The New Diagnostics WG and The Global Plan to Stop TB 2011-2015

Working Group on New Diagnostics

Annual Meeting

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Stop TB Partnership
Geneva

Aims of this presentation

WHO THE STOP TB DEPARTMENT

- Background: the TB situation today
- The Stop TB strategy and the Global Plan to Stop TB 2006-2015
- The revised Global Plan to Stop TB 2011-2015
- The role of new drugs in contributing to the goal of TB elimination by 2050
- The future

The global burden of TB in 2008

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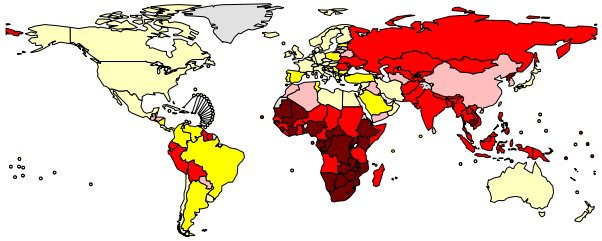

	Estimated number of cases	Estimated number of deaths
All forms of TB	9.4 million (range 8.9–9.9 million)	1.9 million (range 1.6–2.3 million)
HIV-associated TB	1.4 million (15%) (1.3–1.6 million)	520,000 (0.45–0.62 million)
Multidrug-resistant TB (MDR-TB)	440,000 (0.39-0.51 million)	150,000 (0.05–0.27 million)

TB Control Global Targets

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UN Millennium Development Goals

2015: Goal 6: Combat HIV/AIDS, malaria and other diseases

Target 8:	to have halted by 2015 and begun to reverse the incidence…
Indicator 23:	incidence, prevalence and deaths associated with TB
Indicator 24:	proportion of TB cases detected and cured under DOTS

Stop TB Partnership

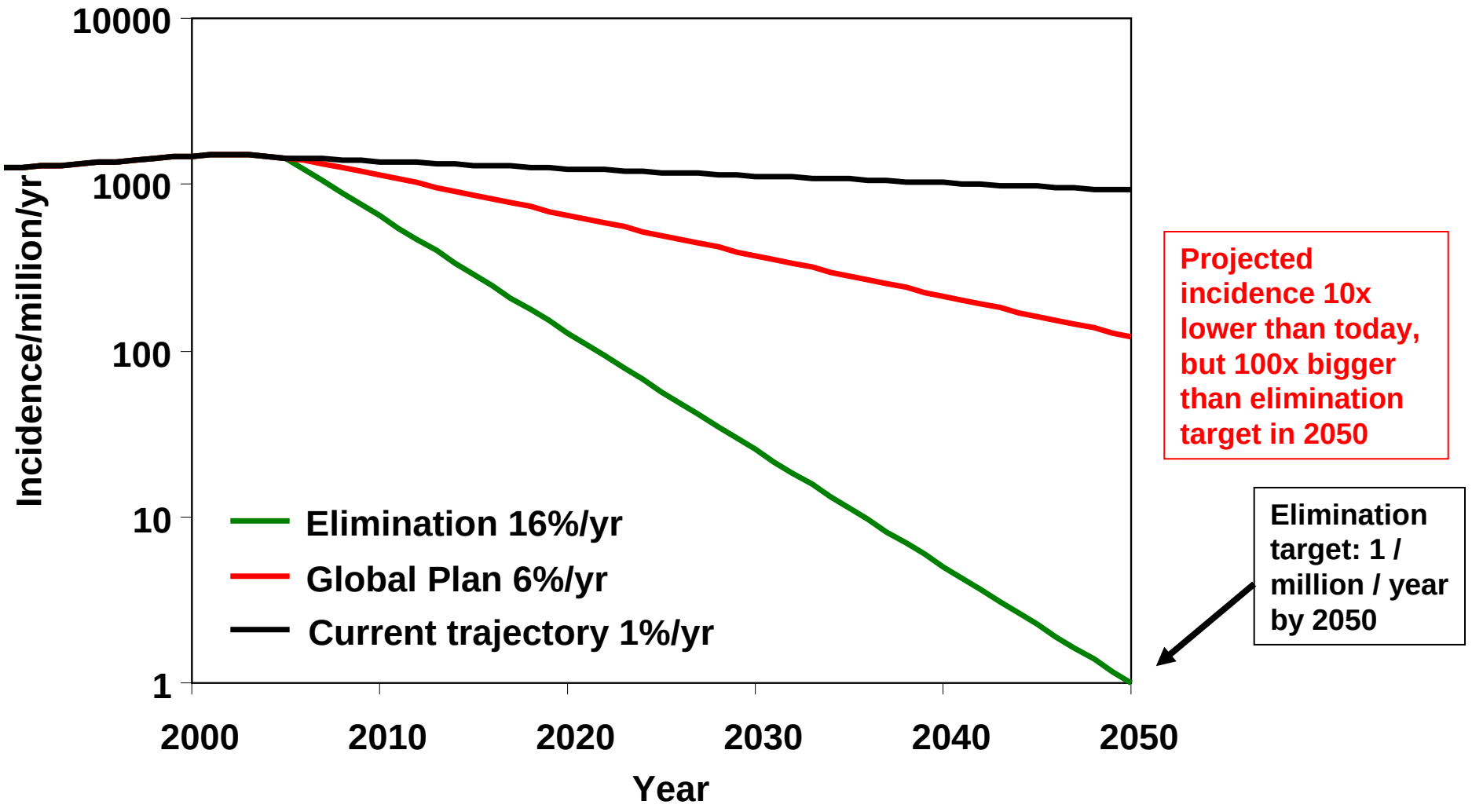
2015: 50% reduction in TB prevalence and deaths relative to 1990 levels

