

# Trends shaping the pharmacovigilance landscape A global perspective



Extended lifespans and an aging population have led to an increase in prevalence of acute and chronic diseases, drug consumption, and consequently leading a growth in the number of adverse drug events. Pharmacovigilance plays a multi-facteted role in maintaining public health by helping identify associated risks, assessing potential beneficial and adverse effects, reinforcing safe and effective usage, and promoting general awareness among patients and the general public.

While the core concepts of pharmacovigilance have remained steadfast, existing corporate infrastructures and business processes were not necessarily designed with the demands of the modern business landscape in mind. This global shift is increasingly highlighting the demands for collaboration and information exchange between your organization and its partners within government entities, academia, and professional associations.

As these trends continue to reshape the medical world, businesses must develop strategies focused on emerging risks and opportunities, re-imagine what is possible, discover new approaches to old challenges, and establish a nimble infrastructure to support sustainable growth.

## **Technology**

Digitization

Digital health tracking and the Internet of Things (IoT) becoming an integral part of healthcare and product safety

**Hot topic:** Data integration from consumer wearables could provide insights into reducing the number and severity of adverse events

#### **Analytics**

Wide data sets must be effectively leveraged to improve reporting and visualize key performance/risk predictors

**Hot topic:** Advanced business intelligence tools can help proactively assess and manage risks throughout a product's lifecycle

To keep up with the accelerating pace of change businesses must look to invest in process and technology enhancements which leverage innovative management practices

Information proliferation, both online and in the cloud, is accelerating and new cybersecurity and privacy regulations are being enacted

## People & Process

#### **The Cloud**

Access to public, private, and hybrid online data storage streamlines connectivity and process automation

Hot topic: Technology roadmaps align business priorities and infrastructure needs amidst evolving internal and external demands

Amidst intensifying regulatory expectations, tougher inspection systems, and a need for instantaneous patient reporting, businesses need to evolve their operational efficiencies

#### **Proactive approaches**

Traditional "Reactive" pharmacovigilance is transforming due to consequences of delays, ecalls, fines, class action suits, and brand damage

**Hot topic:** Leveraging technology to improve timely information flow and developing risk minimization action plans for potentially vulnerable products

#### **Documentation**

Increasing scrutiny over preclinical studies, phase trials, and post marketing surveilance is forcing businesses to improve accountability

Hot topic: EHR mining processes can fuel spontaneous, targeted, event, and ADR reporting

### Upskilling

Evolving business demands require new talents, improved language skills, and proprietary knowledge

**Hot topic:** Dedicated resource training and development is essential to sustain organizational stability

