Approaches for Utilizing Patient Preference Information to Inform Clinical Trial Design

Medical Device Innovation Consortium (MDIC)

MDIC Mission

MDIC's mission is to leverage its unique position as the only public-private partnership of its kind to transform health care into human care. Collaborating with our partners to advance science, we enable transformational medical technology to shape the world we want to live in and make that world possible by shortening the path from innovation to safety to access.

Today's Panel Presentation

Objective: Learn how Patient Preferences can inform study design

	**Barry Liden, JD** (Facilitator) MDIC Science of Patient Input	Intro/Overview	5 min
	**Shelby Reed, PhD** Duke University	Case Study: Heart Failure Patient Preferences	10 min
	Barry Liden	Overview of MDIC Framework	20 min
	**Michelle Tarver, MD, PhD** FDA-CDRH	The Regulator's Perspective	10 min
	All & Audience	Discussion; Q&A	15 min

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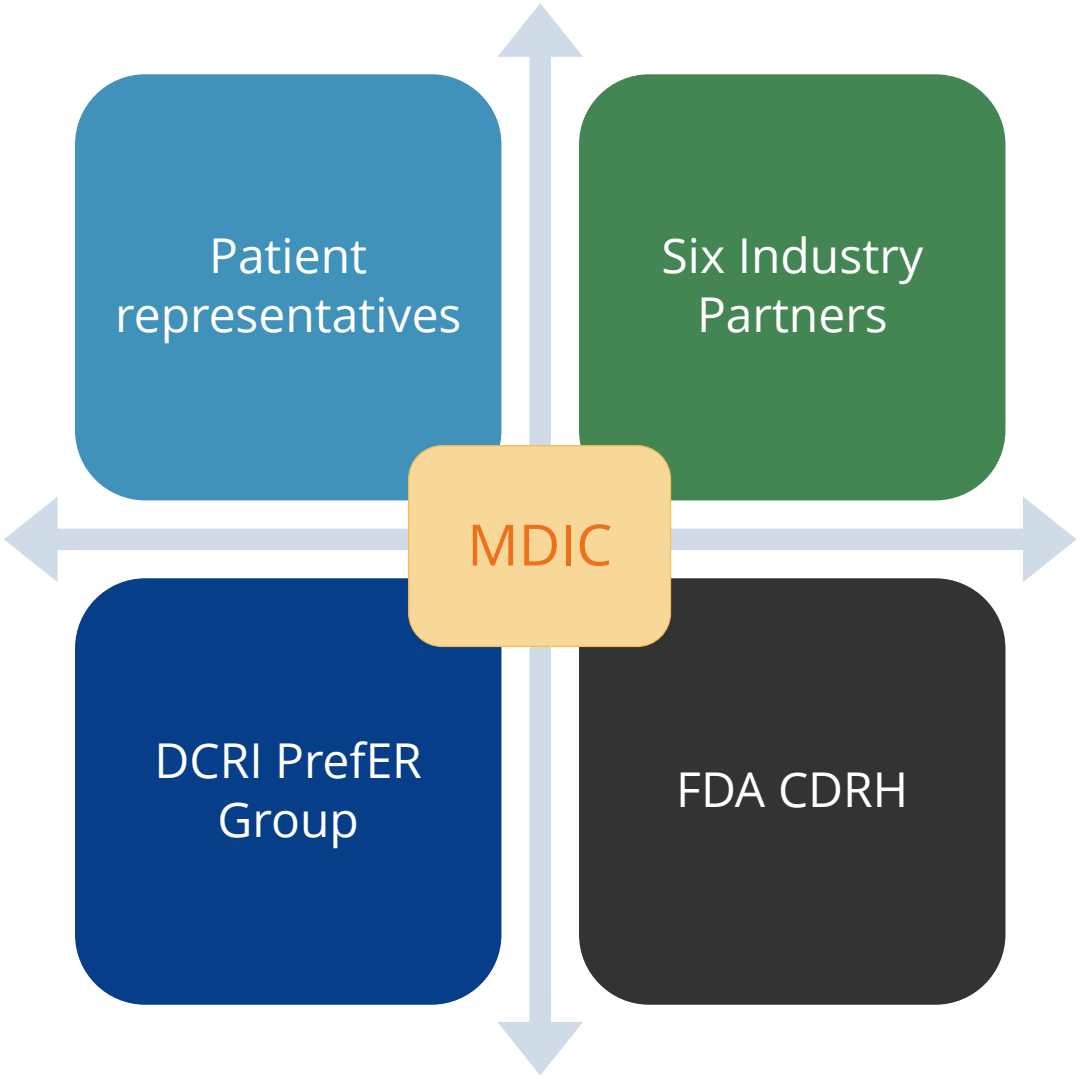
Case Study:
Heart Failure Patient Preferences

Shelby Reed, PhD - Duke University

Background and motivation

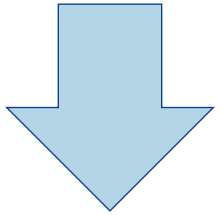
- Applications for utilizing patient preference information in designing clinical trials
  - Prioritizing study endpoints
  - Weights for composite endpoints
  - Preference-weighted PROs
  - Meaningful effect sizes
  - Statistical criteria and power calculations

Collaborative Effort



Study Objectives

- To apply best-practice stated-preference methods to quantify heart-failure patients' willingness to accept therapeutic risks in exchange for improved efficacy.
- Engage patients, providers, device industry representatives and preference-research experts in a collaborative effort.



Inform clinical-trial designs for studying heart-failure devices.

Selecting attributes and choice context

Select decision context and study attributes → Survey development and pretesting → Experimental design and survey programming → Data collection → Analysis and reporting

Potential Attributes

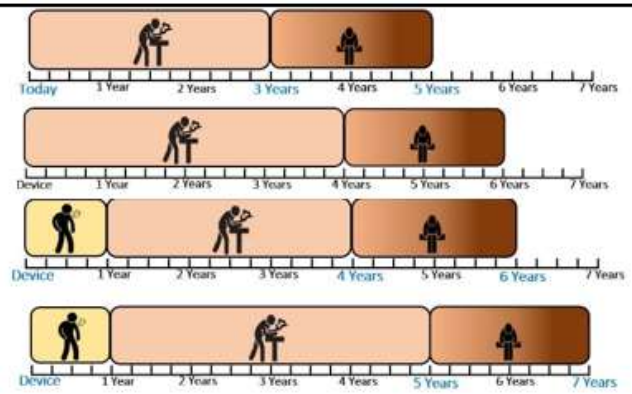
- Functional capacity
- Quality of life improvement
- Number of hospitalizations
- Risk of adverse events associated with device
- Uncertainty about benefit
- Mortality
- Device features

Decision Context

- Motivation for a change in HF management
- Severity of disease
- Device vs. device vs. medication

Attributes and Levels

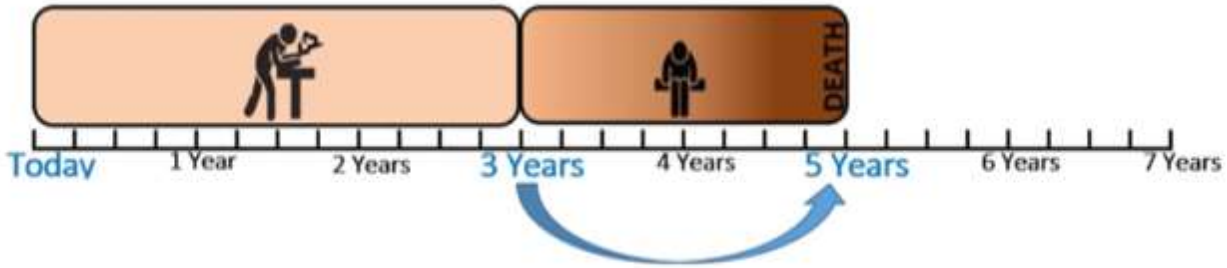
Attributes
Physical functioning and survival
Risk of mortality
Risk of device-associated complications
Remote device programming

Effect Category	Attribute	Levels
Benefits	Years in NYHA class II/III/IV	
Risks	How many people died within 30 days	0 out of 100 (0%) (“no device”) 2 out of 100 (2%) 5 out of 100 (5%) Low-risk arm: 10 out of 100 (10%)* or High-risk arm: 15 out of 100 (15%)*
	Risk of complications leading to additional 2 days in hospital	0 out of 100 (0%) (“no device”) 5 out of 100 (5%) 15 out of 100 (15%) 40 out of 100 (40%)
Device feature	Remote programming	None / No  Yes

Training section extracts

Level '3' represents people who get out of breath and must stop to rest when climbing a flight of stairs. Also, when doing light housework like doing the dishes or running the vacuum, they must stop to catch their breath. They feel comfortable when they are sitting watching television or reading.

