Earlybird Discount on Registration

The Center for Business Innovation
Presents

The Fourth Annual
Medical Device Connectivity Conference & Exhibition

Connecting Medical Devices to People, Workflow & Information Systems

November 1-2, 2012

Joseph B. Martin Conference Center
at Harvard Medical School
Boston, MA

SUPPORTING ORGANIZATIONS

ACCE American College of Clinical Engineering
AAMI Advancing Safety in Medical Technology
ECRI Institute The Discipline of Science. The Integrity of Independence.
HTF Healthcare Technology Foundation
INCOSE International Council on Systems Engineering
RFID in Healthcare Consortium
Wi-Fi Alliance

SUPPORTING PUBLICATIONS

Clinical Innovation + Technology
Digital Health
FierceEMR Mapping the Future of Healthcare Information
FierceHealthIT Weekly News for Health IT Leaders
FierceMedicalDevices
Healthcare Informatics
Healthcare IT News The News Source for Healthcare Information Technology
PSQH Patient Safety & Quality Healthcare

KEYNOTE SPEAKERS

Ed Cantwell, Senior Vice President, West Health Institute

Carol Davis-Smith, CCE, Vice President, Clinical Technology, Kaiser Permanente

Kevin Fu, PhD, Associate Professor, Electrical Engineering & Computer Science, University of Michigan

Tim Gee, Connectologist & Principal, Medical Connectivity Consulting

Julian M. Goldman, MD, Director, MD PnP Program & the CIMIT Program on Interoperability & Medical Director, Partners HealthCare Biomedical Engineering

William Hyman, ScD, Professor Emeritus, Department of Biomedical Engineering, Texas A&M University

Gino Johnson, Senior Vice President, General Manager & Co-Founder, CapSite

Barbara Majchrowski, MHSc, PEng, Senior Project Engineer, ECRI Institute

Venkat Rajan, Industry Manager, Frost & Sullivan

Siddharth Saha, Research Director, Frost & Sullivan

WHO SHOULD ATTEND

- *Executives and clinicians at hospitals, healthcare systems, physician groups and health plans, including biomedical engineering, clinical engineering and IT staff*
- *Medical device and IT company executives, including marketing/sales and engineering staff*
- *Consultants, government officials, academics and the financial community*

SPONSORSHIP AND EXHIBITION OPPORTUNITIES

Sponsorship and exhibition are effective ways to promote your products and services to key decision makers at healthcare provider organizations as well as technology companies. Benefits include space to exhibit at the Conference, passes for staff and clients / potential clients, an advance listing of attendees and exposure on the Conference website. For additional information, please contact TCBI: Tel: (310) 265-2570 Email: info@tcbi.org

PROGRAM CHAIRPERSON'S WELCOME

It's been another great year to be the program chair for the Medical Device Connectivity conference. This year's program is a combination of innovators new to this conference, and a number of past speakers here to provide an update on their connectivity efforts. My thanks for the patience and willingness shown by our speakers this year; thank you for your participation.

Each year there are questions about the theme of the event. Because of the rapid change and innovation of the connectivity market, it is hard to frame the program around one or a few themes. This year, like those of the past, the program is driven by events of the past year.

- The medical device data system market targeting clinical documentation for EMRs has moved beyond the early innovators and is in the midst of adoption by the early majority of the market.
- The alarm notification market is also heating up, drawing increased attention from professional organizations like AAMI and regulators. And this market may break the barrier from early adopters to the early majority soon.
- With the adoption of the systems above, hospitals are starting to consider the impacts on their own operations, reevaluating organizational structures, policies and procedures for dealing with the growing adoption of medical device systems and connectivity.
- Technology changes in wireless and software continue to drive change and innovation.

You will find all the above events reflected in this year's program. Of note are a number of presentations on wireless, the confluence of IT and biomed/clinical engineering, and connectivity case studies.

If your hospital is looking to adopt connectivity or your company is undertaking the development of connectivity products, this event remains the most focused and concentrated educational event of the year.

Best regards,

Tim Gee

Tim Gee, Program Chair
Principal, Medical Connectivity Consulting

MD PnP
Getting Connected for Patient Safety

OPEN HOUSE
CIMIT MEDICAL DEVICE INTEROPERABILITY LAB

On October 31st (the day before the Medical Device Connectivity Conference begins) from 3:00-5:00pm, there will be an Open House for Medical Device Connectivity Conference attendees hosted by the CIMIT Medical Device Plug-and-Play Interoperability Program (MD PnP) in Cambridge, Mass. Federally funded interoperability research and educational demonstrations will be shown by the program team and by collaborators at the Partners HealthCare-based Interoperability Lab. Light refreshments will be available.

Place: 1st floor, 65 Landsdowne Street, Cambridge, MA 02139

http://cimit.org/print/directions.html#CIMITCamb

Please RSVP by email to info@tcbi.org or by phone to (310) 265-2570.

