CARB-X
Combating Antibiotic Resistant Bacteria

Development Stages in Scope
Diagnostics

CARB-X supports diagnostics proposals for bacterial ID and/or AST/AMR 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.

Feasibility: Benchtop feasibility demonstrated with clinical specimens. Sufficient data to support the feasibility of the approach including data that the pathogen of interest can be detected. Scope-out downstream, critical-path activities, evaluate critical requirements and outline a high-level target product profile. For instrument-based systems, develop and evaluate an initial prototype of the system or of high-risk modules, including software. Demonstrate understanding of relevant clinical care pathway and testing algorithms and how product would be differentiated from competition. Continue prototype testing, as required, to support assay development. Finalize diagnostic target(s) and methods for detecting or quantitating target(s). Develop detailed product development plans and finalize critical design requirements. Finalize initial instrument and software architecture, incorporating input on manufacturability of proposed product. Identify and execute commercial agreements with key external development partners. Begin implementing a Quality Management System; draft regulatory strategy, intended use statement, analytical and clinical study plans. Complete technology transfer from Research to Development.

Development: Develop reagents and buffers. Build and test prototypes of components and subsystems. Code and unit test software. Build first release of instrument software for integration testing. Develop protocols for assay and integration testing. Finalize User Interface specification. Produce initial assay lots with quantities sufficient to initiate real-time stability studies on development lots. Demonstrate key product requirements, including sensitivity and specificity, with fully integrated prototype using clinical samples, preferably in the hands of external users. Continue implementation of a Quality Management System. Prepare for pre-submission with the FDA or relevant Stringent Regulatory Authority (SRA).

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

- Late-stage product development (Beta System development)
- Verification and Validation testing
- Pilot lot production of reagents and instruments
- Clinical validation of the technology including demonstration in a relevant clinical environment to support regulatory filings
- Longer term studies in support of regulatory filings such as long-term stability studies.
- Marketing support including submission of marketing approvals.
- Manufacturing of the final instrument to be marketed and associated scale-up activities