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BEST PRACTICES

AWARDS

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2020 | BEST PRACTICES AWARD

PVIP
INTAKE & PROCESSING

RxLogix

2020 GLOBAL
PHARMACOVIGILANCE AUTOMATION SOFTWARE
PRODUCT LEADERSHIP AWARD

Contents

Background and Company Performance

Industry Challenges

Pharmacovigilance (PV), also known as drug safety, is defined as the science and activities to detect, assess, understand, report, and prevent adverse reactions to medicines. PV is an important aspect of the pharmaceutical industry and an essential function within life sciences companies. According to the World Health Organization (WHO) studies, adverse drug reaction (ADR) is the reason for the admission of approximately 5% of hospitalized patients. A recent study by Johns Hopkins University suggests that medical error is the third leading cause of death in America.

Despite recent progress in the area of PV, Frost & Sullivan's research confirms that there are ongoing multiple challenges in the industry. The high volume of PV cases is one of the ongoing challenges for the pharma industry. PV volume has increased due to the rise in medication consumption and the prevalence of chronic diseases. In addition, patients share their ADR cases on social media, blogs, registries, and other sources. Doctors are required by new regulations to report more incidences as well. The COVID Pandemic has the potential to increase the volume of adverse events significantly. With the growing frequency of virtual visits and the likely discussion on social media, tracking AE's will result in increased effort in reporting AE's and follow-ups.

Frost & Sullivan notes that another industry challenge is the steadily rising cost of PV tasks. Increasing data volume and data complexity due to the evolution of regulations for a better understanding of drug safety and high labor costs are the main reasons for high case processing expenditure in the industry. Frost & Sullivan analysts point out that in regards to the COVID-19 pandemic, there is an even greater need to address the current challenges for pharmacovigilance.

Product Family Attributes and Business Impact

Automation Capabilities with High Accuracy

Headquartered in Princeton, New Jersey, in the United States, RxLogix Corporation offers leading PV solutions globally. Founded in 2010 in Irvine, Southern California, the company has grown to become a global niche PV solutions firm with a strong presence in all major pharmaceutical regions in North America, Europe, Japan, and India.

RxLogix is a software company for pharma and life sciences with a sole focus on PV solutions. The company offers an automated adverse event case intake and processing solution, which leverages decades of deep PV domain expertise and extensive Artificial Intelligence (AI) and Machine Learning (ML) capabilities. The product utilizes AI-based and traditional rule-based technologies to automate various case intake and processing functions. The product roadmap is designed to achieve touchless processing for the entire process flow - with no human interaction - within the next few years.

Notably, RxLogix PV Intake & Processing (PVIP) provides capabilities to extract from both structured as well as unstructured source documents. This includes adverse event forms, email, handwritten forms, PDF, Fax, EHR/EMR, free-text reports, and literature articles. RxLogix offers PV solutions in English and other languages such as Spanish, Japanese, and

Chinese leveraging auto-translation capability using deep learning and natural language processing (NLP) techniques. PV Intake & Processing also provides many other automated case processing functions such as automated flagging assistance for medical concepts and classification of product complaints and adverse events and not just focus on the automation of the Intake aspect of case processing.

Accuracy is crucial for PV software, and RxLogix PV Intake & Processing is ranked number one in a recent independent benchmarking study conducted by Frost & Sullivan. PV Intake & Processing processes AE forms with more than 98% accuracy and can extract all key adverse event information from the unstructured narrative with more than 90% accuracy for most fields from any source such as PDF and email, and to add a better user experience, PV Intake & Processing color codes the extracted data in the source documents and provides a confidence score.

Implementation and Delivery Model with Active Customer Support

RxLogix offers solution implementation at client sites on their data center or cloud with a low-risk and result-driven approach leveraging in-house implementation services. The delivery model is truly Software as a Service (SaaS)-based with enterprise licensing and all-inclusive costs (e.g., upgrade, hosting, and support). The SaaS delivery model enables clients to access the latest release of the system and ongoing support through managed services.

