

# Local Manufacturing of Immunobiologics – The Butantan Institute

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# Presentation Highlights

1. What is the main issue or question the presentation addresses?
  - The advantages of local development and production of immunotherapies
2. What is the key finding or ‘takeaway message’?
  - Investments and collaborations are the key
3. How does the research advance HIV prevention efforts?
  - Scientific knowledge acquired during product development

# Successful HIV-related efforts in BRAZIL



The NEW ENGLAND  
JOURNAL of MEDICINE

PERSPECTIVE



## Fighting HIV — Lessons from Brazil

Author: Susan Okie, M.D. [Author Info & Affiliations](#)

Published May 11, 2006 | N Engl J Med 2006;354:1977-1981 | DOI: 10.1056/NEJMp068069



21 JUNHO 2024    



**Nísia Trindade**

**Ministério da Saúde regulamenta as Parcerias de Desenvolvimento Produtivo (PDPs) e o Programa de Desenvolvimento da Inovação Local (PDIL)**

## **PDP - Productive Development Partnerships**

- Main goal: increase the access to medicines
- Brazilian manufacturer + Biopharma
  - Tech transfer in 10 years



**Carlos Gadelha**

## **PDIL - Program for Local Development and Innovation**

- Main goal: increase the number of locally developed medicines
- Brazilian manufacturer + collaborators (or not)



# Brazil's state-controlled vaccine manufacturers



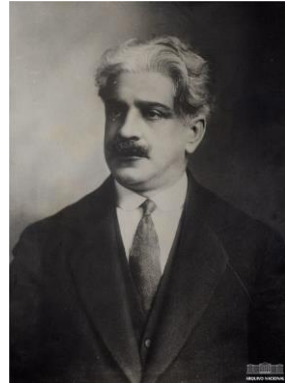
FIOCRUZ



# Fundação Oswaldo Cruz - FioCruz



**FioCruz is created**  
(Federal Serotherapeutic Institute)



1950

**Expansion to other capitals**



**Farmanguinhos and Biomanguinhos**



2021 - 2022

**Covid-19 vaccines**



# Butantan Institute (and Foundation)



Vital Brasil Mineiro de Campanha



Butantan Institute is created

Butantan Foundation

2021 - 2022

1980s

1901

1984

Vaccines and Biotechnology Center

Covid-19 vaccines





# Butantan Institute and Foundation





## Instituto Butantan



### MISSION

To research, develop, manufacture and supply products and services for the health of the population



### VISION

To establish competencies to become the leading global manufacturer of biological products and advanced therapies



