Measuring Access: Tracking Progress and Success for Product Development Partnerships [1]

December 21, 2011

Abstract

Product Development Partnerships (PDPs) are often challenged to ensure that target populations can access products once developed. Ensuring that products reach end-users requires PDPs to develop, manage and track a wide range of activities and information. Having a clear set of indicators that measure progress along the way from R&D to end-user will be useful for PDP project management and performance enhancement.

A set of commonly used metrics for PDPs to track progress toward access goals is currently lacking. The main challenge in developing these metrics is that a 'one size, fits all' approach may not meet the needs of the range of PDPs that have different time lines and very different types of products, among other factors. This Discussion Paper develops a framework for thinking about access metrics from pre-licensure to post-licensure phases related to availability, acceptability, affordability, and adoption of new products.

A set of 26 core and 12 additional indicators are identified based on consultation with 15 PDP staff regarding their major milestones, supplemented by other indicators gleaned from the literature, and discussion with six donor organizations. More than half of the core indicators measure achievements relative to planned activities. The remaining indicators are designed to measure discrete outputs of access-related activities. Next steps include tailoring the indicators to individual PDPs and products, and piloting the use of the indicators for internal management and dialogue with funding agencies.

[1] This paper was prepared by Logan Brenzel, PhD (consultant) on behalf of the PDP Access Steering Committee which is comprised of the following organizations: Aeras, Concept, DNDi, FIND, IAVI, iOWH, IPM, IVAC, IVCC, MMV, MVI, PDVI, and the TB Alliance.

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1. Purpose of the paper

Product Development Partnerships (PDPs) are often challenged to ensure that target populations can access products once developed. While each PDP has its own access objectives, there is growing recognition within the PDP community that access is more than sales volume and speed to market. The PDP Steering Committee has adopted the following definition of access at their 2008 meeting:

> *Access is coordinated set of activities needed to ensure that the products developed will ultimately have an equitable public health impact. Achieving that impact requires products that are available, affordable, and acceptable to end-users, and adopted into developing country health systems (Brooks, et al., 2010).*

Ensuring that products reach end-users requires PDPs to develop, manage and track a wide range of activities and information. Having a clear set of indicators that measure progress along the way from R&D to ultimate use will be useful for enhancing the performance of PDPs in achieving better access. In addition, access metrics may be useful for responding to funding agency requests for more granularity on progress and achievements.

A set of commonly used metrics for PDPs to track progress toward access goals is currently lacking. The main challenge in developing these metrics is that a 'one size, fits all' approach may not meet the needs of all PDPs that have different time lines to product, and very different types of products, including products that will replace older products, those that will have marginal benefits, or those that will cater to specific population groups. In addition, PDPs have various levels of engagement, from carrying out a full range of access-related activities, to facilitating those activities through partners, and advocating for others to undertake activities. In addition, PDPs vary in terms of their transition point from when in the product development process the work of the PDP ends or the nature of their work changes. Finally, geographic and cultural differences of target countries where PDPs focus may also give rise to a range of indicators.

This Discussion Paper has been commissioned by the PDP Access Steering Committee to a) review and analyze across the PDPs what is currently being measured and indicators in use to understand commonalities and differences, and to identify possible gaps in what is currently being measured; b) propose new indicators based on the outcomes of discussions with PDP staff and donors, and how they would be measured. This final Discussion Paper incorporates feedback from the PDP Access Steering Committee meeting in December 2011, as well as written comments provided by PDP staff.

2. Methodology and Framework for Measuring Access

Access indicators are distinguished from outcome and health impact indicators, such as reduced morbidity and mortality associated with the new product. Access indicators are

those that help to track and measure progress towards achieving the greatest level of access to the product by the end-user, whether it be a patient, health care provider, laboratory technician, or a public health and vector control worker. The proposed set of indicators developed for this paper based on the following approach:

2.1 Framework for categorizing and classifying access metrics

For this exercise, selection of indicators is based on a framework for organizing and classifying access-related activities along a pathway toward development of specific products rather than a portfolio of products. This was accomplished through a review of published and unpublished literature (see references). Key aspects of current thinking are consolidated into a single framework illustrated in Table 1. This framework has three dimension: 1) domain of access; 2) type of indicators; and 3) time line of activities, focusing on pre- and post-licensure periods.

