Throughout Europe, Pharmaceutical & Medical Device manufacturers are eagerly working with outside investigators in order to further the knowledge and understanding of the potential uses for their products, through the conduct of investigator initiated research studies. While these studies provide invaluable data and insight into existing products, they are also an expensive undertaking and can at times cause significant strain on the manufacturer as investigators demand additional support and funds to continue research. Compounding these challenges are increasing regulatory reporting requirements and pressure from governing bodies related to the relationships between industry and healthcare professionals. The 3rd Annual European Investigator Initiated Studies Conference will provide attendees with an opportunity to discuss and debate the many challenges faced by medical affairs teams as they look to not only maximize the research and outcomes from these exciting studies, but also minimize risks and costs.

A critical differentiator of the Q1 European IIS conference will be the division of pharmaceutical and medical device corporations at certain junctures throughout the event, giving executives a unique opportunity to discuss challenges with companies developing similar products. Taking into account the vast differences in clinical procedures and research processes for pharmaceutical vs. medical device therapies will ensure that sessions are of the greatest possible relevance. Also unique to this conference program are case study presentations highlighting how innovative corporations have overcome some of the most daunting challenges in investigator research, including detailed case studies on budgeting, working with investigators on milestone payments, as well as where to draw the line between supporting an investigator, and taking on sponsorship of a study. With so many challenges faced throughout this dynamic industry, this conference will once again be the must-attend forum for medical affairs executives during 2013.

**DISTINGUISHED PRESENTERS INCLUDE:**

- Joëlle Rebetez  
  IIS Manager, Global Post-Approval Operations & Medical Affairs  
  ACTELION PHARMACEUTICALS
- Marcus Neureither  
  Director Business Unit Dermatology  
  BIODEN IDEC
- Séverine Durier  
  Medical Affairs Manager Europe  
  ALCION LABORATORIES
- Rudolph Schopf  
  Director of Psoriasis Ambulatory, Senior Physician  
  JOHANNES GUTENBERG UNIVERSITY MAINZ
- Klaas van’t Klooster  
  International Clinical Manager  
  DEPUY SPINE
- Uli Mezger  
  Clinical Research Manager  
  BRAINLAB
- Tino Hauser  
  Director Clinical Affairs & Reimbursement CENEMA  
  BIOTRONIK
- Torsten Böhler  
  Senior Medical Research Manager  
  GAMBRO DIALYSATOREN
- Susanna Dienemann  
  Attorney at Law  
  WACHENHAUSEN RECHTSANWÄLTE
- Alexandra Rieben  
  Clinical Research Manager  
  NOBEL BIOCARE
- Christian Dierks  
  Partner  
  DIERKS + BOHLE ATTORNEYS
- Micheal Ramb  
  Counsel  
  FRESHFIELDS BRUCKHAUS DERINGER
- Sophia Mohammad  
  Senior Manager Clinical Programs  
  EDWARDS LIFESCIENCES INTERNATIONAL
- Ina vom Feld  
  Partner  
  BIRD & BIRD
DAY ONE / MONDAY, SEPTEMBER 16
THIRD ANNUAL EUROPEAN INVESTIGATOR INITIATED STUDIES

8:00 REGISTRATION & WELCOME COFFEE

9:00 DRAWING THE LINE BETWEEN INVESTIGATOR INITIATED AND SPONSOR INITIATED STUDIES
When engaging in investigator initiated studies in Europe, manufacturers are still unsure of when supporting becomes sponsoring, and want to ensure they remain on a compliant ground in their collaboration with external parties. Both in the medical and pharmaceutical industries, drawing a specific and clear line between investigator led and sponsor led trials can be confusing as no clear regulations exist to define the process. By examining common misconceptions and sharing knowledge, specific areas of concern in the collaboration between the manufacturer and the investigator as well as the overall management of the study will be clarified.

