

Failure to Communicate: The Challenges of Implementing New Technology on the Business Process

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ABSTRACT

Introducing new technology, standards, or process within a clinical research company cannot solve the challenges within the business. In almost every case, the most important change that must be managed is the 'people'. The most critical part of implementing something new is the ability to manage the change within the company to ensure the business understands the need for the new 'thing' and the benefit it will bring to the company. Senior management must handle the expectation of both the technology and the business as well as understand the time it takes to ensure success. The business must tackle the learning curve associated with new technology and processes, and gain an understanding of how they must change to reach the overall goals of the company. This paper will discuss why implementation projects often fail and what steps your company can take to have the best chance of success in adopting new technology, standards, or process.

INTRODUCTION

"What we have here is a failure to communicate" is a famous line from the 1967 movie Cool Hand Luke starring Paul Newman. In the movie Paul Newman is a young brash prisoner who refuses to cooperate with the prison captain. During a scene in the movie the captain strikes Newman and says "What we have here is a failure to communicate". While this is an example of one approach to making people conform to your methods, it is probably not the most successful method when trying to encourage people to adopt something new.

Technology alone cannot solve the challenges a clinical research company faces within their business. In fact, in most cases, the most important change that must be managed is the 'people' which is better defined as the systematic approach to dealing with change, both from the perspective of the whole company and on an individual level. For decades, companies have been 'set in their ways' in how they manage the activities in the drug development process. Part of this is people's natural reluctance to change and part of it is the continuing transformation of medical science within clinical research. This creates a challenge in developing solutions and changing the way people work. The most critical part of implementing something new is the people and their ability to manage change to minimize the business growing pains and ensure your users understand the need for the new 'thing'.

This paper will discuss the problems companies face when trying to implement change, describe a few case studies about projects where these problems transpired, and outline a five step process for success. Throughout this paper, when 'change' or 'initiative' is referenced, it is referring to either a change in technology, standards, or process. The content within can apply to any of these new change initiatives.

FAILURE TO COMMUNICATE: THE PROBLEM

Just as the captain told Paul Newman there was a "failure to communicate", a majority of the problems that occur when implementing new change within an organization revolve around the failure to communicate. The problems described below all trace their roots back to the issue of poor communication.

NOT UNDERSTANDING THE BUSINESS NEEDS

A critical failure which can occur at the beginning of a project happens long before you select a technology, define a standard or develop a new process. It is the fundamental problem of not understanding the business requirements

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and defining those requirements clearly and concisely. If you don't clearly articulate the user requirements it is impossible to determine if the potential solution could ever meet the user needs.

In the case of new technology, a favorite vague requirement is the following:

"The system shall have good performance"

This requirement has been listed on almost every request for proposal or set of customer requirements our company has seen. This is a simple example of a requirement which is doomed to failure because it is very subjective by default; performance means something different to every person.

- What actions does the user perform that would be effected by performance?
- What is the baseline expectation of the user?
- Is the user moving information, such as data, that is performance centric?
- What does the end user expect for those predefined tasks?

Depending on the tasks being performed by the user, the long list of performance questions could be asked. Instead of the vague statement listed above, you need to define measurable requirements that match the user's expectations against those specific tasks. Some examples include:

- The system shall load a data set of less than 10Mb within 30 seconds
- The system shall run a SAS program that generates a 100,000 record data set within 5 seconds
- The system shall display a folder of less than or equal to 100 objects within 3 seconds

These become measurable requirements that you can clearly test and document.

The example above is a somewhat cut and dry requirement that is easy to understand. The more challenging requirements to capture and quantify are those involving process. However, the most critical part of implementing a new change is the need to understand the current process; what works in that process and what doesn't work or could be optimized. However, what works for one person might not work for another and you must be able to tease out these differences. Another favorite requirement seen within proposals is the following:

"The system shall be able to run SAS code"

Figure 1 below includes two examples of systems that meet this requirement. Which one would you want to use?

