



Cost-Effectiveness Methods, Analysis, & Challenges for Medical Technology Companies

Offices of Sidley Austin
Washington, DC
June 30 – July 1, 2009

Tuesday, June 30th

8:30 – 9:00

REGISTRATION AND CONTINENTAL BREAKFAST

9:00 – 9:05

Welcome

Thomas Maeder, Executive Director, MTLI, AdvaMed

9:05 – 10:00

Evidence and Health Technology Assessment – Terms, Concepts, and Landscape

Parashar Patel, Vice President, Health Economics & Reimbursement, Boston Scientific

- What is the body of evidence surrounding any medical technology?
- What are the roles of evidence in product clearance/approval, coverage & payment, and clinical adoption?
- What are the types of health economic and health technology assessment data?
- What are cost-effectiveness and comparative effectiveness and how are they used?
- Where does health economic data typically come from?
- What have medical device companies done in these areas?
- Caveats and pitfalls, methodological and other

10:00 – 10:45

Breakout Exercise on Cost-Effectiveness Analysis

Gregory de Lissovoy, Senior Research Scientist, Vice President of Health Technology, United BioSource

- Participants break into small groups to work through an illustrative case study of cost-effectiveness analysis and comparison of several alternative therapeutic approaches. No prior experience is required.

10:45 – 12:00

Methods of Cost-Effectiveness Analysis

John Hernandez, Vice President, Neuromodulation, Health Economics & Reimbursement, Boston Scientific

- Types of analysis and their applications
- Cost Savings Analysis
- Cost Effectiveness Analysis
- Cost Benefit Analysis
- Cost Utility Analysis

12:00 – 1:00

LUNCH

1:00 – 1:45

Cost-Effectiveness in Different Product Types and Therapeutic Categories

Liesl Cooper, Vice President, Global Healthcare Economics, Policy & Reimbursement, Medical Devices, Covidien

- Study designs revisited – different measures and endpoints
- Different product categories or therapeutic applications that illustrate the challenges of choosing the right objectives, study endpoints, and data sources
- The right study for the right purpose

1:45 – 2:30

Case Study: ROI in Bariatric Surgery

*Henry Alder, Director, Reimbursement & Healthcare Economics
Ethicon Endo-Surgery, Inc.*

2:30 – 3:15

Case Study: Deep Brain Stimulation

*Lindsay Bockstedt, Principal Analyst, Health Policy & Payment
Medtronic*

3:15 – 3:30

BREAK

3:30 – 4:15

Opportunities and Risks of Cost-Effectiveness Data

Liesl Cooper, Vice President, Global Healthcare Economics, Policy & Reimbursement, Medical Devices, Covidien

- Internal uses during product development, evaluation, positioning, pricing, etc.
- External uses of data with public and private payers and providers
- Different meanings of “cost” and “effectiveness” to different stakeholders

4:15 – 5:00

Case Study: Using Cost-Effectiveness Data in a Coverage Decision

William Sarraille, Partner, Sidley Austin

- How the U.S. Task Force for Preventive Services approaches cost-effectiveness, and the process of securing a positive recommendation for Medicare coverage of a screening test

5:00 – 5:15

Closing Remarks for the Day

ADJOURNMENT

5:15 – 6:30

RECEPTION

Wednesday, July 1st

8:00 – 8:30

REGISTRATION AND CONTINENTAL BREAKFAST

8:30 – 9:30

Internal Resources

Richard Toselli, Worldwide Vice President of Clinical Evidence & External Relations, DePuy Spine, a J&J Company

- Do you need a health economics team? How do you know?
- What is your business strategy? What products do you make, what are your clinical areas, what is your pipeline?
- Defining objectives and outputs
- Maximizing limited resources: buy or build?
- What is the desired skill mix?

9:30 – 10:30

Panel Discussion: Strategic, Tactical, and Business Considerations

Thomas F. Goss, Vice President, Boston Healthcare Associates

- Anticipating long-term data needs and designing studies and trials that anticipate multiple uses (regulatory approval, coverage and reimbursement)
- Opportunities and risks of designing studies to meet multiple purposes
- Monitoring a changing environment and designing studies that anticipate higher evidence standards
- Integrating value assessment and demonstration into clinical development
- Evaluating the time, cost, and return on additional evidence development

10:30 – 10:45

BREAK

10:45 – 11:30

Case Study: Percutaneous Heart Assist

*Andrew Greenfield, VP, Healthcare Solutions
Abiomed, Inc.*

11:30 – 12:30

Policies and Cost-Effectiveness Around the World

William Sarraille, Partner, Sidley Austin

*James Stansel, Partner, co-head of Sidley's Global Life Sciences Team,
Former Acting General Counsel, U.S. Department of Health & Human Services*

- What criteria are used and how are they applied in key countries?
- The NICE example
- Can companies develop global strategies for generating and using cost-effectiveness information?
- Are data from one country useable in others?

- Examples of successes and less optimal results
- Where is the global trend likely to go, and what should we anticipate domestically?

12:30 – 1:00

Closing Discussion

1:00

ADJOURNMENT

Important Notice

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