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Best Practices in a Clinical Development Project Management Office (PMO) to Achieve a Reference Standard in the Pharmaceutical Industry

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Best Practices in a clinical development Project Management Office (PMO) to achieve a reference standard in the pharmaceutical industry

By
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Overview/Abstract

Medications are developed by the pharmaceutical industry starting with the discovery phase, proceeds to preclinical trials, moves into clinical trials (progressing from Phase I to Phase III), and if the data are positive, may lead to Food and Drug Administration (FDA) approval. Once approved, post-marketing surveillance for safety is required as long as the drug is marketed to consumers. This phase may also include clinical trial Phase IV studies if additional safety testing is required. This process usually takes between ten to fifteen years, with clinical development taking seven to ten years of that time (1). Clinical development can be facilitated by a clinical development Project Management Office (PMO) at pharmaceutical companies. Clinical development PMOs provide value by establishing processes that can be universally adopted by the pharmaceutical industry. This can help simplify product development, and as a result, accelerate time to market. Clinical development project management is a relatively new field in the pharmaceutical industry, and there are few publications and literary reviews regarding standardized best practices, current best practices, and potential best practices for clinical development.

Decreasing the time it takes a drug to reach market can help patients live longer and/or improve their quality of life. Time to market is often driven by the time it takes to test the product in clinical settings. This thesis is focused on analyzing the clinical development project management practices in order to reduce the time to market. The goals of this project were to identify best practices in clinical development project management, compile a reference standard, develop a rubric, evaluate the rubric on a comparator company, and make a recommendation regarding actions required for the comparator company to achieve the reference standard.

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List of Abbreviations

Acronym	Word/Phrase
FDA	Food and Drug Administration
FDCA	Federal Food, Drug, and Cosmetic Act
FTE	Full Time Employee
IND	Investigational New Drug
IT	Information Technology
JIT	Just In Time
NDA	New Drug Application
OTC	Over-the-Counter
PM	Project Management
PMBOK	Project Management Body of Knowledge
PMI	Project Management Institute
PMO	Project Management Office
PPM	Program and Portfolio Management
REMS	Risk Evaluation and Mitigation Strategy
US	United States
WHO	World Health Organization

1. Introduction

The beginning of the regulation of the pharmaceutical industry can be traced back to 1938 when Congress passed the Federal Food, Drug, and Cosmetic Act (FDCA) law. The external landscape of the pharmaceutical industry and drug regulations have made big strides in the past 50-100 years due to various tragedies of the time. This included one of the first mass-deaths reported of over 100 patients due to a sulfanilamide medication used to treat streptococcal infections. The revised formulation used diethylene glycol (antifreeze) to dissolve the drug. This forced legislation to initially regulate safety (2). Regulations later followed regarding drug quality and efficacy. In order to bring a product to market, companies must first seek approval for testing in clinical trials (supported by scientific data), and if the results indicate a therapeutic benefit that outweighs any associated risks, then the company may seek approval to market the product.

1.1 Drug Definition

The term pharmaceutical products refers to medicines or drugs. According to the World Health Organization (WHO), it is important that prescribed products are of good quality, safe, effective and prescribed and used rationally (3). The Food and Drug Administration (FDA) defines drugs as any product that is intended to affect body structure or function for the purpose of diagnosis, treatment or prevention of disease (4).

Pharmaceutical products can be classified as small molecules (chemical compounds), generics (non-branded version of a small molecule), biologics (produced by or part of a living organism) or biosimilars (non-branded version of an existing biologic). These products may also be available either as prescription only or over-the-counter (OTC), and may vary in the formulation (e.g., liquid or tablet) and routes of administration (e.g.,

oral, nasal, or transdermal). Regardless of the classification or formulation, the approval process by the FDA is the same.

The development of small molecule drugs for treating and preventing disease played an important role in the practice of medicine. The history of small molecules spans thousands of years with the use of naturally occurring extracts for medicinal purposes (e.g., aspirin), to present day de novo synthetic organic molecules for drug development (e.g., statins). This has contributed to the improvement of health and increased life expectancy (5).

Generic drugs emerged in the United States in 1984 with the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Act, which changed the pharmaceutical field by making it easier for generic drugs to enter the market (6). The FDA states that a generic drug product must be comparable to the reference drug in terms of strength, performance, safety, quality, method of administration, and dosage form. It is essential that the generic drug have the same intended use as the reference drug (7).

The regulation of biological products began with the Biologics Control Act of 1902. Unlike traditional chemical manufacturing of drugs, biological products are isolated from living organisms. Biological products include vaccines, blood derivatives, and gene therapy products amongst others. Biologics are used in the treatment of cancer and other diseases (8). The most recent development is biosimilars, which are developed from living cells through highly complex manufacturing processes, but “similar” to another biologic already approved by the FDA. An example of a biosimilar is Zarxio (Filgrastim-sndz) (9) which was FDA approved in 2015 and is analogous to Neupogen

(Filgrastim). Both drugs are prescribed to cancer patients following chemotherapy to help decrease the risk of developing neutropenia.

1.2 FDA Drug Approval Process

FDA ensures that the drugs on market, whether brand name or generic, are safe and effective, and that the health benefits outweigh the risks. The process begins at the discovery phase, proceeds to preclinical trials, moves into clinical trials (progressing from Phase I to Phase III), and if the data are positive, may lead to FDA approval. The life cycle management stage includes post-marketing surveillance for safety as long as the drug is marketed to consumers. Post-marketing may also include clinical trial Phase IV studies if additional safety testing is required. The discovery phase involves investigation of thousands of compounds as potential drug candidates. Once a promising compound is found, experiments are conducted to gather initial information on a number of factors, such as how it is metabolized, the potential benefits, dosage, administration, side effects, other drug interactions and effectiveness. Following discovery, further information on these factors are gathered through preclinical trials, which involve both *in vitro* and *in vivo* animal research to evaluate the new drug's safety (e.g., toxicity) and efficacy. Following the data obtained from these tests, an Investigational New Drug (IND) application is submitted to the FDA that includes information on the drug composition, manufacturing, and clinical trial plan. The FDA reviews the IND to verify that the proposed studies, known as clinical trials, focus to ensure clinical trial subject safety. The FDA also verifies that there is informed consent and that human subject protections are in place prior to initiation of clinical trials. If the FDA feels that these criteria are met, the drug under investigation then moves to the clinical stage where the drug sponsor's clinical trials are divided into Phases I, II, and III. In clinical trial Phase I, the focus is evaluating the safety of the drug, and traditionally

involves approximately 20-80 healthy volunteers with the goal of the identifying the drug's side effects, and evaluating how the drug is absorbed, distributed, metabolized and excreted from the body. If the data captured in clinical trial Phase I are positive, the drug transitions into clinical trial Phase II, where traditionally the number of subjects increases into the hundreds. The focus of clinical trial Phase II is learning more about the safety of the drug, including the maximum tolerated dose, and looking for initial efficacy signs in people who have the particular condition or disease. At the conclusion of clinical trial Phase II, assuming the data are positive, the FDA and drug sponsors discuss how the clinical trial Phase III studies will be designed and completed. In clinical trial Phase III, the patient numbers traditionally move into the thousands and the primary focus is to evaluate efficacy, along with continual assessment of safety. Following this phase, a meeting between the FDA and drug sponsor occurs before the submission of a New Drug Application (NDA). The NDA filing is requested by the drug sponsor to gain approval from the FDA to market the drug in the United States, supported by all the data gathered to date as outlined above. Following the receipt of the NDA, the FDA has 60 days to evaluate whether the applicant has provided the information required for FDA review. If sufficiently complete, the FDA review team evaluates the sponsor's data on drug safety and effectiveness. As part of the review process, the FDA will inspect the manufacturing facility(ies) and a subset of the clinical and nonclinical testing sites. If the FDA doesn't evaluate the drug's benefits outweigh the risks, they will issue a "Complete Response Letter", which means that product cannot be sold in the US. The company can then choose to conduct further testing or not pursue the product at all. If the FDA deems that the benefits outweigh the risks, the FDA will negotiate the exact drug label with the sponsor to ensure important information is communicated to health care professionals and patients, and officially approve the product. As it is not possible to predict what happens after the drug is on the market, post-market surveillance of safety

is required. Further studies (clinical trial Phase IV) may also be required to also evaluate specific safety questions. The drug sponsor is also required to submit periodic safety updates to the FDA throughout the drug's marketed life. In addition to sponsor safety reporting requirements, the FDA also provides a mechanism for physicians and patients to voluntarily report adverse events. Should post-marketing safety analysis identify new safety risks, product availability can be restricted (e.g., through a restricted access program, also known as Risk Evaluation and Mitigation Strategy or REMS) or in rarer cases, the drug can be withdrawn from the market.

1.3 Time to Market

In 2013, drug discovery products accounted for about 5,000-10,000 of potential products being developed. Of those potential products, only between 2.5% to 5% move to preclinical. Less than one-half of one percent of products investigated in preclinical stages are approved. The average time from discovery to market for drugs is ten to fifteen years, with a hefty portion of that time spent in clinical trials (six to seven years; Table 1).

Table 1: Average time from discovery to market

	Drug Discovery	Preclinical	Clinical Trials	Approval and Launch
Products in stage	5,000 – 10,000	250	5	1
Duration	3-6 Years		6-7 Years	0.5 – 2 Years

Source: PhRMA, 2013

The top five fastest drug developers average 3.9 to 4.6 years in clinical development Table 2 (1). The fastest developer (Abbott) leads the median clinical trial duration with 47 months as opposed to the fifth fastest developer (BioMarin) at 55 months, almost a half-year difference. Conversely, BioMarin leads with the shortest NDA approval median

duration (6 months), which is due to shorter review times for orphan drugs in comparison to other drugs.

