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Standard data, extraordinary innovations in clinical trials

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As clinical trials require more robust and user-friendly systems to monitor data and conduct effective risk-based monitoring, the use of industry data standards can greatly drive efficiencies and reduce variations in data format from one study to the next. The increasingly wide acceptance of Clinical Data Interchange Standards Consortium (CDISC) standards, and subsequent requirement of the CDISC Study Data Tabulation Model (SDTM) standards, has opened innovation opportunities within the industry.

SDTM standards can be leveraged to create user-friendly, highly visual and interactive environments where any clinical trial team with SDTM data can quickly access and efficiently review patient data while the study is progressing. This includes, but is not limited to, safety review, quality review, supporting dose escalation studies, identifying trends or even integrating data across protocols.

In the past, creating a comprehensive solution that was scalable and didn't require bespoke programming from one study to the next was nearly impossible. However, CDISC standards makes it possible! Software and tools can be built that are reliant on the standards—such as CDASH, SDTM, ADaM—and allow for deployment across many studies, as long as those studies provide data in the agreed-upon CDISC format. This type of solution saves time because the data environment is developed in advance of the trial data being collected. It is rewarding to see how quickly new studies can load data into a tool and make the data available to a study team.

CDISC SDTM has become a standard with a much greater application than its original remit of regulatory submission—it can help foster innovation. The creation of innovative tools allows study data to be brought alive for clinical trial monitoring and review and to positively impact the quality of clinical trials.

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Tammy has nearly 22 years of project, people and technology management experience, all of which are at PPD. In her current role, Tammy leads a team that focuses on developing innovations and executing PPD initiatives that will further the company's ability to shape the future of clinical trials with a current focus on sites and patient access. Tammy was a key member of the Preclarus® development team and continues to manage Preclarus initiatives. Tammy obtained a Bachelor of Science degree in computer science at the University of North Carolina Wilmington.