Welcome

Opportunities and Challenges in mHealth Applications
Mobile Monday DC

Speakers

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

Moderator

Stephanie A. Joyce

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MOBILEMONDAY™

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

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

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

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

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.[1] Intuitively, interventions that target multiple risk factors should improve the prevention of disease better than single risk factor interventions, but systematic reviews of multiple risk factor interventions have produced disappointing results.[2] In this issue of the *Archives*, Spring et al[3] provide examples of 2 innovative research directions that have the potential to improve outcomes in multiple risk factor intervention research.

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[1*], Russell E Glasgow[1], Lynn Etheredge[2] and Amy P Abernethy[3]

mHealth Devices before "mHealth"

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

DecisionQ Overview

- 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……

"Advances in Mobile device Characteristics"

56%
of doctors now use smartphones

"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….

Active instead of "reactive" healthcare….and a continuing trend toward patient empowerment"

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%.**

Exponential Growth in the number of Global mobile subscribers

6.8 billion at the end of 2012 (ITU)

52%
of smartphone owners gather health information on their phones

THE OPPORTUNITY – DIGITAL HEALTH INVESTMENT

TOP INVESTMENT CATEGORIES

Fitness	Education	Reminders	Research	Communication	Enterprise	Referrals	Diagnostics
Apps used for health and fitness	Inform patients and act as reference for physicians	Appointment scheduling, medication alerts	"In the moment" interactions with patients	Used to enhance physician patient interactions and compliance	Mobile extensions to enterprise systems	Used by patients to find docs	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)

$849 Million thru June 2013

$216
$312
$365
$533
$670

$1.401

2012

$890

2011

$757

$343

Source: Rockhealth

JAN   FEB   MAR   APR   MAY   JUN   JUL   AUG   SEP   OCT   NOV   DEC
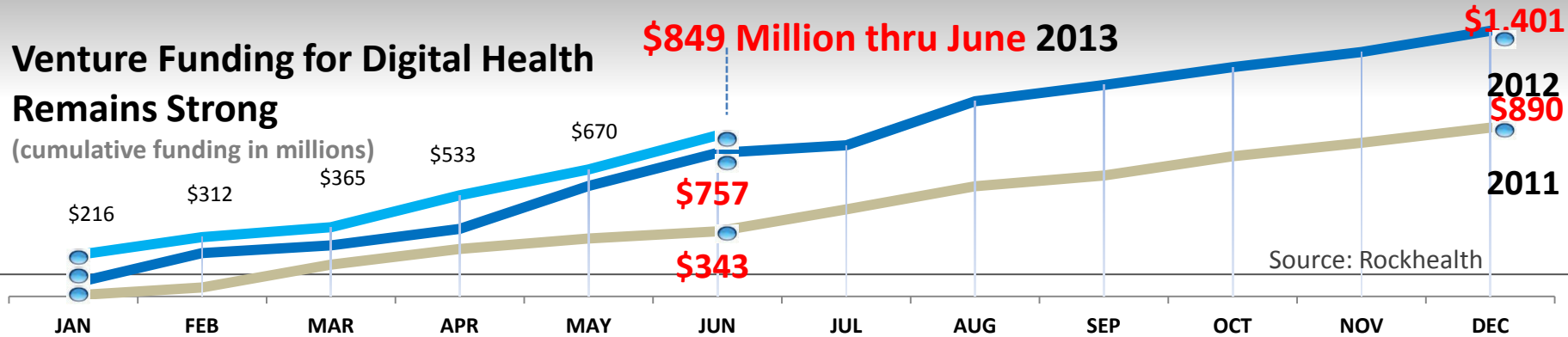
Diagnostic Advances via Pattern Recognition

