

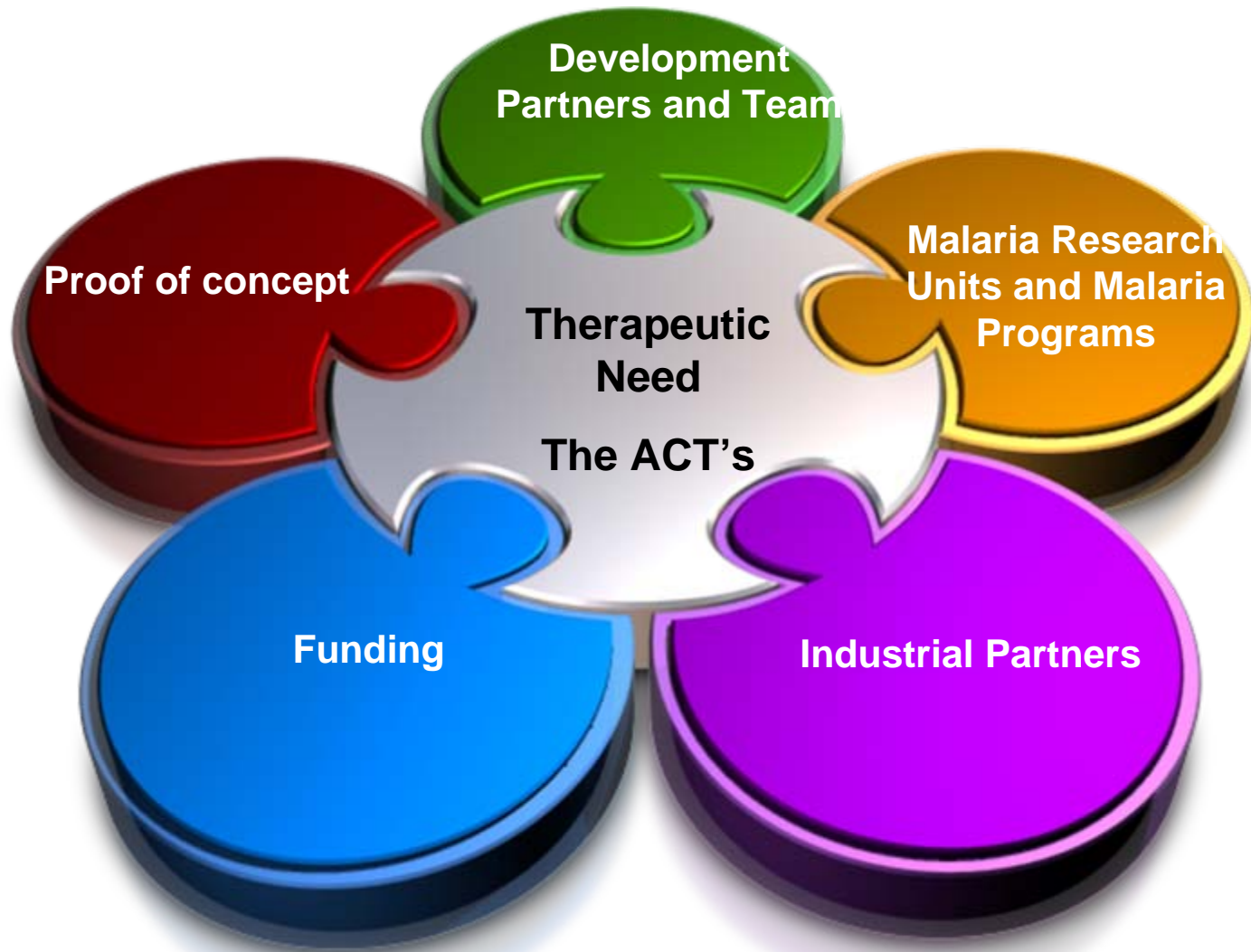
«Partnerships: The way to Successful Antimalarial Development»

