2ND ANNUAL MEDICAL DEVICE INVESTIGATOR INITIATED TRIALS

Maximizing Value from Investigator Initiated Trials within the Device Industry through Overcoming Regulatory, Compliance and Funding Challenges, Aligning Research with Company Strategy and Managing Every Aspect of Investigator Relationships

PROGRAM OVERVIEW:

Around the world, medical device corporations are being increasingly approached by healthcare professionals looking to partner with manufacturers to investigate new uses for marketed technologies. These types of studies are increasingly gaining relevance for the medical device space, where the opportunity for discovering additional uses and benefits for existing products is quite vast. As an increasing number of device companies implement programs to maximize this type of research, regulators have seen the need for monitoring it while making certain that companies appropriately manage the inherent risk factors associated with clinical research.

With increased scrutiny from regulatory authorities on the safety of medical technologies, risk assessment and management has become a top priority, and one that will certainly be addressed throughout the two-day conference program. Also central to this program will be strategies for connecting the overall medical strategy of the corporation alongside any investigator sponsored research as well as developing and maintaining investigator relationships. In order to maximize these studies, companies must also consider funding and support provided while ensuring this assistance is in-line with regulatory guidelines. Unfortunately, compliance issues do not end with funding, and sessions during this segment of the program will also address the Sunshine Act and other key international regulations.

This two-day executive level program, will provide participants with extensive in-depth learning and knowledge share, through case-study driven presentations, high level keynote sessions, as well as round table panel discussions complemented by multiple networking opportunities. Through fostering a sense of collaboration and information share, this unique conference program will help bring clarity to Medical and Clinical Affairs Executives as well as MSLs wishing to maximize investigator Initiated Studies.

DISTINGUISHED PRESENTERS INCLUDE:

Jason G. Jones, MS, CCRP
Global Vice President, Clinical Affairs, Advanced Surgical Devices Division
SMITH & NEPHEW

Onikepe Adegbola, MD, PhD
Chief Medical Officer, Molecular Imaging, Executive Medical Director
GE HEALTHCARE

Robert Galiano, MD
Assistant Professor, Director of Research, Division of Plastic Surgery
NORTHWESTERN UNIVERSITY FeINBERG SCHOOL OF MEDICINE

Georgia M. Arvanitis, PhD
Senior Director, Clinical Sciences & Scientific Fellow
LIFECELL

Margaret Tumas, DVM
Vice President, Medical & Clinical Affairs
SIDLEY AUSTIN LLP

Jihong Qu, PhD, MBA
Director, Clinical Studies, Atrial Fibrillation Division
ST. JODE MEDICAL

John Resman,
Senior Director, Medical Affairs & External Research
MEDTRONIC

Ulf Borg
Director, Clinical Affairs
COVIĐEN

Jasmeet Singh, MD, MPH
Senior Clinical Scientist and Global Medical Safety Reviewer
BOSTON SCIENTIFIC

Harel Deutsch, MD
Assistant Professor of Neurosurgery
RUSH UNIVERSITY MEDICAL CENTER

Deitza Raby
Corporate Counsel & Privacy Officer
HILL-ROM HOLDINGS, INC.

Dr. David Turok, MD
Vice President and Corporate Medical Director
AMERICAN LASER CENTERS

Jodi Akin
VP Global Clinical Affairs
EDWARDS LIFESCIENCES

Craig Sponseller, MD
VP of Medical Affairs
KOWA PHARMACEUTICALS

Jennifer Cartony
Clinical Research Manager
CELLERATION

Martin Kwende, PhD
Director, Clinical Affairs
SPIRACUR

Blake Morrison, PharmD
Senior Director, Medical & Scientific Affairs
ONYX PHARMACEUTICALS

Jonas Hylton, PharmD
Associate Director, Medical Science Liaisons
MEDIVATION

Nicole Liffrig Molife, Esq.
Counsel
ARNOLD & PORTER LLP

Avi B. Markowitz, MD, FACP
Professor, Internal Medicine, Chief, Hematology / Oncology, Bill & Louise Bauer Distinguished Chair, Cancer Research Department, Internal Medicine
UNIVERSITY OF TEXAS MEDICAL BRANCH

Ron Chappuis
Director, Medical Science Liaison
SAGE PRODUCTS, INC.

