

# Welcome

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## Opportunities and Challenges in mHealth Applications Mobile Monday DC

### Speakers

Todd A. Radano  
William Riley, Ph.D.  
Glenn Roland

### Moderator

Stephanie A. Joyce

### WiFi Log-In

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# William Riley, Ph.D.

Chief, Science of Research and Technology Branch  
Division of Cancer Control and Population Sciences  
National Cancer Institute

- SRTB Scientific Priorities
  - Theory development, testing and application;
  - Measure development and testing;
  - Technology development and application;
  - Methodological innovation, particularly in analytic approaches;
  - Data harmonization and research synthesis; and
  - Team science and cross-disciplinary approaches.
- Co-Chair, NIH mHealth Interest Group (mPower)
- mHealth Summit Planning Committee – Research Track (Dec. 8-11)



# mHealth Related Publications

TBM

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## Health behavior models in the age of mobile interventions: are our theories up to the task?

William T Riley, PhD,<sup>1</sup> Daniel E Rivera, PhD,<sup>2</sup> Audie A Atienza, PhD,<sup>3</sup> Wendy Nilsen, PhD,<sup>4</sup> Susannah M Allison, PhD,<sup>5</sup> Robin Mermelstein, PhD<sup>6</sup>

EBN

## Mobile phone-based smoking cessation interventions increase long-term quit rates compared with control programmes, but effects of the interventions are heterogeneous

William Riley and Erik M Augustson

*Evid Based Nurs* 2013 16: 108-109 originally published online February 6, 2013  
doi: 10.1136/eb-2012-101204

Riley et al. *Clinical and Translational Medicine* 2013, 2:10  
<http://www.clintransmed.com/content/2/1/10>

INVITED COMMENTARY

## Leveraging Technology for Multiple Risk Factor Interventions

Health risk behavior change research has focused predominantly on a single risk factor, but most of the general population (58%) has 2 or more chronic disease risk factors.<sup>1</sup> Intuitively, interventions that target multiple risk factors should improve the prevention of disease better than single risk factor inter-

ventions, but systematic reviews of multiple risk factor interventions have produced disappointing results.<sup>2</sup> In this issue of the *Archives*, Spring et al<sup>3</sup> provide examples of 2 innovative research directions that have the potential to improve outcomes in multiple risk factor intervention research.

ARCH INTERN MED/VOL 172 (NO. 10), MAY 28, 2012 WWW.ARCHINTERNMED.COM  
796

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Clinical and Translational Medicine  
a SpringerOpen Journal

PERSPECTIVE

Open Access

## Rapid, responsive, relevant (R3) research: a call for a rapid learning health research enterprise

William T Riley<sup>1\*</sup>, Russell E Glasgow<sup>1</sup>, Lynn Etheredge<sup>2</sup> and Amy P Abernethy<sup>3</sup>

# mHealth Devices before “mHealth”

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**Create & Administer**

protocols with ease using IVR, EDC, and eDiaries



**Collect**

accurate, real time data at the source



**Manage**

results immediately with wireless technology



“Writing a questionnaire with this program is like filling in the blanks on a very detailed outline.”

Shimrit Koren  
Children’s Hospital, Boston



CERTAS Desktop Application

**WHAT IS CERTAS**

CERTAS is a fully integrated electronic data capture (EDC) system that collects data directly from patients & study participants, utilizing electronic patient diaries (eDiaries), wireless technology & interactive voice response (IVR). The EDC is part of a complete study management system that makes real-time data available both at the desktop and on the web. Components of the system include researcher-configurable questionnaires, wireless data collection and retrieval, device alerting capabilities and participant data management.

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**IS CERTAS FOR YOU**

CERTAS addresses the needs of clinical trial sponsors, researchers & clinicians by facilitating the cost-effective means of designing and administering research protocols, collecting data at the source and analyzing and managing the resulting data.

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**Create** dietary regimens with ease on the web

**Record** dietary intake easily with the palm

**Evaluate** results immediately with wireless web sync

**Professional Diet Management Solutions**



“DietMatePro has been very helpful in allowing our patients to track daily and fluid intake. One participant made it a routine to take the PDA with him to the grocery store to help him in selecting healthy foods.”

