Clinical Trial Committee News

Your Expert Source for Insights and Best Practices for Expert Committees | ***Spring 2016***

The Expanding Use of Clinical Trial Committees

As a leading specialty provider of Independent Expert Committees, with its own global network of more than 500 medical experts, ACI Clinical maintains an active role in thought leadership efforts shaping standards and best practices for this increasingly used approach to oversee trial data. This newsletter shares the latest insights, trends and tips for sponsors looking to improve the accuracy of study outcomes through the use of expert committees.

Regulatory Spotlight

Medical Device Adjudication

An upcoming Device Adjudication Think Tank on March 11, 2016, at the ACC Heart House in Washington, D.C., will provide an opportunity to explore the role of endpoint adjudication for medical device trials. Device trials face some unique challenges which an Endpoint Adjudication Committee may help to address: 1) inability to blind patient and/or practitioner; 2) "learning curve" effect for practitioners using new devices; 3) operator variability; and 4) overall device

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Upcoming Events

March 11, 2016, Washington, DC: Medical Device Adjudication Think Tank – Presented by The Cardiac Safety Research Consortium (CSRC) and Medical Device Epidemiological Network (MDEpiNet)

May 4-5, 2016, Philadelphia, PA: 2nd Annual Endpoint Adjudication Conference – Presented by CBI

For additional information on Expert Committees

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Regulatory Spotlight

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trial design and selection of endpoints.

ACI Clinical will participate in the think tank alongside numerous high-level FDA, industry, and academic thought leaders.

Draft FDA Guidance on Safety Assessment for IND Safety Reporting

The public comment period has come to a close for a draft Drug Safety Guidance for Industry released on December 16, 2015. Draft guidance recommendations included the development of a Safety Surveillance Plan, a new Safety Assessment Committee role to oversee, evaluate, and report on patient safety data, and plans and procedures for unblinding of safety data.

CTTI DMC Improvement Project

With the FDA Guidance on Data Monitoring Committees expiring, the Clinical Trials Transformation Initiative (CTTI) is conducting a DMC Improvement Project. ACI Clinical and other participants in the public-private partnership gathered in July 2015 for a two-day DMC Expert Meeting to share project results and develop recommendations for DMC usage, DMC member training, and best practices.

CTTI DMC Project Expert Meeting page:
http://www.ctti-clinicaltrials.org/what-we-do/projects/dmcs/meeting

Current Thinking and Rationale for Endpoint Adjudication

Endpoint Adjudication allows central, standardized assessment of complex endpoints which could otherwise introduce inconsistencies or bias to clinical trial data.

From global variations in standards of care to subjective interpretations of study data, Endpoint Adjudication forms a harmonized data set through review by an independent third party with the right clinical expertise for the endpoint(s) of interest.

While regulatory agencies provide some guidelines recommending when to use an

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Endpoint Adjudication

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adjudication committee in certain therapeutic areas, they do not guide how committees should be formed and operated. This introduces a growing need for industry-wide best practices that recommend the key structural components and methodologies that can ensure efficient and compliant committee activity.

In cooperation with the FDA, the Cardiac Safety Research Consortium (CSRC) (http://cardiac-safety.org/) led an Adjudication Think Tank in November 2013 to explore expert perspectives on ideal endpoint adjudication structure and operation. This process resulted in a set of industry-wide best practice recommendations for adjudication committees.

These adjudication committee recommendations are shared in an article, co-written by ACI Clinical President Dr. Jonathan Seltzer, in the February 2015 issue of *American Heart Journal*.

ACI Clinical has adopted these best practices into our adjudication service offerings in order to help sponsors stay aligned with current regulatory thinking.

CSRC Adjudication Best Practices paper:
http://dx.doi.org/10.1016/j.ahj.2014.11.003
Seltzer, J, Turner J, Geiger, M, et al, Centralized adjudication of cardiovascular end points in cardiovascular and noncardiovascular pharmacologic trials: A report from the Cardiac Safety Research Consortium. Am Heart J. 2015;169:197–204.

Significant Cost Savings with Program-Wide Committees

Many of our pharmaceutical clients, both large and small, are regularly faced with the challenge of conducting multiple clinical trials to study various aspects of a particular drug or device on the path to commercialization. For example, one clinical trial might assess the safety and efficacy of a single drug in a specific patient population, dosing regimen, or indication. At the same time, that product is likely to

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Cost Savings

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be investigated in alternate trials to be approved for other populations, regimens, or indications.

As the clinical development process advances study by study, it can be difficult for companies to take advantage of opportunities for meaningful and cost-saving designs across an entire drug program.

As an expert provider of independent committee services, ACI has gained a unique clinical and operational vantage point to see these missed connections ahead of time. We've found the potential for significant efficiencies and cost savings through a "program-wide" approach to expert committees.

Recently, one of our global pharmaceutical clients was able to achieve a savings of over $2 million through the design and use of a specialized Program-Wide Endpoint Adjudication Committee. This single committee was able to efficiently oversee adjudication of events across three clinical trials. While each trial had a unique protocol, process, and set of endpoints, the similarities related to the drug being tested and overall study timelines, were leveraged to create one committee capable of expertly adjudicating all three studies.

Program-wide committee benefits:

- Significant savings in overall time and cost (especially in committee start-up)
- Meeting, communication, and project management efficiencies
- Improved committee knowledge / awareness of overall product development
- Programming efficiencies

By using this program-wide approach, our clients have been able to avoid the expense and headache of having too many committees, while gaining the efficiencies of a simplified startup, maintenance, and closeout. We've found that a well-designed Program-Wide Committee solution can reduce startup and closeout expenses by 25 to 75 percent and overall committee costs by as much as 15 to 30 percent.