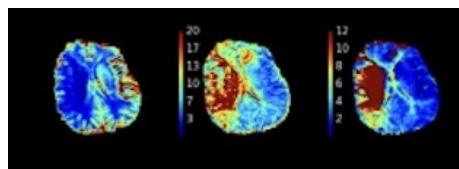


STAIR XII

Stroke Treatment Academic Industry Roundtable



March 21-22, 2023
Washington, DC

"Expanding the Scope of Stroke Treatment"

***New Perspectives on Clinical Trial Enrollment,
Patient Selection and Evolving Therapies***

Dear Colleague,

We invite you and your organization to participate in and co-sponsor STAIR XII entitled "*Expanding the Scope of Stroke Treatment.*"

We are pleased to announce that the much-anticipated STAIR XII Conference is planned and on track.

This is the only event of its kind. It offers a unique opportunity for you and your company to interact with the leading stroke drug, device and imaging research experts from across the globe as well as top FDA regulators and NIH/NINDS scientists. You will participate in improving trial designs, as well as participating in in-depth discussions of regulatory considerations.

Acute Stroke clinical trials are becoming more complex to design and conduct due to a number of factors. The expanded use of mechanical thrombectomy and the synergistic application of thrombolytics often results in reducing the subject pool for trial protocols. Patient selection criteria is now reflecting innovations in advanced imaging. Distinguishing the clinical trial agent/protocol efficacy vs. that of conventional therapy has become challenging. These and other factors have resulted in reducing patient accrual rates, extending the duration of trials and in some cases placed research programs in jeopardy of cancellation.

Added to the sophistication required to mount combined therapy reperfusion trials is the rigor necessary to conduct add-on cytoprotective studies of promising novel agents and innovative devices. As the treatment time window has opened significantly increasing the number of patients eligible for treatment, the opportunity to add protection before, during and after reperfusion is being explored more intently than ever before and is redefining the acute stroke clinical trial landscape.

Taken together, these factors require new strategies, original study designs, insightful protocols, enlightened analytical regimens and applied clinical rigor to fulfill patient enrollment and achieve trial completion. This new frontier raises important questions, poses unique challenges and presents new opportunities to the stroke research, development and treatment communities.

These elements and others that have created the evolving stroke therapy development landscape will be examined at STAIR XII by presenters and participants. Consequently, we are confident that this will be the most influential STAIR conference to date.

True to the STAIR model, via a facilitated consensus process, participants will develop recommendations covering the most compelling and timely questions facing the field today. The final manuscripts containing these consensus statements will be published in the journal *Stroke*. Participants who so wish, will be listed as contributors in these publications.

STAIR XII provides a unique opportunity to address these issues by assembling experts from three sectors:

- 1) Pharmaceutical and device industry leaders and those entering or expanding into the arena
- 2) Federal regulators and NIH scientists, and
- 3) Outstanding stroke academicians from around the globe to participate in rigorous in-depth scientific presentations and discussions of these issues.

We have already confirmed the participation of over 50 of the world's top academic stroke medical center thought leader researchers as well as senior FDA drug (CDER) and device (CDRH) regulators plus a strong contingent from NINDS/NIH.

The STAIR Consensus Conferences are unique in several ways:

- Participants candidly address critical issues from a multidimensional perspective to a depth and degree that is unparalleled in the stroke field
- Large blocks of time are reserved for discussion including presenters, expert panels and the audience
- On the second day of the meeting, we conduct a consensus process which results in recommendations intended to improve stroke therapy R&D as well as clinical application of new approaches
- All conference participants are invited to engage in this collaborative process producing draft consensus statements which are refined by writing committees and submitted to the journal *Stroke*
- All STAIR attendees are given the opportunity to review and comment on the drafts prior to submission
- Every STAIR participant is given the opportunity to be listed as a *contributor* in the publication

All of the previous consensus documents produced by STAIR Conferences I through XI have been published in the journal *Stroke*. The widely referenced STAIR recommendations serve as guidance and benchmarks for the stroke therapy development process.

The STAIR XII theme is:

"EXPANDING THE SCOPE OF STROKE TREATMENT"

New Perspectives on Clinical Trial Enrollment, Patient Selection and Evolving Therapies

The five main conference sessions will address the following critical concerns:

1. **"Acute Stroke Trials: New Data, New Landscape, New Approaches - Part 1"**
2. **"Acute Stroke Trials: New Data, New Landscape, New Approaches - Part 2"**
3. **"How to Enhance Enrollment and Patient Selection in Clinical Trials"**
4. **"Intravenous Thrombolysis / ICH Therapy"**
5. **"Regulatory Perspectives on Key Clinical Trial Issues – FDA; CDER & CDRH"**

Location, Dates and Next Steps

The meeting will be held in the Washington, DC area on March 21st and 22nd of 2023. We will send you specific lodging and conference details when we receive your sponsorship.

We ask you to please complete and return the attached sponsorship form so we may reserve seats at the conference for you and your team members.

Sponsorship and Registration

As before, we are inviting the enthusiastic financial support of the pharmaceutical, device and imaging industries to sponsor this important conference. We receive no federal funding and are fully dependent upon private sector sponsorship to mount and conduct STAIR.

Your sponsorship serves as your registration and provides your organization with a number of seats at the meeting according to your sponsorship level. Your support will help to cover conference-related expenses including; travel, honoraria and lodging for our approximately 50 academic speakers, conference food and beverage for all participants as well as publication development. We are inviting companies to send up to eight representatives to the conference to participate in the discussions and the consensus development process.

STAIR XII Sponsorship/Registration Tiers

<u>Leadership Level</u>	<i>Leading Pharmaceutical, Device and Imaging Companies</i>	\$35,000
Company is invited to send up to eight representatives		
<u>Enterprise Level</u>	<i>Major Pharmaceutical & Device Companies</i>	\$20,000
Company is invited to send up to five representatives		
<u>Mezzanine Level</u>	<i>Start-ups and Smaller Companies</i>	\$10,000
Company is invited to send up to two representatives		

Please complete and return the enclosed Sponsorship Confirmation and Registration form by November 1, 2022 to Gary Houser at: tsghouser@aol.com

If you have questions, please don't hesitate to contact us via email at: tsghouser@aol.com or galbers@stanfordhealthcare.org

The STAIR XII Preliminary Program and a Sponsorship Registration form are attached.

We look forward to your response and participation.

Sincerely,

Greg Albers, MD
Stanford University
STAIR XII Chairman

Marc Fisher, MD
Harvard Medical School
STAIR XII Vice Chair

Gary Houser
The Stroke Group
STAIR XII Coordinator
tsghouser@aol.com

STAIR MISSION STATEMENT

The STAIR Consensus Conferences, via a collaboration of medical academia, the healthcare industry and government agencies, are intended to advance and accelerate stroke research to ultimately result in improved stroke acute treatment, care and prevention.

To achieve this goal, STAIR will:

- *Develop new approaches to overcome barriers impeding stroke drug and device development*
 - *Identify, clarify and communicate the implications of new research to the stroke field*
 - *Publish the consensus recommendations of STAIR participants which address these concerns*
 - *Promote adoption of STAIR recommendations by research, industry, clinical and government communities*
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