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treatment. Sample size is a crucial component of any clinical trial. A trial with a small number of research participants is more prone to variability and carries a considerable risk of failing to demonstrate the effectiveness of a given intervention when one really is present. This may occur in phase I (safety and pharmacologic profiles), II (pilot efficacy evaluation), and III (extensive assessment of safety and efficacy) trials. Although phase I and II studies may have smaller sample sizes, they usually have adequate statistical power, which is the committee's definition of a large trial. Sometimes a trial with eight participants may have adequate statistical power, statistical power being the probability of rejecting the null hypothesis when the hypothesis is false. Small Clinical Trials assesses the current methodologies and the appropriate situations for the conduct of clinical trials with small sample sizes. This report assesses the published literature on various strategies such as (1) meta-analysis to combine disparate information from several studies including Bayesian techniques as in the confidence profile method and (2) other alternatives such as assessing therapeutic results in a single treated population (e.g., astronauts) by sequentially measuring whether the intervention is falling above or below a preestablished probability outcome range and meeting predesigned specifications as opposed to incremental improvement.

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costs of producing federal statistics. The panel's first report described federal statistical agencies' current paradigm, which relies heavily on sample surveys for producing national statistics, and challenges agencies are facing; the legal frameworks and mechanisms for protecting the privacy and confidentiality of statistical data and for providing researchers access to data, and challenges to those frameworks and mechanisms; and statistical agencies access to alternative sources of data. The panel recommended a new approach for federal statistical programs that would combine diverse data sources from government and private sector sources and the creation of a new entity that would provide the foundational elements needed for this new approach, including legal authority to access data and protect privacy. This second of the panel's two reports builds on the analysis, conclusions, and recommendations in the first one. This report assesses alternative methods for implementing a new approach that would combine diverse data sources from government and private sector sources, including describing statistical models for combining data from multiple sources; examining statistical and computer science approaches that foster privacy protections; evaluating frameworks for assessing the quality and utility of alternative data sources; and various models for implementing the recommended new entity. Together, the two reports offer ideas and recommendations to help federal statistical agencies examine and evaluate data from alternative sources and then combine them as appropriate to provide the country with more timely, actionable, and useful information for policy makers, businesses, and individuals.

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