

XCELLERATE

Risk and Issue Management

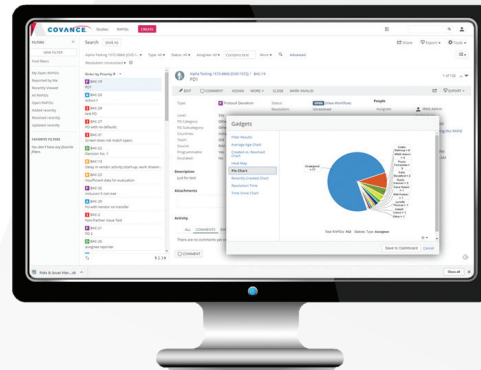
The only truly agnostic solution designed for the entire study team to create, view and manage issues that emerge during the execution of a trial in near real time.

Increase operational efficiency and compliance, reduce risk and add an unprecedented level of transparency.

Overview

Issues are generated throughout the execution of a trial using a variety of disparate systems. This lack of uniformity leads to compliance issues, process inefficiencies and a lack of transparency into the progress of the study.

Xcellerate® Risk and Issue Management creates a single system of record for the study team to create, view and manage issues, including those generated from quality by design, central monitoring and on-site/remote monitoring activities in near real time.



This agnostic system allows CRAs, central monitors, PMs and the rest of the study team to manage all **Risks, Actions, Protocol Deviations, Issues and Decisions (RAPIDs)** from a single custom-built user interface, independent of the underlying trial management systems.

The system enables custom and automated escalation, cascading actions across sites, conversion between issues and protocol deviations, and is fully 21 CFR Part 11 compliant. It increases operational efficiency and ensures that issues are dealt with in a timely and appropriate fashion.

Benefits of Xcellerate Risk and Issue Management

- ▶ Future-proof: Custom-built architecture designed to scale to current and future data volumes
- ▶ Agnostic: Integrates into existing trial management source systems
- ▶ Easy to use: User-centric web and mobile user interfaces
- ▶ Effective: Fast access to critical information with visualizations for metrics reporting and trending
- ▶ Efficient: Advanced workflow engine to accelerate and automate issue resolution
- ▶ Compliant: Audit trail and history tracking supports adherence to ICH GCP and other guidelines

Learn more about our drug development solutions at www.covance.com/Xcellerate

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