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Articulating a Vision for Best Practice Project Management in Drug Development

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Introduction

Until recently, the commercial and financial performance of drug development companies has been one to which many other sectors aspired. Pharmaceutical stocks during the 1990's were considered a safe haven for investors, whatever else was happening in the market. This has changed dramatically over the last five years, as this sector has become one of the few that has seen contraction in real corporate value, in terms of market capitalization and stock returns. A key reason for this decline is the increasingly poor performance of the sector in getting new drugs to market.

The number of new drug approvals in 2007 was the lowest for twenty five years, with only seventeen new molecular entities (NMEs) approved and two novel therapeutic biologics[1]. Adding to the pressure on the life science sector to improve delivery of new drugs to market is the following:

- Three drugs withdrawn or suspended in 2007[a]
- Fifteen marketed drugs came off patent, and faced generic competition
- 2007 was preceded by almost equally as bad previous years in 2005 and 2006

It is the author's contention that the relative lack of project management maturity in the development of drugs is *one* of the major factors inhibiting the ability of pharmaceutical and biotechnology companies to successfully deliver new products to market. New product development in many sectors has been revolutionised over the last twenty or so years by the transition to a 'project-centric' management approach. Yet true projectization (in contrast to what often passes for projectization in drug development) is often fiercely resisted by the scientific communities employed in drug development.

One of the clear lessons from change management across sectors is that reducing resistance to change requires people to have a clear vision and understanding of the proposed new ways of working. As part of the drive to help articulate the vision of a project-centric drug development organization, we have been conducting academic research on what constitutes best practice in drug development project management. This paper

[a] Pergolide (*Permax*), Eli Lilly & Co/Valeant Pharmaceutical International; tegaserod (*Zelnorm*), Novartis AG; aprotinin (*Trasylol*), Bayer AG.

presents some of the early findings of that research, as well as our conjectures on the impact on the development of new drug products of adopting these best practices. The paper also discusses additional research currently underway, which seeks to further develop our understanding of best practice project management in the life science sector.

Brief Methodology

The approach to this research has been based very much on an action research paradigm[2, 3, 4.] The author conducted research at the University of Manchester between 1999 and 2001 on the identification of best practices in the project management of creative design in the construction and engineering sectors. A model of best practice was developed and subsequently tested. The model integrated the Association for Project Management and Project Management Institute bodies of knowledge[5, 6]. This model was adapted to the life science sector based on further field work with consulting clients in the pharmaceutical and biotechnology sectors. The model continues to be refined as significant numbers of people are interviewed using a semi-structured anonymous and confidential 'depth' interview process[7] across many life science organizations. The number of in-depth interviews now exceeds three hundred.

A comprehensive reevaluation of the data set is currently being carried out. A revised best practice model is being developed independent of the original modified model, with data gathered from twenty two depth interviews. This will then be validated by questionnaire[8].

The best practice model of Portfolio, Program, and Project Management in drug development

We have identified best practice in drug development portfolio, program, and project management (D^2P^3M) in a number of key areas and topics. Best practice is broken down into six areas:

1. P^3M Infrastructure
2. Strategy Integration
3. Planning & Control
4. Scientific Integration
5. Commercial Arrangements
6. People & Organization

Within these areas, some of the topics may seem rather arbitrarily categorized; uncertainty management is discussed within the strategy integration topic area for instance, but it should of course also be completely integrated with estimating (in the planning and controlling area). Whilst recognizing this, it is nonetheless necessary to separate these practices in order to write coherently about them.

1. P^3M Infrastructure

1.1 Organisational context for P^3M

Portfolio, program, and project management is seen as an integral part of the organization, providing the 'right brain' and nervous system for all drug development work – good management control. The functional groups provide the heart, blood, muscles, and 'left brain'

of the organization – the actual organs of life and the creativity to thrive. The implication of having technical functions and management control in harmonious balance is a mature, well understood, formalized matrix organization,(operating somewhere between a 'weak' and 'strong' matrix structure).

Achieving this balance is usually one of the outcomes from a sustained change initiative to develop project management competence over several years. Even when best practice project management, as the predominant way of doing drug development, is introduced in a 'big bang' way, the exercise is rarely completed in less than 3 years of intense work.

1.2 Drug development and project lifecycle connection

The drug development and project management lifecycles are directly linked together, with effective stage gate control to manage the transition from one development phase to the next. Peer review of stage gate proposals and presentations is commonly available to all project teams, as well as ad hoc support from Subject Matter Experts.

