

PATH VACCINE PRODUCT DEVELOPMENT ASSESSMENT: SUMMARY OF FINDINGS

The Boston Consulting Group
July 2010

Please note: this project was completed on July 31, 2010. The information collected was relevant and vetted for that time. The current situation will likely be different as the organization evolves.

For questions, please contact:

Wendy Woods (woods.wendy@bcg.com) or Andrew Rodriguez (rodriguez.andrew@bcg.com)

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1. INTRODUCTION

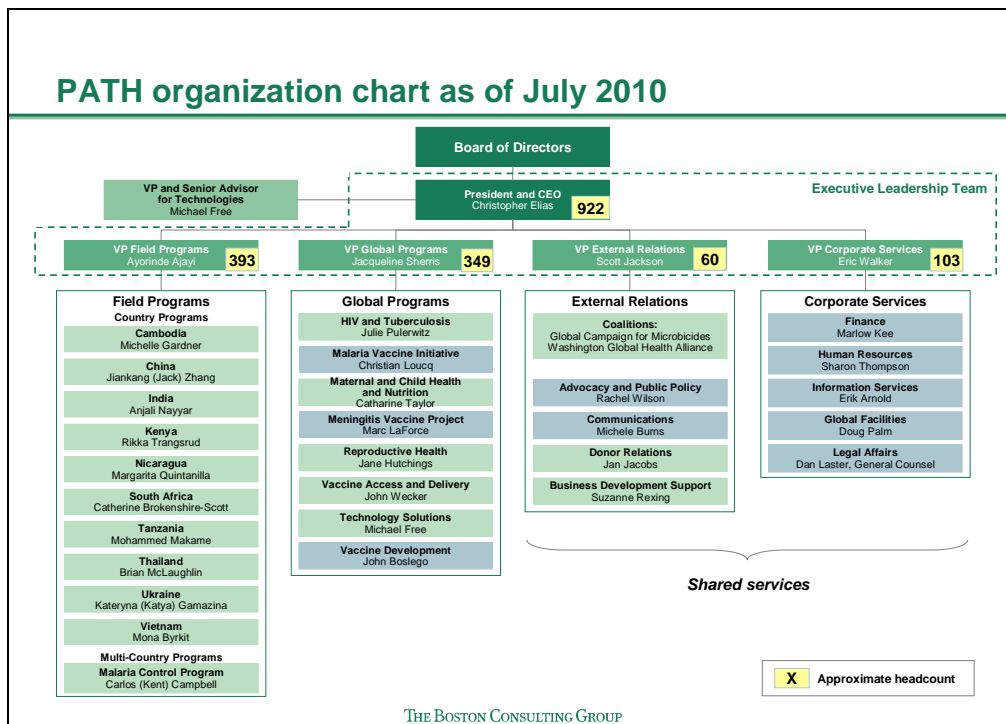
The Bill & Melinda Gates Foundation engaged The Boston Consulting Group (BCG) to complete an external evaluation of the vaccine development programs at PATH. PATH is an international non-profit organization founded in 1977 that “creates sustainable, culturally relevant solutions, enabling communities worldwide to break longstanding cycles of poor health”. Over the past decade, PATH has expanded to include three vaccine development programs funded by the Gates Foundation and other donors: the Vaccine Development Program (PATH-VAC), the Malaria Vaccine Initiative (MVI), and the Meningitis Vaccine Project (MVP). This evaluation was primarily focused on those three programs, including both an evaluation of the organizational processes within the individual programs and an examination of the mechanisms by which the broader PATH organization is leveraged to support their activities.

Within the landscape of product development partnerships (PDPs), PATH is unique in that it:

- Addresses a broad range of disease areas and technologies
- Manages multiple distinct product development programs, i.e. MVI, MVP, and the four groups within PATH-VAC (Enteric Vaccine Initiative, Advancing Rotavirus Vaccine, Pneumococcal Vaccine Project, and Influenza Vaccine Project)
- Has demonstrated efforts to achieve scale efficiency and cross-learning across programs

Against this backdrop, BCG was tasked with assessing drivers of performance at PATH and identifying best practices that could apply for the broader PDP community. This evaluation was therefore focused on how vaccine product development is executed and supported at PATH; it does not address the quality, depth or breadth of the vaccine product portfolios at PATH.

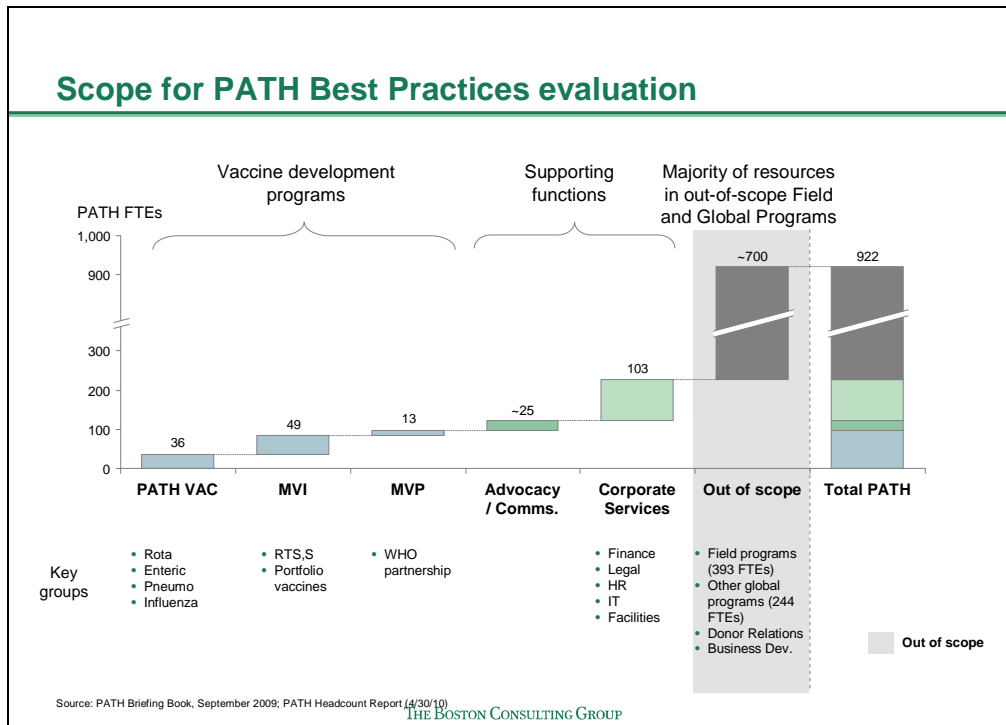
Figure 1: PATH organization chart



As of July 2010, PATH operated 8 Global Programs and 11 Field Programs, all supported by shared Corporate Services and External Relations groups.

The three vaccine product development programs, MVI, MVP and PATH-VAC, were in-scope for this evaluation. Additionally, the corresponding support received from PATH’s Corporate Services functions (Human Relations, Finance, Legal, Information Services, and Facilities) and select External Relations functions that directly contribute to product development efforts (Advocacy and Communications) were also in-scope. We did not analyze PATH’s other Global programs (e.g. Technology Solutions, Vaccines Access and Delivery, etc.) nor the Field Programs in depth, though we did consider synergies across programs. It is important to recognize that, as of the time of the assessment, the in-scope programs and functions, as shown in Figure 2 below, accounted for approximately 225 of PATH’s 900+ global staff and \$108M of its \$257M 2009 budget.

Figure 2: In scope programs and functions for evaluation

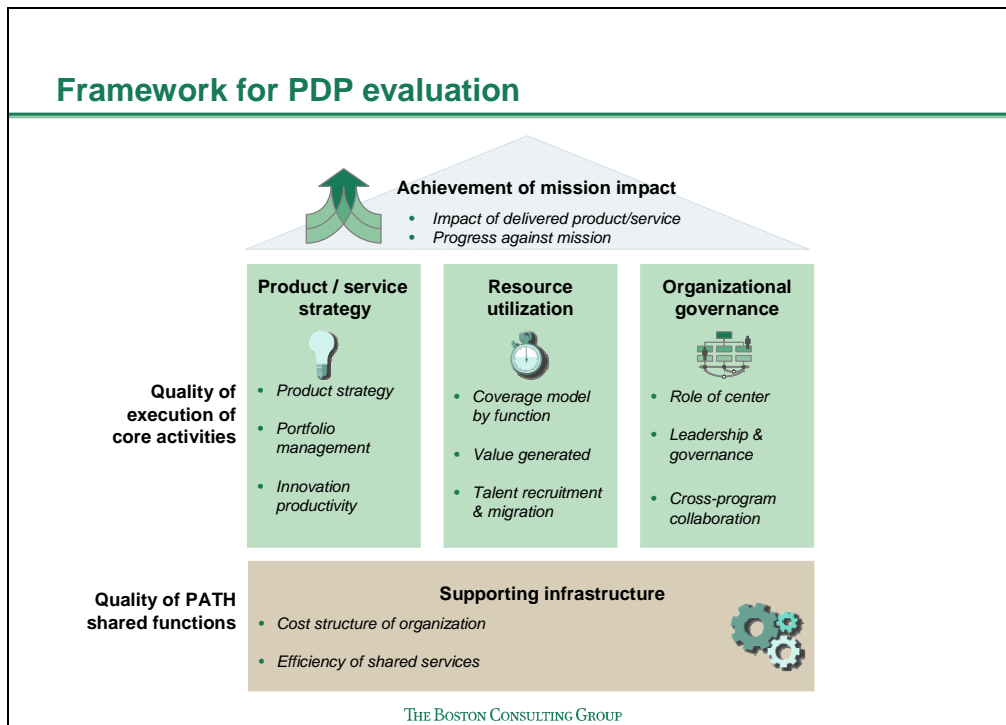


2. METHODOLOGY

The BCG team included deep experience in global health, pharmaceutical R&D, and organizational design. Building on our extensive work with PDPs over the past decade, we integrated relevant elements from previous PDP evaluations (including those performed by other organizations) with BCG’s expertise in evaluating organizational effectiveness and efficiency to develop a comprehensive framework for PDP evaluation. Our hope is that this unique methodology will serve as a reference point to be customized for future PDP evaluations. As shown in Figure 3, we evaluated PATH’s performance along five key dimensions:

