

DNDi's FACT Project: A New Kind of Partnership to Deliver New Products

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Drugs for Neglected Diseases *initiative*

Rationale: The Fixed-Dose ACT Project for Malaria

In 2001

- “WHO recommends in particular the use of drug combinations containing Artemisinin”
 - Artesunate-SP
 - Artemether-lumefantrine (Coartem)
 - **Artesunate-amodiaquine (AS-AQ)**
 - **Artesunate-mefloquine (AS-MQ)**
- For both AS-AQ and AS-MQ
 - No co-formulations
 - No partners

DNDi's FACT Project: Began in 2002

Objectives: 2 fixed-dose ACTs

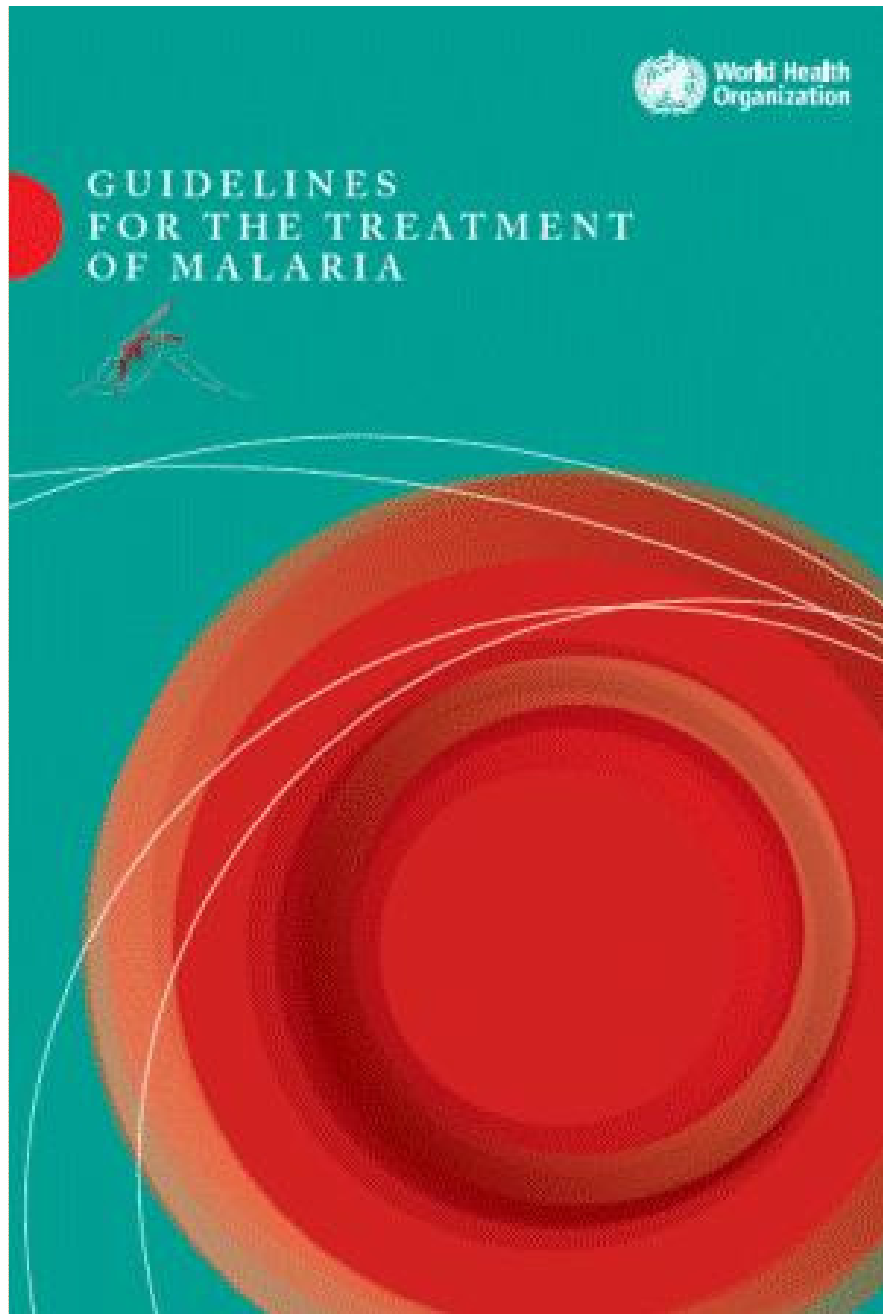
- **Easy** to use:
 - fewer tablets in regimen
 - paediatric strengths
 - ensure drugs are taken together and in correct proportions
- **Affordable**
- **Available** as public good
- Optimized ratio to prevent over- and under-dosing

