

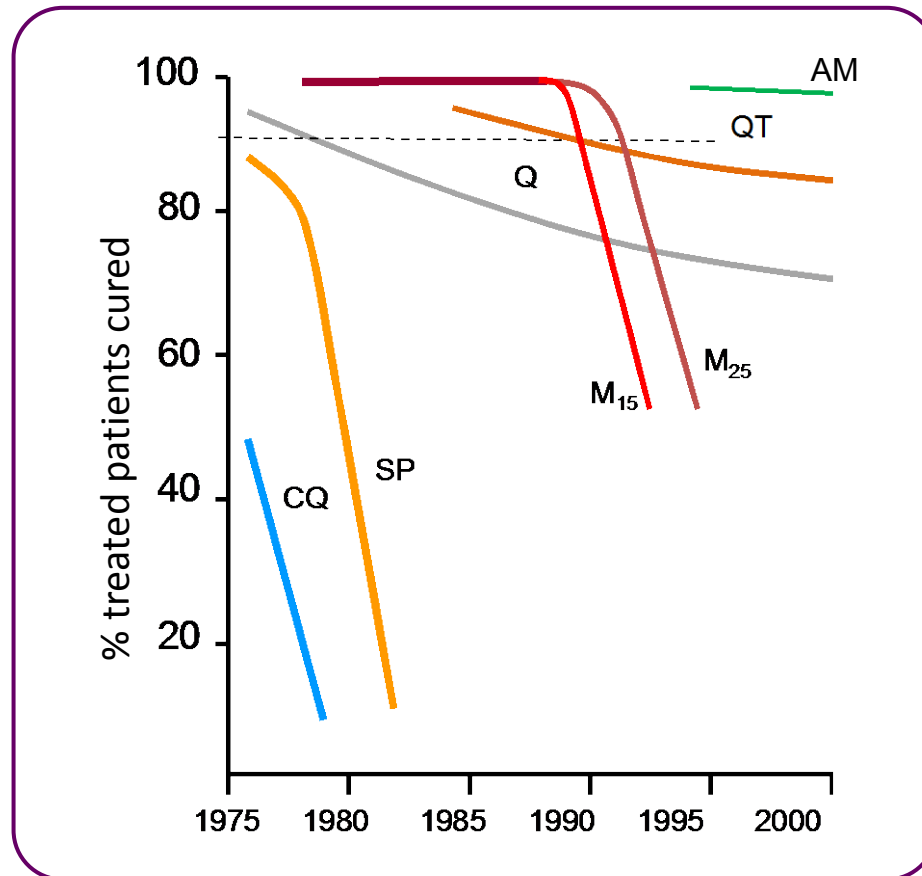


Working in a PDP Business Model

David Reddy PhD
CEO, Medicines for Malaria Venture

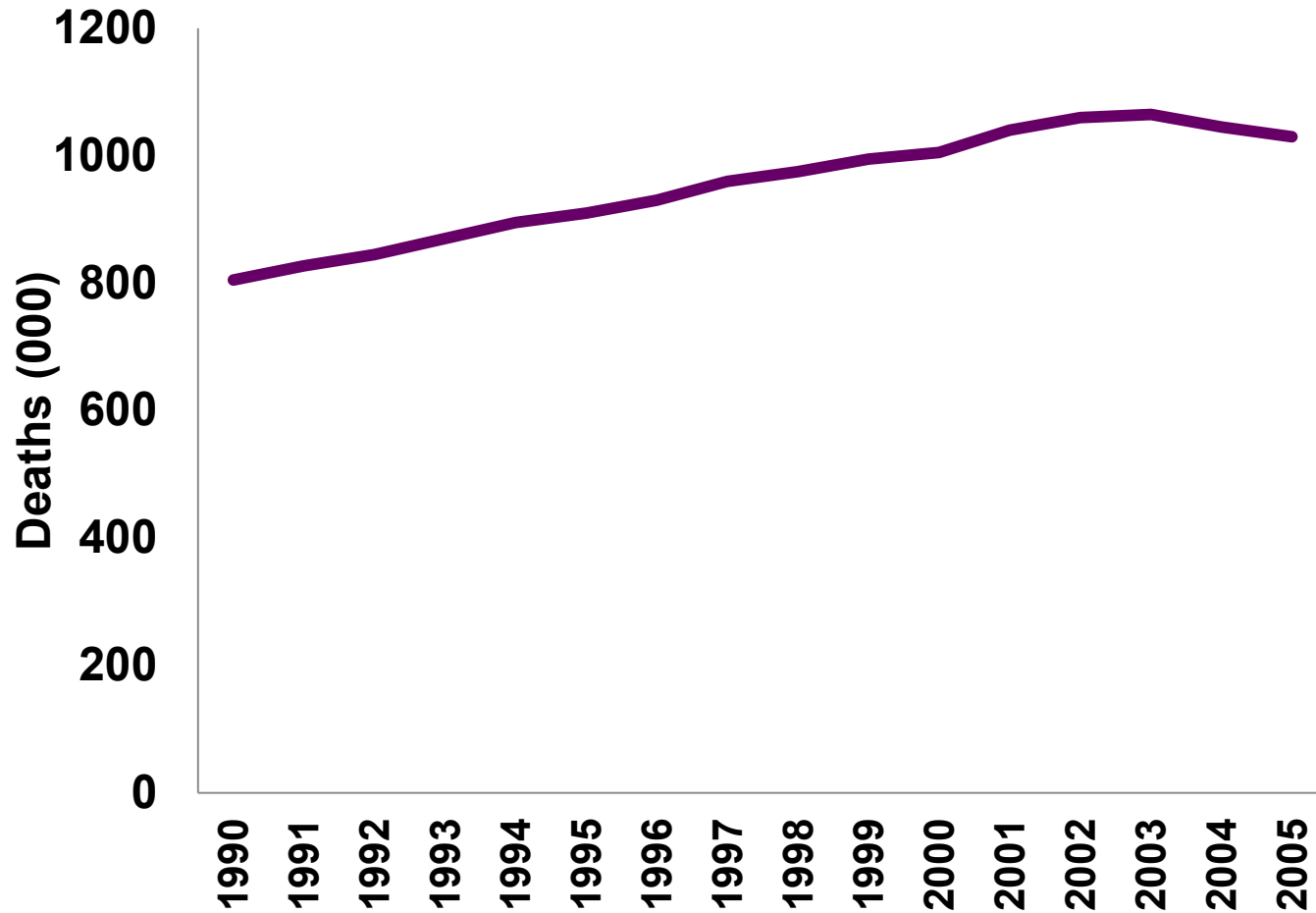
Defeating Malaria Together

Anti-malaria drug resistance 1975-2000

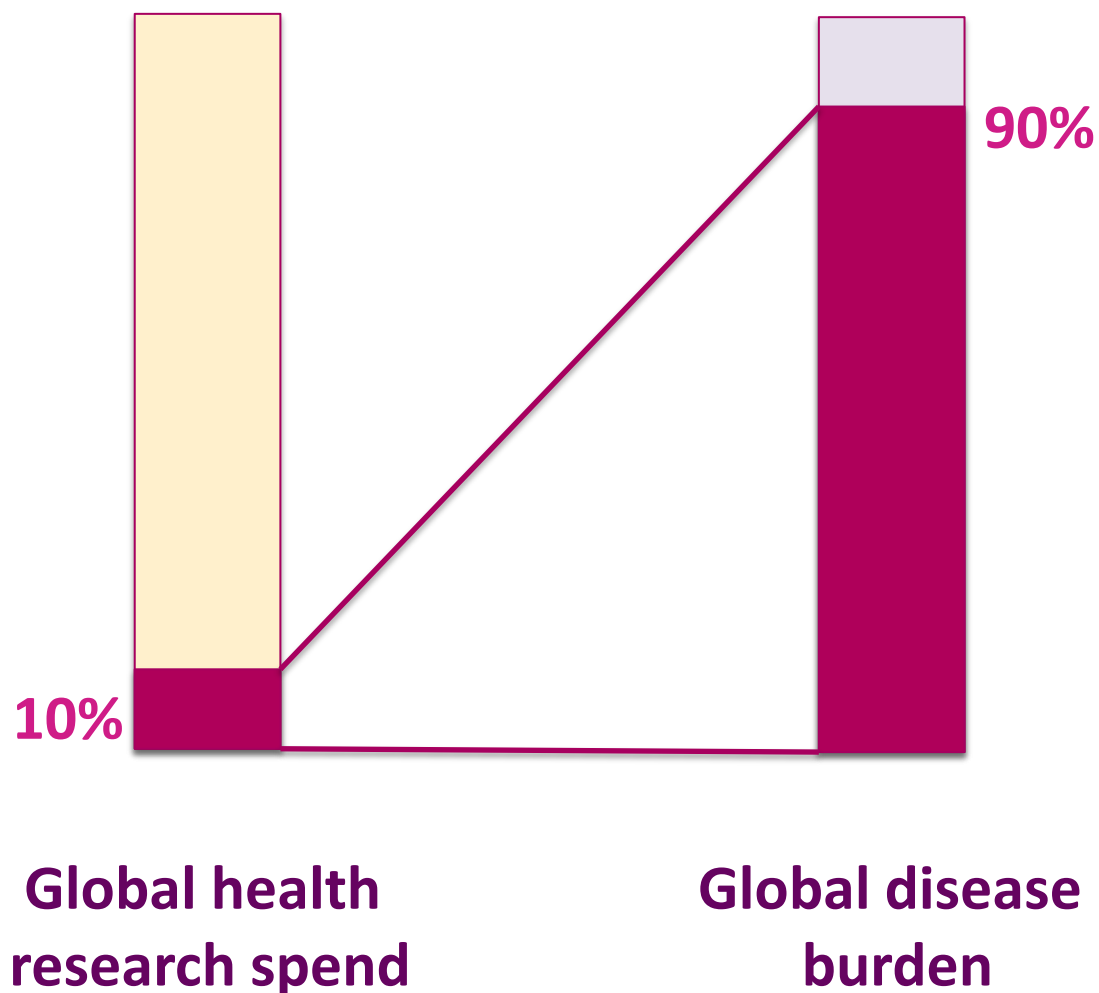


CQ = chloroquine; SP = sulphadoxine-pyrimethamine; M₁₅ = mefloquine 15 