- Achievement of mission and impact
- Product/service strategy
- Resource utilization
- Organizational governance
- Supporting infrastructure

Figure 3: BCG’s comprehensive framework for PDP evaluations



In completing the assessment, we interviewed more than 50 stakeholders across PATH, including the entire executive leadership team (ELT) as well as staff from Corporate Services, External Relations, PATH-VAC, MVI, MVP, and Vaccines Access and Delivery groups. We also spoke with several of PATH’s product development partners and two Board members. Please see Appendix A for a full review of our interviewees. We followed the process below.

Step 1: conducted individual program evaluations

Key Activities

- Completed one-on-one interviews with key personnel of MVP, MVI, PATH-VAC and foundation program officers leading the relationship with these respective programs
- Collected and analyzed quantitative information (including historical and projected uses of funds, FTE allocation, clinical program, product development timelines, etc.)
- Developed a deep understanding of the decision making processes and portfolio management approaches within the vaccine development programs
- Completed outside review of academic and industry literature on key success factors for product development organizations
- Leveraged information and insights from previously completed PDP evaluations
- Identified primary drivers of strong and weak performance and compared across the individual PATH programs as well as other, non-PATH PDPs

Step 2: conducted assessment of PATH as a “host” for the PDPs***Key Activities:***

- Completed one-on-one interviews with the PATH ELT and key personnel of Corporate Services (Information Services, Finance, Legal, and Human Relations) and External Relations (Advocacy, Communications)
 - Specific focus on individuals who have responsibility for and/or the best visibility to the interactions between the PATH center/leadership and the product development programs
- Evaluated the role of PATH’s center (using BCG’s “Role of the Center” toolkit) to characterize and assess the contribution of the PATH’s executive leadership team and central functions
- Mapped the processes and engagement points between the center and individual vaccine development programs
- Identified the areas of value contribution and value drain from the center functions
- Leveraged BCG’s proprietary data to benchmark resource staffing levels and efficiency
- Collected and analyzed quantitative information
 - Including historical and projected uses of funds, FTE allocation, etc

Step 3: synthesized individual evaluations, developed implications and recommendations***Key Activities***

- Synthesized key recommendations from individual vaccine development programs and PATH center evaluations into one combined set of recommendations
- Conducted follow-up interviews to test emerging findings, results, and recommendations with PATH leadership and foundation representatives

3. OVERVIEW OF FINDINGS

Based on our assessment, we determined that PATH-VAC, MVI and MVP are highly-functioning programs with robust internal processes. Further, the broader PATH organization effectively supports vaccine development programs, providing strong leadership and cost-efficient back-office support functions. Specifically, we identified six core strengths at PATH (discussed in more detail in section 4):

- Engagement of external stakeholders
- Decision-making processes that are supported by appropriate analytical tools
- Talent acquisition and retention
- Resource-sharing and collaboration within and across the programs
- Leadership
- Cost efficiency

As PATH continues to grow and evolve, we believe that it could improve by focusing on, and building upon, these core strengths. We recommend that PATH consider five specific items (discussed in more detail in section 5):

- Increased biopharma representation on scientific advisory groups
- Adoption and standardization of best-practice access/delivery analyses
- Expanded collaboration mechanisms
- Centralized knowledge management systems
- Reduced lag between organizational growth and back-office support capacity

Our analysis can be summarized into six key topic areas: decision stakeholders, portfolio management process, talent acquisition, resource sharing and collaboration, the role of center, and cost efficiency. We will consider the supporting analysis for each in turn.

3.1. Decision stakeholders

Through a series of interviews with PATH staff, we analyzed how decisions regarding the vaccine development portfolios are made at PATH.

Our stakeholder analysis had two aims: to identify the internal and external stakeholders that contribute to portfolio decisions, and to describe how the stakeholders interact. As shown below, we found that the portfolio decision processes at PATH-VAC and MVI are roughly similar: project leaders drive portfolio decisions while incorporating input from multiple internal and external stakeholders.

Figure 4: Comparison of decision stakeholders

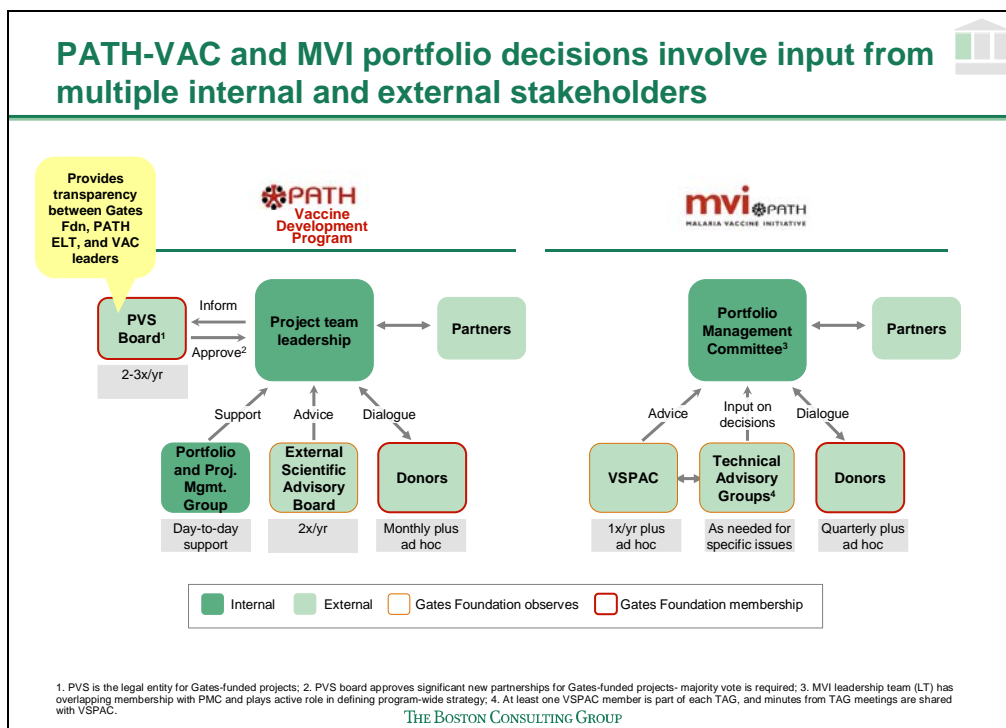
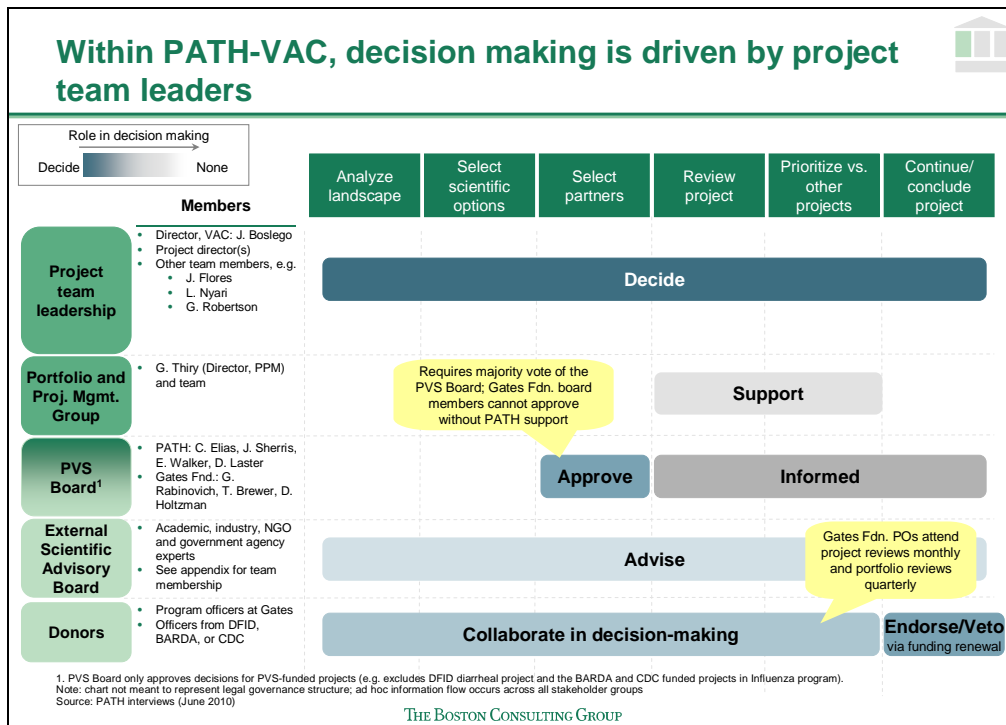


