Closing The Loop: Improving Technology Transfer By Learning From The Past

By

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ABSTRACT

Technology transfer is a significant challenge within the highly regulated pharmaceutical industry. While much focus is put on the logistics and strategy of the process, less attention has been paid to how to change the soft, non-technical aspects of technology transfer program management, even though these cultural, communication, and perception aspects may be just as important for project success.

The goal of this study was to provide recommendations on how to change these factors to improve the likelihood of project success for pharmaceutical technology transfers. The work was conducted at Novartis Vaccines and Diagnostics, a large pharmaceutical manufacturer, so the cases studied here were all transfers of complex vaccine processes and products. While the results were intended to be generalizable to intra-firm technology transfers within pharmaceutical companies, some types of possible transfers were not included in this study. The focus of this thesis was on examining different aspects of how companies manage technology transfer projects and correlating these with how successful those projects have been to look for statistically significant relationships. The approach was two-fold: high level surveys and interviews to qualitatively identify commonly seen issues and subsequent effects, followed by a more detailed quantitative survey of individual projects.

The results of detailed surveys of individual project found no significant correlations between the studied project management factors and success. Since similar quantitative studies have succeeded in the past, the differences between this study and these previous studies were explored to determine why this particular study did not produce the desired results.

Based on the qualitative interview and survey results, the following recommendations were made on how pharmaceutical companies can improve the likelihood of successful technology transfers: 1) increase face-to-face interaction between team members, 2) better align priorities between different functions, sites, and projects, 3) coordinate with corporate senior management to foster collaboration between Research and Technology Development, and 4) fully engage all necessary functions at the start of each project.

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1. Introduction

1.1.Company Overview[1]

Novartis International AG is a major pharmaceutical company formed in 1996 from the merger of Ciba-Geigy and Sandoz, two Swiss companies. The combined healthcare giant is one of the largest healthcare companies in the world with a full range of healthcare products in advanced cancer medication, breakthrough biologics, vaccines, generics, animal health, etc. Like most major pharmaceutical companies, Novartis has historically developed its product portfolio both organically (through internal R&D) and inorganically (through acquisitions).

During the formation of Novartis, Ciba-Geigy brought in its existing 46.5% ownership in Chiron Corporation[2]. Chiron[3] was a biotechnology firm with businesses in biopharmaceuticals, vaccines, and blood testing. The vaccines unit of Chiron was itself composed largely of other acquisitions (e.g. Behring from Germany, Sclavo from Italy, and PowderJect from the UK) between 1998 and 2003. In 2004, production of flu vaccine at Chiron's facility in the UK was suspended by UK health authorities, causing significant supply shortages worldwide. In the wake of this setback, Novartis acquired the rest of Chiron in early 2006 and rebranded their vaccines and blood testing businesses as Novartis Vaccines and Diagnostics (NVD). NVD is a small but growing part of the overall Novartis portfolio that produces a broad spectrum of vaccines including influenza (seasonal and pandemic), meningitis, and various travel vaccines. Within NVD, the TechOps group is tasked with developing and manufacturing all of the marketable products that come out of the Research organization. It is in this TechOps organization that this study was conducted.

1.2.Problem/Motivation

The history of NVD brings cultural and organizational legacies that set the stage for today's challenges. As a product of recent acquisitions, Chiron had not fully integrated their disparate units when Novartis entered the picture. By purchasing Chiron, Novartis was effectively buying three separate companies, each with their own location, culture, processes, history, and values. Historically, these sites were competitors with allegiance to their own products and processes. While NVD is actively working to better integrate the different sites, there has only been a few years under the Novartis umbrella to make

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[1] Novartis Corporate History
[2] Docket C-3725
[3] http://en.wikipedia.org/wiki/Chiron_Corporation

changes, and there are still significant cultural and legacy differences between the sites. These differences can understandably cause tension; it is unreasonably optimistic to ask a site to be eager and willing to work on projects with another site if they feel (correctly or not) that this is a precursor to losing work or jobs at their own site. It is in this potentially protectionist environment that Novartis is trying to implement a framework to homogenize processes, including technology transfer. These challenges are not unique to NVD; many multinational companies face similar integrations challenges amongst their geographically disparate units. To aid in integrating and standardizing these processes, this work examines the soft side of technology transfer, where "soft" is used to mean the non-technical aspects of the transfer. Specifically, what are the factors surrounding human interaction and project/team management that are important contributors towards the success of these projects?

1.3.Hypotheses

There are myriad means to improve technology transfer. However, each comes with costs and tradeoffs that must be weighed against other improvements. The following hypotheses are made about the best opportunities to effectively improve technology transfer for pharmaceutical companies:

Recommendations to Efficiently Improve Technology Transfer

1. Increase face-to-face interaction between team members
2. Better align priorities between different functions, sites, and projects
3. Coordinate with corporate senior management to foster collaboration between Research and Technology Development
4. Fully engage all necessary functions at the start of each project

1.4.Overview of Thesis Organization

The remainder of this thesis will be divided into 4 chapters:

2) Technology Transfer (TT)
   - Background on general TT with particular focus on the pharmaceutical industry
   - General TT process with attention to past issues with NVD TT
   - Metrics used to measure and improve TT

3) Research Method
   - Discussion of qualitative and quantitative methods used to find issues with the TT process and to explore the effect of soft factors on project success
   - Comparison of this work to previous work in the literature

- Results of both qualitative and quantitative methods

4) Recommendations and Discussion
   - Recommendations for improving technology transfer
   - Barriers to implementation
   - Opportunities for further study

5) Final Comments

2. Technology Transfer

While a thorough discussion of general TT is beyond the scope of this thesis, it is useful to discuss some of the basics of TT within a pharmaceutical industry context to ensure understanding of what follows.

2.1.Definition of Technology Transfer

TT is a somewhat nebulous concept without a well-accepted, standard definition. Typical literature definitions can be too vague for an organization to focus around. The definition that will be used for the purposes of this paper (and which better reflects how Novartis uses the concept) *is "the process of sharing of skills, knowledge, technologies, methods of manufacturing, and facilities among organizations[4]"*. This definition is broad, but the specific application of TT within the pharmaceutical industry will be discussed in the next section.

2.2.Types of TT (with focus on pharmaceuticals)

Generically, TT encompasses many different types of transfers. Traditionally (and most prevalently in the literature), TT focuses on bringing new products through the research pipeline to market or shifting manufacturing from developed economies to less developed economies. These transfers (and more) can be broadly classified into vertical and horizontal. Vertical transfer refers to the "transfer of technical information within the various stages of a particular innovative process" while horizontal transfer refers to the "transfer of technical information from one project (or site) to another[5]". Pharmaceutical companies perform both types of transfer in multiple ways; vertical to bring new products to market, and horizontal to change how much of each product is made in each location. Throughout this thesis each type of transfer will be referred to as in Table 1 below:

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[4] http://en.wikipedia.org/wiki/Technology_transfer
[5] Teece 7

Vertical

Transferring From	*Transferring To*	*Abbreviation*
Research (R)	Technical Development (TD)	R-TD
Technical Development	Manufacturing (M)	TD-M
Research	Tech. Dev. at a Contract Manufacturing Organization (CMO)	R-TD:CMO
Technical Development	Manufacturing at a CMO	TD-M:CMO
Tech. Dev. at a CMO	Manufacturing	TD:CMO-M

Horizontal

Transferring From	*Transferring To*	*Abbreviation*
Manufacturing at Novartis	Manufacturing at Novartis	M-M
Manufacturing at CMO	Manufacturing at Novartis	M:CMO-M
Manufacturing at Novartis	Manufacturing at CMO	M-M:CMO

Table 1 - Types of TT at Novartis

This thesis' research examines all types of TT and makes recommendations intended to apply to the TT process as a whole, although not all types are equally important to a given organization. While Novartis faces each of these types, the primary focus for TT improvement efforts within this organization are on development to manufacturing (TD-M) transfers and on horizontal transfers in which the manufacturing of existing, mature products has to be moved to or from another Novartis facility (M-M) or a contract vaccines manufacturer (M:CMO-M and M-M:CMO). Note that a horizontal transfer does not imply that the transfer is simply replication. In fact, replication is the least important part of most TT projects: real "technology transfer involves adaptive engineering or design, while technology utilization describes those cases where little or no modification is necessary[6]". There are many factors that interplay to determine how much local adaptation is required for a transfer; production scale differences, workforce skill set, local regulatory requirements, facilities limitations, existing processes and infrastructure, strategic concerns, and end customer differences all may play a role. These adaptations are unavoidable, and so

[6] Koeppe 273

their frameworks and processes need to be robust enough to handle them. Even without potential adaptations, these manufacturing TTs provide myriad organizational challenges:

First, these intra-organizational transfers are less interesting to participants; they are generally capacity or resourcing decisions that don't involve bringing a new product to market nor are they a primary deliverable for most of the organization.

Second, within the pharma industry there are high regulatory hurdles to clear for these transfers. In most other industries, transferring manufacturing between internal organizations doesn't require any outside oversight or interaction, and for a mature product, these types of transfers are generally unexciting exercises in capital budgeting. For pharma, however, there are a multitude of regulatory bodies that must be satisfied, each tasked with ensuring that the manufacturer is producing a safe and efficacious product. Any facility manufacturing vaccines must be validated to comply with a set of practices for quality control called "current Good Manufacturing Practice" (cGMP). These standards must be adhered to by *each individual site* (and even each individual manufacturing line), not just for the company as a whole, so moving the exact same process from one building to another subjects NVD to a full spectrum of quality validation tests taking months (or years) and likely $MM. These issues multiply for international markets because cGMP requirements vary between countries, and manufacturing facilities are subject to the cGMP not only for their resident country, but for each country that *uses* their product. For example, consider a flu vaccine manufactured in Italy for consumption in the US and the UK whose production is being transferred to Germany. The transferee (Germany) must comply with potentially different requirements for the EU, Germany, FDA (Food and Drug Administration, the pharmaceutical regulatory body in the United States), and MHRA (Medicines and Healthcare Products Regulatory Agency, the regulatory body in the United Kingdom).

Lastly, the seasonal flu vaccine, a huge part of the vaccines industry, is very time-sensitive to the market. According to an NVD executive, there is a very narrow market window during which flu vaccine must be available; a short production delay could cost a company much of the season's market. Thus, any TT involving flu has to be extremely well timed and executed between seasonal cycles.

2.3.TT Process

It is useful to discuss a basic TT process to define terminology and express how complicated and interdependent a TT project is. The pharma TT process is fluid and adapts to the project being considered; however, there are commonalities of process that are important to understand. The process briefly described below is not exactly the one used within NVD during this study (partly because NVD

TT was still in flux, partly for proprietary reasons), but it is representative of the basic ideas of pharma TT.

Kickoff

A high level monthly meeting group composed of senior managers from each function determines that a TT needs to be performed. This applies to different types of TT; the transfer could be vertical (e.g. a product is ready to transition from development to production) or horizontal (e.g. a capacity limit is forecast for a product at a manufacturing site). This kicks off team formation, governance, and the transfer process itself.

Team Formation

As in most companies, NVD does not have a dedicated TT organization. Instead, TT projects are accomplished in a matrix structure in which people within each necessary functional group are assigned to a temporary team that works together for the duration of the transfer and then disbands. Generally, this assignment is part-time and the team members still have their own functional workloads to balance; only rarely is someone fully assigned to a TT project, and only then for projects of high priority or complexity.

Functional managers at both the transferring site ("transferor") and the receiving site ("transferee") contribute resources for each project from among their groups. The exact groups required depends on the transfer, but in general, people from Research, Technical Development, Quality, Supply Chain, Production/Engineering, Project Management, and/or Regulatory Affairs may be involved. These resources form the project team lead by a Project Manager (PM); for most transfers, this team contains 6-10 people, about half from the transferring site and the other half from the receiving site. For large, complicated transfers with significant capital expense, this number could be much larger. The TT team begins to meet, either virtually or in-person, to work through their applicable steps of the transfer. The team is generally granted some level of autonomy to best decide how to conduct the details of the transfer. For some transfers, these teams are physically on the same site, while others require that the teams are in separate locations (often separate countries). Further compounding the complexity, teams working on transfers to or from another company contain members from both Novartis and the counterpart company with all of the legal and intellectual property concerns associated with inter-firm agreements.

Each function (and thus team member) has specific tasks to perform or delegate during each phase of the transfer, but there are significant interactions and interdependencies among the functions that require close coordination within the team. Furthermore, team members are all beholden to their functional

departments, since that is where their permanent job duties lie, setting the stage for potential conflicts between functional projects and TT projects.

Governance

Within any multitasking organization like NVD, there is a need for high level project governance to oversee and guide the project portfolio. After a TT project is kicked off, its governance falls under the purview of a cross-functional steering committee. This committee is charged with guiding the project from a cross-project business perspective and has three main actions:

1. Milestone review of major team decisions (to approve or override them as necessary)
2. Mediate conflicts to balance scant resources between projects
3. Shut down or redirect projects if the business case changes or if the project fails

This steering committee meets periodically at specific points in the project to follow it through to completion and provide high level guidance.

