



SCIENCE OF PATIENT INPUT

Transforming the art and science of patient engagement in regulatory science

The Science of Patient Input (SPI) is a unique program within the Medical Device Innovation Consortium that advances and develops the science of patient input and engagement. Our working groups provide standards, methodologies, and tactical considerations for integration of the patient science into the medical device total product development lifecycle.

The Science of Patient Input and Engagement Program encompasses:

- **Patient Preference:** It is the qualitative or quantitative assessments of the relative desirability or acceptability of attributes that differ among alternative diagnostic or therapeutic strategies.
- **Patient Reported Outcomes:** Any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else.
- **Patient Engagement:** The intentional, meaningful interactions with patients that provide opportunities for mutual learning, shared decision-making, and effective collaborations across the total product life cycle.

These initiatives are advanced through active industry led working groups and patient advisory groups consisting of members from the FDA, medical device companies, patients/ patient groups, and academic institutions. The SPI patient advisory groups comprise of patient volunteers directly engaging with total product lifecycle projects to provide experiential feedback.

Current Projects

Current working project groups include:

- Patient Engagement in Early Phase
- Patient Engagement in Post-Market
- Making PPI More Accessible and Efficient
- Patient Advisory Groups

ABOUT MDIC

The Medical Device Innovation Consortium (MDIC) is a public-private partnership that brings together representatives of the FDA, NIH, CMS, NIST, and other agencies, industry, non-profits, and patient advocacy organizations to improve the processes for development, assessment, and review of new medical technologies.

MDIC coordinates the development of methods, tools, and resources used in managing the total product life cycle of a medical device to improve patient access to cutting-edge medical technology.

We are driving faster, safer, and more cost-effective innovation for patient benefit.

MDIC'S CLINICAL SCIENCE INITIATIVE

The SPI Program falls under MDIC's Clinical Science Initiative. MDIC's Clinical Science Initiative addresses the biggest barriers to collecting adequate clinical evidence in support of new medical technology. Clinical Science stakeholders work together to create blueprints for innovative clinical trials techniques, develop standards and metrics for effective clinical trial designs, and encourage the collection of adequate and appropriate clinical and patient preference data.

LEARN MORE

To learn more about joining any of these active working groups, please reach out to a SPI Team Member at spi@mdic.org

Learn more at: www.mdic.org/program/science-of-patient-input

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