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Funding RAPID Phase II/III

Cost of Current Registry-Based Device Evaluation

Jack Cronenwett, MD

Medical Director Emeritus, SVS PSO

Chief Medical Officer, M2S/Medstreaming

j.cronenwett@dartmouth.edu

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Cost Savings from Registry-Based Studies

- Existing network of sites and data collection mechanism
  - Speed recruitment and reduce data entry training needs
- Minimizes data entry burden for sites
  - Most required data is already being entered in registry
- In PSO, informed consent, IRB approval not required
  - For standard treatment in post-approval space
  - Reduces cost, allows all patients treated to be enrolled
- Only a small addition to existing site-PSO contract needed
  - Cost of negotiating separate site contracts eliminated

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Costs of Registry-Based Studies

- Modifying existing registry to add supplemental data and reporting required for a specific project

- Project Management performed by registry/vendor
  - Monitor site enrollment and data quality
  - Address data queries with sites that arise during analysis

- Payment to sites for entering supplemental data and follow-up time points

- Payment to society for use of registry data, infra-structure and scientific steering committee

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Cost Examples from VQI-Industry Projects

- Factors that determine costs (similar to any device trial)
  - Number of patients and timepoints for data collection
  - Complexity of supplemental data collection
- VQI experience from 5 Projects: (Mean, range)
  - N patients: 240 (75-410)
  - N timepoints: 5 (2-7)
  - Cost per patient: $9K (7-16K) [Industry estimate $14K]
  - Cost per timepoint: $2K (1.5-5) [Industry estimate $3K]
- Appears to reduce cost by at least one-third

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Conclusions

- Registry-based device evaluation projects can be performed more rapidly and at less cost than similar projects conducted by industry

- There is more opportunity for cost reduction if more projects are done, since this allows infrastructure costs to be distributed among more companies

- Use of registry data by multiple stakeholders ultimately reduces the cost for everyone, including the cost of duplicate data entry

- Careful monitoring of these projects increases data accuracy for all stakeholders