



The Center for Business Innovation
Presents

The Third Annual Medical Device Connectivity Conference & Exhibition



*Connecting
Medical Devices to
People, Workflow &
Information Systems*

September 8-9, 2011

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

SUPPORTING ORGANIZATIONS



SUPPORTING PUBLICATIONS



KEYNOTE SPEAKERS



Glen Allmendinger, President, Harbor Research



James Keller, Jr., Vice President, Health Technology Evaluation and Safety, ECRI Institute & President-Elect, ACCE



Ed Cantwell, Senior Vice President, West Wireless Health Institute



Michael Robkin, President, Anakena Solutions



Tim Gee, Connectologist & Principal, Medical Connectivity Consulting



Nat Sims, MD, Assistant Professor Anesthesia, Harvard Medical School, Massachusetts General Hospital



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



Dane Stout, Director Connected Health and Biomedical Communication Practice, The Anson Group

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*

MD PnP
Getting connected for patient safety

OPEN HOUSE CIMIT MEDICAL DEVICE INTEROPERABILITY LAB

On Sept 7th (the day before the Medical Device Connectivity Conference begins) from 4:00-6:00pm, there will be an Open House for Medical Device Connectivity Conference attendees hosted by the Medical Device Plug-and-Play Program at their Interoperability Lab in Cambridge. Interoperability research demonstrations and poster presentations will be shown by the program team and by collaborators from the NIH-funded Quantum Interoperability project. 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.

PROGRAM CHAIRPERSON'S WELCOME



It's been an exciting year since that last Medical Device Connectivity conference in San Diego. So much has happened, and much of it is driving this year's conference program. Numerous new connectivity companies have come to my attention, and I'm now tracking 22 manufacturers of medical device connectivity solutions - almost double the number last year. The manufacturers in this market have been busy.

For this, the the third year of the conference, we're going back to Boston and the lovely Martin Conference Center at Harvard Medical School. There is also a special pre-conference event: an open house at the Medical Device Plug and Play Interoperability program's lab. September 7, from 4pm to 6pm attendees can tour the lab, interact with various demonstrations and chat with program staff. This is a unique experience to visit the only facility of its kind devoted to medical device connectivity.

Clinical documentation for EMRs continues to drive medical device connectivity. But, as you can see from the list below of this year's connectivity milestones and events, clinical documentation is just one front in a wave of connectivity activity. Since last year's conference so much has come to pass:

- The FDA published their final rule for Medical Device Data Systems, and signaled their intent to regulate health care providers who develop their own MDDS solutions.
- The FDA also published the long anticipated draft guidance on mobile apps, clarifying the boundaries around what is and is not regulated medical device software, and laying out a bit of the FDA's enforcement strategy.
- Long term challenges around alarm fatigue and notification have received new levels of attention from FDA and AAMI, resulting in a Medical Device Alarms Summit later this fall.
- An FDA Workshop on Medical Device Interoperability was held a few months after last year's Medical Device Connectivity conference. This event was just part of an effort to develop a regulatory framework tailored to plug and play medical device interoperability. The group behind this event has published a number of important papers this year on interoperability, risk management and other topics.
- Founded in July of 2010, the mHealth Regulatory Coalition has contributed greatly to advancing a different set of regulatory policies for mobile apps and also published important papers this year on the optimal regulatory framework for mHealth medical devices.

On the standards front, IEC 80001 will mark its first year as a formal standard this September. And the Integrated Clinical Environment (ICE) standard (ASTM F2761-2009) has been advanced by a number of grants that will result in the creation of solutions that implement portions of the ICE standard. Both ICE and ongoing efforts by the IHE PCD have seen continued adoption of ISO/IEEE 11072.

This year's conference will explore all of these topics, along with a number of case studies.

The Medical Device Connectivity conference remains the sole industry event dedicated to workflow automation through the integration of medical devices and information systems. And there is no other venue where clinicians, clinical engineers, medical device manufacturers and connectivity suppliers can all meet, learn and exchange ideas.

Thanks in advance to all of this year's speakers for their participation and support of the advancement of connectivity, and this conference. Both their expertise and efforts to share their connectivity experience will create an exceptional conference experience for all attendees.

Yours Truly,

A handwritten signature in black ink that reads "Tim Gee". The signature is written in a cursive, flowing style.

Tim Gee, Program Chair
Principal, Medical Connectivity Consulting



THIRD ANNUAL MEDICAL DEVICE CONNECTIVITY CONFERENCE AGENDA

DAY ONE: THURSDAY SEPTEMBER 8, 2011

7:00 Registration / Sponsor / Exhibitor Showcase &
Breakfast Sponsored By: Summit Data Communications

8:00 **CHAIRPERSON'S INTRODUCTION & OPENING
REMARKS**

**Tim Gee, Connectologist & Principal, Medical
Connectivity Consulting**

8:30 **KEYNOTE ADDRESS: PROGRESS IN PATIENT
CENTRIC CLINICAL CARE**

Revolutionary improvements in the safety and quality of healthcare delivery have been hampered by the inability of medical equipment and electronic health record systems to be fully integrated into smart networks. Given the complexity of both medical technology and clinical care, commercial, technical and regulatory barriers make the realization of medical device operability difficult at best. One effort, the \$10 million NIH Quantum Grant project, "Development of a Prototype Healthcare Intranet for Improved Health Outcomes," builds on the latest technologies that are enabling interoperability in other industries, to empower the global healthcare community to build smart "integrated" clinical environments. Additional initiatives impacting medical device connectivity, including various White House initiatives, will be described.

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

9:15 **KEYNOTE ADDRESS: MEDICAL DEVICES AND
THE INTERNET OF THINGS**

We are living in an increasingly interconnected world. Yet technology has only progressed to the point where there are many proprietary end to end solutions based on custom integration and just a few plug and play interoperable environments. Networking and the Internet have brought us to the next wave of technology evolution, commonly referred to as the Internet of Things (IoT). The IoT breaks down the solos of information limited to proprietary end to end solutions, and makes possible broader views of data that are independent of, and extend beyond, what any one manufacturer can create. This transformation is brought about by the creation of interoperability between devices and information systems. Translated to medical devices, the result is a patient centric view of data produced by the many medical devices attached to patients during an episode of care. Learn how we have reached this inflection point to be in the cusp of the IoT, and review the key barriers to adoption that must be overcome before the IoT is realized on a broad scale. Explore barriers to adoption unique to health care. The different functional components of a medical device IoT will be described, along with potential roles to be played by existing vendors and roles likely to be filled by new entrants. Various scenarios of how the IoT may evolve will be discussed. Health care providers

will gain new insight into technology evolution to help guide acquisition strategies and future procurements. Medical device manufacturers will realize a powerful new framework to enhance business planning and product strategy.

Glen Allmendinger is the founder and President of Harbor Research and has been responsible for managing Harbor and all of its consulting and research activities since its inception in 1984. Glen led in developing the firm's groundbreaking analysis of the impact of the Pervasive Internet and Smart Services — the use of the Internet to accomplish global device and sensor networking that will revolutionize business by unleashing entirely new modes of system optimization, customer relationships, and service delivery. He co-authored "Four Strategies For The Age of Smart Services," Harvard Business Review, October 2005, which is widely regarded as the definitive work on the marketplace disruption that is being driven by smart networked products.

