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Application of Project Information Management System in Non-Clinical Trials

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Abstract: This paper systematically summarizes the application status, achievements and challenges of Project Information Management System (PIMS) in non-clinical trials. By integrating the functions of experimental design, data collection, analysis and report generation, PIMS realizes the digital management of the whole process, significantly improves the efficiency and data quality, and supports the standardization of drug research and development and cross-departmental cooperation. Its four-tier technical architecture meets the requirements of GxP compliance, project management and data governance, which effectively reduces the error rate and shortens the approval period in practical application, and the return on investment reaches 55%. However, it still faces challenges such as poor system compatibility, great resistance to organizational change, insufficient intelligence level, complex transnational compliance and weak sustainability. Therefore, a number of coping strategies, including middleware development, edge computing, micro-service architecture, SaaS model, digital twinning, blockchain, differential privacy, etc., are proposed to provide theoretical support and practical paths for the informationization and intelligent transformation of pharmaceutical R&D.

1. Introduction

Non-clinical trials are an indispensable part of drug research and development chain, and their efficiency, accuracy and data management ability directly affect the speed and quality of new drug discovery. In recent years, with the continuous maturity of advanced technologies such as big data, cloud computing and AI, the application of project information management system (PIMS) in non-clinical trials has gradually become an important means to improve research efficiency and optimize resource allocation [1].

Non-clinical trials cover a series of complex and meticulous experimental processes, ranging from drug screening, pharmacodynamic evaluation, toxicology research to pharmacokinetic analysis. These experiments not only require a high degree of scientific rigor, but also need to deal with massive data and information [2]. Under the traditional management mode, manual recording, decentralized storage and subsequent integrated analysis of data are often time-consuming and error-prone, which has become a bottleneck restricting the efficiency and quality of research. In this context, the introduction of PIMS provides a solution for the modern management of non-clinical trials [3].

PIMS realizes the digital management of the whole process of non-clinical trials by integrating

functional modules such as experimental design, data acquisition, processing, analysis and report generation. It can not only improve the speed and accuracy of data processing, reduce human errors, but also promote the standardization and sharing of data and accelerate the transformation of scientific research results [4]. In addition, PIMS also has powerful project management functions, such as task allocation, progress monitoring, resource allocation, etc., which is helpful to improve the efficiency of team cooperation and ensure that the project is completed on time and in quality. More importantly, with the integration of AI technology, the application of PIMS in non-clinical trials shows a broader prospect. AI algorithm can assist researchers in literature mining, target prediction, experimental design optimization, etc., and further enhance the innovation and success rate of research. At the same time, through deep learning of historical data, the system can also provide intelligent decision support for new drug research and development, and accelerate the process of drugs from laboratory to market [5-6].

However, although PIMS shows great potential in non-clinical trials, its practical application still faces some challenges, such as data security and privacy protection, system compatibility and integration, user training and acceptance. Therefore, it is of great significance to explore the effective application strategy of PIMS and solve the key problems in the implementation process for promoting the information and intelligent transformation of non-clinical trials. The application of PIMS in non-clinical trials is not only the inevitable result of technological progress, but also the key way to improve the efficiency and quality of pharmaceutical research and development. The purpose of this study is to explore the specific application status, effectiveness evaluation and challenges of PIMS in non-clinical trials through comprehensive analysis of relevant literature, so as to provide reference and enlightenment for further research and practice in this field in the future.