2050: elimination (<1 case per million population)

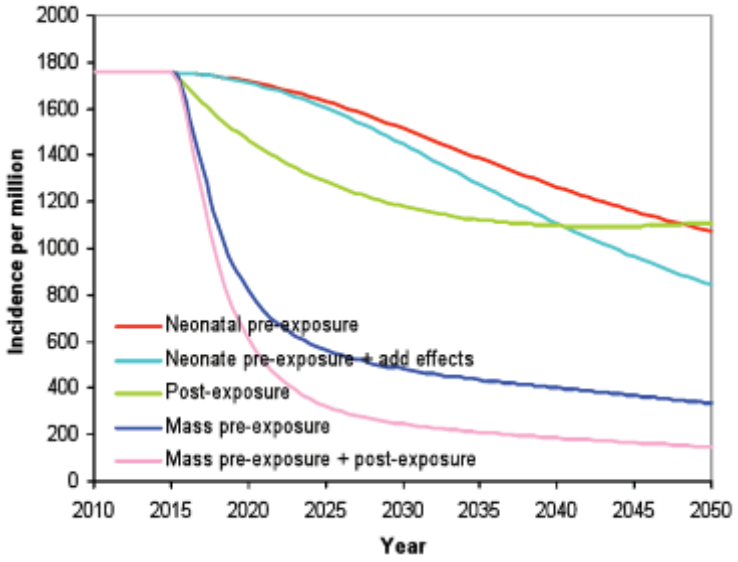
The Global Plan 2006-15 proposed achievements

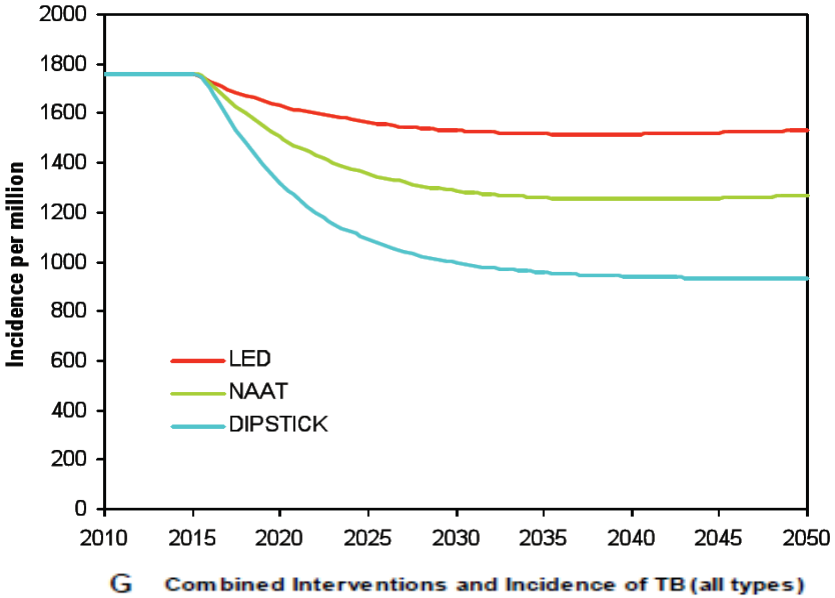
1. MDGs for TB and the Partnership's 2015 targets to halve prevalence and death rates globally
2. Treatment of 50 million people with TB, 3 million TB/HIV co-infected patients on ARV, and 1.6 million with MDR
3. Saving of 14 million lives from 2006-2015
4. The first new TB drug introduced by 2010
5. The "point of care" diagnostics introduced by 2010
6. Develop a new vaccine by 2015

Full implementation of Global Plan: 2015 MDG target reached but TB not eliminated by 2050