FOURTH ANNUAL MEDICAL DEVICE CONNECTIVITY CONFERENCE AGENDA

DAY ONE: THURSDAY NOVEMBER 1, 2012

7:00 *Registration / Sponsor / Exhibitor Showcase & Breakfast Sponsored By: Laird Technologies*

8:00 **CHAIRPERSON'S OPENING REMARKS AND GREETING**
Tim Gee, Connectologist & Principal, Medical Connectivity Consulting

8:30 **KEYNOTE ADDRESS: MEDICAL DEVICE INTEROPERABILITY AS A WICKED PROBLEM**
The term "wicked problem" is defined by Wikipedia as a problem that is difficult or impossible to solve because of incomplete, contradictory, and changing requirements that are often difficult to recognize. This presentation will survey the current state of development of interoperability highlighting where requirements are incomplete, contradictory, and changing.
Julian M. Goldman, MD, is Medical Director of Biomedical Engineering for Partners HealthCare System, where he is responsible for developing strategies, identifying technology trends and guiding Partners to stay on the leading edge of infrastructure and patient care technologies to ensure safety, effectiveness and efficiency. Dr. Goldman is also Director of the Program on Interoperability at CIMIT (Center for Integration of Medicine and Innovative Technology), a principal anesthesiologist in the Massachusetts General Hospital "Operating Room of the Future", and founder of the Medical Device "Plug-and-Play" (MD PnP) Interoperability Program. He has led the MD PnP program from an initial convening of 85 interested stakeholders in 2004 to a global network of over 700 participants from clinical environments, government agencies, medical device vendors, biomedical and clinical engineering, computer science engineering, and standards organizations. The MD PnP program was recognized with the CIMIT 2007 Edward M. Kennedy award for Healthcare Innovation. Dr. Goldman is the recipient of the 2009 American College of Clinical Engineering Professional Achievement in Technology Award, the Association for the Advancement of Medical Instrumentation (AAMI) Foundation/Institute for Technology in Health Care 2009 Clinical Application Award, and most recently, the International Council on Systems Engineering (INCOSE) 2010 Pioneer Award for leadership in the advancement of the state-of-the-art and practice of systems engineering in the biomedical and healthcare fields.
Julian M. Goldman, MD, Director, MD PnP Program & the CIMIT Program on Interoperability & Medical Director, Partners HealthCare Biomedical Engineering

9:00 **KEYNOTE ADDRESS: GOVERNANCE GAP**
Medical device systems are made up of conventional embedded systems devices connected via networks to applications running on general purpose computing platforms. These applications extend the functionality of medical devices and automate workflows such as EMR clinical documentation, alarm notification, remote surveillance, retrospective event review, and therapy delivery. This presentation will explore traditional roles and responsibilities of Biomed and IT departments and explore how those roles have fallen behind the adoption of medical device connectivity technologies.
Tim Gee is Principal and founder of Medical Connectivity Consulting, specializing in workflow automation through the integration of medical devices with information systems, and enabling technologies. Tim has 25 years of experience with expertise in wireless medical devices, converged medical device/enterprise networks, requirements elicitation, regulatory strategy, connectivity, interoperability, diagnostic and point of care workflows, and patient flow optimization. Tim has served providers and vendors, including: Abbott Point of Care, Ascom, Awarepoint, Baxter Healthcare, Biotronik, Capsule, CareFusion, Cisco, Ekahau, GE Healthcare, Hill-Rom, Intel Digital Health, Partners Health, Robert Wood Johnson University Hospital, Spectrum Health, Welch Allyn and others. He is currently an advisor to two startups. Tim speaks frequently at industry conferences and corporate events, national sales meetings and user group meetings. He is on the editorial advisory board of a number of magazines, and publishes the blog Medical Connectivity (www.medicalconnectivity.com), and also participates in industry initiatives.
Tim Gee, Connectologist & Principal, Medical Connectivity Consulting

9:30 **KEYNOTE ADDRESS: MEANINGFUL USE STAGE 2**

With the advent of the HITECH portion of ARRA (i.e., the "stimulus bill"), the country embarked on an unprecedented investment in at least some aspects of health care automation, with the major focus being on Electronic Health Records (EHR). In an effort to ensure the effectiveness of government funded EHRs, the Office of the National Coordinator determined to require, define and regulate the "meaningful use (MU)" of an EHR, i.e. we don't just want EHRs, we want them to make a difference. The required elements of MU are and will be strictly defined for various Stages over a number of years. In this regard MU is not necessarily the same as to use an EHR in a generally meaningful way. One result of the rules for the minimum attributes of MU is that automation of data transfer from medical devices used in monitoring, diagnosis, and therapy may be a part of achieving MU, but in general such automation is not necessarily a requirement of MU at least through the now promulgated rules for Stage 2. Yet it should be remembered that the current MU requirements are not the only potential value of increasing medical device connectivity, i.e. current EHR incentive requirements are not the only reason to seek connectivity. In addition, subsequent stages of MU may include additional connectivity value and/or requirements as has been suggested by advanced concepts that are not yet rules. Starting with a brief review of the current requirements for Stage 1, this presentation will focus on the portions of Stage 2 for which there is possible or actual impact on and from medical device connectivity. Potential technical barriers to using device connectivity to contribute to MU will also be discussed. The presentation will conclude with a look into the future and how subsequent MU Stages may impact the need for medical device connectivity.

Dr. Hyman is Professor Emeritus of Biomedical Engineering at Texas A&M University. He is a Past President of the Healthcare Technology Foundation and Treasurer Emeritus of the FDA Dallas District FDA Medical Device Industry Coalition. His primary areas of professional activity are in medical device design, system safety and human factors, and clinical engineering. He is contributing editor of the Journal of Clinical Engineering and has served as a consultant for the FDA, the National Science Foundation, the National Institutes of Health, NASA and medical device companies. Dr. Hyman is a member of the American College of Clinical Engineering and recipient of their Lifetime Achievement Award, and he is Fellow Emeritus of the Biomedical Engineering Society.

