

Project Management of Non-clinical Trials in Biopharmaceutical Companies

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Abstract:

Based on the theoretical basis of project management, this paper deeply discusses the present situation and problems of biopharmaceutical non-clinical trial project management, and puts forward optimization strategies. It is pointed out that the management of non-clinical trial projects should follow ICH (The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) guiding principles and Good quality management practices for drug non-clinical research (GLP) norms, make scientific decisions based on evidence integration and model-driven, and achieve efficient management through full-cycle dynamic control and matrix collaboration. However, at present, the management of biopharmaceutical non-clinical trial projects still faces some problems, such as insufficient professional quality of personnel, imperfect experimental facilities and management, nonstandard Standard operating procedures (SOP) implementation, weak quality assurance system, and loopholes in data management and file preservation. Therefore, this paper puts forward some optimization strategies, such as defining the project objectives and scope, optimizing the project process, strengthening quality management, enhancing teamwork, rationally allocating resources and strengthening risk management. By implementing these strategies, we can effectively improve the management level of biopharmaceutical non-clinical trial projects, reduce project risks, improve research and development efficiency, provide a strong guarantee for the success of new drug research and development of biopharmaceutical enterprises, and help the high-quality development of biopharmaceutical industry in China.

Keywords:

Biopharmaceutical Companies, Project Management, Non-clinical Trials

1. Introduction

In today's rapidly developing biopharmaceutical field, the research and development of new drugs is a complex and precise project, involving many stages from early discovery to final listing [1]. Among them, non-clinical trials, as a key link in the drug research and development process, are self-evident. Non-clinical trials aim to evaluate the safety, pharmacodynamic characteristics and pharmacokinetic behavior of drugs, and provide scientific basis and guidance for subsequent clinical trials [2]. However, the management and implementation of non-clinical trials is not easy, which requires high professional knowledge, rigorous experimental design, efficient resource allocation and strict quality control.

This paper will focus on the project management of non-clinical trials in biopharmaceutical companies, and discuss how to effectively plan, implement and monitor non-clinical trials to ensure the reliability and compliance of research results. From the perspective of project management, the common challenges and risks in non-clinical trials will be analyzed, and the corresponding management strategies and best practices will be put forward.

2. Theoretical Basis of Project Management

2.1. ICH guiding principle and GLP specification

The guiding principle of ICH (The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) is applied hierarchically according to drug types. ICH M3(R2) provides for two generic toxicity studies, long-term toxicity tests and dose-response relationship analysis for small molecular drugs. ICH S9 provides the flexibility to shorten the research cycle and reduce the use of animals for anti-tumor drugs; ICH S6(R1) For biopharmaceuticals such as monoclonal antibodies, the evidence weight model is adopted to support the selection of a single animal species based on target correlation, and the research design is optimized through special endpoints [3]. Good Practice for Quality Management of Drug Non-clinical Research (GLP) ensures data integrity and traceability by standardizing experimental facilities, personnel qualifications, data recording and quality assurance processes. For example, the research leader is required to be fully responsible for data quality, and the data recording and quality assurance (QA) department independently supervises the experimental compliance [4].

2.2. Evidence integration and model-driven

The scientific basis of non-clinical trials depends on multi-dimensional data integration and modeling analysis. The weight of evidence model (WoE) integrates pharmacological and toxicological data and early toxicity signals to dynamically optimize research strategies, such as shortening the period of chronic toxicity trials based on sufficient target safety data; Combined with pharmacokinetics/toxicokinetics (PK/PD) modeling, the exposure-response relationship was analyzed, the dosage selection was optimized, and redundant tests were reduced. At the same time, we encourage the application of alternative methods and in vitro models, such as organ-like and computer simulation, and follow the 3R principle to improve ethics and cost-effectiveness while ensuring science.

