WHITEPAPER

Is That Heart Attack Really an Adverse Event?

Obesity Trials Require Rigorous Independent Adjudication

wcg™

Without the right independent expertise, sponsors launching obesity trials risk misidentifying adverse events (AE) and creating conflicts of interest. Independent experts can provide a more consistent evaluation of AEs, safety, etc. This helps ensure rigorous regulatory submission and eliminates any perception of conflict of interest.

THE PROBLEM

Sponsors with injectable diabetes therapies are now moving ahead to study how these same therapeutics work in obesity, and they're starting Phase II and III trials. Competition is fierce, so they are moving quickly.

Even with proof-of-concept established, many questions about safety and efficacy remain. That's why these trials require both data monitoring committees and endpoint adjudication committees. The latter is particularly important for cardiovascular endpoints, given the prevalence of metabolic syndrome in those with obesity.

How do you determine whether a cardiovascular event is secondary to an at-risk population or directly related to the therapeutic? What are the comorbidities? Are environmental issues involved?

If a trial participant with diabetes and/or obesity has a heart attack, it is crucial that attribution of its cause be done properly and consistently.

Differences in investigator training, geography and practice situations may cause variation in attribution. Sponsors need experts who can provide rigor and consistency, experts who understand the cardiovascular implications of obesity and diabetes studies. It comes down to

enhancing the credibility of your endpoints. Endpoint adjudication committees, made up of outside experts, can carefully assess each adverse event to determine whether it meets a protocol's AE criteria.

PRACTICAL ASPECTS OF INDEPENDENT REVIEW

Some sponsors try to handle scientific review, including endpoint adjudication, in-house; they fail to realize how much work is required to create these committees–building the technology, creating the charter, etc. Others, realizing they can't manage it in-house, delegate it to a CRO.

Either approach is risky. Both the sponsor and the CRO are vested in the trial's success, so neither can offer a purely independent perspective: There is an inherent conflict between taking actions to do what is right for a trial and taking actions that will advance the trial to the next milestone. Eliminating that perception of bias adds credibility in the eyes of regulators. They expect safety and efficacy endpoints to undergo centralized adjudication by independent medical experts. Sponsors must keep an arms-length relationship with committees and committee members; this requires a third-party company to manage the committees.

Selecting that partner is one of the most critical decisions a sponsor can make.

THE SOLUTION: EXPERTS, EXPERTISE, AND EFFICIENCY

Obesity drug trials would substantially benefit from data monitoring and endpoint adjudication committees. If you can contract with one organization, you put less burden on your sites and your clinical development and operations teams. You increase efficiency.

WCG has deep expertise in both.

We give sponsors access to the best talent in the business. WCG has been involved in obesity drug trials and other trials with cardiovascular endpoints for decades and has adjudicated tens of thousands of cardiovascular endpoints.

WCG's global network of more than 1,200 medical, safety, and statistical experts across therapeutic areas is unmatched. Our experts are, at a minimum, regional thought leaders and many are internationally recognized. Having extensive experience with DMCs, EACs, and IRBs means we can look at a therapeutic area such as obesity and assemble a committee tailored to that condition. We're also able to offer quality statistical support to enhance accuracy and inform decision making.

Working with WCG helps improve endpoint precision; rigorous procedures minimize errors due to false negatives or false positives.

That said, A great committee needs great management. WCG brings clients the largest committee-dedicated staff in the industry, and we've been doing it longer than anyone else.

Our team conducts all meetings in a structured, cost-effective manner with regulatory-appropriate communications and documentation, and we work closely with clients to prepare data for presentation in a way that's easy to evaluate.

By leveraging our global network, internal expertise, and proprietary technology, WCG provides the strategic guidance sponsors need today and for future studies.

PLANNING FOR THE FUTURE

Scientific review isn't a one-size-fits-all endeavor. The right partner will be flexible, able to work on your current trial and across your entire book of business, regardless of therapeutic area.

WCG understands the nuances among therapeutic areas and has the appropriate experts ready to call. We facilitate effective expert review of clinical trials, through data monitoring, endpoint adjudication and safety assessment committees, other signal/biometric analytics services, and, of course, IRBs.

WCG has the people, processes, and technology to ensure the scientific review is done right. We're the only company that can make such a claim. Find out more below.

Learn More About WCG's EACs and DMCs

Our experience, quality, technology, and industry-leading global network will provide you with the customized approach and regulatory edge your study needs.

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