

DEPARTMENT NAME Department Issue Analysis and Solutions White Paper

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BUSA-685: Applied Knowledge Capstone

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April 11, 2024

Abstract

The DEPARTMENT NAME department of the DIVISION NAME, part of COMPANY NAME, faces multiple challenges due to an increased workload. These issues include inter-department communication, job stress, team restructuring and training, record management, database verifications, data transfer validations, and data reconciliation. A literature review of these problems within the business environment as well as interviews have been conducted to develop both solutions and key performance indicators to track their effectiveness. Further research was limited by time constraints and limited access to certain information, but these areas have been identified for future investigation.

Introduction

The DEPARTMENT NAME department of the DIVISION NAME, part of COMPANY NAME, has been experiencing a consistently heavy workload compared to the number of employees, which has negatively impacted activity deadlines and job satisfaction. The history of OLD COMPANY NAME and the COVID-19 pandemic has impacted the increased workload. However, the rapid expansion of a business is common, and extensive research can help identify higher-level problems and potential ways to address them in areas such as job satisfaction, manager stress, records management, inter-department communication, and employee training. Some possible solutions involve restructuring the records management process, promoting job satisfaction through partial cross-training and job specialization as well as monetary rewards, breaking down communication barriers between departments, and reducing the workload of individual managers through activity sharing and rotation or restructuring the management team. Doing so will improve not only the productivity of the DEPARTMENT NAME department but also the level of job satisfaction and unity within the department.

The DEPARTMENT NAME department performs several activities in its day-to-day operations. These are database verifications, data transfer validations, and data reconciliation. In database verifications, the DEPARTMENT NAME department uses test data in a test environment that clones and imitates the actual database to verify that the setup is correct per the agreement with the client. In data transfer validations, an associate data manager will examine test data to ensure all required variables are present in the data transfer file according to the client's specifications. Data reconciliation is the correcting of data erroneously entered into the database and is usually identified by the client. Throughout these activities, who completed the

activity, when, and how long it took them, as well as proof of completion, is recorded on a SharePoint “tracker” specific to that activity.

Database verifications require the associate data manager to compare the setup of a study-specific database to the agreement established by the Project Management department and the client. The associate data manager specifically examines any rules programmed as well as any instances where a test should be blinded at a particular visit. If the database verification is not the initial setup and is a modification of an already-existing database, then DEPARTMENT NAME fees are generally required if the modification involves an external agreement. Normal priority verifications have a general turn-around-time of five business days, while an expedited verification will have a turn-around-time of one to two business days. Discrepancies between the database setup and the agreement or failure to include DEPARTMENT NAME fees when required can result in a delay, causing the turn-around-time to increase.

Data transfer validations are also performed by an associate data manager, who checks the work of a study’s assigned data manager. Like database verifications, the associate data manager creates and then examines test data. The validation confirms that the programming of the data transfer file includes all relevant samples, tests, visits, and demographic or clinical data as requested by the client. The general turn-around-time from the client’s confirmation and agreement of what is required for the first test transfer is fifteen business days. Often, the test data entry is completed by a separate associate data manager than the one performing the data transfer programming validation. A delay in the test data entry leads to a delay in the validation, which may also find issues with the output file or programming, requiring the data manager to make corrections. Delays with the validation can delay the transfer of live data to the client, which may result in frustration with the client or possible risk to a study patient.

Data reconciliation is performed by both data managers and associate data managers. The client will send a list of corrections to be made which generally includes updating the date or time that a sample was drawn or moving the sample to the correct patient appointment if needed. The requests are usually sent in a spreadsheet, with one row considered a single correction request. The turn-around-time varies depending on the number of file rows and ranges from one business day to seven or more business days for files above 150 lines. Delays or failures in correcting the data can result in missed deadlines on the client's end with regulatory bodies, the correct interpretation of results (if the update impacts sample stability and reliability), and potentially patient safety.

Partial cross-training will allow employees to maintain high job satisfaction and job enrichment while enabling them to become subject matter experts in one or two specific activities. The restructuring of managerial activities or the restructuring of management will reduce managerial stress and allow them to focus more on day-to-day issues. An additional record "tracker" of problems that have occurred regardless of whether they had a significant impact, as well as a separate record tracker for miscellaneous activities that do not already have a record tracker or are not frequent enough to warrant a unique record tracker, will allow management to fine-tune their approach to specific issues that happen repeatedly in the department. An increase in the thorough use of records will aid in audits and department decision-making, direction, and requests for additional resourcing.

Creating materials such as a reference flowchart for when DEPARTMENT NAME involvement is necessary (or should be charged) for other departments, such as Project Management or Project Design Management, will allow for greater understanding between departments. High-level and brief training overviews may also be beneficial, but this may not be

feasible depending on time constraints across trainers and attendees. Establishing specific, dedicated contacts for general department-related questions within DEPARTMENT NAME and other departments would be incredibly beneficial due to the slow response time from some team members.

Literature Review, Data Collection, and Interviews

A literature review was conducted to examine existing research surrounding the problems identified problems facing the DEPARTMENT NAME department. In addition, two methods of data collection were used to identify, understand, and provide potential solutions for problems experienced by the DEPARTMENT NAME department. The first method utilized the SharePoint trackers to obtain the metrics of database verification, data transfer programming validation, and data reconciliation. The second method involved qualitative interviews with members of the DEPARTMENT NAME department and an interview with the Project Management Department to evaluate current frustrations and understandings of the problems. All variables involving time are calculated in minutes, and all rounding is done to the nearest second decimal.

The SharePoint trackers for database verification, data transfer programming validation, and data reconciliation for 2023 were downloaded and analyzed to find each activity's various sums and averages, with database verification having the most information. Some limitations include missing due dates or completion dates or an inaccurate time to complete which has impacted some of the calculations. The general department goal is to meet 90% of all deadlines (S. Banerjee, personal communication, March 21, 2024), though some activities not discussed may have a higher requirement. Across all three activities examined, the DEPARTMENT NAME department had an overdue rate of 12.43%, as shown in Table 1. The overall goal is for no more than 10% of activities to be completed after the due date.

