

6th National Conference on

MANAGING LEGAL RISKS IN  
STRUCTURING & CONDUCTING

EARN  
CLE  
ETHICS  
CREDITS



# CLINICAL TRIALS

FEBRUARY 27-28, 2007 • ROOSEVELT HOTEL • NEW YORK CITY

Distinguished Co-Chairs:



**Charlene A. Gallagher**  
Division Counsel, Vaccines  
Wyeth Pharmaceuticals



**Aaron Rodriguez**  
Senior Legal Counsel  
Medtronic, Inc.



**Keith M. Korenchuk**  
Of Counsel  
Covington & Burling LLP

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- **NEGOTIATE** and **DRAFT** key CTA terms that minimize risk
- **ENSURE** properly structured recruitment incentives
- **ASSESS** the impact of legislative proposals on existing registries and databases
- **EVALUATE** the government's authority to require Phase IV studies
- **IDENTIFY** and **MINIMIZE** litigation risks of adverse event reports
- **PAVE** the way for new guidelines on adaptive clinical trials

**Plus!** Intensive 1-day Master Class on:

Managing Legal Risks in Structuring & Conducting

## INTERNATIONAL CLINICAL TRIALS

March 1, 2007

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**Sandra B. Lyons**  
Senior Legal Contract Administrator  
King Pharmaceuticals Research and Development Inc.  
Delegate in 2006

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*The only event covering the complete clinical trials landscape...*

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Clinical trial exposures, liabilities, and risks have never been more daunting — or more real. The clinical trials provisions of recent proposed legislation will have a major impact on FDA authority to require sponsors to conduct Phase IV studies and maintain clinical trial registries. Recent and rampant litigation, including COX-2 trials, have led to increased demand for more transparency in the clinical research process. Questions still remain on the use, ethicality, and accuracy of adaptive trial design, especially after the FDA's announcement that it is taking steps to help facilitate these types of trials. In addition, penalties for noncompliance with proposed drug safety legislation are looming, and damage awards have never been higher. Finally, negative reports continue to flood the media and plague an industry which does not need more bad press.

**American Conference Institute's 6th National Conference on Managing Legal Risks in Structuring & Conducting Clinical Trials** was specifically designed to provide you with an intensive and thorough review of the critical issues that arise in ensuring proper management of your protocols, contracts, consents, and other documents. The distinguished faculty includes legal and compliance experts from pharmaceutical and medical device companies, CROs, and hospital and research institutions, as well as expert attorneys.

*...and which also allows you to navigate clinical trial issues in a global context*

Plus, ensure your conference experience is complete by attending our full-day master class on **Managing Legal Risks in Structuring & Conducting International Clinical Trials**. Given the globalization of clinical trials, this session will provide you with the tools necessary to ensure human subject protection in foreign subject populations, know the popular international choices for clinical trials and the regulations and "watch-out fors" in these areas, and effectively and efficiently negotiate and draft international clinical trial contracts.

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**WHO YOU WILL MEET**

- **Pharma, Medical Device and Biotech companies:**
  - **General Counsel**
  - **Regulatory Affairs**
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  - **Scientific Affairs**
  - **Compliance Officers**
  - **QA/QC Directors**
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- **Health Care Attorneys**
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This course has been approved in accordance with the NY requirements of the **NEW YORK STATE CONTINUING LEGAL EDUCATION BOARD** in the amount of 17.5 credits of which 1.0 will apply to ethics. An additional 7.0 credit hours will apply to master class participation.

