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### Improving Processes in Biostatistics / Programming Departments

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#### ABSTRACT

Innovation is a hot topic in the pharmaceutical industry where the need to drive the speed to market, reduce costs and enhance scientific integrity are key. It is important to define a vision and manage the work needed to accomplish this vision. To do this, you must first understand the company and department needs, create a vision and gain agreement on the necessary steps to implement the vision. Management must work together and agree on a path to take the company forward.

Once the vision is set, it is important to manage the initiatives needed to achieve it. In a typical Biostatistical/Programming department, the maintenance effort and the effort to move forward with innovation / continuous improvement ideas must be balanced. It is helpful to prioritize all initiatives and ensure that key ones are moving forward effectively. This paper will discuss ideas to help go through this process of defining a vision and aligning resources to implement.

#### INTRODUCTION

Biostatistics / Programming departments often have a global footprint. With the many mergers that have been happening with the industry this global department may be made up of offices from various companies or just through location differences due to organic growth. This can lead to a situation where there are different visions for the future and competing goals. When this happens, there could be little central management on initiatives as individuals may start projects that align with their own goals. This can result in duplication of work across initiatives or even competing solutions to a problem. A lack of vision on where the department should be in five years can lead to a department that struggles to take significant steps forward. This paper will propose a path forward to address these pain points and successfully drive growth towards a vision.

#### SETTING THE VISION AND ROADMAP FOR THE DEPARTMENT

The discussion of setting the vision could be the focus of another entire paper. However, this is an important first step in the process. The department needs to have a single vision of the future in order to align innovation and continuous improvement activities. "Your vision lays out a destination; your destination guides your strategy; and strategy chooses action. It's action that leads to success. In those moments of action, having clear direction is crucial for building momentum" (Setting Strategic Direction).

The vision statement is a way for employees to "understand the meaning and purpose of your business" (Fernandes). This statement aligns your department on what you are trying to do. You want the vision statement to be focused, clear, and forward looking. It should be something that is aspirational of where you want to go as a department. Work with leadership and various levels of staff to ensure that there is good representation into the process of determining a vision.

Once you have a vision, the next step is to start pulling together information to determine a road map for the department. This road map helps to lay out the steps needed to achieve the vision. Relevant information here would include overall corporate priorities, industry landscape and your department's current strengths and weaknesses. Working with the department's leadership team, understand what high level steps are necessary to go from current state to achieving the vision. There are some useful visuals to help staff understand these steps. You could map these steps out in swim lane flowchart or various visuals for a roadmap. This will help staff set the steps more clearly and therefore help them get on board with the vision and the strategy for getting there.

#### INVENTORY CURRENT INITIATIVE WORK

Once you have a vision and a roadmap to get there, it is important to survey current continuous improvement activities ongoing in the department. Try to uncover all types of initiative work, including items solely focused within the department and items that are cross functional. The collection should include activities to maintain current tools



as well as improvement activities. To be able to get this transparency, it is very helpful to have the head of the department engaged in the messaging on why this is needed. There is likely to be resistance to centralizing these activities, if people have had relative autonomy before. Collect all the information received in a publicly available spreadsheet or tool. For each initiative make sure to collect information around what is the main purpose of the initiative, what key tasks are they trying to accomplish and how much effort is needed for these tasks. Centralizing the collection of this information allows others to avoid double entry. After the collection period, continue to scrub the list and engage with staff about it over the next several months. If initiatives have not previously been centrally managed, it may take some time to encourage all staff to move to a more centralized model.

## DEFINE AVAILABLE HOURS

In order to manage your initiative portfolio, it is helpful to understand what level of effort the department can support each month on initiative work. All Biostatistics/Programming departments have “day jobs” that need to be accomplished to deliver operational and keep the department highly productive. While it would be wonderful to have unlimited time to push continuous improvement activities forward, there is a natural limit to what a department can support. It is often not an exact science, but more of an art. Factors such as position level and number of staff can be used to build a basic algorithm to model out percentage of staff time that could be dedicated to continuous improvement initiatives.