Table 1: Framework for Access Metrics

Domains of Access	Types of Indicators	Time Line
Availability	Qualitative and Quantitative Measures	Pre-clinical and clinical (-9+ years to 0 years)
Acceptability		Post-licensure (0 to 5 years)
Affordability		
Adoption		

The starting point for the framework was the work of Frost and Reich (2008) that defines three dimensions of access activities within a set of organizational structures and relationships (the architecture). Access activities span the domains of Availability, Affordability, and Adoption. Availability involves making, ordering, shipping, storing, distributing, and delivering a new technology to the end-user. Affordability activities ensure that products are not too costly for users. Adoption involves gaining acceptance and creating demand for new products from global to national levels. The framework discussed by Mahoney, et al (2007) refines adoption into two components: Acceptability to government agencies, health workers, end users and global agencies; and Adoptability, which focuses on the decision and ability of the product to be introduced into health systems. The four As of Availability, Acceptability, Affordability and Adoption serves as the basis for the framework on access metrics, and also corresponds to the definition outlined in Brooks, et al (2010).

In addition, a recent paper describes the flow of access activities from R&D to the end-user and places a time frame around when these activities need to take place in order to ensure maximum access. The framework for access metrics draws upon the flow of activities outlined in Frost et al, 2011. Similarly, a more recent work by Brooks (2011)

subdivides the four access domains into pre-clinical/clinical phase and post-licensure phase. This division is helpful for generating related indicators along the time-line of product development.

Finally, after a consultation (12-13 December 2011) with PDP staff, the framework was further refined based on what PDPs saw as the primary use(s) of the indicators, namely: for internal project management and for dialogue and discussion with donors. Because of the focus on internal project management, the indicators were divided into those that pertain to the pre-clinical and clinical periods (pre-licensure), and those that are relevant to post-licensure period.

2.2 Identification and development of indicators

The identification of indicators was based on the assumption that, for the most part, indicators should be related to critical milestones of product development that contribute to achieving access goals. A questionnaire/set of discussion questions was developed for PDP staff (see Annex 2) that focused on critical milestones related to Availability, Acceptability, Affordability, and Adoption for pre- and post-licensure periods of product development. PDP responses on milestones were aggregated and compared to identify commonalities and gaps in current practice.

Milestones are transformed into measureable indicators. For instance, a milestone related to "creation of a coalition or platform for dialogue with stakeholders" is modified into the indicator: "number of coalitions or platforms created for dialogue with stakeholders relative to plan." Indicators are of two types: process-oriented indicators and discrete indicators. A discrete indicator is one that requires reporting of a single value (quantities and percentages of outputs, or time in months/years). An example of discrete indicator is the "volume of products distributed at country level". Process indicators are those that capture achievement of a milestone, such as, "Product included in WHO Standard Treatment Guidelines."

Recognizing that PDPs are not a homogenous group, indicators are worded in such a way so as to be as specific as possible, while at the same time as widely applicable across the range of PDPs and products. In addition, indicators are worded in such a way to emphasize progress relative to what has been planned by the PDP originally to link them to project management.

The master list of indicators was supplemented by the following:

- Current indicators of access in use by PDPs
- Indicators based on activities and milestones outlined in the paper on timelines by Frost et al (2011) that were absent from the discussion with PDPs
- Indicators generated from other literature describing activities related to country decision-making as outlined in Wells and Brooks (2011) and MMV (2011); and,

activities related to regulatory processes (Milstein, 2008; and Moran, et al, 2011).

- Recommendations from PDP staff during a consultation (12-13 December, 2011).