Table 1

Overall Sample Metrics

Variable	Number
Total number of tasks in entire sample	6934
Total number of on-time tasks in entire sample	6072
Total number of late tasks in entire sample	862
Percentage of on-time tasks in entire sample	87.57%
Percentage of late tasks in entire sample	12.43%

DEPARTMENT NAME. (2024). *DEPARTMENT NAME*.

Brief History of the DIVISION NAME, part of COMPANY NAME

Before being acquired by COMPANY NAME, the DIVISION NAME was known as OLD COMPANY NAME. OLD COMPANY NAME was initially founded by Fred Eshelman as a consulting firm in 1985 before beginning to offer development services. Between 1996 and 2019, OLD COMPANY NAME developed its offerings to include drug development and discovery. During this time, OLD COMPANY NAME was a publicly traded company before being purchased by the Carlyle Group, and it became independent once more shortly after. By 2020, OLD COMPANY NAME had expanded worldwide and had more than 25,000 employees. In 2021, the company was acquired by COMPANY NAME and had 35,000 employees by 2022. Along with its second initial public offering in 2020, OLD COMPANY NAME was able to capitalize on the urgency and opportunities that the COVID-19 pandemic presented by obtaining contracts with multiple pharmaceutical companies developing treatments for the COVID-19 virus. This increased revenue and the pre-pandemic growth allowed the company to expand and grow significantly, taking on even more contracts (OLD COMPANY NAME, n.d.).

Job Satisfaction and Stress and Their Impact on Productivity and Interview Findings

Job satisfaction and high morale are critical to the success of any business. If employees are not given the proper tools to do their tasks, productivity and efficiency will decline.

Similarly, if the needs of the employees are not met, their desire to be productive and efficient will also decline. Repeated or long-term exposure to a negative work environment will decrease their morale, which may decrease their attention to department needs and dynamic situations (Abdul Basit et al., 2018). Job stress can also significantly reduce productivity. In addition to their responsibilities and ensuring productivity amongst their direct reports, managers must also provide guidance and assist their employees in day-to-day activities. Job stress can negatively impact their ability to complete their responsibilities while supporting their direct reports.

Although there is a negative correlation between a manager's job satisfaction and stress, it is not statistically significant, and a manager may still have high job satisfaction despite the stressful environment (Sen, 2008).

Job morale can also impact productivity. According to Spellman (1979), tying a college faculty's salary to enrollment rates would not motivate professors to be more productive. This is likely true for most industries, where employees are encouraged to be more productive for the company's betterment and not necessarily for their benefit. Spellman (1979) also pointed out that employees will likely be more motivated to be productive if their performance is directly tied to their pay. Periodic bonuses based on individual performance throughout the year would likely motivate employees to work harder, knowing they may receive additional rewards beyond the generic and distant annual raise and bonus.

Despite a common perception of a "lazier" or "entitled" workforce amongst younger generations, current research into generational differences indicates that while workplace differences do exist, there is no significant change between generations in terms of workplace

attitude or ethics (Costanza et al., 2012), suggesting that job morale is often tied to personal fulfillment and not necessarily or primarily the success of the company as a whole. Therefore, ensuring high job satisfaction amongst employees is a much more practical target for improving employee productivity across all age ranges instead of corporate statements and slogans about how well the company is or is not doing.

A real or perceived sense of job insecurity can lead to decreased productivity, especially if the employee becomes angry at the organization or experiences shame due to feeling like they do not belong (Guohua Huang, 2021). Deadlines are often perceived as goals or a measure of time management (Waller, 2001), and missing those deadlines may lead to feelings of job insecurity for the employee, more so if they are held liable despite not being at fault or responsible for the missed deadline. While job insecurity may lead to a temporary boost in productivity in quantitative terms, the quality of work will decrease due to stress.

Managers play a vital role in any business. They must relay the demands and requirements of the department that their superior has issued. Sometimes, this can overload their employees with too many goals. Effective time management, communication, transparency, and delegation of their responsibilities can alleviate stress and pressure (Trakaniqi et al., 2022). Prolonged exposure to job stress can lead to burnout. Increased job stress has led to decreased task performance, while burnout can lead to decreased organizational performance (Leung et al., 2011). The rotation of all or some activities and responsibilities may ease the manager's stress and help stabilize or boost their performance.

Job satisfaction was generally high amongst those interviewed within the DEPARTMENT NAME department, but job stress was mixed. More experienced team members, including management, appeared to experience more stress. This is likely due to a greater

awareness of the work environment, and remembering when a process was more straightforward before quality assurance “complicated” the procedure.

Data managers experience a high volume of emails from other departments and clients and are expected to respond quickly. This is a common source of stress (A. John, personal communication, March 20, 2024), and the number of emails to respond to only gets worse when a team member takes paid time off – especially if the client refuses to acknowledge the impending time off (W. Scheele, personal communication, March 20, 2024) or utilize the backup contact. However, the level of stress or feeling overwhelmed on a day-to-day basis does not appear to be an issue for many team members. Missing deadlines can be overwhelming, but if it is not the team member’s fault, it does not weigh as heavily on their conscience. The holidays are generally more stressful, as more people are out of the office, but the workload does not always change (D. Palou, personal communication, March 21, 2024).

Job stress among managers was higher than the rest of the team. The number of different responsibilities and the volume of meetings while assisting the manager’s direct reports or other team members is one primary source of stress (S. Banerjee, personal communication, March 21, 2024; H. Parr, personal communication, March 26, 2024). Resourcing for these demands is not currently available (C. Henry, personal communication, March 26, 2024); thus, someone or something is at risk of being left behind or missed.

Activity Cross-Training Versus Specialization and Interview Findings

A business may have its employees cross-trained across multiple activities or specialize in a single activity. Employees who are cross-trained to perform different types of activities generally allow for a more flexible work environment and increased coverage, while employees

who specialize in a specific activity or a smaller number of activities will generally output a higher level of quality work.

