CONFIDENTIAL

Evaluation of the Global TB Drug Facility

STOP TB PARTNERSHIP
C/O WORLD HEALTH ORGANIZATION

Supporting Exhibits

April 2003

Exhibit 1

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

Approach for GDF evaluation

Pre-work and project kickoff → **Phase I: Diagnostic (6 weeks)** → **Phase II: Evaluation (4 weeks)** → **Phase III: Recommendations (2 weeks)**

Interviewees – International/regional experts and stakeholders

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

Country visits

GDF grantees

- India
- Kenya
- Moldova
- Myanmar
- Nigeria
- Philippines
- Somalia
- Uganda

Non-GDF grantees

- Romania
- South Africa

Exhibit 2

GDF HAS A TWO-PART MISSION: TO EXPAND ACCESS TO HIGH QUALITY TB DRUGS AND TO INDIRECTLY FACILIATE DOTS EXPANSION

Expected impact of GDF

- Direct
- Indirect

DOTS success factors	Description / examples
Drug supply	• A regular, uninterrupted supply of all essential anti-TB drugs
Government commitment	• Government commitment to TB control through DOTS, as evidenced by level of priority given to TB control, establishment of dedicated TB budget, appointment of senior staff, etc.
Infrastructure	• E.g. well-functioning in-country drug distribution, warehouses, clinics, lab equipment
Funding	• Funding for ongoing TB control operations (e.g. salaries, supplies) and for expansion (e.g. training)
Technical assistance	• Building medical / nursing / management capacity

"The Global Drug Facility (GDF) will expand access to, and availability of, high quality TB drugs and will thereby facilitate DOTS expansion"

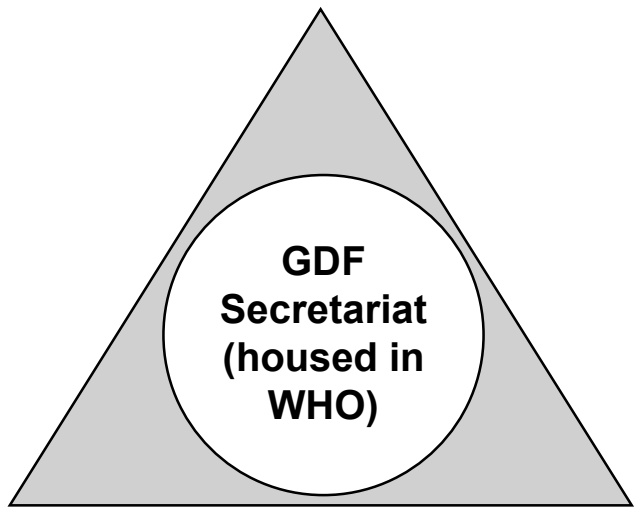
Source: GDF Prospectus; team analysis

Exhibit 3

GDF IS A LEAN PARTNERSHIP WITH COLLABORATING AND CONTRACTUAL PARTNERS AND A SMALL DEDICATED SECRETARIAT

Grant making – collaborating partners from the Stop TB Partnership

- Donors: CIDA, Government of Netherlands, USAID, World Bank



Procurement – Contractual partners*

- Procurement services - UNDP/IAPSO
- Manufacturing - MEG/Svizera
- Quality control/PSI - SGS
- Freight forwarding - Kuhne & Nagle and Mahe
- Quality assurance - SGS & WHO

Technical assistance – collaborating partners from the Stop TB Partnership

- WHO: Units like EDM, STB Department and regional/local offices
- Technical partners: E.g., GLRA, IUATLD, KNCV, MSH, NIPER, MRC, RIT Japan, World Bank, WHO

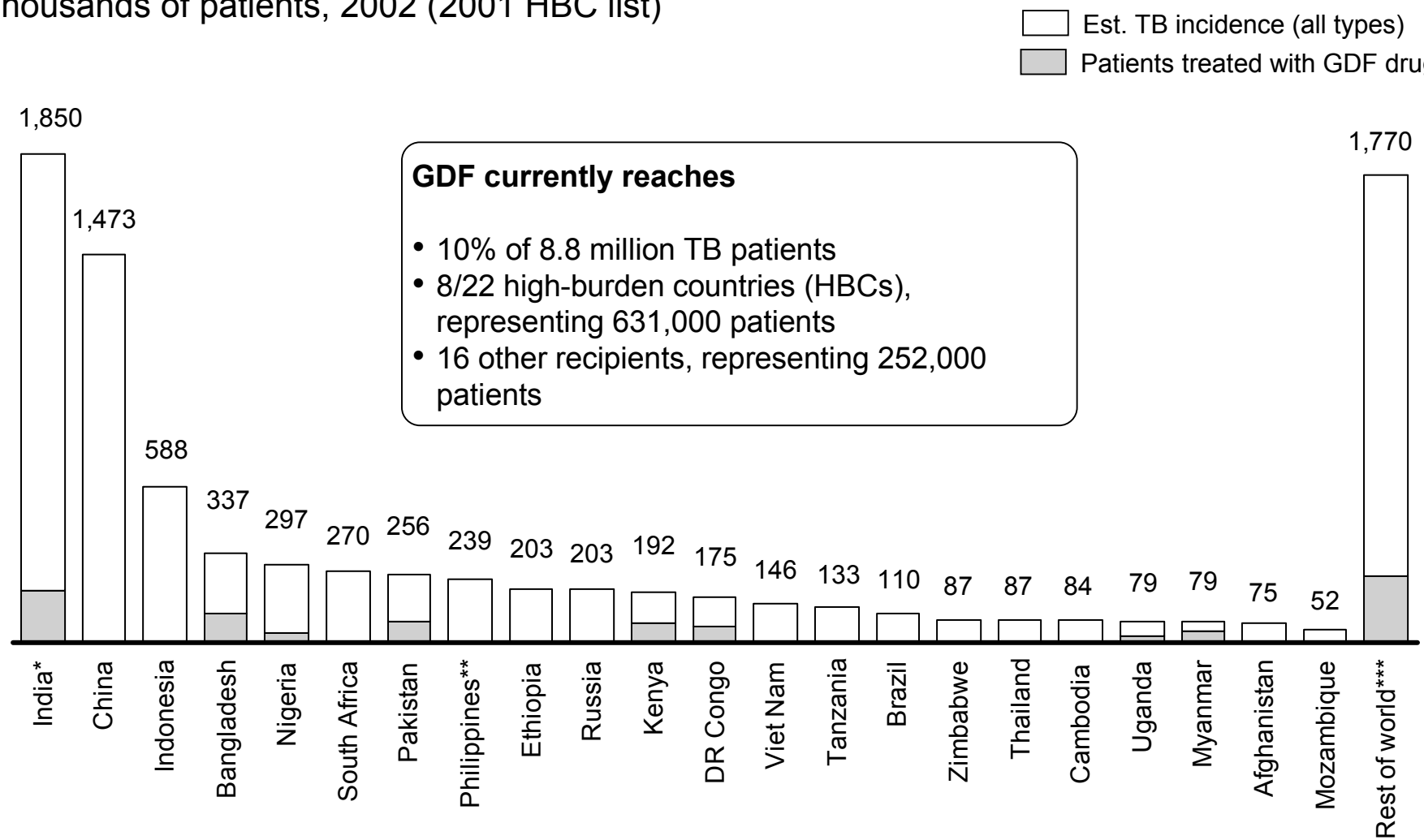
* Could be potentially revised after current round of bidding

Source: GDF

Exhibit 4

GDF HAS DEVELOPED A BROAD REACH ACROSS COUNTRIES IN LESS THAN TWO YEARS OF OPERATION

Thousands of patients, 2002 (2001 HBC list)



