SPARED – The Study of Prostate Ablation Related Energy Devices
A Coordinated Registry Network (CRN) For Prostate Ablation Devices

Public Health Context

- Over 3 million men are living with prostate cancer in the United States.
- In 2017 prostate cancer introduced 161,360 new cases into the U.S.
- 27,730 men living in the U.S. will die this year from prostate cancer.
- Rapid adoption of novel technologies for prostate ablation necessitated need to monitor safety and efficacy in the post market space.
- More companies with novel technologies are applying for clearance/approval (2 devices are currently approved for use).
- The MDEpiNet Center at Weill Cornell has initiated this study in a multi-disciplinary effort.
- Think-Tank meeting was held on July 22, 2016 and spared the formation of a distributed registry system to meet growing needs.

Results

- Thousands of pages of CRF’s were analyzed and pertinent data elements were extracted.
- The SPARED core data elements list is complete, but needs further input from industry, academia, and other key stakeholders to finalize core data elements.
- A score/ranking system was established.
- Preliminary core data set is in motion need to further harmonize with both internal and external input.
- Delphi Consensus manuscript written: Consortium of nationally representative medical device registries.
- Buy-in from representatives present at this year’s meeting reached 9/25/17.

Current Gaps

1. PRO’s not consistently OR completely reported across approved devices.
2. GUDID, PROs, EHR, UDI information needs to be cross-linked with existing data set to reduce burden.
3. Partnerships and Sustainability committees must be selected and roles assigned.
4. Informatics team needs to be assembled.
5. Establish structured reporting system to hold all parties and committees accountable.
6. Come to consensus on the existing core set.
7. Develop methodology so that all ablation devices are equally a part of the coordinated registry network.

How can I get involved?

We need YOU:

- Become a part of the next generation of SPARED.
- We are actively recruiting volunteers to co-chair informatics, sustainability, and prioritization teams.
- Transform the next generation of medical device epidemiology into reality.
- For more information, please contact Dr. Helen Jiang at Hongying.Jiang@FDA.HHS.GOV.

References & Past Events

http://mdepinet.org/event/spared-workshop/
http://mdepinet.org/