



HOOKVAC
THE HUMAN HOOKWORM VACCINE



GLOBAL HEALTH POLICY FORUM
12 JUNE 2014, 13:00-16:00
Remko van Leeuwen



The Vaccine Translational Research Gap





HOOKVAC
THE HUMAN HOOKWORM VACCINE

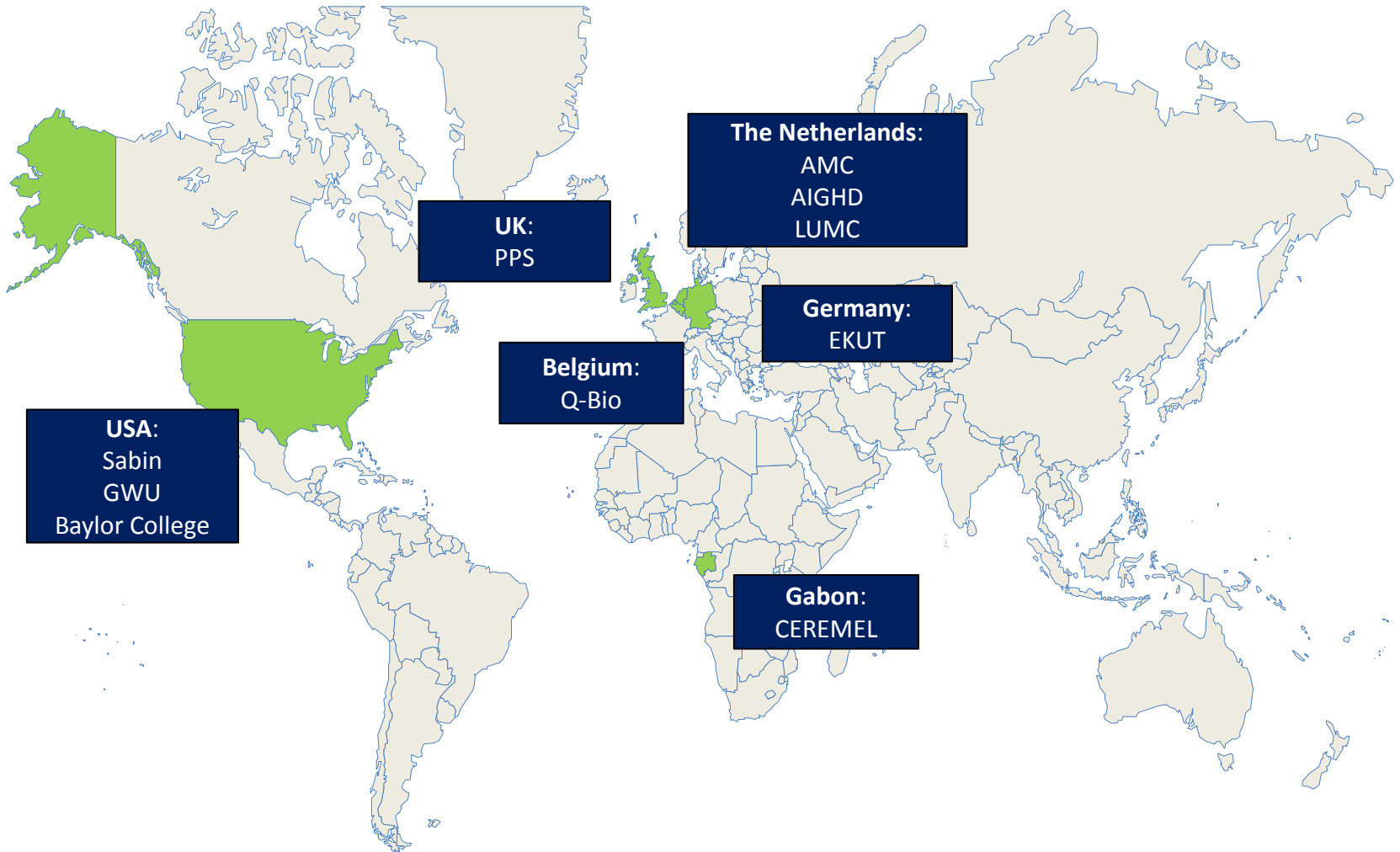


6 MILLION EU GRANT / 4 year

- Vaccine development & manufacturing