* India received a grant to buy drug from local suppliers

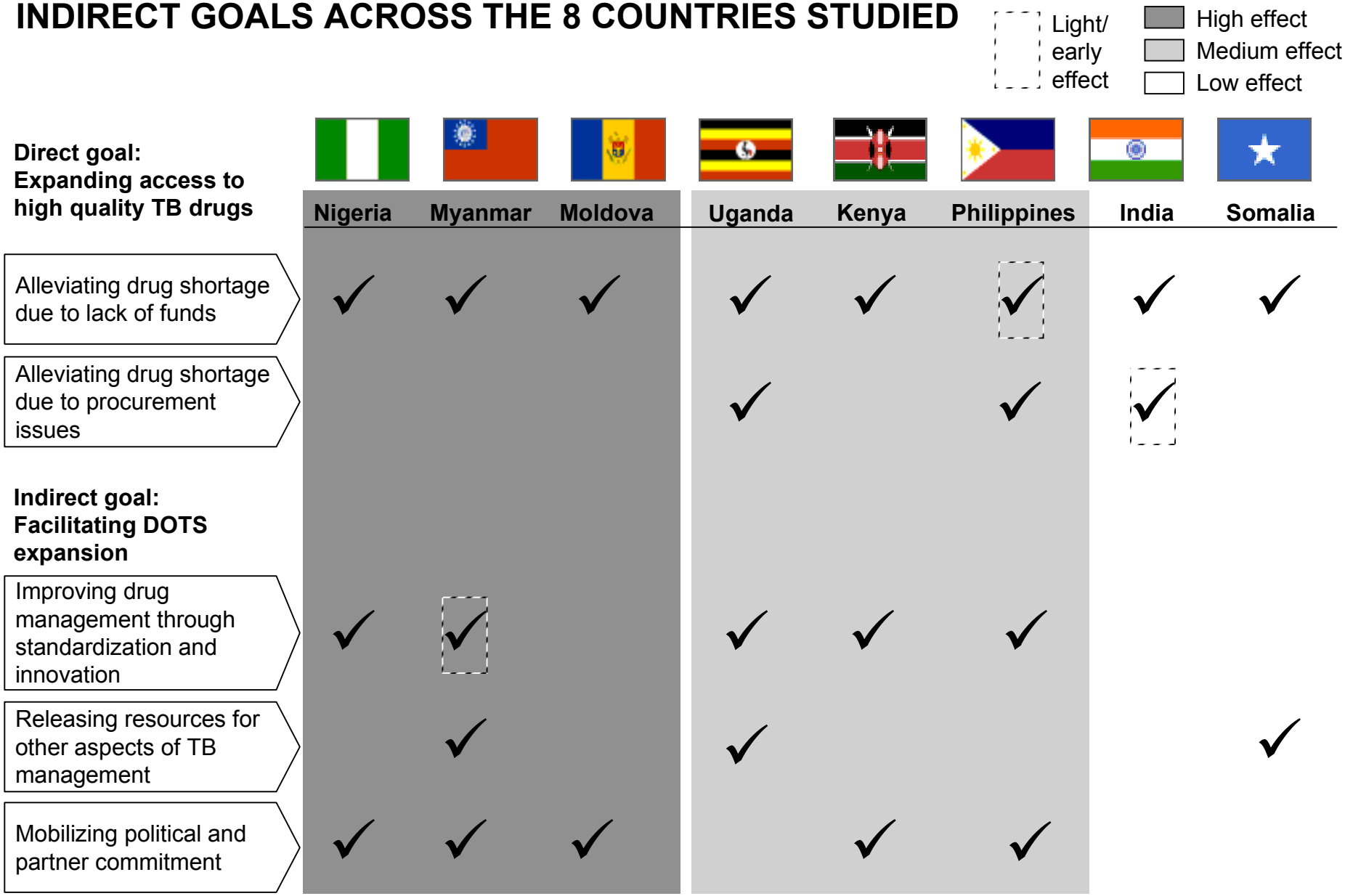
** Direct procurement

*** 16 recipients: Djibouti, DPR Korea, Liberia, Moldova, Somalia, Sudan, Tajikistan, Togo, Armenia, Central African Republic, Congo, Gambia, Mauritania, Uzbekistan, Zambia, Orissa State (India)

Source: WHO; GDF; team analysis

Exhibit 5

GDF HAS HAD A POSITIVE EFFECT ON BOTH DIRECT AND INDIRECT GOALS ACROSS THE 8 COUNTRIES STUDIED



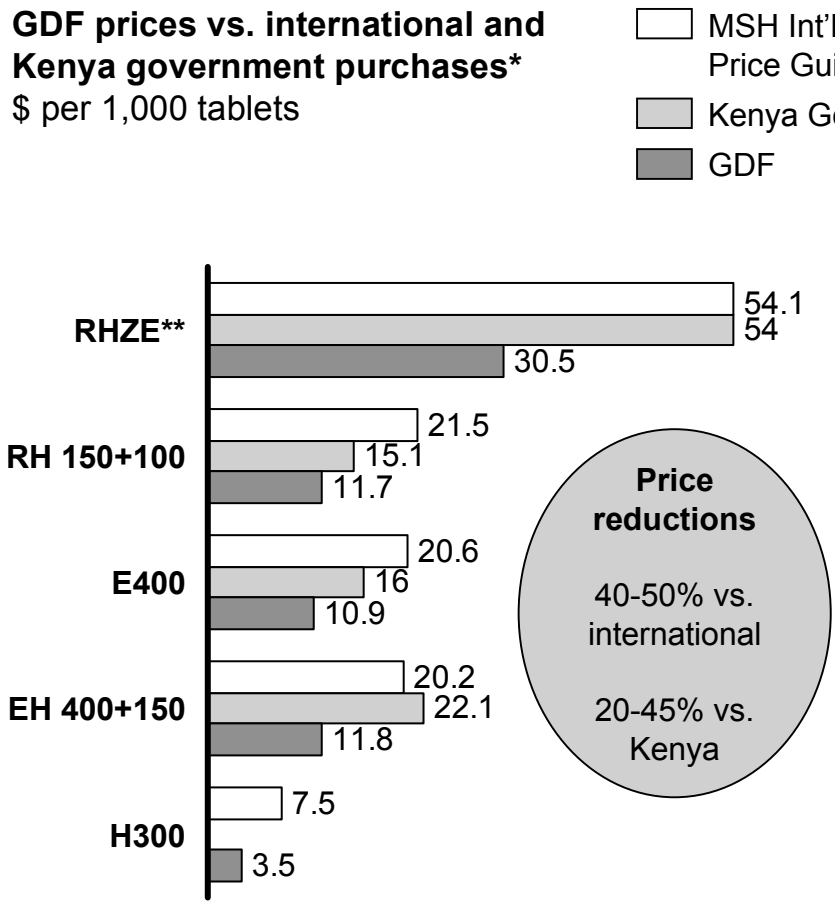
Source: Country visits; team analysis

Exhibit 6

GDF HAS ALSO IMPROVED THE PRICE AND QUALITY OF TB DRUGS, WHICH WILL BENEFIT ALL BUYERS

GDF prices vs. international and Kenya government purchases*

$ per 1,000 tablets



GDF impact on other aspects of TB treatment

- **Standardization and innovation:** Promoted the use of logistically superior, patient-friendly treatment regimens like 4FDC, blister packs, and patient packs. E.g., With GDF encouragement, Myanmar and the Philippines are adopting 4FDC, paving the way for easier drug management, lower risk of monotherapy/ drug resistance and drug leakages
- **"White list" of suppliers:** Used its relationship with WHO to promote the development of a white list of pre-approved TB drug suppliers. This list can now be used by all buyers without routing purchases through GDF
- **Awareness of quality and prices:** 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…*"
- **Facilitated access for underprivileged communities**: Grant conditions of free drugs and focus on countries with GNP < $3000 per capita

* Government of Kenya procurement before GDF

** RHZE 150+75+400+275

Source: GDF, MSH 2002 International Price Indicator Guide, Kenya NTP, team analysis

Exhibit 7

GDF HAS DELIVERS BENEFITS 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%
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

Exhibit 8

GDF IS UNLIKELY TO NEGATIVELY AFFECT LOCAL PROCUREMENT ABILITY. HOWEVER, IT SHOULD INCREASE EMPHASIS ON PLANNING FOR PHASE-OUT

