

MDICx: Science of Patient Input Report: Communicating Benefit/Risk for Medical Devices

Scott Goates, PhD | Abbott

Wendy Selig | WSCollaborative

Heidi Dohse | Tour de Heart

October 2, 2020



MDICx Series
WEBINARS BY MDIC

Agenda

- Introductions
- Presentations
 - Scott Goates
 - Wendy Selig
 - Heidi Dohse
- Q&A through Zoom Q&A box
- Recording and slides will be available on our website:
<https://mdic.org/mdicx-series/webinar-archive/>

Scott Goates, PhD

Senior Advisor, Health Economics and Outcomes Research Medical Devices, Abbott Laboratories

- His current role involves the design and execution of clinical and observational studies with patient reported and economic outcomes.
- Prior to joining Abbott, Dr. Goates worked at the Centers for Disease Control and Prevention where he conducted research and advised senior leadership on a wide variety of high priority public health issues.
- He chairs the Communication working group for the Science of Patient Input within the Medical Device Innovation Consortium.



Wendy Selig

Founder & CEO, WSCollaborative

- Wendy K.D. Selig is Founder and CEO of WSCollaborative, a firm that focuses on defining and implementing strategies for establishing winning cross-sector collaborations in the health care arena.
- Selig has held leadership positions with the Melanoma Research Alliance (MRA), the American Cancer Society (the Society) and the American Cancer Society Cancer Action Network (ACS CAN), the National Coalition of Cancer Research (NCCR), and Rising Tide Foundation for Clinical Cancer Research (RTFCCR).
- She is a consultant with MDIC



Heidi Dohse

Professional Patient Advocate and Heart Patient Founder & CEO, Tour de Heart

- In 1982, Heidi was diagnosed with a rare heart arrhythmia. She underwent a successful AV ablation procedure leaving her heartbeat 100% pacemaker dependent. With the help of her pacemaker, wearable devices, and mobile apps Heidi has the insights she needs to compete in endurance cycling events around the world. In November 2019, she completed her first IRONMAN.
- Heidi is passionate about improving patient outcomes and uses her athletic events as a way to inspire other heart patients and showcase what is possible.
- [Tour de Heart](#) is a non-profit that provides information on using digital health tools / apps to empower individuals to live their best lives.



Best Practices for Communicating Benefit, Risk and Uncertainty for Medical Devices Background

Scott Goates, PhD.

Communications Working Group Chair

October 2, 2020



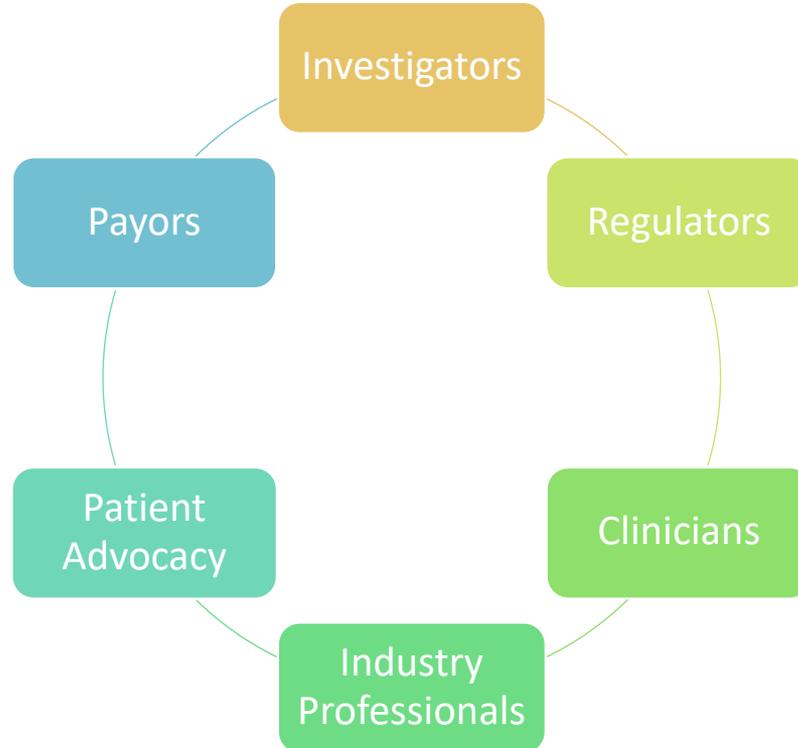
Why was this Study Conducted?

