PharmaSUG 2013 - Paper MS02

Life Cycle of a Data Point - A Tool to Educate the Clinical Development Team on What it Takes to Go From the Clinic to a Submission

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ABSTRACT

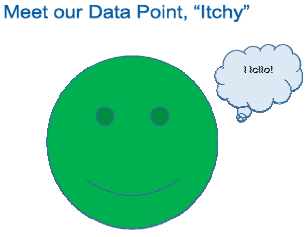
A common issue facing Biometrics and Data Management groups is a lack of understanding from other members of the Clinical Development Team, leading to unrealistic expectations and pressure to shorten timelines. A cross functional group from Biostatistics, Statistical Programming, Statistical Submissions Management, Data Standards, and Data Management got together and developed a presentation to show all of the steps that must be carried out to take data from the point of collection to being included in a submission and discuss how deviating from standards can impact each step. This presentation was very well received by a group of MDs from Clinical and Drug Safety and was recorded as a standalone presentation to be included as mandatory training for those groups and for Clinical Operations going forward. This paper describes the process of developing the presentation and the contents. The conference presentation will include excerpts from the recorded presentation as well.

BACKGROUND

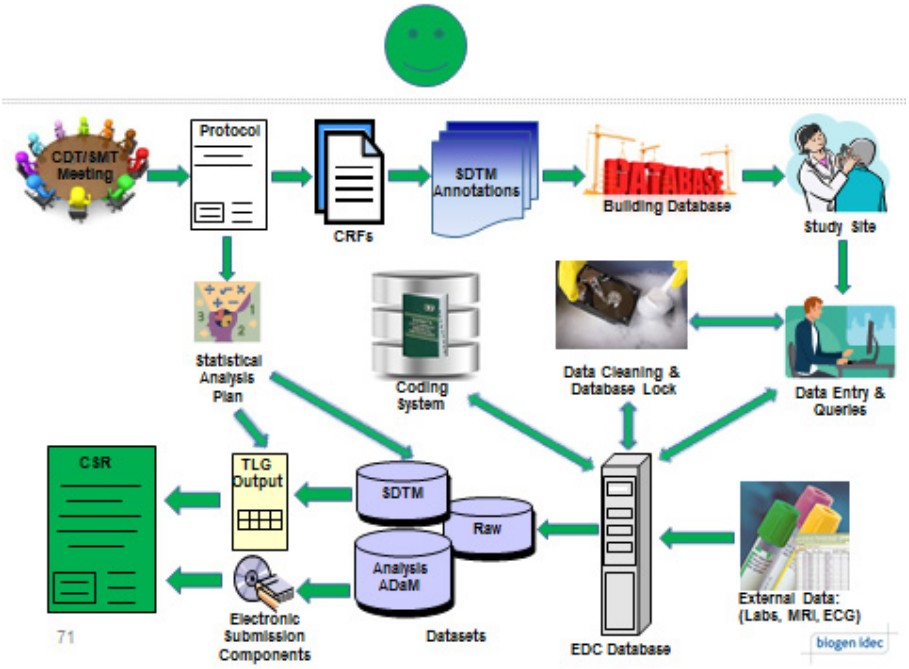
The Biometrics and Data Management leadership teams must answer to upper level management and are continuously being asked to justify their resources and defend timelines to other members of the Clinical Development Team. For a long time, the leadership of the Biostatistics, Statistical Programming, and Data Management departments would present to the management team separately, each with their own strengths and presentation styles. This was reasonably effective but there was recognition that if they combined their efforts, it could be even better. Additionally, there was recognition that these three departments were highly interconnected and the separate presentations were not adequately demonstrating this. The solution was to bring together a group representing all of the functions of Biostatistics, Statistical Programming, and Data Management to put together a combined presentation showing the full life cycle of data and all of the interdependencies between the functions. A team was formed with seasoned veterans from Biostatistics, Statistical Programming, Data Management, Statistical Submissions Management, and Data Standards.

DEVELOPING THE PRESENTATION

In developing the presentation, the first thing we had to do is determine the objectives. One way in which these departments can become more efficient and actually shorten timelines is through greater adoption of standards, so from the beginning it was agreed that one of the goals was to increase acceptance of data standards among the broader Clinical Development Team. So, in addition to showing the steps, and work, that must be carried out to take data from the point of collection to being included in a submission, we wanted to show how deviating from standards can impact each step. We chose to focus on a single data point in the hopes that this would make it very concrete and easy to understand. The data point we settled on was a common adverse event which is something that everyone is familiar with. The adverse event selected was 'Redness and Itching at Injection Site' and the data point it represents was named Itchy.

