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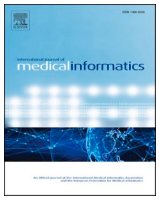

Project Management Digitalisation of the Clinical Research at the University Medical Centre: Good Practice of using REDCap as a Digitalisation Tool

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ABSTRACT

Objective: The digital tool REDCap (Research Electronic Data Capture) was implemented at the University Medical Centre Ljubljana (UMCL) with the goal of digitalising and streamlining research processes. This study aimed to assess the efficiency and transparency of clinical research following the implementation of REDCap.
Methods: The implementation of REDCap for funded research began in 2021. It comprised four key steps: (I) the initial creation of Central Research Registry, followed by additional functionalities including (II) the establishment of the Central Database for 'Pre-Contract Activities' for clinical trials; (III) the integration of Reporting on Research Progress directly into the Central Research Registry; and (IV) the development of a semi-automated Workflow for internal agreements.
Results: Between 2021 and 2023, UMCL established a Central Research Registry using REDCap, transitioning from paper-based to digital data collection for over 2,500 research projects. These projects included clinical trials, national and international studies, as well as academic research. In addition to serving as a registry, the central system provided comprehensive data management, streamlined communication, and enhanced collaboration among stakeholders in clinical trial research at UMCL. The implementation of REDCap significantly reduced administrative burden and shortened the time required to finalise clinical trial agreements from 202 to 147 days. It also improved coordination, transparency, and real-time monitoring of research activities, facilitating more efficient research execution. Additionally, the digitalisation of internal agreements processes between researchers and stakeholders within UMCL improved coordination and expedited research execution timelines. Furthermore, REDCap enabled real-time monitoring of research progress, further contributing to the efficiency and transparency of research activities.
Conclusion: The digitalisation of research processes using REDCap improved the organisation and execution of research, leading to greater efficiency and transparency, reduced administrative workload, and enhanced collaboration. This approach contributed to higher-quality research outcomes and ultimately benefited patient care.

Background

Project management can be defined as a structured approach to the efficient coordination of processes [1–3]. It enhances effectiveness, communication, and collaboration by fostering transparency and accountability [1,3–5]. Traditionally, project management is associated with one-time initiatives that are distinct from routine operations. However, at the University Medical Centre Ljubljana (UMCL), project-based clinical research is a core and continuous institutional activity. As a result, a structured project management framework is integrated into the organization's routine operational processes. Due to the complexity and multidisciplinary nature of clinical research, effective project management is essential to ensure the timely, cost-efficient, and high-quality outcomes [1,2,6,7]. The management of clinical trials is a particularly complex, multi-phase process that spans from initial planning to final completion [7,8].

UMCL, the largest hospital in Slovenia, manages a diverse range of ongoing research projects. Annually, UMCL handles between 150 and 250 new projects and 350 to 450 ongoing funded projects, totalling 500 to 700 projects. Prior to 2021, UMCL relied on paper-based case report forms and manual data entry. Most of the documentation was in paper

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form, making the processes of data collection, storage, and analysis prone to errors. These challenges led to a search for more efficient solutions, resulting in the adoption of the REDCap (Research Electronic Data Capture) tool as part of a broader digital transformation [7,9,10]. REDCap was selected for its widespread international use, secure structure, customizability, and open-source model. Compared to commercial tools, it offered flexibility, low cost, institutional control, and strong community support—key factors for large-scale, regulated research at UMCL. REDCap is a web-based application that facilitates the creation of electronic surveys and data collection forms. In addition to its primary function, it also enables the creation of diverse databases. The application is used by thousands of institutions across numerous countries worldwide [11]. REDCap provides real-time insights [2] and supports data collection, administrative processes, and clinical trial monitoring [9,11].

Herein we report on REDCap implementation in research project management and its outcome.

1. Methods

The increasing complexity of clinical research, regulatory demands, and limited resources have prompted institutions to seek more efficient research management solutions. While many efforts focus on the digitalization of documentation, converting paper-based formats into electronic ones, fundamental changes are often required. In this context, we interpret the implementation of REDCap at the UMCL as an example of digital transformation, rather than mere digitalization. Digital transformation involves changes in processes, people, and structures [10].

