# Complexity Cost Quantification and Modeling for Strategic Portfolio Management

By

**Jan Ma**

B.S. Biological Environmental Engineering, Cornell University, 2007

Submitted to the MIT Sloan School of Management and the Mechanical Engineering Department in Partial Fulfillment of the Requirements for the Degrees of

**Master of Business Administration**
**and**
**Master of Science in Mechanical Engineering**

In conjunction with the Leaders for Global Operations Program at the Massachusetts Institute of Technology

June 2014





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MIT Sloan School of Management, MIT Department of Mechanical Engineering
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## Abstract

This project explores portfolio management and planning through effectively reducing complexity within operations. We apply this to a major healthcare company (referred to as Company X). The anticipated launch of new molecules and formulations into the existing high mix product portfolio presents significant challenges to contain cost and maintain the standard service level of Company X.

Complexity costs associated with manufacturing and supply chain activities are not entirely accounted for in direct production costs. Having transparency to these costs at a brand or SKU level would allow significant improvements in strategic decision making throughout the life cycle of a product. The work outlined in this thesis describes the development of a quantification model to capture operational complexity costs as well as an analysis of potential impact for Company X associated with implementation of the model. This is accomplished through first, identifying and prioritizing complexity cost generators; second, quantifying the costs through application of activity based accounting; third, building and piloting a decision support tool and NPV model. Lastly, process for implementation and application of the model was defined.

The findings from this project provide financial rationale for a 27% reduction in the total product portfolio size, which results in a potential savings of $75M over the next five years, and 50% human resource savings across the Technical Operations and key support functions at Company X. The model can be a powerful tool for optimizing product portfolios with attention to financial, operational, and strategic considerations. Reducing complexity creates the ability to become more discerning about the portfolio composition and enable Company X to focus even more on high growth and life-saving brands.

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## Acknowledgments

I would like to thank all the faculty and staff of the Leaders for Global Operations Program for their support and guidance during this internship and through the past two years.

I would like to thank the managers, sponsors, and colleagues at Company X for their insights, coaching, and advocacy during my time in Basel and through the completion of my thesis. Specifically, Beat Rutishauser for always making time for the 'important stuff' and Erich Battanta, Ute Kessel, and Mario Joseph for their mentorship. Thank you to my local friends who were patient enough to teach me the cultural norms and show me around town, which made my time in Switzerland so enjoyable.

Thank you to my advisors, Don Rosenfield and Josef Oehmen for providing invaluable oversight and feedback throughout the internship and preparation of this thesis. I learned immensely from your expertise, attention to detail, and wisdom.

Thank you to my awesome fellow classmates for all the advice and memories. Especially those in Europe, it wouldn't have been the same without you guys.

I am eternally grateful to my family and friends for being with me every step of the way, making the last two years an unforgettably amazing experience. Thanks mom for being my solid support, sounding board, and tireless cheerleader through the years. Thanks Tey for sticking by me on this incredible journey. You have kept me sane and grounded through all the low and high points; without your love, understanding, and support, none of this would have been possible.

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# 1 Introduction to Pharmaceutical Industry and Focus Company

## 1.1 Pharmaceutical Industry Background

Pharmaceutical companies develop, manufacture, and market patented and generic therapeutics to treat a variety of illnesses. The sector is characterized by high barriers of entry but high rate of return. Lengthy and costly development lifecycles, competition through scale, and diversification of therapeutic targets are hallmarks of the industry. The pharmaceuticals industry has traditionally been a very lucrative business, with a global market value of $300B a year [1]. However, in the recent decades, increasing Research and Development costs, competition from low cost generics, and regulatory pressures has slowly eroded the profitability of this business. Major pharmaceutical firms are continuously seeking means to operate more efficiently and sustain their cost advantages.

## 1.2 Company X Background

Company X is a leading global healthcare company headquartered in Basel, Switzerland. Company X has a diverse portfolio, including pharmaceuticals, eye care, consumer health products, and vaccines. Of all the product categories, pharmaceutical is the largest division, comprising 57% of net sales in 2012.

With operations in over 140 countries, the Technical Operations function manages a large and complex manufacturing and distributions network spread across 49 internal production sites and 280 contract manufacturers. In addition, a product portfolio mix of over 250 brands, totaling over15,000 SKUs makes supply point decisions particularly challenging.

Company X is an industry leader in innovations and has a robust pipeline with 15 new molecules slated for launch in the next three years. The company has experienced rapid and steady growth in recent history, but now faces two major challenges in cost competition and resource allocation due to the rising complexity in its product portfolio and global operations. Disproportionate increase in headcount has supported the growth of the company to date. Yet with large blockbusters going off patent and declining average profitability across the portfolio, Company X can no longer sustain the headcount increase to simultaneously manage the existing product portfolio and anticipated new launches. Becoming more cost transparent in the company bottom line and more strategic in portfolio management will drive competitive advantage for Company X and enable its continued growth in the future.

## 1.3 Challenges Facing Company X

Despite increasing revenue year on year, Company X's profitability has been declining over the past few quarters. Similar to other major players in the industry, Company X faces the exploitation versus exploration dilemma. The company can choose to focus resources on a highly selected portfolio with higher return on investment; alternatively, the company can pursue a diverse portfolio to maximize the potential avenues of a high payoff. Company X has traditionally taken the exploration route, which is now impacting the overall profitability of the company. The rising operational complexity cost of this exploration strategy can be attributed to the company's lack of cost transparency, high mix product portfolio and lack of standardized process to proactively manage brand lifecycle.

The profitability of a product is calculated using only consolidated total production cost, which accounts for the direct cost of manufacturing – variable cost and limited fixed cost. However, there is a third bucket of operational costs, which are currently rolled up into corporate overhead. This indirect cost can actually make up a significant portion of the total carrying cost and should be quantified in profitability calculations and product management decision-making (Figure 1). In addition, consolidated total production costs are only fully visible to global functions and not country organizations producing and distributing products. The varying degree of cost transparency at the local and global levels present another hindrance to reduce complexity costs.

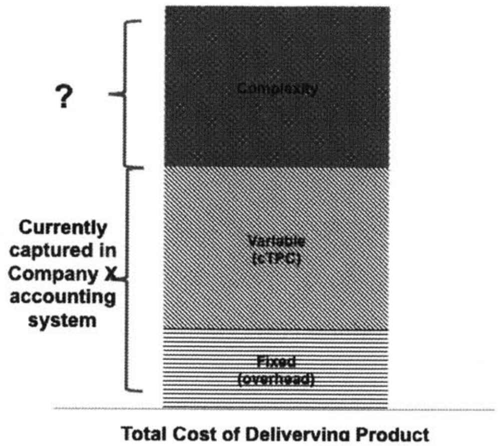


**Figure 1: Indirect operational costs that are not captured in accounting system of Company X**

The pharmaceuticals division is comprised of two main categories of products: patent-protected and off patent. The patent-protected products are in the launch and growth phase of the product lifecycle, characterized by large annual net sales, high gross margins and increasing revenues. The off patent products are older products in the decline phase of the product lifecycle, characterized by small annual net sales, low margins, declining sales, and frequent supply chain disruptions. Unfortunately, the majority of Company X's product portfolio is made up of off patent products. Figure 2 show that 58% of the entire portfolio is comprised of brands with less than $10M in annual revenue; almost all of these brands are off patent products. In total, 58% of the portfolio amount to less than 1% of the annual net revenue of the pharmaceutical business. This extreme disproportionality negatively affects the bottom line of Company X, and is thus the focal point of the complexity reduction effort.

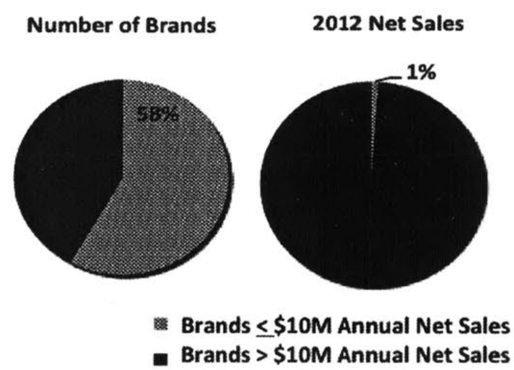


**Figure 2: Product portfolio makeup of Company X**

The proportional workloads of Technical Operations functions vary greatly over the lifecycle of a product (Figure 3). In the External Supply function in particular, Full Time Equivalent (FTE) resource usage ramps up exponentially as a product transitions from maturity to decline phase of the lifecycle. As products age and go off patent, the supply point decision is made to either continue producing the product at the existing site, transfer the entire manufacturing process to another site, outsource the product altogether, or eliminate/divest the product. The majority of these decisions will result in supply chain disruptions and introduce additional regulatory and operational risks. These risks will in turn translate into higher costs for Company X. The product themselves are not penalized for incurring additional costs since these operational costs are swept under the overhead rug with little visibility or clarity. Having a high mix portfolio where over 50% of the portfolio is comprised of these off patent products forces Company X to incur a much higher level of risk and cost than the product portfolio is actually worth.

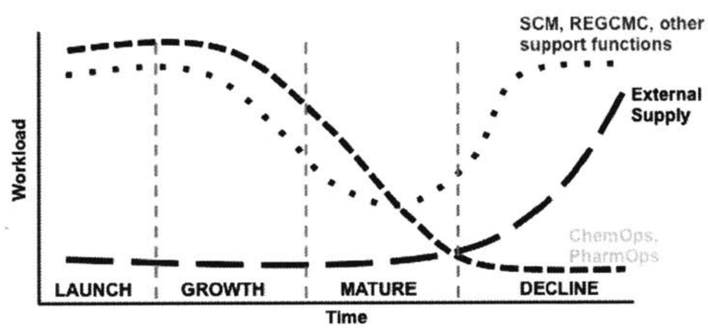


**Figure 3: Functional workload across Technical Operations over the lifecycle of a product**

Lastly, the organization is not adequately structured to proactively handle lifecycle transitions and make supply point decisions prior to an actual supply chain disruption happening. The lack of standardized process and clear ownership for decision-making has resulted in Technical Operations carrying the burden of supporting a large number of non-strategic products awaiting elimination. The existing triage process for transfer, divestment, and elimination decisions is cumbersome, requiring many functional approvals and rework. A typical supply point decision can take upwards of eight months. Company X has attempted an organization-wide effort to drive down complexity in 2010 and proposed over 900 tail end SKUs for product elimination.

These products largely still remains in the current portfolio as requests take so long to process and move through the workflow. Even after a decision is made, execution may take years to complete (Figure 4).

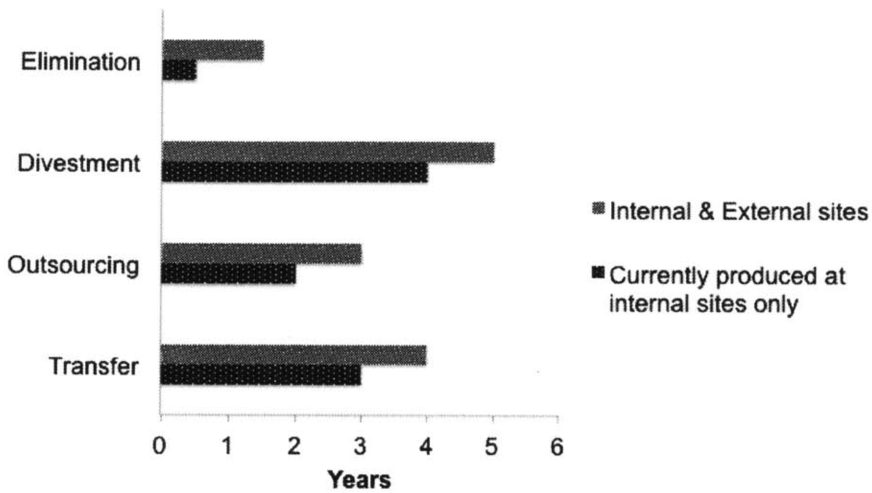


**Figure 4: Average timeframe to complete execution of supply point decisions**

## 1.4 Project Objective

Given the pressures faced by Company X due to increasing operational complexity costs, the company has initiated this effort to gain cost transparency and use the generated data and model to more effectively manage the product portfolio composition.

The main objective is to identify the underlying factors driving complexity cost at the global level, quantify these factors into a cost model to be applied to specific business case evaluations and portfolio wide assessments. The key end user will be the Technical Operations organization carrying out both the decision-making and execution of supply point related matters. Critical design criteria will center on model accuracy, simplicity of user interface, and wide applicability for cross-functional stakeholders.

## 1.5 Hypothesis

Literature and previous projects indicate that operational complexity costs aside from direct production costs contribute greatly to the total carrying cost of a product, particularly towards the end of its lifecycle. We hypothesize that high complexity within an organization can be profitably reduced with the right information and implementation plan over time. Company X can reduce the total product complexity of its portfolio through increasing cost transparency, enabling it to be more strategic in regards to making supply point decisions and managing product lifecycle.