mg/kg body weight; M₂₅ = mefloquine 25 mg/kg body weight; Q = quinine; QT = tetracycline; AM = amodiaquine
Slide courtesy of Professor Nick White

Malaria mortality in Africa 1990-2005



The 10/90 gap: the fatal imbalance





Operating model

Syndicated investment

Governments,
philanthropic

Partnership

Funders,
industry,
academia,
NMCPs, UN
agencies,
CROs

Drug pipeline

R&D and
portfolio
management

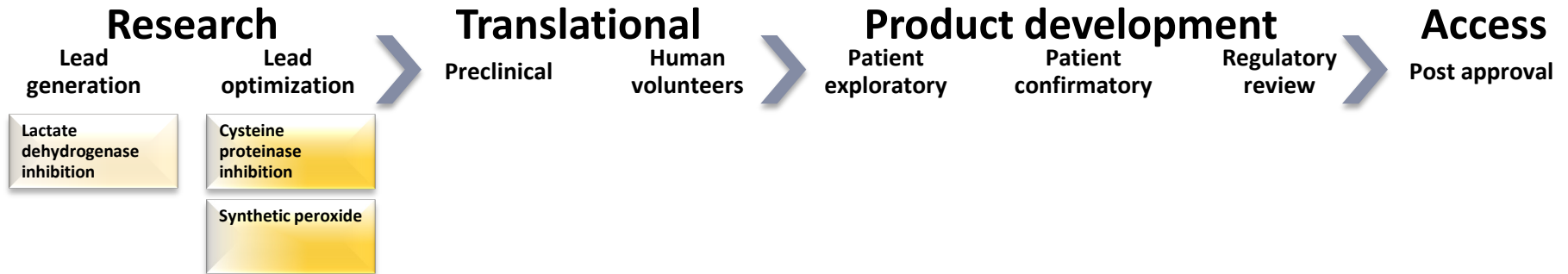
Independent expert scientific review

Supports clinical
candidate
selection and
stage-gating

Strong contractual framework

Increases
access and
good
governance

MMV-supported projects 1999



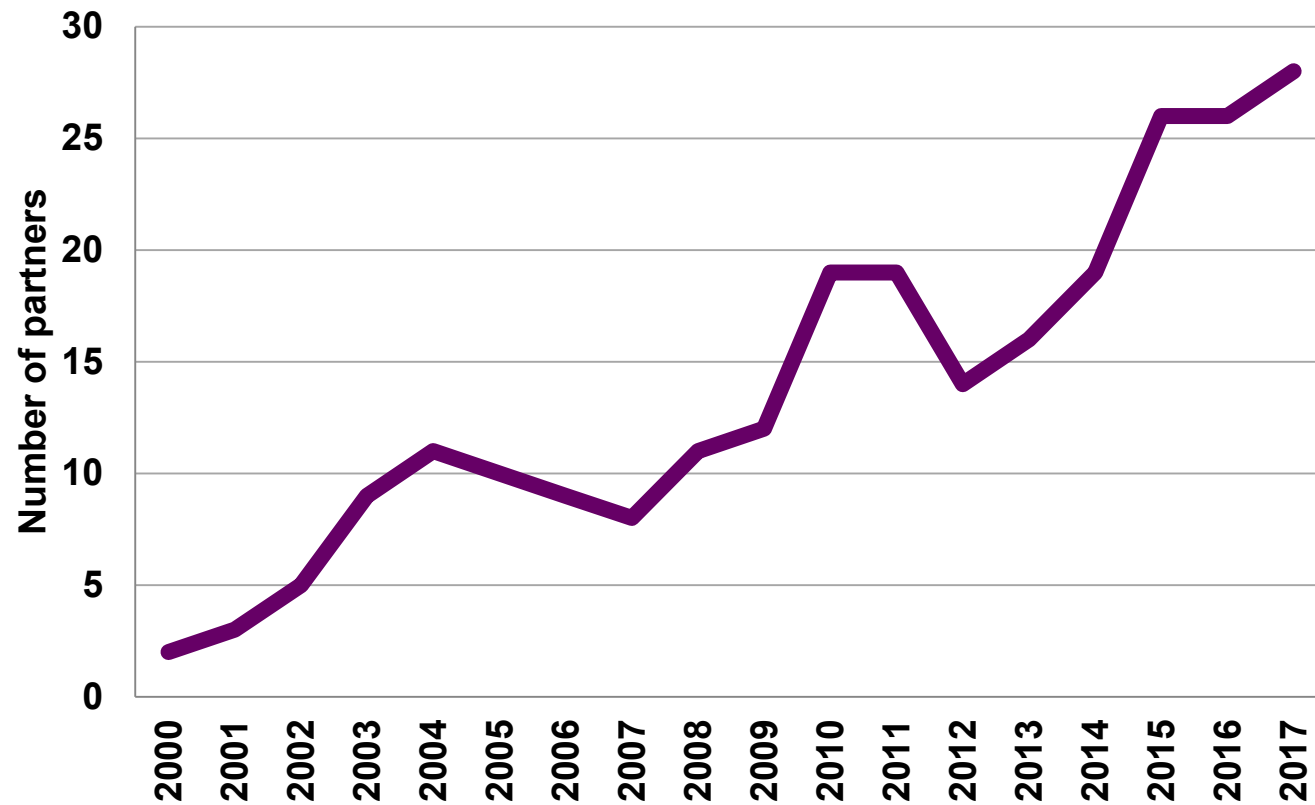
Exploratory projects:

1. DHFR
2. DHODH
3. Heme

Underlying principle

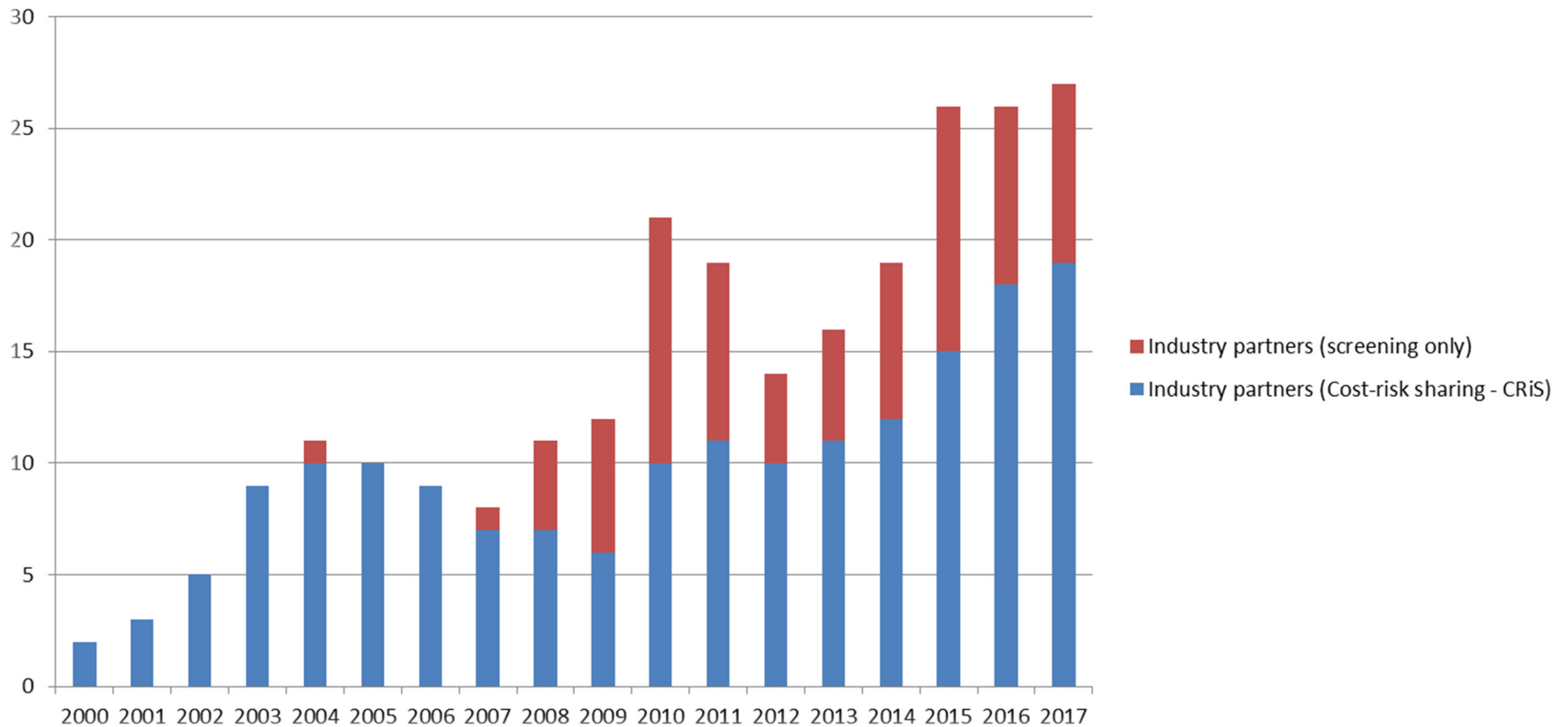
To partner with a party or parties who share our vision and commitment for the development and commercialization of anti-malarial medicines

MMV's industry partners: 2000-2018



Industry partners 2000-2017

No. industry partners



MMV partners have access to ...