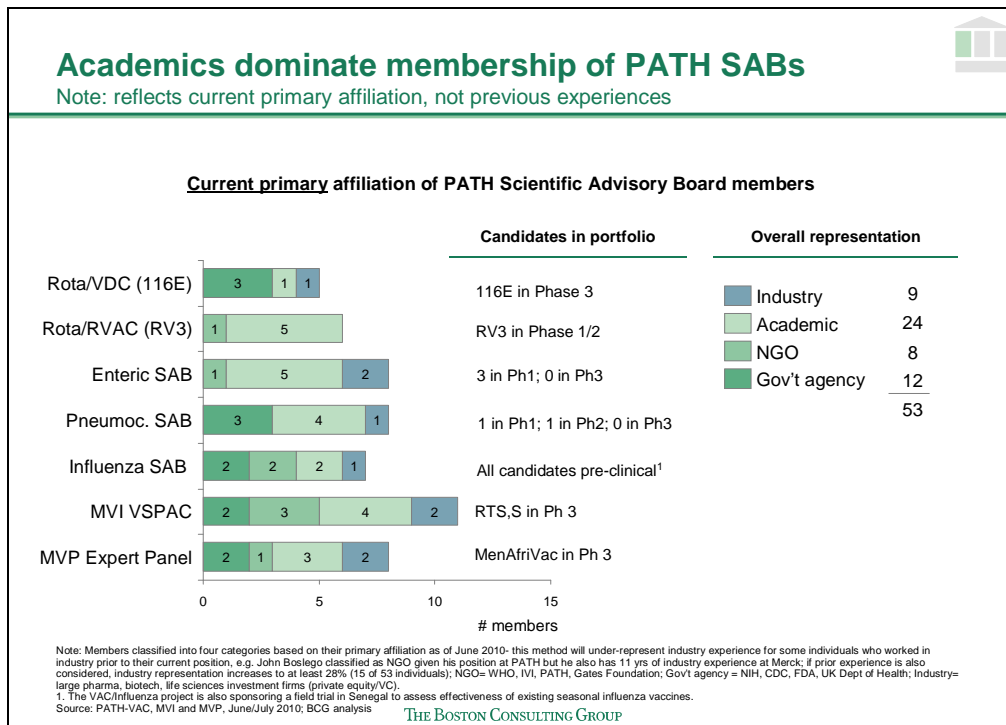
Figure 5: PATH-VAC decision making process example



The external scientific advisory boards (SABs) are an important input into decision making at PATH-VAC, MVI, and MVP. By all accounts, these SABs include committed members with diverse expertise in vaccine R&D and consistently provide valuable advice that informs project decisions and portfolio prioritization.

We examined the current primary affiliations of the membership of these advisory groups, observing that the greatest proportion of members are from academia and government agencies such as NIH and CDC with a smaller proportion of members currently employed in the biopharma industry. It should be noted that this analysis was based on current, primary affiliations and therefore under-represents the extent of industry input due to prior experiences of some SAB members. As the programs evolve their committee membership over time, we believe it will be increasingly valuable to increase representation from the biopharma industry for additional product development and commercial perspectives.

Figure 6: PATH advisory group composition



In the case of PATH-VAC, each of the four projects maintains separate SABs that provide advice on all types of decisions. These SABs typically meet twice annually, with additional meetings scheduled ad hoc for specific, critical decisions. For MVI, the Vaccine Science Portfolio Advisory Council (VSPAC) is a standing body that provides general advice to MVI on portfolio management and strategy. It is particularly important that board members commit to participate over an extended period of time and develop continuity with PATH and its portfolio of projects – as do those in the VAC SABs and MVI VSPAC. This allows members to provide more value-added and beneficial advice.

Additionally, MVI convenes Technical Advisory Groups (TAGs) on a one-time basis to advise on specific decisions (e.g. new projects, phase transitions). TAGs are composed of experts selected specifically for their knowledge of the decision at hand, with at least one VSPAC member on each TAG to ensure coordination. Our stakeholder interviews universally echoed the belief that the TAGs are a highly effective mechanism to optimize portfolio decision making at PATH.

One notable difference between PATH-VAC and MVI is the presence of the PVS Board for PATH-VAC. PATH Vaccine Solutions (PVS) is a separate 501(c)(3) organization that supports PATH-VAC projects with funding from the Gates Foundation. The PVS Board comprises four members from PATH and three members from the Gates Foundation, and it approves all significant new partnerships for Gates-funded projects. Beyond these specific decision rights, the PVS Board also serves as a valuable communication vehicle by promoting transparency and alignment between PATH and Gates Foundation leaders.

Donors play an active, collaborative role in decision-making, providing input on significant decisions including initiation of new projects, partner selection, and project review and prioritization. Via the grant initiation or renewal process, donors endorse or veto decisions to continue or conclude projects.

3.2. Portfolio management process

As an extension of our stakeholder analysis, we next examined how several recent portfolio decisions were made at PATH-VAC and MVI. These representative examples of decisions revealed that PATH brings a

methodical and thoughtful approach to project governance – making data-driven decisions supported by input from a diverse group of stakeholders.

We also investigated the specific tools used to support portfolio decisions at PATH. For this analysis, we used a series of expert interviews and BCG experience to develop a database of portfolio management processes at six major biopharma companies and one non-PATH PDP. This database was then used to benchmark the portfolio management process at the PATH PDPs. We found that PATH PDPs, like leading biopharma companies, use tools such as target product profiles and go/no-go decision criteria to support portfolio decisions.

One key distinction between the PDPs and biopharma companies is related to how the economics of candidates, especially late-stage products, are evaluated. Biopharma companies, true to their commercial missions, rely heavily on quantitative metrics such as expected net present value (eNPV) to assess and prioritize candidates. PDPs, on the other hand, consistent with their global health missions, tend to focus economic analyses on the anticipated supply/demand dynamics and public health impact.

Figure 7: Comparison of portfolio management process

Portfolio prioritization at PATH PDPs is comparable to biopharma industry

| | 1 Target product profiles <i>Product characteristics required to meet pt. needs</i> | 2 Go/no-go decision points <i>Predefined stage-gate criteria</i> | 3 Early stage prioritization <i>Ranking of early-stage candidates</i> | 4 Product economic evaluation <i>Quantitative metrics, e.g., product economics, eNPV, TAM, etc.</i> | 5 Global access evaluation <i>Multi-factor assessment to ensure developing world access including IP cost</i> |
|----------------------|-----------------------------------------------------------------------------------------------|----------------------------------------------------------------------------|---------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|
| | ✓ | ✓ | Periodic qualitative assessment | Ad hoc economic driver and cost profile analyses | ✓ |
| | ✓ | ✓ | Annual internal and external reviews (PMC and VSPAC) | Demand forecasting; modeling of public health impact | ✓ |
| | ✓ | ✓ | n/a | Modeling of public health impact (\$DALY) | ✓ |
| Non-PATH PDP | ✓ | ✓ | Annual external review | Qualitative assessment | ✓ |
| Large pharma | ✓ | ✓ | Qualitative 4-parameter framework | eNPV, efficiency frontier | ✓ |
| Large biotech | ✓ | ✓ | Go/no-go decisions made on rolling basis | eNPV, scenario analyses | ✗ |
| Medium pharma | ✓ | ✓ | eNPV | eNPV | ✗ |

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As the final component of our analysis of PATH PDP governance, we conducted a small number of in-depth interviews with leaders at PATH’s biopharma partners to learn how PATH programs interact with them. Our interviews demonstrated that PATH vaccine development programs take an active, “hands-on” approach to co-managing projects with their biopharma partners. These partner interactions typically consist of structured decision mechanisms such as periodic face-to-face committee meetings and regular teleconferences for project coordination. Although the frequency of interaction with PATH PDP staff can create a reporting burden at times, interviewees nevertheless rated the experience positively due in large part to the practical, product-oriented and transparent nature of the interactions.