AS/AQ (S-A)



AS/MQ (Farmanguinhos)





**In 2006, WHO
strengthens
recommendations.**

ACTS should be:

1. first-line treatment for *falciparum* malaria everywhere
2. in fixed-dose combinations when possible

www.who.int/malaria/docs/TreatmentGuidelines2006.pdf

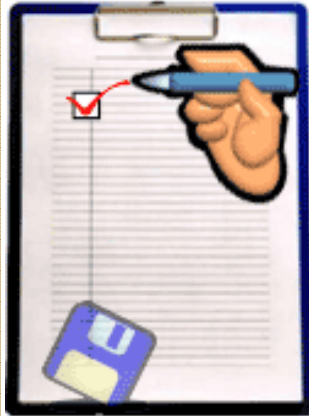
Why Develop Easy-to-Use Fixed-Dose Combinations (FDCs)?

- Facilitate compliance
- Improve use in the field
 - At health centres and at home
- Decrease risks of resistance development
- Better deployment and use of ACTs



Improved therapy for *falciparum* malaria

Transforming the Blueprint into the Blue Tablet



- **Drug substance quality**
- **Small nice tablets - paediatric strengths**
- **Simplified dosing regimen**
- **Simple and adapted packaging**
- **Stable under tropical conditions**
- **International quality documentation**
- **Affordable**

