EU MEDICAL DEVICE POST-MARKET CLINICAL EVALUATION PLANNING

OCTOBER 29-30, 2019 | FRANKFURT, GERMANY

Developing & Implementing Robust Plans to Gather Compliant Post-Market Clinical Follow-Up Data, Practically Defining Clinical Evidence Based on Device Class & Acceptable Information, all while Sharing Solutions to Operational Challenges in Cost-Effective Data Collection

DISTINGUISHED PRESENTERS INCLUDE:

NOTIFIED BODY SPEAKERS:

Itoro Udofia
Head of Notified Body
UL

Anthony Wilkinson
Manager – Global Clinical Focus Team
TÜV SÜD

Caroline Dore Geraghty
Chief Clinical Evaluator for Medical Devices
NATIONAL STANDARDS AUTHORITY OF IRELAND

Pedro Eerdmans
Head of the Notified Body
DEKRA CERTIFICATION BV

MEDICAL DEVICE INDUSTRY EXPERTS:

Klaas Van't Klooster
Clinical Manager
JOHNSON & JOHNSON

Andreas Gmerek
Manager Clinical Development
B BRAUN

Benedikt Þorri Sigurjónsson
Manager of Clinical Evaluation, Medical Office
ABIOMED EUROPE GMBH

Michal Slomczykowski
Medical Director
GEISTLICH PHARMA AG

Sabine Konopka
Director Clinical Affairs
PHENOX GMBH ELIZABETH WEATHERS

Karsten Wallbrück
Director Regulatory & Clinical Affairs Europe
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Senior Clinical Program Manager
MEDTRONIC

Paola Vivoda
Associate Director, EMEA Clinical Operations
ZIMMER BIOMET

Ruben Roijers
Manager, Q&R – Post-Market Surveillance
PHILIPS HEALTHCARE

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Principal Clinical Research Manager
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Kemine Hale
Senior Manager Regulatory & Clinical Affairs
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Josefine Sommer
Senior Associate
SIDLEY AUSTIN LLP

Justyna Kozik-Jaromin
Head of Clinical Affairs
HERAEUS MEDICAL GMBH

Lincoln Tsang
Partner
ARNOLD & PORTER

Basira Salehi
Head of Clinical Science & Regulatory Clinical Evaluation
BIOTRONIK

Leo Hovestadt
Senior QA/RA Manager
ELEKTA

Ela Bingel-Erlenmeyer
Head Clinical Trials
GEISTLICH PHARMA AG

Elizabeth Weathers
Clinical Research Manager
IBA GROUP

Norbert Clemens
Senior Manager Science & Clinical Affairs/DPO
KANEKA PHARMA EUROPE N.V.

Rita Herrenknecht
Clinical Program Manager Cardiac Surgery
LIVANOVA

Jón I. Bergsteinsson
Co-Founder and VP of Global BD
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DAY ONE - TUESDAY OCTOBER 29

7:30 REGISTRATION & WELCOME COFFEE

8:30 CHAIRPERSON'S OPENING REMARKS

8:45 ICE BREAKER: SHARING PERSPECTIVES ON THE POSITIVE INFLUENCE OF ENHANCED POST-MARKET RESEARCH ON THE EU MEDICAL DEVICE MARKET

While the transition toward reinforced regulatory requirements for post-market clinical operations under the MDR challenges the industry, forward-looking executives also recognize a beneficial opportunity to improve product performance and value. By leveraging enhanced research, companies are positioned to reap numerous benefits including the ability to unveil real-world user experience data and design flaws in a more proactive and timely fashion, ultimately enabling prioritization of product improvements. This interactive ice breaker commences the event with an opportunity for all delegates to move around the conference room and engage in brief, targeted conversations with the goal of sharing specific insights into the exciting new developments in the medical device industry prompted by enhanced research requirements.

