

Approaches to Signal Detection in Early Clinical Development

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Rare but severe adverse events are often discovered very late in the development process, sometimes only after a drug enters the market. It is therefore desirable to discover potential safety signals much earlier in the drug development process to take appropriate decisions. The focus of this presentation is on patterns of laboratory data, specifically those related to the liver.

Several numerical and graphical approaches to signal detection that can be applied in early stages of clinical development will be presented and discussed. We advocate a multivariate approach for analysis and stress the importance of graphical methods. It is also shown how multivariate reference ranges can be established and used in the analysis of data from actual clinical studies. The methodology is illustrated with real data.