

Accelerator for Impact (**a4i**)

Creating the future together

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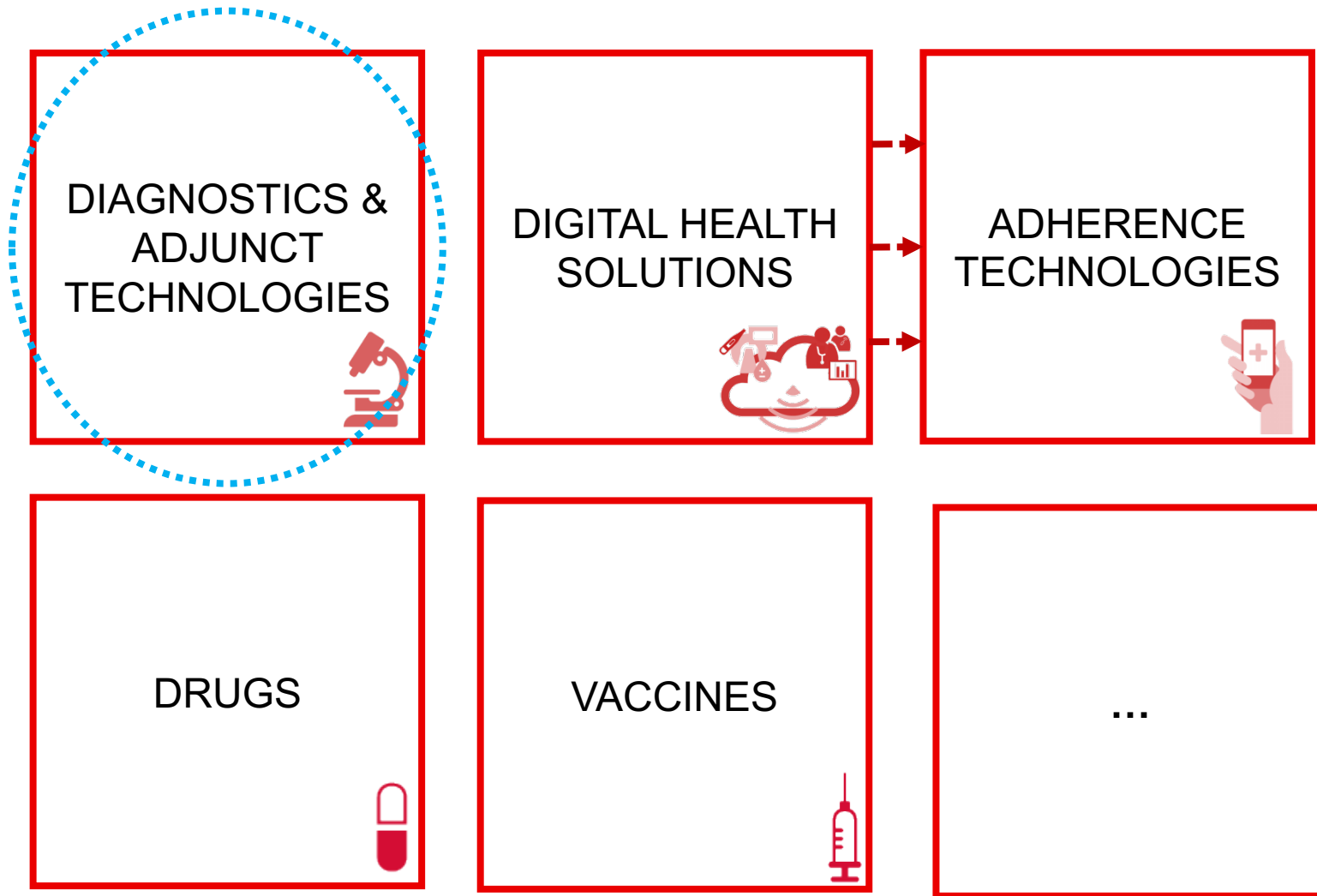
19 June 2017

