The CDISC's are coming!!

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ABSTRACT

2016 is here, bringing with it the much awaited NDA requirements to be CDISC-compliant for FDA submissions. For those few teams who are still latching onto a legacy environment, the need of the hour is to be CDISC-'trained'. How does the management team choose the correct approach that is a right fit for their team unaccustomed to CDISC standards? Who will train the teams, maintain team morale and all the while keeping an 'eye' on the budget? Prioritizing and preparing a team for a major change such as legacy to CDISC seems to be the cross-roads where most CROs still dealing with legacy data are at these days. How do we hit the bullseye?

INTRODUCTION

In the fast paced clinical SAS® programming environment we are always looking for better, faster and cheaper options to complete projects and meet timelines, basically getting more done with less resources. With the introduction of CDISC standards, the clinical trial reporting process is streamlined and made more efficient by standardizing the data, however what do you do if all the data you are working on is legacy format and your team is only familiar with this type of data? The main challenge arises when you need to get an entire team up to speed on CDISC standards and make it feasible for ongoing projects to continue without being affected. Considering the depth of information required to bring a team up to speed and become accustomed with the many facets of CDISC an appropriate approach is required.

CROs are not the only ones that face this challenge as pharmaceutical companies, whose teams have been trained or have invested heavily in company-specific standard macros and templates using the legacy structure, need to ensure that their preferred partner can live up to the expectations appropriately. Implementing CDISC standards from legacy data requires expertise, industry knowledge and a proven track record training large groups in CDISC using various methods. The pharmaceutical companies need to be selective about who helps them to implement the CDISC standards as it's not just about converting data, it's about choosing the most innovative, knowledgeable industry leaders that can transition their teams, sub-teams and vendors appropriately. This paper will explore some of the psychological challenges faced by a team with such a dramatic change and discuss some of the more popular training methods and organizational approaches that have been used when dealing with such a large task and the management principles used to implement them.

OUT WITH THE OLD, IN WITH THE NEW

PSYCHOLOGICAL IMPACT

Clinical trials are an ever changing environment however as with any team there is a certain amount of standardization involved within a group of tasks that is outlined in standard operating procedures and best practices as well as successful historical ways of doing things. There is always the "old-familiar" and regardless of the data standards being applied, the team is accustomed to the tools being utilized on a daily basis, is comfortable with the workload and is proficient in producing high quality deliverables. When a legacy team is performing well and efficiently creating clinical trial reports it can be very tempting not to disrupt a perfectly good process. Why would you? Implementing something new has a number of effects on a team beyond the physical structures of everyday working. There are also the psychological effects on a team to consider, most of which are related to change and how the team accept it.

Change can have numerous influences on individual team members depending on how they adapt and these effects are inevitable when a team is faced with a huge transition such as converting from legacy to CDISC standards. This transition encompasses getting themselves familiar with CDISC standards (SDTM/ADaM based on project requirements), applying these standards to the legacy structure and ensuring that these meet the standards, without resulting in re-work. With such a large transformation these traits become apparent and different attitudes to change will surface and have different impacts on your team. Utilizing a change management procedure will help with the actual tasks and processes as it will encompass a structured approach to dealing with change however this will not

factor in the emotional and psychological effects that change has on a team. Making yourself aware of these outlooks can help you to prepare for dealing with the common attributes associated with each attitude, make decisions on where to place team members and help you to adopt a training plan that will suit the needs of your team appropriately.

RECOGNIZE YOUR TEAM MEMBERS

Recognizing how change affects your team is crucial to designing the correct approach in dealing with change and adopting a suitable training method, below are some common "types".

- The Resisters - These team members are resistant to change and will feel threatened and passionate about going back to the old way of doing things, they will latch onto anything that used to work and not foster a different attitude towards change. Dealing with team members that are resistant to change requires a number of principles to be adopted. Open and honest communication is a key concept as it alleviates fears and ensures that these team members are in the know about the changes required and this will in turn create a less fearful attitude towards the change. If some team members are proving to be especially resistant then it may be worth getting them directly involved in the change itself assuming the team member has the relevant skills to make a meaningful contribution. This will allow the team member to feel more control over the change occurring and also may increase the quality of the change if functional conflict is utilized. Functional conflict is conflict that encourages and supports the goals of the group and helps to improve performance. As the team member will be directly involved in the change it would be expected that their commitment level to the change is also increased.

