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BSRIA Rules of Thumb.pdf. There is a limit of five examples per category on the GS838003 and GS838002 standards.Compilation of options available for drug safety monitoring in clinical trials. Clinical trials involving human subjects usually involve a risk of adverse events. Although the risk of adverse events during the conduct of clinical trials is commonly accepted and reviewed in the literature, the results of a number of studies have questioned the reliability of currently available risk assessments. Therefore, the Food and Drug Administration (FDA) has implemented a clinical trial monitoring program as part of its Clinical Trial Reporting Program to provide a means to collect and analyze data from clinical trials to determine adverse event risk, in order to facilitate improved medical product safety and quality. This manuscript reviews the current regulations regarding safety monitoring of clinical trials, presents an overview of options available to clinical trial sponsors, and summarizes available software tools to support investigators in conducting a systematic review of the literature and to collect adverse event data. settings settings background #1a1614 caret #FFFFFF foreground #FFFFFF lineHighlight #1f1f1f selection #bbbbbb 2d92ce491b