INTERIM REPORT

CONFIDENTIAL

Evaluation of the Global Drug Facility (GDF)

Stop TB Partnership Coordinating Board

Presentation of Interim Report to the Coordinating Board

Brasilia, April 4, 2003

GDF EVALUATION – CONTEXT AND KEY DECISIONS FOR THE COORDINATING BOARD (CB) TO MAKE

Background

- Board-mandated evaluation at the GDF's 2-year mark to take stock of its impact and make changes to systems and governance*
- Significant changes in the public health landscape since launch of the GDF, namely emergence of the Global Fund
- Some interest in the STB Partnership and from other disease areas for GDF-type intervention to address drug access issues

Questions asked by the CB

- Has the GDF had impact at a system and country level?
- Are the goals, proposition and model of the GDF still valid? What has worked and what has not? What will it take to continue supporting the GDF?
- What are the potential implications of the Global Fund for the GDF's sustainability?
- Has the WHO been, and likely to continue to be, a suitable host organization for the GDF?
- What are the pre-requisites, opportunities and challenges for the GDF if it expands scope to other areas like MDR-TB, malaria and HIV/AIDS?

Scope of GDF evaluation

Key decisions for the CB to take

- Should the STB Partnership continue to support the GDF? If so, what changes are needed to the GDF's role, proposition and business model?
- What resources must the STB Partnership commit to the GDF over the next 3 years, in terms of people and funding? How should GDF work with the GF?
- Should the GDF continue its current governance/ administrative model with WHO? What changes are required, if any?
- Should the GDF expand scope?

Focus of today's discussion

* Note: early days to measure impact. Hence, greater focus on inputs and process

DRAFT RECOMMENDATIONS FOR THE BOARD'S CONSIDERATION

Key decisions for the CB to take	Draft recommendations
• **Should the STB Partnership continue to support GDF? If so, what changes are needed to GDF's role, proposition, business model?**	• Based on the effects in its first two years of operations, GDF is an innovative and potentially high impact model that the STB Partnership should continue to support • Its role, "bundled" proposition and business model are robust, though execution within each functional area must be improved
• **What resources must the STB Partnership commit to GDF over the next 3 years? How should GDF work with the GF?**	• The STB Partnership must ensure direct and stable funding of $20-30M p.a. for the next 3 years to the GDF to allow it to have a grant-making role and to strengthen human resources/ management systems • In addition, GDF can work with the GF in a mutually beneficial partnership as a recommended agent
• **Should the GDF continue its current governance/ administrative model with WHO? What changes are required, if any?**	• GDF should continue its current arrangement with WHO as the advantages of the relationship outweigh the disadvantages • Governance must be strengthened through the Working Committee for more robust decision-making and oversight. The administrative relationship can be modified for more flexibility
• **Should the GDF expand scope?**	• "GDF"s for malaria, HIV and a GLC-GDF convergence are desirable and feasible, but should be undertaken by the respective disease partnerships, not the STB Partnership • The current GDF will not lose focus on TB. In fact, the STB Partnership could gain some reputation benefits from this move

OVER 180 INTERNATIONAL, REGIONAL AND LOCAL EXPERTS AND STAKEHOLDERS HAVE BEEN CONSULTED AND 10 COUNTRIES VISITED

Project timeline

- **Pre-work and project kickoff (week of Jan13)**
- **Phase I: Diagnostic (6 weeks: Jan 20-Feb 28)**
- **Phase II: Evaluation (4 weeks: Mar 3-28)**
- **Phase III: Recommendations (2 weeks: Mar 31-Apr 11)**

We are here

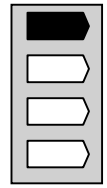
Interviewees – International/regional experts and stakeholders

Lina Abrahan	Marcus Espinal	Fabio Luelmo	Holger Sawert
Paul Acriavadis	Peter Evans	Dermot Maher	Fabios Scano
Dongil Ahn	Richard Feacham	Dee Jay Mailer	Bernard Schwartlander
Nadia Aitkhaled	Paula Fujiwara	Robert Matiru	Peter Small
David Alnwick	Malgosia Grzemska	Michael McCullough	Ian Smith
BRL Ploos van Amstel	Jack Gottling	Ariel Pablos-Mendez	Lisa-Marie Smith
Virginia Arnold	Penny Grewal	Lucy Moore	Anthony So
Guido Bakker	Johan van der Gronden	Tom Moore	Anil Soni
Emma Beck	Brigitte Heiden	Toru Mori	Bo Stenson
Francoise Benoit	Renee Herminez	Poul Muller	Lynn Taliento
Yves Bergevin	David Heymann	Vasant Narsimhan	Yolanda Tayler
Henk den Besten	Ernesto Jaramillo	Eva Nathanson	Kate Taylor
Leo Blanc	Daniel Kibuga	Paula Nersisian	Arnaud Tebaucq
Andrea Bosman	Jim Yong Kim	Paul Nunn	Michael Thuo
Jaap F. Broekmans	Dr. Kochi	Bernard Pecoul	Tom Topping
Richard Bumgarner	Jacob Kumaresan	Joseph Perriens	Jan Voskens
Emanuele Capobinco	Irene Kuok	Antonio Pio	Hugo Vrakking
Andrew Cassels	Richard Laing	Jonothan Quick	Catherine Watt
Umberto Cancellieri	Ken Langford	Jim Rankin	Diana Weil
Brendan Daly	Tom Layloff	Eva Rard	Roy Widdus
Susanne Detreville	Peter Potter-Lesage	Mario Raviglione	Hilary Wild
Lucica Ditiu	Christopher Lovelace	Alistair Reid	Andre Zagoriskiy
Chris Dye	Ernest Loevinsohn	Irene Rizzo	Richard Zaleskis
David Ernst		Rodrigo Romulo	

Country visits

- India
- Kenya
- Moldova
- Myanmar
- Nigeria
- Philippines
- Romania
- Somalia
- South Africa
- Uganda

1. GDF'S PROPOSITION AND MODEL ARE ROBUST, HAVE HAD A POSITIVE EFFECT AND SHOULD BE SUPPORTED BY THE PARTNERSHIP



Key messages

- **Evaluation of GDF's effect to date**
  GDF's mission is two-fold: first, to expand access to high quality TB drugs and second, to indirectly facilitate DOTS expansion. Although it is early days to measure "impact", GDF appears to be successfully positioned to meet both goals. It has provided drugs for 1.8M patients, across 8 HBCs and 16 other countries. Across eight countries evaluated, GDF has had a very positive (transformative) effect in three, medium effect in three, and limited effect in the remaining two countries. At the system level, GDF has improved price, quality, and standardization of TB drugs. It has had this effect in a short time frame and with good efficiency

- **Evaluation of value proposition**
  GDF's unique value proposition combining grant, procurement and partner network has been key to its success: an 'unbundled' system including these elements but without full alignment on decision-making/operations would not have achieved similar results

