

# NIAID – Cuba collaborations for dengue vaccine development

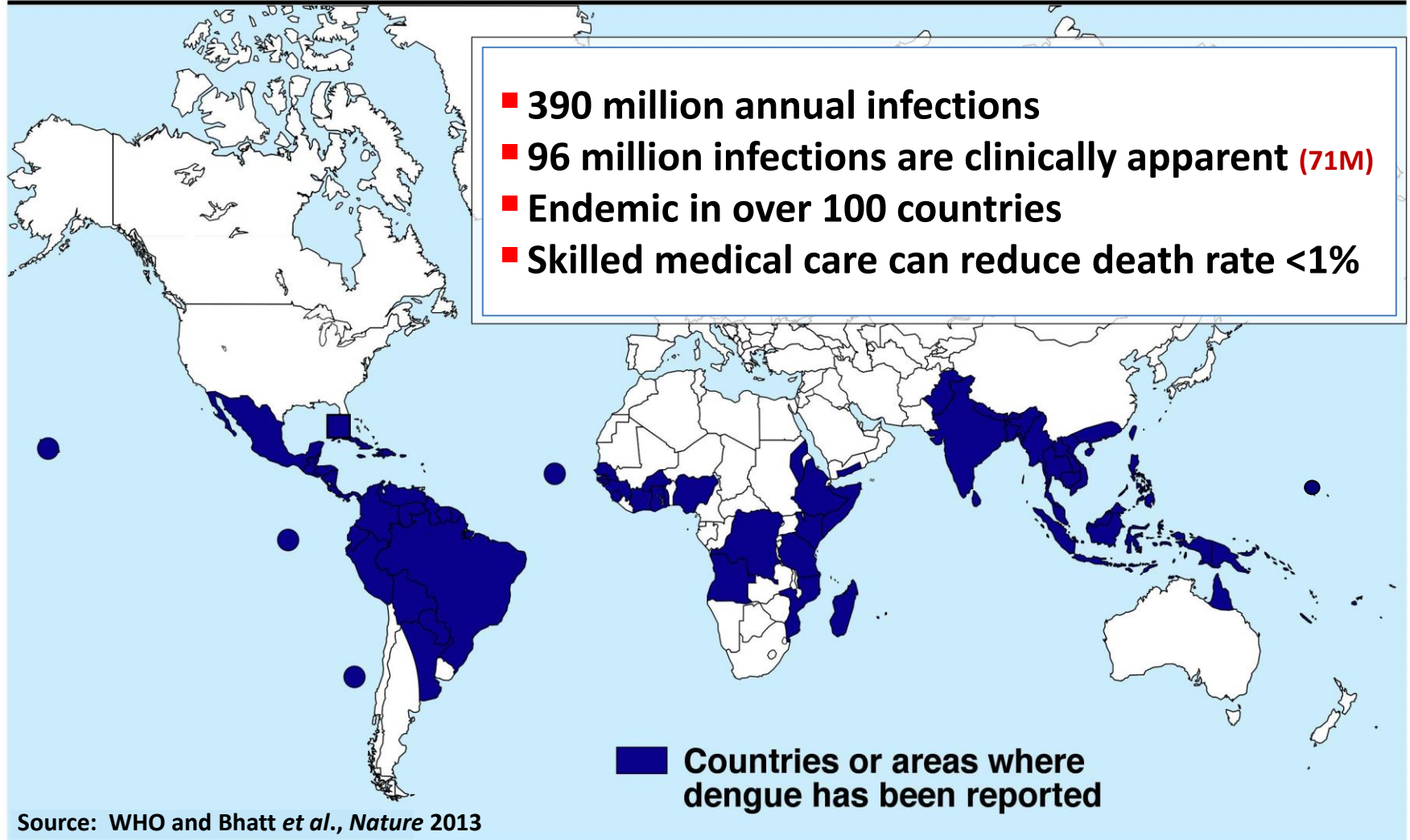
Stephen Whitehead

21 March 2023

Laboratory of Viral Diseases

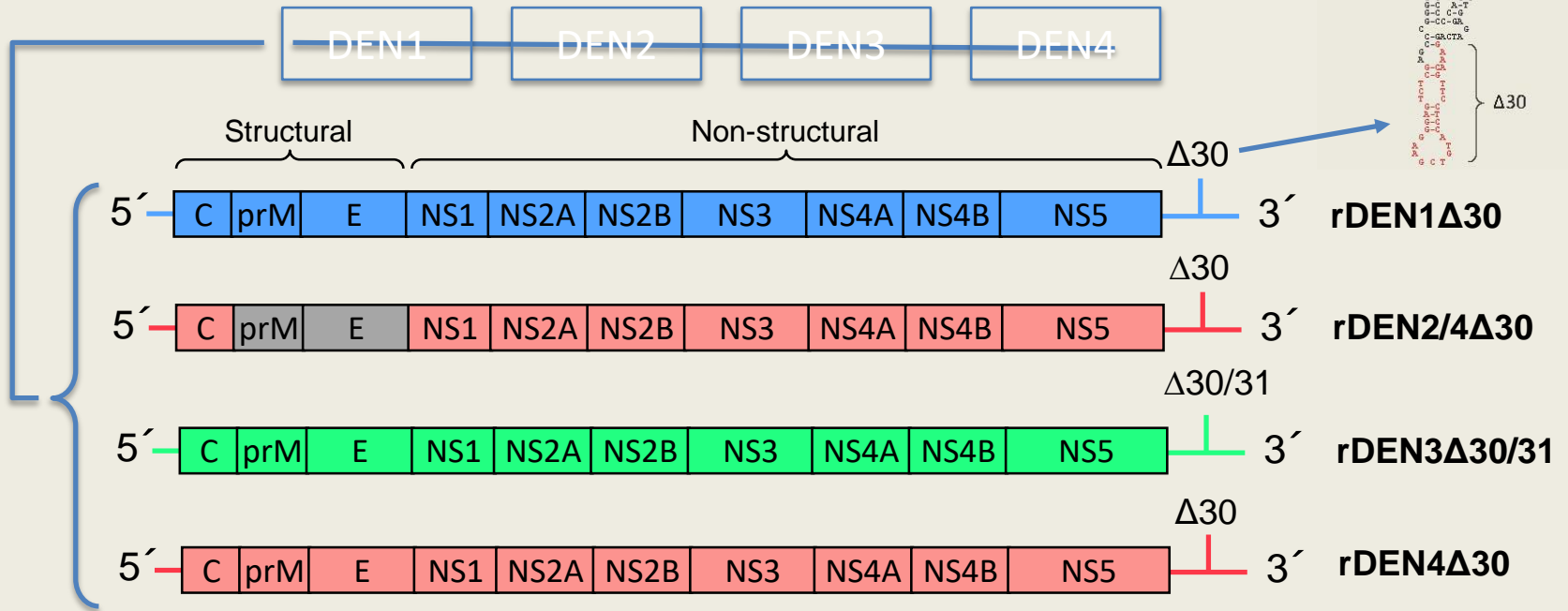
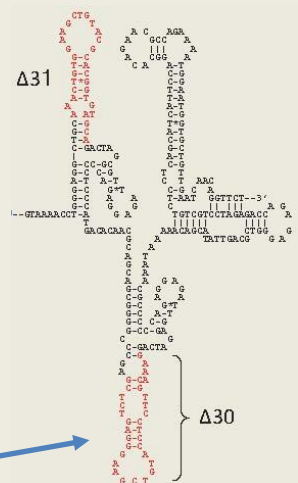


# Dengue: 2.5 Billion People at Risk



Dengue is both an established disease and an emerging/re-emerging disease

# The NIAID live tetravalent DENV vaccine:



<b>NIAID sponsored trials:</b>	DENV monovalent	21
	DENV tetravalent	21
	<b>Total to date</b>	<b>42</b>

# What have we demonstrated?

- Single dose vaccine
- Uniformly infectious and immunogenic in DENV-naïve subjects
- Immunogenic “catch-up” for missing serotypes in sero(+) subjects
- Safe and immunogenic in older adults (50 – 70 years old)
- Safe and immunogenic in infants and children (1 – 18 years old)
- Elicits a strong cross-reactive CD8+ T-cell
- Solid protection against DENV challenge – DENV-2 and DENV-3
- Protection as early as 30 days post vaccination

