Real-Time Monitoring of the Digital Patient in Clinical Trials

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Objective

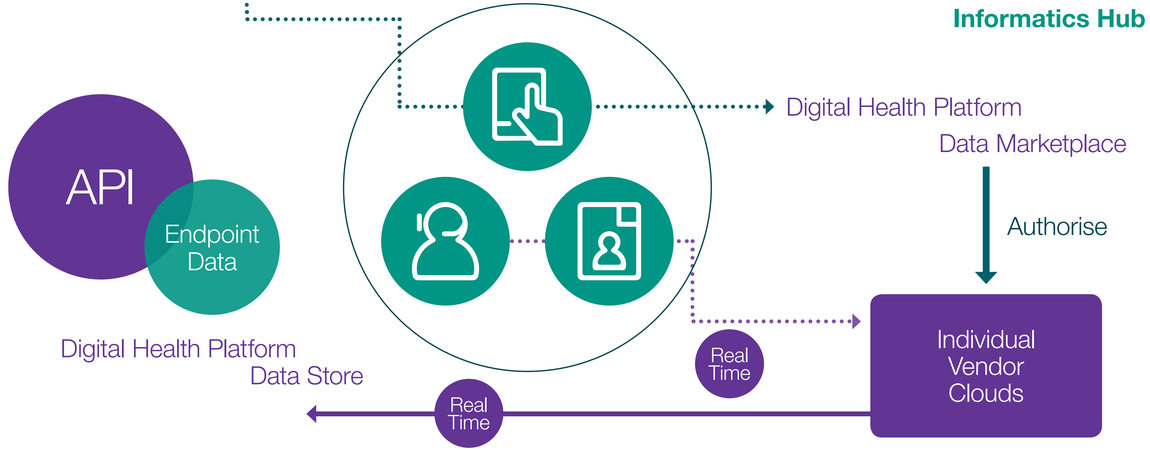
This poster reports a framework for the real-time monitoring of subjects using wearable and patient-centric devices from multiple vendors. Wearable technology is a key component in the design of more patient-centric clinical trials.

Method

We deployed commercially available devices and sensors to a number of healthy volunteers located in non-clinical settings in multiple countries. We used FDA-cleared and consumer devices to generate physiological data similar to that used routinely in clinical trials: heart rate, activity/sleep, oximetry, weight and blood glucose. The data were integrated into an informatics hub via a digital health platform for central analysis alongside user attributes. We used a unique security token to maintain a de-identified flow of data.

Validic Access Token	Validic User ID
UfVU2vL7K-1nySBhss27	VU-1
Wrs4j-B8_dsv61PoFzjp	VU-2
zQRs63VKLxsL3vWq1ohm	VU-3
Ua_oyr2QsjhCXo9nCS6Q	VU-4
5JBeFXWvcFeaseiTnx36	VU-5

Validic User ID	Validic User ID	Gender	Age	Adverse Events
VU-1	01-001	Male	72	2
VU-2	01-002	Male	61	1
VU-3	01-003	Female	65	3
VU-4	02-001	Male	67	1
VU-5	02-002	Female	81	5

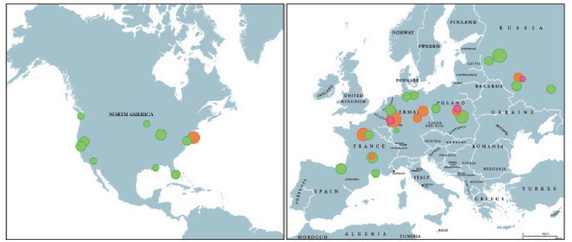


Results

All users successfully used the unique security token provided to them to connect to an online data marketplace maintained by the digital health platform provider, allowing them to authorise the transfer of their data from the device vendor to the digital health platform.

We collected data from the devices via the digital health platform directly into our own informatics hub with a time lag of less than 30 seconds.

We showed that the integrated data could be analysed routinely in the context of risk-based monitoring, safety monitoring, protocol compliance and subject engagement.



Compliance Dashboard

Site ID	Subjects	Activity	Sleep	HR	Wear	Total Score
Site_33	1					
Site_15	5					
Site_23	1					
Site_19	4					
Site_20	8					
Site_48	2					
Site_1	10					
Site_18	6					

Conclusions

To obtain all the outcome measures required by a protocol, multiple devices may be needed. We have implemented a framework to securely collect clinically relevant data from multi-vendor devices into an informatics hub. This approach allows us to measure clinical outcomes objectively and remotely from patients in non-clinical settings going about their daily lives.

Data collection without integration has a limited usefulness, so it was important to show how de-identified data collected through mobile devices can be re-integrated with the full set of clinical data on the patient in a secure environment in real time. Data collected in this way are more objective and have a more transparent audit trail than more traditional clinical outcome assessment instruments. We think there is huge potential in this approach to transform the way we monitor clinical trials, improve the quality of patient data, reduce patient burden, increase patient engagement and redesign the thinking around how we conduct clinical trials.

Disclosure — The authors have no conflict of interest.