3rd Annual

Managing Multi-Jurisdictional Legal and Regulatory Risks in

CLINICAL TRIALS

Business Information In A Global Context

Successfully Complying with Regulations, Meeting Emerging Transparency and Ethical Obligations and Improving Global Clinical Trial Conduct

15th and 16th April 2008 • Renaissance Brussels Hotel • Brussels, Belgium

Distinguished Chair:

Dr. Peter Feldschreiber
Barrister, Four New Square Chambers, (UK), Special Litigation Coordinator in the Medicines and Healthcare Products Regulatory Agency, Department of Health

Hear from Prominent Pharmaceutical Industry Specialists ranging from Senior Legal Counsel to VPs from:

- Pfizer (UK)
- Genzyme Europe BV (The Netherlands)
- Wyeth Pharmaceutical, Pennsylvania (USA)
- Baxter International Inc. Illinois (USA)
- Sensys Medical, Arizona (USA)

Indepth discussions from experts from across the Globe Including:

- VP Scientific & Medical Affairs, PRA International
- Executive Director, Good Clinical Practice Alliance, Europe
- Chief Correspondent for Pharmaceuticals, Financial Times

With Further Commentary from Leading Law Firms Including:

- Lovells
- Dechert
- Sidley Austin
- Covington & Burling
- Kennedys Law
- Fasken Martineau Stringer Saul
- Bird and Bird
- Manches

Register now for the only European event to provide advanced, practice-based guidance covering the complete clinical trials landscape:

- **Manage** and minimise legal exposure to claims and litigation in a multi-jurisdictional environment
- **Consolidate** and standardise documentation in order to have effective compliance procedures
- **Gain** up-to-the-minute information on the applicability of regulations and how to manage related commercial concerns
- **Develop** your understanding of risk management at every stage of clinical trials from the pre-trial stage right through to post-approval surveillance

Up to 20.0 CPD

Featuring interactive, commercially-focused pre-conference workshops on 14th April 2008:

A: Drafting Comprehensive Clinical Trials Agreements

B: Practical Strategies for Managing Clinical Trials Outsourcing and Due Diligence Requirements

see inside for full details

What you told us During Research:

"This is truly an area in which even a great change management plan is not always enough to keep up with the constantly evolving environment"
Charlene Gallagher, Senior Division Counsel Vaccines, Wyeth Pharmaceuticals

"An excellent and timely topic that goes to the heart of the practice"
Paul Gerlach, Partner, Sidley Austin LLP

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Get expert advice on how to manage your legal and regulatory risks by improving your legal, compliance and regulatory processes:

Efficient management from a legal viewpoint, including document standardisation and proficient claims coordination will not only help your company to significantly reduce legal risks with regards to litigation and claims management, but also help manage reputational risks, and drastically reduce associated costs.

As a professional working in the arena of Clinical Trials, you must be able to incorporate key lessons from recent developments into the management of legal risks in structuring and conducting clinical trials. Ensure you have advanced practical know-how at your disposal to deliver strategic guidance on matters such as standardised and uniform application of clinical-trial related regulations, key ethical and transparency challenges and current thinking on reporting obligations and clinical trials outsourcing. Join your peers to exchange lessons learned and increase your knowledge of how recent litigation and legislative trends affect the management of legal risks in structuring and conducting clinical trials.

By putting together a programme heavily focused on results-oriented discussions on the key issues that the industry is faced with today, this **C5** programme will provide integrated and internationally relevant solutions. Learn how to tackle the multiple challenges you are faced with when conducting clinical trials globally.

