Enterprise Risk Assessment and Mitigation Solution (ERAMS)

Business problem.

In the pharmaceutical world, there are different types of risks that can arise during the various stages of drug development, impacting the success of drug development and clinical trials. These risks can cause significant business problems, including delays in drug development, increased costs, regulatory non-compliance, etc. The following steps must be taken at each stage of drug development to mitigate risk:

- During protocol development, sponsors must identify the processes and data that are critical to ensuring human subject protection and the reliability of trial results.
- At the trial and system level (enterprise, vendors, tech, etc.), organizations must identify, evaluate, and control for risks to processes and data.
- For inspection readiness, since drug development activities are subject to regulatory inspections, organizations must proactively assess risk.
- Across levels, overlap happens where one risk can affect multiple areas. Therefore, risks must be identified, monitored, and controlled at different levels (study, process, vendor).

Quantify the business problem.

- Risk assessments are not centralized; they are often done using spreadsheets and PowerPoint slides and are highly reactive
- Risk governance is not data driven and is without a system to balance objective and subjective expertise.
- Sponsors often operationally struggle with the following:
    - Siloed and limited implementation of quality risk management.
    - Inability to define and monitor clear responsibilities and ownership for risk management.
    - An efficient and consistent approach to optimizing workload and ensuring inspection readiness.
    - Consistent and timely documentation of risk-related activities.

The solution.

ZS has developed a digital platform called Enterprise Risk Assessment and Mitigation Solution (ERAMS) to enable enterprises to capture, track, and oversee risks, ultimately leading to better outcomes and advancing medical research.

For most organizations in the pharma industry, risk management is fragmented, manual, inconsistent, and reactive in nature. Hence, there is a need to improve the management and mitigation of risks to ensure successful development, approval, and commercialization of safe and effective drugs.

This solution provides:

- Proactive identification, tracking, and mitigation of critical risks across domains (that is, study, vendor, and process).
- Effective cross-functional collaboration that ensures rapid decision-making and proactive communication.
- Oversight across enterprise risks to facilitate data driven decision making.

The ERAMS solution enables proactive enterprise-level risk management and collaboration across different levels and domains. This enables breaking information silos and bringing stakeholders across domains into one single platform, thus enabling cross-functional collaboration, faster turnaround times, transparency across tasks assignment, etc.

Building this solution on Appian enables:

- Digitize workflows that allow for consistent and effective risk oversight and mitigation and continuous improvements.
- Maintaining sufficient evidence of consistent risk management activities with built-in workflow and documentation.
- Generation of actionable insights and continuous learning from risk management analytics.
- System-driven email notification reminders to ensure efficiency and thorough stakeholder accountability.
- Integration with various platforms, such as CTMS (Clinical Trail Management System) and issue management systems.

Main features.

The main features of the solution are:

- **Centralized Risk Library**
    - A unified risk library to ensure consistency of risk documentation across the organization.
    - End-to-end digital capture and coverage of study, process, and vendor risks.
    - Approval workflows are configured to add/update risks in the risk library.

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- **Digital Risk Management**
  - Enables risk assignment and tracking, controls (KRIs/KQIs/QTLs), and mitigation.
  - Single portal for risks and issues, monitoring, documentation, communication, and governance.
  - The solution enables creating and tracking different versions of RMPs.
  - Approval workflows are configured to close an RMP after successful closure of all identified risks and execution of mitigation actions.
- **Risk Management Analytics**
  - Intuitive and actionable reports for evaluation of risk management effectiveness, risk interconnections, sources, and consequences.
  - Data-driven triangulation of the most critical enterprise risks, enabling intelligent resourcing for risk mitigation.
- **Integration with external systems**
  - ERAMS can be integrated with any external system, such as CTMS, SAP, TMF, issue management system, as per the business' requirements.

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ZS

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