

**Eliminating epidemic meningitis  
as a public health problem  
in sub-Saharan Africa**



***Evaluation of Group A meningococcal  
conjugate vaccine as a tool for elimination  
of epidemic meningitis from Africa: update***

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# Epidemic meningitis in Africa

**Meningitis belt:** from Sudan in the east to Senegal The Gambia and Mali in the west: Sudan, Ethiopia, Chad, Niger, Benin, Northern Nigeria, Northern Ghana, Burkina Faso, Mali, The Gambia, Senegal

**1905: first documented epidemic, Northern Nigeria**

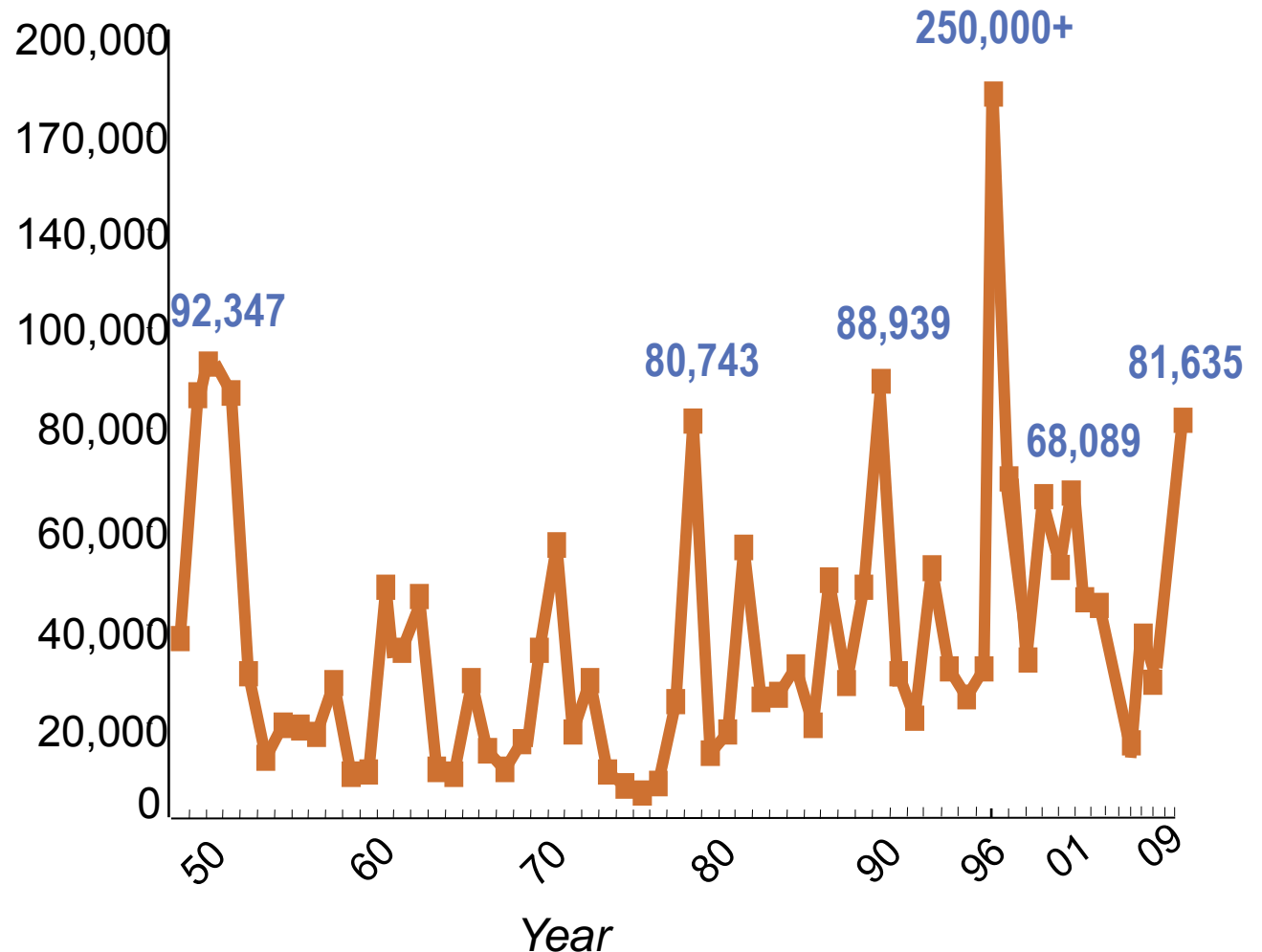
**•1919-1924: second great cycle with over 45,000 deaths in Sokoto, Northern Nigeria**

