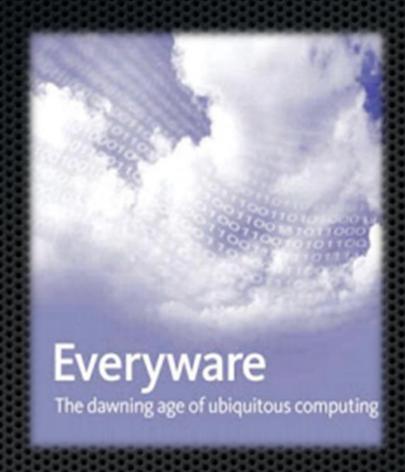


## Overview

- What is Humanisation?
- Looking at the Generations Y, Z and Alpha
- Looking At The Technologies
- Apps When is an App a Device ?
- How Do We Make Sure We Get There? Co-creation of Innovation & Avoiding Technological Determinism

#### The 'Buzzy' Paradigms:



Augmented & Virtual Reality, Ubiquitous Computing, Pervasive Computing, Mobile Computing, Wearable Computing, Humanisation, Multi-Device Interaction, Cloud Computing, Intelligent Systems, Ambient Intelligence, Context-Aware Computing, Adaptive Systems, Machine Perception, Social Computing, Smart Environments, Everyware, and so on

# What is Humanisation?



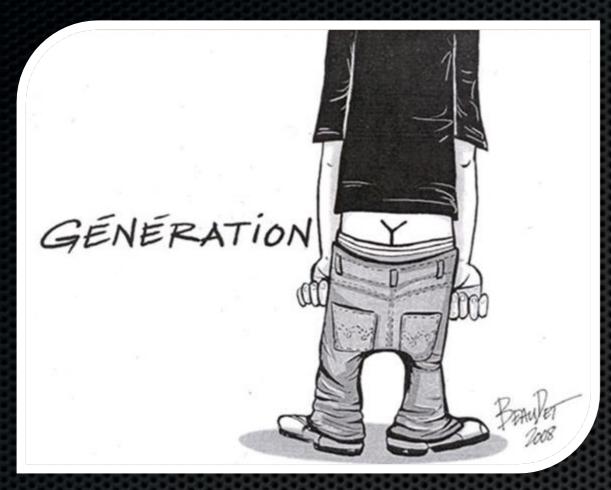
## Definitions

- We're now in the next phase of technology evolution: the humanisation of IT. What does that mean? It means technology that is built for how we naturally use it as human beings – it adapts to our needs not the other way around.
- With a new generation emerging that has interacted with technology from an early age and grown up with an inherent understanding of its capabilities, we are taking control of our digital lives by increasingly customising our connections with people and tools.
- Devices are also self-customising as they become context and intent aware.

## Definitions

We are witnessing the evolution of an intelligent always-on connected world of services that is controlled naturally through gesture, voice and touch...

#### The Generations: Y, Z & Alpha



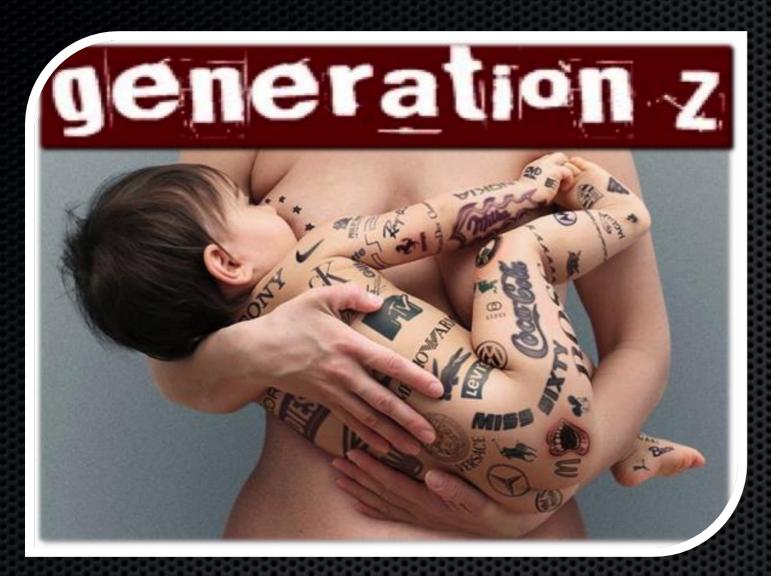
#### The Millennials

- 97% own a computer
- 94% own a mobile phone
- 76% use Instant Messaging
- 69% use Facebook
- 56% own an iPod

#### Born 1981 – 1994

- Programmed for instant gratification.
- Internet-addicted and despite all their connectivity due to likes of cyber bullying and peer pressure often lacking meaningful real-world relationships