Cross-training not only increases the general coverage that a group of activities receives, but it also safeguards against employee absenteeism and reduces the impact of an employee who may be out of the office or not skilled in a particular activity. This impact has only been observed during average workloads, and periods of peak demand may lead to decreased quality as the cross-trained employee attempts to provide coverage for multiple activities. Full cross-training can offer the most flexibility and guaranteed coverage but can be challenging to maintain as employees gravitate towards preferred activities (Easton, 2015). Job satisfaction and enrichment are essential for an employee to succeed, and having to perform a variety of activities will keep them engaged and stimulated (Olivella & Nembhard, 2017); however, if they are responsible for too many activities, then they may feel that they are unable to accomplish individual tasks on time or with acceptable quality.

Specialization allows an employee to become dedicated and highly skilled in a particular activity at the expense of their ability to perform other activities. Specialization can significantly increase the employee's productivity and output quality (Wipperfurth, 2014). Specialization can also reduce the amount of attention and time the manager must give in assigning activities to their employees and ensuring that work is being completed. However, job satisfaction and enrichment can significantly decrease if the employee is misassigned and required to specialize in an activity they do not enjoy or are not skilled at. Single-activity specialization may also lead to burnout and absenteeism, decreasing employee productivity (Marentette et al., 2009).

Partial cross-training trains groups of employees on specific activities, leading to a greater mix of benefits between full cross-training and specialization. Partial cross-training

allows highly specialized or dedicated training in a specific activity while having flexibility and the ability to provide limited coverage when necessary (Easton, 2011). Partial cross-training increases the level of job satisfaction and enrichment the employee has, as they can perform multiple activities while serving as an expert in one area.

The DEPARTMENT NAME department employs full cross-training within the roles of associate data manager and manager, with only a couple of team members being explicitly specialized in one activity. This has led team members to gravitate towards preferred activities and potentially neglect other activities. There is an interest in partial cross-training and specialization, creating sub-teams that primarily focus on an activity or set of activities while still maintaining the ability to complete other activities as needed. One example is a group of team members that focuses on training and onboarding newly hired team members or a team dedicated to programming reports (C. Henry, personal communication, March 26, 2024).

Inter-Department Communication and Interview Findings

Almost all larger businesses will have more than one department in their organizational structure. Multiple departments will often work together to achieve a single goal, such as improving internal processes or assembling separate components of a product. Communication, understanding, and an awareness of potential knowledge gaps between departments will improve productivity in each department and ensure that all stakeholders involved are satisfied with the outcome. Encouraging engagement and understanding between departments can also lead to further innovation and higher employee retention rates (Bhatnagar & Biswas, 2010).

Consistent and accurate communication between departments is critical to the success of any activity. If there is a knowledge gap and an inability to bridge that gap, then the department

lacking the required information will have to engage in signaling theory, which is decision-making without being fully aware of all data points or perspectives. This information asymmetry is often a result of inter-department team members having separate operational purposes and who are not dedicated to consistently working with one another daily. The asymmetry will be worse if team members have competing objectives or interests that do not align with the goals of the other team members' departments (Ehrhardt et al., 2014). Information asymmetry can be reduced between departments by asking specific questions, understanding the how and why (Posner, 2010), and establishing specific contacts who can answer questions when more information is required.

Departments may also engage in some form of competition, primarily if the “loser” is held responsible for the issue. In this sense, competition can reduce knowledge gaps in that it is in the first department's best interest to understand the other department's processes and needs as much as possible to lessen the risk that they are at fault for any issues or conflicts that may arise (Luo et al., 2006). Innovation further occurs when senior management is involved in a supporting capacity and an experienced team member leads the task. Cross-department teams can have a net positive benefit if the organizational structure and culture foster such collaboration (Blindenbach-Driessen, 2015). However, any inter-department competition should remain focused on a shared business goal, and neither department should be actively trying to sabotage the activities or employees of the other department. It is important to show a unified, single front when dealing with customers, and no individual department should be blamed in external contact.

One of the reasons for delays in DEPARTMENT NAME activities is improper or unclear communication between the DEPARTMENT NAME department and other departments,

specifically Project Management and Project Design Management. Project managers will reach out to a study's assigned data manager for information on a pending request and receive a delayed response if any response at all. Even if it is late, providing an updated timeline is still appreciated by the project manager as they can keep the client informed and assured that the work is still being done. Additionally, most project managers are unaware of the technical details of DEPARTMENT NAME activities, and newly hired team members often struggle to understand the difference between DEPARTMENT NAME and IT departments (K. Hoffert, personal communication, March 22, 2024).

While database discrepancies or unclear communication may be the responsibility of the project manager or project design manager, the DEPARTMENT NAME department is not entirely blameless. Data managers need to take ownership of their work and actively engage and discuss requests with the requestor to meet deadlines and help the project manager understand the current situation (C. Henry, personal communication, March 26, 2024). Doing so will promote a sense of dependability and trust between departments and ensure that client expectations are met.

Database Verification Metrics and Interview Findings

Roughly 618 database verifications were completed in the year 2023, and 605 of these had both a listed due date and completion date. Only these 605 database verifications were included in the sample. 534 database verifications were on-time, while 71 database verifications were late, resulting in 11.74% of the database verifications in 2023 being completed after the due date.

As shown in Table 2, most database verifications were completed on-time, and the number of late database verifications did not change drastically based on priority status (normal versus expedited). However, late database verifications took significantly longer than their on-time counterpart and had almost twice the number of rules to be verified. For normal priority blinding, late database verifications had over twice the number. Expedited priority blinding late database verifications had well under twice the number of blinding instances.

Table 2

On-Time and Late Database Verifications Metrics

Priority/deadline	Total number	Average time to complete (min)	Average number of rules/custom tox grades	Average number of blinding instances
Normal on-time	369	130.79	10.15	20.4
Normal late	36	270	18.92	51.92
Expedited on-time	165	169.21	18.68	64.4
Expedited late	35	496.14	33.37	37.77
Total	605	170.69	14.12	35.18

DEPARTMENT NAME. (2024). *Verification tracker*.

