Global Osteoarthritis Program Facing FDA Concerns

THE CHALLENGE

A Phase III Global Osteoarthritis Program in over 30 countries needed an intensive program-wide oversight with a thorough understanding of the regulatory concerns surrounding this drug program.

THE RESULTS

The efficiencies that WCG was able to implement across the program through our Endpoint Adjudication Committee (EAC) and Data Monitoring Committee (DMC) processes allowed the sponsor to achieve **over $1 million in cost savings.**

PROJECT SCOPE

Size:

5	Trial Protocols
3	Committess (2 EACs, 1 DMC)
2,586	Cases Adjudicated
7	DMC Members
164	TFLs

Program Timelines:

START-UP:

6 months

PROGRAM DURATION:

24 months

CLOSE-OUT:

3 months

OUR SOLUTION

WCG established EAC and DMC processes that would very closely monitor the ongoing data, with clear safety alert guidelines and stopping rules, to ensure that patient safety was being properly monitored.

EAC PROCESSES

The EAC members were split into a neurological committee and a cardiovascular committee, which allowed WCG to create two separate charters based on the type of events expected for a more efficient adjudication by the appropriate experts.

DMC PROCESSES

WCG setup the DMC process to include program-wide displays that would allow for summary safety data to be tracked across the program, with additional study-specific TFLs as needed.

As WCG was managing both the EACs and the DMC, we were able to plan the EAC decision data transfers so that the DMC would also receive the latest adjudication data in time for their monthly meetings.