#### The Generations: Y, Z & Alpha

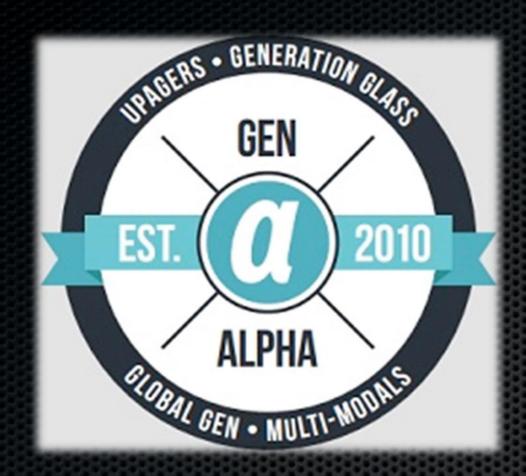




#### Born 1995 – 2009

- Digital Natives born in the modern digital age.
- Technology is infused at birth.
- 1st Generation that didn't experience life before the Internet
- 1<sup>st</sup> Generation that might not reach their potential life expectancy due to sedentary lifestyles and chronic diseases such as diabetes.

#### The Generations: Y, Z & Alpha





#### Born Post 2010

- Predicted they will be the most formally educated generation in history, beginning school earlier and studying longer.
- Will expect and demand fully digital services for all aspects of their lives.
- The children of older, wealthier parents with fewer siblings, they are already being labeled materialistic.

