FSG SOCIAL IMPACT ADVISORS

Toward a New Approach to Product Development Partnership Performance Measurement

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on behalf of the PDP Funders Group

BILL & MELINDA GATES *foundation*

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1. Executive Summary

The PDP Funders Group has called for a landscape study of performance measurement among Product Development Partnerships (PDPs).[1] This white paper reviews the state of practice and then proposes a new framework as a starting point for a future "performance measurement partnership" among donors and PDPs.

FSG Social Impact Advisors (FSG)[2] conducted the study that was sponsored by the Bill and Melinda Gates Foundation with support from the Rockefeller Foundation. FSG reviewed the literature and conducted interviews with more than 60 organizations, including donors, PDPs, and a set of "analogous" organizations comprised of biotech firms, pharmaceutical companies and nonprofits involved in global health. Some 350 individual metrics were collected and analyzed from PDPs and another 250 metrics from analogous organizations.

Key findings from the analysis include:

- Donors vary greatly in the scope and rigor of performance oversight;
- The current state of practice in PDP performance measurement lacks structure and comprehensiveness;
- All PDPs measure common areas such as governance, people, finance, portfolio and R&D project management, but they differ considerably in the:
    - Manner in which they measure individual activities or goals;
    - Measurement priorities reported by management;
    - Sharpness with which they articulate their metrics.
- It is possible to classify PDP performance metrics in a way that makes sense for PDPs and donors.

[1]PDPs can encompass a vast range of collaborative health research activities. While the paper's conclusions may have wider applicability to various health technology R&D consortia, they are primarily targeting a sub-group of ventures that use private sector approaches or resources to tackle R&D challenges, target one or more "neglected diseases," focus on products suited for use in developing countries, employ variants of the multi-candidate/portfolio management approach; take candidates through substantial portions of R&D to commercialization value chain, and primarily pursue public health objectives. This definition is based on a 2004 stakeholder forum on PDPs that raised the need to improve the performance measurement of these entities. The sub-group of ten organizations studied in this report can be found in Appendix A. See: "Combating Diseases Associated with Poverty: Financing Strategies for Product Development and the Role of Public-Private Partnerships," Roy Widdus, Katherine White, IPPPH, 2004. See the appendix for the PDPs considered in this study.

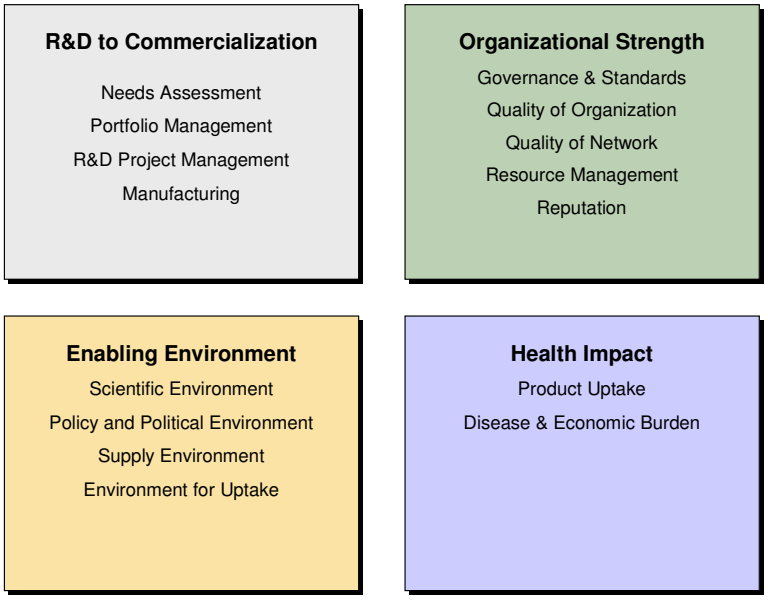
[2] The authors of this study from FSG are Kyle Peterson and Marc Pfitzer, together with Laura Herman, Patty Russell, Mike Stamp, and David Zapol

After assessing the state of performance measurement among PDPs, this paper presents a new performance measurement framework for PDPs. The framework will help donors and PDPs link strategic planning to performance measurement and more clearly communicate about their progress.

The framework offers a more comprehensive set of issues than the conventional array of R&D performance metrics. Four Areas of Performance – R&D to Commercialization, Organizational Strength, Enabling Environment, and Health Impact – reflect the challenging reality of PDPs' efforts to bring new technologies to bear (See Exhibit 1a & 1b). The framework has four levels, allowing for both field-wide applicability and individual PDP customization.

Exhibit 1a

Areas and Dimensions of Performance Measurement



This framework is not meant to be a static diagnostic tool for donors to evaluate PDPs separately from how PDPs manage their own performance. Rather, it is relevant for both the PDP manager and donor and thus serves as the first tangible manifestation of a more integrated and collaborative approach to performance measurement in this field. Deliberately, the framework does not prioritize certain performance issues for donor evaluation. Instead, it provides a platform to enable each PDP and its donors to engage in discussions around performance issues and decide jointly on the specific metrics that best reflect the unique priorities of individual PDPs.

The framework is an important – but not final – step towards improving the state of performance measurement among PDPs and donors. Interviews revealed needed changes in current donor evaluation processes so that they become more consistent, predictable, less burdensome and valuable to both donors and PDPs. FSG recommends that a new "performance measurement partnership" be established between donors and PDPs to improve the value of donor-sponsored evaluations and internal management reviews by PDPs. Such a new performance measurement relationship would seek to:

- Build on pre-investment assessments and periodic business planning efforts;
- Complement internal staff and board performance monitoring processes;

  - Enhance insight generation by providing appropriate support for external information gathering and assessments (e.g. R&D benchmarking, market assessments, health impact assessments);
  - Go beyond validation of PDP decisions and investments to jointly identifying constraints to success and sharing responsibility where appropriate for achieving and measuring progress towards key objectives of PDPs.

To bring about this performance measurement partnership, an action agenda is set forth for both donors and PDPs:

Agenda for Donors:

- Work with PDPs to refine and operationalize the performance framework;
- Encourage individual PDPs to improve the quality of their metrics;
- Identify where PDPS need external support to measure their performance;
- Facilitate the development of a new, partnership-driven approach to PDP performance measurement;
- Use the new approach to support PDPs progress and attract new donors.

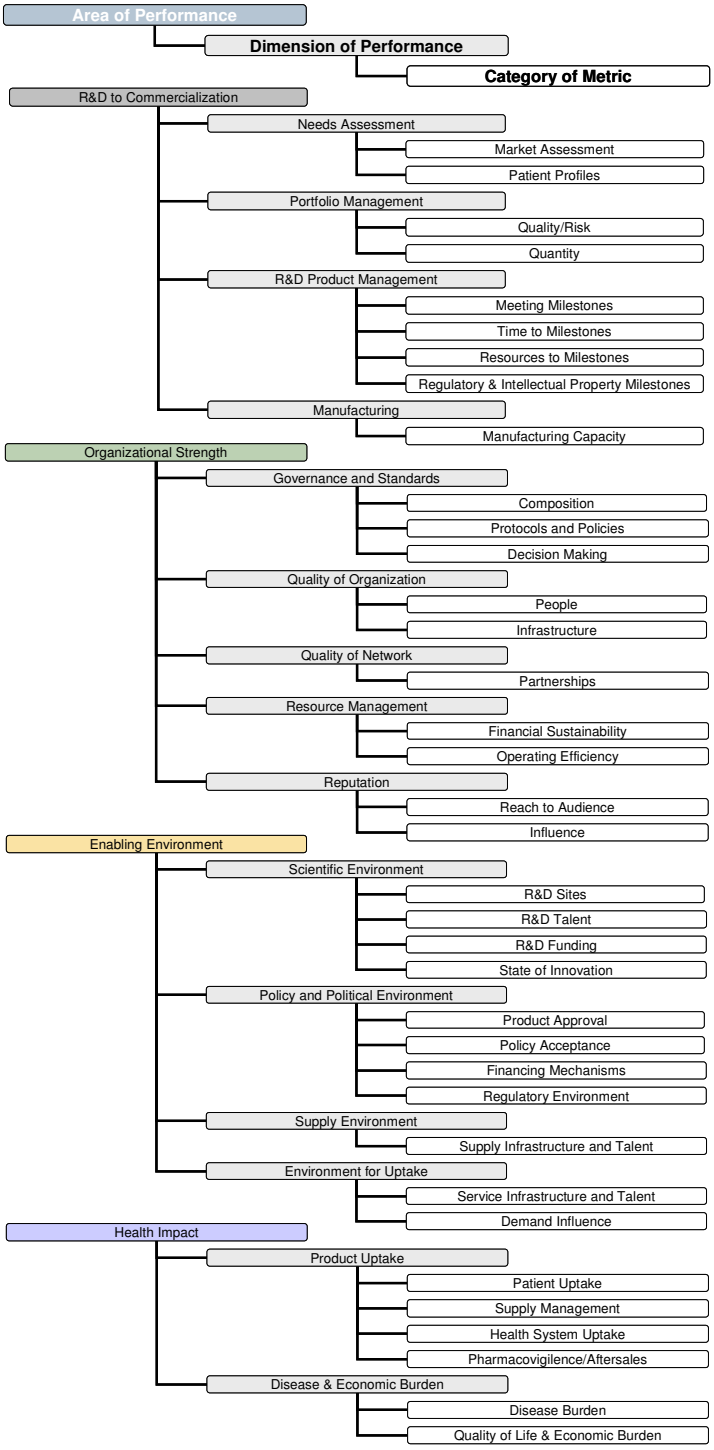
Agenda for PDPs:

- Use the performance framework to organize existing metrics and identify gaps where measurement may be lacking or vague;
- Use the performance framework as a tool to structure business plans, internal monitoring, and structuring performance measurement areas to be supported or tackled by donors.

Exhibit 1b.

Performance Measurement Framework

The proposed performance measurement map captures all the efforts PDPs are now selectively undertaking and measuring. After sorting out PDP's own indicators of performance, FSG identified a natural segmentation around Four Areas of Performance. Based on how the level of focus applied to each area, different layers of detail emerge. As the highest levels, all areas apply to all PDPs. With increasing focus, performance metrics need to be identified to match the specific objectives of each PDP.



2. Introduction: The Need for Better Understanding of Performance Measurement

What does "performance measurement" mean in a new field that is still refining its operating model? This white paper attempts to answer that question by exploring the current and potential state of performance measurement of Product Development Partnerships (PDPs) for the benefit of PDPs and donors alike.

