" and a field for "Patient Zip Code"; "Gender" with radio buttons for "Male", "Female", and "Unknown", where "Male" is selected; "Age at Time of Event" with a date picker (month, day, year) and a checkbox for "Patient is unborn/fetus?"; "Race" with a dropdown menu; "Ethnicity" with radio buttons for "Hispanic or Latino" and "Not Hispanic or Latino"; "Weight" with a text input and a unit dropdown; and a section for "Enter pre-existing medical conditions from available selections" with an "Add Condition" button. At the bottom are "Cancel" and "Next" buttons.



Home

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

Selected Drug:

Peramivir x

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.

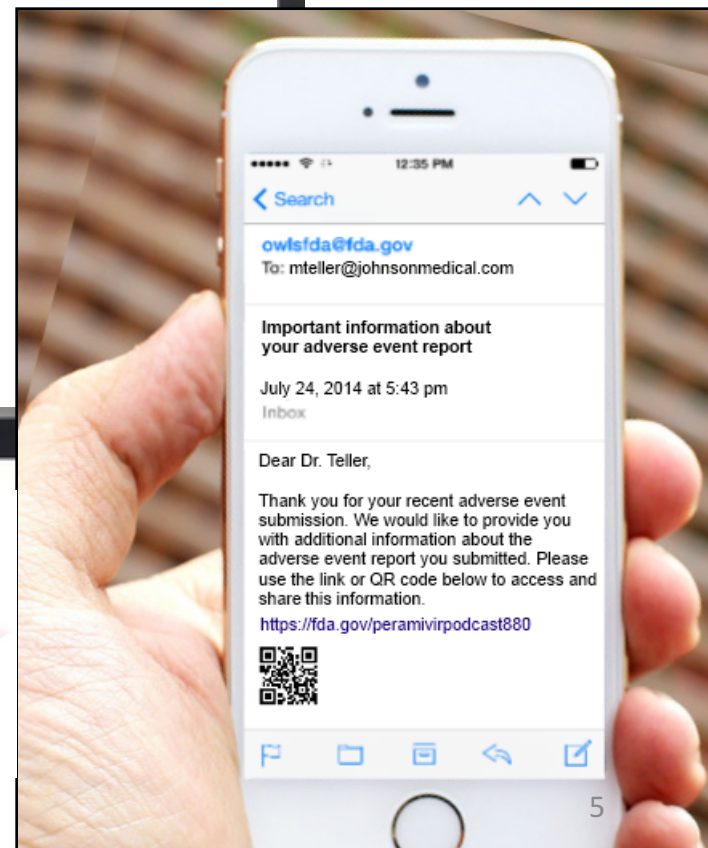
<https://fda.gov/peramivirpodcase880>



Thank you,
FDA

Cancel

Send Message



1

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

- Amarilis Vega with Cynthia LaCivita

DPV

- Scott Proestel and Robert Levin

DMEPA

- Jo Wyeth

RAPID EXTERNAL DATA SOURCES



Visual Look at RAPID Stakeholders

2

4

3

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)

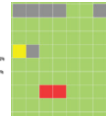
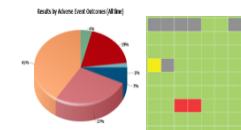
Web Services, Database, Dashboards, Empirica, ArcGIS

- FDA RAPID Contractor Team



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RAPID ANALYTICAL TOOLS



RAPID Dashboard & Data

- OSE
- USCITG
- 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)

1

Mobile Data Collection:

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

2

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

3

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

4

Response Sent to Reporter:

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

5

Perform Analytics :