• How to monitor without sponsoring
• Considering the study drug or COP
• Reporting, data management and study outcomes

José Rebetez, IIS Mgr., Global Post-Approval Operations & Medical Affairs

ACTELOM PHARMACEUTICALS

9:45 CLARIFYING THE CONCEPT AND ROLE OF THE SPONSOR IN INVESTIGATOR RESEARCH
In the collaboration between a life science corporation and an external investigator, clear understanding and utilization of terminology is crucial to ensure a positive start to the trial. The concept, role and responsibility of the sponsor are often misunderstood by healthcare professionals, who are not used to how IIS verbiage and partnerships. From outlining the legal concept of “sponsor” for the physician to clarifying where the sponsor’s role begins and ends, establishing a common terminology framework between both parties early in the collaboration process will secure unambiguous physician/manufacturer relationships.

• Physician appreciation of the manufacturer’s role
• Legal concept and definition of the sponsor
• Sponsoring vs supporting: common misconceptions
• Specific aspects of supporting IIS with complex medical products

Tino Hauser, Director Clinical Affairs & Reimbursement CENEMEA

BIOTRONIK

10:30 COFFEE & NETWORKING BREAK

10:50 CONNECTING INVESTIGATOR INITIATED STUDIES WITH CORPORATE MEDICAL STRATEGY
Ensuring an investigator initiated study can fit in the overall pharmaceutical or medical device corporate strategy is essential before moving forward and contracting. Medical affairs teams must make certain the proposed study matches the company’s medical strategy to justify legitimate allocation of products or financial support, ultimately securing proper utilization of funds and a fruitful collaboration with the physician.

• Disclosing corporate medical strategy for IIS
• Identifying the external study target and value proposition
• Bringing the external trial and corporate goals to come together

Marcus Neureither, Director Business Unit Dermatology

BIOTRONIK

11:35 SECURING INTELLECTUAL PROPERTY (IP) IN EUROPEAN INVESTIGATOR INITIATED STUDIES
When collaborating with external investigators, Sponsors must ensure adequate protection of their existing IP and potential future IP generated through the study. From data generation to relevant publications, the overall documentation and results of the trial represent valuable information that should be carefully considered and secured. Through examination of pro’s and con’s presented in this session, delegates will understand how to develop an efficient and proactive agreement with the external investigator and ultimately maximize IP protection in IIS.

• Outlining the ownership & exploitation of IP & know-how in the agreement
• Copyright considerations
• Site-specific legal requirements (e.g. employee inventorship law)
• Implications of (partial) public funding

Ina vom Feld, Partner, BIRD & BIRD

12:20 LUNCHEON FOR ALL SPEAKERS, SPONSORS & ATTENDEES

1:30 BEST PRACTICES: ESTABLISHING FAIR MARKET VALUE FOR INDIVIDUAL INVESTIGATOR INITIATED STUDIES
When financially supporting an external investigator trial, the manufacturer must ensure transparent and relevant market value payments. Fair Market Value (FMV) was established to actively discourage quid pro quo relationships between healthcare professionals and the life science industry, and ensure physicians will be paid the appropriate and fair amount for their work. Determining what the right amount is in accordance to the study can be challenging especially on an international level, as it requires analysis and comparison of market fluctuation, compliance to relevant regulations and internal budget consideration.

• Implementing a compliant internal FMV methodology
• Data and established methods to determine appropriate amounts
• Clarifying FMV with the external investigator
• FMV and international studies

Michael Ramb, Counsel, FRESHFIELDS BRUCKHAUS DERINGER

EDWARDS LIFESCIENCES INTERNATIONAL

3:00 TRANSPARENCY TRENDS: CLARIFYING US & EU REGULATIONS TO ENSURE IIS COMPLIANCE
In January this year, the US released the Final Sunshine Act regulation requiring disclosure and equity in physician payments by the life science industry and for both pharmaceutical and device manufacturers to provide regulators with detailed and transparent payment reports. European member states present country-specific legislations and requirements of the same nature but with different levels of scrutiny from authorities adding to the complexity of ensuring compliance to transparency trends when monitoring IIS on an international level. Increasing transparency regulations highlight an important shift in health authority’s monitoring of physician and industry collaboration that manufacturers must understand to secure compliance.

