

# STRENGTHENING THE PHARMACEUTICAL INNOVATION CAPACITY IN CENTRAL AMERICA

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National Secretariat of Science , Technology and Innovation

SENACYT

# SYLLABUS

- WHAT IS HAPPENING IN PANAMA?
- INTRODUCTION TO SENACYT
- PHARMACEUTICAL HUB INITIATIVE
  - UNITED DIAGNOSTIC
    - ✓ DISTRIBUTION OF ADDED VALUE
    - ✓ CLINICAL STUDIES
    - ✓ LOCAL PRODUCTION
- Center for Science and Safety in Health for the Americas
- REGIONAL CENTER OF INNOVATION IN VACCINES AND BIOPHARMACEUTICALS
- REQUEST TO SICA

# HEALTH SCIENCES EVOLUTION IN PANAMA



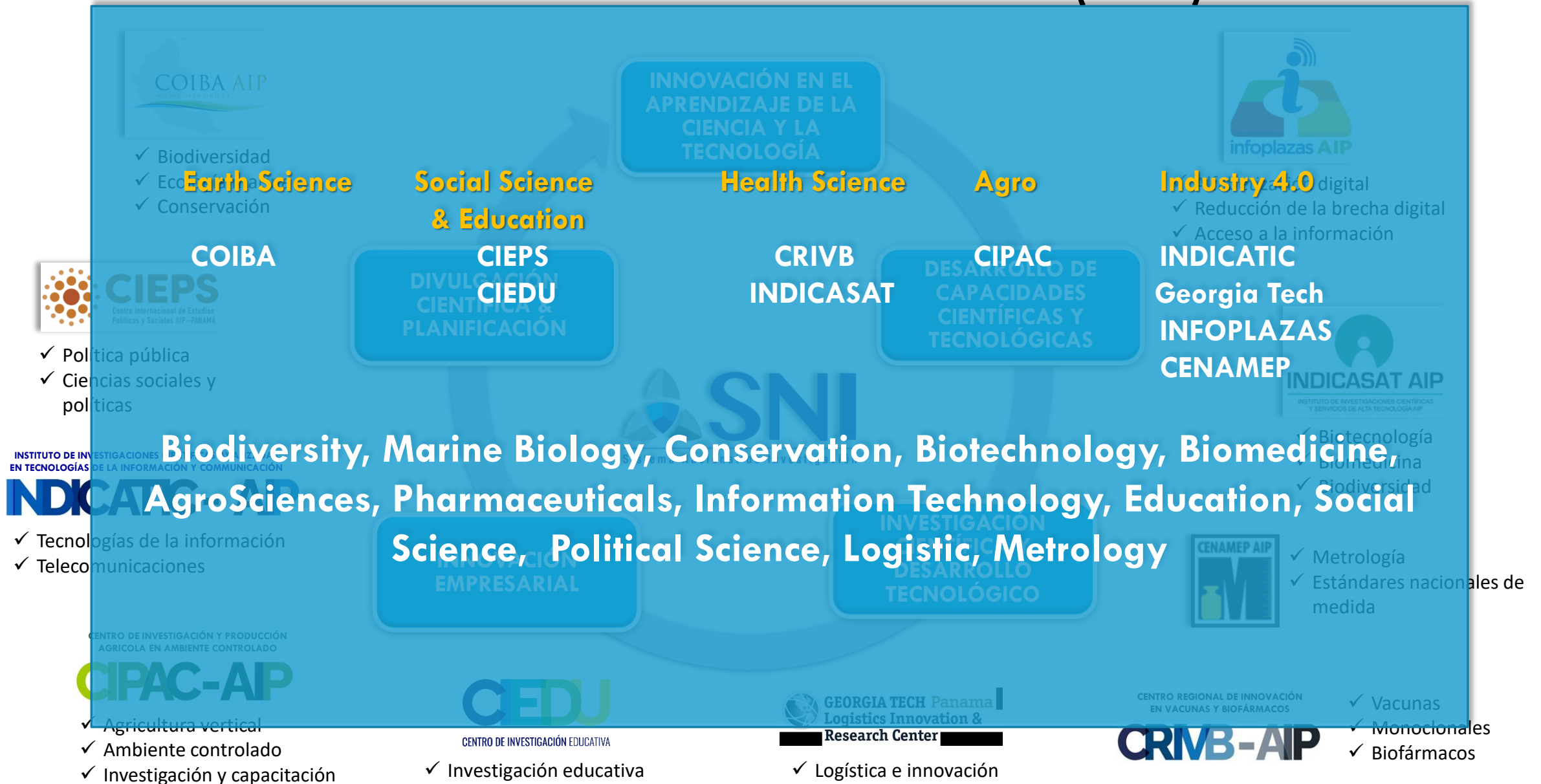
Increasing participation in activities of R+D clinical



- One of the most modern facilities in Central America in sanitary matters.
- The largest hospitable city in Central America
- It will serve more than a million and a half people.
- HEALTH INNOVATION RESEARCH CENTER.

