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TARGET PRODUCT PROFILE (TPP) PLAYBOOK

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1. EXECUTIVE SUMMARY

A Target Product Profile (TPP) is a strategic document that summarizes the features of an innovation needed to address an unmet need. While TPPs are a valuable way to address market shortcomings, they currently remain underutilized. This TPP playbook serves as a resource guide on how to design and conduct a formalized, step-wise, consensus based TPP process. The ideal audience for this playbook is individuals who are interested in administering a TPP process or who are curious to learn more about the process. This toolkit provides detailed guidelines and templates and can serve as a resource for scaling the TPP process.

A. Overview of Market-Shaping Mechanisms and the Role of TPPs

Many unmet needs exist and yet, technologies will not be developed to address these gaps due to market shortcomings. Market-shaping mechanisms can help solve these market failures. Examples of market-shaping mechanisms include Advance Market Commitments (AMCs), purchase guarantees, milestone payments, and innovation prizes¹.

An AMC is a contract where a sponsor agrees to purchase a specified quantity of a product at a specified price, provided it meets some pre-set criteria and qualifications (for example, may reference basic parameters outlined in a TPP). Because it encourages the creation of a product, without directly funding research or development (R&D) or production, AMCs are considered a type of “pull funding.” AMCs reduce the risk to the sponsor, since the sponsor only pays for a product if it exists and is produced². In contrast, loan guarantees, research grants, and other types of “push financing” directly subsidize or finance the input costs for R&D³.

Target Product Profiles can be a useful mechanism to address market failures. The TPP process facilitates an open dialogue between both the supply and demand side, who face high transaction costs, information gaps, or risk imbalances that contribute to these market shortcomings. While TPPs have traditionally been used in healthcare in instances where market intervention is necessary to drive innovation, there is broader applicability to utilize in other industries as well. Additionally, policy makers can utilize the TPP process to engage diverse stakeholders to define a need that may ultimately lead to the development of an AMC. The TPP development approach is innovative with respect to market shaping initiatives in that it (i) follows a formalized step-wise process established for the development of consensus-based TPPs; (ii) recommends including a broad group of stakeholders and representative points of view; and (iii) enables an open dialogue between end-users and product developers which captures trade-offs.

TPPs are often utilized at an early stage in the development process to enable user-defined performance characteristics for a given setting. TPPs can also be applied to assess the profile and match of existing devices for a given context (e.g., adapting newborn care

¹ <https://progress.institute/how-to-reuse-the-operation-warp-speed-model/>

² Recommendation For Advance Market Commitments for Pan-sarbecovirus Vaccines authored by Thomas Kelly (1Day Sooner), Rachel Glennerster (Department of Economics, University of Chicago), and Christopher M. Snyder (Department of Economics, Dartmouth College)

³ <https://www.cgdev.org/publication/operation-warp-speed-encore-case-us-leadership-drive-market-based-global-health>

medical devices designed for resource-limited settings). There is significant potential to use TPPs to address unmet market needs, and yet, they still remain underutilized. Establishing a reproducible methodology for the TPP process demonstrates the potential to replicate this approach for other widespread and burdensome concerns beyond healthcare. For examples beyond the healthcare industry, please reference the [Industry Variations and References](#) section.

B. How to use this document

This playbook includes practical guidance on understanding the purpose and uses of a consensus-based TPP process. Detailed resources and templates are included for reference. Please use the Table of Contents to navigate to the sections of interests as well as the Google Drive to access helpful templates and information.

2. WHAT IS A TARGET PRODUCT PROFILE (TPP)?

A Target Product Profile (TPP) is a strategic document that summarizes the features of an innovation needed to address an unmet need. A TPP outlines the desired characteristics of a target product by defining the intended use, target population(s) and other desired attributes, including safety and efficacy-related characteristics. A consensus-based TPP development process facilitates an open dialogue between the supply side (i.e., product developers, manufacturers, innovators) and the demand side (i.e., government regulatory agencies, international NGOs, end-users). While the ultimate TPP product can be used in a variety of ways (e.g., to inform product development or promote innovation, to guide procurement specifications, guide regulatory frameworks and market shaping efforts, etc.), the development process itself is often critical in fostering a valuable and stimulating discussion between various stakeholders.

A. Background

i. FDA and other U.S. Government Agencies

In the United States, Target Product Profiles (TPPs) were initially used by the Food & Drug Administration (FDA) as a tool to facilitate communication between the pharmaceutical industry, the FDA, and other stakeholders outside of the industry to aid in the new drug development pipeline. Guidance issued by the US Food and Drug Administration (FDA) provides an overview of the purpose and attributes of TPPs, and which requirements for a new drug should be included⁴.