-Shannon Dowell  
Indiana University

Nutrients	Actual	Target
Calories	76	8
Fat Calories	4	0.0
Fat (%)	30	10-15
Saturated Fat (%)	0.84	<10
Cholesterol (mg)	0	<200

DietMatePro Palm Screen Shot

**WHAT IS DIETMATEPRO**

DietMatePro is a comprehensive system for monitoring patients or study participants who are making dietary changes by integrating Palm and Web technologies. DietMatePro allows researchers and clinicians to assign dietary regimens modeled after evidence-based diets (e.g. DASH) or create individualized treatment plans. Alternatively, DietMatePro can be used to monitor dietary intake without providing specific dietary recommendations.

More >

**IS DIETMATEPRO FOR YOU**

DietMatePro addresses the needs of researchers and dietitians by providing a cost-effective method for designing and tailoring original dietary regimens from scratch or by modifying one of the provided evidence based diets, e.g. DASH, etc.

More >



# OPPORTUNITIES AND CHALLENGES IN MHEALTH

A MOBILE MONDAYS PANEL DISCUSSION

SEPTEMBER - 2013



Panel Participant: Glenn Roland  
The Dominion Group Market Research and Consulting



Todd Radano  
President

*1010 Wisconsin Ave NW, Suite 310  
Washington, DC 20007  
[www.decisionq.com](http://www.decisionq.com)*

## DecisionQ Overview

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- Over 15 years of research and development into the most scalable machine learning platform in the industry
- Partner oriented business model with a focus on solving complex, difficult problems
- Extremely experienced modeling and analytical staff
- Over 45 peer-reviewed publications with acknowledged thought leadership
- Extensive IP portfolio

# WHAT IS MHEALTH...HOW DO WE DEFINE THE MARKET?



*“mHealth (also written as **m-health** or **mobile health**) is a term used for the practice of medicine and public health, supported by mobile devices. The term is most commonly used in reference to using mobile communication devices, such as mobile phones, tablet computers and PDAs, for services and information, but also to affect emotional states.”*

**- Wikipedia**

*“Over time, the market for the technology has become so broad that many use the terms Mhealth, Mobile Health, Digital Health, etc. interchangeably.....”*





# THE OPPORTUNITY – WHAT’S DRIVING GROWTH

## Advanced Networks and Security

Networks capable of delivering rich media and protecting patient privacy.....

*“Technology was not robust enough, the physical characteristics of mobile devices were limiting...so past interactions relied heavily on text messaging.....and, that wasn’t very compelling.*

## Healthcare Reform and the Need to Lower Costs

The move toward digital content and improved access to healthcare data....

## Exponential Growth in the number of Global mobile subscribers



6.8 billion at the end of 2012 (ITU)



*“Advances in Mobile device Characteristics”*

**56%**

of doctors now use smartphones

*Active instead of “reactive” healthcare....and a continuing trend toward patient empowerment”*



**52%**

of smartphone owners gather health information on their phones

**31%**

Or 1 in 3 of cell phone owners have used their phones to look for health information. **2 years ago that percentage was 17%.**

