DIGITAL HEALTH TECHNOLOGIES IN
CLINICAL TRIALS & BEYOND...

MAULIK MAJMUDAR, MD
ASSOCIATE DIRECTOR, HEALTHCARE TRANSFORMATION LAB
MASSACHUSETTS GENERAL HOSPITAL
DECEMBER 3, 2016
DISCLOSURES

RESEARCH GRANTS

CONSULTANT/ ADVISORY BOARD

OWNERSHIP INTEREST
BIOSENSING WEARABLES

**Biosensors** are devices that convert a biological recognition element into a signal output

**WEARABLES**
- e.g. AliveCor, Scanadu
- e.g. Google Glass, Oculus Rift

**Wearables** are on- or in-body accessories that enhance the user experience

**FOCUS OF REPORT: BIOSENSING WEARABLES**

- Activity trackers
- Smart watches
- Smart clothing
- Patches and tattoos
- Ingestibles and smart implants
KEY STEPS IN CLINICAL TRIALS

1. IDENTIFY & ENROLL RESEARCH PARTICIPANTS
2. ASSESS COMPLIANCE TO STUDY PROTOCOL
3. DATA CAPTURE & STUDY RELATED VISITS
4. ADVERSE EVENT REPORTING
KEY ISSUES IN CLINICAL TRIALS

SPEED  COST  DATA
IDENTIFYING RESEARCH PARTICIPANTS

The Michael J. Fox Foundation uses Facebook to recruit Ashkenazi Jews for Parkinson's study.

Twitter: The Future of Clinical Trial Recruitment

OFFICE OF RESEARCH AND DEVELOPMENT
VETERANS HEALTH ADMINISTRATION

Guidance for Use of Social Media, Including Facebook or Twitter, and the Use of Craigslist when Recruiting Research Subjects in VA Research
ENROLLING RESEARCH PARTICIPANTS

You’re already carrying a powerful medical research tool.

ResearchKit
WiThings Wireless BP cuff

AliveCor

iBG Star Glucometer

ThinkLabs Digital Stethoscope

Mobile Health Apps

VitalConnect Health Patch

AdhereTech Smart Pill Box

WiThings Smart Weight Scale

STUDY RELATED DATA CAPTURE
STUDY RELATED DATA & STUDY VISITS

Study Questionnaires

Telemedicine - video visits

IMPROVING STUDY-RELATED COMMUNICATION

IMPROVING STUDY-RELATED EDUCATION

IMPROVING RESEARCH PARTICIPANT RETENTION
DIGITAL HEALTH AND CLINICAL TRIALS

Top five observed sources of site dissatisfaction within the clinical trials industry:

1. Tracking clinical trial costs against the budget
2. Accurately forecasting study budget
3. Timely collection of billables against milestones
4. Serious Adverse Events (SAE) reporting
5. Patient recruitment difficulties

Source: 2014 ISCTE Conference Presentation, March 2014

- FASTER RECRUITMENT
- BETTER RETENTION
- LOWER COSTS
- REAL-WORLD DATA, MORE DATA, BETTER DATA
- LARGER SAMPLE SIZES or SHORTER STUDY DURATION
- BETTER EXPERIENCE
NOVEL ENDPOINTS ("SURROGATE BIOMARKERS")

- MS-KINECT CAMERA BASED ASSESSMENT OF GAIT SPEED, 6MWT
- ACCELEROMETER DATA AND EXERCISE CAPACITY/ CARDIORESPIRATORY FITNESS
- PULSE WAVE VELOCITY AND BLOOD PRESSURE
- SMARTPHONE-ENABLED ECG AND ARRHYTHMIA SCREENING/ QTC INTERVALS
- PHOTOPLETHYMOGRAPHY AND BLOOD FLOW/ CARDIAC OUTPUT/ AFIB
BEYOND CLINICAL TRIALS...
SOFTWARE AS A MEDICAL DEVICE

zebra MEDICAL.VISION

ApneaApp

enlitic
SOFTWARE AS A MEDICAL DEVICE

Measure blood pressure using only your iPhone.

No cuff required.
SOFTWARE AS A MEDICAL DEVICE
SOFTWARE AS A DRUG/ THERAPEUTIC

BlueStar® is the first mobile prescription therapy in American mobile healthcare history developed for adults living with type 2 diabetes and their doctors.

Read Our Clinical Trials
SOFTWARE AS A DRUG/ THERAPEUTIC

Clinical and Economic Impact of a Digital, Remotely-Delivered Intensive Behavioral Counseling Program on Medicare Beneficiaries at Risk for Diabetes and Cardiovascular Disease
Fang Chen, Wenqing Su, Shawn H. Becker, Mike Payne, Cynthia M. Castro Sweet, Anne L. Peters, Timothy M. Dall
Published: October 5, 2018 • http://dx.doi.org/10.1371/journal.pone.0163627

Technology-Supported Apprenticeship in the Management of Hypertension
From the Journal of Clinical Outcomes Management, 2014: Technology-Supported Apprenticeship in the Management of Hypertension: A Randomized Control Trial

Effect of Lifestyle-Focused Text Messaging on Risk Factor Modification in Patients With Coronary Heart Disease: A Randomized Clinical Trial
Clara K. Chow, MBBS, PhD; Julie Redfern, PhD; Graham S. Hillis, MBChB, PhD; Jay Thakkar, MBBS; Karla Santo, MBBS; Maree L. Hackett, PhD; Stephen Jan, PhD; Nicholas Graves, PhD; Laura de Keizer, BSc (Nutr); Tony Barry, BSc; Severine Bompignon, BSc (Stats); Sandrine Stepień, MBiostat; Robyn Whittaker, MPH; Anthony Rodgers, MBChB, PhD; Aravinda Thiagalingam, MBChB, PhD
CONSUMERIZATION OF HEALTHCARE
An epiphany at a rock concert helped a sick man invent a device to help himself breathe easier.
QUESTIONS....

1. ARE ALL THE REGULATORY GUIDANCES ALIGNED?

   1. MOBILE MEDICAL APPLICATION GUIDANCE
   2. GENERAL WELLNESS GUIDANCE
   3. SOFTWARE AS A MEDICAL DEVICE GUIDANCE

2. WHAT IS THE DEGREE OF SAFETY, ACCURACY, AND EFFECTIVENESS REQUIRED?

   1. ONE SIZE FITS ALL OR MATCH REQUIREMENTS TO LEVEL OF RISK

3. REGULATORY REQUIREMENTS VERSUS REIMBURSEMENT REQUIREMENTS: SHOULD BE THE SAME OR DIFFERENT?
THANK YOU

MMAJMUĐAR@PARTNERS.ORG

@MDMAJMUĐAR