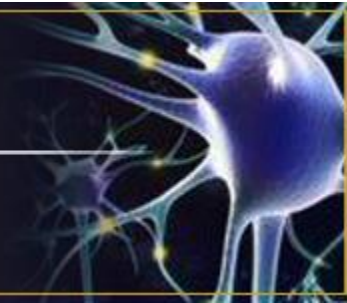


STAIR CONSENSUS CONFERENCES

Stroke Treatment Academic Industry Roundtable



- **8:00 – 8:15 MISSION, GOALS AND OBJECTIVES OF STAIR IX**

STAIR IX Chairman: Greg Albers

- **8:15 – 10:15 SESSION 1: ACUTE STROKE TRIALS: NEW DATA, NEW LANDSCAPE, NEW DESIGNS** *Session Chairs: Marc Fisher and Jeff Saver*

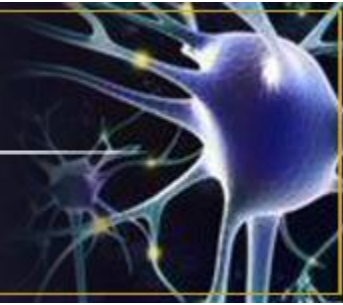
Update on endovascular trial results – *Diederik Dippel, Michael Hill, Jeff Saver, Bruce Campbell, Tutor Jovin, Pooja Khatri*

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ROUNDTABLE PANEL DISCUSSION: Chairs, Speakers, *Peter Rasmussen, J Mocco, Raul Nogueira, Pat Lyden, Sam Zaidat, and FDA and Industry Representatives*

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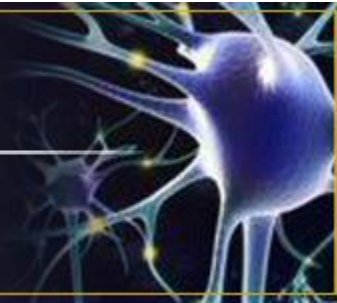


Welcome to STAIR IX

Greg Albers
STAIR IX Chairman

STAIR CONSENSUS CONFERENCES

Stroke Treatment Academic Industry Roundtable



Unique long standing collaboration: Academic, Industry, FDA, NIH

Founded by Marc Fisher and Gary Houser

1st Conference, 1999: Prompted by failures of multiple clinical trials of neuroprotective agents

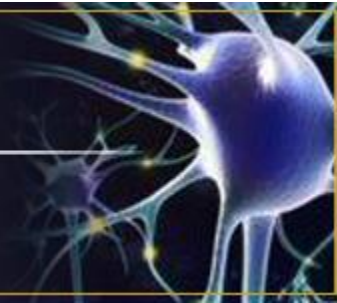
8th Conference, 2013: **Special Report** Recent failure of 3 randomized endovascular trials

Recommendations for Standards Regarding Preclinical Neuroprotective and Restorative Drug Development

Stroke Therapy Academic Industry Roundtable (STAIR)

STAIR CONSENSUS CONFERENCES

Stroke Treatment Academic Industry Roundtable



STAIR Goal *Improve clinical trial methodology by optimizing: preclinical evaluation, study design, patient selection, outcome assessment, collaborations between stakeholders* **Not to rewrite treatment guidelines!**

STAIR Process 5 Sessions on Day 1; 3 Workshops on Day 2;
3 published manuscripts within 9 months

