PDP ACCESS STRATEGY DISCUSSION PAPER
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ABSTRACT

This paper discusses the current status of PDP access strategies, select access strategy challenges, and future considerations for improving access strategies. Data were gathered based on discussions with ten PDP access leaders, five PDP donors and four access experts[2], along with a review of access documents submitted by the interviewees. We found that access strategies are extremely variable. Strategies can be stand-alone or integrated into other documents, confidential or public, explicit or not. They may be developed internally, or supported by outside consultants. PDPs largely lack clear definitions of success for their access work, and the accompanying metrics to track their progress. Defining the PDP's role in supporting post-licensure issues is a critical challenge in access planning. There is a clear tension between donor expectations for PDP involvement at the country-level limited to facilitate uptake of a licensed product, and PDP concerns that gaps in the access architecture will limit the potential impact of their products, possibly justifying a more active role. PDPs see global and country-level advocacy as important for building support for new products, and donors voiced concerns about the timing and intensity of outreach to potentially overburdened ministries of health. Going forward, we suggest that PDPs can more systematically develop their access strategies by differentiating between those access issues that are relevant to the whole portfolio, from those that will vary by product. Defining the portfolio-level issues will enable PDPs to focus their strategy work on the cross-cutting challenges, while creating product-specific plans with product development milestones. There may be opportunities for PDPs to collaborate in the assessment and action associated with some shared post-licensure gaps. Additional research would be needed to more concretely define what those shared activities might be.

PAPER OBJECTIVES

PDPs have been undertaking access-related investments for several years, but not always in the context of a strategic plan. As PDPs consider a more strategic approach to access planning, they are seeking to learn from each other by sharing their individual approaches. The authors recognize that access strategy differs widely by PDP based on the disease, the modalities, the maturity of the portfolio, and the priorities of partners. With this in mind, the objectives of this paper are to:

- Assess the current status of PDP access strategies
- Present diverse perspectives regarding particularly challenging access issues
- Increase the effectiveness of PDPs by sharing a range of approaches to developing an access strategy

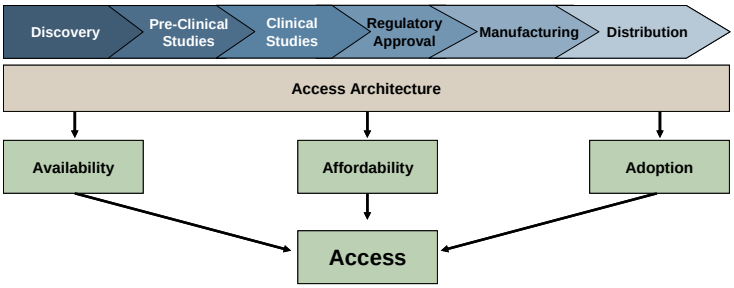
[1] Prepared by Laura Herman (FSG), Amanda Oudin (FSG), Elizabeth Gardiner (TB Alliance), Florence Camus-Bablon (DNDi), and Don Douglas (PDVI), on behalf of the PDP Access Steering Committee, which is made up of the following organizations: Aeras, Concept (Secretariat), DNDi, FIND, iOWH, IPM, IVCC, MMV, MVI, PATH, PDVI, and TB Alliance.

[2] The PDPs that provided input to this research include Aeras, DNDi, FIND, GATB, IPM, MMV, MVI, MVP, PATH, PDVI; please see the complete list of interviewees in Appendix.

Based on the specific terms of reference for this work, the greatest emphasis has been placed on documenting current activity and approaches, although some potential new approaches to the challenges facing PDPs are proposed for discussion.

OVERVIEW OF PDP ACCESS STRATEGIES

How do PDPs define access strategy?[3]



For the purposes of this paper, when we discuss access strategies, we are describing the PDPs' approaches to access across the product development spectrum, from pre-clinical to licensure and uptake. "For PDPs, access refers to a set of coordinated activities needed to ensure that the products developed will ultimately have an equitable public health impact."[4] The access strategy describes the PDP's approach to the access issues it confronts, or expects to confront in ensuring its products reach their intended audiences. As opposed to the long list of activities and analyses that each PDP might undertake, the strategy provides the overall goals, priorities, tactics and metrics that the PDP will rely on to guide the access work. The strategy's goals and priorities inform which of the activities in the long list will be addressed, when, and how they interrelate.

How do PDPs define success for their access work?

The definition of success is arguably the most important starting point for a strategy as it orients the strategy around an overarching goal. For most PDPs the definition of success in access mirrors the overall goals of the organization in terms of health impact, but most definitions provided by interviewees are not very specific. MVI, GATB and MMV provide interesting examples of success definitions:

- MVI: MVI's goal for its first generation vaccine, RTS,S is "to ensure that robust evidence and financial resources are available to all countries in sub-Saharan Africa, allowing each to take a decision if they want to adopt, defer, or not adopt RTS,S into their EPI and/or wider health systems, within one to three years of legal and physical availability". This vision has also been endorsed and adopted by MVI's pharmaceutical partner and owner of RTS,S, GSK. MVI felt that such a vision and definition of success was critical for framing MVI's added value in terms of generating evidence and planning for financing, while most importantly focusing on supporting countries to address malaria as a public health problem. Success is less about whether every country uses MVI's intervention, but instead focuses on the countries selecting the appropriate mix of interventions and strategies relevant for their situation. As a result of this goal, MVI (along with the WHO) has invested in developing and implementing the Malaria Vaccine Decision-Making Framework, which is intended to "strengthen national decision-making processes and avoid the delays seen in introducing other life-saving interventions in the region."[5] See the Appendix for the full decision-making framework.

[3] Graphic adapted from Frost & Reich, "Access: How do good health technologies get to poor people in poor countries?" 2008. "Access Architecture is defined as: A network of organizations involved in access for a particular health technology."
[4] Brooks et.al., "The Role of PDPs in Ensuring Access by Developing Countries to New Healthcare Products" 2008
[5] MVI website

- GATB: GATB's preliminary definitions is that "leading decision makers in countries with more than 70% of the TB burden consider it 'highly likely' that the National TB Program will adopt a TB Alliance-developed regimen within three years of regimen availability." Additionally, GATB aspires to "WHO endorsement and SRA registration of a four-month regimen for DS-TB." These goals were selected to reflect GATB's priority that key stakeholders see the value of its products, and that those products reach patients as soon as possible, based on GATB's efforts laying the groundwork for rapid adoption. [6]
- MMV: The MMV definition of success reflects their evolution as an organization, and provides guidance at the portfolio, rather than product level. Since its first product launch, the access team has refined its definition of success to better reflect the enabling role that it expects to play for all products in the field. The definition now includes creating informed acceptance platforms at the global and country levels, supporting innovative programs to expand access to all malaria products (such as AMFm), and measuring and evaluating the success of MMV products to inform post-launch investments.[7] MMV now defines success more broadly by including a facilitative role supporting all new anti-malarial products that are on the market. MMV's experience highlights the importance of refining and adapting priorities based on experience.

