

Background

Has sufficient background been provided to help evaluate

- The need and the solution?
- The market "space" in which this product would operate?
- The current standard of care?

Unmet Need

- Has the clinical need clearly been stated?
- Has the expected need from the perspectives of the relevant stakeholders been articulated? Has evidence of the need been provided?

Proposed Product/Solution

- Does the application capture the patient subset to which this is applicable?
- Is the expected benefit with this solution/product clear? Is there sufficient evidence to support the expected benefit (stakeholder opinions)?
- Is there a clear characterization of the benefit, e.g., exponential or incremental, faster, smaller, cheaper, easier, safer, more effective, more accurate?
- Does the applicant describe how it would fit with the current physician practice/standard of care?

Market Size

- Has the applicant identified the total market? Has the applicant provided adequate justification for the market size and considered future trends and projections?
- Has the applicant identified the specific addressable target market size and the expected pricing of the product/solution? Is the basis for the justification reasonable (comparable, value/price trade-offs)?

Competitive Landscape

- 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?

Intellectual Property

- Has the applicant described the IP protection strategy in sufficient detail?

- Are the types of IP proposed, or filed, appropriate to protect the invention?
- Are there other forms of IP protection that the applicant should consider that may be more appropriate (e.g., protecting by trade secret instead of filing patent applications)?
- Is the IP tied to the commercialization plan?

Differentiation

- Has the applicant described how the product/solution is better than others that are currently in use and how the product/solution is better than what is expected to come to the market?
- What data should be generated to support differentiation?

Regulatory Path Comments

- Has the applicant described an expected regulatory pathway?
- What regulatory uncertainties/challenges do you foresee?

Reimbursement Comments

- Has the applicant described the product/service that is currently being covered and what would be a comparable?
- Has the applicant included reimbursement rates for the relevant CPT codes?

Funding Requirements

- Are the financing requirements realistic as they are described?
- Are they tied to Go/No-go decisions?

Product Development Milestones

- Does the applicant describe the ultimate goal of the product development plan and when that goal would be achieved?
- Does the applicant describe the major milestones that need to be achieved in order for the plan to be successful? Would the achievement of the milestones increase the value of the product? Does the applicant reference appropriate stakeholders or customers for this validation?
- Are the Go/No-Go decision points described in the plan appropriate?

Potential Risks / Mitigation

Are the potential risks well described with regards to the:

- Scientific goals
- Technical goals
- Personnel
- Market

- Commercialization

Does the applicant describe how those risks can be mitigated?

Personnel

Are the qualifications of the team members appropriate for the work that needs to be done?

Overall Comments