8-Item Checklist for Pediatric MedTech Startups: Health Economics & Outcomes Research

1. **Unmet Need, Stakeholder Mapping, and Behavior Change Assessment**
    - Clearly define the clinical problem and identify all relevant stakeholders (patients, caregivers, clinicians, payers, regulators).
    - Assess whether successful adoption of your device will require changes in behavior or workflow by patients, families, or healthcare providers. Consider barriers to adoption, training needs, and strategies to support sustained engagement.
2. **Clinical and Economic Value Proposition (Including Implementation Feasibility)**
    - Articulate how your device improves outcomes and/or reduces costs compared to current solutions. Specify both clinical benefits (e.g., improved function, fewer complications) and economic advantages (e.g., cost savings, resource utilization).
    - Evaluate and communicate what's required for successful implementation—will patients or providers need new skills, routines, or support systems? Factor these considerations into your value proposition and evidence generation plan.
3. **Comparator, Standard of Care Analysis, and Pricing**
    - Benchmark: Compare your device's outcomes and costs to the current standard of care and competitors.
    - Pricing Strategy: If your device needs to be more expensive for your company to succeed, you must clearly demonstrate added values such as better outcomes, fewer complications, or short and long-term savings. Higher prices can work if supported by strong evidence and a compelling value story but always balance profitability with access.
    - Market Fit: Use market research to understand what payers and providers are willing to pay and consider flexible pricing models (like outcomes-based or bundled pricing) to support adoption.
4. **Pediatric-Specific Outcomes and Measures (Including PROs)**
    - Choose outcomes meaningful for children and families (e.g., milestones, school participation). Speaking with advocacy groups can help!
    - Research and select validated, age-appropriate patient-reported outcome (PRO) measures for your condition—such as EQ-5D-Y or CHU9D. If none exist, consider adapting or developing a tool with input from pediatric experts and families.
    - Make sure your PRO is practical for real-world use and captures changes that matter in your therapeutic area. This can be helpful in defining the problem and demonstrating the value of your innovation.

5. **Reimbursement and Market Access Strategy**

    - Identify and map the specific regulatory and reimbursement pathways in target regions, including coding, coverage, and payment requirements. Engage early with payers to understand expectations.
    - Aligning evidence generation plans with health technology assessment (HTA) guidelines and payer requirements to ensure a smoother pathway to acceptance and adoption.

6. **Data Collection Plan: Clinical Trials & Real-World Evidence**

    - Design clinical trials that emphasize endpoints meaningful to payers, providers, and patients, ensuring robust data collection on safety and effectiveness.
    - Plan for real-world evidence (RWE) generation through registries, electronic health records (EHRs), and patient-reported outcomes (PROs) to demonstrate long-term impact and value in practical settings.

7. **Economic Model Development**

    - Create comprehensive cost-effectiveness models that capture both direct costs, such as treatment expenses, and indirect costs, such as productivity losses or caregiver burden.
    - Develop budget impact analyses and return-on-investment (ROI) models with sensitivity analyses to address payer concerns and validate the financial sustainability of your innovation. These will be personalized to the stakeholders.

8. **Regulatory and Compliance Planning**

    - Ensure device development and evidence generation meet standards of national regulatory bodies (e.g., FDA, CE mark) with adherence to clinical trial protocols and data requirements.
    - Implement strict data privacy and security measures to comply with regulations like GDPR or HIPAA, safeguarding stakeholder trust and legal compliance.