2. PIMS technical architecture

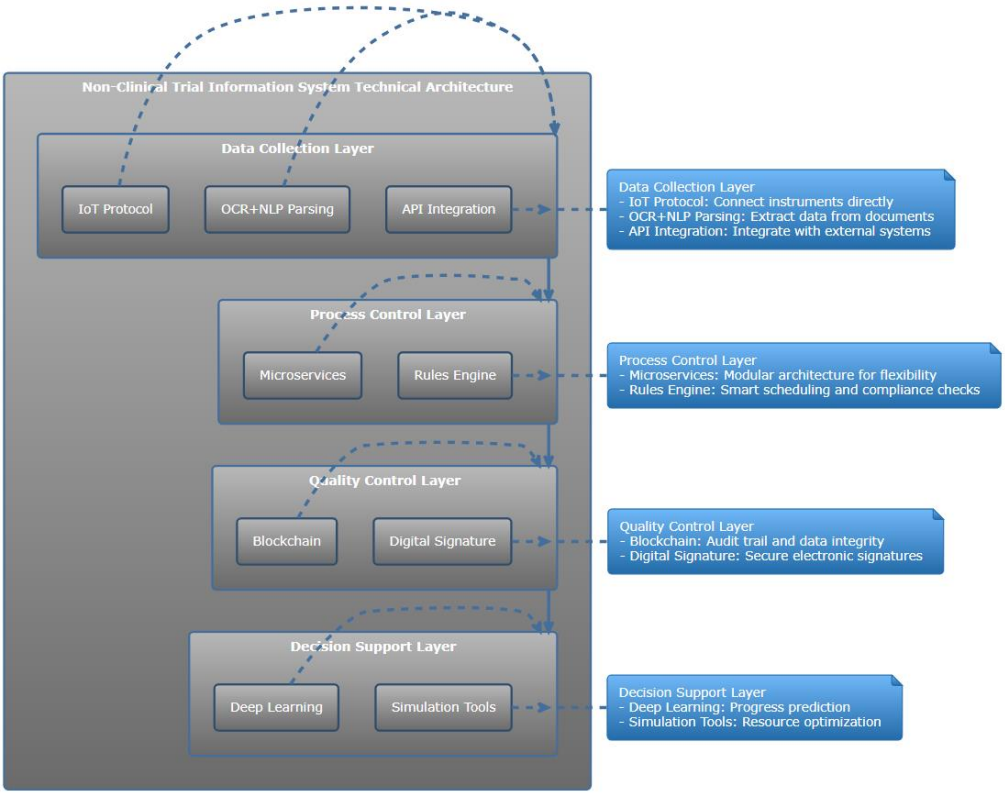

Figure 1 Technical framework of information management system for non-clinical trials

The core theories of non-clinical trial management include GxP compliance, project management and data governance. Based on GLP (Good Laboratory Practice) and GCP (Good Clinical Practice) and other regulatory frameworks, the system needs to meet the requirements of data integrity (ALCOA+ principle), audit trail and electronic signature, and transform the regulatory provisions into functional constraints such as authority classification and operation log encryption [7]. In the aspect of project management, PMBOK or PRINCE2 method is combined to strengthen the relationship between time, quality and compliance for non-clinical trials, and dynamic adjustment algorithm is used to optimize resource allocation, and WBS (Work Breakdown Structure) tool is used to realize fine binding of tasks and SOPs and progress visualization [8]. Data governance covers the whole life cycle from collection, management, cleaning to archiving and destruction. With the help of data consanguinity tracking and differential privacy technology, the safety of data compliance circulation and multinational multi-center cooperation is guaranteed.

The technical framework of non-clinical trial information management system is shown in Figure 1. Non-clinical trial information management system adopts four-layer technical architecture. The data acquisition layer realizes instrument direct connection, OCR+NLP analysis and API docking through the Internet of Things protocol; The process control layer realizes intelligent scheduling and compliance verification based on micro-service and rule engine [9]; Quality control layer combines blockchain and digital signature to ensure audit trail and electronic signature security; The decision support layer uses deep learning and simulation tools to support schedule prediction and resource optimization, and improves the automation, compliance and decision efficiency of experimental management as a whole.

3. Application status analysis

3.1. Pre-clinical research management

Non-clinical trials mainly refer to chemical synthesis, pharmacological and toxicological research, process development, production quality management and compliance verification in the early stage of drug research and development. By integrating the functions of process management, data collection and analysis, resource allocation, etc., the PIMS system supports the activity screening and pharmacological and toxicological experiments in the process of drug discovery through modular design, thus realizing the standardization of experimental processes, and standardizing the design, execution and recording of experiments by using electronic experimental record book. Centralized data storage integrates laboratory information management system (LIMS) and scientific data management system (SDMS) to ensure data traceability. This facilitates real-time updates and interdepartmental collaboration among the chemical, biological, safety evaluation, and other relevant departments via a single unified platform [10].

