EUROPEAN MEDICAL DEVICE INVESTIGATOR INITIATED STUDY

Maximizing Medical Device Investigator Initiated Research through Effective Management of Investigators & Studies, Training on Policies, Procedures & Regulations, all within a Unclear Regulatory Framework in Europe

PROGRAM OVERVIEW

Throughout the medical device industry, manufacturers are struggling with the volume of requests from investigators who are interested in conducting research studies on new and existing products. While these studies were traditionally only led by a select number of key opinion leaders, many doctors and physicians in Europe are now considering these types of studies as a way to advance not only medical technology, but also their own profiles as industry experts. Executives in Medical and Clinical Affairs need to be prepared with strategies and policies which will govern how to best handle these types of research; especially given the rapidly evolving regulatory environment.

A key area for discussion during this program will be methods for the evaluation of potential investigator led studies, as well as opportunities in risk assessment and understanding how to best support investigators. Companies have a wide variety of options when considering investigator research, from fully funding studies, to more hands-off approaches where little support is provided. Fully understanding which approach is most appropriate based on individual companies and scenarios is critical in today’s ever evolving marketplace. Regulatory considerations must also be taken into account, including both regulations impacting clinical research and human subject protection, as well as understanding the regulatory aspects of payment physician, contact with healthcare professionals and fair market valuations.

Throughout the program, interactive sessions will enable professionals to engage in a lively debate and discussion on the challenges and opportunities that investigator initiated research presents to today’s global medical device corporation. As with all Q1 programs, the strictly controlled attendance will minimize participation of outside consultants, providing attendees with an atmosphere focused on knowledge share, learning and networking; ideal for those consultants and solution providing companies looking to enter this exciting market.

DISTINGUISHED PRESENTERS INCLUDE:

Peter Bannister  
Chief Scientific Officer  
EYKONA TECHNOLOGIES

Luc Verhees  
Medical Affairs Director, Europe  
MEDTRONIC

Katrin Leadley  
Chief Medical Officer  
JENAVALE

Célestin Fokoua Mouafa  
Former Medical Director  
AI Medical & Clinical Affairs,  
Neuromodulation – EMEAC  
SAINT JUDE MEDICAL

Marion Gericke  
Clinical Project Leader EMEA  
TERUMO BCT

Michal Slomczykowski  
Medical Director  
GEISTLICH PHARMA

Jörg Kahler  
Partner  
GSK STOCKMANN + KOLLEGEN

Torsten Kayser  
Senior Fellow Clinical Research, International Clinical Research  
BOSTON SCIENTIFIC

Geneviève Michaux  
Of Counsel  
COVINGTON & BURLING LLP

Mark C. Flynn  
Director of Research and Applications  
COCHLEAR BONE  
ANCHORED SOLUTIONS

Michael Ramb  
Principal Associate  
FRESHFIELDS BRUCKHAUS DERINGER

Christopher Bryce  
Industry Practice Leader – EMEA, Chemicals & Life Science  
MARSH

Christoph Engeler  
Counsel  
LATHAM & WATKINS

Media Partners:

PMR

Medical Device Daily™  
The Daily Medical Technology News Source
10:00 ESTABLISHING A COMMON TERMINOLOGY FRAMEWORK: DEFINING “SPONSORS”, AND OTHER CHALLENGES
In establishing the responsibilities between external physicians and device corporations, it is critical that terminology confusions be clarified from the very start of the collaboration. The concept of “sponsor” is at times misunderstood in investigator initiated studies, which leads to confusion in each party’s role and tasks, and ultimately potential time and money lost. Outlining the exact definition and legal concept of what a sponsor is, and what being a sponsor implies, will prevent confusion and optimize collaborations.
- Physician’s understanding of “sponsor” vs industry’s perspective
- Legal definition of the sponsor
- Differentiating funding from sponsoring