Transfer Process

Once a team and steering committee are in place, the team begins a complicated waltz of individual steps, group collaboration, and inter-function interdependencies that weave through from initiation through cGMP production (for manufacturing projects) or Phase I/IIa clinical trials (for early development projects). The transfer itself is much more than simply shifting a set of procedures from one piece of equipment to another. During a typical medium-scale transfer, NVD will transfer physical hardware, technical procedures and methods, business processes, process and product knowledge, supply chains, regulatory responsibility, and unwritten site knowledge and best practices. This process can take anywhere from a few weeks to many years; thus, the process needs to be flexible enough to adapt to a variety of project scopes.

The transfer of intangible items becomes the challenge: it is relatively straightforward to ship product, equipment, and supply chain structure to a new site, but it is much more difficult to transfer the accumulated body of knowledge about the processes to the receiving site. The Standard Operating Procedures (SOPs) that comprise the official, regulated process being transferred are only the visible parts of the knowledge that must be transferred. The bulk of the value added and the differentiator between a mediocre transfer that limps along and requires continued post-transfer support from the transferring site and an outstanding transfer with long-term self-sustainability is the transfer of tacit knowledge. This invaluable resource is the uncodified knowledge and experience in the minds of the people at the transferring site who have spent years working with the product and the processes.

A sample M:M project is shown in Figure 1. Each box represents a task for a specific function that can range from tasks that take only a few days to those that require months of focused efforts. For proprietary reasons, task names have been removed. The tasks are divided by function (horizontal lanes) and by phase of the project (vertical lanes). While it is not shown well on the figure, the phases don't generally take a set length of time to transit – for a project, the Team Formation and Planning phase may take two months while the Tech Transfer phase may take two years. The heavy vertical lines at the end of each phase are the review points at which the steering committee normally checks in on the team, although it may check in during the middle of a phase as well. For simplicity, the complex web of interdependencies between tasks is not shown, although almost every task relies on outputs from the tasks of other functions as inputs. Still, even without the interdependencies, an observer gets a sense of how many different tasks and functions have to be involved for even a relatively straightforward transfer like duplicating production of an existing, marketed vaccine in another location.

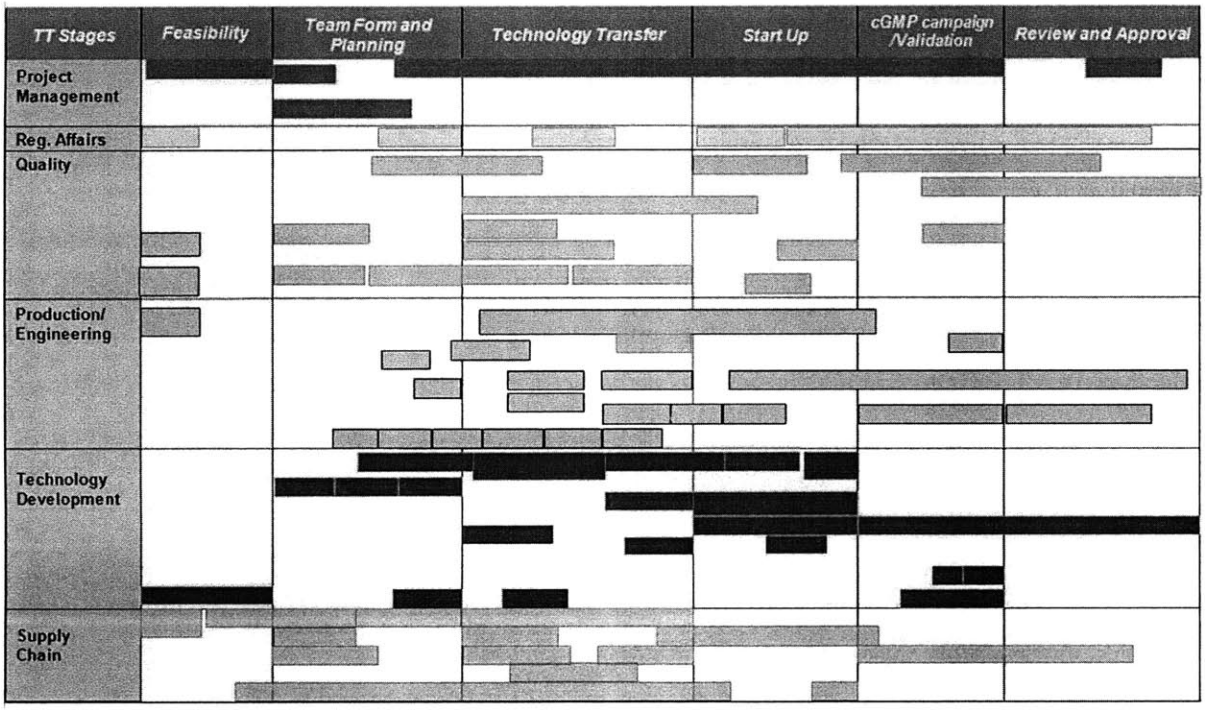

Figure 1 - Example M:M Transfer Steps

2.4.Challenges of International TT

For a multinational that operates sites in different countries, many of these transfers cross national boundaries. The NVD sites are all technically advanced and relatively similar in capabilities; however, any international TT suffers from challenges not faced by purely domestic TT. First, there are distance and communications challenges. Time zones, language barriers, travel time, the impersonality of non-

face-to-face communications, and rework from errors attributable to miscommunications: all of these factors and more increase cost and add delays. International projects also suffer from significant "Allen Curve" effects, in which the communication among team members drops off markedly when they are not co-located[7]. No one is intentionally ignoring their team members, but the colleagues who are physically present get tacit priority over their remote counterparts, leading to a general slowing down of international projects.

Second, these international transfers are much more likely to have acceptance problems. As is well-documented in the literature, ideas originating from another site may generally be viewed distrustfully through a "not invented here" lens[8]. This may be exacerbated if these imported ideas or processes are displacing locally generated ones. Even if the transferee accepts that the transfer is necessary, they may disagree on how the TT project should be managed. The transferee is going to be held accountable to operate and use the ideas post-transfer, so they may (justifiably) be given primary responsibility for the transfer. Conversely, the transferor who developed the ideas or processes may well feel that their expertise puts them in a better position to guide the transfer[9].

Lastly, and potentially most damaging, are cultural problems. These are caused by differences that are hard to quantify and that may not be readily visible because most people take their own culture for granted. Even for knowledge or technology transfers between developed countries on the same continent (as at NVD), there may be significant differences in such cultural norms as perception of time, approach to decision making, labor practices, work ethic, motivating forces, value systems, and attitude towards group activities. Having a common language is no panacea; if the thought processes behind the words are different, miscommunications may occur when the words have different interpretations in each culture - "the meaning of words is in [our minds] rather than in the word itself"[10].

What makes these problems so dangerous is their insidiousness; they are hard to quantify and easily underestimated or forgotten, so they "may not intrude upon the consciousness of those involved on one or both sides of the transfer process"[11].

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[7] Allen, Thomas 234-241
[8] Heller 77
[9] Teece 21
[10] Heller 78
[11] Ibid.

2.5.Significance of TT to Organization

Vertical TT through the product pipeline is unavoidable for any company that introduces new products; to create new vaccines, there must be some path through the value chain of Research → Development → Manufacturing. Some NVD sites have Research, Development, and Manufacturing all present at that site, and a product can go from concept to commercial manufacturing without leaving the site. Other sites do not have all three functions and must always be a participant in inter-site transfers. Thus, some amount of site-to-site vertical transfer is inevitable within NVD. However, it is reasonable to ask that given all of the hurdles to *horizontally* shifting vaccines manufacturing between facilities, why would a company like NVD even bother? Generally, a company is willing to surmount these obstacles for a variety of reasons. Among them:

> *Capacity* – to have the flexibility to adjust production between facilities to meet changes in market demand and balance capacity utilization
> *Cost* – to utilize facilities with inherently lower Cost of Goods Sold (COGS) or reach lower COGS from the economies of scale to be gained by consolidating manufacturing of a product
> *Strategic* – to meet high level business goals or respond to political or social pressure
> *Proximity to market* – to gain access to markets with "local content" laws or with regulatory hurdles that limit importation
> *Resource limits* – to overcome resource constraints on raw materials, labor, infrastructure, etc.
> *Risk management* – to limit spending commitment by transferring production to a CMO until market demand is better known
> *Skill sets/knowledge* – to allow production that requires expensive skills that the company doesn't want to or can't afford to bring to some locations
> *New, innovative perspectives* - improves innovation by giving a different set of people a chance to reexamine existing products and processes and for these new perspectives to improve processes.

Within NVD, the explicit reasons are primarily strategic and skill set for M-M transfers and capacity constraints for M-M:CMO and M:CMO-M transfers. Note that while it is not an explicit reason for TT in NVD, several interviewees related that "new and innovative perspectives" is a strong unrecognized benefit for NVD that contributes to organizational learning and process improvement.

2.6.Metrics

Like any process, quantitative measurement of different attributes of TT is necessary to be able to improve the process. Unlike many other processes, however, metrics for TT are not necessarily easy to define nor are they always agreed upon by different stakeholders. To be able to demonstrate progress, two types of metrics are needed: an *operation* metric and a *performance* metric.

The *operation* metric is a measure of some aspect of how TT projects are managed. This is generally not an easy measurement to make, since the TT process is often very fluid and based on relationships and personal interactions. While it is possible to define hard metrics to measure TT management[12] (e.g. staff turnover), these operations metrics may be more useful when they are softer, less easily quantified measures of team members' perceptions. This is counterintuitive and requires explanation, since perceptions are subject to bias, mood, faulty memory, etc. and may not coincide with objective facts. However, members of a TT project team upon whom the success of the project hinges are not influenced by objective fact, but by their own perceptions of it. Team members have a wealth of knowledge about what happened, what worked, what didn't work, etc., and "what these team members *perceive* to be the case is more important than the actual facts in determining their behavior"[13]. If team members believe that their career progression is determined by how well they perform within their department and not by their performance on TT project teams, then their departmental duties will take precedence over their TT team duties even if their project team performance in fact weighs just as heavily. This may even lead to self-fulfilling prophecy; for example, if people believe that TT project management roles are poor routes to career advancement, then motivated and competent people will work to avoid these roles and they will become relegated to less talented people who already have poor prospects for career progression. Thus, while perceptions are an inherently soft metric, they are well-suited to TT process improvement where team member actions are strongly influenced by the subjective viewpoints of those team members.

The *performance* metric is a measure of how successful a project was. Success can have a number of different measures, both hard and soft, that determine to what degree a project met its intended goal. There are myriad criteria for defining whether "enunciated needs are met, defined requirements are fulfilled, stated goals are attained, performance specifications are achieved, and a required job is done[14]",

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[12] Cooke and Mayes 201
[13] Allen [et al.] 12
[14] Koeppe 273

and hard measures include relative time to completion (or "date slip"), percentage over/under budget, and number of project scope changes. Unfortunately, these hard metrics suffer from two flaws. First, they can be difficult to obtain after the fact. For companies that don't track metrics at all or aren't using the proper metrics, trying to generate metrics to understand a project after the project is completed is challenging. Unless a company has a thorough project tracking system in place, recreating timelines and budgets requires combing through the documentation of individual team members and can produce results that are inconsistent between sources. Second, they don't address the holistic view of the TT project, viz. did the job get done? It is easy to conceive of multiple performance metrics that might move out of phase (e.g. cost and budget), making it challenging to determine if a project was a success or a failure. For example, consider a hypothetical company that improves an operational metric of "senior leadership prioritization of TT projects". If they find that on-time completion improves but budget overruns increase, was this change to prioritization a success or a failure? The solution to avoid this type of problem that is recommended in some literature[15] and used in previous work[16] is to use the soft metric of having senior management rate the overall outcome of the project. By treating senior management as our customer, this method distills all of the different measures into a single number to capture customer satisfaction as an ultimate measure of quality of the process. Furthermore, it is relatively easy to measure; while people's memories of specific dates and budgets may fade, managers at least tend to remember whether a project worked or didn't work overall.

2.7.Quest for improvement

Due to the aforementioned acquisition legacy, each NVD site has had its own procedures for TT with no synchronization or standardization between them. This issue is well known to NVD management, and these disparate processes have come under increased scrutiny as these cross-site issues have hindered the success of TT projects. In an effort to standardize on a single TT process across all of NVD, management has hired outside consultants with experience in pharma TT to bring together all of the sites and functions under one umbrella framework for all TT of all types. This standardized TT framework defines the processes, governance, and team structure for future TT projects. Instead of reinventing the wheel for NVD TT, this consultant-facilitated effort is bringing representatives from each site and function to the table to determine what the site-to-site or function-to-function differences are in the existing processes

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[15] Cooke and Mayes 202
[16] Allen [et al.] 12

and settle on the desired future state so that all sites are moving towards a common project platform. The advantages of this bottom-up, collaborative approach are twofold:

- Ensure that no stakeholder has their voice unheard – this helps get a broader perspective for the new framework while also internally marketing the framework by providing each function with a sense of ownership to help drive compliance with the new process; since every function has a say in defining the process, no one function can claim that they can't use it because it doesn't meet their needs.
- Turn site-specific, non-standard documentation into a standard, living set of documents that doesn't just list steps, but shows order and interdependencies and allows transparency so that all parties know what to expect from other parties (and what is expected of them in turn) at each step of the process.

