Clinical Trial Transparency: New Data Anonymisation Requirements

Faced with new European Medicines Agency (EMA) guidance on the anonymisation of clinical trial data, drug manufacturers targeting the vast EU market have two choices: do what it takes to meet the November deadline – which prioritises clinical study report content – or embrace a smarter and more sustainable strategy that starts with patient-level data. Chris Olinger, CTO of d-Wise,, advises against taking shortcuts.

The growing market expectation for corporate transparency is putting pressure on life sciences to be more open about their clinical trials results. Patients quite rightly want to know the findings of studies they took part in, and other researchers as well as the general public have an understandable interest in monitoring outcomes too. It is a trend that the pharmaceutical industry has seen coming for some time, and at least 20 leading players have already devised their own processes and channels for making their patient-level data more readily available, in anticipation of eventual regulatory intervention.

But now the European Medicines Agency (EMA) has stepped in with its own formal take on the situation. After drafting a new policy for clinical trial reporting (EMA Policy 0070) in 2014, the Agency has now issued a hefty 91 pages of implementation guidance, and life sciences organisations must comply with the new requirements starting from November this year.

While the current marketing authorisation process already requires the submission of clinical study reports (CSRs), the new regulation stipulates that, within 60 days of an authorisation decision (positive or otherwise), the CSRs must be made available in a format that removes any risk of a subject's identity being breached.

Although the industry hasn't quite reached a state of panic in response to the new requirements, concern is running high. November will come around soon enough, and the majority of life sciences companies don't have a plan yet; they are still working out what to do.

The Danger of Cutting Corners

So what do we know? The extensive guidance issued in March prioritises clinical study reports as the primary target for patient anonymisation. This makes it very tempting for organisations to focus any investment and strategy in this area – on sourcing solutions or outsourced services that can take CSR documents and make the requisite changes to anonymise all references to subjects.

This knee-jerk reaction may meet the initial requirements and stave off imminent panic, but it is not very efficient and is not a sustainable, long-term solution. Although the EMA has started with CSRs as its target, the published policy document indicates it is only a matter of time before all of the patient-level data behind those reports will need to be given the same treatment.

The smartest, most comprehensive and cost-effective way to approach patient anonymisation in clinical trial documents 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.

Importantly, this is the only way to ensure that patient-level data is given consistent treatment – which is critical 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. The ideal is that 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 website).

Why the EMA did not begin with the source data in its clinical trial anonymisation requirements isn't clear. Possibly, the Agency thought that starting with CSR reports would make lighter work for organisations in the early stages of adapting to the new demands, shielding companies from the need to worry about the technicalities of thousands of data fields that may be associated with clinical trial data anonymisation.

False Starts

So what are companies doing currently? The industry hasn't had much time to react to the EMA guidance yet, because it is so new. Concerned about the time pressures, some firms have taken the easy way out – engaging external agencies to process CSR documents. Electronic redaction (which is the equivalent of drawing a thick black line through patient information) is not

an option, according to the new guidance. So formulae need to be applied to protect patient A's identity - which could be open to discovery based on the type of study they took part in, their age, race and demographic, and when they attended hospital or clinic, among other bits of information in their clinical data record.

Some early attempts to keep the costs down by using offshore help seem to have backfired, however, creating quality issues and causing some work to need to be redone. In short, it has proved a false economy. Meanwhile, given that a typical application for marketing authorisation 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 of marketing authorisation 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 authorisation submission.

Get it Right First Time

Sticking to the letter of the law and focusing only on the initial requirements of the EMA guidance may be understandable, but it is a short-sighted approach which could lead to more work and cost in the long run. This is something some pharma companies are already starting to find, as their current piecemeal approaches to the challenge begin to struggle.

Another sign of this is that some companies are considering to re-run reports – redoing all of their analyses and recreating study reports using compliant, anonymised patient references. The fact that they are even considering a non-trivial undertaking of this nature, which adds no conceivable value for the business, confirms the level of concern yet lack of real strategy across the industry.

If companies understood how much simpler and less painful the clinical trial anonymisation process would be if they harnessed the right tools and started in the right place, they could avoid much of this stress. Patient-level data is structured and well-organised. This makes it easy to manage any transformations, because this can be done systematically and comprehensively in a few simple steps.

When they have got the hang of it, companies can expect to process an entire clinical study's worth of data in just a 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 long-term gains are substantial. Let's not forget – the EMA will expect fuller data anonymisation before too long; the CSR-only requirement is a temporary step. So there is no avoiding this. And starting with the data is a much more methodical and safe way to go about patient anonymisation; one that simultaneously makes it easier to ultimately anonymise the CSR, while making it less likely that external parties will discover inconsistencies the public reports and data which cause them to get in touch.

Embrace Transparency

Expecting transparency requirements to grow, and building anonymisation options into the original processes, is the best way life sciences organisations can stay ahead of the market and minimise their risk. Although the FDA is not committing itself to the path the EMA has taken, it is conceivable that this will change down the line, so there is no justification for complacency whichever markets pharma organisations are targeting today.

The requirement to produce lay language summaries to make clinical trial findings more accessible to the general public is 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. It's about finding the middle ground – between compliance and patient safeguarding, and the advance and promotion of science. With the right measures in place, pharma should not have to worry about the risk posed by greater transparency. Rather, their concern should be about meeting a 'reasonable expectation' of risk management – one that doesn't sacrifice the science by stripping the value out of the data.

As time ticks by, companies should develop strong resolve – making their goal not simply to meet the minimum current regulatory requirements around CSR anonymisation, but to remember the spirit and wider purpose of the policy. This is to disseminate knowledge, and to empower external communities to find the answers they need more readily – so that the benefits of research and of medicinal advances have the broadest possible reach. That's what real progress looks like.

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.
Email: chris.olinger@d-wise.com
Web: www.d-wise.com