The Product: 1st Fixed-Dose ACT with 3-Year Shelf Life



Reaching Neglected Patients: FACT Project – A Public Partnership

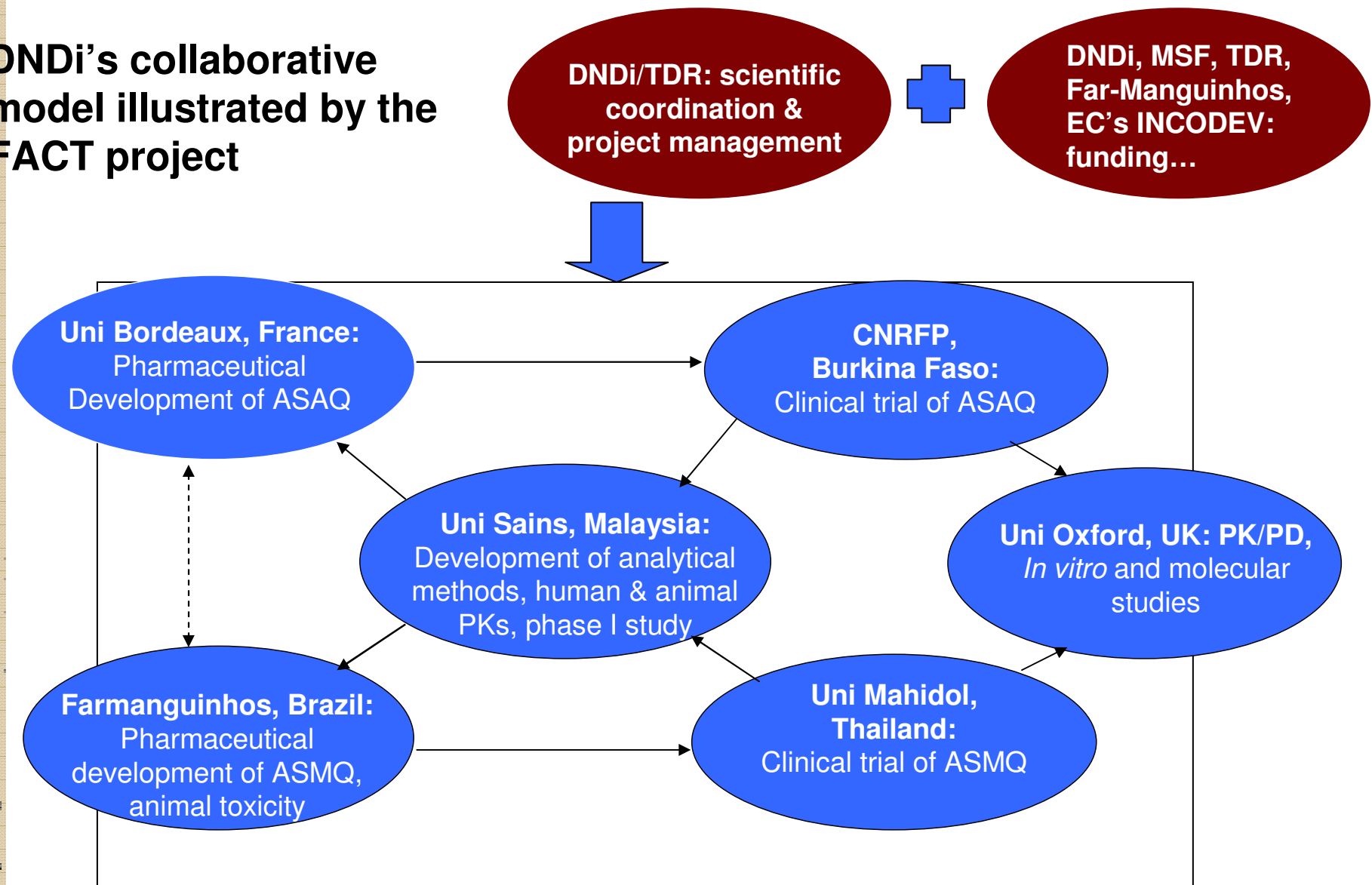
DNDi managed consortium and the project:

- Partners in South (Brazil, Burkina Faso, Malaysia, Thailand) & North (France, UK, Switzerland)
- Sharing capacities & capabilities
- Public sector investments
- Coordinated by DNDi & TDR
- Financing:
 - DNDi, MSF
 - Governments: EU INCO DEV, France, Netherlands, Spain, UK
 - Contribution by each partner



FACT Network

DNDi's collaborative model illustrated by the FACT project



AS/AQ: Artesunate/Amodiaquine

AS/MQ: Artesunate/Mefloquine

PK/PD: Pharmacokinetics/Pharmacodynamics

----- Sharing information

———— Sharing info/data/methods/products

What is “New” in This Partnership?

- **Contribution of public institutes to the consortium**
 - Universities and hospitals
 - Government-funded technology center
 - Foundations
 - TDR
- **Funding**
 - EC INCO-DEV (FP5)
 - Governments
 - DNDi and MSF
 - Partners of the Consortium
- **Delivery of NEW PRODUCT**