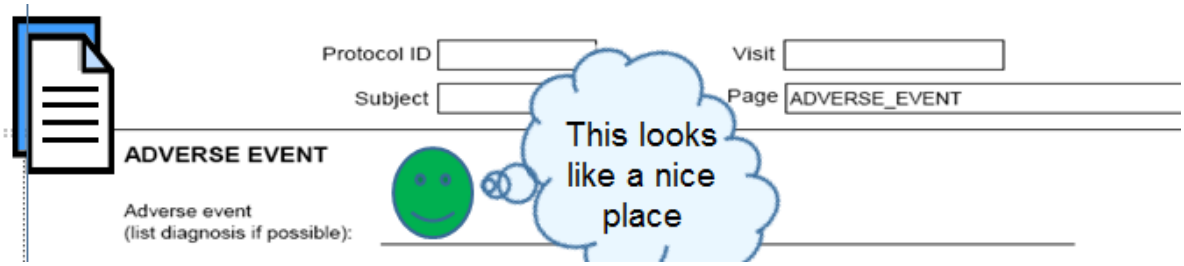


It was decided that the best way to convey the ordering and interdependencies of the steps that a data point must take on its way from the clinic to a submission is to use a flow diagram which we referred to as a process map. Once we mapped out each of the steps, we were able to break them up into meaningful groups and assign them to members of the group who would then develop slides and presentation material. As the presentation was built, we incrementally added each step to the process map until the final step when the completed map was finally presented on slide 71 (see below).



We tried to add some humor at each step along the way to keep the presentation light and engaging, with Itchy the data point making an appearance on every slide. The slides for each section were also tied together by using the icon which represents the section on the process map. Here are some examples:

- Introducing the origins of the data point on the CRF.



- Discussing database design and develolpment.

All along the way, we pointed out the role of data standards in making the process smooth and efficient. Now came the kicker, once we thoroughly explained all of the processes required to get data ready for submission, we went back and showed them the impact on each step of deviating from standards. Recognizing the distinction between the unavoidable deviations to handle study specific non-standard data elements and avoidable deviations made to standard data elements because of individual preferences or lack of planning, we showed two new process maps demonstrating the extra work involved in both scenarios and walked through them using real-world examples. The group gathered together for marathon practice sessions for three weeks leading up to our first presentation until all of the material was memorized and all transitions and handoffs were smooth and seamless.

THE ROAD SHOW

When the day finally came to present to a group of MDs from Clinical and Drug Safety, we were ready. The presentation went well, and the chemistry on the team was fantastic which helped keep the audience engaged. Even though the presentation was well received, we thought it was important to get meaningful feedback from the audience so that we could tweak it and make it even better. This was accomplished by creating a feedback form and enlisting the help of a department manager to guard the door and make sure that the forms were collected. This resulted in some very useful suggestions which were then incorporated.

RECORDING THE STANDALONE PRESENTATION

In order to record the presentation so that it could be loaded to our self-service training tool and be accessible to all members of the clinical team, we needed the right technology. Adobe Captivate proved to be just the right tool for the job. It allowed us to record the slide show with custom timings and transitions and then overlay recordings of our presenters' voices performing the presentation. Since we would no longer be presenting live and our audience would just see the slides and not the presenters, we needed to alter some aspects of our presentation style. This meant that we could not rely on pointing at something or at another member of the team when referring to them, and that we needed to decide whether to speak in the first person, as in 'I am a Statistical Programmer …', or the third person by having Itchy narrate, as in 'The Statistical Programmer must …'. We decided to use the first person with occasional interjections from Itchy itself. It was necessary to prepare a script for this purpose so the presentation on each slide could be flawless. The recording sessions were a challenging new experience for all of us but after many takes, we had a nearly perfect presentation that each of us was proud of.

CONCLUSION

After identifying the goals of increasing understanding among the Clinical Development team of the work that goes into taking data from the clinic to a submission and the role that data standards play in creating efficiencies along the way, we determined to create an engaging cross-functional presentation to convey this information. Much work went into the presentation and the end product was high quality and informative. The initial live presentation was very well received and seems to have achieved its goal as well as being a positive experience for the team. Innovative production techniques were applied to make the presentation a stand-alone training module to be rolled out to the entire Clinical Development group. We are very optimistic that this training will lead to more understanding of the work that Biometrics and Data Management groups do as well as better planning and more adherence to data standards.

ACKNOWLEDGEMENTS

We would like to recognize and thank the contributions of our presentation teammates:

Kim Umans, Biostatistician, Biometrics

Laura Putnam, Clinical Data Manager, Data Management

Kathryn McManus, Data Standards Analyst, Biometrics and Creative Director

Todd Bazin, Clinical Programmer, Data Management

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