Trilogy Associates

Markets ▲ Technologies ▲ Business Development

Addressing the New Realities of Tomorrow's Healthcare Environment

Deep Due Diligence for New-Product Assessment

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A New Focus

- Accurately assessing the opportunity presented by a prospective new product has always been important
- Now, as the U.S. healthcare system evolves, a new focus will become critically important to suppliers:

Comparative Effectiveness

  - This means your new product must be at least as clinically effective as the prevailing method(s), preferably more so
  - But this also means your new product must be at least as economically effective, preferably more so
  - If you fail either of these future tests, your new product won't be cleared to market or won't be paid for

The Rationale

- This new focus is being driven by a pending new emphasis on procedural value:

  Clinical Performance + Societal Cost

- As a supplier you will be required to demonstrate…
  - Improved clinical outcomes, and
  - Reduced societal costs

  … by means of compelling quantitative data, perhaps including the findings of clinical trials
- Details are just now being formulated, but you ignore this pending U.S. government initiative at your peril

Answering the Clinical Questions

- Who will use the product, and for precisely what purpose? Can you access and convince the user?
- Will it improve clinical outcomes? Can you prove it?
- Who will benefit? Patient? Practitioner? Institution? Society?
- Is the procedural transition manageable? Can you overcome “medical momentum”?
- Can you reduce medical error and/or reduce incorrect diagnoses? What evidence do you have?

Answering the Economics Questions

- What are the real net costs to the institution, practitioner, insurer, patient, and society? Are any of these costs (especially societal costs) less than the prevailing accepted alternative(s)?
- Are your cost models credible and defensible? Can your projection of societal costs survive scrutiny?
- What changes in insurer reimbursement policies are in store? Can your new product actually influence these changes?

Case #1: “Me Too” Product

- Questions can be answered rather easily, as parity with prevailing method(s) is likely
- Commercial opportunity and supplier impact likely to be marginal (but perhaps tactically important)
- Significant risk of reduced coverage or reimbursement amounts if an “innovative” alternative product becomes available

Case #2: "Innovative" Product

- *Definition: An "innovative" product yields better clinical and economic outcomes for society*
- Questions will be difficult to answer authoritatively, as rigorous studies may be required
- Commercial opportunity and supplier impact likely to be exceptional and strategically important
- Little risk of reduced coverage or reimbursement amounts
  - More generous reimbursements may be achievable

Steps and Resources Required

1. Awareness and accurate interpretation of the moving target that is U.S. healthcare public policy
2. Familiarity and experience with a wide variety of medtech markets and product classes
3. Connections to relevant clinical communities to initiate in-depth dialogs with physicians for assessment of a product's clinical benefits
4. Awareness of healthcare cost structures and connections to administrative communities for the development of rigorous societal cost models

Need Help?

- Trilogy Associates can support your deep due diligence work in realistically assessing the promise of a planned new product
- We can efficiently address all these and other requirements consistent with the new realities of tomorrow's healthcare environment
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