This data suggests a positive correlation between the time needed and the number of rules or custom tox grades. The correlation between blinding and turn-around-time cannot be determined currently as there are two methods of verifying a study’s blinding, and the faster method is not always available.

There are multiple reasons that a database verification may be delayed. Some clients do not sign modification agreements, which the associate data manager may not be aware of. This can create confusion and delay while waiting for an explanation from the project manager or project design manager (W. Scheele, personal communication, March 20, 2024). Failure to upload clear and proper documentation can also cause delays (S. Banerjee, personal

communication, March 21, 2014), especially if a correction requires the client to review the update and resign any agreement. One of the most common documentation issues is the exclusion of DEPARTMENT NAME fees.

Management will usually notify the team of an expedited priority database verification, or if there are multiple pending database verifications to be completed (W. Scheele, personal communication, March 20, 2024). The project manager or project design manager may contact the assigned data manager for the study with questions to confirm what activities the DEPARTMENT NAME department needs to perform, but slow or no responses force the project management team to move forward without the input of the data manager (K. Hoffert, personal communication, March 22, 2024). Often, this means that the associate data manager will find discrepancies that the project design manager must then correct, which leads to delays in the completion of the database verification.

Across all activities, attitudes towards due dates vary per individual, how demanding the client is, and can depend on the overall department workload. Team members being out of the office can cause an increase in individual workload as well (D. Palou, personal communication, March 21, 2024). This attitude can be worsened if an excessive number of expedited database verifications are submitted in a given period (H. Parr, personal communication, March 26, 2024) and reduces the perceived urgency of expedited verifications on the part of the associate data managers.

The late completion dates found in this sample are the fault of the DEPARTMENT NAME department. The department currently does not track when a database verification is delayed due to reasons outside of the department, such as a discrepancy between the database and the client agreement or technical issues. In these instances, the original due date is pushed

back as the database verification request was not truly ready. Delays often mean work cannot be performed on the specific request; however, the issue may be later resolved as part of a backlog during a higher demand for database verifications. This, in turn, may cause newer requests to be pushed back, or the delayed database verification request will simply be late.

Data Transfer Validation Metrics and Interview Findings

A total of 446 data transfer programming validations were completed in the year 2023. Of these, 211 were completed on-time while 235 were late. This resulted in 52.69% of all validations for the year being completed after the due date. This high percentage is significantly higher than the other two DEPARTMENT NAME activities being examined.

Table 3

On-Time and Late Data Transfer Validation Metrics

Data transfer validation	Average test data entry time (min)	Average data transfer validation time (min)
On-time data transfer validation	76.2	90.9
Late data transfer validation	86.6	150.6
Total data transfer validation	81.7	122.34

DEPARTMENT NAME. (2024). *Data transfer setup*.

The data in Table 3 reveals that late data transfer validations take significantly more time – about 2½ hours compared to the average on-time data transfer validation time of 1½ hours. This may result from late data transfer validations being larger or more complex than the average on-time data transfer validations. The same is likely true for the time needed to complete test

data entry. However, the time needed to enter test data depends on the method used to create the test data and the individual speed of the associate data manager.

One of the reasons that data transfer validations have such a high percentage of late completion is because of the activity’s complexity and time constraints. Due to a heavy workload in other activities, associate data managers do not always prioritize the completion of data transfer validations (W. Scheele, personal communication, March 21, 2024). Technical issues in the database test environment can delay test data entry, causing the validation process to halt. Any updates may also require additional test data or regeneration of the validation files. This is often not enough time to be completed in fifteen business days (A. John, March 20, 2024).

Data Reconciliation Metrics and Interview Findings

Roughly 5,883 data reconciliation files were completed in 2023, and 260,065 rows worth of requests. Of these, 5,327 data reconciliation files were completed on time, while 556 were completed after the due date. This is around 9.45% of all data reconciliation files being processed late. Many late reconciliation files are a combination of a large number of row requests and clients demanding a faster turn-around-time than is standard.

Table 4

On-Time and Late Data Reconciliation Metrics

Data reconciliation	Average number of rows	Average time to complete (min)
On-time data reconciliation	41	47.78
Late data reconciliation	75	84.02
Total	44	50.97

DEPARTMENT NAME. (2024). *Data reconciliation*.

According to the data in Table 4, there is likely a direct correlation between the number of rows and the time needed to complete the file. The number of rows and time needed will increase the turn-around-time. Current turn-around-times are listed in Table 5. Clients are often demanding and do not acknowledge or understand that there are other studies and will request that a data reconciliation be expedited (W. Scheele, personal communication, March 20, 2024) without a justifiable reason.

Table 5

Standard Data Reconciliation Turn-Around-Times

Number of rows	Number of business days
0-15	Same day/one business day
16-25	Two business days
26-50	Three business days
51-100	Four business days
101-150	Five business days
151+	Minimum seven business days

DEPARTMENT NAME. (2024). *Data reconciliation*.

Management often sends out reminders about pending data reconciliations (W. Scheele, personal communication, March 20, 2024); however, there is no automated reminder system currently set up for the data reconciliation SharePoint page and relies upon the manual review (S. Banerjee, personal communication, March 21, 2024). If the overall file is unclear or uncertain, the assigned data manager or client is contacted to provide clarification. This uncertainty risks delaying the request, and updates may not be reflected in the data transfer or database by the date requested by the client.

Documentation, Management, and Retrieval of Records and Interview Findings

Creating, maintaining, and accessing records is vital to any business. Records may contain information ranging from sales and tax forms to day-to-day events. With accurate records, a business can reliably identify trends or inefficiencies that may help it improve its strategy. If an audit is required by the Internal Revenue Service or a licensing or certifying organization and reliable records are not found, then the business could suffer from fines or a reduction in the number or depth of services that it can offer.

