

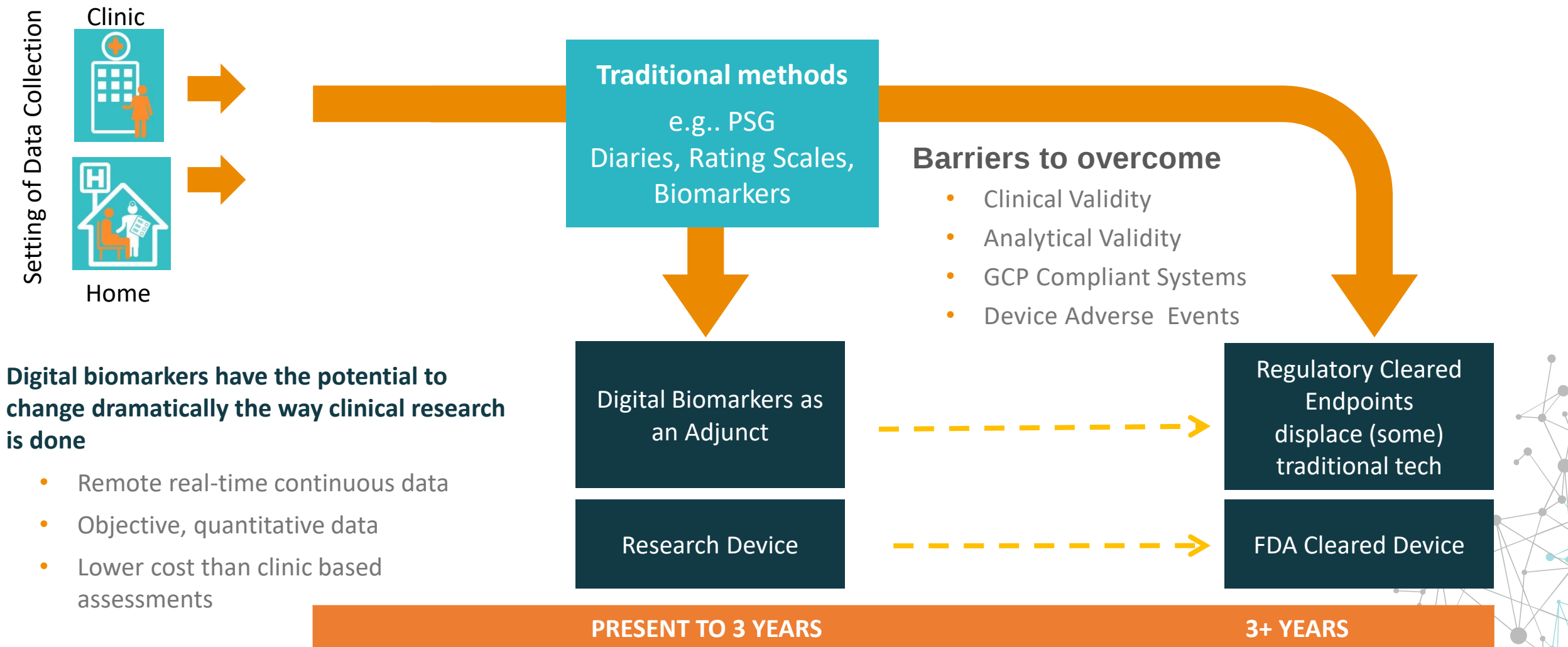
Collaborating to Develop Digital Biomarkers with Passive Data Collection