*Pending Final Confirmation
DAY ONE / THURSDAY, SEPT 27 / MEDICAL DEVICE INVESTIGATOR INITIATED TRIALS

7:00 CONFERENCE REGISTRATION & MORNING COFFEE

7:20 CONFERENCE WELCOME & CHAIRPERSON OPENING REMARKS

8:20 CONFERENCE WELCOME & CHAIRPERSON OPENING REMARKS

8:30 JUSTIFICATION OF INVESTIGATOR INITIATED STUDIES FOR DEVICE COMPANIES

Economic and regulatory restraints in recent years have caused industry-wide cutbacks, which have in turn caused companies to scrutinize and justify expenditures. Amidst these circumstances, investigator initiated trials often provide a cost-effective method for increasing market share, and may be an effective strategy for device companies navigating the economic downturn. By exploring the justification behind IIT program implementation, companies may also develop strategies for ensuring effective studies that assist in the fulfillment of company goals in a turbulent environment.

- Understanding the reasoning & benefits of implementing IIS programs
- Investigator Research to support new indications and new labeling
- Implementing investigator led programs for companies of every size

Onikepe Adegbola, Md, PhD, Chief Medical Officer, Molecular Imaging, Executive Medical Director
GE HEALTHCARE

9:20 PRE-STUDY CONSIDERATIONS TO MAXIMIZE INVESTIGATOR RELATIONSHIPS & STUDY EFFICIENCY

There is no doubt that investigator initiated studies provide a key area of expansion and opportunity for device companies, particularly when corporations maximize physician relationships through the development of cohesive contracts prior to study commencement. Outlining expectations for the partnership and establishing study specific agreements is a vital yet challenging step that sets the tone for a trial and has the ability to dictate such key concerns as timely completion and utilization of results. Through putting in place explicit protocol and guidelines at the onset of a trial, device companies are able to eliminate unnecessary confusion.

- Creative deal structures that create a mutually advantageous environment
- Key considerations to include in contracts prior to study commencement
- Milestone payments tied to results & strategies for timely study completion

Martin Kwende, PhD, Director, Clinical Affairs
SPIRACUR

10:10 COFFEE & NETWORKING BREAK

10:30 EXPLORING THE ALIGNMENT OF INVESTIGATOR SPONSORED RESEARCH TO MEDICAL & MARKETING STRATEGY

There is no doubt that the alignment of IIS with corporate medical and marketing strategies is the ideal outcome for device companies in their collaboration with external investigators, and this coordination must be considered during the initial proposal phase of the research. However, compliance concerns abound as corporations strive to maintain their status as the non-sponsorwhile at the same time maximizing resource allocation, maintaining relationships and pursuing company strategy. Through open and frank dialogue this diverse panel of experts will explore common concerns and hurdles as well as strategies for ensuring these external studies are in line with corporate strategy.

- How can manufacturers compliantly generate interest in studies of interest?
- Can manufacturers determine direction and value proposition of the IIS?
- What strategies may be implemented to align trial and company strategies?

Jodi Akin, Vice President, Global Clinical Affairs
EDWARDS LIFESCIENCES

JASMEET SINGH, MD, MPH, Senior Clinical Scientist and Global Medical Safety Reviewer
BOSTON SCIENTIFIC

Margaret Tomas, DVM, Vice President, Medical & Clinical Affairs

11:20 CASE STUDY: A SMALL COMPANY PERSPECTIVE ON ISR AND WHAT LARGE COMPANIES CAN LEARN

Opportunities for engaging in and benefiting from investigator initiated studies are certainly not exclusive to large companies. However, priorities and strategies may vary greatly for small or young corporations, as such companies often have more limited resources to devote to external research. In order for small companies to ensure maximized return on investment, and therefore justify resource allocation to IIS, heightened attention must be placed upon pre-approval procedures and efficiency throughout the study duration, considerations that manufacturers of all sizes may benefit from.