PDPs develop health technologies for global diseases, drawing upon the science, people, and practices of pharmaceutical/biotech R&D and the collaborative spirit of the global health community. Since the birth of this new type of organization ten years ago, the "day in the life" of a PDP has evolved to look less like an R&D enterprise and more like that of a complex global health actor. Many of the growing pains are unique to this field, for example, integrating a complicated web of partners spanning scientific discovery to technology uptake and ultimately, health impact. These challenges make performance measurement difficult to define and implement.

Donors, too, are learning to support these organizations in the context of countless other health needs, and are pressured to justify their investments to their constituents when most entities are still years from delivering technologies to patients. Many donors confess a lack of capacity to understand the detailed science with which PDPs work and find it challenging to effectively track PDP performance.

As PDPs and donors address their individual performance measurement agendas, they risk talking past each other in terms of desired insights, measurement scope, and even in the language they use to describe performance.

This study identifies three potential repercussions of the status quo on performance measurement:

- Ambiguity about performance measurement in the PDP field creates unnecessary friction among donors and PDPs;
- A lack of shared understanding about how to measure progress puts a drag on field-wide insight development while increasing the administrative burden for both parties;
- A loosely defined approach to measuring performance may discourage new donors from investing in PDPs. In FSG's experience, funders view areas of activity in which they have a limited understanding as higher risk.

Two years ago, donors met in London and discussed the challenges of performance measurement among PDPs. In 2006, on behalf of the PDP Funders Group, the Bill and Melinda Gates and Rockefeller Foundations engaged FSG Social Impact Advisors to investigate a common approach to performance measurement. FSG interviewed more than 60 opinion leaders and reviewed the literature on performance and evaluation in the PDP and analogous fields of biotech, pharmaceuticals, NGOs, and associated industries

such as venture capital investing.[3] Based on this work, FSG developed an approach that draws heavily on a performance measurement framework and a vision for a new "performance measurement partnership" among donors and PDPs.

This study serves as the first comprehensive review of performance measurement in the PDP field. The prior efforts to understand performance metrics in the field of PDPs are limited in scope. Some work has been well regarded, notably Mary Moran's writings that focus on R&D. Roy Widdus and Alison Sander also contributed an important list of "success factors" for PDPs[4]. However it is clear that there is no existing force in the PDP community to bring donors and PDPs together around a shared solution. Further, PDPs are too diverse in their challenges and objectives and stage of organizational development to be diagnosed using a list of simple, standard indicators. FSG's work on evaluation in the social sector reveals that traditional approaches to evaluation where funders impose externally-generated gauges of success are becoming outmoded. The new vision for evaluation is about performance, more frequently measured, more dependent upon clear strategy, more cognizant of the changing world around the desired results and more collaboratively driven by both funder and grantee.[5]

Performance Measurement versus Evaluation

This white paper draws an important distinction between traditional evaluation and the wider concept of "performance measurement." Unlike evaluation that considers progress from an external, investor/donor perspective, performance measurement includes the perspectives and needs of the funder and the grantee/implementing organization. The recommendations in this study are relevant to the donor that is searching for a way to conduct more efficient and helpful evaluations to ensure and communicate return on investment. Equally, the ideas in this study can help PDPs develop better strategic plans and monitor their progress against clear objectives.

FSG's work within the wider social sector suggests that performance measurement proves most useful when it is not merely a tool for external validation, as donor decisions are rarely based on single evaluation results. A recent study conducted by FSG on the subject of evaluation concludes that performance measurement is most valuable when donor and implementer work together to set the terms of performance.

[3] It is difficult, if not impossible, to find perfect comparators for PDPs. These organizations were set up as a new model so identifying analogues is a difficult task. Analogue organizations in this study include organizations that represent the PDP value chain (R&D) but also other facets of PDPs' work (such as advocacy).

[4] See: "Combating Diseases Associated with Poverty: Financing Strategies for Product Development and the Role of Public-Private Partnerships," Roy Widdus, Katherine White, IPPPH, 2004: Annex 9b by Allison Sander and Roy Widdus

[5] *From Insight to Action: New Directions in Foundation Evaluation*; Mark Kramer with Rebecca Graves, Jason Hirschorn and Leigh Fiske, 2007

Based on our analysis, what is needed is not a new checklist for donor evaluation but rather a more accurate representation of the work PDPs are conducting now and in the future, illustrations of how to measure progress against this more realistic set of performance factors and a new relationship between PDP and donor to help strengthen and accelerate performance.

2.1. Perspectives on the Value of a Common Performance Measurement Approach

Unlike other studies that focus only on the needs of either the donor or the grantee, this analysis deliberately attempts to bridge those two perspectives and provide value for both.

Today, donors and PDPs see different potential benefits from a more integrated performance measurement approach. Donors express three main motivations for pursuing a common approach:

1. **Help justify funding decisions.** Donors report a desire to see measures of progress, efficiency, and risk within each PDP and across PDPs to help make the case for continuing or changing support to PDPs.

2. **Simplify the process of PDP evaluation.** Donors note potential benefits of a common approach to evaluation, particularly in terms of a framework, guidance and tools that can reduce the planning and preparation time for evaluations. This is particularly true for donors that have fewer resources to devote to monitoring and evaluation.

3. **Increase support to PDPs.** Current donors would like to help new donors better understand the work and progress of PDPs and thereby attract additional funding to the PDP community.

Not surprisingly, PDPs are more skeptical of common approaches to performance measurement. These organizations hope that any performance measurement initiatives "first, do no harm" to PDPs and do not increase their administrative burden. Nevertheless, most PDPs do see value in a common performance measurement approach from three perspectives:

1. **Reduce the burden of donor monitoring and evaluation**. PDPs find themselves currently under-resourced in responding to numerous donor requests. Several PDPs are concerned that they are constantly burdened by redundant donor audits (although "harmonized" donor evaluations are expected to decrease this burden).

2. **Improve understanding about PDP performance**. PDPs may do similar work, but current efforts to compare PDPs' progress are fraught with definition challenges. One PDP complained that it is compared to another PDP in terms of portfolio size. Upon investigation, the organization discovered that the donor's interpretation was based on differing definitions of a "project." In areas less well-trodden than R&D, ambiguous definitions are even more pronounced.

3. **Inform the PDP performance management process.** Most PDPs do not have the in-house expertise and resources to manage a comprehensive performance measurement process to fulfill both internal and external needs**.** A performance measurement framework and sample indicators would inform PDPs' own strategic planning and improvement. Many PDPs express a desire to learn from peers about how they measure and manage performance.

Donors and PDPs certainly recognize the difficulties in creating a common approach to performance measurement. PDPs question whether one methodology and set of indicators could ever encompass the range of specific activities and missions represented by organizations working across diseases and technologies. Interviewed PDPs also question whether donors would agree to accept a common set of measures possibly at the expense of their own institutional requirements. Donors express concern that there are insufficient resources to move forward with this work. Overall, however, the perceived benefits of creating a common approach to performance measurement outweigh the recognized challenges.

Accordingly, the performance framework and performance measurement vision presented in this white paper go beyond a list of metrics and toward a more transparent, forward looking, predictable, and valuable process to understand how to nurture these important organizations to bring about timely health impact. The recommendations set forth in this study are a first step toward improved performance measurement. Most importantly, they build on the current ways donors and PDPs track performance.

3. State of Performance Measurement in the PDP Field

The state of performance measurement in the PDP field is marked by ambiguity, variable quality, and mixed priorities.

In general, donors tend to engage with PDPs on performance issues in three distinct ways, depending on institutional style and the resources available to manage PDP relationships. PDPs themselves articulate performance metrics in varying ways and with varying degrees of specificity, and do not always cover all areas critical to success. Both PDPs and donors also differ tremendously on the aspects of performance they prioritize.

This adds up to somewhat confusing and patchy landscape of performance metrics with little obvious common ground – a situation compounded by uncertainty over who has responsibility for defining metrics in the first place (see sidebar "Performance Measurement: Who's in Charge?").

Performance Measurement: Who's in Charge?

Reflecting the limited resources available to manage PDP relationships, many donors reported that they lack a structured approach to evaluating PDPs, often relying on the logic of the PDP mission and pipeline progress. Donors report "*investing upfront with some understanding of the results but without a real timeline in mind*," and that "*many donors don't actually want to know much beyond the fact that the PDPs are trying to build drugs/vaccines for the developing world*."

Donors often express interest in seeing evidence of fiscal responsibility – "*we want to know how much money is getting invested towards the product vs. other things*" was a widely-held sentiment – but look to the PDPs to establish their own milestones for evaluation: "*PDPs should lay out the basis on which they should be judged. PDPs should come up with the metrics that track their success."*

However, many PDPs report that, at least in part, they set and measured their performance metrics based on what they understand donor wishes and requirements to be. Indeed, in reviewing the material for this white paper, a number of PDPs expressed the hope that it would illustrate more clearly to them "*what donors want to know*."

3.1. Donors Engage with PDPs in Different Ways

Our research uncovered three "archetypes" of donors – mentors, traditionalists and project supporters – each of which brings different perspectives and habits to monitoring and evaluating the performance of PDPs.

- **"Mentors":** Some donors are deeply engaged with PDPs' day-to-day operating processes. Mentors tend to monitor progress on a very frequent basis, often through dedicated program officers and board members – one donor described how they "*are on boards and know what is going on…The program officers talk to [PDPs] weekly*." PDPs tend to give relatively frequent, highly detailed reports to such donors which summarize and formalize what individual program officers already know for the sake of their colleagues in the donor institution.

- **"Traditionalists"**: Other donors adopt a more distant, light-touch approach once money is awarded. Reports to this group are often more general and focus on a limited set of information, usually agreed upon in advance. This second group has relatively limited capacity to monitor PDP performance and views understanding the details of the PDP model as a challenge. As one donor pointed out, "*This is high-end science, and we are not high-end scientists*."

- **"Project Supporters":** Typically, these donors invest in PDPs only after others have already done so. Their investments often are smaller, and tend to focus on specific deliverables rather than PDP activities as a whole. Performance measurement for these donors is usually less complex in that deliverables are narrower and more defined than those associated with broader operating support.

The different approaches reflect the resources available to donors to manage relations with PDPs, their evaluation styles, and the needs of their stakeholders. The result of these three archetypes, all investing in a relatively small number of grantees, is a hodgepodge of measurement practices focusing on different activities in different ways at different times. One PDP described needing to follow fourteen separate donor reporting procedures. While some donors have already taken action to minimize the burden on PDPs, such as the Wellcome Trust's use of existing reports created for other donors, most request customized information.