3.3. Talent acquisition

During our assessment of PATH, leadership was consistently raised as a key success factor for product development at PATH. PATH staff, Gates foundation program officers, and biopharma partners all consistently rated the leadership of John Boslego (VAC), Christian Loucq (MVI), and Marc LaForce (MVP) as

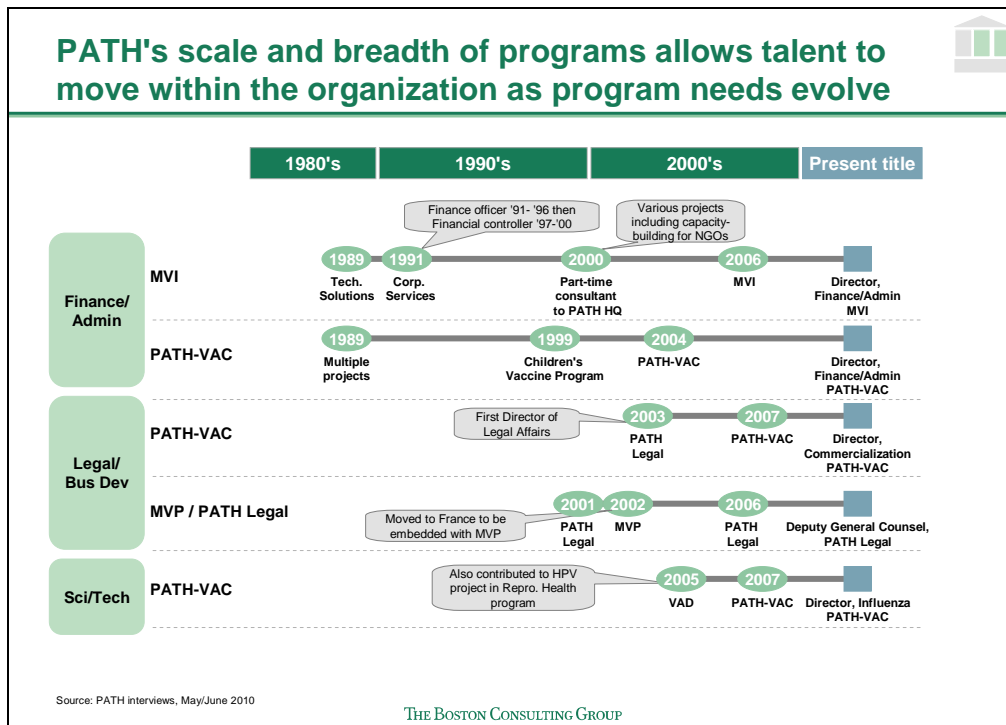
strong, engaged and highly effective. Additionally, the PATH ELT was characterized as adding tremendous value to the PDPs.

Within the PATH organization, we reviewed the background and experience of select talent across not only the ELT, but also the key staff within the different in-scope programs (scientific, technical, commercialization/legal). Of 32 people included in our high-level analysis, 18 had worked in the biopharma industry (9 of whom had experience in one of the top big pharma companies) prior to PATH, combining for approximately 200 years of biopharma experience.

Talent recruitment and retention is a clear driver of success at PATH. First, PATH’s scale assists in the recruitment of talent with deep experience, both because some candidates are more comfortable joining an established and stable organization and because larger scopes of responsibility are more attractive to senior leaders. One specific example comes from the recruitment of a key vaccine program leader. Because PATH could provide an opportunity with multiple disease-area-focused projects, it was able to bring in someone with over 30 years of vaccine development experience including 10 years at a leading pharmaceutical company.

Second, the scale and breadth of programs at PATH allows for talent retention. As the needs of PATH programs evolve, staff members can be rotated between programs. Shown below are the career paths of five staff members, including two people who have been at PATH for over 20 years. This migration of talent would not be possible at small stand-alone programs and allows PATH to accumulate organizational, global health and product development knowledge, a crucial asset enabling effective product development.

Figure 8: Talent migration at PATH



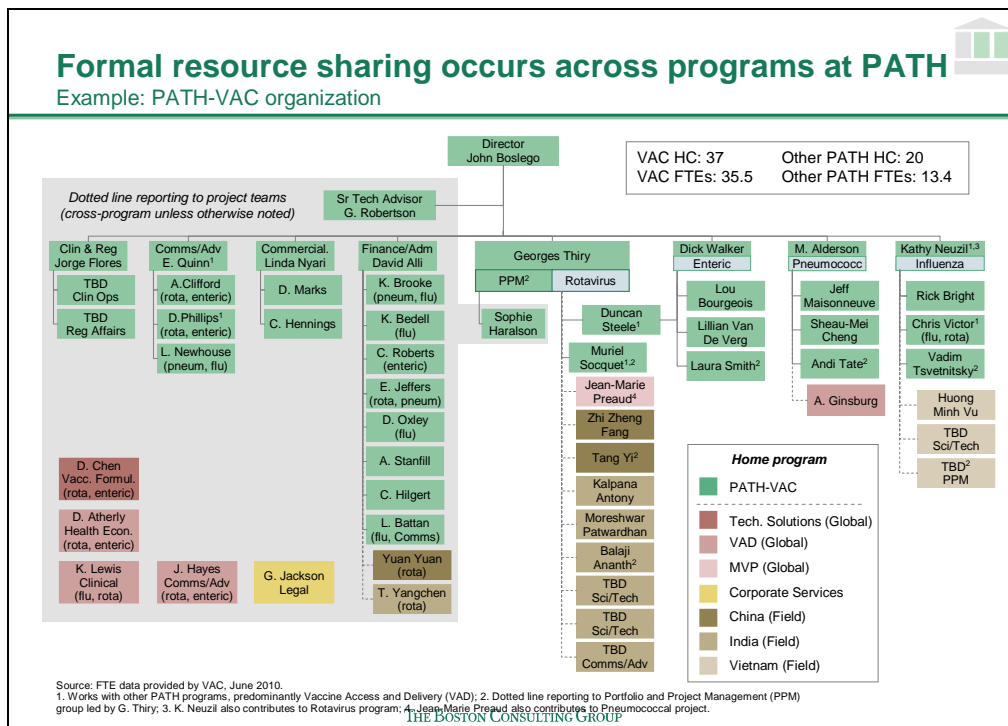
3.4. Resource sharing and collaboration

A key benefit of PATH’s scale is the ability to share resources across programs, projects, and initiatives. Although each employee at PATH is assigned to a designated “home program”, many individual staff members contribute to more than one global or field program. This cross-program sharing is administered via formal level-of-effort (LOE) quantitation (e.g. 60% effort for program A and 40% effort for program B), and salaries are allocated to programmatic budgets accordingly. For global programs, this system enables sharing

of specific types of functional expertise (e.g. vaccine formulation), and is especially useful for instances where programmatic needs do not justify a dedicated full-time equivalent. Additionally, the field programs at PATH support the mission of the global programs by providing in-country support for hiring and administering full-time or part-time employees to support the global programs. This resource sharing model allows PATH to improve the leverage it gets from each individual employee, as well as share experience much more broadly across the organization.

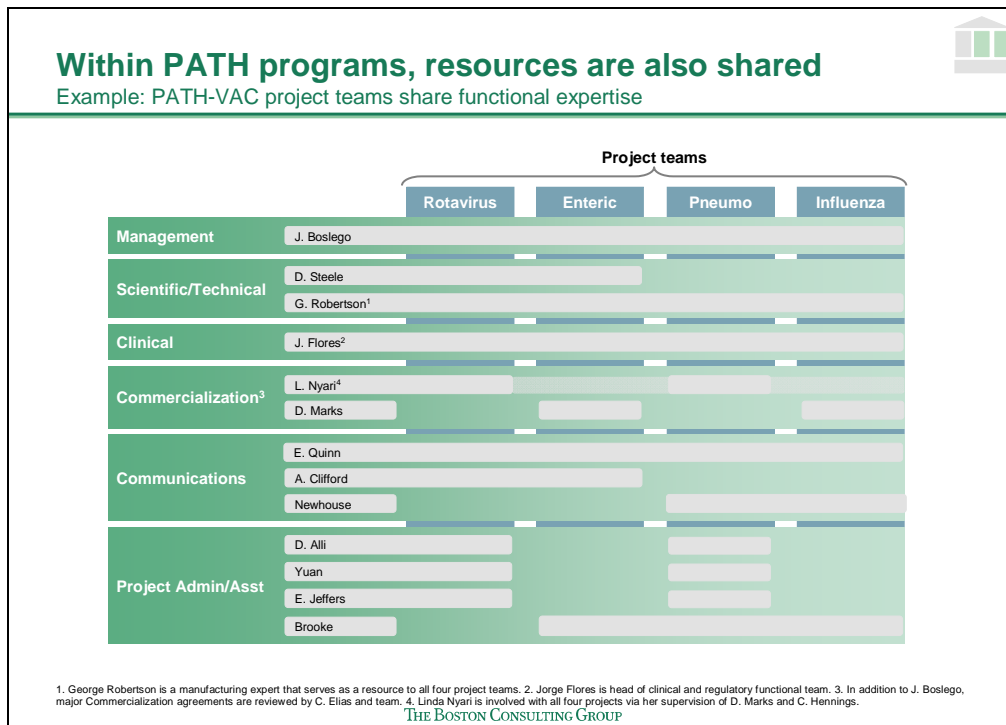
An example of this LOE-based sharing is demonstrated below for the PATH-VAC program which “imports” full- and part-time effort from multiple global and field programs, and “exports” expertise to other PATH programs, most notably the Vaccine Access and Delivery (VAD) program.