Skills required in procurement	Potential GDF impact		Recommendations
• Demand forecasting	Positive	• Application supports forecasting • GDF can mobilize partners to help with demand forecasting	• Continue to mobilize partners to help if this is a bottleneck
• Budget allocation	Positive	• Application encourages TB drug budget line	• Continue to encourage / enforce
• Procurement agent selection, e.g. own procurement dept. versus agency selected via ICB • Supplier evaluation / selection • Price negotiation	Neutral to potentially negative	• In countries with poor overall procurement, reliance on GDF procurement for TB drugs could inhibit development of in-country procurement ability, making the country dependent on GDF or international aid agencies • GDF serves a small part of the universe of procured TB drugs	• **Develop three-step phase-out** – **Phase out grant** – Help build procurement ability – Monitoring / oversight x 2 years • **Help domestic suppliers qualify for 'white-list' status** – Mobilize technical assistance – Offer flexibility on pricing during bidding process*
• Quality assessment • Drug registration and clearance	Neutral to positive	• GDF asks for efficient application of in-country QA, registration, and clearance rules, not waiver	• --
• In-country drug distribution	Positive	• Application helps identify distribution bottlenecks • GDF can mobilize partners to help with in-country drug distribution	• Continue to mobilize partners to help if this is a bottleneck

* For example, 'emerging' suppliers could be allowed to win tender even if bidding x% higher than established suppliers

Source: Interviews, country visits, team analysis

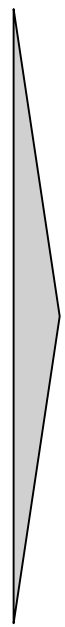
Exhibit 9

GDF's IMPACT ON REGIONAL PROCUREMENT EFFORTS HAS BEEN NEUTRAL AND SHOULD CONTINUE TO BE SO

- Current information from countries served by GDF is that no major regional procurement effort was shelved or undermined as a result of GDF's activities

- GDF's service lines are compatible with regional procurement
  - Regional procurement agents can use GDF direct procurement for qualifying member states. GDF could reach out proactively to these regions to gauge level of interest in region-level purchasing of GDF drugs
  - Countries with own funds have the option to choose GDF procurement / regional procurement / both
  - GDF's grant-in-kind function targets countries in which lack of funds is a bottleneck to drug availability. Grant-making for drugs is not a service offered by regional mechanisms currently

- GDF's mission does not call for it to become a TB drug monopsony. GDF does not aim to grant more than 30% the of world market–indeed there are a number of HBCs that it will likely not serve at all. GDF's control of the supplier base will therefore not be enough to inhibit the development of regional procurement networks, if others are willing to develop them



- To date, GDF has had no observable impact on the development of any potential regional procurement networks
- GDF's mission is compatible with the existence of regional procurement networks
- GDF's could assess regional agents' interest in purchasing of GDF drugs using the regional procurement mechanism

Source: Interviews; team analysis

Exhibit 10

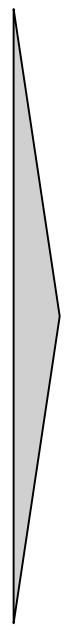
GDF's EFFECT TO DATE ON LOCAL SUPPLIERS HAS BEEN NEUTRAL TO POSITIVE

- **Countries with their own TB drug supply have chosen not to use GDF, even if GDF procurement was cheaper**. E.g. South Africa (where local prices are three times GDF prices) and Romania. GDF impact on these countries' suppliers is therefore nil

- **Many countries served by GDF do not have local TB suppliers, and procured internationally even before GDF's arrival**. E.g. in Nigeria, TB drugs are purchased by technical partners from a number of international suppliers. GDF impact on local suppliers in these countries is therefore nil

- **GDF has stimulated the development of a WHO 'white list' of high-quality suppliers of TB drugs.** Local suppliers who qualify can therefore more easily have access to international markets. Some countries like the Philippines and Romania, have asked about how to encourage their local producers to qualify for the WHO white list. GDF impact in this case is positive

- **GDF has stimulated governments of some countries with local manufacturers to evaluate more closely drug quality and price.** E.g. in Indonesia and Romania. GDF impact in this case is positive



- Information from countries suggests that GDF's impact to date on local TB drug suppliers has been neutral to positive

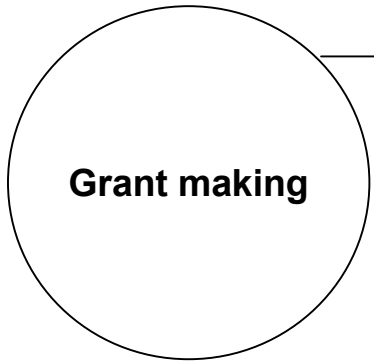
- With the expansion of the WHO white list, GDF will likely be able to be more flexible in meeting country requests for supply of quality drugs from local sources

- Further, GDF could also indirectly help increase price and quality awareness, for example, through its advocacy and influencing the institution of a drug pricing commission in countries where drug prices are many multiples of GDF prices

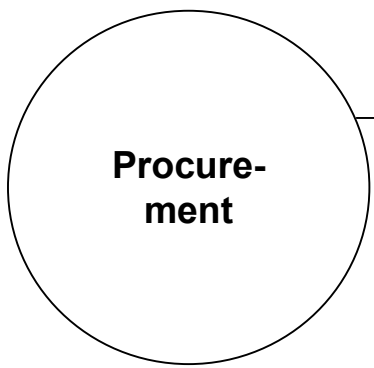
Source: Interviews; team analysis

Exhibit 11

THE GDF MODEL HAS THREE ELEMENTS, EACH WITH ITS OWN BENEFITS



- **Grants increase leverage** of GDF and Stop TB network to mobilize government and partner commitment
  - E.g. The Government of Kenya delivered on its commitment to buy TB drugs after receiving an 'orange light' from the country M&E mission
- **Grants free up resources** to be invested in other aspects of the TB program



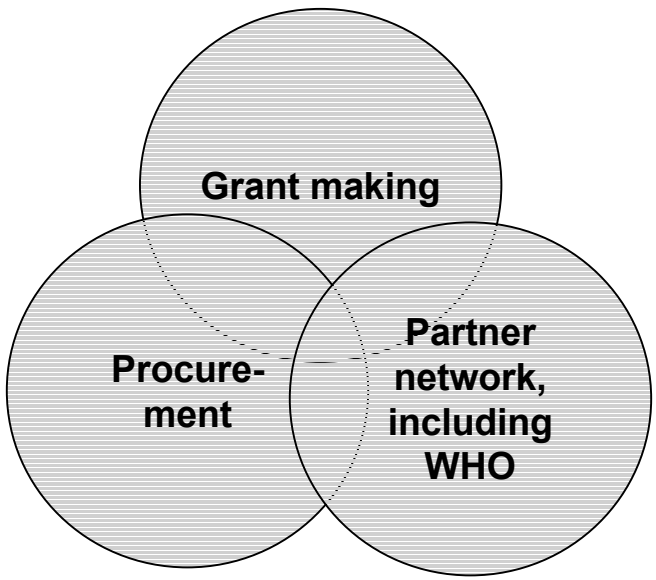
- **Procurement capability** allows GDF to have **impact in countries with funds but poor procurement**, e.g. the Philippines

- **WHO** performs a **normative role** of setting treatment standards, e.g. 4FDC and **certification of manufacturers** via the white list
- **Partners** are already positioned in many countries to provide **in-country technical assistance**

Source: Team analysis

Exhibit 12

IT IS THE BUNDLING OF THESE THREE ELEMENTS IN GDF'S PROPOSITION THAT GIVES IT GREATER IMPACT



- **Grants-in-kind** of **GDF-procured drugs** is more powerful to **mobilize partners** than grants alone
  - Free drugs are "real" products to kick start a program and hence, significantly energize governments and partners
  - Country examples: Moldova, Myanmar, Nigeria
  - *"…Why would anyone build capacity for diagnosis and treatment when there are no drugs to give people at the end of the process?…"*
  - Precedent in leprosy: *"…In leprosy, we changed the world when we were able to give free drugs in '95, everything else happened around that…"*

- **Grants and the partner network** allow GDF partners to provide relevant technical assistance to support the drug grant, not piece-meal or stand-alone support

- **Grants, the WHO link and procurement** allow GDF to **guarantee sufficient demand** to encourage manufacturers to produce the drugs and formulations recommended by WHO, reduce prices and promote standardization/innovations

