Managing uncertainty in drug discovery & development
and the role played by SWOT analysis

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Introduction

During our work helping clients improve their capability to better manage uncertainty, we have found that the differentiation between Uncertainty Management (UM) and SWOT analysis is not always clear. To help separate out the concepts, and place the UM process and SWOT technique within the overall Portfolio, Program and Project Management (P³M) context, we put together this white paper. The discussion is specifically focussed on UM and SWOT in drug discovery and development organisations.

There are three parts to this paper:

1. A comparison of the Uncertainty Management process and the SWOT analysis technique
2. The business value of managing uncertainty
3. Insights on how to build uncertainty management into day-to-day project management

SWOT and UM compared

A reasonable starting point for this section is to define and describe what is commonly understood to be meant by both SWOT and UM.

SWOT

SWOT – Strengths, Weaknesses, Opportunities, and Threats – is a technique used to aid and support strategic thinking, and is commonly employed when developing corporate, divisional, portfolio, program, and project strategies¹. It is also sometimes used when developing department/function strategies. The technique was developed to aid the understanding and summarization of key issues in the business environment and assess the organization's capability (and core competencies) to respond strategically. Therefore the analysis is primarily

¹ Project strategies may be at the drug level, or the functional project level, e.g. clinical trial, regulatory submission, etc.
about defining alternative strategic options to maximize competitive advantage. This applies equally at whatever level of the organization the analysis is carried out at (Johnson, et al, 2006; 148).

In the drug project environment, a SWOT analysis is very useful in the strategy development process. Carrying out a SWOT analysis enables multiple alternative drug project strategies to be developed, refined, and proposed to Governance (Harpum, 2010; 175-192). Business leaders are then able to use the analysis to inform their decisions on what the most effective drug strategy is likely to be, given the overall business position and the competitive environment at the time.

A key differentiator between SWOT and UM is that SWOT is a technique. It is used within a process (strategy development) to understand the environment at a point in time. The environment itself of course changes over time, but usually relatively slowly compared to project timescales, even when those timescales are long, as they are for drug products. SWOT analyses can and should be carried out at regular intervals to ensure that strategic imperatives are still appropriate – typically for drugs during the strategy development phase prior to Governance approval of the following phase of the project. This revisiting of strategy, and application of the SWOT technique, is effective at capturing and indeed shaping emergent strategy over the life of the project (Mintzberg et al, 1998; 112-113). See Figure 1.

![Figure 1: Strategy development in relationship to drug life cycle phases](image-url)
UM

Uncertainty Management is a process used across all business areas to identify, record, prioritize for action, and develop and implement control actions for risks and opportunities. In project contexts it is normally used at an operational level, both during planning, and during execution of the plans. At its most effective, UM is a near continuous process; risks and opportunities are identified on an ongoing basis, and control action is directed towards those risks and opportunities that most warrant action – assessed by the business value likely to be protected or created from the control actions taken (Hamilton, 2001)

Research has shown that highly effective management of risk is highly correlated with successful project outcomes (i.e. projects achieving their objectives) – in fact, it is the leading factor identified by Cooke-Davies (Cook-Davies, 2002). This is related to the interconnectedness of uncertainty to many other project processes, including:

- Initial estimation of project time, cost, and resources during planning/re-planning
- Management of drug value through the lifecycle
- Impact of environmental changes on the project plan (e.g. “recruitment is faster than expected due to identification of previously unknown cohort of accessible patients in Croatia”)
- Information emerging through the team process (e.g. from scientific and clinical studies carried out in the Function’s projects/sub-projects)

For a detailed depiction of the relationships between major project management processes (including strategy and UM) in drug development organisations, see Appendix 1.

