Cognitive Pharmacovigilance
It takes a human an average of 15 minutes to process an inbound case safety report (ICSR). If an ICSR becomes an adverse event (AE), average processing increases to several hours. What if you could utilize advanced robotics, digital process automation, and artificial intelligence (AI) to reduce that time by 70 percent to 80 percent? Virtusa introduces Cognitive Pharmacovigilance (PV) Intake, powered by Pega.

**Challenges**

Life sciences companies are challenged with an increasingly inefficient pharmacovigilance (PV) process resulting in highly resourced departments, duplicated efforts, and increased cost and risk:

<table>
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<tr>
<th>Intake</th>
<th>Case Processing and Data Storage Requirements</th>
<th>Compliance &amp; Reporting</th>
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<td>Increasing quantities and complexities of intake data with a 10-20% increase in annual volumes but &gt;70% are non-serious</td>
<td>Inability to close communication loops on cases resulting in missing key data points needed to complete FDA reporting.</td>
<td>Stringent compliance reporting that varies by region, product, and FDA/EMA and emerging GDPR governance requirements.</td>
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<td>Silo-ed legacy systems and unintegrated intake lead to inconsistent and duplicative AE reporting</td>
<td>Security concerns with using Outlook as a collection point with lost email and long-term data storage limitations</td>
<td>Lack of aggregate outcomes and reporting capabilities with processes that are ripe for human error, unclear responsibilities, mislabeled issues</td>
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**Solutions overview**

Our solution leverages Pega’s process and decision-based technology to create a reusable AE case processing and product compliant environment that provides rapid configurability to address global requirements:

**Key solution features**

- Dynamic intake using natural language processing (NLP), optical character recognition (OCR), language translation, and sentiment analysis
- Omni-channel experience with email, fax, E2B, web flex forms, and social media
- Automated case triage and identification of serious adverse events (SAEs)
- Auto-generated acknowledgment emails to senders and bi-directional communication
- Flexible regional and internal/external storage, access, and privacy model
- Document exchange with case processing system
Superior user experience

- Guide users through case review
- Effective customized dashboard
- Key metadata fields are highlighted for faster analysis
- Increased user adoption
- Relevant info at the relevant time
- Enhanced duplicate detection
- Rich UI look and feel
- Close information gaps via bi-directional communication and strong digital case management

Powerful Pegasystems platform

Virtusa has leveraged the Pegasystems core Pega PRPC and Pega Build for Change® technology to build a PV solution.

This solution is constructed by using deep industry knowledge to deliver a product that streamlines operations across a variety of business functions. The result is effective management of patient safety while being able to stay within a complex atmosphere of changing regulations.

Key benefits

An upfront investment in our PV Solution provides unprecedented opportunity to reduce overall costs, streamline resources, and improve compliance for conducting successful clinical trials:

- Increase productivity and lower costs of overall PV operations by 50-80%
- Speed time to market resulting in lower operational costs and increases margins
- Lowering per case processing costs by reducing paperwork, manual intervention and duplicative efforts
- Ensure that external stakeholders are able to leverage system functionality through multi-browser support for portals
- Detect adverse events earlier to promote safer use of drugs and devices through automated risk and regulatory reporting

Success story

A global pharmaceutical giant sought to automate the manual intake of more than one million ICSR’s (inbound case safety reports) through the application of Digital Process Automation. The goal at project inception was to remove at least 65% of the labor associated with ICSR review, speed their processing and dramatically reduce overall costs.

By taking a programmatic approach to PV Safety, our client is well on their way to delivering on the objectives of multichannel capture, safe storage, digital processing, case management and reporting of all ICSRs.
About Virtusa

Virtusa Corporation (NASDAQ GS: VRTU) is a global provider of digital business strategy, digital engineering, and information technology (IT) services and solutions that help clients change, disrupt, and unlock new value through innovation engineering. Virtusa serves Global 2000 companies in Banking, Financial Services, Insurance, Healthcare, Communications, Media, Entertainment, Travel, Manufacturing, and Technology industries.

Virtusa helps clients grow their business with innovative products and services that create operational efficiency using digital labor, future proof operational and IT platforms, and rationalize and modernize IT applications infrastructure. This is achieved through a unique approach blending deep contextual expertise, empowered agile teams, and measurably better engineering to create holistic solutions that drive business forward at unparalleled velocity enabled by a culture of cooperative disruption.

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