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**AGENDA-AT-A-GLANCE**

	Day 1 – Tuesday, February 27	Day 2 – Wednesday, February 28	Master Class - Thursday, March 1
<b>Morning</b>	7:20 Registration & Breakfast 8:05 Chair's Opening Remarks 8:15 Ensuring Compliance in Clinical Trial Disclosures and Transparency 9:30 Reducing Liability Risks in Disseminating/Disclosing Clinical Trial Information and Results 10:25 Morning Coffee Break 10:40 Identifying and Minimizing Litigation Risks of Clinical Trial Data and Post-Market Adverse Event Reports 11:35 Paving the Way for New Guidelines on Adaptive Clinical Trials	7:30 Breakfast 8:05 Chair's Opening Remarks 8:15 Meeting Heightened Expectations as You Find, Recruit, and Maintain Participants and Sites 9:30 Deal Makers and Breakers When Negotiating Clinical Trial Agreements 11:00 Morning Coffee Break 11:15 Managing and Complying with Clinical Quality Obligations	8:00 Registration & Breakfast 8:30 Chair's Opening Remarks 8:45 Navigating Regulatory Issues in Both the Local and Home Offices: Factors to Consider From the Start 10:15 Morning Coffee Break 10:30 Addressing Variations in the European Regulatory and Legal Framework
<b>Afternoon</b>	12:35 Networking Luncheon 1:45 Reacting to Scrutiny of Clinical Trial Disclosures by the SEC 2:30 Steering Clear of Integrity Problems and Conflicts of Interest in Clinical Trial Research 3:35 Afternoon Refreshment Break 3:50 Building and Improving Partnerships and Alliances With CROs 4:50 Managing IP Rights and Patent Infringement Risks in Clinical Trials	12:00 Responding to FDA Inquiries Regarding the Conduct of Clinical Trials 12:45 Networking Luncheon 1:55 The Dos and Don'ts of Enrolling and Managing Unique Populations 2:35 Afternoon Refreshment Break 2:45 Tips, Traps, and Trends in Informed Consent and Secondary Research 3:55 Managing Patient Privacy and Security in Clinical Research	12:00 Networking Luncheon 1:10 Conducting Clinical Trials in Emerging Markets and Alternative Nations and Regions 2:30 Afternoon Refreshment Break 2:45 Negotiating and Drafting Key Terms in International Clinical Research Agreements that Put You at Risk

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## Day One: February 27, 2007

7:20 Registration & Breakfast ☞

8:05 Chair's Opening Remarks

**Charlene A. Gallagher**  
Division Counsel, Vaccines  
Wyeth Pharmaceuticals (Philadelphia, PA)

8:15 Ensuring Compliance in Clinical Trial Disclosures and Transparency

**Scott M. Lassman**  
Assistant General Counsel, Pharmaceutical Research and Manufacturers of America (PhRMA)  
(Washington, DC)

**Jude E. Walsh**  
Special Assistant, Governor's Office for Health Policy and Finance, State of Maine (Augusta, ME)

### Moderator:

**Erika King Lietzan**  
Partner, Covington & Burling LLP (Washington, DC)

- Meeting the demand for more transparency in the clinical research process
- Assessing the risks and benefits to all stakeholders of increased transparency through clinical trial registries and results databases
- Understanding current federal requirements, including section 113 of FDAMA
- Factoring in voluntary initiatives: PhRMA clinical trial registry policy and clinical study results database
- Assessing the impact of state laws that require registration of clinical trials and/or disclosure of clinical trial results, and identifying other state initiatives that you should monitor
- Staying current on federal legislative proposals (including the Enzi-Kennedy drug safety bill, S. 3807) and their potential impact on existing registries/databases
  - identifying other bills to monitor: what are the stakeholder concerns?
- What you need to know about the WHO initiative and the ICMJE requirements
- Thinking through compliance issues in a complicated international-federal-state-voluntary landscape
- Evaluating the impact of England's Duff Commission recommendations regarding Phase I trials
- Looking ahead to other issues on the horizon, including replacement of peer-review system by electronic databases and disclosure requirements for other FDA regulated products (medical devices, dietary supplements, OTC drugs...)