Table 2: 2014 Fastest drug developers

	Median clinical duration (in months)	Median NDA approval duration (in months)	Total median duration (in months)
Janssen (J&J)	47	10	57
Abbott	47	9	56
Sanofi	51	13	64
Shire	55	19	73
BioMarin	55	6	61

Source: CenterWatch, 2013

Pharmaceutical companies face challenges through the lengthy drug development process (Figure 1). Not only is a pharmaceutical company looking to deliver a product quicker, they are often competing in a race against other companies to be the first in the market. This requires efficiency throughout the organization. The complex product development process from molecule to product involves the management of many business processes such as manufacturing, regulatory strategy, and clinical development.

The analysis of best practices in pharmaceutical industry, specifically in clinical development, where the most time is spent, will help identify standard practices for efficient drug development.

Figure 1: Drug development lifecycle
The drug development lifecycle starts with the discovery phase, proceeds to preclinical trials, and moves into clinical trials, progressing from Phase I to Phase III, and depending on the data, may lead to FDA approval. The life cycle management stage includes post-marketing surveillance for safety as long as the drug is marketed to consumers. Post-marketing may also include clinical trial Phase IV studies if additional safety testing is required.

1.4 Project Management Role in Pharma

Project management has been known to drive success in industries such as information technology (IT) and construction/engineering (10). In the last decade, project management has been adopted by some pharmaceutical sectors, e.g., devices, but not holistically (5).

There are few publications and literary reviews regarding standardized best practices, current best practices, and potential novel best practices for clinical development project management in pharmaceuticals (11). Furthering the knowledge in this area is warranted and would facilitate bringing products to patients sooner without sacrificing quality.

2 Objectives and Strategy

The specific aims of the project were:

I. Establish a reference standard for best practices (Phase I)

II. Develop an assessment methodology (rubric) for the Project Management Offices to the reference as standard (Phase I)

III. Evaluate the rubric (Phase II) using a comparator company

IV. Make recommendations for how the comparator company could achieve the reference standard (Phase II)

This research study involved a three-fold approach: study design, qualitative exploratory research (Phase I), and quantitative confirmatory research (Phase II).

3 Research Design and Methods

3.1 Study Design

The study design involved two phases. Phase I was qualitative and designed to define a reference standard and develop a rubric for the assessment of clinical development project management offices (PMOs). Phase II was quantitative and designed to perform an initial assessment of ability of the rubric to assess a comparator company's conformance with the reference standard.

3.2 Phase I: Reference Standard and Rubric Development

3.2.1 Questionnaire Development

Phase I began with the development of a pilot questionnaire with six, open-ended questions. It was tested on 10 people from Company "A" and revised for a final set of 14 open-ended questions. The final questionnaire can be found in Section 8.2.2.

3.2.2 Sample Group

Following the development of the questionnaire, a sample group of respondents were identified from three sources: 1) LinkedIn (Sunnyvale, CA) using the search term "project management" 2) personal network referrals through the last question of the survey ("Do you have any network contacts you can share in assisting with this research?"), and 3) Program and Portfolio Management (PPM) (New York, NY) Conference messaging platform Bizzabo.

3.2.3 Company Metrics

The companies for which the sample respondents were employed were evaluated on four metrics to establish cutoffs for company size: 1) number of full-time employees, 2) revenue (US$), 3) profitability, and 4) drug pipeline (count). The number of employees needed to qualify as a large company was defined as >10,000, medium as 1,000-9,999, and small as <1,000. The revenue amount needed to qualify as a large company was defined as >$10B, medium as $1B – $10B, and small as <$1B. The profitability size designation for a large company was defined as "Yes", for medium was "Either" (meaning either Yes or No), and for small was "No". The drug pipeline needed to qualify as a large company was defined as >20, for medium as 10 – 20, and for a small company as <10. Company size classification criteria are provided in Table 3.

Table 3: Company size classification

	Large	Medium	Small
Number of employees	>10K	1K – 10K	<1K
Revenues	>$10B	$1B – $10B	<$1B
Profitability (y/n)	Y	?	N
Drug Pipeline	>20	10 - 20	<10

The companies were assigned a unique identifier because permission was not requested to use their company name for this study. To further aid maintaining anonymity, exact metrics obtained from Yahoo! Finance (New York, NY) were rounded.

The mid-sized company with the largest number of potential respondents (41 people) was selected as the comparator company. Personnel at the comparator company were not contacted in Phase 1, but reserved for Phase II of the study.

3.2.4 Data Collection

An introductory e-mail message was sent to the potential pool of respondents to provide background regarding the interviewer and the desired outcome, as well as a request to

schedule a meeting to conduct the interview. One-hour interviews were conducted with the respondents from March to May 2017. Data were captured during the interviews by handwritten notes and post-meeting transcribed into a word processing document.

3.2.5 Data Cleaning

Raw data captured in the word processing document were converted to a spreadsheet and subsequently cleaned by correcting spelling errors, spelling out abbreviations and removing duplicate entries (deduplication). Following a consistency check for correct project management context, high frequency words were identified by requiring that the word or term must have occurred greater than 10 times in the raw data. False positives (i.e., terms included in the results erroneously, such as “that” and “what” being returned for the term “hat”) were removed (Figure 2 and Figure 3).

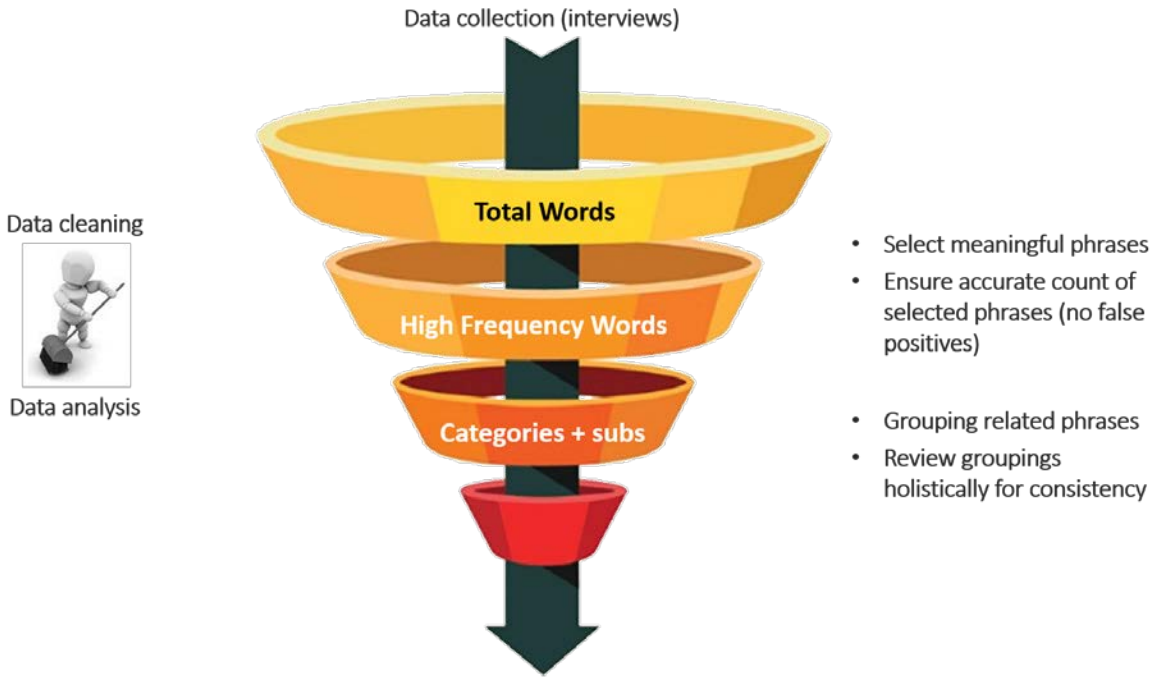

Figure 2: Data collection through reference standard development
Funnel structure depicting the process for reference standard development, starting with total words from interview raw data being narrowed to high frequency words, and then classified into

categories and subcategories to develop the final reference standard definition (denoted by the red band).

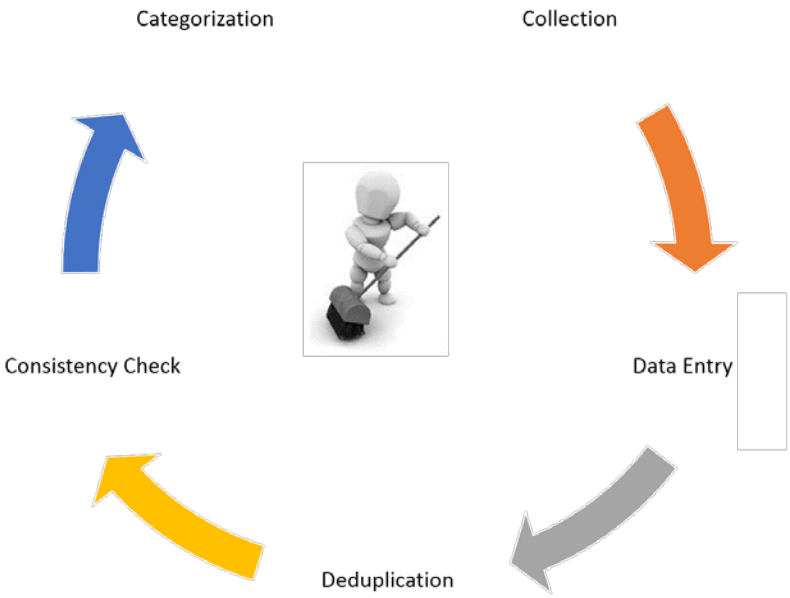

Figure 3: Data cleaning and analysis process
Diagram depicting the process for data cleaning (from collection, data entry, deduplication to consistency check) and data analysis (categorization).

