



Discrete Event Simulation for Dual-Chamber Pacemakers

Situation: **Economic Model Needed to Support Value**

United BioSource Corporation (UBC) was commissioned by the study sponsor, who was looking to support the value of their product, to develop an economic model to estimate the economic and health consequences of managing bradycardia due to sick sinus disease and atrioventricular block with implanted dual- versus single-chamber ventricular cardiac pacing devices (pacemakers).

Challenge: **Insufficient Evidence-To-Date**

Studies have shown that ventricular pacing increases the incidence of atrial fibrillation and the risk of developing pacemaker syndrome, which may require replacement of the implanted device, compared to dual-chamber pacing. In addition, long-term studies completed to date have not shown that the dual-chamber systems improve survival or decrease the number of strokes. These pacemakers are more complex and costly compared to single-chamber devices, and the cost-effectiveness of implanting them has raised concerns about reimbursement.

Solution: **New Modeling Method Handled Risks & Costs**

UBC developed a discrete event simulation (DES) to assess a patient's course following implantation of a pacemaker. DES is a widely used modeling methodology in many fields and was recently introduced to health care research by UBC. DES provides a superior representation of complex clinical states and treatments, properly handles competing risks, is fully time-dependent, transparent and flexible.

The model followed an individual patient's course after implantation for up to five years. Each patient in the simulation could experience complications, pacemaker syndrome, atrial fibrillation, stroke or death. Risk functions were based on published data from the Canadian Trial of Physiologic Pacing and Mode Selection Trial in Sinus-Node Dysfunction. Quality-adjusted life-years (QALYs) and direct medical costs were estimated. Benefits and costs were discounted at 3%.

The model predicted that implanting a dual-chamber device in 1,000 patients prevented 36 patients from developing atrial fibrillation and 168 from developing severe pacemaker syndrome. However, use of this device also resulted in 13 more hospitalizations with complications over a five-year period compared to single-chamber devices. Health benefits resulted in an incremental cost-effectiveness ratio of €260/QALY.

The model supported the product's value story by showing that over time higher initial costs associated with the dual-chamber device may be offset by a reduction in costs associated with re-operations and atrial fibrillation.

UBC accelerates the generation, analysis and communication of real-world evidence.

UBC At-a-Glance

- 1,400+ employees
- 30% of employees hold advanced science degrees
- 10% with doctorate-level
- > 90% client retention rates
- < 10% employee turnover
- 2,000+ peer-reviewed publications
- 365,000 patients
- 82,000 study sites
- 3,000 clinical protocols
- 2,500 health outcomes studies
- > 30,000 investigators trained in 70 countries
- 50 languages
- Trials conducted on six continents

UBC's Core Service Areas

- Peri- and Post-Approval Studies & Registries
- Specialty Clinical Solutions
- Value Generation Solutions
- Scientific Consulting & Communications
- Safety & Risk Management
- Clinical Technologies

Technologies

- Interactive Voice & Web Response Systems (IVRS & IWRS)
- Adaptive Randomization
- Electronic Data Capture (EDC)
- Electronic Patient-Reported Outcomes (ePRO)
- Dynamic Randomization
- Electronic Patient Diaries
- Adaptive Trial Design & Consulting
- Client Portals
- Virtual Meetings & Web-based Learning
- Searchable Databases: MetaHub™, RaterHub™ & Site Databases
- Publication Planning: Datavision™ & Visiontracker™

U.S. Offices:

- Ann Arbor, MI
- Bethesda, MD
- Blue Bell, PA
- Chantilly, VA
- Conshohocken, PA
- Glastonbury, CT
- Kansas City, MO
- Langhorne, PA
- Lexington, MA
- McLean, VA
- Morgantown, WV
- Newtown, PA
- Philadelphia, PA
- San Francisco, CA
- Seattle, WA
- Southport, CT
- Wayne, PA

International Offices

- Budapest, Hungary
- Cologne, Germany
- Geneva, Switzerland
- Goring-on-Thames, United Kingdom
- Horsham, United Kingdom
- Kiev, Ukraine
- London, United Kingdom
- Montreal, Canada
- Moscow, Russia
- Prague, Czech Republic
- São Paulo, Brazil
- Tokyo, Japan

UBC is a global medical and scientific affairs organization that partners with life science companies to develop and commercialize their products. For more information, call us in the U.S. at +1 866 458 1096, in the E.U. at +44 (0) 207 299 4550, or email us at info@unitedbiosource.com.