

Quality Control and Post-Market Data Collection:

Academic and Professional Society View

Safety Evaluation of Atrial Fibrillation Ablation Using a Collaborative
Pan-Stakeholder Critical Path Registry Model:

A Cardiac Safety Research Consortium 'Incubator' Thinktank

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Quality Control

- Importance of a National Atrial Fibrillation Registry
 - Determining what is being done in routine clinical practice
 - Examining the outcomes of atrial fibrillation ablation
 - Comparing the characteristics and outcomes of patients in the Registry with those of patients enrolled in the randomized clinical trials (RCTs)
 - Examining the outcomes of subgroups of patients excluded or not well-represented in the RCTs
 - Quality initiatives (tracking performance, benchmarking, quality measures etc...)

Quality Control

- We need to ensure good quality data collection:
 - Using standardized data elements and definitions developed and agreed upon by national experts in the field
 - Formal training on data collection and entry (includes clear communication of definitions)
 - Submitting data via a secure web-based system

Quality Control

- We need to ensure good quality data collection:
 - Subjecting submitted data to rigorous electronic quality checks. If the data do not pass completeness criteria, participants can clean their data and resubmit as often as needed until the data pass
 - Using a National on-site audit program applied to a random sample of sites

Quality Control

- Data collection for the Registry should be confidential and HIPPA compliant:
 - Ensuring that appropriate safeguards are in place to protect health information and maintain the confidentiality of patient-level data
 - Obtaining appropriate internal approval in accordance with each institution's own policies, and complying with all applicable laws and regulations



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