9:30 Reducing Liability Risks in Disseminating/ Disclosing Clinical Trial Information and Results

**Stuart Kim**  
Regulatory Counsel, Cephalon, Inc. (West Chester, PA)

**Ralph F. Hall**  
Counsel, Baker & Daniels LLP (Indianapolis, IN)

### **Disseminating Results: Appropriate Scientific Exchange or Product Promotion?**

- Defining the line between disclosures of study results that are appropriate scientific exchange and those that may be considered product promotion
- Disseminating results without engaging in illegal promotional activities
  - guidelines for posting outcomes on registries, and press releases and poster sessions on trial outcomes

- Disseminating scientific information without promoting an unapproved product: when is dissemination/disclosure scientific exchange and not promotion?
- Landmines and opportunities created by the Internet
  - ensuring that all information published by the company is accurate
  - assessing the impact of posting clinical trial data

### **Consequences of Disclosing Clinical Trial Information for Off-Label Uses**

- When is the dissemination/disclosure of off-label data not regulated as promotion?
- Avoiding having increased disclosure from trial registries constitute illegal off-label promotion
- Providing fair and balanced information on clinical trials involving commercial products while avoiding charges of off-label promotion
- Assessing liability risks associated with off-label clinical trials
- Responding to non-sponsored off-label trials
- Examining First Amendment implications of disseminating off-label clinical trial information

10:25 Morning Coffee Break ☞

10:40 Identifying and Minimizing Litigation Risks of Clinical Trial Data and Post-Market Adverse Event Reports

**Charlene A. Gallagher**  
Division Counsel, Vaccines  
Wyeth Pharmaceuticals (Philadelphia, PA)

**Joseph K. Hetrick**  
Partner, Dechert LLP (Philadelphia, PA)

- How plaintiffs are using clinical trial data in support of claims, and how you can use the data affirmatively
- Assessing your level of risk in post-marketing studies
- Extent to which government can order a company to do Phase IV post-approval studies
- Evaluating concerns that Phase IV studies are promotional and not bona fide
- Tracking and reporting serious adverse events: who should get the information and how quickly?
- Negating the evidentiary impact of adverse event reports
  - explaining limitations of the FDA adverse event reporting system
  - putting adverse event reports in context for the judge and jury
  - documenting positive outcomes: making your own record
  - the admissibility of adverse event reports

11:35 Paving the Way for New Guidelines on Adaptive Clinical Trials

**Steven E. Irizarry**  
Vice President of Government Relations  
ML Strategies, LLC (Washington, DC)

**Jerald S. Schindler, Dr.P.H.**  
President, Cytel Pharmaceutical Research  
(Cambridge, MA)

- Bracing for the impact of FDA moving forward with developing guidelines for adaptive clinical trials
- Early results on its impact on study length, study numbers, total number of participants, and the likelihood that participants will receive ineffective treatments
- Discussing ethicality and statistical accuracy of such studies
- Maximizing the information that is collected through adaptive clinical trials
- Using adaptive trial techniques to streamline the clinical data collection process

12:35

Networking Luncheon



1:45

### Reacting to Scrutiny of Clinical Trial Disclosures by the SEC

**Elizabeth P. Gray**  
Senior Counsel, **Foley & Lardner LLP (Washington, DC)**  
(former Assistant Director of the SEC Division of Enforcement)

- How FDA and SEC cooperation (Referral Process and Centralized Procedures) have affected scrutiny of clinical trial disclosures
- Complying with SEC reporting requirements pre- and post-approval
- Reconciling FDA/SEC disclaimer requirements
- Factoring in recent enforcement activities by the SEC and FDA
- Lessons learned from *ImClone*, *TKT*, *ICN*, and NY Executive Law 63(12)
- Disclosing clinical trial information that has been made available to the FDA but not publicly disclosed
- Determining what FDA actions to disclose and how to disclose them for accurate interpretation by the securities market
- Alleviating securities concerns: whether databank entries constitute "forward-looking statements" for investor reliance
- Controlling and monitoring material inside information and disclosing material facts to shareholders

2:30

### Steering Clear of Integrity Problems and Conflicts of Interest in Clinical Trial Research

**Karen A. Mullin, J.D., LL.M.**  
Boston University Medical Campus  
Office of Research Administration (Boston, MA)

**Kathleen McDermott**  
Partner, **Blank Rome LLP (Washington, DC)**

#### Conflicts

- Understanding when an interest poses a potential conflict
- Knowing the difference between an individual and institutional interest
- Increasing your focus on both individual and institutional conflicts of interest
- Clearly identifying roles and responsibilities to avoid financial conflicts of interest
- Managing conflicts so they don't create liability
- Developing a conflict of interest policy