The details among projects may vary at an operational level, but the intent is for the framework to be identical. Once the framework is fully integrated into NVD culture, each project will be governed, structured, and conducted in a repeatable, improvable way regardless of the technical details of the project.

3. Research Method

3.1.General Approach

At a high level, the underlying problem is clear from preliminary analysis: TT is done ad hoc with no formal interaction between projects. There are no common project metrics that measure how a project was managed or how well it succeeded, and thus there is no traceability to be used for continuous improvement of TT in general. As part of the larger project to formalize the TT process, this study was performed to bridge that gap in two ways. First, the issues with the existing process were examined **qualitatively,** talking to dozens of people within NVD at all levels, functions, and locations to get a high level sense of where consensus was on what the true problems were. Second, the correlations between metrics measuring how a TT project is carried out and the success of that project were examined **quantitatively** to demonstrate a generalizable method for improving project management. *The end goal was to provide recommendations on one or more overlooked aspects of the TT process that, if modified, would lead to an increased probability of a successful transfer.*

Initially, the scope of the study was ill-defined since NVD didn't have information on where their problems were. Thus, data collection used a two-phased approach as shown in Figure 2 to identify problem areas and then focus in on one or more of those areas (breadth followed by depth). The range of topics was chosen to include all types of TT (e.g. M-M, TD-M, etc) since the goal of the thesis was to examine the TT process as a whole and not just the TT process for a specific type of transfer.

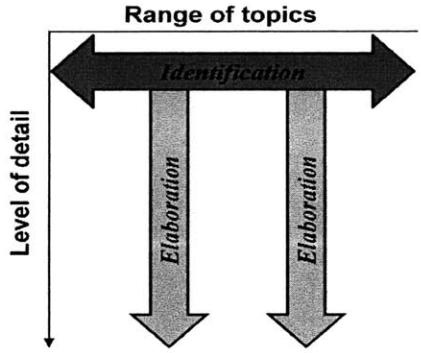

Figure 2 - Method for Data Collection

The basic path used for the study was:

1) Identify problem areas via broad survey and exploratory interviews
2) Define metrics for identified problem areas and for project success

3) Measure metrics for problem areas and for success via targeted surveys and interviews about specific projects
4) Correlate problem area metrics to performance metric to determine which metric(s) has the greatest relative contribution to success
5) Discuss results of survey correlations and employee interviews to make recommendations on how pharmaceutical companies can improve TT

This method could have been reported differently: the identified problem area could be presented as a *fait accompli* and correlated to the performance metric without reporting the background work needed to identify the applicable problem area metric. However, detailing the full method also illustrates which problem area metrics did *not* correlate to success. This is likely just as important since addressing these problem areas, while not a bad idea, should be lower priority than those with a strong correlation to project success.

3.1.1. Previous work done

The method used here is similar to that used in previous studies. This is intentional – the goal of this study was not to invent a new analysis method, but to apply a previously demonstrated method to a new problem. Previous work has generally focused on the equivalent of Problem Identification by shallowly exploring many aspects of TT to see where the generic problems lay[17], and attempts at Problem Elaboration were mixed depending on what was used as a performance metric. A very similar study of TT by the federal government had an ambiguous outcome and concluded "Ideally, such measures should be based on data obtained from users themselves and from systematic observation of user communities."[18] The most relevant previous work was a study of program management in the pharmaceutical industry[19]. In that study, employee perceptions of factors related to program management were compared across companies and to the likelihood of success of individual projects. These were research-intensive new drug development projects that implicitly included vertical TT from research into technical development, so lessons from this study, while a useful guide, may not necessarily be reflected in horizontal manufacturing TT projects.

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[17] Koeppe 277-280
[18] Koeppe 278
[19] Allen [et al.]

This thesis was different than these previous works in the factors under study. Allen and Szulanski had already adequately covered a variety of topics (e.g. locus of management, how staffing/resource decisions are made, and arduousness of the relationship between sites), so this work focused more on factors that had not previously been studied.

3.1.2. Expected challenges

No challenges were expected for the qualitative interviews, but for the quantitative comparisons, the basic challenge expected was getting good data. This is not a technical study; it is social science with many confounding variables. To be believed by management in an extremely technical organization like NVD, recommendations should ideally be backed by statistically significant data that generally requires a large sample size. Since the metrics being used are perception metrics, they are time-intensive to obtain and inconvenience a lot of people pulled away from their day jobs to do interviews and surveys. Furthermore, since this is social science with many confounding variables and the data itself depends on fallible and potentially biased memory, the correlations between the metrics and project success were not expected to be very high. This is not a reason to avoid these kinds of studies; the human interactions measured by social science are usually inherently fuzzy and perception-based, and any research looking for a perfect, clean data set is in for a long wait. Also, even though the correlation coefficients are expected to be low, these TT projects are extremely expensive and time consuming; being able to explain 5% of the difference between successful and unsuccessful projects is significant when project costs can run into the $MM.

Another significant expected challenge was in defining the metrics to be measured. Interviewees, while accommodating, were not generally willing to sit for multiple interviews, so the questions had to be correct the first time. If the metrics to be studied were poorly chosen, the overall result could be negative (no correlations). While enlightening about which metrics do not affect performance, NVD was obviously more interested in identifying metrics that **do** affect performance so they can improve their processes.

3.2.Phase 1 – TT Problem Identification

3.2.1. General Method

The breadth portion of data collection was twofold: a survey and interviews. The survey was given prior to any interviews to allow trusted anonymity, as "data clearly indicate that sensitive information is more frequently, and almost certainly more accurately, reported in self-administered modes than when interviewers ask the questions[20]".

Survey

A 22 question web-based survey was given to find out what general topics people involved in TT at NVD saw as problems. The intent was to gather quantitative data on which to make statistical assessments of perceptions. The survey was given to 100 employees intentionally chosen to represent a broad cross-section of sites, functional roles, and levels in the hierarchy. At the end of the survey, participants were asked to self-identify demographic information (name, site, job function, time at the company, time in the industry). To increase honesty, name and site were optional, even though leaving these blank made it harder to look for demographic differences. The overall goal was to look for areas where employee perception of TT was unfavorable or where there was a significant difference in perception of TT between different demographics (e.g. between sites in different countries).

This survey was not given in isolation – it was multi-purposed as part of a broader effort to improve TT processes at NVD. Thus, the questions were taken from different sources. While three of the questions were tailored for this study, nineteen of the questions were from a proprietary consultant survey that was already slated to be given. It was felt that response rate would be significantly lowered by asking participants to take two surveys, so the existing survey was morphed into a single survey for this study. The existing survey was not intended to be used statistically; it was intended to be a qualitative look at where the general TT issues lay within an organization.

Since perceptions about TT tend to lie on a continuum between two extremes, most of the questions were structured as 5 point[21] Likert items to give a graduated scale for respondents and allow more meaningful statistical conclusions than afforded by a binary (e.g. agree or disagree) scale. Because part of the survey was proprietary, most of the survey questions can't be disclosed; however, the survey topics are shown in

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[20] Fowler 74
[21] Dawes 61-77

the Results section in Figure 3. In conjunction with the consultants working on the larger TT framework problem, the first 19 questions were clustered into 5 broader topics (e.g. "Teams") also given in Figure 3. Which questions went into each group was done arbitrarily in conjunction with the consultants to distill the questions into a more manageable number of topics. This allowed the presentations to the teams working on the project to succinctly show important topics of concern.

Interviews

During the interviews, participants were asked what works well and what doesn't work well in the current TT process and to give specific examples of aspects that have gone well and aspects that have gone poorly. While a survey alone would likely have been able to identify the generic problem areas, the interviews were important for marketing the improvement efforts. It was assumed that employees were resistant to change, especially when they weren't convinced that the change was necessary. The interviews forced participants to think about the TT problems and about their individual trials and tribulations, which helped convince them that the status quo could be improved.

The interviews were performed both by the consultants and by the author. The consultants used the interview results generically to gather anecdotes to convince senior management that the problems were real. The author used the results more rigorously by collating the interview data and distilling specific themes. The intent was to use the interviews both as a data set for discussion and as a guide to how to best structure the surveys to address the most relevant topics.

3.2.2. Statistical Methods

Basic descriptive statistics (mean, standard deviation) were used on the entire survey to guide which areas were self-described as having the most problems. For demographic differences, the individual group sample sizes were too small to make any assumptions about distribution, so a non-parametric Mann-Whitney test was performed to find the difference in the medians of each pair of demographic segments. The choice was made to use 95% significance to avoid drawing false conclusions. The data reliability was assumed to be relatively low, so a strict standard of resolution (tight confidence interval) was used to demonstrate that the differences were real and not coincidences or artifacts of small sample sizes. Lastly, the questions were collapsed and categorized into clusters of similar themes: Continuous Improvement, Governance, Pipeline Management, Teams, and Structured Process. The questions associated with each cluster are shown in Figure 3. To check that these clusters were collapsed appropriately, Cronbach's α was calculated to check for internal consistency to verify that all of the questions that went into the cluster were actually measuring the same topic. A threshold value of $\alpha \geq 0.7$ was used to deem a cluster to be

internally consistent; this threshold is the accepted minimum value for "modest reliability" in "early stages of predictive research"[22].

3.2.3. Results

3.2.3.1. Aggregate trends

Interviews

Based on the results of 68 interviews with TT project team members, a few topics were noted as recurring themes for areas of improvement. These themes are summarized below:

> **No Mechanism for Continuous Improvement**
>
> TT projects have generally been open loop, with little attention to improving the process via feedback during and after the project. Very few projects have any kind of "Lessons Learned" or post-mortem documentation, and the few that do tend to be the projects that did extremely poorly. Projects that do well are accepted as successes without much digging into *why* those projects were more successful and if there are generalizable lessons. Even the projects that do not go well don't have a process to collect issues that happen during the project in real time. For short projects, this may not matter since team members memories can span a few months until a post-project review. However, many of the important projects are multi-year endeavors; for these projects, asking for post-mortem analysis is unrealistically relying on biased memories of events that happened a year or more earlier. In a similar vein, there has not been any collection, tracking, and analysis of cross-project metrics. Even relatively easily measured metrics such as project slip rate, cost under/overruns, number of questions from regulatory bodies, etc. have not been tracked. Lastly, project managers and TT participants are not given the opportunity to learn from each other. While project managers at each site do have their connections and interact with counterparts at different sites, there is no formalized mechanism for knowledge sharing and best practices. Without any of these closed-loop mechanisms to find problem root causes and codify successful methods, a challenge faced and solved by one project manager may have to be repeated by another at a different site.

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[22]Nunnally and Bernstein 264-265

Poor Pipeline and Resource Management

Many interviewees expressed frustration with the high level project pipeline process. While individual TT projects started out properly staffed, new projects (both TT and non-TT) that came up tended to take resources from the existing TT projects. In the absence of transparency into real project priorities, people lived in "fire-fighting" mode and prioritized their work based on whichever project was shouting the loudest. Many projects languished in a "pipeline churn" where they were never cancelled but were stripped of resources so that they would never actually get done. This was a distraction to team members who were simultaneously unable to adequately focus on TT projects and unable to ignore them.

Low Availability of Some Functions

Some functions are spread very thin and are generally assigned to work on many projects simultaneously. Quality, both Quality Assurance (QA) and Quality Control (QC), and Regulatory Affairs (RA) were identified as the functions that were generally least available for the length of the project. Specifically, these functions often came in late during projects and were not often involved at the project kickoff. This led the project teams to make directional choices at kickoff that would later need to be changed when Quality or RA become involved and identified how these choices did not meet their needs. Ideally, all functions would be involved at kickoff since that is where changes can be made for the least cost.

Insufficient Cross-Project Governance

Generally, there is no cross-project governance. Some projects have steering committees to vet high level decisions, but for many lower priority projects, decisions and actions are through back-channel communications where key people have contacts in the other sites that help them get things done in ad hoc fashion with little or no strategic oversight. Without proper oversight, there can arise mismatches and misalignments of priorities and resources between sites. Even when a steering committee exists, the existing steering committees were identified as sometimes being too heavy-handed and overly involved. Many times these committees have very high level executives who already know how they want the project to run. The team doesn't feel empowered to make their own decisions, so they may not even bother and will wait for the committee to tell them what to do. Furthermore, the same few executives are on most of these committees, a model that isn't scalable as the organization grows and the number of simultaneous projects increases.