#### The Technologies – Enhanced Interaction





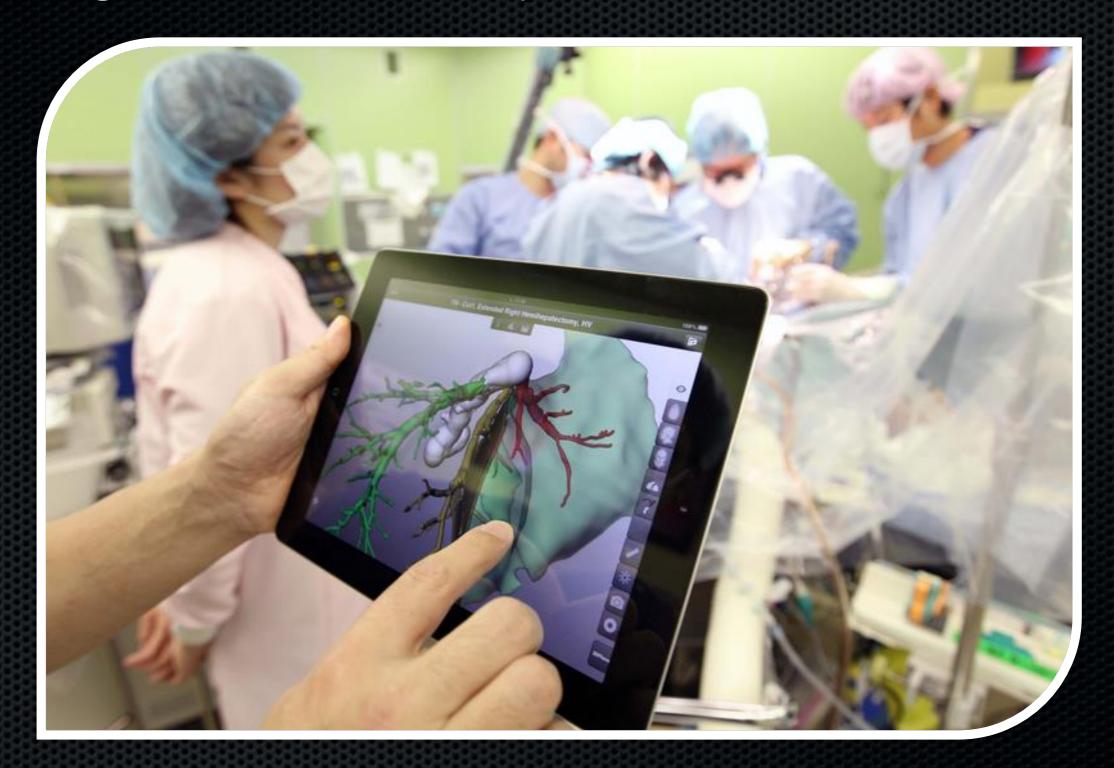




#### Virtual Reality (VR)

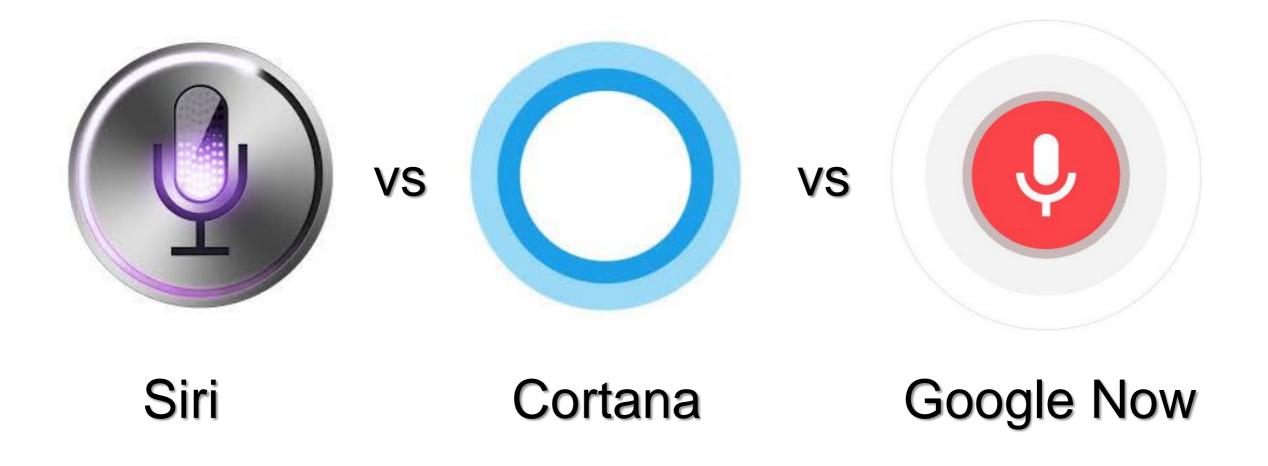


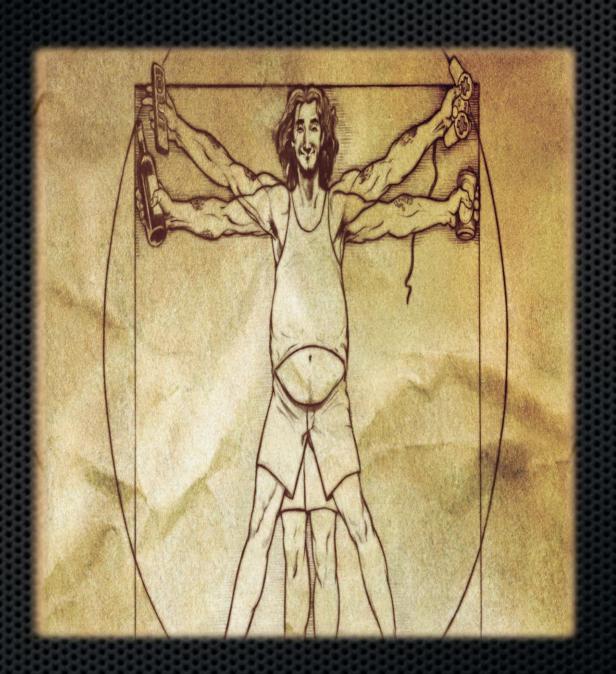