## 1.6 Thesis Structure

***Literature Review***

This chapter explores the work done on complexity management in the context of the pharmaceuticals industry in academic papers and industry publications. The section also reviews past LGO projects related to complexity reduction at Company X and walks through the evolution of focus areas for tackling complexity and associated results. Lastly, we will summarize the approach and rationale for this project and how it builds upon previous work.

***Approach***

This section describes the methodology of building the complexity cost model in addressing product complexity. It details the analysis done to identify underlying factors of complexity cost generators and how these variables were quantified and incorporated into a general cost model. Also included is the approach to mapping out current state and proposing future state of supply point decision making process.

***Results***

This chapter summarizes the results from key pilot projects applying the complexity cost model and initial findings from a portfolio-wide screening. We propose some follow on topics and next steps for Company X.

***Discussion & Next Steps***

This chapter discusses the shortcomings and limitations of the complexity cost model, along with additional considerations on the impact of implementation to Company X.

***Conclusions***

The final section covers the impact of the model on the future decision-making and operations of Company X and summarizes managerial implications for future complexity reduction efforts.

# 2 Literature Review of Complexity Cost Modeling

## 2.1 Defining Complexity in An Organization

Complexity has managerial implications for organizational performance, cost, and operational strategy. While practically important, complexity has not always been clearly defined. Concepts such as uncertainty and novelty have been associated with complexity, but does not aid in understanding and addressing the issue. In the context of supply chain management, complexity has been parsed into detail and dynamic. Detail complexity is the distinct number of components or parts that make up a system (number of products in a portfolio, number of processes in a flow); dynamic complexity refers to a system's interconnected response to unpredictability [2]. Taking this one step further, the dimensions of complexity can be defined as multiplicity, diversity, and interconnectedness of elements within a system. Multiplicity, a component of detail complexity, is the number of elements; diversity, also a component of detail complexity, is how differentiated elements are; interconnectedness, a component of dynamic complexity, is the interactions between elements and associated processes [3]. In application, complexity manifests different forms in products, processes, and people. In the context of products, multiplicity, diversity, and interconnectedness can take on the form of product features, technology, and manufacturing platforms. In the context of processes, complexity is coordination across functions and different practices. In the context of organizations, complexity is the number of departments, differentiation of roles and tasks, or varying level of capabilities. These ideas become more concrete when we apply the dimensions to evaluate the supply chain operations for implications on risk, responsiveness, and cost [4]. Previous research has indicated that increasing product complexity increases inventory and decreases service levels [5]. In these particular studies, product complexity is defined as number of

SKUs. While previous literature established applicable definitions of complexity and complexity's importance in operations management, there has not been extensive work on application of complexity cost analysis and managerial implications in industry.

Complexity is desirable and necessary for many industries. New innovative products that meet evolving customer needs, smarter data management systems to reduce error are all added complexity that have benefited businesses and fueled industry growth. However, unnecessary complexity can inflate operational expenditures and compromise service levels. Complexity within a company is perceived to be highly qualitative and thus is difficult to isolate and define. Wilson and Perumal group complexity into three main categories: product, process, and organization [6]. Product complexity refers to the existing collection of products and services offered by the company. Process complexity is all the steps, linkages, and handoffs required to deliver the products and services to the customer. Organizational complexity is the staff, structure, and governing policies put in place to execute delivery of products and services to the customer. Examples of each type of complexity are given in Figure 5.

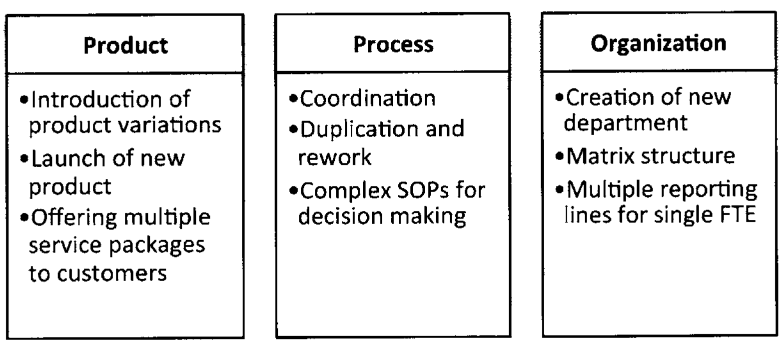


**Figure 5: The three dimensions of complexity and associated examples of each [6]**

Often in an organization, all three dimensions of complexity co-exist and can be represented via a complexity cube (Figure 6). The interactions between the three dimensions drive observable effects such as multiple unprofitable products, long lead times, product shortages, and low service levels. The impact of complexity is difficult to measure by virtue of the nature of complexity cost. These costs are not associated directly with a product. Beyond the financials, complexity can also generate significant opportunity costs. Complexity costs increase geometrically and is not simply a function of the number of products in the system, but instead a function of the linkages between the products, processes, and organization [7]. Since complexity cost is so difficult to measure and control, the ability to effectively manage it can become a company's greatest competitive advantage.

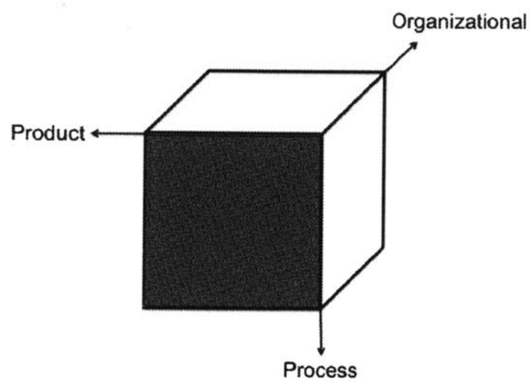


**Figure 6: Illustration of the complexity cube**

To understand the impact of complexity costs on the company, Wilson and Perumal propose to examine the profitability of a company. In a given product portfolio, only 20-30% of the products are profit generating while the remaining 70-80% of the products are actually destroying profits (Figure 7). This whale curve represents the relationship between total products and cumulative revenue. As more complexity is introduced into the system, the rate of complexity costs growth eventually erodes any additional value being created, resulting in an inflection point where profitability takes a downturn. Though this is never the case as reflected by the typical financials. It can only be explained through complexity costs that do not factor into the margin calculations for a product. In order to improve the overall profitability of the company, there are two options: reduce the cost of complexity or reduce the total amount of complexity in the system. Reducing the cost of complexity simply shifts the organization's position along the curve. Conventional methods such as tailed SKU reduction; lean and efficiency projects only move the needle slightly and alleviate some pressure by moving the organization upwards and leftwards on the whale curve. Reshaping or shifting the curve through eliminating complexity altogether from the system can achieve more significant results.

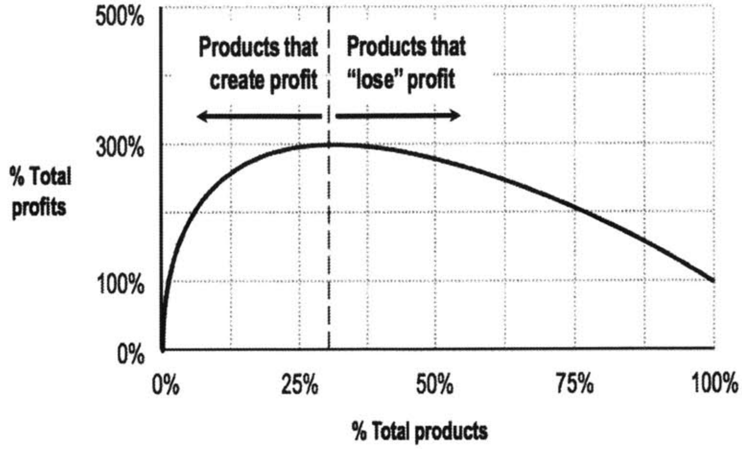


**Figure 7: General profitability curve of a product portfolio [6]**

In summary, complexity arises naturally with the normal operations and growth of the business. Legacy products inherited from mergers and acquisitions, lost leader SKUs that enable the company to expand into new markets, and introductions of product variants to satisfy a broader range of customer demands are all examples of how complexity is continuously introduced into the system. Within the pharmaceutical industry, contractual obligations with health authorities and ethical concerns also contribute to companies taking on additional complexity that may not translate into positive profit or revenue. Over time, without active management and maintenance, the portfolio accumulates more profit-losing products and the total cost of complexity is more visibly felt throughout the company. The complexity exists along three dimensions: product, process, and organization. The cost of product complexity increases geometrically with the number of linkages within a network as more products and processes are introduced. The key challenge to managing complexity is indirect costs associated with complexity are not appropriately calculated or allocated. Most corporate accounting systems do not accurately capture complexity costs because of the existence of "catch-all" accounts that mask the true profitability. In order to reduce complexity, enterprises can either decrease the total amount of complexity, or make complexity cheaper.

## 2.2 Summary of Previous Complexity Reduction Projects

Previous efforts by Company X have focused on both reducing the total amount of complexity and on the cost of complexity. The first complexity reduction effort focused on product complexity. A cross-portfolio analysis was done using financial and strategic criteria to isolate the low hanging fruits for elimination. These were the tail end SKUs [8]. Subsequent projects shifted from complexity reduction at a global portfolio level to local production site level. Efforts included identifying and dash boarding the various components of site-level inefficiencies, quantifying total manufacturing complexity costs trapped in the entire network of production sites by comparing a single SKU plant versus a multiproduct plant [9], [10]. These projects have kept the spotlight on complexity reduction within Technical Operations and allowed the organization to tackle all three dimensions of complexity at both a corporate scale and individual production site level.

This project continues to build upon the previous work. The focus shifted from being more theoretical to being more applicable. The complexity model developed is able to perform brand and SKU-level evaluations of supply point decisions, incorporating sensitivity analysis to enable the user to use the tool for specific business cases and general portfolio assessments. Work to date has taken a top down approach to quantify complexity costs, versus this project, which takes a bottom up approach in data collection and model construction.

## 2.3 Review of Methodologies Used in Complexity Cost Modeling

To quantify the complexity costs for a product, several approaches were evaluated. The pros and cons offered by each approach, and the executional feasibility given time constraints were used to choose the optimal methodology for this project.

***Mixed Integer Linear and Nonlinear Programming***

Application of linear programming to model the entire pharmaceuticals supply chain is frequently cited in academic literature. Mixed integer linear programming (MILP) and mixed integer nonlinear programming (MINLP) formulations have been used to represent the key components of the supply chain with the objective function to maximize net present value or gross margin and constraints on production capacity, allocation, inventory, mass flow, and non-negativity [11]. Complexity in a system is typically quantified by the change in cost or profit. This methodology is used to model complexity by measuring effects of individual variables on minimizing cost or maximizing profit. Other variations of the model include introduction of new products to evaluate impact on supply point decisions, incorporation of demand data to optimize capacity planning, and accounting for opportunity cost of working capital associated with inventory [12]. Monte Carlo simulations are typically used to capture the complexities and risks in key variables. While the MILP/MINLP approach effectively models the entire supply chain system, it is extremely complex to develop. The interdependency of the model components requires many data inputs and deep knowledge of market, product, and manufacturing information (Figure 8). More importantly, the model's core is based on a systemic approach and does not plainly isolate the complexity costs at any single point within the supply chain.

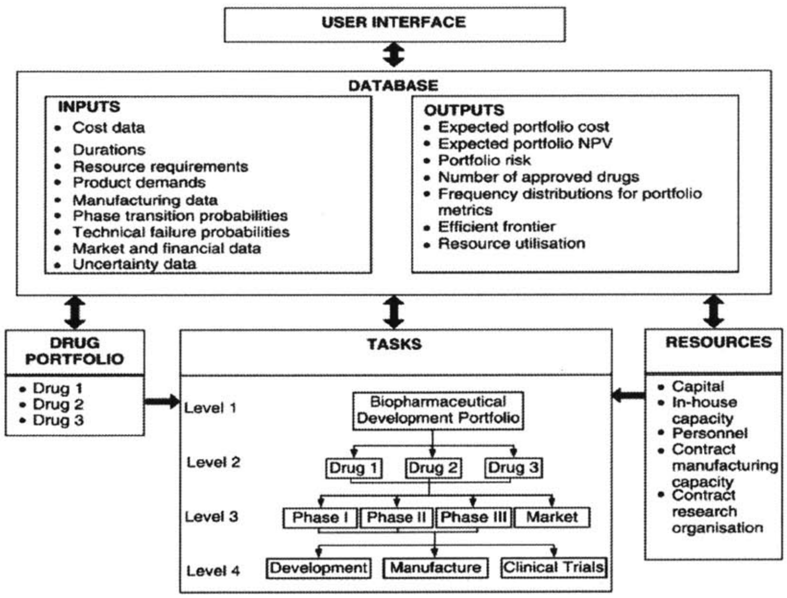


**Figure 8: Sample schematic of a typical MILP supply chain model [13]**

### *Activity Based Costing*

To extensively target only a subset of costs, another methodology to employ is activity based costing (ABC). ABC is driven by the need to accurately reflect the relevant cost information needed for decision-making. This approach traces both direct and indirect expenses to the corresponding products, services, and customers that incur the costs [14]. In matrix organizations, multiple functional involvements across often-different geographical locations are required to deliver the final product or service to the customer. Traditional accounting techniques capture fixed and variable costs to manufacture the product or service and then allocates overhead based on some generalize rule. This has been sufficient for the 1950s' traditional companies. As companies shift to becoming more integrated in the 1990's, offering a greater variety of products and services through more diverse distribution channels, the indirect costs become much more prominent and require proper traceability and assignment (Figure 9).

