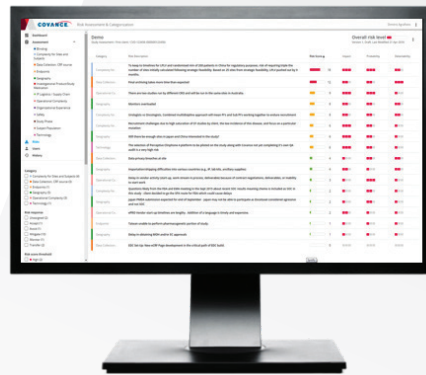# XCELLERATE

Risk Assessment and Categorization Tool (RACT)

Facilitates detailed study risk assessment, identification of critical data and processes, and management of portfolio and study level risks and mitigation plans through a collaborative, electronic process.

The starting TransCelerate template offers guiding questions and considerations for study risk identification, assessment and mitigation. The tool is fully configurable and can be easily tailored to specific needs of different therapeutic areas and programs.

Overview

Studies are becoming more complex with more data sources, more management systems, larger teams and more geographical locations. Study teams need a way of consistently completing a comprehensive risk assessment to enable quality by design.

Using Xcellerate® RACT, study teams identify areas of highest risk and define appropriate mitigating actions. While many risks may cross therapeutic lines, there are inherent risks within each therapeutic area (e.g., endpoint determinations) that require targeted evaluation by trained experts on a case-by-case basis. RACT allows for templates to be created at the therapeutic area level to ask these important questions. Each assessment is stored in a database, allowing interrogation of high-level risks across studies and programs.

Xcellerate RACT is integrated with the Xcellerate Risk Library and Xcellerate Risk and Issue Management. The Risk Library acts as a "lessons learned" mechanism, allowing study teams to review and apply risks from similar programs, and in turn allowing emerging issues to be added to the risk library for future teams to benefit. Integration with Xcellerate Risk and Issue Management allows for the risks to be managed throughout the study. Together, Xcellerate provides an end-to-end solution for quality risk management.

Benefits of Xcellerate RACT

► Efficiency: Replaces traditional excel risk trackers

► Compliant: Reduces possibility that routine or critical events are missed

► Future-proof: Custom-built architecture designed to scale to current and future data volumes

► Agnostic: Integrates with existing trial management source systems

► Customizable: Lead users can easily configure the RACT categories, weighting and templates

COVANCE®

Bringing Quality by Design to Clinical Trial Execution

Xcellerate RACT is arguably the most important risk management application in the Xcellerate suite.

Outputs of the RACT process include:

- ► Critical data and process definition
- ► Study level risk and mitigation strategies
- ► Key risk indicators for central monitors
- ► Definition of risk factors for use in the site risk assessment
- ► Quality tolerance limits

Why Xcellerate RACT?

- ► Customizable risk assessment templates, integration with Risk Library
- ► Identified risks are linked to operational plans, critical data and critical processes
- ► Risks automatically exported from RACT into the Risk and Issue Management system (RIM) when assessment is locked
- ► Detailed information on mitigation actions and contingency planning is completed in RIM
- ► Summary report available for filing into eTMF as record of detailed risk assessment process
- ► Document and plan authors can filter risks in RACT to identify risk mitigation actions to be included in their documents
- ► Detailed risk assessment using RACT may be repeated, using version 1 as basis, if significant protocol or study design changes

"Xcellerate RACT allows my study team to proactively plan for successful study delivery by ensuring that all risks are considered, documented and mitigated. Instead of 'putting out fires,' we execute study plans with control and confidence."

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

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