Development of the peer group and processes to achieve this is not necessarily a huge task, but significant stakeholder work *is* required to persuade senior management and project leaders that there is value in the processes.

1.3 P^3M Governance

P^3M Governance arrangements are non-bureaucratic and flexible, but key criteria are defined and must be demonstrably met on an ongoing basis by projects and programs. Sponsorship exists for programs and projects, with accountabilities defined for the role.

Attaining widespread agreement on the processes can take time, and needs explanation. Senior management must 'walk-the-talk', and require project teams and functions to adhere to the rules as agreed with them.

1.4 Portfolio management

A portfolio of programs and projects (or multiple portfolios dependent on the size and complexity of the organization) is maintained, and managed against business objectives, to ensure the corporate strategy is delivered. Projects are terminated based on scientific and commercial rationale only.

Portfolio management is normally seen as a core competence of life science product development organizations. Maximizing the effectiveness of the portfolio process is based on a rational demonstration that higher value could be obtained from the portfolio if corporate strategy and project strategy were better linked through the portfolio management process.

1.5 Vocabulary

There is a vocabulary for P^3M that is well understood across the business, with a glossary available to all.

Widespread engagement with all stakeholders is required, but usually of a relatively low intensity. A vocabulary is often part of the output of a large scale P^3M best practice change initiative.

1,6 Stakeholder management

Stakeholders of drug development programs and projects are routinely managed as part of the P^3M process and practice. Stakeholder analysis is undertaken, resulting in stakeholder maps and stakeholder management actions which are implemented and monitored.

Whilst good people skills are required to actively manage stakeholders, the analysis, mapping and action planning process is straightforward, and based on a logical approach – the idea being to influence stakeholder behaviors to ensure project success.

2. Strategy Integration

2.1 Linkage of corporate strategy to drug project strategy

There is a clear linkage from corporate strategy, through the portfolio process, to program and project strategy. Projects have a business case that demonstrates how business/portfolio strategy will be delivered. The business cases of all programs and projects follow a consistent pattern, and are reviewed at stage gates. Criteria that define program and project success are proposed and agreed at stage gates for each project, and may include: Critical Success Factors (CSFs); Key Performance Indicators (KPIs); and Benefits Delivery Criteria..

Achieving best practice in this topic area normally requires a significant amount of work. The changes impact at every level of the organization, from executive management to the smallest study teams. Identifying and managing CSFs requires time and skill, and selecting and being managed to KPIs often requires significant cultural change.

2.2 Articulation of project strategy

Clearly articulated program and project strategies are available, setting out how individual programs and projects will deliver the business case. Such strategies typically include high-level views of project planning (schedule, budget, business value, resources required, impact of changes in portfolio prioritization on the plan, future market/science scenarios, and buy-up and buy-down options, etc).

With senior management support, including from the portfolio management team, this is usually straightforward to achieve. Putting together program and project strategies is normally a case of bringing together and clearly articulating existing thinking (and perhaps documentation as well) on the particular program or project. A simple process with templates makes this easier.

2.3 Drug value management

A formal process for managing drug value through the lifecycle exists, and the outputs from drug value analysis inform the portfolio prioritization discussion and calculations. Project leadership is accountable for value delivery, with some of informal or formal internal contracting arrangement in place between the functional groups, the project teams, and Governance/senior management.

Significant cultural change is normally required to achieve best practice in drug value management. Putting in place a formal or informal contract arrangement between drug teams and senior management requires acceptance of the role of functions in supporting this

process. This role is different in nature to the traditional role played by functions (e.g. control of budget often passes to the project team in this process).

2.4 Front-End Loading

Significant Front-end Loading (FEL) of project plans is standard practice, with human resources, as well as budget, made available early in the DDLC. Marketing and other commercial functions input to project decision making and strategy setting from the early in the DDLC.

This is a process requiring, during its early use, a 'leap of faith'. Over time, when the advantages from the early expenditure of resource have been proven, FEL normally becomes a standard practice for the majority of high priority projects.

2.5 Uncertainty management

Risks and opportunities are systematically identified, from scientific, technical, commercial, organizational, regulatory, and program/project sources. These risks and opportunities are consistently prioritized, allocated to named individuals, have action plans developed for them, with appropriate budget line entries, and monitored and followed up on a continuous basis. Risk and opportunity management is fully integrated into the planning processes. Quantitative analysis of risks and opportunities is carried out, and probabilistic interpretations of schedule, budget, and human resource requirements are carried out. Issues are reported and dealt with transparently.