System 1



System 2

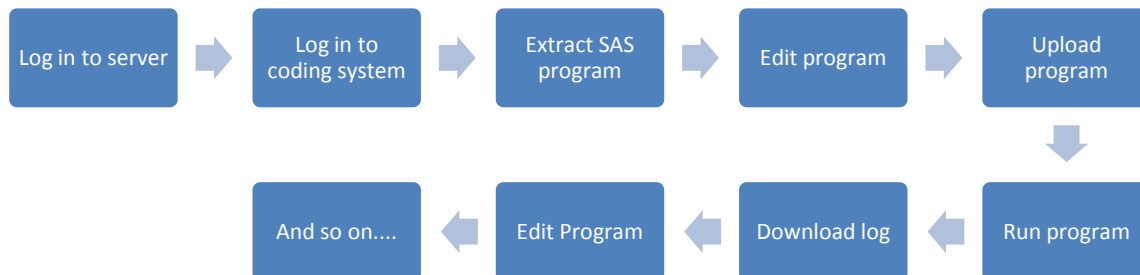


Figure 1. Two systems that support a SAS coding process

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While this example is somewhat facetious, it does provide an example of where technology can meet a user requirement but not meet the needs of users.

LACK OF LEADERSHIP

Another problem that can arise early in a project is either the lack of clear vision or the inability to communicate that vision to the business. The most basic issue which occurs is that the senior leader responsible for solving the business problem doesn't really understand the problem. They don't take the time to submerge themselves into the process challenges their staff are encountering and drill into specific requirements around what needs to change. Instead they throw around a few buzz words such as 'data warehouse', 'workflow', and 'standards' and pick a technology that also includes those same buzz words within their marketing material. As is fairly obvious, this leads to significant headache and frustration when the rubber meets the road and the users are trying to figure out how to define their process around this new technology.

Another fundamental issue often encountered is a leader who has a clear vision and understands the specific business needs, but fails to communicate that message to the all layers of the business. A big red flag goes up when you walk into the first customer meeting, ask a dozen people the purpose of the new initiative, and get a dozen different answers. The leader needs to be able to tailor his message to each of the key stakeholders from his superior who approves the budget to the users who will work with the technology on a daily basis. Too often, leaders don't effectively sell the vision up the chain and do not receive the funding to realize the vision or they don't clearly explain the vision to the business users and gain their buy in. The core business users are not responsible for funding the project but they are the ones who can derail it.

The final challenge faced by senior leadership is the lack of following through on the change and the long term commitment to the implementation. They navigate the challenging implementation phase successfully to only walk away from it on production day. The implementation of new technology or process doesn't end when it's declared production but must continue to be supported so it becomes engrained in the business.

Case Study

In this specific project, a Contract Research Organization (CRO) had decided to implement a large scale clinical data repository across five sites worldwide. Our consultants had met with senior leadership who told us the company had bought these various sites over a four year time period and the goal of the project was to have a centralized data repository with aligned processes. This seems fairly straightforward but alas, things changed quickly. The customer team arrived for training and some of the following questions/comments popped up:

- We just booked our plane tickets two days ago
- Is this a data management system?
- We never work with the other sites so we're not sure why we need this
- Is this just for the programming group?

Based on the initial feedback, it became immediately evident that there was trouble. These comments made it apparent that the core implementation team was not prepared for the training, the vision had not been communicated, and any fears the users had were not addressed. While the external consultant made their best effort to help navigate these huge gaps, the project ultimately failed within six months. The vision had not been fully developed or communicated by the customer's management team and the project could never overcome it.

UNREALISTIC EXPECTATIONS

Probably the single most critical challenge in implementing change is related to the last section and revolves around the ability of senior management to understand and manage expectations. Figure 2 below was introduced while working on implementing technology projects within a pharmaceutical company many years ago and has become our Bible for explaining the challenges of adopting change.

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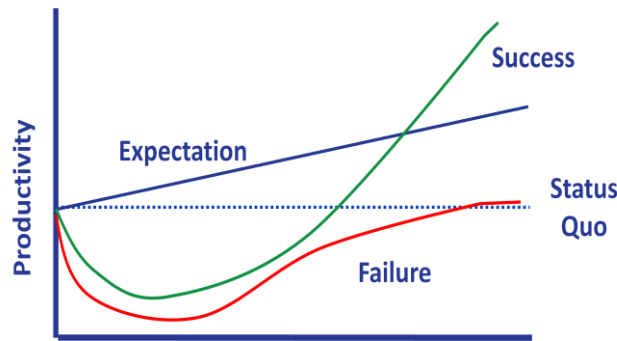


Figure 2. Reality of Adopting Change

In this figure above the status quo represents the current level of productivity which is neither increasing nor decreasing. A majority of the time companies have a misconception that new technology or process will immediately begin to increase productivity with minor bumps in the road. The reality is that with any new change there is a learning curve that people must navigate in learning new functionality, standards, or processes. Just changing the way people work on a daily basis can be your biggest challenge. Most likely your company will see a decrease in productivity as people tackle the learning curve and gain an understanding of how they must change to reach the overall goals of the company.