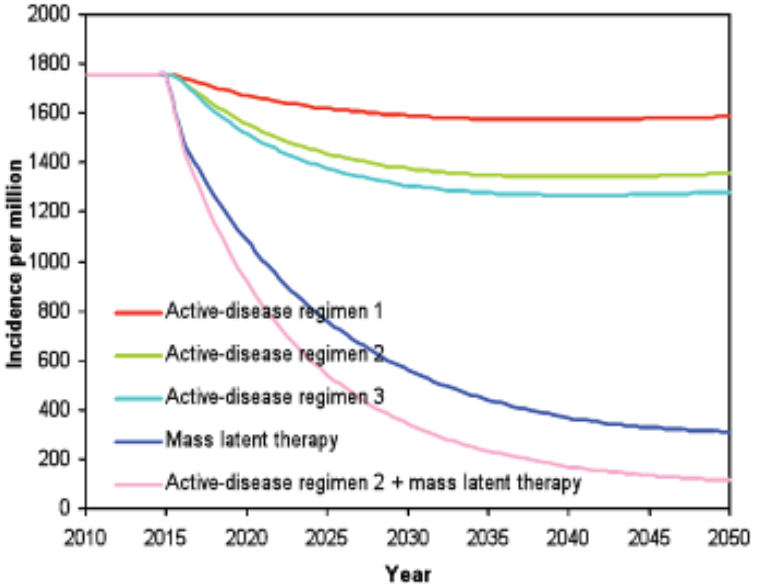


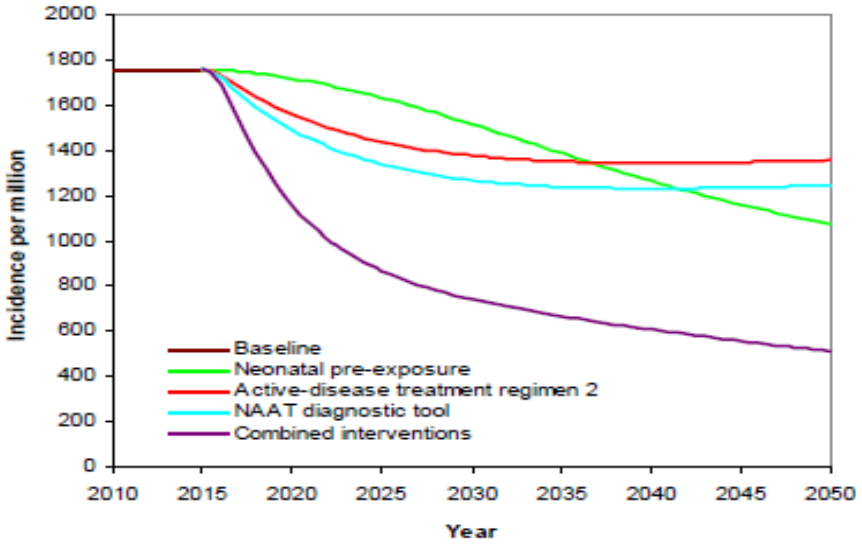
Potential impact of new TB vaccines, diagnostics and drugs in SE Asia





G Combined Interventions and Incidence of TB (all types)





Source: L. Abu Raddad *et al*, PNAS 2009

Global Plan targets – Research and Development

	By 2006	By 2010	By 2015
Vaccines	3 vaccines in phase I trials	9 candidates in phase II trials; at least 2 vaccines in "proof of concept" trials; beginning phase III trials	4 phase III trials carried out; one safe, effective vaccine available
Drugs	27 new compounds in the pipeline	1-2 new drugs registered; treatment shortened to 3-4 months	7 new drugs; treatment shortened to 1-2 months
Diagnostics	rapid culture for case detection and DST in demonstration phase	point of care, rapid culture, improved microscopy, phage detection, simplified NAAT	predictive test for LTBI

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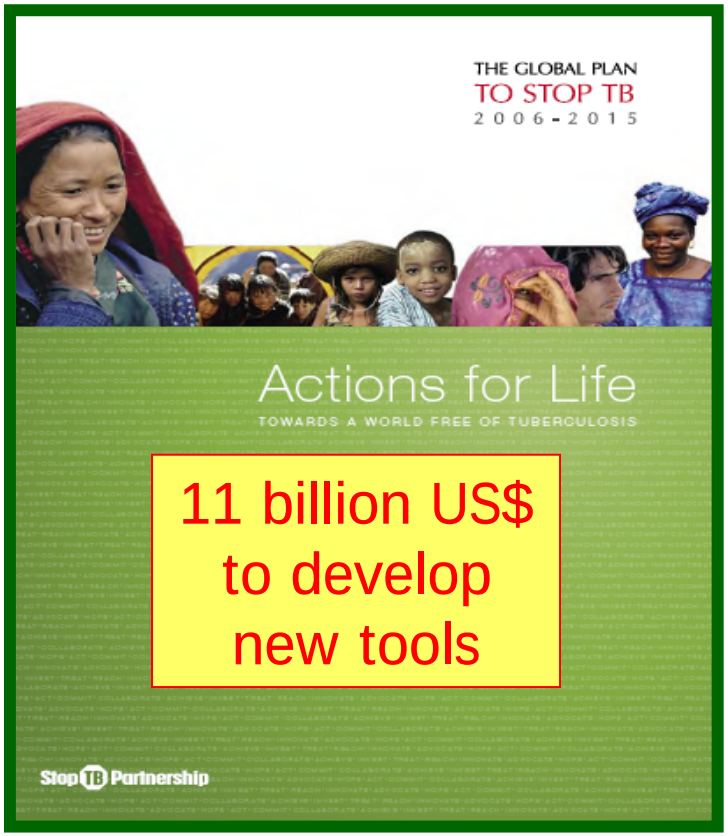
Strengthening the fight

The Global Plan 2006-2015 defined direction and costs



The Global Plan 2011-2015 strengthens the fight

Improve TB Control

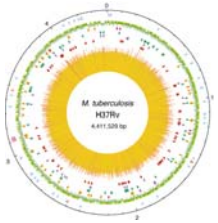
Point of Care Diagnostics of TB

Diagnose all forms of TB in all populations

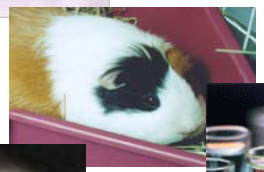
Improved diagnostics at all health care levels

