



**IFV** INSTITUTO  
FINLAY DE  
VACUNAS

# Finlay Vaccine Institute and the Cuban EPI



# Finlay Vaccine Institute

A scientific organization honoring Dr Carlos Juan Finlay



A renowned Cuban  
epidemiologist

**Yellow fever is  
transmitted from infected  
to healthy humans by a  
mosquito**

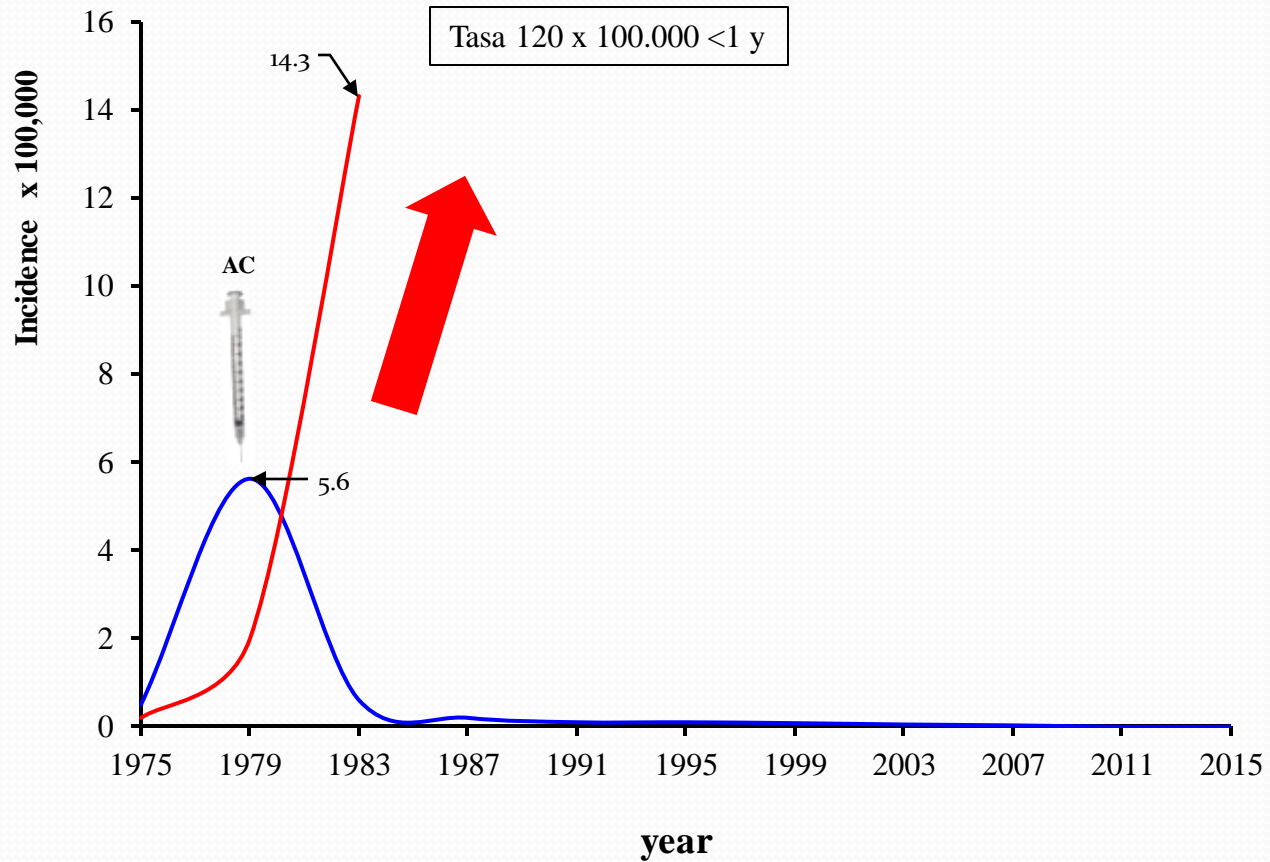


**the base to nowadays knowledge  
of “vector-borne disease.”**

## **A results of the history of vaccine development in Cuba during the last 30 years**

- Development of anti-meningococcal vaccine Vamengoc BC as a response to outbreaks of B meningitis in Cuba in the 80ties.
- Development of a conjugate vaccine against Haemophilus influenzae type b using a fully synthetic antigen.
- Response to emergency WHO call for African epidemics of meningitis and a shortage of vaccines in 2006 with AC and ACW polysaccharide vaccine.
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SOBERANA02 and mass pediatric vaccination.  
SOBERANA 01 and Plus as universal booster dose