# THE ECOSYSTEM OF RESEARCH AND INNOVATION CENTERS

## PUBLIC INTEREST ASSOCIATIONS(AIPs)



# COMPARATIVE ANALYSIS OF SALE PRICES OF MEDICINES IN PHARMACIES: PANAMA IS LOCATED AS THE COUNTRY WITH THE MOST EXPENSIVE MEDICINES



## Sondeo evidencia diferencias

Consultas a farmacias de México, El Salvador, Honduras, Nicaragua y Costa Rica muestran que en Guatemala los mismos medicamentos se pagan a un precio más elevado.



Producto	GUATEMALA	México	El Salvador	Honduras	Nicaragua	Costa Rica	Más caro	% + caro
Leche Enfamil Confort Premium 400 gramos	Q138.15	Q102.60	Q111.49	Q135.67	Q108.78	Q142.25	Q35.55	34.65
Benicar 20 mg 14 tabletas	Q375.00	Q154.05	Q175.37	Q225.05	Q138.10	Q197.28	Q236.90	177.44
Catafiam 25 mg 20 tabletas	Q213.00	Q101.69	Q70.07	Q107.79	Q43.85	Q73.63	Q169.15	381.11
Nexium 40 mg 14 tabletas	Q632.00	Q255.77	Q194.13	—	Q230.31	Q484.51	Q437.87	225.11
Nexium 40 mg 28 tabletas	Q1,126.00	—	Q485.52	Q745.80	—	—	Q639.48	131.11
Aspirina 500 mg 40 tabletas	Q24.00	Q11.83	Q23.22	Q16.63	Q14.52	Q32.20	Q12.17	102.11
Tritace 10 mg cápsulas	Q451.95	Q287.40	Q216.01	Q174.53	Q206.87	Q257.60	Q277.42	158.11
Aprovel 150 mg 28 tabletas	Q842.40	Q341.74	Q251.48	Q316.84	Q381.00	Q343.47	Q590.92	234.11
Cirix 500 mg 12 comprimidos	Q420.15	Q202.08	Q142.15	Q229.47	Q332.45	Q271.91	Q278.00	191.11

# WE HAVE A REGIONAL PROBLEM



Compra conjunta de medicamentos, dispositivos médicos y otros bienes de interés sanitario

SGA: Ocho países construyendo una región de oportunidades

15%

aumentó la tasa del servicio de expedición de registro sanitario de productos farmacéuticos.

35%

es el margen de ganancias que obtienen los grupos económicos impartan las medicinas

## PRECIO DE MEDICAMENTOS EN CENTROAMÉRICA

IBERSATAN 150MG, 30 TABLETAS

COSTA RICA \$8,28

NICARAGUA \$5,14

EL SALVADOR \$9,07

NR

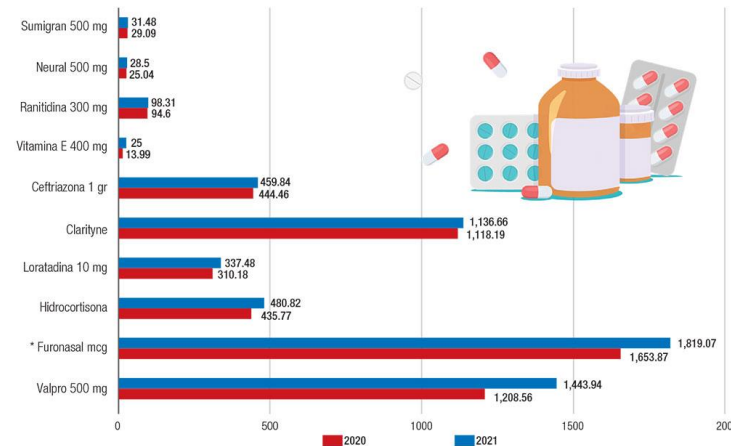
# 30% DE DESCUENTO EN TODOS LOS MEDICAMENTOS\*

\*A partir del 15 de agosto de 2022, se establece un 30% de descuento a 170 medicamentos basado en los precios establecidos al 30 de junio del 2022.

