

Introducing 'Medicines for Malaria Venture', MMV

**Malariology Module Berlin
31 Aug 2006**

**Jörg J. Möhrle PhD MBA
Medicines for Malaria Venture**

Curing Malaria Together www.mmv.org



Medicines for Malaria Venture

MMV In a Nutshell



- Established in 1999, started business in 2000
- Discover, Develop, Deliver....Medicines...for Malaria
- Geneva Based: Swiss foundation (not for profit)
- Public Private Partnership (PPP or PDP)
- 20 Products in the Pipeline, 5 late stage products
- Funding from Foundations, Governments and Companies

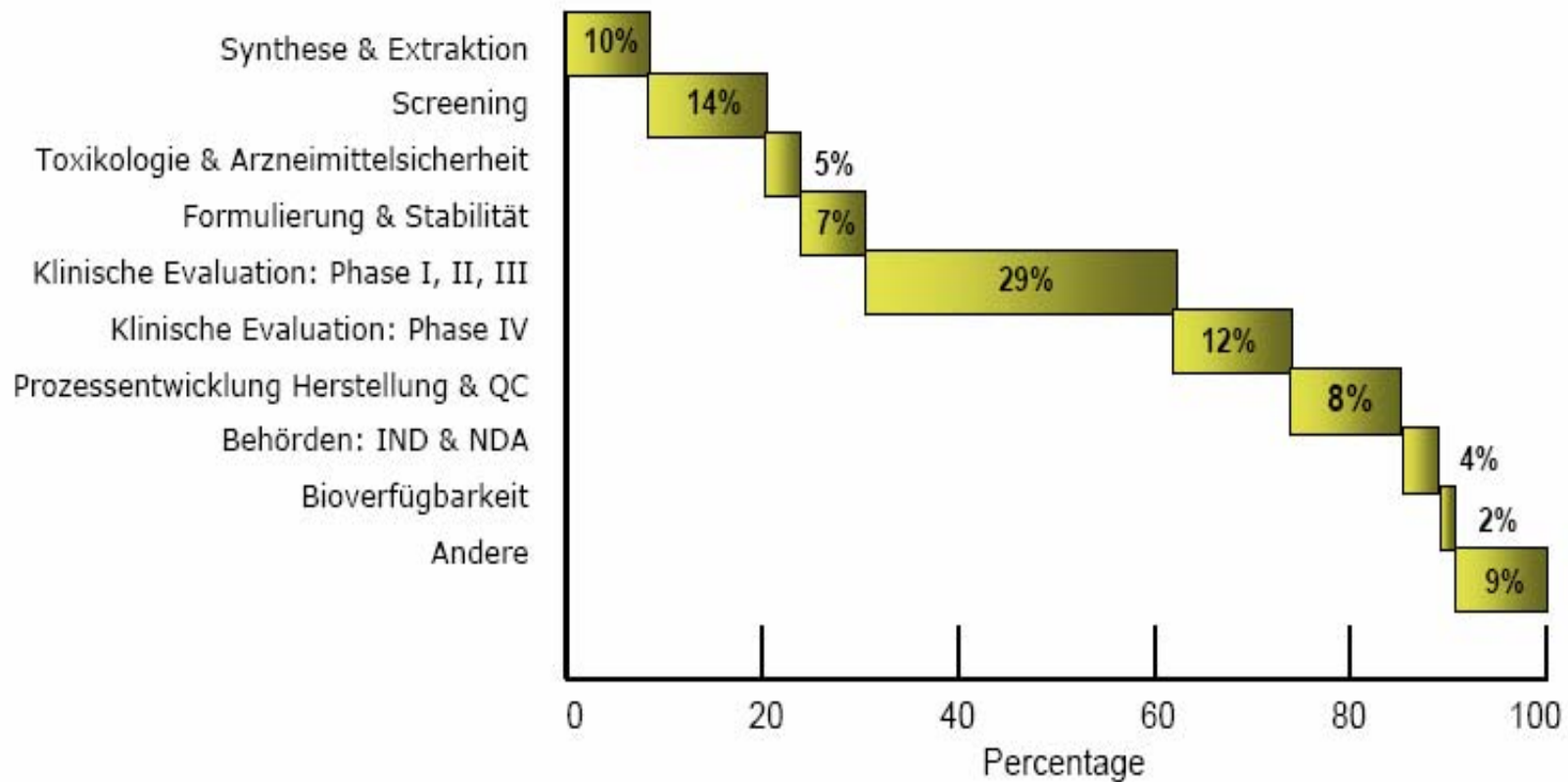
- See www.mmv.org for background and much more



Developing costs for new medications



\$800 Millionen für ein neues Medikament



Drug Development for Neglected Diseases



1975 – 1999

- **1'393 new drugs were made available to the public by the pharmaceutical industryⁱ**
- **But only 13 drugs were developed for neglected diseases during that periodⁱⁱ**

• ^[i] Trouiller P, Olliaro P, Torreele E, Orbinski J, Laing R, et al. Drug development for neglected diseases: A deficient market and a public health policy failure. *Lancet* 2002, 359: 2188–2194.

• ^[ii] Pecoul B, Chirac P, Trouiller P, Pinel J. Access to essential drugs in poor countries: a lost battle? *JAMA*. 1999, 281: 361-67.





- **MMV is a Not-for-Profit foundation operating as a public-private partnership**
- **Created in 1999 by**
 - WHO
 - The World Bank
 - Donor governments (CH, UK)
 - Philanthropic foundations



MMV's Vision and Mission



Our vision is a world in which affordable drugs will help eliminate the devastating effects of malaria and help protect the children, pregnant women, and vulnerable workers of developing countries from this terrible disease.

Our mission is to Discover, Develop and Deliver novel anti-malarial Drugs



MMV Collaboration Principles



- MMV's overall objective is to ensure the sustainable and continuous generation of appropriate new malaria medicines that are accessible to those in need in developing countries at the lowest prices practicable.

- **APPROPRIATE**

- **AFFORDABLE**

- **ACCESSIBLE**



Public Private Partnership? (PPP's or PDPs)



- **Accountable to 'stakeholders' – donors, partners and supporters**
- **Disease or technology focus**
- **Portfolio Management as key value added**
- **R&D management in partnership with private sector and with private sector 'in kind' contributions**
- **Virtual R&D as the rule**
- **Strong links to global players (eg RBM, GMP/WHO)**
- **Long goals with no exits (sustainability – “as long as it takes”)**
- **Collectively manage/fund about 75% of global portfolio of “neglected” disease R&D**
- **Collectively advocate for greater public support for product R&D**



R&D: A contractual balance of obligations and benefits



MMV Input

- \$\$\$
- Drug Profile
- Background IPR
- Link to WHO/Policy
- Malaria Expertise

Public



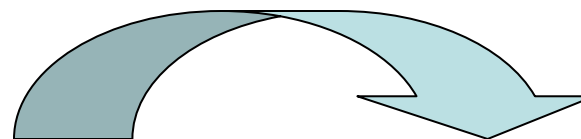
**Joint
R&D
Portfolio**

MMV Gets

- Drug 'Rights' in Endemic Countries
- IPR in 'Field'

Pharma

- Chemistry IPR
- Toxicology
- Know How
- Assets in Kind
- Technology



Private

Pharma/Bio Gets

- Private Sector Rights
- IPR outside 'Field'
- PR Benefit
- HR Benefit
- Validation of Technology



A lean qualified core staff – that depends highly on outside expertise :



Total Headcount

20



Males/Females

9/11



Nationalities

• American	6	Dual	7
• British	2	American	
• Canadian	3	British	
• French	3	Chinese	
• Monaco	1	Lebanese	
• German	1	New Zealand	
• Indian	1	French	
• Irish	1	Swiss	
• Swiss	2		



