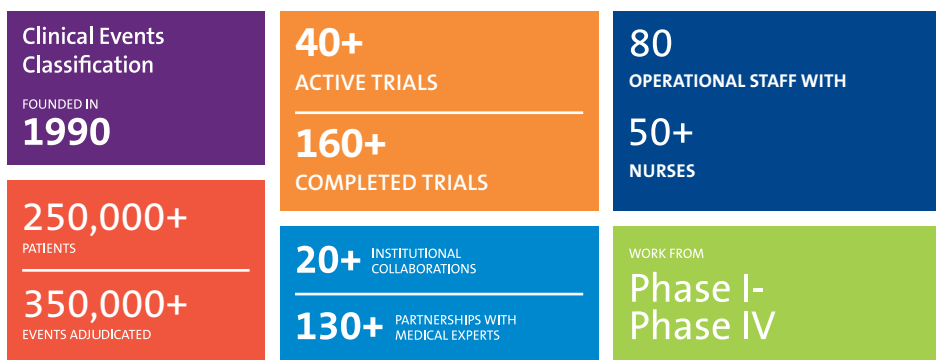


# DCRI CLINICAL EVENTS CLASSIFICATION

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.



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

## CEC SOLUTIONS

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

- Clinical events adjudication processes, performed in 21 CFR part 11 compliant adjudication platforms, 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), Nephrology, Neurology, Oncology, Pediatrics and GI.
- Systematic identification 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.



# DCRI CLINICAL EVENTS CLASSIFICATION

## Find out more about DCRI Clinical Events Classification.

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[dcri.org/acl](http://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

- Continuing to innovate the modern adjudication process created by DCRI CEC

## SAFETY SURVEILLANCE GROUP

DCRI Safety Surveillance ensures on-time ascertainment and clinical evaluation of serious adverse events (SAEs) and other safety events through the development and skilled implementation of protocol-aligned safety management processes. The team has access to best-in-class medical, regulatory, and technologic support, to ensure reliable and accurate safety processes and systems, customized for every project.

Capabilities:

- Specifications and user-testing for configuration of a trial-specific safety database.
- Pass-through service, so the sponsor retains ownership of the safety database while the DCRI prepares the safety management plan (SMP), triages safety events, queries sites, processes updates, and forwards SAE reports.
- Reconciliation of safety event critical fields between clinical and safety databases.
- Ability to leverage the infrastructure of device/disease registries and networks to manage safety events for registry-nested trials efficiently.
- Safety consulting and investigator training.

**120+**

COMPLETED TRIALS

**15+**

ACTIVE TRIALS

**165k+**

EVENTS PROCESSED

## DCRI CLINICAL EVENTS CLASSIFICATION LEADERSHIP



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Cardiology



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Duke Clinical Research Institute

FROM THOUGHT LEADERSHIP  
TO CLINICAL PRACTICE