- Strategies small companies employ to maximize IITs
- Exploring prioritization of attention and resources
- Translating small-company strategies to companies of all sizes

Jennifer Cartony, Clinical Research Manager, CELLERATION

12:10 LUNCHEON FOR ALL SPEAKERS, SPONSOR AND ATTENDEES

1:20 INVESTIGATOR COMMUNICATION & EDUCATION THROUGHOUT THE LIFESPAN OF A STUDY

Throughout the entirety of an investigator led study, communication between the company and physician must be a top priority for both sides, as lack of correspondence may lead to delayed or derailed studies. Device companies must address and reiterate clear definitions and limitations as well as corporate policies and regulatory requirements. To ensure achievement of all goals from a regulatory, industry and manufacturer standpoint, communication that fosters a compliant and collaborative environment is of utmost importance.

- Compliant and proven communication strategies
- Educating investigators on significant risk & IDE submission
- Corporate policy and study specific considerations

Jaydoot Singh, MD, MPH, Sr. Clinical Scientist & Global Medical Safety Reviewer
BOSTON SCIENTIFIC

2:10 AN INVESTIGATOR PERSPECTIVE ON WORKING WITH INDUSTRY: HURDLES & OPPORTUNITIES FOR SUCCESSFUL IITS

IIS often pose challenges for both industry and investigator, as both strive to remain compliant while managing the study and maintaining communication. Staying in contact through trial progression and completion is beneficial, as it ensures study goals are being met, while at the same time bringing to light strategies for adapting current and future IIS based on the experiences of seasoned investigators. By capitalizing on the expertise of investigators, device companies can gain a further understanding of how to work with this important group of stakeholders as well as increase efficiency of future studies.

- Increasing efficiency of IIT conduct through communication strategies
- Common hurdles and successes of IIS from an investigator standpoint
- Understanding what attracts investigators to IIS & industry’s role

Robert Gallano, MD, NORTHWESTERN UNIVERSITY
Harel Deutch, MD, RUSH UNIVERSITY MEDICAL CENTER
Dr. David Turok, MD, MERICAN LASER CENTERS

3:00 COFFEE & NETWORKING BREAK

3:20 OVERCOMING INTERNATIONAL HURDLES TO ENHANCE GLOBAL INVESTIGATOR INITIATED STUDIES

Rapid globalization of the healthcare industry has encouraged expansion of device companies into key international and emerging markets, which provide opportunities for commercialization of products and increased market share. This international progress has also enhanced the accessibility of investigator sponsored research by expanding the pool of potential investigators and study proposals as well as the possibility of reaching new, unrealized markets. However, global IIS also come with their own set of hurdles, and anticipating and overcoming such challenges as complying with regulations, site management and communication is a vital aspect of implementing and reinventing global investigator sponsored programs.

- Developing global programs & overcoming common pitfalls
- Overview of regulations in Europe and other key markets
- Update on the revised ISO 1455 framework

Jodi Akin, Vice President Global Clinical Affairs, EDWARDS LIFESCIENCES

4:10 PANEL ADDRESSING AUDIENCE QUESTIONS: BEST PRACTICES & LESSONS LEARNED FROM MULTIPLE COMPANY PERSPECTIVES

Within the ever-changing and advancing device industry, companies have been required to quickly learn and adapt in order to capitalize on shifts and maintain a competitive edge. As IIS’s have expanded, corporations have established diverse strategies for accommodating to demand. Through the submission of questions from the audience prior to this session, the delegation will obtain tailored answers to specific questions that may lead to key takeaways for implementation into their own programs.

- Key components of successful IIT programs from multiple viewpoints
- Comparing strategies and procedures implemented at various companies
- The best practices and lessons learned for investigator initiated studies

John Resman, PharmD, MEDTRONIC
Ulf Borg, COVIDIEN

5:00 CLOSING REMARKS AND DAY ONE CONCLUSION

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DAY TWO / FRIDAY, SEPT 28 / MEDICAL DEVICE INVESTIGATOR INITIATED TRIALS

7:30 CONFERENCE REGISTRATION & MORNING COFFEE

8:00 OPENING REMARKS & DAY TWO WELCOME

8:10 INTERPRETING AND OVERCOMING LEGAL & REGULATORY BARRIERS FOR INVESTIGATOR SPONSORED RESEARCH

With such landmark events as Healthcare Reform and the Physician Payment Sunshine Act including legislation in the Anti-Kickback Statute and the False Claims Acts, device companies have certainly faced heightened attention from regulators and consumers alike in recent years. This surveillance has impacted ISRs as healthcare professionals seek to avoid negative implications and device companies pursue compliance in a complex environment. Within a regulatory atmosphere that is under scrutiny, companies must take proactive measures to not only protect themselves, but also their investigators.

