



Science Supporting Access

Chris Hentschel
MMV President and CEO

ASTMH

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Curing Malaria Together www.mmv.org



Medicines for Malaria Venture

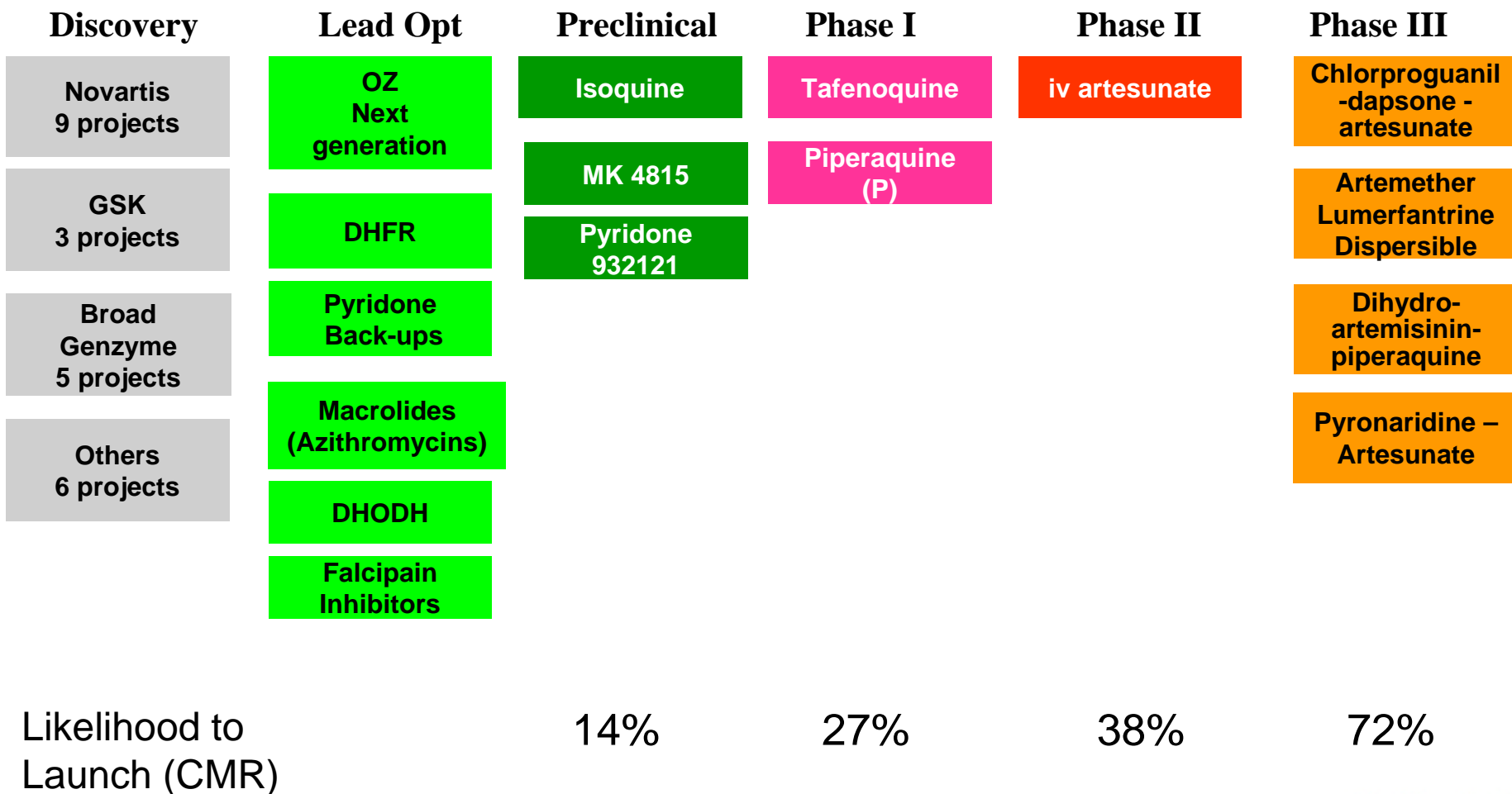
Outline



- MMV's pipeline and development projects
- Why is MMV in access?
- Need for data-driven evidence base
- Conclusions