• Clarifying the US Sunshine Act and reporting obligation for IIS
• Overview of EU transparency legislation and measures relevant for external studies
• Reliability of EU Codes of Conduct for IIS management
• Transparency when working with external physicians internationally

Christian Diersks, Partner DIERKS + BOHLE ATTORNEYS

GAMBRU DIALYSATOREN

2:15 WORKSHOP: SUCCESSFULLY MANAGING EXTERNAL INVESTIGATOR PAYMENTS
Participants in this session will have an opportunity to work on a number of practical exercises, capturing the essential difficulties in physician payment processes and how to translate them into successful payment procedures. The audience will be separated in small working groups per industry and product categorization for an optimized learning experience. Through this problem-based learning approach led by a knowledgeable peer, challenges such as proactive budgeting, efficiently communicating payment modules and implementing milestones will be examined and broken down, ensuring maximized understanding from the audience and efficient take-away strategies.

Sophia Mohammad, Senior Manager Clinical & Programs Manager

3:45 COFFEE & NETWORKING BREAK

4:15 PANEL DISCUSSION: VALIDATING NEW PRODUCT APPLICATION CLAIMS THROUGH IIS
When collaborating with an external investigator, pharmaceutical and medical device companies want to ensure the investigator led study will bring additional value and benefits to the organization. Through supporting external physician studies for new applications of existing and marketed products, the corporation can develop a wider product portfolio, generate additional revenue and improve patient healthcare. By examining how to compliantly collaborate with investigators researching on new applications, and ultimately obtain regulatory clearance for new product indications, participants in this session will have a better understanding of investigator study opportunities for new medical product applications.

• Disclosing open new indication areas for research
• Compliance in new application investigator research
• Obtaining regulatory clearance through the IIS

Torsten Böhler, Senior Medical Research Manager

BIOTRONIK

5:00 TRACK 1 - DEVICE ATTENDEES
MDD REVISION: NEW CLINICAL REQUIREMENTS IMPACT ON EUROPEAN IIS
The European Commission has released the Formal Proposal to the MDD last fall, including new and updated requirements for clinical investigations. At this time, device clinical and medical affairs teams raise the question of what impact these changes and results of the trial represent value information that should be carefully considered and secured. Through examination of pro’s and con’s presented in this session, delegates will understand how to develop an efficient and proactive agreement with the external investigator and ultimately maximize IP protection in IIS.

• Outlining the ownership & exploitation of IP & know-how in the agreement
• Copyright considerations
• Site-specific legal requirements (e.g. employee inventorship law)
• Implications of (partial) public funding

Ina vom Feld, Partner, BIRD & BIRD

5:00 TRACK 2 - PHARMACEUTICAL ATTENDEES
BREAKOUT SESSION: EXCHANGING IDEAS & STRATEGIES
Through this open time for discussion and exchange of ideas, delegates will select 5 topics to thoroughly examine and discuss further in an un-conference format. All delegates will be invited to actively participate in the discussions and debates, allowing for a straightforward peer to peer learning experience.

5:45 CLOSING REMARKS & DAY ONE CONCLUSION

500 N. DEARBORN STREET, SUITE 500
CHICAGO, IL 60654
312.622.8300 (P) 312.602.3834 (F) www.q1productions.com
9:15 PRIORITIZING IIS COLLABORATIONS AND ALLOCATION OF FUNDS IN LIFE SCIENCE COMPANIES

In the current setting where life science organizations are increasingly approached by investigators seeking support for external studies, understanding how to efficiently classify and prioritize study proposals is critical to ensure funds are allocated in a budget-effective manner. Fund allocation is essential for the corporation to first prioritize internal goals and objectives before comparing with investigator led study targets and assessing which proposal is most promising. Through the establishment of a clear IIS budget plan and classification of corporate goals by order of importance, medical affairs teams will ensure they move forward with the most beneficial studies first.

