CARB-X
Combating Antibiotic Resistant Bacteria

CARB-X Vaccines Target Product Profile		
Variable	Minimal Requirement	Ideal Requirement
Primary Product Indication		
Target Population		
Efficacy		
Vaccine modality (e.g., protein, vector, particle, etc.)		
Safety and reactogenicity		
Route and method of administration		
Dose and schedule		
Durability of protection		
Product presentation (eg., liquid, lyophilized, mono or multidose and etc.)		
Dosage form		
Co-administration with other vaccines		
Shelf life and storage		
Competitive Differentiation for Product Launch	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 products 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 those that are currently in clinical development and may represent the standard-of-care in the future.

CARB-X Vaccines 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 of your product.

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 appropriate discussion around relevant aspects.
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 vaccine.
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 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 be demonstrated clinically will help programs focus around key attributes like spectrum, dosing regimens etc. These key claims can be in several areas and some examples are:
    - Microbiology – claims around target organism strain coverage, resistance propensity, activity against pre-existing resistant strains, etc. should help with product differentiation.
    - Clinical – are there goals around levels of clinical success? What evidence will be required to support the specific dosing regimen, and will this be a commercial differentiator?
    - Safety – often the biggest area to enable differentiation claims.
4. Within the patient population section, consider whether the final product would be used broadly or how will the specific patient population be selected, both from the perspective of patient enrollment in trials and how the product would be used after approval. 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, potential stewardship benefits, and cost of goods constraints (if applicable).

Reference:

The CARB-X Vaccines 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

CARB-X Antibodies Target Product Profile		
Variable	Minimal Requirement	Ideal Requirement
Primary Product Indication		
Patient Population		
Treatment Duration		
Route of Administration		
Dosage Form		
Regimen		
Efficacy		
Safety and Reactogenicity		
Therapeutic modality (e.g., antibody, antibody fragment, etc.)		
Co-administration with other drugs		
Shelf life and storage		
Competitive Differentiation for Product Launch	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 products 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 those that are currently in clinical development and may represent the standard-of-care in the future.

CARB-X Antibodies 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 of your product.

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 appropriate discussion around relevant aspects.
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 antibodies.
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 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 be demonstrated clinically will help programs focus around key attributes like spectrum, dosing regimens etc. These key claims can be in several areas and some examples are:
    a. Microbiology – claims around target organism strain coverage, resistance propensity, activity against pre-existing resistant strains, etc. should help with product differentiation.
    b. Clinical – are there goals around levels of clinical success? What evidence will be required to support the specific dosing regimen, and will this be a commercial differentiator?
    c. Safety – often the biggest area to enable differentiation claims.
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