**•1935-1937: third great cycle: Chad 1326 deaths; Nigeria 6456 deaths**

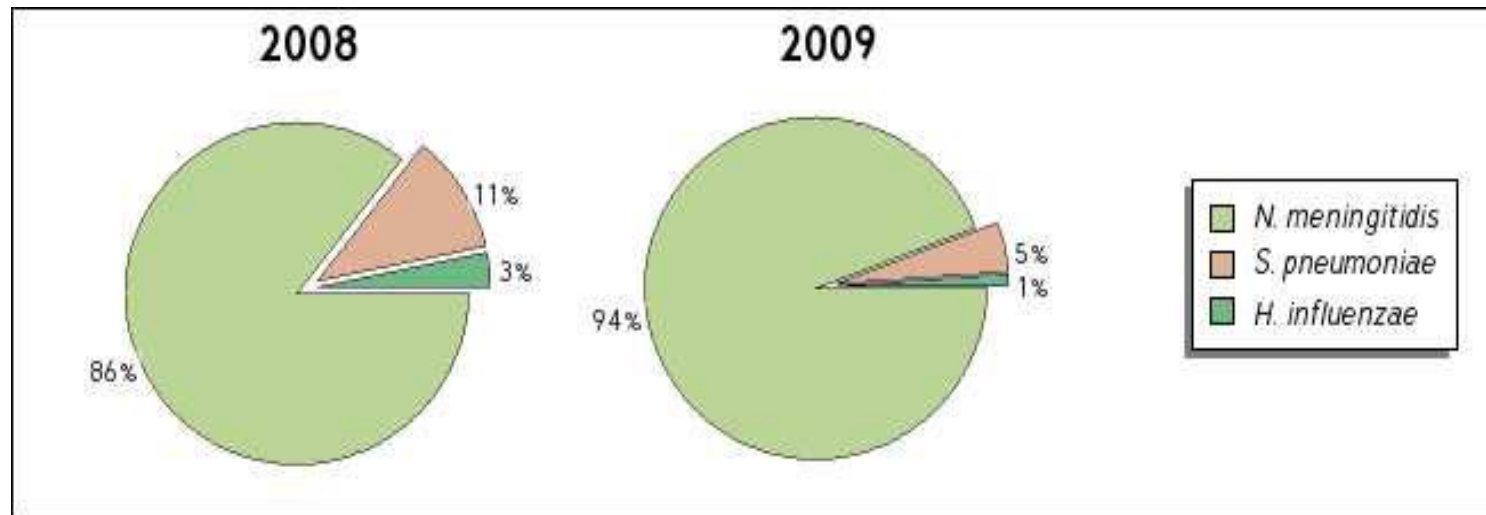
**•1951-60: 340,000 cases with 53,000 deaths**

**•1996-1997: 300,000 cases with 30,000 deaths**

*Number of cases*



# Niger 2009: pathogens' distribution



**1087 Nm:** 1082 Nm A + 3 Nm W135 + 2 Nm X

# The Meningitis Vaccine Project (MVP)

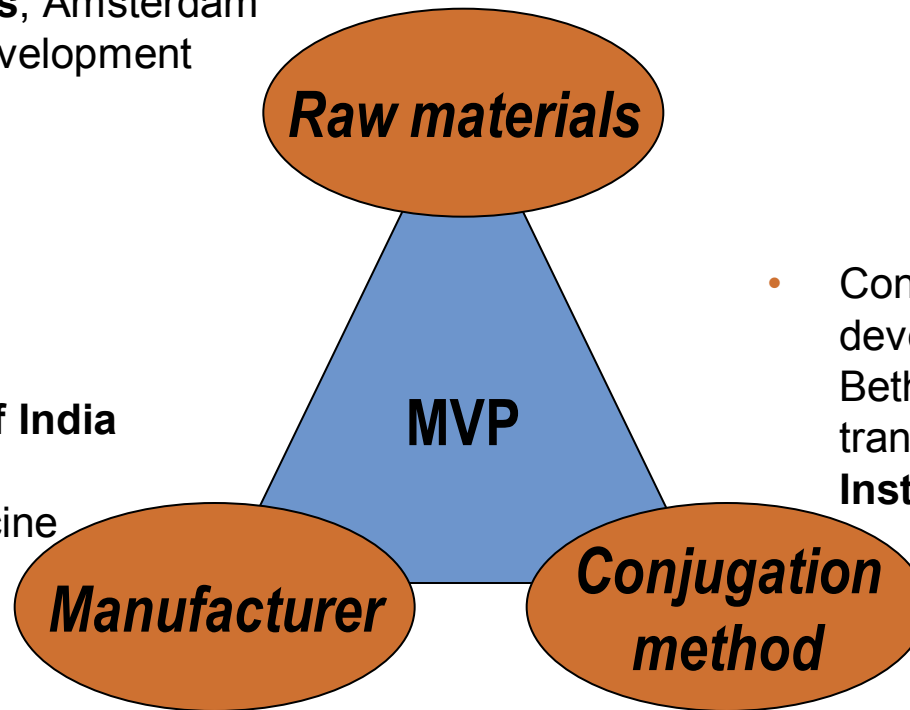
- Funded by the BMGF in June 2001
  - 10 year partnership between WHO and PATH
  - goal of eliminating epidemic meningitis as a public health problem in sub-Saharan Africa through the development, testing, licensure and widespread use of *affordable conjugate* meningococcal vaccines.

# MVP Men A Vaccine Development Model

- A PS produced by **SynCo BioPartners**, Amsterdam for initial development

- **Serum Institute of India** develops and manufactures vaccine

- Conjugation method developed at **CBER/FDA**, Bethesda, USA and transferred to **Serum Institute of India, Ltd**



