EFS Symposium:
Implementation Strategies for Early Feasibility Studies

David R. Holmes, Jr., MD

TVT
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The following relationships exist related to this presentation:
None
EFS Initiative
Where did it come from?

FDA
Industry
Patients

Congress – 21st Century Cures ACT
Hospitals/Health Care institutions
Physicians
Early Feasibility Studies (EFS)

- EFS is a path to early access of innovative device therapies for U.S. patients
- Small, highly monitored studies of the first use of novel, potentially life saving technology
- Device modifications may occur as outcomes dictate
- Typically conducted at sites with highly skilled physician and research staff
Long Term Vision
National EFS Site Network

• The EFS Pilot is the first phase of establishing a National EFS Site Network
• A voluntary, open research network of sites committed to high quality, efficient EFS
• Vision to advance US first-in-world patient access to novel therapies and technologies
Optimal EFS Site Qualities

• A culture of clinical study quality, and a commitment to and enthusiasm for EFS
• A well-developed infrastructure to support clinical studies
• A track record of human subject monitoring and protection and excellence in maintaining study data integrity
• Technically qualified site investigators
• Commitment from the site IRB to expeditiously review EFS submissions or a willingness to defer to a central IRB
• Parallel and timely contracting and IRB processes
• Access to sufficient patient populations with the disease being treated (the intended treatment population); sites with electronic health records may have readily available information in this regard
• A commitment to constrain both direct and indirect costs

CV EFS Pilot: Site Demographics*

Indicates Possible Sites – Selections TBD

Non-profit, Academic
Non-profit, Community
Private
Identified Challenges

- Contracting
- Indemnification
- IRB performance
- Patient Informed Consent
- Development of clinical site Centers of Excellence for carrying out EFS
- CMS Reimbursement
EFS Pilot: Tools and Methods

• Contract:
  • Master Clinical Trial Agreement
  • Contract Language Libraries

• Patient Advocacy: Informed Consent Form Template

• Education: Information for IRBs, research staff, and potential subjects

http://mdic.org/cts/efs/
Questions to be addressed

• What are tangible benefits
  • Sponsors
  • Institutions
  • Regulatory agencies
  • Patients

• How to monitor site performance
  • Target goals

• Will certification be required
  • By whom?

• Can CMS funding issues be resolved?
18 Lawyers Met February 14, 2018
Draft Master Agreement and
Standardized Contract for EFS
EFS Initiative
What have been the deliverables - Educational

- Patient Advocacy: Informed consent template
- Information for IRB’s on specifics of:
  - EFS
  - Device studies
  - Role of Central IRB’s
  - Patient protection