### VALUES

Ethics | Commitment | Efficiency | Quality | Innovation

## Fundação Butantan



### GOVERNANCE

Transparency and responsibilities



### PERMANENCE

Business and investment promoting growth



### EFFECTIVENESS

Better resource allocation in processes and operations





# Butantan

**PRODUCTION**

**CULTURE**

**EDUCATION**

**RESEARCH and R&D**



# Bioindustrial Capacity

Multipurpose Form and Fill Facility

Monoclonal antibody factory

Freeze-dried vaccine production site

CPMV Factory  
BSL-3 Factory

Influenza Vaccine Factory

Cold storage facility

Administrative center

1

2

3

4

5

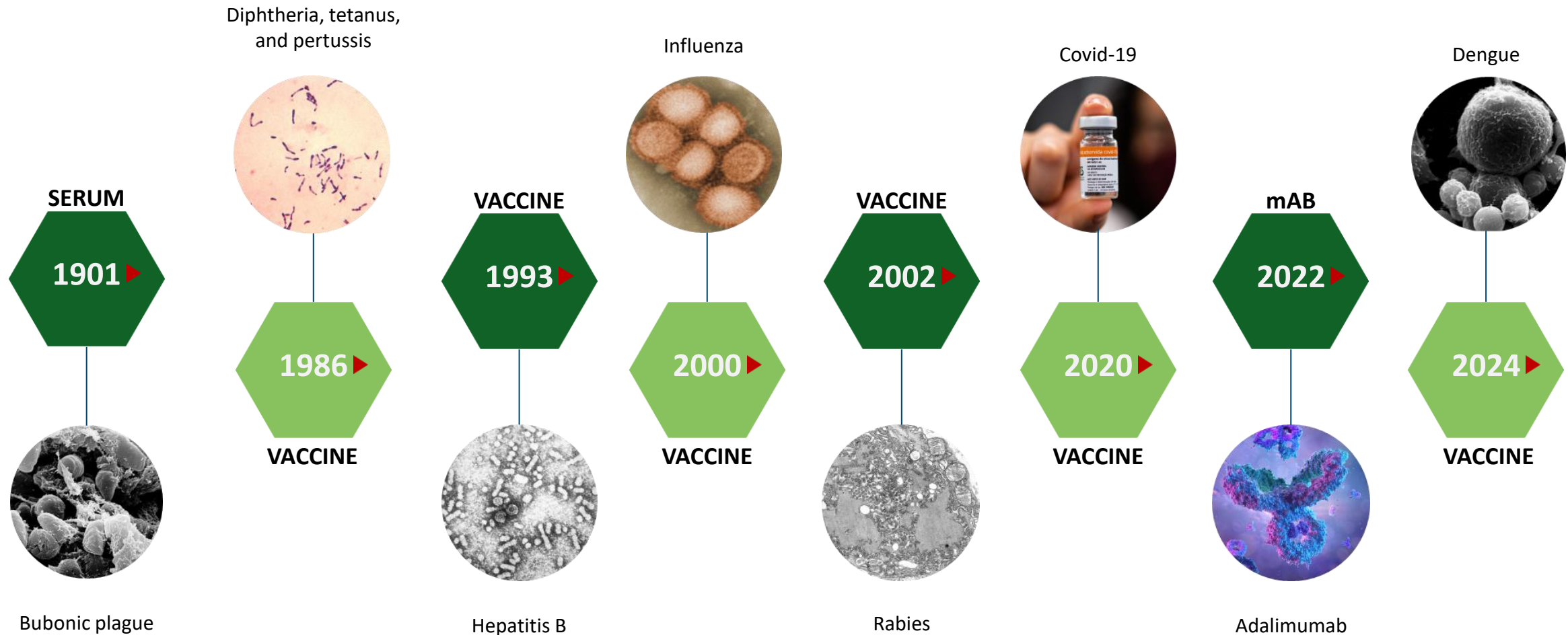
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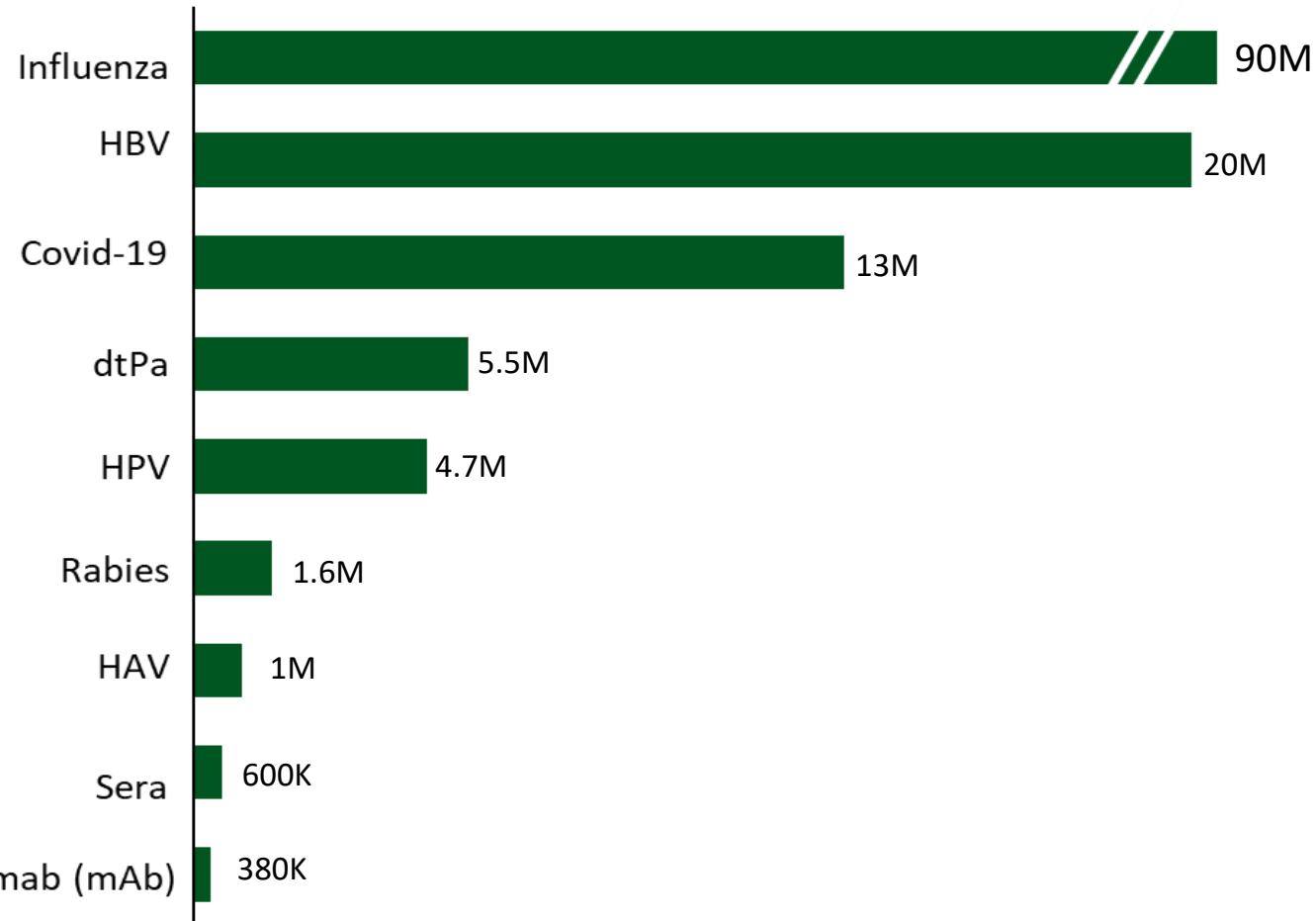


