

Introducing MMV in Access:

**“Working Together to
Maximise Health Impact of
New Anti-Malarials”**

**1st MMV Access Symposium
Livingstone, Zambia
6 May 2006**

Dr Chris Hentschel, CEO MMV

Curing Malaria Together www.mmv.org



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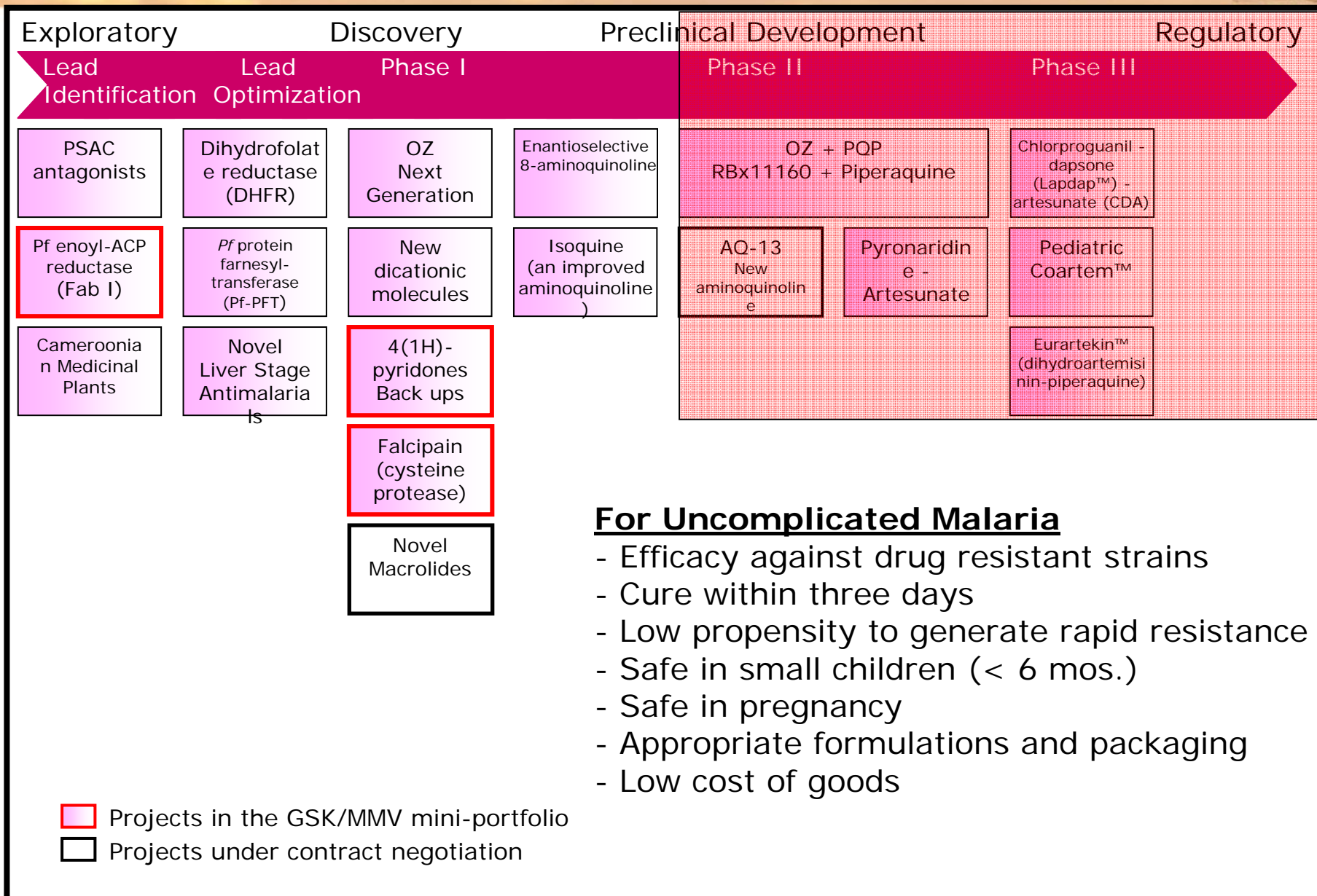
Why MMV Involvement in Access and Delivery Work?



