

Study Endpoints and the Smart use of Technology

February 7th 2018



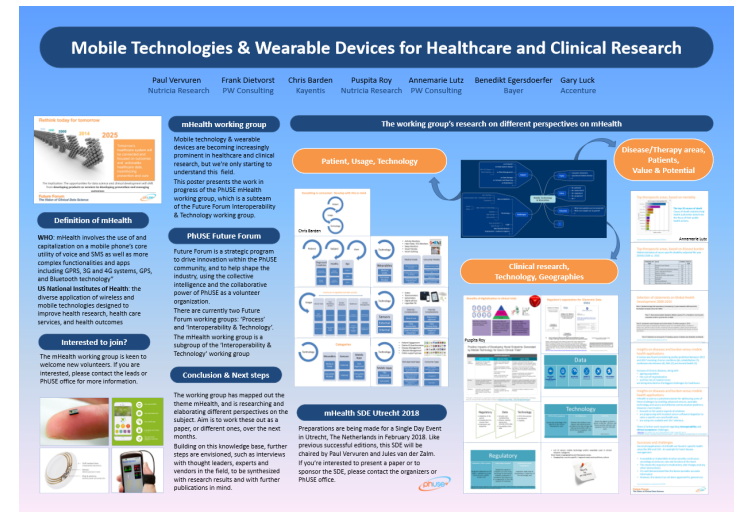
SDE Utrecht February 7th 2018



Study End points and the smart use of technology

Background:

The PhUSE Mobile technology and wearable working group an extension of the future forum interoperability group have been researching differing perspectives in mHealth studies. This presentation builds upon work from the group specifically exploring the link between patient, technology and study purpose first presented in a poster during the Edinburgh conference of 2017.