Jean-René Kiechel
Senior Product Manager, DNDi

November 3-7, 2010
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

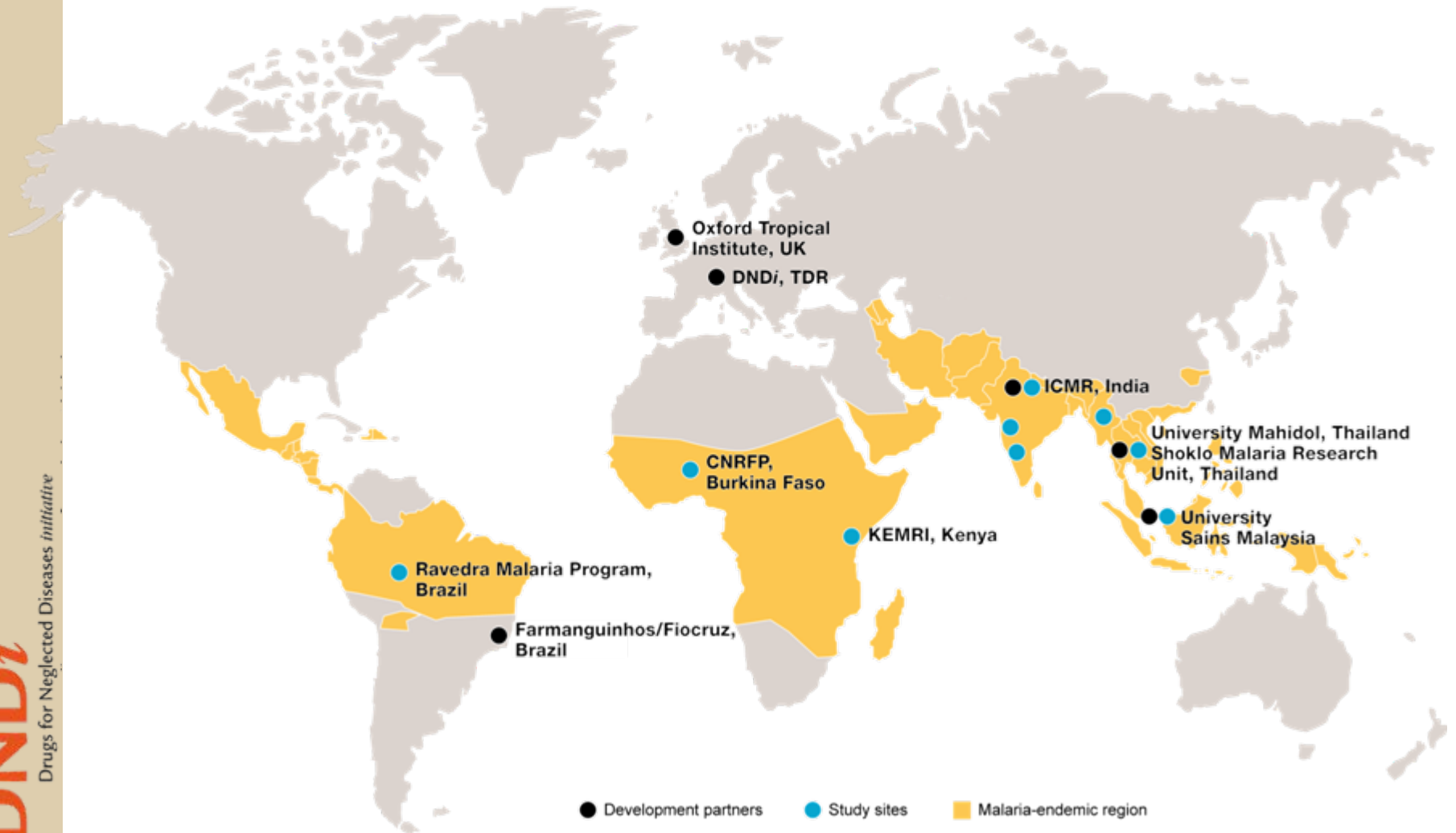
Industrial Partners:
Farmanguinhos
Cipla

