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The Critical Role of Clinical Event Adjudication to Improve Trial Efficiency and Data Quality

New drugs, biologics and devices in development today can be very effective at treating the targeted disease or condition. However, many of these therapies may also have a negative impact on patient outcomes. Regulatory authorities are thus increasingly requiring researchers to demonstrate acceptable safety results for drugs in development.

To meet this requirement, trial sponsors and Contract Research Organizations (CROs) are turning to independent electronic event adjudication committees as the most efficient process to help reduce costs, increase quality, and eliminate clinical bias.

A Clinical Event (or Endpoint) Committee (CEC) is a panel of unbiased experts who perform a central review of suspected endpoints in a blinded fashion. A CEC offers significant trial efficiency and data quality benefits, including:

- Ensuring complete and accurate capture of protocol-defined endpoints
- Collecting quality supporting documentation for the suspected endpoints
- Expert review of endpoints to confirm the endpoint in a standardized fashion
- Accurate and timely review of clinical events
- Reduced bias and variability from participating clinical investigators

Despite these benefits, however, there remain two significant barriers to effective clinical event adjudication. First is a lack of widely accepted academic or industry standards regarding CECs, as well as a lack of regulatory guidance. Second is that traditional manual, paper-based approaches place significant time, cost, and resource burdens on organizations - and are prone to errors and regulatory issues.

How Technology is Transforming Clinical Event Adjudication

As with many other areas of clinical research, innovative new technologies – when combined with scientific and medical expertise – are helping to remove these barriers and drive significant gains in efficiency, data quality, and compliance. The result? Fast, accurate, independent adjudication of clinical events in conformance with regulatory requirements governing clinical trials within all therapeutic areas, including cardiac studies and for Major Adverse Cardiac Events (MACE) committees.

Today's web-based adjudication systems, supported by machine learning, sophisticated algorithms, and medical expertise, offer advantages that inefficient paper-based processes cannot:

Remote collaboration utilizing a single, centralized database allows adjudication committee members located anywhere around the world to securely and efficiently review clinical event dossiers, at any time and in real time –greatly compressing the time required to complete event reviews. Sponsors and CROs can leverage in-house expertise, the expertise offered by companies such as Bioclinica, or a combination to create the best committee for that trial.

Customized workflows enable researchers to electronically manage the complete process around safety endpoints – from notification of an endpoint at a clinical trial site on through to central review by therapeutic experts – for a more efficient, objective, and streamlined process than traditional methods, while delivering added quality and time-saving benefits.

Advanced analytics and reporting offer real-time online access to adjudication results, data reports, and performance metrics, complete and accurate capture and reporting of protocol-defined endpoints, and quality supporting documentation for suspected endpoints.

Advanced security and access control through built-in e-signatures, audit trails, and cloud backups provides security, protection and audit trail transparency while giving adjudicators ready access to the required information on every clinical event type.

Flexible system design eliminates any programming required to model a custom adjudication process, with interoperability with any clinical system and built-in capability to access and view DICOM images from within the application - reducing setup time to as little as two weeks.

Medical Expertise Supported by Technology Innovation Remains the Key to Successful Event Adjudication

When the above innovative technology is combined with proven and independent medical expertise, both sponsors and CROs can replace resource-intensive and inefficient processes with a standardized means to confirm the endpoint, documented in alignment with the clinical protocol.

This means getting the adjudication "essentials" right and enhancing safety and efficacy in clinical trials:

For Sponsors:

- Prespecify and define events in the protocol
- Identify triggers for event type
- Determining what events will be adjudicated
- Prespecify standardized MedDRA queries (SMQs)
- Review and signoff of Charter
- Opinion on KOLs for committee

For CROs:

- Use one database for all CEC activities – a "single source of the truth"
- Streamline data collection
- Quickly identify overdue data from sites
- Quick and easy upload of dossier from sites
- Translation and redaction of source documents
- Clinical review and query management
- Adjudicator Case Report Forms
- Standard and custom tracking and reporting
- Standard regulatory report at completion of trial

As a global leader in scientific- and technology-enabled solutions for clinical research, Bioclinica provides innovative adjudication technology and a global network of medical and scientific professionals who specialize in the specific endpoint areas. **Learn more at bioclinica.com/what-we-do/clinical-adjudication**.

Visit bioclinica.com to learn more

Bioclinica is a global life sciences solution provider that utilizes science and technology to bring clarity to clinical trials – helping companies to develop new life-improving therapies more efficiently and safely. Successful clinical trials require the ability to see key details and uncover hidden insights, and Bioclinica's hundreds of experienced scientific, medical, and domain experts bring unmatched insight across the development lifecycle, from the initial protocol to post-approval. The company's thousands of employees serve more than 400 pharmaceutical, biotechnology and device organizations – including all of the top 20 biopharmaceutical companies and leading CROs – through a network of offices in the U.S., Europe, and Asia.