... intellectual property, in the form of **patents or patentable material, know-how** and **research tools**

... **independent scientific and access expertise** through MMV's network of public and private partners and MMV's External Scientific (ESAC) and Access & Product Management (APMAC) Committees

... **MMV in-house scientific and access expertise:** our 90+ staff collectively represent **extensive experience in pharmaceutical development and/ or delivery** in the public and private sectors

... **financing** through syndicated funding sourced by MMV from funders such as the Bill & Melinda Gates Foundation, the Wellcome Trust, and GHIT

... incentive schemes such as **orphan designation, accelerated regulatory review**, and a **Priority Review Voucher (PRV)** from the US FDA, all of which offer substantial financial rewards

Transferability & exclusivity of intellectual property rights are the cornerstone of MMV's PDP model

- Provides a tool to ensure that quality, safety and other public health goals are met
- Facilitates the process of attracting a commercial partner for the development and commercialization of compounds, in particular through minimization of risk of inappropriate development and/ or commercialization by third parties
- Ensures that promising compounds are developed and commercialized with new partners if existing partners do not proceed



Development and Access commitments

- Built into agreements from an early stage (discovery)
- Become more detailed as project progresses
 - Development – compounds selected for development to be diligently and appropriately developed
 - Affordability – product expected to be made available on no-profit/ no- loss basis in public sector and subsidised private sector
 - Availability – partner commits to make or have made sufficient quantities of product as may be needed to meet public-sector demand
 - Timing – partners work together to determine the timetable for registration and launch in endemic countries

If the partner is unable to deliver on these commitments, the ownership and rights to the product flow back to MMV

Governance

- Joint project teams
 - Jointly execute projects in accordance with a pre-agreed plan & budget
 - Communicate regularly
- Steering Committees
 - Provide strategic advice and direction
 - Approve R&D, regulatory, and Access plans prepared by project team
 - Support the team but also challenge them