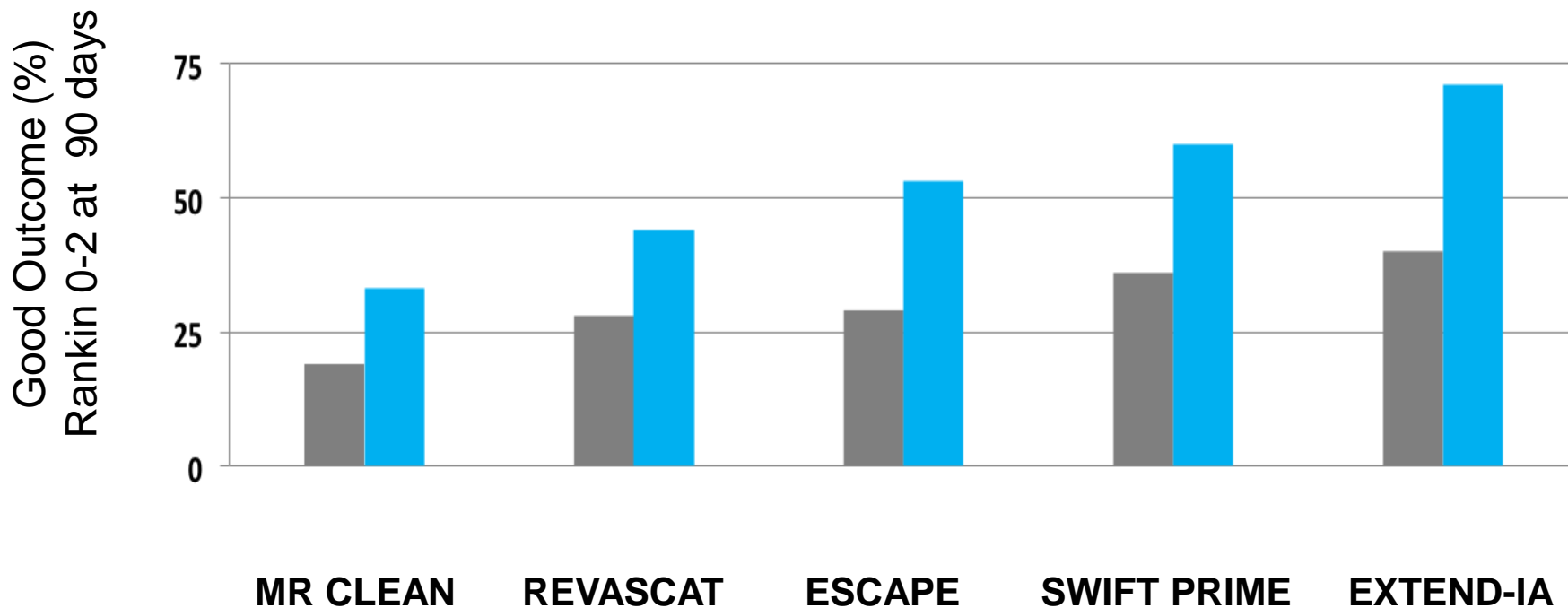
Stroke Treatment Academic Industry Roundtable Research Priorities in the Assessment of Neurothrombectomy Devices

Jeffrey L. Saver, MD; Tudor G. Jovin, MD; Wade S. Smith, MD; Gregory W. Albers, MD;
for the STAIR VIII Consortium

Background and Purpose—The goal of the Stroke Treatment Academic Industry Roundtable (STAIR) meetings is to advance the development of stroke therapies. At STAIR VIII, consensus recommendations were developed for clinical trial strategies to demonstrate the benefit of endovascular reperfusion therapies for acute ischemic stroke.

Summary of Review—Prospects for success with forthcoming endovascular trials are robust.