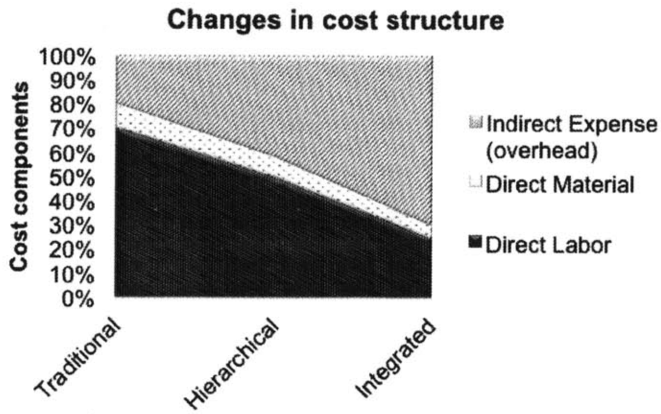


**Figure 9: Indirect costs are displacing direct costs in integrated businesses [14]**

In order for ABC to be useful, it must comply with the realities of the organization. The relevant resource and activity drivers chosen should correctly represent the cost structures and activities in the supply chain. This could be challenging at times because parts of the data required are quantitative translations of qualitative activities. A key point to note with ABC is although the model may not be as sophisticated as the MILP/MINLP approach it does provide the sufficient relevant information for decision-making purposes [15].

***Data Mining and Decision Tree Software***

The final approach evaluated to identify and capture complexity costs is to relook at existing data through new lenses. Because complexity costs are often hidden and unsorted, a simple solution may just be to extract out only the relevant pieces of information. By defining new metrics, the impact of complexity becomes more visible. Automated pattern detection software can serve the purpose of revealing connections in data and exposing patterns not readily detectable by traditional accounting methods [16].

Analytics can process and make sense of large volumes of raw data and make actionable recommendations based on the pre-defined criteria and metrics. While this would make tracking and managing complexity easy, the software infrastructure and support needed would be highly capital intensive and may be a deterrent for adaptation. Decision trees provide a framework to enable management to evaluate options quantitatively, taking into account systematic risks and uncertainties. By enabling better decision-making, decision tree tools can decrease the costs particularly associated with process and organizational complexity [17]. Decision trees have been widely used to model the decision-making process in both product design and supply chain management applications. Probabilities of events that can impact a supply decision and the financial cost associated with the uncertainties can be captured by the decision tree through expected cost functions and the optimal decision determined from the function [18]. Decision trees can also be used for multi-stage analysis with uncertainties to minimize total expect cost [19]. Given the versatility and comprehensiveness of decision trees, it can be a powerful tool in cost analysis.

Selection of the desired approach balanced level of model sophistication and accuracy and the feasibility of execution given the limited project duration and access to needed data and information. Also, usability is another crucial concern. Models that required special software licenses and extensive programming or functional knowledge pose high barrier for adaptation and would not be the ideal choice in this case. Given budget, time, and implementation constraints, Excel and decision tree commercial software was chosen as the backbone to construct the model. Excel requires no specialty training and the ease of use allows flexibility in model construction and modification. A single commercial software license was obtained to pilot the feasibility of using the developed model to enable decision making across multiple functions within Technical Operations.

# 3 Approach to Quantify and Model Complexity Costs

## 3.1 Approach Summary

Company X faces particular challenges in product and process complexity. Chapter 3.2 focuses on the approach to address product complexity. The design of the approach is systematic, iterative, and tightly linked to the data and information gathered during the process. Analysis and recommendations are derived from testing of the theory using case studies. This approach translates into the major phases for the thesis work (Figure 10). The primary phase focuses on identifying the cost drivers within Technical Operations. How to define and prioritize the complexity cost generators are detailed in Chapter 3.2.2. Once the cost drivers are prioritized, they are generalized into a usable model, which is then piloted with select case studies. This is covered in Chapters 3.2.3 – 3.2.10. Chapter 3.3 focuses on the approach to address process complexity. Through current state mapping of lifecycle management decision-making process, we clarify the weak points and make recommendations for reformation. Organizational complexity is briefly discussed only in consideration to its effects on product and process complexity in Chapter 3.4 It will not be investigated in detail within this thesis work.

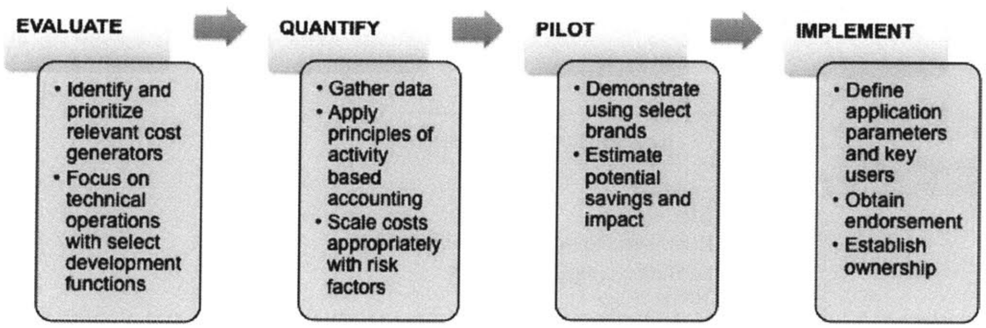


**Figure 10: Summary of thesis approach and project phases**

## 3.2 Product Complexity

To validate the hypothesis that operational complexity costs contribute significantly to the total carrying cost of a product, we need to formulate an accurate account of cost drivers. This is achieved through a complexity cost model via activity-based accounting.

Complexity cost rises proportionally to transactions. High variability in products and services increases the total transactions and activities within the organization. The focus of product complexity cost is on these transactional activities within Technical Operations. Company X uses consolidated Total Product Cost (cTPC) to measure the raw material, labor, and production overhead of a product. The transactional costs are not directly incurred through manufacturing and thus fall outside of cTPC. Instead, they are captured within functional budgets, global overheads, and non-production accounts. To extract these costs, we have to define the activities that generate them. These activities become 'complexity cost generators'.

### 3.2.1 Classification of Complexity Cost Generators

We start with supply point changes that initiate a cascade of activities within Technical Operations global functions. The most common supply point actions during the mature and decline phases of the product lifecycle are summarized in Figure 11. Each action requires support from corresponding functions involved. Within each function, a series of activities are performed for each corresponding supply point action. We then further break down these activities into tasks that can be quantified by FTE hours. The smallest unit of complexity generators is the task, which are performed to accomplish activities required for each supply point action within various functions.

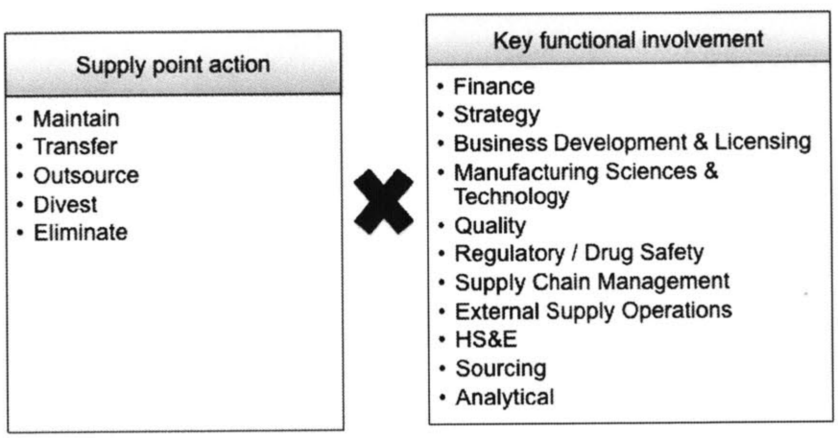


**Figure 11: Identifying cost generating activities by functional involvement in supply point actions**

Once the cost generators are identified, the tasks are filtered and ranked based on the frequency of occurrence and the financial impact. Those tasks that are required on an annual basis, such as product stability testing, complaints handling, quality and HS&E audits, etc. are classified as high frequency. High impact is measured by the FTE hours consumed and the amount of fees and expenses required to conduct the activity. Low frequency, high impact tasks occur infrequently, but when they do, can contribute significantly to complexity costs. An example of high impact and low frequency cost generator is redevelopment cost of existing products that involve bioequivalent studies, which are rare but can amount to upwards of millions of dollars. Others include capital cost of inventory financing and holding; remediation costs for plants, equipment, or site; and opportunity cost of capacity allocation to a low profit product. The model will focus on high impact and high frequency items. We choose to provide guidelines to identify if these factors are in play for specific cases and how to gather the data needed to assess them (Figure 12).

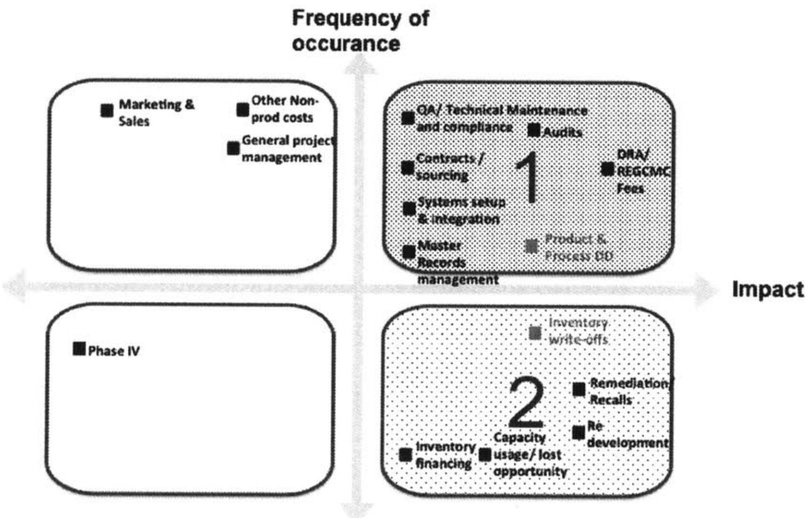


**Figure 12: Classification of complexity cost generating tasks by impact and frequency of occurrence**

The preliminary assessment of cost generators also included indirect costs such as the financing cost of excess safety and bridging stocks due to forecast errors, Phase IV clinical trials, and marketing. For single sourced, chemical, solid oral dosage form products, Company X maintains a target total safety stock of 30 weeks. This is broken down into 18 weeks of Drugs Substance, 8 weeks of Drug Product, and 4 weeks of Finished Product. For a typical slow moving, end of lifecycle product, there is almost zero marketing and Phase IV costs. The capital cost of 30 weeks of safety stock is valued at the consolidated total production cost of the DS, DP, and FP, which is dependent on the product. Finally, warehousing costs are negligible since majority of these end of lifecycle products are produced at fully depreciated and Company X-owned sites. Through initial evaluation, these costs were demonstrated to be minimal compared to the high impact and high frequency cost generators and were thus not included in the evaluation and cost model.

### 3.2.2 Data Gathering

There are two main contributors to the cost of an activity: 1) the FTE resource required to execute the activity and 2) the expenses and fees not directly tied to human resources required to support the execution of the activity. Both pieces of data can be obtained through either accounting invoices or interviews with employees and managers who do the work.

The most direct way to gather the FTE resource usage data is to first break down the supply point action into activities and then decompose the activities into smallest units of discrete tasks by function. Taking an example of the supply point action of 'maintain' Table 1 details the activities required to carry out maintaining a product on an annual basis and all the tasks associated with each activity. The involved functions then provide an estimate of the FTE hours and expenses per task per time that it is performed. If a task is performed on a frequency of greater than one, then the FTE hours will warrant a multiplier. Translating the total FTE hours into dollars and aggregating the fees, we can obtain the total cost of activities and ultimately supply point actions that are driven by product complexity. The advantage of knowing the cost of the smallest unit of activity is the ability to reconfigure and customize costs accurately for unique scenarios.