Significant cultural change is often required to obtain maximum benefit from best practice management of uncertainty (risk and opportunities). Some element of mandatory compliance is usually needed to ensure that functions and project teams maintain the uncertainty management process over the life of the project. Senior management must also become used to accepting that uncertainty of timeline, budget, and resource requirement is reality, and work with that reality. Best practice uncertainty management requires effective planning and control processes to be in place as well (e.g. risk action plans are included in the project scope; these plans cost money, so the budget must include action plan costs).

2.6 Knowledge management

Knowledge is systematically captured from programs and projects, sense making is recognized as a central concern of P^3M; tacit knowledge is recognized as important and effectively leveraged into the organization.

Knowledge management is essentially a behavior-driven series of practices, with some formal process support. Full-scale rollout across an organization takes significant time, but the results come quickly, and momentum can normally be maintained.

3. Planning and Control

3.1 Scope management

The work to be carried out in projects (programs are collections of projects) is tightly defined. Work packages have acceptance criteria associated with them, and are used as the basis of the scheduling process. Standard scope templates are available, with built-in hierarchical relationships, and used as the basis of scope setting. Scope input is sought from all relevant functions, and agreed across the project team and functional groups.

A formalized and standard process is fundamental to best practice in this area. Scope is often called the 'heart of project management', and with good reason – get the scope wrong, and everything that follows is wrong as well. Functional and project teams must work together to agree scope, and some degree of behavioral change is inevitably required to make this happen smoothly and effectively.

3.2 Estimating

Estimating databases are available, and/or sophisticated modeling techniques (algorithms, parametric estimating, etc) are used. Estimating algorithms are owned by non-functional groups, although the expertise within the groups provides the primary model inputs. Risk and opportunity techniques are integrated with estimating, and range estimates are commonly used and understood at all levels of the organization.

Significant change in the understanding of uncertainty is a pre-requisite to achieving best practice in estimating. Organization-wide acknowledgement and recognition that single-point estimates of time, budget, and resources are counter-productive is required, as is behavior change associated with project teams and functions planning with range estimates. Creating and maintaining estimating algorithms takes significant time and effort and requires clear processes and responsibilities to be established.

3.3. Change control

Scope change control is structured, with tolerances set (either organizationally or per project) within which all team members and other stakeholders are able to work. Change outside these tolerances is managed through change control processes (e.g. a change board, or similar), and impacts on schedule, budget, and resource requirements are identified and approved.

Giving the project manager/project team the remit to set tolerance levels for scope change within functions, and then making the decisions that fall outside those tolerance levels on behalf of functional teams, is a major change for most life science organizations. Significant stakeholder work across functions is required to achieve this best practice. The process itself is however straightforward.

3.4 Scheduling

Program and project schedules are created with high quality logic embedded within them. A defined process for linking scope to schedule is followed. A true critical path is determined, with near critical activities also identified and carefully managed. Schedules are baselined at stage gates when approved, and re-baselining only occurs at the next stage gate, or when a major strategic or scope change occurs. Functional group schedules are fully integrated with project schedules, which are also rolled-up to program and portfolio levels for reporting and decision making purposes.

Project managers/leaders need to have a thorough understanding of the theory of network scheduling. Many life science organizations achieve best practice in this topic by bringing in external scheduling expertise (from aerospace, construction, etc) and training them on drug development knowledge. Baselining correctly is a behavioral aspect that can take time to achieve. Rolling out a process for creating integrated schedules across functions and the project takes time in a large global organization. This is due to the need to train significant

numbers of people, and also to implement a software solution across the business that automates the schedule integration process. The network scheduling processes are however straightforward and relatively simple.

3.5 Resource management

Human and other resources (labs, animals, etc) are identified and allocated on the basis of 'right resource, right time, right work – implying that resources are managed at portfolio, program, and project level. Project prioritization determines where resources are allocated when there are competing demands on resources, and these allocations are adhered to. Human Resource functions are closely involved in the resource management process, owning competency frameworks that are used in the decisions on which human resources are allocated to which work. Schedules are resource loaded, and smoothing and leveling of schedules is normal practice.

Resource loaded schedules are the basis for effective resource management. Therefore good scheduling skills are a prerequisite. Capacity management is the logical conclusion of best practice resource management, and achieving this in any organization a major process and change program in its own right. However, the rewards can be very significant in terms of resource utilization. Widespread stakeholder management and communication is required to achieve best practice as non-technical functions must also embrace the process (e.g. HR).