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Disclaimer



I ♥ Gadgets



Study End points and the smart use of technology



Technology – a never-ending universe of expanding choice

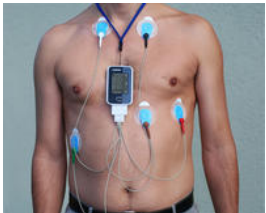
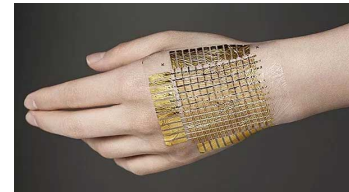


Varying endpoints – Recognised Versus Emerging



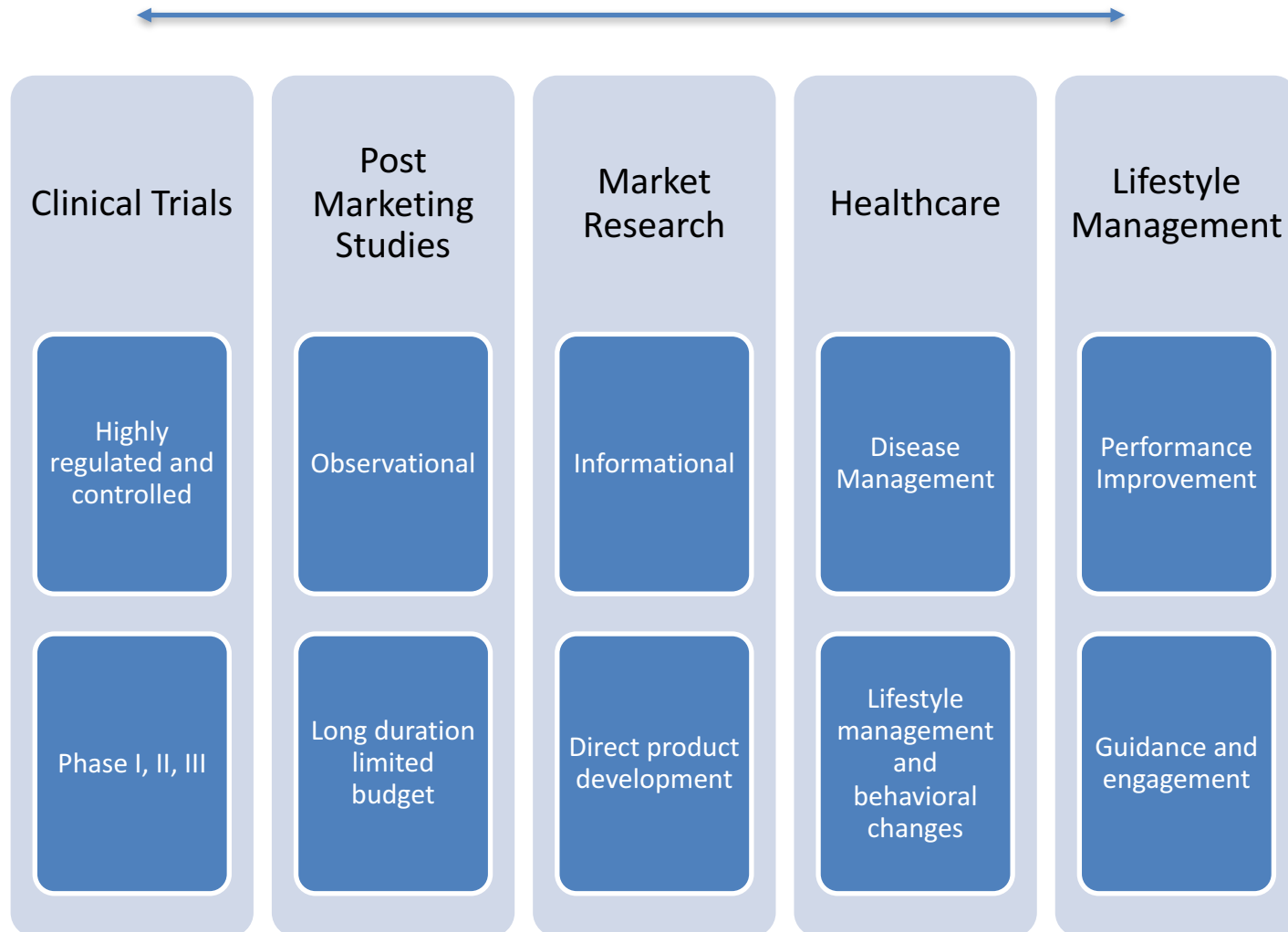
Smart choices linking endpoints to technology via patient case studies