## Medicamentos que presentaron la mayor variación en su precio

Datos: diciembre 2020 a diciembre 2021

\*Octubre 2021



Fuente: Proconsumidor

Lully Luis Reyes-elDinero

## Mercado Centroamericano de Medicamentos

medicamentos innovadores, 39%

7% genéricos sin marca

54% genéricos de marca

\$ 1353.2 millones (a junio 2010)



= 8 ESTADOS MIEMBROS


**IMPLEMENTACIÓN:**  
 - DISTINTA EN CADA PAÍS  
 - ACERVOS INSTITUCIONALES  
 - CULTURA ORGANIZACIONAL  
 - FUNCIONAMIENTO ADMINISTRATIVO

- FACTORES INTERVINIENTES**
- NEGOCIACIÓN POLÍTICA
  - FINANCIAMIENTO
  - MARCOS LEGALES
  - MODELO DE ATENCIÓN
  - AUDITORÍA SOCIAL



ORGANIZACIÓN DE LAS NACIONES UNIDAS  
PARA EL DESARROLLO INDUSTRIAL



OBJETIVO DE DESARROLLO SOSTENIBLE #9  
INDUSTRIA, INNOVACIÓN E INFRAESTRUCTURA

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## Strategy and Action Plan for the Development of Areas of Opportunity in the Pharmaceutical Sector of Panama

### Background:

This strategy and action plan is based on the **Report of Feasibility for a Pharmaceutical Hub**, that was presented by the Panamanian Government in December 2021 by the **United Nations Industrial Development Organization**.



# PHARMACEUTICAL HUB

*The Feasibility Report highlighted 3 areas of opportunity for the development of the pharmaceutical sector of Panama :*

Estrategia y Plan de Acción para el Desarrollo de

**Distribución de Valor Agregado**



Estrategia / Plan de Acción para el Desarrollo de

**Test de Drogas (Ensayos Clínicos)**



Estrategia / Plan de Acción para el Desarrollo de

**Fabricación Nacional de Medicamentos**



# BARRIERS / IDENTIFIED LIMITATIONS

- Lack of pharmaceutical and chemical professionals
- Delays in drug registration ( particularly for the registration of new drug formulations by local laboratories)
- Administrative and scientific difficulty for Biomedical Research
- Weaknesses in the public procurement system for medicines .

# PHARMACEUTICAL HUB

*The Feasibility Report highlighted 3 areas of opportunity for the development of the pharmaceutical sector of Panama :*

Estrategia y Plan de Acción para el Desarrollo de

## Distribución de Valor Agregado



### ACTION PLAN: FOR THE DEVELOPMENT OF THE DISTRIBUTION OF VALUE ADDED:

- **Immediate priority:**
  - ✓ **Marketing** – identify the client base for the services of distribution of value added at a regional level.
- **Short term priority:**
  - ✓ Target selected company-clients and attract them to establish new regional services based in Panama, in collaboration with local companies: example structure incentive package; refine/adjust business offer; new joint venture, value-added services.
- **Long term priority:**
  - ✓ Continous improvement in the efficiency of the distribution of added value in Panama : standardication and continous improvements in regulatory processes.

Estrategia / Plan de Acción para el Desarrollo de

## Test de Drogas (Ensayos Clínicos)



### ACTION PLAN FOR THE DEVELOPMENT OF CLINICAL TRIALS:

- Strengthening of the National regulatory authority in line with PAHO/WHO recommendations
- Simplification and digitization of processes from the registration to the importation of the Research product.
- Organize training programs to develop the necessary human resources ( clinical researchers and technician), according to the marketing plan.
- *Take advantage of opportunity to execute accreditation/ certification against International standards in different aspects, as they emerge and become feasible.*
- *Standardization of protocols in the different ethics committees, greater consistency in the procedures for approval of protocols in the MINSA or the inspection of clinical trial facilities by DNFyD.*

Estrategia / Plan de Acción para el Desarrollo de

## Fabricación Nacional de Medicamentos



### ACTION PLAN FOR THE DEVELOPMENT OF THE NATIONAL MANUFACTURE OF MEDICINES:

- Prepare and execute the plan to make the registration process more transparent; use digitization to improve efficiency and reduce registration times.
- For local laboratories:
  - ✓ Promote the scale of operations directing the public purchase of medicines to them preferably through purchase agreements.
  - ✓ Provide interchangeability data for new products through technology transfer agreements.
  - ✓ **Expand product portfolios.**
  - ✓ Financial assistance to implement GMP updates and acquire new product formulations, raw materials, machinery etc.

# ACTION PLAN- SSTRENGTHENING OF LOCAL INDUSTRY



## A. STRENGTHEN THE LOCAL DRUG INDUSTRY, FACILITATING THE ACQUISITION OF SCIENTIFIC/TECHNOLOGICAL CAPABILITIES

- Education and training of specialized human capital
- Strengthening of equipment, technical and technological support (industrial pharmacy, biopharmacy, análisis of pharmaceutical products)
- Offer bioequivalence studies locally
- Acquisition and application of suitable techniques for quality control.

