



Equitable Access to New Tools and Innovations

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Introduction

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- **Barriers to ‘Access’, particularly Innovation and research & development (R&D)**
 - **‘Equitable Access’ = availability, affordability and appropriate adaptability of essential tools eg LMICs**



Neglected tropical diseases: a case study

- **Group of serious or fatal diseases**
- **Inadequate control/ significant increase of cases in late 20th C**
- **Lack of investment in surveillance / control**
- **Lack of investment in R&D**
- **Lack of tools to diagnose and treat cases**
- **Increased advocacy led to increased global attention**
- **Strengthening of surveillance; WHO playing a leading role**
- **Significant responses by NGOs/ some country programs with donor support**
- **Large long terms donation programs for key drugs**
- **Investment in R&D: creation of PDPs like DNDi**



Differences and challenges?

- **NTDs have key differences**
 - Very small market; no chance of profitability in NTDs: private sector can see opportunities in collaboration especially with public funding on the table
 - Intellectual property therefore less of a barrier
 - System of donations not feasible in TB market
- **Similarities?**
 - Recent gains, but still a lack of innovation, adequate tools and sustainable funding
 - Market incentives are insufficient to drive innovation
 - ‘Fatal imbalance’ on R&D funding still persists



Underlying problems

R&D system is a major impediment to innovation & access

- Current system relies on high pricing as the incentive
- Insufficient funding
- Proprietary 'closed' approach= lack of collaboration & transparency
- **Limited progress may create illusion of success**
- **Need a paradigm shift**



Living within a 'price' driven model



DR-TB DRUGS UNDER THE MICROSCOPE

SOURCES AND PRICES FOR DRUG-RESISTANT TUBERCULOSIS MEDICINES

3rd Edition – October 2013



www.msfaccess.org



www.theunion.org

Total drug prices for an MDR-TB regimen
with Bedaquiline added

Assume \$4000 per patient per treatment course

+

Bedaquiline:

\$900 / \$3000

in a developing country

=

\$5000 to \$7000 per patient per treatment course

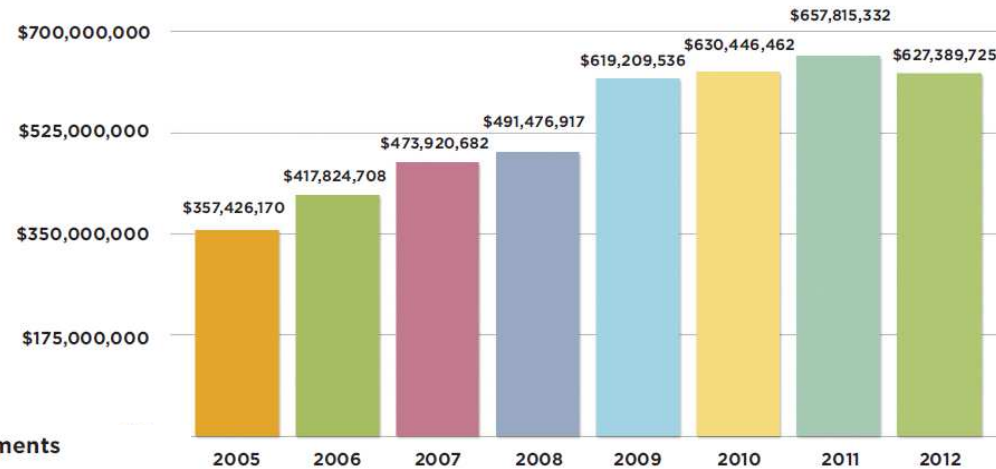
and could be more depending on other drugs used

We still lack good MDR/ PAN TB regimens, prices of regimens may rise, insufficient incentives for investment



Insufficient funding

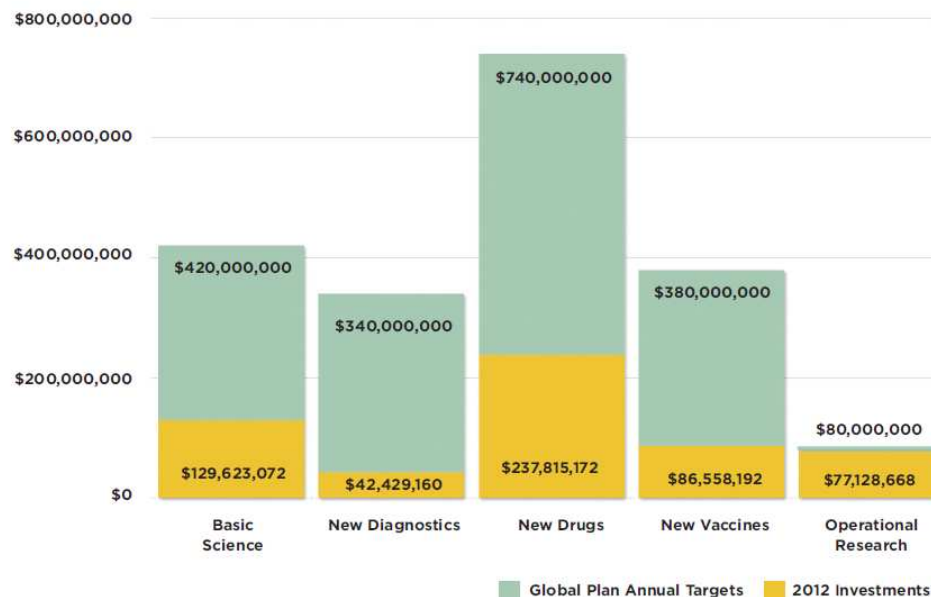
Total TB R&D Funding: 2005-2012



TUBERCULOSIS RESEARCH AND DEVELOPMENT:

2013 Report on Tuberculosis Research Funding Trends, 2005-2012

Annual Global Plan Research Funding Targets versus 2012 Investments



- Global picture: Funding level is actually flat-lining
- Underfunding of all steps in R&D chain
- TB needs are high due to long term lack of investment, poor tools available, tools being a major impediment to scale up
- Needs of special populations neglected: CHILDREN
- Public leadership & re-engagement of private sector URGENTLY needed**



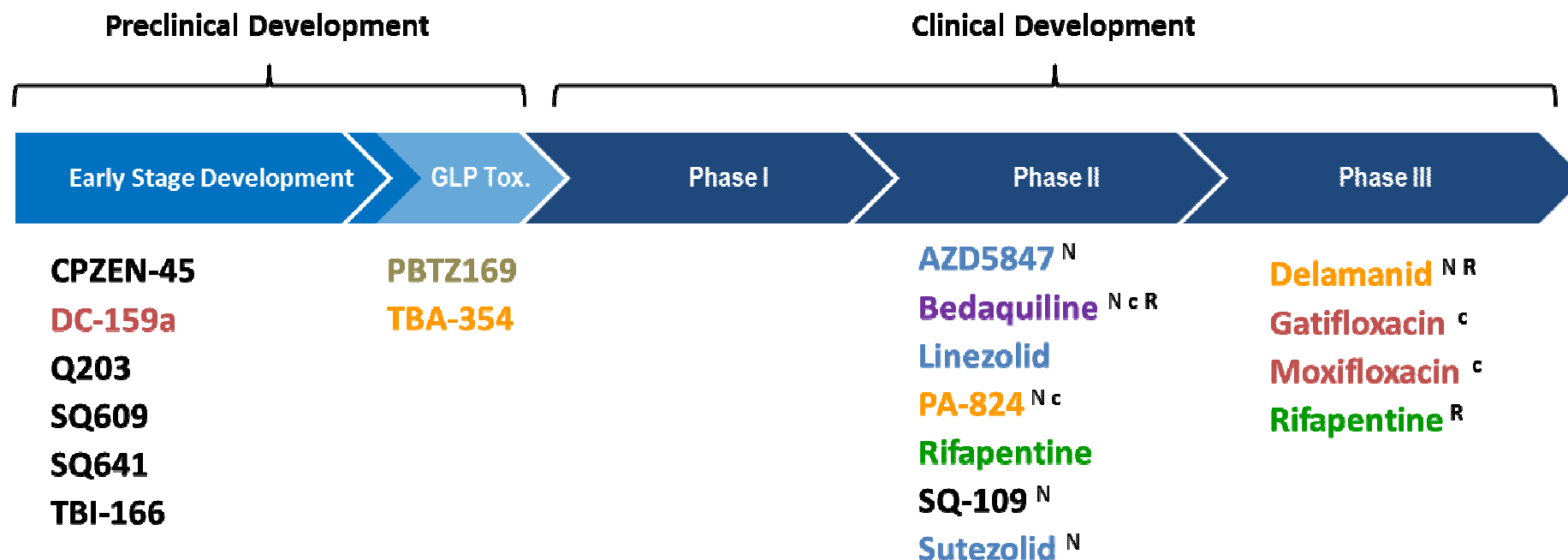
‘Proprietary’ closed approach: failing to deliver for patients

“To hell with TB; I’ve had enough. If you try to make it nice instead of saying it straight, people easily ignore it... It took my hearing away, now it wants to take my life...”



Phumeza, 22, South Africa
Diagnosed with XDR-TB in June 2010

Global TB Drug Pipeline ¹



Chemical classes: fluoroquinolone, rifamycin, oxazolidinone, nitroimidazole, diarylquinoline, benzothiazinone

¹ Details for projects listed can be found at <http://www.newtbdugs.org/pipeline.php> and ongoing projects without a lead compound series identified can be viewed at <http://www.newtbdugs.org/pipeline-discovery.php>.

^c Drug candidate currently in combination regimen in clinical testing

^R Submitted for approval or approved by stringent regulatory authority (i.e., FDA, EMA, WHO Prequalification)

^N New chemical entity



www.newtbdugs.org

Updated: June 2013



Healthy Pipeline?

NCEs in Clinical Development:

Hepatitis C

Phase I	over 15
Phase II	14
Phase III	11

Total: over 40!

TB

Phase I	0
Phase II	5
Phase III	1

Total: 6

Which path for TB?