ACTIVITY	Level 1	Level 2	Level 3
Climbing stairs:	Climb at regular speed	Climb slowly	Must stop to rest
Housework:	Can do	Can do	Must stop to rest
Resting:	Comfortable	Comfortable	Comfortable



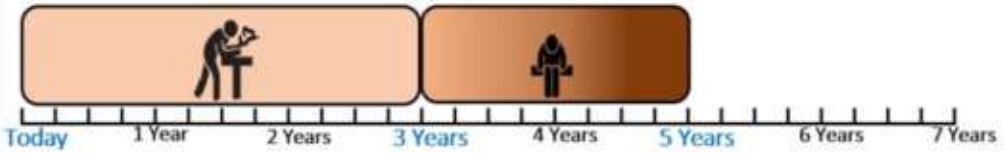
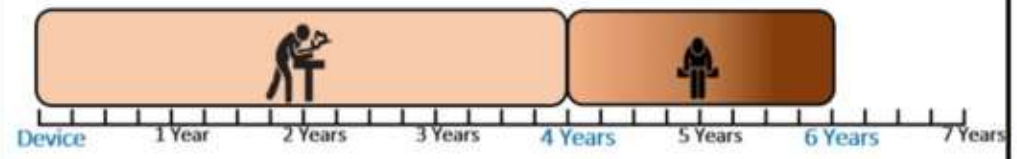
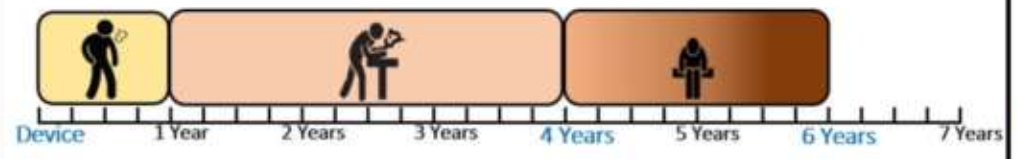
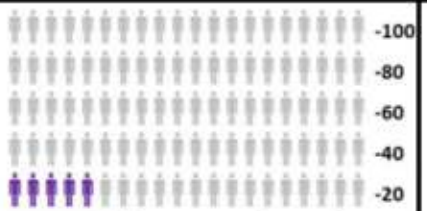
This picture shows by the end of 3 years, their symptoms would get noticeably worse, so that after the 3rd year they aren't able to climb stairs or do housework. Even when resting, they feel tired and out of breath (Level 4).

They would live that way for 2 more years and then die at 5 years.

In the last three months of life, they feel increasingly tired and out of breath.

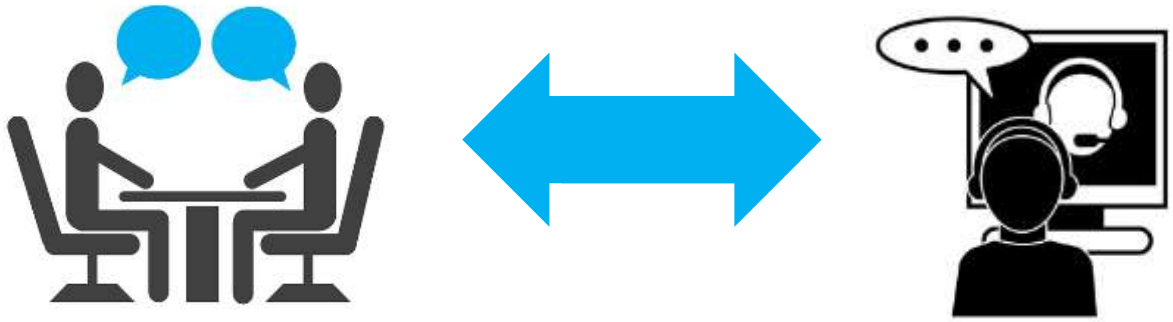
Example Choice Question

Which of the 3 options shown below would you choose?

	Ability to Do Daily Activities	Additional risk of death in 30 days	Risk of complications with 2 extra days in the hospital	Remote Adjustment of Settings	Which would you choose?
No Device		None	None	None	☐
Device A		 2% (2 out of 100)	None	None	☐
Device B		 5% (5 out of 100)	 5% (5 out of 100)	None	☐

Pretesting the survey instrument

- Patients with heart failure from Duke University Health System



- Examples of changes to survey instrument:
  - Added 3 health literacy questions
  - Devised logic-notification experiment
  - Days with NYHA 1-IV symptoms rather than selecting a class
  - Added training for NYHA trajectories, modified graphics, and added comprehension questions
  - Explained potential harms with remote monitoring; not useful in an emergency

Validity Testing

- Study included several validity tests and safeguards
  - Respondent comprehension questions
    - Activity levels/duration and graphics
    - Risks and definitions
  - Randomized logic-notification experiment
  - Straight-lining (response non-variance)
  - Dominance patterns
  - Time to completion
  - Within-set and cross-set monotonicity tests
  - Scope tests

Study Samples

KANTAR

Web-based panel of participants reporting a diagnosis of heart failure

500	Total responses
-11	Straight-liners
489	Final sample size

Duke University Health System

Patients with physician-confirmed heart failure

126	Total responses
-2	Straight-liners
124	Final sample size

Demographics

Characteristic	NHANES* (HF)	Web Panel (N = 500)	DUHS (N = 126)	P-value**
Male, %	48%	52%	47%	0.10
Age in years, mean (SD)	66	64 (12)	66 (11)	0.06
Hispanic or Latino, %		5%	2%	0.33
Race, %				
White		89%	66%	<0.001
Black	24%	8%	32%	<0.001
American Indian/Alaskan native		3%	3%	0.75
Asian		2%	0	0.37
Native Hawaiian/other Pacific islander		0	0	-
Other		1%	0	0.59
Education, %*				
High school or less	28%	19%	23%	0.16
Some college but no degree		28%	19%	
Associate degree/tech school		16%	19%	
4-year degree (+/- some grad studies)		23%	20%	
Graduate or professional degree		14%	19%	

* Komanduri S, et al. *J Community Hosp Intern Med Perspect*. 2017;7(1):15-20. ** p-values correspond to web panel vs. DUHS

Disease characteristics

Characteristic	Web Panel (N = 500)	DUHS (N = 126)	P-value
Days over the past 7 days with… ,mean (SD)			
NYHA I	3.1 (2.9)	3.5 (2.8)	0.22
NYHA II	3.4 (2.6)	3.8 (2.6)	0.21
NYHA III	3.0 (2.8)	3.0 (2.6)	0.80
NYHA IV	0.9 (2.0)	0.9 (1.7)	0.86
Heart failure management			
Take Rx meds	95%	92%	0.13
Changed diet	59%	68%	0.05
Heart valve device	3%	2%	0.78
Heart valve repair/replacement	7%	7%	0.92
ICD	24%	31%	0.13
Cardiac resynch device	2%	2%	1.0
Pacemaker	20%	23%	0.52
Stents	29%	27%	0.69

