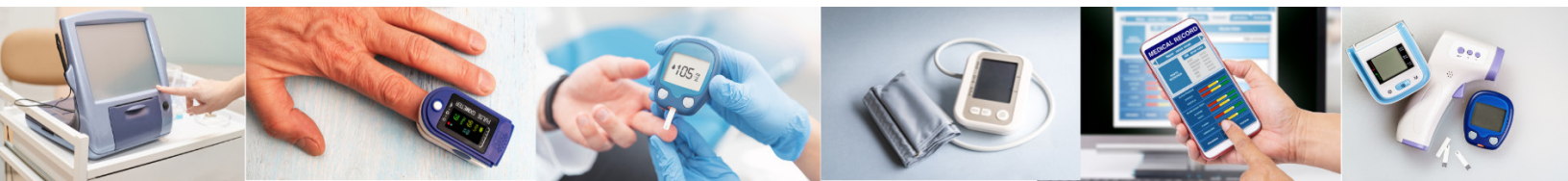
New Design vs. Extending Existing Product Lifetime

Assess whether your organization could benefit from revising an existing product design or developing a new one. Here's a quick checklist to get you started:

Market Analysis	☐ Is there a significant unmet medical need? ☐ How saturated is the current market? ☐ What's the competitive landscape?
Technological Factors	☐ Are there recent technological advancements in the field? ☐ Can existing technology adequately address current needs? ☐ Is there potential for breakthrough innovation?
Financial Considerations	☐ What's our R&D budget? ☐ Can we afford the costs of developing a new product? ☐ What's the potential return on investment for each option?
Regulatory Environment	☐ How complex is the approval process for a new design? ☐ Are there regulatory advantages to modifying an existing product? ☐ Are there upcoming regulatory changes that could impact development?
Intellectual Property	☐ Is there potential for new patents with a novel design? ☐ How strong is our current IP portfolio? ☐ Are there opportunities to extend existing patents?
Manufacturing Capabilities	☐ Can our current facilities handle a new product design? ☐ Would extending an existing product require significant retooling? ☐ What's our capacity for scaling production?
Time to Market	☐ How urgent is the need for the product? ☐ Can we afford a longer development timeline? ☐ Are competitors close to launching similar products?
User Adoption	☐ How receptive are healthcare providers to new technologies? ☐ Is there a learning curve associated with a potential new design? ☐ How satisfied are users with our existing products?
Company Strategy	☐ Does a new design align with our long-term goals? ☐ Does extending existing products fit into your product lifecycle management? ☐ What's our risk tolerance for new ventures?
Patient Impact	☐ Would a new design significantly improve patient outcomes? ☐ Can incremental product improvements sufficiently benefit patients? ☐ Are there safety considerations favoring one approach over the other?



Guidance for effectively using the checklist in a medical product design or life extension capacity:

1. **Assemble a cross-functional team:** Involve representatives from R&D, marketing, regulatory affairs, manufacturing, and finance. This ensures a comprehensive evaluation from multiple perspectives.

2. **Weight the factors:** Not all checklist items are equally important. Assign weights to each factor based on your company's priorities and the specific product category.

3. **Use a scoring system:** For each checklist item, use a scale (e.g., 1-5) to quantify how strongly it favors new design or life extension. This allows for more nuanced decision-making.

4. **Gather data:** Collect market research, competitor analysis, and internal data to inform your responses.

5. **Consider timeframes:** Evaluate both short-term and long-term implications of each option. Some factors may have different impacts over time.

6. **Regulatory landscape analysis:** Consider the regulatory environment. Consult with regulatory experts to understand the full implications of each path.

7. **Patient-centric approach:** Always keep patient outcomes at the forefront. Consider conducting focus groups or surveys with healthcare providers and patients.

8. **Financial modeling:** Develop detailed financial projections for both options, including development costs, time to market, and potential revenue streams

9. **Risk assessment:** Conduct a thorough risk analysis for each option, considering technical, market, and regulatory risks.

10. **Iterative process:** Use the checklist as a living document. Revisit and update it as new information becomes available or circumstances change.

11. **Scenario planning:** Develop multiple scenarios for each option to account for various outcomes and market conditions.

12. **Seek external input:** Consider consulting with industry experts or advisors to gain outside perspective and challenge internal assumptions.

13. **Document the process:** Keep detailed records of your decision-making process. This can be valuable for future projects and for justifying decisions to stakeholders.

14. **Set decision criteria:** Establish clear criteria for what constitutes a decision to pursue new design vs. life extension. This might include threshold scores or other key determining factors.

15. **Plan for both outcomes:** While going through the checklist, start preliminary planning for both options. This can identify unforeseen challenges or opportunities.

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