DRAFT

Workshop on Medical Device Interoperability: Achieving Safety and Effectiveness

Co-Sponsored
by FDA/CDRH, Continua Health Alliance, and CIMIT

FDA White Oak Campus
10903 New Hampshire Ave.
Silver Spring, MD 20993

January 25-27, 2010

INTRODUCTION

Over the past two decades, advances in computing technology have brought many benefits to the US marketplace; similar trends are seen globally. The advances in computing technology have influenced communication (cell phones, email, social media networks), information availability (web 2.0), and consumer expectations. The technology trends include an increase in computational horsepower coupled with a decrease in component size, cost of memory, and power consumption. These advances and expectations are experienced by medical device users and patients. More recently, computational and network technology and the Internet have extended their reach to virtually every medical device that can benefit from the ability to share information. These technology trends are enabling expanded feature sets, allowing diagnostic and therapeutic equipment to be tailored to a range of specialized clinical situations, home care, and portable applications. Devices ranging from personal health devices to high acuity clinical care systems can benefit from integration.

On the other hand, there is a hidden cost to many of these benefits: the challenge of managing ever-increasing complexity in the design and use of medical devices. A significant effort on the part of FDA scientists and engineers is to understand and explore the safety implications of this emerging complexity to assure public health. We recognize that improved product designs are the key to reducing adverse events (for example, via automated interlocks) and enabling new clinical treatments that are greater than the sum of their components. This workshop is a joint effort between FDA/CDRH, and external technology and clinical partners, the Continua Health Alliance, and the Center for Integration of Medicine and Innovative Technology (CIMIT) to explore representative use cases describing interoperable “systems of systems.” The intent of the exploration is to identify potentially hazardous scenarios that arise from these systems and discuss potential solutions for assuring their safety and effectiveness.

Attendees are invited to fully participate in this workshop. We have organized this agenda to facilitate constructive interactions among all attendees with the express purpose of eliciting useful and novel ideas and proposals. Our goal is to help identify potential methods to assure safe, effective, and least burdensome solutions for interoperable medical devices that benefit manufacturers, payors, providers, and most importantly consumers and patients.

The flow of the conference is intended to highlight the various dimensions of the challenges of interoperability. The opening sessions describe both the need for interoperability and the complexity of the problem. The presentations are meant to highlight the various contexts, environments, and applications for interoperable medical devices. Workgroups have been planned so that particular issues can be explored deeply.

We look forward to a productive and simulating workshop.

Workshop Organizing Committee Co-Chairs:

Julian M. Goldman, MD	Massachusetts General Hospital/Harvard Medical School
John Murray	FDA
Michael Robkin	Anakena Solutions
Scott Thiel, MBA, RAC	Roche Diagnostics
Sandy Weininger, PhD	FDA

Day 1: Monday, January 25, 2010, Morning Session

8:00 – 9:00 **CONTINENTAL BREAKFAST**

9:00 – 9:20 **OPENING, LOGISTICS, WELCOME**
Donna-Bea Tillman, PhD
Director, Office of Device Evaluation, FDA/CDRH

9:20 – 10:00 **Relationship of Medical Device Interoperability to the National HIT Infrastructure**

Charles P. Friedman, PhD.
Deputy National Coordinator for Health Information Technology in the Office of the Secretary for Health and Human Services

10:00 – 10:30 **Safety and Effectiveness Challenges in Interoperability**
The challenges of managing the complexity of interoperable systems. The national perspective on interoperability in health care delivery; the national landscape.

Jeff Shuren, MD, JD
Acting Director, FDA/CDRH

10:30 – 10:50 **Setting the Stage: Device, Local, Regional, and National Perspectives on Medical Device Interoperability**
Medical device interoperability can range from the device-to-device interactions around a patient through the exchange of information across disparate public and private sector enterprises.

Doug Rosendale, D.O. F.A.C.O.S
Veterans Health Administration, Office of Health Information, Joint Interoperability Ventures;
Doctor of Osteopathic Medicine and Fellow of the American College of Osteopathic Surgeons

10:50 – 11:20 **BREAK**

11:20 – 11:40 **Clinical Challenges of Interoperable Medical Device Systems**
The clinical proposition of interoperability in high acuity settings. The inherent risks related to using interoperable and non-interoperable devices. Complications of varying acuity levels of risk and performance.

