# Clinical experience with the *P. falciparum* Merozoïte Surface Protein-3/ Long synthetic peptid (MSP3/LSP) in Burkina Faso

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# Introduction

- Vaccines have played a major role in the control of endemic disease in the history of human development

- Despite some progress made in innovating malaria control tools (ITMs, IPTi, IPTp, ACTs, RDTs etc.), the lack of an effective vaccine represent a major obstacle in the way forward for reducing the malaria burden.

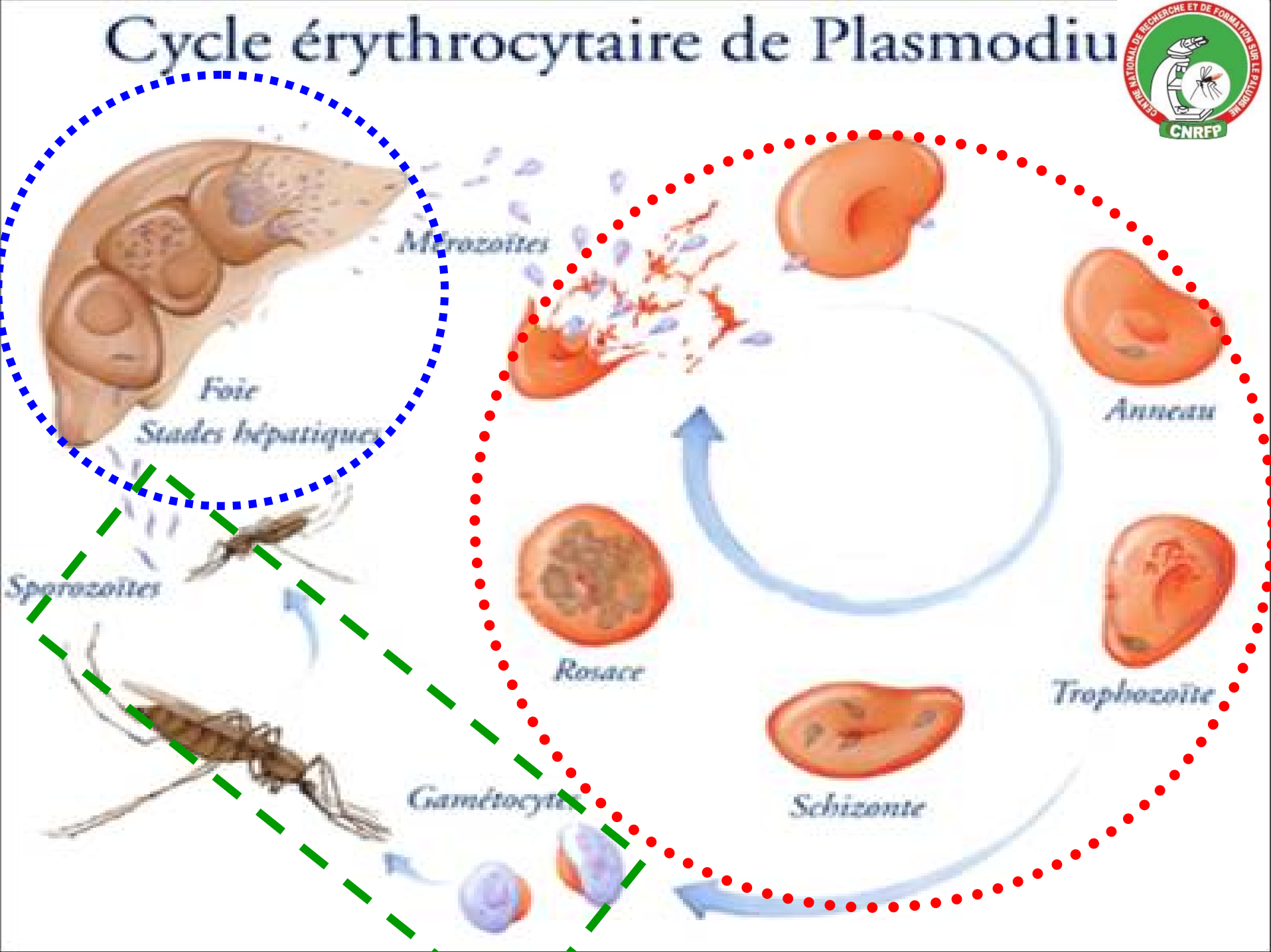
- The promotion of a PPP has been an invaluable booster for key players (industries, Universities, Research institutions etc..) to invest more resources in the development of new candidates malaria vaccines

- On December 2006, around 80 malaria vaccine candidates were at various stages of their development.

