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Industry Registry Experience
Lesson's Learned

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BRINGING INNOVATION TO PATIENT CARE WORLDWIDE

April 27, 2009

Background/Overview - SCD-HeFT NCD Jan 2005 Coverage with Evidence Development Emerges

- Supportive of Medicare's policy goals
  - Ensure access to appropriate care
  - Improve evidence for physician/patient decision making
- Understand: Limited clinical research dollars
  - Choices necessary – which disease, therapy, trial & endpoints
  - Non – duplicative evidence must be meaningful, actionable
- Understand: Administrative burdens and implementation issues
- Acknowledge industry's longstanding expertise & initiative
  - We understand and support evidence based medicine
  - We invest in our own & FDA mandated post market studies
  - We develop robust clinical & economic evidence for physicians, patients & payers
  - We have technology to enhance the process of evidence generation
- The clinical development pathway should be predictable in order to allow industry to plan for and implement studies that meet the needs of all stakeholders without necessitating redundant efforts or loss of valuable time

ICD Therapy Registry: Lessons Learned

- The pathway to national registries should be predictable and transparent
- Specify the purpose of obtaining additional information
  - Improve physician/patient decision making?
  - Determine if pts in registry are same as those in trial?
  - Generate hypotheses for future trials?
  - Determine effectiveness in sub-populations?
  - Restrict coverage/patient access?
- Review existing and planned private and public research efforts for possible leverage
- Leverage private sector expertise in therapy knowledge, trial design & implementation e.g. well-defined questions, definitions, census vs sample
- Define how the data will be used, who will analyze it, who will have access, when and in what form, who will fund it"
- Define roles in educating and compensating providers regarding new requirements
- Other issues – HIPAA, what is the measure of benefit?
- Four years after the decision, have yet to initiate longitudinal enrollment
- Industry initiated registry

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ICD Therapy Registry – Suggestions for Improvement

- Treat current decisions as pilots – perfect them and determine their value
- Registry requirements should be predictable early in the product development process – not a surprise at the end of a rigorous trial
- Registry requirements should be limited to promising products/services where the evidence is not yet conclusive
- When requesting additional evidence we need to specifically identify the data lacking and how the registry will address the gap in evidence
- Determine a method to acknowledge the private sector for landmark work in collaborating with NIH and performing not only SCD-HeFT but multiple other landmark trials.

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Registries & Evidence Based Medicine

- Post-approval registries could be useful in improving evidence in limited circumstances – promising new technologies without adequate current evidence base & no additional evidence development ongoing.
  - NOT AF ablation. ACC guidelines/ HRS consensus statement; BCBS tech assessment and numerous RCTs underway to develop additional evidence.
- Mining claims data does not require a registry
- Industry increasingly invests in evidence development to refine use, define and refine indications, prove value
- Understand value and appropriate uses for registries, real-world data
- Don’t trade off investments in rigorous, hypothesis based appropriately powered sample sized approaches for registries

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