Non-Standard TT Processes

Sites have their own methods, documents, and processes for TT. This applies both to horizontal and vertical transfers within NVD and to transfers to third parties – each transfer uses its own specific framework (or no framework at all). This limits transparency in the overall TT process and frustrates project managers who try to reconcile the different expectations and processes of two different sites working on a single project. A lack of standard processes between sites coupled with poor communications has led to avoidable project delays. Without common processes or at least an understanding of the other site's processes, a given site may expect their counterpart to perform certain tasks that the counterpart is, in turn, expecting the first site to perform. Since the tasks are so interdependent, this ripples through the entire process. For example, if Quality Assurance at the receiving site is waiting on a test that they think Research at the transferring site is going to perform but Research thinks the test is going to be performed by someone else, QA will not get their results. This cascades down the chain, as other groups may well be waiting on results from QA. None of these groups will sit and idly wait – they will work on all of their other projects while they wait, and the project that requires the test will languish in limbo until the project reaches firefighting mode and the root cause is finally sorted out. Common processes would baseline the expectations for all parties and engage both sites so that TT became less of what one interviewee called a one-sided "tech grab".

Survey

After removing spurious responses, the survey had 40 respondents out of 91 potential respondents. Some demographics were better represented than others. Project managers, who tend to be intimately involved with TT projects, were overrepresented. Executive response was poor, which limited how much analysis could be done on whether different parts of the hierarchy saw TT issues the same way. However, this survey was intended to broadly explore possible problem areas so these demographic skews did not interfere with the intent of the survey.

The survey results are shown below in Figure 3 and Figure 4. The survey response choices were scaled 1 to 5 with intent that 1 corresponded to the status quo at a company with little rigor and "informal practices based on individuals' experience" while 5 corresponded to industry best practice for an excellent company that "links processes across internal and external partners".

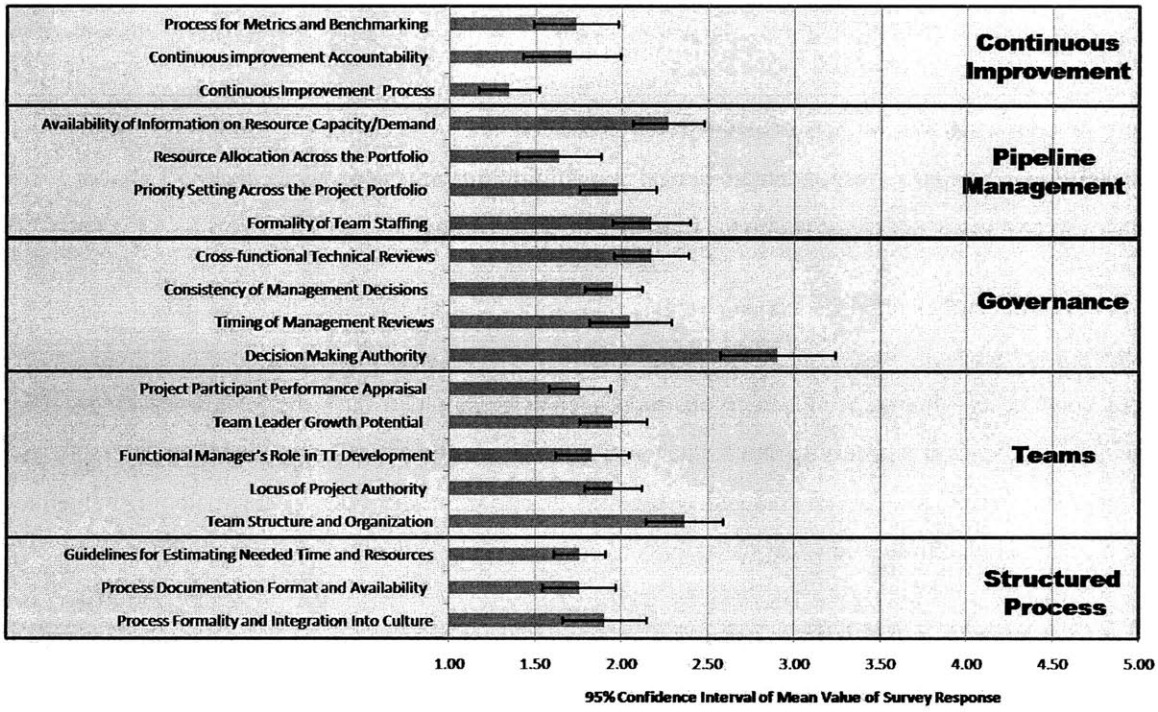

Figure 3 - Results for Exploration Survey

In general, survey respondents did not feel that NVD TT practices were best practice, as evidenced by no question having an average above 3, the midpoint of the scale. The lowest rated topics were "resource allocation across the portfolio" and all questions about continuous improvement. Since continuous improvement was already being addressed by the overall TT framework project, resource allocation was chosen as an important topic to be explored further in the Elaboration Survey. Additionally, though it scored average on the survey, "priority setting across the project portfolio" was a clear weakness from the interviews, so it was investigated as well.

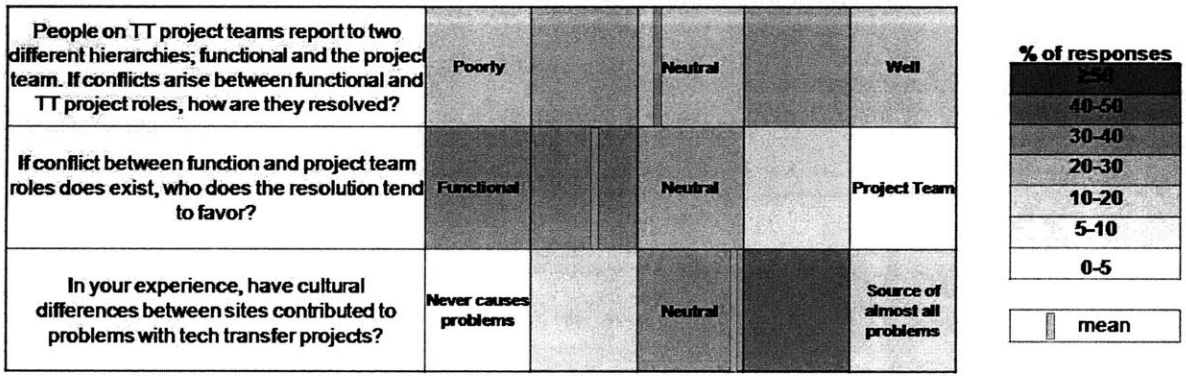

Figure 4 - Results for Conflict Section of Survey

Figure 4 shows the results of the three conflict questions. For the first, respondents had no consensus on how well conflicts between functional and project team responsibilities were resolved. However, there was strong consensus that when these conflicts are resolved, it usually favors the functional responsibilities. Similarly, respondents reported that cultural differences between sites in different countries were a major source of problems that arise in TT projects.

Post-processing demonstrated Cronbach's $\alpha > 0.7$ for some clustering (teams, pipeline, CI) demonstrating that each cluster was measuring the same construct (e.g. pipeline issues) and the data has internal consistency. For some clusters (constructs such as governance and structured process), $\alpha < 0.7$, implying poor choice of clustering. No further investigation was made, since the survey was largely part of another survey and couldn't be changed. However, this poor internal consistency matching helped to guide the second phase interview/survey process to ensure a higher standard of consistency.

3.2.3.2. Demographic differences

First, a few caveats about analyzing this survey for demographic differences. As previously stated, demographic differences should be taken as weak evidence, since many participants chose to keep their anonymity and not enter their demographic information. This caused some demographics to be poorly represented (e.g. executives): no attempt was made to compare these poorly represented groups to any other demographic. Also, remember that correlation does not imply causation.

In general, there were few statistically significant differences between different groups. However, the following differences were noted:

Project managers (PMs) were much more critical in many of their responses, especially those related to the conflicts between functional and TT responsibilities. Specifically, the mean of PM responses was statistically lower for questions about:

- Formality of the TT Process and its Integration into the Culture
- Growth Potential/Career Benefit for the TT Team Leader
- Performance Appraisal Process for TT Team Members
- Timing and Timeliness of Management Reviews for TT Projects
- Basis and Consistency of Management Decisions on TT Projects
- Accountability for TT Continuous Improvement
- How Well Conflicts Between Functional and TT Projects Roles are Resolved

These PMs are the coordinators for TT projects who are assigned to lead projects and have people temporarily assigned to work on their projects. They have little positional authority over team members but are still responsible for getting them to complete the project. The team members working on their projects don't report to them and may not be strongly incentivized to prioritize that specific project, so the PM may constantly be battling for resource attention from the functional organizations. Team members are very competent and motivated – they don't intentionally shirk their TT project duties. However, the matrix structure spreads some people with useful skill sets very thin by assigning them to many different projects that they have to internally prioritize; thus, the PMs are competing for attention with other PMs and with functional managers.

For the question exploring how conflicts are resolved between functional and project roles (the first question in Figure 4), the site in Siena/Rosia, Italy saw conflict resolved more poorly than the sites in Germany and the UK. Most participants left the site response blank and some people who filled in site did not fill in their job function, so the data can't be disaggregated.

3.2.3.3. Working Hypotheses for Exploration in Elaboration Survey

A set of topics were identified as the most commonly cited issues by interviewees and/or as significant issues during the Identification survey. These were codified into working hypotheses and expanded for further exploration in the Elaboration survey. These topics were:

Communication distance

While technology allows team members to communicate in a variety of ways, most identified that face-to-face interaction is the most effective and that physically working with team members from different sites is extremely helpful towards team unity and communication.

Project prioritization

Misalignment of priorities between different functions, sites, or projects is a significant cause of TT problems. One interviewee put it succinctly when he characterized a TT project he worked on as "less a tech transfer and more a tech grab" in which his site was the transferee and prioritized the TT much more highly than the transferor, resulting in less of an equal exchange and more of an unwelcome pull system.

Changes to project team membership

Multiple interviewees reported that functions often change their representative to the TT team during the project execution. This disrupts continuity as the new representative has to come up to speed on the project.

Quality/Regulatory Affairs involvement

Most functions have no choice about when they get involved in a project, since they are directly involved in the mechanics of the transfer from the very beginning. Quality and RA provide a more advisory role in TT projects and are not always involved as early. This leads to rework later on in projects.

Team empowerment

Steering committees were identified as not always allowing the team to make many of its own decisions. This leads teams to stop making any real decisions and just wait to be told what to do, leading to "project lethargy".

Team member focus

TT team members are often spread thin on many TT and non-TT projects and are not necessarily able to give the time and attention to a TT project that they are assigned to give.

Resource transparency

Team members complained that the resources promised to a project and the resources actually delivered to that project often did not seem to match. As newer projects come up, existing projects are looted for resources without transparency into who is resourced to what projects and how much time can realistically be expected from each resource.

The topics chosen were ones that had identified room for improvement and were not meant to be exhaustive. For each topic, one or two hypotheses were made; these are shown below in Table 2. Note that each is given as a negative result since the intent of the Elaboration survey was to disprove the null hypotheses.

Collocation does not affect project success.
Increasing face-to-face communication does not affect project success.
Projects that are prioritized the same by both transferring and receiving sites are no more successful than projects that are prioritized differently by the sites.
A project's priority does not affect the success of that project.
Changing the membership of the project team during the project does not affect project success.
Project success isn't affected by the time at which Quality/Regulatory Affairs become involved.
Whether or not teams are empowered to make their own decisions does not affect project success.
The fraction of time people are working on a particular project does not affect project success.
The number of projects people are working on doesn't affect the success of individual projects.
The transparency of assigning resources to projects does not affect project success.

Table 2 – Hypotheses for Exploration in the Elaboration Survey

In previous work, many questions were used to test the same construct. For instance, Szulanski[23] used 126 questions to test 14 constructs. Unfortunately, time and resource constraints didn't allow that Herculean effort to be duplicated. It was difficult enough to get a high, cross-sectional response rate when asking 12 questions from 128 employees during the midst of an unprecedented pandemic flu vaccine effort – asking more questions would have led to much higher non-response and the perverse effect of getting less data.

3.3.Phase 2 – TT Problem Elaboration & Correlations

3.3.1. General Method

The hypotheses were tested by sending two surveys to TT participants. The elaboration survey contained questions designed to measure the hypotheses' topics for each of 10 different projects, while the success survey measured the overall project success for each of the same 10 projects. The results of the elaboration survey were then correlated on a project-by-project basis to the results of the success survey to determine which topics were most highly correlated to successful projects. The desired output graph (for two metrics) is shown below in Figure 5.

[23] Szulanski 40-43

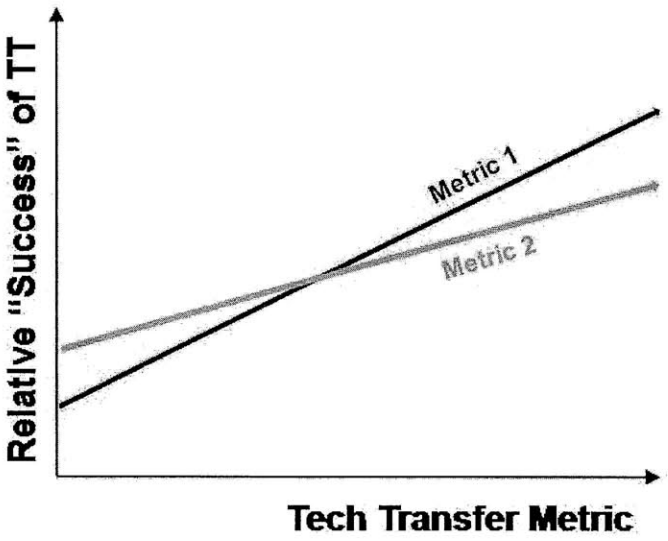

Figure 5 – Metric/Success Correlations

There are myriad factors to improve, and they aren't unknown to managers. Each of the hypotheses is an acknowledged issue, but management lacks the resources to fix them all. Thus, since all questions/hypotheses were expected to correlate to success; the goal was to determine which correlations were strongest to prioritize actions and look for the fixes with the highest return on investment. NVD is currently examining the TT process as a whole during the TT framework project, so now is the ideal time to make changes to the non-technical aspects of the TT process.

