Accenture Life Sciences
Rethink Reshape Restructure...for better patient outcomes

Accenture Accelerated R&D Services:
Pharmacovigilance Services Overview

High performance. Delivered.
“At our company, we are focused on improving lives of patients suffering from severe diseases. To this end, we must secure best-in-class pharmacovigilance capabilities with strategic partners who share a relentless passion for performance. Our partnership with Accenture exemplifies a common clarity of purpose and unwavering commitment that has positioned our safety case processing on a best-in-class trajectory. This robust foundation is providing the stepping stone to explore additional business possibilities together. We are truly proud of the win-win collaboration we have with Accenture and we look forward with great enthusiasm!”

Senior VP, head of QA and safety, global biopharmaceutical company
The current ways of managing pharmacovigilance (PV) are unlikely to be sustainable.

The volume of work is expanding rapidly, at the rate of 10–20% a year. This rising flood comes from higher regulatory expectations, tougher inspection regimes, business growth and more proactive physician/patient reporting.

Life Sciences companies need the operational burden to be taken away so they can focus on the science of safety. They need flexible, scalable operations that run like a well-oiled machine while achieving quality and efficiency objectives. Compliance should be “business as usual” so companies can concentrate their attention on strategic safety governance, benefit-risk management and proactive safety surveillance.

It is possible to avoid the growing operational problem by moving toward an externally managed solution that consistently and routinely achieves required business outcomes using a globally integrated model. As your partner, Accenture will deliver PV outsourcing services through a global operation with an unprecedented compliance record—no critical findings from 300 audits and inspections by clients’ QA and the regulators.

**Providing end-to-end global PV solutions**

A top-20 global pharmaceutical company sought ways to maintain quality while optimizing operations and maximizing efficiency of safety case processing and aggregate reporting. In 2007, the company chose Accenture to build a pioneering full-service PV operation completely supported in India. Over several months, we helped the company transfer knowledge of its processes to a team of 150 drug safety specialists in India. Once operational, the offshore team processed an estimated 90,000 adverse event cases per year, providing services from data entry and medical encoding to medical assessment and quality assurance. They also planned and developed aggregate reports (PSURs and PADERs) to comply with the MHRA and FDA regulations and authored medical communications, including various reports, drug safety narratives and scientific manuscripts. The value generated was clear from the start. The transition was completed ahead of schedule, and the skills and infrastructure provided significant support to the company’s onshore team, ultimately enhancing operations and reducing costs.

**Accenture helps the Life Sciences industry achieve better pharmacovigilance through regulatory compliance, higher productivity, higher quality and strategic safety outcomes**
Accenture can provide the full package—decades of management consulting, stellar BPO execution, and all the technology and analytics required to drive successful R&D outcomes.

**Match the solution to the challenge**

The need for PV outsourcing is a reality for most Life Sciences companies. As we have implemented these services for our customers, we have adapted according to their operating models, outsourcing maturity level and the scale of the challenge being tackled. We achieve a competitive price point by leveraging our offshore delivery network, and we offer a range of services that can be tailored exactly to match the demands of any context:

1. **Discrete, specific need:** Services to augment a PV organization’s existing operations using its own systems and processes; additional capacity provided as needed, with direct oversight of a flexible pool of outsourced resources in our India or China Centers of Excellence.

2. **End-to-end PV:** Fully managed service spanning end-to-end PV services, integrating seamlessly and using a PV organization’s systems and processes; strengthened through our advanced operational excellence capabilities and analytics capability.

3. **Next-generation solutions:** Comprehensive, fully managed service spanning end-to-end PV services in a hosted utility model leveraging our high-performance PV systems and processes to initiate a step change in efficiency and outcomes (see Figure 1).

For more details, see Table 1.

