Duke Clinical Research Institute

DCRI **SAFETY SURVEILLANCE**

Rigorous, Timely Assessment and Reporting of Study Participants' Safety Events

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

Across study phases, intervention types, and therapeutic areas, DCRI Safety Surveillance adapts to each protocol's unique risks, requirements, and safety event data flow to ensure timely capture, assessment, and reporting of SAEs and other safety events for a study's sites and participants, globally.

CUSTOMIZED AND COMPLIANT SAFETY SOLUTIONS

DCRI Safety Surveillance is committed to quality, compliance, and patient safety. Our approach is customized to each sponsor's needs and optimal cost effectiveness:

- Provide specifications and user testing for all EDC forms relevant to safety event reporting; for the project-specific safety database, and on-demand reports
- With DCRI data security and regulatory experts, establish safety event management from DCRI's first awareness to the final report to the sponsor
- Develop and implement protocol-aligned Safety Management Plan with training, instruction, and support across DCRI Safety Associates, all site investigators, and global staff, ensuring consistent safety event processing and reporting
- Processes for rapid safety event discovery and assessment, whether captured via EDC, provider contact, study participant portal or app, or call center logs of healthcare encounters
- Unbiased, blinded medical review of events with an assessment of expedited reporting criteria by DCRI Safety Medical Monitors
- Generation of MedWatch/CIOMs reports for regulatory reporting and site/IRB notification
- DSMB support on request with SAE/safety event reports and presentation
- Safety event reconciliation of critical variables between clinical and safety databases at intervals and pre-database lock
- Analyses of Similar Events, medical review of aggregate AE/SAE listings, safety surveillance/pharmacovigilance research collaborations

DCRI Safety Surveillance
ESTABLISHED IN 1998

165,000+
SAFETY REPORTS ASSESSED

240+
COMPLETED PROJECTS, COMPRISING
98,000+
STUDY PARTICIPANTS

16,000+ CONFIRMED SAES, ADVERSE DEVICE EFFECTS AND EVENTS OF INTEREST

6,200+ MEDICAL REVIEWS BY INDEPENDENT DUKE/DCRI MEDICAL MONITORS

Innovative. Efficient. Reliable.

DCRI SAFETY MEDICAL MONITORS

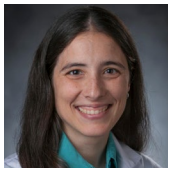
- DCRI / Duke Faculty thought leaders and clinician-researchers
- Providing timely, blinded, unbiased medical review of each safety event reported
- Experts in assessing safety for individual patients, trials of varying sizes, and clinical programs

Jason Lang, MD, MPH

David Kong, MD

Brian Smith, MD, MHS, MPH

Michael Morse, MD, MHS



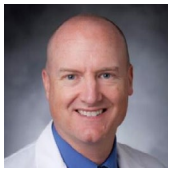
Rachel Greenberg, MD, MB, MHS

DCRI CSI+

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

In addition to Safety surveillance/pharmacovgilance activities, DCRI is fully equipped to provide a cross-functional approach to the medical core trial requirements, ensuring a comprehensive and efficient performance of event adjudication, 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.

DCRI SAFETY SURVEILLANCE LEADERSHIP



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Learn more about DCRI Safety Surveillance

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