



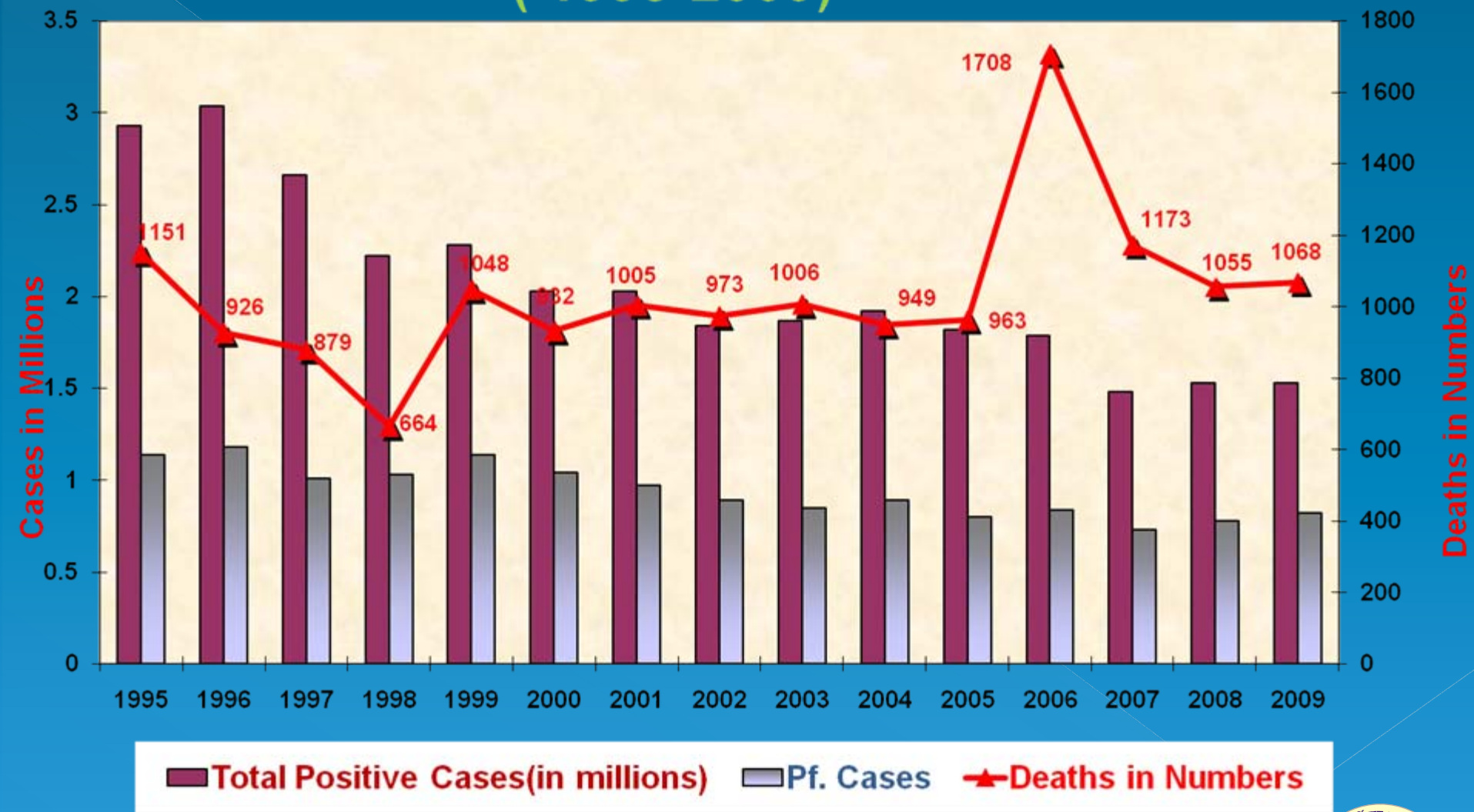
Partnership in India and Beyond

Challenges and Successes of the FACT Project

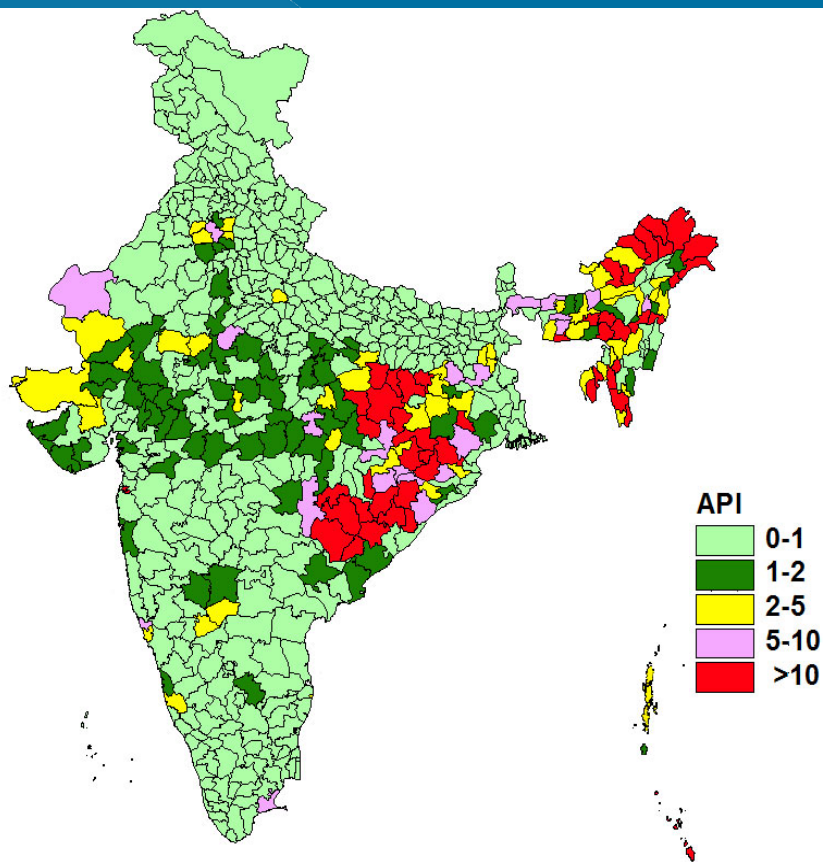
59th Annual meeting of ASTMH
3 - 7 Nov 2010
Atlanta, USA

Neena Valecha
Scientist 'F'
National Institute of Malaria Research
