REVISTA TÓPICOS
ISSN 2965-6672 | Qualis A2

PROJECT MANAGEMENT IN HOSPITAL CLINICAL RESEARCH: CHALLENGES, STRATEGIES AND PERSPECTIVES

GESTÃO DE PROJETOS EM PESQUISA CLÍNICA HOSPITALAR: DESAFIOS, ESTRATÉGIAS E PERSPECTIVAS

Ciências Sociais Aplicadas, Ciências da Saúde • 03/07/2026

REGISTRO DOI: 10.70773/revistatopicos/782857840

Carmela Farias da Silva[1]

Roberta de Almeida da Silva[2]

Cassio Cassel[3]

Luis Fernando Ferreira[4]

Gustavo Escott[5]

Mellina da Silva Terres[6]

Antonio Nocchi Kalil[7]

ABSTRACT

Introduction: Clinical research conducted in large hospital settings involves complex organizational structures, strict regulatory requirements, and multiple stakeholders, demanding robust and adaptive project management approaches to ensure efficiency, compliance, and scientific quality.

Objective: To analyze the main challenges, governance structures, and management strategies associated with clinical research projects in hospital environments, with emphasis on organizational complexity and regulatory demands.

Methods: This study is a narrative review with a thematic synthesis approach. Sources included indexed databases and key guidelines from international and national organizations, including ICH-GCP, ANVISA, and the Project Management Institute (PMI). The analysis was conducted through interpretative synthesis, with studies organized into thematic categories.

Results: Clinical research project management in hospital environments is characterized by high regulatory complexity, resource constraints, and operational variability. Effective governance structures, combined with adaptive and hybrid project management approaches, play a central role in addressing these challenges. Key issues include ethical and regulatory processes, workforce limitations, financial sustainability, and participant recruitment. The integration of structured governance models, performance indicators, and process optimization strategies contributes to improved coordination, compliance, and efficiency.

Conclusion: The adoption of integrated and adaptive management frameworks is essential to ensure the sustainability, quality, and strategic value of clinical research in hospital settings. Strengthening governance and aligning research activities with institutional objectives are critical for enhancing performance and expanding the

impact of clinical research.
Keywords: Clinical Research; Project Management; Research Governance; Hospitals; Health Management.

RESUMO

Introdução: A pesquisa clínica realizada em grandes ambientes hospitalares envolve estruturas organizacionais complexas, exigências regulatórias rigorosas e múltiplas partes interessadas, demandando abordagens de gestão de projetos robustas e adaptáveis para garantir eficiência, conformidade e qualidade científica.

Objetivo: Analisar os principais desafios, estruturas de governança e estratégias de gestão associados a projetos de pesquisa clínica em ambientes hospitalares, com ênfase na complexidade organizacional e nas exigências regulatórias.

Métodos: Este estudo é uma revisão narrativa com abordagem de síntese temática. As fontes incluíram bases de dados indexadas e diretrizes fundamentais de organizações internacionais e nacionais, incluindo ICH-GCP, ANVISA e o Project Management Institute (PMI). A análise foi realizada por meio de síntese interpretativa, com os estudos organizados em categorias temáticas.

Resultados: A gestão de projetos de pesquisa clínica em ambientes hospitalares caracteriza-se por alta complexidade regulatória, limitações de recursos e variabilidade operacional. Estruturas de governança eficazes, combinadas com abordagens de gestão de projetos adaptáveis e híbridas, desempenham um papel central no enfrentamento desses desafios. Questões-chave incluem processos éticos e regulatórios, limitações da força de trabalho, sustentabilidade financeira e recrutamento de participantes. A integração de modelos de governança estruturados, indicadores de desempenho e estratégias de otimização de processos contribui

para a melhoria da coordenação, da conformidade e da eficiência.
Conclusão: A adoção de estruturas de gestão integradas e adaptáveis é essencial para garantir a sustentabilidade, a qualidade e o valor estratégico da pesquisa clínica em ambientes hospitalares. O fortalecimento da governança e o alinhamento das atividades de pesquisa aos objetivos institucionais são fundamentais para aprimorar o desempenho e ampliar o impacto da pesquisa clínica.
Palavras-chave: Pesquisa Clínica; Gestão de Projetos; Governança em Pesquisa; Hospitais; Gestão em Saúde.

