A Systemic Approach for Managing Complexity in Pharmaceutical Research

Dr. Hugo Bertschy, F. Hoffmann-La Roche AG, Basel and
Dr. Pavel Kraus, AHT intermediation GmbH, Liestal, Switzerland

1.0 Introduction

The long-term success of pharmaceutical companies depends on how effectively they can discover and develop new, medically-differentiated pharmaceutical products. Interdisciplinary project teams are in place, which are experts at successfully dealing with the challenges of this complex task. . They must be both highly innovative in order to identify new targets and drug candidates and work systematically within defined boundaries to effectively eliminate unsuccessful approaches early in the drug development process. Making the right choices is a key success factor for keeping costly late-stage project failures at a minimum and thus for investing resources in the best drug candidates.

Working effectively with available knowledge and information is crucial, and numerous initiatives have been introduced within pharmaceutical industries to improve knowledge management (KM). A review of such initiatives in F. Hoffmann-La Roche AG's research organization in Basel showed the need for a holistic approach to knowledge management and its value.

An initiative was launched with two main objectives:

A) To develop a KM concept so as to increase the effectiveness of the research teams, thereby making them more successful
B) To verify the concept's potential (proof of concept)

2.0 Background

2.1 Duality of successful research work

The success of a research project team depends on two main factors: its ingenuity and expertise in what one could call core tasks, as well as its proficiency in handling the complexity of generated knowledge and information.

The first domain consists of the core activities such as biological target identification and validation, modeling and synthesis of chemical compounds, or toxicological and pharmacokinetic investigations. The second domain is a compilation of tasks including data and information management, electronic and face-to-face communication, knowledge expression and capturing, integration of past and new information, or coaching team members and enabling an open and creative atmosphere within the project team.

A project's ultimate success depends on the **expertise and virtuosity of the project teams in simultaneously managing both domains**. This means that project teams must be well aware of the details of their core tasks and they must understand the techniques, instruments and tools available that allow them to deal with knowledge. Finally, they must be able to connect these two abilities on a case-by-case basis.

The level of the research teams' expertise in the domain of core tasks is generally exceedingly high. In comparison, expertise in information and knowledge-based domains is often less evolved and limited to the use of specific applications and tools. A team's performance can be improved by combining the two domains and by improving proficiency in dealing with knowledge and information. A systemic approach was chosen to address this issue.

2.2 Knowledge and information transfer processes

The relationship and distinction between knowledge and information is another cornerstone of this concept and is based on the assumption that knowledge resides only in the human mind. As soon as knowledge is recorded in any way, it becomes information.

Knowledge and information are constantly transformed. For example during workshops, knowledge is developed during conversations (process 1) and becomes information when written down (process 2); this information is then recorded (on cards or slides), placed into a new context (process 3) and then used to build up knowledge later on in the workshop (process 4). These four processes often occur simultaneously during collaborative work. The social aspects of these processes have been described by Nonaka in 1995.