* p-values correspond to web panel vs. DUHS

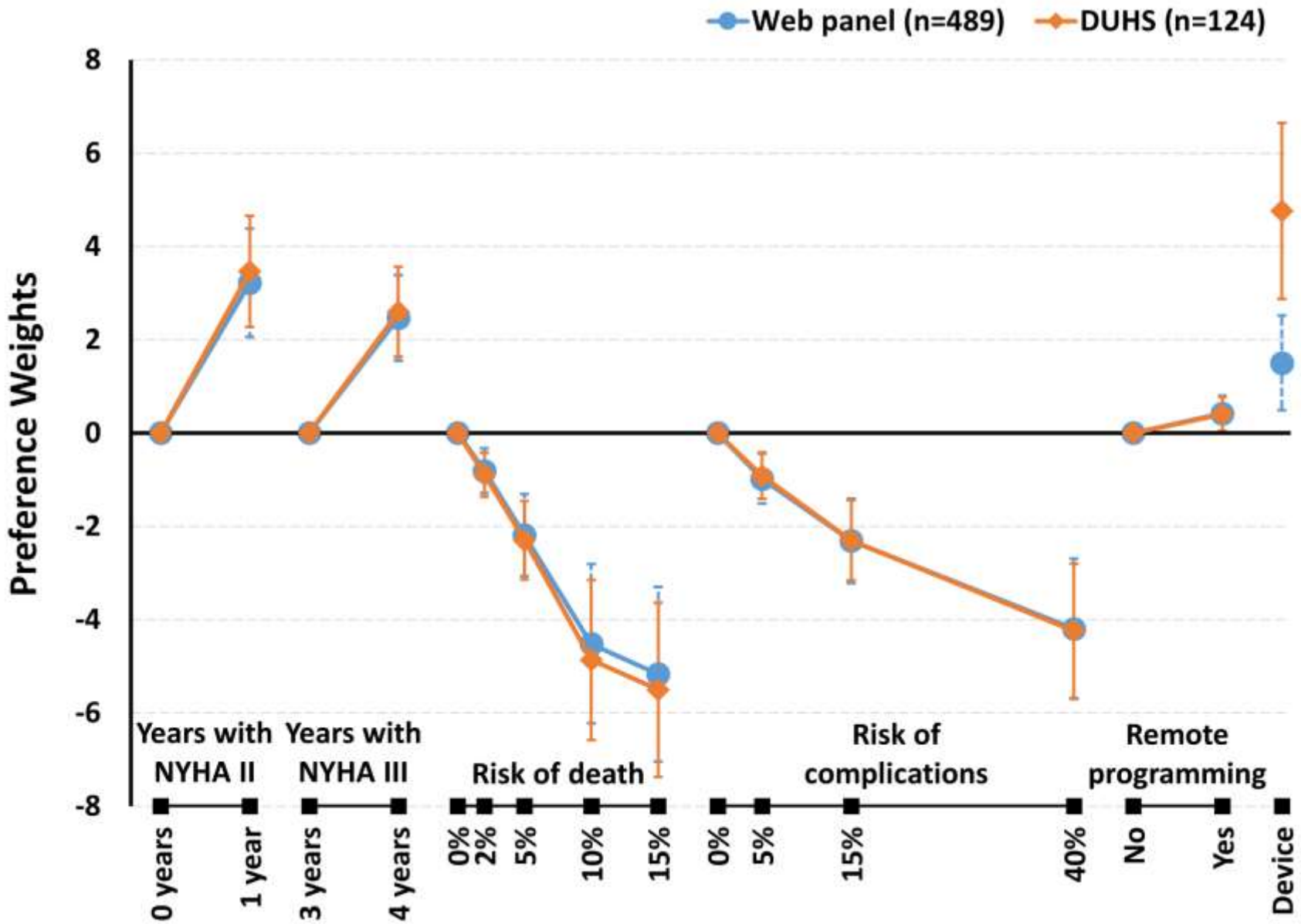
Comprehension Questions

Question description	Web Panel (N = 500)	DUHS (N = 126)	P-value
How easy is stair climbing for Level 3?	82%	91%	0.04
How easy is stair climbing for Level 4?	84%	91%	0.07
Path 2, die at what year?	58%	66%	0.38
Years in level 3?	60%	63%	0.49
Which path shows 2 yrs in level 4?	57%	60%	0.19
How many more died?	84%	92%	0.12
Which showed improvement in activities?	81%	86%	0.17
True/False- problems after hospital stay	56%	65%	0.19

Statistical Analysis Plan

- Random-parameters logit model with effect-coded variables for all levels in each attribute
- Expectations:
  - More positive preferences for longer periods in NYHA III and NYHA II
  - Positive preferences time in NYHA II vs. NYHA III
  - More positive preferences for lower risk of death and complications
  - More negative preferences for the risk of death compared to risk of complications for overlapping levels (i.e. 5% and 15% [high-risk arm])

