

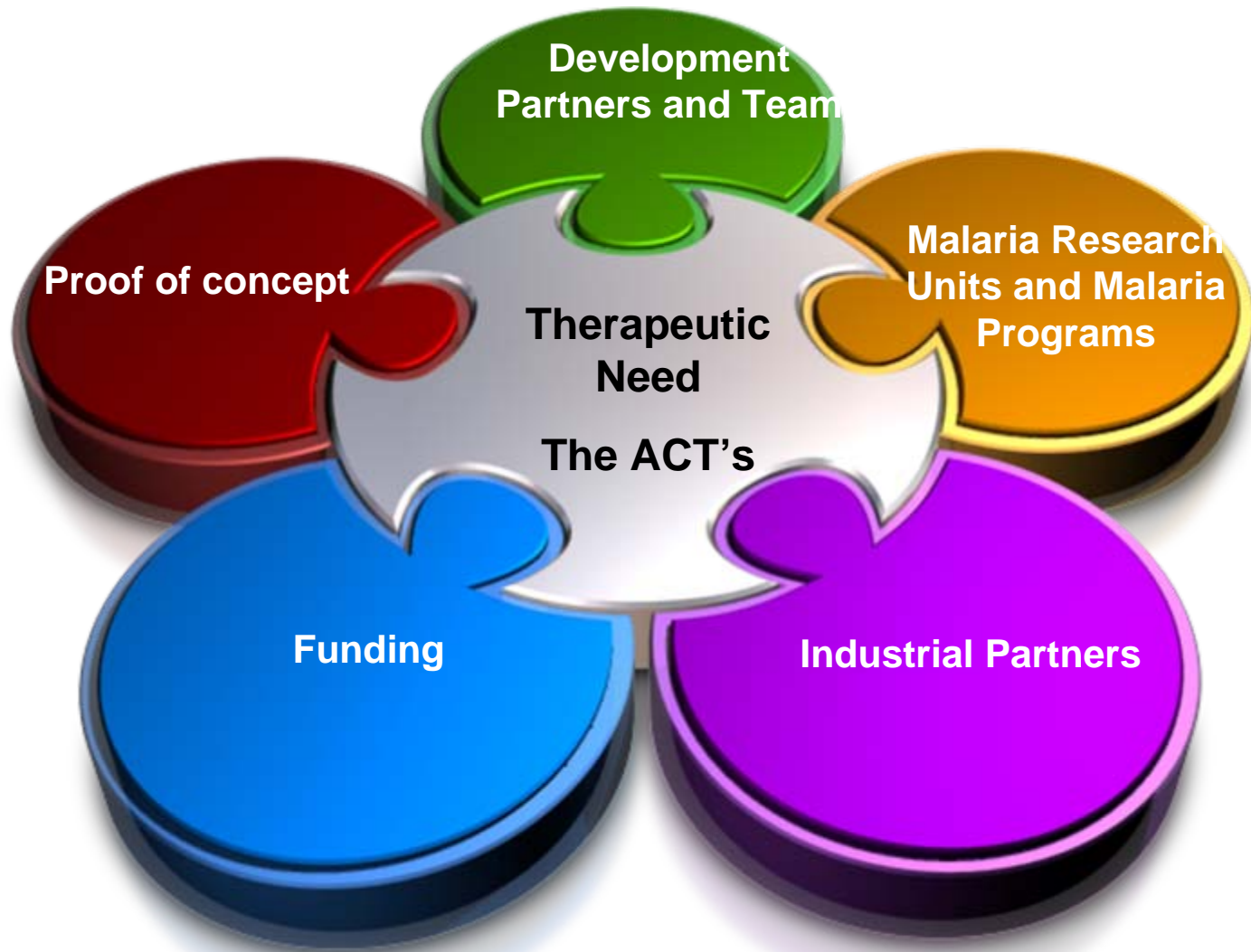
# «Partnerships: The way to Successful Antimalarial Development»

Jean-René Kiechel  
Senior Product Manager, DNDi

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ASTMH 59th Annual Meeting  
Atlanta, USA



