

The promise of wearable technology in clinical trials: a proof of concept to deliver it?

RW02

Jennifer Bradford

PHASTAR, UK



Wearables and Medicine

Clinical Research on the Wearable Technology Bandwagon

by Laurie Withington

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Wearables Move Beyond the Consumer

Consumer-grade wearables begin to merge with professional medical equipment.

01 January 2019 Stephen G. Anderson, SPIE Director of Industry Development [Industry](#)

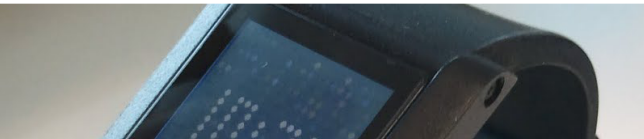
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How Wearable Technology May Potentially Revolutionize Clinical Trials

By [Johanna Mischke](#) - 14 November 2018



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Wearables Can Tell

The proven health trackers saving thousands of lives

By [Matthew Wall](#)
Technology of Business editor

15 November 2016

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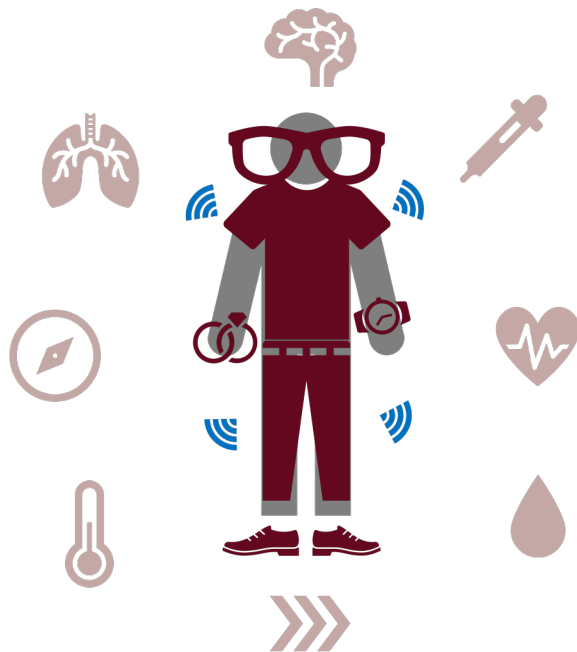
Fitbit May Have a New Way To Detect an Irregular Heartbeat

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Wearables

There are many different types of wearable devices, capturing different types of information about an individual