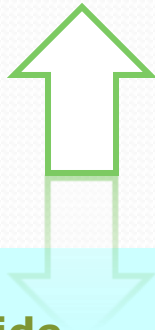
# Meningococcal meningitis in Cuba 1975-2015



**Outbreak of meningococcal group B meningitis in Cuba 1975-1983**

**OMV from meningococcal strain B:4:P1.19,15**

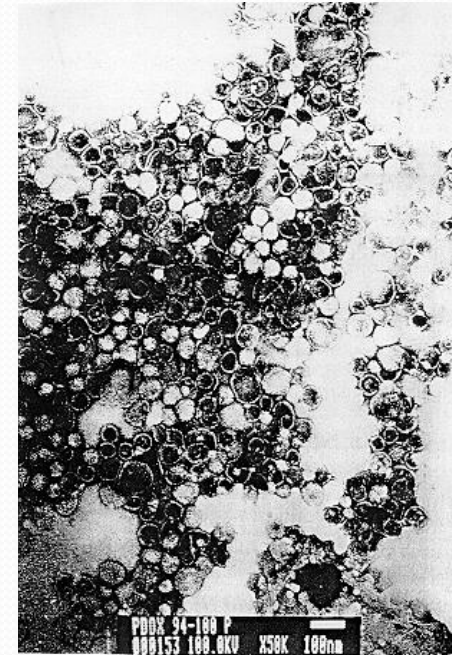
particle  
stabilization



**C Capsular polysaccharide**



***Va-Mengoc-BC  
Finlay Vaccine  
Institute***

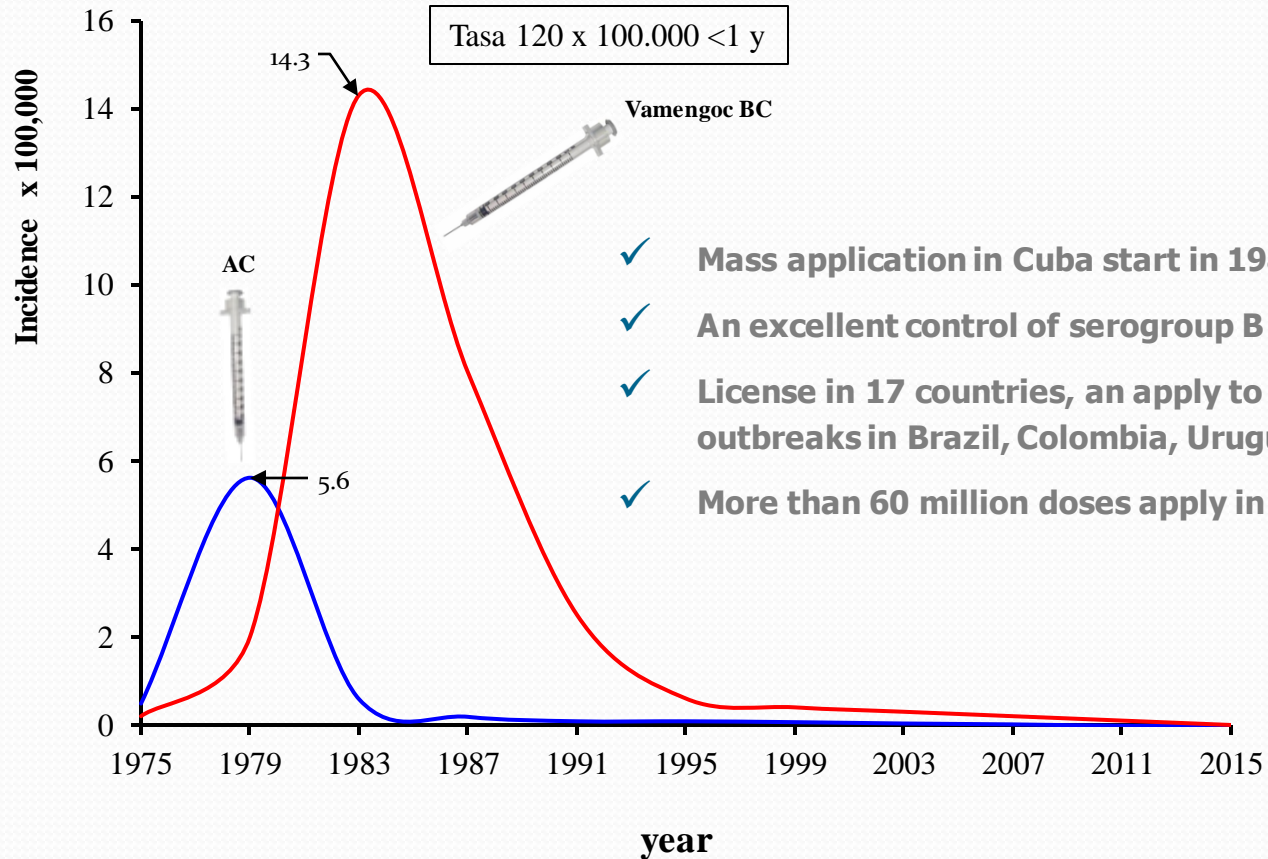


**VA-MENGOC-BC® is a bivalent vaccine**

**OMV of serogroup B meningococcus that includes PorA, Por B, minor OMPs and LOS**

**Capsular polysaccharide of *Neisseria meningitidis* serogroup C.**

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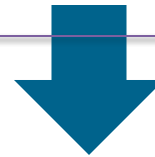
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CENTRO DE QUÍMICA  
BIOMOLECULAR

- Synthetic chemistry to obtain Hib oligosaccharides could become a competitive technology for conjugate vaccine production

The first vaccine with a synthetic antigen produced and commercialized since 2004



- An important scientific and technological advance in the field