# THE OPPORTUNITY – DIGITAL HEALTH INVESTMENT

## TOP INVESTMENT CATEGORIES



### Fitness

Apps used for health and fitness



### Education

Inform patients and act as reference for physicians



### Reminders

Appointment scheduling, medication alerts



### Research

“In the moment” interactions with patients



### Communication

Used to enhance physician patient interactions and compliance



### Enterprise

Mobile extensions to enterprise systems



### Referrals

Used by patients to find docs



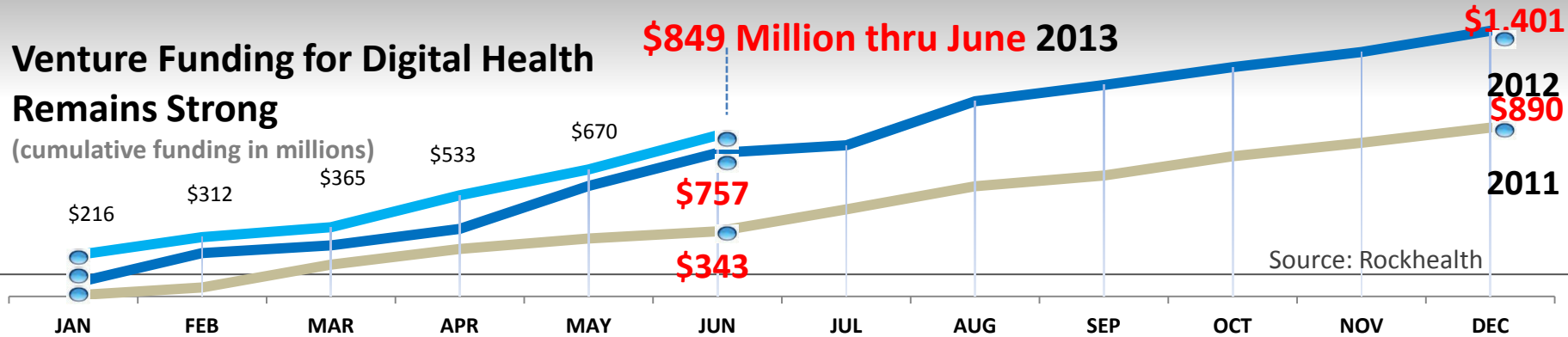
### Diagnostics

Apps intended to diagnose specific illness

“Mobile health app marketplace to take off, expected to reach \$26B by 2017” - Mobile Marketer

## Venture Funding for Digital Health Remains Strong

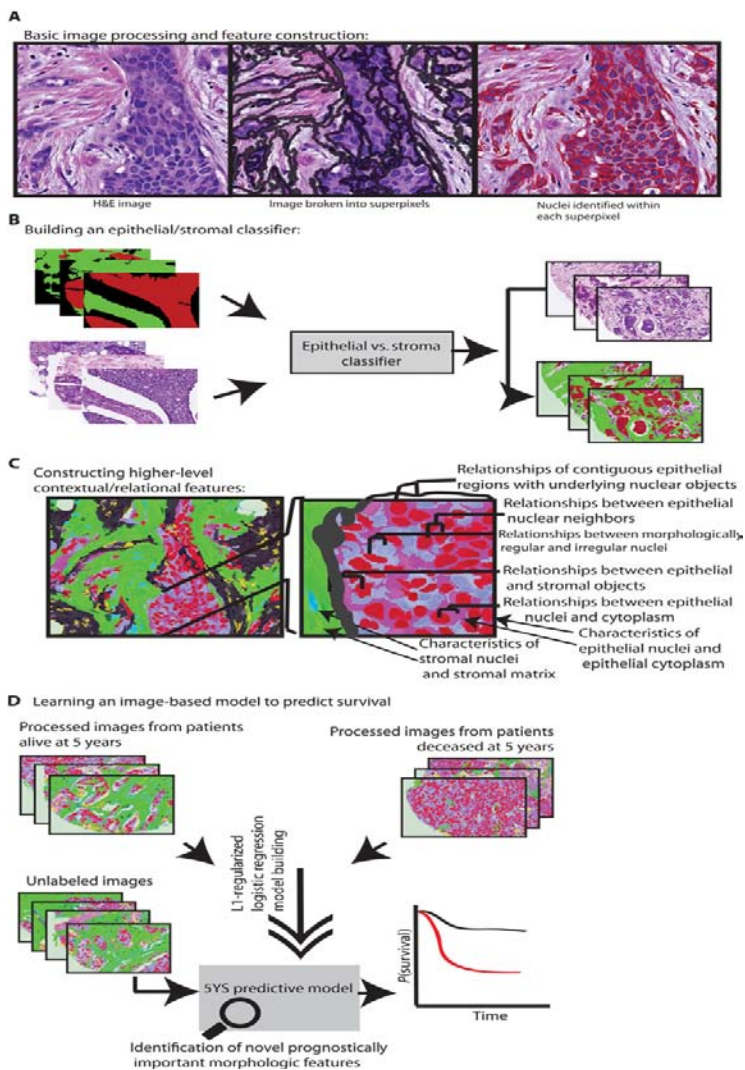
(cumulative funding in millions)



Source: Rockhealth

# Diagnostic Advances via Pattern Recognition

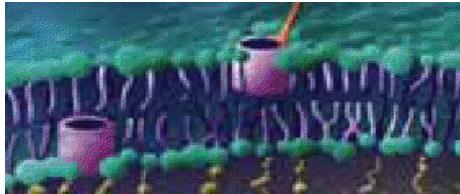
Beck et al., Sci Transl  
Med 2011; 3:1-11