**Target price US\$ 0.40/dose**

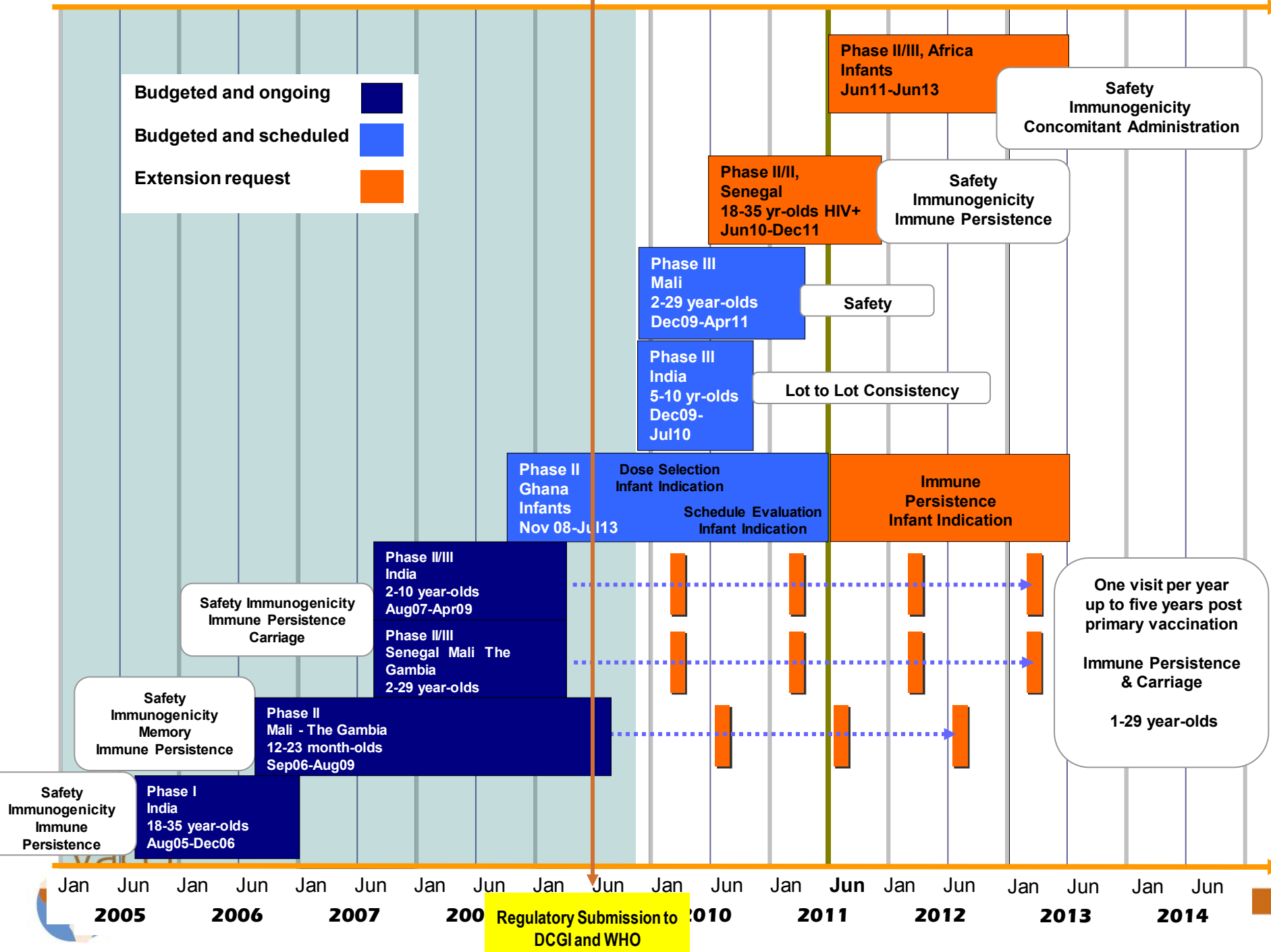
# Men A-TT conjugate vaccine - “MenAfriVac”



# MVP

## Vaccine Introduction Strategy for elimination of epidemics

- Rapidly protect & induce herd immunity
  - Single dose mass vaccination campaigns targeted at 1 to 29 years of age
  - Protection of new birth cohorts
    - within EPI schedule
    - through follow-up mass campaigns targeted at 1 to 4 years of age every 5 years



# Safety Profile of Men A Conjugate Vaccine

# Safety Profile by Study

## 4 weeks after primary vaccination

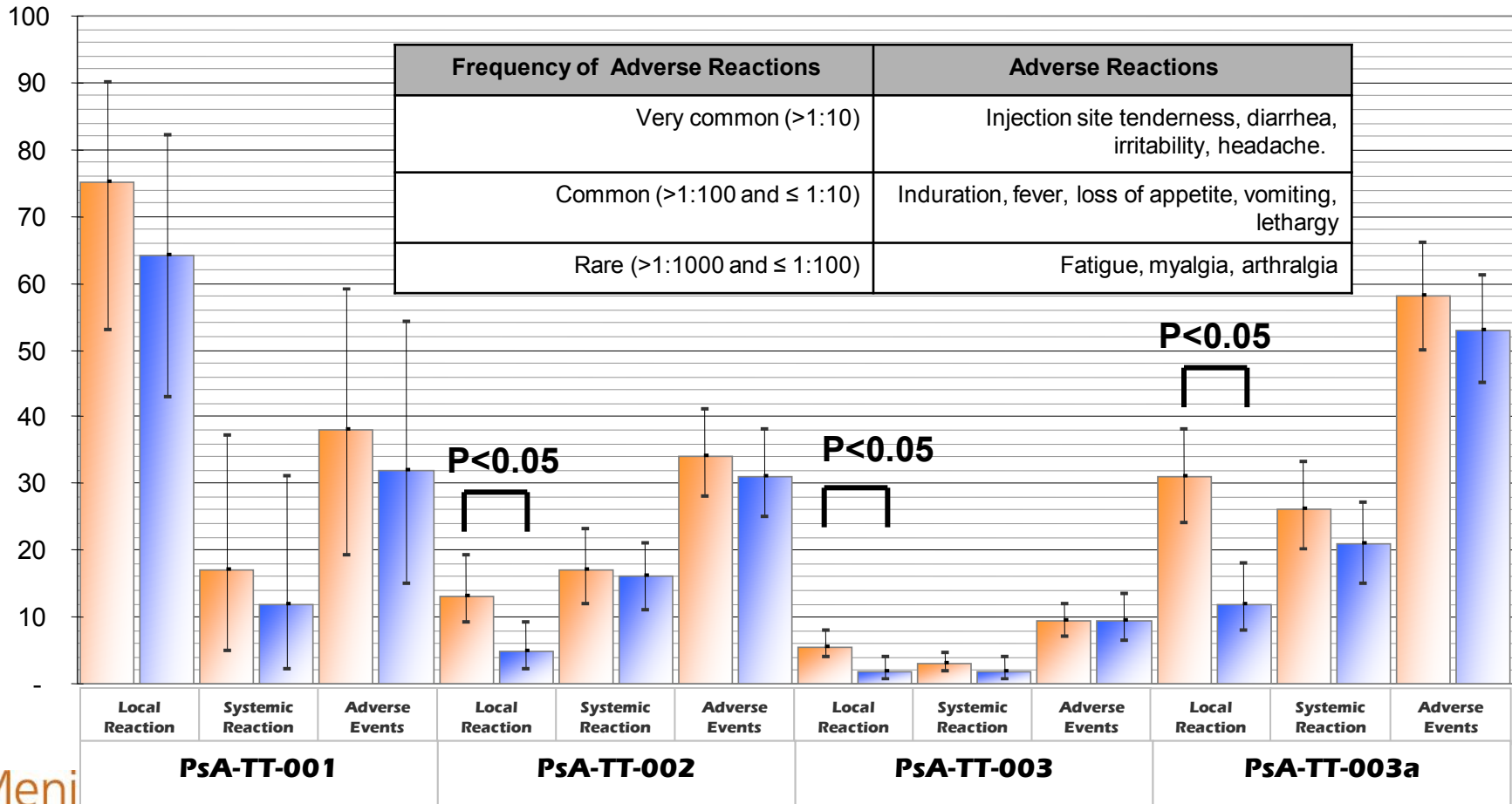
(PsA-TT-001, PsA-TT-002, PsA-TT-003, PsA-TT-003a)