Christoph Engeler, Counsel
LATHAM & WATKINS

10:45 ALIGNING EXTERNAL STUDIES WITH CORPORATE MEDICAL STRATEGY
In the increasing flow of external investigators soliciting medical device organizations for support of their projects, not all proposals correspond to the company’s medical strategy. Clinical and medical executives need to make certain the study they approve goes the same direction as the company, in order to ensure maximized results and legitimate distribution of funds. Examining strategies to fit external studies within the device corporation’s strategy will help ensure proper utilization of funds, and ensure success in company/physician collaborations.
- Communicating the company’s processes, goals and expectations
- Determining the IIS direction and value proposition
- Strategies in bringing the trial and company to a match
Luc Verhees, Medical Affairs Director, Europe
MEDTRONIC

11:30 DETERMINING THE BEST APPROACH FOR EACH INVESTIGATOR INITIATED STUDY
When approached by outside investigators, medical device corporations must carefully examine a physicians’ study intentions to ensure that the study is aligned with the overall corporate strategy, as well as to understand what approach is best in moving forward. There are various approaches that an organization can take, from providing only financial or product support, to fully integrating the study into existing clinical investigations. Evaluating different options in the collaboration with external investigators will provide insight on the best strategies in moving forward in the most efficient manner.
- Identifying the overall study goal to target the appropriate support
- Opportunities in financial support only
- Allocation of free devices and associated risks
- Support in data management
Torsten Kayser, Sr. Fellow Clinical Research, International Clinical Research
BOSTON SCIENTIFIC

12:15 LUNCHEON FOR ALL SPEAKERS, SPONSORS & ATTENDEES

1:45 IDENTIFYING WHICH IIS TO SUPPORT FOR MAXIMIZED RETURN ON INVESTMENT
In this time of rapid expansion of the life science industry, device companies are increasingly approached by external investigators interested in their products and seeking support for studies. While some projects appear to be solid and promising, others might not bring the same successful outcomes and eventually not be worth the company’s investment. Understanding how to assess the potential of external studies will ensure maximization of the company’s time and money.
- Implementing an internal Investigator initiated study assessment process
- Usefulness of having an internal IIS commission regardless of company size
- Determining priorities among all proposals
- Maximizing returns on funding
Peter Bannister, Chief Scientific Officer
EYKONA TECHNOLOGIES

2:30 BEST PRACTICES: ACHIEVING BETTER COLLABORATION BY TRAINING EXTERNAL INVESTIGATORS
When contracting with an external physician for an investigator initiated trial, the device company must ensure that the physician has the proper experience and knowledge to move forward and successfully lead the study. Communicating strategies and knowledge to the investigator raises challenges for both parties, as the clinical and medical teams must provide the best training possible in a timely manner, and engage with the physician for him to understand all important aspects of leading a study overseen by specific regulations. Nonetheless, to ensure that company policy and regulatory requirements are followed, implementation of an internal training strategy will help in achieving a smooth trial.
- Conducting a background check on the physician
- Tailoring physician trainings for each specific study
- Communicating and training on corporate policy
- Clarifying current regulations
Katrin Leadley, Chief Medical Officer
JENALVALVE

3:15 COFFEE & NETWORKING BREAK

3:45 PANEL DISCUSSION: STRATEGIES FOR ENGAGING WITH PHYSICIANS IN INVESTIGATOR INITIATED RESEARCH
For medical device corporations throughout Europe, one of the greatest challenges in conducting investigator initiated research is managing relationships with their physician investigators. From the outset of the proposed study, through to contracting, study progression and conclusion, device company sponsors and study investigators must find common ground in their communication strategies, and ensure that study goals are being met. Understanding how to best work with this important group of stakeholders is critical in the overall success of investigator led research, and will ensure that this research ultimately supports the corporate goals of the device manufacturer.
- Engaging in an IIS as a means of cost-reduction
- Selection criteria: how to identify the appropriate physician and site
- Outlining the exact role of the physician
- Defining and balancing responsibilities
Luc Verhees, Medical Affairs Director, Europe
MEDTRONIC
Célestin Fokoua Mouafa, Former Medical Director AI Medical & Clinical Affairs, Neuromodulation – EMEAC

