

Brigham Ignite Seed and Development Award Application

Full Proposal Review Criteria

Proposal Section	Review Criteria
Background	<ul style="list-style-type: none">• Has sufficient background been provided to help evaluate<ul style="list-style-type: none">○ the scope and nature of the problem?○ the current standard of care?○ the market “space” in which this product would operate?
Unmet Need	<ul style="list-style-type: none">• Has the clinical need clearly been stated?• Has the need been articulated from the perspectives of the relevant stakeholders?• Has evidence of the need been provided?
Proposed Product/Solution	<ul style="list-style-type: none">• Does the application clearly describe the patient subset and setting to which this technology would apply?• Is the expected benefit with this solution/product clear?• Does the applicant describe how it would fit with current physician practice / standard of care?• Is there sufficient evidence to support the expected benefit? Are appropriate proof-of-concept research findings referenced?• Does the envisioned technology deliver unique end user or patient benefit? Is there a clear characterization of the benefit, e.g., exponential or incremental, faster, smaller, cheaper, easier, safer, more effective, more accurate?• Does the technology offer solutions to additional unmet needs (ie. as a potential platform)?
Market Size	<ul style="list-style-type: none">• Has applicant identified the potential market? Has the applicant provided adequate justification for the market size and considered future trends and projections?• Has the applicant identified the addressable target market size? Have the end user/patient populations been estimated realistically?• Has the applicant identified expected pricing of the product/solution?• Is the basis for the justification reasonable (comparable to analogous products, value/price trade-offs)?
Competitive Landscape and Differentiation	<ul style="list-style-type: none">• Has the applicant identified current and anticipated players in the space, and the competitive products they are developing and/or selling?• Has the applicant described the adjacent spaces and substitution options along with how the landscape is shifting or projected to shift?• Has the applicant described how the product/solution would be better than other options that are currently in use?• Is the data provided sufficient to support potential product differentiation?

- Intellectual Property
- Has the applicant described an IP protection strategy? Is the current IP status clearly described with regard to whether:
 - the invention has been disclosed, and if not, when it will be;
 - what will be covered by IP (e.g. formulation, method of use);
 - appropriate IP filings are proposed and/or made, and the status;
 - there have been prior licensing events and if so, how that effects the strategy?
 - Are the types of IP proposed, or filed, appropriate to protect the invention?
- Regulatory Path
- Has the applicant described an expected regulatory pathway?
 - Does the applicant describe regulatory risks in reasonable detail with respect to the stage of development of the technology?
 - What regulatory uncertainties/challenges have been foreseen?
- Reimbursement Pathway
- Has the applicant described products/services that exist in the market currently and how they are paid for?
 - Has the applicant described the anticipated model for paying for the proposed product/service, and whether it is similar or different than how currently available solutions are paid for?
- Project Plan
- Does the applicant describe the ultimate goal of the project and when that goal would be achieved?
 - Does the applicant describe the major milestones that need to be achieved and how success will be measured?
 - Would the achievement of the milestones increase the value of the product?
 - Does the applicant reference appropriate stakeholders or customers for validation?
 - Are the go/no-go decision points described in the plan appropriate?
 - Are any significant potential risks to the plan described, and are potential mitigations included?
 - Do you foresee any significant technical gaps or complexities that are not identified or addressed?
 - Are the plans for technology development anticipated beyond this project reasonable?
- Personnel
- Are the qualifications of the team members appropriate for the work that needs to be done? Does the team demonstrate core competencies and strengths in
 - the scientific and technological domains,
 - technology development experience,
 - clinical evaluation expertise,
 - business development experience,
 - regulatory strategy experience,
 - marketing experience, and
 - IP strategy experience?
 - If deficiencies exist, is there a mitigation plan?