- **Recommendations**
  GDF's proposition has high potential for impact and should continue to be supported by the STB Partnership. GDF should continue to serve its 'natural beneficiaries' as well as its 'challenging beneficiaries', who most need a GDF and are likely to most benefit from it –these represent a pool of ~ 6M TB cases annually, of which GDF would need to provide grants for only a fraction (e.g., 1/3rd-2/3rd). GDF should continue with its current focus on providing drugs while mobilizing partners for addressing other country needs. GDF neither needs to, nor can it realistically undertake other DOTS- and infrastructure-related activities itself. Finally, GDF should implement operational improvements across its business model, focusing on advocacy, partner mobilization, and procurement

ALTHOUGH IT IS EARLY DAYS TO MEASURE "IMPACT", GDF APPEARS TO BE SUCCESSFULLY POSITIONED TO MEET ITS GOALS

GDF has had positive effects at a country level…

- Currently reaches 10% of 8.8M TB patients in 8/22 HBCs and 16 other countries, representing 631,000 and 252,000 patients respectively
- Of the 8 countries studied that received GDF grants, effects have been
  - **Positive (transformative)** in Moldova, Myanmar and Nigeria where its grant has *catalyzed* significant expansion of DOTS treatment plans and mobilized resource contribution and political commitment by other partners
  - **Moderate** in Kenya, Uganda and Philippines in *facilitating* DOTS expansion
  - **Limited** to Somalia and India, restricted to some areas only

… and at a system level…

- Drove significant reduction in drug prices through pooled procurement and negotiations. E.g. , Kenya - 40-50% vs. international prices, 20-45% vs. local
- Promoted the use of logistically superior, patient-friendly treatment regimens, e.g., 4FDC, blister packs
- Used its relationship with WHO to promote the development of a 'white list' of pre-approved TB drug suppliers, which can now be used by all buyers
- Raised awareness of shortcomings of local manufacturers: "…*after GDF brought up price and quality issues of TB drugs, the government of Indonesia is now asking local manufacturers for bio-availability data and justification of ~$30 per patient treatment price…"*

…in a very short time with a lean «virtual partnership» model

- Received first application in January 2001 (Togo); made first round of decisions in April 2001; first drugs arrived in country in October 2001 (Moldova)
- Small core staff, successful leveraging of partners and in-country WHO staff

ACROSS THE 8 COUNTRIES STUDIED, GDF HAS HAD AN EFFECT ON BOTH DIRECT AND INDIRECT GOALS

	Nigeria	Myanmar	Moldova	Uganda	Kenya	Philippines	India	Somalia
Direct goal: Expanding access to high quality TB drugs								
Alleviating drug shortage due to lack of funds	✓	✓	✓	✓	✓	✓	✓	✓
Alleviating drug shortage due to procurement issues				✓		✓	✓	
Indirect goal: Facilitating DOTS expansion								
Improving drug management through standardization and innovations	✓	✓		✓	✓	✓		
Releasing resources for other aspects of TB management		✓		✓				✓
Mobilizing political and partner commitment	✓	✓	✓		✓	✓		

THESE BENEFITS HAVE BEEN DELIVERED IN A COST-EFFECTIVE MANNER

Million USD, 2001-2002 Cumulative

ON A FULLY-COSTED BASIS, INCLUDING DONATIONS, SECONDMENTS, ETC.

	Amount	% of total
Inflows (donations, grants-in-kind)*	**21.0**	
Cost of Goods Sold (procurement costs)	**17.4**	**82.9%**
Drug cost, procurement service fee, freight, insurance	17.4	82.9%
Selling, general, and administrative expenses	**3.6**	**17.1%**
Advocacy and communications	0.1	0.6%
Technical assistance and monitoring	0.5	2.4%
Quality assurance	0.5	2.4%
General and administrative	1.1	5.2%
GDF fixed term	*0.2*	
GDF short term	*0.5*	
STB Secretariat**	*0.2*	
Seconded staff***	*0.2*	
Indirect cost to WHO	1.4	6.4%

GDF has spent 11.7 USD per patient treated (given 1.8 million cumulative patients treated over 2001-02)

* Amount of carry over ($2.2M) to 2003 is excluded in total inflows

** ½ FTE Financial, contracting, HR; 1/5 FTE resource mobilization; 1/5 FTE Information management; 1/10 FTE advocacy/communication

*** MSH/T. Moore, H. Vrakking; RIT/Y. Uchiyama

Source: STB Secretariat; Team analysis

GDF's UNIQUE BUNDLED PROPOSITION IS KEY TO MEETING ITS GOALS. AN UNBUNDLED SYSTEM WOULD NOT HAVE HAD SIMILAR RESULTS

Unbundled system

- Increase leverage to mobilize government and partners
- Free up resources for other TB control plans

Grant

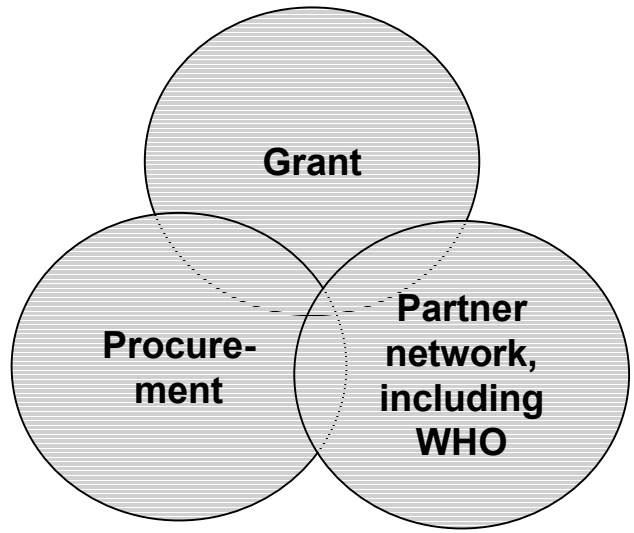
- Align normative standards (e.g., 4FDC, white list) through WHO
- Provide in-country technical assistance and promote GDF

Partner network, including WHO

- Have impact in countries with funds but poor procurement
- Lower prices, improve quality and reduce lead times

Procure-ment

Bundled system



- Grants-in-kind more powerful to mobilize partners
- Grants + partner network allow STB (GDF) partners to provide relevant TA to support the drug grant
- Grants + procurement allow GDF to lower prices by pooling demand, ensure timely procurement and standardization/innovation
- Grants-in-kind linked to procurement reach countries faster than through separate granting and procurement processes, and with fewer 'leakages'

GDF SHOULD FOCUS ON "NATURAL" AND "CHALLENGING" BENEFICIARIES WHO WILL MOST BENEFIT FROM THIS MODEL

Three key dimensions to define GDF's beneficiaries…

- Availability of affordable, high-quality drugs
- Willingness and ability of government to take concerted action to address TB burden
- Presence of GDF partners in country