9:15 PANEL: NOTIFIED BODIES' INTERPRETATION OF MDR-COMPLIANT POST-MARKET REQUIREMENTS

- Factors in evaluating clinical evidence under the MDR
  - » Outlining a satisfactory blend of data
  - » Device maturity influence on NB review
  - » Defining data amounts considered sufficient
- Perspectives in critical components of a thorough PMCF plan
- Addressing timely communication challenges with the industry

PANELISTS:

Caroline Dore Geraghty, *Chief Clinical Evaluator for Medical Devices,* **NATIONAL STANDARDS AUTHORITY OF IRELAND**

Pedro Eerdmans, *Head of the Notified Body,* **DEKRA CERTIFICATION BV**

Itoro Udofia, *Head of Notified Body,* **UL**

Anthony Wilkinson, *Manager – Global Clinical Focus Team,* **TÜV SÜD**

MODERATOR:

Basira Salehi, *Head of Clinical Science & Regulatory Clinical Evaluation,* **BIOTRONIK**

10:15 COFFEE & NETWORKING BREAK

IN-DEPTH STRATEGIZING TO DESIGN ACCURATE PMCF PLANS & DEVELOP SUFFICIENT CLINICAL EVIDENCE

One of the most urgent challenges facing professionals formulating plans for the collection of post-market clinical follow-up data lies in the lack of clear definition for sufficient clinical evidence in the EU MDR. While it is known that insufficient PMCF evidence will preclude a product from the market, over-straining organizational research budgets must also be prevented, and industry is therefore in need of insight into the minimum level of evidence considered acceptable by notified bodies and competent authorities. Companies seek to implement a mixture of active and passive data collection methodologies, typically dependent upon the device classification and maturity, and further complicated when multiple products must be planned for simultaneously.

10:45 PART 1 – PANEL: STRATEGIES TO ENSURE A BLEND OF DATA & ACHIEVE CLINICAL EVIDENCE EXPECTATIONS

- Debating methods for clinical evidence generation & collection
  - » Post-market interventional trails
  - » Extension of pre-market trials
  - » National health service registries
  - » Physician & patient surveys
  - » Purchasing of hospital data sets
  - » Use of patient advocacy group data
- Balancing incorporation of data from multiple sources
- Positioning of unique data sets within the PMCF plan

Leo Hovestadt, ELEKTA

Norbert Clemens, KANEKA PHARMA EUROPE N.V.

Ela Bingel-Erlenmeyer, GEISTLICH PHARMA AG

Rita Herrenknecht, LIVANOVA

11:30 PART 2 – CASE STUDY: POST-MARKET RESEARCH PLANNING BASED ON PRODUCT MATURITY

- Influence of device maturity on post-market research planning
- Determining depth of evidence required for legacy devices
- Practical application of post-market plans for legacy devices
- Satisfying notified body scrutiny for new versus mature products

Leo Hovestadt, *Senior QA/RA Manager,* **ELEKTA**

12:00 LUNCHEON FOR ALL PARTICIPANTS

1:30 PART 3 – EXCHANGE GROUPS: DEFINING SUFFICIENT CLINICAL EVIDENCE BASED ON DEVICE CLASSIFICATION

While PMCF data requirements are enhanced for all families of devices under the MDR, the type and quantity of evidence considered satisfactory by notified bodies will vary based upon device risk classification. The new classification regime has altered the definition of risk inherent to the use of devices, creating challenges for clinical teams in planning for the generation and collection of relevant evidence, and ultimately, in how to design a comprehensive post-market evaluation plan. Delegates will have the opportunity to share challenges faced and solutions reached within specific device classes in an engaging discussion format led by a knowledgeable peer.