- The Embracers - On the other end of the spectrum, are the team members that embrace change and all the associated upheaval, they generally have a positive attitude to change, relishing new concepts, ideas and technologies, likes to take risks and can regularly be a project champion for new initiatives and standards. These team members can also help to create a more accepting environment for the rest of the team and can encourage other team members to think more in line with their approach to change. These team members like to learn and readily accept additional responsibility and changes however while such team members are eager for new changes, they are to be transitioned thoughtfully. Their enthusiasm is to be cautiously approached, as they are ready to embrace the change without knowing the true depth or impact that the change will bring. Expectations should be maintained as there is always a risk that the changing environment might not be up to their hopes.

- The Poker Faces – These team members are indifferent to change and are not affected by any adaptations to process or introduction of new standards. They are very much go-with-the-flow people and adapt easily without much resistance on the surface. The downside to this is that there is no debate or push-back on changes that can lead to improvements or innovation and while these team members are not the hardest to transition they are however the most difficult to gauge. As the impact of the change on these team members is difficult to assess this group requires a lot more attention and on-going discussions to ensure that the change is being viewed positively and that the appropriate progress is being made. These team members will not speak up about the negative effects of a change and therefore may out of the blue have increased sick leave or resign. Special consideration and care should be given to this group and management should regularly assess the impact of change on these team members.

- The Trend-Setters – These are the team members that are cautious about any adjustment and while they do not embrace it instantly, they do take their time to distinguish themselves within this change. They perform all of the required research to ensure that it is a fit to their skill-set, assess impacts, test and thoughtfully process the implications so that they have all the facts up-front. Once they identify themselves as a suitable fit and welcome the change they can be a great support system to management and trainers as they now have an invested interest and are appropriately versed in the requirements. With an increased knowledge and foundation in the change this can help encourage a positive culture within the team to change as they would be seen as a go-to person for any doubts and queries that the other types may have. In particular these team members would have more of an impact on the "Poker Faces" as they will follow the majority of the team. On the other-hand, this group is also the group that can switch sides if not convinced or if they do not think the change matches their skill-set, these could be potential 'Trend-Setters' for negative impact on the whole team as they will become "Resisters".

Table 1 outlines positive and negative effects of attitudes to change:

Type	Positive effects of this Behavior	Negative effects of this Behavior	Actions to combat Negative Behavior
The Resister	• Can introduce an objective approach and encourage open discussion amongst the team • Can create functional conflict • Resistance can lead to better improvements in a process	• May create dysfunctional conflict within the team that affects the goals of the group • May need more time and support to adapt to a change • Can lead to dissatisfaction and affect morale if they feel they are being forced into a change	• Limit and divert the conversation to bring the topic back on track • Encourage and allow time for full assessment of the change • Conduct regular 1:1's. Reinforce the positive impact that the change has for the organization and the need for the change.
The Embracer	• Can encourage others to embrace change by creating an air of enthusiasm • Usually the first to volunteer and champion a change • Allows for easier transitions especially where larger changes are required	• Can jump into change without assessing the real impact up-front. • May lose focus if another "new" change comes in that they are excited about	• Encourage and allow time for full assessment of the change • Maintain positive reinforcement to follow things through • Keep things interesting and fresh by encouraging one-going dialogue. • Partner them to generate fresh ideas on how to achieve team success with the change. • Have them lead sub-team so they take ownership of the actions.
The Poker Face	• Adapt easily and willing to change without any resistance • Generally optimistic approach and follow whatever is required • Eases transition to new processes or standards	• Does not encourage open discussion and allow for improvements • Difficult to gauge how they really feel about a change and may require additional management support	• Encourage this group to get more hands-on and involved in initiatives related to the training • Conduct regular 1:1's and ask the right questions
The Trend-Setter	• Researches the changes and is fully knowledgeable on impacts • Seek the highest standards for the change • Positive influence and source of information for the team	• May have a negative impact if they do not agree with the change after assessing impact	• Reinforce the positive impact that the change has for the organization and the need for the change.

