

# DCRI CLINICAL EVENTS CLASSIFICATION AND SAFETY SURVEILLANCE

Ensuring Patient Safety Through Rigorous Surveillance

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

**500,000+**  
ADJUDICATIONS COMPLETED

**30+**  
TRIALS

**250+**  
COMPLETED TRIALS

**20+** INSTITUTIONAL COLLABORATIONS

**130+** PARTNERSHIPS WITH MEDICAL EXPERTS

**45**

OPERATIONAL STAFF INCLUDING NURSES, RESPIRATORY THERAPISTS AND PHARMACISTS

**45**

ADJUDICATORS

WORK FROM

**Phase I-Phase IV**

## CEC SOLUTIONS

Comprehensive services for the development of highly efficient events adjudication programs include:

- 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 CFR part 11 compliant adjudication systems, that enable secure, global access for all physician reviewers.
- Collaboration in protocol development.
- Access to an international group of clinical experts with experience in clinical trials and event review/adjudication in many therapeutic areas, including: Cardiology (Drugs and Device), Infectious Disease, Nephrology, Neurology, Oncology, Pediatrics and GI.
- Systematic, comprehensive, unbiased, blinded and independent clinical event adjudication of suspected events.
- 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.

## ARRHYTHMIA CORE LABORATORY

In addition to these services, CEC offers high-quality evaluation, adjudication, and validation of electrocardiographic and electrogram review through DCRI's Arrhythmia Core Laboratory. Our experienced adjudicators—comprised of HRS board-certified faculty of electrophysiologists—collaborate with other trial support units, helping to further set us apart.

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



Cardiovascular



Gastroenterology



Infectious Diseases



Medical Devices



Nephrology



Neurology



Oncology



Pediatrics



Respiratory Medicine

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## Find out more about DCRI Clinical Events Classification, Arrhythmia Core Lab and Safety Surveillance.

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[dcri.org/cec](https://dcri.org/cec)

[dcri.org/acl](https://dcri.org/acl)

## 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 EMEA, and first-hand knowledge of the standards they expect

### Innovation

- Adaptable approaches to adjudication models, systems and workflows
- Implementation of complex trigger programming to support a robust and efficient event identification process
- Adjudication algorithms/ auto adjudication processes to programmatically define adjudication values and event type details

## DCRI SAFETY SURVEILLANCE

DCRI Safety Surveillance ensures on-time ascertainment and clinical evaluation of serious adverse events (SAEs), adverse device effects (ADEs), and other safety events through the development and skilled implementation of protocol-aligned safety management processes. Our team of Duke/DCRI faculty Safety Medical Monitors and expert safety associates with clinical nursing and pharmacy backgrounds have access to best-in-class medical, regulatory, and data/technical support, to ensure reliable, timely and accurate safety processes and systems, customized for every project.

### Capabilities:

- Specifications and user testing for EDC forms relevant to safety event reporting, and for the secure, project-specific safety database.
- Writing the protocol-aligned safety management plan, working instructions and site safety report training.
- Reconciliation of safety event critical fields between clinical and safety databases.
- Medical assessment of criteria for expedited event reporting and preparation of MedWatch/CIOMs reports for regulatory reporting, site/IRB notification.
- Safety consulting and investigator training.

**236+**

COMPLETED TRIALS

**15+**

ACTIVE TRIALS

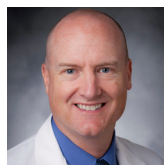
**165k+**

EVENTS PROCESSED

## DCRI CLINICAL EVENTS CLASSIFICATION LEADERSHIP



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**Duke Clinical Research Institute**

FROM THOUGHT LEADERSHIP  
TO CLINICAL PRACTICE