This case demonstrates how the adoption of REDCap resulted in systemic changes to workflows, coordination, collaboration, and research capacity. To address the issue of fragmented oversight, the implementation of REDCap began in 2021 with the creation of Central Research Registry. A four-stage approach was designed to reflect key institutional goals: centralization, transparency, monitoring, and collaboration. The implementation of REDCap was led by the Centre for Clinical Research at UMCL, which initiated the formation of a multidisciplinary team comprising researchers, coordinators, data managers, and administrators. The project followed a phased plan aligned with the four stages, with institutional support ensuring effective governance. Beyond its role as a registry, the system includes features specifically tailored to the needs of clinical trials. It supports data management, streamlined communication, and collaboration among clinical trial stakeholders. The configuration of the Central Research Registry is presented in Fig. 1.

At the UMCL, REDCap is hosted on institutionally managed physical servers within a secure internal IT environment. The system is not cloud-based. It features SSL-secured access, a firewalled perimeter, and daily data backups. User access is controlled through institutional domain authentication and role-based permissions. Email notifications are transmitted via secure SMTP servers maintained by UMCL.

Step I: Establishment of the Central Research Registry.

Step I aimed to centralise project tracking and provide institutional visibility. Before REDCap, projects were managed individually by researchers, without a unified registry or centralised oversight. To address this, the Central Research Registry was developed and structured into five categories: 1) Clinical trials, 2) Nationally funded research programs, 3) National research projects, 4) International projects and 5) Academic studies. We created the respective forms for each category and imported data from various sources. For Nationally funded research programs, and for National research projects overseen by the Slovenian Research and Innovation Agency, digital solutions have already been in place, providing access to data via Application Programming Interfaces (APIs). This allowed us to retrieve and import all available data for these two categories into the Central Research Registry using REDCap's Data Import Tool (CSV import). To extract the data and prepare the necessary CSV files, we developed scripts in the R programming language. For international projects, existing application systems already consolidate relevant data. Approved projects are transferred to the Central Research Registry through pre-prepared CSV files. The same procedures have been established for the internal research (Academic studies).

For clinical trials, which were historically entirely paper-based, new electronic case report forms (eCRFs) had to be developed and data was entered manually.

The Central Research Registry at UMLC has been collecting data from different data-based sources dating back to 2007.

Step II: Establishment of the Central "Pre-Contract Activities" Database.

This step aimed to streamline the complex pre-contract process for clinical trials. Previously, this process relied heavily on paper-based forms and informal communication, leading to inconsistency across