1. INTRODUCTION

Project management plays a central role in the organization and execution of clinical research within large tertiary hospitals, where studies are conducted in highly complex environments characterized by strict regulatory requirements, multiple stakeholders, limited resources, and competing institutional priorities. In this context, clinical research projects require structured planning, coordination across clinical and administrative units, continuous risk management, and systematic monitoring to ensure ethical compliance, scientific rigor, and operational feasibility (Gallin; Ognibene, 2018). Effective project management supports informed decision-making, aligns research activities with institutional strategy, and promotes efficiency throughout the research lifecycle.

In high-complexity hospital settings, clinical research extends beyond scientific production and becomes an important component of institutional development. Well-managed research initiatives contribute to innovation in care, expand access to new therapies, and improve clinical outcomes while reinforcing teaching activities and knowledge generation. From an organizational

perspective, clinical research creates value by integrating care delivery, education, and innovation, and by fostering collaboration among clinical teams, academic institutions, industry sponsors, and funding agencies. These interactions strengthen the hospital's strategic positioning, enhance institutional sustainability and competitiveness, and increase its scientific and social impact within complex healthcare systems (Calvario, 2021).

Within this environment, the governance of clinical research becomes a critical component of institutional management. Research governance refers to the system of policies, procedures, and oversight mechanisms designed to ensure that research activities are conducted ethically, safely, and in accordance with regulatory standards, while also supporting transparency, accountability, and quality in research processes. In large academic hospitals, research governance structures help coordinate multidisciplinary stakeholders, manage institutional risks, and ensure that research activities remain aligned with strategic and societal objectives (Gallin; Ognibene, 2018; Woodin, 2010).

Managing clinical research projects in this environment requires approaches capable of addressing uncertainty, regulatory rigor, and operational variability, factors that have intensified with the increasing complexity of contemporary clinical trials (Marcin et al., 2016). Contemporary project management frameworks increasingly emphasize value generation, stakeholder engagement, adaptability, and integrated quality management, shifting the focus from rigid control mechanisms to outcome-oriented governance. These principles are particularly relevant in hospital-based research, where protocol amendments, recruitment challenges, and resource constraints frequently demand adaptive coordination and

responsive leadership. The A Guide to the Project Management Body of Knowledge (PMBOK® Guide) – Seventh Edition reflects this perspective by proposing a principle-based framework designed to support adaptive management and continuous value delivery across diverse and complex project environments (PMI, 2021).

In response to these operational and regulatory challenges, project management in tertiary hospital clinical research often relies on hybrid models that combine predictive approaches—essential for meeting ethical, regulatory, and contractual requirements—with adaptive or agile practices that provide flexibility during operational execution. Project management and process-improvement frameworks such as PRINCE2, AgilePM, and Lean Six Sigma may be applied to optimize workflows, reduce inefficiencies, strengthen coordination among multidisciplinary teams, and improve compliance with regulatory standards. When implemented within a structured governance framework, these approaches contribute to the delivery of clinical research that is scientifically robust, ethically sound, and strategically aligned with the goals of large academic hospitals (Schweikhart; Dembe, 2009; Pawar; Mahajan, 2017; Lei et al., 2020; PMI, 2021).

To support this discussion, a narrative review approach was adopted, aiming to integrate relevant theoretical and institutional contributions to clinical research management in hospital settings, as described in the Methods section and summarized in Table 1.

2. METHODS

This study is characterized as a narrative review with a thematic synthesis approach, aimed at discussing key aspects of project

management in hospital-based clinical research.

The literature was selected through a non-systematic, purposive approach, focusing on scientific publications and institutional documents relevant to clinical research management, governance, and operational challenges in hospital settings. Sources included indexed databases such as PubMed and Scopus, as well as guidelines and regulatory documents from international and national organizations, including ICH-GCP, ANVISA, and the Project Management Institute (PMI).

The selection of materials was guided by the following criteria: (i) relevance to the topic of clinical research management in hospital environments; (ii) contribution to governance, operational, or strategic perspectives; and (iii) applicability to complex healthcare systems. Classical references in the field were also included, without strict temporal restriction. Although no strict temporal restriction was applied, priority was given to contemporary literature and widely recognized foundational references in the field.

The analysis was conducted through a narrative and interpretative synthesis, with studies organized into thematic categories that guided the structure of the manuscript, including governance, operational challenges, and best practices. This approach allowed for the integration of diverse sources to support a structured and conceptually grounded discussion.

The main references that supported the thematic synthesis and conceptual discussion are summarized in Table 1.

Table 1. Key references and their contributions to clinical research project management.

