Wearable technology and associated data collection apps in clinical trials Mike Bartlett, Senior Enterprise Architect, H Lundbeck A/S



# **Evolving Market**

**Rapidly growing consumer** 

## Huge diversity of sensors

- Activity
- Blood Oxygen (SpO2)
- Blood pressure • EMG
- Breast Cancer  $\bullet$ Screening
- Cardiac arrhythmia

#### • ECG (5 lead) Posture

- Respiration

- Heart Rate

Glucose

• EEG

• EKG

Muscle fatigue

#### Perspiration

### **And form factors**

- Pulse

  - Weight

**Bicycle Helmet** 

• Lower back strap

Mounted Pod

## "The market for wearable technologies

- Temperature

Visor

Watch

Wristband

#### in healthcare is projected to exceed \$2.9 billion in 2016" - IMS Research

Market

Smart Shorts

"By 2016, wearable wireless medical device sales will reach more than 100 million devices annually" - ABI Research

#### **Internet of Things**

## Maturing Regulatory Environment

- UK MHRA Guidance. Medical device stand-alone software including apps: August 8, 2014
- FDA Center for Devices and Radiological Health -General Wellness: Policy for Low Risk Devices - Draft Guidance for Industry: January 20, 2015
- FDA Center for Devices and Radiological Health -Mobile Medical Applications - Guidance for Industry: LOGO CE February 9, 2015
- BS EN13241-EU CE Mark accreditation for Medical Devices

- Ankle Band
- Armband
- Clip • Hat
- Headband
- Headphones
- Shirt Shoe clip  $\bullet$

Multi-wear

- Holistic view of patient by aggregating data from multiple devices
- Evolving interconnectivity of devices
- Emerging de facto standards e.g. Apple Health Kit
- Common APIs



# Opportunities

#### **Pre-Screening data**

- BYOD patient has a data history prior to screening
- Recruitment assist Mining of tracker data to identify potential patients

Supplement data from physical visits

### New data streams

- GPS Respiration
- Skin temperature Activity patterns

#### Inferential data analysis

#### **New Therapeutic approaches**



### Clinical

- At what point does a change from baseline become an AE or SAE ?
- Potential unintentional bias due to feedback to patients
- Endpoint selection plethora of options
- Volumes potentially increase from Mb to Tb range for single study
- Real time data handling, management and review required
- Missing data

Data

- Track changes in disease state or related factors on a shorter interval
- Objectively, remotely and continuously measure patient physiology, behaviour and symptoms
- Chemistry + Technology
- Reminders



#### **Data Privacy**

• Data anonymisation

#### Analysis

- "Big data" approaches
- "Noise removal"
- Regulatory acceptance

### **Fragmentation and Obsolescence**

- Constant updates to hardware and software
- Validation of tools across multiple platforms and OSes

## Lundbeck

#### **Cross Functional Initiative in R&D**

- Anchored in senior management
- Intelligence gathering and research
- Participation in industry initiatives
- Review of technology alternatives
- Wearables in clinical trials PoC in 2016
- Data gathering via phone app under active consideration
- Researching opportunities related to Apple ResearchKit



PROGRESS

1915-2015

LUNDBECK



• Develop and Validate the science of using biosignatures to characterise disease and predict changes in disease state • Encourage innovation and development of novel biosensors and associated knowledge management technology

- Understand regulatory pathways for using remote assessment in healthcare
- Develop standards for information exchange that enable seamless integration of sensor, data capture, data management and analysis technologies

THINC Cognition tool Neuropsychological tests Patient reported outcome PDQ-5D 2-Back TMT - B CRT DSST

