

## RESTROSPECTIVE ENDPOINT ADJUDICATION COMMITTEE

# Supporting NDA Submission for a Drug Targeting Menopausal Vasomotor Symptoms

## THE CHALLENGE

### Aggressive Timelines



A few months prior to the sponsor's NDA submission, the sponsor received regulatory guidance to adjudicate endpoints in order to satisfy regulatory requirements. The sponsor requested WCG's assistance to identify a strategic solution to expanding the adjudication to include all cardiovascular, neurological and thrombotic events of interest while maintaining the original submission timelines, thus leaving less than 4 months to adjudicate all events.

## OUR SOLUTION

### Rapid Start-up



WCG was able to rapidly devise a rigorous adjudication plan which included both a triage system that allowed for swift processing of low probability cases, coupled with a full endpoint adjudication process for those cases which were selected by the committees for full adjudication. Both the triage process and adjudication featured process control measurements to demonstrate reliability.

Operationally, WCG established two separate committees which were contracted, trained, and voting within two weeks.reliability.

## PROJECT SCOPE

**400** Cases  
Adjudicated

- **9,000** Subjects
- **2** Committees
- **6** EAC Members
- **4** Panel Meetings