These definitions have direct impact on access planning. MVI's definition identifies the scope of issues that it must address within its access strategy, by clarifying what information countries need, when, and from what source, to facilitate country decision-making. Their definition narrows the scope of issues that it must address, simplifying their access work to a certain extent, and driving the organization to prioritize activities that will facilitate country decision-making. GATB's definition goes a step beyond MVI's such that success is linked to country adoption. This implies that GATB will work to ensure that its products address key stakeholder requirements, and that the relevant decision-makers will be aware of and enthusiastic about the new products. MMV's definition is the broadest of the three. It reflects the evolution in the organization's understanding of its unique opportunity to drive impact. The goals related to expanding access to all malaria products introduce a significant new level of complexity to MMV's work.

How do PDPs develop their access strategies?

Five PDPs described discrete efforts to create access strategies: MMV's current strategy was defined during the 2008-2012 strategic planning process for the overall organization (although MMV has revised some of the access priorities based on the launch of their first product). Similarly, DNDi has developed "access guiding principles" relevant to the entire portfolio, with a specific and focused strategy at the disease and product levels. Each project has distinct priorities that reflect the unique issues for that project, i.e. emphasis on drug supply sustainability and affordability for leishmaniasis treatments, on disease awareness and recognition for Chagas, on gradual expansion of adoption for sleeping sickness and malaria. PDVI's strategy emerged from extensive work during 2001 to 2004 supported by the Rockefeller Foundation to assess the determinants of innovation; it is described in a paper published in 2007 in Vaccine[8]. The paper lays out the PDVI strategy and compares it with the strategy for a more upstream effort to develop a pneumococcal vaccine.

[6] Interview with Elizabeth Gardiner, GATB

[7] Comments are paraphrased from interview with George Jagoe, MMV

[8] Mahoney RT, et al., *The introduction of new vaccines into developing countries. IV: Global Access Strategies.* Vaccine, 2007 **25**(20): p. 4003-11.

IPM and GATB are currently in the process of creating and/or more formally documenting their strategies. IPM is being supported by a team of external consultants in their strategic planning. GATB is creating its plan internally. These organizations all referenced the use of critical path analysis or decision making frameworks to determine access priorities, linking access work with milestones in the product portfolio. Other PDPs interviewed did not reference a specific strategy-setting process.

How are access strategies communicated?

PDPs communicate their access strategies in various ways. MMV's access strategy is embedded in the organization's overall business plan. MVI doesn't have a publicly available stand-alone strategy, but has a presentation that includes the major streams of access work as well as a cohesive access strategy integrated with the R&D strategy in proposals to donors. MVP summarizes its access strategy in a paper that compares access for a meningococcal A conjugate vaccine with Hep B and HiB vaccines. The PDVI access strategy can be found on its website and within various internal documents and presentations. FIND has a strategy that is a confidential, internal document. Aeras doesn't have a comprehensive access strategy document, but its access approach is part of overall Aeras presentations. DNDi's access strategy is a stand-alone document outlining guiding principles for its access work, complemented with specific work plans embedded into project plans. GATB is currently developing a comprehensive strategy document. IPM has previously articulated its approach to developing an access strategy based on lessons from the introduction of contraceptive technologies. IPM is now completing a year-long process to define its future access strategy.

MMV, DNDi and PDVI stand out as having more formal access strategy documents. These documents share a global view of the critical access issues that confront their portfolios (MMV includes more contextual details) and the associated priorities for their access work. Both organizations are now balancing the perspectives in these documents with the realities of supporting products that are on the market.

- MMV's five year business plan (2008-2012) includes ten pages on access. The major content areas are: an overview of the major challenges to access (including private sector dynamics, etc.), MMV's objectives in terms of adoption of MMV products, expanding the reach of those products and leveraging market insights to shape product development[9] (along with supporting activities), and a summary of the top priorities for the team in the next five years. While all of the content in the strategy has been important and helpful, the MMV team's reflections on the current priorities are quite different. With products now on the market, they are increasingly prioritizing post-licensure activities, such as launching phase IV demonstration trials, expanding uptake and improving adherence.
- DNDi's four-page Guiding Principles document outlines its short and long-term goals, the barriers to access, and the four major areas that it focuses on, along with three to five specific activities associated with each area. Finally, there is mention of how the strategy will be implemented, the link between access and R&D, and the process for updating the plan. The document is largely a conceptual overview of DNDi's approach, and given the diversity in its portfolio, DNDi's more specific access strategies are developed at the project level.
- PDVI's strategy defines six "determinants of innovation" that deal with R&D, manufacturing, domestic markets, international markets/procurement, regulatory affairs, and intellectual property rights management. PDVI believes that these determinants are dynamically linked

[9] MMV, "Ensuring Success and Targeting Eradication: MMV Business Plan 2008-2012" 2008

so that overall progress requires addressing all six determinants for each product. The emphasis among the six determinants varies according to the stage of development of each product and the nature of the company undertaking the development – developing country, biotech or large pharma.

Most of the access strategies that were shared as part of this research do not include a clear set of goals (long or short-term), nor do they mention metrics for tracking the success of their work. GATB and DNDi both mentioned that they are refining their access metrics; DNDi's specific access objectives are regularly updated along with project plans, integrating altogether R&D and access work.

Half of the interviewees for this discussion paper were donors and access experts. In our conversations, they raised several observations with respect to access strategies:

- **Access and Product Development**: Access strategies should outline how access considerations are being incorporated in the design and development of a new product. Developing new products is seen as core to the mission of the PDPs and stakeholders want to see clear mechanisms for mapping end-user requirements to the product development process. This suggests that the failures of current products and end points for new products must be well-understood in order to inform the development of a new TPP and the subsequent go/no-go decisions.
- **Access and Uptake**: Stakeholders want to ensure that PDPs think through the needs and potential roadblocks in taking a product to market. However, donors are especially concerned about PDPs becoming highly engaged in activities at the country level (e.g., health care worker training, patient education, manufacturing, product distribution). They seek as much detail as possible from the access strategy around how the PDPs will leverage other partners in the field, rather than building up internal capabilities for supporting the uptake of a product once it is approved (see Strategic Access Challenges below).
- **Timing for Uptake Planning**: Several donors suggested that uptake planning should be in place prior to initiating a phase III clinical trial so that the PDP understands all of the access considerations around potential use before embarking on this costly phase. It is important to note that securing partner commitments this early may not always be feasible. However, PDPs can systematically identify how a new product will fit within the existing health systems, the potential gaps and partners for uptake (assuming countries have been prioritized), and the extent to which the product will meet or exceed stakeholder expectations.
- **Access Embedded in the Organization**: Access considerations need to be reflected in activities across the PDP; not all access work happens within the access team. The access strategy should address how access issues will be reflected in the clinical trials strategy, manufacturing strategy, and in R&D decision-making (beyond the TPP design mentioned above).