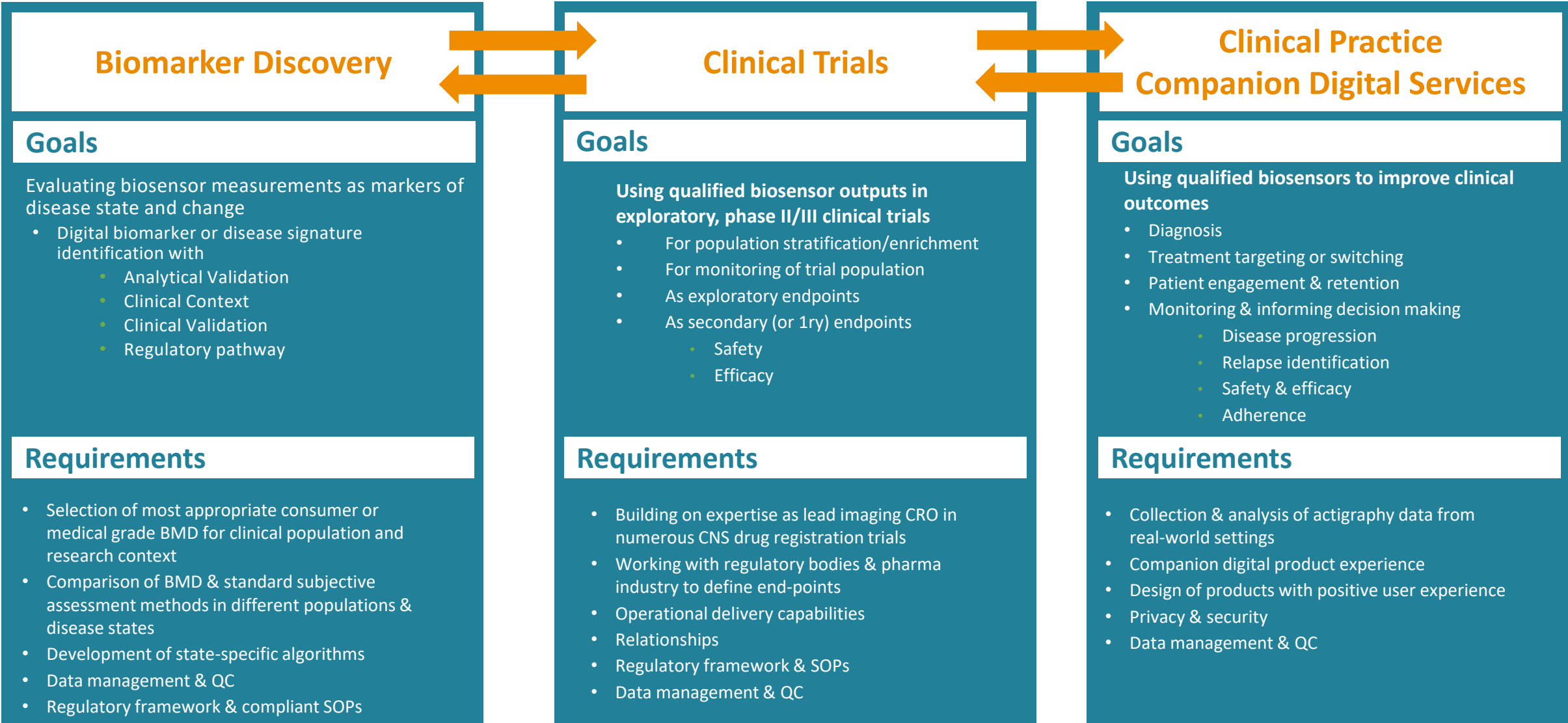
Iain Simpson