- **Grants-in-kind linked to procurement** reach countries faster than through separate granting and procurement processes, and with fewer 'leakages'
  - *"…even if GDF had given them money, it would have been a headache and impact would not have happened so fast. Drugs in kind is great"*

Source: Interviews; team analysis

Exhibit 13

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

Beneficiary segment	Examples	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 to offer assistance, e.g., initiate dialogue through WHO and other partners, contact through multiple channels in pre-application stage
• **"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, non-traditional agents 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, Romania	• 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; the institution of a drug pricing commission in South Africa, where drug prices are 3-4 times higher than GDF prices, may increase sensitivity to GDF's value proposition

"Core" GDF beneficiaries

Source: Team analysis

Exhibit 14

GDF HAS MET MUCH OF THE NON-DRUG RELATED NEED FOR ASSISTANCE BY MOBILIZING ITS PARTNER NETWORK OR THE GOVERNMENT

ILLUSTRATIVE

Most important constraints in HBCs

Constraint	Example from country visits
Human resources	• CIDA funded TB personnel training in Nigeria after GDF grant
Decentralization	• NGOs procuring drugs in Nigeria are coordinating procurement through GDF
Private sector	• PHILCAT and NTP in Philippines are co-championing the PPM pilot applying DOTS principles with a GDF grant
Infrastructure	• Nigerian government (federal and state) committing to infrastructure upgrades • JSI-DELIVER project with Kenya's NTP for in-country drug management
Political commitment	• Moldovan government committing to DOTS expansion plan
Access to DOTS	• DOTS expansion to 16 regions in Nigeria once GDF drugs arrive there
Financing	• Other donors stepping in to Moldova after GDF grant
Community awareness	• Myanmar MOH beginning social mobilization plans with JSI
Monitoring	• …
Drugs	• …
Laboratories	• …
HIV/AIDS	• …

Source: WHO Report 2003: Global TB Control, country visits, team analysis

Exhibit 15

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

From a customer need perspective…

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

From the GDF's operational 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 and fragmented across small groups of countries, 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. These could be, for example,
  - ***Facilitate subject-specific conferences*** (e.g., Washington Conference on Drug Management)
  - ***Share best practices across countries*** (e.g., transition to FDC, use of drug grants in public-private programs)
  - ***Facilitate the publication of guidelines through WHO*** (e.g., 4FDC guidelines/training manual)

Source: Interviews; team analysis

Exhibit 16

EFFECTIVENESS OF GDF'S FULL VALUE PROPOSITION DEPENDS ON IT PROVIDING GRANTS

	GDF intervention	Potential bottlenecks in DOTS expansion
GDF can help address some drug shortage issues via direct procurement alone…	**Direct procurement** • Allows countries to buy quality drugs more cheaply through GDF, and thereby reduce procurement-related problems in drug supply for DOTS	**Drug supply due to procurement issues**
…but having an impact on non-drug bottlenecks is dependent on the 'carrot' of providing grants and the 'stick' of post-grant M&E	**Grants** • Encourage governments to develop strong DOTS plans to win grant and attract other donors	**Drug supply due to funding gaps**
	• With associated M&E, encourage governments to honor commitments and ensure rational use to be eligible for more aid	**Political commitment and planning**
	• Allow funds to be reallocated to meet resource gaps in non-drug areas and be invested in technical assistance • Allow GDF to mobilize and coordinate actions of partners	**Other bottlenecks, For example,** • Human resources • Infrastructure • Laboratories

Source: Team analysis

Exhibit 17

IN THE ABSENCE OF GRANTS, GDF'S IMPACT DIMINISHES ACROSS ALL POSSIBLE SCENARIOS

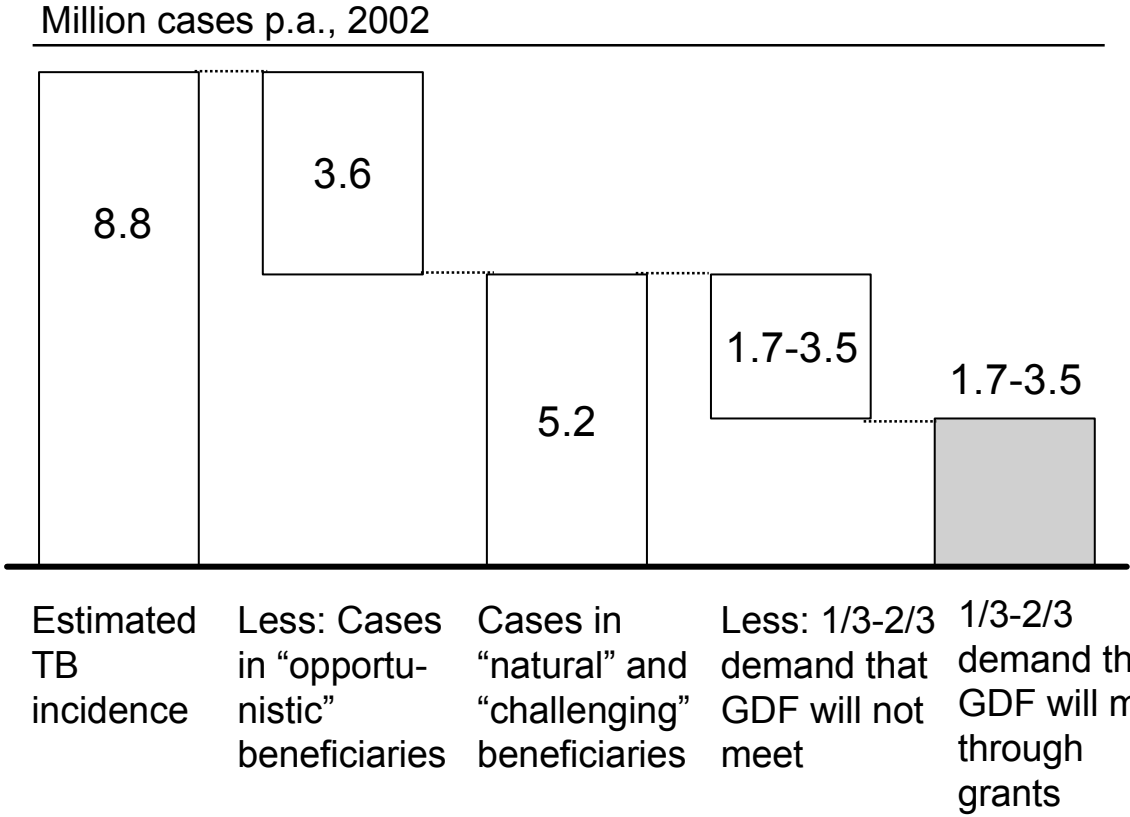
Scenario	Description	Implications for the GDF
Direct procurement agent	• Donor gives grant to country, and maintains M&E function • Country has choice of procurement agent, including the GDF	• The GDF would lose – Financial leverage (both carrot and stick) to encourage DOTS expansion – Ability to promote 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 the GDF as procurement agent	• The GDF would lose financial leverage to encourage DOTS expansion
Mandated procurement agent	• Donor gives grant to country and mandates the GDF as procurement agent • Donors delegates M&E function to the 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 the GDF retains the carrot and the stick • Would any donor give up this degree of control over M&E?