New Delhi , INDIA

Reported Malaria Cases & Deaths in India (1995-2009)



Malaria Endemic Areas



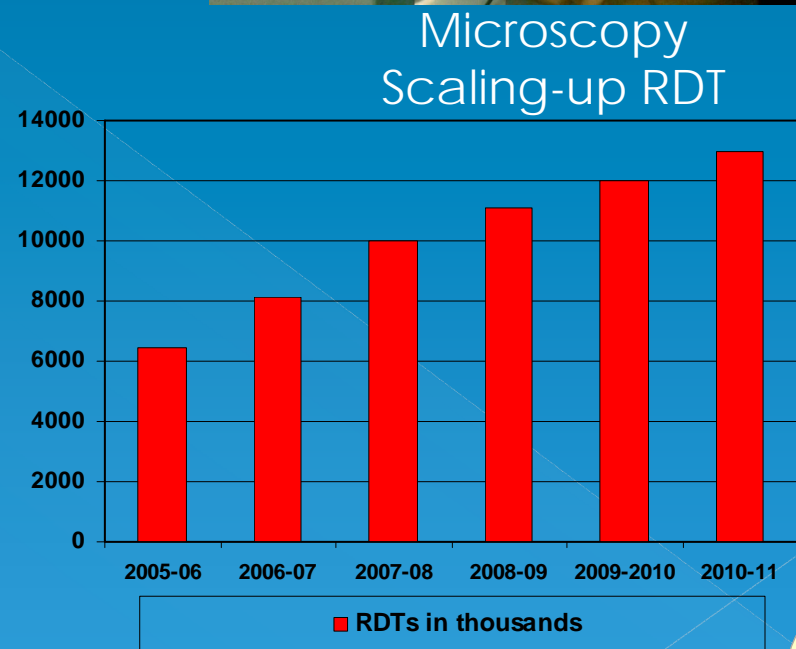
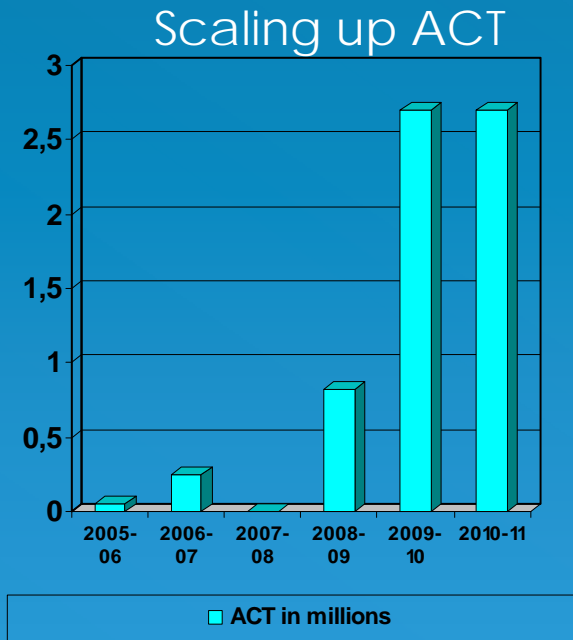
Percentage Contribution of Population, Malaria Cases, Pf Cases and Deaths in 2009 (Compared to the country total)

