

MedTech South/Wholeberg Ventures

Information to Start a Dialogue - Device, Concept, Drug/Molecule, Company

- 1) Concept name
- 2) Problem solved/patient need
- 3) Clinical use description
- 4) Devices it replaces/supplants/competes with, cost thereof, why it's better (identify competitors and their strengths/vulnerabilities)
- 5) History of the idea/device/company
- 6) Potential demand/Market (number of procedures, disease statistics, demographics, world regions, single use/disposable, multi-use, etc.)
- 7) Regulatory approval path and issues (include description of any contact with FDA to-date)
- 8) Reimbursement potential (ICD/CPT Codes, Method of reimbursement for current alternatives – stand-alone reimbursement, included in a kit, included in procedure reimbursement, per use, etc. – range of reimbursement amounts)
- 9) Barriers to use/physician or practitioner acceptance
- 10) Inventors' names/Idea source/Research Institution where discovery originated
- 11) Inventors' areas of expertise
- 12) Intellectual property protection (owned, licensing availability and status, identity of IP owner(s), Freedom to Operate opinion, Status of US and international filings, etc.)
- 13) Licensing terms (royalty percentage, milestone payments, responsibility for future patent prosecution costs, fields of use, geographic scope, etc.)

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- 14) Status and next steps (concept, prototypes exist, preclinical research performed, clinical research, FDA filing/FDA approval/C-Mark, etc.)
- 15) Description of research performed/planned (type of study, endpoints, outcome, GLP/Non-GLP)
- 16) Potential collaboration partners and their roles
- 17) Ballpark development calendar (milestones, durations, dates)
- 18) Milestones (attained, future): end-points, timing, costs
- 19) Business objective/endpoint (develop device, build business package, build complete company, etc.)
- 20) Potential exit targets
- 21) Amount of funding (to-date, sources, needs and associated milestones/usage)
- 22) Potential funding sources
- 23) Who has been approached? Responses? Terms sheets?
- 24) Company name or legal entity currently in place to develop and/or commercialize the device, concept, drug, etc.
- 25) Company principals/team (include bios)

Skill/Area of Expertise	Company Principal Having Skill/Expertise	Additional applicable Principal Name(s)
1) Business Organization & Establishment		
2) Business Plan Development		
3) Fund Raising & Investor Relations		

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4) Medical/Clinical		
5) Device Engineering		
6) Intellectual Property Management		
7) Contracting		
8) Concept Validation (with medical practitioners, device companies, etc.)		
9) Pricing Strategy Development		
10) Financial & Operational Modeling		
11) Bench (In Vitro) Testing		
12) Preclinical Research		
13) Clinical Trials		
14) Regulatory		
15) Reimbursement		
16) Sourcing		
17) Prototype Manufacturing		
18) Branding & Positioning		
19) Marketing		
20) Sales		
21) Channel Partner Relationships		
22) Logistics & Distribution		
23) Billing & Collections		

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24) Finance & Accounting		
25) Legal		

- 26) Leader's motivation
- 27) Medical/Therapeutic area knowledge within team
- 28) Entrepreneurial experience of the team
- 29) Company ownership, forms of ownership, ownership distribution/percentages/shares
- 30) Board of Directors, Board of Advisors (names, web sites, CVs)
- 31) Financial obligations (loans, notes, securities, etc.)
- 32) Legal proceedings (in-process, anticipated, suspected)
- 33) Other encumbrances