Source: Team analysis

Exhibit 18

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

TOP-DOWN ESTIMATE



- 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

Source: Interviews; team analysis

Exhibit 19

GDF'S BUSINESS MODEL HAS SERVED IT WELL IN MEETING THE NEEDS OF AN ORGANIZATION IN A "START UP" MODE

Grant-making

- Sustained donor commitment for years 1 and 2; >80% of funds disbursed
- However, significant shortfall for 2003, and no commitments yet for 2004+
- Limited cash flow planning and unclear communication to the Board
- Limited advocacy and brand-building to broaden funding base

Application/ review

- Awareness building at system/country level largely through emails during application or WHO/STB partners; limited budget for advocacy
- TRC a well-functioning team, highly regarded for its experience, technical expertise and independence
- Processes for application/review set up very quickly, but team overstretched and lead times longer than targeted; M&E systems nascent

Procurement

- First approach for selection of procurement agent/supplier in 2001 designed for rapid launch; however, not fully in line with donor/partner expectations
- Negotiated price reductions significantly below international norms
- Good initiatives on standardization/innovation in products. Can improve through user-friendly disease information and introducing drugs for treatment of children

Coordination of Stop TB partners

- STB partners present and mobilized to some extent in most countries. However, where traditional partners not present (e.g. Somalia), relationships with other partners not proactively established
- Partners positive and helpful in cases where applications come from the NTP. Limited track record where applications come from NGOs/non-traditional partners
- More proactive partner mobilization around identified gaps needed to ensure impact beyond access to drugs alone

Source: Interviews; team analysis

Exhibit 20

GDF MUST IMPROVE OPERATIONS IN THREE KEY AREAS

	Recommendations
Build awareness/ advocacy for GDF	• Engage in significant "brand-building" both with country beneficiaries and donors/STB partners in order to raise more funding, catalyze partners for DOTS expansion and increase leverage with governments. For example, – 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 – Building awareness with key donors, foundations, partnerships and partners
Mobilize partners	• Fully leverage WHO across all countries for advocacy, communication with MoH/NTP, relationships with partners, TA and facilitate drug entry into port • More proactively involve partners, especially non-traditional parties – Strengthen applications with partner input – Encourage 'ownership' of key 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
Strengthen procurement	• 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, as well as economics for GDF, procurement agent and country • Clearly communicate processes/economics of direct procurement to key stakeholders

Source: Interviews; team analysis

Exhibit 21

GDF'S MANAGEMENT TEAM HAS LARGELY MET EXPECTATIONS

● Needs fully met
◑ Somewhat met
○ Not met

Needs in start-up mode	Assessment	Quotes/examples
Lean and innovative management team	◕	• Made GDF operational in a short time with a very lean staff • Used secondments for technical expertise (e.g. procurement , drug management) • High level of commitment, "can do attitude" and willingness to experiment; *"Highest marks for hard work, conscientious, enthusiasm, responsiveness"* • Demonstrated ability to grow into stretch role and if coached, have potential to develop further • However, short-staffed for future growth, with some gaps in skills and formal systems, e.g., brand-building, financial planning and M&E
Dynamic and technically strong leadership	●	• To many partners, Ian Smith represents the GDF – *"Ian has demonstrated excellent management and leadership skills."; "He has found a way to apply private sector approaches in a public sector setting despite huge opposition"* • However, critical vacuum in leadership with current transition
Credibility and access to countries	◑	• Accessed countries through WHO offices and partner links in countries. WHO linkage also provides credibility to solicit applications • However, regional and country WHO staff often unclear on their full role with respect to the GDF and sometimes, over-stretched to meet this additional commitment
Access to technical expertise	●	• TRC highly regarded as a technically competent, independent and well-balanced team with depth of functional and regional expertise – "*One of the most impressive and capable group of people –they take their job seriously"* • TRC processes continuously being improved to reduce lead times, facilitate more informed discussions, reduce travel for members, etc.
Smooth coordination with Stop TB partners and other efforts	◑	• GDF management team seen as being responsive to partners' suggestions and accountable to the STBCB • After initial issues in working with WHO departments, GDF and WHO now actively cooperate, e.g. with the DOTS expansion Working Group and EDM • However, communication with partners and mobilization for TA must be improved

Source: Interviews; team analysis

Exhibit 22

HOWEVER, GOING FORWARD, THE TEAM WILL NEED TO BE STRENGTHENED TO FULLY MEET THE NEEDS OF A GROWING GDF

Key challenges	Issues
Critical leadership transition	• Significant transition with exit of three key people (Ian Smith, Jacob Kumaresan, J.W.Lee) perceived as providing technical credibility, maturity in dealing with partners and ensuring a balanced role for WHO • Critical to find a new leader with a balance of skills – managerial expertise to complement technical skills; political maturity to handle multiple partners; suitably strong profile to be the face of GDF and support its brand-building and fund-raising efforts
Staff shortage and skill gaps; **Few robust professional systems**	• Significant staff shortage to support GDF growth. Current team running at significantly >100% utilization, resulting in de-prioritization of key efforts like M&E, advocacy and strategic planning • Staff perceived to be high on enthusiasm but low on experience. This is exacerbated by short term contracts and contract breaks, causing gaps in institutional memory. Some have also suggested that GDF tap a broader range of expertise through secondments or consulting contracts, beyond WHO • Some skill and system gaps in important functions, namely advocacy/brand building; strategic, financial and operational planning; M&E and knowledge management • Informal style of communication has worked within the team; however, communication with partners, the Stop TB Partnership and Board, in-country agents and WHO have not always been adequate or efficient
Evolving organizational structure	• GDF's reporting structure works on two dimensions - country servicing and functional expertise, both of which are expanding in parallel. Developing an appropriate flexible matrix reporting structure to deliver against this would be critical • Emerging matrix structure matches current functions, but important issues need to be addressed: – Shared responsibility for country between supply and demand side requires close coordination between ARM country officer and supply country officer, which can be cumbersome and cause delays as the team expands – It is not entirely clear where direct procurement function fits into the organizational structure; it will also require marketing and branding efforts that are currently not accounted for (and thus get neglected) – No clear ownership in current structure for GDF financial and business planning, operations and management systems (spread across GDF and STB Secretariats)

Source: Interviews; team analysis

Exhibit 23

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	• With growth in GDF's activities, negotiate with WHO for a cap on payments to WHO (in absolute terms, not as % of budget), to benefit from growing scale of operations • Improve transparency and structuring formats in the reporting of financial payments
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 at least 2 long term positions 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

Source: Interviews; team analysis

Exhibit 24

THE STOP TB PARTNERSHIP MUST ENSURE FUNDING OF $20-30M P.A. TO GDF FOR EACH OF 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%
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

Exhibit 25

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

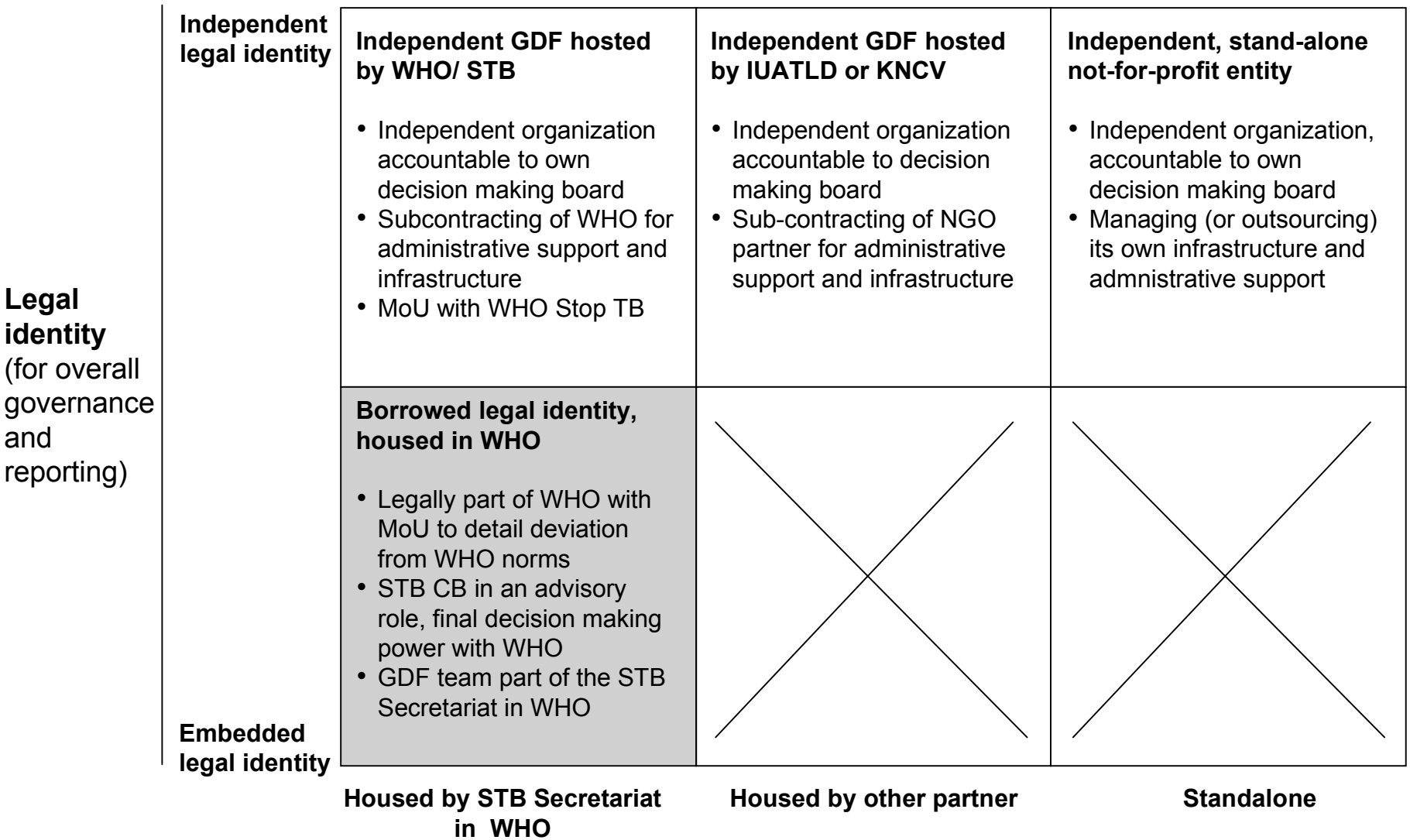
	Description	Issues to explore
Current GDF donors	• CIDA, Netherlands government (« founding » donors) • USAID, World Bank, OSI, DFID	• Views on GDF impact and continuing alignment of GDF operations with donor objectives • Position vis-à-vis Global Fund • "What GDF would have to look like" to continue being funded by current donors
Other TB donors	• JICA, other governments/ bilateral donors, public health-related foundations	• 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	• Mechanics of drug donations • 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