- **Group 1: Class I Devices**

Benedikt Þorri Sigurjónsson, ÖSSUR

- **Group 2: Class IIa & IIb Non-Implantable Devices**
- **Group 3: Class IIb Implantable & Class III Devices**

Karsten Wallbrück, ABIOMED EUROPE GMBH

Justyna Kozik-Jaromin, HERAEUS MEDICAL GMBH

2:15 PANEL: PMCF BUDGET: FINANCIAL FORECASTING & SECURING EXECUTIVE LEADERSHIP BUY-IN

- Strategies for PMCF budgetary planning
- Maximizing buy-in for financial investment
- Addressing clinical budget overspending

Paola Vivoda, ZIMMER BIOMET

Yanela González, NOBEL BIOCARE

Ruben Roijers, PHILIPS HEALTHCARE

3:00 COFFEE & NETWORKING BREAK

OPERATIONAL CHALLENGES IN DEPLOYING A ROBUST PMCF PLAN UNDER THE MDR

3:30 PART 1 – WORKSHOP: STRATEGICALLY MANAGING THE POST-MARKET REPORTING PROCESS

In order to deliver enhanced post-market clinical follow-up plans within the short period of time required by the new regulation, it is essential that companies optimize submission timelines for post-market clinical follow-up plans, clinical evaluation reports, and periodic safety update reports. Manufacturers must also be prepared to re-evaluate and adapt the plan in response to audit feedback and unforeseen circumstances in order to remain compliant over time. Through a collaborative hands-on exercise, participants will gain valuable insight into strategies implemented by others in the field to best plan for and execute large-scale post-market research reporting.

Josefine Sommer, *Senior Associate,* **SIDLEY AUSTIN LLP**

4:30 PART 2 – CASE STUDY: MANAGING THE IMPLEMENTATION OF MDR-COMPLIANT PMCF STUDIES

- MDR-tailored PMCF trial development status
- Objective resource forecasting:
  - » Manpower & team structure
  - » Device life-cycle timeline
  - » Necessary budget
- Challenges in simultaneous PMCF studies
- Lessons learned in study implementation

Sabine Konopka, *Director Clinical Affairs,* **PHENOX GMBH**

5:15 CLOSING REMARKS & DAY 1 CONCLUSION

6:15 CONTINUED NETWORKING: FACILITATED GROUP DINNERS

With the immense value in peer-to-peer interaction and experience sharing, we wish to provide attendees with an opportunity to continue networking after the first day of the conference. Q1 Productions will arrange dinner reservations at local restaurants close to the conference hotel for those interested in joining a group of fellow participants for dinner on October 29th. Please note that dinner expenses must be covered by each participant individually.

EU MEDICAL DEVICE POST-MARKET CLINICAL EVALUATION PLANNING

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DAY TWO - WEDNESDAY OCTOBER 30

7:30 REGISTRATION & WELCOME COFFEE

8:00 CHAIRPERSON'S OPENING REMARKS

8:15 CASE STUDY: OVERCOMING OBSTACLES IN DESIGNING MDR-COMPLIANT POST-MARKET CLINICAL TRIALS

- Exploring factors to determine endpoints for post-market clinical studies
- Managing translation of pre-market studies to the post-market phase
  - » Adapting to indefinite timelines
  - » Location considerations
  - » Budgetary needs
- Special considerations in structuring new MDR-compliant PMCF trials

Andreas Gmerek, *Manager Clinical Development*
B BRAUN

8:45 CONTINUOUS PHYSICIAN OVERSIGHT TO ENSURE RAPID COLLECTION OF QUALITATIVE POST-MARKET DATA

With healthcare professionals' unique position to actively collect product safety and efficacy evidence in the real world setting, clinical affairs teams aim to establish strong relationships with hospital teams as well as robust training geared toward data needs. However, the industry often faces complications with decreasing physician interest and motivation over time in post-market research, as well as with non-compliant practices such as deviations from authorized use. It is therefore incumbent upon the company to motivate the physician to partake in a win-win relationship through carefully-planned communication regarding the mutual goal of device success and improvement, ultimately supporting positive patient outcomes.

