Reliable data collection in clinical trials with remote settings infrastructure for data capture from wearables and mobile sensors

Swiss Medtech Day 2019

leitwert.

ETH
Eidgenössische Technische Hochschule Zürich
Swiss Federal Institute of Technology Zurich

reliable data collection in clinical trials with remote settings

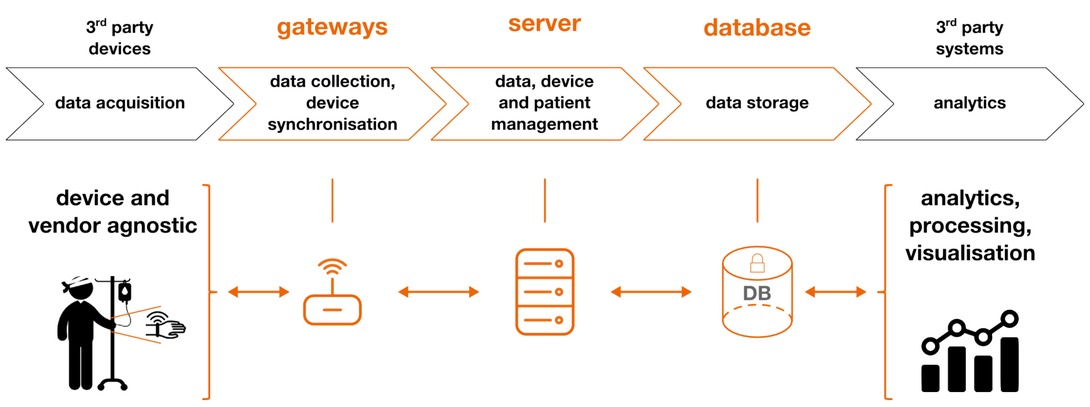
infrastructure for data capture from wearables and mobile sensors

Miro Käch[1], Simon Laube[1], Lukas Geissmann[1], Walter Karlen[2]

[1] Leitwert GmbH, [2] Mobile Health Systems Lab, Institute of Robotics and Intelligent Systems, D-HEST, ETH Zürich

Project Goal

Develop and operate reliable infrastructure for automated data capture from connected biomedical sensors. Scale clinical trials to remote settings with end-to-end ubiquitous technology.



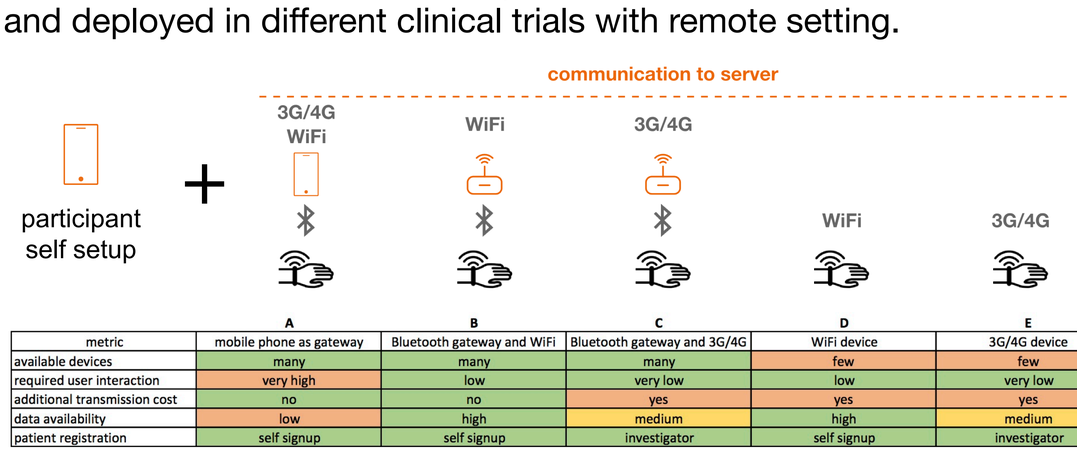
How it works: A gateway collects data when device is in reach and exchanges information with a database. The system is device agnostic so 3rd party applications and systems can be used at both ends.