Some companies may use hours to assess this level of effort. For the purpose of the example, hours will be used. Assume a department of 200 staff. Forty of the staff are management and have more time to spend on initiative work. The remaining 160 staff maintain a high level of project work. For the sake of the example, assume that for the 160 staff, they need to focus on project work for 80% of their time. For the forty management staff, they need to focus on project work for 25% of their time. Assuming a forty hour work week, this means that management has  $40 * 0.75 = 30$  hours a week for non-project work. For the rest of the staff, they have  $40 * 0.2 = 8$  hours a week for non-project work.

The time for non-project work includes things such as training, performance management, career development, conference attendance, recruiting, initiatives, and other similar activities. If there is access to past timesheets across the department, it may be possible to determine percentage for these types of non-project work. This would make the calculation of the final bucket of initiative hours fairly straight-forward. However, this isn't always the case. If there isn't hard data available, an estimate of the expected percentage of initiative time vs other types of non-project work should be made. In this example, the management team estimated that for management staff, 20% of the non-project time was dedicated to initiative work and 10% of the non-project time for the other staff was dedicated to initiative work. This results in  $(40 \text{ staff} * 30 \text{ hrs} * 0.2) + (160 \text{ staff} * 8 \text{ hrs} * 0.1) = 368$  hours per week for initiative work. If four weeks of vacation and holiday time are assumed, then there is a total of  $368 \text{ hours} * 48 \text{ weeks} = 17,664$  hours per year for initiative work.

Using the estimates in the previous paragraph, the available project work hours would be calculated as  $(10 \text{ hrs/week} * 40 \text{ management staff}) + (32 \text{ hrs/week} * 160 \text{ staff}) = 5520$  hours a week. Therefore, there would be  $5520 \text{ hours a week} * 48 \text{ weeks} = 264,960$  hours a year for project work. This means that that initiative work would equate to  $17,664 / 264,960 = 0.067$  or approximately 7% of the time devoted to project work.

This example stepped through one possible approach to determining available time for activities to achieve the vision. This can be approached other ways as well. It is helpful to come at it from a few different approaches and validate the final number or range. The available hours and the approach(es) taken should be vetted by the management team and thereby accepted as the available bucket of hours.

## PRIORITIZE INITIATIVES

Once there is a full picture of hours for initiatives in the year and a full list of initiatives that are ongoing, the process to evaluate current activities against your five year vision can begin. It is likely that there are additional activities needed to achieve your vision. Include these new initiatives in the tracker with expectations for the year around hours and key goals. With this full list, management can start to evaluate what are the most important initiatives for the year. If leadership is in alignment with the plan for the future, this activity should be relatively easy as it is driven by the roadmap. Consideration also needs to be made for needed maintenance activities to keep business tools running and corporate initiatives. Not all initiative hours can flow into the roadmap activities, if there are existing tools that need maintenance and ongoing corporate initiatives that can't be immediately stopped.

A four level scale, such as low, medium, high, and important, allows for an adequate level of distinction between priorities. Key focus should be given to the high and important prioritization levels to ensure these move forward. The lowest level should be evaluated for removal or work put on hold. The medium level would be your “nice to have” initiatives. If there is time they can move forward, but if staff availability is tight, these can be put on hold without impact to your vision. It is important to look at not only the overall initiative in determining prioritization, but



also the tasks that need to be achieved. You may need to streamline the tasks an initiative team wants to complete in the year, to ensure that you have the right hours balance overall. It is tempting to want to prioritize all activities for an important initiative, but they may not all be needed in year one. The more focused your prioritized initiative list is, the more likely you will accomplish your goals for the year.

Using your five year vision, consider starting some of the year four or five initiatives a bit earlier as a “strategizing” initiative. These “strategizing” initiatives shouldn’t be budgeted for as much time, but allow you to focus on evaluating the best approach, collecting feedback, and setting you up for success moving into later years. The goal is to go into the first year of your plan with a solid list of prioritized initiatives that have the leadership team’s support and take the first step towards achieving your five year vision.