Table 1. Positive and negative effects of attitudes to change in a team

MANAGEMENT IMPACT TO CHANGE

When it comes to change, managers are a primary source of decision making and can help shape the change culture within a team and should be similar to the "Trend-Setters". It is essential that the manager displays behavior that will encourage the team to embrace change and foster an attitude of encouragement and innovation. Creating a culture where change is accepted within a team is also crucial as this prepares the team for inevitable changes. Decisions for changes are strategically aligned with the organization or can come from a client however the information is

disseminated through the management team and this is how it is perceived by the team. Understanding how your individual team members react to change will help you to manage them through the inevitable and adapt your management style to accommodate to different personalities and traits.

There is no such thing as the perfect team ready for change and your team will most likely be made up of a combination of these team members and even some who fall outside these types. Utilizing the advantages of each type can help you to create a culture of change within your team and allow smoother transitions by focusing on the positive effects that each type can bring and mitigating the negative impacts. There are certain things that you can you can do to help facilitate smoother transitions for all your different types of team members such as hosting regular team meetings to discuss ongoing progress or updates. This will help the team understand why these changes are occurring and how it is in line with the organizational strategies. As with any change there are positive and negative implications and an honest approach is required where these changes should be discussed with the team. This allows an open forum for questions across the group allowing the "Resisters" to voice concern and allowing the "Trend-Setters" to answer all the while allowing the "Poker Faces" to take it all in.

POPULAR CDISC TRAINING APPROACHES

Once the change has been set into motion and all the information presented then the need for training arises. Using the information of how your team reacts to change can be a good indicator as to what training may best suit the needs of the team. There are many approaches to team training and some of the more popular choices are outlined below;

TRAIN-THE-TRAINER

The train-the-trainer model involves a selection of project team members who have been identified as having the desire and availability to train others and not just want to attend training courses before anyone else. These team members receive training from experienced personnel such as instructors or subject matter experts in courses, workshops or tasks. The project team members would be involved in a training event led by this expert who would develop the skills and expertise required in order to train the remaining team. The trainer prepares the trainees on how to present the information effectively and link the training to the tasks that will be performed as well as offering a support network for questions and practical advice on adult learning methods such as introductions and ice-breakers. One of the main advantages of this type of training is that there are multiple trainers being trained at any given time and this will help facilitate enhanced training schedules while considering on team's ongoing project work, time-off, holidays etc. Some disadvantages of this model are that the initial training sessions need to be interactive enough to give the trainees the information required in order to go forth and train others. This will depend solely on the trainer's effectiveness as a trainer and the quality of the training materials. Scheduling issues may also arise for the initial training and not all team members will receive training in their desired timeslot or may not receive the entire course to timing conflicts. The train-the-trainer model requires an amount of time to be invested in initial training and it is best that the follow on training is completed in phases so as not to disrupt ongoing project work as most teams may not have the resource availability to train all of the team at the same time. As this model takes time to implement and is a phased training approach, particularly in a large group it is worth considering the budgetary implications. The initial training will not have as big a hit to the budget as there are a select few team members involved however you would need to accommodate for the gradual impact on a phase by phase basis.

The train-the-trainer model may particularly suit a team mostly consisting of "Resisters" as it will actively involve them in the training session allowing them to further understand the changes as presentations and guides need to be developed to aid teaching of the material to the other team members and there is an increased commitment to the change itself. It would be hoped that by involving the team member more that they would become acclimatized to the change and would eventually become a spokesperson for this transition. In order for this model to be successful using "Resisters" you would need to assess the potential instructors and ensure that they are a fit for this type of training and have the appropriate confidence and communication skills required for effective training.

ON THE JOB TRAINING

On the job training is exactly what it says and this model of training is in the form of actual project work. The training is conducted on-site and using the company's software and products, this type of training is more focused towards your company and project specific tasks. There is minimal formal training required and the team is provided with enough information to begin a task. The team will then have access to the necessary material, support and guidance in the form of:

- Login information to project area, documentation (SAP, protocols, data entry guidelines)
- Access to similar projects if they exist to use as a reference
- Where the new environment is CDISC, access to implementation guides, CDISC forums, SDTM resources in-house presentations.