### Table 1

<table>
<thead>
<tr>
<th>Discrete, Specific Need</th>
<th>End-to-End Pharmacovigilance</th>
<th>Next-Generation Solutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case capture including electronic data capture for PV service and call center</td>
<td><strong>Data</strong></td>
<td>• Powered by Argus</td>
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<tr>
<td>Case processing</td>
<td>• Integration of a number of the tactical solutions into a fully managed service</td>
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<td>Medical review</td>
<td>• Switch from capacity-based FTE model to unit-based model controlled by SLAs and offering a flexible and variable pricing structure</td>
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<tr>
<td>Aggregate safety reporting</td>
<td>• Advanced operational workflow and analytics</td>
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<tr>
<td>Safety surveillance including searching and signal detection</td>
<td>• Joint incentives and investments in innovation, continuous improvement and operational excellence</td>
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<tr>
<td>Benefit-risk management</td>
<td></td>
<td>• Fully integrated with our innovative electronic data capture utility for case capture</td>
</tr>
<tr>
<td>Advanced operational workflow</td>
<td>Data</td>
<td>• Hosted PV safety warehouse for aggregating cross-industry data to feed safety surveillance and benefit-risk activities</td>
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</tbody>
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For more details, see Table 1.
Build in quality and mitigate the risks of change

Every project does not have to be a large-scale transformation. If you require tactical cost reduction with rapid implementation and the associated control and flexibility, we excel with this model. If you are embarking on a game-changing PV transformation, however, introducing our services can be a significant facilitator of that transformation. We will help you drive your vision forward.

People—patients, healthcare professionals, policy makers and your employees—are at the heart of PV. Our change management and communications experience will help mitigate the risks of adopting new methods, letting you focus on the strategic vision and realize the ultimate patient safety benefits.

Lean, efficient processes, controlled through compliant standard operating procedures, are the backbone of every service we deliver. We can help you to simplify your global workflow with high throughput, replace manual steps with automation, and build in quality to help you get things right the first time.

Figure 1: Comprehensive PV Utility

Inputs from:
- Healthcare professionals
- Patients
- Caregivers
- Sales reps
- Call centers
- Patient support programs
- Registries
- Social media

Improved business outcomes for:
- Biopharmaceutical companies
- Regulators
- Improved product safety for patients
- Improved benefit-risk insights
Accenture's unique capability and experience

Accenture works with Life Sciences clients in more than 50 countries, including pharmaceutical industry leaders, biotech companies, medical device companies and 125+ public health organizations (including seven EU regulators and the FDA). We have a 20-year track record in offshore delivery, and our success has been widely recognized.

For four years in a row, Accenture has been named the #1 outsourcing company by International Association of Outsourcing Professionals. And, for the second year in a row, IDC Health Insights selected us as the #1 Preferred Life Sciences Technology vendor.

Accenture continues to make significant investments in PV technology and operations. We see PV as an area of significant challenge—an area that, by directly benefiting patient safety and improving health outcomes, is fully aligned with our global Life Sciences strategy.

Track record of pioneering in PV

Accenture led the way into PV 22 years ago through our superior implementation of PV processes and technology for the UK Medicines & Healthcare products Regulatory Agency and our support for the definition of key PV standards such as MedDRA and E2B. Over the last decade, we have led the implementation and management of the General Practice Research Database (GPRD) for pharmacoepidemiology and the Sentinel solution for product licensing, PV and cross-industry signal detection.

In 2007, Accenture pioneered PV outsourcing by establishing the first end-to-end offshore service for PV. Today, we:

- Lead the industry in volume, processing more than 500,000 adverse events reports and 300 aggregate reports annually
- Have personnel across PV consulting, PV technology and PV outsourcing
- Have access to PV consulting and technology resources through our ally Foresight and access to PV product knowledge through our Global Strategic Alliance with Oracle
- Cover 11 major therapeutic areas and all types of adverse event cases and aggregate reports.

Operational excellence and continuous improvement

Accenture draws on its years of Lean Six Sigma experience to build industrialized processes for PV and implement them through our global delivery network. The operational excellence of these services is demonstrated by the targets we have achieved across our clients:

- Cost savings of up to 70%
- Potential one-day turnaround time for single cases
- Industry-leading productivity with potential throughput of 1200–1400 cases/FTE/year (subject to client-specific approaches and case input mix)
- Right-first-time method to meet stringent quality targets
- Consistent 99% compliance
- Progressive reduction in labor costs through offshore Centers of Excellence in India and China.

