



Transforming Research through a National Cardiovascular Research Infrastructure

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Transforming Research through a National Cardiovascular Research Infrastructure

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Abstract: Current organizational models for clinical research lack sustaining infrastructure. The Duke Clinical Research Institute and the American College of Cardiology have created the National Cardiovascular Research Infrastructure, a new multi-center translational research model based upon the National Cardiovascular Data Registries program. Existing EHR-based data collection will be integrated with centralized electronic data capture, clinical trial management and other systems. Robust data element definitions with CDISC and HL7 representations will be publicly vetted and implemented.

Introduction and Background: Research capacity and efficiency can be increased using a novel organizational, technical and operational model. The National Cardiovascular Research Infrastructure (NCRI) will achieve this by integrating patient care processes for quality assessment with clinical trials research operations.

The American College of Cardiology (ACC) NCDR registry receives standardized data from 22 certified EHR vendors at over 2300 US hospitals. Duke Clinical Research Institute (DCRI) has conducted hundreds of large research programs with unmatched academic research organization capabilities, and is an NCDR data analysis center. Under NCRI these organizations are partnering to rapidly develop and deploy new informatics methods, tools and knowledge that will change the national capacity for cardiovascular research.

Methods: NCRI will aggressively develop and adopt emerging informatics tools, methods and best practices on large scale. Key components include: 1) Participation and retention of sites through community developed and shared educational programs and research tools; 2) Interoperability among EHR, quality reporting and research systems achieved through robust vocabulary-based data element definitions with representations in CDISC and HL7 RIM based standards; 3) Rapid cycles of feasibility and effectiveness evaluations of using live clinical trials; and 4) An integrated suite of web based services and tools to drive research study operations. The addition of randomization and study

operational modules to the NCDR backbone create an efficient platform for large simple randomized clinical trials.

Results: Success will be measured by participation and retention rates of NCDR hospitals, utilization of tools and services and knowledge generated from this infrastructure not otherwise obtainable.

Discussion: The NCRI creates a sustained improvement in the efficiency and quality of the interaction between the clinical research subject, the clinician investigator, expert guidelines committee, and policymakers. Clinical trials submitted for regulatory approval typically incorporate highly selected patient populations, with eventual confirmation of safety and efficacy in “real-world” post-approval registries. National cardiovascular data registries (such as the American NCDR, the Swedish SCAAR and the Danish WDHR) have become synonymous with post-approval market surveillance. The National Cardiovascular Research Infrastructure will uniquely complete the continuum from research to care guidelines to performance measurement and clinical outcomes measurement back to research hypothesis generation. The informatics platforms adopted, developed and shared by NCRI will contribute beyond cardiology to the clinical research informatics knowledgebase. By accelerating the progress of new research concepts from inception to execution, key decision-makers can fill critical evidence gaps and improve the public health.

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