Glen Allmendinger, President, Harbor Research

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

11:15 KEYNOTE ADDRESS: A CLINICIAN'S PERSPECTIVE ON 5 CONNECTIVITY APPLICATIONS – EXAMPLES OF THE CRAWL, WALK, RUN ADOPTION PROCESS

Few, if any, clinical sites have a greater number of different connectivity systems implemented than Partners HealthCare. Over the past several years, Partners has deployed these systems in a variety of clinical areas, to meet both common and unique goals and objectives. Besides the systems deployed or under development at Partners, Sims includes a few favorite applications pioneered by peers at other institutions. These systems include Advanced Clinical Documentation for EMR adoption, an Anesthesia Information Management System, Vital Signs Capture also for charting, IV medication administration, and Rapid Response Team Notification. The presentation begins with a discussion of the objectives for these systems, and how the results of implementation were measured. The inception of each system will be described along with a case study history spanning needs assessment, design, implementation and outcomes. Key concepts such as patient context, connectivity demands on traditional technology management life cycles, and technology planning are discussed. The presentation closes with a discussion of key considerations for adopting connectivity that spans a variety of different applications.

Nathaniel Sims, MD, is a clinician, teacher, cardiac anesthesiologist, and medical advisor to Biomedical Engineering at Massachusetts General Hospital (MGH). He is also an Assistant Professor of Anesthesia at Harvard Medical School. Dr. Sims is a strategic and hands-on innovator who has developed numerous technologies that make patient care safer and more efficient. Working in interdisciplinary teams involving biomedical engineering, nursing, and various hospital departments, Dr. Sims and colleagues have pioneered improvements in patient monitoring, patient transport, and error-free intravenous drug delivery systems. The overall focus is developing advanced systems technologies to improve safety and patient care while reducing cost. Dr. Sims holds numerous US patents (rights assigned to MGH). Dr. Sims is the 2006 winner of the AAMI Foundation Laufman/Greatbatch

10:00 Sponsor / Exhibitor Showcase & Refreshments Sponsored By: Summit Data Communications

10:30 KEYNOTE ADDRESS: THE MEDICAL DEVICE IS DEAD – LONG LIVE THE MEDICAL DEVICE

Changing customer requirements and advancing technology, especially information technology, has been transforming the medical device industry for many years. This keynote will describe each of the factors contributing to the transformation of the medical device industry. Falling product differentiation in more mature product categories will be considered and compared to the increasing importance of workflow automation in medical device vendor selection. How and why workflow automation is transforming medical devices into information appliances will be presented. As a consequence of these changes, the value generated by proprietary product strategies is falling. Established medical device manufacturers are carefully feeling their ways through these transformations, and how these changes have impacted their business models will be described. Disruptive innovation is also impacting the industry, and the two primary vehicles for creating discontinuities will be explored. The presentation then explores the industry's current state by looking at the role played by connectivity and interoperability, and how it is transforming manufacturers, hospitals and regulators alike. Finally, we will look ahead into the short-term future to consider likely outcomes.

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

Prize for his significant contributions to the advancement of medical instrumentation through development of “smart drug infusion pump” technology and “flexible monitoring” systems, and he is a 2011 recipient of the AAMI Standards Developer Award.

Nat Sims MD, Assistant Professor Anesthesia, Harvard Medical School, Massachusetts General Hospital

12:00 KEYNOTE ADDRESS: MOBILITY IN HEALTHCARE: THE PATH TO A MEDICAL GRADE WIRELESS UTILITY

Health care has yet to harness the full power of the wireless revolution that has transformed other aspects of our lives. Yet wireless medical technology offers one of the greatest opportunities to materially lower health care costs and extend care to a patient regardless of physical or geographic location — “the right care, at the right time, wherever a person may be.” What will it take to get this obvious benefit from this ubiquitous technology?

With the proliferation of wireless devices—both medical and consumer—in health care settings, it is critical for hospital administrators and all of those engaged in the health care enterprise to feel confident that using wireless technologies within patient environments is safe and reliable. However, unlike the wired network, wireless connectivity comes with added levels of complexity—coverage, signal strength and capacity concerns, among others—and impressions about performance and robustness have doubtlessly been seeded with individual experiences surrounding quality of service issues in consumer wireless devices.

West Wireless Health Institute is convening a variety of ecosystem stakeholders to undertake this task. To start, WWHI is bringing together health care leaders such as CIOs who represent the “customer” and have extensive experience in establishing wireless connectivity within their facilities. This group will work with WWHI to create a reference architecture suitable for both new and existing venues. This reference architecture will be owned and self-governed by these healthcare champions over time.

The next step is to proactively engage regulatory agencies and relevant standards bodies for mutual guidance, as we work to define the various levels of assurance needed for wireless health applications that are considered to be medical grade. Think of this stage as “rational risk stratification.”

Once there is consensus from these groups, Wireless Service Providers (WSPs) will be engaged to ensure that the MGWU reference architecture meets the technical and economic requirements for both licensed and unlicensed providers. WSPs are critical to the future of wireless health because of their ability to create a ubiquitous platform both inside and outside the premise of health care facilities.

This keynote presentation will describe each of these phases, explain WWHI’s progress and plans to date, and provide a roadmap and schedule resolving this important industry initiative.

Ed Cantwell is a senior vice president of the West Wireless 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 Wireless Health Institute

12:45 Sponsor / Exhibitor Showcase & Luncheon

2:00 KEYNOTE ADDRESS: CONNECTIVITY ISSUES IMPACTING PATIENT SAFETY

The ECRI Institute is deeply integrated into the delivery of care, through the services and consultation the Institute provides to health care providers and industry. This presentation will highlight both safety concerns and advances resulting from connectivity in the key areas of infusion pump safety, alarm notification, networked medical device systems, human factors and usability. Key factors that determine whether a connectivity capability is a net improvement or reduction in patient safety will be explored. Insights and recommendations for both provider organizations and manufacturers will suggest ways to ensure connectivity improves patient safety and outcomes, rather than detracting from patient care.

James P. Keller Jr. is Vice President, Health Technology Evaluation and Safety. He directs ECRI Institute’s internationally recognized medical device evaluation program, which has been referred to by the New York Times as the “country’s most respected laboratory for testing of medical products.” He is responsible for numerous ECRI Institute print and Web-based publications and databases, consultation services, educational programs, software tools, and instrument design services. He is a recognized expert and frequently invited speaker on a wide range of medical-technology-related topics including patient safety, strategic planning,

and forecasting. Mr. Keller has been with ECRI Institute since 1984. He has a Bachelor of Science degree in zoology from the University of Massachusetts and a Master of Science degree in biological engineering from the University of Connecticut. In 1993, he received AAMI's Biomedical Engineering Achievement Award, which recognizes individual excellence and achievement in the field of biomedical engineering.