## C. PROMOTE TECHNOLOGY TRANSFER ACTIVITIES FROM THE INNOVATIVE GLOBAL INDUSTRY TO THE LOCAL PRODUCER

- Transfer of technology and specialized knowledge
- Incentives, exemptions or credits for International investments
- Strategic alliances



## B. CREATE MARKET CONDITIONS THAT ENCOURAGE THE NATIONAL PRODUCTION OF MEDICINES

- Elevate the local production of medicines to state policy
- Guarantee security of supply
- Local production and purchase of critical use medicines

[Alignment with the “Access to Medicines” Discussion Table in the Presidency of the Republic](#)

# SCIENCE AND SECURITY HUB IN HEALTH FOR THE AMERICAS



## **STATEMENT OF PURPOSE**

The Government of Panama ( through SENACYT and Texas A&M University Health) proposes to establish a Center for Health Sciences and Safety for the Americas through a regional collaborative effort in the Republic of Panama to address the pressing health biosecurity challenges facing the region.

# THE SCIENCE AND HEALTH SECURITY HUB FOR THE AMERICAS

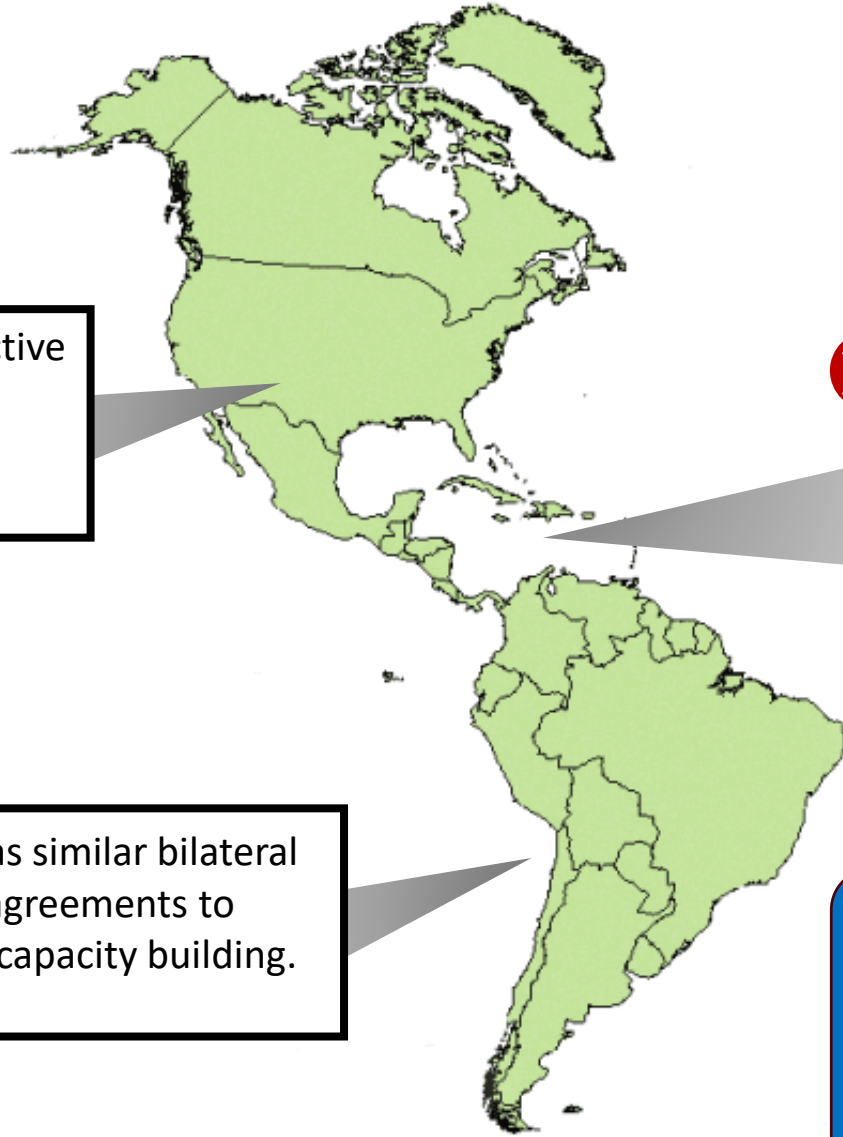
## **Strengthening of Capacities in the Americas**

- Working through a multi-year commitment to the Republic of Panama, the Center for Health Sciences and Safety for the Americas will increase regional capacity for vaccine development and manufacturing, pharmaceutical quality control and assurance, academic alliances, applied Research and workforce development.
- A Center for Health Science and Security will address biosurveillance capabilities, supply chain security, Research, development and manufacturing of products for medical countermeasures to address regional and global health biosecurity threats.

## **The work is in progress**

- The Republic of Panama has partially financed and initiated these efforts through SENACYT.
- Panama and Texas A&M Health have directly committed to delineating structural agreements to facilitate capacity and capacity building in Central America and Panama. Additional assistance is needed from critical stakeholders, industry, and the US Government.

# THE PROBLEM



North America has developed active cross-border collaboration and industry commitment to health security.