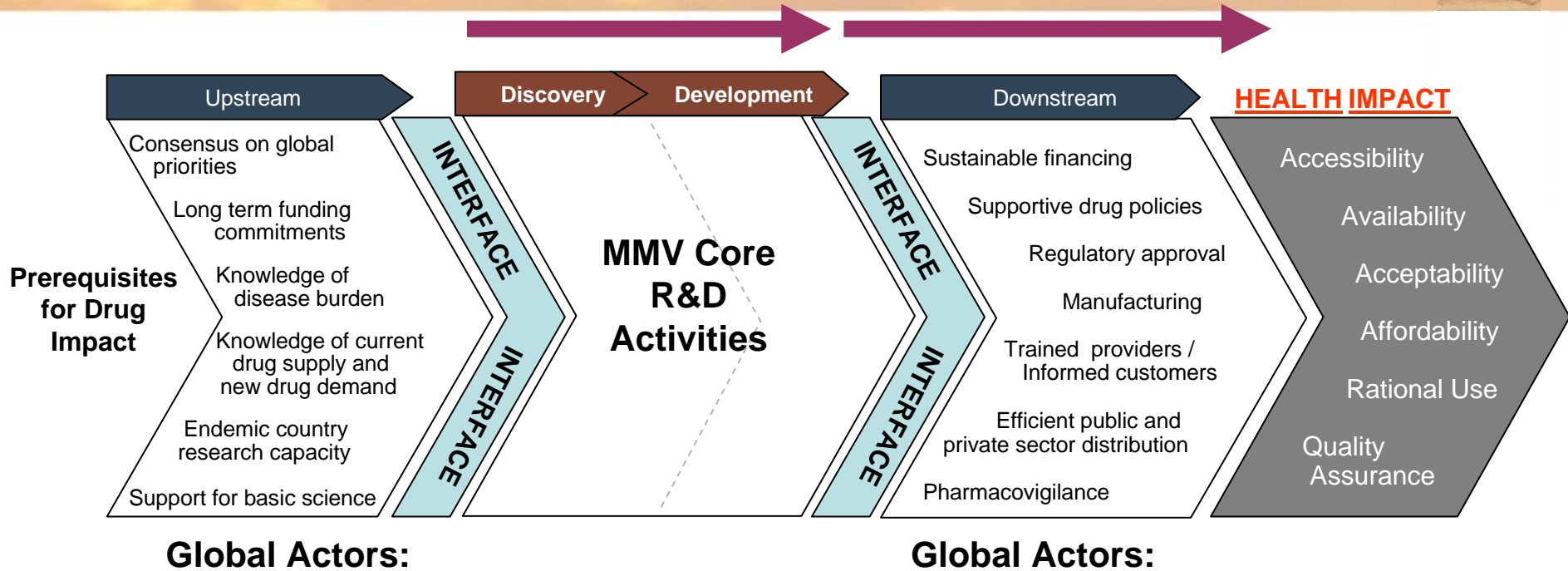
- 2000 Discover, Develop, Register
- 2003 Discover, Develop, Deliver (Passive -Facilitator)
- 2005 Discover, Develop, Deliver. Active Partnership with Industry and Others
- 2006 Delivery execution phase in full swing as well as a rebalancing of the portfolio
- 07-10 Registration of first MMV products
- 10-20 Health impact begins – in time to help contribute to the MDGs



MMV Portfolio Q1 2006 --- a development bolus:



MMV is moving to: The 2003-2007 Business Plan Update



MMV = Discover > Develop > Deliver >

MMV will engage in these interfaces and contribute to activities beyond drug R&D where it has unique and compelling advantages as compared to these global actors

The minimalist engagement model

The True Finish Line



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High Quality affordable drug choice both for the public sector, and also to a seller near you



Counterfeits and poor quality are significant problems in private sector

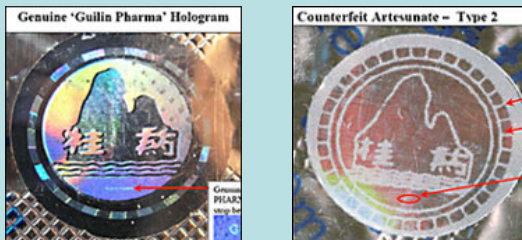


Counterfeits are a significant issue, especially in artesunate monotherapy

- Study found 38% of artesunate bought in SE Asia shops did not contain active drug⁽²⁾

Vietnam	64%
Myanmar	40%
Laos	38%
Cambodia	25%
Thailand	11%

- Counterfeiters getting increasingly sophisticated, e.g. holograms



Poor quality also due to lack of appropriate dosing regimen

- Togo: 70% of home treatments inappropriate⁽³⁾
- Nigeria: 25% of chloroquine treatments are sub-curatives doses⁽⁴⁾
- Zambia: 62% of people don't know dosing of malaria treatment for adults, and 75% for children⁽⁵⁾
- Kenya: 96% of children treated with privately purchased chloroquine received inadequate doses, and 98% received it for less than 3 days⁽⁶⁾