New Randomized Clinical Trials of Endovascular Therapy: *NEJM*, 2014/2015



Endo-vascular

33%

44%

53%

60%

71%

Control

19%

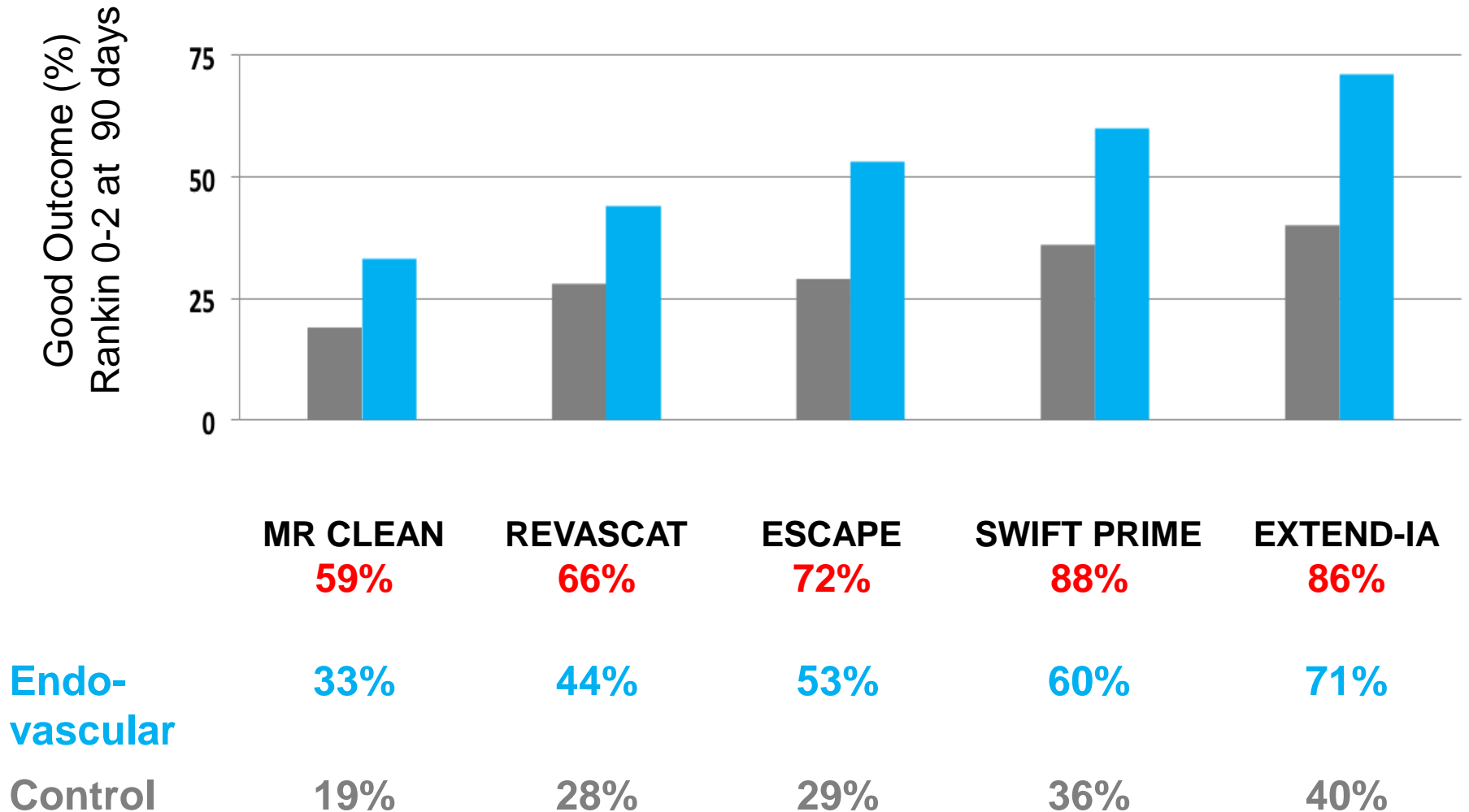
28%

29%

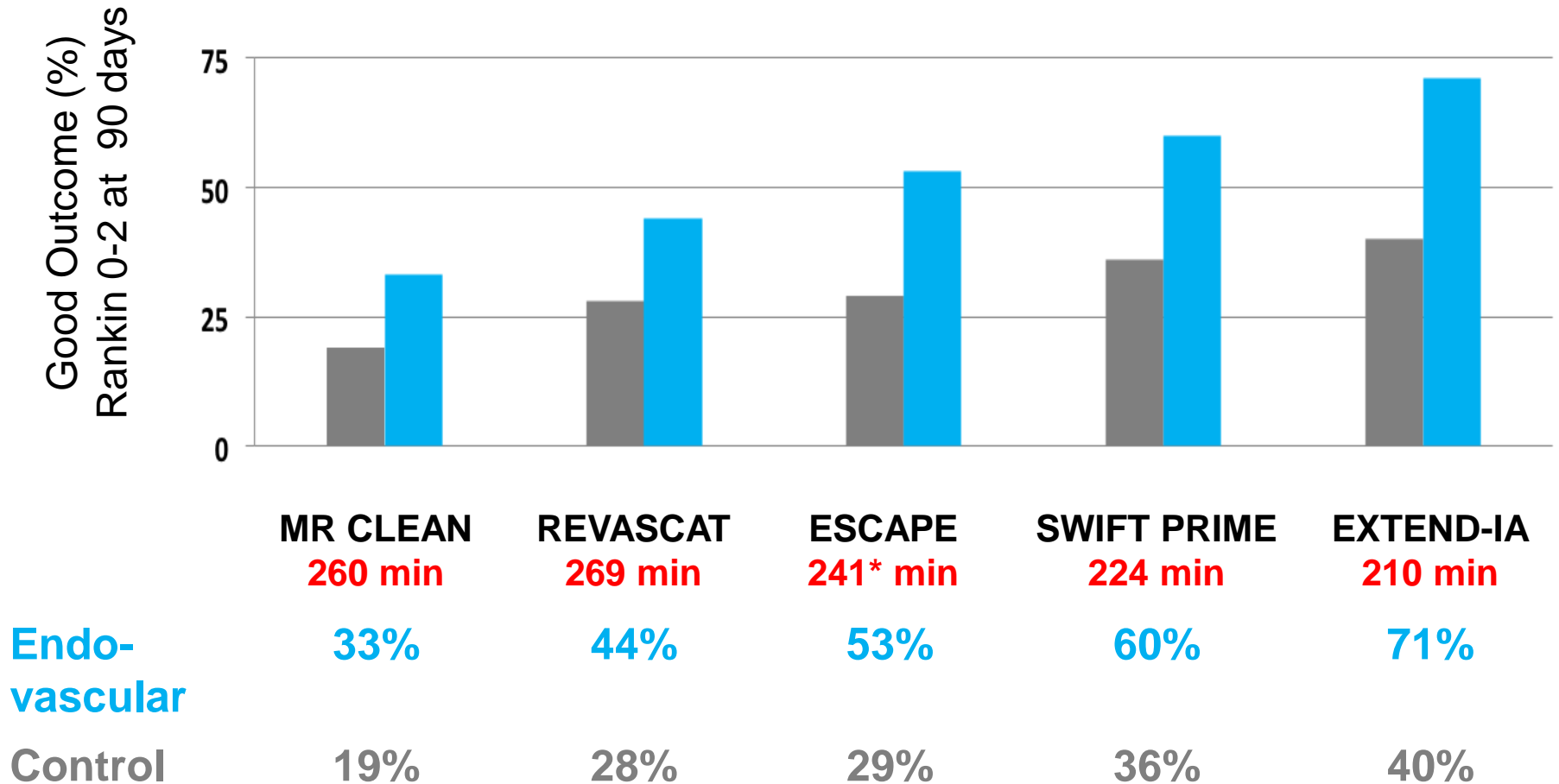