# Phase III TV-003 Efficacy trial

## Sponsor: Butantan Institute, Brazil

**First inoculations: Feb 22, 2016**

Brazil – 16 sites throughout country

16,235 subjects:

- Adults (18-59 years) N= 6072
- Adolescents (7-17 years) N= 5147
- Children (2-6 years) N= 5016

5 year follow-up

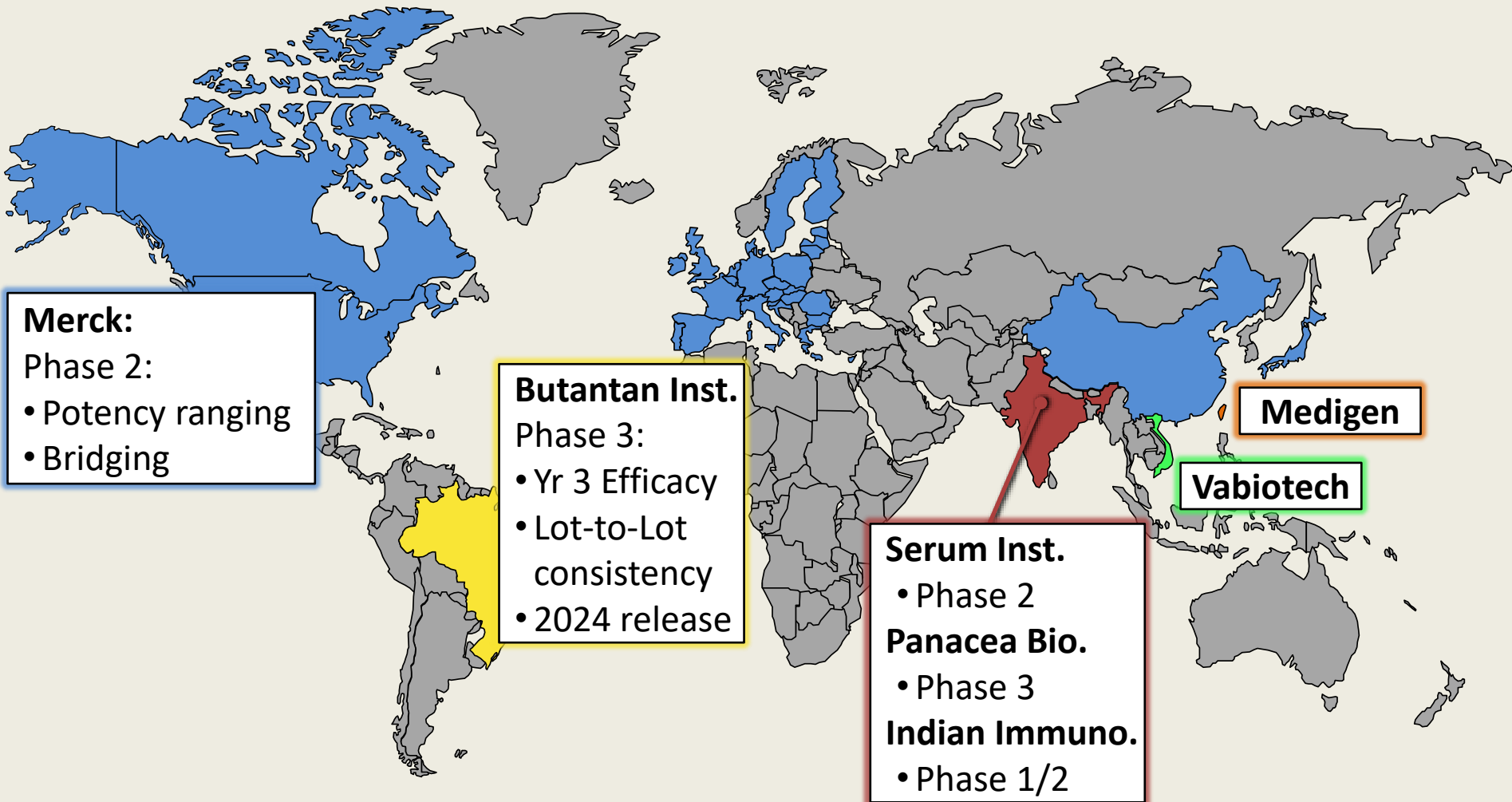
**Enrollment completed: July 4, 2019**  
**No adverse safety signals: 2 – 5+ yrs.**