- MDIC Science of Patient Input (SPI) seeks “to advance the art and science of patient engagement in regulatory science”
- Patient engagement is valuable throughout the medical device life-cycle
- Appropriate communication of risk, benefits and uncertainty required to ensure patient values are accurately reflected in decision making
- Little guidance on communicating risks, benefits and uncertainty in medical devices

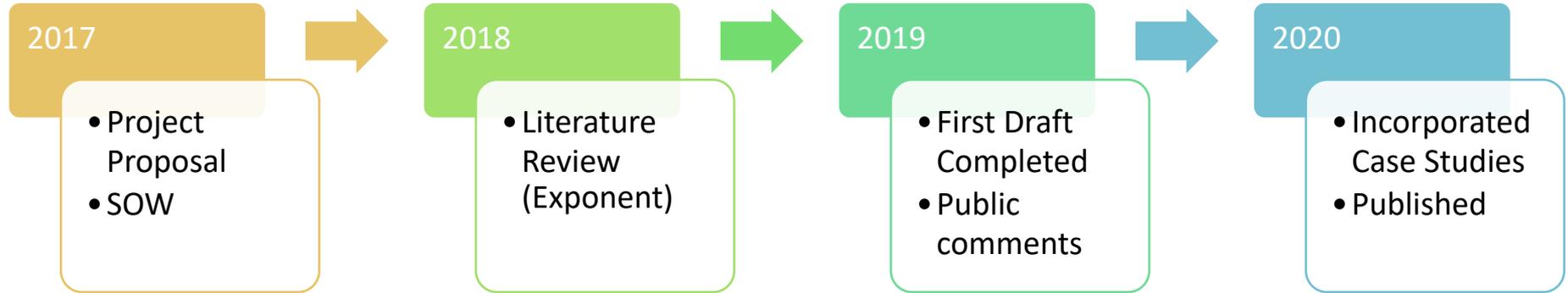
What were the Study Aims?

- Familiarize medical device stakeholders with best practices for communicating benefits, risks and uncertainty to patients and providers
- Designed to be a practical resource
- Include real world case studies
- Identify knowledge gaps that may benefit from further research

Who is this Study For?



Key Milestones



Collaboration and Teamwork

Stephanie Christopher, Providence St. Joseph Health

Brett Hauber, RTI Health Solutions

Heather Howell, NSF International

Ross Jaffe, Versant Ventures

Franchesca Liao, LCGC, Illumina, Inc.