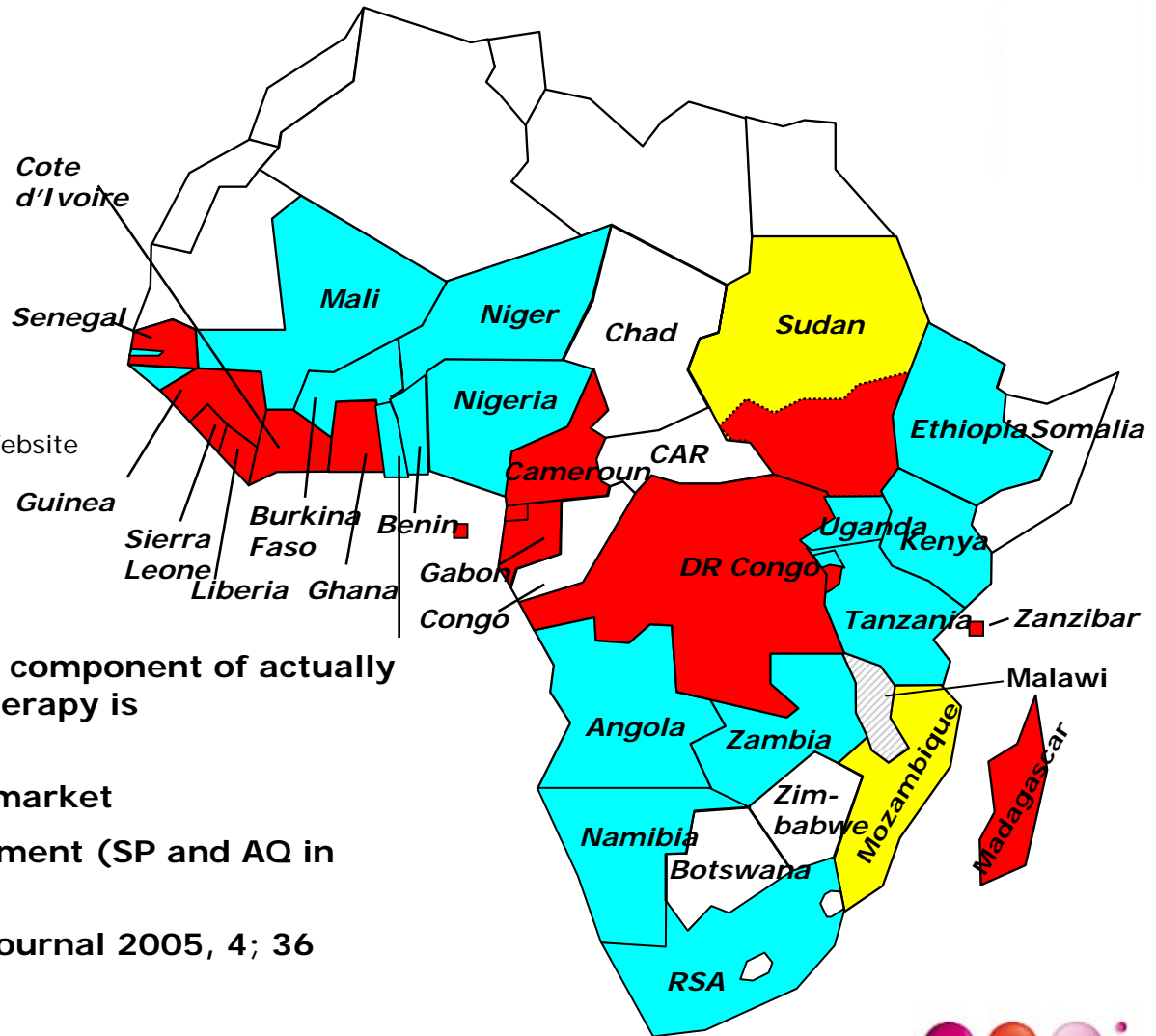
(1) WHO factsheet on counterfeit medicines, May 2005 (2) "Fake artesunate in southeast Asia", The Lancet, June 16, 2001 (3) Deming et al, 1989 (4) Ejezie et al 1990 (5) Makubalo 1991 (6) Kirigia et al 1998
Source: Secondary & primary research

ACT a Positive Story but:



- Artesunate + amodiaquine
- Artemether/lumefantrine
- Artesunate + SP
- In process of Policy Change
- No Information Available

Source: WHO Facts on ACTs, Nov 2005, WHO Website



BUT in all countries ACT are a minor component of actually used drugs and Artemisinin Monotherapy is common/dominant:

- More than 200 drugs available on market
- Only 50 % of 1st and 2nd Line treatment (SP and AQ in 2002) were officially registered

Source: A Amin & R Snow, Malaria Journal 2005, 4; 36

ACT a Positive Story but many issues remain:



- **Weak public sector distribution systems**
- **Private sector: can ACTs displace low quality drugs?**
- **Quality Assurance and training in private sector**
- **1st trimester?**
- **Lack of choice & availability of high quality drugs**
- **Insufficient funds to implement and to sustain drug supply**
- **Mono-therapy Issue; Counterfeits; Poor Quality Drugs**
- **Demand Forecasting: a challenge**
- **Pricing of new drugs**
- **Information Requirements: lack of good data for decision-making**

**ACT USE IS INCREASING, BUT REQUIRES FURTHER SUPPORT
NEW MMV DRUGS OFFER OPPORTUNITIES: INCREASED CHOICE**

Q: Who Spends on Malaria?

