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Risk Assessment Model and Empirical Study of in Vitro Diagnostic Reagent Project Based on Analytic Hierarchy Process

Fengyi Zhao

Business Operation, Intercontinental Exchange, Atlanta, Georgia, 30328, United States
fengyi9803@gmail.com

Abstract: *During the development of in vitro diagnostic reagent project, resource management and risk assessment are key factors to ensure the project success. Especially in the multi-project parallel environment, how to allocate limited resources efficiently and evaluate and control risks reasonably is directly related to the progress and quality of the project. This paper proposes a novel risk assessment model based on analytic Hierarchy Process (AHP) to address this challenge. Firstly, through the comprehensive identification and analysis of the risk factors of in vitro diagnostic reagent project, combined with domestic and foreign related research, a multi-level risk assessment model is constructed. The model divides the risk factors into several levels, and determines the weight of each level through the expert scoring method, so as to realize the priority ranking of different risks. In the empirical study, this study applied the model to the actual in vitro diagnostic reagent project to verify the effectiveness and applicability of the model. The results show that the model based on analytic hierarchy process can significantly improve the accuracy of risk identification, optimize the allocation of resources, reduce the overall risk of the project, and shorten the development cycle. The research in this paper not only provides a systematic risk assessment method, but also provides a feasible solution for enterprises to optimize resource management under multi-project environment, which has important practical value and reference significance.*

Keywords: *In Vitro Diagnostic Reagents, Risk Assessment, Analytic Hierarchy Process, Multi-project Management, Resource Optimization*

1. Introduction

In vitro diagnostic reagents play a vital role in the medical field, providing important data for disease diagnosis and health management through the analysis of body fluids, cells and tissue samples. With increasing public attention to health monitoring and disease prevention, the in vitro diagnostics market is expanding rapidly. Globally, the industry is growing at a compound annual rate of about 5%, particularly in emerging markets and developing countries. At the same time, the frequent occurrence of public health events and emerging infectious diseases has further promoted the demand for in vitro diagnostic products, from hospitals to families, and then to public health departments, the application field of in vitro diagnostic technology continues to expand.

In vitro diagnostic instrument is the core supporting equipment of in vitro diagnostic reagents, and its design and manufacture involve many professional fields such as biology, electronics, optics and machinery. The structure of these instruments is usually composed of precision plastic parts and circuit components, and their design and development require comprehensive technical support across disciplines. In the development process, from preliminary design to final verification, the coordination of all aspects is very important. In particular, the complex structure and high technical requirements of in vitro diagnostic instruments lead to long development cycles, complex processes, and must comply with strict regulations and clinical standards.

In actual project management, the development of in vitro diagnostic instruments often faces the dual challenges of resource allocation and schedule management. Due to the involvement of multiple professional areas, the resource requirements and allocation between different stages of the project are more difficult. Misallocation of resources can lead to project schedule delays and cost overruns, so efficient project management and resource optimization are critical.

To deal with this challenge, this paper proposes a risk assessment model based on analytic hierarchy process. As a systematic decision analysis tool, Analytic Hierarchy Process (AHP) can decompose complex decision problems into multiple levels, and help project teams identify and control risks through quantitative assessment of risk factors at each level. In this paper, the risk assessment of in vitro diagnostic reagent project is carried out by this model, aiming to improve the accuracy of risk identification, optimize resource allocation, and enhance the overall efficiency of project management.

The risk management and resource allocation of in vitro diagnostic reagent project are the key factors to ensure the success of the project and enhance the market competitiveness. The research in this paper not only provides a scientific risk assessment method for in vitro diagnosis industry, but also provides a new solution for resource optimization in multi-project environment, which has significant theoretical significance and practical value.

2. Relevant Research

In the research, many studies have provided important theoretical support and practical guidance for the development and management of diagnostic reagents. For example, NRyo's research has proposed a new type of particle[1] with a co-polymer that contains reactive functional groups in the surface layer, which enables it to chemically bind to ligands and is suitable for latex agglutination. In the expanded layer formed by the particle in ion-exchange water, the density of carboxyl groups ranges from 0.04 group/nm^3 to 0.15 group/nm^3, which provides a reliable basis for the development of in vitro diagnostic reagents and kits, and helps to improve the stability and sensitivity of reagents.

