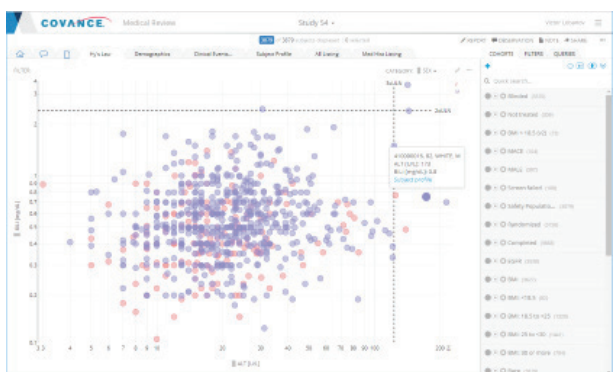# XCELLERATE
# Medical Review

Improve the ease, quality and efficiency of the medical review process

## Overview

Xcellerate® Medical Review allows physicians and clinical scientists to assess clinical issues, safety profiles, protocol deviations, patient eligibility, treatment discontinuation and other data trends suggesting any potential degradation of the trial's integrity or concerns for patient safety.

The Xcellerate Medical Review application was developed in close partnership with our domain experts to meet clinical trial scientific and process requirements. Available as Software as a Service (SaaS), the application offers a number of unique capabilities that set it apart from other solutions employed in the industry.



## Unique Capabilities in Xcellerate Medical Review

▶ Clinically aware visualizations (Hy's Law plot, Subject Profiles, RECIST plot, Kaplan-Meier and others)

▶ Ability to tailor visualizations and create new visualizations with the point and click interface

▶ Comprehensive cohort management and filtering

▶ Advanced collaboration and reporting functions for sharing findings and generating structured reports

▶ Comprehensive support for process enablement with configurable navigation and reporting templates

▶ Integrated functionality to report issues and protocol deviations

▶ Daily or scheduled data updates, ability to identify new patient since last review

## Advanced Visualization Capabilities

Our approach for patient data review utilizes advanced, interactive data visualization capabilities, coupled with our innovative clinical data integration layer to improve the ease, quality and efficiency of the medical review process. Preconfigured, study-specific visualization enables systematic and quick survey of patient data, visualization of trends and outliers, exploration of aggregate data and context-aware drill-down to details. Provided data visualizations are tailored to clinical and safety needs and are designed for interactive and intuitive navigation. Reviewers can quickly focus on subgroups of importance or outliers, and with a few clicks create, highlight and compare arbitrary cohorts. Configurable, context-driven visual guides provide additional information pertinent to the review objectives and facilitate one-click drill-down to related listings, longitudinal views and patient profiles.

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## Records and Communicates Notable Observations

Special attention is given to reporting patient data effectively. Our subject profile visualization allows at-a-glance review of all patients' adverse events, concomitant medications, abnormal lab results and any other important data such as study treatment administrations. The application allows users to record and communicate notable observations with screenshots and live data links. The data and user activity tracking feature enables quick identification of newly enrolled patients or newly reported data of interest since the last data review as well as personalization of visualizations, settings and notes providing an unparalleled user experience.

## Facilitates a Consistent and Repeatable Process

The template-driven reporting feature in Xcellerate Medical Review facilitates a consistent and repeatable review process by systematically guiding the medical reviewer through the preconfigured visualizations with prompts for required analysis steps and annotations. At the end of the review process, which can be interrupted and continued as needed, a medical review report containing tables, listings and figures is generated and saved as a Microsoft Word document.

Comprehensive data review and reporting capabilities enable timely identification, escalation and remediation of findings that increase the robustness and quality of clinical trial execution, improve the reliability of investigational data, safeguard subject safety and ensure adherence to good clinical practice and ethical standards.

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

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