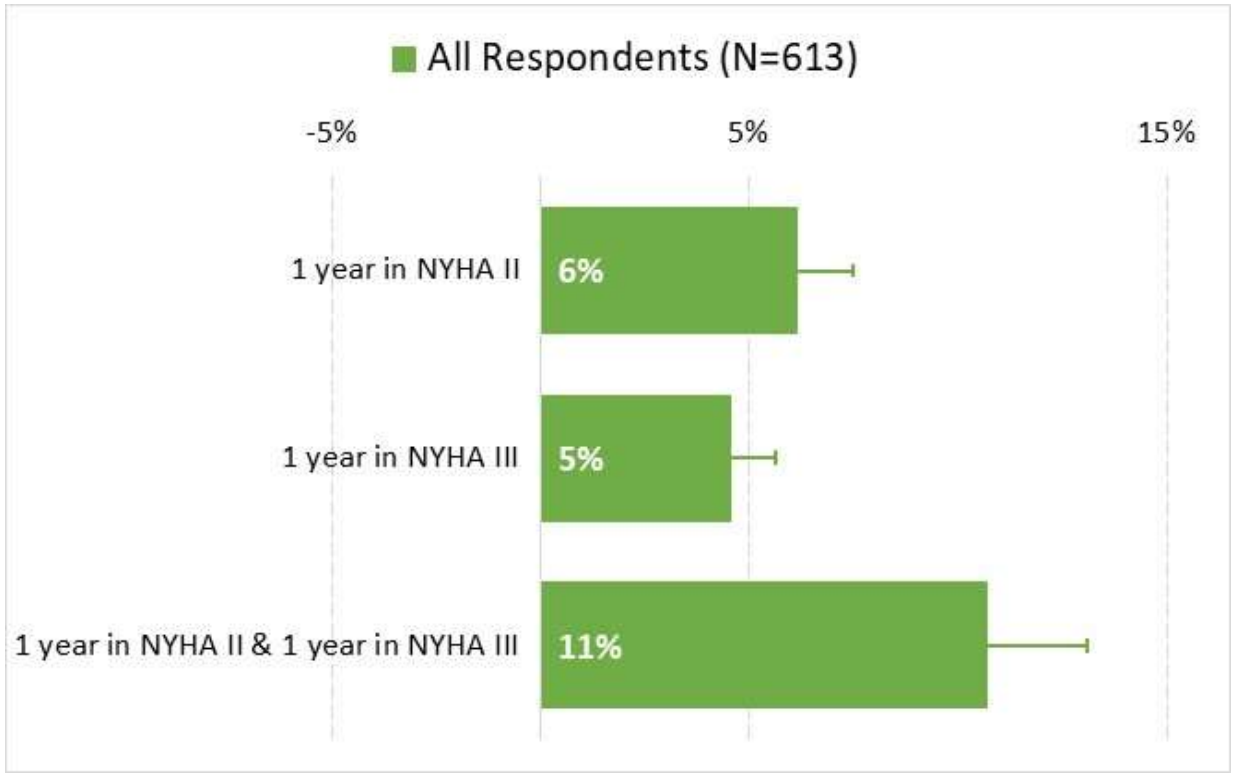
Results



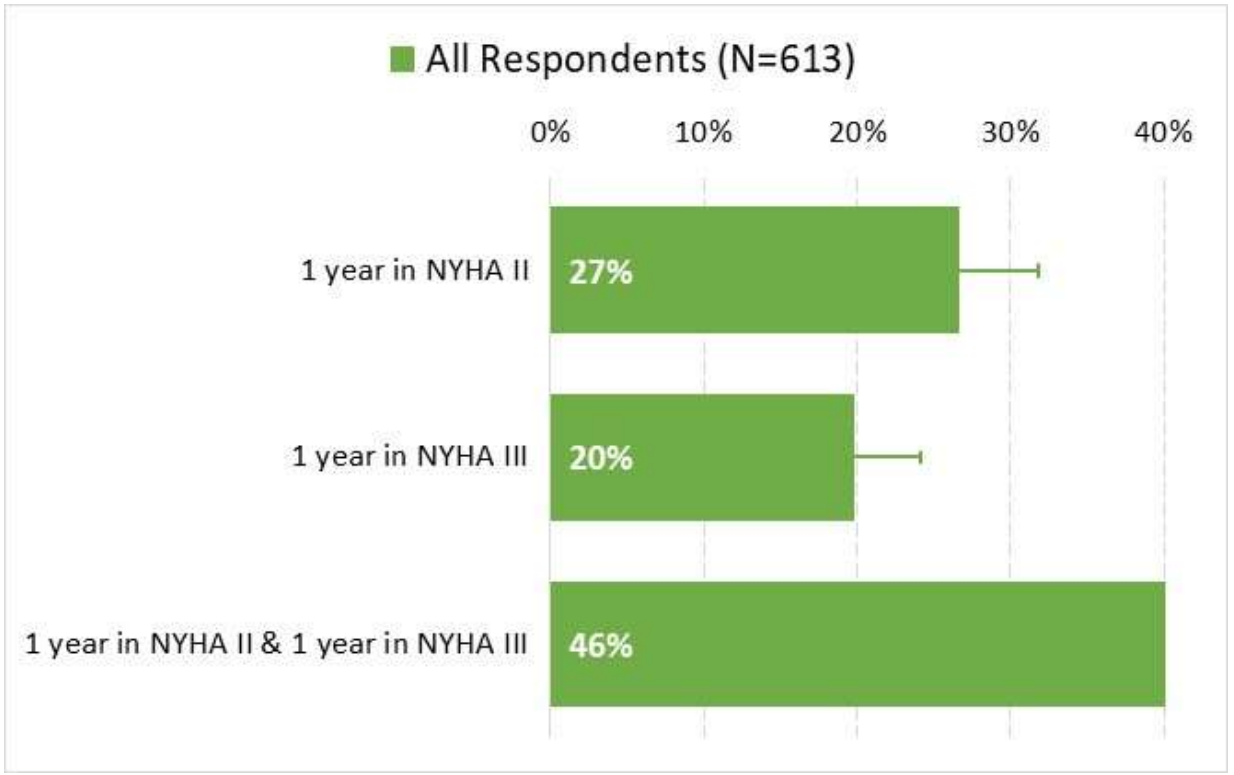
No differences in scale or preferences

Maximum-Acceptable Risk

30-Day Mortality



In-hospital complication



Summary

- Patients agreed that functional status corresponding to NYHA Class and survival represented important heart failure outcomes.
- Overall preference weights were similar between online panel and DUHS participants.
- On average, participants with heart failure preferred a device and were willing to accept a 5-6% risk of mortality for 1-year gains in survival with NYHA II or III functioning.

MDIC's Framework: Using Patient Preference Information in the Design of Clinical Trials

Barry Liden, JD – USC Schaeffer Center for Health Policy & Economics

(Formerly VP, Patient Engagement, Edwards Lifesciences –

Chair of MDIC's Science of Patient Input Working Group)

A patient-centered approach to clinical trial design has many important benefits, including the potential to:

- Improve patient experience in clinical trials
- Accelerate enrollment
- Improve retention and long-term follow-up
- Improve data quality
- Assure that trials are focused on outcomes that matter most to patients
- Support regulatory decision-making activities
- Assist in payer evaluations of value of new medical devices
- Help ensure new technological innovation is focused on bringing the most benefit to patients

Science of Patient Input Steering Committee Members

- Marc Boutin, JD, NHC*
- Dean Bruhn-Ding, RAC, CVRx
- Katie (O'Callaghan) Capanna, FDA CDRH
- Katherine Chowdhury, MA, FDA CDRH****
- Kelly Close, MBA, The diaTribe Foundation
- Heather Colvin, Johnson & Johnson
- Paul Coplan, ScD, MBA, Johnson & Johnson
- Tara Federici, AdvaMed
- Emily Fitts, The diaTribe Foundation
- Jessica Foley, PhD, Focused Ultrasound Foundation
- Pamela Gavin, MBA, NORD
- Scott Goates, PhD, Abbott Laboratories
- Alissa Hanna, Edwards Lifesciences
- Brett Hauber, PhD, RTI***
- Ross Jaffe, MD, MBA, Versant Ventures
- Julia Kenney, The diaTribe Foundation
- Barry Liden, JD, Edwards Lifesciences††
- Franchesca Liao, MS, Illumina
- Alexandra Massoud, Exact Sciences
- Mimi Nguyen, MS, FDA CDRH
- Mike Otlewski, MS, MED Institute Inc.
- Eric Relkin, LivaNova*****
- Liliana Rincon-Gonzalez, PhD, MDIC†
- Anindita Saha, FDA CDRH
- Diana Salditt, FRAPS, Medtronic******
- Peter Saltonstall, NORD
- Melissa Schooley, JD, Abiomed
- Dan Stephens, PhD, Boston Scientific
- Michelle Tarver, MD, PhD, FDA CDRH
- Karena Yan, The diaTribe Foundation

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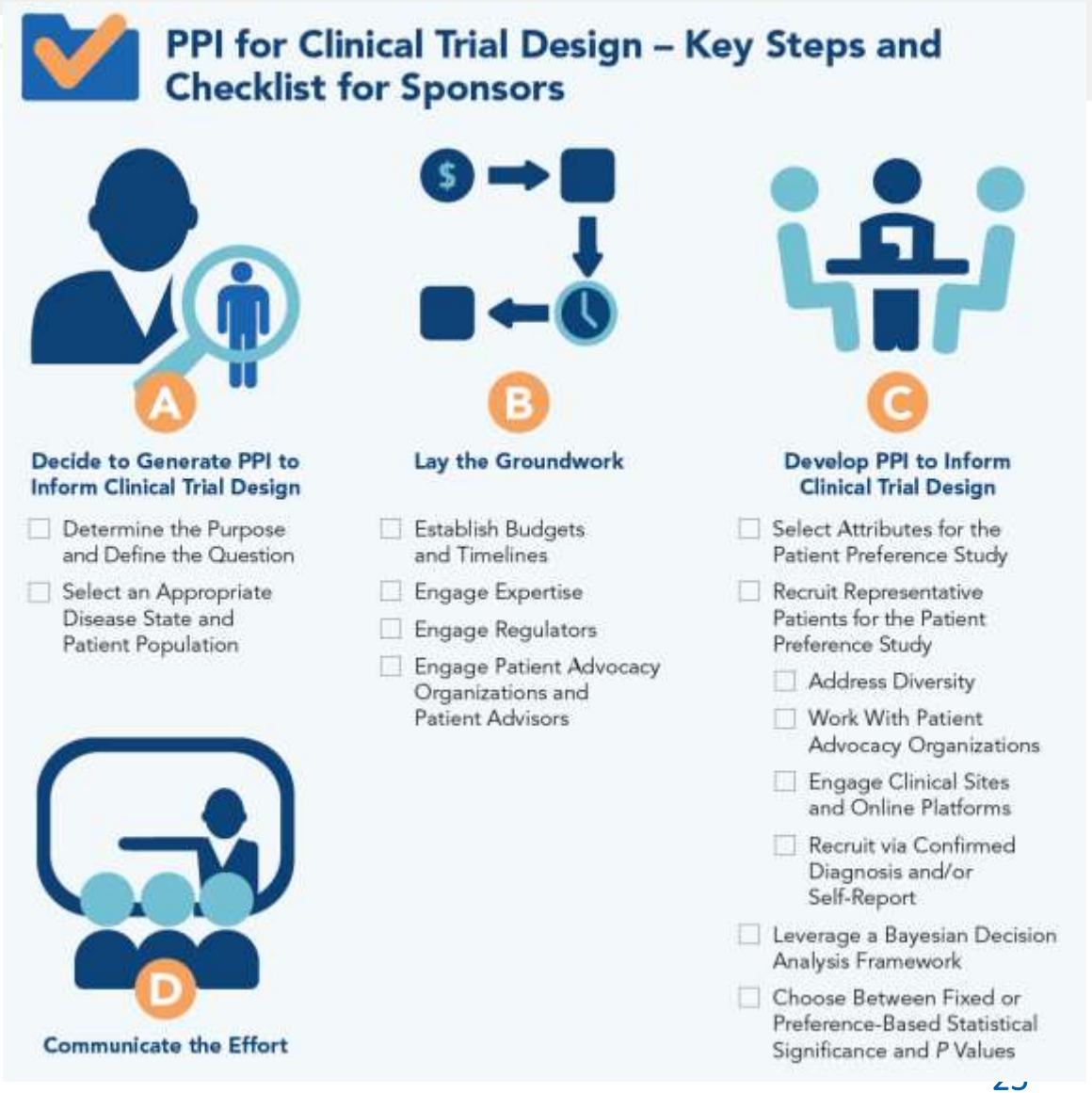
Goals of Framework:

1. Improve patient-centricity
2. Discover new approaches
3. Provide a useful resource



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Highlights of Framework Today

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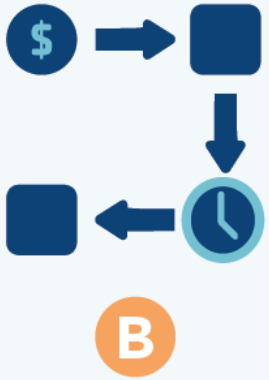
PPI for Clinical Trial Design – Key Steps and Checklist for Sponsors