McGill Summer Institute's 7th Advanced TB Diagnostics Course

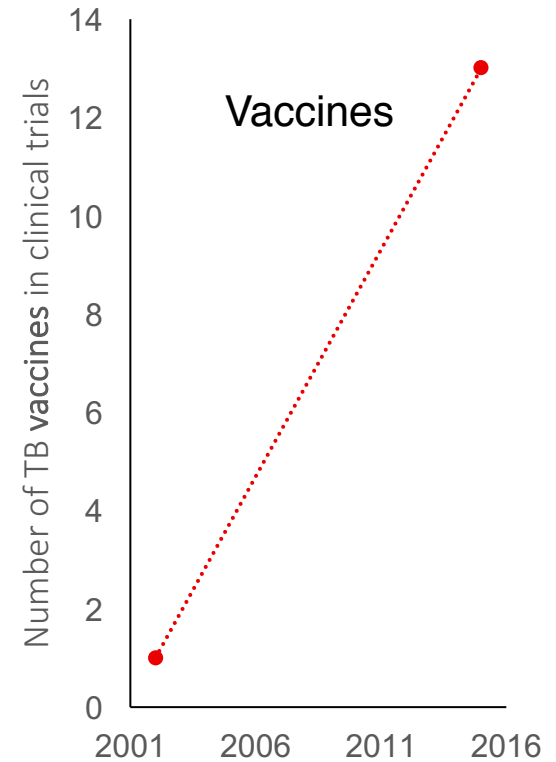
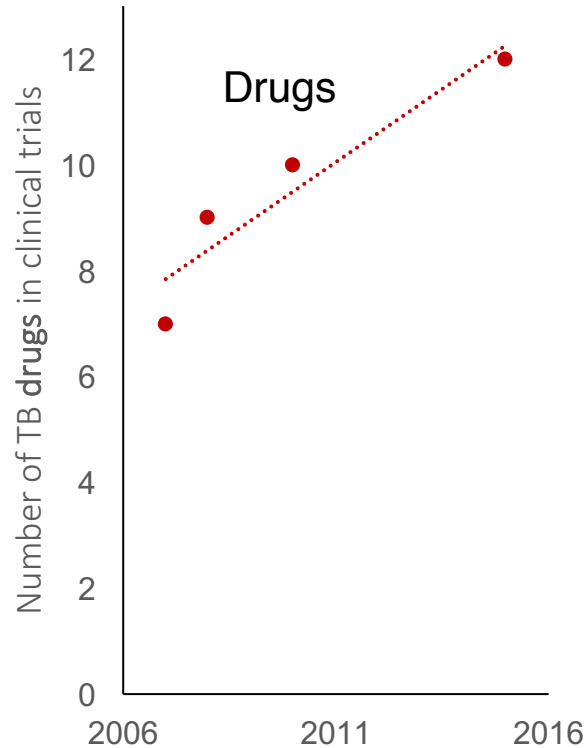
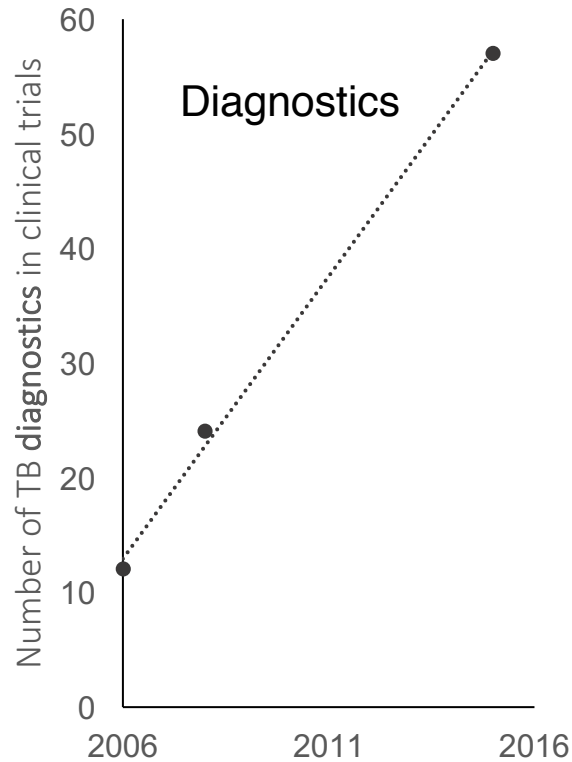
How can we create the future together?



Accelerate the roll-out of promising, new TB tools



PDPs have been successful at catalyzing innovation



1. Medecins Sans Frontieres. TUBERCULOSIS DIAGNOSIS AND DRUG SENSITIVITY TESTING: An overview of the current diagnostic pipeline. Paris: MSF; 2006.
2. Treatment Action Group. 2008 Pipeline Report. New York; 2008.
3. Stop TB Partnership. Global Plan to End TB 2016-2020: The Paradigm Shift. Geneva; 2015.
4. Ginsberg A & Spigelman M. Challenges in tuberculosis drug research and development. Nature Medicine. 2007; 13(3):290-294.
5. van den Boogaard J, Kibiki GS, Kisanga ER et al. New Drugs against Tuberculosis: Problems, Progress, and Evaluation of Agents in Clinical Development Antimicrob. Agents Chemother. 2009; 53(3):849-862.
6. Ma Y, Lienhardt C, McIlleron H, et al. Global tuberculosis drug development pipeline: the need and the reality. Lancet. 2010; 375(9731): 2100-09.

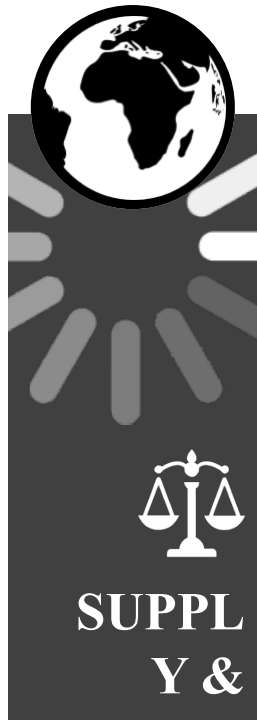
Challenge

The **rapid roll-out of promising, new TB tools** has been **sub-optimal**, contributing to:

- 1.8 million deaths from TB;
- 10.4 million people falling ill with TB; and
- 480,000 developing multidrug resistant-TB (MDR-TB).*



