GenAI's Big Safety Proof Point in Life Sciences: Transforming Pharmacovigilance Case Intake

In pharma R&D, the adverse event case intake process, which takes up so much of Safety/pharmacovigilance professionals' time and is far from efficient in its support of timely interventions, remains ripe for disruption. And now that promise is finally being honoured by next-generation AI technologies. Specifically, Generative AI and Large Language Models are enabling the automation of human-like decision-making, leading to earlier and more accurate conclusions about Safety events. ArisGlobal's Emmanuel Belabe explains the tangible difference this has begun to make.

In the modern world it is expected that any authorised medicinal product designed for human use is safe for patients to consume. Pharmacovigilance (PV) processes, which continuously monitor the effects of drugs once on the market, are intended to uphold that position over time once products have been approved for distribution. Approaches to post-market Safety monitoring have changed little in decades, however, despite soaring volumes of available information. Today these are submitted in an increasing array of formats, via a proliferating range of channels.

The approach of "booking" cases, or determining whether the mandatory elements are present, remains prevalent, with a view to quickly assigning an identifier. This approach doesn't take into account the actual contents of a case, however, which forces PV teams to apply the same treatment to all information. The effect is that all cases are assigned the same priority in the early stages; there is no discretion to allocate teams' bandwidth according to a potential case's complexity/risk.

Tracking all the potential signals, assessing their validity, and responding swiftly to relevant cues, is both an absolute mandate and a very costly and labour-intensive administrative burden. Adverse event (AE) case intake, in particular, represents one of the most overlooked and broken workflows in pharma in its current form.

Modern AI: Moving Away from Rigid Process Automation Towards More Nuanced Deductions

Technology-enabled process automation has long promised to transform the speed, efficiency, and accuracy of AE case intake and triage, by capturing and assessing relevant Safety signals arising via a wide range of channels (including self- or clinician-reported AEs submitted by email, post, phone call, or web portal, as well as mentions via online forums).

Up to now, machine intelligence has not come close to mimicking human powers of data extraction, filtering, inference, or deduction. Early excitement about this potential, while valid, was premature. Early automation systems had to be highly structured and painstakingly trained to recognise every possible format and variant of how important data might show up – from the basics such as a patient's date of birth, to richer detail such as the combination of possible contributors to the adverse event (from the individual's stage of life and overall state of health to other drugs they may be taking). As well as presenting challenges in how systems would recognise and extract the right data, this limited the scope for step changes in Safety process efficiency.

Now, though, Generative AI (GenAI) and Large Language Models (LLMs) are beginning to fundamentally transform AE data collection and their associated workflows, with powerful results. In early pilots, data extraction accuracy and quality have exceeded 90 percent, and overall efficiency gains related to the intake process have topped 65 percent. And that's from a standing start; results will only improve with human oversight and AI adjustments.

The Rise in Prioritisation of Advanced Automation

New advanced automation solutions, which transform the data collection part of the AE case intake process and associated workflows, are resonating hard in an industry that has been crying out for a modern, more efficient way to execute case intake/safety data collection, as volumes of case data soar and pressure mounts to accelerate analysis times.

A recent industry survey[1] confirmed the industry's growing interest in AI-powered automation, revealing that over 75% of pharma R&D organisations already use some form of advanced automation within daily processes today, and more than 70% plan to expand business process automation over the next 18 months.

This appetite for viable solutions has intensified in line with a maturation of AI-powered process automation technology, from early robotic process automation aligned to regimented processes (guided by strict structure and rules, and specified workflow around exceptions management), to a less inhibited approach where the technology understands much more about what it is looking for (irrespective of format), and what to do with it.

GenAI technology, using LLMs, can quickly identify and infer what's relevant and important and reliably summarise key findings for the user – and even make predictions. All without the need for painstaking 'training' (from scratch) by overstretched teams, as well as lengthy system validation. Rather, specialised applications can now be developed that can apply GenAI-type techniques, contextually, to data they haven't seen before – learning from and processing the contents on the fly.

This is a significant advance that has seen pharma companies start to put GenAI AE intake solutions to the test in their operations, under the watchful eye of their Safety professionals. The ability to simply instruct a system to "Scan X document for Y contents" paves the way to faster, higher-quality extraction of more relevant data, no matter how much greater in volume this is, or how much more diverse or complex the sources – reducing the risk of something significant being missed, and improving downstream efficiency.

