Aims/objectives
Source data verification (SDV) is the process of verifying the data acquired when trial participants visit an investigational site during the clinical trial. Recent years have seen considerable interest in approaches that focus on reducing the amount of work required during an on-site monitoring visit, while maintaining the optimum safety for participants and quality for the trial. This study used historical data and simulation methodology to understand the risks and benefits of reduced SDV scenarios.

Method
Data from 30 studies completed in the last five years were acquired and simulations (with at least 200 iterations) were run for four approaches as defined by Tantsyura et al.:1

1. Random SDV approach – Screening and baseline visits are randomly monitored at 20%. Based on the quality assessment from these results, remaining visits are monitored at 20% if the quality is good and 100% if the quality is poor.

2. Declining SDV approach – Screening and baseline visits are randomly monitored at 20%. Based on the error rate from these results, remaining visits are monitored at 20% if the quality is good and 100% if the quality is poor.

3. Three-tiered approach – Data forms are classified into three tiers, with Tier 1 having the most importance. Tier 1 forms are monitored at 100%, Tier 2 forms at 20% and Tier 3 forms not at all.

4. Mixed approach – Data forms are classified as critical or non-critical. During initial visits, all forms are monitored at 100%. In subsequent visits, critical forms are monitored at 100% and non-critical forms not at all.

Errors found in the reduced SDV approaches were compared with the known errors. Cost savings were analyzed in terms of the reduction in the number of person-hours required to do work. Quality impact was determined by the reduction in known errors that were found.

Results
Figures 1 – 4 show results for the four approaches. The ideal outcome is for a given graph to show “Savings on workload” to be high while both “Reduction on critical” and “Reduction on all” are low. Each of the first three approaches was found unfavorable in either quality or cost impact, with the mixed approach being ideal.

Conclusion
Data from previous trials can be used to analyze various reduced SDV scenarios. Clinical trials can be run more efficiently and cost-effectively by reducing the amount of SDV required. The mixed approach is the most promising scenario for an acceptable reduction of SDV.

References