# MDIC’s Virtual Patient Engagement Forum Agenda

**Location:** Virtual – Zoom – ET  
**Date:** November 18, 2020

## Morning Sessions

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| 10:00 AM    | 10:05 AM  | Welcome – MDIC Overview                         | Pamela Goldberg, MBA  
President & CEO, MDIC | Orientation/understanding of:  
• MDIC & Science of Patient Input (SPI)  
• Role of the organization in development of Patient Preferences (PCBR Framework)                                                                                                                                           |
| 10:05 AM    | 10:10 AM  | FDA Perspectives                                | Jeff Shuren, MD, JD  
Director of the Center for Devices and Radiological Health (CDRH), FDA | Learn  
• FDA – CDRH perspectives on Patient Engagement                                                                                                                                                                                  |
| 10:10 AM    | 10:15 AM  | Patient Perspective                             | David Walton  
Patient and Patient Advocate,  
Chief Executive Officer, T1D Exchange | Learn  
• First-hand experience in regard to communicating the medical device technology received                                                                                                                                                          |
| 10:15 AM    | 10:20 AM  | Program Overview                                | Scott Goates, PhD  
SPI Communications Working Group Chair  
Senior Advisor, HEOR, Abbott | Learn  
• Objectives of Forum/workshop  
• What is expected from participants (based on pre-read materials)                                                                                                                                                                 |
| 10:20 AM    | 11:10 AM  | Patient Panel #1: Challenges in Communicating  
Uncertainty and benefit/risk | Jijo James, MD (Moderator)  
Chief Medical Officer,  
Johnson & Johnson Medical Devices  
Patients:  
• Anna Legassie - Joint replacement  
• Jay MacIntosh - Spinal cord stimulator  
Patient Advocacy Group Representatives:  
• Julie Eller - Arthritis Foundation  
• Mariann Farrell - American Chronic Pain Association | • Learn about patient challenges in communications from patient experts  
• Hear specific patient stories and examples of communications challenges  
• Learn from patient advocacy groups a summary of specific challenges experienced by the patient community  
• Gather a summary key issues and challenges                                                                                                                                                                              |
| 11:10 AM    | 11:15 AM  | Break                                           |                                                                     |                                                                                                                                                                                                                       |
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Founder & CEO, WSCollaborative LLC | Learn:  
- Key findings of challenges and best practices of patient communication  
- Focused introduction of key topics to be used during interactive activities |
| 11:25 AM   | 11:40 AM | Understanding Medical Device Information: Cognition vs. MetaCognition | **Ruth Day, PhD**
Director, Medical Cognition Lab, Duke University | • Learn about some of the key issues identified in the science of communicating medical information  
• Opportunity to ask questions of leading expert in field of communication and comprehension |
| 11:40 AM   | 11:50 AM | Q&A Session                                     | **Wendy Selig**
Founder & CEO, WSCollaborative LLC           | **Ruth Day, PhD**
Director, Medical Cognition Lab, Duke University |
| 11:50 AM   | 12:05 PM | Break                                           |                                               |                                                                   |

# Interactive Activity #1

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| 12:05 PM   | 1:20 PM  | Interactive Activity #1; Challenges in Communicating Uncertainty and benefit/risk | Medtronic’s Innovation Lab to facilitate a guided brainstorming session among participants | • Engage in a highly interactive brainstorming session facilitated by leaders in qualitative research to help identify the different ways in which communication can be challenging  
• Provide perspectives and learn from first-hand experiences with communicating difficult topics about medical devices  
• Help shape output for this MDIC initiative, as the learnings from this session will be documented in a companion report. |
| 1:20 PM    | 1:35 PM  | Break                                           |                                               |                                                                   |

# Afternoon Sessions

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| 1:35 PM    | 1:55 PM  | Keynote on Shared Decision Making (SDM)         | **J. Matthew Brennan, MD, MPH**
Associate Professor of Medicine, Duke University School of Medicine | • Learn about one approach to effective communication of medical information to patients |
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| 1:55 PM | 2:00 PM | Edwards Lifesciences Case Study | Barry Liden, JD  
Vice President Patient Engagement, Edwards Lifesciences | - Learn how patient preferences can be incorporated into Shared Decision Making  
- Opportunity to ask questions of leading expert in field of Shared Decision Making |
| 2:00 PM | 2:10 PM | Q&A Session                    | J. Matthew Brennan, MD, MPH  
Associate Professor of Medicine, Duke University School of Medicine  
Barry Liden, JD  
Vice President Patient Engagement, Edwards Lifesciences |                                                                                                               |
| 2:10 PM | 2:15 PM | Break                          |                                                                      |                                                                                                               |
| 2:15 PM | 3:05 PM | Patient Panel #2: Best Practices in communicating uncertainty, benefit or risk and relationship to patient preferences | Sue Peschin, MHS (Moderator)  
President & CEO, Alliance for Aging Research  
Patients:  
- Marianne Sherman - Pacemaker  
- Pat Gray - Insulin pump  
Patient Advocacy Group Representatives:  
- Paul Madden, M.Ed. - American Diabetes Association  
- Mellanie True Hills, CSP - StopAfib.org | - Learn about success stories in communications from patient experts  
- Hear specific patient stories and examples of communications successes  
- Learn from patient advocacy groups where communication has gone well in the patient community  
- Gather a summary key successes and best practices |
| 3:05 PM | 3:20 PM | Break                          |                                                                      |                                                                                                               |

## Interactive Activity #2

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| 3:20 PM | 4:40 PM | Interactive Activity #2: Learn by Doing: Best Practices in Communication | Medtronic’s Innovation Lab to facilitate a communication development exercise among participants | - Engage in a Learn-by-Doing interactive session facilitated by leaders in qualitative research  
- Pilot test the principles and techniques identified in the MDIC Report for communicating about benefit, risk, and uncertainty for medical devices  
- Help shape output for this MDIC initiative, as the learnings this session will be documented in a companion report. |
| 4:40 PM | 4:55 PM | Break                          |                                                                      |                                                                                                               |
## PEF 2020 Conclusion Sessions

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| 4:55 PM | 5:15 PM  | Reflections on the Lessons learned and additional observations | **Barry Liden, JD** *(Moderator)*  
Vice President Patient Engagement, Edwards Lifesciences | • Summarize the key findings from the event and to provide additional observations from stakeholders  
Panel Discussion:  
• Challenges and best practices in communicating benefit, risk, and uncertainty  
• How to increase interpretability  
• Facilitate patient-provider conversation  
• PPI and Labeling  
• PPI and shared decision making |
|         | 5:15 PM  |                                                 | **Brett Hauber**  
Senior Economist and Vice President of Health Preference Assessment, RTI |                                                                                               |
|         | 5:30 PM  | FDA Next Steps                                  | **Jodi Duckhorn**  
Acting Deputy Director for the Office of Communication and Education, CDRH, FDA |                                                                                               |
| 5:15 PM | 5:30 PM  |                                                 | **Heidi Dohse**  
Patient Advocate and Professional Heart Patient  
Founder & CEO, Tour de Heart |                                                                                               |
|         |          |                                                 | **Michelle Tarver, MD, PhD**  
Director of Patient Science and Engagement, CDRH, FDA | • Identify key areas of opportunity for FDA to incorporate some of the lessons learned today. |
|         |          |                                                 | **Alicia Witters**  
Director, Division of Communication, CDRH, FDA |                                                                                               |