A: Both Public AND Private Sectors (Individual Households)



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

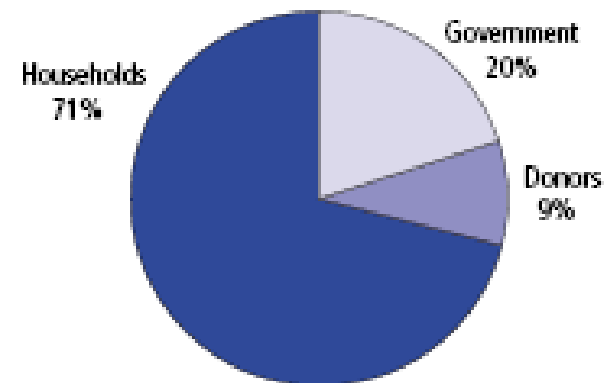
Ghana: ~66% use Licensed Chemical Sellers (LCS) for first line therapy

Togo: ~83% of fevers treated at home

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

Source: "Planning for Success": BCG research for MMV, 2005

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



Source: Uni. York Malaria Expenditure Analysis, Tanzania Case Study, 2000 for RBM



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DOES THE PUBLIC SECTOR REACH THE POOR?

SEAM CONFERENCE 2003



Targeting
Improved
Access

Ndola Prata, MD, MSc
Bixby Program & CEIHD
School of Public Health
University of California, Berkeley

Dar es Salaam
United Republic of Tanzania
December 10–12, 2003

STRATEGIES FOR ENHANCING ACCESS TO MEDICINES

Abstract: Does the Public Sector Reach the Poor?



Authors Conclusion:

- **In most countries the choice of the poor is usually between using private services or not using services at all.**
- **The use of private health care does not differ significantly by socio-economic group.**
- **Financial burden on households is greater for the poor.**