States	% Population	% Malaria cases	% Pf cases	% Death
N.E. States	4	13	17	46
Other high endemic states*	42	67	77	43
Other	54	20	6	11

* Andhra, Chhattisgarh, Gujarat, Jharkhand, MP, Maharashtra, Orissa, Rajasthan

Malaria Control Strategy: EDPT

- Case Detection & management
- Disease Surveillance
- Epidemic Preparedness



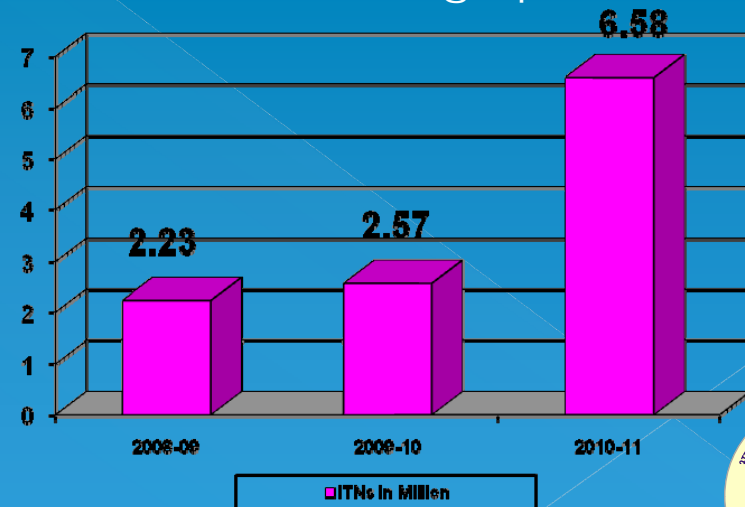
Malaria Control Strategy: IVM

IRS

- Indoor Residual Spraying
- Insecticide treated Bednets (ITNs) & Long Lasting Insecticidal Nets (LLINs)
- Source Reduction