FSG Social Impact Advisors (2007) proposed a set of metrics for performance measurement of PDPs along four dimensions: R&D to commercialization; organizational strength; enabling environment; and, health impact. A few of the proposed quantitative indicators were derived from this source. In addition, an early consultation by MSH (2000) focused on a consultative process for identifying access indicators for pharmaceuticals, vaccines, and health products around the themes of availability, affordability, accessibility, acceptability, and quality. The indicators highlighted in this document overlapped to a large extent with the proposed indicators of access metrics developed for this paper.

This process resulted in a list of over 100 indicators. Indicators were aggregated according to the four "A's" and ordered in terms of the timeframes outlined in Frost, et al (2011). Redundant indicators were removed from the list, and indicators measuring similar types of access-related steps or milestones were pared down on the basis of which indicator was more specific and measureable. The remaining indicators were consolidated to ensure that each time period for each of the domains had a corresponding indicator. However, the PDPs felt that organizing the indicators according to the 4 "A's" was not as useful as categorizing them as pre- or post-licensure. Some of the indicators corresponded to more than one of the access dimensions.

The framework also describes the measurement of indicators. Some indicators can be collected and measured based on internal PDP project management processes or through routine monitoring and evaluation efforts. These indicators are likely to be more easily measured and reported on. Other indicators may require analysis of partner or country data, or require a special survey. These would be more challenging and potentially time-consuming for PDPs.

In addition, indicators are characterized as those related to project management and those that could be viewed as output measures from PDP efforts and uptake at country level. Finally, indicators were classified as core indicators for measuring progress toward access, and additional indicators that would be useful to measure. Core indicators should be measureable by most, if not all, PDPs. This dichotomy was incorporated in order to pare down the list of key indicators, as well as to allow for some flexibility in what PDPs measured based on their specific product.

The current proposed framework of indicators includes 36 core access indicators: 12 correspond to the pre-licensure phase, and 14 correspond to post-licensure phase. An additional 12 indicators would be useful for PDPs to incorporate as relevant.

3. Current Practice of PDPs in Measuring Access

This section summarizes the outcomes of discussions with PDPs and donors, and responses to the questionnaire developed.

There is a range of definitions of success and access currently used by PDPs. Two PDPs use similar definitions of access as their definition of success (DNDi and Areas). One PDP (TB Alliance) utilizes the definition of access developed through the PDP Access Steering Committee. Two PDPs do not yet have a formally approved definition of access (FIND, IPMGlobal) though they work on access-related activities. For two PDPs, success was related to reducing morbidity and mortality, and for the rest of the PDPs, success was related to producing a product. Access is often viewed as a country's decision to adopt a product.

Table 2: Summary of PDP Responses on Milestones

Access Domain	Responses
Availability	The most common milestones related to negotiating/finalizing IP and manufacturer contracts; conducting market research; and holding discussions with relevant stakeholders (pre-licensure), and demand forecasting and supply and distribution issues (post licensure).
Acceptability	The most common milestones related to having field-based TPPs; obtaining necessary country approvals; WHO prequalification and WHO recommendations (pre-license), and creating disease platforms and holding discussions with regional or country regulatory authorities (post-licensure).
Affordability	PDPs focused on pricing strategies, economic impact studies, and IP negotiations as milestones during the pre-licensing phase. Milestones in the post-licensure phase included strategies for long-term financing, discussions with global funders, and development of investment cases.
Adoption	The most common milestones included dialogue and discussion, studies on barriers, demonstration projects and additional studies on health impact, and dissemination of information.

With respect to access-related milestones, there was more convergence than initially expected given the wide range of products and time frames for the PDPs. More detail on milestones came from PDPs that had already launched a product. Table 2 organizes the responses by access domain.

This domain with the most 'gaps' in terms of the range of activities and possible indicators was the affordability domain. Several PDPs mentioned that this was an area that they could do more work in.