3.6 Project budgeting

Project budgeting and annual budgeting are linked processes, with a full lifecycle view of project cost available to decision makers and project managers alike. Project managers have budget accountability for all or major parts of the spend (including clinical), related to the internal contract for delivery noted earlier. Cost is reported against work performed, not invoiced, and cash flow management is project-based. Program and project cash demand is transparently rolled-up to portfolio level to determine total cash flow requirements. Budget line and work package items are directly linked through an enterprise-wide system (ERP and project management systems directly connected).

Bringing direct control of project-based functional budget to project managers/leaders is a difficult and long-term objective for most life science organizations (some have achieved it). Integrating corporate and project budget systems is also a non-trivial activity. The combination of behavior change and system integration demands high effort and energy, with significant stakeholder management required. However, the business benefit derived from the dramatic improvement in R&D budget control this change brings is huge.

3.7 Performance management

Project performance is formally managed and monitored through a performance management process. Data and metrics on performance are gathered, and incremental improvement targets set on a regular basis.

Performance measurement is primarily an exercise in data extraction, which is relatively easy to carry out. Performance management is the next step, where data from the performance measurement process is used to drive performance improvement in project and functional teams.

4. Scientific Integration

4.1 Target Product Profile

A Target Product Profile (TPP) is developed iteratively between the project team, functions, discovery, portfolio management, and senior decision makers. The TPP is 'owned' by the project manager, and changes to TPP are controlled through the change control process, as the findings from studies become available. TPP's form a central plank of project strategy development, and acceptance criteria of work packages is traceable to the TPP acceptance criteria.

Creating the TPP is not generally a problem – most life science organizations do this as a matter of course. Far more difficult to achieve is ownership of the TPP by the project team, and the application of change control to the TPP. Senior management 'walking the talk' is crucial to the success of best practice in this area.

4.2 Organisational capability

Organizational process capability is well understood, both human resource capability (e.g. sufficient experience and expertise exists to carry out the needed studies) and infrastructure capability (e.g. appropriate equipment exists to do the work). Process capability is explicitly reviewed and assessed during TPP development.

Clear understanding of organizational capability is essentially about data gathering, based on a series of straightforward processes. There may be issues related to making visible individuals' capability and competence, as well as process capability in functions.

4.3 Integration of project data

Manufacturing, commercial, and operations are integrated early. Project teams, R&D functions, operations, and manufacturing, etc, have seamless integrated systems. Data used is common. Modeling and simulation are seen as key drivers of productivity (e.g. pipeline modeling at portfolio level, value analysis simulations, as well as technical modeling such as PK).

Information integration may have some cultural component and requires sensitive handling, but the core of achieving best practice is normally about good process, and ICT systems that can support the processes. Ongoing training is required to help functions and project teams to maximize the value of integrated data.

4.4 Configuration management

The overall configuration of the drug is managed proactively – data integrity is assured, Intellectual Property (IP) issues are identified early in the lifecycle, and managed through the project team. Decision-making is tracked over the entire lifecycle. Decision information is readily available to project, program, portfolio, and senior decision makers at all times.

Fundamentally this relies on effective processes more than behaviors. The processes also require reasonably sophisticated data management systems. However, there is a behavior-driven component of effective configuration management, since people must be allowed to make IP issues visible, and there must be a supportive culture that rewards open decision-making

4.5 Information management

An information strategy exists and guides the management and flow of documentation, reports, archiving, and system functionality. The information systems across the organization are integrated, and controlled flows of information into and from the supply chain are standard practice.

Senior management support across the organization is required to ensure that truly integrated information systems can be developed. If the project team are to be responsible for other P^3M best practices (e.g. change control, estimating, configuration management, value management, etc) they require full and accurate data.

5. Commercial Arrangements

5.1 Supply chain management

Project teams play a key role in ensuring that procurement and outsourcing strategies match the needs of the project. Project managers have commercial responsibility for third party supplier contract performance, and work with supply chain professionals on an ongoing basis to optimize the project and product value chain.

Organization-wide support is required to achieve best practice in supply chain management. Processes and practices in use by supply chain management professionals may need adjustment to ensure project managers/leaders are able to be more accountable for the performance of third party suppliers. Achieving best practice is often achieved through a separate and distinct change program run collaboratively between project management and supply chain groups within the organization.

5.2 Procurement

Project teams are involved in vendor qualification, procurement processes (Requests for Information, Requests for Proposals, bid assessment, contract negotiation, etc).

Changes in procedures need to be agreed with procurement/supply chain management. This may require senior management support. Behavior change is also often required from project managers/teams, as well as procurement people.

6. People & Organization

6.1 Integration mechanisms between project and functions

Project management practices and processes are clearly articulated, at a level of detail appropriate to organizational needs. Process and practice is supported by transparent allocation of Accountability and Responsibility for process output (usually recorded in RACI charts – Responsible/ Accountable/ Consulted/ Informed).