Decide to Generate PPI to Inform Clinical Trial Design

- [x] Determine the Purpose and Define the Question
- [ ] Select an Appropriate Disease State and Patient Population



Lay the Groundwork

- [ ] Establish Budgets and Timelines
- [x] Engage Expertise
- [x] Engage Regulators
- [ ] Engage Patient Advocacy Organizations and Patient Advisors

Develop PPI to Inform Clinical Trial Design

- [x] Select Attributes for the Patient Preference Study
- [ ] Recruit Representative Patients for the Patient Preference Study
  - [ ] Address Diversity
  - [ ] Work With Patient Advocacy Organizations
  - [ ] Engage Clinical Sites and Online Platforms
  - [ ] Recruit via Confirmed Diagnosis and/or Self-Report
- [x] Leverage a Bayesian Decision Analysis Framework
- [ ] Choose Between Fixed or Preference-Based Statistical Significance and *P* Values

Communicate the Effort

Determine the Purpose & Define the Question

PPI USE IN CLINICAL TRIAL DESIGN

1. Define primary and secondary endpoints
2. Design composite endpoints
3. Determine endpoint weighting
4. Evaluate statistical components
5. Identify subpopulations

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Engage the Right Expertise

Find experts who have:

- Appropriate rigor and technical expertise to generate data acceptable for use in clinical trial design
- Experience conducting patient preference studies and ability to recruit study participants
- Statistical design capabilities and familiarity with the BDA model
- Patient perspective

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Engage Regulators EARLY AND OFTEN

- Guidance documents
- Early discussions
- Q-sub process

Lessons Learned from Case Studies:

- ✓ PPI Study design needs to be fit for purpose
- ✓ Review staff familiarity with PPI is still developing
- ✓ Patient experts' input can be helpful to regulators' flexibility
- ✓ Endpoint selection may have practical challenges

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Wait, what are "Preferences" again?

Evidence representative of a group

Often obtained from surveys

Characteristics or features

"Qualitative or quantitative statements of the relative desirability or acceptability of attributes that differ among alternative interventions."

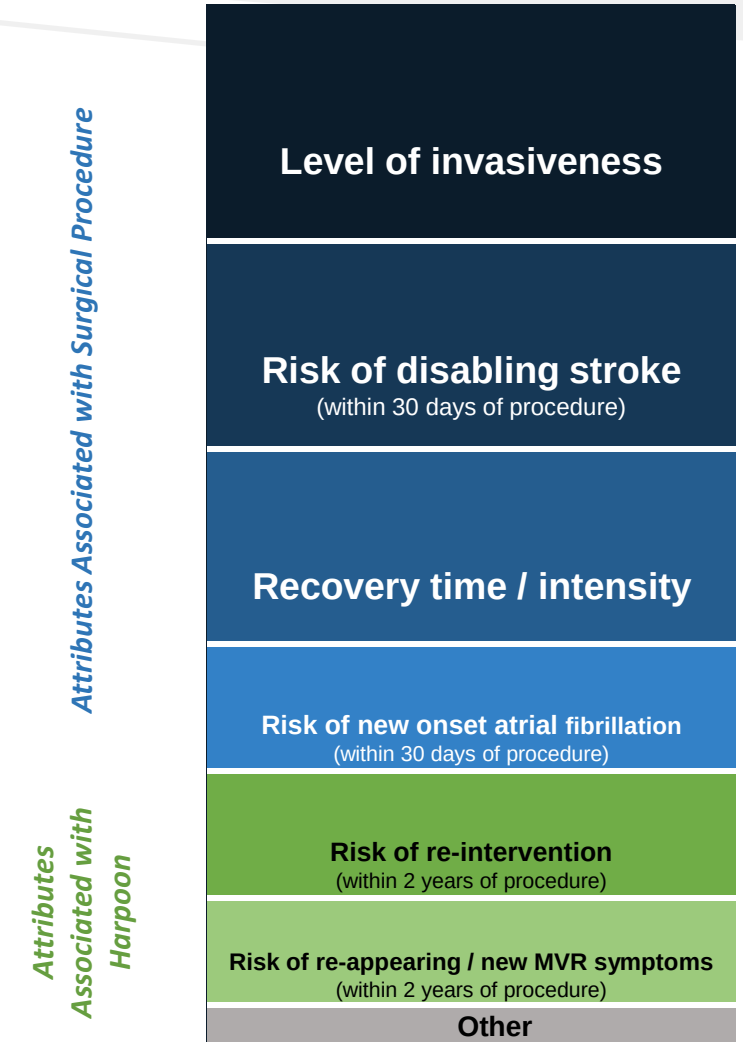
Source: CDRH

Defined by what people are willing to give up

or

- health states
- care processes
- health policies
- other

Relative weight of high-level factors on decision to undergo a procedure to repair / replace mitral valve



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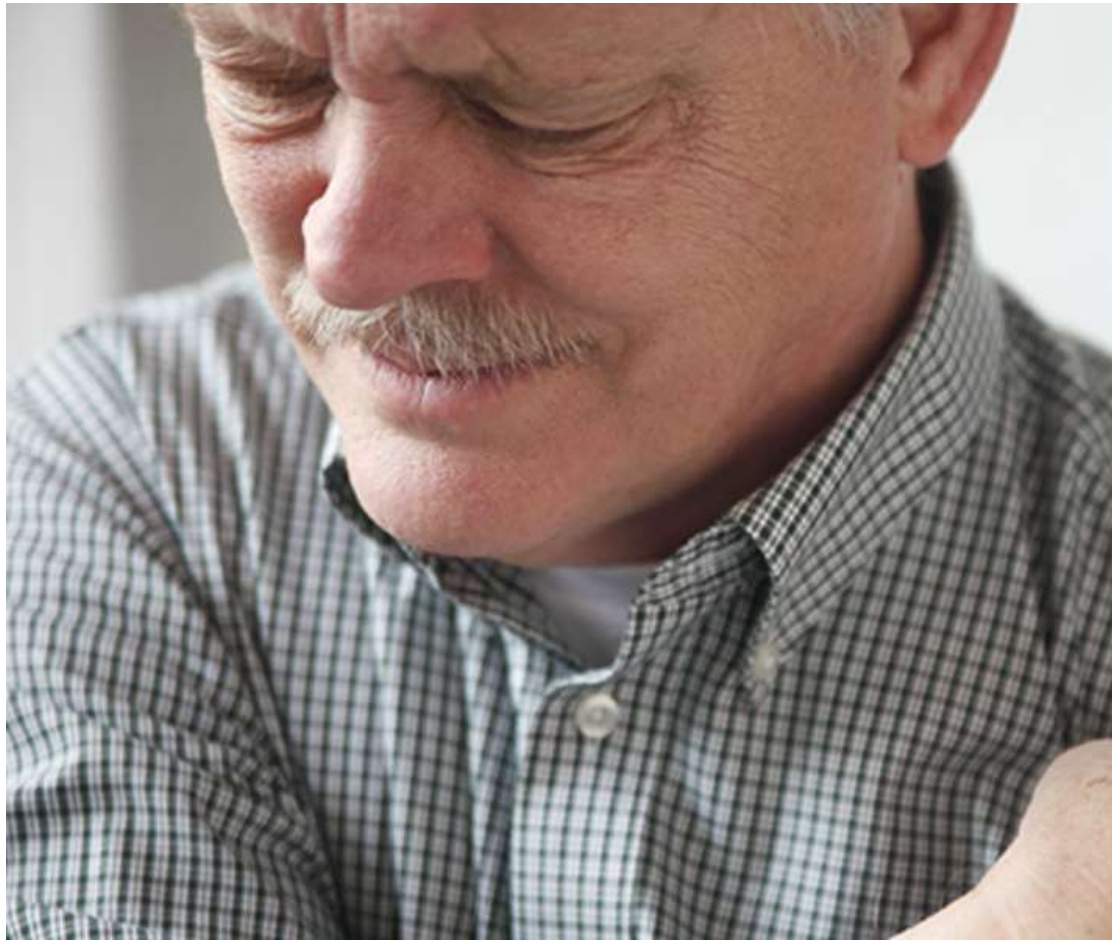
Source: Janssen E, Keuffel EL, Liden B, Hanna A, Rizzo JA. Patient preferences for mitral valve regurgitation treatment: a discrete choice experiment. Postgrad Med. 2022 Mar;134(2):125-142. doi: 10.1080/00325481.2021.2020571. Epub 2022 Jan 11. PMID: 34981982.

