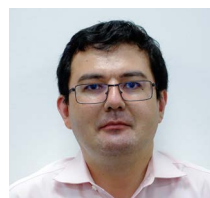


## safetyportal

# Increasing Patient Safety While Reducing Cost and Complexity



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Although it sounds straightforward, global safety reporting of clinical trial adverse events is complicated, time-consuming and extremely expensive. Despite the substantial investment of time and money, research shows that global safety reporting is not protecting patients as well as it could.

Driven by fear of regulatory non-compliance, along with a lack of sophisticated algorithms to ensure appropriate distribution, sponsors tend to over-report adverse events, putting pressure on already overburdened sites to process numerous, non-actionable reports. Unable to keep pace, investigators often miss critical safety information.

According to a recent survey conducted by the Clinical Trials Transformation Initiative (CTTI)<sup>1</sup>, 20% of investigators refused to process safety reports that did not comply with FDA reporting rules. Others admitted to signing off on reports without thoroughly reading them, because they did not believe that the information would improve their trial or make patients safer.

ePharmaSolutions offers the only reporting solution that has been demonstrated to increase compliance and improve patient safety, while saving clients an average of \$500k per study. SafetyPortal prevents over-reporting by addressing the three main challenges sponsors face:

### 1 Lack of global harmonization of reporting rules

SafetyPortal is the only technology-enabled solution that provides tailored distribution rules for over 110 countries. Because it meets the individual legal requirements for each country, SafetyPortal keeps sponsors compliant and prevents investigative sites from receiving safety documents they are not obligated to review.

### 2 Difficulty determining causality

SafetyPortal is built upon a causality-driven engine, which filters documents based on the rules and regulations governing the determination of causality for each country. Because it screens out unnecessary reports, SafetyPortal allows investigators to focus on relevant safety content and easily recognize new safety signals.

### 3 Fear of non-compliance or regulatory repercussion

SafetyPortal automates compliance, ensuring that global distribution - at the compound level - is completed in minutes. In addition to a causality-driven engine and country-specific knowledgebase, SafetyPortal provides real-time tracking of investigator acknowledgements and a single sign-on to guarantee safety and privacy.

By leveraging its global expertise and proprietary technology, ePharmaSolutions is helping sponsors to solve the problem of over-reporting, and helping sites to focus on information that truly impacts patient safety. Having eliminated the need for manual and brute force processes, clients using SafetyPortal report increased regulatory compliance, improved relationships with sites, and achieved a dramatic reduction in their overall cost of distribution.

To learn more, read our white paper, "Managing the Unmanageable: Meeting the Challenge of Appropriate Safety Report Distribution" or visit us at <http://www.epharmasolutions.com/our-solutions/safety-portal> ●

1. Perez, R, Archdeacon, P, Roach, N, et al. Sponsors' and investigative staffs' perceptions of the current investigational new drug safety reporting process in oncology trials. *Clinical Trials* 2017. <http://journals.sagepub.com/doi/pdf/10.1177/1740774517700640>

healthcare's comparatively strict regulations may be too burdensome for the e-commerce giant to make a meaningful impact. And drugs, unlike most goods Amazon sells, cannot be shipped together with other products.

It's not unusual to see a disrupter in a marketplace spark established players to up their game, which is what is happening in the case of CVS. According to PwC, CVS Health operates a pharmacy within three miles of 80% of Americans. Such ubiquity in neighborhoods gives retail pharmacies the chance to redefine themselves, seizing more central roles as key players and partners in the new health economy.

Analysts say CVS Health's bid to acquire health insurer Aetna is a smart way of staving off competition from Amazon.com. The reported \$66 billion deal between CVS and Aetna would be the largest in health insurance history. The move is viewed by many on Wall Street as a strategic play to bolster the defenses of both companies against a potential move by Amazon into the industry.

To counter Amazon's potential encroachment into its space, CVS announced that it plans to bring prescriptions to customers' doors with next-day delivery starting in 2018, akin to Amazon's competitive shipping method for Prime members. According to company reports, free delivery will be available within hours for prescription orders, as well as a selection of OTC products, starting in New York in December. Next in line are Miami, Boston, Philadelphia, Washington, D.C., and San Francisco in 2018, followed by the rest of the country. CVS also reported that it would be partnering with Walgreens Boots Alliance in starting the 30,000-store network in an attempt to reduce costs both for the company and for pharmacy benefit management (PBM) members.

According to RBC Capital Markets Analyst George Hill in a CNBC interview, Amazon's ability to impact the business over the near to mid term is low, but the ability to impact the stock is high. Further, CVS would lose the ability to control its own destiny if it didn't do something. Mr. Hill projected this could be as much \$260 billion in revenue in 2019.

Wal-Mart got into the pharmacy business with a \$4 generic back in 2006, which took a lot of market cap out of the drug retailers, analysts say. Wal-Mart eventually got into mail order in 2007-2008 and had 4,000 locations to pick up a prescription, yet analysts don't really think of the company as being that disruptive.

### More Services

According to PwC research, consumers would embrace more services if offered by their retail pharmacies. And yet, pharmacies are just beginning to leverage their assets and develop business models to relieve the pressure of filling more prescriptions, more quickly, at a lower cost. They say the value chain is being re-engineered by powerful global drivers — downward pressure on costs, increasing prevalence of chronic diseases, an aging population, surging consumerism, the embrace of value-based models, the arrival of new entrants, and transformative advances in technology.

PwC research found that one of the most valuable assets in delivering value-based solutions is the pharmacist, consistently named among the most trusted professionals in the health industry yet largely relegated to dispensing activities in the United States.

And with consumer expectations rising, tools that have classically been used in other consumer-facing industries will need to be applied more liberally to a healthcare setting to determine what, why and how services are delivered. **PV**