3.2. Donor Priorities Vary and Lack Transparency

Even within the three archetypes, donors emphasize different priorities about PDP performance measurement. For example, the U.K. Department for International Development (DfID) and Irish Aid highlight detailed criteria used to assess PDP funding applications and monitor the performance of existing grants:

- DfID assesses PDPs in five key areas:
    - The **strategic fit** with DfID's other activities in the global health arena and beyond;
    - The **funding context** (i.e., the effect DfID funding will have both on a given PDP and other actors on that pipeline);
    - The potential for **impact on poverty and health** in developing countries
    - The **effectiveness and efficiency** of PDP operations;
    - The **balance of risk** between a PDP and its partners.

- Irish Aid identifies three key areas on which it assesses PDPs:
    - **Operations** – the management approach of a PDP, including technical expertise, focus on developing country demand, and quality of portfolio management;
    - **Governance** – the extent to which the PDP is well-run, transparent and accountable;

- **Strategic Fit** – relationship with broader Irish Aid global health goals and the impact of PDP operations on developing country health systems.

While all donors combined may actually measure most aspects of performance, it is evident that individual donors place varying levels of emphasis on selected areas. In addition, the differences among donors compel PDPs to support a number of reporting agendas that only partially overlap with their current measurement priorities. DfID and Irish Aid stand out as two donors that have made their evaluation criteria transparent. That is not the case for many other donors that fund PDPs.

3.3. Gaps Exist in PDPs' Performance Measurement

To understand the current state of performance measurement among PDPs, PDPs were asked to submit their internal and external metrics to FSG. Nine participating PDPs self-reported 350 performance metrics to FSG. The first step was to group the reported metrics into clusters as few PDPs used similar structures to organize their metrics. This lack of a common approach to metric organization is, in itself, an important finding and one that augurs for a structure or framework that clearly and logically groups the metrics that matter to PDPs and donors.

Despite the differences in technology platforms and stages of development among them, there are commonalities in terms of the aspects of performance measured. For example, all of the PDPs include metrics in areas such as governance, people, finance, R&D project management and the size and quality of the portfolio.

However, analysis of these common performance areas highlights notable differences. Many contain metrics from less than half of the PDPs. In some, (e.g. more downstream activities such as manufacturing), reporting emphasis and quality varies tremendously. These differences are reflective of differing strategies and evolving opinions among PDPs and donors, for example, about how much of the health technology value chain any PDP should be responsible for, or measure. The performance measurement differences can also be explained by the fact that some PDPs are younger than others and are still populating and revising their performance measurement systems. In essence, they reflect varying priorities on what needs to be measured and how.

3.4. Measurement Perspectives and Priorities Differ Across PDPs

PDPs articulate similar metrics in different ways. For example, all PDPs report measuring people-related issues, but where the TB Alliance identifies six people-related metrics, covering staff size/location, turnover, salary/benefits, employee relations and legal compliance, AERAS focuses more narrowly on performance-based incentives and education and professional development[6]. There is also a clear difference between PDPs and analogous organizations, such as biotech firms. Analogous organizations place much

[6] A list of example metrics can be found in Appendix B

more emphasis on metrics associated with the qualities and performance of their people, rather than the effectiveness of human resource management on which most PDPs concentrate.

PDPs were asked to identify five performance metrics that were priorities for the management team. The responses also varied notably – very few of the common performance areas (governance, people, finance, R&D project management) contain priority metrics from more than one PDP. This lack of a clear hierarchy of performance metrics is striking; PDPs seem to place more emphasis on the particular set of issues currently at the top of managers' minds rather than a formal set of measures that are representative of overall progress against plans.

3.5. Current PDP Performance Metrics Vary in Quality

Performance metrics also vary substantially in quality across PDPs. The vast majority of the metrics reported by analogous organizations are tightly defined qualitative indicators (e.g. "ISO certification obtained") or quantitative metrics (ratios, time to completion, etc.). However, PDPs report a substantial number of metrics that would be better classified as "activities" (e.g. "establish clinical trials") or more generic metrics where it was not clear how success is judged (e.g., "clinical trial progress"). PDPs working in technology areas where processes are well established and understood, such as drugs and diagnostics, tend to have sharper measures than those that use more experimental processes, such as vaccine and microbicide developers.

3.6. A Common, but Patchy Landscape

On a fundamental level, there is a degree of consensus about the main areas of performance that are critical to PDP success. This consensus can form a solid foundation for a common approach to performance measurement.

Lack of agreement on who has ultimate responsibility for setting performance metrics and varying donor and PDP approaches and priorities, however, leads to a patchy landscape with similar activities measured in many different ways. The lack of a common performance measurement language means that performance analyses do not "travel well" beyond the one audience for whom they are devised. This has the dual effect of increasing the administrative burden on PDPs while reducing the opportunities for transparency and collective learning.

In order to improve on the performance measurement status quo, it will be important that any common approach serves the purposes of both donors and PDPs. Performance measures employed by PDP management need not live separate lives from donors' own performance tracking. A common framework can start to bring clarity, structure, best practice, and collective learning to PDPs and donors alike.

4. Towards a Common Performance Framework

To support PDPs, a common performance framework and process need to represent a diversity of objectives and yet be specific enough to provide guidance to plan work better, improve implementation, and track progress towards goals. This next section is devoted to the performance framework; discussion on performance measurement process will follow in Section Five.

This section proposes a framework that captures the real-life efforts that PDPs undertake on a day-to-day basis. Using the same organizing structure will allow donors and individual PDPs to understand each other and to begin to harmonize their different perspectives on performance measurement. The framework significantly decreases the guesswork around what to measure and how, as it lays out multiple areas for consideration during strategic planning or performance measurement discussions.

The framework will not provide an exhaustive menu of possible metrics for donors to select for PDPs nor is it a diagnostic tool composed of key success factors. Instead, it provides a platform for PDPs and donors to engage in discussions around performance issues and to decide jointly on the customized metrics that best reflect the unique priorities of individual PDPs.[7]

4.1. Four Flexible Levels of the Performance Framework

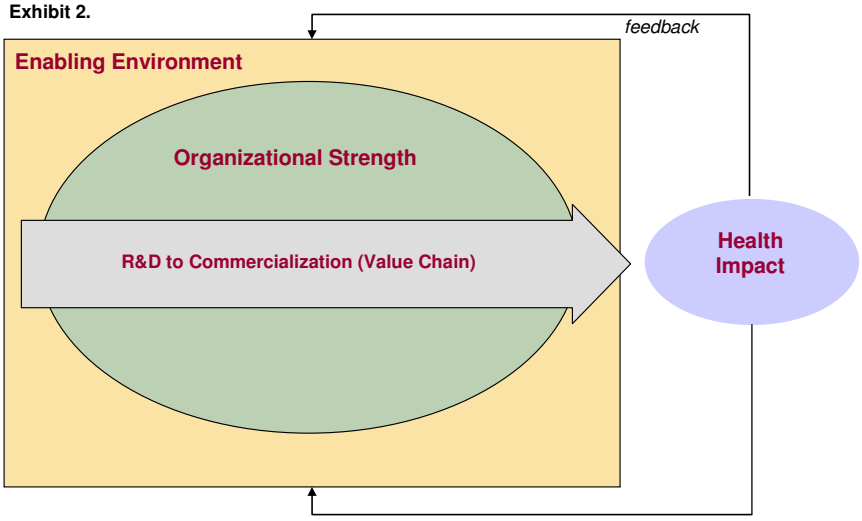
At the broadest level, the framework divides performance measurement into four key *areas of performance*, each of which has multiple *dimensions of performance* that a PDP should consider when developing metrics. The dimensions of performance are shared by all PDPs and form a comprehensive picture of what performance means to the PDP community. However, the way each dimension is prioritized, interpreted, and measured is PDP-specific.

[7] The four-tiered framework resulted from a series of discussions with PDPs and analogous organizations (e.g. biotechnology and pharmaceutical firms, investors), during which FSG compiled a list of all the metrics currently in use to measure performance. Once compiled, it became clear that organizations were measuring things in four main areas: their value chain, their organization, their environment, and their real/projected health impact. After sorting the metrics into these four categories, FSG found a natural segmentation emerging that allowed PDPs to measure these broad categories through different lenses or dimensions specific to each PDP's strategy. Despite this further segmentation, these dimensions were still quite large, and there were categories within each that truly brought to light the richness in the metrics. These categories are interpretations of the data, and some PDPs will naturally be drawn to some categories over others due to their stage of development. Together, these three layers of the framework provide a structured, flexible, and logical home for the fourth layer of the framework, the organization's metrics.

As shown in Exhibit 2, the framework's four main areas serve as a basis for PDP performance measurement:

1. **R&D to Commercialization**: This area assesses all activities in the value chain, from research and development to manufacturing.

Exhibit 2.



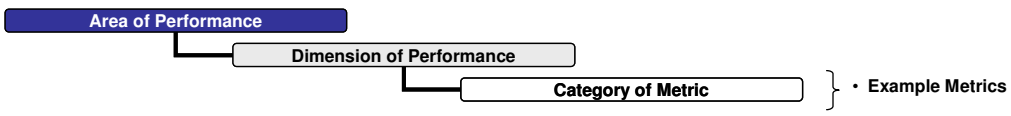
2. **Organizational Strength**: This area assesses the strength of management and human resource systems for PDPs and the vitality of partner relationships.

3. **Enabling Environment**: This area includes the external context in which the scientific activities and organizational development occur. Just as PDPs are filling a unique market gap by collaborating to bring to market technologies for otherwise neglected diseases, PDPs often find it necessary to fill other gaps in the enabling environment. This may include developing clinical trial sites or advocating for international policy around a specific disease. This performance area simply reflects the reality of PDPs' time, people and energy investments.

4. **Health Impact**: This area represents the ultimate measure of success: the effect of the first three areas on lessening the disease burden. Prospective estimates of impact are selectively conducted by PDPs to inform the previous three areas (hence the inclusion of a feedback loop).

Each of these four areas breaks down into three layers of performance measurement: *dimensions, categories* and finally the *metrics of performance*, as seen in Exhibit 3a.

