

# Faster and Flexible Response to Drug Safety Signals

## The Challenge

The Drug Safety process requires pharmaceutical companies to demonstrate a rigorous and ongoing safety surveillance program to support quick action and response on any safety concerns. Recommended actions for each drug can vary further for each type of safety issue depending on the patient data. Failure to respond to safety signals in a timely manner with the most informed response (that has input from all SME's) can negatively impact the brand, reputation, patient trust and result in penalties.

Most pharmaceutical companies manage this process today with a combination of a legacy Drug Safety application (often aging and rigid) complimented with MS Office, SharePoint and emails. This approach does not provide a structured workflow to ensure efficient collaboration amongst SME's to prepare the most accurate and timely response to safety signals.

## The Solution

Responding to drug safety signals requires a coordinated collaboration of various SMEs to ensure the best response goes out within a very short timeframe. The approach should be consistent yet flexible enough to adapt to each safety issue uniquely. The Princeton Blue Drug Safety solution uses a paradigm called Dynamic Case Management (DCM) which allows the drug safety team to define workflows for each drug or therapeutic area during initial setup, and tailor the process for each signal as it comes in. DCM provides a flexible mechanism to dynamically configure the most effective activities for signal analysis and prioritization.

| Drug Safety Pain Points                                     | Princeton Blue Drug Safety Solution  |
|---|--|
| Off-the-shelf solutions have rigid workflow (if at all)     | DCM provides a flexible workflow that can be tailored for each signal.   |
| Lack of automated workflow requires human governance        | Process automation ensures the safety signals are processed in the most efficient manner and within regulatory compliance guidelines.                    |
| Emails, MS Office and SharePoint are used for collaboration | Real-time collaboration ensures all SME's participate in the process at the right time to share their expertise and produce the optimal safety response. |

[See Drug Safety solution demo \(12-min video\)](#)

[Watch Demo](#)

## Build your automated Drug Safety solution in weeks!

Low-code Process Automation technology allows us to build this Drug Safety solution fully integrated with your legacy applications in weeks rather than months. Key features of this rich, mobile-enabled solution include:

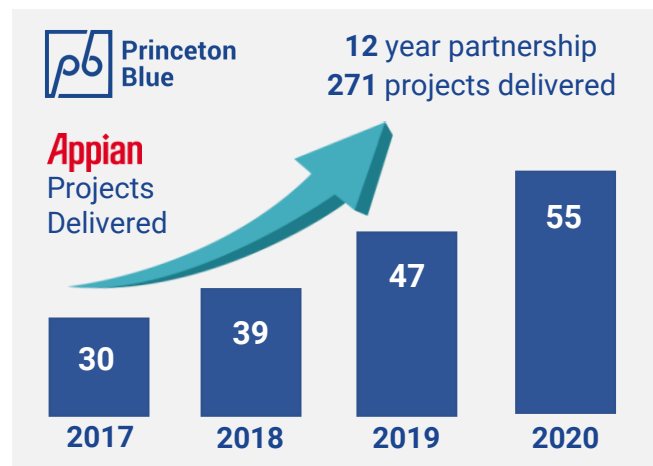
| Feature                | Description   | Business Impact  |
|------------------------|---|--|
| Configurable Workflows | Dynamic workflows can be customized for each drug or therapeutic area and further tailored for each signal based on patient data. | This results in the most inclusive, efficient and timely response to the safety signal.  |
| Signal Response Status | The process creates tasks and assigns them to the right individuals and ensures that they get it done in a timely manner.         | Unified transparency into signal processing status and progression shows team's performance and areas that need attention.                     |
| Collaboration          | Real-time collaboration on case data, findings, and outcomes ensures everyone has access to the latest information in one place.  | Process based collaboration provides an audit trail of who contributed what and when. Proactive alerts ensure a timely response from everyone. |
| Interactive Dashboards | Role-based dashboard and reports provide insights for each safety signal, its status, pace of progression and response readiness. | Pick up early signs of process friction and bottlenecks so the safety process can be continuously improved.                                    |

### About Princeton Blue

For 14 years, Princeton Blue has been a leader in delivering Low-code Process Automation solutions powered by Low-code, BPM and RPA technologies. These modern automation technologies combined with our thought leadership allow us to deliver these automation solutions in 10 to 15 weeks. Princeton Blue is recognized as a leading Low-code Process Automation services provider in several Forrester and Gartner reports.

### About Appian

Appian provides a low-code automation platform that accelerates the creation of high-impact business applications. Appian is the only enterprise automation technology platform to be recognized as a leader in Business Process Management (BPM), Low-code Application Development and Case Management.



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