Traditionally, TPPs were used as a "format for a summary of a drug development program described in terms of labeling concepts". By focusing on the "end game", TPPs would effectively guide the design, conduct, and analysis of trials as well as ensure adequate collection of any additional information required to support labeling. Since specific needs (including labeling claims) are stated at the beginning of development, they serve to guide the design, conduct and analysis of preclinical and clinical trials, helping to guide and

⁴ US Food and Drug Administration. Guidance for industry and review staff Target Product Profile — a strategic development process tool. March 2007. <https://www.fda.gov/media/72566/download>. U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER).

streamline discussions between manufacturers and regulators at all stages of product development⁵. The process highlighted that an open, efficient dialogue could minimize the risk of late-stage drug development failures, increase the probability that optimal safety and efficacy data are available in a timely manner, and often decrease the total time to development.

TPPs continue to be used today to define the ideal attributes of products of interest to government agencies including the ultimate goals of a proposed development effort. For example, [Biomedical Advanced Research and Development Authority \(BARDA\)](#), which promotes the advanced development of medical countermeasures to protect Americans⁶, utilizes TPPs to provide a clear set of aspirational targets that can help focus and guide research and development activities. These TPPs provide structure for the scientific, technical, and clinical information required to achieve a desired outcome and provide stakeholders with a clear vision of the product objectives in order to help guide research and development decisions. Ideally, the BARDA TPPs will lead to products that will be approved by the U.S. Food and Drug Administration (FDA).

ii. International Agencies (e.g., WHO, UNICEF, PATH, FIND, etc.)

Beyond the pharmaceutical industry, TPPs are used universally in other parts of the healthcare sector (e.g., diagnostics, vaccines, therapeutics, and medical devices). Internationally, the [WHO](#) and other non-governmental organizations (e.g., [UNICEF](#), [FIND](#), [PATH](#)) utilize TPPs to help communicate requirements for needed innovations and to guide new product research and development. TPPs can be useful as a planning tool both for industry and regulators, and can help researchers, developers, and manufacturers design products for specific contexts that meet the needs of end-users.

B. Purpose and Definitions

As outlined above, a TPP is a strategic document that summarizes the features of an innovation needed to address an unmet need. A TPP outlines the desired characteristics of a target product by defining the intended use, target population(s) and other desired attributes, including safety and efficacy-related characteristics.

TPPs can serve varying purposes but their overarching goal is to help foster innovation by defining an unmet need. TPPs can be used to guide industry who might be hesitant to pursue R&D without further information on product needs. To do this, TPPs help guide research and development by providing stakeholders with a clear vision of the objectives. TPPs communicate requirements but are not overly prescriptive in defining how to achieve the solution to the problem. It can be challenging to find the right balance between being specific enough to be valuable to the innovator, without infringing upon flexibility. Additionally, there can also be a fine line between defining characteristics that will achieve consensus agreement without watering down the TPP characteristics to insufficient standards.

The TPP development process facilitates an open dialogue between the supply side (i.e., product developers, manufacturers, innovators) and the demand side (i.e., government

⁵ <https://fda.yorkcast.com/webcast/Play/a53d0d5863244464b000249f1ddc9fd31d>

⁶ <https://aspr.hhs.gov/AboutASPR/ProgramOffices/BARDA/Pages/default.aspx>

regulatory agencies, international NGOs, end-users). A well-defined TPP can provide a roadmap for product developers and help ensure that the product in development is ultimately commercially viable.

The table below highlights varying descriptions of TPPs.

Organization	Definition and Purpose
<u>U.S. Food and Drug Administration (FDA)</u>	The purpose of a TPP is to provide a format for discussions between a sponsor and the FDA that can be used throughout the drug development process, from pre-investigational new drug application (pre-IND) or investigational new drug application (IND) phases of drug development through post-marketing programs to pursue new indications or other substantial changes in labeling. The TPP <i>embodies the notion of beginning with the goal in mind.</i>
<u>World Health Organization (WHO)</u>	A target product profile (TPP) <i>outlines the desired ‘profile’ or characteristics of a target product that is aimed at a particular disease or diseases.</i> TPPs state intended use, target populations and other desired attributes of products, including safety and efficacy-related characteristics
<u>UNICEF</u>	Target product profiles (TPPs) <i>communicate requirements for products that are currently not available on the market but that fulfil a priority need</i> to be met in the unique context in which UNICEF and its partners operate. The purpose of TPPs is to guide industry to develop products that meet UNICEF’s needs.