Scaling up LLIN



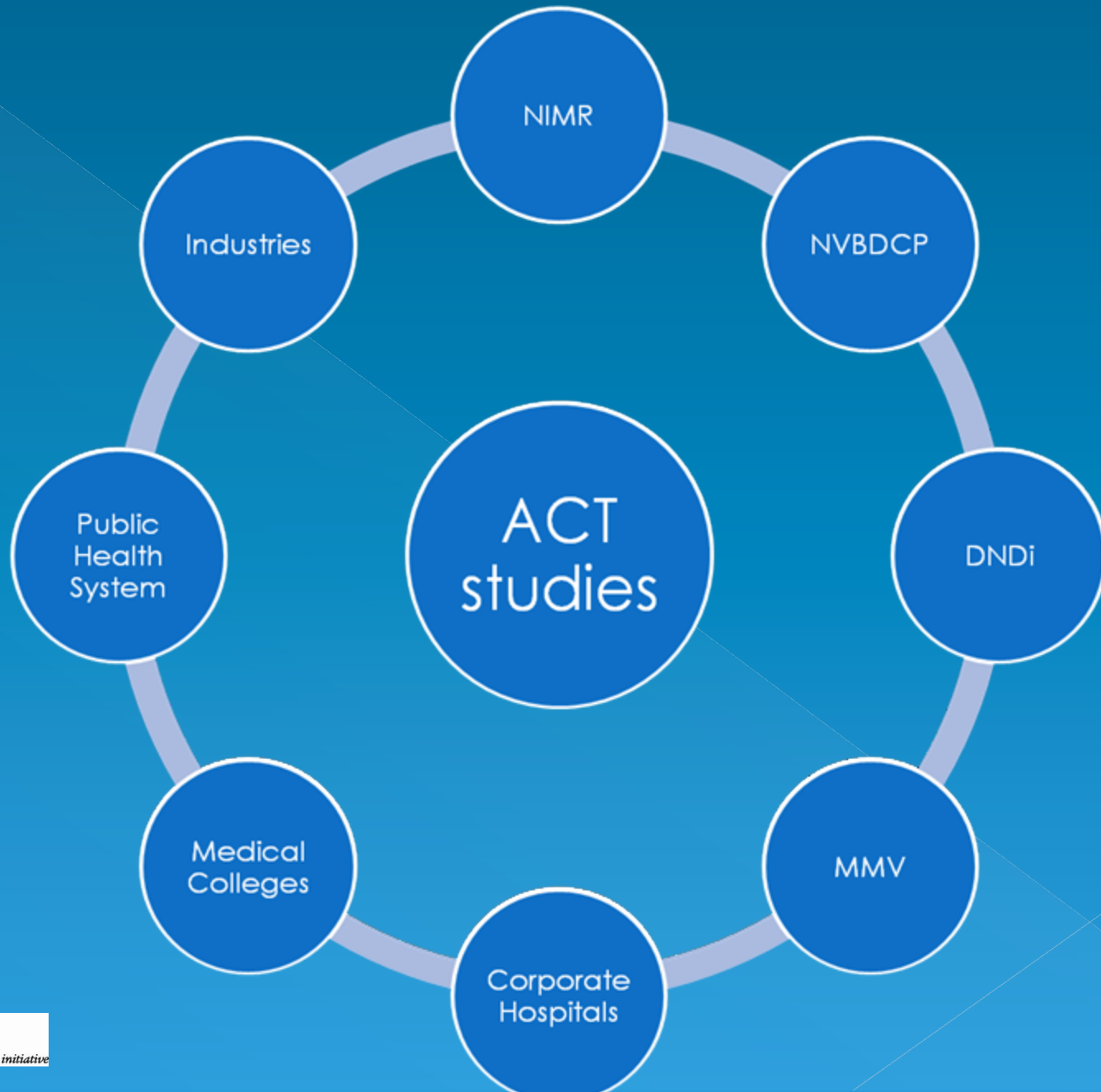
Evolution of ACT

- 1973**
 - First evidence of CQ resistance
- 1982**
 - Drug policy drafted for the first time, Presumptive therapy CQ: (600 mg)
 - PQ RT (5d), SP introduced in resistant Pf areas
- 1995**
 - Presumptive treatment with full dose of Chloroquine
- 1997**
 - Registration of artemisinin derivatives
- 2001**
 - Introduction of $\alpha\beta$ arteether for severe malaria in programme
- 2007**
 - No more presumptive treatment, PQ for 14 days
 - ACT (AS+SP) introduced in India in NER and clusters with >10% resistant Pf districts
- 2008**
 - Trials of AS+AQ, AS+MQ, Artekin, Pyramax accomplished
 - AS+SP extended to 117 districts
- 2009**
 - Registration of AS+AQ
 - Ban on Artemisinin monotherapy
- 2010**
 - ACT extended to Pf cases all over India
- 2011**
 - Registration of AS+MQ FDC

Do we need partnerships?

- Little financial incentive for Industry for malaria
- Only 21 drugs for tropical diseases between 1975 and 2004
- Partnerships bring together academia and industry
- Success stories in India: DNDi & MMV
- GF partnerships with countries limited to distribution of products and 5-10% for evaluation

Partners for ACT studies



Development of ASAQ



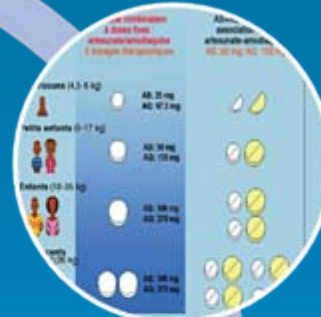
File No. 8-1-1,
Government of India,
Central Drugs Standard Control
Directorate General of Health S.
FDA Bhawan, New Delhi - 110 002.

Form-45
(New rules 123-A, 123D and 123DA)
Permission to Import Finished Formulation of New 1

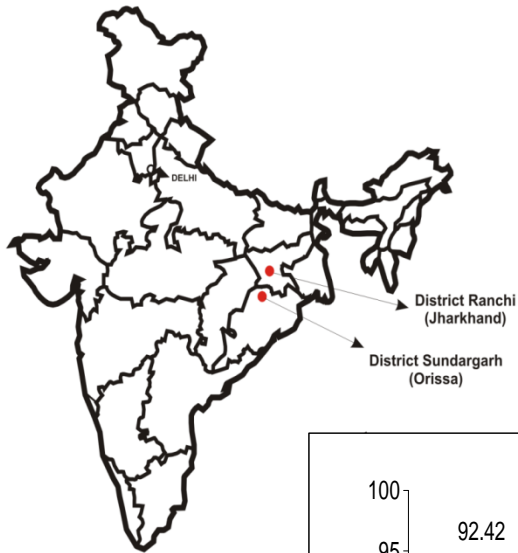
Number of the permission and date of issue MF-720/2009-81

In. Sandoz-Bytaketabo (Sandoz) Limited, 34 A, Sir Mathuradas
Joshi (Road), Mumbai-400063 (Address) is hereby permitted
using new drug Formulation under rule 123-A/123D/123A
(Chemical Name-12345)

