



RISK-BASED MONITORING AND FRAUD DETECTION IN CLINICAL TRIALS USING JMP AND SAS

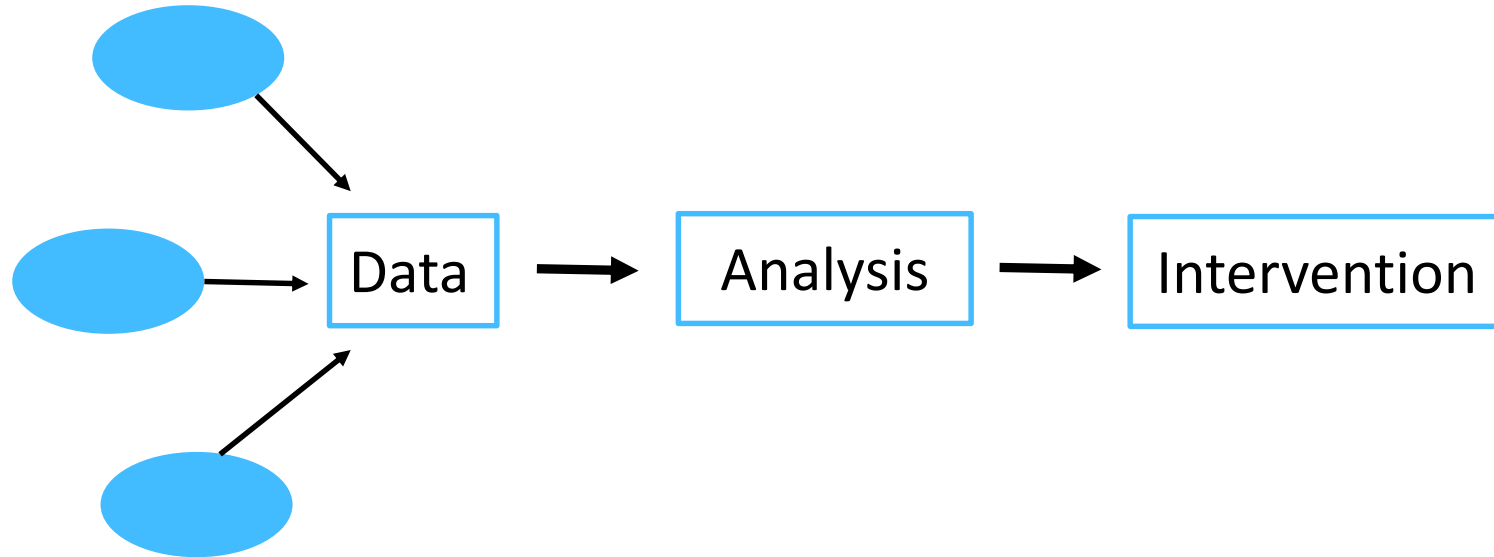


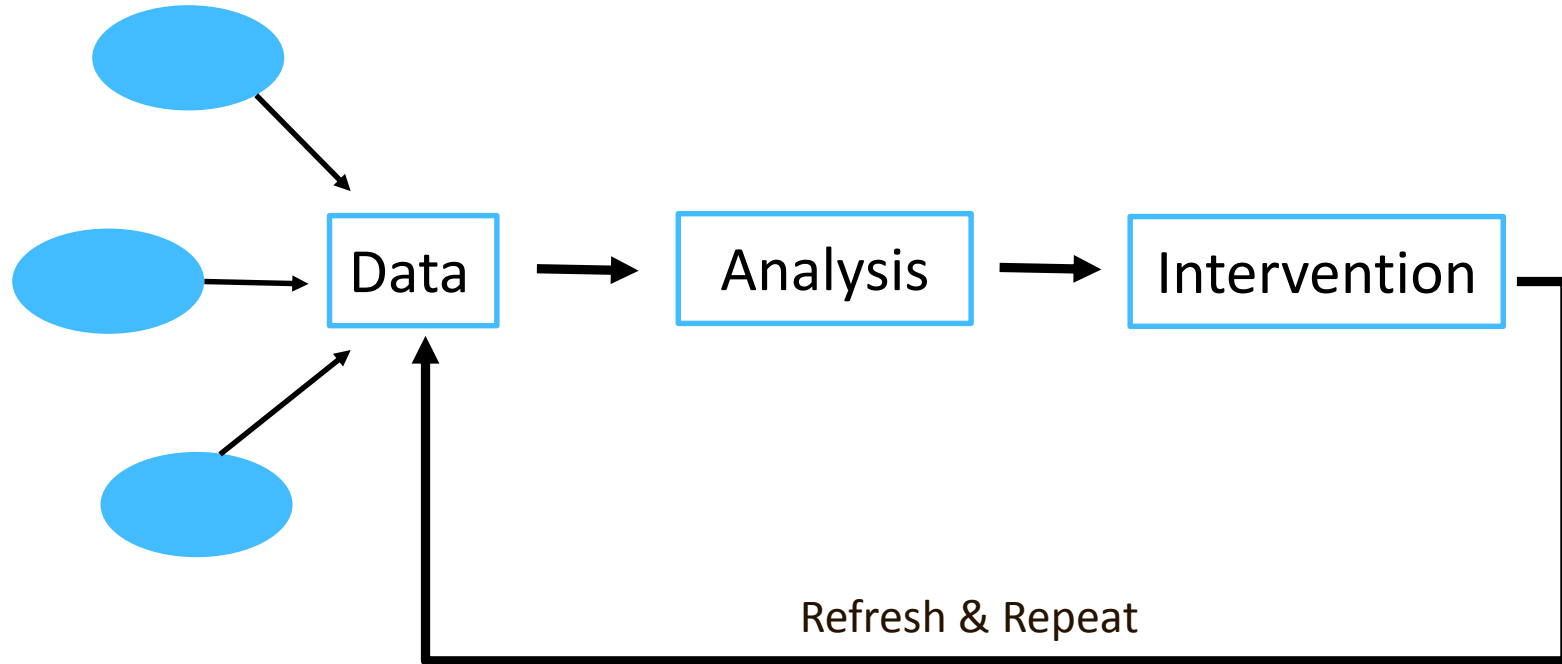
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- Clinical trials are **expensive**
- If study costs continue to rise at the current pace, clinical trials to establish efficacy and tolerability will become impossible to conduct [1]
 - Making drugs unavailable for areas of unmet need
 - Stifling innovation in established treatment areas
 - Placing an extreme price burden on consumers and health care systems

- Estimated that up to one-third of trial costs are due to current monitoring practices, including 100% SDV [2,3]
- Human review is only 85% accurate [3]
- SDV generated 7.8% and 2.4% of overall queries in all and critical data, respectively [4]
- 95% of data findings were or could have been identified from database [5]
- 100% SDV not required or expected by the FDA [6]
- Limited in its ability to provide insight for data trends across time, patients, and clinical sites

- Risk-based monitoring (RBM) makes use of central computerized review of clinical trial data and site metrics
- Determine if and when clinical sites should receive more extensive quality review or intervention
- Good Clinical Practice (GCP) is a cross-functional activity
 - Protect the well-being of study participants
 - Maintain a high level of data quality to ensure the validity and integrity of the final analysis results





- JMP Clinical
 - Combination product of JMP and SAS
 - Identify, review and report on safety and quality issues in clinical trials
 - CDISC
- Relevant features
 - Risk-Based Monitoring platform using TransCelerate recommendations [4]
 - Suite of statistical and graphical tools to detect quality, misconduct, fraud [7-9]

RBM USING JMP AND SAS REFERENCES

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