Reference	Thematic area	Type of source	Main contribution
Gallin; Ognibene (2018)	Foundations / Governance	Book	Establishes core principles of clinical research organization and management
PMI (2021)	Project management framework	Guideline	Introduces adaptive, value-based project management (PMBOK 7th edition)
ICH-GCP (2016)	Regulatory / Ethics	Guideline	Defines international standards for ethical and scientific quality
ANVISA (2022)	Regulatory (Brazil)	Guideline	Provides national regulatory framework for clinical research
Marcin et al. (2016)	Operational complexity	Article	Highlights increasing complexity and infrastructure demands in clinical trials
Mitchell et al. (2022)	Workforce challenges	Article	Discusses workforce limitations and management constraints
Speich et al. (2018)	Financial sustainability	Article	Addresses cost structure and resource allocation challenges
Lei et al. (2020)	Agile management	Article	Explores application of agile methodologies in clinical research

3. GOVERNANCE IN CLINICAL RESEARCH

Governance in clinical research refers to the framework that defines roles, responsibilities, decision-making processes, and oversight of clinical research protocols, including both clinical trials and investigator-initiated studies. Its purpose is to ensure scientific integrity, participant safety, and compliance with regulatory and ethical standards. In alignment with the principles of the PMBOK® Guide – Seventh Edition, clinical research governance encompasses key roles operating at strategic, tactical, and operational levels within research institutions (PMI, 2021; ICH-GCP, 2016; ANVISA, 2022). Table 2 summarizes the relationship between governance structures and clinical research activities, highlighting the different levels of governance and their corresponding responsibilities:

Table 2. Roles and responsibilities in the governance of clinical research centers.

Level	Role	Key Responsibilities	Associated Governance
Strategic	Sponsor (industry, agency, or institution)	Funding, study design, protocol definition, compliance audit	Establishes ethical and contractual guidelines; oversees overall performance
Tactical	Research Manager / Center Director	Planning, budgeting, study portfolio management, compliance with institutional policies	Responsible for internal governance (KPIs, compliance, communication with hospital and sponsor)
Tactical / Operational	Principal Investigator (PI)	Leads the study, ensures ethical and scientific conduct,	Conducts the project in accordance with Good Clinical Practice (GCP); accountable to the national ethics

		supervises team and data	committees (e.g., CONEP/ANVISA)
Operational	Clinical Research Coordinator	Coordinates daily activities (recruitment, monitoring, documentation, audit visits)	Supports adherence to protocols and communication between PI, sponsor, and research center
Operational / Support	Technical Team (nurses, pharmacists, data managers)	Study execution, documentation, participant safety	Works under the supervision of the PI and coordination, ensuring traceability and data quality

These governance structures are essential not only for regulatory compliance but also for enabling coordinated decision-making and strategic alignment in complex hospital environments.

4. CHALLENGES IN CLINICAL RESEARCH PROJECT MANAGEMENT

Project management in clinical research presents specific challenges that distinguish it from other application areas. Although the fundamental principles of project management remain applicable, the highly regulated and ethically sensitive nature of clinical research introduces additional layers of complexity that affect planning, execution, and project delivery. The challenges discussed in this section are grounded in the literature presented in Table 1, which highlights the main structural and operational issues addressed in clinical research management.

4.1. Regulatory And Ethical Complexity

One of the main challenges faced by clinical research project management teams is the regulatory complexity associated with

obtaining approval for clinical studies in Brazil. The regulatory process involves multiple oversight bodies, including the Research Ethics Committees (CEP), the National Research Ethics Commission (Conep), and the National Health Surveillance Agency (ANVISA), each with distinct procedures, documentation requirements, and review timelines.

In general, ethical review begins at the institutional level through the CEP and, depending on the thematic area of the study, may be forwarded to Conep for further evaluation. In parallel, regulatory authorization from ANVISA may be required, particularly in studies involving investigational products. Although official timelines are defined for each stage of the evaluation process for each stage of the evaluation process, practical experience shows that approvals frequently take substantially longer due to requests for clarification, protocol adjustments, and administrative delays (BRASIL, 2012).

In an attempt to modernize and streamline the national research oversight system, Brazil enacted Law No. 14,874/2024, which introduced structural changes to the governance of research involving human participants. The law proposes measures to improve transparency, reduce bureaucratic barriers, and establish the National Research Ethics Authority (INAEP), as well as allowing multicenter studies to be reviewed by a single leading ethics committee. Subsequent regulation through Decree No. 12,651/2025 defined aspects related to the implementation of INAEP and the development of a unified electronic system for protocol submission (BRASIL, 2024; BRASIL, 2025). Despite these advances, the transition period has been marked by regulatory uncertainty and operational adjustments, which continue to pose challenges for research management.

