Abstract

An increasing amount of data are collected through wearable devices during ambulatory, and long-term monitoring of biological signals, adoption of persuasive technology and dynamics of clinical trials information sharing – all of that changes the possible clinical intervention. Moreover, more and more smartphone apps are hitting the market as they become a tool in daily life for many people around the globe. All of these applications are generating a tremendous amount of data, that is difficult to process using traditional methods, and asks for engagement of advanced methods of data processing.

For recruiting patients, this calls for a shift from traditional methods of engaging patients to modern communication platforms such as social media, that are providing easy access to up-to-date information on an everyday basis. These factors make the clinical study progression demanding, in terms of unified participant management and processing of connected digital resources.

Some clinical trials put a strong accent on remote sensing data and patient engagement through their smartphones. To facilitate this, a direct participant messaging, where the researchers give support, guidance and troubleshooting on a personal level using already adopted communication channels, needs to be implemented. Since the process of such support is very time-consuming and often difficult to assure quality, it calls for revisiting methods for performing a randomized control trial.

A system named *Hubro* for electronic management of clinical studies to address many of the identified challenges has been created. The system supports following processes throughout the study: recruitment, randomization, follow up via messaging, automatic usage data collection and patient self-reported data collection through electronic questionnaires – all accessible from one single user interface. Data collected through tailored questionnaires is what is essentially defined as electronic patient-reported outcome per today, which is currently on the rise in a health research setting.

The modular design of the presented system assures the possibility of functionality enhancement in various levels of the data processing chain. The system has loosely coupled architecture and utilizes pluggable computation modules, with support of artificial intelligence.

Therefore, the system can be extended with additional sources data, but also with data post-processing capabilities, which is useful when discovering various insights or detecting specific patterns.

So far, two studies have used this system – with 50 and 8 participants. The Hubro electronic study management system has significantly improved the feasibility of these interventions through streamlined workflow, electronic messaging and data collection support. The Hubro system has saved a considerable amount of time to researchers when managing the study. The usability of the administration interface of the system on various devices such as smartphones and tablets also allowed a quick turnaround when reacting on requests of participants. Although, researchers have reported a steep learning curve for third-party tools integrated with Hubro that are used for usage analytics and questionnaire distribution. Also, as primary candidates for updates in future revisions, they identified an expansion of existing communication capabilities by a secure communication channel directing from participants to researchers; implementation of tools assisting data extraction and formatting; and introduction of reminders and recruitment planning functions.