Exhibit 3a

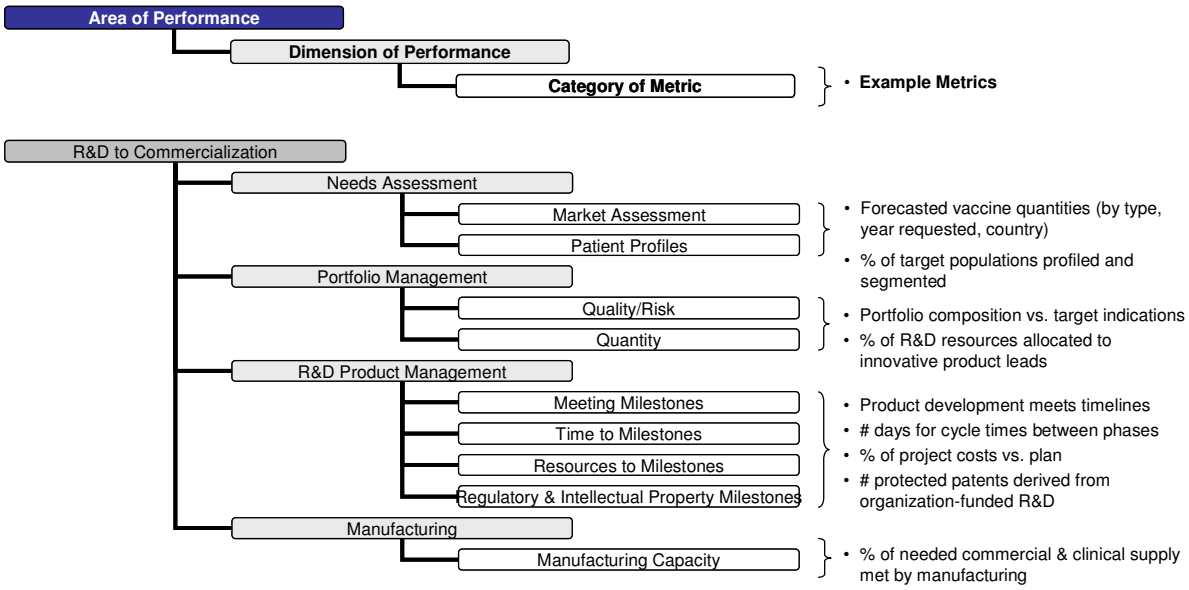


In the first area, labeled "**R&D to Commercialization,**" PDPs measure multiple dimensions of performance ranging from the robustness of their portfolio and ability to manage projects to their ability to potentially manufacture technologies. Similarly, each

of these dimensions is further refined by PDPs. Within each dimension, categories of performance metrics bundle numerous potential metrics that measure similar activities or goals.

Within the dimension of "Portfolio Management" under **R&D to Commercialization**, for example, PDPs measure both the "Quality" of the candidates and the "Quantity/Risk" of candidates as it relates to the PDP's targets for impact. Each is then associated with a number of potential metrics (See Exhibit 3 for a full illustration of this performance area).

Exhibit 3



Beyond dimensions of performance, performance measurement becomes specific to each PDP, reflecting unique operational developments and performance review needs. At the category and metric levels, the framework is no longer prescriptive and provides helpful organizing language as well as sample metrics for PDP-specific customization (see Appendix B for a richer set of metrics). An example from the Foundation for Innovative New Diagnostics (FIND) found below illustrates how a PDP may break down the R&D Project Management dimension into major reporting indicators.

Foundation for Innovative New Diagnostics (FIND)
Area: R&D to Commercialization
Dimension: R&D Project Management

FIND is a classic example of a PDP using strong metrics to **capture insight into the "R&D Project Management" dimension of performance which measures** how effectively the PDP is managing the products within its pipeline.

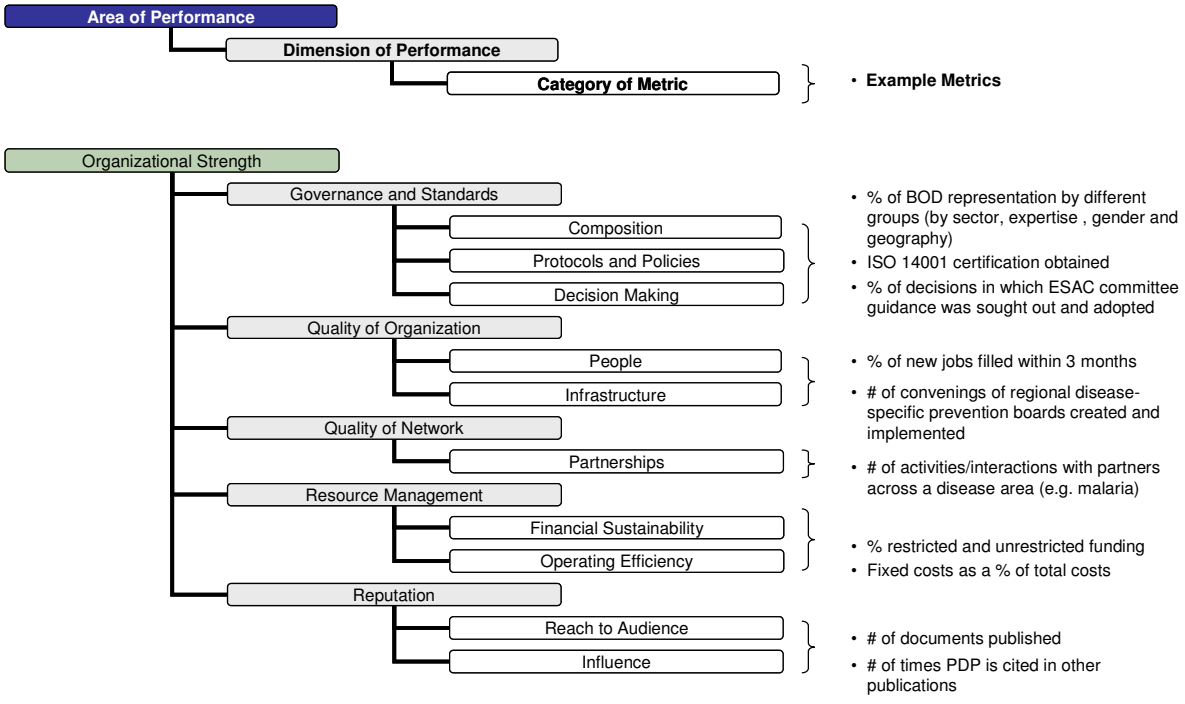
FIND offers a very structured approach to thinking about measuring time and cost with the following metrics (Categories of performance metric: Time to Milestones, Resources to Milestones):

- % of funds released by project milestone (actual vs. projected)
- % of projects reaching next phase of development at or within the time specified in the strategic plan

"We have a strong project management culture and approach, derived or even improved from Roche diagnostics, from where lots of our greatest people come with the aspiration to do even better. We work with independent business units, each with clear milestones and SOPs covering all the phases up to access – demonstration, WHO approval, national approval, transformation into national policy, etc." – FIND

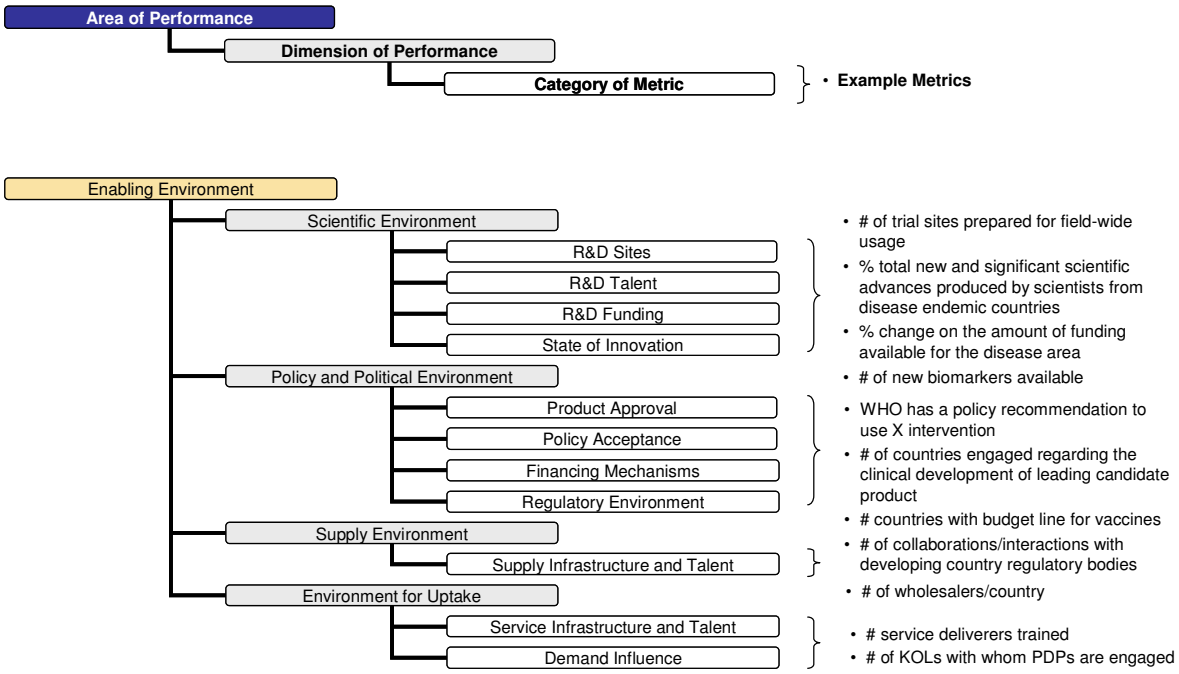
Similarly, within "**Organizational Strength**," PDPs consider multiple dimensions – the sources of advice (e.g., boards, advisory committees, etc.); the presence and application of important operational policies (e.g. ISO standards and mission-related IPR policies) and the overall quality of their networks (e.g., the establishment of complementary partnerships as a result of strong deal-making capabilities); the diversity and strength of their resource management; and finally their reputations. (See Exhibit 4).

Exhibit 4.



The "**Enabling Environment**" Area (Exhibit 5) is focused on dimensions relating to the scientific, policy, supply, and product uptake contexts that accelerate or stymie success.

Exhibit 5.



Meningitis Vaccine Project (MVP)
Area: Enabling Environment
Dimension: Environment for Uptake

The dimension of performance called "Environment for Uptake" captures the overall environment, in which consumers are exposed to and educated on new products, including the extent to which data is tracked that reflects changes to the environment.

MVP is already preparing to influence the context in which its vaccine will ultimately be introduced, and is measuring the success and extent of its on-the-ground readiness with the following metrics (Category of performance metric: Demand Influence):

- # of target groups aware and informed about PDP
- # key contact person(s)/supporters from target disease countries

International Aids Vaccine Initiative (IAVI)
Area: Enabling Environment
Dimension: Policy and Political Context

The dimension of performance called "Policy and Political Context" captures the overall political and financial capital invested in facilitating neglected disease research.

