

Overview and User Guide

Early Phase Patient Engagement (PE) Estimation Tool

July 2025

Introduction

In the medical device industry, there is a common planning challenge in evaluating the appropriate level and type of patient engagement required during the earliest stages of device development. The Early Phase Patient Engagement (PE) Estimation Tool offers best practices to medical device manufacturers to evaluate the level and key considerations for incorporating patient engagement in early stages of clinical discovery and product design.

This tool is meant for planning and benchmarking purposes only. It should not be used exclusively to inform Patient Engagement (PE) decisions, but utilized as part of a broader PE strategy.

Target Audience

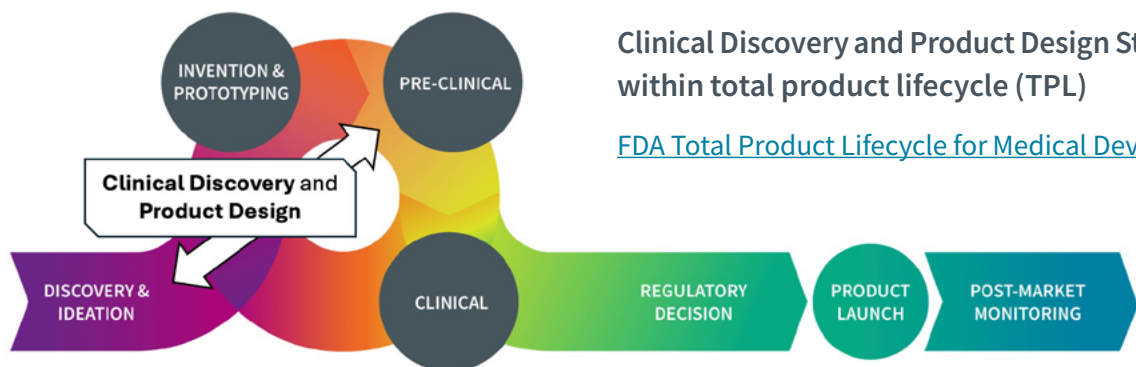
The PE Estimation Tool is valuable for a wide range of users in MedTech and other similar sectors, including but not limited to:

- R&D Teams
- Product Development Teams
- Upstream Marketing, Product Managers
- Clinical Affairs Teams
- Design Engineers and UI/UX Designers
- Human Factors Researchers
- Patient Preference Researchers
- Regulatory & Strategy Teams
- Physicians and Caregivers
- Patient Engagement Teams

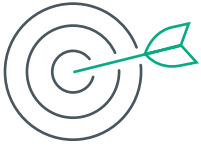
FDA Disclaimer: *The contents of this tool in Microsoft Excel and corresponding Microsoft Word user guide, are the work of medical device industry professionals, as part of Medical Device Innovation Consortium’s (MDIC) Science of Patient Input program. The contents do not represent the official views of FDA CDRH or the U.S. Government. FDA CDRH participates as a member of MDIC and provided subject matter expertise during the initial framing of the project but is not the author of this MDIC publication.*

Overview

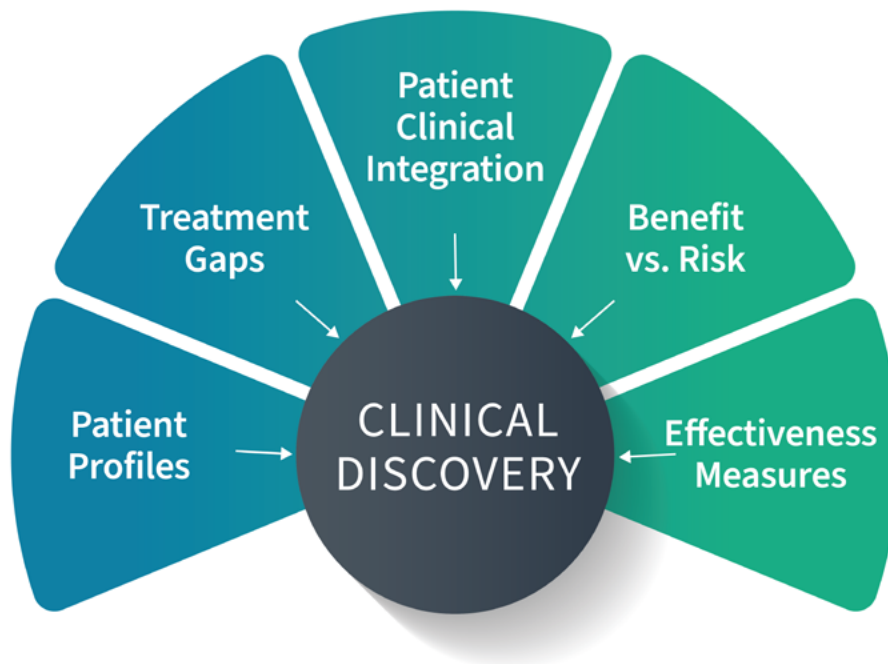
The Patient Engagement (PE) Estimation Tool is designed for use in the early stages of the medical device total product lifecycle (TPL), prior to clinical trials. It consists of a 10-question needs assessment covering the Clinical Discovery and Product Design stages (5 questions per stage). Each question offers 3 defined scoring options with accompanying descriptions. Upon completion, the tool generates a graphical output indicating a recommended level of PE intensity and provides tailored key considerations to guide planning. The goal is to ensure patient input informs key development decisions early, promoting patient-focused device design that is not only more effective but better meets clinical needs.