Michal Slomczykowski, *Medical Director*
GEISTLICH PHARMA AG

9:15 UPDATES TO GOOD CLINICAL PRACTICE STANDARD: ISO14155 REVISION PROCESS

- Sharing practical insights into the ISO14155 revision process
- Highlighting differences between the current 2011 and expected revision (2020 version)
- Next steps for industry in the application of the new standard

Klaas Van't Klooster, *Clinical Manager*
JOHNSON & JOHNSON

9:45 COFFEE & NETWORKING BREAK

10:15 COLLECTING CLINICAL EVIDENCE IN A POST-MARKET SETTING: THREE SUCCESS STORIESS

Planning and executing a successful post-market clinical data collection strategy is a challenge, and the lack of examples of how PMCF studies shall be conducted leaves many uneasy. The requirements for clinical evidence vary depending on the device type and classification, but "proactive" remains a keyword within the regulation. This presentation focuses on three different cases of PMCF studies, based on real use cases from manufacturers that have had success with proactive data collection. The goal is to inspire other manufacturers, and provide guidance for implementing a successful post-market data collection strategy under the MDR.

Jón I. Bergsteinsson, *Co-Founder and VP of Global BD*
SMART-TRIAL

POST-MARKET STRATEGIES & TEAM STRUCTURES ENSURING A COMPREHENSIVE APPROACH TO ENHANCED REQUIREMENTS

Within the new post-market regulatory environment including different concepts and tasks such as PMCF, PMS, PSUR and CER, clinical research teams must be structured so as to effectively combine data sets and optimize the use of internal resources. Confusion currently lies in how to correctly handle one task before the next, in order to ultimately generate and report product safety and efficacy evidence, as well as to package data from different sources efficiently. Team structuring alongside clear defining of the differences and overlap of each operation are key to the compliant management of necessary post-market duties on time and within budget.

11:00 PART 1: LARGE COMPANY PERSPECTIVE

Paola Vivoda, *Associate Director, EMEA Clinical Operations*
ZIMMER BIOMET

11:30 PART 2: MIDSIZED COMPANY PERSPECTIVE

Kemine Hale, *Senior Manager Regulatory & Clinical Affairs*
ADVANCED BIONICS

12:00 CASE STUDY: PRACTICAL CONSIDERATIONS IN ESTABLISHING INDUSTRY-SPONSORED REGISTRIES

- Timing & processes for cost-effective structure
- Cost considerations in industry-led registries
  - » Determining true value of potential insight
  - » Incorporating data cleaning costs into plan
- Ethics committee approval & location selection

Melanie Crystal, *Senior Clinical Program Manager*
MEDTRONIC

12:30 LUNCHEON FOR ALL PARTICIPANTS

1:15 MAXIMIZING REGISTRY DATA: RELEVANCE, ACCESS & ACCEPTABLE USAGE

As clinical research executives increasingly consider registries as a cost-effective tool to obtain relevant real-world clinical follow-up material, uncertainties persist regarding the degree to which registry data will be considered acceptable by notified bodies and competent authorities. Additionally, divergent interpretations surrounding whether registries should be industry-sponsored, as well as the nature of data that can be gathered compliantly, have led to further need for clarification. Industry members seek simplified and practical insight into compliantly structuring registry studies enabling the collection of relevant information useful to achieve post-market evidence goals.

Norbert Clemens, *Senior Manager Science & Clinical Affairs/DPO*
KANEKA PHARMA EUROPE N.V.

2:00 ENHANCING THE USE OF DEVICE DATA GENERATED BY HOSPITALS IN POST-MARKET STRATEGIES

Given the importance of real-world evidence within the framework of MDR, medical device companies are considering device performance data from hospitals as a potential source of valuable information. However, hospital data sets often require resource-intensive cleaning to extract relevant evidence, and limitations instated by GDPR further call into question the viability of the information to meet regulatory demands. Clinical executives are therefore pursuing practical knowledge on successful methods to establish data-driven collaborations with hospitals and compliantly integrate hospital-generated device performance data into PMCF plans.