Few PDPs have a formal system for monitoring access metrics. The International Vaccine Access Center (IVAC) uses the Vaccine Information Management Systems (VIMS) database for tracking global and country-specific information on status of product licensure; trends and projections of vaccine introduction and adoption of products; supply data by formulation; demand forecast vs. actuals; immunization coverage rates; disease burden; status of GAVI applications; wastage rates; meetings held with immunization stakeholders; and, status of introduction evaluations. These data are regularly analyzed and monthly reports are produced and disseminated. Once a year, IVAC holds a 'Data Day' during which time trends in the indicators are discussed.

Another example is the PATH Malaria Vaccine Initiative, Indicators of Success (IoS) that supports development of future funding and assists project teams to focus on critical path activities on both a long- and short-term basis (PATH, 2011). This system of indicators allows for internal evaluation on progress and external reporting to funders and advisors. The framework for these indicators are based on a hierarchy of long-term indicators of success (vision) which are then decomposed into annual indicators of success that focus and help to monitor progress toward achieving the long-term indicators. Decisions and risks to achieving the annual indicators are highlighted in the framework.

For example, a long-term indicator for the malaria vaccine RTS, S is to ensure that all malaria-endemic countries in sub-Saharan Africa have robust evidence allowing them to make a decision, within three years of vaccine pre-qualification, on the use of the product in their programs. An associated annual indicator is "clinical study reports available and finalized in time to support EMA filing."

The long-term indicators are monitored annual by the MVI leadership team, an external advisory committee and funders. The annual indicators of success are monitored quarterly by a portfolio management committee and the leadership team. Indicators are tracked based on a green-amber-red light system. Major risks in achieving these indicators are also identified.

4. Proposed Indicators

This section describes the proposed set of access indicators along the product development pathway from R&D to end-user (see Annex 3). Table 3 summarizes the characteristics of the 26 proposed core access indicators. These are roughly balanced between pre- and post-licensure periods. More than half of these pertain to project management (58%) and the remaining 42% are output indicators. There are slightly more discrete indicators than process indicators (54% compared to 46%). Nearly a third of the indicators pertain to the "Adoption" category (31%).

Table 3: Comparison of Proposed Core Access Metrics

Indicator	Pre-Licensure	Post-Licensure	Total
Total	12	14	26
Management	9	6	15 (58%)
Output	3	8	11 (42%)
Process	11	1	12 (46%)
Discrete	1	13	14 (54%)
Availability	4	3	7 (27%)
Acceptability	2	3	5 (19%)
Affordability	3	3	6 (23%)
Adoption	3	5	8 (31%)

Table 4 below combines the core and additional indicators, for a total of 38 indicators that are evenly divided between internal management and output indicators. Nearly two-thirds are discrete indicators, and one-third of the indicators pertain to "Adoption."

Table 4: Comparison of Total Access Metrics

Indicator	Pre-Licensure	Post-Licensure	Additional	Total (with Additional)
Total	12	14	12	38
Management	9	6	4	19 (50%)
Output	3	8	8	19 (50%)
Process	11	1	3	15 (39%)
Discrete	1	11	9	23 (61%)
Availability	4	3	1	8 (21%)
Acceptability	2	3	4	9 (24%)
Affordability	3	3	2	8 (21%)
Adoption	3	5	5	13 (34%)

5. Donor Perspectives

Five different donor agencies were consulted as part of the preparation of this paper, including Irish Aid, DfID, Wellcome Trust, The Bill & Melinda Gates Foundation, the World Bank, and the Ministry of Foreign Affairs/Netherlands. All of the donors gave support to the idea for PDP monitoring and tracking of access-related indicators. One donor was more interested in PDP performance than access indicators at this time.

The PDP Funder's Group is a consortium of donors in Europe that fund PDPs. To harmonize reporting and reduce transaction costs, a standardized reporting format has been developed for PDPs that is being piloted this year. PDPs will be asked to submit the format by April 2012. Depending upon the outcomes of this pilot, most donor agencies identified the potential value-add of incorporating some access measures into this format.