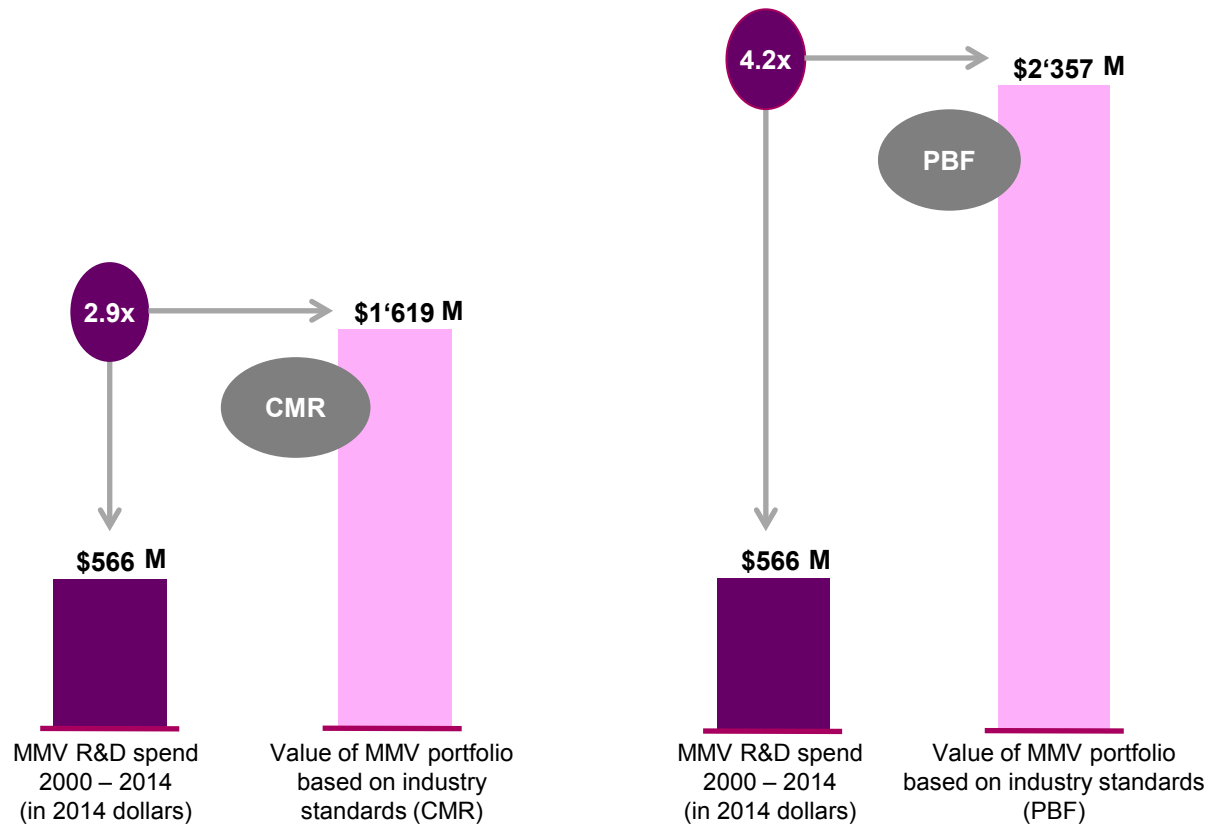


A contract forms the basis,
but is not a substitute for a strong and collaborative partnership

A word on finances

- MMV is a donor- and public-sector-funded organisation
 - Prudent management of funds is a must
 - Benchmarking is integral to agreeing budgets
- Funds are raised by MMV based on proposals typically setting out a specific plan and budget
 - MMV funding is fixed upfront and cannot be open-ended
 - Timeline changes can impact availability of donor funds
 - New activities often necessitate new donor fundraising

Donor investment to create MMV portfolio versus standard industry costs



Note: Figures inflated to 2014 dollars using the CPI inflator for both MMV and industry benchmarks

*Source: CMR (Thomson Reuters pharmaceutical benchmark, 2013 data based on sample of development projects from 2006-2010);
PBF (Pharmaceutical Benchmarking Forum, using data from 13 large pharmaceutical firms, 2010 data)

Leveraging donor funds

**PHARMA
'IN-KIND' SUPPORT**

TOTAL

MMV



£1.00



£1.50



**PHARMA
'MATCHED' FUNDING**














£1.00



£3.50

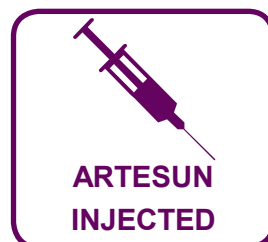
11 launched MMV-partnership medicines saving >1.5 million lives by end 2017

Approved/ ERP	
Artemether-lumefantrine Dispersible Novartis	1 
Artesunate for Injection Guilin	2 
Dihydroartemisinin-piperaquine Alfasigma	3 
Pyronaridine-artesunate Shin Poong	4 
Pyronaridine-artesunate granules Shin Poong	4 
Artesunate-amodiaquine Sanofi	5 
Artesunate-mefloquine Cipla	
Sulfadoxine-pyrimethamine+amodiaquine *	6 
Sulfadoxine-pyrimethamine+amodiaquine **	6 
Rectal artesunate Cipla	
Rectal artesunate Strides	



350 million treatment courses¹ delivered to over 50 countries

Saving >875,000 childrens lives



>100 million vials of Artesun delivered since 2011²

Saving 650,000 more lives³



Reducing uncomplicated and severe malaria episodes by 75%⁴

Protecting 19 million children



Available starting 2017, with 460,000 treatments delivered

Halving disability and death⁶

1. Source – Novartis press release 2017

2. Source – Fosun 2017

3. Additional childrens lives saved by providing injected artesunate versus injected quinine to children with severe malaria – AQUAMAT and SEAQUAMAT studies