Demand has not matched supply for recent TB tools brought to market



20% eligible patients were receiving bedaquiline or delamanid in March 2017*

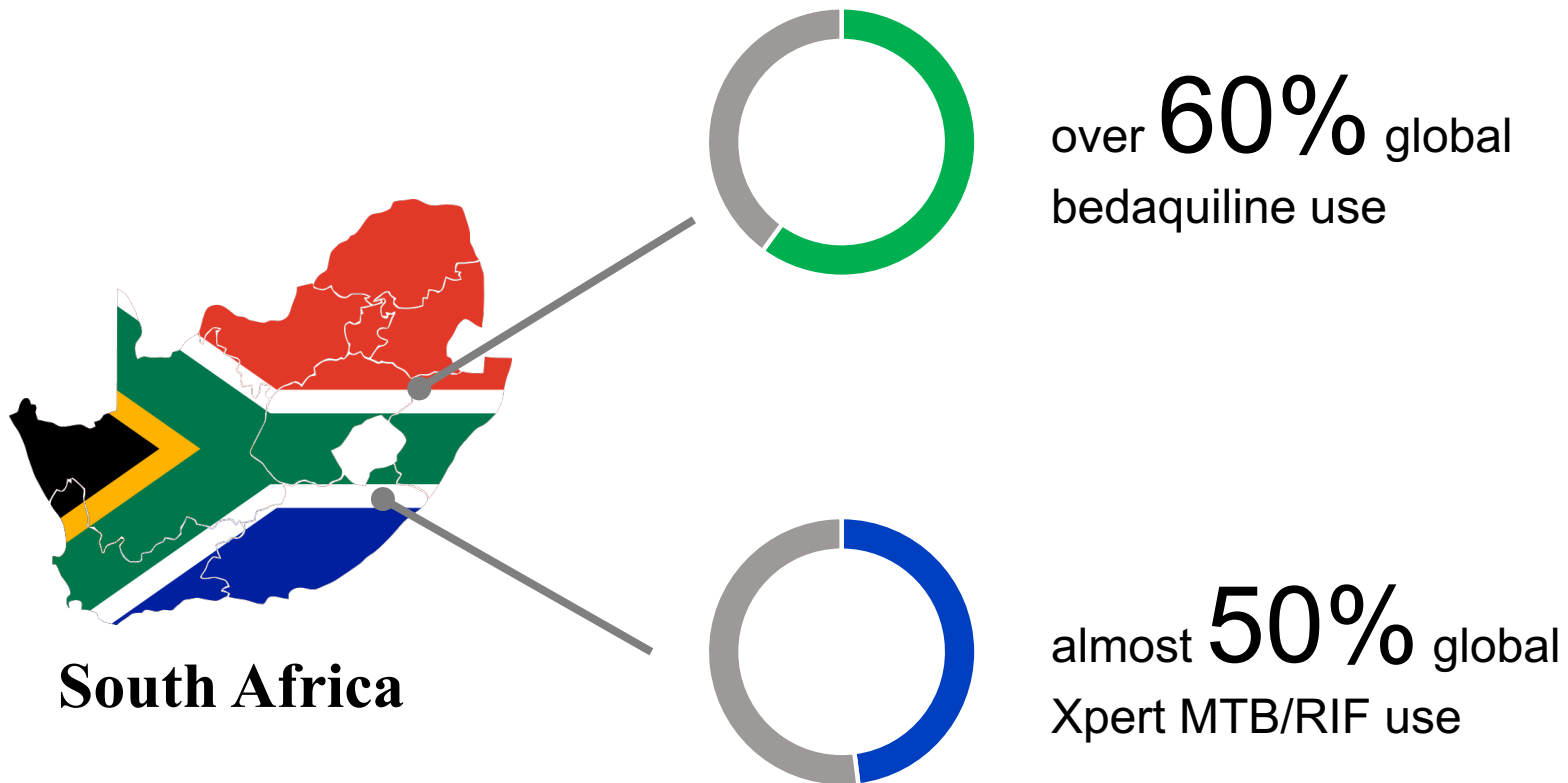
Even when new TB tools are developed,
access and scale-up is still a major issue

4% of diagnosis for TB/HIV patients was by Xpert in a multi-country study, **despite** good access**

*Pai & Furin. Tuberculosis innovations mean little if they cannot save lives. eLIFE. 2017;6:e25956.

**Clouse et al. Low implementation of Xpert MTB/RIF among HIV/TB co-infected adults in the International epidemiologic Databases to Evaluate AIDS (IeDEA) program. PLOS ONE. 2017;12(2):e0171384.

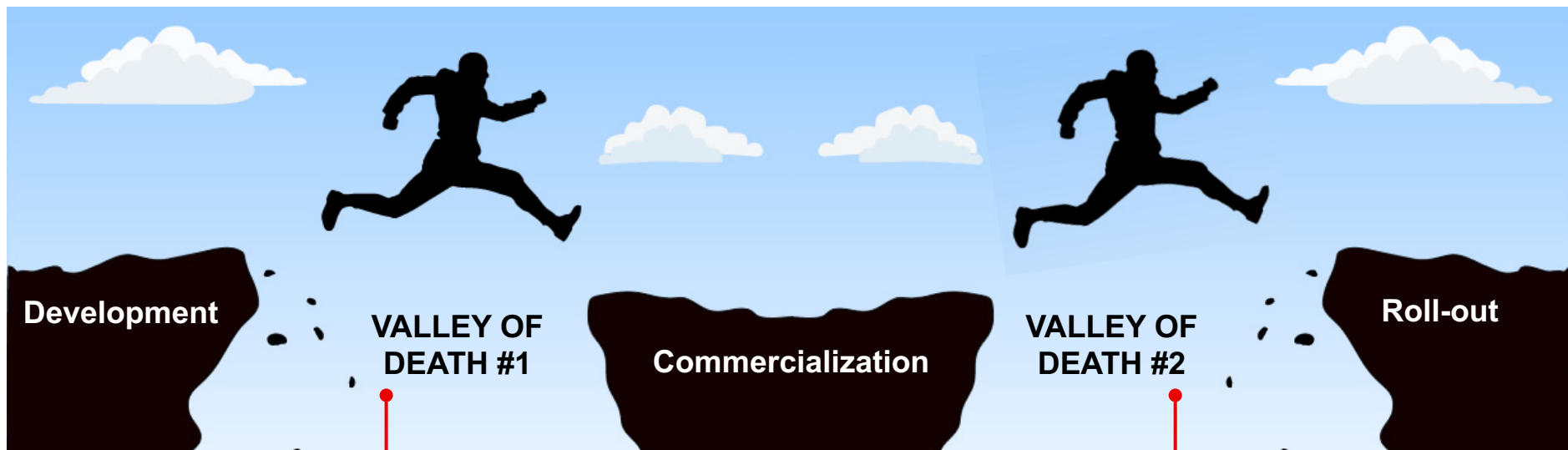
But the problem is not intractable: South Africa has promoted good access and scale-up