Applying Appropriate Controls

A strong aspect of the business case for harnessing GenAI in AE case intake management comes from the scope for handling first-line capture and processing of very high volumes of data – relieving Safety professionals from that labour intensity

and allowing them to delve deeper into the findings and what they might mean.

However letting GenAI take the strain of case intake also removes human limitations such as fatigue, mental overload, distraction, data blindness, and unconscious bias. An AI-powered tool can more efficiently detect patterns and determine trends, with reliable consistency using approaches that are based on precedence. It can draw on the findings of millions of prior cases and assessments, to make credible predictions and unbiased assessments regarding causality (the likelihood of a direct link between a product and a reported adverse event), that are based on probability rather than a gut feel.

Next-generation cognitive computing in the form of GenAI and LLMs – might be considered to be in an adolescent state of maturity currently (largely ready for the world, with some guidance and controls still needed), but the early output is proving very encouraging. Teams are now seeing that the level of oversight, quality review, and sampling that is required to satisfy regulators, develop a track record, and build trust in the technology (*e.g.* its process of learning and decision-making) – is a relatively low hurdle to clear. It helps that the links back to the sources are readily traceable for checking.

Remaining Open and Agile, Primed for Next Opportunities

From here, as pharma companies look to capitalise on GenAI and LLMs to advance their process automation goals, they mustn't focus solely on the potential bottom-line benefits. After all, this is a much-needed chance to re-allocate resources; to elevate Safety professionals' roles from data management to adding new, strategic insight-driven value to R&D decision-making. This then requires provision for change management and transformation 'readiness', not just a choice of the right technology for the job.

In the short term, it is AE case intake that has captured companies' imagination – where unprecedented new insights as well as greater process efficiency promise to revolutionise the function, and its role and value, starting right now. But over time there will be other powerful use cases too, so it's a good idea to allow scope for additional applications in due course (*e.g.* by deploying an enabling 'platform' rather than a single-use application). Strong next contenders for GenAI/LLM treatment include real-time pharmacovigilance assessments and associated decision-making (*e.g.* the earlier identification of unexpected benefits/discovery of new indications); harnessing international Regulatory intelligence to transform marketing authorisation applications and maintenance; and clinical trial modelling, reducing the reliance on traditional clinical studies.

The key to whether GenAI/LLM treatment is appropriate will be the high volumes of data involved in the target processes. Certainly, the more opportunities there are for the advanced automation system to be exposed to information, the faster it will learn to identify, categorise, assess, and deduce what to do, driving ever greater trust in – and reliance – on the technology to do the heavy lifting.

A recommended first step for pharma companies not yet on the path to intelligent automation would be to break down how current processes are currently managed, the core requirements driving those processes, and where any pain points are. The next priority should be to review and rewrite standard operating procedures so that they can evolve with and be improved by advanced technology, both currently and over time as capabilities continue to evolve.

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Step-by-step:

Refining Sustainability Performance in Single-use Drug Delivery Devices

Improving sustainability is critical across all industries as we look to combat rising emissions and ensure global temperatures do not exceed 1.5 C above pre-industrial levels. The healthcare industry – and the pharmaceutical industry which serves it – are certainly no exception to this and have a critical role to play in a drive towards a more sustainable future. In the UK, the National Health Service (NHS) is responsible for around 4% of total emissions so huge strides are needed to reach its ambitious goal of net zero by 2045. As of April 2023, all new NHS contracts above £5 million per annum require suppliers to publish a Carbon Reduction Plan for their UK Scope 1 and 2 emissions and a subset of scope 3 emissions as a minimum.

Remaining a viable partner in this industry is, therefore, likely to necessitate significant changes in the immediate future. Companies are already taking measures to improve everything from the energy efficiency of buildings to weight and plastic content in packaging. However, as readers are aware, there are unique challenges in the medical industry: any efforts to reduce carbon footprint must not be at expense of treatment effectiveness or the safety of patients.