Julian M. Goldman, MD
Director, MD PnP Program and CIMT Program on Interoperability
Medical Director, Partners HealthCare Biomedical Engineering
Attending Anesthesiologist, Massachusetts General Hospital/Harvard Medical School

11:40 – 12:00 **Consumer and Patient Perspective on Innovation and Interoperability in Healthcare**

Dave deBronkart
"e-Patient Dave", e-patients.net; Co-Chair, Society for Participatory Medicine

12:00 – 1:00 **LUNCH**

Day 1: Monday, January 25, 2010, Afternoon Session

1:00 – 1:10 Introduction to Presentations

Presentations highlighting a particular use scenario that shows medical devices acting in an interoperable manner to achieve an intended use will be used to explore safety and effectiveness issues and possible solutions. Presentations related by content have been organized into thematic sessions as indicated below.
Each presentation will consist of a short (5 minute) description of a particular use case or scenario involving interoperable medical devices, a description of the inherent regulatory or safety issues, stakeholders and how they are affected, and proposed solutions. Each group of presentations will be followed by 20 minutes of moderated panel and audience Q&A.

1:10 – 1:50 Session 1: Lessons Learned from Existing Regulatory Practices

Moderator	Brad Thompson	Partner	Epstein Becker Green
NHS	Dr Maureen Baker CBE	Clinical Director of Patient Safety	NHS Connecting for Health, England
Diabetes and Home Management	Linda Ricci	Acting Chief,	FDA/CDRH/ODE Cardiac Electrophysiology and Monitoring Branch
FDA	Mary Brady	Associate Office Director	FDA/CDRH/OSB Home Care Initiatives

1:50 – 2:30 Session 2: Enterprise Issues

Moderator	Michael Robkin	President	Anakena Solutions, Inc
Digital Operating Room	Tom Judd, MS, PE, CCE CPHQ, FACCE	National Project Director, Clinical Technology	Kaiser Permanente
Converged Medical Device and Enterprise Network	Tim Gee	Principal	Medical Connectivity Consulting

2:30 – 2:50 BREAK

2:50 – 3:30 Session 3: Systems-of-Systems Issues

Moderator	Julian Goldman, M.D.	Physician	MGH
Wrangling the human element of interoperability: Defending against Reason's latent flaws and Dekker's drift	GM Samaras, PhD, DSc, PE, CPE, CQE	CEO	Samaras & Associates, Inc
TBD	Frank E. Block, Jr., M.D.	Professor of Anesthesiology	VCU
Using Standard Communications Protocols to Implement Medical Device Plug-and-Play	Dick Moberg	President	Moberg Research, Inc.

3:30 – 4:10 Session 4: Mass Interoperability

Moderator	Brad Thompson	Partner	Epstein Becker Green
Mobile Health	Praduman Jain	CEO	Vignet Inc.
"Tooling" Communities to advance Community Resilience	Dr. Brigitte Pinewski	CMO	PeaceHealth Labs
The Do's and Don'ts of creating an ULP Wireless Network	Mike Paradis	Wireless Sales Manager	Dynastream Innovations Inc.

4:10 – 4:50 Session 5: System Level Risk Analysis

Moderator	Brian Fitzgerald		
Multi-parameter data integration to support clinical decision making	John Zaleski	Department Head, Biomedical Informatics	Philips Research
FiO2 Control in Preterm Infants – A Case for Device Interoperability	Dale Wiggins	Vice President and CTO Healthcare Informatics and Patient Monitoring	Philips Healthcare
The Building Blocks of Clinical Systems	Tracy Rauch	Founder and CTO	DocBox Inc
Managing Risk in Systems of Systems	Peter Kelley	Director of QA/RA	Capsule Technology Inc

4:50 – 5:00 Day 1 Closing Session

Day 2: Tuesday, January 26, 2010, Morning Session

8:00 – 9:00 **CONTINENTAL BREAKFAST**

9:00 – 9:20 **A Short History of Interoperability**
Current technical solutions and perspectives for interoperability. Advantages and pitfalls of design patterns such as Systems of Systems (ICE), Peer-to-Peer (point-to-point standards), Various Industry perspective and approaches to interoperability.

Michael Robkin
Independent Consultant
President, Anakena Solutions

9:20 – 9:40 **Pieces of the Puzzle: Actors in Interoperability**
Many organizations have a role to play in assuring the safety and effectiveness of interoperable medical devices. Many stakeholders and industry segments have to come together to achieve interoperability. Who is involved and what pieces have to come together to create workable solutions to the problem. Consequences for standards bodies, test houses, end users, regulated manufacturers, hospitals, clinicians, consumers, commercial manufacturers.