James Keller, Jr., Vice President, Health Technology Evaluation and Safety, ECRI Institute & President-Elect, ACCE

2:30 KEYNOTE ADDRESS: PROGRESS REPORT: MEDICAL DEVICE INTEROPERABILITY SAFETY WORKING GROUP

In January 2010, a working group was convened to develop an optimal way to provide a regulatory framework for plug and play medical device interoperability, and to identify the hazardous situations common to expected implementations (e.g. acute care, home smart phone hub). This group was founded by members of the FDA, CIMIT, the Medical Device Plug-and-Play Interoperability Program, the Continua Health Alliance, and others. Since its founding, this multi-institutional group has made significant progress. The presentation will define the objectives for the working group and describe the progress to date. Results will be described, including regulatory pathways and a proposed risk model for plug-and-play interoperable medical devices.

Michael Robkin, MBA, is founder and President of Anakena Solutions, specializing in research and implementation of plug-and-play interoperable medical devices – particularly identifying and eliminating barriers to adoption across the healthcare industry. Currently Mike's company is leading the technical deliverables for the 5-year NIH Quantum grant on medical device interoperability for improved health outcomes. Mike was formerly the most senior Enterprise Architect for all Care Delivery systems for a large integrated health care provider, and a founding board member and the Treasurer of the Continua Health Alliance. Mike recently co-chaired The FDA (CDRH) Workshop on Medical Device Interoperability: achieving safety and effectiveness.

Michael Robkin, President, Anakena Solutions

3:00 KEYNOTE ADDRESS: REGULATORY UPDATE ON THE ACTIVITIES OF THE mHEALTH COALITION

The current medical device regulatory framework never anticipated many of the new technologies incorporated into today's medical devices. While the regulatory framework has been found to be remarkably resilient over time, certain shortcomings are being revealed by medical device connectivity and interoperability. The mHealth Regulatory Coalition was created to identify these regulatory gaps, and to help industry and FDA develop guidance to fill these gaps without compromising safety and effectiveness. This presentation identifies regulatory gaps that have been identified to date, describes the

actions taken by the coalition to address these gaps, and progress to date.

Dane Stout runs the Connected Health Practice at Anson, and is focused on assisting clients successfully commercialize wireless, mobile, and networked technologies under existing regulatory policies and rules of the Food & Drug Administration. In addition, the Connected Health Practice works to track and lead the development of new policies that will enable clearer pathways to market for innovation that spans the rapidly converging worlds of telecommunications, information technology, consumer electronics, life science, and healthcare information technology. Mr. Stout has over 25 years of technology industry experience that includes commercial and technical computing systems in life science and healthcare, as well as both business and clinical systems used in the healthcare delivery industry. Prior to joining Anson he served as the Global Market Segment Manager for the Healthcare and Life Sciences Industries at Sun Microsystems, Inc.

Dane Stout, Director Connected Health and Biomedical Communication Practice, The Anson Group

3:30 Sponsor / Exhibitor Showcase & Refreshments Sponsored By: Summit Data Communications

Choose from Track A, B or C

TRACK A – PROVIDERS

4:00A EXPERIENCE IMPLEMENTING MEDICAL DEVICE CONNECTIVITY USING MEDICAL DEVICE GATEWAYS

Effective medical technology management must take into account institutional and clinical needs, available commercial products, and the life cycles of related systems. Medical device connectivity for EMR clinical documentation must take into consideration the life cycle of numerous enabling technologies, like networks, in addition to related systems such as various medical devices, HL7 interface engines, EMR applications and other consumers of medical device data. Defining and synchronizing these life cycles, balancing requirements and project schedules all influence medical technology purchase decisions. This presentation will describe the process Partners completed to assess their needs, identify life cycles and other environmental factors, purchase and implement their clinical documentation solution. The presentation will delve into why Partners chose to use medical device gateways rather than use a third party medical device data system. Lessons learned from this experience will be discussed.

Luis Melendez, Assistant Director, Partners HealthCare Biomedical Engineering, Medical Device Informatics, Massachusetts General Hospital

4:30A USING ALERTS AND ALARMS TO CREATE HOSPITAL INDICATIONS OF CARE FOR IMPROVED PATIENT SATISFACTION AND OUTCOMES

Although core to basic functioning of any clinical unit in the hospital, nurse call is often overlooked as a strategic tool for managing business performance. The hospital's ability to manage the patient's needs with the caregivers response is a key differentiator in determining the hospital's image and financial reward. Many of the management metrics used to evaluate the performance of clinicians in the eyes of the patient are qualitative. We ask "Did you enjoy your stay?" "Were you responded to as quickly as you would like to be?" yet we don't take the time to clearly identify a way to find those answers without a fill in the blank questionnaire. In this presentation we will introduce Indications of Care or IndiCares™ and have an open conversation on how call centers, sales organizations, airports, and manufacturing facilities evaluate productivity and how it can apply to healthcare. This is not a conversation that compares patients to cars, planes, or other inanimate objects – it's a study on how people's needs can be met more effectively by looking at numbers that are produced by technology used every day at the hospital. The status quo for assessing patient satisfaction and safety are generally retrospective. While there are new tools available there is not currently tools to evaluate the response patterns and request patterns as they occur. How can your hospital utilize the current technology to begin to drive towards this information? We will provide concepts and ideas to move hospitals towards better performance evaluation using request and response metrics.

Kourtney Govro, CEO, Sphere3 Consulting

5:00A ARE THERE REALLY PROBLEMS WITH IV INFUSIONS TODAY? A SNAPSHOT LOOK AT 429 IN-PROCESS IV INFUSIONS

The theory behind the use of drug error reduction systems (DERS) by infusion pumps is well established. The reality of the impact of DERS on day to day patient care is less well understood. Northwestern Memorial Hospital did a study on IV medication administration to better understand the impact of DERS on infusion safety; the results were sobering. While DERS contributed to improved safety, this study reveals a wide variety of errors - even some related to DERS themselves - that impacted patient safety and could have resulted in patient injury or death. The presentation then delves into the impact of DERS overrides and the impact of alert fatigue on infusion safety.

Marla Husch RPh, Director of Operations, Central DuPage Hospital

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

TRACK B – MANUFACTURERS

4:00B DEPLOYING MEDICAL DEVICES IN BOTH WI-FI BANDS

In a typical hospital, the 2.4 GHz frequency band is saturated with wireless devices – Wi-Fi, Bluetooth, WMTS, and others. In contrast, the 5 GHz band, which offers seven times more Wi-Fi channels than the 2.4 GHz band, sits relatively unused. Why do so few Wi-Fi devices support 5 GHz, and how can a hospital begin to take advantage of all of this wireless "real estate"? This presentation explains the differences between the bands, explores how 802.11n unlocks the 5 GHz band, and provides guidance on how a hospital can migrate from a single-band deployment to a dual-band deployment.

Chris Bolinger, Vice President Engineering, Summit Data Communications

4:30B CREATING SOFTWARE LIBRARIES TO FACILITATE THE ADOPTION OF STANDARDS BASED MEDICAL DEVICE INTEROPERABILITY

Between thirty to forty percent of healthcare costs (both civilian and military) are attributable to systemic failures in healthcare. To date, technology and standards to prevent these failures have been limited. The incompatibility of medical devices, equipment, and hospital information systems has left patients vulnerable to human error associated with the manual entry of medical data and limitations caused by caregivers not having access to a complete set of continuous patient data as the patient moves between and within treatment facilities. A key barrier to the adoption of plug and play medical device interoperability is the absence of implemented standards available as open source projects or software libraries that can be licensed by manufacturers for incorporation into their devices. This presentation describes a Telemedicine and Advanced Technology Research Center (TATRC) contract that will result in the creation of a software library available to third parties so that they may more easily create products with standards based interoperability capabilities. The scope and capabilities of the software are described, along with other aspects of the project. How the software is intended to be incorporated into medical devices, and the general workflows intended to be supported will be discussed.