**Table 1: Example of data collection process for complexity cost generators**

| ACTIVITIES | DISCRETE TASKS | FTE HOURS PER TASK | EXPENSES/FEES | FUNCTION |
|---|---|---|---|---|
| Technical Maintenance | Annual validation including reports | 1FTE x 3 days | | Manufacturing Science & Technology |
| | Troubleshooting onsite | 5 FTEs x 2 days | | Manufacturing Science & Technology |
| | Annual stability testing | 0 | Cost of stability test | Analytical |
| | Supplier relations team support | 3 FTEs x 4 days | | External Supply Operations |
| Annual audits | cGMP / quality audit | 2 FTEs x 5 days | Travel expenses and fines | Quality Assurance |
| | HS&E technical audit and visit | 1 FTE x 5 days | Travel expenses and fines | HS&E |
| | Follow up and resolution | 3 FTEs x 2 days/audit event | | Quality Compliance |

**Table 1: Example of data collection process for complexity cost generators**

| | | | | |
|---|---|---|---|---|
| Contract Maintenance | Review contracts and make any needed changes | 1FTE x 3 days | | Sourcing |
| | Follow up with issues, negotiations | 1FTE x 3 days/month | | Sourcing |
| ... | | | | |

In instances that data is not reliable for singular tasks and the FTE resource allocation is very distributed within a department, an estimation approach is taken to arrive at the cost per brand per year of a task or activity.

### 3.2.3 Basic Structure of The Complexity Cost Model

Following the identification, classification, and quantification of the key cost generators, it is important to turn this information into a useful format for to enable decision makers to apply the data as suitable for their needs.

It was previously stated that reducing product complexity requires both portfolio-level optimization and individual business case evaluations to cut the non-profitable and nonstrategic product offerings. The intent of the model output is to provide users with a systemic level view and also a specific tool to assess distinct decisions.

The complexity cost model ultimately feeds into a decision tree and also into a Net Present Value (NPV) analysis (Figure 13). The decision tree encompasses the indirect costs of all possible supply point decisions that can be made for a particular product so the user can compare the financial implications of each with regards to complexity. The choices that the tree makes are supply point decisions that would result in possibly incurrence of complexity costs for the product. Because the tree incorporates risk factors and data specific to a product, the decision tree is a tool used at the individual brand level. The expected value of each possible path down the tree is calculated and the model can identify the minimal cost supply point decision for a product at a systemic level. The NPV analysis is intended to evaluate a single supply point decision, incorporating complexity cost data with existing financial data from Company X's S&OP system to provide a comprehensive view of the long-term impact of a decision.

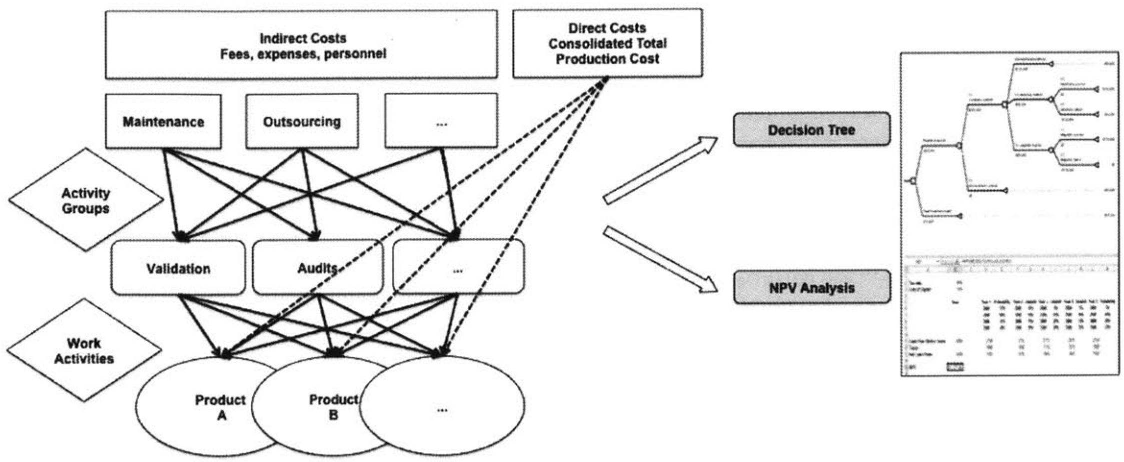


**Figure 13: Complexity cost model structure**

The decision tree component of the model uses a commercial program called TreeAge Pro, which is software with the capability to model entire systems and choose the optimal path depending on calculated end node value. Details behind the construction of this decision tree logic are described in Chapter 3.2.7. This program enables the user to simultaneously evaluate the payouts and costs of all outcomes. The model also takes into account probabilities of success and failure for specific events, such as outsourcing, and calculates the final expected value. The commercial software also has the ability to perform sensitivity analysis around chosen nodes, exclude certain paths in the analysis, and use distributions instead of absolute probabilities for the occurrence of events.

The NPV component of the model is built in Microsoft Excel and is adapted from the finance Capital Appropriation Request (CAR) form, using current budget rates. It takes into account the cash inflows and outflows from impact on net sales, avoided costs, and incremental costs.

In combination, the two components of the model are able to provide a comprehensive overview of the financial aspects of a change request with comparative and sensitivity analysis to ensure a complete business case can be generated.

### 3.2.4 Other Considerations for The Model

A critical design criterion for the model is user interface. There were two purposes the user interface needs to achieve: ease of navigation with limited training on the model, and minimal number of inputs required to run the model. Commercial software is selected for the decision tree and Excel is selected for the NPV analysis based on the familiarity and intuitiveness of the programs. The model will incorporate a large amount of inputs, yet be simple to use for ease of knowledge transfer and sustained application.

The majority of the model has basic assumptions prebuilt into the cells and changes are auto populated based on user input. User will only be required to assemble and prepare the quantitative and qualitative information outlined in Appendix 1.

Depending on the needs of the user, model input can be as simple or as detailed as desired. Appendix 2 shows the generic input interface. All cells in red are the required user inputs. The user only has to indicate anticipated occurrence of relevant lifecycle activities for the next five years and the model automatically calculates the annual complexity costs based on assumptions for a medium risk product. Once the annual total complexity costs are calculated, that data will automatically feed into the NPV model. Should the user want another level of granularity, there is the option to select only the relevant tasks for each lifecycle activity. This is a secondary layer in the Excel model, where all tasks are visible and can be included in or excluded from the complexity cost calculation. The risk level for the product under evaluation can also be modified as desired.

### 3.2.5 Incorporating Risk and Uncertainties into The Model

There are several sets of scaling factors used to adjust the complexity costs and the uncertainties in the model. The first set of factors adjusts for risk. The level risk is evaluated across technical, business, regulatory, and operational categories, applying failure mode and effects analysis (FMEA) and supplier assessment methodology. There are three levels of risk classification: low, medium, and high risk categories; each corresponds to a multiplier on complexity costs. The risk scaling factor is incorporated to appropriately adjust the complexity costs obtained via ABC since the cost figures are average numbers and has a large range across low to high scenarios. The risk factors considered are summarized in Table 2. The risk factors are first rated on severity (scale of 1-7), occurrence (scale of

1-5), and detection (scale of 1-7). The product of these three ratings becomes the standard risk priority. Each risk factor is then scored on a 0-100 scale. An example of the risk factor scoring system for manufacturing technology is provided in Table 3. Finally, the risk factor utility is calculated by multiplying the risk factor score by the risk priority. The risk priority weighting is initially equal for all categories, but can be prioritized by the user, which will then change the risk factor utility. A product with risk factor utility value between 0-25 is deemed low risk, 26-50 is medium risk, and 51-100 is high risk. The multipliers assigned to the risk levels are 1.0, 1.05, and 1.5 respectively. This is based on both observations that complexity costs increases geometrically and also the range of data received through activity-based accounting.

**Table 2: Risk factors by category to scale complexity costs**

| RISK CATEGORY | RISK FACTORS |
|---|---|
| Technical | Manufacturing Technology |
| | Process capability/ validation |
| | Analytical methods |
| Strategic | Strategic positioning |
| | Demand volatility / existing competition |
| | Life saving medicine? |
| Regulatory | Number of markets and regions of sale |
| | Documentation completeness and compliance |
| | Registration compliance |
| Operations | Footprint & capacity |
| | Supply Chain |
| | Contractual Obligations |

**Table 3: Example of risk factor scoring scale**

| Risk Factor Scoring Scale | | | | |
|---|---|---|---|---|
| Low<br>0 | 25 | 50 | 75 | High<br>100 |
| Hard Gelatin Capsules | Tablet | Film Coated Tablets, Sugar Coated Tablets, non-sterile liquids | Transdermal Therapeutic Systems, sterile liquids, creams | Biologics, cell therapy, Advanced Therapy Medicinal Products |

The other set of factors is incorporated to reflect the uncertainties in the execution of supply point actions. Success means that the process reliability, quality, and integrity of the product produced at the new site is the same as the old. On supply point actions such as manufacturing transfer and divestments, successful outcome is not guaranteed. Thus a probability is assigned to calculate expected costs for internal to internal, internal to external, external to external, and external to internal site transfers. These probabilities were converted from Company X's Product Improvement Portfolio (PIP), which tracks risks within manufacturing, analytical, regulatory, and product quality. The probabilities are then adjusted accordingly for low, medium, and high risk products.

These scaling factors are quantitative within the model, but qualitative in nature and origin. It remains up to the discretion of the user to update and adjust as needed.

### 3.2.6 Building The Net Present Value Model

The aggregated complexity cost data from ABC feeds directly into a five-year NPV model. The base scenario evaluated by the NPV model is for product elimination, assuming 100% total loss in sales for the next five years. The model is set up with reversed cash flows. Cash 'inflows' that contribute to a positive NPV are the potential savings in complexity costs and all other costs incurred if the product was not eliminated; cash 'outflows' that contribute to negative NPV is the projected net sales not generated due to the elimination of the product. If strategies are in place to partially recover some of the sales or deplete existing inventory, the user can make modifications to the NPV model.

### 3.2.7 Building the Decision Tree Model

A decision tree maps all out potential outcomes of every single decision within a system. The basic structure of decision trees consists of branches and nodes. Each branch represents a different outcome or decision. Each node defines the properties of the attached branches. Commonly used node types are decision nodes, chance nodes, and terminal nodes (Figure 14). The decision tree can account for uncertainties via the chance node, where the user defines probability of success associated with the outcome. Terminal nodes indicate end of decision and there must be a final payout value associated with each terminal node. The payout value can be defined as a function of variables or as an absolute value.

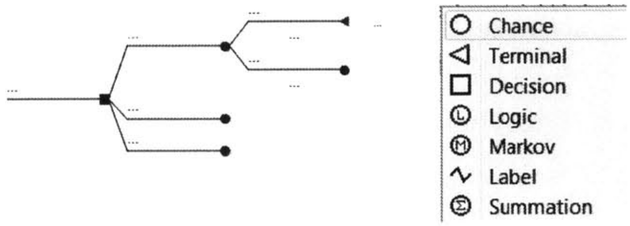


**Figure 14: Decision Tree basic structure**

The use of the decision tree model gives user a systematic view of all possible strategies and compares the cost and benefit tradeoff to enable optimized problem solving. The logic in setting up the model is to enable every strategy that is relevant for a product to be visible, allowing comparison in cost with respect to key variables and uncertainties within the organization. The model is set up with differentiators to isolate the particular problem at hand. Because small molecules and biologics vary so greatly in cost, technical and supply attributes, that is the first differentiator. The focus of this model and project is on small molecules. Within small molecules, the cost of each strategy is driven mainly by the riskiness of the product and the stage in the supply process (DS, DP, FP, and brand). The product risk profile is defined next, from low, medium, to high risk. Risk classification is address in Chapter 3.2.5. The user has the option to run only one risk level or multiple to compare the sensitivity of the cost to risk classification. The next level of differentiator is the stage in supply process. The cost of lifecycle activity management is incurred at 100% at the brand level, but only partially at the DS, DP, or SKU level. The unit defines how much of the total brand cost should be taken into account. Finally, for each unit in the product supply process, the possible strategies are: continue existing or maintain, transfer, outsource, prune, or divest. Maintain means continuing with the current manufacturing and supply of the product, incurring full carrying cost and any additional cost associated with the strategy. Within transfer, there are four permutations of internal and external transfers with associated uncertainties of event success. Outsourcing is defined as the cost of buying product and services directly from a third party.

**There are several key features of the model, highlighted in**

Figure 15. The variables and costs are defined upfront, which gives user full flexibility to modify once and automatically carry throughout the calculations in the entire decision tree. The uncertainties, or random variables in each strategy as defined by the probability of activity success (for example the success rate of an internal transfer) are also defined upfront and only need a one-time alteration to propagate throughout the entire decision tree. The risk classification of the product splits the decision tree into three main branches, allowing the user to progress down a single chosen branch or run all three simultaneously as a comparison. Finally, there is the option to run the model at the brand, DS, DP, and FP levels by excluding the irrelevant branches from the strategy. Ultimately, the model generates the expected costs of all decisions within the system accounting for all uncertainties, using the pre-defined variables.