- **Science 2004, 521-524**

- WIPO Gold medal Patent 2005 WP 01/16146 USA, EPO, Australia, China,

- 2005 Award Technology benefiting humanity from the Tech museum for innovation, San Jose, California





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# Quimi-Vio

1 PS Conjugate to TT	2 µg	<b>Total TT 24 µg</b>
5 PS Conjugate to TT	2 µg	
6B PS Conjugate to TT	4 µg	
14 PS Conjugate to TT	2 µg	
18C PS Conjugate to TT	2 µg	
19F PS Conjugate to TT	2 µg	
23F PS Conjugate to TT	2 µg	

Aluminum phosphate 125 µg

one dose 0,5 mL

0,5 mL

**Quimi-Vio<sup>®</sup>** 

VACUNA CONJUGADA HEPTAVALENTE CONTRA NEUMOCOCOS

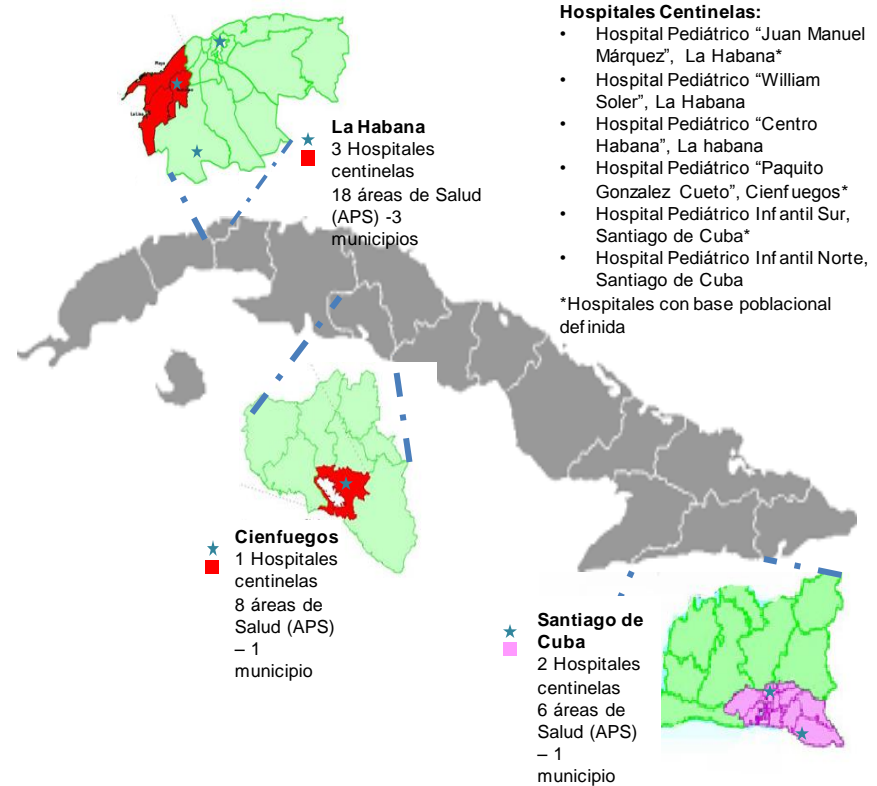
Suspensión para inyección - Inyección intramuscular

Cada dosis (0,5 mL) contiene: Polisacárido de los serotipos Sp 1\*, Sp 5\*, Sp 14\*, Sp 18C\*, Sp 19F\*, Sp 23F\*...2,2 . Polisacárido del serotipo Sp 6B\*...4,4 . Tiomersal... 0,025 mg. \*Conjugados a la proteína portadora TT y adsorbidos a Fosfato de Aluminio. Almacénese de 2 a 8 °C. NO CONGELAR. Protégase de la luz. AGÍTESE ANTES DE USAR.