 - Vaccine clinical testing
 - Advocacy



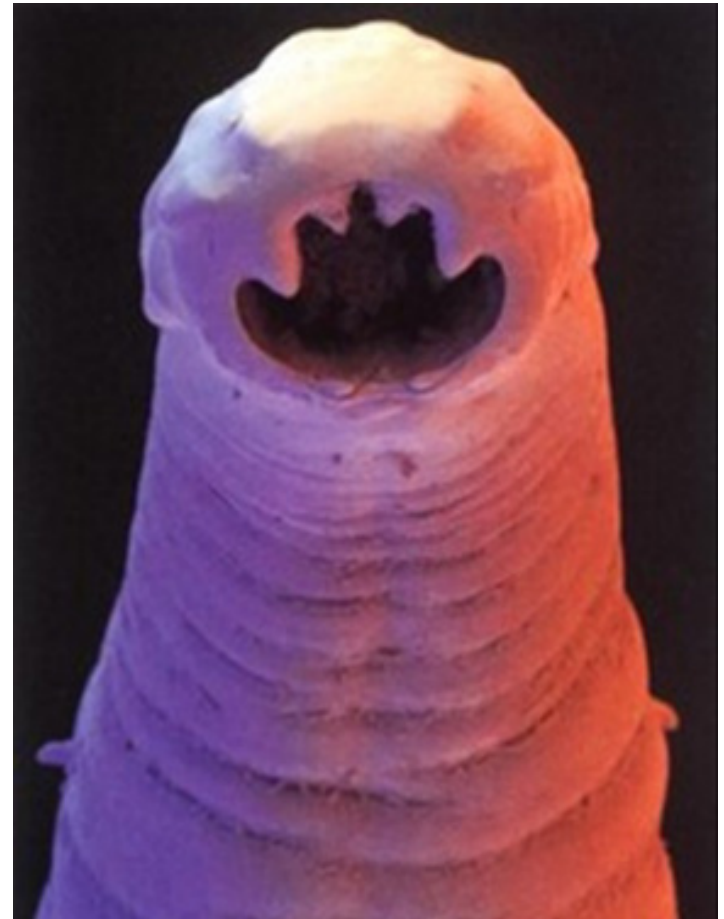
HOOKVAC consortium





Human Hookworm Infection

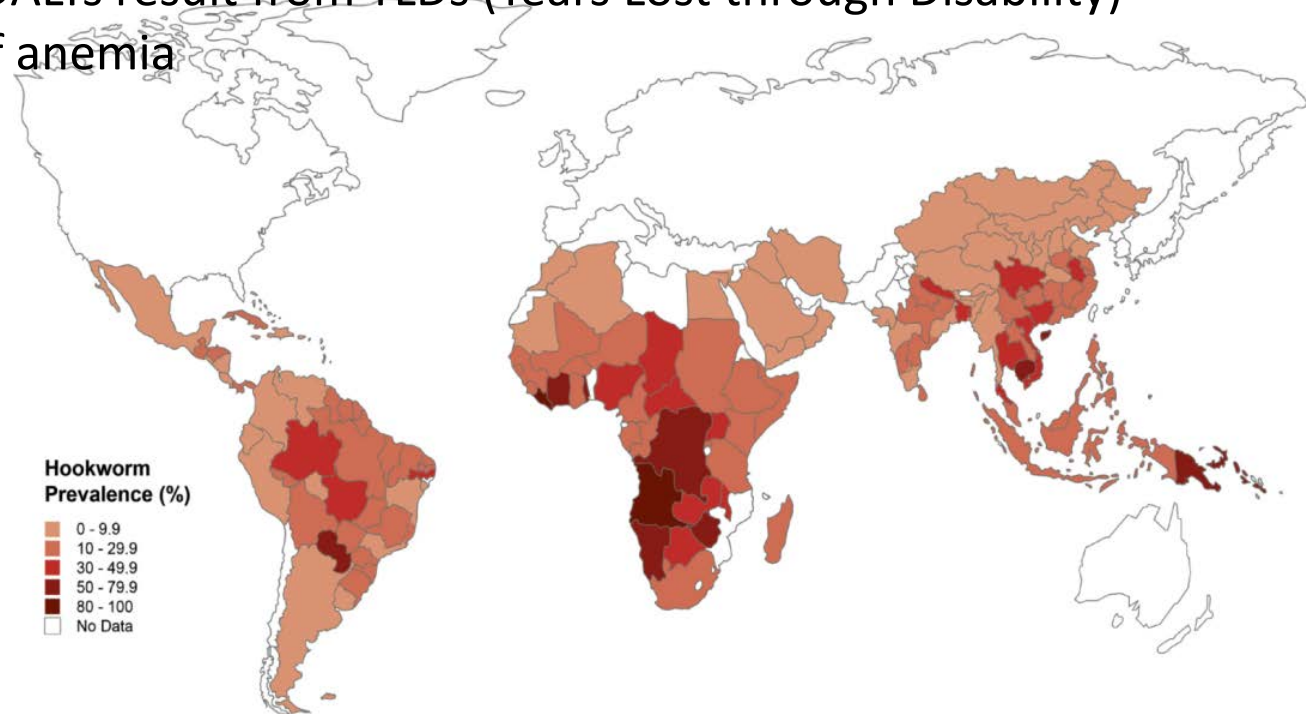
- Highly prevalent neglected tropical disease
- A leading cause of maternal and childhood anemia in low- and middle-income countries





