

**Assessing Markets and Competition
-- A Primer --**

MDG Forum

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Agenda

- The basics
- A case study
- Getting help
- Seven deadly sins

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The Basics

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What's the worst that can happen?

- A. You don't get funded, so you can't get started
- B. Your investors are SOBs that pull you in all the "wrong" directions
- C. Product development takes much longer than expected, so you miss the market window
- D. Your investors cannot exit at a fair valuation
- E. None of the above

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None of the above!

- The worst-case scenario:
 - Your team does a bang-up job developing a great product and gets it to market quickly with a world-class distribution partner!
 - Nobody buys your product because it's the wrong product for its target market!!
- You simply must do a reasonable (and reasoned) job assessing the business opportunity before the hard work starts

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Opportunity Assessment The Elements

- Who are your customers – present and future?
- What's your market, how big is it, and what are its growth prospects?
- Who or what is your competition – present and future?
- What will motivate and discourage adoption, and why? How long will it take?



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Who's the customer?

- First, define the product as best you can
- Then identify the customers: Who must be satisfied in order to achieve success?
 1. User
 2. Purchase influencer (specifying clinician)
 3. Clinical thought leaders
 4. Payer
- Iterate to properly match product to customers

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What's the market?


- With the product and customers defined, attempt to characterize the market and its segments
- Almost never the market characterized in an off-the-shelf report; usually a subset
- Need an educated guess at latent demand in the market available to you at maturity
- Secondary research is a start, but discussions with prospective customers are usually essential
- Oh ...and you must also predict the future!

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Testing Customer Attitudes

- Prospective customers lie! 
 - When not asked the right questions by an experienced interviewer who knows the territory
 - When not expertly led to disclose their real attitudes
 - Because they're human and wish to please
- You must work through respondent attitudes and biases to answer the essential question:
 - What will it take for prospective customers to choose, champion and routinely use your new product?

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What's the competition?

- In the biomedical arena, the most important competition is often the status quo (inertia)
- First consider alternative methods and procedures
- Existing suppliers of similar products are easy to discover and research, especially if public
- Finally, imagine which other firms could enter your space; consider patent literature and hard-science publications

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Why/when will customers buy?

- You can almost always make quick sales to early adopters, but these sales will not sustain a business
- You must convince the larger body of mainstream users to adopt your new product, and that requires application knowledge, resources and time
- The opinions and rationales you hear during customer dialogs will establish the basis of your sales projection

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Case Study

Opportunity for a Noninvasive Method for Assessing Risk of Sudden Cardiac Death* (SCD)

[Relying solely upon secondary research]

Circa 1996

* 80% of 500,000 apparently healthy victims die annually.

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The New Method

- Noninvasive; inherently without risk
- Procedure takes 15-20 minutes; patient at rest
- Operationally equivalent to standard ECG
- Carried out by medical technologist or nurse
- Does not require expensive equipment
- Performance comparable to programmed electrical stimulation (PES) -- a standard electrophysiology (E/P) study -- in assessing risk of SCD

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The Prospective Products

1. Research instrument for investigation by cardiologists and electrophysiologists: \$40,000
2. Peripheral add-on units to clinical ECG machines: \$7,500
3. Fully integrated add-in modules for clinical ECG machines: \$2,500

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U.S. Patient Populations

[Sources: NCHS, NLM, medical societies, Internet]

- Group 1: Programmed Electrical Stimulation (PES), a standard E/P study
 - 200,000 persons (1 procedure per person)
- Group 2: Expanded Diagnostics
 - 4,274,000 persons (>1 procedure per person)
- Group 3: Routine Health Assessment
 - 100,000,000 persons (1 procedure per person)

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Revenue Contributions

- Procedural reimbursements
 - Estimate number of procedures per annum
 - Assume the existence of a disposable component and negotiated revenue per procedure proportional to NewCo's contribution to equipment value
- Equipment sales or leases
 - Estimate equipment placements

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Annual Procedure Counts

[Sources: NCHS, NLM, medical societies, Internet]

- Group 1: 0.2 million events
 - 200,000 patients x 1
- Group 2: 10.8 million events
 - Recent MI: 1 million persons x 6
 - Supraventricular tachycardia: 1.5 million persons x 1
 - Sustained ventricular tachycardia: 0.2 million persons x 6
 - Unsustained ventricular tachycardia: 1.1 million persons x 1
 - Syncope with suspected cardiovascular disease: 0.4 million persons x 2
 - Survivors of cardiac arrest: 0.05 million persons x 3
- Group 3: Fugedaboutit! Upside potential only.