C. Features, Content and Format

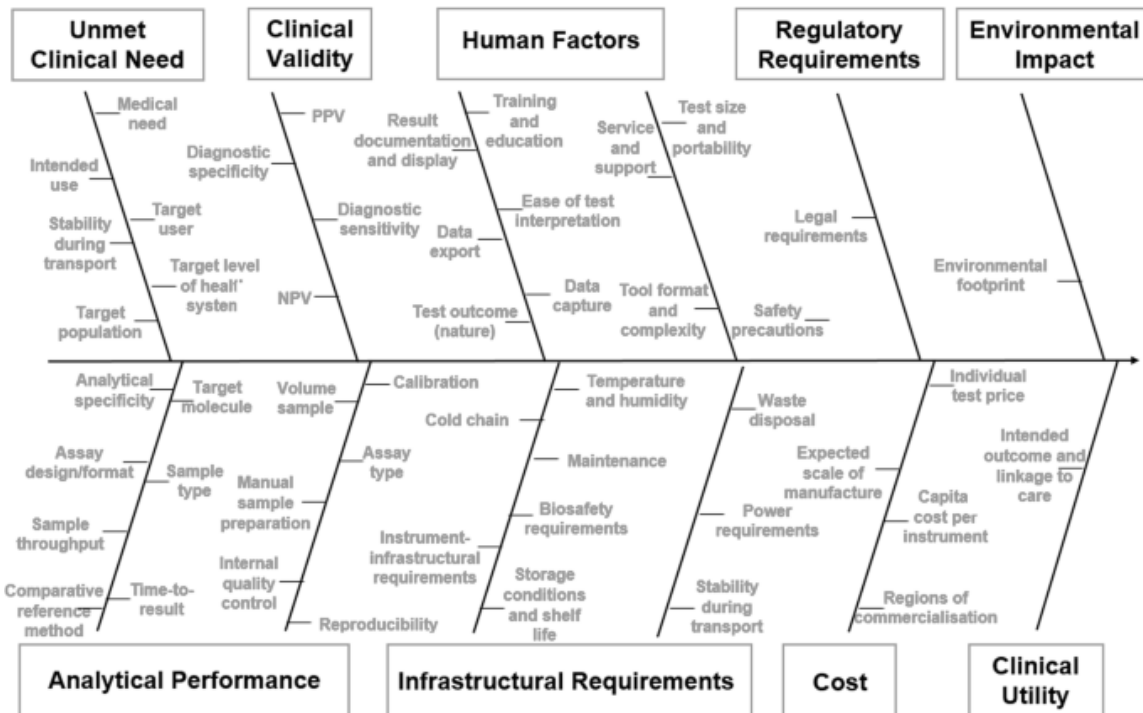
In a systematic review conducted by [Cocco et al.](#), a common decision-making framework was identified which consisted of three distinct phases for TPP development: scoping, drafting and consensus-building (see Figure below for an overview of the activities and methods involved).

Phase/Question	Activities involved	Methods (input sources, stakeholders involved)
<p>1) Scoping TPP <i>What is the scope (e.g. unmet clinical need, test characteristics) of the TPP being developed?</i></p>	<ul style="list-style-type: none"> • Landscape analysis • Reviewing literature and available data • Introductory meetings with stakeholders • Definition test characteristic categories • Definition problem statement and needs • Priority-setting 	<ul style="list-style-type: none"> • Consultation with experts • Literature ○ Academic researchers ○ Industry representatives ○ International public organizations ○ Clinicians ○ Members of disease-specific programs
<p>2) Drafting TPP <i>What are the desirable characteristics for a new test?</i></p>	<ul style="list-style-type: none"> • Draft document • Rounds of revision • Shortening draft 	<ul style="list-style-type: none"> • Consultation with experts • Literature • Models • Meeting input • Available data ○ Academic researchers ○ Industry representatives ○ International public organizations ○ Clinicians ○ Members of disease-specific programs
<p>3) Consensus-building <i>Is there consensus around the characteristics defined in the TPP?</i></p>	<ul style="list-style-type: none"> • Surveys to assess expert agreement • Delphi-like surveys • Consensus meeting 	<ul style="list-style-type: none"> ○ Academic researchers ○ Industry representatives ○ International public organizations ○ Member of disease-specific programs ○ Clinicians

There are several formats for TPPs but typically, they address and define the “minimum” requirements, which refer to the lowest acceptable requirements, as well as “optimal” performance characteristics which refer to the ideal or best case-scenario targets that products should aim to achieve. The goal of the TPP development process should be to ensure that the minimal and optimal criteria are both desirable and realistically achievable. Performance characteristics / product requirements will vary depending on the purpose of the TPP.

