

MARKET ACCESS & PHASE IV SOLUTIONS  
*Experience Forward Thinking*

# INTEGRATED TECHNOLOGY SOLUTIONS FOR DRUG SAFETY



**COVANCE**<sup>®</sup>

# TRANSFORMING SAFETY OPERATIONS BY DELIVERING PROACTIVE INSIGHT, PROCESS EXCELLENCE AND INNOVATION

Technology has forever transformed the entire healthcare continuum and has ushered in new and revolutionary ways to ensure patient and consumer safety. It has also enabled organizations to achieve higher levels of insight, quality and efficiencies by driving down operational costs and rendering information in meaningful ways. Technology has weaved itself into safety operations by being a strategic element of worldwide pharmacovigilance (PV) systems, fundamentally altering the drug safety continuum. To enable transformation, one of the biggest challenges organizations face is how to effectively integrate the complexities of two seemingly separate functions, the technology know-how behind IT and the science behind Safety Operations. Companies that recognize the synergies of an integrated strategy and unified communication process will see greater success in managing the safety of their products, including proactive responses to problems and business priorities.

## COVANCE ADVANTAGE

Increasing market and regulatory pressures have led companies to reassess their business operations and how they impact productivity, operational costs, quality and audit readiness. Technology is an essential enabler of these goals and provides a platform for innovation to support changing business needs.

Figure 1 – End-to-End Patient Safety Capabilities

OFFERINGS	MEDICAL CONTACT CENTER	CASE PROCESSING	MEDICAL REVIEW	AGGREGATE REPORTING	SAFETY SURVEILLANCE
<b>METRICS BASED MATURE PV OPERATIONS</b>	<ul style="list-style-type: none"> <li>▶ AE Reports</li> <li>▶ Medical Information</li> <li>▶ Product Complaints</li> </ul>	<ul style="list-style-type: none"> <li>▶ Triage/Duplicate Check</li> <li>▶ Data Entry                             <ul style="list-style-type: none"> <li>• MedDRA Coding</li> <li>• Narrative Writing</li> <li>• Query Generation</li> <li>• Expectedness</li> </ul> </li> <li>▶ Peer Review</li> <li>▶ Case Validation &amp; Lock</li> <li>▶ Submission to HA</li> <li>▶ Submission to EC/IRB and PIs</li> <li>▶ Literature Monitoring and Review</li> </ul>	<ul style="list-style-type: none"> <li>▶ Medical triage and review of ICSRs/SAEs /SUSARs</li> <li>▶ Analysis of Similar Events (AoSE) Investigator Communication</li> <li>▶ Medical Review of Clinical Trial Safety Data</li> <li>▶ Medical Review of Aggregate Reports</li> </ul>	<ul style="list-style-type: none"> <li>▶ DSUR</li> <li>▶ IND AR</li> <li>▶ Clinical Overviews</li> <li>▶ Addendum to Clinical Overview</li> <li>▶ Integrated Safety Summaries PADERS/ PSURs/PBRERs/CARs</li> <li>▶ Regulatory Response support</li> </ul>	<ul style="list-style-type: none"> <li>▶ IND Safety rule</li> <li>▶ Safety Assessment Committee</li> <li>▶ Active Clinical Surveillance and Post-Approval Safety Studies (PASS)</li> <li>▶ Risk Management Plans including RMPs, REMS</li> <li>▶ Regulatory Communications</li> <li>▶ Signal Detection</li> </ul>
<b>PV SYSTEMS MANAGEMENT &amp; SOLUTIONS</b>	Safety Cloud Services	Argus Enterprise	PV Technology Automation & Innovation	Agency/Partner Gateway Implementation	
	Contact Center Implementation & Hosting	Database Consolidation	Business Intelligence & Analytics	Systems Integration and Customization	
<b>QPPV SERVICES FOR EU</b>	QPPV Support, Deputy QPPV Support, Local Responsible Person for PV Regulatory Communications, Dossier Submission (PSMF, RMP, etc.)				
<b>PV CONSULTING SERVICES</b>	Process Re-engineering & Operational Optimization PV Strategy and Roadmap Audit Support & Inspection Readiness				