# Innovative Advances in “Input”



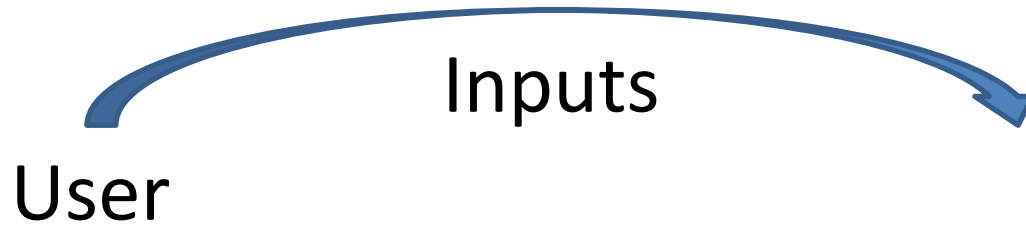
User



**Implantable Biosensors**

Burgess, R21HL090458

# Innovative Advances in “Input”



**WOCKETS SYSTEM VISION**

Multiple, low-cost 3-axis accelerometers stream data in real-time to mobile phone

Sensors miniature, thin, and ergonomic; worn under clothing 24/7

Phone carried in typical fashion (e.g., in pocket)

Pattern recognition algorithms running continuously on phone detect physical activities in real-time

Innovative phone apps possible

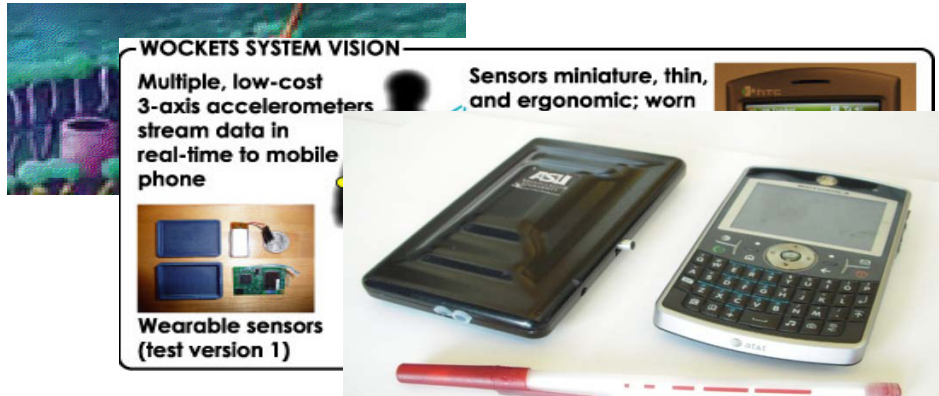
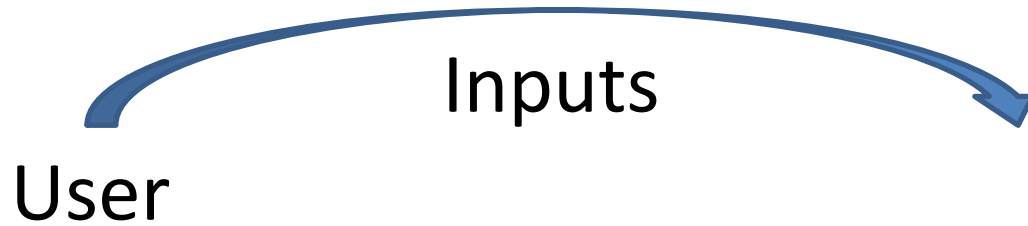
Wearable sensors (test version 1)

Activity	Percentage
sleeping	22%
standing	17%
walking	30%
brisk walking	10%
cycling	2%

Brisk Walking  
4:55 minutes

**Wearable, Waterproof  
Accelerometers**  
Intille, U01HL091737

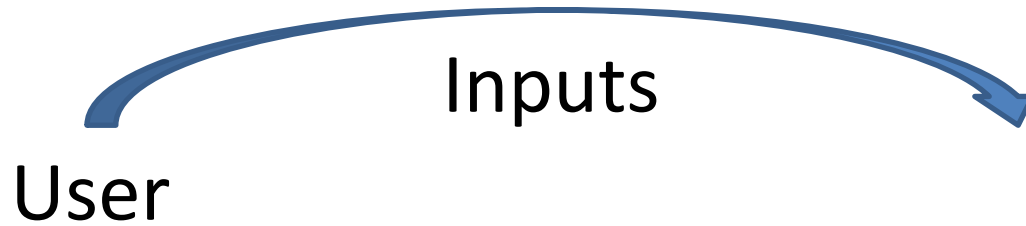
# Innovative Advances in “Input”