#### Integrity

- How data quality problems can lead to FDA data integrity problems and concerns
- Preserving the integrity of trial data from an FDA perspective
- What you need to know about application integrity policies/integrity holds
- Factoring in recent developments in data integrity and reporting to registries

3:35

Afternoon Refreshment Break

3:50

### Building and Improving Partnerships and Alliances With CROs

**Colleen Cox, CCDM**  
Manager, Data Management  
**PROMETRIKA, LLC (Cambridge, MA)**

**Patrick Nealon**  
Senior Director, Clinical Research  
**Genzyme Corporation (Cambridge, MA)**

- What are the criteria used to select a CRO and who is involved in the decision making?

- Determining whether to use one or multiple CROs
- Understanding the role of a niche CRO
- Creating and maintaining positive and productive relationships with service providers
- Using the services agreement to anticipate and prevent areas where the relationship can sour
- Managing outsourced relationships: the challenges, benefits, and risks
- What you need to know about staffing changes, cancellation fees, and changes in scope when sponsors outsource their clinical trial activities to CROs and other specialized service providers
- Ensuring that the CRO and the sponsor speak the same language given that the same phrase can mean different things to different parties
- Helping CROs meet the challenges they face head on:
  - best communication practices
  - handling disputes and delays
  - matching changes in start up timelines with changes in final timelines
  - understanding scope of work and not making requests that are off scope
  - changing sponsor team members
  - factoring in delay in sponsor decisions, leading to overall delay in program
  - if using multiple providers, clearly defining expectations and responsibilities
- Determining who should be negotiating with sites, investigators and other third-party vendors

4:50

### Managing IP Rights and Patent Infringement Risks in Clinical Trials

**Jeffrey I.D. Lewis**  
Partner, **Patterson Belknap Webb & Tyler LLP (New York, NY)**

- Determining whether publication, filing patent applications, or raising capital are potentially infringing activities
- Determining what pre-clinical studies are within the safe harbor
- Using patented comparator compounds and patented research
- During clinical trials, determining what nullifies the safe harbor and what's within and outside the safe harbor
- Resolving issues with patient selection, "personalized medicine," and business method patents
- Recent developments with infringement suits during clinical trials, and strategic and legal considerations behind declaratory judgment actions

5:35

End of Day One

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ETHICS

## Day Two: February 28, 2007

7:30 Breakfast 🍳

8:05 Chair's Opening Remarks

**Aaron Rodriguez**  
Senior Legal Counsel, Medtronic, Inc. (Minneapolis, MN)

8:15 Meeting Heightened Expectations as You Find, Recruit, and Maintain Participants and Sites

**Mark Barnes**  
Partner, Ropes & Gray LLP (New York, NY)

**Austin B. Byrd**  
Vice President Ethics and Compliance  
Smith & Nephew, Inc. (Memphis, TN)

### Incentives

- The questions to ask sites while recruiting them
- Negotiating with sites and investigators on recruitment incentives and pricing/payment terms
- Determining whether sponsors can offer bonuses to investigators for recruiting
- Ensuring that payments or incentives to patients, investigators, non-investigator HCPs, or other third parties are properly structured to avoid fraud and abuse
- Determining fair market value for investigator and/or site payments
- Whether direct payments to participants can be considered coercive
- Latest on physicians receiving fees for referring patients as potential subjects for trials
- Ensuring compensation is in line with the actual work effort of investigators
- Structuring payments to a party other than the one actually performing the study

### Budgets

- Developing a budget and determining/documenting fair market value for data
- Establishing the nexus between the research agreement and the budget
- Starting up: Getting contracts and study budgets agreed upon and sharing contracts and budgets
- Balancing requests for up charges & larger fees for start up expenses with kickback concerns