+

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

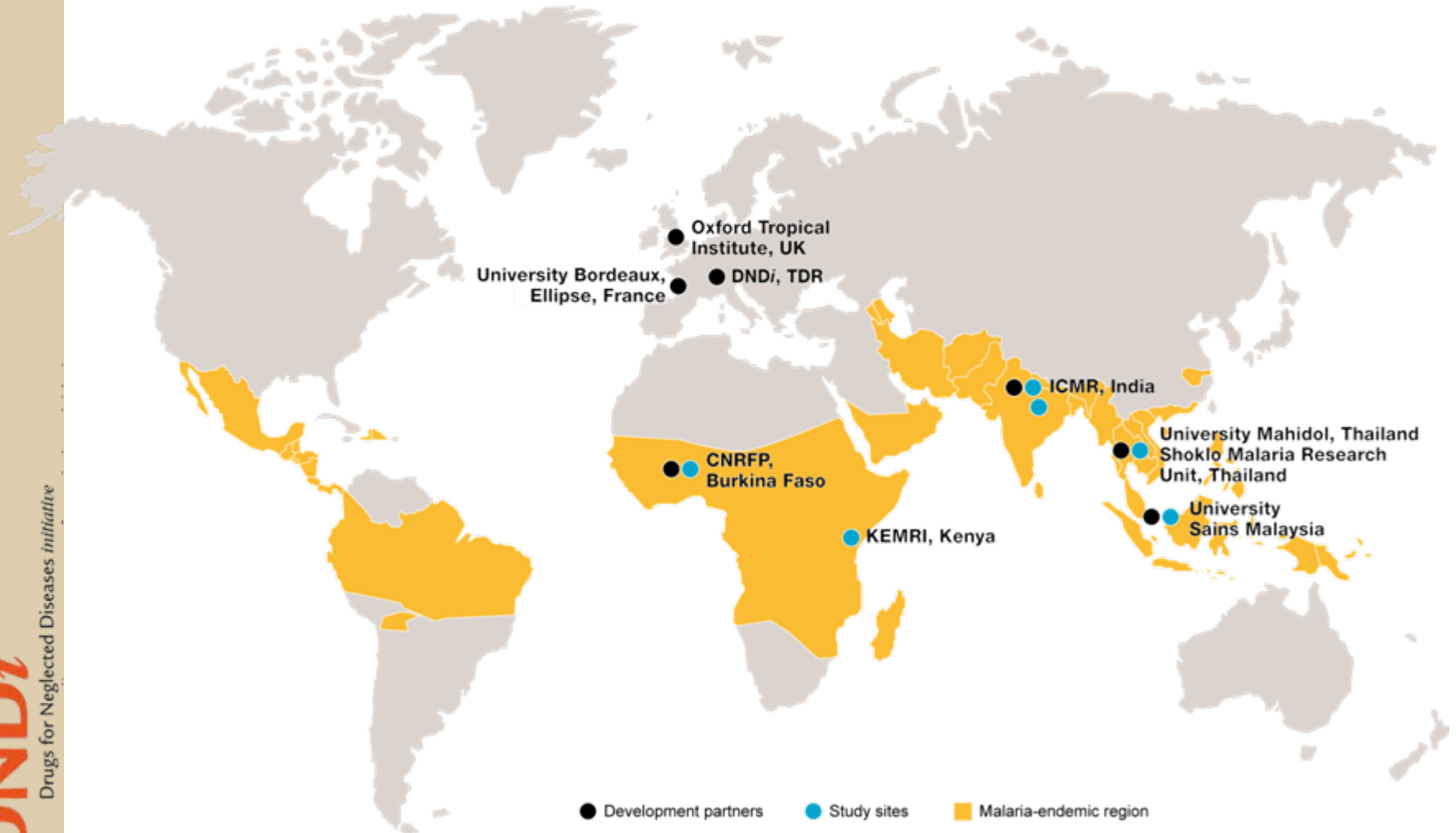
Industrial Partners:
Sanofi-Aventis

+

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)



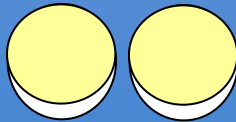
AS: 50 mg
AQ: 135 mg

Children (17-35 kg)



AS: 100 mg
AQ: 270 mg

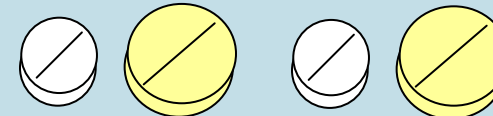
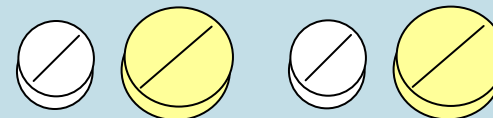
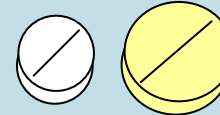
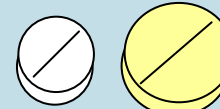
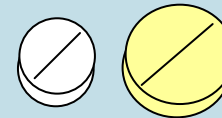
Adults (>35 kg)