Industry-leading technology platform and advanced analytics

Accenture solutions are technology enabled. We have the technology capabilities and know-how to run your operations like a well-oiled machine across both technology and operations. For example:

- Accenture is one of the few service providers certified on the Oracle Life Sciences Hub and one of the largest users of the hub.
- We have global experience transitioning legacy systems to the Oracle Argus Safety Suite, an advanced drug safety, PV and risk management platform. We can help clients adopt a cloud-hosted Argus environment and jump-start implementations.
- Accenture has top-shelf analytics and Life Sciences experience to help clients distil insights from data through real-world signal detection, forecasting and modeling, thereby driving better business decisions and improved business outcomes.
- Our proprietary dashboards and tools create transparency—you see the same strategic, tactical and daily execution metrics as we do in close to real time.
- Our recent acquisition of Octagon provides the industry-leading Quantum platform to facilitate our integration across clinical, PV and regulatory.
Teaming to pioneer successful PV offshoring

A top-20 global pharmaceutical company sought ways to maintain quality while optimizing operations and maximizing efficiency of safety case processing and aggregate reporting.

In 2007, the company chose Accenture to build a pioneering full-service PV operation completely supported in India. Over several months, we helped the company transfer knowledge of its processes to a team of 150 drug safety consultants in Chennai, India.

Once operational, the offshore team:

- Processed an estimated 90,000 adverse event cases per year, providing services from data entry and medical encoding to medical assessment and quality assurance
- Planned and developed almost 90 aggregate reports (PSURs and PADERs) to comply with the MHRA and FDA regulations
- Authored medical communications, including clinical study reports, bioanalytical study reports, outcomes research reports, drug safety narratives and scientific manuscripts
- Served as a seamless extension of the company’s onshore team.

The value generated was clear from the start. The transition was completed ahead of schedule, and the skills and infrastructure provided are a seamless extension of the company’s onshore team. Productivity has been enhanced and operating costs reduced.

Creating the future model of R&D

Accenture is deeply committed to helping pharmaceutical companies address current challenges as well as pre-empt future issues.

Through Accenture Accelerated R&D Services, we bring the next-generation, fully integrated business service that delivers optimized processes across the clinical, regulatory and PV functions around the globe. This solution, supported by outsourced operational activities and enabled by customizable technology platforms, helps pharmaceutical companies bring drugs to market faster, at less cost and with reduced execution risks.

Further, the solution is leading edge, supporting maximum efficiency in R&D as well as the management and measurement of R&D processes. Advanced data analytics drive innovation across companies and help release the full value of the data.

By adopting an externally managed solution that consistently and routinely achieves required business outcomes using a globally integrated model, PV organizations will gain the freedom to focus on the science of safety.

“The detailed end-to-end knowledge of PV, and uncompromising approach to jointly designing procedures and operational measures has been exemplary. The staff recruitment and training during the transition has been outstanding. In Accenture, we have a partner with a shared vision and which jointly strives with us to improve patient safety.”

VP Global Pharmacovigilance
Global biopharmaceutical company
Contact us to learn more
To learn more about how Accenture is helping companies, please visit accenture.com/lifesciences or contact one of our executives:

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About Life Sciences
Accenture’s Life Sciences practice is dedicated to helping companies rethink, reshape or restructure their businesses to deliver better health outcomes and drive shareholder returns. We provide consulting, outsourcing and technology around the globe in all strategic and functional areas—with a strong focus on R&D, Sales & Marketing and the Supply Chain. We have a long history of working hand in hand with our clients to improve their performance across the entire Life Sciences value chain. Accenture’s Life Sciences practice connects more than 10,000 skilled professionals in over 50 countries who are personally committed to helping our clients achieve their business objectives and deliver better health outcomes for people around the world.

About Accenture
Accenture is a global management consulting, technology services and outsourcing company, with approximately 259,000 people serving clients in more than 120 countries. Combining unparalleled experience, comprehensive capabilities across all industries and business functions, and extensive research on the world’s most successful companies, Accenture collaborates with clients to help them become high-performance businesses and governments. The company generated net revenues of US$27.9 billion for the fiscal year ended August 31, 2012. Its home page is www.accenture.com.

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