

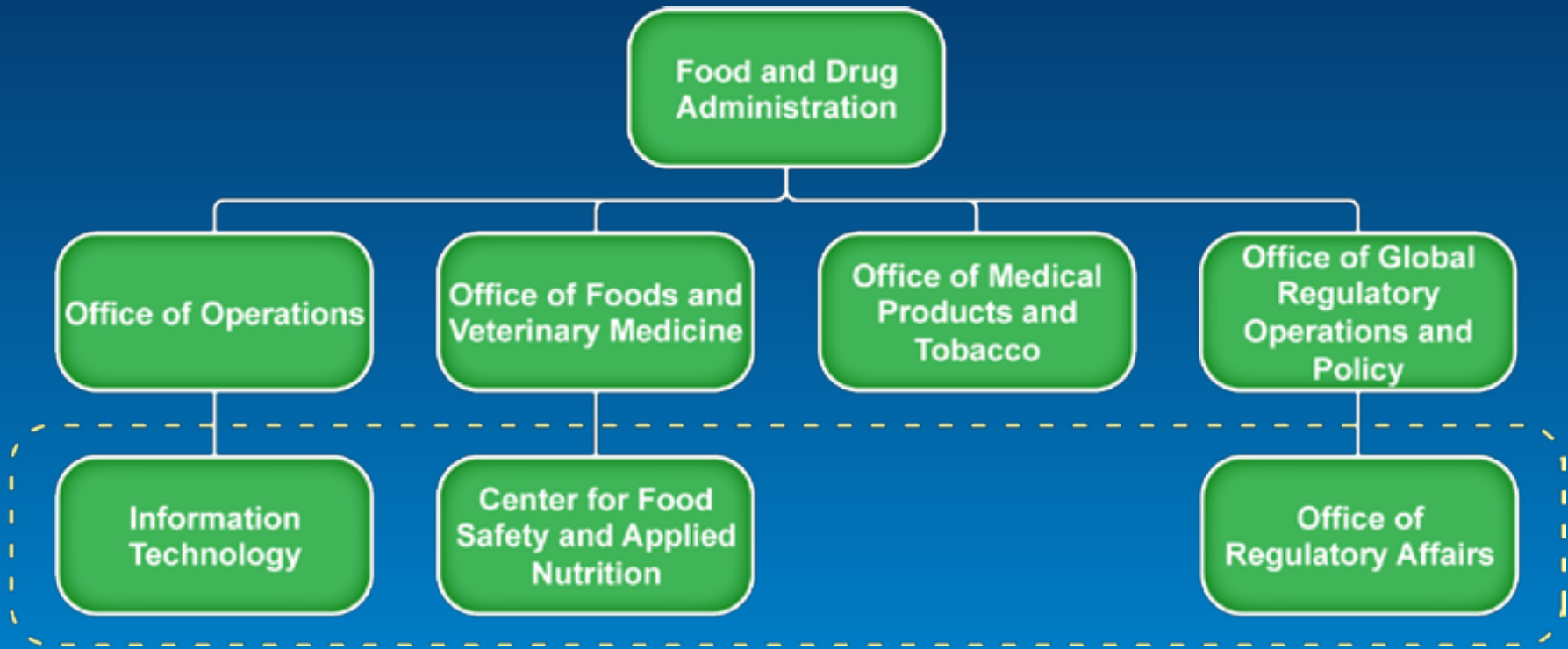
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Developing FDA's Field Investigator's Tool with Mapping (FIT-MAP) Prototype

Kathleen Cheeseman, J.D. - FDA
Socrates Trujillo, Ph.D. - FDA



FDA Organization



CFSAN Culture

Shoestring budget with a long history of using IT to support the scientific work of the center

- Much lower budget than other parts of FDA
- PhD and MS scientists with research backgrounds
- Thus, we have a willingness to fund new IT development as an experiment
- However, application delivery is also expected





VISION and MISSION - To reduce occurrences of food borne illness from produce by implementing the produce safety provisions of the Food Safety Modernization Act of 2011 (FSMA)

- 2013 Salad mix/cilantro (*Cyclospora cayetanensis*) outbreak
 - 631 cases in 25 states (49 hospitalizations)
- 2011 Cantaloupes (*Listeria monocytogenes*) outbreak
 - 147 cases in 28 states (143 hospitalizations), 33 dead
- 2006 Spinach (*E. coli* O157:H7) outbreak
 - 238 cases in 26 states (103 hospitalizations) 5 dead, 31 HUS



During the drafting of the proposed Produce Rule, CFSAN SME's requested data from the FORM FDA 3623 (11/05) Farm Investigation Questionnaire (FIQ) to support requirements

