A Symbol of Excellence

Extending from personal wellness considerations for using wearables in clinical trials

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Wearable technology is now commonplace:

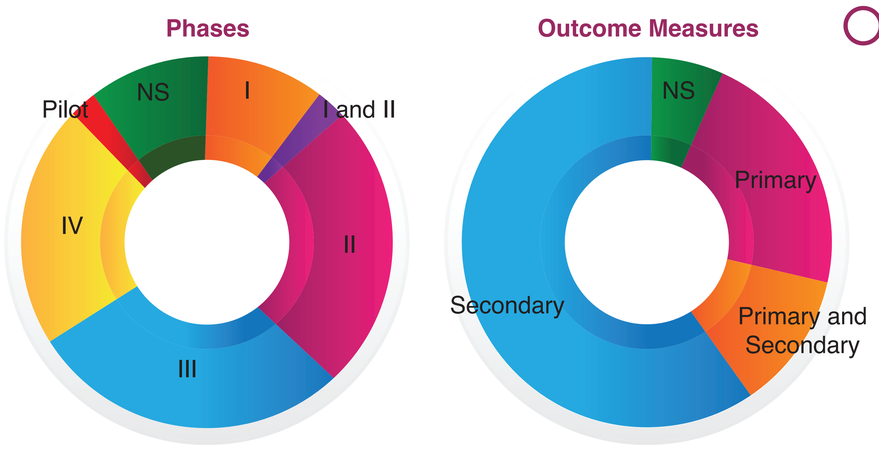
70% of consumers are aware of wearable technology and 1 in 6 owning a device*. It is a rapidly evolving technology with a convergence of sectors- **Military, Sports, Clothing, Health and Wellness and technology giants** resulting in miniaturized sensors and health platforms resulting in a new sector; that of the **quantified self** **

To move beyond the hype and maximise the potential of wearables in clinical trials consideration needs to be given to **Patient Centricity and Device Selection, Validated Clinically Relevant Endpoints, and Standardization**.

*http://www.nielsen.com/us/en/insights/news/2014/tech-styles-are-consumers-really-interested-in-wearing-tech-on-their-sleeves.html

**Gary Wolf http://www.webcitation.org/66TEHdz4d

Clinical Trials using Actigraphy



80% of Clinical Trials that used Actigraphy are in the **CNS therapeutic area. Sleep endpoints** predominate as both **primary and secondary endpoints** across all phases.

Wearables are already used clinical trials:

The vast majority of wearables contain an accelerometer that measures movement. A research tool since the 70's and used for over 15 years in Clinical trials to objectively measure changes in sleep and activity cycles ple applications from qualifying patient populations, tracking compliance and gathering real world objective data. Accelerometers record data in 3 planes. This technology is used in Smart Phones where in combination with a gyroscope it provides the orientation detection- ensuring the screen is always the right way up.

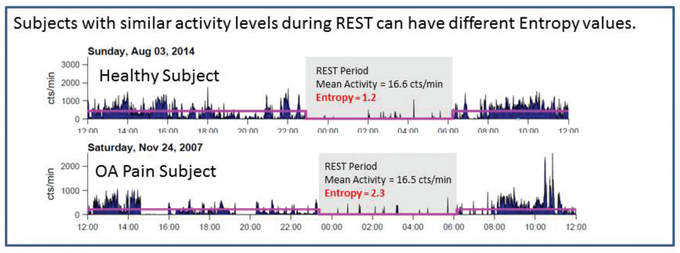
"Instructions for use are simple; **"put on and don't take off"**
Compliance is high over 90%.
Canada Health 2011

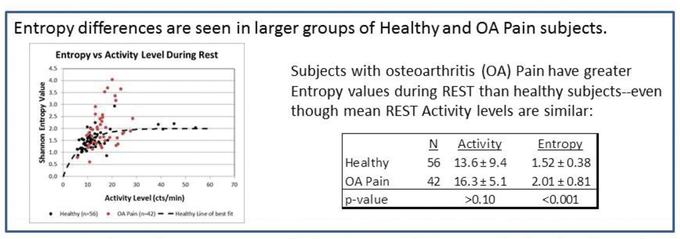
"happy to wear the wrist worn devices for a week or more"
Patient feedback from ProActiv Study
http://www.proactivecopd.com"

Patient Centricity and Device Selection:

"To gather data the patient must wear the devices".
Patients lifestyle, BMI, condition all impact their compliance. Device size and body position, battery recharging, water resistance and transmission process all impact patient compliance. **Newer devices can automatically detect non-wear.**

Example of a Novel Endpoint: Shannon Entropy





	N	Activity	Entropy
Healthy	56	13.6 ± 9.4	1.52 ± 0.38
OA Pain	42	16.3 ± 5.1	2.01 ± 0.81
p-value		>0.10	<0.001

Entropy may reflect an important aspect of pain not revealed by conventional actigraphy analyses.

Validated Clinical Relevant Endpoints:

Selected endpoints should be simple, clinically relevant and result in a a statistically significant measurable effect.

Actigraphy devices can produce vast quantities of data. For optimization of data transmission and battery life, this data is routinely compressed and algorithms identify validated sleep and activity endpoints that objectively measure changes from baseline following therapeutic intervention.

Novel, exploratory endpoints and new algorithms: are being developed for new therapeutic areas; to identify new clinically relevant endpoints and to identify at risk cohort among patient populations.

"**Condition: OHS**
"Actigraphy has the added benefit of providing objective daytime physical activity data" Murphy et al, Thorax (2012)

Condition: Parkinson
"Averaged Actigraphy is considered to be useful in the quantitative detection of drug response to parkinsonian akinesia and its circadian variations, this enables of the lowest dose of drugs needed to alleviate akinesia".
Katayama et al Eur Neurol 2001;46 (suppl 1):11-17

Condition: Neuropathic Pain
"Actigraph measurements of activity levels can be used as an objective measure of functional status in analgesic clinical trials"
Agarwal et al. Pain Medicine Vol 8 Issue 7, 2007."

The Need for Standards: What is an Activity Count ?

There is a lack of equivalence between devices and the data generated by different system compounded by: Proprietary Hardware and Algorithms, different Epochs, sampling rates and accuracy means that data generated from different devices cannot be directly compared.

Even raw data gathered from different devices may not be equivalent*
*Johns et al. Sensor 2013, 13, 14754-14763

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