PsA-TT

PsA



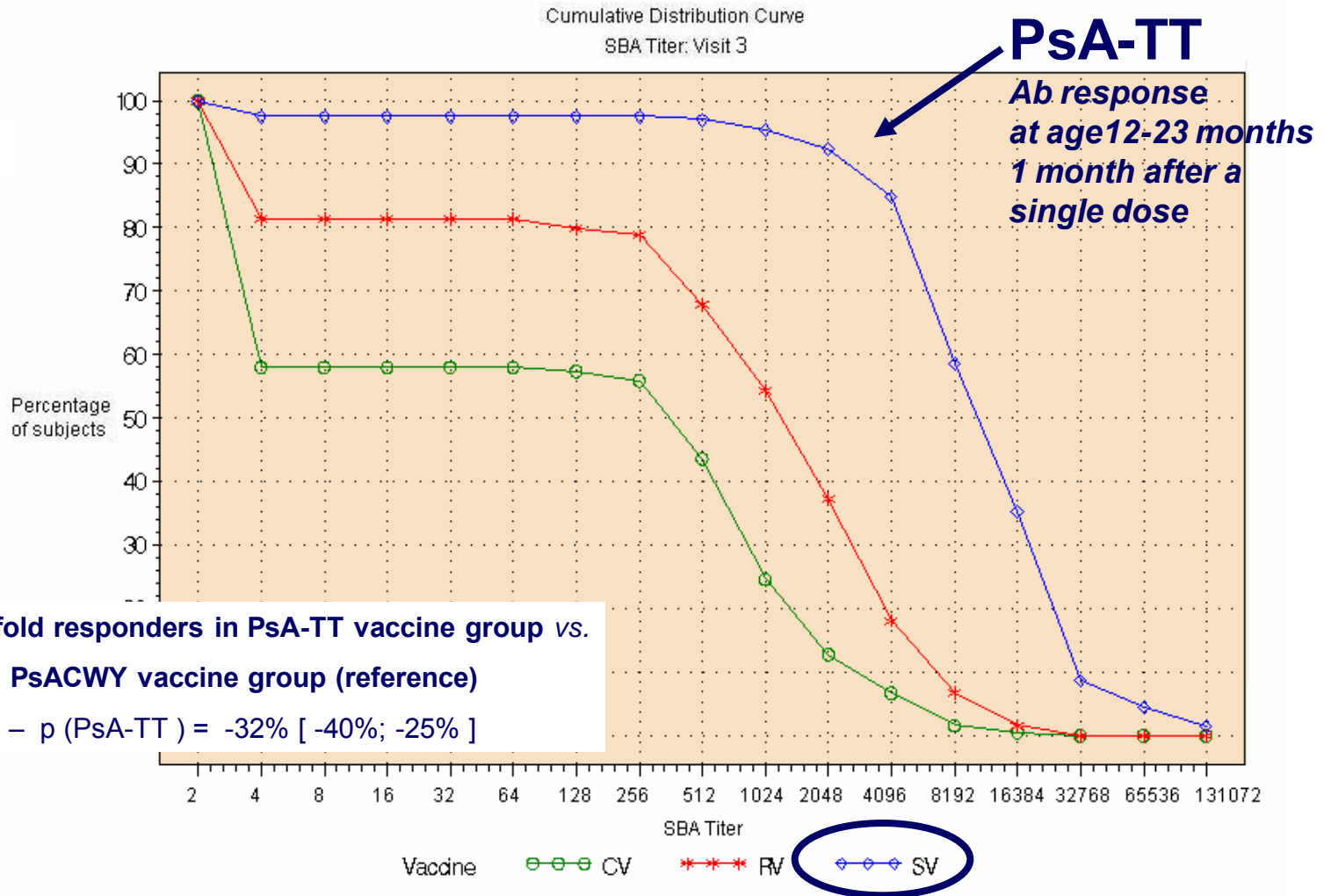
%



# Immunogenicity Profile of Men A Conjugate Vaccine

# MenA rSBA Reverse Cumulative Distribution Titres in 12-23 months old children one month after vaccination-PsATT002 study