6. Implementing Access Measurement

A few PDPs were actively monitoring access-related activities, and were devoting at least 50% of time of one full-time equivalent staff person to monitoring in general. One PDP noted that as the number of products increased, there is a need to have additional staff working in this area. Because the framework is product-specific and not organized for an entire portfolio of products, it may be challenging for PDPs with many products in the pipeline to be actively monitoring access metrics for all products. The feasibility of doing this should be considered in the final prioritization of the proposed metrics.

7. Next Steps

The proposed indicators can be utilized as a "pick list" for dialogue between PDPs and their funders. They may also serve as a useful reference point for PDPs, funding agencies, and relevant partners.

Because the proposed indicators were developed to apply to a wide range of PDPs, the next step will be for PDPs to customize these indicators relative to their own products, timelines, and to their internal project management frameworks. Some PDPs utilize a log-frame for project management whereby activities are linked to strategies and milestones that correspond to a larger organizational or project goal(s). In this case, access indicators can be selected from the list and linked to specific project milestones and activities.

Additionally, one or more PDPs may be interested in piloting these indicators over the next 6 months to a year, and to report back to the Access Steering Committee on their experiences at a subsequent meeting.

An additional task for this assignment was to identify possible access indicators that would be useful in the case of a product that replaces an existing product and which may be marginally more effective than current treatment or prevention. In such a case, it will be important to demonstrate that the new product is cost-effective, affordable, acceptable to end users, and will be readily supplied into the future. Some of the indicators that could be customized for these types of products are outlined in Table 5.

Table 5: Suggested Access Indicators Relevant for Replacement Products

Relevant Indicators	Comments
Product is demonstrated to be a cost-effective investment relative to alternative interventions to achieving the same health outcome	It will be important to demonstrate that the new product is a cost-effective option relative to current products in use or to other types of interventions addressing the same public health issue
Expected cost savings to households associated with the use of this product compared to competitor products	Savings could be in the form of time savings (reduced time to complete treatment and time spent seeking treatment) as well as any cost savings associated with reduced treatment for side effects
Average % retail price mark-up of product in the private sector in target countries	Depending upon other products in the market, % mark-up may help to demonstrate the affordability of the product to the consumer or to the public sector
% of needed supply met by manufacturers	This indicator could be generated relative to other products currently in use to demonstrate sustainable supply
% of rural, poor households that would be willing to pay for the product (at an affordable price)	Willingness to pay by poor, rural households may be useful information for MOH decision-making
% of patients that are fully compliant with their treatment regimen	New products may enhance compliance and subsequent health benefits– this indicator could be linked to estimated years of life lost or DALYs lost (part of CEA above)
% of public and private sector health workers who prefer to use this product rather than other products	This information may also be useful for country decision-making to introduce a product and to ensure provider compliance.

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Appendix I: List of Persons Interviewed

Product Development Partnerships Consulted

- Anne Ginsberg, Vice President Scientific Affairs, Aeras
- Rita Khanna, General Counsel, Aeras
- Richard Mahoney, Coordinator, Policy and Access, Dengue Vaccine Initiative, IVI
- Evan Lee, Senior Policy Officer, FIND Diagnostics
- William Wells, Director of Market Access, TB Alliance
- Elizabeth Gardiner, Vice President of Market Access, TB Alliance
- Heather Kelly, Associate Director, OneWorldHealth
- Clare Pharoah, Associate Counsel, IAVI
- Carla Botting, Director, Product Development and Access, PATH
- Chris Gilmour, Area Lead, Manufacturing Science, International Partnership for Microbicides
- George Jagoe, Executive Vice-President of Global Access, Medicines for Malaria Venture
- Lois Privor-Dumm, Director of Alliances and Information, International Vaccine Access Center
- Meaghan Stack, Research Associate, International Vaccine Access Center
- Tom McLean, Chief Operating Officer, IVCC
- Graciella Diap, Medical Coordinator, FACT Project, DNDi