36%

40%

New Randomized Clinical Trials of Endovascular Therapy: **TICI 2b/3 rates**

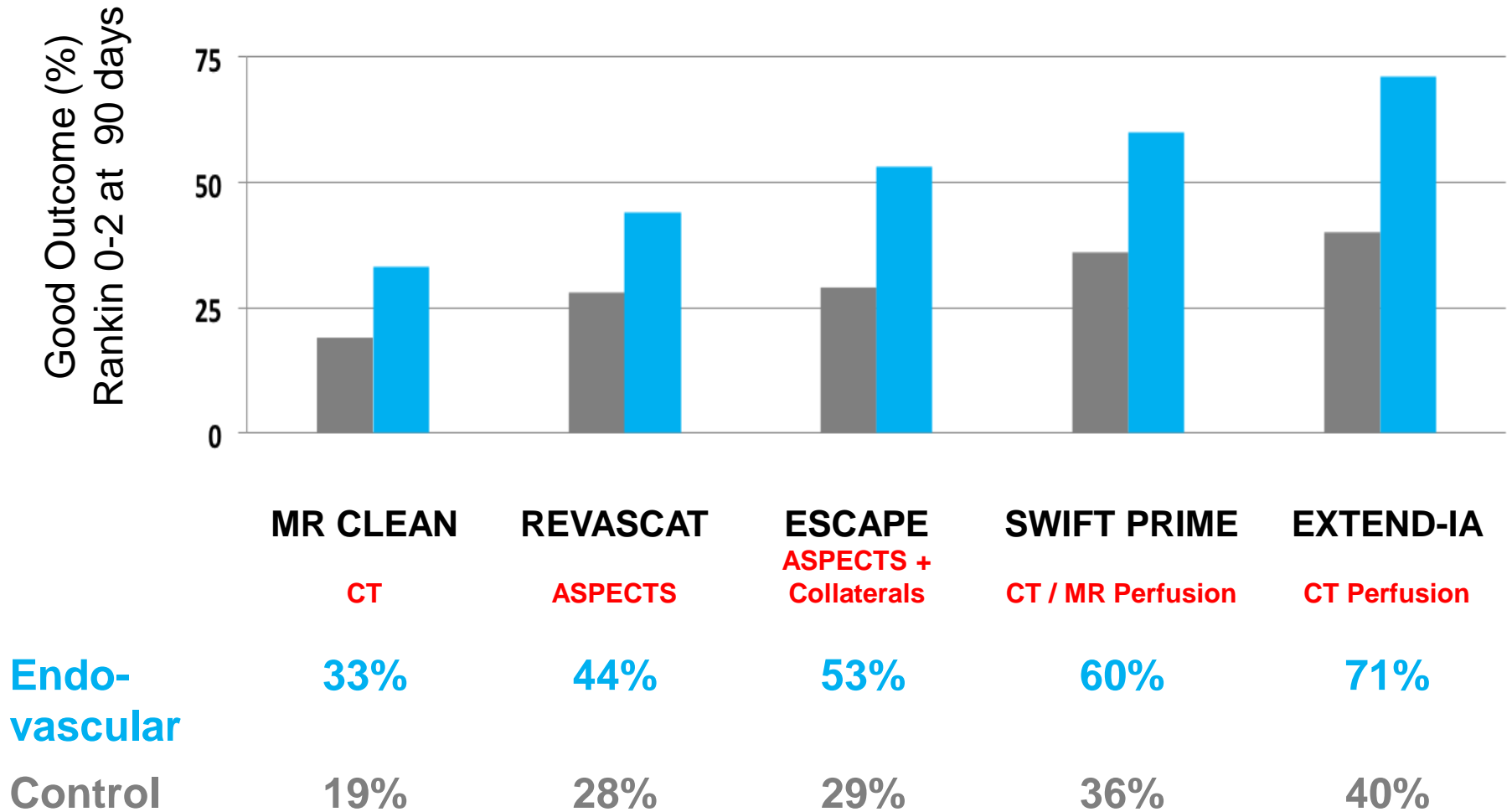


New Randomized Clinical Trials of Endovascular Therapy: Onset to femoral puncture