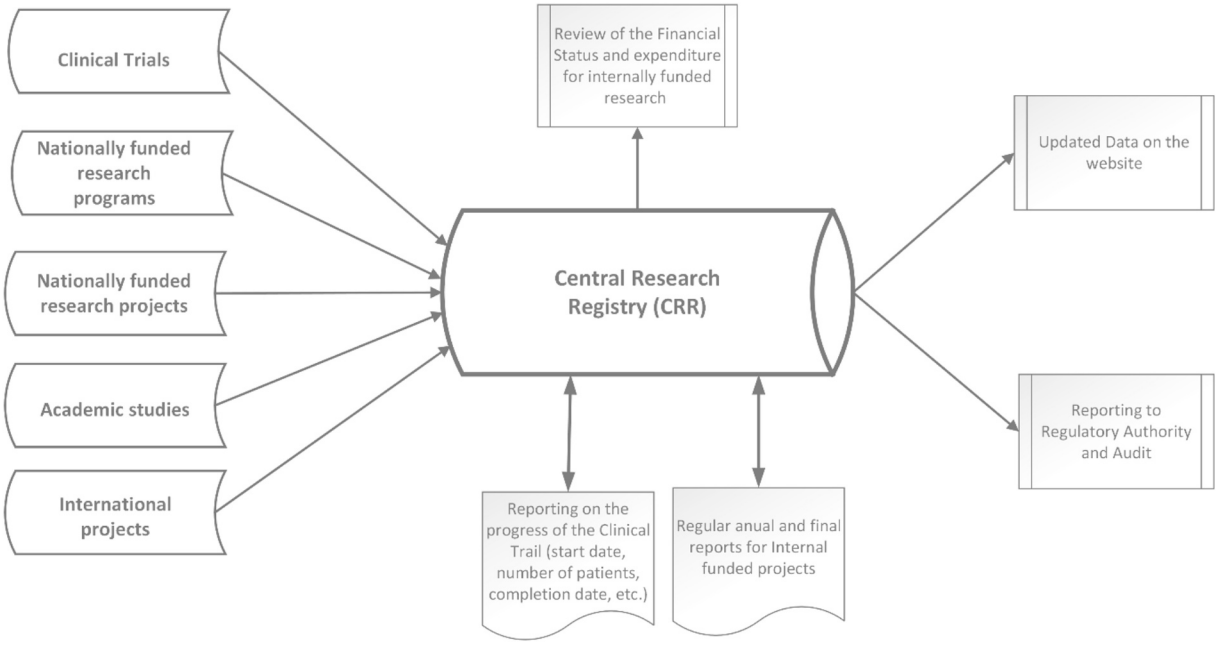

Fig. 1. Scheme of the Central Research Registry in the REDCap.

departments. The new REDCap project introduced a unified digital environment to manage all required steps before finalising clinical trial contracts ('Pre-Contract Activities'). Each step is organised as an event in REDCap, with forms and/or surveys to collect required data for contract finalization between UMCL and the sponsor. This approach not only streamlines clinical trials management but also simplifies the entire process.

Step III: Reporting on Research Progress Directly from or to the Central Research Registry.

The goal of Step III was to simplify reporting requirements and ensure that research progress data is entered directly by the source, improving efficiency and data quality. Before REDCap was implemented, researchers submitted paper reports, which administrative staff had to manually re-enter into the system. To streamline this process, we introduced digital surveys within REDCap and utilised "Survey Distribution Tools" to send questionnaires directly to researchers. Direct data entry by the original source reduced workload and enhanced data accuracy by eliminating transcription errors. For clinical trials, surveys containing essential data were designed for annual reporting and accompanied by multiple reminders. For academic studies, we developed electronic questionnaires tailored to project-specific content. We enabled electronic reports to be sent to reviewers for feedback and approval.

Step IV: Establishment of an Electronic Process for Internal Agreements among Research Collaborators within UMCL.

This initiative aimed to enhance internal collaboration by digitising the agreement process between investigators and hospital departments such as pharmacy and laboratory. Previously, these agreements were managed through email and paper-based communication, resulting in delays and limited traceability. A separate project was established for clinical trials within REDCap. To streamline this, a semi-automated workflow was created through an online survey (Fig. 2). New data entry forms were developed for various stakeholders (e.g., pharmacy, laboratory, radiology, etc.), who receive web links to questionnaires prefilled with study data. These are then confirmed or rejected by the principal investigator.

This approach improves data quality by eliminating the need for manual re-entry of existing information, thus reducing the risk of transcription errors. Once feedback is incorporated into the contract, it is transmitted to Central Research Registry. Additionally, the principal investigator submits details about the study team through an online questionnaire (Fig. 2). Once all required information is collected and the contract is signed, the data is transferred to the Central Research Registry via a predefined XML file. This ensures structured data storage and facilitates the provision of necessary information for audits and mandatory website publications. Staff at the Centre for Clinical Research manage workflow events and are notified upon survey completion.

2. Results

In the period from 2021 to 2023, UMCL's project management underwent digital transformation via the REDCap application and the implementation of several organisational improvements. As of this writing (December 2023), the Central Research Registry contained records for over 2,500 research projects. This expansion was achieved without a corresponding increase in administrative staffing, indicating that digitalisation significantly enhanced institutional capacity. Several stages of the internal projects and clinical trials were completed more efficiently due to a reduction in administrative burdens, particularly in tracking project submission and ensuring timely documentation. Previously, these tasks required extensive manual effort and frequently led to delays. The transition to REDCap thus not only improved operational efficiency but also demonstrated the scalability and sustainability of digital research infrastructure in resource-limited settings.

Step I: Results of the Central Research Registry.

Before 2021, data (except for nationally funded projects and programmes) were often incomplete due to the utilisation of manual management procedures. The Central Research Registry established in 2021, contains records of more than 2,500 projects conducted between 2007 and 2023 (Table 1). The majority of these were academic studies (1744), followed by clinical trials (397), nationally funded (217) and international projects (57). The registry enables real-time tracking of ongoing research. As of 31st December 2023, UMCL had 469 ongoing research projects: 305 academic, 88 clinical trials, 14 international projects, 51 projects funded by the national research agency, and 11 Investigator initiated studies (Table 1).

