

# See How WCG Helped a Mid-tier Biopharma Respond to an Urgent FDA Request, and Adjudicate 400 Endpoints in Just a Few Short Weeks

## THE OVERVIEW

WCG received notification of an urgent FDA request that required rapid adjudication results. The project required urgent review of available materials, convening a panel of Drug Induced Liver Injury (DILI) experts, creating a DILI adjudication database and writing a DILI Charter.

## THE RESULTS

A

In just a few short weeks, we were able to adjudicate **400 endpoints**

B

Critical adjudication start up deliverables achieved within **11 days**

*It gives me great pleasure to send this email acknowledging the whole WCG team for such a wonderful job well done on the recent urgent FDA DILI project. It has been and I am sure will continue to be such a great pleasure to work with WCG. The team is so professional, knowledgeable and kind. We value WCG's advice and can trust them to keep us on course when we start to drift. We had an extremely tight timeline and WCG delivered!*

—VP, MID-TIER BIOTECH

## THE CHALLENGE

1 Find and contract a committee of qualified adjudicators (DILI EXPERTS)

2 Build a new AIMS Adjudication database

3 Write a charter and process guide that would cover 3 protocols in the following unique situations:

- a) ongoing study
- b) locked retrospective studies
- c) a group of subjects that were already adjudicated by previous experts (under no charter), with the ability to incorporate those results in the new process

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## OUR SOLUTION

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Fully contracted a committee of DILI experts through our member network



Held a kick-off meeting with all 5 experts and the Sponsor



Wrote a Charter and process guideline



Developed a complex grouping strategy for events



Built a new adjudication system database



Guided client to avoid continuation of costly mistakes