IAVI is very active in advocating internationally for the HIV/AIDS research as a whole, and not just for the vaccines they are developing. As a result, this PDP places a high priority on promoting national and international acceptance of HIV products and/or creation of policies to support the introduction of a product as seen in the following metric (Category of performance metric: Policy Acceptance):

- # of Collaborations with the MoH and the vaccine community to implement procedures and rules to ensure consistent vaccine work
- # of e-learning modules distributed, and evidence of accessibility/uptake

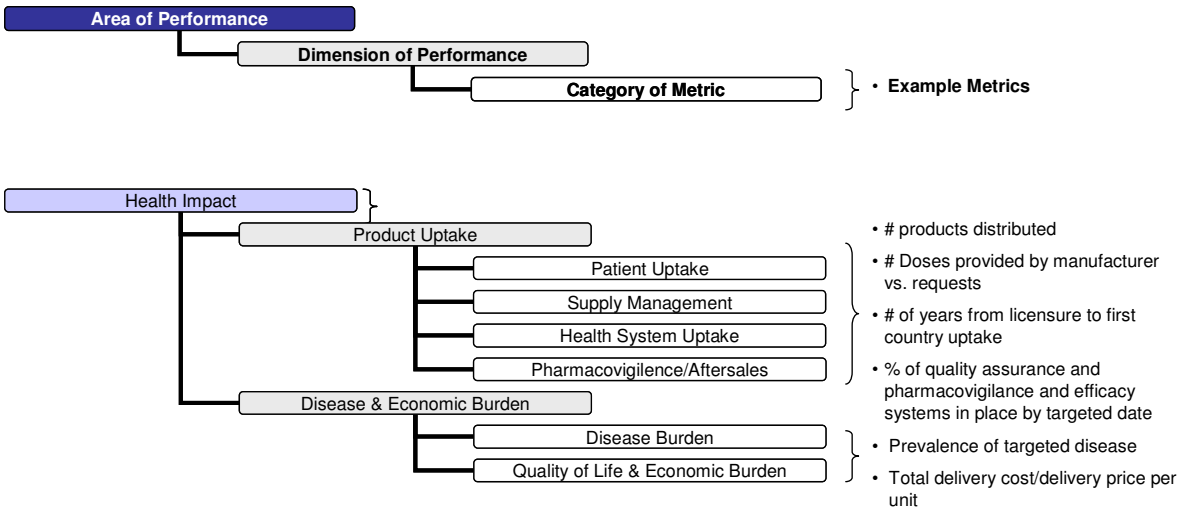
IAVI also advocates for greater financial resource allocation to HIV/AIDS research and products as seen in this metric (Category of performance measurement: Financial Mechanisms):

- % of new funding, incentives, etc. for HIV/AIDS due to legislation adoption

Reporting in this area must result from business planning and carefully weighed strategic choices. The framework provides valuable examples of how to measure progress in the Enabling Environment (see examples from IAVI and MVP above).

Finally, the "**Health Impact**" area (Exhibit 6) speaks to the fundamental mission of PDPs. This area is subject to considerable tension as to the ability and responsibility of PDPs to measure it. Nevertheless, **Health Impact** is certainly the ultimate priority of donors. The inclusion of **Health Impact** in the framework signals the need for a "performance measurement partnership" among donors and PDPs (see Section Five).

Exhibit 6.



It is important to note that the **Health Impact** performance area is controversial for donors and PDPs. "Product Uptake" is considered by some experts as an appropriate final dimension of performance within **R&D to Commercialization** rather than **Health Impact**. At the root of the controversy is the question as to whether PDPs should be involved in any activity related to "Product Uptake." Some PDPs assert that product delivery is an essential part of their remit; they would include activities related to "Product Uptake" within their **R&D to Commercialization** performance indicators. Similarly, the dimension of "Disease and Economic Burden" can be seen prospectively as part of "Needs Assessment" or retrospectively as impact achieved. With the former perspective, it is possible to include "Disease and Economic Burden" under **R&D to Commercialization** rather than **Health Impact**. PDPs and donors, as they build on the proposed framework for application, should continue to evolve the framework's content and categorization.

4.2. From Good to Great Metrics

The sample metrics found in Appendix B demonstrate the characteristics of strong metrics, according to numerous experts. They should provide up-to-date, accurate information that is relevant to strategic goals and can be easily and objectively measured and interpreted.[8]

Priority Metrics for a Biotech Firm

- **Organizational:** Reduce company-wide turnover to 15%
- **Portfolio Progress:** Achieve 80% of critical milestones (e.g. first patient enrolled in clinical study, last patient enrolled in clinical study (dates), filing on time, etc.)
- **Manufacturing:** Complete 100% of planned activities for building a new plant while remaining within allocated budget
- **Strategic:** Source two deals through licensing, acquisition or collaboration to ensure a marketable product in 8 years
- **Financial:** Deliver on $900M in company revenue

While the framework opens the way for a multiplicity of metrics, PDPs should choose the fewest and simplest metrics to guide overall organizational performance and inform funders about progress. Pfizer has a hierarchy of metrics consisting of operational metrics, used to run the organization, and priority metrics, utilized to share progress with stakeholders. Only 14 of the top 150 measures are considered priority metrics, as they capture the essence of progress towards the strategic plan. Operational metrics are clearly distinguishable from the set of priority indicators that tell stakeholders how the organization is delivering on its overall mission. An example of a biotech firm's priority metrics is shown on the right.

4.3. Benefits of a Common Performance Measurement Framework

In summary, the proposed performance measurement framework broadens the definition of performance and creates a common language for PDP management and donors. Three key benefits of the framework are called out below:

[8] Ref. Andrew Neely, Center for Business Performance at the Cranfield School of Management, The American Institute of Chartered Engineers,etc

A more comprehensive and "timeless" representation of PDPs efforts. The framework builds upon research and development, a conventional area for PDPs, to create a more comprehensive picture of important contributors to success: the internal strength of the organization and its networks, the environment in which it operates, and the ultimate success in affecting health impact. The proposed framework articulates a set of indicators that are relevant today and in the future for PDPs.

Performance Measurement:
The Canary of Strategic Clarity

Reflections on performance measurement inevitably unearth questions about strategy. In almost every conversation with donors and PDPs, questions about PDPs' role beyond core R&D activities were mentioned. These questions about an expanded role for PDPs, while challenging, fall neatly into the performance framework's four categories of the "Enabling Environment":

- **Scientific Environment**: The availability of scientific infrastructure such as clinical trial sites in high-prevalent countries and well-resourced basic science budgets to "prime" PDPs' R&D portfolios serve as important examples to PDPs.
- **Policy Environment**: Many PDPs are investing extraordinary resources to influence the policy environment for their new health technologies.
- **Supply Environment:** Some PDPs choose to influence the availability of downstream technology suppliers.
- **Uptake:** PDPs that are closer to product licensure are concerned about weak health care delivery infrastructure in which to deliver their technologies.

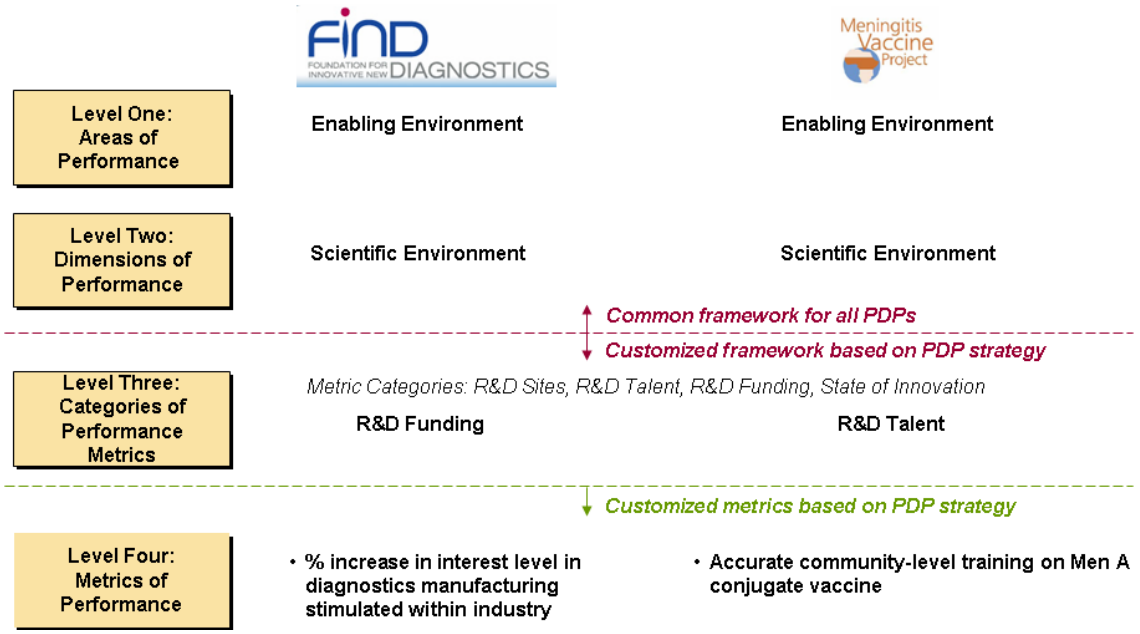
PDPs and donors alike question whether these Enabling Environment issues should be addressed by any one PDP, as a consortium of PDPs or through "hub-like" facilities that would benefit several PDPs.

Some of the performance dimensions expose strategic dilemmas that require discussion among PDPs and donors. Whether or not PDPs *should* participate in all of the dimensions of the framework is a question left for the PDPs and donors to decide jointly (See sidebar on "Performance Measurement: The Canary of Strategic Clarity").

A common platform adaptable to individual organizations. Feedback suggests that the 16 performance dimensions are universal to all PDPs. As illustrated in Exhibit 7, the framework is highly adaptable to each organization's disease or technology focus because it does not prescribe a set of

metrics.

Exhibit 7.



A better basis from which to attract additional funding. The complexity of measuring PDP performance can intimidate some donors that lack staff or specific expertise in health technology R&D. The framework is a helpful tool to explain how PDPs function at a detailed level.

With such clarity of purpose, donors and PDPs can tackle the next challenge of an insightful performance management partnership – namely, the performance measurement process.

5. Recommendations for a Performance Measurement Partnership

The purpose of this study was to surface opportunities to improve the practice of performance measurement among PDPs and donors. FSG recommends four steps to lead to the implementation of the performance framework. Additional suggestions about the process of performance measurement follow these recommendations:

1. **Engage in discussions about the framework to improve its relevancy and value:** The proposed performance framework should start a dialogue among donors and PDPs. Engagement should include additional vetting with individual PDPs and a wider discussion about broader performance measurement goals in a workshop setting.

2. **Individual PDPs should use the framework in planning their work:** The performance framework is a flexible tool that is relevant to all PDPs. While metrics may differ among the PDPs, these organizations can use the first three levels of the

framework to structure and organize business plans to ensure that a comprehensive view is used to guide the articulation and prioritization of activities and metrics. Certainly, most PDPs have strong business plans today. The incremental value of the framework is the comprehensiveness of the activities reflected and the goal-oriented language used.

