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Case Report

Implementing a Clinical Research Database Management System in an Academic Institute: Lessons Learned

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Abstract: Clinical research is a cornerstone of medical advancement, requiring efficient data management and coordination across multiple stakeholders. This study explores the implementation of a digital research management system at the Faculty of Medicine of the University of Porto (FMUP) to address the challenges posed by its extensive and diverse clinical research portfolio. Given the institution's need to centralize research activities, improve efficiency, and ensure regulatory compliance, the CR-Digital project was launched to integrate a comprehensive database management system. Over a two-year period, FUNDANET was selected and implemented due to its adaptability to FMUP's research framework, its ability to enhance collaboration, and its alignment with legal and financial requirements. The implementation process was structured into seven key phases, with the primary challenge being the alignment of diverse departmental objectives and preferences. These ranged from ensuring seamless interoperability with electronic health records to meeting the usability needs of researchers and administrators. Despite these complexities, FUNDANET successfully provided a robust platform encompassing digital research management, clinical study tools, and advanced data analytics, streamlining research workflows and optimizing decision-making processes. This study highlights the lessons learned during the system's deployment, demonstrating the importance of selecting adaptable technological solutions, fostering stakeholder engagement, and implementing structured change management strategies. The insights gained from this project can inform other institutions seeking to modernize their clinical research infrastructure, ultimately contributing to more efficient, transparent, and data-driven research environments.

Keywords: database management systems; research design; clinical trials as a topic; data interpretation; statistics; software

Introduction

Clinical research is a complex and dynamic field that integrates knowledge from multiple scientific disciplines, bridging primary research, pre-clinical studies, and clinical investigations involving human participants [1]. Its primary goal is to expand scientific knowledge on health conditions, improve prevention and treatment methods, and promote public health advancements [2,3]. Clinical research encompasses various study types, from clinical trials that lead to the development of new drugs, medical devices, and procedures, to observational studies that provide real-world evidence on diseases and treatments.

The Faculty of Medicine of the University of Porto (FMUP) is one of Portugal's leading higher education institutions, recognized for its excellence in medical education and its strong commitment

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to scientific research. Over the past five years, FMUP has secured approximately €17 million in competitive funding and €1.3 million from private entities, including pharmaceutical and medical device companies, supporting 89 scientific projects—20 of which have international reach—focused on advancing healthcare research. Between 2018 and 2023, FMUP facilitated 1,159 clinical studies, including 43 clinical trials registered in ClinicalTrials.gov. The majority (80%) of these studies were investigator-initiated observational studies, while 20% were industry-sponsored multicenter trials. These studies took place across more than 100 healthcare institutions and involved over 11,000 participants.

Given the complexity and volume of clinical research at FMUP, a unified digital platform was required to enhance efficiency, improve research coordination, and strengthen regional competitiveness in clinical research. This necessity led to the development of the CR-Digital project ("Digitalizing Clinical Research in the North of Portugal"), a two-year initiative aimed at implementing an integrated research management system.

This paper outlines the key lessons learned during the development and implementation of the CR-Digital project, highlighting challenges encountered, solutions adopted, and the broader impact of digital transformation on clinical research.

Methods

The CR-Digital project (NORTE-01-0145-FEDER-08344) enabled FMUP to acquire, adapt, and implement FUNDANET, a database management software designed to monitor and control key performance indicators (KPIs) within FMUP's clinical research ecosystem.

FUNDANET consists of three core components:

1. **Digital platform management** – Centralized oversight and administration of research projects.
2. **Digital tools for clinical studies** – Support for study design, execution, and data management.
3. **Advanced data analytics** – Tools for real-time research performance analysis and reporting.

The implementation process was structured into seven key tasks (Figure 1):

- **Task 1:** Conducting a comprehensive review of clinical research frameworks and regulations.
- **Task 2:** Selecting a suitable digital platform for research management.
- **Task 3:** Integrating the platform with electronic health records (EHRs).
- **Task 4:** Developing advanced data analytics capabilities.
- **Task 5:** Conducting usability testing and stakeholder validation.
- **Task 6:** Communicating and disseminating project results.
- **Task 7:** Managing technical and financial aspects of the project.

Each task involved defined milestones and deliverables, including detailed reports and a prototype database management system for clinical research at FMUP.