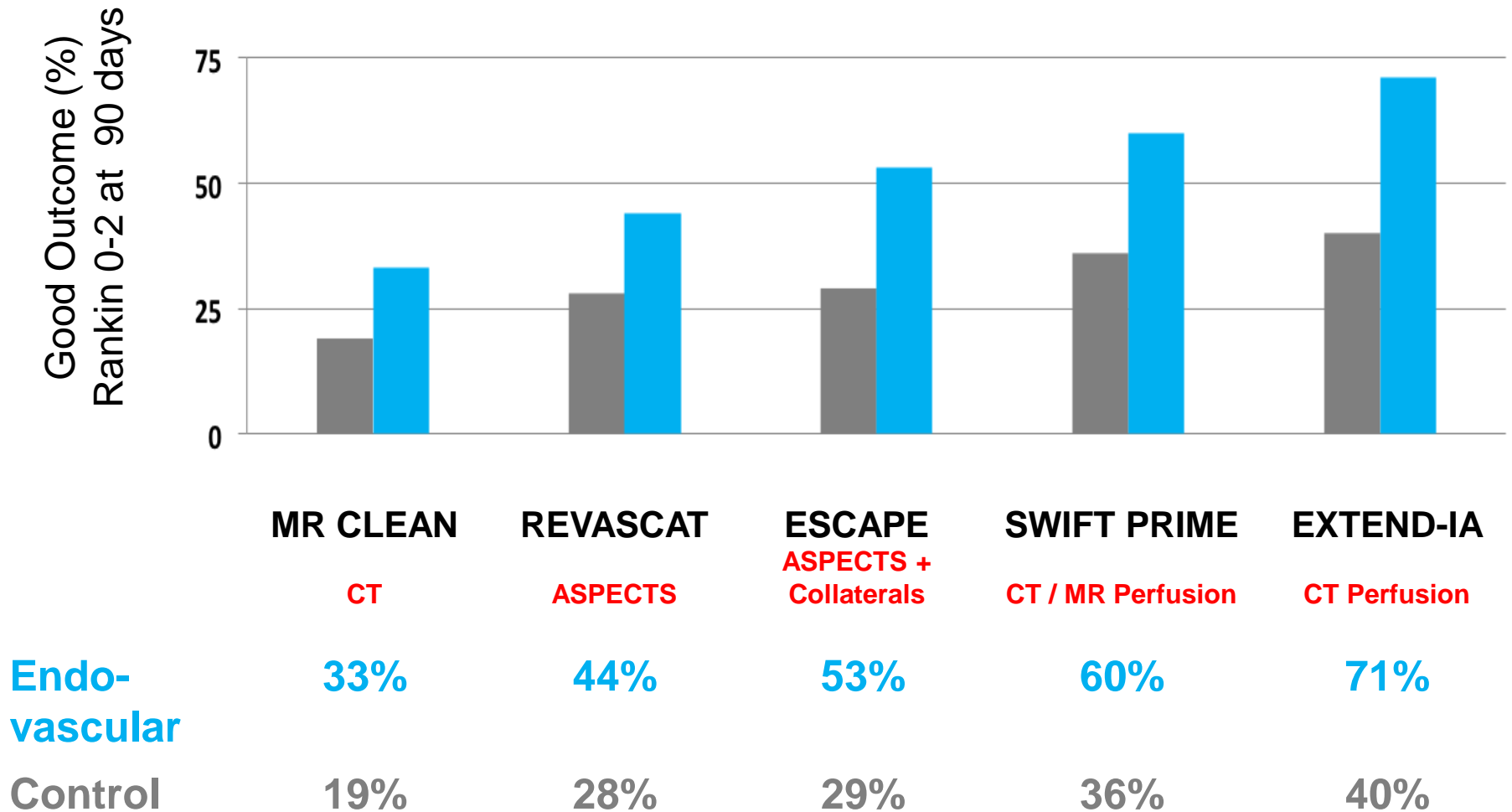


*Onset to 1st reperfusion

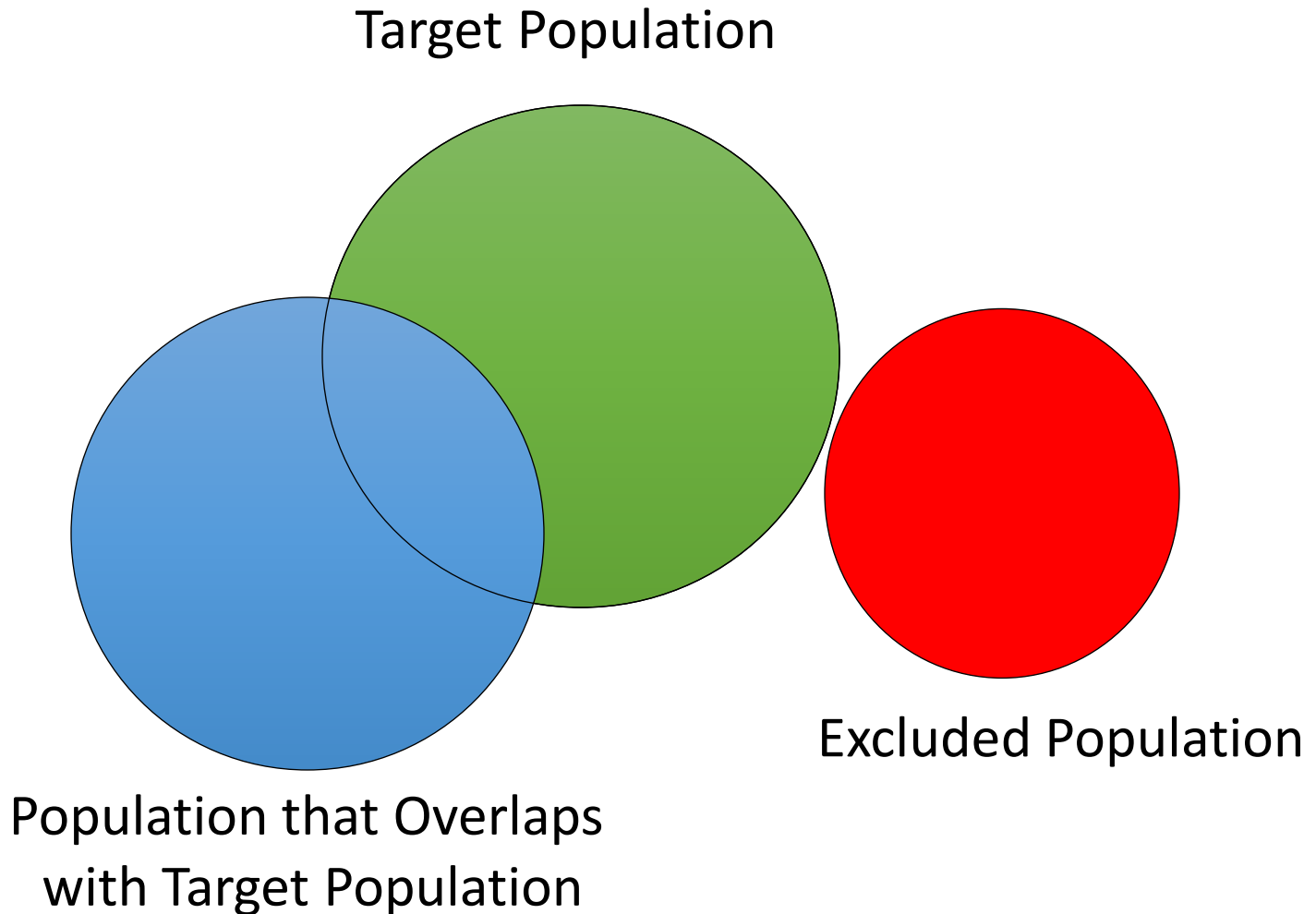
New Randomized Clinical Trials of Endovascular Therapy: **Imaging selection**