**The decision tree model calculates all expected values of every feasible supply point decision, accounting for uncertainties. To consolidate all the various scenarios into a single model, the various risk levels are built as branches off a single tree. In application, the user would choose which risk level to run the analysis on. Within each risk level, the tree then branches to all the product stages that decisions can be made on (**

Figure 15). For a typical pharmaceutical product, a supply point decision can be made at the Drug Substance (DS), Drug Product (DP), Finished Product (FP), or brand level. DS is the active ingredient in the product, DP is the stabilized complete formation of a product, and FP includes all primary and secondary packaging and labels. Company's X accounting system only provides costs for SKUs, which accumulates costs through raw material, DS, DP, and FP stages. In order to reallocate this total cost back to individual stages of a production cycle, a set of adjustment factors were created. Since the complexity costs are mainly calculated at a brand level, a certain percentage is taken for DS, DP, and FP. The percentages are allocated to reflect exponential complexity cost increase with progression up the manufacturing and supply chain. At the DS, DP, FP, and brand level, there are the same sets of decision that can be made: continue production at existing site, transfer, outsource, eliminate, or divest (only for brand). Then the expected complexity costs for each outcome is calculated. Computing the model results in choosing the lowest cost path. The user can freely adjust the cost generators relevant for the product under evaluation. The probabilities of transfer success and risk scaling factors are set on the default level but can be modified.

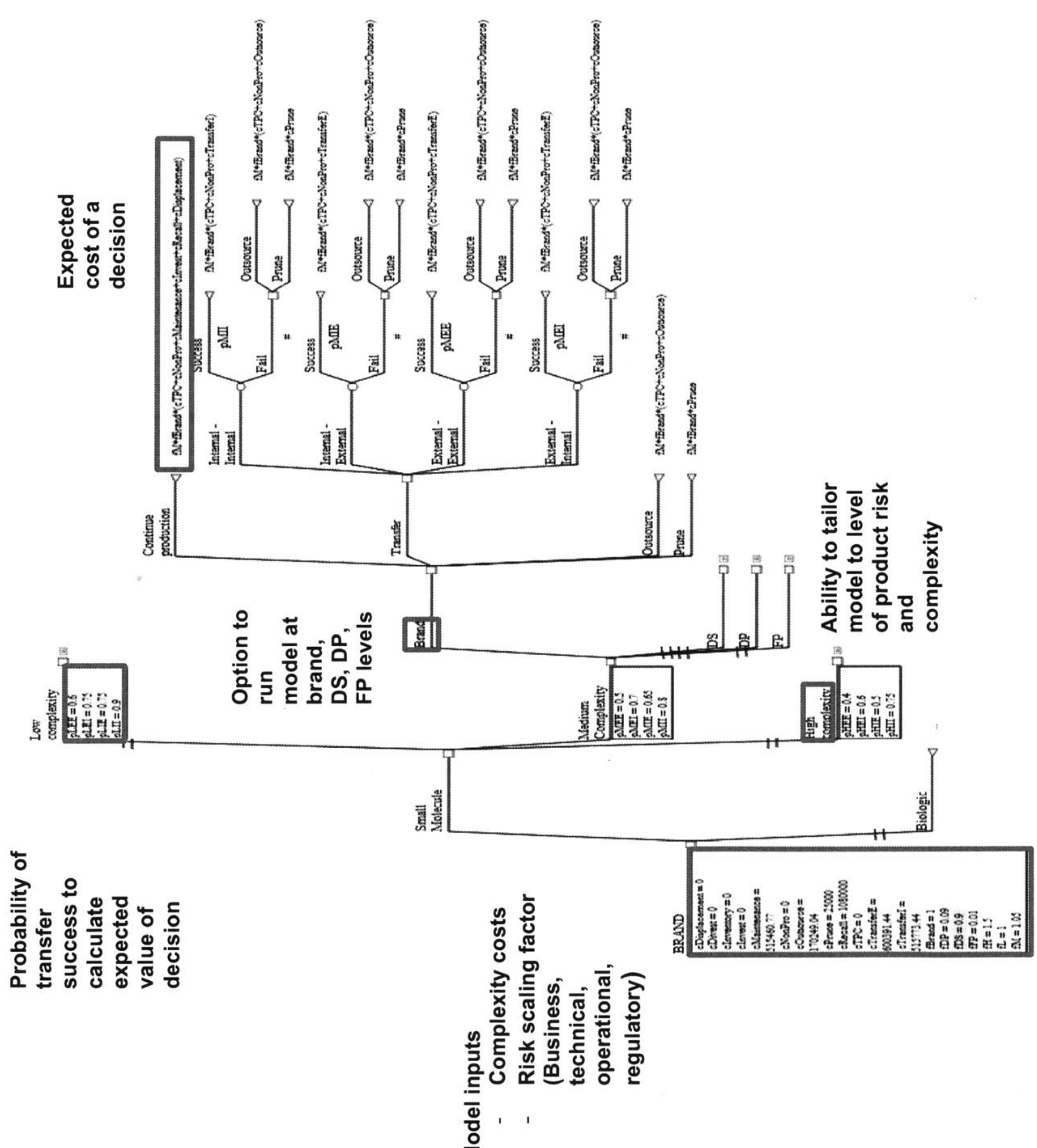

**Figure 15: Skeleton of decision tree model**

### 3.2.8 Data Validation

The model construction was performed via a bottom up approach, aggregating data pieces through activity-based accounting. The final cost for all lifecycle activities per brand per year is estimated from costs of single functional tasks, the smallest unit of activity. Data validation takes a top down approach. The total spends for an entire department, including global and local budgets are captured. Within the total budget, there are overhead support and other SG&A expenses. For model validation, we only want the amount allocated solely to product management. This can be taken as a percentage of the total budget. That percentage will vary based on function. The exact percentage is verified through existing key projects and information gathering from functional heads and key people that perform the work. The total spend budget for brand lifecycle activity management is then divided by the total number of brands to arrive at spend/brand for that particular function. This number should be on the same magnitude as the bottom up number (Figure 16).

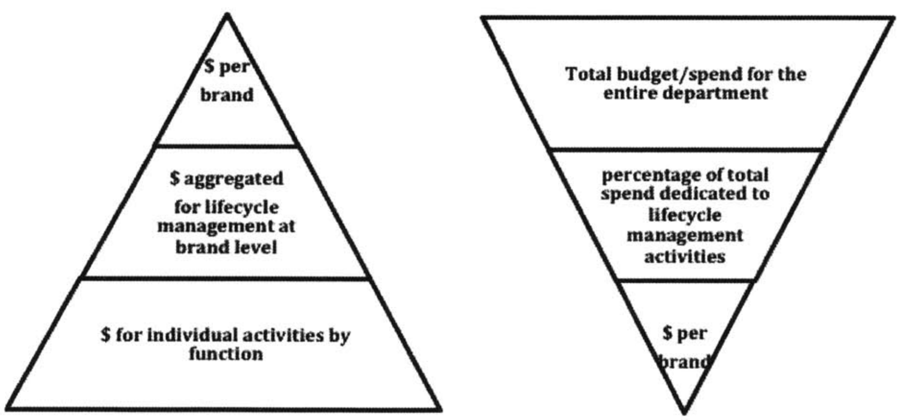


**Figure 16: Model validation schematic**

A major consideration in building the model from the ground up is inclusiveness of all relevant data, which is why it is important that the final number derived from the bottom up approach is sense checked. As detailed in Table 4, the aggregated cost per brand closely matches a heuristic calculation done via a top down approach. It is not critical that the numbers match exactly since there are a series of assumptions used in performing the calculations. The magnitude is what we are concerned about here to ensure that the model can mostly accurately capture the complexity cost range in relative terms across the entire product portfolio.

**Table 4: Model validation data**

| Cost Generating Function | Aggregated Cost | Top down cost | Assumptions |
|---|---|---|---|
| Quality Assurance / Quality Control | **$1.19M** | **$ 1.31M** | 50% of workload dedicated to EM brands, 155 EM brands. (From past 3 yrs Remediation and Recall data) Accounting for all maintenance, transfer support, compliance, remediation, and recall activities |
| Sourcing | **$0.38M** | **$0.29 M** | Only 90 brands supported in 2013 budget. Includes strategic sourcing, contractual work. Top down costs also accounted for allocation of SRT support |
| Manufacturing Science & Technology | **$ 0.58M** | **$ 0.53M** | 80% of workload dedicated to EM brands, 155 EM brands. 50% of $8M budget for revalidation used in 2013. Accounting for all maintenance and transfer support |
| Supply Chain Management | **$ 0.33M** | **$ 0.30M** | 70% of workload dedicated to EM brands, 155 EM brands. Accounting for all maintenance and transfer support |

### 3.2.9 Key Assumptions

There are several categories of key assumptions within the model to enable calculations.

***Activity Cost Assumptions***

The first set of assumptions is the activity costs used to build the ABC matrix, which were derived from estimations by various functions across Technical Operations and Development functions. The majority of the estimations came from External Supply, who has full visibility to activity costs. Additional scaling down may be needed to accurately reflect internal only costs.

In the activity based accounting, cost data for activities are gathered from functional experts who provided the amount in fees and estimated FTE time. The FTE time is translated to cost through percentage of total FTE time required for a task as it correlates to in percentage FTE salary. The FTE time and expected expenses are estimations based on historical data and experience. These numbers vary depending on the complexity of the individual cases. The final inputs into the model were taken as the average, with a multiplier factor to appropriately scale based on case complexity and risk.

### *NPV Model Assumptions*

The NPV model was adapted from previous financial model with assumptions behind tax rate, annual accounts receivable, write offs, and overhead as a % of net sales. These fundamental model assumptions need to be updated annually with input and approval from Technical Operations Business Planning and Analysis department.

### *Decision Tree Model Assumptions*

In order to construct a generalized working model to cover all the possible scenarios within the product portfolio, we introduced several sets of scaling factors to adjust the complexity costs and the uncertainties in the model.

The first set of factors adjusts for product risk. As detailed in Section 3.2.5, risk factors place a product in one of three categories: low, medium, and high risk. The low, medium, and high-risk categories each receive a multiplier on average complexity cost. During the data gathering process, the range of complexity costs were collected for a variety of products that fell into all three categories. Based on the relative costs for each category, a multiplier is assigned as determined by the range of complexity cost data. This multiplier can be adjusted based on additional data evaluated but it is a relative number used to differentiate categories of products within the same portfolio.

The second set of factors adjusts for whether the decision is being made at a DS, DP, FP, or brand level. Company X only calculates total production cost at the finished product level, so all the intermediate costs are not tracked. However, supply point decisions can be made at the intermediate product level, thus it is important to extrapolate the cost of production at each stage of the process prior to finished product. A certain percentage of the finished product cost is taken for the intermediate DS, DP, and FP. The incremental percentages for each intermediate product is not linear since majority of costs are incurred in early stages of manufacturing so the allocated percentages are on an exponential scale to reflect the non-linear complexity cost increase with progression down the manufacturing and supply chain. For example, total complexity cost for a finished product is allocated 90% to DS, 9% to DP, and 1% to FP. The scale chosen is based on information from the technical operations department and exact percentage allocations to DS, DP, and FP can be adjusted easily in the model.

The third set of factors is the probabilities of transfer success for internal to internal, internal to external, external to external, and external to internal transfers. These probabilities were converted from the Product Improvement Portfolio (PIP), with focus on the manufacturing reliability and analytical success rates. The probabilities are then adjusted accordingly for low, medium, and high risk products. PIP comes from reports of individual plant data within Company X's manufacturing network. These sites are distributed globally and often have varying process reliability and other risks even for the same product. The calculated probabilities from existing data should be periodically updated to reflect the current operations status of the business. Sensitivity analysis can be conducted to measure impact of fluctuations to these probabilities on the final optimal decision in the model.

### 3.2.10 Using Case Studies to Validate Model

To test the validity of the data and model, four case studies were chosen as pilots. Following reduction in tail end SKUs, the focus of complexity reduction has shifted to mid-sized brands, with net sales between $1M to $50M and positive profitability. The four products chosen reflected a wide range of revenues, operational complexity, and high-risk complications. The case studies were recommended and endorsed by key stakeholders, as they are products in need of supply point changes. The findings of the model would directly affect the strategy chosen for each product.

## 3.3 Process Complexity

In conjunction with tackling product complexity, we simultaneously worked on understanding and reducing process complexity within Technical Operations and associated functions. The decision making process for supply point changes is not well defined, cumbersome, requiring many approvals, and time consuming. There is a misalignment in goals and incentives between the approving and executing parts of the organization. Outsourcing, transfer, pruning, and divestment activities are reviewed through different but parallel processes. Cross-functional approach was used to identify process gaps, test interventions, and finalize proposed solutions. A current state analysis was performed through process mapping and interviews with each function involved in the work process. From the current state mapping, opportunities for improvement were identified and an ideal state process was proposed with changes to decision ownership and expected cycle time for each process flow step. The new proposed decision making process is summarized in Chapter 4.5.

