

## ***A Risk Approach to Software Validation***

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If you're reading this article, chances are you spend a significant portion of your professional life worrying about data quality. As data managers in the clinical research industry, SCDM members deal regularly with data ranging from incomprehensible scribble on 3-ply paper to electronic data transferred in the latest XML file formats. In many cases, you may see a wide range of delivery formats between your various projects - even within a project. Despite this variation, a couple of undeniable facts persist:

1. The quality of these data is squarely your responsibility and
2. You have no hope of managing this information without some kind of validated, reliable database system

Enter the Data Quality Research Institute (DQRI). Founded by industry expert and CDM advocate Kaye Fendt, the DQRI treats quality as the cornerstone of its mission and has begun to move aggressively toward standards in this area. The DQRI is already attracting significant support from industry, standards groups and regulatory bodies and why not? Quality of data is perhaps the most central obligation of the research community and it is certainly complex enough a topic to evade state of the art technologies and even the most brilliant among us. Quality deserves an Institute.

But DQRI is not just another pretty acronym hanging out a shingle. The first working group to be formed by the institute has been hard at work for almost 10 months now and has presented results at several industry conferences including the SCDM Spring Forum in San Antonio this March. This group, known as the Software Validation Committee is focused on the somewhat vague regulation regarding the validation of clinical trials software. Membership on this committee includes industry, vendors, CROs, academia, and regulatory expertise - an intentional variety of backgrounds designed to bring a wide breadth of experiences to a discussion about revolutionizing the way validation is performed.

The committee began with the premise that existing guidance documents provide insufficient clarity on the topic of data systems validation. Perhaps the most well known requirement stated in the now infamous 21CFR Part 11 guidance is "validation of systems to ensure accuracy, reliability, consistent intended performance..." While this concept is largely self-evident, the specific guidance wording is hardly a prescription for performing acceptable validation activities. By developing a risk analysis model, the DQRI working committee hopes to provide a tool for industry to use when evaluating variations in risk of different software and variations in validation activities based on the risk analysis. Simply put, software with more risk should be more validated. Seems pretty clear but that's where the simplicity ends. Those of us who currently bear responsibility for software development and/or validation know that passing audits or any 3<sup>rd</sup> party evaluation of QA and validation activities is often a crap shoot - each reviewer

having a different take on how much planning, process, QA, documentation is enough. The DQRI committee hopes that the risk model will ameliorate much of this confusion in the following ways:

1. By using a DQRI risk model tool, companies will be prepared to evaluate software tools, programs, features and applications with a consistent methodology.
2. After determining a risk score using the model (briefly described below) companies can define and proceed with a validation plan knowing that the model provides a framework for them to defend their plan of action.
3. Regulatory bodies aware of the risk model will be prepared to evaluate the process a company followed to determine risk and validation approach.

This model may not give companies an exact prescription for validation. Nor will it likely become a blueprint for auditors to follow in their evaluations. More realistically, it will become a common language spoken by these and other stake-holder entities trying to understand how clinical trials software has been designed and validated to perform its function. Debate may still rage about gradations of 'risk' and iterations of validation activity but now, within some kind of commonly understood framework.

Early versions of this model continue to flux and the working committee is seeking widespread industry input to both validate the current direction and generate ideas to continue evolving the model. Feedback from SCDM members attending the Spring Forum was very positive. The model was presented to 60 manager and director level attendees from numerous Bio-Pharmaceutical companies. Clearly there is agreement that variations in risk call for variations in validation practice. Data managers at the conference also endorsed the notion that a multi-tier model tool would be beneficial when struggling with the somewhat subjective notion of risk assignment. Specific feedback from SCDM as well as other conferences is already being fed back into the committee's discussion sessions. Plans are also being made to present results to the FDA who is aware of the working committee and interested in reviewing progress as it happens.

The work of this first DQRI committee is earning praise so far but fine-tuning a model that can be widely applied will require considerable more work and industry input. More broadly, DQRI is actively seeking corporate membership investments to spawn several new working committees on issues related to clinical data quality. SCDM members interested in participating are encouraged to contact Kaye Fendt directly at [KFendt@dqri.org](mailto:KFendt@dqri.org). Specific questions about the risk model can be addressed to me at [costello@nextrials.com](mailto:costello@nextrials.com).