

DCRI Think Tank Roundtable Meetings

1995 - 1999

1999

Pediatric Cardiovascular Trials

December 11-12, 1999

Directors: Stephen P. Sanders, MD, FACC,
Robert M. Califf, MD

[Introduction](#)

Am Heart J 2001; 142: 218-223

[Pediatric issues and diseases](#)

Am Heart J 2001; 142: 224-228

[End points for cardiovascular drug trials in pediatric patients](#)

Am Heart J 2001; 142: 228-232

[Ethical issues in pediatric trials](#)

Am Heart J 2001; 142: 232-236

International Differences in Treatment Effect

August 26, 1999

Directors: Robert Califf, MD, Christopher Granger, MD Magnus Ohman, MD Robert Harrington, MD

[A tale of two countries: Insights from the differences in Canadian/American patterns of care for patients with acute coronary syndromes](#)

Am Heart J 2001; 142(July): 14-20

[Statistical issues relating to international differences in clinical trials](#)

Am Heart J 2001; 142(July): 21-28

Acute Coronary Syndromes Conference

August 6-8, 1999

Director: Robert M. Califf, MD

Genetics of Cardiovascular Disease Conference

April 9-10, 1999

Directors: Christopher Granger, MD, Robert Califf, MD, William E. Kraus, MD, Allen Roses, MD

[Introduction](#)

Am Heart J 2000; 140: S1-S2

[Recommendations for national and local regulatory authorities concerning research in genetic markers of disease](#)

Am Heart J 2000; 140: S1-S5

[Ethical and legal issues in genetic testing to predict risk of heart disease](#)

Am Heart J 2000; 140: S6-S10

[Genetics of coronary heart disease: Current knowledge and research principles](#)

Am Heart J 2000; 140: S11-S26

[Genetic approaches for the investigation of genes associated with coronary heart disease](#)

Am Heart J 2000; 140: S27-S35

[Genetic analysis for common complex disease](#)

Am Heart J 2000; 140: S35-S44

[Genetic susceptibility to cardiovascular diseases](#)

Am Heart J 2000; 140: S44-47

[Genetics, genomics, proteomics: What is a cardiologist to do?](#)

Am Heart J 2000; 140: S48-S50

Antithrombotic Therapy After Prosthetic Cardiac, Valve Implantation

January 8-9, 1999

Am Heart J 2001; 142(July) 7-13

Director: Robert M. Califf, MD

1998

Data and Safety Monitoring: What are the rules?

October 8-10, 1998

Directors: Robert Califf, MD, David L. DeMets, PhD

[Should all trials have a Data Safety and Monitoring Committee?](#)

Am Heart J 2001; 141:154-163;

[Procedures of Data and Safety Monitoring Committees](#)

Am Heart J 2001; 141:289-294

[Making changes in clinical trials](#)

Am Heart J 2001; 141:295-300

[Statistical approaches and policies for the operations of Data and Safety Monitoring Committees](#)

Am Heart J 2001; 141:295-300

[Regulatory issues for Data and Safety Monitoring Committees](#)

Am Heart J 2001; 141:536-541

[Terms of reference for Data and Safety Monitoring Committees](#)

Am Heart J 2001; 141:542-547

[The Data and Safety Monitoring Committee: Some final thoughts](#)

Am Heart J 2001; 141:547-549

Guidelines for Therapeutic Development in Heart Failure

September 8-10, 1998

Director: Robert M. Califf, MD

Advanced Heart Disease

June 4-6, 1998

Directors: Robert Califf, MD, Mike Gheorghade, MD, Barry Uretsky, MD

[Hemodynamics as surrogate end points for survival in advanced heart failure: an analysis from FIRSAT](#)

AHJ 2001; 141:S154-S159

1997

What Is The Impact of Treating Type II Diabetes on Risk of Coronary Events?

November 21-22, 1997

Director: Robert M. Califf, MD

Paper – Introduction: Diabetes & Cardiovascular disease: Current Opinions & Future Directions - many papers in the Proceedings of a symposium

Am Heart J 1999; 138 (S327-S329 – Introduction; (S327-S416; 15 papers)

How Should We Design Phase II Trials in Cardiovascular Disease

October 2-5, 1997, Hilton Head, SC
Am Heart J 2000; 139 (April): S131-S210]
Directors: Robert M. Califf, MD, Kerry L. Lee, PhD

Introduction

Am Heart J 2000; 139 (April): S131-132

Current definitions of phases of investigation and the role of the FDA in the conduct of clinical trials

Am Heart J 2000; 139 (April): S133-135

Challenges in the conduct and interpretation of phase II (pilot) randomized trials

Am Heart J 2000; 139 (April):S136-S142

The role of clinical nonfatal end points in cardiovascular phase II/III clinical trials

Am Heart J 2000; 139 (April):S143-S154
Christopher M. O'Connor, Wendy A. Gattis, Thomas J. Ryan