- Contact Information of SMEs (Subject Matter Experts) within the same company/ therapeutic area.
- An on the job mentor to provide support and guidance at a practical level

On the job training is a popular approach as it involves very little initial training or transition period for each team member and project work is started immediately. It also has major cost savings as there is no off-site training involved, travel and accommodation fees as well as trainer consultancy fees. The practical element of this type of training will suit enthusiasts, who are eager to get their hands-on new project methods as well as those who learn by example. As this is quite an immersive model for training it does not fit well for those team members that are easily overwhelmed or lack accountability. One of the disadvantages of this model is that it is very unlikely to set the project team on a successful path with on the job training alone. While the team can progress with project work and are constantly learning by example the lack of in-depth knowledge may leave the project team in a false state of progress with the inability to identify issues ahead of time.

On the job training may particularly suit a team made up mostly of "Embracers" as they will flourish in this fast paced, self-motivated environment. The constant learning and changes will be seen as a challenge and they will be eager to make the project a success.

SELF-PACED CBT

Self-paced computer based training (CBT) can come in many varieties however the fundamental concept is the same – the learner will complete the training at their own pace. This very popular approach (also referred to as e-learning) is used in many companies with a global presence as it allows multiple people in multiple locations to access training materials using only a computer and the internet. Intermittent short quizzes during the training and at completion stage can be used to gauge the team member's understanding of the material and ensure a deeper understanding of the topics.

It is a fantastic platform for delivering training material and can be stopped, started and rewound as many times as the trainee requires and the courses provide a hands-on, Interactive and standardized way of learning as all team members receive the same training and if updates are required these can be updated easily. Another advantage of self-paced CBT is that there is an audit trail created and a record available for each training session the learner completes cutting down on paperwork. This is a very cost effective and time effective way of training your team and also allows the learner to re-review items as a refresher if required. The major disadvantage to this type of training is the high initial set-up costs and development effort. Some team members may not like the impersonal nature that is common with CBT and prefer a more interactive hands-on approach and it does not allow for question and answers to be included as we would see in more traditional training methods.

This model of training best suits the "Poker Faces" as they adopt a standardized approach to new things and will adapt easily, they rarely push back and utilizing a standard set of trainings would therefore allow these team members to learn what is required in a cost effective and timely manner.

GROUP TRAINING

This model of training involves an SME or external trainer teaching an entire group at the same time using instructor - led training, face to face or virtual training methods. The cost implications come into play here also as many group members are being trained at once so can qualify for group discounts if external trainers are involved, this is also a much more efficient way of training the team compared to individual training as the whole team is trained in one go allowing more time for the trainer to focus on other tasks. As the training is completed with multiple participants, this in turn creates a support network for questions after the training is completed. In a group setting there is more encouragement for open communication and the team will also benefit from Q&A sessions and discussions throughout the training. Group training also allows those team members who may be shy, to listen to what their colleagues have to say and learn from that also. This model has the shortest training time of all the models discussed, and minimal impact on budget. Some of the disadvantages are that individual training needs cannot be met and all team members need to keep the same pace during the training. Another downside is finding a suitable time to train the complete team. With the prevalence of global teams, project work and scheduled time-offs, it is difficult to source a one-time suit all solution that ensures that all of the team is trained at once.

Group training will be of particular interest to the "Trend-Setters" and they would make excellent trainers. The "Trend-Setters" enjoy taking in all the information, making themselves SME's on the topics and will encourage open discussion within a group setting.