# With Partners Bridging Therapeutic Gaps: The FACT Project to fight development of resistance



# The FACT Project Concept

## Increasing Options for Fixed Dose ACT's

2002

- “WHO recommends in particular the use of drug combinations containing Artemisinin”
  - Artesunate-SP
  - Artemether-lumefantrine
  - **Artesunate-amodiaquine**
  - **Artesunate-mefloquine**
- 2006 WHO malaria treatment guidelines

- **2 fixed-dose ACTs**

- **Easy to use:**
  - fewer tablets in regimen
  - paediatric strengths
  - ensure drugs are taken **together** and in **correct proportions**
- **Affordable**
- **Available** as public good



# The **Blueprint** of the **ASMQ Tablet**



- **Quality components (AS, MQ, Excipients)**
- **Smallest possible size (Minimum excipients)**
- **Good aspect (Coating)**
- **Paediatric strengths; rapid disintegration in water**
- **Simple (1 or 2 tablets for 3 days)**
- **Stable (Process and Tropical conditions)**
- **Adequate biopharmaceutical properties**

# Artesunate-Mefloquine Fixed Dose Combination

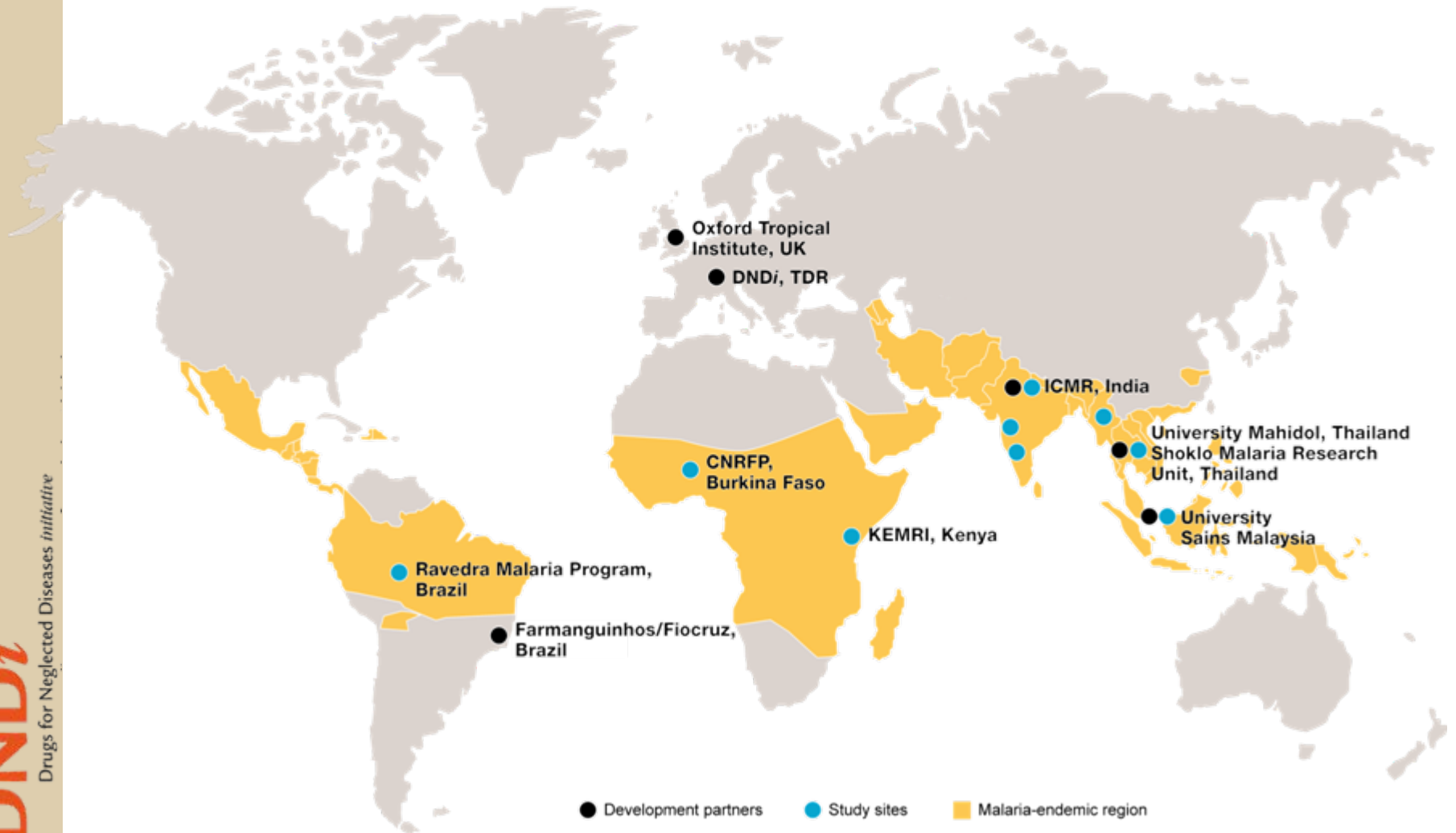
Industrial Partners:  
Farmanguinhos  
Cipla

