CARB-X
Combating Antibiotic Resistant Bacteria

Development Stages in Scope
Diagnostics

CARB-X only supports diagnostics proposals in the development stages outlined below, some guidance is provided below as to typical activities that would be considered in or out of scope in line with these stages.

Characterization of Preliminary Candidates(s) and Feasibility Demonstration: Sufficient data to support the feasibility of the approach including data that the pathogen of interest can be detected. Have an early concept of how it would be utilized in treatment pathways and paradigms and how it would be differentiated from others on the market and in development. Be able to scope out downstream critical path activities, evaluate critical requirements and outline a high level target product profile including provisional specification.

Optimization: Optimization and Preparation for Assay, Component, and Instrument Development. Prepare for test system development. Finalize diagnostic target(s) and methods for detecting or quantitating target(s). Develop detailed plans and finalize critical design requirements. Execute commercial agreements with key external development partners. Identify manufacturing resources, vendor sourcing, and experimental designs.

Product Development: Reagents, components, subsystems and modules - Develop reagents and buffers. Build and test non-GLP prototypes of components and subsystems. Code and unit test software. Begin pilot scale manufacturing preparations. Develop protocols for assay and integration testing Initiate reagent stability testing. Hold pre-IDE meeting with FDA.

System Integration and Testing: Integrate and test alpha and beta instruments/devices, software and assays, evaluating performance and updating specifications. Implement design improvements to address defects discovered during testing. Produce and evaluate pilot lots of reagents and beta (pilot) instruments. Increase the maturity of software. Prepare for clinical testing. Complete short term stability testing of reagents. Technology demonstrated in a laboratory environment including studies on clinical samples (or clinical feasibility studies). Generate a health economics assessment that supports the approach.

Out of scope (too late, beyond CARB-X funding):

- Clinical validation of the technology including demonstration in a relevant clinical environment to support regulatory filings on near market version of diagnostic/device.
- Longer term studies in support of regulatory filings such as long term stability.
- Marketing support including submission of marketing approvals.
- Manufacturing of the final instrument to be marketed and associated scale-up activities

The following are more broadly outside of the scope of the call:

- Research use only instruments
- Biomarker ID and development
- Purely detecting bacterial vs viral without ID or AST
- Surveillance or screening rather than diagnosis
- Informatics proposals

The following can only be included if part of a broader diagnostic development package but will not be considered as an application in isolation

- Library building
- Sample preparation development
- Device design