- Identifying relevant & acceptable hospital information
- Opportunities in data collection partnerships with hospitals
- Cost considerations & ensuring compliance with GDPR
- Appropriately positioning hospital data in the PMCF plan

Ruben Roijers, *Manager, Q&R – Post-Market Surveillance*
PHILIPS HEALTHCARE

2:45 COFFEE & NETWORKING BREAK

3:15 EXCHANGE GROUPS: COMPARING STRATEGIES TO ENSURE GDPR COMPLIANCE IN PMCF DATA COLLECTION

GDPR has opened new challenges for clinical research professionals seeking to obtain post-market clinical evidence from external sources, with many data sets inaccessible due to privacy concerns. Careful consideration must therefore be given to the ownership of information from individual registries, surveys, and other sources in order to proactively guard against investment in data sets that may lead to privacy infringement. Through an engaging peer-to-peer discussion, audience members will have the opportunity to share experiences and best practices in obtaining relevant evidence generated outside of traditional clinical studies, all while remaining compliant with GDPR provisions.

Lincoln Tsang, *Partner*
ARNOLD & PORTER

3:45 OPTIMIZING PATIENT SURVEYS FOR PMCF DATA COLLECTION: FOCUS ON DESIGN, RELIABILITY, AND PRESENTATION OF RESULTS

As clinical research professionals endeavor to provide a well-rounded body of evidence to notified bodies regarding the safety and efficacy of medical devices on the market, many in the industry seek insight into best practices for the use of survey data. While patient surveys are rich in qualitative feedback, challenges reside in extricating complaint information from the responses, as well as in identifying data sufficiently specific to meet authorities' expectations while remaining compliant with privacy standards. In order to ensure the highest level of efficacy and safety evidence, the structure of the survey as well as a thoughtful strategy to analyze and utilize results must be carefully considered.

- Considering the relative value of survey data in PMCF
- Survey structure enabling the collection of targeted data
- Disentangling complaints information from survey data
- Optimizing extraction & use of anonymous survey data

Elizabeth Weathers, *Clinical Research Manager*
IBA GROUP

4:15 CLOSING REMARKS & CONFERENCE CONCLUSION

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KEY SPEAKER HIGHLIGHT:

Dr. Caroline Dore Geraghty
Chief Clinical Evaluator
National Standards Authority of Ireland

Dr. Caroline Dore Geraghty is the Chief Clinical Evaluator of the National Standards Authority of Ireland. Caroline is a graduate of the Royal College of Surgeons Ireland, she is a medically trained doctor who has over 12 years' experience working in a variety of fields of medicine both in the hospital setting and clinic setting. Caroline holds a Master of Science degree in Allergy and a higher diploma in dermatology.

Dr. Itoro Udofia
Head of Notified Body
UL

Dr. Itoro Udofia is the Head of Notified Body at UL. Itoro has over fifteen years' experience working with orthopaedics devices, including nearly nine years working in the BSI Notified Body as Product Expert, Global Head of Orthopaedics and Dentals Devices, and Head of Operations and Training. Itoro has a background in academia and research in biomedical engineering, biotribology and computational modelling of orthopaedic devices. Itoro has worked as a research consultant with leading orthopaedic manufacturers in product development and testing.

Pedro Eerdmans
Leader for Business Line Medical
DEKRA CERTIFICATION

Medical doctor with a PhD in Pharmacology and a passion for medical devices. He has broad experience in the Neurology, Cardiology, Urology, Hepatology and Orthopedics field. Pedro worked in the hospital, service (Clinical Research Organization) and medical industry environment before joining Dekra. His experience in the clinical and regulatory field developed in Director Clinical, VP Medical Affairs and CMO positions managing global clinical and regulatory departments in start-up and large medical device companies. He interacted with most governmental agencies, including the FDA and PMDA, and Notified bodies. At Dekra Certifications Pedro is responsible for the Dekra Notified Body Germany and The Netherlands.