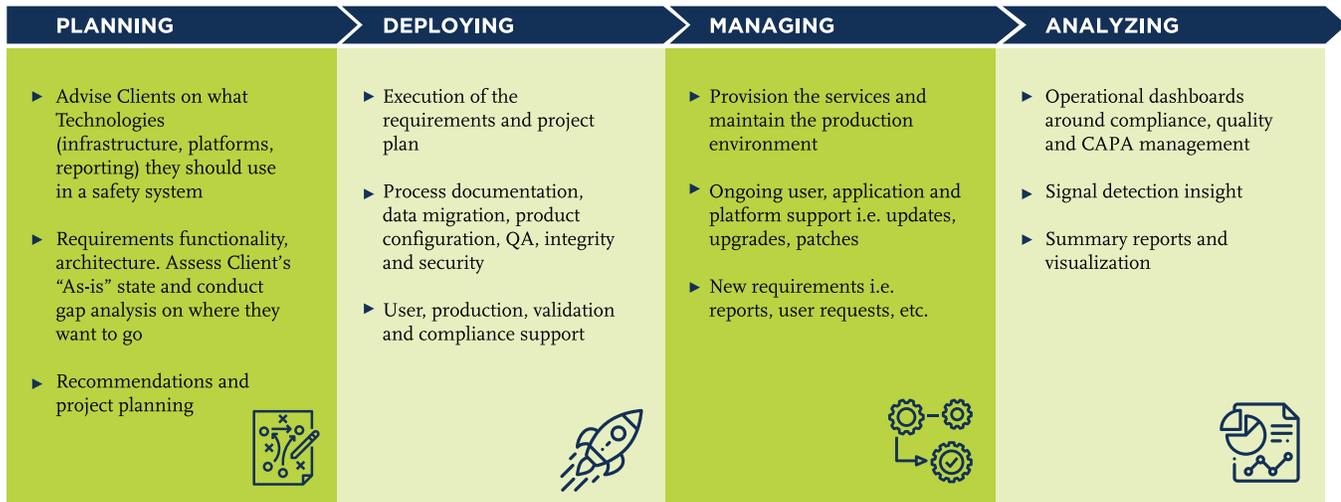
■ Process Services    
 ■ IT Services    
 ■ Consulting Services

As a leading global provider of Patient Safety services, Covance is uniquely positioned to combine our safety expertise with our flexible and full life cycle Safety Technology Solutions. These solutions help life science companies build Pharmacovigilance IT reference architectures, deploy signal detection applications, and create enterprise portals for safety analytics. Our PV Technology and Automation solutions help to transform PV operations and drive efficiencies across the PV continuum and our safety cloud solution offers a full service validated private cloud single tenancy solution based on Argus technology. Our Medical Call Center provides compliant medical information and safety services for medical products. Additionally, we also provide solutions for business intelligence, analytics, querying and reporting, validation and regulatory compliance. We offer companies a global model that ensures the highest standards of compliance, quality and agility for reacting to change, while minimizing cost.

## A FULL LIFE CYCLE APPROACH TO SAFETY TECHNOLOGY

By organizing our process methodologies across four stages, each of which is interconnected, we offer a comprehensive solution that enables project productivity and predictable results.

Figure 2 – Safety Technology Life Cycle



### PLANNING

Our planning services assess your existing technology environment and create innovative and practical strategies that align with your priorities. Covance will plan the delivery of a tailored safety environment to manage your technology priorities for the future while getting value out of your legacy investments. We will explore business opportunities provided by new technology innovation and provide advice on how technology can deliver you more business value.

As a safety database managed service (Figure 2) may make sense for your organization, Covance offers a cohesive program that embraces our key competencies of technology, streamlined processes and tools, people and quality. By unifying and standardizing on our best-in-class processes generated from our IT Quality Management System, we maximize customer productivity and provide audit-ready compliance with regulatory requirements.