# Centinel network

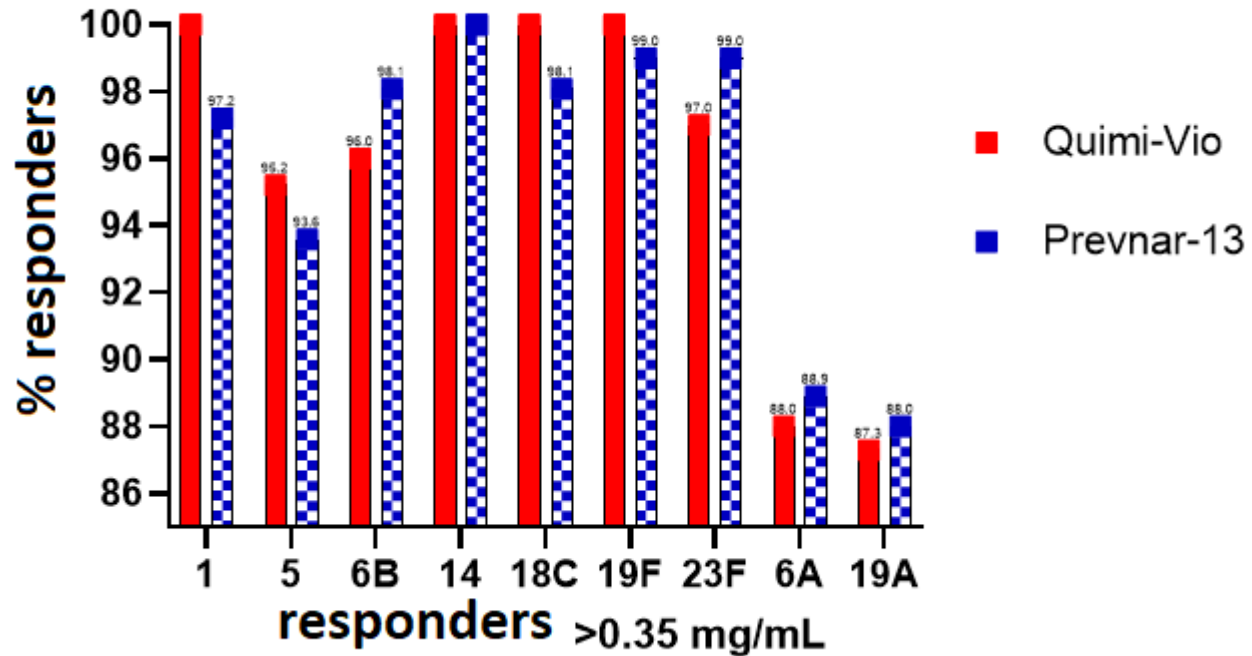
- The network is associate with PCV development
- Is a partnership between FVI and National sanitary system.
- Is a plataform for research, clinical and epidemiological research, impact evaluation ofproducts and technologies introduction .
- Is a centinel system for surveillence of pathogen and disease.

