

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



Medical Innovation – changing business model

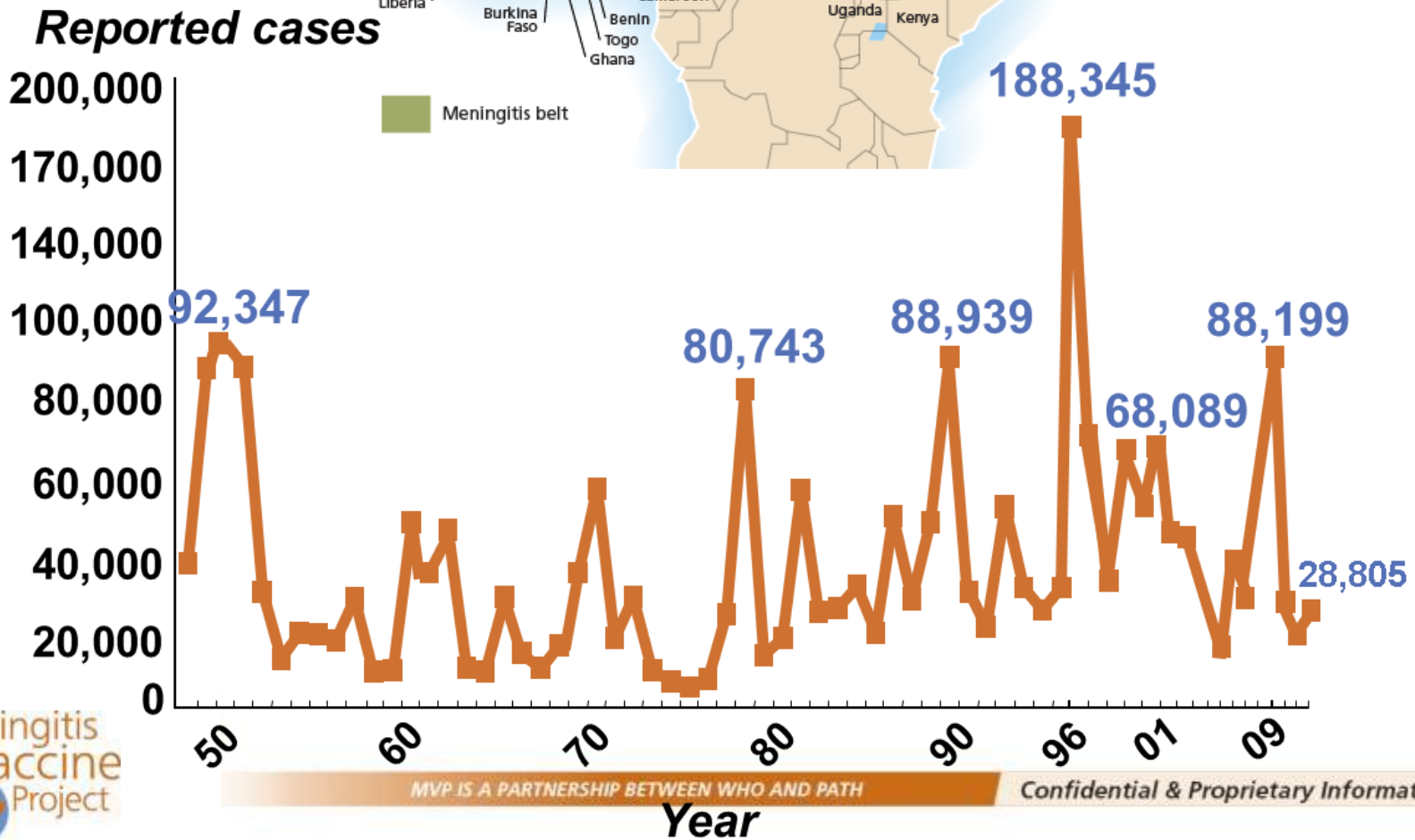
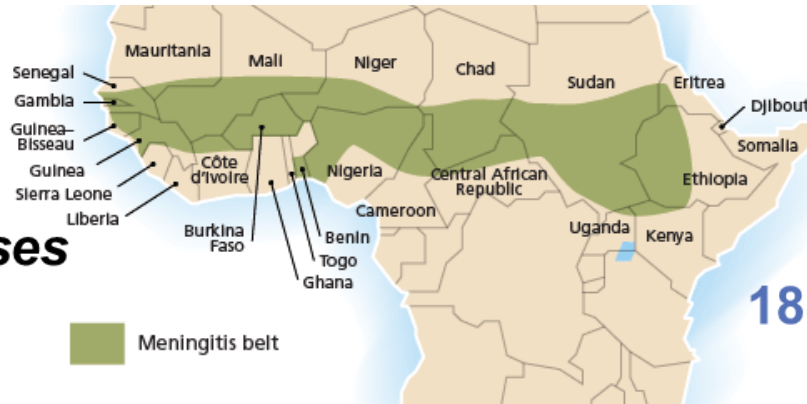
Marie-Paule Kieny, WHO-WIPO-WTO, 5 July 2013