Name of the New drug : FDC of Artemisinin - Artesunate
(Mfr. Sandoz International
Private Limited, 17183)
: Artesunate Tablets

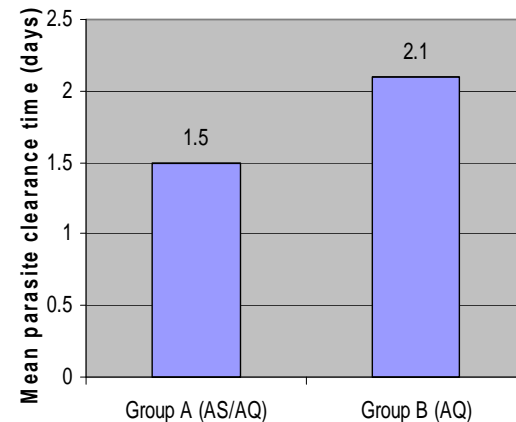
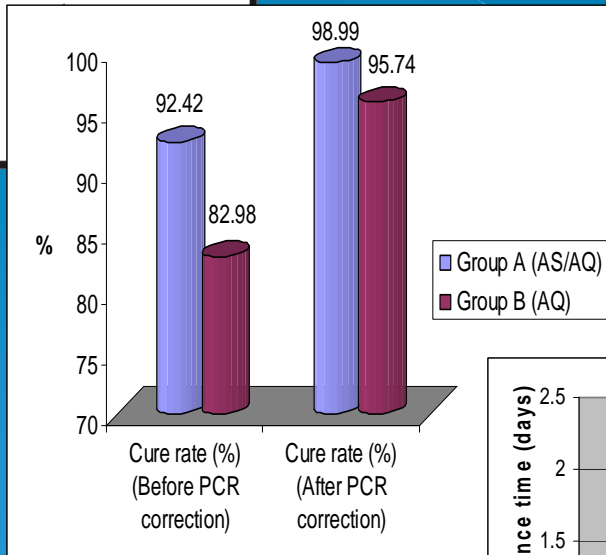


Partnership with DNDi: ASAQ



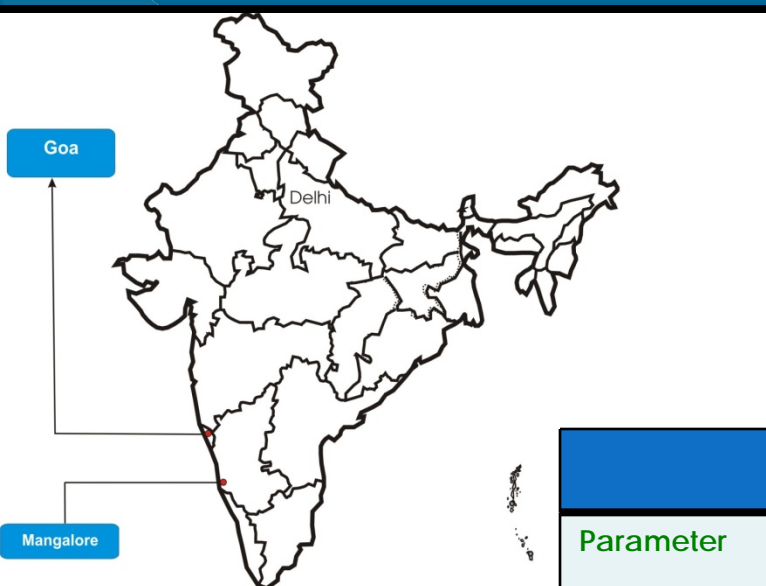
- ASAQ registered in 30 African countries
- 70 million doses distributed
- Phase III trials in India
- Registration with regulatory authority in 2009

Cure Rates (Before and After PCR Correction)



Parasite Clearance Time (PCT)