Attribute Selection Considerations

- Some study designs limit number of attributes
- Tools to reliably measure what matters most to patients might not be available
- PPI study attributes need to align with clinical trial endpoints
  - Comparing new devices to status quo may require using “traditional” endpoints
  - Conversely, patient priorities can move clinicians and FDA
  - Regardless, regulators need a clear, agreed-upon “crosswalk” from PPI attributes to clinical trial endpoints



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Leveraging Bayesian Decision Analysis

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Highlights of Framework Today

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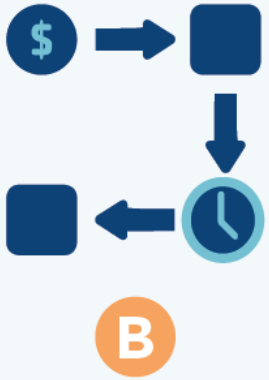

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Communicate the Effort

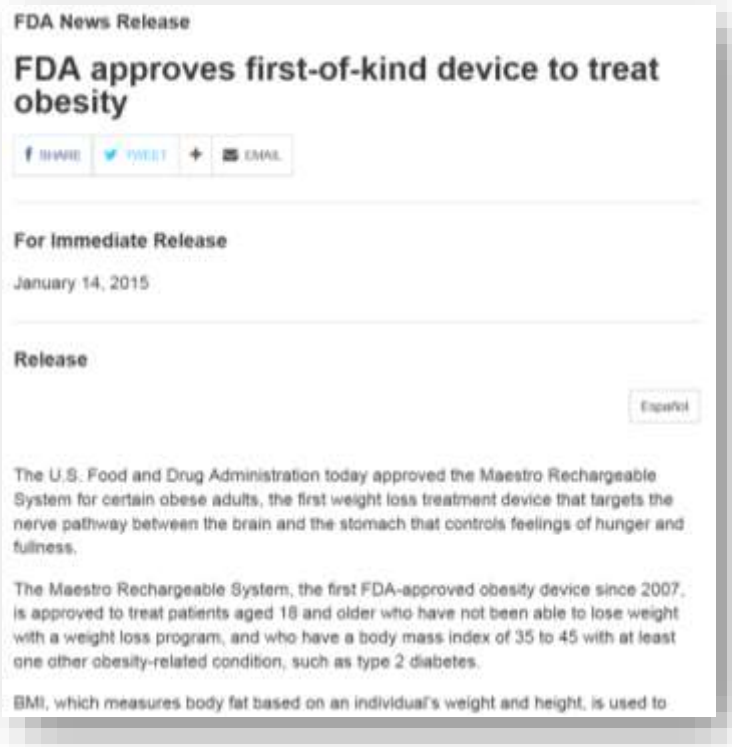
Patient Preference Information & Medical Devices: Guidances and Learnings from the Center for Devices and Radiological Health (CDRH)

Michelle Tarver, MD, PhD
Deputy Director, Office of Strategic Partnerships and Technology Innovation
Center for Devices and Radiological Health
U.S. Food and Drug Administration
michelle.tarver@fda.hhs.gov

Patients are at the Heart of All We Do

Inspired by Patients, Driven by Science

Medical Device Regulatory Impact of Patient Experience Data



FDA News Release

FDA approves first-of-kind device to treat obesity

SHARE TWEET EMAIL

For Immediate Release

January 14, 2015

Release

Español

The U.S. Food and Drug Administration today approved the Maestro Rechargeable System for certain obese adults, the first weight loss treatment device that targets the nerve pathway between the brain and the stomach that controls feelings of hunger and fullness.

The Maestro Rechargeable System, the first FDA-approved obesity device since 2007, is approved to treat patients aged 18 and older who have not been able to lose weight with a weight loss program, and who have a body mass index of 35 to 45 with at least one other obesity-related condition, such as type 2 diabetes.

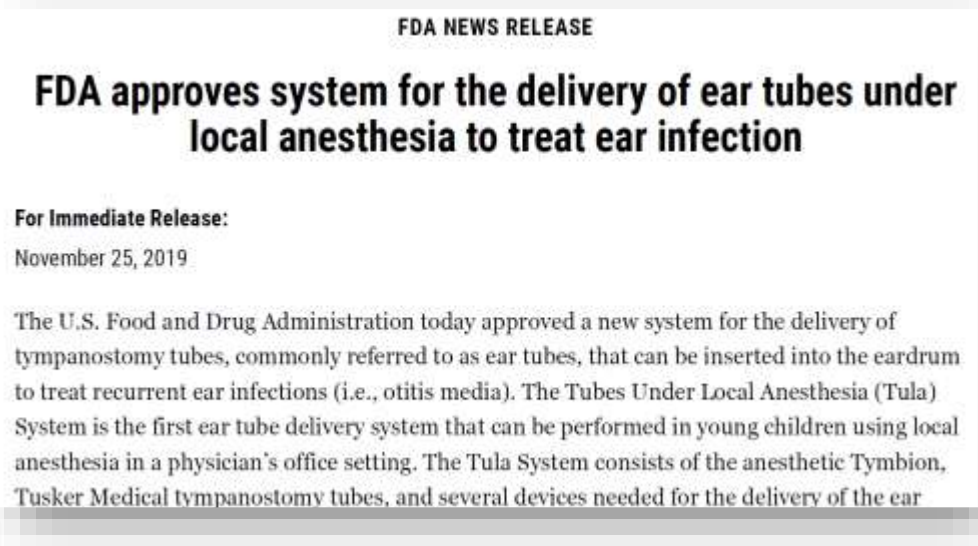
BMI, which measures body fat based on an individual's weight and height, is used to

25 Industry-sponsored regulatory PPI studies completed or in pipeline

NxStage Medical Announces FDA Clearance for Solo Home Hemodialysis Using NxStage® System One™

First clearance of its kind gives trained NxStage patients freedom to dialyze without a care partner

LAWRENCE, Mass., Aug. 28, 2017 /PRNewswire/ -- NxStage Medical, Inc. (Nasdaq: NXTM), a leading medical technology company focused on advancing renal care, today announced that the U.S. Food and Drug Administration (FDA) has cleared its System One for solo home hemodialysis, without a care partner, during waking hours.



FDA NEWS RELEASE

FDA approves system for the delivery of ear tubes under local anesthesia to treat ear infection

For Immediate Release:

November 25, 2019

The U.S. Food and Drug Administration today approved a new system for the delivery of tympanostomy tubes, commonly referred to as ear tubes, that can be inserted into the eardrum to treat recurrent ear infections (i.e., otitis media). The Tubes Under Local Anesthesia (Tula) System is the first ear tube delivery system that can be performed in young children using local anesthesia in a physician's office setting. The Tula System consists of the anesthetic Tymbion, Tusker Medical tympanostomy tubes, and several devices needed for the delivery of the ear

Over 50% of PMAs, HDEs, and de Novos have PROs

Patients & Medical Product Evaluation

Patient Engagement

Clinical Outcome Assessments

Patient Preference Information

Patient-Generated Health Data

Final Guidance:

Principles for Selecting, Developing, Modifying, & Adapting of PRO Instruments for Use in Medical Device Evaluation

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/principles-selecting-developing-modifying-and-adapting-patient-reported-outcome-instruments-use

Topics of PEAC Meetings

1. Patient Engagement in Clinical Trials

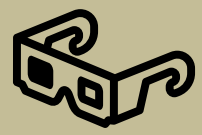
2. Patient-Generated Health Data & Medical Device Safety

