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## Creating a Target Product Profile for New Drug Products

### Context

A Target Product Profile (TPP) is a planning tool introduced by the FDA to streamline the drug development process. Essentially, it emphasizes starting the drug development process with a clear end goal. The TPP offers a structured template summarizing crucial drug labeling details including intended use, target populations, and safety/efficacy-related characteristics. It includes both minimal and preferred product attributes and gives innovators a defined framework to evaluate their drug candidate as they move through the development process. It's designed to be consulted and updated throughout a drug's developmental journey. For example, after you complete your IND-enabling preclinical studies you should verify where the new drug formulation's primary endpoint falls between the minimum and preferred product attributes. The TPP also often helps foster focused interactions between drug developers and the FDA. See the [NHLBI Small Biz Hangout webinar](#) on developing a TPP and the NIH SEED TPP Templates for [Small Molecule Drugs](#), [Biologics](#), [Vaccines](#), and [Cell and Gene Therapies](#).

### Key Concepts

- A TPP can provide the framework to ensure preclinical development (design, conduct, and analysis) supports the intended clinical trial design and therapeutic use.
- A well-organized TPP can facilitate and streamline your interactions with FDA.

### Critical functions of a TPP

The TPP performs several key functions including:

- Strategic Guidance – As a dynamic document, the TPP assists in determining essential product features and prioritizing development phases.
- Regulatory Blueprint – It outlines key labeling concerns and serves as a basis for discussions with the FDA and global health authorities.
- Technical Directory – The TPP elaborates on product attributes vital for quality assurance and the associated manufacturing methodologies.
- Due Diligence Reference – Professional investors and prospective commercial partners refer to the TPP to assess product viability and set valuation parameters.

## Benefits of a TPP

Utilizing a well-designed TPP offers innovators many advantages. It is a best practice for drug developers use a TPP and update it frequently as they move through the regulatory process. A TPP can help ensure the following:

- Enhanced R&D Efficiency – By bridging the gap between R&D and commercial sectors, the TPP reduces unforeseen hazards and streamlines collaborative efforts.
- Positive Regulatory Outcomes – Drug development initiatives integrating a TPP into their BLA or NDA typically experience streamlined reviews with fewer requests for additional information.
- Commercial Success – Drugs shaped with the guidance of TPPs have a [higher chance of success in the market](#).

Ideally, a TPP should be integrated at the inception of a drug development initiative, serving as a roadmap guiding a drug from its discovery phase through clinical trials. This comprehensive strategy ensures the drug's safety, effectiveness, and market fit. Moreover, as fresh data emerges, the TPP can be revised to reflect the most current insights.

Attribute	Minimum	Preferred
Patient Population		
Primary Endpoints		
Interference		
Safety and Tolerability		
Dosing		
Dosage Regimen/Schedule		
Stability		
Process-derived impurities		
Patient Population		

Table 1. Example of a TPP Template

### Resources:

FDA: [Draft Guidance for Industry and Review Staff on Target Product Profile - A Strategic Development Process Tool](#)

FDA: [Q8\(R2\) Pharmaceutical Development](#)

HHS: [Target Product Profile Template](#)