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

**Conference Material:**

Workshop content including agenda, slides, and transcripts are available at: [http://mdpnp.org/FDA_Interop_Workshop.php](http://mdpnp.org/FDA_Interop_Workshop.php)

Web links to video segments are listed with each presentation in this version of the agenda.
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 stimulating workshop.

Workshop Steering and Organizing Committee Co-Chairs:
Julian M. Goldman, MD Mass. General Hospital / Partners HealthCare / CIMIT
John Murray FDA
Michael Robkin Anakena Solutions
Scott Thiel, MBA, RAC Roche Diagnostics
Sandy Weininger, PhD FDA

Please note: To access the video of specific workshop talks, click on the link provided in the agenda for each talk. When the video window opens, go to the “Playing” bar at the bottom of the screen and move the vertical bar to the right to align it with the timestamp for that talk.
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
https://collaboration.fda.gov/p57306401/ [0:1:40]

9:20 – 10:00 Device interoperability and the National Health IT Agenda
Charles P. Friedman, PhD.
Chief Scientific Officer,
Office of the National Coordinator for Health IT
https://collaboration.fda.gov/p57306401/ [0:11:20]

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.
Jeff Shuren, MD, JD
Director, FDA/CDRH
https://collaboration.fda.gov/p57306401/ [1:04:49]

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
https://collaboration.fda.gov/p57306401/ [1:17:28]

10:50 – 11:20 BREAK

11:20 – 11:40 Clinical Perspective on Interoperable Medical Device Systems
Medical device interoperability could enable the integration of devices and IT systems in clinical environments. This integration holds great promise for improving the safety and efficiency of health care delivery.
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
https://collaboration.fda.gov/p57306401/ [2:25:00]

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March 7, 2010
11:40 – 12:00  **Consumer and Patient Perspective on Innovation and Interoperability in Healthcare**
What happens when a technology guy becomes a patient? Or why can't healthcare innovate as fast as the rest of the economy?

Dave deBronkart
"e-Patient Dave", e-patients.net; Co-Chair, Society for Participatory Medicine
https://collaboration.fda.gov/p57306401/  [3:02:57]

12:00 – 1:00  **LUNCH**

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**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**
https://collaboration.fda.gov/p89529623/  [0:13:48]

<table>
<thead>
<tr>
<th>Moderator</th>
<th>Partner</th>
<th>Organization/Role</th>
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<tbody>
<tr>
<td><strong>NHS</strong></td>
<td>Maureen Baker CBE</td>
<td>Clinical Director of Patient Safety NHS Connecting for Health, England</td>
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<tr>
<td><strong>Diabetes and Home Management</strong></td>
<td>Yi Zhang</td>
<td>Visiting Scientist CDRH/OSEL/DESE</td>
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<tr>
<td><strong>FDA</strong></td>
<td>Mary Brady</td>
<td>Associate Office Director FDA/CDRH/OSB Home Care Initiatives</td>
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**1:50 – 2:30  Session 2: Enterprise Issues**
https://collaboration.fda.gov/p89529623/  [1:01:45]

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<tr>
<th>Moderator</th>
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<tbody>
<tr>
<td><strong>Digital Operating Room</strong></td>
<td>Tom Judd</td>
<td>National Project Director, Clinical Technology Kaiser Foundation Hospitals</td>
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<td>Tom McGrane</td>
<td>Principal Solution Consultant Kaiser Foundation Hospitals</td>
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<td></td>
<td>Doug Grey, MD</td>
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# Final Workshop Agenda with Links to Online Video