EV Prokhvatilova's Ampligen-WNV-Genote-1/2/4 diagnostic kit [2] effectively detects West Nile virus (WNV) RNA via real-time reverse transcription polymerase chain reaction (RT-PCR) and successfully distinguishes its genotypes 1, 2 and 4. The kit demonstrated 98.5% diagnostic sensitivity and 99% specificity in 216 clinical samples and 204 biological samples, providing important empirical support for the risk assessment model of the in vitro diagnostic reagent program.

In the field of reagent management, the IVD reagent management system built by Wu Youpeng is based on the browser and server architecture [3], and adopts the Vue framework and SpringBoot to separate the front and back ends, which significantly improves the management efficiency of IVD reagents in hospitals. After the application of the system, the amount of expired reagents in hospitals was reduced by nearly 60%, the inventory time was shortened from 5 hours to 3 hours, and the reagent search efficiency was increased by 50%, indicating that systematic management can effectively reduce risks and improve the safety and effectiveness of reagent use.

D Song's study used hydrogen deuterium exchange mass spectrometry[4] to analyze the interaction between antibodies and epitopes of different manufacturers of cardiac troponin I (cTnI) detection reagents. The study revealed that the bias in quantitative results was due to the ability of antibodies to recognize multiple cTnI complexes. Through in-depth research on epitopes recognized by antibodies, it provided a theoretical basis for improving the consistency of cTnI diagnosis results and further promoted the process of diagnostic standardization.

In a study based on the Chinese population database, ZJia established a national reference material for the detection of cytochrome P450 (CYP) genes related to drug metabolism [5]. DNA extracted from healthy human cell lines combined with multiple sequencing techniques validated 24 polymorphic sites related to drug metabolism, laying a solid foundation for improving the quality of in vitro diagnostic reagents and the accuracy of clinical test results.

Through mass spectrometry and binding kinetics studies[6], PD Warren revealed the epitope deletion of Ber-H2 monoclonal antibodies in recognizing CD-30 biomarkers, indicating that traditional synthetic peptides cannot effectively inhibit antibody binding activity. This provides important data support for the development of new in vitro diagnostic reagents based on Ber-H2.

The data analysis workflow proposed by A Geistanger, combined with linear regression analysis and target anomaly processing algorithm [7], has significantly improved the accuracy and efficiency of automatic evaluation of stability experiments. At the same time, the lipoprotein interference reduction method proposed by TWei [8] uses pretreatment reagents containing lipoprotein digestive enzymes to improve the determination accuracy of hydrophobic analytes.Varatharajah explores the potential application of a Rlearning-based human-machine collaborative recommendation system in the clinical management of COVID-19 [9], with the aim of developing an evidence-based model to predict disease severity and its complications to guide individualized clinical decision making to meet the urgent needs of current and future COVID-19 patient care.

Cao proposes a factor map-based model that uses comorbidities and clinical measurements to predict ICU admissions for hospitalized COVID-19 patients 3 and 7 days in advance [10]. The model was applied to a cohort of COVID-19 patients from a large medical center in Chicago, and results showed that under the influence of the Delta variant, the model had a 7-day forecast AUC of 0.82 and 0.87, respectively, demonstrating better predictive power and robustness than existing methods and providing an effective predictive tool for clinicians in the decision-making process.

These research results not only promote the technological progress of in vitro diagnostic reagents, but also provide strong support for the improvement of risk assessment models, and promote the further development of in vitro diagnostic field.

3. In Vitro Diagnostic Instrument Project Management Status and Problem Analysis

3.1 Project Management Status

The in vitro diagnostic instrument structure development enterprise studied in this paper is a typical project-oriented company, whose organizational structure adopts parallel functional department structure in order to adapt to diversified project needs. The project manager enjoys a higher level of authority in resource allocation and is therefore able to directly manage and allocate the required resources, an approach aimed at improving the efficiency of project execution. However, when multiple projects are being carried out at the same time, resource competition becomes an issue, especially in key positions such as engineers and quality testers, often resulting in increased workloads that affect project schedules and delivery quality.