Figure 9: PATH-VAC staffing model



In addition to cross-program sharing, staff effort is also shared between projects within individual programs. This intra-program LOE sharing is well-demonstrated within the PATH-VAC organizational matrix, with staff from multiple functional teams supporting two or more project teams.

Figure 10: Resource sharing across PATH-VAC projects



Beyond LOE-based resource-sharing, we identified several formal and informal mechanisms that promote collaboration at PATH. Examples include:

- Monthly coordination calls between colleagues from PATH Legal Affairs and the Commercialization staff embedded in the PDPs
- Annual two-week-long meeting for all global and field program leaders
- Regular coordination calls for project administrators from MVI, MVP and PATH-VAC
- VP of Global Programs and VP of Field Programs review all new funding requests and approve the resourcing model across Global and Field programs

Together, these mechanisms serve to increase PATH’s effectiveness. Each individual employee can create a much greater impact by sharing expertise across programs and functions and by trading best practices to address different issues. In many cases, and especially for licensing and partnership agreements, collaboration occurs more freely because the collaborating programs are all part of PATH, eliminating concerns regarding partner confidentiality. One example of the impact from inter-program collaboration comes from an interaction between PATH-VAC and MVI. Because MVI was aware that the pneumococcal project in PATH-VAC was negotiating with a partner to perform pre-clinical product stability testing, MVI was able to secure an amendment to the agreement to include a malaria vaccine candidate for analysis. This type of benefit is simply not available to smaller product development organizations. As PATH continues to grow and mature as an organization, it will be important to consider mechanisms to expand their scale advantage into areas such as vaccine manufacturing and clinical trials.

3.5. Role of Center

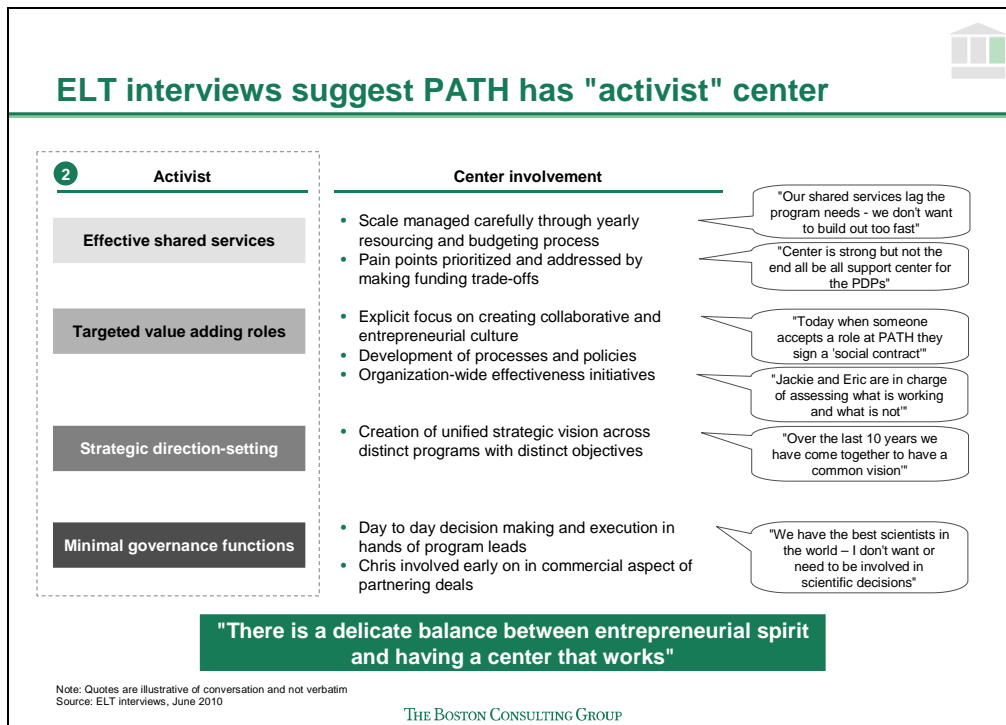
In analyzing the support the broader PATH organization provides to the vaccine focused PDPs, BCG deployed its unique “Role of Center” assessment toolkit. The selection and empowerment of center functions involve a set of strategic choices, which directly impact the mission critical activities of the programs. In this assessment, BCG investigates these strategic choices including the level of authority, its coordinating role, the location of shared services, reporting structures, etc.

We believe that PATH has developed an active Role of Center which engages on critical topics but also provides sufficient flexibility and freedom to the individual vaccine PDPs. PATH’s ELT plays an effective role in fostering entrepreneurship without allowing centripetal forces to drive the organization apart. It sets the overall strategic vision for the organization, establishes a minimal yet effective governance system, actively assesses and addresses support services “pain points” felt by the programs, and drives central initiatives aimed at promoting cross-program and cross-functional collaboration and synergies . The ELT plays a limited role in the day-to-day activities of each PDP; decision making is mostly left to the programs. The ELT focuses on developing efficient, value-adding services and creating an environment of ongoing learning and evolution.

One explicit role retained in the center is assessing and ultimately approving all major new partnerships. PATH’s ELT has developed a tremendous body of experience in structuring deals and evaluating tradeoffs. Given the importance of partnerships to PATH’s product development model, the center plays an active and early role in structuring new deals. This engagement serves to improve PATH’s negotiating position, optimize terms, and improve decision making.

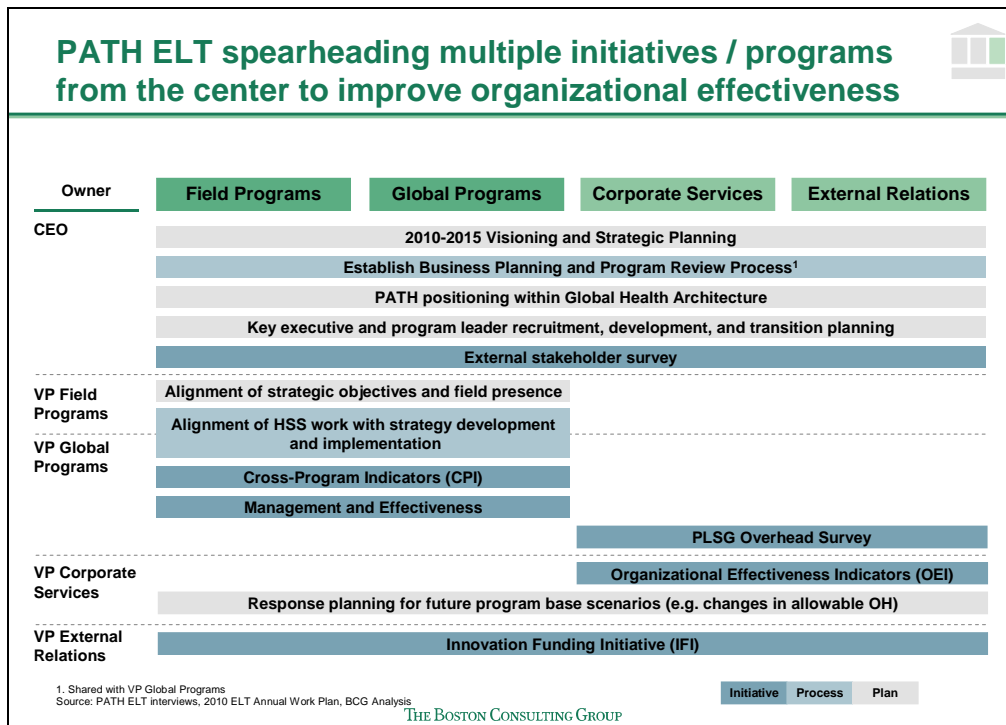
The ELT’s role has been thoughtfully chosen and cultivated over time in order to ensure that programs retain ownership and accountability to deliver on their unique missions. At the same time, PATH ELT has gradually set norms around a “social contract” that ties PATH employees together – with its culture of collaboration, openness, and transparency.

Figure 11: PATH “Role of Center” summary



One additional noteworthy contribution of PATH’s center is the development and management of cross-organizational initiatives, processes, and plans (see Figure 12). The high volume of initiatives that the ELT is driving at present is a direct response to PATH’s recent growth and is focused not only on cross-organizational strategic plans but also cross-program and cross-functional coordination. At present, the workload necessitated by these initiatives is not detrimental to product development at PATH; however, the ELT has agreed that it must remain cognizant of a potential “process/initiative” overload that can detract from the core mission.

Figure 12: Center ELT initiatives



Finally, as mentioned above, one key focus of PATH’s center is to optimize support services across the Global and Field Programs. To assess satisfaction with central shared services, the Program Leaders and Strategy Group (PLSG) conducts a yearly survey of Global and Field Program directors that is focused on measuring both the impact and quality of shared services support. Responsiveness to internal feedback is clearly one of PATH’s strengths. For example, 2009 feedback highlighted an opportunity to significantly improve Finance and HR systems, both of which were addressed as the strategic investments in 2010.