For example, for medical technologies, TPP characteristics can include target operator, target population, target setting, regulatory approval, relevant technical characteristics (e.g., for diagnostic devices: accuracy, range, precision,), therapeutic dose delivered for therapeutic devices (including range and accuracy), cost (including equipment and consumable costs), power requirements (including line voltage requirements, inclusion of battery backup, battery life), and maintenance requirements. This can vary outside of healthcare where the end user needs to be defined.

The Figure below depicts various characteristics included in TPPs from [Cocco et al.’s](#) review.



In [Cocco et al.](#)'s review, some TPPs utilized a time horizon to represent the timeframe within which achieving the specifications described was considered feasible. Of the 44 TPPs included in the review, 7 reported a time horizon, of which 6 were for a horizon of 5 years and 1 was 10 years.

The table below provides a high-level example of product characteristics that can be included in a TPP. Please review the reference TPPs for further detail and information.

PRODUCT CHARACTERISTIC	OPTIMAL (IDEAL)	MINIMAL
Target Population		
Intended Use (e.g., indications and usage)		
Target Setting		
Technical Characteristics (e.g., accuracy)		
Legal Characteristics (e.g., regulatory approvals)		
Manufacturing		
Power Requirements (e.g., battery)		
Price		

D. Consensus Based TPPs

Creating a TPP is a collaborative exercise. Consensus based TPP processes that involve a wide range of stakeholders – such as researchers, industry representatives, clinicians, implementers, policy makers and governments - can facilitate increased buy-in through open dialogue. Specifically, an open dialogue between end-users and product developers can capture trade-offs and allow stakeholders who may otherwise have limited interaction to learn from each other.

Identifying the appropriate stakeholders for inclusion in the TPP process is important. The key stakeholders may vary based on the purpose of the TPP but might include representatives from the following groups: researchers, industry, international public organizations, clinicians, advocacy groups and associations, policy makers, laboratory experts, technical/funding agencies, implementers, modelers, health economists, donors, and market experts. While an independent group may take on the initial task of developing a TPP, collaborating with larger organizations and partners can prove beneficial. For example, having a reputable body publish the final TPP can help foster credibility and build awareness.

Having representation from industry - including established manufacturers, researchers, and early-stage innovators - can prove invaluable in facilitating a healthy and productive dialogue. Industry may sometimes be excluded from these discussions due to perceived conflict of interest concerns. However, representatives from industry bring an important perspective to the discussion which can help to ensure that the clinical and economic benefits are appropriately demonstrated so that the innovation will ultimately be commercially viable.

In the review conducted by [Cocco et al.](#), initial agreement on the draft TPP was often obtained using a survey of the stakeholders with a Delphi-like approach. Following the survey, a consensus meeting with stakeholders and experts was often held and a revised TPP generally agreed upon. Based on the review, the number of participants invited to the consensus-building meetings varied (< 20 participants: n = 5; between 20 and 50 participants: n = 7).

It is possible that consensus may not be achieved on every characteristic in a TPP (e.g., only 70% agreement vs. the pre-determined 75%). If consensus is not achieved both in the TPP survey and during the consensus meeting, this should be noted in the final published report. During the consensus meeting voting, it is important to be clear on the specific characteristic that is being voted upon (i.e., whether it is the minimal or optimal). It can also be helpful to re-frame to participants that “agreement” may mean in some cases “acceptable” (i.e., “I can live with”).

E. Challenges

According to a paper by [Tyndall et al.](#), there is a large amount of untapped benefit that could be gained from earlier and more frequent use of TPPs. Specifically, the development of a TPP provides industry with the opportunity for more meaningful regulatory interactions that could lead to better organized and more successful results.

Limitations of TPPs include that they are relatively static documents despite constantly adapting environments. Having TPPs that are more dynamic in nature and can continue to evolve over the course of product development would prove valuable. A potential solution is to make TPPs “living” documents akin to WHO clinical guidelines, where panels review and solicit feedback from a broader pool of stakeholders bi-annually⁷. Ideally, TPPs should be regularly reviewed and updated as required, as new data emerges, and in response to changes in the external environment.