- Reading Word based documents and scanned paper questionnaires for data
- Entering data into Access databases and Excel spreadsheets for analysis
- Dealing with calling the investigators to confirm data provided during the actual inspection
- If geospatial data was collected it was done with handhelds and copied onto those documents



STRATEGY – Develop and implement a mobile GIS application utilizing a rational questionnaire (RQ) for data collection on a ruggedized, PIV-enabled, Windows 8 tablet

- RQs structure the data providing improved data quality and quantity leading to better analysis
- Geospatial data now incorporated into the business process
- Automation should reduce time to complete the inspection allowing FDA to perform more

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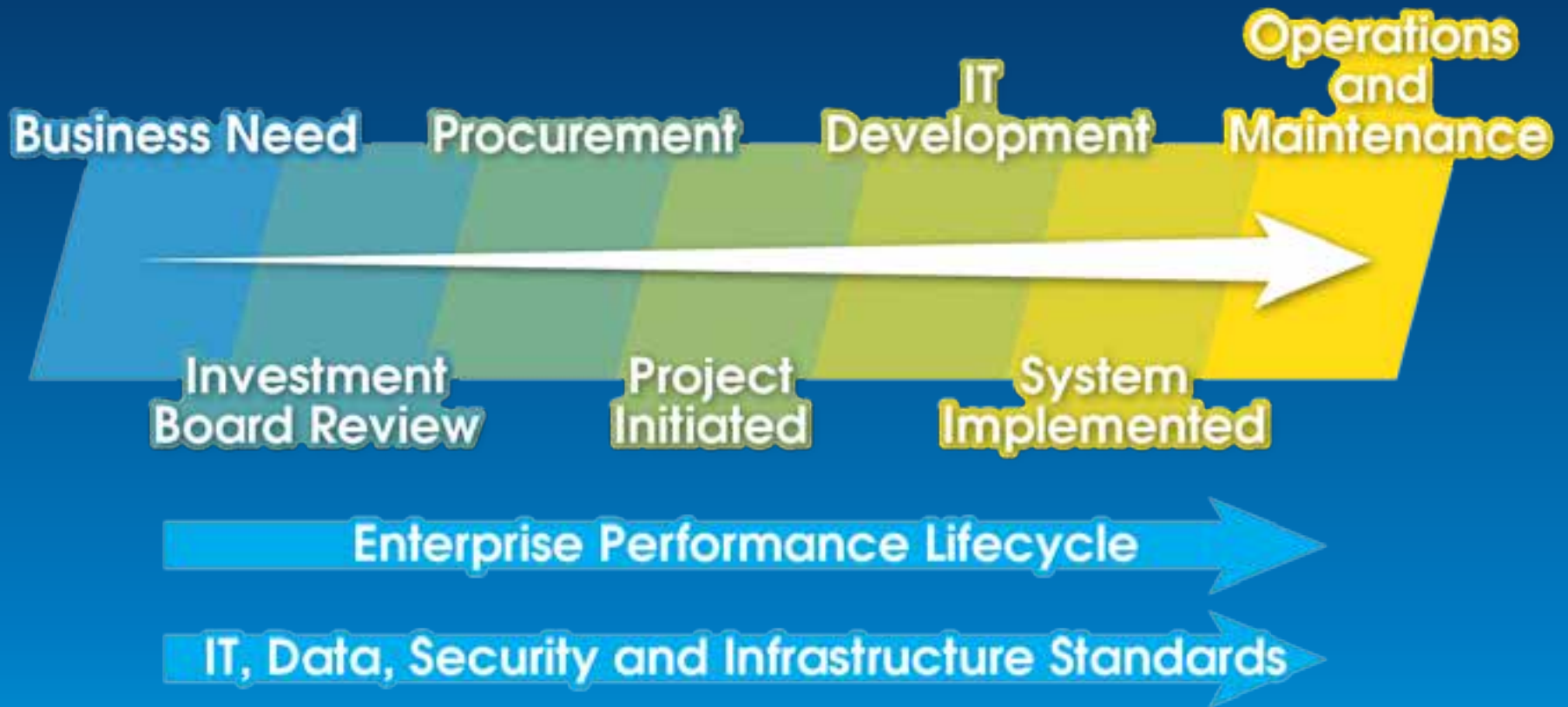
: to become different

: to make (someone or something) different

: to become something else



How the FDA IT Development Process Works



Challenge – Clearly Communicating Vision

Why should we let you build an app for us???

As a Headquarters entity building a tool for use by our field investigators, we have had to communicate both what we are building and why WE (as opposed to THEY) should build.



Bleeding Edge!

The issues have issues...