# Developing and Producing Immunobiologics



# Current Portfolio

## Produced/Distributed volume (2023)



## Serum production

**600 thousand bottles of serum** per year against venomous **animal poison**, **bacterial toxins**, and the **rabies virus**



# Science Park and Museums

447K

visitors to  
the museums  
in 2023



**BIOLOGICAL MUSEUM**



**HISTORICAL MUSEUM -  
TERRA FIRME SPACE**



**MICROBIOLOGY MUSEUM  
PROF. ISAIAS RAW**



**EMÍLIO RIBAS PUBLIC HEALTH  
MUSEUM**



**VACCINE MUSEUM**



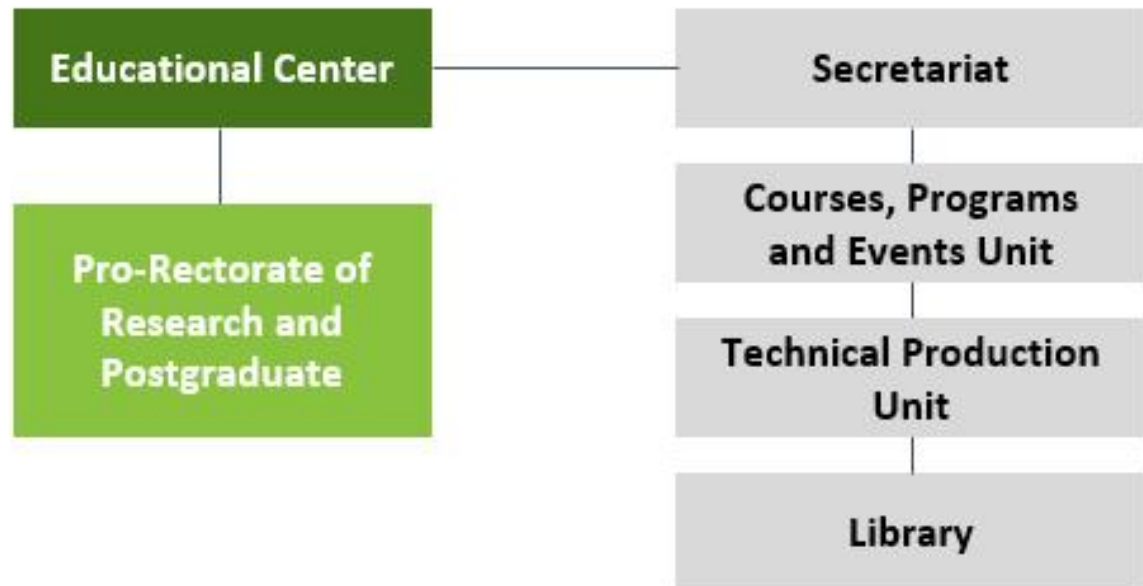
**MONKEY ZOO**





## Scientific Education (ESIB)

Since 2018, Butantan's Higher Education Institution (**Escola Superior do Instituto Butantan - ESIB**) offers extension courses and postgraduate programs in various fields of biological sciences.



# Research with > 200 investigators



## Center of Scientific Development (CDC)

### MISSION

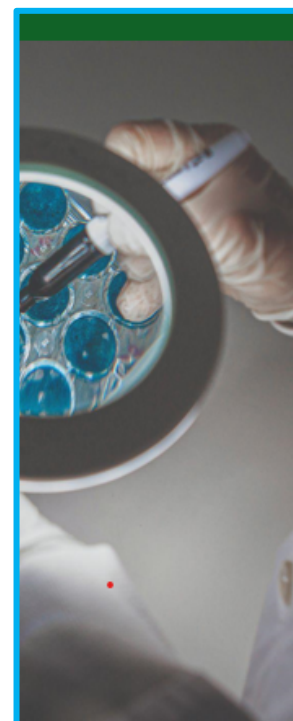
To develop basic and multidisciplinary research integrated with applied research, while enhancing scientific practice, training students, and promoting scientific dissemination, in order to significantly advance knowledge in the fields of health and science.




**CeTICS**  
Center for Research on Toxins, Immune-Response and Cell Signaling



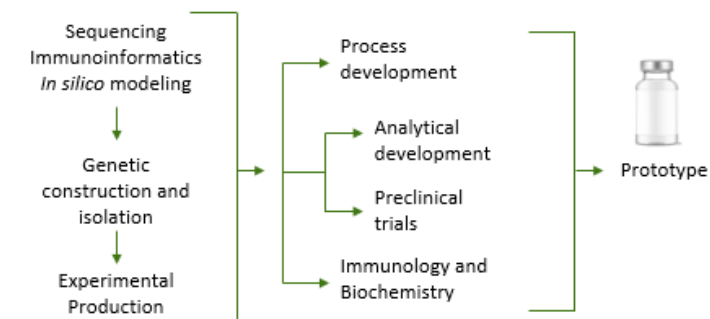
**PITES**  
Technological Innovation Platform for Health Emergencies



## Center for Development and Innovation (CDI)

### MISSION

Support, accelerate and develop institutional projects aimed at the technological enhancement of processes and new products with potential impact in the field of health