*DR-TB STAT March 2017 Task Force Update. [27 March, 2017]; Stop TB Partnership. 2017 <http://www.stoptb.org/wg/mdrtb/taskforces.asp?tf=4>

**FIND. McGill International TB Centre. UNITAID TB Diagnostics Market in Select High-Burden Countries: Current Market and Future Opportunities For Novel Diagnostics. 2015 https://www.mcgill.ca/tb/files/tb/tb_diagnostics_market_in_select_high-burden_countries_current_market_and_future_opportunities_for_novel_diagnostics.pdf

Innovators face two “valleys of death” in the downstream product development lifecycle



DEVELOPMENT => COMMERCIALIZATION

- **Insufficient evaluation** in settings of intended use
- **Weak end-user involvement** in product research and development
- **Mis-alignment** in the product design and manufacturing process

COMMERCIALIZATION => ROLL-OUT

- **Lack of focus** on demand generation
- **Weak engagement** of country decision-makers and stakeholders, including civil society and community
- **Lack of planning and resources** for country adoption

*Engel et al. Addressing the challenges of diagnostics demand and supply: insights from an online global health discussion platform. BMJ Global Health. 2016; 1:e000132.

**Albert et al. Development, roll-out and impact of Xpert MTB/RIF for tuberculosis: what lessons have we learnt and how can we do better? Eur Respir J. 2016; 48:516-525.

Solution

A **coordination platform** that focuses on the **downstream end** of the product development lifecycle and **executes an efficient pathway** to rapidly roll-out promising, new TB tools.



Vision, mission, and impact

Vision: End TB as a public health threat by 2030

Mission: Accelerate the roll-out of promising, new TB tools

Impact: Optimal diagnosis, treatment, adherence, cure, and prevention

Core business

- Drive **efficient product launches** in 3-5 early adopter countries
- Catalyze **sustainable partnership opportunities** between innovators and 3-5 early adopter countries
- Achieve a **return on investment**

Operating principles

- Leverage **key partners' expertise and existing platforms**
- Strengthen **collaboration and feedback loop** between innovators, country decision-makers and stakeholders, including civil society and community, and key partners
- Promote **early engagement with civil society and community**
- Utilize the **venture capital business model**

Values

- Promote **mutually beneficial outcomes** for supply and demand stakeholders
- Promote **country sustainability**
- Promote **financial sustainability**

TECHNICAL

RIGHT
PRODUCT

RIGHT
PERFORMANCE

RIGHT
PRICE

PROGRAMMATIC

RIGHT
UPTAKE

RIGHT
IMPLEMENTATION

**RIGHT
IMPACT**

Proposed co-convener and key partners (TBD/TBC)