*Central America doesn't have*



South America has similar bilateral and multilateral agreements to support regional capacity building.

**This geographic gap creates threats to regional biosecurity, pharmaceutical quality assurance, and supply chain resilience.**



# PANAMA PROPOSES A COLLABORATION TO CREATE A RESILIENT RESEARCH AND DEVELOPMENT ECOSYSTEM THAT STRENGTHENS THE SECURITY OF THE REGION

Sustainable Resilient Scalable

## BIOSECURITY

- Research and development in vaccines
- Bio surveillance
- Environmental monitoring
- Medical countermeasures

## SERVICE

- Center for Innovation in Advanced Development and Manufacturing- CIADM
- College of Pharmacy Quality Control and Assurance(QA/QC)

## WORKFORCE DEVELOPMENT

- National Center for Therapeutic Manufacturing - NCTM
- Pharmacy: Regulatory Science

## APPLIED RESEARCH

- Genomics, therapies, telemedicine
- Clinical trials

## ACADEMIC ALLIANCE

- Medicine
- Nursing
- Pharmacy
- Public Health
- Agriculture



HEALTH



## LEADING INITIATIVES :

1. Strengthening of the capacity for Research, development and local production of vaccines and other drugs of importance in public health for Panama and the region
2. Agricultural and educational practices, to stimulate and protect agricultural production in Panama.
3. Binational Surveillance and Response Network, for the detection of emerging and transmitted infectious diseases.

# Regional Center of Innovation in Vaccines and Biopharmaceuticals- CRIVB

SENACYT, November 2022

# CREATING A VACCINE CENTER FOR THE REGION

## A 2 STEP PLAN

### Center of Research and Development of Vaccines

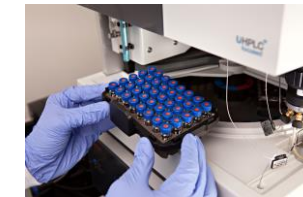
1



Establish an R&D Center and a Product Development Laboratory with capacity for both upstream PD (including mRNA and recombinant proteins) and downstream PD (including large-scale protein purification, analytical/biochemical testing, and product development formulations).

2

### Vaccine and Monoclonal Production Plant



Modular rooms enable the simultaneous development and production of millions of doses of medical countermeasures against some of the world's deadliest threats.

# COLLABORATION PARTNERS



INDICASAT-AIP

INSTITUTO DE INVESTIGACIONES CIENTÍFICAS  
Y SERVICIOS DE ALTA TECNOLOGÍA AIP



REPÚBLICA DE PANAMÁ  
GOBIERNO NACIONAL



REPÚBLICA DE PANAMÁ  
GOBIERNO NACIONAL  
MINISTERIO DE RELACIONES EXTERIORES



INTERNATIONAL  
VACCINE INSTITUTE



FACILITADORES

ENTRENAMIENTO  
BIOFARMACEUTICO

ASESORES TÉCNICOS

SOCIO INDUSTRIAL

SOCIOS ACADÉMICOS



Pan American  
Health  
Organization



Biological E. Limited  
Celebrating Life Every Day



Texas Children's  
Hospital



MASSACHUSETTS  
GENERAL HOSPITAL



Secretaría Nacional de Ciencia, Tecnología e Innovación



# COMPONENTS OF THE CENTER FOR INNOVATION IN VACCINES AND BIOPHARMACEUTICALS

Research and Development of Biologics

Clinical  
Development

Education and  
Training

Regulatory  
Framework

Laboratory of  
Clinical Diagnosis  
and Biotherium

Vaccine Production Plant

# REGIONAL CENTER FOR INNOVATION IN VACCINES & BIOPHARMACEUTICALS



# EXAMPLE OF THE LABORATORY SPACE DESIGN



# REGIONAL CENTER FOR INNOVATION IN VACCINES AND BIOPHARMACEUTICALS

Infectious diseases

Vaccines Research and Development

New medicines and advanced technologies

Translational research

**RESEARCH PROGRAMS**

Microbial Pathogenesis

Virology

Immunology of Infectious Diseases

Biopharmaceuticals

Bioinformatics

**Laboratories**

Recombinant Protein Vaccines

mRNA Vaccines

Anticuerpos Monoclonales y Biofármacos

**Technological Platforms**





# CREATING A VACCINE CENTER FOR THE REGION

## A 2 STEP PLAN

### 1 Centro de Investigación y Desarrollo de Vacunas

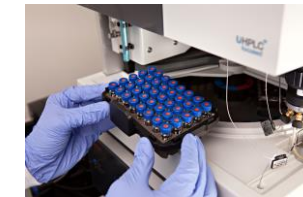


**NEXT  
STEP!**

### 2

### Vaccine and Monoclonal Production Plant

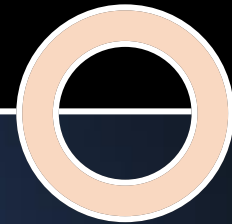
Texas A&M Center for Innovation in Advanced Development and Manufacturing (CIADM)



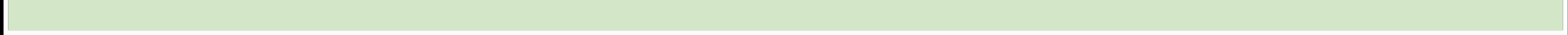
Modular clean rooms enable the simultaneous development and production of millions of doses of medical countermeasures against some of the world's deadliest threats.