The Meningitis Vaccine Project (MVP)

A successful vaccine development for Africa, partnering with a DCVM

- An exemplary partnership with the critical role of a developing country vaccine manufacturer
 - The state-of-the-art development of an affordable vaccine specifically designed to address an unmet major public health need in Africa
 - The diligent registration on this new vaccine paving the way for innovative regulatory pathways
 - A time lag period of 0 year between vaccine licensure and vaccine introduction at public-health scale
 - The development of a strong international scientific network

Epidemic meningitis in Africa: 1948-2012



Epidemic meningitis: impact on families



PATH/Monique Berlier

- More than 10 percent of patients die, typically within 24–48 hours of the onset of symptoms
- 25% of survivors have long-term aftereffects
- Expenditures of 3 to 4 months of disposable income

Source: WHO, Colombini A, Batiano F, Zongo, S, et al. *Costs for households and community perception of meningitis epidemics in Burkina Faso*. *Clinical Infectious Diseases*. 2009 Nov 15;49(10):1520–1525.

Epidemic meningitis: impact on public health

- Marked seasonality with periodic devastating epidemics
- Overwhelms health infrastructures and disrupts routine programs
- Greater than 80% serogroup A



WHO/Kader Konde

The Meningitis Vaccine Project (MVP)

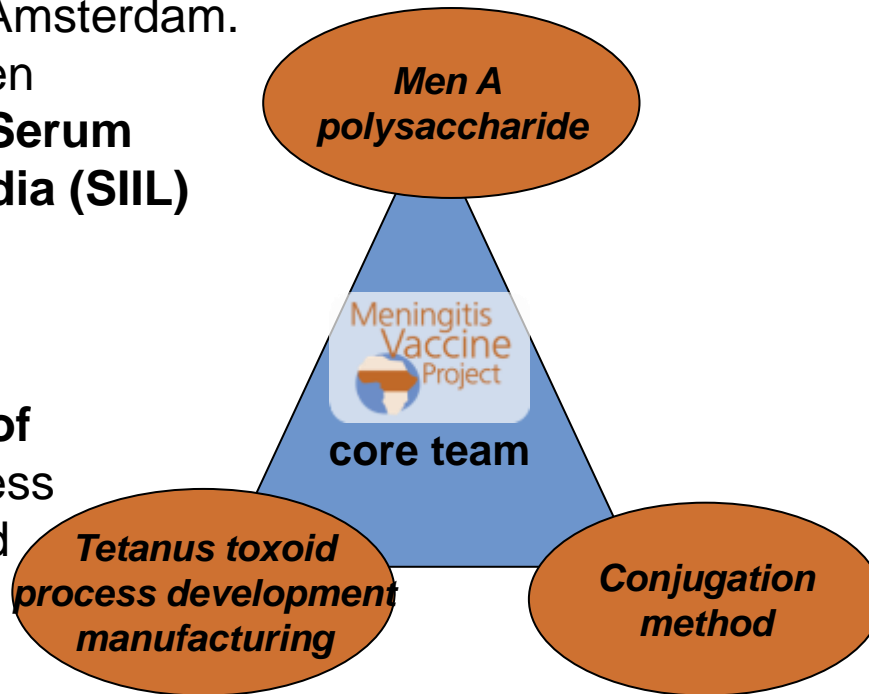
Early development

- **Early 2000:** WHO expert group concludes that development of a meningococcal conjugate vaccine offers an attractive strategy for epidemic control in sub-Saharan Africa
- **April 2000:** group of international experts and delegates from African ministries of health endorse the initiative
- **June 2001:** Bill & Melinda Gates Foundation funds MVP
 - *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 **conjugate** meningococcal vaccines*
