

## Medical Development Group 2007/2008 Program Calendar



### ■ Forum Panels (Foley Hoag Emerging Enterprise Center, Waltham)

- 2007** Sept. 5 Medical Product Launch Strategies  
 Oct. 3 Future of Clinical Diagnostics  
 Nov. 7 Trends in Healthcare Policy: How They Will Affect the Medical Device Industry  
 Dec. 12 How to Identify and Interpret the Voice of the Customer
- 2008** Jan. 9 Successful Clinical Trial Strategies  
 Feb. 6 Getting Your Money Out: Harvesting and Preparing for Acquisition  
 March 5 Full Circle of Innovation — From Surgical Suite Invention to a Surgical Product  
 April 2 Driving Physician Adoption of New Products  
 May 7 Manufacturing Alternatives & Options for Commercialization: Turn Your Idea Into Something You Can Sell  
 June 4 What's New in Neuroscience and Neurotechnology

### ■ Networking Meetings (Pizzeria Uno, Newton Corner)

- 2007** Sept. 19 Small Business Innovation Research Grants  
 Oct. 17 Navigating Through GPOs and IHNs in Developing Contracts  
 Nov. 28 Painless Patenting  
 Dec. 19 HR Strategies for New Companies
- 2008** Jan. 23 Evidence-Based Medicine and Clinical Trial Design  
 Feb. 20 Alternative Financing Strategies  
 March 19 Value Proposition: Creating a Compelling Message  
 April 16 Alliances: How Small Companies Prosper with Larger Companies  
 May 28 IRB: Patient Protection in Clinical Research  
 June 25 Common Contracts Used in the Medical Device Industry  
 July 16 Case Study: Transitioning from Early Stage to Larger Company  
 Aug. 20 Transitioning to a Career in the Medical Device Industry

~~~~~  
 If you are interested in sponsorship opportunities,  
 please contact Mel Prenovitz at [mprenovitz@meddevgroup.org](mailto:mprenovitz@meddevgroup.org) or 617-738-6599  
 or David Kaufman at [dkaufman@meddevgroup.org](mailto:dkaufman@meddevgroup.org) or 617-345-6789.  
 ~~~~~

### ■ Upcoming Events

#### Jan. 23 Networking: Evidence-Based Medicine and Clinical Trial Design

Join us for a session that will provide suggestions for the practical application of Evidence-Based Medicine in clinical development, commercialization activities and timelines.

#### Feb. 6 Forum: Getting Your Money Out: Harvesting and Preparing for Acquisition

#### March 5 Forum: Full Circle of Innovation — From Surgical Suite Invention to a Surgical Product

A case study of NOTES demonstrates how all the players in the medical technology innovation game work together for mutual benefit. At this gathering, we will show how a physician's invention becomes a commercial product, how medical device companies get innovation ideas from their end users and how these new ways of collaboration are shaping the medical device industry.

## Successful Clinical Trial Strategies

January 9, 2008  
 Emerging Enterprise Center at Foley Hoag

### ■ Program Description

You know you have the next blockbuster product. Phase I & II trials were excellent; you passed with flying colors. Phase III failed. Why? Clinical trials are complex and can derail in so many ways. Companies invest millions of dollars conducting clinical trials and for those who only have one product in the pipeline, this outcome for a clinical trial could mean the end of the company.

The moderator will summarize the variables involved in setting up a clinical trial. Then, our expert panelists will discuss three major themes and how to avoid the stumbling blocks that can typically accompany them: 1) The sponsor, investigator, and patient perspective; 2) Trial design on setting up and analyzing the data; and 3) Patient and product liability.

### ■ Moderator

**Regina Au**, Strategic Marketing

### ■ Panelists

**Helen Colquhoun**, Founder and CEO, Pleiad Devices

**Marc Parham**, Founder and President, Interactive Analysis

**Tom Konopka**, Senior Vice President, Business Development & Marketing, Medmarc Insurance Group

### ■ January Forum Champion

**Eric Husgen**, HUB International New England, LLC

### ■ Agenda

- 5:30 – 6:15 Networking and light dinner  
 6:15 – 6:20 MDG announcements  
 6:20 – 6:35 Regina Au, Introduction of Topic and Panelists  
 6:35 – 6:55 Helen Colquhoun — Sponsor, Investigator, Patient Perspective  
 6:55 – 7:15 Marc Parham — Trial Design, Data and Analysis Perspective  
 7:15 – 7:35 Tom Konopka — Liability Perspective  
 7:35 – 8:10 Moderated Panel Discussion  
 8:10 Adjourn

### ■ MDG Mission

MDG's Mission is to contribute to the continuing development of medical devices and other medical technologies by enhancing the professional development of its members, fostering and supporting entrepreneurial thinking, serving as a forum for exploration of new business opportunities, and promoting best practices in enterprise management.

Please pre-register for MDG events.  
 For more information, visit [www.MedDevGroup.org](http://www.MedDevGroup.org).