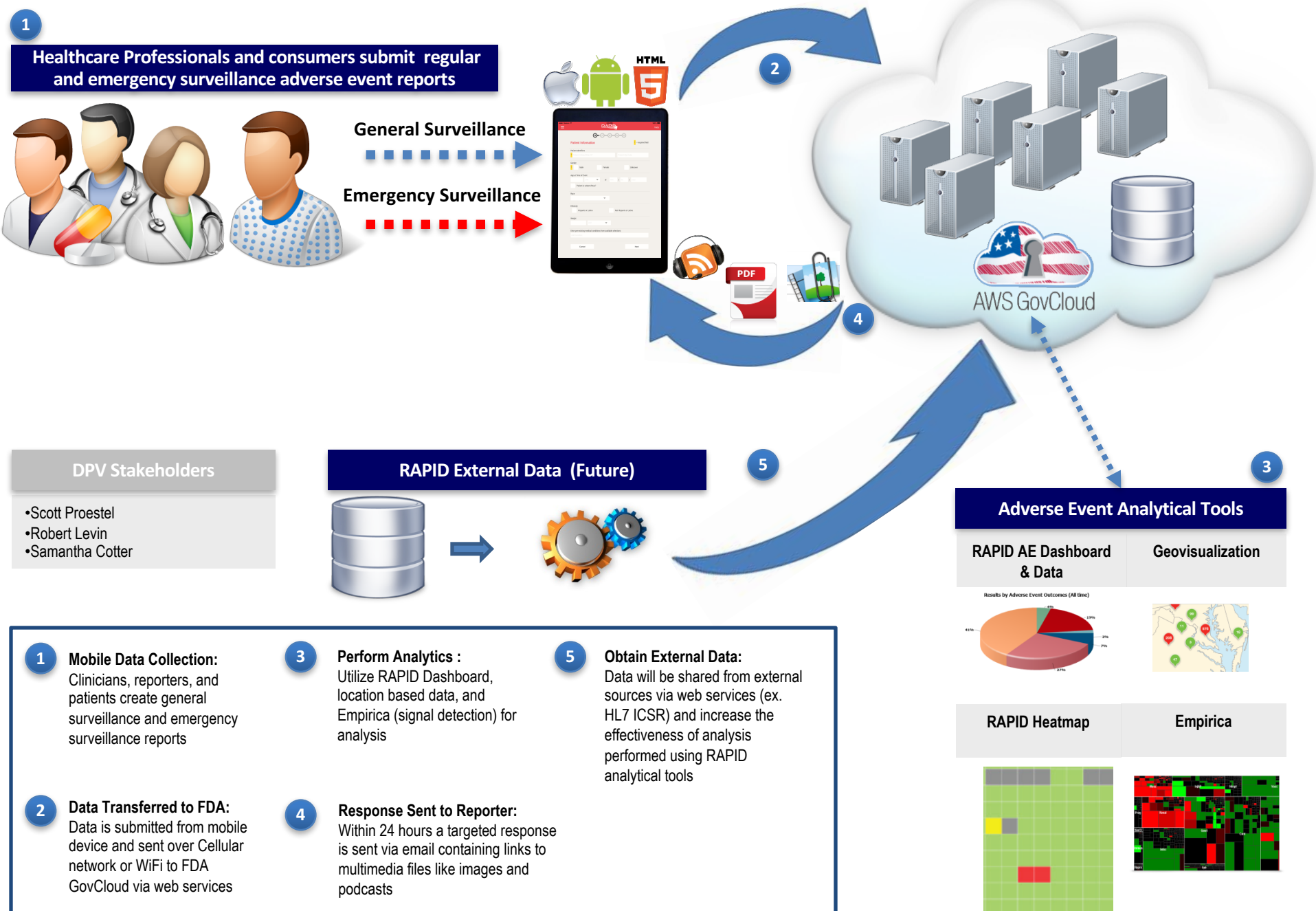
Utilize RAPID Dashboard, ArcGIS (location-based analysis) , and Empirica (signal detection) for analysis