Fundamental to understanding the role UM plays in projects is to recognize that the project plan is wrong – it is only 100% correct when the project has completed. By which time it is no longer a plan, it is a historical document. A plan by definition is about what we anticipate we should do, in the future, to achieve our objective(s). Unless we can predict the future with 100% accuracy, the plan must be wrong. It is our educated, carefully thought out planned series of activities (with time, cost, and human resource implications included) of what we think we must do. However, reality always interferes with our plans! “No plan survives contact with the enemy” (von Moltke, 1892). The future is uncertain, and the UM process is about trying to control the uncertainty as much as is reasonably possible, given the likely business benefits to be achieved from the expenditure of time and resources to carry out the proposed control actions.

Figure 2 shows the cyclical nature of the UM process. Risks and opportunities – comprising the mirror image halves of the overall uncertainty of a project – and the actions taken to manage
them, should normally be reviewed on a monthly basis, simultaneously with the monthly review of project progress.

The business value of managing uncertainty

There are several sources of business value when uncertainty is managed well, as follows:

1. ‘Knowable’ high impact high probability risks are identified earlier and effectively managed
2. Highly inefficient ‘fire fighting’ of project issues (risks that have happened) is significantly reduced
3. Opportunities are identified much earlier than is normally the case
4. The organisation can stop ‘reinventing the wheel’

‘Knowable’ high impact risks are identified earlier and effectively managed

A large number of risks and opportunities are knowable in advance of them happening. Without a UM process there is no specific way to ensure these risks and opportunities are proactively identified, and action taken to control them, at an operational level. The experience of a risk occurring and a number of people saying “that happened on my last project” is widespread. Frequently that risk could have been removed, or at least effectively mitigated.
The uncertainty inherent in estimates made when planning is often not verbalized and documented, and rarely discussed rationally as part of the Governance decision making process. Range estimates taking account of the uncertainties in the future are not provided by project teams, and not asked for by Governance. Yet this ignores the reality that the plan is wrong – a good estimate (educated guess!) of what could be achieved in the future.

The UM process ensures knowable risks and opportunities are identified early; plans are made to take account of them, and action taken to remove the risks and maximize the opportunities. Plans are inherently more realistic from the beginning, and emerging uncertainty during the project is identified and managed. The ability of projects to deliver reliably against plans is dramatically improved in organizations where UM is implemented and used correctly.

The business implications are wide ranging: resources can be allocated more reliably to work (the schedule is more realistic and we know better when we need people to do work); realistic expectations of additional budget requirements to cover the possibility of risks happening are created; Governance acquire a significantly more accurate picture of the overall risk profile of the portfolio of projects; at a corporate level, the contribution of the portfolio of drugs in discovery and development can be properly integrated into the overall corporate risk exposure; and ultimately more realistic expectations can be set with patients and the markets.

Highly inefficient ‘fire fighting’ of project issues is significantly reduced

A great deal of energy and time is wasted as project teams and functional teams allocate people at short notice to deal with risks that occur, but that could either have been avoided, or at least advance plans made to manage if they did occur. The impact on the project progress is often significant, with focus taken off the main activities and placed on the fire fighting activities.

Additionally, where functional projects/sub-projects have to get involved to deal with the outcomes of unpredicted risks in other functions on their own work, project progress is further delayed. (An example might be an unpredicted, but knowable, risk that API materials are delayed. The risk happens. This delays the production of clinical trial materials. This impacts at some point in time on other functions contributing to the overall project such as regulatory, clinical operations, etc. People are allocated to deal with the immediate problem caused by the risk, and other planned work is not carried out on other projects. In this way, knowable but unmanaged risks that happen cause significant ripple effects across the organisation. Planned work in many areas is impacted by a risk that could have been avoided or mitigated through the effective use of a UM process.)
Opportunities are identified much earlier than is normally the case

The UM process ensures opportunities are identified at the same time as risks. Opportunities are outcomes from uncertain events in the future with a positive impact on the process (risks are outcomes with a negative impact). The process inherently manages opportunities, since they are merely the mirror image of risks. See Figure 3. Opportunities identified are project specific, and action can be taken to maximize the potential upside outcomes, and make sure the business benefit of opportunities is actually realized. This is generally not the case where no project related opportunity management process exists. An example where identifying and managing opportunities can make a significant difference is the early completion of a clinical study. This is rarely planned for. If a study does finish early the people needed to get from last patient last visit to data lock are working on other activities – they weren't expecting an early finish to the study. This means that an attempt can be made to reallocate people onto the work that has arrived earlier than expected, but it inevitably will disrupt work being carried out on other projects. Normally the final data lock date does not come forward in time from an early study finish for this reason. The opportunity to progress the project more quickly than planned has been wasted.