3.2. Production quality management

Table 1 Specific application of PIMS in drug production, inspection and release

Functional module	Application scenario	Realize the effect
Batch record management	Real-time input of production parameters	Avoid the error rate of paper records
Deviation and CAPA management	Automatically trigger the corrective and preventive measures process	The timeliness of problem handling is improved.
Audit trail	Meet the requirements of regulatory agencies	Audit preparation time is shortened

In the process of drug production, inspection and release, PIMS system realizes real-time input

of production parameters through batch record management, which effectively reduces the error rate of paper records; With the help of deviation and CAPA management module, the correction and prevention process is automatically triggered, which significantly improves the timeliness of problem handling; At the same time, the perfect audit trail function meets the regulatory requirements such as FDA, which greatly shortens the audit preparation time. The specific application of PIMS in drug production, inspection and release is shown in Table 1.

3.3. Cross-domain collaborative management

Facing the challenges of resource coordination brought by diversified projects such as generic drug research and development and API process optimization, PIMS supports cross-disciplinary collaborative management, and effectively improves the efficiency and flexibility of parallel execution of multiple projects by dynamically allocating task priorities and sharing resource pools (including personnel, equipment and budget).

4. Methods and results of effectiveness evaluation

The key indicators of a pharmaceutical company before and after the deployment of PIMS are analyzed, as shown in Table 2. The comparison before and after the deployment of PIMS in a pharmaceutical company shows that the experimental data entry time is reduced from 3.2 hours to 1.5 hours each time, and the efficiency is improved by 53%. The frequency of inter-departmental communication is reduced from 4 times a week to 1 time, and the communication efficiency is improved by 75%; The project delay rate decreased from 25% to 12%, with an improvement rate of 52%.

Table 2 Comparison of process efficiency

Index	Pre-deployment (average)	After deployment (average)	Lifting range
Experimental data entry is time-consuming	3.2 hours/time	1.5 hours/time	53%
Inter-departmental communication frequency	Four times a week	Once a week	75%
Project extension rate	25%	12%	52%

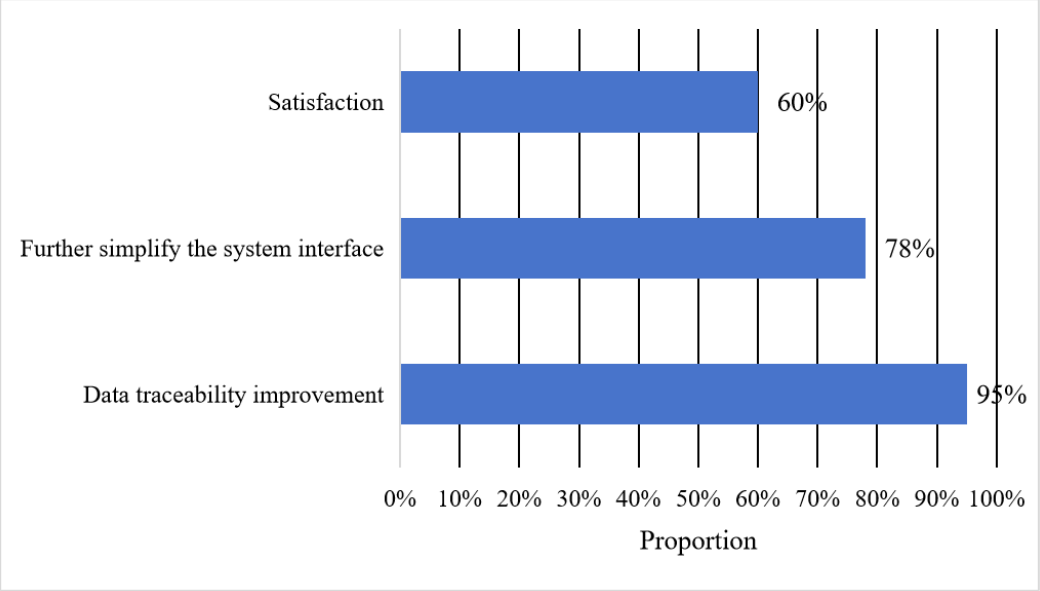

Figure 2 User satisfaction survey

The questionnaire survey of 50 users shows that, as shown in Figure 2, 95% of users approve the improvement of data traceability of the system, 60% are satisfied with the function of automatic report generation, but 78% of users' feedback systems have complicated interfaces and need to be further optimized.

