## Clinical Differentiators

**Clinical Differentiator 1. Efficacy:** eg 15% reduction in a composite endpoint in high-risk patients with documented CHD (incl. ACS) or CHD risk-equivalent disease with/without additional risk predictors on current standard clinical therapy. …

**Clinical Differentiator 2. ....**

**Clinical Differentiator 3.….**

## Economic Differentiators

**Economic Differentiator 1.**

**Economic Differentiator 2.**

## Pricing & Reimbursement Assumptions

**Future Pricing & Reimbursement Environment**

**Price Range & Reimbursement Goal**

## Other Assumptions (Technological Trends, Diagnostic Tests, Biomarkers)

## Key Considerations for a Minimum Acceptable Profile

## Global Peak Sales Value Range

e.g., £300-£700m
### Key Questions to Consider in TPP Discussions

| **Product Goal** | • A single sentence describing the strategic intent of this profile  
• What is it that is trying to be delivered |
| **Target Patient Population** | • Which specific subpopulations of this disease does the opportunity lie and the geographic strategies? |
| **Current & Future Standard of Care (Products / Classes in Development)** | • How high is the hurdle for a new entrant?  
  - efficacy level of current gold standard  
  - level of genericisation  
  - future standard of care (~10 years forward)  
  - may need to distinguish between payer and physician perspectives |
| **Unmet Medical Need** | • What is the unmet need that is seen by the physician and patient as well as the payer?  
  • Have you any market research to underpin this? |
| **Clinical Differentiators** | • What clinical differentiators do you need to deliver in order to create medical value?  
  • Need to be specific about which Efficacy parameters (depth, speed, sustainability) – with clarity on efficacy safety hurdles so that studies can be designed appropriately eg endpoints where appropriate  
  • What other aspects drive incremental clinical differentiation Safety, tolerability, dosing |
| **Economic Differentiators** | • Aspects that drive value such as cost of illness, cost effectiveness, incremental value in sub-population)  
  • Are there any Economic Differentiators that may deliver medical value (less time off work or less hospitalizations?) |
| **Reimbursement & Pricing** | • What does the future pricing & reimbursement environment look like?  
  • Have you delivered enough medical value?  
  • What would someone pay for this increment?  
  • If the molecule was successful in every way, what medical value would it have in the market place over what already exists?  
  • Which elements of the TPP would drive a positive reimbursement?  
  • Need to think about Price & Reimbursement in terms of (Current Standard of Care / Future Standard of Care/ New Assets / Across regions (US/EU/EMAP)  
  • Reimbursement levels may change depending on the sub-segment of patients that is targeted |
| **Other** | • What Diagnostic Tests / Biomarkers would be needed to define sub-population segment?  
  • What technological trends are affecting the delivery of a an asset to this market eg Biopharmaceutical? |
| **Key Considerations for a Minimum Acceptable Profile** | • What are the absolute requirements for a minimum acceptable profile eg must have Clinical differentiator 1 – but 2 & 3 would not have success in their own right  
  • Please consider the trade-offs between the attributes that may go to produce a minimum acceptable profile – may need to refer to attributes not mentioned as key value drivers |