Beck et al., Sci Transl Med 2011; 3:1-11
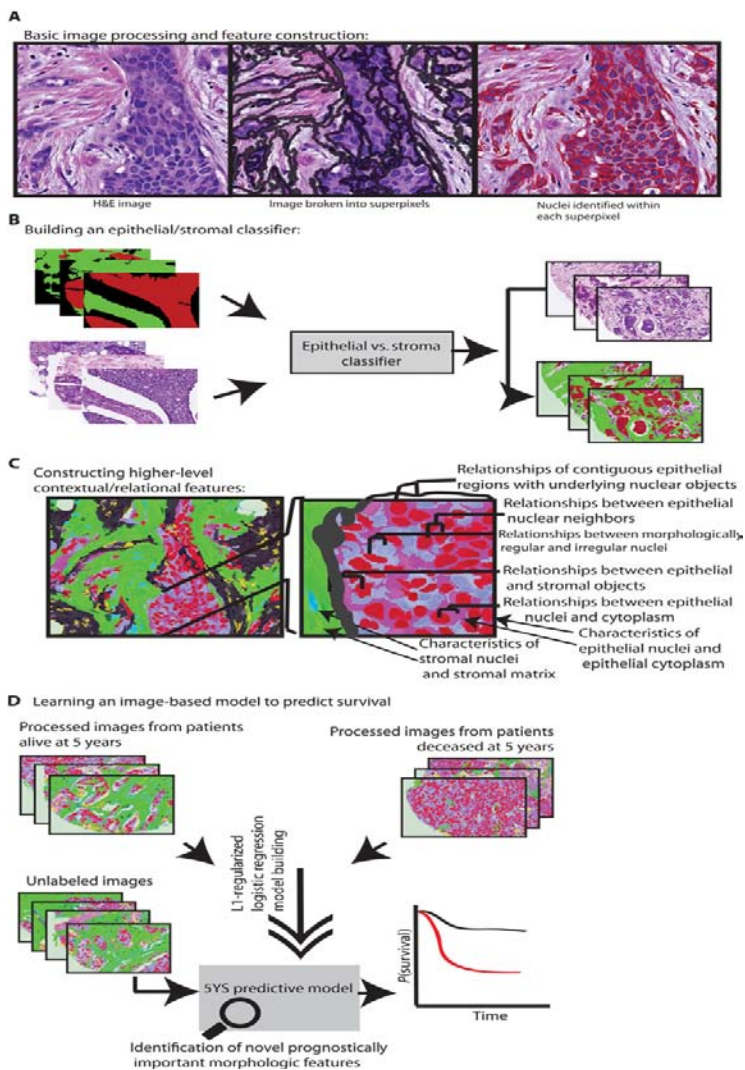
Innovative Advances in "Input"
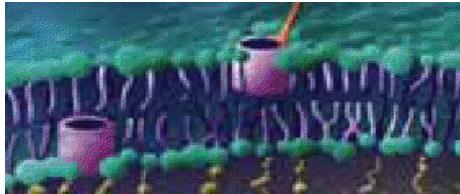

Inputs

User

Implantable Biosensors
Burgess, R21HL090458

Innovative Advances in "Input"

Inputs

User

WOCKETS SYSTEM VISION

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

Wearable sensors (test version 1)

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, Waterproof Accelerometers
Intille, U01HL091737

Innovative Advances in "Input"
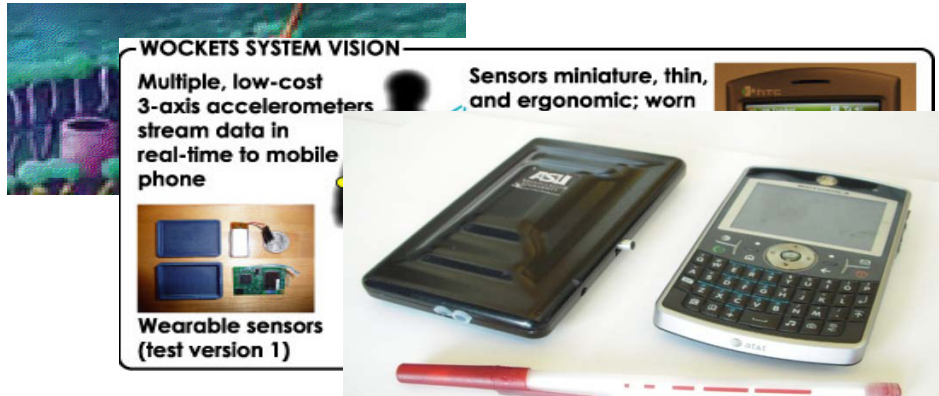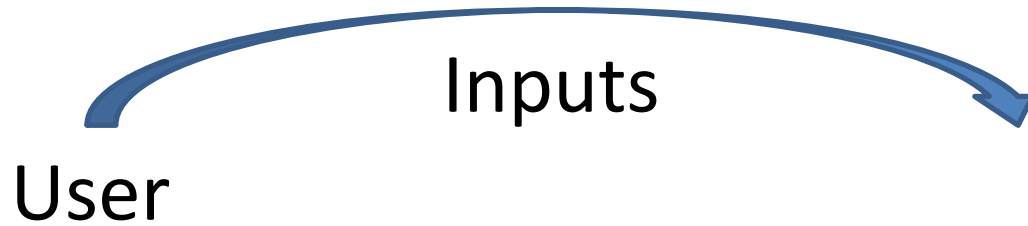
Inputs

User

Personal Chemical Exposure Sensors
Tao, U01 ES016064

Innovative Advances in "Input"

Inputs

User

WOCKETS SYSTEM VISION

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

Sensors miniature, thin, and ergonomic; wo...