William Hyman, ScD, Professor Emeritus, Department of Biomedical Engineering, Texas A&M University

10:00 *Sponsor / Exhibitor Showcase & Refreshments*
Sponsored By: Laird Technologies

10:30 **KEYNOTE ADDRESS: REPORT FROM THE AAMI/ FDA INTEROPERABILITY SUMMIT 2012**

On October 2-3, 2012, AAMI and the FDA co-convened a summit on the integration of medical devices with a focus on patient safety. This two-day event delved into the complex issues surrounding interoperability and sought to identify steps to improve device integration and enhance patient safety. Multi-disciplinary stakeholders - providers, engineers, manufacturers and regulators - worked to identify the most pressing priorities that need to be addressed. This presentation will report on the Interoperability Summit, providing an overview of the proceedings and describing the findings, recommendations and next steps produced by this meeting.

In her position as Vice President of Clinical Technology at Kaiser Permanente, Carol Davis-Smith coordinates and implements corporate strategies and initiatives related to the clinical technology lifecycle, as well as integration of biomedical devices with other devices into the information technology framework. Carol joined Kaiser Permanente from Premier, Inc., where she served as director responsible for the development, marketing, and delivery of clinical capital lifecycle consulting services. Carol is a certified clinical engineer with more than 20 years experience in academic and not-for-profit medical centers, group purchasing, and consulting. She has provided support in all areas of capital lifecycle management with specific focus on clinical engineering management and technology assessment. Carol is a member of the Association for the Advancement of Medical Instrumentation (AAMI) and the American College of Clinical Engineering (ACCE). She is also a member of the AAMI Board of Directors and the AAMI Technology Management Council. Over the past 20 years, Carol has presented and published papers on a variety of clinical engineering and capital contracting topics. Carol holds a master's of science degree in electrical and computer engineering – clinical engineering from the University of Arizona and a bachelor's of science in bioengineering technology from the University of Dayton.

Carol Davis-Smith, CCE, Vice President, Clinical Technology, Kaiser Permanente

11:00 **INTRODUCTION TO CLINICAL DOCUMENTATION DATA VALIDATION**

The largest medical device connectivity market segment by far, is the acquisition of data for clinical documentation of vital signs in EMRs. Even this straightforward connectivity application is not without some controversy. That controversy is whether or how acquired medical device data should be validated before it is included as part of the medical/legal record. This brief presentation will discuss the key issues around data validation, including how this issue is impacted by different physiological parameters, data acquisition use cases, and different data visualization options.

Tim Gee, Connectologist & Principal, Medical Connectivity Consulting

11:15 **PANEL DISCUSSION: CLINICAL DOCUMENTATION DATA VALIDATION**

This panel discussion will explore the issues around the validation of medical device data that is acquired for

clinical documentation in EMRs. Panelists will discuss what types, and in what circumstances data should be validated, how and when data should be validated, and how data - both unvalidated and validated - should be made available to the EMR user.

Moderator:
Tim Gee, Connectologist & Principal, Medical Connectivity Consulting
Panelists:
Tracy Rausch, Founder & Chief Technology Officer, DocBox
Carol Davis-Smith, CCE, Vice President, Clinical Technology, Kaiser Permanente
Shahid Shah, CEO, Netspective Communications LLC
William Hyman, ScD, Professor Emeritus, Department of Biomedical Engineering, Texas A&M University

12:00 *Sponsor / Exhibitor Showcase & Luncheon*

1:30 **KEYNOTE ADDRESS: MEDICAL DEVICE CYBERSECURITY: THE FIRST 164 YEARS**

We've all seen the news stories about hacking implanted pacemakers and patient worn insulin pumps. However, what keeps me up at night is a more mundane security problem: unavailability of patient care. When conventional malware shuts down a cath lab, seriously ill patients can be subjected to unnecessary risk of transport. When a medical system is not available for use, patients do not receive the quality of care they deserve. This presentation will explore the risks, realities and countermeasures of medical device system security. Systems considered will range from purpose-built systems like pacemakers and programmers to embedded system medical devices interconnected on enterprise wide IT infrastructures. The effectiveness of current methods, tools and countermeasures will be discussed, with an emphasis on continuing gaps and vulnerabilities. Best practices for manufacturers and providers will be presented, as well as predictions on emerging risks.

Dr. Fu's research interests include security, privacy, safety, and energy management for embedded systems. His most recent research pertains to improving the security of pacemakers and defibrillators, and enabling energy-aware computation on RFID-scale embedded systems. Dr. Fu served as a visiting scientist at the Food & Drug Administration, the Beth Israel Deaconess Medical Center of Harvard Medical School, and MIT CSAIL. He is a member of the NIST Information Security and Privacy Advisory Board. He previously worked for Bellcore, Cisco, HP Labs, Microsoft Research, and Holland Community Hospital. Dr. Fu was previously an Associate Professor of Computer Science at University of Massachusetts Amherst. Kevin received his PhD in Electrical Engineering and Computer Science from MIT.

Kevin Fu, PhD, Associate Professor, Electrical Engineering & Computer Science, University of Michigan

2:00 **KEYNOTE ADDRESS: MEDICAL DEVICE INTEGRATION: PUTTING IT ALL TOGETHER**

While still relatively small, the medical device integration (MDI) market is growing rapidly, garnering increasing attention from the Wall Street community over the past few years. Based on the results of the first quantitative market research study on medical device connectivity, this presentation provides a detailed look at today's MDI landscape and how it translates into tomorrow's market opportunity. Topics covered include market adoption, vendor market share, desired solution attributes, and drivers behind integration among others.

Co-founder of CapSite, a Burlington, VT based healthcare technology research and advisory firm, Gino Johnson has over two decades of experience in the healthcare industry. His career has encompassed various marketing, business development and leadership positions, including 12 years with IDX Systems Corporation (acquired by GE Healthcare). In his current role as Senior Vice President and General Manager, Mr. Johnson provides strategic direction, overseeing CapSite Database management and Consulting Services. Mr. Johnson received a B.S. in Business Administration from the University of Vermont.