Discussion Questions:

- Do PDPs see **advantages to having more formal access strategy documents**? What is the rationale for representing access strategies in various documents?
- To what extent **are PDPs planning to identify specific goals for their access work** in the short, medium and long term? What will drive the identification of these goals?

STRATEGIC ACCESS CHALLENGES

What role will PDPs play in access post-licensure?

This is one of the central issues challenging PDPs in their access planning. There is an ongoing tension as PDPs feel responsible for ensuring that their products have impact, but recognize that they don't have the mandate, skills or resources to be heavily involved in product introduction, or sales and distribution. PDPs, donors and experts all agree that it is not acceptable for PDPs to ignore the challenges associated with their products reaching their target patients. Nor is it acceptable or desirable to start building manufacturing plants or hiring legions of sales people. PDPs all recognize the importance of "coordinating, facilitating, advising, catalyzing and filling gaps" but due to the relatively limited collective experience to date, it is difficult to know how these roles will play out in practice. Further, there is a great deal of confusion over what is specifically meant by "post-licensure" or "downstream" and the types of activities that might be undertaken. For the purposes of this research, these terms were used interchangeably, and generally referred to country-level activities that might be required to ensure uptake, and eventually health impact.

For vaccine PDPs, there is a general consensus that public health systems do an acceptable job of distributing vaccines to the target populations, so ensuring financing was frequently cited as the biggest hurdle to end-user availability. For MVI, MVP and Aeras, GAVI provides a convenient centralized financing mechanism, which simplifies their access planning to a certain extent. Because PDVI is supporting the development of vaccines that are not yet included in the GAVI portfolio, it is working on a "bottom-up" or country-generated financing strategy. PDVI has conducted extensive policy-maker surveys that indicate there is a much higher priority for dengue vaccines in endemic countries than is found in GAVI that relies heavily on mortality as the dominant criterion.

DNDi's "Platforms"

Description

- Objective: strengthen clinical research capacity and assist GCP clinical development in endemic areas
- Structure: researchers, government individuals, NGOs and WHO, coordinated by DNDi around specific diseases in a geographic area
- Role: primarily facilitate exchanges, training, and capacity building to conduct GCP clinical trials
- Process: meet twice a year for a program review, and an update on the plan of action

Implications

Because of their involvement since the start of a project, platform members become natural partners for country decision making. They facilitate exchanges: gather relevant information on country issues, programs, and processes and convey relevant information to in-country decision makers.

For therapeutic PDPs, the country-level distribution mechanism is not as straightforward given the complexity of distribution through both the private and public sectors. While the Global Fund may be helpful on the financing issues & regulatory issues for HIV, malaria and TB products, in-country decision making, logistics, pricing, Phase IV, pharmacovigilance and patient and practitioner education are expected to be significant challenges. See sidebar on DNDi's "platforms"[10] as a mechanism to assist with clinical trials that in turn facilitates in-country product adoption. PDPs expect to continue to learn from each others' experiences as more PDPs launch products in both sectors. In the mean time, therapeutic PDPs continue to take on this wide range of issues in their access work.

[10] Interview with Florence Camus-Bablon, DNDi

Commercial partners are expected to play a major role in post-licensure activities wherever possible. MMV, DNDi, GATB, PDVI and IPM all mentioned that many of these partners are best equipped to ensure registration, rally in-country distribution partners, create practitioner and patient education materials, ensure pharmacovigilance, etc. Their planning around these issues will depend on the extent to which commercial partners are willing to take responsibility for these activities, which is likely to vary from product to product.

For PDPs interested in the kind of tools that might facilitate decision-making around post-licensure activities, INSEAD created a decision-making framework for MMV in 2009. While this framework doesn't feature prominently in MMV's current strategy, it is a helpful example of how PDPs might consider the criteria that would guide their relative levels of effort on various activities. See the Appendix for the full framework.

Donors and access experts expressed a near universal concern that PDPs will be too involved at the country level driving adoption and uptake. They believe that PDPs have been created to *develop* new products and should largely limit their attention to ensuring that new products are developed to address major access considerations that limit the effectiveness of current products. One funder stated that "PDPs should focus on their core business to get appropriate products developed and launched into the global marketplace, and not worry about the 'last mile'." From donors, the concern may come from a worry that since PDPs don't necessarily have the appropriate core competencies on staff, they will require additional financial resources to create redundant functions (redundant across PDPs and/or redundant with global actors). Many of the PDP donors already support global coordinating mechanisms, technical assistance providers and country governments to address issues related to improving access to medicine and driving uptake at the country level. They emphasize the importance of PDPs highlighting relevant gaps and advocating for others to take action, rather than building up their own capabilities.

Depending on the timeline to product introduction, the approach to gaps recommended above may be unsatisfactory for many PDPs. PDP goals with respect to health impact may compel them to pursue a more active strategy, when known gaps are not effectively addressed by the existing global health architecture. There is also a concern that some of the existing global coordinating mechanisms are spread too thin to take on issues that may impact only one disease, or product. Several PDPs mentioned the challenge of translating broad donor sentiment into concrete access strategies with defined endpoints for PDP involvement since the level of effort is also expected to vary by country. Where PDPs identify gaps, it is critical that they share this information with donors as soon as possible so that the global community can hopefully respond in a timely manner either to address the gap, or to help the PDP position itself to take a more active role in filling the gap. Over time, this approach may begin to build the architecture needed to more smoothly introduce and drive uptake of new products.

Discussion Questions:

- Are there examples **of PDPs effectively managing the concerns of donor**s? What types of analysis or evidence is required to build support for a PDP taking a more active role when that is warranted?
- To what extent **can PDPs define their access work in terms of only those issues that are relevant to new technologies** (regulatory strategies, country-level decision-making, etc), versus issues that are endemic to public health systems (distribution, practitioner education, etc)? Would this delineation more concretely address donor concerns? Is this delineation realistic?
- How **can PDPs document the range of potential post-licensure activities** that it might consider in

order to set expectations with respect to its role in ensuring impact? Can these be defined for the PDP writ large? Would it be helpful to articulate the specific activities (e.g., targeted studies to address outstanding questions associated with uptake versus activities related to the 'last mile') that are or are not in scope as a way to begin setting expectations with stakeholders?