Basic Science	Translational Studies	Preclinical Studies	Clinical Studies/Trials	Operational Studies/Trials










Objectives for New Diagnostics R&D

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1. To address existing knowledge gaps obstructing development of new diagnostic tools

- biomarkers and platform discovery

2. To develop a portfolio of new diagnostic tests

- identify candidates for detection of all forms of TB in all age groups, including MDR-TB and LTBI founded on 1.
- address specific diagnostic needs at various levels of public health systems in high-burden countries

Objectives for New Diagnostics R&D

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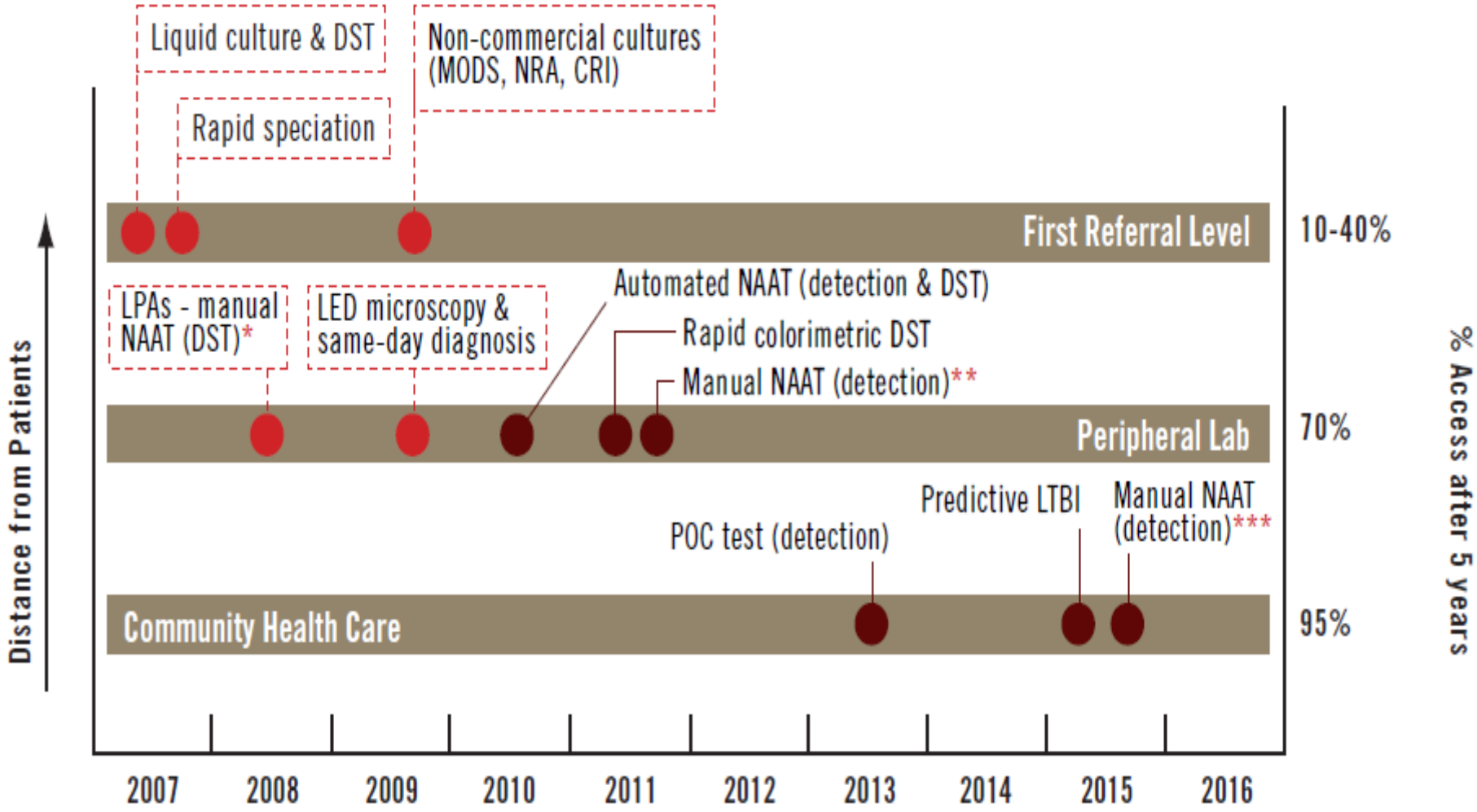
3. To evaluate the portfolio of new diagnostic tools, demonstrate patient benefit and predict likely impact

- conduct accuracy and validity studies
- assess effectiveness of any new diagnostic tool at the required level of health service and in all target populations
- assess the impact of new tests on case-finding, and access to treatment