RxLogix currently has several clients in production or are implementing PVIP:

No.	Client	Infrastructure/Hosting Platform	Implementation Status
1	Tier 1 (Top 10) Pharmaceutical Company	Client's VPC on AWS cloud platform	In production since ~2 Years ago, Migration to RxLogix Cloud and Phase 3 upgrade on-going. Planned go live Q1 2021
2	Tier 2 (Top 50) Pharmaceutical Company	Client's on-premise installation	In production <1 year. Phase 2 upgrade – go-live Q1 2021
3	Tier 3	RxLogix' hosted AWS cloud platform	Production deployment was completed in May 2020. Phase 2 upgrade –go-live Q1 2021
4	Tier 1 (Top 25) EU headquartered Pharmaceutical Company	RxLogix' hosted AWS cloud platform	Production Deployment Completed in Sep' 2020. Phase 2 implementation on-going with Planned go-live in Dec' 2020

5	Tier 1 (Top 25) US-headquartered Pharmaceutical Company	RxLogix' hosted AWS cloud platform	Under Implementation, Planned go-live Q1 2021
6	Tier 1 (Top 40) US-headquartered Pharmaceutical Company	Client's VPC on AWS cloud platform	Under Implementation, Planned go-live Q4 2021

The above table provides information only on PVIP. RxLogix's other PV software products are in production at more than 45 Pharmaceutical companies. US Food & Drug Administration (FDA) is implementing their PV Reports, PV Analytics, and PV Signal solutions for the entire patient drug safety in the United States.

The RxLogix integrated PV Suite provides clients with the flexibility to implement modules incrementally in addressing the needs of the entire PV departments, including aggregate reporting and signal detection. The approach allows clients to start reaping the benefits and efficiencies of the new intake system without having to wait for a long time and provides more time to users to adapt to the change from the old system and processing (change management).

RxLogix has a popular customer consortium model in place for its product, collaborating with clients for continuous improvements to stay compliant with upcoming regulations. RxLogix provides managed services support during and upon implementation of PV Intake & Processing, adhering to the "follow the sun" approach in providing 24/7 support for clients.

Conclusion

With the rise in data complexity and volume of adverse event cases today, Frost & Sullivan notes that pharmaceutical and life sciences companies are increasingly in need of an automated and accurate end-to-end PV solution to address specific industry challenges - such as frequent regulation updates and the rising cost of PV tasks. Nicely responding to these challenges and leveraging its considerable expertise in pharmacovigilance, RxLogix offers the best-in-class PV solutions with multiple automation capabilities and high accuracy in results.

With its deep PV domain expertise, commitment to being fully automated, and active customer consortium, RxLogix offers an industry-leading solution. With its strong overall performance, RxLogix has earned the 2020 Frost & Sullivan Global Product Leadership Award in the Pharmacovigilance Automation Software industry.

Significance of Product Leadership

Ultimately, growth in any organization depends on customers purchasing from a company and then making the decision to return time and again. A comprehensive product line filled with high-quality, a value-driven option is the key to building an engaged customer base. To achieve and maintain product excellence, an organization must strive to be best in class in three key areas: understanding demand, nurturing the brand, and differentiating from the competition.

Understanding Product Leadership

Demand forecasting, branding, and differentiating all play critical roles in finding growth opportunities for a leading product line. This three-fold focus, however, must be complemented by an equally rigorous focus on pursuing those opportunities to a best-in-class standard. Customer communication, customer feedback, pricing, and competitor actions must all be managed and monitored for ongoing success. If an organization can successfully parlay product excellence into positive business impact, market share will inevitably increase.

Key Benchmarking Criteria

For the Product Leadership Award, Frost & Sullivan analysts independently evaluated 2 key factors, Product Family Attributes and Business Impact, according to the criteria identified below.

