DCRI **CLINICAL EVENTS CLASSIFICATION**

Ensuring Patient Safety Through Rigorous Surveillance

The DCRI Clinical Events Classification group uses innovative strategies, including integrated adjudication and data management processes, 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.

A PROVEN INDUSTRY LEADER

Clinical Events Classification
FOUNDED IN
1990

200,000+
PATIENTS

185,000+
EVENTS ADJUDICATED

50+
Active projects

100+
Completed projects

80
Operational staff with
50+
nurses

20+ INSTITUTIONAL COLLABORATIONS

130+ PARTNERSHIPS WITH MEDICAL EXPERTS

WORK FROM
Phase I-Phase IV

CEC SOLUTIONS

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

- Consulting expertise in clinical events adjudication processes, including electronic data capture and paper-based trials
- Collaboration in protocol development
- Access to an international group of clinical experts with experience in clinical trials and event review/adjudication
- Systematic identification of suspected events
- Preparation and review of event packets
- Liaising with regulatory agencies
- Preparing peer-reviewed publications on clinical events adjudication processes and results

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
- Kidney Disease
- Medical Devices
- Oncology
- Pediatrics
- Respiratory Medicine

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Find out more about DCRI Clinical Events Classification.

Matt Wilson, RN
Director, CEC-SS
919-668-8525
matthew.d.wilson@duke.edu

dcri.org/cec

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

The Safety Surveillance team ensures comprehensive ascertainment and evaluation of safety information by coordinating the development and implementation of the SAE process for DCRI trials. The group develops projects specific safety management plans, and are responsible for SAE management and safety medical monitoring activities across trials.

Services include:

- Full service of trial safety databases or pass-through service, wherein the sponsor holds the trial safety database
- Receiving and processing site-reported events of interest, pregnancy, UADEs via eCRF, etc.
- Reviewing and processing negatively adjudicated events (NAE), including further medial review to determine whether the NAE represents a potential serious adverse reaction

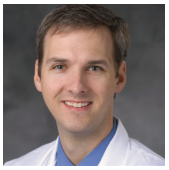
95+
trials closed

nearly **40**
active trials

165k+
events processed

DCRI CLINICAL EVENTS CLASSIFICATION LEADERSHIP

Renato Lopes, MD, PhD
Co-Director, Clinical Events Classification, Co-Director, ICE-SS, Professor of Medicine, Cardiology



Schuyler Jones, MD
Co-Director, Clinical Events Classification, Associate Professor of Medicine, Cardiology

Karen Alexander, MD
Director, Safety Surveillance, Co-Director, ICE-SS

Matt Wilson, RN
Director of Operations Clinical Events Classification-Safety Surveillance

Linda Lillis, MS
Associate Director Clinical Events Classification-Safety Surveillance

Duke Clinical Research Institute | FROM **THOUGHT LEADERSHIP** TO **CLINICAL PRACTICE**

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