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Procedural Revenue Potential

- Group 1: \$5 M per annum
 - 0.2 million events x \$25
- **Group 2: \$270 M per annum**
 - 10.8 million events x \$25
- Group 3: Assume \$0 to start

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Equipment Sites

[Sources: NCHS, NLM, medical societies, Internet]

- Research instrument
 - ~½ of 800 E/P labs = 400 sites
- High-end enhanced ECG
 - 21,650 hospital sites
 - Stress test labs, cardiac ICUs, E/P labs
 - 15,140 specialty practices
 - Cardiology, physical/rehab medicine, aerospace medicine
 - Each unit shared by 2 physicians

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Equipment Sites

[Sources: NCHS, NLM, medical societies, Internet]

- General-purpose enhanced ECG
 - 33,375 hospital sites
 - Non-cardiac ICUs, ERs, step-down units
- Peripheral add-on units
 - 40,735 non-cardiology physicians
 - Internists, family practitioners, pediatricians, geriatric specialists
 - Each unit shared by 2 physicians

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Equipment Revenue Potential

- Research instrument: \$5.3 M
 - 400 units @ \$40,000 = \$16 million
 - 3-year life
 - NewCo share = 100%
- High-end enhanced ECG: \$14.6 M
 - 29,220 units @ \$18,000 = \$526 million
 - 5-year life
 - NewCo share = 13.9% (\$2,500 per unit)

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Equipment Revenue Potential

- General-purpose enhanced ECG: \$16.7 M
 - 33,375 sites @ \$12,000 = \$400 million
 - 5-year life
 - NewCo share = 20.8% (\$2,500 per unit)
- **Peripheral add-on units: \$25.5 M**
 - 20,367 units @ \$7,500 = \$153 million
 - 6-year life
 - NewCo share = 100%

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U.S. Market Potential

Annual Equipment Revenue Potential	\$62 M
Annual Procedural Revenue Potential	\$79 M *
TOTAL:	\$141 M
<i>Sanity check: U.S. replacement ECG equipment market circa 1996</i>	<i>\$140 M</i>

* Based upon NewCo's share of total equipment value = 28.7% of \$275 M.

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Competition

[Sources: NLM, medical societies, Internet]

- E/P studies
 - Gold standard method for SCD
 - Too expensive and time-consuming for large patient populations
- ECG studies (resting, stress & ambulatory)
 - Not definitive for SCD
 - ECG installed base (both curse and blessing)
 - Marquette, HP (Philips), Del Mar, Zymed, Spacelabs

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Competition

[Sources: NLM, medical societies, Internet]

- Cambridge Heart
 - Method developed at Harvard & MIT
 - Requires pacing at >100 bpm under controlled conditions
 - Applicable during bicycle stress testing?
 - Only directly competitive threat to date
 - Not commercially successful to date (1996)
 - [If you don't know why, try to find out.]

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Market Penetration

- Efficacy demonstration for a screening test is an imposing hurdle – expensive and time consuming clinical trials
- Thought leaders can help
- Clinician conservatism will retard adoption
- Directly competitive entries present little threat
- Reimbursement is unpredictable*

* Cambridge Heart revenues are ~\$4M 13 years after founding.

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NewCo's U.S. Prospects

- Aside from research product placements, product sales revenue not anticipated for at least 2 years
- Thereafter, adoption likely to be slow for a new screening method
 - Peak sales not expected to exceed half the available market, i.e. \$70 million
 - Achievable perhaps 7-10 years following regulatory clearance (typical of new screening technology)