3. **Individual PDPs should strengthen their performance measurement**: As evident in this report, all reviewed PDPs practice some level of performance measurement. However, PDPs are not measuring activities in all areas that might be relevant to them today. In a practical sense, management should use the framework as a tool to reveal where the organization needs to focus new performance measurement attention. Likewise, there are opportunities to sharpen individual metrics by making them more specific. The list of metrics found in Appendix B is relevant on a selective basis.

4. **Donors and PDPs should use the performance framework to guide a more productive "performance measurement relationship":** As a minimum step, donor–led evaluation teams could use the framework to ensure that appropriate time is devoted to each performance area (this would be a departure from previous evaluations where the issues were narrow and considered of questionable value to the PDPs). Beyond using the framework as a guide on an ad hoc basis, it could become the accepted reference for all donors and thus a standard tool that would make "performance assessments" more predictable and comprehensive. The use of the framework could help to accelerate planning efforts behind joint assessments, for example, by guiding a prioritized set of issues that need special attention or determining the skill sets of people who should participate on the assessment team. It is important

PDP Evaluation that Fall Flat

Donors have carried out only two formal evaluations of PDPs included in this study (MMV and IAVI). On that limited basis, PDPs raise strong concerns about the value of these evaluations, as well as the more frequent but less formal check-ins. Specifically, PDPs worry about the unpredictability of the issues that will be tackled in a donor-sponsored evaluation:

"Evaluations today provide very little help to our work going forward – in fact, they're a burden." – PDP

"Each donor is looking at different issues and wants to evaluate us in their own way." – PDP

"The amount of time that I spend with donors sending me people, the WHO wanting to know how we're doing, GAVI, The Global Fund-- we're only so many people and this is overwhelming." – PDP

"Evaluators reviewed MMV as if it were an academic project, as opposed to as a non-profit company, with governance, contracts, etc. – Donor

that both donors and PDPs are involved in discussions about moving from traditional evaluation to performance assessments using the framework as a helpful guide.

Using the performance framework to upgrade current evaluations is actually a very low bar for this community to clear. This study should trigger a "game changing" impulse to create the most productive performance measurement platform possible to help donors and PDPs. When PDPs discuss metrics, they find it impossible to constrain the conversation to a passive table of measures. Rather, they look to a transformed relationship where donors and PDPs emphasize a more predictable and helpful model of operational and strategic assessment, benefiting from more external sources of data and validation.

While the narrow purpose of this study was to identify and improve what is measured by PDPs and donors, interviewees invariably injected ideas and concerns about how performance is measured and the support (or lack thereof) needed to do so effectively. An improved state of performance measurement for PDPs and donors must address concerns about how it is actually conducted.

5.1. Recommendations Requiring Further Exploration

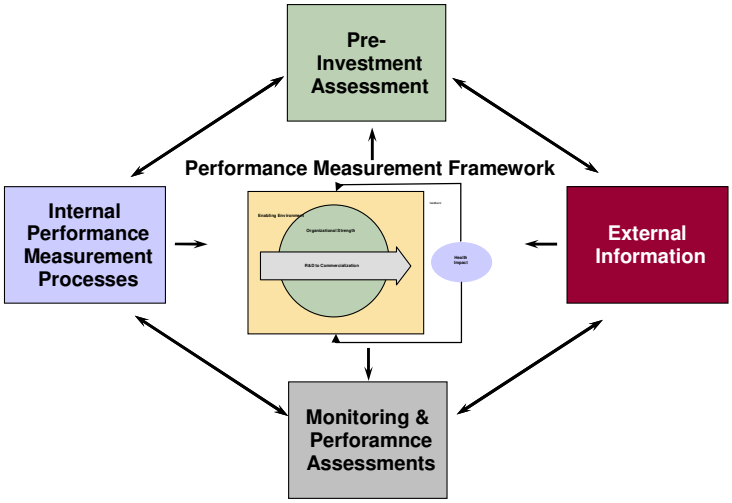
Analogous organizations interviewed for this study approach the process of performance measurement from a completely different perspective. Pharmaceutical and biotech firms do not view performance evaluation as a grand event that occurs every three years, but rather as an almost hourly part of doing business. Shareholders of these firms receive a constant and objective stream of feedback about the financial health, pipeline potential, management competence, and revenue/sales of these firms, through management news releases or analyst reports. Even for biotech start-ups that do not have the benefit of analysts reporting on their progress, venture capital firms conduct "evaluations" on a quarterly basis by sending in teams of experts to review progress on stated goals. The purpose of these reviews is not to validate a smart investment, but rather to help the start-up address constraints and determine what resources are needed to help the organization succeed.

Admittedly, pharmaceutical and biotech firms are not perfect analogues for comparison of evaluation approaches with PDPs. Though similar in terms of output, pharmaceutical and biotech companies manage much broader portfolios, operate in therapeutic areas that are highly competitive and dynamic, and benefit from constant outside analysis because they are profit-seeking. While it would be impossible to duplicate the type of external "evaluations" conducted for pharmaceutical and biotech companies, the underlying principles of these appraisals and critiques – **frequent, forward-looking, consistent, and predictable** – are noteworthy for PDPs and donors.

A performance measurement partnership is proposed in Exhibit 8, and builds on the findings from this study. The four pillars of this partnership consist of:

- Rigorous **pre-investment assessments** or periodic business planning efforts that are supported by donors and build consensus around strategic priorities for resource allocation
- **Internal performance measurement** processes based on:
  - Operational metrics covering all areas of performance, for on-going review by key management
  - Progress and impact measures that serve PDP senior management and boards in making more fundamental changes in business plans and resource allocations
- **External information** provided with donor support to enrich performance assessments
- **Monitoring** PDPs' activities for "hands-on" donors who need on-going information and can assist management in making short-term tactical changes, and periodic **performance assessments (as newly defined in this paper)** of key progress and impact measures.

Exhibit 8.
A Performance Measurement Partnership
that Incorporates the Best Practice Insights from this Study



The evaluation or assessment process should therefore no longer be based on a set of priority parameters determined independently by donors. The role of performance assessment in this context should be about joint objective setting, verification of progress, understanding of deviations from plan and questioning the on-going validity of objectives. Donors can act on all these points by supporting strategic reviews, using the suggested framework as a basis for progress reporting, and enriching PDP reports with complementary, third party information (e.g. R&D benchmarks and analyses of gaps in the enabling environment). In the process, donors might uncover gaps in the PDPs' enabling environment that are of essential importance to the PDPs' success and therefore require financial support.

The vision is to integrate PDPs' own performance management with donor evaluation processes and create a unique reporting process for each PDP and its many donors. Here lies the tremendous opportunity to reduce the burden and value of performance reporting. The benefit, however, will come at the cost of donors' increased focus on planning, improved coordination with each other, and willingness to align their funding with established components of the PDP performance framework.

5.2. External Expert Sources of Information for Performance Measurement

While interviewees encourage the pursuit of a new way to conduct performance measurement, some donors and PDPs express concern about the resources and expertise available to add insights about PDP performance.

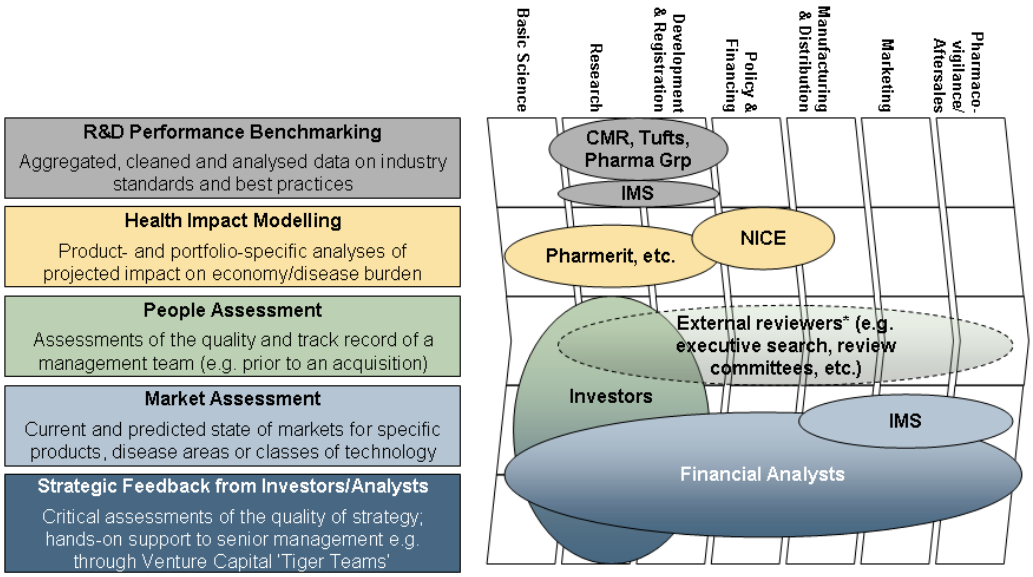
It is interesting to note that analogous organizations that take a different approach to performance measurement also benefit from supporting organizations that sit within their industry cluster. In the pharmaceutical industry, supporting organizations provide benchmarks for time and dollars devoted to R&D phases for various therapeutic categories and market intelligence about provider interest in projects under development.

Exhibit 9 shows a sample of the organizations that provide performance insights to pharmaceutical and biotech firms. For example, the Centre for Medicines Research (CMR) benchmarks R&D performance against industry peers, by producing detailed reports on how well a given company is performing relative to the average in its comparator group (organizations working on the same chemical entities/biologicals/disease areas). Companies learn about the efficiency (time to transition from one step to next 100 steps) and productivity of their R&D pipelines. The resulting reports expose trends and areas of high variance with benchmarked peers.

Analogous firms cite the value of these supporting organizations in terms of their ability to provide independent, current, and referenced data upon which to make more informed decisions.

Exhibit 9.

Pharma/Biotech Draws on a Constellation of External Sources of Performance Insights



In contrast, PDPs and donors have few specialized supporting organizations to draw upon for objective data about the performance of this young community. Certainly, PDP advisory/scientific committees play a very valuable role in providing ongoing critiques about investments in projects and other key decisions. But the personnel who are members of these committees may not always be objective and they have limited time to devote to the PDP.

Support for performance measurement is a topic that needs further discussion by donors and PDPs. Additional analysis could be conducted to identify a "preferred provider" list of organizations that could be adapted to suit the needs of PDPs and the donors who fund them. This step may yield only marginal results as organizations currently serving pharmaceutical and biotech companies have little to no experience with infectious diseases or the developing world. Donors may need to consider creating organizations that cater to the specific requirements of PDPs.

