Are Regulatory Service Providers Over-estimating AI's Potential Impact on Process Transformation?

Advanced digital tools are certain to play a pivotal role in the redesign of labour-intensive regulatory processes, but there is a danger that AI's potential contribution is being over-hyped to life sciences firms. Alan White, CEO of Arriello, warns that the key to ROI is in the application.

Within the next three years, the pharma and biotech industries will be at a point of deploying AI and machine learning to transform the pace and productivity of routine regulatory processes, according to Deloitte[1]. By 2022, automated writing of clinical study reports will be happening as standard, using natural language processing – industrialising the conversion of structured study data into text narratives. Meanwhile leading firms will have automated up to 95 per cent of regulatory filing, saving up to a year in their launch cycles, it claims.

But is there a danger that the industry is being over-sold on the promise of AI? Where manufacturers are outsourcing routine processes to external solutions and services companies, and being promised the earth in terms of smart automation, they must be clear about what exactly they are being promised and what measurable, visible impact any proposed new innovation will have on their operations. This is particularly the case for mid-range pharma companies and smaller biotech firms, which may not benefit to the same degree from automated process efficiencies as Big Pharma, because their needs are not of the same scale.

It's all too easy to set unrealistic expectations of how quickly AI-enabled improvements will filter through to the bottom line. In the meantime, procurement managers and department heads need to be able to demonstrate improved value and efficiency in the here and now.

The good news is that technology-enabled transformation can happen on a much more modest and focused scale, and still have a big impact – today. Indeed, the more focused and specific the target use case and its mapping to a known 'pain point', the greater the chance at making a significant difference in a reasonable timeframe, and without major disruption to the status quo.

Targeting PV Pain

Take pharmacovigilance (PV) and the role drug companies' sales people are expected to play in reporting any adverse reactions experienced by patients linked to any of their organisation's products (for instance, if such information is relayed during face-to-face or phone-based client meetings). If this reporting task is left to chance, happens manually and/or (because sales people are human) left until some later point, the quality and value of the sales agent's input is likely to be relatively poor. They may scribble some notes for someone else to transcribe later, and/or forget to capture the fuller details that are needed for a complete PV report. They know they have a responsibility to pass on this feedback, but for a busy on-the-road sales rep this just isn't a priority.

But what if a simple yet clever software tool could make light work of PV reporting for those frontline teams? What if they could simply input and dictate all the required details straight into a secure mobile app, then move on? This would alleviate pressure on the sales rep, who has other more pressing tasks to attend to. It would also save on painstaking follow-up work by PV/safety teams and contract service providers, who ordinarily would have to try to verify any ambiguity and fill any gaps after the event – and at a point when it might be difficult to track down the clinician or pharmacist with the original case notes.

The intelligence in a software solution like this could be in the smart workflow, prompts and auto-filling of information fields, and the ability to link voice notes to a file containing additional case data. It would also be in the tool's ability to capture some of this data in a structured way as part of the recording process.