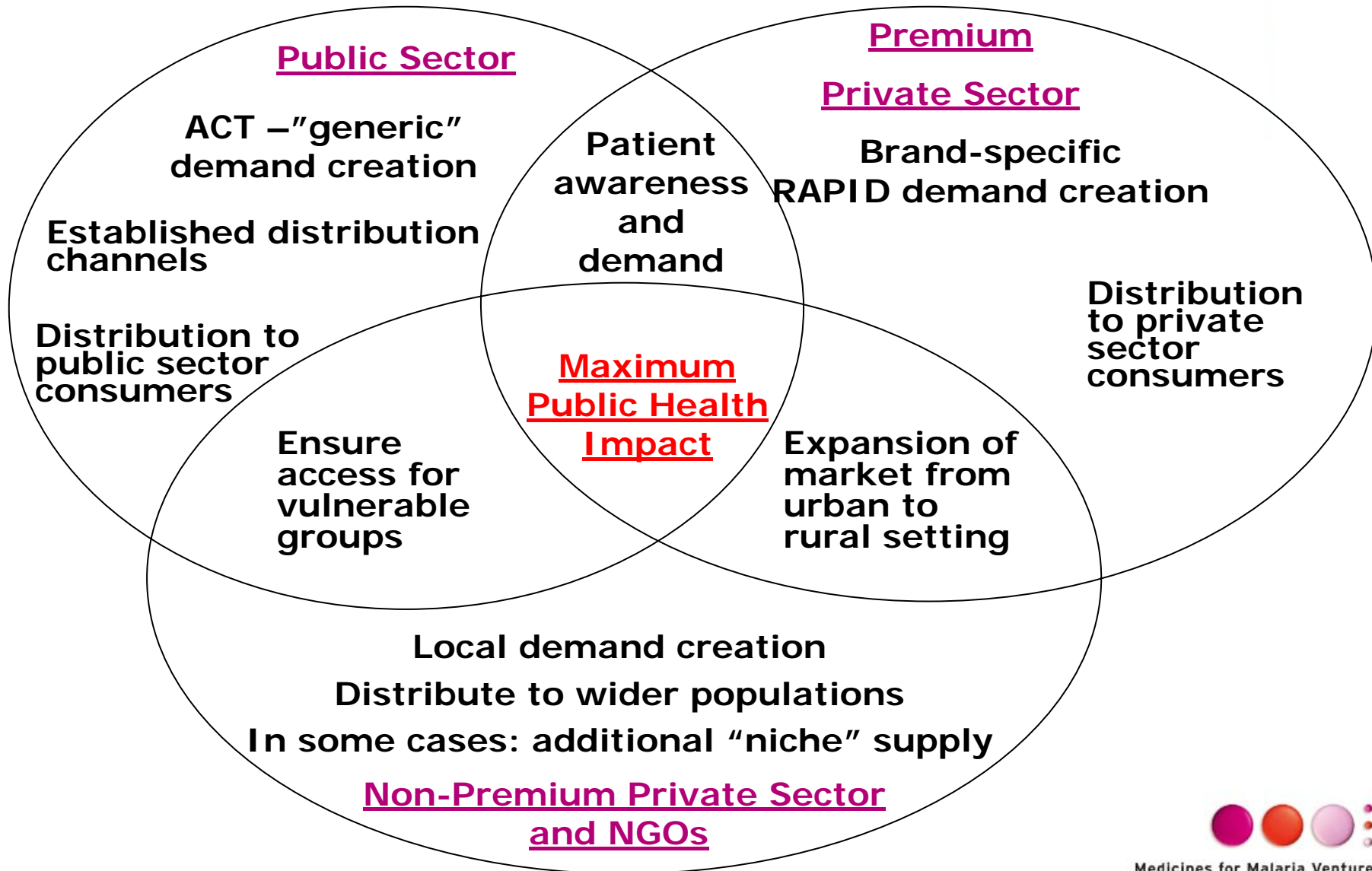
MMV Access Objective

MAXIMISE HEALTH IMPACT THROUGH LAUNCH OF NEW DRUGS AND FORMULATIONS

Harness both private AND public supply strengths



Public – Private Sector Dynamics



Key Questions for Roll-out of New Drug: AIM: MAXIMISE HEALTH IMPACT



- **Where & When to Launch: ensuring maximum availability**
- **Demand Forecasting and Manufacturing Capacity**
- **Price & Financing: lowest possible price, maximise availability**
- **Distribution Channels (from manufacturer to warehouse)**
- **Delivery Channels
(public / private pharmacy, social marketing, EPI link up etc)**
- **Quality Assurance, Pharmacovigilance**
- **Resources Required: partners, resources, information**
- **Measuring Health Impact**

Strategy: Public-Private Partnership is key for Delivery of Antimalarial Drugs



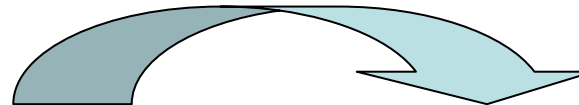
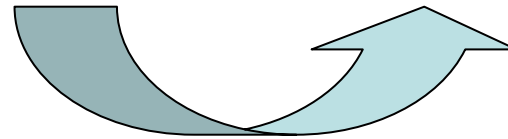
MMV Input

- \$\$
- IPR
- 'Need' Profile
- Partner Drugs
- Link to Policy/WHO, etc
- Link to downstream partners
- India Office
- Link 'pull' mechanisms –GFATM, PMI etc
- Link to IFC

Pharma + Multinationals

- Manufacturing
- QA
- Regulatory
- Delivery Assets
- Delivery Know How
- Liability Insurance

Public



Private

Public Gets

- Drug choice
- Affordable supply in markets relevant to Health Impact

Private Gets

- Lower risk and cost
- Premium private market
- PR & HR Benefit



... but the direction is clear



Chapter 1

Discover/Develop

- CSO
- Partners
- Advisory Group
- Project Plan
- Project Staff
- Budget

Chapter 2

Deliver

- VP Global Access
- Partners
- Advisory Group
- Global Access Plan
- Project Staff
- Budget

Delivery Access Plan Imperatives for MMV and Partners



- ➔ *Availability*
- ➔ *Affordability*
- ➔ *Acceptability & Quality*
- ➔ *Delivery*

Proposed MMV access plan - Availability



Availability

Policy Environment

Approval by SRA / National Regulatory Authority?

Is drug included in WHO/national Standard Treatment Guidelines?

Is drug on WHO/national EDL?

Product Development

What is the target population?

Is formulation appropriate for storage and distribution?

Demand

What is the local market like?
Which countries will be covered?

What other treatment options are available?

Manufacturing

Selection criteria?

Is raw material secured?

Regulatory

Is it approved by NDRA?

Will/When/where will Phase IV be done?



Proposed MMV access plan - Affordability



Affordability

Pricing

How does price impact on existing products?

How do mark-ups and distribution choice affect consumer price?

What is the final price to consumer

Is ex-factory price limit / corridor in the contract?

Financing

What financing sources are available?

Will GFATM fund the product?

What are other affordability issues?



Proposed MMV Access Plan - Acceptability & Quality



Acceptability & Quality

Acceptability

What training and/or incentives are needed for providers?

Are consumer education programs developed?

Product QA

Are standards established?

How can MMV ensure standards are met?

Pharmacovigilance

Is there a monitoring program in place?



Proposed MMV Access Plan - Delivery



Delivery



How to evaluate coverage levels?

Is supply chain established?

Have demand forecasts been done?