Academic Qualifications

• PH.D.	8
• M.D.	1
• M.B.A.	2
• M.P.H	1
• BA/BSc.	7
• Diplomas	2



Languages

- English
- French
- Portuguese
- Chinese
- Arabic

Spoken

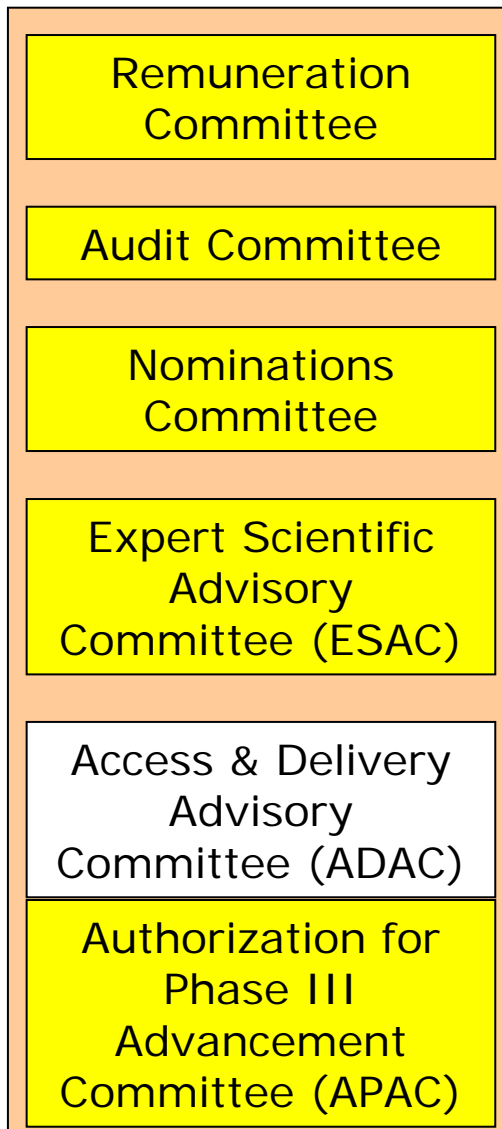
- German
- Indian Languages
- Italian
- Russian



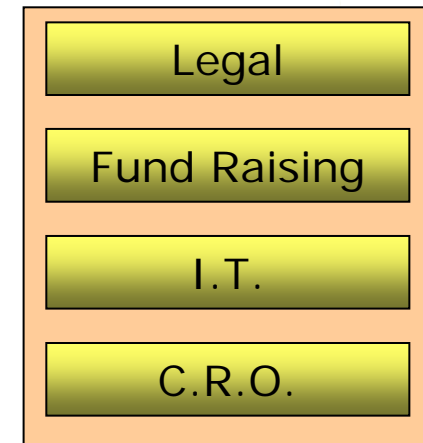
MMV Uses Many Types of Outsourced Support:



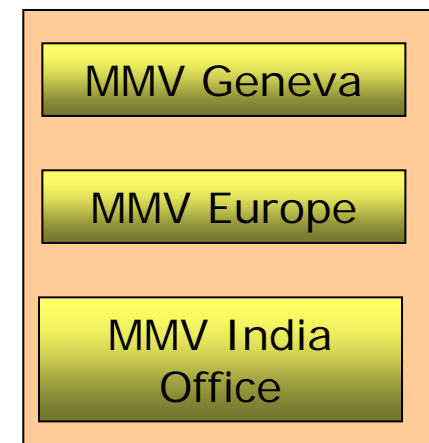
Key Committees



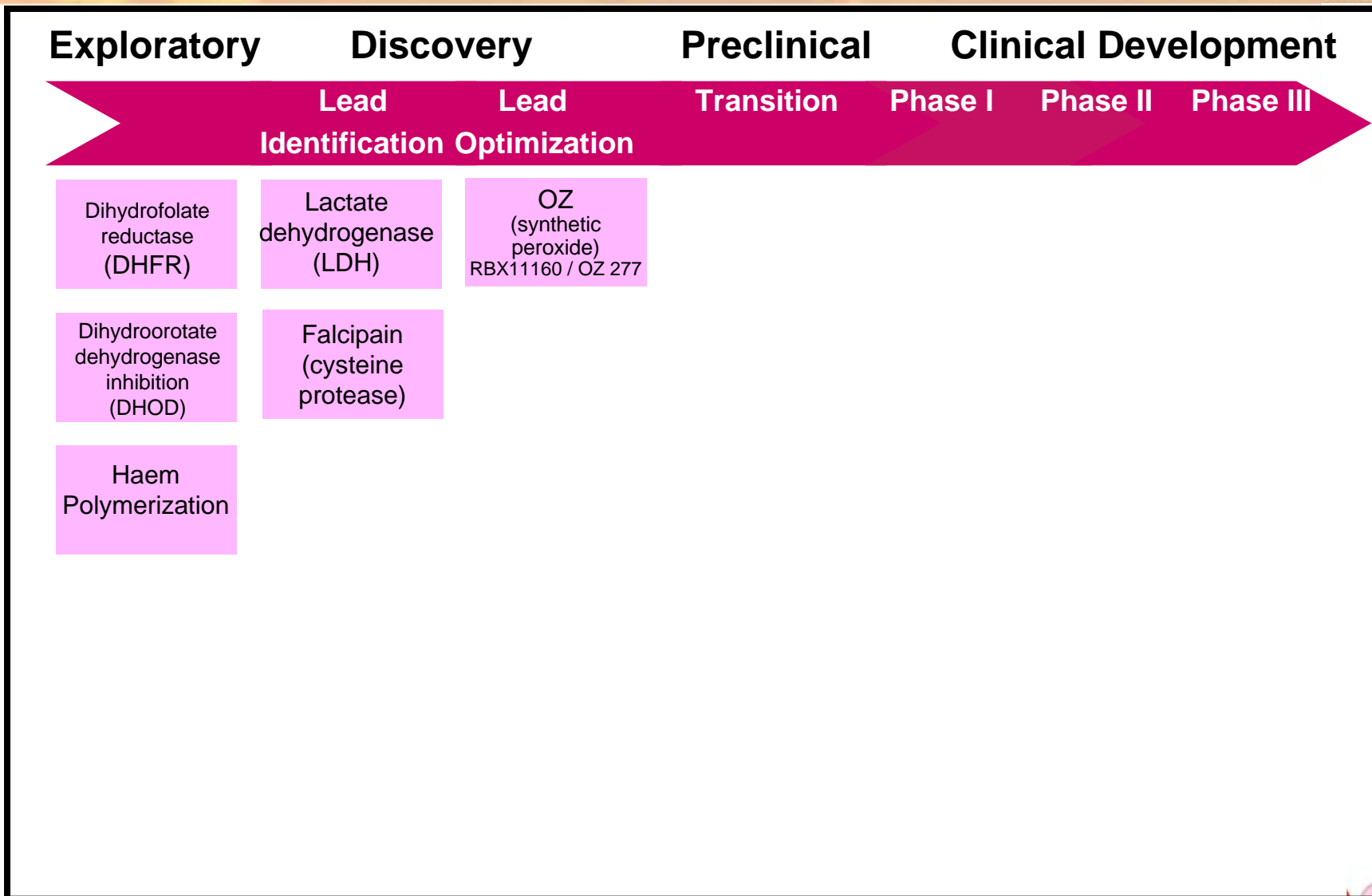
Outsourced Support



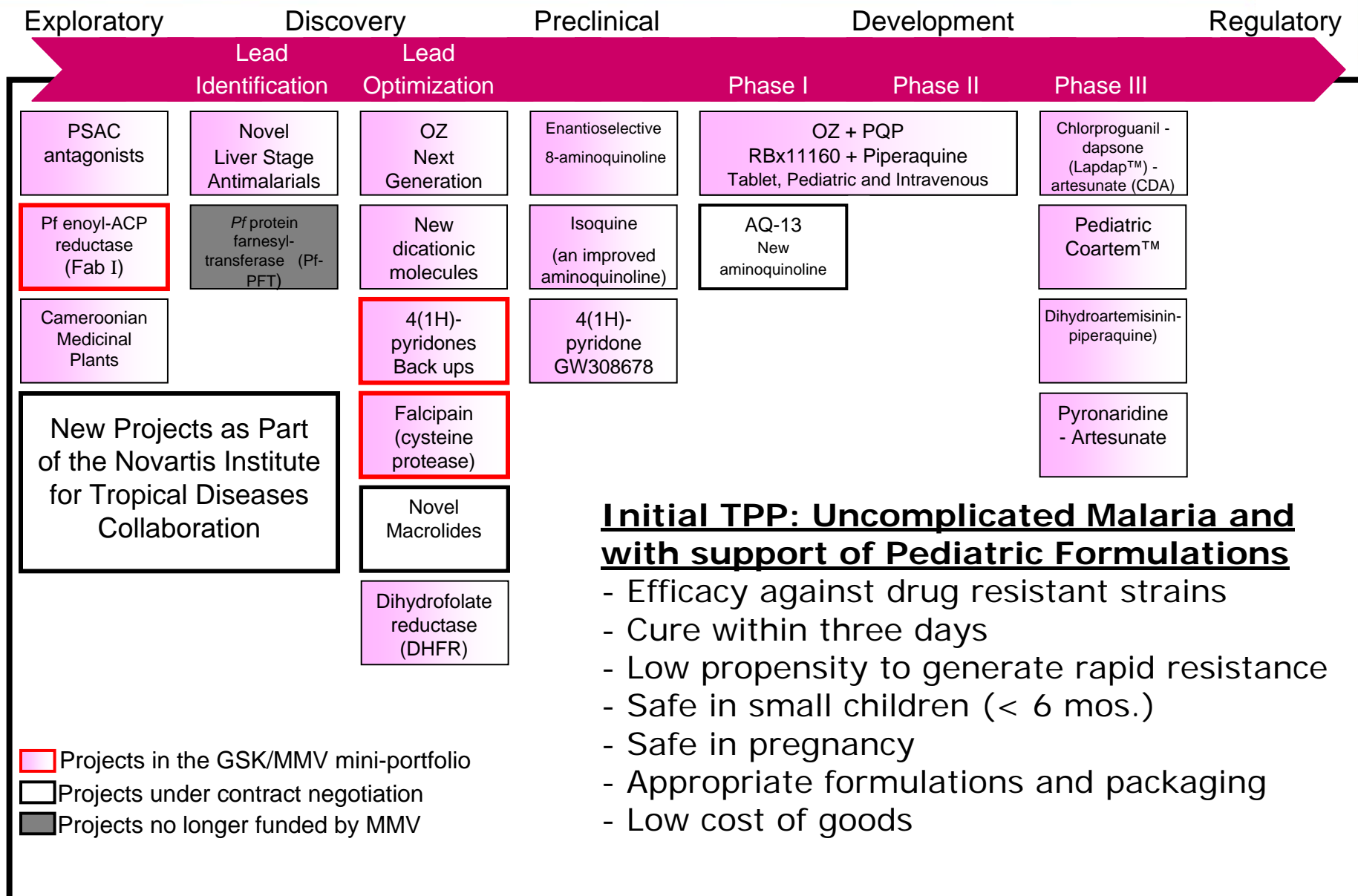
Geographic Presence



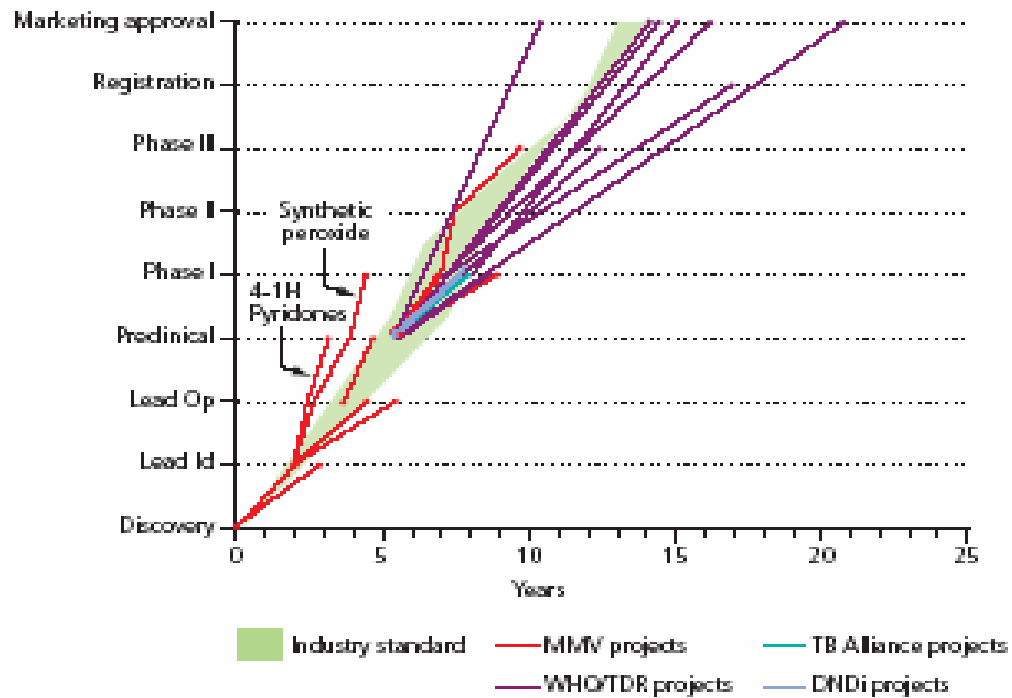
MMV Portfolio 2001



MMV Portfolio 3rd Q 2006



Drug Development Performance of PPP

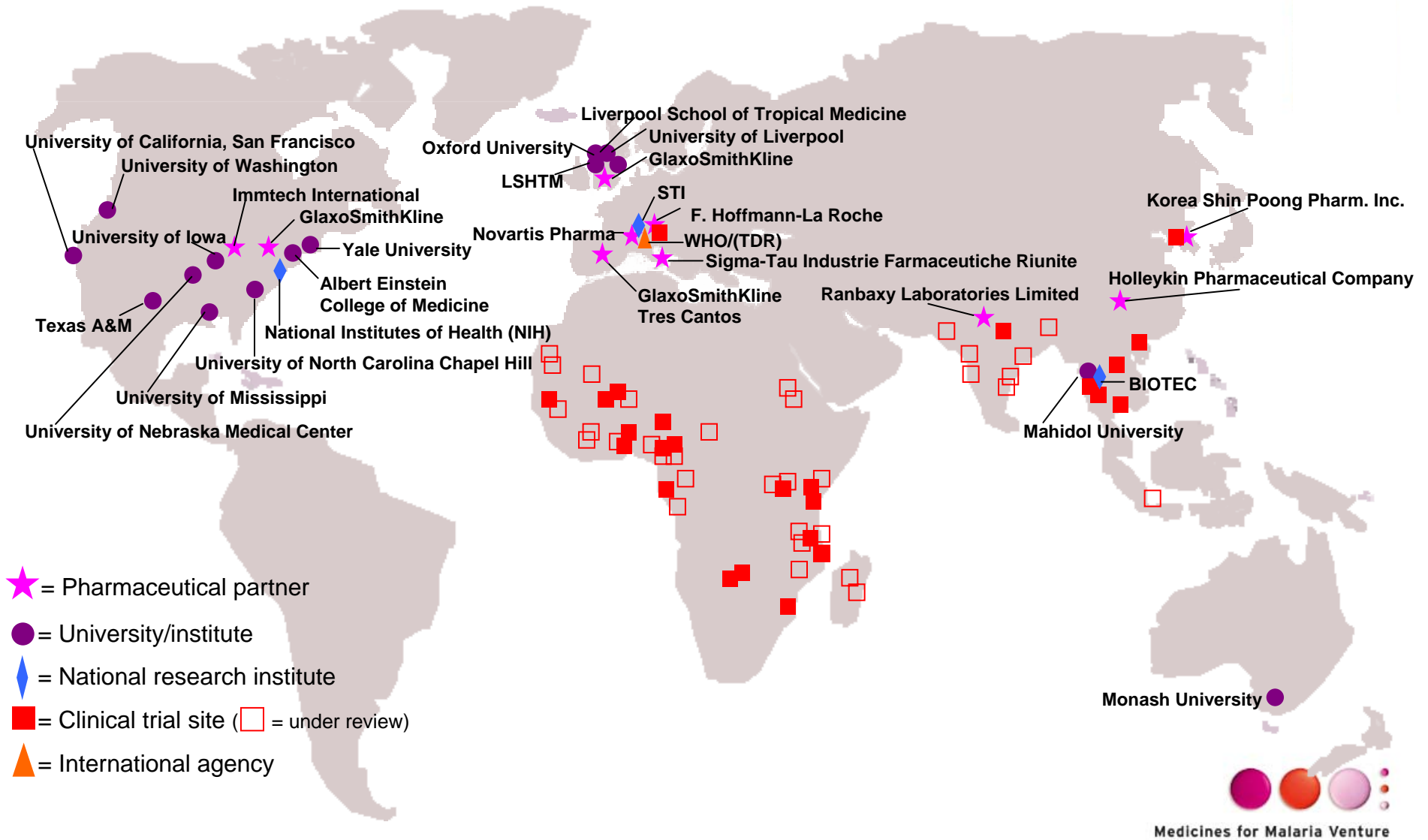


Ref: Moran, Mary; Ropars, Anne-Laure; Javier, Guzman; Jose, Diaz; Garrison, Christopher. 'The new landscape of neglected disease drug development.' LSE Health and Social Care. London 2005



Medicines for Malaria Venture

MMV: A Global Network of R&D Partners...



Summary Portfolio Development



- **Largest jointly managed antimalarial R&D portfolio in history**