**CENTD**

Centre of Excellence in New Target Discovery



**CeRDI**

Center for Research and Development in Immunobiologicals



**CeVIVAS**

Center for Viral Vigilance and Serologic Evaluation





# Anti-venom products



**Snakes**

**Spiders**



**Caterpillars**



**Scorpions**





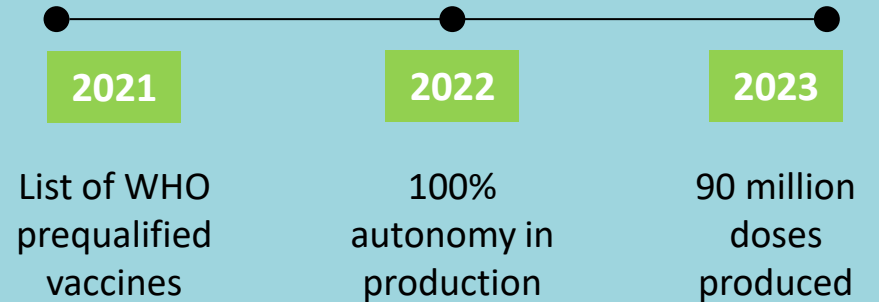
# Trigger warning – Moving bugs



# Influenza: a success case

★  
**90**  
million  
doses

**100%** of the flu  
vaccines offered by the  
National Immunization  
Program



★  
**10.5**  
million  
doses

exported to **5 countries**  
in 2022/2023 through PAHO

## Development

**QIV (tetravalente flu)** - Main phase 3 study completed, phase 3 study in infants ongoing

**Adjuvanted (IB160)** – Phase 3 in planning

**H7N9** – Phase 1 completed

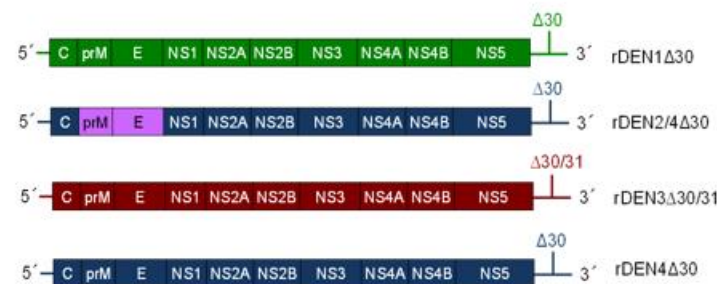
**H5Nx** – Phase 1 protocol submitted to Anvisa

MOU with **Human Vaccine Institute** (Univ. Duke, NC)

# Novel products in development



## Current partnerships Co-development: TV-003



Steve Whitehead

## Internal development Avian influenza

Phase 1 clinical study protocol  
submitted to Anvisa

- Evaluating better antigen/adjuvant combos (USA)
- Implementing novel in vitro assays to predict vaccine efficacy (Australia)
- Characterizing our sera's crossreactivity against non-Brazilian species (Latin America / Africa)
- Isolation and identification of new therapeutic targets from venomous caterpillars (UK)



# 2023 Leadership

## Instituto Butantan



Esper  
Kallás

Instituto Butantan  
Director



Rui  
Curi

Instituto Butantan  
Deputy Director and  
Director of the  
Education Center



Sandra  
Coccuzzo

Director of the Scientific  
Development Center  
at Butantan



Ana Marisa  
Chudzinski-Tavassi

Director of the Center  
for Development  
and Innovation  
at Butantan



Giuseppe  
Puorto

Director of  
the Cultural  
Development Center  
at Butantan

## Fundação Butantan



Saulo  
Nacif

Fundação Butantan  
Executive Director



Marcio  
Lassance

Fundação Butantan  
General Superintendent



Gustavo  
Mendes

Director of Regulatory  
Affairs, Quality Control,  
and Clinical Studies



Lucio  
Gama

Director of International  
Scientific Partnerships



Flávio  
Borgheresi

Fundação Butantan  
Legal Director

# We are not alone

**PAHO**



Pan American  
Health  
Organization



World Health  
Organization

Americas Region

**Strengthening Local Manufacturing Capacities to Improve Equitable Access to Vaccines in Latin America and the Caribbean - supported by Global Affairs Canada (GAC)**

**Fiocruz joins global network of vaccine manufacturers and strengthens the potential of the Global South**

29/07/2024

**giz** Deutsche Gesellschaft  
für Internationale  
Zusammenarbeit (GIZ) GmbH

**Expanding local vaccine production in South Africa**

# Thank you

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