3.2.6 Data Analysis

Analysis involved grouping high-frequency words into categories, sub-categories and sub-sub categories, terms and attributes (the classification scheme outline and definitions can be found in Section 8.1). These groupings were reviewed holistically for consistency and correct categorical context (Figure 3).

3.2.6.1 Statistical Analysis

To evaluate whether there was a difference in results based on company size, the data analysis tool in Microsoft Excel 2013 (version 15.0, Redmond, WA) for an ANOVA: Two-Factor without Replication statistical analysis was used.

3.2.7 Reference Standard and Rubric Development

The reference standard was developed by applying a cutoff to the high frequency words. The numbers for the highest frequency word in each of the four top level categories were totaled, then divided by four (for the number of categories), and subsequently divided by four again to separate into quartiles, and then rounded to the nearest whole number. This method was selected over the use of the absolute count of the term in order to filter out terms that fell in the bottom quartile. The high frequency words meeting the cutoff became the terms that comprised the reference standard.

The rubric was developed by creating actionable descriptions (i.e., attributes) of the terms in the reference standard. The descriptions were taken from the Phase I interviews.

3.3 Phase II: Rubric Evaluation and Comparator Company Recommendations

The Phase II objectives were to evaluate the rubric and make recommendations for how a comparator company could achieve the reference standard.

3.3.1 Questionnaire Development

The rubric developed in Phase I was converted into a Likert scale questionnaire which asked to what degree the respondent felt each attribute was being practiced at their company on a five-point scale (Strongly Disagree [1], Disagree [2], Neither [3], Agree [4], or Strongly Agree [5]).

3.3.2 Sample Group

During Phase I (Section 3.2.2), the mid-sized company with the largest potential pool of respondents was reserved for Phase II. A mid-size company was thought to be a suitable comparator company as it would incorporate elements of both large and small companies.

3.3.3 Data Collection

A LinkedIn message was sent to the potential pool of respondents introducing the objective of the study and a link to the questionnaire in SurveyMonkey® (San Mateo, CA; Section 8.2.3). The message was sent and all responses were completed in April 2018.

3.3.4 Data Analysis

An average company was defined as a company performing at its sizing class, which is arbitrarily set with baselines that were neither too high nor low. To translate into a measurable metric on the Likert scale 5-point scale, numeric results from each top level cat average was totaled and >3.0 cutoff was set which is the mean of a 5-point scale. The cut-off was also required to evaluate the comparator company after the survey was conducted to set performance baselines for activities being/not being practiced.

4 Results

4.1 Phase I: Reference Standard and Rubric Development

The objectives of Phase I were to develop a reference standard and associated rubric for the assessment of clinical development PMOs.

4.1.1 Response Results

A total potential pool of 127 respondents was identified from three sources: 1) LinkedIn (n=79), 2) referrals (n=29), and 3) Project and Portfolio Management (PPM) conference

messaging platform Bizzabo (n=19). Of the 127 potential respondents contacted, 23 people expressed interest and received a copy of the final questionnaire comprised of 14 questions. Seventeen of 23 completed the questionnaire with two (3%) from LinkedIn, eleven (38%) from referrals, and four (21%) from Bizzabo. The response rate was 12%, 65%, and 24% for LinkedIn, referrals, and Bizzabo, respectively. The overall response rate was 13% (Table 4). This response rate was lower than what was previously reported in a study where surveys of individuals had an average response rate of 53%, while surveys of organizations had an average response rate of 36% (12).

Table 4: Participant pool, respondents, and overall percent per platform

Platform	Potential Pool	Actual Respondents	Response %	Overall %
LinkedIn	79	2	3%	11.76%
Referrals	29	11	38%	64.71%
PPM Bizzabo	19	4	21%	23.53%
Total	127	17	13%	100%

4.1.2 Company Metrics

The 17 respondents were from 15 companies, with three respondents from the same company. The 15 companies were evaluated based on the criteria set in Section 3.2.3, with four classified as large, five as medium and seven as small (Table 5).

Table 5: Number of responses by company

Company size	Total number of interview respondents	Total number of companies
Large	6	4
Medium	4	4
Small	7	7
Total	17	15

Source: Yahoo!Finance, 2017 (13)

Evaluating each company's revenue and drug pipeline against the number of full-time employees (FTE) provides metrics to measure their performance relative to their peers. For example, of the four companies classified as large, Companies 1 and 2 have a

revenue/FTE value of $600K each, while Companies 3 and 4 have a revenue/FTE value of $1M each, implying that Companies 3 and 4 are performing better relative to Companies 1 and 2. The pipeline/FTE ratio of Company 1 is 0.0006, for Companies 2 and 3 are 0.001, and for Company 4 is 0.002, implying that Company 4 is performing better than the other three companies (Table 6).

Table 6: Company metrics of respondents

Company ID	FTE	Revenue (US$)	Profitable	Drug Pipeline	Size Classification	Respondents	Revenue/ FTE (US$)	Pipeline/ FTE
1	90,000	60B	Y	50	Large	3	600K	0.0006
2	30,000	20B	Y	40	Large	1	600K	0.001
3	30,000	30B	Y	40	Large	1	1M	0.001
4	20,000	20B	Y	40	Large	1	1M	0.002
5	9,000	30B	Y	40	Medium	1	3.3M	0.004
6	8,000	6B	Y	10	Medium	1	750K	0.001
7	1,000	500M	N	10	Medium	1	500K	0.01
8	1,000	2B	N	20	Medium	1	2M	0.02
9	500	3M	N	10	Small	1	6K	0.02
10	300	300M	Y	10	Small	1	1M	0.03
11	200	NA	NA	10	Small	1	NA	0.05
12	100	1M	N	5	Small	1	10K	0.05
13	100	10M	N	10	Small	1	100K	0.1
14	100	NA	NA	1	Small	1	NA	0.01
15	100	NA	N	10	Small	1	NA	0.1

Source: Yahoo!Finance 2017 (13)
FTE = full-time employees
NA = Not available
Drug Pipeline = set of drug candidates that a pharmaceutical company has under discovery or development and any given point in time.

4.1.3 Categorization Overview

The 17 interviews culminated in a total of 5,712 words relevant to project management context, which were further cleaned using the method outlined in Section 3.2.5, resulting in 540 high frequency words. The high frequency words were then grouped into four top level categories: 1) Soft Skills, 2) Hard Tools, 3) Organizational Structure, and 4) PMO Components. Each of the categories had multiple sub-categories and sub-subcategories (Table 7).

The Soft Skills category had 14 sub-categories (alphabetical, number of terms per category indicated in parenthesis after the term): Collaboration (8), Communication (54), Experience (9), Flexibility/Versatility (12), General (9), Humility (1), Innovative (6), Looks after best interests of project (1), Reading People (3), Relationship Building (6), Strategy (14), Tact and Diplomacy (2), Team Management (8), and Trust (9). The 54 terms in Communication were divided into four sub-subcategories: General (24), Project Management (PM) Specific (20), Processes (3) and Team Management (7). The Soft Skills sub-categories included in the reference standard were Communication (the three sub-subcategories of General, PM Specific and Team Management), Experience, General and Strategy.

The Hard Tools category had two sub-categories: Processes (128) and Technology (29). The 128 terms in Processes were divided into 10 sub-subcategories: Budget (32), Contracting (1), Deliverables Management (8), General (10), Lifecycle Management (2), Matrices (4), Meeting Management (16), Resource Management (15), Technology Strategy (5), Timelines (18), and Training (17). The 29 terms in Technology were divided into nine sub-subcategories: Collaboration (2), Communication (5), Dashboards (6), Deliverables Management (1), Document Control (6), Hardware (1), Lifecycle Management (1) PPM (2), and Timelines (5). Although Timelines are found in both the

Processes and Technology sub-categories, they are defined differently, where Timelines in Processes is defined as creating timelines and Timelines in Technology is defined as a tool, such as a Gantt chart. The Hard Tools sub-category Processes included in the reference standard were Budget, Deliverables Management, Meeting Management, Resource Management, Timelines, and Training. There were no Technology sub-categories included in the reference standard.

The Organizational Structure category had 10 sub-categories: Alliance Management (14), Constraints (14), Culture (6), Efficiencies (14), General (12), Governance (34), Integration (4), Matrix Organization (26), Silo Organization, (3), and Transparency (2). The 14 terms in Constraints were divided into two sub-subcategories: General (9) and Turnover (5). The 26 terms in Matrix Organization were divided into three sub-subcategories: General (8), PM Role (7), and Teams (11). The Organizational Structure sub-categories included in the reference standard were Alliance Management, Efficiencies, General, Governance, and the Teams sub-subcategory of Matrix Organization.

The PMO Components category had five sub-categories: Alignment (13), General (5), Methodologies (17), PM Role (62), and Portfolio Management (6). The 62 terms in PM Role were divided into four sub-subcategories: General (44), Leadership (2), Strategic (11), and Tactical (5). The PMO Components sub-categories included in the reference standard were Alignment, Methodologies, and PM Role (with two sub-subcategories General and Strategic).