- **2001–2002: Project constraints,** African public health officials emphasize the key importance of a low vaccine price for a sustainable supply (**< \$0.5 USD per dose**)

MenA vaccine development

Group A polysaccharide produced by **SynCo BioPartners**, Amsterdam. Technology then transferred to **Serum Institute of India (SIIL)**

Serum Institute of India (SIIL) process development and manufacturing

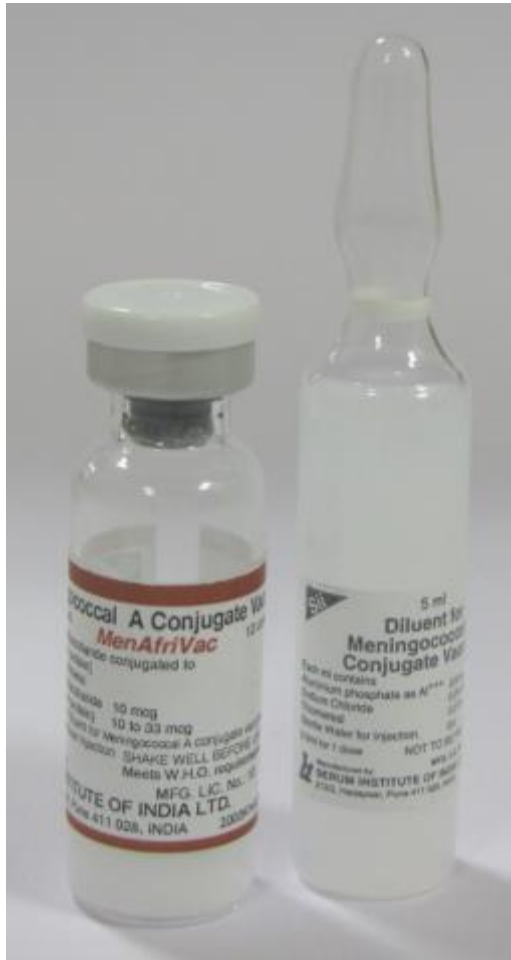


Conjugation method developed at **CBER/FDA**, Bethesda, USA; transferred and scaled-up at **Serum Institute of India (SIIL)**

Target price US\$ <0.50/dose

MenA conjugate vaccine

MenAfriVac®



PATH/Monique Berlier

Conclusions from clinical trials

- Is well tolerated and safe
- Induces superior and longer lasting immunogenic response
- Boosts anti-tetanus immunity



WHO/Rodrigue Barry

Licensure and prequalification

- MenAfriVac® licensed by Drugs Controller General of India in December 2009
- WHO prequalification awarded in June 2010



SIIL/S. Vinayak

MenAfriVac introduction

Strategy



- Inducing strong herd immunity through single dose mass vaccinations targeting 1–29 year olds with high vaccine coverage in 26 countries of the meningitis belt
- Protecting new birth cohorts
 - Follow-up campaigns every 5 years for the under 5 year olds **or**
 - Routine immunization through introduction into the EPI by 2015
- Enhancing surveillance and epidemic response throughout vaccine introduction and beyond

2010: Phased introduction and rollout in three countries

- District-level introduction (1.2 million vaccinated in Burkina Faso, Mali, and Niger) in September 2010
- Results presented to WHO Global Advisory Committee on Vaccine Safety who deemed the vaccine safe
- Rollout in 1–29 year olds in Burkina Faso, Mali, and Niger in December 2010, prior to meningitis season
 - Burkina Faso 11.5 million vaccinated
 - Mali 4 million vaccinated
 - Niger 4 million vaccinated