⁷ <https://www.who.int/publications/who-guidelines>

Furthermore, while TPPs outline desired product characteristics that can help guide manufacturers in the development of products for consistent quality and performance, qualitative human factors may not be represented. While human-centered design approaches are important, TPPs often place an emphasis on more objective measurements such as technical or quantitative specifications.

Finally, extensive research evaluating the impact and success of TPPs has yet to be conducted.

F. Distinction between TPPs and Advanced Market Commitments (AMCs)

While traditionally TPPs have been used as a means of further defining an unmet need, there may be an opportunity to leverage TPPs when designing AMCs. AMCs utilize “pull funding” where a sponsor only pays for a product that is commercially available and meets a designated set of pre-specified criteria. A TPP can be used to define the pre-specified criteria by outlining the proposed characteristics for an ideal product that a sponsor would ultimately be willing to purchase.

TPPs and AMCs, though sometimes used in conjunction together, accomplish fundamentally different goals. The goal of a TPP is to define the specific attributes of a potential innovation required to address an unmet need. TPPs can be used as pre-cursors to design specifications, yet remain distinct. An AMC is a contract where a sponsor agrees to purchase a specified quantity of a product at a pre-determined price. An AMC may specify that if an innovation is developed that meets the requirements of pre-determined specifications, then a defined quantity of the product will be purchased at a set price. Separately, a price may be included as a characteristic in a TPP, but this is generally not the same as the negotiated price defined by an AMC. The TPP characteristic of price should be clearly defined (e.g., ex-works price, end consumer price, etc.). In an AMC, a negotiated price might differ from the TPP price characteristic based on guaranteed purchase quantities, terms, etc. While there are benefits to including price as a characteristic in a TPP (e.g., might provide helpful reference to innovators), careful consideration should be given to avoid confusion between the two. Furthermore, quantities for purchase are not defined in TPPs. Therefore, while a TPP may be useful in defining the product specifications for an AMC, there are clear distinctions as a TPP does not provide quantities or negotiated purchase prices required for an AMC contract.

TPPs often define both the optimal and minimally accepted performance and operational characteristics. For example, the optimal characteristic refers to the ideal target, whereas the minimal refers to the lowest acceptable target. While ideally developers would strive to achieve a product that meets all of the optimal product characteristics, providing a range could theoretically be useful to define funding tiers in AMCs.

3. RESOURCES

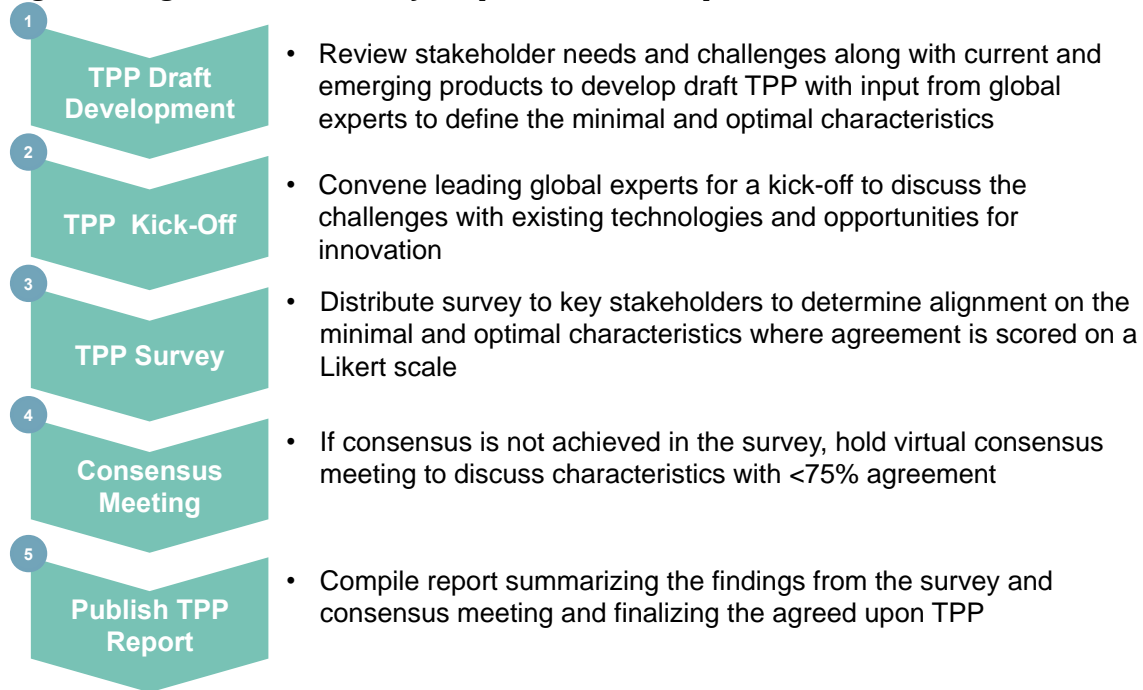
A. Roadmap of process

To create your own TPP, please refer to some of the key high-level steps below (see Figure):