## **IMPLEMENTING THE PLAN**

The planning stage sets you up for success, but the implementation stage will be key to achieving the vision. The central initiative tracker will drive what activity is ongoing through the year. However, it is necessary to have someone to monitor the initiatives and ensure the department is implementing the plan successfully. Depending on the size of the list of initiatives, it could be one person or a small team of staff who are accountable to oversee this work. These staff will be called initiative oversight leads. The initiative oversight leads will need to meet periodically with the initiative leads to provide support when there are road blocks and ensure the initiative leads are staying focused on the key tasks to be accomplished. Initiative oversight leads should be at a senior enough level to make decisions and help drive activities forward. However, they shouldn’t be actively participating in the initiatives in general. They are there for guidance and escalation. This allows them to be over a number of initiatives without being overwhelmed by the task. This also helps feed information across initiative teams where topics may overlap. There may be work that one initiative team is doing that is useful for another team to know. The oversight leads can help facilitate the sharing of information across groups to drive further success. The oversight lead can also serve as a mentor to the initiative leads to help them build successful skills around leading initiatives. Initiatives may be staffed by employees that are not in their direct reporting line or even at their same physical location and may have different ways of communicating and varying levels of commitment. As the oversight leads build these skillset in the initiative leads, success becomes even easier for the department. The most focus should be on the high and important initiatives. Initiative oversight leads should touch base monthly with initiative leads to ensure progress is as expected and teams are fully engaged. For lower prioritization level initiatives, it is helpful to meet quarterly or twice a year. This helps ensure nothing has changed in the prioritization of the initiative and be in the loop on any progress that has occurred. With this high level of oversight on the initiatives and agreement across the leadership team on priorities, the department is able to achieve goals with a higher level of certainty.

## **CONTINUE THE CYCLE**

Fast forward to the end of year one, hopefully the department has been successful in completing a number of goals and is looking forward to planning year two. It is important to do two things here: 1) stop and celebrate successes as a department. It has taken a lot of work and focus to achieve the completed goals and hopefully significant progress on other key goals has been made, even if they aren’t fully completed; 2) go back to your five year vision and start to plan out year two. Evaluate what is still remaining from year one and what needs to be done in year two. Through the review of the five year vision, it may be identified that there are some items that need to be revised. The industry trends may have changed or perhaps corporate goals have shifted. It is important to ensure that these goals are all still relevant. In addition, it is important to make sure that everyone remembers what these goals are as they go into year two planning. The planning for year two should go a bit more smoothly, since there is already agreement on the ongoing initiatives in the department and progress that has been made. Year two planning should involve a reach-out to all the initiative leads to collect their recommendations for tasks for the following year and hours that would be driven by these tasks. The initiative oversight leads can help facilitate this process and provide an initial set of review. Then the updated tracker with year two tasks and hours can go back through leadership review and discussions. This process should be kept fairly short to ensure progress is made such that there is a final decision before year two starts. Once there is agreement on the prioritization of the initiatives, tasks and hours to be accomplished, it is rolled out to the department and the implementation phase begins again!

## **CONCLUSION**

Having a clearly defined vision and roadmap enables Biostatistics / Programming departments to have a unified direction and allows staff to align on decisions around initiative time. Once this vision and roadmap are in place, the departments need to evaluate current activities and make a plan for achieving the vision. A process for prioritizing initiatives and implementing on these priorities will enable successful implementation of this plan.

By refining this process over the years and driving a consistent message that focuses on the department and road



map, the department can work together to take significant steps forward. There may be bumps along the way and years where goals are not fully achieved, but it is important that momentum continues. The stronger the focus is across the department, the more forward motion that can be made. Visibility and celebrating successes are important steps in achieving this shared focus and continuous momentum. As each year ends, re-evaluate the end goals and ensure they are still appropriate and the planned path is still optimal. With all these parts in play, the department can celebrate their successes and implement their vision for the future.

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