Donors

- Sue Kinn, DfID
- Diarmuid McLean, Irish Aid
- Val Snewnin, Wellcome Trust
- Daniel Korbel, Wellcome Trust
- Armin Fidler, World Bank
- Greg Widmeyer, Senior Program Officer, Bill & Melinda Gates Foundation
- Rachel Lenington, Bill & Melinda Gates Foundation
- Marja Esveld, Senior Policy Advisor, Health and Social Development, Department Health and AIDS Division, Ministry of Foreign Affairs

Others

- Rehan Hafiz, Country Program Officer, GAVI Alliance (formerly Ministry of Health and Family Welfare, Pakistan
- Florence Camus-Bablon, formerly Senior Access Advisor, Drugs for Neglected Diseases Initiative
- Adeeb Mahmud, FSG Social Impact Advisors
- Kyle Petersen, Managing Director, FSG Impact Advisors

- Hima Bhatavia, Clinton Health Access Initiative
- Michael Reich, Professor, Harvard School of Public Health
- Carolyn Hart, Director, John Snow, Inc.
- Dana Aronovich, Project Manager, John Snow, Inc.
- Stefanie Meredith, Global Health Consulting
- Alan Brooks, Consultant

Annex 2: Summary of Questions for PDP Staff

PDP Access Steering Committee Discussion Paper:
Metrics to track progress and success on access to new products
Logan Brenzel, PhD (loganbrenzel@gmail.com)

November 15, 2011

1. Rationale and background

Product development partnerships (PDPs) and donors have recognized that ensuring access to new products is a complex challenge. Creating access to new products requires PDPs to track, develop, and manage a wide range of information at country, regional, and global levels. For PDPs, defining success in access is critical. At the 2008 PDP Access meeting, participants agreed to the following definition of access:

> *"For PDPs, access refers to a coordinated set of activities needed to ensure that the products developed will ultimately have an equitable public health impact. Achieving that impact requires products that are available, affordable, and acceptable to end users, and adopted into developing country health systems."*

The PDP Access Steering Committee (SC) has developed a series of Discussion Papers on key issues facing PDPs. The purpose of these Discussion Papers is to explore and document PDP experiences and challenges with regard to access. Although each PDP has its own access objectives, a set of common metrics to track progress on access as defined above, is lacking or ill-defined. Therefore, the purpose of this Discussion Paper is to outline a set of metrics that PDPs could use to track progress and success in achieving access to new products or products under development. The objectives of the paper are to:

- Review and analyze the indicators that are currently being measured to reflect access and success by PDPs; and,
- Propose a set of indicators based on this review and discussions with PDP staff, donors, and country nationals.
- Identify how these indicators can be tracked by individual PDPs.

The main audience of the Discussion Paper is the PDPs themselves, along with their donors. A draft of this paper will be discussed at an upcoming PDP Access Steering Committee meeting 12-13 December, 2011.

The following list of questions will help to structure our discussion on measuring access and success. The answers to these may vary depending upon the product, and the goal is to capture the range of experience.

1. How does your PDP define success? (generally or for a specific product)

2. How does your PDP define access? (generally or for a specific product)

3. How are success and access linked?

4. How do you see the definition of access developed by the Access Steering Committee being integrated into the efforts of the PDP?

> *"For PDPs, access refers to a coordinated set of activities needed to ensure that the products developed will ultimately have an equitable public health impact. Achieving that impact requires products that are available, affordable, and acceptable to end users, and adopted into developing country health systems."*

5. What is your role regarding access to the products developed by your PDP?

6. Could you identify critical milestones/activities that relate to ensuring success and/or access for your products prior to licensure relating to availability, affordability, acceptability, and adoption?

7. Could you identify critical milestones/activities that relate to ensuring success and/or access for your products post- licensure related to availability, affordability, acceptability, and adoption?

8. At what point will the work of this PDP end, and a transition to another entity occur (in terms of ensuring access and uptake of your product(s)?

9. Does this PDP have, or is the PDP currently developing, a framework, mechanism or a process for measuring and tracking access milestones or steps? Are there any indicators that you use internally to track progress on access? Please describe these indicators, how often they are collected/measured/discussed and sources of data.