About the Clinical Discovery Stage

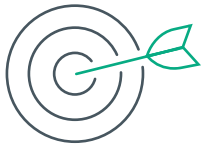


Goal: Provide an assessment framework during the clinical discovery stage to guide the level and type and patient engagement inputs necessary to form a comprehensive understanding of the unmet clinical need and guide product ideation. Incorporate key Patient-Oriented Research Questions in the development of requirements for a viable solution in design stage.

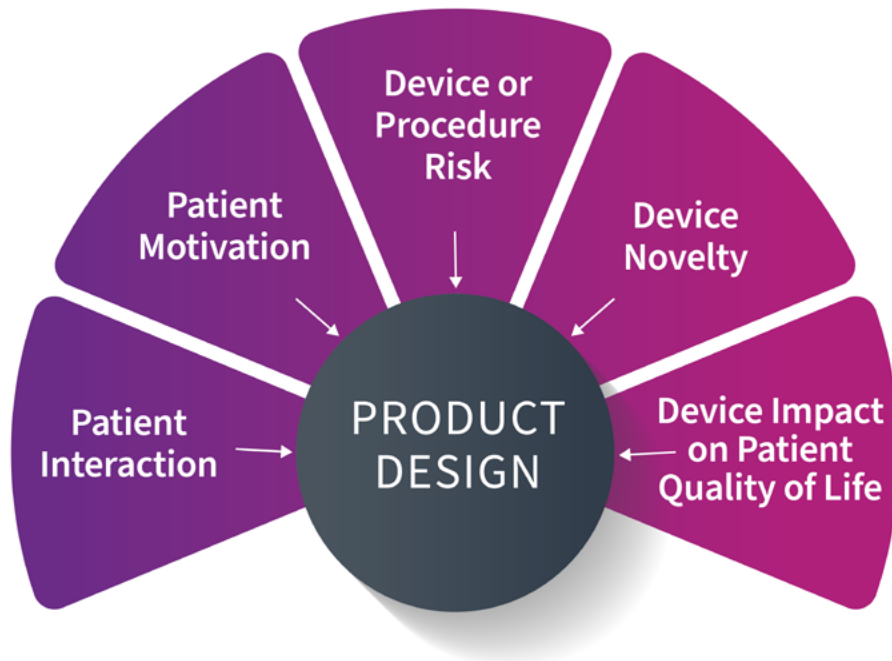


- **Patient Profiles:** Evaluate how heterogenous patient demographics and socioeconomic factors are relevant to the clinical need.
- **Treatment Gaps:** Evaluate from the patient perspective, to what degree the standard of care meets or doesn't meet the clinical need.
- **Patient-Clinician Integration:** Assess the level and frequency of patient-clinician integration and shared decision making.
- **Benefit vs. Risk:** Evaluate how known or established the benefit vs. risk profile is for this clinical need for the patient.
- **Effectiveness Measures across Care Continuum:** Evaluate the accessibility, effectiveness measures, and evidence of clinical, social, and economic impact measures throughout the patient's care journey.

About the Product Design Stage:



Goal: Incorporate patient insights into product features, usability, and safety. Incorporate key Patient-Oriented Research Questions in the development of requirements for a solution going into clinical trial development.