IXICO

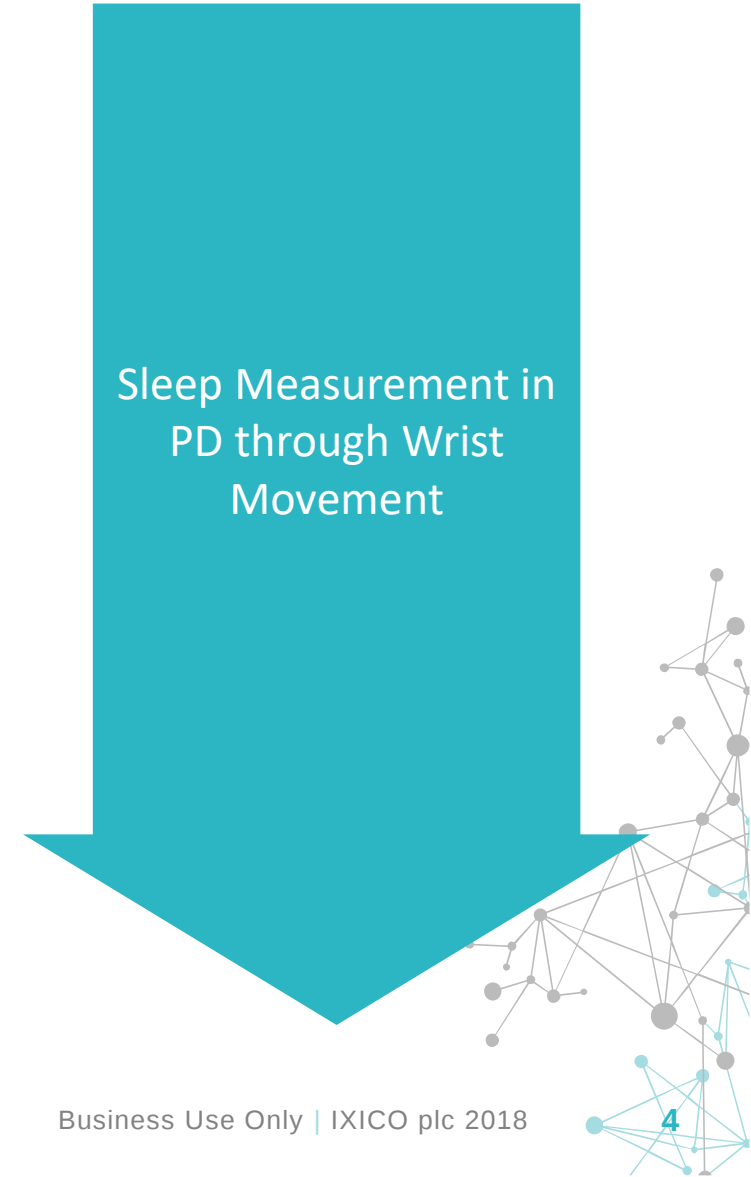