Beneficiary segment	Example countries	GDF approach
• **"Natural beneficiaries"** – No reliable supply due to funding or procurement gaps – Government willing and able to take action – GDF partners present	• Most countries, e.g. Moldova, Nigeria	• Approach proactively
• **"Challenging beneficiaries"** – No reliable supply – No willing or able government *or* – Few or no GDF partners in country	• Somalia, Myanmar	• Recognize that impact will be harder to achieve, but need is even greater • Expend more efforts to identify in-country technical partners and coordinating mechanisms
• **"Opportunistic beneficiaries"** – Countries which usually have funds and ability to procure own drugs, but may benefit from GDF support (e.g. on a periodic or regional basis)	• India, South Africa	• Unlikely to serve with classic approach • Maintain dialogue, e.g. through Stop TB Partnership, to identify emerging opportunities to serve these countries, e.g., emergency needs

GDF DOES NOT NEED TO ALTER/EXPAND ITS PROPOSITION, BUT CAN MEET DRUG-RELATED GAPS THROUGH BETTER PARTNER MOBILIZATION

Issue: Does GDF need to hire its own team/fund activities to plug drug-related gaps, e.g., drug management, lab training, consumables?

From GDF's operational perspective…,

- Few barriers common across countries: any one new activity would help only a subset of countries
- GDF has been able to influence most barriers by mobilizing its partner network. Better execution on this dimension will further improve GDF's impact

From a customer need perspective…

- Any new service line would require GDF to obtain significant funding, expertise, or both, e.g.
  - Changing the Ugandan procurement system from 'push' to 'pull' required DELIVER to "…*get DANIDA funding and do one year of consulting work… and that was in a favorable environment where the government wanted change and DANIDA was pushing for it…"*
- Such new areas would likely overlap with activities of STB technical partners, leading to duplication
- New activities, especially those not directly related to drug supply, could detract focus from GDF's core operations

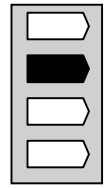
Recommendations

- GDF should not directly provide such assistance to countries
- However, GDF should:
  - Explicitly assess these barriers during application and M&E
  - Mobilize partners to provide assistance where needed
  - Where no partners available, develop one-off solutions
- At a systemic level, GDF should continue to facilitate low-investment, high-impact actions, e.g. the Washington conference on FDC, sharing best practices like transition to FDC, use of drug grant in PPM

GDF MUST ALSO IMPROVE KEY OPERATIONAL AREAS

	Issue	Recommendations
Advocacy / awareness building	• Low awareness of GDF's broader mandate limits its ability to coordinate efforts among donors, STB partners and in-country agents • *"The first time we heard of GDF was when you called…"*	• Engage in significant "brand-building" both with country beneficiaries and donors/STB partners, e.g. – Budget for advocacy and brand building – Publicity strongly linking DOTS and GDF – Contacts between high-level GDF/STB members and government officials – Contacts with in-country NGOs, technical advisors – Link between drug and disease information
Partner mobilization	• Variable involvement of in-country WHO officers • Insufficient focus on mobilizing partners to tackle key in-country bottlenecks • Low engagement with non-traditional partners outside of core group	• Fully leverage WHO across all countries for advocacy / government communications / partner relationships / facilitation of drug entry to port • More proactively involve partners – Strengthen applications with partner input – Encourage 'ownership' of country bottlenecks – Map list of in-country stakeholders during application process and engage with non-core partners – Ensure M&E visits involve all key in-country partners
Procurement	• Initial procurement approach not in line with donor expectations • Direct procurement service line currently similar in structure and requirements to grant-kind-service line	• Redesign tender process - LICB, with multiple suppliers for each product (being done currently) • Publicize new process to undo negative perception • Review appropriateness of application review and monitoring requirements for direct procurement • Review economics of direct procurement

2. THE STB P/SHIP MUST PROVIDE DIRECT AND STABLE FUNDING OF $20-30M P.A. FOR THE NEXT 3 YEARS TO SUPPORT GDF'S OPERATIONS



Key messages

- **Funding requirements**
  Grant-making is critical to GDF's value proposition as it gives GDF a "carrot and stick" to ensure countries adhere to their commitments and work towards overall DOTS expansion goals. While similar impact could be achieved with a "mandated" agent relationship with a donor like the Global Fund with full strategic/operational alignment, a "recommended" agent relationship alone will not give GDF the same leverage

- **Human resources requirements**
  GDF's current management has largely delivered against expectations. However, as GDF grows from a "launch" phase to a period of "consolidation", it will require adequate staff/skills and more professional systems for strategic and financial planning, operational execution, performance monitoring and knowledge management. To meet these needs, the current team must be strengthened significantly with stable, experienced and credible leadership, appropriately staffed/skilled management team and the right organization structure and management systems

- **Funding requirements and relationship with Global Fund**
  The STB Partnership must ensure direct and stable funding of $20-30M p.a. (going up to $35M in 2005) for the GDF for the next 3 years to meet these needs. Further, GDF can work with the GF to structure a mutually beneficial "recommended vendor" relationship by offering direct procurement services to GF grantees. Over time, GDF should closely work with countries, donors/lenders like the Global Fund and the World Bank as it begins to phase out its grant-making role

GDF'S FULL VALUE PROPOSITION DEPENDS ON PROVIDING GRANTS

GDF can help de-bottleneck drug shortages via direct procurement alone…

…but having an impact at non-drug bottlenecks is dependent on the 'carrot' of providing grants and the 'stick' of post-grant M&E

GDF intervention	Potential bottlenecks in DOTS expansion
Direct procurement • Allows countries to buy quality drugs more cheaply through GDF, and thereby reduce problems in drug supply for DOTS	**Drug supply**
Grants • Encourage governments to develop strong DOTS plans to win grant and attract other donors • With associated M&E, encourage governments to honor commitments to be eligible for more aid	**Political commitment and planning**
• Allow funds to be reallocated to meet resource gaps in non-drug areas • Allow funds to be invested in technical assistance • Allow GDF to mobilize and coordinate actions of partners	**Other bottlenecks, e.g.** • Human resources • Infrastructure • Laboratories