- Everything is fresh off the assembly line (or even still in beta)
- Nothing seems to work out the box
- We have to figure out how to do everything before we can do it
- And lose one month due to the government shutdown



Challenge – Selecting **OS** and Mobile Device

Concept stage decisions

OS and Device selection are joined at the hip:

- FDA is Windows 7 shop, but....
- We wanted “modern” OS to support touch screen
- iOS had been rejected by FDA – so it was out
- Our application for Android was rejected
- We were going to give up and go to Win7 when our CTO stepped up and approved us to join the FDA Windows 8 pilot



Challenge – Selecting OS and Mobile Device

Concept stage decisions

OS and Device selection are joined at the hip:

We wanted

- PIV Card Reader
- GPS
- Touchscreen
- Camera
- Wi-Fi and 3G
- Windows 8.0
- Sanitizable



We selected the
Panasonic FZ-G1 Toughpad



Approving the Hardware and Software

More and more ITIM reviews...

All of FIT-MAP's items were reviewed and approved

- The operating system
- The mobile device
- FIT-MAP
- Win 8.1 development tools
- New versions of common software



Challenge – Win 8 to Win8.1 to Win8.1 Update 1

The bleeding edge moves...

- We are approved for Windows 8 then Windows 8.1 is released
- FDA decides that we will adopt Windows 8.1
 - The 8.0 to 8.1 caused design rework for us to adopt the line of business user interface
- Then comes Windows 8.1 Update 1
 - The 8.1 to 8.1 Update 1 bricked our Toughpads till we figured out a driver issue



Challenge – Toughpad Issues

Murphy's Law strikes, and again, and again...

- Making the Touchpad's soft keyboard work with Checkpoint, the hard drive encryption software used by FDA
- Updating BIOS to support Win8.1
- Replacing the GOBI modems at the Panasonic Service Center to support Win8.1 GPS



Challenge – Choosing the Architecture

What's a Win 8 App Store App?

GOAL: The greatest experience possible for the user using all the newest bells and whistles for mobile apps

Problem #1:

- Even after choosing Win8.x we had choices of type of application.

Solution #1:

- Develop a Win 8 App Store App



Challenge – Choosing the Architecture

You want me to approve Beta Code?!?!?!?!?

Problem #2:

- A Win 8 App Store App required new Esri Software – ArcGIS Runtime SDK for .Net. But Esri hadn't released it – it was in private Beta

Solution #2:

- Become accepted to the beta program,
- Do some custom work to bridge gaps while in Beta, and
- Delay development of some functionality till production release



Challenge – The Rational Questionnaires

The heart of CFSAN's need

- So we thought we were slick – we had most of the data defined that we would need in the rational questionnaires
- We documented it all in an Excel Spreadsheet

Problem #3:

- Excel lacks the ability to build in business rules logic around forms. And when the inevitable change occurred, business rules would break.

Solution #3:

- Muddle thru the pilot – and find a tool for the next time (Suggestions welcomed)!



Challenge – Disconnected Maps and Images

Esri Online is great for the office, but....

While FDA inspects domestic and foreign firms, the pilot is limited to domestic USDA farms and sprout operations

- Given an address or set of coordinates, we'd like map packages automatically generated
- Because water can potentially be the source/vehicle of produce contamination – packages required topo, streets, and images



Understanding our world.

Challenge – Disconnected Maps and Images

Esri Online is great for the office, but....

We quickly gave up on the idea of auto generating the packages for the pilot

Problem #4:

- So what do we do about map packages when Online didn't work for disconnected maps?

Solution #4:

- Esri to the rescue. In April, they updated Online to support maps for disconnected use



Understanding our world.

Challenge – Disconnected Maps and Images

Esri Online is great for the office, but....

Problem #5:

- We have disparate bandwidth in the field – so if the map package is too big, it can't be downloaded in a reasonable time frame

Solution #5:

- Manage the size of the download to ensure it can be downloaded in a reasonable time frame at site with low bandwidth



Understanding our world.

Challenge – Disconnected Maps and Images

Esri Online is great for the office, but....

Problem #6:

- Lacking auto generated map packages, we don't have any GIS Analysts in the field to create map packages for the Investigators

Solution #6:

- Created a workflow and supporting app to allow an HQ GIS Analyst to create the map package and put in a place an Investigator can download it to FIT-MAP



Understanding our world.