Partnership with DNDi: ASMQ

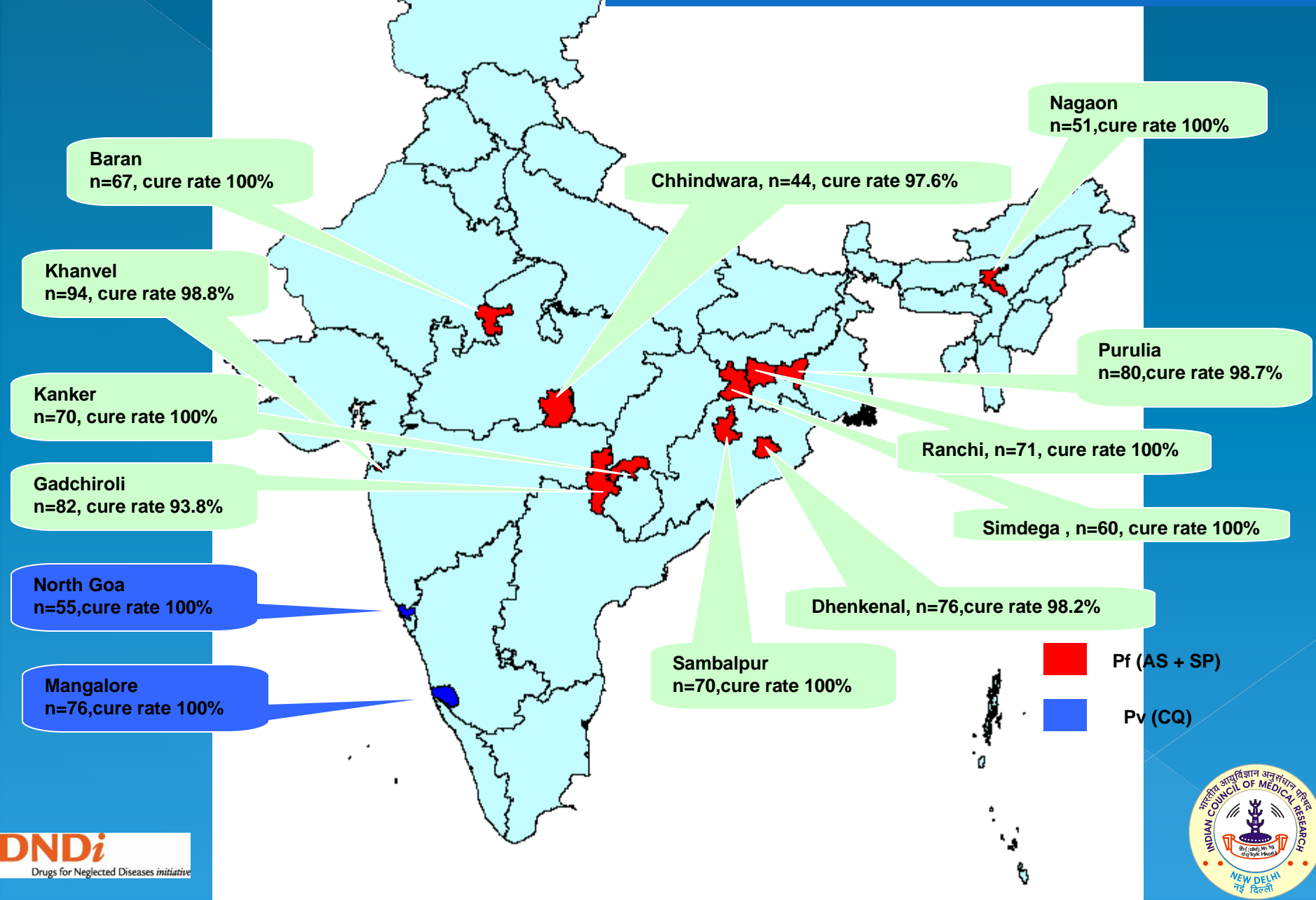


63 Day Cure rate	
Parameter	n (%)
No. of patients with ACPR	65 (98.48)
Cure rate (%)	98.48
95% CI of cure rate	91.8, 100.0

PCR corrected 63 Day Cure rate	
Parameter	n (%)
No. of patient available for PCR genotyping	1 (1.5)
No. of patients with new infection	1 (1.5)
No. of patients classified as cured after PCR genotyping	66 (100%)
95% CI of cure rate	94.6, 100.0

Partnerships: NVBDCP

Therapeutic efficacy of ACT in Drug Policy



Partnerships:



- Development of two FDC's
Eurartesim
Pyramax for Pf and Pv
- Packaging for Pyramax
- Plans for implementation research
- Representation in technical committees

An Open-Label, Randomised Study of Dihydroartemisinin-Piperaquine Versus Artesunate-Mefloquine for Falciparum Malaria in Asia

Neena Valecha^{1*}, Aung Pyae Phyo², Mayfong Mayxay^{3,4}, Paul N. Newton^{3,5}, Srivicha Krudsood⁶, Sommay Keomany⁷, Maniphone Khanthavong⁸, Tiengkham Pongvongsa⁹, Ronnatrai Ruangveerayuth¹⁰, Chirapong Uthaisil¹¹, David Ubben¹², Stephan Duparc¹², Antonella Bacchieri¹³, Marco Corsi¹³, Bappanad H. K. Rao¹⁴, Prabash C. Bhattacharya¹⁵, Nagesh Dubhashi¹⁶, Susanta K. Ghosh¹⁷, Vas Dev¹⁸, Ashwani Kumar¹⁹, Sasithon Pukittayakamee⁶

PLOS one

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Efficacy of new ACTs (2005-09)