Our panel of experts has a strong commercial focus, thorough market understanding and includes experts from pharmaceutical and medical device companies, hospital and research institutions and CROs as well as expert lawyers and regulatory/government representatives. **Join them to identify and resolve the critical questions that clinical trials industry faces today.**

Conference Highlights Include:

- Panel discussion on emerging issues relating to transparency
  - Led by the Chief Correspondent on Pharmaceuticals at the Financial Times
  - Panellists include EU and US lawyers and in-house counsel
- First-hand insight from the lead trial counsel for Vioxx Litigation on reducing your exposure to litigation
  - Critical lessons to be learnt from Vioxx
- Debate on critical issues concerning in a global market with reference to the US Foreign Corrupt Practices Act
  - Analysis of recent investigative cases by the SEC and US Department of Justice
  - Key takeaways for European counterparts
- Regional Focus on India
  - How India is approaching its emerging status as a power house for the global pharmaceutical industry and clinical trials venue

Who Should Attend?

Pharmaceutical, Biotech and Medical Device Companies:

- General Counsel and In-House Lawyers
- Heads of Compliance and Regulatory Affairs
- Heads of Clinical Research
- Managers for Clinical Trials
- Senior managers for Quality Assurance and Quality Control

Private Practice Law firms:

Partners and Associates specialising in:

- Life Sciences
- Product Liability
- Clinical Trials
- Mass Tort Litigation

Global Sponsorship Opportunities

C5, along with its affiliate organization based in New York, American Conference Institute (ACI), works closely with sponsors to create the perfect business development solution. With over 500 conferences in the US, Europe, Russia and CIS, Canada and China, C5/ACI provides a diverse portfolio of first-class events tailored to the senior level executive. For more information about this event or our global portfolio, please contact: Colin Carter on +44(0)20 7878 6933 or email c.carter@C5-Online.com

AGENDA HIGHLIGHTS AT-A-GLANCE:

Critical Updates

- Critical Regulatory and Legislative Updates: New Considerations for Phase I Trials and Implementing the EU Directive 2001/20/EC
- Adopting the Proposed EMEA Guidelines on High-Risk Medical Products
- Securing Valid Informed Consent and Upholding Ethical Integrity

Executive Discussions

- Meeting the Demand for Increased Transparency in the Clinical Research Process
- Critical Issues Concerning Compliance in a Global Market
- Creating Successful Sponsor and CRO Partnerships and Drafting Succinct Contracts to Provide Optimal Balance
- Conducting Clinical Trials in Emerging Markets: Regional Focus on India

Legal and Regulatory Risk Management

- Analysing Comparative Risks of Undertaking Clinical Trials Internationally in Various Jurisdictions and Handling Associated Trans-National Claims avoiding the Hazards of Diluting Data Authenticity when Outsourcing Clinical Trials Data
- Forecasting and Developing Clinical Budgets for Conducting Trials Internationally
- Maintaining Compliance and Minimising Liability When Posting Clinical Trials Data
- Managing risks Associated with Use of Clinical Trial Data in Litigation Proceedings: Outsourcing from a Litigation Perspective
- Developing an Effective Adverse Event Reporting and Post Approval Surveillance Programme
- Reconciling European and International Ethical Obligations in Conducting Clinical Trials
- Balancing and Standardising Local and Foreign Insurance Policies

Pre-Conference Workshops: 14th April 2008

Workshop A: 9.00-12.00 (8.30 Registration)

Master Class on Drafting Comprehensive CRO and Site Agreements

Led by:

Paul Ranson, Partner
Fasken Martineau Stringer Saul

Francesca Boateng-Muhammad, Associate
Fasken Martineau Stringer Saul

Disputes arising over payment, IP and control of or access to data are all too common in both CRO and Site Agreements, but careful drafting of the agreement provisions can save a lot of time and money by preventing or significantly decreasing the likelihood of such disputes. This hands-on, interactive workshop will provide practical solutions to real-world challenges commonly encountered during clinical trial agreement negotiations.