Economic end points in phase II trials

Am Heart J 2000; 139 (April):S155-S157
Daniel B. Mark, Tracey A. Simons

Select-drop designs in clinical trials

Am Heart J 2000; 139 (April):S158-S160
Susan S. Ellenberg

Sample size and interim analysis issues for dose selection

Am Heart J 2000; 139 (April):S161-S165
Kerry L. Lee

Equivalence and noninferiority trials

Am Heart J 2000; 139 (April):S166-S170
Jay P. Siegel

Design and interpretation of equivalence trials

Am Heart J 2000; 139 (April):S171-S176
Thomas R. Fleming

Estimating the distribution of quality-adjusted life with censored data

Am Heart J 2000; 139 (April):S177-S181
Anastasios A. Tsiatis

Chronic ischemic heart disease

Am Heart J 2000; 139 (April):S182-S188
Michael Gent, Robert M. Califf

Acute ischemic heart disease

Am Heart J 2000; 139 (April):S189-S192
Christopher B. Granger, Allan Skene

Surrogate end points in cardiovascular disease trials

Am Heart J 2000; 139 (April):S193-S196
Thomas R. Fleming

An FDA perspective on antiarrhythmic drugs in phase II trials

Am Heart J 2000; 139 (April):S197-S199
Raymond Lipicky

The development of antiarrhythmic drugs

Am Heart J 2000; 139 (April):S200-S201
Lloyd Fisher

Current perspectives on the design of phase II trials of new drugs for the treatment of heart failure

Am Heart J 2000; 139 (April):S202-S206
Milton Packer

Design of phase II trials in congestive heart failure

Am Heart J 2000; 139 (April): S207-S210
David L. DeMets

Economics and Cost Effectiveness in Evaluating the Value of Cardiovascular Therapies

April 18-20, 1997, St. Petersburg, Florida
Directors: Robert M. Califf, MD, Daniel B. Mark, MD, MPH

Evaluating the economic implications of cardiovascular therapeutics

Am Heart J 1999; 137(May): S35-S144]

1996

Markers of Hemostasis and Platelet Activity in Acute Coronary Syndromes: Role in Drug Development and Patient Monitoring

December 7-9, 1996, Pinehurst, NC

Director: Robert M. Califf, MD

Introduction

Am Heart J 1998; 136 (October): S1-S6

Coagulation markers and outcomes in acute coronary syndromes

Am Heart J 1998; 136 (October): S7-S18

Pathobiology of thrombin in acute coronary syndromes

Am Heart J 1998; 136 (October): S19-S31

Glycoprotein IIb/IIIa inhibitors in acute coronary syndromes: Pathophysiologic foundation and clinical findings

Am Heart J 1998; 136 (October): S32-S42

Relation between inhibition of platelet aggregation and clinical outcomes

Am Heart J 1998; 136 (October): S43-S50

Progress in point-of-care laboratory testing for assessing platelet function

Am Heart J 1998; 136 (October): S50-S65

Management of Patients with Advanced Heart Failure II

October 18-19, 1996

Directors: Mihai Gheorghide, MD, Robert M. Califf, MD, Robert O. Bonow, MD

See below links.

Am Heart J 1998; 135 (June): S201-326

1995

The Importance of Myocardial Necrosis

December 2-4, 1995

Directors: Robert M. Califf, MD, Eric Topol, MD, Rick Kuntz, MD

Management of Patients with End-Stage Heart Failure I

October 20-21, 1995, Orlando, Florida; October 18-19, 1996, Palm Beach, Florida

Robert Califf, MD, Robert Bonow, MD, Mihai Gheorghiade, MD

[Introduction](#)

Am Heart J 1998; 135 (June): S201-S203

[Clinical definition and epidemiology of advanced heart failure](#)

Am Heart J 1998; 135 (June): S201-S215

[The pathophysiology of advanced heart failure](#)

Am Heart J 1998; 135 (June): S216-S230

[Current medical therapy for advanced heart failure](#)

Am Heart J 1998; 135 (June): S201-S248

[Current and novel pharmacologic approaches in advanced heart failure](#)

Am Heart J 1998; 135 (June): S249-S263

[Beyond drug therapy: Nonpharmacologic care of the patient with advanced heart failure](#)

Am Heart J 1998; 135 (June): S263-S284

[Outcomes and costs within a disease management program for advanced congestive heart failure](#)

Am Heart J 1998; 135 (June): S284-S292

[Optimizing therapy for complex or refractory heart failure: A management algorithm](#)

Am Heart J 1998; 135 (June): S293-S309

[Heart failure associated with preserved systolic function: A common and costly clinical entity](#)

Am Heart J 1998; 135 (June): S309-319

[Advanced congestive heart failure: What do patients want?](#)

Am Heart J 1998; 135 (June): S320-326