Feature

Balancing openness and privacy: clinical trials

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Summary

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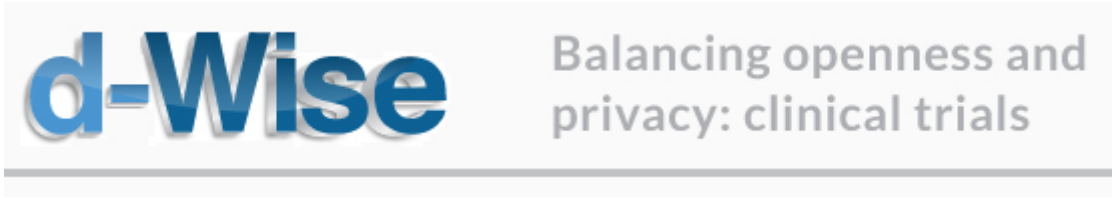

The drive to improve the transparency and collaborative nature of life sciences processes has reached clinical study reports, which must now be opened up for external access. This must happen in line with new EMA guidance on safeguarding subjects' identities. The associated de-identification process is no small feat, so the temptation for manufacturers is to find a shortcut to delivering this in time for the November deadline. But focusing on clinical study reports in isolation won't leave companies any better

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prepared for the next raft of requirements, warns Chris Olinger of d-Wise

In this era of openness, where the aim is not just to ensure patient safety but also to improve consumer confidence, there is growing pressure on life sciences firms to be more transparent about their clinical trials among other processes.

In March, the EMA issued detailed guidance based on its 2014 Policy 0070 for clinical trial reporting. As of November this year, organisations will need to make 'de-identified' clinical study reports (CSRs) available within 60 days of a marketing authorisation decision, even if this isn't a positive result.

With just months to achieve compliance, the temptation is to focus on the current goal alone - i.e. the CSR. Yet it is only a matter of time before all of the patient-level data behind those reports will have to meet the same requirements. The smarter approach to de-identification then is to start here, with the underlying data - because everything else flows from that.

This is also the only way to ensure that study findings retain their scientific meaning and value. Any ambiguity could create more work down the line for internal teams, once clinical trial findings are in the public domain and questions start to arise.

Where firms have already embarked on work to bring documentation in line, there is evidence of some of the dangers of taking shortcuts. Some organisations have taken on external agencies, often offshore, to process CSR documents - applying agreed formulae that will shield the identity of clinical trial participants (electronic redaction is not an option, according to the new guidance). However the focus on getting through the backlog quickly has in some instances led to consistency and quality issues, requiring work to be redone. Another approach, which is far from efficient, is to re-run reports using compliant, de-identified patient references.

It would be far better – far less risky, and ultimately more cost-effective - if companies adopted a more holistic strategy to patient data treatment. The source data (i.e. patient-level data) behind individual documents is structured and well organised, which means teams are able to transform the affected information systematically and comprehensively in a few simple steps. It is not unrealistic to expect to get through an entire clinical study's worth of data in one day. Amending study reports is then simply a matter of intelligent 'search and replace'.

The only real way life sciences organisations can stay ahead of the evolving requirements and minimise their exposure to risk is to anticipate what's coming next as well as prepare for what's happening right now. That means building patient de-identification options into the original processes, rather than for each set of output.

About the author

Chris Olinger has more than 30 years experience delivering software solutions. Most notably, he spent 14 years at SAS where he led the development of the SAS Output Delivery System (ODS). As R&D product manager, Chris led a team of developers charged with creating ODS, now a core component of SAS software used in nearly all SAS solutions. Chris has authored many technical papers and is a highly respected and much sought after industry speaker. As CTO of d-Wise Chris has a special interest in technology that can help transform the Health and Life Sciences industries.

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