## 3.4 Organizational Complexity

Organizational complexity is not directly addressed in this project. It is considered for awareness and implementation purposes. Company X is a matrix organization with a massive global workforce footprint. There is an innate tension between global functions and the country businesses. Each Country Pharma Organization (CPO) is responsible for the health of their business. They primarily serve the needs of the country and have strong power over portfolio choices. However, CPOs does not have visibility to the global cost of products. They only see local costs and margins, without knowledge to the global expenses and final margin on the products that they sell. The different key performance metrics used in global and local reward systems also spurs disparity in operational strategy and execution.

At the global level, functional silos are a big hindrance to data sharing, project collaborations, and gaining alignment. Portfolio management work is divided by lifecycle activities and is not owned by a single group. Divestment related decisions are analyzed and made by the Business Development and Licensing Group. External Supply Organization makes outsourcing and contract manufacturing decisions. The Supply Chain Management and Pharmaceutical Operations groups make internal supply chain decisions. Supporting functions such as Finance and Strategy provide oversight and input as needed. A single product undergoing various lifecycle activities requiring the involvement from all the functions usually receives piecemeal strategies that are reactive in nature to deal with the current issue at hand. An optimized lifecycle management decision is difficult to make proactively and comprehensively given the hurdles of this organizational structure. This is notably important in discussing implementation challenges of complexity reduction

# 4 Results of Model Application

## 4.1 General Findings

The major findings of the complexity cost model are split into two categories: implications at the portfolio level and specific results for each case study. The activity based accounting data indicates that for an average sized brand with medium risk that is in the maturity to decline phase of its lifecycle, there is an annual $2.2M in operational complexity cost that the company incurs to maintain the manufacturing and distribution of this product. The breakdown of sources for these complexity costs is summarized in Figure 17.

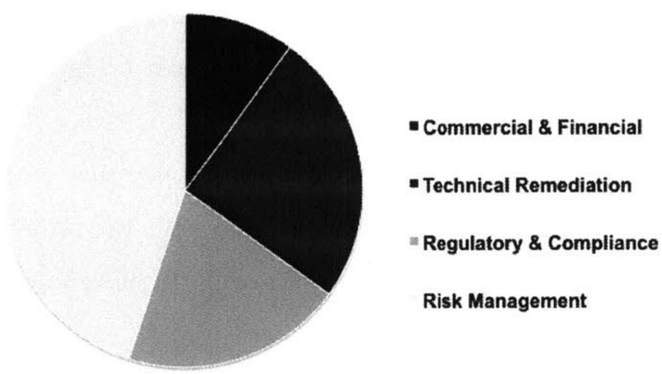


**Figure 17: Breakdown of major complexity costs by category**

Average sized brand is defined as brands with annual net sales between $5-50M. Medium risk is defined by the risk rating described in Chapter 3.2.5. The $2.2M per year includes the base cost to maintain the product and the incremental cost from supply point actions. There are a series of activities associated with just keeping a product alive. This requires the involvement of many functions and drains a significant percentage of FTE resources. Incremental cost from supply point actions include the cost of transferring, outsourcing, eliminating, and divesting a product. For a medium risk product, we can anticipate a certain number of supply point changes within a year and the associated probabilities of execution success. Thus the expected value of complexity cost for these activities can be calculated.

At the portfolio level, 67 brands were identified for elimination. The brands selected all had similar profiles of being off patent products at the end of their lifecycles, with annual revenue less than $10M, and meet the medium to high-risk criteria for incurring supply point change costs. The 67 brands translate into a 27% reduction in the total number of brands and a significant reduction in complexity. The reduction impacts net annual net revenue by 0.05%, which is negligible compared to the potential savings of $75M and the FTE resources freed up to allow Company X to focus on more strategic launch and growth products (Figure 18).

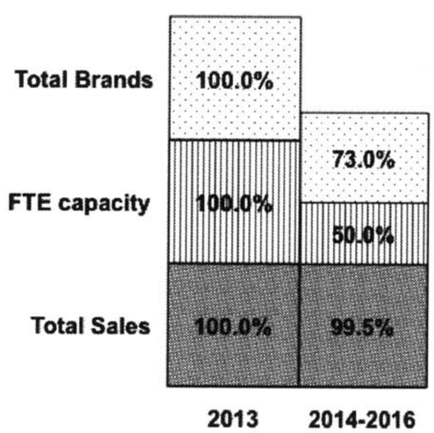


**Figure 18: Portfolio effects of complexity reduction**

## 4.2 Case Study 1 – High Risk Category: Brand A

Brand A is an off patent mature to decline phase product. It has annual sales of over $20M globally and is deemed by the World Health Organization as a life saving drug. Given the size of the brand and all the technical and regulatory complications, Brand A is categorized as a high-risk product characterized by binding supply agreements, technical challenges in manufacturing processes, and number of markets impacted. Decision and NPV analysis were performed. The complexity costs for the next two years is significantly high due to anticipated supply point changes in sourcing from new drug substance supplier, upgrading the testing monograph for the drug product, and potential manufacturing site transfers and consolidations. It is evident from Figure 19 that without accounting for operational complexity costs; the gross margins are healthy enough to warrant continuation of the existing operations. With the complexity costs added, five-year profitability look very different. However, NPV analysis of the brand elimination scenario yielded a loss of $15M. Brand elimination is the most effective way to reduce product and process complexity, however in this case, a negative NPV of $15M is too compelling for management to consider outright pruning of the entire brand. This is a general lesson for products within the portfolio that may carry high complexity costs, but can offset the costs generated by the magnitude of the revenue. In this case, brand-level pruning is not financially feasible; therefore complexity reduction should be assessed on single SKU basis or at the DS, DP levels through performing a similar analysis on subsets of the production value chain.

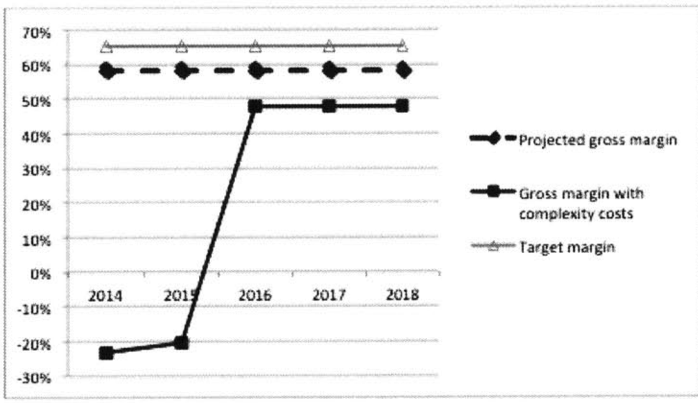


**Figure 19: Five year gross margins forecast for Brand M**

A DS level analysis was then performed using the decision tree model to assess the optimal supply point decision based on complexity costs. All potential outcomes were evaluated and the lowest cost option for Brand A DS is to outsource the drug substance, meaning a direct purchase from a supplier. Without the complexity cost model and transparency to all the resources that Brand A actually consumes, the business would have faced unseen continued margin erosion from manufacturing in house since management would not have had the appropriate data to evaluate other options when brand level pruning was out of the question. With suggested implementation of DS outsourcing, Company X would be able to save on average $1.8M in complexity costs per year in the long run.

## 4.3 Case Study 2 – Medium Risk Category: Brand B

Brand B is another off patent product in the maturity to decline phase of its lifecycle. The brand has 65 SKUs, totaling over $7M in annual sales. With a highly fragmented supply network, anticipated manufacturing upgrades, and major competition, Brand B is rated in medium risk category. Similar base scenario of brand elimination was assessed for Brand B. With existing assumptions, Brand B exhibits average gross margin of 67% over five years. In reality, with all the complexity costs, the recalculated average five-year gross margin drops down to only 4%. This analysis greatly alters perception of how profitable Brand B truly is and provided data for a business case to evaluate pruning, divestment, and transfer options for the product. Five year NPV analysis yielded a loss of $0.06M. While this is not a positive number, the loss is small enough that the benefits for brand elimination would outweigh the short-term financial disadvantage. Conservative assumptions were taken for lost sales in this particular instance, so minor modifications would enable NPV to become positive for brand elimination. Without cost transparency, products with as much sales as $7M would never have been considered for elimination. The business case acknowledging operational complexity costs enabled Company X Technical Operations to approve the elimination of Brand B.

## 4.4 Case Study 3 – Low Risk Category: Brand C

Brand C is an off patent local brand sold only in one country. The two SKUs of the brand total $0.3M in annual sales. Brand C has a regional supply chain and no major exposures. It falls within the low risk category. It was mentioned above that for an average brand, there is about $2.2M in operational complexity costs per year. In this particular case, Brand C's net sales are only $0.3M, so the assumptions for the complexity cost model were adjusted appropriately. With the adjustments, brand elimination yielded gains of $7,700 on the five year NPV analysis.

It is evident from this case study that for very small brands with annual net sales less than $5M, the complexity cost model assumptions have to be adjusted accordingly. This is addressed in Chapter 5 discussions.

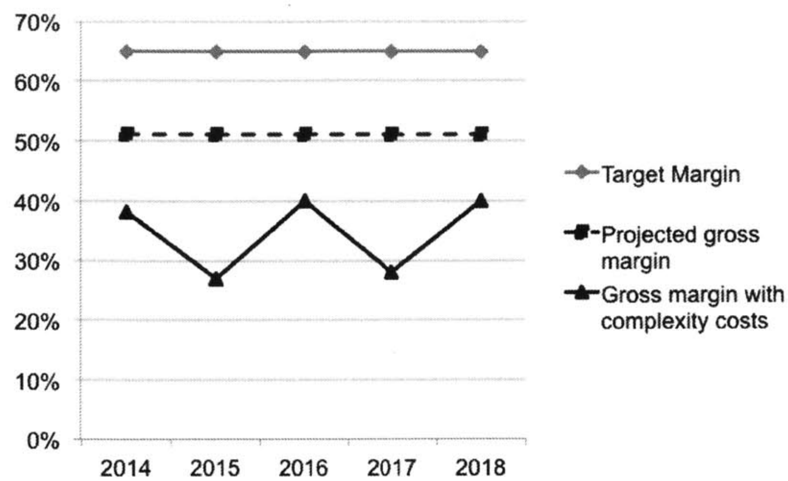


**Figure 20: Five year gross margins forecast for Brand R**

## 4.5 Process Complexity Results

To tackle process complexity, an effective pruning process to retire products becomes increasingly important with growing portfolio complexity. Company X's existing process for making supply point decisions is slow, with modest business impact. Current state mapping of the existing process indicated over 15 functions were involved in 21 discrete actions and information flows. The initial requests for supply point changes came in inconsistent formats and were often incomplete. Weak linkages between the Technical Operations and commercial functions created bottlenecks in the process. A lack of clear criteria for escalation and approval resulted in requests arrested in evaluation phase for months on end.

A systematic solution focused on initiation, evaluation, decision, and execution is proposed to simultaneously address multiple weak points in the workflow. Three next steps were identified: standardize workflow, define ownership, and track information. The existing process for new product launches has a standard evaluation template with a specified list of required data and information. Supply point evaluations can adapt a similar standard format. A single submission point and one-way process flow can ensure streamlined operations and minimize rework. The second proposed strategy is to clearly defined roles and expected cycle time for each process step. Submitted requests should progress through the initiation, evaluation, and decision gates within a required target time frame and it will be the responsibilities of each process step owner to monitor progress. Prior to execution, all stakeholders involved would align to the overall timing and expectations. Finally, an improved data management system is needed to track progress and provide a one stops shop for templates, guidelines, and traceability (Appendix 4).

# 5 Discussion & Next Steps

## 5.1 Shortcomings and Limitations of The Model

We should also acknowledge some limitations with this model. The intended application of the model is for both discrete business case evaluation and portfolio wide assessment. However, the portfolio has a high assortment of products that vary in annual sales, margins, operational footprint, and stage of lifecycle. The complexity cost model seeks to increase cost transparency for more proactive brand management and strategic decision-making. The focus of this complexity reduction effort is on the subset of the portfolio that is off patent, less profitable, and presents disproportionate return on operational risks. This may not be relevant for all products. The cost model is not applicable to launch and growth brands. These products' high revenues and margins make them strategic brands that are not appropriate for elimination or divestment. On the flip side, launch brands may have negative gross margins in the first few years following market launch. The negative margins will distort complexity cost calculations. While there are still complexity costs associated with these launch and growth brands, the potential value of elucidating this information is minimal since it will not impact major managerial decisions.

In addition to relevancy corresponding to the product lifecycle, the model's applicability is also limited by the size of the product. The optimal subset of the portfolio is products with annual revenue of $5-50M. These brands have an ideal complexity cost to margins ratio that would enable complexity costs to become a compelling reason for pivotal supply point decisions.

