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New EMA Guidance on Clinical Trials and Anonymization

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From November this year, any drug manufacturer selling products in Europe will need to comply with new EMA guidance on the anonymization of clinical trial data. The temptation is to focus on the immediate requirements —around clinical study reports — because of the approaching deadline. The smarter approach, however, is to manage anonymization starting with patient-level data. Dave Handelsman explains.

Improved transparency is a priority in life sciences, which is putting pressure on drug manufacturers to be more open about their clinical trials results. The industry has seen the trend coming for some time, and many leading players have already devised their own processes and channels for making their patient-level data more readily available.

From November this year, however, companies will need to follow formal guidance from the European Medicines Agency (EMA). After drafting a new policy for clinical trial reporting (EMA Policy 0070) in 2014 the Agency issued 91 pages of implementation guidance in March this year, which pharma companies must now act on. For now, this focuses on clinical study reports (CSRs), stipulating that, within 60 days of a marketing authorization decision, these documents must be made available in a form that removes any risk of a subject's identity being breached.

Looking beyond the letter of the law

The instinctive reaction to this requirement might be to adopt solutions or outsourced services that can take CSR documents and make the requisite changes to anonymise all references to subjects. Although this approach might stave off imminent panic, it is not a sustainable, long-term solution and could be more costly and time-consuming in the long run: the published policy document indicates it is only a matter of time before all of the patient-level data *behind* the CSR reports will need to be given the same treatment.

A more comprehensive and cost-effective way to approach patient anonymisation in clinical study documents, then, is to start with the patient-level data. Everything else flows from that, so get it right first time and everything from thereon in should be

watertight. In the long term, this will also save a lot of time, expense and risk.

This is also the only way to ensure that patient-level data is given consistent treatment – which is vital in ensuring that study findings retain their scientific meaning and value. If different algorithms are applied to patient anonymisation between documents and data, it becomes increasingly difficult to rejoin the dots if researchers later need to perform further cross-referencing and analysis.

Introducing unnecessary complexity could also create more work for companies down the line, as they find themselves called up to address numerous follow-on questions once clinical trial findings are in the public domain. As willing as they might be to meet growing market expectations around transparency, manufacturers don't particularly want to invite an open-ended discussion – administrative work that could tie up valued resource. Rather, interested parties should be able to serve themselves - finding all the answers they require through a designated portal (it is possible that the EMA will eventually channel all of the data through a central public web site). It is not clear why the EMA did not begin with the source data in its clinical trial anonymisation requirements: perhaps it sought to shield companies from the need to worry about the technicalities of thousands of data fields that may be associated with clinical trial data anonymisation.

The risks of taking shortcuts

Because the EMA guidance is so new, the industry hasn't had much chance to react to it yet. Electronic redaction (the equivalent of drawing a thick black line through patient information) is not an option, according to the new guidance. Aware of the time pressures, some firms have turned to external agencies to process CSR documents – ie to apply formulae that will protect a patient's identity, which could be open to discovery based on the type of study they took part in, their age, race and demographic, when they attended a clinic, etc.

Early attempts to keep the costs down by using offshore services appear to have backfired, however, creating quality issues and causing some work to need to be redone. In other words, it has proved a false economy. Meanwhile, given that a typical application for marketing authorization may comprise 50 separate studies, keeping track of the different formulae that have been used to protect patients' identities is creating its own issues. And what of all the old studies that may still have relevance to drugs being brought to market today? What scale of workload may be required to bring all of this archived content into line?

With just 60 days from marketing authorization to turn around all relevant CSR content, or suffer some form of penalty, it makes more sense that companies focus on a more holistic strategy for addressing trials' patient data, rather than individual manifestations of that data. This promises to be more economical in the long term, is more reliable, and means firms could prepare compliant, anonymised CSRs so that these are ready on the shelves at the time of marketing authorization submission.

Focusing solely on the initial demands of the EMA guidance may be understandable, but it could lead to more work and cost in the long run - something some pharma companies are already starting to find. Some companies are even considering re-running reports – redoing all of their analyses and recreating study reports using compliant, anonymised patient references. This is a non-trivial undertaking which adds no conceivable value for the business, and highlights the level of concern yet lack of real strategy across the industry.

The clinical trial anonymisation process could be much simpler if companies harnessed the right tools and started in the right place. Because patient-level data is structured and well organised, any modification to that data can be done systematically and comprehensively in just a few steps. Once they have found their stride, companies can expect to process an entire clinical study's worth of data in just one day. Once the master data has been given the anonymisation treatment, amending the study reports becomes a simple matter of intelligent search and replace; the hard work has already been done.

The overall investment isn't much more to do things this way, but the benefits are substantial. Remember: the EMA will expect fuller data anonymisation in due course; the CSR-only requirement is temporary. And starting with the patient-level data is a much more methodical and safe way to go about anonymisation - one that simultaneously makes it easier to produce conformant CSRs, while making it less likely that external parties will discover inconsistencies in the public reports and data which could prompt them to get in touch.

Keeping the wider goals in mind

Looking at the bigger picture is the best way that companies can 'future proof' their activities too, as transparency requirements are likely to grow — if anything. Although the FDA is not committing itself to the path the EMA has taken, it is not beyond the realms of possibility that it could make similar demands in future.

Meanwhile, the requirement to produce lay language summaries to make clinical trial findings more accessible to the general public provides a further indication of how important data sharing is becoming. In this age of digital connectivity and growing consumer consciousness, populations are exercising their right to know more about the studies in which they are participating, the products they are buying and the processes behind them. If not the case already, it will soon get to a point that companies that do not share their data risk being cast under a shadow, causing consumers to wonder what they may be trying to hide.

Patient privacy will always be paramount, so the life sciences industry needs to be clever about this and find the middle ground – between compliance/patient safeguarding and the advance and promotion of science. With the right measures in place, pharma can reasonably fulfil their risk management needs without sacrificing the science in the process.

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