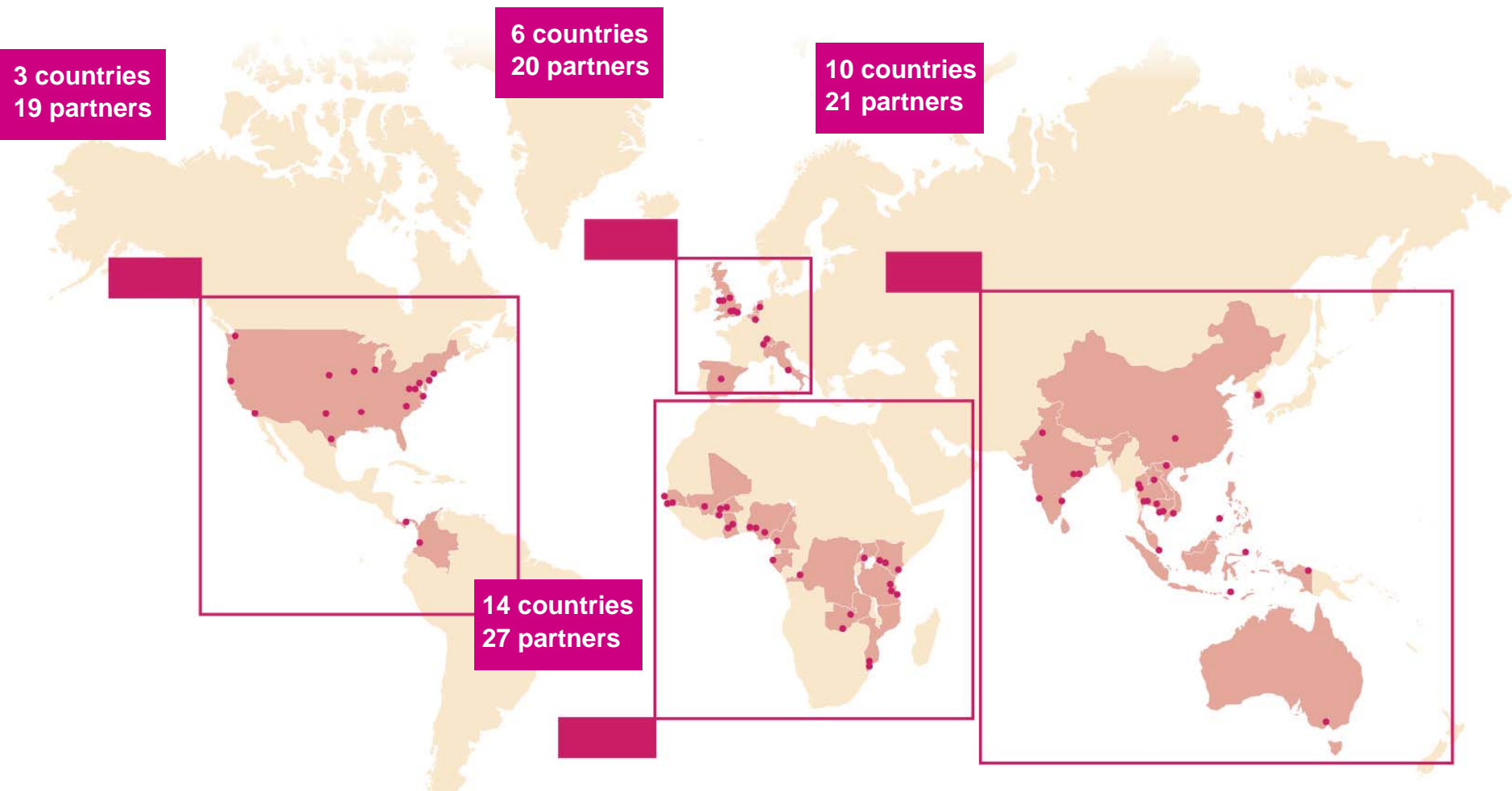
MMV: Discovery and Development projects and now Delivery too



