Product Profile: Diagnostic

A product profile provides a structure for the scientific, technical, clinical, and market information that is required to achieve a desired commercial outcome. It provides all stakeholders with a clear vision of the product objectives and helps guide research and development decisions. It is a dynamic strategic document that should be reviewed throughout the development process. *It identifies the aspirational and minimal product attributes and claims that are key indicators for success. These will be the thresholds that you will use to determine if your product's testing and metrics are acceptable.*

While filling out this form, consider how the diagnostic compares to and improves upon its competitor.

Product Name	
Product Description Detailed description of the product including its parts/components, the mechanism by which the diagnostic targets the clinical disease, if it will be used independently or in combination with other diagnostics and if software is involved	
Unmet Clinical Need Description of the unmet clinical need and how the product will change medical practice. Consider how the clinical need is currently addressed.	
Intended Use Name of analyte, specific indications, characteristics of the target population and users, diagnostic setting (lab, point of care), specimen type, and timing	
Freedom to Operate and IP Position Consider the novelty of your technology and patent eligibility. Describe the extent of interactions with the technology transfer office. Please include a list of the various types of IP filed or granted (including patent application number, issued patent number, title, status and date) and the major types of claims (e.g., composition of matter claims, use claims, process of manufacturing claims). Also list the IP events anticipated during development.	

Manufacturability The ease and cost of manufacturing including: availability and cost of starting material; scalability of manufacturing process; total yield from readily available starting material; and competitor's cost.		
Comparative Diagnostic & Reference Methods Clinical reference method and current diagnostic(s) that will be used for comparison. Also include a brief competitive analysis of developing diagnostics.		
Assay Interpretation Criteria to be used during clinical trial (especially important for qualitative assay)		
Performance Requirements How much or how well the device must perform, including sensitivity/specificity, positive and negative predictive values, reproducibility/precision, limit of detection, and cross/reactivity. Review these characteristics here. *This should **NOT** be the observed measurements of the diagnostic. This information should list the target and minimal criteria the diagnostic must meet to be considered successful. The criteria will guide the decision making process and provide you with a checklist of metrics your diagnostic must meet.*	***Target***	***Competitor***
Human Factor Considerations Contraindications and design considerations to ensure safe and effective use by the target population and users	***Target***	***Competitor***
Single Analyte Is your assay a single analyte of a multiplex assay?		

CLIA Waiver Likelihood of a CLIA Waiver		
Packaging Packaging necessary for the diagnostic. Consider how it will be stored; home or hospital setting; the expected shelf life, etc. *Packaging of comparative diagnostic should be referenced.*		
Labeling Labeling necessary for the diagnostic including labeling to identify components, measurements, results, etc. *Labeling of comparative diagnostic should be referenced.*		
Nonclinical Testing Additional testing (e.g. efficacy) that will be performed, including bench, in vivo, computer simulations, sterility, biocompatibility, robustness, etc. Consider how you will scale-up fabrication for testing.		
Clinical Studies Study model, testing, and clinical data necessary to support use and for FDA clearance. Consider competitive position and marketing strategy.		