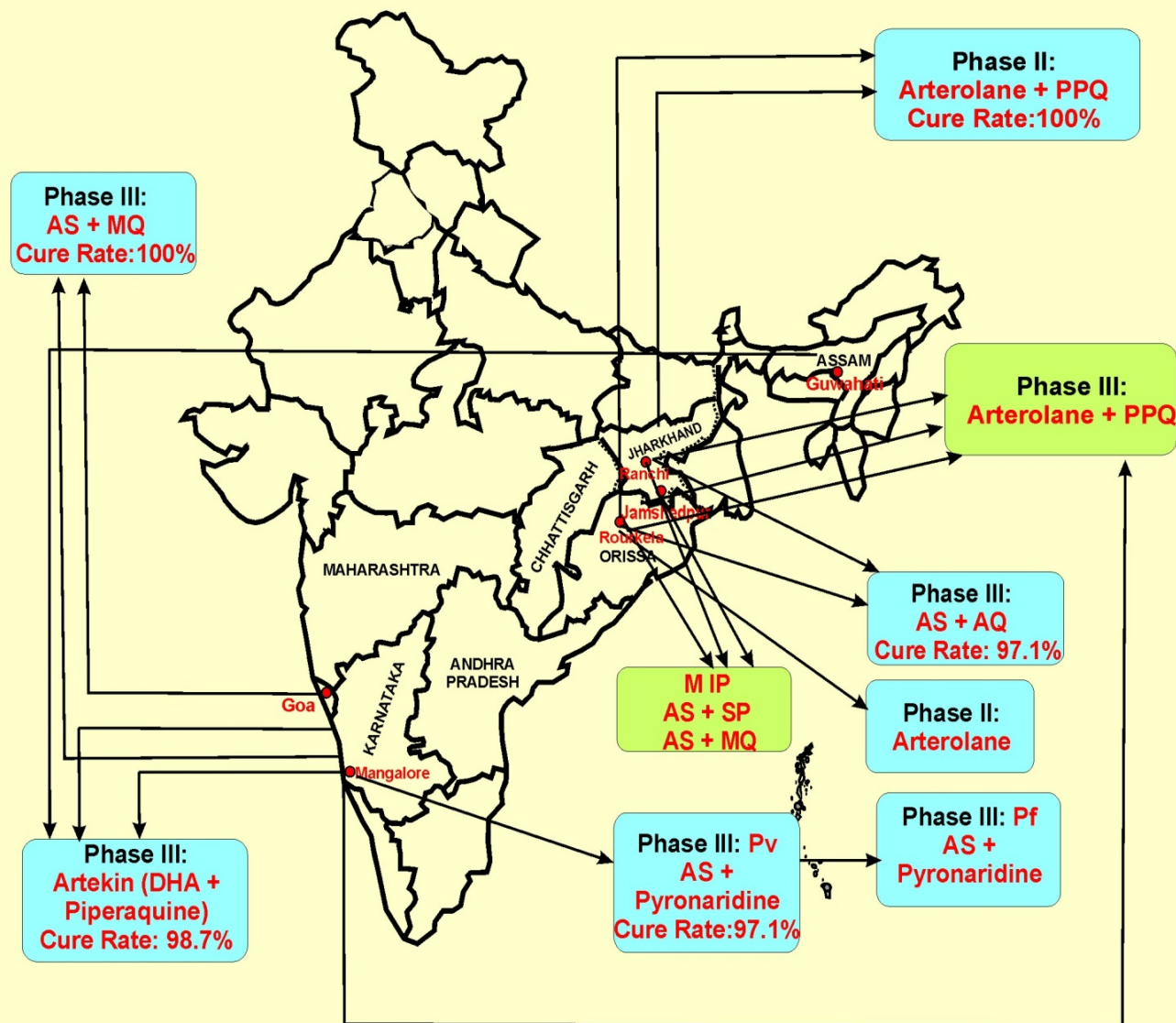
- Trials with fixed dose ACTs & new drugs
- Teams have been trained For GCP – ICH

Linkages

- Ispat General Hospital Rourkela
- Community Welfare Society Rourkela
- Kasturba Medical Hospital Mangalore
- Maha Devi Birla Hospital Ranchi
- Goa Medical College Goa
- Civil Hospital Maihar
- TATA Main Hospital Jamshedpur

