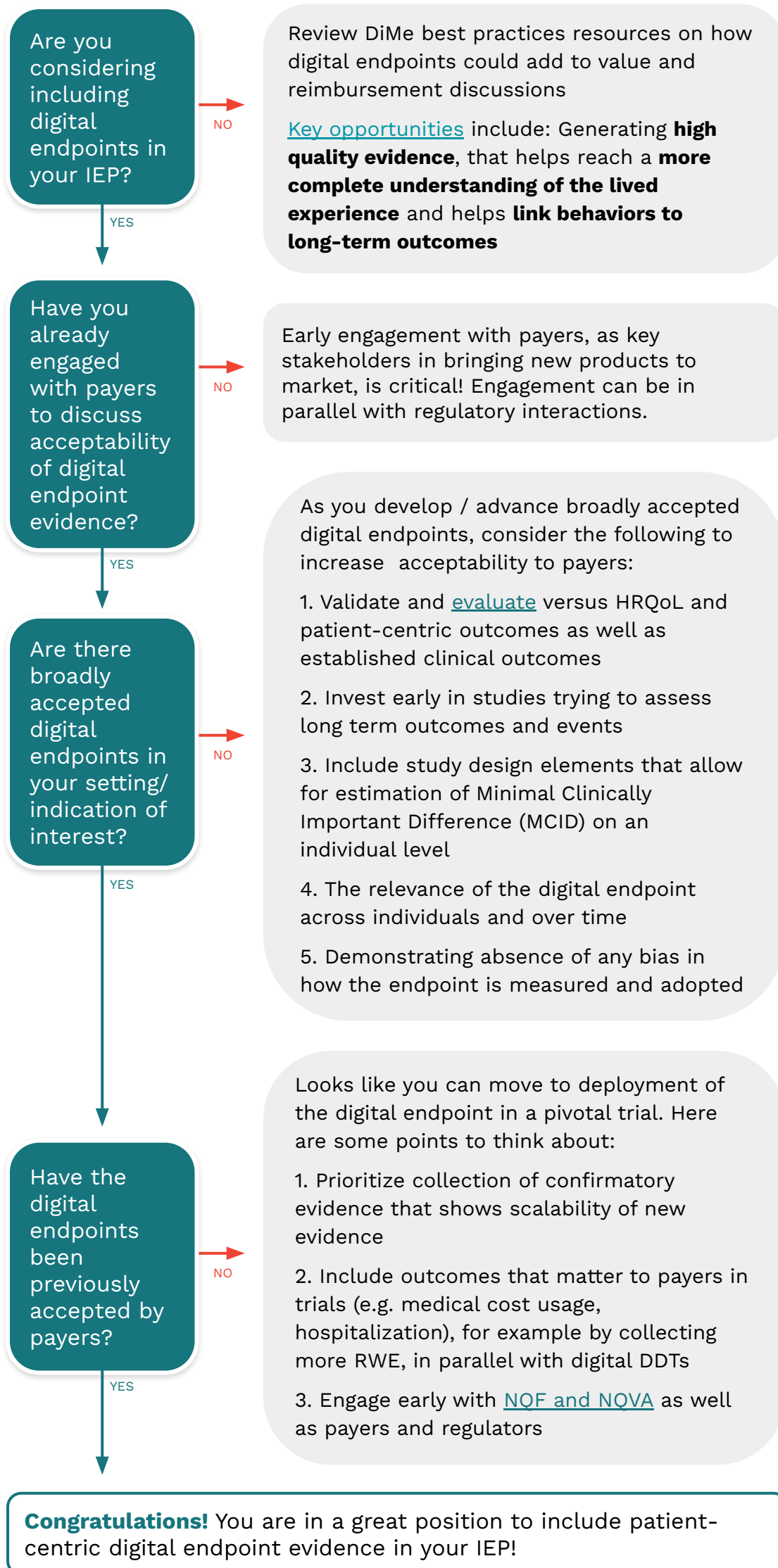


Decision tool for integrating digital endpoint evidence into your Integrated Evidence Plan



Who is this tool for? Pharmaceutical companies developing new drugs and other medical products evaluated using data derived from digital endpoints. A secondary audience is vendors developing digital clinical measures for use as digital endpoints in trials of new drugs and other medical products.

When should they use it? As early as possible in the Integrated Development Plan (IEP) development process, or ideally, even earlier in the product lifecycle (e.g. in early clinical development).

What is it for? This tool will help you decide if there is an opportunity to include digital endpoints in your IEP, and if so how to go about it.

What Is An Integrated Evidence Plan?

An Integrated Evidence Plan (IEP) are processes and documents which create a robust strategy connecting labeling concepts and goals for the new product to the development strategy and the evidence-generating trials and studies in the program.

Building off previously generated data, the IEP focuses on evidence that needs to be generated to advance stakeholder decision-making. The IEP “defines how the evidence will be generated within each clinical trial and real-world observational study, and how this will be leveraged to satisfy patient, physician, provider, payer, and regulatory requirements as defined.”

Although IEPs look slightly different from company to company, they all aim to increase productivity by helping companies plan for and assess the likelihood of getting a product to market. IEPs also include criteria for terminating programs if evidence requirements are not met, mitigation plans and strategies for expansion, if appropriate.



The **3Ps** of Digital Endpoint Value
 PATIENTS · PHARMA · PAYERS