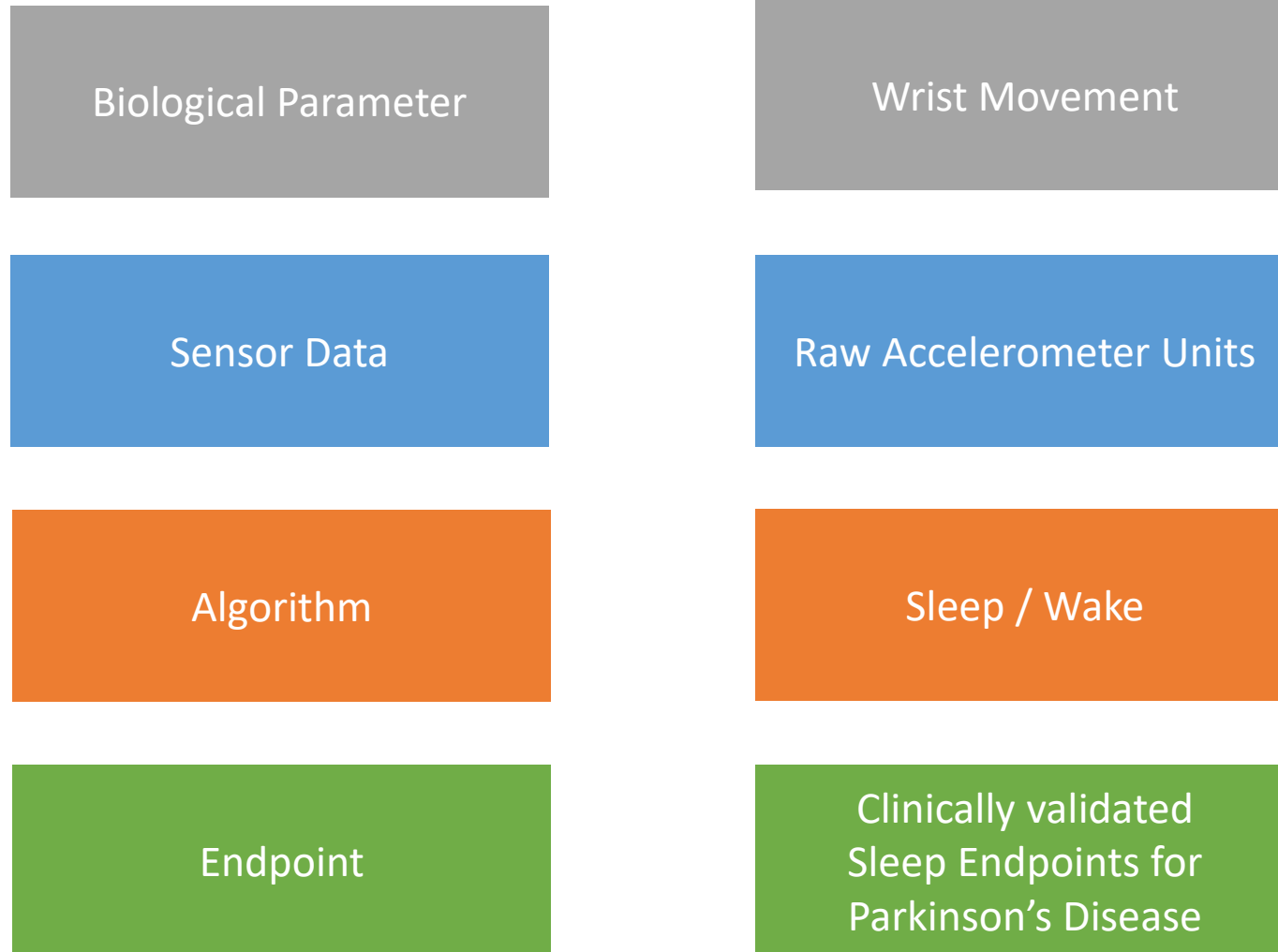
June 2018