Although the DIVISION NAME utilizes electronic and paper records to store data, the DEPARTMENT NAME department is exclusively dependent on electronic records. These records are governed by Title 21 CFR Part 11, which applies to records that have been “created, modified, maintained, archived, retrieved, or transmitted” electronically and that a detailed audit trail and history of the record be maintained (Part 11, Electronic Records; Electronic Signatures - Scope and Application, 2003). For the DEPARTMENT NAME department, most records are documentation that the database, data transfer, or data reconciliation has been verified, updated, and completed so that every instance of department involvement in a study is documented. Records also include client agreements, electronically signed per Title 21 CFR Part 11. Failure to adhere to these regulations may result in the U.S. Food and Drug Administration taking legal action against the company, or it may result in a loss of study contracts if client audits have similar findings. International businesses, including the DIVISION NAME and COMPANY NAME, must also generally adhere to guidelines set forth by the International Organization for Standardization, in this case, ISO 15489, which sets the international standard for business record management (International Organization for Standardization, 2018). ISO 15489 regulations largely complement or overlap with Title 21 CFR Part 11.

Proper documentation and record-keeping should be efficient, and going beyond the legal requirements can reveal inefficient or unnecessary procedures within the business, identify areas of improvement, and potentially save time and money (Brichford, 1972). Good record-keeping practices can enhance the ability of a business to make reliable decisions based on quantitative data and not solely on subjective or biased personal experiences and reports. Good record-keeping should fulfill requirements and add value to the business in a way that allows the records to be used for the employees' benefit (Lin, 2015).

The SharePoint system that the DEPARTMENT NAME department uses is very complicated to set up and is not robust. Email notifications about due dates are sometimes inconsistent, files fail to upload, trackers may not submit at all, and the pages are not very user-friendly (A. John, personal communication, March 20, 2024). Multiple interviewees stated that a software or website other than SharePoint would be preferred (D. Palou, personal communication, March 21, 2024; C. Henry, personal communication, March 26, 2024). Most records are also stored per Standard Operating Procedures, often outdated, unclear, or difficult to read (S. Banerjee, personal communication, March 21, 2024), creating further confusion and errors in proper documentation.

Solutions and Key Performance Indicators

There are several solutions available to address each area that has been examined. Database verification, data transfer programming, data reconciliation, and records management all have independent solutions with some overlap, while job stress, management, and team restructuring have overlapping solutions. The key performance indicators for each activity or area will vary. They may need to be adjusted depending on the overall expectations and

workload of the department, such as if a major client begins doing business midway through the year.

Solutions and Stress Key Performance Indicators for Job Stress and Team Restructure

An informal restructuring of the team would have multiple benefits. A restructuring can encourage personal growth in each team member, promote job satisfaction, reduce stress, and reduce the number of overdue activities. Most, if not all, of the solutions presented would also benefit many of the areas already discussed.

Similar to the concept of a primary team member for the data transfer validation, one or two people being responsible for each major activity and encouraging them to become subject matter experts will challenge them to grow and more productively contribute to the team. If there are no pending requests for that activity, they should assist in other activities. This can help negate the adverse effects of specialization, such as low job enrichment or stimulation, while also helping the team member feel important to the larger company. However, extra caution should be taken when deciding who will focus on what activities, as choosing the wrong person may create more issues than it solves.

These semi-dedicated team members can also serve as points of contacts for their activity. If someone has a question, they will serve as the first person to ask. In some activities, such as database verification, these points of contact can also be the go-to team member for other departments who may have questions when submitting a request specific to that activity. This will lighten the burden on individual data managers who may not be able to respond to every individual question that they receive. Having specific points of contact for other departments will also improve inter-department communication.

The DEPARTMENT NAME department is also overworked in regards to due dates and the workload is too heavy for the current number of team members. Management's workload is also heavy, and a consistent 40-hour work week seems out of reach with all of the managerial responsibilities and assisting their direct reports in day-to-day activities. Excluding management and senior data managers, the team is currently made up of 29 team members – fifteen data managers and fourteen associate data managers. Once again, excluding management and senior data managers and including the primary and secondary/backup data manager role on a study, each data manager or associate data manager is involved in an average of 81.48 studies. For associate data managers, this can be in addition to other work for studies not directly assigned to them.

There are currently two associate data manager positions open at the time of writing, which would bring the below-management/senior data manager team to 31 team members. Hiring two additional data managers would increase the team's size to 33. A team size of 33 would reduce the average team member's study load from 81.48 to 71.6, or a 12.13% decrease. The team of 29 is currently split between two managers, and a team of 33 would increase the direct reports for each manager to sixteen and seventeen. The hiring of an additional manager could instead reduce the number of direct reports for this hypothetical team down to just 11 direct reports. Not only would an additional manager help manage the team itself, but they would be able to absorb some of the workload that the other two managers are experiencing. The number of department activities will only increase as the company continues to expand, and continuing to overload the department risks an increase in burnout, turnover, and more frequent quality events and mistakes being made.

Actual financial data and statistics were unavailable for salary, however using a standard 1.4x formula to calculate the true cost per employee and a guesstimate of the base pay of an associate data manager (\$60,000), data manager (\$75,000), and manager (\$90,000), the total annual pay for the hiring of two associate data managers, two data managers, and a manager would be around \$511,000. Taking into account a standard 4% annual raise, the total cost from the first year of service to the third year of service would be about \$1,595,137.60. However, these numbers are likely not accurate, and further research would need to be conducted at the management level.

All of these solutions can improve the quality of work and job satisfaction in the DEPARTMENT NAME department. A key performance indicator for this solution is self-report surveys from each team member on their level of job satisfaction and stress on a semi-annual basis, and a specific focus on those team members who have been partially specialized. A six-month period will also give time to team members and management to learn, adjust, and become skilled in the department activities. Another key performance indicator could be a decrease in recorded quality events with the Quality Assurance department. To a lesser extent, a reduction of overdue activities may also signal effectiveness but this could also be a result of any of the other proposed solutions presented in this paper.

Solution and Satisfaction Key Performance Indicator for Inter-Department Communication

Communication between the DEPARTMENT NAME department and other departments is currently struggling to maintain consistent, reliable, and clear communication, particularly with the Project Management and Project Design Management department. The intended goal of the two proposed solutions is to both require DEPARTMENT NAME to be more responsive and

to increase understanding of both the DEPARTMENT NAME department for other departments, as well as DEPARTMENT NAME's understanding of those departments. Doing so will not only increase collaboration but also help build a better work culture.