*Medical grade
wearables*



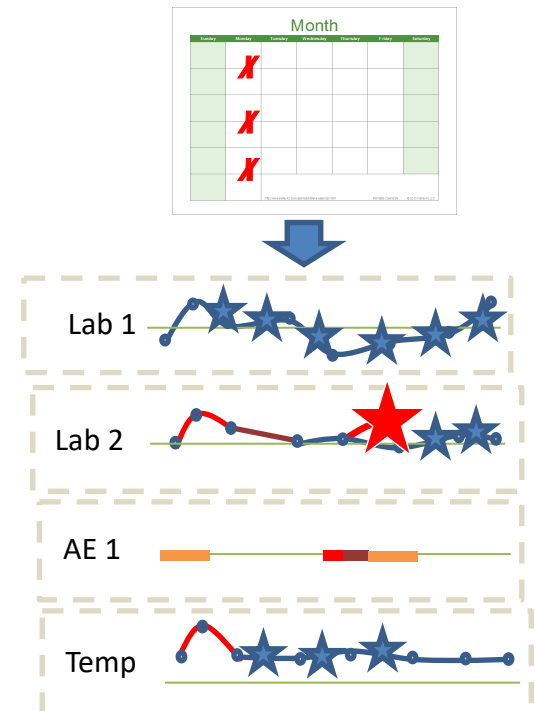
Vs

*Consumer grade
wearables*

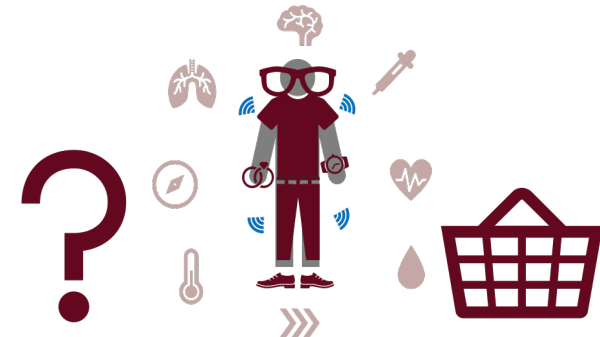
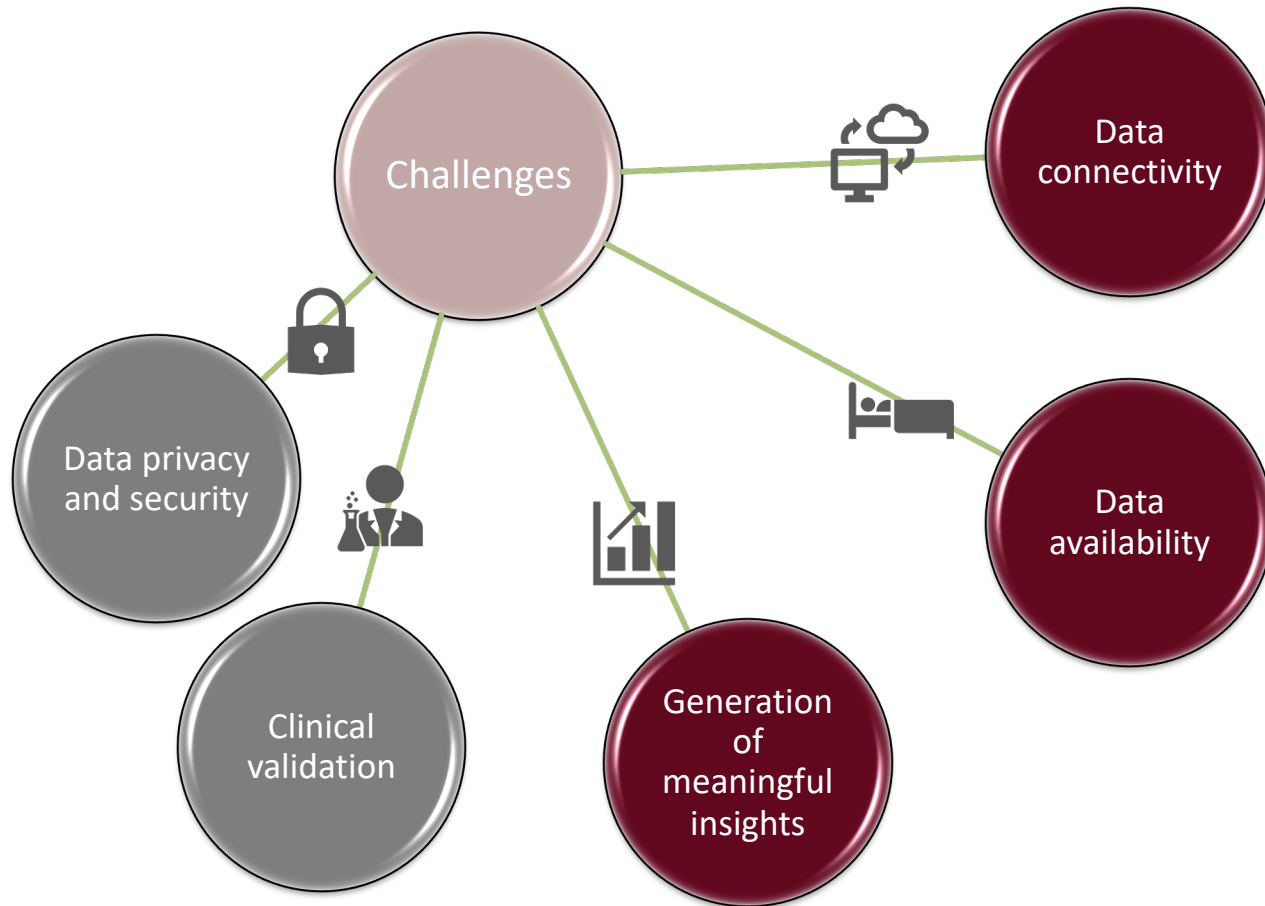


Wearables and Clinical Trials

- Wearables offer promise in clinical trials and healthcare more generally with the potential to:
 - provide richer baseline information
 - contribute to understanding the safety and tolerability profile
 - Novel endpoints and/or objective measures of subjective outcomes
- Many clinical trials collect data at specified time-points or visits that maybe a week or two apart potentially longer.
- Over the course of a trial it is possible to build a picture for each participant.
- Could wearables help to fill in the gaps?



