

Current Thinking and Rationale for Endpoint Adjudication

Addressing Growing Clinical Trial Complexity with Independent Endpoint Adjudication Committees

Endpoint Adjudication is an emerging support tool in the modern clinical trials environment. It 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, the Endpoint Adjudication process forms a harmonized data set which has been reviewed by an independent third party with the right clinical expertise for the endpoint(s) of interest.

Although regulatory agencies in Europe and the U.S. provide guidelines which recommend when to use an Endpoint Adjudication Committee, there is no formal, detailed information provided regarding how the committees should be formed and operated. This gray area introduces the need for standardization through adjudication committee best practices. By recommending key structural components and methods, these best practices ensure committee activity that is efficient and regulatory compliant.

A notable source of early best practice recommendations is the **Cardiac Safety Research Consortium (CSRC)**. In cooperation with the FDA, the CSRC engages stakeholders from industry, academia, and government to share data and expertise. Several recent CSRC Think Tanks have focused on exploring

expert perspectives on ideal endpoint adjudication structure and operation.

The results of a November 2013 FDA and CSRC Adjudication Think Tank were published in the February 2015 issue of *The American Heart Journal*, and share many adjudication committee best practices and recommendations for cardiovascular and non-cardiovascular trials.

RESOURCES

CSRC ADJUDICATION BEST PRACTICES PAPER:

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.**

<http://dx.doi.org/10.1016/j.ahj.2014.11.003>

WEBSITES:

The Cardiac Safety Research Consortium (CSRC)

<http://cardiac-safety.org/>

ACI Clinical

<http://www.aciclinical.com/>

THE ACI CLINICAL ENDPOINT ADJUDICATION SOLUTION

INDUSTRY-LEADING ENDPOINT ADJUDICATION COMMITTEE (EAC) MANAGEMENT

As an industry leader in EAC management, ACI brings clients the largest dedicated committee staff in the industry, a global network of qualified medical experts that can serve as members, and a proprietary technology that is designed specifically to support adjudication workflows. Our executive leadership remains deeply involved in private-public thought leadership efforts that focus on shaping endpoint adjudication best practices.

Supported by our purpose-built committee management software, AIMS™

Our proprietary AIMS™ technology is purpose-built for committee management. AIMS™ streamlines processes and diminishes administrative burden, allowing committee members to focus on providing their expert assessments. AIMS™ makes online data review and communication as seamless as possible for committee members, sponsors and other personnel spanning the globe.

The ACI team administers the system, managing all data and content to ensure appropriate review and a complete audit trail for all activity. With the power of AIMS™ and the support of our experienced project oversight, ACI makes committee member recruitment, training, invoicing, communication and overall committee management as straightforward, efficient and constructive as possible.

Specialized Adjudication Committee Solutions

- Standing Adjudication Committees
- Risk-based Adjudication
- Programmatic Adjudication
- Low case counts to global mega trials
- Efficient case packet assembly of multiple file types including Diacom image capabilities
- Flexible voting and decision form creation
- Automated distribution of cases to EAC Members
- Real-time reporting for rapid turnaround
- Clinician-friendly case packets
- 21 CFR Part 11 compliant

Endpoint Adjudication is thought to be helpful in studies with the following characteristics:

- Complex and/or subjective endpoints
- High enrollment or long duration
- Global or cultural differences across sites
- Endpoint of interest differs from the investigator's therapeutic specialty
- Study cannot be blinded

ACI Clinical
3 Bala Plaza West, Suite 402
251 St. Asaphs Road
Bala Cynwyd, PA 19004

www.aciclinical.com

+1-484-429-7200