Tracy Rausch CCE, CTO and Founder, DocBox Inc.

5:00B BEST PRACTICES FOR EMBEDDED MEDICAL DEVICE AND GATEWAY SOFTWARE APPLICATIONS

Application development for general purpose computing platforms differs substantially from the development of embedded systems software and medical device management / integration gateways. Applying best practices from one discipline to the other can reduce unnecessary costs, delays in time to market, and help reduce regulatory clearance issues. Mr. Shah will discuss how to apply current software application development

strategies and methodologies to embedded medical device and connectivity software for implementation of patient context management, workflow automation, alarm notification, and other key medical device system features commonly implemented on general purpose computing platforms.

Shahid Shah, CEO, Netspective Communications LLC

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

TRACK C – REGULATORY

4:00C ONE HOSPITAL SYSTEM'S INITIAL EXPERIENCE WITH MDDS AS A MANUFACTURER

After more than two years, the FDA published the final MDDS rule this past February. In the final rule, the FDA specifically called out health care providers and how they may meet the legal threshold of a medical device manufacturer by having developed their own software for acquiring data from medical devices. The prospect of being regulated by FDA is daunting enough for medical device manufacturers, but seems an overwhelming prospect for provider organizations. Rob Hyatt describes the process taken by Intermountain Health to assess the final rule's application to their software, assess the impact of becoming a registered medical device manufacturer and adopting the Quality System regulation. Having worked for many years at medical device manufacturers, Rob will compare and contrast the challenges and opportunities provider organizations and conventional manufacturers must face with MDDS.

Rob Hyatt, Director Clinical Systems QA/RA, Intermountain Healthcare

4:30C APPLYING BEST PRACTICES AS RISK CONTROL MEASURES DURING THE DESIGN OF A WIRELESS MEDICAL IT NETWORK

This session covers two topics related to wireless medical IT networks: the general challenges and solutions for the design, deployment and management of a converged Wi-Fi network, and the fundamental principles of applying risk management during these stages as defined in the draft technical report IEC/TR 80001-2-3 Ed. 1.0 Application of risk management for IT-networks incorporating medical devices – Part 2-3: Guidance for wireless network. Phil is the chair of the Wi-Fi Alliance Healthcare Task Group that recently released a white paper on the successful implementation of Wi-Fi in Hospitals, as well as the co-chair of the committee developing the IEC 80001-2-3 Wireless Guidance Technical Report.

Phil Raymond, Wireless Architect, Philips Healthcare, Patient Monitoring Systems

5:00C NEW EFFORTS IN GUIDANCE AND INDUSTRY STANDARDS IN SUPPORT OF MEDICAL DEVICE CONNECTIVITY

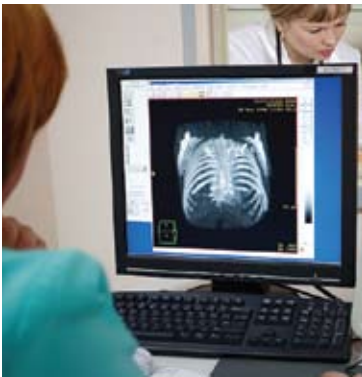
The convergence of healthcare IT and medical technology management is having a significant impact on industry and providers. The premier association representing medical technology management, the Association for the Advancement of Medical Instrumentation, is leading a record number of standards development efforts around medical device connectivity. This presentation provides a survey of many of the standards, guidance and industry best practices efforts that are underway today under the aegis of AAMI. Specific projects and efforts will be described, noting their progress. Information will be provided to those interested in becoming involved in these standards development efforts.

Joe Lewelling, VP Standards Development, AAMI

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.



THIRD ANNUAL MEDICAL DEVICE CONNECTIVITY CONFERENCE AGENDA

DAY TWO: FRIDAY SEPTEMBER 9, 2011

7:30 *Sponsor / Exhibitor Showcase & Breakfast Sponsored
By: Cardiopulmonary Corp.*

Choose from Track A, B or C

TRACK A – PROVIDERS

8:00A **CHAIRPERSON'S OPENING REMARKS**
**John Zaleski, PhD, CPHIMS, VP of Clinical
Applications and CTO, Nuvo**

8:30A **CLINICAL DOCUMENTATION EXPERIENCE
USING PHILIPS GATEWAYS TO EPIC EMR**
Clinical documentation remains the primary driving application for the adoption of medical device connectivity. Several approaches are available to providers to acquire medical device data for documentation in the EMR. The University of Florida/Shands Hospital looked at several approaches in light of their own needs assessment. This presentation will describe the needs assessment and vendor selection criteria, and how they arrived at their preferred solution. An overview of their solution will be provided, including the basic workflow and medical devices supported. Lessons learned from the planning and implementation phase of the project will also be presented.

**Craig Bakuzonis, Director, Clinical Engineering,
Shands at the University of Florida**

9:15A **EPISODIC VERSUS CONTINUOUS WIRELESS
CONNECTIVITY: ARE MEDICAL DEVICES AND
NETWORKS READY FOR REAL TIME DATA?**
There is no more demanding medical device connectivity application than continuous patient monitoring and alarm notification. As more medical device systems migrate from closed dedicated networks to the enterprise network, questions about the safety of continuous networking applications have arisen. This presentation compares and contrasts episodic and continuous applications, and provides data on two different wireless continuous patient monitoring applications. The presentation provides detailed specifications and performance data, including statistical data on how this application has impacted patient outcomes at Dartmouth Hitchcock.

The presentation closes with recommendations on how providers can make the transition from episodic to continuous applications.

**Brian Long, CWNA, Director, Field Systems
Operations, Masimo**

10:00 *Sponsor / Exhibitor Showcase & Refreshments Sponsored
By: Cardiopulmonary Corp..*

10:30A **INCREASED PATIENT SAFETY, WORKFLOW
IMPROVEMENTS, AND FINANCIAL BENEFITS
REALIZED FROM THE IMPLEMENTATION OF A
VIRTUAL CARE ENVIRONMENT WITH REAL-
TIME CRITICAL DATA FROM PHYSIOLOGICAL
MONITORS AND LIFE SUPPORT DEVICES**

In today's healthcare climate of increasing patient acuity and decreasing resources, Indiana University Health took on the challenge of creating a remote bedside monitoring program. The history of the program is discussed, starting with the drivers for establishing Inpatient Telemedicine, the lessons learned along the way, and the resultant improvements to patient safety, outcomes, workflows, and resource utilization. Monitoring 305 critical and progressive care patients via live feeds of disparate patient monitoring devices from multiple locations, the inpatient virtual monitoring unit uses the latest technology and real time patient surveillance software to capture, consolidate, manage alarms, trends, and deliver to the EMR, time-sensitive patient and device data. The comprehensive picture of a patient's condition monitored by 24 hr. staff results in earlier clinical interventions, decreased mortality, and reduced costs.