Market evolution: biosensors and digital biomarkers





Framework for validation of biosensor derived endpoints - Example, Sleep in PD from a wrist worn accelerometer



Extracting Clinical Value From Actigraphy Metrics



- Activity

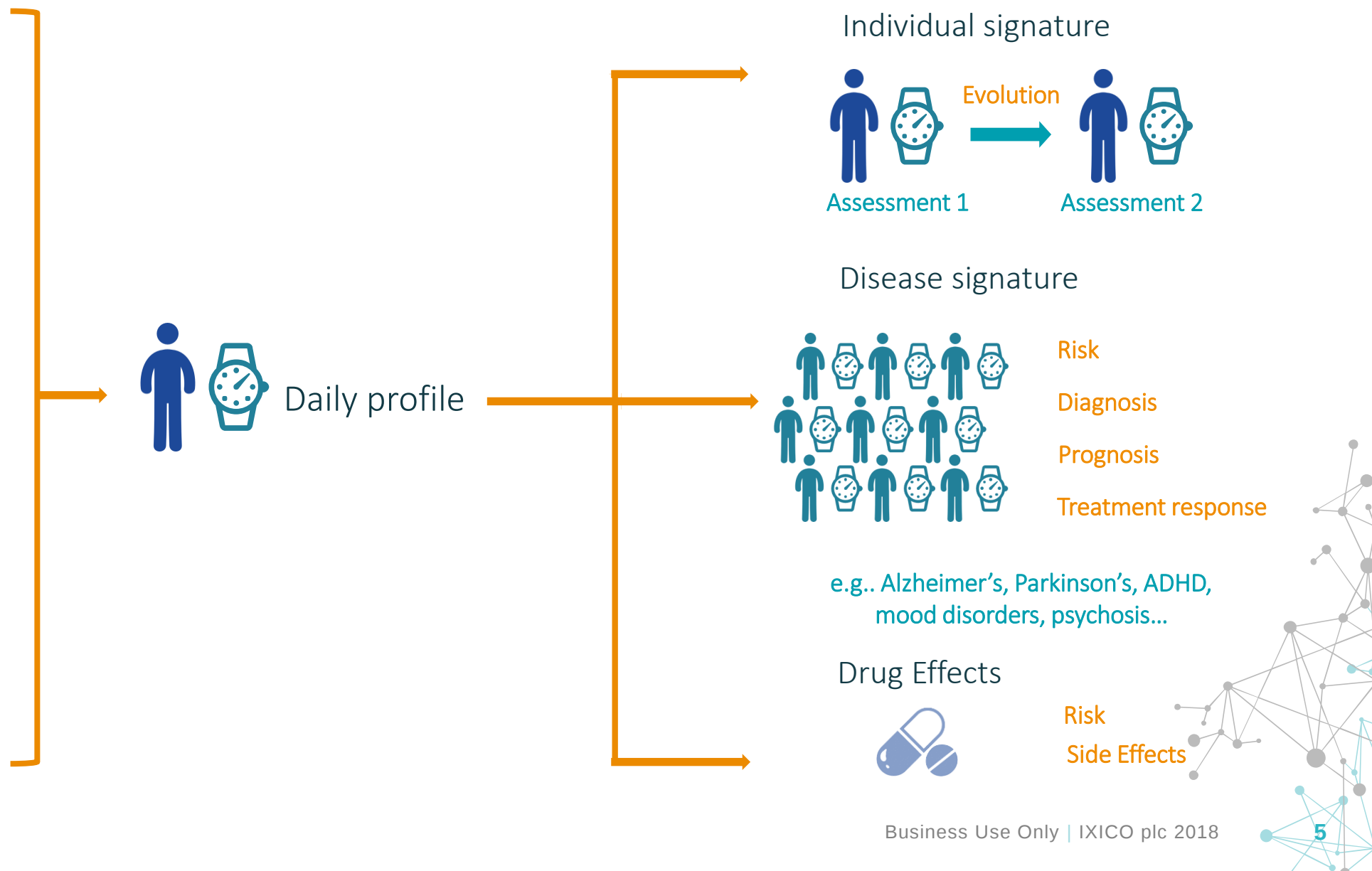
- day time activity
- evening activity
- nocturnal activity
- quantity and quality
- tremor
- bradykinesia
- PD on/off
- falls
- etc.

- Sleep

- sleep latency
- sleep efficiency
- number of awake times
- awake time duration
- circadian rhythm
- sleep stages
- etc.

- Mood and Behaviour

- Depression
- Social Withdrawal



GCP compliant approach to wearables: IXICO's (current) approach

Issue	(Current) IXICO Solution
GCP Compliant Data Collection	Closed data management.... Building on >10 years imaging
Data Privacy	Device handling by site. No cloud transmission
Data Format	Raw data - provides maximum flexibility in analysis
Device independent	“bridging strategy” to new technology
Clinically meaningful	“Gold Standard” Studies support algorithm development and validation
Data integrity	Simple device operation with data local download
Easy “User interface”	Data returned by hand or in post – no need for smart phone, Wi-Fi etc.
Low site and patient burden	Passive device - fit and forget
Blinded data collection	Passive device - fit and forget