AS: 100 mg
AQ: 270 mg

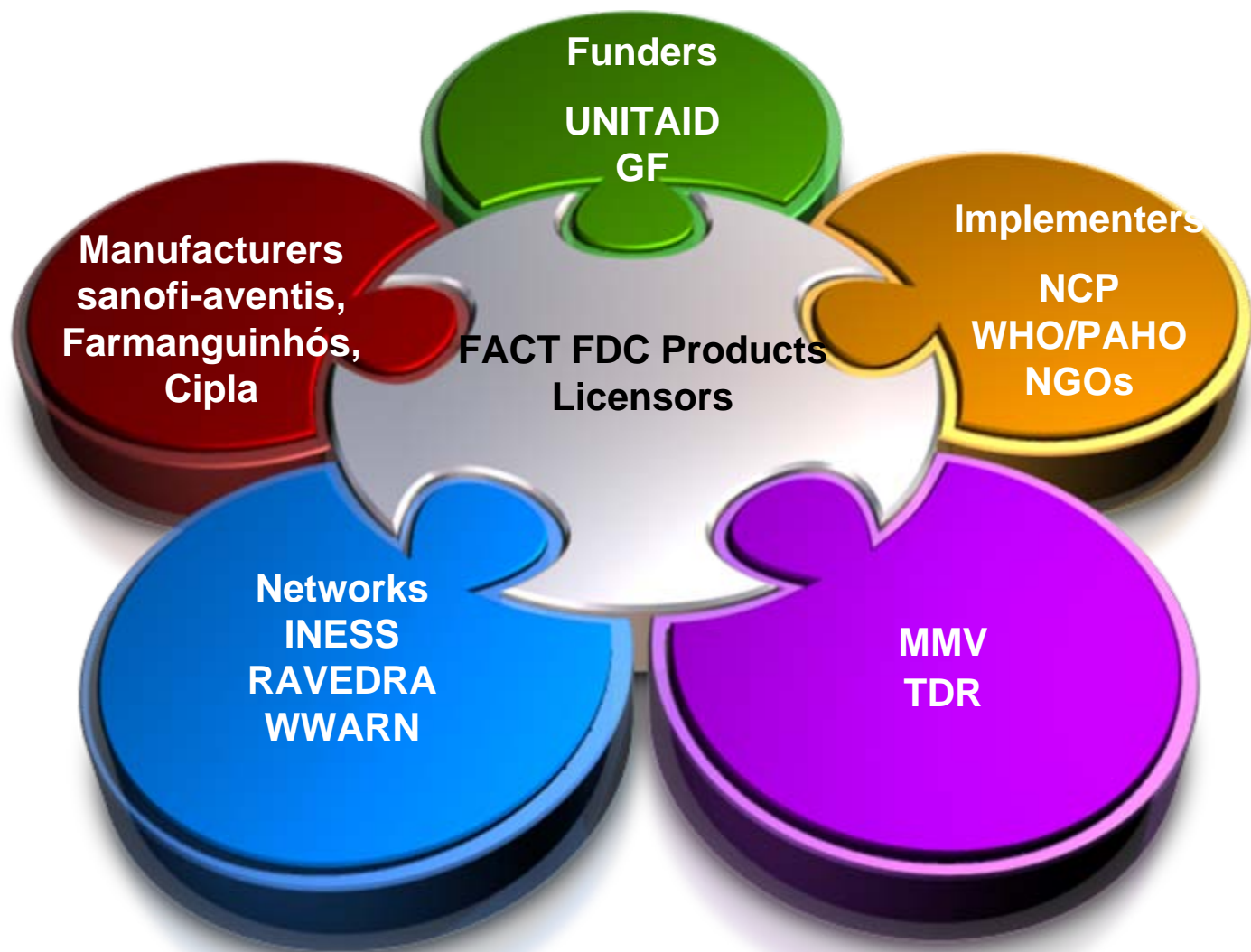
Co-blastered non-fixed AS+AQ Artesunate-amodiaquine

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**

TDR, Far-Manguinhos, Universiti Sains Malaysia (USM), Mahidol University; Shoklo Malaria Research Unit (Mae-Sot), University of Oxford (UK), Cipla (India), Catalent, Quintiles, MSF Foundation, ICMR (India), GVK (India), KEMRI (Kenya), CNRFP (Burkina Faso), NIMR (Tanzania),, Dr Neena Valecha (India), PrSornchai Looaresuwan (Thailand), Dr. Elizabeth Ashley, Dr. Piero Olliaro (TDR), Dr. W.Taylor, Pr. V.Navaratnam (University Sains Malaysia), Dr. Marcos Boulos (Brazil), Dr B.Ogutu (Kenya), Dr B.S. Sirima (Burkina Faso) , Dr. Guy Mazue, Pr Nick White & Dr. François Nosten (Thailand).