5.3. Performance Measurement Partnership: Action Agenda

This study should be considered as a catalyst for conversation among donors and PDPs. Some of the recommendations require further research and exploration. Other points from this study are immediately actionable. A list of next steps for both donors and PDPs follows:

5.4. Agenda for Donors:

- Work with PDPs to refine and operationalize the performance framework;
- Encourage individual PDPs to improve the quality of their metrics;
- Identify where PDPS need external support to measure their performance;
- Facilitate the development of a new, partnership-driven approach to PDP performance measurement;
- Use the new approach to support PDPs progress and attract new donors.

This study has also surfaced a number of issues requiring strategic clarity. While it is beyond the scope of this exercise, it is important to note that donors and PDPs would benefit from discussions about the degree of involvement of PDPs in "Enabling Environment" issues and downstream delivery activities.

5.5. Agenda for PDPs:

- Use the performance framework to organize existing metrics and identify gaps where measurement may be lacking or vague;
- Use the performance framework as a tool to structure business plans, internal monitoring and structuring performance measurement areas to be supported or tackled by donors.

Voices from PDPs and Donors:
Reactions to the FSG Study on Performance Measurement

PDP comments about FSG's recommended performance measurement approach center upon three issues: the omission of advocacy in the performance framework**;** the resources/responsibility for measurement; and anxiety (by PDPs) about using the framework as a tool to compare PDPs.

PDPs have asked why advocacy is currently not found in the performance framework. A review of PDPs' metrics reveals real confusion with the measurement of advocacy. The framework attempts to untangle multiple meanings of advocacy to place more emphasis on the goal of advocacy efforts. For example, PDPs advocate for the support of scientific research related to the disease area in which they work. PDPs also advocate for policy changes within developing countries to influence guidelines of care and for their own sustainability by articulating their missions to the media or requesting additional funding from donors. All of these forms of advocacy are captured in the framework within the Organizational Strength and Enabling Environment areas.

The question of measurement resources and responsibility reveals a continuing tension between donors and PDPs. **Health Impact** has raised many questions about whether PDPs will be responsible for measuring the reduced burden of disease, for example. This suggests the need to combine forces with donors to ensure proper resourcing of core activities and the performance management associated with these efforts.

PDPs worry about donors' interest in using the framework as a tool to compare the relative strength of PDPs. While donors certainly expressed a desire (and lack of ability) to compare the relative merits of PDPs today, PDPs are concerned that the framework could be used against them in an unfair way. It is important to point out that the framework does not include a "handicap" or hardship factor for similar metrics (e.g., % of pre-set milestones reached) for widely different technologies that require more time or resources.

PDP funders reviewing the study anticipated greater value from this work in improving performance measurement between individual PDPs and donors, rather than in harmonizing how donors measure them. Accordingly, they concluded that the applicability and value of the proposed approach should be first tested with pilot PDPs and further enriched through consultations with the wider PDP community.

These recommendations serve as an important start towards transforming the performance measurement relationship among donors and PDPs. However, there are challenges to moving this agenda forward on both sides. Donors have competing demands and varying reporting needs to make improvements for all PDPs. PDPs face similar issues, augmented by continuing notions that each organization must have its own unique performance approach. These obstacles can be overcome if donors, in particular, make the action items above a priority.

6. Appendix A

Background on FSG Social Impact Advisors

FSG Social Impact Advisors is a 501(c) (3) nonprofit social enterprise that works with foundations, corporations, governments, and nonprofits to accelerate social progress by advancing the practice of philanthropy and corporate social responsibility. FSG was founded in 1999 by Professor Michael E. Porter and Mark R. Kramer as Foundation Strategy Group, LLC, and converted to nonprofit status under its new name in 2006.

FSG achieves its mission in three ways:

- Advice – Providing consulting services for corporations, foundations, and NGOs on strategy development and evaluation.
- Ideas – Publishing articles and white papers that generate new ways of thinking about social progress and corporate social responsibility
- Action – Catalyzing long-term initiatives that address critical challenges and opportunities facing the field

With offices in Boston, San Francisco, Seattle, and Geneva, FSG Social Impact Advisors' international team of full-time consultants combines the highest standards of strategy consulting with a deep understanding of philanthropy and the nonprofit sector.

Project Process and Methodology

The 8-month process for this project consisted of three phases:

- Phase I (September-November 2006) – Conduct interviews with 12 experts, 11 donors and 10 PDPs to assess the need for a common approach for performance measurement;
- Phase II (November 2006 – January 2007) – Conduct additional interviews with PDPs and more than 30 analogous organizations to understand current practice of performance measurement and create a draft framework for performance measurement;
- Phase III (January – May 2007) – Solicit feedback on the draft framework from a select number of PDPs and donors, draft a white paper on the results, and hold a workshop with project participants to solicit comprehensive, formal feedback.

PDPs Included in this Study

Product Development Partnerships (PDPs)	Location	Target Disease	Product	Website
Aeras Global TB Vaccine Foundation (AERAS)	USA	Tuberculosis	Vaccine	http://www.aeras.org
Drugs for Neglected Disease Initiative (DNDi)	Switzerland	Visceral leishmaniasis, human African trypanosomiasis, & Chagas disease	Drug	http://www.dndi.org/
Foundation for Innovative New Diagnostics (FIND)	Switzerland	human African trypanosomiasis, tuberculosis, malaria	Diagnostic	http://www.finddiagnostics.org/
Global Alliance for TB Drug Development (GATB/TB Alliance)	USA	Tuberculosis	Drug	http://new.tballiance.org/
Institute for One World Health (iOWH)	USA	Visceral leishmaniasis, diarrheal disease, malaria, Chagas disease	Drug/Vaccines	http://www.oneworldhealth.org/
International Aids Vaccine Initiative (IAVI)	USA	HIV/AIDS	Vaccine	http://www.iavi.org/
Medicines for Malaria Venture (MMV)	Switzerland	Malaria	Drugs	http://www.mmv.org/
Meningitis Vaccine Project (MVP)	France	Meningitis	Vaccine	http://www.meningvax.org/
The International Partnership for Microbicides (IPM)	USA	HIV (Prevention)	Drugs	http://www.ipm-microbicides.org/
The Pediatric Dengue Vaccine Initiative (PDVI)	Korea	Dengue	Vaccine	http://www.pdvi.org/

Donors included in this study

Donors	Location
Bill & Melinda Gates Foundation	USA
Canadian International Development Agency (CIDA)	Canada
Department for International Development (DfiD)	UK
Dutch Ministry of Foreign Affairs (Minbuza)	Netherlands
European Union	Belgium
Irish Aid	Ireland
KfW Bankengruppe	Germany
National Institute of Allergy and Infectious Diseases (NIAID)	USA
Rockefeller Foundation	USA
The Wellcome Trust	UK
United States Agency for International Development (USAID)	USA

Experts interviewed for this study

Experts
Bob Fryatt, WHO
Carol Medlin, Institute for Global Health
Davy Koech, Kenya Medical Research Institute (KEMRI)
Federico Gomes de las Heras, GSK Tres Cantos
François Bompart, Sanofi-Aventis
Mary Moran, London School of Economics
Michael Free, PATH
Paul Herrling, Novartis
Richard Laing, WHO
Robert Ridley, WHO/TDR
Roy Widdus, Global Futures Health Network
Stephen Matlin, Global Forum for Health Research

Analogous Organizations Included in this Study

Analogous Organizations	
Biotech/Pharma	**Advocacy Groups**
Biogen Idec	Médecins Sans Frontières (MSF) Campaign for Essential Medicines
Crucell	AIDS Vaccine Advocacy Coalition (AVAC)
Genentech	Faster Cures
Genzyme	
Tibotec	**Analysts/Consultants**
BD Diagnostics	The Centre for Medicines Research (CMR) International
Novartis	IMS Health Americas
Roche	Pharmerit
Pfizer	Tufts
Nonprofits & Multilaterals	**Venture Capitalists**
Academy for Educational Development (AED)	Anonymous VC specializing in biotech
Cystic Fibrosis Foundation	Oxford Bioscience
Futures Group	
Global Alliance for Vaccines and Immunization (GAVI)	**Purchasers**
The Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM)	National Institute for Clinical Excellence (UK)
Michael J. Fox Foundation	
Population Services International (PSI)	
The United Nations Children's Fund (UNICEF)	
World Health Organization/The Special Programme for Research and Training in Tropical Diseases (WHO/TDR)	

7. Appendix B

Framework, Sample Metrics and Definitions

Area	Dimension	Category	Metric
R&D to Commercialization	Needs Assessment	Market Assessment	# vaccine doses forecasted (by type, year, country).
			# and profile of drugs currently in development or on the market that address X disease (e.g. HIV, TB)
			# of completed product due diligence reports
			% of key opinion leaders surveyed who state that product profile meets needs
			Complete market research on prescriber preferences and prescribing habits
		Patient Profiling	% of target populations profiled and segmented
			# and type of barriers to uptake identified by patient segment
	Portfolio Mgmt	Quality/Risk	% success rates by product and phase of development
			# of candidates targeting known vs. breakthrough mechanisms of action
			# new chemical entities registered
		Quantity	# of new candidates identified
			# compounds tested
			# leads identified for optimization
			# of projects killed
			# active projects in each stage of development (discovery, preclinical, clinical)
	R&D Project Mgmt	Meeting Milestones	% of pre-set milestones reached
			Enroll first patient in trial (by x date)
			Enroll last patient in trial (by x date)
			Hit 85% of milestones
		Time to Milestones	time to complete each step of the process
			% of total completion time by phase
			# days for cycle times between phases
			# clinical trial sites ready in < 6 mo
		Resources to Milestones	% of project costs vs. plan
		Regulatory & Intellectual Property Milestones	# protected patents derived from organization-funded R&D
			Complete First FDA Filing
			Both KOL input & recruitment plan reviewed & endorsed for regulatory approval
			Intellectual Property contracts secured for all Phase II products
	Manufacturing	Manufacturing Capacity	% over/under time allocated for completion and validation of manufacturing facility
			% of needed commercial & clinical supply met by manufacturing

Level	Name	Definition
Area	R&D to Commercialization	
Dimension	Needs Assessment	The demand conditions which determine the success or failure of a product
Category	Market Assessment	The state of the potential market across diverse supply and demand conditions considering current and future demand factors such as the competitive landscape
	Patient Profiling	An assessment of the targeted population's characteristics in terms of demographics, geography, disease state, etc.
Dimension	Portfolio Management	Assessment of overall quality and quantity of product candidates the portfolio
Category	Quality/Risk	The type of compounds in portfolio relative to targets, chances of success, level of financial exposure, etc.
	Quantity	The number of compounds/projects in a portfolio
Dimension	R&D Project Management	Assessment of management of projects within the R&D portfolio
Category	Meeting Milestones	Primarily binary approach to assessing completion of specific project tasks
	Time to Milestones	Progress or completion of project task within a specific targeted period of time
	Resources to Milestones	Relative dollars/staff time/other resources allocated to each project
	Regulatory and Intellectual Property Milestones	Progress or completion of tasks related to gaining regulatory approval and securing intellectual property rights for products
Dimension	Manufacturing	Assessment of the organization's ability to appropriately have manufactured the product
Category	Manufacturing Capacity	The ability and extent to which a organization can produce the product to meet clinical and commercial needs