Step II: Implementation of the Central "Pre-Contract Activities" Database for clinical trials performed at UMCL.

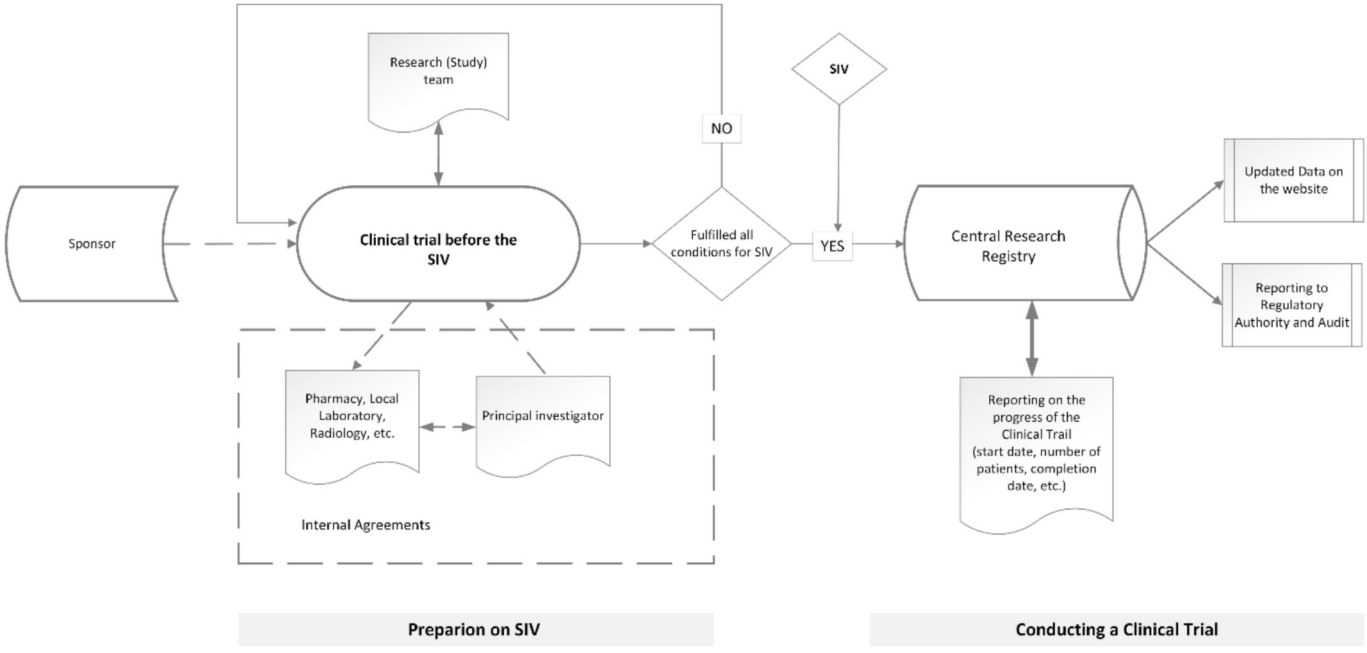

Fig. 2. Pre-Contract Activities scheme and the project management of a Clinical Trial (SIV= Site Initiative Visit).

Table 1
Central Research Registry (CRR) data summary.

Type of the research	CRR (1998–2006)	CRR (2007–2023)	CRR (Ongoing, December 2023)
International and EU projects	NA	57	14
Programs and projects funded by the Slovenian Research and Innovation Agency	113	217	51
Clinical trials	NA	397	88
Academic studies	NA	1744	305
Investigator Initiated Study	NA	20*	11
Total:	**113**	**2435**	**469**

NA- Data not available, *Data available from 2020 onwards.

The "Pre-Contract Activities" database was implemented in REDCap in 2022. It encompasses all steps from site selection to contract execution, enabling real-time data entry and oversight. Following site selection, the process proceeds with the appointment of the Principal Investigator and the listing of suitably qualified personnel in REDCap. The platform integrates key pre-contract steps involving internal stakeholders (e.g. pharmacy, local laboratory, radiology, etc.) and supports agreement revision processes (e.g. legal, financial, GDPR). Once all required approvals are obtained, the Site Initiative Visit (SIV) is conducted. The database provides real time contract status (Fig. 2). The platform ensures a systematic and efficient control of pre-contract processes in clinical research. Furthermore, it guarantees that all required data are collected and, upon contract signature, transferred to the Central Research Registry using REDCap's XML export/import function.