## Working Plataform



# Infant trial

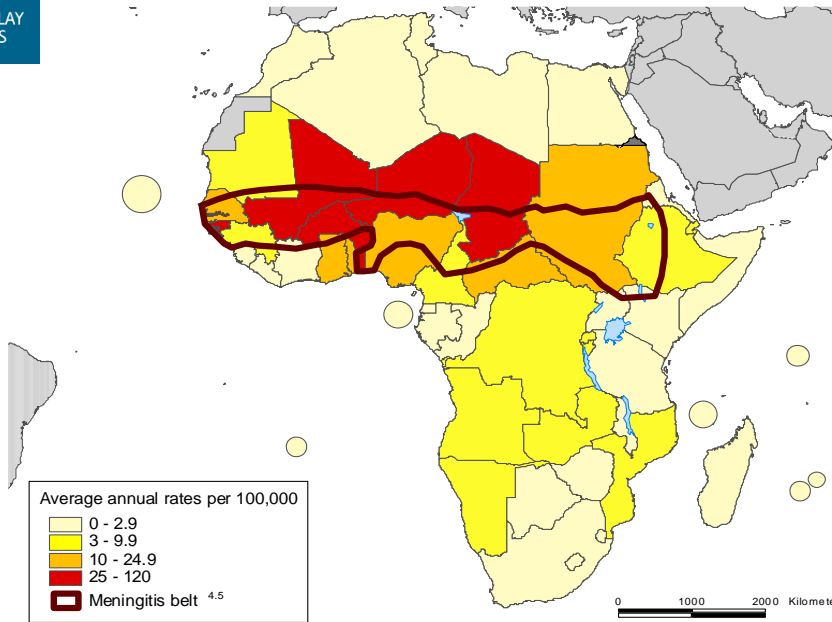
## Quimi-Vio vs Pevnar-13



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# MENINGOCOCCAL MENINGITIS



Meningitis belt: 21 countries  
400 millions persons at risk

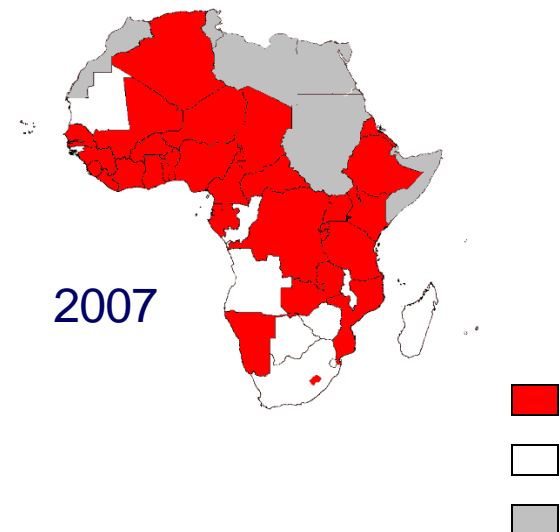
## High incidence

África: 250-1000/100,000

10-20 fatality

20-30 % sequelae

A devastating epidemic of 1996–1997 (with more than **250,000 cases** of disease and over **25,000 deaths**),





World Health  
Organization

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 In reply please refer to: C11-370-3  
 Your reference: Dr Concepción Campa-Huergo  
 Presidenta - Directora General  
 Instituto Finlay  
 Ave. 27 Nº 19005  
 La Colónela, La Lisa  
 Ciudad de la Habana  
 A.P. 16017, C.P. 11600  
 Cuba

# Big Pharma stop the production of anti-meningococcal polysaccharide vaccines

July 17 2006

## WHO call for help

Vaccine companies from emerging countries

### Antimeningococcal AC Polysaccharide vaccine

For African countries.

17 July 2006

Dear Dr Campa-Huergo,

**Meningococcal AC Polysaccharide Vaccine — Supply 2007–2008**

The availability of meningococcal AC vaccine for the next two epidemic seasons (2007 and 2008) will be limited to approximately 30 million doses. The World Health Organization (WHO) and the International Coordinating Group (ICG) are very concerned about the public health consequences of this reduced production and are currently evaluating alternatives on the short, medium and long term to ensure the adequate supply of this vaccine for the coming years. WHO estimates that at least 15–20 million additional doses of Meningococcal AC PS will be needed for 2007 and 30–50 million doses for 2008.

If no solution is found to bridge the gap, countries with under immunized population may face major public health crisis when affected by severe outbreaks. Therefore, we would like to visit the Finlay Institute in order to discuss potential vaccine supply from your company to increase the accessibility to meningococcal vaccines for outbreak response.

The three main objectives of this visit are:

1. To collect information on the availability, production capacity, composition, formulation, presentation and expected prices for the supply of this vaccine. What would be the timeframe, constraints and needs? How could WHO contribute to accelerate and overcome these issues?
2. To evaluate the production process, production yields (fermentation and purification), quality assurance and quality control procedures for Men AC.
3. To discuss future plans for Meningococcal vaccines, conjugate, combinations, etc.

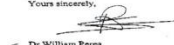
Re: Mission permanente de la République de Cuba auprès de l'Office de Nations Unies à Genève et des autres organisations internationales en Suisse  
 PAIXO attention: Ms Maria de Los Angeles Corda, Regional Adviser for vaccines  
 Country Office, Cuba, attention: Ms Susana Madrigal

We would like to suggest a 2-3 day visit during the week of 4-8 September 2006. We kindly ask you to let us know the dates that are agreeable to you. The WHO visiting team will be composed of two WHO Headquarters staff members.

