

XCELLERATE

Action Alerts

An automated tool to boost clinical study monitoring and improve quality management



Xcellerate® Action Alerts is a fully automated solution that continuously monitors study data and sends alerts and notifications to project team members based on specific study, country, site or subject performance criteria.

- ▶ Apply standard templates for common metrics to quickly deploy and customize study action alerts.
- ▶ Receive notifications when performance thresholds are met, study, country or site milestones are reached, subjects are enrolled or missed visits, issues are reported and more.

Overview

Studies are becoming more complex, requiring more data sources, more trial management systems, larger teams and more geographical locations. To successfully manage quality, study teams need a way of ensuring that they are aware of both expected and exceptional metrics and events across all systems in near real-time.

Xcellerate Action Alerts brings confidence that the right team members are alerted when actions may need to be taken, replacing the time-consuming and unreliable manual surveillance processes many study teams use today.

The alerts can be driven from any study data that is available electronically. Alerts can contain high-value information including study, country, site and subject detail, the operational metric and risk values, suggested actions to be taken, as well as specific details such as adverse events and protocol deviations.

Benefits of Xcellerate Action Alerts

- ▶ Efficiency: Reduce reliance on manual surveillance processes
- ▶ Quality: Proactively detect and address operational issues
- ▶ Compliance: Reduce the possibility that routine or critical events are missed
- ▶ Flexibility: Integration with any trial source system
- ▶ Convenience: Receive alerts and notifications via email
- ▶ Ease of Use: Alerts and notifications are logged, tracked and reportable from within the system

Bringing Efficiency to Clinical Trial Execution

Using Action Alerts' standard template or custom rules, the team can be notified in near real-time when events occur, reducing risk and increasing both efficiency and patient safety.

Primary Target	Event Monitored	Trigger	Value-Add
CRA Lead	SDV backlog	Outstanding page count exceeds predetermined limit	Basic implementation of adaptive, volume-based monitoring strategy: focus CRA time on sites needing assistance
CRA Lead	Potential patient discontinuation	Patient visit not recorded on scheduled visit date	Near real-time capability gives CRA opportunity to intercede before visit window closes
PM Lead Data Lead	Last patient in	Number of enrolled patients meets required patient count	Prevent expensive, and noncompliant, over-enrollment
PM Lead	Number of withdrawn patients	Number of withdrawn patients nears or meets predefined Quality Tolerance Limits (QTL)	Near real-time tracking of patient withdrawals. Set an alert to trigger once QTL is approached, then receive new alerts for each additional patient withdrawal

Xcellerate Action Alerts: More Impactful When Leveraged with the Xcellerate Suite

Xcellerate Action Alerts can be deployed as a standalone, Software as a Service (SaaS) solution, but when paired with other products in the Covance Xcellerate suite it yields even greater value:

- ▶ **Xcellerate Risk and Issue Management (RIM):** Xcellerate Action Alerts can log actions directly into RIM where they will be assigned to the relevant team member, and tracked holistically with all study risks, actions, protocol deviations, issues and decisions.
- ▶ **Xcellerate Risk Review:** Actions raised by Xcellerate Action Alerts are available for review in Xcellerate Risk Review, and are considered part of the comprehensive site risk assessment.

"Xcellerate Action Alerts gives me peace of mind that events important to my study will be found and actioned immediately. This allows us to solve an issue before it turns into a bigger problem."

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

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