Co-convener: FIND

Strategic Enabler 1: Civil society and community engagement

STBP's Communities, Rights, & Gender Team

Strategic Enabler 2: Political will

STBP's Advocacy Team

Stage 1

Stage 2

Stage 3

Stage 4

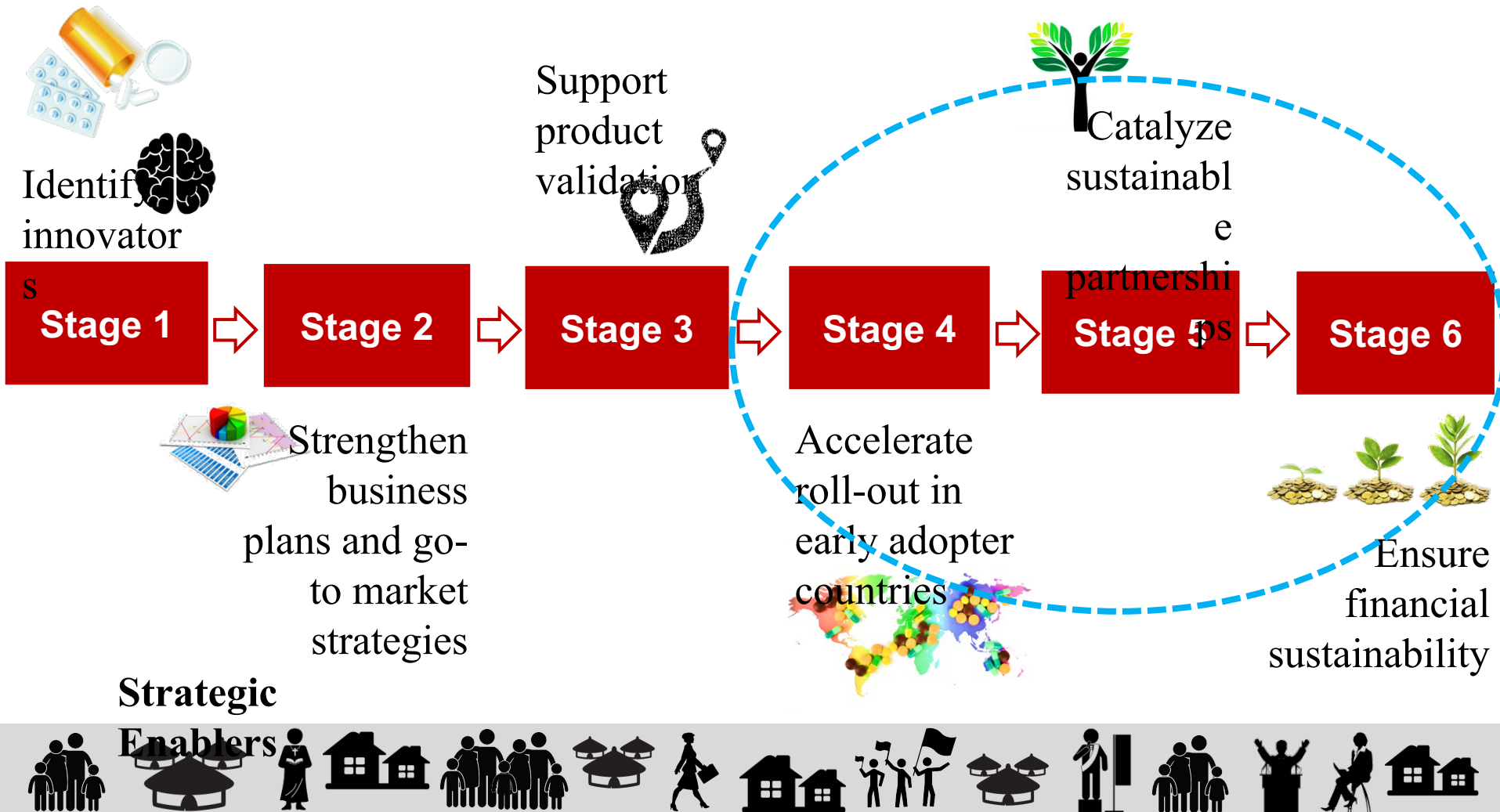
Stage 5

Stage 6

Some of the implementation partners for each stage will be determined through an open call for proposals

***Ex. for TBDx**

6 sequential stages



Stage 4: Accelerate roll-out in 3-5 early adopter countries (some activities to run parallel with Stages 1-3; TBC)

1

Convene annual Innovators & Adopters Workshops between innovators, country decision-makers and stakeholders, including civil society and communities, and key partners.

2

Support development of country profiles and country tailored roadmaps for introduction in 3-5 early adopter countries, including convening country/regional consultations.

3

Convene focus group discussions with end-users before product launches.

4

Convene training workshops for civil society and communities.

5

Conduct country-driven demonstration and cost-effectiveness studies, including identifying technical support needs, in 3-5 early adopter countries.

6

Expand the scope and scale of the initial conduct country-driven demonstration and cost-effectiveness studies beyond the 3-5 early adopter countries.

7

Support the inclusion of WHO recommended products in National Strategic Plans and Global Fund concept notes/grants in 3-5 early adopter countries.

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1st Innovators & Adopters Workshop (Oct. '17): First area of focus will be on TBDx and adjunct technologies

1

LANDSCAPE

Current and upcoming TB tools (0-5y)

Increase visibility to TB products pipeline for countries to plan and advocate for new tools

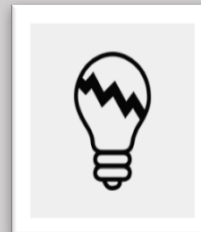


2

CRITICAL PATH

From product development to launch

Improve awareness of the sequence of stages, activities, and partners from research to roll-out

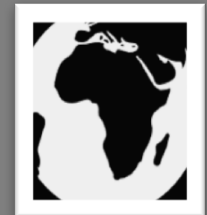


3

ROADMAPS

Country tailored pathway for Introduction

Map decision-making process for TBDx and adjunct technologies



Stage 5: Catalyze sustainable partnerships (TBC)



1

Work with early adopter countries to identify and develop a menu of potential projects addressing the underlying determinants of TB for innovators to support in their countries (e.g., reducing air pollution, promote vocational training, promote gender equity, etc.).

