# Target Product Profile: Therapeutics

A product profile provides a structure for the scientific, technical, clinical, and market information that is required to achieve a desired commercial outcome. It provides all stakeholders with a clear vision of the product objectives and helps guide research and development decisions. It is a dynamic strategic document that should be reviewed throughout the development process. *It identifies the aspirational and minimal product attributes and claims that are key indicators for success. These will be the thresholds that you will use to determine if your candidate's testing and metrics are acceptable.*

**While filling out this form, consider how the therapeutic compares to and improves upon its competitor.**

| **Product Name** | |
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| **Product Description**<br>Brief description of the therapeutic including its purpose, route of administration, dosage, and if it will be accompanied by a companion diagnostic. | |
| **Unmet Clinical Need**<br>Description of the unmet clinical need and how the product will change medical practice. Consider how the clinical need is currently addressed. | |
| **Indication**<br>Target disease or manifestation of a disease and/or population. Include examples of specific patient population(s). | |
| **Comparative Therapeutic**<br>Current therapeutic(s) that will be used for comparison and a brief competitive analysis of developing therapeutics | |
| **Mechanism of Action (MOA)**<br>The mechanism by which the product produces an effect on a living organism. | |

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| **Clinical Pharmacology**<br><br>Pharmacokinetic information, distribution and pathways for transformation.<br><br>*This should **NOT** be the specific pharmacology of the compound you are investigating. This information should list the acceptable criteria a developmental candidate must meet to be considered a lead candidate. The criteria will guide the lead clinical candidate decision making process and provide you with a checklist of metrics your compound must meet.* | |
| **Target Metrics**<br><br>List your target and include the following metrics:<br><br>***Small molecule targets***: druggability, novelty, validation, and potential mechanistic-based toxicity<br><br>***Antibody targets***: if it is a surface protein, likelihood of delivering a therapeutic effect with your specific antibody approach (naked antibody, conjugated antibody, immunotherapy), validation, and specificity of expression. | |

| Developmental Candidate Selection Criteria | | | |
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| **Freedom to Operate and IP Position**<br><br>Consider the novelty of your technology and patent eligibility. Describe the extent of interactions with the technology transfer office. Please include a list of the various types of IP filed or granted (including patent application number, issued patent number, title, status and date) and the major types of claims (e.g., composition of matter claims, use claims, process of manufacturing claims). Also list the IP events anticipated during development. | | | |
| **Manufacturability**<br><br>The ease and cost of manufacturing including: availability and cost of starting material; scalability of manufacturing process; total yield from readily available starting material; and competitor's cost. | | | |
| **Developmental Candidate Potency**<br><br>The developmental candidate's targeted potency in a biochemical assay, cell-based assay and animal model. Consider potency of competitors.<br><br>*This should **NOT** be the observed measurements of the compound you are investigating. This information should list the acceptable criteria a developmental candidate must meet to be considered a lead candidate. The criteria will guide the lead clinical candidate decision making process and provide you with a checklist of metrics your compound must meet.* | ***Biochemical assays:*** | ***Cell-based assay:*** | ***Animal model:*** |
| **Developmental Candidate Specificity**<br><br>The developmental candidate's targeted specificity as compared to other members of the target family, and against a broader panel of proteins.<br><br>*This should **NOT** be the observed measurements of the compound you are investigating. This information should list the acceptable criteria a developmental candidate must meet to be considered a lead candidate. The criteria will guide the lead clinical candidate decision making process* | ***Compared to other members of the target family:*** | ***Against a broader panel of proteins:*** | |

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| *and provide you with a checklist of metrics your compound must meet.* | | | |
| **<u>Biocompatibility</u>**<br>ADME/PK Properties, on-off rate, solubility, stability<br>*This should **<u>NOT</u>** be the observed measurements of the compound you are investigating. This information should list the target and minimal criteria a developmental candidate must meet to be considered a lead candidate. The criteria will guide the lead clinical candidate decision making process and provide you with a checklist of metrics your compound must meet.* | ***Target:*** | ***Minimal:*** | ***Competitor:*** |
| **<u>Safety & Toxicology</u>**<br>Safety & toxicology profile and requirements to be met (e.g. non-clinical toxicology). Include testing that will be conducted prior to entering clinical testing.<br>*This should **<u>NOT</u>** be the observed measurements of the compound you are investigating. This information should list the target and minimal criteria a developmental candidate must meet to be considered a lead candidate. The criteria will guide the lead clinical candidate decision making process and provide you with a checklist of metrics your compound must meet.* | ***Target:*** | ***Minimal:*** | ***Competitor:*** |

| Lead Candidate Criteria | | | |
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| **Primary Efficacy Endpoints**<br>The most important clinical outcome measure. Ideally should be easy to interpret and sensitive to treatment differences.<br>*This information should list the target and minimal efficacy endpoints the clinical candidate must meet to obtain a successful positive clinical trial result.* | ***Target:*** | ***Minimal:*** | ***Competitor:*** |
| **Secondary Efficacy Endpoints**<br>Additional criteria that may be met during a clinical trial, but that are not required to obtain a successful positive clinical trial result | ***Target:*** | ***Minimal:*** | ***Competitor:*** |
| **Dosage and Administration**<br>Route and site of administration, dosage volume and frequency, administrating location and personnel.<br>*This information should list the target and minimal criteria the clinical candidate must meet.* | ***Target:*** | ***Minimal:*** | ***Competitor:*** |
| **Contraindications**<br>Known or expected contraindications | | | |
| **Packaging & Labeling**<br>Packaging and labeling necessary for therapeutic. Consider how it will be stored and administered; home or hospital setting; the expected shelf life, labeling of measurements etc.<br>*Packaging and labeling of comparative therapeutics should be referenced.* | | | |

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| **Preclinical Testing**<br><br>Additional testing (e.g. efficacy) that will be performed prior to entering clinical testing, including bench, in vivo, computer simulations, sterility, biocompatibility, robustness, etc. Consider how you will scale-up for testing. | |
| **Clinical Studies**<br><br>Study model, testing, and clinical data necessary to support use and for FDA clearance. Consider competitive position and marketing strategy. | |