A lack of responsive data managers appears to be the most frequent complaint by project managers (K. Hoffert, personal communication, March 22, 2024). Requiring data managers to respond to and at least acknowledge all questions, regardless of whether an answer is immediately available, would greatly improve perception within the Project Management department. Whether this is through Microsoft Teams messages or email should be determined between the study's assigned project manager and data manager. Many of the questions asked by project managers generally involve providing an estimated completion date for a pending DEPARTMENT NAME request, and even if it will be completed late project managers can give a more accurate timeline to the client, who may otherwise become frustrated with continuous delays.

The lack of understanding has also been acknowledged by the management team of DEPARTMENT NAME, who would like to see data managers take more ownership of their work and be more proactive in communicating with project managers (C. Henry, personal communication, March 26, 2024). Having quarterly "seminars" on the DEPARTMENT NAME department's day-to-day activities may help better demonstrate our needs and workload to project managers and project design managers. High-level tutorials and walkthroughs of various activities, such as database verifications or data transfer validations will help other departments better understand what DEPARTMENT NAME team members see from their perspective and what they need to complete a request. If other departments can do the same, it would help

DEPARTMENT NAME see the perspective of those colleagues and the pressure that they are under.

The key performance indicator for this task will be much more difficult to measure within a specific period due to fluctuations in the company's overall workload. Additional discussion on training may be needed to fine-tune presentations, and direct communication between a data manager and project manager or project design manager may not be consistently feasible. While these solutions may not show reduced missed deadlines overall, they will help reduce stress and anxiety between inter-department team members. An initial satisfaction survey of one department's perception of DEPARTMENT NAME and vice versa before implementing any solutions and then periodically after implementing solutions would give an idea of how effective the solutions are. Quarterly reviews would be the most time-effective. The pre-implementation survey and the percentage of those satisfied with the DEPARTMENT NAME department would set the baseline. A goal of a 10% increase in satisfaction each year (with an intended 30% increase after three years) would reflect significant improvement, or an overall target goal of 95% satisfaction within five years if the baseline is already greater than 70%.

Solution and Turn-Around-Time Key Performance Indicator for Database Verification

There are two main solutions to improve the cost-effectiveness and turn-around-time of database verifications. The first solution is to raise the minimum number of hours for the DEPARTMENT NAME fee to three hours, and the second solution is to increase understanding within the Project Management department about when the DEPARTMENT NAME fee is required.

The first proposed solution is to increase the DEPARTMENT NAME fee minimum hours per database verification. These fees are assessed before the actual database verification, which often differs in completion time from the fees charged. A total of 335 database modifications were submitted for database verifications in 2023. Of these, 251 were normal priority and 84 were expedited. These numbers assume every database modification was an external modification and that the fee for every modification was the standard two hours or a hypothetical three hours. This lack of data can be resolved by tracking the number of hours charged and the modification type in the verification tracker.

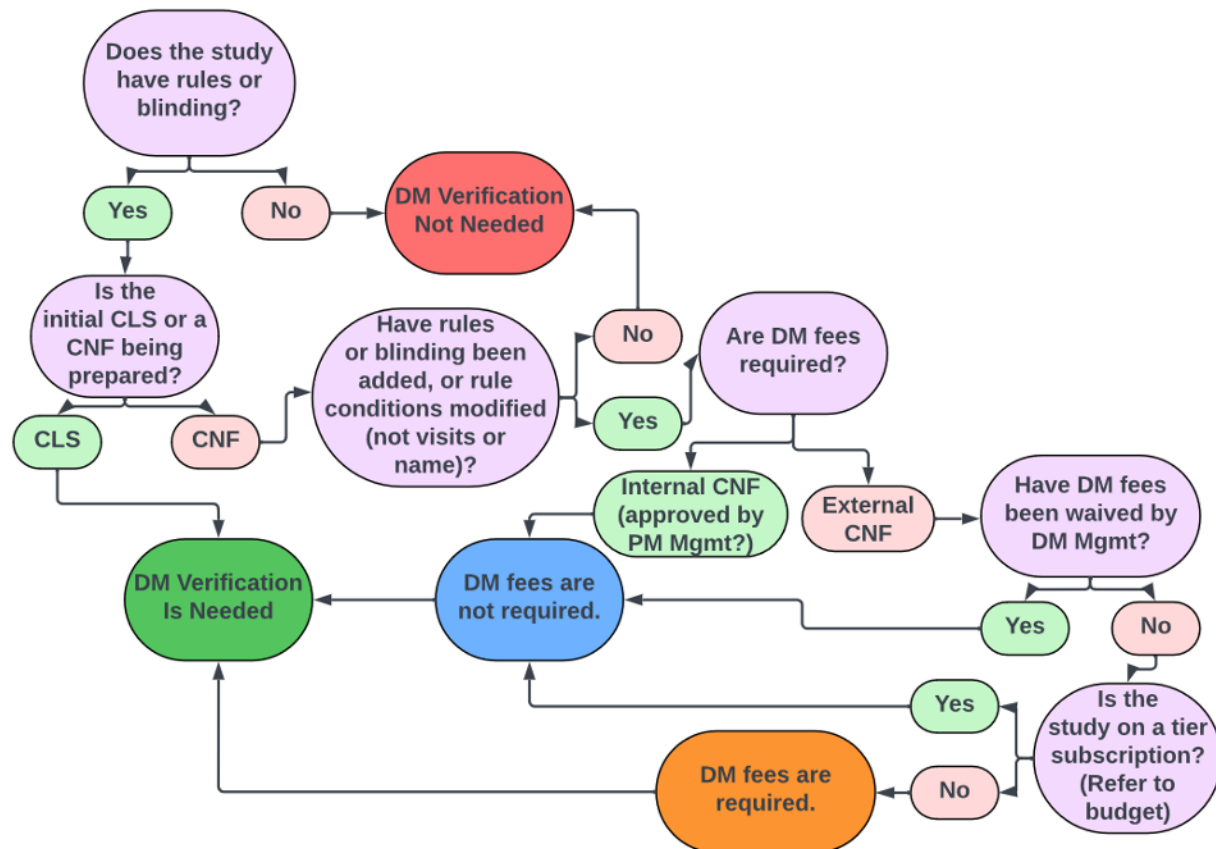
The number of overall verifications where a due date and completion date were present in 2021 was 488, 586 in 2022, and 605 in 2023, with a three-year average of 559.67 database verifications per year. These numbers exclude verifications where the due date was at the start of the year or the completion date at the end of the previous year. The increase in the number of database verifications per year is likely to increase, and raising the minimum number of hours to three hours will be more reflective of the average time that was needed to complete a verification in 2023. Further research is needed, however, to calculate the true cost of external modifications as the current average time includes initial database verifications and internal modifications, which do not have DEPARTMENT NAME fees.