Area	Dimension	Category	Metric
Organizational Strength	Governance & Standards	Composition	% of BOD representation by different groups (by sector, expertise, gender and geography)
			# of PDP partner representatives involved in PDP governance structure (e.g. board, advisory group, etc.)
			# of end-users represented on governing committees
		Decision Making	% of portfolio selected by rigorous algorithms and processes
			# of board agenda points leading to concrete decisions
			% of portfolio decisions in which Scientific Advisory Board committee guidance was sought out and adopted
		Policies and Protocols	% of SOPs implemented
			ISO certification processes established
			External audits completed as a % of total audits
	Quality of Organization	Infrastructure	# of convenings of regional disease-specific prevention boards
			Time to make new offices fully functional
		People	% of managerial level jobs filled within an average of 3 months
			Incentive structures in place
			% of staff with different sector backgrounds (e.g. public sector, industry, etc.)
			% progress against agreed upon personal objectives
			% of R&D staff published within the last year
			% of team members expressing job satisfaction
			% turnover of high-performing staff
	Quality of Network	Partnerships	% of partners in endemic countries
			# of industry partners
			# signed partnership agreements
			# of activities/interactions with partners across a disease area (e.g. malaria)
			# advocacy partnerships to achieve policy objectives
			X% of partners who report (via survey) high satisfaction and measurable benefit from their PDP relationship
	Resource Management	Financial Sustainability	% funds raised against annual target
			Non-Gates Foundation funding as %age of total (compliance with US foundation law)
			Time to depletion of reserve
			# of new donors per year
			% restricted vs. unrestricted funding raised
		Operating Efficiency	Affordability of unit cost target achieved within X percent range
			Fixed costs as a % of total costs
			Overhead/disbursement ratio
			% over/under of targeted CAGR of 25%
	Reputation	Influence	# and type of awards received
			# of times partners or global leaders use PDP-specific information (citations, quotes, etc.)
		Reach to Audience	# of new political commitments attributable to PDP-specific work
			# of publications disseminated
			# media reach audits by outlet, byline, headline and "beat"
			# pages viewed, downloaded and context of searches

Level	Name	Definition
Area	Organizational Strength	
Dimension	Governance & Standards	Assessment of the composition of the organization's governing bodies, rigor of the decision making process and the robustness of the policy structure
Category	Composition	Quality and diversity of experience of the governing bodies (management team, boards, advisory committees)
	Decision Making	Rigor of decision making (use of candidate selection criteria, diversity of advice sought, engagement of board, agenda items decided upon, etc.)
	Policies and Protocols	Assessment of procedures and policies (audit policies, IP management policies, timing of board reviews, etc.)
Dimension	Quality of Organization	Assessment of the organization's talent pool and the infrastructure in which they work
Category	Infrastructure	Infrastructure and systems in place to execute on strategy
	People	Quality, quantity, diversity of talent and the organization's systems for professional development
Dimension	Quality of Network	Assessment of the PDP's network of partnerships
Category	Partnerships	Quality and diversity of local, national, and international networks and partners
Dimension	Resource Management	Assessment of the organization's ability to attract financial support and its ability to operate an efficient organization
Category	Financial Sustainability	Management, quantity, flow and diversity of funds
	Operating Efficiency	Resource (human, financial) expenditure relative to output achieved
Dimension	Reputation	Recognition for the organization's mission and its leadership influence on other key stakeholders
Category	Reach to Audience	Breadth of exposure of different stakeholders to organization's work, product, ideas, etc.
	Influence	Extent to which organization's ideas have influenced others resulting in changes in funding, policies, etc.

Area	Dimension	Category	Metric
Enabling Environment	Scientific Environment	R&D Funding	% of annual public funding increase/decrease for all neglected disease and appropriate financial mechanisms for addressing neglected diseases
			% annual change in funding available for the disease area
		R&D Sites	# of research institutions in disease endemic countries strengthened and/or operationalized
			$ provided for communication support for clinical trials in Africa and other regions
			% clinical trial sites with which the PDPs engages that meet GCP standards
			# local advisory groups created in clinical trial sites
		R&D Talent	# MSc, # PhD/doctoral degrees completed
			# persons trained in short courses
			% total new and significant scientific advances produced by scientists from disease endemic countries
		State of Innovation	# of new biomarkers available
			# enabling publications
			# research instruments, guidelines for infectious diseases developed/ published
	Policy and Political Environment	Financing Mechanisms	% increase of global financial commitment to fund R&D for target disease (goal: doubled)
			# countries with budget line for vaccines
			% of new funding, incentives, etc. due to legislation adoption
			# countries with budget lines for purchase of intervention
			New financing mechanisms
		Policy Acceptance	# of engagements with regional groups for the purpose of information exchange
			# of countries engaged regarding the clinical development of leading candidate product
			# of collaborations with the MoH and the vaccine community to implement procedures and rules to ensure consistent vaccine work
		Product Approval	Develop timely plans for product licensure in appropriate countries
			# of countries approving and currently distributing technology
			# countries including [X technology] in national five year disease plans
			WHO has a policy recommendation to use X intervention
		Regulatory Environment	# of collaborations/interactions with developing country regulatory bodies
	Supply Environment	Supply Infrastructure and Talent	# of suppliers for WHO pre-qualified, GAVI-approved vaccines
			# of distribution and delivery channels (shipments, outlets, etc.)
			# of wholesalers/country
	Environment for Uptake	Demand Influence	% of community advisory processes established
			# of KOLs with whom PDPs are engaged
			# of target group aware and informed about PDP, evidence of community awareness
			# key contact person(s)/supporters from target disease countries
		Service Infrastructure and Talent	# service deliverers trained
			#, % health facilities supervised per national guidelines
			#, % districts with labs with complete diagnostic capacity/adequate supplies
			# health workers (by category) per 100,000 pop. (by category)
			# community workers, existing NGO workers trained
			% of pop. within reach of basic health services
			#, % of population covered by key services (e.g. PMTCT, Malaria, etc.)

Level	Name	Definition
Area	Enabling Environment	
Dimension	Scientific Environment	The overall investment in the people and infrastructure that contribute to and innovate the field of neglected disease research
	R&D Funding	The extent to which financial resources have been dedicated to research & development for neglected diseases beyond those required for a specific product
Category	R&D Sites	The extent to which resources have been dedicated to building up research and clinical sites of use beyond those required for a specific product
	R&D Talent	The extent to which resources have been dedicated to building up research & development talent of use beyond that required for a specific product or organization
	State of Innovation	The extent to which the field has fundamentally advanced (quality and quantity of new targets and molecules available for research, etc.)
Dimension	Policy and Political Environment	The overall political and financial investment in facilitating neglected disease research
Category	Financing Mechanisms	Breadth and depth of financial support in place to encourage and maintain adoption rates of new tools for global health
	Policy Acceptance	Assessment of national and international governing body acceptance of the product and/or creation of policies to support the introduction of a product (updated WHO guidelines, incorporation into national health strategies, etc.)
	Product Approval	Approval of product by various governing bodies (e.g. national health systems, WHO Pre-qualification, etc.)
	Regulatory Environment	Assessment of the evolution of the regulatory environment overall, and not just how it pertains to a specific product
Dimension	Supply Environment	The networks and resources for distributing products in different countries
Category	Supply Infrastructure & Talent	The overall distribution networks and management in place for all therapies in a given country/region/local
Dimension	Environment for Uptake	The overall environment in which consumers are exposed to and educated on health seeking behavior and new products, and the ability to track the data that reflects changes to the environment
Category	Demand Influence	Ability to create an environment conducive to consumer uptake through education programs, local partnerships, communities, etc.
	Service Infrastructure & Talent	The quality and quantity of trained professionals (e.g. NGOs, advocates, peer counselors) and resources available in a targeted area to deliver product to targeted audiences

Area	Dimension	Category	Metric
Health Impact	Product Uptake	Patient Uptake	Retention rates (% patients continuing to use product over a period of time or repeat refills)
			# people receiving treatment with counseling
			# products distributed
		Supply Management	# doses provided by manufacturer vs. requests
			Total # stock out days of drug in last month vs. all storage facilities
			#, % health facilities or central warehouses with no stock out days during last month
		Health System Uptake	# of days over/under target date for building a vaccine delivery strategy by country
			Share of MD attention (market research) %
			# and types of "detailing" prescribers receive from different drug reps
			# of years from licensure to first country uptake
			# of countries introducing product 5-10 years post licensure
		Pharmacovigilance/Aftersales	# of collaborations with stakeholders to define issues of post-marketing surveillance
			# of longitudinal snapshots of market trends tracked and reported
			% of quality assurance and pharmacovigilance and efficacy systems in place by targeted date
	Disease & Economic Burden	Disease Burden	% of high risk audiences receiving product
			Prevalence of targeted disease
			# of lives saved
			% increase in patient satisfaction as a result of the intervention vs. baseline (no intervention)
		Quality of Life & Economic Burden	# DALY/Averted
			Determine cost-effectiveness of a product (as determined through trials with economic analysis or, if further upstream, through modeling)
			Ratio of Net monetary benefit (NMB) vs. R&D costs
			Total delivery cost/delivery price per unit

Level	Name	Definition
Area	Health Impact	
Dimension	Product Uptake	Assessment of the consumer and system's willingness to purchase the product and the organization's ability to evaluate the uptake
	Patient Uptake	The extent to which product is being purchased (absolute numbers, numbers relative to competitors, etc.)
	Supply Management	The ability and extent to which a organization monitors and satisfies demand with supply
Category	Health System Uptake	The extent to which non-patient populations (physicians, health plans) have accepted and endorsed the product
	Pharmacovigilance/Aftersales	Evaluation of uptake (longitudinal studies, assessments of initiatives, etc.)
Dimension	Disease and Economic Burden	The projected effects that the intervention will have on the market from a disease and cost perspective
Category	Disease Burden	The projected effects that the intervention will have on the market from a disease perspective (morbidity, mortality, etc.)
	Quality of Life & Economic Burden	The projected effects this intervention will have on the quality of life of its users and the cost to the health system (DALY, QUALY, Cost Effectiveness)