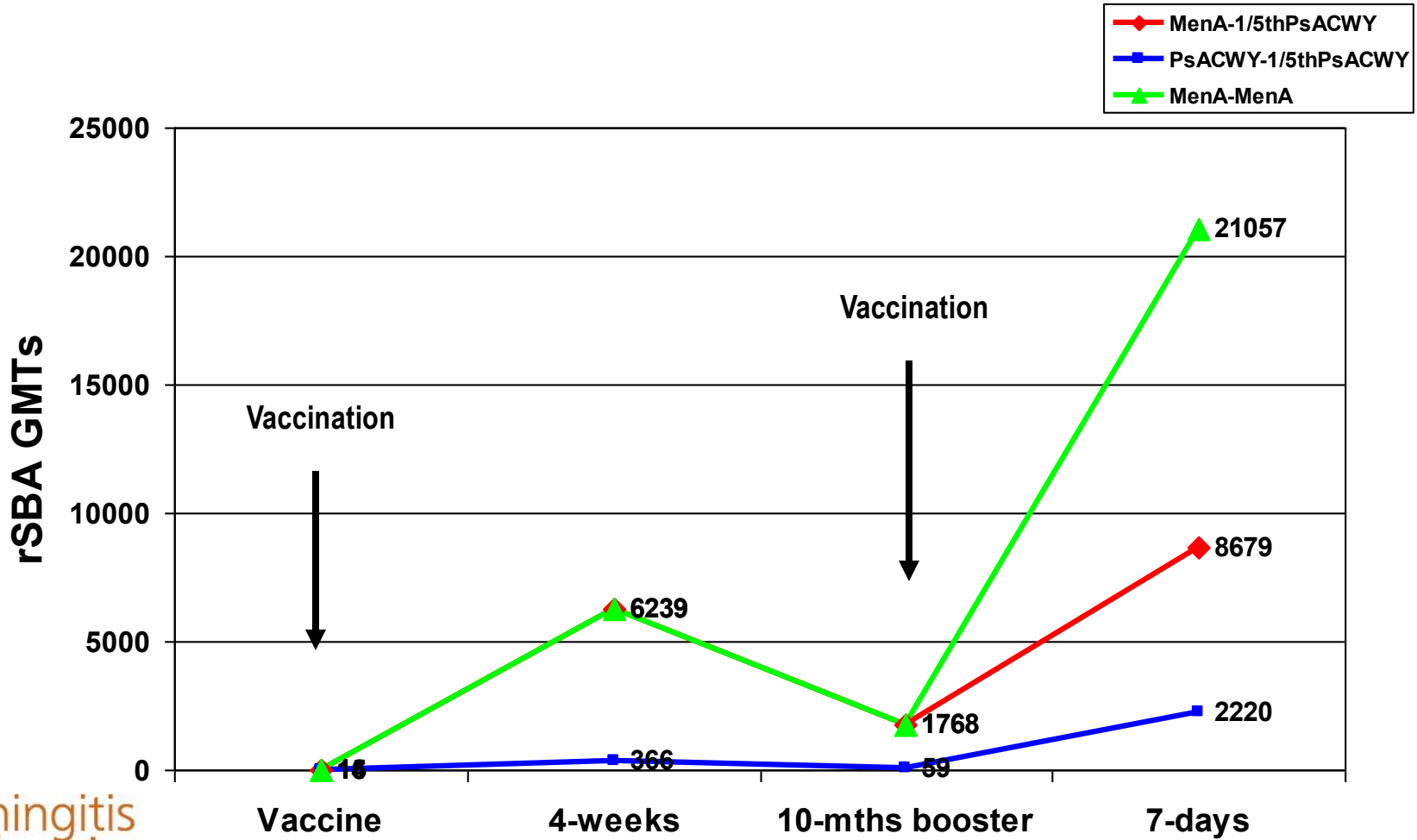
- PsA-TT
- PsACWY
- Hib-TT



**96% (190/198) 4-fold responders in PsA-TT vaccine group vs. 64% (123/193) in PsACWY vaccine group (reference)**

$$\Delta = p(\text{PsACWY}) - p(\text{PsA-TT}) = -32\% [-40\%; -25\%]$$

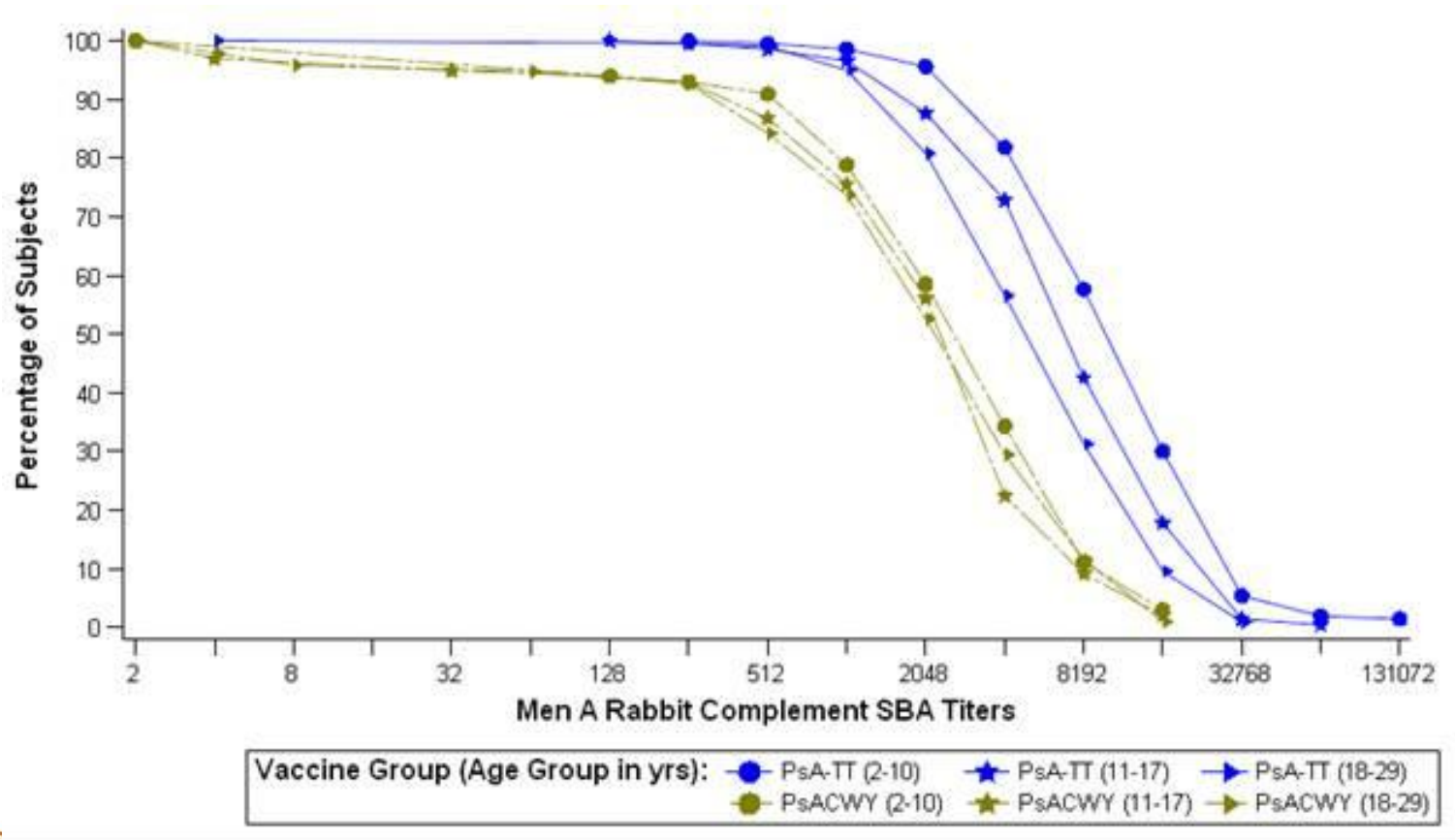
