

# White Papers and Publications Committee Update

**FDA White Oak**  
Silver Spring, MD  
October 24, 2017

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VP Medical Affairs Cardiovascular  
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**CARDIAC SAFETY**  
RESEARCH CONSORTIUM

# CSRC “White Papers”

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- White papers “usually cover challenging areas of cardiovascular safety, describing what is known and not known, and to propose paths forward...”
- Summary of CSRC sponsored ‘Think Tanks’
- All papers involve active participation from academia, industry and regulators but are not regulatory documents
- Great opportunity for knowledge sharing!
  
- CSRC publication policy available on-line  
<https://www.cardiac-safety.org/>

**40 published papers (5 in 2017 so far!)**  
**3 writing groups now actively working**

All involving academia, industry and regulators



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# Long-term electrocardiographic safety monitoring in clinical drug development: A report from the Cardiac Safety Research Consortium

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This white paper, prepared by members of the Cardiac Safety Research Consortium (CSRC), discusses important issues regarding scientific and clinical aspects of long-term electrocardiographic safety monitoring during clinical drug development. To promote multistakeholder discussion of this topic, a Cardiac Safety Research Consortium–sponsored Think Tank was held on 2 December 2015 at the American College of Cardiology's Heart House in Washington, DC. The goal of the Think Tank was to explore how and under what circumstances new and evolving ambulatory monitoring technologies could be used to improve and streamline drug development. This paper provides a detailed summary of discussions at the Think Tank: it does not represent regulatory guidance. (*Am Heart J* 2017;187:156-69.)

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# Use of endpoint adjudication to improve the quality and validity of endpoint assessment for medical device development and post marketing evaluation: Rationale and best practices. A report from the cardiac safety research consortium



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This white paper provides a summary of presentations, discussions and conclusions of a Thinktank entitled “The Role of Endpoint Adjudication in Medical Device Clinical Trials”. The think tank was cosponsored by the Cardiac Safety Research Committee, MDEpiNet and the US Food and Drug Administration (FDA) and was convened at the FDA's White Oak headquarters on March 11, 2016. Attention was focused on tailoring best practices for evaluation of endpoints in medical device clinical trials, practical issues in endpoint adjudication of therapeutic, diagnostic, biomarker and drug-device combinations, and the role of adjudication in regulatory and reimbursement issues throughout the device lifecycle. Attendees included representatives from medical device companies, the FDA, Centers for Medicare and Medicaid Services (CMS), end point adjudication specialist groups, clinical research organizations, and active, academically based adjudicators. The manuscript presents recommendations from the think tank regarding (1) rationale for when adjudication is appropriate, (2) best practices establishment and operation of a medical device adjudication committee and (3) the role of endpoint adjudication for post market evaluation in the emerging era of real world evidence. (Am Heart J 2017;190:76-85.)

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# Prevention of sudden cardiac death in the young: Developing a rational, reliable, and sustainable national health care resource. A report from the Cardiac Safety Research Consortium



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This White Paper, prepared by members of the Cardiac Safety Research Consortium, discusses important issues regarding sudden cardiac death in the young (SCDY), a problem that does not discriminate by gender, race, ethnicity, education, socioeconomic level, or athletic status. The occurrence of SCDY has devastating impact on families and communities. Sudden cardiac death in the young is a matter of national and international public health, and its prevention has generated deep interest from multiple stakeholders, including families who have lost children, advocacy groups, academicians, regulators, and the medical industry. To promote scientific and clinical discussion of SCDY prevention and to germinate future initiatives to move this field forward, a Cardiac Safety Research Consortium–sponsored Think Tank was held on February 21, 2015 at the US Food and Drug Administration's White Oak facilities, Silver Spring, MD. The ultimate goal of the Think Tank was to spark initiatives that lead to the development of a rational, reliable, and sustainable national health care resource focused on SCDY prevention. This article provides a detailed summary of discussions at the Think Tank and descriptions of related multistakeholder initiatives now underway: it does not represent regulatory guidance. (Am Heart J 2017;190:123-131.)

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Accepted Manuscript

Drug-Induced Cardiac Abnormalities in Premature Infants and Neonates

Luana Pesco Koplowitz MD, PhD, Gary Gintant PhD, Robert Ward MD, Dominique Heon MD FRCPC, Muriel Saulnier PhD, Jeff Heilbraun MS

PII: S0002-8703(17)30214-4  
DOI: doi: [10.1016/j.ahj.2017.07.014](https://doi.org/10.1016/j.ahj.2017.07.014)  
Reference: YMHI 5489

To appear in: *American Heart Journal*

Received date: 27 July 2017  
Accepted date: 27 July 2017



## Accepted Manuscript

Enabling Social Listening for Cardiac Safety Monitoring: Proceedings from a DIA-CSRC Co-sponsored Think Tank

Harry A. Seifert MD, MSCE, FISPE, Raleigh E. Malik PhD, Mondira Bhattacharya MD, Kevin R. Campbell MD, FACC, Sally Okun RN, MMHS, Carrie Pierce, Jeffrey Terkowitz, J. Rick Turner PhD, DSc, FASH, FACC, FESC, Mitchell W. Krucoff MD, FACC, FAHA, FSCAI, Gregory E. Powell PharmD, MBA, BS Pharm, RPh

PII: S0002-8703(17)30254-5

DOI: doi: [10.1016/j.ahj.2017.08.021](https://doi.org/10.1016/j.ahj.2017.08.021)

Reference: YMHJ 5519

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# Papers in Progress...

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- Is There A Role For Pharmacokinetic/Pharmacodynamic Guided Dosing For Novel Oral Anticoagulants?- Submitted for publication  
Lead - Noel Chan
- Real World Evidence : A Report from the CSRC  
Lead - Mary Jane Geiger
- VT-ICD Think Tank Proceedings  
Lead - Jonathan Seltzer



# Comments

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- Agreement for publication in the American Heart Journal; editorial review and approval will be expedited for CSRC papers that have undergone extensive discussion and review by key stakeholders within the CSRC internal peer review process
- Similar understanding with the journal - Therapeutic Innovation & Regulatory Science, formerly the DIA Journal
- To further the mission of the CSRC, new members (e.g. scientists not previously involved in CSRC papers), a trainee, a fellow or similar junior level scientist, may be designated as the “primary writer” of the manuscript under the guidance of the project leader

# Committee Members

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