Transitioning to Plastic Substitutes

In parenteral drug delivery, drug stability, anti-contamination and infection control are paramount, so changing materials requires rigorous suitability testing and regulatory scrutiny. To address plastic waste, the logical place to start is, therefore, with products that pose less risk to patients or healthcare professionals, such as packaging, disposable masks, gloves, and coverings and wound care. In fact, commodity plastics from items including tubing, films, packaging, connectors, labware, IV bags, catheters, face masks, housings, luers, membranes, sutures and more make up the majority (70%) of medical plastic waste.4 Meanwhile, syringes form just one part of the remaining 30%. Commodity plastic alternatives are the low hanging fruit for medical products, where the easiest gains could be made, and with highest impact.

This is not to say we should not seek a substitute material for the petroleum-derived plastics used in most single-use drug delivery devices. However, the industry needs a transition plan that considers the current level of need for delivery devices and pre-filled syringes. Given the impact on patient health, there must be a steady supply of such devices in their current form while research into recycled materials or bio-based plastics is ongoing. It must also be noted that the sector has carefully considered biodegradable options. However, biodegradability can sometimes affect stability and drug integrity in prefilled pharmaceutical products.

Aside from material changes, it is more straightforward to focus on reusable drug delivery products that are also easily remanufactured and where their disposable element is easily recycled. This reusable approach is also appropriate for digital devices, where it is clear that the cost and waste from a disposable electronic component would be unacceptable. In a digital or connected auto-injector, a disposable element is still required to meet safety and regulatory requirements, so the most practical solution is to design a minimum disposable unit within a reusable 'shell' holding the electronics.

Breaking Down Product Design

Though we must continue to develop single-use plastic devices, these can still be optimised to improve their carbon footprint in the interim. Device manufacturers can make sustainability improvements in a number of areas without compromising usability. However, companies must examine the entire product lifecycle to make meaningful modifications. Examining elements of a device in isolation is not enough; tweaks intended to improve sustainability in one area can have unintended consequences in another.

Taking a holistic view of the product involves looking at concept development, material selection, design and engineering, manufacturing, packaging, transportation, sales, use, and end-of-life disposal. Optimisation in these areas relies on a collaboration between different segments of a business and ideally, these considerations should be incorporated during the earliest stages of development, creating products that are truly 'sustainable by design'. While manufacturers have already started this task through evolutions in packaging and transportation, risk reduction, manufacturing efficiency, time to market and safety and regulatory compliance, industry could

go even further. More focus is needed in improving energy efficiency, material usage and recycling, and end of life disposal.

Modifications to individual drug delivery devices will of course vary depending on the product itself and the needs of users. Creating products that are easier and cheaper to recycle, for example, relies on the simplicity of the design, for easier disassembly or remanufacturing.

Reducing waste and transportation costs can be achieved by optimising device size and reducing the weight and plastic content of packaging. Owen Mumford Pharmaceutical Services' Aidaptus® auto-injector, for instance, weighs just 28g (without the syringe). Replacing metal components with other suitable materials can also make an impact on the environmental burden of processing and shipping devices. However, any moves to reduce or replace a material or component must still prioritise patient safety and usability.

With the Aidaptus product, the design sought to derisk device choice for pharmaceutical partners with an approach that streamlines processes and therefore contributes to reducing impact – all while maintaining ease of use for patients. Aidaptus has a wide design envelope, giving pharma companies the flexibility to make changes to formulation, fill volumes or needle sizes without having to change device. This reduces risk during drug development and life cycle management – removing the need for additional verification testing, human factors studies and regulatory documentation. All this also helps to reduce time to market for the final combination product. Aidaptus' ability to support multiple drug formulations means it can be used across a number of products in a company's portfolio, and having a single platform for multiple applications further reduces impact at the manufacturing level.

Sharing Solutions

As we action closer towards milestone targets for emission reduction, it's likely we will move on from single-use plastics within our drug delivery devices. But until materials are developed that are able to support the exceptional demand for these products, we can focus on the overall sustainability performance of plastic-based devices. Continuous progress is necessary not only for internal sustainability goals but also to reassure pharma companies that manufacturer partners are on the right path. It is a balancing act; companies need to show a willingness to introduce more sustainable products, while also remaining competitive and maintaining usability – all the while considering patients, clinicians and regulators. Given this complexity, the pace of this progress will be much quicker if the industry as a whole can find ways to work together to find appropriate materials and solutions.

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