PROGRAM OVERVIEW:

Throughout the US, medical device corporations face daily challenges in conducting their clinical research studies that are entirely different and more challenging than the hurdles faced by the pharmaceutical industry. This vibrant and quickly evolving industry has for many years looked to Q1 productions as their source of education and networking opportunities as they look to structure and conduct clinical studies that meet various internal and external expectations. In our 6th Annual US Medical Device Clinical Research conference, we will focus on a wide range of the specific challenges that the device industry faces, throughout their clinical trial. Also of great importance and relevance will be evolutions in the regulatory framework, along with the recent 510k changes that have so dramatically impacted the industry.

Opening keynote presentations will highlight the many hurdles faced by the industry, and how companies can come together to best structure and manage their clinical research. From bridging the gap between marketing, reimbursement, R&D and clinical teams in order to meet multiple objectives, to laying the groundwork for not only approval-based studies but also studies that will support alternative indications through investigator driven research, this program will deliver on a wide range of the topics executives need to address over the course of the next six to eight months.

Sponsoring the Q1 Medical Device Clinical Research Conference is a unique opportunity unlike other available conference programs, bringing medical device companies small and large to the table, where they have an opportunity to discuss so many of their specific challenges in a unique environment. Whether new to the industry, or an industry veteran, this program will provide networking and educational opportunities that are unparalleled. Join us, for what will certainly be yet another exciting and truly informative meeting.
11:45 COMPARATIVE EFFECTIVENESS RESEARCH & THE FUTURE FOR DEVICE CLINICAL RESEARCH

With Congress allotting $1.1 billion to conduct and fund comparative effectiveness research studies, many companies are eagerly trying to gain clarity on how this research will be evaluated by healthcare practitioners, insurers & government authorities. Many believe that comparative effectiveness research can help manage a particular condition while using the most effective devices and remain cost-efficient. This presentation will consider whether that will necessarily be the case. Regardless, it is imperative for companies to understand when to conduct head-to-head clinical studies with a competitor.

- Understanding what clinical evidence is increasingly required by Medicare
- Appreciating FDA’s expanding use of “Section 522” orders for postmarket surveillance studies

Beverly H. Lorell, MD
Senior Medical and Policy Advisory, FDA Life Sciences Team
KING & SPALDING LLP

5:30 DAY ONE CONFERENCE CONCLUSION
BIOMET ORTHOPEDICS, LLC

Keli K. Hankee, Manager of Clinical Affairs

9:45 SUCCESSFULLY MANAGING OUTSOURCED CLINICAL TRIALS

Implementing business and management techniques while selecting CROs ensures that companies identify and contract with the most qualified and applicable CRO to effectively manage the site. Creating a partnership with the CRO will guarantee shared goals are understood and benefit the overall team relationship. Much like any major business proposition, it is important to consider budgeting, timing, and the functionality of a CRO to effectively manage an outsourced trial.

• Steps of successful CRO selection
• Budgeting outsourced studies
• Developing and managing vendor contract
• Optimizing relationship between sponsor and a CRO

Kunal Sampat, PMP, Clinical Project Manager III

ABBOTT VASCULAR

10:30 COFFEE & NETWORKING BREAK

11:00 PANEL DISCUSSION: OVERCOMING POSSIBLE FUNDING OBSTACLES

Companies funding their own trials should plan for unforeseen changes possibly elongating the timing of a study and inevitably increasing the cost of the overall trial. Research organizations also face funding obstacles in providing appropriate scientific data proving the necessity of a device to receive federal funding. This open discussion will allow for participants to discuss strategies of how to overcome funding obstacles seen in both federal and private sectors.

• Creating a trial design while demonstrating clinical evidence that is acceptable to all stakeholders
• Understanding extremely limited funding opportunity for research
• Best practices in overcoming mid-trial funding losses

Jason R. Waggoner, PhD, Clinical Scientist

ETHICON ENDO-SURGERY, INC., A JOHNSON & JOHNSON COMPANY

Beth Carson, Senior Clinical Affairs Specialist

SPINE WAVE, INC.

11:45 CONDUCTING POST MARKET SURVEILLANCE TO MEET REGULATORY EXPECTATIONS

Understanding the requirements needed for post market surveillance to fulfill appropriate regulatory standards is a constant obstacle faced by device companies. It is necessary to develop strategies to ensure efficiency in long-term tracking of patients and accuracy in data collection. Clarification is needed on FDA section 522 requirement and strategies accurately inform stakeholders of any time delays and costs accrued.