Areas to be covered include:

- Dealing with early termination clauses
- Outlining the obligations and scope of work of each party
- Factoring in site obligations to cooperate with inspections/audits
- Defining "confidential information" in the agreement
- Identifying publication rights and obligations
- Establishing clear IP and data ownership rights in the agreement
- Juggling the IP and publication rights between sponsor and institution/investigator
- Determining indemnity type and indemnity alternatives
- Balancing financial disputes with the need to obtain data
- Understanding recent changes in clinical trials insurance coverage

Workshop B: 12.30-15:30 (12.00 Registration)

Practical Strategies for Managing Clinical Trials Outsourcing and Due Diligence Requirements

Led By:

Sally Shorthose, Partner
Bird and Bird LLP

Mary Smillie, Associate
Bird and Bird LLP

The EU Clinical Trials Directive defines sponsor as an individual, company, institution or organisation that undertakes the responsibility of initiation, management and/or financing of a clinical trial. Even if such tasks are delegated the "ultimate responsibility" for the trial still rests with the sponsor, therefore any duties and functions delegated must be clearly agreed in writing. The defence of due diligence is available under the directive which absolves the sponsor of liability if they undertook all "reasonable precautions" and exercised "all due diligence" to avoid commission of the offense. The execution of proper due diligence reports and exhaustive documentation policies are therefore essential for all pharmaceutical companies, researchers and insurers in the field. Through this workshop we aim to understand, standardise and mitigate the legal risks associated with such projects.

Areas to be covered include:

- Managing the complexities of the responsibilities of running international trials
- Gaining authorisation to conduct clinical trials in Non EU countries
- Best practices for appointing representation in the host country with local regulatory authorities and contractual obligations
- Understanding insurance policies of local providers
- Creating and standardising the documentation necessary to mitigate legal risks
- Understanding "sufficient evidence" to raise a sufficient defence to a court or jury
- Political and regulatory uncertainty of host jurisdiction and how this impacts due diligence

Conference Day One: Tuesday 15th April 2008

8.00 Registration and Coffee

8.30 Conference Chair's Opening Remarks

Dr. Peter Feldschreiber, Barrister, Four New Square Chambers, (UK), Special Litigation Coordinator in the Medicines and Healthcare Products Regulatory Agency, Department of Health

8.45 Critical Regulatory and Legislative Updates: Re-evaluating European Laws and Practices

Francis P. Crawley, Executive Director
Good Clinical Practice Alliance, Europe

- Analysing the current status of the EU Directive on GCP (Directive 2001/20/EC)
- Successfully reconciling variances in European member state laws on clinical trials
- Understanding the impact of the EU Regulation on Medicines for Children
- New regulatory frameworks for Phase I studies: EMEA CHMP Guidelines, ABPI Guidelines, & MHRA Accreditation in the UK
- Adopting a legal position and practice appropriate to multi-country European clinical trials

9.30 Proposed EMEA Guidelines on High-Risk Medical Products

Rosanna Cooper, Managing Partner
RT Cooper Solicitors

- Outlining the factors to be considered in the non-clinical testing strategy and design: Continued integration and review in an "iterative process"
- Balancing the safety of the volunteers against the value of the targeted results: How to document such information efficiently in the protocol design
- How to justify the choice of population on a case-by-case basis: The increased importance of effective compliance and documentation
- Stopping rules for the individual subject, cohort and trial and the importance of an "independent drug safety monitoring board"
- Training of staff and determining a treatment strategy in cases of a "predictable risk" of a specific adverse reaction: Developing and documenting such strategy in the protocol
- Justifying the choice of site for clinical trials: Is it appropriately equipped with relevant facilities, trained staff and expertise?

10.00 Morning Refreshments

10.30 Securing Valid Informed Consent and Upholding Ethical Integrity

Anne Ware, Partner
Covington and Burling (Product Liability and Mass Tort Litigation)

Grant Castle, Partner
Covington and Burling (Life Sciences and HealthCare)

- Current debate on consent forms and provision of information to patients participating in trials
- The MHRA proposals on working with children
  - using trials for emergency care medicines in children without initial consent
    - assessment of the degree of caution required
    - managing the associated exposure to risk
  - key exceptions to the general rule that informed consent must be obtained by the minor's parents or legal representative
- Ensuring ethical integrity of the consent process when working with patients in international trials
  - how do you guarantee that consent is not a result of cultural factors, economic needs or coercion
  - accounting for differences in customs, language barriers and definitions of 'informed consent'
  - documenting your patients' consent in order to minimise your future risks
  - approving a consent template that includes a confidentiality language appropriate to differing national standards and in compliance with the EU Directive guidelines