We evaluated the time span from site selection to contract signing for 39 clinical trials beginning in 2022 (Table 2). Of these, 14 were managed manually using MS Word forms, while 15 were managed via REDCap. In manually managed group, the median duration was 202 days (mean 229 days), whereas in the 'REDCap' group, the median duration was 147 days (mean 157 days) (Table 2). This reflects a significant 65-day reduction (CI 95 %: 15 to 143 days, $p = 0.01$; bootstrap test for difference in medians) (Fig. 3). The semi-automated approach, which includes the use of REDCap web surveys to collect essential data, supports the institutional objective of reducing the median time to under 100 days from the initial invitation to the final contract agreement for clinical trials.

Step III: Results from internal surveys conducted through the REDCap system.

Surveys regarding the status of clinical trials were distributed to Principal Investigators in October 2022, April 2023, and October 2023. In October 2022, 66 % of recipients responded within 18 days, with reminders sent on the 7th and 14th day. To improve participation, the subsequent surveys were extended to 29 days, with three reminders sent on the 7th, 14th and 21st day. This adjustment led to an increase in on time response rates – rising to 80 % in April 2023 and 92 % in October 2023 (Fig. 4).

Step IV: Establishment of an Electronic Process for Internal Agreements among Research Collaborators within UMCL.

In the final phase, an electronic process for internal agreements was implemented at UMCL. As illustrated in Table 3, the reported timeframes reflect the first year following the introduction of semi-automated surveys for clinical trials. The median time required to collect essential data such as the names, roles, and contact information of the study team members, was 4 days. Internal agreements with Pharmacy had a median completion time of 14 days, while agreements with the Laboratory took a median of 24 days (Table 3). As demonstrated in Fig. 5, shorter durations occurred when only two stakeholders were involved (Centre for Clinical Research – Principal Investigator). Slightly longer durations occurred when three parties were involved (Centre for Clinical Research – Pharmacy/Laboratory – Principal Investigator). Although reliable pre-digitalisation data are unavailable for comparison, these metrics provide a valuable baseline for monitoring internal processes and identifying potential bottlenecks. Similar, digital forms have also been developed for Radiology and other potential collaborators.

3. Discussion

REDCap enabled UMCL to expand its research portfolio without additional staffing, demonstrating how digital tools enhance institutional capacity and operational efficiency. Prior to digitalisation, processes were paper-based, fragmented, and prone to error. With the implementation of REDCap, UMCL transitioned to a centralised, structured system that now supports over 2,500 projects. This shift aligns with the people-process-technology framework [10], involving coordinated changes in workflows, roles, and technical infrastructure to improve research management.

As supported by existing literature, effective project management is essential for the structured planning, implementation, and monitoring [1,6,12,13]. Hospitals require tools such as registries and accessible, high-quality research data to support these functions [5,12,14]. The Central Research Registry, established in 2021 using REDCap, has improved data accuracy and accelerated the workflow from data collection to finalization.

Beyond gains in efficiency and transparency, digitalisation also mitigated a critical organisational risk that is often overlooked: the over-reliance on individual staff members as sole holders of operational knowledge [1,10,15]. Previously, research coordination relied heavily on experienced personnel who managed paper-based documentation and administrative processes. This posed significant risks during periods of absence, resignation, or retirement. With REDCap, essential information is centralised and systematically structured, enabling transparent, team-based study management. This built-in redundancy reduces the risk of knowledge loss and operational disruption.

Conducting a clinical trial is a complex process that spans multiple phases, from initial planning to final completion [7,16]. The digitisation of administrative tasks, such as those supported by REDCap, enables real-time monitoring of research progress, continuous data entry, and the cross-referencing of collected data. Consistent with findings from previous studies [2,16,17], the transition from paper-based to electronic systems improved efficiency, reduced error rates, and decreased the time spent on administrative tasks at UMCL. This digital transformation has not only enhanced research management but has also fostered greater collaboration and transparency among the institution's various stakeholders.