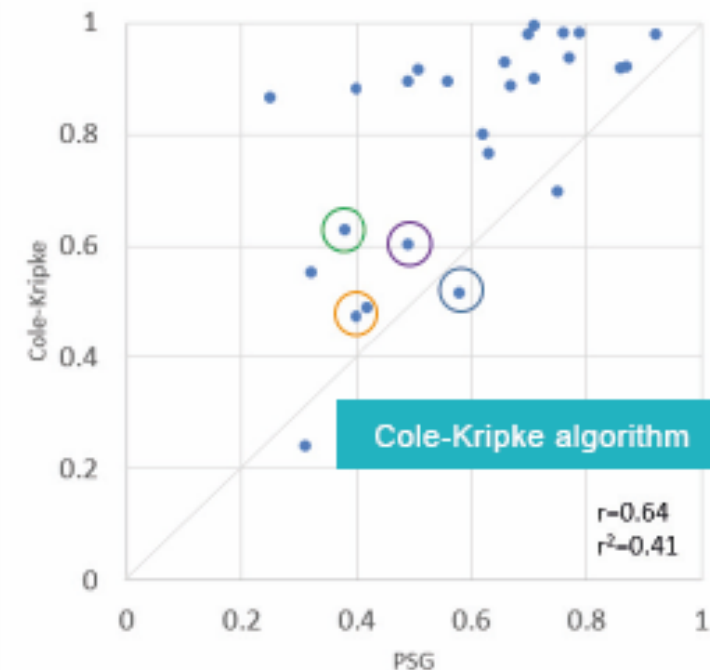
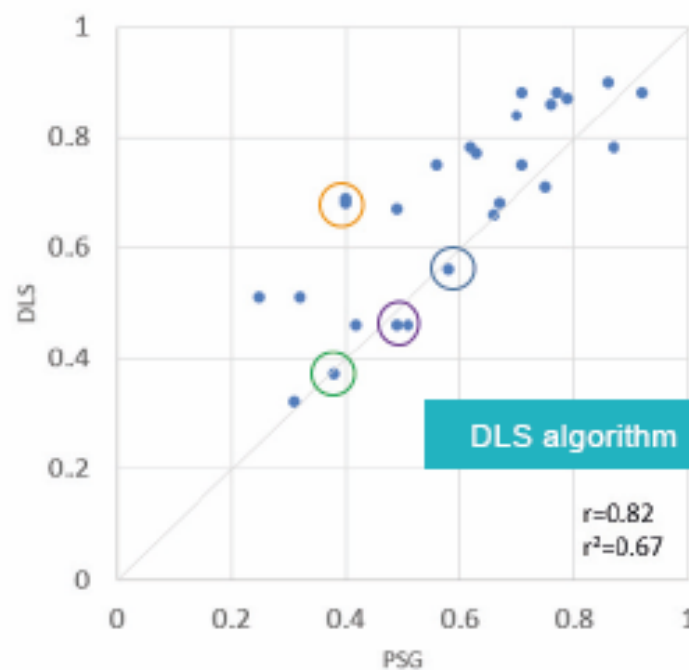
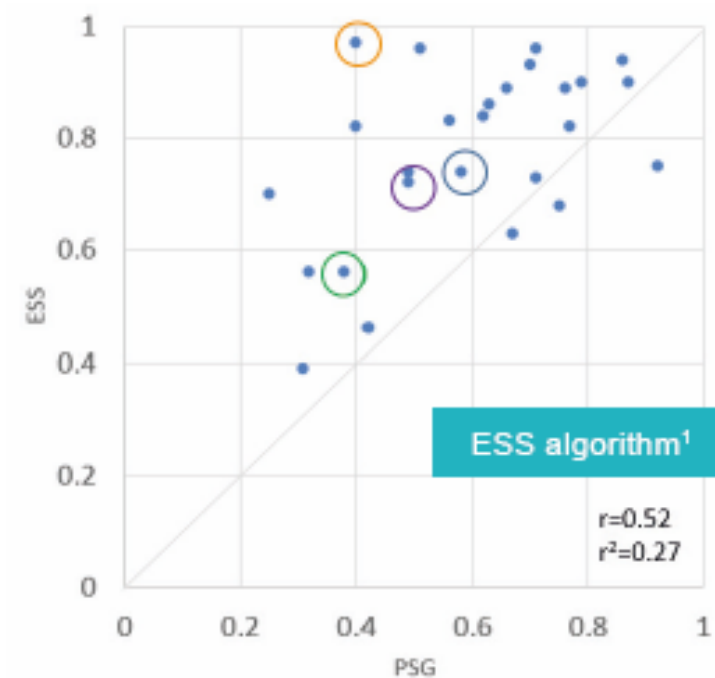
Digital Biomarker Discovery

Example: Development of actigraphy-based measures for sleep using gold standard PSG data