6

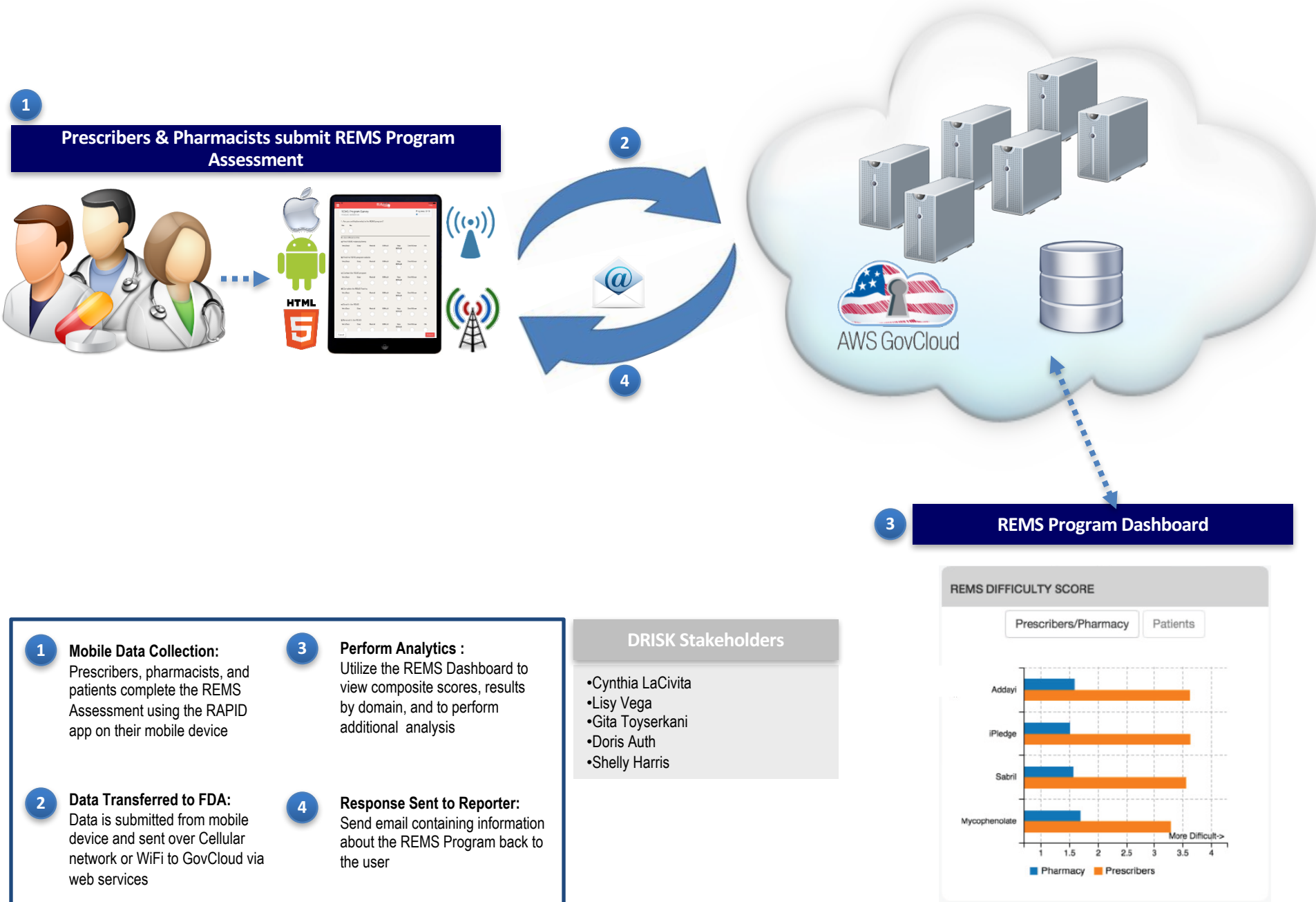
Obtain External Data:

