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# Research grant management schemes in the pharmaceutical industry

**Abstract**

Historically in Japan, funding to academia for medical and pharmaceutical research has been made by the private sector, such as pharmaceutical companies, with research grants accounting for largest proportion. Today, there is a strong need to increase transparency in collaborative activities between pharmaceutical companies and academia, including the use of such grants. This paper discusses future considerations in grant management schemes based on Deloitte's knowledge on the current situation for pharmaceutical companies in Japan.

## What are grants?

The aim of grants provided by pharmaceutical companies to academia is to promote medical and pharmaceutical research. Grants are generally categorized as follows:

- Research Grants: grants to support research and educational activities of academic institutions
- Grants to Academia: grants to support academic societies
- General Grants: grants to support business operations and activities of academic institutions

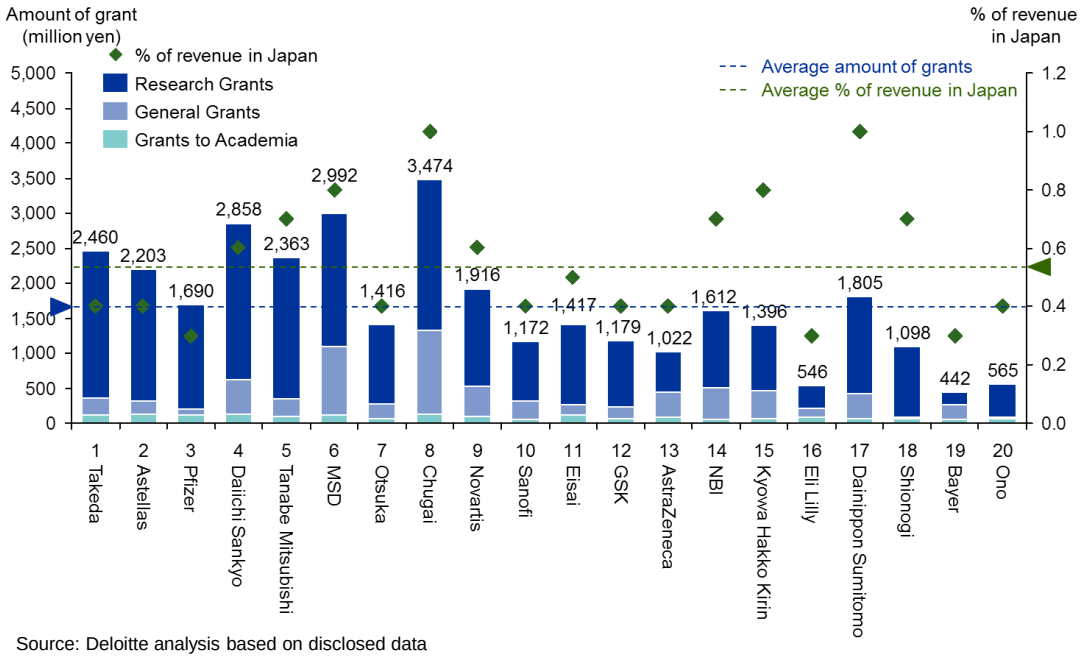
## Current situation of grants in the pharmaceutical industry

In Japan, unlike in the US and European countries, medical and pharmaceutical research in academia strongly relies on support from the private sector, including pharmaceutical companies. Provision of large amounts of grants by pharmaceutical companies is currently a topic of public scrutiny. It has been common that pharmaceutical companies fund physician-led clinical research projects on their own products through grants. Also, the contracts governing such grants typically do not stipulate usage of the funds, so grants have been treated as a source of flexible funding for researchers.

In January 2011, the Japanese Pharmaceutical Manufacturers Association (JPMA) published the "Transparency Guidelines for the Relationship between Corporate Activities and Medical Institutions*1", referred to below as "Transparency Guidelines". These guidelines are consistent with the Sunshine Act*2 in the US, and aim to ensure proper funding from pharmaceutical companies to academic institutions. Under the Transparency Guideline, the JPMA member companies are required to disclose payments to academia, including grants, made in FY2012 and beyond.

Figure 1 shows total amount of grants made by the top 20 companies by revenue in Japan. On average, the amount of grants by company is approximately 1.7 billion yen, accounting for 0.6% of revenue in Japan.