3.3.1.1. Elaboration Survey

This survey measured the independent variable for the hypotheses by asking participants in tech transfer projects to evaluate their perceptions of how the hypothesized topics were conducted on a particular project. The survey was aimed at people who had actually done work on the project, not on the manager in charge of the project. Most of the survey recipients were also interviewed, but the survey ensured that everyone saw the same questions in the same format to limit error. The participants were intentionally cross-functional and at different sites to limit functional and geographic biases. However, there was a good deal of unavoidable overlap between projects, since some people (especially project managers) tended to work on many different TT projects. An example survey is shown in Appendix 1.

Most of the questions were answered using a 5 point Likert scale. A few that had numerical answers (e.g. what fraction of your time did you work on this project?) were given as numerical textboxes. To limit the chance of respondents rating everything uniformly positive without reading the questions just to finish the

survey, the scale on half the questions was intentionally reversed such that the more "positive" seeming factor was decreasing instead of increasing.

It was recognized that people are poor at some of these estimates. For example, people are not generally good at estimating how their time is apportioned[24]. Ideally there would be actual physical records for some of this data (e.g. number of times that physical meetings occurred could be gleaned from Outlook Calendars or meeting minutes), but no such data exists, so personal estimates were used.

To be included as a project in this study, each project survey had to receive at least four valid responses to prevent one opinion from excessively skewing the results. These responses to each question were averaged to determine the final score for that factor for that project. Ideally, more respondents would be better, but many TT teams are small or the members have left NVD since the transfer. Thus, for some of the projects, even getting four responses meant getting a 100% response rate from the remaining team members. Ninety-one project team members received a survey, and each of the 10 projects had 4-8 respondents. For some projects, the team members were not spread well among functions so that the responses were skewed towards a particular function.

3.3.1.2. Success Survey

An online survey was distributed electronically to 37 senior managers to measure the performance metric for each project. The survey was simple – for each project under consideration, recipients were asked to rank the performance of the TT project team on a 5 point Likert scale for each project they knew enough about to be qualified to rate. Since some teams were more experienced or technically qualified and would naturally be held to a higher standard and expected to succeed more, survey recipients were specifically asked to normalize their ratings by judging performance compared to how they expected that particular team to perform. Lastly, recipients were asked not to judge based on technical issues, only on the non-technical aspects that have cross-project applicability and affect team performance. The goal is to learn how to better manage TT projects, not to examine technical failures (e.g. one project had delays due to bacteriophage contamination of a recombinant protein that was purely a technical issue; this type of problem is out of scope). Some recipients were unable to rate more than one or two projects, but certain key recipients were able to rate most of the projects due to their cross-project responsibilities. The survey and survey results are shown in Appendix 2 with project names removed for confidentiality.

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[24] Menzel 19

3.3.2. Results

The intent was to demonstrate a broadly applicable set of correlations that could guide efforts to improve the soft, non-technical aspects of TT; unfortunately, the work instead demonstrates the limitations of the method used. While it was recognized that correlation does not necessarily imply causation, it was hoped that some useful correlations could be teased out to guide improvement. Instead, **no statistically significant correlations were found.** For each relationship, Pearson's correlation coefficient was calculated. Correlations that at first glance appear reasonable fall apart upon closer examination, and results are inconsistent and inconclusive. Similar methodology to that used in this research has been successfully demonstrated by others[25] [26] [27], so the *differences* between how this research was conducted and how previous research was conducted are assumed to contain the reasons why this work did not show the hoped for results. These differences are explored in the Discussion section of this thesis.

3.3.2.1. Data

Graphs of the raw results are shown in Appendix 3. For illustrative purposes, linear trendlines have been plotted; note that these are purely a visualization aid and that actual relationships may not be linear.

A few of the relationships look as expected based on the initial interview and survey results. For instance, success increases as project priority increases. However, these results are subject to considerable doubt. Some of relationships were not in the expected direction. While this isn't in itself bad (the original assumption about which direction was "correct" could be wrong or a confounding factor that hasn't been recognized could be skewing individual projects), the correlation values are also low.

The more significant problem with the survey results is that the projects' success scores were very tightly clustered around 3 ("performed as expected") with little variance between success scores. This caused the projects that had notable lower success scores to have very high statistical leverage and control the direction of the correlation. Thus, the apparent correlation is generally controlled by one or two individual points from poorly performing projects instead of showing a true trend created by all of the projects. When the high leverage projects are removed, the remaining projects have almost no variance in success score and the relationship becomes much noisier with a weaker correlation score. An example of this is demonstrated by the correlation of how often project team members were changed to how

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[25] Szulanski 27-43
[26] Allen [et al.]
[27] Hansen 776-793

successful the project was. The presumption was that projects with an ever-rotating team would have less continuity, more learning curve issues, and tend to be less successful. Figure 6 shows the relationship and, as expected, the trendline is that as team members are changed less, the project tends to be more successful with a Pearson's correlation of 0.41. However, the slope of the trendline (and correlation) is strongly driven by a single project (circled). When this project is removed in Figure 7, the slope changes dramatically and the correlation is now -0.28.

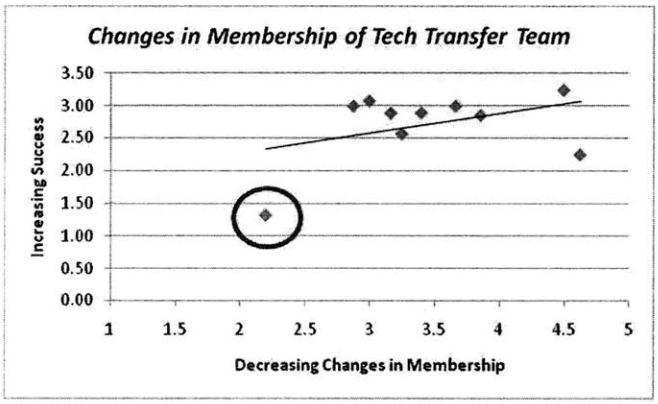

Figure 6 - Raw Data from Example Correlation

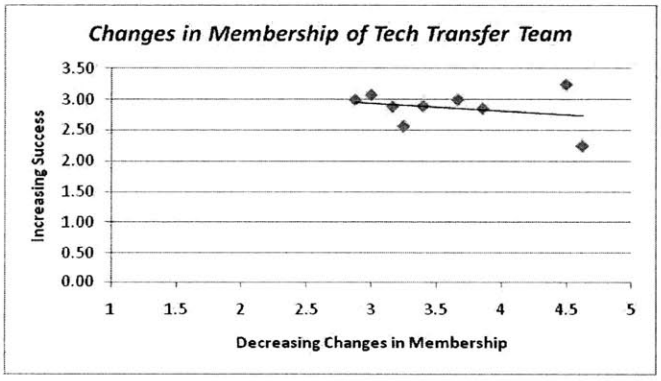

Figure 7 - Example Correlation with High Leverage Point Removed

For each metric, Pearson's correlation coefficient (r) was calculated and a 95% confidence interval was constructed for the true population correlation coefficient (ρ) using the Fisher transformation[28]. To evaluate the effect of the project with the worst success score on the overall correlation, r and the 95% confidence interval on ρ were also calculated with that project removed. These results are tabulated below in Table 3.

	All Projects		*Worst Scoring Project Removed*	
Metric	r	95% confidence interval for ρ	r	95% confidence interval for ρ
Process of Assigning Resources	0.27	(-0.43, 0.77)	-0.40	(-0.84, 0.36)
Changes in Membership of Tech Transfer Team	0.41	(-0.30, 0.82)	-0.28	(-0.80, 0.47)
Site-to-Site Priority	0.37	(-0.34, 0.81)	-0.18	(-0.75,0.55)
Project-to-Project Priority	0.41	(-0.30, 0.83)	0.55	(-0.18, 0.89)
Function-to-Function Priority	0.29	(-0.41, 0.78)	-0.16	(-0.74, 0.56)
Co-locating For At Least One Week	-0.11	(-0.64, 0.56)	0.65	(-0.02, 0.92)
Entire Team Meeting Face-to-Face	0.15	(-0.53, 0.71)	-0.11	(-0.72, 0.60)
Physical Meetings w/ Someone From Other Site	-0.16	(-0.72, 0.52)	-0.09	(-0.71, 0.61)
How Early Did Regulatory Affairs Get Involved?	0.11	(-0.56, 0.69)	-0.50	(-0.87, 0.25)
How Early Did Quality Get Involved?	0.48	(-0.22, 0.85)	0.49	(-0.26, 0.87)
Fraction of Time Spent on Project	-0.41	(-0.83, 0.30)	0.15	(-0.57, 0.74)
Number of Simultaneous Projects Worked On	0.18	(-0.51, 0.73)	-0.00	(-0.67, 0.66)
Team Decisions Overrode By Steering Committee	-0.63	(-0.90, -0.00)	0.17	(-0.56, 0.75)

Table 3 - Correlation Coefficients for Elaboration Survey

In all cases, the 95% confidence interval overlaps zero, so ρ cannot be said to be significantly different than zero (completely uncorrelated).

[28] Smithson 28

3.3.3. Discussion of Quantitative Results

The quantitative analysis of technology transfer performance was unsuccessful in supporting the working hypotheses, so we are left with two options. The first is that there are no relationships between the indicators that we used to measure how a project is managed and how successful the project is, and the second is that there are real relationships that were not statistically demonstrated due to the limitations of the survey method used. Previous research[29] [30] [31] has shown that the correlations are very real for many aspects of project management, so the second option is assumed true. Thus, there must be problems with this particular implementation of the quantitative method, and any hypotheses need to be supported qualitatively via interviews and observations from NVD. This leads to the question – what was different here that caused the study data to be less useful? In the remainder of this chapter, the failure modes for the quantitative evidence are discussed, and in the next chapter, recommendations are made based on the qualitative discussion in chapter 3.

The differences between previous work and this work fall into four categories: challenges with the surveys, project scope, metrics under study, and the NVD team structure during the research.

Survey Challenges

The underlying problem with the Elaboration Survey data presented here was that there was very little variance within the success scores; the success scores were too clustered around 3 ("performed as expected"). Of the ten projects, only three had a mean success score outside the range 2.86-3.25. This was unexpected – the survey was pretested with some of the recipients, and these pilot survey reviews showed more variance. The low variance led to the high leverage of some projects that was discussed earlier; the three projects with low success had undue influence on the correlations. For future work, a success survey should be more tightly focused; in this case, the survey would have been more useful if it had ignored the high end of the success range (since no recipient responded that *any* project "significantly exceeded expectations") and expanded the low end of the success range to provide more granularity and variation in the results.

The second and more fundamental survey issue was that the performance metric was not truly an independent measure of the success of the project, especially for poorly performing projects. The basic

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[29] Szulanski 27-43
[30] Allen [et al.]
[31] Hansen 776-793

assumption underlying the research was that success is at least partly determined by how the project was conducted but that how the project was conducted is not *ex post facto* determined by success. The intent was to correlate a metric of team member perception to a measure of success based on management perceptions for each project. Implicitly assumed in this is that the independent variable (team member perception) is solely dependent on the project, not on the dependent variable (management perception of project success). That is,

> Performance Metric = f(team member perception)
> Management Perception of Project Success = f(Performance Metric)

During interviews, it was discovered that this is not the case for retrospective perceptions of poorly performing projects. Instead,

> Performance Metric = f(team member perception, **management perception of project success**)
> Management Perception of Project Success = f(Performance Metric)

The mistake was in assuming an open loop correlation. Instead, causal closed loop feedback led to a self-fulfilling prophecy; team members knew that the organization considered the project under study to be a failure, which skewed their recollection and perceptions of the project. This invalidates the simple statistical regression used to look for correlations.

Project Scope

The intent was to demonstrate a broadly applicable set of correlations that could guide future efforts; unfortunately, the work instead demonstrates the limitations of trying to achieve this with this method at a single company over a short time span. To ensure results are more convincingly generalizable, typical previous research has examined multiple companies over a multiyear timeframe. Examining a single company has drawbacks; for instance, all projects may be of a certain type or may all be affected by a company specific factor. Some studies have been able to get useful statistics from within a single company, but they were able to gather data from a much larger and more diverse mix of projects and teams[32]. In a company like NVD where TT projects are significant expenses, there may not be many TT projects in motion at any one time. During the timeframe of this study, this was exacerbated by preparations for H1N1 flu pandemic vaccine, which took an atypical amount of resources. This study

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[32] Hansen 776–793

examined nearly *all* of the TT projects that occurred within an 18 month time span and still only had a sample size of 10 projects. This low project count makes using sample statistics challenging, as the confidence intervals on sample statistics with so few degrees of freedom are extremely wide. Furthermore, the small sample size made it difficult to categorize these projects into appropriate, distinguishable classifications while still maintaining statistical relevance. To increase sample size, projects of different types were combined into one sample set, confounding differences between project types. For instance, there may be useful correlations for TD-M projects that can't be drawn from this data because it includes other types of projects (e.g. M-M:CMO, R-TD, etc) or interesting statistics from projects based in one location vs. those based in another location, but since each type had only one or two projects, these couldn't be broken out separately.

