



Clinical adjudication services are a key element for any clinical trial consideration today.

Medpace's therapeutically-focused expertise in Clinical Safety combined with use of proprietary ClinTrak technology is the best choice for your next project requiring clinical adjudication.

With recent updates in global regulatory requirements, clinical trials requiring centralized, formal adjudication of clinical events or endpoints are becoming critical. Trials involving adjudication require effective communication and adjudication processes which are enhanced by an electronic system that offers real-time information on patient outcome data. Communication between Sponsors, clinical adjudication committee (CAC) members, Clinical Safety, Data Management, and Investigators on a singular system allows the CAC to review and rapidly arrive at the critical endpoint for study decisions.

Streamlining adjudications and communication not only allows all relevant patient data to flow quickly to all decision makers, but also keeps the trial timelines intact by managing endpoint target numbers.

Why Choose Medpace?

Medpace provides complete adjudication services, including organizing, coordinating, and managing all aspects of implementing a CAC. Experience includes selection, contracting, and management of the CAC, development of the Charter and decision rules, adjudication package compilation and processing, and training of project team members.

Because of the frequent overlap between safety events (SAEs) and events requiring adjudication, these services are provided by the Medpace Clinical Safety department which has resulted in more efficient and higher quality event processing. Medpace has managed the adjudication process for over 20 trials, a majority of those being global and in a wide variety of therapeutic areas.

Adjudication Services provided by Medpace Clinical Safety:

- In-house Medpace Medical Experts provide clinical support, team training, and practical experience in adjudication processing and regulatory requirements
 - Associates have healthcare related degrees (i.e. RNs, pharmacists, MDs) allowing for critical and clinical review of all CAC packages prior to provision to CAC
 - Global capabilities with offices in the US and Europe
 - Ability to detect unreported clinical events or SAEs; pre-identification of potential events to allow for more rapid turnaround of cases to CAC
 - Effective communications: one point of contact for clinical events and SAEs for both Sponsors and Investigative sites
 - Ability to operate under many different models and levels of involvement in adjudication services (with or without pharmacovigilance services)
 - 12 years experience in providing adjudication services
 - ClinTrak Electronic Adjudication Module (EAM)

Electronic Adjudication Services with ClinTrak

In order to facilitate rapid and efficient adjudication of events, Medpace developed an electronic adjudication module within its proprietary web-based study management system, ClinTrak®. The system is fully validated 21 CFR part 11 compliant and integrated with the full suite of ClinTrak systems.

After processing and review by Medpace Clinical Safety, adjudication packages are posted within ClinTrak Electronic Adjudication Module (EAM) for CAC review. CAC members receive real-time electronic notification that a package is ready for review. CAC members enter formal adjudications into the ClinTrak system for inclusion in the final adjudication database.

Sponsors using ClinTrak EAM experience more rapid turnaround of adjudications, in days versus weeks. Utilization of ClinTrak EAM leads to cost efficiencies related to reduce shipping of documents and telecommunication costs compared to traditional paper-based adjudication.

ClinTrak EAM Features:

- Extreme flexibility
 - Dedicated ClinTrak EAM Data Managers and Database Programmers
 - Modules customized to meet the needs of the project and Sponsor
 - Standard, ad-hoc, and customized reports
 - Shortened system development start-up timelines
- Web-based; user friendly for CAC
- Electronic CAC package preparation and posting for adjudicator review
- Electronic collaborative workspace for all relevant stakeholders in the process
- Interactive interface designed for accelerated adjudication process and sign-off
- Electronic management of tie breaker system between adjudicators, resulting in accelerated adjudication matching and query resolution
- Multilingual capabilities
- Electronic audit trail for all entries and activities
- Integration with full suite of ClinTrak systems with single sign-on for ClinTrak Trial Management System

About Medpace

Medpace is a leading global full-service clinical research organization providing Phase I-IV core development services for drug, biologic, and device programs. With medical and regulatory expertise in multiple therapeutic specialties, Medpace has assembled the industry's most experienced and therapeutically focused teams to execute at every level of the company's operations, providing complete and seamless drug development services.

Medpace creates strategic partnerships with pharmaceutical and biotechnology companies to provide the most efficient and cost-effective path to drug development — from program planning and execution to product approval.

Contact Information

Medpace, Inc.,
5375 Medpace Way,
Cincinnati, Ohio 45227 USA
Toll-free: +1.800.730.5779
Tel: +1.513.579.9911
Fax: +1.513.579.0444
E-mail: info@medpace.com