in all phases of the two studies, while the system developer has provided technical support (service availability assurance and data extraction support).

2) Based on the feedback from the researchers, the following new functionalities and system updates would be appreciated: integration of reminders to the researchers; integration with more advanced recruitment capabilities other than those currently implemented; recruitment scheduling and monitoring; notifications; more secure implementation of the messaging function.
3) The previously mentioned connection between the systems' user-ID (anon-ID) and data in third-party systems (Piwik/Matomo, LimeSurvey) was confusing when performing various operations such as fetching user data or exporting usage logs. Two respondents raised this issue. Another concern was expressed about the utilization of the third-party tools – the app usage analytics platform (Piwik/Matomo) and the survey platform (LimeSurvey), specifically questioning their choice due to their complexity and low user-friendliness. These tools are complex, designed to suit a wide range of use cases, and therefore they are coupled with a variety of options and settings, that might be confusing for researchers/study administrators, who only need to use a specific subset of these functions. Although, within the narrowed portfolio of alternatives, these tools stand out among other choices in terms of integration possibilities.
4) Researchers mentioned the following optimizations to minimize manual efforts and frequent check-ups in the following ways - a better process of keeping track of the recruited patients, i.e. placing them into groups; more understandable user-interface; easier distribution of questionnaires and tools (applications); more streamlined process of questionnaire completion checks, and a user interface to interact directly with the LDAP servers (e.g. removing participants).
5) From the researcher's point of view, it was suggested to implement a two-way messaging function, which would mitigate the necessity to use an ordinary e-mail as a primary communication channel from patients to researchers. Also, the user interface for user's look-up based on their e-mail addresses was perceived as a candidate for improvement, as it required a manual effort in terms of e-mail client utilization as discussed within Question 2. Terms *Texts* and *Messages*, used in the Hubro system, were seen as potentially misleading and confusing for an uneducated researcher using the system. From the patient's perspective, a case was reported when a patient was able to only fill half of the questionnaire, due to accidentally clicking on send button. Re-submitting the un-finished questionnaire (i.e. an edit function) should thus be implemented.
6) PI/project manager was able to use the Hubro functions to recruit and randomize study participants through the smartphone, e.g. when travelling. The Hubro system and its third-party components are web-based and responsive so that they can be used with mobile devices such as tablets or smartphones.
7) Mixed opinions have been reported on the user-friendliness of Hubro's user interface. All agreed that it was a complex and steep learning curve for both main third-party components, the Piwik/Matomo and LimeSurvey. The complexity of these tools was discussed in question 3.

Researchers stated that no negative feedback has been reported about Hubro from the study participants.

In addition, we present a summary of identified missing functions, functions that need improvement and problems with the Hubro system in Table 2.

Response categories	Summarized responses
Appreciated functions	• Reliability • Cost-effectivity • Convenience of participant management
Functions that should be implemented in a more user-friendly way	• Easier user-interface • Integration of reminders • Integration with more advanced recruitment capabilities other than those currently implemented • Recruitment scheduling and • monitoring notifications • More secure implementation of the messaging function
Problems with the Hubro system	• User's look-up (deanonymization) based on their e-mail addresses requires much manual effort • Should allow editing and re-submission of questionnaires

Table 2 Summary of identified missing functions, functions that need improvement and problems with the Hubro system.

As mentioned, most of the functionalities were implemented and used. However, data analysis was only performed to a limited degree using Hubro. Data extraction, organization and analysis was performed manually through a collaboration between a researcher and a developer. This took several months (not effective time, but to coordinate) and data needed to be shared via a separate secure research platform. The secure data-sharing platform required additional and un-planned set-up of the files and granting access. The bulk of the un-planned work included the researcher learning three different formats of anonymous data as well as how to reformat, translate and analyse them using a more well-known program such as Microsoft Excel. This reinforced the challenges as well as opportunities of developing the Hubro system further, to support also more of the last parts of clinical trials, analysis and conclusions.

4 DISCUSSION

Considering the nature of health data, rolling the Hubro system out as a service to end-users might be troublesome, due to compliance matters. Also, a naïve, on-premise distribution might be complicated because of many onboarded components resulting in a significant workload on IT system operators. The way for seamless delivery and

operation could be a use of self-sealed container-based architecture orchestration through the management system like Kubernetes, bringing in the best of both worlds – an easily manageable and configurable system running on hardware located within the premises of the institution, or within a cloud computing environment.

The concept of a user ID and anonymous ID was introduced to provide study participants with a way to quickly join the study, i.e. by providing a 5 characters identifier (user ID) that was connected fully qualified GUID-based identifier (anonymous ID) in the database. Both identifiers have to be used when performing basic operations such as, e.g. extracting user data from the database, deanonymizing the user, which introduces an additional level of manual effort. In future, this concept should be revisited and implemented in a more user-friendly manner.

It is also important to note, that Hubro, currently, neither collects nor generates documents formally required by regulatory authorities or compliance protocols i.e. Trial Master File (TMF) or its electronic equivalent (eTMF), that must be maintained alongside the electronic study management system separately in a dedicated repository. Similarly, the Hubro keeps a very limited audit trail of specific actions, that require access to the link table, or the implemented link function respectively (deanonymization).

5 CONCLUSION

The motivation behind the need to move to new study management methods is driven by the fact that traditional methods for clinical interventions may provide outdated results, given the fast pace of technological advances. Therefore, it is necessary to react on current trends and evaluate these changes promptly. Inadequate old methods are used on new types of interventions that involve the processing of vast amount of data, dynamic support and troubleshooting of potential participant's technical problems during the study and inclusion of various types of new technology. Commonly used clinical trial study management systems are too scattered and time-consuming, to provide results in a reasonable time as they are not systematically addressing the identified challenges.

The system we designed proved to improve areas of recruitment, enrollment, engagement, and retention of participants into an RCT and a clinical trial. Use of the system objectively improved the time spent managing individual patients in the study. Also, the primary investigator (PI) stated the feedback from audience was overly positive when presenting the system to other researchers at conferences, workshops, and other occasion. Although there are several other products available out on the market, none of them is integrating such a generic toolset, aiding the process of patient recruitment, randomization, survey and consent distribution, patient follow-up, data processing and trial closure. Inconclusive clinical trials, because of clinical trials' disrupted nature, may result in a delay of development of optimal treatment practice, and/or an additional financial burden.

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