# rSBA Immuneresponse to primary vaccination, 10 months persistence and immuneresponse to booster – IMMUNOLOGICAL MEMORY- in 12-23 months old from two African countries



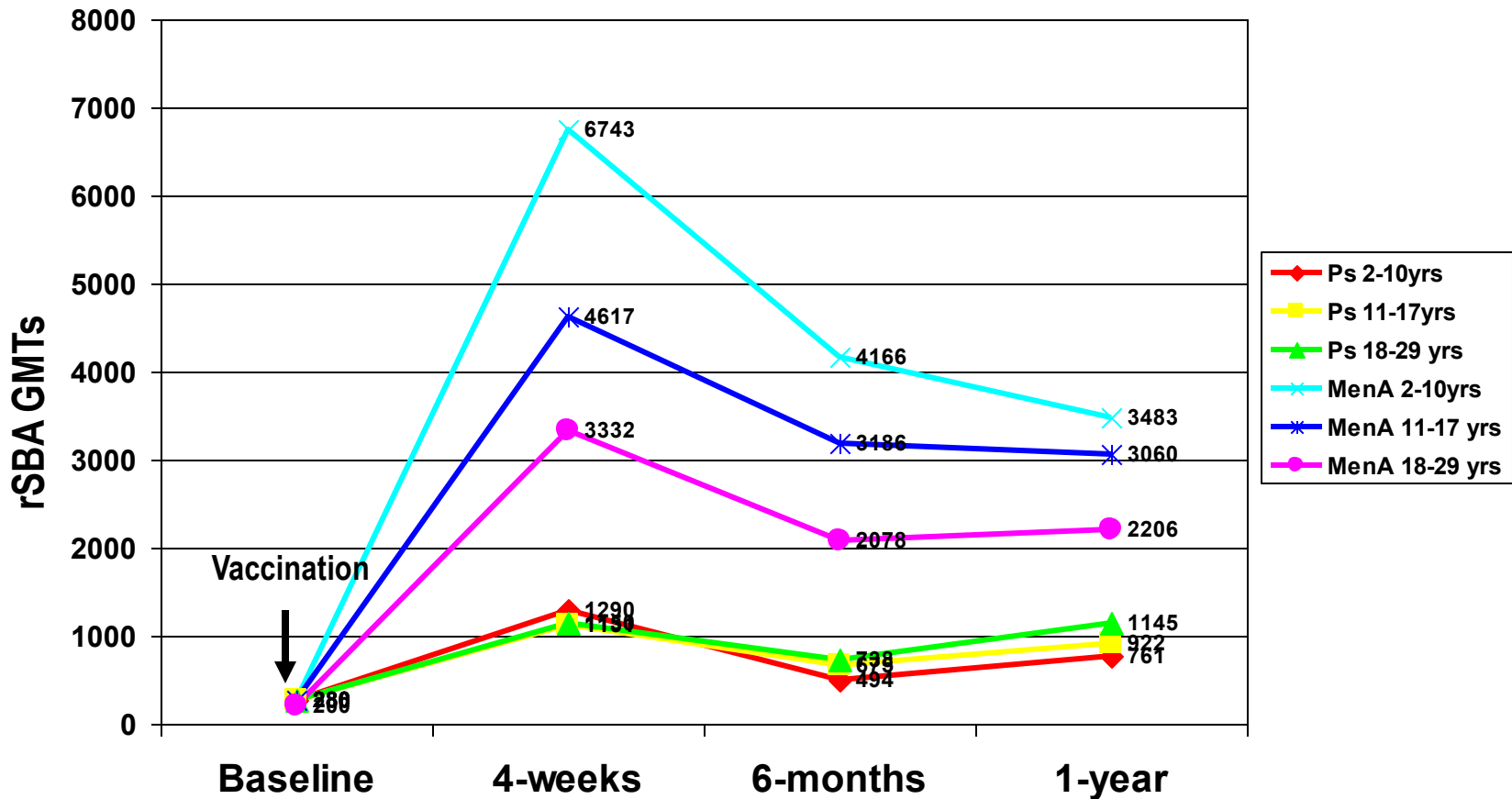
*Proportion of subjects with Men A rSBA  $\geq$  4-fold rise at four weeks after vaccination with reference to baseline titres in 2-29 years old (Mali, Gambia, Senegal, India)*