- Overview of nomenclature and terminology involved in IISs
- Statutes & regulations that apply to IIS & the agencies that enforce them
- Exploring consequences of non-compliance

Deiltah Raby, Corporate Counsel & Privacy Officer  
HILL-ROM HOLDINGS, INC.
Meenakshi Datta, Partner  
SIDLEY AUSTIN LLP

9:00 ASSESSMENT OF IIT PROPOSALS TO ENHANCE RESOURCE ALLOCATION AND MAXIMIZE RETURN ON INVESTMENT

As investigator initiated studies are conducted to a greater extent throughout the healthcare industry, life science companies are increasingly approached by external investigators for study support. While IISs are advantageous, proposals must be stringently examined in order to justify investment and avoid unnecessary risk. Particularly in the current economic environment, it is paramount for companies to put in place proposal valuation guidelines and processes in order to enhance return on investment of time, resources and support.

- Implementing IIS assessment processes and committees
- Determining priorities among proposals, allocating resources & headcounts
- Maximizing ROI for funding and study support

Georgia M. Arvanitis, PhD, Sr. Director, Clinical Sciences & Scientific Fellow  
LIFECELL
Craig Sponseller, MD, VP of Medical Affairs  
KOWA PHARMACEUTICALS

9:50 COFFEE & NETWORKING BREAK

10:20 MAXIMIZING IITS THROUGH MANAGING INVESTIGATOR RELATIONSHIPS: FROM QUALIFICATION TO EVALUATION

Prior to accepting a proposal for an investigator initiated study, companies must explore and review multiple considerations, not the least of which is the capabilities of the investigator. Whether working with healthcare professionals with whom a company has a longstanding relationship or with new investigators, challenges often arise, from restricted enrollment through to lackluster data entry. To ensure efficient and effective study completion, manufacturers must develop and implement strategies for not only qualifying healthcare professionals prior to study commencement, but also for evaluating the investigator throughout the trial.

- Exploring types of criteria for qualifying investigators
- Evaluating new investigators vs. HOs with long-term relationships
- Assessing investigators throughout and at study completion

Ulf Borg, Director, Clinical Affairs  
COVIDIEN
Blake Morrison, PharmD, Sr. Director, Medical & Scientific Affairs  
ONYX PHARMACEUTICALS

11:10 FACILITATING INVESTIGATOR INITIATED PROGRAMS WITHIN THE CURRENT ECONOMIC ATMOSPHERE

Within the current economic environment, dwindling funding and restricted budgets are certainly key concerns for life science companies. With heightened attention surrounding the efficient use of resources and capital, the effective management of investigator initiated studies amid restricted resources is a constant consideration. In order to allocate adequate funding to maximize studies and minimize cost, companies must take into account such budgetary factors as milestone payments that encourage efficiency, strategies for overcoming studies that are not enrolling and unique funding avenues such as company match grants.

Jason G. Jones, MS, CCRP, Global Vice President, Clinical Affairs, Advanced Surgical Devices Division  
SMITH & NEPHEW

12:00 LUNCHEON FOR ALL SPEAKERS SPONSORS & ATTENDEES

1:10 PANEL DISCUSSION: BENCHMARKING INDUSTRY THOUGHT LEADER COMPENSATION AND FMV DETERMINATION

The Office of Inspector General of the Department of Health and Human Services has declared that the healthcare industry must compensate thought leaders and consultants for their companies at a Fair Market Value in order to avoid the appearance of offering inducements for the promotion of their products. Although the OIG created FMV, they have yet to provide a clear determination of what compensation is appropriate for industry to offer thought leaders for their services. This panel discussion will bring together pharmaceutical and medical device companies, regulators and physicians to discuss the controversial topic of FMV and provide conference attendees with a framework of thought leader compensation best practices during this time of regulatory uncertainty.