New Randomized Clinical Trials of Endovascular Therapy: **Imaging selection was not intended to identify all patients who benefit**

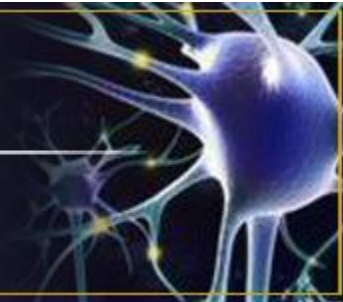


Interpretation of Results in Subgroups



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Stroke Treatment Academic Industry Roundtable



Role of the Stroke Imaging Research Investigators (STIR) at STAIR

Special Reports

Acute Stroke Imaging Research Roadmap II

Table 1. General Requirements for Imaging in Stroke Clinical Trials

Speed: In therapeutic trials, the benefits of additional imaging should be balanced against potential treatment delay; workflow should be optimized on the basis of best practice

Standardization: Acquisition parameters and perfusion post processing should be standardized (by common software processing at centers or centralized processing) and should conform to minimum, protocol-defined, common standards

Quality control: A well-defined image quality control process should be implemented to ensure that the predefined study imaging protocol is respected and to minimize the number of protocol violations

Reproducibility: If imaging is used to define patient selection then either a system for standardized central image processing and automated analysis, or appropriate training for neuroimaging raters at participating centers, should be undertaken. Imaging methods should have demonstrated acceptable interobserver and across-center reliability

Centralization: Central analysis of imaging outcomes should be conducted as the reference standard in multicenter trials. A system for standardized central image processing and interpretation, blinded to clinical information and local investigator decision, should be implemented

Welcome to STAIR IX

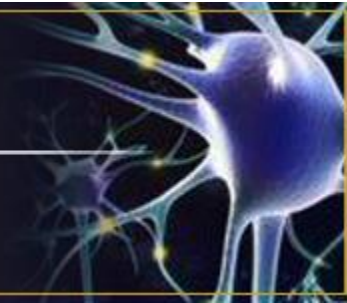
Thank you to our Sponsors, Max Wintermark / STIR, Carlos Pena and Billy Dunn / FDA, Gary Houser

Packed agenda, passionate opinionated participants, merciless session moderators will maintain order and time

Fasten your seatbelts and enjoy the meeting

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