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AccelSafe:
AdverseEvent Intelligence Agent

Solution Overview

Current State of the Industry

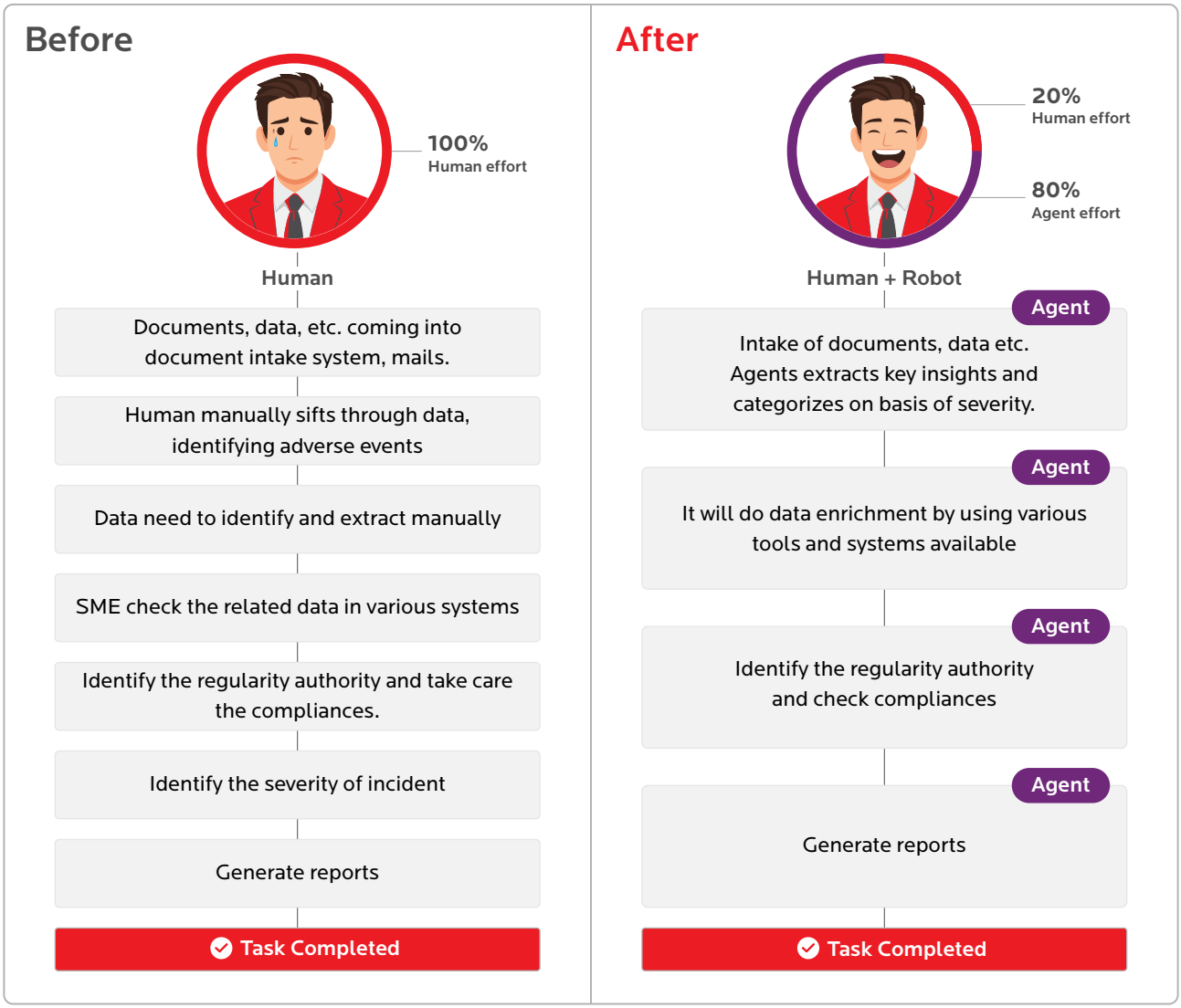
Pharmacovigilance is central to ensuring patient safety by continuously monitoring adverse drug reactions (ADRs) and related risks across the drug lifecycle. However, traditional processes remain manual, fragmented, and difficult to scale. These processes are time-consuming, error-prone, and increasingly unsustainable as case volumes grow.