In the progress management of a single project, enterprises mainly use the critical path method, which helps the project team identify the key tasks that affect the overall schedule by clarifying the logical relationship and critical path among activities. The main workflow of the project covers the design, manufacturing and assembly verification of the parts, and the overall construction period is approximately 80 working days. Although the duration and resource requirements of different activities vary, the core processes remain relatively consistent across projects. In this process, bioengineers play a crucial role in the test paper design, their workload is large and requires rapid response, and the workload of quality inspectors increases as the project progresses. Structural engineers are mainly responsible for the design of the product structure, and their involvement is relatively short, so it is particularly important to allocate these key resources properly to avoid project delays caused by insufficient manpower.

In multi-project parallel management, enterprises hope to effectively deploy existing resources to support the smooth progress of multiple projects without increasing human resources. At present, the company plans to launch five projects at the same time, including heart disease, kidney disease and blood sugar diagnosis products. Projects vary in technical complexity and resource requirements, so without an effective resource coordination mechanism, teams can be overworked, which further affects project quality and timeliness.

The current resource allocation strategy is mainly based on the priority of the project, high-priority projects can get more resource support, while low-priority projects need to wait for resources to become available. This strategy can be effective in focusing superior resources on key technical challenges, but it can also cause some projects to stall due to insufficient resources. Therefore, the next part will discuss how to use analytic hierarchy process to carry out project risk assessment, improve the overall efficiency and effect of multi-project management through scientific resource allocation optimization, and thus reduce the potential risks in project implementation.

3.2 Priority Evaluation and Analytic Hierarchy Process

In the process of risk assessment of in vitro diagnostic reagent projects, the research company usually relies on project prioritization to formulate resource allocation strategies to ensure efficient use of limited resources. By prioritizing projects, companies can ensure that high-priority projects get the resources they need, while lower-priority projects need to move forward when resources are not available. This strategy effectively solves the problem caused by resource limitation on the schedule of multiple projects, so as to ensure that important projects can get resources first and promote their smooth implementation. In practice, companies must systematically assess project priorities to optimize resource allocation and develop reasonable scheduling strategies for low-priority projects to avoid the delays they face.

In the priority evaluation of multiple projects, quantitative evaluation method can provide more scientific and objective basis for analysis. Specific quantitative evaluation methods include mathematical programming, fuzzy comprehensive evaluation, improved TOPSIS method based on entropy weight and analytic Hierarchy Process (AHP). Because of its convenient operation and strong applicability, analytic hierarchy process (AHP) is widely used in multi-indicator decision-making. This method breaks down decision-making factors into multiple levels such as goals, criteria and options, and obtains the weight of each factor through qualitative and quantitative analysis means, providing scientific support for priority evaluation.

Project priority evaluation is a complex and multi-dimensional process, which needs to consider multiple influencing factors. Therefore, the scoring method provides a more scientific and reasonable evaluation framework for the evaluation process. The main scoring indicators include project duration, market prospect and financial return. In terms of duration, it is necessary to comprehensively assess the delivery time of the project and the potential impact of its delay on the overall schedule; The market prospect needs to pay attention to the potential share of the product in the market and the degree of technological innovation; The financial return mainly considers the market price of the product and its expected profit.

4. Project Schedule Modeling and Optimization

4.1 Multi-project Schedule Modeling

In the modeling process of multi-project scheduling problem, it is assumed that the activities of each project are independent of each other, and there is no sequential relationship between the activities of different projects, and the only constraint is reflected in the competition for shared resources, so the connection between multiple projects is mainly manifested in the competition for these shared resources. To effectively describe this problem, a specific mathematical notation is used to represent key elements such as the number of projects, the number of activities, and the resource requirements, where each project contains several activities, and all projects share multiple variable resources. The duration of the activity, the cut-off time and the amount of resources required are reflected in the model, while the start and finish time of the activity can be calculated by simple calculation. In this model, the tight before and tight after relationships of activities are an important component, they ensure the logical order between activities and the proper allocation of resources. In order to optimize the scheduling effect of multiple projects, a mathematical model with the goal of minimizing the maximum project duration is adopted, and corresponding constraints are set to ensure that the activities cannot be started before all the immediate activities are completed, and the total demand for resources does not exceed the supply of resources at any time.