Navigating that trough in the adoption curve is critical to realizing the potential of the new technology or process. If you can successfully navigate this hurdle you will travel along the success curve and eventually meet and even sometimes exceed your expectations. If you don't manage this process effectively you will end up deviating away from that curve and end up back where you started, and in the process, spend a significant amount of money and have a group of frustrated business users.

Case Study

Within this project, a mid-size pharmaceutical company was implementing an ETL solution to help them automate the transformation of their clinical data and hopefully create reusability across studies and users. In this case, the vision had been communicated and the team understood the project goals. However, the external consultant once again knew there was trouble when the first three project meetings were cancelled because the customer project leader didn't show up. This was followed by an e-mail that asked for an installation of the software and they would start 'using it'.

This continued throughout the first few months of the project leading to user frustration and eventually limited use of the software within the company. The project leader did not have time to set expectations for the team, tackle the challenges users might have, and help people understand the 'change' they needed to address. Senior leadership is also to blame, because they did not make sure the project leader had the time and resources to make the project a success.

WRONG TEAM

Another key component in having a successful implementation is to make sure you have the right people leading and participating on the project team. Figure 3 below is another component that lives in our technology implementation Bible.

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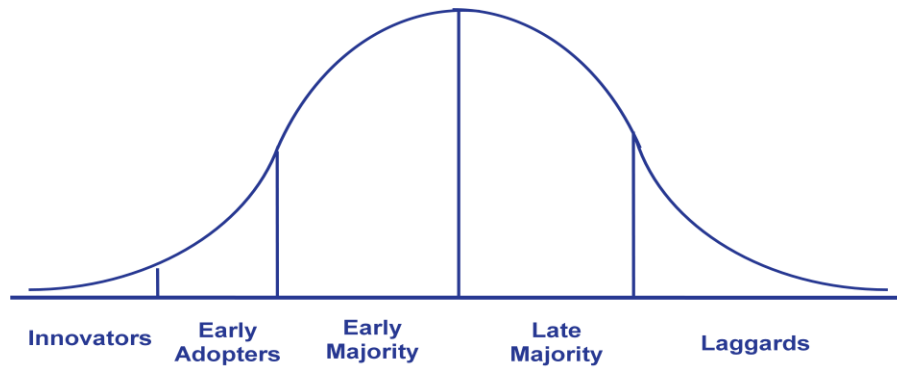


Figure 3. Distribution of a Company's Business Users

This graph represents the distribution of people you have within your organization and their pension for adopting change. At the far left you have the 'Innovators'. These are the individuals who stand in line overnight to buy the newest release of the iPod. They always want the newest gadget, but sometimes don't think through the business need. The second group, the early adopters, is your key group because they welcome change but also need a clear understanding of the business need and vision. This group will usually drive and hopefully manage the implementation process to success. The two groups in the middle, the early and late majority are the largest groups within your company and are usually just go with the flow people who are focused on doing their job. They might be reluctant to change but aren't vehemently opposed to it. Finally, at the far right are the laggards, the individuals who are stuck in their ways and will need to be dragged kicking and screaming into any change. If possible, this group would still be using punch cards if they had their choice.

The key message to take away from this figure is that if you don't have team members with a vision (Innovators) or people who are open minded to change (Early Adopters/Early Majority) research has shown the project is doomed to fail.

Case Study

This project involved implementing a Global UNIX Platform within a large pharmaceutical company after a merger in which users were working on a variety of platforms (i.e. UNIX, PC, and VMS). Instead of building a robust team that involved people from across the previous companies and platforms, as most often happens, they grabbed users who had time. In this case, the Project Leader was an opinionated and diehard UNIX geek who proceeded to select members of the team that only shared his view of what and how the project should work.