#### Augmented Reality



Fraunhofer MEVIS augmented reality iPAD app for liver surgery

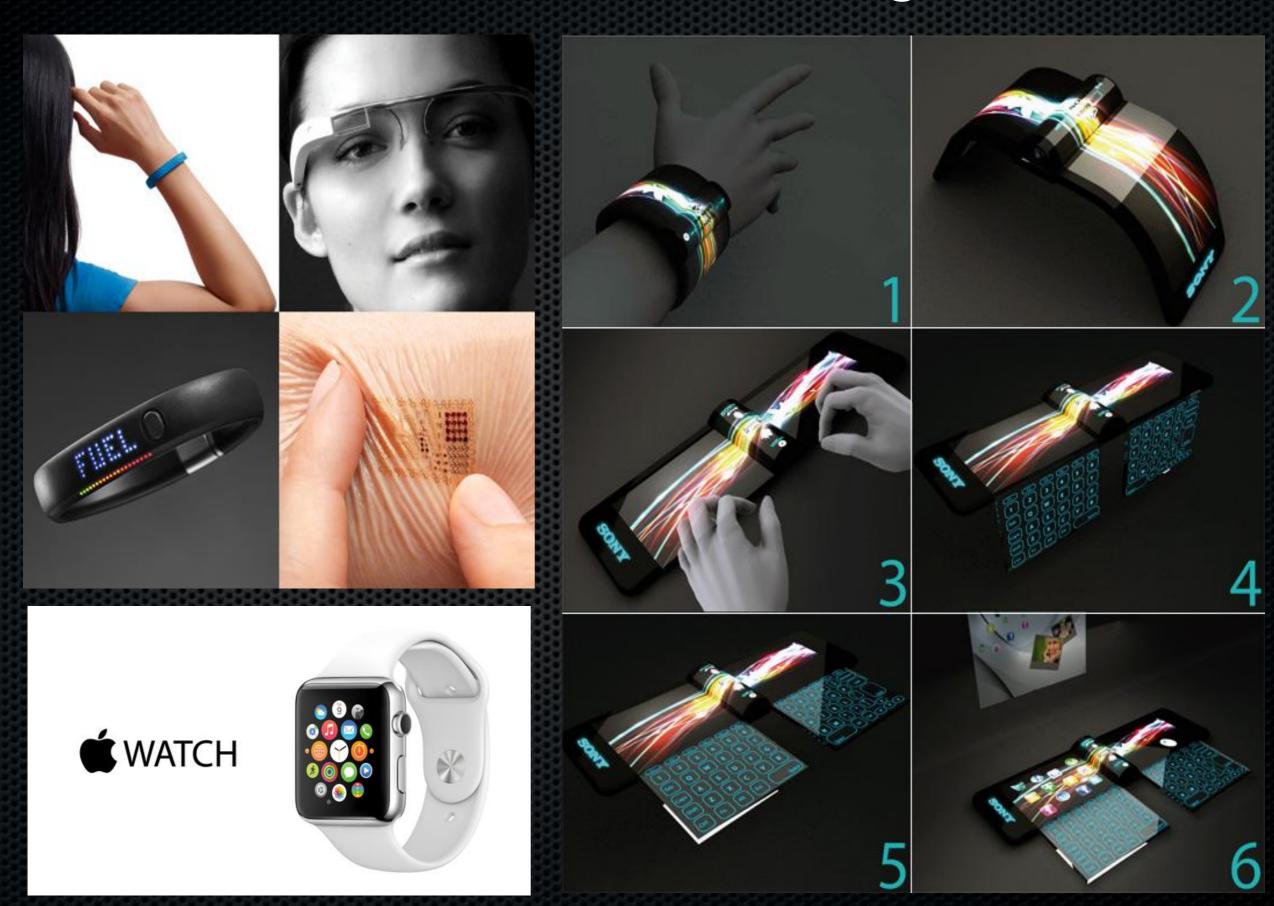
# The Technologies – Speech & Natural Language