3.6. Cost efficiency

In 2009, PATH expenses were \$257M, of which \$108M were driven by the three vaccine product development programs. PATH’s spend can be segmented into two major buckets:

- Program base: spend on program related activities only, of which a portion is allocated to fund central support functions
- Above base: spend which primarily passes through the organization to sub-grantees

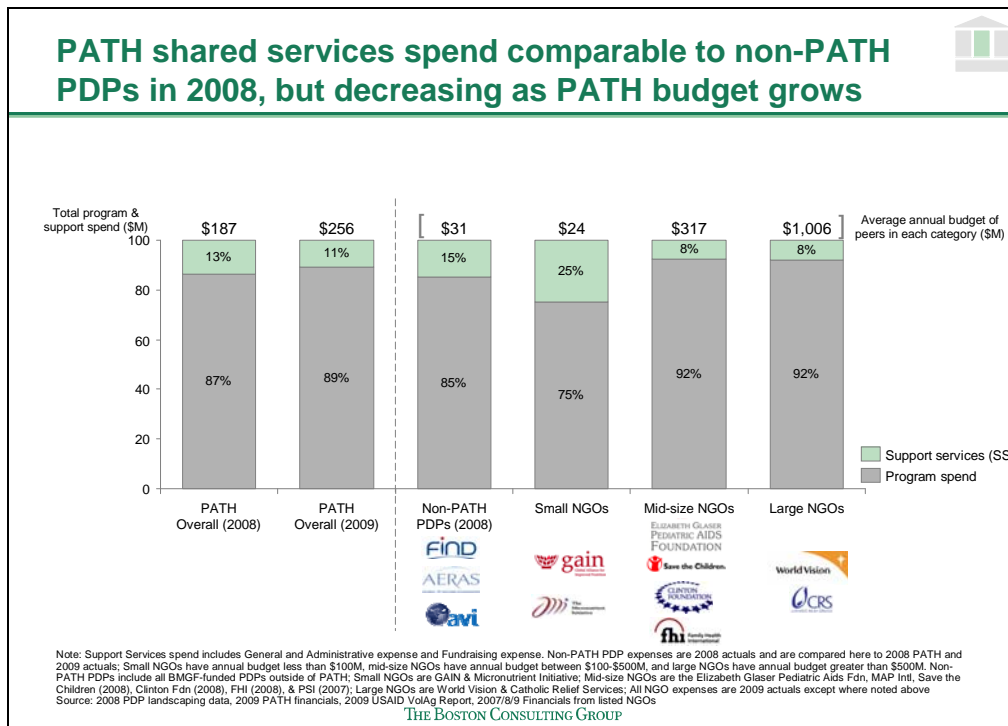
Given the nature of their operating model, the vaccine development programs have a larger portion of spend allocated to “above base” than other parts of PATH. A majority of funds (~80% of total spend) passes through the vaccine development programs to sub-grantees. This is consistent with the operating model of leveraging partners to implement many of the relevant development activities.

In order to understand the efficiency of the spending of these funds, we initiated a benchmarking exercise. One caveat to note: there are no perfect benchmarks for PATH. Given the diverse nature of its activities, PATH has no direct parallel. Against that backdrop, we examined representative analogs (NGOs and PDPs) and benchmarked at the functional level (HR, IT, Finance, Legal) to triangulate on the cost efficiency question.

As noted in the figure below, PATH’s spend on support services as a percentage of operating expenses rests in line with other medium and large sized NGOs (such as FHI, Save the Children, Clinton Foundation). It should

be noted, that due to inconsistencies in accounting across NGOs, the numbers shown in the figure below should be interpreted as approximations rather than absolutes.

Figure 13: Shared services spend benchmarking

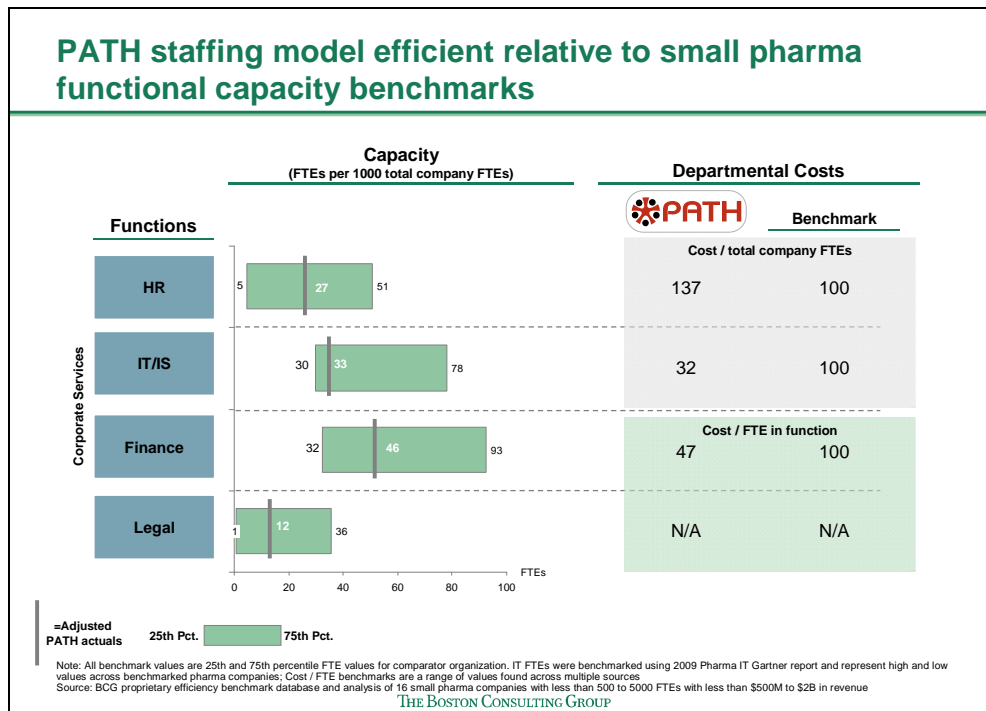


Digging deeper, we benchmarked individual functions within PATH’s corporate services at a granular level – both the capacity (e.g. number of FTEs) and the cost (spend per FTE). To do so, we leveraged BCG’s proprietary data sources on resource capacity levels and costs; data sources developed over hundreds of public and private sector engagements.

Our analysis demonstrates PATH’s leanness compared to benchmark (see figure). PATH’s HR, Finance, and Legal support are well in line with BCG capacity benchmarks (meaning functional FTES per 1000 total FTES) and IT was closer to the 25th percentile of biopharma comparators. On the departmental cost side, PATH is leaner than industry comparators in both IT and Finance.

As with all benchmark data, this information should be viewed as guideposts. Our data sets skew heavily towards private sector clients in the biopharma industry, which will likely invest more heavily in IT systems and pay higher wages. In addition, staffing and accounting differences across organizations make direct comparisons difficult. Regardless, there is clear consistency in which PATH exceeds benchmarks on the cost and capacity dimensions.

Figure 14: Corporate Services efficiency benchmarks

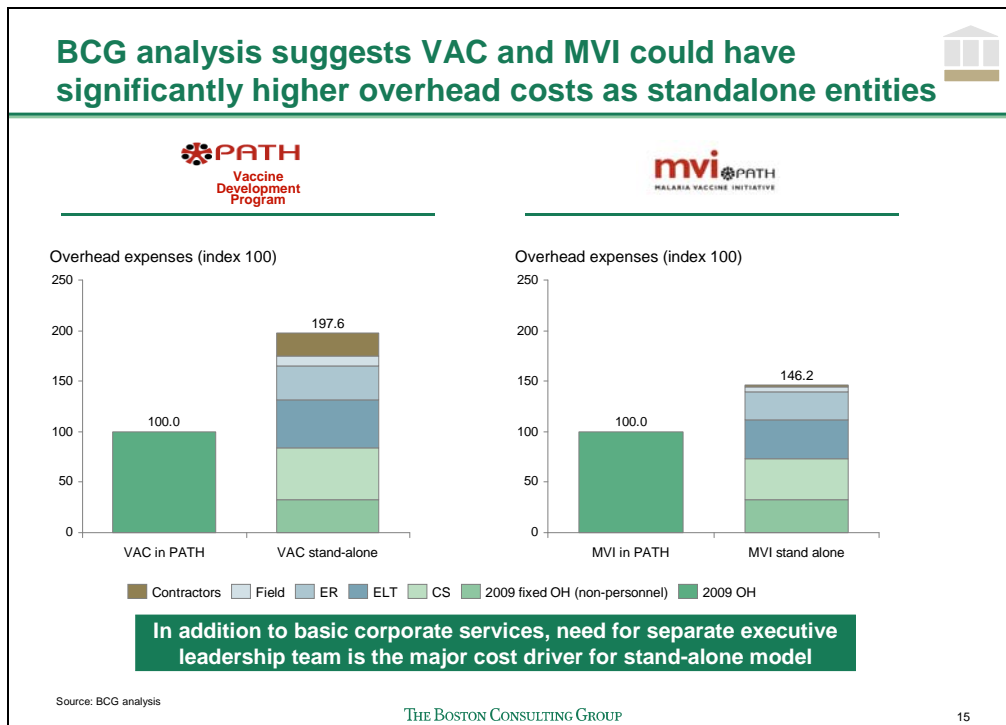


To further test our hypothesis that PATH managed the central functions in a lean fashion, we initiated a scenario analysis. The goal of this exercise was to address the hypothetical question, "If PATH-VAC and MVI were stand-alone entities rather than programs within PATH, how would their overhead costs change?"