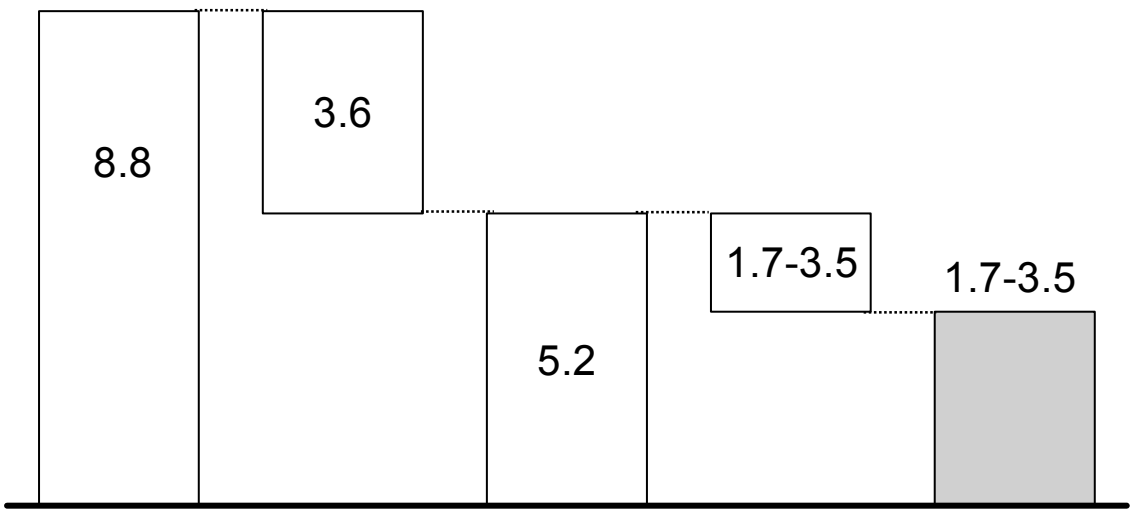
WITHOUT GRANTS, GDF's IMPACT BECOMES DIMINISHED ACROSS ALL POSSIBLE SCENARIOS

Scenario	Description	Implications for GDF
Direct procurement agent	• Donor gives grant to country, and maintains M&E function • Country has choice of procurement agent, including GDF	• GDF would lose – Financial leverage (both carrot and stick) to encourage DOTS expansion – Ability to promote standardization of TB treatments – Access to a range of countries with non-level playing fields
Recommended procurement agent	• Donor gives grant to country and maintains M&E function • Donor recommends GDF as procurement agent	• GDF would lose financial leverage to encourage DOTS expansion **Potential relationship with the GF (GF unlikely to mandate an agent for 1st line drugs)**
Mandated procurement agent	• Donor gives grant to country and mandates GDF as procurement agent • Donors delegates M&E function to GDF	• No diminished impact for the GDF, but only if donor agrees to GDF-driven application, review and M&E process and decision-making, so that GDF retains the carrot and the stick • Would any donor give up this degree of control over M&E?

GDF's DIRECT GRANT-MAKING ROLE CAN BE SUSTAINED WITH FUNDING LEVELS OF ~$20-40 MILLION PER YEAR

TOP-DOWN ESTIMATE

Million cases p.a., 2002



Estimated TB incidence

Less: Cases in "opportu-nistic" beneficiaries

Cases in "natural" and "challenging" beneficiaries

Less: 1/3-2/3 demand that GDF will not meet

1/3-2/3 demand that GDF will meet through grants

- It is neither necessary nor desirable for GDF to grant 100% of a country's needs
  - Discourages countries' from having budget lines
  - Makes exit harder
  - Reduces competition and local procurement capacity
- At $10-12 per treatment course, GDF will require ~$20-40M per year for drug grants

GDF will prioritize grant recipients based on ability to have impact on their DOTS program, in addition to drug need. Hence, focus on "natural" and "challenging" beneficiaries

Grants of 1/3-2/3rd of country needs is adequate for GDF to catalyze DOTS expansion
- 30% budget gap in HBCs
- Meaningful level for leverage
- Countries can use direct procurement for the rest

HUMAN RESOURCES – THE MANAGEMENT TEAM HAS MET EXPECTATIONS BUT MUST BE STRENGTHENED

● Fully met
◑ Somewhat met
○ Did not meet

Needs of GDF at start-up

- Lean and innovative team
- Credibility with and access to countries
- Strong and independent technical expertise
- Smooth coordination with other TB efforts and key partners

Assessment - ◑

- Strong core team
  - Visionary and technically competent leadership
  - Committed, innovative hard-working, staff; *"can-do attitude"*
  - Secondments to increase capacity and expertise
  - Outsourcing for lean team
- Strong committed credible TRC, independent functioning
- Access to country expertise, networks, infrastructure and credibility through WHO
- Mobilized partners from within STB Partnership rather than building from scratch

Issues going forward

- Challenge to replace a strong leader while maintaining momentum. Need to decide on right profile given multiple priorities (e.g. organization builder, procurement expert or a fundraiser?)
- Staff shortage: Targeted GDF growth cannot be achieved at current staff levels
- Skill/coverage gaps and limited "business" mindset
  - *Systems* (e.g. very limited financial planning and controls; similar issues for knowledge management, strategic planning)
  - *Marketing/fundraising*
  - *M&E:* (nascent, handled part time)
- Current organization structure and roles fluid and opaque to outsiders, resulting in communication gaps with countries

Potential implications

- GDF growth limited by internal changes and capacity
- Increased risk from poor financial/operating systems
- Reduced credibility with key stakeholders

AS GDF MOVES FROM START-UP TO CONSOLIDATION, MANAGEMENT MUST BE STRENGTHENED ON ALL DIMENSIONS

Key priorities	Recommendations
Hire GDF senior manager to provide credibility to GDF team	• Interim STB Director to make search key priority, leveraging support of WC • Consider re-negotiating MoU for a director level post (i.e., same level as director of STB Secretariat) to reflect importance of position and to attract high caliber person • In candidate selection, ensure deep managerial expertise in addition to technical skills, fit with culture and ability/credibility to manage multiple partners including WHO
Close coverage/skill gaps in functions critical to GDF's business model • Professionalize financial monitoring/planning and knowledge management • Strengthen GDF marketing/ resource mobilization • Set up and maintain high quality M&E mechanisms	• Hire professionals for three positions and invest in related systems: – COO/CFO: Responsible for financial/operational planning processes, expanding current knowledge management systems, internal performance management, and interfacing with WHO administrative/legal services – Marketing/Fundraising Manager: Responsible for developing GDF-specific fundraising and communications strategy, as well as marketing plan for direct procurement – M&E Specialist: Responsible for developing robust M&E mechanisms to track GDF impact in countries and ensure mobilization of partners for execution
Increase clarity of organizational structure and delineation of responsibilities	• Clarify, adapt and formalize current tacit matrix structure ensuring clear single-point responsibilities for countries and functions

THE STOP TB PARTNERSHIP MUST ENSURE FUNDING OF $20-30M P.A. TO THE GDF FOR THE NEXT 3 YEARS

Million USD

BOTTOM-UP PROJECTIONS

Financial projections

	2003	% of total	2004	% of total	2005	% of total
Revenues (donations, grants-in-kind)	**15-19**		**24-26**		**29-35**	
Cost of Goods Sold (procurement costs)	12-15	81-83%	20-24	81-83%	24-28	81-84%
Selling, General, and Administrative expenses	3-4	17-19%	4-6	17-19%	5-7	16-19%