4.2. Human Resource Constraints

Another critical challenge in clinical research centers concerns the availability and allocation of qualified human resources. Many research centers operate with small multidisciplinary teams that must manage multiple protocols simultaneously, often with overlapping responsibilities. The technical complexity of clinical trials requires highly trained professionals, including investigators, study coordinators, data managers, and regulatory specialists.

However, the allocation of personnel across studies rarely considers the operational complexity of each protocol. In many institutions, workload distribution is performed empirically, without standardized models to estimate the human resources required for study execution. Although some authors have discussed operational challenges in clinical research management, few structured approaches exist for quantifying protocol complexity and translating it into staffing requirements (Mitchell et al., 2022).

4.3. Financial Sustainability

Financial sustainability also represents a significant challenge for clinical research projects, particularly within hospital settings. Clinical studies require substantial investment in infrastructure, specialized personnel, laboratory procedures, data management systems, monitoring activities, and regulatory compliance. In some institutions, these costs are underestimated, which can compromise operational stability and long-term research capacity.

Structured financial planning and adequate budgeting are therefore essential components of project management in clinical research. Well-developed financial strategies can support investments in

professional training, technological infrastructure, and operational efficiency, while also reducing staff turnover and improving research performance (Speich et al., 2018).

4.4. Participant Recruitment

Participant recruitment remains one of the most critical operational challenges in clinical research. Recruitment difficulties may arise from restrictive eligibility criteria, limited patient availability, low adherence to study participation, or conflicts with routine clinical care.

From a project management perspective, these issues represent operational risks that can affect timelines, costs, and study feasibility. Effective management therefore requires continuous monitoring of recruitment indicators, proactive risk mitigation strategies, and adaptive planning. The use of agile or hybrid project management approaches, as suggested in the PMBOK® Guide – Seventh Edition, can support more flexible coordination and faster response to unforeseen challenges, while maintaining the ethical and methodological rigor required in clinical research (Speich et al., 2018).

4.5. Best Practices In Clinical Research Governance

In response to the challenges described above, several best practices have been proposed for clinical research in hospital environments. Effective implementation depends on structured management aligned with ethical, regulatory, and scientific standards. The adoption of project management practices consistent with the PMBOK® Guide – Seventh Edition can enhance operational efficiency and improve value delivery to stakeholders. Agile

management tools—such as iterative planning cycles, short review meetings, and adaptive scheduling—enable continuous adjustments while maintaining data quality and regulatory compliance. Additionally, the implementation of Standard Operating Procedures (SOPs) and Key Performance Indicators (KPIs) contributes to process standardization, traceability, and performance monitoring (PMI, 2021; Sajdak, 2013).

Another relevant practice is the establishment of a Project Management Office (PMO) dedicated to clinical research. In hospital settings, PMOs can function as governance hubs that align research activities with institutional strategy, optimize resource allocation, and support coordination among multidisciplinary teams. Institutions that adopt integrated governance structures tend to demonstrate greater operational efficiency and stronger institutional returns from research activities.

Finally, successful clinical research programs depend on the development of a research-oriented organizational culture. Integrating clinical research with teaching activities, such as medical residency and academic training programs, fosters continuous learning and innovation. In this context, collaborative leadership—emphasized in the PMBOK® Guide – Seventh Edition—becomes essential for coordinating researchers, study coordinators, administrators, and sponsors through transparent communication and shared responsibility. Together, these practices strengthen governance, promote scientific development, and enhance the strategic value of clinical research within healthcare institutions (Brown, 2019; Shen, 2023).

4.6. Best Practice Example

As an illustrative example, the Multidisciplinary Clinical Research Center at Santa Casa de Porto Alegre Hospital is presented to contextualize the application of governance and management principles discussed in this review. During its initial stage (2021–2022), the Center established foundational governance structures, including defined roles, core Standard Operating Procedures, and regulatory workflows, ensuring compliance with international and national standards such as ICH-GCP and regulations from Agência Nacional de Vigilância Sanitária (ANVISA). This stage provided institutional stability and standardized operational processes necessary to support the expansion of clinical research activities.