- **Patient Interaction:** Assess the patient interaction expected during the lifetime of the device.
- **Patient Motivation:** Gauge patients' ability or motivation to discern design elements of the device and if patient perspective is sought for device options.
- **Device or Procedure Risk:** Determine the patient's perceived level of risk during device use or implantation.
- **Device Novelty:** Evaluate to what extent this device has potential to change the standard of care.
- **Device Impact on Patient Quality of Life:** Estimate to what extent (or degree) this device directly impacts patient quality of life.

User Guide

1 Assess the stage of development process:

Stages:

- **Clinical Discovery:** If a user has identified a target clinical unmet need and population but hasn't yet pinpointed a novel device concept, this stage focuses on discovery.
- **Product Design:** If a user has already identified a device concept, this stage assists manufacturers in mapping out the amount of PE required.

Gather relevant patient and product information for each category within the respective Clinical Discovery and Product Design stages.

- Collaborate with relevant stakeholders as needed to assist in value selection.

2 Complete the Questionnaire

Per the user's needs, the user selects values from the drop down in the two-section questionnaire:

- Open the the PE Estimation Tool Excel File, and proceed to the 'START' tab. After reading the 'START' tab, proceed to the 'INPUT' tab.
- Complete the 'INPUT' tab questionnaire by selecting the values for the blue cells using the drop down that best describes your product and development phase needs.
 - Input score of 1, 2, or 3 for each question category for respective phases on the 'INPUT' tab.
- After completing the questionnaire, proceed to the 'OUTPUT' tab which includes the overall PE activity level score and key research considerations for your specific needs.
 - The tool will automatically calculate the level of patient engagement needed per user's responses.

3 Results Interpretation

Review the graphical output provided by the tool on the 'OUTPUT' tab.

Using the provided index, determine the level of Patient Engagement (PE) recommended based on the user's selection.

Early and Frequent PE throughout Development

- Ideal for comprehensive patient engagement, ensure continuous input throughout the development process. (Methods suggested: Systematic Patient Input Elicitation, Benefit-Risk Trade-offs Assessment)

High PE in Development and Decision Making:

- Encourage patient engagement in key decision-making processes and product feature development. (Methods suggested: Systematic Patient Input Elicitation)

PE Can Provide Valuable Directional Input

- Provides useful patient insights to guide the development process. (Methods suggested: Focus groups, quantitative/qualitative survey)

Limited PE in Product Development:

- Basic patient engagement methods that can still provide valuable information. (Methods suggested: Basic surveys, informal feedback sessions)

Results Interpretation (continued)

Review the calculated Patient-Oriented Research Questions to benchmark and guide next steps of patient research within the 'OUTPUT' tab.

- Select questions are displayed in bold and highlighted in green, based on user's specific product development scenario.
- The full list of key patient-oriented research questions are available for review in the 'ALL RESEARCH QS' tab within the PE Estimation Tool Excel.
 - This complete set of research questions can be used as a reference to all users regardless of their product, clinical area of interest, or stage in the development process.
 - The scoring reflected in the PE Estimation Tool highlights which subset of these questions to prioritize in the user's research, tailored to the context of a specific product development scenario.

4

Iterate and Refine:

Use these results to assist and benchmark the planning of patient engagement in the early medical device development process to help elevate the patient centricity of the product.

- Continuously refine early-stage approach based on new insights and feedback.
- If needed, return to the PE Estimation Tool and begin Step 2 to re-evaluate a product design on the 'INPUT' tab.
- If needed, view or search the 'ALL RESEARCH QS' tab containing all category items to benchmark areas to improve patient centricity in development.

Conclusion

The Early Phase Patient Engagement (PE) Estimation Tool utilizes industry best practices to empower stakeholders to assess patient engagement needs in the early phases of product development. Leveraging this Tool, the aim is to help enable proactive decision making around downstream implementation of patient engagement practices. Promoting patient-focused design throughout the development process will prove to produce better outcomes for both patients and the medical device industry.

MDIC Early Phase Working Group Mission

Objective: Advance the science of patient input strategically across the total product lifecycle by shaping and informing the regulatory science around when and how to incorporate patient preferences and engagement in the early development of medical devices.

Visit [MDIC's Center for Evidence & Patient Engagement](#) for more patient input resources.

MDiC Medical Device
Innovation Consortium

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