



Use Cases for Life Sciences: Pharmacovigilance

Is it really possible to address compliance and promote patient safety with less effort?

Challenge.

- Global, cross-functional nature of mission critical process for tracking and managing drug safety signals.
- Large, global workforce.
- Different regulations across different regions.
- Hundred of products.
- High reliance on paper.
- Legacy applications and information silos are causing major bottlenecks.
- Low compliance rates are creating significant delays in adjudication of the safety signal.

Solution goals.

- Dramatically increase efficiency of signal tracking.
- Improve compliance rates with health authority regulations.
- Centralize information from across many systems.
- Overhaul reporting for fast, complete auditing on-demand.

Sample app: safety information tracking system.

Business case.

- Legacy paper-based process is dangerously inefficient.
- Low compliance rates due to high risk of missing strict filing deadlines.
- Lack of a central, secure repository negatively impacts auditing.

Approach.

- Automate key steps to concurrently speed processes and reduce errors.
- Unify data from across systems to create a single view for all.
- Create a reporting mechanism where current reports are available on demand.

Company profile.

Large, multi-national pharmaceutical company.

100,000+ employees.

Global presence across 100+ countries.

Hundreds of marketed products.

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Results.

- Reduced report generation from 6 days to seconds.
- Increased compliance with Health Authority regulations to >99.99%.
- Automated key process steps to dramatically decrease signal adjudication time.
- Continuously impacting patient safety and health.
- All in just 16 weeks.



Existing applications.

CLINICAL: Site Initiation — Readiness — Effectiveness Study Start Up, "1572", IP (Green Light), Global CRO Contracts, Pre-approval Inspection

CMC: High Throughput Experiment Tracking, Global Compound Ordering, LIMS

REGULATORY: Regulatory Operations, IDMP, e-Submissions and Publishing, Online 510K FDA Review

PV: Safety Information Management, Safety Signal Tracking

COMPLIANCE: Anti-Bribery and Corruption (FCPA), Third-Party Intermediaries, Sunshine Act

COMMERCIAL: Sales Force Automation, Contracts

IT: Asset Management. vs. Resources, Statements of Work Management

HR: Onboarding, Recruiting

