

# Shrinking New Drug Development Lead Times Using Knowledge Communities

## Pfizer Japan Inc.

Drug giant Pfizer Japan Inc. (Pfizer) is looking to increase speed and productivity in its clinical development process by shrinking the amount of lead-time it needs to launch new drugs. Pfizer's new-drug clinical development unit, J-clin, is spearheading the company's efforts to find a solution to this challenge—one that all pharmaceutical makers face. J-clin is taking full advantage of REALCOM's KnowledgeMarket as a solution to rationalize clinical development processes.

### Two Conflicting Issues, One Resolution

Pfizer's J-clin (new drug clinical development unit) began practicing knowledge management for two reasons. One, through mergers and consolidations, Pfizer has grown its business and organization tremendously over the past several years. It merged with Warner Lambert in June 2000 and consolidated with Pharmacia in April 2003. Pfizer is now a drug titan, covering a vast range of ailments. And that's just its pharmaceuticals business. At the same time, its organization has swelled to about 6,000 employees in Japan alone, and J-clin now employs 420 people, three times its past size.

"As our organization ballooned, we had to deal with how to bring everyone under one figurative roof," says Katsuyoshi Shimatani, managing director and head of the clinical development unit at Pfizer.

Environmental changes in new drug development were another factor. For several years now, as health awareness has risen, beliefs about drugs have changed. In addition, Japan, US and Europe agreed to the international standard, International Conference on Harmonisation (ICH). Subsequently, the ICH revised the standard for conducting clinical studies, Good Clinical Practice (GCP), in 1997 for enactment the following year. The revision forced drug makers to meet more stringent GCP guidelines.

"J-clin started with the objective of responding to such environmental changes, conducting quality clinical studies and bringing appropriate new drug candidates to market quickly. But we were up against two conflicting and concurrent challenges; bring together an expanding organization on the one hand, improve work quality and speed on the other. To meet those challenges, we needed a system capable of resolving both issues. It had to support our needs to: share information and know-how in the shortest time possible; facilitate training and knowledge acquisition; and communicate seamlessly with all J-clin staff," says Mr. Shimatani.

### A Forum for Frank and Day-to-day Exchanges

To resolve these issues, J-clin turned to REALCOM's KnowledgeMarket. Using the knowledge communities that run on KnowledgeMarket's platform, J-clin first set out to improve how its staff shared and made use of successes and failures from past new drug development efforts. Of course, each clinical development project needs to share this type of knowledge to avoid hitting the same pitfalls and repeating the same mistakes. To resolve this issue and share know-how (knowledge), J-clin had held periodic meetings called "Lessons Learned" comprising members from each project. The meetings provided a forum for exchanging know-how and opinions. J-clin documented this information and, by doing so, sought to preserve

that knowledge as assets. But as project work loads reach their maximum, members have less time to devote to other work, and organizers found that, "it was the best we could do to time the meetings with lulls in work loads, such as after clinical study notifications or filings."

"So we changed the format of Lessons exchange. We wanted to be able to exchange and absorb cutting-edge knowledge learned by all development staff, in real time," says Toshiko Miyawaki, J-clin's knowledge management promotion officer.

She adds, "Each department at J-clin has staff with expertise in their respective fields. Beginners can ask experts and get appropriate answers. But the experts are unaware of what is puzzling the beginner until he asks. One reason we introduced knowledge management was to resolve these issues involving how staff acquire knowledge. We used KnowledgeMarket's Q&A function as a means to that end."

According to Ms. Miyawaki, besides sharing successes and failures from the new drug clinical development process, J-clin set a number of other objectives for its knowledge management implementation: unearth experts' tacit knowledge to be shared among all development staff; shrink time required to obtain new drug approval; eliminate reworking before new drug approval; and practice core values (Pfizer's corporate code of ethics).

### Designing an Active Community of Information Sharing

To achieve the goals listed above, J-clin began operation of knowledge management for its entire staff in October 2002.

But the company says it faced unexpected challenges after the full knowledge management launch. On J-clin community, the knowledge community for all J-clin staff, perhaps out of self-consciousness, information providers spent time and nerves polishing their compositions before exposing them to every department member. That also made it difficult for users to post questions. Even then, once a question was indeed posted, answers came back with great speed, some times only minutes after the question was posted.