REDCap-based pre-contract management in clinical trials represents a major initiative supporting research at UMCL. Monitoring pre-contractual activities helps ensure steady progress toward contract finalisation. Existing literature highlights that the duration of the pre-contract phase is influenced by ethical approvals, regulatory requirements, institutional procedures, and the complexity of the trial itself [3,5,6,8,16,18]. However, reports on contract negotiation timelines are limited and often lack comparability across studies [3,5,6,17]. At

Table 2
Time (in days) required for Clinical Trial agreement before and after implementation of 'Pre-Clinical Research' procedure.

When	n	Median	IQR	1st Q	3rd Q	Mean (SD)	Range	p-value
Manually managed 'Pre-Contract Activities'	14	202	108	163	271	229 (108)	39 – 429	0.01
REDCap managed 'Pre-Contract Activities'	25	147	99	103	202	157 (100)	18 – 425	

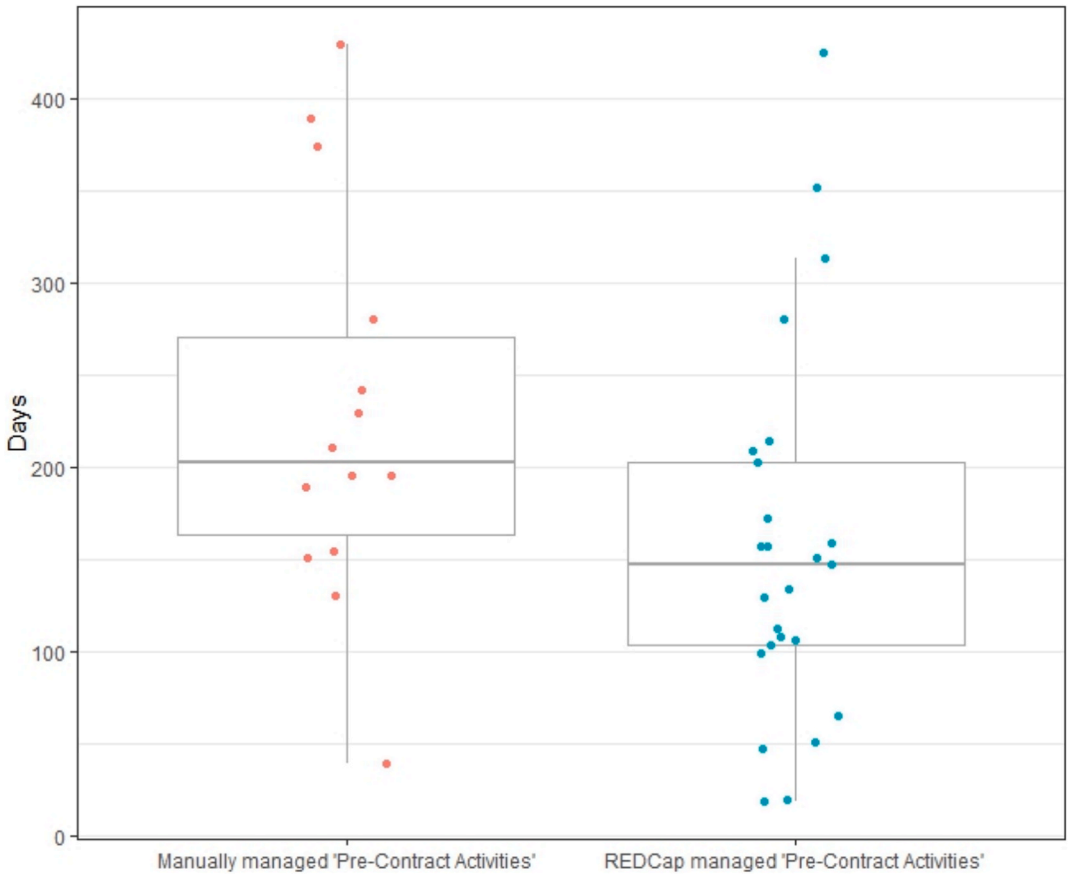

Fig. 3. Duration (in days) required for Clinical Trial agreements before and after the implementation of "Pre-Clinical Activities" procedure.