**R. Renee Johnson, RN, MBA, IT Clinical Project
Manager, Indiana University Health**

11:00A **DEVICE INTEGRATION AT RADY CHILDREN'S
HOSPITAL - SHAPSHOTS IN TIME**
A pragmatic view of the reality of device integration, this presentation focuses on describing Rady's initial assumptions about device integration based on the existing infrastructure, how those assumptions changed over time and the implications for the final integration design, how Rady adjusted their solution along the way, how they

constituted their teams for success, and lessons learned from clinical, biomed, network, and nursing teams. The presentation will also cover workflow requirements and Best Practices that resulted from the process. Rady's device integration initiative was part of the Inpatient Documentation phase of their Epic installation focusing on nursing interaction with devices. This enterprise-wide installation supports 408 Philips monitors in 12 units across 3 buildings, and 300 Alaris Smart Pumps. The scope of the deployment covered NICU, Critical Care, MedSurg, Hem/Onc and BMT, Medical Beds, ED, PACU, and OR. The discussion will also address the resulting monitoring environment based on the installed solution.
Sheldon Gilmer, Interface Engineer, Rady Children's Hospital

11:30A NETWORKED MEDICAL DEVICES AND THE IEC80001 STANDARD: ARE YOU READY?

Presented as an interactive discussion, this presentation goes from the basic questions about what IEC80001 is all about, to what implementing the standard at your hospital really means. Attendees will discuss where they are in the education and adoption process and the speaker will answer questions and provide suggested best practices. The focus of the presentation will be on implementation issues around developing a cross functional implementation team, how to use responsibility agreements with suppliers to gain needed risk management data, and the basics of risk management. The presentation will close with a discussion of best practices for approaching risk management with wireless network infrastructure and alarm notification applications.
Rick Hampton, Corporate Manager Wireless Communications, Partners HealthCare System; member IEC80001 committee, co-chair wireless technical report workgroup

12:00 CLOSING PLENARY PANEL DISCUSSION

The experts on this year's closing plenary panel will gaze into their crystal balls and tell us what they're expecting to see around the evolving regulation of Medical Device Data Systems, and regulatory changes expected for mHealth applications and systems. Adoption trends of the industry standards discussed in the program will be discussed, with a focus on the resulting impact for health care providers and manufacturers both. The initiatives of many organizations presented at the conference will be analyzed, with an eye towards determining what impact their efforts will have on the industry. Finally, the panel will wrap up with a discussion of the emerging trends in connectivity beyond simple "plumbing" or moving data from devices to some target system. This discussion will delve into applications beyond simple clinical documentation to consider how connectivity applications will drive improvements in patient safety and outcomes, staff productivity, and lower operating costs.

Moderator:

Tim Gee, Connectologist & Principal, Medical

Connectivity Consulting

Panelists:

Glen Allmendinger, President, Harbor Research
Rob Hyatt, Director Clinical Systems QA/RA, Intermountain Healthcare
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
Kourtney Govro, CEO, Sphere3 Consulting
Craig Bakuzonis, Director, Clinical Engineering, Shands at the University of Florida
Ed Cantwell, Senior Vice President, West Wireless Health Institute

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

TRACK B – MANUFACTURERS

8:00B CHAIRPERSON'S OPENING REMARKS

Shahid Shah, CEO, Netspective Communications LLC

8:30B SYSTEM DESIGN CONSIDERATIONS FOR MEDICAL DEVICE MANUFACTURERS

In recent years, medical devices have grown more complex and sophisticated as advances in wireless communication, security protocols, USB, persistent storage, and portable touch screens with graphics have made their way into medical equipment. With lives dependent on their reliable operation, these devices have strict safety requirements as well as stringent security needs due to the sensitive patient data they store. As a result, development and deployment of medical device software is usually time-consuming and expensive. Green Hills Software and Silex Technology America will discuss how RTOS selection and Wi-Fi implementation can impact the safety, reliability and security of medical devices. In addition, we will discuss how the Green Hills/Silex partnership can dramatically reduce your development cost and time-to-market.

Jim McElroy, Director – Industry Business Development, Green Hills Software

Mark Prowten, Director – OEM Embedded Wireless, Silex Technology America

9:15B MEDICAL DEVICE SECURITY: DEFINING THE NEED AND SOLUTION

As medical devices evolve into information appliances for use in enterprise network environments, manufacturers continue to be challenged by security and authentication challenges. While security requirements are increasing from the market as a whole, certain customers have set the security bar very high. This presentation will introduce a basic security framework and describe how each framework component addresses specific security threats

faced by networked medical devices. Special attention will be given to meeting the federal government's FIPS 140-2 and Suite B encryption.

Kurt Stammerger, CISSP - VP Market Development, Mocana

10:00 *Sponsor / Exhibitor Showcase & Refreshments Sponsored By: Cardiopulmonary Corp.*

10:30B KEY CONSIDERATIONS AND BEST PRACTICES FOR INTEGRATING MEDICAL DEVICES ON A SHARED ENTERPRISE NETWORK

Driven by a need to reduce cost while increasing the efficiency, quality and safety of patient care, healthcare delivery organizations (HDOs) are demanding that medical device manufacturers develop and support products that can utilize the HDO's enterprise IT network (wired/wireless). These products include; patient-worn and portable patient monitors, infusion pumps and a myriad of other medical devices and applications. This creates many new considerations, challenges and process changes for the medical device manufacturer pre and post deployment. Additionally, the recently ratified IEC80001 (Application of Risk Management of IT Networks Incorporating Medical Devices) standard provides instruction for MDMs (medical device manufacturers) and healthcare providers intended to mitigate risk. This presentation will outline the drivers and evolution of medical devices and applications operating on shared networks and provide a framework for pre-deployment testing to characterize and better predict how networked medical devices will operate on a shared enterprise network. This described framework will determine the design criteria, infrastructure requirements and the best practice deployment guidelines to achieve the required SLA (service level agreement).

Tom Boston, Project Engineer, GTRI
Dave Hoglund, CEO and Founder, Integra Systems

11:00B OPTIMIZING DEVICE INTEROPERABILITY THROUGH MODEL-BASED SYSTEMS ENGINEERING

This presentation focuses on applying the concepts of systems engineering to the modeling and simulation of medical devices and their critical system interfaces. Device development is a multidisciplinary effort and the use of model-based analysis and simulation in the early stages of the design strategy allows clinicians and engineers to understand the risk, cost, and complexity of proposed systems. In particular the interfaces between components, subsystems, and ultimately patient and device are critical to define and optimize. This presentation describes the use of integrated functional analysis coupled with requirements for system interface design to improve the way complex clinical systems operate.

Brett Malone, PhD, VP Business Development, Vitech

11:30B REMOTE MEDICAL DEVICES THROUGH THE CLOUD

More and more industries are using the Cloud as a central place to manage devices and store data. This presentation will look at ways that the medical industry can use the Cloud. There are two primary uses. The first is the management of devices, making sure they have the latest software updates, are configured properly and have been serviced. The second is the collection of information about the devices as well as the patient data they collect.