Source: Interviews; team analysis

Exhibit 26

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

Option chosen



Source: GDF Prospectus; interviews; team analysis

Exhibit 27

THE GOVERNANCE MODEL HAS MODERATELY SATISFIED THE NEEDS OF GDF

● Fully met
◑ Somewhat met
○ Did not meet

What the GDF needed at start-up

- 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

Needs met to some extent…

◑

- 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 from STB donors
- Quick set-up time without a politically contentious process, by not setting up a board from scratch
- 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" on governance

…but roles to be clarified

What GDF needs:

- Active engagement of the governing body in setting strategic direction and clear mandate for decision making
- Strong oversight ("audit") of financial and operational aspects, performance monitoring and succession planning
- Clear ownership of legal liability

However,

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

Source: Interviews; team analysis

Exhibit 28

CLEAR ROLES MUST BE DEFINED FOR WHO, THE STOP TB BOARD AND THE WORKING COMMITTEE

Requirements

- Clear "legal" responsibility for the GDF
- Strong processes for decision-making and oversight
- Appropriate balance in roles of the STB Partnership and WHO
  - – The Partnership is critical to deliver the 3-part proposition
  - – WHO is the only party that can have with legal liability for GDF

Recommended governance model

WHO

- Legally responsible for GDF
- Holds final veto power on all decisions; acts through STB Director
- Has effective control, exercised through
  - – STB Director as Chairman of the WC
  - – Large presence on CB of WHO or WHO-nominated people

STB Partnership – Coordinating Board

- Technically, "advisor" role, making recommendations to WHO, as it cannot legally influence decisions
- In practice, is a strong influencer, as donors on the CB control fund flow into the Trust Fund
- Hence, acts as the "Board" for the GDF; makes recommendations on strategy, provides oversight

Working Committee*

- STB Board delegates "operational" oversight of GDF to the Committee

GDF Management

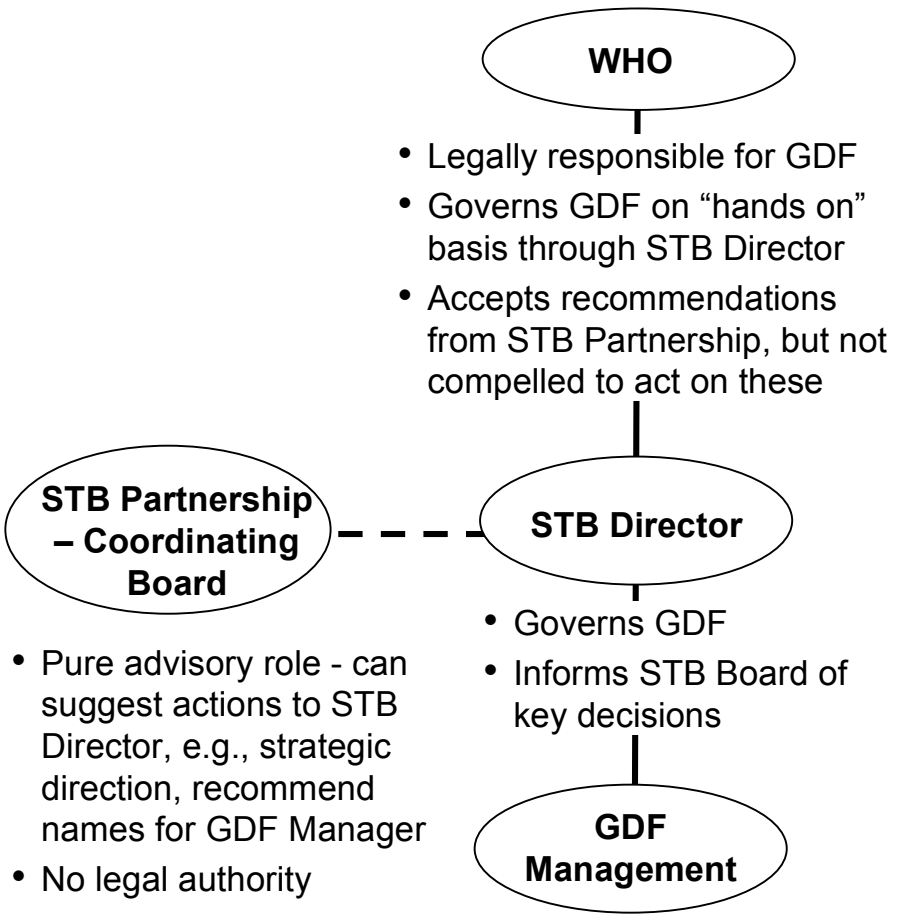
* The Board sets up the WC to "operationalize" its role, given the Board is a 27-member group that meets only 2X a year

Source: Interviews; team analysis

Exhibit 29

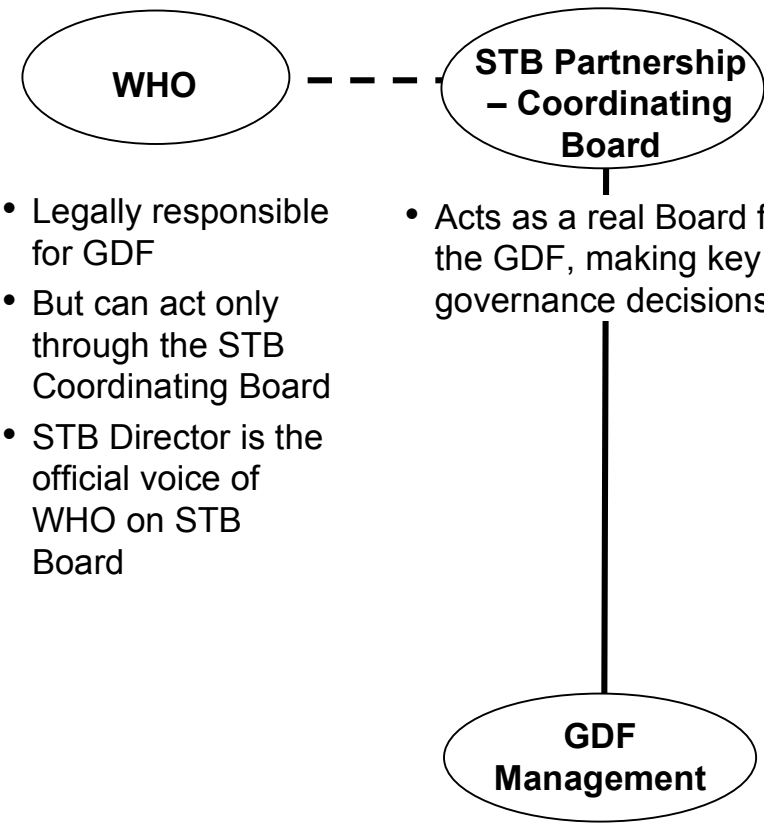
ALTERNATIVE MODELS WERE CONSIDERED AND REJECTED