## Wearable Technologies

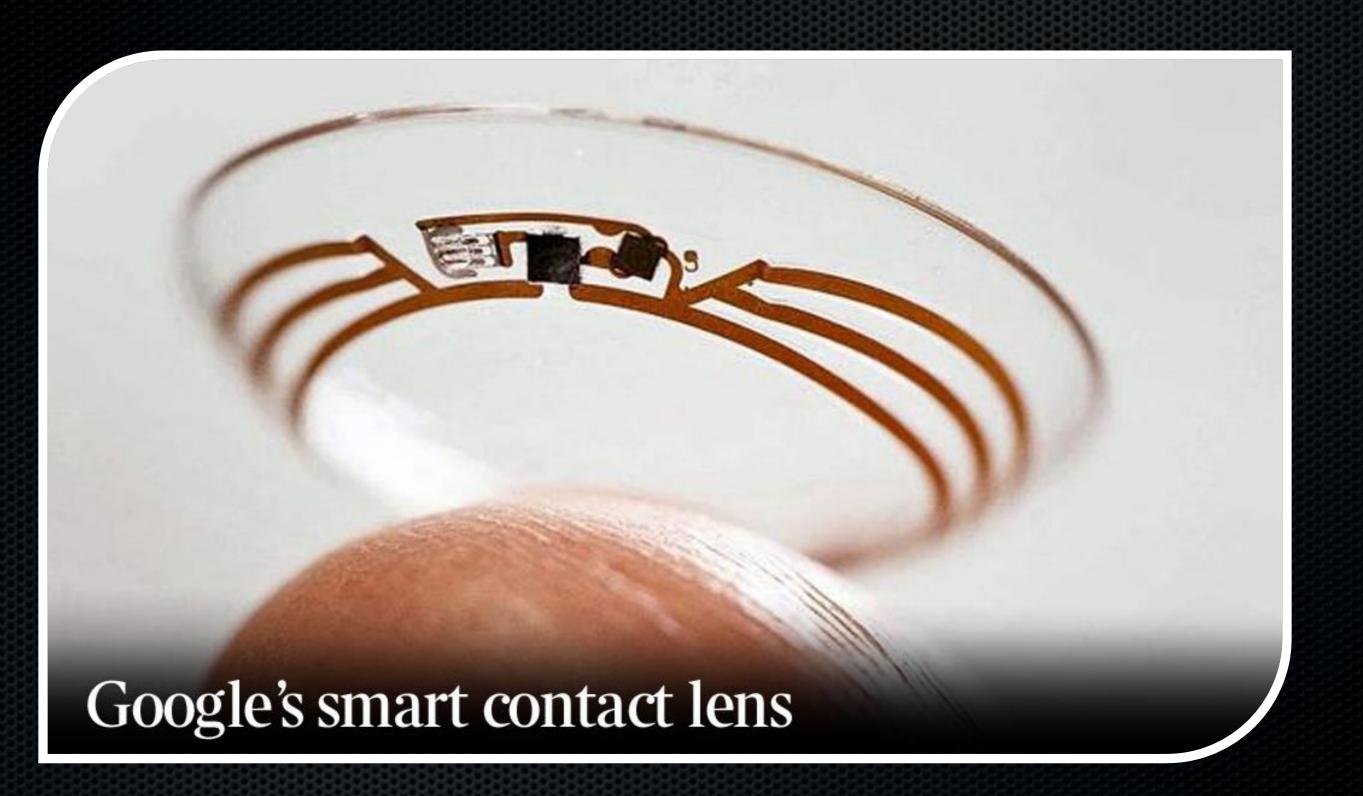


# Wearable technology can be generally classified

as:

- . Carried Mobile phone
- Body-mounted Wrist watch/glasses
- Garment integrated Textile based
- Implanted Pace maker

Dunne, L. E., S. P. Ashdown, and B. Smyth. Expanding garment functionality through embedded electronic technology. J. Text. Apparel Technol. Manage. 4:1–11, 2005.