• Understanding the requirements of FDA-mandated section 522
• Designing post-trial methodologies effectively and efficiently
• Informing stakeholders post market surveillance progress
• Benefits of FDA’s tracking system to ensure timely completion

Mary Beth Ritchey, RN, MSPH, PhD, Associate Director for Postmarket Surveillance Studies - Division of Epidemiology, Office of Surveillance and Biometrics

CDRH, FDA

Douglas M. Hansell, MD, MPH
Chief Medical Officer, Americas Executive Medical Director

GE HEALTHCARE

12:30 LUNCHEON FOR ALL CONFERENCE ATTENDEES

1:45 DEFINING ADDITIONAL OPPORTUNITIES TO UTILIZE CLINICAL RESEARCH DATA

Data collected during a clinical study can produce additional developments to further knowledge of the device’s effects on a particular patient population. Scientific research can advance the medical understanding of devices and their effect on various populations, which can ultimately allow for future treatment developments. Publishing clinical data results can lead to improvements in current scientific knowledge and further ensures the best treatment is provided to the patient.

• Publishing medical articles and studies
• Development of online, open access journals
• Scientific information exchange versus off-label promotion
• Determining when to do IIT versus directed study

David Appleby
Director, Biostatistics and Clinical Research

SMITH & NEPHEW, ADVANCED SURGICAL DEVICES DIVISION

David L. Horwitz, M.D., Ph.D., FACP
Chief Medical Officer

JOHNSON & JOHNSON DIABETES INSTITUTE

2:45 ANALYZING UNFORESEEN CHALLENGES AND SOLUTIONS IN CLINICAL RESEARCH

Unanticipated obstacles can arise in all phases of clinical trials and often result in significant time delays and higher costs. The implementation of a novel device often requires surgeons and other clinical staff to be trained on a specific skill assisting in them learning new procedures. Human errors need to be properly documented as to not effect data providing necessary evidence to receive regulatory approval. Ensuring that the clinical staff is thoroughly educated pre-trial on all aspects of device implantation, standard operating procedures and possible side effects of device on a patient group will help to reduce mistakes made.

• Training doctors for surgeries on novel devices to overcome learning curve
• Taking human error into account while charting study data
• Educating clinicians on smart technology use

Steven Dooca
Senior Clinical Research Manager

STRYKER INSTRUMENTS

3:30 UTILIZING FAILURE MODES AND EFFECT ANALYSIS TO IMPROVE OVERALL TRIAL

Creating a clinical study that produces the appropriate evidence needed for regulatory approval while also reducing costs is crucial to the success of the overall study. Implementing traditional risk & quality management tools help to improve research strategies. Firm evaluation of clinical design in the beginning stages will help in eliminating possible problems seen in later stages.

• Improving tools used in clinical design
• Discovering potential flaws of studies before study is executed
• Evaluating evidence to utilize for additional study phases

Pat Baird
Lead Designer

BAXTER HEALTHCARE

4:15 DAY TWO CONFERENCE CONCLUSION
SPEAKER SPOTLIGHT:

Mary Beth Ritchey, RN, MSPH, PhD
Associate Director for Postmarket Surveillance Studies
Division of Epidemiology, Office of Surveillance and Biometrics
CDRH, FDA

Lynne Kelley, MD, FACS
World Wide Vice President Medical Affairs, Medical Surgical Systems
BECTON DICKINSON

Lynne Kelley, MD, FACS, is the World Wide Vice President, Medical Affairs for Medical Surgical Systems at Becton Dickinson. Dr. Kelley is a board certified general and vascular surgeon having received her medical degree from Dartmouth Medical School and completed her Residency in General Surgery at Dartmouth Hitchcock Medical Center. During her training she was awarded an NIH sponsored research grant at Harvard Medical School. She completed a Fellowship in Vascular Surgery at Harvard Medical School, Massachusetts General Hospital and the Marco Polo Fellowship in Endovascular Surgery at the University Paris Hospital, Henri Mondor.

Dr. Kelley was an assistant professor of vascular surgery and radiology at Yale University. In 2005 she joined Boston Scientific where she was the medical director for the peripheral interventions and vascular surgery business as well as the neuro-interventions business. In January 2011 Dr. Kelley joined Becton Dickinson as the World Wide Vice President of Medical Affairs Medical Surgical Systems. She leads a team of medical professionals in a wide variety of activities including clinical trials, safety evaluations, product development and key opinion leader management and development. Lynne is also an integral member of the business team determining strategy and execution for both organic and inorganic growth opportunities.