We highly appreciate your willingness to collaborate with WHO and your contribution to the very important issue of Meningococcal vaccine supply for the African Meningitis Belt countries.

We are at your disposal for any additional information you may require.

Yours sincerely,

  
 Dr. William Pera  
 Coordinator  
 Epidemics Readiness and Intervention (ERI)  
 Department of Epidemics and Pandemic Alert and Response (EPAR)



# A South-South solution

- ✓ Agreement between Finlay Institute and Bio-Manguinhos to produce the vaccine.
- ✓ Technical committee between regulatory agencies (ANVISA – CECMED)
- ✓ Supply a vaccine to WHO for African countries .



Cuba

Production of API, expertise.



Brasil

Shortest way to registration,  
Final filling

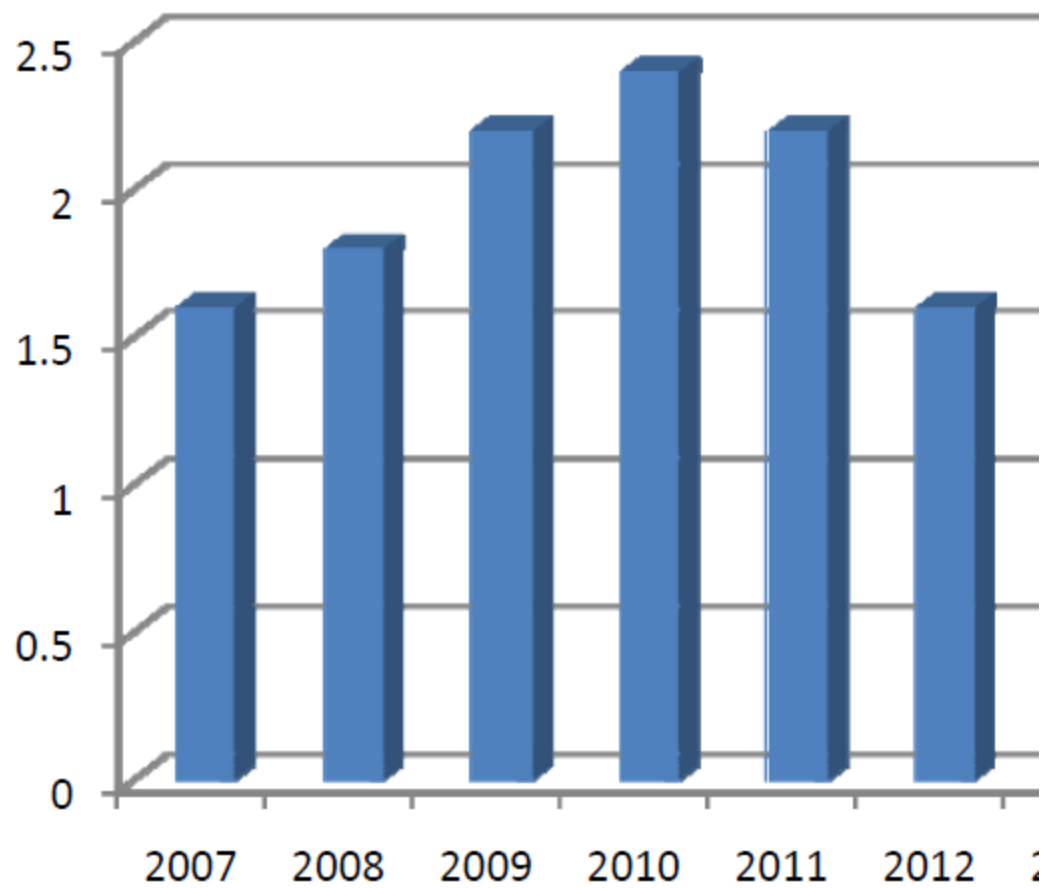


# New facility for the production of A and C active Polysaccharide (cuban investment)

2006-2012



Number of doses: 12 MM

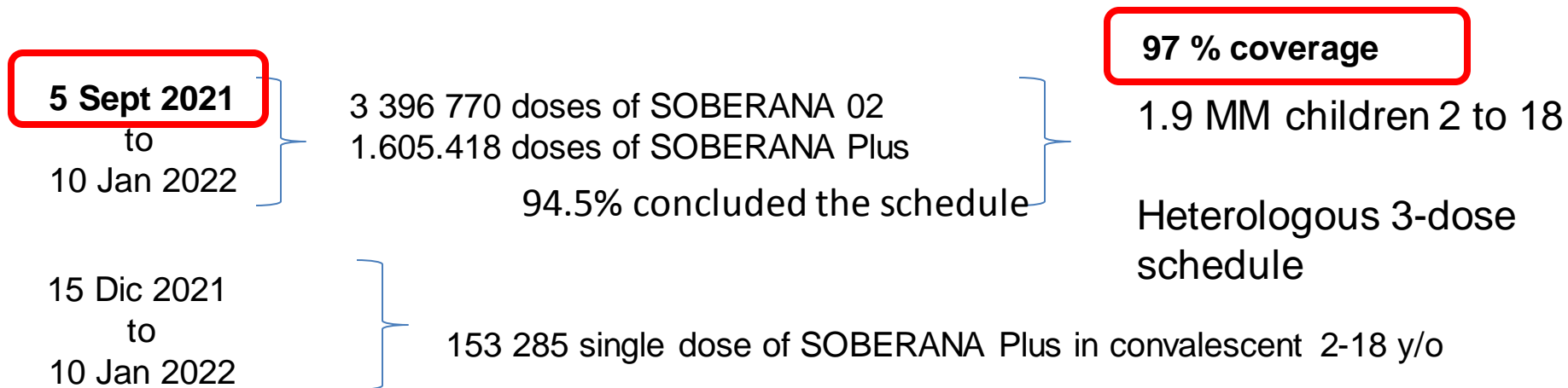


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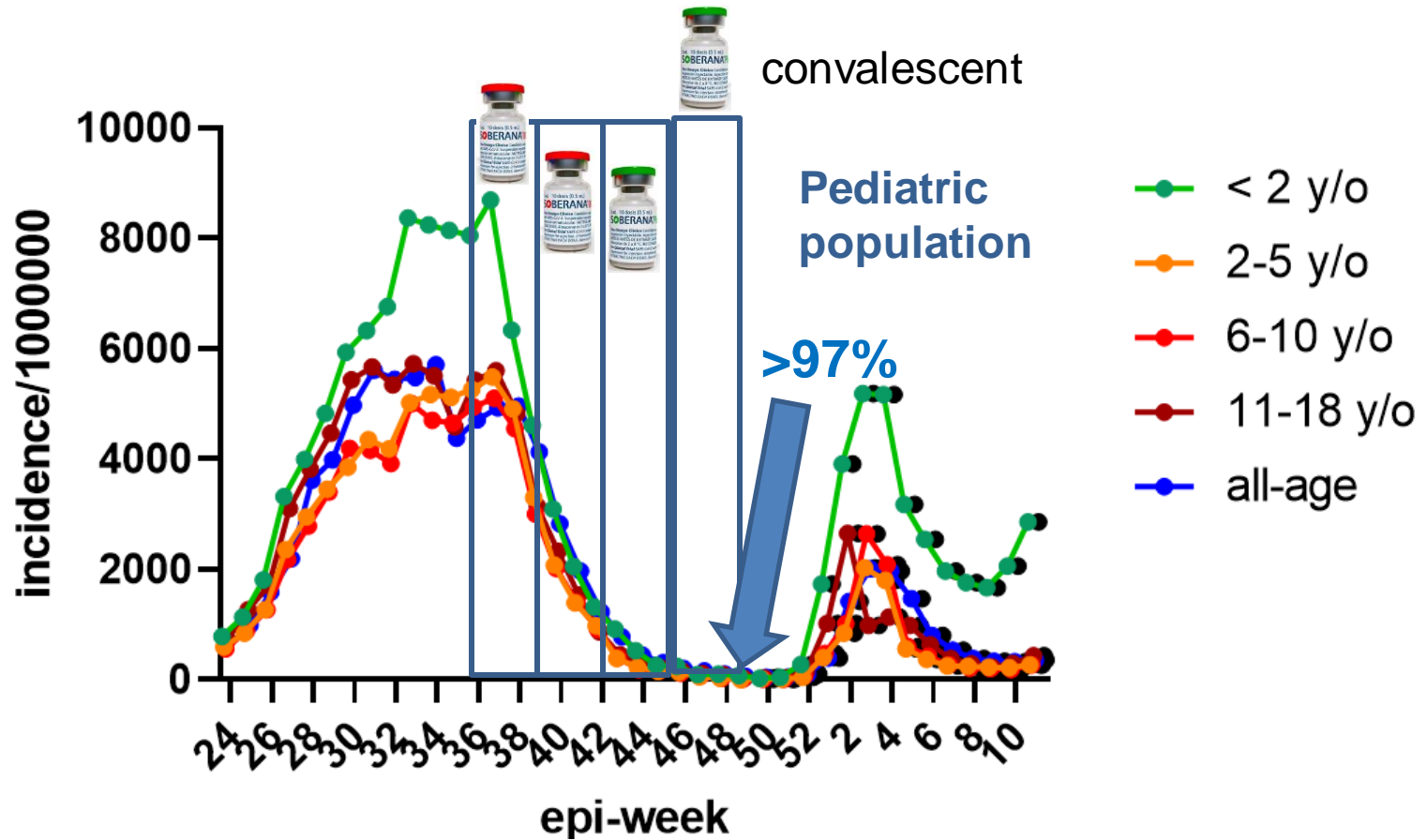
# Pediatric National Mass vaccination campaign with **SOBERANA**