## WHAT IS THE SOLUTION FOR SICA?

- A diplomatic strategy that positions Central America as the desired region to lead this initiative of coordination of the biosecurity response of the Americas.

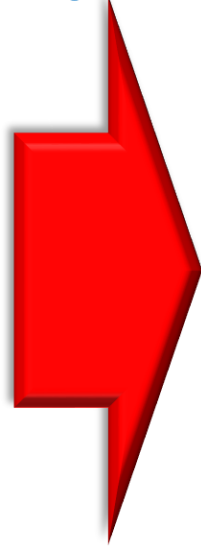


GRACIAS  
POR SU  
ATENCIÓN



# REGIONAL CENTER FOR INNOVATION IN VACCINES AND BIOPHARMACEUTICALS

## CENTRO DE INVESTIGACIÓN Y DESARROLLO DE VACUNAS



## PLANTA DE MANUFACTURA DE VACUNAS Y BIOFÁRMACOS



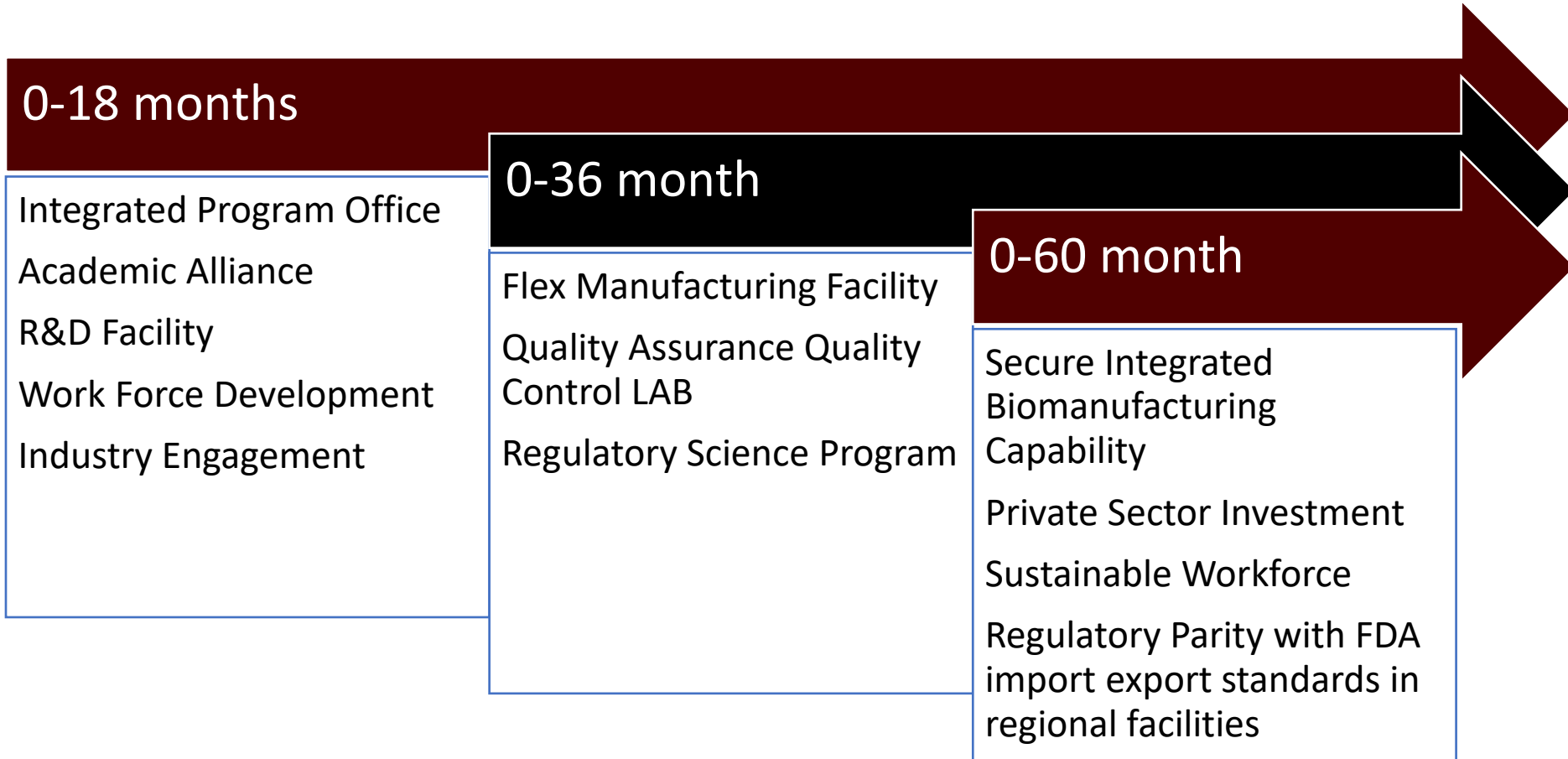
Mobile rooms allow simultaneous development and production of millions of doses of medical countermeasures.