Table 7: Categorization overview (alphabetical)

Category (n)	Sub-categories (n)	Sub-subcategories (n)
Soft Skills (14)	Collaboration (8)	
	Communication (54)	N=4: **General** (24), **PM Specific** (20), Processes (3), **Team Management** (7)
	Experience (9)	
	Flexibility/Versatility (12)	
	General (9)	
	Humility (1)	
	Innovative (6)	
	Looks after Best Interests of Project (1)	
	Reading People (3)	
	Relationship Building (6)	
	Strategy (14)	
	Tact & Diplomacy (2)	
	Team Management (8)	
	Trust (9)	
Hard Tools (2)	**Processes** (128)	N=10: **Budget** (32), Contracting (1), **Deliverables Management** (8), General (10), Lifecycle Management (2), Matrices (4), **Meeting Management** (16**), Resource Management** (15), Technology Strategy (5), **Timelines** (18), **Training** (17)
	Technology (29)	N=9: Collaboration (2), Communication (5), Dashboards (6), Deliverables Management (1), Document Control (6), Hardware (1), Lifecycle Management (1), PPM (2), Timelines (5)
Organizational Structure (10)	**Alliance Management** (14)	
	Constraints (14)	N=2: General (9), Turnover (5)
	Culture (6)	
	Efficiencies (14)	
	General (12)	
	Governance (34)	
	Integration (4)	
	Matrix Organization (26)	N=3: General (8), PM Role (7), **Teams** (11)
	Silo Organization (3)	
	Transparency (2)	
PMO Components (5)	**Alignment** (13)	
	General (5)	
	Methodologies (17)	
	PM Role (62)	N=4: **General** (44), Leadership (2), **Strategic** (11), Tactical (5)
	Portfolio Management (6)	

*Items indicated in Bold were included in the reference standard definition

4.1.3.1 Overview of Categories

When looking at the aggregated results, the distribution across the four categories was fairly even. Soft skills and Organizational Structure were 26% each, Hard Tools and PMO components were 29% and 19%, respectively (Figure 4).

To determine whether company size affected the distribution, the four categories were analyzed by company size (Section 4.1.2). The category distribution for large companies was 21% for Soft Skills, 35% for Hard Tools, 26% for Organizational Structure, and 18% for PMO Components. The category distribution for medium companies was 25% for Soft Skills, 37% for Hard Tools, 18% for Organizational Structure and 20% for PMO Components. The category distribution for small companies was 32% for Soft Skills, 19% for Hard Tools, 28% for Organizational Structure and 21% for PMO Components. ANOVA: Two-Factor without Replication statistical analysis of these results found no statistical significance, with a p-value of 0.41 (Figure 4 and Table 8). Thus, results were only analyzed at the overall level, not by company size.

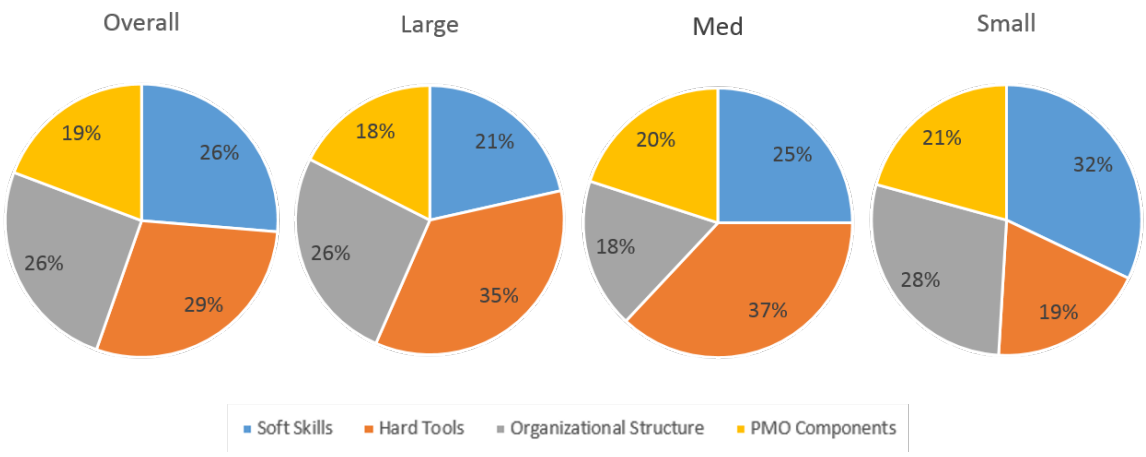

Figure 4: Top level category distribution overall and by company size
Top level category distribution overall and by company size (large, medium, and small). ANOVA analysis found no statistically significant difference in the distribution based on company size (p-value = 0.41).

Table 8: Statistical analysis of top level category distribution by company size

ANOVA: Two-Factor Without Replication						
SUMMARY	**Count**	**Sum**	**Average**	**Variance**		
Soft Skills	3	78	26	31		
Hard Tools	3	91	30.33333	97.33333		
Organizational Structure	3	72	24	28		
PMO Components	3	59	19.66667	2.333333		
Large	4	100	25	55.33333		
Medium	4	100	25	72.66667		
Small	4	100	25	36.66667		
ANOVA						
Source of Variation	**SS**	**df**	**MS**	**F**	**P-value**	**F crit**
Rows	176.6667	3	58.88889	1.113445	**0.414591**	4.757063
Columns	0	2	0	0	1	5.143253
Error	317.3333	6	52.88889			
Total	494	11				

SS: Sum of squares
Df: Degrees of freedom
MS: Mean squares
F: F Statistic, variance of the group means (Mean Square Between)/mean of within group variances (Mean Squared Error)
F-crit: Probability value can occur (p value less than alpha)

The overall category distribution for three of the top level categories (Soft Skills, Hard Tools, and PMO Components) had a single sub-category distinctly larger than the rest of their sub-categories, while Organizational Structure showed a more even distribution across sub-categories. The distribution of sub-categories (from highest to lowest) for Soft Skills was 38% for Communication, 10% for Strategy, 8% for Flexibility/Versatility, 6% each for Collaboration, Experience, General, Team Management and Trust, 4% for Innovative and Relationship Building, 2% for Reading People and 1% each for Humility, Looks after Best Interests of the Project and Tact and Diplomacy. The Hard Tools sub-category distribution was 82% for Processes and 18% for Technology. Organizational Structure sub-category distribution was 26% for Governance, 20% for Matrix Organization, 11% each for Alliance Management, Constraints, Efficiencies, 9% for General, 5% for Culture, 3% for Integration, 2% each for Silo Organization and Transparency. PMO Components sub-category distribution was 60% for PM Role, 17%

for Methodologies, 13% for Alignment, 6% for Portfolio Management, and 5% for General (Figure 5).

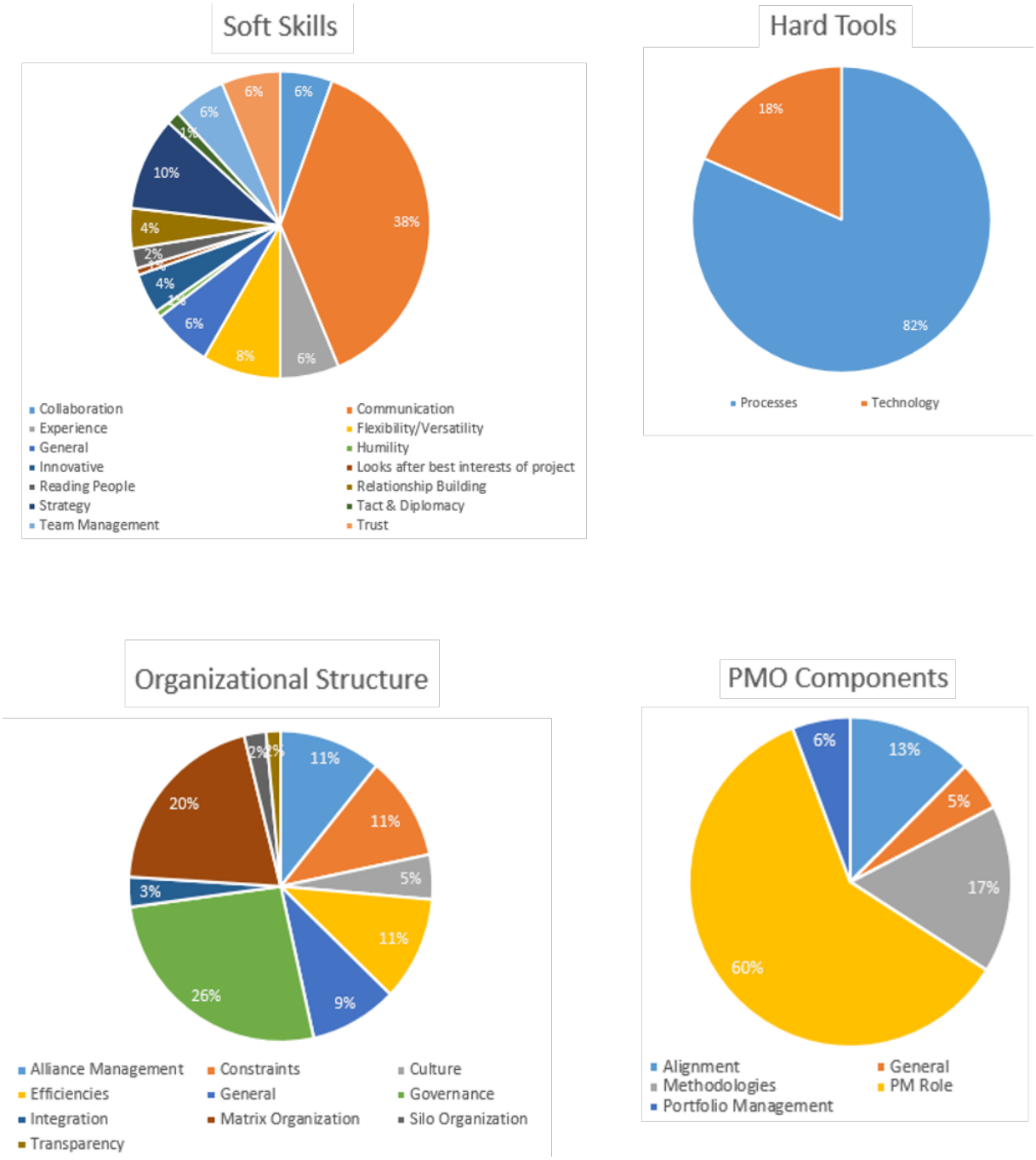

Figure 5: Sub-category distribution by top level category overall
The sub-category distribution overall for three of the top level categories (Soft Skills, Hard Tools and PMO Components) had a single sub-category distinctly larger than the rest of their sub-categories while the sub-categories for Organizational Structure were more evenly distributed

4.1.4 Reference Standard Definition

The objective of the reference standard definition was to create a rubric that could be used by pharmaceutical companies to evaluate and improve clinical development project management performance. The initial list of categories (including sub and sub-subcategories) totaled 65. Definition of each category with three to seven attributes would have produced a reference standard with hundreds of attributes, which was deemed too large to be usable. To produce a more manageable reference standard, a cutoff of ≥ 6 (Section 3.2.7) was applied resulting in 21 categories (indicated in bold in Table 7). These categories were then defined using words taken directly from the respondent interviews in Phase I to produce a total of 72 attributes (Section 8.3.2).