1. Identify Key Stakeholders for Draft TPP Development
2. Hold Kick-Off to Publicize TPP
3. Distribute TPP Survey

4. Consensus Meeting to Finalize TPP
5. Publish TPP

Figure 1: High-level overview of the process to develop a TPP



Step 1: Identify Key Stakeholders for Initial Draft TPP Development

A scoping exercise may be used to provide an overview of the problem, define the unmet need and address the limitations associated with existing technologies. This can include a review of published literature, completion of a ‘landscape analysis’ or interviews with key stakeholders. If a specific need cannot be identified, a [use case analysis](#) can be valuable to further define the various competing needs prior to TPP development. This can often result in the creation of separate TPPs based on varying use cases.

Establishing a working group of key stakeholders and experts upfront can be instrumental in the ultimate success and adoption of the TPP. This can be formal or informal, but can be valuable in gaining critical feedback to inform the initial TPP draft development.

The initial TPP draft can either be prepared in collaboration with the established working group, or with a smaller group (e.g., TPP authors) and then shared with the other key stakeholders. While it can be intimidating, the initial draft TPP does not need to “get everything right” immediately as the purpose of the TPP process is to gather feedback from experts and refine the TPP through future surveys, meetings, and conversations.

Step 2: Hold Kick-Off to Publicize TPP

Once an initial TPP has been developed, hold a Webinar or kick-off event to introduce the TPP process to a broader audience of key stakeholders in order to gain buy-in early on. The event can include panelists from both industry and end-users to discuss the challenges faced and opportunities for innovation. Gathering stakeholders and sharing information

upfront about the TPP process can help to publicize the process, collect names/emails of registrants to share the TPP survey with, and convene the necessary stakeholders.

Step 3: Distribute TPP Survey

In follow up to the kick-off, distribute the TPP survey for completion. Generally, the link can be distributed via email. Ideally, a minimum of 25 participants would participate in the survey (see here for more information on [consensus based TPPs](#)). Since participation rates may be low, this may require a large base of stakeholders for outreach. Make sure to set a reasonable deadline (e.g., a few weeks) for the survey and note that continued follow-up and reminders may be required. Sometimes, individual meetings may be beneficial.

Various methods can be utilized for developing the survey (e.g., [Qualtrics](#)). For a TPP survey example, please click [here](#). When building the TPP survey, ask respondents to provide a statement on their level of agreement with each of the proposed product requirements. Agreement can then be scored on a Likert scale ranging from 1 to 5:

- 1=disagree
- 2=mostly disagree
- 3= neither agree nor disagree
- 4=mostly agree
- 5=fully agree

An option to opt out with the selection of “Other - Do not have the expertise to comment” should also be included. If participants do not agree with the product requirement (i.e., they selected 1, 2 or 3) they should provide an explanation with comments. For each product requirement, a percentage agreement can be calculated for both the Minimal and Optimal requirements utilizing the ratio of the sum of number of respondents who selected 4 and 5, to the sum of numbers of respondents who gave any score (from 1 to 5 where 5=fully agree, 4=mostly agree, 3=neither agree nor disagree, 2=mostly disagree and 1=disagree). Consensus for the survey characteristics should be pre-defined (e.g., more than 50% of respondents provide a score of at least 4 on the Likert scale). A classic Delphi process requires at least two rounds of survey ahead of an in-person meeting, however, if consensus is generally achieved in the first round of the survey, often times a second round is not administered.

Figure 2: Likert Scale Example

1. EXAMPLE CHARACTERISTIC: Please rate your level of agreement with the statements under optimal and minimal. *Note: The optimal and minimal requirements define a range.*

	1-Disagree	2-Somewhat Disagree	3-Neither Agree nor Disagree	4-Mostly Agree	5-Fully agree	6 - Do not have the expertise to comment
Optimal: Desired or ideal target	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Minimal: Lowest acceptable target	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Figure 3: Percentage Agreement Calculation

Selection	1 - Disagree	2 - Somewhat Disagree	3 - Neither Agree nor Disagree	4 - Mostly Agree	5 - Fully Agree	6 - Do not have expertise to comment
# of Respondents	1	3	2	8	15	4