Product Family Attributes

> Criterion 1: Match to Needs
> Criterion 2: Reliability and Quality
> Criterion 3: Product/Service Value
> Criterion 4: Positioning
> Criterion 5: Design

Business Impact

> Criterion 1: Financial Performance
> Criterion 2: Customer Acquisition
> Criterion 3: Operational Efficiency
> Criterion 4: Growth Potential
> Criterion 5: Human Capital

Best Practices Award Analysis for RxLogix

Decision Support Scorecard

To support its evaluation of best practices across multiple business performance categories, Frost & Sullivan employs a customized Decision Support Scorecard. This tool allows research and consulting teams to objectively analyze performance according to the key benchmarking criteria listed in the previous section, and to assign ratings on that basis. The tool follows a 10-point scale that allows for nuances in performance evaluation. Ratings guidelines are illustrated below.

RATINGS GUIDELINES

9–10 Excellent

7–8 Good

4–6 Fair

1–3 Poor
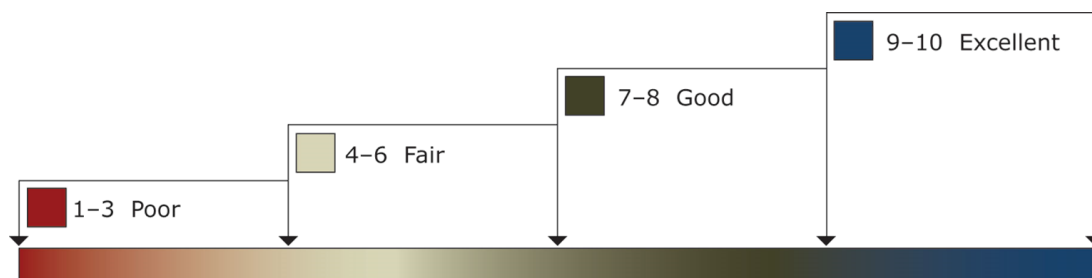
The Decision Support Scorecard considers Product Family Attributes and Business Impact (i.e., the overarching categories for all 10 benchmarking criteria; the definitions for each criterion are provided beneath the scorecard). The research team confirms the veracity of this weighted scorecard through sensitivity analysis, which confirms that small changes to the ratings for a specific criterion do not lead to a significant change in the overall relative rankings of the companies.

The results of this analysis are shown below. To remain unbiased and to protect the interests of all organizations reviewed, Frost & Sullivan has chosen to refer to the other key participants as Competitor 2 and Competitor 3.

Measurement of 1–10 (1 = poor; 10 = excellent)			
Product Leadership	Product Family Attributes	Business Impact	**Average Rating**
RxLogix Corporation	**9.1**	**8.9**	**9.0**
Competitor 2	8.5	8.1	8.3
Competitor 3	8.1	7.8	8.0

Note: This list originated with 60 identified, shortlisted to 25, further shortlisted to Top 8, followed by the winner.

Product Family Attributes

Criterion 1: Match to Needs
Requirement: Customer needs directly influence and inspire the design and positioning of the product family.

Criterion 2: Reliability and Quality
Requirement: Products consistently meet or exceed customer expectations for performance and length of service.

Criterion 3: Product/Service Value
Requirement: Products or services offer the best value for the price, compared to similar offerings in the market.

Criterion 4: Positioning
Requirement: Products or services address unique, unmet needs that competitors cannot easily replicate or replace.

Criterion 5: Design
Requirement: The product features an innovative design, enhancing both visual appeal and ease of use.

Business Impact

Criterion 1: Financial Performance
Requirement: Overall financial performance is strong in terms of revenue, revenue growth, operating margin, and other key financial metrics.

Criterion 2: Customer Acquisition
Requirement: Product strength enables acquisition of new customers, even as it enhances retention of current customers.

Criterion 3: Operational Efficiency

Requirement: Staff is able to perform assigned tasks productively, quickly, and to a high quality standard.

Criterion 4: Growth Potential

Requirements: Product quality strengthens brand, reinforces customer loyalty, and enhances growth potential.