Use of the cutoff of ≥ 6 (Section 3.2.7) resulted in certain terms with higher absolute values not being included. For example, in the Soft Skills category, Flexibility/Versatility had a total count of 12 terms. However, when distributed by company size, they all fell into the bottom quartile: large (5), medium (2), and small (5), and so did not reach the cut-off (>6). Experience, on the other hand, had a total of 9 terms. The company size distribution was large (0), medium (8), and small (1). The medium count of eight fell above the >6 cut-off (i.e., outside the bottom quartile), so was included in the reference standard definition. The same was applied to the remaining top level categories (Hard Tools, Organizational Structure, and PMO Components). The individual categories had variable number of sub-subcategories and some sub-categories with additional context required a third level of categorization. Raw data for the word counts, organized by category (and sub and sub-sub) and company are provided in Table 19.

4.1.5 Reference Standard Rubric

The reference standard definition (72 attributes) was then converted into 72 actionable statements, i.e., the reference standard rubric, Section 8.3.2).

4.2 Phase II: Rubric Evaluation and Comparator Company Recommendations

The Phase II objectives were to evaluate the rubric and make recommendations for how a comparator company could achieve the reference standard.

4.2.1 Response Results

Of the total potential pool of respondents of 41 people contacted via LinkedIn, 22 people expressed interest and received a copy of the 5-point Likert scale survey comprised of 72 questions (see Section 3.3.1). Of the 22 that expressed interest, six respondents completed the survey (27% response rate). For Soft skills, which had 22 attributes, all of the responses were above the 3.0 cut-off, with the mean (median) of the six responses ranging from 3.6 – 4.5 (3.5 – 4.5). None of the six respondents Strongly Disagreed. There was one Disagree response each for three attributes (information sharing is concise, information sharing is precise, and PMs are effective at ensuring issues are appropriately shared across teams). Hard Tools had 24 attributes, with the mean (median) of the six responses ranging from 2.5 – 4.0 (2.5 – 4.0). Four of the Hard Tools attributes were below the 3.0 cut-off. Four of six respondents Strongly Disagreed with four attributes (Organization Tracks Actuals Against Budget, Team Members are Kept to a Minimum, PM Training Leverages Project Management Body of Knowledge [PMBOK], and Organization Provides Just-in-Time [JIT] Training [i.e., relevant training is provided just before needed]). There were Disagree responses for all but three attributes. Organizational Structure had 14 attributes, with the mean (median) of the six responses ranging from 2.8 – 3.8 (3.0 - 4.0). All of the responses for Organizational Structure attributes were above the 3.0 cut-off. None of six respondents Strongly Disagreed. Neither agree nor disagree responses accounted for a majority of responses. PMO components had 11 attributes, with the mean (median) of the six responses ranging from 2.5 – 4.2 (2.5 – 4.0). All but one of the responses for PMO components attributes were

above the 3.0 cut-off. One of six respondents Strongly Disagreed with one attribute (organization leverages PMBOK practices). There were four Disagree responses for three attributes (PMs ensure portfolio and product strategies are developed, PMs help teams to think strategically, organization leverages PMBOK practices, and PMs assist in establishing agreed upon product development plans).

4.2.2 Data Analysis

In order to evaluate the usability of the rubric, four factors were analyzed: 1) response rate, 2) completion rate, 3) completion time and 4) response variation. The survey response rate was 27%, which was higher than the response rate from LinkedIn (11.76%), lower than the response rate from referrals (64.71%) and comparable with the response rate for the Bizzabo platform (23.53%). All of the respondents (n=6) that started the survey, completed it. The time for completion ranged from 7:01 minutes to 51:12 minutes, with five out of six respondents' completion times under 17 minutes. The average completion time of all the respondents was 18 minutes, and was 11:34 minutes if the one outlier (51:12 minutes) was excluded. Responses were varied both within each individual respondent's results and across respondents, i.e., no respondent answered all statements with the same value, nor did any respondents answer all questions identically.

In order to evaluate the performance of a comparator company relative to the expectations of an average company (defined as a score of 3.0), the overall mean and median values of the survey results were calculated for each of the four categories. The mean (median) for Soft Skills was 4.8 (4.0), for Hard Tools 3.9 (3.4), Organizational Structure 3.9 (3.4) and PMO Components 4.3 (4.3) (Table 9 and Supplementary Table 19).

Table 9: Comparator company overall mean and median values

	Soft Skills	Hard Tools	Organizational Structure	PMO Components
Mean	4.8	3.9	3.9	4.3
Median	4.0	3.4	3.4	4.3

The comparator company, a mid-sized company identified in Phase I and reserved for Phase II testing (Section 3.2.3) had 7,300 employees with a revenue of $12B, and was profitable with 17 products in the pipeline (Table 10).

Table 10: Comparator company size evaluation

	Medium	Comparator Company
Number of employees	1K – 10K	7,300
Revenues	$1B – $10B	$12B
Profitability (y/n)	Y or N	Y
Pipeline	10 - 20	17

Source: Yahoo!Finance 2017 (13)

5 Discussion

The objectives of Phase I were to define a reference standard and develop an associated rubric for the assessment of clinical development PMOs. The Phase II objectives were to evaluate the rubric and make recommendations for how a comparator company could achieve the reference standard.

5.1.1 Phase I: Reference Standard and Rubric Development

Each of the four top level categories had themes. Soft Skills had three themes: Communication, Strategy, and Experience. Hard Tools themes centered on Processes, with sub-themes of Budget, Deliverables Management, Meeting Management, and Resource Management, Timelines, and Training. Although Timelines are found in both subcategories (Processes and Technology), they are defined differently, where Timelines in Processes is defined as creating timelines and Timelines in Technology is

defined as a tool, such as a Gantt chart. Organizational Structure had themes around Governance, Efficiencies, and Teams. PMO Components included themes around the PM Role, Methodologies and Alignment (Figure 5).

Although Soft Skills had three themes (i.e., Communication, Strategy, and Experience), the theme of Communication was dominant, representing more than one-third of the attributes (38%). This reveals not only the need for good communication, but how easily poor communication can become an issue. The reference standard provides best practices needed to effectively communicate by specifying the attributes required, e.g., direct, concise, and precise.

The Hard Tools themes focused on processes, accounting for 82% of the terms for this category, highlighting the difficulty in achieving good processes. The processes necessarily incorporate technology (which is important to meet specific needs), however, technology alone cannot meet all the needs. Therefore, a focus on processes for budgeting, training, and resource management are important as best practices.

The Organizational Structure themes were Governance (26%), Efficiencies (11%) and Teams as part of a Matrix Organization (20%). The data suggest that Governance is important because of its role in decision making. Therefore, a focus on Governance ensures that the organization has specific decision making and escalation pathways. Efficiencies focused on reducing the amount of time that processes required and on ensuring that “trains run on time”. Data on Teams as part of Matrix Organization focused on the need for teams to manage the project (called “project teams”).

The PMO Components category had themes around the PM Role (62%), Methodologies (17%) and Alignment (13%). The data suggest that an important component to a PMO is the organization’s understanding of what the project manager does and how their role

fits into the overall team structures. Methodologies focused on the importance of leveraging the Project Management Body of Knowledge (PMBOK) from the Project Management Institute (PMI). Alignment focused on ensuring that the organization was internally aligned, and highlighted the importance of establishing agreed upon goals and objectives.

The results reveal that the four top level categories can be grouped into two designations: “individual” and “organizational”. Soft Skills and Hard Tools fit into the “individual” designation because these categories are performed by an individual. Organizational Structure and PMO Components fit into the “organizational” designation because they are performed at the company level. For example, General Communication in Soft Skills consists of attributes of concise and direct communication. Although that could be considered an organizational designation (since all-around communication is important), the skill must first occur at an individual level in order for communication to impact the level of the organization. Organizational Structure includes Governance, which can only occur at a company level.

5.1.2 Phase II: Rubric Evaluation and Comparator Company Recommendations

The Phase II objectives were to evaluate the rubric and make recommendations for how a comparator company could achieve the reference standard.

The evaluation of rubric usability involved four factors: 1) response rate, 2) completion rate, 3) completion time and 4) response variation. The response rate was 27%, which is on the higher end of what was seen in Phase I for non-referrals (none of the respondents were referrals). All of the respondents that started the survey, completed it, indicating that they were not deterred by the survey despite it being comprised of 72 questions. Five out of six respondents required less than 12 minutes to complete the survey, indicating that the time required for completion was not onerous. There were

variations in the responses selected (both individually and across the sample group), indicating that respondents read the statements before responding.

