CARB-X
Combating Antibiotic Resistant Bacteria

CARB-X Therapeutics – Target Product Profile		
Variable	Minimal Requirement	Ideal Requirement
Primary Product Indication		
Organisms covered		
Patient Population		
Treatment Duration		
Delivery Mode		
Dosage Form		
Regimen		
Efficacy		
Risk/Side Effect(s)		
Competitive Differentiation Envisioned for Product Launch (consider marketed products + those in developments)	Minimal Requirement	Ideal Requirement
Specific Populations Claims		
Key Differentiating Claims		
Overall Value Proposition: Summarize what the desired product would bring to the infectious disease physicians armamentarium:		

Competitive Differentiation Matrix			
	Competitor 1	Competitor 2	Competitor 3
Overview: Brief description of how the competitor is used clinically, whether it is considered standard-of-care. Are there dosing restrictions in certain populations etc.?			
Differentiation Areas: What liabilities do the competitor molecules possess and which attributes will your product have/need to enable penetration into the marketplace? Add rows for each general category (e.g. safety, dosing regimen etc.)			
Clinical Comparator: Will this compound likely be a comparator used during clinical development of your product?			

The competitor products should also include molecules that are currently in clinical development and may represent the standard-of-care in the future.

CARB-X Therapeutics – Guidance Notes

Please find below some aspects you may wish to cover within the Target Product Profile, this is not a comprehensive list and should be added to as appropriate to best describe the positioning.

1. It is important to have an aspirational goal as well as a minimal requirement. This is not necessarily as a prescriptive formula but more of a way to ensure that there is a discussion around relevant aspects. The minimal requirement should be clinically and commercially relevant.
2. A good TPP should be assembled with knowledge (and acknowledgment) of the competition and where areas of improvement can and should be made. Thinking significantly about the competition should enable increased attention to the aspects that would best differentiate the final product and not just result in another me-too therapeutic.
3. The TPP should include some "Key claims for product launch" - both at a minimum level, which should provide enough differentiation of the product from others used for the specific indication, but also some aspirational product claims. Thinking about what claims can be made at launch should focus thinking toward the best preclinical data package and clinical trial design to be able to have those claims demonstrated. Although clinical trial strategies may be in the future for some early projects, deliberation about what eventually will need to demonstrated clinically will help programs focus around things like spectrum, dosing regimens etc. These key claims can be in several areas and some examples are:
    a. Microbiology – claims around spectrum, resistance propensity, activity against pre-existing resistance etc. and should help with product differentiation.
    b. Clinical – are there sub-types of infections that are treatable or goals of clinical success levels? Will the product be a monotherapy, or would a combination be advantageous to superior treatment? What evidence will be required to support a specific dosing regimen, and will this be a commercial differentiator?
    c. Safety – often the biggest area to enable differentiation claims.
4. Within the patient population section, it is easy with antibacterial to state the broadest indication without thought as to whether the final product could be used empirically or how will the specific patient population be selected, both from the perspective of patient enrollment but also to how the product would be used clinically. We encourage applicants to think about patient stratification needs and methods. Intentions to address specific sub-populations (e.g. pregnant, nursing, and pediatric) should also be noted.
5. Given that one focus of some CARB-X funders in LMIC, there should be comments with respect to access, prevalence, cost of goods constrains (if applicable).

Reference:

The CARB-X Therapeutics structure is based off the NIH TPP. Please see the web link for examples. The CBER Office of Cellular, Tissue and Gene Therapies (OCTGT) web page for industry education also has a Webinar on TPP