WHO SHOULD ATTEND THIS Q1 CONFERENCE:

Executives that will be most interested in participating in this conference program will be those involved in conducting clinical research for medical devices throughout the US, in order to achieve regulatory and reimbursement support. Understanding how to navigate the clinical landscape is a challenging process and our panel of expert presenters has over 200 years of combined experience successfully conducting studies. If you are involved in this process, or are considering entering into the market, this conference is ideal. Job titles of executives that will be most applicable for this program include VPs, Directors and Managers of:

- Clinical Research and Clinical Trials
- Clinical Trial Operations
- Clinical Affairs
- Medical Affairs Professionals
- Medical Directors
- Clinical Research Scientists
- Regulatory Affairs
- Chief Scientific Officers
- Chief Medical Officers
- Clinical Programs
- Clinical Research Coordinator
- Patient Registry Solutions
- Patient Recruitment Solutions
- Electronic Data Capture
- Electronic Patient Reported Outcomes

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 exhibit and documentation sponsors. Organizations most suitable for this type of exposure provide services and solutions including:

- Global Clinical Research Organizations
- Localized Clinical Research Organizations
- Regulatory Consultants
- Reimbursement & Market Access Experts
- Data Management Software Providers
- Patient Registry Solutions
- Patient Recruitment Solutions
- Electronic Data Capture
- Electronic Patient Reported Outcomes

PREVIOUS ATTENDEES INCLUDE:

Dir, Regulatory Affairs, Abbott Medical Optics
Clinical Studies Manager, Abbott Spine
Sr. Clinical Research Associate, Abbott Vascular
Director, Reimbursement, Acclarent
Director, Clinical Research, Acclarent
VP Regulatory & Quality, Acorn Cardiovascular
Director, Clinical Affairs, AGA Medical
Sr. Director Clinical Affairs, AGA Medical
Sr. Clinical Manager, Anulex Technologies
Clinical Research Manager, AptaTech
Director, Clinical Affairs, ArthroCare
Director, Clinical Science, B.Braun
Director, Clinical Affairs, Bard Peripheral Vision
Clinical Marketing Mgr., Baxano
Sr. Director, Clinical Ops., Baxter Healthcare
Director, Clinical & Regulatory, Biomet
Sr. Clinical Project Manager, Biotronik
Manager, Clinical Studies, Boston Scientific
VP Clinical, Coloplast
VP Regulatory Affairs, Coloplast
Clinical Affairs Manager, Cook Medical
Director, Health Economics, Coviden
Sr. Manager, Clinical Affairs, Coviden
Director Clinical & Quality, DePuy Spine
Scientist, Clinical Affairs, Ethicon Endo-Surgery
Director Clinical Affairs, ev3
Regulatory Affairs Manager, GE Healthcare
VP of Clinical Affairs & Reimbursement, InterceptENT
Sr. Director Clinical Affairs, Integra LifeSciences
Manager, Clinical Affairs, J&J Ethicon
Clinical Affairs Manager, Johnson & Johnson
Clinical Project Manager, Johnson & Johnson
Sr. Director, Clinical Research, Mako Surgical
Sr. Manager, Health Economics, Medtronic
Sr. Director Clinical Affairs, Medtronic
Regulatory Affairs Director, Nuvasive
Group Director, Ortho Clinical Diagnostics
Mgr, Clinical & Medical Affairs, Ortho Clinical Diagnostics
VP Clinical Research, Orthovita
Clinical Research Manager, Ossur
Clinical Trials Manager, Otto Bock
Director of Medical Affairs, Otto Bock
VP Clinical & Regulatory, Regenesis Biomedical
VP Medical & Regulatory Affairs, ResMed
Manager, Health Economics, ResMed
Sr. Director Clinical Operations, Roche
Group Director, Clinical Affairs, Smith & Nephew
Dir, of Biostatistics & Clinical Research, Smith & Nephew
Clinical Project Manager, Sorin
Sr. Clinical Monitor, Stryker
Sr. Clinical Research Manager, Stryker
Regulatory Affairs Analyst, Stryker
Regulatory Affairs Manager, Tornier
Global Clinical Research Mgr., Tornier
Sr. Manager, Clinical Research, WL Gore
Clinical Operations Associate, Welch Allyn
Sr. Manager Clinical Studies, Wright Medical
Sr. Manager, HEOR, Zimmer
Associate Director, Global Health Policy, Zimmer