### Billing

- Appropriate patient cost reimbursement provisions for a clinical trial agreement
- Effective & compliant trial billing: costs incurred during a trial that are reimbursable
- Services to be covered by the sponsor and those to be billed to the third-party payor (Medicare)
- The latest on groups urging CMS to avoid restrictions on Medicare-covered research

9:30 Deal Makers and Breakers When Negotiating Clinical Trial Agreements

**Elena Adolphus**  
Senior Corporate Counsel, Pfizer Inc (New York, NY)

**Catherine Horrigan, Esq.**  
Of Counsel and Head of Research Negotiations  
Team/Office of General Counsel  
Cleveland Clinic Foundation (Cleveland, OH)

**Christine Pierre, RN**  
President, RxTrials, Inc. (Ellicott City MD)

### Moderator:

**Jan E. Murray**  
Partner, Squire, Sanders & Dempsey L.L.P.  
(Cleveland, OH)

- Identifying the parties, including the CRO and the PI's relationship to the site
- Identifying and protecting ownership of IP and data, results, and conclusions
  - factoring in concerns of tax exempt bond-financed institutions
  - differences between investigator-initiated and sponsor-initiated agreements
- Confidentiality
  - how growing demands for transparency in clinical trials impact confidentiality
  - addressing the sponsor's responsibilities to shareholders, regulators, and public versus PI's responsibilities to patients, public, and sponsor
  - the appropriate balance between the need to keep clinical trial information confidential and the desire of investigators to publish data
- Publication
  - sample language for publishing rights
  - negotiating a reasonable publication strategy with academic sites
- Term and termination: what's the difference; what obligations survive; who can terminate and when; and what happens to the participants?
- Indemnification
  - appropriate indemnity and insurance provisions for clinical trial agreements
  - tying out indemnification clauses closely to appropriate risks
  - determining appropriate indemnification provisions in light of trial type (pre- and post-marketing studies)
  - who is indemnifying whom, and for what?
  - covering trial-related injuries in clinical trial agreements
  - other risk transference mechanisms: limitations of liability and vicarious liability
  - differences in investigator-initiated and sponsor-initiated trials
- Insurance: understanding and procuring clinical trial insurance and subrogation
- Planning for disagreements and handling disputes and delays: submitting to a governing law or jurisdiction and the impact of arbitration clauses

11:00 Morning Coffee Break ☕

11:15 Managing and Complying with Clinical Quality Obligations

**Gary C. Messplay**  
Partner, Hunton & Williams LLP (Washington, DC)

### SOPs and GCP Compliance Risks

- Requiring investigator GCP training and SOPs
- Development and enforcement of, and evaluating compliance with, SOPs and GCPs
- Identifying and managing GCP standards and compliance risk factors
- The relationship between litigation risk and GCP violations that occur during trials
- Determining whether a study conducted according to GCP may still face litigation

### Auditing, Monitoring, and Safety Reporting

- Conducting clinical trial audits for quality assurance and to ensure regulatory compliance
- Employing effective study monitoring consistent with FDA requirements
- What you must know about interim access to results by DSMBs or others

- Incorporating the FDA March 2006 Guidance for Clinical Trial Sponsors
- Special challenges in safety reporting, and responding to pressures to improve safety

## 12:00 Responding to FDA Inquiries Regarding the Conduct of Clinical Trials

**Marc J. Scheineson**  
Partner, Alston & Bird LLP (Washington, DC)

- Defining the clinical trial for the FDA
- Identifying and defining the problem, and preparing an effective response
- Preparing for trial audit inspections – 482s and the inspection process
- How your response to inquiries can prevent and impact litigation
- Replying to findings: inspection of sites (483s), and criminal, civil, administrative actions
- Avoiding the most common scenarios that lead to FDA warning letters
- Factoring in debarment issues, and IND/IDE and adverse event requirements
- Negotiating with the FDA on appropriate endpoints