One of the most recurring problems experienced in database verification is the absence of DEPARTMENT NAME fees for external modifications. This either costs the DEPARTMENT NAME department money because the fee is then waived due to urgency, or it costs time for the client and study start date because the document must be updated and the client informed of the fees. The solution to improve the turn-around-time of database verifications is the creation of a flowchart for the study's assigned project manager and project design manager to reference.

Figure 1 serves as an example of this flowchart. This will reduce the uncertainty of whether DEPARTMENT NAME fees must be included or if a study requires database verification to be performed by the DEPARTMENT NAME department. As a secondary effect, it may also reduce the number of questions submitted to the study's assigned data manager and consequently lighten their workload.

Figure 1

Is DM Verification and DM Fees Required?



Solutions for inter-department communication may also reduce the backlog of database verifications where the associate data manager is waiting for an issue to be resolved by another department.

Roughly 11.74% of database verifications completed in 2023 were completed past the due date for which the DEPARTMENT NAME department was responsible. While this proposed solution does not necessarily address areas where the department is at fault, it will help reduce the backlog of delayed database verifications caused by other departments. The target goal is to keep the percentage of late database verifications at or under 10%, meaning a reduction of at least 1.74% compared to the previous year. Analysis of the database verification SharePoint trackers every quarter and an annual review in early 2025 will allow management to see if the proposed solutions have reduced the number of late database verifications. Reliably determining

the solution's effectiveness may only be evident after a year, as many database verifications are submitted during the beginning and end of the year and should be included in the final sample pool. If the number of late database verifications is still above 10% per year by the start of 2028 or a decreasing trend is not present by the second year, additional solutions will need to be investigated.

Solution and Turn-Around-Time Key Performance Indicator for Data Transfer Validations

Around 52.69% of data transfer validations completed were overdue in the year 2023. While this may include validations other than data transfers, their completion dates being past the due dates is still an issue. Two potential solutions are available: increasing and enforcing the standard turn-around-time for data transfer validations and dedicating a small number of team members to prioritize their completion.

The current turn-around-time for data transfer validations is fifteen business days from the signing of the data transfer agreement to the first transfer. This also includes test data entry, often submitted as a semi-separate request. As shown in Table 6, increasing the total turn-around-time to twenty days, with five days allocated solely to test data entry and the remaining fifteen to the actual programming and validation work, would provide significantly more time and reduce the stress on the data manager. Should this solution not be possible, the data manager could enter a due date specifically for test data entry and later update it for the completion of the actual data transfer validation (A. John, personal communication, March 20, 2024). However, this solution may not be as effective due to the amount of manual work required in updating the due date.

The other solution is to select one to two team members to prioritize data transfer validations above all other activities and generally only aid in other activities when there are no pending data transfer validations or their assistance has been requested by management. However, a careful evaluation of who will be selected for this should be performed. The team members will still require job enrichment, and being partially specialized in a task they do not enjoy may result in them seeking employment elsewhere. One potential remedy for this is to also task the team member with finding ways to improve the data transfer validation process and requesting their assistance on any modifications to its standard operating procedure document. This solution will likely be more effective than solely increasing the turn-around-time, but is riskier due to the potential for low job satisfaction. The role should also be given to someone who has a lower number of study assignments as a secondary data manager so as not to overwhelm them.

Key performance indicators would be reviewing the data transfer validation SharePoint trackers quarterly and annually to see if the number of late data transfer validations is down. While the target goal should be no more than 10% late, an initial goal of around 40% will allow management to see if the solutions have had any meaningful impact or if the reason for late completions is due to something other than the turn-around-times. Improvements should be reflected after a full quarter compared to the previous year's same timeframe in the SharePoint trackers. If the number of late data transfer validations is not below 22.69% within three years, additional measures will be needed.

Solutions and Quality Key Performance Indicators for Data Reconciliation

The number of late data reconciliation files in the year 2023 was around 9.45%, which is below the 10% target goal. The modified target goal for data reconciliation will instead be 9% to

demonstrate a commitment to the continuous improvement of turn-around-times, but the primary goal will be quality improvement. Many data reconciliation files returned to the client have poor responses or incorrect updates being made to the database. Part of this reason is poor enforcement of the turn-around-time. To improve the quality of data reconciliation, two primary solutions have been proposed: an adjustment of the standard turn-around-times based on the number of rows in the file and stricter enforcement, as well as a greater emphasis on requests that have been marked urgent. Ideally, improvements will be reflected in the SharePoint tracker data within six months, but a full year will give a better idea by including the impact of seasonal fluctuations.

One of the reasons for lower quality work, as well as the data reconciliation files that are late, is due to the current standard turn-around-times. Clients often ignore these turn-around-times and often expect a large number of corrections to be done within a couple of days. Increasing the turn-around-time and enforcing them will not only further reduce late data reconciliation files but also give team members more time to work through the files and carefully read each request without making assumptions or erroneous updates. An example is given in Table 6, but more research is needed to determine a more realistic number of business days needed based on the number of rows.