Wherever Rural Poverty and Tropical Climates Overlap

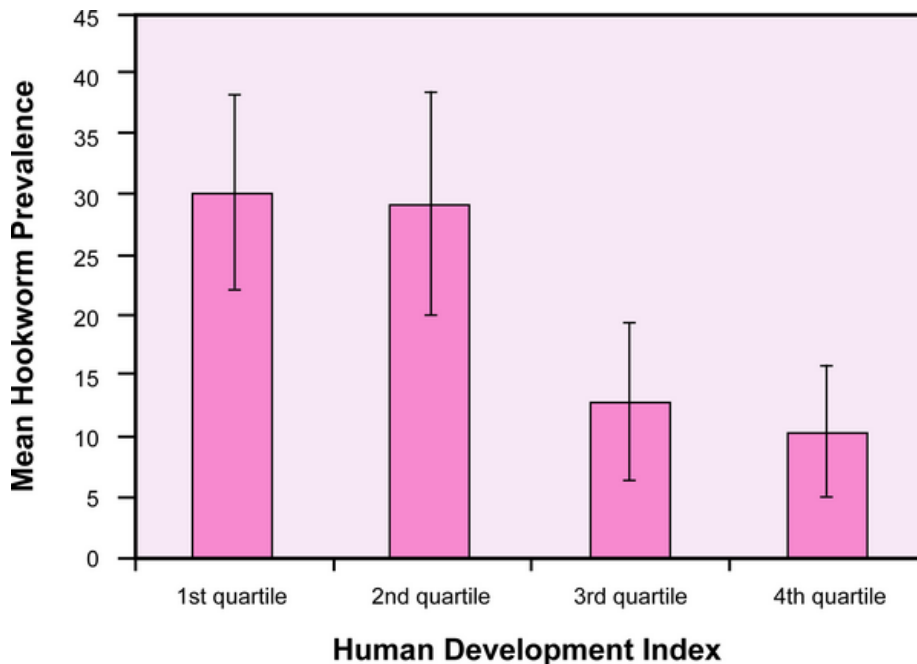
- 444 million cases
- 3.2 million DALYs
- The leading NTD along with schistosomiasis and leishmaniasis
- All of the DALYs result from YLDs (Years Lost through Disability) because of anemia