10. What resources have been put behind measuring and tracking access in your PDP? How many staff, how much staff time on average, and what has this cost?

10. What challenges and constraints do you anticipate to measuring or tracking access to future products? What have been the lessons learned?

11. Does your PDP have an approach that you think would be useful for other PDPs in terms of a framework for measuring access steps and milestones? What aspects do you think would be most useful?

12. Are there any documents, reports, or other materials that would be useful for us to review prior to developing this paper?

Thank you for your participation in this survey of PDPs. The responses will be kept confidential and collated and fed back to you prior to preparation of the draft report to ensure accuracy.

Annex 3: Proposed Core and Additional Access Indicators

No.	Pre-licensure Indicators	Priority	Focus	Type of Indicator	Measurement	Access Dimension
1	Clearance from patent holders obtained at each go/no go decision point	Core	Management	Process	PDP records	Availability
2	Negotiated agreements with manufacturing partners completed (including pricing for affordability, regulatory/licensing requirements, technology transfer, demonstration projects, IP requirements)	Core	Management	Process	PDP records	Availability
3	Clinical study reports finalized prior to regulatory filing	Core	Management	Process	PDP records	Availability
4	Number of coalitions or platforms created (i.e., relevant WHO, regional, scientific or regulatory agencies, national scientific or regulatory agencies, MOH representatives, among others) to facilitate dialogue on product development at global, regional and national levels relative to plan (%)	Core	Management	Process	PDP records	Availability
5	TPP revised based on stakeholder feedback on target populations, prices, presentation, dosage form and schedule, packaging, feedback from health workers and households, barriers to uptake, expected efficacy, and other field requirements	Core	Management	Process	PDP records	Acceptability
6	Product included in WHO Standard Treatment Guidelines, WHO Essential Drug List, and/or global financing agency policy/product list	Core	Output	Process	PDP records	Acceptability
7	Pricing strategy vetted and approved by advisory group (as part of TPP and also closer to market)	Core	Management	Process	PDP records	Affordability
8	Product is demonstrated to be a cost-effective investment relative to alternative interventions to achieving the same health outcome	Core	Output	Process	PDP records, study results	Affordability
9	Commitment obtained from global financing body(ies) to support initial country level introduction (e.g., GAVI Alliance, Global Fund, UNITAID, etc.)	Core	Management	Process	PDP records	Affordability
10	In-country presence established (from an office to periodic visits by staff and consultants, to local champions) relative to planned presence	Core	Management	Process	PDP records	Adoption
11	Standard evidence package for country-decision making is disseminated at global, regional, and national levels relative to planned dissemination (%)	Core	Management	Process	PDP records	Adoption
12	Time (months) from WHO recommendation of the product to adoption into target countries (average)	Core	Output	Discrete	PDP records	Adoption

No.	Post-licensure Indicators	Priority	Focus	Type of Indicator	Measurement	Access Dimension
1	Strategic demand forecast reviewed and approved by relevant stakeholders (e.g., global financing body; technical and advisory groups)	Core	Management	Process	PDP records	Availability
2	% of needed supply met by manufacturers	Core	Output	Discrete	PDP and partner records	Availability
3	Volume of products distributed at country level	Core	Output	Discrete	PDP and partner records	Availability
4	No. of country regulatory submissions relative to planned submissions (%)	Core	Management	Discrete	PDP and partner records	Acceptability
5	% of countries in which the product is the 1st line recommended treatment described in the national guidelines or national strategy	Core	Output	Discrete	PDP and partner records	Acceptability
6	% of target countries licensing the new product (relative to planned numbers)	Core	Management	Discrete	PDP and partner records	Acceptability
7	Number of discussions held with Ministry of Finance and Ministry of Health in key countries on costs and economic benefits of the new product relative to planned discussions (%)	Core	Management	Discrete	PDP and partner records	Affordability
8	Avg % retail price mark-up of product in the private sector in target countries	Core	Output	Discrete	Survey	Affordability
9	% of rural, poor households that are willing to pay for the product	Core	Output	Discrete	Survey	Affordability
10	Number of champions actively engaged in dialogue with key national decision-makers (program managers, regulatory authorities, WHO country staff, MOF staff, local researchers) and/or through relevant technical working groups (e.g., inter-agency coordinating committee for vaccines, health sector coordinating committee, national aids coordinating committee, etc) relative to planned engagement (%)	Core	Management	Discrete	PDP and partner records	Adoption
11	Number of countries that have adopted the product relative to countries forecast to adopt (%)	Core	Output	Discrete	PDP and partner records	Adoption
12	Number of target countries actively using available decision-making and planning tools for the product, relative to expected countries (%)	Core	Management	Discrete	PDP and partner records	Adoption
13	Actual demand for the product compared with demand forecast in target countries (%)	Core	Output	Discrete	PDP and partner records	Adoption
14	Market share of product (in private sector) relative to target share (%)	Core	Output	Discrete	Survey	Adoption