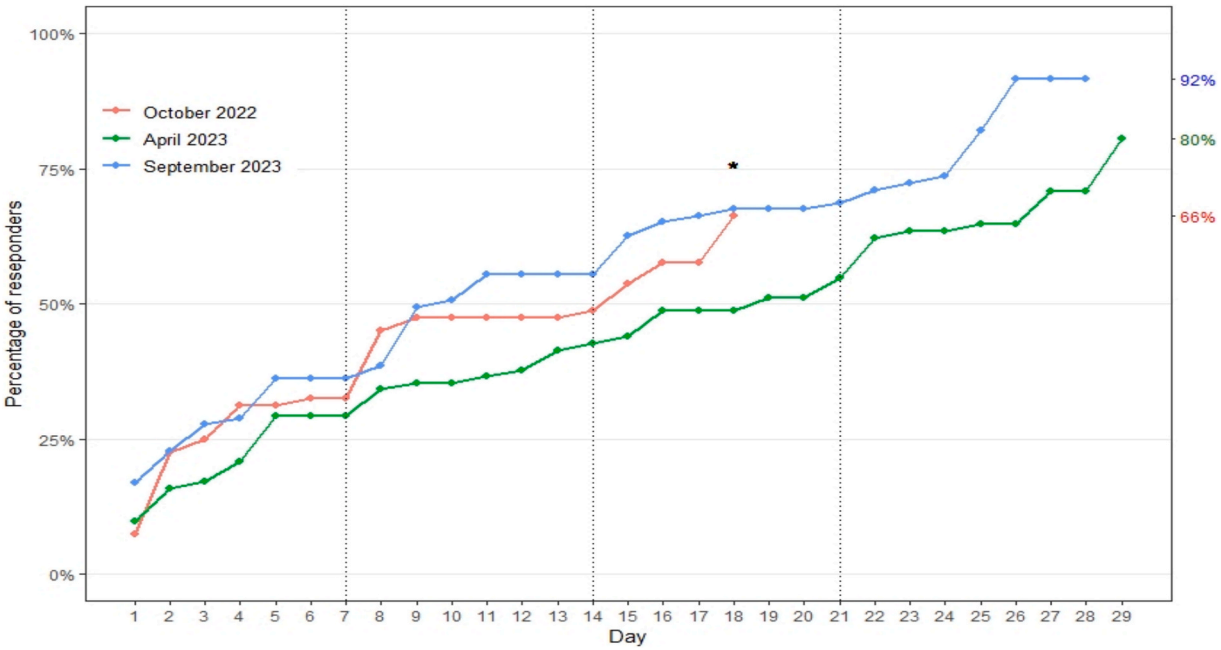

Fig. 4. The percentage of responders (principal investigators of clinical trials) for ongoing Clinical trials by day. The dotted lines represent remainders sent to researchers on the 7th, 14th and 21st day. * *The information collection period was 18 days in October 2022 and 29 days in April and September 2023.*

UMCL, REDCap contributed to a substantial reduction in the site-to-contract timeline – from 202 days to 147 days. This 65-day improvement reflects both the benefits of digitalisation and increasing user familiarity among staff. In addition to accelerating contracting, REDCap enabled real-time monitoring of research activities, continuous data entry, and streamlined administrative workflows.

The usage of REDCap enabled simple surveys that raised responses rates from 66 % to 98 % in one year, as researchers found the process fast

Table 3
Time (days) required to establish internal agreements among collaborators for clinical trial (Local Laboratory and Pharmacy in UMCL).

What	n	Median	IQR	1st Q	3rd Q	Mean (SD)	Range
Laboratory	4	24	10	18	28	22 (12)	5 – 34
Pharmacy	9	14	17	5	22	15 (13)	1 – 41
Study Team	10	4	10	1	11	8 (10)	1 – 26