- Establishing a yearly IIS budget plan
- Gauging study relevancy and aftermath
- Classifying and prioritizing corporate goals
- Allocating support in order of study relevancy

Séverine Durier
Medical Affairs Manager Europe
ALCON LABORATORIES

10:00 COFFEE & NETWORKING BREAK

10:30 CASE STUDY: ENSURING TIMELINES ARE MET BY THE INVESTIGATOR

A critical challenge faced by life science corporations when collaborating with external physicians in investigator initiated studies is to ensure milestones are met according to initially planned timelines. Too often, investigator initiated research lag behind, resulting in time and budget constraints for the manufacturer. Through proactive communication, planning and preparation of the physician as well as establishing an incentive-driven compensation strategy, manufacturers will secure results on time.

- Establishing a precise & strict chronological plan with the investigator
- Emphasizing the importance of timelines
- Establish consequences of non-adherence
- Aligning incentives and payments with target benchmarks

Alexandra Rieben
Clinical Research Manager
NOBEL BIOCARE

11:15 PANEL DISCUSSION: OVERCOMING PHYSICIAN DISENGAGEMENT IN INVESTIGATOR INITIATED STUDIES

Throughout all investigator initiated studies conducted every year in the pharmaceutical and device industries, some are unfortunately cancelled before completion, generally due to investigator departure. In this particular situation, medical affairs teams face a crucial challenge as products or financial support have already been provided and the manufacturing corporation expects return on this investment. By opening discussion between the panelists and the audience, strategies will be examined to effectively classify and prioritize study proposals. Through the establishment of a clear IIS budget plan and classification of corporate goals by order of importance, medical affairs teams will ensure they move forward with the most beneficial studies first.

- Tailoring contract templates for distinct investigator research
- Impact of terminology in investigator research contracts
- Must-have clauses to ensure external study compliance
- Reviewing and clarifying the contract with the investigator

Susanna Dienemann
Attorney at Law
WACHTENHAUSEN RECHTSANWÄLTE

2:00 MAXIMIZE STUDY OUTCOMES THROUGH CONTINUAL IMPROVEMENT OF INTERNAL IIS STRATEGY

Throughout Europe, pharmaceutical and medical device corporations of all sizes are faced with an increasing number of investigators looking for support for study support, while also facing internal pressure to optimize all studies and ensure tangible outcomes from supported research. This pressure has caused many organizations to rethink their IIS strategies and work to implement internal strategies that are aligned with overall corporate research goals and which will ultimately support the corporation in the best possible way. Ensuring the continual improvement of investigator research strategies, and regularly reviewing plans will enable medical affairs teams to move forward with confidence that their supported studies are benefiting the corporation.

- Key aspects of an internal strategy development
- Implementation of investigator research strategy
- Identification of common pitfalls in external collaborations
- Improving and streamlining processes to maximize outcomes

Klaas van’t Klooster, International Clinical Manager
DEPUY SPINE

2:45 DECLINING INVESTIGATOR INITIATED STUDIES WHILE MAINTAINING POSITIVE PHYSICIAN RELATIONSHIPS

When approached by an increasing number of external investigators each year, manufacturers face the challenge of turning down trials that do not fit the corporation’s strategy and goals. Seldom will an external physician seek approval for a study that he does not deem promising for both parties and declining the proposition can damage the physician relationship, resulting in refusal or lack of involvement in future collaborations. Establishing a corporate strategy which clearly outlines parameters for IIS disapproval as well as how to deliver this decision in a fair and transparent manner will help in safeguarding positive physician relationships.