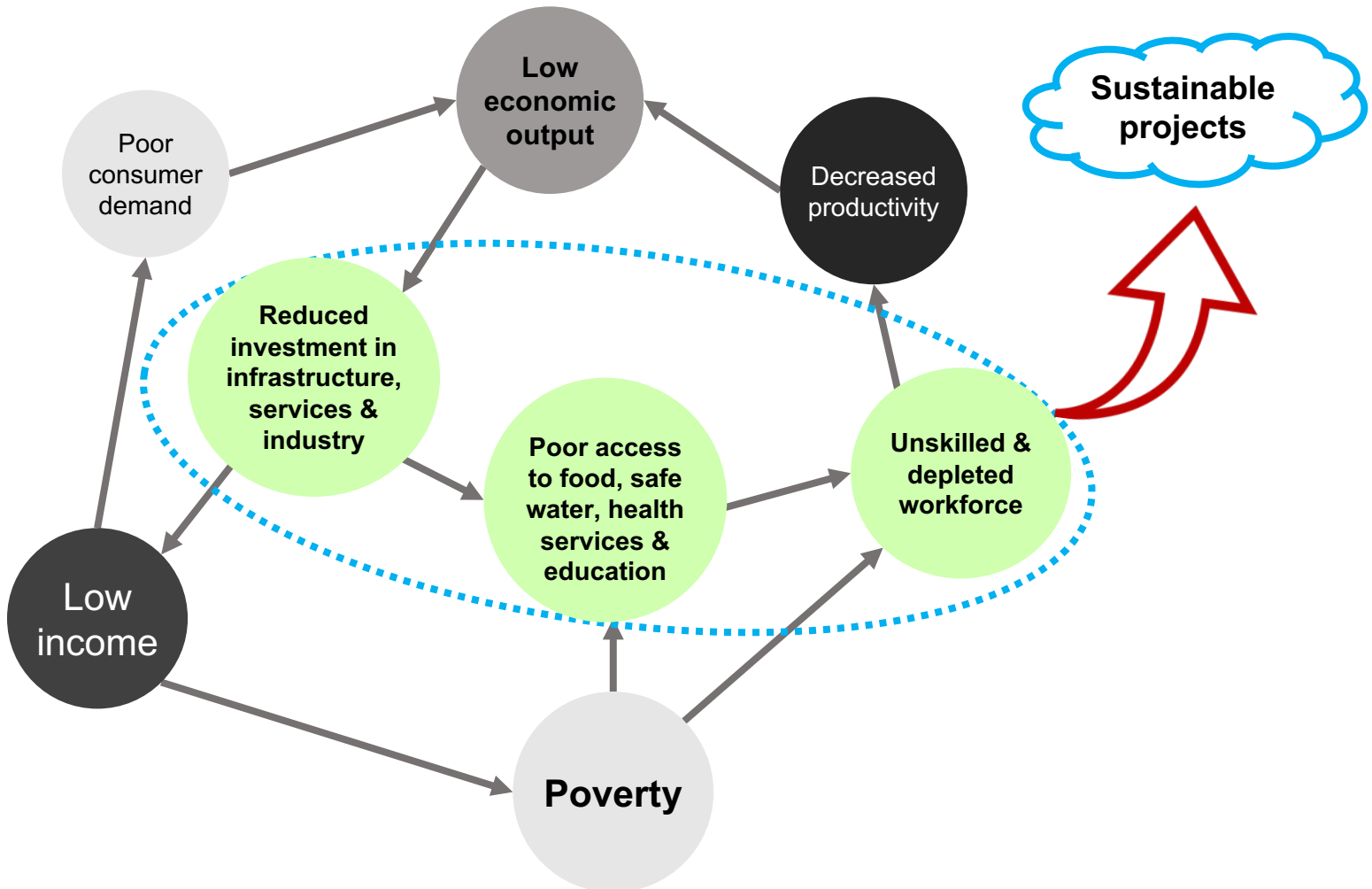
2

Draft concept note/proposal detailing activities, outcomes, and impact.

3

Work with early adopter countries and innovators to support and implement sustainability projects.

How can innovators and early adopter countries work together to solve fundamental problems?



Source: WHO/Oxfam/Health Poverty Action/Plan Canada

Stage 6: Ensure financial sustainability (TBC)



Venture Lab (vLAB) Trust Fund

Blends capital from the public/private sector and market investors

Return on Investment

Market investors receive a financial return



Replenishment

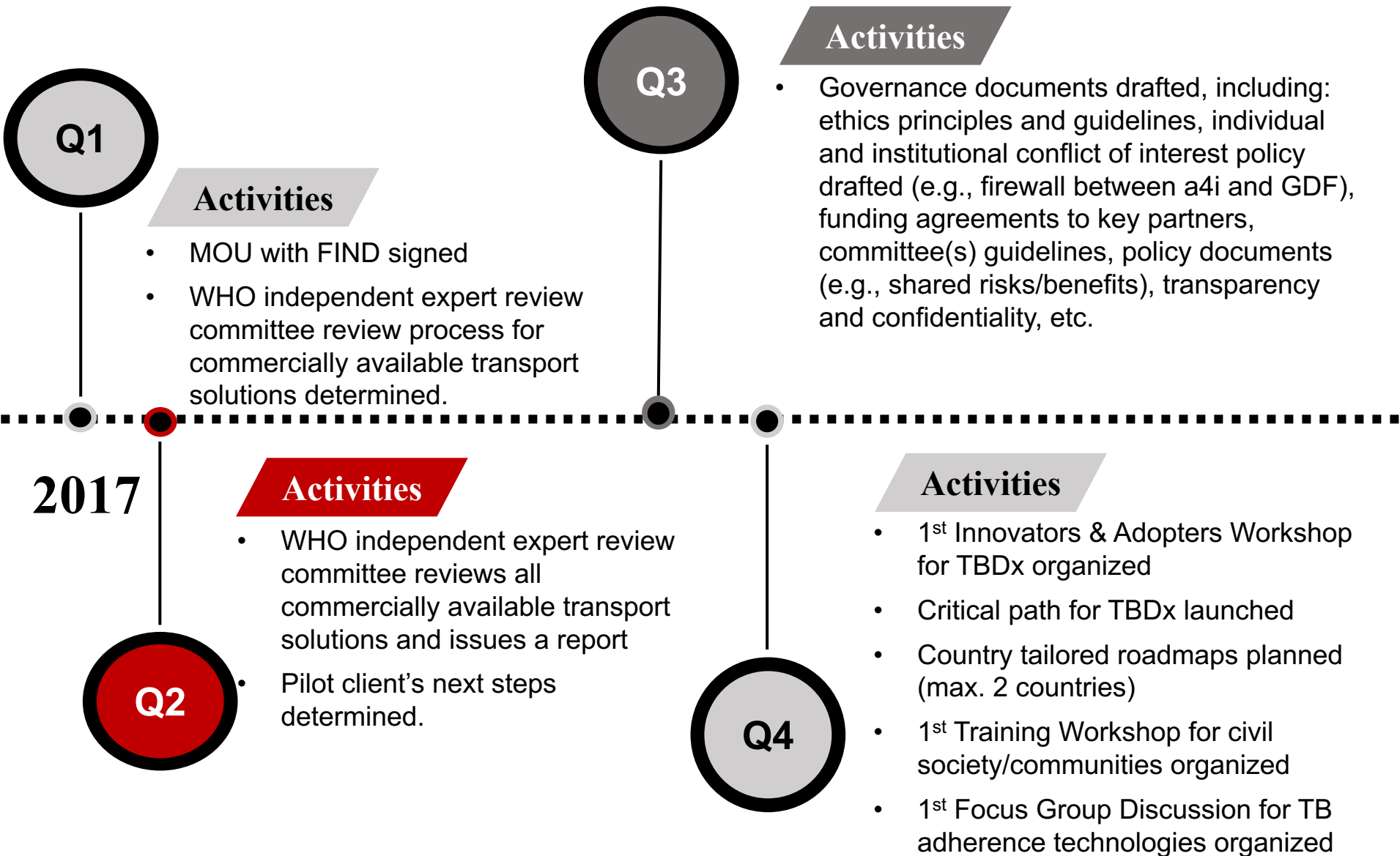
Innovators supported by a4i will financially contribute back into the vLAB trust fund

