

Clinical Case: Enhancing medical monitoring with visualization and analytics

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Monitoring ongoing clinical trials is a crucial activity for sponsors mandated by the FDA. Some of the important goals are the early detection of safety issues, assurance of proper trial conduct at remote sites, and tracking efficiency and cost. Generating a comprehensive picture of the current state of a trial involves integrating a variety of data sources, including case report forms, laboratory results from contract labs, and safety reports. Since the volume of data is large and is updated repeatedly during the trial, tools to assist in quickly and thoroughly interrogating the data are greatly needed. Of particular importance is the ability to see both aggregate views containing multiple patients as well as the capacity to drill down to individual patients' data points. Here, we present Clinical Case, a tool that has been developed within the Janssen organization and is used for this purpose. Clinical Case provides the ability to quickly integrate SDTM datasets, define both standard and ad hoc data views, and provide regular data updates. Both standard and user-configured views can be persisted, which can be composed of a variety of interactive graphics, including typical visualizations, such as box plots, scatter plots, line charts, tree maps, heat maps, etc., as well as visualizations specifically designed for clinical data, such as the Hy's Law plot, patient timelines plot, and integrated subject listings. The user can define subsets of patients for filtering and highlighting data and use these to compare data across multiple domains. Integrated into the system is the ability to manually annotate patients and data, as well as communicate with trial administrators.