Suzanne Schrandt, Arthritis Foundation

Wendy Selig, WSCollaborative

Liliana Rincon-Gonzalez, MDIC

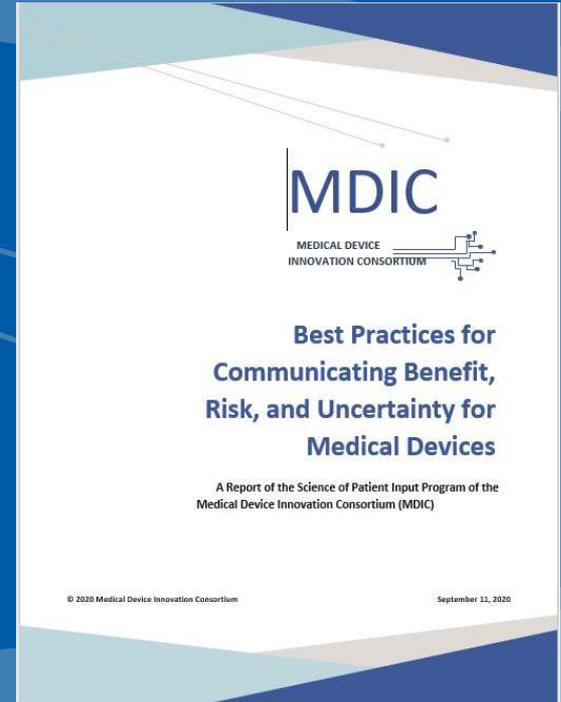
Desiree' Steele, MDIC

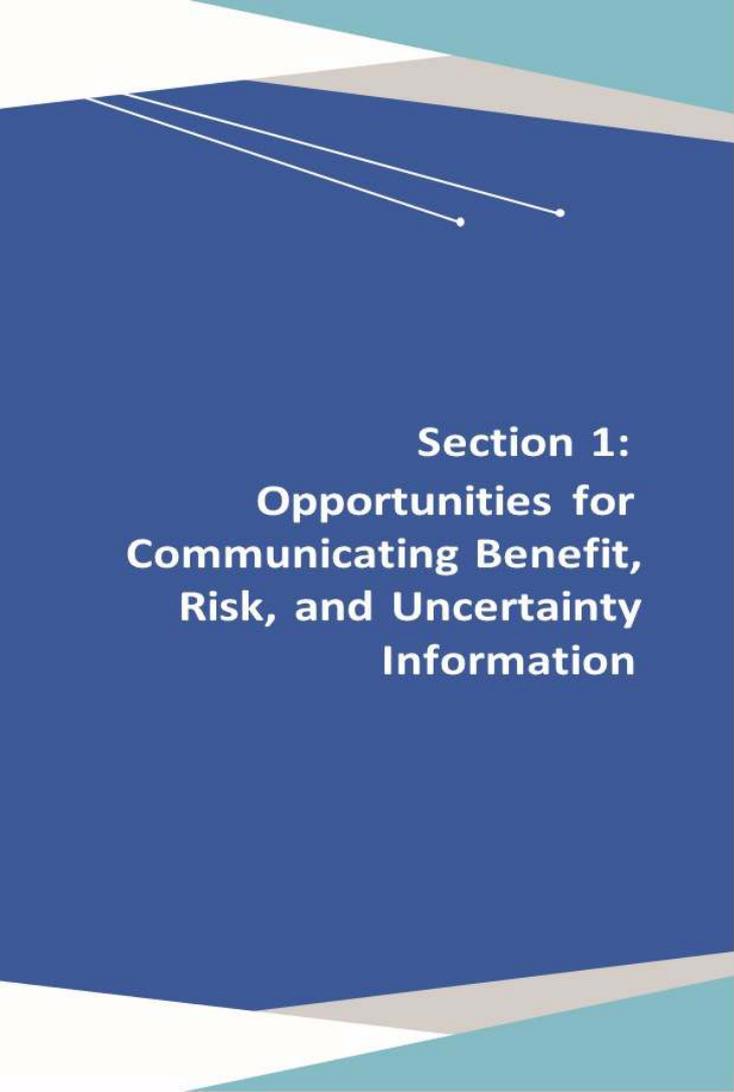
SPI Committee, MDIC



MDIC Science of Patient Input Communications Report: Key Takeaways

Wendy Selig
Founder & CEO
WSCollaborative

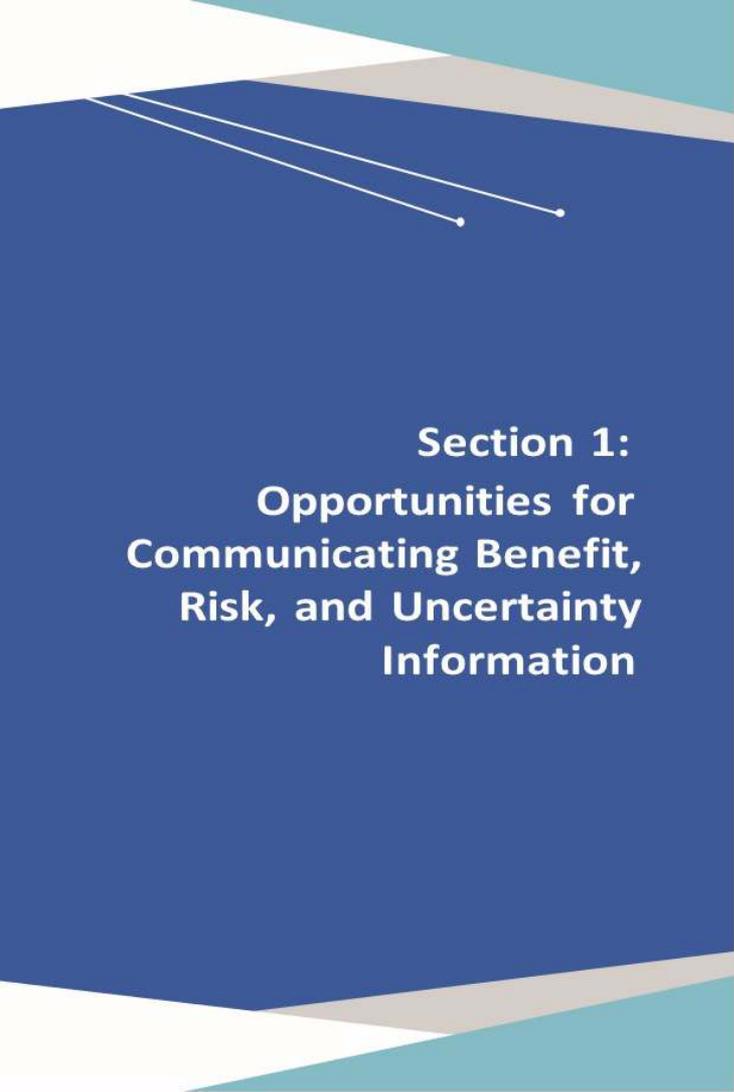




**Section 1:
Opportunities for