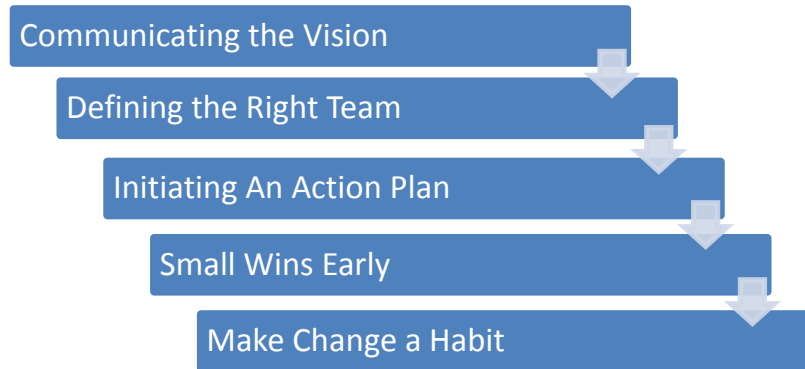
The project leader did not try to understand the fears and challenges from users who had not previously used the UNIX platform, leading to a lot of frustration and animosity as well as a very slow adoption curve. A project that was designed to be completed within 6 months ended up lasting over 2 years. In addition, the final implementation had inconsistent processes and did not lead to the efficiencies promised.

5-STEP PLAN FOR SUCCESS

If you Google 'technology change management' on the internet, you will get many different ways of doing 'it'. The following five step process (Figure 4) will outline a strategy for implementing change within your company that has been very successful with our customers.

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Figure 4. 5-Step Plan for Success



For this exercise, let's use the following example as a theoretical project. Within Utopia Pharmaceuticals, senior leaders clearly see the pains around not having their data and processes centralized. They have different groups reinventing the wheel and data that cannot be shared globally. They must move to a centralized platform for data and workflow with global processes. The Global Vice President of Data Management has been identified by the President of the company to lead this effort. Throughout the plan specific illustrations of the five steps will be highlighted which examples of how to successfully implement the plan.

COMMUNICATING THE VISION DOWN

A phrase that is often overused but still applies is the following:

"tell your audience what you are going to tell them, tell them, and then tell them what you told them"

This might be cliché but it fits well with implementing change within your company. The key message is that you can never communicate too much during this process. However, you have to make sure that communication is clear, concise, and delivered frequently and within a process people will embrace.

Figure 6 outlines the process for defining and communicating the vision.

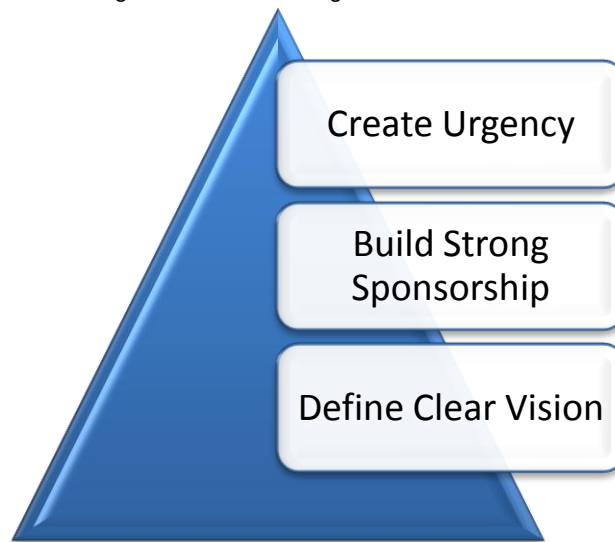


Figure 6. Communication the Vision

Create Urgency

While this might sound counterintuitive, the first step of communication is to yell "FIRE" within the proverbial crowded theater. While you might be scratching your head about this step, you have to create a sense of urgency within your company; the company needs the equivalent of a heart attack. There has to be a widespread sense that if the company doesn't change their ways, and soon, the organization is going to have serious issues. For example, if the team can't respond to FDA questions about the data more rapidly the company is in jeopardy of the FDA delaying, or even worse, denying the critical submission. If the submission is delayed or fails, the company loses money, people lose jobs, and the downward spiral begins.

