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Signal Management in Excel is Stifling Pharmacovigilance Innovation

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By Jim Davis [1]
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Advera Health Analytics has spent hundreds of hours in 2019 discussing signal management with pharmacovigilance leaders. Most conversations are detailed discussions of statistics, workflow, and technical features and benefits. However, when combined together we've uncovered some interesting bigger picture take-aways. One issue that has become clear is that using Excel for signal management and safety issue tracking is stifling pharmacovigilance innovation.

As a brief primer for readers who may be unfamiliar, Good Pharmacovigilance Practices (GVP) require marketing authorization holders (MAH) of a drug to perform safety signal detection and keep track of all activities that takes place in the investigation of a safety issue. The burden is on the MAH to track and report emerging safety issues. More information can be found in Advera Health's *Complete Guide to GVP Module IX for Signal Management*[2].

Given the importance GVP places on signal management, all organizations must have a tracking system in place. The decision organizations must make is how to implement that tracking system: with fit-for-purpose software-are-a-service (SaaS) or a generic tool like Excel. In order to better understand the choices now being made by pharmacovigilance leaders, it is important to understand different viewpoints.

Typically, the opinions fall into three distinct buckets.

Bucket 1—all in one software

Many forward-thinking pharmacovigilance leaders put best-practices such as fit-for-purpose signal management software in place as early as possible. They believe that in-sourcing this critical aspect of drug safety will add value to the organization and save them time and money in the future. They understand that signal management software reduces the organizational risk that Excel can introduce in regulatory audits, with lost or corrupted spreadsheets, and through a lack of systemic knowledge transfer. They build the business case early and receive buy-in from executive leadership. They never touch Excel for safety issue tracking. With a seamless, all-in-one SaaS solution they leverage pre-built analytics to generate safety insights that benefit the entire organization.

Bucket 2—the stop-gap

Much like Bucket 1, pharmacovigilance leaders in this group believe in best practices using a SaaS approach to signal management. However, they are unsure how to build the business case or have been unsuccessful getting buy-in from executive leadership at an early stage. They have not been able to properly deliver a business case strong enough to convince leadership that pharmacovigilance isn't just a cost center and that future benefits will outweigh near term costs. Instead, they create stop-gap solutions using Excel and other generic tools. Their processes do work, but the bulk of their time is spent making them work. They scramble to simply comply with regulations and the pain only grows as the business scales.

Bucket 3—perpetually not ready

Much like Bucket 2, pharmacovigilance leaders in Bucket 3 are using solutions like Excel and other generic tools. They believe that they these solutions are sufficient for now. A time may come for a switch to a proper software solution, but that time is not now. The intentions of leaders in this Bucket 3 are noble; they know their organization is tight on budget, they may have a relatively low safety case count, or their product(s) may have a "really clean safety profile". They don't even try to make the business case for a software-based approach. Unfortunately, leaders in this bucket are doing more long-term harm than good. The resources spent maintaining their processes consume their time and the time of their team members unnecessarily, especially as the business grows. Over time, they become unable to add value to other areas of the organization because they don't have the right tools in place to generate insights quickly. And, unfortunately, this approach only serves to perpetuate the perception that pharmacovigilance is merely a cost-center.

The path forward—death to excel based signal management

In an article previously published in Applied Clinical Trials in November 2018, *Pharmacovigilance Software is Having Its Salesforce Moment* [2], we discussed

how pharmacovigilance is finally catching up with other industries when it comes to adopting SaaS solutions. Cloud-based backend infrastructure and modern user experiences are transforming the way insight is generated and providing tools that safety reviewers actually want to use.

Do users actually want to use Excel? A newly released study[1] on usability from an adjacent industry shows Excel gets a failing grade, second only to electronic health records (EHR). What might seem “manageable” or “good enough” now, quickly escalates into unwieldly processes with users burdened with complicated non-specific systems. And the longer an organization goes without a fit-for-purpose solution, the resources needed to transition to one are greater and more burdensome.

Next generation, cloud-based SaaS signal management platforms exist to manage both clinical and post-marketing safety case reports in a GVP Module IX compliant way that can fit into any budget, in any size company. They can be implemented early and easily and scale alongside the business needs of the MAH over time.

Signal management software creates efficiencies and mitigates regulatory risk for even the earliest stage company As a new decade approaches, both business and IT leaders should prioritize evaluation, selection, and implementation of this capability as early as possible to establish a foundation of organizational success in the years ahead.

Jim Davis *is the Executive Vice President at Advera Health Analytics, Inc.* [3]

References

1. The Association Between Perceived Electronic Health Record Usability and Professional Burnout Among US Physicians. Melnick, Edward R. et al. Mayo Clinic Proceedings, Volume 0, Issue 0
2. https://info.adverahealth.com/gvp-module-ix-for-signal-management-the-complete-guide [4]

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