Background

Clinical trials are transitioning from capturing single data points in time by trained personnel to continuous data collection using wearables. The shift from controlled environments to the point of care in remote settings or at patients home leads to new challenges.

A major challenge is to ensure high data quality and availability. The goal of our approach is to **enable remote data collection at scale** without the need to increasing the efforts and skills of participants.

The system is based on the Leitwert DMS platform, which is used in stationary settings in hospitals for continuous monitoring of hospitalized patients (a co-development with the University Hospital Basel). The application for hospitalized patients in stationary settings was presented at this conference in 2018. In cooperation with academic partners and medical device companies the system has since been further developed and deployed in different clinical trials with remote setting.



metric	A mobile phone as gateway	B Bluetooth gateway and WiFi	C Bluetooth gateway and 3G/4G	D WiFi device	E 3G/4G device
available devices	many	many	many	few	few
required user interaction	very high	low	very low	low	very low
additional transmission cost	no	no	yes	yes	yes
data availability	low	high	medium	high	medium
patient registration	self signup	self signup	investigator	self signup	investigator

Strategies for end to end connectivity: It can be differentiated between devices that require a gateway to communicate with the internet (A, B, C) and those that are able to establish a direct connection (D, E). The best strategy depends on the specific tasks, the participant group, type and amount of data to be transmitted as well as the geographic setting and available devices. A, B and C were used in different projects, a trial with setup D is in planning.

Contact

Miro Käch miro@leitwert.ch +41 44 512 29 60

https://clinics.leitwert.ch/

Innovation

We combine our automated data capture system with mobile applications and web services for participant self registration, on-boarding and optional direct investigator - participant communication.

This not only facilitates compliance monitoring: it paves the way for **systematic integration of wearable medical devices in clinical trial workflows** such as continuous measurements of vital signs or other sensor data.

Scalability and reliability is achieved by sophisticated **resilient system design**. Risks like interruptions in the communication infrastructure are mitigated based on comprehensive data buffering and self recovering systems.

Besides increasing the quality and efficiency of data collection in trials and **lowering participant burden** and **data acquisition cost** the presented approach allows systematic objectification of patient reported outcome trough digital biomarkers**.**

The system is **Good Clinical Practice (GCP) compliant** and can directly interact with the investigator's preferred Electronic Data Capture (EDC) systems (e.g. RedCap) via Application Programming Interface (API).

The scalability will be demonstrated and validated in an international device validation trial with up to 1000 gateways, starting in Q2 2019.

Business Potential

Continuous and reliable data collection remains a major challenge in the medical field. At the same time, there are major market trends that rely on solid data capture. For example, the number of clinical trials - in the pharmaceutical industry only - has quadrupled from 2009-2019, new and stricter regulations like MDR will further increase the need for efficient and economical methods for clinical trials especially for the medical device industry in 2020ff.

Furthermore, advances in sensor and bio technologies drive the development of wearable medical devices, which target remote settings (e.g. for chronic disease management) and in turn are required to be validated in clinical trials themselves.
Finally, data analytics technologies like artificial intelligence (AI) drive the demand for large amounts of high quality data. Based on these developments, there is a huge unmet need for reliable data capture infrastructure which can only be expected to increase even more in the future.

For medical device companies: sensor and device **validation trials** are facilitated and accelerated while collection of large amounts of raw data pave the way for algorithm development or training of AI models.

For pharmaceutical companies and CROs: we provide **continuous real time real world data** from validated medical devices for Phase I – IV clinical trials.

For clinical research: we enable exploratory studies for the development of next generation devices, digital biomarkers and data driven treatment concepts.

Beyond: the DMS technology stack is also well suited as middleware for **telehealth applications** e.g. to complement video chatting with live streams of vital signs and medical sensor data.