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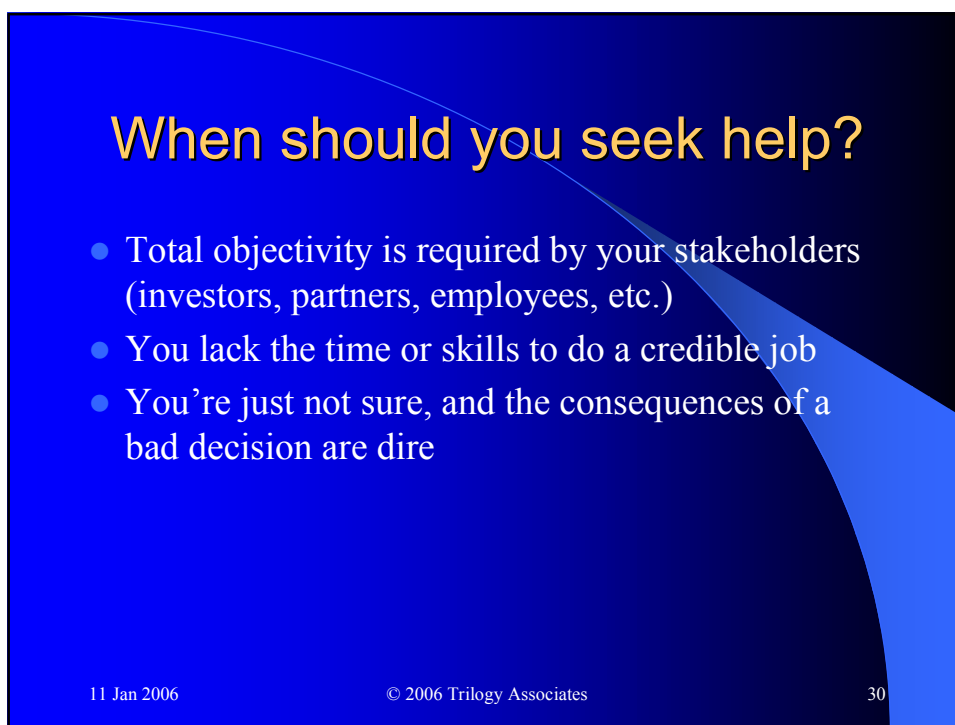
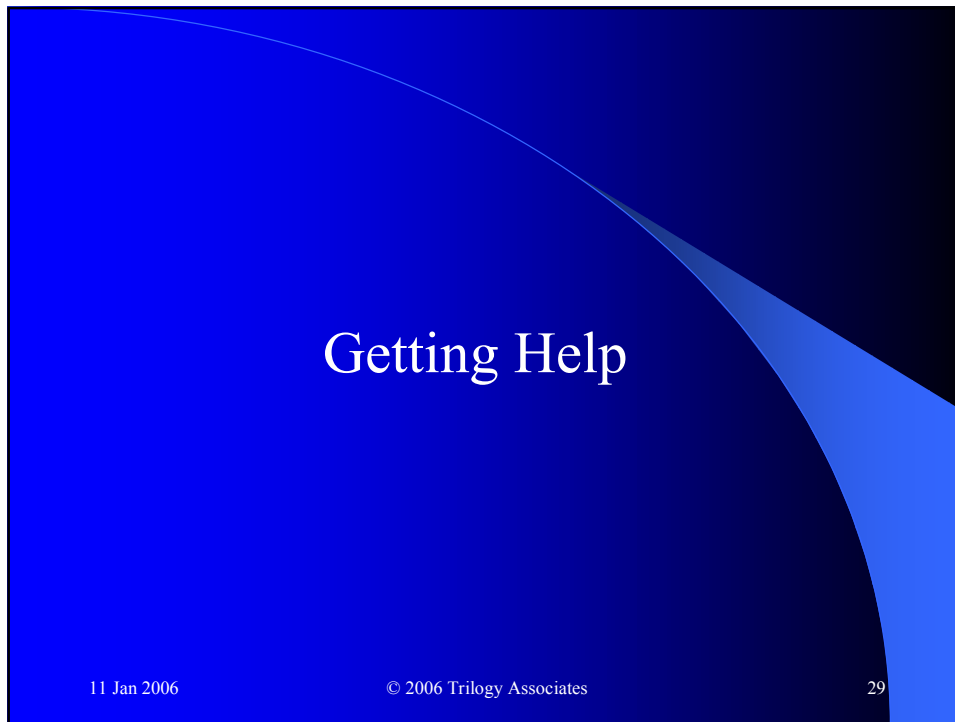
Conclusions

- This opportunity is unlikely to attract VC interest
 - Big numbers don't necessarily mean big opportunities
- Consider:
 - Seek out angel investor(s) or F/F/F
 - Seek out a strategic corporate partner/investor
 - Patient monitoring (e.g. Philips)
 - Physician office equipment (e.g. Welch Allyn)
 - Bootstrap development and out-license technology
 - Seek another opportunity
 - Usually distasteful but sometimes the best option

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Working with Consultants

- Make the assessment's objectives and your personal aspirations crystal clear
- Do at least some of the work yourself, then test your consultant's understanding and methodology; do they "feel" right?
- "Name brand" firms seldom work for start-up budgets
- Beware hiring for equity; will you get objectivity?

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Bad Advice: The Seven Deadly Sins of Opportunity Assessment

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Sin #7

Keep your product concept fluid and
your product description vague.....

.....that way you can readily deflect
constructive criticism.

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Sin #6

Tomorrow's competitors
equals
today's competitors.

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Sin #5

You must always satisfy your stakeholders.....

.....so be sure your market “estimates” match the revenue projections.

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Sin #4

Just use the data in that 5-year-old F&S report.....

.....it’s not exactly your market, but it’s close enough.

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Sin #3

Customer enthusiasm
equals
customer orders.

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This slide features a dark blue background with a lighter blue curved graphic on the right side. The text is centered and presented in a white serif font.

Sin #2

Never speak to prospective
customers.....

..... they will derail your carefully
formulated product plans.

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Sin #1

Don't waste your resources doing
market research

.....just ask your Scientific Advisory
Board.

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39

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40