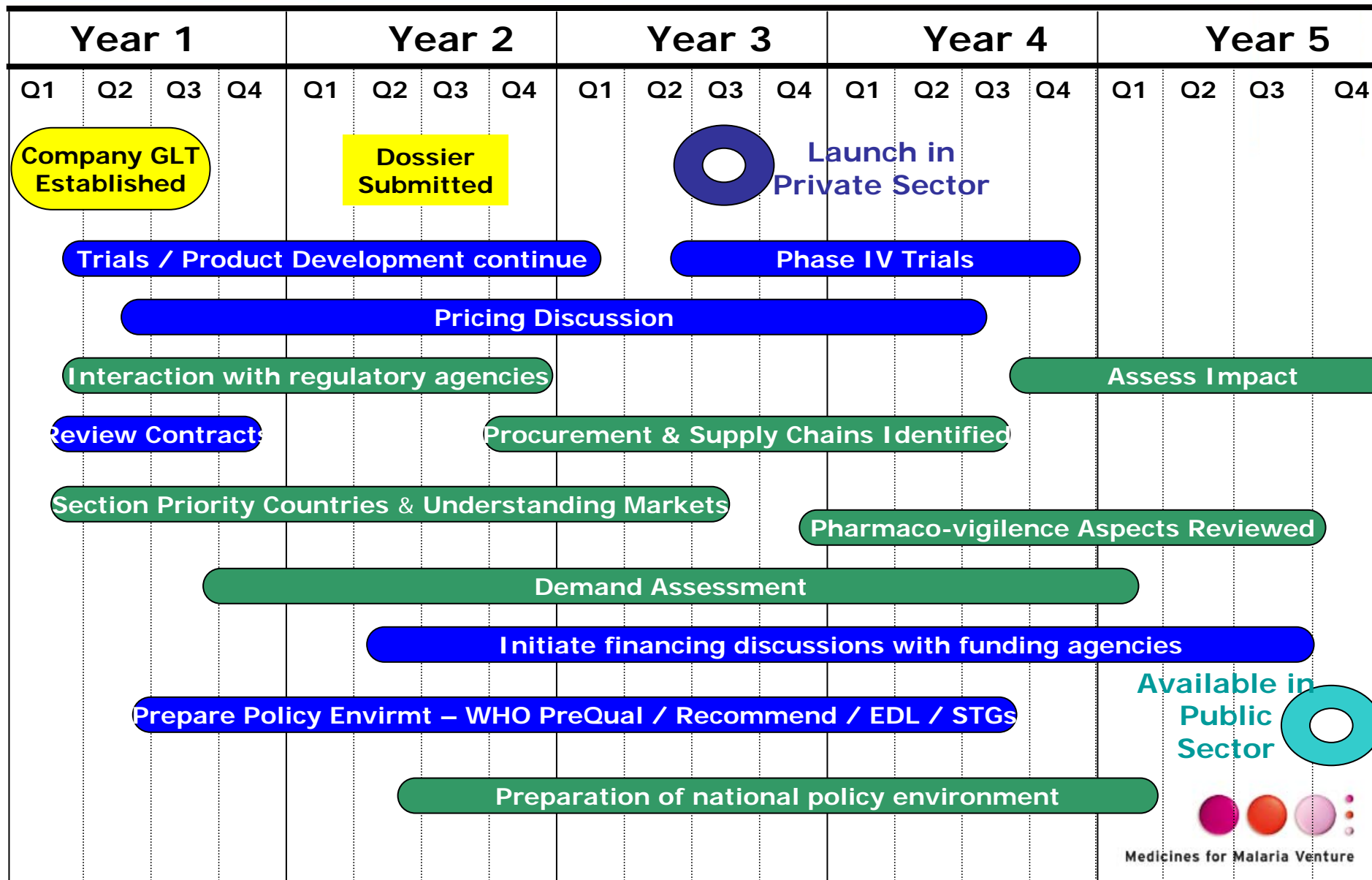
What are the coverage needs?

Have distribution partners/systems been identified and developed?