+

DNDi/TDR:  
scientific coordination  
& project management

+

Funding: EU's INCODEV,  
France, Netherlands,  
Spain, UK, MSF



# Artesunate/Mefloquine: Tablets & Dosing



## Low-Strength

**MQ: 50 mg/tab**

**AS: 25 mg/tab**



## High-Strength

**MQ: 200 mg/tab**

**AS: 100 mg/tab**



	MQ		AS	
Age	# tabs/d	mg/d	# tabs/d 25mg/100mg	mg/d
6-11m	1	50	1x25mg	25
1-5y	2	100	2x 25mg	50
6-11y	1	200	1x100mg	100
≥12y	2	400	2x 100mg	200

# Artesunate-Amodiaquine Fixed Dose Combination

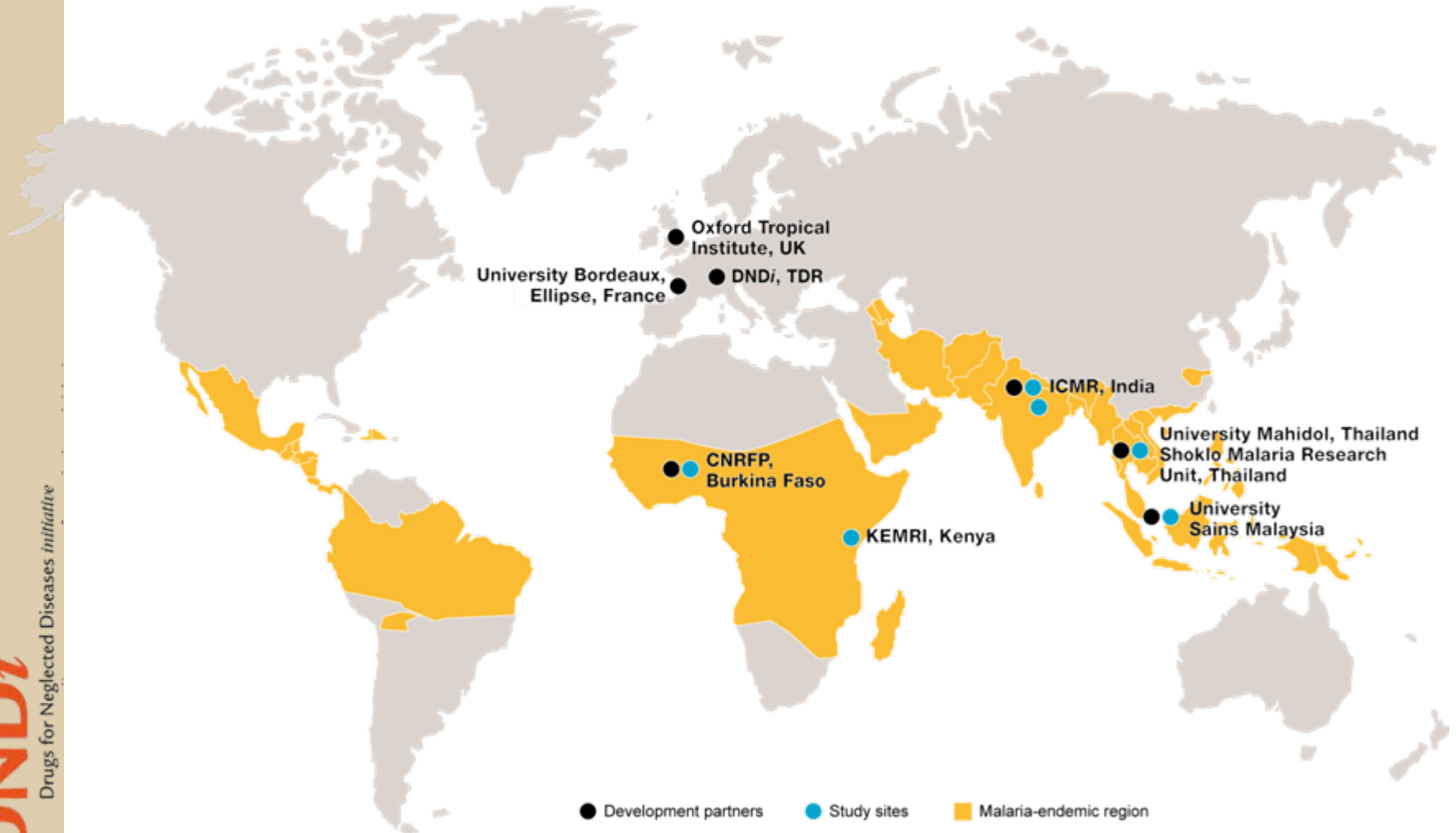
Industrial Partners:  
Sanofi-Aventis

+

DNDi/TDR:  
scientific coordination  
& project management

+

Funding: EU's INCODEV,  
France, Netherlands,  
Spain, UK, MSF



# Simplified 3-Day Dose Regimen of AS/AQ

## NEW Fixed-dose AS/AQ Artesunate/amodiaquine

3 dosage strengths available

Infants (<8 kg)



AS: 25 mg  
AQ: 67.5 mg

Young Children (8-17 kg)



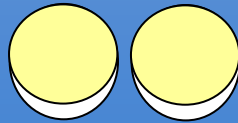
AS: 50 mg  
AQ: 135 mg

Children (17-35 kg)



AS: 100 mg  
AQ: 270 mg

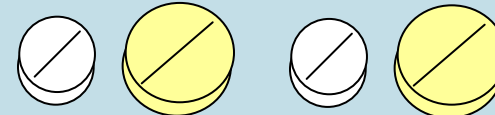
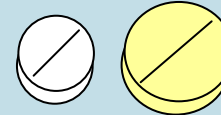
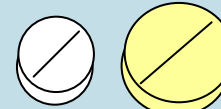
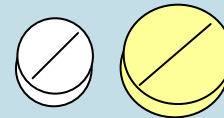
Adults (>35 kg)