No.	Additional Indicators	Priority	Focus	Type of Indicator	Measurement	Access Dimension
1	% of health facilities or districts with product stock-outs at the time of survey	Useful	Output	Discrete	Survey	Availability
2	Number of countries in which anti-product lobby interests have been identified and are engaged relative to plan (%)	Useful	Management	Process	PDP and partner records	Acceptability
3	% of patients that are fully compliant with their treatment regimen	Useful	Output	Discrete	Survey	Acceptability
4	% of public and private sector health workers who prefer to use this product rather than other products	Useful	Output	Discrete	Survey	Acceptability
5	% of Phase IV/Demonstration projects conducted compared to planned	Useful	Output	Process	PDP and partner records	Acceptability
6	% of target countries incorporating the cost of the product into program budgets relative to plan	Useful	Output	Discrete	MOH survey	Affordability
7	Budget impact of the cost of the product likely to be affordable to countries (<5% Government Health Expenditure)	Core	Output	Process	PDP records, study results	Affordability
8	Necessary support to supply, logistics, and cold chain systems at country level identified and provided, relative to planned support (%)	Useful	Management	Discrete	PDP and partner records	Adoption
9	Number of laboratory personnel, health workers, or other national counterparts trained relative to planned (%)	Useful	Management	Discrete	PDP and partner records	Adoption
10	Number of countries supported in their applications for global funding relative to number expected to be supported (%)	Useful	Management	Discrete	PDP and partner records	Adoption
11	Number of end-users of the product relative to expected number of users (%). This indicator could be further disaggregated by income level, gender of user, and source of care (public or private sector) as needed.	Useful	Output	Discrete	Survey	Adoption
12	Time (in months) between first receipt of product and 30% coverage of the target population	Useful	Output	Discrete	PDP and partner records	Adoption

Logan Brenzel is a health economist and independent consultant. She has nearly 30 years of health financing and development experience worldwide, including extensive experience working with ministries of health and finance on approaches to priority setting, financial sustainability, health financing and reform, results-based financing and development effectiveness. Logan currently provides ongoing technical support and advice to the Bill & Melinda Gates Foundation on immunization financing and health systems. She recently completed an analysis of the financial sustainability of the Affordable Medicines Facility – malaria (AMFm) for The Global Fund; and has developed a methodology for evaluating the cost-effectiveness of results-based financing for The World Bank. In her previous seven-year assignment at the World Bank, she provided technical and policy support to the GAVI Alliance as co-chair of the Health Systems Strengthening and Immunization Financing and Sustainability Task Teams. She has served as a health-financing advisor to the Minister of Health in Ethiopia; managed a regional health financing and reform initiative in the Latin America and Caribbean for USAID; and, was a faculty at the Sir Arthur Lewis Institute for Social and Economic Research at the University of the West Indies. She has written extensively and conducted seminal work on financing and economic evaluation of public health interventions. Logan has a PhD in Health Economics from the Johns Hopkins University School of Hygiene and Public Health and an MS in Health Policy and Management from the Harvard School of Public Health. Her undergraduate degree was from Stanford University.