Some Challenges



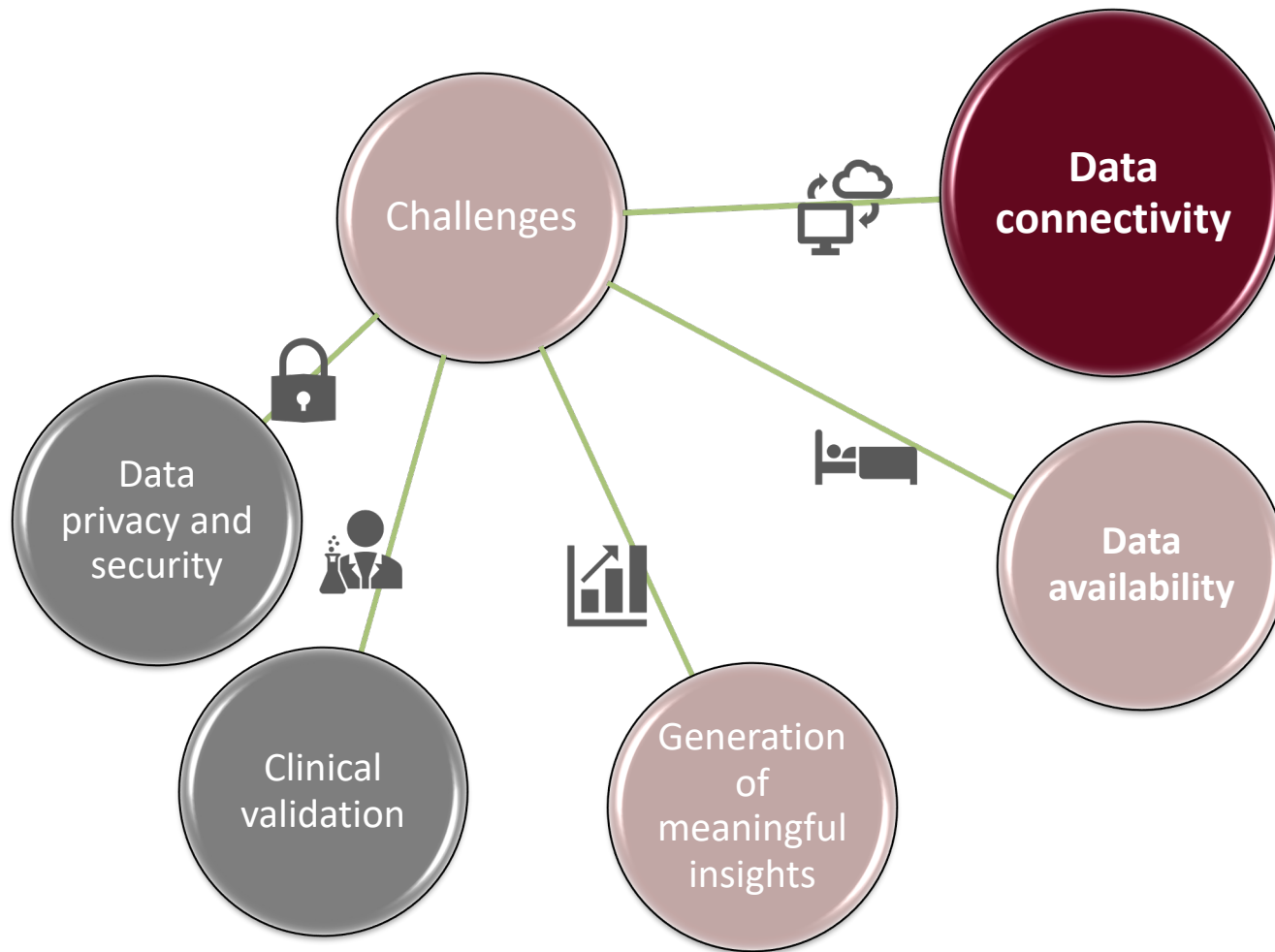
Wearables Study

- 15 Volunteers from UK-based PHASTAR employees recruited to a 1 month long study
- Provided with a FitBit Inspire HR to wear on non-dominant arm for 1 month
- At the end volunteers asked to download their sleep and activity data
- Volunteers also completed the WHO-5
 - A validated short self-reported measure of current mental well being over the previous 2 week period