2.3. Full cycle dynamic control

Non-clinical trial project management should run through the whole process of risk identification, assessment and response, and comprehensively consider three types of risks, such as unknown target toxicity, GLP deviation and delayed supply of animal models [5]; Coping strategies include pre-risk assessment in the design stage to optimize the experimental scheme, and dynamic monitoring of project progress through critical path method, giving priority to ensuring key task resources and ensuring efficient and compliant research.

2.4. Matrix collaboration and agile execution

Non-clinical trials of biopharmaceuticals need to be promoted under the cooperation of multidisciplinary teams, and meet the needs of rapid iterative research

and development. Usually, matrix project management structure is adopted, functional teams are divided vertically according to specialties, and resources are integrated horizontally with projects as the core to improve collaborative efficiency; At the same time, agile management tools are introduced, such as short-period review mechanism, electronic experiment notebook, Jira and other digital platforms, to achieve efficient data sharing and accurate task tracking, and to ensure flexible and efficient project advancement.

3. Present Situation And Problems of Non-Clinical Trial Project Management of Biopharmaceuticals

3.1. Current situation

In recent years, China has strengthened the management of non-clinical trials of biopharmaceuticals, and constantly improved relevant laws and regulations, such as GLP. At the same time, the international ICH guidelines also provide technical guidance for the research of biological products [6]. The leading biopharmaceutical enterprises have established an efficient platform for pharmacological, pharmacokinetic and toxicological research, realizing the seamless connection from molecular screening to clinical trials, especially in the non-clinical research of ADC drugs, and developed a variety of detection methods for analytical objects according to their complex structural characteristics. With the rapid development of the industry, outsourcing to professional contract research organizations (CRO) for non-clinical trials has gradually become a trend. Choosing a suitable CRO company is very important for project management, which involves the evaluation of its qualifications, experience, facilities and quality assurance system.

3.2. Existing problems

Non-clinical trials face many challenges, including irregular implementation and incomplete records caused by insufficient professional quality and training of personnel; Imperfect experimental facilities, lax management and improper maintenance and calibration of instruments and equipment affect the accuracy of experimental data; Operation deviation and record loss caused by imperfect standard operating procedures (SOP) and inadequate implementation; There are defects in the quality assurance system, such as insufficient authority and independence, which affect the authenticity and reliability of data; Problems in data management and file preservation, such as lack of standardization of electronic data collection and imperfect management of sample retention. In addition, although China's GLP specification is in line with international standards, it still needs to be improved in details, especially in the aspects of electronic collection of test data and sample retention of test products [7]. The design and interpretation of non-clinical trials of biopharmaceuticals require high requirements, especially for biological products with complex structures such as ADC drugs, it is necessary to consider factors such as animal species selection and repeated toxicity test design, and conduct customized research according to their unique properties, which puts higher requirements on the professional ability of the research team.

Remarkable progress has been made in the management of biopharmaceutical non-clinical trials, such as the improvement of laws and regulations, the development of technology platform and the rise of outsourcing services, but it still faces some problems, such as insufficient personnel and training, imperfect experimental facilities

and management, nonstandard SOP implementation, weak quality assurance system, loopholes in data management and file preservation, challenges in international integration, and complicated trial design and interpretation. These problems not only affect the quality and reliability of non-clinical trials, but also restrict the healthy development of biopharmaceutical industry. Therefore, biopharmaceutical enterprises need to strengthen internal management, improve the quality of personnel, improve experimental facilities, strictly implement SOP, strengthen quality assurance system, standardize data management and file preservation, and actively integrate with international advanced norms to improve the overall level of non-clinical trial project management.

4. Optimization strategy of non-clinical trial project management of biopharmaceuticals

Optimizing the management of biopharmaceutical non-clinical trial project is a systematic project, which needs to start from many aspects, such as determining project objectives and scope, optimizing process, strengthening quality management, improving teamwork, rationally allocating resources and strengthening risk management. By implementing the above optimization strategy, the project management level can be effectively improved, the project risk can be reduced, the research and development efficiency can be improved, the success of new drug research and development for biopharmaceutical enterprises can be guaranteed, and the high-quality development of biopharmaceutical industry in China can be helped.

