



## Developing Studies for Prostate Ablation Related Energy Devices (SPARED)

### CRN Think-Tank Meeting

May 3, 2018

The Great Room, White Oak Campus, Silver Spring, MD



## AGENDA

<b>8:00-8:50</b>	<b>Registration</b>	<b>Presenter/Affiliations</b>
<b>8:50-9:00</b>	<b>Welcome and Introductions</b>	Benjamin Fisher, <i>FDA</i> Jim Hu, <i>WCM</i>
<b>Update on CRNs and SPARED</b>		
	<i>Moderator:</i> Benjamin Fisher, <i>FDA</i>	
9:00-9:20	CRN Community of Practice	Art Sedrakyan, <i>WCM</i> Danica Marinac-Dabic, <i>FDA</i>
9:20-9:30	Overview and update on SPARED CRN	Jim Hu, <i>WCM</i>
9:30-9:45	FDA Update (Current and future regulatory perspectives)	Charles Viviano, <i>FDA</i>
9:45-10:00	Q/A Discussions	
<b>10:00-10:15 Break</b>		
<b>Update on Core Data Elements, Collection, and Sharing</b>		
	<i>Moderator:</i> Art Sedrakyan, <i>WCM</i>	
10:15-10:25	Data Sharing	Jim Hu, <i>WCM</i>
10:25-10:30	REDCap Data Collection Tool (online demo)	Molly Nowels, <i>WCM</i>
10:30-11:00	Core Data Elements (Logistics of data collection, etc.)	James Wysock, <i>NYU</i> Michael Gorin, <i>JHU</i>
<b>SPARED Industry Partners - New Partners</b>		
11:00-11:10	Cryo On-Line Database (COLD) Registry	John Eberts, <i>Healthtronics</i>
11:10-11:20	TULSA-PRO Prostate Ablation	Mathieu Burtnyk, <i>Profound Medical</i> Goldy Singh, <i>Profound Medical</i>
11:20-11:30	European PGA Data Framework	Roland Van Velthoven, <i>Koelis</i>
11:30-11:40	Fighting Cancer with NanoTHERm therapy	Larry Kessler, <i>MagForce</i> David Hammond, <i>MagForce</i>
11:40-11:45	Q/A Discussions	

## 11:45-12:00 Working Lunch

### Existing Industry Partners

12:00-12:15	EDAP TMS	Hugo Embert, <i>EDAP</i>
12:15-12:30	SonaCare Medical HEAT Registry Update	Mark Carol, <i>SonaCare</i>

### Informatics contribution

*Moderator:*

Charles Viviano, *FDA*

12:30-1:00	Standard Data Capture	Terrie Reed, <i>FDA</i> Behnaz Minaei, <i>FDA</i>
1:00-1:15	Q/A Discussions	

## 1:15-2:45 Sub Committee Discussions

### Partnership & Sustainability

Topics, Partnership & Sustainability Industry and Societies

- Contracts, DUAs, BAAs, potential partnerships for funding

*Moderators/Co-chairs:*

Fernando Bianco, *URNC*

Jim Hu, *WCM*

### Clinical Informatics – Room 1504

Topics, Clinical Informatics – informatics people to join here

- Finalize the core minimum data definitions, informatics solutions on data collection, implementation and sharing.

*Moderators / Co-chairs:*

Michael Gorin, *JHU*

James Wysock, *NYU*

### Topics, both groups:

- Members self-introduction
- schedule regular meetings
- define group deliverables
- propose milestones/timelines

## 2:45-3:00 Sub Committee Reports

### 3:00-3:15 Closing Remarks – action items for next Phase

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| <ul style="list-style-type: none"><li>• Summarize Visions and Expectations for this CRN</li><li>• Set Milestones and Timelines for the Next Phase</li></ul> | Charles Viviano, <i>FDA</i> ,<br>Jim Hu, <i>WCM</i> |
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