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Getting Ready for PDUFA V
The New “GCP”: Governance, Communication, Planning
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ABSTRACT

With the recent approval of PDUFA V legislation, sponsors are both encouraged and hesitant of what lies ahead. For many, the day has come where upper management can finally be told...these data standards are required for submissions. For others, perhaps a blessing in disguise. For all, we now need to strategize and plan for our road to success in data standards implementation.

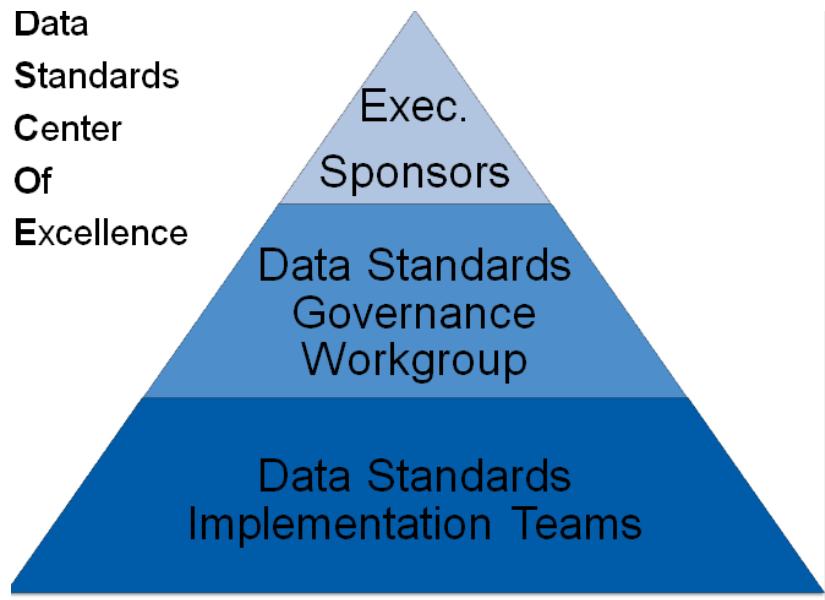
This presentation will follow the 3 critical strategies for success: Planning, Communication, and Governance. Having gone through multiple standards-based submissions, these three strategies have been identified as key to accomplishing the daunting task of conformance. I will discuss the three strategies including lessons learned and recommendations for future submissions.

INTRODUCTION

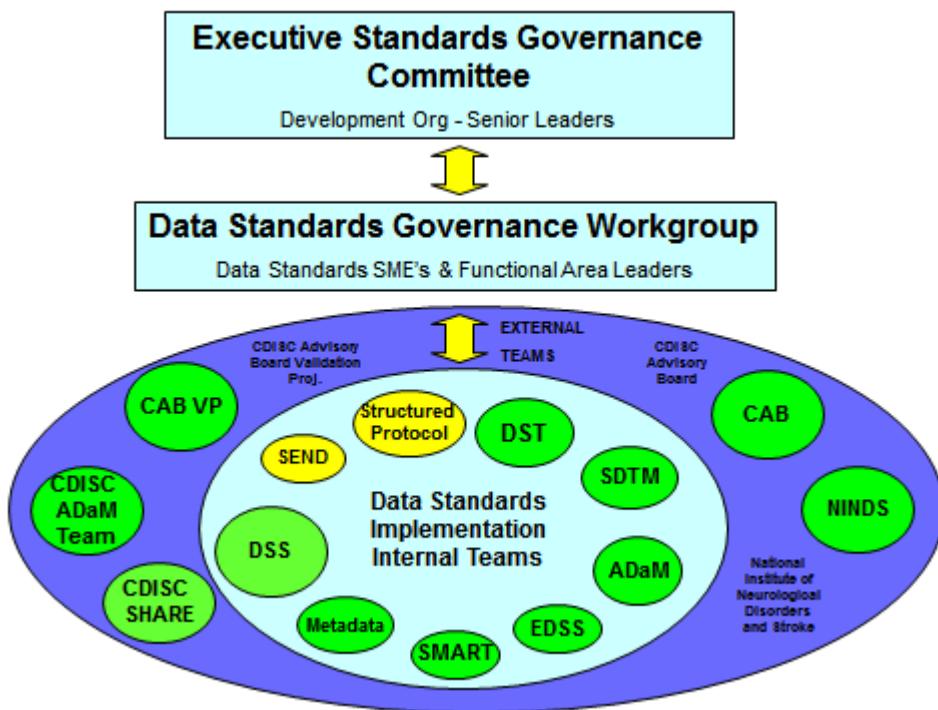
In July of 2012, the President signed PDUFA V into legislation. PDUFA V contains what many in the pharmaceutical and biotechnology industries have been waiting for, and what many have been dreading...the requirement of **standardized** electronic data submissions. I think it is finally recognized that this is the correct path forward to higher quality submissions and key to a faster, more efficient review process complete with more capabilities than it had before. There are three components that are crucial for biotech/pharma companies to meet the timelines of PDUFA V without compromising quality of the submission. All of these components have to do with proactive processes...many companies are still in a reactive phase of data standards implementation, and that is going to make meeting the regulations very difficult and in some cases next to impossible. These three components are: Governance, Communication, and Planning or as I like to call them, the new “gcp”.