Between 2022 and 2023, the Center implemented a structured operational model based on functional segmentation of activities and performance monitoring through Key Performance Indicators (KPIs). These indicators enabled systematic monitoring of regulatory timelines, recruitment performance, protocol deviations, and audit outcomes. At the same time, the Center expanded its infrastructure and adopted hybrid management practices—such as Kanban boards and iterative planning—consistent with recommendations for agile project management in clinical research (PMI, 2021; Lei et al., 2020; Shen et al., 2023).

From 2023 onward, the Center progressed toward operational maturity through continuous quality improvement, multidisciplinary workforce training, and integration with teaching and residency programs. These initiatives addressed challenges related to workforce sustainability and strengthened a research-oriented institutional culture (Mitchell et al., 2022). By 2024, Santa Casa had consolidated a stable research ecosystem with standardized processes, improved audit performance, and increased study

feasibility acceptance, positioning the institution as a national reference in hospital-based clinical research governance.

This example is intended to illustrate the practical application of governance and management principles discussed in this review, rather than to provide empirical evaluation. Overall, these challenges highlight the need for integrated management approaches that combine regulatory expertise, resource optimization, and adaptive operational strategies, reinforcing the importance of structured governance models in clinical research environments.

5. FUTURE PERSPECTIVES

The approval of Law No. 14,874/2024 represents an important milestone for the development of clinical research in Brazil. The new regulatory framework is expected to improve the efficiency and transparency of the national research oversight system, strengthening collaboration among industry, healthcare institutions, and academic organizations. These changes may contribute to increased international investment, expand the number of clinical trials conducted in the country, and enhance Brazil's participation in global research initiatives.

From a hospital perspective, the expansion of clinical research may generate significant institutional benefits. Beyond scientific production, research activities contribute to improvements in clinical processes, quality standards, and patient safety. They also promote diversification of funding sources, strengthen institutional reputation, and expand opportunities for professional development within multidisciplinary teams. In addition, increased participation in

clinical trials can facilitate access to innovative therapies and support the generation of evidence relevant to national healthcare systems.

In this context, the consolidation of modern governance models will become increasingly important. The establishment of Project Management Offices (PMOs) dedicated to clinical research, the adoption of integrated digital systems, and the use of value-oriented performance metrics—aligned with the principles of the PMBOK® Guide – Seventh Edition—may support hospitals in managing research activities more efficiently and sustainably.

6. CONCLUSION

Clinical research project management requires an adaptive and multidisciplinary approach capable of balancing regulatory rigor, operational efficiency, and innovation. As discussed throughout this study, the increasing complexity of clinical trials demands governance models that integrate strategic planning, stakeholder coordination, and continuous performance monitoring. In hospital settings, structured management practices—supported by Project Management Offices (PMOs), standardized processes, and value-oriented frameworks such as the PMBOK® Guide – Seventh Edition—can enhance the efficiency, transparency, and sustainability of research activities. From this perspective, clinical research should be understood not only as a scientific endeavor but also as a strategic mechanism for institutional development, knowledge generation, and improvement of healthcare systems.

REFERENCES

ANVISA. Manual de Boas Práticas Clínicas. Brasília: ANVISA, 2022.

BRASIL. Decreto nº 12.651, de 7 de outubro de 2025. Regulamenta a Lei nº 14.874/2024. Diário Oficial da União, Brasília, 2025.

BRASIL. Lei nº 14.874, de 28 de maio de 2024. Dispõe sobre a pesquisa clínica com seres humanos. Diário Oficial da União, Brasília, 2024.

BRASIL. Resolução nº 466, de 12 de dezembro de 2012. Aprovar as diretrizes e normas regulamentadoras de pesquisas envolvendo seres humanos. Conselho Nacional de Saúde, 2012. Disponível em: https://www.gov.br/conselho-nacional-de-saude/pt-br/atos-normativos/resolucoes/2012/resolucao-no-466.pdf/view. Acesso em 20 de março de 2026.

BROWN A. Understanding corporate governance of healthcare quality: a comparative case study of eight Australian public hospitals. Brown BMC Health Services Research (2019) 19:725, https://doi.org/10.1186/s12913-019-4593-0.

CALVARIO E. Intangible benefits of clinical trials: a survey on a hospital research Community. Ann Ist Super Sanita 2021 Jan-Mar;57(1):18-25. https://doi.org/10.4415/ANN_21_01_03.

GALLIN, John I.; OGNIBENE, Frederick P.; JOHNSON, Laura Lee. Principles and practice of clinical research. 3. ed. Amsterdam: Elsevier/Academic Press, 2018.

INTERNATIONAL COUNCIL FOR HARMONISATION (ICH). E6(R2) Good Clinical Practice: Consolidated Guideline. Geneva: ICH, 2016.