PATH/ Monique Berlier

Official launch day – health workers



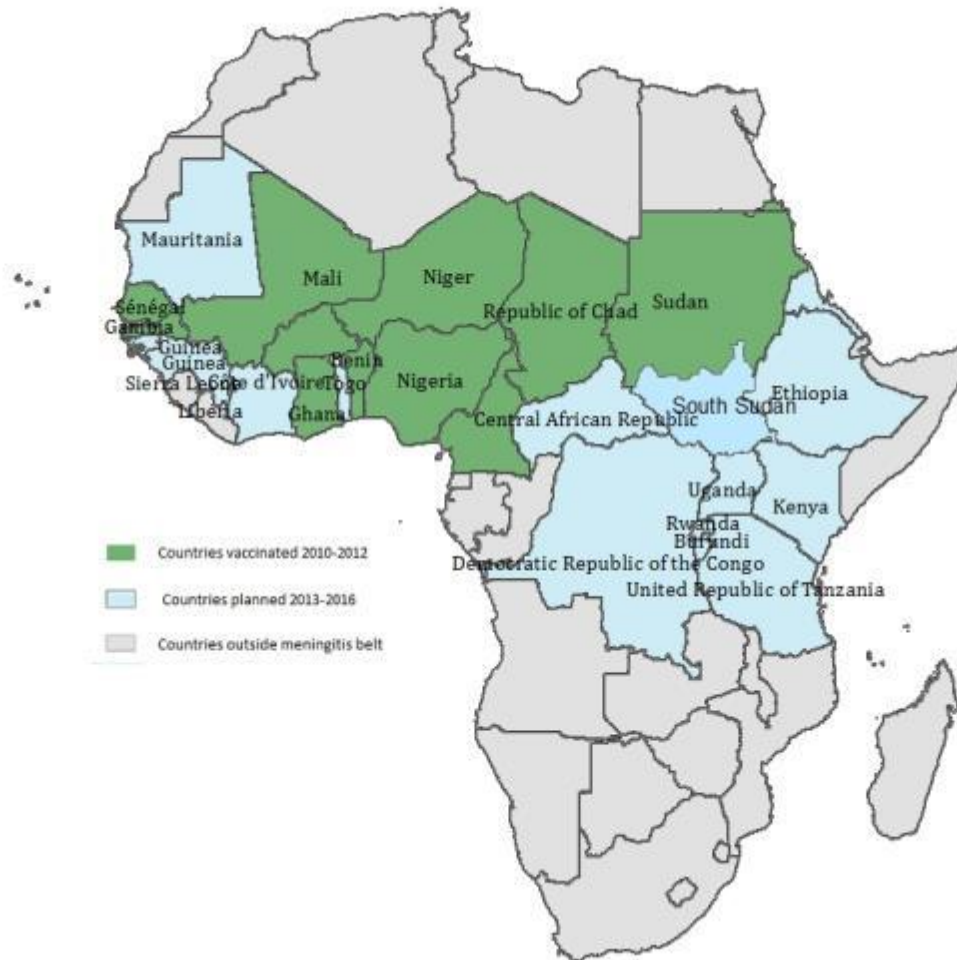
PATH/ Gabe Bienczycki

Official launch day – school children



PATH/ Gabe Bienczycki

MenAfriVac Roll-out 2010-2016



MenAfriVac Introduction

Some early evidence ...

