New Approach to Project Portfolio Management for New Drug Development

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OVERVIEW: Regulatory harmonization, driven by the ICH regulatory committee founded in 1991, established an infrastructure for pharmaceutical firms to make global use of their clinical test data for registering new drugs in Japan, the USA, and the European Union (EU). This deregulation forces pharmaceutical firms to face stiff competition in the world market. Therefore, it is important to be able to efficiently manage individual projects to maximize the expected profits within a tolerable risk limit. It is also essential to balance the profits and risks of their project portfolio because of the many other scheduled projects in it. Hitachi has applied a risk budgeting concept to manage the assets of pension funds. This financial management concept/technique is a scientific solution to portfolio management, because it enables fund managers to control the financial risks at the portfolio and individual asset levels to maximize profits. The concept of risk budgeting has an excellent potential for application to managing the project portfolios of pharmaceutical firms. Hitachi provides comprehensive solutions to pharmaceutical clients with its new-drug-development project-management solutions/new-drug-development management-support system and project portfolio management techniques developed through advanced financial research.

INTRODUCTION

REGULATORY harmonization, driven by ICH* since 1991, established an infrastructure for pharmaceutical firms to make global use of their clinical test data to register new drugs in Japan, the USA, and the European Union (EU). Deregulation has forced pharmaceutical firms to face stiff competition in the world market. It is important for these firms to manage individual projects efficiently to maximize their expected profits within a tolerable risk limit. It is essential for them to balance the profit and risk of their project portfolio, because of the large number of scheduled projects in it.

Hitachi provides comprehensive solutions to portfolio management clients in the pharmaceutical industry at the portfolio and the individual project levels. Our solution will help assure them of profit, while controlling their project portfolio risks to enable them to maximize their profit within tolerable risk levels for new drug developments.

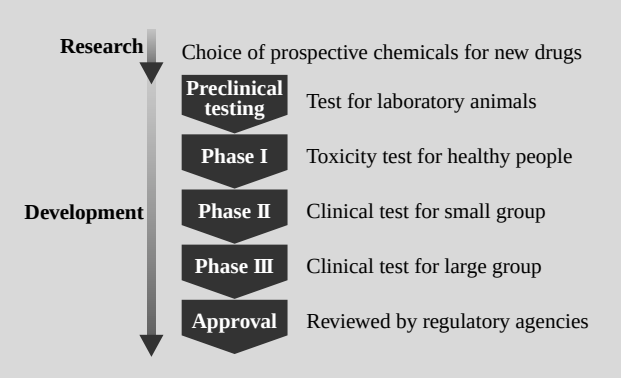

Fig. 1—New Drug Development Process.
The process for new drug development consists of five stages that follow the research phase.

NEW DRUG DEVELOPMENTS AND RISK MANAGEMENT

New Drug Developments

Fig. 1 shows the process of new drug development, in which a specific chemical in the research phase is tested for use in a pharmaceutical product. The development phase consists of five stages: "Preclinical testing," "Phase I," "Phase II," "Phase III" and "Approval." It usually takes more than ten years to

* International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use

complete all stages. Therefore, the budgets and resources for the project must be carefully planned and managed.

We expect that the investments in new drug projects will be rewarded by their future potential returns after the product is put on the market (see Fig. 2). However, there are far fewer successful projects than there are unsuccessful ones in the pharmaceutical industry because of the many critical business risks. Therefore, pharmaceutical firms keep several dozens of projects in their project portfolio to stabilize their long-term business earnings. They must also maintain a good balance in the profit and risk aspects of their project portfolio.

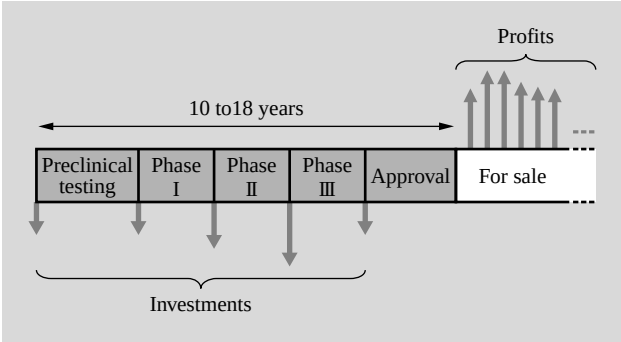

Fig. 2—Investments and Profits in New Drug Development. Investments in new drug projects are expected to produce future gains after the product is put on the market.