![Figure 3: Uncertain events, risks, and opportunities](image)

Other opportunities can be identified earlier and action initiated to capture the business benefit available. Additional indications can be spotted. Line extensions started earlier. Significant improvements to the Target Product Profile generated and acted on.
The organisation can stop ‘reinventing the wheel’

An established and well working UM process allows the effectiveness of risk and opportunity action plans to be understood over time, and lessons learned from the projects related to the management of risks and opportunities captured. It is frequently the case that project teams are unable to know whether a proposed action plan for a risk or an opportunity has been used in past projects. Often there is a similar case, but the knowledge is not available.

This means that project teams are repeatedly ‘reinventing the wheel’ as new plans are made to address risks and opportunities that have been managed previously. This is inefficient use of resources, and often means suboptimal action plans are created and implemented.

Historical records of risks and opportunities that actually happened is also an invaluable source of information when planning new projects. Projects are better able to plan to avoid risks that frequently occur, and build in opportunities that have been missed in previous projects. This leads to high quality plans, where the uncertainties are more clearly understood and planned for from the very beginning of the project.

**Insights on how to build uncertainty management into day-to-day project management**

Bringing any changed way of working into an organisation is challenging, and the adoption of UM is no exception. Several factors need to be addressed for a successful implementation of a new process in drug discovery and development environments.

1. The teams must believe there is value to the process
2. Senior stakeholders and decision makers must also be aligned
3. The process must be ‘fit for purpose’
4. The project and functional communities must feel some ownership of the process
5. Careful piloting and implementation is vital
6. Maintenance of the process is important after implementation

**The teams must believe there is value to the process**

The value of UM is most effectively demonstrated by taking a team through the process on a live project they are working on. People need to experience the actuality of the UM workshop, rather than be lectured about it (or be asked to read about it). Finding out that there is little bureaucracy involved, that the process can be simply facilitated by a non-team member, and experiencing the outcome of exchanging – in a structured way – information about the uncertainty in the project is normally sufficient to overcome most resistance. The most
frequent comment we hear from teams after such a session is “we have never talked that much about the project and we all now better understand what needs to be done to manage the future”. This often believed by the team to be the greatest value added by the process.

Senior stakeholders and decision makers must also be aligned

Since the UM process brings significant business value above the team level, senior stakeholders should also be aligned to the need for the process. Furthermore, it is very helpful if they are prepared to make public their alignment and desire for the process to be implemented. In order to achieve this, work needs to be done with these stakeholders to help them understand the value of the process, as well as guide them towards effective use of the risk and opportunity information that will be fed to them.

An effective process for understanding overall business risk is generally accepted as a prerequisite to meet corporate Governance requirement (Sarbanes-Oxley in the US, The Combined Code on Corporate Governance in the UK, and similar legislation elsewhere). The risks in the product development portfolio are very significant in organisations spending a large proportion of retained profit on research and development (R&D). Therefore it is arguable that a failure to effectively identify and manage R&D risks, and manage them as part of the overall corporate risk process, leads to non-compliance with legislation. See Figure 4.