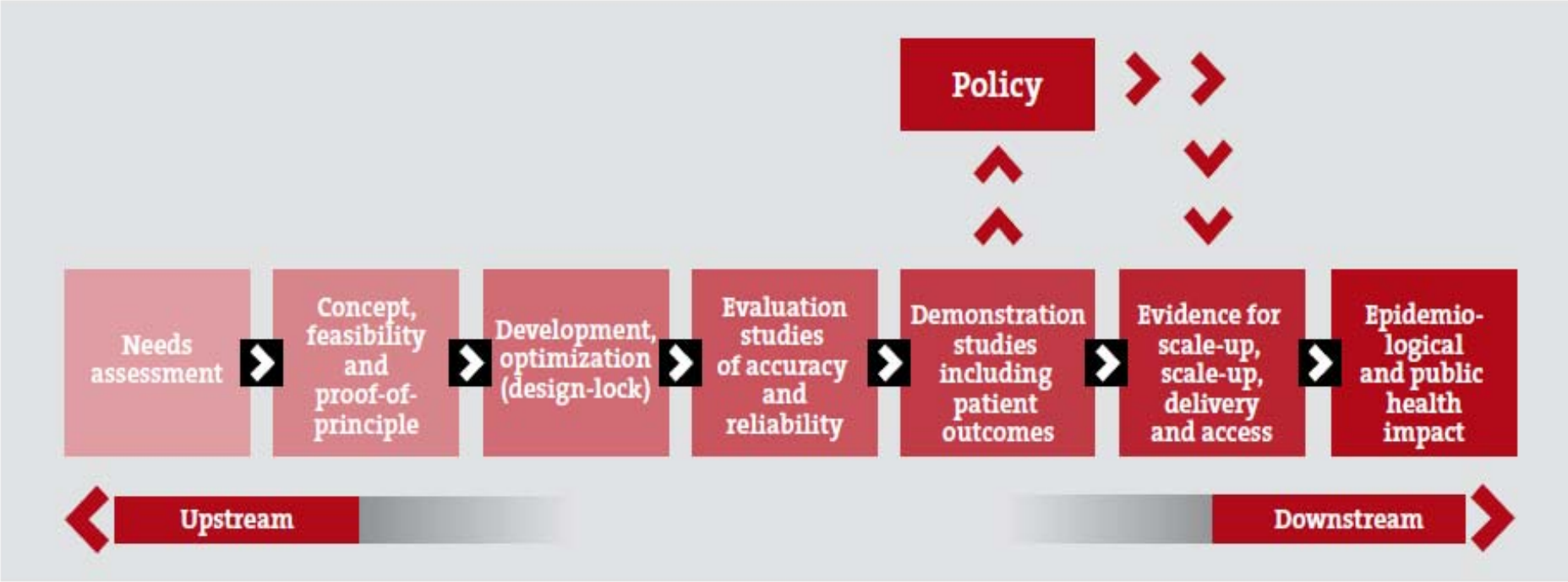
4. To ensure wide availability of new diagnostic tools in endemic countries

- operational and impact assessments studies to inform on the benefits for the patient and health systems.
- ensure implementation and uptake of new tests at requested level of health care
- harmonize regulatory requirements for TB diagnosis

Targets for introduction of new diagnostic tests 2006–2015



TB diagnostics pathway, from need assessment to delivery



Expected Achievements 2015

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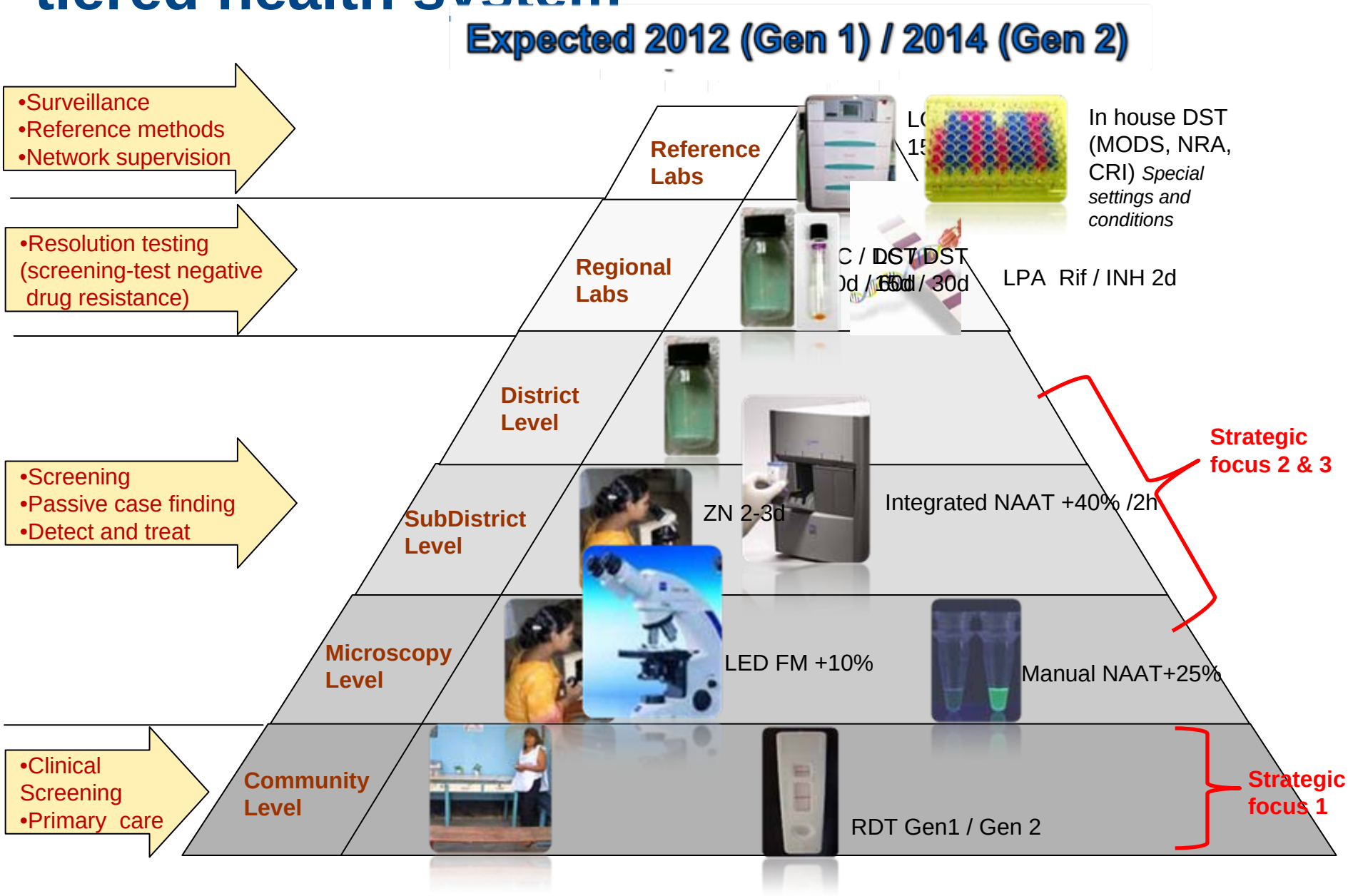
- New markers for determination of LTBI, disease progression, active disease, and first- and second-line drug resistance are identified and validated;
- Improved and new technical platforms to meet required target specifications are developed;
- A portfolio of new and improved diagnostics tests meeting the disease target specifications up to validated design-locked products is developed;
- Evaluation and demonstration studies, specifically in paediatric and TB/HIV co-infection patient groups, are conducted:

Expected Achievements 2015

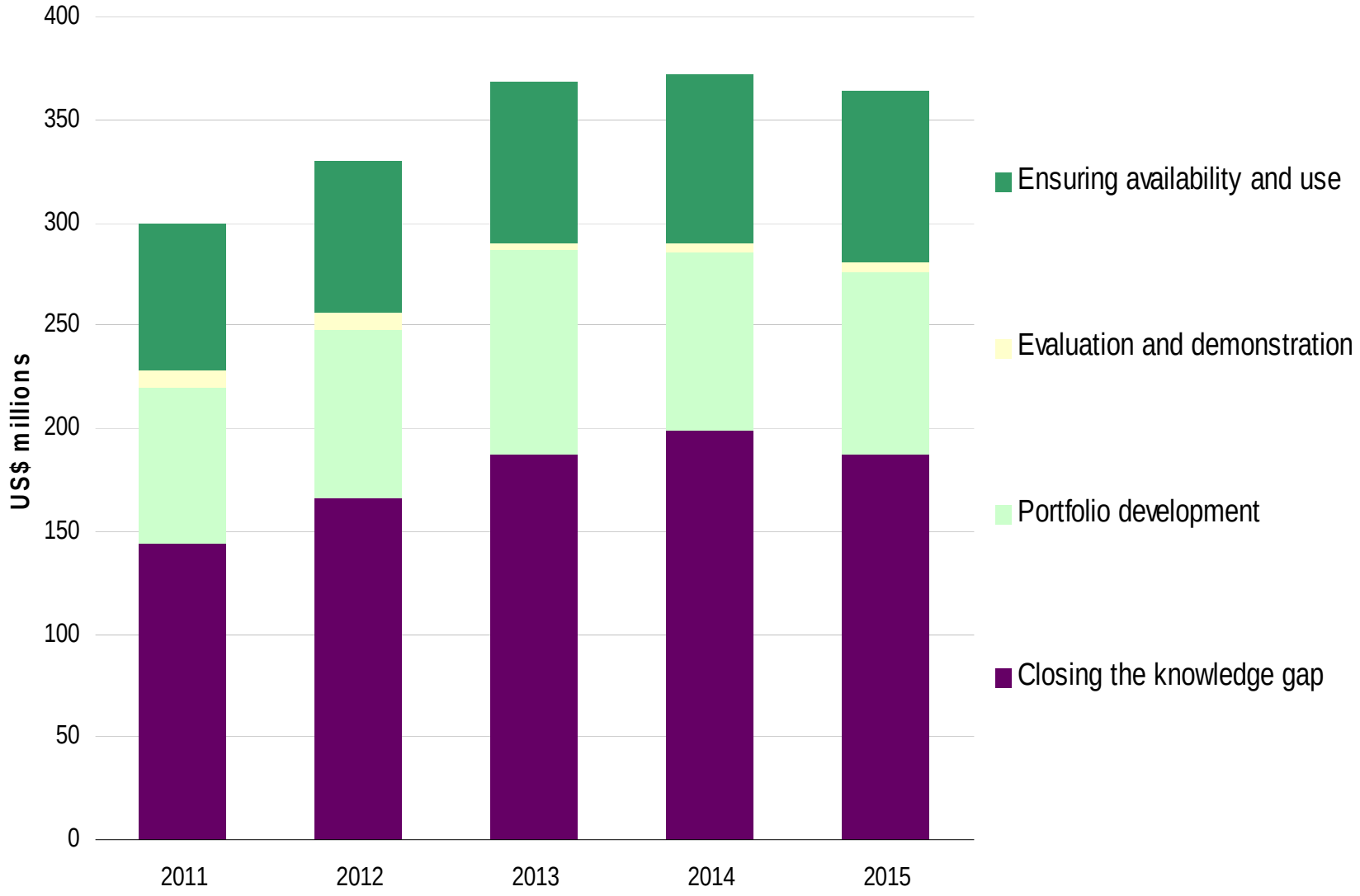
WHO THE STOP TB DEPARTMENT

- Impact of new diagnostics on case-finding, access to treatment, patient benefit, cost-effectiveness, equity and poverty has been evaluated;
- Operational research studies carried out to evaluate how to optimally deliver