Metrics Under Study

As noted earlier, the specific metrics examined in this research were different from those in previous studies. This was intentional, but it does create the possibility that there appeared to be no strong correlations because the metrics examined really don't correlate to project success. However, since the metrics covered a broad range of topics and there are other identified difficulties with the survey data, this possibility is unlikely.

Team Structure

In a similar vein to the confounding of project types to get sufficient sample size, different types of teams had to be combined to achieve minimum sample size for each project. Prior to the ongoing TT framework project, NVD did not have a "standard" team; team structure and membership was ad hoc, so some teams were structured completely differently than others. For some of the project data points, the entire project team consisted of only a few people who only represented a few functions. This led to some apples-to-oranges comparisons, in which the perceptions of a team that was almost completely composed of one function were compared to the perceptions of a team composed of another function. Ideally, the teams would have all had the same cross-functional membership, but this was impossible within the bounds of the projects available.

4. Recommendations and Discussion

The twofold approach to quantitatively and qualitatively exploring improvement to the TT process met with mixed success. The qualitative method garnered valuable data and insight into what the problems were and how to improve them, but the quantitative method did not yield these same useful results. In this section, the qualitative results are used to make recommendations and discuss barriers to implementation within NVD and pharmaceutical organizations. Interviews with team members of the projects with low success scores are particularly helpful here, since interviewees for these projects had very different experiences than the interviewees for projects with average success scores.

4.1.Recommendations

The change having the most impact is already underway: implement a continuous improvement program to allow the status of the TT process to be assessed via rigorously tracked metrics. The reason this study was so challenging was that this work attempted to retrospectively generate some of these metrics. This relied excessively on memories and allowed hindsight bias to interfere with the perceptions of how projects were managed. As noted earlier, using perceptions isn't necessarily bad, but it is bad when the perceptions are selectively affected after the fact by the success or failure of the project. With proper metrics in place, these problems can be alleviated and future improvement efforts can be better guided by which in-process metrics have tracked with success.

Beyond implementing metrics, the following improvements are recommended:

1. *Increase face-to-face communication between team members*

   For a multinational company in which team members may speak different languages and may have very different backgrounds, face-to-face communication can't be underestimated, especially at the beginning of each project. Ideally, this would include co-locating project team members to one site for a period of time. The most useful people to co-locate are those who were involved in the actual production or process, since most of the hurdles and threats to timeline are technical and solved much faster by co-located technical experts. This also allows the PM to focus on non-technical issues, as a common complaint of PMs is that they spend too much of their time acting as the intermediary on minor technical issues and not enough time on planning and coordination of the project as a whole. Multiple interviewees also noted that many projects are international and most of the team members are not using their primary language to communicate: they stated that face-to-face interaction was much more effective in overcoming the language barrier. Since co-location is not always possible, teams should at least periodically have time to physically

interact. This is often expensive, but necessary to increase the sense of shared ownership of the project and let the team make the human connection that causes team members to help their teammate not just because they are required to, but because it is someone with whom they have a good working relationship.

2. *Better align priorities between different functions, sites, and projects*

   Efforts are currently underway at NVD to move in this direction, but transparency is crucial. People will respond to what they perceive is the priority, and if priorities seem misaligned to team members, they will prioritize their work accordingly. Since sites preferentially assign resources to high priority projects, a site that makes a project a low priority may not be able to sufficiently staff the project. In this case, the tight interdependency between the TT task for the two sites mandates that *whichever site prioritized the project lower takes precedence*; if the transferring site makes a project low priority and the receiving site makes it high priority, the receiving site won't get very far on the project because they will be waiting on actions and results that aren't forthcoming. Interviewees for the worst performing project noted that it was apparent to team members that neither site was interested in completing the transfer even though senior management had stated that it was a high priority – this contributed to the failure of the project as it dragged on without the attention it needed to succeed. Thus, ensure that all parties understand and agree to the priority and consider the perception of the project by the organization. This requires stepping back from the technical challenges and considering the sites and functions as collections of individuals with their own needs, wants, and agendas. For example, in the worst performing project mentioned earlier, interviewees noted that one site was reluctant to perform the transfer because they were afraid of losing jobs. By recognizing and meeting non-technical challenges like this, NVD can improve the success of transfers and gain trust that the needs of the individual sites, functions, and people are being addressed.

3. *Coordinate with corporate senior management to foster collaboration between Research and Technology Development*

   While much of the TT focus at NVD is on horizontal transfers, the vertical transfers that make up the product pipeline are just as important. Five of the TT team members that were interviewed had worked on R-TD projects. The interviewees repeated a few common themes about particular difficulties they have had with these transfers. Notably, there is seen to be a misalignment between the perspectives of Research and Technology Development. Manufacturing and TD

both fall within the same TechOps organization and have the same senior managers, so their motives tend to align. Research, however, falls within its own Research hierarchy with different leadership and objectives. In fact, one interviewee noted that that he has an easier time on transfers with a TD group in another country than he does with the Research group on his own campus. Since Research and TD are completely separate, problems arise during the TT overlaps when the two parties disagree on who owns what parts of the transfer and who is responsible for problem resolution. Research would like to transfer the product early and allow TD to take over scaling the process up to production; this would allow Research to reallocate the resources from that product to a different one. TD, on the other hand, would like a longer handoff between Research and TD to ensure that they fully understand the vaccine product/process so they will be able to change it for manufacturability. While there is a Stage Gate process in place to help ensure the vaccine product/process is ready to transfer from Research to TD, this Stage Gate process is not strictly adhered to and products are passed to TD without being completely understood by TD. Thus, it is recommended that coordination occur much earlier between these groups. At the very least, members of TD should be brought into Research meetings well before the Stage Gates to allow TD to see glaring problems while they are still (relatively) inexpensive to fix. Since Research and TD are in different organizations, this effort needs to be led by senior management within the NVD corporate hierarchy. The benefits of this are immediate: on one project where TD sought out early involvement, they found that Research wanted to use materials that hadn't been qualified for manufacturing and would take six months to approve. These materials were then investigated in parallel by TD before the official TT kickoff meeting and were approved before the start of the TT with no delay to the project.

4. *Fully engage all necessary functions at the start of each project*

Some functions are not always involved early on in all TT projects. Specifically, Quality and Regulatory Affairs may not be directly impacted in the early stages of projects and don't have people that are specifically assigned to projects. However, this has caused issues with projects as the project team may structure the transfer in a way that does not meet certain Novartis quality or regulatory standards. The quality and regulatory requirements for a proper transfer are not intuitive and depend on the details of the transfer, including specific details of the country of production and the countries in which the product is to be sold. This makes it difficult for team members outside of these functions to accurately structure projects to meet these requirements. Multiple interviewees noted that projects have had costly rework when these functions later reviewed the plans and determined that they were inadequate. Fixing this problem requires a

commitment from the senior management of each function to allocate resources to projects early in the project timeline.

Some of these recommendations are already being implemented independently of this study.

4.2.Barriers to implementation

The most significant barriers to implementation are in changing the status quo of how projects are currently done. As noted earlier, TT project team members are assigned ad hoc to projects, so very few people are on TT projects often enough to be interested in learning a new process for TT. Many of the people involved in TT projects have a lot of subject matter knowledge and have been around awhile at their own sites – they've seen change initiatives come and go while they continue to "get the job done". In this environment, it is important to get buy-in from the people who will be tasked with implementing changes during their day-to-day work. Thus, the primary focus should be on getting PMs to implement changes. Since the PMs work on a lot of TT projects and are known in the organization as the resident experts on how to run projects, they can set the example for how to use the new processes in the future.

Many of the recommendations on how to improve TT require changes to how projects are resourced. In most cases, these changes mandate more resources be allocated to TT projects, which is difficult to do when these resources are already at capacity on so many other projects. Short of hiring more people (which may be expensive and politically difficult), *the only way to achieve this is to have fewer projects.* Interviewees noted that some projects may be the favorite projects of senior management or that the market has shifted to make certain project unviable but that management isn't always willing to cancel a project that significant resources have been spent on. This makes it more challenge to resource those projects with real impact; thus, the organization needs to be more willing to cancel or suspend projects that are not priorities.

Another potential challenge is in balancing different aspects of TT improvement to ensure that one apparently positive change doesn't negatively impact something else. It is dangerous to look at a project or an improvement area in isolation, since all efforts take place within the greater system. For example, it has been demonstrated that the best solution for improving knowledge transfer is co-location[33] because of more frequent encounters and communications and increased responsiveness to requests from people who

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[33] Allen, Thomas 234-241

are physically nearby. However, large scale co-location for projects is not always possible for a few reasons: besides being prohibitively expensive, it prevents people in matrix organizations from working on their departmental duties (or just moves the distance problem from their TT project to their departmental work). Thus, even though co-locating may look like a great solution for a particular project, it may threaten to cause other projects to founder or be delayed as necessary resources are reallocated. Whether true or not, this appearance of a zero sum game threatens the buy-in necessary for improvement efforts.

To aid in marketing the changes and ensuring compliance, NVD should ensure that participants see quick successes. Pharma projects in general move at a slow clock speed (primarily due to understandably high regulatory hurdles), and TT projects can take years. If changes are implemented but no results are seen to reinforce the behaviors, the changes won't stick in organizational memory. A phased pilot program with periodic gate reviews is currently planned within NVD to generate this process stickiness.

4.3.Opportunities for Further Study

The clearest opportunity for future work is to repeat this study with a broader scope or under more rigorous, less time-constrained conditions. Specifically, this could be done in two ways; the primary intent of either method is to get more differentiated, better data:

- As a coordinated effort across multiple companies and a longer timeframe. This is how this work is generally done in the literature.

- Within NVD after the new TT framework has been in place for a few years. Part of the standardization effort is the implementation and tracking of a variety of metrics for measuring both the conduct and the success of the project as it happens. This has three major advantages that could allow it to succeed where this effort has encountered significant difficulty:

    - *Adaptability* – if the metrics being reported are not measuring what they are intended to measure, they can be changed. This would help solve the problem of insufficient variation in metrics that was seen in the success score. If respondents aren't providing enough variation to a certain metric, the scale or scope of the metric can be modified to be more useful.
    - *Governance* – these metrics are reported to and discussed with senior management, so there is more incentive for respondents to spend time thoughtfully assessing the project state as opposed to quickly running through a survey to "get it out of the way"

- *Immediacy* – Standard reported metrics that rely less on retrospective memory. This may seem contradictory with the statements earlier that it is perception that matters, but the new metrics process captures the perceptions *as they happen* instead of relying on biased hindsight to generate them after project completion.

5. Final Comments

Technology transfer is often seen as a problem to be tackled with more structured processes or innovative IT solutions. These are important aspects of the problem, but these efforts may well be doomed to fail without considering the human factors that go into knowledge transfer processes. While the inherently qualitative nature of the human factors makes them difficult to measure, the approach outlined in this paper is an underutilized, structured approach to quantify the qualitative. The importance of understanding these human factors can't be overstated. In the words of a senior manager at NVD, "We're a very technically focused organization; we don't normally look at these soft issues and usually go for the big expensive engineering solutions. We've spent a lot of money on these solutions without looking at how they fit into our culture, and that hasn't always been money well spent."

Appendix 1 - Example Elaboration Survey

Project #1 Elaboration Survey

1. Project #1

This short survey examines a few aspects of tech transfer to see if there are trends across many projects that we can use to improve how we conduct tech transfers.

This survey measures YOUR perceptions of the project. Please answer only about Project #1, not about other projects you've worked on. You may not know enough about some questions to be able to give an objective answer, but your perception is what matters so please give your best answer on what YOU saw and felt during the project.

If you absolutely don't feel comfortable with a question or you really don't have any idea how to answer, please put that as a comment in the question or at the end.

The results of the survey will be used anonymously and will be combined with all other participants before being released. PLEASE BE HONEST. We can't improve tech transfer unless we get honest feedback. Your name will not be attached to any comments or responses - it is only necessary so that I know who has completed the survey and who hasn't.

1. How did you feel the project was prioritized by the other site compared to how it was prioritized by your site?

	prioritized much higher by other site	prioritized the same by both sites	prioritized much lower by other site
Project was:	○	○	○

Comments

2. How did you feel this project was prioritized by Novartis compared to how your other projects (both tech transfer and non-tech transfer) were prioritized?

	much lower priority than my other projects	prioritized about the same as my other projects	much higher priority than my other projects
Project was:	○	○	○

Comments

3. In general, how did the different functions (QA, QC, Engineering, etc.) within the tech transfer team prioritize the project compared to each other?

	every function prioritized it at the same level	one or two functions prioritized differently, but most were aligned	every function had their own priority for the project
Different functions:	○	○	○

Comments

Project #1 Elaboration Survey

4. What percentage of people from the sending site spent at least a week total at the receiving site working on this project?

