

Checklist: Screening Your New-Product Opportunity

Patient and Customer Benefits

Will your product improve the patient's longevity, state of health, or quality of life?
Will your product perform its intended function adequately and reliably?
Is the product easy to use, and does it fit current patterns of medical practice?
Will clinicians profit or facilities reduce costs as a result of product use?
Does the product offer other societal or economic benefits?

Clinical Adoption and Competition

How much of a change in clinical practice will be necessary? Will that change be viewed favorably? Is your new approach already widely understood and appreciated?
What proof of efficacy and safety will be required for adoption by most clinicians?
To what extent do clinicians already seek change (improvement) in the status quo?
How well are your product and your company positioned against existing competitors?
Is a competitive upset technology or a capable new supplier imminent?

Commercialization Risks and Costs

What's the likelihood that the intended product can be successfully developed and produced?
What level of investment is required? Is that investment justifiable?
Will partnering be required to develop, produce and/or distribute the product?
Have prospective partners been identified? Are they likely to be responsive?

Available Market

How many potential sites of product use exist in the region(s) of interest?
How many medical procedures can be affected by, or stimulated by, your product?
What fraction of this total market is actually accessible to your company?
Are your pricing, distribution and competitive assumptions realistic?

Pricing, Profitability and Healthcare Costs

Will use of your product actually reduce total healthcare costs?
What are customers willing to pay? How do you know?
Does the intended purchase price make sense in light of the existing or expected insurance reimbursements to clinicians and facilities?
Given the expected market realities, can your company make enough money with this product?

Regulatory Constraints

Is the product likely to require FDA pre-market notification (510(k)) or pre-market approval (PMA)? How do you know?
What other regional regulatory approvals are likely to be necessary?
Have all these requirements been taken into account in estimating commercialization costs and time-to-market?

Intellectual Property

Will you have complete freedom to operate, or will certain technologies have to be licensed?
Are the necessary licenses likely to be available under mutually acceptable terms?
Can your company develop a strong IP position of its own?