Hookworm and Poverty

- Links with poverty
 - Hookworm occurs in the setting of rural poverty
 - Hookworm causes poverty
 - 40% reduction in future wage earning (Bleakley et al)
 - 20% increase in labor supply (Baird et al)





Steps in Vaccine Development₂



- Identification of target antigens
- Understanding of pathologies
- Natural history of disease
- Done mostly outside of the "Big Pharma"

- Antigen production
- Assay development
- Animal model dev.
- Preclinical tox

- Phase I**
- Safety
 - Initial immunogenicity

- Phase II a**
- Dose finding
 - Dose/schedule finding
 - Immunogenicity

- Phase II b**
- Early POC

- Phase III**
- Large scale safety
 - + Lot to lot consistency
 - + Non inferiority (combos) or
 - Efficacy





Steps in Vaccine Development³

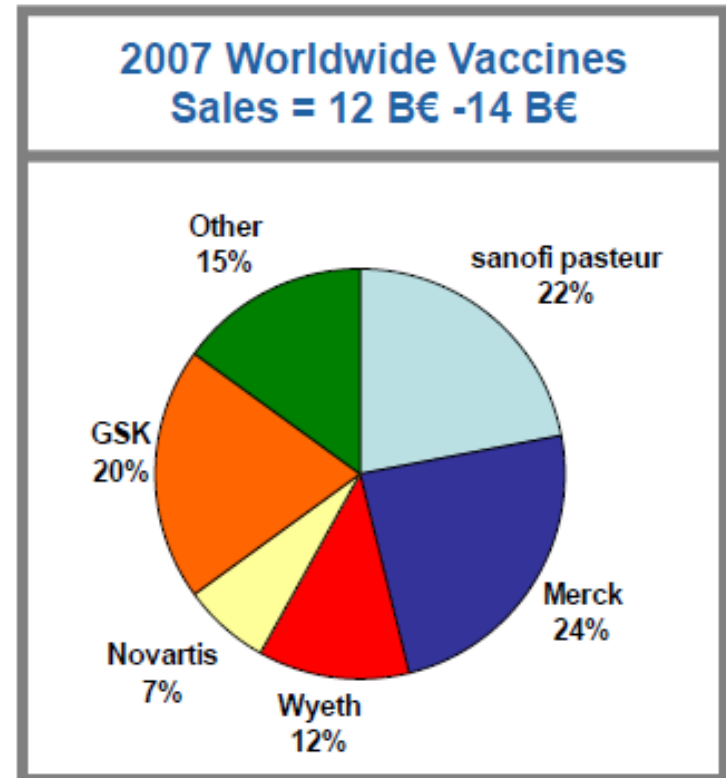
- Long and **Complicated** process
 - Usually takes **10-15** years
 - **Many** vaccine candidates fail for every success
 - Costs: **\$ 100- \$ 700** million per successful vaccine





*So who is willing to take that
financial risk..?*

Vaccines: Only a Small Portion of Pharmaceutical Market, But Increasingly Important



Source: IMS Health Market Prognosis (includes IMS Audited and Unaudited markets). All information current as of March 28, 2008.



Vaccine market

- For NTDs, not-for-profit PDPs have been playing a key role in funding vaccine research and development.