Option 1



Pros: No ambiguity on governance. WHO explicitly and actively responsible
Cons: Little influence/role for STB partners, who could limit support and undermine effectiveness of the GDF

Option 2



Pros: No ambiguity on governance - STB Partnership responsible
Cons: Unlikely to be acceptable or allowable for WHO if it has final legal liability. STB Board has no legal position

Source: Interviews; team analysis

Exhibit 30

POTENTIAL ROLE OF THE WORKING COMMITTEE

ILLUSTRATIVE – NOT EXHAUSTIVE

Context

- The Working Committee is a subset of the Stop TB Coordinating Board, to "operationalize" the Board's role with respect to GDF
- It does not replace the Board's responsibility or decision-making powers on any GDF-related matters
- It is intended to provide closer oversight and guidance for GDF in areas that the Board is typically meant to oversee
- The WC should be a 4-6 member group drawn from the STBCB, representing groups and expertise relevant to GDF. It should meet (in person or conference call) every quarter or more often, as needed by GDF

Potential role of the Working Committee

The WC would be entrusted with four roles:

- Review robustness of the GDF management team's actions and recommendations and ensure these are supported by an adequate fact base
- Ensure appropriateness of procedures ("audit") for key decisions and that necessary approvals have been obtained
- Provide expert guidance in areas requested by the Board
- Flag major concerns to the Board and advise course of action, on operational and policy matters

The WC would execute these roles in many areas. For example,

- GDF's annual budget and cash flow planning, including financial projections for next three years and funding situation
- GDF's annual strategic plan and operating plan
- TRC decisions
- Procedures for major external contracts made by GDF, e.g. procurement, supply
- Major financial transactions
- Candidates short listed for senior positions in GDF

Source: Team analysis

Exhibit 31

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 and 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/AIDS 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**

Source: Team analysis

Exhibit 32

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

MDR-TB: Good support from GLC	Malaria: RBM willing but needs to build capability	HIV/AIDS: Lack of clarity on partnership itself
• Well-regarded body with strong technical review, credibility with donors, support of the STB Partnership • Discussions in progress for convergence of GDF and GLC	• Interested in using GDF model for advanced anti-malarials • However, much skepticism on capability of the current RBM Partnership - *"RBM is at least 6 months away from becoming a well-functioning partnership"*	• Highly political and contentious area, no clarity on decision-making body • Perceived historical enmity between TB and HIV groups; *"'GDF' for HIV is a nonstarter.. The chasm has not healed"*

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

✓Robust negotiation process for continuous reduction in prices ✓Funding from STB donors to the GDF *or* mandated procurement agent status with key donors	✓Standardization of treatment regimens and protocols, at system/regional/country level ✓Well-functioning RBM Secretariat and Partnership (e.g., clear goals, global malaria strategy, partner roles) ✓Country level commitment, able program managers, plans ✓Robust negotiation process for continuous price reduction ✓Funding from RBM donors	✓Well-defined partnership with clear mandate on access ✓Standardization of treatment regimens and protocols at system and country level ✓Country level commitment, support for lifetime care ✓Robust negotiation process for continuous price reduction ✓Funding from key donors *or* mandated procurement agent status with key donors

Source: Interviews; team analysis

Exhibit 33

MDR-TB, MALARIA AND HIV/AIDS HAVE UNIQUE ACCESS-RELATED NEEDS, WHICH REQUIRE SOME MODIFICATIONS TO THE GDF MODEL

MDR-TB (GLC process)

- **More rigorous application, review and M&E**
  - Rational use more critical; limited reliable data on resistance pattern
- **Relatively higher funding need, but may not need own grants**
  - GLC-negotiated price=$1,600/ treatment on an average
  - However, may not need own grant making given preferred pricing relationship with supplier and mandated agent relationship with GF
- **Emphasis on advocacy and work through specialized centers**
  - Few countries have identified and prioritized MDR-TB issues
- **Modified negotiation approach with suppliers**
  - Products either patented or restricted supplier base
  - Hence, price negotiation done by GLC/MSF vs. procurement agent

Malaria

- **Pre-work on technical guidelines at regional and country level**
  - No comprehensive data on drug resistance patterns; few revised drug policies
  - Standardized treatment guidelines possible only at a regional level
- **Ability to work with non-traditional partners (private sector, NGOs)**
  - Treatment at community level
- **Modified negotiation approach with suppliers**
  - Products either patented or restricted supplier base
  - Some supply issues different from pure generics

