

Clinical Adjudication in Obesity Trials



Independent clinical adjudication of efficacy and safety endpoints in obesity trials is essential to fully understand the potential benefits and risks of GLP-1 agonists and other treatments beyond the loss of weight. A trusted clinical adjudication partner can be critical in ensuring clinical trial data is reliable and demonstrates the compound's full therapeutic potential while meeting trial timelines with confidence.

Perceptive's clinical adjudication team has a combined 60 years of experience managing and supporting clinical event adjudication services, including extensive work in several obesity trials. Through this experience, we have established robust, regulatory-compliant, efficient processes to mitigate the challenges associated with adjudicating efficacy and safety endpoints in obesity and weight loss trials.

Challenges:

Some of the challenges commonly experienced supporting clinical event adjudication in obesity trials include the following:

- ▶ Events requiring adjudication span multiple therapeutic areas in a single trial (i.e. cardiology, neurology, gastroenterology, nephrology, endocrinology, hepatology)
- ▶ Large variance in the number of events requiring adjudication across trials (i.e. < 50 events, >10,000 events)
- ▶ Event-driven trials requiring rapid turn-around times
- ▶ Coordination of global committees of various sizes across multiple time zones

Extensive Network of Key Opinion Leaders

Perceptive's clinical adjudication team has established connections with over 250 global experts and key opinion leaders across all therapeutic areas to serve as clinical adjudication committee members. These existing relationships and collaborations allow us to efficiently compile committees to adjudicate the wide variety of event types associated with efficacy and safety endpoints in obesity trials. Based upon individual trial needs, we can establish one large committee, encompassing several therapeutic areas, or separate smaller committees for each therapeutic area. We have the flexibility to contract with independent committee members or collaborate with committees from academic centers.



250+
Global Experts
& Key Opinion
Leaders

Operational Support

Perceptive's clinical adjudication operational model includes clinical adjudication specific SOPs, templates, manuals, and processes to ensure accurate, robust, and timely initiation of clinical event adjudication services for obesity trials. Comprehensive, experienced management and coordination of event adjudication processes from trial start-up to close-out are essential to preventing backlogs/delays, and meeting/exceeding trial timelines. Utilization of a customized electronic adjudication system provides transparency of clinical adjudication processes, while also providing efficient, flexible adjudication paradigms necessary for the various event types, such as parallel independent adjudication,

third reviewer discordance resolution, and scheduled virtual committee meetings. On demand adjudication results provides the client access to real time data necessary for event-driven trials.

Perceptive's clinical adjudication team includes experienced clinical reviewers to facilitate the rapid collection of event-specific source data, ensuring clinical relevance to reported event prior to submission to committee. Given that obesity trials may include five more event types requiring adjudication, the clinical reviewer role is essential to decrease event processing turnaround times and to obtain relevant, quality source data.

Meet the Experts

With decades of experience and a proven track record, Perceptive's clinical adjudication team provides the flexibility and scalability client's need for efficient, high-quality independent clinical event adjudication committees to support their GLP-1 agonist and other obesity treatment trials.



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How can we help?

To learn more about partnering with Perceptive for clinical adjudication, contact:

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