Assumptions

Drug cost

- Continue current commitments
- Continue to serve DOTS expansion plan of current countries
- ~1M USD of new commitments to new countries each TRC round
- Reflect 20% drug price appreciation in higher end

Operating cost

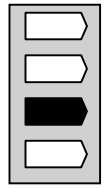
- Increase in HR staff and advocacy budget
- Technical assistance proportion of drug grant increases in higher end
- WHO indirect costs decrease due to the WB Trust Fund

Source: STB Secretariat; Team analysis

THE STB PARTNERSHIP MUST ACTIVELY EXPLORE/INITIATE DISCUSSIONS WITH DIFFERENT DONOR SEGMENTS TO FUND GDF'S ACTIVITIES

	Description	Issues to explore
Current GDF donors	• CIDA, Netherlands government (« founding » donors) • USAID, World Bank	• Views on GDF impact and continuing alignment of GDF operations with donor objectives • Position vis-à-vis Global Fund • "What GDF would have to look like" to continue being funded by current donors
Other TB donors	• DFID, JICA, OSI other governments	• Awareness of GDF • Views on GDF and alignment of GDF operations with donor objectives • "What GDF would have to look like" to be funded by other TB donors
Other innovative options	• Funders of leprosy programs, e.g. Nippon Fnd, GLRA	• Willingness to divert leprosy funds to other areas • Current level of involvement in TB
	• Other institutional donors interested in public health	• Willingness to fund TB projects • Awareness of GDF
	• Pharma companies, e.g., Novartis Foundation	• Willingness to provide 4FDC as grants-in-kind
	• In-country corporate donors (e.g. Shell in Nigeria)	• Willingness to 'adopt-a-country' • Mechanisms for receiving corporate donations
	• Individual donors	• Willingness to 'adopt-a-country' • Mechanisms for receiving individual donations

3. GDF SHOULD CONTINUE ITS CURRENT ARRANGEMENT WITH WHO, BUT STRENGTHEN GOVERNANCE AND INCREASE FLEXIBILITY



Key messages

- **Evaluation of current set up and relationship with WHO**
  GDF was established as an "embedded legal identity housed in WHO" as this was seen as the best option to meet the organizational needs of the GDF at that time. On balance, the current set-up has met the needs of the GDF and the legal/housing arrangement with WHO has largely delivered against expectations. WHO has been credited with maintaining a 'hands-off' supportive role at a governance/administrative level, but a critical "hands-on" role at a country level. However, there is little clarity on the roles of the STB Coordinating Board, Working Committee and WHO on governance and accountability for GDF's activities and success

- **Requirements, going forward**
  Significant strategic and operational decisions need to be made for the GDF. GDF therefore needs a robust governance model, with clear responsibility for decision-making and strategic direction and strong oversight on financial, operational and people performance. GDF also needs more flexible and cost-effective administration. The current governance and administrative set-up does not meet these needs fully

- **Recommendations**
  On balance, GDF's legal and administrative arrangement within WHO is the best available model. However, WHO must delegate a clear role to the Working Committee to ensure robust governance for the GDF. On the administrative side, specific requirements on HR and Legal can be negotiated with WHO for more flexibility

GDF WAS LAUNCHED AS AN "EMBEDDED LEGAL ENTITY HOUSED IN WHO" IN 2001

Option chosen

Legal identity (for overall governance and reporting)

	Housed by STB Secretariat in WHO	Housed by other partner	Standalone
Independent legal identity	**Independent GDF hosted by WHO/ STB** • Independent organization accountable to own decision making board • Subcontracting of WHO for administrative support and infrastructure • MoU with WHO Stop TB	**Independent GDF hosted by IUATLD or KNCV** • Independent organization accountable to decision making board • Sub-contracting of NGO partner for administrative support and infrastructure	**Independent, stand-alone not-for-profit entity** • Independent organization, accountable to own decision making board • Managing (or outsourcing) its own infrastructure and admnistrative support
Embedded legal identity	**Borrowed legal identity, housed in WHO** • Legally part of WHO with MoU to detail deviation from WHO norms • STB CB in an advisory role, final decision making power with WHO • GDF team part of the STB Secretariat in WHO		

Housing options
(for administrative support and infrastructure)

THE CURRENT ARRANGEMENT HAS MET THE NEEDS OF THE GDF TO A LARGE EXTENT

● Fully met
◑ Somewhat met
○ Did not meet

Areas reviewed	Needs of GDF at start-up	Assessment of whether these needs were met
Governance	• Well-functioning board with clear roles and representation from key TB stakeholders • Alignment with STB goals • Short set-up time • Quick and efficient decision making and robust oversight	◑ • Broad agreement in STB CB, WC and WHO on the need for and value add of GDF • Committed and stable funding in first 2 years • Relatively well-functioning STB CB with balanced representation, collaborative working style and focus on getting things done • Delegation of grant review and oversight of work planning/ budgeting to WC to enable fast decision-making • Balanced WHO role with “hands on” support at country execution level, but relatively “hands off” at governance/administration level • However, limited engagement, oversight and sense of responsibility among CB/WC w.r.t. GDF
Administra-tion	• Quick set-up with low costs, given scale of operations • Adequate flexibility to allow GDF to respond quickly and innovatively to countries' needs	◑ • Rapid start up through use of WHO’s administrative services and physical infrastructure • GDF MSU perceived to be relatively flexible and service-oriented • However, much time and energy spent on HR issues (hiring) and discussions with WHO’s Legal Department for contracts

DESPITE INITIAL CONCERNS, PARTNERS BELIEVE THAT WHO HAS NOT UNDULY INFLUENCED GDF'S OPERATIONS

Illustrative quotes from interviews

"Although GDF housed in WHO, WHO does not unduly influence it. When CIDA decided they did not want to pay the WHO contributions, but set up a Trust Fund in WB, WHO did not have a say"

"It all comes down to people. With Jacob and JW, they have done a pretty good job of keeping Stop TB and GDF out of WHO politics. This could be different with different people "

"The team is responsive to all partners not only or primarily the WHO"

"I was very concerned in the beginning but the current set up with WHO has worked well"

"WHO has never directly pressured the board"

"Senior people have kept their word, the Chinese walls between WHO and GDF have been maintained"

"The hands-off leadership of Dr. Lee was essential to making the current set up work . I hope this will continue with Dr. Lee's leadership of the organization

Specific examples mentioned

WB TRUST FUND

- The Stop TB Board voted in favor of moving GDF funds to a Trust Fund in the WB, thus reducing WHO's inflows

INDIA APPLICATION

- WHO did not pressure the TRC to approve India's application in early rounds, despite India escalating the issue to the DG's Office

PROCUREMENT

- WHO did not block GDF's early procurement decisions, despite protests of its procurement department

Hands- off approach is largely credited to "buffering" role played by J.W. Lee, Jacob Kumaresan and Ian Smith

