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

The Fourth Medical Device Connectivity Conference & Exhibition is focused on workflow automation through the integration of medical device and information systems. Relevant enabling technologies are also a focus and include: wireless, networking, real time location systems, alarm notification, privacy and security, risk management and related topics. The acute care (hospital) market is the principal focus of this event, although extensions into ambulatory markets from acute care is a growing trend that will be covered.

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

Management consultants, government officials, academics and the financial community

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RFID in Healthcare Consortium
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For information on speaking, sponsorship/exhibition opportunities and/or registration, please contact:
Satish Kavirajan, Managing Director, TCBI:
Ph: 310-265-2570 Email: sk@tcbi.org

DAY ONE, THURSDAY, NOVEMBER 1, 2012

7:00 ***Registration / Sponsor / Exhibitor Showcase & Breakfast***

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

8:15 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 Act portion of ARRA (i.e., the "stimulus bill"), the country embarked on an unprecedented investment in health care automation. An often overlooked, but major source of data to be automated is the data generated by medical devices used in diagnosis, therapy delivery and monitoring of patients. In an effort to ensure the effectiveness of this automation, the Office of the National Coordinator determined to leverage a concept referred to as "meaningful use." The end result of Meaningful Use is that the automation adopted by providers is used in meaningful ways that produce tangible and quantifiable benefits. This automation roadmap is broken into a number of Meaningful Use stages with specific operational milestones. Providers are currently being reimbursed for a portion of their technology investments based on meeting Meaningful Use Stage 1 requirements. Stage 2 requirements were finalized earlier this summer. Starting with a brief review of Stage 1 Meaningful Use and its impact on connectivity, this presentation delves into the portions of Stage 2 Meaningful Use that also impact on medical device connectivity. This assessment will consider the impact Stage 2 requirements will have on medical device and connectivity product features and time constraints presented by the Stage 2 schedule. Generally available commercial solutions will be discussed, noting where Stage 2 requirements are met and any gaps that may result. Potential barriers to realizing Meaningful Use requirements will be discussed. The presentation wraps up with a look into the future and how subsequent Meaningful Use Stages will deal with 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***

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, 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 joins 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, 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 hacked implanted pacemakers and patient worn insulin pumps. Besides these recent high profile hacks, more conventional medical devices have suffered from hacks and malicious software for years. 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.

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 Ph.D. 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, an 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***

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
Ron Seide, Former President, Summit Data Communications, VP/GM, Connectivity Products Business Unit, 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***

DAY TWO, FRIDAY, NOVEMBER 2, 2012

7:30 ***Sponsor / Exhibitor Showcase & Breakfast***

Concurrent Sessions: Choose Either 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 MANAGING MEDICAL DEVICE SYSTEMS WITH CMMS
The extension of medical devices using general purpose computers and networks has extended the need and role of change management and computerized maintenance management systems. Often the IT and clinical engineering or biomed departments split the support of medical device system components, raising questions about gaps between separate inventories, double counted components and coordinating activities between two departments. This presentation will explore these issues and describe the change management and

CMMS used to manage medical devices at the University of California Davis Medical Center. The extensive medical device systems at UC Davis will serve as examples of how these issues have been handled.
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
Shahid Shah, CEO, Netspective Communications LLC
Paul Frisch, PhD, Chief of Biomedical Physics and Engineering, Memorial Sloan-Kettering Cancer Center
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 information from one system to the next seen with connectivity; interoperable systems are sufficiently knowledgeable about one another 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

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- New and existing industry standards efforts
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Moderator:

Tim Gee, Connectologist & Principal, Medical Connectivity Consulting
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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 to 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

OPTIONAL POST-CONFERENCE WORKSHOP TWO

MEDICAL DEVICE WIRELESS ENABLEMENT

Workshop Hours: 2:00 to 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.