How are PDPs considering the options of branded versus generic product positioning?

Branding was not a top of mind concern for most PDPs, who mentioned that this decision will largely be made by the commercial partners. Three PDPs shared explicit perspectives on the positive use of branding:

- PDVI and IPM mentioned the use of brands to drive differential pricing strategies.
- MMV discussed the importance of divorcing itself from the brands of its commercial partners in order to maintain its objective positioning with global, regional and country stakeholders. At the same time, to drive impact, MMV wants to encourage commercial partners to bring their significant marketing and consumer research resources to the introduction of a branded product.

Conversely, three PDPs expressed caution or concern when it comes to branding:

- MVI looks to avoid or minimize branding by pharma partners as brands are not typically used with vaccine products in immunization programs in developing countries.
- Believing that competition is the best mechanism for expanding a market and driving down prices, DNDi questioned the rationale of supporting branded products when quality generic products become available.
- GATB raised the concern regarding potential competition between generic products and the originator brand when the product comes off patent.

How does advocacy link to access strategies?

Similar to the terms "post-licensure" and "downstream", "advocacy" is not interpreted consistently across interviewees. While it was not explicitly defined, nearly every PDP mentioned that advocacy is an important tool for ensuring eventual access to new products. All PDPs interviewed described their advocacy at the global level with respect to private, bilateral and multilateral institutions. At the country level, the types of activities that are carried out relate more to understanding the health systems, gathering feedback on potential product characteristics, understanding regulatory requirements, and otherwise engaging key opinion leaders and decision makers. Most of this outreach is critical to facilitate the introduction of a new product. MMV also described advocacy at the country-level with other organizations to highlight problems around stock-outs and to ensure that the appropriate government officials understand the situation so that together they can start to identify potential solutions.

Donors and experts voiced several concerns about PDP advocacy at the country level. First, they worry that PDPs may be "pushing their own products" which can be interpreted as their being a champion for their commercial partners. "They are perceived as salesman for a technology, rather than a disinterested player looking to advance public health. They have chosen certain technologies in their portfolios and they are biased in favor of their technologies." [11] Second, they worry that relationship building activities may raise expectations long in advance of new products being available if it is done

[11] Anonymous interviewee

too early (See Appendix for snapshot of PDP portfolio introduction timeline). Third, there is a concern that if many PDPs are engaging at the country level simultaneously, the outreach may be "overwhelming" to thinly staffed ministries of health. These concerns are important to consider when PDPs are developing their access and advocacy strategies, although where individual ministers are focused on specific diseases, it may be less of a concern. When PDPs are communicating with donors they may want to take additional measures to communicate their sensitivity to these issues and the extent to which they see real, versus perceived risks.

Discussion Questions:

- How important is it that **PDPs better coordinate their outreach at the country level** (e.g., by disease, by modality)? How can PDPs leverage global coordinating bodies as mechanisms to communicate with ministers (e.g., WHO, GAVI, Global Fund, UNICEF)? To what extent could these groups be positioned to drive changes towards new regimens? Would PDPs trust these mechanisms as sufficient for informing ministers, or would PDPs still see a need for outreach around specific products? Are there vehicles for coordination that would be acceptable to PDPs?
- Should and if so how could PDPs create **joint access functions** among a variety of PDP & products, perhaps as a joint venture?
- How can PDPs **articulate their post-licensure role in terms of a product champion**, tasked with identifying the global architecture requirements to support a new product (based on Reich et al)? Would this be a helpful distinction with respect to the advocacy role PDPs envision at the country level?

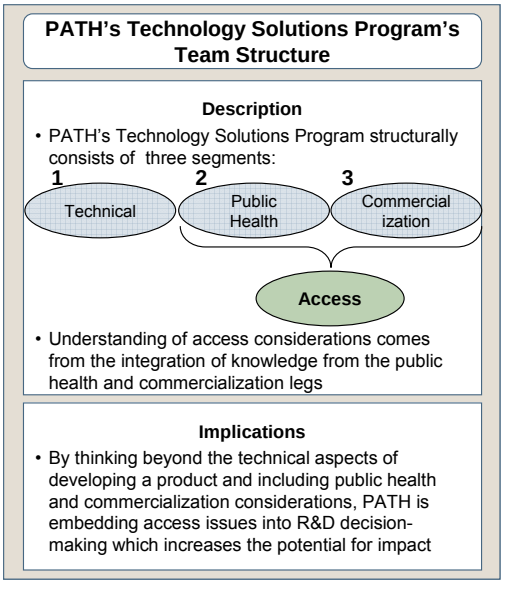
How do PDPs ensure that access considerations are reflected across the organization?

All PDPs emphasized the importance of including access considerations in R&D decisions, clinical trial strategies, manufacturing plans, etc. While the access team may be formally responsible for ensuring products reach their intended audiences, success depends on consistent access priorities being reflected throughout the organization. Donors and experts also emphasized this point, especially with respect to R&D – they see PDPs as first and foremost creating products that patients need, as opposed to those that "the scientists think are cool."

There is also consensus that input at the earliest stages of product development is ideal, and access staff at many PDPs described their role in shaping TPPs. However, many PDP access staff recognized that it is challenging to find formal opportunities to integrate with R&D colleagues beyond the TPP stage. PDVI emphasized the challenge associated with bringing access concerns to bear when the commercial partner is managing the entire R&D process. Four PDPs described formal internal arrangements:

- MVI: The Director for Policy & Access chairs a multi-disciplinary team that develops TPPs.
- MMV: One access team member is included in the Product Development Team for late stage products.
- GATB: A new process will include an access team member in R&D decisions via quarterly meetings of the R&D and access teams.
- DNDi: Access is embedded with R&D and "disease strategies, plans and teams" incorporate R&D, business development, access and communication.

The PATH Technology Solutions Team offers an integrated team approach that may be instructive to other PDPs. Drawing on



three competencies, two of which reflect access considerations, the team structure is designed to bring strong access expertise into the product development process. See sidebar on PATH's structure[12] as a unique example of embedding access in the product development process.

FUTURE CONSIDERATIONS

PDPs have largely taken an informal approach to developing their access strategies. They build annual workplans with an eye towards the issues that are most relevant to the critical path of product development, while also trying to maintain momentum on longer-term issues, where resources allow. In an effort to support PDPs in the efficient, timely development of access strategies, the following ideas are offered for the Steering Committee's discussion.

What value is gained from articulating an access strategy?