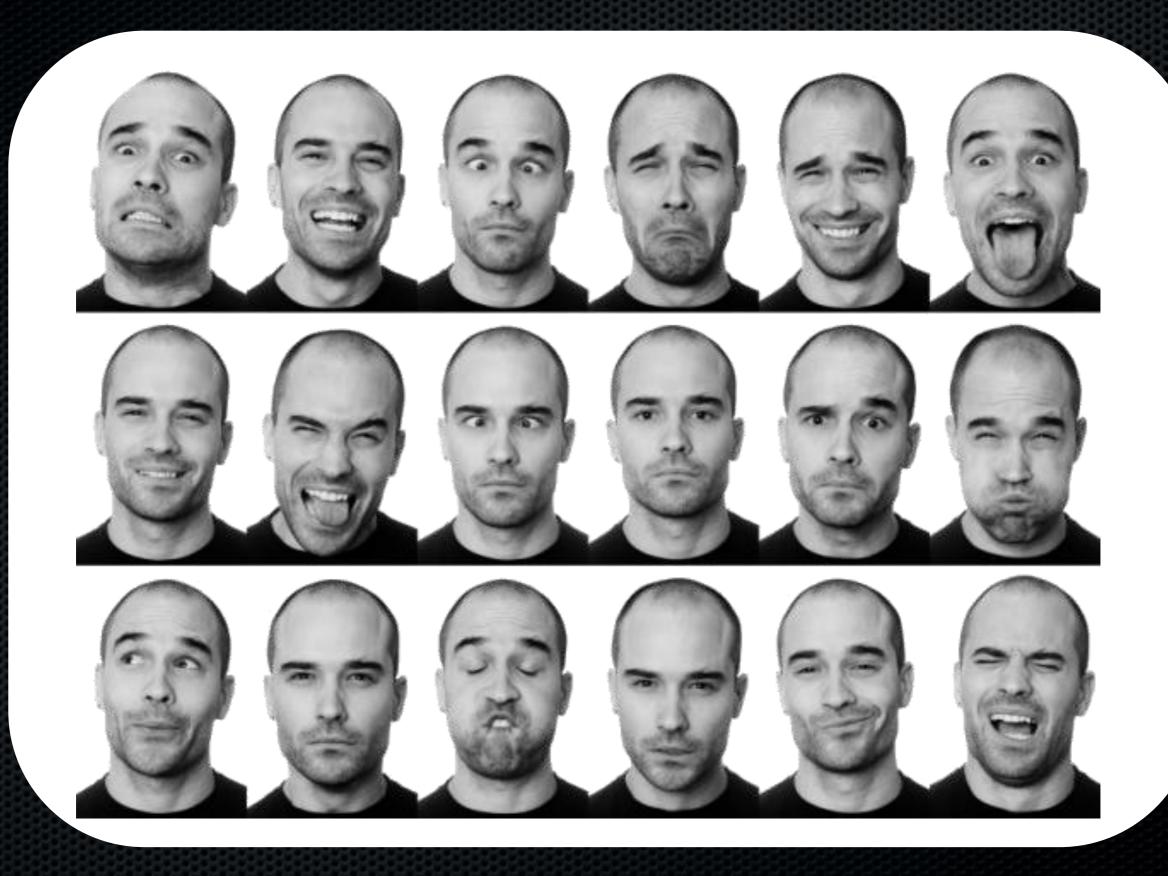
# Finalist







### Affective Computing ...



#### The Technologies – Robotics & Al



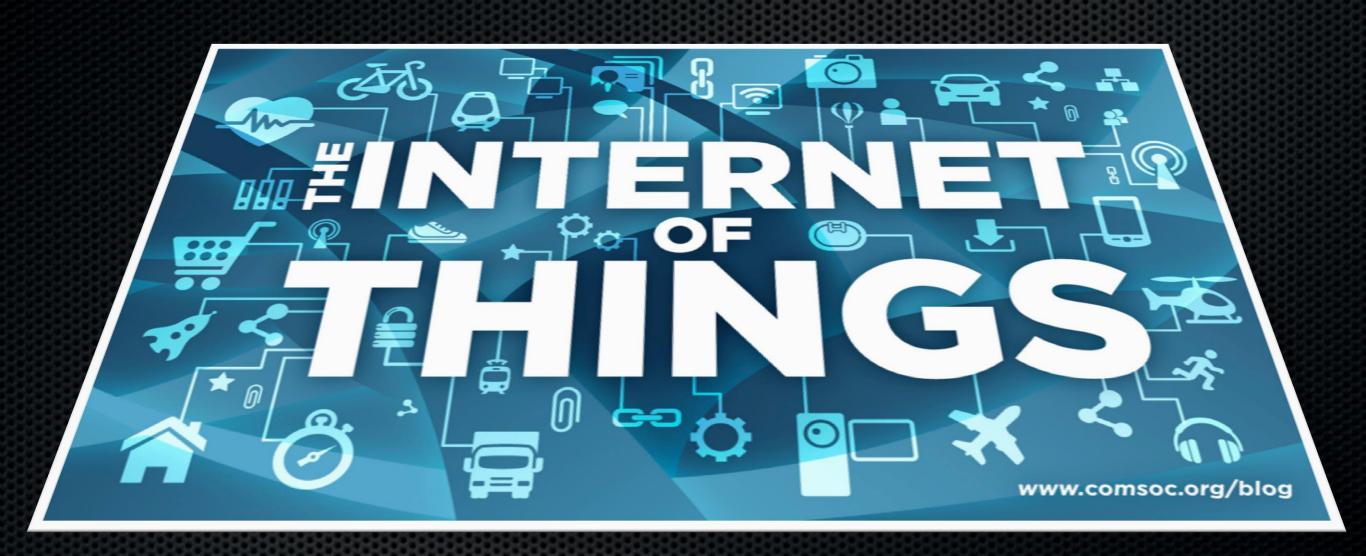
#### The Technologies – Robotics & Al



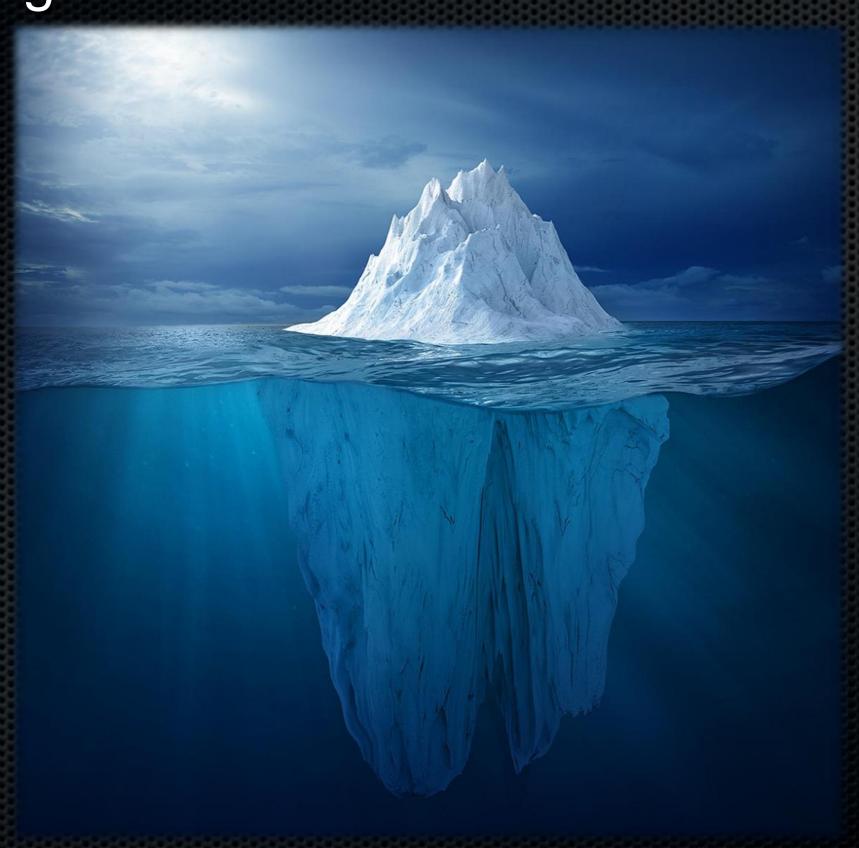
### The Technologies - Beyond BYOD to BYOX



#### The Technologies – IoT and IoE



# Big Data – Context Aware & Sentiment Mining



#### Apps and when is an App a Device?



#### When is an App a Device?





Keep one thing in mind ...