Building on HR cost data and a set of staffing assumptions, we estimated that, as stand-alone entities, MVI's overhead costs would increase by approximately 50% and PATH-VAC's overhead would nearly double. Two factors were primarily responsible for driving the overhead cost increase: the need for additional staff in back-office functions (e.g. Finance) and the need for an additional senior management team (e.g. Chief Finance Officer). These data are illustrative of the cost benefit from PATH's scale; because PATH-VAC, MVI and other programs share the Corporate Services functions and the PATH ELT, overhead costs are reduced.

It would certainly be possible to manage PATH VAC and MVI as standalone entities without increasing the overhead costs by this significant degree. However, to do so comes with compromises. The breadth and depth of experience of senior management and the service levels provided by the support functions would not be nearly as comprehensive.

Figure 15: Scenario analysis of PATH-VAC and MVI overhead costs



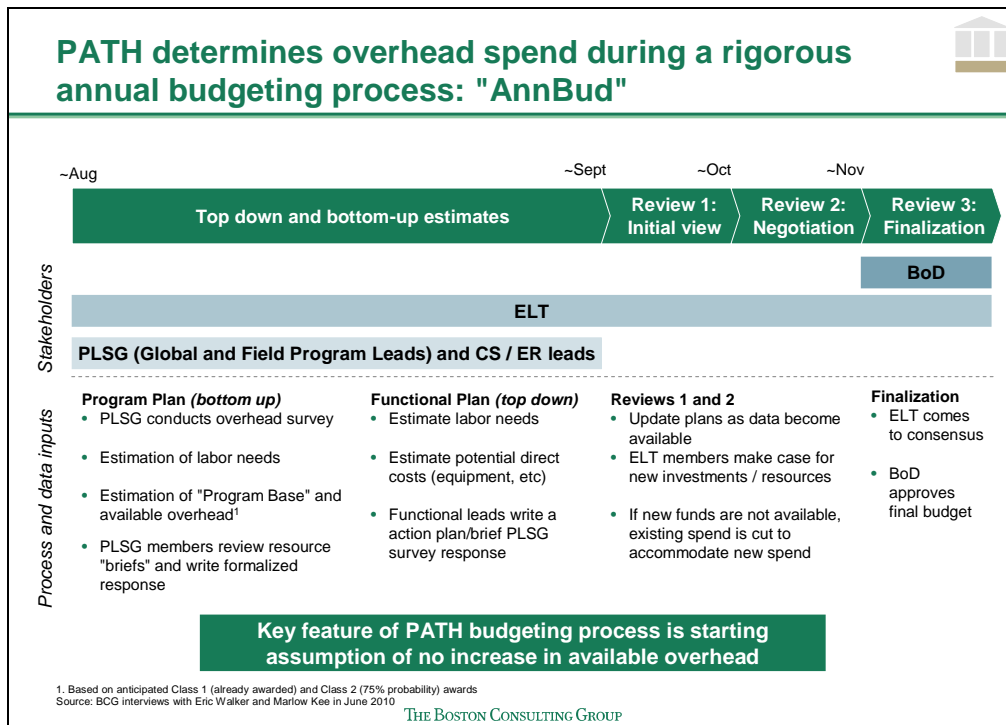
As a complement to this benchmarking and scenario analysis, we examined the process by which budgets are created and agreed upon. This assessment of the annual overhead budgeting process led to a greater understanding of how PATH determines the optimal allocation of funds.

A key feature of PATH’s Annual Budgeting (“AnnBud”) process is the starting assumption that no additional overhead spend will be available for new projects. This mentality is critical in keeping PATH a lean organization. An additional clear best practice in PATH’s budgeting process is the development of both bottom up and top down budget estimates which are developed by the Program Leads and central function leads (called the Corporate Services and External Relations leads respectively e.g. CS and ER leads). Both estimates are reconciled through two ELT reviews during which existing spend is often cut to make room for new programs or initiatives deemed higher priority. The budget must then be approved by consensus and is subsequently approved by the Board of Directors.

Relative to other organizations we have seen as well as compared to BCG best practices in the design of annual budgeting processes, we believe that the AnnBud process is both an effective tool in gathering the requirements of the organization and also a key motivating factor in PATH’s ability to maintain low expenses.

For reference, below are the key steps of this budget process.

Figure 16: Annual overhead budgeting process



Overall, our analyses of PATH’s total spend and departmental costs and capacity suggests that PATH is lean relative to other global health NGOs in terms of support services overhead and lean in comparison to biopharma comparators in terms of departmental costs. This leanness is the explicit intent of PATH’s ELT.

As discussed below, some pain points result from “over leanness”. For example, in the 2009 survey of program leaders, Finance, HR and IT were identified as pain points, with insufficient support levels provided to the global and field programs. The ELT initiated an internal review and determined that inadequate investments had been made in these areas, particularly on IT systems support which affect Finance. Going forward, we recommend PATH explore new ways to reduce these pain points that have resulted from maintaining a lean cost structure during rapid growth.

4. PATH STRENGTHS

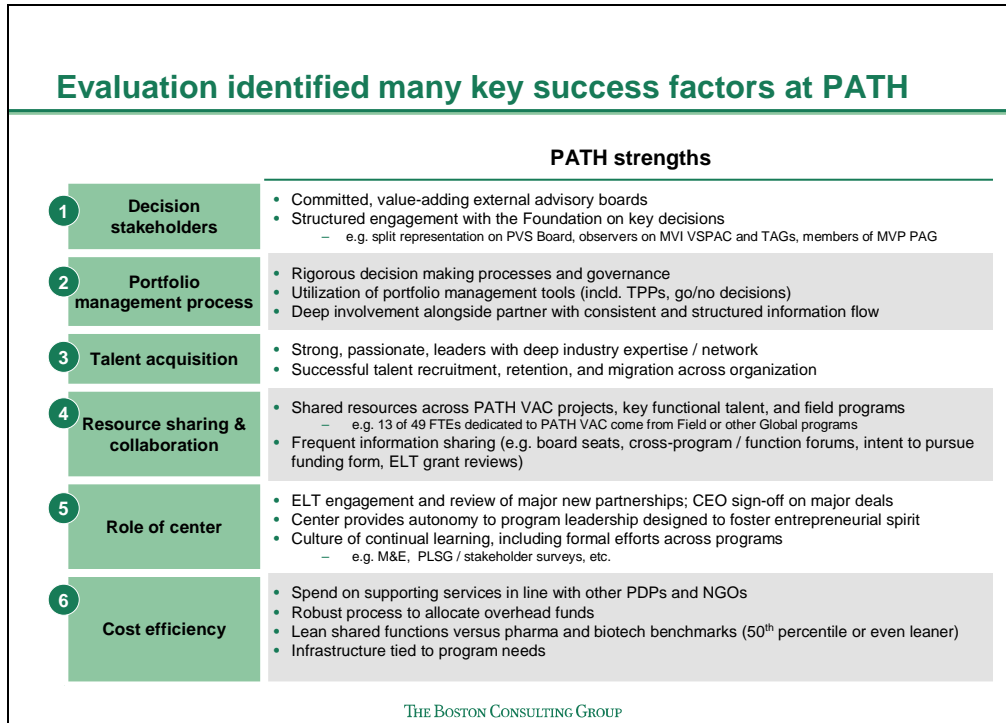
Overall, BCG’s analysis shows PATH to be a highly functioning and introspective organization that continues to aspire to greater impact and efficiency.

PATH’s product development process is supported by a rich set of outside advisors, clear decision making processes, and robust analytical tools. In addition, the product development efforts benefit deeply from the high calibre of talent at PATH, due in no small part to the stability and attractiveness of PATH’s mature organization, and the ability to share resources across projects and leverage PATH’s global network of expertise.

In addition, the product development programs at PATH are supported by the PATH executive leadership team and central shared functions. The ELT has succeeded in fostering an entrepreneurial spirit and drive through a program-led but centrally supported organization. The centralized back office functions serve to improve efficiency and create leverage for the programs.

Below is the summary of the best practices that we identified at PATH across all dimensions of the assessment.