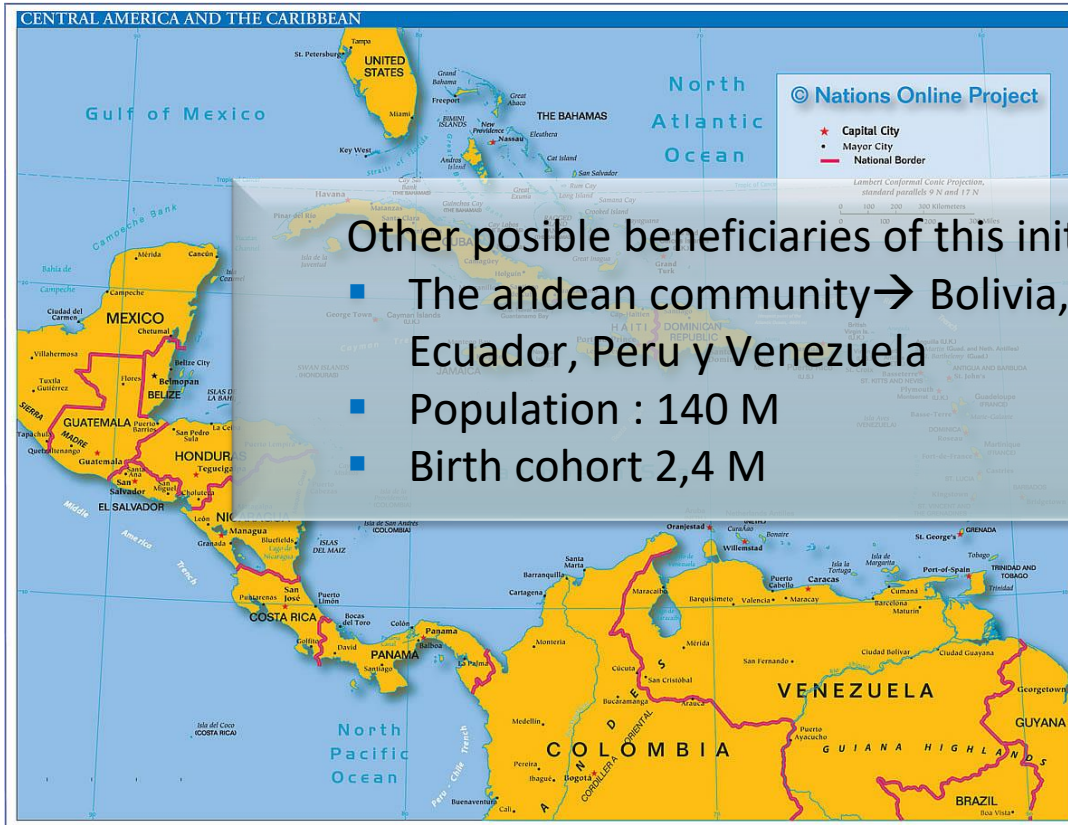
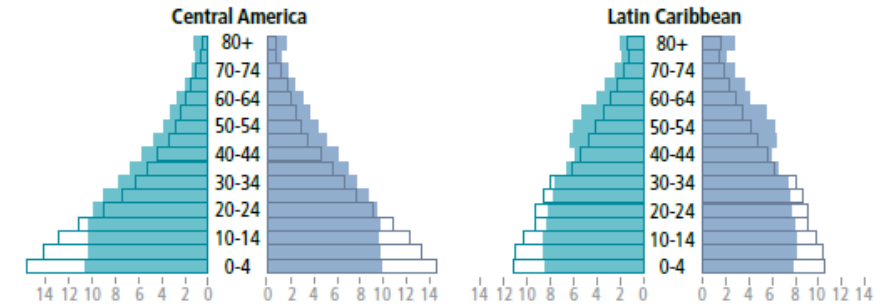
Establishment of a **Regional Center** for the **Discovery and Development** of vaccines of public health importance.

Develop the **manufacturing capacity** of vaccines and biopharmaceuticals of human importance, to protect public health and ensure **national and regional security**.