11.15 Meeting the Demand for Increased Transparency in the Clinical Research Process

EXECUTIVE DISCUSSION

Moderator:

Andrew Jack, Pharmaceuticals Correspondent
Financial Times UK

US Perspective:

Joseph Hetrick, Partner
Dechert

Charlene A. Gallagher, Senior Division Counsel Vaccines
Wyeth Pharmaceuticals

EU Perspective:

Marc Dalby, Partner, Lovells LLP,
Former Legal Director at Merck Sharp & Dohme

- Does increased access to information mean a better informed public?
- Avoiding over-reporting
  - minimising the legal, reputational and litigation risks associated with sensitive data
  - how plaintiff lawyers are using available data to push their cases
- Considerations surrounding communications tools and protocols
  - do scientifically accurate documents aimed at researchers and physicians constitute effective communication to patients?
  - ensuring documents are written to be scientifically accurate and precise – and whether this is an effective communication tools for patients
- Posting information on unapproved therapies and exploratory studies
  - current thinking on registering Phase I trials
    - minimising the impact of premature reports on investment and special considerations for smaller companies
    - managing disclosure
- What are the benefits of standardising the level of information available to the public at a global level?

12.15 Networking Lunch

1.45 Avoiding the Dilution of Data Authenticity when Outsourcing Clinical Trials Data

Linda Hockersmith, Vice President Clinical & Regulatory Affairs
Sensys Medical

- Insight into Sensys Medical's tried and tested data risk analysis procedure and how it facilitates a structured approach to risk analysis
- Identifying potential members of your analysis team
  - formulating a process to identify, rank and assign data issues
    - the role of legal representatives, scientists and statisticians
- Determining whether the data from sites in developing countries will be accepted for inclusion with data generated from more traditional locations
- Maintaining privacy in the light of patient rights legislation in different countries
  - clarifying the impact of increased electronic patient record keeping
  - which consent, confidentiality and security issues should you be looking at now?
- Comparative analysis the US and Europe
  - ccurrent US legal requirements and FDA policies regarding the inclusion of foreign trials
  - how the EU is approaching data authenticity

2.30 Comparative Risks of Undertaking Clinical Trials Internationally and Managing Claims on Multiple Fronts

Shane Sayers, Partner
Kennedys Law

- Determining the strength of local clinical trials expertise
- Considering local legal systems and how they operate
  - reliability of the courts
  - local laws on clinical trials and claim culture
  - finding reliable legal representation
  - timing and cost of litigation
- Assessing potential damages and potential claims value
  - spotlight on recovery trends in various countries
- Successfully coordinating claims across jurisdictions through one "virtual" law firm
  - harnessing the benefits of instructing one law firm to co-ordinate your global legal response
- Effective protocols for handling claims:
  - which reasonable general guidelines for settlements can be pre-agreed?
  - what is the validity of such agreements in court?
  - alternatives to using the courts
- Case study on the mechanics of handling trans-national claims successfully to minimise legal and reputational damage

3.00 Forecasting and Developing Budgets for Conducting Clinical Trials Internationally

Check **www.C5-Online.com/clinical** for speaker updates

- Allocating resources and timescales
  - putting together a budget to maximise revenue when budgeting for international trials
- Developing study budgets within a research & development portfolio
  - documenting fair market value for data and sites
- Reviewing sponsor considerations when developing a study budget for international trials
  - aligning your international CTA provisions with your budgetary constraints
- Successful international data management
  - dealing with translations and avoiding common related pitfalls
  - best practices for managing cultural differences
  - accounting for the impact of exchange rate fluctuations

3.45 Afternoon Refreshments

4.15 Best Practices for Minimising Liability When Posting Clinical Trials Data

Charlene A. Gallagher, Senior Division Counsel Vaccines
Wyeth Pharmaceutical

- Preventing off-label and product liability claims associated with under-reporting and over-reporting of data
- Determining the extent to which data from ongoing trials should be distributed: deciding where scientific exchange ends and drug promotion begins
- How to avoid language that could be construed as promotional while providing fair and balanced information on clinical trials
- Understanding common liability risks arising from posting of data by establishing a data review process
- Identifying and minimising risks associated with investigator initiated studies: What can you do to minimise such risks?