In terms of return on investment, taking an enterprise as an example, the deployment cost of PIMS is about 2 million yuan, and the total annual saved labor cost and compliance risk loss after the system goes online reaches 3.1 million yuan, achieving a 55% return on investment, showing good economic benefits.

5. Challenges and coping strategies

5.1. Technical challenge

In the management of non-clinical trials, PIMS faces technical challenges, such as lack of system compatibility and standardization, insufficient real-time data processing ability, and high system scalability and maintenance cost. In order to solve these problems, aiming at the compatibility of the system, the strategy of developing middleware and promoting industry standardization is put forward to overcome the data acquisition delay and high error rate caused by the inconsistency of interface protocols of different devices and the differences of transnational data formats. Facing the problem of insufficient real-time data processing ability, it is suggested to improve data processing speed and monitoring response efficiency by integrating edge computing and introducing streaming computing engine. For system scalability and high maintenance cost, it is recommended to adopt micro-service architecture transformation and cloud native migration scheme to improve system scalability and reduce maintenance cost.

5.2. Human resistance and organizational management challenges

In organizational management, it faces the challenges of lack of change management mechanism, contradiction between authority and data security, and knowledge transfer and skill gap. Researchers' resistance to process standardization and unclear responsibilities between departments lead to low system utilization rate and overdue projects. The adoption rate and clear division of labor can be effectively improved through agile pilot and the application of RACI (Responsible, Accountable, Consulting and Informed) matrix. Excessive simplification of authority and false alarm of audit trail function can enhance data security and reduce compliance burden through dynamic authority model and AI-driven audit. The problem of the knowledge that has not been precipitated by senior researchers after retirement and the long training period for newcomers can be solved by constructing knowledge maps and popularizing low-code tools, so as to speed up knowledge transfer and enhance the independent development ability of business departments.

5.3. Data analysis and intelligent bottleneck

Data analysis and intelligent application in non-clinical trials face the bottleneck of unstructured data processing and insufficient predictive analysis ability. Experimental map recognition relies on manual and natural language processing (NLP) to solve the problem of low accuracy. Deep learning model optimization and domain knowledge embedding can improve processing efficiency and accuracy. In terms of project early warning and resource scheduling, traditional methods are difficult to cope with dynamic changes, so it is necessary to introduce digital twinning technology and reinforcement learning algorithm to realize risk prediction and resource dynamic optimization, so as to comprehensively improve the intelligent level of data analysis.

5.4. Compliance challenge

Non-clinical trials are faced with transnational regulatory differences and compliance challenges of ethical privacy protection. The requirements of multinational laws and regulations lead to rising costs, and there is a conflict of encryption standards in cross-border data transmission. The dynamic compliance engine can automatically adapt to national standards and combine with blockchain technology to realize transnational audit traceability, which can effectively deal with regulatory problems. At the same time, there is a risk of disclosure of subjects' private data, and the ethical review process is insufficiently digitized. It is necessary to introduce differential privacy technology and smart contracts to improve data security and greatly shorten the approval time.

5.5. Return on investment and sustainability challenges

Small and medium-sized enterprises have low willingness to adopt because of high initial investment and long payback period, and the large proportion of hardware costs also affects the operating budget. By promoting SaaS mode and adopting hardware-cloud collaboration scheme, the use cost can be effectively reduced and the resource allocation can be optimized. The technical debt problem in system customization and upgrade maintenance is prominent. It is necessary to reduce upgrade conflict through modular architecture design and realize visual management with the help of technical debt kanban, so as to improve the sustainable iterative ability of the system and control the growth of maintenance cost.

