



# editorial



**Mark R. Cunningham**

## Driving operational excellence across research

### Introduction

The famed Scottish researcher, Alexander Fleming, never set out to discover penicillin; it was an 'accident'. This is the current paradox faced by pharmaceutical and biotech companies who strive to align innovation and cutting edge science with the quest to identify new drugs. Clearly, in the current challenging environment, the vision of a 21st century drug discovery organization cannot be 'we will do science and rely on accidents to develop drugs', and so how does an organization harness the function of Research to generate medicines that were as impactful as penicillin was in the early part of the 20th century?

In this article I define Research as the set of scientific functions that support activities from identifying new targets, through generating new molecular entities (NMEs) to the launch of a new drug in an appropriate disease indication. In this setting, the Research division (Discovery, Biomarkers and *In Silico* analysis) within the Immunology Therapeutic Area of Centocor Research & Development, Inc and Johnson & Johnson Pharmaceutical Research & Development, L.L.C., has invested in a core function called 'Strategy and Business Planning' (S&BP). S&BP is charged with developing the

appropriate environment for Research strategy execution. This article is aimed at describing the S&BP function and the methods it employs to support drug discovery and development from an integrated small and large molecule portfolio.

### Strategy and business planning principles

- As a core function of drug discovery and development, S&BP is dedicated to providing planning and operational leadership to the complete processes of Research Immunology.
- The S&BP team uses expertise in science and business to maximize the quality of individual Research functions, projects and portfolio level analysis.
- S&BP builds and maintains relationships with key internal/external partners to drive collaborative activities that support functional, project and portfolio deliverables.
- S&BP optimizes team performance and functional interactions by providing tools, processes and guidance to drive efficiencies and enable decision-making.
- S&BP focuses on facilitating reviews for resource allocation and decision-making and provides real-time access to Research Immunology pipeline information.
- S&BP enables its quality systems strategy through the application of a customized Microsoft SharePoint® collaborative tool.

### Strategy execution

It has been reported that the two crucial elements to strategy execution are Communication and Decision Rights and these have become drivers for S&BP [1]. Governance within Research is clearly defined by two bodies: (1) the Research Immunology Scientific Council (RISC) and (2) the Research Immunology Management Board (RIMB). RISC membership covers the complete drug discovery and development process and has the decision rights over pre-NME portfolio transitions and research strategies. RIMB is an operational board that has decision rights on topics associated with budgets, people, facilities and processes. It is the responsibility of S&BP to ensure that these leadership bodies are effective in driving high-quality decision-making and communication so that the efforts of a lab scientist conducting an experiment align with the translational differentiation strategy developed by a project team. To accomplish this, an emphasis must be placed on systems that collect and communicate the data that is relevant to the decision-making forum.

Beyond this, activities of the S&BP team can be described using the terms *Research Planning* and *Research Operations*.

### Research Planning and Research Operations

S&BP Research Planning provides the 'architecture' for drug discovery and then partners with the development organization to support clinical and product life cycle activities. The planning activities include crucial path discussions as soon as a project enters the portfolio, regular milestone meetings with scientific leaders to track progress and conflict resolution with resource providers. Terminology on a diverse set of target- and asset-based projects is standardized so that both small- and large-molecule projects can be viewed as a single portfolio. The A3 lean principle [2] is used to focus discussions by providing templates for information sharing and tools are tailored to work in an environment where the predictability horizon is approximately three months. Scientists are not asked to manage complex Microsoft project files, rather S&BP have the responsibility to work with leaders to define crucial paths, identify key milestones and provide real time information for stakeholders on issues resolution and progression.

S&BP Research Operations strives for operational excellence [3] by the development of enabling processes that do not restrict innovation but provide a mechanism to maximize resource and minimize misalignment of activities. Scientists will, rightly, reject process for process sake when their motivation is exploration of novel scientific space; it is the responsibility of S&BP to develop the appropriate environment and lighten the load of operational processes to enable a focus on scientific innovation.

In support of these Planning and Operational activities, S&BP have invested time in Microsoft SharePoint as a quality system by taking educational classes, participating in cross-Pharma forums and developing a strategy-appropriate use.

### SharePoint as a collaborative tool

S&BP has evolved a SharePoint strategy that now enables the effective management of projects by the Research functional and portfolio teams. The features found to be of particular use are as follows:

- (1) *Workflow approval*: Electronic approval of information for efficient governance; sending a single PowerPoint slide that has a team recommendation, with relevant information and risk mitigation strategy, enabling virtual stage-gates transitioning.
- (2) *Libraries and reporting*: Metadata, tagged and stored in a single location that can be 'viewed' depending on the query; libraries are used to manage complex processes, for example, external collaborations (request, negotiation, execution, payments and closure), and project-related information (crucial paths, monthly updates and decisions).
- (3) *Workspace for teams*: Interactive space to coordinate meetings, manage agendas and track actions; scientific and function leadership teams use this simple interface to manage interactions in standardized and centralized environment.

Of note, is the ability to embed schematic views, derived from MindManager® or Microsoft Project® files, to represent project paths, for example, a key milestone map for Biomarker teams to view so that resourcing around samples from clinical trials is appropriately forecasted and managed.

It is also important to realize that SharePoint is not an archiving system, teams that purely create folders of information are missing the full impact of this elegant collaborative tool and, in essence, are generating a series of filing cabinets. In this area, S&BP have identified a cloud archiving system (Merrill Corporation's Virtual DataSite®) that complements SharePoint and provides a host of excellent features for long-term searchable archiving.

### Building relationships and handling corporate processes

As facilitators of many processes, the S&BP function focuses on relationship and community building. Once established on a foundation of trust, a community of cross-functional representatives under the leadership of S&BP becomes a powerful mechanism to align activities behind the strategic goals of the Research function. In addition, a foundation of quality systems, enabling process and real time information management, S&BP can provide a valuable interface for corporate process management. Examples are Health Care Compliance (HCC), Business Planning, and the complete process of contract management. In a working environment where HCC is becoming an integrated aspect of Research activities, S&BP (via SharePoint) can set up workflow approvals to align budget spend with scientific strategy generating transparency for all activities and supplementing dedicated systems. This becomes crucial for risk management, where knowing corporate process in detail and having a dedicated function such as S&BP, enables a traceable record of compliance to be established as a platform for fast and prudent risk taking.

### The future

Over the past few years, the S&BP function has evolved in step with the growth and the requirements of the Immunology Therapeutic Area. We operate in a mode of 'continuous improvement' that drives operational excellence. This mindset enables us to increase project and strategy planning, to decrease urgent issues and to drive a focus of effective execution against priorities. This investment in Research architecture, systems and processes ensures that both communication and decision rights are enabled and strategies are executed effectively.

### Conclusions

I believe a strategic business focus successfully applied in the earliest stages of scientific discovery, that aligns itself with the needs of the patient receiving a new drug in 10–15 years, has a positive impact on drug discovery and development. The S&BP function would not exist without the need for effective planning and operational excellence in Research where we are dedicated to the generation of transformational patient solutions [4].

### References

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### Mark R. Cunningham

145 King of Prussia Road, Radnor, PA 19087, United States  
email: [mcunnin2@its.jnj.com](mailto:mcunnin2@its.jnj.com)