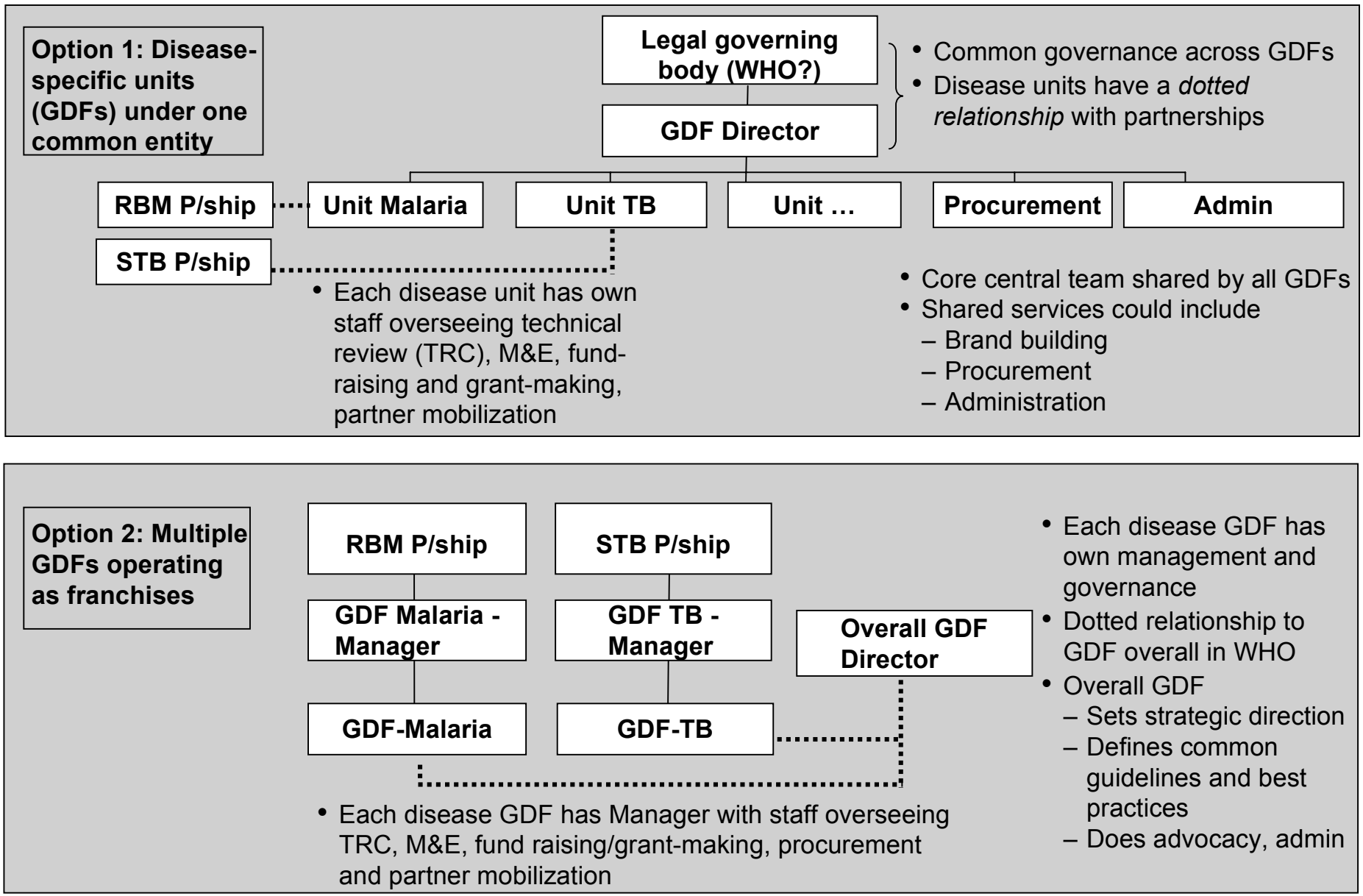
HIV/AIDS

- **Pre-work on standardization at system and country level**
  - Need consensus and WHO-mandated treatment regimens
- **More sophisticated negotiation approach and political management**
  - Highly visible political and contentious issues
  - Multi-sectoral stakeholders
  - Debate around patent rights, TRIPS, regional and local procurement/supply, drug grants, etc.
- **Similar issues to MDR-TB**
  - More rigorous application, review and M&E
  - Emphasis on advocacy and work through specialized centers
  - Modified negotiation approach with suppliers
  - Significantly higher funding need but may not need own grants

Source: Interviews; team analysis

Exhibit 34

TWO ORGANIZATION APPROACHES TO CREATE DISEASE-SPECIFIC GDFs



Source: Interviews; team analysis

Exhibit 35

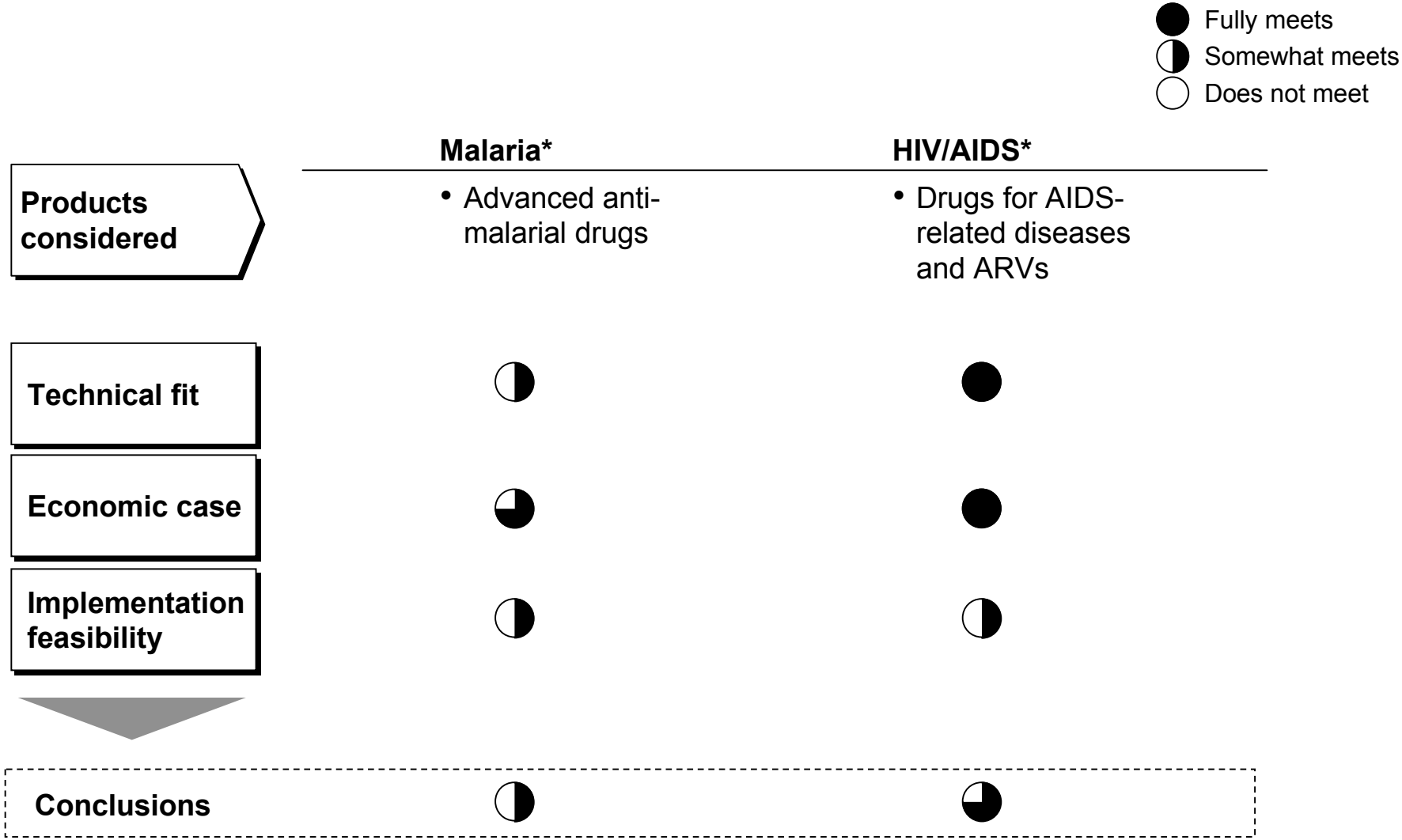
DISEASES/PRODUCTS MUST FULFILL THREE CRITERIA TO BENEFIT FROM A A "GDF" MODEL

Criteria	Key elements	Description
Technical fit	• Rational drug use critical	• Technical review and M&E needed to enforce right treatment protocols to minimize risk of creating resistance and transmission
	• Standardization/innovation possible and necessary	• Treatment standardization and innovations in drug delivery (e.g. packaging) important for compliance, treatment success and drug management
+		
Economic case	• Global pooled procurement superior to regional/local mechanisms	• Buying power leverage to significantly reduce prices, ensure quality, influence product norms and stabilize demand forecasts
	• Unmet treatment demand due to drug shortages	• Drug shortage - due to resource gaps and/or procurement problems - a key issue in disease control
+		
Implementation feasibility	• Availability of partnership support in-country	• Current/potential support assured for technical assistance from in-country partners
	• Government commitment	• Willingness to launch a national disease control program with adequate funding/ people support and infrastructure

Source: Team analysis

Exhibit 36

MALARIA AND HIV/AIDS LARGELY MEET THESE CRITERIA



* Commodities like bednets and condoms are not included here

Source: Interviews; literature review; team analysis

Exhibit 37

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

Diagnostics/ preventives	Assessment	Recommendation for GDF expansion
• **Sputum cups** • **Glass slides**	**Technical fit** • Standardization and quality not critical issues **Economic case** • Basic products – commodity pricing • Cheap local production often available, hence government commitment for global sourcing unlikely • Not material cost item in TB budget	**No** • Mobilize partners if identified as shortcoming during application
• **Microscopes** • **Reagents**	**Technical fit** • Technical assistance needed, but can be provided through partners • Standardization helpful, but not critical. Can be coordinated through NTP **Economic case** • Not material cost item in TB budget • Access not an issue in a critical mass of countries (only in 4/22 HBC – WHO 2003 report)	**Conditional yes, only if -** • Explicitly check for quality of lab facilities during application and M&E • Work through NTP or mobilize partners, if identified as a shortcoming • Expand on a systematic basis *only if* – Critical mass of countries find shortages a key barrier to DOTS implementation – Partner support is unavailable

Source: Interviews; literature review; team analysis

Exhibit 38

"GDFs" FOR MALARIA AND HIV/AIDS 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 model can be effective for patented and commodity products "*

Synergies at system and country level

- Relatively good brand awareness of GDF in some countries
- 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

- Increased visibility for Stop TB could encourage new partners and donors to lend support
- Potentially improved cost-effectiveness through shared infrastructure for brand building, procurement and administration
- Potentially improved leverage for GDF brand in countries with combined scope

And

- No risk of loss of focus on TB or need for STB Partnership to invest own people/funds for "expansion"

Source: Interviews; team analysis