The interviews suggest that access strategies may be important in order to:

- Define major success criteria for a PDP in terms of its ability to impact public health in the target populations
- Reflect how end-user requirements inform product decision-making at each milestone in the product development process
- Define the general approach to major areas of access activities (e.g., country decision making, regulatory, pricing, manufacturing, market research, Phase IV and pharmacovigilance), thus increasing organizational understanding and consensus around access work
- Bring a data-driven perspective to determine which access work is needed when to inform internal resource allocation and demonstrate how the access activities are appropriately "paced" with the anticipated progress of individual products under development
- Articulate the PDP's role vis a vis partners' roles, thus informing the terms appropriate for partner agreements
- Demonstrate access team accountability for specific goals
- Reinforce internally that access is not managed solely by the access team but that responsibility is integrated across the organization
- Communicate a cohesive, comprehensive access approach to external stakeholders

At the same time, product development is dynamic, and access work will evolve as PDPs shift from developing products, to also supporting new products in the field. An access strategy can lay a foundation for a few years, and then will need to be revised. To be useful, an access strategy needs to be more than an interesting academic document – it needs to drive the priorities of the team to ensure the PDP delivers on the goals that are most relevant to the portfolio.

What should be included in an access strategy?

There is no single answer given the PDP differences by disease, modality and the status of various portfolios. At a very high level, we would expect a robust strategy to include a specific period of time (e.g., a 3-year or a 5-year strategy), principles or criteria that will guide various elements of the work (if specific plans can't be developed), clear goals and the accompanying rationale (data or hypotheses), metrics for tracking progress, and a process for learning and revising the strategy. Many strategies are

[12] Interview with Steve Brooke, PATH

also accompanied by implementation plans or workplans, which identify the specific activities and tasks that need to be accomplished in order to achieve the goals.

In terms of specific content, PDPs may find it helpful to distinguish between the access-related issues that are relevant at the portfolio versus product levels, and, for the PDPs working in a single disease area, focus their access strategies on the more cross-cutting, portfolio-level issues. This will allow PDPs to separate those issues that require very detailed planning (based on the fate of an individual product) from those issues that it must address, regardless of the fluctuations in the portfolio. PDPs can prioritize their planning efforts around the topics that will have the broadest impact, sequencing the more detailed planning exercises for products that may still be many years away.

While the specific content for an access strategy will vary by PDP, the following list of topics is likely relevant to the majority of PDPs:

- Definition of success (supporting the organization's overall goal)
- Access goals for next X years
- Scope of access activities for the PDP (e.g., country decision making, regulatory, pricing, manufacturing, market research, Phase IV and pharmacovigilance) and definition of access architecture
- Principles that will guide commercial partnerships (see "PATH guiding principles for private sector collaboration" http://www.path.org/files/ER_gp_collab.pdf)
- Overview of stakeholder needs (including patients) and the thresholds that will guide TPPs
- Policies that will link access considerations to go/no-go R&D decisions
- Criteria that will inform country selection
- Anticipated regulatory pathway, including a plan to detect and assess adverse events
- Framework that will determine the PDPs and access partners' role in post-licensure activities
- Goals and approach to supporting global-level policy & financing decisions
- Goals and approach to supporting country-level policy & financing decisions
- Metrics for tracking progress against goals
- Triggers that will launch product-specific "impact plans" (see below)
- Process for refining strategy (timing, responsibility, etc.)

For most PDPs, this list is a necessary, but not sufficient set of data for an access strategy. Many PDPs can move beyond guidelines and principles in their access strategies to share tangible plans and approaches, or to identify key questions that require further investigation. For many PDPs, specific strategies and plans will depend on the selection of countries, which may be done at the portfolio level, but may also be product-specific. It is not until countries have been prioritized that PDPs have a manageable unit of analysis to focus on in many of their access planning activities.

What is included in product-specific impact plans?

PDPs anticipate developing product-specific launch plans or product introduction plans. (There is not consensus as to the difference between these plans. They all relate to the planning associated with taking an individual product to market.) To make this a more active endeavor, PDPs can think about "impact plans", to work through the many issues that are not relevant at the portfolio level and to guide product introduction and facilitate uptake. These plans should evolve as products achieve specific milestones, driving towards increasingly granular levels of detail. The following data are eventually required for product introduction and may be completed based on product-specific milestones: prioritized countries; key hurdles to access globally and per country; requirements for policy adoption;

gaps in local manufacturing capacity and a manufacturing plan; channel dynamics of the public and private sectors; key competing products; characteristics of the intended user; distribution strategy, financing strategy; partners; projected cost effectiveness; exit strategies; etc. If these topics can be generalized across the portfolio, they would be included in the portfolio-level access plan. However, based on our discussions with PDPs, it seems that many of these elements are product specific, and it is sometimes difficult for PDPs to try to define these elements when actual products are still many years away. As PDPs launch more products, they will likely find that some of the issues addressed for one product will be relevant to another (even if not relevant to the whole portfolio).

The timing for these plans will vary, but donors and experts have suggested that strategies to drive uptake ought to be in place before a phase III trial is launched. It may be difficult to engage specific key government partners in serious discussions in the absence of positive phase III outcomes. However, to the extent that PDPs have worked with endemic countries to identify priority countries and their needs early on, they can produce a mapping of country-specific gaps and key potential partners when and if the product is ultimately launched. This will determine the PDP's role post-licensure.

What is the different between the portfolio access strategy and a product impact plan?

The difference between the two plans will vary by PDP. The portfolio access strategy may be largely conceptual (e.g., guidelines and principles) for PDPs addressing multiple diseases in multiple regions. These PDPs may find that there is relatively little in the way of specific planning that is cross-cutting (e.g., DNDi). Detailed access planning is completed based on individual products. For other PDPs, such as MVI, the single disease focus and definition of success may enable more of the access strategy to be defined at the portfolio level.

With portfolio-level access strategies and product-specific impact plans in place, PDPs can define their workplans and track their progress systematically. Where clear access goals can be set, teams can then prioritize the activities that will enable them to achieve those goals. There have been many efforts to define the long list of access activities that PDPs should address. Most of these can be better assessed and prioritized in the context of clear portfolio and product-specific strategies.

What mechanisms could efficiently address shared post-licensure access hurdles?

When PDPs identify a barrier to access, they can try to partner, or convince others to address the barrier, particularly as some of these barriers will impact the introduction of multiple products. For example, a weak public health sector supply chain will stymie the use of vaccines and therapeutics. At some point the number of approved vaccines will require a step change in cold chain capacity. Where various PDPs will confront the same issues, what is the best mechanism for a coordinated response? As PDPs have more products moving into phase III trials and target countries are being identified, there is an opportunity to pool resources to assess where overlapping access barriers might occur within the same countries or regions and motivate stakeholders, donors and partners to act. Coordination by modality will sometimes have merit. For example, as vaccine PDPs identify their priority countries and estimate their product launch dates, an analysis of the existing cold chain capacity will be essential for planning for uptake. The findings from that analysis could inform health systems strengthening funding to prepare for the new vaccines.