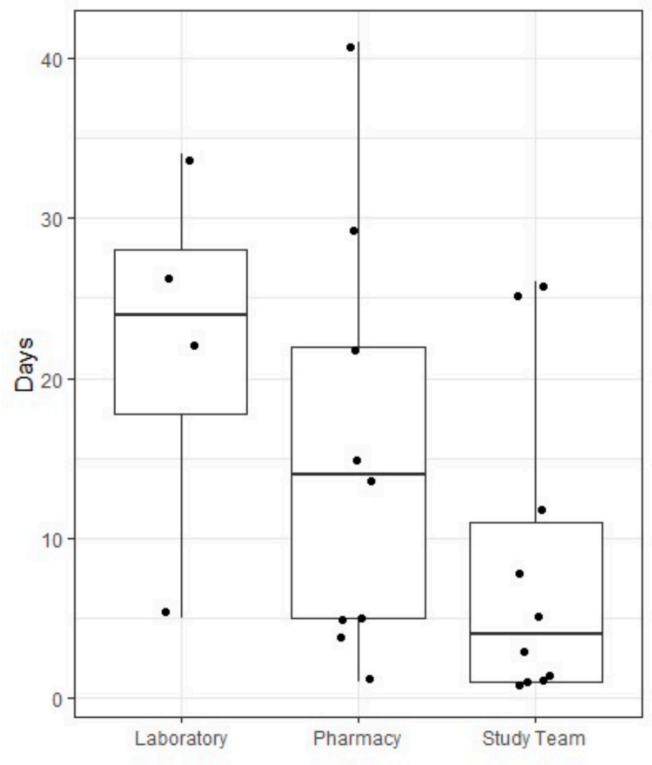

Fig. 5. Time (days) required to establish internal agreements between laboratory or pharmacy and Study Team, and for obtaining information on collaborators in a Study Team.

and user-friendly. The digitisation of administrative processes enabled researchers to focus more on science, enhancing research outcomes. This supports findings that ease of use is critical for the acceptance of new technology during the digitisation process, and a key factor in users' willingness to adopt it [15,19,20].

The digitalisation of internal agreements through REDCap replaced paper-based processes, considerably improving collaboration, tracking, and reimbursements. This transition enabled departments to participate in a clear and more transparent manner. The streamlined system allowed units, including laboratories and pharmacies, to track the services provision, facilitate interdepartmental collaboration, and accelerate administrative procedures. While principal investigators adapted quickly, some departments, particularly laboratories, experienced delays due to missing documentation. These findings support previous reports on the importance of effective interdepartmental coordination for successful research [1,3,16], highlight REDCap's role in optimising workflows, reducing errors, and improving efficiency, and underscore the need for proper preparation and resource allocation in research operations. Moreover, by reducing administrative workload, REDCap enabled researchers to concentrate more fully on scientific work, thereby enhancing research quality.

Despite these improvements, several areas still require further optimization. In particular, the internal agreement processes involving laboratories and pharmacies have been identified as bottlenecks. In the present study, the median time to finalise internal agreements was 24 days for laboratories and 14 days for pharmacies. Addressing these delays – especially through better stakeholder engagement and more effective document management – will support UMCL's goal of completing trial agreements within 100 days, thereby increasing institutional competitiveness. Continued adaptation and refinement of REDCap will be essential to sustaining efficiency gains. Streamlining processes empowers researchers to focus on scientific work with reduced administrative burden and increased transparency.

4. Conclusion

The implementation of REDCap at UMCL enabled the development of a comprehensive and secure central database and improved project management across diverse research activities. The digitisation of several administrative and operational processes ensured centralised and reliable data collection, streamlined workflows, and increased transparency across departments. These improvements reduced administrative burden and enhanced collaboration. Furthermore, researchers gained improved access to critical data for reporting and publications through the Central Research Registry. Our experience supports previous findings that well-governed digital transformation initiatives can enhance institutional performance, provided there is alignment across technology, processes, and people.

Beyond the operational benefits, this experience offers broader insights into how digital transformation can be successfully implemented in highly regulated, resource-constrained environments. Unlike many large-scale IT projects, success at UMCL was not driven by commercial platforms or external consultants but rather by internal coordination, active user involvement, and the phased deployment of open-source infrastructure. This approach led to institutional change not only in process efficiency, but also in governance, legal compliance, and interdisciplinary collaboration. These lessons may be valuable for other public healthcare systems aiming to implement scalable and sustainable digital transformation initiatives.

CRediT authorship contribution statement

Zdenko Garašević: Writing – original draft, Methodology, Investigation, Formal analysis. **Franc Strle:** Writing – review & editing, Supervision, Conceptualization. **Martina Jaklič:** Writing – original draft, Visualization, Methodology, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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