When experience matters for a Data monitoring Committee (DMC) and Independent Statistical Group

Since the FDA established guidelines for the use of independent DMCs, a wide array of organizations have entered this complex area where clinical trials and statistics intersect.

Our significant and focused experience paired with our top-notch statistical know-how makes deft at navigating complex and unexpected challenges that arise during interim monitoring. The added value of our seasoned DMC reporting group is particularly advantageous in the following situations:

- Studies in which there is an increased risk of a safety concern (e.g., an invasive procedure)
- Studies where there is prior information suggesting the possibility of toxicity with the study treatment
- Studies being performed in a potentially fragile population, such as children, pregnant women, the elderly, etc.
- Studies being performed in a population at elevated risk of death or other serious outcomes
- Studies with high enrollment or long duration across multiple sites
- Studies including an interim analysis for futility or efficacy

When experience matters for a Endpoint Adjudication Committee (EAC)

There is a growing trend observed within the industry to adjudicate important endpoints, outcome events, and even inclusion/exclusion criteria that determines whether patients are eligible for a study. Adjudication continues to expand beyond traditional cardiac adjudication into a wide variety of other therapeutic areas and medical device studies.

The independent adjudication process is used to make sure that reliable, consistent definitions are provided to regulators and the scientific community, which is especially thought to be helpful in the following situations:

- Studies with complex or subjective endpoints
- Studies that are unable to be blinded
- Studies with high enrollment or long duration
- Studies that deal with global or cultural differences across sites
- Studies where the endpoint of interest differs from the therapeutic specialty of the investigator