Public funding of vaccine industry R&D is growing outside Europe - EVM

European public funding* has declined in recent years

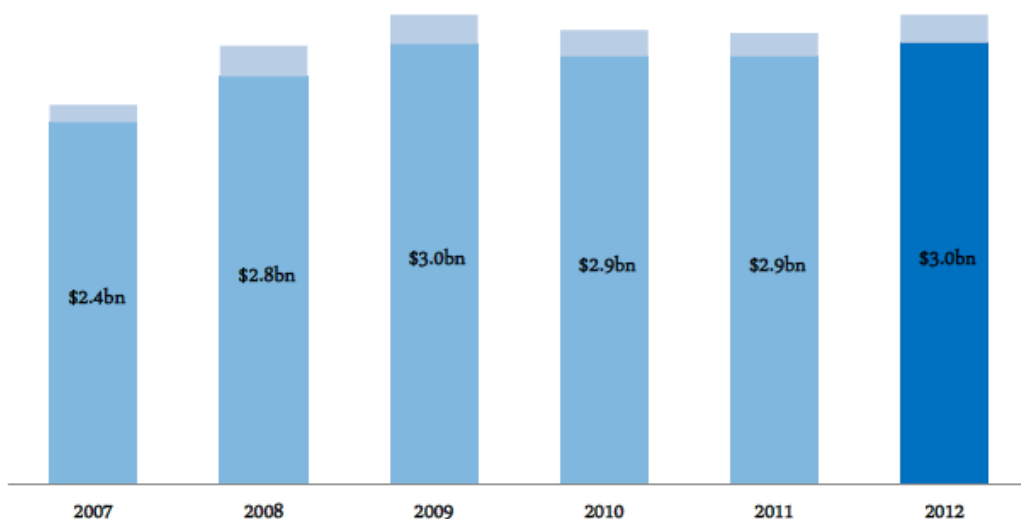


*Funding of survey participants' R&D projects
Source: EVM survey 2008



Overall spending on product development in Global Health

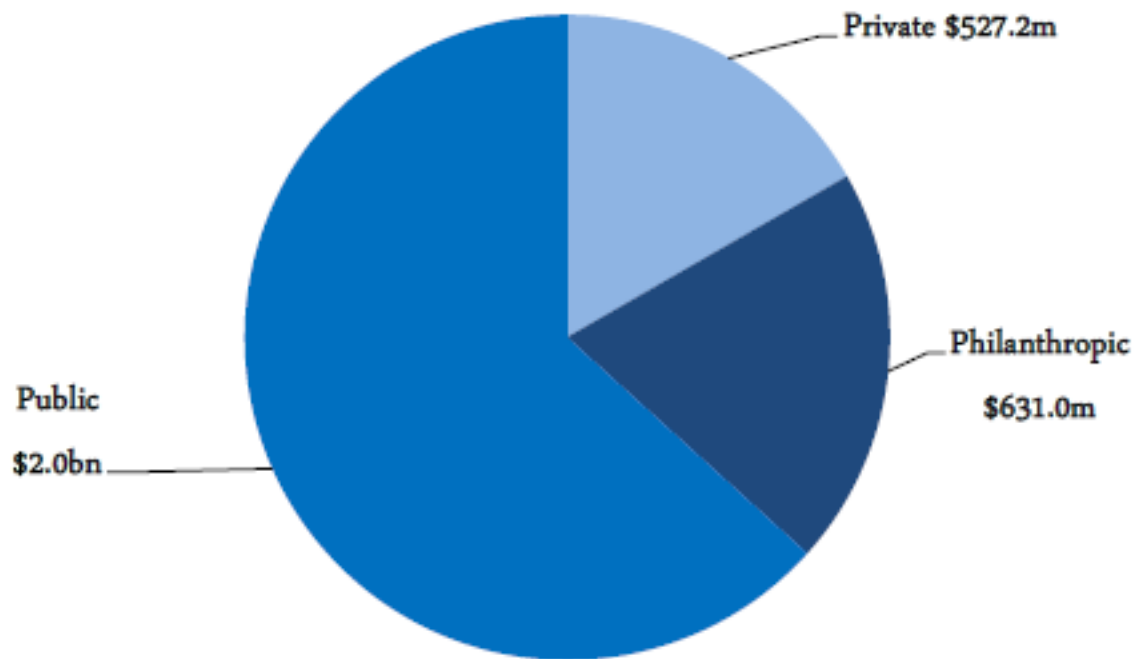