Coordination by disease might also be desired where endemic countries may benefit from capacity and decision making process strengthening. . In this case, PDPs can work together to reinforce the capacity

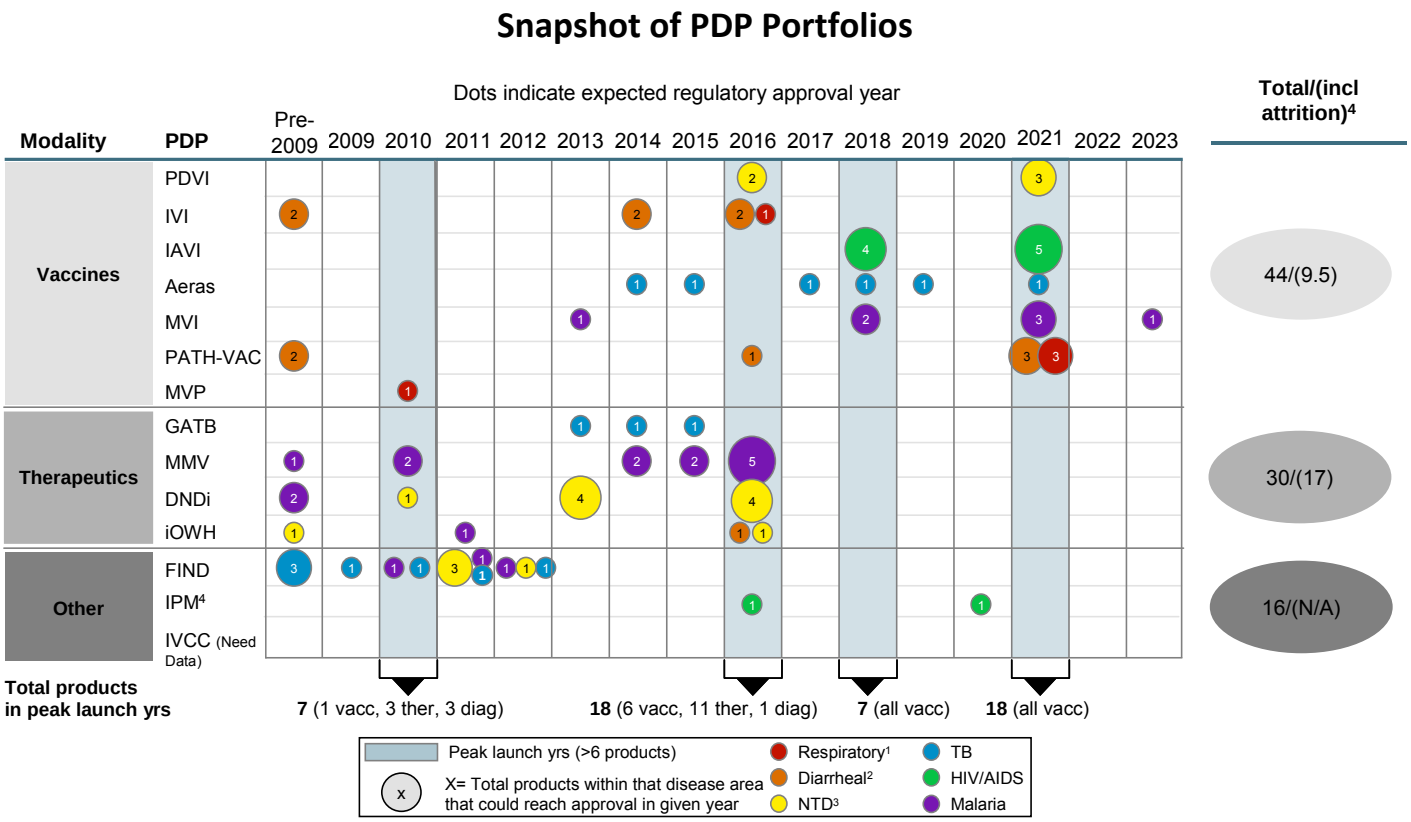
of a potential in-country system for a disease area, identifying financial support to engage in global-level dialogues, advocating for additional resources for the country efforts to introduce new products, and facilitating important relationships with advocates in other countries.

Discussion Questions:

- To what extent **would a portfolio versus product distinction facilitate access planning**? Would the distinction help set expectations with donors who may be eager to see detailed introduction plans before they are relevant? Are the issues **that are portfolio versus product-specific easily defined? What other ideas would help facilitate joint action** to remedy shared access hurdles? Is joint action desirable to PDPs?
- Some activities may be coordinated and addressed jointly by PDPs, possibly via a specific coordinating vehicle; these may include: country /regional regulatory approval, Coordination of outreach at country level, pharmacovigilance, others?

Appendix:

Snapshot of PDP Portfolios, June 2009[13],[14]



1. Includes pneumonia and meningitis 2. Includes cholera, typhoid, and rotavirus 3. Includes HAT, visceral leishmaniasis, chagas, hookworm, and dengue 4. IPM products listed are a subset of all candidates in development. This is due to IPM's novel approach to Phase III clinical trials, which includes forced product attrition
Sources: To estimate time until launch, survey responses from the 2008 PDP Access meeting were used where available. Next, public sources were referenced including the STOP TB website and PDP websites. Where no launch dates were available, vaccine launch dates were estimated using industry averages published by BIO, the biotechnology industry association (Pre-clin=3yrs, PI=2yrs, PII=2 years, PIII=2 yrs, Reg=3yrs). Drug launch dates were estimated using the industry averages as reported in a 2007 IFPMA report (Pre-clin=1yr, PI=1yr, PII=1.5yrs, PIII=2.5yrs, Reg=1.5yrs). Microbicide launches were estimated using data from the IPM Strategic Plan 2009–15. For all estimates, it was assumed that candidates were starting the current phase 5. Drug attrition was estimated using industry averages of success by phase, published by IFPMA in 2007 (Pre-clin=0.01, PI=0.7, PII=0.5, PIII=0.5, Reg=0.9). Vaccine attrition was estimated using industry average success rates by phase, published by Andrew Farlow from the University of Oxford in the TB Vaccine Scoping Study, 2008 (Pre-clin=0.6, PI=0.8, PII=0.6, PIII=0.75, Reg=0.9). Microbicide attrition is assumed to be included in IPM's total expected products. IPM uses a novel approach to Phase III clinical trials, which includes forced product attrition. Diagnostic attrition was excluded because diagnostics follow a unique regulatory path

[13] BCG/BMGF Design Team, "Snapshot of PDP Portfolios" 2009
[14] Update: NECT combination for sleeping sickness was launched by DNDi and WHO in 2009