- Determining consistent and transparent FMV compensation plans
- Bridging the gap between OIG lack of guidance & industry best practices
- Discussion of FMV from a legal, industry and physician perspective

Nicole Liffrig Molife, Esq., ARNOLD & PORTER LLP
Muriel Siadak, SEATTLE GENETICS
Avi B. Markowitz, MD, FACP, UNIVERSITY OF TEXAS MEDICAL BRANCH
Deiltah Raby, HILL-ROM HOLDINGS, INC.
Meenakshi Datta, SIDLEY AUSTIN LLP

2:10 FOCUSING ON THE EXPECTATIONS OF THOUGHT LEADERS FROM A KOL PERSPECTIVE

Pursuing new thought leader relationships within the current healthcare environment can be extremely challenging given the increasing industry regulations and the unruly calendars of physicians and surgeons. Key opinion leaders are self-directed, goal-oriented and they must find relevance in what they are doing. Understanding what KOLs find to be valuable when working with companies is an important factor to consider when organizing and developing strategies for capturing their interests. Through the thought leader perspective, attendees will gain insight on regulatory issues, compensation and what KOLs are looking for in a company before agreeing to work with them.

- KOLs on what compensation is appropriate for their time & expertise
- Attracting and maintaining the attention of key opinion leaders
- What makes a company stand out to thought leaders?

Avi B. Markowitz, MD, FACP, Professor, Internal Medicine, Chief, Hematology / Oncology, Bill & Louise Bauer Distinguished Chair, Cancer Research Department, Internal Medicine  
UNIVERSITY OF TEXAS MEDICAL BRANCH

3:00 TRANSITIONING RELATIONSHIPS FROM KOL INVESTIGATORS TO THOUGHT LEADERS FOR THE LONG-TERM

Investigator Initiated Studies are an important component of the overall success of clinical research and development for pharmaceutical and device companies. By working with innovative physicians and surgeons to conduct clinical research on products approved or in the pipeline, companies may gain vast rewards including an ideal formation of relationships between industry and thought leaders alike. However, medical affairs professionals must establish a systematic plan for organizing, reviewing and approving proposals from KOL investigators as well as navigating those relationships into long-term thought leaders for the company. This case study will showcase the positive impact investigator initiated studies have had on one successful company’s thought leader initiatives and the regulatory and budgetary restraints that were overcome in the process.

- Recruiting key opinion leaders specifically for investigator initiated trials
- Recognize compliance issues and develop plans to overcome the hurdles
- Develop systematic plans for organizing, reviewing & approving proposals

Jonas Hyfton, PharmD, Associate Director, Medical Science Liaisons  
MEDIVATION

3:50 CLOSING REMARKS AND CONFERENCE CONCLUSION

ABOUT THE ORGANIZERS:

Q1 Productions designs and develops webinars, training courses, conference programs and forums aimed at specifically targeted audiences in order to provide strategic and timely information. Through a rigid production process focused on end-user research and design, our team is able to understand the immediate business concerns of today’s leading executives. Whether focusing on new or pending legislative issues, enhanced business processes or technologies that will drive efficiency and customer service, our programs provide solutions to the urgent needs of our attendees.

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ATTENDEE PROFILE:
Executives that will find this program of greatest relevance are those currently working in Investigator Initiated Trials and Investigator Sponsored Research within medical device and diagnostic corporations. Job titles of those executives that will find this program to be most applicable to their job functions include:

- Medical Affairs
- Medical Science Liaisons
- Clinical Affairs
- Clinical Research
- External Research
- Medical Directors

SPONSORSHIP OPPORTUNITIES:
At this time, there are a variety of sponsorship and exhibition opportunities available for companies wishing to increase their visibility and participation in the program, ranging from keynote speaking opportunities through to exhibitor and documentation sponsors. Organizations most suitable for this type of exposure provide services and solutions including:

- Clinical Trial Consultants
- Clinical Research Organizations
- Compliance Consultants
- Regulatory Experts
- IIT Software & Data Management
- Contract Solutions

FEEDBACK FROM LAST YEAR’S EVENT:

“Excellent, extremely useful, very relevant, good practical advice”
-3M

“Engaging & helpful to see what others are doing at a detailed level”
-AMERICAN MEDICAL SYSTEMS

“Very helpful and enlightening”
-CELLERATION

“Excellent, relevant information, spot on!”
-COOK, INC.