Gino Johnson, Senior Vice President, General Manager & Co-Founder, CapSite

2:30 **KEYNOTE ADDRESS: THE CHALLENGE OF CONNECTIVITY WITH PHYSIOLOGICAL MONITORING SYSTEMS**

One of the most pervasive medical device systems found today in hospitals are physiological monitoring systems. In addition to their primary function of continuous, real-time patient monitoring, they can connect to a hospital's enterprise wired and wireless network to provide clinical documentation into EMRs, remote surveillance, ancillary alarm notification, and retrospective event review of patient data. Facilitating such connectivity typically requires the participation of multiple vendors, involvement of several departments within the hospital, and the implementation of various connectivity solutions that may use proprietary interfaces or industry standards such as HL7. The resulting system of systems can be challenging to configure and maintain. ECRI Institute has recently undertaken a study of physiological monitoring systems and has encountered numerous connectivity issues. This presentation will explore some of most prevalent and interesting connectivity issues that are part of today's crop of physiological monitoring systems. Attendees will learn best practices regarding connectivity including system installation, configuration, project management, and ongoing management.

Barbara Majchrowski is a Senior Project Engineer with ECRI Institute, a nonprofit independent research organization. She is responsible for evaluating medical technology for their safety, efficacy, and usability. She also provides content for ECRI Institute's journal Health Devices on various healthcare topics. As a subject matter expert, Ms. Majchrowski participates in numerous consulting projects and medical device-related incident

investigations. She received the Association for the Advancement of Medical Instrumentation's Biomedical and Instrumentation & Technology (BI&T) Outstanding Paper Award in 2010 for the article "Medical Software's Increasing Impact on Healthcare and Technology Management".

Barbara Majchrowski, MHSc, PEng, Senior Project Engineer, ECRI Institute

3:00 **KEYNOTE ADDRESS: TRANSITION TO CONNECTIVITY**

Hospitals started adopting medical device connectivity in the 1980s. Starting with high volume and/or high risk applications, many initial connectivity efforts were in diagnostic areas, surgery and the ICU. In the intervening years, connectivity has matured and expanded. Departments like the clinical lab and diagnostic imaging have become heavily automated. Departments like pharmacy are not far behind. The challenging connectivity applications of today are those that are highly variable. Unlike many diagnostic studies, or connectivity involving semi conscious or unconscious patients, today's challenges seek to automate highly variable workflows, like medication administration, and/or medical device interoperability where devices must automatically adjust to a patient's changing clinical condition. This presentation will look at the path moving forward, envisioning how hospitals in the near future could be configured to operate with full integration of medical device connectivity solutions. The roles of ecosystem stakeholders will be explored, considering how payors, manufacturers, providers and technology assessment entities impact connectivity solution adoption. Changing customer needs will be considered and framed against current barriers and challenges to adoption. How new and emerging technologies are shaping connectivity solutions will be discussed, along with evolutions and innovations in business models impacting manufacturers and health care providers both.

Venkat Rajan is the Industry Manager within Frost & Sullivan's Advanced Medical Technologies practice. He has extensive market intelligence gathering and custom consulting experience, with particular expertise in orthopedics, advanced woundcare, cardiovascular, surgery settings, robotics/navigation, oncology/cancer, long-term patient care, wellness and healthcare business models. He maintains particular skill in blended primary and secondary research methodologies, market strategies, complex forecast model development, identification and qualification of emerging white space opportunities, and international as well as domestic market proficiency. His extensive expertise in healthcare markets range from laboratory research, hospitals, major medical device manufacturers, and third party research. Venkat also has a Masters in Biomedical Engineering from the University of Texas in Austin, Texas.

Siddharth Saha, Global Program Manager for Frost & Sullivan's Advanced Medical Technologies practice, has more than a decade of healthcare experience. Within his role, he mentors and manages a team of research analysts, while overseeing the process of identifying, researching and analyzing the key market challenges, issues and opportunities in healthcare. Siddharth also performs a client engagement role, managing functions from value proposition demonstration, design to fulfillment, and project steering for custom consulting assignments. His knowledge base covers a broad range of sectors, including medical imaging diagnostics, healthcare informatics, medical devices, patient monitoring and clinical diagnostics. Siddharth also has a Masters in Hospital Management.

Venkat Rajan, Industry Manager, Frost & Sullivan
Siddharth Saha, Research Director, Frost & Sullivan

3:30 *Sponsor / Exhibitor Showcase & Refreshments*
Sponsored By: Laird Technologies

4:00 **KEYNOTE ADDRESS: EMERGING BEST PRACTICE FOR DEFINING REQUIREMENTS FOR MEDICAL GRADE WIRELESS UTILITY**

Building on last year's presentation, "The Path to a Medical Grade Wireless Utility," this presentation explores the emerging best practices for eliciting the requirements and ultimately the design of a true utility grade wireless infrastructure. Hospitals are particularly challenging wireless environments whether they entail existing physical plant, brand new construction or both. Likewise the applications and devices supported by wireless infrastructure varies from site to site. The emerging best practices described work to define an application and physical plant roadmap resulting in a utility grade wireless infrastructure.