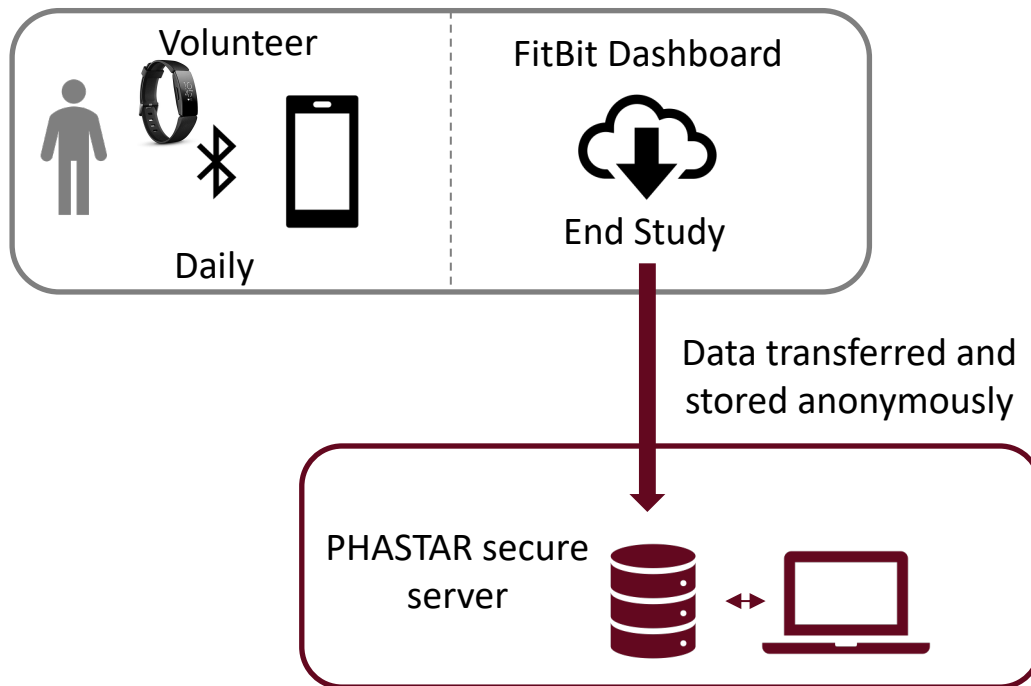


Image taken from
<http://www.fitbit.com>

Some Challenges

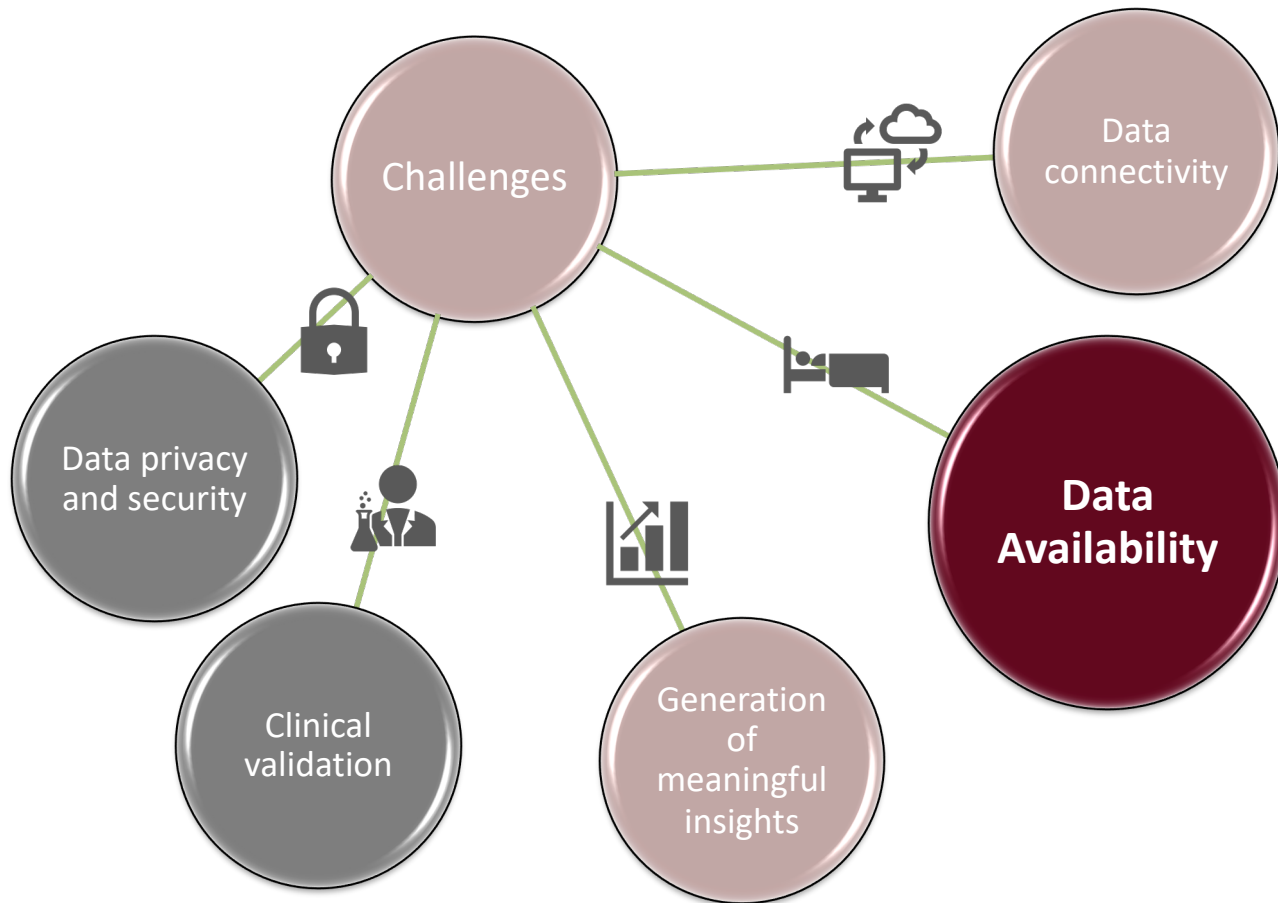


Challenge 1: Data Connectivity



- Data access relied on volunteer downloading their own data
- Anonymity was to be maintained
- Not feasible on a larger scale.

Some Challenges



Challenge 2: Data Availability–Types of Data

The data was a daily summary of:

Activity



- Calories burned
- Steps
- Distance
- Minutes sedentary
- Minutes lightly active
- Minutes fairly active
- Minutes very active
- Activity calories

Sleep

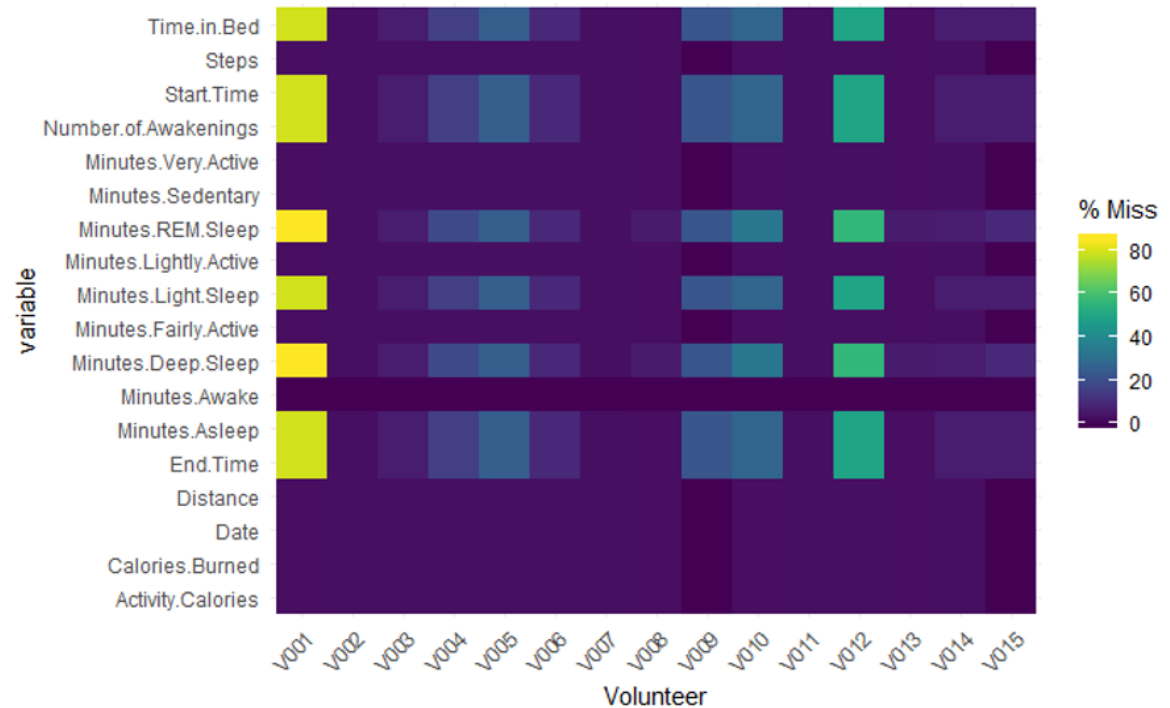


- Start and end time of sleep
- Minutes asleep
- Minutes awake
- Number of awakenings
- Time in bed
- Minutes REM sleep
- Minutes Light sleep
- Minutes Deep sleep