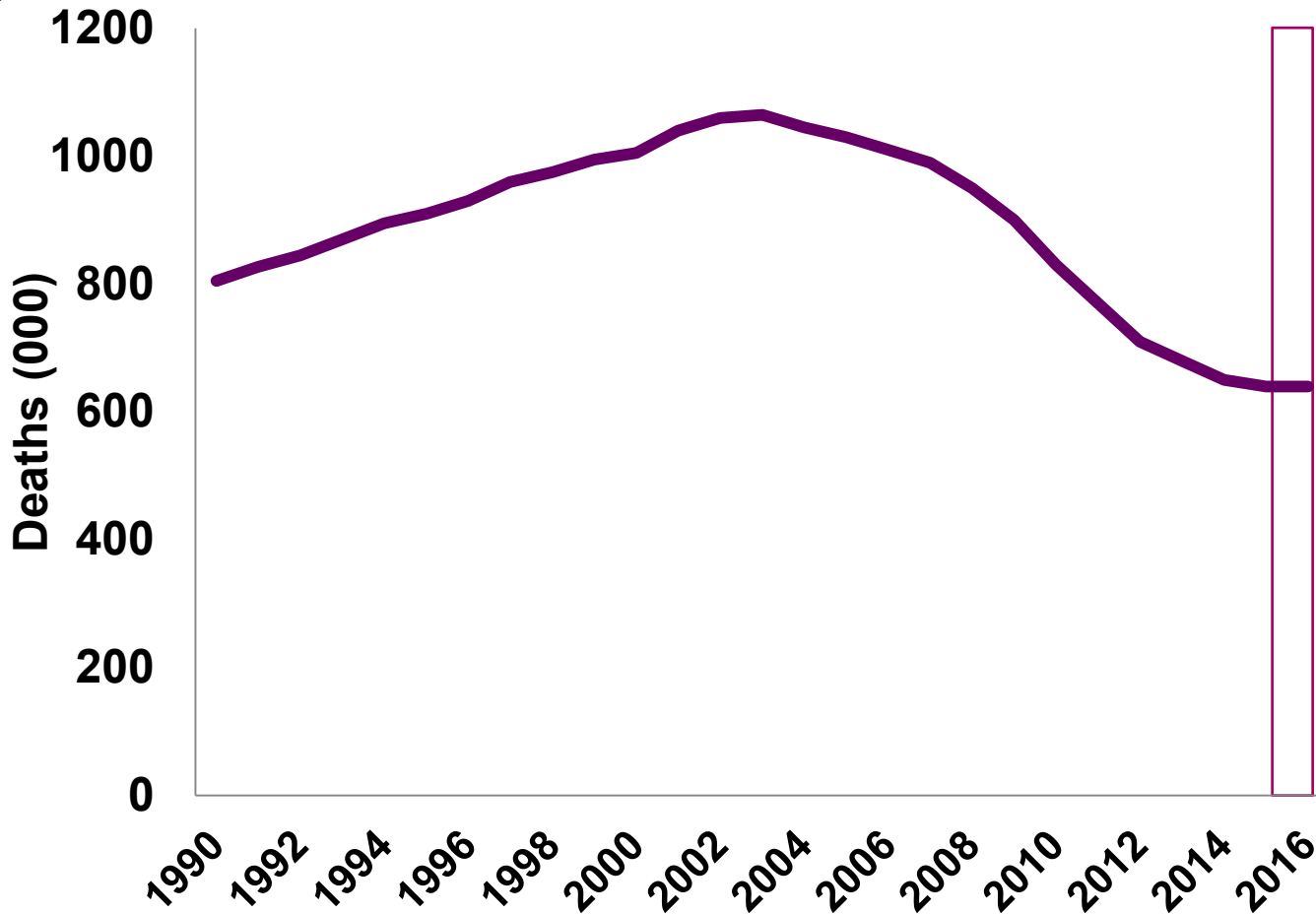
4. WHO

5. Guilin distribution data (2017)

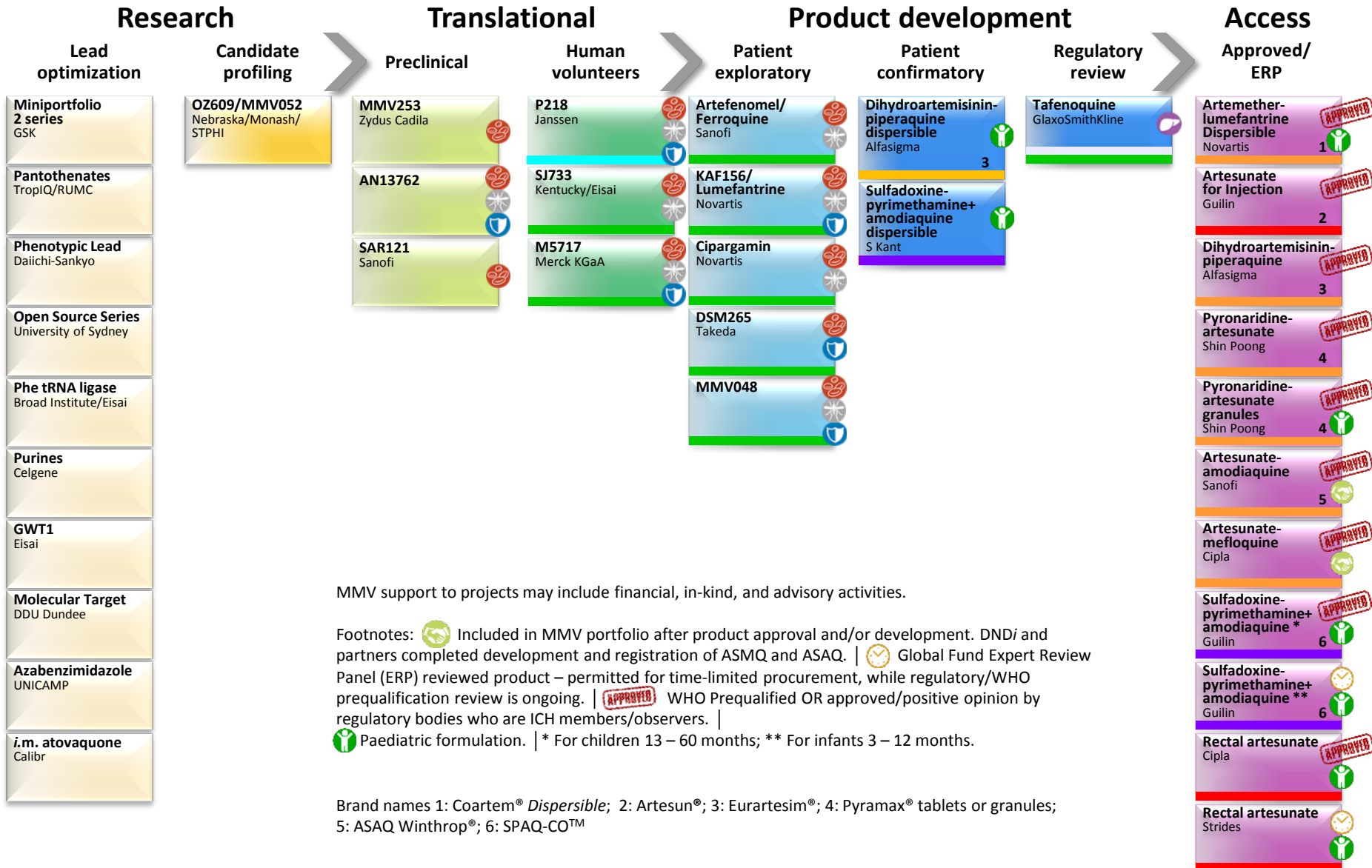
6. WHO TDR Study 13

Malaria mortality in Africa 1990-2015

but in 2016 progress has stalled



MMV-supported projects April 2018



MMV support to projects may include financial, in-kind, and advisory activities.

Footnotes: Included in MMV portfolio after product approval and/or development. DNDi and partners completed development and registration of ASMQ and ASAQ. | Global Fund Expert Review Panel (ERP) reviewed product – permitted for time-limited procurement, while regulatory/WHO prequalification review is ongoing. | WHO Prequalified OR approved/positive opinion by regulatory bodies who are ICH members/observers. | Paediatric formulation. | * For children 13 – 60 months; ** For infants 3 – 12 months.

Brand names 1: Coartem® Dispersible; 2: Artesun®; 3: Eurartesim®; 4: Pyramax® tablets or granules; 5: ASAQ Winthrop®; 6: SPAQ-CO™

18/27 active industry partners have been included in 'partner portfolio' since start 2012

	Industry Partners				
	Partner type	Location	Region	Discovery	Development
Abbvie	Top 25 pharma	USA	NA	x	x
Astellas	Top 25 pharma	Japan	Asia	x	
Boehringer Ingelheim	Top 25 pharma	Germany	EU	x	
Celgene	Top 25 pharma	USA	NA	x	
Chiromics	Private	USA	NA	x	
Cipla	Top 25 generics	India	Asia		x
Daiichi Sankyo	Top 25 pharma	Japan	Japan	x	
Eisai	Large cap	Japan	Japan	x	x