Ed Cantwell is a senior vice president of the West Health Institute, based in San Diego, California, where he leads a medical grade wireless initiative. Most recently, he served as director of 3M Corporation's Wireless Business Unit and as chairman, president, and chief executive officer of InnerWireless, which he founded in 2000. Cantwell's wireless experience began while working for Texas Instruments, where he led a number of high technology businesses and successfully obtained spectrum allocations from the FCC. What started as an incubator project there became SpectraPoint Wireless, and Cantwell served as its president and CEO. Before founding SpectraPoint, Cantwell held several positions within TI's Defense Systems and Electronics Group, where he helped to develop a variety of communications systems. He also served as an Air Force fighter pilot for 12 years. Cantwell graduated from the University of Michigan's executive training program and is a Graduate of the Air Force's fighter weapons school. He holds a Bachelor of Science Degree in Mechanical Engineering from Duke University.

Ed Cantwell, Senior Vice President, West Health Institute

4:30 **INTRODUCTION TO WIRELESS SPECTRUM PANEL DISCUSSION**

Wireless spectrum available for medical device applications has been especially unsettled lately. This year, passage of the Middle Class Tax Relief and Job Creation Act of 2012, reallocated half the radio spectrum for WMTS, which is used for hospital cardiac telemetry monitoring. Also this year, the FCC allocated spectrum for wireless Medical Body Area Networks. These changes have occurred against a drumbeat of concern about Wi-Fi spectrum "filling up" or reaching capacity. This brief presentation will frame recent actions in this area, and describe some of the industry initiatives under discussion. Considerations for both health care providers and manufacturers will be introduced to frame the following panel discussion.

Tim Gee, Connectologist & Principal, Medical Connectivity Consulting

4:45 **PANEL DISCUSSION: WIRELESS SPECTRUM**

Wireless spectrum available for medical device applications has been especially unsettled lately. This year, passage of the Middle Class Tax Relief and Job Creation Act of 2012, reallocated half the radio spectrum for WMTS, which is used for hospital cardiac telemetry monitoring. Also this year, the FCC allocated spectrum for wireless Medical Body Area Networks. These changes have occurred against a drumbeat of concern about Wi-Fi spectrum "filling up" or reaching capacity. This panel discussion will explore the implications and potential outcomes for planned and potential wireless spectrum changes. Both health care providers and medical device manufacturers perspectives will be explored.

Moderator:

Tim Gee, Connectologist & Principal, Medical Connectivity Consulting

Panelists:

Alan Lipschultz, President, HealthCare Technology Consulting

David Hoglund, President & Founder, Integra Systems, Inc.

Chris Bolinger, Director, Product Management, Laird Technologies

Ted Cohen, Director of Clinical Engineering, UC Davis Health System

Ed Cantwell, Senior Vice President, West Health Institute

5:30 *Day One Concludes; Sponsor/Exhibitor Showcase & Networking Reception*

ABOUT THE CONFERENCE ORGANIZER

The Center for Business Innovation (TCBI) organizes conferences and exhibitions for the U.S. and international markets. TCBI is an independent company that is well-positioned to provide objective, balanced information and analysis on a wide range of topics. TCBI currently focuses on organizing programs that offer detailed and practical instruction on clinical, technological, financial, strategic and regulatory aspects of healthcare. These programs are carefully designed to meet the information needs of executives, clinicians and IT staff from hospitals, managed care organizations, physician groups, long-term care facilities, postacute care providers, pharmaceutical/biotechnology companies, medical device companies, information technology vendors and other organizations in the rapidly evolving healthcare industry. For additional information, please visit **www.tcbi.org**.

FOURTH ANNUAL MEDICAL DEVICE CONNECTIVITY CONFERENCE AGENDA

DAY TWO: FRIDAY NOVEMBER 2, 2012

7:30 *Sponsor / Exhibitor Showcase & Breakfast*

Choose Sessions in Track A or Track B

TRACK A – HEALTHCARE PROVIDERS

8:00A **CHAIRPERSON'S OPENING REMARKS**
William Hyman, ScD, Professor Emeritus, Department of Biomedical Engineering, Texas A&M University

8:30A **MEDICAL DEVICE SYSTEM IMPACTS: ONE INSTITUTION'S DIRECTION**
Medical device systems are one of the chimeras of health care - part embedded system device most of us recognize as medical devices, and part information system running on enterprise IT infrastructure. For years, hospitals have taken the King Solomon approach to medical device systems informally dividing responsibilities for these systems between IT and clinical engineering or biomed departments. Starting several years ago with a shift in reporting structure from Facilities to IT, early innovator hospitals are rethinking best practices around medical device systems. One such institution is Cedars-Sinai Medical Center in Los Angeles. After a lengthy search, the hospital IT department recently filled a newly created director position targeting medical device systems. This presentation will describe some of the medical device system challenges facing the industry and Cedars in particular, and discuss how Cedars is responding to these challenges. Both organizational structure and changes, along with specific projects and technologies will be reviewed.
Jennifer Jackson, Director of Clinical Engineering & Device Integration, Cedars-Sinai Medical Center

9:00A **CASE STUDY: CLINICAL ENGINEERING/IT CONVERGENCE**
Contemporary medical device systems are a modern day chimera, part conventional medical device and part information technology. Seven years ago, with a growing number of medical device systems being deployed enterprise wide, Spectrum Health in Grand Rapids, Michigan, started to re-think how these systems were maintained and supported. The result is a fascinating and unique journey where Spectrum reconstituted IT and clinical engineering functions to optimize the servicing and management of medical device systems. This presentation describes the initial rationale for rethinking the conventional clinical engineering/IT split and describes the progress made over the past seven years. Also presented will be obstacles overcome and a discussion of what they would do differently in hindsight.
Robert Rinck, Director of Information Services, Spectrum Health

