

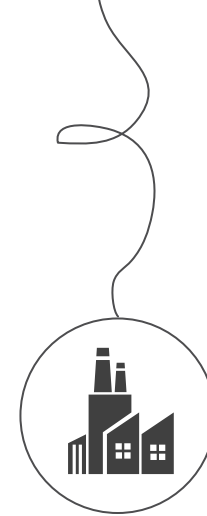
INDUSTRY PERSPECTIVE

The majority of commercially available Safety Systems (e.g. Argus, ARISg, AERS) focus on data entry, report generation and report submission; offering little in the way of “improved and cost effective” safety processes. Critical business capabilities such as workload management, performance monitoring, operational forecasting, reporting and safety analytics are at best rudimentary.

Pharmaceuticals aspire to be able to perform beyond the current capabilities of reporting adverse events on time and detect signals. Their longitudinal objective is to continually monitor and improve a drug’s risk/benefit balance with the benefit of enhanced data to support a conclusion. A structured Signal Management and Risk Benefit Management approach with a defined workflow and integrated processes is the need of the hour.

Some of the challenges in Pharma Covigilance (PV) area that Pharma companies are facing of late:

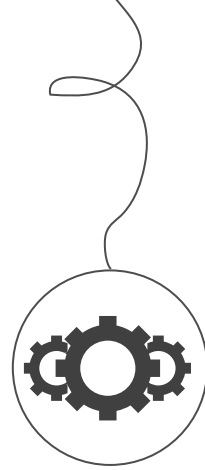
- PV is rendered to a mere compliance activity than a lever for competitive advantage
- PV process is currently executed in silos with multiple COTS products with varied complexities and limited interoperable capabilities
- Existing products are more focused on data operational level than being insightful
- Current products cannot deliver end-to-end big picture view of the entire PV cycle
- Changing regulatory guidelines limit the adaptability of the existing COTS based PV processes



HCL SOLUTION

HCL’s Drug Safety Utility Platform (DSUP) allows sponsors’ externalize clinical safety and spontaneous AE reporting. It is a cost-effective, cloud based utility model for AE Case Management, Aggregate and Spontaneous Reporting and improved Signal Intelligence and Risk Management. It offers the PV Organization improved case transactional throughput, reduced transactional cost, and improved drug safety reporting and overall faster time to benefits in a rapidly evolving industry.

PV AREAS COVERED BY OUR SOLUTION



Workload management and compliance

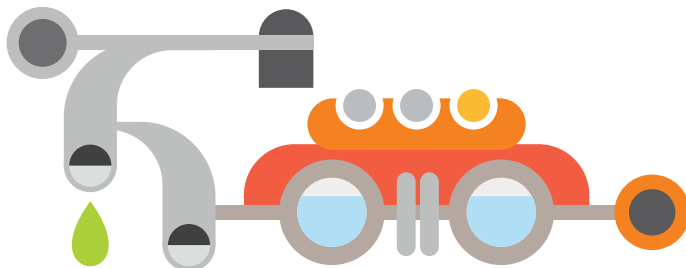
- PSUR Processing
- Interactive dashboards for operational control of internal SLAs
- Region, RX team, individual metrics reports
- Resource work load monitoring and re-leveling dashboard
- Case aging report with the ability to reassign cases in process to ensure they will be processing on time.
- Parallel Case Handling
- SDEA monitoring

Case Intake

- Mobile enabled intake module for field force data entry
- Automated data transfer from call center solutions e.g. Siebel CRM, to remove redundant data entry
- Initial categorization, duplicate checking and routing of AE vs PTC vs Medical Enquiry

Enhanced Signal Management

- Full life cycle management of signal analysis and detection coupled with decisions workflow
- Semi-automated reconciliation utility with CDW and external sources
- Advanced notification based on event triggered alerts for proactive monitoring and effective organizational communications management



KEY FEATURES



Reliable cloud based technology platform with a simplified end-to-end business process enablement



State-of-the-art BPM layer providing orchestration of existing processes coupled with new functionality



Complete built in proactive signal detection management



Reporting, safety analytics and data visualization



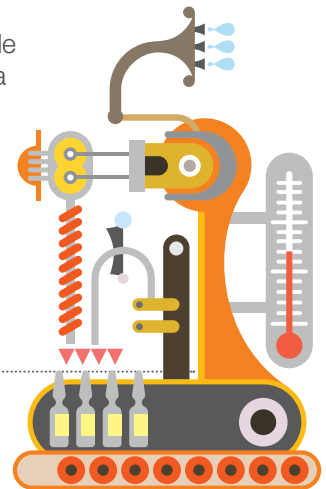
Aligns with fully integrated risk management through a single platform and one version of truth



Enhanced customization and flexibility: Configurable region-specific business rules, workflows, and data visibility