Joel Young, Senior VP of R&D and CTO, Digi International

12:00 CLOSING PLENARY PANEL DISCUSSION

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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
Kourtney Govro, CEO, Sphere3 Consulting
Craig Bakuzonis, Director, Clinical Engineering, Shands at the University of Florida
Ed Cantwell, Senior Vice President, West Wireless Health Institute

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

TRACK C – REGULATORY

8:00C CHAIRPERSON'S OPENING REMARKS

Dane Stout, Director Connected Health and Biomedical Communication Practice, The Anson Group

**8:30C PANEL DISCUSSION: WHO'S ON FIRST?
DISCUSSION ON REGULATORY TRENDS AND
PREDICTIONS**

The group will discuss potential gaps and duplicate efforts by the numerous regulatory efforts currently underway. The panel will also prognosticate on future FDA trends, both new guidance documents, and rules, plus a discussion of expected FDA enforcement efforts and changes in regulatory discretion. Issues around health care providers as medical device manufacturers will be explored, and consider what providers can do to manage regulatory risk. Finally the group will take questions from the audience.

Moderator:

Tim Gee, Connectologist & Principal, Medical Connectivity Consulting

Panelists:

Joe Lewelling, VP Standards Development, AAMI
Michael Robkin, President, Anakena Solutions
Rob Hyatt, Director Clinical Systems QA/RA, Intermountain Healthcare
Dane Stout, Director Connected Health and Biomedical Communication Practice, The Anson Group

Data Systems, and regulatory changes expected for mHealth applications and systems. Adoption trends of the industry standards discussed in the program will be discussed, with a focus on the resulting impact for health care providers and manufacturers both. The initiatives of many organizations presented at the conference will be analyzed, with an eye towards determining what impact their efforts will have on the industry. Finally, the panel will wrap up with a discussion of the emerging trends in connectivity beyond simple “plumbing” or moving data from devices to some target system. This discussion will delve into applications beyond simple clinical documentation to consider how connectivity applications will drive improvements in patient safety and outcomes, staff productivity, and lower operating costs.

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Craig Bakuzonis, Director, Clinical Engineering, Shands at the University of Florida
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10:00 *Sponsor / Exhibitor Showcase & Refreshments Sponsored By: Cardiopulmonary Corp.*

Track C concludes at 10:00 am. Please choose from Track A or Track B for the sessions from 10:30 am to 12:00 noon.

12:00 **CLOSING PLENARY PANEL DISCUSSION**
The experts on this year’s closing plenary panel will gaze into their crystal balls and tell us what they’re expecting to see around the evolving regulation of Medical Device

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

**OPTIONAL POST-CONFERENCE WORKSHOP ONE
VENDOR AGNOSTIC ALARM DESIGN AND PERFORMANCE METRICS**

Workshop Hours: 2:00-6:00 pm

Although core to basic functioning of any clinical unit in the hospital, nurse call is often overlooked as a strategic tool for managing business performance. The hospital’s ability to manage the patients needs with the caregivers response is a key differentiator in determining the hospital’s image and financial reward. We will dive deeper into the Indications of Care or IndiCares™ and have an open conversation on how call centers, sales organizations, airports, and manufacturing facilities evaluate productivity and how it can apply to healthcare. This is not a conversation that compares patients to cars, planes, or other inanimate objects – it’s a study on how people’s needs can be met more effectively by looking at numbers that are produced by technology used every day at the hospital. To establish metrics for performance the alarm design must have consistent standards: Garbage in Garbage out.

This class includes presenting the concept of providing a common language for Clinical Alarm Design--one that creates consistent structure in the hospital using terminology that is transferable across technology. We will explore the existing integration technology platforms and discuss the flexibility options of using the common language within their structures. Value: Financial incentives are being presented to hospitals linked directly to the patients satisfaction with their stay, one of the key indicators of that satisfaction is whether their needs were met promptly. The status quo for assessing patient satisfaction and safety are generally retrospective.

While there are new tools available there are not currently tools to evaluate the response patterns and request patterns live state. How can your hospital utilize the current technology to begin to drive towards this information? We will provide concepts and ideas to move hospitals towards better performance evaluation using request and response metrics. A vendor agnostic approach to workflow design provides the hospital with consistent standards from visioning to implementation. It provides patient and caregiver perspective to the process and aligns the hospital's core values with the ultimate outcomes. This will also help to create a consistent management of the information going forward. Handouts/Takeaways: Alarm Design Process Map Worksheet, Terminology and Documentation Theology Glossary, White Papers on Design and Performance Metrics, and Performance Metric Worksheet.

Workshop Instructor:

Kourtney Govro, CEO, Sphere3 Consulting

The ability to critically evaluate the physical workflow of caregivers, anticipate the needs of patients, understand the capabilities of technology, and mesh them all together to make decisions from a vendor agnostic perspective is a niche skill set. The journey that Kourtney Govro has taken over the past 12 years has shaped her clinical alarm expertise to make her highly sought after in the industry. Her career started when she was 16 and attended her first Nurse Call training class. After college she worked in the family business of training clinicians on the technology. Later she moved into design of integrated clinical alarm systems and worked closely with several consulting, architect and engineering firms. She has participated in hospital technology implementations, large and small, leading teams. She has taken that professional experience and her personal patient story to create Sphere3. She applied her extensive knowledge into software tools that are used to improve clinical workflow and continuous improvement processes. Her vision of providing a client facing user friendly platform to manage the requests of patients balanced with the capacity of the clinical unit called Aperum™ launches in April. Her tools and methodologies have been used by HCA Hospitals, University of Missouri Health System, St. Luke's Health System, and More. She has worked in a consulting capacity for AmCom Software, and Biamp Systems. Kourtney has an MBA from University of Missouri Kansas City. She now serves as a Resident at that campus. She works in the Innovation Center with students developing new healthcare technologies. In addition she has various certifications from the systems industry. Kourtney is part Owner of All Systems Designed Solutions, Inc. and CEO Sphere3.

OPTIONAL POST-CONFERENCE WORKSHOP TWO DISTRIBUTED ANTENNA SYSTEMS IN HOSPITALS: BEST PRACTICES

Workshop Hours: 2:00-6:00 pm

Just like the explosion of wireless LANs in hospitals, a similar trend has occurred with mobile phones, broadband adapters for laptops, and Blackberries. A new era has arrived whereby physicians, patients, and their families will demand to use these devices. Since the events of September 11th, the need for in-building public safety communication coverage has become a critical requirement as many jurisdictions adopt coverage requirements, including those referenced in the National Fire Prevention Act (NFPA 2009) code. This workshop will focus on why in-building broadband coverage is required, review potential policies and procedures for the use of mobile devices, and finally an overview of the different designs of distributed antenna systems (DAS). While there has been concern about the use of broadband devices in the presence of medical devices, it has been shown that there is little or no EMI concern. The fact remains that the implementation of a DAS will greatly reduce this potential. A variety of business models will be described for wireless carrier coverage. This includes a single carrier model as well as a multi-carrier model. Additionally, the requirement of mandated public safety coverage will be also covered. In light of this, a variety of ways to finance the DAS infrastructure, from either carrier funding or self-funding, will be discussed. The different underlying technologies used in DAS will be described, including the needed design and propagation modeling requirements. A review will be made of the underlying solutions to include passive designs and fiber fed active based designs. This will additionally include the past and current use model of 802.11a/b/g, 802.11n, voice over IP and WMTS with the technical and financial caveats. While the initial marketing of these combined services may sound attractive, at the end of the day, technical requirements like the link budget will determine practicality. Consideration will also be given to the design requirements of the leading wireless LAN manufactures when combining a wireless LAN onto a DAS. What does the future hold for DAS in healthcare and what are some of the prevailing solutions on the horizon? The session will end with this and your questions and comments.