Figure 17: Summary of PATH strengths



5. OPPORTUNITIES FOR PATH

We identified five areas for potential improvement at PATH:

1. Increase biopharma industry representation on scientific advisory groups

Although academic, NGO and government agency backgrounds provide relevant vaccine R&D expertise, we believe that commercial and pharmaceutical development perspectives are especially valuable for product development organizations. As shown above, based solely on current affiliations, biopharma industry representation on the PATH vaccine development SABs is less than 20%. Although this clearly under-represents the extent of industry input due to prior experience, we nevertheless believe that PATH programs would benefit from increasing the proportion of members actively engaged in product development on their SABs, provided that conflicts of interest can be appropriately managed.

2. Develop standardized access/delivery analyses to support portfolio prioritization and decision-making within individual product development programs

In the current model, analyses of market access, uptake and delivery are conducted ad hoc by the individual vaccine development programs at PATH. Moreover, significant variability exists within and across PATH vaccine development programs in depth and quality of these analyses. In the same way that standardized frameworks are helpful in supporting scientific decisions about product portfolios, we believe that implementing rigorous access/delivery frameworks that are standardized and represent the best-in-class from across PATH will be helpful for integrating commercial considerations into portfolio decisions. These frameworks would include factors such as modelling of cost effectiveness, impact, and projected cost of goods over the product lifecycle; anticipated acceptability among target users; and physical delivery considerations such as delivery channel capacity and cold chain requirements.

3. Continue to expand mechanisms, whenever cost effective and feasible, for collaboration between programs

As outlined above, one of PATH's greatest strengths is the depth and breadth of its activities, facilitating collaboration and expertise sharing across programs. We believe that PATH should continue to seek ways to exploit this scale advantage. As the organization continues to grow, adjustments to the organization such as organizational matrices, shared function and service center models should be considered for areas such as Regulatory and Commercialization. Additionally, cross-program contracting and/or preferred vendor relationships could be explored for certain activities such as the execution of clinical trials and/or vaccine manufacturing. Lastly, co-location of specific functional expertise should be considered to foster cross-fertilization across programs.

4. Build knowledge management systems to support expertise-sharing across the organization

A number of mechanisms, both formal and informal, currently exist at PATH for expertise-sharing. We believe that PATH could bolster cross-program sharing even further by working with Information Systems as a strategic partner to develop centralized knowledge management systems. One example of such a system would be a keyword-searchable database of people within PATH. For instance, if a PATH staff member was working on a submission to the Indian national regulatory authority, he or she might search the database to identify another PATH staff member in one of the other Global or Field Programs with the experience in Indian regulatory issues. Additionally, sharing of documents such as project management tools and partner agreements could be facilitated across programs by the development of a centralized document repository.

5. Seek whenever possible to reduce the lag between organizational growth and the capacity of back-office support systems

Because PATH's funding is primarily tied to specific projects, and because grant cycles are inherently uncertain, it is challenging for PATH to execute an integrated strategy to manage organizational growth. As a result, PATH is intentionally cautious with overhead expenses, resulting in relatively lean Corporate Services and External Relations functions. As PATH looks to scale-up the organization to support anticipated program growth, we believe that it will need to invest in infrastructure and information technology systems. This will likely require that PATH actively seeks funding for infrastructure support from their strategic donors. PATH could also consider moving additional selected functions (e.g. software development, paralegal contract support, etc.) to a service center model. This would allow programs to be "charged" directly for time allocated from those functions and therefore free up overhead dollars for capital investments in core systems.

There are tradeoffs inherent in each of these recommendations, and we recognize that an in-depth consideration of the risks would be required before taking action in any of these areas.

6. IMPLICATIONS FOR PRODUCT DEVELOPMENT

Overall, the PATH assessment highlights several key success factors that contribute to PATH's strong performance.

First, PATH's strong leadership and entrepreneurial, introspective culture are essential elements of the PATH model. Stakeholders repeatedly mentioned leadership as one of the top elements of PATH's successful outcomes. And PATH's culture is the clear outcome of its executive leadership team and the thoughtfulness that they apply to the mission, people, and processes within PATH. When thinking about product development more broadly, it is important to carefully consider leadership and culture within the organization in question.

While it would be difficult to replicate these "softer" elements in a wholesale fashion, they are tightly linked to a set of structural best practices that can be applied more systematically in product development outside of PATH.

6.1. Process discipline ensures quality decisions

Process discipline exists in several ways throughout the PATH organization:

- **Mission:** singularly focused mission of the PATH vaccines programs ensures discipline, ownership, and accountability for outcomes
- **Governance:** Committed external advisory boards with clear decision rights improve transparency and create accountability
- **Portfolio management:** rigorous portfolio management tools ensure robust analysis and set checks and balances
- **Partner selection:** Executive engagement in partner selection and contract terms improves negotiating position and strengthens achievable terms
- **Tracking mechanisms:** Monitoring and evaluation (M&E) framework for tracking progress against program goals and advancement of product pipeline accelerates institutional learning

Other product development organizations should evaluate their processes and seek to replicate this level of discipline in their own internal decision making and management structures.

6.2. Program synergies improve outcomes

Due to its breadth of global and field programs, PATH has a unique advantage in that it can pool expertise, share talent, and leverage its experience across efforts. For example:

- Experts in specific functions (e.g. regulatory, manufacturing, clinical trial design) can be shared across PATH VAC projects in different disease areas and across the different vaccine development organizations within PATH more broadly to increase leverage
- Frequent information sharing (e.g. cross PDP board seats, cross-program/function forums, intent to pursue funding form, ELT grant reviews) improves knowledge base for decision making
- Connections to field programs improve effectiveness in clinical trials, registration, etc. by offering a built in local network of relationships and infrastructure

Other PDPs should seek to develop partnerships with PATH or other PDP organizations to leverage the benefits of their collective experience and network of capabilities.

6.3. PATH size and scope is valuable

The PATH organization realizes the benefits of critical mass and breadth of programs across disease areas and around the world. Scale drives efficiency for the back-end infrastructure services, while also allowing PATH to exploit nodes of expertise throughout the organization. Stability of a larger organization improves PATH's ability to secure and leverage top talent. While most other PDPs do not have the luxury of PATH's scale and breadth of programs, they should evaluate mechanisms through which to develop cross-PDP partnerships or external shared function support to create additional leverage.

7. ACKNOWLEDGEMENTS

We would like to thank the Bill & Melinda Gates Foundation and PATH for their support and collaboration in this assessment. During the course of the effort, we spoke with all of the relevant program officers at the Gates Foundation, multiple partners of the PATH vaccine programs, as well as over 40 PATH personnel - many of whom took the time to provide feedback on our analysis and findings at several points throughout the project. This perspective and input not only enhanced our understanding of the organization and its operating model, but also helped us to refine and deepen our findings.

Please do not hesitate to reach out to Wendy Woods (woods.Wendy@bcg.com) or Andrew Rodriguez (rodriguez.Andrew@bcg.com) to discuss these results in more detail.

APPENDIX A: INTERVIEW LIST

| More than fifty stakeholder discussions conducted (I) | | |
|-------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Organization | Interviewee(s) | Role / key topics |
| BILL & MELINDA GATES foundation | Richard Adegbola, David Brandling-Bennett Janice Culppeper, Jessica Milman Tom Brewer, Doug Holtzman, Niranjani Bose Art Martinez, Hannah Kettler Erik Iverson Rob Lin Chris Wilson Rip Ballou (alumnus) | MVP structure, performance MVI structure, performance PATH VAC structure, performance Advocacy / GHTC function Legal / BD function Direct and indirect funding PDP portfolios PDP performance |
| PATH | Hugh Chang Christopher Elias Scott Jackson Rachel Wilson Michele Burns Eric Walker Marlow Kee Sharon Thompson Erik Arnold Dan Laster Ayorinde Ajayi Jacqueline Sherris John Wecker | Special Initiatives President and CEO External Relations Advocacy Communications Corporate Services Finance HR Information Services Legal Affairs Field Programs Global Programs Vaccines Access & Delivery |
| PATH BOD | Molly Coye Steve Davis | Health technology expertise / PDP Forum PATH evolution; China expert |

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| More than fifty stakeholder discussions conducted (II) | | |
|--------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Organization | Interviewee(s) | Role / key topics |
| PATH Vaccine Development Program | John Boslego Georges Thiry Mark Alderson Kathy Neuzil Dick Walker George Robertson Duncan Steele Jorge Flores Eileen Quinn Linda Nyari David Alli | Vaccines Development Portfolio Management / Rotavirus Project Pneumococcal Vaccine Project Influenza Vaccine Project Enteric Vaccine Initiative Science and Technical Clinical & Regulatory Communications & Advocacy Commercialization & Corporate Partnerships Finance & Administration |
| mvi PATH MALARIA VACCINE INITIATIVE | Christian Loucq Ashley Birkett Alan Brooks Carla Botting Sally Ethelston Leander Lauffer Katya Spielberg | Malaria Vaccine Initiative Pre and Early Clinical R&D Policy & Access Commercial Affairs & PD Communications & Advocacy Business Development Finance & Administration |
| Meningitis Vaccine Project | Marc LaForce Kim Kertson Colleen Ottoson Simonetta Viviani | Meningitis Vaccine Project Project Administration Legal (PATH) Regulatory / Clinical |

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