

Template — Target Product Profile (TPP)

MILESTONE DEFINITION	DECISION CRITERIA	EXAMPLE DATA REQUIREMENTS	GATE REVIEW GUIDELINES
<p>Target Product Profile initiated</p> <p>(*The TPP is initiated prior to the LCS gate review and is updated & reviewed during development through to the DTF gate review)</p>	<ul style="list-style-type: none"> ▪ Product-specific content per BMGF TPP template requirements is provided; examples include: <ul style="list-style-type: none"> – Drug need, use case, market, and impact on global health defined – Product characteristics required to show benefit (Minimum TPP / Optimistic TPP), such as efficacy, safety, and duration of treatment outlined – Aligned with disease-specific strategies of the BMGF and partner organizations (e.g., all product development co-partners, WHO, etc.) <p>Note: In portfolio grants, a TPP is initially disease area focused and is replaced by a product-specific TPP once a preclinical candidate has been selected</p>	<ol style="list-style-type: none"> a) Indication, use case b) Target population c) Global health impact d) Proposed mechanism of action e) Primary endpoints and secondary endpoints (e.g., safety, efficacy, duration of treatment, etc.) f) Manufacturability g) Formulation, dosing, and stability h) Route of administration i) Shelf-life and storage j) Cost and delivery considerations driven by disease burden analysis (e.g., target countries, primary target, delivery channel) k) Product registration strategy 	<ul style="list-style-type: none"> ▪ At early development stages, all variables may not be fully known; teams should develop TPP based on available information (i.e., draft TPP is sufficient at the LCS gate review) ▪ TPP will be updated as data are generated throughout the drug development process, the competitive landscape evolves, and new disease data emerge ▪ TPP updates and completion timing are product specific; specific data requirements and timelines should be developed at project initiation and monitored through milestone gate reviews ▪ TPP should be finalized prior to the DTF gate review (i.e., prior to registration)

Additional Resources - *Target Product Profile (TPP)*

Add'l Resources

- TPP Examples

1. TPP Overview Article-

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3479626/>

2. FDA TPP-

<http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm080593.pdf>