9:30A **USING YOUR CMMS TO HELP MANAGE NETWORK-CONNECTED MEDICAL SYSTEMS**
Many modern medical devices are now network connected. For many years, Clinical Engineering departments have used computerized maintenance management systems (CMMS) to help manage their repair and maintenance activities, including documentation, workorder management, maintenance scheduling, product recall management, regulatory compliance and more. The extension of medical devices into complex, IT-connected systems of systems has extended the need and role of CMMSs to include system-level documentation, IT security, change management and other related issues. Often the IT and clinical engineering departments split the support of medical device system components, raising questions about gaps between separate inventories, double counted components and coordinating activities between the two departments. This presentation will explore these issues and describe some of CMMS features used to manage IT security, change management, and other IT issues in the management of network-connected medical devices using several examples from UC Davis Health System.
Ted Cohen, Director of Clinical Engineering, UC Davis Health System

10:00 *Sponsor / Exhibitor Showcase & Refreshments*

10:30A **IDENTIFYING AND WORKING TO RESOLVE CONFLICTING WIRELESS SYSTEM REQUIREMENTS**

The use of wireless technology in hospitals has exploded over the last several years and it promises to continue. This growth has resulted in a growing requirement to manage wireless networks, and better plan how wireless applications are adopted in hospitals. This presentation is a case study of how a hospital developed their wireless networking plan, including wireless medical devices. Descriptions of solution specifications and how wireless networking impacted medical device vendor selection are also discussed.
Alan Lipschultz, President, HealthCare Technology Consulting

11:00A **CLINICAL DOCUMENTATION CASE STUDY**
A growing number of hospitals are looking to automate clinical documentation workflow by acquiring data from medical devices and inserting it into the patient's electronic record. The initial phases of this implementation have been completed at Dartmouth-Hitchcock Medical Center. This presentation will delve into the project plan at Dartmouth-Hitchcock, recount the major project milestones and explore the lessons learned. Workflow automation through the integration of medical devices and information systems has a long ways to go, and the presentation will wrap up with future integration projects and how medical device connectivity has transformed the organization.
Mark Herder, Sr. Programmer/Analyst, Interface Team, Dartmouth-Hitchcock Medical Center

11:30A **CONNECTIVITY LESSONS LEARNED**
With the paucity of adopted industry standards and limited multi vendor systems, selecting and implementing connectivity solutions must be done with a combination of systems and technologies from various vendors. Common challenges revolve around patient context, the proliferation of systems nurses are expected to operate, and maintaining one-off interfaces. In the current environment adopting a spectrum of connectivity solutions - clinical documentation into EMRs, alarm notification, remote surveillance, etc. - is like a chess game where moves and acquisitions must be planned out a number of steps in advance. This presentation will review one major institution's experiences adopting connectivity. Systems discussed will include various clinical documentation systems, messaging middleware systems, and other connectivity solutions.
Paul Frisch, PhD, Chief of Biomedical Physics and Engineering, Memorial Sloan-Kettering Cancer Center

12:00 **CLOSING PLENARY PANEL DISCUSSION**
This year's closing plenary panel discussion represents attendees' last opportunity to query panelists with their unanswered questions. Panelists will prognosticate and opine on the direction of future trends impacting medical device connectivity. Topics will include:

- New and existing industry standards efforts
- Wireless medical devices and radio frequency spectrum allocations and adoption
- The evolution in hospital operations to cope with medical device systems of systems
- Expected changes in the numerous market segments that make up medical device connectivity

Moderator:
Tim Gee, Connectologist & Principal, Medical Connectivity Consulting
Panelists:
Jennifer Jackson, Director of Clinical Engineering & Device Integration, Cedars-Sinai Medical Center
Barbara Majchrowski, MHSc, PEng, Senior Project Engineer, ECRI Institute
Carol Davis-Smith, CCE, Vice President, Clinical Technology, Kaiser Permanente
Paul Frisch, PhD, Chief of Biomedical Physics and Engineering, Memorial Sloan-Kettering Cancer Center
Shahid Shah, CEO, Netspective Communications LLC
Julian M. Goldman, MD, Director, MD PnP Program & the CIMIT Program on Interoperability & Medical Director, Partners HealthCare Biomedical Engineering

1:00 *Conference Concludes; Luncheon for Attendees of Optional Post-Conference Workshops*

TRACK B – MANUFACTURERS

8:00B **CHAIRPERSON'S OPENING REMARKS**
Chris Bolinger, Director, Product Management, Laird Technologies

8:30B **SELECTION CRITERIA FOR MEDICAL DEVICE RADIOS**
Wireless enablement of medical devices is not for the faint of heart. There are many challenging requirements placed on wireless radios: power consumption and management, overhead for authentication and encryption, antenna design and RF performance, and more. This presentation will describe the most important key criteria for implementing an effective radio design in a medical device. A survey will highlight many of the radio options available, and provide insight into the track records of various types of radios and implementation strategies.
David Hoglund, President & Founder, Integra Systems, Inc.

9:00B **FIPS 140-2 SECURITY - WHAT IS IT, WHY IT'S IMPORTANT, HOW TO GET IT**
The Federal Information Processing Standard (FIPS) Publication 140-2, is a U.S. government computer security standard used to accredit cryptographic modules. Initially published on May 25, 2001 this standard is required by Department of Defense and Veterans Administration hospitals. For many years, specialized equipment like

medical device systems have received waivers from having to comply to FIPS 140-2. However, pressure is growing for manufacturers of all kinds to comply with this data security requirement. Along with greater insistence on the part of government agencies to comply with FIPS 140-2, health care providers outside of the federal government view FIPS 140-2 as an increasingly relevant and desirable standard. Looking at the application of the standard to Wi-Fi, this presentation describes what is contained in the standard and how hardware and software products are tested and certified as compliant. Compliance implications are discussed for medical device manufacturers and federal health care facilities. The applicability of the standard in non federal hospitals is also explored.