Findings
OVERALL



\$92.1m higher in 2012 than
in 2011



Overall spending on product development in Global Health

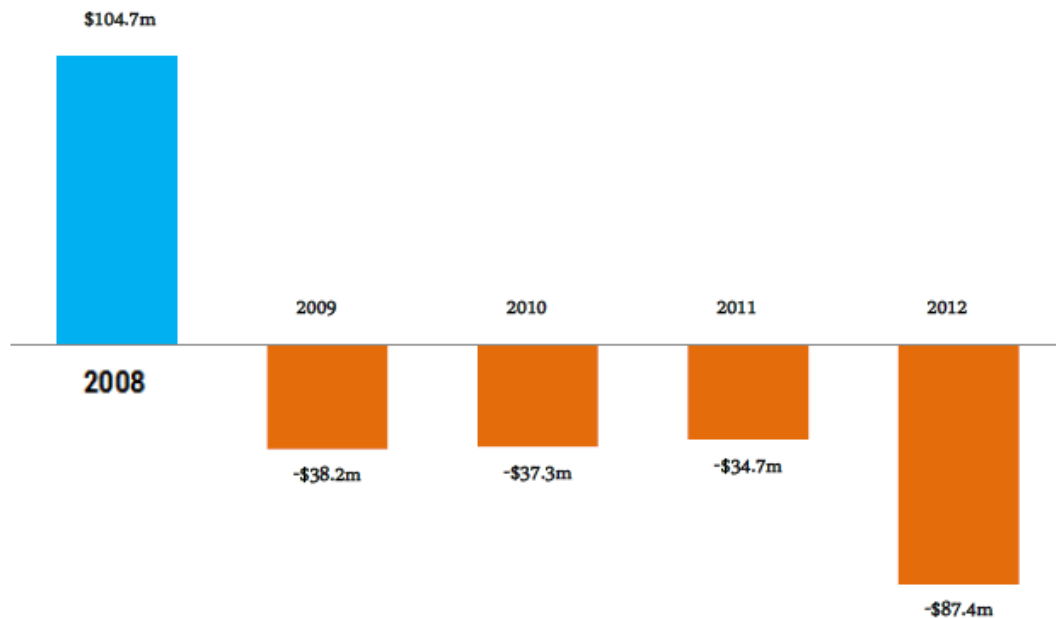


All sectors increased funding in 2012



Overall spending on product development in Global Health

Findings
PDP FUNDING



The biggest decrease yet in PDP funding

– down \$87.4m (-20%)

