

Science of Patient Input (SPI) Webinar Series

From Stories to Evidence: Quantitative patient-preference information to inform product-development and regulatory reviews

MDIC's Science of Patient Input Project is pleased to present this three-part webinar series designed to shed light on how to convert the patient experience into usable evidence for regulatory and non-regulatory applications.

Who should watch?

- Medical device and medical product developers interested in incorporating patient preferences at various stages of the total product life cycle.
- Patient groups interested in initiating patient preference studies
- Regulators interested in understanding patient preference data

After each webinar, MDIC will provide a brief recap and links to additional resources. Register for the series [here](#).

If your company would like more information on getting started in this area, please visit our resource page at mdic.org/spi/resources/ or contact SPI Program Director, Stephanie Christopher at schristopher@mdic.org.

Part One:

Quantitative Patient Preference Studies Across the Total Product Life Cycle

Originally Recorded on February 15, 2018

Speakers:

Shelby Reed, *Professor, Duke School of Medicine*

F. Reed Johnson, *Professor, Duke School of Medicine*

Juan Marcos Gonzalez, *Assistant Professor, Duke School of Medicine*

Watch the webinar and download the slides here: <http://mdic.org/mdicx/#StoriesEvidencePartOne>

Summary:

There has been increased interest and regulatory support for patient preference studies, including discrete choice experiments (DCEs), to quantify patient preferences within the medical device community in line with the shift and commitment to patient-centered healthcare.

In a DCE, respondents indicate choices among hypothetical alternatives that consist of a combination of features. The statistical analysis of the pattern of choices indicates the relative importance of the features.

In this webinar, experts from Duke School of Medicine discussed the features of discrete choice experiments and provided real-world examples of these experiments at five stages of the total product life cycle (TPLC) for regulatory and non-regulatory applications:

1. TPLC Stage: Clinical Development

Application: Weighted PRO Endpoints

Example: Using a DCE to develop preference-weighted scores for a cancer quality of life patient-reported outcome (PRO) instrument

[Watch the discussion](#), starting at 22 min.

Read the cited paper: [Mohamed, Hauber, Johnson et al. *Patient*. 2010](#)

2. TPLC Stage: Regulatory Review (25 min) – Listen also at 1 hour 12 min

Application: Benefit-Risk Determination

Example: Patient benefit-risk preference determination for weight-loss devices (FDA Obesity Study) and the first FDA approval based in part on patient preference data.

[Watch the discussion](#), starting at 25 min

Read the cited paper: [Ho, Gonzalez, Lerner et al. *Surgical Endoscopy*, 2015](#)

3. TPLC Stage: Access

Application: Value

Example: Value frameworks that go beyond the traditional elements of cost and clinical benefit for evaluating new medical technologies

[Watch the discussion](#), starting at 42 min

Read the cited paper: [Lakdawalla, Doshi, Garrison et al. *Value in Health*, 2018](#)

Additional reading:

[“Assessing the Financial Value of Patient Engagement: A Quantitative Approach from CTTI’s Patient Groups and Clinical Trials Project”](#)

Levitan, Getz, Eisenstein et al. *Therapeutic Innovation & Regulatory Science*, 2017

4. TPLC Stage: Guidance

Application: Evidence Reviews

Example: Comparative effectiveness analysis comparing benefits and harms of TNF- α inhibitors to corticosteroids in Crohn's Disease

[Watch the discussion](#), starting at 49 min

Read more about [this PCORI-funded research project](#)

5. TPLC Stage: Use

Application: Personalized Medicine

Example: A decision aid for first-time shoulder dislocation to help the patient and physician choose between surgery or physical therapy

[Watch the discussion](#), starting at 56 min

Read the cited paper: [Streufert, Reed, Orlando et al. Orthop J Sports Med. 2017](#)

Audience Q&A:

The webinar panelists and officials from FDA answered audience questions. [Listen to the Q&A](#), starting at 1 hr 9 min.

- *How do we bring together PROs and DCEs to provide a better picture of the patient experience?*
- *How should industry share patient preference data with regulators? How can these data be translated from the benefit-risk section of the submission to post-submission documents like the label?*
- *How is patient preference assessment applied beyond the US regulatory environment, specifically, with the EMA?*
- *Are there any recommendations for recruiting patients for DCEs?*
- *ISPOR recently published an oncology article on personalized PROs. Is there such a thing as personalized patient preference?*

Related Links:

[MDIC Patient Centered Benefit-Risk \(PCBR\) Framework](#)

[MDIC Science of Patient Input \(SPI\) Project Page](#)

Other Webinars in this Series

- [Part 2: Example applications and lessons learned—instrument development](#)
- Part 3: *Example applications and lessons learned—analysis and reporting* (Coming soon! April 19, 2018)