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(February): 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;  
Proceedings 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 Gheorghiade,  
MD, Barry Uretsky, MD  
Hemodynamics as surrogate end points for  
survival in advanced heart failure: an analysis  
from FIRST  
AHJ 2001; 141:S154-S154

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
Director: 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 Gheorghiade, 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
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): S249-S263

**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