AS: 100 mg  
AQ: 270 mg

## Co-blastered non-fixed AS+AQ Artesunate-amodiaquine

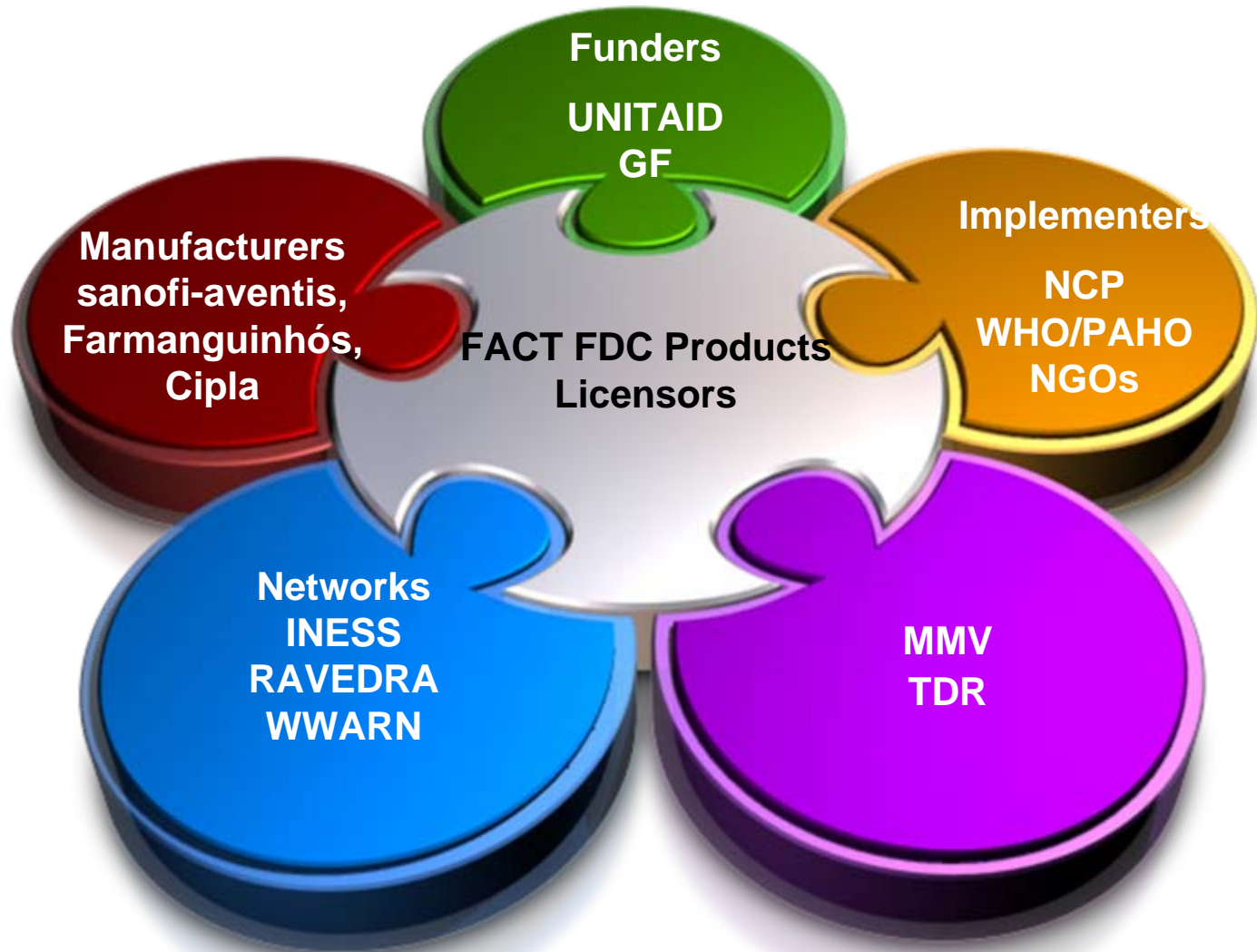
AS: 50 mg; AQ 153 mg





# FACT Project

## New Partnership for Implementation



# FACT Project and Consortium

## Acknowledging Partners

- **ASAQ**

TDR, University of Bordeaux/Tropival/Ellipse, Catalent, University Sains Malaysia (USM), Cardinal Systems, CNFRP; Burkina-Faso; KEMRI (Kenya), ICMR (India), Epicentre, MSF foundation, University of Oxford (UK), IRD, Dr Sirima (Burkina Faso), Pr. V. Navaratnam, Dr Neena Valecha (India), Dr Ogutu (Kenya), Dr.Mohd Suhaimi Ab. Wahab MD (Malaysia), Dr P. Guerin, Dr Liz Ashley, Pr P. Brasseur; Dr.Piero Olliaro, Dr. W. Taylor, Dr. Guy Mazue, Pr Nick White & Dr. François Nosten (Thailand)

- **ASMQ**

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