TPP WORKSHOP

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September 11th , 2025

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THE TPP – A POWERFUL TOOL IN DRUG DEVELOPMENT

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Definition and Purpose of a TTP

- A TPP in the Pharma, Biotech and Life Sciences context is a **strategic document that describes the targeted properties of a product to be developed**. It is the blueprint of the product to be approved and marketed.
- A TPP is a **cross-functional document** aligning the contributions of various functions. It requires a **consensus process** towards a mutual goal and typically contains the following information:
  - ✓ Therapeutic indication and specific target patient population
  - ✓ Unique selling proposition indicating uniqueness, competitiveness, and product differentiation
  - ✓ Efficacy: primary and secondary endpoints for clinical stage, decision-relevant in vitro and in vivo data for preclinical stage projects (in comparison to SoC)
  - ✓ Safety and tolerability criteria
  - ✓ Formulation, dosing schedule, therapy duration

- A TPP **indicates strategic stop/go criteria.**
- It is a living document: early stage TPP's will be less specific and become more detailed as the project proceeds.

IN ADDITION TO TARGET, A TPP MAY INCLUDE MINIMUM AND UPSIDE PROPERTIES FOR BETTER CLARITY

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scope of investment *walk-away threshold* *lucky outcome / more investment*

PRODUCT NAME Target Product Profile	Target	Minimum	Upside
Indication ('Label')			
USP			
Patient Population			
Mono- or Combination Product			
Efficacy			
Primary Endpoint			
Secondary Endpoint(s)			
Treatment duration			
Safety & Tolerability			
Formulation / Treatment Mode			

EXAMPLE FOR AN ANTI-INFECTIVE IN EARLY DEVELOPMENT

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PRODUCT NAME Target Product Profile	**Target**	**Minimum**	**Upside**
Indication ('Label')	For 1st line therapy of complex urinary tract infections (cUTI) including pyelonephritis		
USP	The first oral therapy for complex UTI with less resistance development compared to SoC		
Patient Population	General population ≥ 18 years (including patients at risk of multiple drug resistance)		Children at the age of 12+ years
Mono- or Combination Product	Monotherapy		Monotherapy or combination therapy with carbapenemes, piperacillin, tazobactam, cefiderocol, and ceftazidim
Efficacy			
Primary Endpoint	Non-inferior efficacy compared to SoC (carbapenemes), cure rate ≥90%		Cure rate ≥95%
Secondary Endpoint(s)	Clinically meaningful reduction of resistance development according to both clinical and microbiological measures compared to carbapenemes		Statistically significant and clinically meaningful reduction of resistance development Robust in vitro evidence for effective disruption of biofilms
Treatment duration	7 - 14 days	14 days	
Safety & Tolerability	No severe hepatotoxic effects, no QT -prolongation, only mild GI effects	Liver toxicity monitoring on days 4 and 8 in patients aged ≥60 years and in patients diagnosed with forms of chronic hepatitis	Can safely be applied in combination with other commonly used antibiotics (SoC)
Formulation / Treatment Mode	Capsule / oral application, 1 x 1 capsule/day, independent of meals	Capsule / oral application, 2 x 2 capsules/day	

FUNCTIONS MAY HAVE THEIR SPECIFIED TPPS

… in particular in Pharma

Clinical Development

PRODUCT NAME Target Product Profile	Target	Minimum	Upside
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USP	The first oral therapy for complex UTI with less resistance development compared to SoC		
Patient Population	General population ≥ 18 years (including patients at risk of multiple drug resistance)		Children at the age of 12-18 years
Mono- or Combination Product	Monotherapy		Monotherapy or combination therapy with carbapenemes, piperacillin, tazobactam, cefiderocol, and ceftazidim
Efficacy			
Primary Endpoint	Non-inferior efficacy compared to SoC (carbapenemes), cure rate ≥90%		Cure rate ≥98%
Secondary Endpoint(s)	Meaningful reduction of resistance development according to both clinical and microbiological measures compared to carbapenemes		Statistically significant reduction of resistance development Invitro evidence for effective disruption of biofilms
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Project Management

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RECOMMENDATIONS

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Every R&D Organization Requires TPPs to succeed in the shortest possible time

- A TPP is created with the final product in mind**, thinking backwards from the end**.
- The **TPPs in drug discovery** require a development section in order to work towards to an accepted goal.
- There is no adequate investment, reliable sales forecast, development plan, risk assessment or valuation without a TPP.
- It is important to consider the **market, the prescriber, the patient perspectives** as early as possible – e.g., do market research!
- There may be obstacles or resistance to TPPs in your organization – create them as best as you can.

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