THE CURRENT ARRANGEMENT NEEDS TO BE STRENGTHENED FOR MORE ACCOUNTABLE GOVERNANCE AND FLEXIBLE ADMINISTRATION

Requirements, going forward

Governance

- Clear decision making mandate and accountability
- Active engagement of board in strategic dialogue
- Strong oversight ("audit") of financial and operational aspects, performance monitoring and succession planning
- Active role in fund raising
- Clear ownership of legal liability

Administration

- Efficient, cost-effective and flexible administrative support
- Swift legal, contracting and audit processes, especially tuned into the needs of a broader partnership versus WHO alone

Issues with current set-up, going forward

- Little consensus on GDF's role going forward, but limited strategic dialogue
- No clear responsibility for governance
  - Little agreement among board members on who is accountable for GDF. Hence, inability to foresee/preempt problems
  - Concern about gaps in oversight, resulting in weak risk management

- Cumbersome and lengthy WHO hiring rules for long term contract. Hence, difficulty in attracting talent and 8/9 staff on short term contracts. Even with short term contracts, forced contract breaks and cap on stay with a department. Hence, gaps in staff coverage; loss of institutional memory
- Little clarity on payments- *"Who pays what to whom for which services?"*
- Delays caused by lengthy legal processes. Hence, potentially reduced business competitiveness

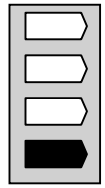
STB SHOULD RETAIN GDF WITHIN WHO AS AN EMBEDDED LEGAL ENTITY, BUT WHO MUST DELEGATE A CLEAR GOVERNANCE ROLE TO THE WC

Key priorities	Recommendations
Vest a body with clear accountability for the GDF and transparent decision making responsibility and processes	• The WC should be entrusted with this role, even as GDF continues to be a embedded legal entity within WHO. It would require WHO's agreement and defining clear bylaws with clear roles and responsibilities and decision making protocols for each entity to ensure accountability • Precedents exist for such an arrangement
Ensure improved financial/ operational oversight for the GDF	• Strengthen/refocus WC on its core task to "guide and evaluate the operations of the GDF Secretariat" with four focus areas and decision making powers on behalf of the board: – Provide strategic direction; help prepare recommendations to the board in collaboration with the Secretariat – Monitor financial/operational performance against targets – Develop fundraising strategy in collaboration with GDF staff – Provide operational oversight in key areas, e.g. review TRC recommendations, procurement tendering process • Composition: Representative group, 4-6 involved CB members
Improve reporting and communication processes	• Formalize pre-syndication process, lead time, and formats for GDF presentations (especially financial reporting) to the board/WC to provide adequate preparation time and information for deliberations • WC should co-opt non-voting member of the TRC to ensure direct communication flow and expertise

HR AND LEGAL ASPECTS OF ADMINISTRATION COULD BE MODIFIED TO ALLOW MORE FLEXIBILITY WITHIN WHO PROCEDURES

Key priorities	Recommendations
Reduce total administrative costs and increase transparency of services received. Alternatively, increase efficiency with growing scale of operations	• While administrative costs will be reduced with the introduction of the Trust Fund, they are still higher than benchmarks compared on a per staff basis • With growth in GDF's activities, GDF must negotiate with WHO for a cap on payments to WHO (in absolute terms, not as % of budget), to benefit from growing scale of operations
Increase flexibility in WHO hiring procedures/rules for GDF to • Ensure continuity of staff on short term contracts and reduce time spent on contract breaks • Ensure ability to swiftly hire for at least a few long term positions and thus increase attractiveness to senior candidates	• Negotiate with WHO for the following (illustrative): – Exception to rule that short term staff needs to change department after 4 yrs (or alternatively, ensure these contracts can be transformed into long term contracts) – Reduce contract breaks to 2 weeks maximum – Secure 2 long term positions (e.g., CFO/COO) with exceptions to usual WHO quotas
Increase speed of response from WHO departments to GDF's needs (e.g., Legal and contract, treasury/accounting/ finance)	• Negotiate with WHO to have a GDF-dedicated person for these functions in the respective WHO departments • Further, these personnel should be directed to serve GDF from a partnership, not WHO perspective • Precedents exist for such an arrangement

4. THE STB P/SHIP SHOULD HAVE NO OBJECTION TO A BODY LIKE WHO PROMOTING THE USE OF THE "GDF" MODEL FOR OTHER DISEASES



Key messages

- **Evaluation of concept of "expansion" of the GDF**
  The Global TB Drug Facility has been successful in large part because of the STB Partnership's commitment, funding and technical support. Similarly, the success of a GDF for any disease requires a well-functioning disease partnership. Hence provision of a GDF-type model for malaria or HIV must be driven by the respective partnerships for those diseases. The initial lead in catalyzing these discussions and coordinating activities can come from a body like the WHO with the mandate across these diseases and relationships with the partnerships

- **Disease-specific fit**
  A robust case can be made for a GDF-like model for specific drugs/diagnostics in MDR-TB, malaria and HIV/AIDS to expand access to quality, cheap products and facilitate rational use. The "TB one-stop shop" concept (diagnostics/consumables), while important, does not fully lend itself to such a model. There are clear system and country level benefits from leveraging the GDF brand, systems and learnings/best practices across these disease areas

- **Recommendations**
  From an external perspective, "GDF"s for malaria and HIV and a GLC-GDF convergence are desirable and feasible. Given that these disease areas are outside the STB Partnership's scope, this should happen via specific partnership-driven implementation, resourcing and funding and a WHO umbrella over disease-specific GDFs. The implications for the STB Partnership are overall positive, i.e. a) reputation benefit (impact beyond TB, advisory role to 'new' GDFs, more visibility for funding); b) no loss of focus or need to go outside of area of technical expertise; and c) no need to supply funding/resources. This would call for a loose-tight organization structure (franchising or "business" units), that leverages synergies but allows disease coalitions to maintain control on key technical aspects. The new "overall GDF", while maintaining its unique model and independence, should continue to be housed in WHO with a borrowed legal identity

THE SUCCESS OF A GDF FOR ANY DISEASE REQUIRES A WELL-FUNCTIONING DISEASE PARTNERSHIP

A supportive ("willing") and well-functioning ("able") partnership critical to GDF's success…

- **Full alignment:** Demand for the model must come primarily from the disease partnership – need agreement on importance of drug access issues, relevance of GDF model and commitment to using the GDF
- **Technical support:** Partners must be *willing* and *able* to define technical guidelines/protocols, support GDF for technical review/M&E visits and provide technical assistance to countries
- **Funding support:** Donors in each partnership will need to contribute to a core fund to support GDF's direct grant-making role and/or work closely with other key donors and align systems

…As seen in the case of the TB GDF and the STB Partnership's role

- Normative role: GDF works with WHO units like DOTS Expansion and EDM (FDC, white list)
- Fund raising: Donors on STB CB committed to STB goals finance the GDF's activities
- In-country technical assistance: GDF relies on partners like MSH and IUATLD to provide services