Digital Biomarker Discovery

Comparison of Actigraphy Algorithms Versus PSG



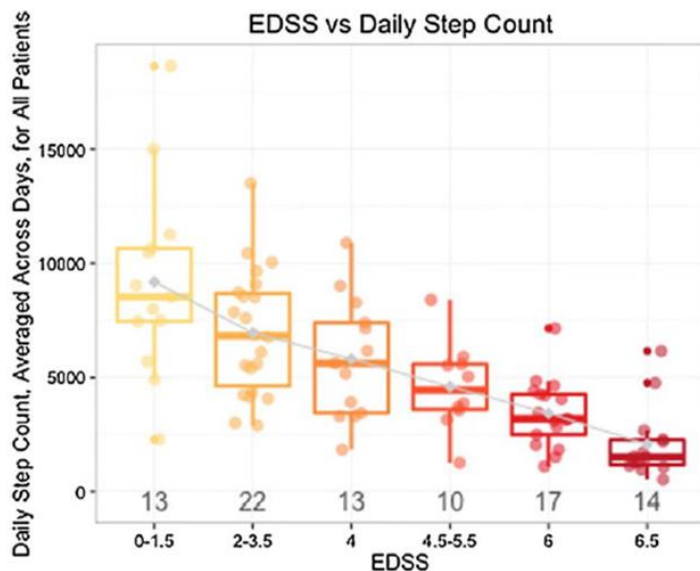
CONTEXT
CONTEXT

Presented at MDS 2017 (Vancouver) and Alzheimer's Association Research Round Table, June 2017

Digital Biomarker Discovery

Developing Measures Avoiding Excessive Site and Patient Burden

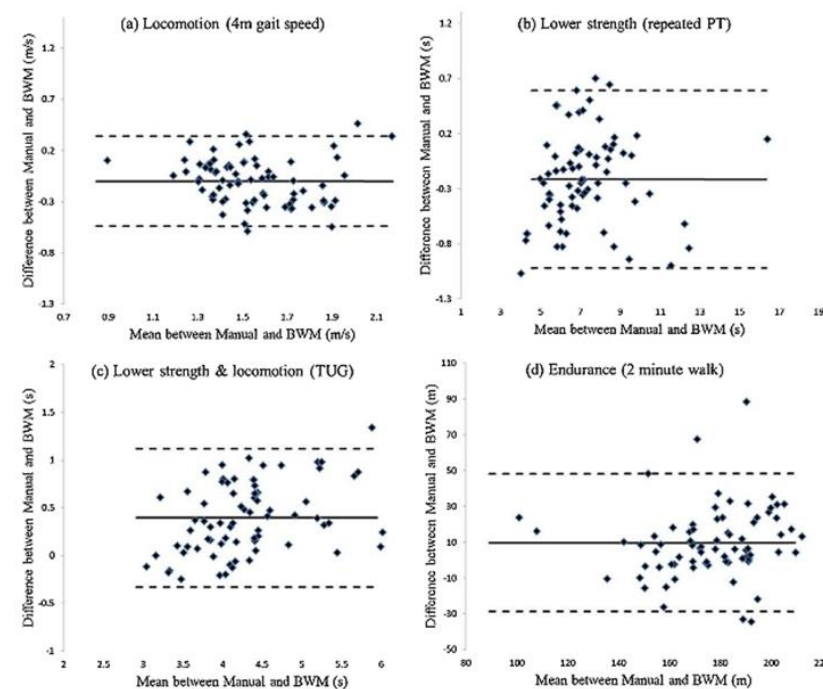
Correlating Step Count to EDSS using Consumer Device



Average daily step count (measured using the Fitbit Flex) versus EDSS

Block et al J Neurol. 2017 Feb;264(2):316-326. doi: 10.1007/s00415-016-8334-6. Epub 2016 Nov 28.