Communicating Benefit,
Risk, and Uncertainty
Information**

Clinical Context

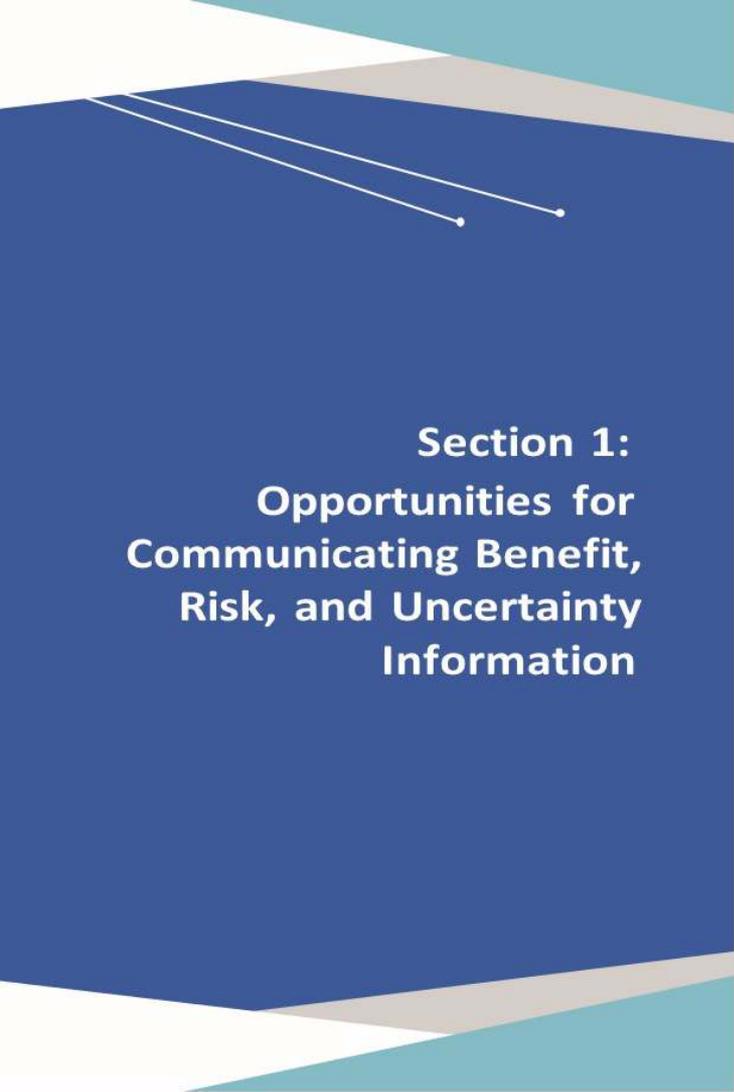
- **Recruitment and consent of clinical trial participants**
- **Inform the content of a product label for a commercially available device**
- **Support discussions among providers and patients at the point of care delivery**
- **Provide notification of recall or changes made to a device.**



