Brigham Ignite Seed and Development Award Application

Full Proposal Review Criteria

Proposal Section	Review Criteria
Background	- Has sufficient background been provided to help evaluate - the scope and nature of the problem? - the current standard of care? - the market "space" in which this product would operate?
Unmet Need	- 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	- 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	- 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	- 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?