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This kind of pain is behind almost every major change initiative. A company shouldn't go through the massive expense and resource of implementing new technology or process as an academic exercise. The company does it because they believe that if they don't change, it will severely impact your company's bottom line. In many companies, the reasons to change are compelling, but only to the senior leadership team. Even one level down, there's no sense of pain and when there's no pain, changing behavior and attitudes just feels like a nuisance. People across the company need to realize bad things will also affect them. Layoffs, cuts in bonuses, and other negative things could impact every person. The point is that you have to show people how their livelihood could be affected by the pains and only their willingness and ability to change will improve the outlook.

In our hypothetical company, the Vice President of Utopia Pharmaceuticals must clearly communicate to the regional directors of data management that their need to consolidate. The VP must provide examples where mistakes were made, processes were replicated, and a regulatory agency or sponsor asked for information that the company could not provide in a timely fashion. People need concrete examples, and senior leadership must provide them. For example, the VP must highlight that the company uses two different internal data management systems and three different external EDC vendors across their sites. Therefore, the company reinvents the wheel every time they set up a new study.

Build Strong Sponsorship

As mentioned before, a majority of failed change initiatives happen because of a lack of leadership. The usual scenario is that the leadership team sits around nodding their heads in agreement when the change initiative is proposed and discussed. However, when reality sets in any significant change unavoidably creates pain and angst. Inevitably, you will have to deal with the resistance of those who feel threatened, and this resistance to lead and support the change can be seen in a variety of ways from delaying responses, blaming others, and nodding their head in agreement while disrupting the project at every opportunity.

Any change within a company is dependent on relationships between people. The most critical relationships to focus on initially are those among the people who will lead the implementation project. You must clearly understand any concerns or fears they might have and work toward alleviating those fears. Another recommendation is to reevaluate how performance metrics are assessed and awarded to make sure project leaders are rewarded for moving the project forward. The key is to build a senior leadership group whose fears are addressed, supports the change, and is rewarded for delivering on the change effort. This senior group must have absolute confidence that the Senior Leader is completely behind this effort and will support them in knocking down walls if necessary.

In the case of Utopia Pharmaceuticals, the Vice President must meet with his data management directors multiple times to clearly articulate the vision, but more importantly get feedback from these individuals and capture any issues they or any of their staff might have. Once these issues are captured the Vice President can work with the Directors to mitigate these challenges. In addition, the VP must clearly state that both resources and money will be available to execute on the vision and if any challenges crop up, the team will be supported in addressing them.

Define Clear Vision

Once the senior leadership group buys into the change initiative, they need to develop a clear and compelling vision that is designed for all levels of the business. This sounds obvious but it's surprising how often there is confusion about why the company is implementing the new technology or process and what is the expected outcome. It is critical to spend a significant amount of time at the beginning of the project bringing clarity to the reason for the change. What will success look like and what's the plan for getting there?

Even if the project is complex and the plan for achieving the vision is complicated and lengthy you must wrap up the message into something simple and concise that fits on a business card. Once you have a clear vision of what needs to change, that vision has to be communicated to every nook and cranny of the company. Not only does it need to be communicated but the message must take different forms depending on your audience. It can involve web postings, e-mails, presentations, and other forms of communication. However, the best method to really drive home the vision is to walk around, chat, and ask questions. This will allow you to gather additional insight into any reservations your business users might have. This message must be beaten like a drum over and over and over again until users are dreaming about it in their sleep.

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Within Utopia Pharmaceuticals, the Vice President has defined the following vision: “Our Company will align on a single data management and repository solution allowing us to align processes globally sites and share information across our groups”. The Vice President will then visit every site and meet with the teams to explain the vision to the teams at a granular level specific to their role. In addition to these meetings, the VP should develop and implement a plan for the Directors to continuously extract information from users with regular meetings. The individual Directors should be delivering the tailored message to their group at every meeting, every e-mail correspondence, and more importantly, listen and observe the user’s response. All of this information will help iteratively refine the vision and the plan.

DEFINING THE RIGHT TEAM

Once the senior leadership has agreed on the vision, communicated the vision to the user community and reached consensus on the requirements, it is time to initiate the project. All discussions up to this point have revolved around the role of senior leadership. What has not been addressed is the team that will be on the ground, in the weeds, implementing the solution. Just as the other steps in this process are important, defining the right team is critical for success. As described earlier, if you don’t have the Innovators and Early Adopters who will embrace change and understand the business need, your implementation will be doomed.