"Intended Use"

#### FDA Medical Device Data Systems (MDDS)

Medical Device Data is defined as "any electronic data that is directly available from a medical device or that was obtained originally from a medical device"

- Transmit Systems connected directly or indirectly which transmit medical data\*. This
  includes a healthcare facility's IT network (see IEC 80001-2)
- Store Any device which stores medical device data\*. Devices include hospital file servers and backup devices
- Convert (Translate) Permitted to convert/translate medical device data\* but is not allowed to alter the content in any way. An example of such translation is conversion of a DICOM image to JPEG format.
- Display Prior to the ruling all devices used to display medical device data\* were considered to be accessories to the parent device or they had to undergo separate classification.

Changes in MDDS classification has been dramatic over the last 3 years.



# Medical Device Exceptions

- EHR Electronic Health Records
  - EHR, PHR (Personal Health Record ) and CPOE (Computer Physician Order Entry) all fall outside the limited intended use of a MDDS.
- Connected Health Systems
  - In telehealth, telemedicine and remote patient monitoring systems the overall system is not considered a medical device even though the peripheral devices are all CE marked as medical devices.
- Mobile Devices
  - Can avoid regulatory controls if software applications developed to display medical data are not intended for diagnostic use or treatment.



#### Mobile Medical App Manufacturers

- For mobile medical apps that qualify as devices, manufacturers must meet the requirements associated with the applicable device classification. A mobile medical app, like other devices, may be classified as class I (general controls), class II (special controls in addition to general controls), or class III (premarket approval).
- A mobile medical app manufacturer may include anyone who initiates specifications, designs, labels, or creates a software system or application for a regulated medical device in whole or from multiple software components. This term does not include persons who exclusively distribute mobile medical apps without engaging in manufacturing functions; examples of such distributors may include owners and operators of "Google play," "iTunes App store," and "BlackBerry App World."



# Apps Disclaimers

#### Philips Vital Signs Camera App

Disclaimer: The Vital Signs Camera App is not intended for diagnosis or for clinical monitoring or decision making. Measurements and statistics are provided for entertainment purposes only ...

#### **Taconic System App**

The contents of this site and app, such as text, graphics, images ... are for information purposes only. Any content found on this app is not intended to be a substitute for professional medical advice, diagnosis, or treatment. ... Never disregard professional medical advice or delay in seeking it because of something you have read or encountered on our site or app.



# Interesting Developments

- FDA issues 1st enforcement letter to a Mobile App Manufacturer.
  Biosense Technologies, the uChek system was never cleared via
  510(k). The app, uChek Urine Analyzer, uses a phones camera to
  read urine dipsticks.
- Apple says it only accepts medical dosage information submitted by the medicine's manufacturer. Physician-led medical app review site iMedicalApps pointed out that a number of medical app developers have received rejection notices from Apple because they included medication dosage information in their app.
- Apple's new health-based features from iOS 8 onwards is bringing your personal well-being measurements to the iPhone / IPAD. This is a wellness based app so currently falls outside the device category but will this change over time with data aggregation and other apps making use of this data?



# Apple and the FDA

FDA has just recently released the summary of the meeting with the Apple. 10th June 2014

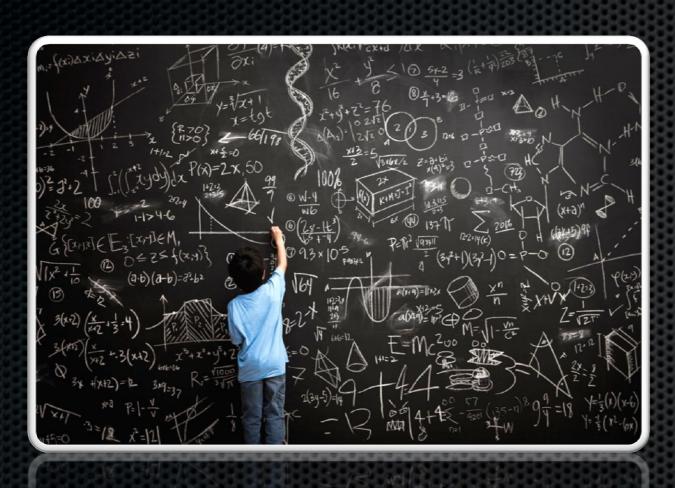
"... FDA will regulate based on the intended use of a device."

"... The current mobile medical app guidance indicates that FDA does not view apps that are purely educational or informational as medical devices. Apps that actively measure something are considered diagnostic. For instance, a glucometer may be unregulated if the intent is for a user to follow their blood sugar for the purposes of better nutrition. If the glucometer is marketed for diabetics, however, it would more likely be regulated as a medical device. The FDA looks at how devices are actually used. If the manufacturer advertises the device for an unapproved use and the FDA sees a lot of off-label use that is potentially dangerous, the FDA may regulate after the fact..."





