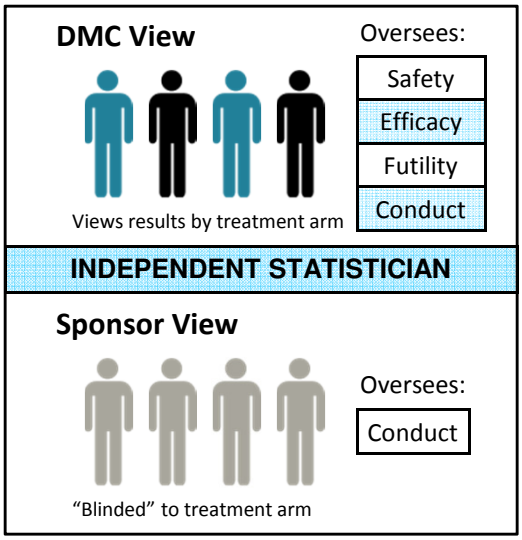
STATISTICAL SIGNIFICANCE

Any drug, device, or vaccine legally sold in the United States must go through a rigorous process of approval and oversight. Statisticians are vital at all stages to get safe, effective drugs and devices to market quickly and to monitor them thereafter.

Data Monitoring Committees Improve Clinical Trials

MAINTAINING ETHICAL AND SCIENTIFIC INTEGRITY:

Clinical trials last for many years. In that time, many things can go wrong. An experimental treatment may prove dangerous and harm patients, or it may be so effective that patients who are not in the trial should have access right away. The study may be poorly run, or have flaws that mean we will never find out if the new treatment is safe and effective no matter how long the study goes on. Someone needs to keep an eye on the study to avoid hurting patients in the trial, or prolonging the suffering of patients outside the trial who would benefit from the new treatment, or just wasting a lot of time and money. The sponsor is not allowed to peek at the data, but an independent group could.



Clinical Trials

Clinical trials are used to test new treatments against a placebo (sugar pill) or existing treatment. Patients are assigned to a treatment arm randomly, like flipping a coin. Clinical trials are often organized and paid for ("sponsored") by a pharmaceutical company or a government agency. To make sure experimental patients and placebo patients are treated exactly the same way, patients participating in the clinical trial, the doctors that provide care, and the study sponsor are not told which treatment patients receive ("blinding"). The sponsor must not review trial results until the study is complete.

ROLE OF THE DMC:

A Data Monitoring Committee (DMC) is a group of expert doctors and statisticians who are independent of the study sponsor. They are not allowed to profit financially or otherwise from the outcome of the clinical trial, and they are not involved in the operation of the trial. They are experts in the disease area and statistical methods. The DMC reviews data while the study is ongoing. They see safety and effectiveness results by treatment arm and decide if the study should continue. The study should continue if it is safe for participating patients.

INTERMEDIARY BETWEEN DMC AND SPONSOR:

Another independent group can support the DMC. These statisticians are also unaffiliated with the sponsor and will not profit from the outcome of the trial. They receive treatment assignment data from one source, and safety and effectiveness data from the sponsor. They combine these data and provide the results to the DMC, preserving the sponsor's blind. DMC reports should be concise, clear, and accurate to allow for the best possible decision-making.

More information documenting the contributions of statistics to our country and society is available from the American Statistical Association. Visit www.amstat.org/outreach/statsig.cfm. The American Statistical Association is the foremost professional society of statisticians, representing 18,000 scientists in industry, government, and academia: www.amstat.org.