The first recommendation is to define two key roles on the team. The first is a very well organized Project Manager with a technical background. This person needs to be responsible for managing the scope of the project, all communications both upwards and downwards, and tracking the tasks that need to be delivered. The second role is a Technical Lead or Manager who will focus on the technical components of the implementation including tracking technical requirements, mapping the business process on top of the technology, potentially configuring the solution or developing add on value components, and other specific technical needs. While these two roles could be filled by the same person, our past experience has shown the skills necessary to fill these roles successfully have very different personalities. In the case where the same person has tried both, they do one job very well and the other job not so well. Both of these roles must have a clear understanding of the vision and business requirements, and more importantly, they must be given the time and resources to execute the project and not be doing it “when they have time” around their day job.

After defining these two roles, you must fill out the rest of implementation team very similar to how you would field a football team (whether it is American Football or European Football). You have already identified the Goalkeeper (project manager) and the star Striker (Technical Manager). Now you have to fill out the rest of your team with Midfielders and Fullbacks. The goal is to identify roles within the team that are either needed for their skill set, their geographical location, or specific experience within the company. Also, remember that almost all team members should come from the Innovator/Early Adopter/Early Majority categories with maybe one or two from the Late Majority. While this might be a bit blunt, we suggest ignoring the last group as you will have to drag them kicking and screaming no matter how much time you spend trying to convince of them of the change initiative.

Finally, you need to decide how many people you should include on the team. If you have too few people, you will not have a good representation of your business users; if you have too many, consensus will become impossible. This is very dependent on the size of the project, but in general, as long as you make sure the key stakeholder groups are represented, you should not have more than 6-10 core people on the implementation team. If other business users feel left out, explore creating an extended support team or prototype group who can provide feedback along the way and feel like they are contributing.

The VP of Data Management at Utopia Pharmaceuticals has identified an Associate Director of Data Management at his corporate office to lead the project and requested a Manager within IT to be the Project Manager. In addition, he has requested each of the three regional Data Management Directors to identify two people, one person that works with the data management solutions and one that works with the data repository. Therefore, a team of eight people was created to lead this implementation.

INITIATING AN ACTION PLAN

The next step involves the core team sitting down and mapping out the implementation plan. The first goal is to define a project charter. The project charter will include the statement of business needs, an agreement of what the project is will deliver, identification of project dependencies and technologies, and the roles and responsibilities of all the team members involved. The project charter basically defines the boundaries of the project, no matter what type of project management methodology you use. The project charter will define some of the following components:

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- Goals and objectives of the implementation as defined by senior leadership
- Roles and Responsibilities of each team member
- Communication matrix for all issues and questions
- List of tasks and associated timeline

Within the project charter, the roles and responsibilities as well as the communication matrix are critical to everyone on the team. Each team member must know the 'what' and 'when' of their responsibilities. Once everyone on the team clearly understands the project charter it is time to work the action plan.

If every step has been followed up to this point, the leadership is aligned, everyone understands the vision, requirements have been defined, and the right team has been chosen, the action plan should come close to running on autopilot. While everyone knows the implementation will not run by itself, having this foundation in place will make executing the action plan much easier. One key component to keep in mind is that every task or decision the project team agrees to must align with the goals and objectives of the vision. So as each task is defined or decision discussed the first question should be "Does this thing align with our objectives?"

In the case of Utopia Pharmaceuticals, the entire team had a three day meeting to define the project charter. The team defined two sub-teams, one focused on implementing the database components and the process for data flowing in and out of the organization, and the second group focused on implementing the front end user interface components. A leader was identified for each subgroup and those leaders reported to the Project Manager and Technical lead. The overall team met once a week and the sub-teams had scrums three times a week. The team defined tasks and timelines to complete the implementation in six months.

SMALL WINS EARLY

One of the problems with major change initiatives is that they take so long; People shouldn't have to wait until the end of a huge initiative to get positive feedback. The team should focus on planning in early wins within the project and in the midst of a complex implementation, it is vital to design some early deliverables that show added value to the company. Project plans can be designed to yield visible, measurable improvements almost immediately and early wins are critical to creating a climate where people will keep pushing all the way to the end.