**Personal Chemical Exposure Sensors**

Tao, U01 ES016064

# Innovative Advances in “Input”

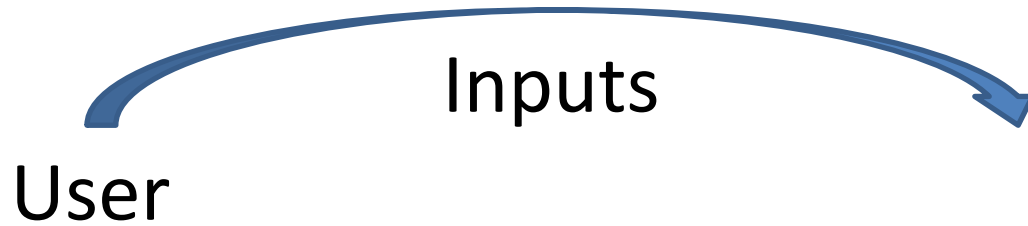


User



Wireless Salivary Biosensors  
Shetty, U01DA023815

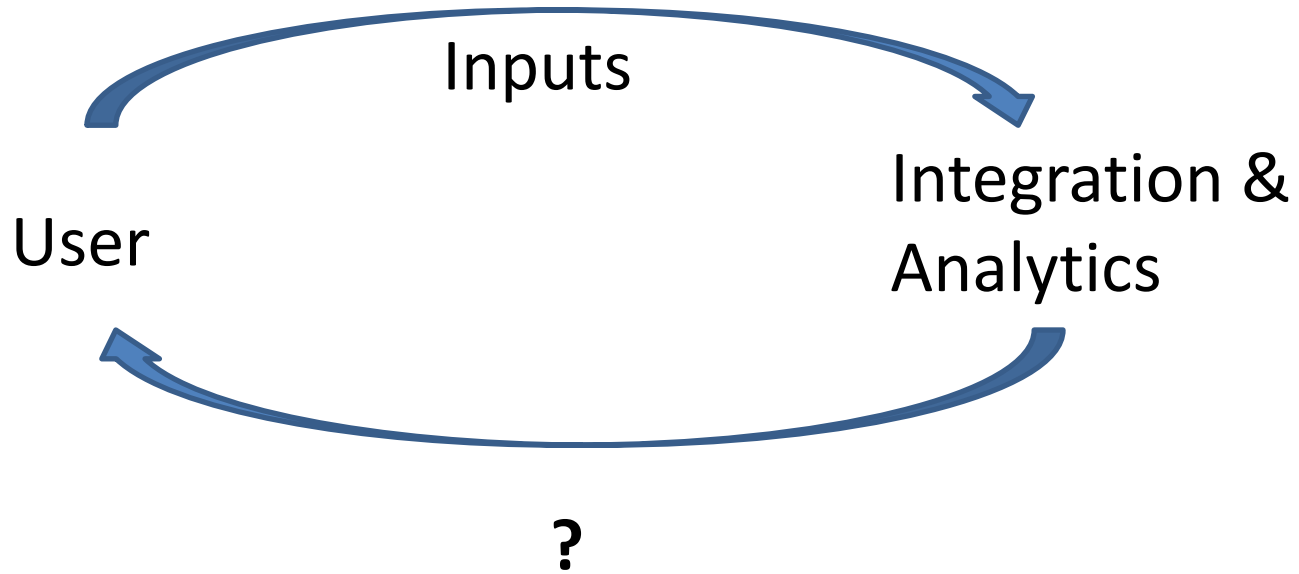
# Innovative Advances in “Input”