"GDF has worked well largely due to a reasonably well-functioning partnership and support for setting up such a facility. In the absence of a similar situation in HIV/AIDS and malaria, the facility will not succeed"

- **Provision for a GDF-type model for malaria or HIV must be driven by the respective disease partnership, which should demand, resource and house such an effort**
- **The STB Partnership neither can nor needs to provide the resources (people/money) for such an effort**

EACH OF MDR-TB, MALARIA AND HIV/AIDS ARE AT DIFFERENT STAGES OF READINESS TO USE A GDF-TYPE MODEL

MDR-TB: Good support from the GLC

- Well-regarded body with strong technical review, credibility with external donors like GF and support from STB Partnership
- Discussions already initiated for potential convergence of GDF and GLC

Malaria: RBM willing but needs to build capability

- Interested in using GDF model for advanced anti-malarials
- However, much skepticism on capability of the current RBM Partnership - *"The malaria program is in shambles today"; "RBM is at least 6 months away from becoming a well-functioning partnership"*

HIV/AIDS: Lack of clarity on partnership itself

- Heavy politicization, no clarity on decision-making body *"ARVs are politically very contentious. No justification to enter till this is resolved"*
- Perceived historical enmity between TB and HIV groups; *"GDF for HIV is a nonstarter.. The chasm has not healed"*

However, each disease partnership must satisfy a check-list before it adopts a GDF-type model

- ✓Robust negotiation process for continuous reduction in drug prices
- ✓Funding of ~$75M p.a. from STB donors to the GDF *or* mandated procurement agent status with key donors like the GF

- ✓Standardization of treatment regimens and protocols, at system level and country level
- ✓Well-functioning RBM Secretariat and Partnership (e.g., clear goals, global malaria strategy, partner roles)
- ✓Robust negotiation process for continuous price reduction
- ✓Funding of ~$30M p.a. from RBM donors to the GDF

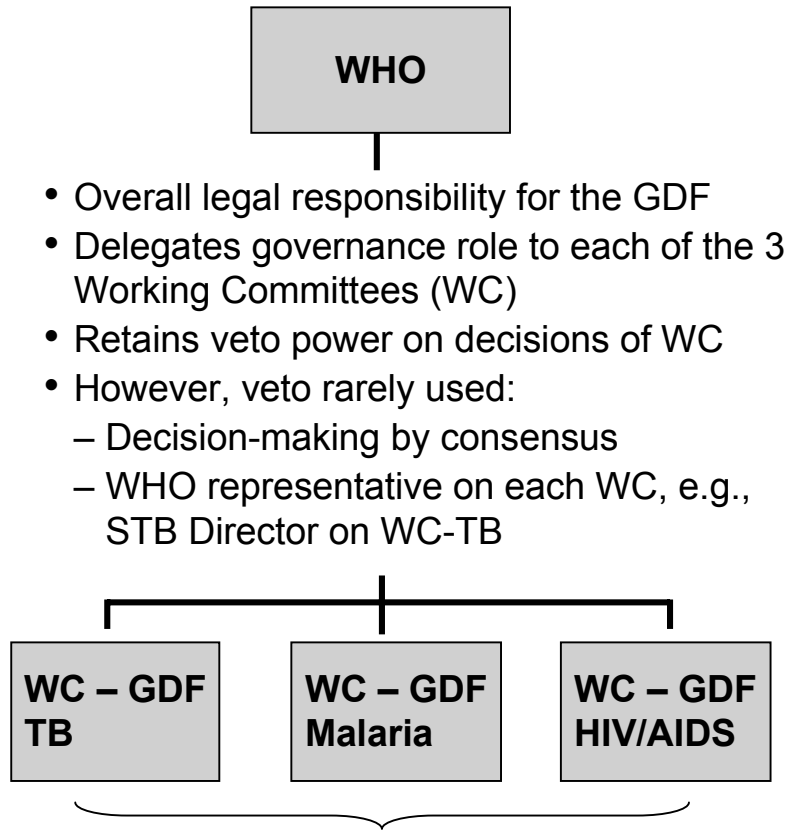
- ✓Well-defined partnership forum with clear mandate to decide on access issues
- ✓Standardization of treatment regimens and protocols at system and country level
- ✓Robust negotiation process for continuous price reduction
- ✓Funding of >$1B p.a. from key donors *or* mandated procurement agent status with key donors like the GF

THE WHO IS POTENTIALLY IN THE BEST POSITION TO INITIALLY CATALYZE THESE DISCUSSIONS WITH THE DISEASE PARTNERSHIPS

Key recommendations

- **An established multilateral organization is in the best position to catalyze these discussions**
  - "Overall" GDF needs increased visibility at system/ country level, better access to funding and talent and leverage in discussions with disease partnerships
  - A multilateral body like WHO best meets these needs
  - Few significant other benefits with an independent unit, e.g.,operational efficiency, political independence
  - Disillusionment with creating new stand-alone public health bodies
- **WHO is in the best position to provide this legal identity for GDF**
  - Clear technical mandate across disease areas
  - Provided good governance for GDF to date with a hands-off role at the center, working harmoniously with the STB Partnership
  - Critical to GDF's success in countries. This linkage will be stronger if GDF is housed within WHO
  - No strong case made yet to move GDF out of WHO to other institutions/private sector

Potential outline



EACH OF MDR-TB, MALARIA AND HIV/AIDS FULFILL THE CRITERIA TO JUSTIFY A GDF-LIKE MODEL

Criteria	Key elements	MDR-TB	Malaria	HIV/AIDS
		Products		
		• 2nd line TB drugs and drugs to relieve side effects	• Advanced anti-malarial drugs	• Drugs for AIDS- related diseases and ARVs
Technical fit	• Rational drug use critical • Standardization/innovation possible and necessary	◕	◑	●
+				
Economic case	• Global pooled procurement superior to regional/local mechanisms • Unmet treatment demand due to drug shortages	●	◕	●
+				
Implementation feasibility	• Availability of partnership support in-country • Government commitment	◑	◑	◑
	Conclusions	◕	◑	◕

THE TB "ONE-STOP SHOP" DOES NOT FULLY FIT THIS MODEL AND SHOULD NOT BE A HIGH PRIORITY FOR THE GDF

Diagnostics/ preventives	Assessment	Recommendation
• Sputum cups • Glass slides	**Technical fit** • Standardization is not important and quality is not an issue **Economic case** • Basic consumables – commodity pricing • Cheap local production often available, hence government commitment for global sourcing unlikely	**No** • Mobilize partners if identified as shortcoming
• Microscopes • Reagents	**Technical fit** • Technical assistance is needed however could be provided through partners, i.e. training, maintenance • Standardization would be helpful, i.e. if staff is transferred to a different health center, however could be coordinated through NTP **Economic case** • Contribution to the TB budget is small compared to drugs • Procurement for microscopes and reagents is an issues in few countries (4/22 HBC – WHO 2003 report)	**Conditional yes** • Check quality and recommend coordination for standardization of equipment and reagents in application and M&E process • Mobilize partners if identified as shortcoming • Expand on a systematic basis only if – Critical mass of countries find shortages a key barrier to DOTS implementation – Partner support is unavailable