In the project schedule, effective priority rules are adopted to determine the priority of resource allocation for activities. These rules are designed to ensure that resources can be allocated rationally in the context of resource constraints. Although critical path and plan review techniques are common schedule management tools, they assume that resources are unlimited, which is often not true in practice. Therefore, it is necessary to determine the activity cycle and its tight before and tight after relationship by using the single code network diagram, and calculate the objective function to minimize the total project duration through the project schedule priority rule. The project priority rule ensures that important projects receive adequate resources, while also taking into account small projects to achieve overall balanced development. In the classification of priority rules, the priority rules based on project network mainly focus on the tight before and tight after relationship of activities, but do not consider the limitation of resources. Priority rules based on critical path make use of the earliest start time and the latest finish time of the activity. Resource-based priority rules, on the other hand, make decisions based on the resource requirements of activities.

In the application of hybrid priority rules, the above rules are combined to generate a more ideal scheduling plan by integrating multiple influencing factors. By considering the number of immediate activities and resource utilization, hybrid priority rules can achieve higher efficiency in resource allocation. In the in vitro diagnostic instrument structure development project, considering the diversified functions and high market value of electronic products, the priority development of electronic products has become the current strategic direction, and the increase in the number of activities in the development process and its complexity make effective priority arrangements appear

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particularly important. Therefore, the adoption of such a priority rule can effectively reduce the impact of possible problems in the test process on the construction period. At the same time, optimizing resource utilization and balancing resource allocation to avoid resource idling and waste have also become important goals of priority rules. Based on the consideration of project priorities, this paper ensures that the activities of important projects can be prioritized in the case of limited resources. Through a comprehensive assessment of the number of immediate activities for each activity and their resource requirements, more flexible project schedule adjustment is achieved to ensure the efficient use of resources and thus promote the smooth implementation of the project.

4.2 Schedule Plan Modeling Optimization Analysis Selection

In the process of in vitro diagnostic reagent project risk assessment model and empirical research based on analytic hierarchy process, the multi-project schedule optimization model constructed effectively realizes the optimized project plan through specific priority rules. The model assumes that all activities are arranged using a single code network diagram and that the project network plan is constructed based on the critical path method. On this basis, in order to ensure the feasibility of the schedule, the duration and logical sequence of all activities are clearly defined, and the duration, resource requirements and indivisibility of activities are clearly defined. In addition, during the implementation of the project, once the activity has started, it cannot be stopped or suspended, while the demand for resources remains fixed throughout the project lifecycle and cannot be divided.

When prioritized, a schedule is developed to ensure that daily resource demands do not exceed maximum capacity, so that high-priority projects are able to maintain a reasonable duration due to their high resource allocation, while lower-priority projects, despite their low resource allocation, have the flexibility to initiate certain activities when resources become available for a short period of time. This makes the project plan more flexible. This flexibility allows lower-priority projects to be interspersed between higher-priority projects, increasing the flexibility of project members' work schedules.

In particular, the multi-project scheduling process begins with an initial schedule derived from a breakdown of the work structure, which does not take into account resource constraints and reflects only logical relationships and activity duration constraints. Based on this, the current time is set and the available amount of a resource is determined at that time, so that all available project activities are moved into the eligible activity set. Next, the project manager calculates and orders priority values according to the priority rule, so that once an activity is scheduled, it is removed from the activity set and occupies the corresponding resources until the corresponding resources are released after the activity is completed.

In the process of activity scheduling, when an activity is finished, the next eligible activity will be added to the list to be scheduled, and the project manager will select the next activity to start according to the current available resources. This process will be repeated until all activities are arranged. If there is an update in the project or an activity needs to be added/removed, the project manager can effectively manage the priority of the project activity by re-scheduling the project according to the above model and ensuring that the priority rules remain the same throughout the process.