# *P. falciparum* MSP-3/181-276

- MSP3 is a long synthetic peptide containing the amino-acid sequence 186-276
- Blood-stage malaria vaccine candidate vaccine
- Adjuvant = Alumn Hydroxide

# Cycle érythrocytaire de Plasmodiu



# First clinical experience in naive volunteers

- In 2002 Phase 1 a study in Switzerland
- Primary endpoint: safety and reactogenicity
- Vaccination schedule: 0, 1, 4 months
- 35 naives volunteers recruited
- 14 days follow up for solicited symptoms and 28 days follow up for unsolicited symptoms
- Serious adverse events recorded throughout the study duration

# First clinical experience in naive volunteers

- Vaccine was safe and well tolerated
- Vaccine has induced antibodies capable of neutralizing the *Plasmodium falciparum* in in vitro assays

# Clinical experience in semi immune volunteers

- Phase 1b trial conducted in Burkina (village of Balonghin) in 2003
- 30 adults male volunteers included
- 3 injections of the MSP3-LSP in sub coetaneous
- 14 days follow up for solicited symptoms and 28 days follow up for unsolicited symptoms
- Serious adverse events recorded throughout the study duration (1 year)

# Clinical experience in semi immune volunteers

- Primary Objective
  - Reactogenicity and the safety of 3 doses of 30 µg MSP3

- Secondary Objectives
  - Humoral immune response to the malaria candidate vaccine antigens,
  - Cell-mediated immune response to the malaria candidate vaccine antigens

# Clinical experience in semi immune volunteers

- Both vaccines were well tolerated, no unexpexted adverse reactions were reported. No serious adverse events were reported.

- The safety profile of the MSP3-LSP vaccine does not appear to differ substantially from the one of the control vaccine (tetanus toxoid)

# Clinical experience in semi immune volunteers

- Non significant induction of antibody responses probably due to the level of pre existing immunity in adults.

- The data are consistent with some enhancement of cell mediated immune responses occurring following vaccination with MSP3-LSP vaccine.

# Clinical experience in non immune volunteers

- Phase 1 b study in children aged 1-2 years
- Double blind randomized controlled, dose escalation trial
- 45 children recruited
- Two study groups: Group 1 (15µg MSP3/LSP) and group 2 (30 µg)

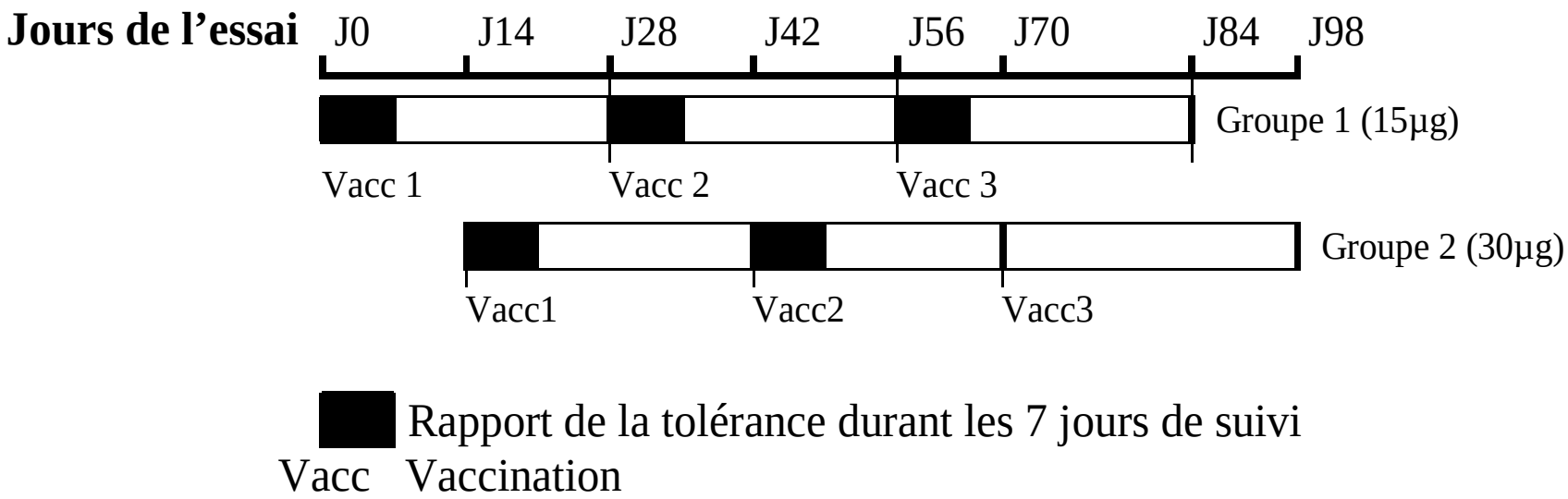
- Main endpoints
  - Safety and reactogenicity
  - Immune response (humoral and cell-mediated)