Device Overload – So what's right for my study?

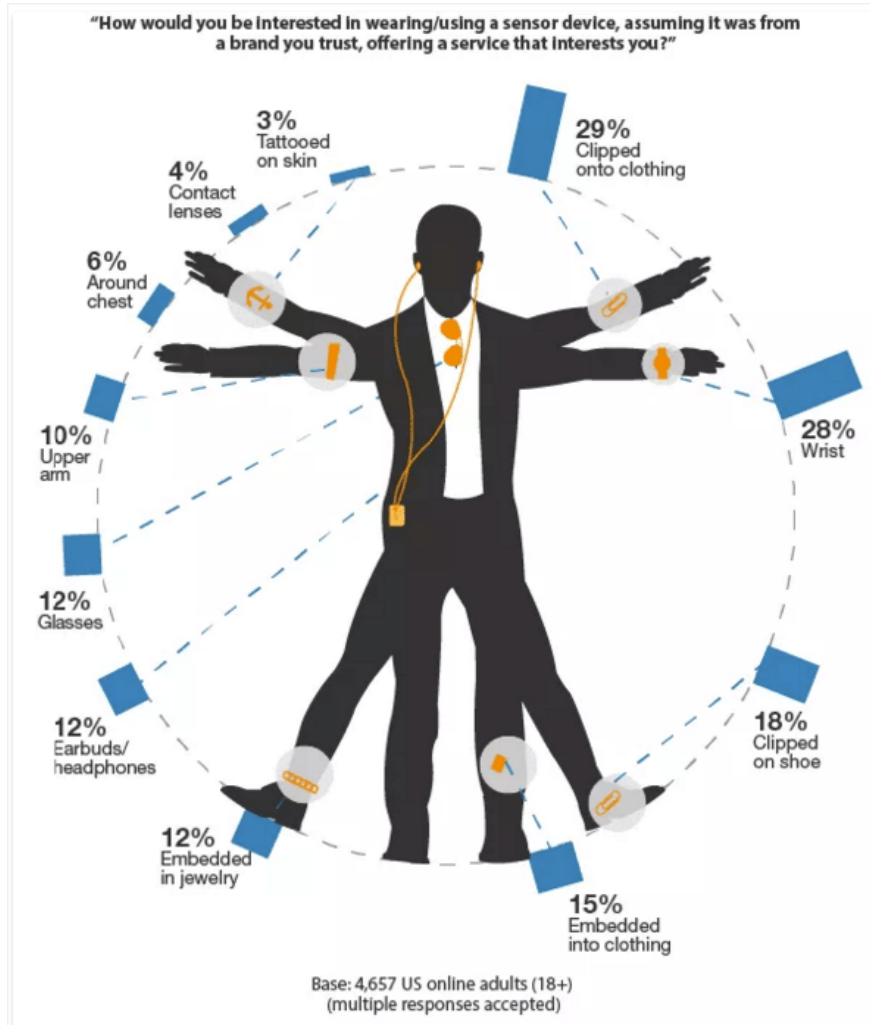


Study Endpoints

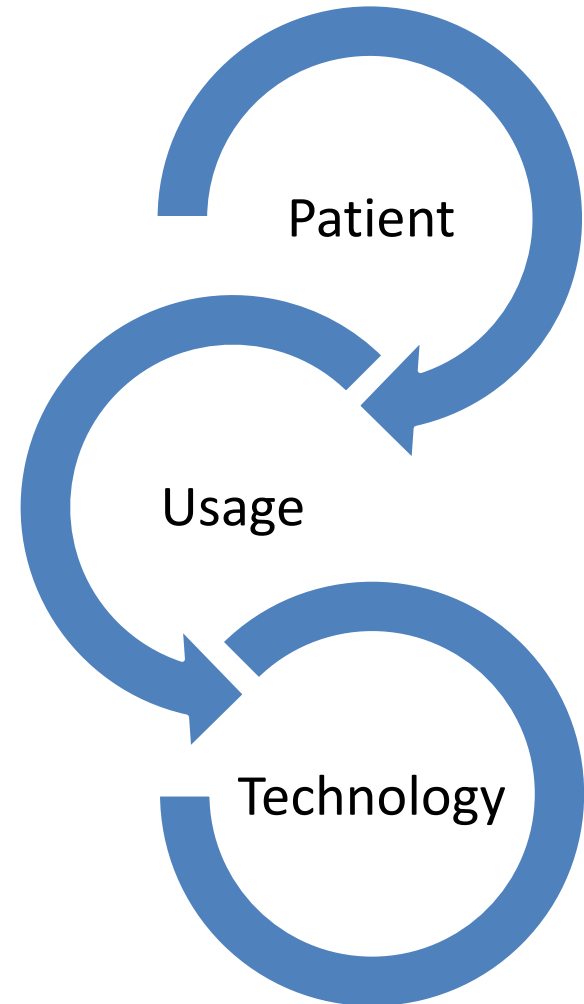
Continuum of regulation and data security