By applying the above priority rules, combined with existing resource requirements and maximum capabilities, project managers can achieve optimal resource allocation for multiple projects. In this process, the input of project activities, the determination of logical relationships between activities, and the setting of duration and resource usage will be the key steps. With the maximum available resources set, the initial activities of all projects can start smoothly. In the subsequent scheduling of activities, the project manager will schedule according to the priority to ensure that the high-priority project can obtain the required resources first, and when the resources are sufficient, the flexibility to arrange the start of the low-priority project.

Through the construction of multi-project schedule optimization model, not only the effective use of resources is realized, but also the execution efficiency of the overall project is improved by reasonable arrangement of the duration of each project, thus enhancing the ability to cope with risks. In the implementation process, the Gantt chart clearly shows the construction period of each project, and ensures that the work arrangement of all types of engineers is evenly distributed in time through the optimal allocation of resource requirements, avoiding the phenomenon of idle or excessive occupation of resources. As a result, the overall efficiency of project management has been significantly improved, while costs have been effectively controlled.

In an empirical study of the in vitro diagnostic reagent project risk assessment model based on analytic Hierarchy process, the results of the priority ranking method and the improved WRUP priority rule method are compared, and the latter is significantly better than the former in shortening the project duration. Table 12 shows the difference between the two methods in the project duration of different diagnostic products, in which the priority ranking method shows a shorter project duration in the diagnosis of heart disease and kidney disease, and the objective function of the maximum project duration is also in line with the actual needs of the company, providing a guarantee for the simultaneous launch of the product portfolio.

In multi-project management, high-priority projects get higher access to resources to ensure their smooth progress. The priority rule method not only considers the comparison between projects, but also attaches importance to the specific arrangement of each activity. For example, although an activity of a kidney disease diagnosis project may be scheduled before a pregnancy diagnosis project, the priority rule method allows the pregnancy diagnosis project activity to be prioritized because of its higher priority. This flexibility allows the priority rules approach to manage the scheduling of activities more effectively and in line with the research objectives. Although the prioritization method supports high-priority projects significantly, low-priority projects often lack resource security, resulting in delays, especially when the number of projects is large, and the overall efficiency is affected. The priority rule method ensures the activity arrangement of low-priority projects when resources are abundant through dynamic resource allocation, thus improving the overall execution level.

The dynamic adjustment characteristic of priority rule method enables enterprises to have a high degree of flexibility in project management and can quickly respond to changes in project progress. This flexibility is particularly suitable for complex large-scale project networks, where priority rules established at the beginning of a project can be maintained throughout the process, enhancing management stability and reliability. As an effective multi-project schedule planning method, priority rule method not only has a simple calculation process, but also can meet the actual needs of enterprises, promote the reasonable allocation of resources and the optimization of project schedule, so as to show a good application prospect in the risk assessment of in vitro diagnostic reagent projects.

5. Conclusion and Prospect

Through the analysis of the current project management status of the company, this study systematically summarizes the problems existing in multi-project management, and draws lessons from relevant researches at home and abroad to put forward targeted solutions and methods, thus forming a multi-project schedule plan for resource optimization allocation. In this process, we first made clear the idea of solving the problem, used the analytic hierarchy process to transform the priority of the project from qualitative analysis to quantitative analysis, and carried out the project schedule planning under the condition of unlimited resources through the project priority ranking method, which showed that the method was simple and suitable for the situation of a small number of projects. In view of the complexity of resource constraint in multi-project management, we propose an improved method of maximum resource utilization and priority rule of immediate relationship, which is not only easy to operate, but also more in line with the actual needs of enterprises. The model constructed in the study is relatively simple, the number of projects is limited, and the application of priority rules is mainly focused on activity and resource constraints, so it fails to cover all the complexities that projects may face. In order to further enhance the validity and practicality of the research, future research should incorporate more advanced algorithms and software programming, while exploring the development of enterprise information support platforms to promote sustainable development of enterprises in increasingly complex project environments.

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