LEI H; O'CONNELL R; EHWERHEMUEPHA L; TARAMAN S; FEASTER W; CHANG A. Agile clinical research: A data science approach to

scrumban in clinical medicine. Intelligence-Based Medicine 3-4 (2020) 100009, https://doi.org/10.1016/j.ibmed.2020.100009.

MARCIN, Judith S. et al. Clinical trial complexity and the role of clinical research infrastructure. *Academic Medicine*, Philadelphia, v. 91, n. 9, p. 1235–1240, 2016.

MITCHELL EJ, GOODMAN K, WAKEFIELD N, COCHRAN C, COCKAYNE C, CONNOLLY S et al. Clinical trial management: a profession in crisis? Trials (2022) 23:357 https://doi.org/10.1186/s13063-022-06315-8.

PAWAR RP; MAHAJAN KN. Benefits and Issues in Managing Project by PRINCE2 Methodology. International Journal of Advanced Research in Computer Science and Software Engineering, Volume 7, Issue 3, March 2017.

PROJECT MANAGEMENT INSTITUTE (PMI). A Guide to the Project Management Body of Knowledge (PMBOK® Guide) – Seventh Edition. Pennsylvania: PMI, 2021.

SAJDAK R, LISAANN T, THOMAS KS. The importance of standard operating procedures in clinical trials. J Nucl Med Technol 2013 Sep;41(3):231-3. https://doi.org/10.2967/jnmt.113.121467.

SCHWEIKHART SA; DEMBE AE. The Applicability of Lean and Six Sigma Techniques to Clinical and Translational Research. J Investig Med. 2009 October; 57(7): 748–755. https://doi.org/10.231/JIM.0b013e3181b91b3a.

SHEN L, ZHAI Y, PAN AX, ZHAO Q, ZHOU M, LIU J. Development of an integrated and comprehensive clinical trial process management

system. BMC Medical Informatics and Decision Making (2023) 23:61, https://doi.org/10.1186/s12911-023-02158-8.

SPEICH B; VON NIEDERHÄERN B; SCHUR N; HEMKENS LG; FÜRST T, BHATNAGAR N. Systematic review on costs and resource use of randomized clinical trials shows a lack of transparent and comprehensive data. Journal of Clinical Epidemiology 96 (2018) 1-11, https://doi.org/10.1016/j.jclinepi.2017.12.018.

WOODIN, Karen E. Managing clinical trials: a guide for the study coordinator. 2. ed. Burlington: Jones & Bartlett Learning, 2010.

---

[1] Santa Casa de Porto Alegre Hospital, Teaching and Research, Porto Alegre, RS, Brazil. Multidisciplinary Clinical Research Center, Santa Casa de Porto Alegre Hospital, Porto Alegre, RS, Brazil. Federal University of Health Sciences of Porto Alegre (UFCSPA), Postgraduate Program in Information Technology and Health Management, Porto Alegre, RS, Brazil.

[2] Federal University of Health Sciences of Porto Alegre (UFCSPA), Postgraduate Program in Information Technology and Health Management, Porto Alegre, RS, Brazil.

[3] Santa Casa de Porto Alegre Hospital, Teaching and Research, Porto Alegre, RS, Brazil. Multidisciplinary Clinical Research Center, Santa Casa de Porto Alegre Hospital, Porto Alegre, RS, Brazil.

[4] Santa Casa de Porto Alegre Hospital, Teaching and Research, Porto Alegre, RS, Brazil. Federal University of Health Sciences of Porto Alegre (UFCSPA), Postgraduate Program in Medicine: hepatology, Porto Alegre, RS, Brazil.

[5] Santa Casa de Porto Alegre Hospital, Teaching and Research, Porto Alegre, RS, Brazil. Multidisciplinary Clinical Research Center, Santa Casa de Porto Alegre Hospital, Porto Alegre, RS, Brazil.

[6] Federal University of Health Sciences of Porto Alegre (UFCSPA), Postgraduate Program in Information Technology and Health Management, Porto Alegre, RS, Brazil.

[7] Santa Casa de Porto Alegre Hospital, Teaching and Research, Porto Alegre, RS, Brazil. Multidisciplinary Clinical Research Center, Santa Casa de Porto Alegre Hospital, Porto Alegre, RS, Brazil. Federal University of Health Sciences of Porto Alegre (UFCSPA), Postgraduate Program in Medicine: hepatology, Porto Alegre, RS, Brazil.