% spending at least 1 week

5. How often did the entire project team (or almost the entire team) meet face-to-face over the course of the project?

	weekly or more often	monthly	every few months	less than every few months but not never	never
Team met face-to-face					

Comments

6. Some transfers are local (both transferring and receiving sites are in the same facility) while some are more distant. On average, how often did you physically meet with someone from the other site on this project?

	weekly or more often	monthly	every few months	less than every few months but not never	never
Met face-to-face with someone from other site					

Comments

7. Were there significant changes in the membership of the tech transfer team during this project?

	Most or all team members changed during the project		Some team members changed roles, many stayed the same		No changes in team members
Changes					

Comments

8. At what point in the tech transfer did these functions become significantly involved?

	at or before kickoff		midstream		at the end
Quality					
Regulatory Affairs					

Comments

Project #1 Elaboration Survey

9. Approximately how many times were team decisions overridden by the steering committee?

Overridden

10. On average, what fraction of your work time did you spend on this project?

Fraction of time

11. While working on this project, how many other different projects were you working on (both tech transfer and non-tech transfer)?

other projects

12. How clear to you was the process of assigning resources to this project?

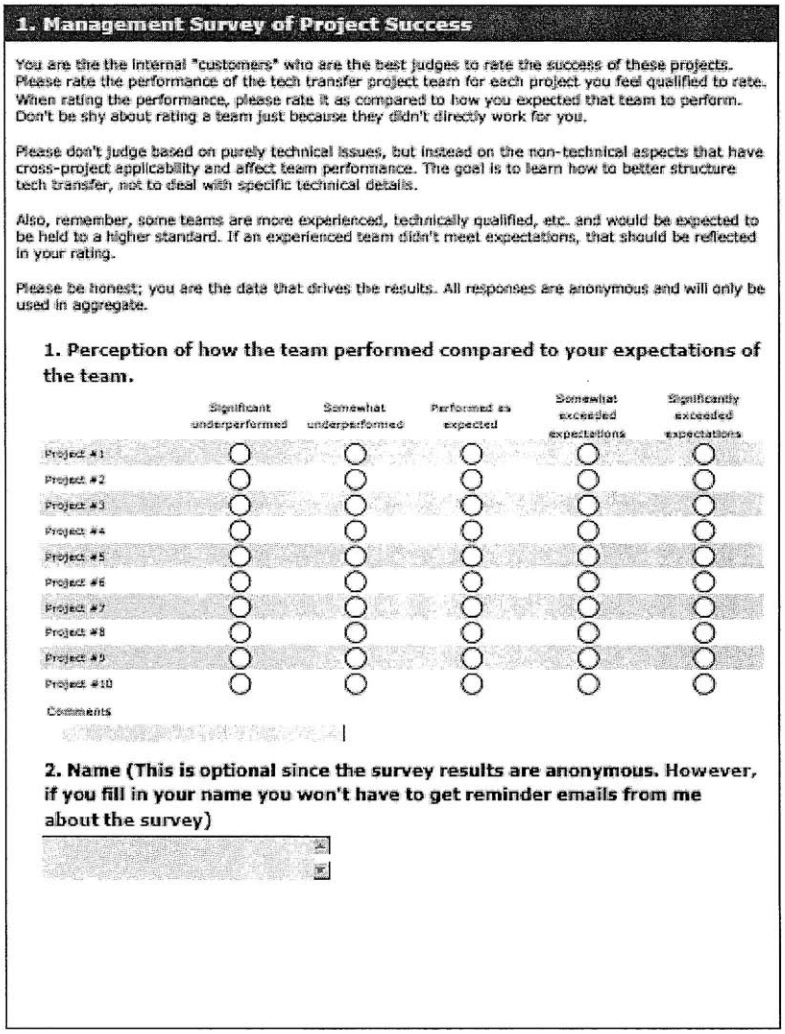
	extremely unclear		somewhat clear		completely clear
Process was					

Comments

13. Name

14. Comments/Questions

Appendix 2 - Management Success Survey with Results



1. Management Survey of Project Success

You are the the internal "customers" who are the best judges to rate the success of these projects. Please rate the performance of the tech transfer project team for each project you feel qualified to rate. When rating the performance, please rate it as compared to how you expected that team to perform. Don't be shy about rating a team just because they didn't directly work for you.

Please don't judge based on purely technical issues, but instead on the non-technical aspects that have cross-project applicability and affect team performance. The goal is to learn how to better structure tech transfer, not to deal with specific technical details.

Also, remember, some teams are more experienced, technically qualified, etc. and would be expected to be held to a higher standard. If an experienced team didn't meet expectations, that should be reflected in your rating.

Please be honest; you are the data that drives the results. All responses are anonymous and will only be used in aggregate.

1. Perception of how the team performed compared to your expectations of the team.

	Significant underperformed	Somewhat underperformed	Performed as expected	Somewhat exceeded expectations	Significantly exceeded expectations
Project #1	○	○	○	○	○
Project #2	○	○	○	○	○
Project #3	○	○	○	○	○
Project #4	○	○	○	○	○
Project #5	○	○	○	○	○
Project #6	○	○	○	○	○
Project #7	○	○	○	○	○
Project #8	○	○	○	○	○
Project #9	○	○	○	○	○
Project #10	○	○	○	○	○

Comments

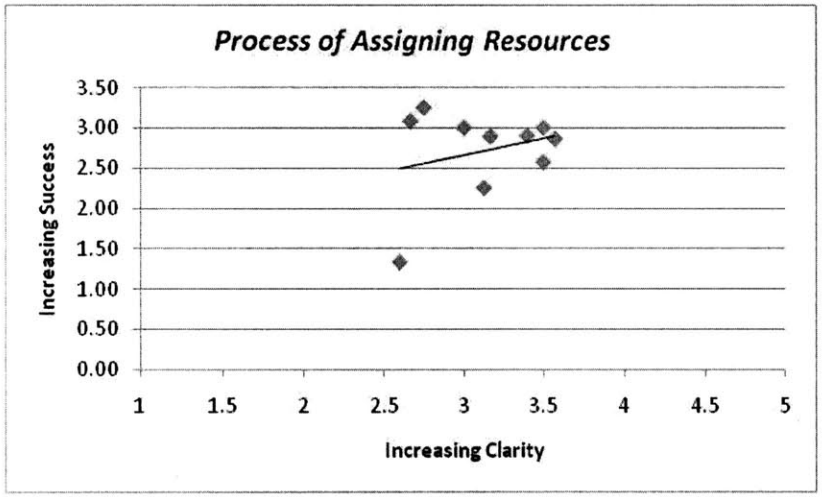
2. Name (This is optional since the survey results are anonymous. However, if you fill in your name you won't have to get reminder emails from me about the survey)

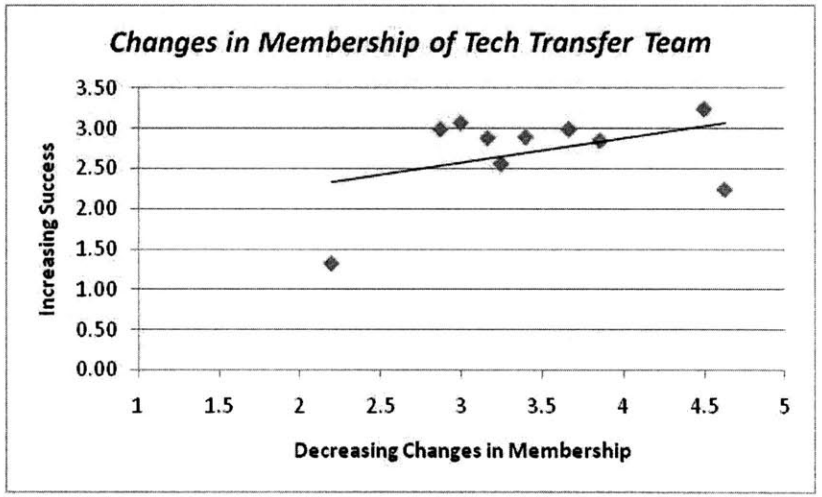
Project #	Mean Success (scale of 1 to 5)
1	2.90
2	2.86
3	2.57
4	2.89
5	3.08
6	2.25
7	1.33
8	3.00
9	3.25
10	3.00

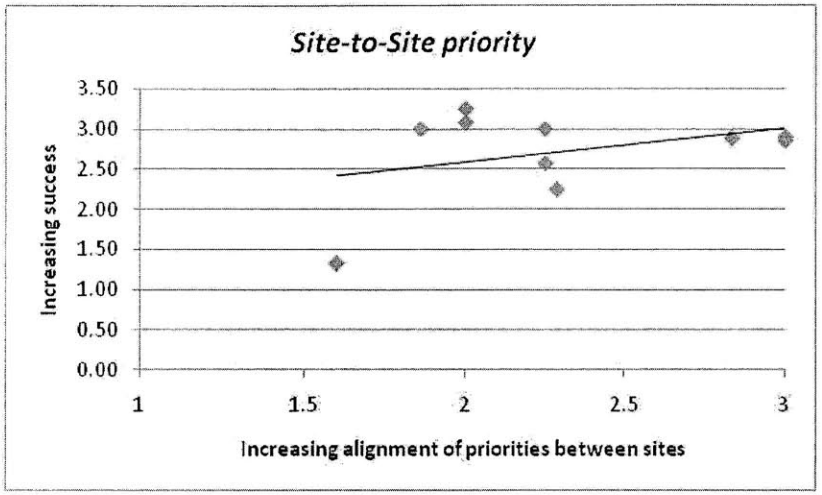
Success Scores - Overall	
Mean Success	2.7
St. Dev. Success	0.91
% Projects with Success < 2.75	30%
% Projects with 2.75 ≤ Success ≤ 3.25	70%
% Projects with 3.25 < Success	0%

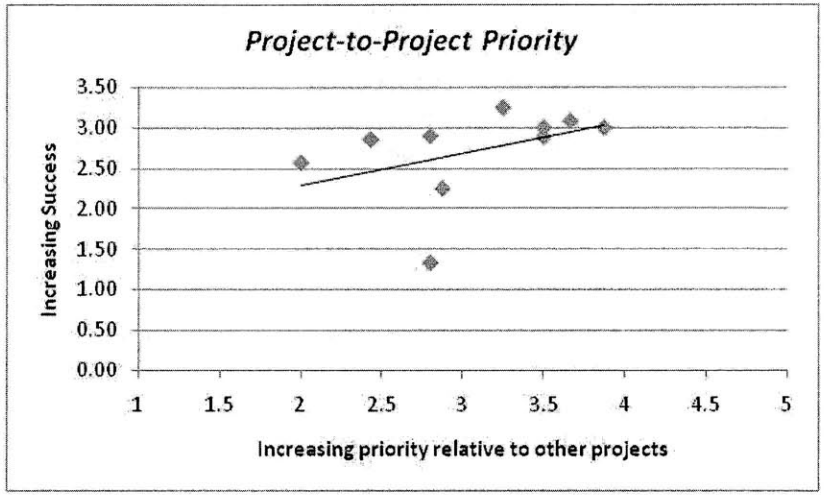
Appendix 3 – Graphs of Data from Metrics Surveys

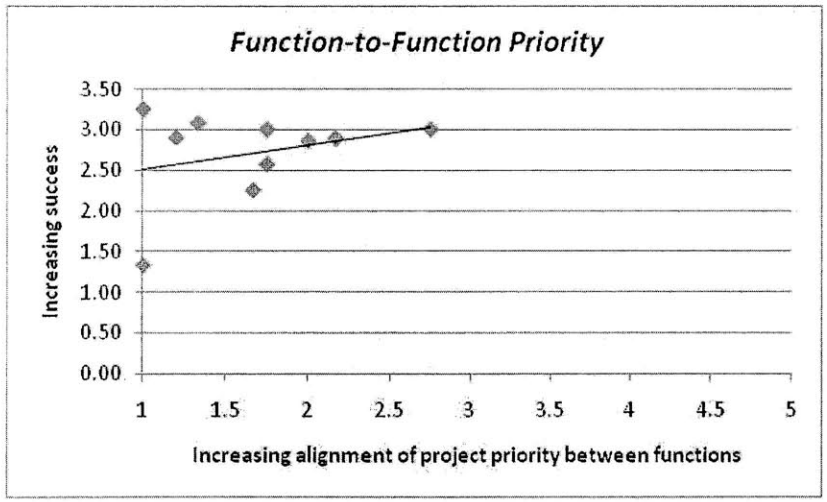
Most metrics are plotted such that the metric (x-axis) increases with positive expected correlation to success. These expectations are based on interviews prior to the survey and may not be true. The exceptions are the last two shown and are two of the numerical (non-Likert) questions: "Number of Team Decision Overridden by the Steering Committee" and Number of Simultaneous Projects Worked On By Team Members". For these two projects, the results are the raw uncoded mean response, and the x-axis is scaled so that the expectation was that as the metric increased, success would decrease.