Small is Often Most Impactful

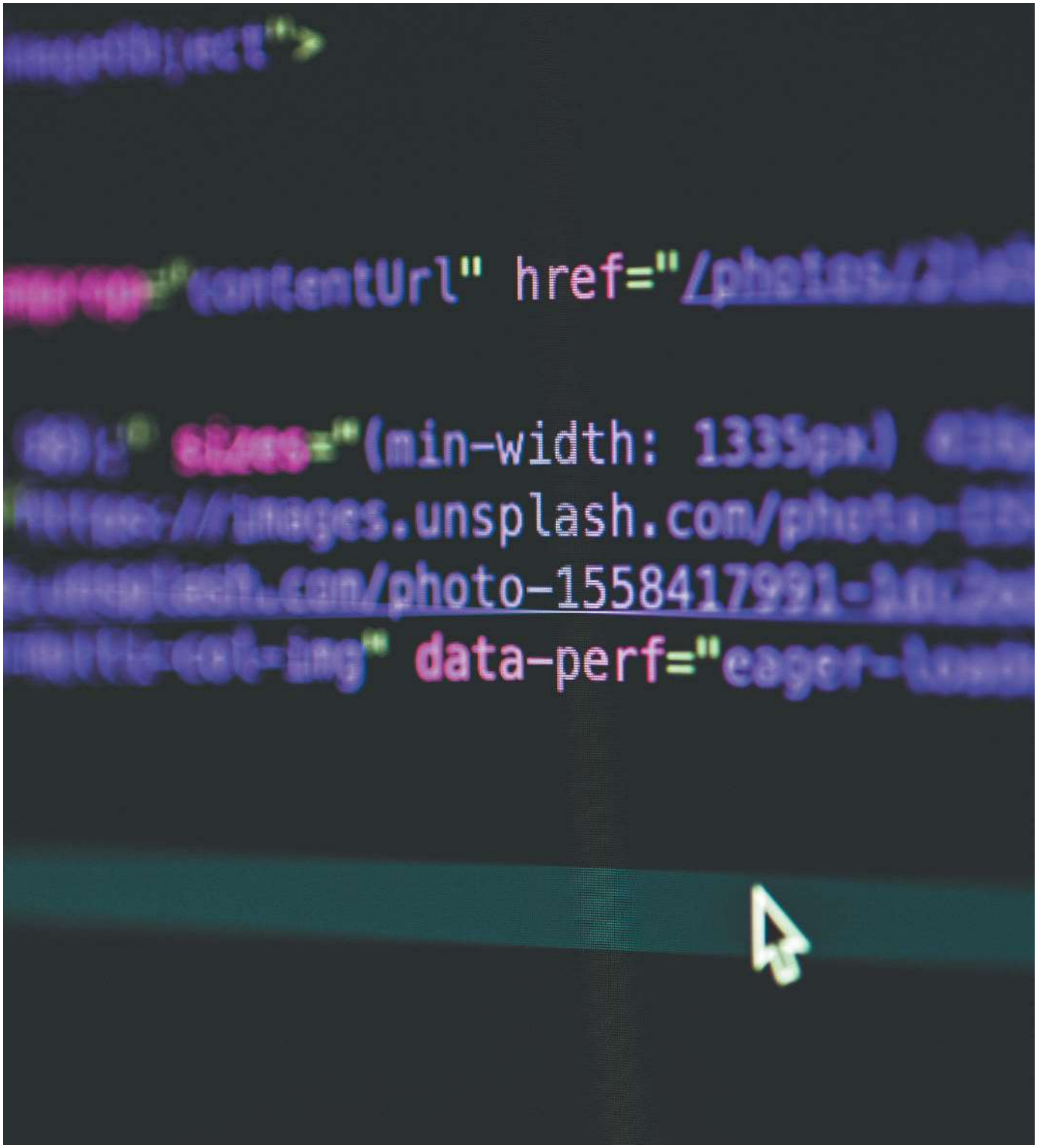
It is in specific applications of advanced software tools that business process service providers can really add value for their life sciences clients, especially for smaller-scale operations that can't readily spare staff's time for manual form-filling and case follow-up.

When manufacturers are being enticed by talk of AI and process automation, then, it is important that they are able to ground this in tangible everyday experiences – and understand the specific ways any new innovation will change their own workloads and resource use. If firms can have direct input into process improvements and where intelligent automation will be most useful, so much the better.

Companies need to be careful, too, that they are not carried away by overly ambitious expectations, especially where the proposed application of AI is on a grander scale. This can happen when firms fall under the spell of hyper-scale cloud-based analytics services, which offer to slice and dice data in all sorts of novel ways to distil insights they might never have spotted otherwise. But, without the right controls and quality/accuracy safeguards in place, firms might never really be able to fully rely on the findings, and deliver practical value from them. Alternatively, they may incur all sorts of additional work to get to that point, which ends up undermining the business case.

From a PV perspective, even tools which 'automatically' read, extract and interpret text from documents, and put them into context – ostensibly to save a team of people from having to do it – could potentially create more work than they save, or certainly at this still-early point along AI's maturity curve. And of course, doing powerful things with data all starts from an assumption that the source data is definitive and of robust quality…

A better use of budget might be to use the technology to ensure that the right data is collected in the first place, as in the example above about transforming the way drug companies' sales



reps provide adverse events information back to PV and safety teams.

Certainly, AI is only valuable to organisations if it transforms painful processes for the better. In which case, life sciences manufacturers should assess their specific requirements and find a suitable partner that can help apply the right technology most effectively.

REFERENCES

1. The future awakens: life sciences and health care predictions 2022 (Deloitte, November 2017)

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