- Strong evidence of effect on carriage

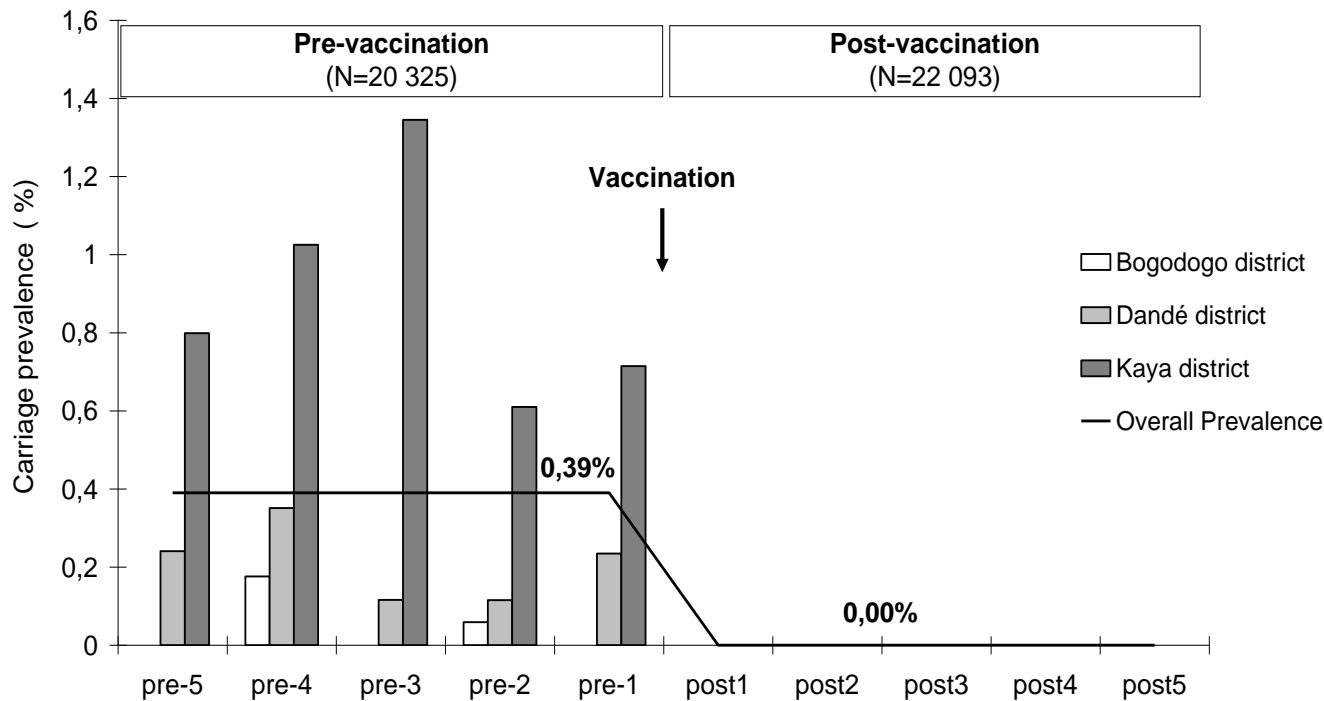


Figure 2. Impact of MenAfriVac vaccination on carriage of *N. meningitidis* serogroup A

Kristiansen PA, Diomandé FVK, Ba AK, et al. *Impact of the serogroup A meningococcal conjugate vaccine, MenAfriVac, on carriage and herd immunity.* Clinical Infect Dis 2012. Published Online October 19, 2012. doi:10.1093/cid/cis892.