The development of highly effective project teams depends on successful integration mechanisms between functions and project teams. These mechanisms require senior management support and buy-in, without which the RACIs and associated processes are likely to be ignored.

6.2 Individual competence

The relationship between people accountable for the drug science and those accountable for project management is well understood, documented, and adhered to. Competency frameworks exist to support the differing roles that these people play. Career ladders for scientific and management routes are harmonized.

Individual role descriptions need to match the RACIs that support project and functional integration. This may require significant effort in some organizations, where long standing role expectations may need to be challenged. Setting up career ladders for non-functional specialists can also require significant change effort to overcome historical resistance.

6.3 Project team structure and roles

Roles and responsibilities for portfolio managers, project managers, sub-project managers (e.g. Functions' representatives on the project team), other representatives on project teams, functional management, study team project management, etc, are aligned, and documented.

Creating the most effective project team structure cannot be achieved without agreement and buy-in from senior functional management. The key role played by the functional representatives on the project team must be recognized, and the importance of project management competence for that role established and promoted at senior levels.

Creating effective project teams is considered to be a key leadership competence. The organization places emphasis on team building skills, and proactively supports this activity. Team performance is formally rewarded, using a range of performance indicators.

6.4 Articulation of P^3M process & practice

Project management practice – "How we do things around here" – is articulated and disseminated effectively throughout the business. The level of detail and style of articulation of practice is consistent with the organizational culture. This practice is widely endorsed by executives and senior management – and they 'walk the talk'.

Articulating an agreed set of processes and practices is not normally a difficult task, but getting compliance with mandated aspects of those processes can be. Senior management must be visible and voluble in supporting the need for the processes/practices to be used, and reinforce the mandatory nature of some aspects of those processes.

6.5 Conflict management

Conflict is accepted as an inevitable part of working in a matrix organization, and is managed positively to ensure rational decision-making occurs, which always delivers the best result for the company. Individuals are supported proactively on an ongoing basis to ensure conflict related stress is recognized and effectively contained.

An open acknowledgement of the conflict engendered by working in a matrix environment is required by senior management in the first instance, as well as clear expectations of how that conflict will be managed. All levels of the organization need to engage in the process of conflict management, including learning how to manage it positively. Achieving senior management visibility and support for the process – 'walking-the-talk' – often requires significant effort.

6.6 Formal project and functional goal alignment

The tension between project team membership and functional group membership is acknowledged. Individuals have project and functional goals that are aligned, that also align to corporate goals. Project performance at an individual level is assessed and weighted appropriately with functional performance. High project-oriented performance is recognized and rewarded at the team and individual levels. Project managers and others are supported and rewarded for transparency of decision making and reporting. All project and functional sub-project team members are supported when recommending project 'kill' decisions.

Setting up aligned goal setting procedures, with direct connection between corporate, brand, project, and functional goals is a significant task. The process must include project-orientated performance reward for functional people, and this is normally the more difficult aspect to achieve, since functional power may be perceived to be being diluted.

6.7 Negotiation

Individuals and teams negotiate effectively, and influence project stakeholders appropriately. The importance of these skills is underlined with effective training programs, and they are reflected in the appropriate competency frameworks.

Since this is effectively a behavioral skill, supported by well– established practices, it is relatively simple to achieve. Training for all levels of the organization, in a standardized process, can be done reasonably quickly.

Conclusion

The life science sector faces some very significant challenges in increasing the number of new drugs brought to market. The sector's productivity needs to improve dramatically to deliver drugs for many areas where there is significant unmet medical need. Without improved productivity, the sector also faces serious shortages of revenues, and hence the likelihood, eventually, of reduced spending on R&D.

One of the critical areas for improvement in the sector is the effectiveness with which drug projects are managed. Current practice in many organizations is far from the levels of capability found in other sectors that face comparable technical and creative challenges (software, aerospace). This paper presents a view of what best practice project management can be in this sector. Further research to test this model is currently underway, using a 'depth' interview and questionnaire approach. Firms from the United States and Europe are involved in this research project.

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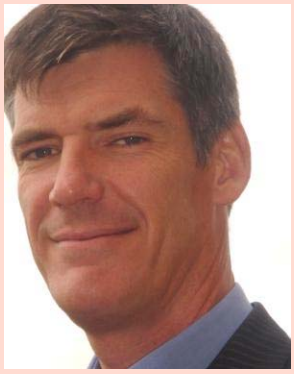

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