The Use of Connected Devices in Human Research

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Abstract

Human research typically involves a high degree of complexity from study setup to data review. This area also comprises a broad array of study types with a myriad of variables that can be challenging to capture in an ambulatory setting. The complexity of ambulatory studies also increases greatly as the types of products included in these studies evolve. The use of novel and innovative digital technologies could help to fundamentally simplify study setup, execution, and data review to better accommodate changing product complexity and to provide more inclusive endpoints to address regulatory concerns. In order to address this need, a research platform, PUB Central, was created to build a link to a variety of connected devices and unify study setup across a range of human research categories.

Introduction

PUB Central was developed as a web-based research hub that allows for study setup, automation of surveys and questionnaires, integration of connected devices (such as for real-time physiological measures), built-in data analytics, and the addition of machine learning tools for the prediction of harmful or potentially harmful constituent outputs. By leveraging this platform with a variety of connected devices, the collection of physiological attributes (heart rate, blood pressure and sleep cycles) and behavioral use patterns (puffing characteristics) can be combined while maintaining the security of subject data. Utilizing connected devices with a unified software solution eases the collection of complex data sets in ambulatory environments and simplifies the requirements of subject participation in studies.
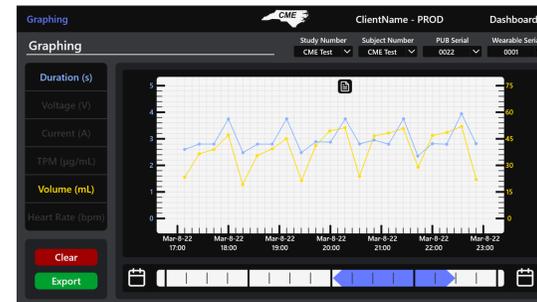
Customized Research Hub
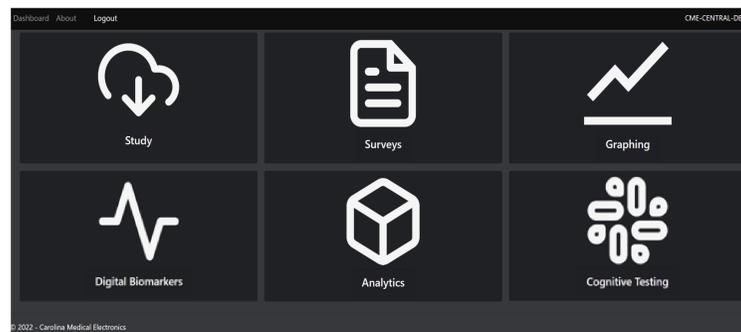
An adaptable research hub (PUB Central) was created to provide a robust tool kit to provide solutions for study setup, shipment tracking, survey creation, automation of survey parameters, cognitive testing and data analytics.
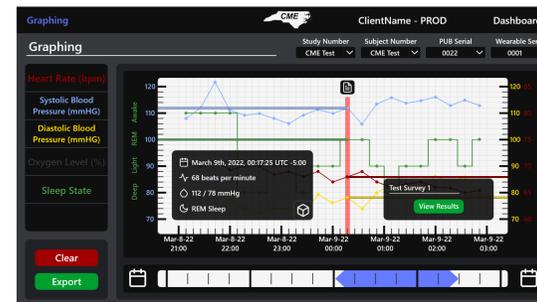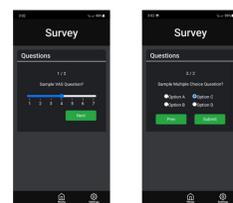
PUB Central

Connected Devices

Topography

Wearables

### The Mobile Applications

PUB App

CME Wear

Surveys can be manually triggered or automatically assigned based on:

- Variables specific to study endpoints
- Participant start/end dates
- Aggregated values
- Discrete variables with predefined thresholds.

Data transfers are achieved through a combination of an Android SDK (software development kit), Bluetooth connectivity and a dedicated web-based survey cloud. Utilizing these tools allows for data transfer across a range of connected devices.

The Environment

Host
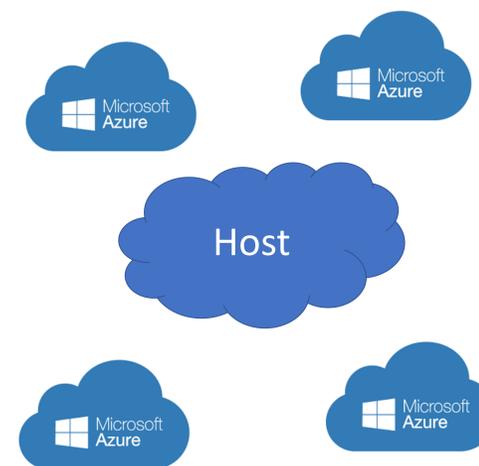
Through a strategic vendor partnership, individual clouds are created for each group to allow for data segregation and individualized Research Hubs. This gives ownership to each group , or area within an organization, while reducing costs for subsequent software needs.

Expanding Endpoints

Common ENDS Endpoints   n = 71

Variable	Mean	St. Dev.
Mean Puffs Per Day	117.9	+/-77.36
Inter-puff Interval [IPI] (Secs)	4137.53	+/-8377.21
Mean Puff Duration (Secs)	2.14	+/-0.93

Expanded ENDS Endpoints   n = 64

Variable	Low Frequency Users		High Frequency Users	
	Mean	St. Dev.	Mean	St. Dev.
Mean Daily Puffs	33.27	+/-16.34	204.02	+/-47.51
Mean Daily Sessions	7.13	+/-5.55	63.63	+/-34.38
Session Length (Secs)	129.54	+/-265.33	81.97	+/-182.67
IPI with Sessions (Secs)	39.56	+/-59.02	33.34	+/-44.88
Puffs within Sessions	4.55	+/-7.36	3.20	+/-4.06
Mean Puff Duration (Secs)	2.21	+/-1.35	2.18	+/-1.04

By utilizing connected devices, data can be captured in an ambulatory setting allowing for cumulative time-series records to be obtained. This also allows for the expansion of common behavioral endpoints and the ability to differentiate patterns of use with study populations.

*Data presented here are from a 3-week long Alto Topography study.

Conclusions

The Product Use and Behavior Instrument has been used to collect over 3.5 million data points and 1.3 million puffs in the last 3 years across 6 products. The system is adaptable to any ENDS or THP.

Linking connected devices through an integrated software platform, and the establishment of developer accounts with independent wearable companies, allows physiological metrics to be captured directly into the cloud database. This functionality provides a clear path toward compliance with global regulatory standards.

By shifting methodology toward digital platforms and connected devices, more robust datasets are achievable through real-time data collection. These platforms, in conjunction with connected devices, also provides a pathway toward improved reproducibility and reduced variability across study categories.

The future in this space will be dictated by agreed upon standards within the industry around security parameters, connected device to mobile application communication, and clearly defined controls around software and mobile application access.

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