Risks in New Drug Development

New drug developments are exposed to two types of risks as below:

(1) Technical risks: serious side effects, less effective than existing products

(2) Market risks: volatility of drug prices, getting beaten by a competitor

To reduce these risks, pharmaceutical firms can:

(1) Suspend or postpone risky projects

(2) Adapt effective/existing chemicals for other diseases or forms

(3) Develop jointly with another firm

(4) Buy external projects and sell internal projects

However, they also need more choices at the portfolio management level to attain better performance.

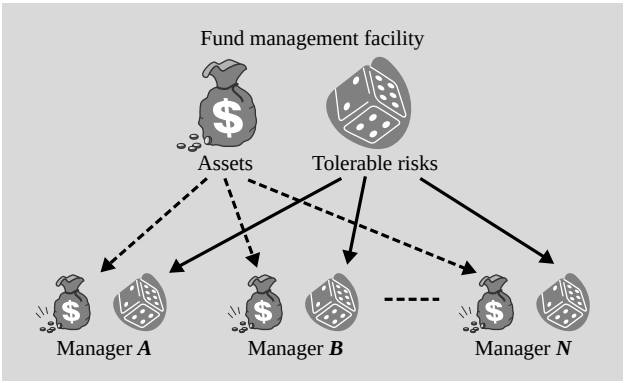

Fig. 3—Risk Budgeting in Pension Assets Portfolio Management.
The management facility allocates assets and tolerable risks to each fund manager, who then invests the assets in tolerable risks.

PORTFOLIO MANAGEMENT IN NEW DRUG DEVELOPMENTS

Risk Budgeting

In pension asset portfolio management, fund management facilities allocate their assets to fund managers, who are responsible for investing these assets in bonds or securities. The allocation decision should be made considering the expected profits and risks in their portfolio. However, the actual risk may be different from the expected one, because it is possible for fund managers to take greater or fewer risks than expected in conventional portfolio management.

Risk budgeting is a revolutionary concept for pension asset management. Based on this approach, each manager is assigned both assets and tolerable risks (see Fig. 3), and they can then invest the assets under the tolerable risk limit. Therefore, this helps fund management facilities track the gap between the total risk of their portfolio and the actual risks taken by their fund managers.

Hitachi has already applied this concept to feasible mathematical problems and implemented a fast solver/solution. Hitachi has also applied them to actual pension asset management schemes.

Risk Budgeting in New Drug Development

It is possible for pharmaceutical firms to apply the risk budgeting concept to their project portfolio management. Allocating expected profits and tolerable risks to each development project helps them control the total risk of their portfolio under tolerable levels. In addition, project portfolio management leads to continuous portfolio restructuring whenever a project passes or fails a stage (see Fig. 4). The concept of risk budgeting, therefore, has strong potential for applications to project portfolio management in pharmaceutical firms.

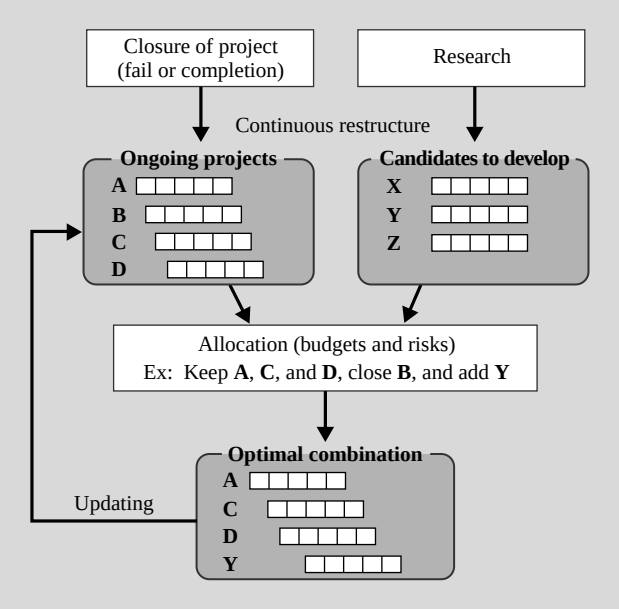

Fig. 4—Restructuring of Project Portfolio.
A project portfolio is continuously restructured whenever a project passes or fails a stage.