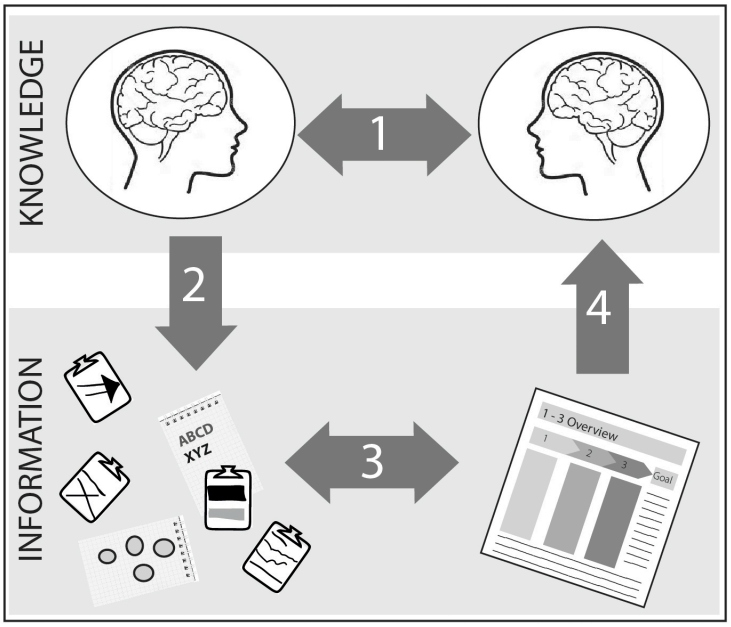

Figure 1: Knowledge - Information Transfer Processes

No.	Process	Key tasks or success factors
1	Direct knowledge exchange	Presentation and facilitation techniques, personal communication, rhetoric
2	Knowledge to information	Timely documentation, personal notes, visualization, taxonomy, controlled vocabulary, seamless integration of business processes
3	Information transformation	Coding, information organization, database interfaces, seamless information architecture, information workflow, information lifecycle
4	Information to knowledge	Controlled vocabulary, taxonomy, local depiction, visualization, scanability, timely accessibility, searchability, depth of context

Because every one of these processes is equally important in research work, a high level of proficiency is required for each. In this respect, this systemic approach differs from other knowledge management approaches that tend to overemphasize or neglect one or the other of these four processes.

3.0 JOIN – A systemic approach to Knowledge Management

JOIN is a concept developed for systemic knowledge management in research. JOIN has also been the name of an initiative within Roche research organization in Basel, that aimed at joining the two types of knowledge domains.

Increasing proficiency in dealing with knowledge and information is based on the following JOIN management activities:

- Situational requirements analysis for current and future tasks
- Continuous identification and collection of good practices
- Linking good practices with situational requirements
- Development of new practices, techniques and applications

The following set of systemically-connected measures was adopted to enable the knowledge management activities mentioned above:

3.1 Situational requirements analysis for current and future tasks

A categorization grid was developed to perform the situational requirements analysis. The grid helps to position tasks within the information/knowledge domain and connects needs with potential solutions. The four knowledge and information transfer processes constitute the basis for the categorization grid.

In order to identify these transfer processes in practical day-to-day work, two research teams were observed over the course of several weeks. During this time, their methods for working with knowledge and information were mapped at various degrees of granularity to the transfer processes and then clustered. The result was a categorization grid with six key tasks critical for complex research work:

Grid Category	**Activities in this category enable research project teams to:**
Data exchange	Exchange data seamlessly using attributes (controlled vocabularies) and appropriate interfaces to establish structured storage and easy data access.
Information presentation	Present information in a logical and systematic manner. This includes structuring and visualizing content, organizing main messages, and explicitly developing arguments.
Information and process visualization	Convert relevant information into visual form, thus facilitating communication; map processes with information in a chronological context as a prerequisite for the ability to access information quickly.
Integration of new and past information	Efficiently merge new and past information based on former insights. This includes a review process for past information based on new data and information, reformulating past conclusions, revisiting and revising arguments.
Knowledge documentation and knowledge visualization	Document expertise in a given context. Documentation includes various types of expertise (reasoning, arguments, explanations, examples, principles, past analogies, etc.), circumstances, and the connection between them both.
People communication; ensuring sufficient knowledge flow	Create conditions to provide a basis for mutual trust and full, unrestricted knowledge contribution to facilitate discussions dealing with uncertain conditions and encourage new innovative approaches to solutions.

The above categorization grid provides a link between the concept of knowledge and information transfer processes and practical daily routine. It includes innovative approaches, such as knowledge visualization and other supporting activities. With its help, it is possible to classify the daily tasks of researchers and the challenges associated with them. . At the same time, the grid makes it possible to allocate the techniques, services and systems used for such activities. Thus, the tasks and the techniques can be linked or joined, enabling the systemic assessment of situations in highly innovative research work.

3.2 Continuous identification and collection of good practices

The systemic assessment of situations requires specific expert knowledge. Observations of the two research teams show that teams would benefit from support for their knowledge and information work. Simultaneously, this type of team support identifies and records a team's working practice. This dual role of team support makes it possible to harvest good practices in organizations.

