Use of Data Pooling in Drug Risk Assessment at US FDA - A Clinical Perspective

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Most clinical trialsAdesigned to support efficacy, often have insufficient sample size to provide a reliable estimate to a rare safety event. Therefore data pooling technique is often employed to overcome such a problem.
Based on prior drug risk assessment working experience at US FDA, and by using publicly available data, the presenter attempts to discuss, from a clinical perspective, some key issues associated with the inappropriate use of data pooling technique in drug risk assessment. These issues include: lack of appropriate time adjustment, possible case ascertainment bias, and clinical heterogeneity. The issues are highlighted in US FDA's Guidance on Pre-marketing Drug Risk Assessment.

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