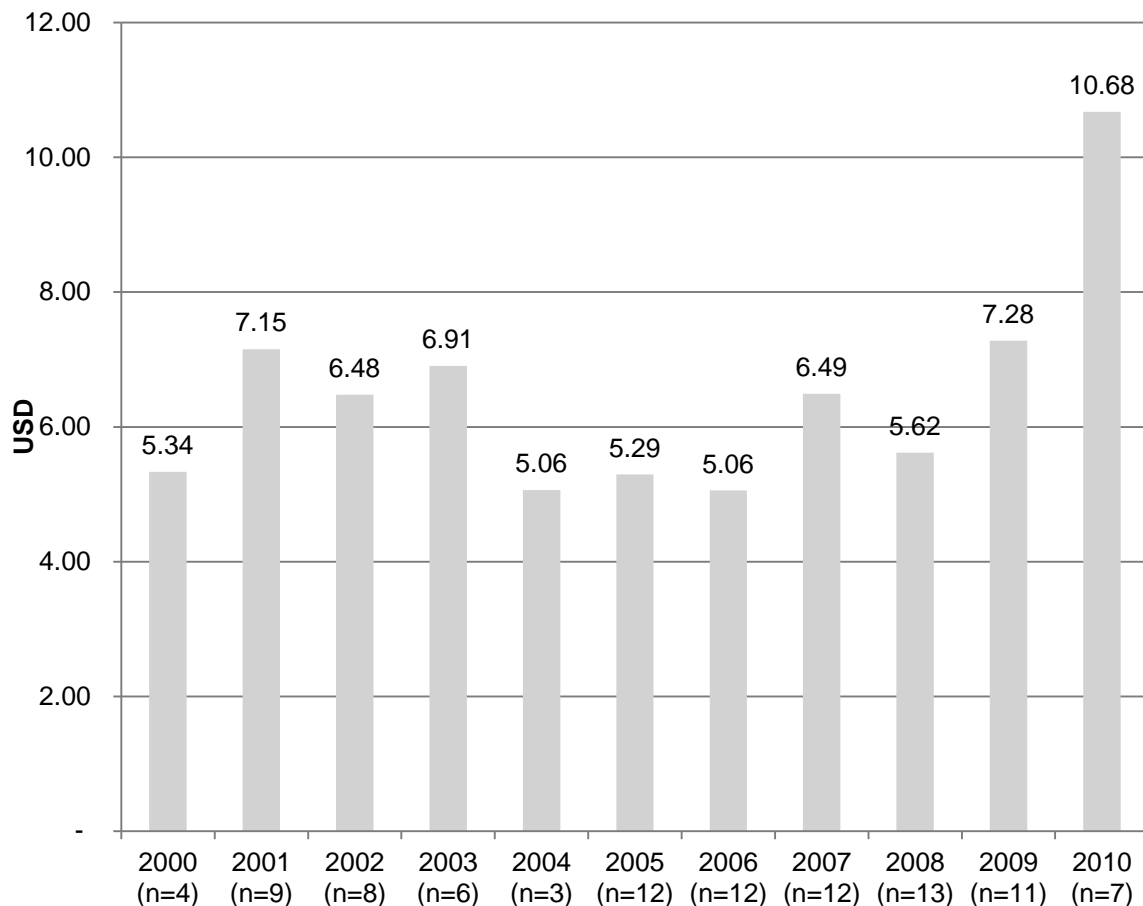


...and delivery funding issues...

- Cost per child fully immunized- US\$30- exceeds most governments' total per capita public health expenditure
- Fiscal gaps in immunization budgets are growing rapidly
 - Countries are underinvesting
 - Chronic external donor dependency
 - Newer vaccines are driving up costs



Average spending on routine immunization per child in 15 SIF* countries (2000-2010)



Sources:

WHO/UNICEF JRF, cMYPs, FSPs,
country EPI manager reports.
http://www.who.int/immunization_financing/data/en/

Sabin Sustainable Immunization Financing
(SIF) Program





So what needs to change..?



What is needed in Europe?

- To foster European Efforts for a global impact
- To maintain and strengthen European Infrastructure : European leadership in vaccine R&D as driver force



What is needed for HOOKVAC..?

- Partner early to allow affordable production processes transferable to manufacturers in endemic regions.
- Modify the rules for pre-qualification (from mortality prevention to disease prevention)
- Fundraising for further development (100M+)



Local Partnering..!

ROTAVAC

- The vaccine may be available for a price as low as 54 rupees per dose (0,61 EUR), whereas originator Rota vaccines costs around 1,000 rupees (12 EUR), and much higher prices in developed countries (90-100 EUR).



From HOOKVAC to EUROPAID

- Scale up and optimize production of both antigens to allow affordable production processes transferable to manufacturers in endemic regions.



HOOKVAC consortium



Kick-off meeting in Amsterdam



That's all Folks!