Choose the right tool for the right job



Source: North American Technographics® Consumer Technology Survey



Activity monitors in case studies

Primary Endpoint



MotionWatch 8



Lifestyle management



fitbit charge 2™

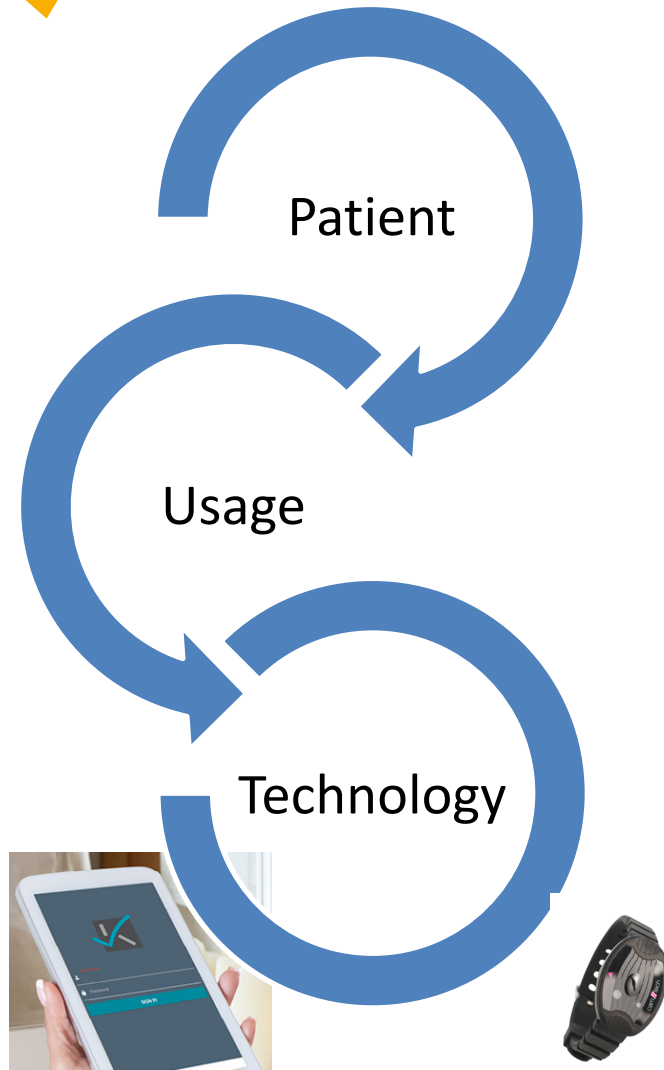


Marketing /Screening tool

Apple WATCH



Case Study 1 – Classical Clinical trial



600 adults –**Elderly Population:**

Male and female patients with symptomatic HFrEF who are ambulatory managed by a primary care physician

Phase IIIb Cardio Vascular Study in Heart Failure patients to assess impact of drug on daily activity

Primary Endpoint: To assess changes in **daily** non-sedentary daytime activity between baseline and after 12 weeks of treatment

Secondary: To assess changes from baseline in mean daily non-sedentary daytime physical activity **classified by its intensity**

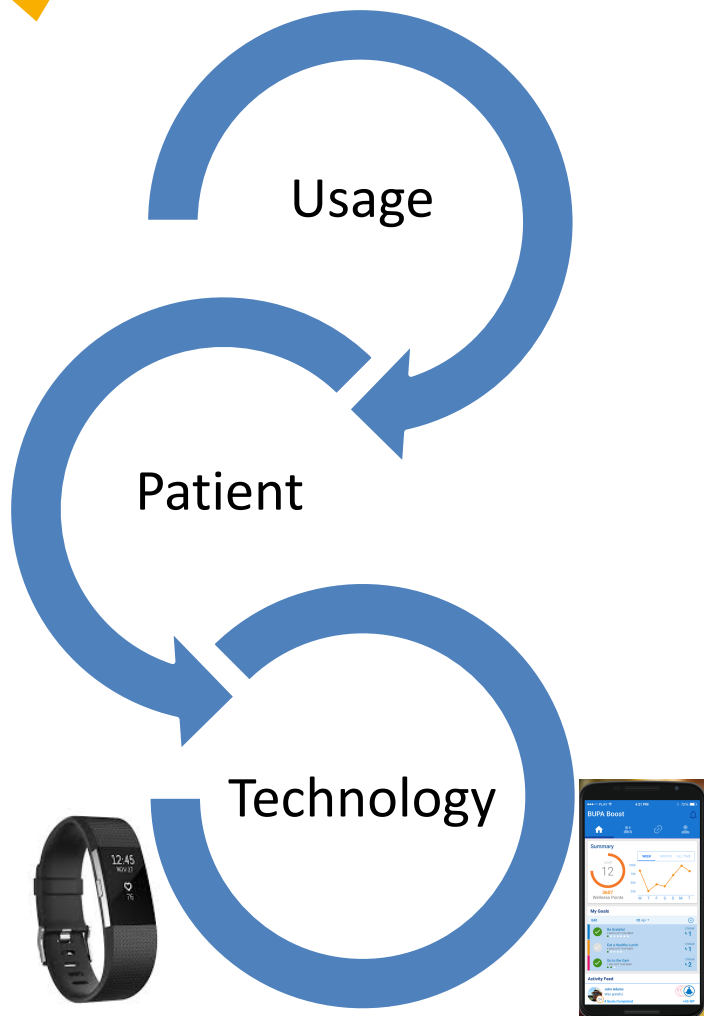
Efficacy Assessments: Actigraphy, 6 minute walk test ,5 Quality of life Questionnaires (EQ5D,PGA,PhyGA,PSQI & SF-12)

A Medical Grade activity monitor was selected due to need of accurate continuous measurement over 3 month time period.