The rubric was used to evaluate a comparator company's performance relative to the reference standard and whether that aligned with its performance relative to its peers. Based on the reference standard, the comparator company was ranked as performing above average in all Soft Skills attributes. Four attributes in Hard Tools were identified as needing additional work: 1) clear processes for adding resources and/or changing priorities, 2) organization-wide timeline templates with standard durations, 3) PM training to leverage PMBOK, and 4) organization-provided JIT training. One attribute each in Organizational Structure (the organization has the right-sized infrastructure in place), and PMO Components (the organization leverages PMBOK practices) were also identified as needing additional work.

In theory, the reference standard rubric should reflect whether the performance of the company is at, above or below its performance measures relative to its peers. Based on the company metrics established in Section 4.1.2 and the mean and median analysis in Section 4.2.2, the comparator company appears to be doing incrementally better than average mid-sized companies, which is consistent with the Phase II results in Table 10.

5.1.3 Limitations and Future Research

As with all research, there are limitations to this study. One example is geographical, as all the respondents were solely from the West coast of the United States (US). Therefore, it is unknown whether this information will hold true for other regions of the US and/or for other countries. Both Phase I and Phase II sample groups were small so the findings could change with larger cohorts. For example, "Soft Skills', Team Management" doesn't appear for small size companies. This might be an artifact of the small sample size or it might be replicated in a larger cohort and thus identified as an

area worth further exploration. Finally, the study was not able to comprehensively evaluate and/or validate the accuracy and precision of the rubric, company metrics definition, and the cut-offs. As the ultimate goal is to decrease the amount of time for clinical development in pharmaceutical companies, one way to determine whether the reference standard is causative rather than solely correlative would be to measure clinical development time pre- and post-implementation of the reference standard.

6 Conclusion

The objective of all projects is to be on time, on budget, and within scope. In clinical development, that means safety and effectiveness within the intended population as quickly as possible. Average time to market for a drug in development is ten to fifteen years, and of that, seven to ten years are spent in clinical development. While a general project management standard for PM methodologies and techniques is outlined in the PMBOK by the PMI and best practices outlined for many industries, there are no current publications supporting project management in clinical development nor current performance measures based on clinical development project management best practices. Hence there is a need for defining best practices for clinical development project management. To meet this need, Phase I defined a reference standard and actionable guide (rubric) for the assessment of clinical development PMOs. The Phase II evaluated the usability of the rubric as a tool for identifying areas of strength and opportunity for clinical development project management best practices. Although further work is necessary, this research sets the foundation for more effectively leveraging clinical development project management to expedite bringing products to patients.

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8 Appendix

8.1 Reference Standard Classification Scheme

The reference standard classification scheme uses the following hierarchy:

- Category – highest level in the scheme, total of four
    - Sub-category – groupings within categories
        - Sub-subcategory – groupings within sub-categories
            - Term – actual word taken from Phase I interviews. Reference Standard at this level (subset of total items).
                - Attribute – Description of term created using information taken from Phase I interviews. Rubric at this level (limited to terms in Reference Standard).

8.2 Interview Questions

8.2.1 Study Design

Questions:

1. What does the Center of Excellence mean to you?
2. What best practices/strategies do you employ to successfully complete your tasks?
3. What pitfalls do you avoid & how?
4. Tell me a little bit about your career path, how did you move into PM?
5. Based on your current experience in the field, what have you done differently to be more productive or to stay ahead of the game?
6. Do you have any internal or external contacts you can share in regards to assisting with my COE Research?

8.2.2 Phase I

Questions:

1. What does a Project Management Center of Excellence mean to you?
2. What PPM best practices/strategies have you personally observed (or perhaps used) that were helpful in teams/work streams to completing tasks and/or deliverables?
3. Are there specific pitfalls you have observed when trying to implement project/portfolio practices at companies you've been a part of? Some pitfalls may be situations such as: Undefined goals, scope changes, lack of accountability, lengthy decision-making processes, issues with change management, or lack of communication.

4. What difficulties with interpersonal interactions in team dynamics have you observed and were there specific tools and techniques you have seen project managers apply to avoid or resolve difficulties?
5. Regarding the PM's you've worked with, are there certain types of backgrounds or characteristics that the most effective PM's share?
6. Based on your current experience in the field, what have you done differently to be more productive or to stay ahead of the game?
7. What has your company done differently to be ahead in terms of innovation and creativity in PPM?
8. What best practices/strategies/toolkits does your company leverage to successfully complete tasks?
9. What are some PPM best-practices you've experienced with previous employers?
10. What are best-practices you noticed were different (yet positive) from standard practices at your current employer?
11. Based on your industry experience, what do you feel companies do well in regards to PPM? How do they do those things?
12. What and how would you like to do things differently in a Project Management Office if given the opportunity?
13. Do you have any internal or external PPM contacts you would be willing to share for participation in this survey?
14. What tools, best practices, systems or rules would you include in a Project Management Center of Excellence?

8.2.3 Phase II

Likert-scale Survey Questions:

Soft Skills

1. Communications in my organization are direct and to the point without being rude
2. Messages are tailored to the audience
3. Messages are conveyed with humility
4. Humor is used appropriately in communications
5. Information is shared in a timely manner
6. Information sharing is concise
7. Information sharing is precise
8. PMs are effective at communicating information internally and externally (e.g., teams, management, outside company, etc.)
9. PMs are effective at communicating constraints and potential solutions
10. PMs are effective at ensuring issues are appropriately shared across teams
11. PMs are able to effectively share the pros and cons of mitigations
12. PMs have real-time, high level knowledge of the project
13. PMs are able to effectively communicate bad news
14. PMs regularly check in with stakeholders

15. PMs leverage multiple communication methods effectively to obtain responses from team members
16. PMs check the "pulse" of the team during meetings
17. PMs are able to guide team meeting discussions so they remain constructive and productive
18. Programs are prioritized at a portfolio level
19. Trade-off decisions factor in both program and portfolio levels
20. Competitive intelligence is used to inform portfolio and product strategy
21. Organization provides opportunities for both formal training and hands on experience (including feedback)
22. Soft skills are highly valued

Hard Tools

23. My organization has a current annual budget and five-year plan
24. Projects are funded based on probability of success at the portfolio level
25. Organization tracks actuals against budget
26. Cost modeling & forecasting is used to inform budget and five-year plan
27. Projects have clearly identified deliverables
28. Responsibility for project deliverables is clearly identified
29. Delivery of project deliverables is tracked against internal and external commitments
30. Clear process for escalating potential delays in meeting project deliverables per internal and external commitments
31. Team members are kept to a minimum
32. Meeting agendas and minutes are developed and distributed in a timely manner
33. Action Item, Decision and Issues (ADI) logs are maintained
34. Risks are documented and evaluated
35. Resource needs are identified
36. Regular reviews of needed vs available resources are conducted
37. Clear process for adding resources and/or changing priorities to reduce workload in the event there are not enough resources to meet the need
38. Timelines are developed and maintained
39. Timeline projected vs actuals tracked (particularly for critical path)
40. Clear escalation process if timelines exceed agreed upon thresholds
41. Organization has timeline templates with standard durations
42. Organization has the ability to conduct scenario planning
43. Timelines are used to decrease overall development duration
44. Organization provides training for team members including team tools/processes/best practices, e.g., critical path understanding
45. PM training leverages Project Management Body of Knowledge (PMBOK)
46. Organization provides Just-in-Time (JIT) training (i.e., relevant training is provided just before needed)

Organizational Structure

47. Organization has clear escalation pathways
48. Organization has clear decision making pathways
49. Decisions in my organization are unambiguous and specific
50. Decisions in my organization are documented and readily retrievable
51. Cross-functional teams make product development faster, cheaper, and/or higher quality
52. Cross-functional teams in my organization have a clear purpose and scope
53. Team members have clear understanding of their role
54. Organizational best practices are established which are appropriate to the product development phase
55. Organizational best practices are leveraged to quickly set up teams, tools, and processes
56. Organizational best practices lead to decreased product development time
57. Organizational best practices are continuously improved through process improvement initiatives
58. Organization effectively leverages partnerships to extend resources and/or capabilities
59. Organization effectively leverages partnerships to share and/or reduce risks
60. Organization has the right-sized infrastructure in place to support projects

PMO Components

61. Does your organization have a formal PMO
62. Roles are clearly defined for PM and team members
63. PM's scope is cross-functional
64. PMs ensure teams meet organizational objectives/goals
65. PMs ensure portfolio and product strategies are developed
66. PMs help teams think strategically
67. Organization has and uses established methodologies, processes, tools, and training
68. Organization leverages PMBOK practices
69. PMs assist in establishing agreed upon goals and objectives
70. PMs assist in establishing agreed upon product development plans
71. PMs track organizational progress against goals and objectives
72. PMs escalate issues as appropriate

8.3 Reference Standard and Rubric Development

8.3.1 Reference Standard

Table 11: Soft Skills Terms

Communication: General	Communication: PM Specific	Communication: Team Management	Strategy	Experience	General
Direct	Needs to be able to communicate at all levels internally and externally ("PM and Project Lead, cross-department, can communicate at all ends, up and outward, bottom up to top down, executives")	Escalation tactics for obtaining a response from team members (Face to Face, telecom)	Prioritization at program level	Combination of formal training and hands on experience with feedback	Soft skills are more important than hard skills
Flexibility	Effectively able to communicate constraints and potential solutions (Communicates why things can't be done, if can't be done ask for more resources) to Management	Take "pulse" at team meetings	Trade-offs at program and portfolio level	Experience	
Humble	Communicates issues across team	Stop/Control conversation in meetings	Leveraging Competitive intelligence to inform strategy		
Sense of humor	Show pros/cons of mitigations				
Timeliness ("quick")	Real-time knowledge of project, high level				
Concise	Able to communicate bad news				
Precise	Regularly check-ins with stakeholders				