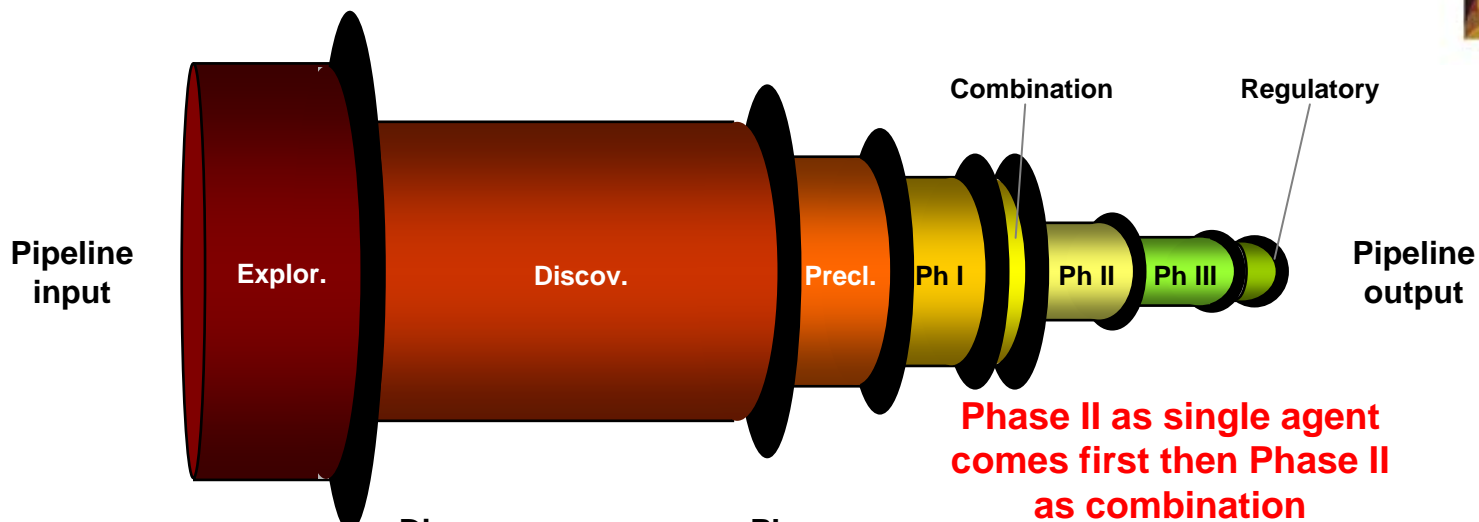
MMV works with partners in 33 countries



- Over 80 academic, industry and endemic country partners
- More than 600 scientists, clinicians, public health experts



Pipeline: timelines and attrition



	Explor.	Discov	Precl.	Phase I	Comb.	Ph II	Ph III	Regul.
POS	30% 95%	40%	55%	70%	90%	50%	65%	
Cum POS	30% 1,3%	12%	7%	5%	4%	2%	1,5%	
Phase length (quarters)	8	20	3	2	0	3	4	1
Phase cost (k USD)	250-500 500	1.00 500	2.000	1.5-2.0	6.00-9.00	6.000/drug	12.000	

**Cumulative probability of completing pipeline is 1.3 %
With approx 10 years of elapsed time**



Access = Delivering innovation for patients



- **Short term – Launch up to four ACT products 2008/9**
- Medium term – Expansion: severe malaria, *P. vivax*, and IPT (pregnancy and infants)
- Medium term – Pipeline: new molecules to replace artemisinin
- Long term – Increase mini-portfolios, innovative therapies and strategies for eradication



Four products supported by MMV likely to enter the market in next few years



Arthemether
Lumefantrine
Dispersible



DHA PQP



Pyronaridine
Artesunate



CDA

- But the market often fails to deliver drugs to the poor
- Our products will only achieve health impact if available
 - at the **right** time
 - at the **right** price
 - at the **right** place
 - With the **right** information



...especially among the target population



MMV's Mission

- To ensure **accelerated access** to and **responsible use** of MMV-supported products to achieve health impact



More studies needed to better profile late stage drugs for policy adoption



- Pivotal studies (Phase III) prove efficacy and safety in limited numbers and population in well-controlled studies
 - Not under real-world conditions
 - strict inclusion / exclusion criteria, hospital environment, run by global and national experts, etc.
 - **Small numbers (1000-2000 patients)**

Phase IIIb / IV studies



More studies needed to better profile late stage drugs for policy adoption



- Special populations
 - HIV AIDS; pregnancy, <5kgs, malnourished
- Calibration for age-weight groups
- Pharmacovigilance
- Effectiveness
- OTC rescheduling
- Safety databases
- Multiple first line treatment to protect pharmacophore

Many players
involved but funding
is an issue



Science is needed to support policy change



- Changing first line treatment
- Deploying multiple first-line treatments
- Ensuring responsible dispensing and use of antimalarials
- Safeguarding the therapeutic life of ACTs and delay onset of resistance
- Crowding out ineffective treatment





Need to close the cycle