**Section 1:
Opportunities for
Communicating Benefit,
Risk, and Uncertainty
Information**

Non-Clinical Context

- **Internet**
- **Social media platforms,**
- **Within patient advocacy constituencies**
- **Peer-to-peer conversations & mentorship among patients and caregiver communities**



**Section 1:
Opportunities for
Communicating Benefit,
Risk, and Uncertainty
Information**

Multiple Settings to Consider

- **Clinical Research & Regulatory Review**
- **Inclusion of Patient Preference Information in Product Labeling**
- **Shared Decision-Making (SDM)**
- **Patient Decision Aids**
- **Direct to Consumer Advertising**
- **Online Search for Health Information**
- **Social Media Channels**
- **Patient Advocacy Organizations**

Section 2: Key Concepts

Definitions of Key Concepts

- **Benefit**
- **Harm**
- **Risk**
- **Patient Preference Information**
- **Risk Tolerance**
- **Uncertainty Attitude**
- **Shared Decision Making**
- **Patient Decision Aid**

Section 3:
Key Factors in
Communicating Benefit-Risk
Information to Patients:
The Clinical Setting

Key Factors: Communication in the Clinical Setting

- **Relevant Provider Characteristics**
- **Relevant Patient Characteristics**
- **Relevant Message Components:**
 - **Content**
 - **Statistical Concepts**
 - **Formatting & Framing**

**Section 4:
Best Practices and
Available Tools
for Device Developers**

Overall Approach

- **Avoid solely verbal descriptions of uncertainty.**
- **Avoid fractions, decimals, and different denominators when presenting risks of multiple treatments.**
- **Describe the benefits and risks in absolute scales instead of relative terms**
- **Use multiple formats simultaneously (e.g., verbal frequency, percent, and icon array/pictograph).**
- **Describe uncertainty in both positive and negative frames to avoid cognitive bias.**
- **Pre-test the communication format.**

Section 4:
Best Practices and
Available Tools
for Device Developers

Patient Decision Aids

Development process includes:

- Participation of stakeholders in its development
- Gathering, selecting, and appraising evidence to inform its content
- Evaluation testing

Components of the PDA should include:

- Explicit description of the decision
- Description of the health problem
- Information on options and their benefits, harms, and consequences
- Values clarification (implicit and explicit)
- Numerical probabilities
- Tailoring of information or probabilities
- Guidance in deliberation
- Guidance in communication
- Personal stories
- Reading level or other strategies to help understanding

