

How Digitalization Can Transform Patient Safety Outcomes

During the COVID-19 pandemic, patient monitoring became heavily digitalized due to travel and social distancing restrictions. Technology – such as wearables and other devices – is an increasing part of disease management and offers a much more convenient approach to previously laborious health care processes, along with enhanced insights for pharma sponsors.

Moving forward, one of the key opportunities for expansion of digitalization is to handle patient safety proactively, in real time. *In Vivo* spoke with IQVIA's Updesh Dosanjh, practice leader in safety AI, about his hopes for the future to improve patient outcomes.



UPDESH DOSANJH, PRACTICE LEADER
IN SAFETY AI, IQVIA TECHNOLOGIES

What I think this technology has the opportunity to do is move us from being reactive to proactive.

While we can never eliminate AEs, with the right platforms in place these can be detected as they're happening, and information communicated to the safety team right away, who can give patients and their physicians the correct advice. Within the ecosystem of wearables now, we can see what happens physiologically each time they take their treatment. If that changes from the baseline, a set of questions can pop up on their phone, asking if they have done any abnormal activity. We can move into the world of continuous safety monitoring, enabling us to proactively manage patient health care.

***In Vivo*: With regards to data arising from adverse events (AEs), what problems can arise in the traditional reporting process?**

Dosanjh: Traditionally, if a patient experiences an AE, they go to the doctor, they report it, and that event is analyzed to determine the existence of a problem. There are a lot of gaps within that process. Firstly, you expect the patient to recognize they've had an AE related to that drug, then that they will report it to their doctor. Realistically, patients may not know they've had an AE, and if they do, they may not understand that it is related to their treatment. There may also be barriers preventing them going to the doctor and reporting it.

Even once the AE has been reported, there is a very clunky process with many different people involved before the information makes it to the safety team who are qualified to make an assessment. This causes notable delays, but also distortion in the circumstances of the AE, which could result in the wrong judgement from safety personnel.

Devices can help because they are monitoring constantly, so there is more data for pharma companies to review and react to after an AE is communicated. But again, if we consider that less than 10% of patients who experience these events actually report it, that still leaves 90% of patients untouched.

How can pharma companies directly benefit from mitigating these communication bottlenecks in AE reporting?

The real benefit to you as a company is that you can start using the data. For example, you can drive understanding of additional patients who you can access by getting a much more targeted understanding of where the risk-benefit for patient groups is. There could be a whole group to expand into that they are currently not targeting but now can because they know more information about them. Additionally, we can get extremely close to real-time analysis, which enables companies to carry out safety interventions much closer to the event. This will enable companies to make it much safer for patients to interact with their therapies.

How does IQVIA Vigilance Platform utilize data from wearables to improve safety operations?

As we discussed, there needs to be new infrastructure that can utilize the data. IQVIA Vigilance Platform (IVP) has the ability to handle massive data fast, an open architecture that allows simple integration of data sources, and a design that allows rapid, near real-time, analysis. IVP has the ability to receive data from any source, so you remove all the traditional barriers that exist today.



What other technologies are creating efficiencies and improving safety in pharma?

With all this data coming in, you can't then drop it into a traditional manual process and expect to keep up. This is where a platform designed for speed and automation helps. IVP has multiple capabilities that enable you to keep up with the flow of data:

- **Fast SaaS platform designed for billions of transactions:** without this, you can't receive or process data automatically;
- **Automated data trawling:** the system has to be able to analyze data without humans having to constantly specify parameters and run queries; for example the IVP Signal Module runs all the time, looking for signals;
- **Raw data analysis:** traditional systems need all of the data to be coded, then reports run, then human review. In IVP, Natural Language Processing lets you review data in its 'as-is' state and identify relationships between products, events and relevant temporal relationships in real time from the raw data. You don't need coded data to identify risks;
- **Fast and comprehensive data visualization tools:** if you need to export data to another system to view and manipulate it, you are going to be spending time cleaning up data, organizing it, etc. IVP's built-in visualization tools provide enterprise, big data-handling capabilities so you are reviewing data in near real-time;
- **Flexible platform:** it's critical to have a platform that allows simple data access for clients to allow feeding into other systems

What is your advice for anybody starting their digitalization journey, and how can IQVIA support this?

The two most important things are to choose the right partners, ones with industry experience and a shared vision, and to have a realistic assessment of your organization. IQVIA's

Safety Automation Maturity Matrix (SAMM) enables companies to assess their current state, build a plan and associated business case, with step-by-step guides to take them from a manual organization to a digital organization. However you approach this, having a comprehensive approach is key to success. We are all familiar with the many failed projects in the industry and the reasons for failure today are the same as they have always been, so this is where SAAM helps organizations to avoid repeating the mistakes of the past through the digitalization journey.

What does the future hold for digitalization in safety?

Digitalization is coming, that isn't up for discussion. The only debate is whether you will be a company who waits, possibly to have newcomers bypass you and leave you looking in from the outside, or one who takes the right steps to move forward now with the right partners and embraces the changes to help you have better, safer products in more markets, more quickly.

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Updesh Dosanjh, IQVIA Technologies