100 000 000th vaccination

Cotonou, Benin, 15 November 2012



WHO/Bachir

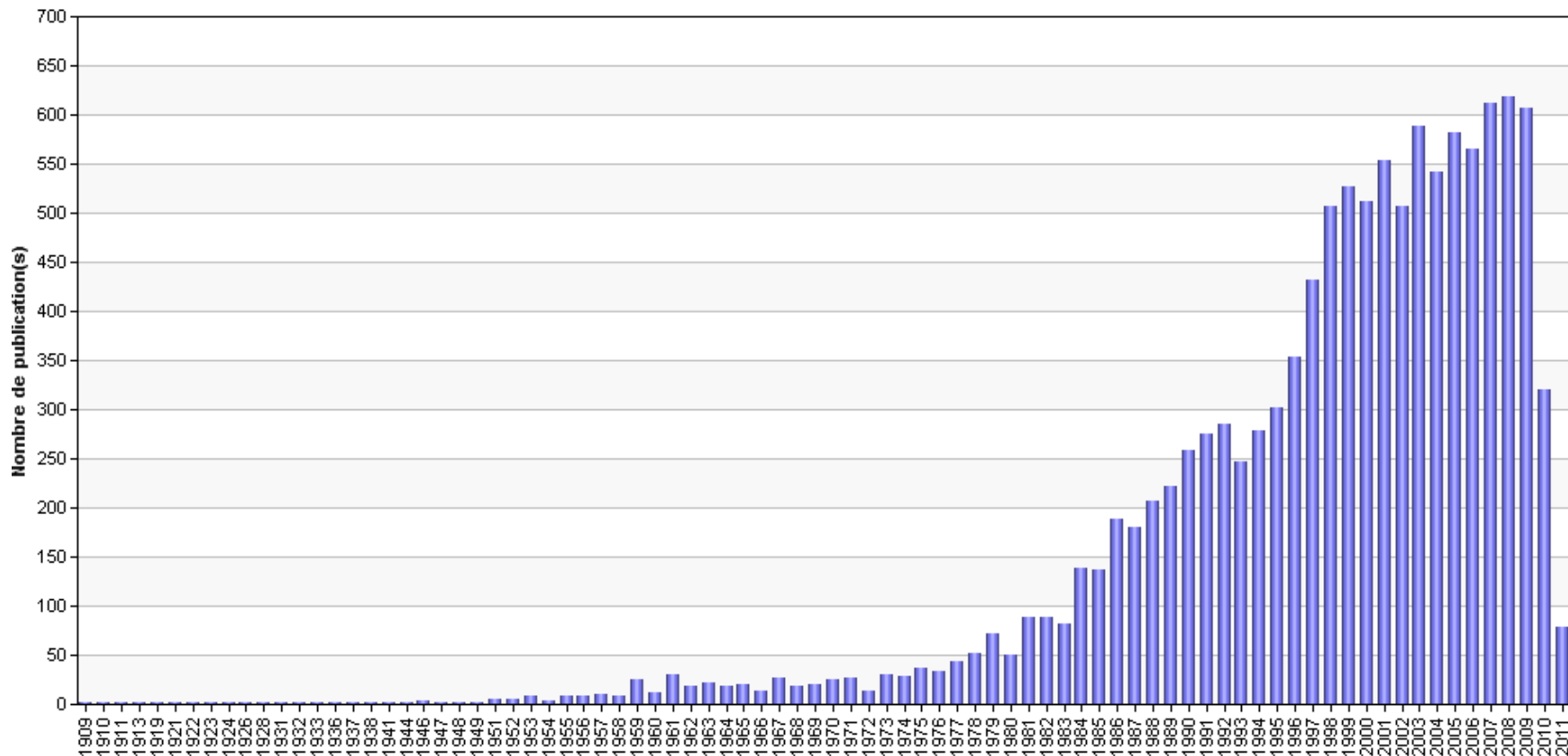
Meningitis Vaccine Project: Expected public health outcomes

- Over 10 years this effort will prevent
 - 1.3 million cases
 - 130,000 deaths
 - 250,000 cases of disability
- Free up public health resources currently used annually to combat meningitis epidemics
- Remove financial drain on families and communities from epidemics