Collaborators / Sponsors

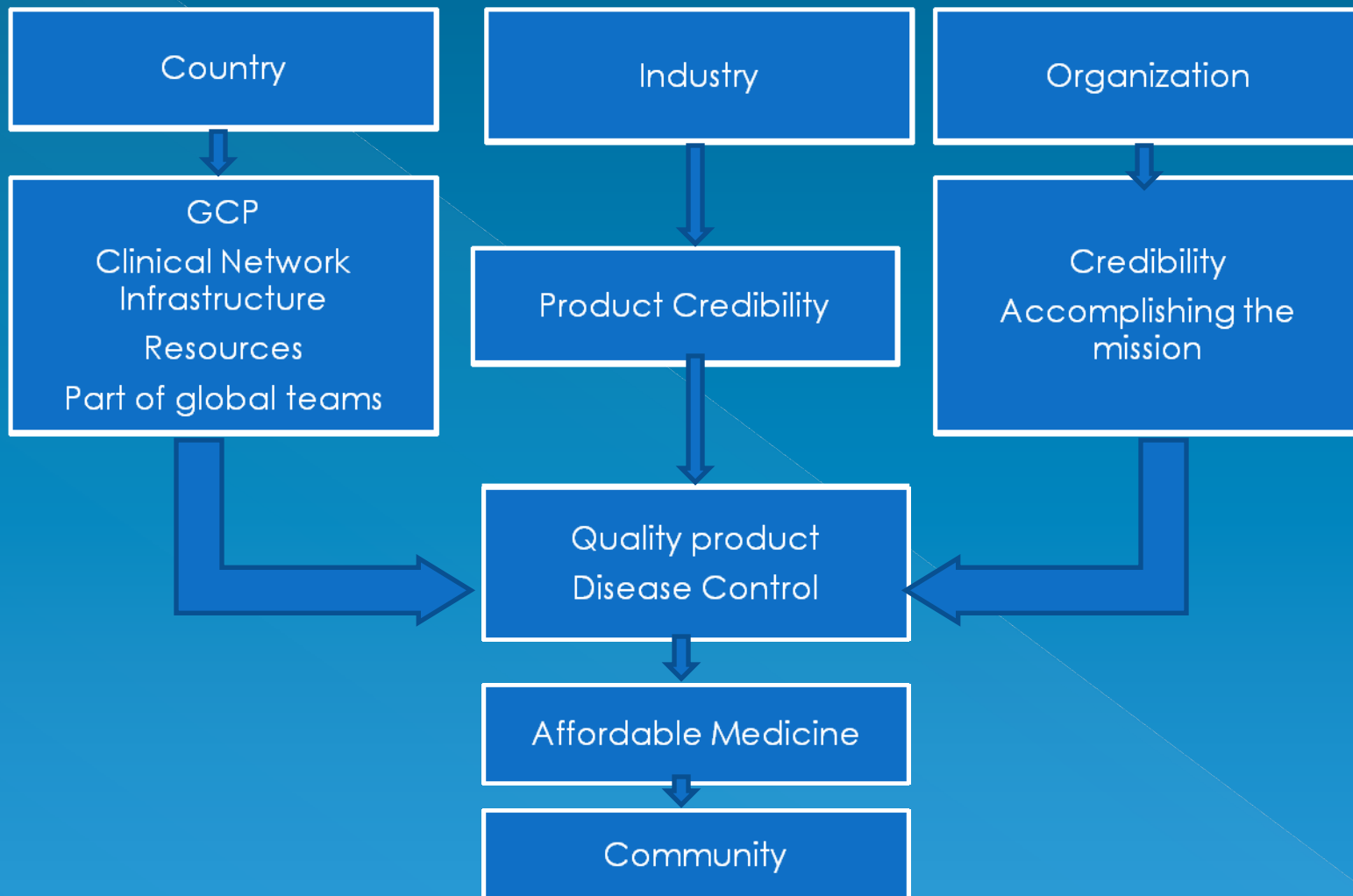
- MMV
- DBT
- IISc, Bangalore
- Ranbaxy
- DNDi
- Sigma Tau
- Shing Poong



Partnership for Access/ Implementation

- Collaborative process with Input from Govt./Stakeholders
- Work with manufacturer on no profit/no loss structure
- Focus on lowering price outside profit /competition motive and by technology transfer
- Farmanguinhos in Brazil, Cipla in Asia, Sanofi Aventis in Africa
- Advocacy to improve representation of products, pharmacovigilance

Partnership Gains



Partnership for development of ACT in India: SWOT Analysis

Strengths

- Involvement of academia
- Acceptable to all partners
- Financial support

Weaknesses

- Variable epidemiology
- Common protocols may not be acceptable
- Delay in approvals
- Restriction in material / data sharing

Opportunities

- PPP
- Initiatives to promote rational treatment

Threats

- Apprehension of industry
- Sustainability

Key Message

Focus on portfolios and disease control rather than specific products

Acknowledgements

- Govt. of India
- DND*i*
- Collaborating Hospitals
- NVBDCP
- State Health Authorities
- NIMR & Its Field Units