5.00 Closing Remarks & Conference Adjourns

CONFERENCE DAY TWO: WEDNESDAY 16TH APRIL 2008

8.00 Registration and Coffee

8.30 Conference Chair's Opening Remarks

Dr. Peter Feldschreiber, Barrister, Four New Square Chambers, (UK), Special Litigation Coordinator in the Medicines and Healthcare Products Regulatory Agency, Department of Health

8.45 How Outsourcing Increases your Risk of Litigation and How Clinical Trial Data is being Used in Litigation Proceedings

Joseph Hetrick, Partner
Dechert (US)

- How clinical trial data is being used in contemporary US pharmaceutical litigation
  - use of clinical trial data to establish causation, and support liability
  - establishing the foundation for punitive damages through use of data
- Recognising how outsourcing can give claimants more support for their current liability themes and how to limit such risks
- Assessing whether foreign trials provide relevant and reliable data for domestic patients

- Determining legal merit and credit worthiness of data collected from outsourcing
  - key requirements for successfully establishing evidential creditworthiness
- Successfully managing foreign trials: Could negligence lead to liability and criminal prosecutions beyond current tort recovery provisions?
- Minimising litigation risks arising when dealing with naïve populations

9.30 Morning Refreshments

10.00 Developing an Effective Adverse Event Reporting and Post-Approval Surveillance Programme

Priya Mannan, Senior Counsel
Baxter International Inc.

- Examining current statistics on adverse event reporting
- What are the regulators saying and how are companies responding?
- How to minimise legal and reputational risk by adopting an integrated and comprehensive approach to post-approval surveillance
- Key considerations for your surveillance programme
  - managing current regulatory requirements
  - acting on adverse event reports received from healthcare professionals and customers including patients
  - actively responding to product complaint calls
  - preparing data for inclusion in periodic safety update reports
  - successful epidemiologic analysis and new strategies for deducting and analysing external data sources
  - using registries for continuous safety monitoring
  - facilitating internal training for continued active product surveillance
- Establishing an internal compliance framework to address issues of safety and efficacy
  - managing reporting requirements from first-in-man to post-market launch
- Update from the US on claims-based data and its importance
  - use of the UK Practice Research Database (GPRD) by the FDA for pharmaceutical investigations
- Determining if current market dynamics discourage companies to provide adequate resources required for comprehensive post-market study programmes?

10.45 Effectively Reconciling European and International Ethical Obligations in Conducting Clinical Trials

Dr Richard Nicholson, Editor, Bulletin of Medical Ethics
Founder of the Association of Research Ethics Committee

- Documenting ethical conduct to protect against future litigation risk
- Overcoming the challenges of enrolling patients when there is no ethics board
  - formulating standardised requirements: what to include
  - reconciling ethical requirements with cultural and jurisdictional realities
- Providing oversight and training on human research ethics in relation to local customs and language barriers
  - site-specific considerations
  - educating physicians, nurses and coordinators

11.30 Balancing and Standardising Local and Foreign Insurance Policies

Andrew Catton, Underwriting Executive
Miller Insurance Company

- Establishing the parameters of what constitutes adequate insurance
- Guidance on limits, liability and exclusions
- Current insurance industry guidance for companies conducting clinical trials
- Key coverage issues when insuring international clinical trial projects
- Effective strategic planning for smaller companies to achieve their insurance goals: What are the hazard drivers that underwriters look out for?
- Unique considerations for smaller companies looking for insurance and managing liability

12.15 Networking Lunch

1.45 Critical Issues Concerning Compliance in a Global Market and How Clinical Trials are Impacted

EXECUTIVE DISCUSSION

Moderator:

Paul V. Gerlach, Partner
Sidley Austin, EU Life sciences

Panellists:

Priya Mannan, Senior Counsel
Baxter International Inc.