Global Health Bond*

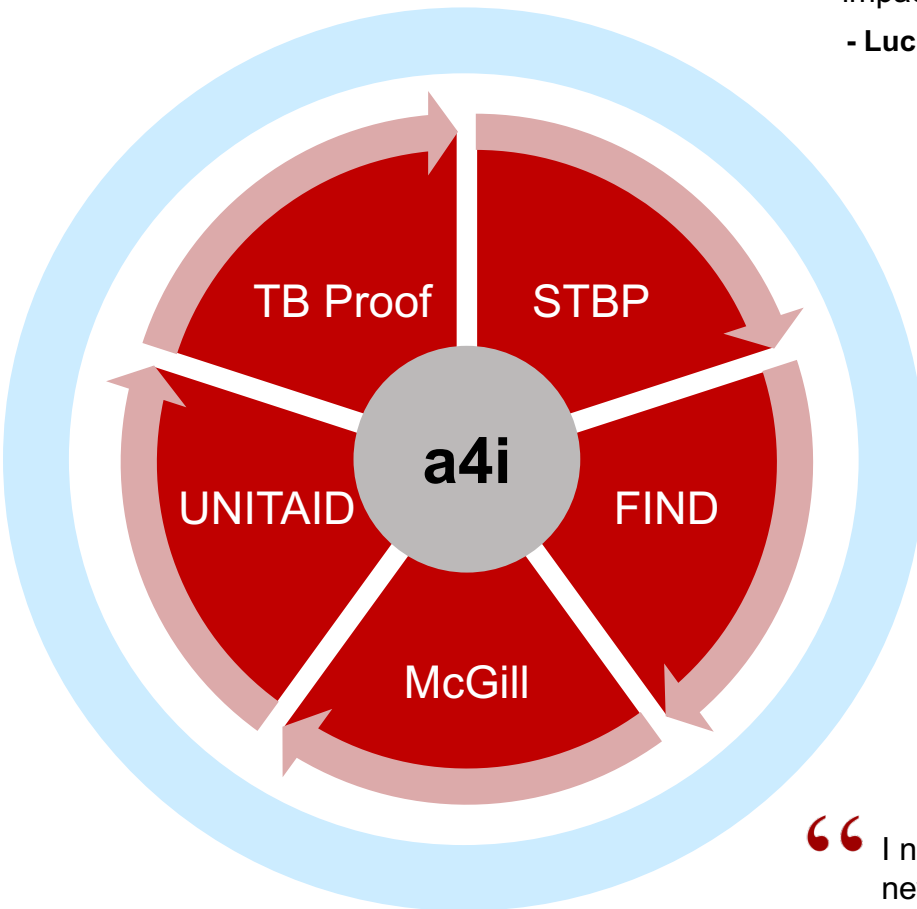
Royalty streams will securitise the bond

**Traditional debt instrument that can be publicly traded on market exchanges and sold to impact investors and institutional investors, such as endowment and/or pension funds.

Next steps and key milestones (TBC)



Acknowledgments and testimonial from initial key partners



“ a4i will establish a framework ... which will result in a dramatic impact to ending a disease that needlessly claims so many lives. ”
 - Lucica Ditiu, Executive Director of Stop TB Partnership

“ We need [a4i] to drive innovation ... We can wait no longer to meet the critical diagnostic needs of the four million missing TB patients who go undiagnosed or unreported each year. ”
 - Catharina Boehme, CEO of FIND

“ ... promising innovations need to navigate a long, complex pathway to reach patients who really need them. An honest broker like a4i is necessary to pave the way, build momentum, and address demand and supply issues. ”
 - Madhukar Pai, Associate Director of McGill International TB Centre

“ The launch of [a4i] will mobilize the best of private and public enterprise to deliver state-of-the-art diagnostics and treatments that are essential to getting the job done. ”
 - Lelio Marmora, Executive Director of UNITAID

“ I nearly died from liver failure from the TB medication. Having new treatment with less side effects would be wonderful. It is treating the person, not only the disease. ”
 - Ingrid Oxley, XDR-TB Survivor, TB Proof

“The best way to predict your future is to create it.”

-Abraham Lincoln





Thank You

<http://www.gbchealth.org/crossing-the-valleys-of-death-in-tb-from-development-to-roll-out/>

History

Dec 2014

STBP is approached by DNA Genotek Inc.

Oct 2016

1st Stakeholder Consultation is held in Liverpool, United Kingdom.

Nov 2016

STBP officially launches a4i as a joint venture with initial key partners.

Checkpoints (TBC)

S1:S2 Checkpoint

- Innovator is recommended, reviewed, and approved by the various committees/groups*
- Innovator signs project agreement with STBP

Stage 1

Identify innovators

Stage 2

Strengthen business plans

S3:S4 Checkpoint

- Product receives guidance and recommendation from WHO

Stage 3

Support product validation

Stage 4

Accelerate roll-out

Stage 5

Sustainable partnerships

Stage 6

Financial sustainability

S2:S3 Checkpoint

- 3-5 early adopter countries are identified.

S4:S5/6 Checkpoint

- Roll-out terms specified in the project agreement are met

Stage 1: Identify innovators with promising, new TB tools (to be piloted for 6 months)



FIND's Technology Review
(with selection criteria from a4i's
Delivery Working Group (DWG))

Web-based Submission

Initial Analysis (8w)

In-Depth Analysis (3m)

**FIND's Scientific Advisory Sub-
Committee Recommendation ***

a4i's DWG Review

STBP's Executive Committee Approval

Supported by a4i

***Ex. for TBDx**

Stage 1: Selection criteria (TBC)



1. Baseline requirement

- a. Products not defined as a priority by existing target product profiles (TPPs) but fills a market need.

