

Target Product Profile (TPP) Process

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- **A Target Product Profile (TPP) is a strategic development tool which summarizes a drug product’s development goals, ideally as expressed in terms of its labeling and promotional concepts.**
- **The TPP document format correlates each development goal to planned or completed clinical testing and/or development activities.**
- **Using the TPP process early and consistently in product development dialogue with the FDA maximizes the efficiency and clarity of key development decisions (“Beginning with the end in mind”).**
- **TPP is a product of joint, pan-industry/FDA collaboration.**

WHAT IS A “TPP?”

- **Patients, Healthcare Providers, FDA and Industry Can Benefit from TPP:**
 - TPP Leverages “beginning with the end in mind.”
 - Identifies and clarifies supportive clinical plans and/or development activities prior to executing pivotal trials (“Avoid surprises”).
 - Pathway of early, clearer dialogue and oversight for key development concepts (e.g. Biomarkers, PRO’s, new disease states, product-differentiating attributes, etc).
 - Coordinates FDA reviews over more than one office (e.g. combinational products).
 - Creates an external process around which sponsors and the agency may optimize their internal procedures to create greater efficiency and contribute to lowering product development costs.

BENEFITS OF THE TPP PROCESS

Despite benefits, TPP under-utilized

- **1997:** Original joint, pan-industry/FDA team produces TPP framework, leveraged on product labeling concepts.
- **2007:** FDA issues Draft TPP Guidance Document, incorporating 1997 effort.
- **2007 – to date :** Despite benefits, TPP under-utilized; Industry and Agency mistook TPP as labeling, not conceptual development tool.
- **June 2012:** Joint FDA-Lilly “call-out” at 2012 Annual Drug Information Association (DIA) meeting, to re-engage TPP and help finalize Draft Guidance Document.
- **Late 2012 – March 2013:** Joint pan-industry/FDA team meets for candid discussion and revisions to TPP Guidance Document.

Result: TPP as a strategic development tool, expressing development goals with supporting planned or completed testing.

TPP HISTORY

2012 Team formed by cross-functional volunteers (e.g. Medical, Outcomes, Regulatory, Ad/Promo, Clinical, etc.) from the Drug Information Association Annual Meeting (June 2012)

Composition:

- FDA (CDER, CBER), Abbott (Abbvie), Amgen, Bausch, Eisai, J&J, Merck, Millennium, Shire, and Lilly.

Objective:

- Revise TPP into a strategic development process.
- Clarify the pathway to introduce key development concepts (Biomarkers, PRO's, new disease states, product-differentiating attributes, etc).
- TPP's Value Proposition: *"Do the planned or completed clinical activities support the labeling or promotional concept indicated?"*

TPP: 2012 – 2013 TEAM

By using the TPP, a sponsor and FDA can determine appropriate validation and inclusion in labeling

- Common pitfalls associated with PRO use[†]:
 - Inappropriate assessment tools
 - Inappropriately designed studies
 - Label and/or promotional claims not appropriate for what was measured.
- TPP can help avoid pitfalls:
 - Sponsor can identify development goal of using a PRO as measure of a secondary endpoint outcome.
 - Presenting this early in development dialogue with FDA allows agency to determine proper validation and acceptance of PRO instrument.
 - Sponsor can properly design trials to determine PRO data.
- Having begun with end in mind, agency and sponsor can determine how to present the concept into labeling and/or promotion.

[†] Reference: “Substantial Evidence and Other Standards in Promotion,” Elaine Hu Cunningham, DIA Workshop, Feb. 2013

TPP EXAMPLE USE – PATIENT REPORTED OUTCOME (PRO)

TPP can be used for FDA approval of product differentiating statements[†]

- Sponsor has cellular product for treatment of burns.
- Early in development, sponsor uses TPP to indicate to FDA a proposed claim: “helps restore normal skin structure and function” by “facilitating tissue replacement and repair.”
- FDA is able to determine additional testing (efficacy studies, histological study/biopsy) is needed.
- Sponsor able to develop pivotal trial(s) investigating efficacy, safety and substantiation of claim.

[†] Reference: “The Target Product Profile,” Dr. Bruce Schneider, CBER/FDA, FDA Webinar, April 2012.

TPP EXAMPLE USE – PRODUCT DIFFERENTIATING STATEMENTS

Use of TPP early in development dialogue can clarify requirements[†]

- Sponsor has a drug acting on an established therapeutic target but with novel mechanism of action
- Sponsor can use TPP to identify importance of novel mechanism to development program.
- Agency can help sponsor determine what clinical substantiation is needed to support sponsor's labeling and promotion concepts.

[†] Reference: "Target Product Profile – A Strategic Development Process Tool," FDA Draft Guidance Document, 2007.

TPP EXAMPLE USE – NOVEL DRUG

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TPP – CONTACTS FOR FURTHER INFORMATION