How AI can help minimise compliance risks

Dr Joe DiCapite, Vodori Director of Strategy, discusses why he believes a revolution in material review software is coming.

What does material review involve and what challenges does it present for the pharmaceutical industry?

The pharmaceutical industry reviews and approves all its promotional content, as well as some non-promotional content, primarily to reduce the risk of breaking strict compliance rules. This process involves rigorous scientific accuracy checks, as well as subjective decision making about risk management. It can be labour intensive and can divert attention from other high value activities.

How do you see material review changing over the coming years?

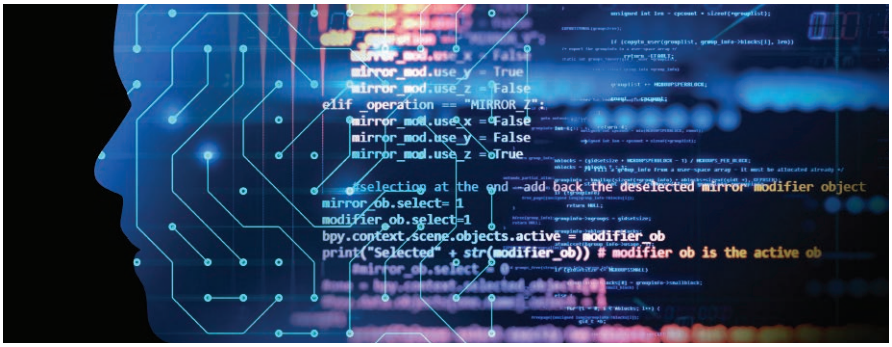
Pharma has historically been slow to adopt practices that are common in the tech space. However, COVID-19 has forced a digital transformation in pharma, and I think this will lead to more rapid adoption of practices that are common in tech. One area that I believe will drive a revolution is the use of artificial intelligence (AI) in promotional and non-promotional risk management.

Do you really believe AI can help companies solve such a complex problem, and reduce their compliance risk?

Yes, without doubt. It is all a question of where you choose to use AI. Initially we see machine learning (ML), which is just a small part of AI, as an area that can certainly help. It will not be able to solve the complex issues yet, but what it can do, and in some cases is already doing, is reduce the workload on straightforward tasks like reference checking, identifying frequently flagged strings of text, etc; all the while giving the review team more time to focus on the truly complex and ambiguous areas. I also believe that the more software companies use this approach, the faster competition will drive progress.

Surely even relatively simple tasks in material review still need the human touch?

In my experience, around half of the issues that cause problems for companies result from human error, rather than companies strategically pushing the limits.



It has been proven in so many different fields now, that computers are far more reliable than humans in identifying the type of errors that are tripping up companies.

In my own experience, I have seen regulatory black triangles that are not black and countless times absolute risks have not accompanied relative risks – these are two very specific things that smart computers do not miss, yet busy reviewers can.

So the human touch can be both positive and negative!

What lessons can pharma take from other sectors?

The biggest lesson is to ensure that some healthy competition is injected into this historically single player software space. In the tech space, competition is fierce and vendors are changed frequently to ensure companies receive market leading support. Proper competition will enable companies to effectively tender for new vendors, and also at contract renewal, to ensure they are getting the best solution.

Secondly, do not forget good business practices. Speaking as a member of the review team, there are countless improvements that we all know we should make, but don't always do. For example, early collaboration on materials, distinguishing between mandatory and suggested comments, effective use of material review meetings – these all contribute to better review processes.

Finally, innovation does not have to be algorithms and computer science. We have data showing that focusing on user wellbeing drives improvements. Around-the-clock access to human customer support (which is surprisingly uncommon) improves user satisfaction, speeds up review and helps companies achieve their financial goals. This is the type of improvement that proper competition should bring – it's not difficult to implement, but companies often choose not to.

I moved from the pharma industry into the tech space as I think pharma can learn a lot from tech. I want an overhaul of how material review is executed in life science. That comes from product innovation within our company, which will in turn drive on other companies in this space.

Dr Joe DiCapite

Joe is Director of Strategy UK/EU, Vodori. He has spent most of his career working in commercial teams in medium to large pharmaceutical companies and is now supporting Vodori as they expand with a new European base in the UK.

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