

**Research Consensus Panel for the Development of a Research Agenda in
Peripheral Arterial Disease (PAD)
Marriott Hotel at the Newark Liberty International Airport
Teaneck, New Jersey
Thursday, April 10, 2008
9:00am – 3:00pm**

Meeting Agenda

To define a prioritized research agenda for PAD, including topics amenable to basic science/technology research, pilot clinical research, and multi-center clinical trials. This process will involve several steps:

PANEL DISCUSSION: Key aspects of the already-existing knowledge base for each research domain will be summarized by a panel member. A moderated discussion will be held to address the following questions for each domain:

1. What are the most important clinical questions that could realistically be answered now through pivotal multi-institutional clinical trials or registries?
2. What are the most promising future directions that merit pre-clinical or early clinical exploration in the field of PAD?
3. What critical alliances must be developed to advance the prioritized research, and how can SIR Foundation and CAIRR best support these initiatives?

PRIORITIZATION: Based upon the discussion, a summary list of potential research studies will be created. The panelists will rank the research projects in order of priority. The results will be compiled into a final rank list.

PROTOCOL DEVELOPMENT: The top-ranked research priority will be examined by the panel. A basic framework research protocol designed to address this question will be developed, with a strong focus on determining how to study the outcomes that are clinically meaningful.

9:00-9:30	Introduction & Meeting Goals	John Rundback, MD Stephen Kee, MD
9:30-9:40	Mechanical and unique biological considerations in the SFA and tibial arteries	Robert Smouse, MD
9:45-9:55	Medical therapy and exercise trials for PAD	Michael Jaff, DO
10:00 -10:10	Surgical bypass trials for SFA and tibial disease	Alan Lumsden, MD
10:15 -10:25	Completed and ongoing Level I/II device trials	Barry Katzen, MD
10:30-10:40	Proteomics and serologic surrogates for PAD Trials	Jeffery Olin, MD
10:45-10:55	Imaging surrogates for PAD trials	Robert Lookstein, MD
11:00-11:10	Emerging and future technologies for PAD	John Rundback, MD
11:15-11:25	Regulatory objectives and outcomes measures for PAD trials	David Buckles, PhD

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| 11:30-11:55 | Research priority discussion – Panelists review and consolidate topics |
| 12:00-1:00 | Topic Ranking Instructions, Panelists Rank Topics & Lunch
(Scores are Collected, Talled, and Entered on Screen) |
| 1:00-1:30 | Discussion of Topics |
| 1:30-3:00 | Study design/protocol development for pivotal study |
| 3:00 | Summary and meeting conclusion |

PANEL MEMBERS

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Meeting Methodology

PAD Research Presentations and Discussion

- Introduction and meeting goals
- Presentations
- Panel discussion – each panel member discusses their view of the pressing needs in cardiovascular imaging research (two rounds around the table).

Determining Research Priorities

- Each panelist and audience member writes down ONE or TWO clinical priorities and ONE basic science priority, option to write down ONE organizational priority if they have one to suggest.
- Panelist priorities are written on screen during break
- Panel reviews all of the submitted priorities and makes effort to consolidate/combine priorities
- Panel agrees to any combinations that are made
- Priorities are copied and circulated to panelists and audience for voting.
- Scores are tallied, ranked and viewed by everyone on screen

Resolving Ties

- If there are two priorities that are closely tied, two protocol summaries are developed (details below)
- If there are three or more priorities that are closely tied, the closely tied priorities are circulated to the panel on a piece of paper for another round of weighted voting.
- The scores and rankings are viewed by everyone on screen
- (This process continues until one or two top priorities emerge)

Protocol Summary Development

Once one or two priorities are identified, the group begins to discuss the topic(s) seeking to address the following by the end of the meeting:

1. Why was this area identified as the top priority?
2. What is the public health significance in studying this area?
3. What is the basic structure of the study?