Challenge 2: Data Availability – Missing Data

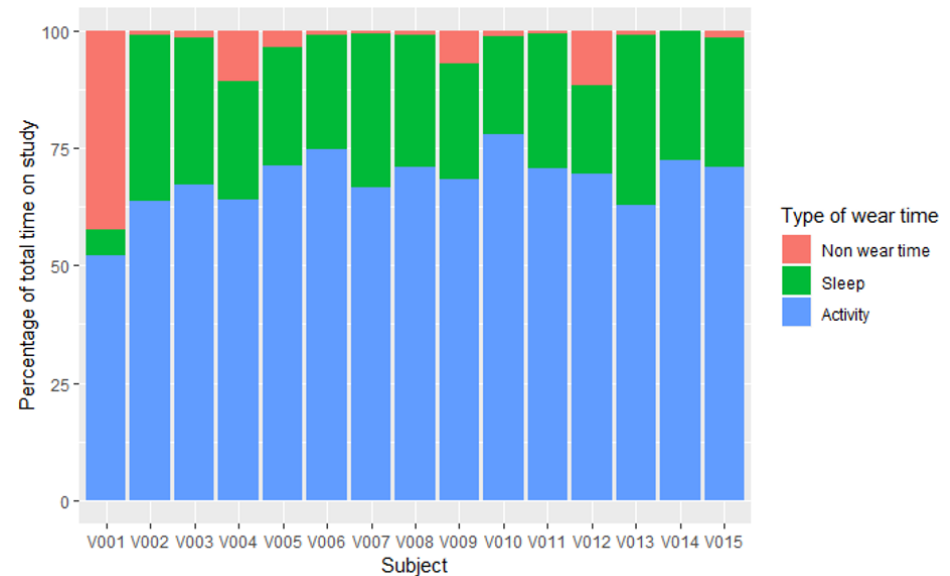
Some missing data is easy to measure:

- Day time activity but no sleep information or
- Time to sleep/wake up but no sleep cycle information

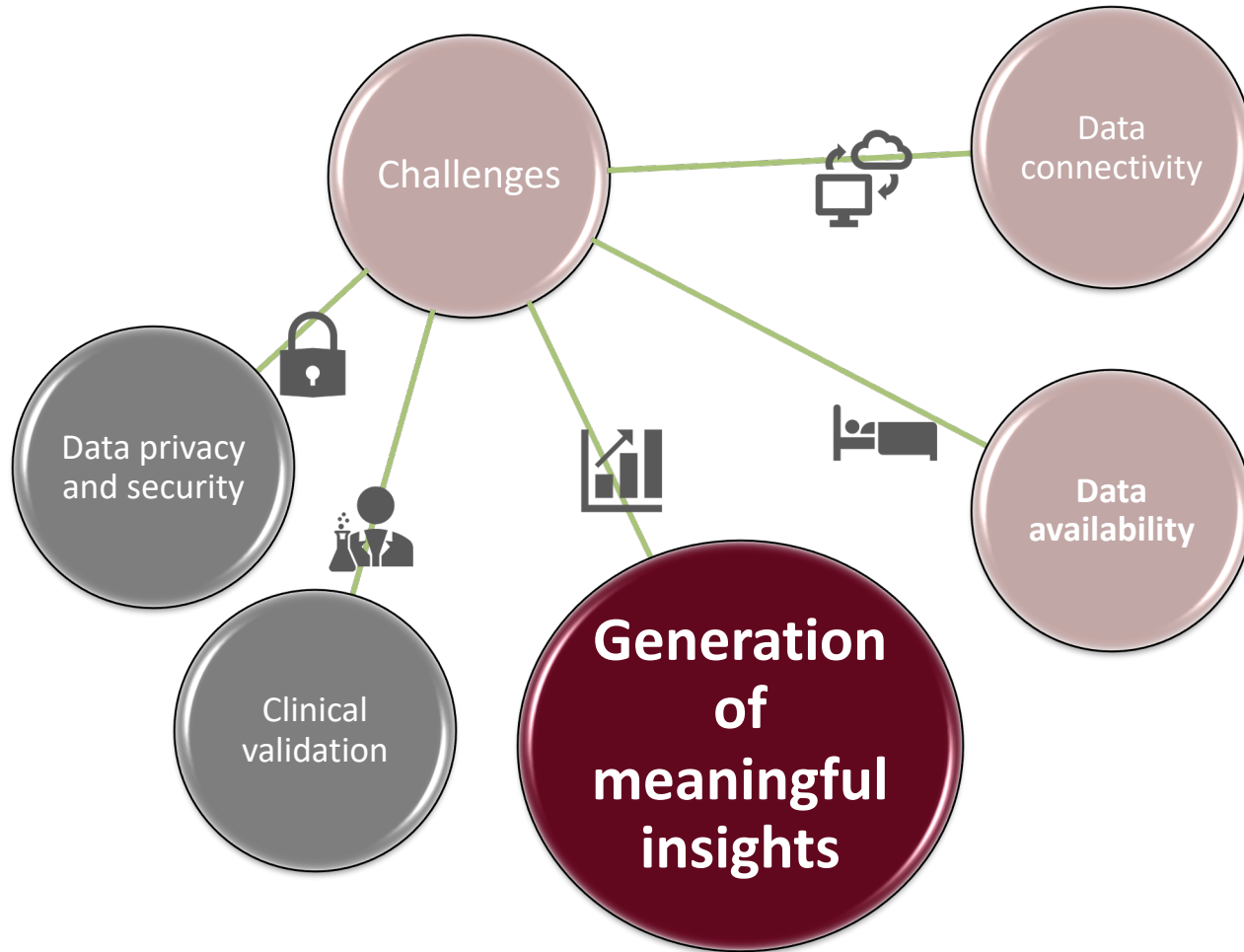


Challenge 2: Data Availability – Non wear time

- More challenging to estimate
- Not directly reported
- Estimated by the number minutes per day (1440) minus the minutes active or in bed
- However, sometimes results would be reported during suspected non-wear time