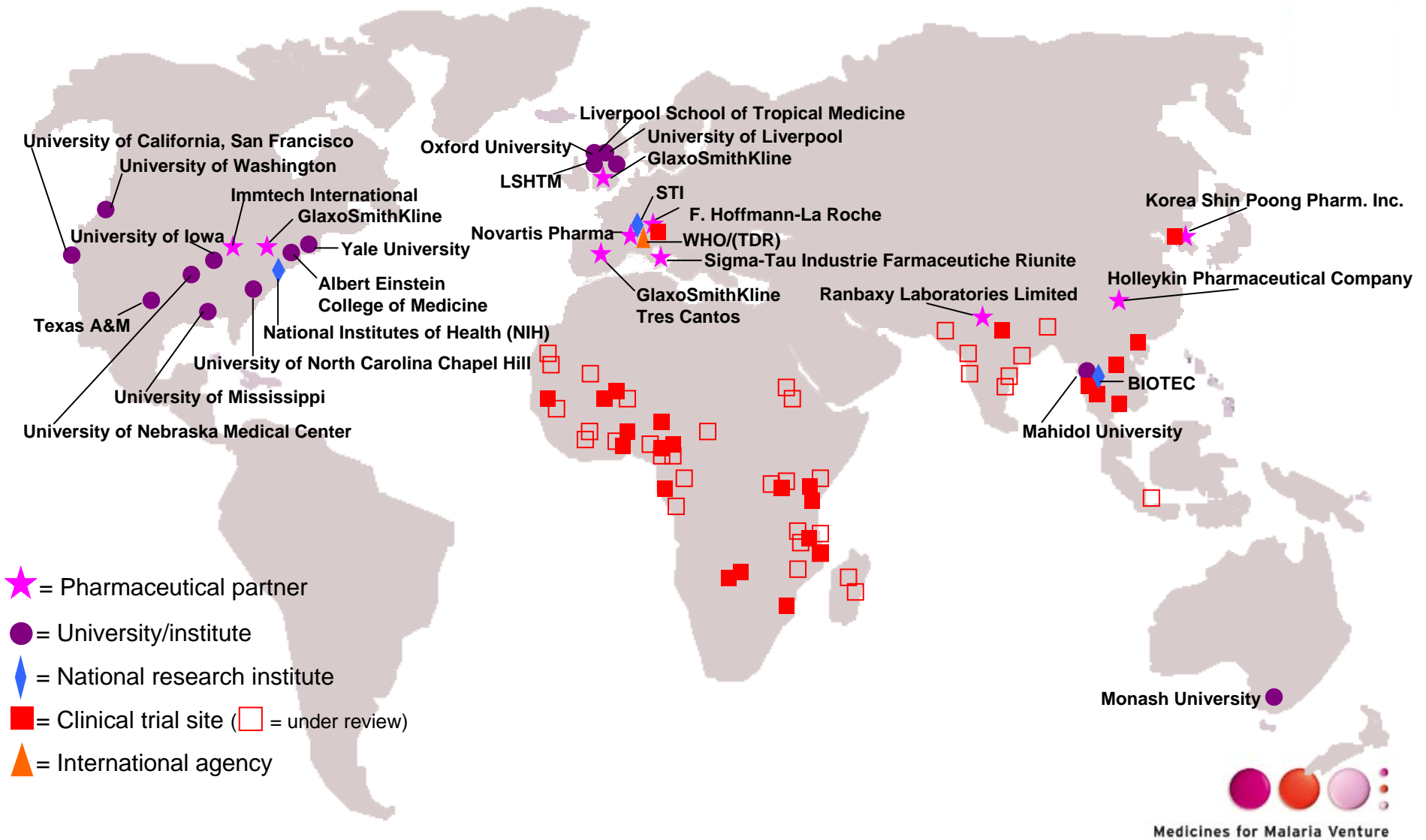
- Public sector
- Private sector



Global Access Plan – Example Milestone/Activity calendar



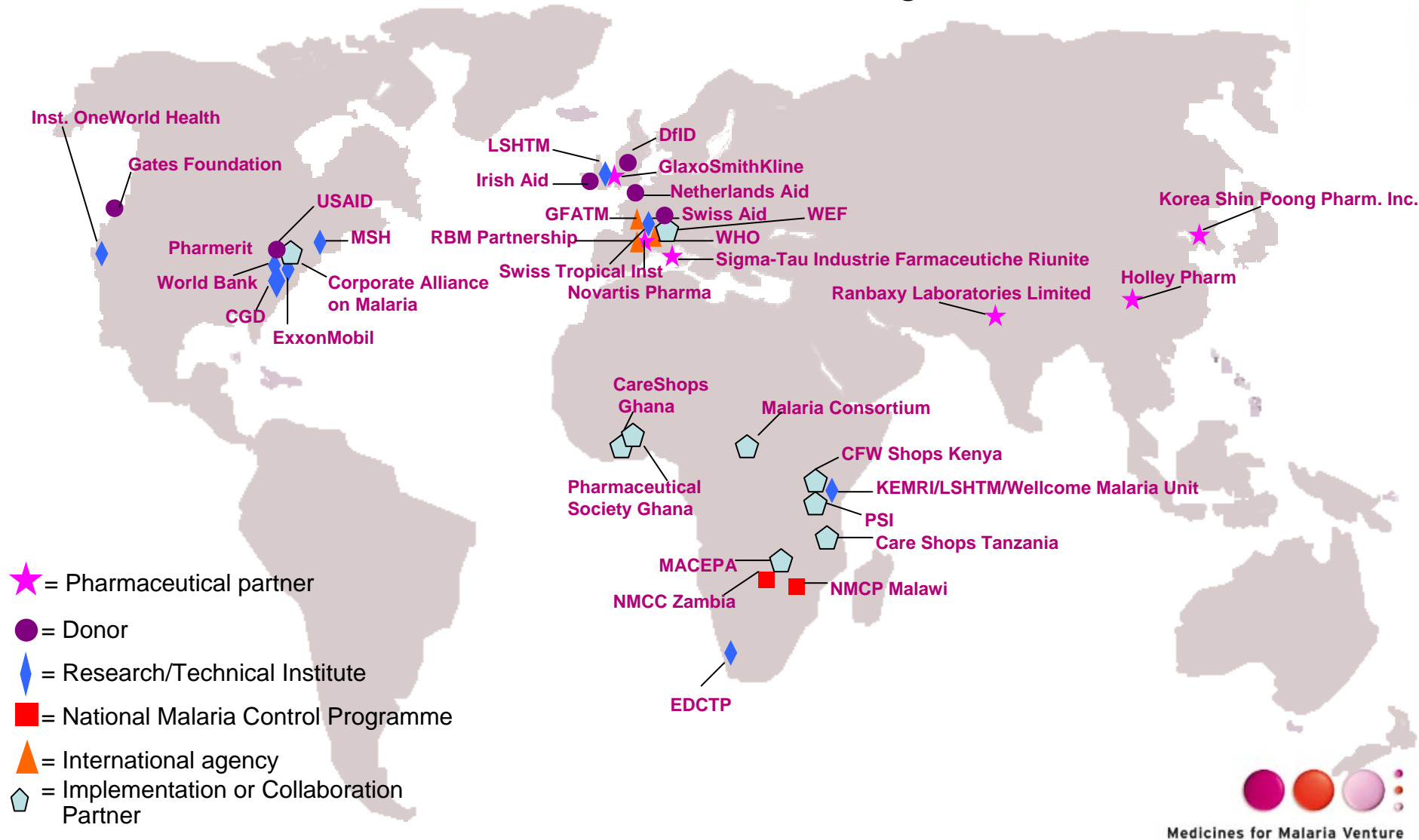
MMV: A Global Network of R&D Partners...