African sites	PsA-TT vaccine (N = 604)				PsACWY vaccine (N = 296)			
	Age group (years)	N	n	% (95%CI)	N	n	% (95%CI)	
	2 to 10	202	172	85 (80-90)	97	52	54 (43-64)	
	11 to 17	202	155	77 (70-82)	99	39	39 (30-50)	
	18 to 29	198	144	73 (66-79)	94	43	46 (35-56)	
	<b>ALL 2 to 29</b>	602	471	78 (75-82)	290	134	46 (40-52)	

# Reverse cumulative distribution MenA rSBA titers 4-weeks after vaccination in 2-29 year olds from three African countries 4-weeks after vaccination—by age group—



# rSBA GMTs one-year persistence in 2-29 years old from three African countries vaccinated with either one dose of PsACWY or MenA conjugate vaccine



# MenAfriVac has the characteristics of a conjugate vaccine

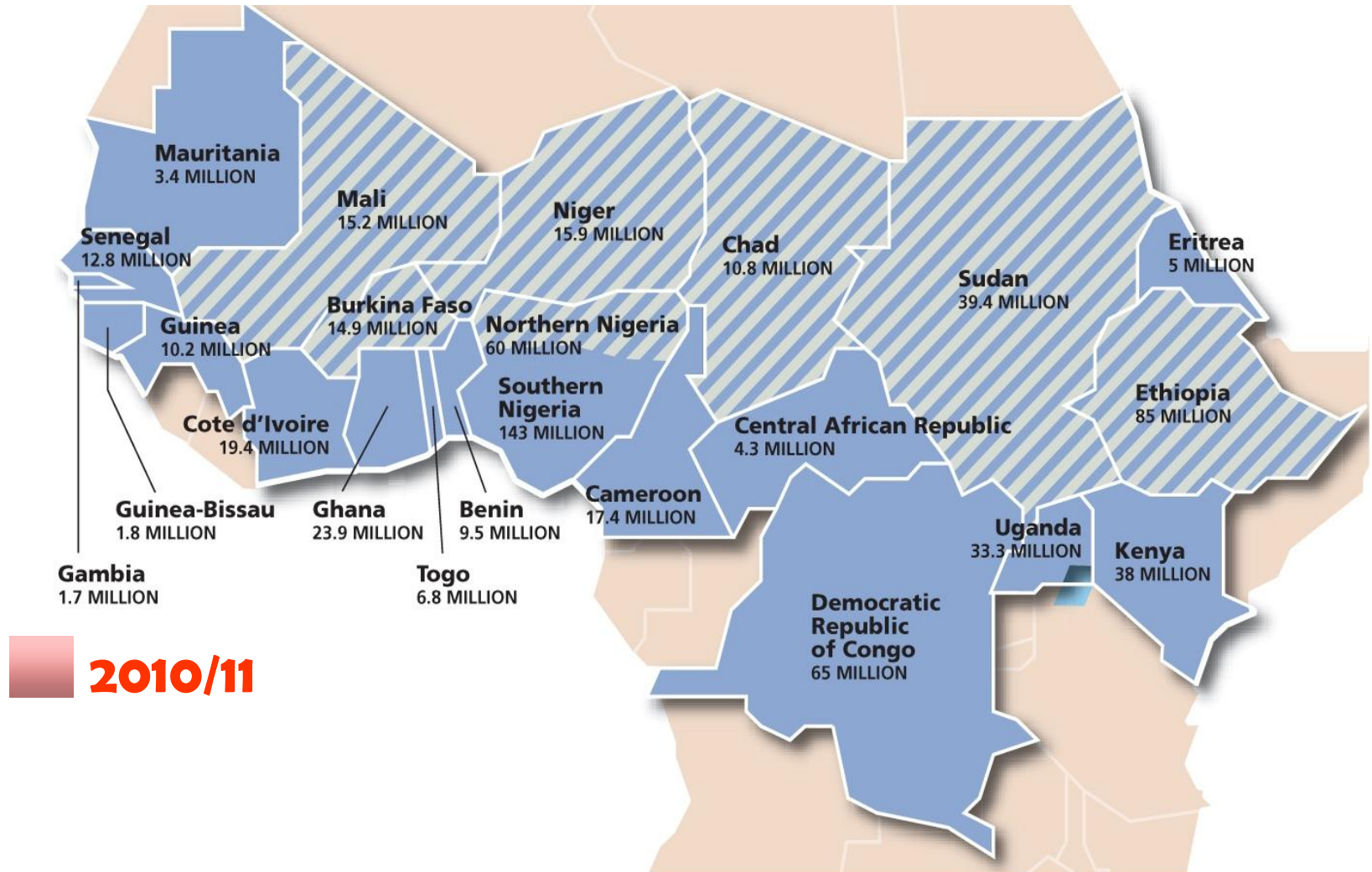
- MenA conjugate vaccine has shown an equivalent safety & tolerability profile than the licensed polysaccharide and Hib vaccines in the 1-29 year olds in Africa and in India
- MenA-TT conjugate shows the characteristics of a conjugate vaccine
  - **Superior immunogenicity in 1- to 29 year olds vs. Polysaccharide vaccine**
  - **Effective priming for immunological memory in 12-23 month olds**
  - **Inducement of bactericidal antibodies persisting at sustained levels in 1-29 year olds vs. Polysaccharide vaccine**