■ **Biographies**



**Regina Au**

**Regina Au** is a senior marketing professional with extensive experience in the biotech, medical device and pharmaceutical industries. Her specialty is collaborating with companies to assess the potential for new products and services and then developing initiatives to help ensure a successful market launch. She brings a disciplined approach to conducting the deep analysis that leads to the setting of realistic objectives from which all effective marketing and sales initiatives flow. Her work often entails: determining market size and potential, conducting competitive intelligence, defining clinical differentiation, determining competitive advantages, and developing compelling positionings. Ms. Au honed her skills at some of the most successful companies in their respective industries: Merck & Co., Genzyme Corporation, The Clinipad Corporation, Radi Medical Systems and NMT Medical.



**Helen Colquhoun**

**Helen Colquhoun** holds degrees in genetics and medicine from the University of Edinburgh and spent several years practicing clinical medicine before entering the life science industry in 1988. Dr. Colquhoun began working in the pharmaceutical industry for a large U.S. company and her main responsibilities were drug development program management and pharmacovigilance. In 1995, she set up as an independent consultant and found that she spent increasingly more time working with medical device and drug delivery companies in the U.S. and E.U. In 1999, she co-founded Pleiad, a full-service clinical research organization specializing in clinical trials for medical device companies. Dr. Colquhoun is the CEO of Pleiad and has been based in the U.S. since 2003.



**Mark Parham**

**Marc Parham** is president of Interactive Analysis which is a consultancy that specializes in the uses of advanced computer simulations to understand how new pharmaceuticals fail in Phase III clinical trials despite promising early results in Phase II trials. For more than 12 years, Mr. Parham has analyzed unanticipated and often baffling results of failed clinical trials to uncover hidden problems with the protocol or related manufacturing specifications. As a result he has learned why early promising results are often not translated into successful drugs on the first attempt, but can be "rescued" with the proper analysis. Today, his focus is on applying the knowledge learned from numerous Phase III failures to help companies avoid similar failures going into Phase III trials. He uses a unique combination of prior knowledge and the client's own Phase II clinical data to accurately predict clinical outcome when clients propose changes in the clinical protocol or manufacturing specifications.



**Tom Konopka**

**Tom Konopka** is senior vice president, business development & marketing for Medmarc Insurance Group, the medical device industry-created underwriter of products liability insurance. During Mr. Konopka's 19 years at Medmarc, he has led the company's underwriting, loss prevention, sales and marketing functions. In these capacities, he has been responsible for developing business solutions that meet the evolving insurance and risk management needs of manufacturers and distributors of medical technology and life sciences industries. Among these are strategic alliances with The Hartford, a Fortune 100 company that provides business insurance which complements Medmarc's offering and BioMedic Insure, a France-based insurance service provider specializing in providing liability insurance for clinical trials conducted outside North America. A past president of the Washington, D.C., chapter of the Society of Certified Property and Casualty Underwriters, Mr. Konopka also holds a bachelor's degree in accounting and a master's degree in business administration.

■ **MDG Officers, 2007-2008**

President	Lisa Sasso	lsasso@meddevgroup.org
Vice President	Ed Berger	eberger@meddevgroup.org
Secretary	Joyce College	jcollege@meddevgroup.org
Treasurer	Jim Goell	jgoell@meddevgroup.org

■ **MDG Board of Directors, 2007-2008**

Board Member	Barbara Bix	bbix@meddevgroup.org
Board Member	Kevin Hahnen	khahnen@meddevgroup.org
Board Member	John Merhige	jmerhige@meddevgroup.org
Board Member	Bob Palladino	rpalladino@meddevgroup.org
Board Member	Eleanor Repetto	erepetto@meddevgroup.org
Board Member	Jerry Shapiro	jshapiro@meddevgroup.org
Board Member	Marty Sklar	msklar@meddevgroup.org

■ **MDG Committee Chairs, 2007-2008**

Programming	Olga Taylor	otaylor@meddevgroup.org
Networking	Regina Au	rau@meddevgroup.org
Membership	Brian Shoemaker	bshoemaker@meddevgroup.org
Marketing	Judy Isaacson	jisaacson@meddevgroup.org
Sponsorship	Mel Prenovitz	mprenovitz@meddevgroup.org
Sponsorship	David Kaufman	dkaufman@meddevgroup.org
Alliances	Alan Kivnik	akivnik@meddevgroup.org
Alliances	Olga Cherniavsky	ocherniavsky@meddevgroup.org
Operations	David Miller	dmiller@meddevgroup.org

■ **MDG Volunteers, 2007-2008**

Dianne Grattan, Programming  
 Richard Halpern, Programming  
 Eric Peterson, Web Site Calendar  
 Mike Toomey, Publicity

***We are always looking for volunteers to help make our forums and networking successful. Please email the chairperson above if you would like to get involved with MDG.***

■ **MDG Alliance Partners**

128 Innovation Capital Group	www.128icg.com
Beacon Alliance	www.beaconalliance.org
C-Net Boston	www.boston-consult.com
E-Net Boston	www.boston-enet.org
MIT Enterprise Forum	www.mitforumcambridge.org
Merrimack Valley Venture Forum	www.mvvhf.org
North Shore Technology Council	www.nstc.org
WPI Venture Forum	www.wpiventureforum.org
Women Entrepreneurs in Science and Technology	www.westorg.org