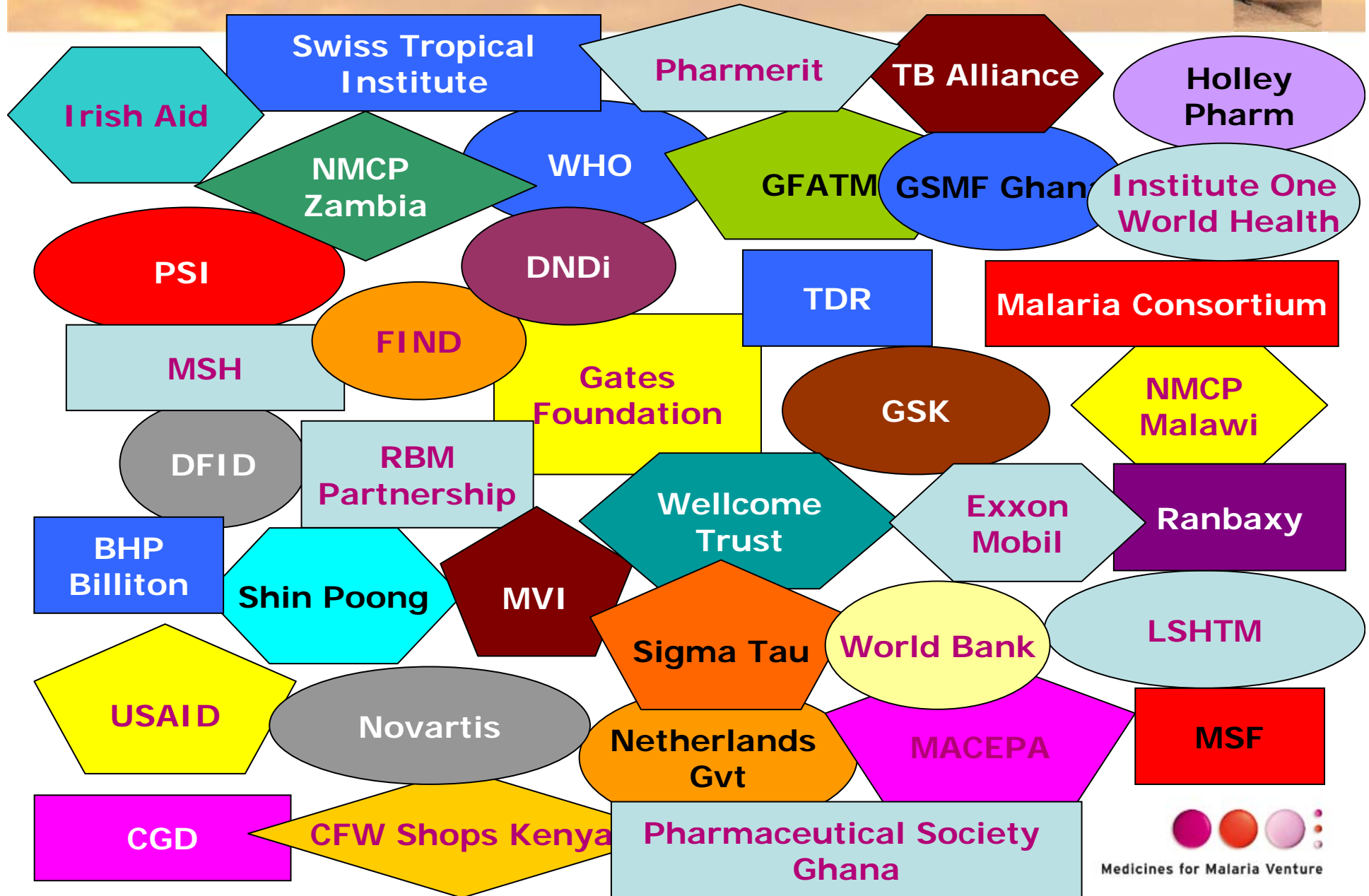
MMV: ...Now Creating a Future Network for Access & Delivery



Potential Partners for Access: to May 2006



Many Different Areas of Expertise



Discussion – How can we work together?



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THANK YOU

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