

TPP planning guide

For HCP concept testing

A practical structure for connecting a target product profile to the decision, audience, evidence, and trade-offs a study needs to examine.

Adapt the profile to the decision

Adjust it for the indication, product stage, intended audience, and decision. Keep uncertainty visible instead of filling gaps with invented detail.

Educational use only. This guide is not a regulatory-ready TPP, clinical evidence assessment, medical recommendation, or prediction of prescribing.

Decision, indication, and audience

Complete the context before writing product attributes or selecting HCP respondents.

01 Decision and indication

Decision this profile should inform:

Indication or use case:

Development stage:

02 Target population and setting

Population in scope:

Care setting and geography:

Stage of use:

03 Unmet need and current practice

What is difficult today?

Current options or practice:

Evidence and open questions:

Keep the research audience distinct

The people who would receive or use the product may not be the same as the HCPs you recruit for concept testing. Specify both, including specialty, role, setting, geography, experience, and exclusions.

Product concept, performance, and trade-offs

Make the comparison understandable without implying that the profile proves a claim.

04 Product concept

Product name or code:

Mechanism or mode of action:

Route, regimen, and practical attributes:

05 Performance, safety, and tolerability

Relevant endpoints or characteristics:

Supported safety or tolerability information:

Minimum and ideal targets, if useful:

06 Differentiation and trade-offs

Fair comparator:

Proposed difference:

Trade-off the study should explore:

A concept test can explore

Comprehension, relevance, perceived fit, attribute priorities, trade-offs, and what information HCPs need before evaluating the idea further.

It cannot establish

Efficacy, safety, approval, market access, representative opinion, future prescribing, or a predetermined conclusion.

Evidence, assumptions, and missing information

Make the status of each statement visible before it becomes a stimulus or question.

Evidence record

Source or document

Locator or page

Date and reviewer

What still needs confirmation

Suggested evidence labels

SOURCE-BACKED FACT

A claim with a traceable source and locator.

OPERATOR-CONFIRMED INPUT

Context confirmed by the accountable team or reviewer.

HYPOTHESIS / ASSUMPTION

A proposition or working premise that still needs testing.

MISSING EVIDENCE

A known gap. Leave the field open until someone can support it.

Review gate

Before fielding, confirm that the profile is approved for the intended audience, the comparison is fair, claims have an accountable source, and privacy, regulatory, legal, and methodological owners have reviewed their parts.

Questions for the HCP concept test

Use the profile to define what the study should learn, then keep method and interpretation with qualified researchers.

01 What is this concept intended to do, in your own words?

02 Which part feels most relevant to the stated unmet need?

03 Which attribute or trade-off would matter most in practice?

04 What information would you need before evaluating the concept further?

05 What could make the concept difficult, inappropriate, or irrelevant in your setting?

Before you field

Define the HCP audience and exclusions
Pretest comprehension and burden
Record sampling and method choices

Plan quality checks and transparent reporting
Keep interpretation tied to the decision

Link the approved profile to the questionnaire, stimuli, fieldwork plan, and decision record.

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