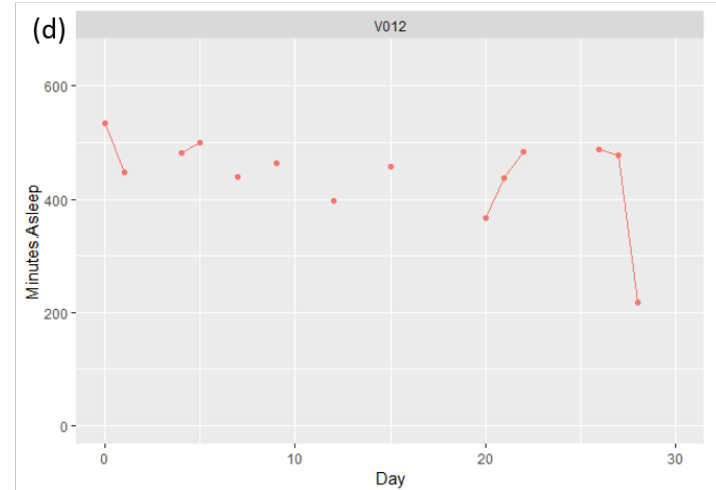
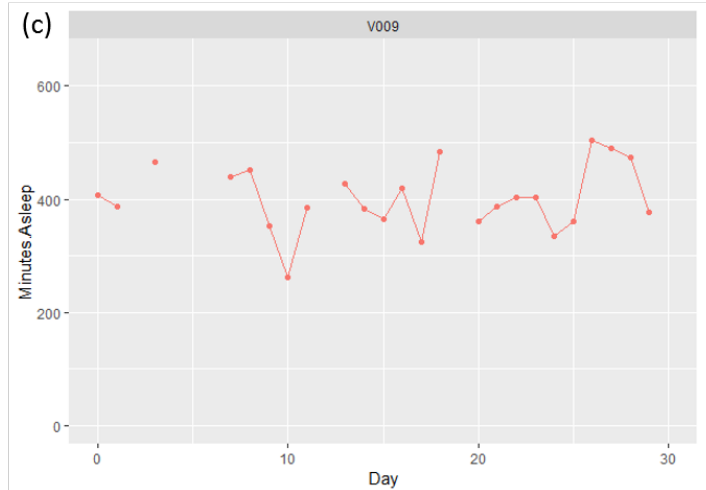
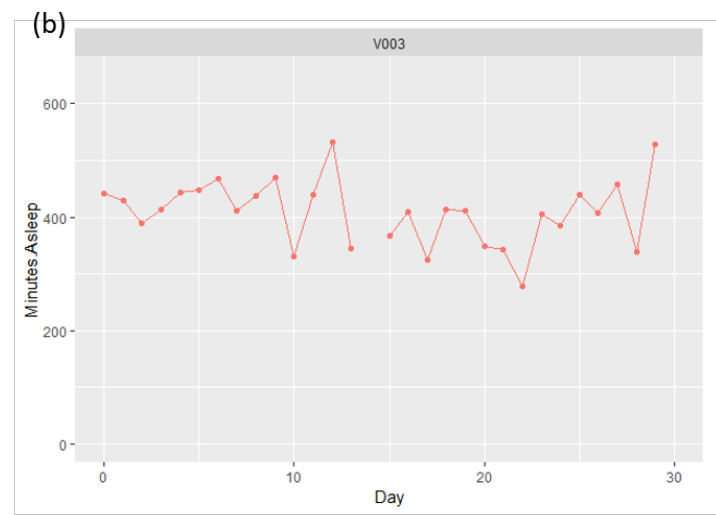
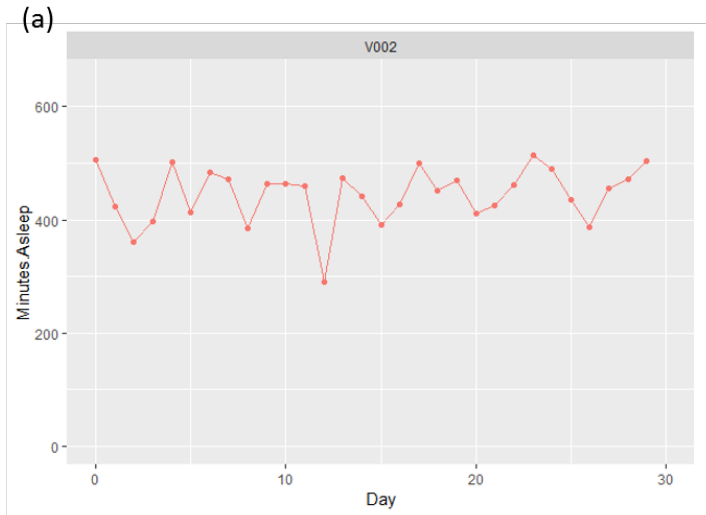


