

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

Accenture Accelerated R&D Services Overview





Strategy | Consulting | Digital | Technology | Operations

The first fully-integrated, technology-enabled, global business service that improves R&D cross-functional processes, insights and outcomes.



Life sciences research and development (R&D) organizations face unprecedented business pressures, including increasingly stringent health authority requirements, unsustainable fixed cost models, and the complexity of managing numerous vendor partners and technology systems. Addressing these issues strains current capacity and operating models and diverts precious resources from the desired focus: bringing differentiated new products to market.

To help clients address these challenges, Accenture offers Accelerated R&D Services, a next-generation, fully-integrated solution that helps clients increase R&D quality and speed, while simultaneously helping reduce costs and operating complexities. Accenture helps our clients focus on the science of new products.

Creating the future model of R&D

Accenture acquired Octagon Research Solutions, an industry-leading provider of Regulatory capabilities and technology solutions. Octagon's capabilities and experience complement Accenture's current market leadership in clinical and pharmacovigilance (PV) operations, as well as our established global scale and reach. Adding Octagon to our dedicated Life Sciences practice is the latest in a series of investments Accenture has made to support ground-breaking R&D services.

Through Accenture Accelerated R&D services, we bring a fully integrated business service that delivers enhanced processes across the clinical, regulatory and PV functions around the globe. This solution, supported by outsourced operational activities and enabled by customizable technology and infrastructure, will allow pharmaceutical companies to bring drugs to market faster, at less cost and with reduced execution risks.

Teaming to deliver 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 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 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.

Figure 1: Accelerated R&D Services

Current Model



Current Issues/Challenges

- Serial process (sub-optimal)
- Significant technology refresh needed
- Unsustainable cost
- Inconsistent quality
- Multiple external providers (10-40 per client)



Data &

Analytics

Regulator

Accelerated R&D Services

Clinical



- 30-40% lower cost
- 10-15% improved speed to market
- Consistent quality; Full Transparency
- Variabilized costs

Future Opportunity

- Integrated and optimized end-to-end processes
- Enabled by integrated technology
- Analytics driven insights to improve clinical, regulatory, and safety outcomes
- Financing options

Accenture's unique capability and experience

We work with life sciences clients in more than 50 countries, including industry leaders as well as 125+ public health organizations. 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 the International Association of Outsourcing Professionals. And, for the second year in a row, IDC Health Insights has selected us as the #1 Preferred Life Sciences Technology vendor.

Deep R&D experience

- 20+ years helping clients
- Service 17 of the top 40 global pharmaceutical companies in R&D

- Pioneered and currently support five of top 10 pharmaceutical companies in BPO
- 5th largest user of the FDA electronic submissions gateway
- A leading provider of conversion (of data to CDISC standards) and training services

Operational excellence and continuous improvement

- Business process outsourcing for the entire product lifecycle.
- Understanding of how to enhance any process for improved productivity, with a focus on quality and innovation

Industry-leading technology platform and advanced analytics

- Proprietary software, or ability to work across other vendor's software
- ViewPoint®/Quantum: Platform designed for managing the drug development lifecycle from data collection to submission.
- Process-management approach credited with cutting timelines by 30%.

- Integrates submission publishing and assembly with process management and metrics
- Relationships with market-leading technology companies:
 - Oracle: LSH, Argus
- SAS
- Extensive services around software
- Advanced analytics that provide informed insights and help drive alignment both within and across functions.

Global delivery and reach

- 50+ global delivery locations, with combination of onshore and offshore professionals
- 2500+ professionals around the globe focused on R&D services
- Dedicated delivery teams who deeply learn clients' processes and systems and continuously look for improvement opportunities on our clients' behalf.

Figure 2: Accelerated R&D Services - Offerings



Accenture helps clients achieve

Accelerated R&D

- 30%+ cost reduction
- 10-15% improved speed to market
- Consistent quality, full transparency
- · Variabilized costs and financing options
- Industrialized regulatory submissions processes
- Submissions-ready data standards built into tools
- Continuous updates of applications-as-a-service in keeping with regulations and best practices
- Freedom to focus on the science of new products

Clinical

Regulatory

- Improved identification of trial sites and investigators by making optimal use of site performance data
- Increased effectiveness of monitoring investigator sites through proactive analysis of data (we identify a variety of risks and manage them through targeted interventions, reducing the burden of on-site monitoring while improving quality and protocol adherence).
- Improved program design, enhanced decision-making and assisted patient safety by harnessing analytics

- Achieved 100% of submissions on schedule
- Reduced clinical/non-clinical error rate to 5%
- Increased efficiency/reduced cost of operations by 40%
- Improved reports quality by 30% and single case quality by 65%
- Implemented improved regulatory timelines, leading to reduced FDA audit/ questioning
- Increased agility to respond to changing regulatory requirements

•	Cost	savings	of up	to	70%
-	CUSL	Savings	or up	ιU	10%

Pharmacovigilance

- 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 (e.g., 99% of fields correct)
- Consistent 99% compliance
- Progressive reduction in labor costs through offshore Centers of Excellence in India and China

Delivering high-quality regulatory submissions much more efficiently

Accenture helped a top-10 global pharmaceutical company double its regulatory submissions, achieve schedule goals, and dramatically increase efficiency. Since 2009, Accenture has worked with this client to deliver approximately 10,000 regulatory submissions, across the spectrum of activities.

Accenture doubled the number of submissions (+112% of annual submissions) over the projected baseline, using only 5% more hours. This resulted in a 50% improvement in hours per submission and an equal per-submission cost reduction.



Creating the first cloudbased clinical aggregation layer solution with top 10 global pharmaceutical company

A global top-10 pharmaceutical client sought to streamline its fragmented outsourced activity and to establish strategic relationships with just a few partners. In order to drive efficiency, the company agreed that the business partners could use their internal systems and processes to capture both operational and clinical data for clinical trials. To meet the client's business need, Accenture Life Sciences created a clinical aggregation layer (CAL). This company needs easy access and control over all its data—and the clinical aggregation layer (CAL) provides a scalable solution, based on industrystandard technology, that gives consistent and comprehensive data access to alliance partners, internal teams and external industry sources.

The resulting data transparency was unprecedented: this was the first time data could be shared across multiple providers and platforms. Accenture's end-to-end managed service for clinical development was founded on optimized process execution, enabled by marketleading and integrated technology and leading-edge analytics capabilities, using a pay-for-performance business model.

Accenture created a service that can now benefit the entire pharmaceutical industry. This clinical trial data access and exchange can help companies increase innovation, mitigate risk and reduce costs.

Contact us to learn more About Accenture Life

To learn more about how Accenture is helping companies, please visit accenture.com/lifesciences or contact one of our executives:

Kevin K. Julian Managing Director kevin.k.julian@accenture.com

Seth Levine Managing Director seth.m.levine@accenture.com

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 more than 336,000 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\$30.0 billion for the fiscal year ended August 31, 2014. Its home page is www.accenture.com.

Stay Connected



Accenture Life Sciences Blog

Accenture experts share insights and opinions on opportunities and challenges in the pharmaceutical and medical technology industry.

www.accenture.com/LifeSciencesBlog

Copyright [©] 2015 Accenture All rights reserved.

Accenture, its logo, and High Performance Delivered are trademarks of Accenture.