**note that respondents who opted out (i.e., selected 6) are NOT included in the percentage agreement*

Calculation:

Example

$\frac{\# \text{ of respondents who selected 4 + \# \text{ resp. selected 5}}{\# \text{ resp. selected 1} + \# \text{ resp. selected 2} + \# \text{ resp. selected 3} + \# \text{ resp. selected 4} + \# \text{ resp. selected 5}}$

$\frac{8 + 15}{1 + 3 + 2 + 8 + 15} = 79\%$ Agreement

Step 4: Consensus Meeting to Finalize TPP

Upon completion of the survey, consensus should be reached on the final TPP. Hold an in-person or virtual consensus meeting gathering stakeholders to engage group discussion. While it can vary based on the pre-achieved level of agreement in the survey, at least two hours for a consensus meeting should be budgeted to allow ample time for discussion. A pre-specified percentage agreement should be used to establish consensus (e.g., 75% agreement). At the consensus meeting, the focus can be directed towards areas of disagreement (e.g., product requirements on which fewer than 75% of the respondents agreed, or on which a distinct subgroup disagreed). [Mentimeter](#) or [Zoom polling](#) can be used to capture voting at the consensus meeting. It is important to be very clear during the consensus meeting as to the specific characteristic (e.g., whether it is the minimal or optimal target) being voted on. It is possible that meeting participants may fail to reach pre-defined consensus, in which case, this should be noted in the final published report.

Step 5: Publish TPP

In follow up to the consensus meeting, an extensive report should be compiled summarizing the findings from the survey and consensus meeting and finalizing the agreed upon TPP. This can be published by the TPP developer or a partner organization (e.g., if working with WHO can be published on their website). Academic papers are a route that can be simultaneously pursued as well, though timing may vary depending on the journal.

B. Sample slides

Click [here](#) to review sample slides.

C. Conflict of Interest Form

Collecting participants conflict of interest disclosures may be valuable. Click [here](#) to review a sample conflict of interest form.

D. Template for TPP development and report writing

Click [here](#) to review helpful templates.

4. INDUSTRY VARIATIONS AND REFERENCES

Included below are reference links to TPPs.

A. TPP Reference

- i. [FDA \(2017 Notice, 2009 Guidance for Industry Pharmaceutical Development, 2007 Webinar, 2007 Guidance for Industry and Review Staff Target Product Profile — A Strategic Development Process Tool\)](#)
- ii. [UNICEF](#)
- iii. [WHO](#)
- iv. [FIND](#)
- v. [DNDi](#)
- vi. [NIH](#)
- vii. [UK Gov](#)
- viii. [PATH](#)

B. Literature Reference

- i. Cocco, P., Ayaz-Shah, A., Messenger, M.P. et al. Target Product Profiles for medical tests: a systematic review of current methods. BMC Med 18, 119 (2020). <https://doi.org/10.1186/s12916-020-01582-1>.
- ii. Tyndall, A., Du, W. & Breder, C. The target product profile as a tool for regulatory communication: advantageous but underused. Nat Rev Drug Discov 16, 156 (2017). <https://doi.org/10.1038/nrd.2016.264>.
- iii. Gal M, Francis NA, Hood K, Villacian J, Goossens H, Watkins A, et al. (2018) Matching diagnostics development to clinical need: Target product profile development for a point of care test for community-acquired lower respiratory tract infection. PLoS ONE 13(8): e0200531. <https://doi.org/10.1371/journal.pone.0200531>.
- iv. Breder C, Du W, Tyndall A. What's the Regulatory Value of a Target Product Profile? Trends in Biotechnology. (2017) <https://doi.org/10.1016/j.tibtech.2017.02.011>.

C. Healthcare

- i. Vaccines
 - a. [Laboratory-Based SARS-CoV-2 Viral Detection Tests. UK Medicines & Healthcare products Regulatory Agency. 2021.](#)
 - b. [Wellcome Trust Ebola Vaccine](#)
- ii. Drug Development and Therapeutics
 - a. [Target Product Profile: Point-of-Care Malaria Plasmodium falciparum Highly Sensitive Rapid Diagnostic Test. PATH. 2015](#)
- iii. Diagnostics
 - a. [High-priority target product profiles for new tuberculosis diagnostics: report of a consensus meeting. WHO. 2014.](#)
- iv. Medical Devices > Newborn Care
 - a. [Newborn target product profiles. UNICEF and NEST360. 2020.](#)

D. Infrastructure

- i. The Center for Global Development (CDG) is exploring the use of an Advanced Market Commitment (AMC) to incentivize the creation and production at scale of cheaper seal and road materials. The goal is to define the parameters of what a “winning product” through the use of a target product profile once a set use case has been defined.