Chris Bolinger, Director, Product Management, Laird Technologies

9:30B **ENTERPRISE SUPPORT APPLICATIONS FOR MEDICAL DEVICES**

Medical device connectivity brings to mind the connections - wired or wireless - and the need to communicate with the target system, often an EMR or nurse-carried mobile devices. But beyond these immediate, top of mind concerns lies a constellation of less obvious requirements for a medical device connectivity system. This presentation will delve into the myriad of details and requirements necessary for a world-class connectivity solution. Such a system must be able to support system deployment, provisioning, service automation and software update automation. A properly specified and designed connectivity solution can provide remote service for the attached medical devices. Each of these application areas will be explained with a discussion of typical requirements and examples of implementation and design strategies.

John Dougherty, President, Dougherty Systems, Inc.

10:00 *Sponsor / Exhibitor Showcase & Refreshments*

10:30B **DEVELOPING A MULTI VENDOR SYSTEM FOR MEDICAL DEVICE INTEROPERABILITY**

Interoperability goes beyond the simple passing of data from one system to the next as accomplished with connectivity; interoperable systems are sufficiently knowledgeable about one another and the information they exchange to be able to send or receive data and then use that data in new operations. To date, most true interoperability has been available only through proprietary end-to-end solutions from a single vendor - or, more often than not, not available at all. This presentation will describe the development of a working interoperable system made up of medical devices from multiple manufacturers and based on the Integrated Clinical Environment (ICE) standard. The standards and technologies this system utilizes will be described, and the overall operation will be presented. The presentation will close with a discussion of how this system will be used, and the potential impact this system will have on the industry.

Tracy Rausch, Founder & Chief Technology Officer, DocBox

11:00B **HOW TO USE OPEN SOURCE AND OTHER LOW-COST DESIGN TECHNIQUES TO BUILD SAFETY-CRITICAL BACKEND AS A SERVICE (BAAS) CLOUD SOLUTIONS**

Medical devices can no longer be seen as standalone components because of the significant clinical data they collect. Creating connected devices is a major requirement for most manufacturers and this talk with show how to use modern, open source and open software architecture techniques to build connected devices and deliver them as a real Backend as a Service (BaaS) or on-premise platform.

This is an in depth technical presentation on how to define, design, and build modern safety-critical medical device platforms and Meaningful Use compliant EHR gateways. The discussion starts with a quick background on comparative effective research (CER) and patient-centered outcomes research (PCOR) and the kinds of data the government is looking to leverage in the future to help reduce healthcare costs and improve health outcomes. After defining why data is important, the talk will cover the different techniques for collecting medical data – such as directly from a patient, through healthcare professionals, through labs, and finally through medical devices; the presentation will cover which kinds of data are easy to collect and what are more difficult and how technical challenges to collection can be overcome using modern cloud-based SaaS and BaaS techniques. After covering the data collection area the talk will provide a quick overview of a modern medical device platform architecture which the speaker calls “The Ultimate Medical Device Connectivity Architecture” answering questions around architecture, specifications, and design of modern (connected) medical devices. Presentations of open source software and other inexpensive design techniques for implementing connected architectures will be covered. When you’re done with this presentation you will be armed with knowledge about medical device gateways, what new Meaningful Use rules might require when connecting EHRs to gateways, and how to design and architect gateways that can stand the test of time and be interoperable over the long haul.

Shahid Shah, CEO, Netspective Communications LLC

11:30B **BYOD - BRING YOUR OWN DEVICE: IMPACT ON HEALTHCARE**

With the growing popularity of smart phones and tablet computers, hospitals are facing increasing pressure to accept user’s personal devices within the health care provider organization. This presentation will delve into the implications of BYOD when used as part of FDA regulated medical device systems. The impact BYOD has

on system management and support will also be explored.
David Hoglund, President & Founder, Integra Systems, Inc.

12:00 **CLOSING PLENARY PANEL DISCUSSION**

This year's closing plenary panel discussion represents attendees' last opportunity to query panelists with their unanswered questions. Panelists will prognosticate and opine on the direction of future trends impacting medical device connectivity. Topics will include:

- New and existing industry standards efforts
- Wireless medical devices and radio frequency spectrum allocations and adoption
- The evolution in hospital operations to cope with medical device systems of systems
- Expected changes in the numerous market segments that make up medical device connectivity

Moderator:

Tim Gee, Connectologist & Principal, Medical Connectivity Consulting

Panelists:

Jennifer Jackson, Director of Clinical Engineering & Device Integration, Cedars-Sinai Medical Center
Barbara Majchrowski, MHSc, PEng, Senior Project Engineer, ECRI Institute
Carol Davis-Smith, CCE, Vice President, Clinical Technology, Kaiser Permanente
Paul Frisch, PhD, Chief of Biomedical Physics and Engineering, Memorial Sloan-Kettering Cancer Center
Shahid Shah, CEO, Netspective Communications LLC
Julian M. Goldman, MD, Director, MD PnP Program & the CIMIT Program on Interoperability & Medical Director, Partners HealthCare Biomedical Engineering

1:00 *Conference Concludes; Luncheon for Attendees of Optional Post-Conference Workshops*

OPTIONAL POST-CONFERENCE WORKSHOP ONE
DESIGN TECHNIQUES TO BUILD SAFETY-CRITICAL BACKEND AS A SERVICE (BAAS) CLOUD SOLUTIONS

Workshop Hours: 2:00-6:00 pm, Friday, November 2nd

Building on the conference session on safety-critical Backend as a Service (BaaS) cloud solutions, this workshop goes into greater depth and detail on how to use modern open source and open software architecture techniques to build connected devices and deliver them as a real Backend as a Service (BaaS) or on-premise platform.