Table 12: Hard Tools Terms

Processes: Budget	Processes: Deliverables Management	Processes: Meeting Management	Processes: Resource Management	Processes: Timelines	Processes: Training
Annual budget and five-year plan developed and current	Clear identification of project deliverables	Keep number of team members to a minimum	Identification of resource needs	Develop & maintain timelines	Have training for team members which includes team tools/processes/best practices, e.g., critical path understanding
Portfolio of Projects funded based on probability of success	Clear identification of who's responsible for what project deliverables	Meeting agendas and minutes: developed and distributed in a timely manner	Regular evaluation of resource needs relative to available resources	Track actuals against projected, particularly for critical path	PM training leverages Project Management Body of Knowledge (PMBOK)
Track actuals against budget	Track project deliverables against internal and external commitments	ADI logs maintained	Mechanism for decision making if more resources are required than available to either 1) add more staff or 2) change priorities to reduce workload	Mechanism for escalating if timelines exceed agreed upon thresholds	Just in time (JIT) training (i.e., conducted before using)
Cost modeling (to inform budget)	Mechanism for escalating if project deliverables not tracking to meet internal and external commitments	Risks evaluated and documented		Timeline templates with standard durations	
				Ability to conduct scenario planning	
				Timelines leveraged to find ways to shorten overall development duration	

Table 13: Organizational Structure Terms

Governance	Matrix organization: Teams	Efficiencies	Alliance Management	General
Clear communication pathways	Cross-functional teams make product development faster, cheaper, and/or higher quality	Have established organizational best practices which are right sized to the project phase	Effectively leverage partnerships to extend resources and/or capabilities	Right-sized infrastructure set-up and in place to support projects
Clear decision making process	Teams have a clear purpose and scope	Leverage organizational best practices to facilitate quickly setting up teams, tools and processes	Effectively leverage partnerships to share and/or reduce risks	
Decisions are unambiguous and specific	Team members understand their role	Organizational best practices lead to decreased product development time		
Decisions are documented & readily retrievable		Continuously improve through process improvement initiatives		

Table 14: PMO Components Terms

PM Role: General	PM Role: Strategic	Methodologies	Alignment
Role is clearly defined both for PM and other roles with which the PM interacts	Ensures portfolio and product strategy developed	Established methodologies, including processes, tools and training	Help establish agreed upon goals and objectives
Scope is cross-functional	Helps teams think strategically	Methodologies appropriately leverage PMBOK practices	Helps establish agreed upon product development plan
Responsible for ensuring team meets organizational objectives/goals			Tracks progress against goals and objectives
PM Role: General			Escalates issues as appropriate

8.3.2 Rubric Development

Table 15: Soft Skills Attributes

Communication: General	Communication: PM Specific	Communication: Team Management	Strategy	Experience	General
Communications in my organization are direct and to the point without being rude	PMs are effective at communicating information internally and externally (e.g., teams, management, outside company, etc.)	PMs leverage multiple communication methods effectively to obtain responses from team members	Programs are prioritized at a portfolio level	Organization provides opportunities for both formal training and hands on experience (including feedback)	Soft skills are highly valued
Messages are tailored to the audience	PMs are effective at communicating constraints and potential solutions	PMs check the "pulse" of the team during meetings	Trade-off decisions factor in both program and portfolio levels		
Messages are conveyed with humility	PMs are effective at ensuring issues are appropriately shared across teams	PMs are able to guide team meeting discussions so they remain constructive and productive	Competitive intelligence is used to inform portfolio and product strategy		
Humor is used appropriately in communications	PMs are able to effectively share the pros and cons of mitigations				
Information is shared in a timely manner	PMs have real-time, high level knowledge of the project				
Information sharing is concise	PMs are able to effectively communicate bad news				
Information sharing is precise	PMs regularly check in with stakeholders				

Table 16: Hard Tools Attributes

Processes: Budget	Processes: Deliverables Management	Processes: Meeting Management	Processes: Resource Management	Processes: Timelines	Processes: Training
My organization has a current annual budget and five-year plan	Projects have clearly identified deliverables	Team members are kept to a minimum	Resource needs are identified	Timelines are developed and maintained	Organization provides training for team members including team tools/processes/best practices, e.g., critical path understanding
Projects are funded based on probability of success at the portfolio level	Responsibility for project deliverables is clearly identified	Meeting agendas and minutes are developed and distributed in a timely manner	Regular reviews of needed vs available resources are conducted	Timeline projected vs actuals tracked (particularly for critical path)	PM training leverages Project Management Body of Knowledge (PMBOK)
Organization tracks actuals against budget	Delivery of project deliverables is tracked against internal and external commitments	Action Item, Decision and Issues (ADI) logs are maintained	Clear process for adding resources and/or changing priorities to reduce workload in the event there are not enough resources to meet the need	Clear escalation process if timelines exceed agreed upon thresholds	Organization provides Just-in-Time (JIT) training (i.e., relevant training is provided just before needed)
Cost modeling & forecasting is used to inform budget and five-year plan	Clear process for escalating potential delays in meeting project deliverables per internal and external commitments	Risks are documented and evaluated		Organization has timeline templates with standard durations	
				Organization has the ability to conduct scenario planning	
				Timelines are used to decrease overall development duration	

Table 17: Organizational Structure Attributes

Governance	Matrix organization: Teams	Efficiencies	Alliance Management	General
Organization has clear escalation pathways	Cross-functional teams make product development faster, cheaper, and/or higher quality	Organizational best practices are established which are appropriate to the development phase	Organization effectively leverages partnerships to extend resources and/or capabilities	Organization has the right-sized infrastructure in place to support projects
Organization has clear decision making pathways	Cross-functional teams in my organization have a clear purpose and scope	Organizational best practices are leveraged to quickly set up teams, tools, and processes	Organization effectively leverages partnerships to share and/or reduce risks	
Decisions in my organization are unambiguous and specific	Team members have clear understanding of their role	Organizational best practices lead to decreased product development time		
Decisions in my organization are documented and readily retrievable		Organizational best practices are continuously improved through process improvement initiatives		

Table 18: PMO Components Attributes

PM Role: General	PM Role: Strategic	Methodologies	Alignment
Roles are clearly defined for PM and team members	PMs ensure portfolio and product strategies are developed	Organization has and uses established methodologies, processes, tools, and training	PMs assist in establishing agreed upon goals and objectives
PM's scope is cross-functional	PMs help teams think strategically	Organization leverages PMBOK practices	PMs assist in establishing agreed upon product development plans
PMs ensure teams meet organizational objectives/goals			PMs track organizational progress against goals and objectives
			PMs escalate issues as appropriate

9 Supplementary Figures and Tables

Table 19: Term count by company identifier and top level category

Company	Soft Skills	Hard Tools	Organizational Structure	PMO Components	Total
1	16	60	33	18	33
2	14	6	5	5	5
3	5	7	9	15	9
4	14	7	12	2	12
5	17	8	6	6	6
6	0	1	6	7	6
7	3	24	5	2	5
8	5	4	1	5	1
9	3	0	14	7	14
10	10	10	13	12	13
11	10	5	6	11	6
12	5	2	8	3	8
13	14	16	11	6	11
14	11	1	6	3	6
15	15	6	2	2	2
Total	**142**	**157**	**137**	**104**	**540**