Prerequisites for Success

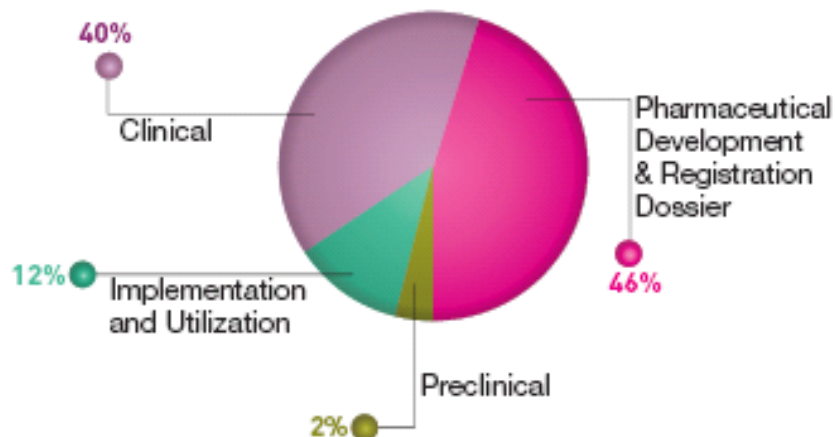
- **Project management**
- **Expert advice**
- **Long-term commitment of Consortium members**
- **Basics and implementation of good practices (GCP, GLP, GMP)**
- **Support by CRO's like Quintiles and Catalent**
- **Early & ongoing regulatory input and feedback**

How to Guarantee Quality in a Decentralized Organization?

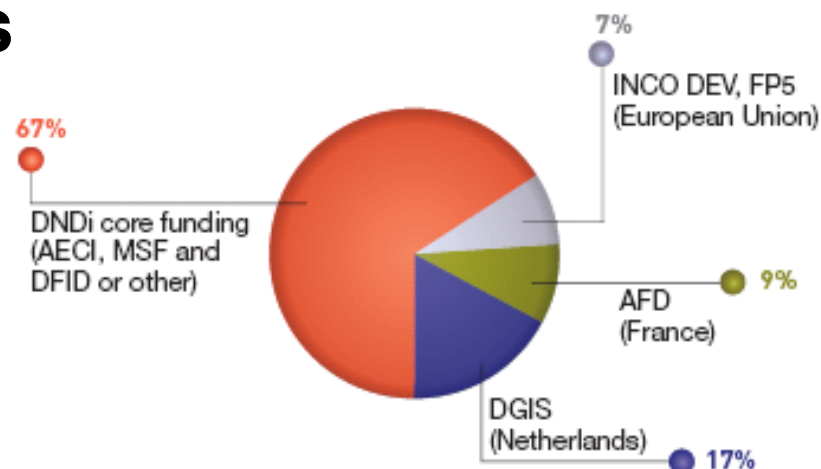
- **Audit of Pharmacy and Analytical data**
- **ERB reviews of clinical studies**
- **Centralized data analysis**
- **Audit of clinical studies**
- **Support by CROs**
- **Mock GMP Inspection**
- **Progress review and development plan presentation to regulatory agencies**
- **Format of Regulatory File**

At What Cost?

- 7.8 million Euros with important in-kind contributions from Farmanguinhos/Fiocruz, TDR, & other partners



Projected Expenditure Breakdown by Development Stage



Funding Resources by Donor

Outlook: Implementation



- New partnerships with regional and country experts
 - **Present:** Brazil: ongoing intervention study by national authorities
>17,000 patients
 - **Future:** Latin America: Bolivia, Ecuador, Peru, Venezuela
- Asia & Africa
 - Industrial partner: Cipla/techonoly transfer
 - Ongoing & planned studies: India, Myanmar (MSF), Tanzania
- Special populations
- Co-morbidities

Acknowledgments:

Project Partners:

- TDR
- Farmanguinhos
- MSF
- EU's INCODEV Programme
- Universiti Sains Malaysia (USM)
- Mahidol University
- Shoklo Malaria Research Unit (Mae-Sot)
- University of Oxford (UK)
- Catalent
- Quintilles
- Unitox, Genotox
- Abbott (Knoll)
- Roche

Project Investigators and Partners:

- Pr. Nick White
- Dr. François Nosten (Thailand)
- Pr. Sornchai Looaresuwan (Thailand)
- Dr. Elizabeth Ashley
- Dr. Piero Olliaro (TDR)
- Dr. W. Taylor
- Pr. V. Navaratnam (University Sains Malaysia)
- Dr. Marcos Boulos (Brazil)

Thank you!



Looking forward to more partners to assure delivery of therapeutic innovations to patients...