



Clinical Adjudication Service

Bioclinica's Clinical Adjudication Service provides a key role in determining the efficacy and safety endpoints needed to analyze clinical trial outcomes, which are critical in determining a clinical trial's success.

Determining acceptable safety results during a clinical trial by way of independent electronic event adjudication committees is the most efficient process to assist sponsors in reducing costs, increasing quality, and eliminating clinical bias. Bioclinica's Clinical Adjudication Service gives sponsors the ability to electronically manage safety endpoints from notification of an endpoint at a clinical trial site through central review by therapeutic experts.

Bioclinica's Clinical Adjudication team is comprised of nurses and dedicated project managers with over 15 years of experience in the clinical trial industry, and have extensive relationships with KOLs in numerous therapeutic areas. Our Clinical Adjudication Service is completely customizable in order to best meet a sponsor's adjudication requirements. Our vast library of eCRF logic and safety and efficacy parameters is designed to meet adjudicator, sponsor, and regulatory data delivery compliance needs.

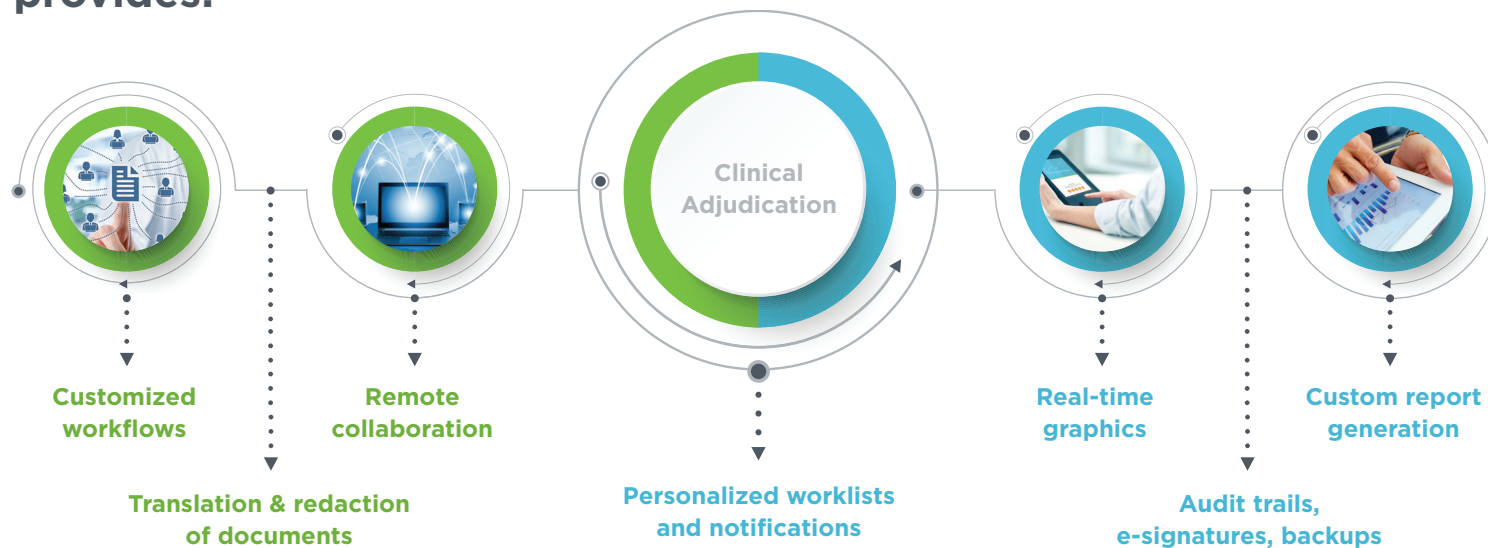
A centralized adjudication process provides sponsors with a dependable and repeatable process for standardized clinical endpoint data interpretation and analysis, and assists with critical go and no-go decisions during a trial.

SPONSOR BENEFITS

- ✓ **Comprehensive medical expertise across all therapeutic areas**
- ✓ **Standardized event definition across all event types**
- ✓ **Meets FDA guidance criteria for endpoint adjudication**
- ✓ **Efficient and automated adjudication workflows**
- ✓ **Real-time access to data enabling faster adjudication**
- ✓ **Ease of electronic process reducing manual errors and costs**
- ✓ **Real-time online access to adjudication results and data reports**
- ✓ **Data visualization of research site, user and adjudicator performance metrics**
- ✓ **Integrated global language translation and redaction services**
- ✓ **24/7/365 live support**



A combination of platform technology and experienced clinical adjudication team provides:



A one-stop-shop for the clinical adjudication process powered by automated technology enabling adjudication in real-time results.

- ✓ Centralized location for all clinical adjudication activities
- ✓ Creation of clinical site manual
- ✓ Clinical site training on data submission
- ✓ Development of the adjudication charter
- ✓ Adjudicator selection assistance with sponsor approval
- ✓ Committee management
- ✓ Clinical nurse review and query management
- ✓ Creation of customized electronic adjudication case report forms per FDA guidance
- ✓ Standard and custom reporting
- ✓ Ongoing and final data delivery to sponsor