CARB-X
Combating Antibiotic Resistant Bacteria

Development Stages in Scope
Vaccines

What CARB-X considers a "Hit" when identifying your project/program in "Hit-to-Lead"?

- Vaccine antigen(s) has been identified and supportive immunogenicity data in appropriate animal models have been generated.
- Understanding of the presence and sequence heterogeneity of antigen(s) across isolates that are epidemiologically-relevant to the proposed patient population

Hit-to-Lead (Lead Generation)

- Characterization of the immune response to the antigen(s) *in vivo*, with mechanism for protection defined
- Determination of the optimal antigen expression (or vaccine production) system
- Preliminary characterization for product quality attributes (lab scale) such as purity, protein conformation, stability, yield, etc., as appropriate
- Adjuvant/formulation screening studies
- Standardization of methods to assess immunogenicity in relevant animal models

Lead Optimization

- Determination of final vaccine product composition (e.g., adjuvant, delivery platform, etc.)
- Qualification of assays to assess immunogenicity and functional antibody and/or cellular response
- Determination of Immunogenicity/efficacy in animal models with route of immunization, regimen, and endpoints to reflect clinical plans
- Assay development to quantitate potency
- Cell bank generation (research)
- Reproducibility runs performed at lab scale and appropriate analytical characterization
- Assessment of stability profile
- Tech transfer and scale-up of vaccine production
- Development of analytical assays for vaccine product release
- Elaboration of a clinical development plan
- Pre-IND consultation (or guidance sought from another relevant regulatory body)

Pre-Clinical (IND Enabling)

- Production and release of Master (and Working, if appropriate) Cell banks
- Qualification and validation of the analytical release assays
- Upstream and downstream process development for GMP scale
- Engineering run
- Toxicology studies
- GMP manufacture of vaccine material for clinical study
- Product characterization at production scale to demonstrate purity, stability, and potency, and product released as per regulatory guidelines
- Submission of IND to US FDA (or clinical trial application to another relevant regulatory body)

Phase 1

- Dose-escalation study in healthy volunteers to determine safety, to include endpoints for assessing immunogenicity and potential vaccine efficacy
- Activities related to Phase 2 readiness, (e.g., vaccine manufacture, assay validation, plans for onward clinical development, etc.)