Figure 3 – Covance Safety Database Managed Service

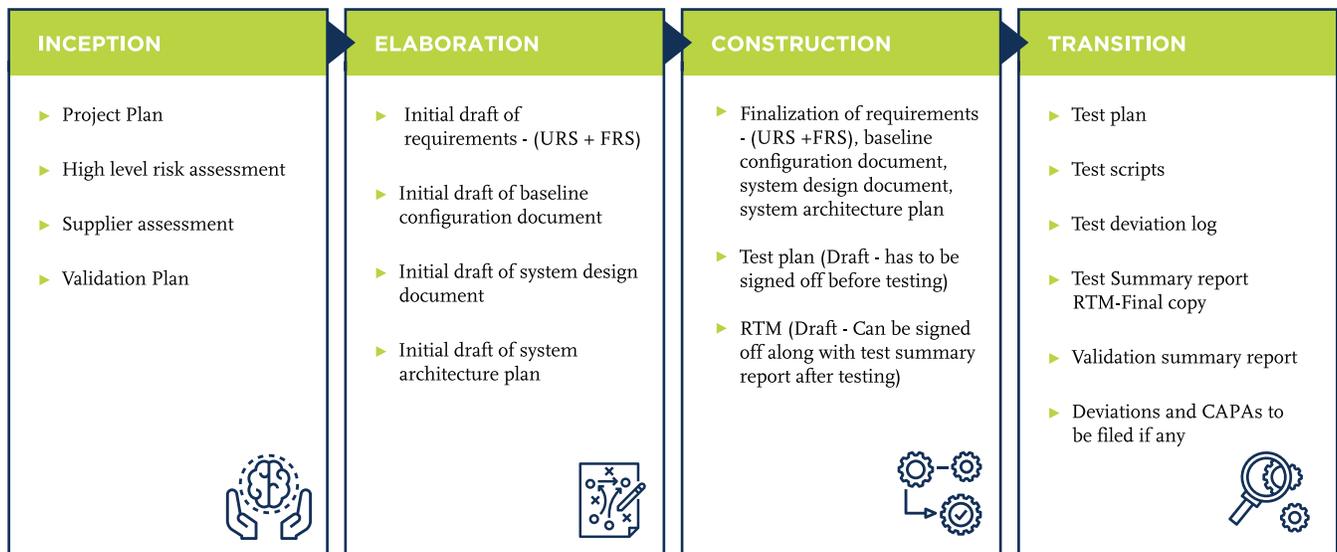


Covance projects are governed by our defined SOPs for project planning, while such processes are designed to be flexible, scalable and capable of supporting the planning needs of a wide range of projects and customer engagements. The planning phase provides clarity on project objectives, a phased work breakdown structured approach, resources required, the level of effort anticipated and a project schedule.

## DEPLOYING

Successful deployment of new Safety Technology Solutions is challenging for companies as they have a wide organizational impact. Our four-phase deployment life cycle (Figure 3) follows a defined Software Deployment Life Cycle (SDLC) based on the Rational Unified Process, providing clear direction and focus on the path to be followed for each customer engagement.

Figure 4 – Covance Deployment Life Cycle



Each phase is defined and enables the project team to focus on a particular aspect of the project, with specific milestones required. These milestones clearly indicate the progress of the project and ensure that the project deliverables meet strict quality standards.

The goals of each phase are as follows:

- ▶ Inception – Understand the scope of the project and conduct detailed project planning
- ▶ Elaboration – Understand and document the specifications for the architecture as well as the business requirements
- ▶ Construction – Build the architecture, install the application and qualify the hardware and software
- ▶ Transition – Define the verification phase where the functionality is tested and the user acceptance testing is done

Covance also offers a preconfigured safety technology platform to reduce deployment time. This system is achieved by prequalifying a safety technology application which reduces testing and documentation time requirements.

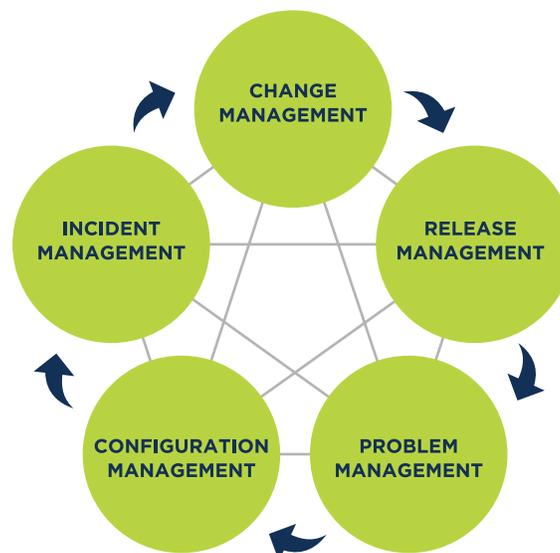
## MANAGING

Once your application solution moves to production, our Safety Technology Managed Service provides measured service levels to ensure operational excellence. Our managed services include Service Support (Platform, Application and User) and Service Delivery.

## SERVICE SUPPORT

A well-thought-out application and user support strategy ensures that quality Technology Services are delivered to the business and operations. Covance helps life sciences organizations manage changes and problems in the safety technology infrastructure and ensure services are provided effectively and with optimum quality. Application Support Services includes a comprehensive solution for managing a variety of application service components depicted in Figure 4, offering customers a thorough and dependable solution.

Figure 5 – Comprehensive Application Life Cycle Support Basic Framework



User Support Services provides information and problem solving services, ensuring that customers maximize the value of the deployed safety technology solution. The user support processes include incident tracking and severity escalation procedures to produce predictable results. These services engage in typical ITIL (Information Technology Infrastructure Library) support as depicted below.