MenAfriVac is expected to provide individual protection, inhibit nasopharyngeal carriage and produce herd immunity effect at population level



**For elimination of meningitis epidemics in the meningitis belt countries**

# Proposed MenA conjugate vaccine introduction



## KEY



Meningitis belt country



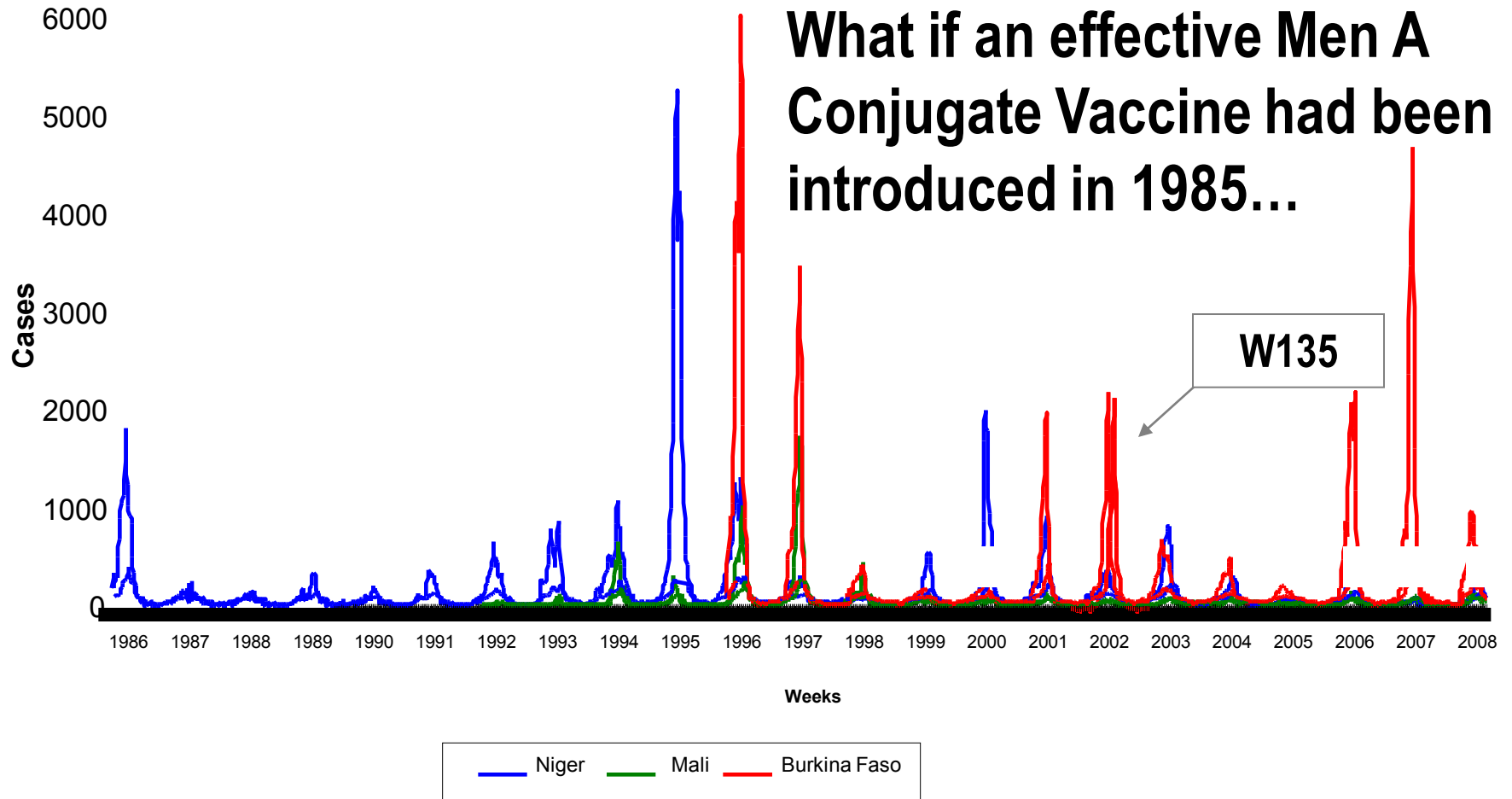
Hyperendemic country



Non-meningitis belt country

**Country Name**  
2009 POPULATION

# Reported meningitis cases in Burkina Faso (1997-2008), Mali (1992-2008) and Niger (1986-2008)





Meningitis Vaccine Project