- **Over 50 cutting-edge research entities including universities, clinical research centres and non-profit organizations as well as pharmaceutical/biotech company based in 34 countries in Africa, America, Asia, Australia and Europe (see “MMV at a Glance” leaflet).**
- **The MMV portfolio has now reached an optimal size approx 20 projects, with 11 discovery projects, 4 preclinical projects, and 5 projects in clinical development.**
- **“Most companies would be delighted by having a portfolio so heavy in late stage projects “**

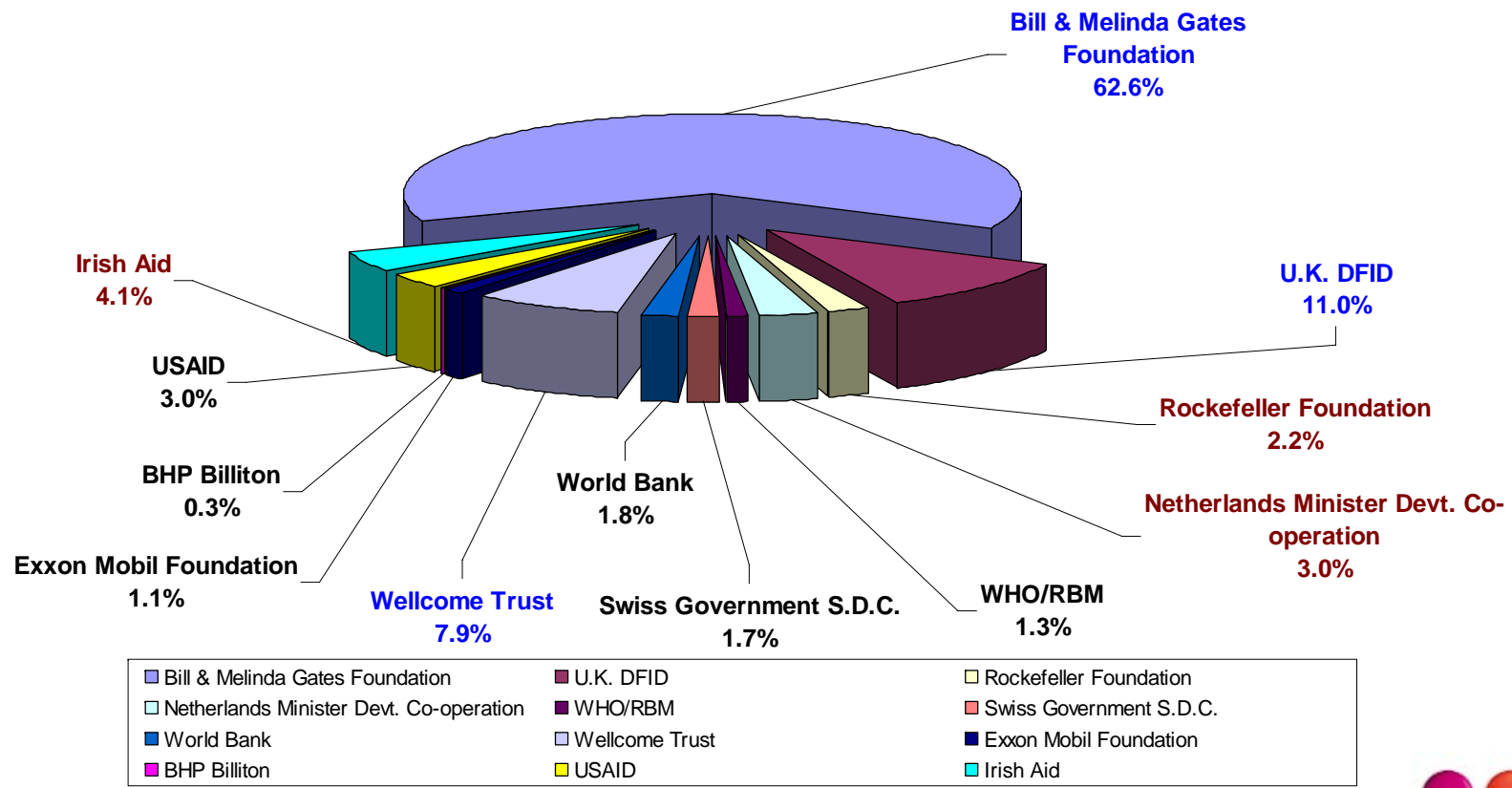


May 2006 – 2010, \$263m - but conditional on milestones



MMV - Medicines for Malaria Venture funding from Foundation to 2010 (May 2006)

(Total Received/Pledged \$263 Million)