# Timelines



# WHAT IS THE GEOGRAPHICAL SCOPE OF THE INITIATIVE?



Country	Population	Year
Guatemala	16,581,273	2018
Cuba	11,116,396	2018
Haiti	10,788,440	2018
Dominican Republic	10,298,756	2018
Honduras	9,182,766	2018
Nicaragua	6,085,213	2018
Panama	3,800,644	2018
Puerto Rico	3,294,626	2018
Jamaica	2,812,090	2018
Trinidad and Tobago	1,215,527	2018
Belize	385,854	2018
Banamas, ine	332,634	2018
Barbados	293,131	2018
Saint Lucia	165,510	2018
Grenada	112,207	2018
Saint Vincent and the Grenadines	101,844	2018
Antigua and Barbuda	95,882	2018
Dominica	74,027	2018
Cayman Islands	59,613	2018
Saint Kitts and Nevis	53,094	2018

## CA&C DEMOGRAPHY

- Population of 94,9 M <sup>1</sup>
- 1,78 million of births
- In 2017, CAC countries had an accumulated GDP close to 400.000 M of dollars, making the región the 19th largest economy in the world.<sup>2</sup>
- The purchase of vaccines in CAC is done through the PAHO Revolving Fund
- National vaccine producers in LAC are based in Brazil, Argentina, Mexico and Cuba.
- Except for Cuba, no other producer offers vaccines to the countries of the región.

**Caribbean:** Anguilla, Antigua and Barbuda, Aruba, Bahamas, Barbados, British Virgin Islands, Cayman Islands, Cuba, Curaçao, Dominica, Dominican Republic, French Guiana, Grenada, Guadeloupe, Guyana, Haiti, Jamaica, Martinique, Montserrat, Puerto Rico, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Sint Maarten, Suriname, Trinidad and Tobago, Turks and Caicos Islands, United States Virgin Islands. **Central America:** Belize, Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, Panama.

1. Core indicators 2019. Health trends in the Americas. PAHO 2019; 2. <https://www.mckinsey.com/featured-insights/americas/unlocking-the-economic-potential-of-central-america-and-the-caribbean#>

# COLLABORATION UPDATE

- The Department of State requested Texas A&M to coordinate the biosecurity response for Central America
- Texas A&M is trying to position it for the DS to work with TAMU to bring funds and expertise to Central America through Panama. The idea is that we encourage Panama to be the biosafety and biomanufacturing hub in Central America as a trusted partner.
  1. Willingness of Panama to support the effort in the country as part of a larger global initiative
  2. Regulatory science as a cornerstone to ensure that everything produced is exportable
  3. Room to start operations so the effort can start immediately.
- The idea is to create biosafety and manufacturing centers using Panama as a proof of concept and then take it global as part of a larger US Government effort.
- Two leads are being followed to bring the manufacture of vaccines and monoclonal antibodies to Panama:
- Helix Nano, a biotech company with a program funded by Gates Foundation, to produce an mRNA-based COVID-19 vaccine.
- Welcome Trusts LEAP, which is investing in distributed mRNA manufacturing and is interested in a pilot modular facility.
- We are also exploring the possibility of bringing the production of countermeasures in Panama against monkeypox.

# Why Panama?

**The Republic of Panama is ideally suited for the development of multi-discipline efforts to address biological threats to populations and supply chains in the Americas**



- ✓ Diverse population
- ✓ Stable economy
- ✓ Strategic geolocation
- ✓ Importance to global commerce

- The National Secretary of Science, Technology and Innovation (SENACYT)'s vaccine R&D initiative has served as a focal point for stakeholder engagements to establish in-country capabilities for vaccines and biotherapeutics R&D
- SENACYT is expanding its relationship with Texas A&M biomanufacturing advanced development expertise to support these activities



1. Identification, recruiting and hiring of a Director of international stature.
2. Recruitment of researchers and technical personnel.
3. Training of researchers and technical personnel.
  - Baylor College of Medicine y el Texas Children's Hospital Center for Vaccine Development - EEUU
  - Texas A&M University - EEUU
  - Biological E Limited (BioE) - India
  - International Vaccine Institute – Corea
4. Design and adaptation of the physical space → INDICASAT's old building
5. Adequacy of Research and development laboratories
6. Purchase and installation of equipments
7. Start of activities 2024



SETTING UP THE REGIONAL CENTER OF INNOVATION IN VACCINES AND BIOPHARMACEUTICALS



## LOCATION OF THE CENTER

- Located in Building 219, Polígono Central Norte, La Cuadra Zone
- The total área of the building is of 1,424 m<sup>2</sup>
- The rehabilitation Works ( which include demolitions, renovation of slabs and roofs, electrical connections, construction of stair, facades and construction of parking lots)
- Estimated completion date of improvements : February 2024