4:30 DEVELOPING A COHESIVE INVESTIGATOR INITIATED STUDY CONTRACT
When supporting an investigator-led study, once the role of the device company in the trial is determined, a thorough and study-specific contract must be issued to display all terms of the agreement between both parties. Establishing the most appropriate terminology and fully outlining all aspects of the collaboration can be challenging, especially when the contract is drafted by different teams within the device company. The contract being the overall alliance statement between the physician and the device company, ensuring that it is intelligible, exhaustive and perfectly explicit on targets and processes will guarantee a successful start to the study.
- Connecting legal and clinical teams to draft the contract
- Establishing a partnership plan to tailor for each study
- Utilization of appropriate terminology
- Must-have clauses
Mark C. Flynn, Director of Research and Applications
COCHLEAR BONE ANCHORED SOLUTIONS

5:15 CLOSING REMARKS & DAY ONE CONCLUSION
First.

DAY TWO / TUESDAY, APRIL 24 / EU MEDICAL DEVICE INVESTIGATOR INITIATED STUDY

8:00 REGISTRATION & COFFEE

8:20 CHAIRPERSON’S OPENING REMARKS
Christoph Engeler, Counsel
LATHAM & WATKINS

8:30 OBTAINING & SECURING IP PROTECTION WHEN CONDUCTING EXTERNAL RESEARCH STUDIES IN THE EU, FOCUS ON GERMANY

When establishing a trial contract and partnership with an external physician, intellectual property considerations are critical. Medical device corporations need to secure well in advance the data and publications relevant to their product, as well as the overall outcomes of the trial. Through real-life case study examples and a focus on one of the key-European markets, participants in this session will understand how to ensure the device organization achieves successful IP outcomes.

- Establishing agreements on IPs and patents
- Considerations on publications and copyrights
- Case-study practical do’s and don’ts

Jörg Kahler, Partner
GSK STOCKMANN + KOLLEGEN

9:15 ESTABLISHING CLEAR STUDY PROTOCOLS WITH EXTERNAL INVESTIGATORS

Developing a study protocol for clinical research is always a delicate step as it must thoroughly cover all aspects of the trial. When supporting investigator initiated studies, this task often becomes even more complex in the sense that the physician is not always fully aware of the company procedure and the exact requirements for this matter. While the external investigator should be the one to develop the protocol, it is advised for the device company to work together on this particular step to ensure the best possible start to the study.

- Strategies in co-development of the protocol
- Defining the exact terms of the investigation
- Communicating the necessity of protocol adherence to the physician

Marion Gericke, Clinical Project Leader EMEA
TERUMO BCT

10:00 COFFEE & NETWORKING BREAK

10:30 ISO 14155 REVISION: CLARIFYING NEW REQUIREMENTS WITH INVESTIGATORS

The release of the revised ISO 14155 framework has resulted in a number of significant changes in study safety measures, data management, and the overall conduct of medical device clinical research studies. These regulatory revisions also impact any clinical research being conducted by outside investigators, and in many cases the responsibility of communicating regulatory requirements to physicians and investigators is left to industry representatives. Engaging in a proactive dialogue with investigators, as well as having a firm understanding of the impact of regulatory revisions is essential in maintaining a high level of regulatory compliance across all research studies.

- Gap analysis for the revised standard
- Updating protocols for trials launched under 14155:2003
- Training of the physician on ISO 14155:2011

Célestin Fokoua Mouafa, Former Medical Director AI Medical & Clinical Affairs, Neurmodulation – EMEAC
SAINT JUDE MEDICAL

11:15 OVERCOMING COMPLIANCE HURDLES IN THE FUNDING OF AN IIS & FAIR MARKET VALUE

When planning the financial support of an investigator-initiated study, an increasingly tight regulatory framework means that determining how much money should be allocated to the physician and the study is a delicate step. The consequences of getting this wrong can be severe. Increasing Fair Market Value (FMV) trends and general compliance requirements should therefore be carefully considered before moving forward, to optimise the overall compliance of both the device company and the healthcare professional. By examining these requirements and the concept of fair market value in more detail - and how to calculate it - participants in this session will improve their compliance with key anti-bribery and corruption principles.