4.1. Clarify the project objectives and scope

Before the start of the project, the project team needs to communicate closely with all parties and accurately determine the non-clinical trial objectives according to the overall strategy of drug research and development and market demand. If innovative biopharmaceuticals are developed to treat diabetes, the objective of non-clinical trials should be clearly to evaluate the hypoglycemic effect, safety index and pharmacokinetic characteristics of drugs in animal models, and provide solid data support for subsequent clinical trials. Goals should follow the SMART principle, as shown in Figure 1, that is, Specific, Measurable, Attainable, Relevant and Time-bound, which is convenient for project implementation and monitoring.

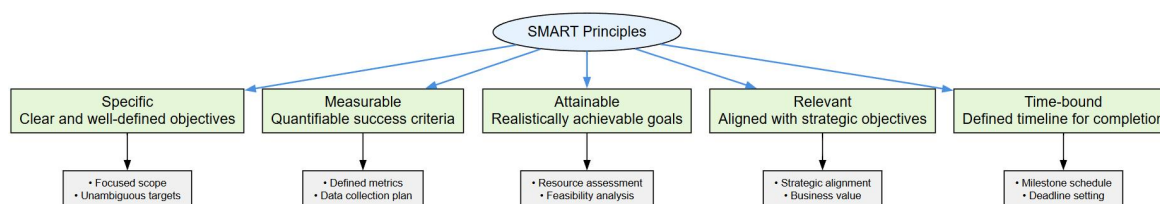


Figure 1. SMART principle.

The work involved in non-clinical trials is sorted out in detail, including safety pharmacological tests, single and repeated drug toxicity tests, reproductive toxicity tests, genetic toxicity tests, etc. Clear the specific content, method, sample size and time node of each test to prevent the project scope from spreading [8]. Formulate a detailed project scope statement, covering the project objectives, deliverables, work boundaries and acceptance criteria, as an important basis for project implementation and change management.

4.2. Optimize the project process

According to the requirements of laws and regulations and scientific principles, design a reasonable test flow, reduce unnecessary steps and improve test efficiency. Using the concept of concurrent engineering, some experiments that can be carried out simultaneously can be carried out in parallel on the premise of ensuring scientificity and compliance. For example, when repeated toxicity tests are carried out, the sample collection of toxicity kinetics tests is started simultaneously, which shortens the project cycle. Regularly evaluate and optimize the test process, and combine the application of new technologies and methods to continuously improve the efficiency of the process.

Establish a perfect process monitoring mechanism, and use project management software to track the test progress, the completion of key nodes and the use of resources in real time. Set up key performance indicators (KPI), test the on-time completion rate, data accuracy, etc., conduct KPI assessment regularly, and find out the problems existing in the process in time [9]. According to the monitoring and assessment results, organize an expert team to analyze the reasons, formulate targeted optimization measures, and continuously improve the project process.

4.3. Strengthen quality management

Non-clinical trials of biopharmaceuticals are regulated by strict laws and regulations, and the project team must study deeply and strictly abide by relevant laws and regulations at home and abroad. Establish a quality management system that meets the requirements of laws and regulations, clarify the quality standards and operating specifications of each link, and ensure that the test data is true, accurate, complete and traceable. Strengthen the follow-up research on the changes of laws and regulations, adjust the project quality management strategy in time, and ensure the compliance operation of the project. Implement total quality control from personnel, equipment, materials, methods, environment and other aspects. Conduct strict qualification review and training for testers to ensure that they have professional knowledge and operational skills; Maintain and calibrate the test equipment regularly to ensure the stable and reliable performance of the equipment; Strictly control the quality of test objects, reference materials and experimental materials, and standardize the procurement, storage and use processes; Optimize the test method and carry out full methodological verification; Control the experimental environmental conditions to ensure compliance with the test requirements. Establish key points of quality control, focus on monitoring and auditing key test steps and data, and find and correct quality problems in time.