GOVERNANCE

Approximately 3 years ago, it was recognized that there was a need for an internal governance organization to oversee all of the data standards activities that were both ongoing and yet to begin. As the governance organization began to form, many things were evident that were necessary for this framework to succeed. First, governance needed to be cross-functional. Many times when we implement standards, we don't take enough care to realize the impact our work has on other departments throughout the company. Implementing data standards many times means changes to process....which is usually impactful on others outside of our own function. So, we knew we had to include members from Biostatistics, Data Management, Statistical Programming, Data Standards, and Clinical Operations at a minimum. Second, there needed to be a hierarchical structure with different degrees of participation, and the most appropriate team members placed in each level. Below, you will see the early design of the governance structure.



After the three layered structure was decided up, then we started to assign roles and responsibilities to each layer. The middle layer, or the data standards governance workgroup would become the workhorse of the governance organization and would be crucial to keep standards implementation rolling along. This committee would be responsible for many things including most importantly, the overall strategy, vision and mission for how the company would approach integrating data standards into the organization as a whole. They would serve as an “umbrella” under which sat the data standards implementation teams. These teams would be the “owners” of the standards. Cross-functional teams that would lay the groundwork for how the different standards (CDASH, SDTM, ADaM, Define.xml, etc) would be implemented. Not the easiest of feats. Below illustrates this next stage of the creation of the governance organization.



You can see that the different types of employees that make up the top two tiers of the organization, and a representation of the many implementation teams in the bottom tier. Note that this also includes the many external teams that are represented, as that is also a key component to having the most up to date knowledge of standards implementation strategies.

Once the governance organization is in place, then the duties of the middle tier, the governance committee itself can determine what its responsibilities are. Remember, governance is not about making decisions, but deciding who can decide. These include the following:

- Governance of the standard CRFs
 - With a suite of CDASH compliant standard CRFs, issues often arise when teams would like to propose changes to the standards. These arguments need to be heard and then redirected to the appropriate people/teams needed to make final decisions on how or if the standard pages can and should be changed.
- Raising awareness of the standards strategy
 - All too often, those that work in standards find themselves constantly hitting the same wall. How do we get others in the organization to understand the what, why, and how of data standards. It can seem like a constant struggle, but the governance team can put in place education programs, trainings, etc. to help illustrate the needs to others. With the onset of PDUFA V, this is becoming much more important, and also easier.
- Ensuring appropriate resources to participate in external teams
- Develop a standards infrastructure to correctly, consistently, and in a harmonized manner, implement data standards on new and ongoing work

COMMUNICATION

The second component of the new “gcp” is communication. In terms of preparing for PUDFA V, I am talking mainly about communication with the regulatory departments at your company, and with the FDA themselves. It seems like common knowledge that this would need to be a big part of preparation, but with large amounts of work, internal timelines to meet, etc., this can often be overlooked and either brought into perspective when it's either too late in the process, or not at all.

Communicating with the regulatory personnel within the company is key to a successful submission of any kind. Add in federal regulations and it becomes a necessity. Mainly because regulatory personnel are not typically subject matter experts in the field of data standards implementations and they need to be made aware of what those of us that are, are actually doing.

In addition, sponsor companies need to communicate with the FDA. This in some cases may be not even be possible without the above step (communicating with regulatory) in place. Communicating with FDA gives us the opportunity to describe our approach and intentions of how we plan to meet PDUFDA V and gives the FDA the opportunity to agree or disagree with our strategy. All too often questions come up very late in the game and we find ourselves asking, I wish I knew what FDA would think about this.

PLANNING

The third and final component of the new “gcp” is planning. We all plan every day, for all the various tasks we do on a daily basis....both in and out of work. Meeting a goal such as PDUFA V can be daunting for anyone, but would be less intimidating if a plan is in place. It is recommended to initiate a data standards plan, from the get-go of any early phase program about to enter the development process. Data standards plans could include many things, including but not limited to:

- Versions of standards models being used
- Standards implementation and harmonization strategies
- Plans for sample submissions
- Anticipated issues and proposed solutions
- Submission strategies
- Data validation plans

Once a data standards plan is in place, then the communication process mentioned above can begin to take shape. This should be an ongoing dialogue, and the data standards plan is a living document and process designed to follow the lifecycle of a drug program.

CONCLUSION

In order to ensure a smooth and relatively painless transition to meeting PDUFA V requirements, it is crucial to implement a process that will support the wonderful and meaningful work drug companies perform while confirming the regulations have been met. It is important to note how PDUFA V is more than just a law put into place that we now have to abide by, but a shift in the data environment that marks a significant turning point....one towards a new age of higher quality, increased efficiency, and better transparency of the work we all do. The new "GCP" strategy will help guarantee these goals are met and empower people to know that they are managing their programs efficiently and effectively.

CONTACT INFORMATION

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Author Biography

Joanna Koft is a lead analyst in data standards with Biogen Idec, Inc. After several years as a SAS programmer, she made a transition to focus on the strategy and implementation of data standards. Working in the Biostatistics organization within Biogen Idec, she has gained extensive experience with the implementation, harmonization, and governance of many clinical data standards (including SDTM and ADaM) in preparation for a regulatory filing.