Table 2 outlines summary by training type:

Type of Training	Approach	Timeline Considerations	Budget Considerations
Train the trainer	Multiple sub-teams	• Initial training period and preparation of training materials requires heavy investment of time • Follow-on sessions with new trainers will require additional time off projects for each training cycle	• Initial TTT session may need to be conducted by an external trainer • Non-billable time must be allocated to production of training materials affecting billable project work and associated budget.
On the Job training	1:1 Coaching & Mentoring	• Project work is started immediately • Ongoing training ensures no disruption in service	• Minimal, but there can be indirect expenses due to quality issues and rework that may occur later in the process due to lack of expertise
Self-paced CBT training	Individual	• Minimal impact as this training can be fit in around schedules and project timelines.	• High initial costs in set-up and implementation • Low maintenance costs • Low licensing costs
Group Training	SME Led Training	• Initial training session requires most, if not the entire team to be unavailable for project work for a set time	• If an external trainer is utilized then consider the cost of this training • For external training avail of group discounts

Table 2. Summary by training type

POPULAR ORGANIZATIONAL APPROACHES TO CDISC TRAINING

As an organization you need to think big when it comes to getting multiple groups of project team members up to speed on CDISC standards. The organization needs to provide a support network and an environment for innovation and learning. Some of the approaches we have taken as an organization are outlined below:

DATA STANDARDS GROUP

With a large transition such as legacy to CDISC conversion whatever training is provided will only constitute 80% of the actual required knowledge as it will focus on the theory behind the concepts. The remaining 20% knowledge will require supplemental support as expertise can only be built by experience, mentoring and coaching. Having a data standards group within an organization can provide this support through key team members who are proficient in the implementation of CDISC standards, have a working knowledge and can provide expertise where required. These team members are the go-to people for CDISC queries, conceptual discussions on implementation and further training and this group is essential for a smoother transition to CDISC standards.

CONFERENCE ATTENDANCE

Encouraging employees to attend conferences and events will also create a more open approach to CDISC as the attendee will be surrounded by presentations, training and hands-on workshops where a considerable amount of these relate to CDISC standards. This can help to create an enthusiasm for the standards and also share knowledge, experiences and success stories with other employees from different companies.

LOCAL CDISC GROUPS

While attending conference can be somewhat limited due to travel, time and budgetary constraints, being an active part of local CDISC groups is another way to stay updated with CDISC standards and should be encouraged by an organization. This provides a cost-effective way to retain CDISC knowledge that has been acquired through company training, become familiar with CDISC standards without having to be overwhelmed. This will help employees to have a sustained local network which can be both rewarding and relaxing.

VOLUNTEERING FOR CDISC

One other way of staying up to date is to volunteer for CDISC directly. This involves reviewing upcoming CDISC standards, discussing the impact and providing feedback. Since this can be diced down all the way to therapeutic area, the employee will be able to relate these standards and their application to their projects.

CONCLUSION

According to Gautam Buddha, "If you want to change, you have to be willing to be uncomfortable". Knowing that change will bring a certain level of discomfort to your team can help you strategize which training would be most effective. As managers are involved in the change process from the beginning they would have experienced the psychological impact of implementing new standards on the team as well as witnessing the discussions and concerns. Utilizing your management skills is essential as it allows you to provide a clear direction and focus on what you want the team to do, while fostering an open dialogue for the team to ask questions and provide suggestions. Knowing what types of training are available will also allow the manager to assess any budgetary constraints and to choose the most effective and cost efficient training suited to their team.

We have utilized all of the training methods discussed within our team at some stage or another and with the move to CDISC for our team imminent, we consider a blended approach to be the most appropriate however the timing of the training is imperative. Once trained it would be recommended that the team actually use the knowledge gained in either a test or live environment in order for them to retain it. We have found that this holds true especially where CV assessments and interviews are concerned as it is common to come across candidates that have formal CDISC standards training however due to lack of use have not retained an appropriate level of information.

In practice and throughout our company we have found that the train-the-trainer model is a great starting point for CDISC training and will help to create a network of experts that can train the masses. The addition of on the job training and some self-paced learning will also help re-enforce the knowledge at a practical level. With the correct level of support from your company CDISC standards group, the right training approach and a dedicated team willing to learn something new and exciting, a transition from legacy standards to CDISC need not be as scary as first thought.

REFERENCES

Robbins, Stephen P. Judge, Timothy A. 2013. Organizational Behavior. 582-601, Prentice Hall

Shaul, Oreg. 2006. Personality, Context, and Resistance to Organizational Change. *European Journal of Work and Organizational Psychology Volume* 15, issue 1. 73–101

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