- Building a transparent system for approvals and declines
- Liaising with marketing & sales teams to maintain positive relationships
- Providing timely and professional feedback on study requests

Uli Mezger, Clinical Research Manager
BRAINLAB
WHO SHOULD ATTEND:
Within the Pharmaceutical and Medical Device industries, organizations that will find this program of greatest applicability will be those charged with the responsibility of identifying, reviewing and managing investigator initiated research requests and the overall conduct of external investigator research. With sessions delving into multiple tracks to meet the specific requirements of both pharmaceutical and device researchers, with their unique positions within the industry, this program will be of great and immediate value to participants. Job titles of most relevance include:

- Medical Affairs
- Medical Directors
- Medical Advisors
- Medical Science Liaisons
- Medical Liaisons
- Medical Strategy
- IIS / IIR Executives

SPONSORSHIP OPPORTUNITIES:
Q1 productions offers a wide variety of sponsorship opportunities to forward-thinking corporations looking to connect and work with pharmaceutical and medical device corporations throughout Europe. Products and services of interest to this particular audience working in the Investigator Initiated Research space include:

- Clinical Research Organizations
- Electronic Data Capture Specialists
- Clinical Operations Management
- Subject Recruitment Consultants
- Intellectual Property Protection Firms
- Data Analytics Consultants
- Electronic Clinical Research Software

PREVIOUS ATTENDEES:

- Medical Director, Abbott
  Manager, Medical Strategy, Abbott Medical Optics
- Associate Director, Clinical Programs, Actelion
- Post Market Trial Manager, Alcon Laboratories
- Head R&D Medical Affairs, Alcon Management
- Medical Manager, Astellas Pharmaceuticals
  Clinical Research Manager, AstraTech AB
- Manager, Clinical & Scientific Affairs, Bausch & Lomb
- Study Manager, Clinical Operations, Bausch & Lomb
- Medical Director, Baxter
- Medical Advisor, Bayer Healthcare
- Medical Affairs Manager, BD
- Medical Director, BD
- Leader, Clinical Science, Berlin Heart
- Medical Affairs Manager, Boehringer-Ingelheim
- Medical Liaison Manager, Boehringer-Ingelheim
- Sr. Fellow, Clinical Research, Boston Scientific
- Clinical Research Manager, Brainlab AG
- Executive Director, CSCOe, Bristol-Myers Squibb
  European Lead, CSCOe, Bristol-Myers Squibb
- Clinical Project Leader, CardiANBCT Europe
- Medical Affairs Manager, Cephalon
- Medical Science Manager, Cephalon
- Research Network Manager, Cochlear
- Clinical Studies Specialist, Cochlear
- Director, Research & Applications, Cochlear
- Director, Medical Affairs, Coloplast
- Clinical Development Manager, Crucell Switzerland
- Clinical Specialist, Drager Medical
- Senior Medical Liaison, Eli Lilly
- European Medical Director, Eli Lilly
- VP Medical Support, Gambro
- Director, Medical Strategy, Gambro
- VP Medical Affairs, Europe, Genzyme
- Medical Affairs Manager, Ipsen
- Research Scientist, Janssen Biologics
- IIS Lead, Johnson & Johnson
- IIS Manager, Leo Pharma
- Medical Director, Medical Affairs, Leo Pharma
- Manager, Medical Affairs, Lifescan
- Head, External Research Programs, Medtronic
- Sr. Manager, Clinical Programs, Medtronic
- Sr. Medical Affairs Manager, Merz Pharmaceuticals
- Clinical Research Manager, Nobel Biocare
- Global Medical Director, Novartis
- Medical Scientific Relations Manager, Pfizer
- Global IIR Group Leader, Pfizer
- Medical Advisor, Pfizer Norway
- MGM Director, Pfizer Japan
- Clinical Study Manager, Philips Healthcare
- Clinical Science Study Manager, Philips Healthcare
- Manager, Global Medical Affairs, Roche
- VP Diabetes Medical Affairs, Sanofi Aventis
- Director, Clinical Affairs, Sorin
- Director, Clinical Affairs, Synthes
- Head, Medical Affairs, Teva Pharmaceuticals
- Medical Director, The Medicines Company
- Global Clinical Research Manager, Tornier
- Clinical & Sales Director, Vivoline Medical AB

AND MANY MORE!