## 12:45 Networking Luncheon



## 1:55 The Dos and Don'ts of Enrolling and Managing Unique Populations

**Amy Fortenberry**  
Director of Regulatory Affairs  
DMF Management Systems, LLC (Atlanta, GA)

- Effective strategies and key questions to ask for enrollment of subjects
- Reviewing the proposed advertising, flyers, and information sheets about the study
- Identifying sources of potential subjects
- Recent developments on research subjects with impaired decision-making capacity
- Considering age, gender, race, and financial demographics of the proposed enrollment pool
- Issues associated with enrollment of children, inmates, and the elderly
- Factoring in delays in patient identification and enrollment
- Clarifying misconceptions: are participants confused over “treatment” v. “research”?
- Ensuring adequate enrollment while avoiding appearance of coercion or compromise of trial design
- Getting the covered entity, sponsor, IRB/privacy board to work together an enrollment plan

## 2:35 Afternoon Refreshment Break

## 2:45 Tips, Traps, and Trends in Informed Consent and Secondary Research

**Tamara J. O'Black, CIP**  
Regulatory Affairs Administrator  
Park Nicollet Institute (Minneapolis, MN)

**Jennifer S. Geetter**  
Associate, McDermott Will & Emery (Washington, DC)

### Informed Consent

- Update on emerging trends in informed consent: assessing the impact of new guidance and regulations
- Crafting a sound consent document: avoiding pitfalls and ensuring consistency
- IRBs, sponsors and sites – the “push, pedal, pull” process of consent approval
- Beyond the document: issues of responsibility/liability and the consent as contract
- Defining populations and assessing vulnerability

- Weighing emergency versus emergent-setting research
- Banking and secondary use of biological samples
- Ensuring quality and monitoring for compliance

### Secondary Research

- Understanding what is meant by the term “secondary research”: why you're doing it even when you think you're not
- Assessing general trends relevant to the increasing importance of secondary research: research materials as “assets” (e.g., genomics, drug metabolism)
- The relationship of secondary research to data/biological sample banking and the three stages of secondary research: deposit, security, and withdrawal
- Referencing primary legal authorities governing banking
  - specific informed consent/recruitment issues raised by tissue banking
  - what you must know about tissue manufacture/transplantation

## 3:55 Managing Patient Privacy and Security in Clinical Research

**Aaron Rodriguez**  
Senior Legal Counsel, Medtronic, Inc. (Minneapolis, MN)

**Jennifer Daniels**  
Attorney, Blank Rome LLP (Philadelphia, PA)

- Conducting clinical research within the framework of HIPAA
- Determining when state privacy law will and will not be preempted
- Understanding the international privacy environment and strategies for transfer of data to the United States
- Understanding how privacy and security laws may impact the use of electronic medical records for research purposes, including in clinical trial recruitment
- Exploring privacy concerns related to the use of stored biological samples
- Reviewing useful contractual provisions in clinical trial agreements, and agreements with vendors and suppliers
- The utility of non-identified datasets
- How HIPAA has changed the landscape for trial sponsors
- Performing recruitment activities under the various HIPAA pathways
- Where may data appropriately flow?
- Deciphering the EU Privacy Directive and various approaches to its implementation
- Managing HIPAA and EU Privacy Directive simultaneously
- Beyond legal requirements: other issues that impact use of patient data

## 5:00 Conference Ends

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# MANAGING LEGAL RISKS IN STRUCTURING & CONDUCTING INTERNATIONAL CLINICAL TRIALS

March 1, 2007  
Roosevelt Hotel • New York

8:00 Registration & Breakfast ☕

8:30 Chair's Opening Remarks

*Keith M. Korenchuk, Of Counsel  
Covington & Burling LLP (Washington, DC)*

8:45 Navigating Regulatory Issues in Both the Local and Home Offices: Factors to Consider From the Start

*Patricia Lovell-Hoare, Head of International Regulatory Affairs, Chiltern International Limited (United Kingdom)*