So, J-clin spun off smaller communities from the department-wide community. More specifically, it launched a community for its regulatory affairs department and another comprised exclusively of employees involved in quality assurance of clinical study data.

The effort to create an environment where people can feel comfortable making postings by narrowing the theme or participants was a success, and communities saw active exchanges, according to the company.



Katsuyoshi Shimatani, managing director and head of the clinical development unit at Pfizer Japan Inc.

In light of these circumstances, Mr. Shimatani provides the following evaluation and future direction for knowledge management. "I think it's safe to say that we are using the information-sharing system based on KnowledgeMarket very effectively. Moving forward, we face the challenge of how far we can grow the system's reach. In that sense, I want to study and improve on a day-to-day basis how to effectively allocate the communities and operate them beyond J-clin."

J-clin is working on a plan to extend its KnowledgeMarket community to its clinical development units overseas. This is a rare example of the American company Pfizer taking a new system born in Japan and rolling it out globally.

J-clin's knowledge management efforts continue to evolve and expand as it pursues its ultimate goal of shrinking times to market for new drugs.

#### CASE STUDY OVERVIEW

##### Purpose of knowledge management

- Increase clinical development speed and productivity
- Share successes and failures from clinical development processes
- Unearth experts' tacit knowledge and share it among all development staff
- Shrink time required for new drug approval and eliminate reworking
- Improve quality of clinical development work and practice core values

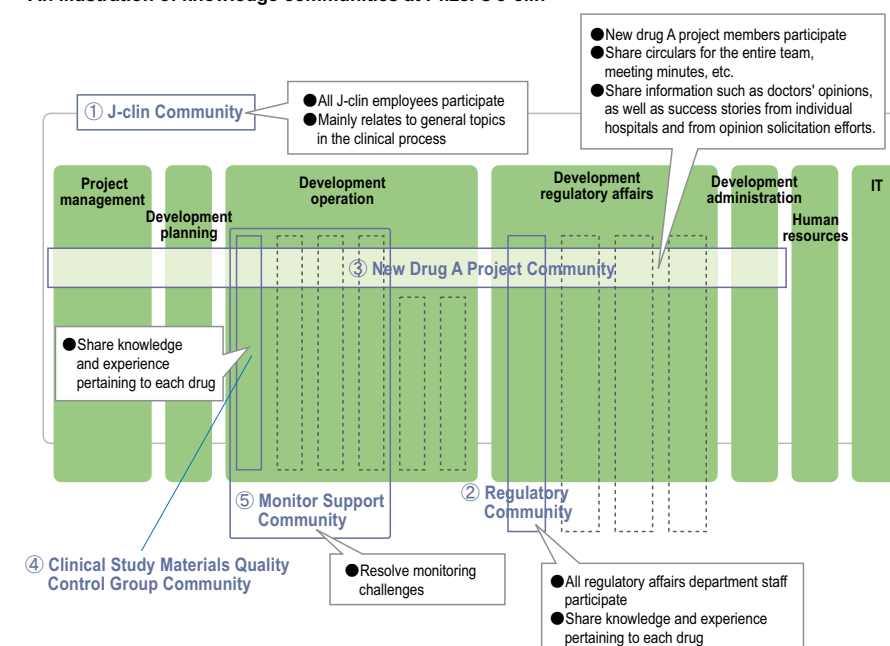
##### Benefits from knowledge management

- Exchange knowledge needed and cutting-edge information in real time and increase work efficiency
- Increase project management quality by openly sharing best new-drug development practices within the organization
- Improve skills of all staff by promoting active information exchange on theme-based communities

##### Number of users

- Approximately 420 (all employees of J-clin, Pfizer's clinical development unit)

An illustration of knowledge communities at Pfizer's J-clin



#### USER'S PROFILE

Company name:  
Pfizer Japan Inc., Japanese subsidiary of Pfizer (US)

Capital: 64.8 billion yen  
Employees: 6,024

Areas of business:  
Manufacture, sale and licensing (in and out) of ethical drugs, nonprescription drugs, animal drugs and agricultural chemicals.

Places of operation:  
Head office, 4 manufacturing and research facilities, 3 research labs.

Revenue: 308,116 million yen (FY2003 results)

URL: <http://www.pfizer.co.jp/>