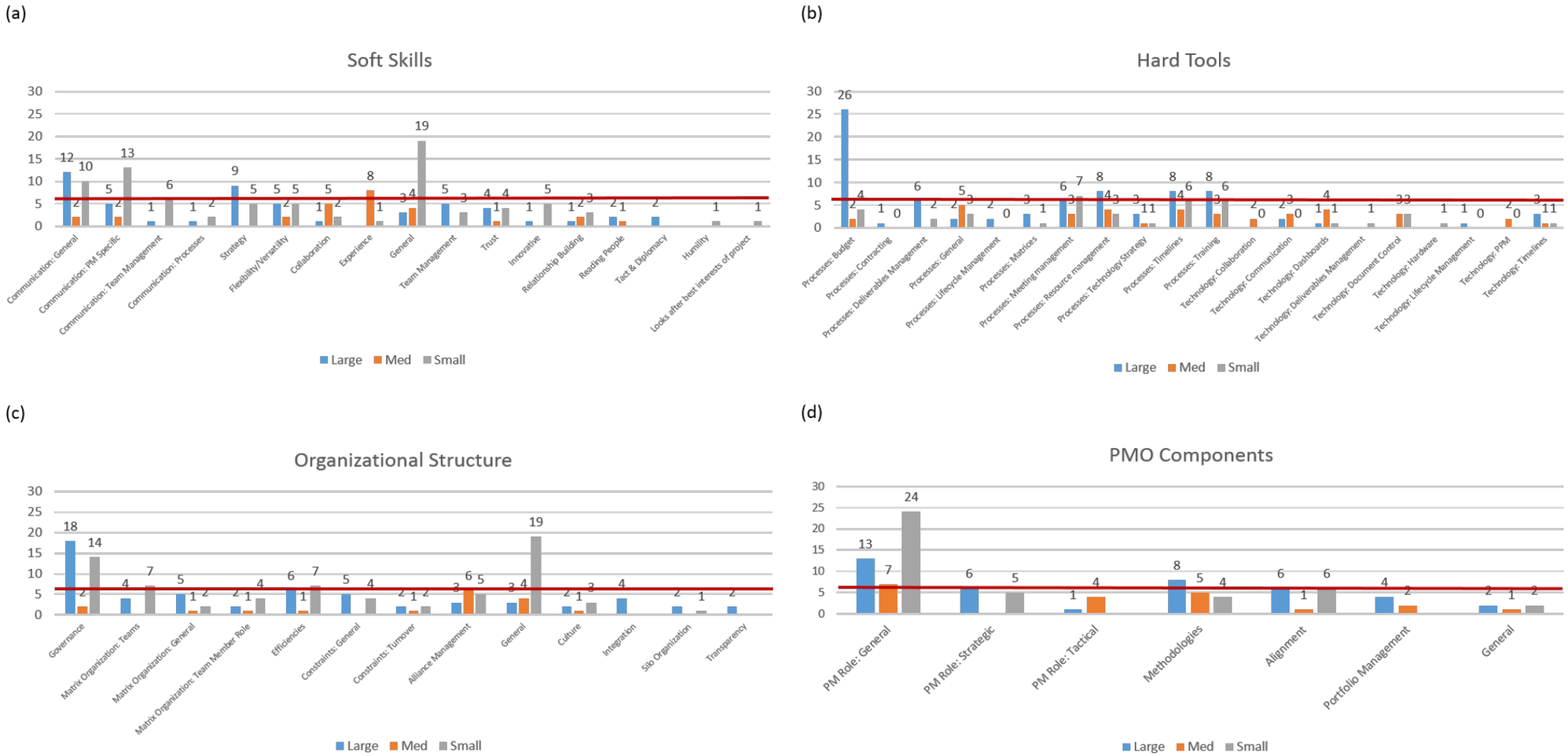

Figure 6a-d: Phase I term counts and reference standard definition cut-off
Top level categories by attribute and company size with the cut-off (>6) for the reference standard applied.

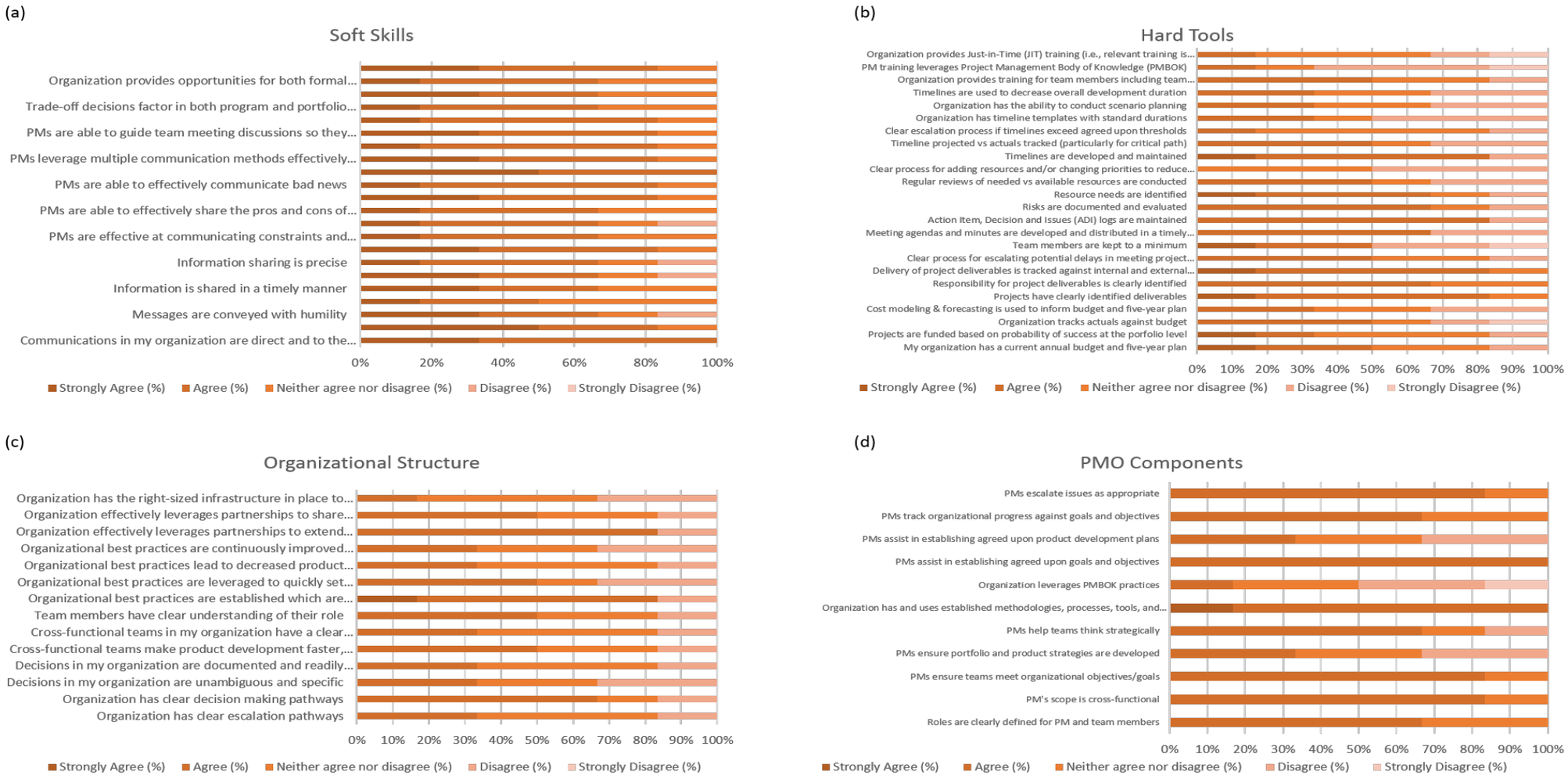

Figure 7a-d: Phase II survey results (raw data)
Phase II survey responses providing assessment of company's performance (percentage) relative to each attribute.

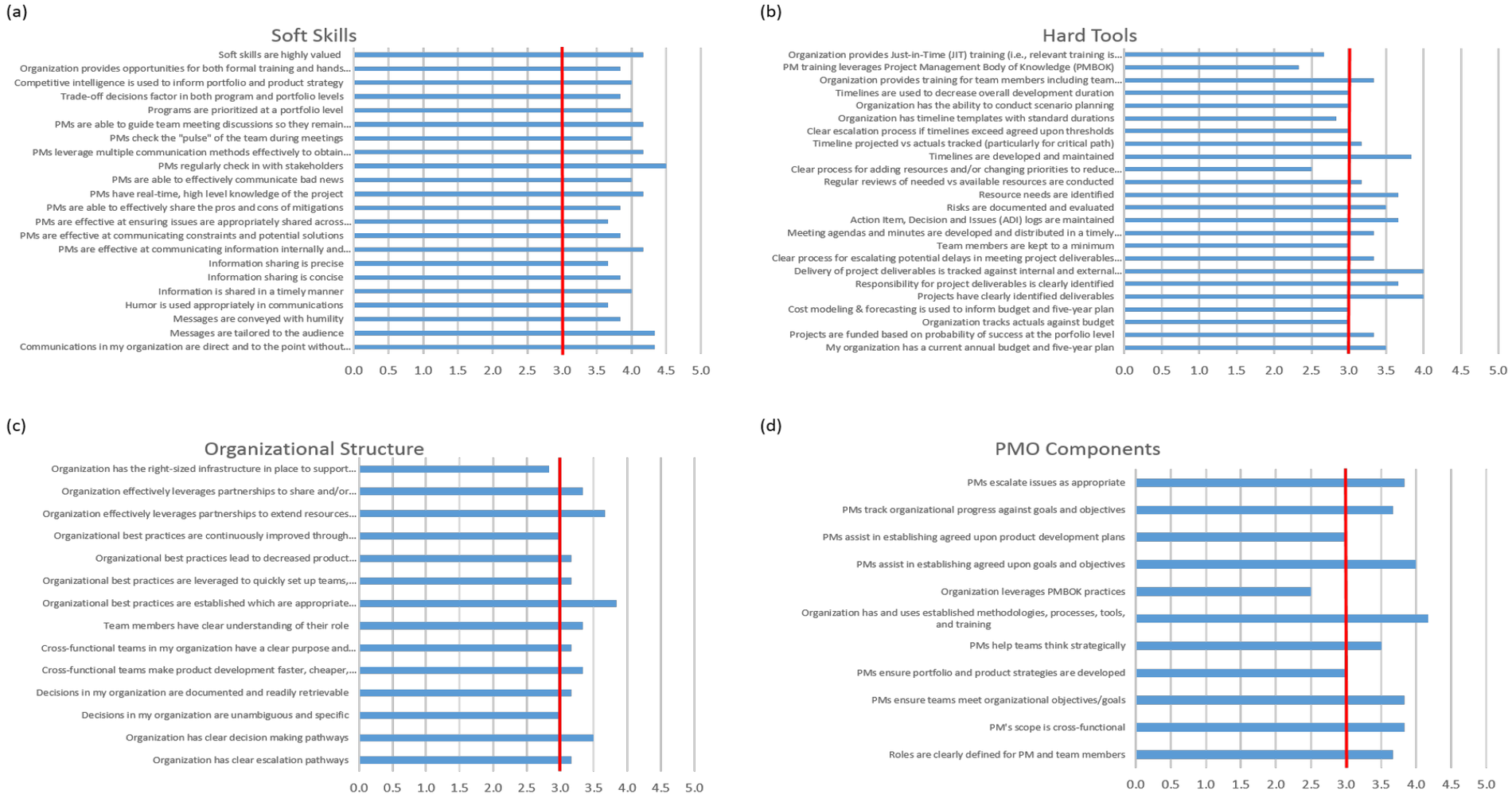

Figure 8a-d: Phase II survey results (mean) and evaluation cut-off
Phase II comparator company survey results by top level categories relative to evaluation cut-off (>3.0 as indicated by the red line).