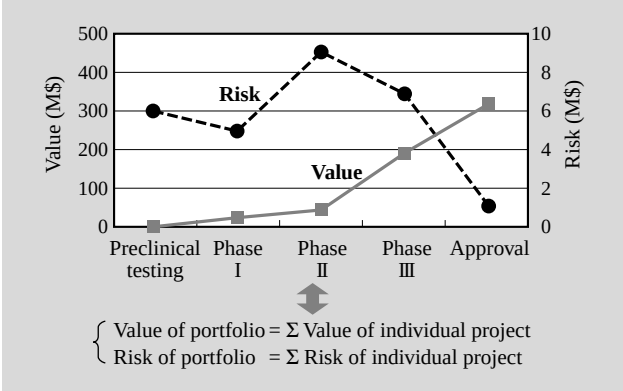

Fig. 5—Value and Risk Assessment of New Drug Development.
The project value increases as it progresses through the development stages, and the risk is highest in the middle of the development stage.

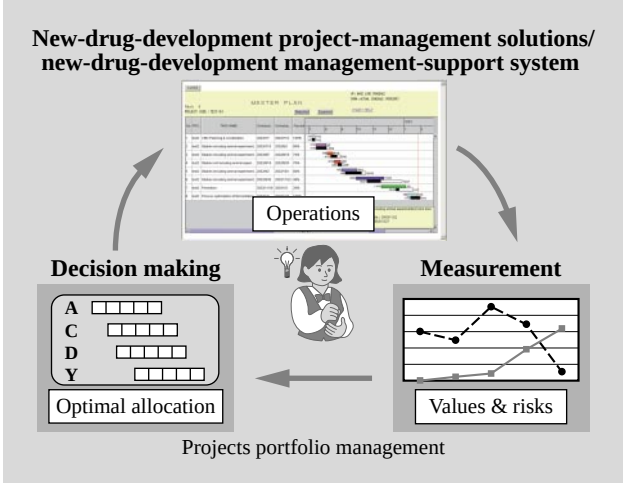

Fig. 6—Hitachi's Solution to New Drug Development.
Hitachi combines its new-drug-development project-management solutions/new-drug-development management-support system and portfolio management techniques to provide comprehensive solutions to project portfolio management for pharmaceutical firms.

Value and Risk Measurement of New Drug Development

As far as the technical risks are concerned, the value and risk of a new drug project could be measured from historical success probabilities at all stages. The project value is the mean profit through the project lifetime. On the other hand, the project risk is the mean loss of the project through the development period. The value and risk indices are calculated using the following formula.

Value =
Success probability × Profit – Investment … (1)

Risk =
[100 (%) – Success probability] × Investment … (2)

As shown in Fig. 5, the project value increases as it progresses through the development stages, while the risk is highest at the middle of the development stages. The risk peak is recorded at the low success probability and large investment requirement stage.

The value and risk of the project portfolio are the total of the values and risks of all the projects. More detailed models, including discount cash flow and real options, have been applied to managing an actual project portfolio, and enabled us to measure, approve, and manage the value and risk of an actual project portfolio.

SOLUTION FOR PROJECT PORTFOLIO MANAGEMENT IN NEW DRUG DEVELOPMENT

To successfully manage a portfolio for a new drug project, it is critical to immediately identify any problem areas that could potentially spoil the project portfolio. Additionally, resource allocation and rescheduling of projects are very complex problems, because they involve several sectors in a pharmaceutical firm.

To guard against these difficulties, a new-drug-development project-management solutions/new-drug-development management-support system is a key solution tool developed by Hitachi. By combining it

with portfolio management technologies, Hitachi can best help its pharmaceutical clients achieve comprehensive project portfolio management (see Fig. 6). Hitachi will support them from project value and risk measurement to the management and operation of the project portfolio. Hitachi also offers support for concept development, planning and system integration.

CONCLUSIONS

Hitachi's comprehensive solution for project portfolio management in new drug development combines its new-drug-development project-management solutions/new-drug-development management-support system and risk budgeting technology as a new approach to project portfolio management. Hitachi will support its clients in the pharmaceutical industry to maintain their high profitability in the worldwide market.

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(3) Seiyaku-navi, http://www.seiyaku-navi.co.jp in Japanese.

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