Criterion 5: Human Capital

Requirement: Company culture is characterized by a strong commitment to product quality and customer impact, which in turn enhances employee morale and retention.

Decision Support Matrix

Once all companies have been evaluated according to the Decision Support Scorecard, analysts then position the candidates on the matrix shown below, enabling them to visualize which companies are truly breakthrough and which ones are not yet operating at best-in-class levels.
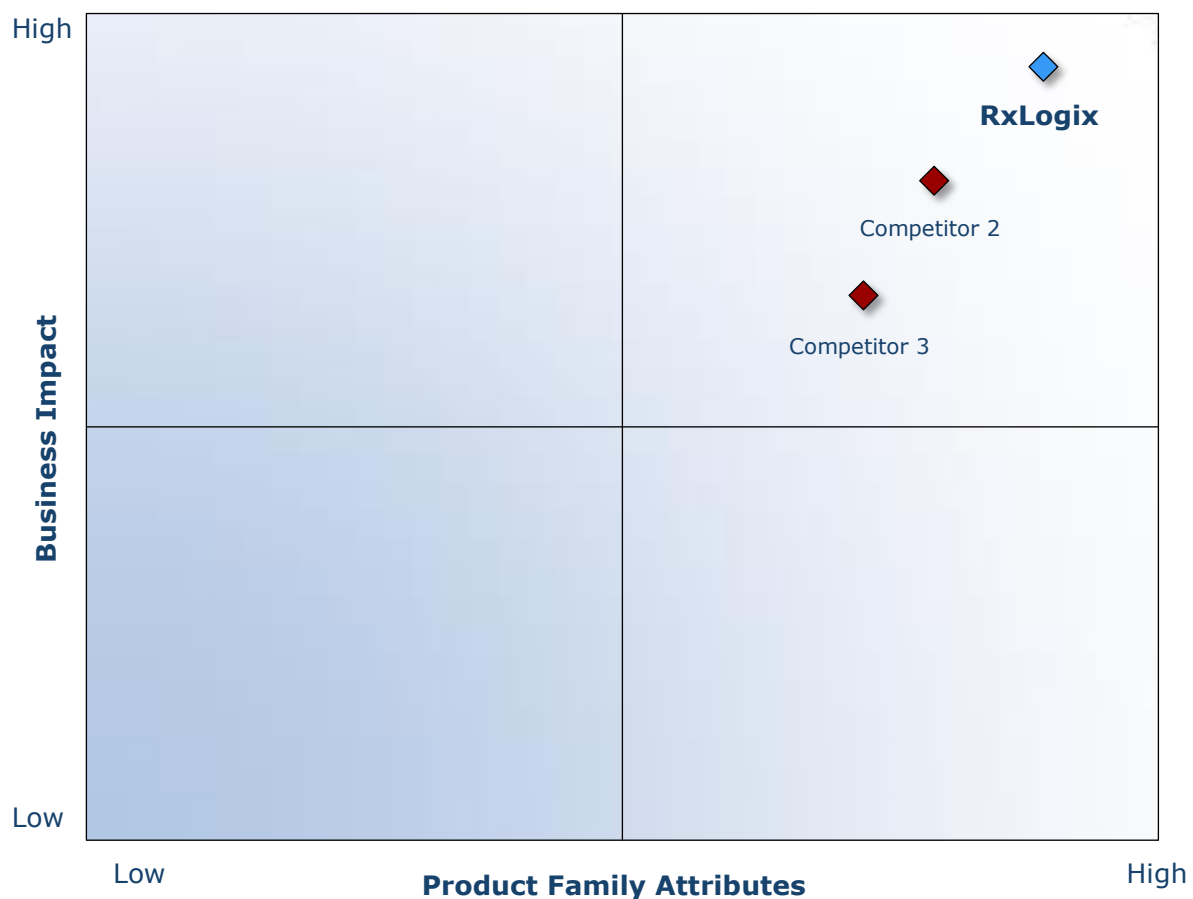
Best Practices Recognition: 10 Steps to Researching, Identifying, and Recognizing Best Practices

Frost & Sullivan analysts follow a 10-step process to evaluate Award candidates and assess their fit with select best practices criteria. The reputation and integrity of the Awards are based on close adherence to this process.