Wearable sensors (test version 1)

#14 SHETTY

39
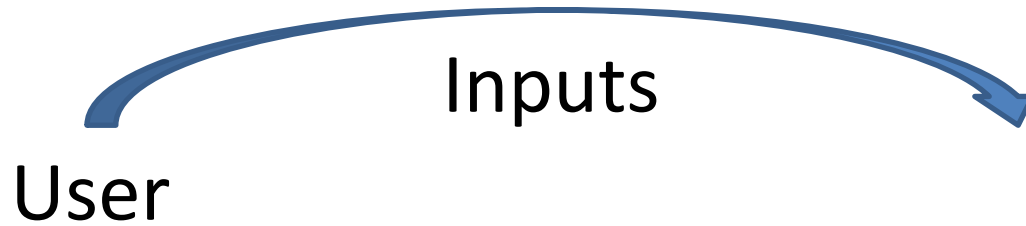
Wireless Salivary Biosensors
Shetty, U01DA023815

Innovative Advances in "Input"

Inputs

User

Miniature Microscope
Ozcan, R21EB009222

But Where's the Output?

User

Inputs

Integration & Analytics

?
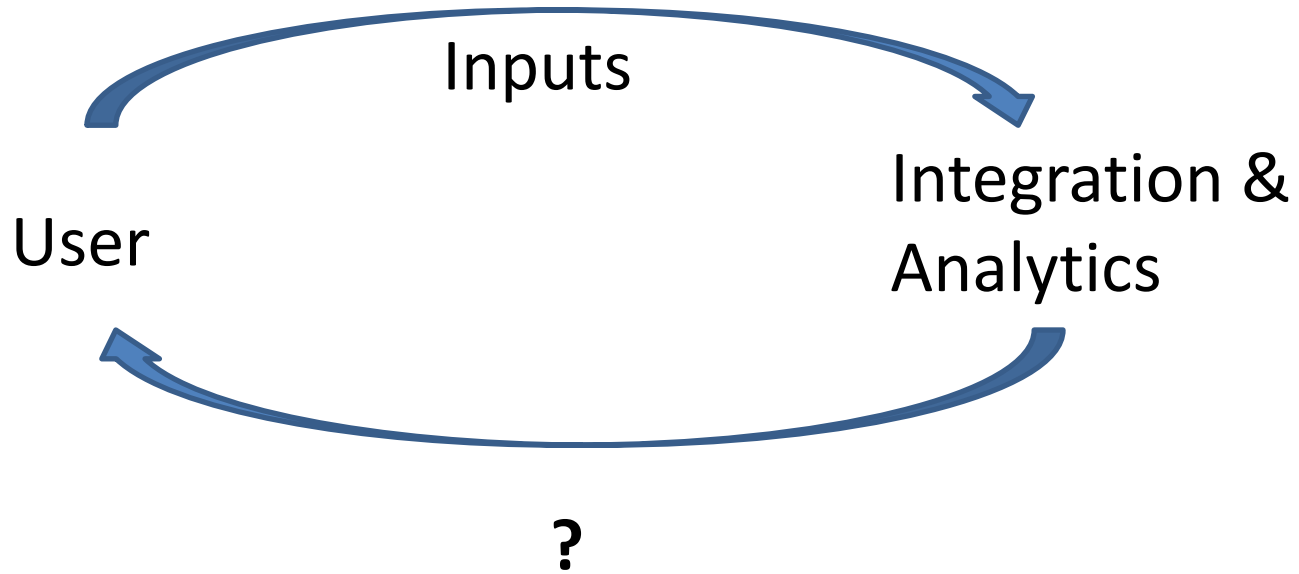
CHALLENGE - FDA OVERSIGHT

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 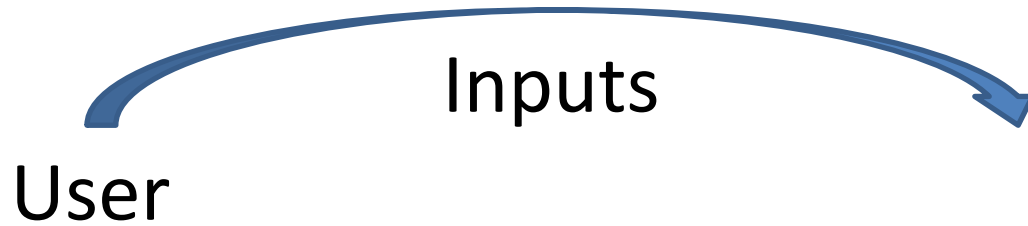in the cure, mitigation, treatment, or prevention of disease in man, or intended to affect the structure or any other function of the body……

"Final guidance will clarify selective enforcement but unlikely to change overall oversight approach…"
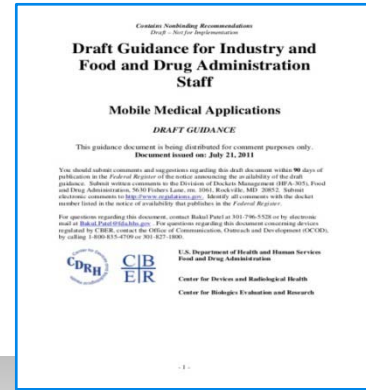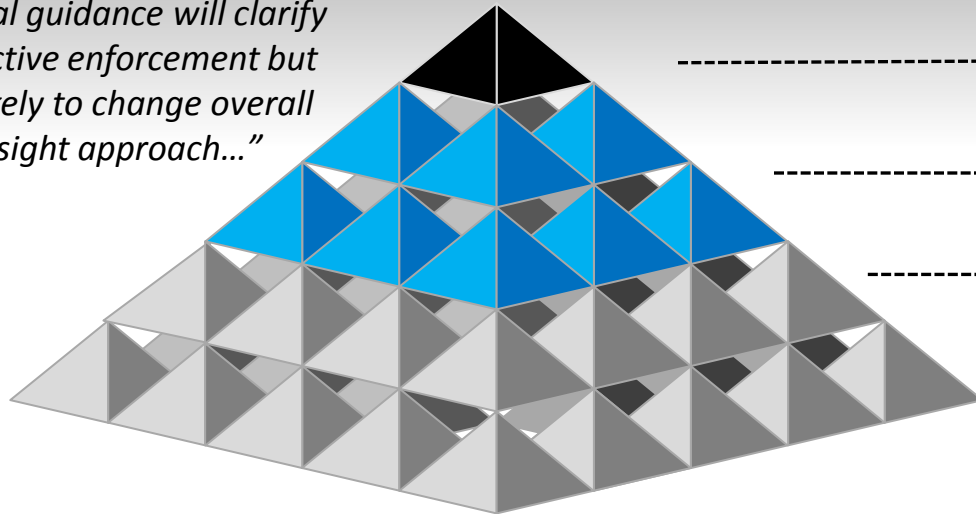
Scope of guidance/oversight

Medical Apps that require approval

Other apps not considered Mobile Medical apps

Source: FDA.gov

2012   **2013**   **Final guidance: October 2013**

July 2011
Draft guidance released

March 2013
Final guidance pending

Breaking News: FDA Guidelines Released

Today the FDA released "Mobile Medical Applications: Guidance for Industry and FDA Staff" (see Client Alert at www.arentfox.com)
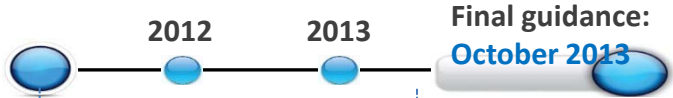
- "[S]hould be viewed only as recommendations" and does not "establish legally enforceable responsibilities[.]"
- Core principle: risk to consumers' health in the event of malfunction
  - Unlikely to investigate apps that simply organize EHR and information about prescribed treatments or that automate 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

