



# Expert Committees

## Independent Committees

Endpoint Adjudication Committees

Data Monitoring Committees

Safety Assessment Committees

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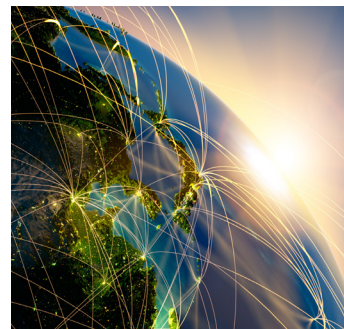
ACI Clinical was founded in 2001 as a niche specialty company within the clinical research industry. For more than a decade, we have focused on driving best practices in managing Independent Expert Committees by combining internal expertise with our strong academic relationships to deliver a fully integrated approach. ACI Clinical operates globally having supported more than 600 projects with more than 100 compounds for Pharma, biotech, academia, device, and CROs in nearly all therapeutic areas. Our proprietary technologies help to facilitate committee interactions and our global network of more than 500 medical, statistical and safety experts that can serve as committee members and advisors for clients in order to deliver high-value solutions that enhance trial integrity.



## Expert Committees for Clinical Trials

## Endpoint Adjudication Committees

As a leader in Endpoint Adjudication Committee (EAC) management, ACI brings clients the largest committee dedicated staff in the industry, a global network of qualified medical experts that can serve as committee members, and a proprietary technology designed for an efficient, user-friendly adjudication workflow. In addition, our executive leadership team remains deeply involved in public-private thought leadership efforts that focus on shaping adjudication best practices so that we consistently deliver top rated performance metrics and services to our clients.



## Data Monitoring Committees

For more than a decade, ACI has specialized in efficient design and delivery of Data Monitoring Committees (DMCs) that harmonize with FDA, EMA and ICH guidance. Our experienced project teams work closely with clients to identify and recruit the proper clinical and statistical experts, and to prepare data for presentation in an “easy-to-evaluate” clinician fashion. ACI Clinical's experienced project managers are specially trained to conduct all DMC meetings in a structured, cost effective manner with regulatory appropriate communications and documentation.



## Safety Assessment Committees

ACI provides full-service Safety Assessment Committee (SAC) management in accordance with the recommendations made in the FDA's December 2015 Draft Guidance for Industry. ACI supplements our client's in house safety procedures with an efficient methodology for conducting unblinded reviews of individual and aggregate safety events against pre-established event rates.



## Expert Management

ACI's full-service committee support includes the option of complete outsourcing on all member related activities, including access to our global expert network. Expert Management also includes:

- Fair market value and Sunshine payment reporting
- Identification and qualification of candidates
- Rate negotiation and contracting
- Invoice preparation and payment management throughout project

## Technology Enabled

ACI's committee services are designed to be highly efficient with industry leading performance metrics. We utilize proprietary advanced systems to enable the projects and ensure high-quality, regulatory-compliant deliverables.

- Proprietary AIMS® adjudication system
- Automated DMC workflow platform
- CDISC data standards for regulatory submissions

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