# Clinical experience in non immune volunteers

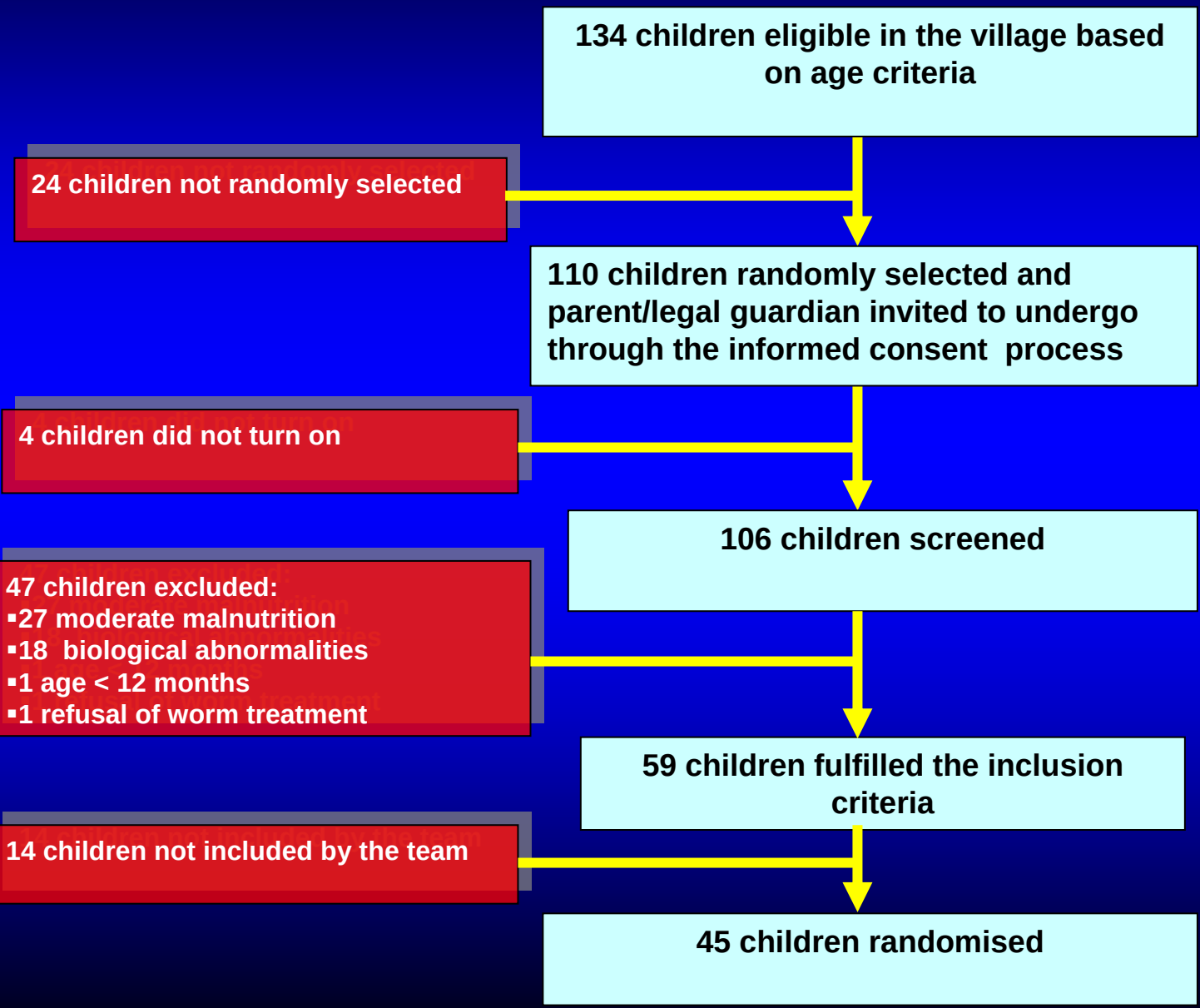
- 7 days follow up for solicited symptoms and 28 days follow up for unsolicited symptoms
- Serious adverse events to be recorded throughout the study duration (1 year)

# Immunization schedule

- 3 injections days 0, 28 et 56
- Follow up : 12 month after dose 1



# Trial profile



# Current status

- Study conclusion visit (day 84) completed for both groups
- Data entry is in process
- Immunological samples processing ongoing
- Study final report planned for 1Q2008
- Decision to proceed to phase 2b in children pending to the outcome of this study

# Conclusion

- Clinical experience with MSP3 malaria candidate vaccine has shown that the vaccine was safe and well tolerated
- Proof of concept studies are awaited to confirm whether the vaccine is effective against P. falciparum malaria in children living in endemic countrie