**Figure 1: Grants made by top 20 companies (revenue basis) in Japan (2012)**




Source: Deloitte analysis based on disclosed data

Remarks: *1: Published in January 19, 2011 and revised in March 21, 2013
*2: Law enacted in March, 2010 that requires disclosure of payment made in FY2013 in 2014

Research grants account for more than 70% of all grants. On average, each company gave approximately 1.3 billion yen, or 0.4% of revenue (Figure 2). The absolute amount of research grants is greater among the 1st to 10th companies than those ranked 11th to 20th. No significant difference is seen when the amount of grants is measured as a percentage of revenue. These figures indicate that the amount of grants correlates to scale of business.

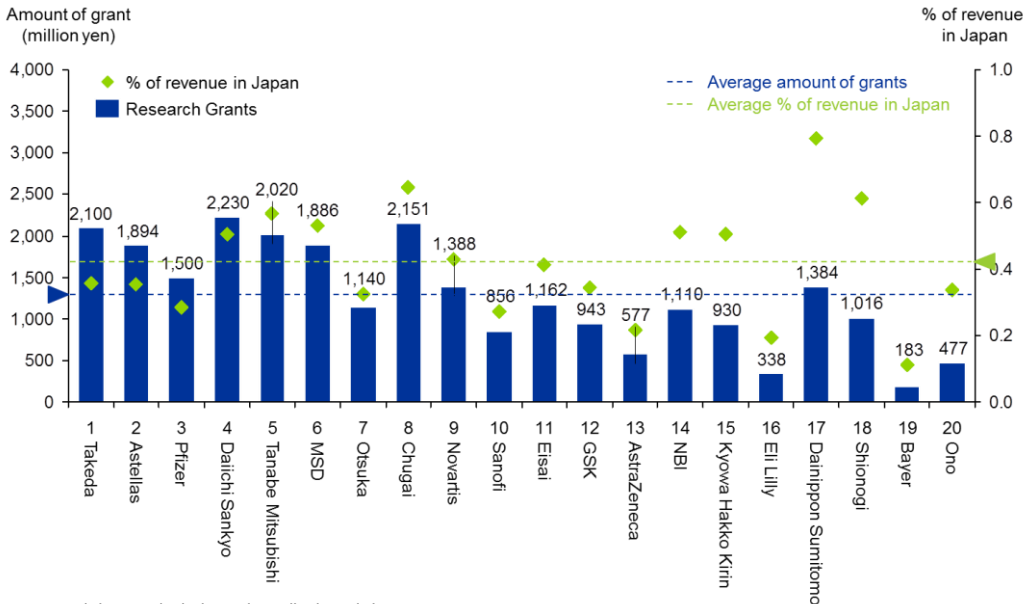
However, compared with foreign companies, a higher ratio of research grants to revenue is seen among domestic companies. This might indicate that higher focus on cost-control and greater control of grants by global HQs in foreign companies results in a relatively lower amount of grants. Although Japanese companies are also trying to control the amount of grants, the effort is not as strong than in foreign companies.

## Grant management schemes in pharmaceutical companies

Media attention to funding of physician-led clinical research is increasing, due to the initiation of information disclosure based on the Transparency Guidelines and the recent data fraud scandals in clinical research funded by academic grants. Hence, pharmaceutical companies are facing a need to tighten discipline of grants. At present, foreign companies tend to have stricter grant management schemes. For example, almost all foreign companies have a grant committee to supervise grants provisions. On the other hand, domestic companies either do not have such committees, or the committees do not wield meaningful control over grants .

The ideal scheme of grant management includes a grant committee consisting of members from different departments to ensure objectivity and transparency in decision making. Moreover, since “grants should not be made with any promotional purpose”, it is not necessary to include Sales members in the committee (and, in fact, such inclusion should be avoided if possible); inclusion of members from indirectly involved departments such as Research and Development (in terms of contribution to scientific pursuit) and Legal and Compliance (to ensure objectivity) should be considered. Naturally, the Chairman of the committee should be selected from a division with a sufficient level of independence (e.g. Medical Affairs), given the balance of power within the company.

**Figure 2: Research Grants made by top 20 companies (revenue basis) in Japan (2012)**




Source: Deloitte analysis based on disclosed data

We have seen several companies that do not have clear criteria for approval in grant committees. There should be written criteria in order to maintain equality of review process and for subsequent reviews. The criteria should be consistent with the individual company's perspective, in terms of type of research (e.g. target therapeutic areas) and quantity (e.g. cap of amount of grants).