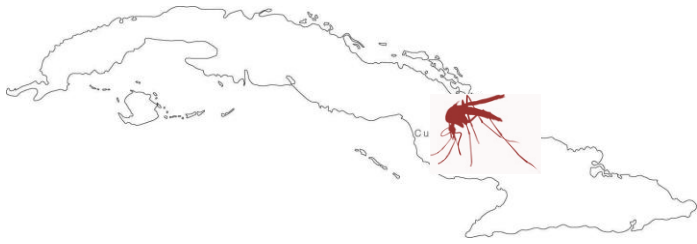
<b>2 year follow up</b>	<b>Efficacy according to DENV serostatus at time of vaccination</b>		
	<b>Overall</b>	<b>Sero ( + )</b>	<b>Sero-naive</b>
<b>Any serotype*</b>	<b>80%</b>	<b>89%</b>	<b>74%</b>
<b>DENV-1</b>	<b>90%</b>	<b>97%</b>	<b>86%</b>
<b>DENV-2</b>	<b>70%</b>	<b>84%</b>	<b>58%</b>

\* No cases of DENV-3 or DENV-4 during 2-year observation

# Dengue technology licensing partners

## Current status





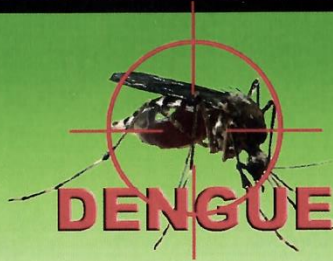
# What about Cuba?

Dengue remains a health concern in Cuba – 2022

## How will we make vaccine or vaccine technology available to Cuba?

- 2015** 14<sup>th</sup> *International Dengue Course*, IPK  
Dr. Maria G. Guzman – First for US participants
- 2016** NIAID / IPK conference  
*Exploring Opportunities for Arbovirus Research Collaboration*
- 2017** 15<sup>th</sup> *International Dengue Course*, IPK  
Dr. Maria G. Guzman
- 2018** Meeting with Dr. Gerado Guillen, Director of Biomedical Research, CIGB  
*Discuss ongoing NHP study of the NIAID vaccine in monkeys primed with a subunit vaccine candidate developed in Cuba.*  
*Study was conducted in collaboration with Vabiotech in Vietnam.*
- 2023** 18<sup>th</sup> *International Dengue & Other Emergent Arboviruses Course*, IPK  
Dr. Maria G. Guzman

This is where relationships between Cuba and NIAID began in 2015



INSTITUTO DE MEDICINA TROPICAL "PEDRO KOURI"  
**XIV CURSO INTERNACIONAL DE DENGUE**  
"PEDRO KOURI" TROPICAL MEDICINE INSTITUTE  
**XIV INTERNATIONAL DENGUE COURSE**


**CERTIFICADO**      **CERTIFICATE**


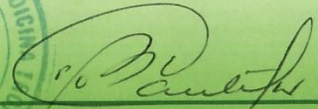
A (TO): \_\_\_\_\_  
COMO (AS): \_\_\_\_\_  
*Steve Whitehead*  
*Profesor*

TEÓRICO/THEORETICAL (X); PRÁCTICO/PRACTICAL( ); CARTEL/ POSTER ( ).

POR HABER PARTICIPADO EN LAS ACTIVIDADES CIENTÍFICAS / FOR PARTICIPATING IN THE SCIENTIFIC ACTIVITIES.

LOS DÍAS 10 AL 21 DE AGOSTO DE 2015, LA HABANA, CUBA / FROM 10- TO 21 AUGUST 2015, HAVANA, CUBA

  
Prof. María G. Guzmán, MD, PhD. DrCs.  
Coordinadora/Coordinator  
Directora del Centro Colaborador OPS/OMS para el Estudio del Dengue y su Vector/  
Director of the PAHO/WHO Center for the Study of Dengue and its Vector

  
  
Prof. Nereyda Cantelar MD.PhD. DrC  
Vicedirectora Docente IPK/ Deputy Director of the Teaching Division