There are two key components to gaining small wins early. The first might sound counter intuitive to defining a optimal process, but one way to ensure early success is to not try to make the process perfect up front. You can almost apply a implementation method similar to agile development within the software world. Within agile development, a team defines small tasks that can be completed inside a predefined timeframe (e.g. two weeks) and works towards defining concrete tasks to meet that goal. In this case, have the team put together a quick plan based on the business requirements and their initial understanding of the system. If difficult discussions arise regarding the process or functionality, the team should do their best to defer the challenge or define quick workarounds. The goal is to define the initial process rapidly versus perfectly. Once you have this initial process in place, identify a small group as your guinea pigs to execute a prototype within a narrow scope and evaluate the results. Then use those results to adjust and expand the process tackling the more difficult questions as you continue this effort. The team can continue to iterate building and refining on the process until they believe they have defined a robust working practice.

Using this methodology, the team must be weary in the beginning to not define a scope that is too narrow. If your initial process and prototype gives the business very little or no benefit, you immediately have introduced doubt on behalf of the business which could potentially be hard to overcome.

The implementation team at Utopia Pharmaceuticals decided that their initial quick win was to standardize how the data was received. They defined a process along with the technology to require data be delivered in a standard format. So instead of receiving data in SAS, Excel, text files, they required all data be received in ODM xml. They then used the automated tools within the technology to import the ODM file into their data management system. In this case they only focused on the format of the data and not the content. Standardizing content would be addressed later in the project.

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MAKE THE CHANGE A HABIT

The final step is to embed the change in the culture of your company. New behaviors, even when they are clearly beneficial, take time to become habits. In companies, research has shown that spaced repetition is the best way to insert new habits. This means users are taught a new piece of functionality or process and then set free to apply the piece to their work. After a few weeks they are brought back together and the functionality or process is presented again along with additional steps. This iterative process is repeated at regular intervals. This method sounds like common sense, but in most cases, companies skip the follow-up. They teach the concept once and then walk away. When this happens all that work to develop the process is wasted, and people revert back to their old familiar ways.

Spaced repetition is an effective way to make change stick and to make the whole idea of change permanent within your company's culture. Within each spaced repetition, you're not only reviewing and reinforcing what has been learned, you're also introducing new functionality or process. Another key message you are delivering to users is that there is no end to change. Change becomes a part of their everyday habit. As your company improves the way they adjust to change, users become more flexible and adaptable and they realize change is not something that is dreaded, resisted, and sabotaged. Instead it can be fun and energizing.

At Utopia Pharmaceutical, the implementation team started by teaching the users who worked with vendors how to import the ODM files into the database. Then two weeks later they gathered feedback, reviewed the process again, and added a session on understanding the details of ODM structure as well as how to write edit checks against the imported data. The team continued the process with this group until the process of importing and validating the data became a habit.

CONCLUSION

While the process outlined in this paper for success seems simple and straightforward, real change is hard. Real change takes time and you cannot give up when the first results fall short of perfect. Everyone should remember any skill you have learned in your life from learning to walk to generating your first SAS report – the first few tries were pretty feeble.

Many change initiatives are declared failures and abandoned long before they are given a chance to succeed. Too many senior leaders jump at every little hiccup, failing to see the large improvement that is slowly developing. There are always compelling reasons to implement a new technology or process; otherwise why do it? It's not necessarily that managing change is a new challenge, but that you make sure you do it right.

First you must define a clear vision, have buy in from senior leadership, be able to communicate that vision to different types of stakeholders, and define concise requirements that everyone agrees with. Second, you must define the right team who have broad skills, represent the right business stakeholders, and support the need for change. Third, you have to develop and initiate an action plan that clearly defines responsibilities, team structure, and deliverables. Fourth, you have work on getting small wins quickly and not try to climb Mount Everest on the first try. Finally, you must hold on to the rollercoaster and continue to push forward with embedding the change within the organization.

What was described in this paper sounds great, but also might sound like a very difficult goal to achieve. Can implementing technology be successful without getting every step right? Of course it can. It all depends on the technology, the process you are trying to change, and how committed your leadership and company are to the change. The process defined within this paper can be applied to any size change initiative from implementing the new version of Microsoft Word to implementing a global enterprise wide clinical reporting environment. Hopefully, the steps outlined here will give you and your company something to reflect on the next time you take on the challenge of implementing change.

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