- Understanding the regulatory framework and how this applies to IISs
- Understanding current FMV trends worldwide
- Strategies in establishing successful compliance and FMV internal processes

Michael Ramh, Principal Associate
FRESHFIELDS BRUCKHAUS DERINGER

LUNCHEON FOR ALL SPEAKERS, SPONSORS & ATTENDEES

1:15 ENSURING FINANCIAL DISCLOSURE IN INVESTIGATOR INITIATED STUDIES

After a number of cases shedding light on excessive fund transfers, regulatory bodies of the life science industry are strongly pushing health professionals towards full disclosure of all financial transactions when collaborating with external investigators. While the United States have implemented the Sunshine Act, which aims at a better control of payments between healthcare professionals and the industry, the European framework remains country-specific. When deciding to support an investigator initiated study, it is critical that both the device company and the physician understand the relevant legal framework and the aftermath of non-compliance.

- Examining the US Sunshine Act & its potential impact on EU companies
- Upcoming legislations in European countries
- Strategies to remain “transparent”

Geneviève Michaux, Of Counsel
COVINGTON & BURLING LLP

2:00 RECOGNIZING OPPORTUNITIES IN MAXIMIZING THE OUTCOMES OF INVESTIGATOR STUDIES

When contracting with external investigators, device corporations must assess which benefits the study can bring to the company, and how to maximize return on investment. The overall data generated by external trials is an important source of new information on existing devices and can ultimately save time and money to the device company, as well as bring prominence to the company name through successful study outcomes. Understanding which benefits lay in investigator initiated study data will ensure clinical and medical executives make the most of the collaboration.

- Intellectual property considerations on study data
- Ensuring proper data monitoring and visibility on results
- Opportunities in utilizing IIS data: publication planning

Michał Słomczykowski, Medical Director
GEISTLICH PHARMA

2:45 SUCCESSFUL INSURANCE PLANNING IN INVESTIGATOR INITIATED STUDIES

In all studies involving humans, making sure patients are properly covered and the device corporation is sufficiently protected through appropriate insurance policy is crucial. When supporting an investigator initiated study and collaborating with an external physician, the main challenge resides in developing the appropriate coverage plan, as it must be tailored to meet needs of the specific external trial and outline liabilities of both parties. Addressing hurdles in insurance planning and how to overcome them in an efficient manner will help participants rest assured that both patients and the device company remain safe throughout the study.

- Differences and parallels between company-led trials and IIS
- Identifying IIS-specific needs
- Outlining responsibilities between both parties
- Combining physician medical liability insurance with the device corporation insurance
- Protecting the device company in IIS

Christopher Bryce, Industry Practice Leader – EMEA, Chemicals & Life Science
MARSH

3:30 CLOSING REMARKS & CONFERENCE CONCLUSION
PREVIOUS ATTENDEES INCLUDE:

Chief Medical Officer, 3M
Director, Clinical Affairs, 3M
Medical Director, Abbott 
Associate Director, Clinical Program Lead, Actelion
Director, Global Medical Affairs, Alcon Laboratories
Manager, Global Medical Affairs, Alcon Laboratories
VP Medical Sciences, Allergan
Clinical Program Manager, American Medical Systems
Medical Information Manager, Astellas Pharmaceuticals
VP Clinical Affairs, Atrium Medical
Clinical Research Project Manager, B.Braun Medical
Study Manager, Clinical Ops Europe, Bausch & Lomb
Medical Director, Baxter International
Medical Advisor, Oncology, Bayer Healthcare
WW VP Medical Affairs, Becton Dickinson
Medical Liaison Manager, Boehringer-Ingelheim
Clinical Research Manager, Celleration
Sr. Medical Affairs Manager, Cephalon
IIS Program Lead, Clinical Research, Codman & Shurtleff
Head, Clinical Research, Coloplast
Manager, Clinical Trial Services, Cook
VP Medical Affairs, Coviden
Director, Medical Science Liaison, Coviden
Medical Information Specialist, Crucell Switzerland
Medical Affairs Director, CSL Behring
Clinical Program Manager, DePuy Spine
VP Clinical Affairs, Edwards Life Sciences
European Neuroscience Medical Director, Eli Lilly
Director, Clinical Affairs, Ethicon Endo-Surgery
Sr. Director, Clinical Marketing, GE Healthcare
VP Medical Affairs Europe, Genzyme
Medical Affairs Manager, Grunenthal
Director, Clinical Affairs, Integra Life Sciences
Medical Affairs Manager, Ipsen
Research Scientist, Janssen Biologics
IIS Lead, J&J Global LClinical Operations
Operations Mgr., Professional Affairs, Kinetic Concepts
VP Global Clinical Development, Kinetic Concepts
Investigator Initiated Study Manager, Leo Pharma A/S
International Medical Advisor, Leo Pharma A/S
Manager, Medical Affairs, Life Scan
Director, Global Clinical Research, Medtronic Diabetes
Medical Science Liaison, Medtronic
Global Medical Affairs Manager, Merz Pharmaceuticals
Global Brand Medical Director, Novartis
Global Medical Affairs Lead, Pfizer
Global Investigator Initiated Research Lead, Pfizer
Cardiac Biomarker Manager, Roche Diagnostics
VP Global Diabetes & Medical Affairs, Sanofi-Aventis
VP Clinical Affairs, Chief Medical Officer, Smith & Nephew
Director, Biostatistics & Clinical, Smith & Nephew
Healthcare Compliance Officer, Stryker Neurovascular
Director, Clinical Affairs, Stryker Neurovascular
Medical Director & Advisor, Swedish Orphan Biovitrum
Sr. Medical Affairs Manager, Teva Pharmaceuticals
Head, Medical Development, Teva Pharmaceuticals
Medical Director, Medicines Company – Germany
Sr. Clinical Project Lead, Medicines Company – UK

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VP Clinical Affairs, Edwards Life Sciences
European Neuroscience Medical Director, Eli Lilly
Director, Clinical Affairs, Ethicon Endo-Surgery
Sr. Director, Clinical Marketing, GE Healthcare
VP Medical Affairs Europe, Genzyme
Medical Affairs Manager, Grunenthal
Director, Clinical Affairs, Integra Life Sciences
Medical Affairs Manager, Ipsen
Research Scientist, Janssen Biologics
IIS Lead, J&J Global LClinical Operations
Operations Mgr., Professional Affairs, Kinetic Concepts
VP Global Clinical Development, Kinetic Concepts
Investigator Initiated Study Manager, Leo Pharma A/S
International Medical Advisor, Leo Pharma A/S
Manager, Medical Affairs, Life Scan
Director, Global Clinical Research, Medtronic Diabetes
Medical Science Liaison, Medtronic
Global Medical Affairs Manager, Merz Pharmaceuticals
Global Brand Medical Director, Novartis
Global Medical Affairs Lead, Pfizer
Global Investigator Initiated Research Lead, Pfizer
Cardiac Biomarker Manager, Roche Diagnostics
VP Global Diabetes & Medical Affairs, Sanofi-Aventis
VP Clinical Affairs, Chief Medical Officer, Smith & Nephew
Director, Biostatistics & Clinical, Smith & Nephew
Healthcare Compliance Officer, Stryker Neurovascular
Director, Clinical Affairs, Stryker Neurovascular
Medical Director & Advisor, Swedish Orphan Biovitrum
Sr. Medical Affairs Manager, Teva Pharmaceuticals
Head, Medical Development, Teva Pharmaceuticals
Medical Director, Medicines Company – Germany
Sr. Clinical Project Lead, Medicines Company – UK

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