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

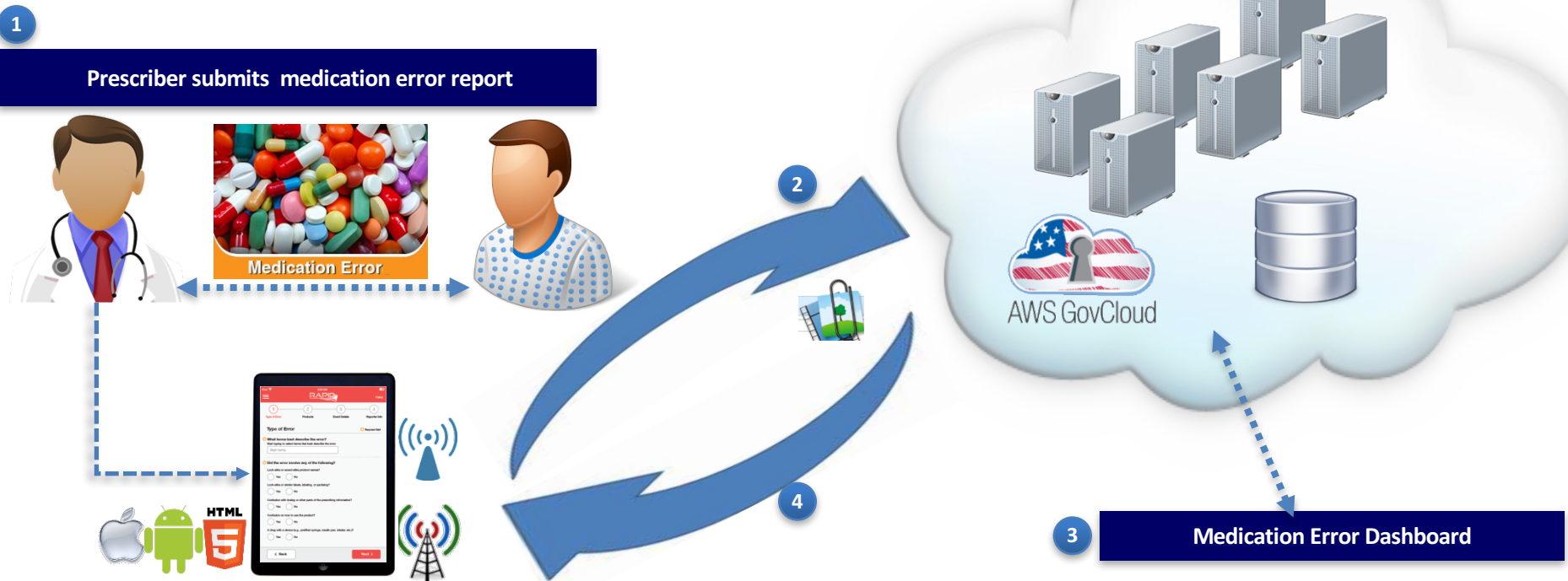
DPV - Adverse Event Report Use Case



DRISK - REMS Assessment Use Case



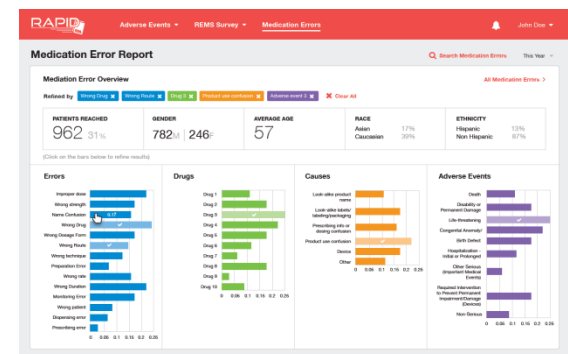
DMEPA – Medication Error Use Case



- 1 Mobile Data Collection:**
Prescriber completes a Medication Error Report and attaches an image using the RAPID app on their mobile device
- 2 Data Transferred to FDA:**
Data is submitted from mobile device and sent over Cellular network or WiFi to GovCloud via web services
- 3 Perform Analytics :**
Utilize the Medication Error Dashboard to view overview of the medication error reports that are being submitted
- 4 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

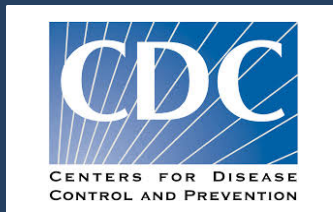


Trigger examples: influenza order, blood culture order, sputum culture order, CXR order

(ESP) Safety or Clinical data



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



Secure Data Broker
HHS & Booz Allen Hamilton

Data Aggregated &
De-identified



Geolocation, case and
site reporting, resource
deployment overlay



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-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

Drug-AE Filter:

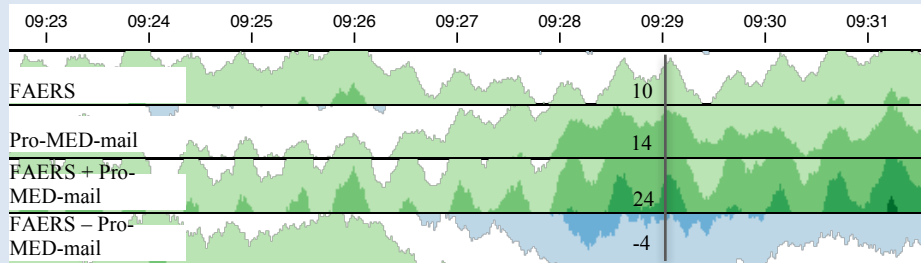
- All drugs in which 1 or more cases are fatal
- All drugs in which 50% of the adverse event cases are reported in pediatrics

Disproportionality Metric Filter:

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

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?