Workshop Instructor:

David Hoglund, CEO and Founder, Integra Systems

David H. Hogle is the CEO and Founder of Integra Systems, Inc. (www.integrasystems.org), a fourteen year old wireless and medical device design and connectivity consultancy. Mr. Hogle 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. Hogle 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. Hogle is co-author on a patent for device connectivity and has others pending patent. Mr. Hogle 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.

OPTIONAL POST-CONFERENCE WORKSHOP THREE HOW TO USE OPEN SOURCE SOFTWARE AND OTHER LOW-COST DESIGN TECHNIQUES TO BUILD SAFETY-CRITICAL MEDICAL DEVICE PLATFORMS AND MEANINGFUL USE EHR GATEWAYS

Workshop Hours: 2:00-6:00 pm

This is an in depth technical presentation and workshop on how to define, design, and build modern safety-critical medical device platforms and Meaningful Use compliant EHR gateways. The workshop starts with a quick background on comparative effectiveness 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 workshop 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. After covering the data collection area the workshop will dive deep into a modern medical device platform architecture which the speaker calls “The Ultimate Medical Device Connectivity Architecture” – providing an in-depth overview and 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. Finally, the workshop will cover details 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.

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. For the past 15 years Shahid has held the positions of CTO, VP of Technology, Chief Software Architect, or Enterprise Architect at large enterprises. His technology expertise includes service-oriented and event-driven architectures, Java/JEE, .NET, and agile development; his healthcare focus starts with an emphasis on Meaningful Use policy, MU certifications, e-health, EMRs, data integration, and legacy modernization. Shahid is 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 has 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.

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Medical Connectivity Consulting

www.medicalconnectivity.com

Medical Connectivity Consulting serves medical device and health care IT manufacturers, and health care provider organizations. Founded in 2004, the company provides insight, strategy development, planning and execution targeting workflow automation through the integration of medical devices and information systems, and enabling technologies. Principal Tim Gee delivers most services, supplemented by a network of industry experts. Engagements typically entail top of mind knowledge and experience, analysis and problem solving skills honed over many years, and the provision of additional resources for specific projects or tasks. Services for manufacturers span product development, regulatory strategy, sales, marketing and operations. Provider services include technology management and planning, process reengineering, and traditional vendor selection. Medical Connectivity Consulting consistently delivers high value services, saving clients both time and money.

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Healthcare IT News offers healthcare IT executives timely, pertinent news every month. Jesse H. Neal Award Winning coverage includes new technologies, IT strategies and tactics, statutory and regulatory issues, as well as provider and vendor updates. Published in partnership with HIMSS, Healthcare IT News reaches more than 54,000 subscribers, including IT management, C-suite and general management, and clinical executives at hospitals and IDNs, group practices, ambulatory care facilities, home healthcare organizations, as well as healthcare payers, consultants and vendors. Website: www.healthcareitnews.com.



www.healthcaretechnology.com

Healthcare Technology Management's mission is to provide practical, useable knowledge and insight from the people responsible for advancing the safety and quality of medical devices and technology, while offering strategies to reduce costs on equipment purchases, services, parts and increase overall department efficiency. The Healthcare Technology portfolio includes a monthly print and digital magazine, fully interactive website, daily news, weekly newsletter and interactive blogs where our readers can interface and interact on the full lifecycle of healthcare technology.

SUPPORTING PUBLICATIONS



www.mddionline.com

MD+DI is a monthly magazine with a multimedia portfolio written exclusively for original equipment manufacturers of medical devices and IVD products. MD+DI's editorial quality has won it an unparalleled degree of trust from the industry. MD+DI offers the most comprehensive information on technologies, trends, and product development to help industry professionals develop, design, and manufacture medical products.



www.mobihealthnews.com

MobiHealthNews chronicles the healthcare sector's adoption of mobile technology, a convergence of two industries that is shaping the future of how healthcare is delivered to the patient on-the-go, at home and at their place of care. The publication tracks innovations and helps define sustainable business models for this emerging wireless health industry, online at mobihealthnews.com and in the MobiHealthNews free, weekly eNewsletter.

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www.psqh.com

Patient Safety & Quality Healthcare (PSQH) is a respected source of research, news, and practical tools for improving the safety and quality of healthcare. Readers of PSQH include clinical practitioners and directors, hospital executives, patient safety officers, risk managers, quality directors, IT professionals, engineers, business leaders, policy makers, and educators, among others. This diverse community of professionals also supplies the feature articles, research, case studies, and opinions published in PSQH. PSQH offers a print and digital bi-monthly magazine, and a monthly eNewsletter. For more information, visit www.psqh.com.

SUPPORTING ORGANIZATIONS



www.accenet.org

The American College of Clinical Engineering (ACCE) was founded in 1991 with the commitment to enhance the profession of clinical engineering. With members in the United States and abroad, the ACCE is recognized internationally as a leading professional society for clinical engineers with a mission to:

- Establish a standard of competence and to promote excellence in clinical engineering practice.
- Promote safe and effective application of science and technology in patient care.
- Define the body of knowledge on which the profession is based.
- Represent the professional interests of clinical engineers.

Visit www.accenet.org for more information



www.aami.org

The Association for the Advancement of Medical Instrumentation (AAMI), a nonprofit organization founded in 1967, is a unique alliance of more than 6,000 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, IT World Reference CD, and standards, particularly 80001 (Managing Medical IT) are likely of interest. Consider other AAMI products, membership, and involvement in the IT standards committee.