novel diagnostic services in routine TB programmatic settings, including related costs and resources needed;
- Newly validated tools for TB diagnostics are fully registered, and methods for registration harmonized

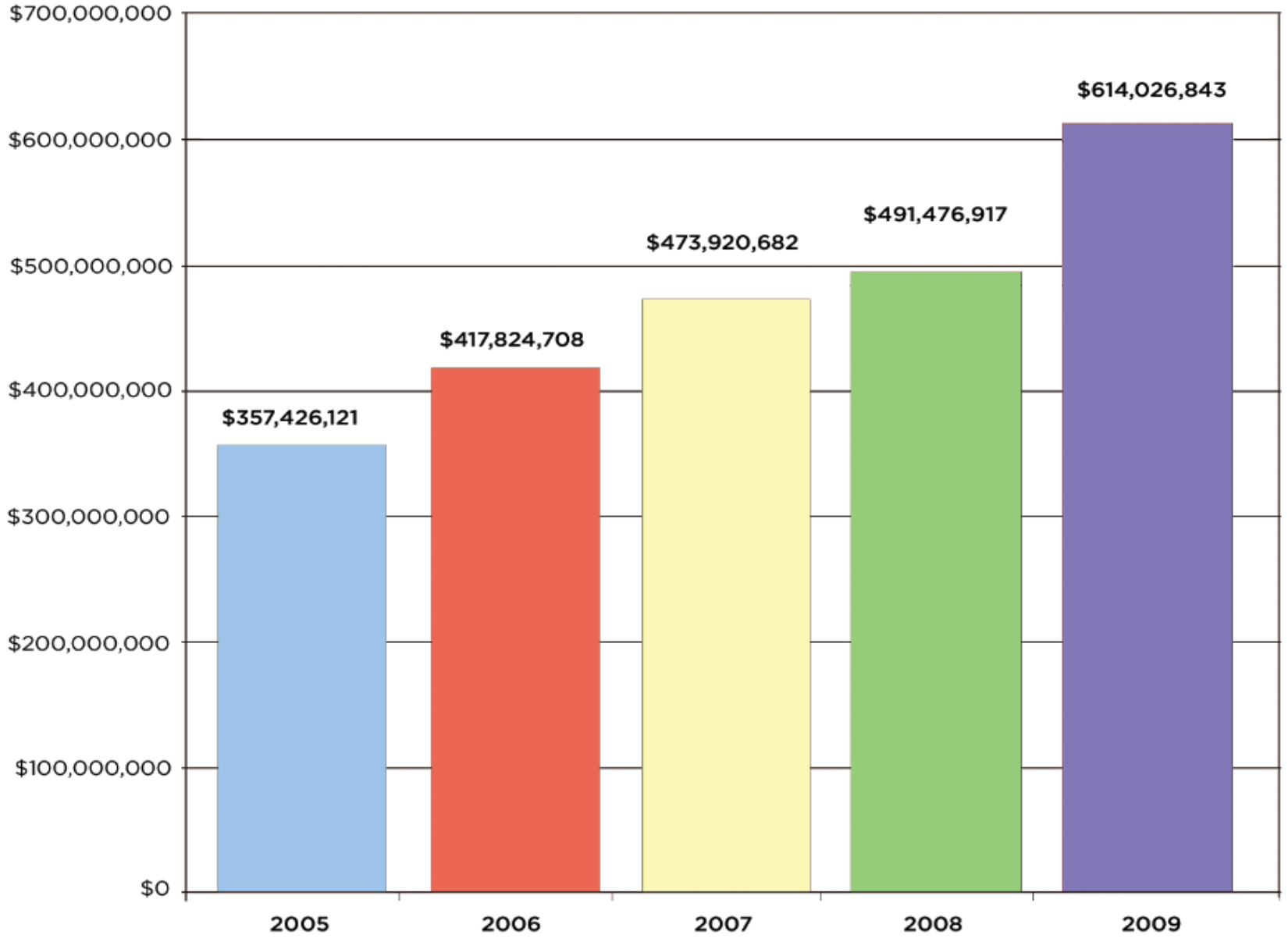
Integration of new tools in the tiered health system