STEP		OBJECTIVE	KEY ACTIVITIES	OUTPUT
1	**Monitor, target, and screen**	Identify Award recipient candidates from around the world	• Conduct in-depth industry research • Identify emerging industries • Scan multiple regions	Pipeline of candidates that potentially meet all best-practice criteria
2	**Perform 360-degree research**	Perform comprehensive, 360-degree research on all candidates in the pipeline	• Interview thought leaders and industry practitioners • Assess candidates' fit with best practices criteria • Rank all candidates	Matrix positioning of all candidates' performance relative to one another
3	**Invite thought leadership in best practices**	Perform in-depth examination of all candidates	• Confirm best practices criteria • Examine eligibility of all candidates • Identify any information gaps	Detailed profiles of all ranked candidates
4	**Initiate research director review**	Conduct an unbiased evaluation of all candidate profiles	• Brainstorm ranking options • Invite multiple perspectives on candidates' performance • Update candidate profiles	Final prioritization of all eligible candidates and companion best practices positioning paper
5	**Assemble panel of industry experts**	Present findings to an expert panel of industry thought leaders	• Share findings • Strengthen cases for candidate eligibility • Prioritize candidates	Refined list of prioritized Award candidates
6	**Conduct global industry review**	Build consensus on Award candidates' eligibility	• Hold global team meeting to review all candidates • Pressure-test fit with criteria • Confirm inclusion of all eligible candidates	Final list of eligible Award candidates, representing success stories worldwide
7	**Perform quality check**	Develop official Award consideration materials	• Perform final performance benchmarking activities • Write nominations • Perform quality review	High-quality, accurate, and creative presentation of nominees' successes
8	**Reconnect with panel of industry experts**	Finalize the selection of the best practices Award recipient	• Review analysis with panel • Build consensus • Select recipient	Decision on which company performs best against all best practices criteria
9	**Communicate recognition**	Inform Award recipient of recognition	• Announce Award to the CEO • Inspire the organization for continued success • Celebrate the recipient's performance	Announcement of Award and plan for how recipient can use the Award to enhance the brand
10	**Take strategic action**	Upon licensing, company is able to share Award news with stakeholders and customers	• Coordinate media outreach • Design a marketing plan • Assess Award's role in strategic planning	Widespread awareness of recipient's Award status among investors, media personnel, and employees

The Intersection between 360-Degree Research and Best Practices Awards

Research Methodology

Frost & Sullivan's 360-degree research methodology represents the analytical rigor of our research process. It offers a 360-degree view of industry challenges, trends, and issues by integrating all 7 of Frost & Sullivan's research methodologies. Too often, companies make important growth decisions based on a narrow understanding of their environment, resulting in errors of both omission and commission. Successful growth strategies are founded on a thorough understanding of market, technical, economic, financial, customer, best practices, and demographic analyses. The integration of these research disciplines into the 360-degree research methodology provides an evaluation platform for benchmarking industry participants and for identifying those performing at best-in-class levels.

360-DEGREE RESEARCH: SEEING ORDER IN THE CHAOS

About Frost & Sullivan

Frost & Sullivan, the Growth Partnership Company, helps clients accelerate growth and achieve best-in-class positions in growth, innovation and leadership. The company's Growth Partnership Service provides the CEO and the CEO's growth team with disciplined research and best practices models to drive the generation, evaluation, and implementation of powerful growth strategies. Frost & Sullivan leverages nearly 60 years of experience in partnering with Global 1000 companies, emerging businesses, and the investment community from 45 offices on 6 continents. To join Frost & Sullivan's Growth Partnership, visit http://www.frost.com.