



SOC Research Projects Update

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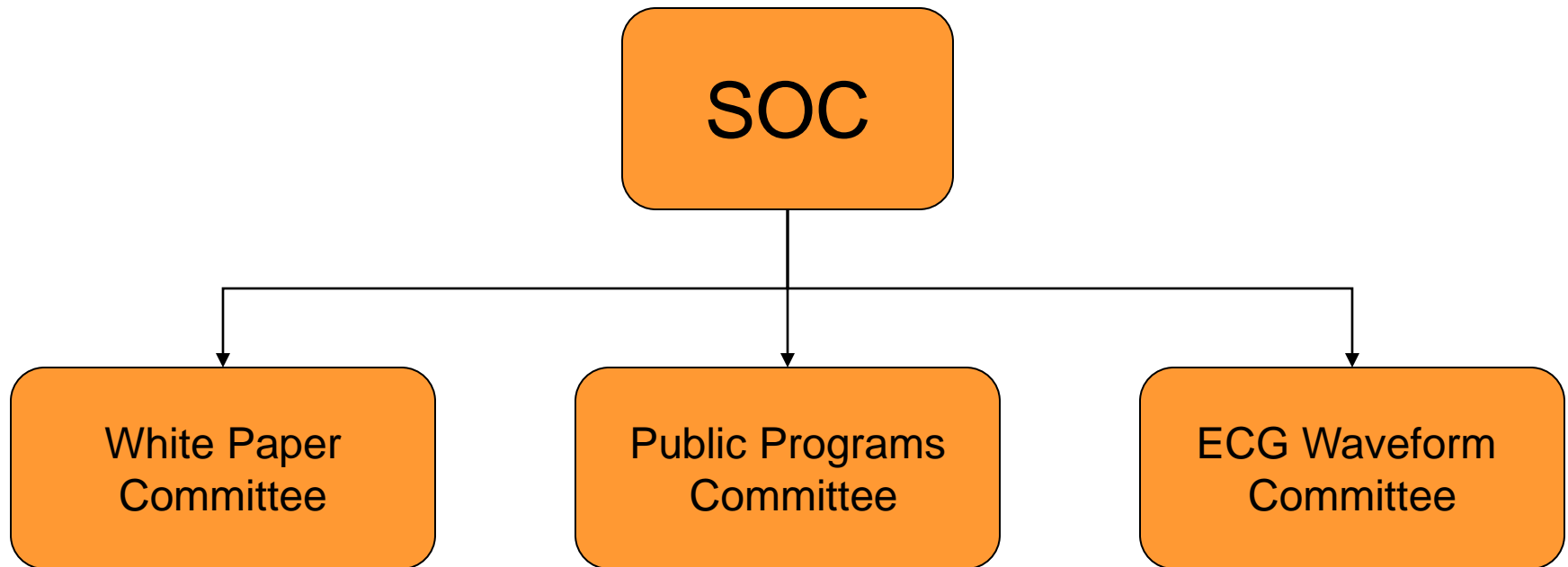
Office of the Chief Scientist

FDA

SOC Membership

- Benjamin Eloff, PhD – FDA (co-chair)
- Ignacio Rodriguez, MD – Roche (co-chair)
- Paul Kligfield, MD, FACC – Weill Medical College, Cornell University
- Philip Sager, MD, FACC, FACP, FAHA – Pharmaceutical Consultant
- Thomas Todaro, MD, JD, FACC, FCLM – Medpace
- Borje Darpo, MD, PhD – Pharmaceutical Consultant
- Peter R. Kowey, MD, FACC – Lankenau Hospital and Medical Research Center
- Wojciech Zareba, MD, PhD, FACC, FESC – University of Rochester Medical Center
- Marcia Yaross, PhD – Biosense Webster
- Norman Stockbridge, MD, PhD – FDA
- Eric L. Michelson, MD, FACC – AstraZeneca
- Gary Gintant, PhD – Abbott Laboratories

Scientific Oversight Committee



CSRC Research Projects

- Dual Anti-Platelet Therapy (DAPT) trial
- Safety of Atrial Fibrillation Ablation Registry Initiative (SAFARI)
- Study of Access site For Enhancing Percutaneous Coronary Intervention for Women (SAFE-PCI for Women)
- FDA JANUS databases for T2DM
- Cardiac Troponin Biomarker Development
- ECG Warehouse

DAPT Today

- Started with FDA AC meeting 2006
- 3 CSRC think tank meetings 2006-08
- Funding of \$120M contributed by 6 industry sponsors and NIH
- International trial coordinated through Harvard Clinical Research Institute
- Enrollment began October 2009
- 20,000 patients (15k DES + 5k BMS) planned
- 4 year estimated trial duration

DAPT lessons

- Public-private partnerships provide an ideal setting for addressing large-scale public health issues
- Regular open communication provides pathways for consensus and collaboration among otherwise competing entities
- Developing the business model and its fine details is a difficult but vital step

Safety of Atrial Fibrillation Ablation Registry Initiative (SAFARI)

- ~50,000 ablation procedures performed per year for AF in US
- Rapidly evolving technique & technology
- Scientific studies supporting use of ablation in medical practice
 - Small (~300 pts or less)
 - Short (12-month follow-up)
 - Narrow (predominantly younger, healthy population, little structural disease, mostly PAF)
 - Performed at centers of excellence
- Unclear picture of real-world patient expectations
- FDA postmarket surveillance challenging with off-label use

SAFARI Today

- 2 Think Tank meetings: April 2009, January 2010
- 2 whitepapers published
- Management transferred to ACC for eventual incorporation into NCDR registry family
- Currently developing detailed business plan to support full registry development

SAFE-PCI for Women

- Bleeding and vascular complications are a major issue for PCI procedures and are associated with increased morbidity and mortality
- Women are at increased baseline risk of bleeding
- Trans-radial access vs. femoral access observed to have fewer (50-60%) complications, but radial procedures performed less often in women
- Hypothesis: “Compared with the femoral approach, the radial approach to PCI in women superior with respect to bleeding and vascular complications and non-inferior with respect to procedural failure”

SAFE-PCI for Women

- \$5M raised from 6 sponsors, FDA, and NIH
- 3000 women to be randomized to femoral-access or radial access PCI
- Enrollment begun September 2011
- Evaluate vascular complications at 24 hours and procedural failure
- Trial to be run in collaboration with ACC-NCDR, DCRI under NCRI program

JANUS T2DM Data

- JANUS project in process of translating 51 studies in T2DM population
- Project team assembled following diabetes think tank
- Currently working to refine research questions designed to provide a deeper understanding of population safety profile
- Published results will allow for smarter trial designs in the future

Cardiac Troponin Biomarker Development

Long term objective:

- To enable the efficient use of cTn as a cardiac safety biomarker in drug development.

Objective of this first proposal:

- To characterize inter-individual variability and time-course of cTn elevations in
 - Healthy volunteers confined to a typical CPU environment for a week or more (e.g. more than 7 days);
 - Patients with locally advanced or metastatic cancer with previous treatment(s) of interest.

Contact Nenad Sarapa, if interested

More?

- Ongoing discussions to develop new proposals
 - Here
 - Think tank meetings
 - White Papers
 - With partner organizations
- If you have a proposal, please submit it