This workshop will cover the different techniques for collecting medical data through medical devices and how technical challenges to collection can be overcome using modern cloud-based SaaS and BaaS techniques. After covering the data collection area the talk will go in depth into modern medical device platform architecture, which the speaker calls "The Ultimate Medical Device Connectivity Architecture" – providing example architectures and answering questions about specifications and design of modern (connected) medical devices. Examples of open source software and other inexpensive design techniques for implementing connected architectures will be covered. When you're done with this workshop you will be armed with knowledge about medical device gateways and how to design and architect gateways that can stand the test of time and be interoperable over the long haul.

Workshop Instructor:

Shahid Shah, CEO, Netspective Communications LLC

Shahid N. Shah is the CEO of Netspective Communications, a software consultancy whose actionable advice and disciplined approach delivers custom software for in-house, outsourced, or offshore solutions. Shahid's an expert at discovering practical technology solutions to real-world business initiatives, especially in the government, healthcare and financial services industries. His expertise includes standards development, enterprise architecture analysis and design, interoperability planning, legacy modernization, and related work. He's worked at NIH on standards, Executive Office of the President (White House) and OMB on helping define the needs for standards, and at various commercial healthcare firms like CardinalHealth and COMSYS. In addition to working with C-Suite executives he continues to help engineering teams with architecture and development advice. He is an influential thought leader and a winner of Federal Computer Week's coveted "Fed 100" award given to IT experts that have made a big impact in the government and runs three successful blogs. At http://shahid.shah.org he writes about architecture issues, at http://www.healthcareguy.com he provides valuable insights on how to apply technology in health care, at http://www.federalarchitect.com he advises senior federal technologists, and at http://www.hitsphere.com he gives a glimpse of the health-care IT blogosphere as an aggregator.

OPTIONAL POST-CONFERENCE WORKSHOP TWO
MEDICAL DEVICE WIRELESS ENABLEMENT

Workshop Hours: 2:00-6:00 pm, Friday, November 2nd

Many activities in health care delivery are inherently mobile; patients, equipment and staff are constantly moved and redeployed to meeting changing needs at the point of care, in surgery and other therapy delivery areas and in diagnostics. Consequently, a growing number of medical device systems are being implemented with wireless, rather than wired connectivity. This workshop will explore in detail the many considerations and issues that must be addressed when wirelessly enabling a medical device. Starting with radio frequency spectrum selection and standards-based versus custom radio solutions, this workshop will present criteria and trade-offs around the basic building blocks of wireless enablement. How to frame make or buy decisions regarding radios and receivers will be presented in the workshop. Additional considerations for wireless enablement will include the importance of antenna placement and radio frequency performance on the wireless medical device. Certification and go-to-market considerations, such as the expertise and resources required to install, service and support wireless medical devices will also be covered.

Workshop Instructor:
David Hoglund, President & Founder, Integra Systems, Inc.

David H. Hoglund is the President and Founder of Integra Systems, Inc. (www.integrasystems.org), a fifteen year old wireless and medical device design and connectivity consultancy. Mr. Hoglund has also worked for companies such as Siemens Medical, Cerner, Biotronik, Motorola, General Electric, Draeger Medical, Johnson Controls and CommScope. The described experience of Integra Systems spans wireless medical device solution deployment over converged networks, strategic competitive positioning for these solutions, and the ability to drive these solutions from testing, validation, and through the IDE, FDA 510k approval process as well as EMC and EMI testing. Integra Systems, Inc. provided the design and experience to architect the first ever converged data, voice, and real time patient monitoring application on an enterprise network in 2005, thus giving us the depth of experience to help many companies in this regard. Integration and design experience extends from the integrated WLAN, broadband DAS, and BAS. Technical integration experience comes from all phases of 802.11a/b/g/n, WMTS, RFID, RFLS, PAN, MAN, DAS, and the FMC. Clients include but are not limited to Siemens Medical Systems, Philips Medical Systems, CareFusion, Covidien, Welch Allyn, Capsule Technologies, Drager Medical, RTKL, AwarePoint, Centrak, Aruba Networks, Ruckus Wireless, GTRI, Burwood Group, SOLID Technologies, Netspective, TCG, Smiths Medical, Sotera Wireless, Lantronix, AVTECH, several venture and angel funded start-ups, and numerous integrated delivery networks. Mr. Hoglund has published many white papers with corporations as well as with IEEE, AAMI, and HIMSS and has spoken both domestically and on an international basis. Mr. Hoglund is co-author on a patent for device connectivity and has others pending patent. Mr. Hoglund is a graduate of Northern Illinois University, pursued graduate studies in biochemistry and management as well as served as an officer in the United States Air Force.

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Natalie Sheerer
526 South Main Street, Suite 805
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Contact:
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The Association for the Advancement of Medical Instrumentation (AAMI), a nonprofit organization founded in 1967, is a unique alliance of nearly 7,000 members from around the world focused on advancing safety in medical technology through effective standards and educational programs, and publications. AAMI is the primary source of consensus and timely information on medical instrumentation and technology. The IT Horizons series, the Health IT Collection, IT-related conferences, and standards, particularly 80001 (Managing Medical IT) are likely of interest. For more information about AAMI products, membership, or involvement in the IT standards committee, visit the AAMI website.

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