- 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:
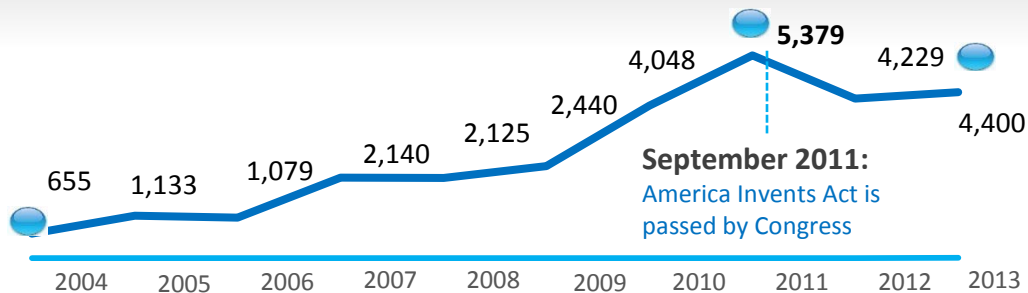
  MobileMedicalApps@fda.hhs.gov

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…

- 655 (2004)
- 1,133 (2005)
- 1,079 (2006)
- 2,140 (2007)
- 2,125 (2008)
- 2,440 (2009)
- 4,048 (2010)
- **5,379** (2011)
- 4,229 (2012)
- 4,400 (2013)

September 2011:
America Invents Act is passed by Congress

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

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.
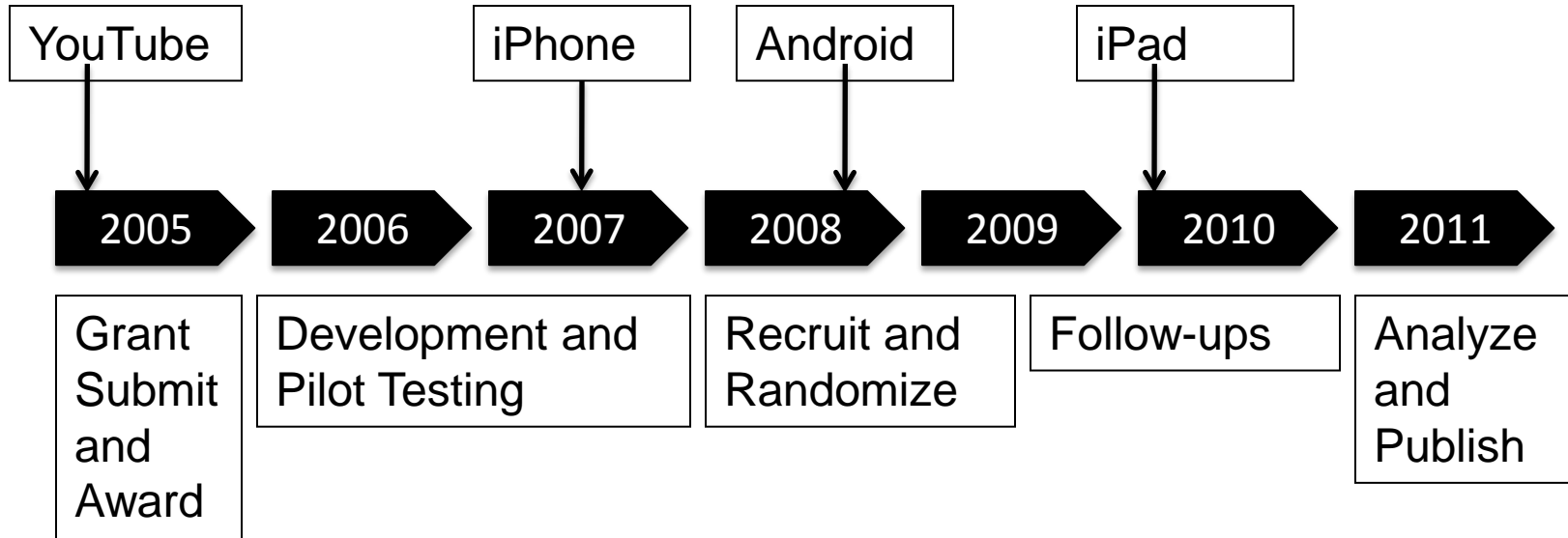
1800 Alexander Bell Drive, Suite 515
Reston, VA 20191
703-234-2360 Phone
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Technology Outpaces RCTs

Thank You For Joining Us

- Next MoMo: October 7, 2013
  Data and Analytics Go Mobile
  http://dcmomo.com

- Ask about the HIMSS mHealth Summit
  December 8-11, 2013, and find out how to
  receive the Arent Fox discount

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