Measuring Physical Capability Using a Single Sensor

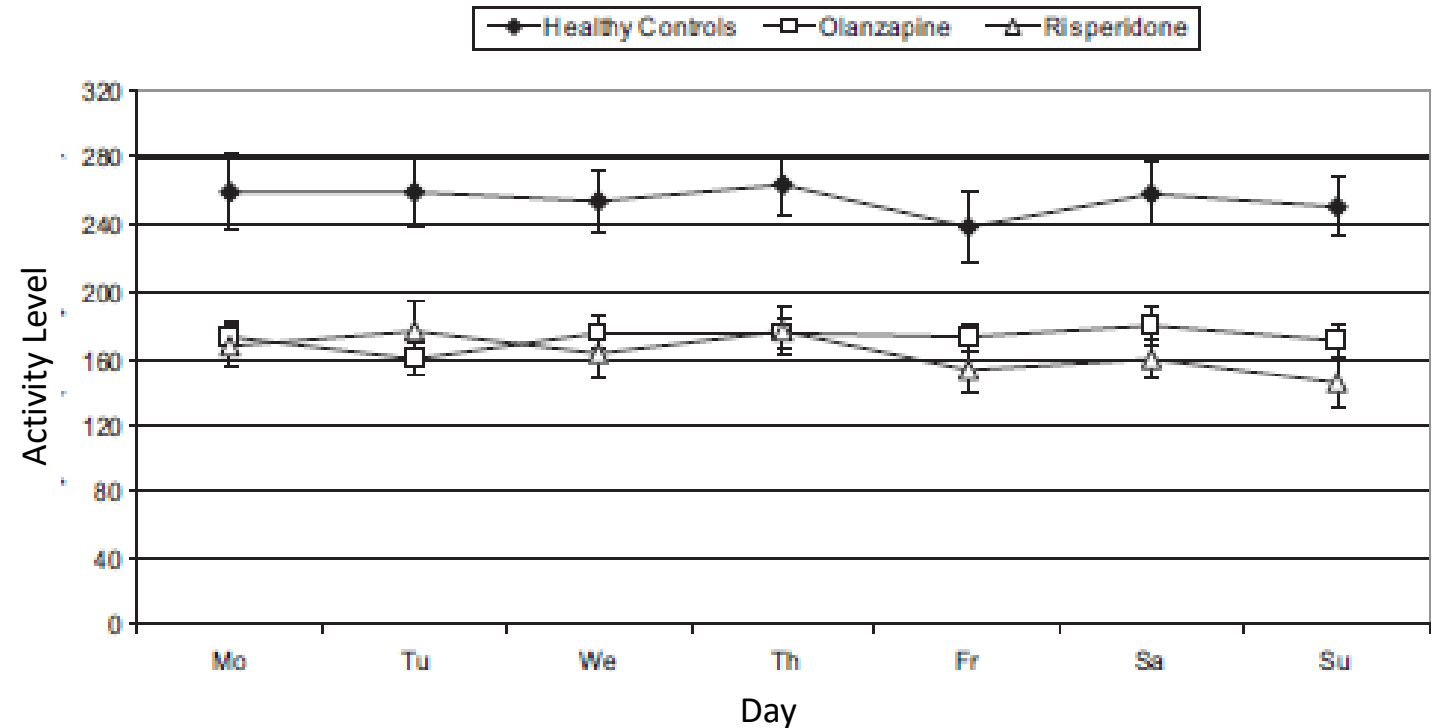


iCap: Instrumented assessment of physical capability, Godfrey et al (2015)

Use of Actigraphy in Schizophrenia - Wichniak et al 2011



- Measured activity levels in subjects treated with olanzapine and risperidone versus healthy controls
- Found significant reduction in 24hr daily activity, lower daytime activity and longer time in bed
- Saw no difference in activity between olanzapine and risperidone treated groups
- Noted that choice of position of Actigraph is important and difficulty in comparing with other studies



Seventy-three patients with schizophrenia (n = 64) or schizophrenic form disorder (n = 9) : Age (29.2± 10.2 years)

Wichniak A, et al 2011, *Actigraphic monitoring of activity and rest in schizophrenic patients treated with olanzapine or risperidone*. J Psychiatr Res. 2011 Oct;45(10):1381-6..

Moving Forward through Building Partnerships