3. Communicating Cybersecurity Vulnerabilities

4. Artificial Intelligence & Machine Learning

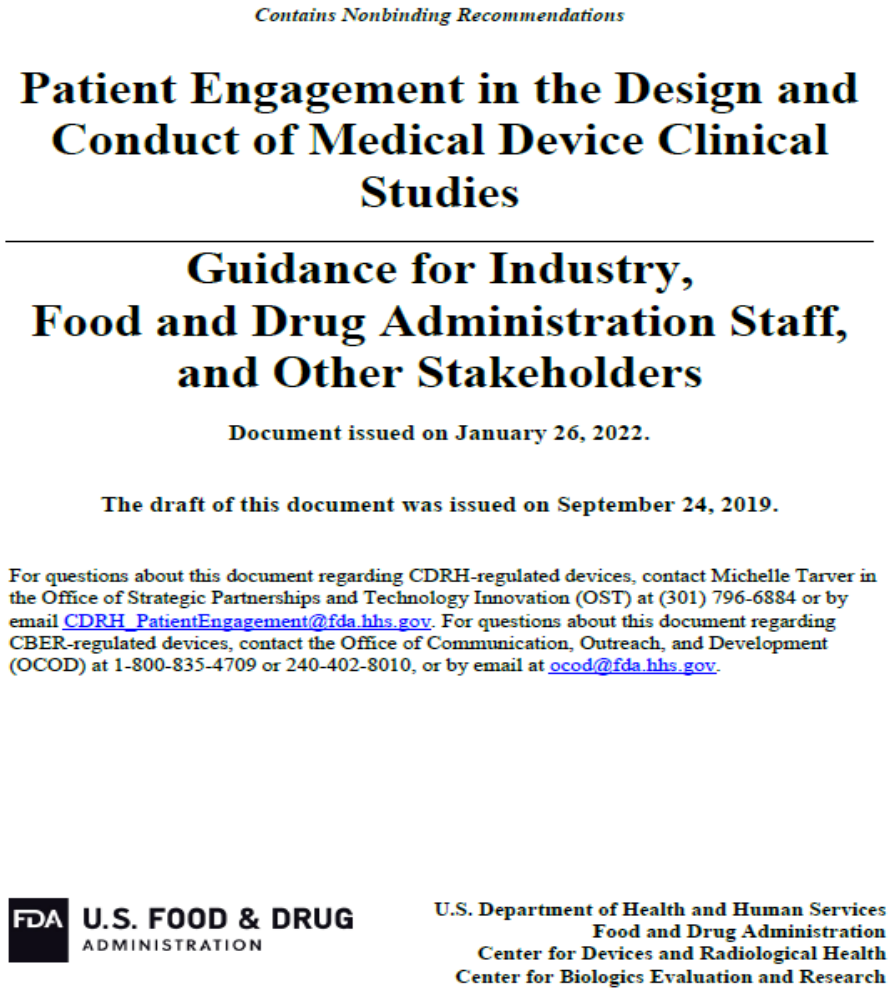
5. Medical Device Recalls

6. **July 12-13, 2022:** Augmented and Virtual Reality Devices



https://www.fda.gov/advisory-committees/advisory-committee-calendar/july-12-13-2022-patient-engagement-advisory-committee-meeting-announcement-07122022#event-information

CDRH Encourages Patient Engagement Through Guidance



Contains Nonbinding Recommendations

Patient Engagement in the Design and Conduct of Medical Device Clinical Studies

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Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders

Document issued on January 26, 2022.

The draft of this document was issued on September 24, 2019.

For questions about this document regarding CDRH-regulated devices, contact Michelle Tarver in the Office of Strategic Partnerships and Technology Innovation (OST) at (301) 796-6884 or by email CDRH_PatientEngagement@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov.

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https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-engagement-design-and-conduct-medical-device-clinical-investigations

MDUFA 5 Draft Recommendations: Patient Science and Engagement

Continue engaging patients and incorporating their perspectives in the regulatory process:

- Facilitate patient engagement through patient-friendly educational content
- Explore ways to advance health equity by incorporating data and perspectives from diverse patients
- Expand patient science review expertise and capacity
- Improve the regulatory predictability and impact of patient science, including shared examples
- Hold public meeting on patient-generated health data (PGHD) for collecting COA data and for remote clinical trials
- Issue draft guidance on incorporating clinical outcome assessments (COA) into premarket studies and update patient preference information (PPI) guidance

Core Principle: Structured Data Collection

Structured approach to collecting information on patient's lived experience with condition

- Allows aggregation of data from multiple people facilitating quantitative assessments
- Facilitates consistent assessment of concept of interest (measures what we intend to measure)
- Can be used to show treatment benefits as well as natural history of disease
- Facilitates healthcare provider and patient discussions
- Minimizes noise in clinical investigations if well-defined and characterized

Patient Preference Information Meets a Need

- Opportunity to integrate real-world perspectives into decisional frameworks
- Puts healthcare providers' and regulators' perspectives in context with patients' perspectives
- Informs patients' priorities in a list of many outcomes
- Illuminates patients' tolerance for adverse events in exchange for
  - Quality of life benefits
  - Earlier access to potentially effective treatments
  - Convenience

Use of Patient Preference Information

Device Development

- Identify unmet medical need
- Understand what matters most to patients about their disease or treatment

Clinical Trial Design

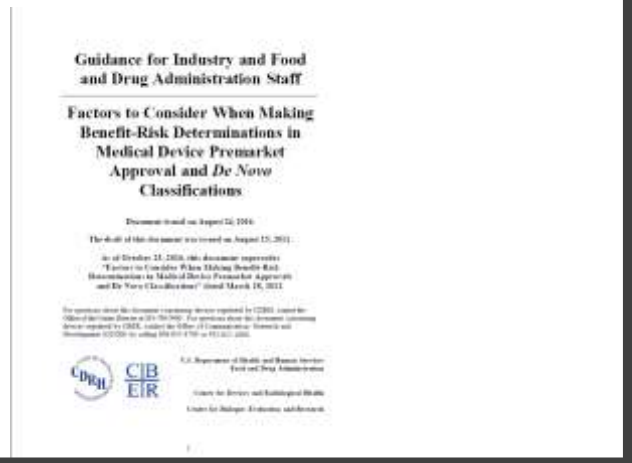
- Inform endpoint selection
- Inform performance goal
- Inform uncertainty (alpha error) and sample size

Benefit-risk Assessment

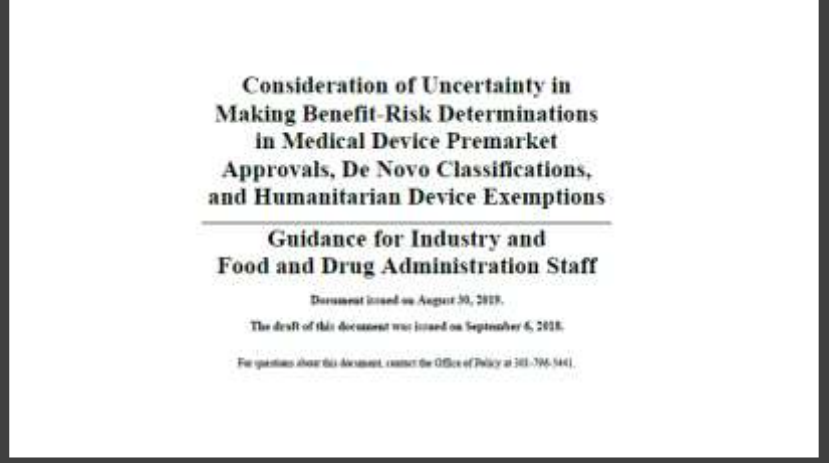
- Clarify what matters most to patients about their disease or treatment
- Illuminate patient benefit-risk tradeoffs
- Identification of subgroup preferences

Post-Market Decisions

- Post-market benefit-risk re-assessment for compliance
- Inform studies of new or expanded use populations


Guidance for Industry and Food and Drug Administration Staff

Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and *De Novo* Classifications

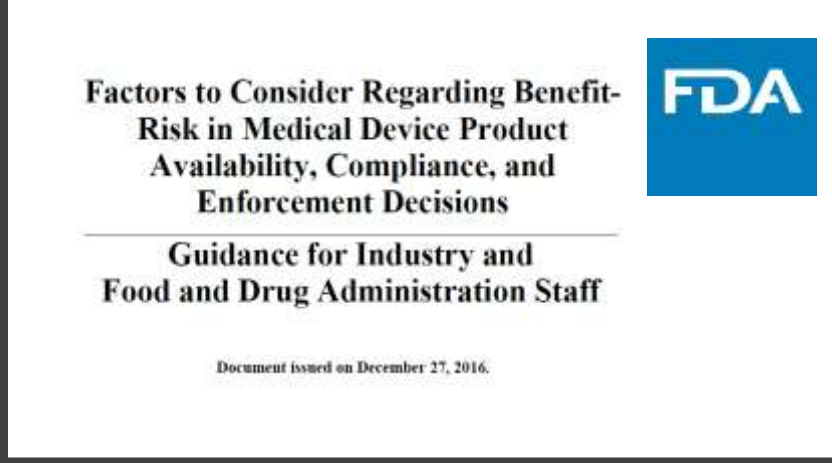

Consideration of Uncertainty in Making Benefit-Risk Determinations in Medical Device Premarket Approvals, De Novo Classifications, and Humanitarian Device Exemptions

Guidance for Industry and Food and Drug Administration Staff

Document issued on August 30, 2019.

