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E-trials are here to stay. Rob King and Dr Michael Bowden explain why the validation of such trials is a must-do job.

When the US Food & Drug Administration (FDA) posted regulations for electronic records and signatures in the Federal Register on 20 March 1997, the idea of a broad-based software solution for e-trial management was as elusive as wireless electronic data collection at the investigational site is today. The situation has changed rapidly. Open any industry publication and a glance at the myriad of advertisements promoting e-trial software confirms that we are in the midst of a revolution in the availability of software solutions for data capture and clinical data management tailored specifically to our industry. Of course, we still have to remind ourselves that more than 90% of trials are still conducted with first century support from stylus and paper. But we cannot ignore the fact that e-trials are here to stay and that they promise to deliver many of the efficiencies that we have all desired for so long.

If you have not yet participated in an e-trial, you soon will.

Background

As with any fundamental change in an industry or use of new technology, government agencies, professional associations and internal and external customers inevitably propose new regulations, guidance and expectations. Just in the last four months, eight countries have proposed or enacted new legislation concerning general use of electronic signatures and records.

In this whirl of electronic activity, the most common question related to e-trials is – is your system validated? In the USA, it all started for clinical trial professionals when the now infamous ‘Part 11’ took effect on 20 August 1997. The new regulation seemed harmless at first glance. The actual regulation is barely two pages long. A slight throbbing at
Depending upon who assesses your system, it can be declared compliant or non-compliant.
how you will test/analyse your hypotheses. Identify your validation team, their roles and the resources to conduct the validation. Do not proceed to the next step in your process without documented approval from responsible parties.

• During the validation process, have tools in place to measure and track your progress and whether the system is meeting your pre-defined specifications. If something is not working, fix it and document how you did it and that it now works. Just as you should have a clear audit trail of data in a clinical trial, the specifications in the system should be traceable as well.

At the end, you should have a history file of all the effort and results of your validation just as you would a study master file. Archive your history file and keep it for as long as you keep any study documentation for any trials conducted with the system.

If you are still worried that your system has not been fully validated and documented, draft a plan of how you will address it and improve your validation process. Due diligence goes a long way towards assuring others that you made your best effort.

As e-trials become more widespread, industry knowledge of validation will evolve and will be more widely disseminated in terms that we can all understand. The FDA is rumoured to publish guidance on validation any day now, followed by guidance on time stamps and audit trails.

So when the question is asked – is your system validated? Help is out there, more is on the way, and if you can design trials to test wondrous, new drugs and devices, you can utilise some of those same skills to successfully validate your e-trial systems.

Authors

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