*Grail Walsh Sipes, Associate  
Covington & Burling LLP (Washington, DC)*

### FDA and Data Risk Factors

- Determining whether data from sites in developing countries will be accepted for inclusion with data gathered from more traditional locations
- Understanding justifications and drivers for conducting clinical trials overseas, while maintaining appropriate controls with regard to protocol design, patient safety, ethics, reporting requirements, and data quality
- Obtaining FDA approval and data verification for studies abroad
- Ensuring compliance with U.S. regulatory requirements so that data obtained is useful for U.S. filing

### Partners

- Selecting the CRO: Critical due diligence to determine experience and qualifications and whether to use a local or U.S.-based CRO
- Delegating and communicating responsibilities: Determining which tasks will be undertaken by each party and the extent of CRO decision-making authority

### Informed Consent

- Factoring in national variations on informed consent, and using U.S.-required informed consent provisions in conjunction with national models
- Clearing cultural hurdles on who consents, control and view of medical care, and definitions of "informed"
- Developing an informed consent document that is compliant with review outcomes from Ethics Review Committee

10:15 Morning Coffee Break ☕

10:30 Addressing Variations in the European Regulatory and Legal Framework

*Gerhard Fortwengel, Director, Head of Quality Systems  
Actelion Pharmaceuticals Ltd (Allschwil, Switzerland)*

*Keith M. Korenchuk, Of Counsel  
Covington & Burling LLP (Washington, DC)*

- Understanding the legal framework for clinical trials in the EU
- Globally addressing the goals, successes, and confusion of clinical trial directives and how to comply with them: ICH-GCP, EU-CT Directive, EU-GCP-Directive, and beyond
- What you must know with regard to EudraCT, CAs, and ECs

- Manufacture, import, & labeling IMP requirements
- The variability in European legal frameworks for advertising, recruiting, and reimbursement
- Adapting to recent changes and variability in safety reporting requirements and inspections
- Conducting post-marketing surveillance studies and clinical assessments with a primarily scientific or educational purpose, in line with IFPMA Code requirements
- FCPA compliance issues that arise in international clinical trials

12:00 Networking Luncheon 

1:10 Conducting Clinical Trials in Emerging Markets and Alternative Nations and Regions

*Nermeen Varawalla, MD, DPhil (Oxon), MBA  
Vice President Corporate Development  
PRA International (Reading, Berkshire, UK)*

- Overcoming the initial hurdles:
  - local languages, cultural, and belief system variations
  - overcoming difficulties surrounding access to patients
  - political/exploitative factors to consider and ensuring human subject protection
  - data standardization and obtaining trial authorization
- Advantages and disadvantages of, "watch out for," and best practices in conducting clinical trials in alternative nations and regions:
  - Latin America, Russia, India, and China

2:30 Afternoon Refreshment Break

2:45 Negotiating and Drafting Key Terms in International Clinical Research Agreements that Put You at Risk

*Betty Yan, Partner, Reed Smith LLP (Princeton, NJ)*

*Amy Dow, Attorney  
Epstein Becker & Green, P.C. (Chicago, IL)*

- Defining the obligations and scope of work of each party
- Factoring in site obligations to cooperate with inspections/audits
- Defining "confidential information" in the agreement
- Defining publication rights and obligations
- Establishing clear IP ownership rights in the agreement
- Balancing the IP and publication rights between sponsor and institution/investigator
- Determining indemnity type and indemnity alternatives
- What you need to know about debarment, certification, and other requirements for U.S. filing
- Determining governing laws and whether the host country will allow U.S. laws to govern
- Preparing the contract with an eye on party identification, signatures, and third-party rights
- Minimizing risk through insurance: coverage & availability
- Market changes in clinical trials insurance: What's covered and what's not?
- Choosing the appropriate insurance for the territory
- Determining the need for separate insurance policies for each country involved in the trial

4:15 Master Class Ends

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MANAGING LEGAL RISKS IN  
STRUCTURING & CONDUCTING

# CLINICAL TRIALS

FEBRUARY 27-28, 2007 • ROOSEVELT HOTEL • NEW YORK CITY

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Master Class

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## INTERNATIONAL CLINICAL TRIALS

MARCH 1, 2007

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