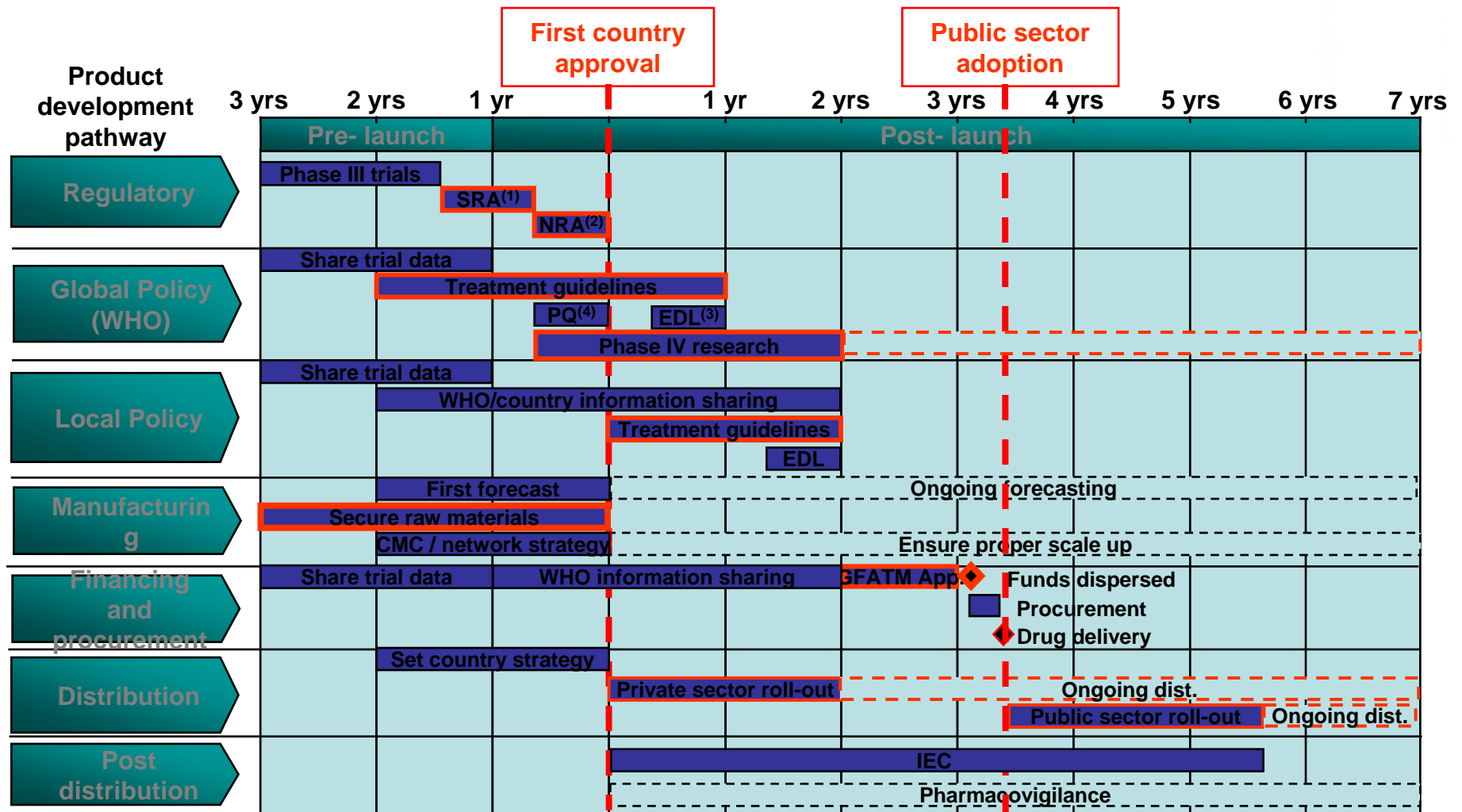


The True Finish Line



Medicines for Malaria Venture

PUBLIC MARKET IMPLEMENTATION IN KEY COUNTRIES COULD TAKE SEVERAL YEARS




(1) Stringent Regulatory Authority (e.g., EMEA, FDA, other)

(2) National Regulatory Authority endemic country; may require additional small scale local studies

(3) Essential Drug List; (4) Pre-qualification

Source: WHO website, GFATM research, interviews

 Ongoing activity
 Direct uptake impact

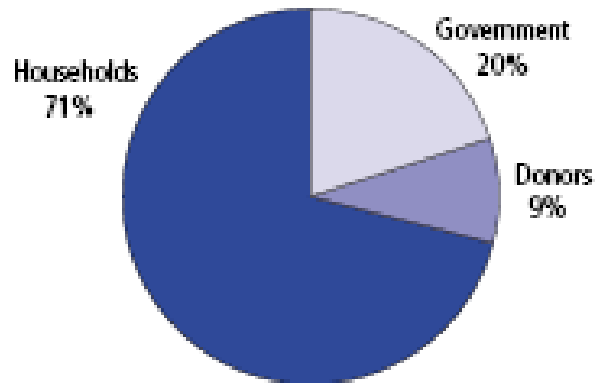


Medicines for Malaria Venture

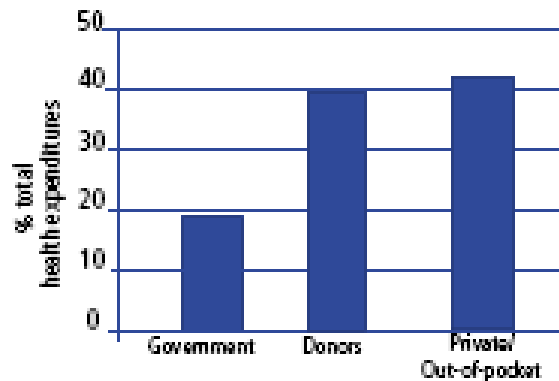
Who Spends on Malaria?



Total malaria expenditures by source in the United Republic of Tanzania, fiscal year 1998