Sandy Weininger, PhD
Senior Biomedical Engineer
FDA/CDRH/Office of Science and Engineering

9:40 – 10:00 **Making it Happen: Manufacturer Perspectives on Medical Device Interoperability**
What are the issues that a manufacturer must address throughout a product's lifecycle as a result of interoperable medical devices. What solutions are practical for both regulated and non-regulated manufacturers.

Scott Thiel, MBA , MT (ASCP), RAC
Roche Diagnostics
Global Regulatory Affairs Diabetes Care
Regulatory Affairs Program Manager

10:00 – 10:20 **BREAK**

10:20 – 11:00 Sessions 6: Software Issues

Moderator	Rick Schrenker	Systems Manager, Biomedical Engineering	Massachusetts General Hospital
Safety and Effectiveness Issues in Electronic Medical Records	John Denning	Consultant	Independent
Medical Device Data Patient Context Challenges	Luis Melendez	Assistant Director, Partners HealthCare Biomedical Engineering, Medical Device Integration and Informatics	Massachusetts General Hospital

11:00 – 11:40 Session 7: Integration and Interoperability Issues in a Regulated Environment

Moderator	Scott Thiel	Chair Regulatory Working Group Regulatory Affairs Program Manager	Continua Roche
Interoperability through integration	Renate A. MacLaren, Ph.D.	Director, Regulatory Affairs	Integrated Medical Systems, Inc.
VitalLink; A universal interface between medical devices and IT /cCommunications systems	Alasdair MacDonald	CEO	TeleMedic Systems Ltd
Toward a plug-and-play system for medical devices: lessons from case studies.	Dave Arney	Student	University of Pennsylvania

11:40 – 12:20 Session 8: Standards, Interfaces and Interoperability Issues

Moderator	Dave Osborne	Manager, International Standards Standards & Regulations Department	Philips Medical Systems
Impact of ARRA/HITECH on Device Connectivity: Safe? Effective? Say what?!	Todd Cooper	President	Breakthrough Solutions Foundry, Inc.
Connectivity? Integration? Plug and Play? What is the Interoperability end game?	Ken Fuchs	Principal Engineer	Draeger Medical Systems, Inc.
Helping the Cause of Medical Device Interoperability Through Standards-based Test Tools	John J. Garguilo	Computer Scientist	DoC/NIST
Semantic Interoperability for Medical Device Data Interchange	Paul Schluter, Ph.D.	Principal Engineer	GE Healthcare - Monitoring Solutions

12:20 – 1:00 **LUNCH**

Day 2: Tuesday, January 26, 2010, Afternoon Session

1:00 – 1:10 **Introduction to Breakout Working Sessions #1**
These breakout sessions provide time to discuss the issues raised in the scenario presentations in more detail. They are organized first by stakeholder responsibility and then by technical expertise. Final group structure will be determined based on registration.

1:20 – 3:00 **Breakout Working Sessions #1 (in parallel by interest group: e.g. Consumer, FDA, Manufacturer, Clinical, Hospital)**
- Discovered issues (criticality, priority)
- Proposed solutions (gaps, implementation issues, dependencies with other factors, guidance document content)

3:00 – 3:40 **Report out by working session (10 min each)**

3:40 – 4:00 **BREAK**

4:00 – 4:10 **Introduction to Breakout Working Sessions #2**
Description and rationale for separation by problem domain.

3:20 – 5:00 **Breakout Working Sessions #2 (in parallel by issue domain: e.g. standards, safety, privacy, quality, cost)**
- Discovered issues (criticality, priority)
- Proposed solutions (gaps, implementation issues, dependencies with other factors, guidance document content)

5:00 – 5:40 **Report back by working session (10 min each)**

Day 3: Wednesday, January 27, 2010, Morning Session

8:00 – 9:00 **Continental Breakfast**

9:00 – 11:30 **FDA Report Back**
Future Work and Findings

- Future Landscape & Future System-of-systems description
- What elements are needed to assure safety & effectiveness
- Possible Guidance Document content
- Proposed work for existing Standards bodies.
- Possible areas for further Research (IT, Clinical, Effectiveness, QA)

Proposed work for CIMIT and Continua
Draft summary message from the Workshop committee

Audience Q&A

11:30 – 11:45 **CIMIT and Continua**
Overall Findings and Next Steps for CIMIT and Continua

11:45 – 12:00 **Closing**

12:00 **ADJOURNMENT**

NOTE: This is a draft agenda. Session times and dates may be changed. Please check the website for updated information