- Organizations face rising pressure from unstructured and inconsistent data, complex multi-source intake, rapidly evolving regulatory requirements, and limited specialist capacity. These challenges increase operational costs, delay reporting timelines, and elevate regulatory and patient-safety risk.
- Failure to correctly identify reporting authorities or comply with submission standards can result in severe penalties, reputational impact, and delayed safety signals-making compliance accuracy as critical as speed. Fines such as FDA penalties of up to $1M per violation and EMA penalties up to €10M. Inconsistent, high-volume safety data slows timely decision-making and raises both regulatory exposure and patient-safety risk.

Overview: The Solution of Future

- AccelSafe introduces a fail-safe, automation-led approach to adverse event intake and reporting. It uses an internal agent-based framework to process unstructured inputs such as emails, extract and validate critical information, and prepare compliant reports, including Medical Device Reporting (MDR) submissions where applicable -significantly reducing manual effort while improving consistency and accuracy.
- The agent enriches missing data in real time using a live internal database, classifies severity, determines the appropriate regulatory authority - the U.S. Food and Drug Administration (U.S. FDA) or the European Medicines Agency (EMA), and ensures all reports align with the latest compliance standards.
- The solution spans the full adverse event lifecycle. By augmenting human decision-making with intelligent automation, AccelSafe enables scalable operations, reduces manual effort, and strengthens speed, quality, and control across adverse event workflows.

Adverse Event Management Reimagined



The agent-based adverse event solution automates high-effort steps across the adverse event lifecycle-from intake and enrichment to severity categorization and report generation. Industry analysts suggest clear efficiency gains, with leading global consultancies estimating a **40-70% potential reduction** in case-processing effort and indicating **40-75% possible cost efficiencies** across high-volume workflows.

- With UiPath Agentic capabilities, safety teams automate data extraction, entry, severity checks, and report creation, improving data quality, accelerating analysis, and reducing manual workload.
- These capabilities strengthen compliance, speed regulatory approvals, and improve experience for clinicians and SMEs, while also increasing accuracy, consistency, and overall patient-safety outcomes.

Business Outcomes

01 3x–5x improvement in intake triage and routing productivity

Adverse event intake cycles reduced from weeks to days 02

03 Significant reduction in manual processing effort

End-to-end traceability and audit readiness across adverse event workflows 04

05 Higher accuracy and consistency in safety data

Reduced compliance gaps, reporting errors, and rework 06

07 Faster Identification of high severity critical cases

Automated U.S. FDA/EMA regulatory report creation 08

Differentiators

Agent-driven orchestration, not isolated automation	Unstructured-to-structured data transformation at scale
Built-in compliance and regulatory alignment	Human-in-the-loop model for clinical validation

Use Case: Adverse Event Intake Automation

Location: Global | **Customer type: Pharmaceuticals / Life Science**

Challenges	AccelSafe	Results
10-20% AE volumes growing yearly.	Automated & standardized workflows.	**3X** Improvement in safety operations productivity.
Manual and fragmented intake processes.	Cognitive AI-driven decision support.	**3-5X** Faster triage and routing.
Complex data from multiple sources.	Integrated with safety systems of record	**~10 days** Intake timelines reduced.
Unsustainable staff workload.	U.S. FDA/EMA-aligned reporting, including Medical Device Reporting (MDR) where applicable.	**Up to 40%** reduction in operating costs.

The Transformation

From	To	Outcome
Manual processing, slow & error-prone, siloed operations.	Intelligent automation, AI-driven decision, Connected workflows.	Proactive risk mgmt. scalable operations, Better patient safety.

Source: Birlasoft Analysis, McKinsey, KPMG

Accelerating Impact

Birlasoft combines the power of domain, enterprise, and digital technologies to reimagine business processes for customers and their ecosystem. Its consultative and design thinking approach makes societies more productive by helping customers run businesses. As part of the multibillion-dollar diversified CKA Birla Group, Birlasoft with its 11,500+ professionals, is committed to continuing the Group's 170 year heritage of building sustainable communities.

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