

Motivation for Fraud

- Obtain a desired result, e.g. 'statistical significance'
- Monetary gain, enhancement of prestige
- Compensate for laziness, sloppiness in data collection
- Include subjects who would otherwise be excluded

Data Items in Clinical Trials Prone to Fraud

- Eligibility criteria
- Repeated measurements
- Adverse events
- Compliance
- Subject diaries

Questions for Consideration

1. How was fraud detected?
2. Why was fraud committed?
3. What have been the consequences of fraud?
4. Statistically, how do we handle data when some data are suspected or confirmed as fraudulent?
5. Can we use statistical methods to detect or confirm suspected instances of fraud?
6. What measures, if any, can we take to prevent future episodes of fraud?