# How Do We Get There?







"Innovation is significant positive change"

(Berkun, 2013)

# Industry and Consumer Tension Technology Push vs. Demand Pull



- Balance design versus engineering
- Avoiding technological determinism

# Lead User Innovation and Living Labs Approach

co-creation

exploration





evaluation

experimentation



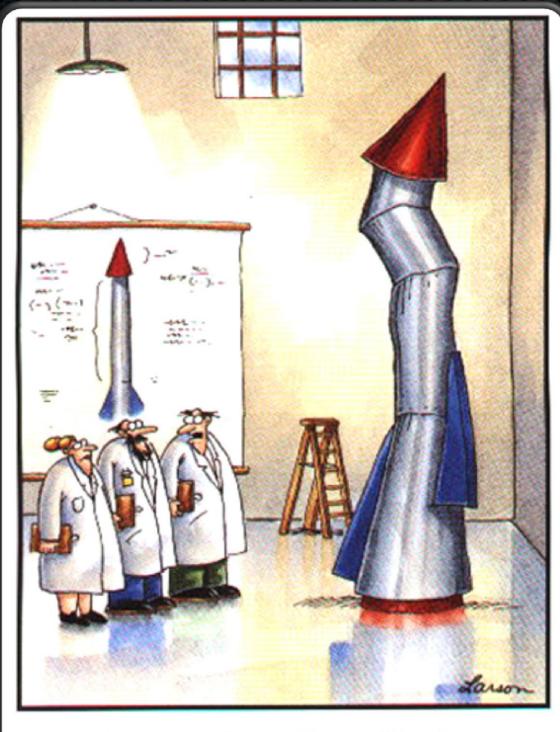
#### Challenges

- Inter-disciplinarity
  - . Where we are now:
    - . ABC (Clinical)
  - Needs to be Community-orientated
    - . ABCC (Clinical & Community)
- User-centered and user led to meet ill-met or unmet needs
  - Balance design versus engineering
  - Avoiding technological determinism
- Interoperability
- Service evolution
- Business models

# UX UX UX !!!!!

Inconsistent Consistent Organised Unrefined Misleading Understandable Simplistic Effective USETU Fresh Controllable Clear Straightforward Usiness like mbiguous CCESSIONE Contracting Contracting

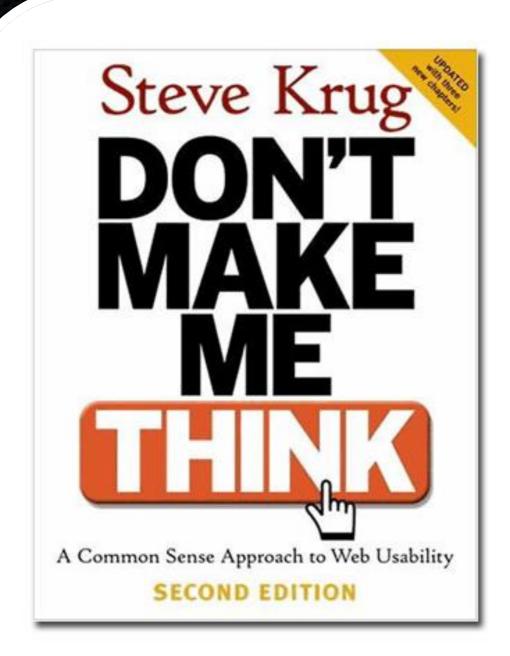
#### It's Not Rocket Science!!!!

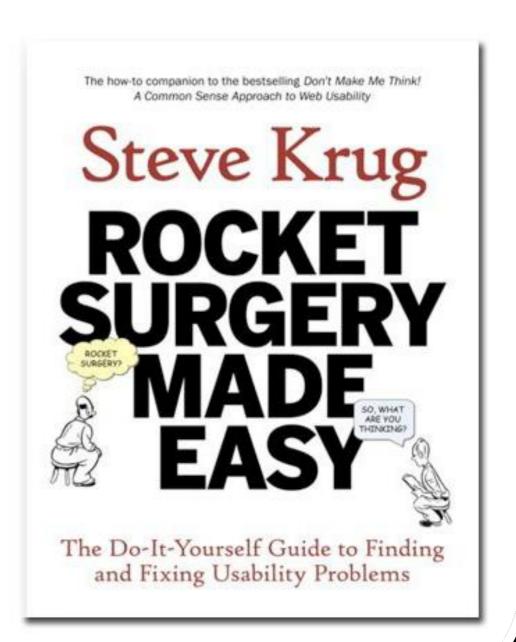


"It's time we face reality, my friends. ... We're not exactly rocket scientists."

© Gary Larson

#### Some light bedside reading !!!





# Thank You

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