6. Conclusion

The application of PIMS in non-clinical trials realizes the digital management of the whole process of non-clinical trials by integrating functional modules such as experimental design, data collection, processing, analysis and report generation, which significantly improves the speed and accuracy of data processing, reduces human errors and promotes the standardization and sharing of data. In terms of technical architecture, PIMS adopts four-layer technical architecture, including data acquisition layer, process control layer, quality control layer and decision support layer, which improves the automation, compliance and decision efficiency of experimental management as a whole. The analysis of application status shows that PIMS has shown good application effect in preclinical research management, production quality management and cross-disciplinary collaborative management. By analyzing the key indicators of a pharmaceutical company before and after the deployment of PIMS, it is found that the time of experimental data entry, the frequency of cross-departmental communication and the project delay rate have all improved significantly. However, PIMS also faces some challenges in practical application, such as lack of system compatibility and standardization, insufficient real-time data processing ability, high system scalability and maintenance cost, human resistance and organizational management challenges, data analysis and intelligence bottlenecks, and compliance challenges. In view of these challenges, we need to adopt corresponding strategies, such as developing middleware and promoting industry standardization, integrating edge computing and introducing streaming computing engine, transforming micro-service architecture and cloud native migration scheme, applying agile pilot and RACI matrix, optimizing deep learning model and embedding domain knowledge, automatically adapting dynamic compliance engine to national standards, popularizing SaaS mode and adopting hardware-cloud collaborative scheme, etc.

References

[1] Cao, D. W., Li, P., Huang, S. B., Yu, L. Y., & Wen, J. H. (2024). Progress in the construction of information management systems for drug clinical trials in medical institutions. Chinese Journal of Hospital Pharmacy, 44(17), 2056-2061.

[2] Wang, Y., Zhang, X. S., Zhang, L. N., Zhang, J. W., & Liu, Y. L. (2024). Construction and application of an information management platform for drug clinical trial inspection. Pharmaceutical and Clinical Research, 32(2), 184-187.

[3] Gan, G. Q., Zheng, J., Yang, H. F., Wu, B., & Chen, Y. (2024). Exploration and practice of information management in the diagnosis and treatment process of subjects in clinical trials. Hainan Medical Journal, 35(16), 2387-2392.

[4] Ma, H. P., Sun, Y. L., Zhao, N. P., Gao, B., Zhang, Y., & Zhang, L. (2023). Application of information technology in the management of drugs used in institutional clinical trials. Chinese Journal of Hospital Pharmacy, 43(23), 2692-2695.

[5] Cao, D. W., Li, P., Huang, S. B., Chen, R. B., & Wen, J. H. (2024). Discussion and practice on the segregation method of clinical trial costs for hospitalized subjects. Medical Herald, 43(10), 1632-1636.

[6] Li, J. C., Wang, Y. F., Shen, L., Xu, J., Zhai, Y., & Wu, M. L., et al. (2023). Thoughts on the information construction of the pharmacy in clinical trial centers. Chinese Journal of Modern Applied Pharmacology, 40(17), 2341-2345.

[7] Xin, C., Gai, Y. B., Jiang, W. B., Tian, H., Zhang, Y., & Wei, L. L. (2025). Construction and application of an information module for anticoagulant monitoring in patients with extracorporeal membrane oxygenation. Chinese Journal of Modern Nursing, 31(10), 1278-1283.

[8] Ye, Z. H., Yan, Y. Y., Zhu, Z. E., & Chen, Y. (2024). Discussion on the risks and countermeasures in the implementation of investigator-initiated pediatric drug clinical research based on drug management. Chinese Journal of Medical Science and Research Management, 37(05), 424-428.

[9] Cheng, M. M., Kang, C. Q., Guo, J. M., & Liu, H. Y. (2024). Application of an information platform in the management of clinical trial drugs in a hospital. Journal of Pharmaceutical Sciences of PLA, 37(4), 334-337.

[10] Wu, L. N., Liu, F. T., Ma, X. F., Yan, Z., & Yan, B. H. (2023). Construction and practice of the information management system for traditional Chinese medicine clinical trials. Chinese New Drugs Journal, 32(9), 927-933.