Section 4:
Best Practices and
Available Tools
for Device Developers

Leveraging Online Resources

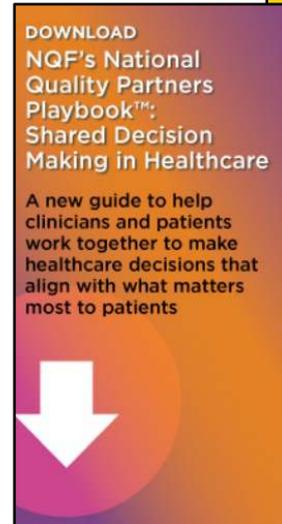
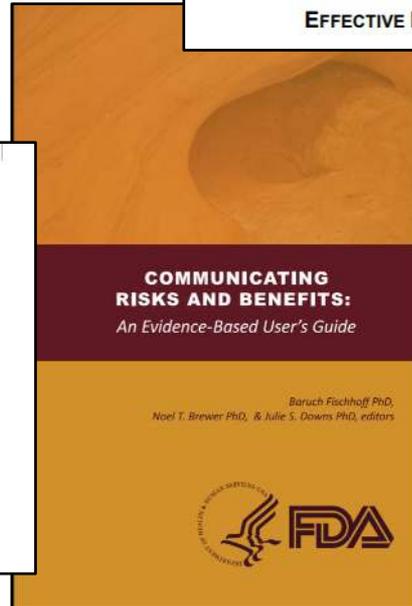
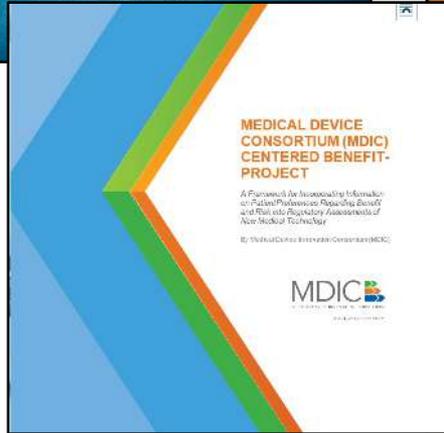
- **Include relevant benefit, risk, and uncertainty information in lay terms on public websites**
- **Provide materials that can be accessible to patients through an internet search**
- **Make frequent updates to ensure accuracy of content**
- **Avoid misleading and reveal material facts**
- **Benefit information should be accompanied by risk information**
- **Include the most serious risks associated with the product**
- **Provide a hyperlink to allow direct access to more complete risk information**
- **The prominence of risk information should be comparable to the benefit information**
- **If adequate benefit and risk information, as well as other required information, cannot all be communicated reconsider using that platform** 20

**Section 4:
Best Practices and
Available Tools
for Device Developers**

Building Partnerships with Patient Advocacy Organizations

- **Integrate an assessment of patient group expertise, assets, and value to your program.**
- **Match patient group expertise and assets to the specific needs of your program.**
- **Ensure that patient groups are essential partners and not token voices.**
- **Establish guiding principles and clear lines of communication to facilitate a fit-for-purpose process for collaborating with patient groups.**
- **Measure the impact of your engagement with patient groups.**
- **Establish ongoing relationships with patient groups and communicate openly with them on a regular basis.**

Resources



Best Practice Checklist for Successful Communication

01

Explicit description of the decision

02

Description of the health problem

03

Information on options and their benefits, harms and consequences

04

Values clarification (implicit and explicit)

05

Numerical probabilities

06

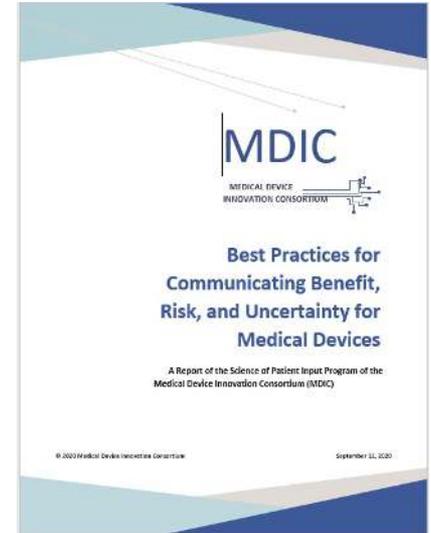
Personal Stories

07

Patient Preference Information

08

Presentation strategies to help understanding



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Best Practices for Communicating Benefit, Risk and Uncertainty for Medical Devices: Patient Perspective