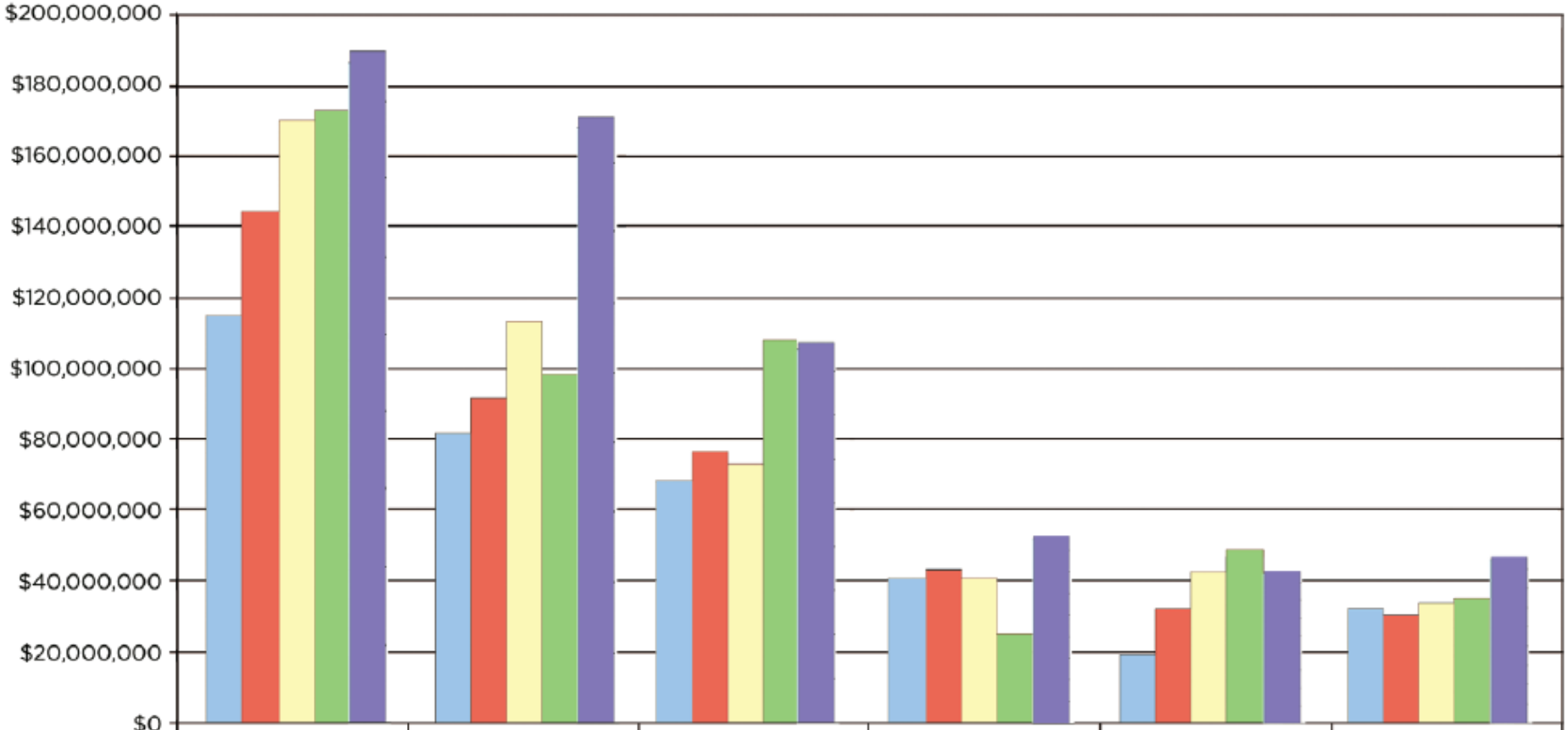
Funding required for New Diagnostics, 2011-2015
Total: USD 1.9 billion



Total TB R&D Funding: 2005–2009



Investment in TB R&D by Research Category: 2005–2009



	Drugs	Basic Science	Vaccines	Unspecified	Diagnostics	Operational
2005	$114,862,738	$81,892,167	$68,351,530	$40,741,527	$19,408,124	$32,170,084
2006	$144,336,532	$91,643,009	$76,555,111	$43,205,600	$31,890,329	$30,194,127
2007	$170,233,497	$113,325,202	$73,225,383	$40,734,199	$42,435,113	$33,967,288
2008	$174,178,052	$98,728,019	$109,337,224	$25,032,930	$49,788,950	$34,411,742
2009	$188,330,418	$170,258,389	$108,822,858	$57,820,524	$41,399,434	$47,395,222

Key challenges and opportunities that can facilitate or impede the Plan's success

- Increased investment in R&D since 2005 (71 %!) and commitment to research expressed by various bodies
- However, insufficient funds overall
- TB community needs to present the case better to political leaders and stakeholders;
- Development of a *Roadmap for International Research to eliminate TB*
- Based on consensus-driven global TB research agendas and systematic reviews;
- Promote the need for harmonized funding of TB research so as to target revolutionary discoveries that will foster better care and control for the elimination of TB

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- Inés Garcia-Baena

Thank you for your attention !