E. Emergency Response

- i. [High-performance emergency multi-purpose tent](#)
- ii. [Faecal sludge and wastewater management in emergencies – treatment product](#)
- iii. [Rapid water quality detection method or portable kit](#)

F. Climate

G. Agriculture

- iv. The Clinton Health Access Initiative (CHAI) in partnership with Prevail has launched a clean cooling initiative with the goal to drive a rapid transition to next-generation, affordable room Air Conditioners in India / emerging markets. Their approach centers on building a large-scale Advance Market Commitment that will incentivize manufacturers to develop, commercialize, and drive high market penetration of next-gen affordable room ACs. They have developed a TPP summarizing key attributes of a product that can ideally achieve significant market share in India with a market entry of 2025-2026.

H. Energy

I. Technology – Software

- ii. In the Software Development industry, the word ‘requirement’ defines what the goal is, what the customers exactly need, and what will increase business for the company⁸. Success is ultimately defined by how well the requirements are met. Acceptance Criteria, or pre-established standards or requirements that a product or project must meet, are often utilized as well.
- i. TPPs can also be used as a key strategic document to specify the features of the intended priority information & communication technology (ICT) product. TPPs help to shape its development, aligning the needs of end-users with the direction taken by the developers to satisfy the demand. For example, the WHO published a [Target product profile for priority digital health products for Tuberculosis \(TB\)](#).

5. FREQUENTLY ASKED QUESTIONS (FAQS)

How “polished” does the initial draft TPP need to be?

The initial TPP draft can then either be prepared in collaboration with the established working group, or with a smaller group (e.g., TPP authors) and then shared with the other key stakeholders. While it can be intimidating, the initial draft TPP is still a work-in-progress and does not need to “get everything right” immediately. The purpose of the TPP process is to gather feedback from experts and refine the TPP through future surveys, meetings, and conversations.

How can you ensure participation from key experts and stakeholders?

Establishing an initial working group with key opinion leaders (KOLs) and credible experts can be valuable in helping to identify other important stakeholders for inclusion. Additionally, collaborating or partnering with a respected agency in the field can help to bolster support.

How do you ensure the appropriate level of representation from various stakeholders?

Establishing a working group to develop the initial draft TPP and holding a kick-off event or webinar can be a helpful way to include key stakeholders at the early stages of the TPP development process. Webinars and kick-off events can be useful in identifying new stakeholders (as participants can share the event information with their network) as well as collecting emails and information on registrants. When emailing participants to complete

⁸ <https://www.softwaretestinghelp.com/user-story-acceptance-criteria/>

the TPP survey, follow up may be required. This may be in the form of individual emails or even setting up individual meetings. In order to ensure that certain organizations are not overly represented in the survey, it may be helpful to reach out to members of the same organization on one email chain so that they have insight as to who else has been invited to participate.

What is a benchmark on how many people should participate in the TPP survey and consensus meeting?

Ideally, a minimum of 25 participants would complete the TPP survey. In a review conducted by [Cocco et al.](#), initial agreement on the draft TPP was often obtained using a survey of the stakeholders with a Delphi-like approach. Following the survey, a consensus meeting with stakeholders and experts was often held and a revised TPP generally agreed upon. Based on the review, the number of participants invited to the consensus-building meetings varied (< 20 participants: n = 5; between 20 and 50 participants: n = 7).

What happens if consensus is not achieved for a specific characteristic?

It is possible that consensus may not be achieved on every characteristic in a TPP (e.g., only 70% agreement vs. the pre-determined 75%). If consensus is not achieved both in the TPP survey and during the consensus meeting, this should be noted in the final published report.

What is the difference between the minimal and optimal characteristics in a TPP?

There are several formats for TPPs but typically, they address and define the “minimum” requirements, which refer to the lowest acceptable requirements, as well as “optimal” performance characteristics which refer to the ideal or best case-scenario targets that products should aim to achieve. The goal of the TPP development process should be to ensure that the minimal and optimal criteria are both desirable and realistically achievable. Performance characteristics / product requirements will vary depending on the purpose of the TPP.

What if there are multiple potential users and challenges that need to be solved?

A TPP requires a defined unmet need, so if a specific need cannot be identified, a [use case analysis](#) can be valuable to further define the various competing needs prior to TPP development. This can often result in the creation of separate TPPs based on varying use cases.