INSEAD's Post-Licensure Decision Making Framework for MMV, 2009[15]

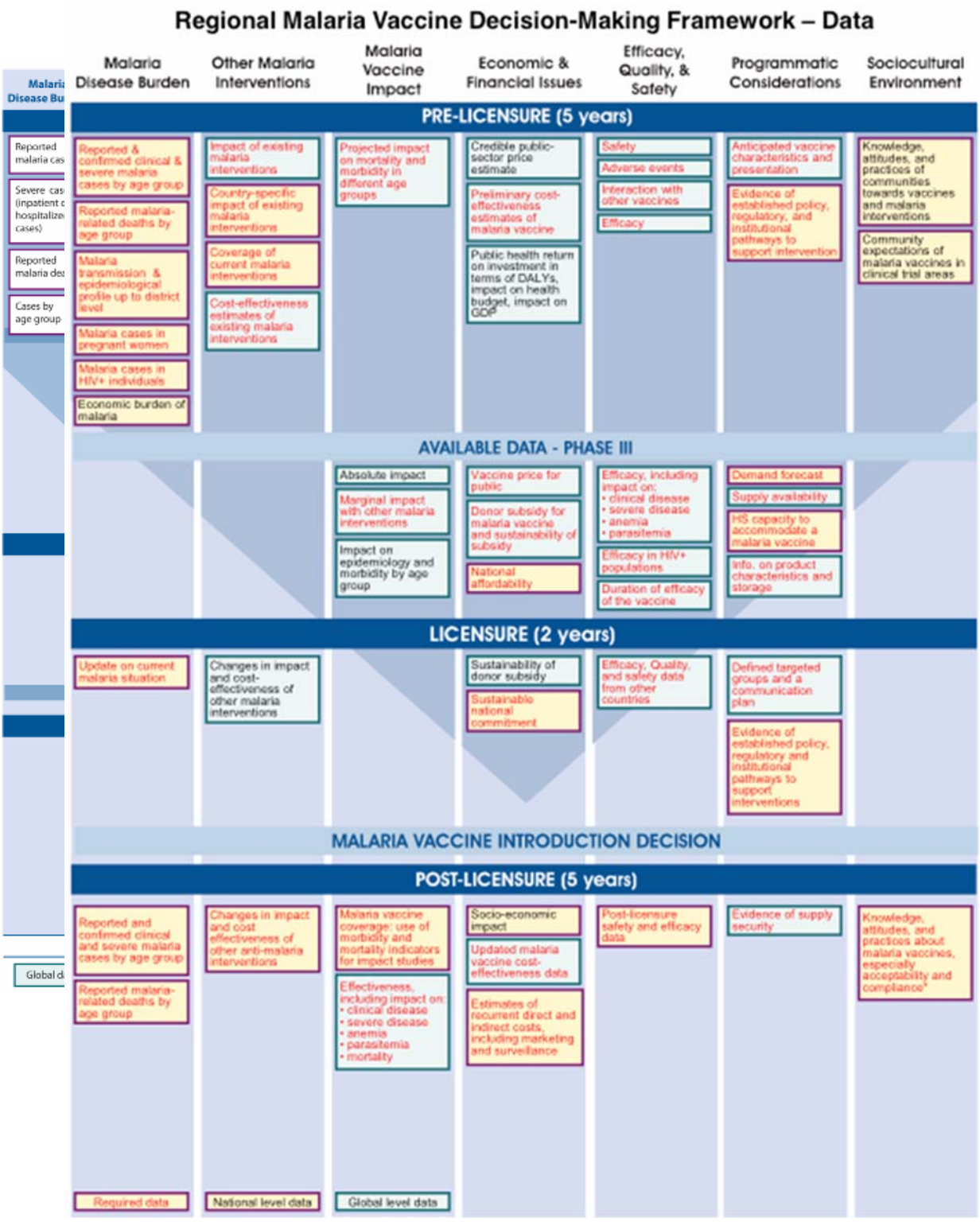
INSEAD Post-Licensure Decision-Making Framework for MMV

Activity	Needs of MMV Developing Partner*	Strength / competence of MMV relative to external partner	High transaction cost of working with external partner	Global public good
Availability				
• Market sizing and demand forecasting	√		√	√
• Manufacturing/Production				
• Procurement	√		√	√[1]
• Distribution and delivery				
Affordability				
• Affordability to government and NGO buyers				√[1]
• Affordability to out of pocket private buyers	√			√[1]
Acceptability				
• Inclusion in WHO recommended drug guidelines	√	√	√	
• Inclusion in national standard treatment guidelines	√	√	√	
• Acceptance by prescribers / dispensers			√	
• Acceptance by end-patient/care givers			√	

Note:* "MMV Developing Partner" refers to the commercial partner. 1 Even though the activity itself may not directly create a public good, creating knowledge on how to best carry out the activity is a global public good.

[15] Yadav and Stapleton, "A Decision Framework for the Access Strategy of Medicines for Malaria Venture" 2009

Malaria Vaccine Decision-Making Framework[16]



