Duke Clinical Research Institute

DCRI **CLINICAL EVENTS CLASSIFICATION**

Independent Review of Efficacy in Clinical Research Through the Generation of High-Quality Adjudicated Endpoint Data

The DCRI Clinical Events Classification (CEC) group uses innovative strategies, including streamlined data workflows, so that adjudicated endpoint data are available on time for the Independent Data Monitoring Committee (IDMC), database lock, and other important timelines throughout a trial.

Clinical Events Classification

FOUNDED IN
1998

250,000+ PATIENTS

550,000+
ADJUDICATIONS COMPLETED

20+
INSTITUTIONAL COLLABORATIONS

130+
PARTNERSHIPS WITH MEDICAL EXPERTS

30+ TRIALS

300+ COMPLETED TRIALS

20
OPERATIONAL STAFF INCLUDING NURSES, RESPIRATORY THERAPISTS AND PHARMACISTS

90
ADJUDICATORS

WORK FROM
Phase I-Phase IV

CEC Phase II Committee

4,000+
COMMITTEE MEETINGS

17,500+
INDIVIDUAL REVIEWER COMMITTEE HOURS

78,000+
EVENTS REVIEWED IN COMMITTEE

A comprehensive approach for the development of highly efficient events adjudication programs includes:

- A tailored approach to efficacy review and event validation that is adaptable to protocol requirements in both model and cost.
- Clinical events adjudication processes, performed in 21 Code of Federal Regulations (CFR) part 11 compliant adjudication systems, that enable secure, global access for all physician reviewers.
- Collaboration in protocol development.
- Clinical preparation and review of event packets dossiers within a secure adjudication system.
- Proven leadership in providing adjudication guidance aligned with regulatory agencies.
- Leadership in peer-reviewed publications on clinical events adjudication processes and results.
- Robust quality control processes that ensure accurate data.
- Access to an international group of experts, including faculty thought leaders and CEC adjudicators experienced in clinical trials and event review/adjudication in many therapeutic areas.
- Systematic, comprehensive, unbiased, blinded and independent clinical event adjudication of suspected events with emphasis on quality and event turnaround times.

The DCRI CEC team provides expert adjudication activities that are unique and customizable to each trial. Discover the specialized approach that sets us apart:

- The DCRI established one of the first event adjudication groups worldwide to perform independent and unbiased event adjudication as a key element in providing trial endpoint data.
- Operational excellence with a core CEC team that has extensive event adjudication and clinical experience.
- A successful history leading event adjudication activities and promoting confidence in the management and processing of events/cases.
- Trial tested processes and systems ensure project timelines are met with the highest level of quality and rigor expected by regulatory agencies, including adjudication process development in collaboration with the FDA.
- Input on clinical endpoint definitions, eCRF collection of key endpoint data, and collaboration with Safety Surveillance on negatively adjudicated events assures consistency with clinical practice and regulatory expectations and minimizes the burden of source document collection.

Innovative. Efficient. Reliable.

THE BACKBONE OF OUR WORK

CEC's work affects patient lives and is one of the most critical steps in the clinical research process to ensure accurate clinical outcomes. Each project is met with a commitment to:

Efficiency

- Rigor and discipline in every project
- Streamlining communications and seamlessly managing the adjudication process
- Continuing the proven track record of meeting or exceeding milestones

Accuracy

- An obsession with quality
- The drive to get it done right the first time to avoid double work
- Extensive experience submitting data to the FDA and EMA, with first-hand knowledge of the standards they expect

Innovation

- Adjudication algorithms/auto adjudication processes to programmatically define adjudication values and event type details
- Leadership in future advancements in adjudication, including the use of electronic medical records and machine learning to streamline adjudication of clinical events
- Implementation of complex trigger programming to support a robust and efficient event identification process

DCRI CSI+

+ Clinical Events Classification (CEC); + Safety Surveillance (SS);
+ Imaging Core Lab (ICL); + Arrhythmia Core Lab (ACL); + Hemodynamics Core Lab (HCL)

In addition to CEC activities, DCRI is fully equipped to provide a cross-functional approach to the medical core trial requirements, ensuring a comprehensive and efficient performance of safety surveillance/pharmacovigilance, as well as core labs for centralized imaging interpretation of electrophysiology and/or of imaging across several modalities. DCRI's collaborative approach across our core trial medical adjudication activities offers streamlined systems and operations to systematically generate validated, high-quality data.

Learn more about DCRI CEC and CSI+

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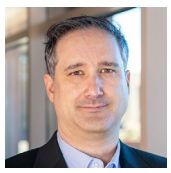

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dcri.org/cec

CEC is essential to secure FDA or EMA approval for drugs and devices in a wide range of therapeutic areas, including:

- Cardiovascular
- Neurology
- Infectious Diseases
- Gastroenterology
- Medical Devices
- Nephrology
- Oncology
- Pediatrics
- Respiratory Medicine

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