The output of the model hinges on the data and assumptions that were used to construct the decision tree and NPV models. These numbers may change year-to-year, requiring regular sense check and updates. It is important to bear in mind that the results are more indicators of magnitude of costs to provide the supply chain with relevant information for decision-making purposes.

## 5.2 Further Model Development

The scope of our efforts was centered on Technical Operations specific costs at the global level. The next phase in making the model more comprehensive and precise is to expand both the breadth and depth of the input data. Additional indirect costs such as the lost sales from supply disruptions can be included in the NPV analysis to reflect a more accurate depiction of various scenarios. The model can also incorporate the hidden costs from development and commercial functions, which were not accounted for in this study.

The current version of the model does not automatically link to Company X's S&OP data and relies on user input to capture the required information for analysis. Refinement of the model can link inputs to the SAP system and pull real time revenues, margins, and volumes. This would minimize the mistakes from transferring data while also guaranteeing the most accurate analysis from the most updated information.

For an alternative model structure, we propose to use square root costing method to benchmark against activity-based accounting. The square root method is based on the concept that costs (such as inventory) are proportional to the square root of volume. Low volume products contribute disproportionately to the administrative cost, setup time, and inventory based on the inverse square root of volume relationship [20]. The analysis can be done for specific product segments, similar to ABC, high-risk items can be isolated and their complexity costs quantified. If square root costing yields similar results, then the model can be severely simplified.

## 5.3 Next Steps for Company X

### 5.3.1 Implementation Challenges

Following the declaration of a strategic 40% reduction in total portfolio SKUs by the Pharmaceuticals division head, there has been significant momentum and support from the top down for applying complexity reduction tools to alleviate cost and inefficiencies associated with the high mix portfolio. While this mandate has synced well with our efforts to leverage increased cost transparency to reduce complexity, there are still real challenges in implementation.

Strategically, Company X always focused on revenue generation and not cost reduction, particularly at the expense of losing sales. This mentality is especially strong, as anticipated sales loss from blockbusters expiration, estimated in billions from the patent expiration, is typically compensated through driving additional sales through SKU proliferation and market expansion. This is antonymous with complexity reduction, which will cut the product portfolio variety and thus total sales. The ultimate approver for brand level changes, including elimination and divestment, is the franchise organization, which have not traditionally been concerned with operational complexity and compounding hidden cost as long as net revenue is on the rise. It will take an organizational mind shift to accept and execute the results from complexity cost evaluation.

From a political angle, the highly fragmented organization produces functional separation and each distinct function is driven by its own set of metrics and incentives. Organizations within Company X interpret complexity reduction differently and seek to implement the version that best benefits their own functions. Ultimately, buy-in is absolutely critical from key functions that bridge Technical and Commercial Operations to ensure successful implementation.

### 5.3.2 Application of The Model

Complexity reduction is a highly strategic issue for an organization that requires careful management of stakeholders and alignment between decision makers and influencers. We have directed efforts to ensure that the results from the complexity cost model are valuable and applicable for key stakeholders, and to gain recognition and support early.

Functional endorsement has been built into the planning and implementation of the model from very early on. This complexity cost modeling effort has been led out of the External Supply Operations organization within Technical Operations, but with a high level of involvement from Finance, Business Development and Licensing, and Supply Chain Management. The project steering committee has representation from all the main functions that have provided input and direction throughout the progression of the project.

To fully implement complexity reduction, we need to bridge the gap between the influencers and the decision makers. No single function has accountability for portfolio management. Currently work is done ad hoc and not proactively. Finance and global strategy are two groups, who have strong linkages to commercial functions. They were tasked to convey to the franchise function that overall business strategy of recouping lost sales can alternatively be achieved through cost savings and driving sales of priority brands through reallocating and focusing limited resources. This opens the door to communication and agreement from the management levels of Technical and Commercial Operations on a set of criteria for the usage of the complexity reduction model. Establishing and strengthening this connection should make the decision making process more prompt and effortless.

Finally, an implementation plan is developed that assigns ownership and outlines the roll out and maintenance plan for the complexity cost model. Champions are chosen from each sub function and trained on model application. They are responsible for marketing and training their own groups within Technical Operations. A committee of highly experienced personnel from the strategy groups is chosen to evaluate the model on a 12-18 month cycle. Their proximity to daily operations and knowledge of brand level supply chain allows them to effectively evaluate and amend the assumptions and input data to the mode. Finance business planning and analysis organization is given the ownership of the overall model. They are the gatekeepers to validate changes in assumptions and updates to the input data. Their involvement provides the confidence for commercial functions to continue adaptation and use of the model. The implementation plan capitalizes on the functional expertise of each function, enabling seamless collaboration between Technical and Commercial Operations for brand lifecycle management. The results from complexity reduction will be captured and clearly quantified to sustain its application.

# 6 Conclusion

## 6.1 Summary of Work and Findings

This work was driven by the need support growth and productivity by improving portfolio management and planning at a global pharmaceuticals company. The main objectives are to identify the underlying factors driving complexity cost at the global level and develop a model to enable more proactive lifecycle management.

First we established the three dimensions of complexity that typically exists in large matrix corporations, and chose to focus on product and process complexities for Company X. To tackle product complexity, we developed an ABC based cost model to measure true profitability of a product and increase cost transparency within the organization. Through identification and quantification of cost generators, we developed an understanding of the sources of hidden costs and how they contribute to the rising total carrying cost in a high mix portfolio. The model was piloted on several case studies and proved to be an important decision making factor for supply point change requests. To tackle process complexity, we mapped the current state of lifecycle management decision-making process, which involved Technical and Commercial Operations. Recommendations to address weak points and gaps to streamline the process were proposed.

Finally, we scaled the potential impact of reducing complexity cost across the broader product portfolio by selecting the brands with high risk profiles and known high complexity and aggregating the average cost per brand. The findings from this effort yielded an estimated $75M in potential savings that the organization can achieve through a 27% reduction in portfolio size based on eliminating 67 high-risk brands with an average complexity cost of $1.2M per brand. In addition, about 50% of the total FTE capacity of Technical Operations dedicated to end of lifecycle products can be freed up simultaneously with this reduction. While the monetary savings is valuable, the greater implication is the reduction in portfolio size and FTE requirements. For every brand eliminated, a series of tasks and activities can be eliminated from each function within Technical Operations. This has huge impact for cross-functional allocation of resources and risk reduction, allowing Company X to concentrate on more strategic and high growth components of the portfolio.

Complexity reduction literatures to date have only provided guidance on the levers that can affect a company's cost competitiveness. This thesis project has progressed the principle of complexity reduction to application in an actual corporate setting. Functional tools were developed catered to maximizing utilization. Piloting the complexity cost model with actual business cases under evaluation demonstrated the value and potential impact of the tool for decision-making and portfolio evaluation. Continued research is recommended to expand the scope of complexity cost modeling to include the entire supply chain network, from global to local levels. The focus of this effort was only global operational costs, which does not account for all the manufacturing and distribution nodes within the supply network. Consolidation plan to reduce the total number of nodes and achieve target cost savings require modeling the entire system as a whole. A similar ABC approach can be taken to profile each type of node that exists within the network so the total complexity cost in the system for a particular product can be aggregated. Another opportunity to build upon this work is to quantitatively measure the impact of complexity reduction results in the long run. This requires establishing a correlation matrix of dollars, FTE, and capacity saved for each unit of complexity removed.

## 6.2 Managerial Implications

As major competitors within the pharmaceutical sector look for ways to become more cost competitive, tackling complexity can be extremely effective and beneficial for the organization in both short and long term. The findings from this work indicates mature to decline phase products that have a medium to high risk rating and whose annual revenue is less than $50M can be significantly affected by complexity costs. These hidden costs can negatively impact margin by 25% to 250%. For an enterprise like Company X, whose product portfolio is disproportionately skewed towards mature to decline phase products, it is advised to conduct annual evaluations to monitor growth of complexity costs. The insight from this work regarding decision-making is that complexity accumulates between the interactions of product, process, and organizational dimensions. The linear costs are direct costs such as material and labor, which correlates to revenue increases. The complexity costs grow at a geometric rate, which ultimately forces the profitability curve to take a downturn (Figure 21). This inflection point cannot always be anticipated, thus complexity management forces management to take a more proactive approach to lifecycle management. It requires action to be taken before too much complexity cuts into a product's profitability. This is a significant paradigm shift for many companies where the existing strategy has been to maximize the revenue generation power of a product well into the decline phase of its lifecycle.

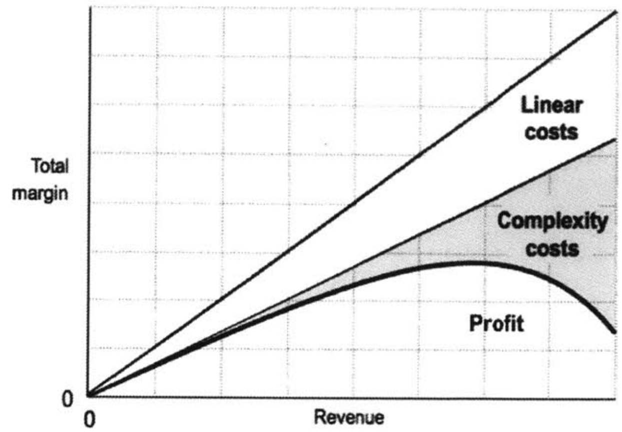


**Figure 21: Profitability whale curve [6]**

Lifecycle management from a financial standpoint typically only incorporates direct costs into the analysis. This method of accounting does not provide a comprehensive picture that permits management to make the optimal strategic decision. Common cost cutting efforts only relieves a little bit of the trapped complexity costs but does not yield significant improvement. The value equation can be modified only through extracting and eliminating the total amount of complexity along multiple dimensions of complexity.

Execution of complexity reduction must simultaneously be supported with effective decision-making processes. Current supply point decisions are made in a reactive manner, only addressed when faced with supply disruptions and active issues. The process improvements proposed bring an organized and quantitative component, streamlining the required information and standardizing the flow of information and approvals for supply point decisions cross functionally. If implemented, a standard decision making process can significantly shorten the cycle time for a decision to be made. Currently duration range from three months to one year due to repetitive evaluation, lack of information, inefficient meetings and discussions. The evaluation time in the case of Brand B to reach a decision was one day. This demonstrates the power of having the right information and tools presented in a standardized way to enable a much more efficient process.

Management must also consider feasibility of complexity reduction strategies based on organizational structure and incentive systems. Complexity costs accumulate at an exponential rate, but complexity removal occurs at a stepwise rate. Impact is felt at pivotal points after a buildup of multiple efforts culminate in the release of a sizable amount of cost. A concerted effort involving cross-functional participation is necessary to sustain the endeavor. A clear definition of a larger benefit for the organization should be used to motivate complexity reduction work. This mitigates any concerns of the value in complexity reduction.