Built-in case management and business rules engine



BUSINESS BENEFITS

Multiple pricing models

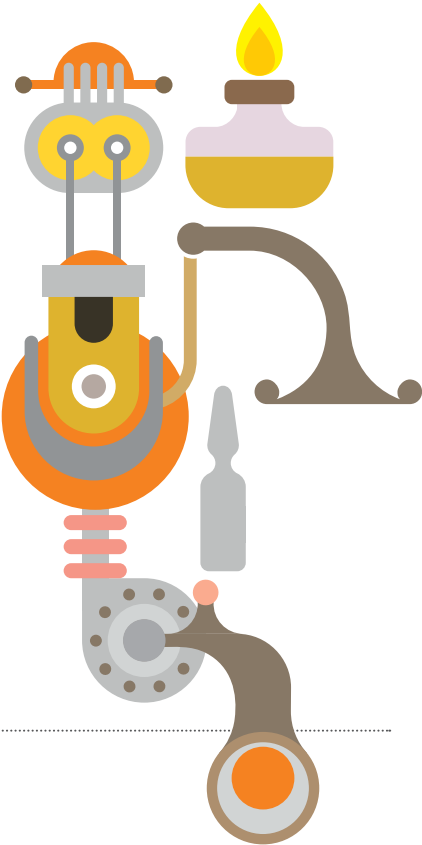
- Monthly service fee
- Software as a Service
- Transaction based pricing
- Easily scalable both upside and downside, reducing the overhead

Quality

- Enhanced communication
- Reduction in human error
- Benefit of enhanced data to support a conclusion

Operational Efficiency

- End-to-end business process enablement
- Reduce Safety Platform Implementation Life-Cycle
- Simplified operations, operational efficiency and flexible operating models



WHY HCL

Domain Expertise

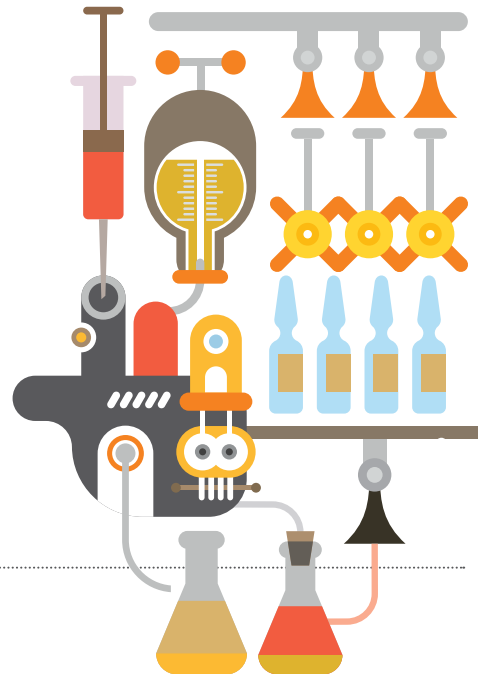
- HCL rated as a 'Leader in Drug Safety Services – Vendor Assessment, IDC MarketScope report, Feb13
- Strong team with proven multiple years of PV domain and strategic consulting expertise

Process Excellence

- Lean Six Sigma Deployment
- Business Process Reengineering Initiatives to optimize back office
- PathFinder : Process Design
- Strong Change Management Track Record
- BPM Capability: Pega, Appian, Oracle Fusion

Technology Expertise

- Largest Pharma R&D IT Support in Industry
- Implementation of global Integrated Clinical Platform
- Product Development partnership with industry leading Original Equipment Manufacturers (OEMs)



ABOUT HCL TECHNOLOGIES

HCL Technologies is a leading global IT services company, working with clients in the areas that impact and redefine the core of their businesses. Since its inception into the global landscape after its IPO in 1999, HCL focuses on 'transformational outsourcing', underlined by innovation and value creation, and offers integrated portfolio of services including software-led IT solutions, remote infrastructure management, engineering and R&D services and BPO. HCL leverages its extensive global offshore infrastructure and network of offices in 31 countries to provide holistic, multiservice delivery in key industry verticals including Financial Services, Manufacturing, Consumer Services, Public Services and Healthcare. HCL takes pride in its philosophy of 'Employees First, Customers Second' which empowers our 85,194 transformers to create a real value for the customers. HCL Technologies, along with its subsidiaries, had consolidated revenues of US\$ 6.5billion as on 31st March, 2014 (on LTM basis).

HCL – LIFE SCIENCES & HEALTHCARE

HCL is one of the market leaders in life sciences & healthcare IT service providers. HCL's clientele includes nine of the top ten global pharmaceutical companies, six of the top ten health insurers, one of the largest payer conglomerates in US and top five service providers in UK. With experienced and certified technology and domain specialists, HCL offers services in the critical areas of drug discovery, clinical development, drug safety, Pharmacovigilance, regulatory compliance, manufacturing and plant automation, sales and marketing, member experience management, fraud, waste and abuse management, ICD-10 transformation and others.



For more information
write to us at:
contact.lsh@hcl.com



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