FIT-MAP | Overview / Intro Screen

HIGHLAND FARMS

Overview

Map

Questionnaires

Pictures

Files

Samples

FDA Forms

EIR

History

Inspections

HIGHLAND FARMS

00001463
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2014-05-04
Assigned

Creative Food Imports Limited

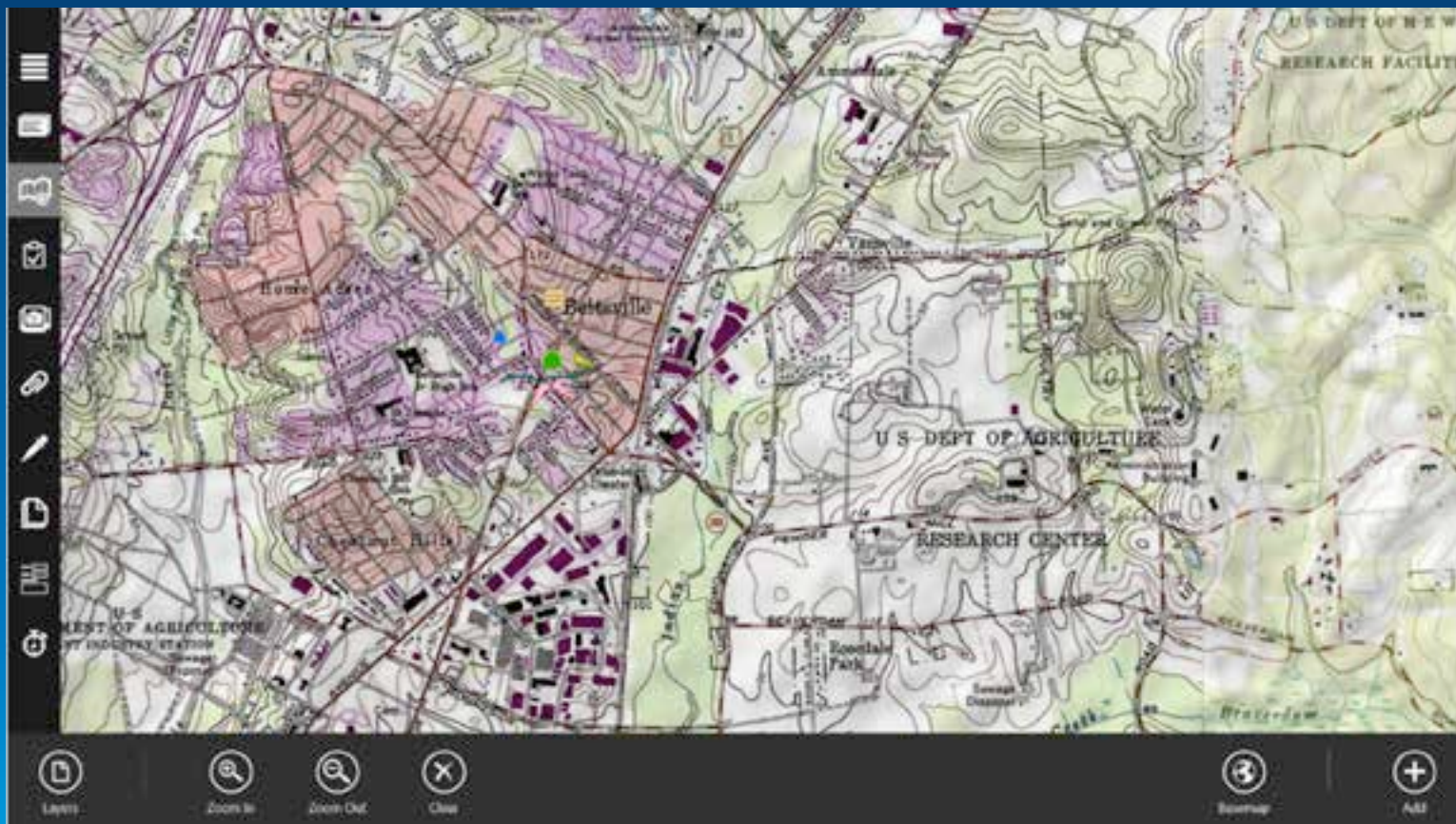
112114
443140

Ready to Download
101/104





FIT-MAP | Topographical Map





FIT-MAP | Image with User Added Feature



Challenge – Integration with Other Systems

It only is a success if it works with everything else...

- FDA has complex business processes and integrated supporting IT systems that have been developed over MANY years
- FIT-MAP has integration points on the front and the back where data has to be pulled and pushed from other systems at the beginning and end of it's process



Challenge – Policy Changes

You think IT development is hard...

- FDA policies have not caught up with technology...
- Adopt new policies or limit the tech to follow existing policies?
- Form FDA 483 – follow existing with modification
- EPLC Documentation for Agile Development – adopted new



Results

- Tablets with Win8.1 on the FDA network and folks can use as laptop replacement
- Second Development release completed (will be by mid July)
- On track to completed by end of FY14



Next Steps

- Obtain ATO
- Perform the Pilot (Oct 14 – Jan 15)
- Evaluate the Pilot
- Incorporate feedback
- Promote to Production FDA-Wide
- Repeat as necessary to add more functionality to meet FDA's needs