**Miniature Microscope**  
Ozcan, R21EB009222



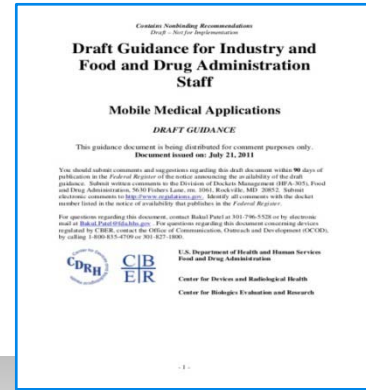
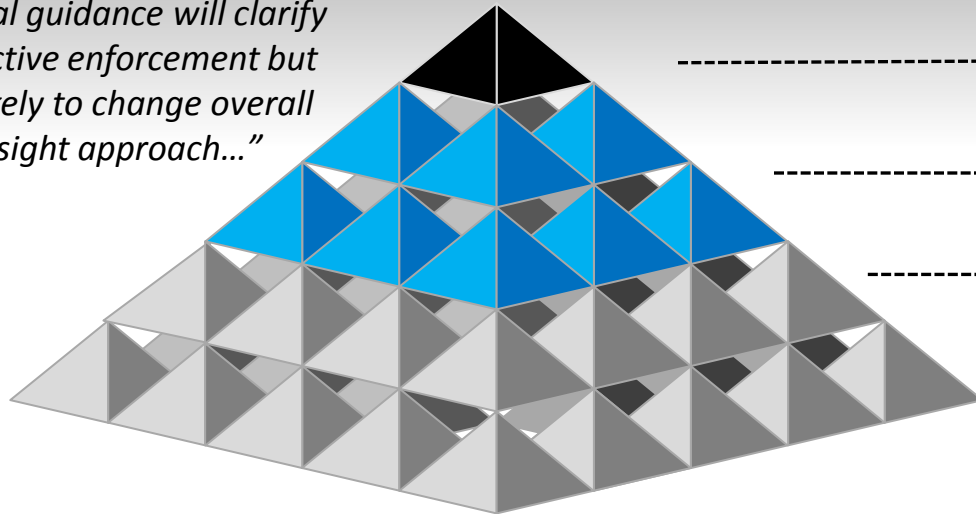
# But Where's the Output?



# CHALLENGE - FDA OVERSIGHT

*FDA definition:...an instrument, apparatus, implement, machine, contrivance, implant, or in vitro that is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man, or intended to affect the structure or any other function of the body.....*

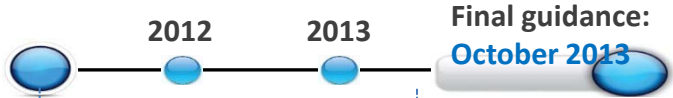
*“Final guidance will clarify selective enforcement but unlikely to change overall oversight approach...”*



Scope of guidance/oversight

Medical Apps that require approval

Other apps not considered Mobile Medical apps



July 2011  
Draft guidance  
released

March 2013  
Final guidance  
pending

Source: FDA.gov

# Breaking News: FDA Guidelines Released

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Today the FDA released “Mobile Medical Applications: Guidance for Industry and FDA Staff” (see Client Alert at [www.arentfox.com](http://www.arentfox.com))

- “[S]hould be viewed only as recommendations” and does not “establish legally enforceable responsibilities[.]”
- Core principle: risk to consumers’ health in the event of malfunction
  - Unlikely to investigate apps that simply organize EHR and information about prescribed treatments or that automate tasks for a health care provider
  - Likely to investigate apps that enable a health care provider to make specific diagnoses and apps that turn PDA into an electrocardiography device

***Is it merely organizing information or is it rendering/enabling specific diagnoses?***

# Guidelines Continue to Develop

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- New Report expected January 2014, as “a start of the process”; will seek additional comment
- FTC and FCC retain respective jurisdictions over telecom, consumer protection, and competition law
- FDA has established an email account to field questions about the Guidelines:

[MobileMedicalApps@fda.hhs.gov](mailto:MobileMedicalApps@fda.hhs.gov)

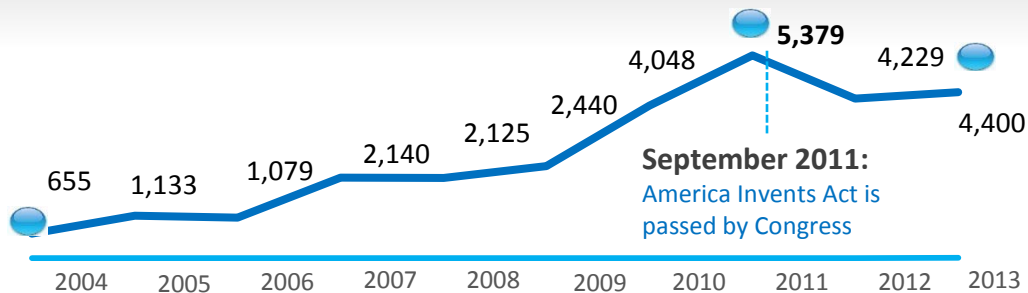
# CHALLENGE - PATENT-ASSERTION ENTITIES

...patent assertion entities (also called patent trolls) do not manufacture goods themselves but profit from licensing agreements that they often enforce via the threat of litigation.....