# Appendix 1: Complexity Cost Measurement Metrics

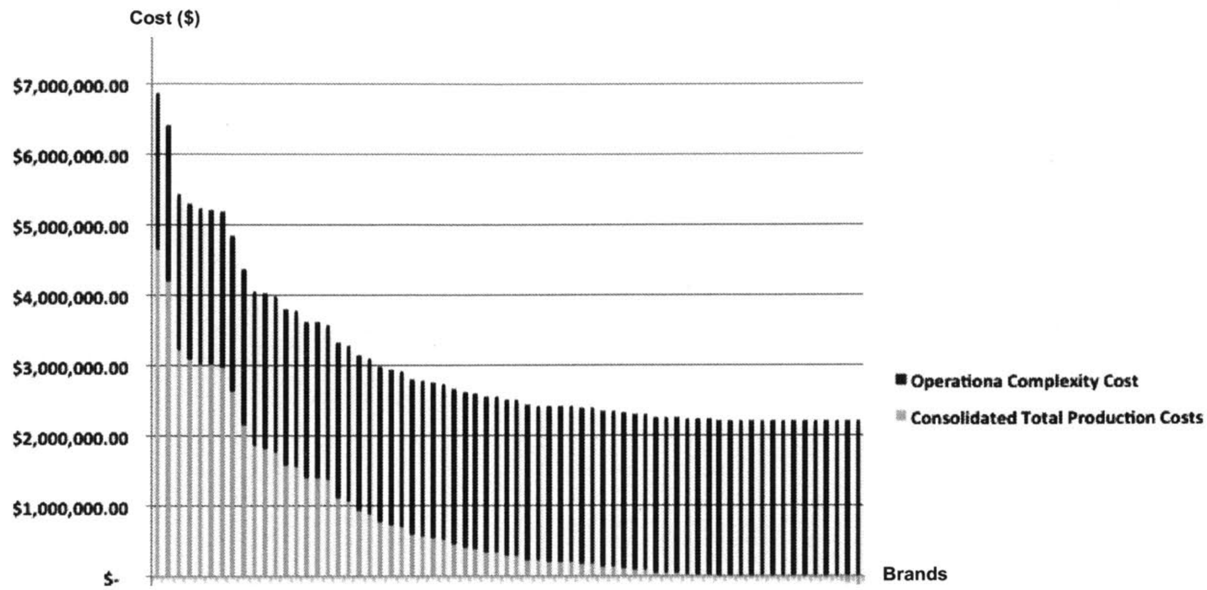


**Figure 22: Complexity Cost as Percentage of Consolidated Total Production Cost**

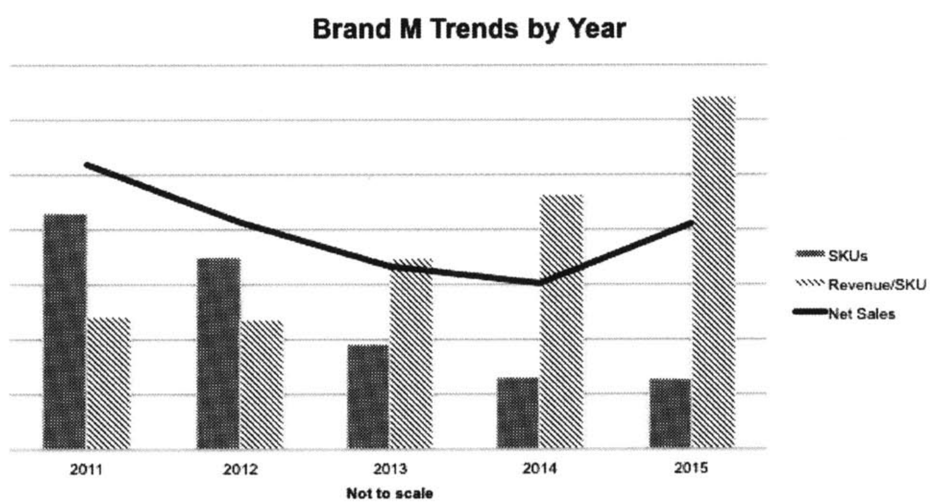


**Figure 23: Relationship between Revenue and total SKUs for Brand M**

# Appendix 2: Model Inputs and Data Table

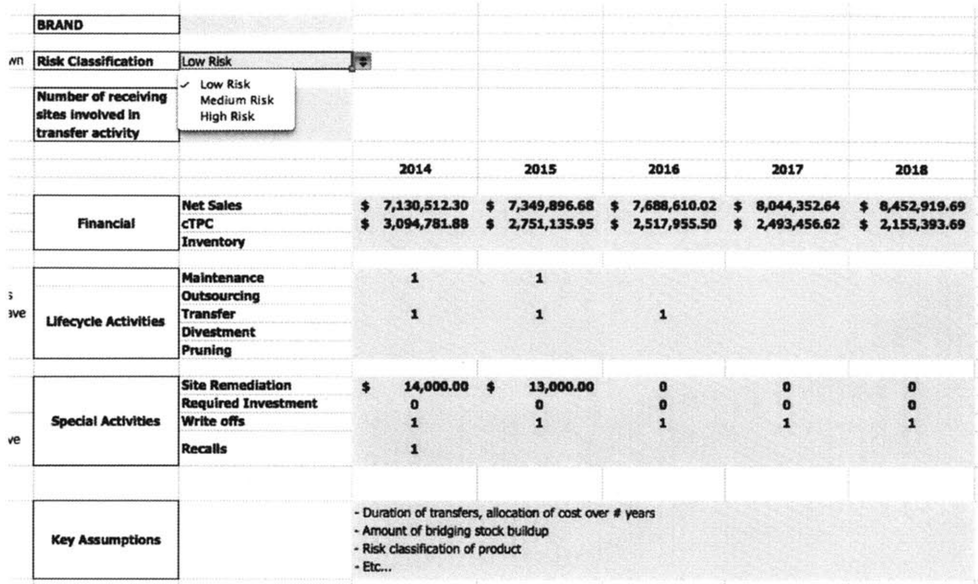


**Figure 24: Complexity Cost Model Main User Input**

**Table 5: Required Input Data by User**

| REQUIRED DATA | DATA SPECIFICATIONS | CATEGORY | SOURCE |
|---|---|---|---|
| 5 year forecast net sales (Global Sales Forecast) | USD, or convert at fiscal Budget | Quantitative | TO BPA |
| 5 year forecast margins/cTPC | USD, or convert at fiscal Budget | Quantitative | TO BPA |
| 5 year forecast inventory and accounts receivable | USD, or convert at fiscal Budget | Quantitative | TO BPA |
| Anticipated change activities and the scope | Scope and cost of activities:<br>- DS/DP/FP impacted<br>- Markets impacted<br>- One-time costs (write offs, remediation costs, investments, etc.)<br>- Executional challenges | Qualitative & Quantitative | Brand LCM, TO Strategic Facilitators |
| Brand supply structure | DS, DP, FP and marketed countries information | Qualitative | Brand LCM |
| Brand level information | Existing contracts and obligations, lifesaving status | Qualitative | Brand LCM, CPO, SRM, TO Strategic Facilitators |

# Appendix 3: Complexity Cost Model Outputs

| USDk at Bud13 rates | 2014 | 2015 | 2016 | 2017 | 2018 |
|---|---|---|---|---|---|
| *Brands* | *7,130,512* | *7,349,897* | *7,688,610* | *8,044,353* | *8,452,920* |
| *SKUs* | *0* | *0* | *0* | *0* | *0* |
| **Total Sales loss** | **7,130,512** | **7,349,897** | **7,688,610** | **8,044,353** | **8,452,920** |
| **Incremental sales from switch** | **0** | **0** | **0** | **0** | **0** |
| **Net Sales impact** | **(7,130,512)** | **(7,349,897)** | **(7,688,610)** | **(8,044,353)** | **(8,452,920)** |
| *Brand cTPC* | *3,094,782* | *2,751,136* | *2,517,956* | *2,493,457* | *2,155,394* |
| *SKUs* | *0* | *0* | *0* | *0* | *0* |
| **Total cTPC** | **3,094,782** | **2,751,136** | **2,517,956** | **2,493,457** | **2,155,394** |
| **Incremental cTPC from switch** | **0** | **0** | **0** | **0** | **0** |
| *cTPC not avoided* | *(356,526)* | *(367,495)* | *(384,431)* | *(402,218)* | *(422,646)* |
| *Indirect Complexity Costs* | *3,885,845* | *2,811,426* | *1,262,205* | *241,331* | *253,588* |
| **Total COGS** | **6,624,101** | **5,195,067** | **3,395,730** | **2,332,570** | **1,986,335** |
| **Royalties** | **0** | **0** | **0** | **0** | **0** |
| **Gross Profit (inc. Royalties)** | **(506,411)** | **(2,154,829)** | **(4,292,880)** | **(5,711,783)** | **(6,466,584)** |
| ***% of Sales*** | ***7%*** | ***29%*** | ***56%*** | ***71%*** | ***77%*** |
| *Local DRA activities+safety* | *0* | *0* | *0* | *0* | *0* |
| **Total Regulatory costs** | **0** | **0** | **0** | **0** | **0** |
| *% of Sales* | *0%* | *0%* | *0%* | *0%* | *0%* |
| *Branded M&S + Bad Debt Loss* | *(142,610)* | *(146,998)* | *(153,772)* | *(160,887)* | *(169,058)* |
| *General Marketing* | *(178,263)* | *(183,747)* | *(192,215)* | *(201,109)* | *(211,323)* |
| **Total M&S** | **(320,873)** | **(330,745)** | **(345,987)** | **(361,996)** | **(380,381)** |
| *% of Sales* | *-0.045* | *-5%* | *-5%* | *-5%* | *-5%* |
| **G&A allocated** | **(142,610)** | **(146,998)** | **(153,772)** | **(160,887)** | **(169,058)** |
| *Other taxes (inc. import tax)* | *0* | *550,227* | *503,591* | *498,691* | *431,079* |
| *Divestment income* | *0* | *0* | *0* | *0* | *0* |
| **Other Income & Expense** | **0** | **550,227** | **503,591** | **498,691** | **431,079** |
| *% of Sales* | *0* | *7%* | *7%* | *6%* | *5%* |
| **EBIT** | **(969,895)** | **(2,082,346)** | **(4,289,048)** | **(5,735,975)** | **(6,584,945)** |
| ***% of Sales*** | ***-0.13602035*** | ***-28%*** | ***-56%*** | ***-71%*** | ***-78%*** |
| **(Tax expense)/Credit** | **145,484** | **312,352** | **643,357** | **860,396** | **987,742** |
| *Tax rate %* | *15%* | *15%* | *15%* | *15%* | *15%* |
| **Earnings after Tax** | **(824,411)** | **(1,769,994)** | **(3,645,691)** | **(4,875,578)** | **(5,597,204)** |
| *Inventory* | ***0*** | ***0*** | ***0*** | ***0*** | ***0*** |
| *Acc. Receivable* | *(1,172,139)* | *(1,208,202)* | *(1,263,881)* | *(1,322,359)* | *(1,389,521)* |
| **Cost on WoC** | **(105,493)** | **(108,738)** | **(113,749)** | **(119,012)** | **(125,057)** |
| **Net Result** | **(929,903)** | **(1,878,732)** | **(3,759,440)** | **(4,994,591)** | **(5,722,261)** |

| | |
|---|---|
| **5-year NPV** | **(12,594,762)** |
| **Discount Factor** | **9%** |

**Figure 25: Sample NPV Analysis Output**

# Appendix 4: Additional Results

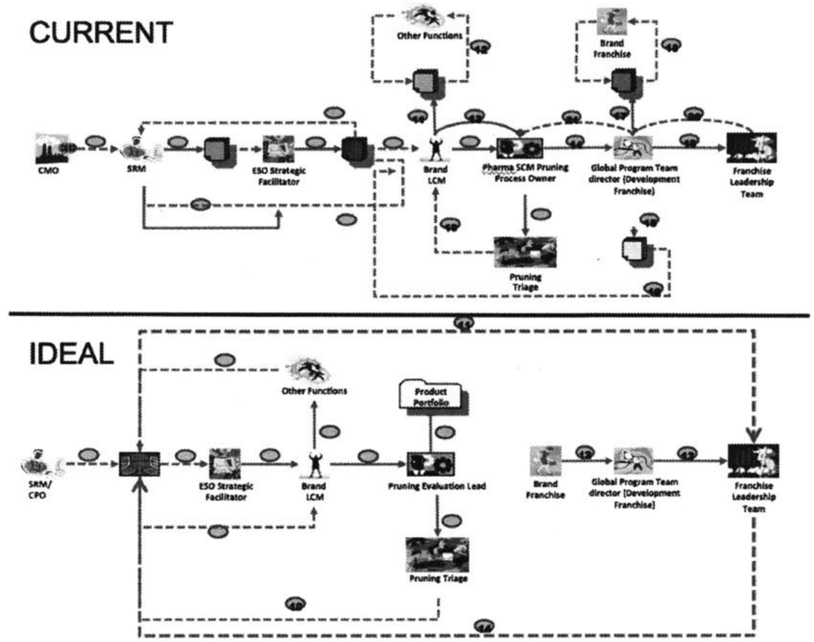


**Figure 26: Current and Ideal State Mapping Results for Lifecycle Management Decision Making Process**

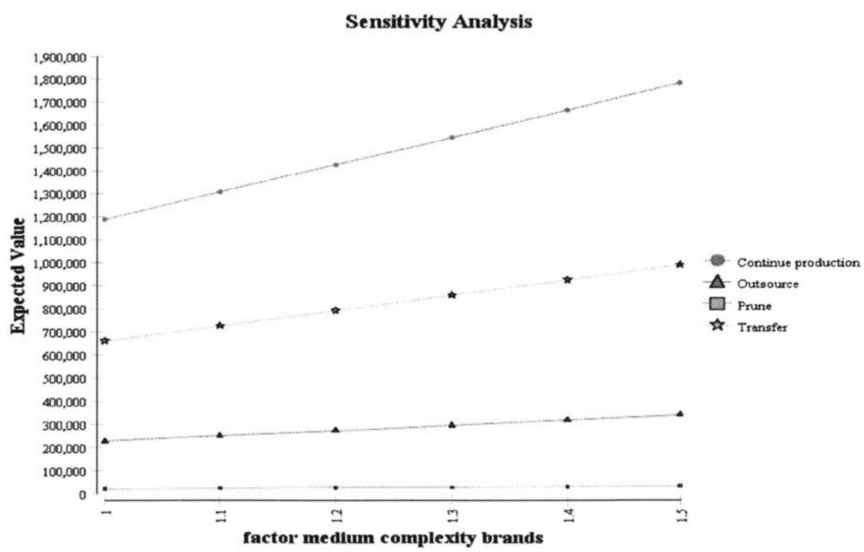


**Figure 27: Sensitivity Analysis of Decision Tree Model**

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