Eli Lilly	Top 25 pharma	USA	NA	x	
GSK	Top 25 pharma	UK/ Spain	EU	x	x
Janssen GPH	Top 25 pharma	USA	NA		x
Merck KgaA	Top 25 pharma	Germany	EU	x	x
Mitsubishi Tanabe	Mid-cap	Japan	Japan	x	
Novartis	Top 25 pharma	Switzerland	EU	x	x
OP Bio Factory	Private	Japan	Japan	x	
Pfizer	Top 25 pharma	USA	NA	x	
Roche	Top 25 pharma	Switzerland	EU		x
S. Kant	Generics	India	Asia		x
Sanofi	Top 25 pharma	France	EU	x	x
Shin Poong	Small-cap	Korea	Asia		x
Sigma Tau	Private	Italy	EU		x
Strides	Generics	India	Asia		x
Sumitomo Dainippon	Mid-cap	Japan	Japan	x	
Takeda	Top 25 pharma	Japan	Japan	x	x
TropiQ	Private	Netherlands	EU	x	
UCB Celltech	Large cap	Belgium	EU	x	
Zydus Cadila	Top 25 generics	India	Asia		x

Key lessons learned

- The PDP model can be highly successful
- Private sector partners possess capabilities needed to successfully address the AMR challenge, but have different needs & barriers to entry - these require different incentives and support
 - Financial risk-sharing (syndicated investment, PRV)
 - Use of intellectual property to frame rewards and responsibilities
 - Strategic alignment and external validation
 - Technical guidance (disease-specific, drug development and registration, market knowledge)
 - Advocacy and reputational enhancement / protection

MMV are Grateful to our Committed Funders



BILL & MELINDA
GATES foundation

ExxonMobil



National Institutes
of Health (NIH/NIAID)



wellcome trust



SPONSORED BY THE