For the most part, project teams will initially need support in their efforts to assess situations and identify the appropriate good practice, while at a later stage, the emphasis will focus mainly on information work. At that stage, one that corresponds to a higher maturity level, a junior supporter will be adequate to help the project team. This team support will create an opportunity for faster learning and act as a learning organization switchboard. In this way, teams will be able to improve their work methods by cultivating the quality of their tacit group knowledge.

3.3 Linking good practices with situational requirements

The identification and categorization of critical knowledge tasks is the role of the first JOIN management activity. The second activity allows the delivery of good practice and harvesting of the same across various teams. The third step is a systemic link between needs and good practice solutions for each actual situation. They must be available for both: the team support and the research teams. The ideal delivery option is an interactive self-service repository.

The navigation in this repository is based on the visualized micro processes of research work. These role-specific processes were recorded in a detailed survey of daily tasks. Some of these tasks are defined as «adjuventive tasks», which support the practical knowledge work in a detailed granular way. They are the key success factor of good practice.

The self-service repository functions as a storage site and interface for key information on knowledge work support and the corresponding «adjuventive tasks». Each task within the micro processes is linked with the necessary techniques, instruments or tools. Instructions for use are explained with examples, links to tools and templates are provided. Ideally, this repository is accessed via an Intranet Solution Portal, which can be further developed into a Process Collaboration Portal.

3.4 Development of new practices, techniques and applications

Further organizational development can only be assured if good practices are continuously improved. To do so, improvement needs are continuously collected during team support activities. In a specifically-designed workshop, participants categorize and validate issues and formulate potential initiatives. Subject matter experts from various research teams representing all relevant functions are needed to assure a holistic view. The result of the workshop is a well-balanced portfolio consisting of improvement opportunities that cover all areas of the categorization grid. Thus, the identified solutions already have a buy-in from representatives across the organization.

4.0 Approach verification

Due to the nature of pharmaceutical R&D projects (more than ten years from lab to market), it is impossible to directly measure the effectiveness and success of a team. However, the four modules were developed and tested with both a research team in a critical project phase and with peers from relevant research functions. Feedback collected in structured interviews and from questionnaires showed that the concept was well received by research project leaders and that it has the potential to create significant improvements.

5.0 Conclusions

The initiative provided a straightforward concept to improve effectiveness of research teams. The JOIN concept considers the highly complex nature of research work in pharmaceutical discovery, and provides an integrative systemic approach that takes its multifaceted nature into account. It enables project teams to deal appropriately with knowledge and information processes along with their actual innovation work.

JOIN concept has clear linkages to the systemic viability steps. Through the continuous improvement the serviceability and flexibility is ensured. Best practices can be gathered on multiple occasions and used as components in other contexts. This synergistic recycling protects resources.

The team support as an organizational function is a stable structure providing central guidance for the best practice delivery. This delivery enables learning cycles from the research teams to the team support and back. Teams are encouraged to use the recipe book autonomously in a self-service fashion and thus organize their work more efficiently. This is ideal in a scientific research environment needing a great degree of freedom and fostering qualitative growth.

Implementation of the JOIN concept is a long-term effort and was not part of this initiative.

Information about the authors:

Dr. Hugo Bertschy works for F. Hoffmann-La Roche Ltd in Research Informatics in Basel, Switzerland. For more than a decade, he leads and contributes to knowledge management and organizational development projects in life science industries. His main areas of interest are innovation management, complexity management, scientific records and information management, people motivation and coaching.

hugo.bertschy@roche.com

Dr. Pavel Kraus is senior partner at the management consulting company AHT intermediation GmbH in Liestal, Switzerland. He lectures on innovation and knowledge management at the university for applied sciences in Bern and Muttenz.
Prior to that he held a position as Knowledge Networking Officer for Roche Diagnostics. He serves as the president of the Swiss Knowledge Management Forum.

pavel.kraus@aht.ch / www.aht.ch / www.skmf.net