Table 6*Modified Data Reconciliation Standard Turn-Around-Times*

Number of rows	Number of business days
0-20	Two business days
21-50	Three business days
51-80	Four business days
81-110	Five business days
110-140	Six to seven business days
141-170	Eight to nine business days
171+	Minimum ten business days

The data reconciliation SharePoint tracker has a checkbox to mark whether the request is urgent. While some team members utilize this feature, it does not receive much attention. Reorganizing the SharePoint columns and displays to emphasize whether the box is checked, as well as encouraging team members to utilize the urgent flag when necessary, will help other team members know which requests to prioritize out of the list of requests with the same due date. Doing so will aid the data manager and maintain a good relationship with the study team on the client's end.

In addition, the internal quality of data reconciliation as a process can be improved by requiring the data manager who has completed a data reconciliation request to run an SQL file detailing any open exceptions that may have been triggered and taking the necessary action to close them. In the DEPARTMENT NAME department, exceptions are triggered by creating potential data discrepancies while performing data reconciliation. The data manager must close all exceptions that they have triggered, or notify the Global Site Services department that they are unable to close the exception. Failure to do so results in an increased workload for Global

Site Services as they must now investigate an exception that does not need any investigation or the exclusion of data from a data transfer.

The key performance indicator for quality will be difficult to analyze but should begin with tracking the number of quality complaints by clients during a thirty-day period before implementation and then another thirty days after implementation. Complaints surrounding standardized turn-around-times should be recorded, but not included in the total number of quality of complaints for this metric. This will require team-wide participation in their studies and an additional short-term SharePoint tracker or possibly the use of Microsoft Planner. The thirty-day period before implementation will set the baseline number of quality complaints, multiplied by twelve to get a hypothetical number of annual complaints. The goal will be to reduce the number of complaints regarding quality or recurring issues by 10% each year, with a 30% decrease in the number of quality complaints after three years.

Solutions and Key Performance Indicator for Improving Record Management

One of the most common complaints in the DEPARTMENT NAME department is how frustrating it is to use SharePoint, which often leads to inaccurate or missed documentation. Some of the comments include frequent upload issues and generally not being user-friendly (A. John, personal communication, March 20, 2024), a general desire for an entirely separate system (D. Palou, personal communication, March 21, 2024), and a more robust, accessible, and less time-consuming system (S. Banerjee, personal communication, March 21, 2024). The recurring theme in each interview was a desire to replace the SharePoint system completely. One proposal involved using the Cherwell ticket software (C. Henry, personal communication, March 26, 2024), but that system is being retired in favor of ServiceNow for IT, of which further information is currently unavailable but may be a viable replacement for SharePoint. Two

alternatives have been proposed to reduce the use of, but not necessarily replace, SharePoint: JIRA and Planner.

JIRA may not be able to be accessed by external users such as project managers, so it would not work well for inter-department collaboration activities like database verification. However, it could be used to track internal activities like data reconciliation or data transfer validation. Due to time constraints, further evaluation of JIRA was not possible, but it is worth further investigation in the future.

Planner is a Microsoft application available to Microsoft 365 users. Anyone can create a group, add members, and assign tasks. The more limited version available to the department, access is all-or-nothing and the design could result in someone accidentally marking a pending task as complete. However, Planner could be utilized for special projects, sub-teams, individual tracking, issue reporting, and miscellaneous tracking. Custom fields are not possible, so time tracking would be limited beyond the due date and completion date. Issues or projects such as IT tickets, PPI, or SOP updates could be listed in Planner so that the team can check on the status of an item.

Regardless of whether SharePoint is replaced, a separate tracker for miscellaneous tasks should be created to track the activities of each team member more accurately. Another tracker specifically for any issues across all activities would also help identify trends and areas of recurring issues, especially if another department is involved. This would provide further information and improve decision-making to resolve repeat problems.

A key performance indicator for improving record management is not truly available at this time. Performing a test run of JIRA and Planner and evaluating feedback may provide

further insight and direction, but it appears that SharePoint will not be fully replaced at this time. One current constraint is that whatever replaces SharePoint must already be available as a tool and cannot be an additional expense for the department.

Limitations and Future Research

Due to time constraints and missing data, several limiting factors may slightly alter the data or outcome of some of the solutions. For example, the roughly thirteen studies missing a completion date or due date could not be calculated in the statistics, and several data reconciliations were completed in zero minutes according to the tracker. This affects the sample size and the accuracy of the calculations. Financial data was also unavailable. However, the conclusions drawn from the data would likely not change drastically. Time constraints also prevented further investigation of Jira and Planner, as well as a walkthrough or demonstration of the newer ServiceNow system being deployed. Planner appears to be useful for individual use or sub-team projects, and preliminary data suggests that ServiceNow may be a viable replacement for SharePoint at the possible cost of requiring any modifications to be completed by the IT department.

Several other issues were mentioned in interviews that were unable to be explored due to time constraints. These include automation of certain tasks, improving the review process of results-containing reports, standard operating procedure process improvement and overhaul, improved hiring profiles, an overhaul of the database test environment, and modifying certain test setups. These are all valuable ideas that would reduce stress and improve turn-around-times and quality within the department and should be further investigated at a later date.

Conclusion

The DEPARTMENT NAME department of the DIVISION NAME, part of COMPANY NAME, has several problems or issues that can be resolved or improved upon. By increasing the size of the team and adding a manager, job satisfaction and productivity among individual team members can be enhanced and stress can be reduced. This will also better equip the department to handle the increasing workload. Further restructuring the team would allow for partial cross-training with semi-specialization, enabling certain team members to focus on specific activities and serve as points of contact when another team member has a question. The introduction of high-level training on DEPARTMENT NAME activities for other departments and increased reference material would improve inter-department communication and collaboration. This, in turn, would improve the turn-around-times for certain activities like database verification. By increasing the standard turn-around-times for data transfer validation and data reconciliation, the department can foster an environment of higher quality work and fewer client complaints. The creation of additional trackers for miscellaneous activities and issues will allow management to have a better understanding of the department's operations and identify recurring issues that need to be addressed. Finally, by continuing to research alternatives to SharePoint such as Jira, Planner, or ServiceNow, the department can significantly improve the day-to-day work of the team, who have expressed their dissatisfaction with SharePoint as a tool.

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