

# IDEA HARVEST

## Structured concept generation and down-selection for complex medical device challenges.

Early in medical device development, uncertainty is high, but the cost of changing direction is still relatively low. Idea Harvest is a focused, milestone-driven engagement that helps your team define a difficult development problem, generate credible alternatives, compare trade-offs, and decide what to prototype or test next.

| 4-6 WEEKS        | 2-4 LEADS              | 3 MILESTONES            | CLIENT IP               | DEFINED FEE            |
|------------------|------------------------|-------------------------|-------------------------|------------------------|
| TYPICAL DURATION | FROM A BROAD PORTFOLIO | KICKOFF, INTERIM, FINAL | YOUR IDEAS REMAIN YOURS | FIXED OR NOT-TO-EXCEED |

### WHEN IDEA HARVEST FITS

Idea Harvest is useful when:

- An unresolved technical or clinical limitation is blocking progress.
- Several architectures are plausible, but the trade-offs are unclear.
- A next-generation device needs alternatives to the current approach.
- Prior art or competitive constraints require design-around options.
- The team is preparing to invest in prototypes or testing but is not aligned on what to build.

### HOW IDEA HARVEST WORKS

- 01 REVIEW** Existing concepts, program history, test data, user feedback, and relevant prior art.
- 02 FRAME** Problem statement, constraints, assumptions, and success criteria.
- 03 GENERATE** Alternative mechanisms, architectures, and design approaches.
- 04 EVALUATE** Clinical value, usability, feasibility, risk, cost, and development effort.
- 05 RECOMMEND** Prioritized leads and a focused plan for prototyping and testing.

### WHAT THE ENGAGEMENT DELIVERS

- A written problem and design brief.
- A portfolio of candidate concepts supported by sketches, mechanisms, architectures, or operating principles.
- A transparent comparison against agreed clinical, usability, technical, business, and development criteria.
- An optional preliminary review of relevant patents and published applications, including design-around considerations and invention disclosure support.
- Two to four prioritized leads with advantages, risks, unresolved questions, and development considerations.
- A recommended next phase identifying the prototypes, experiments, analyses, and resources required.
- An interim review and final working session with your team.

### WHERE THIS FITS

|                                                                                    |                                                                            |                                                                                        |
|------------------------------------------------------------------------------------|----------------------------------------------------------------------------|----------------------------------------------------------------------------------------|
| <b>01 IDEA HARVEST</b> 4-6 weeks<br>Define the problem and decide what to develop. | <b>02 PROVE</b> scoped<br>Build targeted prototypes and generate evidence. | <b>03 DEVELOP</b> scoped<br>Advance the selected concept toward preclinical readiness. |
|------------------------------------------------------------------------------------|----------------------------------------------------------------------------|----------------------------------------------------------------------------------------|

Each phase is scoped and approved separately.

### THE M11 TEAM

Mountain's 11 assembles a focused team of senior product-development specialists around each client's specific challenge. The core studio is supported by the M11 Consortium, a trusted network of engineering, clinical, regulatory, quality, intellectual-property, manufacturing, and commercialization experts.

Together, the team brings more than 50 years of implantable-device experience and hundreds of issued patents across cardiovascular, neurovascular, structural heart, and general surgical applications.

Capabilities include self-expanding nitinol implants, balloon-expandable metallic devices, ePTFE and other biocompatible polymers, catheter systems, rapid prototyping, bench testing, failure analysis, and durability.

### HOW WE WORK

- Client IP protection: comprehensive NDAs, secure communication, and strict internal protocols. Your ideas remain yours throughout our partnership and beyond.
- Potential conflicts are disclosed promptly and managed transparently.
- Three core milestones - kickoff, interim review, and final working session - keep progress, scope, and decisions visible.
- Scope, assumptions, deliverables, and the fixed or not-to-exceed fee are agreed before work begins.

## START WITH A 45-MINUTE SCOPING CONVERSATION

Bring a defined development challenge and one or two people closest to it. We will clarify the problem, identify the expertise and information needed, and send you a written problem frame you can use either way — along with a tailored Statement of Work if Idea Harvest is the right next step.