It should be noted that some companies have already begun to implement improved systems on their own, without being compelled to do so by industry codes (such as the "Basic rules for support for clinical research from pharmaceutical companies, released by the JPMA on April 22nd, 2014).

In foreign companies, approval from HQ is required for certain procedures, in addition to that from management of the Japanese affiliate. This means that there is a hurdle in obtaining approval for something that is unfamiliar to Westerner stakeholders (including research grants for example). However, this situation turns out to provide a reasonable risk management scheme, preventing violation of regulations and reducing risks to reputation. In domestic companies, obtaining approval for grant provision is relatively easier because decisions are usually made within Japan. Also, there are cases in which insufficient review process, such as decision-making by line managers or only by circulating application to top management, creates risk for the company.

Although it has not been tried yet, inviting external experts as objective third parties in the decision making process can be a good option to maintain transparency. Of course, before exploring this option, companies must establish appropriate internal frameworks to prevent unnecessary risks. At the least, grants must be handled by divisions unrelated to Sales and Marketing and without interests in influencing physician researchers, such as Legal and Compliance.

Further efforts to increase transparency in grant approval processes would include a shift from application through Sales and Marketing personnel to direct web-based application. However, eliminating involvement of Sales and Marketing could result in insufficient communication with researchers and might negatively affect relationships with them. Involvement of Sales members is therefore still necessary, however, companies should establish an appropriate scheme where employees with close relationships with researchers can avoid biasing the decision-making process through conflict of interests.

Some pharmaceutical companies are currently trying to reform their grant management scheme using the techniques described above. As they do so, they may face with an internal conflict between divisions in charge of grant management under the new model and Sales and Marketing, due to Sales and Marketing's resistance toward altering the current amount of grants and procedures. To implement the transformation to the new model, strong leadership of internal and external experts in grant management is required.

For companies currently without an established framework, it is imperative to review the current procedures and to adopt stricter grants management scheme.

## Future support for clinical research from pharmaceutical industry

As noted above, on April 22nd, 2014 JPMA issued a notice titled “Basic rules for supporting clinical research from pharmaceutical companies“ to 72 member companies:

- Support for clinical research: Funding or provision of materials for clinical research on the provider’s own products must be conducted based on a contract, with statement of a return policy of unused fund or materials. Pharmaceutical companies must not provide services that may raise doubts on neutrality of research and research results (e.g. data analysis).
- Research grants: Research grants should not be provided to fund clinical research of the provider’s own products. An internal function that is independent of Sales and Marketing should undertake a thorough check for potential conflicts of interest before making the decision of whether or not to provide the grant, and background information on the decision must be documented and stored.

As a result of this notice, research grants for clinical research of the provider’s products are banned. There is an urgent need for personnel in charge of grants to notify and provide training to company members quickly and sufficiently, and monitor external communications.

## Recommendations

Considering the recent changes in grant-related guidelines and the current status of each company, the following points must be considered:

- Proper adoption of new industry codes in grant provision process
  - The “Basic rules for supporting clinical research from pharmaceutical companies“ calls for changes in grant provision. Measures to avoid potential conflicts of interest between pharmaceutical companies and researchers and a scheme to enhance transparency into the grant provision process should be developed.
- Appropriate policies and scale of grants
  - Define criteria consistent with industry standards, considering the purpose of grants; contribute to medical and pharmaceutical research.
  - The goal should not be to simply decrease total amount of grants; rather the total amount of grants should be reviewed and defined from the following perspectives: changes in industry regulation (e.g. physician-led clinical research requires a contract); scale of grants suited to business size; selection of therapeutic / geographic areas from disease trends and epidemiological perspective; well-balanced selection of research themes.
- Alternative measures to support academic research
  - Develop a scheme where continuous support to medical and pharmaceutical research can be provided (e.g. in the form of so-called *itaku kenkyu*, that is, forming contracts separately for individual lines of research).
- Sustainable compliance with regulations
  - Be prepared for future changes in industry codes and / or regulations, so that timely revisions of corporate rules / processes can be made.
  - Establish measures to minimize future risks to reputation that could damage business: an error prevention scheme to ensure / enhance regulatory compliance; operational frameworks that allow early detection and quick reaction to issues through routine self-monitoring.

To achieve a successful transformation of the grant management scheme, it is important to have extensive discussions with Sales and Marketing function under strong leadership. Also, change management is critical to prevent potential risks before they turn into real problems, ultimately striving for excellence as a pharmaceutical company.

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