- ▶ Level 1 (Service Desk) first contact and resolves basic issues
- ▶ Level 2 provides application expertise and addresses most issues. When needed, L2 staff can draw resources from an extended Support Expertise Framework, such as Oracle Database Administrators and Microsoft Solutions Architects, to ensure timely resolution to more complex user issues.
- ▶ Level 3 engages expert support directly from the technology vendor. Typical support requirements are ensuring product consulting (e.g., addressing software bug fixes, recommending software enhancement requests etc.) troubleshooting, proactive problem identification and performance tuning.

## **SERVICE DELIVERY**

Covance offers a management approach that allows for clear service definition, defined roles and responsibilities, and expected standards for service quality, availability and timeliness. Our clients receive the following reports as part of service delivery:

### **Monthly ticket analysis report**

- ▶ Monthly security reports indicating attacks and phishing events
- ▶ Quarterly application uptime reports
- ▶ Quarterly application root cause analysis reports for Severity 1 (critical) incidents
- ▶ On-demand application root cause analysis for any non-Severity 1 incidents, upon customer request

### **In all Covance Managed Services for safety applications, customers also benefit from best-in-class technology delivery in:**

- ▶ Robust backups and disaster recovery with periodic disaster recovery drills support
- ▶ General backup and restore strategy
- ▶ Data center physical and logical security
- ▶ World-class data center infrastructure

## **ANALYZING**

Data visibility and the ability to understand what your data is telling you are critical for your business today. Technology is changing the way business operates, helping to streamline processes and ensuring that information is shared, managed, and acted upon. However, with a significantly large volume of data emerging from traditional sources as well as social media, the task of analyzing this data is far more complex. Through data analytics services, Covance provides its customers with the ability to leverage this data to extract meaningful insight for driving critical business decisions.

## The data analysis services are broadly classified into three areas:

- ▶ **Operational Dashboards:** As part of Pharmacovigilance operations, it is critical to closely monitor the operational parameters which in turn drive Compliance, Quality, Productivity and CAPA Management. It is important to continuously analyze data to detect early warning indicators that could have a bearing on business and compliance performance. Over the years, Covance has capitalized on its deep pharmacovigilance domain expertise, combined with its technology capability, to devise multi-tiered metrics and analysis techniques, which demonstrate consistent delivery levels far exceeding operational goals.
- ▶ **Continuous Process Improvement:** With regulatory changes happening within the Life Sciences industry, the bar is being raised. Given this increasing demand, it is imperative for the Life Sciences industry, and service providers like Covance, to continuously improve on existing processes to deliver better results. Through the application of data analysis and visualization techniques, far more insight, that can drive operational improvement in existing processes, is possible. These process improvements have a direct impact on Compliance, Quality and Productivity.
- ▶ **Signal Detection:** Identifying new potential risks and developing risk minimization action plans to prevent or mitigate these risks is at the heart of all pharmacovigilance activities. Covance has the knowledge, technology and expertise to qualitatively and quantitatively assess safety data, identify new safety signals and develop risk management plans (RMPs).

## BENEFITS TO CUSTOMERS

By combining our strength in the drug safety space with technology solutions and services, we offer a global delivery model that ensures the highest standards of compliance, quality and agility in reacting to change. Our solutions will help create the ideal environment for innovation and continuous improvement across the entire drug product life cycle.

Figure 6 – Covance Advantage

COVANCE ADVANTAGE	CLIENT VALUE
<ul style="list-style-type: none"> <li>▶ Pharmacovigilance COE (Center of Excellence) and best in class processes</li> <li>▶ Global Delivery Model</li> <li>▶ Focus on quality and compliance</li> <li>▶ Best in class resources in TAs, safety, medical and safety technology experts</li> <li>▶ 10+ years of end-to-end safety experience in life science</li> <li>▶ Experience in providing managed application service solutions with integrated technology platform services</li> <li>▶ Partnerships with leading safety technology providers</li> </ul> 	<ul style="list-style-type: none"> <li>▶ Access to best-in-class and proven processes that result in human, capital and process efficiencies</li> <li>▶ Access to high quality resources around the clock and a cost-effective business model</li> <li>▶ Improved quality and complete regulatory compliant solutions and deliverables through the Covance Quality Management System</li> <li>▶ Access to thought leaders, greater insight and sound advice to continually improve operations</li> <li>▶ Proven track record and ability to scale seamlessly</li> <li>▶ Align customer technology teams to more strategic initiatives to improve life sciences business performance</li> <li>▶ Access to the most innovative and leading technology platforms and tools</li> </ul> 

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Covance is the drug, medical device and diagnostics business segment of LabCorp, a leading global life sciences company. COVANCE is a registered trademark and the marketing name for Covance Inc. and its subsidiaries around the world.

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