Dr. Basira Salehi
Senior Manager Clinical Science & Regulatory Clinical Evaluation
BIOTRONIK AG

Dr. Basira Salehi leads the clinical science and regulatory clinical evaluation teams at Biotronik for vascular intervention, CRM and EP devices. Her teams ensure compliance to MEDDEV and MDR, through planning, appraisal and evaluation of clinical data throughout the life cycle of the devices. She is currently managing both teams as senior manager. Basira holds a PhD in Neuroscience from polytechnic university of Lausanne (EPFL) as well as a degree in Physics engineering, followed by a postdoc in clinical research, and years of experience in medical device industry.

ATTENDEE PROFILE:

Executives that will find this program of greatest relevance are those currently working to plan for and fulfill post-market clinical research requirements within medical device corporations. Job titles of those executives that will find this program to be most applicable to their professional functions include:

- Clinical Research
- Clinical Affairs
- Clinical Operations
- Post-Market
- Post-Market Surveillance
- Biostatistics
- Clinical Quality Assurance

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:

- Survey software
- EU clinical research consulting services
- Regulatory consulting services

PREVIOUS Q1 ATTENDEES INCLUDE:

Director, RA, Clinical & Quality Assurance, **3D MATRIX EU**
Director of Regulatory & Clinical Affairs, Europe, **ABIOMED**
Head Clinical Developmt & Medical Affairs EMEA, **ALCON**
Manager Clinical Services, **AO FOUNDATION**
Clinical Research Director, **ATRO MEDICAL**
Senior Clinical Study Manager, **BAUSCH & LOMB**
Manager Regulatory Affairs, **BENTLEY INNOMED**
Clinical Affairs Director, **BENTLEY INNOMED**
Director R&D and Clinical Trials, **BIOCLIN**
Director, Clinical Research, **BIOSENSORS EUROPE**
VP Quality Management, **BONESUPPORT**
QRA Senior Specialist, **CARDINAL HEALTH**
Director Marketing & Clinical Affairs, **CARDIOBRIDGE**
Clinical Affairs Director, **CARL ZEISS MEDITEC**
Project Manager Clinical Affairs, **CARL ZEISS MEDITEC**
Clinical Affairs Manager, **CELLAVISION**
Clinical Operations Manager EMEA, **COCHLEAR**
Head of Medical Affairs, **COLOPLAST**
Director, Medical Comm., RA, **COOK MEDICAL EUROPE**
Clinical Expert, **DEKRA CERTIFICATION**
Director of Clinical Affairs, **EDWARDS LIFESCIENCES**
Co-Chair, Clinical Workgroup, **COCIR**
Senior Director Clinical Operations, **ENDOTRONIX**
Chief Medical Officer, **ENDOTRONIX**
Regulatory Affairs Director, ENZYMATICS Head, **Clinical Science** Support, **GEISTLICH PHARMA AG**
Clinical Director, **HIGHLIFE MEDICAL**
Medical Officer, Medical Devices, **HPRA IRELAND**
Sr Dir. Regulatory Policy Innovation, M. Devices, **JNJ**
VP, Regulatory & Clinical Affairs, **LUNGPACER MEDICAL**
Chief Medical Officer, **MAQUET CARDIOPULMONARY**
Dir. Clin. Risk Mngmt & Documentation, **MAQUET CARDIO**
Head of Hearing Science & Clinical Research, **MED-EL**
Program Manager EU MDR, **MEDTRONIC**
Regulatory Affairs Manager, **MEDTRONIC**
Director of Clinical Affairs, **NEW VALVE TECHNOLOGY**
Chief Clinical Evaluator for Medical Devices, **NSAI**
VP Regulatory & Clinical Affairs, **NXSTAGE MEDICAL**
Clinical Research Director, **ORTHOFIX**
Clinical Testing & Research Manager, **ÖSSUR**
Clinical Trial Manager, **OTICON MEDICAL**
Director Clinical Affairs, **PHENOX**
Clinical Program Manager, **PHILIPS HEALTHCARE**
Lead, WW Regulations/Standards, **PHILIPS HEALTHCARE**
Clinical Analyst, **PHILIPS IGT-S**
Clinical Trial Manager, **PHILIPS IMAGE THERAPY SYSTEMS**