2. Product requirements

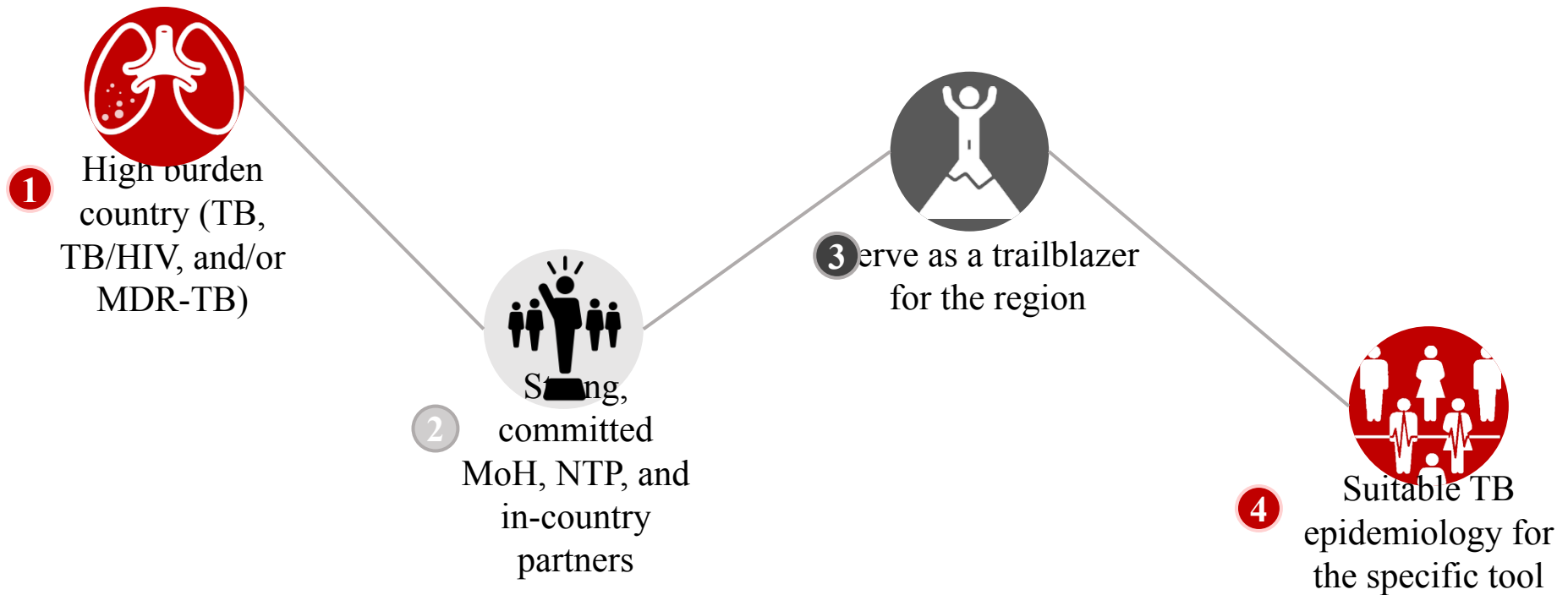
- a. Product has design-lock.
- b. Product has a high score for all relevant **ASSURED** criteria for diagnostics:
 - **A**ffordable
 - **S**ensitive and **S**pecific (analytical and diagnostic sensitivity and Specificity in case of diagnostics)
 - **U**ser-friendly (integration in local settings/algorithms , ease of use for targeted end user, training requirements)
 - **R**apid and **R**obust (time to result, hands-on time, throughput, environmental stability)
 - **E**quipment-free or low complexity equipment (infrastructure requirements, environmental stability, system integration)
 - **D**eliverable (distribution plan, transportation stability).
- c. Product has delivered promising results with clinical samples.

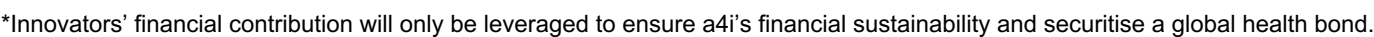
3. Innovator requirement

- a. High probability of success
 - Strength of team (qualified executive leadership)
 - Resources (product development/manufacturing expertise/capabilities, infrastructure, outsourcing, manufacturing, distribution)
 - Quality and regulatory strength
 - Technology readiness and time to market
 - Financial health (financial reports/audits, short-term demands, red flags, acquisition plans)
 - Company history and track record

***Ex. for TBDx**

Stage 4: Selection criteria for early adopter countries (TBC)





Key metrics (TBC)

Objective 1:
Implement pathways to
introduction and scale-up

Reduced roll-out timeline
of months per a4i stage
(*annual*)

Country pathways mapped
of roadmaps developed
(*annual*)

Objective 2:
Generate country demand

of national introductions in
early adopter countries
(*annual*)

Objective 3:
Increase coverage or
utilization rates*

% of target rates achieve in
early adopter countries
(*annual*)

Objective 4:
Generate sustainable
partnerships

of projects developed and
implemented in early
adopter countries
(*3y*)

Objective 5:
Increase coordination

% of innovators, countries,
and partners reporting
“excellent” or “very good”
in a survey
(*annual*)

Objective 6:
Utilize the venture
capital model

% of total funding coming
from market investors
(*3y*)

* Indicator to be determined based on product area and target to be determined with the early adopter countries.

SWOT analysis

STRENGTHS

- Buy-in and interest from innovators and country decision-makers/stakeholders, including civil society and communities, and key partners
- Increased collaboration by critical actors to solve market breakdowns
- Risk and benefit sharing between critical actors

WEAKNESSES

- Lack of capital and human resources
- Lack of established reputation and mechanism
- No mechanism to hold key partners accountable without grant agreements/MOUs

OPPORTUNITIES

- Strong network of STBP key partners, working groups, and internal implementing teams
- Interest from public and private sector donors regarding sustainable financing for development
- Ability to change how the global development/health space engages with innovators

THREATS

- Reputational risk from engaging with innovators
- Ethical risk from receiving royalties from innovators
- Potential perceived and/or real conflict of interest between a4i and GDF