SUPPORTING ORGANIZATIONS



www.ecri.org

ECRI Institute, an independent nonprofit with more than 40 years of healthcare experience, offers a full spectrum of healthcare and information technology management services for healthcare organizations worldwide. Our unique experience allows us to offer unparalleled vision on complex technology issues with decision support guidance, equipment planning services, hazard and recall management, and health technology evaluations. We provide information and technical assistance to the healthcare community to support safe and cost effective patient care and assist them in planning how new technologies will impact services and operations. The results of ECRI Institute's research and experience are available through its customized consulting and membership programs, publications, information systems, technical assistance, laboratory services, and seminars. ECRI Institute is designated an Evidence-based Practice Center by the U.S. Agency for Health Research and Quality.



www.thehtf.org

The Healthcare Technology Foundation is a non-profit IRS 501(c)(3) charitable organization. Its mission is to improve healthcare delivery outcomes by promoting the development, application and support of safe and effective healthcare technologies. Major initiatives of the Foundation include clinical alarm safety, tools for managing integrated technology risk, the development of patient oriented technology safety brochures, the promotion of clinical engineering excellence through training and recognition programs, and the support of clinical engineering certification through the Healthcare Technology Certification Commission. Website: www.thehtf.org
Contact: Tobey Clark Email: tobey.clark@uvm.edu



www.incose.org

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www.rfidinhealthcare.org

The RFID in Healthcare Consortium advocates the safe and effective use of wireless based technologies in healthcare, assisted living, and nursing homing facilities. Our members are concerned with issues and solutions that pertain to the successful use of RFID, RTLS, and wireless technologies for patient care and safety. Consortium efforts include: delivering educational programs, support for standards, development of enchmark specifications, best practices, and sponsorship of educational events for all interested parties in the healthcare sector. Please join us. www.rfidinhealthcare.org.



www.wi-fi.org

The Wi-Fi Alliance is a global non-profit industry association of hundreds of leading companies devoted to the proliferation of Wi-Fi technology across devices and market segments. With technology development, market building, and regulatory programs, the Wi-Fi Alliance has enabled widespread adoption of Wi-Fi worldwide. The Wi-Fi CERTIFIED™ program was launched in March 2000. It provides a widely-recognized designation of interoperability and quality and it helps to ensure that Wi-Fi enabled products deliver the best user experience. The Wi-Fi Alliance has completed more than 10,000 product certifications to date, encouraging the expanded use of Wi-Fi products and services in new and established markets. Wi-Fi®, Wi-Fi Alliance®, WMM®, Wi-Fi Protected Access® (WPA), the Wi-Fi CERTIFIED logo, the Wi-Fi logo, the Wi-Fi ZONE logo and the Wi-Fi Protected Setup logo are registered trademarks of the Wi-Fi Alliance. Wi-Fi CERTIFIED™, Wi-Fi Direct™, Wi-Fi Protected Setup™, Wi-Fi Multimedia™, WPA2™ and the Wi-Fi Alliance logo are trademarks of the Wi-Fi Alliance.

You may register by: Mail: TCBI, 944 Indian Peak Rd., Suite 120, Rolling Hills Estates, CA 90274
Phone: (310) 265-0621 Fax: (310) 265-2963 Email: info@tcbi.org Online at www.tcbi.org

Phone Registration Hours: 9 am to 4 pm Pacific Time

For information on registration fees, please see the next page (back cover of brochure)

SUPPORTING ORGANIZATION DISCOUNT

TCBI is offering a \$100 discount on the applicable registration fee for members of the American College of Clinical Engineering, (ACCE), Association for the Advancement of Medical Instrumentation (AAMI), ECRI Institute, International Council on Systems Engineering (INCOSE), RFID in Healthcare Consortium and the Wi-Fi Alliance. TCBI is also offering a \$100 discount to board members of the Healthcare Technology Foundation. Please note that supporting organization discounts cannot be combined with each other; however, the supporting organization discount may be combined with the earlybird discount.

EARLYBIRD DISCOUNT

You must register and pay by August 26, 2011 to receive the \$100 earlybird discount on registration fees.

GROUP DISCOUNT

Organizations sending three or more registrants to the conference may qualify for an additional group discount. Please note, however, that category two registrants already receiving \$200 in other discounts do not qualify for the additional group discount unless there are four or more registrants from the same organization. Whether a registrant receives a group discount will depend on other discounts already received, the number of individuals from the registrant's organization that are attending the conference, and the category of registration. Please contact TCBI for details. Ph: 310-265-0621 Email: info@tcbi.org.

PAYMENTS

Payments must be made in U.S. dollars by Visa, Mastercard, Discover, American Express, company check (drawn on a US bank), or by wire transfer. Please make checks payable to The Center for Business Innovation and send to: TCBI, 944 Indian Peak Rd., Suite 120, Rolling Hills Estates, CA 90274. In the memo area of the check, please write the name of the registrant and the conference code **C125**. For information about wire transfers, please contact TCBI: Tel: (310) 265-0621, Email: info@tcbi.org.

CONFERENCE LOCATION

Joseph B. Martin Conference Center at Harvard Medical School, 77 Avenue Louis Pasteur, Boston, MA 02115

Tel: (617) 432-8990. For additional information, including directions and parking, please visit: www.theconfcenter.hms.harvard.edu

HOTEL INFORMATION

BEST WESTERN PLUS - Boston The Inn at Longwood Medical, 342 Longwood Avenue, Boston, MA 02115. To make hotel reservations, please call 1 (800) GOT-BEST or (617) 731-4700 and mention "TCBI" to receive our preferred group rate of \$179 plus tax for single/double. The \$179 rate applies only for the nights of September 7th and 8th. However, the hotel may offer the \$179 rate on other nights based on availability. Cancellations must be made by 4:00 pm Eastern time on the day of arrival to avoid penalty. If a cancellation is made after 4:00 pm on the day of arrival, the hotel will charge a no-show fee for one night room and tax. Please note that this is the hotel closest to the Joseph B. Martin Conference Center at Harvard Medical School, where the conference is being held. The hotel is a five minute walk from the Conference Center. Rooms are limited so if you need hotel accommodations we encourage you to make your reservation as soon as possible. Please note that the cutoff date for receiving our discounted hotel rate is August 19, 2011.

CANCELLATION POLICY

For cancellations received in writing:

| | |
|---|---|
| Four weeks or more prior to the event | Full Refund or Credit Voucher |
| Between two weeks and four weeks prior to the event | \$200 Cancellation Fee or Full Credit Voucher |
| Two weeks or less prior to the event | No Refund; Full Credit Voucher Will Be Issued |

Credit vouchers may be applied toward any future TCBI event within one calendar year.

If TCBI decides to cancel any portion of this event, the organizers are not responsible for covering airfare, hotel or any other costs. Speakers, networking events and the agenda are subject to change without notice. This cancellation policy applies only to delegate registrations, not sponsorships.

SUBSTITUTIONS

Registrant substitutions may be made up to the day of the event.

FREE PRESS PASSES AVAILABLE

To find out if you qualify for a free press pass, which is usually offered to full-time journalists, please email info@tcbi.org or call (310) 265-0621.

Conference Registration Form

Name: _____

Job Title: _____

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City: _____ State: _____ Zip: _____

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I accept the Cancellation Policy on the previous page.
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To be added to our mailing list, please email info@tcbi.org

Third Annual Medical Device Connectivity Conference & Exhibition, Sept. 8-9, 2011, Boston, MA

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| <input type="checkbox"/> I am a member of ACCE, AAMI, ECRI Institute, INCOSE, RFID in Healthcare Consortium and/or the Wi-Fi Alliance and qualify for a \$100 supporting organization discount on the applicable registration fee above. <i>Please underline the organization through which you are receiving the discount.</i> | |
| <input type="checkbox"/> I am a board member of the Healthcare Technology Foundation and qualify for a \$100 supporting organization discount on the applicable registration fee above. | |

Supporting organization discounts cannot be combined with each other; however, the supporting organization discount can be combined with the earlybird discount.

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Phone Registration Hours: 9 am to 4 pm Pacific Time

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Register online at www.tcbi.org

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