Paul Ranson, Partner
Fasken Martineau Stringer Saul

Dr. Dennis Joseph, Lead Regional Operations Director
Pfizer

Jim Kinnier Wilson, Partner
Manches LLP

- Bribery and Corruption: Importance of OECD and United Nations Conventions on Corruption and the U.S Foreign Corrupt Practices Act (FCPA or Act)
- How to neutralize the dual threat of U.S. enforcement actions and local investigations for illicit payment activity that occurs in international subsidiaries
- Brief analysis of recent investigative cases by the Securities and Exchange Commission (U.S) and US Department of Justice
  - recent international news: Schering-Plough, Micrus Corporation and Diagnostic Products Corporation
  - developments of note in countries as diverse as China, Mexico, Turkey, Poland, France and Taiwan
- Identifying the need to adopt and maintain effective FCPA and other relevant compliance programs by healthcare and pharmaceutical companies
- Ensuring vendor and third party quality assurance activities are effective and meet expectations
  - understanding what systems sponsors must have in place
  - effective oversight of third parties and outsourced studies

2.45 Afternoon Refreshments

3.15 Creating Successful Sponsor–CRO Partnerships

Douwe Witteveen, Director EU BMRA Legal & Contracts Management, Genzyme Europe BV

- Examining your options when choosing CROs: are large global CROs better partners than regional ones that have territory-specific know-how?
- Identifying CROs with the right capabilities for the particular trial in question
- How to transfer responsibilities to a CRO while maintaining control on the quality and integrity of the trial data
- Clearly establishing the identity and the obligations of the sponsor and the CRO: Identifying performance standards in the light of GCP and other laws and regulations
- Establishing clear standards of apportioning liability based on the scope of responsibility

4.00 Capitalising on the Growth of Clinical Trial Opportunities in the Emerging World: Overcoming Common Constraints

Dr. Nermeen Varawalla, VP Scientific & Medical Affairs
PRA International

- How to guarantee swift, meticulous and cost-effective clinical trial's conduct in India
- Requirements for developing infrastructure, processes and resources to expedite the process and how this can be achieved
- Overcoming human resource and expertise challenges to meet the heightened demands of clinical trials in the region
- Considering India's regulatory and bureaucratic processes
  - critical challenges and how to neutralise them
- Understanding the local healthcare sector's practices and how they affect the efficient running of clinical trials

4.45 Closing Remarks & Conference Ends

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Business Information In A Global Context

DON'T MISS THE INTERACTIVE PRE-CONFERENCE WORKSHOPS ON:

A: Drafting Comprehensive Clinical Trials Agreements

B: Practical Strategies for Managing Clinical Trials Outsourcing and Due Diligence Requirements

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ADMINISTRATION DETAILS

CONFERENCE
Date: 15th and 16th April 2008
Time: 8.30 am (8.00 am Registration and Coffee)
Venue: Renaissance Brussels Hotel
Address: Rue du Parnasse 19, Brussels, 1050 Belgium
Tel: +32 2 505 2929 Fax: +32 2 505 2555
Web link: www.C5-Online.com/clinical

MASTER CLASS
Date: 14th April 2008
Time: Workshop A - 9.00 am (8.30 am Registration)
Workshop B - 12.30 pm (12.00 pm Registration)

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14 hours conference only (Master Class 3 hours each) towards Continuing Professional Development hours (Law Society Reference No: BJEUFO).

DOCUMENTATION

If you are not able to attend, you can buy copies of the presentations provided to delegates on the day of the event. Please send us this completed booking form together with payment of £350 per copy requested. For further information please call +44 (0) 207 878 6888 or email enquiries@c5-online.com.

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