4.4. Improve teamwork

Non-clinical trials of biopharmaceuticals involve biology, pharmacology, toxicology, pathology, statistics and other disciplines, and it is necessary to set up interdisciplinary professional teams. Team members should include project managers, researchers, quality assurance personnel, data management personnel, etc., with rich professional knowledge and practical experience. Clarify the responsibilities and division of labor of each member, establish an efficient communication and coordination mechanism, and promote information sharing and cooperation among team members. Establish a regular project communication meeting system, such as weekly meeting and monthly summary meeting, report the project progress, solve problems and coordinate resources in time. Using modern information technology,

build a project communication platform to facilitate team members to communicate at any time. Strengthen team building activities, enhance understanding and trust among members, and create a good team atmosphere. Encourage team members to actively participate in project decision-making and problem solving, give full play to their respective professional advantages, and enhance the overall cooperation ability of the team.

4.5. Rational allocation of resources

According to the project objectives, scope and schedule, scientifically evaluate the demand for human, material and financial resources. Make a detailed human resources plan, and define the number of professionals, skill requirements and working hours required at each stage; Reasonably arrange the purchase and lease plan of test equipment and instruments; Prepare the project budget accurately, including personnel salary, equipment purchase, reagent consumables, animal feeding and other expenses. Ensure that the resource demand plan closely matches the actual demand of the project to avoid waste and shortage of resources. According to the priority and critical path of the project, the resources are allocated reasonably to ensure that the resources for key tests and key links are sufficient. Establish a resource sharing mechanism to improve resource utilization efficiency. Such as equipment and instruments that can be shared by multiple tests, the use time should be arranged reasonably; For idle resources, timely deployment or disposal. Regularly evaluate and analyze the use of resources, and dynamically adjust the resource allocation scheme according to the progress of the project to ensure the smooth progress of the project.

4.6. Strengthen risk management

Using various methods such as brainstorming, Delphi method and checklist method, the possible risks of non-clinical trial projects are comprehensively identified. Risk types include technical risk, regulatory risk, resource risk, time risk and external environmental risk. Record the identified risks in detail, and make clear the risk characteristics, possible influence scope and occurrence probability.

According to different types of risks, formulate corresponding coping strategies. For technical risks, carry out technical pre-research and verification in advance, and invite experts for technical guidance; For regulatory risks, pay close attention to the dynamics of regulatory policies and strengthen communication with regulatory authorities; For resource risk, establish talent reserve mechanism, equipment emergency plan and diversified fund raising channels; For time risk, optimize the project schedule and set a reasonable buffer time; For external environmental risks, formulate emergency response plans to improve the project's ability to resist risks. Regularly evaluate and adjust the effectiveness of risk response measures to ensure that risks are always under control.

5. Conclusions

In the project management of biopharmaceutical non-clinical trials, ensuring the reliability and compliance of research results depends on effective planning, implementation and monitoring. It is very important to follow the ICH guiding principles and GLP specifications to ensure scientific nature and data integrity, and provide standardized experimental procedures and technical guidance. Through multi-dimensional data analysis and model-driven methods, such as evidence weight model, research design can be optimized, animal use can be reduced, and ethics and cost-

effectiveness can be improved. Full-cycle dynamic control emphasizes risk identification, evaluation and response, and combines agile management tools to promote flexible project advancement. Matrix collaboration and agile execution are helpful for interdisciplinary teams to collaborate efficiently and support rapid iterative R&D requirements. Although progress has been made, it still faces problems such as personnel quality and facility management. Enterprises need to strengthen internal management, enhance professional ability, improve facilities, strictly implement SOP and strengthen data management. Implementing optimization strategies such as defining objectives and strengthening quality management can significantly improve project efficiency and reduce risks. In the face of continuous technical progress and regulatory updates, continuous improvement of project management process is the key to adapt to new challenges and opportunities.

Conflicts of Interest

The author declare that there is no conflict of interest regarding the publication of this article.

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