MONOPOLY MODEL

Conditions:

- Profits set priorities
- High public funding
- Collaboration and data sharing discouraged



**HIGH-COST
R&D**

Result:

- Monopoly market: anti-competitive
- No accountability on price setting



HIGH PRICES

NEEDS-DRIVEN MODEL

Conditions:

- Health needs set priorities
- Collaboration and data sharing encouraged



**PRO-HEALTH
R&D**

Result:

- Free-market: competition
- Accountability on price setting: focus on quality, fair prices



FAIR PRICES



WHO CEWG: an Opportunity

Research and Development to Meet
Health Needs in Developing Countries:
Strengthening Global Financing
and Coordination



Report of the Consultative Expert Working Group on Research
and Development: Financing and Coordination

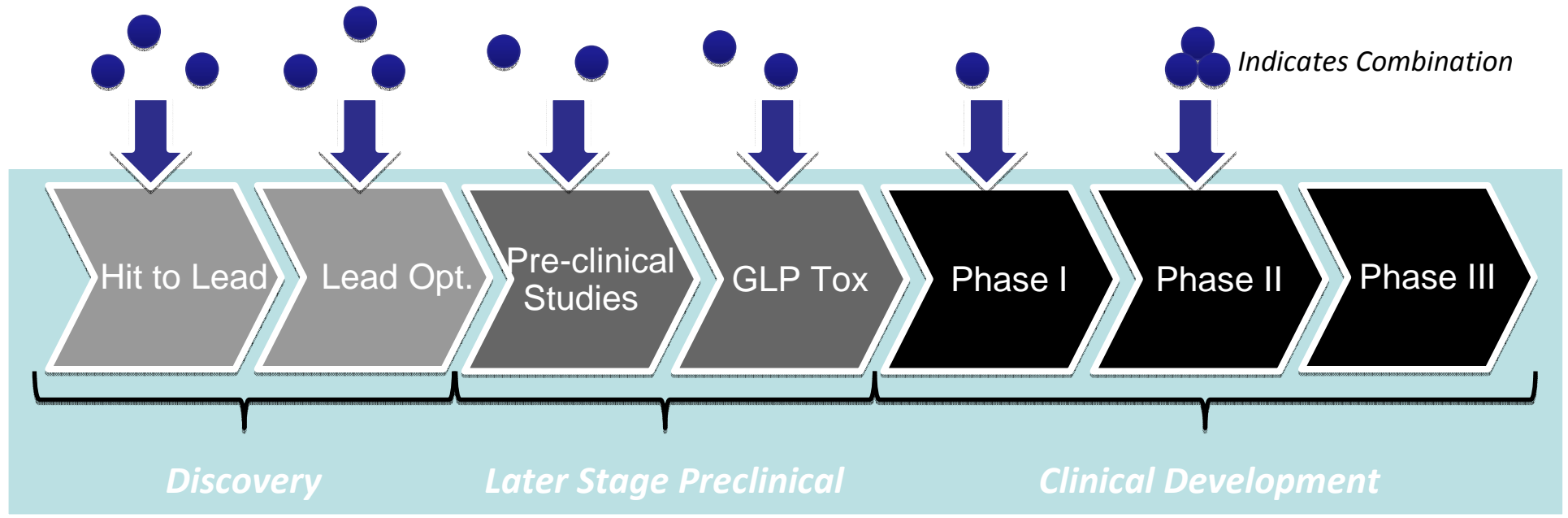


Member States agreed to
launch health R&D
demonstration projects:

- Open approaches, open source & open access schemes
- Prizes, in particular milestone prizes
- Equitable licensing & patent pools



Open Collaborative Model






★ Small, early-stage Milestone Prize (Size 1; mix of small financial and recognition prizes) for licensing the compound to the Open Collaborative Framework

★ Milestone Prize (Size 2) for entering clinical development (Phase I)

★ Milestone Prize (Size 3) for combination regimen successfully completing Phase II

Legend

-  Various TB Compounds
-  Milestone Prizes
-  Grant funding

Grant funding for studies from the fund

Grant funding for Phase III from existing and new sources



Medical innovation is: Tool/method + access → Impact

“I’ve beaten XDR-TB! Getting cured at last is very exciting. It was scary at first. But you live in hope – hope that one day you will be cured. I didn’t want to be a TB statistic and that kept me going”



Phumeza
Cured of XDR-TB in August 2013



Online action Support the #TBmanifesto

msfaccess.org/tbmanifesto

TEST ME, TREAT ME
A DRUG-RESISTANT TB MANIFESTO



[SIGN NOW!](#) [MEET OUR COMMUNITY](#) [VIDEOS](#) [UPDATES](#) [INFOGRAPHICS](#) [CAMPAIGN TOOLKIT](#)

Phumeza,
co-author of the DR-TB Manifesto
and recently cured of XDR-TB!



SIGN NOW TO SUPPORT THE
**'TEST ME,
TREAT ME'**
DR-TB MANIFESTO!

Full name

Your email

NEXT

[READ THE MANIFESTO](#)



Let the world know!



#TBmanifesto