![Figure 4: The relationship of risk management to corporate compliance and Governance.](image-url)
The process must be ‘fit for purpose’

A common complaint from organisations is that processes are over engineered, too complex, and do not bring the business value promised. When this is the case, people in organisations find ways of circumventing the process. In some environments this can be controlled reasonably effectively, and business process compliance is mandatory. In the drug development industry compliance with business processes is very hard to enforce. The solution to this is that the UM process must be simple, low intensity, and seen to clearly add value – to make peoples’ lives easier not more difficult. ‘Fit-for-purpose’ processes are required, and this is equally applicable to UM as to other processes. And the fundamental UM process is very simple! There is no need for complication. We have seen this approach work in many drug discovery and development environments, in organisations of all sizes (Pfizer and GSK through to 60 person technology platform firms) and all cultures (USA, UK, Switzerland, Sweden, Malaysia, Egypt in life science environments; and additionally Sudan, China, Singapore, Malaysia, and all over Europe and the USA in engineering industries).

The project and functional communities must feel some ownership of the process

Ensuring that the community that is expected to adopt a process is involved in the development of the process seems reasonably obvious. This need to involve users in the design phase of a process is very important in the drug discovery and development industry, where non-compliance with business processes carries little risk for the individual. Building ‘fit for purpose’ processes requires the involvement and contribution of the community – in this case the project, portfolio, functional, and senior stakeholders. Gaining such contribution to process development work needs care and careful management, but is eminently doable.

Careful piloting and implementation is vital

Piloting new processes is a simple and effective way to build awareness and organisational ‘pull’ for new processes. It also allows the process to be tested under safe conditions, and improved with the contribution of the people taking part in the pilots. Following successful piloting, implementation takes care and persistence, with clear roll-out objectives established and supported by senior stakeholders. Depending on the size of the community expected to use the process, it may be useful to have an individual appointed with responsibility for leading the implementation. The person appointed should always be internal to ensure credibility and avoid the perception that a process is being imposed on the community by ‘outsiders’.
Maintenance of the process is important after implementation

Once the first round of implementation has been completed, it is normally useful to have some level of continued support for the project community related to the new process. This is easily provided if the individual responsible for roll-out, as described above, continues to be available to support the teams. Occasional refresher sessions, where teams are supported by one of the non-team UM facilitators, are also helpful in maintaining teams’ ability to use the UM process efficiently.

Larger organisations can benefit from developing a small pool of expert UM facilitators. They can become expert in the use of UM, and we have seen some companies encourage these people to build an informal UM community of practice. Since the individuals involved are all likely to be working on their own work, aside from UM support, they are seen as experts within the project community, rather than people that are external to the group and interfere.

References


Appendix 1: Interrelationship of major project management processes in pharma and biotech organizations

The diagram relates the major project management processes in drug discovery and development, from the functional project/sub-project level, through the drug project itself, to the therapy area portfolio process. This series of processes is then related to the corporate strategic process. In this way, the project management process can be seen as the primary mechanism for the delivery of corporate strategy in the R&D organisation.
ABOUT THE AUTHOR

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Author

Dr Pete Harpum’s research has been in several related areas, both as an academic and as a management consultant. In academe his doctoral research included managing design in aero-engine R&D environments. Other academic research includes the project manager's role in managing technical aspects of projects, and managing fuzzy front-end project work in life science companies. Pete has led academically rigorous consulting research on practitioners' perspectives of best practice project management in drug companies.

Pete’s vision is built on several strands of thinking: Firstly that project management is the fundamental approach applied in many industries to New Product Development. Secondly, that factors leading to project success have consistently been shown by the research to be related overwhelmingly to behavioural aspects and the context in which projects are carried out. Thirdly, project management can be applied holistically, and should encompass the front-end work of projects to translate corporate/R&D strategy into project strategy, business case definition, and negotiation and agreement of realistic project goals.

Pete is Affiliate Professor at Grenoble Ecole de Management, teaching on the Advanced Master's Degree in Biotechnology Management. He also carries out post-graduate lecturing and research on P3M for The University of Manchester, Chalmers Business School, and Manchester Business School. He has edited for Wiley the book Portfolio, Program, and Project Management in the Pharmaceutical and Biotechnology Industries, published in 2009 (ISBN: 978-0-470-04966-2). He has also published on design management, project methodologies, capacity management, management control, project success factors, and best practice in life science project management.

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