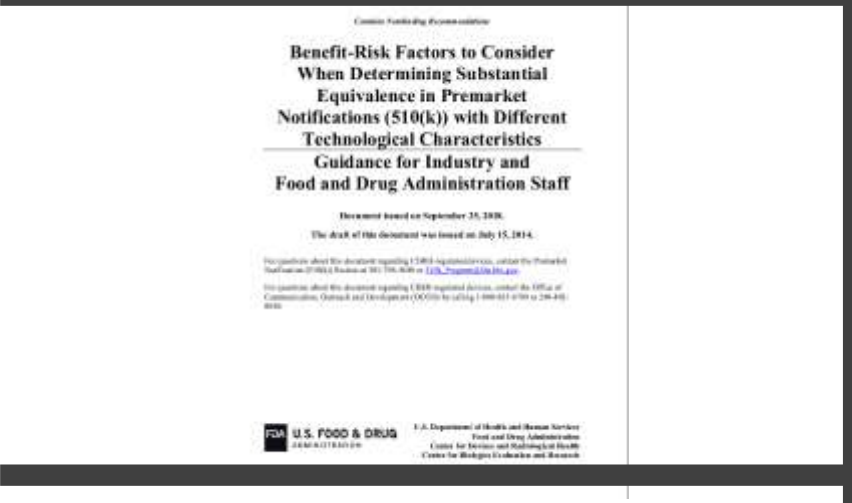
The draft of this document was issued on September 6, 2018.

For questions about this document, contact the Office of Policy at 301-796-5441.


Factors to Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions

Guidance for Industry and Food and Drug Administration Staff

Document issued on December 27, 2016.


Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications (510(k)) with Different Technological Characteristics

Guidance for Industry and Food and Drug Administration Staff

Document issued on September 19, 2018.

The draft of this document was issued on July 15, 2014.

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Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions

Guidance for Investigational Device Exemption Sponsors, Sponsor-Investigators and Food and Drug Administration Staff

Document issued on January 13, 2017.

Device Benefit-Risk Guidances

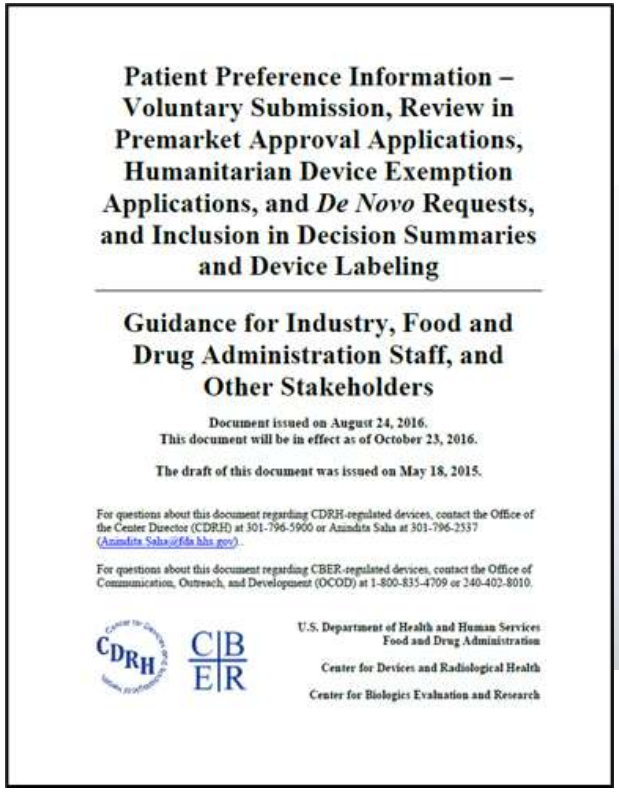
Recommended Qualities of Patient Preference Studies

Well-designed and conducted patient preference studies can provide valid scientific evidence regarding patients' risk tolerance and perspective on benefit. This may inform FDA's evaluation of a device's benefit-risk profile during the PMA, HDE application, and *de novo* request review processes.

A. All about Patients
   - Patient Centeredness
   - Sample Representativeness
   - Capturing Heterogeneous Patient Preferences
   - Comprehension by Study Participants

B. Good Study Design
   - Established Good Research Practices
   - Effective Benefit-Risk Communication
   - Minimal Cognitive Bias
   - Relevance

C. Good Study Conduct and Analysis
   - Study Conduct
   - Logical Soundness
   - Robustness of Analysis of Results



Patient Preference Information – Voluntary Submission, Review in Premarket Approval Applications, Humanitarian Device Exemption Applications, and *De Novo* Requests, and Inclusion in Decision Summaries and Device Labeling

Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders

Document issued on August 24, 2016.
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For questions about this document regarding CDRH-regulated devices, contact the Office of the Center Director (CDRH) at 301-796-5900 or Anindita Saha at 301-796-2537 (Anindita.Saha@fda.hhs.gov).

For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010.

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PPI Reviews: Lessons Learned

- Be clear about the research question (PPI) and the applicability to the clinical trial
- Consult regulatory bodies early and often
- Develop a thoughtful plan for recruiting patients to align with indications for use
  - Ensuring heterogeneity and generalizability of the study sample
  - Including under-represented populations
- Involve patients in the development process
- Assure patient comprehension of attributes and levels used in the survey
- Ensure PPI attributes align with outcomes of interest in clinical studies
- Pre-specify analysis plan and potential subgroup analyses
- Determine all the ways in which the PPI study will be used (e.g., BDA)
- Provide sufficient information for regulatory bodies to assess the quality of the study and the evidence

Take Home Points

Solid qualitative work grounds a patient-centric quantitative preference study

- ❑ Informs attribute selection
- ❑ Ensures patient comprehension of attributes and levels

Consult FDA early when designing PPI studies for a regulatory context

- ❑ Ask for the Patient Science & Engagement Team Members to be consulted
- ❑ Be clear about the regulatory question you want your study to answer

Develop a plan for recruiting patients

- ❑ Ensure heterogeneity & generalizability of sample
- ❑ Include under-represented populations
- ❑ Determine criteria for disease validation

Ensure PPI benefit and risk attributes align with outcomes of interest in clinical studies to inform benefit-risk decision

Journey from Concept to Care

Supporting a Paradigm Shift

- CDRH has made significant progress in advancing the science of patient input, integrating that science into medical device evaluation, and making interactions with patients part of our daily business culture

Understand the Value Proposition for Patients

- Understanding the patients' perspectives and proactively incorporating them into medical device evaluation will help promote and protect public health

Explore Novel Applications of Patient Input

- Emerging methods and technologies afford more opportunities to integrate patient perspectives seamlessly into the evaluation of medical technologies

Journey Together in Pre-competitive Space

- Working collaboratively across the healthcare ecosystem will help broaden the inclusion of the patients and their diverse voices in all aspects of health and wellness

Resources

FDA CDRH Websites:

Patient Engagement : https://www.fda.gov/about-fda/center-devices-and-radiological-health/cdrh-patient-engagement

PEAC: *https://www.fda.gov/about-fda/cdrh-patient-engagement/cdrh-patient-engagement-advisory-committee*

Patient & Caregiver Connection: *https://www.fda.gov/about-fda/cdrh-patient-engagement/cdrh-patient-and-caregiver-connection*

Patient Preference: https://www.fda.gov/about-fda/cdrh-patient-engagement/patient-preference-information-ppi-medical-device-decision-making

Patient-Reported Outcomes: https://www.fda.gov/about-fda/cdrh-patient-engagement/patient-reported-outcomes-pros-medical-device-decision-making

Contacts for Medical Devices

- For Patient-Reported Outcome Questions:
  CDRH-PRO@fda.hhs.gov
- For Patient Preference Information Questions:
  CDRH-PPI@fda.hhs.gov
- For Patient Engagement Questions:
  CDRH_PatientEngagement@fda.hhs.gov
- For Collaborative Community Questions:
  - CDRHCollabCommunities@fda.hhs.gov


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Today's Panel Presentation

Objective: Learn how Patient Preferences can inform study design

	**Barry Liden, JD** (Facilitator) MDIC Science of Patient Input	Intro/Overview	5 min
	**Shelby Reed, PhD** Duke University	Case Study: Heart Failure Patient Preferences	10 min
	Barry Liden	Overview of MDIC Framework	20 min
	**Michelle Tarver, MD, PhD** FDA-CDRH	The Regulator's Perspective	10 min
	All & Audience	Discussion; Q&A	15 min

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