PATH/Monique Berlier

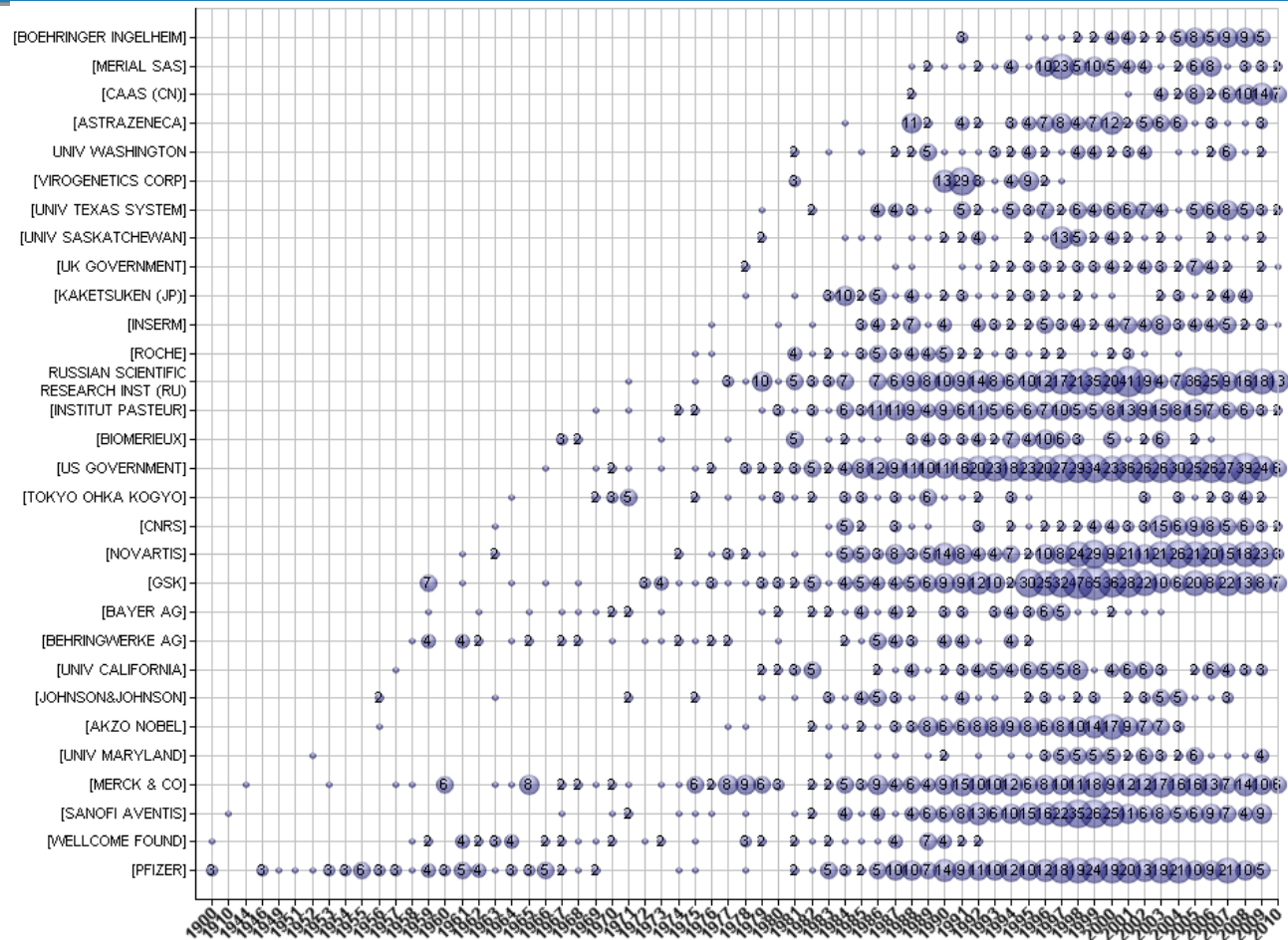
Vaccine patenting activity



● http://www.wipo.int/patentscope/en/programs/patent_landscapes/reports/vaccines.html



Who is doing the patenting



Patent ownership

- An exponential rise in the number of patents on vaccines.
- Big industry patenting fairly constant – therefore rise in ratio of non-industry: industry patent ownership
- Very significant for vaccines against TB, HIV, malaria etc.



Vaccine Development Models

- Past vaccines:
 - Few patents, majority within industry.
 - Minimal technical uncertainty
 - Normally 5-10 licenses taken.
 - Moderate transactional costs.
- For future vaccines:
 - Many patents, few within industry
 - High technical uncertainty
 - Large number of licenses needed to ensure FTO
 - High transactional cost.

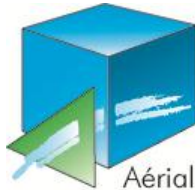
For new vaccines to be developed, manufactured, and made accessible where they are most needed, alternative business models are required.



BILL & MELINDA GATES foundation



Meningitis Vaccine Project



Recherche en Santé Humaine



ROBERT KOCH INSTITUT



DiagnoSearch



In collaboration with health authorities of 26 countries in sub-Saharan Africa and of India