AdvaMed
Advanced Medical Technology Association

QUALITY CONTROL & POST-MARKET DATA COLLECTION

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BRINGING INNOVATION TO PATIENT CARE WORLDWIDE

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Background

- No study is better than the quality of the data
- To date, a variety of measures have been implemented to ensure quality control and safety reporting in IDE trials
  - Compliance with (Maintenance to) GCP and FDA requirements
  - Protocol Design
  - Statistical analysis plan
  - CFR 11 Compliant, validated data management systems
  - IRB approval
  - DSMB/Core Lab
  - Site Training/Pt Consenting Process
  - Monitoring/Audit
  - HIPAA
- Quality Control starts with clear definitions; appropriate procedures and training
- Attention to site selection criteria is critical to ensuring compliance to quality standards
  - Access to qualified personnel
  - Availability of data management tools/equipment
  - Site oversight

What Works Well Today

- Data collection driven by well-defined variables in protocol, statistical plan, and safety reporting; standards applied where appropriate
- Utilization of Guidelines
- Electronic data capture ensures data (consistency) quality and reduces rework & expense
  - Eliminate paper CRF
  - Site personnel enter data via “pick lists”
  - Query management tools ensure completion of data fields; question “out of range” variables
  - CFR 11 compliant data management system; allows visibility to who has accessed system, and any modifications made, and when
- Prospectively defined elements of standard reports
  - Allows quick and easy report generation for a variety of purposes
- Prospectively defined key “signals” for focused review of safety/adverse event rates
- Prospectively defined monitoring plan/audit schedule
- Access to database is controlled
- FDA post-approval study authority; early problems with study order compliance have been addressed

What is Missing or Broken?

- Identification of objective and key elements of proposed registry are not yet clearly defined
  - Data points MUST be well-defined and relevant to the designed objective of the registry, not for other purposes
  - Objective and scientific data collection is critical
  - Data should be collected in a specific manner to individual components of AF ablation systems
  - Sufficient standards should be developed to ensure valid data entry.
  - Guidance for extraction and data analysis is needed to ensure integrity of complied data and subsequent valid reporting
- Governance related to patient privacy, confidentiality of manufacturer, physician, and hospital data must be developed

Highest Priority Short-Term (1-3 years)

- Ensure that proposed collection of safety variables is consistent with objective of registry
- Determine safety hypothesis and key “signals”
- Who is primarily responsible for oversight
- Clearly defined:
  - Proposed registry protocol
  - Operations manual for sites
  - Informed consenting with “opt-out”
  - Site training
  - Data management plan
    - CRF, data entry, validation, access, analysis
  - Monitoring plan
    - Surveillance, feedback loop to sites
  - Stopping rules for futility or objectives met

Highest Priority Long-Term (3-5 years)

- Evaluate whether or not registry is meeting intended purpose
- Are data “signals” representative of “real world”
  - Are the inferences, conclusions based on valid, accurate data?