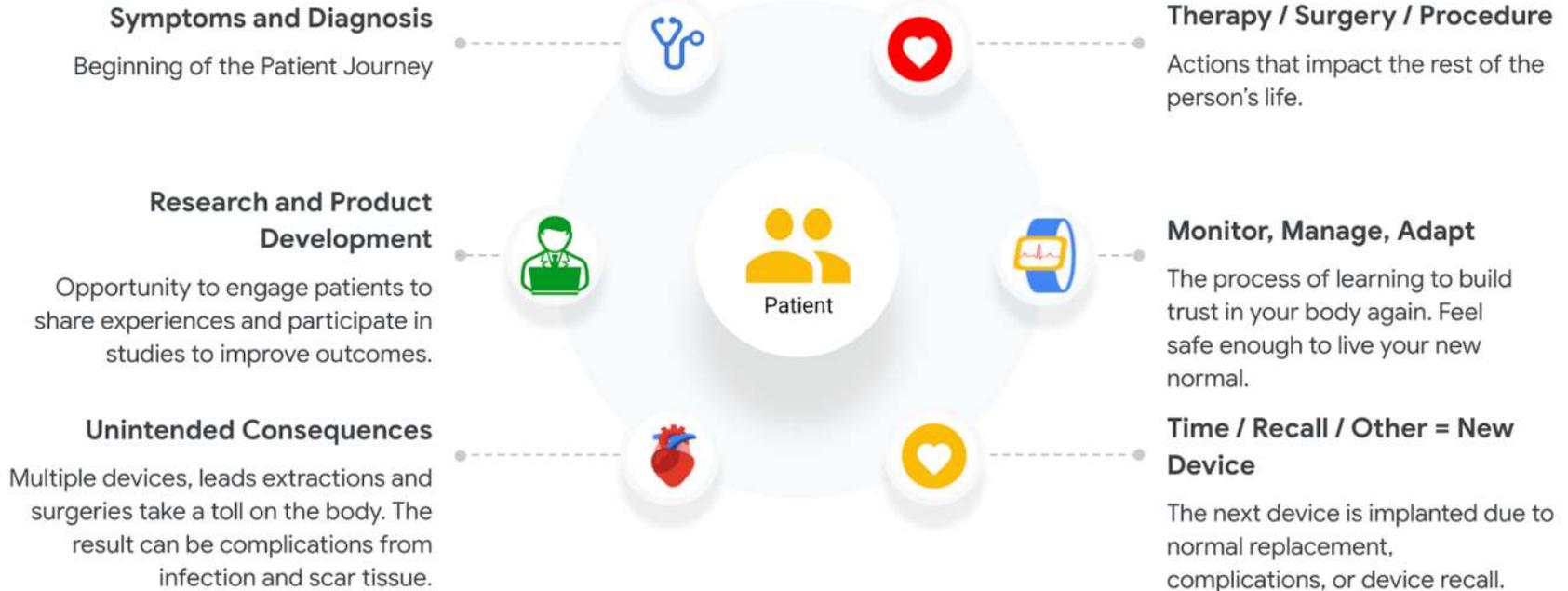
Heidi Dohse

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Patient Lifecycle vs. Product Lifecycle



Audience Q&A

Please submit your questions through the Zoom Q&A box



Liliana Rincon-Gonzalez, PhD
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Scott Goates, PhD
Abbott Laboratories



Wendy Selig
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Heidi Dohse
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Thank You!

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MDIC Website

<http://mdic.org>

SPI Website

<https://mdic.org/program/science-of-patient-input/>

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