Some Challenges



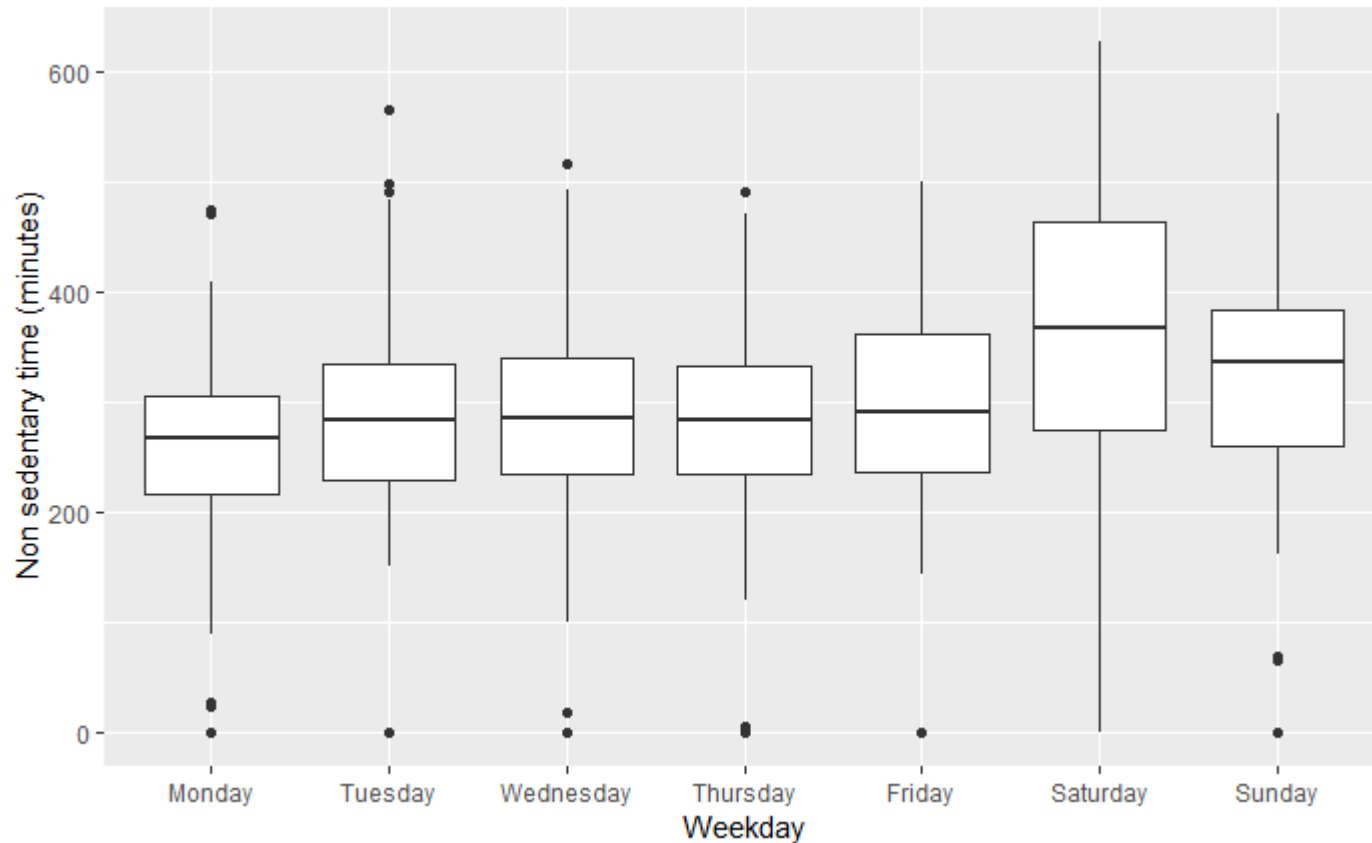
Challenge 3: Generating meaningful insights

Individual Patient Level



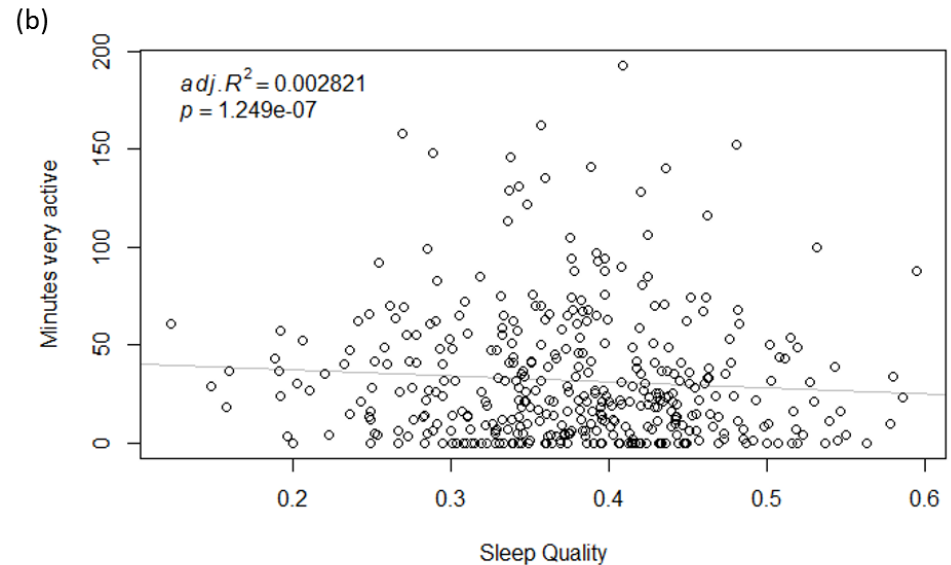
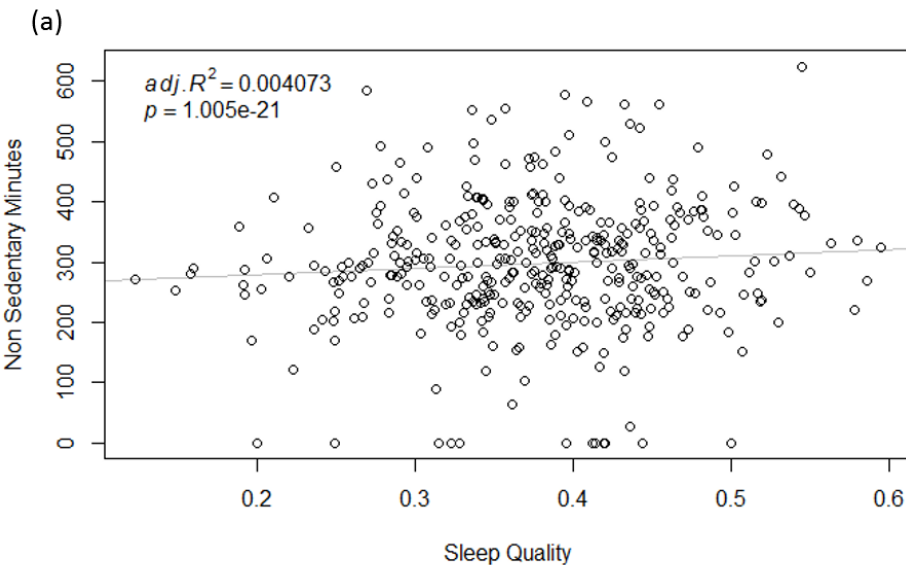
Challenge 3: Generating meaningful insights