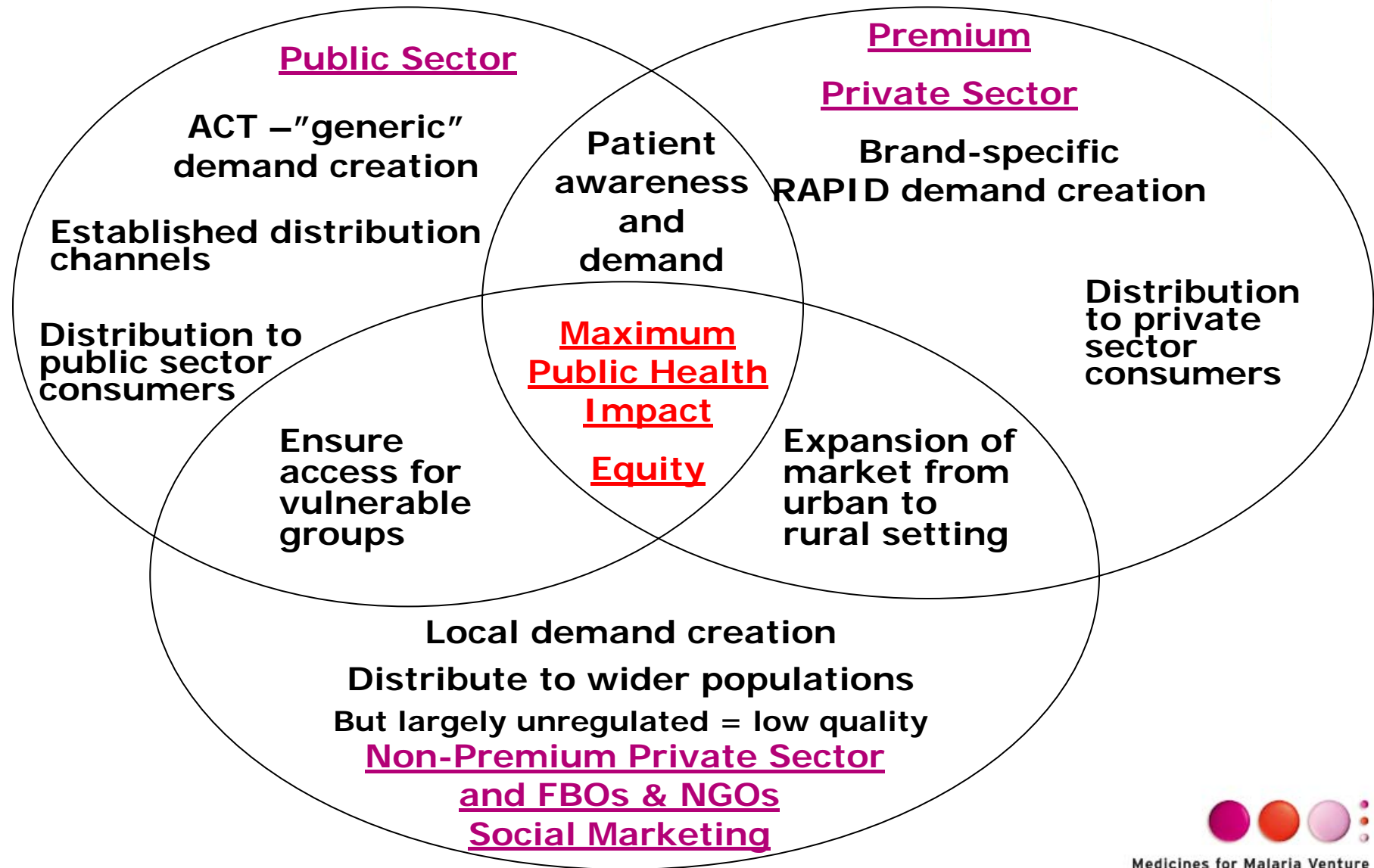
Contribution of different sources in African health expenditure



- Private sector spending dominates over public sector
- Private sector is more rapidly accessible than public sector
- Households spend up to 30% of their income on malaria interventions
- Subsidies are being explored to make ACTs more affordable



Public – Private Market Sector Dynamics



Key Questions for Roll-out of New Drug



- **Where & When to Launch: ensuring maximum availability**
- **Demand Forecasting and Manufacturing Capacity**
- **Supply Chain Management**
- **Price & Financing: lowest possible price, maximise availability**
- **Distribution and Delivery Channels**
- **Information on new drugs – forward planning**
- **Quality Assurance, Pharmacovigilance**
- **Resources Required: partners, resources, information**
- **Measuring Impact**



Access and Delivery (A&D): A contractual balance of obligations and benefits



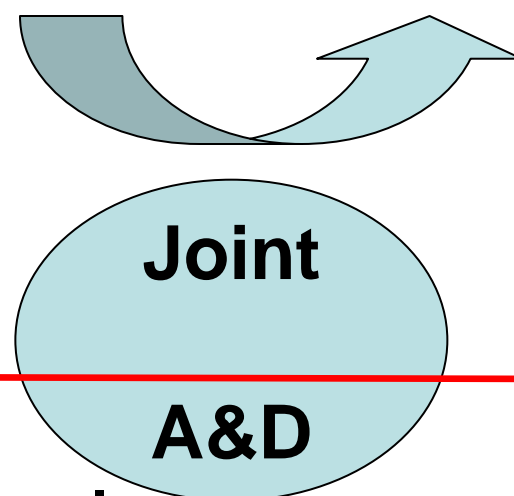
MMV Input

- \$\$\$ mobilization of external support
- Advocacy
- Links to Global Fund PMI etc.
- Foreground IPR
- Need Profile
- Links to WHO, RBM and country policy makers
- Malaria specific Access Expertise, Advice (eg ADAC) and planning (GAPs)

Public

Public Gets

- Affordable Drug Supply
- Private distribution in DEC
- Return on non DEC Sales
- Benefits of pooled procurement
- Available supplies
- Quality products
- Health Impact



Pharma + Multinationals

- Manufacturing
- QA
- Supply Chain & Delivery Know How
- Assets in Kind
- Liability Insurance

Private Gets

- Sales in non DEC
- IPR outside 'Field'
- PR Benefit
- Guaranteed high sales volume
- Dependable clients



Key Technical Advisory Committees



Access & Delivery Advisory Committee (ADAC)

Members: Awa Coll-Seck—Chair Executive Director RBM Chairperson

Members will be appointed from the following areas of expertise: Epidemiology, Regulatory, Quality Assurance/ Pharmacovigilance, Malaria Treatment & Coverage (Clinical), National Drug Policy Formulation, Finance, Pricing, Procurement / Supply Chain Logistics, Treatment / Local Delivery (Systems), Demand Creation / Marketing / Comms OR / Phase IV, Economics of Malaria / Willingness to Pay / Health Outcomes,

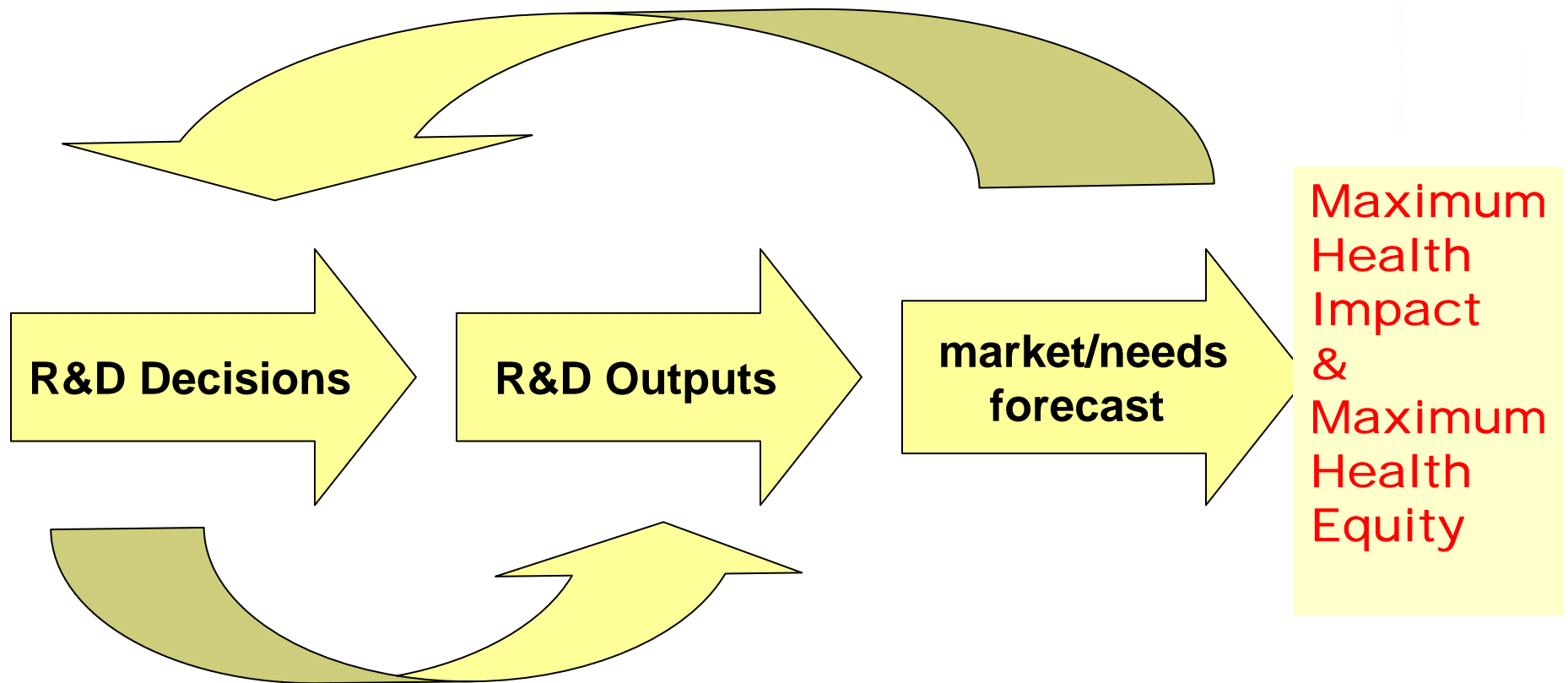
Terms of Reference

To advise on the development and implementation of product access plans to ensure timely and effective delivery of new anti-malarial drugs in malaria endemic countries