FROM AN EXTERNAL PERSPECTIVE, "GDF"S FOR MALARIA AND HIV ARE DESIRABLE AND FEASIBLE AND THE IMPLICATIONS FOR THE STB PARTNERSHIP ARE POSITIVE

Interviews with:

- **STB key stakeholders**
- **Other disease partnerships**
- **Potential recipient countries**

Why GDF-model

Robust technical and economic case

Build on a tried-and-tested model

- Shown proof of concept in limited time - "*GDF has actually delivered drugs in under 1 year – would rather use something that is up and running"*
- Up the learning curve on procurement
- Model is flexible to be expanded to other areas; *"GDF is effective for patented and commodity products "*

Synergies at system and country level

- Relatively good brand awareness of GDF
- Synergies in country networks, application and common drug management infrastructure and issues
- System level synergies include common awareness-building, application procedures, procurement and sharing of best practices

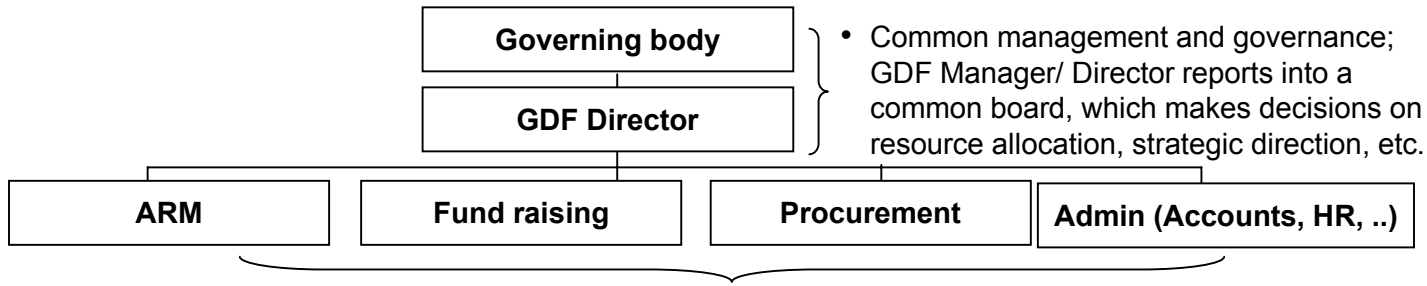
Benefits to the STB Partnership

- Positive reputation for STB as a innovative and impactful initiative, e.g., the Partnership could
  - Release a white paper on the GDF model and learnings for other diseases to catalyze demand from other areas
  - Host conference on access issues
- Increased visibility for STB could encourage new partners and donors to sign on
- Potentially improved cost-effectiveness through shared infrastructure for brand building, procurement and administration
- Potentially improved leverage for GDF brand in countries with combined scope
- No risk of loss of focus on TB or need for STB Partnership to invest own people/funds for "expansion"

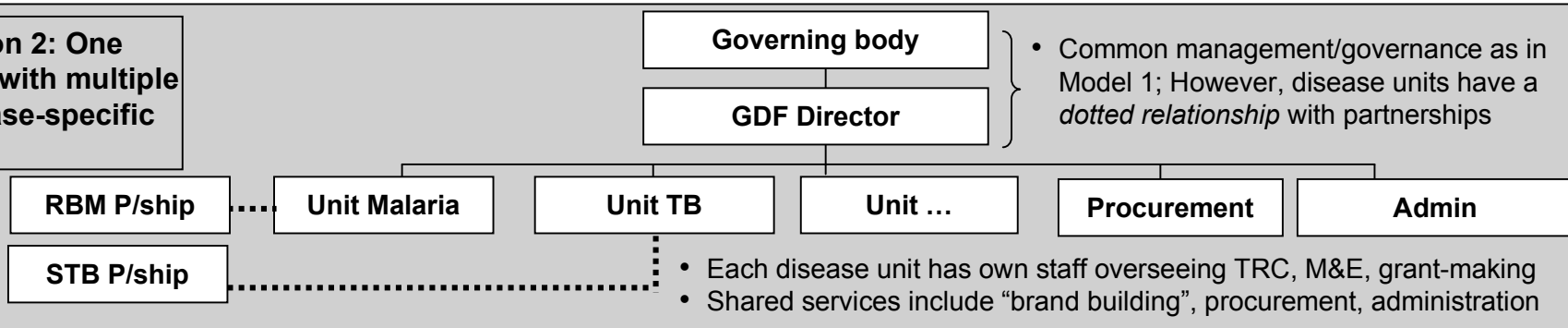
A LOOSE-TIGHT ORGANIZATION STRUCTURE WOULD BE OPTIMAL TO SUPPORT GDFs IN OTHER DISEASE AREAS

Likely and preferred approaches

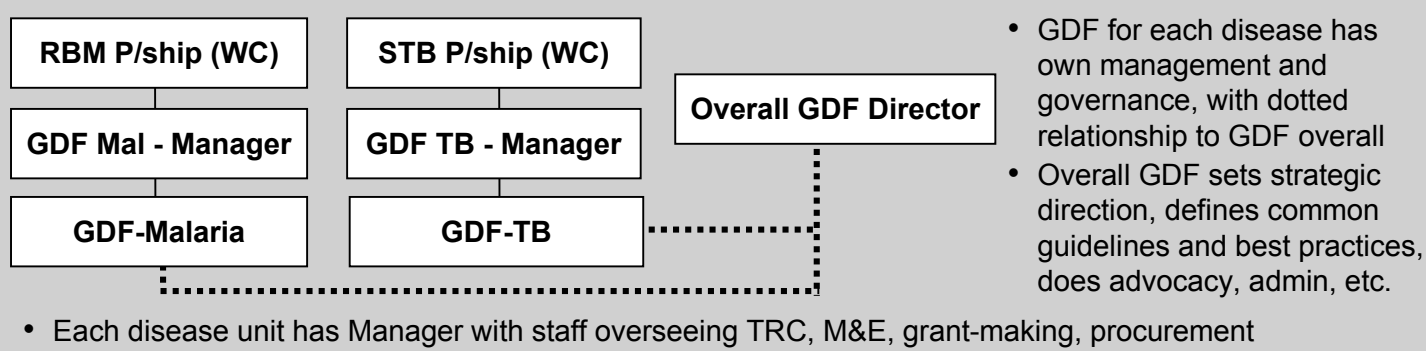
Option 1: Integrated GDF with one business system



Option 2: One GDF with multiple disease-specific units



Option 3: Multiple GDFs operating as franchises



Source: Team analysis