- **PatentFreedom.**



Patient-assertion Entity involvement in Patent Litigation over time...



Source: PatentFreedom

*“Dumbass patents are crushing small business”* — Mark Cuban

Although legislation (Leahy-Smith America Invents Act (AIA)) was enacted in 2011 to curb the activities of these entities, they still pose a significant risk to the emerging market for innovation in the Digital Health/MHealth space.



December 8-11, 2013 at the  
Gaylord National Resort and  
Convention Center



## 5 USEFUL LINKS FOR MORE INFORMATION:



rockhealth.com



mhealthnews.com



mobithinking.com



mobihealthnews.com



wirelesshealth.wordpress.com



[groland@thedominiongrp.com](mailto:groland@thedominiongrp.com)



*I'm always interested in  
connecting with like-minded  
professionals on Linked IN.*



*I'm not that big on tweeting,  
my life isn't that interesting.*

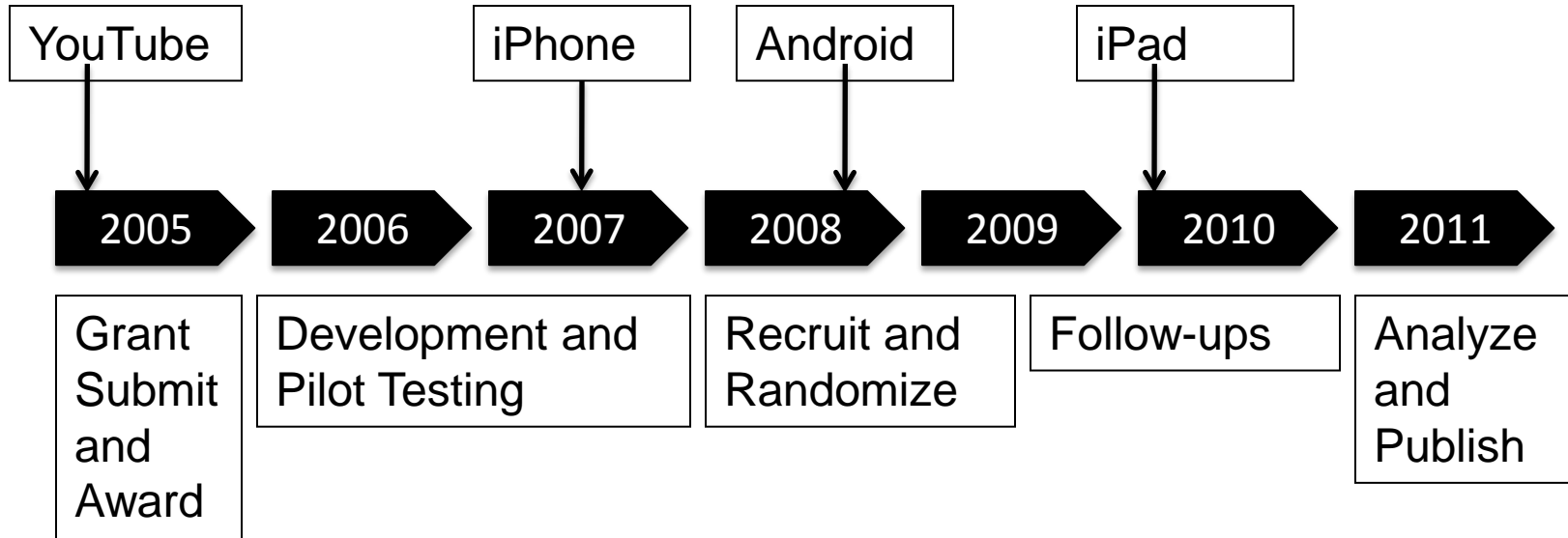


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# Technology Outpaces RCTs



# Thank You For Joining Us

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Data and Analytics Go Mobile  
<http://dcmomo.com>
- Ask about the HIMSS mHealth Summit  
December 8-11, 2013, and find out how to  
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