[16] http://www.malvacdecision.net

Regional Malaria Vaccine Decision-Making Framework – Process

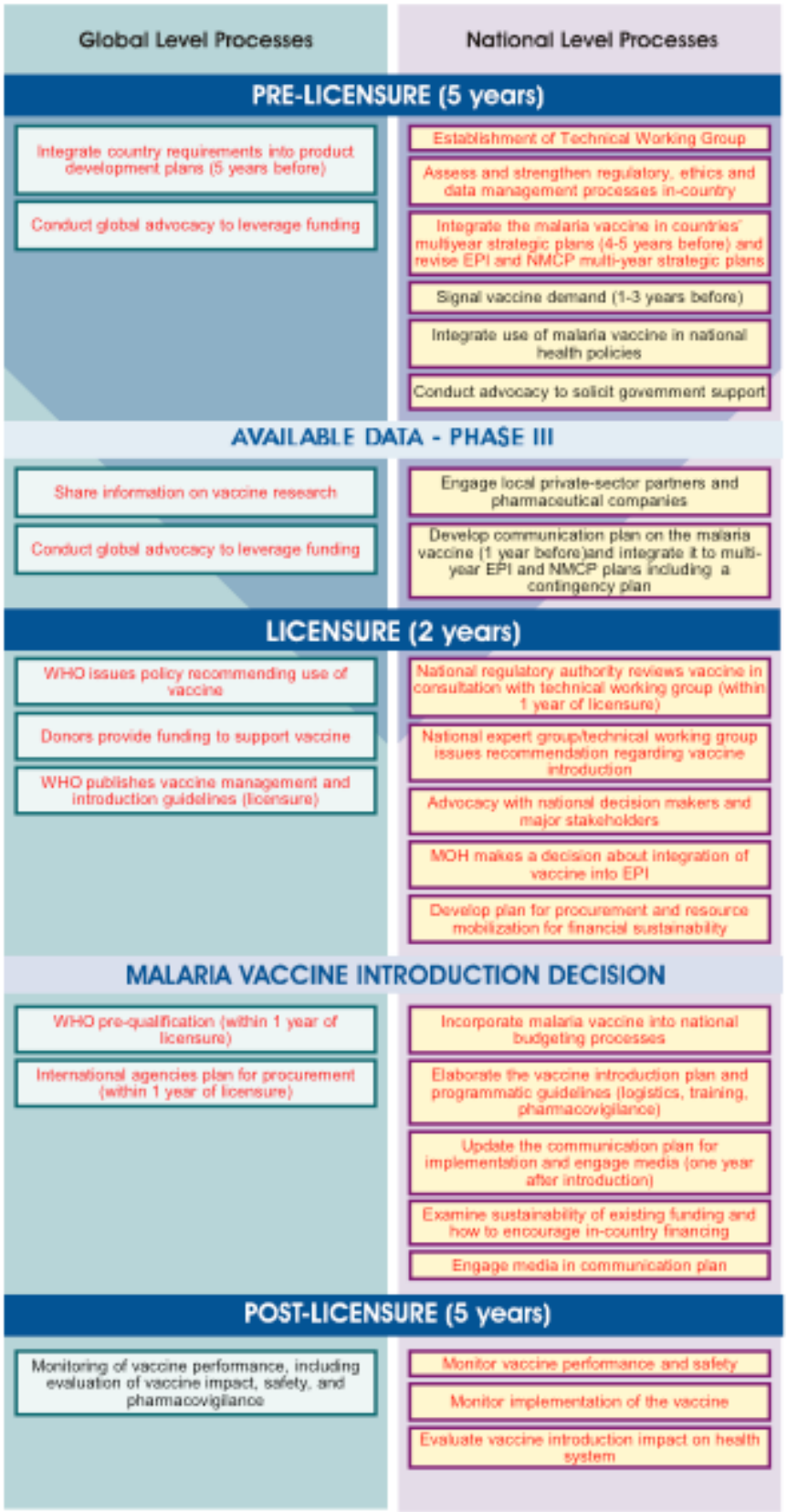


Table of interviewees

#	Name	Title	Organization
PDPs			
1	Lew Barker	Senior Medical Advisor	Aeras
2	Alan Brooks	Director, Policy and Access	PATH Malaria Vaccine Initiative (MVI)
3	Florence Camus-Bablon	Senior Access Advisor	Drug for Neglected Diseases initiative (DNDi)
4	Rich Mahoney	Director, Vaccine Access	Pediatric Dengue Vaccine Initiative (PDVI)
5	Don Douglas	Senior Program Officer, Vaccine Access	Pediatric Dengue Vaccine Initiative (PDVI)
6	Elizabeth Gardiner	VP Market Access	Global Alliance for TB Drug Development (GATB)
7	Penny Grewal	Director, Global Access	Medicines for Malaria Venture (MMV)
8	George Jagoe	Executive Vice President, Global Access	Medicines for Malaria Venture (MMV)
9	Marc LaForce	Project Director	Meningitis Vaccine Project (MVP)
10	Evan Lee	Senior Policy Officer	Foundation for Innovative New Diagnostics (FIND)
11	Thomas Mertenskoetter	Executive Director of External Relations, Europe	International Partnership for Microbicides (IPM)
DONORS			
12	Patricia Atkinson	Business Officer in Infectious Diseases	Bill and Melinda Gates Foundation (BMGF)
13	Marja Esveld	Senior Policy Advisor, Health, Gender and Civil Society Department	Netherlands Ministry
14	Sue Kinn	Research Manager	UK Department for International Development (DFID)
15	Guy Stallworthy	Senior Program Officer - Global Health Global Health Delivery	Bill and Melinda Gates Foundation (BMGF)
16	Saul Walker	Senior Access to Medicines Policy Advisor	UK Department for International Development (DFID)
EXPERTS			
17	Emma Back	Consultant / potential draft reviewer	Ex-DFID
18	Steve Brooke	Advisor, Commercialization & Corporate Partnerships	PATH
19	Steve Chapman	SVP and CTO	PSI
20	Nel Druce	Policy Advisor	HLSP

Authors Biographies

Laura Herman, Managing Director, FSG

Laura has over 14 years of experience advising corporations, foundations, and international nonprofit organizations on strategy development, program design, evaluation, market analyses, and organizational alignment. She is a senior leader at FSG and has worked with clients to address a wide range of global health and development issues. Laura currently leads FSG's Global Health impact area. She has led research in dozens of countries in Africa, South Asia, and Latin America where she has evaluated in-country operations of partners, assessed impact and opportunities for new initiatives, and developed relationships for long-term strategic initiatives. She has published several papers and frequently represents FSG speaking at conferences around the world.
Before FSG

Laura started her career at Deloitte Consulting, focused on large-scale organizational change initiatives. In addition to her client work, Laura took a leave of absence in 2004 to work in Tanzania, where she conducted cost analyses of various social marketing programs for Population Services International. Laura holds an MBA from Stanford Graduate School of Business with a Certificate in Public and Nonprofit Management, an MA in International Policy Studies from Stanford University, and a BBA in International Business from the University of Michigan.

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Amanda Oudin, Associate Consultant FSG

Amanda Oudin applies her knowledge and experience in global health and development to strategy and evaluation questions across all of FSG's client sectors. Amanda has worked with foundations, corporations, and nonprofits on a broad range of projects from global health and development to local community engagement. In particular, she worked with the Bill & Melinda Gates Foundation on its five year HIV strategy, with two pharmaceutical companies, Eli Lilly and Merck, on their international corporate social responsibility efforts, with the John S. and James L. Knight Foundation building their community engagement initiative for St. Paul, MN, and with a community foundation in Dallas, Communities Foundation of Texas, on a strategy for its discretionary grantmaking around improving the lives of Dallas' working poor. She is also an active member of the Global Health impact area.

Prior to FSG, Amanda worked at the Institute for OneWorld Health assisting in the management of a phase III clinical trial in India. During graduate school, she established an emergency transport system in rural Uganda through a fellowship program with the Blum Center for Developing Economies. Amanda has worked on global health projects in India and Uganda, created an HIV Global Policy for Levi Strauss & Co., and has published a thought-piece on the ethics of international clinical trials. She has also volunteered with an organization in San Francisco providing homeless youth with resources to move off the streets. She holds a Masters in Public Policy from the University of California, Berkeley and a BS in Molecular, Cell and Developmental Biology from the University of California, Los Angeles.

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