

Rapid Safety Adjudication to Secure Timely FDA Submission

BACKGROUND

While adjudication committee review is not always required, in some instances, the FDA directly requests it prior to moving forward. Without expert adjudication, sponsors risk encountering delays or quality issues and missing first-to-market advantage. This case study explores WCG's pivotal role in swiftly adjudicating a rare safety event for a top five pharmaceutical company's Phase III study investigating an innovative therapy for a rare adverse event.

With WCG's pivotal support, this sponsor moved toward FDA submission in record time. After receiving feedback from the FDA, a rare safety event required adjudication before an FDA submission. The adjudication was part of the final barrier to submission, prompted by agency feedback. WCG was engaged to deliver a rapid adjudication solution under tight timelines.

CHALLENGES

The sponsor faced an exceptionally compressed timeline, driven by internal and regulatory pressure. To meet FDA requirements for independent adjudication of safety events, WCG provided the sponsor with a finalized adjudication charter within just two and a half

weeks. Moreover, WCG's committee was formed and ready to adjudicate within four weeks, exceeding the client's expected eight-week start-up timeline. Additionally, the sponsor's internal governance processes introduced frequent changes and escalations, including shifting deadlines and urgent requests for expedited results. Success was defined by meeting or exceeding the FDA's requested timeline – specifically, delivering a final draft charter before the targeted date without sacrificing quality or scientific rigor.



STRATEGIC SOLUTIONS

WCG's collaboration with the sponsor began with an introductory meeting focused on understanding the study goals and mapping out a tailored approach for the trial. WCG's scientific and regulatory team, including project leaders, data managers, and clinical specialists, worked seamlessly with the client to define scope, understand deliverables, and assign expert committee members, all while expediting every step of the project journey.

Faced with extraordinarily tight timelines, WCG didn't just meet expectations, we exceeded them. The WCG team leveraged proven processes and deep relationships to accelerate every milestone. By utilizing our templated charter documents – which both the sponsor and WCG collaborated to refine – and our strong rapport with committee members, WCG compressed its standard delivery times. This led to WCG executing a streamlined review and voting process at an industry-setting pace. Through relentless collaboration and agility, WCG demonstrated our commitment to going above and beyond, ensuring we surpassed the sponsor's urgent objectives.

Key elements of the solution included:

- » **Charter Development:** WCG deployed a proven adjudication charter template and customized it by gathering input from the client's clinical leads. The draft charter was delivered within one week, significantly ahead of the standard two-week turnaround, enabling an accelerated start-up timeline.
- » **Committee Formation:** Member contracting and onboarding were driven in parallel with start-up activities. WCG's adjudication committee consisted of four members to ensure flexibility for rapid panel meetings and detailed voting. The onboarding of all members was completed within four weeks, accelerating the start-up timeline and exceeding client expectations of an already expedited eight weeks for the start-up process.
- » **Transparency & Proactive Communication:** WCG facilitated transparent updates between the members and the sponsor. Through open discussion and the provision of clarifying high-level slides, panel members demonstrated a deep understanding of the safety event and voting decisions. This approach enabled clear decisions, ultimately reassuring the client of WCG's commitment to communication and high-quality adjudication.
- » **White-Glove Service:** The WCG team was highly responsive, hosting frequent meetings, providing ad hoc support, and facilitating real-time alignment between clinical specialists, data management, project management, and sponsor stakeholders.
- » **AIMS Technology Enablement:** WCG's Adjudication Information Management System (AIMS) empowered committee members to review cases, vote, and consolidate detailed notes enhancing clarity and transparency. This technology ensured sponsors received comprehensive feedback and supported the accelerated timeline with seamless collaboration.

RESULTS & IMPACT

WCG's agile approach and expertise enabled the client to meet the tight regulatory timeline:

5 **days** after the initial sponsor meeting, the draft adjudication charter was delivered to allow for expedited discussions ahead of submission – one half of the standard turnaround time for such pivotal documentation.

4 **contracted committee members** were operational within four weeks to deliver timely reviews. They adjudicated all available events swiftly, while maintaining quality and detailed notes.

21 **safety cases** were rapidly adjudicated, ensuring the client could proceed with its FDA submission as planned and with confidence. With WCG's comprehensive rationale documentation and realignment meetings, the sponsor gained reassurance in the committee's clinical reasoning.

5 **days** following the initial decision transfer, with subsequent transfers perfectly synchronized alongside panel meetings and voting. Despite evolving requests and moving deadlines, all key decisions and data transfers were delivered in advance of the outlined deadlines to meet internal analysis needs.

“Thank you so much for assembling the committee at record speed. We all really appreciate the hard work WCG has put into supporting us on the charter development and for how responsive you've been along the way!”

Senior Director,
Clinical Development Scientist

CONCLUSION

WCG is committed to delivering customized, client-centric, and technology-enabled solutions which accelerate clinical research at every step. Through transparent communication, integrity, and collaboration, WCG empowered this sponsor to meet regulatory demands and advance patient safety—fulfilling our mission to improve lives by accelerating research, together.