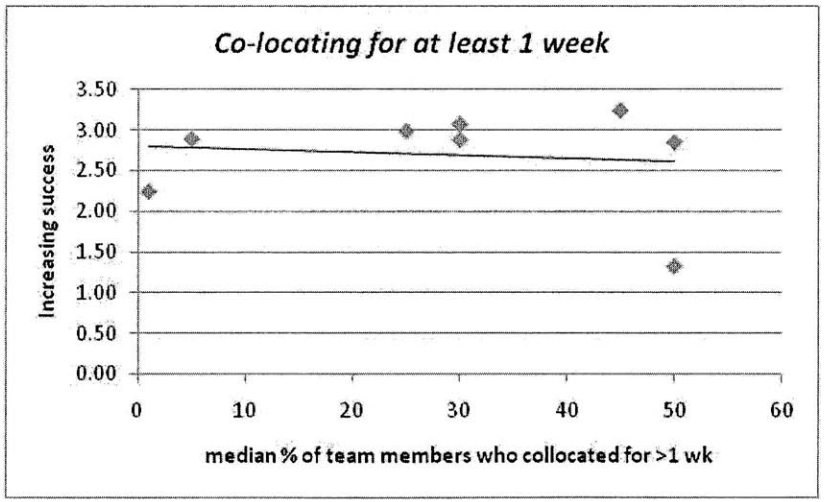


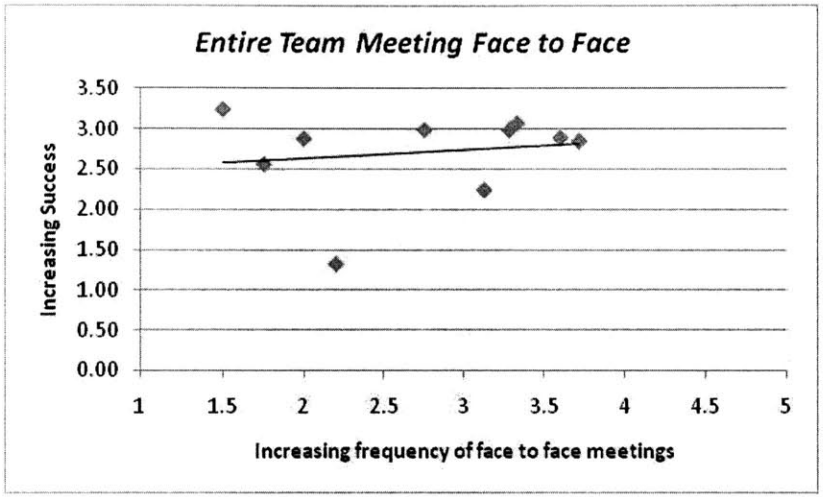


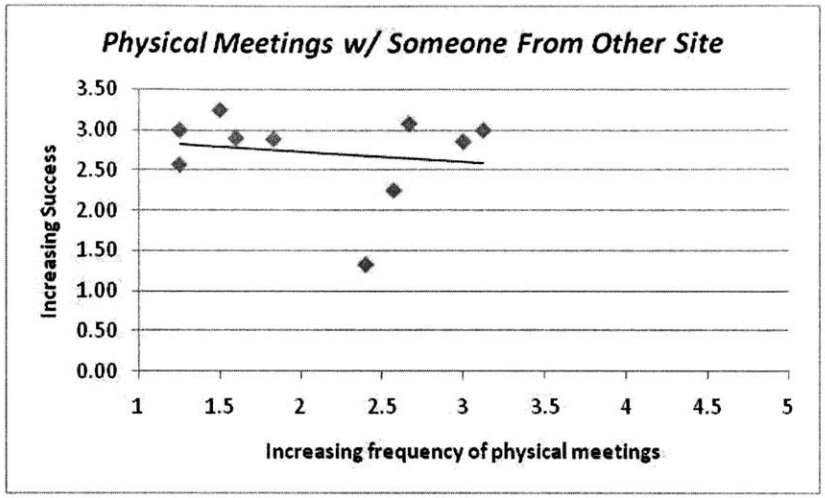

Site-to-Site priority
Increasing success
3.50
3.00
2.50
2.00
1.50
1.00
0.50
0.00
1
1.5
2
2.5
3
Increasing alignment of priorities between sites

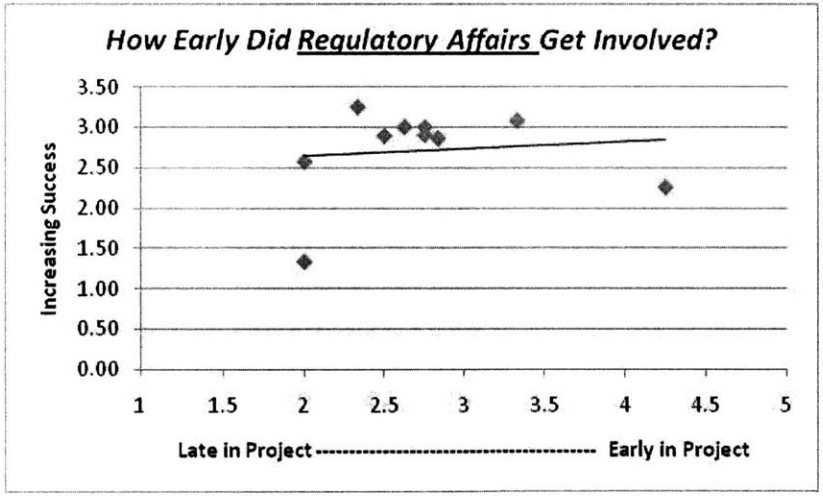

Project-to-Project Priority
Increasing Success
3.50
3.00
2.50
2.00
1.50
1.00
0.50
0.00
1
1.5
2
2.5
3
3.5
4
4.5
5
Increasing priority relative to other projects

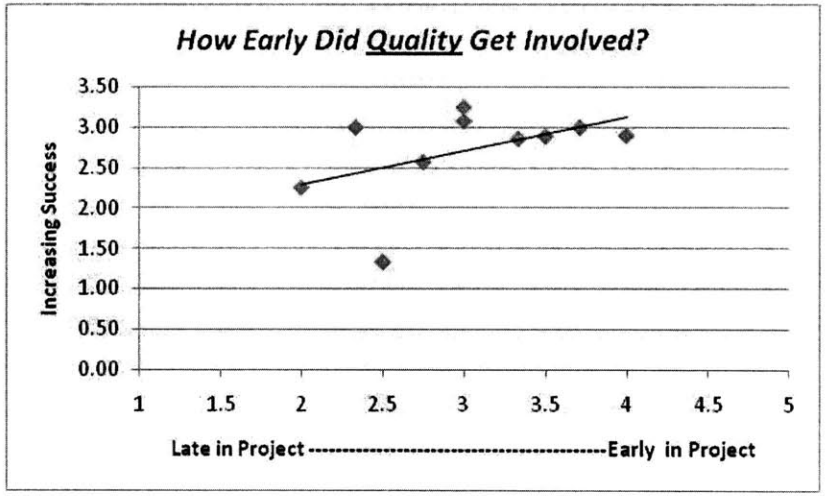

Function-to-Function Priority
Increasing success
3.50
3.00
2.50
2.00
1.50
1.00
0.50
0.00
1
1.5
2
2.5
3
3.5
4
4.5
5
Increasing alignment of project priority between functions

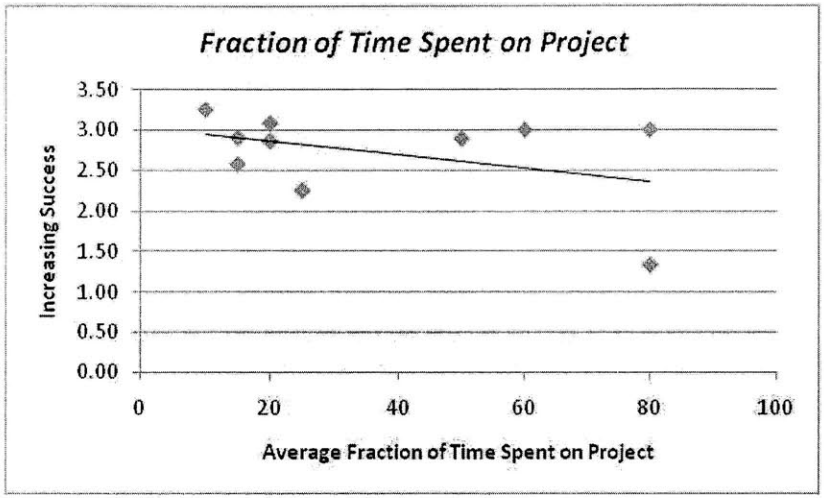

Co-locating for at least 1 week
Increasing success
3.50
3.00
2.50
2.00
1.50
1.00
0.50
0.00
0
10
20
30
40
50
60
median % of team members who collocated for >1 wk

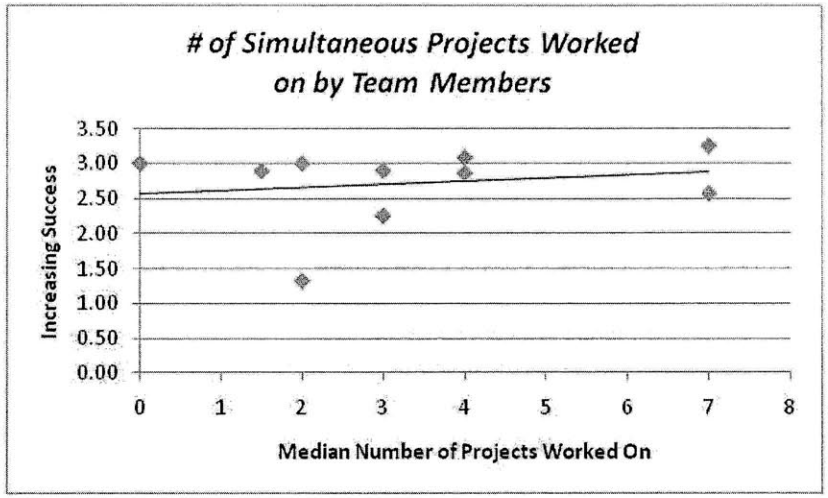

Entire Team Meeting Face to Face
Increasing Success
3.50
3.00
2.50
2.00
1.50
1.00
0.50
0.00
1
1.5
2
2.5
3
3.5
4
4.5
5
Increasing frequency of face to face meetings

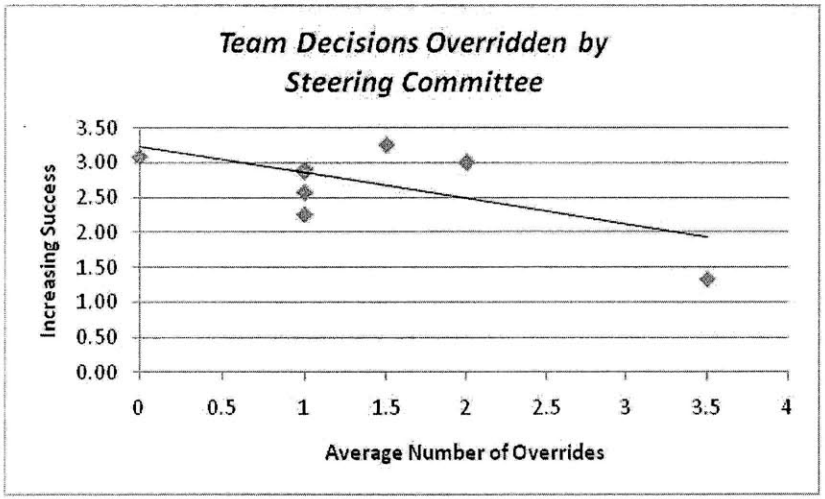

Physical Meetings w/ Someone From Other Site
Increasing Success
3.50
3.00
2.50
2.00
1.50
1.00
0.50
0.00
1
1.5
2
2.5
3
3.5
4
4.5
5
Increasing frequency of physical meetings


How Early Did Regulatory Affairs Get Involved?
Increasing Success
3.50
3.00
2.50
2.00
1.50
1.00
0.50
0.00
1
1.5
2
2.5
3
3.5
4
4.5
5
Late in Project ---------- Early in Project


How Early Did Quality Get Involved?
Increasing Success
3.50
3.00
2.50
2.00
1.50
1.00
0.50
0.00
1
1.5
2
2.5
3
3.5
4
4.5
5
Late in Project ----------Early in Project


Fraction of Time Spent on Project
Increasing Success
3.50
3.00
2.50
2.00
1.50
1.00
0.50
0.00
0
20
40
60
80
100
Average Fraction of Time Spent on Project


# of Simultaneous Projects Worked on by Team Members
Increasing Success
3.50
3.00
2.50
2.00
1.50
1.00
0.50
0.00
0
1
2
3
4
5
6
7
8
Median Number of Projects Worked On


Team Decisions Overridden by Steering Committee
Increasing Success
3.50
3.00
2.50
2.00
1.50
1.00
0.50
0.00
0
0.5
1
1.5
2
2.5
3
3.5
4
Average Number of Overrides

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