To provide more general advice & information to the CEO on appropriate strategies to achieve the MMV access and delivery goals



Market Pull: **ADAC**



Technology Push: **ESAC**



Wanted: High Quality convenient affordable drugs
at a seller near you



Medicines for Malaria Venture

Many Issues in the Non-Premium Sector for Access & Delivery



- **Regulation/enforcement virtually non-existent: quality and price control mechanisms are limited**

Kenya: ~60% of fevers treated at home with locally purchased herbs or drugs;

Ghana: ~66% use Licensed Chemical Sellers (LCS) for first line therapy;

Togo: ~83% of fevers treated at home,

Burkina Faso: ~87% mild / 54% of severe fevers treated outside professional services

- **Low quality and counterfeit drugs are widespread**

Kenya: more than 200 drugs available on market, only 50 % were officially registered (A Amin & R Snow, Malaria Journal 2005, 4; 36)

- **Who can pay? Malaria costs for poor households**

10% or more of income is spent on malaria prevention and treatment (S Russell, Am. J. Trop. Med. Hyg., 71(2 suppl), 2004, 147 and Onwujekwe, Health Policy, 2000, (54) 143)

- **Equity issue:** very poor don't seek treatment from public sector (Ndola Prata, SEAM conf 2003 and B Uzochukwe, Int. Jnl for Equity in Health, 2004, 3:6)



MMV has started analyze/model the likely effect of key variables on pipeline drugs:



Conclusions: Health Benefit of MMV products are dependent on

- **Presence of 'alternate/competitor' products (initially ACTs)**
- **Promotion and Policy environment**
- **Time to private market***
- **Time to public market***
- **Price (Subsidy)**
- **Additional indications e.g. pediatric or pregnant women**
- **Shelf life**
- **Country Variables (existing malaria control programs, market segmentation)**
- **Emergence of resistance**

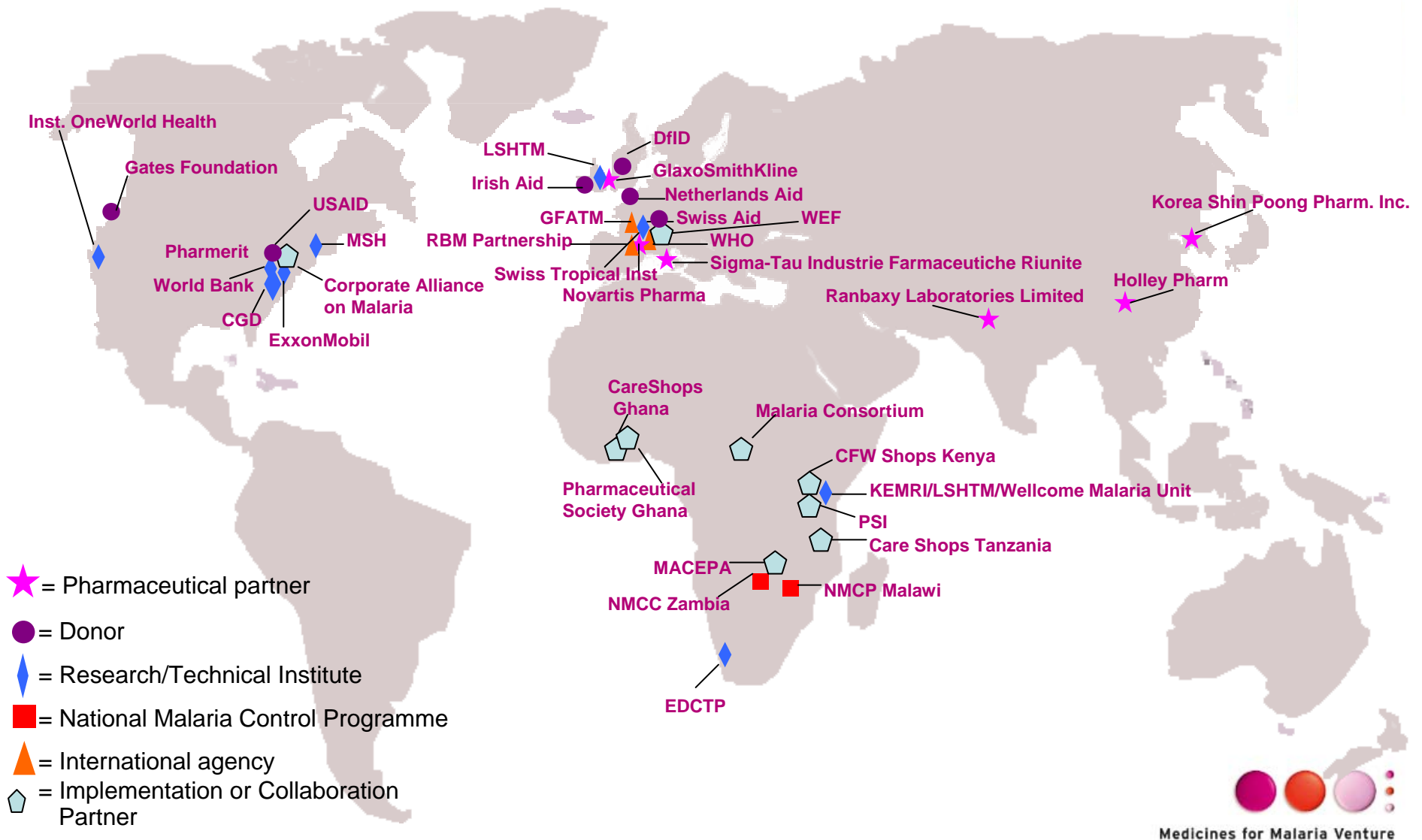
- ***first mover advantage in innovation is significant**