Specific Device features

- Lightweight and waterproof (no need to remove)
- Ability to determine small intensity activity changes in Elderly population
- Long battery life (no need to remove to charge)
- No display to influence activity,
- Capable of measuring sleep patterns

Case Study – Lifestyle Management



Physical **Activity** Wearables in the Police Force: The PAW-Force Trial

This study aims to assess the effectiveness and feasibility of introducing wearable fitness technology (Fitbit™ **activity monitors** linked to the 'Bupa Boost' smartphone app) as a motivator for increasing physical **activity** within the police force Officers

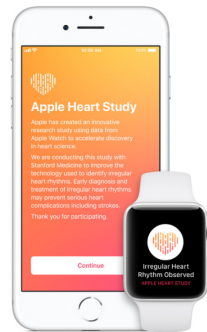
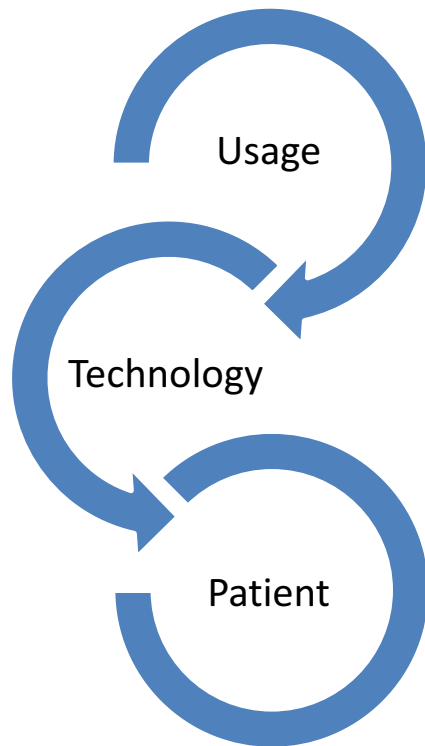
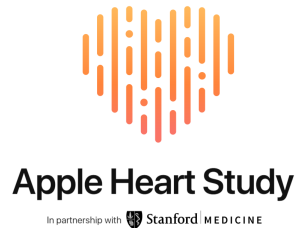
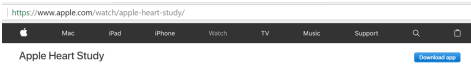
- 12 weeks initial use (individual goal-setting in weeks 1-6)
- Social features of the app in weeks 7-12)
- Followed by a further five months of optional use (as desired by the participant).

Policing is an increasingly sedentary occupation and high levels of physical and psychological morbidities are reported by officers and staff

Approximately 180 Police officers -

Fitbit Charge 2 low cost Commercially available activity monitor
Bupa boost app – Wellbeing app allows for a personal goals around fitness , mindfulness nutrition and behaviour
With Competitive leader board interaction

Apple Heart Study – Marketing / Screening



Listed of Clinicaltrials.gov

Study Type : Interventional open label Clinical trial

Primary purpose Screening

The **Apple** Heart Study (AHS) is a research study conducted to evaluate whether the **Apple** Heart Study App can use data collected on the **Apple** Watch to identify irregular heart rhythms, including those from potentially serious heart conditions such as atrial fibrillation

Apple iPhone & Watch – Biotelemetry ECG Patch

Enrolment by app store simply download app

eConsent accepting terms or no participation

Watch will passively monitor HR

Patient engagement by notification of irregular Heart rhythms

Sent ePatch to wear to confirm heart rhythms in more detail

500,000 Adults over age of 22

Inclusion Criteria:

Possession of iPhone (5s or later) with iOS version 11.0.

Apple Watch (Series 1 or later)

Current resident of the United States

Proficient in written and spoken English, defined by self-report of comfort reading, writing, and speaking English on iPhone.

Valid phone number associated with iPhone, ascertained from self-report.

Valid email address, ascertained from self-report.

Conclusion



Technology is getting smarter but careful implementation of the technology is as important as the technology itself



Providing a framework of guidance will lead to stronger designed studies.



We should take advantage of new mobile and wearable technology by using novel and innovative endpoints to enrich data sets and improve study outcomes

Cartoon first published May 2004 !

THE PHONES OF DR. MOREAU



PHONE + DIGITAL
CAMERA + ELECTRIC
TOOTHBRUSH



PHONE + MP3 PLAYER +
NOSE-HAIR TRIMMER +
CRÈME-BRÛLÉE TORCH



PHONE + P.D.A. + BLOOD-
SUGAR TESTER + CURLING
IRON + OYSTER KNIFE

Thank You for your attention

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SDE Utrecht February 7th 2018