“The speakers were very experienced and extremely professional with their presentations. The conference was well worthwhile and I gained a lot of insight and information that I brought back to my team. I look forward to applying this information sometime in the near future”
-MIRAMAR LABS

PREVIOUS ATTENDEES INCLUDE:
Clinical Affairs Director, ATOS MEDICAL
VP, Clinical Affairs, ATRIUM MEDICAL CORPORATION
Clinical Research Project Manager, B. BRAUN MEDICAL
WWVP, MedAffairs, MedSurg, BECTON DICKINSON
Clinical Projects Manager, BIOMATIQUES
Sr. Med Dir, BOSTON SCIENTIFIC
Clinical Research Manager, CELERATION
Senior Director of Clinical Affairs, CELONOVA
CEO, CENTER FOR CLINICAL RESEARCH SOLUTIONS, INC.
IIS Prgm Leader, Clin Research, CODMAN & SHURLEFF
Head of Clinical Research, COLOPLAST
Manager of Clinical Trial Services, COOK INC.
Vice President of Medical Affairs, COVIDENT
Director, Medical Science Liaisons, COVIDENT
Senior Director of Clinical Affairs, COVIDENT
Global Medical Director, STI, COVIDENT
Sr Dir, Tissue Regen R&D & Clinical Affairs, DAVOL INC.
Clinical Project Manager, DEPUY SPINE
Project Ldr ClinOps, DUKE CLINICAL RESEARCH INSTITUTE
Asst Dir, ClinOps, DUKE CLINICAL RESEARCH INSTITUTE
Vice President of Clinical Affairs, EDWARDS LIFESCIENCE
Global Vice President of Scientific Research, ELEKTA
Director, Clinical Affairs, ETHICON ENDO-SURGERY
Senior Director, Clinical Marketing, GE HEALTHCARE
Director of Clinical Affairs, INTEGRA LIFE SCIENCES
Senior Director of Clinical Affairs, INTEGRA LIFESCIENCES
Director of Medical Affairs, JOHNSON & JOHNSON
Group Manager, Clinical Affairs, JOHNSON & JOHNSON
Ops Manager, Professional Affairs, KINETIC CONCEPTS
Interim VP, Global Clinical Dev, KINETIC CONCEPTS
Director of Professional Affairs, KINETIC CONCEPTS, INC.
HCC Director, AHS and TSS - US, KINETIC CONCEPTS, INC.
Sr Vice President of Clinical & Regulatory Affairs, LANX
Clinical Science Liaison, LANX
Manager, Medical Affairs, LIFESCAN
Partner, MCGUIREWOODS
Global Manager for Clinical Contracting, MED INSTITUTE
Executive Project Manager, MED INSTITUTE
Director, Global Clinical Research, MEDTRONIC DIABETES
Medical Science Liaison, MEDTRONIC DIABETES
Senior Manager of Clinical Affairs, MIRAMAR LABS
Di, Clin & Med Affairs, PATHWAY MEDICAL TECH
Director & Team Leader, Global IIR, PFIIZER
Global Medical Lead, Musculoskeletal Disease, PFIIZER
Cardiac Biomarker Manager, ROCHE DIAGNOSTICS
Vice President of Medical & Clinical Affairs, R. S. MEDICAL
Partner, SAUL EWING LLP
Vice President of Medical, Regulatory & Quality, SI-BONE
Partner, SIDLEY AUSTIN LLP
Vice President of Clinical Affairs, CMO, SMITH & NEPHEW
Dir, Biostatistics & Clinical Research, SMITH & NEPHEW
Health Compliance Officer, STRYKER NEUROVASCULAR
Manager, STRYKER NEUROVASCULAR
Director of Clinical Affairs, STRYKER NEUROVASCULAR
Sr Med Dir, Clin Research, SUNOVION PHARMACEUTICALS
Scientific Affairs Manager, SYSMEX
Operations Manager, THE MAYO CLINIC
RA Specialist, UNIVERSITY OF ARKANSAS MED SCIENCES
Sr Research Compliance, UNIVERSITY OF MICHIGAN
Mgr, Project Management, UNIVERSITY OF MICHIGAN
Adjunct Associate Professor, UNIVERSITY OF MINNESOTA