Across a Clinical Trial Population



Challenge 3: Generating meaningful insights

Investigating Relationships in the Data



Challenge 3: Generating meaningful insights

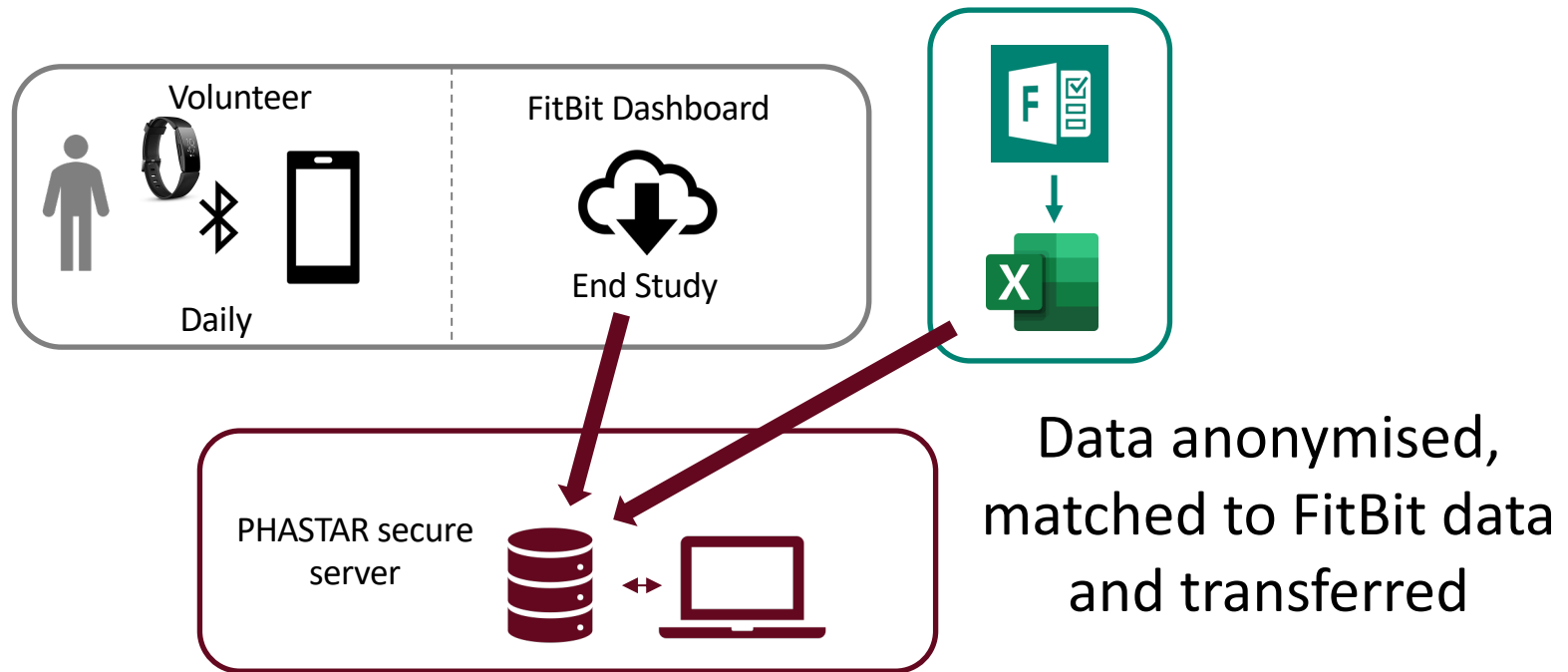
As an objective measure of Subjective Outcomes

- Can the data from FitBit be used as an objective measure of subjective outcomes?
- Example general well-being
 - The World Health Organization's five well-being index (WHO-5)* is a short self-reported measure of current mental well-being over the previous 2-week period
 - Participants completed the questionnaire at the start, during and at the end of the study



Challenge 1: Data Connectivity

Aggregating WHO-5 questionnaire results with the FitBit data



Challenge 3: Generating meaningful insights

Using FitBit data to Model WHO-5 scores (well-being)

Apply multiple regression with repeated measures to FitBit data and WHO-5 scores.

Effect	Standardized Estimate of Coefficient	P-value (5% Significance level)
Intercept	-0.01981	0.0029
Baseline WHO-5	-0.5725	0.0007
Mean Calories Burned	-0.4286	
Mean Minutes Asleep	-2.8852	
Mean Minutes Deep Sleep	3.6535	
Mean %Deep Sleep	-2.8826	
Median Steps	0.6561	

*Model A estimates for coefficients
(AICc score 228.5)*

Effect	Standardized Estimate of Coefficient	P-value (5% Significance level)
Intercept	-0.02602	0.0022
Baseline WHO-5	-0.5751	0.0021
Mean Calories Burned	-0.3611	0.0410
Mean Minutes Time in Bed	-0.5054	0.0056
Median Steps	0.5278	0.0031

*Model B estimates for coefficients
(AICc score 238.9)*

Challenge 3: Generating meaningful insights

How does the FitBit data effect the WHO-5 scores

WHO-5(b) score most impacted by increasing number of daily steps followed by reducing their time in bed.

Apply multiple regression with repeated measures to WHO-5(b) scores.

Increasing median daily steps by 1000 will raise the WHO-5(b) score by 3.1

Reducing the mean time in bed by 30 minutes will raise the WHO-5(b) score by 4



	Estimate	Standard Error	t value (5% significance level)
Intercept	3.6535	0.029	129.007
Baseline WHO-5(b)			
Mean %Deep Sleep	-0.3611	0.0410	-8.81
Mean %D	-0.5054	0.0056	-90.0
Median S	0.5278	0.0031	170.0

B estimates for coefficients
(AICc score 238.9)

Summary

- There are many challenges associated with the use of data from wearable devices in clinical trials
- Devices and manufacturers record different parameters and make different measures available
- Generating meaningful insights can be challenging given the large, noisy data produces
- With more data it may be possible to have objective measures for more subjective events which could offer value to physicians, clinical trial teams and patients.

Thank You, Questions?

Acknowledgments

The authors would like to thank all volunteers who took part in the study or contributed data.