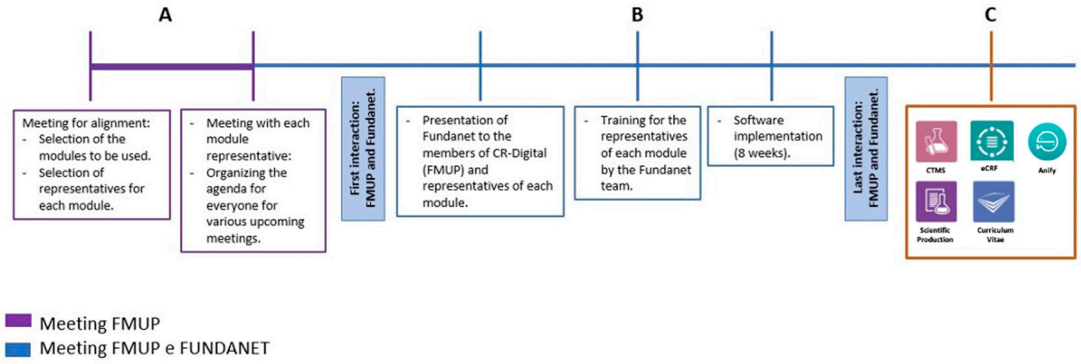

Figure 1. Overview of the project tasks throughout implementation.

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Figure 2. - FUNDANET implemented modules at FMUP.

Results

The implementation of FUNDANET at FMUP introduced a Clinical Trials Management System (CTMS) with five key functionalities:

1. **Project management** – A centralized platform for trial documentation, stakeholder coordination, and integrated data handling.
2. **Recruitment and follow-up** – Tools for patient monitoring, automated scheduling, version control, and anonymized data tracking.
3. **Laboratory management** – Oversight of sample collection kits, test records, kit reception, consumption control, and linkage to patient consultations.
4. **Financial management** – Contract monitoring, clinical trial budget tracking, unbilled activity management, and automated billing proposals.
5. **Performance analytics** – Real-time data visualization through Power BI, generating research performance indicators such as study typology, scope, patient recruitment rates, and institutional participation levels.

Despite its benefits, implementation faced several challenges:

- **Task 1:** Identifying research infrastructure models aligned with FMUP's goals while ensuring compliance with EU and national regulatory frameworks.
- **Tasks 2-4:** Addressing diverging stakeholder preferences, balancing clinician requirements with institutional data governance policies.
- **Task 5:** Securing stakeholder engagement and ensuring usability tests provided meaningful insights for system optimization.
- **Task 6:** Achieving consensus among research departments on communication and dissemination strategies.
- **Task 7:** Navigating bureaucratic complexities related to EU funding regulations and extensive reporting obligations.

Discussion

The CR-Digital project sought to define strategic priorities for leveraging digital technologies in clinical research. Several key insights emerged from the implementation process:

- **The role of digital transformation in research efficiency:** The introduction of a centralized digital platform significantly enhanced efficiency by streamlining project management, reducing administrative burdens, and ensuring compliance with regulatory requirements. Prior to implementation, research teams operated in silos, leading to inefficiencies in data access and duplication of effort. FUNDANET addressed these issues by providing a unified and structured workflow for all stakeholders.
- **Challenges in aligning stakeholder interests:** One of the most significant barriers to implementation was the need to reconcile the differing objectives of various departments. While clinical researchers prioritized ease of data entry and trial setup, administrative teams were more

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concerned with data security, compliance, and financial oversight. By involving all key stakeholders early in the decision-making process, FMUP was able to facilitate adoption and minimize resistance to change.

- **Interoperability and data integration:** Seamless integration with electronic health records was a critical factor in the platform's success. Ensuring that patient data from multiple sources could be harmonized and securely managed was essential for enhancing research accuracy and reliability. The interoperability of FUNDANET with existing hospital and research databases improved data accessibility while maintaining patient confidentiality.
- **Regulatory and financial challenges:** As a publicly funded initiative, the project had to comply with stringent EU funding regulations, requiring rigorous financial tracking and transparent reporting. The experience gained in managing these compliance challenges has provided a roadmap for future large-scale research digitization initiatives.
- **Impact on clinical research scalability and innovation:** By providing real-time analytics and performance tracking, FUNDANET has not only optimized ongoing research projects but has also laid the groundwork for scaling future research efforts. The ability to generate comprehensive data reports has improved decision-making and resource allocation, fostering a culture of data-driven research.

This study underscores the importance of strategic planning, stakeholder engagement, and technological adaptability in implementing research management platforms. The lessons learned from the CR-Digital project can serve as a reference for other institutions aiming to digitize their clinical research processes.

Conclusion

A well-designed clinical trial management platform enhances research efficiency, enables real-time data access, automates critical tasks, and ensures regulatory compliance. Digital transformation in clinical research provides significant advantages, including improved participant recruitment, optimized data collection, adherence tracking, and streamlined trial execution.

The CR-Digital project has reinforced FMUP's position as a leader in clinical research in Northern Portugal. By leveraging digital technology, FMUP has successfully optimized research operations, reduced costs, and created a more efficient and competitive environment for investigator-driven studies. This initiative serves as a model for other institutions seeking to enhance their clinical research capabilities through digital innovation.

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