**Chair, KP Biomedical Device Integration Council Vice-Chair, KP National Product Council**

### Converged Medical Device and Enterprise Network

<table>
<thead>
<tr>
<th>Time</th>
<th>Session Title</th>
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<tr>
<td>2:30 – 2:50</td>
<td>BREAK</td>
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<tr>
<td>Moderator</td>
<td>Julian M. Goldman, MD, Physician, MGH/PHS/CIMIT</td>
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<tr>
<td><strong>Systems of Systems Issues</strong></td>
<td>Frank E. Block, Jr., MD, Professor of Anesthesiology, Virginia Commonwealth University</td>
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<td><strong>Using Standard Communications Protocols to Implement Medical Device Plug-and-Play</strong></td>
<td>Dick Moberg, President, Moberg Research, Inc.</td>
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<td><strong>Wrangling the human element of interoperability: Defending against Reason’s latent flaws and Dekker’s drift</strong></td>
<td>GM Samaras, PhD, DSc, PE, CPE, CQE, CEO, Samaras &amp; Associates, Inc.</td>
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<tr>
<td>3:30 – 4:10</td>
<td><strong>Session 4: Mass Interoperability</strong></td>
<td><a href="https://collaboration.fda.gov/p89529623/">https://collaboration.fda.gov/p89529623/</a></td>
<td>[2:47:40]</td>
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<tr>
<td>Moderator</td>
<td>Brad Thompson, Partner, Epstein Becker Green</td>
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<td><strong>Mobile Health</strong></td>
<td>Praduman Jain, CEO, Vignet Inc.</td>
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<td><strong>“Tooling” Communities to Advance Community Resilience</strong></td>
<td>Dr. Brigitte Pinewski, CMO, PeaceHealth Labs</td>
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<td><strong>The Do’s and Don’ts of Creating an ULP Wireless Network</strong></td>
<td>Mike Paradis, Wireless Sales Manager, Dynastream Innovations Inc.</td>
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<tr>
<td>4:10 – 4:50</td>
<td><strong>Session 5: System Level Risk Analysis</strong></td>
<td><a href="https://collaboration.fda.gov/p89529623/">https://collaboration.fda.gov/p89529623/</a></td>
<td>[3:25:35]</td>
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<tr>
<td>Moderator</td>
<td>Brian Fitzgerald, Deputy Director, Center for Division of Electronic and Software Engineering; Office of Science and Engineering Labs; CDRH/FDA</td>
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<td><strong>Multi-parameter data integration to support clinical decision making</strong></td>
<td>John Zaleski, PhD, CPHIMS, Department Head, Biomedical Informatics, Philips Research North America</td>
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<td><strong>FiO2 Control in Preterm Infants – A Case for Device</strong></td>
<td>Dale Wiggins, Vice President and CTO Healthcare Informatics, Philips Healthcare</td>
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<th><strong>Interoperability and Patient Monitoring</strong></th>
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<tr>
<td><strong>The Building Blocks of Clinical Systems</strong></td>
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<td>Tracy Rausch</td>
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<tr>
<td><strong>Managing Risk in Systems of Systems</strong></td>
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<td>Peter Kelley</td>
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4:50 – 5:00  Day 1 Closing Session

6:00 – 8:00  Reception at Sheraton Washington North Hotel
Sponsored by the Continua Health Alliance

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  
President, Consultant  
Anakena Solutions  
https://collaboration.fda.gov/p25617965/ [0:03:30]

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  
https://collaboration.fda.gov/p25617965/ [0:28:50]

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  
Medical Device Interoperability Workshop  
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https://collaboration.fda.gov/p25617965/ [0:49:00]

### 10:00 – 10:20
**BREAK**

### 10:20 – 11:00
**Sessions 6: Software Issues**
https://collaboration.fda.gov/p25617965/ [1:37:20]

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<tr>
<th>Moderator</th>
<th>Systems Manager, Biomedical Engineering</th>
<th>Massachusetts General Hospital</th>
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<tbody>
<tr>
<td><strong>Safety and Effectiveness Issues in Electronic Medical Records</strong></td>
<td>John Denning</td>
<td>Consultant</td>
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<tr>
<td><strong>Medical Device Data Patient Context Challenges</strong></td>
<td>Luis Melendez</td>
<td>Assistant Director, Partners HealthCare Biomedical Engineering, Medical Device Integration and Informatics</td>
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### 11:00 – 11:40
**Session 7: Integration and Interoperability Issues in a Regulated Environment**

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<tr>
<th>Moderator</th>
<th>Chair, Regulatory Working Group; Regulatory Affairs Program Manager</th>
<th>Continua Roche</th>
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<tbody>
<tr>
<td><strong>Interoperability through integration</strong></td>
<td>Renate A. MacLaren, PhD</td>
<td>Director, Regulatory Affairs</td>
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<tr>
<td><strong>Universal interface between medical devices and IT / Communications systems</strong></td>
<td>Alasdair MacDonald</td>
<td>CEO</td>
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<tr>
<td><strong>Toward a plug-and-play system for medical devices: lessons from case studies</strong></td>
<td>Dave Arney</td>
<td>Doctoral Candidate</td>
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### 11:40 – 12:40
**Session 8: Standards, Interfaces and Interoperability Issues**