Performed at 19,313 vaccination sites all across the country

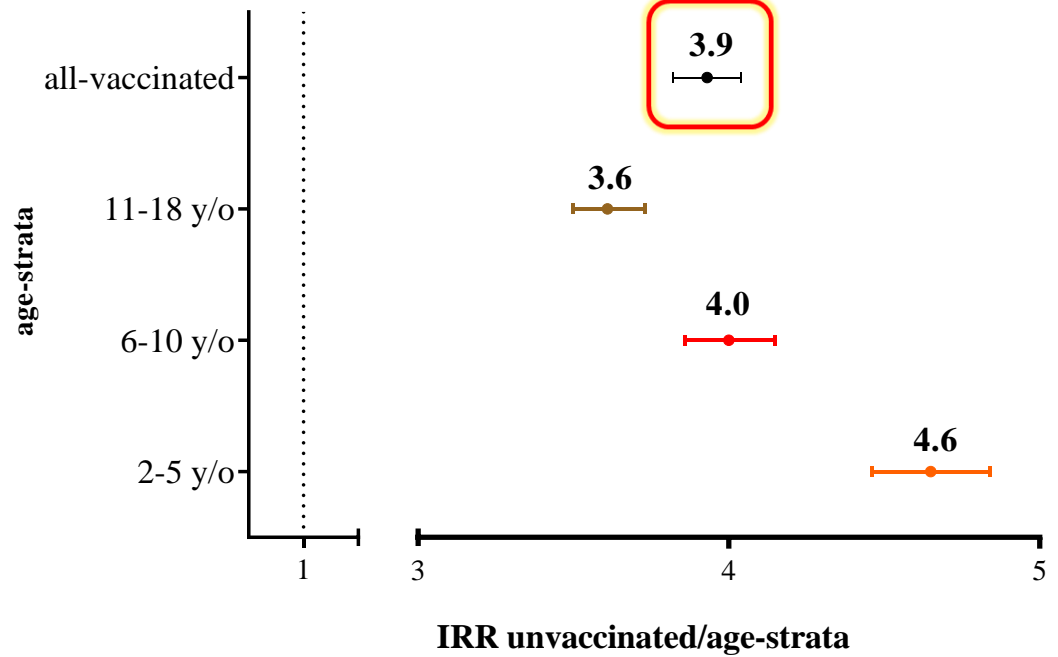
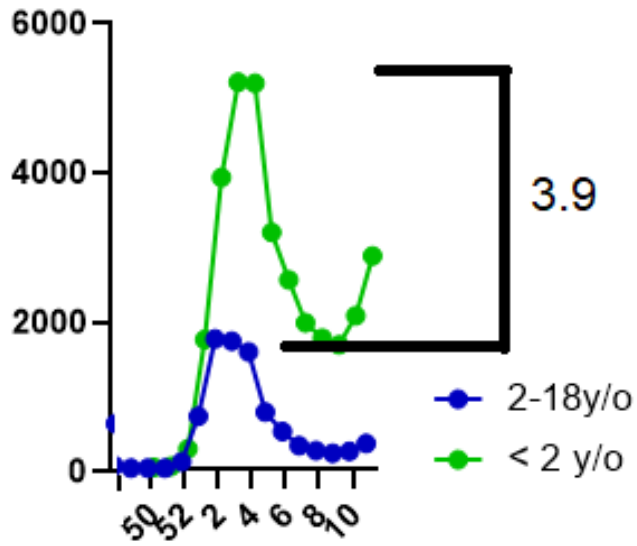


**>6 Mill doses of SOBERANAs vaccine in pediatric population 2-18 y/o.**

**Vaccination in Nicaragua: 1 Mill children 2-10 y/o (3 Mill doses)**



# Pediatric population 2=18 y/o vs <2 y/o



Development of a polysaccharide pneumococcal vaccine for elderly.  
Use of innate immunity stimulation with N.m. OMV.