MMV: ...Now Creating a Future Network for Access & Delivery



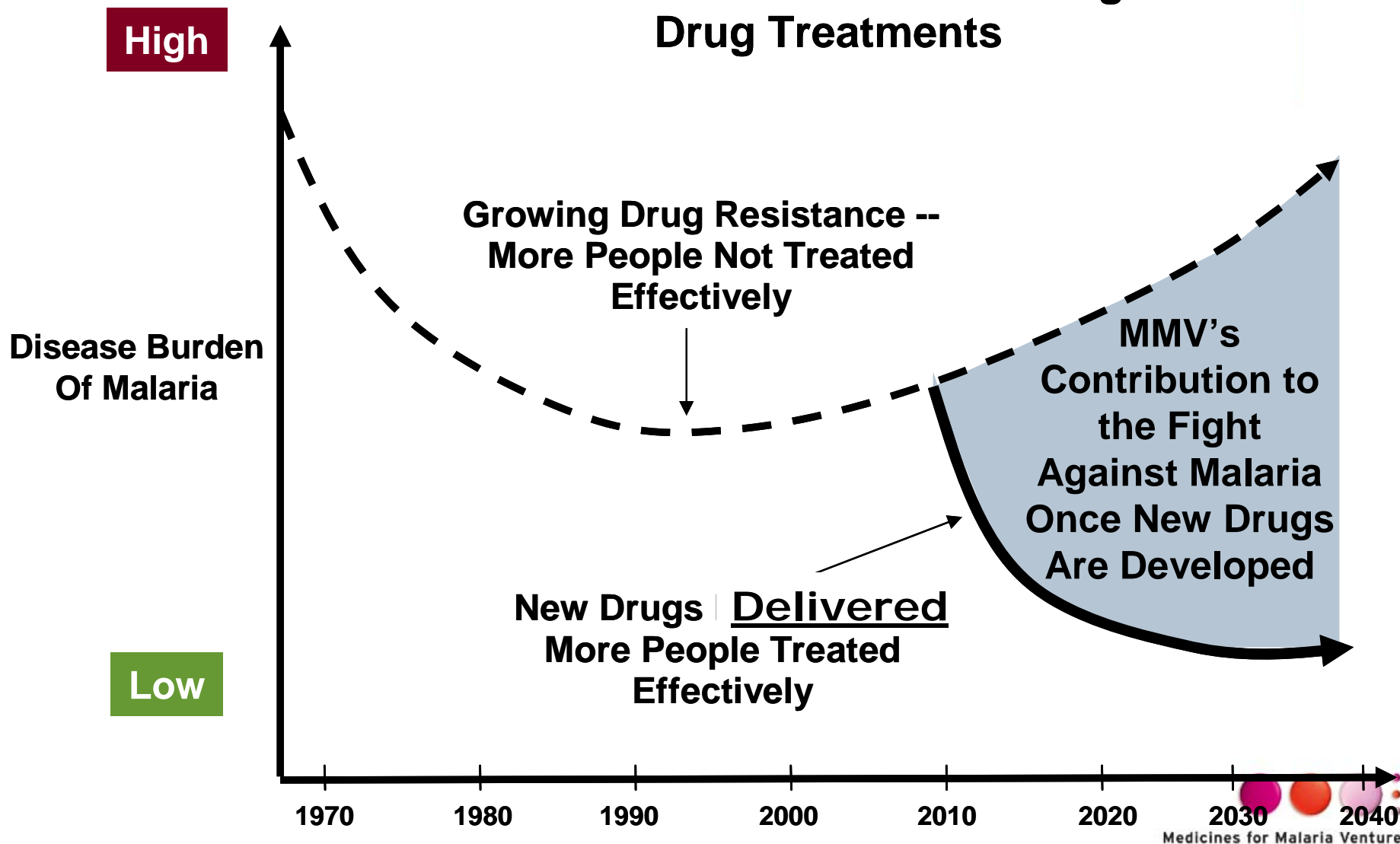
Potential Partners for Access:



Health impact is not just an aspiration – it is happening



Reduced Malaria Incidence Through New Drug Treatments



But this changed and will continue to change over time: See www.mmv.org



- 2000 Discover, Develop, Register
- 2003 Discover, Develop, Deliver (Passive -Facilitator)
- 2005 Discover, Develop, Deliver. Active role endorsed by MMV Board
- 2006 Delivery planning/fundraising activities in full swing
- 2008-10 Registration of first MMV products
- 2010-20 Growing focus on Health Impact*
- * Possibility of greater 'downstream integration' with other PDP's

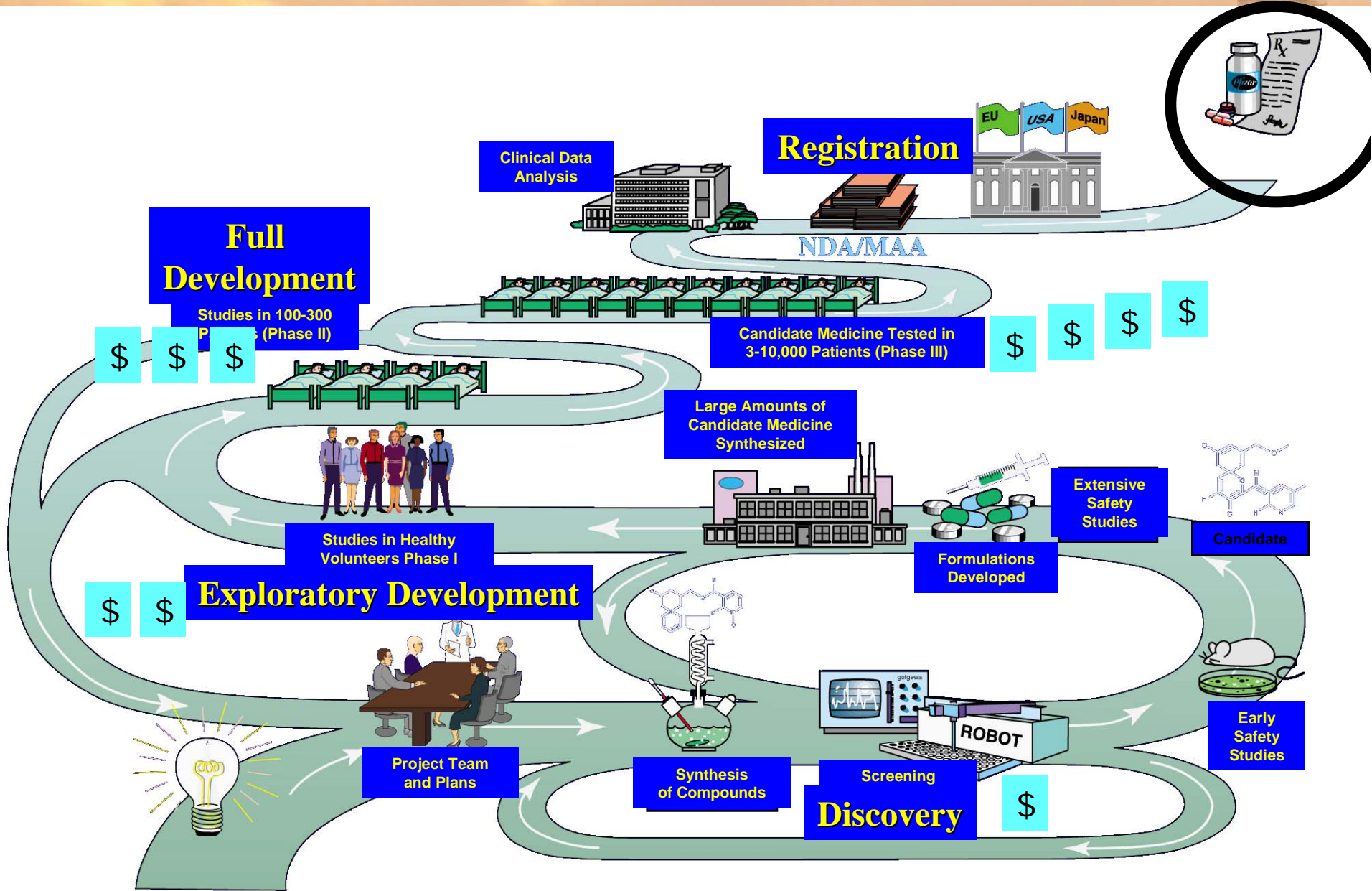


Thank you for your attention!



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Early Focus ...



Delivery Access Plan Imperatives for MMV and Partners