<table>
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<tr>
<th>Moderator</th>
<th>Manager, International Standards, Standards &amp; Regulations Department</th>
<th>Philips Medical Systems</th>
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<tbody>
<tr>
<td><strong>Impact of ARRA/HITECH on Device Connectivity: Safe? Effective? Say what?!</strong></td>
<td>Todd Cooper</td>
<td>President</td>
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<tr>
<td><strong>Connectivity? Integration? Plug and Play? What is the Interoperability end game?</strong></td>
<td>Ken Fuchs</td>
<td>Principal Engineer</td>
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<tr>
<td><strong>Semantic Interoperability for</strong></td>
<td>Paul</td>
<td>Principal Engineer</td>
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</table>
12:40 – 1:30 LUNCH

1:30 – 1:40 **Introduction to Breakout Working Sessions**
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.

1:40 – 3:00 **Breakout Working Sessions #1** (concurrent)
- Discovered issues (criticality, priority)
- Proposed solutions (gaps, implementation issues, dependencies with other factors, guidance document content)

**High Acuity Regulated Manufacturer Breakout Session**
[https://collaboration.fda.gov/p98311968/](https://collaboration.fda.gov/p98311968/) [0:07:20] (first part)
[https://collaboration.fda.gov/p46885825/](https://collaboration.fda.gov/p46885825/) [0:00:00] (second part)

**Low Acuity Breakout Session**
[https://collaboration.fda.gov/p43609764/](https://collaboration.fda.gov/p43609764/) [0:00:00]

**Hospital/Provider Breakout Session**
[https://collaboration.fda.gov/p28243961/](https://collaboration.fda.gov/p28243961/) [0:00:00]

**Research Policy Breakout Session**
[https://collaboration.fda.gov/p14916895/](https://collaboration.fda.gov/p14916895/) [0:00:00]

**Infrastructure Breakout Session**
[https://collaboration.fda.gov/p76954099/](https://collaboration.fda.gov/p76954099/) [0:00:00]

3:00 – 3:40 BREAK

3:40 – 5:00 **Breakout Working Sessions #2** (concurrent)
- Discovered issues (criticality, priority)
- Proposed solutions (gaps, implementation issues, dependencies with other factors, guidance document content)

**High Acuity Regulated Manufacturer Second Breakout Session**
[https://collaboration.fda.gov/p79789115/](https://collaboration.fda.gov/p79789115/) [0:00:00]

**Low Acuity Second Breakout Session**
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https://collaboration.fda.gov/p16937097/ [0:00:00]

Hospital/Provider Second Breakout Session  
https://collaboration.fda.gov/p20943231/ [0:00:00]

Research Policy Second Breakout Session  
https://collaboration.fda.gov/p67463150/ [0:00:00]

Infrastructure Second Breakout Session  
https://collaboration.fda.gov/p44245561/ [0:00:00]

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<tr>
<th>Time</th>
<th>Session</th>
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<tr>
<td>8:00 – 9:00</td>
<td>Continental Breakfast</td>
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<td>9:00 – 9:10</td>
<td>Housekeeping</td>
<td>[0:00:00]</td>
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<tr>
<td>9:10 – 10:15</td>
<td>Breakout Sessions Report Back</td>
<td>[0:06:10]</td>
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</table>
| 10:45 – 11:15| Wrap-Up Panel Session: When is my Smartphone a Medical Device?  
John Murray, FDA  
Brad Thompson, Epstein Becker Green | [1:41:00] |
| 11:15 – 11:30| FDA CDRH UDI Update                               | [2:11:00] |
| 11:30 – 11:45| Organizing Committee Wrap Up                      | [2:31:00] |
| 11:45        | ADJOURNMENT                                       |           |

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http://mdpnp.org/FDA_Interop_Workshop.php

Links to videos for each presentation and session are listed above in the agenda.